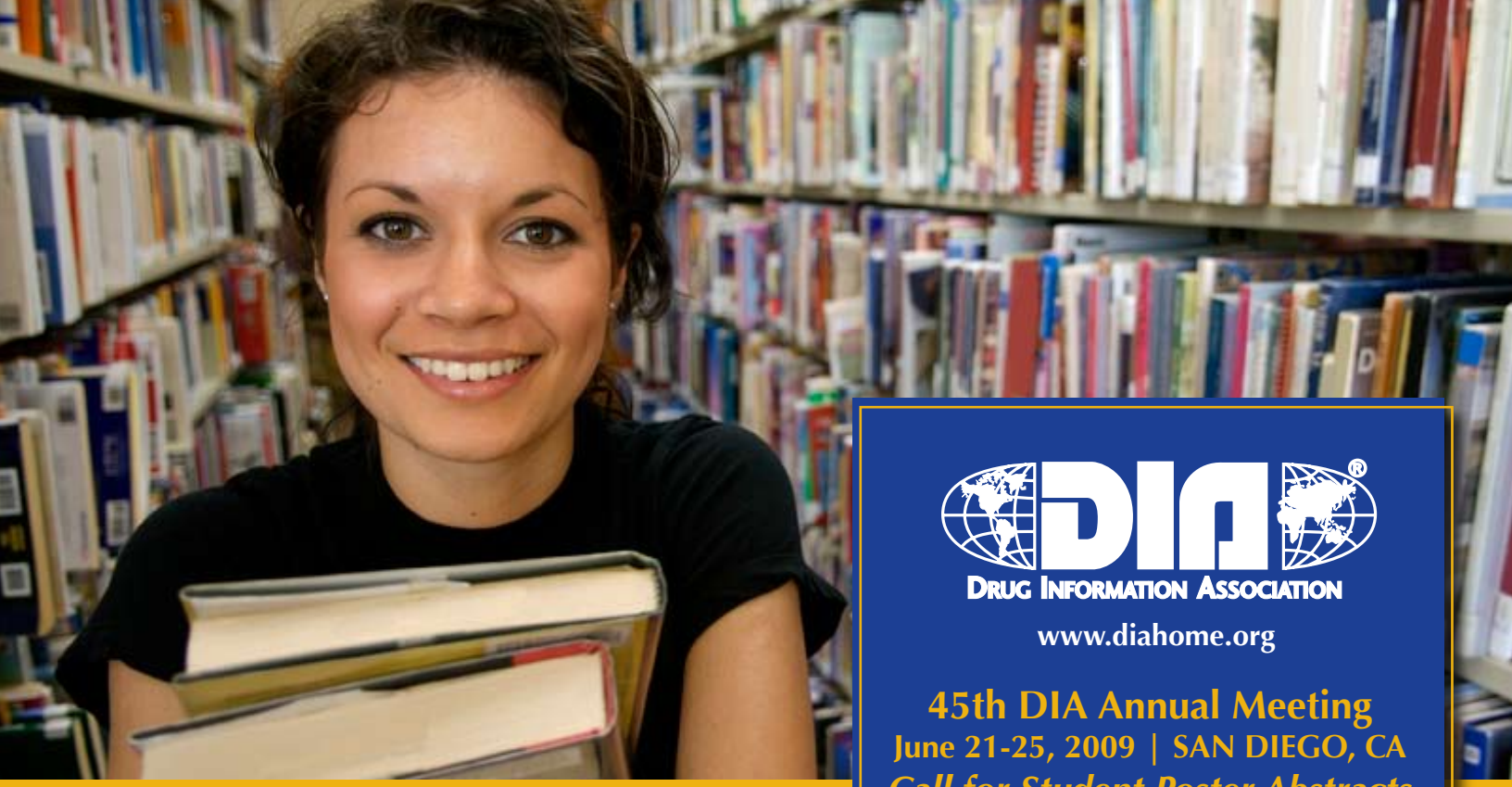

GENERAL SUBMISSION REQUIREMENTS

(Please read the following instructions carefully; incorrect or incomplete abstracts will not be considered.)

1. Students must demonstrate they are eligible to submit. Contact the Drug Information Association via email at **Susan.Spivak@diahome.org**, Subject: Request a call for student abstract verification form. Students must request this document, complete and return it to DIA prior to the **March 30, 2009** COB deadline. Medical residents, fellows, and postdoctoral candidates are considered students. Research must originate from an academic institution. Abstracts submitted without verification forms will be returned to the author.
2. Past DIA Annual Meeting or EuroMeeting student poster presenters are ineligible.
3. Abstracts must be received through the DIA website by **March 30, 2009**.
4. A student may submit only one abstract.
5. Abstracts may not refer to specific brand names.
6. Submitted abstracts must include the following sections:
   - Abstract Title (250 characters)
   - Abstract Objective (300 characters)
   - Abstract Method (300 characters)
   - Abstract Results (300 characters)
   - Abstract Conclusion (300 characters)
7. Abstracts will be reviewed, and authors will be notified of results by **April 27, 2009**.
8. If an abstract is accepted, one author or coauthor must attend the DIA Annual Meeting to present the abstract during the Student Poster Session on **Monday, June 22, 2009**, and have it printed in the conference program and in the Drug Information Journal.
9. DIA grants permission to publish your abstract after it appears in the Drug Information Journal (DIJ), provided the publication includes a credit line indicating that your abstract was first published in the DIJ and specifying the volume and issue numbers (volume 43, issue 4).
10. The attending author or coauthor is expected to attend the DIA Student Forum, which is scheduled for **Sunday, June 21, 2009** from 3:00-5:00 PM.

DRUG INFORMATION ASSOCIATION

www.diahome.org

45th DIA Annual Meeting

June 21-25, 2009 | SAN DIEGO, CA

Call for Student Poster Abstracts

Deadline: March 30, 2009

The Drug Information Association invites eligible students to submit a poster abstract demonstrating research results to a diverse audience of pharmaceutical drug development professionals. The Student Poster Session will be held on **Monday, June 22, 2009** at the San Diego Convention Center.

The theme of the 45th DIA Annual Meeting is "Better Medicines: Improving Safety with Every Step."

Selected student poster presenters will receive (1) complimentary meeting registration for (1) listed author, a maximum of 3 nights hotel room and tax only, coach air travel expenses, and a per diem allowance of $50.00 per day for a maximum of 3 days.

A maximum of 20 selected abstracts will be published in the July edition of the Drug Information Journal and distributed to over 20,000 members of the Drug Information Association. In addition, accepted abstracts will be included in the Student Poster Session which offers a total of $4500 in prize money awarded to student winners based on the following criteria:

- Bona fide research project
- Specific objectives and hypothesis
- Analysis of actual data and results
- Clear methods
- Conclusions

Presenters must prepare a poster to fit a 4′× 8′ poster board (four feet high and eight feet wide).

Each author will be scheduled for a 2 to 3 minute presentation of their work, including questions and answers from the judges.

All abstracts must be submitted online. The deadline for submitting online poster abstracts is March 30, 2009. To submit an abstract for the Student Poster Session at DIA's 45th Annual Meeting, please visit www.diahome.org/DIAHOME/GetInvolved/AbstractSelectAMeeting.aspx
Questions? Contact Susan.Spivak@diahome.org; Tel: 215.442.6139

The theme of the 45th DIA Annual Meeting is "Better Medicines: Improving Safety with Every Step." Abstracts should address one of the following interest areas represented by the Program Tracks offered in the Annual Meeting Program.

AHC/IS–ACADEMIC HEALTH CENTERS/INVESTIGATOR SITES

AHC topics/issues in drug development and safety should focus on issues of special significance and complexity for academic health centers. Topics include:

- Contracts and budgets
- Investigator-initiated protocols and grants
- IRBs and human subject protections
- Data collection and management
- Health information technology
- HIPAA
- Risk assessment
- Risk management
- Education and training
- Clinical research monitoring
- Regulatory requirements
- Publication
- Compliance to ensure quality data and integrity of the clinical trials process

Investigator sites abstracts should address topics and issues related to the operations, conduct, and management of clinical trials at investigative sites, such as:

- Subject recruitment,retention,and management
- Practice organization
- Attracting the right studies for your site
- Grant negotiation and management
- IRB and HIPAA requirements
- Using metrics to manage studies/personnel

AD–ADVERTISING

The topics relate to the advertising and promotion of pharmaceuticals and how marketing/advertising materials and programs are regulated by the FDA, including:

- FDA enforcement activities
- Policies involving CME, off-label uses, DTC advertising, and promotional programs
- Justice Department, US Attorney's Offices, and OIG activities to pursue fraud and abuse cases
- Initiatives dealing with the marketing and promotion of pharmaceuticals. Internal company policies relating to compliance with all applicable regulations

BT–BIOTECHNOLOGY

The biotechnology track will present topics related to discovery and early development of novel products, such as:

- Oligonucleotide therapeutics
- Somatic cell and stem cell therapies
- Tissue-engineered products
- Gene therapies
- Vaccines
- Manufacturing and quality control
- Novel assays and delivery technologies
- Bioethical considerations
- Successful strategies for enabling first-in-human trials
- Identifying key elements of due diligence exercises for novel products
- Immunogenicity: current state of regulatory guidance, preclinical and clinical assays, and technologies to reduce immunogenicity
- Roles of academic research labs and "incubators" in supporting early biotech companies
- Science- and risk-based CMC and GMP initiatives
- Quality-by-design approaches to pharmaceutical development
- Updates on ICH quality guidances
- FDA's recent CMC and GMP guidances
- Scientific challenges in technology transfer from laboratory to pilot to production scales
- Regulatory challenges in global CMC submissions
- Modern regulatory analytical methods and manufacturing controls

CDM–CLINICAL DATA MANAGEMENT

Abstracts should focus on the most current and forward-thinking topics as they relate to the clinical data management function and its current and future role in the industry. We encourage the submission of abstracts that are thought provoking and even controversial, if necessary. Topics include:

- Challenges in mergers and acquisitions
- Global cooperation
- Working with development partners
- Managing data from external suppliers
- Ensuring high data quality and delivering reliable and meaningful data
- Rigor of data cleaning for various types of studies
- Interactions with other functions
- Broadening the responsibilities of data management. Novel approaches, demonstrating more efficient processes in data management other ideas as they apply to the spectrum of data management activities

CR/CS–CLINICAL RESEARCH AND DEVELOPMENT/CLINICAL SUPPLIES

Abstracts should address topics related to clinical trial operations, conduct, management, and implementation, including clinical/regulatory strategy for specific indications.

CR abstracts should address

- Tactics/processes/tools
- Site identification and management
- Audit readiness (site and sponsor)
- Patient enrollment and retention
- Clinical staff and site training and the use of metrics to assess study progress and efficient execution of clinical trials

CS abstracts should address

- Leading-edge technologies to improve the efficiency and logistics of the clinical supply chain
- Information technology to streamline communication between CR and CS
- Procedures to minimize the traditional overage of CS needed to conduct clinical trials

CP–CLINICAL SAFETY AND PHARMACOVIGILANCE

The underlying CP theme will be the exploration of topics that positively impact the prescriber-patient interaction, including how to effectively manage benefits and risks of medical products and devices as part of an integrated PV system. Topics include:

- Individual and aggregate case management
- Communication of patient safety data at all phases of development
- New regulatory requirements
- MedDRA®,SNOMED and other coding terminologies

Electronic case reporting

- Software
- Management and use of safety databases

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- Data mining
- Signal detection
- Compliance and auditing
- Product safety information (labeling)
- Clinical science applied to adverse experiences, eg, pharmacogenetics
- Pharmacoepidemiology
- Risk management

EBM/IMP–EVIDENCE-BASED MEDICINE/IMPACT (IMPACT OF MEDICAL PRODUCTS AND THERAPIES)

This track area focuses on current issues related to the generation, analysis, and utilization of evidence to assess the impact of medical products on health outcomes, patient-reported outcomes, and health expenditures as they relate to clinical practice and drug coverage issues. The use of actual case examples is strongly encouraged. Topics include:

- Obtaining, measuring, and evaluating evidence
- Pharmacoeconomics and cost-effectiveness
- Health services research
- Pharmacoepidemiology (non-safety related)
- Federal legislative proposals to start a health technology institute

EC–ECLINICAL

Abstracts should focus on the topics below.New proposals and reports of methodologies are encouraged, as the realm of clinical trials begins to embrace the sharing of data along the continuum of discovery through patient care. Topics include:

- Development of technology, standards, policies, and procedures for the reporting, capture, analysis, submission, and archiving of information created within the process of clinical development

ERS/DM–ELECTRONIC REGULATORY SUBMISSIONS/ DOCUMENT MANAGEMENT

Abstracts should address topics of interest to document and records management (DM), and electronic regulatory submission development (ERS) professionals.
ERS topics include:

- Electronic submission formats (eCTD, eINDs, eBLAs, NEES)
- Submission standards
- Technologies
- PLR, SPL, PIM, RPS
- Global eLabeling challenges/opportunities for harmonization
- Global submissions (challenges, regional differences,etc.)
- Impact to the sponsor's organization
- Regulatory authority readiness and future directions

DM topics include:

- Document management
- Workflow
- Document tracking
- Streamlining the document management process
- Managing documents in an electronic environment
- Document archiving

GCP–GOOD CLINICAL PRACTICES

Abstracts submitted should address topics/issues related to domestic and international GCP, including:

- International clinical trial disclosure law and effects on the clinical trial lifecycle
- GCP regulatory inspection practices and findings
- Auditing practices and techniques
- Evolving role of the auditor
- Quality risk management
- Off-shore quality management challenges
- Intelligent monitoring
- Issue management,GCP,and CAPA: Effective identification and follow up of issues

IT–INFORMATION TECHNOLOGY

Abstracts related to the following topics should be submitted to the IT track.
SYSTEM AND SERVICE DELIVERY

- Virtualization case studies
- Outsourcing,eg,financial benefits/results,vendor selection/management, intellectual property concerns,contractual negotiations,regulatory issues,security/reliability of outsourced systems/operations
- Rapid Methods: Case studies of projects with rapid development methods, including web-based development,eXtreme Programming (XP) techniques, rapid application development (RAD) methods

DATA ARCHITECTURE

- Metadata Management and the Semantic Web,including terminology glossaries,data dictionaries,information taxonomies (particularly in regards to standards harmonization) and ontologies,metadata standards, and metadata management
- Electronic health records and clinical research

MA–MARKETING

Topics should address the following topics:

- Lifecycle management
- Portfolio analysis/techniques
- Market preparation
- Marketing research
- Tactical program implementation

MC-MEDICAL COMMUNICATIONS

Session abstracts should address topics related to the practice and provision of drug or medical information as it relates to internal or external customers including healthcare professionals and consumers,including:

- Provision of on-label and off-label information
- Response document creation and maintenance
- Literature evaluation
- Contact center issues
- Innovative technologies
- Legal and regulatory issues of medical communications
- Implementation and technical issues regarding field-based medical communications

MW–MEDICAL WRITING

The focus of this track will be on sharing experiences and best practices, defining skills required,and the impact of changes in this global environment. Topics include:

- Writing components of the CTD
- Requirements for the electronic environment
- Ethical publication practices
- Registry requirements
- Writing for patients
- Pediatric and special populations
- Writing for a website
- Medical writing in cross-functional teams
- Pharmacovigilance and writing of safety documents
- Medical writing in Japan,China,India,and South East Asia
- Writing for a website
- Needs of the freelance writer

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NC–NONCLINICAL LABORATORY SAFETY ASSESSMENT

The nonclinical laboratory safety assessment track will focus on emerging scientific and regulatory issues related to the assessment of the safety of regulated products.Topics for abstracts include:

- Laboratory studies evaluating pharmacokinetics and effectiveness of products, biomarkers of toxicity,predictive pharmacology, predictive models for preclinical safety,and animal disease models
- New methodologies and experimental techniques and current guidance on their use in preclearance testing
- Operational and management issues related to international harmonization,regulatory compliance,quality management,and the reporting and presentation of study results
- ICH updates (S6 in particular)
- Pharmaceuticals in water/environment
- Nonclinical evaluation of vaccines and adjuvants
- Use of nonanimal alternatives in pharmaceutical development

NHP–NATURAL HEALTH PRODUCTS

The natural health products (NHPs) track will represent complex or "poly molecular" products and ingredients from any source.Abstracts should be related to:

- The discovery,development,regulation,growing/harvesting,manufacturing, pre-clinical and clinical evaluation,quality control,validation,safety monitoring,sale, advertising,and promotion of NHPs
- Product characterization
- Sourcing
- Lot-to-lot standardization
- Design and implementation of preclinical and clinical trials
- GXPs
- Dose selection
- Methodologies
- Trial management
- Novel study designs
- Regulatory filing requirements for the mainstream development of poly molecular products in the US and foreign countries
- Utilization of "prior human use"data,bioassays,CMC approaches,impact of domestic and foreign policy directives

OS–OUTSOURCING

Abstracts should address topics related to the outsourcing of activities in connection with the drug development process. Presenters are encouraged to include the use of case studies of successes (as well as less successful case studies) with any of these topics:

- Clinical research
- Investigative sites
- Project management
- Challenges of outsourcing drug development activities to Latin America will be given special consideration

PM/FI–PROJECT MANAGEMENT/FINANCE

PROJECT MANAGEMENT abstracts should address topics and issues related to the project and portfolio management of the drug development process, such as:

- Planning
- Scheduling
- Resource management
- Risk management
- Team creation/development
- Leadership,negotiation,conflict resolution
- Establishing a project management culture
- Training project managers
- Best practices and new paradigms that address the new challenges faced by the pharma industry,and the value added by the project management

FINANCE abstracts should address topics and issues associatedwith the financial aspects of product development,including:

- Budgeting for R&D (corporate and/or project level)
- Contracting with CROs and investigators
- Standardizing accounting practices within pharmaceutical companies, particularly from a global perspective
- Acquisition of venture capital
- Mergers and acquisitions

PP–PUBLIC POLICY/LAW

Topics should relate to issues and concerns in the following areas:

LEGAL ISSUES

- Liability
- IP rights
- Competition legislation
- Contracting with suppliers,healthcare professionals,CROs

LEGISLATION (CURRENT AND FUTURE) in the areas of:

- Authorization
- Manufacturing
- Prescribing
- Use of medical products
- Pricing and reimbursement systems

ETHICS

- Research
- Development
- Marketing of medical products

RA–REGULATORY AFFAIRS

Session topics should include drugs and biologics and developments on recent legislative initiatives concerning emerging therapies, without neglecting the field of medical devices and combination products.The track tends to be 50% "international" by design, so as to reflect the strong globalization and harmonization trends of today. Topics include:

- The regulatory process and mechanisms
- Technical issues that impact the regulatory process
- The regulatory profession and its daily practice
- Special regulatory challenges of today or tomorrow
- Innovative regulatory approaches
- Practical,everyday issues
- The perspective of government regulators
- Political and regulatory environment
- Case studies
- Recent legislative initiatives in the US and EU
- Pediatric regulatory requirements
- Biosimliars
- Critical Path
- Personalized medicines

RD–R&D STRATEGY

This track focuses on strategic issues that relate to R&D performance, the external environment,and overall corporate strategy. Topics include:

- Efforts to improve R&D efficiency
- Economics of pharmaceutical development
- Industry structure
- Implementation of regulatory initiatives

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- External forces that influence industrial R&D
- Technical vs.commercial risk: How do we measure it? What do we do about it?
- Industry-academia collaborations for translational research: Who's doing it well? How are they doing it?
- Adapting your clinical program to the new threshold for safety: Moving from strategy to practice

ST–STATISTICS

Abstracts should address topics related to the application of statistics throughout the entire drug development process,including:

- Innovative or novel clinical trial designs (eg,adaptive trials,Bayesian trials,Phase II dose response estimation,Phase II/III trials,and noninferiority trials)
- Sample size considerations (eg,sample size re-estimation)
- Analysis of pharmacogenomic data
- Modeling and trial simulation
- Statistical monitoring/interim analysis of safety and efficacy
- Statistical methods for analyzing data (eg,multiple endpoints,data mining, and meta-analyses)
- Novel visual/graphical displays of data or automated/IT tools to enhance statistical analysis
- Recent developments in "regulatory statistics"(eg,ICH guidelines and CPMP Points to Consider)
- Statistical methods for portfolio optimization and prioritization of drugs in development
- Design and analysis of multiregional trials
- Safety signals
- Operational issues associated with outsourcing
- Discovery and establishment of reliable biomarkers
- Critical Path "opportunities"
- Multiplicity issues in efficacy/safety analysis
- Handling of missing data

TR/PD–TRAINING/PROFESSIONAL DEVELOPMENT

Sessions should focus on models for the training, education, and development of pharmaceutical professionals,including:

- Global training and education strategies
- Career development strategies
- eLearning,online training,and distance learning strategies
- Training in multicultural environments
- Leveraging multimedia and Web 2.0 in training and education
- Certification issues in training and education

VA–VALIDATION

Validation abstracts should focus on various current,effective,efficient,and quality methodologies for computerized system validation to ensure compliance, data integrity and quality performance across the various GXP areas.We encourage the sharing of actual case studies or inspection experiences.Topics include:

- Protection of source data
- Outsourcing
- Risk management
- Strategies for handling global or distributed systems
- Dealing with new technologies
- Effective auditing of computerized systems for their specified purpose

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