Accelovance

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A PROVEN APPROACH to ACCELERATED CLINICAL DEVELOPMENT

Control Over Operations —> Enhanced Productivity —> Cost & Time Savings = RESULTS!

FLEXIBLE SERVICE OFFERING TAILORED TO MEET YOUR NEEDS

- Full CRO Services
- Wholly Owned Research Dedicated Clinical Sites
- Patient "Management": Recruitment, Retention, Compliance
- CLINICAL Call Center
- Late Stage/Safety Service

Recognized as "2009's BEST CRO" with a Vaccine Industry Excellence (ViE) award, Accelovance's innovative approaches have driven clinical productivity and performance within the niche market of Vaccines but ***also address*** quality, cost-savings, speed and partnering needs of other therapeutic areas.

We uniquely combine our ownership of six (6) clinical research sites and internal patient management (not just recruitment, but retention and compliance also) solutions to create operational efficiencies that enhance quality, site and study productivity, and the timely delivery of research programs. We engage with Sponsors directly or through another CRO – we are flexible to any working arrangement. Let's evaluate the impact we can make on your next clinical study.

Let our results serve as examples of the ***tangible value*** Accelovance can bring to a Sponsor:

- **25-75% reduction** in study/enrollment timelines
- **20-25% cost-savings** vs. standard industry pricing
- Accurate Pricing = **no CRO generated change orders**
- **Partnership and Commitment** = communication and shared success

CRO Services: flexible to meet your needs. Project Management, Regulatory Affairs, Quality Assurance, Medical Monitoring, Clinical Monitoring, Data Management, BioStatistics, Safety and Late Stage Services. Accelovance serves as an extension of your team – offering these services as needed and flexible to work with other preferred vendors. Our ownership of sites gives the CRO team the additional patient and operational perspective necessary to effectively manage the study.

Clinical Sites: wholly owned and research dedicated. Our six (6) clinics average 3,000 SF in size and are staffed with full time Accelovance employees. Quality is emphasized through centralized SOPs and corporate training programs. Each clinic is positioned for highly coordinated and/or high volume enrollment; offering the Sponsor predictability and performance assurances.

Patient Management: more than recruitment and retention. Accelovance proactively recruits patients through its own databases, media and community outreach. Our innovative approaches pre-qualify patients prior to study start to find the ***right patient*** for the study. This planning allows for predictable, controlled and timely enrollment along with higher retention and compliance rates.

Clinical Call Center: surveillance, retention, compliance. Let clinically trained agents help manage your patients through their study visit schedule and beyond. Accelovance has managed programs with 400 patients to 19,000 patients in a cost-effective manner by pairing experienced agents who understand clinical research with robust technology that maximize efficiencies and reporting.

Should a sponsor wish to explore an opportunity in China's rapidly growing pharmaceutical market, **Accelovance China** has offices in Shanghai and Beijing, PR China providing small pharma/biotech and multinational pharma companies with CRO and market registration services.

Services: Clinical R&D, Data Management, Inpatient/Outpatient Facilities, Patient Compliance, Patient Recruitment, Pharmacovigilance, Project Management, Rx to OTC Switch, Trial Management, Vaccine Development

Algorithme Pharma

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As a worldwide leader in clinical research and bioanalysis, Algorithme Pharma provides a wide range of services in bioequivalence and early stage development (Phase I/IIa) studies to pharmaceutical and biotechnology industries.

With over 400 beds, state-of-the-art bioanalytical facilities, and 600 dedicated employees, Algorithme Pharma delivers first-class services to each client.

Successfully audited by US FDA, Brazil's ANVISA, France's AFSSAPS, Canada's TPD, UK's MHRA and Austria's AGES regulatory authorities, Algorithme Pharma is committed to on-going dedication to excellence.

Services: Analytical Assay Development and/or Laboratory Service, Clinical Pharmacology, Clinical R&D

HOUSE AD

Almac

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Take control of your clinical supply chain.

ALMAC offers an integrated supply chain management solution that draws from the expertise of our best-in-class **clinical trial supplies** and **IVR/IWR Based** services. Our integrated solution does more than just combine related services under one roof; it incorporates supply planning, technology implementation, and project oversight into a unified study start-up and management approach that optimizes the supply chain at each level.

How Almac manages this process

- **Lead Almac Contact:** A lead Project Manager is allocated to oversee and drive forward the project internally between both disciplines and from an inventory/drug supply management perspective.
- **Shared Master Project Plan:** All key deliverable dates are presented in a joint Project Plan, illustrating all milestones for packaging, distribution and the development/implementation of the IVRS.
- **A clear view of the full distribution process:** Almac's standardized drug ordering processes allows for consideration of shipping transit times, import licence lead times, depot management requirements and effective management of the kit lists shared between client, distribution and IVRS vendors.
- **Integrated reporting:** Almac's integrated web report utilizes data from both clinical trial supply shipping reports and distribution reports from the IVRS. This combined approach permits linkage of IVRS order numbers alongside shipping references and AWB information, providing the full life cycle of drug shipments. One single unique username and password is provided to users for the integrated web report, the clinical trial supply standard web inventory and distribution reports and the standard and customizable IVRS web reports.

BENEFITS TO OUR CLIENTS

• Leverage of joint expertise • Reduced vendor management • Accelerated study start-up • Rapid adaptation to study

Services

Our clinical technology solutions:

- IXRS™ (Interactive Voice and Web Response Systems)
- Data Integration
- ePRO (Electronic Patient Reported Outcomes)
- Clinical Hotline
- Biostatistical Services
- Adaptive Trial Design

Our clinical trial supply solutions:

- Clinical trial supplies management
- Comparator sourcing
- Over-encapsulation
- Packaging (blistering, bottling, carding)
- Labeling of clinical supplies
- Global distribution and depot network
- QP release and analytical services
- Returns, accountability and destruction

About Almac: The Almac Group comprises five closely integrated divisions offering a broad range of services from R&D, translational genomic services, API manufacture, product development, clinical trial supply and technology (IVRS/EDC), to commercial-scale manufacture. Almac provides services to over 600 companies including all the world leaders in the pharmaceutical and biotech sectors. The company has over 2,500 employees and is headquartered in Craigavon, Northern Ireland. US operations are based in Pennsylvania, North Carolina and California. Construction of the company's new $100m North American Headquarters started in July 08 and is expected to be completed late 2010.

To find out more about Almac visit **www.almacgroup.com**

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Services: Clinical Supplies/Distribution/Packaging, Clinical Trial Design, Electronic Diary/Dictionary/Translator, Project Management, Randomization (Automated/Centralized/Vocal Computer), Statistical Services/Meta Analysis

Almac

4-Color AD

Archimedes Inc.

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Archimedes is a healthcare modeling company that enables you to:

- Lower the risk of failure of your clinical trials by predicting the relative value of inclusion and exclusion criteria on different (sub)populations, and optimizing trial size and duration.
- Distinguish your drug's clinical and economic benefits from those of standard treatments and competitor drugs with regard to specific (sub)populations.
- Determine which candidate treatments have the greatest efficacy and in which demographic targets.
- Answer critical questions about efficacy, costs, and target markets.

The Archimedes Model was first developed in 1996 by David Eddy, MD, PhD, who is known for pioneering the theory and application of evidence-based guidelines. With the help of a large team of scientists, medical directors, and software engineers, the current model is a flexible, large-scale simulation model of human physiology, diseases, interventions, and healthcare systems.

The Model is written at a high level of detail using object-oriented programming and runs on a distributed computing network. At its core are hundreds of ordinary and differential equations that represent human physiology and the effects of diseases. The Model also includes detailed aspects of healthcare systems to analyze downstream clinical events, utilization, and costs.

The Archimedes Model is validated by simulating clinical trials and comparing the results against the results of the actual trial in the real world. To date, more than 50 landmark clinical trials have been used to validate the Model.

The Model has been used by companies such as Eli Lilly, Myriad Genetics, GSK, as well as the CDC, the ADA, and Kaiser Permanente to produce substantial savings, improved healthcare, increased revenues, and faster time to market.

For more information: **www.archimedesmodel.com/case-studies.html**

Healthcare modeling and the Archimedes Model give you answers to questions that would be impossible to address through evaluation studies or clinical trials due to high costs or other restrictions.

Contact us for a presentation and find out what we can do for you.

Services: Clinical Trial Design, Consulting, Disease Management/Health Outcomes, Efficacy Studies, Health Economics, Market Research/Product Communication, Medical Communications, Pharmacoeconomic/Pharmacoepidemiology Studies, Pharmacokinetic/Pharmacodynamic Modeling, Statistical Services/Meta Analysis

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AVERION

A Leading International Clinical Research Organization

Averion International Corp. is a full-service international CRO with proven expertise in supporting global clinical trials for pharmaceutical, biotechnology and medical device companies. Our well designed trials span the development lifecycle from first-in-man through regulatory approval and beyond. We provide our comprehensive capabilities throughout North America, Europe and beyond. Our teams specialize in oncology, cardiovascular, medical device and dermatology studies.

Averion International's core competencies are in product agency registration support, trial design, site selection, project management, medical and site monitoring, data management, biostatistical analysis, pharmacovigilance, medical writing, metrics development and full clinical trial management services throughout the clinical trials lifecycle.

Averion is committed to providing clients with critical thinking, customer service and quality deliverables. Our over 25 years of experience allows us to optimize each investigational product's chance for success.

We are dedicated to ensuring that each clinical trial is executed to the highest possible standards. For companies worldwide, Averion is a trusted partner in clinical research.

Averion International provides you entry to a broad array of services:

Clinical Research Services

- Strategic Planning
- Feasibility Studies
- Project and Site Management
- Project Development
- Data Management
- Database Development
- Metrics Consulting
- Monitoring
- Quality Assurance
- Biostatistics
- Medical Writing
- Data Monitoring and Clinical Endpoint Committees
- Post-Marketing Studies, Safety Surveillance and Registries
- Regulatory and Product Registration Support

In addition to our services offerings, we provide our clients with validated systems to most efficiently run their programs, inclusive of: CTMS, IVRS, EDC, Remote Data Browsing, Database Management, Document Management Systems and Safety Surveillance Systems.

Visit Averion International at **http://www.averionintl.com/** to learn how we can help lead you to success.

Services: Clinical Trial Design, Clinical Trial Monitoring, Data Management, Data Safety Monitoring Board Services, Medical Devices/Combination Products, Pharmacovigilance, Project Management, Regulatory Affairs/Regulatory Strategy, Statistical Services/Meta Analysis, Strategic Planning and Implementation

BARC

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BARC

Bio Analytical Research Corporation (BARC) is an independent global central laboratory that supports the pharmaceutical and biotechnology industry in the development and approval of new therapeutic agents by managing the laboratory component of clinical trials. BARC is committed to providing central laboratory services that meet the highest quality standards, with rapid delivery of laboratory data. Worldwide testing is performed on equivalent instrumentation and integrated into a single global database with identical reference ranges and reports.

BARC was founded in 1985 by medical pathologists and has since developed a worldwide network of clinical laboratories. Today, BARC has subsidiaries in North America, Europe, South Africa and Australia, and a network of laboratories in South America and Asia.

BARC's flexibility and service orientation toward investigators and sponsors, ensures fast set-up and seamless operation. Our unique business model enables us to offer both routine and specialized testing at highly competitive prices.

- From Routine to Esoteric Testing (PCR, cytopathology, microbiology, vaccine serology)
- PK and Genomics Handling
- Global Equivalent Results
- Result Reporting within 24 hours
- Quality Assurance
- Worldwide Logistics
- Project Management
- Customized Reporting
- Customized Supplies and Documentation
- Web Tools and Remote Data Access
- Electronic Data Transfer
- Competitive Pricing
- Controlled Long Term Storage
- CRO Planning Information

Services: Analytical Assay Development and/or Laboratory Service, Central Laboratory Services, Clinical R&D, Clinical Trial Design, Data Management, GCP Compliance, Project Management, Quality Assurance/Control, Trial Management, Virology

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BioClinica, Inc. is a leading global provider of integrated clinical trial technologies and advanced clinical trial services. BioClinica supports pharmaceutical and medical device innovation, including:

- Imaging Core Lab services
- Electronic Image Transport
- Electronic Data Capture (EDC)
- Data Management services
- Interactive Voice Response and Web Randomization services (IVR/IWR)
- Clinical Trial Supply Chain Design and Optimization solutions

BioClinica services maximize efficiency and manageability throughout all phases of the clinical trial process. With more than 2,000 successful trials completed to date, BioClinica supports the clinical development of many new medicines from early phase trials through final approval.

Imaging Core Lab Services
As the world's leading independent Imaging Core Lab (ICL), BioClinica offers a full suite of medical image management solutions for the lifecycle of your trial and for a wide range of imaging modalities. Our state-of-the-art, regulatory-compliant core labs located in the United States and Europe have processed and assessed over 5 million images. BioClinica's experience and quality processes deliver world-class service to 11,000 sites around the globe. We can help you manage any aspects of the imaging component of your clinical trial — from expert scientific consultation, study start-up and initiation, imaging and data capture, collection, image quality control and processing of image data, to expert blinded review and delivery of final results.

Our extensive therapeutic and diagnostic experience includes, but is not limited to, Oncology, Cardiology, Neurology, Rheumatology, and diagnostic contrast imaging agents. We have expertise with CT, MRI, SPECT, PET, Nuclear Medicine, Ultrasound, X-Ray and nearly all other imaging modalities.

eClinical Services
BioClinica helps you get the most from your clinical data by combining best-in-class technology with expert data management and support services, including integration with a wide range of clinical trial applications. Our eClinical solutions provide full support in the areas of study builds, study deployment, site assessments, hosting and validation, data integration, data management, IVR/IWR, training, clinical trial supply management and planning, and industry standards.

Electronic Data Capture
BioClinica Express makes clinical trials more efficient and easier to manage. BioClinica Express is a comprehensive EDC solution that uses time-tested, stable technology to provide a central hub to coordinate and organize the collection and dissemination of clean data. With the high performance and intuitive interface of BioClinica Express, you can keep investigators happy, monitor protocol compliance and close studies faster, while still meeting all regulations and guidelines — all at a predetermined price that helps you to best manage and control your trial costs.

Clinical Trial Supply Management
The BioClinica Study Optimizer allows you to design and simulate unlimited clinical supply chain scenarios from a global level all the way down to the site level. You can test and model for a wide range of parameters — simulated results can be analyzed and modified, and then optimized, to create the ideal clinical supply chain design. Then actual results can be looped back into the Optimizer to refine your planning and maximize clinical trial supply visibility and control.

Services: Case Report Forms, Central Laboratory Services, Clinical Study Reports, Data Management, Electronic Data Capture, Electronic Diary/Dictionary/Translator, Imaging, Project Management, Randomization (Automated/Centralized/Vocal Computer), Training

BioResearch Monitors, Inc.

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Quality Assurance Audits for Good Clinical Practice and Regulatory Compliance Services for Pharmaceutical Research & Development (GCP, GMP, GLP)

BioResearch Monitors is a leading independent provider of research-related quality assurance audit and compliance consulting services. Since 1992, BioResearch Monitors has been providing worldwide QA services to major and emerging pharmaceutical and biotechnology companies, CROs and related organizations sponsoring and/or conducting research within the purview of FDA's Bioresearch Monitoring Program, ICH Good Practice guidelines and related multinational quality standards. BioResearch Monitors is dedicated to ensuring data quality and regulatory compliance in all phases of pharmaceutical research. The directors of BioResearch Monitors have been managing and conducting quality assurance operations since the inception of FDA's Bioresearch Monitoring program. Our Quality Assurance Associates are all highly qualified, with advanced degrees and significant, relevant industry and/or medical experience.

Good Clinical Practice: To ensure that scientific and ethical standards are met in the conduct of clinical trials, BioResearch Monitors uses proprietary computerized audit tools, customized for each project, to efficiently and consistently collect, analyze and report quality assurance audit findings. This focused systems oriented approach to quality assurance is designed to assess and validate study conduct and documentation to assure regulatory compliance and conformance to protocol, SOP and contractual requirements. Our methodology fully evaluates the activities and documentation underlying study data integrity and GCP ethical and regulatory requirements. To maintain independence and objectivity in performing Quality Assurance evaluations, BioResearch Monitors does not conduct or manage clinical trials.

GCP services for domestic and worldwide clinical trials include, but are not limited to:

- Pre- and post project placement audits of Investigator Sites, IRBs, CROs and SMOs;
- Central and local clinical, biopharmaceutical, electrophysiology and imaging laboratory audits;
- EDC, data management and data validation audits;
- Study file and regulatory documentation reviews;
- Drug accountability and reconciliation audits;
- Database, final report and regulatory submission audits;
- Computer systems validation audits;
- Preparation of Sponsor/Monitor and Clinical Investigator sites for regulatory inspection;
- Training of quality assurance and clinical research personnel;
- Development and review of Standard Operating Procedures;
- Adjunct clinical trial coordination and monitoring;
- Prospective and retrospective clinical study data collection and CRF completion.

Good Laboratory Practice: GLP services include sponsor and contract laboratory facilities inspections; Critical phase inspections; SOP development and review; Data and final report audits; Adjunct QAU functions.

Good Manufacturing Practice: GMP services are principally related to Clinical and Nonclinical investigational products and include inspections of in-house and contracted drug product and drug substance manufacturing, packaging and labeling; Process and scale-up validations; QA/QC systems evaluations; Product complaint investigations; Logistics, storage and distribution audits.

Please call **BioResearch Monitors, Inc.** to discuss how our Quality Assurance programs and services can add value and confidence to your research projects.

Services: Bioanalytical Data Audits/Laboratory & Validation Evaluation, Clinical Trial Monitoring, Computer System Validation, Consulting, Contract Auditing, Data Validation, GCP Compliance, GLP Compliance, GMP Compliance, Quality Assurance/Control

Brand Institute, inc.

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Brand Institute is the world's premier brand name development and research consultancy firm, sustaining over 15 years of experience in providing the healthcare/biotech and consumer/B2B industries with unparalleled brand name development, market research, trademark and design services. Its subsidiary, Drug Safety Institute, provides a state-of-the-art model for proprietary and nonproprietary research, medication error prevention analysis associated with labeling of pharmaceuticals, biological products and medical devices. We utilize an exclusive methodology, which was developed by former governmental regulatory personnel and is compliant with regulatory standards.

Brand Institute holds a proven track record of 77% of FDA name approvals, 46% of Health Canada, 71% of EMEA and 41% of MHLW name approvals, differentiating us from any other company in this highly specialized market.

Brand Institute's branding experts will assist you in all phases of your brand name development initiatives and will ensure you on-time deliverables and a successful name approval. We are committed to providing services essential for positioning, creating, evaluating and designing great brands.

Our core competencies are:

- Brand Strategy/Architecture
- Name Development
- Line Extensions
- Corporate Identity
- Market and Safety Research
  - Online Quantitative/Qualitative Studies
  - Creation and Assessment of Proprietary and Nonproprietary Names
- Regulatory Submissions/Rebuttals
- Trademark Risk Assessment
- Design Services

Brand Institute has offices strategically located in the U.S., Canada, Europe and Asia in order to provide optimal and attentive service. Below is contact information for our regional and international offices:

Austin	*Chicago*	*Frankfurt*	*Geneva*
+1 (512) 369-9100	+1 (312) 475-9600	+49 (0) 6196-400-966	+41 (0) 22-819-1753
London	*Los Angeles*	*New York*	*Ottawa*
+44 (0) 207-240-2200	+1 (310) 830-6111	+1 (212) 557-2100	+1 (613) 761-1100

Raleigh-Durham	*Rockville*	*San Francisco*	*Tokyo*	*Toronto*
+1 (919) 572-9311	+1 (301) 984-1055	+1 (415) 421-3200	+81 (0) 3-6861-7517	+1 (416) 622-5777

Services: ADE Evaluation/Drug Safety Assessment, Claims Support Studies/Safety and Efficacy Studies, Clinical R&D, Clinical Study Reports, Consulting, Market Research/Product Communication, Project Management, Regulatory Affairs/Regulatory Strategy, Regulatory Document Preparation

CAC Corporation

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CAC Corporation is an IT system consulting and system integration provider and contract service organization (CSO) comprised of 700 professionals and specialized in pharmaceutical research, development and post-marketing. Founded in 1966, CAC has clients in industries such as banking, securities, insurance, media and food/consumer goods. CAC has provided consulting, system integration and system operation for more than 50 pharmaceutical companies, including global pharmas, for over 30 years.

Our policy is contained in our logo, PRASMA, which stands for Pharmaceutical R&D Advanced System Management and covers contract services from new key compounds findings to post-marketing management.

Our Services:

- **Tutorial Services:** CAC tutorial services on Japanese pharmaceutical rules and regulations which are provided by drug safety and pharmacovigilance experts are available on an ad hoc basis.
- **Consulting Services and Safety Database Implementation Services:** Consulting services for searching, understanding and evaluating global safety databases under the new regulation environment in Japan are provided according to the extent of interest of the client. Intensive E2B consulting covers the so-called Green Book.
- **Computerized System Validation Services:** CAC provides consulting services on how to handle computerized system validation (CSV) and electronic signatures/electronic records (ER/ES). Compliance training services are also provided. CAC has extensive experience in developing and implementing global policies and standards for CSV and ER/ES covering three main regions: the EU, the US and Japan.
- **Data Validation and Legacy Data Conversion Services:** Starting from validation of the existing database system, legacy data conversion from a client's old system to a new system is an area in which CAC has continuing experience. CAC carries out such activities through intensive discussions with clients and based upon the client's approval.
- **e-Submission Services through CAC Gateway:** EDI and Gateway were built for the MHLW, FDA and EMEA and secure e-Submission to those authorities is a new focus of CAC. CAC is a member of the e-Prompt project sponsored by the FDA and has been certified by the FDA for e-Submission. Recently CAC accomplished the mandatory steps for e-reporting to EudraVigilance via Gateway and allowed clients to exchange safety information with EMEA.
- **Safety Data Entry, MedDRA® Coding and Medical Evaluation Services:** CAC provides safety data entry, MedDRA®-J coding and medical evaluation services to any pharmaceutical client, regardless of the client's location. This service enables American and European pharmaceutical companies to grasp their comprehensive drug profiles and run their signal detection tools on their own databases.
- **Hosted Services and Risk Management Services:** CAC hosts application services through which pharmaceutical companies can use the CAC's secure database as if it were their own and keep signal detection/risk management close at hand.
- **External Audit and Global SOP Preparation Services:** CAC provides pharmacovigilance external audits and supports to establish pharmacovigilance systems which cope with FDA and EMEA's inspection. CAC supports to prepare global SOPs and maintain pharmacovigilance IT systems which meet global requirements. CAC's accurate knowledge of FDA and EMEA's regulations and IT skills enabled clients to handle global regulations.

Other services available only in Japan are new drug application to the MHLW, clinical and safety data management, and system operation services. Our system implementation, integration and operation services also cover preclinical R&D.

CAC is compliant with FDA 21 CFR Part 11 and the Japanese "e-doc" laws. CAC is competent in consulting, evaluation of global safety databases and implementation of such packages according to FDA 21 CFR Part 11 and the Japanese "e-doc" laws.

Services: ADE Evaluation/Drug Safety Assessment, Adverse Event Management/Software, Computer System Validation, Data Management, Document Management, Electronic Data Capture, Electronic Submissions Preparation, Medical Writing, Software Development & Evaluation, Statistical Services/Meta Analysis

The Cambridge Group Ltd.

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Innovative Talent & Support Solutions for Clinical Trials

Since 1976, The Cambridge Group, Ltd. has steadily grown into one of the most respected talent resource firms in clinical trials. We have achieved our industry leading reputation in the Pharmaceutical/Biotech/CRO industries by engaging our key strength – the ability to foster, develop, and maintain excellent working relationships with the pharmaceutical community to deliver outstanding talent services to our clients.

Scope of Services

- Permanent Placement
- Contract Staffing
- Dynamic Resource Management: Unique clinical solutions which include Clinical Project Teams, Outsourcing, Functional Service Provider

Areas of Specialization:

* Clinical Operations
* Clinical Data Management
* Quality Control/Quality Assurance
* Biostatistics
* Bioinformatics
* Clinical Systems
* SAS/Statistical Programming
* Regulatory Affairs

Permanent Placement

For four decades, The Cambridge Group Ltd. has successfully placed permanent employees across all levels and specialties within clinical trials. Whether you need a Senior Biostatistician, or a VP of Clinical Operations, our experienced recruiters stand ready to solve your talent acquisition challenges. We are passionate about our work and have access to every resource necessary to provide you the strongest candidates for your positions.

Contact for Permanent Searches:

Traci Palmer - Partner, Clinical Operations
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Torey Vizzo - Partner, Biostatistics
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For all other services:
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From big pharma to emerging biotech, we have the experience and relationships to provide key talent and support, nationwide.

Services: Clinical Trial Monitoring, Consulting, Data Management, Electronic Submissions Preparation, Medical Writing, Project Management, Regulatory Affairs/Regulatory Strategy, Statistical Services/Meta Analysis, Temporary Services and/or Permanent Placements, Trial Management

Cambridge Regulatory Services Ltd.

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Contact Person: Karen James, Mike James

Services: Chemistry/Manufacturing/Control, Consulting, Leaflet (PIL) Testing, Drug Master File (DMF), Dossiers, Expert Reports, Licensing/Acquisitions, Pharmacovigilance/Labeling, Regulatory Affairs/Regulatory Strategy, Rx to OTC Switch, eCTD, Scientific advice, Due Diligence (Cambreg)

A Personal Service from Experienced Professionals

Based in Cambridgeshire, one of Europe's top drug development and biotech hot spots, Cambridge Regulatory Services is one of the UK's fastest growing regulatory affairs support organisations.

Cambreg has given over ten years service to a wide variety of companies ranging from virtual biotech companies and start ups to global pharma multinationals. Cambreg's reputation for honest, common sense advice and on time project delivery has ensured that the Company's growth has been enhanced by high levels of repeat business and personal recommendations.

Specialising particularly in helping companies without a European presence and who are therefore not fully conversant with the European regulatory requirements.

Co-Director, Dr Mike James spent 11 years at the MHRA, where he reviewed over 2,000 CTAs (clinical trial application) including more than 400 biotech products of all classes. He now specialises in helping clients with their clinical trials applications and offering specialist advice on EU clinical trials requirements and marketing authorisation applications for biotechnology drugs.

The Company offers a full range of regulatory services for drugs at all stages of development and can provide strategic advice for the development of new entities and formulations, the preparation of regulatory documents for clinical trials and marketing authorisations for application through national, mutual recognition and centralised routes. Post approval maintenance activities such as annual reports for CTAs and variations to marketing authorisations.

Cambridge Regulatory Services has expertise in the following areas:

Regulatory Consultancy and Advice on

- Regulatory requirements and strategies
- Scientific advice meetings
- Data evaluation for product acquisition Due Diligence
- Development programmes to meet Regulatory requirements

Dossier Preparation for

- Marketing Authorisation Applications (CTD format)
- Clinical Trials Applications (IMPDS)
- Investigator's Brochures
- Summaries and Overviews ('Expert Reports'), Drug Master Files
- Variations, safety updates, renewals, labelling, leaflets

Procedure Management

- MRP/DCP and Centralised
- Submission and follow through of applications
- Meetings between clients and the Agencies
- Hearings and appeals

Other Services

- Pharmacovigilance
- eCTD Publications
- User Tests of Patient Leaflets
- Paediatrics

Services: Chemistry/Manufacturing/Controls, Consulting, Drug Master File Dossiers, Expert Reports, Licensing/Acquisitions, Patient Information Leaflets (PIL)/Labeling, Pharmacovigilance, Regulatory Affairs/Regulatory Strategy, Regulatory Document Preparation, Rx to OTC Switch

CanReg Inc.

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Contact Person: Darrell Ethell

GLOBAL REGULATORY CONSULTING:
Across Disciplines. Through the Lifecycle. Around the World.

CANREG is a consulting firm dedicated exclusively to regulatory affairs consulting for the pharmaceutical, biotechnology and medical device industries. More than 100 in-house consultants and staff support our clients around the world. **CANREG** has successfully negotiated drug and medical device approvals in more than 60 countries. Our senior consultants have over 30 years experience dealing with the Food and Drug Administration (FDA), Health Canada, and European regulatory agencies.

Wherever the product is in the development process or post-marketing stage, **CANREG** can help navigate the path forward. Global regulatory agencies continually revise guidance documents, requirements and regulations. **CANREG** clients benefit from working with a partner actively involved with these changes every day. For many clients, this translates into shortened time-to-clinic and ultimately, time-to-market.

CANREG provides global regulatory services for drugs, biologics, medical devices, natural health products, food, Over-The-Counter (OTCs), and cosmetics, including:

- Global Marketing Authorizations (NDA, NDS, MAA)
- Clinical Trial Authorizations (IND, CTA)
- QA Services/GMP Auditing
- Regulatory Assessment and Strategy Development
- eCTD Services and Regulatory Publishing
- Pharmacovigilance and Medical Information Support
- Medical Writing
- Training

Our 22,000 square foot building in Dundas, Ontario has been designed for the efficient development of regulatory submissions. **CANREG** also has an office in Montreal, Quebec. We have a Regulatory Operations Department that is responsible for electronic and paper publishing of all submissions. A Quality Assurance Department reviews all work before it is released.

http://www.canreginc.com/ or 1 (866) 722-6734

Services: Chemistry/Manufacturing/Controls, Consulting, Drug Master File Dossiers, Electronic Submissions Preparation, Medical Devices/Combination Products, Pharmacovigilance, Quality Assurance/Control, Regulatory Affairs/Regulatory Strategy, Regulatory Document Preparation, Training

CareFusion Research Services

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Phone: +1.714.919.3361
Fax: +1.714.919.3361
Internet: www.carefusion.com/researchservices
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Contact Person: Michael Taylor

Research Services from CareFusion (formerly Cardinal Health Research Services) is a global market leader providing customized hardware, software and services to support all phases of clinical research. We are committed to designing the most effective solution for your unique trial protocol. For respiratory, cardiac safety and any trial requiring electronic patient-reported outcomes (ePRO), our inclusive solutions and dedicated experts provide you with complete support. Our innovative technology and services ensure the most accurate data and efficient trial management.

Major Products

Site Products

- **MasterScope® CT** is a unique diagnostic device platform for protocol-driven data collection in Spirometry, ECG, IOS and ePRO delivering consistent, regulatory compliant, high-quality data.
  - FlowScreen® CT ~ The world's first Spirometer with an integrated full-page color printer
  - CorScreen® CT ~ 12-Lead ECG with Integrated HES® Interpretation and electrode test program
  - SpiroPro® CT ~ Your complete handheld spirometer and pulse oximeter for clinical trials

Home Monitoring Products, including ePRO

- AM3® ~ The *new* and *improved* gold standard in Peak Flow monitoring and electronic Diary
- AM2+ ~ The gold standard in Peak Flow monitoring and electronic Diary
- ABPM+ ~ The new standard in Ambulatory Blood Pressure Monitoring
- COR12+ ~ The new generation of digital ECG Recorders
- **VIA**Motion™ ~ The most comprehensive activity monitor for clinical trials
- **VIA**Pen™ ~ Bridging the gap between paper and electronic data capture
- **VIA**Pad® ~ Advanced eDiary designed exclusively for use in clinical trials

Major Services

- **Protocol Consulting.** Our protocol consulting services provide a dedicated, trained and experienced staff to meet with you to review study protocol and identify the right product and solution combination to best address your needs.
- **Project Management.** A dedicated Project Manager is assigned to every project, providing a single point of contact for any and all aspects of your trial.
- **Education and Training.** Our education department offers complete, condensed and protocol specific trainings, all which are concluded with a certification process, ensuring accurate results for your trial.
- **Inventory Management.** Our logistics department is experienced in shipping product all over the globe and can assist in ensuring your product gets to your trial, wherever and whenever it is needed.
- **Data Management.** After your data is securely transmitted and received, our data management team offers solutions for data corrections and organization.
- **Data Analysis (CorLab® & OverRead™).** Our cardiac safety and respiratory Corelabs are the best in the business and offer data analysis solutions to help ensure accuracy of your study.
- **Technical Support.** All of our technical support is in-house (not outsourced), providing the best and most accurate support available.

Company Experience

CareFusion Research Services has proven experience and success with most of the top 20 pharmaceutical companies in the therapy areas of Respiratory, Cardiac Safety and any trial requiring electronic patient-reported outcomes (ePRO). In the last 5 years, our technology has been used in over 225 international trials in over 70 countries.

Services: Cardiovascular Monitoring/Pulmonary Diagnostics, Digitized QTc Analysis, Disease Management/Health Outcomes, Electronic Data Capture, Electronic Diary/Dictionary/Translator, Medical Devices/Combination Products, Project Management, Quality Assurance/Control, Software Development & Evaluation, Spirometry/Challenge Testing

CareFusion

4-Color AD

Cetero Research

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Internet: www.cetero.com/cso
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Contact Person: John Capicchioni

Knowledge. Trust. Service.

Cetero Research is the leading provider of clinical pharmacology, bioanalytical, and specialty Phase II-IV CRO services to the pharmaceutical, biotechnology and generic industries. You can count on the people behind our services. Our scientists and medical staff have unmatched knowledge and experience to provide accurate, reliable data. Cetero develops practical approaches specifically designed to accommodate your research needs. We have demonstrated a proven track record of delivering accurate data when you want it, in a format you want, with an unwavering commitment to quality.

Scope of services

- **Clinical Pharmacology**
  With six clinical sites across North America and more than 25 years of clinical pharmacology experience, Cetero is the clinical pharmacology specialist. Our repertoire of clinical pharmacology study experience includes first-in-human, proof-of-concept, interaction, bioavailability, PK/PD and TQT studies.
- **Bioanalytical**
  Cetero's experienced R&D team can develop and validate methods, or transfer your method to our laboratories. With nearly 50 LC/MS/MS and three laboratories in North America, Cetero offers method development, transfer and validation; LC/MS/MS; immunochemistry; and custom synthesis.
- **Cardiac Safety**
  CORWatch, Cetero's suite of cardiac safety services, provides you with the ability to accurately evaluate the potential for unintended effects of drugs on the heart. With an impressive track record of conducting more than 40 TQT trials since 2005, Cetero is your cardiac safety specialist. By creating the first true integration between a top clinical pharmacology CRO and a top core lab, the Cetero-Cardiocore alliance is able to provide clients with integrated, turnkey delivery of TQT studies, with one contract, one project manager and one final report.
- **Environmental Exposure Chambers**
  The Environmental Exposure Chambers (EECs) are a validated, rapid and FDA-accepted clinical solution for the development of small molecule drugs, immunotherapies and therapeutic devices. Our seven chambers are ideal for a broad range of indications within the respiratory, immunology and ophthalmic areas.
- **Phase II-IV CRO Services**
  Cetero can assist with planning, managing and monitoring your Phase II-IV clinical program. Our experienced clinical trial management team can conduct site initiation, selection and management. Coupled with our in-house clinical and scientific affairs services, rest assured your late-stage drug development needs will be met.
- **Central Lab**
  Cetero's Central Lab provides accurate results with fast turnaround time. The biochemical profiles, packaging and logistics are tailored to your specific protocol requirements and are seamlessly integrated with our clinical operations. Cetero is responsive to your unique requirements for central laboratory services.
- **Therapeutic Areas of Expertise**
  Allergy, Asthma, Dermatology, Diabetes

Services: Analytical Assay Development and/or Laboratory Service, Central Laboratory Services, Clinical Pharmacology, Data Management, Inpatient/Outpatient Facilities, Investigational Site/Network, Patient Recruitment, Pharmacokinetic/Pharmacodynamic Modeling, Therapeutic Specific Research, Trial Management

Charles River Clinical Services

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Fax: +1.253.593.5181
Internet: www.criver.com
email: askcharlesriver@crl.com
Contact Person: Colleen Hoke

Charles River is a global contract research organization offering an extensive range of preclinical and clinical services to the pharmaceutical and biotechnology industries. We provide innovative solutions and strategic program advice to manage the transition from preclinical to early-phase clinical studies. Charles River utilizes an integrated approach that generates appropriate information for rapid decision-making and can help us determine unique strategies that maximize resources and optimize results based on your specific objectives. Our firsthand knowledge in the development of a wide range of compounds and our experience with global regulatory agencies can help you create an efficient, successful program.

With expert staff, a state-of-the-art facility, comprehensive service capabilities and 250 beds, we have the expertise and resources to successfully execute a full range of early-phase clinical trials to help you achieve your goals.

- 250 beds in four units
- Specialized units for
  - Radiolabeled trials
  - Cardiac safety trials
- High-volume screening area
- Comfortable, monitored activity areas
- Pharmacy and radiolabeled materials pharmacy
  - Clean room dose-prep compliant (USP 757)
  - Biosafety Level 2 certified
- Versatile clinical procedure bays
- Processing laboratory
- Electronic sample management system
- Commercial kitchen
- Private monitor rooms

Whether you need a single study or are looking to outsource a full program, our capacity and portfolio of services allows us to offer more flexibility in scheduling and choice from a full list of study designs.

- First-in-human (single and multiple ascending dose)
- TQT/cardiac safety
- Bioavailability/bioequivalence
- Drug-drug interaction
- Pharmacokinetics/pharmacodynamics
- Microdosing and radiolabeled AME
- Food effect
- Vaccine

In order to optimize your overall clinical program, Charles River offers a full range of services to support the conduct of Phase 0-IV clinical studies.

- Protocol design and writing
- Bioanalysis
- Immunology
- Immunogenicity
- Pharmacokinetics

Services: Analytical Assay Development and/or Laboratory Service, Clinical Pharmacology, Consulting, Data Management, Inpatient/Outpatient Facilities, Pharmaco EEG Studies, Preclinical Development Services, Protocol Development, Statistical Services/Meta Analysis, Toxicology

CIRION Clinical Trial Services Inc.

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Email: businessdevelopment@cirion.com
Contact Person: Fraser R. Day

CIRION is a leading provider of Central Laboratory services for clinical studies. We offer a complete range of project management services, logistical and analytical services, a broad portfolio of safety and specialized assays, including biomarkers, and development and validation services.

Our mission is to provide unsurpassed excellence through our state-of-the-art Central Laboratory and services enhanced by the scientific capabilities and know-how of a highly skilled research laboratory team. Our expertly trained scientists work in an environment supported by high-tech computerized management systems and laboratory equipment.

Our team is committed to quality assurance exceeding industry standards to ensure reliable results and uncompromised service.

Full Service Central Laboratory

- Experienced Project Management Team
- IATA-Compliant Specimen Collection Kits
- International Site Support
- Customized Project Material
- Worldwide Shipment Management and Tracking
- GLP-Compliant Specimen Storage
- Data Management with Flexible Reporting Capabilities
- Real-Time Data Cleaning
- Secure Web Access
- Next-Day Results on Safety Testing
- Broad Portfolio of Specialized Assays, including Biomarkers

Development & Validation Services

- Biomarker Assays: Exploratory, partial and full validation
- Pharmacokinetic (PK) Assays
- Anti-Drug Antibody (ADA) Assays: Screening and confirmatory
- GLP and Non-GLP Validation
- Extensive Menu of Methods:
  - Cell-Based Assays
    - Neutralizing Antibodies
    - Activity/Potency Assays
    - Cell Proliferation
    - Cell Line Conditioning and Characterization
  - Immunology
    - ELISA, ELISPOT
    - Meso Scale (Single and Multiplex)
    - Luminex (Single and Multiplex)
    - Flow Cytometry
  - Molecular Biology
    - DNA and RNA Extraction
    - Real-Time PCR (qPCR)
  - Cytogenetics
    - Fluorescent In Situ Hybridization (FISH) Assays
    - Interphase FISH Assays
  - Microbiology
    - Antibiotic Susceptibility
    - Microorganism Identification

By-the-Book Quality

- Strict adherence to GCP & GLP regulations
- Accreditations from the College of American Pathologists (CAP) and the Center for Disease Control (CDC)

Reaching Further To Answer Your Needs™

Services: Analytical Assay Development and/or Laboratory Service, Biological Specimen Collection/Storage/Distribution, Central Laboratory Services, Clinical R&D, Diagnostic Test Evaluation, Microbiology Testing/Services/Surveillance, Project Management, Virology

ClearTrial, LLC

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email: info@cleartrial.com
Contact Person: Mike Lange

Clinical Trial Software for Integrated Planning, Forecasting, Outsourcing and Project Tracking

ClearTrial helps life sciences companies drive operational efficiencies and accelerate clinical development through the industry's only software platform for integrating and managing clinical trial operations from Plan to Cash™. Through this fast, accurate, and consistent web-based framework, our customers quickly create clinical trial cost, resource, and timeline forecasts they can trust … more efficiently negotiate and manage outsourced studies and licensing arrangements … and easily track projects against a detailed operational plan to pinpoint cost variances, underperforming studies, and accrued liabilities – in minutes.

Top 20 biopharmaceutical companies, Clinical Research Organizations (CROs), medical device companies and small biotechs have all embraced ClearTrial software. These organizations have come to rely on ClearTrial's industry intelligence, embedded clinical knowledge, and activity-based planning approach to add speed, flexibility, accuracy, and consistency to their clinical operations.

With the ClearTrial Software-as-a-Service (Saas)-based system, you get clinical software that seamlessly integrates across your clinical development processes, increasing efficiency and performance:

PLAN

Assess multiple clinical development strategies, determine the one that best meets your business goal, and in minutes generate accurate forecasts for costs, resources, and timelines – at the study or portfolio level.

SOURCE

Gain speed and consistency and cut costs in the outsourcing function through fast, consistent RFP development, streamlined contract negotiations, and greater visibility to cost and resource requirements.

TRACK

Get visibility and control over projects that are underway through instant dashboard view of project status and Earned Value against planned, automated accruals tracking, and quick, accurate reforecasting for change orders and midstream study adjustments.

Services: Clinical R&D, Clinical Trial Design, Consulting, Cost Benchmarking/Financial Consulting, Licensing/Acquisitions, Project Management, Software Development & Evaluation, Standard Operating Procedures, Strategic Planning and Implementation, Trial Management

ClinAudits, LLC

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Contact Person: Cheri Wilczek

ClinAudits, LLC, provides quality assurance and regulatory compliance auditing and regulatory consulting services to the pharmaceutical, biotechnology, medical device and biological industries. We serve your needs for compliance with GCP, GMP, and GLP. While specializing in Good Clinical Practice (GCP) audits of clinical research trials, ClinAudits' services extend to Phase I-IV clinical studies of **pharmaceuticals**, as well as serving the needs of clients developing **medical devices**, **biotechnology**, **biologicals**, **gene therapy agents** and **Rx to OTC** drugs.

Since 1994, ClinAudits has delivered these services both **domestically** and **internationally** including locations in North America, South America, Europe, Asia, Africa and Australia. ClinAudits has a team of auditors, located in the U.S. and Canada, with an extensive experience in clinical research and drug development. This experience encompasses a broad range of disciplines including, but not limited to: Oncology, Infectious Diseases, Respiratory Diseases, Central Nervous System (CNS), and Dermatology.

AUDITING SERVICES include:

GCP: Auditing to comply with FDA regulations, ICH Guidelines, and local governmental regulatory guidelines or company-specific SOPs and guidelines • Investigator Site Audits • Audits of Contract Research Organizations (Pre-qualification and Post Capability) and CRO managed studies • Pre-placement assessment of study sites • Central and Specialty Laboratory Audits • Clinical Trial Supply Audits/Drug Depot • IVRS Audits • Final Study Report Audits • Adverse Event Reporting System Audits/Drug Safety/Pharmacovigilance • Clinical Pharmacology and Phase I Units • Document Archiving, Trial Master File or Records Management Systems • Monitor Training/Monitoring Department • Computer Validation Systems • Gene Therapy Audits • Institutional Review Board (IRB)/EC Audits • Patient Registries • Database Audits • Electronic Submissions Audits • Sponsor/Monitor Process/System Audits • Mock-FDA or Other Governmental Authority Audits • Remediation • SOP Documentation Systems • 21 CFR Compliance • CAPA Review, Reconciliation and Close-out

GLP: Audits of Safety or Specialty Laboratories • Pre-clinical Laboratories • Laboratories associated with Manufacturing Facilities • Mock FDA or Other Governmental Authority Audits • Computer Validation • Facility Design • Qualification of GLP Facilities • SOP development and documentation systems

GMP: Audits of: • Setup/Review Stability Programs and Data • Process/Equipment Validation • Vendor Facilities (API, Bulk, and Commercial) • Batch Record Review and QC Checking • Computer Validation • Facility Design • Qualification of GMP Facilities • Mock FDA or Other Governmental Authority Audits • SOP Development/Documentation Systems

CONSULTING SERVICES can serve your needs to:

• **Train QA** and clinical research personnel at your facility or the study site • **Provide QA staff** to come to your facility for **internal projects** • Develop/review/revise **Standard Operating Procedures** • Develop or review **FDA IND safety updates** • **Medical Writing** • Design and implement **clinical project workflow/timelines** (project management) • **Regulatory Affairs** submissions including preparing filings for **IND, PLA, NDA, BLA, IDE, PMA, and 510k** • **Post submission inquiries**, updates, and reviews • Review of **Serious Adverse Event Reporting**, labeling, packaging, and marketing materials

Personalized, professional consulting for regulatory compliance with domestic and international standards can be provided for companies that are:

• **Growing** • **Outsourcing** • **Downsizing**

Our competitive advantage lies with delivering high quality service, being responsive to each client's specific needs, and to providing solutions that are timely, cost-effective and add-value. If you seek to capitalize on your core competency, improve your return, increase your flexibility, and reduce your risk, our experienced consultants can provide you with compliance services. We can ensure that your critical compliance activities are completed on time and in a resource-effective manner.

Services: Bioanalytical Data Audits/Laboratory & Validation Evaluation, Computer System Validation, Contract Auditing, GCP Compliance, GLP Compliance, GMP Compliance, Quality Assurance/Control, Registries, Regulatory Affairs/Regulatory Strategy, Standard Operating Procedures

ClinDatrix, Inc.

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email: louise.murphy@clindatrix.com
Contact Person: Louise M. Murphy, PhD, MBA

A Quality Full-Service CRO

ClinDatrix is committed to providing a personalized approach to the critical aspects of clinical research, data management, and statistics in the biotechnology, medical device, and pharmaceutical industries.

ClinDatrix applies knowledge and experience in project management and clinical monitoring and links these efforts tightly with professional data management and biostatistics. ClinDatrix has global capability through European, South American, Australian and Asian affiliates.

Project Management

We specialize in working with small to medium size companies to offer a customized approach to deliver the project on time and on budget. Services include contract management of clinical research sites, outsourcing management of contractors, timeline planning and tracking, monitoring, CRA training and trip report review.

Clinical Monitoring and Site Performance Metrics

Site selection, initiation, and clinical trial monitoring all contribute to a successful project. Our staff, working together with you and the site, is totally committed to your success. Services include investigator selection and recruitment, site evaluation, investigator meetings, onsite training and a battery of services and performance metrics related to the scheduled site visits.

Protocol and Case Report Form Development

A good protocol in conjunction with a thorough CRF design can eliminate a number of problems in a project. Utilize our expertise for this task.

Data Management and Statistics

Our data managers can shorten the time for project database design, implementation, and validation by using our fully validated database management system. Through application of quality processes and standards, accurate clinical databases are produced for analysis and reporting. We prepare and review Data Management documentation to include any or all of the following: Data Management Plan, Quality Control Plan, Edit Specifications Document (data validation standards), Clinical Data Review Manual, Data Management Quality Control Checklists, Data Management Project Binder, Data Validation, and Cleaning Systems. Our statisticians and statistical programmers provide a full range of statistical services.

ClinDatrix has implemented Oracle Clinical 4.5.3 and can now offer our clients the advanced capabilities of this industry-standard database, including Remote Data Capture and Safety Database Management.

Regulatory Strategy

Regulatory services are provided through our Alliance Partner, Ground Zero Pharmaceuticals, Inc.

Consulting

Consulting is offered in any of the service areas. Medical device engineering expertise can be provided to assist with Design History Files, Technical Files and Quality Systems.

Services: Case Report Forms, Clinical Trial Design, Clinical Trial Monitoring, Data Management, Medical Devices/Combination Products, Project Management, Protocol Development, Regulatory Affairs/Regulatory Strategy, Statistical Services/Meta Analysis, Trial Management

Clinical DataFax Systems Inc.

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Internet: www.datafax.com
email: info@datafax.com
Contact Person: Wayne Taylor, President

Clinical DataFax Systems Inc. (CDSI) provides both fax and EDC (electronic data capture) solutions for clinical trial data management. Since its introduction almost 20 years ago, DataFax has evolved to become the preferred fax solution of clinical researchers worldwide. In 2008 CDSI expanded the server platform choices to include Sun Solaris, Apple OS X and Novell SUSE Linux. Client applications are available for these platforms and for Microsoft Windows. In addition, CDSI now offers hosted services to customers that prefer an outsourced solution.

Flexibility and Security

- collect data using both fax and EDC in the same study
- collect some case report forms by fax and others by EDC
- use fax at some clinical sites and EDC at others
- switch sites from one method to the other at any time during a study

iDataFax - EDC Features

- secure data transmission using SSL encryption
- intuitive patient binder interface with data screens that match the printed paper version
- easy work flow guides are provided by patient, visit and page status icons
- data entry aids: legal value checks, consistency checks, help messages, color coding
- users can enter comments and reasons to explain values or changes
- users can read and respond to any queries from the study coordinating center

DataFax - Fax Processing Features

- automatic indexing of each page received by fax
- ICR/OCR reads numbers, dates, check boxes, and visual analog scales
- split screen review of faxed pages and the corresponding data records
- create bookmarked PDFs for each patient, each site, all SAE reports, etc.

Other Features

- work flow management for data reviews
- flexible patient scheduling including multiple cycles and conditional events
- automatic tracking of required visits and data forms
- user defined lookup tables for coding, spell checking, acronym expansion, etc.
- generic edit checks that can be reused across studies
- audit trail of all changes made to data fields, queries and reasons
- user defined roles encapsulate study permissions for different users
- standard study management reports
- interface to ORACLE, PostgreSQL, MYSQL and SAS
- online user guides for training and support

Clinical DataFax Systems Inc. provides software, training, study setup, and ongoing client support. An active user group meets annually to share experiences, demonstrate innovative solutions, and recommend directions for software development.

For more information, or to arrange a demo, please visit our web site at **www.datafax.com**

Services: Case Report Forms, Clinical Trial Monitoring, Data Management, Data Validation, Electronic Data Capture, Remote Data Entry, Site Performance Metrics

clinIT AG

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email: max.horneck@clinit.net
Contact Person: Dr. Max Horneck

clinIT serves as a unique provider of all information technology required for the realisation of clinical documentation tasks. Our clinical trial software TRI@L-IT is based on the needs of clinical data management and is designed for both statistical analysis and for the data transfer into the customers' data base. It has been successfully deployed in numerous trials integrating centres all over the world. Our offer comprises the following services:

1. Electronic data capture using our standard Internet software TRI@L-IT. As the software does not require local installation or local data storage, it is particularly suitable for companies wishing to integrate this technology easily with little effort into their own projects. The modularity of our tools allow most flexible adaptation to your projects' specific requirements. The very same data base can be used for the realisation of a whole range of clinical documentation tasks, i.e. clinical (approval) trials, observational trials with special features like implementation of a guideline-based treatment recommendation for the practitioner, investigator initiated trials, competence networks and others. We attach great importance to the support of your internal processes and infrastructure.
2. Central Randomization via telephone and web is fully integrated in the TRI@L-IT eClinical solution. Standard randomisation schemes are supported as well as complex adaptive study designs. Additionally it allows sponsors and study management to control recruitment in real time. Drug supply management can be supplied with detailed drug consumption data. For investigators, assignment is unpredictable even in open trials; thus bias can be reduced. The IVRS system used by clinIT guides the investigator through a dialogue in which all required information is entered by means of a touch-tone phone. On request, clinIT serves toll-free phone numbers in almost every country of the world. clinIT may set up helpdesks to different extents depending on the customer's needs.
3. A special PartnerPro Training Program to provide EDC competence with TRI@L-IT. By modularized training of the involved personnel, PartnerPro enables you to:
   - Provide your customers with EDC management directly via your own project – and monitoring staff.
   - Optimize the use of TRI@L-IT for your projects by integrating and tailoring it to your specific internal processes, SOPs and structures.
   - Enhance the expertise of your key staff in trial management where it matters: on the interface to the client.
   - Participate in the development process of our software.

These are our highlights at one glance:

- Many years of experience in worldwide deployment
- Integration of the selected project team's previous experiences and standard procedures
- Our software especially supports bundled projects because it allows the definition of standards, procedures and processes to be used in an optional number of studies. This also holds for the effective data quality management which is reflected in an intelligent flexible data validation procedure comprising both on-line edit checks and off-line generated queries. All queries are proceeded and answered within the EDC system itself. Thus, an efficient conduct of several trials appropriate for meta analysis can be offered to a reasonable price.
- Integration of external data sources into the eClinical platform to provide a single portal view for the project manager
- Full service offer through existing co-operations with internationally positioned partners
- Full regulatory compliance confirmed in numerous audits, GCP compliance, FDA CFR 21 Part 11 compliance
- Automatic validated software development process from the protocol
- Very fast communication between client (browser) and server, therefore extremely short loading times of the input masks and a high level of acceptance among the investigators
- Uniform consistent, largely self-explaining user interface, allowing the handling with minimum training

Services: Case Report Forms, Data Management, Data Validation, Electronic Data Capture, Randomization (Automated/Centralized/Vocal Computer), Registries, Remote Data Entry, Software Development & Evaluation, Telephone Support, Training

CompleWare Corporation

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Iowa City, IA 52244-3090, United States
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Fax: +1.319.626.8750
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email: info@compleware.com
Contact Person: John Weiler

CAPTURE AND MANAGE CLINICAL RESEARCH DATA USING INTEROPERABLE, INNOVATIVE TECHNIQUES TO IMPROVE SPEED, ACCURACY, AND EASE OF THE DATA ENTRY PROCESS

CompleWare Corporation (CW) has been fulfilling its mission of providing outstanding, integrated products and services for the capture and management of clinical research data since 1985. Products are ready to deploy for in-licensing through the CompleSoft Division to collect and manage virtually all clinical trial data.

CompleClinical®

- ➢ Capture, manage, validate, and display all eClinical data using one efficient, integrated solution
- ➢ Log on with a single CompleWare unified user name/password to view all data at one Web location
- ➢ Perform central review of case report form (CRF), spirometry, electrocardiogram (ECG), and electronic patient reported outcome (ePRO) data
- ➢ Produce online reports and study metrics at the subject, site, and protocol level to follow study progress and metrics

HomeCDL™ and HomeCDL-Online™

- ➢ Collect diary and other ePRO, spirometry, Holter, and blood pressure data electronically between visits
- ➢ Enter physiological data online with no local database
- ➢ Fully integrated with other CRF data including ePRO data
- ➢ Generate multiple reports to follow study progress and metrics

Randomize IT®

- ➢ Enroll, randomize, terminate, and track subject visits
- ➢ Enter site data through two possible portals (telephone and Internet)
- ➢ Print enrollment logs and randomization data online 24/7 from the *RandomizeIT®* web site
- ➢ Receive randomization confirmations via email and fax

WebCDL® and ClinDataLink®

- ➢ Capture all physiological and laboratory data (e.g. spirometry, ECG, pulse oximetry) in the clinic using plug-and-play devices in a store-and-forward system
- ➢ Define each clinical study protocol using a protocol wizard
- ➢ Export data to a central Web server where results can be viewed online and queries can be generated
- ➢ Generate and import queries electronically to eliminate paper and transcription of data
- ➢ Create a source document entry and a CRF entry simultaneously, electronically

WebCRF®

- ➢ Integrate, manage, and view all clinical trial data with ultimate ease
- ➢ Define, modify and administer virtually any CRF with full validation and informative flags using an Administrative Tool, requiring no custom programming and ensuring rapid study start-up
- ➢ Track and resolve data management and monitoring queries online

WebEPRO®

- ➢ Allow subjects to enter ePRO data online
- ➢ View and manage all ePRO data fully integrated with other CRF data

Centralized Spirometry & ECG Review

- ➢ Software and hardware designed to collect and transmit data automatically, using the Internet, from sites to a central location where data are visualized on the web
- ➢ Full data management activities
- ➢ Centralized review of all spirometry, ECG and Holter data by highly qualified physicians, respiratory therapists, and technicians to assure the highest quality data and the proper interpretation of results
- ➢ Electronic annotations of ECG tracings by cardiologists using CompleECG™, producing HL7 compliant datasets that meet all requirements to be posted to the ECG warehouse

In-House Help Desk Services

- ➢ Live technicians providing knowledgeable support for site, CRO and sponsor personnel 24/7
- ➢ Streaming for troubleshooting and training
- ➢ Multi-lingual support for international studies

Full Service Contract Research Organization

- Clinical Trial Design
- Monitoring
- Statistical Analyses
- Regulatory Submissions
- Data Management
- Final Clinical Study Report

Compleware®... lean eClinical Innovation, Integration and Quality!

Services: Cardiovascular Monitoring/Pulmonary Diagnostics, Case Report Forms, Data Management, Digitized QTc Analysis, Electronic Data Capture, Electronic Diary/Dictionary/Translator, Project Management, Protocol Development, Remote Data Entry, Spirometry/Challenge Testing

Comply Services BVBA

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Contact Person: Katrin Spaepen

We make eSubmissions.

Comply Services is an independent services and business management consultancy organisation that successfully delivers outsourced publishing services and Regulatory Affairs to life science companies worldwide.

We provide one-stop regulatory advice and operational services:

- eSubmission publishing services
- eSubmission and eDMS consultancy
- Regulatory Affairs and Regulatory Intelligence services

Our assets:

- flexible access to a pool of highly skilled experts in regulatory
- proven processes and validated systems
- full outsourcing capabilities in regulatory services

Talk to us about:

- achieving a successful marketing authorization application to regulatory agencies worldwide
- moving towards operating in a truly “e” environment
- outsourcing of your regulatory needs

Proven processes and the quality of Comply Services’ specialist team can be demonstrated through our record of uncomplicated approval by the regulatory authorities. In addition to that we will be happy to provide you with client references.

Services: Change Management/Implementation, Consulting, Document Management, Electronic Submissions Preparation, Medical Writing, Project Management, Regulatory Affairs/Regulatory Strategy, Regulatory Document Preparation, Standard Operating Procedures, Workflow Assessment/Re-engineering

COMSYS Clinical

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email: jbalcom@comsys.com
Contact Person: Jim Balcom

COMSYS Clinical (Data Management, SAS Programming, Biostatistics)

For over 25 years, COMSYS Clinical has provided tactical and strategic Data Management, Clinical Programming and Biostatistical services to our pharmaceutical, biotechnology and medical device clients across North America and Europe. Our experience and understanding of the clinical process within these environments have enabled us to become one of the premier Functional Service Providers in the country. On average, we assist in the completion of over 100 studies per year. Our dedicated teams have experience in all phases of the clinical trial including pre-clinical. Our services include:

- Data Management and Clinical Programming FSP Programs
- Outsourced Clinical Programming Services
- Clinical Output Validation
- Data Mapping
- Clinical Application Development
- PK/PD Programming
- Commercialization Support
- Medical Writing Support
- On-site Data Management, Clinical Programming and Biostatistical Contractors

Our services are provided to our clients either on-site or off-site from our three Clinical SAS Centers of Excellence facilities located in New Jersey, Michigan and California.

COMSYS Global Enterprise Content Management

The deep experience, capabilities and resources of COMSYS' Global Enterprise Content Management Practice (GECM), a premier translation, localization, multilingual publishing and multimedia development provider, leverages the worldwide pharmaceutical, medical device and clinical study expertise of COMSYS Clinical to deliver tailored, salient clinical translation, localization and globalization solutions. COMSYS brings unparalleled experience in technical translation, localization and multilingual production in over 135 languages to clients in the medical-services industry, with a tight focus on, and capabilities surrounding, pharmaceuticals, rater training, health care, medical devices and technology.

As a leading provider in the health-services sector, over 40% of COMSYS' commercial sector globalization clients are in the healthcare, life sciences, and pharmaceutical sectors. We have long-standing preferred and exclusive provider relationships with multiple top-ranking global companies in the pharmaceutical and medical device sector and several multiyear service relationships with Fortune 500 leaders in the industry.

Services: Claims Support Studies/Safety and Efficacy Studies, Client/Server Database Development and Migration, Consulting, Data Management, Document Management, Medical Writing, Pharmacokinetic/Pharmacodynamic Modeling, Programming (Database/SAS/etc), Statistical Services/Meta Analysis, Translations

Concentrics Research, LLC

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Internet: www.concentricsresearch.com
email: julie.aker@concentricsresearch.com
Contact Person: Julie L. Aker, President and CEO

Concentrics Research – *"Client Centered Strategies"*

Concentrics Research is a unique CRO specializing in late-stage research. Due to our creative approaches to research, we are often known by our clients as the "Thinking CRO." With more than 20 years of expertise in clinical research and regulated healthcare marketing research, we create custom research to meet your unique needs.

Our low staff turnover rate of <5% and our return business rate of 90% demonstrate our commitment to our staff and our clients. Concentrics' service, stability and expertise provide you with extra value in every study. At Concentrics, we are "centered" around you – your specific drug or device, your specific research needs, your commercialization goals. No two studies are exactly the same. Our staff of specialists surrounds your team and your drug/device with concentric circles of knowledge, experience, service and performance excellence.

The discipline of good science combined with creative and strategic thinking provides a powerful framework. We start with your goals in mind and work backward from each of them to assure that we have built innovative and effective solutions. Often these goals can be integrated to save time and money.

Products and Services

- Research Design Consultation
- Protocol Development
- Project Management
- CRF, ICF, Diary Development
- Central IRB
- Site Selection and Contracting
- Site Management
- Specialized Patient Recruitment
- Adverse Event Monitoring
- Monitoring
- IVR, EDC Solutions
- Data Management
- Biostatistics
- Medical Writing
- Report Writing

Clinical Research Division

At Concentrics, our staff has conducted over 700 projects in a wide range of therapeutic areas. We perform Phase II, Phase III and Phase IV research. Nearly 65% of our work is in the customized Phase IV area related to health outcomes, quality of life, new indications, claims, head-to-head comparisons, post-marketing surveillance, safety monitoring and a variety of long-term tracking studies.

Regulated Healthcare Market Research Division

At Concentrics, our Regulated Healthcare Market Research Division is talented in designing and conducting custom qualitative and quantitative research. Our research includes concept, attitude and usage, prescription medicine information, claims support, and product testing with consumers, patients, healthcare professionals and caregivers.

Rx-to-OTC Switch

At Concentrics, we have conducted switch studies for more than 20 years. In recent years, we have worked on more than 75% of the successful switch programs and have developed good, working relationships with the FDA. Our services include comprehension testing of labels, educational materials, patient brochures and medication guides in addition to self-selection studies, special population studies, actual use studies and post-launch studies.

Pre-Approval and Post-Approval Integrated Research

Our company is unique, in that we have two distinctly different and separate divisions within the same facility. The two divisions, **Clinical Research** and **Regulated Healthcare Market Research**, operate independently. However, we have strategically combined these two areas to produce synergy that is used to capitalize on early market insights, save time, and enhance commercialization efforts.

Services: Claims Support Studies/Safety and Efficacy Studies, Consulting, Consumer Testing, Patient Compliance, Patient Information Leaflets (PIL)/Labeling, Project Management, Protocol Development, Regulatory Affairs/Regulatory Strategy, Rx to OTC Switch, Trial Management

Corporate Translations, Inc.

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PHARMACEUTICAL AND BIOTECH TRANSLATION EXPERTS

Corporate Translations is the only translation company that is ISO 9001:2008 and EN 15038:2006 certified in providing both translation and linguistic validation services and solutions to the pharmaceutical, medical device and biotech industries.

CORPORATE DESCRIPTION: Corporate Translations, a Certified Women's Business Enterprise, was founded in 1990 to specifically answer the demand for high quality translation services in pharmaceutical, medical device and biotech industries. With over 20 years of acquired knowledge in these highly regulated industries, it has become a recognized expert in project managing both complex and simple translation and linguistic validation projects specifically for these business sectors. Focusing specifically on the needs of the life science industry informs all of the company's work and has made it a trusted and leading provider of translation and linguistic validation solutions to over 500 of the world's top pharmaceutical, CRO, medical device and biotech companies, including Pfizer, J&J, and Novartis.

MAJOR PRODUCTS/MARKETS SERVED: Corporate Translations is one of the only translation companies that has proclaimed its commitment to, and focus on, the life science industry exclusively. The company specializes in determining the most appropriate translation and desktop publishing solutions for a wide variety of documents and other media specifically for the life science industry. In addition, Corporate Translations is a recognized industry leader in validating Patient-Reported Outcomes instruments using a strict linguistic validation methodology endorsed by regulatory bodies worldwide. The company also offers online document libraries, translation memory databases, publication services, design and printing of poster presentations for submission to conferences, and manuscript development for submission to professional journals. Corporate Translations prides itself in understanding its clients' complex needs and exceeding their expectations.

SERVICES:

Technical Translation:

- Expertise in over 100 languages
- NDAs, CRFs, INDs, Informed Consents, ePROs, Packaging, Package Inserts, Expert Reports, Technical Manuals, Patient Diaries, Articles, MSDS, Technical Data Sheets, Marketing Materials, IVRs, Web Sites, PR, Commercials
- Notarized Certification of Accuracy

Linguistic Validation of Patient-reported Outcomes Instruments:

- Face Validation
- Harmonization
- Survey Research Expert Review
- Cognitive Debriefing
- Validation Reports
- Poster Presentation Design
- Abstract & Manuscript Preparation

Support Services:

- Multi-platform Desktop Publishing
- Translation Memory Databases
- Document Libraries
- Archive Saving Discounts
- Order Tracking
- Design and Printing

Corporate Translations – *"Driven by Definition"*

Services: Translations

Covance Inc.

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email: info@covance.com
Contact Person: NA

Covance, with headquarters in Princeton, NJ, is one of the world's largest and most comprehensive drug development services companies, with annual revenues greater than $1.7 billion, global operations in more than 25 countries and over 10,000 employees worldwide.

Offering the most comprehensive portfolio of discovery, preclinical, clinical development and commercialization services, Covance has the people, processes, client service, and global resource capabilities to respond to biotechnology and pharmaceutical clients' toughest drug development challenges.

Guided by a mission to help bring the miracles of medicine to market sooner, Covance is committed to consistently delivering superior service every time.

- Discovery Services
- Preclinical Development
- Clinical Development
- Commercialization
- Strategic Partnering & Integrated Drug Development

Services: Central Laboratory Services, Clinical Pharmacology, Clinical Trial Monitoring, Health Economics, Imaging, Pharmacoeconomic/Pharmacoepidemiology Studies, Preclinical Development Services, Registries, Toxicology, Trial Management

Criterium, Inc.

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Criterium, Inc. is a full-service, global CRO (contract research organization) offering a unique mix of high-quality clinical research services, real-time data acquisition and personalized communication processes to manage a clinical trial from initial planning to approval, on time and on budget. Founded in 1991, the Criterium team provides a high level of therapeutic expertise, high-quality clinical development services, and highly efficient processes to pharmaceutical, biotechnology, and medical-device companies.

Using innovative products to improve efficiencies, Criterium's staff is able to handle large-scale clinical projects while providing the personal attention lacking in larger CRO's. Our centralized clinical trial data management environment provides a compliant, standardized methodology for processing, validating and presenting real-time information to clinical trial management and monitors. Criterium has developed and managed Interactive Voice Response System (IVRS), automated fax and online data capture and reporting for over a decade. At Criterium we manage the data every day for timely decision making, rapid data editing and on time delivery of the final deliverable – usually a final study report.

At our foundation, Criterium clients receive:

- **Quality Solutions** that meet or exceed the clients' expectations for the entire clinical-research process, from initial planning to approval, which can be customized to fit each client's specific needs. Data transmitted centrally are reviewed by teams that work closely together, every day, at the same location.
- **Reduced Costs** by transforming "traditional" monitoring tasks to centralized monitoring through workflow using proprietary technologies without the additional purchase of expensive computer hardware and software.
- **Accelerated Timelines** through placement of studies at sites based on their ability to enroll and evaluate valid patients while still using site friendly proprietary tools that do not burden their staff for more rapid data collection: sites and patients enter data directly into the study databases for daily monitoring. Our database of international sites capitalizes on seasonality factors where appropriate.

Criterium has offices in **New York, California, Florida, South Africa, India, Russia, Israel, Canada and The Netherlands** to provide personal service to clients throughout the world. All are supported by modern standardized technologies that have been developed and are maintained in our New York headquarters.

We have earned a worldwide reputation as a leading contract research organization, with successful experience in all phases of clinical research and across major therapeutic areas. Because of our emphasis on being **agile**, our people, processes and technology combine to meet our clients' unique and changing needs.

At Criterium, who we are, what we do, and how we do it are centered on our service reputation: an uncompromising "Always Delivers" attitude in everything we do.

Get To Know Us!

Visit http://www.criteriuminc.com/ for further information.

Services: Clinical Trial Design, Clinical Trial Monitoring, Data Management, Efficacy Studies, Electronic Data Capture, Project Management, Randomization (Automated/Centralized/Vocal Computer), Regulatory Document Preparation, Remote Data Entry, Trial Management

CRL Global

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Contact Person: Erica Watson

Your clinical trials ... our global expertise ...

Clinical Reference Laboratory (CRL Global Services) is a global full service central laboratory founded on solid scientific expertise and a strong customer service focus. CRL has been serving the pharmaceutical industry since 1995 and offers a wide range of testing including Chemistry, Hematology, Urinalysis, Endocrinology, Serology, Biomarkers, DNA and RNA extraction, genotyping, and sequencing.

Global locations include:

- USA
- Europe
- Australia
- Japan
- South Africa
- Singapore
- South America

CRL Global Services' certifications include CAP, CLIA, NGSP level 1, and participation in several standardization programs such as National Heart, Lung and Blood Institute Lipid Standardization Program.

Services: Central Laboratory Services, Genetics Research, Mass Spectrometry, Virology

CROM Group

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"Expertise you can rely on ..." **"Quality by Design"**

For more than 15 years, CROM Group (a full-service CRO) has been conducting clinical development programmes in Central and Eastern Europe, and as such has greater experience in these regions than even the largest CROs. CROM Group works across all therapeutic areas including, but not limited to, oncology, respiratory, cardiovascular, metabolic, HIV, CNS, vaccines and medical devices.

CROM Group is headquartered in Verona, Italy, and since commencing operations has grown steadily and now operates subsidiaries in Germany, Poland, Ukraine, Russia, the United Kingdom and the United States of America. These subsidiaries, and our own staff located in many other European countries, provide an established infrastructure through which CROM Group is active across the whole of Europe and the USA.

Whilst CROM Group routinely works with many of the largest multinational pharmaceutical companies, we remain a mid-sized organisation and offer an adaptable structure to our sponsors who quickly establish direct contacts with the project team, including our senior management. Our pro-active approach includes 'Quality by Design' – our determination to review all aspects of our operations, including those of each individual project, with a view to avoiding problems rather than relying solely on our ability to react to issues when they arise.

The heart of CROM Group is our team of more than 170 professional staff, all of whom have substantial experience in multinational clinical trials. Highly qualified medical experts and project managers supervise and coordinate all clinical projects ensuring that our Sponsor's trials are conducted to the highest quality standard, on time and to budget. Because CROM Group successfully retains its staff, the entire project team typically remains constant throughout the lifespan of each study. Our team is also experienced in conducting 'rescue studies' where the performance of other CROs has not satisfied the Sponsor.

Quality management and quality assurance are kept under constant review and are assiduously implemented by CROM Group. Quality assurance is guaranteed through the integrated, certified quality system ISO 9001:2000 first achieved in 2002 when few competitor companies had considered such accreditation important. Our quality system is revised quarterly and thoroughly reviewed every two years by an external and independent auditor.

CROM Group is also acutely aware that the success of any project is dependent on effective site management by experienced and well trained clinical research associates.

Central to success of any clinical trial is appropriate site selection. Having completed over 500 trials, CROM Group has close links to a large number of high quality, motivated investigational sites with high recruitment potential. Our established presence 'on the ground' in these locations ensures that our feasibility analyses are detailed and accurate, allowing our Sponsors to select countries and sites optimally to meet their trial timelines.

CROM Group is convinced that technological innovation is one of the key factors for success. Continuous investments in state of the art technology (such as CTMS, IVRS, EDC, electronic document management, etc.) underline our commitment.

Perhaps the most pertinent indicator of the level of satisfaction experienced by sponsors who choose to work with CROM Group is the high number of sponsors who return to CROM Group with their projects time and again. We are proud of this level of repeat business and hope that this encourages you to find out more about us.

Services we offer to our clients include: Clinical Project Management, Feasibility, Site Selection, Regulatory Affairs, Clinical Trials Monitoring, Medical Monitoring, Pharmacovigilance, Data Management & Statistics, Quality Assurance, Logistics, Drug Management, Medical Writing

Services: Clinical Trial Design, Clinical Trial Monitoring, Data Management, Investigational Site/Network, Medical Writing, Pharmacovigilance, Project Management, Quality Assurance/Control, Regulatory Affairs/Regulatory Strategy, Statistical Services/Meta Analysis

CRS Clinical Research Services Andernach GmbH

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Fax: +49 2632 992401
Internet: www.crs-group.de
email: david.surjo@crs-group.de
Contact Person: Dr. David Surjo

Employees: 185

CRS is a full service CRO in phase I-IV. The holding comprises three Phase I subsidiaries, CRS-Kiel, CRS-Moenchengladbach and CRS-Mannheim. Each unit has between 17 and 32 years of experience in clinical trials Phase I - II. Additionally, the Mannheim/Gruenstadt unit is also engaged in the coordination of Phase III – IV trials and offers Bioanalytics, Medical Writing, Clinical Data Management & Statistics also as modular services.

Clinical Studies Phase I-IIa
With 195 beds in total, CRS is one of the top three CROs in Europe. Additionally, the units provide capabilities for ambulatory trial designs. Supplementary to standard human pharmacology work in Phase I, CRS offers clinical trials in renal and hepatic impaired patients, thorough QTc trials with various central ECG labs and additional assessments of PD parameters in CNS, gastrointestinal research, and pneumology.

Clinical studies Phase I-II

- First in man
- Proof of concept
- Safety and tolerability
- Dose finding
- Bioavailability and bioequivalence
- Microdialysis (tissue distribution)
- Food-Drug interaction, Drug-Drug interaction
- Pharmacokinetic/pharmacodynamic trials
- Skin safety/pain models
- Telemetry ECG recording
- Thorough QTc trials according to the guidelines
- Monitoring

Clinical Studies Phase III-IV
The department Clinical Development of CRS also offers conduction and Project Management of your Clinical Studies Phase II-IV with a full range of services, including strategic planning, clinical development, consultancy and regulatory expertise to move a product forward in development, i.e.:

- Phase II-IV clinical trial management
- Project Management
- Site selection and qualification, training and support
- Clinical and medical monitoring
- Electronic Data Capture and management
- Patient registries
- Strategic consulting
- KOL/advisory board identification and management
- IND/IDE consultation

Bioanalytical Department of CRS
is GLP certified since 1992 and FDA inspected (1991 and 2002, 2008). Within more than 30 years, more than 300 analytical methods have been developed and validated. The analytical equipment complies with international standards.

CTSM and IMPs of CRS
is equipped to handle IMPs, staffed with qualified persons according to §14 AMG (German Drug Law), GMP certified and possesses the manufacturing licence.

Clinical Data Management of CRS
offers services in study planning such as statistical trial planning, CRF design, randomization and design of data structures. Throughout study conduction our team can offer database set-up, data entry with Oracle Clinical, data transfer to third parties, data validation including programming as well as query management, medical coding and biometrical/PK evaluation.

Medical Writing of CRS
takes over study protocols and integrated reports according to ICH as well as IBs, PSURs publications, lectures, posters, pharmacological/toxicological reports and clinical expert reports. All systems of Clinical Data Management are validated according to 21 CFR part 11.

Quality Assurance of CRS
is centrally organised for the whole CRS Group. The department is responsible for performing audits during clinical and bioanalytical studies according to GCP, GLP, GMP and the respective legal requirements.

Services: Clinical Trial Design, Clinical Trial Monitoring, Consulting, Data Management, Efficacy Studies, GCP Compliance, GLP Compliance, GMP Compliance, Project Management, Trial Management

DaVita Clinical Research

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E-mail: sharon.parker@davita.com
Contact Person: Sharon Parker

DaVita Clinical Research (DCR) is a Phase 1-4 clinical trial service business specializing in renal-related drug and device research and development. We have two decades of experience, we are the nation's largest renal research network and we have the largest end stage renal disease (ESRD) clinical data warehouse.

Phase 1:
The DCR Phase 1 organization is a hospital-based research site with multiple specialty populations and capabilities for first-time in-human studies. DCR has conducted over 500 protocols with our physicians and is the leader in renal research, specialty populations and complex medical procedures.

Capabilities and Services:

- Rapid Study Start Up (<18 days)
- On-Site State-licensed Pharmacy
- **Specialty Services**
  - Bioavailability
  - Bioequivalence
  - GFR Testing
  - Mass Balance
  - Pharmacokinetics
  - Pharmacodynamics
  - QTc Studies
  - Radiolabel Studies
  - Safety and Tolerance
- **Specialty Populations**
  - Chronic Pain/CNS
  - Diabetics (Type 1 and 2)
  - Healthy Elderly
  - Hepatic (mild, moderate, severe)
  - CV New York Heart Association (Class I – IV)
  - Pulmonary
  - Pre-renal failure (mild, moderate, severe)
  - Renal failure (HD and PD)
  - Slow Metabolizers

Site Management Organization:
The DCR Site Management Organization develops and markets the highest quality services available for customers needing clinical trial planning, site management and recruitment of patients with ESRD and chronic kidney disease (CKD).

Capabilities and Services:

- Access to over 107,000 ESRD patients
- Over 500 experienced research physicians
- CKD research experience
- Site-specific patient identification
- Protocol Risk Assessment
  - Sensitivity analysis
  - Design feasibility
- Trial Management
  - One contract for the largest U.S. renal network
  - Rapid Site Activation
  - Web-based real time clinical trial reporting

Medical Informatics:
The DCR Medical Informatics team analyzes, develops and markets the highest quality services available for customers in need of electronic information related to ESRD and CKD.

Products and Services:

- Limited Data Sets
- Biostatistical Services
- Customized Data Extracts
- Market Dynamics Research
- Therapeutic Market Share Reports
- Clinical Outcomes Reports

Services: Efficacy Studies, Inpatient/Outpatient Facilities, Investigational Site/Network, Medical Writing, Pharmaco EEG Studies, Pharmacoeconomic/Pharmacoepidemiology Studies, Programming (Database/SAS/etc), Protocol Development, Publications (Books/Journals), Statistical Services/Meta Analysis

DDN Medical Affairs

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Contact Person: Carole DeRoche, President

DDN Medical Affairs
CONNECT PROTECT SUCCEED

We focus on the safety of your customers and products so you can concentrate on developing more of both.

DDN Medical Affairs provides drug safety, product information, and regulatory affairs services for life science companies. These services support the commercial success of your company by connecting your customers with accurate and timely information about the safe and appropriate use of your products and by protecting your company through compliance with FDA regulations. DDN Medical Affairs enables our clients to focus on their strategic business objectives while we focus on operational functions of the business.

Our Staff

Senior management includes professionals with collective industry experience of over 50 years with a broad spectrum of medical information and communication, regulatory and marketing experience.

Healthcare professionals include physicians with post-marketing safety experience as well as individuals with clinical experience in pharmacy and nursing as well as industry experience.

Regulatory affairs staff has over 20+ years submission experience for adverse event reporting, post-approval changes, annual reports, and labeling development and management.

Our Services

Adverse Events – When we interact with your healthcare providers and patients, your commitment to safe and appropriate product use comes through. All adverse events are documented and processed by our healthcare and medical staff. Individual case reports and periodic reports can be prepared and submitted for you.

Product Information – We provide accurate, balanced, timely information with personal attention and thoroughness for your customers – healthcare providers, patients and consumers. Standardized responses are typically provided on the initial contact. We can help you develop customized responses to complex and uncommon questions.

Product Quality Complaints – Every contact is an opportunity to preserve and build customer satisfaction and loyalty. We assist with product return to manufacturer and compensation to the user based on your business rules. All complaint contacts are processed through closure by our staff with regulatory experience.

Structured Product Labeling Services (SPL) – Let our SPL specialists complete the conversion process for you. Keep your staff focused on its key priorities. Our solution ensures your content of labeling, establishment registration, drug listings and NDC labeler code requests meet the new requirements quickly and accurately.

DDN Medical Affairs

Connect – Attentive to your customer needs

Protect – Attuned to regulatory developments

Succeed – Aligned with your goals

To learn more, please visit our Website at www.DDNMedicalAffairs.com

Services: Professional Call Center, Adverse Events, Product Quality Complaints, Product Information, Labeling

Services: ADE Evaluation/Drug Safety Assessment, Chemistry/Manufacturing/Controls, Medical Communications, Medical Devices/Combination Products, Medical Information, Patient Information Leaflets (PIL)/Labeling, Pharmacovigilance, Regulatory Affairs/Regulatory Strategy, Regulatory Document Preparation, Telephone Support

Dr. Manfred Köhler GmbH

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Established in 1991 as a specialist biometrics and statistics company, we offer the full range of biometrics services, from consultancy services in the planning phase through CRF design, design and implementation of monitoring aids, double data entry, raising of queries, SAS programming and statistical analysis to final study report writing and biometrics support in the publication phase. Most of our staff members (statisticians, SAS programmers, software developers, coding managers, data managers, data entry personnel) have been employed with the Dr. Manfred Köhler GmbH for five years and more.

Our team provides expert support and advice for the following key elements:

Preparation

- Protocol design
- CRF design
- Monitoring Aids design
- Biometric consulting
- Simulation

Execution

- CRF cleaning
- Data entry
- Query management
- Database status reporting

Evaluation

- Coding
- Statistical analysis
- Documentation
- CIOMS II reporting

Finalisation

- Final study report
- Publication writing
- Data transfer (CDISC format)

Together with our affiliate company, clinIT AG (see corresponding entry in this directory), we are one of the very few providers worldwide covering all technical aspects of EDC trials:

1. Central randomisation by means of an Interactive Voice Response System
2. Electronic Data Capture using our own standard Internet software TRI@L-IT, developed and field-tested by our company in more than 100 studies
3. Training of study nurses, investigators and site monitors in EDC handling
4. Data management including central data monitoring
5. Statistical Analysis

These services have been successfully provided globally for a considerable number of large-scale international multi-center clinical trials. We are proud to say that many of our customers have been relying on our services for many years and a substantial number of trials. It is our highest priority to allow our partners the intensive and cooperative handling of their projects and full adaptation to their project's special requirements.

Services: Case Report Forms, Clinical Study Reports, Clinical Trial Design, Data Management, Data Validation, Database Conversions, GCP Compliance, Randomization (Automated/Centralized/Vocal Computer), Remote Data Entry, Statistical Services/Meta Analysis

Duke Clinical Research Institute

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email: help@dcri.duke.edu
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The Duke Clinical Research Institute (DCRI) is the world's largest academic clinical research organization. We combine the clinical expertise and academic leadership of a premier teaching hospital with the full-service operational capabilities of a major contract research organization.

With more than 1000 faculty and staff, the DCRI is capable of conducting any clinical research project, from the smallest pilot study to truly global megatrials, medical device trials to outcomes and quality of life analyses. Our experience stretches from Phase 1 to Phase 4 and beyond, encompassing post-approval analyses and health economics.

Our faculty are all practicing physicians in these specialties, applying cutting-edge research in their own patient care. Their informed input on study design and interpretation creates more efficient, practical, and hard-hitting research.

Our faculty focus on disseminating research results, publishing more than 300 articles per year in peer-reviewed journals. Their effects on patient care and the state of medicine are felt around the world.

Services
We provide every service needed for successful research, including project management, data management, site management and clinical monitoring, biostatistics, safety surveillance, and medical communications. This full portfolio of abilities means our clients, who include pharmaceutical and medical device makers, biotech companies, and government agencies, can find a tailored research plan that meets their needs.

Our abilities do not end with a project's conclusion. We know that successful research in today's climate also includes post-approval studies for a complete submission package and a communications strategy for effective dissemination of results.

Expertise

- The DCRI has conducted studies at more than 3592 sites with more than 5000 investigators in 64 countries.
- More than 581,230 patients have been enrolled in DCRI studies.
- More than 400 Phase 1-4 trials and outcomes research projects have been completed by the DCRI.
- The DCRI has published more than 4600 articles in peer-reviewed journals.

Services: Clinical R&D, Clinical Trial Design, Clinical Trial Monitoring, Data Management, Medical Communications, Project Management, Regulatory Affairs/Regulatory Strategy, Statistical Services/Meta Analysis, Therapeutic Specific Research, Trial Management

eClinical Solutions, a division of Eliassen Group

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Contact Person: Jeff Rogers

Impacting Lives By Changing the Way You Think About Your Data.

About Us: eClinical Solutions, a division of Eliassen Group, offers leading-edge clinical trial data management and statistical programming expertise to complement technology solutions that improve the efficiency, speed and quality of clinical trials in pharmaceutical, biotech and medical device firms. Respected for the hands-on experience that our team offers, eClinical Solutions has designed a proprietary, quality-assured methodology for customizing clinical trials along with a collaborative and proactive project management approach supporting sponsor organizations during the trial. The combination of clinical trial expertise and the leveraging of industry standards provide the security in knowing that the clinical trial data is being well managed by a service partner.

Our model is designed to give our clients maximum flexibility and scalability based on their needs. Our team of clinical data management, statistical programmers, training and consulting experts work with you to facilitate our range of services which include:

- EDC Services
- Data Management Services
- Statistical Programming Services
- Training Solutions
- Reporting Solutions (including jReview and Business Objects)
- User Acceptance Testing (UAT)/Validation Services
- Clinical Data Repository Solutions
- Strategic Consulting (including SOP development, Vendor Selection, CDISC Consulting)

Benefits of Working with eClinical Solutions

eClinical Solutions offers expertise in solving the challenges you face, industry experience working with similar clients on other engagements, and a dedicated professional staff with a track record of achievement. The eClinical Solutions team partners with you to leverage your clinical data. After all, it is the data that determines if that next drug, product, or device can change a patient's quality of life — the impact we have on this process is our passion.

- **A Diverse Team of Industry Experts** – eClinical Solutions assembled a team of experts with various backgrounds, offering diverse resources to our clients. eClinical Solutions' project leaders possess an average of 16 years of experience in biotech, pharmaceutical and CRO organizations. Each team member understands the importance of the process-oriented methods necessary to ensure consistent quality.
- **Proven Capabilities and Unique Approach** – eClinical Solutions leverages the capabilities and experience we have acquired through years of implementing successful solutions for clients. We provide customized solutions using a dedicated team for each and every project. Our strength lies in our ability and flexibility to effectively match these solutions to your requirements. Even after service delivery, we validate acceptability of results by utilizing proven quality assurance and client satisfaction methodologies.
- **Customized Delivery Solutions** – eClinical Solutions, a division of Eliassen Group, provides the flexibility of various delivery models to meet your needs. We take the time to assess your company size, structure, goals and financial capabilities, while also looking at your corporate objectives from a program level versus just looking trial by trial. Partnering with eClinical Solutions ensures that you receive the appropriate solution with optimum cost savings, project accuracy and efficiency, as well as high-quality deliverables. eClinical Solutions assists our clients in implementing both short-term solutions and long-term scalable strategic plans allowing them to achieve their objectives as opposed to taking the "cookie cutter" or "one-size fits all" approach.

We are committed to being:
Your Strategic Solutions Partner of Choice Optimizing Clinical and Patient Data Utilizing Best of Breed Technologies.

For more information, go to www.eclinicalsol.com or call (866) 961-3542.

Services: Change Management/Implementation, Computer System Validation, Data Management, Data Validation, Database Conversions, Electronic Data Capture, Programming (Database/SAS/etc), Standard Operating Procedures, Technology Assessment, Training

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Cardiac Safety and ePRO Solutions

Based in Philadelphia, PA, ERT is a provider of technology and services to the pharmaceutical, biotechnology and medical device industries. The Company is a market leader in providing centralized core-diagnostic electrocardiographic (ECG) technology and services to evaluate cardiac safety in clinical development. Their ePRO Solutions™ provides a simple, immediate conduit to the Sponsor's most valuable asset – the patient. This phone based system captures throughout the Complete Patient Experience – from Recruiting and Screening, Assessments and Diaries through Suicidality Monitoring. ERT harnesses internet and telecommunications technology and services to streamline the clinical trials process by enabling its customers to automate the collection, analysis and distribution of clinical data in all phases of clinical development.

- **EXPERT® ECG – Digital Collection, Analysis and Distribution of Cardiac Safety Data**
  - EXPERT 2®, ERT's market leading analysis and data management platform, is the heart of ERT's operations providing scalable capacity and flexible workflow processing in a secure and validated environment
  - Flexible and scalable capacity and throughput to support the full-range of studies from single center to global, multi-center trials
  - Full cardiac safety capabilities ranging from digital collection and analysis to paper processing including rescue projects for all clinical trial phases
  - ERT is an industry thought leader with experts available to consult on medical and regulatory issues related to cardiac safety study design, data evaluation and reporting
  - Industry leaders for Thorough QTc/ECG Trials (TQT/TET), having completed significantly more than any other core lab
  - ERT provides best-in-class 12-Lead Digital ECG devices for standard cardiac safety or Holter collection with our inventory of validated devices
  - Global experience spanning 6 continents currently supporting concurrently over 500 studies and 20,000 sites
  - Global, 24/7 customer care, logistics and site support with comprehensive translation capabilities
  - SOP-driven, cross-functional Project Assurance methodology encompasses planning, set-up, monitoring and close out activities which ensures effective study conduct and drives performance metrics
  - My Study Portal provides sponsors with on-demand data access in a secure web platform in addition to flexible reporting options and XML waveform viewing as well as interactive access for sites to resolve queries, manage supplies, and access reports
  - Regulatory compliance excellence
  - ERT is experienced in partnerships across the clinical services spectrum and has established relationships with several providers including partners in Japan
- **ePRO Solutions™**
  - A telephone based system that makes the collection of critical Patient Reported Outcomes simple, immediate and cost effective
  - Quick implementation of recruiting tools and patient diaries without expensive training and logistics
  - Access to over 60 clinical assessments, providing unsurpassed reliability and reproducibility without the bias, training and expense of human raters
  - A cutting edge solution to the FDA's suicidality monitoring directive, the eC-SSRS can be quickly added to any trial

The Complete Patient Experience

- Accelerated Recruitment
- Consistent Screening
- Unbiased Assessments
- Compliant Diaries
- Increased Compliance
- Real-time Safety Monitoring
- Suicidality Monitoring

Services: Cardiovascular Monitoring/Pulmonary Diagnostics, Clinical R&D, Clinical Study Reports, Consulting, Digitized QTc Analysis, Electronic Diary/Dictionary/Translator, Expert Reports

Eurofins Medinet

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Contact Person: Eloy del Toro

Eurofins Medinet is a global organization fully focused and dedicated to providing standardized, high quality global central laboratory services to support all phases of clinical trials. With over 20 years of experience and scientific accomplishment, our laboratory testing portfolio has become one of the widest available in the biopharmaceutical industry and offers the synergy of integrated safety assessment, exploratory biomarkers, end point biomarkers, biomarker development, PK/PD, therapeutic drug monitoring, proteomics, metabolomics, immunogenicity testing, genomic testing and a full range of services to support anti-infective drug development.

Eurofins Medinet supports its customers with 6 wholly-owned and harmonized laboratory facilities located in **Europe:** Breda (Netherlands), Paris (France), **North America:** Washington DC (USA), Denver (USA), and **Asia:** Singapore and Shanghai (China). When required we extend our global coverage through standardized partners, e.g. in Japan, India, South Africa and Latin America.

Eurofins Medinet is committed to providing the highest quality services, accurate, timely results capturing the planned completion date, and expert advice from our highly qualified team of experienced scientists. As data integrity is of paramount importance, we continually monitor both data quality and our laboratory operations to ensure that the highest standards are maintained.

- Full package of safety and efficacy parameter
- Standardized instruments and analytical methods enable the use of global reference intervals
- Integration of Bioanalytical, Genomic and Anti-Infective Services in one project
- Global standard operating procedures
- Accreditations, certifications and endorsements for a wide range of regulatory requirements such as: CAP, CLIA, ISO15189, ISO17025 and GLP
- Global coverage to minimize sample transportation and logistics
- Single point of contact at Project & Data Management
- Open and pro-active communication
- Dedicated to investigator sites
- Logistics support and courier management
- Global LIMS system
- Real time online access to global database

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Services: Analytical Assay Development and/or Laboratory Service, Central Laboratory Services, Consulting, Mass Spectrometry, Microbiology Testing/Services/Surveillance, Nonclinical Pharmacology, Pharmacokinetic/Pharmacodynamic Modeling, Preclinical Development Services, Therapeutic Specific Research, Virology

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Contact Person: Penny Johnson, Vice President, Account Management

Services
Clinical Trial Monitoring/Site Management, Clinical Trial Management, Data Management, Medical Writing, Drug Safety

ExecuPharm, Inc. (EP) is a staffing and outsourcing company specializing in matching qualified clinical-research professionals with appropriate positions in pharmaceutical and biotechnology clients. With more than 15 years dedicated to clinical development, EP is one of the industry's most experienced providers of staffing services and one of the industry's largest providers of FSP services. The EP management team includes executives with extensive clinical-operations experience at leading sponsors, EP recruiters average more than 10 years of experience, and EP clinical professionals offer experience well above industry averages.

Competitive Advantage
For maximum flexibility and scalability, EP offers four service models:

- **Traditional staffing:** supplying clinical professionals as needed
- **Functional service provider (FSP):** outsourcing an entire function, such as study management or monitoring, for a clinical development program
- **Cross-functional:** outsourcing two or more functions, such as clinical trial management and site monitoring, for a clinical development program
- **Hybrid:** combining traditional staffing with either FSP or cross-functional outsourcing to maximize flexibility in staffing a clinical development program

In all service models, EP provides access to a large, pre-screened talent pool, exceptional training, responsive management, and an unwavering commitment to reduce our clients' operational burdens.

Services: Change Management/Implementation, Clinical Trial Monitoring, Data Management, Project Management, Strategic Planning and Implementation, Temporary Services and/or Permanent Placements, Training

Fast4wD Ogilvy

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SPECIALIZED PATIENT RECRUITMENT AND RETENTION ... ANYTIME, ANYWHERE

Experienced, seamless, global clinical trial recruitment and retention is now available to you. Whether you need help in the Americas, Europe or Asia, Fast4wD Ogilvy has over 8 years experience to meet your recruitment and retention challenges.

With offices in the US and Europe, we have the staff and the skills to give you smart, efficient and cost-effective solutions. As a preferred provider to major pharmaceutical clients, we know what you need and how to deliver it fast.

WITH FAST4wD OGILVY, YOUR STUDY IS IN SAFE HANDS

STRATEGY

How do we analyze your study?

Through our global experience and in-depth market knowledge, we analyze your clinical protocols and provide you insightful, strategic program recommendations. You will receive:

- ➢ Protocol analysis from a healthcare communications perspective
- ➢ Assessment of the relevant disease-state and target population
- ➢ Identification of recruitment barriers and country-specific patient sensitivities
- ➢ Evaluation of culturally-appropriate local implementation

SPEED

How do our seamless global communications streamline your trial?

We can rapidly assess your clinical issues by:

- ➢ Using global concept testing to create study identities with cross-cultural appeal
- ➢ Identifying appropriate patient sources and pathways to recruit worldwide
- ➢ Producing tailored materials rapidly to support your study sites
- ➢ Maximizing recruitment through site support, targeted media and efficient patient processing

SOLUTIONS

How do we solve your clinical trial challenges?

Our global approach provides you with leading edge solutions. We give you a competitive advantage through:

- ➢ Proven tactics successfully implemented in programs in more than fifty countries
- ➢ Innovative techniques such as Confident Consent Workshops, Recruitment Strategy Planning and Pathway Mapping
- ➢ Metrics that quantify success

PARTNER WITH FAST4wD OGILVY TO COMPLETE YOUR CLINICAL TRIAL TEAM

SKILLS

What expertise do we offer?

Our globally experienced scientific, medical, marketing and creative specialists will team with you to deliver solutions tailored to your needs. Our skills include:

- ➢ Strategic planning and health communications
- ➢ General marketing, social marketing and advertising
- ➢ Creative design and production
- ➢ Scientific writing
- ➢ Knowledge of adherence barriers and retention strategies
- ➢ Clinical healthcare experience

Why have other companies selected Fast4wD Ogilvy?

"When I look for a recruitment company, I look for a company which is innovative, has therapeutic experience and excellent project management skills. I have found those attributes in Fast4wD Ogilvy for my last several trials."

Services: Advertising, Consulting, Medical Communications, Medical Writing, Patient Compliance, Patient Education, Patient Recruitment, Training

FGK Clinical Research GmbH

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Internet: www.fgk-cro.com
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Contact Person: Dr. Edgar Fenzl

A full service, owner-driven, European-based CRO

You need full commitment – for best results – in every phase.
FGK Clinical Research GmbH – The Clinical Trial Optimizer

FGK Clinical Research GmbH is a full service contract research organization offering a complete range of clinical development and consulting services to pharmaceutical, biotechnology and medical device companies.

Services:

- Clinical trial management and clinical monitoring
- Data management
- Biostatistics
- Medical writing
- Quality assurance
- Pharmacovigilance
- Consulting services in drug development, regulatory affairs and biostatistics

With more than 60 highly skilled and experienced people, FGK operates out of Munich on local and global projects, covering clinical studies from phases II to IV. FGK has extensive experience in all major therapeutic areas and clinical research fields, which allows it to effectively design, manage and analyze your development programs and clinical trials.

A network of strategic partners allows us to meet your needs regarding extended drug development services. With our operative partners, we can operate cross border and provide you the services requested for the performance of multinational clinical trials.

FGK approaches each project, whether large or small, with dedicated, highly motivated, small teams and a full commitment to achieving and even exceeding your objectives. A single, experienced project manager is assigned to your project, since we know it is vital to establish seamless communication and build up a good relationship with you from the very beginning.

We listen to our clients and always look for proactive, responsible solutions to ensure that all difficulties are solved and no problems occur. FGK is committed to quality, customized service and the protection of the client's confidentiality. The background of our personnel not only includes extensive experience in the pharmaceutical industry but also strong start-up company experience, which means we understand the culture and environment of small and emerging companies. At FGK we work with a network of carefully selected partner companies to provide a range of services to complement our own. This enables us to offer monitoring services all over Europe and the US.

We are also able to provide you access to and expertise in leading EDC technologies, which helps provide high-quality clinical trial data in the shortest possible time.

FGK has implemented a high-level IT system which includes a fully redundant system with several backups at different locations. One of these backups is a high level security data center outside of Munich to prevent any data loss.

FGK's team has expertise in a variety of key therapeutic areas, including Central Nervous System, Oncology/Haematology, Cardiovascular, Hepatology, Gastroenterology, Immunology, Dermatology, Rheumatology, Respiratory Diseases, Gynaecology, Infectious Diseases, Ophthalmology and Urology.

Services: Clinical R&D, Clinical Study Reports, Clinical Trial Design, Clinical Trial Monitoring, Data Management, Data Validation, Medical Writing, Project Management, Protocol Development, Quality Assurance/Control

Formedix

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Internet: www.formedix.com
email: wecanhelp@formedix.com
Contact Person: Mark Wheeldon, CEO

Formedix is a leading provider of software and consultancy services based on emerging data standards developed by the Clinical Data Interchange Standards Consortium (CDISC).

Since our inception in 2000, Formedix has delivered CDISC software and services that have resulted in time and cost savings in every key area of the clinical trial process from study set-up through to submission.

Formedix launched the first CDISC Study Design Tools, Origin Study Modeller™ and Origin Submission Modeller™ which output CDISC Database Metadata (Operational Data Model (ODM) and Submission Metadata (CRT-DDS, define.xml) to streamline the creation of database and dataset specifications. Origin Study Modeller™ has been proven to deliver a three fold reduction in study database design time and is used by market leading biotechnology, pharmaceutical and medical device companies worldwide.

In addition, to our Origin™ Study Design tools Formedix has developed Submit™, a data transformation engine which replaces manual programming effort with a CDISC metadata driven conversion process. Now the production of proprietary and CDISC Study Data Tabulation Model (SDTM) datasets from any type of raw data source is simple and scalable.

Formedix is one of the oldest members of CDISC with CDISC Registered Solution Provider status and representation on the CDISC Industry Advisory Board. Our lead CDISC consultant contributes to the ODM Technical Team where he won two CDISC awards for furthering development of this model.

Formedix was one of the first implementers of the content standards developed by the Clinical Data Acquisition Standards Harmonization (CDASH) initiative producing ODM forms, presenting at conferences/webinars and delivering training sessions on how best to implement CDASH alongside other CDISC models.

As well as our suite of CDISC software solutions, Formedix offers a comprehensive range of CDISC Planning, Preparation and Implementation Consultancy services which are designed to help a Company at any point in their CDISC adoption cycle.

Services: Clinical Trial Design, Consulting, Data Management, Database Conversions, Electronic Data Capture, Electronic Submissions Preparation, Programming (Database/SAS/etc), Software Development & Evaluation

Global Clinical Trials, LLC

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Global Clinical Trials (GCT) – Premium Eastern European and Russian CRO
Regionally Specialized Since 2001

Global Clinical Trials (GCT) is a full service contract research organization (CRO), specialized in performing clinical development activities in Eastern Europe and Russia. GCT has been performing clinical research in this growing and dynamic region of the world since 2001. Our regional focus, experienced project managers, involvement of upper management, and concentration on client satisfaction has helped us grow by more than 25% each year. More than 80% of our business comes from repeat clients. Managed by a team of clinical research professionals with over 50 years of combined industry experience, GCT maximizes the benefits of the region with a complete understanding of international research standards.

Experienced Team Members
Global Clinical Trials maintain a staff of project managers who are all medical doctors with many different backgrounds and specialties; experienced in clinical research and patient care services. GCT project managers each have a minimum of 5 years industry experience supporting and managing clinical programs. Our CRAs all have medical or biological degrees with an average of 3 years of industry experience. Our team of dedicated research professionals has worked to develop strong relationships with each site, based on mutual respect and a scientific understanding among peers.

Flat Management Structure with a Focus on Clinical Operations
GCT is focused 100% on the clinical, regulatory and logistical needs of your trial. To keep overhead to a minimum GCT outsources Data Management to a partner in India allowing us to invest exclusively in what we do best; manage and monitor clinical trials. We maintain a Flat Management structure. This allows us flexibility in contracting while keeping our management involved in the success of each and every project.

Logistical Support
GCT will handle all importation and exportation requirements for your trial from the beginning to the end. For those instances where our clients need to ship study materials, GCT will carefully and completely walk you through the labeling and shipping procedures required for each country we support. Let our local experience be your international strength.

A World of Savings
Through our regional partnerships we have the capability to introduce our clients to other regional CROs around the world with a proven record of success. These experienced CROs have established themselves in their region by providing premier service, building their company one client at a time. This model allows for significant savings while providing the most experienced and dedicated personnel available.

Market Approval
With the knowledge and experience of our dedicated regulatory unit, GCT can also support your post marketing regulatory needs. In addition to regulatory services associated with clinical research, GCT offers full regulatory support for drug and medical devices registration in Russia. Once you've proven your product safe and effective, let GCT help provide access to the growing Russian market.

Regional Focus with Global Perspective
Global Clinical Trials is an experienced regional full service clinical research organization with a track record of success. Let GCT introduce you to this exciting and successful region, and let us demonstrate why, with GCT, this is the best area in the world for quality clinical research.

www.gctrials.com

Services: Clinical R&D, Clinical Trial Monitoring, Comprehensive Drug and Biologic Development, Data Management, GCP Compliance, Metabolism Studies, Patient Recruitment, Project Management, Regulatory Document Preparation, Trial Management

GXP International

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Contact Person: Dr. Teri Stokes

Common Sense Computer Validation

Founded in 1996, GXP International helps clients prepare their organization for audits and inspections of computerized systems and electronic data practices to GCP, GLP, GMP, and 21 CFR Part 11 standards. From Top 10 pharmaceutical companies to startup biotech firms, CROs, and software/system suppliers, we have helped clients develop and implement a practical and realistic way to meet regulatory requirements within the parameters of defined business goals. This global consultancy is based on the 20 years of computer validation experience of Dr. Teri Stokes and has resulted in satisfied clients and referral projects in Europe, North America, and Asia.

Each engagement is customized to client needs and usually includes a combination of the services listed below:

Management Control Services
- Develop Company Policy for Computerized System Validation and for Electronic Data Quality
- Develop SOPs for Validation Package Management (IQ/OQ/PQ), Formal Testing Practices, and Business Review
- Develop the Master Validation Plan for a Computerized System or Electronic Data Capture Project
- Develop User Requirements Specification for a Regulated Work Process to Be Computerized
- Design Quality Management Systems for Computer Validation and Electronic Data Quality Practices
- Document Software Development Life Cycle (SDLC) in Internal/External Supplier Groups
- Document End User Work Process Life Cycle for Electronic Data Handling in GXP Regulated Areas
- Develop and Deliver Certificate Training Programs on Relevant Regulations, System Concepts, and Validation Practices

System Reliability Services
- Develop Validation Plans for IQ/OQ/PQ of a Specific GCP/GLP/GMP Computerized System
- Develop Master Test Plan Process for IQ/OQ of Software Projects and System Test Plans for IQ/PQ in User Acceptance
- Develop Test Case Descriptions, Test Scripts, Trace-ability Matrices to URS and FRS
- Develop Test Summary Reports and Validation Summary Reports
- Develop SOPs for Data Center Management
- Define Configuration Management Logs and IT/IS Service Level Agreements

Data Integrity Services
- Develop Tools for Non-computer Professionals to Use to Identify GXP Systems in their Work Process and Make an Initial Assessment of System Quality Status, e.g. CRA qualification of site systems capturing primary endpoint data in a GCP trial, QA Audit of Batch Record Systems at a Contract Manufacturer, QC Review of Systems at Contract Labs
- Develop an Electronic Data Quality Plan Process and Format for Protocol Teams to Use in Preparing for Roll Out of Electronic Data Capture and Electronic Data Entry in GCP Studies

Auditable Quality Services
- Perform Walk-through Reviews of IQ/OQ/PQ Packages in Progress at a Client Site
- Conduct Baseline Gap Analysis Audits of Computerized Systems and e-Data Practices for GXP Compliance
- Conduct Vendor Audits for GXP Compliance on Behalf of Clients
- Conduct Mock-Inspection Audits to Prepare Clients for Regulatory Inspections
- Develop Audit SOPs for QA Practices During Audits and Inspections
- Review Client SOPs for Validation and Electronic Data Quality Practices

Visit our website: www.GXPInternational.com

Services: Computer System Validation, Consulting, Contract Auditing, Electronic Data Capture, GCP Compliance, GLP Compliance, Quality Assurance/Control, Randomization (Automated/Centralized/Vocal Computer), Software Development & Evaluation, Training

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Harrison Clinical Research

Harrison

Harrison Clinical Research (HCR) is an independent contract research company founded in 1987 in Munich with regional offices in Austria, Belgium, France, Israel, Italy, Poland, Russia, Spain, Ukraine, United Kingdom, and the USA (HCRAmerica). Through our affiliation with a CRO in Japan, Harrison Clinical Research can provide truly international service for the development of your products.

Harrison Clinical Research Munich was awarded the ISO 9001 certification on March 26, 1998 for the "Design and evaluation of clinical trials for the pharmaceutical and medical device industry including performance of Phase I trials and the management and monitoring of Phase II/III/IV trials". HCR has been engaged in national and multi-national Phase II and Phase III clinical studies according to FDA, European and local regulations. From our locations in Belgium, Germany, France, Italy, Spain, and United Kingdom we are able to monitor and manage clinical studies throughout Western Europe. Our offices in Austria, Poland, Russia, and the Ukraine cover the Eastern European countries.

Our services are designed to meet your specific needs in the clinical development and registration of pharmaceutical products and medical devices. HCR offers a selection of activities in order to provide an individual and client-oriented approach to your project.

The Data Management and Biostatistics Group offers support in the layout of CRFs, data entry, statistics and the preparation of clinical protocols and reports.

In our Phase I unit located in Munich we can perform first administration to man, single, multiple dose tolerance, interaction, pharmacokinetics, bioequivalence studies and special populations such as hepatic and renal impairment and the elderly.

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Services: Cardiovascular Monitoring/Pulmonary Diagnostics, Clinical Pharmacology, Clinical Study Reports, Clinical Trial Monitoring, Data Management, Efficacy Studies, Pharmacokinetic/Pharmacodynamic Modeling, Statistical Services/Meta Analysis, Training, Trial Management

Howard M. Proskin & Associates, Inc.

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Contact Person: Howard M. Proskin, PhD

Howard M. Proskin & Associates is an established, independent statistical consulting firm incorporated in 1993.

Our staff includes a variety of experienced professionals including statisticians, SAS® programmers, report writers, and support personnel. We pride ourselves in providing a wide range of statistical and related services to our clients in a cost effective and timely manner, in compliance with the standards of Good Clinical Practice (GCP).

Our Experience

Howard M. Proskin & Associates has extensive experience in the analysis of clinical research data from studies in the pharmaceutical, medical device, and consumer products areas. We have provided data analysis and programming services in support of submissions to the FDA, EMEA, and other regulatory agencies, including NDAs, PMAs, and 510(k)s. Our experience includes providing programming and statistical services in support of pharmacokinetic and pharmacodynamic studies. The range of therapeutic areas we have served includes extensive experience in the areas of ophthalmology, GERD, and dental studies.

Clinical Trial Services

Our services include an array of statistical and related services, from study design through final documentation and reporting.

Statistical Services

- Study Design
- Sample Size/Power Calculations
- Randomization
- Data Analysis/Interim Safety Analysis

Specialized processing

- WinNonlin Processing of Pharmacokinetic Data
- MedDRA Processing of Adverse Event Data
- WhoDrug Thesaurus Coding
- Processing of Digitrapper™ Data from GERD Studies

SAS® Programming Services

- Data Summary Tables
- Data Listings
- Graphs, Charts and Figures
- Quality and Edit Checks on Client Database

Study-Related Documentation

- Statistical reports
- Clinical Study Reports
- Case Report Form Design
- Statistical Analysis Plans
- Manuscripts, abstracts and presentations

Services: Data Safety Monitoring Board Services, Programming (Database/SAS/etc), Randomization (Automated/Centralized/Vocal Computer), Statistical Services/Meta Analysis

Hubbell Consulting, LLC

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Hubbell Consulting, LLC provides regulatory consulting, clinical trial management, and medical/regulatory writing services to the pharmaceutical, biotechnology, and medical device industries, and to contract research organizations worldwide. We strive to apply our experience and expertise in research and development and in regulatory affairs to contribute to these industries and improve human health. We emphasize quality, collaboration, commitment, communication, respect, and responsibility. We focus on our clients' needs and priorities, adhering to agreed upon timelines and striving to uphold the values of accountability, confidentiality, expertise, excellence, integrity, and reliability. For over 21 years, Hubbell Consulting has built a reputation of excellence in project execution and delivery. The Hubbell Consulting team is comprised of individuals with many years of experience in scientific communications, clinical research and regulatory affairs. Hubbell Consulting has extensive experience in Phases 1-4 of clinical development and in a large variety of therapeutic areas. Services provided by Hubbell Consulting include the following:

Regulatory Affairs Consulting: Hubbell Consulting advises our clients to ensure that they fulfill regulatory, scientific and clinical requirements and comply with the laws and regulations required by worldwide regulatory agencies. Our consultants work directly with regulatory agencies on our clients' behalf. Hubbell Consulting has experience in the following areas:

- Regulatory strategy development
- IND and IDE submissions and maintenance (including Annual Reports)
- GCP, GLP and GMP audits
- Develop strategy and run Pre-IND, Pre-NDA meetings
- Pre-IND, Pre-NDA briefing packages
- Presentations to the FDA
- Negotiations with FDA
- Responses to FDA inspections (483s) and other FDA correspondence
- 505(b)(2) strategy and NDA submissions
- eCTD preparation (CSE, CSS, ISE, ISS)
- Due diligence for technology licensing
- Toxicology package development

Clinical Trial Management Services: Hubbell Consulting provides clinical trial management services, all performed under GCPs and in accordance with ICH guidelines and the Declaration of Helsinki. These services include:

- Clinical strategy development
- Identification, audit, negotiation and selection of clinical sites, CROs, clinical laboratories and third party clinical supplies packaging sites
- Preparation and submission of IRB/IEC documents
- Designing CRFs (paper and electronic), diaries, and clinical study forms
- Performance of site qualification, initiation, monitoring visits and close out visits
- Writing study monitoring reports
- Reviewing clinical data
- Expediting data clarification and missing data resolution
- Performance of day to day oversight of the clinical trial
- Performance of due diligence for technology licensing

Medical and Regulatory Writing Services

Hubbell Consulting provides a complete approach to medical and regulatory writing and can assist your company in the development, preparation, and review of documents in support of regulatory submissions and clinical trials, including:

- Clinical Study Reports (CSRs)
- Clinical Protocols
- Informed Consent Documents
- Case Report Forms
- Study Reference Manuals
- Patient Diaries
- Clinical Trial Registry documents
- Safety Narratives
- Investigator's Brochures (IBs)
- Investigational New Drug (IND) Applications
- IND Annual Reports
- New Drug Applications (NDAs)
- Abbreviated New Drug Applications (ANDAs)
- Drug Master Files (DMFs)
- eCTDs (CSE, CSS, ISE, ISS)
- 505(b)(2) Searches and Summaries
- Marketing Applications
- Orphan Drug Applications
- Drug Establishment Registration
- Standard Operating Procedures (SOPs)
- Meeting Reports
- Manuscripts for Publication

Services: Claims Support Studies/Safety and Efficacy Studies, Clinical R&D, Clinical Study Reports, Clinical Trial Design, Consulting, Medical Writing, Protocol Development, Regulatory Affairs/Regulatory Strategy, Regulatory Document Preparation, Trial Management

ICON plc

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ICON plc (NASDAQ – ICLR)
ICON is a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries. We specialise in the strategic development, management and analysis of programs that support Clinical Development – from compound selection to Phase I-IV clinical studies.

Headquarters
Dublin, Ireland

Financial Information
ICON's revenue for FY ending 31 December 2008 was US$865 million. ICON trades on the NASDAQ and Irish (ISEQ) exchanges.

Employee Numbers
ICON currently has over 7,100 employees in 71 offices in 38 countries.

Products and Services
ICON offers a broad range of specialised services to assist pharmaceutical, biotechnology and medical device companies to bring new treatments to market faster. Our services span the entire lifecycle of product development and can be adapted to suit small local trials or large global programs.

- Phase I-IV Clinical Trial Design, Management and Review
- Clinical Pharmacology
- Bioanalytical Laboratory Services
- Clinical Pathology
- Protocol Design
- Biomarker Services
- Pharmacodynamic/Pharmacokinetic Analysis
- Data Management
- Medical and Safety Services
- Biostatistics
- Interactive Technologies – IVR, IWR, ePRO
- Patient Recruitment
- Medical Imaging
- Global Central Laboratory Services
- Medical Writing
- Program Management
- Contract Staffing

Markets Served

North America, South America, Europe, Africa, Middle East, Asia, Pacific Rim

Services: Central Laboratory Services, Clinical Trial Monitoring, Data Management, Data Safety Monitoring Board Services, Electronic Data Capture, Health Economics, Imaging, Medical Writing, Pharmacokinetic/Pharmacodynamic Modeling, Pharmacovigilance

ICON plc

4-Color AD

idv Data Analysis & Study Planning

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Internet: www.idvgauting.de
email: admin@advgauting.de
Contact Person: Dr. Volker W. Rahlfs

idv Data Analysis and Study Planning was established in 1966 by Dr. Volker W. Rahlfs, C. Stat., (President of idv). In the meantime more than 600 clinical studies have been planned and successfully performed. Dr. Rahlfs and his team have published more than 100 biometrical articles in well-known scientific periodicals.

Primary services offered by idv:

Clinical Studies

- Study protocol
- Professional data management
- Clinical study reports
- Audits of study protocols and study reports
- Validated randomization
- Seminars and training courses for statisticians and practical workers

Production of software for

- Sample size determination and randomization
- Data analysis, including statistics and graphing
- Report generating
- AE reporting
- Adaptive study design (Two-stage)
- Meta-analysis
- Software for working according to FDA 21 CFR, Part 11

Areas of experience and expertise cover the whole field of internal medicine, surgery, orthopedics, neurology, psychiatry, urology, dermatology and ophthalmology, medical diagnostics.

idv Specialties:

- Study planning according to New Biometry of ICH Biostatistics Guideline E9: operationalization of study objectives, sample size determination, adaptive design
- Powerful confirmatory analysis procedures (US and European requirements) that allow for reduction of sample sizes
- Quality and efficiency audit of study protocols and study reports
- Proxy at regulatory authorities and expert for answering list of deficiencies from authorities
- Re-analyses of inefficient or old, hitherto unacceptable studies
- Meta-analyses for efficacy and safety as required by current guidelines

Features of the ICH-Study-Report Manager (idv's latest software release):

- Reports of twice the length can be managed in half the time
- GCP standard: reports are validated and conform to GCP guidelines
- Reliable results conforming to ICH guidance E3 and E9

Services: Case Report Forms, Clinical Study Reports, Clinical Trial Design, Data Management, Diagnostic Test Evaluation, Programming (Database/SAS/etc), Protocol Development, Software Development & Evaluation, Statistical Services/ Meta Analysis, Training

Imperial Clinical Research Services, Inc.

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email: info@imperialcrs.com
Contact Person: Sandy Reedy

Clinical Research Solutions from Imperial

Imperial's Accelerated Trial Solutions – Control Cost, Manage Risk & Improve Study Timelines

Clinical Study Teams are challenged with navigating the complexities of a rapidly evolving clinical research environment. These critical areas include the following:

- **Recruitment**
- **Study Initiation**
- **eClinical**
- **Study Material Development**
- **Global Requirements**
- **Real-Time Information**

➢ **Recruitment**
- ✓ Educational Solutions
  - Site Education Materials
  - Patient Education Materials
- ✓ Retention
  - Site and Patient Tools
- ✓ Translation Services
- ✓ Registry Solutions
- ✓ Patient/Physician Outreach
- ✓ Concept Development

➢ **Study Initiation**
- ✓ Site Recruitment Materials
- ✓ Investigator Meeting Materials
- ✓ Design Services
- ✓ Imperial Marketplace®

➢ **eClinical**
- ✓ eCRF Source Document Design
- ✓ EDC Contingency
- ✓ EDC Reference Material
- ✓ EDC Launch Kits
- ✓ eArchiving
- ✓ EDC Study Closure

➢ **Study Material Development**
- ✓ Consulting
- ✓ Theme and Concept Graphic Design
- ✓ Design from Protocol
- ✓ PRO Documents
- ✓ Medical Writing
- ✓ Translation Services
- ✓ Proposal Defense Prototypes
- ✓ 3-D Collaborative Proofing

➢ **Global Requirements**
- ✓ Translation Services
- ✓ Global Logistics Expertise

➢ **Real-time Information**
- ✓ Imperial Marketplace®
  - Project Status
  - Study Material Management
  - Inventory Management
  - Global Logistics Tracking
  - Collaborative Project File-Sharing Environment

Imperial understands which is why for 35 years the life science industry has turned to Imperial for meaningful and relevant solutions by improving timelines and implementing integrated study solutions such as Clinical Trial Materials, International Logistics and Information Management.

Services: Case Report Forms, Clinical Trial Design, Medical Writing, Patient Education, Patient Recruitment, Translations

INC Research

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Therapeutic Foresight. Trusted Results™

INC Research, a global contract research organization, invests in its customers' success with proven therapeutic foresight and a trusted approach to advance drug and device development. The company's Trusted Process® method of conducting Phase I – IV trials means customers experience certain trial excellence, helping to minimize potential risk factors and leading to more informed and confident development decisions. Its seasoned project managers and clinicians deliver unsurpassed scientific expertise and service in a therapeutically focused environment.

INC Research has special expertise in the following areas:

- Cardiovascular
- Central Nervous System
- Endocrinology
- Infectious Diseases
- Oncology
- Pediatrics
- Respiratory
- Women's Health

Additional INC Research Global Services include:

- Biostatistics
- Clinical Trial Monitoring
- Cognitive Services
- Contracts & Functional Services
- Data Integration & Warehousing
- Data Management
- Drug Safety
- IVRS/IWRS
- Medical Monitoring
- Medical Writing
- Patient Recruitment & Retention
- Post-Approval Services
- Project Management
- Quality Assurance
- Regulatory Services
- Strategic Consulting

With operations in 40 countries, INC Research has the capabilities to deploy a study on any scale. Whether the scope of your project is a full service international study or requires only select regional services, INC Research can meet your needs.

Services: Clinical Trial Design, Clinical Trial Monitoring, Data Management, Medical Writing, Patient Recruitment, Programming (Database/SAS/etc), Project Management, Regulatory Affairs/Regulatory Strategy, Statistical Services/Meta Analysis, Trial Management

IntegReview Ethical Review Board

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Contact Person: Melissa Meyer

Applying ethics and integrity to human research while accelerating the IRB process through Internet technology, IntegReview provides the highest level of customer service while providing flexibility to meet the specific needs of each client. IntegReview provides unsurpassed ethical review services from diversified, experienced, knowledgeable board members as well as consultants while acting as an advocate for research study participants. The IRB process is accelerated without compromising accuracy or the protection of the rights and welfare of research study participants.

IntegReview has a proven track record of providing ethical review of research in a timely manner. Committee members and staff are highly trained and readily available to provide personalized, responsive, knowledgeable service.

Clients have 24/7 instant access to study documents via the Internet within twenty-four to forty-eight hours of board review. This real-time communication system is password protected and encrypted for security.

IntegReview's success continues to grow by word-of-mouth endorsement from pharmaceutical and medical device companies, contract research organizations, and study sites. All committees are registered with the Office for Human Research Protections (OHRP).

FDA, pharmaceutical companies, contract research organizations, as well as AAHRPP perform regular inspections of our processes. An FDA inspection in July 2009 resulted in no findings.

CERTIFICATION: Staff and board members have earned certifications, such as Certified IRB Professional (CIP), Certified Clinical Research Professional (CCRP) and Certified IRB Manager (CIM).

ACCREDITATION: IntegReview is proud to have earned full accreditation from the Association for the Accreditation of Human Research Protection Programs in 2007.

MISSION STATEMENT

IntegReview is committed to protecting the rights and welfare of human subjects participating in research by:

- ➢ Striving to go above and beyond federal regulations
- ➢ Ensuring research is ethical and safe
- ➢ Providing education for all parties involved in research

IntegReview is committed to maintaining superior customer service without compromising ethical values by:

- ➢ Providing rapid, quality service
- ➢ Assisting clients with ethical compliance
- ➢ Demonstrating respect
- ➢ Offering flexibility

SERVICES:

- ➢ Review of Phase I-IV drug studies, medical device studies, behavioral science studies
- ➢ Single and multiple investigator review
- ➢ Unscheduled meetings, as requested
- ➢ Multiple weekly board meetings
- ➢ Personalized attention to client needs
- ➢ Forty-eight hour turnaround
- ➢ Instant access to study documents via Internet
- ➢ Downloadable forms and e-submissions
- ➢ Presence at investigator meetings
- ➢ Translations
- ➢ Competitive fees

HOW OUR CLIENTS BENEFIT

- Drug can be shipped to sites faster
- Real-time Internet access to study documents
- Internet website access to downloadable forms
- Sample informed consent written below 8th grade reading level

Let IntegReview be your choice in IRB services for your next research study.

Services: Review Board Services

inVentiv Clinical Solutions

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BUILT TO FIT

Early in the history of inVentiv Clinical Solutions, we made a decision that would have a profound impact on our company. We decided to build our business through a customer-centric approach. Our orientation would be to the needs and behaviors of our customers rather than internal drivers determined by short term business trends. This has allowed us to nimbly meet customer requirements as they change, and provide services and frameworks to be flexible and solve problems.

It is a simple formula that explains how we're "Built to Fit".

Flexibility around customer needs, with Infrastructure, Intelligence, and Integrity to Tailor Solutions that accelerate results.

At inVentiv Clinical, we understand the increased regulatory and price pressures faced by the biopharmaceutical industry today. That's why we offer a range of flexible services to fit your specific needs. As a strategic partner, we are nimble enough to change with you, helping you develop the best plan to tackle your resource and development needs at each stage. So whether you need full clinical development solutions, a dedicated team of professionals working without the constraints of co-employment, or simply a few contractors for an upcoming project, we can help you can retain control of your resources, drive costs down and accelerate results.

Clinical Development Solutions: Complete Phase I-IV clinical trial management services offered as full service or functionally-based services, including: project management, clinical monitoring, data management, biostatistics and programming, medical writing, regulatory consulting/liaison and pharmacovigilance.

Strategic Resource Groups: Dedicated, flexible teams that allow longer-term relationships with research-critical personnel and eliminate co-employment.

Resource Management Services: Industry-leading permanent and contract recruiting services to help you manage your resources throughout shifting needs.

Quality Promise

Quality is our way of life ... At inVentiv Clinical Solutions, we are committed to providing superior clinical research services in support of our clients' clinical development pipelines. We believe that the only way to achieve quality excellence is to build it into our systems and processes while investing in training. Visit the Quality Policy section of our website for more information on our commitment to quality in everything we do.

Locations

inVentiv Clinical is headquartered in Houston, TX, with offices in Baltimore, MD; Chicago, IL; Indianapolis, IN; New York, NY; Orlando, FL; Philadelphia, PA; San Francisco, CA; Somerset, NJ; Southport, CT; and international locations in Madrid, Spain; Mumbai, India; and Sao Paulo, Brazil.

Value Add – From Clinical to Commercialization

inVentiv Clinical is a division of inVentiv Health, Inc. (NASDAQ: VTIV). As part of inVentiv Health, we bring clients a wide range of healthcare solutions beyond simply clinical trial management and staffing. inVentiv Health delivers customized clinical, sales, marketing and communications solutions through its four core business segments: inVentiv Clinical, inVentiv Communications, inVentiv Commercial and inVentiv Patient Outcomes. inVentiv Health currently works with over 200 unique pharmaceutical, biotechnology, and life sciences clients, including all top 20 global pharmaceutical companies.

For more information about inVentiv Clinical Solutions please visit us at **www.inventivclinical.com**

Services: Clinical Trial Monitoring, Data Management, Medical Devices/Combination Products, Medical Writing, Patient Recruitment, Pharmacovigilance, Programming (Database/SAS/etc), Regulatory Affairs/Regulatory Strategy, Statistical Services/Meta Analysis, Trial Management

Investigator Location Services

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Newport Beach, CA 92660, United States
Phone: +1.949.417.0437
Fax: +1.413.410.0120
Internet: www.invlocate.com
email: jbollert@invlocate.com
Contact Person: Joe Bollert, PhD

Investigator Location Services, Inc. (ILS), the largest study broker, has instant access to over 20,000 experienced investigators in all medical specialties and practice settings.

- Recruiting is free to sponsors and CROs as investigators pay our fees.
- ILS rapidly locates interested investigators with capacity for your study.
- Investigators typically have 10 or more years of clinical research experience.
- Investigators are extra motivated to perform since they pay ILS a fee at study launch.

Accomplishments:

ILS has recruited 6800+ investigators on 620+ protocols including difficult to place studies for 285+ sponsors and CROs. 80% of our business is repeat business.

Experience:

ILS has eight years experience recruiting investigators for pharmaceutical, biotech, medical device, diagnostic and CRO companies. Executive management has 40 years of clinical trial experience.

Services: Investigational Site/Network

Investigator Support Services

3232 North Elston Avenue
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Fax: +1.773.278.2935
Internet: www.phonescreen.com
email: phonescreen@researchsite.net
Contact Person: Bozena Szorc

PhoneScreen offers 24/7/365 solutions for patient and provider healthcare communications. With more than 20 years of experience, seasoned project management staff, and a client-focused approach, our customized services enhance projects in all stages of the product lifecycle. Our HIPAA-compliant call centers offer the expertise and technologies to maximize response rates for programs of any size and scope.

Call Center Services
PhoneScreen supports various communication needs through the use of live operators and interactive response tools that may be tailored to your specifications.

- **Patient Recruitment** – Centralized screening identifies eligible respondents to reduce screen failures and increase enrollment.
- **Retention and Compliance** – Appointment reminders, patient location, diary capture and personalized communications.
- **Approved Product Services** – Adverse events reporting, data collection, patient registries, advertising response and health surveys.
- **Site Support** – Enrollment monitoring, patient tracking, answering services, nearest site referral, patient education and dietary guidance, appointment scheduling, and warm transfer.

Operator Capabilities
Live operators handle inbound and outbound calls with thorough project knowledge, sensitivity and professional courtesy. Professional operators deliver cost-effective solutions for a broad range of services and multilingual capabilities to support demographically targeted campaigns. For complex programs, nurse operators offer the healthcare expertise to ensure effective patient communications.

Interactive Response Tools
Automated Technologies manage essential data with the programming flexibility to support projects ranging from data collection to health surveys. These tools may be utilized individually or in combination with live operators for maximum value and effectiveness.

- **Interactive Voice Response (IVR)** – Voice-activated systems utilize keypad recognition to increase efficiency and reduce costs.
- **Interactive Web Response (IWR)** – Online forms utilize dynamic scripting to generate questions and share information based on prior responses.

Reporting
Online reports streamline project tasks, delivering the real-time metrics necessary for effective performance monitoring. Management-level metrics identify successful strategies, trends, and response rates to maximize your budget. Project summaries and drill down allow tracking of key performance indicators and detailed data analysis. User-friendly data management tools deliver patient information, for tracking study tasks and data updates.

Services: Adverse Event Management/Software, Data Management, Market Research/Product Communication, Medical Communications, Patient Compliance, Patient Education, Patient Recruitment, Registries, Telephone Support

invivodata inc

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invivodata, inc. Simply Better Data

invivodata combines behavioral science, information technology, and clinical research expertise to capture high quality clinical trial data directly from patients. invivodata's **electronic Patient Reported Outcomes (ePRO) solutions**, which are based on over 20 years of research, deliver reliable patient self-reported data by driving patient compliance with the protocol and eliminating recall biases that plague paper-based self-report data.

invivodata's solutions – **DiaryPRO®,** a field-based ePRO system **and SitePRO®** for site-based PRO data collection – include comprehensive trial-support services that facilitate the collection of ePRO data, web-based access to study data and operational reports that give researchers and sponsors visibility into study progress, and scientific and regulatory consulting on the use of PRO data in a regulated environment.

With scientific expertise and knowledge of ePRO best practices, regulatory requirements and patient behavioral sciences, invivodata's solutions are unique in that they:

- **Help sponsors to support labeling claims.** invivodata's solutions provide sponsors with trustworthy data that can be used reliably in new drug applications.
- **Provide more efficient trial management.** Unlike other ePRO solutions on the market that are focused simply on collecting patient data, invivodata's solutions provide proactive patient and site management functionality, reduce the data management requirements of a given study, and are designed to support a quicker database lock.
- **Provide flexibility to accommodate study needs.** invivodata's solutions help support shorter development timelines, allow for seamless mid-study changes with in-field updates and allow for thoughtful changes which may be required to meet evolving regulatory considerations.

Sponsors using DiaryPRO and SitePRO in their clinical trials benefit from invivodata's strong foundation of scientific and regulatory expertise, innovative technology and ePRO operational insight. invivodata's solution has been used in more than 275 clinical programs and is the industry-leading ePRO system in delivering primary efficacy data for FDA drug approvals. At least 7 successful New Drug Applications have been granted to sponsors utilizing invivodata's ePRO system in their clinical programs – including the first NDA granted using primary data collected on an eDiary platform.

PRO Consulting, Inc. Refining Patient Reported Outcomes

PRO Consulting, a division of invivodata, inc., provides **consulting services to help clinical research teams effectively develop, execute, and document patient reported outcome (PRO) strategies to support their clinical research objectives.** The PRO Consulting team has more than 140 years of cumulative experience in psychometrics, PRO study design, migrating and validating electronic solutions to collect PRO data, and has extensive experience working with the FDA and other regulatory bodies.

PRO Consulting's expertise lies in collecting efficacy data in clinical trials. Our scientific and regulatory experts know how to optimally select PRO measures to assess treatment effect, and support decisions with regulatory bodies. **Our expertise is in the area of measuring signs and symptoms that are the basis of the primary endpoints in clinical programs and trials.** No one knows more about collecting definitive patient reported efficacy outcomes data than PRO Consulting.

PRO Consulting offers an array of services to help clinical researchers define and articulate a conceptual framework and endpoint model, establish PRO measurement properties and population-specific relevance, and provide expert guidance and support in regulatory submissions and meetings. PRO Consulting also provides deep expertise in the evaluation of migration requirements when moving from paper assessments to an electronic platform, validation of the resulting electronic version of the instrument, and documentation of these efforts to support regulatory submissions.

Regardless of your clinical program's needs, PRO Consulting will provide confidence that your PRO measures will best support your label claims.

Services: Adverse Event Management/Software, Claims Support Studies/Safety and Efficacy Studies, Clinical Trial Design, Electronic Data Capture, Electronic Diary/Dictionary/Translator, Health Economics, Patient Compliance, Protocol Development, Registries, Regulatory Affairs/Regulatory Strategy

IRB Services (Institutional Review Board Services)

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Internet: www.irbservices.com
email: info@irbservices.com
Contact Person: Jennifer Bruce, Business Development

REAL REVIEWS ... IN REAL TIME.

Serious about human subject protection since 1993.

Institutional Review Board Services (IRBS/IRB Services) was founded in 1993 in response to a perceived need for a mechanism to expedite Ethics Reviews of proposed clinical research in Canada, USA and other countries. Quick turnaround times and reviews that can withstand the scrutiny of regulatory bodies are the core of the company's mission. As a result, this company has developed a reputation for reviews that are thorough, fair, precise and timely.

- **National coverage: National Scope, Local Perspective (CANADA/USA)**
  IRB's in Toronto, Montreal, Vancouver, Boca Raton
- **Rapid turnaround**
  Two to Three meetings per week; ad hoc meetings as required
- **Multilingual Staff** (English, French, Spanish)
  Translation Service available
- **GCP Training/Auditing Service**
  On-site GCP training services
- **Experienced**
  Collectively, IRBS's IRB/REB members have 100's of years of research/research ethics experience and reviewed 1000's of protocols conducted in Canadian and American academic and private centers.
- **Administratively flexible**
  No complicated submission forms or templates to fill out
- **Reasonable fees**
  US or Canadian currency Project quotes available

Services: Clinical Trial Design, GCP Compliance, Protocol Development, Regulatory Affairs/Regulatory Strategy, Review Board Services

KAI Research, Inc.

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Rockville, MD 20852, United States
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Fax: +1.301.770.4183
Internet: www.kai-research.com
email: kai@kai-research.com
Contact Person: Selma Kunitz, President

We have 23 years of experience applying in-depth knowledge of research methodology and processes, medical informatics, and safety monitoring to an array of clinical studies. KAI has a unique, professional, multidisciplinary team that offers substantive understanding of the particular requirements of the regulated clinical trials environment. KAI utilizes its comprehensive knowledge of the health research process to support studies for the biopharmaceutical industries and the National Institutes of Health (NIH). KAI staff members blend clinical, research, data management, quality assurance, safety monitoring and computer systems and programming expertise to provide creative, cost-effective, and practical assistance.

KAI aims for the highest level of quality for its clients, supports them in a collaborative and collegial manner, and is committed to their total satisfaction. KAI has a reputation for excellence based on a combination of experience, expertise, problem solving techniques, communication skills, and the flexibility to adapt to challenging demands. KAI's areas of excellence include:

CLINICAL STUDIES – "full service" clinical study assistance from study design through successful regulatory approval. KAI provides methodological guidance, identifies and initiates sites, coordinates study operations, performs statistical analysis, and prepares the regulatory submission.

CLINICAL DATA MANAGEMENT – validated, electronic data capture (EDC) system appropriate for the data management needs for all phases of clinical studies and compliant with CFR 312. KAI customizes its EDC, Smart Study™©, composed of off-the-shelf, state-of-the-art components to meet the specific demands of each study. The EDC provides robust data editing and project management modules that describe real-time study and site performance.

MEDICAL AFFAIRS SUPPORT – pharmacovigilance, safety monitoring and product information support. KAI identifies and reports drug-specific adverse events to the Food and Drug Administration (FDA) and other countries' regulatory agencies for marketed drugs and treatments under study. KAI Medical Monitors capture adverse event information, probe for required information, and submit time-sensitive and periodic regulatory reports for over 60 marketed drugs. KAI also provides safety surveillance for numerous ongoing clinical trials.

REGULATORY SUPPORT – FDA submissions support. KAI assists clients in preparing and submitting IND, NDA, and aNDA applications. KAI's team of regulatory support experts review client strategies, and propose suggestions, as necessary; review previous studies; prepare an informed action plan and time line; and prepare complete submission.

ELECTRONIC DATA CAPTURE SYSTEM

KAI has developed an internet based electronic data capture system that provides features which allow rapid deployment of domestic and international clinical trials. Smart Study©™ is a proven system that has been used extensively for industry and NIH clinical trials.

Features: • 21 CFR 11 compliant – Fully documented and has been audited by industry and government • Platform – Built around SQL Server 2000 database • Capacity – Capable of handling hundreds of sites and thousands of participants per study • Response time – Very rapid – no long waits for pages to load • Edits – Both real time and batch edits • Format – Screens mimic paper CRFs • Interface – Uses Windows Explorer format that hierarchically displays study, site, participant, visit and eCRF • Coding – MedDRA® autocoder for adverse events and Who-Drug autocoder for medications • Analysis – Interface with SAS to produce data sets with accompanying formats and labels • Management Tools – A battery of standard reports as well as a report generator to produce customized reports • Site Tools – Web based calendar for scheduling participant visits

KAI maintains a training/help desk staff that can respond to users' needs at any hour of the day. We are committed to supporting our clients and users.

Studies: **Recent areas of study supported by Smart Study© ™:** • ADHD • Alzheimer's disease • Cancer • CNS – Stroke, MS, PD • Hypertension • Pain and inflammation • Pediatric studies • Substance abuse • Type II diabetes

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Services: Case Report Forms, Client/Server Database Development and Migration, Data Management, Data Safety Monitoring Board Services, Electronic Data Capture, Medical Information, Pharmacovigilance, Protocol Development, Quality Assurance/Control, Randomization (Automated/Centralized/Vocal Computer)

Kronos Communicated Data, Inc.

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Internet: www.kronosdata.com
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Contact Person: Elida Ramberger

From proposal to "locked databases," **KRONOS COMMUNICATED DATA, INC.**, a woman-owned SBA company, maximizes the advantages of study specific systems for the successful collection and utilization of data by delivering turnkey solutions tailored to study needs. **Kronos** develops and licenses IxRS (IVRS & IWRS) solutions for all phases of clinical trials, registries, diaries and outcomes.

REPUTATION FOR EXCELLENCE

- IxRS (IVRS & IWRS) portal for real-time database access
- Seventeen years designing cutting-edge technology solutions for clinical research
- Small business responsiveness and flexibility
- Fully supported: HelpDesk, training, and user manuals
- International systems in native languages
- Confirmations of all database transactions per users' choice – e-mail, fax or text
- 21 CFR Part 11 compliant
- In-house research develops innovative solutions for increasingly complex study

SOLUTIONS

REPORTING: Real-time data reports, accessed hierarchically. All reports custom designed to improve user interface and minimize time spent searching for information.

REAL-TIME AUTOMATED SECURITY MANAGEMENT SYSTEM (RASMS): Updates to RASMS real-time for updating site information, site personnel, and inventory requirements; receive confirmation real-time that your updates have been applied to the database.

SCREENING/RANDOMIZATION: Investigational sites access the database via IxRS to input data. Baseline data captured for patient eligibility and outcome measures for all phases of clinical trials**.** Centralized, automated randomization employing numerous allocation schemes, including adaptive design, balancing, minimization, cross-over and delayed treatment assignment.

CLINICAL SUPPLY MANAGEMENT: Centralized management on-line, automated supply at patient and site inventory levels. Supply forecasting for just-in-time inventory management eliminates unnecessary drug in the field. Adaptive resupply, by patient, based on multiple global depots.

REGISTRIES: Track treatment outcomes and contribute to evidence-based medicine using patient registries.

FOLLOW-UP: Phone, e-mail, fax and text reminders notify patients and sites of expected input, upcoming study appointments/interventions. Improve compliance with triggers for failed inputs from patients and sites. Exception reports generated real-time enhance data reliability by reducing monitoring time and effort.

PATIENT DIARIES AND OUTCOMES: Capture baseline status for endpoints and follow-up data for outcomes as related to both the clinical and patient perception of treatment. Improve reliability with real-time reminders for missed entries. Incorporate patient education with prompts about their role in the study.

CONTACT: Elida Ramberger, CEO at kronos@kronosdata.com or 941-966-1400

Visit our Website: http://www.kronosdata.com

Services: Clinical Supplies/Distribution/Packaging, Disease Management/Health Outcomes, Electronic Data Capture, Electronic Diary/Dictionary/Translator, Intra/Internet Development, Patient Compliance, Randomization (Automated/Centralized/Vocal Computer), Registries, Remote Data Entry, Software Development & Evaluation

LabConnect, LLC

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LabConnect provides integrated, one-stop solutions for your laboratory service needs. Through the combined expertise of our worldwide network of leading laboratories, we provide customized laboratory service solutions designed to meet your unique requirements. Our "open platform" approach enables us to combine our scientific expertise with unparalleled project management and client service tools to ensure the success of your trial.

LabConnect – The world's local central lab. Global Reach. Local Expertise.

LabConnect has become a recognized industry leader in the central laboratory industry by providing our clients with a broad spectrum of analytical capabilities, global project management, and an extensive package of support services. Our commitment to our clients' success has enabled us to achieve outstanding client retention rates while our business model enables us to provide our services at a significant cost savings to our clients.

LabConnect is the industry's fastest growing central lab for several reasons:

- We're experts in simplifying the coordination of our clients' complicated and diverse laboratory testing needs from general safety labs through molecular diagnostics, specialized oncology assays, biomarker analysis, pharmacokinetic analysis and method development/validation
- LabConnect's worldwide laboratory network boasts more experience, in-house advanced diagnostics and comprehensive on-the-ground, country-specific expertise than any other central lab operating in the emerging markets
- Sites consistently rank LabConnect as #1 in the following categories:
  - Best Client Service Staff
  - Best Lab Kits
  - Best Lab Reports
  - Best Lab Requisition Forms
  - Best Overall Service
  - Best Study Training & Manuals
- Sites and sponsors love our simple, secure and timely LabReport™ technologies which provide real-time visibility of lab results including historical results of out-of-range values at a single glance

To learn more about LabConnect's full range of laboratory services, please visit our website at **http://www.labconnectllc.com/** or contact us at **206.322.4680**.

Services: Analytical Assay Development and/or Laboratory Service, Biological Specimen Collection/Storage/Distribution, Central Laboratory Services

M2S, Inc.

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DATA TO THE HIGHEST POWER

M2S, Inc., founded in 1997, is a privately owned company that specializes in data and image management services. M2S, located in New Hampshire, has become an industry leader in clinical trials image management, medical registries and advanced radiographic image analysis, serving the pharmaceutical, biotech, surgical and medical device industries.

In the early 1990's M2S developed advanced state-of-the-art 3D modeling for aortic aneurysms. These models, combined with sophisticated measurement tools and pre-surgery software, became invaluable for pre-operative vascular surgery planning and established M2S as a respected leader in endovascular image management.

M2S provides a comprehensive offering of core laboratory imaging services for clinical trials including protocol development, electronic image collection, independent review, archiving and real-time web-based data management. With the recent acquisition of the DXA Resource Group, M2S has expanded its clinical trials offering and expertise. DXA is currently the most commonly used technique for measuring bone mineral density and body composition.

In June, 2009 M2S launched the Clinical Data Pathways product which is a web-based system providing physicians, clinical researchers, hospitals, and medical centers with a unified and secure source for data management, as well as outcome reporting and data sharing among multiple institutions. Additionally, to further compliment its service profile, M2S entered into a partnership agreement with ResearchPoint Global (RPG), a joint-venture, full-service CRO with an established presence in nearly 70 countries. The partnership will provide M2S' clinical trials clients with access to RPG's integration of services, including international regulatory support, patient recruitment, and site selection and management.

M2S has created a technological infrastructure that provides state-of-the-art computing power for unmatched performance, all based on a secure web interface. All M2S services focus on increasing operational efficiency, reducing total cost and maintaining or enhancing clinical quality.

For more information, please visit www.m2s.com.

Services: Clinical R&D, Data Management, Imaging, Medical Devices/Combination Products, Project Management, Registries, Remote Data Entry, Software Development & Evaluation, Telephone Support, Training

MaxisIT Inc.

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MaxisIT Inc. – Maximize your returns

MaxisIT is a leading, enterprise-class clinical software and specialized clinical functional services provider that offers a unique blend of both clinical trial domain and core IT expertise with a thorough understanding of pharmaceutical & life sciences industry's data standard (CDISC & HL7) and regulatory compliance needs. As one of the fastest growing companies, we have been **Ranked No. 15** in the Top 50 Technology Companies by **Deloitte** (NY, NJ, CT) in **2008, No. 43** in the Top 100 IT Services Companies Nationwide by **Inc. in 2008 and No. 355** in the Top 5000 Fastest Growing Private Companies by **Inc. in 2008**.

Our software-suite **CT Renaissance**™ has won the **Bio-IT World 2009 Best of Show Award** under the Clinical Trials and Research category. Enterprise-class, completely integrated and automated software suite for clinical trials, ***CT Renaissance***™, offers the most efficient, web-based software solutions that involve no IT footprint at the point of use, capture all the regulatory requirements and are available at the most competitive investment that guarantees return. With the help of *CT Renaissance*™, our customers are able to focus on core research, constantly innovate and scale-up, make faster deliverables and smarter business decisions.

As simple as using a web-based email account, this software-as-a-service oriented, internet solution helps MaxisIT's small to large customers worldwide manage their clinical trials and produce clinical deliverables ranging from the protocol to the eCTD – anytime, anywhere, on-demand. All the functional processes are integrated and automated based on industry standards, reusable meta-data and parameter driven processes. These services oriented web-based software solutions provide the means to accommodate multiple trials and global user-base in parallel, role-based, secured and collaborative work environment.

Available as independent software solutions and also as an integral part of *CT Renaissance*™:

- **eCollabora:** Web-based collaborative medical writing, reviewing and tracking solution supporting geographically distributed user base in a single and secured environment → Standardized yet customizable templates of Protocol, SAP, CSR, SOPs, Investigator Brochure, CRF and other medical writing.
- **eXchange:** Data Exchange and Data Conversion Application → A true performance enhancer for daunting CDISC conversion tasks.
- **eNsure:** CDISC Validation application → Validation of SDTM, ADaM
- **eNalyze:** Statistical Computing Environment that provides complex statistics and clinical reports at your finger-tips. Enhances the work environment and management of larger, multiple studies with global statistical user base. Provides better control over your statistical deliverables with integration to machine readable statistical analysis plan and clinical study reports. Automated batch and/or real-time production of clinical reports and patient profiles, TLGs, interim reports, etc.
- **eDefine:** Automates generation of the Define.XML document.
- **eSubmit:** Electronic Submission platform that provides capabilities for building and validating eCTD and SPL R4 with minimum user intervention.
- **eAdaptive:** A pioneering platform that offers single source visibility of cross-functional and across the trials reports under one interface. Ability to support scenario planning and predictive analysis for Adaptive Clinical Trials utilizing a single source of truth.
- **eRoI:** Centralized repository of data, Metadata and documents in version controlled and audit trailed environment.
- **eControlPanel:** Trial Business Process Management and Monitoring Platform. Offers functionalities to track progress, business process review, planning, user management, access control, deliverable finalization, performance tracking, Trial Management, Patient Randomization, Sample Size Determination.

CT Renaissance™ suite enables strategic business initiatives such as Adaptive Clinical Trials and Enterprise wide clinical trial integration architecture possible and within reach.

Contact our product specialist today:
sales@maxisit.com | 877-MAXISIT (629-4748) Toll free | 732-494-2005 ext. 101 | http://www.maxisit.com/

Services: Client/Server Database Development and Migration, Clinical Study Reports, Data Management, Database Conversions, Document Management, Electronic Submissions Preparation, Medical Writing, Programming (Database/SAS/etc), Software Development & Evaluation, Statistical Services/Meta Analysis

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Since 1981, McCarthy Consultant Services Inc. has been a leading company of specialists in Canadian regulatory affairs and quality assurance for the pharmaceutical, medical device, Natural Health Product and biotechnology industries. At McCarthy Consultant Services, we understand the industry need for expert assistance and that's why our Associates are all former Health Canada or well experienced industry veterans to provide you with knowledgeable, professional expertise that you can trust.

Pharmaceuticals

New Drug Submissions (NDS), Supplemental New Drug Submissions (S/NDS), Clinical Trials Applications (CTA), Applications for D.I.N. numbers, Preparation of Plant Master Files, Preparation of Drug Master Files (USA), Provincial Formulary Submissions, Labelling and Advertising Reviews, GMP Audits, ISO 9000 Audits, GMP Training, QA Systems Design and Management, Government Liaison and Strategy, Validations

Medical Devices

Device licence submissions and device establishment licence applications, Regulatory compliance trouble shooting, Regulatory Strategy, Quality System audits (GMP and ISO), SOP writing, Validations

Natural Health Products

NHP Compliance Issues, Site Licencing, Reviewing Ingredient Declarations, Determination of Allowable Claims, Compliance Review of Labels, Bilingual Translations, Advertising Copy Review, Approvals of Electronic Advertising Copy, Government Liaison and Strategy, Natural Product Number (NPN) applications, GMP Audits and Training, SOP Writing

Services: Consulting, Contract Auditing, Electronic Submissions Preparation, GMP Compliance, Medical Devices/Combination Products, Quality Assurance/Control, Regulatory Affairs/Regulatory Strategy, Regulatory Document Preparation, Rx to OTC Switch, Standard Operating Procedures

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Services: Consulting, Contract Auditing, GMP Compliance, Medical Devices/Combination Products, Quality Assurance/Control, Regulatory Affairs/Regulatory Strategy, Regulatory Document Preparation, Rx to OTC Switch, Standard Operating Procedures, Training

MedComm Solutions

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"Raising the Standard of Performance in Medical Information Call Centers"

MedComm Solutions is the premier provider of drug and medical information call center solutions for the biotechnology and pharmaceutical industries. MedComm Solutions offers fully integrated drug and medical information services and call center solutions that can be rapidly deployed. Since 1998, we have been providing customized services to meet the specific needs of your product(s) and the marketplace.

SERVICES AND CAPABILITIES

Medical Information Call Center Operations

- Toll-free, comprehensive drug/medical information services
- Inbound and outbound call center
- State of the art telephony, computer equipment and facilities
- Validated medical database, compliant with 21 CFR Part 11
- Support for all customers – healthcare professionals and consumers/patients
- Staffed by PharmD's with extensive clinical and pharma industry experience
- All calls answered live within 4 rings by pharmacists front line
- Educational materials and literature fulfillment within 24 hours of request
- 24/7/365 availability of clinical staff

Safety Reporting

- Identification, initial intake and documentation of adverse experience reports
- Detailed SOPs to comply with client/FDA requirements for safety reporting

Product Quality

- Identification, intake, and documentation of product complaints
- Retrieval of suspect product
- Product replacement/credit

Clinical Trials

- Protocol and product information
- Screening callers for eligibility
- Recruitment for study participation
- Referral of eligible candidates to study sites
- Randomization to study drugs

Marketing and Support Programs

- Staffing of Medical Affairs booth at trade shows with comprehensive services on-site
- REMS/Risk management programs
- Sales staff training
- Field-based Medical Science Liaison support
- Patient assistance programs
- Crisis/product recall phone support
- Patient/User registry programs

HOW MEDCOMM SOLUTIONS IS DIFFERENT:

- Fully Integrated Services. At MedComm Solutions, our experience and breadth of services allows us to independently handle and process virtually all inquiries.
- Pharm.D. Staffing. Our clinical staff are exclusively Pharm.D.s with clinical and industry experience. When your product demands the highest level of clinical support – MedComm Solutions can deliver the value your customers are seeking.
- Outcomes Oriented. We provide Medical Information services that meet the needs of your customers and help you achieve success in the marketplace.

Services: ADE Evaluation/Drug Safety Assessment, Consulting, Medical Communications, Medical Information, Patient Compliance, Patient Education, Patient Recruitment, Pharmacovigilance, Registries, Telephone Support

Medidata Solutions Worldwide

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Medidata Solutions (**www.mdsol.com**) is a leading global provider of hosted clinical development solutions that enhance the efficiency of customers' clinical development processes and optimize their research and development investments. Medidata products and services allow customers to achieve clinical results more efficiently and effectively by streamlining the design, planning and management of key aspects of the clinical development process, including protocol development, investigator and contract research organization benchmarking and budgeting, and clinical trial data capture, management, analysis and reporting.

Major Products and Services

Medidata CRO Contractor™, an outsource planning and contracting solution with exclusive access to CROCAS®, the industry database of thousands of negotiated outsourcing arrangements, puts data-driven analytic tools in the hands of research sponsors to optimally plan, budget and manage CRO relationships. Used by clinical, project management, contracting and finance professionals worldwide, CRO Contractor provides up-to-date data on activities and costing from over 4,000 sponsor contracts with more than 250 global CROs in an Internet-accessible, easy-to-use workspace.

Medidata Designer™ is a cutting-edge protocol authoring and trial design tool that helps guide clinical research teams through the protocol creation process, also automatically populating downstream trial applications such as electronic data collection and data analysis systems.

Medidata Grants Manager™, an investigator site contract benchmarking tool, helps trial managers optimize investigator grants by ensuring fair and consistent site payments and mitigating compliance risks. With exclusive access to the PICAS® database, the only clinical cost database derived from negotiated agreements between sponsors and investigators, Grants Manager includes data from nearly one quarter of a million grants and contracts and more than 27,000 protocols in more than 1,400 indications in an Internet-based platform.

Medidata Rave® is the industry-leading electronic data capture, management and reporting solution on a single platform supporting both EDC and CDMS functionality. Flexible, configurable and scalable, Rave provides intuitive interfaces, advanced eLearning tools and accessibility from any Internet-ready computer. Built on industry standards and offering a web-based API, Rave has been seamlessly integrated with a wide range of clinical trial applications.

Medidata understands the end-to-end clinical process and offers in-depth services to support customers' needs. Medidata provides state-of-the-art support, hosting, training and consulting services to support Medidata products and the clinical trial lifecycle. From study design, trial planning, trial execution through to study close, Medidata can provide the right services to meet customers' clinical research goals.

Services: Clinical Study Reports, Cost Benchmarking/Financial Consulting, Data Management, Electronic Data Capture, Protocol Development, Remote Data Entry, Site Performance Metrics, Trial Management

Medifacts International

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Contact Person: Jennifer Grigonis

Medifacts International is dedicated to providing quality cardiac core lab services to pharmaceutical, biotech and medical device companies that are developing therapeutic drugs and products.

Our primary mission is to provide our expertise in the acquisition of data necessary to determine the safety and/or efficacy of drugs or devices involved in clinical trials. Medifacts International has been instrumental in shaping the industry by setting standards of quality and unsurpassed service. Today, as cardiovascular experts with international reach, Medifacts International continues to lead the industry by upholding this standard of excellence.

With over 23 years of experience and offices in the US, Europe, and Asia, Medifacts is a global leader in cardiac safety monitoring services. Our integrated cardiac safety services include:

- ECG
- Holter
- Ambulatory Blood Pressure Monitoring (ABPM)
- T-SMBP
- Home and Office Blood Pressure Monitoring
- Other modalities (Spirometry, Echocardiography…)
- Arterial compliance monitoring
- Diagnostic telemonitoring

In support of these services, Medifacts provides:

- Global presence with offices and operational capabilities on 3 continents
- Expert feedback in program and protocol design
- Project management
- Site support (24x7x365)
- Comprehensive, hands-on training of equipment and procedures offered on-site, at Investigator meetings, or via teleconference
- Final report writing contribution
- Protocol writing
- Equipment provision
- Full ‘gold standard’ ECG analysis

Medifacts International’s scientific expertise, proprietary WebHeart® technology, global presence and recognized quality leadership has established Medifacts as one of the top 3 providers worldwide in comprehensive cardiac safety and efficacy services and the global leader in providing ABPM services.

WebHeart® is a proprietary, global, Web-based platform that offers a complete solution to acquiring, displaying, measuring, and managing Cardiac Safety data in clinical trials. This system allows for real-time access to ECG and Ambulatory Blood Pressure data. Because no actual programming is needed, the time and cost of both study setup and data submission are dramatically reduced. All ECG data can be converted into an XML format that meets FDA requirements and protocol setups are easily configured and expanded to accommodate additional information.

Medifacts International’s scientific expertise, proprietary WebHeart® technology, global presence and quality leadership are recognized throughout the industry as the company is increasingly selected as the partner of choice by pharmaceutical and biotech drug developers.

Services: Cardiovascular Monitoring/Pulmonary Diagnostics, Clinical Study Reports, Consulting, Data Management, Digitized QTc Analysis, Disease Management/Health Outcomes, Expert Reports, Protocol Development, Statistical Services/Meta Analysis, Training

Medpace Clinical Pharmacology

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Internet: www.medpacecpu.com
email: cpuinfo@medpace.com
Contact Person: Robert Wessel

The Medpace Clinical Pharmacology Unit (Medpace CPU) focuses on Phase I and IIa confined/controlled pharmacokinetic/pharmacodynamic studies utilizing special patient populations, and healthy volunteers with first-in-human capability. The Medpace CPU, a 65-bed research facility, provides a full range of clinical research services, including clinical protocol design and development, pharmacokinetic, drug development consulting, project management, data management, statistics, and medical writing.

The Medpace CPU is part of the Medpace corporate campus, providing close proximity to the services of the Medpace family of companies, including Medpace Reference Laboratories (MRL), Medpace Bioanalytical Laboratories (MBL), Imagepace, and the Medpace core ECG laboratory. All data from the Medpace CPU, MBL, MRL, Imagepace, and the core ECG lab are integrated into ClinTrak®, the Medpace proprietary study management database, providing sponsors and study managers near real-time access to all critical study data.

In addition, the Medpace CPU offers a wide range of study capabilities including:

- Dose escalation
- Dose response
- BA/BE
- Drug interaction
- Food effect
- Single/multiple dose
- First in man
- Thorough QT/QTc
- Safety/tolerability

Effective Recruitment

In keeping with the Medpace approach of providing therapeutically focused clinical development services, the Medpace CPU focuses on defined subject populations and therapeutic areas. The dedicated subject recruitment division – in cooperation with the renowned Metabolic and Atherosclerosis Research Center (MARC) led by Dr. Evan Stein – facilitates efficient recruitment of these populations.

Areas of focus include:

- Type 2 diabetes
- Metabolic syndrome
- Cardiovascular disease
- Elderly
- Obesity

Centrally Located Facility

The Medpace CPU is centrally located in Cincinnati, Ohio, approximately 20 miles from the Cincinnati, Northern Kentucky International Airport.

Site features include:

- 30,000-square-foot facility with two units
- Total of 65 beds
- Three hospitals within five miles
- On-site secured, monitored Investigational Drug Service/Pharmacy
- On-site core ECG laboratory – official Mortara partner
- Subject recruitment division with a searchable electronic database
- 24-hour availability of certified advanced cardiac life support (ACLS) personnel
- Master clocks with GPS synchronization to atomic time
- Abundant parking for staff and volunteers
- Public transportation within four blocks
- Generator back-up for continual power supply

The Latest Equipment

The Medpace CPU features state-of-the-art diagnostic and surveillance equipment, including:

- 12-lead cardiac telemetry – Mortara with 24-hour data storage capabilities
- Resting 12-lead Mortara ECGs
- Fully stocked emergency crash cart with oxygen and suction pump devices
- Zoll M Series defibrillator and external pacing device

The unit also has the capacity for IV infusion studies, Holter monitoring, and pulmonary function testing

Services: Clinical Pharmacology, Clinical Trial Design, Consulting, Data Management, Medical Writing, Pharmacokinetic/Pharmacodynamic Modeling, Project Management, Protocol Development, Statistical Services/Meta Analysis

Medpace, Inc.

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Medpace is a leading global full-service clinical research organization providing Phase I-IV core development services for drug, biologic, and device programs. With medical and regulatory expertise in multiple therapeutic specialties, Medpace has assembled the industry's most experienced and therapeutically focused teams to execute at every level of the company's operations, providing complete and seamless drug development services. Medpace creates strategic partnerships with pharmaceutical and biotechnology companies to provide the most efficient and cost-effective path to drug development – from program planning and executing to product approval.

Global Reach
With clinical trial experience in over 40 countries, Medpace has the global reach and capability to conduct studies and assist with regulatory requirements worldwide.

Major Services
The Medpace approach creates a therapeutically focused project team, increasing the quality of every service, including the following:

- Medical Expertise
- Regulatory Affairs
- Safety/Pharmacovigilance
- Clinical Operations
- Data Management
- Biostatistics
- Quality Assurance
- Medical Writing
- Cardiac Safety
- Interactive Voice Response System

The Medpace Group of Companies

Medpace Clinical Pharmacology
The Medpace Clinical Pharmacology Unit (Medpace CPU) is a state-of-the-art Phase I, IIa facility with a core ECG lab focusing on confined/controlled pharmacokinetic/pharmacodynamic studies utilizing human volunteers, with first-in-man capability.

Medpace Reference Laboratories
Medpace Reference Laboratories (MRL) is a central laboratory with locations in Leuven, Belgium; Beijing, China; Mumbai, India; and Cincinnati, USA. The expertise within Medpace Reference Laboratories includes coagulation, cardiovascular diseases, oncology, lipids, diabetes, and other metabolic diseases.

Medpace Reference Laboratories offers clients analytical support during all stages of the drug development process, with more than 76,000 square feet dedicated to laboratory operations and specimen storage. Preparation, packaging, and delivery of all supplies and materials necessary for specimen collection are also managed within the laboratory facilities.

Medpace Bioanalytical Laboratories
The Medpace Bioanalytical Laboratories (MBL) provides bioanalytical services in all stages of drug development – from discovery to post-marketing. Led by an executive management team that averages 10-20 years of pharmaceutical and bioanalytical study experience, Medpace is focused on providing accurate, high-quality results in a timely, secure and cost-effective manner. Medpace Bioanalytical Laboratories experts work in collaboration with the medical and regulatory experts at Medpace to partner with your team to transfer and validate difficult compound assays and ensure fast turnaround of analyses.

Imagepace
Imagepace provides centralized core lab capabilities for managing standard, as well as innovative imaging modality including magnetic resonance imaging (MRI), computed tomography (CT), and bone densitometry or dual-energy x-ray absorptiometry (DXA). Standardized procedures and scientific and operational expertise connect imaging requirements with other clinical components of the study.

Services: Clinical Pharmacology, Clinical Trial Design, Clinical Trial Monitoring, Data Management, Imaging, Medical Writing, Protocol Development, Regulatory Affairs/Regulatory Strategy, Therapeutic Specific Research, Trial Management

Medpace Reference Laboratories

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Medpace Reference Laboratories – Full-Service Central Laboratory

Medpace Reference Laboratories (MRL) has more than 76,000 square feet dedicated to laboratory operations and specimens at locations in Leuven, Belgium; Beijing, China; Mumbai, India; and Cincinnati, US. All laboratories have state-of-the-art, high through-put instrumentation and long-term sample storage units. Preparation, packaging, and delivery of all supplies and materials necessary for specimen collection are managed within the laboratory. Providing the highest quality analytical support to Sponsors and investigational sites, the laboratory offers a comprehensive test menu for safety, efficacy, and endpoint testing. The laboratories use identical methodologies for most analyses and perform ongoing cross-validation of tests to ensure consistent results. MRL offers a full range of global laboratory services, including:

- Protocol support
- Project management and study set-up
- Customized collection kit production
- Comprehensive test menu
- Expert professional and technical personnel
- Cutting-edge technologies in every testing area
- Real-time data management and reporting
- Long-term sample storage at a variety of temperatures down to -70ºC, with ready retrieval of archived samples

Laboratory Analysis
MRL is fully accredited by the College of American Pathologists (CAP) and is compliant with the Clinical Laboratory Improvement Amendments (CLIA-88). MRL laboratories are NHLBI-CDC Part III standardized for total cholesterol, triglycerides, and HDL cholesterol and NGSP Level I standardized for hemoglobin A1C. All Medical Technologists are certified by the American Society for Clinical Pathology (ASCP) and have extensive experience in central laboratory operations. With expertise in every aspect of laboratory testing, from sample collection and test performance to blinding and result reporting, laboratory personnel have the knowledge and understanding to accurately process and analyze samples and report study data.

Global Reach
With locations in Belgium, China, India, and the US, MRL offers global central laboratory services to North America, Canada, South and Central America, the Pacific Rim, South Africa and all of Europe including coordinated project management, correlated analytical methodologies, integrated data management, and reporting.

Features include:

- Customized reporting and delivery options to accommodate international and study-specific requirements
- Global project management
- Global SOPs
- Coordinated production and shipping of specimen collection kits
- Global cross-validation of testing methods
- Industry appropriate quality assurance and accreditation

Locations:

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Services: Central Laboratory Services, GCP Compliance

META Solutions, Inc.

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META Solutions, Inc. is a regulatory compliance consultancy that provides a broad range of solutions and services to the pharmaceutical, biotechnology, medical device, and related service industries. We have, since our founding in 1987, assisted over 200 clients in managing regulatory compliance risk and improving information management.

META Solutions' Consulting Services include the following:

- Regulatory Compliance Assessments and Audits
- Regulatory Compliance Risk Management Services
- 21 CFR 11 Consulting Services
- Business Process and Technology Planning and Analysis
- Computerized Systems Validation Services
- Regulatory Compliance Remediation Services
- Regulatory Compliance Training Services
- Clinical Data Management Services

META Solutions is committed to managing regulatory compliance risk and promoting regulatory compliance. META assists clients to manage regulatory compliance risk by: (1) identifying non-compliant areas, (2) assessing the likelihood and potential impact of losses due to non-compliance, and, (3) developing solutions, guidance, and training to minimize the likelihood and impact of losses due to non-compliance. META helps clients maintain regulatory compliance by auditing and assessing policies, procedures, and documentation against pertinent regulatory compliance requirements and guidance; identifying regulatory compliance deficiencies; and developing practical recommendations to remedy the deficiencies.

Our principal and senior consultants have performed over 300 regulatory compliance assessments, audits, and inspections in over 40 countries. We provide expert consultation to develop comprehensive remediation plans, and the required experienced consultants to implement and correct regulatory compliance problems. We have a thorough and practical understanding of international regulatory requirements and expectations as a result of our experience with client projects in North and South America, Europe, Asia, Africa, and the Middle East. *META Solutions* is a globally recognized industry leader in the fields of computer systems validation, electronic document management, and regulatory compliance. Our Clinical Data Management department has processed data for over 20 sponsors, 75 studies, and over 5,000 subjects. Data processed by META has been included in three successful NDA submissions. We have experience in most major therapeutic areas and devices, and all phases of product development.

META Solutions consists of a dynamic and complementary team of individuals with the necessary skills and experiences to ensure the successful design, development, implementation, and support of advanced technology products and services in the pharmaceutical and related industries. Because we specialize in the pharmaceutical industry, META can effectively perform these services with minimal startup time. Our firsthand experience with global regulatory requirements and typical in-house quality assurance, data processing, document management, and systems development and validation procedures help to assure that we can fulfill your expectations. META also has the technical expertise and resources to analyze and resolve your data and information management problems. Our consulting staff is familiar with the computer hardware, operating systems and applications software that are utilized in this industry. Our experience and resources provide significant flexibility in the approach that is selected to meet your needs.

Services: Computer System Validation, Consulting, Contract Auditing, Data Management, GCP Compliance, GLP Compliance, Quality Assurance/Control, Standard Operating Procedures, Technology Assessment, Training

MORIAH Consultants

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Internet: www.moriahconsultants.com
email: michael@moriahconsultants.com
Contact Person: Michael R. Hamrell, PhD, RAC, FRAPS, President

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MORIAH Consultants provides regulatory affairs and clinical research consulting to the pharmaceutical, biotech and medical device industries. The firm provides a full range of regulatory and clinical services including regulatory strategic planning, preclinical pharmacology/toxicology assessment, clinical study design, compliance audits, review/preparation of regulatory applications, representation and/or liaison with regulatory agencies and scientific groups, and expert witness services. The firm has dealt with Regulatory Authorities in numerous countries and supervised all aspects of product development and approval.

Regulatory Affairs

- Review, assessment, and critical evaluation of Investigational New Drug (IND) Applications, New Drug Applications (NDA), Abbreviated New Drug Applications (ANDA), Biologics License Applications (BLA) and device applications (510k and PMA)
- Representation, contact, or liaison with regulatory agencies and scientific groups (e.g., FDA, CHMP, EMEA, NIH)

QA Compliance

- Conduct site monitoring, site and investigator GCP audits, design and implementation of GCP/GLP/GMP compliance programs, including Part 11 compliance
- Conduct training and educational seminars and courses on Regulatory Affairs, GLP/GCP Quality Assurance, and Clinical Audits

Medical/Technical Assessment

- Evaluation, review, assessment, and assistance at all levels in writing, editing, and coordination of product related reports and manuscripts
- Expert witness testimony related to drug, biologic and device adverse reactions, product development issues and labeling claims

Dr. Hamrell has a unique background, with over 30 years experience in regulatory affairs, clinical research and drug development with academia, the FDA, NIH and in industry. He also worked for 8 years at the FDA and NIH in the development of drugs, biologics and vaccine products.

Services: Comprehensive Drug and Biologic Development, Consulting, Contract Auditing, GCP Compliance, GLP Compliance, GMP Compliance, Quality Assurance/Control, Regulatory Affairs/Regulatory Strategy, Regulatory Document Preparation, Training

Novotech

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email: julia.jones@novotech-cro.com
Contact Person: Julia Jones, Executive Director, Business Development

Novotech is a leading Asia Pacific focused clinical CRO headquartered in Australia with operations throughout the region

Novotech is internationally recognized as the leading Australia based clinical CRO. With a track record of over 14 years and hundreds of clinical trials from First-in-Man to post approval services, Novotech's full service offering includes:

- Feasibility Assessment
- Project Management
- Monitoring
- Biometrics Services (Clintrial®, SAS, WinNonlin®, EDC)
- Pharmacovigilance (Empirica Trace®)
- Quality Assurance Audits
- Regulatory Affairs Consulting
- Third Party Vendor Management, including Contracts Management
- Local Sponsorship

Markets Covered

Novotech's clients are predominantly US and European based pharma and biotech companies engaged in Phase II/III registration studies for FDA and EMEA submissions. Novotech's services are provided in the following markets:

Australia, India, Malaysia, New Zealand, the Philippines, Singapore, South Korea, Taiwan, Thailand

Novotech is committed to further expansion in the region, and routinely partners CROs from other regions for seamless service delivery on global projects, for which it is regularly audited to FDA requirements.

www.novotech-cro.com/

Services: Adverse Event Management/Software, Case Report Forms, Clinical Study Reports, Clinical Trial Monitoring, Data Management, GCP Compliance, Pharmacovigilance, Project Management, Statistical Services/Meta Analysis, Trial Management

nSpire Health, Inc.

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Fax: +1.303.666.5588
Internet: www.nspirehealth.com
email: mbrown@nspirehealth.com
Contact Person: Michael Brown

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nSpire Health develops and manufactures respiratory care products and provides related services. The company is focused on cardiopulmonary diagnostics, respiratory core lab services, and disease management solutions designed to improve health care productivity while increasing the overall quality of patient care. nSpire Health is the exclusive provider of PiKo® home lung health monitors, KoKo® Spirometers, and HDpft™ systems, the most accurate and precise pulmonary function testing systems worldwide.

nSpire Health's Clinical Trial division is uniquely positioned within the respiratory health market to provide you with research grade diagnostic equipment as well as core lab services. By integrating our device manufacturing expertise we are able to 'custom fit' equipment specific to your study parameters.

Our extensive centralized data management services utilize the research grade KoKo® Diagnostic Spirometer and PiKo®, the world's first personal home lung health monitoring device. We are continually developing our products and services, bringing you the most innovative technology available.

Recently nSpire Health introduced PiKoLogic®, a fully integrated spirometry and electronic diary system allowing real-time connectivity with recording of critical parameters and daily diary content for the most demanding clinical trial protocols.

nSpire Health's award winning technologies are continually redefining accuracy and establishing new standards for diagnosing, treating, and managing lung diseases. Researchers feel confident in choosing the leader.

nSpire Health has provided clinical trial core lab services to the world's preeminent pharmaceutical companies, with over 140 clinical trials in the past 7 years involving both pediatric and adult users. We have provided global support to over 5,000 investigative sites in 50 countries. Our quality review team has reviewed more than 1 million PFT's. Our experience includes clinical trials as large as 500 sites spanning 34 countries. nSpire Health offers Centralized Spirometry, Pulmonary Diagnostics, Challenge Testing, E-Diary, and Data Management for Phase I- IV Clinical Trials including Asthma, COPD, and inhaled therapeutics.

Newly released nSpire Health On-line self-paced training curriculum consists of several linked courses, detailing the information needed by a clinical trial site. Each curriculum is electronically tracked with instantaneous reporting on compliance, usage, and certification level. Under development are modules covering other facets of our clinical trial, asthma and spirometry, and pulmonary laboratory diagnostic systems.

nSpire Health offers Centralized Spirometry, Pulmonary Diagnostics, Challenge Testing, eDiary, and Data Management for Phase I-IV Clinical Trials including Asthma, COPD, and inhaled therapeutics.

nSpire Health is committed to revolutionizing the way the world detects and treats respiratory diseases.

Services: Cardiovascular Monitoring/Pulmonary Diagnostics, Clinical Trial Design, Clinical Trial Monitoring, Data Management, Disease Management/Health Outcomes, Efficacy Studies, Electronic Diary/Dictionary/Translator, Project Management, Spirometry/Challenge Testing, Training

Nucro-Technics

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email: fanaras@nucro-technics.com
Contact Person: John C. Fanaras, President

Since 1970 **Nucro-Technics**, a Pharmaceutical Contract Support Organization has been a partner to the pharmaceutical companies around the world. In a modern facility of 58,000 square feet and with a staff of over 135 scientists, our services include:

- Acute and Subchronic Toxicology
- Biotechnology Pharmaceutical Services
- Analytical Services
- Bioanalytical Services
- Genetic Toxicology
- Stability Management
- GMP Audits
- Microbiological Services
- Method Development & Validation
- Biological Assays
- Quality Control Services and QA Compliance
- Medical Devices
- Regulatory Affairs (INDs, NDAs)-Canada

Nucro-Technics is fully compliant with GLP / GMP regulations, and all our GLP studies are audited comprehensively by our Quality Assurance Department. Our commitment to quality, timeliness, pharmaceutical expertise and client growth has driven our company's success. Our multi-disciplinary services assure our clients that all aspects can be handled professionally.

Nucro-Technics will act as the legal agent for international companies that wish to have a presence in Canada, as well as act on their behalf in all Regulatory, Quality Control and GMP compliance issues.

Nucro-Technics' international success relies above all on its dedicated group of professionals. A group determined in achieving their goals and who have a high level of responsibility as well as understanding of the customer's needs and constraints.

Nucro-Technics is inspected and is in full compliance with FDA, and Health Canada. The company is also certified for ISO 9001:2008, and accredited by AAALAC International.

Foreign sponsors of R&D with a Canadian presence can benefit from Canadian tax credits. The Canadian tax credit is a cash refund of up to 35% towards R&D expenditures. Nucro-Technics can assist you in securing these funds.

Services: Analytical Assay Development and/or Laboratory Service, Dissolution Testing, GLP Compliance, GMP Compliance, Microbiology Testing/Services/Surveillance, Quality Assurance/Control, Regulatory Affairs/Regulatory Strategy, Regulatory Document Preparation, Stability Studies/Testing, Toxicology

Omnicare Clinical Research

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email: moreinfo@omnicareCR.com
Contact Person: Deborah Brewer

Omnicare Clinical Research provides clinical development services to pharmaceutical, biotechnology, nutraceutical and medical device companies through our office locations in 31 countries worldwide.

As a premier Phase I-IV CRO, we feature diverse therapeutic expertise and a comprehensive scope of clinical service offerings. Additionally, we are an industry leader in geriatric clinical trials.

Omnicare Clinical Research focuses on providing clients with a superior drug development experience through strong project management, exceptional service and proactive solutions.

People who really care. In a company where it really matters.™

Services: Clinical Supplies/Distribution/Packaging, Clinical Trial Monitoring, Data Management, Medical Writing, Pharmacovigilance, Project Management, Quality Assurance/Control, Regulatory Affairs/Regulatory Strategy, Statistical Services/Meta Analysis, Temporary Services and/or Permanent Placements

Outcome

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Contact Person: Renee Hurley

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Overview: Outcome is the market leader in patient registries, peri- and post-approval studies, and integrated technologies for evaluating real-world outcomes. We provide services and technologies focused on evaluating the safety, effectiveness, value, and quality of healthcare products, therapies, and services.

Our teams have designed, developed, and managed an industry-leading number of patient registries including many of the largest and most well-recognized programs for disease outcomes, safety, and risk management. Our programs span the globe, with thousands of sites across North America, Europe, Asia, South America, Africa, and Australia.

In addition to working with life sciences companies, we also partner with many providers and healthcare organizations, specialty associations, hospital associations, pharmacist associations, managed care organizations, state departments of public health, Quality Improvement Organizations (QIOs), and government agencies.

We are also actively involved in supporting federal initiatives in regulating and promoting post-approval research. Outcome is an AHRQ DEcIDE Research Center, one of 13 research centers selected to conduct accelerated practice studies about the outcomes, comparative clinical effectiveness, safety, and appropriateness of healthcare items and services, as a component of AHRQ's Effective Health Care initiative. Through Outcome's role as a DEcIDE Center, the company was awarded the task order to develop the landmark federal handbook "Registries for Evaluating Patient Outcomes: A User's Guide," released in May 2007.

Programs: We design and implement the following programs:

- Patient Registries
- Post-Approval and Phase IV Studies
- Observational Studies
- Phase IIIb/Expanded Access
- Quality Measurement
- Risk Management/REMS
- Safety & Surveillance
- Health Outcomes/Health Economics
- Quality of Life/PROs
- Patient Retention
- Performance Tracking Systems
- Instrument Validation Studies
- Controlled Distribution Programs
- Health Interventions
- PLAs

Services: We have assembled an outstanding group of experts in program design and management, epidemiology, statistics, health economics, technology, integrated services, and related regulatory (safety, coverage, privacy) aspects of registries, peri, and post-approval programs. This team assists you with all aspects of your study:

- Determining what type of program is the best choice to reach your goals
- Working with the initial planning group to explore purpose, objectives, and feasibility
- Developing your protocol and incorporating our knowledge of real-world, practical, clinical research success factors
- Establishing a governing structure to address key questions that arise from the design through dissemination of results
- Recruiting and managing sites in a manner which maximizes site and patient acquisition and retention
- Providing the central program coordination function that focuses on clean data and quality assurance and manages the day-to-day issues from implementation through analysis
- Providing analysis and reporting, including facilitating and/or creating publications and presentations at scientific meetings

Support: Outcome's focus on the customer extends into every aspect of your program. Our focus on customer service begins with viewing ourselves as your strategic partner, designing the best possible program, and integrating the right technologies. It continues with being responsive to your needs, recommending solutions, and managing change. And, it exceeds your expectations by providing site management (help desk) support often described as best-in-class.

Technology: Outcome's research solutions integrate specialized technology into every phase of a study. We believe that technology plays a critical role in a successful registry or post-approval program and building the solution around the most appropriate technologies improves efficiency, ROI, and site satisfaction, and decreases the time to results. Our patented technologies are unique because they are specifically designed for evaluating real-world outcomes.

Services: Claims Support Studies/Safety and Efficacy Studies, Clinical Trial Design, Data Management, Disease Management/Health Outcomes, Electronic Data Capture, Health Economics, Pharmacoeconomic/Pharmacoepidemiology Studies, Project Management, Protocol Development, Registries

Pacific Biometrics, Inc.

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email: contact@pacbio.com
Contact Person: Patrick Jackle

The Value of Expertise

Pacific Biometrics, Inc. is a premier biomarker services laboratory in the Clinical Trials Industry. By providing specialized clinical biomarker services to Pharmaceutical and Biotech Companies this facility has helped to bring novel small and large molecules to the advancement of modern medicine.

PBI is on the leading edge of technology providing sponsors with best in class testing in many therapeutic areas including:

- Cardiovascular Risk
- Metabolic Diseases
- Musculoskeletal
- Inflammation (Oncology and Neurology)
- Nutritional Health

Biomarker Laboratory Services
PBI serves the needs of sponsors by providing CAP, CLIA and GLP compliance. Specialty testing services in our GLP compliant lab are specifically designed to support the unique needs of biotherapeutics development. These services include:

- Immunogenicity Testing
- Anti-Drug Antibody Assays
- Cell Based Assays
- Multiplexing
- Novel Biomarker Development
- Experienced Technology Transfer Skills

PBI maintains a high percentage of PhD scientists on staff to personally review each customer's protocol and oversee assay validations.

PBI offers:

- Biomarker Laboratory Services
- CAP, CLIA, GLP Compliance
- Pre-clinical, Phase I-IV Clinical Trials
- Validations
- Immunogenicity Testing
- ADA Assays
- Cell Based Assays
- Multiplexing
- Novel Biomarker Development
- Experienced Technology Transfer Skills
- Dedicated Scientific Oversight
- Personal Attention to each project

Services: Analytical Assay Development and/or Laboratory Service, Central Laboratory Services, Data Management, Diagnostic Test Evaluation, Efficacy Studies, GLP Compliance, Metabolism Studies, Preclinical Development Services, Project Management, Therapeutic Specific Research

Palm Beach CRO

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email: asimon@palmbeachcro.com
Contact Person: Arthur Simon, PhD

Palm Beach CRO is a full service Contract Research Organization providing clients and sponsors full clinical trial expertise throughout North America. We are a therapeutically focused contract research organization that provides clinical support to pharmaceutical (RX and OTC), biotechnology and medical device companies. As a small to medium size CRO, we are able to provide high quality and cost efficient services, rapid turnaround and pro-active efforts to deliver on-time completion. In addition, the attention to details by the vastly experienced founders and staff offer strategic clinical insight and operational flexibility.

The programs PBCRO manage range from proof-of-concept studies, through small multicenter trials through Phase III.

Therapeutic Areas of Expertise

We pride ourselves in being pro-active and have worked in the following clinical areas:

- Cardiovascular (hypertension, angina, arrhythmias, CHF)
- Dermatology (alopecia, eczema, psoriasis, seborrhea, onychomycosis)
- Gastrointestinal (ulcerative colitis, IBS, GERD)
- Skeletal (OA, RA)
- Muscular (spasms)
- Pulmonology (Asthma, COPD)
- CNS (opiod, NSAID, sleep, pain)
- Women's Health care (vulvovaginal infections, postmenopausal, HRT)
- Nutritional (Satiety, weight loss, osteoarthritis)
- Oncology
- Urology (OBD, SUI)

Palm Beach CRO Services Offered

- Site Evaluation
- Project Management
- Protocol Preparation
- Case Report Form and Ancillary Form Preparation
- Site Documentation & Contracting
- Investigational Drug Management
- Investigators Meeting
- Site Initiation
- Interim Monitoring Visits
- Site Closeout
- Data Management
- Data Analysis
- Medical/Scientific Writing

Services: Claims Support Studies/Safety and Efficacy Studies, Clinical Trial Design, Clinical Trial Monitoring, Consulting, Consumer Testing, Efficacy Studies, Medical Devices/Combination Products, Protocol Development, Rx to OTC Switch, Trial Management

Palm Beach Research Center

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Fax: +1.561.689.0654
Internet: www.PalmBeachResearch.com
email: David@PalmBeachResearch.com
Contact Person: David Scott, MBA, CEO

Palm Beach Research Center (PBRC) is a dedicated independent site founded in 1994 which has been expanding its capabilities through its CRO division (PalmBeachCRO).

We are located 4 miles from the Palm Beach International Airport (PBI) and 40 minutes from the Fort Lauderdale/ Hollywood International Airport (FLL) which makes our location an easy destination for sponsors.

PBRC is committed to providing clinical services that meet the highest quality standards with rapid and high enrollment of patients.

The Clinical functions are divided into separate groups for patient recruitment, medical, coordinators, regulatory, quality assurance, data entry and medical writing. All groups take pride and have intergraded functions hence, the "ownership" with the individual staff is outstanding.

OBJECTIVE OF PROFILE

PBRC conducts Phase I-IV trials at its dedicated center, its affiliated sites and the PBCRO conducts multi-center trials as a full service CRO throughout the USA and India.

PRODUCT/SERVICE OVERVIEW

PBRC and PBCRO are dedicated to advancing the clinical development of drugs, devices and vaccines to ultimately improve the Quality of Life for patients. Our multidiscipline therapeutic areas of expertise consist of:

- Analgesics — OA, migraine, back pain, tennis elbow, fibromyalgia
- GI — IBS, GERD, colitis, gastritis
- Internal Medicine — diabetes, obesity, hyperlipidemia, hypertension, satiations, metabolic syndrome, smoking cessation
- Dermatology—hair growth, psoriasis, eczema, acne, wrinkles, solar lentigines
- Pulmonary Disease — COPD, asthma, allergies
- Viral — colds, flu
- Rx to OTC switches
- Vaccines
- Women's Health Care — PMS, dysmenorrhea, vaginal candidiasis, vaginosis, vulvar and vaginal atrophy, HRT, hot flashes, sexual dysfunction

COMPETITIVE ADVANTAGES

Our experienced research team is designed to streamline efforts and reduce costs to assure the maximum efficacy and to help design clinical protocols that will increase the sponsor's chance for success. Our team members will become an extension to the sponsor's team.

Services: Advertising, Clinical R&D, Clinical Trial Design, Clinical Trial Monitoring, Inpatient/Outpatient Facilities, Investigational Site/Network, Project Management, Protocol Development, Rx to OTC Switch, Trial Management

PAREXEL International

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Fax: +1.781.768.5512
Internet: www.parexel.com
email: info@parexel.com
Contact Person: Karen Wills

PAREXEL International, a leading global biopharmaceutical services organization, has been a proven partner of pharmaceutical, biotechnology, and medical device companies for the past 27 years. Together with our customers, we have applied PAREXEL's expertise, resources, and technologies in a shared mission to develop life-saving therapies for patients around the world.

Strategic partnerships are more important than ever to meet the challenges of the rapidly changing biopharmaceutical market. For more than two decades, PAREXEL has designed effective partnership models that complement the needs of our customers. As the biopharmaceutical industry has evolved, we have transformed our business to deliver new levels of strategic partnering that help our customers reduce fixed costs, shorten development timelines, and speed the delivery of safe and effective treatments to market. This new approach relies on integrated, long-term relationships that emphasize flexibility, trust, and a deep sense of accountability to maximize the value of the relationship for each partner.

PAREXEL's unsurpassed global network of experts and resources makes us the partner of choice for your complete development needs across every phase of the product lifecycle, every therapeutic area, and every geographic region. Our strategic services and expertise include full clinical research capabilities, early-phase development, regulatory compliance, innovative patient recruitment approaches, global reimbursement and market-access strategies, and industry-leading technologies.

PAREXEL's expertise in Phase I/IIa and Proof-of-Concept studies enables our customers to make earlier, better-informed product decisions that decrease the risk of late-phase failure. Our technology company – Perceptive Informatics – offers an eClinical suite that represents a new level of clinical system integration, as well as innovative medical imaging technologies that help our customers utilize biomarkers and surrogate endpoints to quickly assess safety and efficacy across a broad range of therapeutic areas.

In today's environment, maximizing market penetration, enhancing product positioning, and increasing patient support are ever-increasing challenges for pharmaceutical and biotechnology companies. PAREXEL's PACE™ (Peri-Approval Clinical Excellence) team is a dedicated global unit that provides customized late phase strategies and scientific solutions that allow our clients to seamlessly and cost-effectively move from product development to commercialization and reimbursement.

As PAREXEL partners with our customers to reach their goals and assist in the development of innovative treatments, we draw on our core strength: the high caliber of our people. The dedication to excellence shared by our employees – focused on integrity, client service, quality, teamwork, and ownership – drives us in working together to make our customers more successful. This commitment has resulted in multiple awards honoring the Company's performance, including the biopharmaceutical industry's *Scrip* Award for Best Contract Research Organization in December 2008.

Headquartered near Boston, Massachusetts, PAREXEL operates at 70 locations in 52 countries around the world, and has approximately 9,300 employees.

PAREXEL Services:

- Global Regulatory Compliance
- Early Phase Clinical Development Services
- Phase II – IV Clinical Research Services
- Reimbursement and Market Access Strategies
- Medical Communications

Services: Clinical Pharmacology, Clinical Trial Design, Consulting, Data Management, Imaging, Medical Communications, Patient Recruitment, Pharmacovigilance, Regulatory Affairs/Regulatory Strategy, Trial Management

Perceptive Informatics, Inc.

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Internet: www.perceptive.com
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Contact Person: Kathleen Pomykola, Senior Director, Marketing

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Perceptive Informatics is the industry's leading eClinical solutions provider and we help customers accelerate the drug development process through innovation. Our product portfolio is built on leading-edge technology and is combined with extensive medical and clinical expertise, as well as a deep understanding of the regulatory environment.

Our eClinical solutions can help you improve efficiency and productivity, and ultimately reduce the costs associated with clinical research. Perceptive Informatics' products and services include:

ClinPhone® RTSM (Randomization and Trial Supply Management)
Uses sophisticated IVR and IWR systems to effectively screen and randomize patients and manage study drug inventory. ClinPhone RTSM solutions are powered by proven and fully-validated technologies and supported by robust system infrastructure. A 24-hour multilingual help desk is available to assist with queries.

Medical Imaging
Perceptive offers trial consulting, image collection, independent image analysis and review, and regulatory submission. We use the latest technology and cover a wide range of therapeutic areas. Perceptive is successfully using MR, CT, and PET scans, X-ray, DXA, ultrasound and digital photography, as well as other advanced imaging modalities, as surrogate endpoints.

Clinical Trials Management Systems (CTMS)
Perceptive offers two distinct CTMS solutions. IMPACT® provides the top global pharmaceutical companies a flexible solution with feature breadth and depth and TrialWorks® is well-suited to emerging biopharmaceutical companies that demand rapid implementation and low total cost of ownership. In addition, our Initiator™ software is specifically designed for Phase I unit management and incorporates planning, resourcing, operations, data capture and recruitment applications.

Electronic Data Capture (EDC)
The DataLabs® EDC solution enables clinical study sponsors and their service providers to streamline the clinical data management process. DataLabs incorporates the advantages and flexibility of hybrid technology, unifying paper data entry and EDC into a single clinical data management platform.

Electronic Patient-Reported Outcomes (ePRO)
Perceptive's industry-leading ePRO solutions encompass best-of-breed offerings and consulting for the two most commonly used solutions—device-based and IVR.

Solutions
Perceptive Informatics is at the forefront of research and development, ensuring we provide innovative solutions to meet our customers' evolving needs. Ranging from complex adaptive trials to sophisticated integrations to enterprise portals, we are able to provide leading solutions for all of your clinical technology requirements underpinned by robust infrastructure, product breadth, and clinical and technology expertise.

Perceptive Informatics is the technology subsidiary of PAREXEL International Corporation.

Services: Consulting, Electronic Data Capture, Electronic Diary/Dictionary/Translator, Imaging, Patient Recruitment, Randomization (Automated/Centralized/Vocal Computer), Site Performance Metrics, Trial Management

Pharma Compliance Partners, LLC

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Fax: +1.847.265.5983
Internet: www.phrmacompliance.com
email: jjessen@phrmacompliance.com
Contact Person: JoAnn Jessen

Collaborating with pharmaceutical companies and clinical service providers in the areas of quality assurance compliance, project management, clinical research drug and device monitoring support services, regulatory affairs (submissions, review, and strategy), and clinical operations.

FDA GCP
ICH GCP
EU Directive
GLP
GMP
21 CFR Part 820
21 CFR Part 11

Quality Assurance:

- Vendor Audits (GMP, GLP, GCP)
- Investigational Site Audits
- Bioanalytical Laboratory Audits
- Clinical Study Report Audits/Reviews
- Database Audits
- Part 11 System Audits
- General System/Internal Audits
- Pre-inspection Preparation
- Process Implementation
- Quality Assurance Training

Clinical Research and Clinical Operations:

- Project Management
- Clinical Monitoring - Drug & Device
- Technical Writing
- Medical Writing
- Standard Operating Procedures
- Clinical Financial Analysis
- Process Implementation
- Clinical Research Training

Regulatory Affairs:

- Submissions
- Review
- Strategy

Services: Clinical Trial Monitoring, Consulting, GCP Compliance, Nursing Services, Project Management, Quality Assurance/Control, Regulatory Affairs/Regulatory Strategy, Standard Operating Procedures, Training, Trial Management

Pharmaceutical Development Group, Inc.

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email: cjaap@pharmdevgroup.com
Contact Person: Charles Jaap

PDG was founded in 1999 by Dr. Cheryl Blume and has quickly become a leading regulatory consultant to the pharmaceutical industry. Headquartered in Tampa, Florida, PDG is a recognized leader in providing a wide variety of pharmaceutical consulting services to organizations of all sizes, both international and domestic. PDG assists pharmaceutical firms in the navigation of the U.S. FDA submission and approval procedures for all products regulated by the FDA.

PDG consists of a multidisciplinary team of scientists whose mission is to provide professional product development consulting services and the development of winning regulatory strategies for the pharmaceutical industry. PDG's competencies include pharmaceutical development across the spectrum of prescription, OTC, generic, and innovator drug products, biologic products, and medical devices.

PDG's experience includes the design, execution and oversight of all facets of product development, including strategic design of regulatory programs, all phases of clinical studies (Phases I-IV), non-clinical programs, formulation and CMC related assignments, manufacturing practices and statistical assignments. PDG's regulatory submission expertise includes but is not limited to:

- Development and Coordination of Pre-IND/ Pre-NDA Briefing Packages
- Coordination of Regulatory Meetings with FDA
- Preparation of INDs/IDEs
- Coordination of Drug/Device Master Files (DMF/MAF)
- Preparation of 505(b)(1) and 505(b)(2) NDAs
- Preparation of ANDAs
- Preparation of PDP, PMA/HDE and 510K applications
- Preparation of BLAs
- Review of Non-Clinical and Clinical Literature
- Design of Non-Clinical and Clinical Protocols
- Amendments, Supplements, Quarterly and Annual Reports

PDG's full range of pharmaceutical consulting services include but are not limited to:

- Preparation for GCP/GLP and cGMP inspections and follow-up activities
- Assistance with field corrections and recall activities
- Scientific and technical writing
- Preparation of NIH and other grants including CRADA, SBIR, STTR, PEPFAR
- Patent and Trademark assistance
- Quality assurance assistance
- Risk management action plans
- FDA consultant
- Compilation of SOPs across all functional areas
- Global pharmacovigilance and post marketing surveillance responsibilities
- Designation as the regulatory point of contact for both U.S. and international manufacturers

PDG and/or staff of pharmaceutical consultants are members of the following organizations:

- American Association of Pharmaceutical Scientists
- American Pharmacists Association
- BioFlorida
- Drug Information Association
- Generic Pharmaceutical Association
- International Society of Pharmacoepidemiology
- Regulatory Affairs Professional Society
- The Academy of Pharmaceutical Sciences

All of PDG's 100+ regulatory submissions have been successful, with no significant deficiencies. For example, our first notice from FDA for our most recent NDA submission was an approvable letter, followed shortly thereafter by FDA approval. Based on results like these, many of our clients have asked us to compile multiple additional submissions.

Services: Clinical Pharmacology, Clinical Trial Design, Comprehensive Drug and Biologic Development, Consulting, GMP Compliance, Medical Devices/Combination Products, Pharmacovigilance, Regulatory Affairs/Regulatory Strategy, Rx to OTC Switch

PharSafer Associates Ltd

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Fax: +44 01483 685 922
Internet: www.pharsafer.com
email: graemeladds@pharsafer.com
Contact Person: Graeme Ladds

PharSafer® Associates Ltd – Global Specialists in Clinical & Post-Marketing Safety

We are a niche CRO specialising in both Drug Safety and Medical Information. Our clients are from many backgrounds in the Pharma Industry – Biotech; generic; OTC; Innovator and are from the USA/Canada; Europe to Southeast Asia.

We formed 7 years ago and operate out of the UK offices. The Company was started by Graeme Ladds, a safety professional with over 20 years in the Pharma Industry in many senior Safety positions in large multi-national Pharma. All of our staff are highly skilled safety professionals with backgrounds in science; pharmacy; physicians.

We perform full safety vigilance for Companies including electronic ADR reporting from our validated safety database and especially in helping Companies with the complex legislation that operates around the world to ensure compliant safety reporting.

We help Companies with specific Project based tasks also, with multi-national audits for Pharmacovigilance and GCP; Regulatory Inspection preparation and conduct; safety database implementations; PSUR and Periodic Report writing; SOP writing; routine scientific literature reviews for safety information; Annual Safety Report writing; Pharmacovigilance training; writing Risk Management Plans; producing and maintaining safety data exchange agreements with marketing partners/ distributors; Clinical Expert Reports; the detailed description of Pharmacovigilance systems document (an EU requirement) without which a licence will not be granted.

We have undergone our own Regulatory Inspections on site for clients against our own procedures and ensure that our own high training standards (which involve staff gaining post-graduate diplomas in Pharmacovigilance) ensures that our staff can meet all of our client and Regulatory requirements. Most staff have many years experience working in multi-national safety Companies.

We have a number of strategic alliances with specialist Companies in other disciplines such as Regulatory; GMP; Pre-Clinical; Marketing; Data Management and Statistics; Clinical Laboratories and GLP to help with a central approach to your drug development and marketing.

We have trained pharmacists and physicians to answer medical enquiries on your products too, building and utilising FAQs; producing Marketing reports and focused literature reviews.

For further information on our Company and how we can help you, please contact us via the information ports mentioned.

Services: ADE Evaluation/Drug Safety Assessment, Adverse Event Management/Software, Claims Support Studies/Safety and Efficacy Studies, Expert Reports, GCP Compliance, Medical Devices/Combination Products, Medical Information, Pharmacovigilance, Remote Data Entry, Training

Phase Forward

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Fax: +1.781.890.4848
Internet: www.phaseforward.com
email: elaine.maynard@phaseforward.com
Contact Person: Elaine Maynard

Phase Forward offers a global, integrated clinical research suite to meet drug development needs from study set-up, through analysis and submission:

- Data Capture and Management
- ePRO and Late Phase
- Randomization and Trial Supply Management
- Phase I Clinic Automation
- Safety and Strategic Pharmacovigilance
- Clinical Data Repository and Statistical Control Environment

Our products and services have been used in over 10,000 clinical trials involving more than 1,000,000 trial study participants at over 290 life sciences companies, regulatory agencies and public health organizations.

In addition, the company provides services in the areas of application implementation, hosting and validation, data integration, business process optimization, safety data management, and industry standards.

Services: Adverse Event Management/Software, Clinical Trial Design, Clinical Trial Monitoring, Data Management, Data Validation, Electronic Data Capture, Electronic Submissions Preparation, Pharmacovigilance, Remote Data Entry, Trial Management

House AD

PRA International

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Phone: +1.919.786.8200
Fax: +1.919.786.8201
Internet: http://www.prainternational.com
email: endpoints@praintl.com
Contact Person: Tami Klerr-Naivar

PRA International, one of the world's leading global clinical research organizations, conducts clinical trials in more than 65 countries across six continents. PRA provides outsourced clinical services for all therapeutic areas, across all phases of pharmaceutical and biotech drug development, with particular focus in the following therapeutic areas: Oncology and Hematology, Neurosciences (neurology and psychiatry), Cardiovascular, Infectious Disease and Allergy/Respiratory.

PRA's therapeutic expertise, global reach and project experience, combined with extensive local knowledge and our differentiating **P**E**R**SON**A**L ELEMENT enable our project teams to deliver consistent and on time performance for our clients. This unique PRA philosophy – THE **P**E**R**SON**A**L ELEMENT – recognizes that true client service comes only from trained, empowered and dedicated employees who are encouraged to use innovation and their personal commitment to accelerate the development life-cycle.

PRA's Early Development Services (EDS) group provides comprehensive services for Phase I and Phase IIa clinical research, bioanalytical research and data support. Our expertise is primarily with more complex types of studies in which safety and intelligent design are critical factors.

PRA's Product Registration group has been instrumental in helping our clients conduct complex, global, multi-center trials and has supported our clients in achieving more than a dozen drug approvals across a range of therapeutic areas.

PRA's Late Phase Services group supports global and regional Post-approval studies, assisting sponsors with the Post-Marketing process by planning and conducting Post-Authorization Safety Studies/Safety-Surveillance Studies, Drug Utilization Studies, Registries, Restricted Access Programs, Risk Evaluation and Mitigation Strategies/EU-RMP, and Diagnostic and Biomarker Research.

To learn more about PRA International, please visit

http://www.prainternational.com/ or e-mail endpoints@praintl.com

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Services: Analytical Assay Development and/or Laboratory Service, Clinical Pharmacology, Clinical Trial Monitoring, Data Management, Pharmacoeconomic/Pharmacoepidemiology Studies, Pharmacovigilance, Registries, Regulatory Affairs/ Regulatory Strategy, Statistical Services/Meta Analysis, Trial Management

PRA International

4-Color AD

Precision Research, Inc.

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Fax: +1.610.296.1745
Internet: www.precise.net
email: ngoldstein@precise.net
Contact Person: Neil Goldstein, MD

OUR NAME IS OUR BUSINESS

At **Precision Research, Inc.** we are small enough to give your smallest projects our undivided attention, yet versatile enough to handle a full spectrum of clinical research challenges. We resource our responsibilities appropriately to assure ALL our clients receive the personal service they deserve and expect, with attention to detail on all our projects. At **Precision Research, Inc.** we are committed to providing high quality work within your timeline and budget requirements.

Take advantage of our proven leadership:
Neil H. Goldstein, MD and Donald A. Paris, MS, the co-founders of **Precision Research, Inc.**, have over 40 years of collective clinical industry experience.

Benefit from our full complement of experienced and professional Medical Writers, Clinical Managers, and Quality Control experts.

The capability to provide the services you need:

- Medical Writing – virtually any document, including:
  Phase I-IV Clinical Study Reports
  Investigator Brochures
  Briefing Documents
  Long-term Safety Updates
  Clinical Protocols
  Abstracts and Manuscripts
  Clinical Sections of NDAs, BLAs, CTD documents, including
  - Clinical Efficacy Summaries
  - Clinical Safety Summaries
  - Clinical Overviews
- Submission-ready Document Preparation:
  - Utilizing Adobe Acrobat®, ISI ToolBox®
  - Insertion of PDF Bookmarks and Hyperlinks
  - Submission-ready output in accordance with ICH and CFR guidelines
- Medical Consulting
- Clinical Trial Management
- Auditing and Quality Control
- Drug Safety Surveillance

Expertise in a wide range of therapeutic areas:

- Infectious Diseases
- Pulmonary Medicine
- Rheumatology/Bone Metabolism
- Allergy/Asthma
- Immunology
- Gastroenterology
- Hematology/Oncology
- Cardiovascular Medicine
- Antibacterial Mouthwashes and Surgical Hand Scrubs
- Diagnostic Imaging
- Medical Devices
- Plasmapheresis
- Drug Delivery (including liposomes)
- Dental Implants and Cleansers

Services: Clinical Study Reports, Consulting, Document Management, Expert Reports, Medical Writing, Project Management, Quality Assurance/Control, Regulatory Document Preparation, Standard Operating Procedures, Trial Management

Premier Research Group Limited

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Internet: www.premier-research.com
email: jessica.barag@premier-research.com
Contact Person: Jessica Barag, Marketing Manager

Premier Research is a leading global, solutions-driven CRO committed to therapeutic focus and operational expertise to deliver clinical trial services of the highest quality for biopharmaceutical and medical device companies.

From protocol design and feasibility assessments through final study report, Premier Research excels in providing expert project teams that evaluate the unique needs of each client and provide solutions catered to their specific project requirements. We offer a comprehensive selection of services for every phase of your clinical development.

- Regulatory Affairs
- Clinical Trial Management
- Clinical Research Centers
- Medical Affairs and Strategic Consulting
- Pharmacovigilance
- Data Management
- Biostatistics
- Medical Writing
- IVRS/IWRS
- Quality Assurance
- Functional Sourcing

Premier Research has a global reach with 30 offices across North America and Europe and partnerships in Latin America, Asia, South Africa, Australia and the Middle East. Our broad operational footprint allows many options for enrollment and enables access to diverse patient populations. Our sponsors directly benefit from our regional employees and their detailed knowledge of the local clinical research environment and ability to communicate with investigators and regulatory bodies in their own language.

Focus
We are a leader in clinical research for analgesia, neuroscience, oncology, and infectious disease and has a breadth of experience in medical device and pediatric clinical research. The development of new drugs and devices for the treatment of conditions in the above areas presents unique challenges requiring a depth of knowledge and experience throughout the project team and the organization that only a therapeutically focused CRO like Premier Research can offer.

Expertise
Through our highly experienced and dedicated project teams, in-house medical experts and relationships with numerous key opinion leaders throughout the industry, Premier Research possesses the scientific expertise and operational excellence to successfully plan and execute the most challenging studies.

Quality
Quality of the highest level is central to all aspects of Premier Research's clinical services. All Premier Research employees are committed first and foremost to fulfilling each customer's requirements in a timely, accurate and cost-effective manner. Our success with repeat business is proof to the quality of our service.

For further information about Premier Research, visit www.premier-research.com.

Services: Clinical Trial Monitoring, Data Management, Inpatient/Outpatient Facilities, Medical Writing, Pharmacovigilance, Project Management, Randomization (Automated/Centralized/Vocal Computer), Regulatory Affairs/Regulatory Strategy, Statistical Services/Meta Analysis, Trial Management

PRL Central Laboratory Services

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Overland Park, KS 66210, United States
Phone: +1.913.339.0489
Internet: www.prlwecare.com
email: scot.stubenhofer@prlwecare.com
Contact Person: Scot Stubenhofer

PRL Central Laboratory Services one of the best kept secrets in the business, a great value with incredible service. We specialize in comprehensive diagnostic testing, with a focus on protocol requirements. We serve all phases of clinical research on a global basis, providing each client with accurate study set-up, timely results delivery and validated data management. Our credentialed and tenured laboratory professionals employ advanced clinical testing systems in a state-of-the-art facility. Comprehensive quality control and proficiency testing programs verify accuracy and reliability. PRL is operational 24 hours per day, 7 days per week, which provides the necessary flexibility to meet project needs and insure rapid results turnaround.

Solutions Oriented Project Management

Experienced PRL project professionals expedite study start up, monitor progress from initiation to close-out, assure timelines and provide site support and assistance. Protocol requirements drive service deliverables, implementation plans and quality parameters.

- PRL Project Managers are degreed Laboratory Professionals, who bring extensive clinical laboratory experience to your project
- They recognize that Clinical Investigational Sites are a critical cog in the timely completion of your trial. As such, they are concerned not only about the trial sponsor's level of satisfaction but also about Focus on Sites Satisfaction and Responsiveness
- The experience in project management and PRL's training and culture ensure that they anticipate issues and respond with solutions oriented plans
- Finally are Project Managers are dedicated to your project. To us dedicated not only means in their commitment to ensure your project a success, but their retention through the life of your project. It is not our practice to change Project Managers on a project, because other opportunities come along.

Scientific Consultation Services

Our team of over 20 Board Certified Pathologists is available to provide scientific advice on study procedures and study results.

Personalized Logistics Management

PRL Central Laboratory Services works with each client to design study specific specimen kits and requisitions, and provides detailed collection and processing instructions. Transportation procedures preserve specimen integrity, allow tracking control and assure accountability. Specimen shipments are received via commercial courier Monday – Saturday by 9:00 am CST. Customer support representatives are available for site assistance.

PRL will manage your sample logistics and laboratory data collection even in the situation where the study requires esoteric testing not performed at PRL or if pharmacokinetic testing is required.

Timely Laboratory Data Management/and Reporting

PRL provides a fully customizable laboratory database configuration. Our proprietary information system and data management practices comply with regulatory requirements, and conform to industry standardization models and methods.

- Laboratory data acquired – correct, complete, secure, with real-time data scrubbing
- Laboratory data accessible – on-line data review, archived data retrievable for 15 years
- Laboratory data delivered – printed reports, verbal results notification, custom electronic data transfer formats

Flexible Reporting Options

We understand that every study has its own data laboratory reporting needs. PRL presents test results as protocol objectives indicate – in conventional and SI units, flagged per protocol requirements for demographics, alert values, deltas, toxicity grading, and blinded as specified. Study management reports are available.

Services: Central Laboratory Services, Diagnostic Test Evaluation, Histopathology/Cytology

Promedica International

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Contact Person: Shannon Stoddard

PEOPLE . PROCESS . PERFORMANCE

Promedica International (PMI) is a full-service Contract Resource Organization (CRO) servicing the medical device, biotechnology and pharmaceutical industries. Founded in 1985, we are a privately held, women owned, multi-million dollar corporation. PMI is headquartered in Costa Mesa, California. Our company experience shapes our understanding of the many clinical and regulatory challenges facing healthcare providers and the healthcare industry today.

Our professional staff and consultants have insight and expertise acquired across a broad range of medical specialties/therapeutic areas. Our ISO-certified work processes provide each project uninterrupted consistency, accuracy and attention to detail. Our clients benefit from our large company systems and processes with small company responsiveness. These organizational assets – people and processes – are the driving forces behind our goal to provide a level of performance that meets professional standards of quality and reliability for each client, regardless of size or location.

HOW WE WORK

PMI provides skilled, dedicated project teams using scalable technology and process tracking to match your project requirements and organizational structure. Our project team members have FDA, industry and healthcare practical experience and understand product development, testing, clinical study and approval processes.

OUR VALUED CLIENTS

PMI has provided services for hundreds of companies over the past two decades. We are proud of our track record with both early stage and established companies introducing break-through technology to the US marketplace. For PMI case studies and client comments, please see our web site at **www.promedica-intl.com/about PMI_performance.htm**.

OUR EXTENSIVE THERAPEUTIC EXPERIENCE

Our compiled experience over the past 24 years covers a broad range of therapeutic areas: Anesthesiology/Respiratory Therapy, Cardiovascular, Cosmetic & Reconstructive Procedures, Dental, General/Plastic Surgery, Hematology, Homeopathy, Neurological, Nutrition, OB/GYN, Oncology, Ophthalmology/Optometry, Orthopedic, Otolaryngology. Beyond this list and for a brief description of our most recent experience in any specific area, please visit our web-site: **www.promedica-intl.com/aboutPMI_performance_ts.htm**. Our site also covers our in-depth expertise in Aesthetics, Ophthalmology and Medical Devices.

OUR RANGE OF SERVICES

- PREPARATION OF REGULATORY SUBMISSIONS
- PROJECT MANAGEMENT: Project Set-up/Initiation Activities, Ongoing Project Activities, Close-Out/Completion Project Activities
- CLINICAL STUDY DESIGN, MANAGEMENT AND MONITORING: Site Recruitment and Qualification, Site Training, Subject Recruitment, Study Monitoring and Site Management
- CLINICAL DATA MANAGEMENT: EDC and Paper Data Entry, using state-of-the-art technology
- BIOSTATISTICS: Pre-Study, During the Study, Post Study, Additional Support
- AUDITING AND TRAINING FOR GCP (ACCME accredited) AND ISO COMPLIANCE
- PREPARATION OF REGULATORY SUBMISSIONS
- STRATEGIC PLANNING FOR PRODUCT INTRODUCTIONS
- MEDICAL WRITING
- PRODUCT COMMERCIALIZATION – COMMUNICATIONS BRANDING see WWW.PROMEDICABRAND.COM

We appreciate the time you have taken to review this information about Promedica and invite you to learn more about how we may be of service to you by visiting our web site: www.promedica-intl.com

Services: Clinical Study Reports, Clinical Trial Monitoring, Data Management, Electronic Data Capture, GCP Compliance, Medical Devices/Combination Products, Medical Writing, Programming (Database/SAS/etc), Project Management, Statistical Services/Meta Analysis

PROMETRIKA, LLC

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Internet: www.prometrika.com
E-mail: cgallant@prometrika.com
Contact Person: Chris Gallant

Quality, Integrity and Innovation in Clinical Research Services

Founded in 2003, PROMETRIKA, LLC, is a woman-owned contract research organization led by some of the pharmaceutical industry's most experienced and successful clinical research professionals. With headquarters in Cambridge, MA, PROMETRIKA provides a full range of clinical research services to pharmaceutical, biotechnology and medical device companies. PROMETRIKA's team has managed hundreds of clinical trials from Phase 1 pharmacokinetic crossover trials to Phase 4 long-term multi-center studies in a broad range of therapeutic areas including cardiovascular disease, dermatology, inflammatory and metabolic disorders, oncology, respiratory disease, central nervous system, and medical devices. The company has extensive experience in all areas of clinical trial management, including strategic planning, data collection and analysis, new drug applications (NDAs), electronically submitted common technical documents (eCTDs) and other regulatory filings for the FDA and the EMEA.

Unmatched Experience in Clinical Research

The clinical research professionals at PROMETRIKA have a long history of project team collaboration and staff continuity, resulting in a highly efficient workflow and superior performance every step of the way. Over 75% of PROMETRIKA statisticians have Ph.D.'s and approximately 50% of our clinical data managers are CCDM-level, certified by the Society for Clinical Data Management. With extensive experience in clinical research within sponsor companies as well as CROs, the clinical research professionals at PROMETRIKA are uniquely positioned to identify and implement the critical elements of a successful sponsor-CRO collaboration. Our ability to bring together the optimal skills and resources for every client need allows us to plan and execute clinical research programs with superior service and precision.

A Commitment to Excellence and Regulatory Compliance

At PROMETRIKA, our mission is to help our clients achieve their goals of efficient and successful drug development by providing innovative perspectives on the design and management of their clinical trials and by delivering high quality databases, study reports and final dossiers for regulatory submission. In addition to extensive experience in understanding and guiding clients through the regulatory and filing procedures at the FDA and the EMEA, PROMETRIKA team members have an in-depth knowledge of cGCPs and the ICH guidelines pertinent to study design, clinical trial conduct, data management, biostatistics and programming and report preparation. We keep our team ahead of the curve in all areas of regulatory compliance through ongoing staff training and a company-wide commitment to the highest standards in quality control and quality assurance procedures.

Offering a Comprehensive Range of Clinical Research Services

Clinical Operations: Comprehensive analysis and expert assessments related to study feasibility, protocol design, project planning, risk, vendor and timeline management, clinical monitoring, timely site and patient recruitment, regulatory study/site document management, clinical site and vendor audits, and Data and Safety Monitoring Board (DSMB) meetings.
Data Management: Electronic data capture (EDC), paper based studies, case report form (CRF) and database design, double data entry, data validation and review, adverse event and medication coding and database integration and migration.
Biostatistics and Statistical Programming: Biostatistical support for all phases of drug development from preclinical to Phase 4, study design and protocol development including adaptive designs, statistical analysis plans, SAS® programming, integrated NDA safety and efficacy summaries, meta analyses, electronic CTDs, statistical support for Data Safety Monitoring Boards (DSMB) and Independent Data Monitoring Committees (IDMC).
Medical Writing and Regulatory Submissions: Development and submission of clinical documents, briefing documents for FDA meetings, preparation of INDs, generation of protocols for every phase and indication, Clinical Study Reports (CSR), preparation of all clinical sections of NDAs in traditional or CTD format, and commercialization support including journals, articles, and abstracts.
Consulting Services: Expert analysis and guidance related to statistical, regulatory and clinical operations, project management, SOP development, training manuals, and FDA communications/meeting participation on behalf of the sponsor.

Come visit us at www.prometrika.com

Services: Clinical Trial Design, Clinical Trial Monitoring, Data Management, Electronic Data Capture, Electronic Submissions Preparation, Medical Writing, Pharmacokinetic/Pharmacodynamic Modeling, Programming (Database/SAS/etc), Project Management, Statistical Services/Meta Analysis

PROSAR

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Fax: +1.651.641.0341
Internet: www.prosardrugsafety.com
email: mbieniek@prosarcorp.com
Contact Person: Mike Bieniek

PROSAR. Ensuring Safety and Providing Quality Services.

PROSAR is a leading provider of pharmacovigilance and medical information services to the pharmaceutical and biotechnology industries. PROSAR Pharmacovigilance Service provides adverse event processing including intake, follow-up, coding, assessment for seriousness and expectedness, medical review, and completion of MedWatch and periodic safety reports. PROSAR Medical Information Service provides responses to inquiries from healthcare professionals and patients regarding dosage, indications and contraindications, etc. PROSAR staff is also available to document product complaints. Our call center is staffed by pharmacists and nurses who are available to answer questions from patients and healthcare professionals, day or night.

CoreServices:

- Pharmacovigilance services
- Medical Information services
- Product Complaint documentation
- 24/7 Call Center

Features:

- Staffing by pharmacists and nurses.
- Ability to receive and document adverse event calls.
- Ability to process phone calls, emails, faxes and post mail.
- Systematic review of medical literature to identify reportable adverse events.
- Preparation of MedWatch forms and periodic reports.
- Response to medical information requests from healthcare professionals and patients.
- Development of initial responses, standard response letters and FAQs.
- Client access to case documentation through web-based application PROSAR Case Explorer™.

Benefits:

- Reduce costs of staffing and infrastructure without sacrificing quality.
- Minimize risk by having a comprehensive pharmacovigilance program in place.
- Enhance patient care by providing medical information 24/7.
- Meet the Adverse Event reporting requirements of FDA.

PROSAR is equipped with state-of-the-art call center technology and our safety database is compliant with 21 CFR Part 11. We provide a seamless interface with clients' medical, regulatory and quality departments and contribute to already established pharmacovigilance and medical information practices. We also help start-up companies establish the infrastructure needed to stay in compliance. **The results:** A comprehensive post-market solution that meets clients' needs while allowing them to focus on other mission-critical activities.

For more information about PROSAR visit www.prosardrugsafety.com

Services: ADE Evaluation/Drug Safety Assessment, Adverse Event Management/Software, Medical Information, Pharmacovigilance, Telephone Support, Toxicology

Prosoft Software, Inc.

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Internet: www.prosoftsoftware.com
email: d.rom@prosoftsoftware.com
Contact Person: Dror Rom

Prosoft Software, Inc. is a CRO that specializes in Data Services with a focus on Data Management, Biostatistics, and Medical Writing. In addition to our menu of CRO services, Prosoft has developed several software packages to help expedite clinical trials.

With experience in all 4 phases of clinical trials in the areas of Cardiovascular, Dermatology, Respiratory, Allergy, CNS, Oncology, and Immunology, and others, Prosoft provides services in the area of protocol development, data management, biostatistics, clinical site monitoring, and medical writing. All information systems are completely integrated into a comprehensive data services system at a substantial cost savings.

Our data services and reporting tools include:

eNroll – an eIVR (IVRS) enrollment system supporting internet and phone enrollment with a dynamic or static randomization, drug supplies and enrollment tracking

eDC – our web based electronic data capture system is CFR 21 part 11 compliant, CDISC compliant and allows data entry from study sites, or by our own personnel

eDSMB – an integrated approach to reviewing safety data using eXclinical, our dynamic, user friendly, interactive data review software. eDSMB is a suite of services tailored for data safety review by DMC/DSMB. eXclinical can be used in face to face meetings or via a web cast, which allows for a substantial cost savings.

Services: Clinical Trial Design, Clinical Trial Monitoring, Data Management, Data Safety Monitoring Board Services, Data Validation, Electronic Data Capture, Medical Writing, Project Management, Protocol Development, Statistical Services/ Meta Analysis

Quality and Compliance Consulting, Inc.

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Internet: www.qc2.com
email: qc2@qc2.com
Contact Person: Jason Bertram

Quality and Compliance Consulting, Inc. (qc2) provides worldwide audit and consulting services to the pharmaceutical, medical device, and biotechnology industries. Since 1996, we have conducted more than 1,900 audits in 40 countries.

Our expert staff will help you find practical solutions for regulatory compliance issues, develop and maintain quality systems, and ensure the validity and accuracy of your study data. In addition, our audits will assist you in assessing the adequacy of site, vendor, and sponsor study conduct and compliance with FDA regulations and guidelines, ICH GCPs, local and international regulations, protocol, and SOPs.

Our clients include start-up to multinational pharmaceutical, medical device, and biotechnology companies, contract research organizations, bioanalytical and toxicology laboratories, institutional review boards, university and private medical research centers, and investigators.

Your company will benefit not only from our experience and expertise, but also from the personal attention we give to each project and our dedication to providing high quality, cost-effective services.

Our services include:

GCP, GLP, and BioAnalytical Audits

- Investigative Sites (In-Study or Pre-FDA Inspection)
- Phase I Units and PK/PD Studies
- Institutional Review Boards
- Clinical Trial Files - Essential Documents
- Clinical Trial Data Listings
- Clinical Trial Reports, ISSs, and ISEs
- Toxicology Laboratories and Studies
- BioAnalytical Laboratories, Method Validation, and Assays

Sponsor, CRO, and Vendor Audits (Qualification or In-Study)

- Computer System Validation and 21 CFR Part 11 Compliance
- Electronic Data Capture
- Data Management Systems and Biostatistics
- Clinical Operations and Project Management Systems
- Medical Writing
- Regulatory Affairs
- Safety Systems and Medical Monitoring
- Interactive Voice Response Systems
- Central Reading Facilities (ECG, Radiology, etc.)
- Clinical Pathology Laboratories and Esoteric Testing
- Investigational Product Packaging, Labeling, and Distribution
- Due Diligence Audits

Standard Operating Procedures, Training and Customized Workshops, and Consulting

- Gap Analysis of Existing SOPs
- Revision of Existing SOPs
- Preparation of New SOPS
- Training on GCPs and GLPs, SOPs, and Quality Assurance
- Audit Plan Development
- Audit Follow-Up and Review of Corrective Actions
- Preparation for FDA Inspections, and Mock FDA Audits

Services: Bioanalytical Data Audits/Laboratory & Validation Evaluation, Computer System Validation, Consulting, Contract Auditing, Data Validation, GCP Compliance, GLP Compliance, Quality Assurance/Control, Standard Operating Procedures, Training

Quality Data Services, Inc.

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email: nkohl@qdservices.com
Contact Person: Nancy A. Kohl

Quality Data Services — We hold our clinical trial services to the highest standards — YOURS !

Your Full Service CRO Partner Throughout the Life of Your Clinical Trial.

QDS Specializes in You

Whether you are performing small outpatient studies or large, complex international trials, you need a cost-effective, timely, customized solution to match your clinical development needs. That solution is a partnership with QDS; a full-service contract research organization dedicated to providing high-quality and tailored services to the biopharmaceutical industry. QDS understands you and the requirements of the intricate and rapidly changing world of the clinical research industry.

The Partnership Begins with You

You can choose to have QDS provide a package of complete clinical research products and services or to complement your staff by providing support in the area you need. For our hosted solutions, you decide which products would best fit your needs. For services, use your procedures and templates, or have ours customized to fit your project needs.

QDS's QDRx eClinical Suite – "Your Prescription for Success"

EDC	**–**	**ELECTRONIC DATA CAPTURE**
CTMS	**–**	**CLINICAL TRIAL MANAGEMENT SYSTEM**
IWR	**–**	**INTERACTIVE WEB RESPONSE**
SAFETY	**–**	**SAFETY MANAGEMENT**

QDS Services:

- CLINICAL DATA MANAGEMENT
- PROJECT MANAGEMENT
- CLINICAL MONITORING
- ANALYSIS AND REPORTING, including CDISC Solutions
- MEDICAL WRITING

The Rest is Up to QDS

- We provide dedication
- We deliver experience
- We offer true partnership
- We inspire confidence

Clinical Trial Experience

Significant Experience in Various Therapeutic Areas including:
Oncology, Cardiovascular, Respiratory, CNS, Immunology, Drug and Device trials

Experience with Phase I-IV Studies

Experience with Multi-center Trials and International Data

Experience with Electronic Data Capture and Data Integration

Contact QDS and Let the Partnership Begin

Services: Clinical Trial Monitoring, Data Management, Database Conversions, Electronic Data Capture, Medical Devices/Combination Products, Medical Writing, Programming (Database/SAS/etc), Project Management, Statistical Services/Meta Analysis, Trial Management

HOUSE AD

Quorum Review IRB

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Contact Person: Arri Burgess, Director, Customer Relations

Quorum Review IRB: When Performance Matters.

Quorum Review is an independent ethics review board that is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Quorum was founded in 1992 by a small group of individuals with a wealth of experience in clinical research human participant protection. Quorum's founders believed an IRB could strive to protect human participants without giving up a focus on customer service.

See why research organizations choose Quorum:

- **AAHRPP accredited:** The Association for the Accreditation of Human Research Protection Programs accredits high-quality human research protection programs to promote excellent, ethically sound research. AAHRPP accreditation means that Quorum has demonstrated a commitment to high standards of patient protection and regulatory compliance.
- **Quality and accuracy at all times:** Quorum conducts a thorough quality check on all outgoing documents, to ensure that sites receive high quality approval documents that are free of errors.
- **Prompt turnaround:** We guarantee a 24-hour turnaround on eligible site submissions (from submission to document posting). And with a prompt amendment review cycle, plus expedited translation services, you'll gain efficiencies when it matters most.
- **Rapid site start-ups:** With easy-to-use online forms, multiple Board meetings a week, and a dedicated Site Support Team available from 5 AM PT – 5 PM PT, we deliver the fastest site start-up in the industry.
- **Secure access to an on-line electronic portal:** The OnQ™ portal is a powerful information hub providing sponsors, CROs and investigators immediate access to all Board correspondence, site start-up status as well as on-line submission capabilities.
- **Streamlined site submission requirements:** Quorum's submission paperwork focuses on collecting the information the IRB needs to know. Quorum's submission paperwork focuses on collecting the information the IRB needs to know.
- **Single point of contact:** At Quorum, there's no need to guess about who to call for assistance. Quorum assigns one Quorum representative to each study, and that person will serve as the single point of contact for the life of the study.
- **Canadian and US Review:** Quorum has one of the few ethics review boards accredited to review studies in both the United States and Canada*. Quorum can manage and coordinate submissions from either side of the 38th parallel using a single point of contact per study.

  * Certain provincial restrictions that apply to most other central REBs in Canada also apply to Quorum Review.
- **Streamlined process for working with institutions:** Quorum has worked with researchers from hundreds of institutions and we offer the same prompt turnaround times to our institutional researchers as we offer to our other researchers.
- **Experience as diverse as your needs:** Our board has a deep knowledge and understanding of a broad range of therapeutic areas as well as medical devices, nutraceuticals, cosmetic products and social and behavioral research.
- **Timely and accurate review of Phase I investigational drugs:** Quorum offers a dedicated Phase I team that is specially trained in the unique needs of Phase I studies. We offer flexibility and faster timelines in our Phase I processes.
- **Simplified process for Qualified Minimal Risk studies:** With a streamlined submission process, aggressive volume pricing for large studies and rapid study start-up processes, we're ideally prepared to support minimal risk research.

Quorum oversees research in accordance with U.S. and Canadian human research subject protection regulations, guidelines set forth by the International Committee on Harmonisation (ICH), and principles of the Belmont Report.

To learn more about Quorum, visit our website at www.quorumreview.com

Services: Review Board Services, Translations

Quorum Review, Inc.

4-Color Ad

RCRC Independent Review Board

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Fax: +1.512.382.8902
Internet: www.rcrc-irb.com
email: priscilla.short@rcrc-irb.com
Contact Person: Priscilla Short

RCRC Independent Review Board has been a leading provider of professional IRB services for greater than 20 years. We are committed to providing quality IRB professional services while providing first-class customer service. We strive to partner with research sites and Sponsors/CROs to assist in the successful and timely completion of research studies.

Fully Accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)

Mission Statement
RCRC IRB is passionately committed to the protection of the rights and welfare of clinical research participants. Our board and professional staff are dedicated to the provision of ethical reviews of the highest quality, combined with impeccable customer service. Our goal is to continually enhance our human research protection program to include effective, efficient and innovative processes.

Scope of Services
RCRC provides IRB review for all phases of biomedical research in a variety of therapeutic areas and behavioral/social sciences research for single-site and multi-site trials.

Core Services

Weekly Meetings

– IRB meetings are held twice weekly, additional meetings scheduled upon request

Streamlined submission process

– Comprehensive on-line guidance documents
– Investigator/Site-specific documents retained on file for future submissions

24-48 hour turnaround time

– Email notification of IRB action within 24 hours of the meeting
– Study documents available within 24-48 hours

Full-time IRB member on-staff

– Serves as primary point of contact throughout the duration of the study
– Allows for faster response times for approval of expedited items

GlobeSync™ Virtual Workspace

– Web-based IRB document delivery and repository
– Provides real-time access to IRB study documents enabling a more efficient document delivery
– Advanced security features
– Multiple levels of quality review

Additional Services
Affiliation with the Commonwealth of Massachusetts
Affiliation with Collaborative IRB Training Initiative (CITI) to provide training to Investigators and Research Staff
Development of client-specific template ICD, upon request
Research Site Audits
Foreign translation services

Services: Review Board Services

Recruitech International

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Contact Person: Cindy Bratton

RECRUITECH® INTERNATIONAL
LEADERS IN CLINICAL STAFFING

Recruitech International is a dynamic global leader in clinical development outsourcing, specializing in staffing the top Pharmaceutical, Biotechnology, and CRO companies. Recruitech's skilled teams are committed to raising quality standards in a timely and cost-efficient manner.

Our experienced and dedicated industry personnel will provide unparalleled expert assistance in all areas of clinical development, including:

- Clinical Research
- Project Management
- Regulatory Affairs
- Drug Safety
- QA/QC
- Data Management
- Biostatistics
- Medical Writing

Recruitech International incorporates the comprehensive clinical services of a CRO combined with the cost-effectiveness of a high-quality staffing firm. Whether looking for a temporary or permanent opportunity, Recruitech International always finds the perfect fit for both client and candidate.

Additionally, Recruitech International provides the very best compensation plan in the industry; therefore our candidate dedication is stronger than the competition. Our global staff strives to provide our clients with the most qualified and motivated candidates by means of our rigorous screening process.

Recruitech International

"Clinical Development Staffing"

Expert in clinical team building.

Services: Clinical Pharmacology, Clinical R&D, Clinical Trial Monitoring, Consulting, Data Management, Medical Writing, Project Management, Quality Assurance/Control, Regulatory Affairs/Regulatory Strategy, Temporary Services and/or Permanent Placements

REGISTRAT-MAPI

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Contact Person: Carolyn Maki, Vice President, Business Development

REGISTRAT-MAPI provides a complete spectrum of services to optimally design and implement Phase IIIb–IV clinical studies, registries, post-marketing studies, safety surveillance, risk management programs and patient reported outcomes. REGISTRAT-MAPI provides strategic solutions to its global clients to optimize clinical and commercial benefits that contribute to a successful product launch and support ongoing commercialization and clinical efforts.

REGISTRAT-MAPI resources include 450 employees, nine offices, experience in 32 countries, and more than 40 clients including nine of the top ten biopharmaceutical firms. Over the past five years REGISTRAT-MAPI has conducted projects involving more than 15,000 sites and 181,000 patients.

Our personnel collectively apply years of multidisciplinary experience working specifically with the complexities and nuances of large observational and clinical studies.

Focused Expertise

- Post-marketing Requirements
- Phase IIIb–IV Studies
- Disease/Product Registries
- Pregnancy Registries
- Risk Management Programs
  - REMS, EU-RMP, PLAS
- Safety Surveillance Studies
- Epidemiology Studies
- Patient Reported Outcomes
- Product Commercialization
- Market Access
  - Product Utilization Studies
  - Pharmaco-economic Studies
  - Retrospective
  - Database Studies
  - Chart Reviews

Specialized Services

- Strategic Consulting
- Clinical Services
- Safety Management
- Project Management
- Regulatory Management
- Site Enrollment & Training
- Site & Patient Retention Strategies
- Data Management
- Statistical Programming
- Biostatistics
- Medical Writing & Publications
- Quality Assurance
- Call Center
- EDC & Integrated Technologies
- Global Reach
- Epidemiology

Innovative Technologies

Integrated, Customized Technologies designed to support Late Phase studies

- REGISTRAK®
  - Site Relationship Management System
- EDC
- OCR/ICR Fax Scanning
- IVR
- Interactive Web Response/ePROs
- Web Enabled Survey System
- Client Extranets
- Integrated Document Imaging
- Program Specific Internet Portals

REGISTRAT-MAPI

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Other Office Locations

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London, Paris, Rome,
Frankfurt, Utrecht

http://www.registratmapi.com/

Services: Adverse Event Management/Software, Clinical Trial Design, Data Management, Electronic Data Capture, Pharmacoeconomic/Pharmacoepidemiology Studies, Programming (Database/SAS/etc), Protocol Development, Registries, Statistical Services/Meta Analysis, Trial Management

Regulatory Affairs, North America Inc.

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Contact Person: Nancy Chew

RANA is a consortium of professionals founded by Nancy Chew, a well-known and widely respected expert in regulatory affairs. Ms. Chew and her colleagues are filling the need for a small, highly effective team of experienced specialists fluent in product development services for FDA regulated products. This team works on the philosophy of long-term relationships, unimpeachable integrity, and absolute top-level work. They have earned a reputation for flexibility, total project strategies and, above all, practical solutions to complex problems.

The RANA consortium comprises only professionals known personally through prior collaborations.

Our experience includes the development of small molecule pharmaceuticals and well-characterized proteins in all reviewing divisions of CDER as well as complex regulatory projects including gene therapy and combination products.

RANA has long-standing relationships with European regulatory consultancies well placed to provide advice and liaison with local authorities and provide for local language requirements.

From technology transfer to first-in-human studies, to clinical characterization and marketing applications, Regulatory Affairs, North America has the expertise to move your products through FDA.

RANA offers consulting services to the pharmaceutical and biotechnology industries.

Regulatory Services
- Identify and prioritize strategic regulatory options
- Advise on US and European registration strategies
- Plan, rehearse, and conduct FDA meetings
- Act as liaison and official Correspondent for FDA matters (US Agent)
- Coordinate with FDA staff to implement new regulatory procedures
- Review and comment on submissions/dossiers
- Mentor innovators, entrepreneurs, and founders in the regulatory process

Product Development Services
- Plan and execute product advancement through strategically optimal regulatory processes
- Integrate regulatory strategy with research and development programs
- Coordinate pharmaceutical product development
- Develop and manage preclinical drug development programs
- Research and write white papers and position papers

Submission Services
- Submissions planning, development oversight, and review
- Briefing Documents
- Orphan Products Applications
- Electronic submissions
- INDs, Amendments, Annual Reports
- FDA Response Letters
- DMFs and Registration Dossiers including NDAs, 505(b)(2) applications, BLAs

Services: Comprehensive Drug and Biologic Development, Consulting, Drug Master File Dossiers, Electronic Submissions Preparation, Licensing/Acquisitions, Nonclinical Pharmacology, Preclinical Development Services, Regulatory Affairs/ Regulatory Strategy, Regulatory Document Preparation, Strategic Planning and Implementation

ResearchPoint

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Dedication, Expertise, Global Reach

ResearchPoint is a full-service CRO providing clinical trial services worldwide to the pharmaceutical, medical device and biotech industries. Established in 1999, ResearchPoint has grown steadily, building our expertise, our processes and our sponsor relationships to become a leading, trusted CRO, providing our sponsors with the ideal outsourcing experience from study start-up through delivery of the final report.

With headquarters in Austin, Texas, ResearchPoint is able to offer global reach through its membership in ResearchPoint Global, a worldwide partnership comprised of CROs and technology service providers with local and regional regulatory, cultural and logistical expertise in 60 countries around the globe. The partnership operates from a common set of global SOPs, similar to those of any global organization, with all members holding a financial interest in the success of ResearchPoint Global.

ResearchPoint has provided support for more than 160 clinical projects across all major therapeutic specialties. Our track record of new and repeat contract awards is a testament to our ability to anticipate study challenges, our dedication to overcome them and our energy to deliver quality results on-time and on-budget.

Comprehensive service offering

Project Management
Data Management and Biostatistics
Clinical Monitoring
Quality Systems
Medical and Safety Monitoring
Site Selection and Site Management
Medical Writing
Protocol and Regulatory Support
Clinical Phase I Services
Rescue Studies

Offices in

Austin, TX (headquarters)
Malvern, PA

Partner Offices in

Buenos Aires, Argentina
Bucharest, Romania
Edmonton, Canada
Gebze, Turkey
Kiev, Ukraine
Langenfeld, Germany
Mexico City, Mexico
Princeton, NJ
St. Petersburg, Russia
Sandown, South Africa
Sofia, Bulgaria
Zagreb, Croatia
West Lebanon, NH

Services: Case Report Forms, Clinical Trial Design, Clinical Trial Monitoring, Data Management, Efficacy Studies, Medical Writing, Project Management, Protocol Development, Statistical Services/Meta Analysis, Training

SGS Life Science Services

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Fax: +1.301.556.0850
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Contact Person: Ronald Baker

SGS' Life Science Services has 30 years of experience as a global contract service organization providing integrated solutions from preclinical activities to Phase I-IV trials, Bioanalytical and Quality Control testing. SGS' state of the art facilities include: **2 Phase I units** with a total of 184 beds, **2 bioanalytical labs**, and **Phase II-IV clinical trial management** offices across Europe, North America and Asia.

Clinical Pharmacology: SGS' clinical units in Antwerp, Belgium, and Paris, France, have a wealth of experience in First in Man, PK/PD, BE/BA, interaction, C14 ADME and Proof of Concept trials. Clients benefit from favorable regulatory environments in with very short phase I trial approval times of two and four weeks, respectively.

Bioanalysis: A GLP certified and FDA inspected laboratory network, SGS has an international reputation for assay of drugs in biological fluids and complex method development and validation. Services include: Drug sample bioanalysis (24 LC-MS/MS), Animal metabolite profiling and balance studies (14C-labelled drug), Toxicicokinetic analyses and In-vitro cell-assays, Immune function testing: immunogenicity, flow cytometry, cytokine multiplexed ELISA.

Phase II-IV Management: SGS has conducted over 800 Phase II-IV trials with patients in Western, Eastern and Central Europe, Russia, and North America. Monitoring and management offices are located in the USA, France, Spain, Czech Republic, Poland, Romania, and Singapore.

Biometrics: As one of the largest independent data management teams in Europe, SGS supports all in-house and external project needs for clients' clinical trials, powered with Clinitrial®, Oracle Clinical® and SAS®. SGS is fully CDISC compliant and successfully experienced in full electronic FDA submissions.

SGS Regulatory Affairs offers consulting in both European and U.S. registration of Biotech and, Prescription drugs, veterinary products and medical devices with comprehensive EMEA and FDA authorities' expertise.

Pharmacovigilance services such as SAE and ADR reporting, medical writing of PSURs, safety reports and expert reports are also available.

Outsourcing of skilled staff to adjust the size of your project team to the current workload.

Contact SGS

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When you need to be sure about your CRO

Services: Clinical Pharmacology, Clinical Trial Design, Clinical Trial Monitoring, Data Management, Inpatient/Outpatient Facilities, Mass Spectrometry, Pharmacokinetic/Pharmacodynamic Modeling, Project Management, Statistical Services/ Meta Analysis, Trial Management

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Contact Person: Aniruddh Patwardhan

SIRO Clinpharm Pvt Ltd

• SIRO Clinpharm Pvt Ltd is an independent, full service International CRO founded in India • Set up in 1996, SIRO has been conducting ICH GCP compliant clinical trials in India for global pharmaceutical and biotech companies • Vast experience in conducting Phase I to IV clinical trials • Expertise across a wide therapeutic spectrum • Passed 160+ audits by MNC clients and third party sponsors • SIRO has undergone inspections conducted by foreign regulatory authorities like EMEA and Indian regulatory authorities like DCGI for some of its Investigator sites • SIRO is privately owned and professionally managed • Backed by leading global private equity giants • SIRO is in the process of globalizing its operations and has set up offices in the USA, Israel and in Europe at Germany, Romania, Estonia, Greece, Czech Republic and Spain.

Other facts:

• Over 17 years in the Contract Research Business • Acquired Omega Mediation, a Germany based CRO which was set up in 1992, in April 2008 • Most of the top global pharma companies as clients • 400 employees across India, Europe, Israel and US • Managed > 295 clinical operations studies, > 320 Clinical Data Management studies • Over 70,000 clinical trial subjects recruited • Working with > 3000 sites across geographies • > 150 CSRs, about 20 manuscripts, >3000 narratives completed • Publications for medical journals • Projects on Oracle Life Sciences Application Suite • US office for Client service and Project Management • Countries we cover – Austria, Baltic States, Belgium, Bulgaria, Czech Republic, France, Germany, Greece, India, Israel, Netherlands, Poland, Romania, Russia, Spain, Sri Lanka and Switzerland

Alliances:

Cambridge Regulatory Services

- SIRO has formed an alliance with CambReg Ltd, a full scope regulatory services company
- Alliance will help companies wishing to register human medicines of any kind including new small molecule or biotech entities, Biologics and Herbals as well as Generics.
- Services in regulatory affairs advice, submissions and compliance
- Services include preparing CTAs, MAAs in eCTD format, PIPs, PUMAs, etc and managing DCP/MRP across whole of the EU

Advanced Clinical Trial Solutions

- This alliance has enabled SIRO to expand its Oncology Clinical development and patient recruitment expertise to North America.
- ACT Solutions and its clients benefit by gaining access to SIRO's clinical study management, patient recruitment, data management, biostatistics and medical writing capabilities in India and European countries.

Accolades:

2009: Dr. Nimita Limaye, VP, CDM elected ***Vice Chair*** of Society for Clinical Data Management (SCDM), USA; Dr. Tanuja Korde awarded ***Study Manager of the Year*** by Indian Society for Clinical Research (ISCR); Winner of CII's (Confederation of Indian Industry) ***Corporate Wellness*** award for healthy workforce category in the services sector
2008: Winner of ISCR's (Indian Society for Clinical Research) ***Best CRA*** award; Dr. Nimita Limaye, VP, CDM is the ***first Asian*** to be elected to the Board of the Society for Clinical Data Management (SCDM), USA
2007: Winner of Frost and Sullivan **Partner of Choice** award for clinical trials in India
2005: Proximare ***Best of India*** contract R & D award in the Drug Discovery Services Category

EUROPE HEADQUARTERS

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OTHER OFFICES

OMEGA MEDIATION
GREECE, Athens
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CZECH REPUBLIC, Prague
SPAIN, Barcelona
USA, Princeton, NJ

Services: Case Report Forms, Clinical Study Reports, Clinical Supplies/Distribution/Packaging, Clinical Trial Monitoring, Data Management, Electronic Data Capture, Medical Writing, Pharmacovigilance, Quality Assurance/Control, Trial Management

STATKING Consulting, Inc.

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Internet: www.statkingconsulting.com
email: jeff@statkingconsulting.com
Contact Person: Jeff Osterhaus

Since 1989, **STATKING Consulting Inc. (SCI)**, located in Cincinnati, OH, has provided **biostatistics, clinical data management and data related support services** to clinical research & development departments of major pharmaceutical and emerging medical device and biotech companies. Our professional staff of statisticians, SAS programmers, clinical data managers and clinical research associates has over 100 years of combined experience in clinical trial services.

The STATKING staff has worked on trials in over 20 therapeutic areas. STATKING Consulting has particular expertise in the design and analysis of clinical trials in the following therapeutic areas:

Medical Devices – Women's Health – CNS – Delivery Systems
Gastroenterology – Renal/Nephrology

The STATKING staff has worked with Clients to prepare and submit IDEs, INDs, clinical study protocols, NDAs, PMAs and BLAs. The STATKING staff has interacted with FDA statisticians and FDA committee members concerning our Client's submissions.

Below is a sample of the services **STATKING Consulting Inc.** offers to clients engaged in pre-clinical, phase I-IV and post marketing clinical studies.

- **Biostatistical Consulting**
  - Protocol Development
  - Experimental Design Consultation
  - Interim Analyses/Interim Analysis Plans
  - Randomization Lists
  - Power and Sample Size Calcs
  - Statistical Analysis Plans
  - Data Monitoring Committees
- **Clinical Data Management**
  - CRF Design and Development
  - Data Entry & Verification
  - Data Management Plans
  - Data Query & Resolution
  - Autoencode AEs (MedDRA®)
  - Autoencode Conmeds (WHO)
- **Statistical Programming**
  - SAS® Programming for Integrated Safety and Efficacy Summaries
  - SAS® Programming for Efficacy and Safety Tables, Listings and Graphs (TLG's)
  - SAS® Programming for PK Data Analyses
  - SAS® Programming for DMC/DSMB TLG's
- **Statistical Reporting**
  - Integrated & Stand Alone Statistical Reports
  - Interim Analysis Reports
  - DMC Meeting Data Reports
- **Clinical Study Monitoring**
  - Initiation/In-Study/Close-out Monitoring Visits
  - Data Monitoring
- **Medical Writing**
  - Integrated Clinical Study Reports (ICH E3 format)
  - Electronic Document Integration

For more information on SCI, call today to receive an informative business summary or visit our web site at **http://www.statkingconsulting.com** to learn more about our services and our qualifications.

SAS is a registered trademark of SAS Institute Inc., Cary, NC, USA.

Services: Case Report Forms, Clinical Study Reports, Clinical Trial Monitoring, Data Management, Data Safety Monitoring Board Services, Medical Writing, Programming (Database/SAS/etc), Protocol Development, Statistical Services/Meta Analysis, Trial Management

StatWorks, Inc.

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Contact Person: Mark Paul, CEO

From Data to Results

We fit the pieces together

Who are we?

StatWorks, Inc is a specialty CRO with its main focus on biostatistics and data management. We can assist you in all phases of development, and our attention to detail is unsurpassed. Our success results from our obsession with quality, our deep technical expertise, and our commitment to service. Many of our customers utilize our data services to gain consistency, independence, and standardization for their development programs.

What can we do for you?

For over a decade, StatWorks has provided a broad range of the following services to biopharmaceutical and medical device development companies:

- Protocol Design
- Sample Size Calculation
- Randomization
- Summary Tables, Listings, and Graphs
- Statistical Analysis and Report Writing
- Safety Monitoring Board Management
- Report Writing
- Quality Assurance
- Case Report Form Design
- Data Entry
- Electronic Data Capture
- Data Integration
- Data Validation
- CDISC® Services

What eClinical services do we provide?

StatWorks is setting a new industry standard for Electronic Data Capture (EDC) usability. We provide our customers with a *license free* EDC platform that is not only flexible, reusable, and secure, but run by experienced data managers and statisticians on our in-house systems. Our eClinical services will improve data quality, accelerate data acquisition and management, and reduce clinical development costs.

What is our therapeutic experience?

Our senior staff has extensive experience in the following therapeutic areas: Antibiotics, Cardiology, Depression, Diabetes, Epilepsy, Hypertension, Oncology, Ophthalmology, Pain Management, Parkinson's Disease and Rheumatoid Arthritis.

For a complete list, visit us online at **http://www.statworks.net/**

Why contract with StatWorks?

StatWorks has been providing quality service to our clients for over 13 years. We have successfully completed Phase I through IV studies with our primary focus on high quality on-time deliverables. This focus has allowed us to grow organically from many repeat and referral customers. As a specialty CRO, we are able to fulfill research needs by offering a depth of knowledge and level of responsiveness at a more cost-effective price than many of our larger counterparts.

StatWorks ... Quality, Innovation, Flexibility, Service

Services: Case Report Forms, Consulting, Data Management, Data Validation, Document Management, Electronic Data Capture, Medical Writing, Programming (Database/SAS/etc), Project Management, Statistical Services/Meta Analysis

Symbiance, Inc.

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Fax: +1.609.243.9007
Internet: www.symbiance.com
email: mdoctor@symbiance.com
Contact Person: Michael Doctor, Senior Director, Business Development

Symbiance is a dynamic and growing contract research organization. Symbiance's operations are built on a history of providing clients with exceptional services in clinical data management and biostatistics, as well as medical writing. Symbiance has been very successful in the statistical analysis of data and the writing of eCTDs, including ISEs and ISSs. Symbiance is also experienced in converting raw data into CDISC-compliant datasets (SDTM and ADaM). Additionally, we excel in integrating and hosting global clinical data for use in data mining and regulatory submissions. Our forte is cost-effective, efficient, and reliable services.

Symbiance is dedicated to meeting the challenges of the future. We continue to strengthen our analytical capabilities through the acquisition of advanced database and data transmission technology, while utilizing the latest statistical methodologies. To assure quality and continuity for our clients, we are committed to hiring and retaining personnel with extensive experience.

Symbiance services include:

Biostatistics

- Protocol Review
- Sample Size Estimation
- SAP (Statistical Analysis Plan) creation/review
- SAS Programming for tables, listings and figures (TLFs)
- Biostatistical Analysis – interim and final
- Provide Statistical Reports

Data Mining

- Integrating multiple global clinical trials into a Global Data Repository (GDR)
- Hosting, maintaining and updating the GDR
- Mining the GDR data to support marketing strategies and/or regulatory registration

Data Management

- CRF design/development/review
- Double data entry and verification
- Electronic Data Capture (EDC)
- Data queries and resolutions
- Medical coding using the latest versions of MedDRA® and WHO.

CDISC Implementation

- Mapping raw data to SDTM
- Creating ADaM datasets

Medical Writing

- Integrated Clinical Study Reports (CSR)
- ISS and ISE
- Electronic Common Technical Documents (eCTD) for sNDA and NDA

Recent Therapeutic Areas

Anti-infective
Cardiovascular
Central Nervous System (CNS)
Gastrointestinal (GI)
Oncology
Rheumatology
Urology

Services: Clinical Study Reports, Data Management, Electronic Data Capture, Electronic Submissions Preparation, Medical Writing, Programming (Database/SAS/etc), Protocol Development, Quality Assurance/Control, Regulatory Document Preparation, Statistical Services/Meta Analysis

Synteract, Inc.

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Contact Person: Ali Sadighian

Established in 1995, **Synteract** is a global full-service Contract Research Organization, dedicated to meeting the clinical development needs of the biotechnology, medical device, and pharmaceutical companies. We have earned a reputation for responsiveness and reliability – ask for references, our clients will attest to this! We have accomplished this by focusing on the unique needs of each client and tailoring our services to meet those needs, while maintaining the highest standards and meeting all requirements for superior quality. We work as part of your team, always striving to help you meet your goals. Synteract has provided clinical trial services on 1000+ studies to over 200 companies, including **all phases** and across **a wide range of therapeutic areas including**:

Oncology	Ophthalmology	Gastroenterology	Nephrology
Central Nervous System	Immunology	Genitourinary	Orthopedic
Cardiovascular	Anti-Infective	Hematology	Dermatology
Respiratory	Endocrinology	Hepatic	

SYNTERACT PROVIDES EXCEPTIONAL SERVICES TO MEET YOUR SPECIFIC NEEDS

Clinical Study Management

- Program/Study Planning & Management
- Study Start-Up
- Regulatory Document Management
- Site Monitoring and Management

Biostatistics

- Study Design
- Statistical Analysis Plans
- Table/Listing/Figure Programming
- Data Analysis
- DMC Establishment/Coordination
- CDISC

Remote Internet Access

- Data Browse and Query (Integrated Review™)
- Study Status Reports, CRF/Query Viewing
- Serious Adverse Events

Central Randomization

- IVRS and IWRS
- Randomization (Schedule or Dynamic)

Data Management

- SYNCapture™ (EDC)
- Clinical DataFax™ (Fax or DDE)
- Clintrial™ (DDE)
- Third-Party EDC Products

Medical/Safety/Regulatory

- Strategic Planning
- Regulatory Project Management and Submisssions
- Medical Monitoring
- Oracle® AERS (Database Hosting or Safety Services)
- Pharmacovigilance
- E2B Gateway

Medical Coding

- MedDRA®, WHO-DRUG Coding
- SynCoder™ AutoCoder/OnLine Coder

- Drug Inventory Control
- Patient Diaries

For the past five years, Synteract has consistently been named by the San Diego Business Journal as one of the top 100 fastest growing companies in San Diego County. Synteract, with a current staff of ~300, is headquartered in Carlsbad, California (San Diego) with a branch office in Research Triangle Park, North Carolina, a Phase I Unit in Lenexa, Kansas and an office in Prague, Czech Republic.

Synteract, Inc., Concourse Building, One Copley Parkway, Suite 410, Morrisville, NC 27560, Telephone: +1.919.462.4809
Synteract s.r.o, Na Strzi 65/1702, 140 00 Praha 4, Czech Republic, Telephone: +420 22 191 546
Vince & Associates Clinical Research, 6600 College Boulevard, Suite 300, Overland Park, KS, Telephone: +1.913.696.1601

SYNTERACT – SHARED WORK – SHARED VISION

Services: Case Report Forms, Clinical Trial Design, Clinical Trial Monitoring, Data Management, Medical Writing, Pharmacovigilance, Programming (Database/SAS/etc), Project Management, Randomization (Automated/Centralized/Vocal Computer), Regulatory Affairs/Regulatory Strategy

Syreon Corporation

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Contact Person: Brendan Keown

Syreon: A Leading Canadian Contract Research Organization

Syreon provides clinical trial support services to pharmaceutical companies throughout the world, providing high quality information for crucial decisions in drug development and clinical use.

We offer a full range of CRO services, including data management, biostatistics, medical writing and project management, including our cutting-edge electronic data capture (EDC) technology to enable real-time data entry and reporting and streamlined coordination of local and global clinical trials.

Services

Syreon provides a broad range of services ranging from study design and operation through to analysis, reporting and publication of results for phase I to IV and observational clinical trials.

Project Management:

- Skilled and detailed supervision of timelines and deliverables and close coordination of all stakeholders
- Study conduct in compliance with detailed protocols, GCP and applicable regulations
- Routine and detailed communications
- Meticulous study and site management

Data Management:

- Collection, tracking, processing, querying, validation and export of both paper-based and electronic data
- Case report forms customized to study protocols
- Database programming in ClinTrial™
- Central lab data seamlessly imported into the clinical database with options for direct entry via EDC
- Data coding using the WHO drug dictionary and MedDRA® performed by trained coding specialists
- Database lock and export in SAS, or in a pre-specified format, to meet the needs of each Sponsor

Biostatistics:

- Study design, development/execution of analysis plans
- SAS programming of tables, listings and figures
- Ongoing analysis for data safety monitoring boards and scientific advisory committees
- Independent biostatistical consulting including analyses of pre-existing datasets and meta-analyses

Medical Writing:

- Clinical trial protocols and clinical study reports
- Medical publications including abstracts, manuscripts and posters/presentations for scientific symposia

Global Presence for International Research

To date we have successfully trained and supported over **1000 Investigative sites** across a wide range of study phases and therapeutic areas in **35 countries** in all corners of the world.

Our expertise, EDC technology and global capability combined with our focus on customer service make Syreon a leader amongst CROs.

For more information, visit our website at http://www.syreon.com/

Services: Clinical Trial Design, Clinical Trial Monitoring, Data Management, Electronic Data Capture, Medical Writing, Project Management, Protocol Development, Registries, Statistical Services/Meta Analysis, Trial Management

Target Health Inc.

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Fax: +1.212.681.2105
Internet: www.targethealth.com
email: jmitchel@targethealth.com
Contact Person: Jules T. Mitchel

Target Health Inc. is a full service e*CRO with full-time staff dedicated to all aspects of drug, biologics and device development. Areas of expertise include ***Regulatory Affairs, Clinical Research, Project Management, Biostatistics, Data Management, and Medical Writing. Software products include Electronic Data Capture (EDC)***, utilizing ***Target e*CRF®,*** our proprietary Internet-based Clinical Trial System, ***Coding of Medical Terms*** for MedDRA® and WHO DRUG using ***Target Encoder®***, ***Target CTMS™*** for ***Project Management*** and ***Target Document®*** for ***Document Management***. Target Health's Pharmaceutical Advisory Dream Team (PADT) assists companies in strategic planning from Discovery to Market Launch.

ACCOMPLISHMENTS

Target Health Inc. represents over 30 domestic and international clients at FDA, submits approximately 3 original INDs per year, 3-4 510(k)s and is currently involved with 15 active INDs and 2 active IDEs. Target e*CRF has been used in 4 approved NDAs, 1 approved BLA, 2 approved MAAs and 10 approved PMAs. Three of the approvals occured in 2009. Since 1999, Target e*CRF has been used in over 200 studies with 17 unique drug, biologic and device approvals world-wide.

LIST OF INDICATIONS

3rd degree burns, autoinflammatory diseases, cardiology, cardiac diagnostic, cardiac surgery, cystic fibrosis, end-stage renal disease, Gaucher's disease, gout, hepatitis diagnostic, HIV diagnostic, hereditary angioedema, human head lice, infertility, jaundice prevention, juvenile rheumatoid arthritis, macular degeneration, menopausal symptoms, osteoarthritis, nocturia, osteoarthritis, pancreatic cancer, periodontal disease, pre-eclampsia diagnostic, public health, prostate cancer, renal cell carcinoma, rheumatoid arthritis, scleroderma, ulcerative colitis, wound healing

SERVICES

A. Regulatory Affairs: Meet with the FDA to discuss and negotiate development strategies; prepare and submit: Pre-IND/IDE briefing documents; IND (paper and eIND) and IND amendments; IDE; 510(k); NDA (paper and eCTD); PMA (paper and eCopy); Orphan Drug Designation requests.

B. Clinical Research: Prepare protocols, case report forms and informed consent forms; perform clinical trial qualification, initiation, monitoring and closeout visits; prepare clinical sites for FDA inspection; perform Quality Assurance audits.

C. Biostatistics: Calculate sample size; generate randomization codes; statistical analyses using Statistical Analysis System (SAS®); meta analysis.

D. Data Management: EDC data collection, retrieval and management through our proprietary Web-based data capture system, Target e*CRF®, http://www.demoecrf.com/; prepare electronic files with documentation; data archiving.

Target e*CRF® is the company's innovative eClinical trial EDC software solution package. Target e*CRF® has been used in over 200 clinical trials since 1999 with 17 approvals world wide. In 2009, Target e*CRF was used for the pivotal trials for 3 approved products. Target Health Inc. clients include Fortune 100 companies as well as many smaller companies.

E. Medical Writing: Write integrated ICH clinical study reports; manuscripts.

F. Strategic Planning: Work closely with the sponsor, medical, scientific, toxicology, manufacturing and business experts to clearly delineate development requirements with a philosophy of efficiency and expediency; evaluate available and competitive technologies.

G. Toxicology: Development plans; protocol development; site identification monitoring; final reports; regulatory submissions.

H. Manufacturing: Product and process development; analytical methods development and analyses; GMP audits; pre-approval inspections.

Services: Clinical Study Reports, Clinical Trial Design, Clinical Trial Monitoring, Consulting, Data Management, Electronic Data Capture, Electronic Submissions Preparation, Medical Writing, Programming (Database/SAS/etc), Strategic Planning and Implementation

HOUSE AD

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THOMSON REUTERS

THOMSON REUTERS

Intelligent information to accelerate research, scientific discovery, and innovation

Thomson Reuters is the leading source of intelligent information for professionals around the world. We supply the intelligent information our customers need to succeed in fields that are vital to developed and emerging economies such as law, financial services, tax and accounting, healthcare, science and media.

Our life sciences knowledge and information are essential for drug companies to discover new drugs and get them to market faster, for researchers to find relevant papers and know what's newly published in their subject, and for businesses to optimize their intellectual property and find competitive intelligence.

Our solutions include:

BIOMARKERcenter

The first database to provide standardized terminology and reliable classification for biomarkers at all stages of drug development, supporting translational research.

IDRAC ®

The world's largest collection of regulatory texts, regulatory summaries, and exclusive regulatory intelligence reports.

Thomson Pharma®

Competitor intelligence database integrating pharmaceutical data sources, unique abstracts, commentaries and analysis.

Newport Premium™

Advanced product targeting, business development and API sourcing database for generic pharmaceutical companies, OTC drug and API manufacturers.

Prous Science Integrity®

Scientifically-focused drug R&D database integrating biological, chemical and pharmacological data on more than 300,000 compounds.

To find out more, go to:

science.thomsonreuters.com

Services: Consulting, Data Management, Document Management, Electronic Submissions Preparation, Medical Writing, Publications (Books/Journals), Regulatory Affairs/Regulatory Strategy, Regulatory Document Preparation, Software Development & Evaluation, Standard Operating Procedures

Thomson Reuters

4-Color AD

TKL Research, Inc.

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Internet: www.tklresearch.com
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Contact Person: Darcee Strube

TKL Research, Inc. - Large enough to deliver and small enough to care

Founded in 1944, TKL Research, Inc. (TKL) is the oldest full-service, independent **C**linical **R**esearch **O**rganization in the United States. TKL assists Pharmaceutical, Biotech, Generic, OTC and Device companies in the delivery of safe and effective drugs to the marketplace. TKL is divisionally operated with a full-service CRO, five fully dedicated research clinics (including a Phase 1 Unit which augments our extensive site database) and a Patient Recruitment Division; all integrated to provide seamless program management from Phase 1 through Phase 4. TKL has recently expanded our geographical reach to include a European office located in Munster, Germany to provide coverage in both Eastern and Western Europe. Our continued success is grounded in our reputation for commitment to quality of clinical service offerings project timelines, and tight budget control. We offer multi-disciplinary and experienced project teams, located in both our US and EU offices.

Phase 1 Services:

Our Phase 1 Pharmacology Unit is designed to ensure maximum efficiency in a unique setting to provide customized trials to meet demanding protocols. We offer a full compliment of Phase 1 protocols to meet the needs of a dermatology community as well as Bioequivalence, First-in-Human, Proof-of-Concept and PK/PD trials.

Phase 2-4 Development Services:

TKL has international reach with clinical trials currently being conducted in North America, Latin America, Australia and Eastern & Western Europe. Our Clinical Research expertise includes Phase 2-4 studies offering comprehensive, full-service capabilities for multi-center trial management and execution.

Recruitment Management:

Predictive Enrollment Partners (PEP), the Recruitment Management division develops custom, centralized recruitment plans for multi-center trials, designs creative and effective advertising programs, refines strategies for each site and actively manages the patient from screening through enrollment process.

Therapeutic Areas:

At TKL Research Inc., experience and reputation for quality are coupled with close partnering with our Sponsors to provide customized clinical research programs. TKL is a therapeutically focused CRO with extensive staff experience, database of qualified investigators and extensive track records of executing programs in diverse therapeutic areas and patient populations including: Dermatology, Gastroenterology, Anti-Infective, Pain Management, Women's Health, Ophthalmology and Diabetes.

Services:

- Strategic and Clinical Plan Development
- Study Feasibilities and Investigator/Site Identification
- Project Management
- Study Design
- Recruitment Management
- Clinical Monitoring
- Data Management
- Biostatistics
- Medical Writing
- Regulatory Consultant Services
- Quality Assurance
- Electronic Regulatory Submissions (IND & NDA)

Services: Claims Support Studies/Safety and Efficacy Studies, Clinical Study Reports, Clinical Trial Monitoring, Data Management, Medical Writing, Patient Recruitment, Project Management, Rx to OTC Switch, Statistical Services/Meta Analysis, Trial Management

Trio Clinical Research, LLC

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Providing Innovative Clinical Research Solutions

Trio is an innovative clinical research services company supporting the pharmaceutical, biotechnology and medical device industries in their quest to bring novel products to market.

Building upon years of experience in the pharmaceutical CRO & staffing industries, Trio's founders created a unique business model to overcome the traditional challenges that are all too often experienced by biopharmaceutical companies when outsourcing their clinical trials. Our focus is on what we do best – clinical operations – while we seek complementary service partners that are the best at what they do. This model provides sponsors several advantages, including therapeutic alignment of the project team, engaged project team members, easily-scaled resourcing up and down, project team stability and the industry's strongest site relationships.

The Trio Difference

Trio's unique approach has enabled us to accomplish some notable achievements, including:

- Time-on-site reduction of 27%
- Project team retention rate > 92%
- Query rate < 6%
- Repeat business rate > 91%
- Sites approved and FPI in 7 weeks

Our Experience

Clinical Research Professional (CRP) Experience. Trio has more than 60 in-house full-time CRPs from which to staff our clients' projects along with an unparalleled network of 500+ independent contract CRPs with whom we work on a routine basis. Grown via a referral-basis only, our CRPs bring an average of 11+ years industry experience to our clients' project teams.

Therapeutic Experience. Trio has experience supporting phase I-IV clinical trials across a wide-range of therapeutic areas, including infectious disease, oncology, CNS, dermatology, respiratory, and cardiovascular to name a few.

Services

Trio addresses the limitations of the CRO and traditional staffing industries by offering our clients three customized solutions for solving their clinical trial needs.

Clinical Trial Management

Trio provides comprehensive services in support of our clients' clinical research needs.

- Project Management
- Clinical Monitoring
- Site Management
- Query Management
- Data Management
- Biostatistics
- Medical Monitoring
- Safety
- Medical Writing
- Regulatory Consulting
- Quality Assurance

Functional Outsourcing

Trio also provides experienced, dedicated CRPs to our clients based on a function rather than a specific project or task. Whether it's Clinical Monitoring, Drug Safety or Medical Writing, Trio can provide functional support to assist with your clinical program.

Resourcing

Sometimes our clients simply require the services of a single CRP. Whether it's a Clinical Monitor, Project Manager or Medical Writer, Trio can staff our clients' clinical trials with a wide range of experienced professionals.

Services: ADE Evaluation/Drug Safety Assessment, Clinical Study Reports, Clinical Trial Monitoring, Data Management, Medical Writing, Project Management, Protocol Development, Quality Assurance/Control, Regulatory Document Preparation, Statistical Services/Meta Analysis

United BioSource Corporation

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Contact Person: Dan Donovan

United BioSource Corporation (UBC) is the premier global provider of evidence-based pharmaceutical services that integrates scientific and operational expertise with innovative technology solutions to support global development of medical products for life sciences companies.

> "We created UBC to meet increasing industry demand for better data to determine how new products will perform in the real world—from both economic and clinical perspectives." *Mark Clein, President and Chief Financial Officer.*

UBC's unique strength is the generation, analysis and communication of real-world evidence throughout the product life cycle. We are passionate about bringing together the best scientific minds, the best technology and the most experienced project managers to give our clients unparalleled support. UBC has particular interest in two critical areas of need: R&D productivity and the post-approval market. We specialize in the post-approval market to support increased Phase IV studies and registries around safety, cost effectiveness and comparative effectiveness endpoints.

Given the reality of dramatically rising research and development costs, UBC offers specialty services that improve the efficiency, integrity and quality of clinical data. These services are characterized by high scientific content and technologic intensity. UBC works with sponsors directly, as well as in collaboration with global CROs.

UBC's Core Service Areas

Peri- and Post-Approval Studies & Registries: • Biostatistics & Programming • CME and CE • Large Streamlined Studies • Peri- and Post-Approval Programs • Phase IIIb - IV Solutions • Registries • Risk Management

Specialty Clinical Solutions: • Centralized Rating • Computerized Cognitive Testing • Inter-Rater Reliability Measuring • Patient Recruitment and Retention • Rater Training, Certification and Rater Monitoring • Scale Translation and Acquisition • Site Profiling and Credentialing • Site Selection and Retention • Training of Investigators, Physicians and Site Personnel • Web-Based Investigator Meetings

Value Generation Solutions: • Database Analysis • Epidemiology • Evidence Generation Planning • Health Care Data Capture • Health Economics • Health Outcomes Research • Meta-Analysis & Systematic Reviews • Pricing and Reimbursement

Scientific Consulting & Communications: • Adaptive Trial Solutions • Comprehensive Medical Publication Solutions • Evidence Generation Planning • Health Science Policy • Regulatory Strategies • Risk Evaluation and Mitigation Strategies

Safety & Risk Management: • Large Streamlined Safety Studies • Pharmacovigilance • Registries • Risk Assessment • REMS • RiskMAPs • Safety Processing

Clinical Technologies: • Adaptive Trial Solutions • Datavision™ & Visiontracker™ • EDC • eLearning • ePLAS and ETASU • eRegistries • eROs, ePROs & eDiaries • IVRS & IWRS • Technology Integration • Virtual Meetings

UBC's Experience: *Experienced in every major therapeutic category, UBC scientists have supported the development of hundreds of prescription and over-the-counter medicines, biotechnology products and medical devices—during all stages of the product life cycle.*

UBC At-a-Glance: 1,300 employees; 30% of employees hold advanced science degrees; > 90% client retention rates; < 10% employee turnover; 2,000+ peer-reviewed publications

Global Results: 365,000 patients; 82,000 study sites; 3,000 clinical protocols; 2,500 health outcomes studies; 20,000 investigators trained in 60 countries; 50 languages; Trials conducted on six continents

UBC Locations: UBC is headquartered in Bethesda, Maryland and has sixteen locations across the U.S. Our main European office is strategically located in London, United Kingdom, with offices, staff and/or resources in ten international locations.

Services: Data Management, Disease Management/Health Outcomes, Health Economics, Medical Writing, Patient Recruitment, Pharmacovigilance, Registries, Regulatory Affairs/Regulatory Strategy, Statistical Services/Meta Analysis, Strategic Planning and Implementation

The University of Iowa Pharmaceuticals

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The University of Iowa Pharmaceuticals (UIP) is a Food and Drug Administration-registered pharmaceutical manufacturing facility, which occupies 24,000 square feet at the University of Iowa College of Pharmacy and 7,000 square feet at the University of Iowa Research Park. UIP provides contract pharmaceutical services including pre-formulation studies, formulation development, clinical supply manufacturing, small scale commercial manufacturing, analytical method development and validation, routine quality control analysis, stability studies, and active pharmaceutical ingredient and excipient release testing. UIP is licensed by the DEA to handle controlled substances (Schedules I – V) and is capable of handling potent compounds.

UIP has been developing formulations, manufacturing products, and conducting analytical testing in compliance with Good Manufacturing Practices for over 30 years. Senior scientific staff average over 20 years of experience. In addition to our full time staff, UIP has access to the University of Iowa, College of Pharmacy Pharmaceutics Faculty for collaboration.

UIP is capable of producing most types of pharmaceutical dosage forms. These dosage forms include sterile injectable solutions, emulsions, and suspensions; sterile lyophilized (freeze-dried) powders; topical and oral solutions, emulsions, and suspensions; ophthalmic and otic preparations; tablets (uncoated and film or functional coated); and hard gelatin capsules (powder or hot melt filled).

The sterile processing area is capable of handling batch sizes ranging from a few hundred to 5,000 or more finished units. This area is supported with a hot loop Sterile Water for Injection, USP system, 48 square foot Hull lyophilizer, Pure Steam Generator, Flexicon Filling, Stoppering, and Crimp Sealing Machine and other modern sterile processing machinery. UIP has the capability to terminally sterilize products. Once products are filled and sealed into vials, the products and vials are 100% visually inspected and can be labeled according to client specifications.

The solid dosage form processing area is capable of handling batch sizes ranging from a few hundred to several hundred thousand dosage units. Processing capabilities include micronization, milling, sieving, high shear blending/granulation, roller compaction, low shear blending/granulation, fluid bed granulation/coating/drying, oven drying, hard capsule filling, tablet compression, powder filling, and tablet or capsule coating. The facility is equipped with supplied breathing air, allowing full, air-tight protective gowning; has negative room pressure differentials; and single-pass, high-efficiency filtered supply and exhaust air. Each potent material handling room is equipped with a two-stage shower and gowning room. The area is fully temperature and humidity controlled, with the capability to depress humidity levels when required for hygroscopic or moisture sensitive materials.

The solid dosage forms staff has extensive experience with the production of blinded comparator products which are produced using a variety of means, including placing products into empty capsule shells and overfilling with inert powders, milling commercially available products and filling the resultant powder into empty capsule shells, removing ink logos from commercially available tablets or capsules, film coating over existing brand marking, or production of look alike placebo dosage forms.

The University of Iowa Pharmaceuticals' (UIP) Analytical Method Development and Validation Group has extensive experience developing and validating methods for use in testing active pharmaceutical ingredients (API) and drug products. Methods are developed and validated to analyze in-process, finished product and stability samples, as well as swabs to verify the cleanliness of manufacturing equipment. All validations are performed according to FDA-ICH guidelines, client-approved protocols and standard operating procedures. Routine Quality Control testing is performed on in-process and finished product samples, as well as rinse or swab samples to verify cleanliness of manufacturing equipment for batches made by UIP and can also be performed on products made at other sites. Stability testing is performed according to FDA-ICH guidelines, client approved protocols and standard operating procedures. Available stability storage conditions include -80ºC, -20ºC, 2 to 8ºC, 25ºC/60% RH, 30ºC/65% RH, 40ºC/75% RH, Xenon-arc Light Cabinet, and customized conditions (such as freeze/thaw cycling).

The University of Iowa Pharmaceuticals (UIP) has a rigorous quality assurance program designed to ensure that FDA Good Manufacturing Practices (GMP) are met.

Services: Analytical Assay Development and/or Laboratory Service, Chemistry/Manufacturing/Controls, Clinical Supplies/Distribution/Packaging, Dissolution Testing, Formulation Development, GMP Compliance, Stability Studies/Testing, Standard Operating Procedures

the Uppsala Monitoring Centre

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The **Uppsala Monitoring Centre** provides focused products to the pharmaceutical industry, clinical research organizations, and governmental agencies. We serve all kinds of organizations that are involved in drug discovery, clinical research and drug safety – providing the tools and services to optimize development and life cycle management of drugs.

"Tools and resources to enhance clinical trials and drug safety operations"

Clinical Data Management:

WHO Drug Dictionary Enhanced
The world's most comprehensive dictionary of medicinal product information.

WHO Combined Dictionary
In the Combined Dictionary conventional drugs and herbal drugs are seamlessly integrated – you can code, analyze and report using the same tools as you do with the WHO Drug Dictionary Enhanced.

WHO Drug Dictionary Browser
Enables immediate access and understanding to all features of the dictionaries with no additional software.

WHO Drug Dictionary Web Training
Available for users wanting to increase efficiency and productivity in using the WHO Drug Dictionaries.

Classroom Training in North America
The UMC has initiated collaboration with PSI International, Inc. as the preferred partner to provide training sessions for the WHO Drug Dictionaries. For more information please see www.umc-products.com/training.

Pharmacovigilance:

Vigibase - the WHO ADR database
A unique collection of international drug safety data - useful information about the safety profile of your products and your competitors'

Publications
Publications concerning e.g. crisis management and effective communication in pharmacovigilance

Services: Adverse Event Management/Software, Data Management, Pharmacovigilance, Training

Uppsala

B & W Ad

Validation Associates, Inc.

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Contact Person: Nancy Gallo Tucker

Validation Associates, Inc.
Computer System Validation Specialists

For over 10 years, Validation Associates, Inc. has specialized in providing a practical approach to Computer System Validation project consulting and training services.

PROJECT CONSULTING

- Providing Validation Project Management
- Providing Document Templates
- Preparing Validation Plans and Reports
- Preparing Test Protocols and Reports
- Developing Test Scripts and Test Data
- Performing Risk Assessments
- Evaluating Systems to 21 CFR Part 11
- Performing Vendor Audits
- Developing/Evaluating SOPs
- Reviewing Validation Documentation

SEMINARS

Customized On-Site Training Sessions

Any of the topics described in the seminars listed below can be included in a customized course.

Computer System Validation in FDA-regulated Industries – 2 Days

This seminar combines computer system validation theory with a "how to" approach. Attendees complete varied validation tasks using document templates and activities based upon a software application.

Risk Management Applied to Computer System Validation – 1 Day

This seminar reviews FDA expectations and a risk management process based on GAMP, NIST, and ISO. The focus is on Risk Assessment and Risk Mitigation activities for computer system validation efforts.

Achieving and Maintaining 21 CFR Part 11 Compliance – 1 Day

This seminar reviews the requirements, FDA guidance, and industry positions on the Electronic Records & Electronic Signatures rule, and discusses mechanisms to ensure that a system remains compliant throughout its lifetime. Attendee activities include a gap analysis and preparation of a remediation plan.

Auditing Computer System Providers – 1 Day

This seminar reviews the process and practical techniques for conducting audits. Attendees perform inspection activities of a software vendor's documentation using an audit checklist and an audit report template.

Certified Software Quality Engineer (CSQE) Refresher – 2 Days

This seminar reviews the American Society for Quality (ASQ) CSQE Body of Knowledge. It reviews software quality concepts and is a refresher class for individuals planning to take the ASQ CSQE exam.

Call or visit our web site for current session dates and locations.
All of our seminars can be delivered on-site at your location.

Validation Associates, Inc. is certified as a Women's Business Enterprise by the
Women's Business Enterprise National Council (WBENC) and the Women's Business Enterprise Council of PA-DE-sNJ.

Services: Computer System Validation, Consulting, Contract Auditing, Project Management, Quality Assurance/Control, Software Development & Evaluation, Standard Operating Procedures, Temporary Services and/or Permanent Placements, Training

Vitalograph

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Vitalograph® has manufactured respiratory diagnostic equipment for the healthcare industry since 1963 and the name Vitalograph is synonymous with spirometry in many countries around the world. The name Vitalograph is also synonymous with quality, as many of our spirometers in everyday use are more than 30 years old! As a consequence, our equipment is favored by opinion leaders and clinical researchers who need reliable and accurate measurements.

For respiratory clinical trials requiring electronic data capture, we provide two key products with centralized data services that are successfully used by major pharmaceutical companies and biotechs in global studies:

1) Spirotrac® Centralized Spirometry System for clinic based serial spirometry

2) Electronic PEF/FEV1 Diary for patients to use at home.

Vitalograph® provides global support throughout a respiratory clinical trial, from training to data lock, via a network of subsidiaries and distributors.

Vitalograph® operates an ISO9001 R&D and manufacturing facility and all products comply with international performance requirements and are registered to FDA510K and CE.

Vitalograph also provides centralized data services for all therapeutic areas where respiratory side effects need to be monitored.

Vitalograph's QA review over-reading service is provided via independent experts.

Vitalograph provides its VIEWER web portal for study personnel to access data and reports to aid effective monitoring of a clinical trial.

In addition to simple spirometry, Vitalograph also provides systems for monitoring FeNO, FRC and DLco.

Services: Cardiovascular Monitoring/Pulmonary Diagnostics, Data Management, Electronic Data Capture, Electronic Diary/Dictionary/Translator, Programming (Database/SAS/etc), Project Management, Remote Data Entry, Software Development & Evaluation, Spirometry/Challenge Testing, Telephone Support

Wainwright Associates Limited

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email: enquiries@wainwrightassociates.co.uk
Contact Person: Dr. Chris Wainwright

Our team of highly skilled consultants can assist in product development, regulatory affairs, pharmacovigilance and licensing relating to medicinal products, medical devices and other healthcare products. Services are customised to clients' individual needs and cover all the specific activities listed below. We also provide training on all the listed topics.

Product Development Planning
Advice on applicable legislation
Recommendation of best route to market
Borderline issues addressed
Strategic regulatory planning of R&D programmes
Study design and protocol development
Scientific consultancy

Regulatory Submissions
Presubmission meetings and liaison with authorities
Clinical trial authorisations and ethics submissions
Electronic (eCTD) submissions
Marketing authorisations via centralised, decentralised, mutual recognition and national procedures
Licence maintenance: variations, change of ownership, change of legal status
Orphan designation
Paediatric investigation plans
Scientific advice procedures

Appeals & Hearings
Re-examinations, Arbitration & Referrals
Guidance throughout the procedure
Preparation of written responses
Preparations for presentations
Rehearsals and mock appeals
Leadership in oral explanations

Medical Device Services
Classification and best route to market
Preparation of technical files, quality manuals and risk assessments
CE Marking

Audits
GCP, GMP, GLP, GDP
ISO 9001 & ISO 13485
Pharmacovigilance/device vigilance

Pharmacovigilance
Clinical study & post-marketing case processing
EU QPPV
PSURs, annual safety reports, SOPs
Strategic advice & inspection preparations

Technical Support in Litigation Cases
Advice to the legal profession on pharmaceutical, preclinical, clinical and regulatory issues
Location of suitable documents to form competent evidence
Expert witness

Product Literature
Writing SPC, PIL & label texts and design of artwork
User testing
Advertising compliance

Global Regulatory Intelligence
Determination of regulatory requirements worldwide
Local support for national regulatory submissions
Local advisors in over 60 countries

Licensing
Searches for new products
Licensing negotiations
Evaluation of opportunities
Location of licensing partners
Technical/regulatory due diligence

Services: ADE Evaluation/Drug Safety Assessment, Electronic Submissions Preparation, Expert Reports, Medical Devices/Combination Products, Patient Information Leaflets (PIL)/Labeling, Pharmacovigilance, Protocol Development, Regulatory Affairs/Regulatory Strategy, Regulatory Document Preparation, Rx to OTC Switch

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Medical Information Contact Center Services 24/7

WRB Communications Inc., a dynamic and innovative company, specializes in the development and management of health information programs. Our programs are provided through the integration of a "live" medical professional staff, state-of-the-art technological solutions and most importantly, through well communicated and tested standards of excellence.

Our approach to business is focused on partnerships, quality and flexibility. We become a client's partner and serve a dual role — consultant and service provider. We offer flexibility in terms of program design, operations and technical solutions. We apply our quality performance standards to every program to meet and exceed our client's expectations.

Our Focus
WRB provides services to major pharmaceutical, biotech and device manufacturers, as well as start-up companies. We support multiple departments within an organization including: Medical Communications, Drug Safety, Quality Assurance, Sales and Marketing and Customer Service.

Core Services:

- ✓ **Medical Communications — Product and Disease Information**
- ✓ **Adverse Event Reporting**
- ✓ **Product Complaint Reporting**
- ✓ **Customer Service**
- ✓ **Risk Management Programs**

WRB provides customized programs to meet each client's specific requirements. Our programs are designed to function as an integrated service. We offer inbound and outbound programs that encompass a variety of services and are applicable during all phases of the product marketing cycle. The programs serve patients, consumers and healthcare professionals. Programs are designed to provide product information, enhance customer service, increase patient compliance, promote product awareness, drive product sales and build brand loyalty.

Services: ADE Evaluation/Drug Safety Assessment, Adverse Event Management/Software, Medical Communications, Medical Information, Medical Writing, Patient Compliance, Patient Education, Pharmacovigilance, Registries, Telephone Support

XERIMIS Inc.

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Customized Clinical Packaging

XERIMIS INC. is a privately held cGMP firm providing customized clinical packaging services on a global basis. XERIMIS addresses the clinical packaging needs of pharmaceutical, biotechnology and clinical research organizations of all sizes, for each phase of development. XERIMIS' services enable pharmaceutical sponsor firms to complete the clinical testing of new drug compounds in a blinded, unbiased manner, in support of new drug applications to the FDA and foreign regulatory bodies.

XERIMIS INC. was founded by Peter Bernardo, Ph.D. (President & CEO) and Loretta Bernardo. Prior to establishing XERIMIS, the Bernardo's originated two successful firms which achieved worldwide recognition within the pharmaceutical industry – SIMIREX INC. (U.S.A.) and SIMIREX EUROPE (U.K.) SIMIREX INC. was established in 1988 and SIMIREX EUROPE in 1996 – both firms provided full-service clinical packaging services, and both were then sold to a large CRO in 1998. That base experience and exemplary reputation subsequently led the Bernardo's to the establishment of XERIMIS, founded in 2001.

YOUR PROJECT – YOUR TIMELINE

SERVICES:

- Phase I through Phase IV Project Management.
- DEA Licensed & Approved for Schedule III through V products.
- Protocol Analysis, Package & Label Design, Supply & Distribution Strategies and Timeline Management.
- Primary & Secondary Packaging: Frozen, refrigerated and room temperature drug products.
- Thermoform & Coldform Blister Packaging.
- Automated & Manual Bottle Filling.
- Multi-Lingual Label Generation & Labeling: Open, Single Panel, Two-Part and Double-Blind Labels.
- Warehousing & Distribution (For trials packaged by Xerimis, the sponsor or third parties): Monitoring at Controlled Room Temperature, Refrigerated & Frozen Conditions - Global Distribution at Controlled Temperatures.
- Import/Export Coordination.
- Global services available via strategic-alliance with UK-based pharmaceutical firm, as well as the utilization of additional strategically located depots – to facilitate the distribution of supplies for any-sized global trial.
- Sourcing of commercial items, including comparator products, medical devices and ancillary materials.
- Receipt, Accountability & Destruction of Returned Supplies.

OUR GOAL

Our mission is to build relationships with clients and provide customized quality services of the highest order, with the swiftest response and absolute dependability. We know what a missed deadline in the pharmaceutical industry can mean – a failed or weakened opportunity, possibly a financial disaster – but most importantly, a patient without a possible cure. Successful clinical programs are produced through partnerships in responsibility and planning. XERIMIS offers the highest standard of service and professionalism, drawing on more than seventy-five years of collective experience in the clinical packaging field.

EXPERIENCE COUNTS

XERIMIS, located in Moorestown, New Jersey, is situated in the midst of the country's pharmaceutical hub. Moorestown enjoys a close proximity to both Philadelphia (only 15 minutes away), and New York City (just 90 minutes to the North).

Services: Clinical Supplies/Distribution/Packaging, Consulting