

30 YEARS OF EUROMEETING

DIA EUROPE 2018

17-19 April | Basel, Switzerland

Join us at the Crossroads of Healthcare



FINAL PROGRAMME

DIAGlobal.org/Europe2018 | [#DIAEurope](https://twitter.com/DIAEurope) 2018



DIA Europe 2018

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DIA Europe 2018

THOUGHT LEADERSHIP

What was discussed at EuroMeeting 2017

In a world in which new therapies are being developed at a phenomenal rate, is innovation always the answer?

DIA EuroMeeting 2017 brought stakeholders together to collaborate on when, where, and how innovation leads to advances in health care product development.

Experts at the meeting discussed:

| Global Regulatory Convergence:

"No one has ever systematically looked at our [EMA and FDA] differences, what is the source of it? ... We are starting to see more of an uptake of joint scientific advice. Particularly on areas where the resources are scarce, the patients are few. Our job is to make simple for the companies as well as for the regulatory agencies, as we do have different procedures that can be a challenge"

| Value and Access:

"There is an issue about sustainability of health care - are we able also in the future pay for these medicines and how much are we willing to pay for them? DIA plays a role in bringing different parties together to the table. We have new ways in dealing with the evolving insights how to treat the patients. The need of having different parties together is really growing."

- **Ri de Ridder**, Director General, Belgian National Insurance, RIVIZ-INAMI

| Trends in Clinical Operations:

"The future entails:

- Study protocols to be designed evidence-based when using Electronic Health Records (EHRs)
 - EHRs to facilitate access to patients for research
 - Registries are a way to bring patients closer to research
 - Social networks for specific diseases may replace more complex registries"
- Senior Vice President, Drug Development Services, CNS, for ICON plc

| Patient Engagement:

"These patient insights help us improve the therapeutic options and delivery technologies, adherence tools and patient-reported outcomes AND the clinical trials experience, just to name a few of the important consequences."

- **Susan Forda**, Vice President of International Regulatory Affairs, Eli Lilly and Company Limited

| Addressing Industry Concerns:

Audience Poll Question: *Are we as Europeans getting the innovation that society wants and needs?*

57%, a majority, responded "No"

To tackle that a panel of key stakeholders in the European medicines system shared their views on how to innovate, engage and evolve in a regulatory setting which ensures that innovations reach patients.

We thank everyone who joined and actively engaged at DIA EuroMeeting 2017.



DIA Europe 2018 PROGRAMME COMMITTEE

I Programme Steering Committee

The Regulatory Science Co-Chairs:



Luca Pani

Professor, Department of Psychiatry and Behavioral Sciences University Of Miami School Of Medicine, USA



Michelle Rohrer

Global Head of PD Regulatory and Policy at F. Hoffmann-La Roche and Genentech, Switzerland

The Value and Access Co-Chairs:



Jens Grueger

Head of Global Pricing and Market Access, F. Hoffmann-La Roche, Switzerland



A.R (Ad) Schuurman

Head of the International Department of the National Health Care Institute (ZIN), Netherlands

The Translational Medicine and Science Chair:



Salah-Dine Chibout

Global Head of Discovery and Investigative Safety (DIS) and Global Head Therapeutic Areas in Preclinical Safety, Novartis, Switzerland; Chair of InnoMeds, EFPIA

I Programme Advisors

Vivianne Arencibia

Global Head of External Engagement, Group Quality, Novartis, Switzerland

Sabine Atzor

Head of EU Regulatory Policies, F. Hoffmann-La Roche, Switzerland

Ursula Busse

Quality Intelligence, External Relations, Group Quality, Novartis, Switzerland

João Duarte

Associate Director, Europe Regulatory Policy and Intelligence, Takeda, UK

Sabine Haubenreisser

Principal Scientific Administrator, International Affairs, European Medicines Agency (EMA), EU

Cordula Landgraf

Head of Networking, Swissmedic Switzerland

Francesco Pignatti

Head of Oncology, Haematology, Diagnostics, European Medicines Agency (EMA), EU

Bettina Ryll

Founder, Melanoma Patient Network Europe, Sweden

Claudine Sapède

Global HTA and Payment Policy Lead, F. Hoffmann-La-Roche, Switzerland

DIA Europe 2018

PROGRAMME COMMITTEE

I Topic Leaders



Indranil Bagchi

Vice President and Franchise Head, Global Value & Access, Novartis Oncology, USA



Isabelle de Zegher

Vice President, Integrated Solution, PAREXEL Informatics, Belgium



Petra Dörr

Deputy Executive Director, Swissmedic, Switzerland



Vicki Edwards

Vice President, Pharmacovigilance Excellence and QPPV, AbbVie, UK



Georgy Genov

Head of Signal Management, European Medicines Agency (EMA), EU



Anthony Humphreys

Head of Division, Scientific Committees Regulatory Science Strategy, European Medicines Agency (EMA), EU



Merete Jørgensen

Director, Global Clinical Registry, Novo Nordisk, Denmark



Jordi Llinares Garcia

Head of Scientific and Regulatory Management, Human Medicines Evaluation Division, European Medicines Agency (EMA), EU



Manfred Maeder

Head Device Development and Commercialization, Biologics Technical Development and Manufacturing (BTDM), Novartis, Switzerland



Thomas Metcalfe

Strategic Innovation Leader, Pharma Development F. Hoffmann-La Roche, Switzerland



Sharon Olmstead

Global Head, Development and Regulatory Policy and Intelligence, Novartis, USA



Holger Maria Rohde

Director, Regulatory Project Management, Merck, Germany



Thomas Senderovitz

Director, Danish Medicines Agency (DKMA) Denmark



Fergus Sweeney

Head of Division, Inspections, Human Medicines Pharmacovigilance and Committees, European Medicines Agency (EMA), EU



DIA Europe 2018

PROGRAMME TOPICS

DIA Europe 2018: 9 Topics designed to advance health care outcomes through innovation across 8 core thought leadership streams



Clinical Development



Data and Data Standards



Patient Engagement



Pharmacovigilance



Preclinical Development and
Early-Phase Clinical Research



Regulatory Science



Translational Medicines
and Science



Value and Access

- Topic A Can Regulators and HTA Bodies Create Synergies for Patient Access?
- Topic B What are Necessary Steps towards Outcome-Driven Health Systems?
- Topic C Medicines of the Future: What Will Innovation Need and Bring?
- Topic D How Can Better Outcomes Be Enabled by Big Data?
- Topic E What is the Future of Pharmacovigilance?
- Topic F What Can Stakeholders Expect from Clinical Trial (Development), Transparency and Medical Information?
- Topic G A New Era for Medical Devices and Diagnostics. How Is The Impact?
- Topic H Drug Development and Regulatory Approval - Reference Points around the Globe or Globalisation?
- Topic I How Can We Enable Clinical Research in Europe Further?

DIA Europe 2018

GENERAL INFORMATION A-Z

App

The DIA Global App is designed to enhance participants' meeting experience and provide valuable information in one place. Create your session agenda, network with attendees and Exhibitors, and connect to DIA resources, social media channels, member communities, and more.

How to get the App:

- Search for "DIA GLOBAL" in the App store or in Google Play, and download
- Sign in with the email address you used to register for the event
- If it is your first time using the App, use the password "global".
- If needed, use the reset password link to set your password
- Select DIA Europe 2018

Only registered attendees have access to the mobile app. You can find assistance at the Registration Desk.

Certificate of Attendance

Certificates of attendance will be available on the DIA website under My Transcripts after the meeting.

Cloakroom/Baggage

The cloakroom is located at the main entrance.

Conference Bags

As we are going paperless, we will no longer be producing conference bags in order to reduce waste and create a sustainable event.

Continuing Education Credits

DIA meetings are accredited by the SwAPP (Swiss Association of Pharmaceutical Professionals) Commission for Professional Development (CPD) and SGPM (Swiss Society of Pharmaceutical Medicine).

DIA Europe 2018 has been awarded up to 17.25 CPD credits from the Faculty of Pharmaceutical Medicine (FPM) of the Royal College of Physicians (RCP) of the UK. Medical practitioners who are eligible for credits can click on <http://www.fpm.org.uk/cpd/registration> for more information. If you are already a CPD member, please go directly to <http://cpd.fpm.org.uk> to claim your credits.

DIA Booth

Find out more about all DIA can offer you, how membership can advance your career, how to join a DIA Community, submit an article for publication and lots more. Stop by at the DIA Booth in the Exhibition Hall. See "Exhibition" for opening hours.

DIA Community Network Area - Level 2 Foyer

A dedicated area is available for you to meet with your fellow community members throughout the conference or to learn more about DIA Communities

Exhibition

Visit the Exhibition, with 100+ companies and service providers in a single venue. With many new companies exhibiting this year, the exhibition offers more opportunities than ever to connect with participants.

Tuesday	08:00 - 19:30
Wednesday	08:00 - 18:30
Thursday	08:00 - 13:00

Please see the exhibition floor plan and list of exhibiting companies in the Exhibition Guide at the end of this programme, or use the interactive floor plan in the "DIA Global" mobile app.

Exhibitor Services

The Exhibition Services Desks will be situated next to the Registration desk at the entrance of the conference centre.

First Aid

A medical professional will be on duty during conference hours. Please contact any DIA staff member or host/hostess who will be able to assist.

Help Desk

If you have any questions about DIA Europe, from finding session rooms to networking activities, stop by the DIA Help Desk located at the entrance of the Exhibition Hall. Alternatively, any staff member or DIA host/hostess will be more than happy to be of assistance.

Monday	13:00 - 18:00
Tuesday	07:00 - 17:00
Wednesday	08:00 - 17:00
Thursday	08:00 - 13:00

Hotel Accommodations Desk

KIT Group GmbH is the official hotel agent for the DIA Europe 2018 in Basel. If you have any queries about hotel accommodation, please visit the counter at the registration area.

Internet Access / Wi-Fi

We provide free basic wireless internet access in all area spaces of the venue. To utilise this service, simply connect to the complimentary WiFi.

WiFi Network: DIA Europe 2018

Username: 2086522072

Password: 1596

Lost and Found

All items will be stored at the DIA Registration Desk until the end of the conference.

Messaging Services

Download the "DIA Global" mobile app and use the messaging function to set appointments or send messages to other attendees.

Name Badge

Name badges must be worn at all times in the Conference Center. Participants will incur a € 25 fee for badge reprints. If you have misplaced your badge, you will be required to have a badge reprinted. Please visit Attendee Onsite Registration located in the registration area. Identification will be required.

Please note, allowing exhibitors to scan the barcode on the front of your badge will provide them with your contact information. No children under the age of 18 years will be allowed in the Exhibition Hall due to liability issues.

Posters

Posters (electronic) will be displayed in Poster Zone on the ground floor. Come and talk to our poster presenters during breaks. A selected group of professional poster presenters will share their research results on various topics. Oral presentations where authors can provide a 5 minute overview of their work will be delivered in the Innovation Theatre located in the exhibition hall.

DIA Europe 2018

GENERAL INFORMATION A-Z

Presentations

Presentations will be available to full conference attendees on the DIA web site from 16 April until 15 October 2018. Presentations are made available to full conference attendees only.

To access presentations, visit www.DIAglobal.org and log into your account, then and follow the links for the DIA Europe presentations.

Recharging Station

A recharging station lounge is available in the Members Lounge on the Exhibition Floor.

Refreshments/Lunches

Refreshments and Lunches will be served each day in the Exhibition.

Tuesday, 17 April

10:30 - 11:00	Morning tea/coffee with snack
12:30 - 14:00	Lunch
15:30 - 16:00	Afternoon tea/coffee with snack

Wednesday, 18 April

10:00 - 10:30	Morning tea/coffee with snack
12:00 - 14:00	Lunch
15:15 - 16:00	Afternoon tea/coffee with snack

Thursday, 19 April

10:00 - 10:30	Morning tea/coffee with snack
12:00 - 13:00	Lunch

Registration

The self scanning kiosks and registration desks at the Congress Center Basel will be open on the following days and times:

Monday, 16 April	13:00 - 18:00
Tuesday, 17 April	07:00 - 17:00
Wednesday, 18 April	08:00 - 17:00
Thursday, 19 April	08:00 - 13:00

Security

We take the safety of our participants very seriously. Please help us by cooperating fully with the security personnel on duty and wear your badge at all times. Only participants with a valid conference badge will be allowed into the conference center.

Services for the Disabled

All the rooms at the congress centre are fully accessible to participants with disabilities.

Social Media

Stay connected with your colleagues around the world and all of the innovation happening in Basel by following #DIAEurope2018 with social media.

- Upload pictures to Instagram
- Tweet updates
- Connect with colleagues on LinkedIn
- Share the excitement with colleagues on Facebook

Search @DrugInfoAssn to follow DIA

Speaker Resource Center

All speakers are required to visit the Speaker Resource Center located on level 2 (Rio) and re-check their slides at least 2 hours before the start of their session(s).

Monday, 16 April	13:00 - 18:00
Tuesday, 17 April	07:00 - 18:00
Wednesday, 18 April	08:00 - 18:00
Thursday, 19 April	08:00 - 14:00

Follow @DrugInfoAssn



DIA Europe 2018

DIA EUROPE IS GOING GREEN



Help us make this event a Green Conference.

All the following measures will contribute considerably to a sustainable event:

- Use the **App**. The final Programme, exhibition floorplan and all useful information about DIA Europe 2018 won't be printed: everything is accessible from the **website**, and from the **App** during the event! *To download the App, search for "DIA Global" in the App Store or in Google Play.*
- No conference bags, notepads or pens will be given - to **reduce waste**.
- A **USB Stick** will be attached to your lanyard for electronic storage of information
- **Get your personalised, reusable coffee cups**. Instead of wasting disposable coffee cups, you can re-use these cups during the 3-day event.
- Travel to and from Basel by train. Check out the Deutsche Bahn Event ticket option at the Congress Center. Also, most attractions can be reached by foot or via the public transport system in Basel. **Use the Basel Card!** Each guest staying at a hotel in Basel, receives this Mobility Ticket upon check-in, which allows free use of the public transportation in Basel during your stay.
- Take part in our **social and sport activities within walking distance** of the conference venue - check the App for more information!
- You will have access to **electronic Posters** on display during and after the conference

Thank you for helping us create a sustainable event!

Stay Connected

Navigate DIA Meetings from Your Smart Device with DIA's App



The DIA Global App is designed to enhance your meeting experience and provide valuable information in one place.

With the mobile app you have the conference at your fingertips:

- ✱ Create and manage your personal agenda
- ✱ Search for speakers, attendees and exhibitors to connect and network
- ✱ Interactive floor plans
- ✱ Share your DIA Europe experiences through photos, posts, and more
- ✱ Activity stream provides real-time updates
- ✱ Interaction with your social media channels

To download, search for "DIA Global" in your app store

How to get the App:

- Search for **"DIA GLOBAL"** in the App store or in Google Play, and download
- Sign in with **the email address you used to register for the event**
- If it is your first time using the App, use the password **"global"**
- If needed, use the reset password link to set your password
- Select **DIA Europe 2018**



DIA Europe 2018 EMEA INSPIRE AWARDS

Outstanding Contribution to Global Health

Awarded to an individual, group or organisation in the region who has made significant and innovative contributions to advancing global health



Peter Bachmann

Head International Liaison Office and Conferences, Federal Institute for Drugs and Medical Devices (BfArM)

Peter Bachmann has studied biology and chemistry and has a Doctorate of Natural Sciences (Pharmaceutical Biology) from the University of Würzburg (Germany). Following a JSPS postdoctoral fellowship at Kyoto University (Japan) and a DFG Fellowship at the Institute of Food Research in Norwich/UK, he has worked at the Institute of Pharmaceutical Biology at the Technical University Braunschweig/Germany, until he joined in 1999 the Federal Institute for Drugs and Medical Devices (BfArM, Germany), Department of 'Drug Approval'.

Following positions as Head of Subunit 'Variations' (2000-2002), Head of Unit 'Mutual Recognition Procedures' (2002-2005), Senior Expert for 'Drug Regulatory Affairs' in the Executive Department 'European and International Affairs' (2005-2011), and Head of Unit 'Coordination Group' (2011-2017), he holds currently the positions as Head 'International Liaison Office and Conferences' and as Deputy-Head of the Executive Department 'European Union and International Affairs'.

He was the German representative to the MRFG (2002 – 2005), the German CMDh Member (2005 – 2011), the elected Chair of the CMDh (2011-2017), and a member of the International Generic Drug Regulators Programme (IGDRP) Steering Committee (2012-2017).

Currently he is acting as the German NtA Member (since 2002), a Member of the European Union Network Data Board and the European Union IDMP/SPOR Task Force (since 2018), a Member of the International Pharmaceutical Regulators Programme (IPRP) Management Committee (since 2018) and as a member of different other European and International AdHoc Working Parties.

He is a lecturer for 'Drug Regulatory Affairs' at the Universities of Bonn, Duisburg-Essen, Basel and Copenhagen, a honorary member of the 'Middle-European Society for Regulatory Affairs' (MEGRA), a honorary life-time TOPRA-member, a former member and Vice-Chair of the DIA Advisory Committee Europe (2007 – 2013), DIA Board of Directors (2013 – 2016) and is currently serving at the DIA Council of Regulators.

Excellence in Service Award

Awarded to the "member of the year" who has consistently provided outstanding service as a DIA volunteer in the EMEA region, and who has contributed to the advancement of DIA's mission.



Jürgen Kübler

Quantitative Scientific Consultant, QSciCon

Jürgen Kübler received a Masters degree in Statistics and a PhD in Statistics from the University of Dortmund, Germany. Jürgen joined Bayer AG in 1992 as statistician. He initially worked as project leader for the therapeutic area CNS in the department Clinical Datapools International. In 1999 Jürgen was named Head of Clinical Datapool International renamed to Integrated Analyses in 2000. Jürgen was appointed Head of Global Statistical Science in 2004. Effective September 1, 2005 Jürgen joined Novartis Pharma in Switzerland, where he most recently held a position as Global Head, Statistical Safety Sciences. In November 2011 Jürgen joined CSL Behring where he most recently held the position of Global Head, Quantitative Safety Sciences. Jürgen founded Quantitative Scientific Consulting in January 2017.

Jürgen has published in statistical and scientific journals, regularly gives scientific presentations and organized various sessions at scientific conferences. He was president of the German Region of the International Biometric Society from 2014 to 2015 and served as council member from 2000 to 2004. Over the past 20+ years Jürgen continuously contributed to DIA as speaker, session chair, programme committee member and chair of the European Statistics Community and active member of community's global core team.

DIA Europe 2018

EMEA INSPIRE AWARDS

Excellence in Service Award



Vicki Edwards

VP, Pharmacovigilance Excellence and QPPV, Abbvie Inc.

Vicki Edwards qualified as a pharmacist in 1981 and started her career in hospital pharmacy. In 1983 she specialised in Drug Information Services and moved to Kuwait to set up and run the first National Drug Information Centre. The Centre became a showpiece for the Ministry of Public Health and every visiting Healthcare related dignitary was taken to see the activities of the new project. After a slow start the centre began to provide a valuable information service to healthcare professionals in Kuwait. Unfortunately the project came to an abrupt end in 1991 with the advent of the first Gulf War.

On her return to the UK, Vicki spent the next four years in community pharmacy. Working for a large chain of community pharmacies, she worked closely with general practitioners, local nursing homes, a cancer hospice and a private hospital to provide pharmaceutical services to the local patient population.

In 1996 Vicki joined GlaxoWellcome and started her career in pharmacovigilance. In 2002 she moved to AstraZeneca UK Ltd as the Drug Safety Manager moving on to become Head of Drug Safety & Medical Information. Whilst AstraZeneca UK is a marketing company, the Drug Safety department played a significant role in pharmacovigilance activities within the global organisation.

Vicki then moved to Abbott Laboratories Ltd in October 2005 as European Qualified Person for Pharmacovigilance (EU QPPV). In January 2013, Abbott Laboratories Ltd separated into two independent pharmaceutical companies, new Abbott and AbbVie. Vicki moved to AbbVie as EU QPPV and Head of Affiliate Safety Excellence (ASE). In this global role, in addition to fulfilling legal responsibilities of the EU QPPV, Vicki led a team of regional staff responsible for ensuring that all AbbVie Affiliate PV functions are compliant with company standards and local regulations and also a team dedicated to coordinating the production of aggregate safety reports to meet global needs. She is now Vice President, Pharmacovigilance Excellence and QPPV and is responsible for PV obligations for Organised Data Collection activities, oversight, governance and provision of safety and risk management information to Affiliate PV and medical staff and for the global PV quality management system. Vicki is a regular speaker at Pharmacovigilance conferences and teaches on several academic pharmacovigilance courses. Vicki is the Chair of the EFPIA pharmacovigilance Expert Working Group.



Jan Petracek

CEO, PrimeVigilance

Dr. Jan Petracek qualified as a physician from Charles University in Prague and holds a Master of Science with Distinction in Quality and Safety in Healthcare from Imperial College London.

Jan has over 18 years of experience in all areas of pharmacovigilance, being former Head of Risk Management Section at European Medicines Agency, Head of Pharmacovigilance in the Czech Republic, Head of Strategy and Development of the Czech National Authority, and member of CHMP Pharmacovigilance Working Party.

He was trained as the inspector within the Benchmarking of the European Medicines Authorities, assessing performance of regulatory authorities in the EU and helping to set benchmarks for regulatory approaches and performance.

He participated in development of several national, European, ICH and CIOMS guidelines. He was the lead author of the EMA Guideline on Safety and Efficacy Follow-up - Risk Management of Advanced Therapy Medicinal Product, and member of the ICH E2F Expert Working group on Development Safety Update Reports.

He contributed to development of new regulatory pathways as a member of the EMA Innovation Taskforce, including biosimilars, nano medicines, and challenging combination products.

Jan is a very active trainer for number of DIA international pharmacovigilance courses, and is an elected member of the Advisory Board - International Society of Pharmacovigilance. He also works as EU QPPV for major innovative companies, performs complex audits, strategic consultancy, and leads fast growing organisations as entrepreneur and CEO for the last 8 years.



DIA Europe 2018

PROFESSIONAL POSTERS

Poster presenters will share their research results in various topics.

E-Posters

Our poster programme is seeing some exciting changes in 2018!

Posters will be now displayed electronically and can be viewed in the e-Poster Zone located on the ground floor foyer outside session rooms Lima and Kairo.

Oral presentations

Presenters will provide a 5-minute overview of their work. These presentations will be held in the Innovation Theatre located in the Exhibition Hall during break times from Tuesday-Thursday. Times are indicated for those giving an oral presentation.

List of Posters by Thought Leadership Stream



CLINICAL DEVELOPMENT

Matching Clinical Trials with Patients: Global Patient Search and Identification Using De-Identified EHRs

Tigran Arzumanov, Head of Sales, Clinerion, Switzerland

Oral Presentation scheduled Tuesday, 17 April, 12:57-13:02

Pediatric Challenges in Orphan Drug Development, a Review of Issues and Possibilities

Nadia Assenova, Sr. Director Regulatory Affairs, EMEAC, Alexion Pharma GmbH, Switzerland

Oral Presentation scheduled Tuesday, 17 April, 10:54-10:59

Quality Focus of Nestlé Clinical Studies in Nutrition

Hélène Clavien, Quality Manager, Nestlé Research Center, Switzerland

Oral Presentation scheduled Tuesday, 17 April, 13:03-13:08

Avoiding Waste by Reducing the Number of Inconclusive Trials in Paediatric Clinical Research

Anouar Fanidi, PhD Student, Université Claude Bernard Lyon 1, France

Oral Presentation scheduled Tuesday, 17 April, 10:30-10:35

Impact of Statins on Total mortality, through their Action on Cardiovascular Mortality – A Meta-Regression Approach

Mathilde Galaup, Student, Université Claude Bernard Lyon 1, France

Oral Presentation scheduled Tuesday, 17 April, 12:45-12:50

Is Systematic Review an Answer to Gather High Level of Evidence from Clinical Studies?

Henna Khan, Team Leader, APCER Life Sciences, India

Oral Presentation scheduled Tuesday, 17 April, 10:48-10:53

Efforts for Certification of the Institutional Ethics Committee in Kanazawa University Hospital, Japan

Toshinori Murayama, Professor & Chairman, Department of Clinical Development, Kanazawa University Hospital, Japan

Sex and Gender Interaction in Randomised Controlled Trials: A Meta-Epidemiological Approach

Didem Sen, Student, Université Claude Bernard Lyon 1, France

Oral Presentation scheduled Wednesday, 18 April, 15:51-15:56

Survey on Study Nurses and Clinical Research Coordinators Insights in the Operational Quality of Clinical Trials

Martin A. Sieber, Professor, University Bonn Rhein Sieg, Germany

Oral Presentation scheduled Tuesday, 17 April, 10:36-10:41

A Review of Genetic Variants Related to Edema Risk Using PPAR Agonists in Type 2 Diabetes

Zianya Torrado, Clinical Research student, Université Claude Bernard Lyon 1, France

Oral Presentation scheduled Tuesday, 17 April, 12:51-12:56

Reassuring Local Confirmatory Clinical Trials for Drug Registration in Russia

Natalia Vostokova, COO, IPHARMA, Russian Federation

Oral Presentation scheduled Tuesday, 17 April, 10:42-10:47



DATA AND DATA STANDARDS

Turn Compliance into Value – Decrease Complexity, Increase Compliance and Reduce Total Costs of Ownership of Your Next RIM

Romuald Braun, Vice President Strategy Life Sciences, AMPLEXOR, Switzerland

Oral Presentation scheduled Wednesday, 18 April, 15:27-15:32



PATIENT ENGAGEMENT

Vision DMD - Project for Duchenne Muscular Dystrophy

Dimitrios Athanasiou, Patient Advocate, Muscular Dystrophy Association Hellas, Greece

Multimedia Authoring and Management Using Your Eyes and Mind (MAMEM)

Dimitrios Athanasiou, Patient Advocate, Muscular Dystrophy Association Hellas, Greece

Social Media Platform Dedicated to Rare Diseases, Using Collective Intelligence for the Generation of Awareness and Knowledge

Dimitrios Athanasiou, Patient Advocate, Muscular Dystrophy Association Hellas, Greece

GSK Medical Information in Pharma 2.0: The Italian Journey

Lara Benardi, Medical Information Support, GSK, Italy

Oral Presentation scheduled Wednesday, 18 April, 10:12-10:17

How Patient's Preference and Interest are taken into Account for the OD Designation and OD Maintenance in the EU

Camille Metais, Regulatory Affairs Senior Director, Alexion Pharma, Switzerland

Oral Presentation scheduled Wednesday, 18 April, 10:06-10:11

DIA Europe 2018

PROFESSIONAL POSTERS

Patient Support Programs: Governance Model and Best Practice for Patients and Healthcare Professionals

Daniel Richter, Medical Process Manager, Merck KGaA, Germany
Oral Presentation scheduled Wednesday, 18 April, 10:00-10:05

A MILEstone - Creating the European Industry Association for Medical Information

Jill Voss, Franchise Head Medical Information, Communications & Events, Novartis, Switzerland
Oral Presentation scheduled Thursday, 19 April, 10:18-10:23



PHARMACOVIGILANCE

Aggregate Reports: Quality Control, feedback and Continuous Improvement
Dominique Coleman, Director of Aggregate Reporting, Safety Aggregate Reporting and Analytics, IQVIA, Ireland

Educational Material, the Most Common Tool for Risk Minimisation: Analysis of Published European Public Assessment Reports

Kalindi Hapani, Team Lead, RMP, APCER Life Sciences, India
Oral Presentation scheduled Thursday, 19 April, 12:15-12:20

Evaluating Long-Term Effects of Gene Therapy Medicinal Products (GTMP) - What about the Patients' Experience?

Asha Hareendran, Senior Research Leader, Evidera, UK
Oral Presentation scheduled Thursday, 19 April, 12:21-12:26

SDRs Detected in Social Media Using Various Levels of Machine Learning and Natural Language Processing

Schei Dattner, VP Sales - Europe, Data2Life, Germany
Oral Presentation scheduled Wednesday, 18 April, 10:00-10:05

Concordance in Assessment/Preparation of EU - Risk Management Plans (RMPs): Analysis of CMDh List of Safety Concerns

Harshil Patel, Team Lead, Pharmacovigilance, APCER Life Sciences, India
Oral Presentation scheduled Thursday, 19 April, 12:27-12:32

Pre/Post Survey to Assess the Effectiveness of Updated Risk Minimisation Materials for an Orphan Disease: Wave 1 Result

Nawab Qizilbash, Clinical Epidemiologist, OXON Epidemiology, Spain
Oral Presentation scheduled Thursday, 19 April, 10:00-10:05

Risk Minimization Evaluation: A Patient-Centric Framework for Evaluation Integrating Qualitative and Quantitative Methods

Annalisa Rubino, Senior Research Scientist, Evidera, UK
Oral Presentation scheduled Thursday, 19 April, 12:33-12:38

From Clinical Trial to Post-Marketing Signal Management: A Continuum

Margot Stam Moraga, Director, Benefit-Risk Management, IQVIA, Switzerland



PRECLINICAL AND EARLY CLINICAL DEVELOPMENT

Advancing Precision Medicine in Rheumatoid Arthritis: The Impact of Biomarkers on Outcomes and Cost

Grant Lawless, Associate Professor, Pharmaceutical and Health Economics,

University of Southern California, USA

Oral Presentation scheduled Wednesday, 18 April, 10:18-10:23

A Phase 1 Pilot Trial to Explore Safety, Pharmacokinetics, and Bioavailability of Intranasal Remimazolam in Healthy Subjects

Frank Schippers, VP Global Clinical Development, PAION Deutschland, Germany

Oral Presentation scheduled Wednesday, 18 April, 10:24-10:29



REGULATORY SCIENCE

Global Regulatory Challenges Encountered during Early-Stage Development of Gene Therapy Medicinal Products

Sarah Jurmeister, Senior Regulatory Affairs Specialist, PPD, UK

CMC, cGMP and Quality Considerations for US and EU Marketing Applications When Using Manufacturing Sites in Emerging Markets

Clare Ryder, Associate Director, Regulatory Affairs, PD, UK
Oral Presentation scheduled Thursday, 19 April 10:24-10:29

A Critical Appraisal of Guidelines on Strategies used to identify and Mitigate Risks for First-in-Human Clinical Trials

Maximilian Siebert, Student, Université Claude Bernard Lyon 1, France
Oral Presentation scheduled Thursday, 19 April, 10:12-10:17

Regulatory Environment Reforms in China 2015-2017

Bill Wang, Director, Regulatory Affairs, PPD, China
Oral Presentation scheduled Thursday, 19 April, 10:06-10:11



TRANSLATIONAL MEDICINES AND SCIENCE

Driving Forward to New Treatments: Examining Lung Cancer through the Human Lens

Emer Byrne, Digital Strategy Consultant, Accenture, UK
Oral Presentation scheduled Wednesday, 18 April, 15:39-15:44

How the Explosion of Healthcare Information is Already Speeding Up Clinical Development

Pedro Manzione, Sr. Global Solutions Manager, IQVIA, Switzerland
Oral Presentation scheduled Wednesday, 18 April, 15:45-15:50

Do Non-Steroidal Anti-Inflammatory Drugs Affect Sport Performance in Healthy People?

Amanda Ragalin, Pharmacy Student, Institut De Pharmacie Industrielle de Lyon, France
Oral Presentation scheduled Wednesday, 18 April, 15:33-15:38



VALUE AND ACCESS

How Medical Affairs Teams Can Create Added Value for HCPs, Patients and the Business by Increased Collaboration

Isabelle Widmer, Medical Affairs Consultant, elytra, Switzerland
Oral Presentation scheduled Wednesday, 18 April, 15:21-15:26



DIA Europe 2018 HIGHLIGHTS



DIAmond Sessions

DIAmond Sessions are Tuesday-Thursday, and include 10 global hot topics with regulatory, payer, industry, and patient perspectives. These panel conversations are can't-miss opportunities to listen to and engage with many of the key stakeholders involved in each topical area.



Conference Wrap-up

Thursday 19 April | 13:00-14:00

CONFERENCE INSIGHTS AND OUTCOMES - RAPID FIRE SESSION

This must-attend 'Rapid Fire' session is an excellent opportunity to hear what you have missed in the sessions that you could not attend! All Topic Leaders will have 3 minutes on stage to share the essence from the presentations and discussions in their topics by delivering summaries of novel insights and key takeaways from the DIA Europe 2018. DIA is capturing emerging knowledge and insights in order to advance selected topics after the meeting.

New Attractions for 2018

DIA is happy to announce the arrival of the following at the DIA Europe 2018:



DIAlogue Sessions

DIAlogue sessions are dynamic, outcome-focussed sessions where stakeholders converge to solve a real problem. Preparatory groundwork will be laid out by the session organisers and presented to the audience as a preface to interactive discussion.



Content Hub

Dynamic, inspired and concise talks will be given in a relaxed setting. Engage with fellow attendees who have designed a 30-minute presentation offering you rapid insight or a deeper perspective in a subject of value.



Engage and Exchange (E&E)

Share ideas, exchange experiences, and enhance your understanding of a topic that's important to you! Actively participate in this collaborative learning environment, with a 45-minute session led by a facilitator.



Spotlight Sessions

Spotlight sessions are quick updates which focus on prominent topics relevant to current European policy. These sessions take place during lunch. Please have your lunch in the Exhibition Hall before the session starts.

DIA Europe 2018

OPTIONAL SHORT COURSES

Short Course 1 | Monday 16 April | 14:00-17:30

Wettstein (Swissotel)



WORKSHOP: REVISION OF THE EU CLINICAL TRIAL RISK MITIGATION GUIDELINE

Jan Willem Van der Laan, Section on Pharmacology, Toxicology and Kinetics (FTK), Medicines Evaluation Board (MEB), Netherlands
Elke Stahl, CTFG Co-Chair; Clinical Trial Unit, BfArM, Germany
Ulla Wandel-Liminga, Scientific Director, Medical Products Agency (MPA), Sweden

In July 2017, the EMA released a revised 'Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products'. This workshop aims to explain/teach the guidance, with involvement of assessors from regulatory agencies.

The course will begin with presentations on the nonclinical issues and discussions on Dose Selection. The second part will focus on design elements and key aspects of the FIH and Early Clinical Trials and clinical monitoring. The speakers have been members of the drafting group involved in the finalisation of the guideline.

Learning Objectives

At the conclusion of this short course, attendees will be able to:

- Recognise the revisions of the Guideline in relation to the previous version from 2007.
- Identify the regulatory issues for designing new First-in-Human and early clinical trial protocols

Target Audience

This course is designed for non-clinical and clinical experts in pharmaceutical industry involved in drug discovery and early clinical development; CROs, consultants, project managers, employees of FIH clinical trial units, regulatory affairs professionals, and regulatory assessors involved in clinical trial approval.

Short Course 2 | Monday 16 Apr 14:00-17:30

Helvetia 4 (Swissotel)



HOT TOPICS IN PHARMACOVIGILANCE

Sabine Brosch, Principal Scientific Administrator, European Medicines Agency (EMA), EU

Anja Van Haren, EudraVigilance Coordinator, Medicines Evaluation Board (MEB), Netherlands

This short course will provide a forum to discuss the experience gained with the launch of the new EudraVigilance system, the simplified ADR reporting and access principles as well as the application of the provisions set out in Good Pharmacovigilance Practice Module VI, for which revision 2 was published in the 3rd quarter of 2017. The course will also address highlights of the signal management pilot, which was initiated in February 2018.

The course will provide an update on the initial implementation experience, discuss practical examples, address frequently asked questions and next steps.

Learning Objectives

At the conclusion of this short course, attendees will be able to:

- Discuss recent updates to GVP Module VI based on practical examples
- Describe the initial implementation experience with EudraVigilance
- Understand the impact of the simplified adverse reaction reporting and access to EudraVigilance
- Discuss highlights of the signal management

Target Audience

This short course is designed for Qualified Persons Responsible for Pharmacovigilance (QPPVs) and pharmacovigilance experts including ICSR data entry and processing specialists.



Short Course 3 | Monday 16 April | 14:00-17:30**Helvetia 5 (Swissotel)****MOVING FROM RISK MANAGEMENT TO BENEFIT-RISK MANAGEMENT – EMBEDDING PHARMACOVIGILANCE PRINCIPLES INTO THE PRODUCT LIFE CYCLE**

Shelley Gandhi, Director Pharmacovigilance and Drug Safety, NDA Group, UK

Bill Richardson, Medical Advisor, NDA Group, UK

Pharmacovigilance, or the activity of monitoring the safety of medicines in clinical use and taking appropriate action to minimise risk, is governed by a range of new EU legislation, a new Pharmacovigilance Risk Assessment Committee (PRAC) and guidance. The value that can be gained from adopting a benefit-risk management system not only addresses known and potential risks to support the current regulatory status of products but also will feed into the further development of a product with regards to new indications and potentially moving from prescription only to over the counter.

This short course will discuss how access to robust evidence on emerging risk in post-authorisation phase, good data on how a medicine is used in clinical practice, and data on background rates in the exposed population; gathering evidence throughout the product life cycle will help move companies to a benefit-risk system. The ultimate challenge is working towards an integrated regulatory system, enabling users to query across all information within a company, designing safety studies, monitoring the effectiveness of the risk management systems and gathering robust evidence from clinical practice. The lessons learned and our experiences so far with post-authorisation commitments (e.g. BRMPs, PASS, PSURs) will be reviewed as will whether these commitments really do support an acceptable benefit-risk profile. This will include the novel approaches to managing benefit-risk to meet the needs of licensing medicines in biotechnology such as advanced therapies. Communicating benefit-risk will also be discussed as the new legislation will push for greater patient involvement within a benefit-risk system. Better methodologies and tools are required to support this integrated approach and adoption of a quality management system across global enterprise could achieve this.

Learning Objectives

At the conclusion of this short course, attendees will be able to:

- Learn about effective strategies and the current thinking on risk mitigation in the context of benefit throughout the product life cycle.
- Understand how to access to robust evidence about emerging risk.
- Discover what the principles are for proportionate risk based assessment.
- Conquer those hurdles which get in the way to a systematic approach by reflecting on how these might be tackled

Target Audience

Professionals in companies or regulatory authorities who are involved in pharmacovigilance operations and with responsibilities for post marketing clinical safety including those who are involved in:

- | | |
|-------------------------------------|---|
| • Pharmacovigilance | • Data analysis |
| • Regulatory | • Epidemiology |
| • Clinical research | • Labelling |
| • Risk management | • Quality assurance and compliance |
| • Medical product safety assessment | • Qualified Person for Pharmacovigilance (QPPV) |

Short Course 7 | Monday 16 April | 14:00-17:30**Helvetia 3 (Swissotel)****GUIDANCE FOR PATIENT INVOLVEMENT IN PHARMACEUTICAL INDUSTRY-LED RESEARCH**

Tamás Bereczky, Communications Advisor, European AIDS Treatment Group (EATG), Belgium

There is an increasing need to draw on patient knowledge and experience in order to understand what it is like to live with a specific condition, how care is administered and the day-to-day use of medicines.

Structured interaction with patients of all age groups and across conditions, their representatives and other stakeholders is necessary and allows the exchange of information and constructive dialogue at national and European level where the views from users of medicines can and should be considered. It is important to take into account that healthcare systems as well as practices and legislation might differ.

It is acknowledged that the patients' contribution to the discovery, development and evaluation of medicines enriches the quality of the evidence and opinion available. Existing codes of practice for patient involvement with various stakeholders do not comprehensively cover the full scope of research and development (R&D). EUPATI has published guidance which aims to support the integration of patient involvement across the entire process of medicines research and development.

EUPATI has developed these guidance documents for all stakeholders aiming to interact with patients on medicines research and development (R&D). This training will use hands-on exercises and case studies to illustrate the considerations that must be made when deciding to engage patients, and offer advice on how this can be done in different settings. Since there is no one-size fits all when it comes to incorporating patient engagement processes into existing workflows, participants will be guided by the trainers and group discussions on when it is appropriate to deviate from guidance provided to account for specific circumstances, national legislation or the unique needs of each interaction. This training will cover the following topics:

- Defining 'Patient'
- Transparency
- Suggested working practices
- Identifying Patients
- Compensation
- Written Agreements

Learning Objectives

At the conclusion of this short course, attendees will be able to:

- Identify opportunities where patients can be meaningfully engaged in all stages of medicines R&D
- Apply best practices to in-company workflows and SOPs when working with patients
- Adapt the values of guidance for patient engagement as necessary to comply with legislation and in-company policy

Target Audience

Professionals working in pharmaceutical industry R&D (discovery, clinical, regulatory, patient relations, communications) looking to establish partnerships to actively engage with patients, patient advocates, and representatives of patient organisations in a fair and meaningful manner.

OPTIONAL SHORT COURSES

Short Course 5 | Tuesday 17 April | 09:00-12:30

Kairo 1-2

GENOMICS IN CLINICAL DEVELOPMENT

Thomas Szucs, ECPM, University of Basel and Helsana Health Insurance, Switzerland

Urs Meyer, Biocenter, University of Basel, Switzerland

Genomics is an emerging field using genetic information of individual patients as basis for diagnostic or therapeutic decision-making. Knowledge of all the human genes and their functions would allow effective preventive measures, and change drug research strategy and drug discovery development processes. The potential implication of genomics and pharmacogenomics in clinical research and clinical medicine is the possibility to treat diseases according to genetic and specific individual markers, selecting medications and dosages that are optimised for an individual patient. The possibility of defining patient populations genetically may improve outcomes by predicting individual responses to drugs, and could improve safety and efficacy.

Genomic medicine already has a recognised impact in diverse fields of oncology, pharmacology, rare and undiagnosed diseases. Identification of genetic causality of diseases enables new approaches in drug discovery and development, followed by promising new diagnostic and therapeutic options. Consequently, reimbursement strategies need to be adapted to these advanced concepts.

Genomics in Clinical Development

- Introduction to molecular-genetic principles
- Potential of genomic medicine
- Challenges and limitations
- Legal and ethical aspects

Pharmakogenomics

- Genetics and drug effects and mechanisms
- Drug interactions
- Pharmakogenomics/Pharmakogenetics in daily medical practice
- Preventive gene testing
- Outlook and future concepts

Personalised Medicine

- Targeted prevention and therapy
- Clinical application of personalised medicine
- Economical aspects
- Outlook and future concepts

Learning Objectives

At the conclusion of this short course, attendees will be able to:

- Identify and appraise the basic concepts of genomic medicine
- Outline the impact of genomic information on future drug development, disease risk identification and diagnosing
- Explain the impact of genomic medicine on therapeutic decision making, drug selection and personalised dosing
- Determine frontiers and potential risk of genomic medicine

Target Audience

Professionals working in industry, regulatory authorities or academia, who are interested to get insights into the basic concepts and future impacts of genomic medicine in drug development.



Short Course 4 | Tuesday 17 April | 09:00-12:30

Shanghai 1-2

THE SCIENCE OF LAY LANGUAGE COMMUNICATION APPLIED IN A PHARMACEUTICAL CONTEXT: READABILITY AND UNDERSTANDING OF DOCUMENTS

Thomas M. Schindler, Head Medical Writing Europe, Boehringer-Ingelheim Pharma GmbH, Germany

Claudia Thoms, Institute of Communication Science and Theory of Communication, University of Hohenheim, Germany

Oliver Haug, Managing Director, H&H Communication Lab GmbH – The Readability Resource, Germany

This course will present the scientific background and the application of readability concepts for documents in the pharmaceutical industry. An overview of the history of readability research and introduce the different methods for the assessment of readability will be provided. Besides different readability formulas (Flesh-Kincaid Reading Ease, LIX, SMOG & Co.), qualitative models for the ease of understanding (e.g. Hamburg model) will be introduced. The strength and weaknesses of the various instruments will be discussed. To set the context the results of recent international literacy surveys will be summarised and the impact of their findings on the writing of documents for lay audiences assessed.

The second part will summarise the typical barriers for comprehension of written material and will show real-world solutions. Using examples from lay summaries and informed consent the impact of terminology, sentence length, word choice, and tonality on the ease of understanding will be demonstrated. The importance of the adequate structuring and layout of text, especially for readers with limited reading skills will be highlighted. Participants will learn different ways of establishing quality gates and benchmarks for lay-friendly text, from implementing writing rules to the management of terminology and the maintenance of a lay language glossary. A short in-class exercise will help participants to apply the information to the writing and improving of a pharmaceutical text.

Learning Objectives

At the conclusion of this short course, attendees will be able to:

- Assess the usefulness (and also the limits) of the different instruments used to assess the readability as well as the ease of understanding (Hamburg Index) of texts.
- Explain the importance of sentence length, word choice, layout and tonality and other factors related to the understanding of texts.
- Recognise factors to be taken into account for effective communication with a lay audiences
- Develop an approach for implementing company standards for the writing of lay-friendly texts

Target Audience

Professionals involved in the writing of documents for study participants to either increase recruitment or retention and people active in the writing of lay summaries of clinical study results or similar documents. This includes people in clinical operations, medicine, and medical writing.





DIA Europe 2018

SPECIAL SESSIONS



WHO/Swissmedic Signature Session

Tuesday 17 April | 09:00-10:30



TOWARDS ACCESS 2030: HOW CAN STRENGTHENING OF REGULATORY SYSTEMS CONTRIBUTE?

Session Chair:

Petra Dörr, Deputy Executive Director, Swissmedic, Switzerland

Various initiatives and programs are under way to improve access to quality medicines in low- and middle-income countries (LMIC). An important component of achieving this goal is to strengthen the regulatory systems of those countries. Many stakeholders (and many resources) are involved and engaged. However, what does Regulatory Systems Strengthening (RSS) actually mean in the context of Access 2030 in LMICs and do all these efforts show tangible results? What are the outcomes we are trying to achieve through RSS and how can we improve these outcomes?

Keynotes:

Towards access 2030: An Overview of WHO Efforts in Regulatory Systems Strengthening

Emer Cooke, Head, Regulation of Medicines and Other Health Technologies, Department of Essential Medicines and Health Products, WHO, Switzerland

What Can Regulators in LMIC Do to Better Utilize the Scarce Resources in Order to Improve the Access to Priority Medicines?

Mimi Darko, Chief Executive Officer, Food and Drugs Authority, Ghana

Multi-stakeholder Panel:

Moderator:

Murray Lumpkin, Deputy Director – Integrated Development (Regulatory Affairs), Bill and Melinda Gates Foundation, USA

Panelists:

Thomas Cueni, Director General, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), Switzerland

Petra Dörr, Deputy Executive Director, Swissmedic, Switzerland

Guido Rasi, Executive Director, European Medicines Agency (EMA), EU

Nicola Bedlington, Secretary General, European Patients' Forum, Belgium

Alex Schulze, Co-Head Division Global Programme Health, Swiss Agency for Development Cooperation, Switzerland

Hiiti Sillo, Group Lead, Country Regulatory Strengthening, WHO, Switzerland

Nathalie Strub Wourgraff, Medical Director, Drugs for Neglected Diseases initiative (DNDi), Switzerland



IMI PREFER Satellite Session

Tuesday 17 April | 09:00-10:30



PATIENT PERSPECTIVE IN BENEFIT-RISK ASSESSMENTS DURING THE MEDICAL PRODUCT LIFE CYCLE

Session Chair:

Conny Berlin, Global Head, Quantitative Safety and Epidemiology, Novartis; PREFER Industry Lead, Switzerland

Patient involvement in development of medicinal products is a topic rapidly evolving. However, how can patient preferences be elicited? Can it be used for regulatory decision making about benefits and risks of medicinal products?

This session presents expectations, needs and concerns of different stakeholders and promising approaches how to address these.

Exploring and Eliciting Patient Preferences: Why, When and How

Esther de Bekker-Grob, Associate Professor of Health Economics and Health Preferences, Erasmus School of Health Policy and Management, Erasmus University, Netherlands

Patients as Collaborators in Research

Isabelle Manneh-Vangramberen, Projects Coordinator, European Cancer Patient Coalition (ECPC), Belgium

Patient Preference Studies in Regulatory Decisions: Opportunities and Challenges

Sabine Haubenreisser, Principal Scientific Administrator, International Affairs, European Medicines Agency (EMA), EU

DIA Europe 2018

OPENING KEYNOTE SESSION

Keynote Session

Tuesday 17 April | 16:00-18:00

A DIGITAL REVOLUTION AT THE CROSSROADS OF HEALTHCARE



George Savage, MD

Co-Founder, Chief Medical Officer
Proteus Digital Health

George will bring his experience with Proteus' ingestible sensor platform as a case study, together with other examples across Digital Medicine. He will be joined by the DIA Europe Steering Committee to examine a balanced perspective on the future of digital technology through topics such as:

- Development Hurdles
- Approval, Access and Acceptance
- Behaviours and Adherence
- Privacy Challenges
- Technological Opportunities

BIOGRAPHY

Dr. George Savage is Chief Medical Officer and Co-Founder of Proteus Digital Health, and formerly the company's vice president of research and development. He sees Digital Medicines as an invaluable collaboration platform for patient and physician, integrating information about a patient's response to therapy directly into everyday healthcare.

George is focused on developing the clinical and economic evidence needed to secure global regulatory approvals and spur widespread adoption of Proteus' ingestible sensor platform. He is a member of the team of leaders from both Otsuka and Proteus that created and secured FDA approval for Abilify MyCite®, the world's first Digital Medicine manufactured with an integrated ingestible sensor.

He serves on the board of the California Life Sciences Association, the Boston University College of Engineering advisory council, and in 2016 was elected a Fellow of the American Institute for Medical and Biological Engineering.



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DIA

DIA Europe 2018



DIAMond Sessions are Tuesday-Thursday, and include 10 global hot topics with regulatory, payer, industry, and patient perspectives. These panel conversations are can't-miss opportunities to listen to and engage with many of the key stakeholders involved in each topical area.

DIAMond Session 1

Tuesday 17 April | 11:00-12:30



EUROPEAN REGULATORY TOWN HALL MEETING: EMA RELOCATION AND IMPLICATION FOR CENTRALISED ACTIVITIES

Moderator:

Melanie Carr, Head of Stakeholders and Communication, European Medicines Agency (EMA), EU

The European Regulatory Town Hall will provide an opportunity to update on recent developments and future direction of the EMA, the European Commission and the EU regulatory network, with specific focus on the relocation of the EMA and the business continuity plans that are in place.

- Come listen to the latest issues from a panel consisting of senior leadership from the EMA and National Competent Authorities.
- Update on timelines for EMA's relocation and next steps
- Business continuity plans and measures being taken to address stakeholders needs
- Spotlight on EMA's priorities to 2020
- Update from the European Commission on the state of play and next steps
- Work ongoing to prepare for Brexit from CHMPs perspective
- Response of the European Medicines Regulatory Network to prepare for Brexit
- Stakeholders expectations for Brexit and beyond

Panelists:

Nicola Bedlington, Secretary General, European Patient's Forum, Belgium

Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, MPA, Sweden

Nathalie Moll, Director General, EFPIA, EU

Csilla Pozsgay, Director General, National Institute of Pharmacy and Nutrition, Hungary

Guido Rasi, Executive Director, European Medicines Agency (EMA), EU

Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, MPA, Sweden

DIAMond Session 2

Tuesday 17 April | 11:00-12:30



PAYER TOWN HALL MEETING: WHO FAIR PRICING

Moderator:

A.R. (Ad) Schuurman, Head of the International Department of the National Health Care Institute (ZIN), Netherlands

Discussions in health care are moving from innovation and science to economics and affordability. Due to current developments in technology (many new, effective products), combined with high prices demanded by companies, the sustainability of health care systems is threatened. Expensive treatments for some patients displace effective treatments for other patients: the concept of solidarity, on which our health care systems are built, is disappearing.

In this session we will explore the possibility of Fair Pricing by turning the process upside down: Can society decide the price for the products, treatments and healthcare they want access to? If so, can manufacturers deliver these products at a price the health care system is willing and able to pay?

Andrew Rintoul, Innovation, Access and Use, WHO, Switzerland

Anna Bucsecs, Project Advisor, MoCA, Austria

Alexander Natz, Secretary General, EUCOPE, Belgium

Simone Boselli, Public Affairs Director, EURORDIS, France





DIA Europe 2018



DIAMond Session 3

Tuesday 17 April | 14:00-15:30



REALISING THE POTENTIAL OF FUTURE BIOMEDICAL INNOVATION: THE ROLE OF INTENSIFIED EU COOPERATION ON HTA

Moderator:

Tim Wilsdon, Vice President, Charles Rivers Associates, UK

In light of the evolving medicine development paradigm and the limited resources of national HTA agencies it becomes increasingly apparent that the currently national and sub-national approach to the assessment of relative clinical efficacy of medicines will unlikely allow EU patients to optimally realize the potential benefits of the evolving drug development paradigm and future biomedical innovation.

More recently the EMA and EUnetHTA have proposed a new framework for parallel early scientific advice which will be tested and further refined as part of the temporarily funded EUnetHTA JA3 programme. This development represents considerable progress, but the question remains how to increase efficiency and depth in the assessment of the relative clinical efficacy of innovative medicines at and after launch.

Participants of this panel will present their perspectives on how to further advance the EU cooperation between national HTA agencies, EMA and other stakeholders on the assessment of the relative efficacy of medicines.

- Why - Value proposition of EU REA collaboration
- How? Pilot experiences in EUnetHTA JA3 and the specific challenges of lifecycle approach
- How? Importance of constructive pre- and post-launch engagement between industry, EMA and HTA agencies including first experience with new joint EUnetHTA/EMA evidence plan platform and the role of the new "ad hoc" HTA/regulatory agencies SYNERGY group
- Outlook? The European Commission proposal for a sustainable cooperation post-2020

Panelists:

Michael Berntgen, Head of Product Development Scientific Support Department, European Medicines Agency (EMA), EU

Ansgar Hebborn, Head, Global Market Access Policy, F. Hoffmann-La Roche, Switzerland

Niklas Hedberg, Chief Pharmacist, Dental and Pharmaceutical Benefits Agency, TLV, Sweden

François Meyer, Advisor to the President, International Affairs, HAS, France

Ioana Siska, Policy Officer, Health Technology Assessment, European Commission, EU

DIAMond Session 4

Tuesday 17 April | 14:00-15:30



WILL BIG DATA CHANGE DRUG DEVELOPMENT'S APPROACH?

Session Chair:

Thomas Senderovitz, Director, Danish Medicines Agency (DKMA) Denmark

Will Big Data enable change in clinical development and how? Hear the view of senior leaders from the industry in this DIAMond session

Personalised Medicine, demand for early treatment, genomic treatment and increased complexity of trials force us to rethink the way we approach clinical development, moving from 7-12 years of work to 3-5 years for most of the products

- We need to understand how to increase the number of conclusive trials and come with smarter designs
- We must move away from the sequential RCTs to multi-channel studies of different type
- We need to understand how to leverage clinical care data and mHealth in addition to legacy clinical trial data
- We must adapt collaboration models between regulators/ HTA and sponsors
- We need to secure the right level of skill sets across the industry
- This will enable to bring drug faster to patients, at a more sustainable cost.

However it will change the risk paradigm, increasing risk during post approval

In this DIAMond Session chaired by Thomas Senderovitz, Director General Danish Medicines Agency, top leaders from regulatory and pharmaceutical organisations will share their view on the impact of Big Data in clinical development, submission and reimbursement.

Panelists:

Christa Wirthumer-Hoche, Chair, EMA Management Board; Head, AGES, Austria

Ameet Nathwani, Group Chief Medical Officer, Executive Vice-President, Sanofi, France

Dimitrios Athanasiou, Duchenne Patient Advocate, Muscular Dystrophy Association Hellas, Board Member in UPPMD and EMA Patient Expert for DMD, Greece

Sy Pretorius, Senior Vice President & Chief Scientific Officer, PAREXEL, USA

DIA Europe 2018



DIAMond Session 5

Tuesday 17 April | 11:00-12:30



INTERNATIONAL PHARMACOVIGILANCE

Session Chair:

Esteban Herrero-Martinez, Director Regulatory Policy and Intelligence, AbbVie, UK

Pharmacovigilance is of increasing focus and importance internationally. Although welcome, huge variations in approach, legislative maturity, resource and fast-moving change are a challenge for all. We all have a responsibility to support development of effective pharmacovigilance systems globally to protect patients and support medicine delivery. With multiple activities worldwide and scarce resources, important key stakeholders must understand each other's activities and support each other to achieve the same ultimate objectives.

A panel of experts (stakeholders, regulators, industry, emerging market) will discuss the latest issues.

Panelists:

Amr Saad, Founder, The Egyptian Pharmacovigilance Center (EPVC), Egypt

Bahija Gouimi, Founder, AMAL, Morocco

Raj Long, Senior Regulatory Officer, Integrated Development, Global Health, Bill and Melinda Gates Foundation (BMGF), UK

Emer Cooke, Head, Regulation of Medicines and Other Health Technologies, Department of Essential Medicines and Health Products, WHO, Switzerland

June Raine, Chair PRAC, Director Vigilance and Risk Management of Medicines Division, Medicines & Healthcare products Regulatory Agency (MHRA), UK

Sue Rees, EU QPPV, Executive Director, Global Safety, Amgen, UK

Xavier Kurz, Head of Surveillance and Epidemiology Service, European Medicines Agency (EMA), EU

DIAMond Session 6

Wednesday 18 April | 08:30-10:00



EVIDENCE GENERATION IN MEDICINES DEVELOPMENT FOR RARE PATIENT POPULATIONS: CHALLENGES AND OPPORTUNITIES

Session Co-Chairs:

Michelle Rohrer, Global Head of PD Regulatory and Policy at F. Hoffmann-La Roche and Genentech, Switzerland

Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, MPA, Sweden

This session will focus on challenges and opportunities on pre- and post-authorisation evidence generation in rare patient populations, as identified by patients, regulators, HTA bodies and industry. The discussion will center around the following topics: choice of control, endpoints (biomarkers, clinical outcomes, PROs), therapeutic indication, post authorisation evidence generation/ registries. Following a brief description of key challenges in four topic rounds the panel will bring in perspectives based on concrete cases and examples and discuss on opportunities and solutions. The session

will touch but not focus on real world data and as such complement other sessions on that theme.

Rob Hemmings, Statistics and Pharmacokinetics Unit Manager, Medicines and Healthcare products Regulatory Agency (MHRA), UK, UK

Niklas Hedberg, Chief Pharmacist, Dental and Pharmaceutical Benefits Agency, TLV, Sweden

Dimitrios Athanasiou, Duchenne Patient Advocate, Muscular Dystrophy Association Hellas, Board Member in UPPMD and EMA Patient Expert for DMD, Greece

DIAMond Session 7

Wednesday 18 April | 08:30-10:00



EXPLORING USE OF ARTIFICIAL INTELLIGENCE: TRUST IN TECHNOLOGY, OR TRUST IN EACH OTHER?

Moderator:

Patrick Brady, VP, Regulatory Policy and Intelligence, Bayer, USA

Technology is transforming how we do business. As technological capabilities such as artificial intelligence and machine learning rapidly advance, how will we work together and interact with such innovative technologies to augment knowledge and analytical capacity? What skills are needed for success and what does it mean for trust and relationships?

Panelists:

Detlef Hold, Global Strategy Lead Knowledge Cycling, PD Faster Filing PMO, Genentech/Roche, USA

Thomas Senderovitz, Director, Danish Medicines Agency (DKMA), Denmark

Elena Bonfiglioli, Regional Business Leader, Health and Life Sciences, Microsoft Corporation, EMEA, Belgium

DIAMond Session 8

Wednesday 18 April | 08:30-10:00



PATIENT CENTRICITY BEYOND THE TALK

Session Chair:

Bettina Ryll, Founder, Melanoma Patient Network Europe, Sweden

Patient-centricity is the talk of the day - but what does successful and systematic implementation really look like? What works? What doesn't? And why? Join us for an in-depth discussion about patient-centricity with thought leaders in their respective fields of work.

Panelists:

Philippe Legenne, Executive Medical Director, Amgen, Belgium

Christopher McCabe, Executive Director & CEO, Institute of Health Economics, Canada

Marisa Papaluca-Amati, Head of Scientific Support Office, Specialised Scientific Disciplines Department, European Medicines Agency (EMA), EU



DIA Europe 2018



DIAlogue SESSIONS

DIAlogue 1 - Session 1010

Tuesday 17 April | 13:00-15:30



THE NEW EMA FIRST-IN-HUMAN (FIH) GUIDELINE: NON-CLINICAL ASPECTS

Session Co-Chairs:

Salah-Dine Chibout, Global Head of Discovery and Investigative Safety (DIS) and Global Head Therapeutic Areas in Preclinical Safety, Novartis, Switzerland; Chair of InnoMeds, EFPIA

Jan Willem van der Laan, Senior Assessor Pharmacology- Toxicology, MEB and EMA Chair of Safety Working Party, Netherlands

The EMA has released the revised “Guideline on Strategies” to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products” on the 25th July 2017. This new guidance has come into effect on the 1st of February 2018. During this supersession (150 minutes duration) we will engage in a dialogue with a panel of different stakeholders (e.g. regulators, industry, CROs, academics, etc.) on the most important aspect of the guideline (nonclinical strategy, FIH-dose-selection, sentinel dosing, stopping dose criteria, protocol, etc.). Our aim is to align understanding and implementation of this new important document. Two real-life case studies from industry, differencing in the level of uncertainty, will be presented. Each case study will be followed by a panel discussion featuring non-clinical and clinical industry experts, and various representatives from European regulatory agencies.

Case Study 1

Joseph Brady, Senior Director, Pfizer, USA

Case Study 2

Andreas Hartmann, Executive Director Preclinical Safety, Therapeutic Area Head Neuroscience, Novartis, Switzerland

Panelists

Charles Benson, Medical Fellow, Eli Lilly & Co, USA

Roy Forster, Group Scientific Director, Citoxlab, France

Walter Janssens, Senior Assessor Preclinical Department Research & Development, Federal Agency for Medicines and Health Products, Belgium

Peter Pertel, Global Head of Translational Medicine for Infectious Diseases, Novartis Institutes for BioMedical Research, USA

Sarah Robertson, Senior Director, Clinical Pharmacology, Vertex, USA

Beatriz Silva Lima, NDA Advisory Board, UK

Elke Stahl, CTFG co-chair; Clinical Trial Unit, BfArM, Germany

Ulla Wandel Liminga, Scientific Director, Medical Products Agency (MPA), Sweden

Kirsty Wydenbach, Deputy Unit Manager, Clinical Trials Unit, Medicines and Healthcare products Regulatory Agency (MHRA), UK

DIAlogue 2 - Session 1104

Thursday 19 April | 08:30-10:00



THE ROLE OF UNMET NEED IN REGULATORY AND PRICING DECISION MAKING

Moderator:

Inka Heikkinen, Senior Scientist, DIA, Switzerland

Unmet need is an important criterion for medicines to qualify for facilitated and accelerated regulatory review and approval processes. Yet slightly different definitions of the term are used by the EMA. Some payers have special considerations for medicines of high unmet need, like the End of Life criteria in the UK. More often, however, when it comes to health technology assessment (HTA) and price negotiations, payers argue that unmet need is not well defined or not clearly demonstrated. Patients have another personal perspective. The lack of common interpretation leads to inconsistent signals for companies when looking at their RandD prioritisation models and the actual patient access. As a result, medicines that have achieved fast regulatory approval on grounds like unmet need may lose that advantage during the subsequent market access processes. In this dialogue session, we will explore two areas in detail:

Can stakeholders align on a common definition of unmet need that would provide more predictability for all?

Should there be a different assessment of price relative to value in drugs that address areas of unmet need?

Panelists:

Dimitrios Athanasiou, Duchenne Patient Advocate, Muscular Dystrophy Association Hellas, Board Member in UPPMD and EMA Patient Expert for DMD, Greece

Jens Grueger, Head of Global Pricing & Market Access, F. Hoffmann-La Roche, Switzerland

Niklas Hedberg, Chief Pharmacist, Dental and Pharmaceutical Benefits Agency, TLV, Sweden

Jordi Llinares Garcia, Head of Scientific and Regulatory Management, Human Medicines Evaluation Division, European Medicines Agency (EMA), EU

A.R. (Ad) Schuurman, Head of the International Department of the National Health Care Institute (ZIN), Netherlands

DIA Europe 2018

CONTENT HUB / ENGAGE & EXCHANGE



Content Hub talks are dynamic, inspired talks that will take place in the Innovation Theatre in the Exhibition Hall. Engage with fellow attendees who have designed a 30-minute presentation offering you rapid insight or a deeper perspective in a subject of value.

Wednesday, 18 April, 10:30-11:00

ENDPOINTS IN CLINICAL RESEARCH

David Montgomery, Vice President, Science Exchange, Oncology, Pfizer Ltd., UK



Wednesday, 18 April, 11:15-11:45

LESS THAN PERFECT? CLINICAL EFFICACY DATA SUPPORTING APPROVAL OF NEW DRUGS: FOCUS ON APPROVALS BASED ON A SINGLE PIVOTAL TRIAL

Anne Vinther Morant, Senior Specialist, Regulatory Science & Advocacy, H. Lundbeck A/S, Denmark



Wednesday, 18 April, 14:00-14:30

ENABLING AND CONSTRAINING FACTORS IN COMMERCIAL ATMP DEVELOPMENT: LEARNING FROM THE ESCHER- ATMP STUDY

Renske M.T. ten Ham, Division of Pharmacoeconomics and Clinician Pharmacology, Utrecht University, Netherlands



Wednesday, 18 April, 14:45-15:15

KEY LEARNINGS FROM THE FIRST EUROPEAN PATIENT ADVOCACY ADVISORY BOARD FOR LEBER'S HEREDITARY OPTIC NEUROTHETAPY (LHON)

Vanessa Ferreira, Patient Advocacy Manager Europe, Santhera Pharmaceuticals, Switzerland



Wednesday, 18 April, 16:00-16:30

DRIVERS, BARRIERS AND BENEFITS OF A UNIFIED CLINICAL OPERATING MODEL

Franciska Darmer, Vault eTMF Strategy, Veeva Systems, UK



Wednesday, 18 April, 16:45-17:15

THE MASTER'S DATA MANAGEMENT FROM THE 'SINGLE PLACE OF TRUTH'

Olaf Schoepke, Director of Strategic Development, Samarind Ltd., UK



Thursday 19 April 09:15-09:45

HOW PARTNERING WITH THE REGULATORY INTELLIGENCE FUNCTION ENABLES INNOVATIVE REGULATORY AND DRUG DEVELOPMENT STRATEGIES

João Duarte, Associate Director, Europe Regulatory Policy & Intelligence, Takeda, UK

Lucile de Champs, EU Regulatory Intelligence Lead, PDR, F. Hoffmann-La Roche, Switzerland



Share ideas, exchange experiences, and enhance your understanding of a topic that's important to you! Actively participate in this collaborative learning environment, with a 45-minute session led by a facilitator.

Wednesday, 18 April, 15:15-16:00

E&E: THE SHARED INVESTIGATOR PLATFORM – REVOLUTIONISING COMMUNICATION BETWEEN SITES & SPONSORS

Moderator:

Sylvia Eberhardt, Global Studies Leader, F. Hoffmann - La Roche, Switzerland

Come learn how 19 Industry sponsors have worked with investigators sites to create an innovative platform that will improve study conduct and remove significant administrative burden on investigator sites.



DIA Europe 2018

LEADER OF TOMORROW PROGRAMME

Pre-Conference Day | 16th April

15:00-17:00 SESSION LOT1 | VISITS AT INDUSTRY SITES

Three pharmaceutical companies based in Basel are opening their doors to young professionals and students to visit their facilities. The attendees will have the opportunity to:

- hear the story of the companies' most historical moments and milestones
- discover the life cycle of a product from a pool of molecules into a life saving treatment
- learn how companies operate and what different departments do
- exchange thoughts with the experts.

F.Hoffmann-La Roche	Novartis	Actelion
Grenzacherstrasse 124, 4070 Basel	MainGate, Fabrikstrasse 2, 4056 Basel	Hegenheimerstrasse 95, 4123 Allschwil
Welcoming Words	Welcoming Words	Welcoming Words
Company Intro and Outlook	Personal Success Stories	Company Intro and Outlook
Facility visit	Facility visit	Facility visit
Closing Words	Closing Words	Closing Words

Who is it for? Young professionals and students (see the criteria at the end)

Registration is complimentary but mandatory to receive a pass to enter. Registrations cannot be processed on the day.

Important! The attendees will have to pre-register at this form for the 16th April activities.

Registrations are closed.

18:00-19:30 PROFESSIONAL DEVELOPMENT SESSION

SESSION LOT2 | REGULATORY AFFAIRS: ONE AREA, MANY CAREERS! | HELVETIA 3 (SWISSOTEL)

Speakers:

Cordula Landgraf, Head of Networking, Swissmedic, Switzerland

João Duarte, Associate Director, Europe Regulatory Policy & Intelligence, Takeda, United Kingdom

Sini Eskola, Director, Regulatory Affairs, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

Cécile Bertin, Associate Regulatory Program Manager, F. Hoffmann La Roche, Switzerland

Annette Mollet, Head Education & Training, University of Basel, Switzerland

Regulatory Affairs (RA) professionals tend to start their career in the regulatory area either by chance or by a very informed decision. Either way, they tend to lead quite successful careers, either in the regulatory field, sometimes in another field by using skills and competences mastered in regulatory in other areas. However, not two regulatory careers are the same.

Regulatory affairs professionals are needed now more than ever: technology advances are shaping the development of medicines and targeted treatments at a very rapid speed, while patient accessibility and use of medicines remains a key priority for health systems in Europe. Proficiency in medicines regulation is required by many stakeholders to address these challenges.

This Workshop intends to showcase some of the most common careers in regulatory affairs and hopefully inspire young professionals in the area to develop to their full potential. Speakers from regulatory affairs in the industry, regulatory authority, trade association and academia will outline their initial career experiences and the positive impact that regulatory affairs had in their professional lives. A panel discussion will also take place to advise and help young professionals on their first steps in career development.

SESSION LOT3 | VALUE AND ACCESS | HELVETIA 4 (SWISSOTEL)

Speaker:

Vaidyanathan Srikant, Senior Partner and Managing Director, The Boston Consulting Group (BCG), Switzerland

Martina Laus, Group Quality External Engagement, Novartis

Market Access as a function has been growing in importance over the last decade. This trend is expected to accelerate given the pace of change across all aspects of the healthcare value chain (e.g. informatics, comprehensive diagnostic, new medicine technology, increasing cost pressure, personalization). In this session we will start with where Market Access as a function is coming from and where we expect it to be heading and conclude with the new capabilities that would be needed to be successful in Market Access.

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SESSION LOT4 | MAKING THE MOST OF MENTORING

Healthcare Businesswomen's Association (HBA)

Penelope Wood, Head, Cross-Portfolio Insights, F. Hoffmann-La Roche, Switzerland

Eva McLellan, Director, Oncology Pipeline, F. Hoffmann-La Roche, Switzerland

Gabriele Matthias, Senior Scientific Associate, Friedrich Miescher Institute for Biomedical Research, Novartis, Switzerland

Svetlana Daguerre, Regulatory CMC Senior Manager, Novartis, Switzerland

This session will give you an opportunity to understand how to build a successful mentoring relationship. Learn about different types of mentor/mentee arrangements, how to identify a suitable mentor, how to approach one, what to say & what to expect. Learn about your own role as a mentee, and how it may help you in your personal & professional development. You will also have the chance to hear from senior leaders & ask questions of those who have themselves benefited from rewarding mentoring relationships.

19:30- 21:00 | SESSION LOT 5

LEADER OF TOMORROW: NETWORKING RECEPTION

We are pleased to welcome the local young professionals and students as well as the ones traveling from abroad to the pre-conference networking reception, specially designed for this particular groups of professionals. Take the chance to meet your peers and network with some of the DIA Europe exhibitions in a very relaxing atmosphere.

Day 1 | 17 April

09:00-10:30 | SESSION LOT6 | LEADER OF TOMORROW: VENI, VIDI, VICI | BOSTON 1-2

João Duarte, Associate Director, Europe Regulatory Policy & Intelligence, Takeda, United Kingdom

Sini Eskola, Director, Regulatory Affairs, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

Cécile Bertin, Associate Regulatory Program Manager, F. Hoffmann La Roche, Switzerland

Audience: Professionals with maximum 5 years of experience

The life science environment offers various opportunities in different fields and multiple career paths are possible.

This session intends to help young professionals in approaching the key milestones and decisions at the beginning of their careers and help them finding their best individual career path.

In an open discussion, speakers will share personal career stories and try to tackle key questions one can ask when starting its career.

11:00-12:30 | SESSION LOT7 | LEADER OF TOMORROW: CREATING RELEVANT OPPORTUNITIES | BOSTON 1-2

Alex Khatuntsev, Senior Vice President, Head of Human Resources, Idorsia Pharmaceuticals, Switzerland

Martina Laus, Group Quality External Engagement, Novartis

Audience: Students

In this session you will have an opportunity to address your questions related to identifying the most suitable to your values and interests career path in the life science industry. You will learn how to identify and develop your skillset enabling your success, get practical recommendations from the industry professionals on effectively navigating through recruitment process, and find out more about the differences between working for a "big pharma" or a "small biotech". This tutorial, we believe, will raise your awareness about possible career choices, future opportunities, and about various ways for continuous personal and professional growth.

12:30 - 14:00 LEADER OF TOMORROW LUNCH (COMMUNITY AREA)

Day 2 | 18 April

LEADER OF TOMORROW: OPPORTUNITIES FOR ENGAGEMENT AT THE MEETING

Day 3 | 19 April

10:00 - 12:30 SPEED NETWORKING WITH EXPERTS



DIA Europe 2018

SCIENTIFIC PROGRAMME

TOPIC A

CAN REGULATORS AND HTA BODIES CREATE SYNERGIES FOR PATIENT ACCESS?

Topic Leader:

Jordi Llinares Garcia, Head of Scientific and Regulatory Management, Human Medicines Evaluation Division, European Medicines Agency (EMA), EU

Session 0101 | Wednesday 18 April | 10:30-12:00

COLLABORATION ACROSS DECISION MAKERS TO FACILITATE PATIENT ACCESS: RECENT ADVANCES AND FUTURE NEEDS

Session Chair:

Michael Berntgen, Head of Product Development Scientific Support Department, European Medicines Agency (EMA), EU

It is widely recognised that there is a need to ensure collaboration across decision makers in healthcare to facilitate patient access to innovation. Scoping such collaboration requires reflections based on wide ranging views from multiple stakeholders. However there is rarely an articulation what concretely these different groups are expecting from each other and whether this is addressed by actions.

These impulse statements will be addressed:

- The interrelationship of significant benefit and added value – how to bridge the gap?
- Introducing innovation in clinical practice – which guidance and recommendations are necessary?
- Designing a data package that meets the review by decision makers and the internal “TPP” – what influences do we see?
- Planning for what is becoming available for review and access – which information do we need?
- Transfer of evidence (aka extrapolation) – which opportunities and challenges exist?
- Optimisation of development plans – how to plan for post-licensing evidence generation?

Panelists

Daniel O'Connor, Medical Assessor, Medicines and Healthcare products Regulatory Agency (MHRA); Member COMP, UK

Gesa Pellier, Head DRA Europe, Novartis, Basel

Donald Singer, Executive Committee, European Association for Clinical Pharmacology and Therapeutics (EACPT), UK

Peter Mol, Vice-Chair SAWP; Head Clinical Assessor, Medicines Evaluation Board, Netherlands

Deborah Morrison, Senior Scientific Advisor, NICE, UK

A.R. (Ad) Schuurman, Head of the International Department of the National Health Care Institute (ZIN), Netherlands

Session 0102 | Wednesday 18 April | 14:00-15:15

REGULATORY ACCESS PATHWAYS TO FACILITATE EARLY ACCESS AND HTA SYNERGIES

Session Chairs:

Jordi Llinares Garcia, Head of Scientific and Regulatory Management, Human Medicines Evaluation Division, European Medicines Agency (EMA), EU

Indranil Bagchi, Vice President and Franchise Head, Global Value & Access, Novartis, USA

In this session we will discuss the experience of early access pathways from a regulatory point of view and how these instruments are experienced by industry stakeholders. In addition, the point of view of HTA agencies, in particular HTA uptake of the outcomes of these instruments and how the remaining uncertainties impact HTA decisions will also be discussed. The influence/opportunity of current initiatives such as parallel advice and late dialogues with regulators can be explored in this context.

EMA View

Sabine Haubenreisser, Principal Scientific Administrator, International Affairs, European Medicines Agency (EMA), EU

Faster Regulatory Approvals and Better Access for Patients – Progress towards Squaring the Circle

Simon Bennett, Director, Global Regulatory Policy EU Lead and GEMS Interim Lead, Biogen Ltd, UK

HTA Body View on Early Access Experiences

François Meyer, Advisor to the President, International Affairs, HAS, France

Session 0103 | Wednesday 18 April | 16:00-17:30

ENHANCING EVIDENCE GENERATION ACROSS THE PRODUCT LIFE CYCLE

Session Chair:

Alison Cave, Principal Scientific Administrator, European Medicines Agency (EMA), EU

Through the use of specific case studies the session will highlight opportunities across the product life cycle but also describe the challenges in producing robust and reproducible data of sufficient quality for regulatory decision making.

Use of Registry Data for Defining Clinical Care Pathways, Unmet Need and the Future – Registry Trails

Edward McKone, Professor, School of Medicine, St. Vincent's University Hospital, Ireland

Upholding and Enhancing Robust and Effective Real World Evidence Generation

Andrew Bate, Senior Director, WSR Epidemiology Group Lead, Pfizer, UK

John Rigg, Head of Predictive Analytics, IQVIA, UK

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SCIENTIFIC PROGRAMME

Panel with

David Martin, Associate Director for Real World Evidence Analytics, Food and Drug Administration (FDA), USA

Deborah Morrison, Senior Scientific Advisor, NICE, UK

Session 0104 | Thursday 19 April | 08:30-10:00

ATMPs

Session Chair:

Ana Hidalgo-Simon, Head of Specialised Scientific Disciplines, European Medicines Agency, EU

Parallel Scientific Advice ATMPs with HTAs

Anja Schiel, Senior Adviser / Statistician, Unit for HTA and Reimbursement, Norwegian Medicines Agency, Norway

ATMPs Access to Patients and the HTA Perspective

Rimma Berenstein, Scientific Advisor, Pharmaceuticals Department, Gemeinsamer Bundesausschuss (Federal Joint Committee), Germany

Panel discussion with **François Meyer**, Advisor to the President, International Affairs, HAS, France and **Deborah Morrison**, Senior Scientific Advisor, NICE, UK



TOPIC B

WHAT ARE NECESSARY STEPS TOWARDS OUTCOME-DRIVEN HEALTH SYSTEMS?

Topic Leaders:

Indranil Bagchi, Vice President and Franchise Head, Global Value & Access, Novartis Oncology, USA

There is a lot of discussion currently on the shift from volume-based to value-based care delivery. This requires adequate infrastructure, capability and outcomes assessment to ensure appropriate reward for innovation and value delivered. In multiple sessions, the topic of 'Outcomes Driven Health Systems' will address key questions related to this theme.

Session 0201/0401 | Wednesday 18 April | 10:30-12:00

HAS THE TIME FOR BIG/REAL WORLD DATA FINALLY ARRIVED?

Session Chair:

Shahid Hanif, The Association of the British Pharmaceutical Industry, UK

This session will discuss the current and future use of Big Data to support regulatory decision-making and reimbursement, identifying the outcomes that demonstrate value through the use of Big Data, and whether these data are accessible. In addition, it will describe how Big Data can be used to inform operational predictability and scientific validity of study conduct.

Using Big Data in Regulatory and Health Care Decision Making – Where Are We Now, and What about the Future?

Andrew Roddam, Vice President & Global Head Epidemiology, GSK, UK

IMI Big Data for Better Outcomes: Supporting the Evolution towards Outcomes-Focused, Sustainable Healthcare Systems in Europe

Shahid Hanif, The Association of the British Pharmaceutical Industry, UK

Clinical Research: The Application of Geographically Relevant Data for Operational Predictability and Scientific Validity

Louise Parmenter, VP, Global Head, Scientific Affairs, IQVIA, UK

Panel Discussion with **David Martin**, Associate Director for Real World Evidence Analytics, Food and Drug Administration (FDA), USA



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Electronic Data and Document Management – The Next Industrial Revolution

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SCIENTIFIC PROGRAMME

Session 0202 | Wednesday 18 April | 14:00-15:15

PATIENT CENTRICITY – WHAT DOES IT REALLY MEAN?

Session Chair:

Bettina Ryll, Founder, Melanoma Patient Network Europe, Sweden

Of late, there has been lot of focus on patient centricity. This session will explore critical questions around this topic: How can a patient-centered approach become a comprehensive mission for health care? How can we focus and reflect on patient priorities and experience as a form of evidence?

Patient-Generated Data: Are We Prepared for the Tsunami?

Alison Bourke, Scientific Director, IQVIA, UK

Patient Communities, Data Generation and Improved Health Outcomes

Christopher McCabe, Executive Director & CEO, Institute of Health Economics, Canada

All.Can – Using Patient-Based Perceptions of Waste to Improve Outcomes and Sustainability of Cancer Care

Suzanne Wait, The Health Policy Partnership, UK

Session 0203 | Wednesday 18 April | 16:00-17:30

HEALTH ECONOMICS OF FUTURE THERAPEUTIC CONCEPTS

Session Chair:

Annette Mollet, Head of Education and Training, ECPM Institute of Pharmaceutical Medicine, University of Basel, Switzerland

Health systems throughout the world are faced with demands for additional services and rising costs. Health care decision makers need to identify efficient medical strategies and to choose the right interventions to maximise the achievable benefits for the patient within the available budgets. The concept of personalised medicine not only promises to enhance the life of patients and to increase the quality of clinical practice and targeted care pathways, but also to lower overall health care costs through early-detection, prevention, accurate risk assessments and efficiencies in care delivery. In this session, the view and impact of both the pharmaceutical industry and the health care insurance are introduced. In addition, current cases from an EBE-EFPIA study comparing different European countries will highlight the value of personalised medicine and the access for patients.

The Rationale for Personalised Health Care

Guido Papa, Head, Pricing & Market Access Excellence, F.Hoffmann - La Roche, Switzerland

The Case for the Value of Personalised Medicine – A European Perspective

Eelko den Breejen, Vice Chair EBE/EFPIA Personalised Medicine Working Group; International Health Policy Leader, F. Hoffmann-La Roche, Switzerland

Making Personalised Health Care Work

Thomas Szucs, ECPM, University of Basel and Helsana Health Insurance, Switzerland

Session 0204 | Thursday 19 April | 08:30-10:00

VALUE AND ACCESS – HOW DO WE STRIKE A BALANCE BETWEEN BOTH?

Session Chair:

Indranil Bagchi, Vice President and Franchise Head, Global Value & Access, Novartis Oncology, USA

Ensuring access at appropriate value is a balancing act. This session will address some of the key questions on the topic: How can we improve access to medicines, while ensuring value for innovation is maintained? Is there a way to balance different stakeholder perspectives, when it comes to value and outcomes assessment? Session will include a depiction of patient, payer and regulatory perspectives, before a discussion on harmonisation and a path forward.

Managed Access Agreements – A New Frontier in Germany?

Evert Jan van Lente, Director EU-Affairs, AOK Bundesverband (Federal Insurer), Germany

Outcome-Focussed Access Agreements: Payer Perspectives

Edmund Jessop, Public Health Adviser, Specialised Commissioning Team, National Health Service, UK

Factors Leading to Difference between Regulatory and Market Access Decisions for Drugs in Six Cancers Internationally

Jan McKendrick, Senior Director, PRMA Consulting, UK

Session 0205 | Thursday 19 April | 10:30-12:00

SUSTAINABILITY OF HEALTH CARE FUNDING - ARE WE PREPARED FOR TOMORROW'S FUNDING CHALLENGE?

Session Chair:

Vaidyanathan Srikant, Senior Partner and Managing Director, The Boston Consulting Group, Switzerland

The current system of funding for health care is not sustainable. This session will brainstorm solutions for this challenge. Multi-stakeholder working group (e.g. Regulators, HTA members, Payers, Policy makers, Pharmaceutical Industry) across the globe, to explore sustainable options addressing the financing challenge health care systems are likely to face in the coming years.

Access to Medicines Innovation: Seven Points to a Sustainable System

Indranil Bagchi, Vice President and Franchise Head, Global Value & Access, Novartis Oncology, USA

Panel discussion:

Luca Pani, Department of Psychiatry and Behavioral Sciences University Of Miami School Of Medicine, USA

Panos Kanavos, Deputy Director, LSE Health, London School of Economics, UK

Ken Kaitin, Professor and Director, Tufts Center for the Study of Drug Development, USA

DIA Europe 2018

SCIENTIFIC PROGRAMME

TOPIC C

MEDICINES OF THE FUTURE: WHAT WILL INNOVATION NEED AND BRING?

Topic Leaders:

Anthony Humphreys, Head of Division, Scientific Committees
Regulatory Science Strategy, European Medicines Agency (EMA), EU

Thomas Metcalfe, Strategic Innovation Leader, Pharma Development F.
Hoffmann-La Roche, Switzerland

Session 0301 | Wednesday 18 April | 10:30-12:00

NOVEL THERAPEUTIC APPROACHES

Session Chair:

Dolca Thomas, Vice President Translational Medicine for
Immunology, Inflammation and Infectious Disease,
F. Hoffmann-La Roche, Switzerland

Many novel therapeutic approaches are on the horizon which the promise to address the unmet needs of patients. However, some of these approaches will challenge current approaches to drug development, regulation and the health technology assessment. A multi-stakeholder round table.

Panelists:

Sheuli Porkess, Interim Director Research, Medical & Innovation, ABPI, UK

Corinne de Vries, Head of Science and Innovation Support, European
Medicines Agency (EMA), EU

Niklas Hedberg, Chief Pharmacist, Dental and Pharmaceutical Benefits
Agency, TLV, Sweden

Tomasz Lawniczek, Clinical Science Specialist, Novartis, Switzerland

Session 0302 | Wednesday 18 April | 14:00-15:15

DIGITAL HEALTH - WHAT IS THE LANDSCAPE LOOKING LIKE FOR MEDICINES?

Session Chair:

Chris Walker, VP Head of Regulatory Affairs Europe Amgen, UK

The advent of digital health is set to revolutionise healthcare, establishing new technologies and data insights that deliver greater value to healthcare systems, enhancing clinical decision making and ultimately improving outcomes for patients. This session will provide an overview of the current state of play of policy and regulatory developments in Europe so that medicines developers and digital technology providers for the life sciences sector should be aware of.

Digital Biomarkers – Case Study

Christian Gossens, Global Head, Early Development Workflows, F.
Hoffmann-La Roche, Switzerland

New Technologies and New Approaches to Involve Patients to Improve Medicinal Product Information

Gesine Bejeuhr, Regulatory Affairs/Quality, vfa, Association of Research-
Based Pharmaceutical Companies, Germany

The Regulator's View on the Need to Regulate and Challenges to Keep Pace with Technology Development

Marisa Papaluca-Amati, Scientific Committees Regulatory Science
Strategy, European Medicines Agency (EMA), EU

Panel Discussion with **Ernst Hafen**, Professor, Institute Molecular Systems
Biology, ETH; MIDATA, Switzerland

Session 0303 | Wednesday 18 April | 16:00-17:30

THE NEW DATA ECOLOGY - HOW TO INCENTIVISE AND ENABLE MORE SHARING OF DATA?

Session Chair:

Brigitta Monz, Global Head Real World Data, Immunology,
Infectious Diseases, Ophthalmology & Neuroscience,
F. Hoffmann-La Roche, Switzerland

In an era where access to data and integration of different data sets is seen as being essential to generate new insights and drive new discoveries, what approaches should be taken to encourage sharing of data between patients, health care systems, academic institutions and industry? A multi-stakeholder round table.

Data Sharing in Oncology – Research Organisations, Academic Institutions and Industry

Rolf Stahel, Chair Comprehensive Cancer Center Zürich, Clinic of
Oncology, University Hospital Zürich, Switzerland

Sharing of Data for Observational Studies: Opportunities and Challenges

Shuvayu S. Sen, Executive Director, CORE, Merck Research Laboratories,
USA

Data Sharing – The Regulator's Perspective on Optimal Use Pre- and Post-Approval - What is and Should be Possible?

Nikolai Constantin Brun, Danish Medicines Agency (DKMA) Denmark

ROE- Return on Engagement - Data Sharing from the Patient Advocacy Perspective

Bettina Ryll, Founder, Melanoma Patient Network Europe, Sweden

Session 0304 | Thursday 19 April | 08:30-10:00

COLLABORATIVE FRAMEWORKS AND PUBLIC PRIVATE PARTNERSHIPS (PPPS) AS DRIVERS OF INNOVATION

Session Chair:

Corinne de Vries, Head of Science and Innovation Support,
European Medicines Agency (EMA), EU

A condensed overview of the current state of play when it comes to PPPs from an EU perspective and their key role in bringing together the latest research and cutting-edge technology to boost innovation and entrepreneurship in the pharmaceutical sector, to meet the challenges faced by patients and society as a whole.



DIA Europe 2018

SCIENTIFIC PROGRAMME

Accelerating Innovation through Public Private Partnerships: IMI as an Example

Pierre Meulien, Executive Director, Innovative Medicines Initiative (IMI), Belgium

Advancing Innovation with Novel Methodologies - C-Path's PPP Approach to Achieving Regulatory Acceptance

Martha Brumfield, President and Chief Executive Officer, Critical Path Institute, USA

The IMI SAFE-T Consortium: Engaging with Regulators to Enhance Success and Opportunities of Public Private Partnerships

Gerd A. Kullak-Ublick, Global Head, Mechanistic Safety, Chief Medical Office and Patient Safety, Novartis, Switzerland

Session 0305 | Thursday 19 April | 10:30-12:00

PRECISION MEDICINE AND PERSONALISED HEALTH CARE

Session Chair:

Marisa Papaluca-Amati, Scientific Committees Regulatory Science Strategy, European Medicines Agency (EMA), EU

Disease modifying therapies allow to look at the trajectory of disease combining in silico and real world clinical data. This session will review progress towards prevention and personalised medicine combining biological plausible advances in scientific methods and their application within healthcare systems.

Elmar Nimmesgern, Innovative and Personalised Medicine Unit, Directorate General for Research and Innovation European Commission, EU

Virginia Acha, Executive Director, Global Regulatory Policy, MSD, UK

Bettina Ryll, Founder, Melanoma Patient Network Europe, Sweden

Donald Singer, Executive Committee, European Association for Clinical Pharmacology and Therapeutics (EACPT), UK



TOPIC D

HOW CAN BETTER OUTCOMES BE ENABLED BY BIG DATA?

Topic Leaders:

Isabelle de Zegher, Vice President, Integrated Solution, PAREXEL Informatics, Belgium

Thomas Senderovitz, Director, Danish Medicines Agency (DKMA) Denmark

Personalised Medicine, demand for early treatment, genomic treatment and increased complexity of trials force us to rethink the way we approach clinical development, moving from 7-12 years of work to 3-5 years for most of the products. This topic explores why we think Big Data will enable a different approach in clinical development, how it will enable this change and what we should do as an industry to maximise the value of Big Data, learning from other industries and adapting our competencies.

Session 0201/0401 | Wednesday 18 April | 10:30-12:00

HAS THE TIME FOR BIG/REAL WORLD DATA FINALLY ARRIVED?

Session Chair:

Shahid Hanif, The Association of the British Pharmaceutical Industry, UK

This session will discuss the current and future use of Big Data to support regulatory decision-making and reimbursement, identifying the outcomes that demonstrate value through the use of Big Data, and whether these data are accessible. In addition, it will describe how Big Data can be used to inform operational predictability and scientific validity of study conduct.

Using Big Data in Regulatory and Health Care Decision Making – Where Are We Now, and What about the Future?

Andrew Roddam, Vice President & Global Head Epidemiology, GSK, UK

IMI Big Data for Better Outcomes: Supporting the Evolution towards Outcomes-Focused, Sustainable Healthcare Systems in Europe

Shahid Hanif, The Association of the British Pharmaceutical Industry, UK

Clinical Research: The Application of Geographically Relevant Data for Operational Predictability and Scientific Validity

Louise Parmenter, VP, Global Head, Scientific Affairs, IQVIA, UK

Panel Discussion with **David Martin**, Associate Director for Real World Evidence Analytics, Food and Drug Administration (FDA), USA



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Session 0402 | Wednesday 18 April | 14:00-15:15

NEW COLLABORATION MODELS WITH REGULATORS AND PATIENTS

Session Chair:

Brian Mayhew, Executive Director, Regulatory Policy, Novartis

This session will explore how the utilisation of advances in technology (such as big data, wearables, cloud computing) will open new opportunities and challenges for collaboration between companies with regulators, payers and patients: Is the present interaction model appropriate; should authorities be involved earlier in data collection and analysis, and how will this change patient engagement?

Impact of Digital Technology on Drug Development

Scott Askin, Global Director, Digital Development, Novartis, Switzerland

Regulator Perspective on the Use of New Technology for Evidence Generation on Regulatory Decision Making

Alison Cave, Principal Scientific Administrator, European Medicines Agency (EMA), EU

Patient Perspective

Trishna Bharadia, Ambassador, MS Society, UK

Session 0403 | Wednesday 18 April | 16:00-17:30

NEEDED COMPETENCIES FOR BIG DATA – LEARNING FROM OTHER INDUSTRIES AND FROM 10 YEARS OF IMI EXPERIENCE

Session Chair:

Peter Shone, Corporate Vice President, R&D Engineering, PAREXEL Informatics, UK

Big Data has been in production across many other industries, yet we still struggle within pharma and we are lagging behind. This session will focus on lessons learned from other industries, such as aeronautics, and from 10 years of IMI projects involving Big Data.

Lessons Learned from IMI: How Pharma Industry Must Adapt to Manage Big Data & Digital Transformation Effectively

Stephan Korte, Head Public Private Partnerships, Novartis, Switzerland

Democratising AI for Better Outcomes

Elena Bonfiglioli, Regional Business Leader, Health and Life Sciences, Microsoft Corporation, EMEA, Belgium

Lessons Learned from Aeronautics Industry

Peter Shone, Corporate Vice President, R&D Engineering, PAREXEL Informatics, UK

Session 0404 | Thursday 19 April | 08:30-10:00

OVERVIEW OF MAJOR BIG DATA PROJECTS ACROSS EU, US, JAPAN

Session Chair:

Toshiyoshi Tominaga, Associate Executive Director, PMDA, Japan

There are several initiatives across sponsors and regulators that are evaluating how Big Data can accelerate drug development and impact regulatory landscape. This session will provide an overview of different ongoing initiatives in Europe, Japan and US – including IMI, EMA Big Data Taskforce in Europe, and projects coordinated by PMDA in Japan and FDA in the US.

HMA-EMA Joint Big Data Taskforce

Alison Cave, Principal Scientific Administrator, European Medicines Agency (EMA), EU

FDA View

David Martin, Associate Director for Real World Evidence Analytics, Food and Drug Administration (FDA), USA

Regulator's Utilisation of Big Data in Pharmacovigilance Activities

Kazuhiro Kajiyama, Safety Reviewer, PMDA, Japan

Session 0405 | Thursday 19 April | 10:30-12:00

BIG DATA MANDATES STRICT DATA GOVERNANCE

Session Chair:

Isabelle de Zegher, Vice President, PAREXEL Informatics, Belgium

Big Data is more than technology, even more so in our industry where we have to comply with data privacy rules, manage many different formats of data, reconcile data and terminologies. This session will focus on the need for “big data governance” and focus on some aspects such as anonymization, EHR integration and proactive management of data standards.

How Risk-Based Anonymisation Leads to Improved Clinical Outcomes

Khaled El Emam, Founder/Director, Real World Evidence Solutions, Privacy Analytics, Canada

Leveraging Point-of-Care Real-World Electronic Health Records (EHR) Data to Support Clinical Research and Improve Health Outcomes

Aaron Kamau, CEO, Anolinx, USA

Solving the Data Chasm in Clinical Trials: E2E Data Standards Management

Julius Kusserow, Head of Data Standards, PAREXEL, Germany

A New Horizon for Semantic Interoperability and Data Integration using a Meta Data Repository (MDR).

Srivinas Karri, Director, Clinical Warehousing Cloud Strategy, Oracle, UK



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TOPIC E

WHAT IS THE FUTURE OF PHARMACOVIGILANCE?

Topic Leaders:

Vicki Edwards, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie, UK

Georgy Genov, Head of Signal Management, European Medicines Agency (EMA), EU

The importance of pharmacovigilance continues to increase along with complexities in data collection, scientific methodology, technology advances and resource constraints. This session will take a look at innovative approaches to benefit/risk management, risk communication and measuring the impact of pharmacovigilance activities and discuss the experience with recently implemented elements of the Pharmacovigilance legislation.

Session 0501 | Wednesday 18 April | 10:30-12:00

ENHANCING BENEFIT-RISK MANAGEMENT THROUGH THE PRODUCT LIFE CYCLE

Session Chair:

Steve Mayall, Principal Consultant, Pope Woodhead and Associates, UK

Structured benefit-risk assessment and digital innovation are two key emerging areas. This session will describe practical experiences and challenges when performing benefit-risk management from multiple perspectives and propose best practices.

Regulator Perspectives

Jordi Llinars Garcia, Head of Scientific and Regulatory Management, Human Medicines Evaluation Division, European Medicines Agency (EMA), EU

Digital Risk Management: Opportunities and Challenges

Helen Edelberg, Head, Medical Safety Assessment, Innovative Medicines & Global Safety Risk Management, USA

The Benefits and Risks of Performing Structured Benefit-Risk Assessments

Steve Mayall, Principal Consultant, Pope Woodhead and Associates, UK



Session 0502 | Wednesday 18 April | 14:00-15:15

INNOVATIVE APPROACHES TO SAFETY INFORMATION

Session Chair:

Brian Edwards, Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd.; Vice-President ACRES, UK

Effective communication remains the prime way we communicate benefit-risk. This session will examine new techniques based on systems theory, reengineering our case management process and the optimal application of automation and new technology and how this can better contribute to protecting patients.

A Proposal for a New Systems-Based Approach to Medication Errors

Brian Edwards, Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd.; Vice-President ACRES, UK

Are Non-Serious Solicited Adverse Events Adding Value to Safety Surveillance?

Karolyn Kracht, Associate Director, Safety Decision Analytics, AbbVie Inc., USA

How Cognitive Computing Will Revolutionise Safety in the Next Decade

Michael Braun-Boghos, Director of Safety Analytics, Oracle Health Sciences, Germany

Session 0503 | Wednesday 18 April | 16:00-17:30

MEASURING IMPACT OF PHARMACOVIGILANCE IN THE EU

Session Chair:

Saad Shakir, Director, Drug Safety Research Unit (DSRU), UK

European pharmacovigilance underwent major changes in 2012, but the effectiveness and impact of the changes to pharmacovigilance processes have not been measured using a systematic approach. To this end, in 2016 PRAC adopted its "Strategy on Measuring the Impact of Pharmacovigilance Activities" and the ENCePP Special Interest Group on Impact was set up. The session will cover selection of methods to study impact and will provide an update on progress of the Special Interest Group.

Introduction to the ENCePP Special Interest Group on Impact and an EMA perspective

Xavier Kurz, Head of Surveillance and Epidemiology Service, European Medicines Agency (EMA), EU

Measuring the Impact of Product Withdrawals and Other Major Pharmacovigilance Actions on the Public Health Burden in the EU

Saad Shakir, Director, Drug Safety Research Unit (DSRU), UK

Measuring the Impact of Pharmacovigilance Activities: Opportunities and Pitfalls

Agnes Kant, Director, Netherlands Pharmacovigilance Centre Lareb, Netherlands



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Session 0504 | Thursday 19 April | 08:30-10:00

FIVE YEARS ON – PHARMACOVIGILANCE LEGISLATION DELIVERS ON LONG-PROMISED ELEMENTS

Session Chair:

Shelley Gandhi, Strategic Advisor, Pharmacovigilance and Drug Safety, NDA Group, UK

The main aims of the Pharmacovigilance (PV) Legislation in 2012 were to strengthen the protection of public health and rationalise PV by simplification of rules and procedures for all stakeholders, decreasing duplication, better definition of roles and responsibilities while simultaneously increasing transparency and further engaging healthcare professionals and patients. This session will focus on the experiences and assess the role of EudraVigilance (EV) as the single database in the EEA for ICSRs, how EV signalling is being piloted and examine the new PRAC process for public hearings to determine whether we are delivering on our aims which had been laid out 5 years ago.

Speakers:

Margaret Walters, Deputy EU QPPV, MSD, UK

Steve Hobbiger, Head Global Medical Governance and QPPV, GSK, UK

Yusuf Tanrikulu, Principal PV Process Leader, F. Hoffmann La-Roche, Switzerland

Session 0505 | Thursday 19 April | 10:30-12:00

BENEFIT/RISK COMMUNICATION TOOLS THAT WORK: TOWARDS A TAILOR-MADE DRUG FACTS BOX?

Session Chair:

Ragnar Löfstedt, Professor of Risk Management, Director of King's Centre for Risk Management, King's College

This panel will bring together key actors from the science, patient, regulation, and manufacturing sides to explore the implications of designing sensitive benefit/communication tools.

Frederic Boudier, Associate Professor in Risk Management, University of Stavanger, Norway

David Haerry, Founder, Positive Council Switzerland, Switzerland

Agnes Kant, Director, Netherlands Pharmacovigilance Centre Lareb, Netherlands

Priya Singhal, Senior Vice President and Global Head of Safety and Benefit Risk Management, Biogen, UK

Melanie Carr, Head of Stakeholders and Communication, European Medicines Agency (EMA), EU

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TOPIC F

WHAT CAN STAKEHOLDERS EXPECT FROM CLINICAL TRIAL (DEVELOPMENT), TRANSPARENCY AND MEDICAL INFORMATION?

Topic Leader:

Merete Jørgensen, Director, Global Clinical Registry, Novo Nordisk, Denmark

Transparency and open information on clinical research is reaching new levels, since the International Committee of Journal Editors (ICMJE) in 2004 published their requirements for public trial registrations, as a prerequisite for publication in the scientific literature.

Today transparency of information is done to satisfy ethical policies for openness as well as to meet regulatory requirements and guidelines globally. It covers information on protocols, clinical reports, summaries for lay persons and sharing of data with independent researchers for use in secondary analyses.

Provision of the information has led to building new areas of responsibilities, working processes at trial sponsor- as well as at regulatory institutions, to ensure transparency and handle compliance.

Session 0601 | Wednesday 18 April | 10:30-12:00

EMA PROACTIVE TRANSPARENCY – CLINICAL DATA PUBLICATION (POLICY 0070)

Session Chair:

Melanie Carr, Head of Stakeholders and Communication, European Medicines Agency (EMA), EU

With more than one year of experience of publishing clinical data in the EU, this session will feature different stakeholders perspectives on the impact that this increased level of transparency is having. Panelists will share some of the lessons learned and best practices that have emerged with successful submissions and publication as well as areas where there is still further room for improvement.

Experience and Lessons Learned to Date

Joao Ferreira, Clinical Data Publication Manager, European Medicines Agency (EMA), UK

SME and Big Pharma Perspectives on the Publication Process

Silvia Nosari, Chief Regulatory Affairs Officer, Adienne Pharma & Biotech, Italy

Stephen Bamford, Director, Head of Data Transparency, Janssen R&D, UK

How Use Can Be Made of the Data – An Academic's Viewpoint

Sarah Nevitt, Department of Biostatistics, University of Liverpool, UK

Why Increased Transparency is Important for Patients

David Haerry, Founder, Positive Council Switzerland, Switzerland

Session 0602 | Wednesday 18 April | 14:00-15:15

DATA SHARING AND SECONDARY USE OF DATA

Session Chair:

Merete Jørgensen, Director, Global Clinical Registry, Novo Nordisk, Denmark

Transparency of clinical information and sharing of person level data has been increasing over the last couple of years. Views of the challenges as well as the benefits experienced will be shared. The aim of the session is to share views on how to make the best out of the efforts that are put into sharing the wealth of information.

Aligning Clinical Trial Transparency with Clinical Development Programme

Oladayo Oyelola, Director, Clinical Trial Information Disclosure, Daiichi Sankyo Inc., USA

Experience in Sharing Clinical Data for Secondary Use

Martin Schumacher, Professor, Institute for Medical Biometry and Statistics, University of Freiburg, Germany

Sharing of Individual Patient Data (IPD) – Data Utility Considerations

Ingeborg Cil, Lead, Clinical Trial Data Anonymization, Clinical Trial Transparency, Shire, Austria

Session 0603 | Wednesday 18 April | 16:00-17:30

DRAWING THE BOUNDARIES OF DATA DISCLOSURE IN CLINICAL TRIALS

Session Chair:

Marie Manley, Partner, Head of the UK Life Sciences, Sidley LLP, UK

EU Clinical Trials Regulation: Preparing for Implementation

Marie Manley, Partner, Head of the UK Life Sciences, Sidley LLP, UK

Expectations/Challenges in Regulatory Use of Clinical Documents – Continued Need for Redactions/Anonymisation of Clinical Regulatory Documents

Speaker invited

Further Issues and Priorities to Be Solved

Sini Eskola, Director, Regulatory Affairs, EFPIA, Belgium

Arianna Greco, VP Head of Legal, Europe and Canada, Alnylam, Switzerland

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Session 0604 | Thursday 19 April | 08:30-10:00

**MAKING CLINICAL TRIAL INFORMATION ACCESSIBLE:
EXPERIENCES IN DEVELOPING INFORMED CONSENT FORMS
AND LAY SUMMARIES OF STUDY RESULTS**

Session Co-Chairs:

D.K. Theo Raynor, Professor of Pharmacy Practice, University of Leeds, UK
Thomas Schindler, Head Medical Writing Europe, Boehringer Ingelheim Pharma, Germany

Nothing is more important than properly informing patients about clinical trials – learn from experience on how to do it better.

**Applying User Involvement and User Testing to Improved Consent Forms
- The Process and Findings**

D.K. Theo Raynor, Professor of Pharmacy Practice, University of Leeds, UK

Developing a Company-Wide Strategy for Improving and Implementing
Jan Lynge, Head of Clinical Pharmacology, Novo Nordisk, Denmark

Challenges and Solutions in the Writing of Lay Summaries of Study Results

Kamila Sroka-Saidi, Senior Medical Writer, Boehringer Ingelheim, Germany

Company-Wide Implementation of a Lay Summary Process – Do's and Don'ts

Thomas Schindler, Head Medical Writing Europe, Boehringer Ingelheim Pharma, Germany

Session 0605 | Thursday 19 April | 10:30-12:00

**THE PROMISE AND REALITY OF CLINICAL TRIAL
TRANSPARENCY INITIATIVES**

Session Chair:

Thomas Wicks, Chief Strategic Officer, TrialScope, USA

The past decade has seen a virtual explosion of trial disclosure requirements and expectations around the world. This panel discussion will discuss the successes, challenges, and opportunities for improvement, looking back over the past ten years and forward to the expected developments in the next five.

Joao Ferreira, Clinical Data Publication Manager, European Medicines Agency (EMA), UK

Deborah Collyar, President, Patient Advocates in Research (PAIR), USA

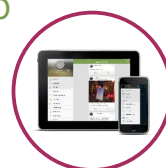
Sini Eskola, Director, Regulatory Affairs, EFPIA, Belgium

Karla Childers, Senior Director, Strategic Projects, Johnson & Johnson, USA

Jennifer Miller, Assistant Professor, NYU School of Medicine, and Founder, Bioethics International, USA

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TOPIC G

A NEW ERA FOR MEDICAL DEVICES AND DIAGNOSTICS. HOW IS THE IMPACT?

Topic Leader:

Manfred Maeder, Head Device Development and Commercialization, Biologics Technical Development and Manufacturing (BTDM), Novartis, Switzerland

Session 0701 | Wednesday 18 April | 10:30-12:00

IVD REGULATION AND THE UPCOMING CHANGES IN REGULATORY LANDSCAPE

Session Chair:

Claudia Dollins, Head Global Regulatory Affairs, Biomarkers and Diagnostics, Merck Group, Germany

The implementation of the new IVD Regulation introduces new challenges for all stakeholders involved whether it is companion diagnostic and personalised medicines developers or the EMA, National Competent Authorities or Notified Bodies. This session will examine the impact of this new regulatory landscape for all stakeholders and highlight new possible opportunities and areas of collaboration to ensure that companion diagnostics and their paired personalised medicinal products are successfully brought to the market.

Anna Hallersten, Head Regulatory Policy Europe, Roche Diagnostics, Switzerland

Sue Spencer, Global Service Line Director Regulatory at UL, UK.

Stephen Lee, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Session 0702 | Wednesday 18 April | 14:00-15:15

REGULATORY – HOW TO SUBMIT A COMBINATION PRODUCT OR DRUG DEVICE COMBINATION GLOBALLY

Session Chair:

Manfred Maeder, Head Device Development and Commercialization, Biologics Technical Development and Manufacturing (BTDM), Novartis, Switzerland

This session will provide an overview of how new European medical devices regulation (MDR) as well as recent updates from FDA are impacting stakeholders. Speakers from industry and regulatory will share their views with the audience.

Global Perspective for a Drug Device Combination Product Submission

Stephanie Horn, Pharma Technical Regulatory Combination Products/ Medical Devices, F. Hoffmann-La Roche, Switzerland

Coordination for Submissions of Combination Products in the EU

Elisabeth Kapeller, Senior Regulatory Affairs Manager - Medical Device, Sandoz, Austria

Session 0703 | Wednesday 18 April | 16:00-17:30

CHALLENGES IN THE CURRENT REGULATORY LANDSCAPE CONSIDERING FDA AND MDR EXPECTATIONS

Session Chair:

Shayesteh Fürst-Ladani, Managing Director, SFL Regulatory Affairs and Scientific Communication, Switzerland

This session will provide an overview of how new European medical devices regulation (MDR) as well as recent updates from FDA are impacting stakeholders. Speakers from industry and regulators will share their views with the audience

A European Regulatory Authority Perspective on the New EU Device Regulations

Niall MacAleenan, Medical Device Lead/Clinical Assessment and Policy Manager, Health Products Regulatory Authority (HPRA), Ireland

How MDR Impacts Medical Device Manufacturer

Karin Schulze, Head Medical Devices and Combination Products, SFL Regulatory Affairs & Scientific Communication, Switzerland

Industry Preparation to Comply with the FDA and MDR Regulatory Requirements

Murray Malin, Medical Director, Abbvie, USA

Session 0704 | Thursday 19 April | 08:30-10:00

LIFE CYCLE MANAGEMENT ACTIVITIES OF DRUG DEVICE COMBINATIONS

Session Chair:

Amanda Matthews, Director, Regulatory CMC, Pfizer, UK

This session will cover lifecycle management for drug/device combination products and some of the specific points to consider. In addition regulatory challenges with global development will be shared with a focus on post-approval considerations for a prefilled syringe from an EU perspective.

Life Cycle Management of Combination Products from Development to Product Retirement

Mike Wallenstein, Executive Director QA / Senior Compliance Officer, Novartis, Switzerland

Overcoming Regulatory Challenges within PFS and Auto Injector Development and Life Cycle Management

Vikas Jaitely, Associate Director, Pharmaceutical Sciences & CMC Regulatory Intelligence, Merck, Switzerland

Life Cycle Challenges for On-Market Products

Cornelia Kruettli, Head of Product Care, F. Hoffmann-La Roche, Switzerland

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Session 0705 | Thursday 19 April | 10:30-12:00

IMPACT OF HUMAN FACTORS ON THE DEVELOPMENT OF COMBINATION PRODUCTS

Session Chair:

Muriel Didier, Human Factors Team Head, Novartis, Switzerland

The visibility of Human Factors in the development of combination products has greatly increased in the last 5 years (in terms of regulation, the number of Human Factors experts, delays in product approvals because of usability issues...). How do Human Factors support the ultimate objective of bringing to market combination products that fulfill the user needs?

Lee Wood, Co-Founder, MedHF, Switzerland

Chin-Wei Soo, Global Head, PTR Combination Products/Devices, Genentech, USA

Andrew Warrington, DayOneLab, Switzerland

Edward Oakeley, DayOneLab, Switzerland



TOPIC H

DRUG DEVELOPMENT AND REGULATORY APPROVAL - REFERENCE POINTS AROUND THE GLOBE OR GLOBALISATION?

Topic Leader:

Petra Dörr, Deputy Executive Director, Swissmedic, Switzerland
Sharon Olmstead, Global Head, Development and Regulatory Policy and Intelligence, Novartis, USA

Increasing globalisation of drug development is a fact – but how do regulators and the regulated industry around the world keep pace with it? Harmonisation of requirements is expanding to new regions, reliance on each other's evaluations and other means of work sharing are on the rise. Learn more about how we can make globalisation of drug development work!

Session 0801 | Wednesday 18 April | 10:30-12:00

UPDATE ON PMDA'S ACTIVITIES

Session Chair:

Toshiyoshi Tominaga, Associate Executive Director, PMDA, Japan

PMDA will share the latest details regarding its policies and initiatives and other related strategic directives. The goal of the session will be to keep participants informed of the agency's handling of the most critical issues.

MHLW and PMDA's General Policies on Regulating Innovative Products
Nobumasa Nakashima, Director, Office of International Regulatory Affairs, Minister's Secretariat, MHLW,

PMDA's Innovation and Review System in Japan

Tatsuya Kondo, Chief Executive, PMDA, Japan

New Pharmacovigilance Approach; Use of Real World Data

Shiobu Uzu, Chief Safety Officer, PMDA, Japan



Session 0802 | Wednesday 18 April | 14:00-15:15

PAEDIATRIC POLICY INITIATIVES: GLOBALISATION OF PAEDIATRIC DRUG DEVELOPMENT BEST PRACTICE OR IMPERIALISM OF PRACTICE? PANEL DISCUSSION

Session Chair:

Christina Bucci-Rechtweg, Head, Pediatric and Maternal Health Policy, Global Regulatory Affairs, Novartis, USA

Paediatric legislation implementing a system of obligations and rewards has led to a significant increase in paediatric studies. Whilst studies conducted are multinational, regional regulatory objectives may not serve global research needs. This session will utilise a series of cases which highlight the global nature of paediatric drug development.



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Panelists:

Julia Bielicki, Attending Physician Pediatrics & Pediatric Infectious Diseases, Medical Coordinator ASC, Basel University Children's Hospital, Switzerland

Angelika Joos, Executive Director, Global Regulatory Policy, MSD (Europe) Inc., Belgium

Frank van den Ouweland, Clinical Review, Swissmedic, Switzerland

Cesare Spadoni, Founder and Chairman of the Board, aPODD (accelerating Paediatric Oncology Drug Development), UK

Session 0803 | Wednesday 18 April | 16:00-17:30

RELiance AND WORK SHARING @ WORK – STATE OF PLAY AND HANDS-ON EXPERIENCE FROM TWO CASE STUDIES

Session Chair:

Cordula Landgraf, Head of Networking, Swissmedic, Switzerland

Regulatory agencies around the globe increasingly rely on other regulators work products and embark on work sharing concepts to leverage resources and increase efficiency. What does that mean in practice and what are the experiences so far?

Setting the Scene: Introduction to Reliance and Work Sharing Initiatives

Cordula Landgraf, Head of Networking, Swissmedic, Switzerland

Regulator's and Applicant's View on the First Generic Medicines Work Sharing Trial (GMWST) of the ACSS Consortium

Michael Banks, Senior Vice President, Global Head Regulatory Affairs, Teva Pharmaceuticals Europe, UK

Chantal Pfäffli, Case Manager, Swissmedic, Switzerland

IGDRP Work Sharing Activities: Leveraging on the EU's Centralised and Decentralised Procedure

Peter Bachmann, European Union and International Affairs, BfArM, Germany

Session 0804 | Thursday 19 April | 08:30-10:00

GMP CONVERGENCE – A KEY PART OF REGULATORY SYSTEM STRENGTHENING

Session Chair:

Barbara Allen, Director Global Quality Systems, Eli Lilly and Co., Ireland

GMP standards and associated inspections are important components of strong regulatory system. This session will explore approaches and progress on GMP standard convergence, aligned inspection processes and regulatory authority cooperation.

GMP Convergence – Industry Perspective

Stephan Rönninger, Director, External Affairs Europe, International Quality, Amgen (Europe) GmbH, Switzerland

WHO Activities on Regulatory System Strengthening

Alireza Khadem Broojerdi, Scientist, Regulatory Systems Strengthening (RSS), WHO, Switzerland

GMP Harmonisation and GMP Inspection Reliance from a PIC/S Perspective

Boon Meow Hoe, Chairman PIC/S, Health Sciences Authority, Singapore

Session 0805 | Thursday 19 April | 10:30-12:00

LIFE CYCLE MANAGEMENT – THE UNKNOWN BARRIER TO ACCESS

Session Chair:

Ursula Busse, Quality Intelligence, External Relations, Novartis, Switzerland

The lack of a harmonised global regulatory framework for post-approval changes leads to supply chain complexity, hinders manufacturing innovation, increases the risk of quality failures and contributes to the issue of global and country specific drug shortages. This session will cover current challenges and highlight ongoing initiatives towards a sustainable global environment for pharmaceutical product life cycle management

Life Cycle Management – Fast Track or Hurdle Race?

Nadia Beaudoux, Regulatory Affairs Manager, Lilly, France

ICH Q12: Solutions to Facilitate Post-Approval Change Management throughout a Product's Life Cycle

Jean-Louis Robert, CHMP Member, Luxembourg

International Efforts to Ensure Sustained Product Supply over its Life Cycle

Thomas Schreitmüller, Global Head Regulatory Policy, F. Hoffmann-La Roche, Switzerland

DISCUSS THE NEW PATHWAYS OF RARE DISEASE TREATMENTS IN EUROPE



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TOPIC I

HOW CAN WE ENABLE CLINICAL RESEARCH IN EUROPE FURTHER?

Topic Leaders:

Holger Maria Rohde, Director, Regulatory Project Management, Merck, Germany

Fergus Sweeney, Head of Division, Inspections, Human Medicines Pharmacovigilance and Committees, European Medicines Agency (EMA), EU

Major changes being brought about by upcoming regulations will require transformations in development organisation for the facilitation of efficacious clinical research in Europe. The increasing availability of real word data raises challenges as to how it can be integrated, validated and used. Organisations need to adapt to regulatory requirements and opportunities which enable new research methodologies at the interface of regulatory, data science and patient's needs.

Session 0901 | Wednesday 18 April | 10:30-12:00

NEW EUROPEAN CLINICAL TRIAL REGULATION: A NEW PARADIGM WITH MAJOR IMPACT ON CLINICAL TRIAL STAKEHOLDERS

Session Chair:

Elke Stahl, CTFG co-chair; Clinical Trial Unit, BfArM, Germany

Are stakeholders ready for implementation of the EU Clinical Trial Regulation? Challenges, expectations and progress will be updated by Members States and sponsors.

The Implementation of the Clinical Trial Regulation at Member State Level: The State of Play in Belgium

Greet Musch, General Director DGPRE, Federal Public Health Services (FAMHP), Belgium

Is Industry prepared? Experiences from the German Pilot as an Example for Challenges for Industry

Thorsten Ruppert, Senior Manager Research, Development and Innovation, German Association of Research-Based Pharmaceutical Companies (vfa), Germany

Key Aspects to Consider to Ensure CTR Implementation Impacts Positively Non-For-Profit Clinical Research

Anastassia Negrouk, Head of International Regulatory and Intergroup Office, EORTC, Belgium

Session 0902 | Wednesday 18 April | 14:00-15:15

REGISTRY STUDIES: WHAT ARE THE EXPECTATIONS FROM THE REGULATORS?

Session Chair:

Maren von Fritschen, Managing Director, AddOn Pharma, Germany

Registries can play an important role not only in monitoring the safety of medicines but also in providing adequate source for regulatory decision making. High quality patient registries can make valuable contributions to the evaluation and monitoring of medicines for public health benefit. The objective of the European Medicines Agency Patient Registry initiative is to facilitate discussions at an early stage in the authorisation procedure to increase use of existing patient registries and to support the creation of a new registry based on standard methodological approaches. This session will provide insides in challenges and opportunities for the use of registries in decision making processes based on case studies and the regulator's expectations.

What Are the Expectations from the Regulators?

Xavier Kurz, Head of Surveillance and Epidemiology Service, European Medicines Agency (EMA), EU

Case Study on a Global Registry of Soliris (eculizumab) for an Additional Indication

Nadia Assenova, Sr. Director Regulatory Affairs, EMEAC, Alexion Pharma GmbH, Switzerland

Case Study on a CHMP Approval for an OMP on Accelerated Assessment Based on Registry Data

Chay Morgan, Head EU, Biomarin Pharmaceutical Inc., USA

Session 0903 | Wednesday 18 April | 16:00-17:30

NOVEL AND INNOVATIVE CLINICAL TRIAL DESIGNS: FROM ADAPTIVE/SEAMLESS DESIGNS TO THE TRIAL OF THE FUTURE

Session Chair:

Mireille Muller, Regulatory Policy Director, Novartis, Switzerland

Multiple-trial design options are required to increase efficiency in clinical trial conduct in increasingly complex conditions and smaller populations while maintaining scientific value and data quality to meet the needs and wants of all stakeholders.

Platform Trials

Michael Krams, Global Head of Quantitative Sciences, Janssen Pharmaceuticals, USA

Regulatory and HTA Challenges with Innovative Clinical Trials

Sacha Wissink, MSD, Netherlands

Regulator's Perspective: Master Protocols – Risks and Benefits

Benjamin Hofner, Statistical Assessor and Researcher Section Biostatistics, Paul-Ehrlich-Institut, Germany

Empowering Phase II Clinical Trials to Reduce Phase III Failures

Daniele De Martini, Milano-Bicocca University, Italy



DIA Europe 2018

SCIENTIFIC PROGRAMME

Session 0904 | Thursday 19 April | 08:30-10:00

SMARTER CLINICAL TRIALS THANKS TO REAL WORLD DATA

Session Chair:

Holger Maria Rohde, Director, Regulatory Project Management, Merck, Germany

In the session we will discuss innovative ways to leverage RWD/RWE to optimise clinical trial design, such as the fine-tuning of a targeted population, improvement of site selection and patient recruitment, but also to complement traditional development in changing (or increasing?) regulatory requirements. How can we increase efficiency of clinical trial design, mitigate against avoidable delays and costs, and unlock advanced “what if” scenario planning options in the trial design process? What kind of data and design can complement evidence from clinical trials, in which situations this could be helpful to fulfil regulatory requirements?

Will RWE Replace Evidence Coming from Clinical Trials in the Future?

Patrice Verpillat, Merck KGaA, Germany

How Can Real World Data Improve the Early Clinical Development Process?

Michel Francois Denarie, Sr. Principal, Data Scientist, IQVIA, USA

The Role of Real World Data in the Regulatory Setting

Aldana Rosso, Senior Advisor Biostatistics, DKMA, Denmark

HOT TOPICS / STAND ALONE

Session 1000 | Tuesday, 17 April, 14:00-15:30

MAJOR REFORMS AND STRENGTHENED INTERNATIONAL COOPERATION – WHAT IS HAPPENING IN CHINA?

Session Chair:

Carol Zhu, SVP, Managing Director, DIA China

The Chinese legal framework for medical products has undergone major reforms in the last years. The new pieces of legislation are now coming into force one by one. It is most relevant for companies to be abreast with the changes the new legislation brings for this important market.

In addition, the China Food and Drug Administration has strengthened and enhanced its international cooperation. The underlying strategy as well as some recent developments will be outlined, such as the role and involvement of CFDA in ICH and ICMRA.

- Reforms Part 1: Overarching Goals/Major Objectives and Timelines
- Reforms Part 2: Key Element of Reform on Drug and Medical Device Review and Approval
- International Cooperation: CFDA's Strategy and Priorities

China Regulatory Reform in Review and Approval and Global Collaboration

Xiaoling Qin, Deputy Director General, Dept. of International Collaboration, China Food and Drug Administration (CFDA), China
Xiangyu Wang, Division Director, Dept. of International Cooperation, China Food and Drug Administration (CFDA), China



New Approaches from China Regulatory Authority to Foster Innovation

Wendy Yan, SVP and Head of Regulatory Affairs, BeiGene (Beijing) Co., Ltd., China

Impact of the China Regulatory Reform and Post-ICH

Panel discussion with speakers and Melly Lin, Senior Regulatory Manager, CMC policy, Roche (China) Holding Ltd. and Jessica Liu, Head of International Business, TigerMed, China

Session 1100 | Wednesday 18 April | 08:30-10:00

NCA SHOWCASE: BREXIT IMPLICATIONS FOR THE EU27 NETWORK AND DECENTRALISED ACTIVITIES

Session Chair:

Christa Wirthumer-Hoche, Chair, EMA Management Board; Head, AGES, Austria

This session gives the floor to the National Competent Authorities (NCA) to discuss their local progress, burning topics, and stakeholder engagement regarding Brexit.

Brexit Implications for the HMA Multi-Annual Work Programme

Christa Wirthumer-Hoche, Chair, EMA Management Board; Head, AGES, Austria

Sharing the Workload between NCAs:

HMA Brexit Task Force

Hugo Hurts, Chair of the Task Force, Executive Director, Medicines Evaluation Board (MEB), Netherlands

Focus on MRP/DCP

Laura Oliveira Santamaria, Chair CMDh; Head of RRAA Division, Human Medicines Department, AEMPS, Spain

Stakeholder needs and activities:

How is Industry Preparing?

Virginia Acha, Executive Director, Global Regulatory Policy, MSD, UK

Strengthening and Optimisation of Regulatory Procedures

Stan van Belkum, Co-chair of ROG, Acting Director, Medicines Evaluation Board (MEB), Netherlands



Session 1001 | Wednesday 18 April | 10:30-12:00

FIGHTING THE FAKES – PREPARING FOR UPCOMING EU MEDICINE SERIALISATION

Session Chair:

Patrizia Tosetti, Policy Officer, DG Health and Food Safety, European Commission, EU

Is Europe ready for medicine serialisation? European and national regulators, together with industry, will outline the state of play of the upcoming serialisation rules, current issues of concern and the next steps towards a timely and smooth application of the rules in 2019.

Implementing the Safety Features – The EU Rules on Medicine Serialisation

Patrizia Tosetti, Policy Officer, DG Health and Food Safety, European Commission, EU

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Implementing the Safety Features – Challenges for Industry

Mihai Rotaru, Project Manager Market Access, EFPIA, Belgium

Implementing the Safety Features – Challenges for Competent Authorities

Manuel Ibarra, Technical Adviser, AEMPS, Spain

Track & Trace in the Global Context - The ICMRA Supply Chain Integrity Project

Agnès Saint-Raymond, Head of Portfolio Board, Head of International Affairs, European Medicines Agency (EMA), EU

Session 1002 | Wednesday 18 April | 14:00-15:15

ICMRA – THE FUTURE OF MEDICINES AND CHALLENGES FOR INTERNATIONAL REGULATORS

Session Chair:

Ian Hudson, Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA), UK

The International Coalition of Medicines Regulatory Authorities (ICMRA) will explore some of the key challenges and opportunities for medicines regulation presented by emerging technologies and novel pathways across the international landscape. The session will be delivered by members of ICMRA's Executive Committee who represent the European medicines regulatory system, including a number of leading regulators. Presentations will include examples drawn from members' current experience of emerging technologies and an overview of ICMRA's strategic priorities moving forward, including artificial intelligence, software, ATMPs and 3D printing. The session will conclude with a panel discussion of questions raised by the audience.

A Brief Introduction to ICMRA

Ian Hudson, Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Overview of ICMRA's Strategic Priorities

Supriya Sharma, Associate Assistant Deputy Minister of Health Products and Food Branch, Health Canada, Canada

Example of Emerging Technologies - ATMPs

Tatsuya Kondo, Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Example of Emerging Technologies – Digital, Artificial Intelligence/ Software

Lorraine Nolan, Chief Executive, The Health Products Regulatory Authority (HPRA), Ireland

Example of Emerging Technologies – 3D Printing

John Skerritt, Deputy Secretary, Health Products Regulation Group, Therapeutic Goods Administration (TGA), Australia

ICMRA Moving Forward – The 'Innovation' Priority Project

Lorraine Nolan, Chief Executive, The Health Products Regulatory Authority (HPRA), Ireland

Q&A session with panelists and **Agnès Saint-Raymond**, Head of Portfolio Board, Head of International Affairs, European Medicines Agency (EMA), EU

Session 1101 | Wednesday 18 April, 10:30-12:00

LEARNINGS FROM THE FIRST 10 YEARS OF THE PAEDIATRIC REGULATION – BACK TO INFORM ON THE FUTURE?

Session Chair:

Simon Bennett, Director, Global Regulatory Policy EU Lead and GEMS Interim Lead, Biogen Ltd, UK

In late 2017, the EC finalised their report on 10-years of experience with the Paediatric Regulation, which included a positive agenda of actions that may lead to enhanced efficiency in the development and implementation of paediatric investigation plans. This session provides the opportunity to hear directly from the European Commission about the recommendations in their report and the rationale behind them. The session will also include contributions from other key stakeholders, including industry and academia, who will present their views on the opportunities presented within the EC report to improve the current implementation of the paediatric regulation.

View from the European Commission

Florian Schmidt, DG SANTE, European Commission, EU

View from Academia

Mark Turner, Senior Lecturer in Neonatology; Co-Director, International Neonatal Consortium, Liverpool, UK

View from Industry

Heidrun Hildebrand, Global Program Head, Research & Development, Pharmaceuticals, Pediatric Development, Bayer, Germany

Session 1003 | Wednesday 18 April | 16:00-17:30

RUSSIA AND THE EURASIAN UNION – REGULATORY CHALLENGES AND OPPORTUNITIES

Session Chair:

Susanne Ausborn (Osborne), Pharma Technical Regulatory, Regulatory Policy Lead EEMEA, F. Hoffmann-La Roche, Switzerland

The regulatory landscape in Russia and the "single market" of the Eurasian Union are rapidly evolving. Experts will share their perspectives on recent developments in the region and discuss the challenges we are facing with sometime very unique regulatory requirements. Examples for constructive dialogue between industry and regulators will be shared which is critical to bring and safe and efficacious drugs of high quality as fast as possible to the patients and maintain them on the market.

Regulatory Harmonisation within the Eurasian Union – Where Do We Stand?

Dzmitry Razhdzestvenski, Head, Division for Coordination of Common Market for Drugs and Medical Devices Formation, Technical Regulation and Accreditation Department, Eurasian Commission, Russian Federation

Regulatory Developments in Russia and How it Fits into the EAEU Developments

Sergey Glagolev, Deputy Chief, Division for State Control of Medical Products; Chief, Department for Pharmacovigilance, Federal Service for Supervision in Health Care (Rosdravnadzor), Russian Federation

Establishing EEU Guidance - Driving Towards Regulatory Convergence - Industry Perspective

Elena Popova, Senior Director Regulatory Affairs & Healthcare Policy, Association of International Pharmaceutical Manufacturers (AIPM), Russian Federation

Recent Developments and Challenges in Russia - Industry Perspective

Andrey Bulimov, Head of RA Partner Business CEE & LATAM, Vifor Pharma, Switzerland



DIA Europe 2018

SCIENTIFIC PROGRAMME

Session 1004 | Thursday 19 April | 08:30-10:00

ICH INFO DAY PART 1

Session Chair:

Petra Dörr, Deputy Executive Director, Swissmedic, Switzerland



Part 1 of the ICH Info Day (Session 1004) has two sections; the first examines the way the 'new ICH' operates, and second looks at how ICH selects new topics for harmonisation as well as an overview some key guidelines. Part 2 of the ICH Info Day (Session 0905) focuses on the Efficacy suite of guidelines, in particular the renovation of E6 and E8 GCP guidelines, E17 Multi-regional clinical trials and E9 estimands.

The new ICH

ICH has changed the way it operates and governs itself. The first part of this session gives an overview of the changes, including a focus on the development of forward strategies for guideline development or revision. It will describe the benefit of ICH for the future and how inclusion of new regulatory and industry members is creating a greater ICH footprint and enlarging the 'regulatory space'.

Has the ICH Reform been a Success?

Lenita Lindström-Gommers, ICH Assembly Chair, European Commission, EU

The New Role of IFPMA in ICH

Sarah Adam, Manager, Regulatory Affairs, IFPMA, Switzerland

Overview of Key Guidelines

The second section of this Session and its partner Session 0905 will discuss the process by which ICH selects new topics for harmonisation and take a look at some key guidelines, giving attendees the opportunity to understand their potential impact on the regulation and development of new medicines.

Overview of Current Work in Guideline Development and New Topics Selection?

Petra Dörr, Deputy Executive Director, Swissmedic, Switzerland

E19 Optimising Safety Data Collection

Peter Mol, member E19 Working Group, EMA, EU

E11 Paediatric Guideline Suite

Solange Corriol-Rohou, Member E11A Working Group, EFPIA, EU

Questions & Answers discussion with all panelists, together with **Dawn Ronan**, Director of the ICH Secretariat, Switzerland

Session 0905 | Thursday 19 April | 10:30-12:00

ICH INFO DAY PART 2

Session Chair:

Agnès Saint-Raymond,

Head of Portfolio Board, Head of International Affairs, European Medicines Agency (EMA), EU

Part 2 of the ICH Info Day looks at the Efficacy suite of guidelines, in particular the renovation of E6 and E8 GCP guidelines, E17 Multi-regional clinical trials and E9 estimands.

E8 and E6 Renovation Plan of Action - Putting GCP in the Context of the 'E Family'

Agnès Saint-Raymond, Head of Portfolio Board, Head of International Affairs, European Medicines Agency (EMA), EU

E17 Multi-Regional Clinical Trials

Toshiyoshi Tominaga, ICH Assembly and Management Committee Vice-Chair, MHLW/PMDA Japan



E9(R1) Estimands

Rob Hemmings, Rapporteur E9(R1) Expert Working Group, EMA, EU

Questions & Answers and Panel discussion with all panelists, together with patient and industry representatives.

Session 1005 | Thursday 19 April | 10:30-12:00

KEY INITIATIVES IN EUROPE TO WALK THE TALK IN PATIENT-FOCUSED MEDICINES DEVELOPMENT - AN INTERACTIVE UPDATE AND DISCUSSION WITH DIFFERENT STAKEHOLDERS

Moderator:

Lode Dewulf, Chief Patient Officer, Servier, France

Health stakeholders agree on the importance of improving patient engagement (PE) across all phases of medicines development. What can we learn from the experience and perspectives of different stakeholders? How can we use these insights to address challenges and barriers and forge a more collaborative, connected PE ecosystem? What tools are available or in co-creation and how can we measure the impact of our PE efforts? Join us for a dynamic session that will explore these themes, and be an active participant by selecting priority topics to be addressed by PE leaders from diverse stakeholder groups.

Mathieu Boudes, Coordinator, PARADIGM, European Patients' Forum (EPF), France

Neil Bertelsen, Chair, Patient and Citizen Involvement in HTA IG, Health Technology Assessment international (HTAi), Germany

Søren Skovlund, Lead, Value Based Diabetes Care PRO Programme, Aalborg University, Denmark

Nicholas Brooke, Executive Director, Patient Focused Medicines Development (PFMD), Brussels, Belgium

EMA representative invited

Session 1105 | Thursday 19 April | 10:30-12:00

TURKISH REGULATORY SESSION

Moderator:

Melek Bostancı Önoğlu, Head of RA, Boehringer Ingelheim, Turkey

The Government of the Republic of Turkey has set about positioning Turkey as one of the top ten global economies by 2023. The Industry Strategy Plan of Turkey emphasises and presents Turkey as "the ideal of Eurasia's production base in medium and high technological products". As a part of the said target and wide-spread plans, Turkey has been implementing the "Health Transformation Programme" since 2004 by which major developments in the healthcare sector and improved access to healthcare services and treatment options have been achieved. Accordingly, increasing the volume of locally manufactured high value added new drugs and treatments to meet the healthcare needs of the growing population is one of the significant target that the authorities make great effort to achieve by highly-debated localisation project.

PIC/S Process & Improvements Localization in Pharma Industry

Gülşen Yılmaz, Quality Manager of Inspectorate, Medicines and Medical Devices Agency, Turkey

Regulatory Process in Turkey

Tuncay Paşaoğlu, Supervisor of Coordination Unit, Drug Registration Department, Medicines and Medical Devices Agency, Turkey

Early Access to Medicines in Turkey

Selma Unlu, Senior Partner, NSN Law Firm, Turkey





SPOTLIGHT SESSIONS

Spotlight sessions are quick updates which focus on prominent topics relevant to current European policy. These sessions take place during lunch. Please have your lunch in the Exhibition Hall before the session starts.

Session SP01 | Tuesday, 17 April, 13:00-13:45

CAT SPOTLIGHT: WHAT'S ON THE HORIZON FOR ATMPs IN THE NEAR FUTURE?

Moderator:

Duane Schulthess, Managing Director, Vital Transformation, Belgium

Martina Schüssler-Lenz, Chair CAT, Deputy Head, Section Advanced Therapy Medicinal Products, Paul-Ehrlich-Institute (PEI), Germany

Jacquelyn M. Awigena-Cook, Associate Director, Regulatory Policy & Intelligence, EMEA Regulatory Affairs, Celgene, UK

Evert Jan van Lente, Director EU-Affairs, AOK Bundesverband (Federal Insurer), Germany



Session SP02 | Tuesday, 17 April, 13:00-13:45

EFPIA SPOTLIGHT: PHARMACEUTICALS IN THE ENVIRONMENT

Session Chair:

Sini Eskola, Director, Regulatory Affairs, EFPIA, Belgium

Come and participate the discussion on the hot policy topic on the upcoming EU strategy of Pharmaceuticals in the Environment (PIE) expected to be published by summer 2018! Different key stakeholders will be invited to present their ideas and solutions on how to address the issue from regulatory science, legislative/policy and voluntary action basis. Each citizen can play their part in disposing their medicines correctly - what else can and should be done? (Interactive voting poll will be utilised to get the best out of the discuss)

Bengt Mattson, Head of CSR & Environmental Affairs, Pfizer Health, Sweden

Katarina Nedog, Senior Manager, Safety and Regulatory Affairs, Medicines for Europe, Belgium

Ines Rönnefahrt, Environmental Risk Assessment of Pharmaceuticals, German Environment Agency (UBA), Germany



Session SP03 | Wednesday, 18 April, 12:30-13:30

ADAPT SMART SPOTLIGHT

Moderator:

Duane Schulthess, Managing Director, Vital Transformation, Belgium

The objective of ADAPT SMART was to establish a multi-stakeholder enabling platform to facilitate and accelerate the availability of transformative medicinal products, and engage a dialogue with relevant stakeholders for the coordination of MAPPs (Medicines Adaptive Pathways to Patients) related activities. MAPPs, as framework for the adaptive pathways development concept, seeks to foster access to beneficial treatments for the right patient groups with high unmet medical needs at the earliest appropriate time in the product life-span, in a sustainable fashion.

IMI ADAPT SMART, as a Coordination and Support Action (CSA) within the Innovative Medicines Initiative (IMI) will soon come to a close, and it is time to reflect on what has been achieved and what could be next steps. The panel session will involve ADAPT SMART consortium members.



Michael Berntgen, Head of Product Development Scientific Support Department, European Medicines Agency (EMA), EU

Mathieu Boudes, Coordinator, PARADIGM, European Patients' Forum (EPF), France

Solange Corriol-Rohou, Senior Director, Global Regulatory Affairs & Policy, Europe, AstraZeneca Global Medicines Development, France

Evert Jan van Lente, Director EU-Affairs, AOK Bundesverband (Federal Insurer), Germany

Session SP04 | Wednesday, 18 April, 12:30-13:30

TRANSCCELERATE SPOTLIGHT: HOW IS MULTI-STAKEHOLDER COLLABORATION DRIVING INDUSTRY CHANGE?

Session Chair:

Jennifer Burgess, Executive Director of Engagement, TransCelerate BioPharma Inc., USA

This thought-provoking session will bring together a diverse panel of industry leaders for a candid and innovative conversation about what is needed to transform the current ecosystem and bring therapies to the patients that need them. This panel discussion will address:

- What is working today amongst industry collaborations, and how will the 'next generation of collaborations' be different?
- Is collaborative R&D, pooling data and insights from academia, sponsors, and CROs in our near future?
- What roles will regulators, consortiums, technology providers, and other stakeholders play?

Panelists:

Michelle Rohrer, Global Head of PD Regulatory and Policy at F. Hoffmann-La Roche and Genentech, Switzerland

Janice Chang, Senior Vice President, Global Operations, TransCelerate BioPharma, Inc, USA

Sini Eskola, Director, Regulatory Affairs, EFPIA, Belgium

Matt Cooper, Business Development & Marketing Director at NIHR Clinical Research Network Coordinating Centre, National Institute for Health Research (NIHR), USA





WELCOME TO THE 2018 EXHIBITION

Prepare to be overwhelmed and excited about the abundance of information available in the Exhibition Hall. This is an essential part of your conference experience. Every aisle is filled with displays of the latest product innovations and tools to help make your job easier and more rewarding. DIA Europe 2018 is where talent and experience meet.

We urge you to schedule several visits to the Exhibition Hall at any time it is open to examine the wide variety of new materials available and to speak with representatives of the exhibiting companies.

All refreshment, lunch breaks, and receptions are taking place in the Exhibition Hall. All offer an excellent opportunity to visit exhibitors in a casual, yet professional setting, and at your own pace. At the same time, you can network with friends and colleagues.

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COFFEE

MORNING AND AFTERNOON
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CHARGING LOUNGE

CONNECT WITH
HEALTH CARE
COMPANIES AS
THEY SHOWCASE
THEIR NEWEST
PRODUCTS

EXHIBITION HALL OPENING HOURS

Tuesday, 17 April 2018: 08:00-19:30

Wednesday, 18 April 2018: 08:00-18:30

Thursday, 19 April 2018: 08:00-13:30

TUESDAY
“WELCOME TO BASEL”
RECEPTION

INNOVATION THEATRE
PRESENTATIONS

WEDNESDAY
‘EXHIBITOR MEET AND GREET’
RECEPTION

DIA Europe 2018

INNOVATION THEATRE PRESENTATIONS

Participating Exhibiting companies will showcase their expertise and solutions in this year's schedule

DIGITAL R&D TRANSFORMATION

Accenture

Tuesday, 17 April | 13:30-14:00
Innovation Theatre, Exhibition Hall

Speaker: **Andrew Finlayson**

Exploration of how unchanged methods and the rising cost of drug development that could be better invested in creating life-changing treatments and personalised patient care.

DEMYSTIFYING THE MULTILINGUAL COMPLEXITIES IN THE REGULATORY CYCLE



RWS
Life Sciences

Tuesday, 17 April | 15:30-16:00
Innovation Theatre, Exhibition Hall

Speaker: **Sheena Dempsey**

RWS Life Sciences' Sheena Dempsey addresses challenges of seeking regulatory approvals and nuances of linguistic requirements of regional authorities.

DRIVING THE CHANGE TO NEXT-GENERATION CONNECTED PLATFORMS AND SERVICES IN LIFE SCIENCES



DXC.technology

Wednesday, 18 April | 12:00-12:30
Innovation Theatre, Exhibition Hall

Speaker: **Sharad Khusal**, Life Sciences Global Build Lead, DXC Technology

The age of the life sciences silo business model is transforming. Companies are recognizing the need of a connected ecosystem to manage the entire life cycle of a product.

CAN AUTOMATION TRANSFORM REGULATORY LIFECYCLE MAINTENANCE?

Accenture

Wednesday, 18 April | 12:40-13:10
Innovation Theatre, Exhibition Hall

Exploration of automation for lifecycle maintenance: defining why the time for change is now, where automation can be applied, the potential benefits and approaches for industry for implementing automation projects.

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Agile PV	30
AMPLEXOR	39
Analytical Services International	8
APCER Life Sciences	119
Appian Software Switzerland LCC	98
Applied Clinical Trials	94
ArisGlobal	20
Asphalion S.L.	62
Astra Zeneca	91
Atrium	23
AXPHARMA SAS	59
Barrington James	55
BaseCon	18
BGO Software	99
Biomapas	116
Bio-Optronics	115
BIOSCRIPT	82
Blue Reg Pharma Consulting	56
C3i Solutions	71
CK QLS	118
Clinical Contract Research Association	11
Clinical Professionals	6
CliniThink	22
ClinTec International Ltd.	60
ConsilX	2
CPRD, The Clinical Practice Research Datalink	85
CTC Resourcing Solutions	74
DADA Consultancy B.V.	37

Company	Booth Number
Diamond Pharma Services	21
DLRC Ltd	38
Docshifter	77
Donnelley Language Solutions	123
Dora Wirth Languages	27
Dot Compliance	26
Drug Safety Research Unit	112
EidosMedia	36
ERT	76
EUDRAC Ltd	41
European Center of Pharmaceutical Medicine	28
European Medicines Agency	24
EXTEDO GmbH	65
F. Hoffmann - La Roche	45 & 46
G&L Scientific Inc	33 & 34
German Language Services	97
GXP-Engaged Auditing Services	122
Healthcare Businesswomen Association (HBA)	51
i4i Inc.	31 & 32
Ideagen	113
Inpharmatis	83
Insight Medical Writing	9 & 10
Integrated Clinical Systems, Inc.	90
Intexo Srl	84
Kayentis	120
Klifo A/S	14
Lean IT Consulting	57
Luto Research Limited.	16
MAIN5 GmbH & Co KGaA	3
MasterControl, Inc.	47

EXHIBITING COMPANIES AS OF 29 MARCH

Company	Booth Number
MDCPartners	100
MedDRA MSSO	58
Medical Affairs Professional Society (MAPS)	86
Medicines Evaluation Unit	5
Medrio, Inc.	108, 109, 110 & 111
Montrium	48
mt-g medical translation GmbH & Co KG	49 & 50
MyMeds&Me Limited	7
NDA Group	72 & 73
NIHR CRN	12
NNIT	66, 67, 68 & 69
Novartis	1
Novella Clinical Resourcing	13
Oracle Corporation	63 & 64
Pharma D&S	78
Pharmaceuticals and Medical Devices Agency (PMDA)	53
PharmaLex	106
Pharmathen S.A.	42
Pope Woodhead & Associates Ltd.	25
PQE	95
PrimeVigilance	43 & 44
PRMA Consulting	29
Productlife Group	80 & 81
Real Life Sciences	79
Regulatory Pharma Net s.r.l.	19
RWS Life Sciences	4
Scinopsis Medical Writing	107
SEC Recruitment	121
SeQure - PM Clinical Ltd	96
SFL Regulatory Affairs & Scientific Communication	54

Company	Booth Number
Statistics and Data Corporation (SDC)	88
Sveikuva	17
SWISSMEDIC - Swiss Agency for Therapeutic Products	15
Synchrogenix, A Certara Company	92 & 93
Tigermed Consulting	105
TOPRA	87
TranScrip	89
TransPerfect	70 & 75
Trilogy Writing & Consulting	35 & 40
Universal Medica	52
Uppsala Monitoring Centre	61
Veeva Systems	101
Veristat	114
XClinical GmbH	103
Xendo B.V.	104

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EXHIBITOR DIRECTORY

SUMMARIES PROVIDED BY EXHIBITING COMPANY AS OF 29 MARCH 2018

AB Cube

Booth 117



Website: <https://www.ab-cube.com/>
Email: raphaelle.courtay@ab-cube.com
Contact: Raphaëlle Courtay

AB Cube, a 10 years old publisher, provides the international healthcare industry with multivigilance softwares (Pharmacovigilance, Medical device vigilance, Cosmetovigilance, OS...) managing safety data, in compliance with European and worldwide regulatory requirements. All AB Cube solutions are validated according to GAMP5 and FDA 21CFR part 11.

ADAMAS Consulting

Booth 102



Website: www.adamasconsulting.com
Email: carly.davenport@adamasconsulting.com
Contact: Carly Davenport

ADAMAS is one of the largest QA consultancy organisations in the world and well respected within the healthcare industry. ADAMAS strives to provide cost-effective services of the highest value. ADAMAS manage QA projects in all areas of GxP. ADAMAS use their own internal QMS with full time consultants that are highly experienced and knowledgeable.

Agile P V

Booth 30



Website: www.agilepv.com
Email: dan.feith@agilepv.com
Contact: Dan Feith

Born from customer need, AgilePV provides intuitive, secure, and validated PV, Safety and Regulatory solutions that help organizations mitigate risk and enhance visibility within patient safety processes. We have new tools, so stop by!

AMPLEXOR

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Website: www.amplexor.com
Email: sherri.hughes-smith@amplexor.com
Contact: Sherri Hughes-Smith

AMPLEXOR Life Sciences assists organizations developing pharmaceutical drugs, medical devices, and biotechnology with launching products and breaking into new markets quickly. Its proven solutions and professional/business services expedite the creation and delivery of consistent, compliant, high-quality global content—both physical and digital.

Analytical Services International

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Website: <https://www.bioanalytics.co.uk/>
Email: stewart.hollington@bioanalytics.co.uk
Contact: Stewart Hollington

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Website: www.apcerls.com
Email: amarpreet.singh@apcerls.com

APCER Life Sciences has been providing comprehensive drug safety, medical information, medical writing, regulatory, QA and auditing services to life sciences companies since 2007. Currently, APCER has five offices and more than 700 employees globally: Princeton, NJ, USA; London, England, UK; Wan Chai, Hong Kong; New Delhi and Ahmedabad, India.

Appian

Booth 98



Website: www.appian.com

Appian delivers a digital transformation platform that accelerate the time it takes to build and deploy powerful, modern applications, on-premises or in the cloud. The world's most innovative life sciences organizations use Appian to revolutionise their customer experiences, transform operations, and master regulatory compliance. www.appian.com.

Applied Clinical Trials

Booth 94



Website: www.appliedclinicaltrials.com/

Applied Clinical Trials is the authoritative, peer-reviewed resource on clinical trials and the only brand dedicated exclusively to clinical trials providing effective solutions to challenges within this tightly regulated environment. Applied Clinical Trials is available in print and digital – including webinars, video and e-newsletters.

ArisGlobal

Booth 20



Website: www.arisglobal.com
Email: alowe@arisglobal.com
Contact: Alex Lowe

ArisGlobal transforms the way life sciences companies bring new products to market. Our LifeSphere™ cognitive technology integrates machine-learning capabilities to automate the product lifecycle. Our deep expertise combined with long-term perspective delivers insights, efficiency, compliance, and lowers TCO through multi-tenancy.

Asphalion S.L

Booth 62



Website: www.asphalion.com
Email: custrell@asphalion.com
Contact: Cristina Ustrell

Asphalion is an international Scientific and Regulatory Affairs consultancy. We collaborate with Pharma and Biotech companies facilitating Drug Development and Regulatory Affairs projects for Drugs, Biologics, Biosimilars, ATMPs and Medical Devices. We now have a team of over 80 employees with backgrounds in all areas of life sciences.

AstraZeneca

Booth 91



Website: www.astrazeneca.com
Email: liz.mayne@astrazeneca.com
Contact: Liz Mayne

EXHIBITOR DIRECTORY

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Atrium

Booth 23



Website: <https://www.atriumcph.com/>
Email: tj@atriumcph.com
Contact: Tina Jensen

"Regulatory Affairs and Pharmacovigilance - Training, Seminars and Conferences! 23 modules offered in cooperation with the University of Copenhagen, University of Southern Denmark and The Danish Health and Medicines Authority, can lead to: • Master Degree at the University of Copenhagen, Denmark • Diploma • Individual Modules"

AXPHARMA

Booth 59



Website: www.axpharma.com
Email: hmasset@axpharma.com
Contact: Hélène Masset

Created in 2001, AXPHARMA is a contract services organisation which is specialized in vigilances and medical information. Our full-service offers includes local and european delegation, case management, medical writing, literature screening and medical information. We also support our customers in carrying out trainings, audits and consulting.

Barrington James

Booth 55



Website: www.barringtonjames.com
Email: bpearce@barringtonjames.com
Contact: Ben Pearce

Barrington James is a Global specialist recruitment consultancy with offices in Europe, the USA and Asia Pacific that work across the Healthcare sector.

BaseCon A/S

Booth 18



Website: www.basecon.com
Email: sales@basecon.com
Contact: Sven Kjær Nielsen

"BaseCon offers a slim and effective Pharmacovigilance System for collection, analysis, reporting and submission of adverse events to medical products in accordance with EU regulation 726/2004 as amended et al. Offered as a service, thus taking the burden of setup of secure and controlled server environment off the shoulder of the customer!"

BGO Software

Booth 99



Website: www.bgosoftware.com
Email: lidia.todorova@bgosoftware.com
Contact: Lidia Todorova

BGO Software develops software that empowers businesses and helps transform society. We craft software for the Department of Health (UK), a Fortune 100 Pharmaceutical Corporation and we are an official Progress Premier Partner & Microsoft Gold Partner. We create custom IT Solutions for the Clinical Research, Healthcare, & Pharma Industries.

Bio-Optronics

Booth 115



Website: www.bio-optronics.com
Email: lmiceli@bio-optronics.com
Contact: Lauren Miceli

Bio-Optronics, the creator of Clinical Conductor CTMS, is a leading software and services company that creates user-focused software and services for healthcare organizations that positively impacts the lives of patients around the world. Clinical Conductor CTMS is an established clinical trial management system designed to help businesses run the world's best research.

Bioscript

Booth 82



Website: www.bioscriptgroup.com
Email: Jackie.Richards@bioscriptgroup.com
Contact: Jackie Richards

Bioscript is a global, independent agency group offering regulatory writing and strategic scientific communications to international pharmaceutical, biotechnology and medical device companies. We have grown organically over 13 years, forging long-term client partnerships, offering cohesive strategic planning and seamless implementation.

BLUEREG GROUP

Booth 56



Website: www.bluerreg-group.com
Email: chifflet.johanna@blue-reg.com
Contact: Johanna Chifflet

"BlueReg is an international consultancy company specialised in development, regulatory affairs, quality management and pharmacovigilance for the pharmaceutical industry.

We provide tailored consulting services including expert advice and hands-on operational execution and have developed long term partnerships with clients."

C3i Solutions

Booth 71



Website: www.c3isolutions.com
Email: stefaan.vanassche@c3isolutions.com
Contact: Stefaan Vanassche

C3i Solutions: BPO with 35-years history of handling complex and sensitive interactions in the life sciences industry. From basic medical inquiries to complex adverse event intake, case processing and aggregate reporting, C3i Solutions provides an end-to-end solution for all of your PV needs including product safety, MI and regulatory compliance.

Clinical & Contract Research Association

Booth 11



Website: www.ccra.org.uk
Email: mail@ccra.org.uk
Contact: Ms Sue Dilks

If you are serious about the conduct of clinical trials to the highest standards and take any part in the industry (CRO or service provider in this sector) come and talk to us about membership! CCRA is the UK trade association which represents this sector and provides enhanced business opportunities, a badge of quality and a voice for the industry.

Clinical Practice Research Datalink (CPRD)

Booth 85



Website: www.cprd.com
Email: [tara.t-nheadley@mhra.gov.uk](mailto: tara.t-nheadley@mhra.gov.uk)

CPRD is a governmental, not-for-profit research centre, facilitating and conducting public health observational research and interventional real world clinical trials using electronic health records. The depth of its longitudinal data makes CPRD the observational research data provider of choice for regulators, industry and academics globally

EXHIBITOR DIRECTORY

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Clinical Professionals

Booth 6



Website: <https://www.clinicalprofessionals.co.uk>
Email: info@clinicalprofessionals.co.uk
Contact: Daniel Patterson

Clinical Professionals is a pan European life sciences staffing business dedicated to the pharmaceutical, biotech, medical device, CRO and drug discovery industries. We provide clinical development, medical technology and commercial professionals to life sciences organisations on a permanent, retained, "hosted contract", FSP and freelance basis.

Clinithink

Booth 22

Website: www.clinithink.com
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Clintec International Ltd

Booth 60



Website: www.clintec.com
Email: sjohnston@clintec.com
Contact: Stephanie Johnston

ClinTec International is an award winning expert in global Clinical Research as a Functional Service Provider (FSP), with operations in more than 50 countries. As an entrepreneurial company, ClinTec strategically aligns its services with clients' needs, offering customized innovative clinical research solutions with a focus on Oncology and Rare Disease.

ConsilX

Booth 2



Website: www.consilx.com
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Contact: Darpan Ahuja

We find the data provenance and collaboration capabilities of Blockchain very powerful. Coupled with other technologies this technology disruption can dramatically impact clinical trials and patient health outcomes. Our first product is patient focused and empowers the patient digitally to contribute as an Informed Collaborator in a clinical trial.

CTC Resourcing Solutions

Booth 74



Website: www.ctcresourcing.com
Email: info@ctcresourcing.com
Contact: Mario Neyerlin

Founded in 1997, CTC is a recruitment and training organisation for Life Sciences. We excel at finding specialist talent for contract and permanent roles and also provide ongoing development via highly valued training portfolio. We are regarded as the gold standard by our clients when it comes to identifying and developing talent.

DADA Consultancy B.V.

Booth 37



Website: www.dada.nl
Email: Office@dada.nl
Contact: Patty Robins

DADA Consultancy provides you with tailor-made support. We have long-term partnerships with our clients, based on our continuous high quality of work. Our experienced consultants can provide you with a fitting solution to problems you may encounter in Regulatory Affairs, Pharmaceutical Development, Pharmacovigilance and Clinical projects.

Diamond Pharma Services

Booth 21



Website: www.diamondpharmaservices.com
Email: info@diamondpharmaservices.com
Contact: Nicholas Littlebury

"Diamond Pharma Services is a leading technical & scientific consulting group with an emphasis on the following areas: •Regulatory Affairs: Product Concept to Registration and Beyond •Product Development: Nonclinical, CMC and Clinical Aspects •Pharmacovigilance: Clinical trials, Post-Marketing and QPPV Services •Compliance: GxP & QP Services"

DLRC Ltd

Booth 38



Website: www.dlrc.co.uk
Contact: Email: enquiries@dlrc.co.uk

DLRC is a forward-thinking regulatory affairs consultancy that understands the individual needs of clients. Our broad experience supports pharma and biotech companies globally, delivering successful paediatric plans, PRIME and Orphan designations, health authority interactions, CTA and marketing authorisation submission strategies and approvals.

Donnelley Language Solutions

Booth 123



Website: www.donnelleylanguagesolutions.com
Email: carolina.arias@dfsco.com
Contact: Carolina Arias

Donnelley Language Solutions helps human and animal health companies around the world to communicate with confidence. We do that by providing end-to-end localization solutions empowered by technology which are tailored to needs of the different functions within these organizations. Decades of long term client relationships with global life sciences companies attest to our commitment to go above and beyond their needs in order to reach their goals.

Dora Wirth Languages Ltd

Booth 27



Website: www.dwlanguages.com
Email: s.j.wirth@dwlanguages.com
Contact: Samuel J. Wirth

DWL has over 53 years' experience in providing translation services in the following specialist areas: regulatory affairs, clinical research, medical research, medical publishing, medical devices, manufacturing and legal. A strong commitment to quality and service make DWL your reliable partner for global life science translation solutions.

Drug Safety Research Unit (DSRU)

Booth 112



Website: www.dsru.org
Email: elizabeth.lynn@dsru.org
Contact: Dr Elizabeth Lynn

DSRU is an independent unit with respected pharmacovigilance, pharmacoepidemiology and risk management expertise. We offer consultancy and conduct post-authorisation safety studies in primary and secondary care. With our in-depth grasp of medicines regulations we also run registries, risk minimisation, drug utilisation and European network studies.

EXHIBITOR DIRECTORY

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ECPM University of Basel

Booth 28

Website: www.ecpm.ch
Email: ecpm@unibas.ch
Contact: Katja Suter/Beatrice Schmid

The European Center of Pharmaceutical Medicine is the leading institute for training in drug development. Since its foundation in 1991 we have trained over 1800 integrated drug developers. Being a part of the medical faculty of the University of Basel we offer a neutral platform to bring together experts and to exchange knowhow and to network.

EIDOSMEDIA

Booth 36



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Email: massimo.barsotti@eidosmedia.com
Contact: MASSIMO BARSOTTI

EidosMedia is a global leader in structured authoring, component-based authoring and multi-channel publishing. Based on advanced digital technologies, our platforms enable a modular, collaboration-based approach to workflow with significant benefits in productivity, oversight and compliance at every stage of the document life cycle.

ERT

Booth 76



Website: www.ert.com
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Contact: Molly Cappotelli

ERT is a global data and technology company that minimizes uncertainty and risk in clinical trials so that its customers can move ahead with confidence. With nearly 50 years of clinical and therapeutic experience, ERT balances knowledge of what works with a vision for what's next, so it can adapt without compromising standards.

EUDRAC Group

Booth 41



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Email: carole.pugh@eudrac.com
Contact: Carole Pugh

EUDRAC is a regulatory affairs & pharmacovigilance consultancy based in UK, Germany & France. Our services to pharma & medical device companies extend through the development, registration, market launch & life cycle management phases, including e-CTD publishing. Our clients value our high quality work performed according to project timelines.

European Medicines Agency

Booth 24



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Contact: Beatrice Fayl von Hentaller

The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources put at its disposal by member states for the evaluation, supervision, and pharmacovigilance of medicinal products.

EXTEDO GmbH

Booth 65



Website: www.extedo.com
Email: info@extedo.com
Contact: Thomas Kessler

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes. Today, EXTEDO enables more than 35 regulatory authorities and over 700 maintained customers across 60 countries to deliver Effortless Compliance™.

F. Hoffmann-La Roche

Booth 45 & 46



Website: www.roche.com

Roche is a global pioneer in pharmaceuticals and diagnostics, focusing on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best possible way. Visit www.roche.com.

German Language Services

Booth 97



Website: www.germanlanguageservices.com
Email: richard@germanlanguageservices.com
Contact: Richard Patrick

German Language Services is a translation service provider focusing exclusively on the German <> English language pair. For over 35 years, our pharmaceutical clients have benefited from our consistent, technically accurate translations that are perfectly reflective of the original document in form and content. Stop by our booth and get to know us!

GXP-Engaged Auditing Services GmbH

Booth 122

Website: www.GXP-Auditing.com
Email: Barbara.Heumann@GXP-Auditing.com
Contact: Barbara Heumann

GXP-Engaged Auditing Services – as the largest independent Quality Assurance provider located in mainland Europe, with a global network of over 60 consultants, we have the right solution for your QM and auditing needs.

Healthcare Businesswomen Association (HBA)

Booth 51



Website: www.hbanet.org
Email: anajimenezorgaz@gmail.com
Contact: Ana Jimenez Orgaz

When members of the Healthcare Businesswomen's Association come together, it's with a shared purpose: to be a united force for change. We connect diverse groups of both women and men, across all healthcare and life science disciplines. By taking focused action to advance our mission, we're creating a powerful movement that directly drives professional opportunity and corporate growth.

i4i Inc.

Booth 31 & 32



Website: i4i.com
Email: contact@i4i.com
Contact: Ruth Wylie

i4i is a world leader in structured content solutions. Our innovative technology, regulatory and standards expertise support enhanced global compliance with our platform to connect, control, track & analyse the content & data in your documents. Intelligent reuse, rich data capture & jurisdictional alignment delivers consistency & compliance.

Ideagen

Booth 113



Website: www.ideagen.com
Email: info@ideagen.com

Ideagen's solutions for document collaboration and control make reviewing and making changes to documents more effective and efficient. Together, PleaseReview and Q-Pulse standardise and automate the document control process from a request for change, through review, acceptance or rejection of changes, approval, distribution and acknowledgement.

EXHIBITOR DIRECTORY

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INSIGHT MEDICAL WRITING

Booth 9 & 10



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Contact: Tim Griffiths

"Our documents ensure smooth progress through approval and beyond. A clear, accurate and quality-led service. We are the reliable, flexible and highly qualified team who always deliver on time and on budget. • Writing • Clinical • Editing • Regulatory • Quality control • Pharmacovigilance • Data transparency • Medical marketing"

Integrated Clinical Systems, Inc.

Booth 90



Website: www.i-review.com
Email: eherb@i-review.com
Contact: Eric S Herbel

Integrated Clinical Systems - developers of JReview® - the fastest and easiest way to review, graph, visualize, report, analyze, do patient profiles and patient narratives and Risk Based Monitoring & data quality analytics for your clinical data. Works with SAS datasets, Oracle databases and Oracle LSH, Medidata Rave, drug safety databases

Intexo S.r.l.

Booth 84

Website: www.intexo.it
Email: claudia.bertozzi@intexo.it
Contact: Claudia Bertozzi

INTEXO is a consulting company which aids the healthcare sector's Companies by supporting their Regulatory Affairs and Market & Patient Access functions with its experience and in-depth knowledge of the business dynamics and needs. Our core value is the integration of science, regulatory processes and market dynamics, in order to accompany the product throughout its entire life cycle, anticipating the context and seizing the opportunities at any stage of development.

Kayentis

Booth 120



Website: www.kayentis.com
Email: kayentis@kayentis.com
Contact: FREDERIQUE MARION

"Kayentis is a global provider of (eCOA) solutions for patient data collection in clinical trials.

Kayentis adds value to data quality and clinical trial efficiency with innovative and intuitive solutions and has two development priorities: Patient Engagement and Enabling Risk-based Monitoring"

KLIFO A/S

Booth 14

Website: www.klifo.com
Email: mette.widen@klifo.com
Contact: Anne Tingsgård

KLIFO is an established and integrated drug development consultancy. We provide end-to-end expert capabilities enabling our partners to maximize opportunity, mitigate risks, drive innovation and achieve efficient project advancement.

Lean IT Consulting

Booth 57



Website: www.plm-software-leanit.com
Email: info@leanitconsulting.ch
Contact: Raffaele Marranzini

"Innovation Management and Product Lifecycle Management (PLM) software solutions for the Healthcare industry. Cloud and on-premise software solutions for Idea Management, New Product Development and Launch Planning including Regulatory processes management. More info at www.leanitconsulting.ch"

Luto Research Limited

Booth 16



Website: www.lutoresearch.com
Email: solutions@lutoresearch.com
Contact: Kirstin Blackwell

Luto are experts in producing clear communications through good information design. We write and design great digital and print communications and then test them with real people to make sure the information meets their needs.

MasterControl

Booth 47



Website: www.mastercontrol.com
Email: info@mastercontrol.com
Contact: Eliana Valcarcel

"Regulated companies worldwide use MasterControl software to bring life-improving products to more people sooner. MasterControl Business Excellence Platform™ (BxP) accelerates ROI and increases efficiency by automating and managing the product lifecycle in a way that is easy to scale, implement, validate and use."

MAIN5

Booth 3



Website: www.main5.de
Email: diana.kuellmer@main5.de
Contact: Diana Küllmer

MAIN5 GmbH & Co. KGaA is a privately held Management Consulting company headquartered in Frankfurt, Germany. MAIN5 focuses on strategy, process and solution consulting for international life science organizations in its regulatory business domains such as R&D, Regulatory Affairs, Pharmacovigilance and Quality Management. The associated MAIN5 Institute provides dedicated seminars for innovative project methodologies and leadership development in life science industry.

MDCPartners

Booth 100



Website: <https://www.mdcpartners.be/>
Email: info@mdcpartners.be
Contact: David Cocker

MDCPartners specializes in business intelligence and strategic consultancy for the pharmaceutical and biotech industry. We combine drug development expertise with the latest data sciences to provide clinical trial optimization, medical expert identification, and competitive intelligence.

MedDRA MSSO

Booth 58



Website: www.meddra.org
Email: mssorequest@meddra.org

MedDRA - the Medical Dictionary for Regulatory Activities - is a medical terminology used to classify adverse event information associated with the use of biopharmaceuticals and other medical products (e.g., medical devices and vaccines).

Medical Affairs Professional Society (MAPS)

Booth 86

Website: www.medicalaffairs.org
Email: info@medicalaffairs.org
Contact: Travis Hege

MAPS is the premier non-profit global society for Medical Affairs (MA) professionals. We aim to elevate the role of Medical Affairs to be a partner with Commercial and R&D by promoting excellence across MA functions, developing guidelines to support industry standards, providing learning & development, and encouraging professional collaborations.

EXHIBITOR DIRECTORY

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Medicines Evaluation Unit Ltd

Booth 5



Website: www.meu.org.uk
Email: drogers@meu.org.uk
Contact: David Rogers

Medicines Evaluation Unit (MEU) Ltd is one of the UK's leading contract research organisations. An MHRA Phase 1 Accredited Site, possessing extensive pharmaceutical, scientific and clinical expertise, in a state-of-the-art hospital-based facility. MEU's bespoke database (ICARUS) assists rapid recruitment ensuring we meet our clients' timelines.

Medrio Booth 108,109,110 & 111



Website: www.medrio.com
Email: sales@medrio.com

Medrio is a leading healthcare technology company providing eClinical solutions including EDC, eSource, and ePRO for clinical research. Founded in 2005, the company's cloud-based software platform and mobile suite of products deliver fast, flexible, and easy-to-use tools for the collection and management of clinical data and patient reported outcome responses.

mt-g medical translation GmbH & Co. KG

Booth 49 & 50



Website: <http://mt-g.com/>
Email: jenniferhaya@mt-g.com
Contact: Jennifer Haya

Quality is the priority for mt-g. As a language service provider, we specialise exclusively in medical and pharmaceutical translations in the following areas: medical technology, global regulatory affairs, clinical studies, marketing and communications in the medical and pharmaceutical industry as well as dentistry and dental technology.

MyMeds&Me Limited

Booth 7



Website: www.mymedsandme.com
Email: andy.watson@mymedsandme.com
Contact: Andy Watson

MyMeds&Me is a leading SaaS provider of web-based adverse event and product quality capture solutions for life sciences. Our vision is to develop and deliver web-based data capture solutions in a short time-frame that support the transformation of the end-to-end pharmacovigilance process, providing benefits to Pharma companies, CROs and regulatory agencies whilst improving assessment of patient safety

NDA Group

Booth 72 & 73



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Email: anna.perrin@ndareg.com
Contact: Anna Perrin

NDA is a world leading drug development consultancy. We streamline global drug development to get important medical therapies to patients faster. Our experts are leaders in clinical and regulatory drug development, payer strategy and High-stakes meeting preparation. NDA supported over 40% of the new medicinal products approved in the EU 2013-2017.

NIHR

Booth 12



Website: www.nihr.ac.uk/Industry-study-support
Email: matt.cooper@nihr.ac.uk
Contact: Matt Cooper

The National Institute for Health Research Clinical Research Network? is the research delivery arm of the UK's National Health Service (NHS). We are funded by the government to provide a range of free services to life science companies and CROs to support rapid study set-up and patient recruitment into all phases of clinical research studies.

NNIT

Booth 66, 67, 68, 69



Website: www.nnit.com
Email: mtld@nnit.com
Contact: Mads Torry Lindeneg

"NNIT is an international consultancy in the development, implementation, validation and operation of IT for the life sciences industry. We create value for our clients by treating their IT as if it were our own and, of course, we meet the industry's strictest requirements for quality."

Novartis

Booth 1

Novartis is an international pharmaceutical company based in Basel, Switzerland. In our portfolio, there are patented drugs, generic drugs and eye care products. We use science-based innovation to develop high-quality medicines and products that can deliver better patient outcomes in growing areas of healthcare.

Novella Clinical Resourcing

Booth 13

Website: novellacr.com
Email: sraney@novellaclinical.com
Contact: Stephanie Raney

Novella Clinical Resourcing, a Quintiles company, is a global leader in providing comprehensive resourcing solutions across all disciplines of clinical research. Headquartered in Morrisville, N.C., Novella Clinical Resourcing has been matching clinical professionals with rewarding opportunities since 2005.

Oracle Corporation

Booth 63 & 64



Website: www.oracle.com/healthsciences
Email: healthsciences_ww_grp@oracle.com
Contact: Kate Andrews

Oracle provides the only eClinical platform made up of best-of-breed solutions powered by the #1 data and cloud technology in the world. With us, life science organizations can manage and unify all elements of the clinical development lifecycle in a safe, secure and compliant manner, while also being open, collaborative and adaptive to change.

Pharma D&S

Booth 78



Website: www.pharmades.it
Email: apieri@pharmades.it
Contact: Andrea Pieri

"Pharma D&S is a European Service Provider in following main areas: • Pharmacovigilance, • Regulatory Affairs, • Quality and Process, • Clinical Research and Medical Information. Our Mission is to support Lifescience Companies with flexibility and integrated competencies. A panel of 140 consultants support + 400 companies in + 1500 projects."

Pharmaceuticals and Medical Devices Agency

Booth 53



Website: <https://www.pmda.go.jp/english/index.html>
Email: sato-miho@pmda.go.jp

Office of International Programs The Pharmaceuticals and Medical Devices Agency (PMDA) is the Japanese regulatory agency focuses on three key service areas: scientific reviews of medical products, safety measures, and relief services for persons suffering from adverse health effects, in collaboration with the Ministry of Health, Labour and Welfare (MHLW). PMDA will continue to endeavor proactively to safeguard and promote the nation's health and safety, while strengthening its partnerships with other countries and regions.

EXHIBITOR DIRECTORY

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PharmaLex


Booth 106

Website: www.pharmalex.com
▶ PHARMALEX Email: josefine.cladd@pharmalex.com
Contact: Josefine Cladd

PharmaLex is one of the largest providers for Development Consulting, Regulatory Affairs, Quality Management & Compliance and Pharmacovigilance, Epidemiology & Risk Management worldwide. Our experts cover early strategic planning activities through regulatory submission processes and guide you to market approval and product maintenance activities.

Pharmathen S.A.


Booth 42

 Website: www.pharmathen.com
Email: edova@pharmathen.com
Contact: Evangelia Dova

Pharmathen, located in Athens, Greece, was founded in 1969. With 3 state-of-the-art R&D laboratories, Pharmathen's core business is the out-licensing of complex generics & advanced pharmaceutical technologies to pharma companies globally. Over & above, Pharmathen aspire to deliver top-class pharmacovigilance services safeguarding regulatory compliance & market presence for clients' products.

Pope Woodhead


Booth 25

 Website: www.popewoodhead.com
Email: laura.waite@popewoodhead.com
Contact: Laura Waite

Huron's Life Science practice comprises Huron Life Science Strategy and Pope Woodhead, and is part of a continuum of offerings that supports the development and commercialization of pharmaceutical products and services.

PQE Group


Booth 95

 Website: www.pqegroup.com
Email: info@pqegroup.com
Contact: Ulrike Malordy

Your Complete Quality Solution Provider. Global partner supporting you worldwide in Data Integrity, Qualification, Compliance, Regulatory Affairs and Third Party Audits. ISO9001 certified consulting services company. Global capabilities deliverable throughout the entire product quality life cycle, at competitive prices.

PRIMEVIGILANCE


Booth 43 & 44

 Website: www.primevigilance.com
Email: florence.denance.habek@primevigilance.com
Contact: Florence Denance Habek

PrimeVigilance is focused on providing high quality, fully compliant pharmacovigilance & medical information services, with over 500 in-house employees, supporting pharma, biotech & generics companies in managing their products' global pharmacovigilance activities from clinical through full post marketing within their EU, US & international markets.

PRMA Consulting


Booth 29

 Website: www.pрмаconsulting.com
Email: info@prmaconsulting.com
Contact: Jan McKendrick

PRMA Consulting is an independent specialist consultancy solving some of the most challenging market access issues facing pharmaceutical and biotechnology companies today. We pride ourselves on being one of the most well-informed consultancies across the globe, and offer an extensive service portfolio. We look forward to meeting you on stand 29.

Productlife Group


Booth 80 & 81

 Website: <https://productlifegroup.com/>
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Contact: Laura Lambs

ProductLife Group specialises in helping international life sciences organisations more effectively get their products and therapies to market by providing those clients with functional support across all of the regulated stages of the product life cycle—from development to launch, to postmarketing. Visit us at www.productlifegroup.com.

Real Life Sciences

Booth 79

 Website: www.realstaffing.com
Email: dia2018@realstaffing.com
Contact: Tom Way

Real Life Sciences is a global leader in the provision of pharma, biotech and medical devices recruitment services. Working across Europe, the US and Asia Pac we are one of the world's most extensive life sciences recruiters. #inspiredbyyou is the mindset at the core of everything we do, ensuring we place our customers' needs first and foremost.

Regulatory Pharma Net srl


Booth 19

 Website: www.regulatorypharmanet.com
Email: accounting@regulatorypharmanet.com

Regulatory Pharma Net (RPN) offers full Regulatory Affairs, Pharmacovigilance and Market Access assistance during the development, registration and maintenance phase of medicinal products. The highly qualified RPN team works with its clients, complementing their skills and resources to help them overcome obstacles in the management of RA activities.

RWS Life Sciences

Booth 4

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"RWS Life Sciences is the world's second largest life sciences translation practice providing a full suite of language solutions exclusively for life sciences. Our proven methodology, industry leading technology, and specialized translation professionals make us well qualified to translate all types of content across the life sciences industry."


Scinopsis

Booth 107

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Contact: H    ne Sardet

SEC Recruitment

Booth 121

 Website: <https://www.secrecruitment.com>
Email: chris.howard@secrecruitment.com

It's easy to say, 'we're different' as a recruitment business, which is why at SEC we like to show our candidates and clients that we are through our actions and our delivery. We are a life sciences and IT specialist recruitment agency that lives by four core values of trust, honesty, integrity and commitment.

seQure Life Sciences

Booth 96

Website: www.sequirelifesciences.com
Email: info@sequirelifesciences.com
Contact: Daniela Marozzi

seQure provides expert pharmacovigilance, quality management and assurance, regulatory and computer system validation solutions to drug and device companies to help them meet regulatory requirements.

EXHIBITOR DIRECTORY

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Email: data@sdcclinical.com
Contact: Jim Townsend

SDC delivers top-tier clinical trial services to pharma, biologic, and device/diagnostic companies. With strategic scientific consulting and clinical data services (biostatistics, data management/EDC, and IRT/IWRS) expertise at our core, our services are scalable via our strategic partnerships to provide full service clinical trial solutions.

Sveikuva, UAB Booth 17



Website: www.sveikuva.lt
Email: sk@sveikuva.lt
Contact: Stanislovas Kasparavicius

Sveikuva has been established in 2003. Today we are offering range of consulting activities in regulatory and pharmacovigilance fields in EU and CIS countries.

Swissmedic Booth 15

Website: www.swissmedic.ch
Email: nicole.luethi@swissmedic.ch
Contact: Nicole Lüthi

Swissmedic is the national authorisation and supervisory authority for drugs and medical products. The agency ensures that only high-quality, safe and effective medical products are available in Switzerland, thus making an important contribution to the protection of human and animal health.

Synchrogenix Booth 92 & 93



Website: www.synchrogenix.com
Email: sales@synchrogenix.com
Contact: Lauren Sobocinski

Synchrogenix provides regulatory & communications strategy, science, & services to pharmaceutical, device, & tobacco companies worldwide. From submission strategy & reg ops leadership, to regulatory/medical writing, to transparency & disclosure compliance, we combine expertise with technology-enabled solutions to propel products to patient access.

TranScrip Booth 89



Website: www.transcrip-partners.com
Email: michelle.kingston@transcrip-partners.com
Contact: Michelle Kingston

TranScrip's Drug Safety & PV team work on a wide range of projects from early clinical development to post licensing PV. Examples for both large & small companies include ongoing signal management & development of safety regulatory documentation i.e. periodic reports & Risk Management Plans. We offer EU QPPV services & relevant training programmes.

TransPerfect Booth 70 & 75



Website: www.transperfect.com
Email: tscott@transperfect.com
Contact: Terra Scott

TransPerfect Life Sciences specialises in supporting global development and commercialisation of drugs, treatments and devices designed to improve and save lives. Our comprehensive solutions include eTMF and eClinical technologies, paper TMF migration, pharmacovigilance and safety solutions, translation and language services, and call centre support.

Trilogy Writing & Consulting Booth 35 40



Website: www.trilogywriting.com
Email: cleagh.sinclair@trilogywriting.com
Contact: Cleagh Sinclair

Trilogy is a medical writing consultancy focused specifically on clinical regulatory documentation. We work as an outsourcing partner for pharmaceutical companies of all sizes: proactively planning, coordinating and writing their clinical documentation to meet timelines, with a readability that reduces the time for review and approval.

UNIVERSAL MEDICA Booth 52



Website: www.universalmedica.com
Email: rafi.mardachti@universalmedica.com
Contact: Rafi Mardachti

Universal Medica is a Global Contract Services Organization which offers a full range of services including Medical Information, Medical Communication, Crisis Management and Communication, Pharmacovigilance and Risk Management, Real-World Evidence and Market Access.

Uppsala Monitoring Centre Booth 61



Website: www.who-umc.org
Email: info@who-umc.org
Contact: Anna Mattsson

Uppsala Monitoring Centre is a non-profit foundation and centre for international service and scientific research. Our vision is a world where all patients and health professionals make wise therapeutic decisions in their use of medicines. Our mission is to support and promote patient safety through effective global pharmacovigilance practice.

Veeva Systems Booth 101



Website: <https://www.veeva.com/eu/>
Email: laura.garrido@veeva.com
Contact: Laura Garrido

"Veeva Systems Inc. is a leader in cloud based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva has more than 600 customers, ranging from the world's largest pharmaceutical companies to emerging biotech. For more information, visit www.veeva.com/eu"

XClinical GmbH Booth 103



Website: www.xclinical.com
Email: sabine.birkner@xclinical.com
Contact: Sabine Birkner

XClinical's software suite Marvin comprises a CDISC-certified EDC system and numerous functional modules to support the clinical data management process in every language. Marvin is easy to use without the need of programming knowledge. This facilitates an easy and very cost-effective conduct of all types of clinical studies. Marvin your Study!

Xendo BV Booth 104



Website: www.xendo.com
Email: info@xendo.com

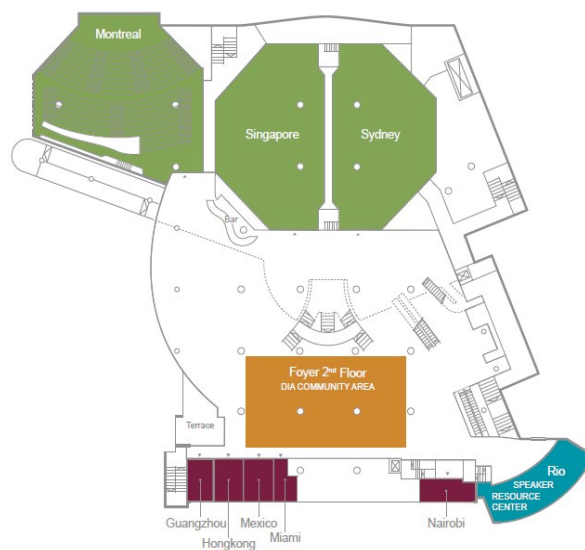
"Xendo is a leading consultancy and project management organisation in the fields of (bio)pharmaceutical products, medical devices and healthcare. Together with the recently acquired Sofus Regulatory Affairs, over 220 experienced and highly educated professionals offer their expertise ranging from strategic advice and project management to auditing, operational support and training."

DIA EUROPE 2018 FLOORPLAN

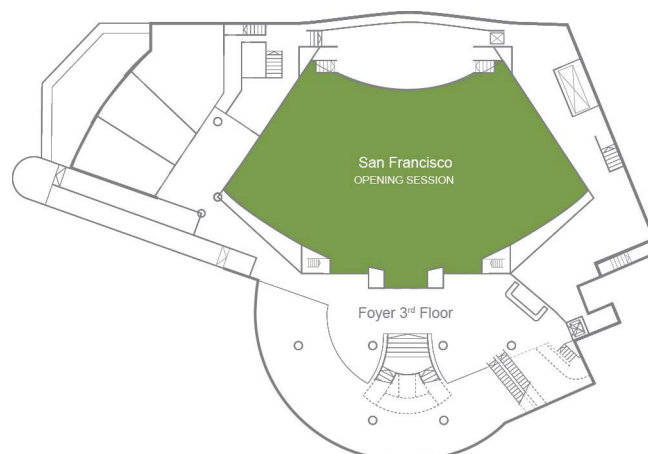
Ground Floor



2nd Floor



3rd Floor



EXHIBITION HALL FLOORPLAN



DIA Europe 2018

NETWORKING

Networking is an integral part of DIA Europe 2018. Past attendees tell us that the networking opportunities at DIA Europe are one of the key reasons for attending. Each year, DIA Europe offers numerous opportunities to catch up with existing contacts and to make new ones in a relaxing setting. **All networking events at DIA Europe 2018 are included in the registration fee.**

Visiting the DIA Europe 2018 Exhibition Hall

The Exhibition provides a perfect forum for attendees



and speakers to network with more than 100 exhibiting companies. With virtually every facet of the life sciences industry represented - CROs, technology vendors, research centers, academia, and much more. The Exhibit Hall is one of the busiest places at the meeting.

“Welcome to Basel” Opening Reception

Tuesday, 17 April
17:30–19:30



Join us and celebrate Basel Carnival during the Opening Reception!

Basler Fasnacht is part of the city’s identity – culturally speaking, it is at the heart of its creative energies and represents three days when the city goes wild. Owing to its uniqueness and quality, it has been added to the UNESCO intangible cultural heritage list. Experience how Basel is turned upside-down during what locals call the “three best days” in the year – which, for us would be the three days of DIA Europe 2018!

Wednesday Exhibitor Networking Reception in the Exhibition Hall

Wednesday, 18 April
17:30–18:30



Don’t miss this great opportunity to meet exhibitors and peers with similar interests! There will be dedicated zones on the exhibition floor highlighting each of the eight thought-leadership streams – to ensure you meet new and old colleagues who share the same interest area.

Lunch Breaks



Take advantage of the lunch hours in the Exhibit Hall to visit more than 100 exhibiting companies.

Tuesday, 17 April | 12:30–14:00
Wednesday, 18 April | 12:00–14:00
Thursday, 19 April | 12:00–13:00

Refreshment Breaks



Mid-morning and mid-afternoon breaks will be held in designated areas of the Exhibit Hall.

Tuesday, 17 April | 10:30–11:00 and 15:30–16:00
Wednesday, 18 April | 10:00–10:30 and 15:15–16:00
Thursday, 19 April | 10:00 – 10:30

Poster Sessions



The DIA Poster Sessions provide the opportunity for individuals to present their research and offer an excellent venue for extended informal discussion with meeting attendees. There will be a dedicated area in the exhibit hall for Student and Professional Posters. Oral Presentations will also be scheduled.

Follow @DrugInfoAssn



DIA Europe 2018

PRACTICALITIES

| CONFERENCE AND EXHIBITION VENUE



DIA Europe 2018 will take place at the:

Congress Center Basel
Messeplatz 21
4058 Basel, Switzerland
www.congress.ch

| ABOUT BASEL



With 196,000 inhabitants, Basel is the third largest city in Switzerland, situated in the very northwest of the country near the French and German borders. The city, located on the Rhine, offers its visitors a unique mix of modern and historical architecture.

In Basel, you will find a unique concentration of innovative companies, research institutes and academic institutions, a cosmopolitan culture, an international environment and business-friendly conditions. The city on the Rhine is a center for life sciences as well as the chemical and pharmaceutical industries.

| ACCESSIBILITY

In Basel, everything is right at your doorstep. Thanks to the EuroAirport Basel-Mulhouse-Freiburg, Basel is easily accessible from all major European cities and all European airport hubs. You can reach the city centre in only 20 minutes from the EuroAirport and all major meeting hotels are within walking distance from the Old Town. Furthermore, the city is integrated in the European high speed train network and served by the French TGV and the German ICE. The Zurich Airport with its many international connections can be reached in approx. 75 minutes via a direct railway connection.

| FREE PUBLIC TRANSPORT AND GUEST WIFI

Your personal BaselCard will be handed to you when you check in to your hotel. The attractive features of the BaselCard include free use of public transport, free surfing on the guest WiFi plus a 50% discount on admission to Basel's museums, Basel Zoo, Theater Basel and much more.

| HOTEL BOOKINGS

We have negotiated special conference hotel rates with K.I.T. Group GmbH for DIA Europe 2018. Please be advised that DIA has only contracted K.I.T. Group GmbH as exclusive hotel agent for DIA Europe 2018. Bookings are available online at <https://react-profile.org/HBS/public/DIA2018/init/Regular>.



DIA 2018

GLOBAL ANNUAL MEETING
BOSTON | JUNE 24-28



DIAglobal.org/DIA2018