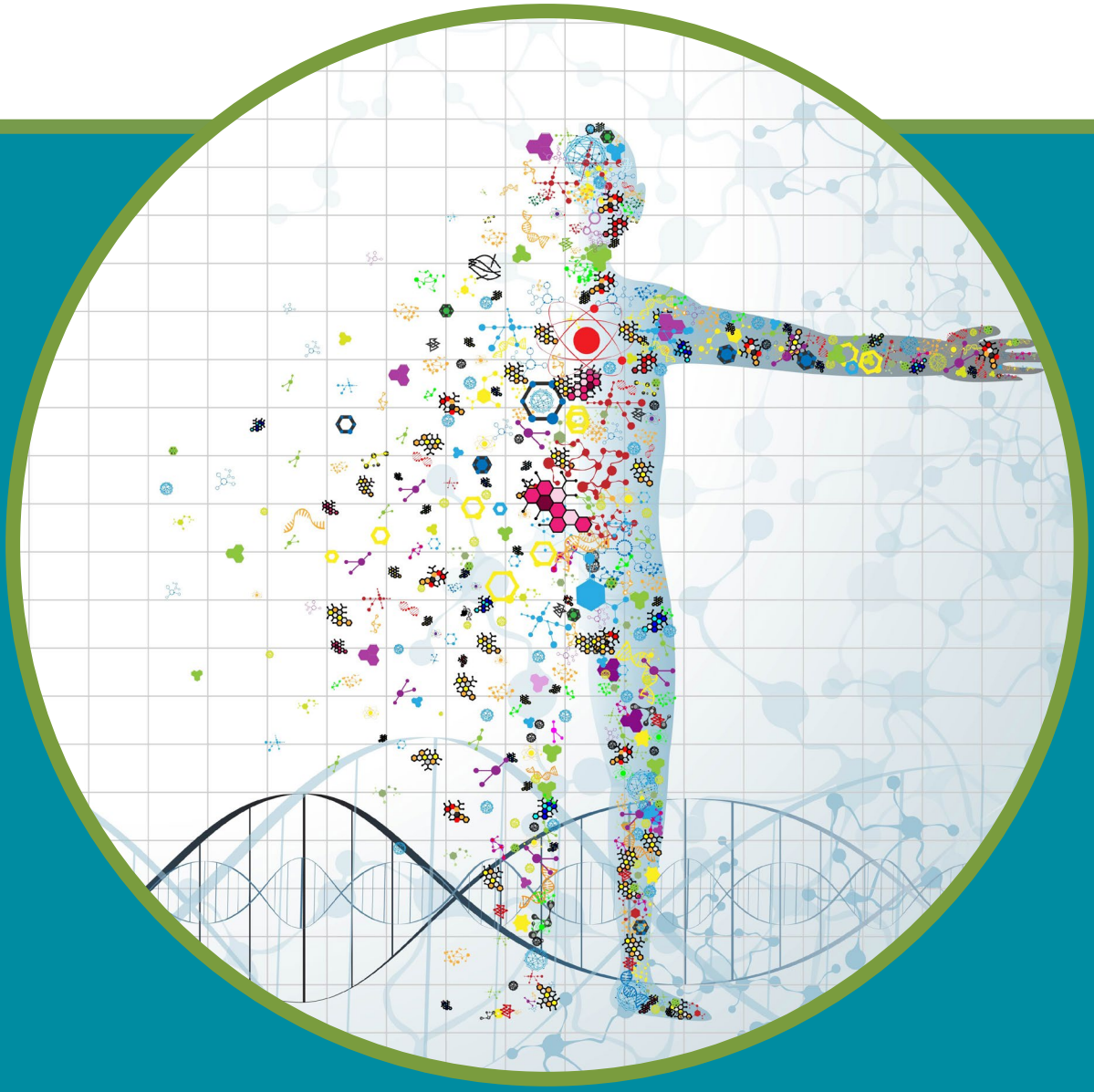
30 YEARS OF EUROMEETING

DIA EUROPE 2018

17-19 April | Basel, Switzerland

Join us at the Crossroads of Healthcare



PRELIMINARY **PROGRAMME**

DIAGlobal.org/Europe2018 | #DIAEurope 2018

DIA Europe 2018

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Preliminary Programme status 1 February, subject to change
check back online for regular updates

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DIA Europe 2018

MEETING BENEFITS

OVERVIEW

In 2018 we celebrate 30 years of bringing together stakeholders at the DIA EuroMeeting. On this landmark occasion, and to align this European flagship meeting with all the DIA regional flagship meetings occurring across the globe, we are renaming the gathering, DIA Europe 2018. This new name reflects not only regional alignment but also a change in approach to more directly and proactively focus on the expressed needs and interests of our constituents.

We convene these platforms around the globe, from the DIA Global Annual Meeting in the United States, to regional meetings in China, Europe, India and Japan, to provide you with a neutral forum to discuss current issues, with the goal of uncovering new ways of working and new solutions for patients. We welcome participants from across the entire drug development industry. By incorporating representatives from the full life sciences landscape we facilitate open collaboration. We ensure that industry, payors, patients and regulators, all have an equal voice.

We look forward to welcoming everyone to DIA Europe's home in Basel, Switzerland.

WHAT MAKES DIA EUROPE 2018 DIFFERENT?

DIA Europe 2018 is unique in presenting the entire health care value chain ranging from policy and regulations to R&D, marketing and access.

During an intense and stimulating three days, you will learn, debate and grow. You gain new perspectives from people you may already know, but also from contacts with whom you will want to learn more.

WHY ATTEND?

1. You will explore the latest solutions and challenges in health care.
2. You will network and build relationships with trend setters.
3. You will gain both a broader and more nuanced perspectives in the areas of e.g. regulatory science, clinical research and operations, value demonstration, and patient outlooks.

The resulting knowledge transfer and lasting partnerships will reduce the burden of regulatory barriers, and uncover pathways to address patient needs, thereby benefiting your business both now and in the future.

WHO WILL YOU MEET?

The DIA Europe 2018 attracts:

- Corporate Executives and decision makers
- Pharmacovigilance professionals
- Clinical development professionals
- Authority Representatives and Regulatory Affairs Professionals
- Patient advocates
- Value demonstration leads
- Clinical research and operations professionals

In addition, the DIA Europe 2018 exhibition will introduce you to a broad range of health care service providers that join the conference to collaborate with you on innovative solutions for your organisation.

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

Programme **Steering Committee**

The Regulatory Science Co-Chairs:

Luca Pani
Luca Pani, Professor, Department of Psychiatry and Behavioral Sciences University Of Miami School Of Medicine; Executive Director of Global Medical Innovation NeuroCog, 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

Programme **Advisors**

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

Sabine Atzor
Director Regulatory Affairs, 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

Topic **Leaders**

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

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

Petra Dörr
Deputy Executive Director, Swissmedic, Switzerland

Vicki Edwards
Head of Affiliate Safety & Compliance Excellence, QPPV, AbbVie, UK

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

Anthony Humphreys
Head of Sector Regulatory Affairs Committee Support and Community Procedures, 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 Developent 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

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 onstage 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 session 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.

- Endpoints in Clinical Research
- The Master's Data Management from the 'Single Place of Truth'
- Genomics: Improving Scientific Insights from Clinical Trials
- Drivers, Barriers and Benefits of a Unified Clinical Operating Model
- Enabling and Constraining Factors in Commercial ATMP Development: Learning from the Escher- ATMP Study
- How Partnering with the Regulatory Intelligence Function Enables Innovative Regulatory and Drug Development Strategies
- Clinical Evidence to Support Marketing Authorisations: Focus on Regulatory Approvals Based on a Single Pivotal Trial

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.

- Walking the Walk in Patient-Focused Medicines
- A Robust Therapeutic Area and Asset Strategy Serves as a Basis for all Functional Planning
- There is a Link between Company Culture and Productivity- Interactive Workshop

OPTIONAL SHORT COURSES

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

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
David Jones, Expert Pharmacotoxicologist, Clinical Trials Unit, Medicines and Healthcare products Regulatory Agency (MHRA), UK
Elke Stahl, CTFG Co-Chair; Clinical Trial Unit, BfArM, Germany

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 | 14:00-17:30

HOT TOPICS IN PHARMACOVIGILANCE

EMA Instructor Invited
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 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

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

OPTIONAL SHORT COURSES

Short Course 3 | Monday 16 April | 14:00-17:30

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

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

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

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.

OPTIONAL SHORT COURSES

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

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 6 | Tuesday 17 April | 09:00-12:30

CURRENT MEDICAL DEVICE MARKET SURVEILLANCE AND VIGILANCE REPORTING REQUIREMENTS IN EUROPE – CONCEPT AND BEST PRACTICES

Details to be confirmed

Short Course 7 | Monday 16 April | 14:00-17:30

GUIDANCE FOR PATIENT INVOLVEMENT IN PHARMACEUTICAL INDUSTRY-LED RESEARCH

EUPATI Representative invited

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.

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 programmes are underway to improve access to medicines in low- and middle-income countries. 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, do all these efforts show tangible results? Would better coordination improve the overall outcome? And what else need to be done to achieve the goals?

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
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 Wourgraft, 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

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.

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

Session in development

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 build, 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?

Session in Development

DIAmond Session 3

Tuesday 17 April | 11:00-12:30

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

Additional panelists invited.

DIAmond SESSIONS

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:

Karl Broich, President, BfArM, Germany

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

DIAmond Session 5

Tuesday 17 April | 14:00-15:30

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:

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

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

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

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

Bahija Gouimi, Founder, AMAL, Morocco

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

DIAmond SESSIONS

DIAmond Session 6

Wednesday 18 April | 08:30-10:00

EVIDENCE GENERATION IN MEDICINES DEVELOPMENT FOR FRAGMENTED AND 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 new innovative ways of evidence generation, such as single arm trials (Phase 1b), indirect comparisons (historic controls) and the impact of next generation sequencing on evidence generation. To discuss these complex topics, regulators, HTA bodies, patients and industry will review challenges and opportunities on the basis of case studies. 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

Additional speakers invited

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:

Mark Mayer, Senior Advisor–Global Regulatory Policy and Intelligence, Eli Lilly & Company, USA

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

Additional speakers invited

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

DIAlogue SESSIONS

DIAlogue 1 - Session 1010

Tuesday 17 April | 13:00-15:30

THE NEW EMA FIRST-IN-HUMAN (FIH) GUIDELINE PART 1: 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

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 will come into effect on the 1st of February 2018. During this session we will engage in a dialogue with the different stakeholders (e.g. regulators, industry, academics etc.) on the non-clinical aspects of the guideline. Our aim will be to ensure aligned understanding and implementation of this new important document. It is expected that the discussions during this session will help shaping a written training manual that includes early practical examples on implementation of the non-clinical aspects. The clinical aspects of the guideline will be discussed in the following session.

DIAlogue 2 - Session 1104

Wednesday 18 April | 10:30-12:00

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

YOUNG PROFESSIONALS AND STUDENTS PROGRAMME

For the anniversary edition, DIA would like to announce the "Leader of Tomorrow" programme, specially prepared for young professionals and students, to help them shape their competencies and career path.

At the Networking Reception you will have a chance to learn about different organisations in the pharmaceutical sector and explore professional development opportunities, while enjoying networking with your peers from other organisations in a casual atmosphere. This reception will be free of charge.

The "Leader of Tomorrow" programme at DIA Europe 2018 will kickoff with a workshop created specifically for you so you can learn from leaders and experts on how to excel in your current and future roles. You will have the possibility to hear from thought leaders from all over the pharmaceutical sector. DIA Europe is the forum that brings together the top representatives from all stakeholder groups, and offers structured networking opportunities to your rising star peers and senior professionals.

Become a DIA Leader of Tomorrow

Tick all the boxes of the challenge to help keep you engaged and eager to get involved. What is the award? **Free entrance for the entire event.**

We want to hear from you. DIA will organise a feedback session during the **18 April lunch** where you can **contribute your ideas** on how we can improve even more for future events.

Pre-Conference Day | 16th April

14:30–17:00 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 do different departments do
- exchange thoughts with the experts.

Hosts:

- F.Hoffmann-La Roche
- Novartis
- Actelion

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.

https://www.surveymonkey.com/r/8FCYP6S

18:00–19:30 PROFESSIONAL DEVELOPMENT SESSION

REGULATORY AFFAIRS

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

VALUE AND ACCESS

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

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 needed to be successful in Market Access.

R&D

Industry Representative invited

19:30- 21:00

LEADER OF TOMORROW: WELCOME TO BASEL – 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.

DIA Europe 2018

YOUNG PROFESSIONALS AND STUDENTS PROGRAMME

Day 1 | 17 April

09:00–10:30 LEADER OF TOMORROW: THE RACE TO THE TOP

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

Audience: Professionals with maximum 5 years of experience

Learning Goals:

- How to nail your first major promotion?
- Benefits of being an individual contributor vs manager?
- Tips and tricks to get visibility, to be selected for important projects
- Moving horizontally vs vertically
- Specialist vs generalist

11:00–12:30 LEADER OF TOMORROW: THE NEW GENERATION AWAKENS

Alex Khatuntsev, Human Resources Director, Idorsia Pharmaceuticals, Switzerland

Audience: Students

Learning Goals:

- How to shine in interviews?
- How to create opportunities:
- Learn how to develop a plan for their career
- Self-knowledge: Know your values, skills, strengths, weaknesses and passion.
- Knowledge and skills: In a specific area of expertise, but in any other fields as well (e.g. social media)
- Ability to analyse opportunities and make sound decisions.
- Good CVs and cover letters

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

10:30 – 12:30 INNOVATION THEATRE

Thousands of Members in 80 Countries, Across 20+ Communities

DIA Members work together to speed innovation in global health care product development to encompass your own health care system and the broader region.

Neutrality is key to the DNA of DIA. As the only global, membership organization, DIA is dedicated to bringing health care product development professionals together in a trusted, neutral environment to share insights and make advancements in health care product development and life cycle management. With thousands of engaged, global members comprised of professionals from pharmaceuticals, biotechnology, government, academia, and patient groups, DIA is the premium resource for individuals seeking to increase their knowledge, connect with global stakeholders, and truly drive insights to action in their everyday job functions.

Why Join DIA:

- DIA communities, a dynamic network of like-minded individuals looking for solutions, providing a discussion forum, and seeking to find solutions by harnessing the power of a network beyond your own organisation
- Access to a broad range of focused conferences, meetings, and training opportunities that will allow you to enrich your own knowledge, your understanding of the health care system you work in, and give you the ability to integrate best practices from multiple health care systems
- Member-exclusive subscriptions to the DIA Daily and Therapeutic Innovation & Regulatory Science (TIRS)
- Be part of a global forum where everyone can freely, openly, and accurately share information on diseases, treatment modalities, regulatory policies, clinical trial development, value and access, and more
- Unique access to thought leadership that is not available elsewhere
- Favorable rates on conferences and trainings

Learn More and Join at DIAglobal.org/Membership

DIA

DIA Europe 2018 | SCHEDULE

Monday, 16 April 2018

14:00-18:00	Registration Hours	
14:00-17:30	Short Courses	

Tuesday, 17 April 2018

07:00-18:00	Registration Hours			Registration Hours		
09:00-10:30	Swissmedic/WHO Signature Session			IMI PREFER Satellite Session		09:00-12:30 Short Courses
11:00-12:30	DIAmond Session: EU Regulatory Town Hall - EMA Relocation and Implications for Centralised Activities			DIAmond Session: Payer Town Hall - WHO Fair Pricing		
12:30-14:00						
14:00-15:30	DIAmond Session: Realising the Potential of Future Biomedical Innovation: The Role of Intensified EU Cooperation on HTAs	DIAmond Session: Will Big Data Change Drug Development's Approach?	DIAmond Session: International Pharmacovigilance		CFDA Topics	DIAlogue: The New EMA First-in-Human Guideline
16:00-18:00	Conference Keynote Session followed by					

Wednesday, 18 April 2018

	A	B	C	D	E	F	G	H	I		
Topic	Can Regulators and HTA Bodies Create Synergies for Patient Access?	What are Necessary Steps towards Outcome-Driven Health Systems?	Medicines of the Future: What Will Innovation Need and Bring?	How Can Better Outcomes Be Enabled by Big Data?	What is the Future of Pharmacovigilance?	What Can Stakeholders Expects from Clinical Trial (Development), Transparency and Medical Information?	A New Era for Medical Devices and Diagnostics. How Is The Impact?	Drug Development and Regulatory Approval - Reference Points around the Globe or Globalisation?	How Can We Enable Clinical Research in Europe Further?	Hot Topics/Stand-Alone Sessions	
08:00-18:00	Registration Hours										
08:30-10:00	DIAmond Session: Evidence Generation in Medicines Development for Fragmented and Rare Patient Populations			DIAmond Session: Exploring Use of Artificial Intelligence: Trust in Technology, or Trust in Each Other?				DIAmond Session: Patient-Centricity Beyond the Talk			NCA Showcase: Brexit Implications for the EU 27 Network and Decentralised Activities
10:00-10:30	Coffee Break in the Exhibition Hall										
Session 1 10:30-12:00	Session 0101 Collaboration across Decision Makers to Facilitate Patient Access Recent Advances and Future Needs	Session 0201/0401 Has the Time for Big/Real World Data Finally Arrived?	Session 0301 Novel Therapeutic Approaches	Session 0201/0401 Has the Time for Big/Real World Data Finally Arrived	Session 0501 Enhancing Benefit-Risk Management through the Product Life Cycle	Session 0601 EMA Proactive Transparency – Clinical Data Publication (Policy 0070)	Session 0701 IVD Regulation and the Upcoming Changes in Regulatory Landscape	Session 0801 Update on PMDA's Activities	Session 0901 New European Clinical Trial Regulation: A New Paradigm with Major Impact on Clinical trial Stakeholders		Session 1101 Middle East Updates
12:00-14:00	Lunch in the Exhibition Hall										
Session 2 14:00-15:15	Session 0102 Regulatory Access Pathways to Facilitate Early Access, HTA Synergies	Session 0202 Patient Centricity – What does it Really Mean?	Session 0302 Digital Health - What is the Landscape Looking Like for Medicines?	Session 0402 New Collaboration Models with Regulators and Patients	Session 0502 Innovative Approaches to Safety Information	Session 0602 Data Sharing and Secondary Use of Data	Session 0702 Regulatory – How to Submit a Combination Product OR Drug Device Combination Globally	Session 0802 Paediatric Policy Initiatives: Globalisation of Paediatric Drug Development Best Practice or Imperialism of Practice?	Session 0902 Registry Studies: What Are the Expectations from the Regulators?	Session 1002 ICMRA – The Future of Medicines and Challenges for International Regulators	
15:15-16:00	Coffee Break in the Exhibition Hall										
Session 3 16:00-17:30	Session 0103 Enhancing Evidence Generation across the Product Life Cycle	Session 0203 Health Economics of Future Therapeutic Concepts	Session 0303 The New Data Ecology - How to Incentivise and Enable More Sharing of Data?	Session 0403 Needed Competencies for Big Data - Learning from Other Industries	Session 0503 Measuring Impact of Pharmacovigilance in the EU	Session 0603 Drawing the Boundaries of Data Disclosure in Clinical Trials	Session 0703 Challenges in the Current Regulatory Landscape Considering FDA and MDR Expectations	Session 0803 Reliance and Work Sharing @ Work - State of Play and Hands-On Experience	Session 0903 Novel and Innovative Clinical Trial Designs: From Adaptive/ Seamless Designs to the Trial of the Future	Session 1003 Russia and the Eurasian Union – Regulatory Challenges and Opportunities	
17:30-18:30	Networking Reception in the Exhibition Hall										

Thursday, 19 April 2018

08:00-14:00	Registration Hours										
Session 4 08:30-10:00	Session 0104 ATMPs	Session 0204 Value and Access- How Do We Strike a Balance between Both?	Session 0304 Collaborative Frameworks and Public Private Partnerships as Drivers of Innovation	Session 0404 Overview of Major Big Data Projects across EU, US, Japan	Session 0504 Benefit/Risk Communication Tools that Work: Towards a Tailor-Made Drug Facts Box?	Session 0604 EMA Proactive Transparency – Clinical Data Publication (Policy 0070)	Session 0704 Life Cycle Management Activities of Drug Device Combinations	Session 0804 GMP Convergence – A key part of regulatory system strengthening	Session 0904 Smarter Clinical Trials Thanks to Real World Data	Session 1004 ICH Info Day Part 1	Session 1104 DIAlogue: Unmet Need in Regulatory and Pricing Decision Making (Part 1)
10:00-10:30	Coffee Break in the Exhibition Hall										
Session 5 10:30-12:00		Session 0205 Sustainability of Health Care Funding - Are We Prepared for Tomorrow's Funding Challenge?	Session 0305 Precision Medicine and Personalised Health care	Session 0405 Big Data Mandates Strict Data Governance	Sesison 0505 Five Years On - PV Legislation Delivers on Long-Promised Elements	Session 0605 The Promise and Reality of Clinical Trial Transparency Initiativese	Session 0705 Impact of Human Factors on the Development of Combination Products	Session 0805 Lifecycle Management – The Unknown Barrier to Access	Session 0905 ICH Info Day Part 2	Session 1005 Learnings from the First 10 years of the Paediatric Regulation – Back to Inform on the Future?	Session 1105 Turkish Regulatory Session
12:00-13:00	Lunch in the Exhibition Hall										
13:00-14:30	Conference Insights and Outcomes - Rapid Fire Session										

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?

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

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

Additional speakers invited

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

HTA Body View on Early Access Experiences
Speaker invited

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

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

Session in development

SCIENTIFIC PROGRAMME

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

ATMPS

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

Session in development

TOPIC B

WHAT ARE NECESSARY STEPS TOWARDS OUTCOME-DRIVEN HEALTH SYSTEMS?

Topic Leaders:
Indranil Bagchi, Vice President & Head, Solid Tumors Franchise, Global Value & Access, Oncology, Novartis Pharmaceuticals Corporation, 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.

Real-World Research: The Application of Geographically Relevant Data for Operational Predictability and Scientific Validity
Louise Parmenter, QuintilesIMS, UK

IMI Big Data for Better Outcomes: Supporting the Evolution towards Outcomes-Focused, Sustainable Health care Systems in Europe
Shahid Hanif, The Association of the British Pharmaceutical Industry, UK

DIA Europe 2018
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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, QuintilesIMS, UK

Patient Communities, Data Generation and Improved Health Outcomes
Maarten Van Baelen, Medicines for Europe, Belgium

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.

Health Economic Impact of Genomic and Genetic Testing
Jens Grüger, Head of Global Pricing and Market Access, F.Hoffmann - La Roche, Switzerland

How Can We Afford Personalised Health Care – The Payer's View
Thomas Szucs, ECPM, University of Basel and Helsana Health Insurance, 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

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 & Head, Solid Tumors Franchise, Global Value & Access, Oncology, Novartis Pharmaceuticals Corporation, 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.

Key Learnings from the First European Patient Advocacy Advisory Board for Leber's Hereditary Optic Neurotherapy (LHON)
Vanessa Ferreira, Patient Advocacy Manager Europe, Santhera Pharmaceuticals, Portugal

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, USA

Panel discussion:

Luca Pani, Professor, Department of Psychiatry and Behavioral Sciences University Of Miami School Of Medicine; Executive Director of Global Medical Innovation NeuroCog, 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

SCIENTIFIC PROGRAMME

TOPIC C

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

Topic Leaders:
Anthony Humphreys, Head of Sector Regulatory Affairs Committee Support and Community Procedures, 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 Head of Medical Affairs & Clinical Research, ABPI, UK

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

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 EuropeAmgen, UK

The Digital Health revolution is well underway and has had significant impact on traditional approaches to health care. This session will examine the impact that Digital Health technologies is having on the development of medicines and the delivery of information about medicines to health care professionals and patients.

Drug Development Acceleration
Speaker invited

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

Patient's Role and Experience of Digital Technology
Speaker invited

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, Opthamology & 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.

Session in development

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

COLLABORATIVE FRAMEWORKS AND PUBLIC PRIVATE PARTNERSHIPS 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 PPP s 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.

Antimicrobial Resistance (AMR) - Collaborating across the RandD, Regulatory and Access Continuum to Address This Threat
Kevin Carl, Director, Global Regulatory Affairs, Novartis, USA

Session in development

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

PRECISION MEDICINE AND PERSONALISED HEALTH CARE
Session Chair:
Marisa Papaluca-Amati, Head of Scientific Support Office, Specialised Scientific Disciplines Department, 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 health care systems.

Session in development

DIA Europe 2018

SCIENTIFIC PROGRAMME

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.

Real-World Research: The Application of Geographically Relevant Data for Operational Predictability and Scientific Validity
Louise Parmenter, QuintilesIMS, UK

IMI Big Data for Better Outcomes: Supporting the Evolution towards Outcomes-Focused, Sustainable Health care Systems in Europe
Shahid Hanif, The Association of the British Pharmaceutical Industry, UK

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
Badhri Srinivasan, Head, Global Development Operations, 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
Session Chair:
Peter Shone, Corporate Vice President, RandD Engineering, PAREXEL Informatics, UK

Big Data has been in production across many other industries, yet we still struggle within Pharma. This session will focus on lessons learned from other industries such as police, aeronautics and commodities - that we could leverage within drug development.

Lessons Learned from Security Industry
Speaker invited

Lessons Learned from Aeronautics Industry
Peter Shone, Corporate Vice President, RandD Engineering, PAREXEL Informatics, UK

Lessons Learned from Commodity Industry
Speaker invited

SCIENTIFIC PROGRAMME

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.

IMI Task Force
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 Kamauu, 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

TOPIC E

WHAT IS THE FUTURE OF PHARMACOVIGILANCE?

Topic Leaders:
Vicki Edwards, QPPV and Head of Affiliate Vigilance Excellence, 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 Llinares Garcia, Head of Scientific and Regulatory Management, Human Medicines Evaluation Division, European Medicines Agency (EMA), EU

Digital Risk Management: Opportunities and Challenges
Helen Edelberg, Executive Director and Head of Global Safety Risk Management, GPVandE, BMS, USA

The Benefits and Risks of Performing Structured Benefit-Risk Assessments
Steve Mayall, Principal Consultant, Pope Woodhead and Associates, UK

DIA Europe 2018
SCIENTIFIC PROGRAMME

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-Bogos, 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
Fergus Sweeney, Head of Division, Inspections, Human Medicines Pharmacovigilance and Committees, 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

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

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 Bouder, Associate Professor in Risk Management, University of Stavanger, Norway

David Haerry, Founder, Positive Council Switzerland, Switzerland

Agnes Kant, Director, Netherlands Pharmacovigilance Centre Lareb, Netherlands

Carmen Bozic, Senior Vice President, Head of Global Development, Biogen, USA

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

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

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 health care 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

SCIENTIFIC PROGRAMME

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

Prepare for EMA Phase II Policy 0070 – Data Utility Considerations
Ingeborg Cil, Lead, Clinical Trial Data Anonymization, Clinical Trial Transparency, Shire, Austria

EMA View
Joao Ferreira, European Medicines Agency (EMA), UK

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
O. O. 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

Session in development

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

DRAWING THE BOUNDARIES OF DATA DISCLOSURE IN CLINICAL TRIALS
Session Chair:
Marie Manley, Partner and Head of Regulatory Practice Bristows LLP, UK

EU Clinical Trials Regulation: Preparing for Implementation
Marie Manley, Partner and Head of Regulatory Practice Bristows 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
Speaker invited

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

SCIENTIFIC PROGRAMME

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.

Session in development

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:
Christine Mayer-Nicolai, Head Global Regulatory & Scientific Policy, Merck, 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
Chin-Wei Soo, Global Regulatory Head – CMC/Combination Products, Genentech, USA

The Importance of Science and Regulation
Tim Chesworth, Senior Director, Regulatory Affairs, AstraZeneca, UK

SCIENTIFIC PROGRAMME

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

Session in development

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

Sherri Biondi, Director Device Development at 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
Kazuhiko Mori, Councilor for Pharmaceutical Affairs, Minister's Secretariat, MHLW, Japan

PMDA's Use of Real World Data and Other Big Data for Product Review and Safety Measures
Tatsuya Kondo, Chief Executive, PMDA, Japan

PMDA's International Cooperation Including the Operations of PMDA Asia Training Center
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.

Session in development

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 andCo., 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
Speaker invited

International Inspectorates – Update of PIC/S Activities
Boon Meow Hoe, Chairman PIC/S, Health Sciences Authority, Singapore

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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
Hye-na Kang, Team Leader, Department of Essential Medicines and Health Products (EMP), World Health Organization, Switzerland

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 | 13:00-12:00

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

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

Case Study on a Global Registry of Soliris (eculizumab) for an Additional Indication
Martine Zimmermann, Global Head of Regulatory Affairs, 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 Mueller, 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.

From Adaptive Designs to the Trial Designs of the Future
Michael Krams, Global Head of Quantitative Sciences at Janssen Pharmaceuticals

Coping with Complexities of Development at an Unprecedented Breadth and Scale
Sacha Wissink, Executive Director, Regulatory Affairs EMEA, MSD, Netherlands

Empowering Phase II Clinical Trials to Reduce Phase III Failures
Daniele De Martini, Associate Professor, Milano-Bicocca University, Italy

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?

How Can Real World Data Improve the Early Clinical Development Process?
Michel Francois Denarie, Senior Principal Data Scientist, Quintiles, USA

Will RWE Replace Evidence Coming from Clinical Trials in the Future?
Patrice Verpillat, Merck KGaA, Germany

The Role of Real World Data in the Regulatory Setting
Anne-Louise Svendsen, DKMA, Denmark

HOT TOPICS / STAND ALONE

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

CFDA HOT TOPIC: MAJOR REFORMS AND STRENGTHENED INTERNATIONAL COOPERATION – WHAT'S HAPPENING IN CHINA?

Session Chair:
Invited

The Chinese legal framework for medical products has undergone major reforms in the last years. The new piece 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 Elements of Change in the New Legislation
- International cooperation: CFDA's strategy and priorities

Panel discussion with partner regulatory authority and industry representative

SCIENTIFIC PROGRAMME

Session 1100 | Wednesday 18 April | 10:30-14:00

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
Speaker to be confirmed

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 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.

Panelists:
Ian Hudson, Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA), UK
Tatsuya Kondo, Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
John Skerritt, Deputy Secretary, Health Products Regulation Group, Therapeutic Goods Administration (TGA), Australia
Agnès Saint-Raymond, European Medicines Agency (EMA), EU

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.

Recent Developments and Challenges in Russia - Industry Perspective
Speaker invited

Regulatory Harmonisation within the Eurasian Union – Where Do We Stands?
Dimitiri Rozhdestvensky, Head, Division for Coordination of Common Market for Drugs and Medical Devices Formation, Technical Regulation and Accreditation Department

Establishing EEU Guidance -.Driving Towards Regulatory Convergence - Industry Perspective
Elena Popova, Regulatory Director, AIPM

Session 1004 | Wednesday 18 April | 08:30-10:00

ICH INFO DAY PART 1

Session in development

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

ICH INFO DAY PART 2

Session in development

Session 1005 | 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:
Invited

- Regulator (preferably EMA) to report on EC-EMA specific actions (deferrals, transparency, regular updates on the paediatric medicines landscape in the EU)
- Industry looking at practical suggestions for a better handling of the applications for PIPs
- Academic/clinician on opportunities to discuss paediatric needs in an open and transparent dialogue

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

TURKISH REGULATORY SESSION

Session Chair:
Invited

Session in development

DIA Europe 2018

BASEL, SWITZERLAND | 17-19 APRIL

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EMEA.Exhibition@DIAglobal.org

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With over 12 hours of dedicated exhibition hall time, there is no need to worry about competing with educational sessions or other special events.

6 COMPANY PROFILE IN CONFERENCE MATERIAL

With your company profile listed in the exhibit guide, online and on our conference app, attendees will know right where to find you.

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EXHIBITING COMPANIES

AS OF 21 NOVEMBER

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Appian Software Switzerland LCC
Applied Clinical Trials
Aris Global Ltd.
Asphalion S.L.
Atrium
AXPHARMA SAS
Barrington James
BaseCon A/S
BGO Software
Biomapas
Bio-Optronics, Inc.
BIOSCRIPT
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Clinical Contract Research Association
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CliniThink
ClinTec International Ltd.
DADA Consultancy
Diamond Pharma Services
DLRC Ltd
Docshifter
Dora Wirth (Languages) Ltd.
Dot Compliance
Drug Safety Research Unit
ERT
EUDRAC Ltd
European Center of Pharmaceutical Medicine, University of Ba
European Medicines Agency
EXTEDO GmbH
F. Hoffmann - La Roche Ltd
Feith Systems and Software
G&L Scientific Inc
German Language Services GmbH
Hangzhou Tigermed Consulting Co., Ltd.
i4i Inc.
Ideagen Plc
Inpharmatis
Insight Medical Writing
Integrated Clinical Systems, Inc.
Kayentis
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PharmaLex GmbH
Pope Woodhead & Associates Ltd.
PQE
PrimeVigilance Ltd
PRMA Consulting
Productlife Group
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SWISSMEDIC - Swiss Agency for Therapeutic Products
Synchrogenix, A Certara Company
TOPRA
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Universal Medica
Uppsala Monitoring Centre
Veeva Systems Spain
Veristat, Inc.
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Xendo B.V.

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.

Exhibition Hall Only passes are available, please contact EMEA.Exhibition@DIAglobal.org to request your pass.

MORNING
WELCOME
COFFEE

MORNING AND AFTERNOON
REFRESHMENT
BREAKS WITH THE EXHIBITORS

DAILY
LUNCH
BREAKS

ENERGY BOOSTER
MOBILE DEVICE/LAPTOP
CHARGING LOUNGE

CONNECT WITH HEALTH CARE COMPANIES AS THEY SHOWCASE THEIR NEWEST PRODUCTS

EXHIBITION HALL
OPENING HOURS

Tuesday, 17 April 2018: 10:00-19:30
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
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
18:00–19:30

Join us for the Opening Reception to mingle and network with your peers and colleagues.

Wednesday Exhibitor Networking Reception in the Exhibition Hall

Wednesday, 18 April
17:30–18:30

Network with 100+ exhibiting companies at the DIA Exhibitor Networking Reception held in the Exhibit Hall.

We invite you to also take advantage of the additional features of the Exhibition Hall.

Other networking events such as speed networking sessions, communities' activities and much more are in preparation. Detailed information will be available in the advance programme, stay tuned.

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 and 14:00-14:30

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.

More details will follow soon.

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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

With the Mobility Ticket, you can use the public transportation within the city free of charge and get free access to the guest WiFi when you stay overnight at a hotel in Basel.

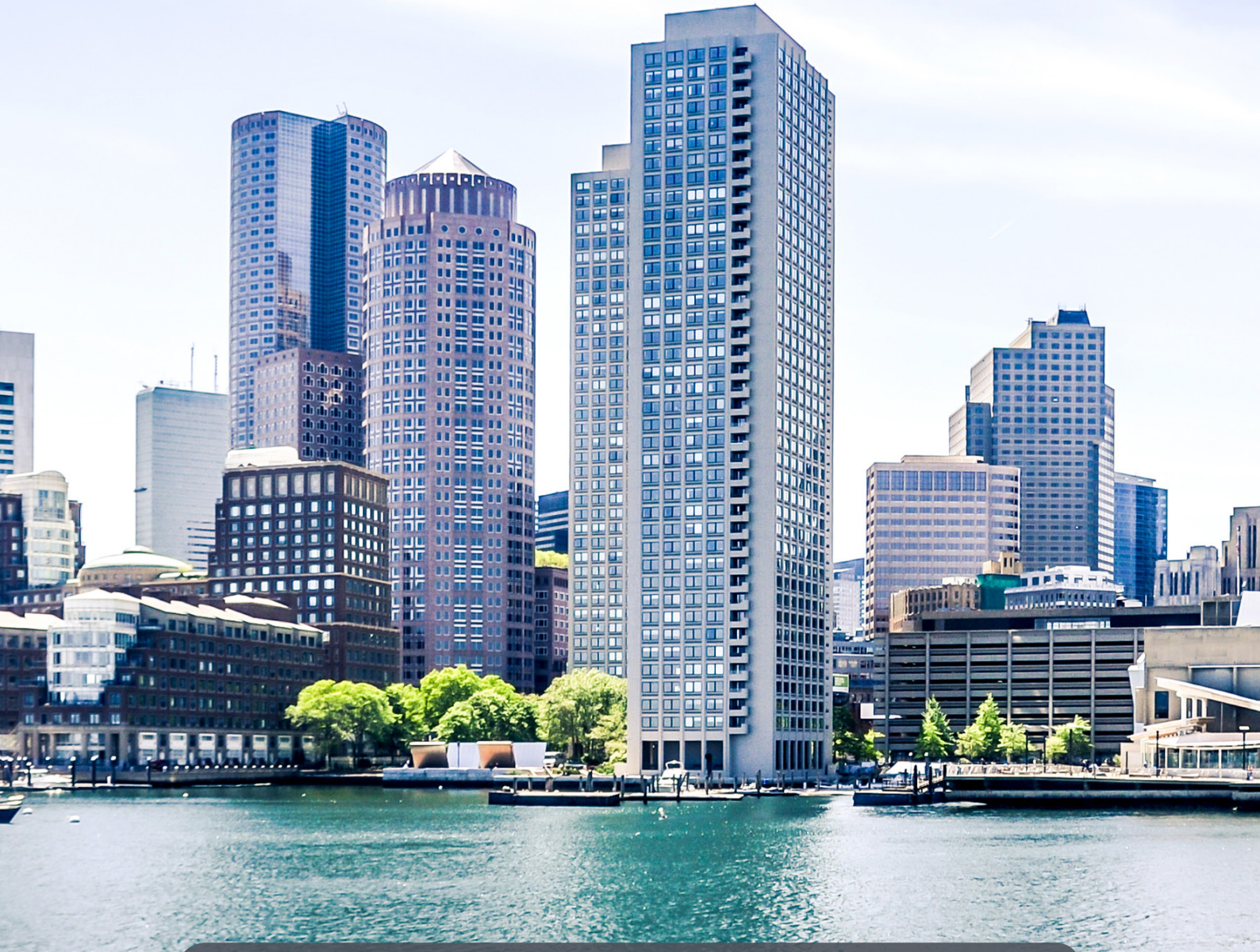
| HOTEL BOOKINGS

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



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