29th Annual

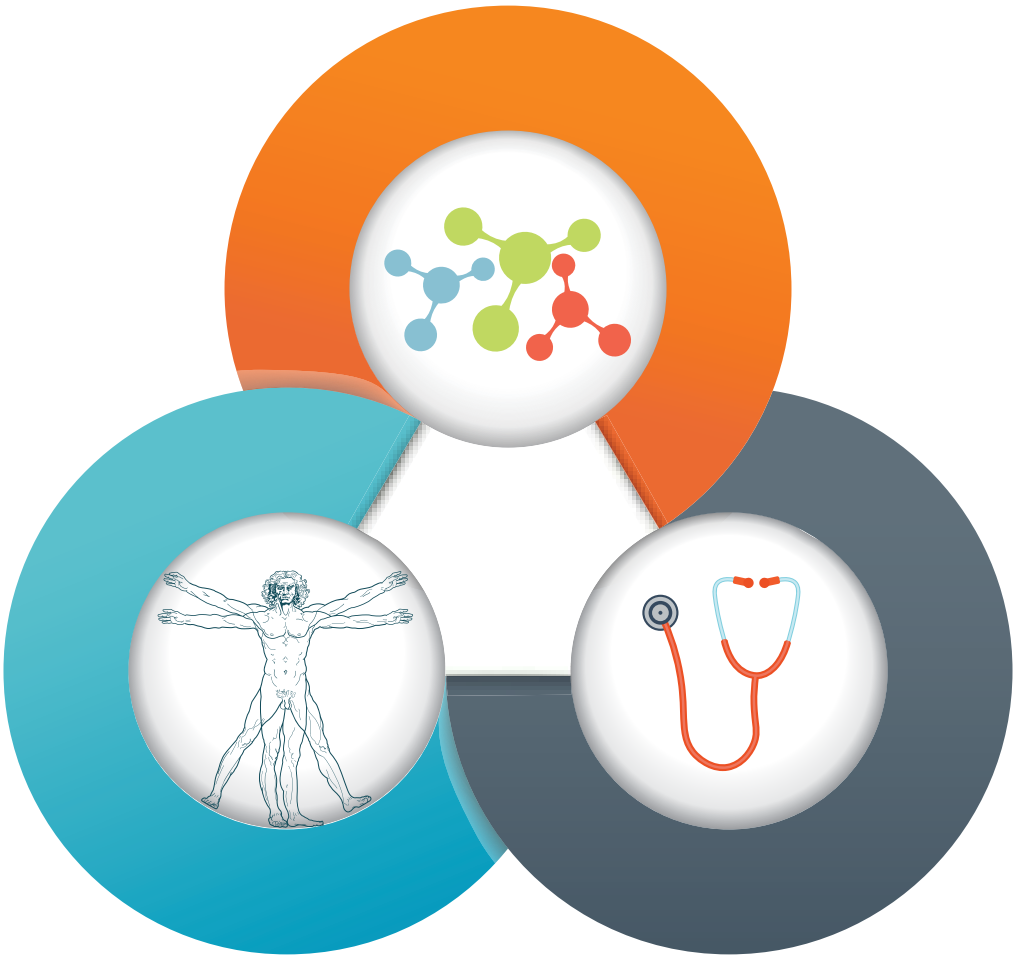
EUROMEETING

GLASGOW | 2017

29-31 MARCH

TRANSLATIONAL HEALTH CARE

FROM BENCH TO BEDSIDE - AND BACK



FINAL **PROGRAMME**

DIA

DIAglobal.org/EM2017

EuroMeeting 2017

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Message from the DIA Global Chief Executive and EMEA Senior VP & Managing Director

Dear Colleagues,

A very warm welcome to the 29th DIA EuroMeeting! This year's theme is Translational Healthcare: From Bench to Bedside and Back. We have chosen to hold this important conference in Glasgow, a great city that houses three universities, and is the center for much of Scotland's educational and scientific activity. This activity is broadly manifest from the numerous start-up companies to multinational corporations, such as AstraZeneca, whose GLAZgo Discovery Centre aims to find new ways of understanding disease and targeting pathology in key research areas.

We are very grateful for the excellent work of our co-chairs, Ian Hudson, CEO, Medicines & Healthcare products Regulatory Agency (MHRA), UK, and Susan Forda, VP International Regulatory Affairs, Eli Lilly & Company Ltd, UK, who, together with this year's Programme Committee, have curated a rich and diverse offering for you. Expect much more cross-functional debate and much more patient engagement!

You might be curious about this year's meeting theme. Translational Healthcare, not yet a widely used term, reflects the fact that translational elements have entered medicines development beyond the classic definition that focuses on prediction of human efficacy and safety from animal models or biomarkers. Translational healthcare has a much broader meaning and includes the incorporation of learnings, insights, and data from the use of medicines in the post marketing phase into early R&D, to influence the direction of innovation. We have built a large part of this year's conference around this future directed theme.

The Digital Revolution in Health Care is the theme of the Opening Plenary. We have invited experts in this area to take you through the journey from disruptive to enabling technologies, and illuminate digital healthcare from patient, industry, IT, and regulatory perspectives. Be prepared for an enlightening discussion.

The increasing implementation of Precision Medicine offers innovative treatments to patients with an unprecedented benefit/risk balance. However, the challenges it poses to Clinical R&D are tremendous - the narrow windows of selection of patients eligible for treatment increase screening failure rates and study start-up costs. Patient recruitment often becomes a task for highly specialized clinical trial sites, and new development partnering solutions are needed. This year we have two highly cross-functional DIAmond sessions, in addition to a Clinical Research Theme, dedicated to the latest thinking and solutions to these challenges.

Sustained Market Access for innovative medicines is also a challenge nowadays, but solutions are emerging. This year's DIA EuroMeeting will host a closed workshop with the Boston Consulting Group Market Access Roundtable working group to leverage insights from the multi-stakeholder health care community typical for a DIA Flagship event. Outcomes & learning from this workshop will be presented to DIA EuroMeeting attendees in a dedicated Market Access Roundtable Update session.

If you are curious about where Patient Engagement is going beyond the evaluation of drugs in the post marketing phase, then join us at the Roundtable with the Innovative Medicines Initiative (IMI). Patient insights and patient data play an increasingly important role in the evaluation of healthcare offerings once a drug is on the market, but the role and value of an enhanced patient voice during R&D, in particular during clinical development, is yet to be established. Come, listen, and discuss why and how patients might be engaged during the early stages of medicines development. Get the lessons learned from existing early engagement cases.

Everyone is talking about Brexit and, according to the UK Prime Minister, the end of March will see the start of negotiations between the UK and the EU on various terms surrounding the referendum. Consequently, we have decided to channel the inevitable discussions at DIA EuroMeeting into a dedicated session. Hear from different health care stakeholder groups from within the UK and the wider EU regarding what implications this step could have for the development of, and access to, medicines.

We will also be hosting a DIA Community Luncheon, together with Patients and Patient Advocates. Come and learn how we plan to enhance these professional online communities to fuel our strategic goal to make DIA Insights your go-to resource for the best thinking on the many daily challenges we all face to advance our professions and our health care products ecosystem as a whole.

And, to ensure that you get the most out of the DIA EuroMeeting, we invite you to a specially designed session that will cover all parallel discussions, including those that you may have missed. The new Rapid Fire Session at the close of the meeting will summarize all novel insights and knowledge that have been developed and shared during the conference. Come and experience the new DIA EuroMeeting "in-a-box".

Please do not forget to visit the rich exhibition area where selected service providers offer many solutions to your business needs. The DIA Smartphone App allows the set-up of state-of-the-art Business-to-Business connections. Finally, use the ample opportunities to network with your colleagues and reconnect with friends at our DIA receptions.

Our wish is that you gain important new insights from this DIA EuroMeeting and develop many new contacts to support your professional work to provide safe, efficacious, and accessible medicines to patients worldwide.

Barbara Lopez Kunz
DIA Global Chief Executive

Holger G Adelmann
DIA EMEA Senior VP & Managing Director

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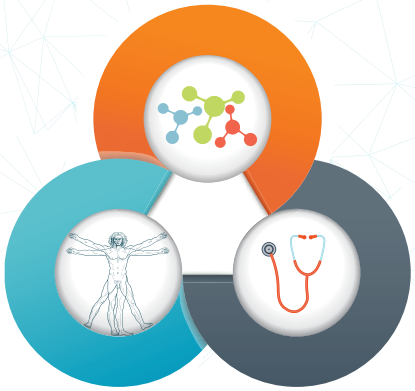

SCHEDULE AT-A-GLANCE

Tuesday, 28 March 2017

Registration Hours:

15:00-20:00	Exhibitor Registration and Set-up
15:00-18:00	Attendee and Speaker Registration*

* Avoid the rush on Wednesday by picking up your badge and conference material on Tuesday afternoon

Wednesday, 29 March 2017

Registration Hours:

07:00-09:30	Exhibitor Registration and Set-up
08:00-18:00	Attendee, Speaker and Exhibitor Registration

Schedule:

09:00-12:30	Pre-Conference Short-Courses and Special Sessions
10:00-19:30	Exhibit Hall Open
10:30-11:00	Coffee Break in the Exhibit Hall
11:00-12:30	Regulatory Town Hall Meeting
10:00-19:30	Conference and Exhibition Open
12:30-14:00	Lunch & Oral Poster Presentations in the Exhibit Hall
14:00-15:30	Opening Plenary Session
15:30-16:30	Extended Refreshment Break & Innovation Theatre Activities in the Exhibit Hall
16:30-18:00	Parallel Scientific Sessions - Session 1
18:00-19:30	"Welcome to Glasgow" Civic Reception Courtesy of The Rt Hon The Lord Provost of Glasgow in the Exhibit Hall

Thursday, 30 March 2017

Registration Hours:

08:00-18:00	Attendee, Speaker and Exhibitor Registration

Schedule:

08:00-09:00	Welcome Coffee in the Exhibit Hall
08:00-18:30	Exhibit Hall Open
09:00-10:30	DIAmond Sessions 1 & 2
10:15-11:00	Coffee Break & Innovation Theatre Activities in the Exhibit Hall
11:00-12:30	Parallel Scientific Sessions - Session 2 Choose from Parallel Sessions
12:30-14:30	Lunch & Innovation Theatre Activities in the Exhibit Hall
12:45-13:15	Speed Networking in the Exhibit Hall
13:00-14:00	DIA Communities - Meet and Eat in the Exhibit Hall
14:00-15:30	Parallel Scientific Sessions - Session 3 Choose from Parallel Sessions
14:00-15:30	Exhibition Guest Passes
15:15-16:00	Coffee Break & Innovation Theatre Activities in the Exhibit Hall
16:00-17:30	Parallel Scientific Sessions - Session 4 Choose from Parallel Sessions
17:30-18:30	Networking Reception in the Exhibit Hall

Friday, 31 March 2017

Registration Hours:

08:00-13:30	Attendee, Speaker and Exhibitor Registration

Schedule:

08:00-09:00	Welcome Coffee in the Exhibit Hall
08:00-13:30	Exhibit Hall Open
09:00-10:30	DIAmond Sessions 3 & 4 Choose from Parallel Sessions
10:15-11:00	Coffee Break & Innovation Theatre Activities in the Exhibit Hall
11:00-12:30	Parallel Scientific Sessions - Session 5 Choose from Parallel Sessions
12:30-13:30	Lunch in the Exhibit Hall
13:30-14:30	Rapid Fire Session
14:30	End of Conference

DIA

EuroMeeting 2017

A MESSAGE FROM THE CO-CHAIRS

Susan Forda
Vice President,
International Regulatory Affairs
Eli Lilly & Company Ltd, UK

Dear Colleagues,

The 2017 DIA EuroMeeting in Glasgow represents an ideal time and setting to discuss the evolving European and Global healthcare environment; to reflect on the outcome of recent changes such as alternative regulatory pathways; and to look ahead at emerging developments, such as how the rise of Big Data might impact medicine development, regulation, access and use.

With certainty, global medicine development and patient care has never been more complex. We're witnessing an evolution of science through the establishment of novel biomarkers and a better understanding of the genetic components of diseases. Still, the attrition rate for medicines in development remains high and the timelines preceding the availability of a new medicine lengthy. Meanwhile, the burden of unmet medical need within society has never been more acute. Patient Access to innovative medicines is an ever increasing challenge. These are the realities we, in medicine development, regulation, delivery and, often as patients, face.

These complex challenges require collaboration of multiple stakeholders – regulators, clinicians, patients, payers and medicine developers – who are equally resolute to the task.

The motto of the 2017 DIA EuroMeeting, 'From Bench to Bedside- and Back', reflects the growing impact of "back-translation" of learnings from the real life patient world into R&D.

In closing, mindful of the current realities, yet charged by the collective objective of improving patient care, together with our DIA colleagues, we look forward to seeing you at the DIA 29th Annual EuroMeeting in Glasgow.

Ian Hudson
Chief Executive
MHRA, UK

EuroMeeting 2017

PROGRAMME COMMITTEE

Theme **Leaders**

Gert Bos
Executive Director and Partner, QServe, Netherlands

Claes Buxfeldt
Global Price and Reimbursement Director, AstraZeneca, Sweden

Salah-Dine Chibout
Chair of InnoMeds, EFPIA, Global Head Discovery & Investigative Safety/Preclinical Safety Therapeutic Areas, Novartis, Switzerland

Gaby Danan
Pharmacovigilance Expert, France

Hans-Georg Eichler
Senior Medical Officer, European Medicines Agency (EMA), EU

Zaide Frias
Head of Human Medicines Evaluation Division, European Medicines Agency, (EMA), EU

Juan Garcia Burgos
Head of Public Engagement (Ad Interim), European Medicines Agency (EMA), EU

Jens Heisterberg
Vice President, Regulatory Intelligence, Novo Nordisk, Denmark

Geneviève Le Visage
Head EU Regulatory Intelligence & Policy, Novartis, Switzerland

Trine Moulvad
Vice President Regulatory & Pharmacovigilance, Zealand Pharma, Denmark

Ana Palma
Global HTA & Patient Access Lead, Sobi, Belgium

Agnes Saint Raymond
Ad Interim Head of International Affairs, European Medicines Agency, EU

Terje Peetso
Policy Officer, Unit H1 - Health and Wellbeing, Directorate-General Communications Networks, Content and Technology (DG CONNECT), European Commission, EU

Gerhard Schlüter
VP, Head GRA TA Specialty Medicine, Bayer, Germany

Steffen Thirstrup
Medical Advisor, Regulatory Advisory Board, NDA Group, UK

Phil Tregunno
Signal Management Unit Manager, Medicines & Healthcare products Regulatory Agency (MHRA), UK

Hans van Bruggen
Senior Regulatory Affairs Scientist, eCTDconsultancy/ Qdossier, Netherlands

John Wilkinson
Director of Devices, Medicines & Healthcare products Regulatory Agency (MHRA), UK

EuroMeeting 2017

PROGRAMME COMMITTEE

Overall Programme **Advisors**

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

Martin Harvey Allchurch
Principal International Affairs Officer, European Medicines Agency (EMA), EU

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

Susanne Keitel
Director, European Directorate for the Quality of Medicines & HealthCare (EDQM), EU

Jürgen Kübler
Quantitative Scientific Consulting, Germany

Marloes van Bruggen
Regulatory Programme Manager, F. Hoffmann-La Roche, Switzerland

Theme **Advisors**

Sabina Hoekstra-van den Bosch
Global Regulations and Standards, Lead for European Regulation, Philips Healthcare, Netherlands

Francisco Peñaranda Fernandez
Head of Department, Business Data and Analytics, European Medicines Agency (EMA), EU

Margaret Walters
Deputy EU Qualified Person for Pharmacovigilance, Merck, Sharp & Dohme Ltd, UK

Get Social!

Stay connected with your colleagues around the world and all of the innovation happening in Glasgow by following #DIAEuro17 with social media.

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

Search @**DrugInfoAssn** to follow DIA.

#DIAEuro17

EuroMeeting 2017

GENERAL INFORMATION A-Z

Conference & Exhibition Venue

The 29th Annual EuroMeeting takes place at:

Scottish Event Campus - SEC
(Previously SECC)
Exhibition Way, Glasgow G3 8YW, UK
For more information, visit www.sec.co.uk

App

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

Accessing the EuroMeeting 2017:
- Sign in with the email address used to register for the conference.
- Password: ***global***
- Click on the events icon
- Select 29th Annual EuroMeeting 2017

Only registered attendees have access to the mobile app. You can find assistance at the DIA Booth in the Exhibit Hall.

ATM

There are two Clydesdale Bank ATMs in the West lobby of the SEC Centre and one on the ground floor of The SSE Hydro.

Business Center

The business center is located in the concourse.

Certificate of Attendance

Certificates of attendance will be emailed to participants who have picked up their badge after the conference. Certificates will not be printed onsite.

Cloakroom/Baggage

The cloakroom is located in the Foyer of Hall 4. There is a charge of 2£ per coat/jacket or luggage item.

The cloakroom is open as follows:
Wednesday 08:00 – 20:00 | Thursday 08:00 - 20:00 | Friday 08:00 – 14:00

Conference Bags

All attendees with a full meeting registration can collect a conference bag from the Conference Bag Distribution Point in the Foyer of Hall 4. Participants must bring their bag voucher received when collecting their badge (Booth personnel do not receive a bag).

Continuing Education Credits

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

The 29th Annual EuroMeeting has been awarded with 16 CPD credits from the Faculty of Pharmaceutical Medicine (FPM) of the Royal College of Physicians (RCP) of the UK. Medical practitioners who are eligible for credits can click on http://www.fpm.org.uk/cpd/registration for more information. If you are already a CPD member, please go directly to http:// cpd.fpm.org.uk to claim your credits.

DIA/Patient Booth

Find out more about all DIA can offer you, how membership can advance your career, how to join a DIA Community, submit an article for publication and lots more. DIA actively promotes the involvement of patient representatives in the EuroMeeting. Since 2006, more than 200 patient representatives have been involved as participants, speakers, session chairs, and also in the Programme Committee. Stop by at the DIA Booth in the Exhibition Hall to meet and network. See "Exhibition" for opening hours.

Exhibition

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

Wednesday	10:00 – 19:30
Thursday	08:00 - 18:30 | Exhibit Guest Passes 14:00 - 15:30
Friday	08:00 - 13:30

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

Exhibitor Services

The Exhibitor Services Desks (stand building, onsite services and shipping) are located in the Exhibition Hall.

First Aid

A well-equipped Medical Centre is located at the east end of the concourse in the SEC Centre. A medical professional will be on duty during conference hours. Contact the DIA Onsite Registration Information Desk in the entrance hall for assistance. Alternatively, any staff member or DIA host/hostess will be more than happy to be of assistance.

Help Desk

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

Wednesday	10:00 - 19:30
Thursday	08:00 - 18:30
Friday	08:00 - 13:30

Should you have general questions about the venue, accommodation or Glasgow, visit the SEC general information desk located on the ground floor of the SEC Centre adjacent to the main doors. The information desk will be open during conference times.

GENERAL INFORMATION A-Z

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

Lost and Found
All items will be stored at the DIA Registration Desk in the Foyer of Hall 4 until the end of the conference.

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

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

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

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

Presentations
Presentations will be available to full conference attendees on the DIA web site from 23 March until 15 October 2017. Presentations are made available to full conference attendees only.

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

Recharging Station
A recharging station lounge is available in the back of the Exhibition Hall.

Refreshments/Lunches
Refreshments and Lunches will be served each day in the Exhibition Hall. Enjoy extended refreshment and lunch hours to visit more than 100+ exhibiting companies.

Wednesday

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

Thursday

08:00-09:00	Welcome Coffee
10:15 - 11:00	Morning tea/coffee with snack
12:30 - 14:30	Lunch
15:15 - 16:00	Afternoon tea/coffee with snack

Friday

08:00-09:00	Welcome Coffee
10:15 - 11:00	Morning tea/coffee with snack
12:30 - 13:30	Lunch

Registration
The self-scanning kiosks and registration desks are located in in the Foyer of Hall 4 of the SEC and will be open on the following days and times:

Tuesday	15:00 – 18:00
Wednesday	08:00 – 18:00
Thursday	08:00 – 18:00
Friday	08:00 – 13:30

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

Services for the Disabled
All the rooms at the congress center are fully accessible to participants with disabilities.

Social Media
Stay connected with your colleagues around the world and all of the innovation happening in Glasgow by following #DIAEuro17 with social media.

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

Search @DrugInfoAssn to follow DIA

Speaker Resource Center
All speakers are required to visit the Speaker Resource Center located in the Foyer of Hall 4 on the Ground Level and re-check their slides at least 2 hours before the start of their session(s).

Tuesday	15:00 - 18:00
Wednesday	08:00 - 18:00
Thursday	08:00 - 18:00
Friday	08:00 - 13:00

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DIA AWARD WINNERS

Excellence in Service Award

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

Lillian Auberson-Huang

Medical Information Lead, Region Europe Medical Affairs, F. Hoffmann-La Roche Ltd., Switzerland

Lillian Auberson has a diverse career in Medical Information and Communications. She has a career of over 20 years in the pharmaceutical and biotechnology sector and is currently Medical Information Lead for Region Europe at F. Hoffmann-La Roche, Ltd. Previously, she was Head of Global Medical Information at Actelion Pharmaceuticals and Senior Director at Novartis Pharma. Lillian is an international leader with an established track record for developing and inspiring high performing teams, implementing global programs in regulated environments, delivering integrated services for medical information, as well as capturing customer insights. In 2014, she became a founding member of the Medical Information Leaders Europe (MILE) group that is dedicated to working collaboratively across pharmaceutical companies to address common issues, as well as share best practice and knowledge. MILE began a collaboration with EFPIA in 2016, and Lillian is Chair of its Medical Information Working Group.

Since its inception, Lillian has contributed to the European DIA Medical Information and Communications Conference, as program organising committee chair, member and speaker. This conference became a stand-alone meeting in 2014 and celebrated its 10th anniversary in 2016. She significantly contributed to the success of the conference by being part of the organizing committee, chairing sessions, speaking, providing innovative topics and using her wide spread network to identify speakers. Lillian also helped to grow the DIA Medical Communications Community in Europe.

Outstanding Contribution to Health Award

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

Lembit Rägo

Secretary-General, Council for International Organizations of Medical Sciences (CIOMS), Switzerland

Lembit Rägo, MD, PhD, serves as Secretary-General of Council for International Organizations of Medical Sciences (CIOMS) since April 2016. Prior to joining the WHO in 1999, he was Professor of Clinical Pharmacology at Tartu University in Estonia, and the founder and first Director General of the Estonian Drug Regulatory Authority, State Agency of Medicines. In 1999 he joined the World Health Organization (WHO) Headquarters, Geneva, as Coordinator of Quality Assurance and Safety Medicines (QSM) team. In this capacity, Dr Rägo laid the foundation to the WHO Prequalification of Medicines Programme (PQM) and strengthened pharmacovigilance and regulatory support related activities. The PQM was instrumental in getting quality medicines to millions of HIV/AIDS, malaria and tuberculosis patients in developing countries. The programme has also been very successful in developing regulatory capacity. In 2002 he became the main organiser of the WHO biennial International Conference of Drug Regulatory Authorities (ICDRA), bringing together regulators from around 100 countries worldwide.

In 2013 he was appointed to be the first head of WHO's newly formed unit Regulation of Medicines and Other Health Technologies (RHT). For the first time in WHO history, all regulatory issues related to medicines, vaccines and other biologicals, and medical devices including in vitro diagnostics were joined into one single unit. The unit covers technical norms and standards, safety and vigilance, prequalification and regulatory systems strengthening for all regulated health products. This key unit of more than 125 staff members determines WHO's policy on regulatory issues. He was longstanding WHO observer to the ICH, International Pharmaceutical Regulators Forum (IPRF) and International Coalition of Medicines Regulatory Authorities (ICMRA). For more than a decade he served as Uppsala Monitoring Centre Board member and was responsible for publishing WHO Drug Information. Lembit has given support for regulatory systems development and regulatory capacity building, in particular within the African region. He is advocating for access to safe high quality medicines for everyone, and everywhere, through building effective competent regulatory systems.

Dr Rägo regularly participates in DIA Annual Conferences in US and in conferences in regions such as Asia, Africa, Europe and Middle East, and has been a speaker and chair in over 25 DIA Events.

DIA AWARD WINNERS

Excellence in Leadership Award

Awarded to an individual that has shown regional leadership in improving health care and making positive impact on other stakeholders

Jan Geissler

Director, European Patients Academy on Therapeutic Innovation (EUPATI), Founder & Managing Director, Patvocates, Germany

Jan Geissler is founder and managing director of Patvocates, a think tank and consultancy in patient advocacy, acting as advisor on patient advocacy, health policy and social media. For the past 6 years, he has been working for the European Patients' Forum as the Director of the 'European Patients Academy on Therapeutic Innovation' (EUPATI), a project funded by Innovative Medicines Initiative.

EUPATI has developed educational material and training courses to educate patient and patient advocates about medicines development processes. He continues to be responsible for EUPATI's future evolution. He is also coordinator of the work package of the new IMI big data project HARMONY, coordinating stakeholder input from patient organisations, HTA bodies, regulators and other stakeholders.

After his university diploma in Business studies in the UK and Germany in 1999, Jan held various management positions in telecom, R&D and media think tanks before he focused his professional life on patient advocacy in 2008. Being a leukemia survivor who took part in various clinical trials, Jan founded the online patient community Leukaemie-Online.de in 2002. In 2003, he co-founded the European Cancer Patient Coalition. In 2007, Jan also co-founded the CML Advocates Network connecting 113 leukemia patient groups from 83 countries today. He is representing patients in various advisory boards, committees and expert groups e.g. of the European Commission (European Commission Expert Groups on Cancer Control and Rare Diseases), ECCO (Patient Advisory Committee), ESMO (Patient Advocacy Working Group), EORTC (Institutional Review Board) and the International CML Foundation (Scientific Advisory Board). He is also a member of the European Hematology Association's (EHA) European Affairs Committee.

Jan has served on the EuroMeeting Programme Committee helping to coordinate the participation of patients and has been a session and speaker for EuroMeeting and Clinical Forum.

Stay Connected

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

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

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

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

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

Access the EuroMeeting 2017:

- Sign in with the Email Address You Registered for the EuroMeeting 2016
- Password: ***global***
- Click on the Events Icon
- Select 29th Annual DIA EuroMeeting 2017
- Need assistance? See us at the DIA Booth in the Exhibition Hall for support

POLLING/VOTING BY THE AUDIENCE VIA THE DIA EUROMEETING APP

Sessions marked accordingly will have the added element of voting/polling by the audience to enhance interactivity and discussion. Polling/voting will be conducted via the DIA app. In order to participate attendees must have downloaded the app in advance of the start of the session. Instructions are available in the session room. Arrive early and make sure your device is ready when voting starts.

EuroMeeting 2017

PROFESSIONAL POSTERS

A selected group of professional poster presenters will share their research results in various topics. The Professional Posters are located in the Exhibition Hall near the Innovation Theatre

Authors will provide a 5-minute overview of their work will be delivered. Presentations will be held in the Innovation Theatre located in the Exhibition Hall during break times on Wednesday and Thursday.

P01 **Manon Exposito, Pharmacist Project Manager, Universal Medica, France**
Development of a Matching Dictionary between Lay and Corresponding Scientific Terms to Detect Web Reported Adverse Events
Oral Presentation scheduled Wednesday 29 March 13:15-13:20

P02 **Sophie Bonnet and Pascale Vermare, Students of EUDIPHARM programme, Claude Bernard University of Lyon, France**
Avoid the Waste in Paediatric Clinical Trials

P03 **Romuald Braun, Managing Director, uanotau gmbh, Switzerland**
A Day in Life of a Variation - How to Automate a Change Request to Generate All Required Submissions and Documents
Oral Presentation scheduled Wednesday 29 March 13:29-13:34

P04 **Bill Wang, Director, PPD, China**
China Regulatory Environment Reforms: Changes and Impact
Oral Presentation scheduled Wednesday 29 March 13:42-13:47

P05 **John Whitebrook, Managing Director, Deloitte, USA**
Pharmacovigilance Innovation: Practical Approaches
Oral Presentation scheduled Wednesday 29 March 15:22-15:27

P06 **Claudia Hernandez, Associate Director Regulatory Affairs, Sunovion Pharmaceuticals Inc., USA**
Clinical Trial Application versus Ethics Committee Approval Rates for Global Paediatric Placebo-Controlled Trials

P07 **Jeffrey Ho, Principal, Navitas Life Sciences, UK**
Exploring Common Operational and Organisational Pharmacovigilance Risks across Multiple Companies and Regions
Oral Presentation scheduled Wednesday 29 March 12:47-12:52

P08 **Khairul Faizee, Head of Business Development, Clinical Research Malaysia, Malaysia**
The Common Reasons of Feasibility Study Rejections among Malaysian Investigators and Initiatives Undertaken by the Government
Oral Presentation scheduled Wednesday 29 March 13:01-13:06

P09 **James Duhig, Director, Behavioral Sciences, Abbvie, USA**
Knowledge Task Data and Health Literacy: Comparison of Capability Assessments
Oral Presentation scheduled Thursday 30 March 12:47-12:52

P10 **Florian Eichmann, Principal Scientific Affairs and Real World Evidence, Late Stage, Inventiv Health, Germany**
Quality Standards for Real World Evidence - Finding a Way through the Late Stage G'X'P Study Jungle
Oral Presentation scheduled Thursday 30 March 13:01-13:06

P11 **Toshinori, Murayama, Professor and Chairman, Department of Clinical Development, Kanazawa University Hospital, Japan**
The Management of Un-Notified Clinical Trials by the Electronic Medical Record System in iCREK, Kanazawa University in Japan

P12 **Benedicte Vanderroost, GRACS Quality and Compliance Lead EMEA, Merck, Belgium**
Quality Management: How to Engage Affiliates in Fostering a Quality and Compliance Culture to Satisfy Regulatory Requirements
Oral Presentation scheduled Thursday 30 March 13:15-13:20

P13 **Peter Schüler, Senior VP Drug Development Services – CNS, ICON, Germany**
Expect the Unexpected: Not Everything goes According to Plan with Data Monitoring Committees!

P14 **Robert Brathwaite, Senior Manager, Deloitte, USA**
Artificial Intelligence uses in Pharmacovigilance

P15 **Renjit Babu, Perrine Faure, Gaëlle Frugier, Johanne Gafsi, Students of EUDIPHARM programme, Claude Bernard University of Lyon, France**
Strategy to Reduce Cholesterol – A Review of Two approaches: Target and Fixed-dosage
Oral Presentation scheduled Thursday 30 March 13:36-13:41

P16 **Jai Mahich, Associate Director, Cognizant Technology Solutions, UK**
Strategy Planning for Uncertainty in an Ever-Evolving Regulatory & Pharmacovigilance Environment
Oral Presentation scheduled Thursday 30 March 13:42-13:47

P17 **Colin Hayward, Chief Medical Officer, Premier Research Group Ltd., UK**
Increasing Compliance for Global Medical Coverage for Clinical Trials

SESSIONS RELEASED

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McCormick Place
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OPTIONAL SHORT COURSES

WEDNESDAY 29 MARCH 2017 | 09:00 - 12:30

Short Course 1 | Wednesday 29 March | 09:00-12:30 | Dochart 1

CHOOSING MEASURES OF TREATMENT BENEFIT: ESTIMANDS AND BEYOND

Robert Hemmings, Unit Manager, Statistics and Pharmacokinetics Unit, Medicines and Healthcare products Regulatory Agency (MHRA), UK
Wolfgang Kothny, Clinical Development Medical Director, Novartis Pharma, Switzerland
Mouna Akacha, Senior Expert Statistical Methodologist, Novartis Pharma, Switzerland

Randomised clinical trials are often considered the gold standard in drug development as they are expected to be free from baseline confounding. However, randomisation does not protect from bias due to events that occur after randomisation, e.g. discontinuation of treatment, treatment switching etc.

At present, these post-randomisation events are dealt with implicitly by choices made about the data collection and statistical analysis. In particular, the ITT approach may not always lead to clinically meaningful treatment effects. In order to improve transparency and ensure alignment between trials objectives and statistical approaches, it is necessary to clearly define the treatment effect (estimand) which is to be targeted in a clinical trial. The ICH has reinforced this need by tasking a working group to develop an addendum to the main statistical guidance in drug development – the ICH E9.

This addendum is expected to be released for public consultation by mid-2017 and will likely result in a substantive evolution to traditional clinical trial design, conduct and analysis. In particular, this is a multi-disciplinary effort that requires a common understanding beyond the statistics community. In this course we will provide a non-technical introduction and encompass clinical, statistical and regulatory perspectives.

Learning Objectives
At the conclusion of this tutorial, attendees will be able to:

Recognise that events which occur after randomisation, e.g. treatment switching, can introduce challenges in:
1. Defining suitable measures of treatment benefit (estimands)
2. Interpreting clinical trial results

Adopt a structured framework to formulate precise measures of treatment benefit such that:
1. The challenges mentioned above are mitigated
2. Informed discussions can take place at the design stage

Target Audience
This tutorial is designed for professionals working in clinical drug development and regulatory affairs who are involved in the design, conduct, analysis and reporting of clinical trials.

Short Course 2 | Wednesday 29 March | 09:00-12:30 | Boisdale 1

HOT TOPICS IN PHARMACOVIGILANCE

Sabine Brosch, Principal Scientific Administrator, European Medicines Agency (EMA), EU
Gaby Danan, Pharmacovigilance Expert, France
Subhash Mistry, Manager Systems Management, Pharmacovigilance, GSK, UK
Richard Ventham, Project analyst, Systems management group, Pharmacovigilance, GSK Biologicals, Belgium

This short course will provide an overview of the recent updates to the Good Pharmacovigilance Practice Module VI based on several case studies. It will give an overview of the operational aspects and business processes based on the legal provisions that place a shared responsibility on MAHs, NCAs and the European Medicines Agency as regards the follow up of individual cases and the duplicate management but will also address processes related to the nullification and amendment of ICSRs. Finally, frequently asked questions will be addressed in relation to the preparation for the simplified reporting of suspected adverse reactions and the access to EudraVigilance.

Learning Objectives
At the conclusion of this short course, attendees will be able to:
- Discuss recent updates to GVP Module VI based on several case studies
- Describe the follow up process and duplicate management process based on the shared responsibilities between MAHs, NCAs and the EMA
- Understand how to prepare for 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

WEDNESDAY 29 MARCH 2017 | 09:00 - 12:30

Short Course 3 | Wednesday 29 March | 09:00-12:30 | Boisdale 2

INTRODUCTION TO THE REGULATION OF MEDICAL DEVICES AND MEDICAL SOFTWARE

Sabina Hoekstra-van den Bosch, Global Regulations and Standards, Philips Healthcare, Netherlands
Erik Vollebregt, Attorney, Axon Lawyers, Netherlands

This short course will give a condensed overview of the EU device legislative system and the principles and philosophy supporting them. It will also explain the definition of a medical device, the delineation between medical devices and pharmaceuticals and the provisions on combination products. Legal provisions for medical software, regulated as a medical device will be highlighted. The characteristics and the organisational structure of the medical device sector and the role of the various stakeholders will be discussed as well as the concept of risk classification of medical devices and the relationship between risk classification and conformity assessment procedures.

This short course will cover the headlines of the EU regulation of in vitro diagnostics, with a focus on the differences to the medical device regulation. Theoretical concepts will be illustrated and supported by practical examples.
Finally, we will look ahead into the main changes resulting from the ongoing revision of the medical device and in vitro diagnostic regulations.

Learning Objectives
At the conclusion of this short course, attendees will be able to:
- Understand the main characteristics of the EU medical devices regulatory system, how it operates and how to bring a medical device to market
- Understand the delineation between pharmaceutical and medical devices
- Learn about the regulation of medical software and medical apps
- Discover the main changes resulting from the currently ongoing legislative review process

Target Audience
Professionals in the pharmaceutical or medical device area (e.g. regulatory affairs, clinical development), who are:
- Interested in a condensed overview of the EU medical device regulatory system
- Involved in the development and marketing of drug device combinations
- Interested in medical software regulation

Short Course 4 | Wednesday 29 March 09:00-12:30 | Alsh

MOVING FROM RISK MANAGEMENT TO BENEFIT-RISK MANAGEMENT – EMBEDDING PHARMACOVIGILANCE PRINCIPLES INTO THE PRODUCT LIFE CYCLE

Shelley Gandhi, Director Pharmacovigilance and Drug Safety, NDA Group, UK
Bill Richardson, Medical Advisor, NDA Group, UK

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

This short course will discuss how access to robust evidence on emerging risk in post-authorisation phase, good data on how a medicine is used in clinical practice, and data on background rates in the exposed population; gathering evidence throughout the product life cycle will help move companies to a benefit-risk system. The ultimate challenge is working towards an integrated regulatory system, enabling users to query across all information within a company, designing safety studies, monitoring the effectiveness of the risk management systems and gathering robust evidence from clinical practice.

The lessons learned and our experiences so far with post-authorisation commitments (e.g. BRMPs, PASS, PSURs) will be reviewed as will whether these commitments really do support an acceptable benefit-risk profile. This will include the novel approaches to managing benefit-risk to meet the needs of licensing medicines in biotechnology such as advanced therapies. Communicating benefit-risk will also be discussed as the new legislation will push for greater patient involvement within a benefit-risk system. Better methodologies and tools are required to support this integrated approach and adoption of a quality management system across global enterprise could achieve this.

Learning Objectives
At the conclusion of this short course, attendees will be able to:
- Learn about effective strategies and the current thinking on risk mitigation in the context of benefit throughout the product life cycle
- Understand how to access to robust evidence about emerging risk
- Discover what the principles are for proportionate risk based assessment
- Conquer those hurdles which get in the way to a systematic approach by reflecting on how these might be tackled

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OPTIONAL SHORT COURSES

WEDNESDAY 29 MARCH 2017 | 09:00 - 12:30

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 5 | Wednesday 29 March | 09:00-12:30 | Carron 2

THE PHARMACEUTICAL REGULATORY ENVIRONMENT IN JAPAN: OVERVIEW OF ORGANISATION, OPPORTUNITIES AND PROCEDURES
Alberto Grignolo, Corporate Vice President, PAREXEL International, USA
Yoshiaki Uyama, Director, Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Significant changes in Japanese pharmaceutical regulations and procedures are impacting the development of new drugs in Japan as well as global development programs. This short course will describe the major drivers of the regulatory system, including the Pharmaceuticals and Medical Devices Agency (PMDA) and Ministry of Health, Labor and Welfare (MHLW), regulatory procedures during drug development (consultations with PMDA and Clinical Trial Notifications), the integration of Japan drug development with East Asian and global drug development, orphan drug regulation, accelerated development and approval opportunities for regenerative and other innovative therapies, and J NDA preparation and review. Several development strategies available to address Japanese requirements for new drug approval, as well as selected post approval requirements, will be discussed.

The benefit of the short course is that participants will gain a practical understanding of the specific steps necessary to prepare a registration strategy for Japan, to meet with the Japanese Authorities, to submit successful clinical trial and marketing applications, and to enter the Japanese pharmaceutical market.

Learning Objectives
- Describe the Japanese regulatory procedures during development, registration, and post approval (e.g. Consultation, MRCT design, CTN, J NDA, safety reporting)
- Discuss specific attributes of the Japanese regulatory system and their impact on local and global development

Target Audience
This short course is designed for professionals in regulatory affairs, project management, and clinical development who are involved with global development projects that include Japan.

Short Course 6 | Wednesday 29 March | 09:00-12:30 | Carron 1

CLINICAL IMPLEMENTATION OF BIOMARKERS AND STRATEGIES FOR COMPANION DIAGNOSTICS
Klaus Dücker, Senior Director - Clinical Biomarkers & Companion Diagnostics Biopharma, R&D Global Early Development, Merck Group, Germany
Claudia Dollins, Associate Director, Global Regulatory Affairs, Companion Diagnostics, Merck Group, Germany

The first part of this short course will discuss critical steps to be considered during late stages of preclinical development to ensure successful translation of preclinical biomarker testing into a clinical trial context. Focusing on targeted oncology treatments, the session will provide an overview of assay development criteria, to include specimen, analyse, and sample stability/integrity, and sample complexity. We will further examine the impact of sample acquisition and sample logistics on biomarker data quality.

On the topic of pharmacodynamic biomarkers, the session will provide following insights:
- Their value in the context of proof of target modulation of a therapeutic agent
- Their ability to support dose selection and schedule decision
- Consideration of testing in the target vs. surrogate tissue
- The utilisation of proximal and distal pharmacodynamic markers

The first part of this session will conclude with a case study for how a biomarker defined population can support rationale drug development to potentially accelerate development timelines. The latter part of this session will focus on regulatory considerations and requirements relevant to co-development efforts.

Initially, the regulatory portion of this session will provide an introduction to selected IVD regulatory frameworks. The basic understanding of the regulatory framework will then serve as the foundation of a discussion of regulatory considerations for trial conduct to include the elements of risk evaluation and regulatory implications. Moreover, elements to consider for trial design and implementation to facilitate future regulatory approval (such as specimen annotation and handling considerations) will be discussed.

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OPTIONAL SHORT COURSES

WEDNESDAY 29 MARCH 2017 | 09:00 - 12:30

Learning Objectives

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

- Understand the key aspects & challenges of clinical biomarker development & qualification
- Outline critical considerations for clinical trial suitable biomarker testing
- Appropriate utilisation of pharmacodynamic biomarkers (e.g. prove target modulation, rationale dose selection)
- Understand regulatory considerations for development of a predictive biomarker candidate into a companion diagnostic

Target Audience

This short course will be very useful for everyone dealing with biomarkers in discovery, development, and registration:

- Scientists
- Medical Directors
- Programme Leads
- Project Managers
- Regulatory Experts
- Biomarker Strategists
- Personalised Medicine Leads
- Medical Affairs Professionals
- Diagnostics Providers

SPECIAL SESSIONS

Wednesday, 29 March | 09:00-10:30 | Hall 2

UK SATELLITE SESSION
CERTAINTY VERSUS ACCESS: UNMET NEED AND THE DECISION MAKER'S DILEMMA

Session Chair: **Ian Hudson**, Chief Executive, Medicines & Healthcare products Regulatory Agency (MHRA), UK

Certainty versus Access: Who needs what, when and how? This session explores the challenges and opportunities in unmet medical need, with presentations illustrating initiatives where the UK is participating.

Timely Access to Medicines – What, When and How: MHRA View
Robert Hemmings, Statistics and PK Unit Manager MHRA , co-opted member of CHMP and chair of the CHMP's Scientific Advice Working Party (SAWP), Medicines & Healthcare products Regulatory Agency (MHRA), UK

Timely Access to Medicines - Balancing the Data Requirements of HTA and Medicines Regulatory: NICE View
Sarah Garner, Associate Director - Science Policy and Research, National Institute for Health and Care Excellence (NICE), UK

Post-Authorisation Data Collection: What Can be Achieved and How?
Tjeerd van Staa, Professor of eHealth Research, Farr Institute, University of Manchester, UK

Certainty versus Access – Are There Viable Policy and Methods Solutions?
Panel discussion with chair, speakers, , Alan MacDonald, Vice-Chairman, Scottish Medicines Consortium, Consultant Rheumatologist, NHS Grampian, and Nick Crabb, Programme Director, Scientific Affairs, NICE, UK

Wednesday, 29 March | 09:00-10:30 | Hall 1

IMI SATELITTE SESSION
PATIENT CENTRICITY:
WHAT IS IT AND HOW CAN WE MAKE IT MEANINGFUL? A ROUND TABLE DISCUSSION

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

Patient centricity has never been so much in the spotlight. Patient insights and patient data play an increasingly established role in the valuation of healthcare offerings once a drug is on the market; but the role and value of an enhanced patient voice during R&D, in particular during clinical development, is yet to be established.
This panel session will focus on patient engagement during research & clinical development. Panellists will present case studies, lessons learned and examples of best practices. The discussion will aim to demonstrate the value of patient involvement in medicines R&D, and will address the following questions and issues:

- What does patient centricity mean to different stakeholders?
- Why do we need patients to be engaged at an early stage of medicines development? What are the lessons learned from existing cases?
- What are the challenges in early patient involvement?
- How should patients be engaged for the impact to be real and meaningful?

Panellists:
Magda Chlebus, Director Science Policy, EFPIA, Belgium
Juan García-Burgos, Head of Public Engagement (Ad Interim), European Medicines Agency (EMA), EU
Magda Gunn, Scientific Project Manager, Innovative Medicines Initiative (IMI), Belgium
Florian Klett, EUPATI Fellow, Switzerland
Debra Michaels, Senior Scientist, DIA, USA
Kay Warner, Patient Engagement Lead, Patients in Partnership, Global Franchise Executive Management, GSK, UK

SPECIAL SESSIONS

Wednesday, 29 March | 11:00-12:30 | Lomond

EUROPEAN REGULATORY TOWN HALL MEETING

Polling/Voting offered. See page 11 for App details

Moderator: **Avril Daly**, Vice-President, Eurordis, France

Pharmaceutical-sector regulators and industry are faced with the need to innovate, engage and evolve. The European Regulatory Town Hall is opportunity for senior leadership from the European medicines system to highlight some of the key scientific and regulatory challenges and opportunities facing agencies as we look out to 2017 and beyond.

Part One
Engaging in Science, Approaching Innovation

Part Two
Evolving our Procedures and Processes, Engagement

Pierre Meulien, Executive Director, Innovative Medicines Initiative (IMI), Belgium
Guido Rasi, Executive Director, European Medicines Agency (EMA), EU
Thomas Senderovitz, Director General, Danish Medicines Agency (DKMA), Denmark
Christa Wirthumer-Hoche, Chair of EMA Management Board, and Head Austrian Medicines & Medical Devices Agency (AGES), Austria

Wednesday, 29 March | 14:00-15:30 | Clyde Auditorium

OPENING PLENARY

'From Disruptive Technologies to Empowering Technologies in Healthcare'

Our lives as patients, regulators and scientists are being disrupted by new technologies. They have been transforming our environment at every step of medicines development. It will not reverse or stop but, on the contrary, accelerate. Now is the time to stop being disrupted by it and build a model that would allow us to fully enable it – and be enabled by it!

Panellists:
Alison Cave, Principal Scientific Administrator, European Medicines Agency (EMA), EU
David Haerry, EATG, EU
Joseph Scheeren, Senior Vice President, Head Regulatory Affairs, Pharma and Consumer Health, Bayer Consumer Care, Switzerland
James Streeter, VP, Life Sciences Product Strategy, Oracle Health Sciences, USA

Co-Moderators:
Susan Forda, Vice President, International Regulatory Affairs, Eli Lilly & Company Ltd, UK
Ian Hudson, Chief Executive, Medicines & Healthcare products Regulatory Agency (MHRA), UK

EuroMeeting 2017

NETWORKING EVENTS

Refreshment and Lunch Breaks

Meet with your colleagues to plan your day, and discuss what you learned the day before, all while networking with other attendees and take advantage of extended breaks to visit more than 100+ exhibiting companies. All refreshment breaks and lunches will be held in designated areas of the Exhibit Hall.

We invite you to also take advantage of the additional features of the Exhibit Hall during extended coffee breaks and lunch hours.

Wednesday
10:30-11:00 Coffee Break | 12:30 - 14:00 Lunch | 15:30 - 16:30 Afternoon tea/coffee with snack

Thursday
08:00-09:00 Welcome Coffee | 10:15 - 11:00 Morning tea/coffee with snack
12:30 - 14:30 Lunch | 15:15 - 16:00 Afternoon tea/coffee with snack

Friday
08:00-09:00 Welcome Coffee | 10:15 - 11:00 Morning tea/coffee with snack
12:30 - 13:30 Lunch

Speed Networking

Thursday, 30 March 2017 | 12:45 - 13:15
Exhibit Hall
Speed Networking provides a framework where each participant will meet at least six new professionals during an informal and interactive 30 minute session.

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.

- Professional Poster Session #1
  Wednesday, 29 March 2017 | 10:00 – 18:00
- Professional Poster Session #2
  Thursday, 30 March 2017 | 09:00 – 17:30
- Professional Poster Session #3
  Friday, 31 March 2017 | 09:00 – 12:30

See page 12 for Oral poster presentations schedule

NETWORKING EVENTS

"Welcome to Glasgow" Civic Reception Courtesy of The Rt Hon The Lord Provost of Glasgow

Wednesday, 29 March 2017 | 18:00 – 19:30 | Exhibit Hall, Ground Level

Join us in the Exhibit Hall for a Scottish Opening Reception to mingle and network with your peers and colleagues.

Thursday Networking Reception in the Exhibition Hall

Thursday, 30 March 2017 | 17:30 – 18:30

Exhibit Hall

Network with 1,500+ attendees at the Thursday Networking Reception held in the Exhibit Hall.

DIA Communities

DIA Community Networking Area

Exhibit Hall

A dedicated area is available for you to meet with your fellow Community members throughout the week or to learn more about DIA's Communities. Each table will include a sign related to a specific Community Interest Area. Look for the designated area in Exhibit Hall, where you can relax and enjoy an informal opportunity to network.

Communities Meet & Eat

Thursday, 30 March 2017 | 13:00 - 14:00

Exhibit Hall

Join your Communities Live at the EuroMeeting!
We encourage all new and expert Communities members to join us at the Communities Meet & Eat.

This networking event is a great way to learn more about the opportunities within the Communities platform, as well as a chance to meet your colleagues directly.

Visiting the Exhibit Hall

The DIA 29th Annual EuroMeeting Exhibition provides a perfect forum for attendees and speakers to network with 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.

EuroMeeting 2017

HIGHLIGHTS

DIAmond SESSIONS

Following the big success of the "DIAmond" sessions at the DIA Global Annual Meeting in Philadelphia in June 2016 you can look forward to continued cross-faculty discussions.

DIAmond Session 1 | Lomond
Thursday 30 March | 09:00-10:30

MAJOR REGULATORY CHALLENGES ENABLING DECISION MAKING FOR EARLY PATIENT ACCESS: REGULATORY TOOLS AND SOURCES OF RWE

Session Co-Chairs:
Karl Broich, President, Federal Institute for Drugs and Medical Devices (BfArM), Germany
Joseph Scheeren, Senior Vice President, Head Regulatory Affairs, Pharma and Consumer Health, Bayer Consumer Care, Switzerland

The commitment for enabling early patient access to new innovative medicines is one of the major challenges in regulatory science. From a regulator's perspective, early access tools are in place in the EU and the US in order to support early approval. In addition, real world evidence (RWE) presents a significant opportunity to improve regulatory decision making. Technological advances permit collection of real world data (RWD) from an increasing number of sources like patient registries and electronic patient records etc., while new artificial Intelligence approaches permit to translate these data into RWE.

This cross functional DIAmond session will discuss opportunities and challenges from the regulator (EU and US), industry and patient perspective.

Early Access to Medicines in the EU - Regulatory Tools and Challenges in the Context of Other Regions
Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, MPA, Sweden

Current Status and Challenges of Early Access Tools and the Opportunities of Real-World Evidence (RWE) for Regulatory Decision Making in the US
Sandra Kweder, Deputy Director, Europe Office, Office of International Programs, FDA, USA

Major Challenges for Industry and Opportunities for Real World Data Generation Including Patient Registry to Enable Regulatory Decision Making
Badri Rengarajan, Medical Affairs Lead, ASPIRE Unit, Actelion, USA

Panel discussion with all participants and Elizabeth Vroom, Chair, United Parent Projects Muscular Dystrophy (UPPMD), Netherlands

DIAmond Session 2 | Hall 1
Thursday 30 March | 09:00-10:30

CURRENT TRENDS AND SOLUTIONS IN GLOBAL CLINICAL OPERATIONS

Session Chair:
Peter Schüler, Senior VP Drug Development Services – CNS, ICON, Germany

Polling/Voting offered. See page 11 for App details

Precision medicine targets better defined, but smaller populations. More drugs get developed in such smaller populations. Orphan drug designations (FDA) increased steadily from 195 in 2010 to 354 in 2015. This creates new challenges from site and subject identification to subject adherence and retention. Real-world data play a new role to support the adaptive and conditional approval process. Patient centricity is finally understood as a key to success for development.

Evidence-Based Feasibility and Protocol Design
Joachim Luithle, VP, Head of Clinical Project Management Cardiology, Coagulation and Hematology, Bayer Healthcare, Germany

Novel Use of Real World Data in Clinical Trials and Interventional Studies
Janet Valentine, Director, CPRD, Medicines & Healthcare products Regulatory Agency (MHRA), UK

The Patient Registry for Patient Pool Enrichment and Post-Approval Evidence
Peter Schüler, Senior VP Drug Development Services – CNS, ICON, Germany

What Do 'Digital Immigrant' and' Digital Native' Patients Want?
Jacqueline Bowman, Principal, Third-i bvba, Belgium

A Platform Approach to Make Precision Medicine Studies Doable
Sarah Cooper, Business Development Manager, NIHR, UK

EuroMeeting 2017

HIGHLIGHTS

DIAmond SESSIONS

DIAmond Session 3 | Lomond
Friday 31 March | 09:00-10:30

GLOBAL REGULATORY CONVERGENCE - STATE OF PLAY AND OUTLOOK FOR THE FUTURE

Session Co-Chairs:
Spiros Vamvakas, Head of Scientific Advice, European Medicines Agency, (EMA), EU
Iman Barilero, Chief Regulatory Science, Patient advocacy and Pharmacovigilance Officer, Axcella Health, USA

The session will provide examples of initiatives undertaken by regulators to support innovative drug development and regulatory science-based decision making, and will present initiatives with enhanced patient perspectives on the medicines R&D processes of the treatment development life cycle. We will also explore the views from a patient group, FDA, and EMA on the impact of regulatory convergence and ways forward to maintain sustainable global drug development and an effective regulatory process.

EMA-FDA Collaboration in the Context of Scientific Advice, Including the Parallel Qualification Procedures and 'PRIME Breakthrough'
Tomas Salmonson, Chair CHMP, Senior Scientific Advisor, MPA, Sweden
Rob Hemmings, Member CHMP, Unit Manager, Statistics and Pharmacokinetics Unit, Medicines and Healthcare products Regulatory Agency (MHRA), UK

ICH E17 Multi Regional Trials and Addendum E6
Armin Koch, Head, Institute of Biometry, Hannover Medical School, Germany

Conversion from a Patient Engagement Perspective at Key Decision Points of Drug Development: How Can We Find a Common Approach to Supporting Innovation and Drug Development - and Possible Areas of FDA-EMA Collaboration?
Dimitrios Athanasiou, Duchenne Patient Advocate, Muscular Dystrophy Association Hellas, Board Member in UPPMD and EMA Patient Expert for DMD, Greece

Panel Discussion: Where should regulators focus their efforts towards global convergence in the next 5 years? Session participants will discuss their views on regulatory collaboration and convergence and focus on the way forward.

DIAmond Session 4 | Hall 1
Friday 31 March | 09:00-10:30

CLINICAL DEVELOPMENT PARTNERING 2.0 – MULTI-STAKEHOLDER EFFORTS TO REDUCE INVESTIGATOR SITE BURDEN

Session Chair:
Diana Anderson Foster, Director, Strategic Partnership Development, Society for Clinical Research Sites (SCRS), USA

Our Industry is celebrating some amazing achievements - pharmaceutical organisations are spending more than ever on R&D, product pipelines have nearly doubled in the past 10 years, and innovation is being highlighted every single day.

Despite these successes, clinical research remains costly and inefficient. Site Investigators continue to face significant challenges in working with CROs and Sponsors. Could collaboration drive the change so desperately needed in the industry?

This session will explore the efforts underway between three industry organisations that are working together to reduce administrative burdens placed on investigator sites, and increase study success. Please join leaders from the Society for Clinical Research Sites (SCRS), The Association of Clinical Research Organizations (ACRO) and TransCelerate BioPharma, Inc. to better understand solutions that will address protocol complexity, monitoring structures, communications, contracts, and budgets.

Reducing Administrative Burdens in the Conduct of Research: A CRO Perspective
Karen Noonan, Vice President, Global Regulatory Policy, Association of Clinical Research Organizations (ACRO), USA

Transformation through Collaboration
Paul Duffy, Director of Clinical Research UK & Ireland, UK Country Lead, TransCelerate BioPharma, Inc., UK

Site Master Data: Where Are We Today and What the Future Holds
Diana Anderson Foster, Director, Strategic Partnership Development, Society for Clinical Research Sites (SCRS), USA

How Site Master Data Can Improve the Working Relationship between Sites, Sponsors and CROs
Andrew Gebbie, Principal Solution Consultant, Medidata, UK

EuroMeeting 2017

SCIENTIFIC PROGRAMME

THEME 1

GLOBALISATION OF HEALTH CARE PRODUCT DEVELOPMENT - WHAT ARE THE CURRENT SUCCESSES AND CHALLENGES?

Theme Leaders:
Agnes Saint-Raymond, Ad Interim Head of International Affairs, European Medicines Agency, EU
Gerhard Schlüter, VP, Head GRA TA Specialty Medicine, Bayer, Germany

We have all seen the increasing globalisation of the pharmaceutical sector over the past decades. How has this globalisation impacted patients, regulators, industry and other actors? The Globalisation Theme will look at what has been achieved and where more progress is needed, with a focus on global drug development, quality standards, collaborations and trade negotiations.

Session 0101 | Wednesday 29 March | 16:30-18:00 | Boisdale

GLOBAL DOSSIER FOR CLINICAL DEVELOPMENT
Session Chair:
Mira Pavlovic, Director, Medicines Development and Training Services (MDT) Services, France

Throughout the world differences in available treatment options, therapeutic and disease management guidelines, regulatory requirements, and criteria for pricing and reimbursement make common clinical development a major challenge. However, requirements to support product registration and access to market are more or less the same whatever the region: to provide evidence that a product is effective and safe when administered to patients with a given disease and when compared to placebo and/or a standard of care. We shall discuss requirements for a global product development and standardisation of outcomes for benefit-risk and relative effectiveness assessment in Europe and in the US.

Global Dossier – Acceptance of Foreign Data (industry view)
Friedrich Asmus, Global Clinical Leader Ophthalmology, Bayer Pharma, Germany

Global Dossier – Regulatory View
Luca Pani, CHMP and SAWP Member, Voluntary Professor, Department of Psychiatry and Behavioral Sciences
University of Miami, USA

Session 0102 | Thursday 30 March | 11:00-12:30 | Boisdale

UPDATE ON PMDA ACTIVITIES
Session Chair:
Toshiyoshi Tominaga, Associate Executive Director (for International Programs), Pharmaceuticals and Medical Devices Agency (PMDA)

In this session, members of PMDA's executive staff will provide updates regarding the latest advancements made in responding to the needs and expectations of PMDA's stakeholders in Japan and worldwide, as part of the agency's continuing efforts to realize the goals of its International Strategic Plan 2015 and other recent policy objectives. This session will include presentations from both PMDA and MHLW executives as well as time for Q&A.

Takao Yamori, Executive Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Shinobu Uzu, Chief Safety Officer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Nobumasa Nakashima, Office Director for International Regulatory Affairs, Ministry of Health, Labour and Welfare (MHLW), Japan

Session 0103 | Thursday 30 Mar 14:00-15:30 | Boisdale

QUALITY STANDARDS ACROSS THE GLOBE – EVOLUTION AND ENFORCEMENT
Session Co-Chairs:
Susanne Keitel, Director, European Directorate for the Quality of Medicines & HealthCare (EDQM), EU
Ana-Maria Oltean, Quality Assurance & Regulatory Affairs Officer, Asphalion, Spain

The interactive session will highlight the challenges globalisation poses for the availability of medicine and look into possible solutions international collaboration can offer for industry and regulators.

GCP and GMP Non-Compliance and What It Means for the Availability of Medicines in the EU
Anabela Luis de Lima Marçal, Head of Inspections and Human Medicines, European Medicines Agency (EMA), EU

Quality Standards across the Globe – Tackling the Impact of the Globalisation of Pharmaceutical Operations
Koen Nauwelaerts, Manager Regulatory Affairs and Quality, Medicines for Europe, Belgium

Regulatory Submission and Inspections in Emerging Countries – How Does International Collaboration Affect Them?
Susanne Ausborn, Head CMC Policy &International Operations EEMEA, Roche, Switzerland

SCIENTIFIC PROGRAMME

Session 0104 | Thursday 30 March 16:00-17:30 | Boisdale

VACCINE PANDEMIC PREPAREDNESS - NEW APPROACHES

Session Chair:
Murray Lumpkin, Lead for Global Regulatory Systems Initiatives, Bill and Melinda Gates Foundation, USA

Attendees will have the opportunity to learn about the new approaches to vaccine pandemic preparedness based on lessons learned from the Ebola crisis. Speakers from WHO, the CEPI initiative, and a multinational vaccine manufacturer will present their views on the current efforts underway to be much better prepared for the next pandemic than we were for Ebola.

WHO's R&D Blueprint for Pandemic Preparedness
David Wood, Coordinator: Technologies, Standards, and Norms Team, Word Health Organisation (WHO), Switzerland

CEPI and Its Approach for Vaccine Pandemic Preparedness
Frederik K. O. Kristensen, Senior Medical Officer, Coalition for Epidemic Preparedness Innovations (CEPI), Norway

Efforts of Vaccine Manufacturers
Jean Lang, Associate Vice President RD, Sanofi Pasteur, France

Session 0105 | Friday 31 March | 11:00-12:30 | Boisdale

IMPACTS OF TRADE NEGOTIATIONS FOR REGULATOR AND INDUSTRY COOPERATION

Session Co-Chairs:
Maria Trallero, Director Trade Policy, EFPIA, Belgium
Anabela Luis de Lima Marçal, Head of Inspections and Human Medicines, European Medicines Agency (EMA), EU

EU trade policy is focussing increased attention on fostering regulatory convergence, including flagship trade agreements like EU-US TTIP. This session will look into the opportunities and challenges faced - learning from policy-makers' perspectives, industry's expectations, and academics' recommendations. This session will comprise of panellists' presentations followed by Q&A.

EU's Trade Strategy and Regulatory Convergence
Ignacio Iruarrizaga, DG Trade, Head of Unit Trade in Services, Directorate-General for Trade, European Commission, EU

Can Trade Agreements Deliver Closer Cooperation in Pharmaceuticals? An Industry Perspective
Charles Faid, Director EU Government Affairs, Pfizer, Belgium

Strengthening Regulators' Cooperation through Bilateral and Plurilateral Initiatives – FDA perspectives
Sandra Kweder, Deputy Director, Europe Office, Office of International Programs, FDA, USA

THEME 2

INNOVATION OF HEALTH CARE PRODUCT DEVELOPMENT - WHAT ARE THE KEY SUCCESS FACTORS?

Theme Leaders:
Salah-Dine Chibout, Chair of InnoMeds, EFPIA, Global Head Discovery & Investigative Safety/Preclinical Safety Therapeutic Areas, Novartis, Switzerland
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency (EMA), EU

The ever-increasing challenge to keep pace and to accelerate medical innovation can only be answered by combining forces of multiple stakeholders: Joining forces of pharma- and non-life science companies, SMEs, academia, HTA, payers, regulators, and patient organisations that collaborate in Public-Private Partnerships (PPPs) is the adequate answer to achieve new approaches towards the complex biology of diseases.

Session 0201 | Wednesday 29 March | 16:30-18:00 | Forth

CREATING A FRAMEWORK FOR INNOVATION I: INCENTIVES AND REGULATORY FRAMEWORKS

Polling/Voting offered. See page 11 for App details
Session Chair:
Salah-Dine Chibout, Chair of InnoMeds, EFPIA, Global Head Discovery & Investigative Safety/Preclinical Safety Therapeutic Areas, Novartis, Switzerland

Patients, healthcare providers, and society as a whole benefit from innovation in the pharmaceutical sector. The patients benefit by potentially gaining access to new and efficient medications. The healthcare providers benefit by being able to provide/choose between different treatment options. Ultimately society benefits by having healthier population with potentially better quality of life. Pharmaceutical research and development is a long and expensive process, therefore, appropriate incentives and appropriate regulatory framework need to be in place for creating and maintaining an environment for innovation. During the session we will explore what could be the role of global product partnerships, regulatory, and health insurance systems in building the right incentives and regulatory framework to support innovation which will ultimately benefit the patients, health care providers and society as a whole.

Global Product Partnerships Experts Play a Key Role in Driving Innovation
Wolfgang Stoiber, Managing Director, JSB-Partners, LP, USA

Support from Regulatory Processes
Ian Hudson, Chief Executive, Medicines & Healthcare products Regulatory Agency (MHRA), UK

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A New Model for Health Insurance Systems
Ad Schuurman, Head of the International Department, National Health Care Institute (ZIN), Netherlands

Session 0202 | Thursday 30 March | 11:00-12:30 | Carron

CREATING A FRAMEWORK FOR INNOVATION II: INFRASTRUCTURE AND COLLABORATIONS

Polling/Voting offered. See page 11 for App details
Session Chair:
Salah-Dine Chibout, Chair of InnoMeds, EFPIA, Global Head Discovery & Investigative Safety/Preclinical Safety Therapeutic Areas, Novartis, Switzerland

The pace of innovation in the areas of technology and pharmaceutical industry has been very rapid in the past decades. When there is a rapid development appropriate infrastructure and collaboration need to be established in order to further build and foster development in the area of innovation. During this session we will discuss what kind of infrastructure and collaboration for innovation is available (e.g. science hubs for innovations, public-private partnerships under the umbrella of Innovative Medicines Initiative) or emerging (externalisation of research and cross-sector integration) and how this may impact the medical innovation in the next years and decades.

Externalistion of Research
Michel Van Speybroeck, Director Data Sciences, Janssen (J&J), Belgium

PPPs: IMI2
Magda Chlebus, Director Science Policy, EFPIA, Belgium

Integration of Non-Life Science (Data-) Companies in Pharma Innovation Process
Tony Bartlett, Business Development, Europe, SomaLogic, Inc., UK

Science Hubs for Innovation
Carlo Incerti, Head of Global Medical Affairs, Genzyme, Italy

Session 0203 | Thursday 30 March | 14:00-15:30 | Hall 5

LEVERAGING INFORMATION BEYOND RANDOMISED CLINICAL TRIALS: HOW REAL WORLD DATA CAN CONTRIBUTE TO DECISION-MAKING

Session Chair:
Frank Bretz, VP, Head Statistical Methodology and Consulting, Novartis, Switzerland

This session reflects on how recent scientific developments are both necessitating and enabling new ways of leveraging information beyond randomised clinical trials. Robust new methods of data collection and synthesis could be adopted earlier in pharmaceutical R&D and the healthcare decision-making process through patient-level data sharing agreements and from real world data. Different approaches shall be discussed and illustrated with examples.

Threshold Crossing: A Useful Way to Establish the Counterfactual in Clinical Trials?
Franz König, Professor, Medical University of Vienna, Austria

Connecting the Dots: Real-World Evidence and Platform Trials
Michael Krams, Global Head of Quantitative Sciences, Janssen Pharmaceuticals, Inc., USA

The Realities of Real-World Data - An HTA Perspective
Sarah Garner, Associate Director - Science Policy and Research, National Institute for Health and Care Excellence (NICE), UK

Session 0204 | Thursday 30 March | 16:00-17:30 | Hall 5

DO PAYERS AND PATIENTS HAVE A ROLE IN SUPPORTING INNOVATION? A ROUND TABLE DISCUSSION

Session Chair:
Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency (EMA), EU

Academia and private sector companies are the pillars of innovation in the life sciences. Patients also enable innovation by enrolling in clinical trials, and most regulators would now consider support for innovation that benefits patients to be a part of their mission.

The majority of healthcare payers, whether public or private, do not see support for innovation as an integral part of their remit, in spite of their ever increasing importance as decision makers in the healthcare system and society.

This session will explore if payers should and – if yes - how they can support biomedical innovation that will ultimately benefit patients. In addition, the growing role for innovation of patients and caregivers beyond participation in clinical trials will be examined.

Topics for discussion include: Can payers and patients steer investment? Can payers be launch customers? (When) Should payers and patients engage with industry during drug development? What level of uncertainty should payers and patients accept?

MEDEV Perspective
Ad Schuurman, Head of the International Department, National Health Care Institute (ZIN), Netherlands

Patient Perspective
Nicola Bedlington, President, European Patients Forum, Austria

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

SCIENTIFIC PROGRAMME

Session 0205 | Friday 31 March | 11:00-12:30 | Hall 5

CREATING A FAVOURABLE ENVIRONMENT FOR ADVANCED THERAPY MEDICINAL PRODUCTS (ATMPS)

Session Chair:
Eduardo Bravo, CEO, Tigenix, Spain

Existing barriers for the successful commercialisation of ATMPs in Europe and the plans to remove, at least partially, some of them will be discussed.

Improving the Regulatory Environment for ATMPs in Europe
Paula Salmikangas, Chair Committee for Advanced Therapies (CAT), Senior Researcher, Fimea, Finland

Reimbursement Challenges Facing ATMPs
Deborah Morrison, Senior Scientific Adviser, National Institute for Health and Care Excellence (NICE), UK

Existing Barriers for the Commercial Success of ATMPs
Andrea Chiesi, Director R&D Project and Portfolio Management, Chiesi Farmaceutici, Italy

THEME 3

CURRENT CHALLENGES IN CLINICAL RESEARCH

Jens Heisterberg, Vice President, Regulatory Intelligence, Novo Nordisk, Denmark
Steffen Thirstrup, Medical Advisor, Regulatory Advisory Board, NDA Group, UK

Careful planning, conduct, and monitoring of clinical trials are essential parts of every development programme. Sessions in this theme will be covering data-driven trial management, translational research and discussing your readiness for the new EU clinical trial regulation and how GCP-findings may have implications for the benefit-risk balance of your product. Finally, this hands-on session will focus on immunogenicity assessment of new biologicals.

Session 0301/0601 | Wednesday 29 March | 16:30-18:00 | Lomond

BENEFIT/RISK COMMUNICATION: TOWARDS A PATIENT-CENTRED APPROACH

Session Chair:
Ragnar Löfstedt, Professor of Risk Management, Director of King's Centre for Risk Management, King's College London, UK

Regulatory agencies and pharmaceutical companies across the Atlantic have shown a large appetite for identifying and developing effective benefit/risk communication towards patients, healthcare professionals and the general public. This panel discussion will assemble representatives from all major parties involved to assess the progress achieved and suggest concrete ways to further improve benefit/risk communication.

Speakers:
Francesco Pignatti, Head of Oncology, Haematology, Diagnostics European Medicines Agency (EMA), EU
Frederic Bouder, Assistant Professor in the Department of Technology and Society Studies, Maastricht University, Netherlands
David Haerry, European AIDS Treatment Group (EATG), Belgium

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DIAmond Session 2 | Thursday 30 March | 09:00-10:30 | Hall 1

CURRENT TRENDS AND SOLUTIONS IN GLOBAL CLINICAL OPERATIONS

Session Chair:
Peter Schüler, Senior VP Drug Development Services – CNS, ICON, Germany

Precision medicine targets better defined, but smaller populations. More drugs get developed in such smaller populations. Orphan drug designations (FDA) increased steadily from 195 in 2010 to 354 in 2015. This creates new challenges from site and subject identification to subject adherence and retention. Real-world data play a new role to support the adaptive and conditional approval process. Patient centricity is finally understood as a key to success for development.

Evidence-Based Feasibility and Protocol Design
Joachim Luithle, VP, Head of Clinical Project Management Cardiology, Coagulation and Hematology, Bayer Healthcare, Germany

The Clinical Practice Research Datalink as a Practical Example of How to Use Electronic Healthcare Records
Janet Valentine, Director, CPRD, Medicines & Healthcare products Regulatory Agency (MHRA), UK

The Patient Registry for Patient Pool Enrichment and Post-Approval Evidence
Peter Schüler, Senior VP Drug Development Services – CNS, ICON, Germany

What Do 'Digital Immigrant' and' Digital Native' Patients Want?
Jacqueline Bowman, Principal, Third-i bvba, Belgium

A Platform Approach to Make Precision Medicine Studies Doable
Sarah Cooper, Business Development Manager, NIHR, UK

Session 0302 | Thursday 30 March | 11:00-12:30 | Hall 5

EU CLINICAL TRIAL REGULATION AND ITS IMPLICATIONS

Session Chair:
Steffen Thirstrup, Medical Advisor, Regulatory Advisory Board, NDA Group, UK

The new EU clinical trials regulation (CTR) will come into force in 2018 aiming for a more streamlined process with clearer roles and responsibilities. It will fundamentally change the way clinical trial applications are assessed and what information will be publically available. Is your organisation ready to meet these challenges?

Will Early-Phase Trials Suffer or Benefit?
Bruno Speder, Head Clinical Regulatory Affairs, SGS Life Science Services, Belgium

Ensuring a Swift and Timely Transition to Compliance with the CTR
Lene Grejs Petersen, Senior Adviser, Clinical Trials, Danish Medicines Agency (DKMA), Denmark

Ethical Assessment of Clinical Trials Following EU CTR Implementation – Are we Ready for Changes?
Anna Kubik, KCR, Poland

Session 0303 | Thursday 30 March | 14:00-15:30 | Carron

IMMUNOGENICITY ASSESSMENT – RISK-BASED APPROACHES

Session Chair:
Markku Toivonen, NDA Advisory Board - Scientific Director, NDA Group, UK

Immunogenicity data prior to approval are generally limited and further systematic testing is usually required. Risk-based approaches to immunogenicity assessment in the pre- and post-authorisation phases informs necessary risk minimisation strategies and selection of optimal data collection and analysis methods for the completion of missing information.

Risk-Based Approach to Immunogenicity Assessment
Paul Chamberlain, Biopharmaceutical Development and Immunology Specialist, NDA Advisory Services Ltd., UK

Generating Data that Matter for Post-Authorisation Evaluation of Immunogenicity
Gerrit Jan Wolbink, Researcher, Sanquin, Netherlands

Immunogenicity from the Risk Minimisation Perspective
Thijs Giezen, Member EMA Biosimilar Medicinal Products Working Party (BMWP), Hospital Pharmacist, Foundation Pharmacy for Hospitals in Haarlem, Netherlands

Session 0304 | Thursday 30 March | 16:00-17:30 | Carron

GCP FINDINGS AND THE BENEFIT-RISK BALANCE

Session Co-Chairs:
Jens Heisterberg, Vice President, Regulatory Intelligence, Novo Nordisk, Denmark

Even with all efforts to ensure good clinical trial quality, critical GCP non-compliance may arise – detected by monitors, GCP auditors or inspectors. This session addresses the situation when things have gone wrong. How do the findings influence the benefit-risk evaluation? When is data integrity impacted? Can the clinical data still be of use? And how can the collaboration between clinical development/clinical operations staff and GCP auditors within companies and between clinical assessors and GCP inspectors within agencies be optimised?

When Things Go Wrong: How Do GCP Findings Impact the Benefit-Risk Balance? Can We Still Use the Data?
Nancy S. Breekveldt-Postma, Senior Clinical Assessor, Medicines Evaluation Board (MEB), Netherlands

SCIENTIFIC PROGRAMME

Clinical Development/Operations Staff and GCP Auditors – Are We Aligned? Industry Perspective
Liliana Christina Hansen, Vice President, R&D Audits, Novo Nordisk, Denmark

Clinical Assessors and GCP Inspectors: Different roles – Can the Interface be Optimised? Case Examples and Agency Perspective
Gabriele Schwarz, Head of the GCP Inspectorate, German Federal Institute for Drugs and Medical Devices (BfArM), Germany

DIAmond Session 4 | Friday 31 March | 09:00-10:30 | Hall 1

CLINICAL DEVELOPMENT PARTNERING 2.0 – MULTI-STAKEHOLDER EFFORTS TO REDUCE INVESTIGATOR SITE BURDEN

Session Chair:
Diana Anderson Foster, Director, Strategic Partnership Development, Society for Clinical Research Sites (SCRS), USA

Our Industry is celebrating some amazing achievements - pharmaceutical organisations are spending more than ever on R&D, product pipelines have nearly doubled in the past 10 years, and innovation is being highlighted every single day.

Despite these successes, clinical research remains costly and inefficient. Site Investigators continue to face significant challenges in working with CROs and Sponsors. Could collaboration drive the change so desperately needed in the industry?

This session will explore the efforts underway between three industry organisations that are working together to reduce administrative burdens placed on investigator sites, and increase study success. Please join leaders from the Society for Clinical Research Sites (SCRS), The Association of Clinical Research Organizations (ACRO) and TransCelerate BioPharma, Inc. to better understand solutions that will address protocol complexity, monitoring structures, communications, contracts, and budgets.

Reducing Administrative Burdens in the Conduct of Research: A CRO Perspective
Karen Noonan, Vice President, Global Regulatory Policy, Association of Clinical Research Organizations (ACRO), USA

Transformation through Collaboration
Paul Duffy, Director of Clinical Research UK & Ireland, UK Country Lead, TransCelerate BioPharma, Inc.

Site Master Data: Where Are We Today and What the Future Holds
Diana Anderson Foster, Director, Strategic Partnership Development, Society for Clinical Research Sites (SCRS), USA

How Site Master Data Can Improve the Working Relationship between Sites, Sponsors and CROs
Nina Pruitt, Senior Director, Global Product Marketing Payments, Medidata Solutions, UK

Session 0305 | Friday 31 March | 11:00-12:30 | Carron

TRANSLATIONAL RESEARCH: TRANSITION BETWEEN RESEARCH AND DEVELOPMENT PHASES, APPLIED CLINICAL BIOMARKERS

Session Chair:
Richardus Vonk, Head of Drug Discovery Statistics, Bayer Germany

This session will look into key aspects of decision making at the boundary of pre-clinical and clinical development.

Decision Criteria in Early Clinical Development
Richardus Vonk, Head of Drug Discovery Statistics, Bayer Germany

Applied Bayesian Statistics in Early Phases for Effective Decision Making
Bruno Boulanger, CSO and Co-Founder, Arlenda, Belgium

Translational Decision Making in Clinical Oncology
Speaker invited

SCIENTIFIC PROGRAMME

THEME 4

eHEALTH/BIG DATA/ MASTER - AND REFERENCE DATA MANAGEMENT

Theme Leaders:
Terje Peetso, Policy Officer, Unit H1 - Health and Wellbeing, Directorate-General Communications Networks, Content and Technology (DG CONNECT), European Commission, EU
Hans van Bruggen, Senior Regulatory Affairs Scientist, eCTDconsultancy/Qdossier, Netherlands

The amounts of information gathered during the development, production, maintenance and usage/user experience of drug products and medical devices is massive. All this data should give us faster and better knowledge for safeguarding patients. But how do we improve the knowledge gain; what are the prerequisites?

Session 0401 | Wednesday 29 March | 16:30-18:00 | Dochart

INNOVATION THROUGH EHEALTH DATA
Session Chair:
Terje Peetso, Policy Officer, Unit H1 - Health and Wellbeing, Directorate-General Communications Networks, Content and Technology (DG CONNECT), European Commission, EU

Big data provides the ability to track, explain, and predict events by analysing and combining data sets from multiple sources. However, how can we use this eHealth data in innovation to improve health care and research?

The Bigger Picture on Big Data and Health Outcomes
Dipak Kalra, Clinical Professor of Health Informatics and Director, CHIME Institute of Health Informatics, UCL, UK

The Re-Use of Electronic Health Record Data
Nadir Ammour, Clinical Sciences & Operations, Sanofi R&D, France

Treatment Effects, Genetic Tests and Infectious Disease Outbreaks - Can Big Data Help?
Kevin Wing, Research Fellow, London School of Hygiene and Tropical Medicine, UK

Session 0402 | Thursday 30 March | 11:00-12:30 | Dochart

BEST SOLUTIONS FOR MASTER DATA MANAGEMENT
Session Chair:
Francisco Peñaranda Fernandez, Head of Department, Business Data and Analytics, European Medicines Agency (EMA), EU

Industry and regulators will face new challenges (globalisation, personalised medicines, new technologies, transparency/access, etc.) in the coming years while the old product continues (i.e. lack of regulatory capacity, need for new skills, international collaboration and harmonisation, etc.). Identification of Medicinal Products (IDMP) is much more than a legal compliance project - it is an opportunity to develop a new way of conducting business as well as a new way for designing the process in, and defining the culture of, an organisation. Through IDMP we can redesign many of our current business processes, while increasing the provision of timely, accurate, and re-usable master data.

Master Data in Global Clinical Development Operations, an Opportunity to Improve Operational Efficiencies
Guido Claes, Director Master Data Standards, Global Clinical Development Operations, Janssen Pharmaceutical Companies, Belgium

NDC - The Unique Identifier for Drugs in the U.S.: Past, Present, Future
Leyla Rahjou-Esfandiary, Lead CSO, Office of Compliance, CDER, Food and Drug Administration (FDA), USA

Why IDMP Will (and Should!) Act as a Catalyst for Change across your Entire Organisation
Michael Braun-Boghos, Director of Safety Analytics, Oracle Health Sciences, Germany

Session 0403 | Thursday 30 March | 14:00-15:30 | Dochart

EU TELEMATICS BEYOND COST AND TIMELINES
Session Chair:
Klaus Menges, Project Manager, Federal Institute for Drugs and Medical Devices (BfArM), Germany

The accessibility of master data from the Article 57 database seems to offer new opportunities to save workload and improve data quality. However, multiple factors are involved such as IDMP iterations, controlled vocabulary, systems and platforms, fees, and public guidelines and will require a critical path analysis for dependencies, conditions and adaptations before realising benefits.

Implementation of an IDMP Compliant Database and Maintaining Up-To-Date Regulatory Data Challenges - The European Medicines Regulatory Network
Francisco Peñaranda Fernandez, Head of Department, Business Data and Analytics, European Medicines Agency (EMA), EU

SCIENTIFIC PROGRAMME

What Can Industry Stop Doing after Implementation of ISO-IDMP? A Regulatory View
Ulrike Vollmer, Head Site Global Submissions Management, Bayer, Germany

What Can Regulators Expect to Benefit after Implementation of ISO-IDMP? A Regulatory View
Klaus Menges, Project Manager, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Session 0404 | Thursday 30 March | 16:00-17:30 | Dochart

INTEROPERABILITY: AVOIDING BABYLONIAN CONFUSION

Session Chair:
Hans van Bruggen, Senior Regulatory Affairs Scientist, eCTDconsultancy/ Qdossier, Netherlands

Semantic interoperability is the most underestimated feature within integration of systems and information sharing. Where Google and DBpedia have been embraced by wide audiences, the pharmaceutical industry is lacking behind. This session will introduce semantic interoperability and show case studies from industry.

Semantic Interoperability toward Data Integration: Operational Data or Scientific Data?
Isabelle de Zegher, Vice President, PARAXEL Informatics, Belgium

Semantic Data Normalisation for Effective Knowledge Graphs
Todor Primov, Product Manager/Life Science R&D, Ontotext, Bulgaria

How Data Standardisation Enables Better Data Science: Analytical Data Perspectives from the Allotrope Consortium
Geoff Gross, Senior Data Scientist, OSTHUS, USA

Session 0405 | Friday 31 March | 11:00-12:30 | Dochart

FROM INVENTIVE IDEAS TO IMPLEMENTED INNOVATION

Session Chair:
Tiia Metiäinen, Manager, Regulatory Affairs, EFPIA - European Federation of Pharmaceutical Industries and Associations, Belgium

What have been the successes and challenges in implementing eHealth applications such as using wearables, apps and social media in clinical trials, leveraging electronic medical records to detect adverse drug reactions and cloud based drug safety systems? This session will explore these issues through case examples and provide food for thought and further debate on the role of eHealth for the benefit and safety of patients.

Use of Wearables, Apps and Social Media in Clinical Research
Beata Strzyminska, Medical Director, Premier Research, Poland

Leveraging the Cloud for Pharmacovigilance Systems
James Brown, Specialist Leader, Deloitte Consulting, USA

Development and Validation of Algorithms for the Detection of Statin Myotoxicity Signals from Electronic Medical Records
Mun Yee Tham, Regulatory Specialist, Health Science Authority, Singapore

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THEME 5

PHARMACOVIGILANCE

Theme Leaders:
Gaby Danan, Pharmacovigilance Expert, France
Phil Tregunno, Signal Management Unit Manager, Medicines & Healthcare products Regulatory Agency (MHRA), UK

The regulatory and scientific environment in global pharmacovigilance is changing rapidly, requiring flexibility and adaptation from all stakeholders. This year the theme will focus on the main strategic and operational changes to provide more insights, explanations, and perspectives to understand the changes. Simplification of ADR reporting, new developments in signal management, including data from social media will impact current structures and processes as information for patients becomes increasingly important. The Pharmacovigilance and Risk Assessment Committee (PRAC) is instrumental in these changes and is committed to evaluating the impact of the new PV processes on public health.

Session 0501 | Wednesday 29 March | 16:30-18:00 | Hall 1

GLOBAL PHARMACOVIGILANCE & RISK MANAGEMENT IN 2025 – PANEL DISCUSSION

Session Chair:
Mick Foy, Group Manager, Vigilance, Intelligence, and Research Unit, Medicines & Healthcare products Regulatory Agency (MHRA), UK

The session will look beyond our current systems and requirements and consider the big opportunities and challenges for pharmacovigilance over the next 10 years. Global experts from inside and outside the EU will offer their perspectives on key issues and future developments through an interactive panel discussion.

Panelists:
June Raine, Chair PRAC, Director Vigilance and Risk Management of Medicines Division, Medicines & Healthcare products Regulatory Agency (MHRA), UK
Gerald Dal Pan, Director, Office of Surveillance and Epidemiology, Food and Drug Administration (FDA), USA
Sir Munir Pirmohamed, David Weatherall Chair in Medicine, Consultant Physician, Royal Liverpool University Hospital, UK
Sabine Brosch, Principal Scientific Administrator, European Medicines Agency (EMA), EU
Steve Hobbiger, Vice President and QPPV, R&D, GSK, UK
Bettina Ryll, Founder, Melanoma Patient Network Europe, Sweden

Session 0502 | Thursday 30 March | 11:00-12:30 | Hall 1

MOBILE TECHNOLOGIES AND SOCIAL MEDIA ANALYTICS FOR SAFETY MONITORING AND COMMUNICATION – PANEL DISCUSSION

Polling/Voting offered. See page 11 for App details
Session Chair:
Phil Tregunno, Signal Management Unit Manager, Medicines & Healthcare products Regulatory Agency (MHRA), UK

The session will explore how we maximise the opportunities afforded by mobile technologies and social media to improve patient safety on a global level. It will discuss impact for patients, examples of real world use of social media and implications for existing regulatory frameworks.

Panelists:
Marilyn Metcalf, Head, Centre of Innovation, GlaxoSmithKline, USA
François Houÿez, Treatment Information and Access Director, EURORDIS, France
Shanthi Pal, Group Lead, Medicines Safety, Safety & Vigilance, World Health Organization, Switzerland
Phil Tregunno, Signal Management Unit Manager, Medicines & Healthcare products Regulatory Agency (MHRA), UK

Session 0503 | Thursday 30 March | 14:00-15:30 | Hall 1

HOW OPTIMAL REGULATORY DECISION MAKING RELIES ON EXCELLENT REGULATORY SCIENCE

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

The session will explore how excellent regulatory science is used to support high quality recommendations by regulatory scientific committees. In light of the growing interest in the discipline of regulatory science how can regulatory decision making maximize this opportunity?

The New SCiRS initiative – Interaction between Committees and Regulatory Science
Anthony Humphreys, Head of Scientific Committees Regulatory Science Strategy, European Medicines Agency (EMA), EU

Vision for Regulatory Science from the Academic Perspective
Marieke De Bruin, Director, Copenhagen Centre for Regulatory Science, Copenhagen University, Denmark

Regulatory Science and Advanced Therapies – An International View
Delphi Coppens, PhD Student, Utrecht University, Netherlands

Vaccines, Biological Medicines and Regulatory Science for Optimal Public Health Decisions
Philip Bryan, Expert Assessor, Vaccines Biologicals and Advanced Therapies, Medicines and Healthcare products Regulatory Agency (MHRA), UK

SCIENTIFIC PROGRAMME

Session 0504/0904 | Thursday 30 March | 16:00-17:45 | Lomond

PATIENT LEAFLETS, EDUCATIONAL MATERIALS AND PATIENTS – HOW TO INCREASE THEIR EFFECTIVENESS IN THE REAL WORLD

Session Co-Chairs:
Wendy Huisman, EU QPPV, Teva Pharmaceuticals Europe, Netherlands
D.K. Theo Raynor, Professor of Pharmacy Practice, University of Leeds, UK

Patients need good information to help them make choices about medicines and maximise their safe use. Patient leaflets and educational materials play a key role – but the need for improvement of their content and distribution has been identified. Key stakeholders will outline the issues and possible solutions prior to a panel and audience discussion.

Improving Patient Leaflets & Educational Materials – General Principles
D.K. Theo Raynor, Professor of Pharmacy Practice, University of Leeds, UK

Patient Leaflets – What do the 'Shortcomings' Reports Tell us?
Jan MacDonald, Group Manager, Access & Information for Medicines & Standards (AIMS), Medicines & Healthcare products Regulatory Agency (MHRA), UK

Educational Materials – The Real World vs the Ideal World
Wendy Huisman, EU QPPV, Teva Pharmaceuticals Europe, Netherlands

Patient Input – Where, When and How?
Neil Betteridge, International Liaison Officer, Public Affairs, European League Against Rheumatism (EULAR), UK

Patient Leaflets 'Shortcomings' Reports – What Next?
Kristina Kurgonaité, Policy Officer, Directorate-General for Health and Food Safety Medicines: Policy, Authorisation and Monitoring, European Commission, EU

Session 1104 | Thursday 30 March | 16:00-17:30 | Hall 2

REAL WORLD EVIDENCE IN PHARMACOVIGILANCE - MAKING THE MOST OF THE DATA

Session Chair:
Katherine Donegan, Pharmacoepidemiology Research & Intelligence Unit Manager, Medicines & Healthcare products Regulatory Agency (MHRA), UK

The value of real world evidence extends well beyond use in these more traditional pharmacoepidemiology safety studies and there is scope for using such data in different ways throughout the product lifecycle. This session will analyse the current European landscape for real-world evidence and describe several ongoing projects to optimise the use and value of real world data in supporting pharmacovigilance.

Building EU Capacity to Access and Analyse Real World Evidence
Alison Cave, Principal Scientific Administrator, European Medicines Agency (EMA), EU

Harnessing the Power of UK Primary Care Data for Pharmacovigilance
Rachael Williams, Research Programme Manager, Clinical Practice Research Datalink, UK

Strengthening Our Evaluation of Safety Signals Using Electronic Health Care Data
Katherine Donegan, Pharmacoepidemiology Research & Intelligence Unit Manager, Medicines & Healthcare products Regulatory Agency (MHRA), UK

Maximising the Value of Registries
Peter Mol, Head Clinical Assessor, Medicines Evaluation Board (MEB); Assistant Professor, University Medical Centre Groningen, Netherlands

Session 0505 | Friday 31 March | 11:00-12:30 | Hall 1

EUDRAVIGILANCE, THE NEW ICH E2B(R3) ICSR AND THE EU TELEMATICS PROGRAMME - HOW TO PREPARE FOR CHANGE

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

The new EudraVigilance system will be subject to an independent audit in the 1st quarter of 2017. Six months following the announcement of the successful outcome of the audit, major business process changes will apply including the use of the new ICH E2B(R3) format. NCAs and pharmaceutical companies need to prepare for these important changes. Initiatives to improve operational efficiencies in support of data evaluation will be also presented.

The New EudraVigilance System – Change Management Planning in the EU and a Pperspective from a Member State
Fátima Hergy, Farmacêutica, National Authority of Medicines and Health Products, (INFARMED), Portugal

Change Management Planning - A Perspective of the Pharmaceutical Industry
Margaret Walters, Deputy Qualified Person for Pharmacovigilance, Merck Sharp & Dohme Ltd, UK

FaCE Facts Project - Operational Efficiencies Targeted in Support of Data Evaluation
Mick Foy, Group Manager, Vigilance, Intelligence, and Research Unit, Medicines & Healthcare products Regulatory Agency (MHRA), UK

SCIENTIFIC PROGRAMME

THEME 6

REGULATORY SCIENCE

Theme Leaders:
Zaide Frias, Head of Human Medicines Evaluation Division, European Medicines Agency, (EMA), EU
Trine Moulvad, Vice President Regulatory & Pharmacovigilance, Zealand Pharma, Denmark

At the 2017 EuroMeeting the Regulatory Science Theme will consist of several cross-functional topics that will debate how EU and Global Regulatory initiatives strive to support, harmonise and improve requirements to stimulate medicinal product innovation, their development, approval and ultimate patient access. Emphasis will therefore be on the major opportunities and challenges the EU and Member States regulatory systems are facing and how these are being tackled.

Session 0301/0601 | Wednesday 29 March | 16:30-18:00 | Lomond

BENEFIT/RISK COMMUNICATION: TOWARDS A PATIENT-CENTRED APPROACH

Session Chair:
Ragnar Löfstedt, Professor of Risk Management, Director of King's Centre for Risk Management, King's College London, UK

Regulatory agencies and pharmaceutical companies across the Atlantic have shown a large appetite for identifying and developing effective benefit/risk communication towards patients, healthcare professionals and the general public. This panel discussion will assemble representatives from all major parties involved to assess the progress achieved and suggest concrete ways to further improve benefit/risk communication

Speakers:
Francesco Pignatti, Head of Oncology, Haematology, Diagnostics European Medicines Agency (EMA), EU
Frederic Bouder, Assistant Professor in the Department of Technology and Society Studies, Maastricht University, Netherlands
David Haerry, European AIDS Treatment Group (EATG), Belgium

DIAmond Session 1 | Thursday 30 March | 09:00-10:30 | Lomond

MAJOR REGULATORY CHALLENGES ENABLING DECISION MAKING FOR EARLY PATIENT ACCESS: REGULATORY TOOLS AND SOURCES OF RWE

Session Co-Chairs:
Karl Broich, President, Federal Institute for Drugs and Medical Devices (BfArM), Germany
Joseph Scheeren, Senior Vice President, Head Regulatory Affairs, Pharma and Consumer Health, Bayer Consumer Care, Switzerland

The commitment for enabling early patient access to new innovative medicines is one of the major challenges in regulatory science. From a regulator's perspective, early access tools are in place in the EU and the US in order to support early approval. In addition, real world evidence (RWE) presents a significant opportunity to improve regulatory decision making. Technological advances permit collection of real world data (RWD) from an increasing number of sources like patient registries and electronic patient records etc., while new artificial Intelligence approaches permit to translate these data into RWE.

This cross functional DIAmond session will discuss opportunities and challenges from the regulator (EU and US), industry and patient perspective.

See page 22 for session details

Session 0602/0902 | Thursday 30 March | 11:00-12:30 | Lomond

EMA'S POLICY ON CLINICAL PUBLICATION: OPPORTUNITIES, CHALLENGES AND MEASURING SUCCESS

Session Co-Chairs:
Marie-Agnes Heine, Head of Communication, European Medicines Agency
Susan Forda, Vice President, International Regulatory Affairs, Eli Lilly & Company Ltd, UK

The implementation of EMA's policy on the publication of clinical data (policy 70) will open up huge opportunities for the wide use of these data by stakeholders, which is expected to result in benefits for public health. EMA is the first regulatory authority worldwide to provide such broad access to clinical data. As of October 2016, for every new medicine, citizens, including researchers and academics, are able to directly access thousands of pages from clinical reports submitted by pharmaceutical companies to EMA in the context of marketing-authorisation applications. This session will elaborate on the opportunities and challenges that the new policy brings.

EMA's Policy 70: Status of Implementation
Anne-Sophie Henry-Eude, Head of Documents Access and Publication, European Medicines Agency, EU

Opportunities and Challenges the Policy Brings
Susan Forda, Vice President, International Regulatory Affair Eli Lilly & Company Ltd, United Kingdom

How Can Academics Use the Data and Can Clinical Study Reports Be Leveraged as Big Data?
Tom Jefferson, Senior Associate Tutor, Centre for Evidence-Based Medicine, UK

SCIENTIFIC PROGRAMME

Panel Discussion - How to Measure Success - Collecting Evidence to Determine Positive Public Health Impact

Session 0603/1003 | Thursday 30 March | 14:00-15:30 | Lomond

THE FUTURE OF THE EU ORPHAN DRUG NETWORK

Session Chair:
Keith Watson, Director of Regulatory Policy & Intelligence, AbbVie, UK

This session discusses the significant benefit and similarity orphan consultations and explores what this means for the EU orphan sector. We will explore the drivers behind the new requirements, strategic product considerations and discuss the impact for industry, regulators and importantly, the patients themselves.

Web Application to Assess Similarity
Pedro Franco, Director of Europe for Global Regulatory & Scientific Policy, Merck Serono Europe, UK

Challenges and Opportunity in the Orphan Regulatory Framework
Kristina Larsson, Head of Orphan Medicines, European Medicines Agency (EMA), EU

The Patient Need in the Context of European Rare Diseases
Virginie Hivert, Therapeutic Development Director, EURORDIS, France

Session 0604 | Thursday 30 March | 16:00-17:30 | Hall 1

EARLY ACCESS TOOLS: 10 YEARS' EXPERIENCE AND LESSONS LEARNED WITH CONDITIONAL MARKETING AUTHORISATIONS IN EU

Session Co-Chairs:
Zaide Frias, Head of Human Medicines Evaluation Division, European Medicines Agency, (EMA), EU

This session will look at the experience accumulated over 10 years and explore some of the challenges identified by various stakeholders for the early access tool of conditional marketing authorisation (MA). The latter include variable uptake in therapeutic areas, reasons for the apparent reluctance in applying for this regulatory pathway, difficulties with establishing initial positive benefit-risk balance and confirming it through generation of comprehensive data post-approval.

Patients' View on Conditional Marketing Authorisation
Elizabeth Vroom, Chair, United Parent Projects Muscular Dystrophy (UPPMD), Netherlands

What Difference a Conditional Marketing Authorisation Route Makes for the Applicant's Filing Strategy?
Karin Van Baelen, Head of Global Regulatory Affairs, Janssen Pharmaceutical Companies, Belgium

Scientific Assessment and Regulatory Decision Making
Tomas Salmonson, Chair of Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency (EMA), EU

DIAmond Session 3 | Friday, 31 March | 09:00-10:30 | Lomond

GLOBAL REGULATORY CONVERGENCE - STATE OF PLAY AND OUTLOOK FOR THE FUTURE

Session Co-Chairs:
Spiros Vamvakas, Head of Scientific Advice, European Medicines Agency, (EMA), EU
Iman Barilero, Chief Regulatory Science, Patient advocacy and Pharmacovigilance Officer, Axcella Health, USA

The session will provide examples of initiatives undertaken by regulators to support innovative drug development and regulatory science-based decision making, and will present initiatives with enhanced patient perspectives on the medicines R&D processes of the treatment development life cycle. We will also explore the views from a patient group, FDA, and EMA on the impact of regulatory convergence and ways forward to maintain sustainable global drug development and an effective regulatory process.

See page 23 for session details

Session 0605 | Friday 31 March | 11:00-12:30 | Lomond

THE 3R'S: REINVIGORATING, REPURPOSING AND RECLASSIFICATION

Session Chair:
Daniel O'Connor, Medical Assessor, Medicines & Healthcare products Regulatory Agency (MHRA), UK

Reinvigorating older drugs includes repurposing and reclassification (switch), creating both opportunities and challenges for industry and regulators, whilst maximising the potential public health benefits of medicines for patients. Hear from different experts, with lessons learned from repurposing in oncology, regulators taking up the challenge and switch by design, the proactive structured approach to reclassification.

Reinvigorating Older Drugs in Oncology
Pan Pantziarka, Scientist, Anticancer Fund, Belgium

Reclassification and Repurposing - Regulatory Initiatives
Keith McDonald, Deputy Director, Medicines & Healthcare products Regulatory Agency (MHRA), UK

Switch by Design - Challenges and Opportunities for Reclassification
Christelle Anquez-Traxler, Regulatory and Scientific Affairs Manager, AESGP, Belgium

EuroMeeting 2017

SCIENTIFIC PROGRAMME

THEME 7

MEDICAL DEVICES AND COMBINATION PRODUCTS

Theme Leaders:
Gert Bos, Executive Director and Partner, QServe, Netherlands
John Wilkinson, Director of Devices, Medicines & Healthcare products Regulatory Agency (MHRA), UK

With the new MDR (medical device) and IVDR (in vitro diagnostics) regulations being published early 2017, the year to come will be key in bringing the implementation of the new EU legislation to a start. Changes and additional requirements are massive, and as there will be no grandfathering, only timely and effective management of the transition will ensure products can stay on the market at the end of the transition period.

Session 0701 | Wednesday 29 March | 16:30-18:00 | Seminar Suite

KEYNOTE SESSION: HEADLINES OF THE NEW EU MDR & EU IVDR
Session Chair: **Sabina Hoekstra-van den Bosch**, Global Regulations and Standards, Lead for European Regulation, Philips Healthcare, Netherlands

This session will address changes in the EU MDR and IVDR and what this implies for manufacturers.

Explanation of Changes in Legal Framework
Graeme Tunbridge, Medicines & Healthcare products Regulatory Agency (MHRA), UK

Consequences for Big Manufacturers and how to Implement
Céline Bourguignon, Director, Government Affairs EMEA Medical Device & IVDs Department, Johnson & Johnson, Belgium

Consequences for Small Manufacturers and how to Implement
Gert Bos, Executive Director and Partner, QServe, Netherlands

Session 0702 | Thursday 30 March | 11:00-12:30 | Seminar Suite

CONSULTATIONS FOR COMBINATION PRODUCTS AND SUBSTANCE-BASED MEDICAL DEVICES
Session Chair: **Sabina Hoekstra-van den Bosch**, Global Regulations and Standards, Lead for European Regulation, Philips Healthcare, Netherlands

MHRA System and Changes
Elizabeth Baker, Group Manager, Licensing Division, Medicines & Healthcare products Regulatory Agency (MHRA), UK

Notified Bodies' Perspective
Speaker invited

Practical Examples and Advice for Manufacturers
Waldo Weijers, Secretary Coordinator Consultation Procedures, Medicines Evaluation Board (MEB), Netherlands

Session 0703 | Thursday 30 March | 14:00-15:30 | Seminar Suite

BALANCING CLINICAL EVALUATIONS VERSUS CLINICAL STUDIES
Session Chair: **Sabina Hoekstra-van den Bosch**, Global Regulations and Standards, Lead for European Regulation, Philips Healthcare, Netherlands

Authority View
Tom Melvin, Medical Officer, The Health Products Regulatory Authority (HPRA), Ireland

Industry Perspective
Gert Bos, Executive Director and Partner, QServe, Netherlands

Notified Body Perspective
Bassil Akra, Global Director, Clinical Centre of Excellence, TÜV SÜD Product Service, Germany

Session 0704 | Thursday 30 March | 16:00-17:30 | Seminar Suite

POST-MARKET SURVEILLANCE AND VIGILANCE – GLOBALISATION AND DATA POOLING
Session Chair: **Eric Klasen**, Vice President Regulatory Affairs & Quality, Medtronic, Switzerland

What is in the Law, What is Reportable?
Bassil Akra, Global Director, Clinical Centre of Excellence, TÜV SÜD Product Service, Germany

Practical Industry Interpretation of Reportability and How to Prepare for Trend Reporting
Philippe Soly, Director of Global Regulations, European Authorised Representative, Philips Healthcare, France

Agency Cooperation and Cross-Agency Reporting – Legal View
Reinhard Berger, Department for Medical Devices Market Surveillance, Austrian Medicines & Medical Devices Agency (AGES), Austria,

Session 0705 | Friday 31 March | 11:00-12:30 Seminar Suite

IVD AND COMPANION DIAGNOSTICS IN THE ERA OF PERSONALISED MEDICINES
Session Chair: **Anja Wiersma**, CEO and Senior Consultant, mi-CE Consultancy, Netherlands

Scoping and Definitions of Personalised Medicine, Difference in Interpretation between Device and Pharma World, and the Role of Diagnostics in Personalised Medicine
Stephen Lee, Biosciences Team Manager (IVD, IVF + MD) Medicines & Healthcare products Regulatory Agency (MHRA), UK

What is an IVD, How Are They Regulated, and IVDR Provisions on Companion Diagnostics
Sue Spencer, Head of Global of Medical Device Services, UL, UK

Successful Cooperation or Hurdles and Mutual Misunderstanding?
Luc van Hove, CEO MARACA International, Principal Consultant QARAD, Belgium

The 9th DIA China Annual Meeting

May 21-24, 2017
Shanghai International Convention Center
www.eventbank.cn/event/6677/

Drug Innovation Driven by Unmet Medical Needs

On May 21-24, 2017, the DIA China Annual Meeting will bring together global pharmaceutical professionals to discuss critical topics and themes surrounding the regulation, discovery, development, and life cycle management of health care products. The theme of this meeting, "***Drug Innovation Driven by Unmet Medical Needs***," will attract more than 2000 pharmaceutical R&D professionals from different continents and regions, involved at all levels of the health care product development spectrum. Please join us to discuss recent and upcoming transformational changes for China's innovation and regulatory environments.

This year will also debut our special DIAmond Sessions, which will introduce global views into our perspective of the Chinese pharmaceutical eco-environment. Sessions will model the experience from the global DIA 2016 Annual Meeting in the US. As the largest multidisciplinary event in DIA Asia, other highlights will include 100+ exhibit booths and a new, unique hub for R&D and emerging companies to showcase themselves in "***Innovation Hub***."

Come and join our neutral, global platform to exchange knowledge, advance change, and cross collaborate towards patient-centric biopharmaceutical innovation.

13 themes

2000+ participants

100+ exhibitors

Program Co-chairs:

Ning XU, MD, PhD, MBA
Executive Vice President
Head of Clinical Development and Regulatory Affairs, Zai Lab

Bin XUE
Director-General
China Center for Food and Drug International Exchange, CFDA

Themes:

- Regulatory Science
- CFDA Townhall
- Multi-collaborations – A Pathway to High Quality Studies
- Oncology Drug Development
- Quantitative Science in Transformation
- Focus on Medical Value to Satisfy Unmet Patient Needs
- Biologics & Biosimilar
- Patient Safety – A Constant Focus
- The Strategy and Implementation of Early Clinical Development for Innovative Drugs
- China-Anchored Drug Development and Entrepreneurship Forum
- Rare Disease, Unsatisfied Market Demand

Conference
contact **Ms. Runshan CHEN** | Email: runshan.chen@DIAglobal.org | Tel: +86. 10. 57042653

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SCIENTIFIC PROGRAMME

THEME 8

HTA, VALUE AND ACCESS

Theme Leaders:
Claes Buxfeldt, Global Price and Reimbursement Director, AstraZeneca Gothenburg, Sweden
Ana Palma, Global HTA & Patient Access, Lead, Sobi, Belgium

In an evolving environment including adaptive approaches and fast-track designation, drugs are being taken to patients with more limited data that previously. This comes with challenges from payer and HTA (Health Technology Assessment) bodies.
How can we improve the process of demonstrating the value in this challenging environment? What requirements are underpinning decisions made?
How can we leverage the use of RWE (real-world evidence) data for the increasing demand of stakeholder requirements of observational data?
How can we improve future techniques to better fit challenges coming from diverging requirements as well as earlier need of reliable data?

Session 0801 | Wednesday 29 March | 16:30-18:00 | Carron

ADAPTIVE APPROACHES AND PATIENT ACCESS - PUSHING PAYER BOUNDARIES OR FACILITATING NEW PAYMENT MODELS?
Session Chair:
Solange Corriol-Rohou, Senior Director, Regulatory Affairs & Policy, Europe, AstraZeneca Global Medicines Development, France

Adaptive pathways should enable patients' earlier access to promising treatments in areas of high unmet medical need. This is certainly a sensitive and controversial concept for which value needs to be supported by scientific evidence. What evidence should be generated, which tools and methods could enable MAPPs, or are missing and thus need development? What criteria would need to be fulfilled for products to be eligible to enter such pathways?
In addition, implications of such pathways for access decisions at the national or regional levels remain to be explored. How will HTA bodies, payers and manufacturers deal with product value uncertainty and how might this affect solutions in the form of managed-entry agreements?
These are questions that will be addressed by ADAPT SMART consortium members.

Scientific Drivers of Progress – Gaps and Opportunities
Solange Corriol-Rohou, Senior Director, Regulatory Affairs & Policy, Europe, AstraZeneca Global Medicines Development, France

MAPPs Engagement Criteria – Patient Perspective
Mathieu Boudes, Operations and Project Manager, EURORDIS, France

Pushing Payer Boundaries or Facilitating New Payment Models?
Jacoline Bouvy, Scientific Adviser, National Institute for Health and Care Excellence (NICE), UK

Session 0802 | Thursday 30 March | 11:00-12:30 | Alsh 2

VALUE DEMONSTRATION PLANNING FOR PHARMACEUTICAL COMPANIES TO SUPPORT PRICING AND REIMBURSEMENT - OPPORTUNITIES AND CHALLENGES
Session Chair:
Claudine Sapède, HTA & Payment Policy Lead, Roche, Switzerland

Value demonstration is critical in receiving access for patients for new medicines today and in the future. In an environment where new possibilities open to get regulatory approval quicker than usual, new challenges appear for decreasing uncertainties in value demonstration for payors and HTA bodies. This session will present new findings and results and explore new possibilities.

Findings from a Fast-Track Drug
Chris Hoyle, Director, Payer and HTA Policy, AstraZeneca, UK

Conclusions from an Adaptive Pathways Project
Regina Seidel, Global Regulatory Strategist, Bayer, Germany

Using Real World Evidence to Demonstrate Value
Adrian Cassidy, Real World Data Science, Roche, Switzerland

Session 0803 | Thursday 30 March | 14:00-15:30 | Alsh 1

REAL WORLD EVIDENCE FOR THE FUTURE
Session Chair:
Sophie Langenskiöld, Senior Lecturer, Department of Public Health and Caring Sciences, Uppsala University, Sweden

There is a growing trend to request RWE from both regulatory and HTA bodies to facilitate rapid market entrance and to assure sound coverage and reimbursement decisions. However, without a dialogue as to what evidence is needed, and what quality of the evidence is expected, there is a risk that the wrong evidence is collected with the result that this trend might be jeopardized. This session is about the challenges and opportunities of providing sufficient evidence to support regulatory and HTA decision making.

Challenges in the Utilisation of Real-World Data in Regulatory Decision Making
Alison Cave, Principal Scientific Administrator, European Medicines Agency (EMA), EU

SCIENTIFIC PROGRAMME

The Need for Real-World Evidence for Reimbursement in the Future
Douglas Lundin, Chief Economist, TLV, the Dental and Pharmaceutical Benefit Board, Sweden

Real-World Evidence from Pragmatic Trials
Pieter Stolk, Program Manager Escher, The Lygature Platform for Regulatory Innovation, Netherlands

Real-World Evidence from Observational Studies
Sophie Langenskiöld, Senior Lecture, Uppsala University, Sweden

Optimising Patient- or Physician-Level Real-World Data Collection and Usage
Eduardo Sobreviela, Director, Biostatistics, Linical, Spain

Session 0804 | Thursday 30 March | 16:00-17:30 | Alsh 2

THE PATIENT AT THE CENTRE OF ADAPTIVE APPROACHES

Session Chair:
Danie du Plessis, SVP, Head Worldwide Medical Affairs, GlaxoSmithKline, UK

How has patient involvement in drug development impacted regulatory and value assessment and decisions over the years? What more can be done to improve the possibility for patients to get access at launch?

What Matters to Patients?
Mathieu Boudes, Operations and Project Manager, EURORDIS, France

Involvement of Patients in Drug Development
Katarina Halling, Head PRO Team, Global Medical Affairs, Sweden

Strengthening the Patient and Carer Voice in HTA
Jennifer Dickson, Public Involvement Coordinator, Scottish Medicines Consortium, UK

Patient Perspective on Patient-Centricity
Neil Bertelsen, Chair, Patient and Citizen Involvement Interest Group, Health Technology Assessment international (HTAi), Germany

Session 0805 | Friday 31 March | 11:00-12:30 | Alsh 1

THE PILLARS OF DECISION MAKING: REGULATORS, HTAS, PAYERS / BUDGET HOLDERS

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

The Adaptive Pathways concept, originally developed by regulators, is now a reality being tested. Within this new system, regulators are leading the way but still awaiting the other partners – HTAs, payers/budget holders, investors – to come at the table. In this session we will hear from these partners the dilemmas they are facing within this adaptive concept and what do they plan to do to overcome it.

Introduction: Adaptive Approaches – Such a Fantastic Promise! How Can We All Deliver on It?
Dimitrios Athanasiou, Duchenne Patient Advocate, Muscular Dystrophy Association Hellas, Board Member in UPPMD and EMA Patient Expert for DMD, Greece

HTA View
Jacoline Bouvy, Scientific Adviser, National Institute for Health and Care Excellence (NICE), UK

Budget Holder / Payer View
Ri de Ridder, General Director, RIZIV-INAMI, Belgium

Industry View
Anne-Virginie Eggiman, Vice President, Regulatory Science, Bluebird Bio, USA

Investor's View
Jack Scannell, Analyst, UBS, UK

SCIENTIFIC PROGRAMME

THEME 9

INFORMATION ON MEDICINES, MEDICAL WRITING AND DOSSIER GENERATION

Theme Leader:
Juan Garcia-Burgos
Head of Public Engagement (Ad Interim), European Medicines Agency (EMA), EU

In an age of instant communication where society demands openness and involvement in decision making, meaningful engagement with patients, health professionals, researchers and the public at large, information on medicines needs to be timely, transparent and straightforward. Effective strategies are needed to deal with the burgeoning mass of information emerging from the regulatory process. The quality of the information prepared at each stage of evaluation is key to empowering patients to participate in decision making, minimising risks of medicines, and building trust in medicines and their regulation. The sessions within this theme will explore how the careful preparation of readily-accessible information at different times of a medicine's life cycle has become central to medicines regulation.

Session 0901 | Wednesday 29 March | 16:30-18:00 | Alsh 2

INFORMATION ON MEDICINES FOR LAY AUDIENCES

Session Co-Chairs:
Melanie Carr, Head of Stakeholders and Communication Division, European Medicines Agency (EMA), EU
D.K. Theo Raynor, Professor of Pharmacy Practice, University of Leeds, UK

We live in the era of transparency and communication, where it has never been easier for lay people to find information related to health and medications. However, patients still struggle to find reliable information that is easy to understand. While improvements have been made in the past, many challenges still remain to be addressed and this session will explore these.

The Challenges of Health Literacy – Where Do Patients Look for Information on Medicines?
Michael Wolf, Associate Professor, Medicine and Learning Sciences, Associate Division Chief, Northwestern University, USA

Information for Patients from Regulatory Authorities – The EMA Experience
Juan García-Burgos, Head of Public Engagement (Ad Interim), European Medicines Agency (EMA), EU

Clinical Trial Results for Laypersons - Implementing the EU Guidance
D.K. Theo Raynor, Professor of Pharmacy Practice, University of Leeds, UK

Panel Discussion with **Kaisa Immonen-Charalambous**, Co-Chair PCWP, Director of Policy, European Patient's Forum, Belgium and **Thomas Schindler**, Head Medical Writing Europe, Boehringer Ingelheim Pharma, Germany

Session 0602/0902 | Thursday 30 March | 11:00-12:30 | Lomond

EMA'S POLICY ON CLINICAL PUBLICATION: OPPORTUNITIES, CHALLENGES AND MEASURING SUCCESS

Session Co-Chairs:
Marie-Agnes Heine, Head of Communication, European Medicines Agency
Susan Forda, Vice President, International Regulatory Affairs, Eli Lilly & Company Ltd, UK

The implementation of EMA's policy on the publication of clinical data (policy 70) will open up huge opportunities for the wide use of these data by stakeholders, which is expected to result in benefits for public health. EMA is the first regulatory authority worldwide to provide such broad access to clinical data. As of October 2016, for every new medicine, citizens, including researchers and academics, are able to directly access thousands of pages from clinical reports submitted by pharmaceutical companies to EMA in the context of marketing-authorisation applications. This session will elaborate on the opportunities and challenges that the new policy brings.

EMA's Policy 70: Status of Implementation
Anne-Sophie Henry-Eude, Head of Documents Access and Publication, European Medicines Agency

Opportunities and Challenges the Policy Brings
Susan Forda, Vice President, International Regulatory Affair Eli Lilly & Company Ltd, United Kingdom

How Can Academics Use the Data and Can Clinical Study Reports Be Leveraged as Big Data?
Tom Jefferson, Senior Associate Tutor, Centre for Evidence-Based Medicine, UK

Panel Discussion - How to Measure Success - Collecting Evidence to Determine Positive Public Health Impact

Session 0903 | Thursday 30 March | 14:00-15:30 | Alsh 2

MAKING SUBMISSION DOCUMENTS TRANSPARENCY- READY: CHALLENGES, APPROACHES, AND BEST PRACTICES

Session Chair:
Thomas Schindler, Head Medical Writing Europe, Boehringer Ingelheim Pharma, Germany

Quality of dossiers submitted for marketing authorisation remains a key aspect during assessment of new applications. With new transparency initiatives being implemented, in particular the EMA policy 70, the way

clinical documentations is written as well as the quality of data presentation gains even more relevance. In addition, adequate measures have been put in place to ensure that personal data and commercially confident information is protected. This session will help participants to implement the requirements of Policy 70.

What the EMA Has Learnt from the First Publications of Clinical Dossiers
Anne-Sophie Henry-Eude, Head of Documents Access and Publication, European Medicines Agency

Writing Transparency- Ready Clinical Reports - How Far Should We Go?
Kirsten Herbach, Principal Medical Writer and Team Lead, Boehringer Ingelheim Pharma, Germany

Guiding Teams through the Transparency Requirements for Clinical Dossiers
Julia Forjanic Klapproth, Senior Partner, Trilogy Writing & Consulting, Germany

Session 0504/0904 | Thursday 30 March | 16:00-17:45 | Lomond

PATIENT LEAFLETS, EDUCATIONAL MATERIALS AND PATIENTS – HOW TO INCREASE THEIR EFFECTIVENESS IN THE REAL WORLD

Session Co-Chairs:
Wendy Huisman, EU QPPV, Teva Pharmaceuticals Europe, Netherlands
D.K. Theo Raynor, Professor of Pharmacy Practice, University of Leeds, UK
Patients need good information to help them make choices about medicines and maximise their safe use. Patient leaflets and educational materials play a key role – but the need for improvement of their content and distribution has been identified. Key stakeholders will outline the issues and possible solutions prior to a panel and audience discussion.

Improving Patient Leaflets & Educational Materials – General Principles
D.K. Theo Raynor, Professor of Pharmacy Practice, University of Leeds, UK

Patient Leaflets – What do the 'Shortcomings' Reports Tell us?
Jan MacDonald, Head Patient Information Quality, Medicines & Healthcare products Regulatory Agency (MHRA), UK

Educational Materials – The Real World vs. the Ideal World
Wendy Huisman, EU QPPV, Teva Pharmaceuticals Europe, Netherlands

Patient Input – Where, When and How?
Neil Betteridge, International Liaison Officer, Public Affairs, European League Against Rheumatism (EULAR), UK

Patient Leaflets 'Shortcomings' Reports – What Next?
Kristina Kurgonaité, Policy Officer, Directorate-General for Health and Food Safety Medicines: Policy, Authorisation and Monitoring, European Commission, EU

Session 0905 | Friday 31 March | 11:00-12:30 | Alsh 2

THE IMPORTANCE OF GOOD COMMUNICATION IN RISK MANAGEMENT

Session Co-Chairs:
June Raine, Chair PRAC, Director Vigilance and Risk Management of Medicines Division, Medicines & Healthcare products Regulatory Agency (MHRA), UK
Paul Fleming, Technical Director, British Generic Manufacturers Associations, UK

Recent years have seen a transformation in the way risks relating to medicines are communicated in Europe. Efforts have focused on making messages more effective, disseminating these rapidly, and engaging the public during the assessment. This session will explore how these changes have brought the European model to its current status, whether it now makes a more effective contribution to medicines safety and public health, and the new challenges that lie ahead.

Helping People to Understand Uncertainties and Risks of Medicines
Frederic Bouder, Assistant Professor in the Department of Technology and Society Studies, Maastricht University, Netherlands

Communicating Safety Information to Health Care Professionals in Europe
Anna-Marie Coleman, SCOPE, Vigilance Assessor, Human Products Monitoring, The Health Products Regulatory Authority (HPRA), Ireland

Incorporating Patients' Views in Safety Communication
Kaisa Immonen-Charalambous, Co-Chair PCWP, Director of Policy, European Patient's Forum, Belgium

Communicating Benefit-Risk – What Has Changed and What Lies Ahead?
Juan García-Burgos, Head of Public Engagement (Ad Interim), European Medicines Agency (EMA), EU

SCIENTIFIC PROGRAMME

THEME 10

SPECIAL POPULATIONS

Theme Leader:
Geneviève Le Visage
Head EU Regulatory Intelligence & Policy, Novartis, Switzerland

2017 sees the 10-year anniversary of the implementation of the Paediatric Regulation, and the report from the European Commission on its impact gives all stakeholders an opportunity to 'take stock' and reflect on what has been done, and what could be done better. Come and discuss whether the regulation has delivered on its objectives in an interactive session where audience and panel both will be able to express their opinions. See also how paediatric development can be improved, with a better use of juvenile toxicity studies or extrapolation, and the development of better pharmaceutical forms for children.

The theme will also explore those hard-to-reach special populations in clinical trials - adolescents, pregnant women and geriatric patients, and how the framework for significant benefit and similarity are being revisited, as new technologies start to deliver new medicines for orphan diseases.

Session 1001 | Wednesday 29 March | 16:30-18:00 | Alsh 1

10 YEARS ON: HAS THE PAEDIATRIC REGULATION ACHIEVED ITS AIMS? A PANEL DISCUSSION

Polling/Voting offered. See page 11 for App details
Session Chair:
Angelika Joos, Executive Director Global Regulatory Policy, MSD (Europe) Inc., Belgium

The Paediatric Regulation is up for a second review in 2017. The EU Commission is currently analysing policy options in this regard and a report analysing the state of play is expected in June. This round table discussion will reflect on the experience, current successes and proposals for optimisation in line with the laws' objectives after 10 years.

The Paediatric Regulation is up for a second review in 2017. The EU Commission is currently analysing policy options in this regard and a report analysing the state of play is expected in June. This round table discussion will reflect on the experience, current successes and proposals for optimisation in line with the laws' objectives after 10 years.

Legal Perspective
Genevieve Michaux, Partner, Meyer Brown Europe, LLP, Belgium

Founder's Perspective
Daniel Brasseur, Paediatrician, Belgium

Industry Perspective
Christina Bucci-Rechtweg, Global Head, Pediatric & Maternal Health Policy, Novartis, USA

Patient Perspective
Virginie Hivert, Therapeutic Development Director, EURORDIS, France

Session 1002 | Thursday 30 March | 11:00-12:30 | Alsh 1

OPTIMISING THE DEVELOPMENT OF PAEDIATRIC MEDICINES

Session Chair:
Johannes van den Anker, Professor, Department of Paediatric Pharmacology, University Children's Hospital Basel, Switzerland

This session will look at the learnings of the first 10 years of the Paediatric Regulation for the development of paediatric medicines (formulation, toxicology, clinical development) and discuss how we can draw from this learnings and see what the next 10 years may bring.

Extrapolating Efficacy and Safety for Pediatric/Rare/Orphan Diseases: Adult Data, Drug and Disease, Modeling and Simulation
Thomas Laage, Premier Research, USA

Updates on Nonclinical Development of Pediatric Drugs
Beatriz Silva Lima, University of Portugal, NDA, UK

Age-Appropriate and Acceptable Paediatric Dosage Forms: Making Medicines Child Size
Roy Turner, Technical Project Leader, Drug Product Operations, Actelion, Switzerland

Session 0603/1003 | Thursday 30 March | 14:00-15:30 | Lomond

THE FUTURE OF THE EU ORPHAN DRUG NETWORK

Session Chair:
Keith Watson, Director of Regulatory Policy & Intelligence, AbbVie, UK

This session discusses the significant benefit and similarity orphan consultations and explores what this means for the EU orphan sector. We will explore the drivers behind the new requirements, strategic product considerations and discuss the impact for industry, regulators and importantly, the patients themselves.

Future of Similarity in the Context of Orphan Drug Legislation
Pedro Franco, Director of Europe for Global Regulatory & Scientific Policy, Merck Serono Europe, UK

Challenges and Opportunity in the Orphan Regulatory Framework
Kristina Larsson, Head of Orphan Medicines, European Medicines Agency (EMA), EU

The Patient Need in the Context of European Rare Diseases
Virginie Hivert, Therapeutic Development Director, EURORDIS, France

SCIENTIFIC PROGRAMME

Session 1004 | Thursday 30 March | 16:00-17:30 | Alsh 1

CONDUCTING TRIALS IN HARD-TO-REACH POPULATIONS: ADOLESCENTS, PREGNANT WOMEN AND OLDER PEOPLE

Session Chair:
Mireille Muller, Regulatory Policy Director, Novartis, Switzerland

There are many aspects to consider in diversifying clinical trial enrollment and retention especially in underrepresented populations like adolescents, pregnant women and older people. The changing face of medical product R&D and technological advancement, coupled with an informed and engaged population, means exciting times are ahead.

Clinical Trials in Pregnant Women: Glass Half Full or Half Empty?
Ida Niklson, Managing Director, I.D.D.A. Pharma Consulting, Germany

Adolescents as Active Partners in Clinical Trial Design - How to Get Them Involved
Pamela Dicks, Manager Scottish Children's Research Network, Royal Aberdeen Children's Hospital, The Golden Jubilee National Hospital, UK

Proposal for Guidance on Medical Research for and with Older People in Europe
Laurence Hugonot-Diener, Psycogeriatrics, Hopital Broca Aphp et Medforma, France

HOT TOPICS STAND ALONE

Session 1101 | Wednesday 29 March | 16:30-18:00 | Hall 2

THE EVOLVING ROLE OF CLINICAL BIOMARKERS AND BIO BANKING IN TODAY'S SEARCH FOR INNOVATIVE CURE

Session Chair:
Barbara Voith, Head Global Clinical Sciences Operations, Bayer, Germany

Clinical biomarkers and biobanking are increasingly pivotal for patient selection, prediction of therapeutic efficacy, as well as new target selection and -validation. We will review how biomarkers are increasingly unfolding the interaction of the tumour with the immune system, the art of Biomarker sampling and -analysis, as well as the role of modern biobanks.

Connect Research and Clinical Development - Unleash the Full Power of Data and Samples to Enhance Biomarker-Based Decision Making
Barbara Voith, Head Global Clinical Sciences Operations, Bayer, Germany

The Role of the Biomarker in the Tumour Microenvironment – Novel Insights How Tumours Tame the Body's Immune System
Jeff Evans, Professor of Translational Cancer Research and Director of the Institute of Cancer Sciences, University of Glasgow, UK

High-Quality Clinical Biomarker Sampling and –Analysis, Novel Technologies and Processes
Hartmut Juhl, Founder and Chief Executive Officer, Indivumed, Germany

Patient Aspects of Bio Banking and Biomarker Re-Use – The Tension Field between Research and Bioethics
Jane Hair, Biorepository Manager, NHS Research Scotland

Collecting Biospecimens from Cancer Patients in Trials and Routine Care: Optimising Opportunities and Research Impact
Russell Petty, Professor of Medical Oncology, University of Dundee, UK

Session 1102 | Thursday 30 March | 11:00-12:30 | Hall 2

MARKET ACCESS ROUNDTABLE UPDATE: FINANCING OF THERAPEUTICS IN EUROPE – BEYOND TRADITIONAL APPROACHES

Session Co-Chairs:
Inka Heikkinen, Senior Scientist, DIA EMEA, Switzerland
Indranil Bagchi, Vice President and Head, Payer Insights and Access, Global Health and Value, Pfizer Inc., USA

This session is being co-developed by DIA and the Boston Consulting Group Market Access Roundtable working group, a group consisting of industry leaders who recently worked on Alternative Funding Models. The problem statement of the white paper reflects the European health care systems' ability to provide an equal access to care and the funding gap for the emerging innovative treatments, fueled by the silos existing within the HTA system and resource inefficiency. The potential solutions could be co-payment, private insurance, employer-supported models and new payment models.

The session aims to debate and discuss the problem statements and solutions, and communicates the discussions that took place in a closed workshop with other stakeholders (HTA bodies, payers, regulators).

Industry View for Financing of Novel Therapeutics in Europe
Indranil Bagchi, Vice President and Head, Payer Insights and Access, Global Health and Value, Pfizer Inc., USA

Patient View for Financing of Novel Therapeutics in Europe
David Haerry, European AIDS Treatment Group (EATG), Belgium

Regulator/Payer View for Financing of Novel Therapeutics in Europe
Luca Pani, CHMP and SAWP Member, Voluntary Professor, Department of Psychiatry and Behavioral Sciences
University of Miami, USA

EuroMeeting 2017

HOT TOPICS/STAND ALONE

Session 1103 | Thursday 30 March | 14:00-15:30 | Hall 2

BREXIT – WHERE ARE WE NOW?

Polling/Voting offered. See page 11 for App details

Session Chair:
Alan Morrison, Vice President Regulatory Affairs International, MSD, UK

Brexit will impact on the established European Regulatory environment over the next decade. It may create potential new opportunities for deeper integration of the operational processes of the EU Regulatory Network, however, and may also create potential risks for regulatory business continuity that could be harmful to patients.

This session will provide an overview of the current state of play of the political process from a UK as well as an EU perspective. It will seek views from important healthcare stakeholder groups, such as industry, regulators and patients on the longer term impact as well as practical aspects that need to be considered to avoid unintended consequences for EU and UK citizens while fully respecting the political decisions. Multiple stakeholder perspectives will look at the post Brexit scenario from a UK perspective but also from the EU and global regulatory environment view. Key stakeholders will discuss in a panel debate the impact of the expected changes on their organisation and how they will capitalise on potential opportunities or mitigate potential risks to the regulatory business.

Panellists:
Virginia Acha, Executive Director Research, Medical and Innovation, ABPI, UK
Karl Broich, President, Federal Institute for Drugs and Medical Devices (BfArM), Germany
Elizabeth Kuiper, Director of European Affairs, EFPIA, Belgium
Jonathan Mogford, Director of Policy, MHRA, UK
Nick Meade, Director of Policy, Genetic Alliance UK
Guido Rasi, Executive Director, European Medicines Agency (EMA), EU
Saad Shakir, Director, Drug Safety Research Unit (DSRU), UK

Session 1104 | Thursday 30 March | 16:00-17:30 | Hall 2

REAL WORLD EVIDENCE IN PHARMACOVIGILANCE - MAKING THE MOST OF THE DATA

Katherine Donegan, Pharmacoepidemiology Research & Intelligence Unit Manager, Medicines & Healthcare products Regulatory Agency (MHRA), UK

The value of real world evidence extends well beyond use in these more traditional pharmacoepidemiology safety studies and there is scope for using such data in different ways throughout the product lifecycle. This session will analyse the current European landscape for real-world evidence and describe several ongoing projects to optimise the use and value of real world data in supporting pharmacovigilance.

Building EU Capacity to Access and Analyse Real World Evidence
Alison Cave, Principal Scientific Administrator, European Medicines Agency (EMA), EU

Harnessing the Power of UK Primary Care Data for Pharmacovigilance
Rachael Williams, Research Programme Manager, Clinical Practice Research Datalink, UK

Strengthening Our Evaluation of Safety Signals Using Electronic Health Care Data
Katherine Donegan, Pharmacoepidemiology Research & Intelligence Unit Manager, Medicines & Healthcare products Regulatory Agency (MHRA), UK

Maximising the Value of Registries
Peter Mol, Head Clinical Assessor, Medicines Evaluation Board (MEB); Assistant Professor, University Medical Centre Groningen, Netherlands

Session 1105 | Friday 31 March | 11:00-12:30 | Hall 2

ICMRA - A GLOBAL COALITION OF MEDICINES REGULATORS

Session Chair:
Ian Hudson, Chief Executive, Medicines & Healthcare products Regulatory Agency (MHRA), UK

An update will be provided on the Coalition's progress to date and to demonstrate its unique strategic position in being able to support other initiatives aimed at tackling global issues. The session will be rounded out with Q&A, providing an opportunity for the audience to gain a greater understanding of ICMRA and its strategic role, as well as priorities.

Introduction to ICMRA
Rita Purcell, Deputy Chief Executive, The Health Products Regulatory Authority (HPRA), Ireland

Contribution to Tackling the Issues of Globalisation
Guido Rasi, Executive Director, European Medicines Agency (EMA), EU

ICMRA Moving Forward
Ian Hudson, Chief Executive, Medicines & Healthcare products Regulatory Agency (MHRA), UK

Panel Discussion:
Q&A with chair, speakers, and **Toshi Tominaga**, Associate Executive Director (for International Programs), Pharmaceutical and Medical Devices Agency (PMDA), Japan

HOT TOPICS/STAND ALONE

NEW! Conference Wrap-Up

Friday 31 March | 13:30-14:30 | Lomond

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 Theme Leaders will have 3 minutes on stage to share the essence from the presentations & discussions in their themes by delivering you summaries of novel insights and key takeaways from the DIA EuroMeeting. DIA is capturing emerging knowledge and insights in order to advance selected topics after the meeting.

EuroMeeting 2017

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INNOVATION THEATRE PRESENTATIONS

Participating Exhibiting companies will showcase their expertise and solutions in this year's schedule

Identifying and assessing drug-drug interactions for more successful analysis and prioritisation of drug candidates

Wednesday, 29 March 2017 | 15:45-16:15
Innovation Theatre, Exhibition Hall

Dr. Sherry Winter, Senior Solution Marketing Manager, Elsevier

Successful drug development requires anticipating safety and regulatory issues as early as possible. To preclude drug approval challenges, preclinical safety assessment and clinical development teams require tools that enable data-driven drug discovery and development. This session will introduce how comprehensive information and innovative analytics enable a more thorough understanding of the dynamics of drug metabolising enzymes and transporters, for more confident identification and assessment of potential drug-drug interactions and more comprehensive risk mitigation strategies.

Unifying Regulatory Information Management Processes

Thursday, 30 March 2017 | 15:30-16:00
Innovation Theatre, Exhibition Hall

Paul Attridge, Sr Director Strategy, Veeva Systems
Riccardo Sciabica, Sr Solution Consultant, Veeva Systems

This session will introduce you to the challenges and risks associated with approaching Regulatory Information and Submission Management as disparate processes. We will present a unified process model and unified applications that can significantly improve the processes, leading to greatly reduced compliance risks, improved business oversight and significantly improved value for your business. We will highlight the approach using a live demonstration.

Regulatory Vendor Promises – Innovations or Buzzwords?

Thursday, 30 March 2017 | 10:30-11:00
Innovation Theatre, Exhibition Hall

- The following topics will be addressed:
- The magic of multitenancy
- One source of truth
- The only eCTD Tool used at agencies
- Bringing the industry to the loud
- Integral by design
- Continuous publishing
- Next Generation of RIM

Cognitive Computing in Pharmacovigilance: The Game-Changer

Friday, 31 March 2017 | 10:30-11:00
Innovation Theatre, Exhibition Hall

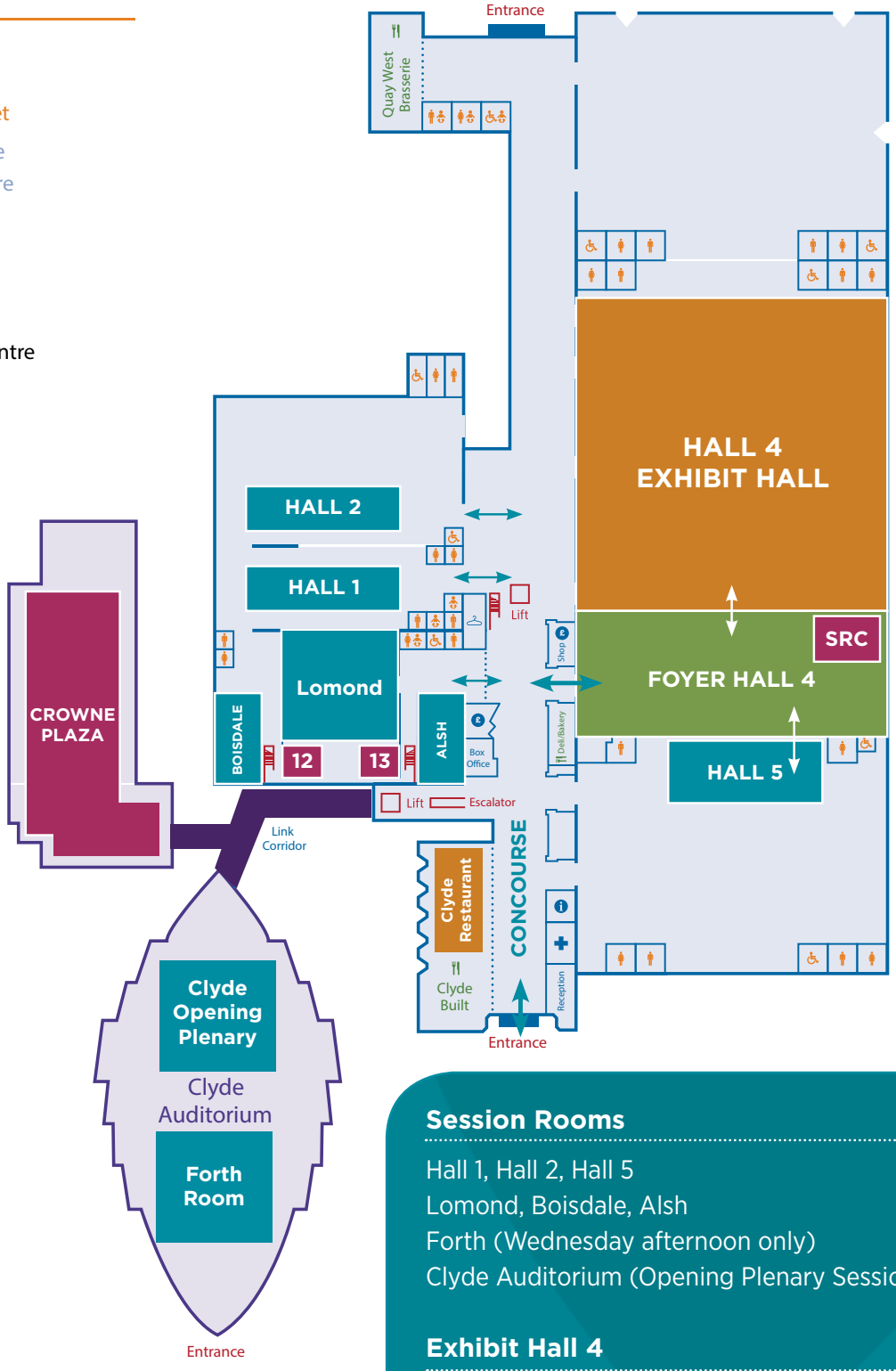
Dr. Vivek Ahuja, VP, Global Pharmacovigilance

Technological advancements are rapidly impacting the way pharmacovigilance obligations will be fulfilled by marketing authorization holders. The modus operandi of conducting pharmacovigilance operations is expected to change significantly by the year 2020. Automation, artificial intelligence, machine learning, cognitive computing, proactive pharmacovigilance are shaping the new paradigm of the safety world. Achieving compliance at a lower cost and higher quality is much closer as a goal today than it was ever before. This session will focus on how automation is soon going to change the pharmacovigilance world forever and what it holds for you.

GROUND **LEVEL**

Key

- Male toilet
- Female toilet
- Disabled toilet
- Cash machine
- Medical Centre
- Information
- Food & drink
- Taxi rank
- Bus stop
- Exhibition Centre station



Session Rooms

Hall 1, Hall 2, Hall 5
Lomond, Boisdale, Alsh
Forth (Wednesday afternoon only)
Clyde Auditorium (Opening Plenary Session only)

Exhibit Hall 4

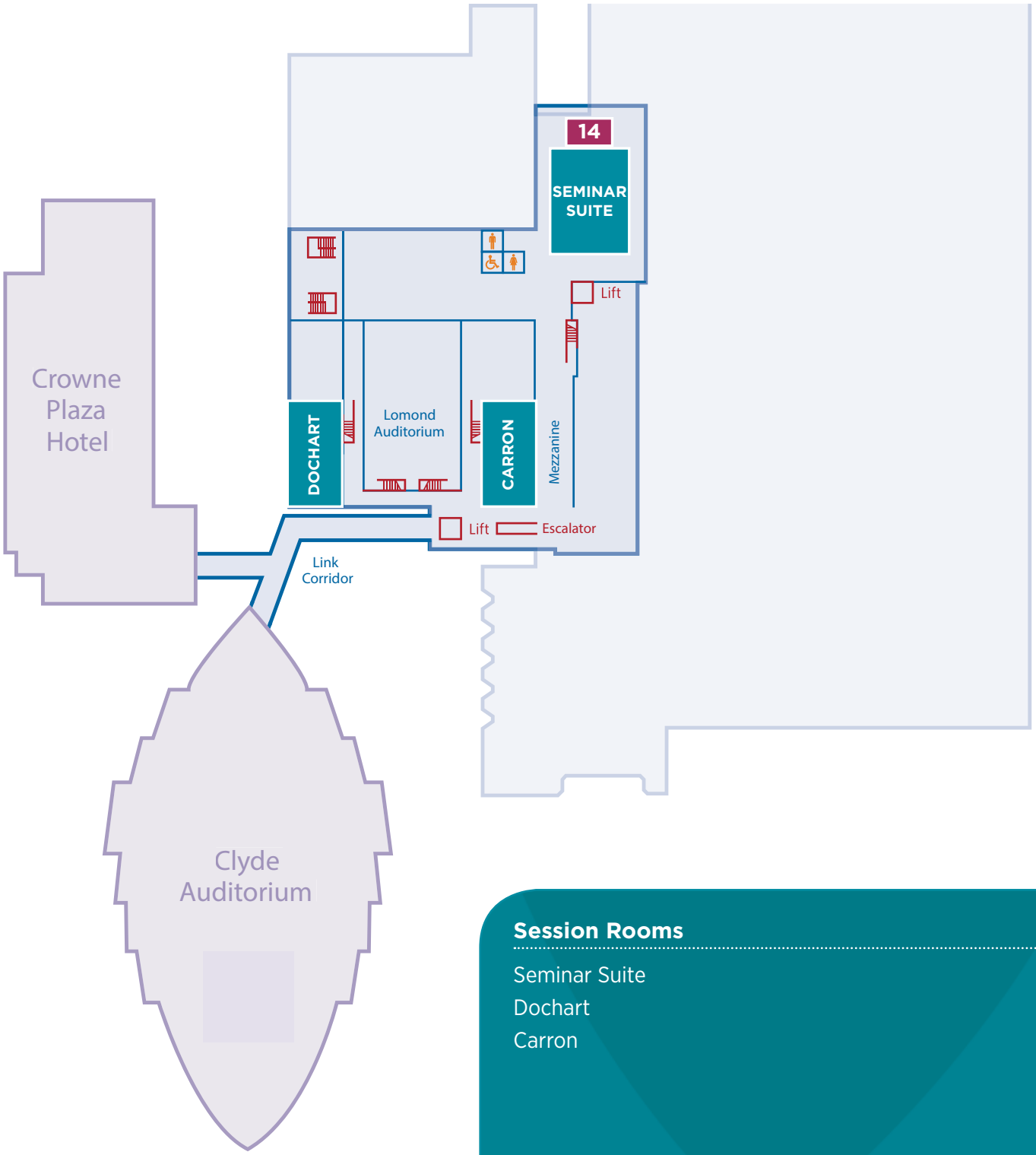
Exhibition
Innovation Theatre, Posters, Speed Networking, Communities Networking Area & Lunch, Coffee & Lunch Breaks, Receptions, Rechargin Lounge

Foyer Hall 4

Registration & Bag Distribution
Cloakroom | Speaker Resource Center

29th Annual
EUROMEETING
GLASGOW | 2017
29-31 MARCH

LEVEL **ONE**



Session Rooms

Seminar Suite
Dochart
Carron

29th Annual
EUROMEETING
GLASGOW | 2017
29-31 MARCH

DIAglobal.org/EM2017

EXHIBIT HALL **FLOOR PLAN**

WELCOME TO
THE EXHIBITION ARENA

Prepare to be overwhelmed and excited about the abundance of information available in the Exhibit 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. The EuroMeeting is where talent and experience meet.

We urge you to schedule several visits to the Exhibit 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.

MORNING
WELCOME
COFFEE

MORNING & AFTERNOON
REFRESHMENT
BREAKS WITH THE EXHIBITORS

DAILY
LUNCH
BREAKS

ENERGY BOOSTER
MOBILE DEVICE/LAPTOP
CHARGING LOUNGE

CONNECT WITH HEALTHCARE COMPANIES AS THEY SHOWCASE THEIR NEWEST PRODUCTS

EXHIBITION HALL
OPENING HOURS

Wednesday, 29 March 2017:	10:00 - 19:30
Thursday, 30 March 2017:	08:00 - 18:30
Friday, 31 March 2017:	08:00 - 13:30

WEDNESDAY
"WELCOME TO GLASGOW"
RECEPTION

INNOVATION THEATRE
PRESENTATIONS

THURSDAY
'EXHIBITOR MEET & GREET'
RECEPTION

EXHIBITING COMPANIES AS OF 20 MARCH 2017

Company	Booth Number
4C Pharma Solutions, USA	F21
AB Cube, France	B12
Acadustri Limited, UK	F23
ADAMAS Consulting Ltd, UK	F18
Adis, Springer Nature, UK	G23
Agile PV, USA	F6
Alpharmaxim Healthcare Communications, UK	G17
AMPLEXOR Life Sciences, Italy	B19
APCER Life Sciences, UK	E10
Appian, UK	F7
Applied Clinical Trials, USA	F1
ArisGlobal, USA	E15
arivis AG, Germany	B10
Asphalion S.L, Spain	F13
AXPHARMA Life Sciences, France	C13
Barrington James, UK	C2
BaseCon A/S, Denmark	C8
Basel Tourismus	G24
Biomapas, Lithuania	F26
Clarivate Analytics, UK	C3
Clinical & Contract Research Association (CCRA), UK	G8
Clinical Practice Research Datalink, UK	B5
Clinical Professionals, UK	G5
Clinical Research Malaysia (CRM), Malaysia	B1
ClinTec International, UK	D2
Commonwealth Informatics, USA	G13
Corporate Translations, Inc., USA	F25
Cunesoft GmbH, Germany	F27

Company	Booth Number
DADA Consultancy B.V., Netherlands	C12
Denys Research Consultants, Belgium	F20
DIA	DIA Booth
DIA Basel 2018 Sales Booth	G25
Diamond Pharma Services, UK	A1
DLRC Ltd, UK	B8
Donnelley Language Solutions, UK	B20
Dora Wirth Languages, UK	F14
Drug Safety Research Unit, UK	F30
eClinicalHealth Limited, UK	G19
EIDOSMEDIA, Italy	F3
Elsevier BV, Netherlands	G16
EMA - European Medicines Agency, UK	B11
ENNOV, France	B6
ERT, USA	D3
EUDRAC Group, UK	E9
Europital, Belgium	D8
EXTEDO, Germany	E8
Falcon Consulting, USA	C18
FDA Quality and Regulatory Consultants, USA	D1
Foresight Group International AG, USA	B3
i4i Inc., Canada	D9
Ideagen, UK	G12
INSIGHT MEDICAL WRITING, UK	B15
Integrated Clinical Systems, Inc., USA	C5
Intralinks, UK	F15
IntraScience, UK	F8
Iperion Life Sciences Consultancy, Netherlands	F16

EXHIBITING COMPANIES AS OF 20 MARCH 2017

Company	Booth Number
Life Science Academy, Italy	G22
LucidLab – a division of H&H Communication Lab GmbH, Germany	G15
Luto Research Limited, UK	F22
Mapi, France	E3
MasterControl, Inc., USA	E14
MeddiQuest Regulatory Affairs Limited, Ireland	B7
MedDRA MSSO, USA	D5
Medicademy, Denmark	B9
Medicines Evaluation Unit Ltd, UK	G7
Medpace, Netherlands	A18
Moravia IT s.r.o., Czech Republic	B14
mt-g medical translation GmbH & Co. KG, Germany	E17
MyMedsandMe Ltd, UK	F12
NDA Group AB, Sweden	C10
NHS Research Scotland, UK	G1
NNIT, Denmark	C17-C19
Nordtext, Latvia	C4
Onix Life Sciences Ltd, UK	F10
Oracle Health Sciences, UK	C6
Patients Direct, UK	D10
Paul-Ehrlich-Institut, Germany	G14
Pharmaceuticals and Medical Devices Agency, Japan	B13
PharmaLex SAS, France	F28
Pharmathen S.A., Greece	B16
Pilgrim Quality Solutions, USA	B18
Pope Woodhead, UK	C16
PQE, Italy	B2
PrimeVigilance Limited, UK	E7

Company	Booth Number
ProductLife Group, France	C21
Promedim Ltd, UK	G10
Prudentia Group, USA	E16
Real Life Sciences, UK	C1
Regulatory Pharma Net, Italy	D6
Rephine Limited, UK	B21
S G Research International, USA	B4
SEC Recruitment Ltd, UK	A16
SQN - Syne qua non, UK	F11
Stefanini, Belgium	C14
Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE), UK	A3
Synchrogenix, USA	C22
Synevo Central Labs, Belgium	E1
Tarius A/S, Denmark	E12
The Regulatory Affairs Company™, UK	G6
ThreeWire, Inc., USA	C9
Tissue Solutions Ltd, UK	F24
TRAC - The Regulatory Affairs Consultancy, UK	D7
TransPerfect, UK	D4
Trilogy Writing & Consulting, Germany	D14
UNIVERSAL MEDICA, France	E6
Uppsala Monitoring Centre, Sweden	E13
Veeva Systems UK Limited, UK	B22
Veristat, UK	D12
Xendo B.V. & Sofus Regulatory Affairs AB, Netherlands	C20

EXHIBITOR DIRECTORY

SUMMARIES PROVIDED BY EXHIBITING COMPANY AS OF 20 MARCH 2017

4C Pharma Solutions ..... Booth F21

Website: www.4cpharma.com
Email: info@4cpharma.com
Contact: Dr.Muhammad Ahmad

4C Pharma Solutions, named in the top 10 CROs by Pharma IQ, is a fast-growing service provider organization in Pharmacovigilance, Medical Information Call Centre and Regulatory Affairs. 4C is ISO 9001 & 27001 certified. 4C is an Oracle partner with fully validated Argus and eXtedo eCTD Manager in-house reducing your technology and processing costs.

AB Cube ..... Booth B12

Website https://www.ab-cube.com/
Email: raphaelle.courtay@ab-cube.com
Contact: Raphaëlle Courtay

AB Cube, a 10 years old publisher, provides the international healthcare industry with multivigilance softwares (Pharmacovigilance, Medical device vigilance, Cosmetovigilance, OS...) managing safety data, in compliance with European and worldwide regulatory requirements. All AB Cube solutions are validated according to GAMP5 and FDA 21CFR part 11.

Acadustri Limited ..... Booth F23

Website: www.acadustri.com
Email: enquiries@acadustri.com
Contact: Dr Justina Orleans-Lindsay

Acadustri provides expert medical writing solutions to the pharmaceutical industry, with specialist services in pharmacovigilance medical writing (eg, EU RMPs, PBRERs and DSURs). The Acadustri team offers authoritative guidance on document content and structure to support all stages of drug development, with bespoke solutions for small and medium enterprises.

ADAMAS Consulting Ltd ..... Booth F18

Website: www.adamasconsulting.com
Email: carly.davenport@adamasconsulting.com
Contact: Carly Davenport

ADAMAS is one of the largest QA consultancy organisations in the world and well respected within the healthcare industry. ADAMAS strives to provide cost-effective services of the highest value. ADAMAS manage small and larger QA projects in all areas of GxP. ADAMAS use their own QMS and their consultants are highly experienced and knowledgeable.

Adis, Springer Nature ..... Booth G23

Website: http://adis.com
Email: gemma.ryder@springer.com
Contact: Gemma Ryder

Adis is a leading global provider of drug-focused content and solutions. Alongside journals and books, we offer AdisInsight – a platform supporting better-informed strategic decision-making with accurate, comprehensive coverage of drugs in development worldwide – and Adis Pharmacovigilance - the expert solution for regulatory literature monitoring.

Agile PV ..... Booth F6

Website: www.agilepv.com
Email: katherine.long@agilepv.com
Contact: Katherine Long

AgilePV is a suite of validated pharmacovigilance software solutions that help mitigate risk and enhance visibility within patient safety. Unlike companies that rely on customization or acquisitions, AgilePV is delivered Off-the-Shelf by the same experts who write the managed software. AgilePV offers an array of solutions including RMP Commitment Tracking and Adverse Event Processing.

Alpharmaxim Healthcare Communications ..... Booth G17

Website: www.alpharmaxim.com
Email: william.hind@alpharmaxim.com
Contact: William Hind

Alpharmaxim is a communications agency focused exclusively on the healthcare sector. We are committed to helping clients develop and communicate compelling evidence-led stories that enable stronger engagement. Our services range from strategic planning to the delivery of tactical elements that bring plans to life in an impactful and compliant manner.

AMPLEXOR Life Sciences ..... Booth B19

Website: www.amplexor.com/lifesciences
Email: Elvis.pacelat@amplexor.com
Contact: Elvis Pacelat

AMPLEXOR Life Sciences helps pharmaceutical, medical device & biotechnology organizations launch products quickly. Its solutions and services globally expedite the creation and delivery of compliant and high-quality data convergence. Its services include technology consultancy, management services, technical writing, translation & validation.

APCER Life Sciences ..... Booth E10

Website: apcerls.com
Email: simon.johns@apcerls.com
Contact: Simon Johns

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory, and technology resources to ensure that patients receive the safest, most effective therapies possible. Learn why APCER earns a perfect Net Promoter Score in client surveys.

Appian ..... Booth F7

Website: www.appian.com
Email: Info.uk@appian.com
Contact: Cindy Cheng

Appian delivers a digital transformation platform that accelerate the time it takes to build and deploy powerful, modern applications, on-premises or in the cloud. The world's most innovative life sciences organizations use Appian to revolutionise their customer experiences, transform operations, and master regulatory compliance. www.appian.com.

EXHIBITOR DIRECTORY

SUMMARIES PROVIDED BY EXHIBITING COMPANY AS OF 20 MARCH 2017

Applied Clinical Trials ..... Booth F1

Website: www.appliedclinicaltrialsonline.com/
Email: melissa.devlin@ubm.com
Contact: Melissa Devlin

Applied Clinical Trials is the authoritative, peer-reviewed resource on clinical trials and the only brand dedicated exclusively to clinical trials providing effective solutions to challenges within this tightly regulated environment. Applied Clinical Trials is available in print and digital – including webinars, video and e-newsletters.

ArisGlobal ..... Booth E15

Website: www.arisglobal.com
Email: alowe@arisglobal.com
Contact: Alex Lowe

ArisGlobal is the leading provider of integrated solutions for pharmacovigilance & safety, regulatory affairs, clinical development and quality and compliance in medical communications. Life science companies use ArisGlobal's solutions to build and maintain the trust they need with their customers, medical practitioners and regulatory bodies around

arivis AG ..... Booth B10

Website: www.arivis.com
Email: info@arivis.com

arivis AG is a market leading software company focused on the life sciences industry. With a broad product portfolio, our solutions address industry and academic environments. We offer software solutions as well as services provided by our experienced IT project engineers and experienced subject matter experts.

Asphalion S.L ..... Booth F13

Website: www.asphalion.com
Email: custrell@asphalion.com
Contact: Cristina Ustrell

Asphalion is an international Scientific and Regulatory Affairs consultancy. We collaborate with Pharma and Biotech companies facilitating Drug Development and Regulatory Affairs projects for Drugs, Biologics, Biosimilars, ATMPs and Medical Devices. We now have a team of over 80 employees with backgrounds in all areas of life sciences.

AXPHARMA Life Sciences ..... Booth C13

Website: www.axpharma.com
Email: contact@axpharma.com

«AXPHARMA Life Sciences Services is a contract service organization dedicated to the outsourcing of all vigilances and 24/7 Medical Information.

EUDRAVIGILANCE changes in 2017 from E2BR2 to EB2R3 will be an important challenge for Pharma Industry and AXPHARMA will be ready to support you.

Consulting, PV audits... Integrated services Europ and MENA»

Barrington James ..... Booth C2

Website: www.barringtonjames.com
Email: bpearce@barringtonjames.com
Contact: Ben Pearce

Barrington James are a Global specialist recruitment consultancy with offices in Europe, USA and Asia that work across the Healthcare sector. Our structure, with separate divisions and dedicated consultants for the markets we serve ensures a thorough, professional and intelligent approach in both permanent and interim solutions. Our tailored methodologies include contingency database search and executive search.

BaseCon A/S ..... Booth C8

Website: www.basecon.com
Email: contact@basecon.com
Contact: Sven Nielsen

BaseCon has been providing a unique, time saving Drug Safety database with a easy way to achieve drug safety compliance since 1999. We've been able to establish benchmarks for simplicity, flexibility, security, and efficiency of drug safety IT solutions.

Biomapas ..... Booth F26

Website: www.biomapas.eu
Email: bd@biomapas.eu; info@biomapas.eu
Contact: Egle Pavyde,

Associate Director Business Development Biomapas – a full service, ISO 9001:2015 certified CRO, with deep expertise in clinical research, regulatory affairs, medical writing and pharmacovigilance services. For more than 15 years Biomapas is supporting Pharmaceutical, Biotech and Medtech companies with client based solutions in Europe and former CIS region.

Clarivate Analytics ..... Booth C3

Website: www.clarivate.com
Email: Christine.cort@Clarivate.com
Contact: Christine Cort

Clarivate Analytics accelerates the pace of innovation by providing trusted insights and analytics to customers globally, enabling them to discover, protect and commercialize new ideas, faster. An independent company with over 4,000 employees, we own and operate leading businesses focused on scientific and academic research, regulatory standards, pharmaceutical and biotech intelligence, and IP management.

Clinical & Contract Research Association (CCRA) ..... Booth G8

Website: www.ccra.org.uk
Email: mail@ccra.org.uk
Contact: Sue Dilks, Director of Operations

If quality and reliability matter to you, please come to visit us and learn how important membership of a recognised trade association is to a company, be it as a supplier of services to, or a user of these services, in the drug development process. CCRA is the UK trade association for the CRO sector and is committed to maintenance of the highest standards.

EXHIBITOR DIRECTORY

SUMMARIES PROVIDED BY EXHIBITING COMPANY AS OF 20 MARCH 2017

Clinical Practice Research Datalink ..... Booth B5

Website: www.cprd.com
Email: tara.thumba-naikheadley@mhra.gsi.gov.uk
Contact: Tara Headley

CPRD is a governmental, not-for-profit research centre, facilitating and conducting public health observational research and interventional real world clinical trials using electronic health records. The depth of its longitudinal data makes CPRD the observational research data provider of choice for regulators, industry and academics globally.

Clinical Professionals ..... Booth G5

Website: www.clinicalprofessionals.co.uk
Email: info@clinicalprofessionals.co.uk
Contact: Yvette Cleland

Clinical Professionals are Europe's leading Life Science staffing provider offering outsourced solutions via Functional Service Provision (FSP) and traditional, high quality staffing solutions. We recruit for a variety of roles including permanent, freelance, contract and interim vacancies and operate a Life Science Training Academy for the industry

Clinical Research Malaysia (CRM) ..... Booth B1

Website: www.clinicalresearch.my
Email: audrey.ooi@clinicalresearch.my

Clinical Research Malaysia exists to advance global health solutions for a brighter, more hopeful future for the people by providing speedy and reliable end-to-end clinical research support for quality studies and to position Malaysia as the preferred global destination for industry-sponsored research.

ClinTec International ..... Booth D2

Website: www.clintec.com
Email: info@clintec.com

ClinTec International is an award winning expert in global Clinical Research as a Functional Service Provider (FSP), with operations in more than 50 countries. As an entrepreneurial company, ClinTec strategically aligns its services with clients' needs, offering customized innovative clinical research solutions with a focus on Oncology and Rare Disease.

Commonwealth Informatics ..... Booth G13

Website: www.commoninf.com
Email: lwaldron@commoninf.com
Contact: Lori Waldron

Commonwealth Informatics is a global provider of cloud-based analytics products and services for medical research and healthcare delivery. Pharmaceutical and biotechnology companies, government regulatory agencies, and academic research groups use Commonwealth products and services to deliver innovative data analysis solutions to their teams.

Corporate Translations, Inc. ..... Booth F25

Website: www.corptransinc.com
Email: sdempsey@corptransinc.com
Contact: Sheena Demspey

«Corporate Translations provides quality language solutions quickly and cost-effectively.

Corporate Translations is the leading and trusted provider of language solutions specifically for the life science industry. With over 26 years of experience, Corporate Translations has become a recognized expert in successfully managing complex translation projects for the world's top pharmaceutical and CROs.»

Cunesoft GmbH ..... Booth F27

Website: www.cunesoft.com
Email: info@cunesoft.com
Contact: Rainer Schwarz

Cunesoft provides a sophisticated and integrated regulatory operations solution that unifies DMS, eCTD, IDMP and RIM capabilities as well as its innovative document data mining solution purpose built for IDMP readiness. For more information, please visit www.cunesoft.com.

DADA Consultancy B.V. ..... Booth C12

Website: www.dada.nl
Email: office@dada.nl
Contact: Patty Robins

DADA Consultancy, is an independent, state-of-the art consultancy agency. We provide tailor-made support to the pharma industry, where our quality of work and the knowledge of our staff can provide you with a fitting solution to any problem you may encounter in Regulatory Affairs, CMC/Quality, Pharmacovigilance or Clinical activities.

Denys Research Consultants ..... Booth F20

Website: www.drc-bvba.be
Email: Vanessa.parrein@drc-bvba.be
Contact: Vanessa Parrein – Business Development Manager

Denys Research Consultants (DRC) is a well-established full service clinical research organization offering high quality services for the academic research, pharmaceutical, biotech and medical devices industry. We provide international clinical trial services in project management and monitoring for Phase I through Phase IV Clinical Trials.

DIA Europe, Middle East & Africa ..... DIA Booth

Website: www.DIAglobal.org
Email: emea@diaglobal.org

DIA is the global forum for knowledge exchange that fosters innovation to raise the level of health and well-being worldwide.

EXHIBITOR DIRECTORY

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Diamond Pharma Services ..... Booth A1

Website: www.diamondpharmaservices.com
Email: rdavis@diamondpharmaservices.com
Contact: Roley Davis

«• Regulatory Affairs: From Product Concept to Registration and Beyond
• Product Development: Nonclinical, CMC and Clinical Aspects
• Pharmacovigilance: Clinical trials, Post-Marketing and QPPV Services
• Compliance & Quality: GxP and QP Services»

DLRC Ltd ..... Booth B8

Website: www.dlrc.co.uk
Email: enquiries@dlrc.co.uk
Contact: Dianne Lee

DLRC is a forward-thinking regulatory affairs consultancy that understands the individual needs of clients. Our broad experience supports pharma and biotech companies globally, delivering successful paediatric plans, PRIME and Orphan designations, health authority interactions, CTA and marketing authorisation submission strategies and approvals.

Donnelley Language Solutions ..... Booth B20

Website: www.dfsco.com/languagesolutions/
Email: carolina.arias@dfsco.com
Contact: Carolina Arias

«Donnelley Language Solutions is a leading provider of specialised localisation services and translation technology to businesses worldwide.

With over 25 years of experience and more than 6,000 specialised and accredited linguists, we create, translate, localise and harmonise multilingual content for clients worldwide.»

Dora Wirth Languages ..... Booth F14

Website: www.dwlanguages.com
Email: s.j.wirth@dwlanguages.com
Contact: Samuel J. Wirth

Translation service providers specialising in life sciences especially regulatory affairs, clinical and medical research

Drug Safety Research Unit ..... Booth F30

Website: www.dsru.org
Email: elizabeth.lynn@dsru.org
Contact: Liz Lynn

DSRU is an independent academic unit with respected pharmacovigilance, pharmacoepidemiology and risk management expertise conducting post-authorisation safety studies in primary and secondary care. Methods include European network studies, Specialist Cohort Event Monitoring (SCEM), Modified Prescription-Event Monitoring (MPEM) and drug utilisation.

eClinicalHealth Limited ..... Booth G19

Website: www.clinpal.com
Email: sharvey@eclinicalhealth.com
Contact: Suzie Harvey

eClinicalHealth, developer of the revolutionary Clinpal™ patient engagement platform, was founded in 2012 to provide innovative clinical trial solutions. Today, Clinpal™ supports studies in 42 countries across a wide variety of therapeutic areas, and enables remote research via direct-to-patient study models.

EIDOSMEDIA ..... Booth F3

Website: www.eidosmedia.com
Email: Francesca.maggi@eidosmedia.com
Contact: FRANCESCA MAGGI

«EidosMedia is a global leader in structured-content management and publishing solutions.

Based on advanced digital technologies, EidosMedia platforms operate at a more granular level than conventional document-management systems. They enable a modular, team-based approach to workflow with significant benefits in productivity, oversight and compliance at every stage of the project life cycle.»

Elsevier BV ..... Booth G16

Website: https://www.elsevier.com/rd-solutions/pharma-and-life-sciences-solutions
Email: l.dimaiuta@elsevier.com
Contact: Laura Dimaiuta

Elsevier is a world-leading provider of information solutions that enhance the performance of science, health, and technology professionals, empowering them to make better decisions, and deliver better care.

EMA - European Medicines Agency ..... Booth B11

Website: www.ema.europa.eu
Email: Beatrice.fayl@ema.europa.eu
Contact: Beatrice Fayl von Hentaller

The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources put at its disposal by member states for the evaluation, supervision, and pharmacovigilance of medicinal products.

ENNOV ..... Booth B6

Website: www.ennov.com
Email: contact@ennov.com
Contact: Ferréol PEREZ CASTILLO

With over 15 years' experience and 500 clients worldwide, Ennov makes the most integrated, cost-effective and user-friendly software for Life Sciences. Our 4 mobile solutions: Quality, Regulatory, Clinical and Pharmacovigilance integrate with your workflow to help you reach your compliance and productivity goals faster.

EXHIBITOR DIRECTORY

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ERT ..... Booth D3

Website: www.ert.com
Email: eresearch@ert.com
Contact: Sheryl Walder

ERT is a global data and technology company that minimizes uncertainty and risk in clinical trials so that our customers can move ahead with confidence. With more than 40 years of clinical and therapeutic experience, ERT balances knowledge of what works with a vision for what's next, so it can adapt without compromising standards.

EUDRAC Group ..... Booth E9

Website: www.eudrac.com
Email: carole.pugh@eudrac.com
Contact: Carole Pugh

EUDRAC is a regulatory affairs & pharmacovigilance consultancy based in UK, Germany & France. Our services to pharma & medical device companies extend through the development, registration, market launch & life cycle management phases, including e-CTD publishing. Our clients value our high quality work performed according to project timelines.

Europital..... Booth D8

Website: www.europital.com
Email: info@europital.com
Contact: a.popovic@europital.com

Europital is an international organization dedicated to Scientific Research and Medical management of Clinical Trials. We provide our medical expertise in a flexible end-to-end model tailored for the business needs of our clients in the pharmaceutical sector.

EXTEDO ..... Booth E8

Website: www.extedo.com
Email: info@extedo.com
Contact: Thomas Kessler

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes. Today, EXTEDO enables more than 35 regulatory authorities and over 700 maintained customers across 60 countries to deliver Effortless Compliance™.

Falcon Consulting ..... Booth C18

Website: http://www.falconnest.com/
Email: lowmanj@falconnest.com
Contact: John Lowman

Falcon Consulting Group is a global Clinical Quality Assurance (CQA) and GCP consulting firm. Falcon's large team of full-time employees performs GCP Audits (Site/Vendor/PV) and other services in the US, EU, Asia, Africa and South America.

FDA Quality and Regulatory Consultants..... Booth D1

Website: www.fdaqrc.com
Email: chris@fdaqrc.com / michelle@fdaqrc.com
Contact: Chris Rush and Michelle Thompson

FDA Quality and Regulatory Consultants was founded in 2009 by Christopher Rush after having worked at the US FDA for five years with the goal to provide sound scientific and technical expertise in quality assurance, regulatory affairs and compliance to pharmaceutical, medical device and biotech clients. We are your consultant partner.

Foresight Group International AG ..... Booth B3

Website: http://www.foresightgroup.com
Email: neller@foresightgroup.com
Contact: Nicole Eller

Foresight Group is a global management and technology consulting company focused exclusively on drug safety and risk management solutions. We provide hosted safety solutions, specializing in PV process design and optimization, safety database implementation, ad hoc and custom reporting, risk management and inspection readiness and response.

i4i Inc. ..... Booth D9

Website: www.i4i.com
Email: rwylie@i4i.com
Contact: Ruth Wylie

i4i is a world leader in the development of structured content applications. i4i has brought its innovative technology and regulatory expertise to the Life Sciences industry. Our solutions enhance compliance delivering intelligent content reuse and tracking of key Corporate, Clinical, CMC, Safety and Labelling documents.

Ideagen ..... Booth G12

Website: www.ideagen.com
Email: claire.mccluskie@ideagen.com
Contact: Claire McCluskie

Q-Pulse is a quality, safety and risk management solution from Ideagen which supports clients to meet internationally recognised standards and regulations. Our solutions encourage adoption of a risk-based approach to quality and compliance management, giving you the confidence that your products and services are safe and fit for purpose.

INSIGHT MEDICAL WRITING ..... Booth B15

Website: www.insightmw.com
Email: tim.griffiths@insightmw.com
Contact: Tim Griffiths

«Our documents ensure smooth progress through approval and beyond.

A clear, accurate and quality-led service. We are the reliable, flexible and highly qualified team who always deliver on time and on budget.

? Writing ? Clinical ? Editing ? Regulatory ? Quality control

? Pharmacovigilance ? Data transparency ? Medical marketing»

EXHIBITOR DIRECTORY

SUMMARIES PROVIDED BY EXHIBITING COMPANY AS OF 20 MARCH 2017

Integrated Clinical Systems, Inc. ..... Booth C5

Website: www.i-review.com
Email: eherbel@i-review.com
Contact: Eric S. Herbel

Integrated Clinical Systems - developers of JReview® - developed specifically for clinical data review -the fastest and easiest way to review, graph, visualize, report, analyze, do tabular & graph patient profiles and patient narratives. Integrated with OC, SAS datasets, Oracle LSH, Medidata Rave, OmniComm TrialMaster, EntimICE, ThoughSphere ClinDAP.

Intralinks ..... Booth F15

Website: www.intralinks.com/solutions/life-sciences
Email: emiddleton@intralinks.com
Contact: Ed Middleton

Intralinks is the leading content collaboration platform for life sciences, serving 9 of the 10 largest biopharma firms globally. Our security and governance capabilities are engineered to protect high-value information in tightly regulated industries, supporting ISO 207001 certification, FDA 21 CFR Part 11 validation and HIPAA compliant file sharing.

IntraScience ..... Booth F8

Website: www.transcrip-partners.com
www.indegene.com
Email: paul.branthwaite@transcrip-partners.com
Contact: Paul Branthwaite

IntraScience provides a full spectrum of clinical, regulatory, safety and medical affairs from early development to mature products, uniquely combining an entire range of global operational activities associated with large pharmacovigilance and medical affairs CROs with therapeutic input from experienced industry trained staff in Europe and the US.

Iperion Life Sciences Consultancy ..... Booth F16

Email: info@iperion.nl
Contact: Karel Bastiaanssen / Eva Klarenaar

As one of the first companies involved in completing a full cycle IDMP program, Iperion is recognized as a leading consultancy company. Our pragmatic and hands on approach towards IDMP compliance differentiates us in the market. Iperion's team of varying experts delivers a customer specific strategy handling all your IDMP compliance challenges.

Life Science Academy ..... Booth G22

Website: www.LSacademy.it
Email: enrico.pedroni@easy-b.it
Contact: Enrico Pedroni

«LS Academy is the EasyB's business unit, running technical and scientific training and conferences for professionals involved in the discovery, development, and life cycle management of pharmaceuticals, medical devices and related medical products.

Furthermore, scientific translations, publishing and market research services.»

LucidLab – a division of H&H Communication Lab GmbH ..... Booth G15

Website: www.lucid-lab.eu
Email: info@lucid-lab.eu
Contact: Oliver Haug (CEO)

LucidLab is a division of H&H Communication Lab GmbH. We are specialized in transferring medical information into lay friendly language. Our unique software based process for quality assured communication and a team of experts provide you with all expertise needed in the publishing cycle of medical information.

Luto Research Limited ..... Booth F22

Website: www.luto.co.uk
Email: solutions@luto.co.uk
Contact: Denise Donaghy

Luto's experienced team can help to create or enhance your health communications. This includes Package Leaflets, Instructions for Use, Clinical Trials information and other materials such as educational or marketing tools. We also provide full usability and readability testing services to support your EU and USA regulatory submissions.

Mapi ..... Booth E3

Website: http://www.mapigroup.com
Email: aflori@mapigroup.com
Contact: Agnès Flori

Mapi Group has over 40 years of experience supporting Life-Science companies in utilizing Patient Reported Outcomes measures, Value communications and Commercialization support, Strategic Regulatory Services, and gathering Real-World Evidence on Pharmaceuticals, Biologicals, and Medical devices. Mapi Group is the premier provider of Health Research and Commercialization services to Life-Sciences companies.

MasterControl, Inc. ..... Booth E14

Email: events@mastercontrol.com
Contact: Jill Bumgardner

MasterControl quality management software enables regulated companies to increase compliance while reducing time to market. MasterControl solutions include quality management, document control, audit management, clinical/regulatory management, training management, supplier management, CAPA and more.

MeddiQuest Regulatory Affairs Limited ..... Booth B7

Website: www.meddiquest.com
Email: meddiquest@meddiquest.com
Contact: Neil R Armstrong

«MeddiQuest is an engineering-based Regulatory Affairs consultancy for Medical Devices. We specialize in helping new businesses or those with technologies that are new or in an extended application.

From intracranial drug delivery to foot baths; São Paulo to Berlin, if you need regulatory, quality, risk management, technical, commercial or market expertise MeddiQuest is there to help!»

EXHIBITOR DIRECTORY

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MedDRA MSSO ..... Booth D5

Website: www.meddra.org
Email: mssorequest@meddra.org
Contact: Scott Vitiello

MedDRA - the Medical Dictionary for Regulatory Activities - is a medical terminology used to classify adverse event information associated with the use of biopharmaceuticals and other medical products (e.g., medical devices and vaccines).

Medicademy ..... Booth B9

Website: www.medicademy.net
Email: tj@medicademy.net
Contact: Tina Jensen

«Medicademy – Regulatory Affairs and Pharmacovigilance - Training, Seminars and Conferences!

23 modules offered in cooperation with the University of Copenhagen, University of Southern Denmark and The Danish Health and Medicines Authority, can lead to:

•Master Degree at the University of Copenhagen, Denmark

•Diploma

•Individual Modules

Medicines Evaluation Unit Ltd ..... Booth G7

Website: www.meu.org.uk
Email: financeteam@meu.org.uk
Contact: David Rogers

«The Medicines Evaluation Unit (MEU) MHRA Phase 1 Accredited Site.

The MEU is one of the UK's leading contract research organisations, possessing extensive pharmaceutical, scientific and clinical expertise. We provide fast volunteer recruitment, within a state-of-the-art hospital based research facility. We have completed over 330 studies to date.»

Medpace ..... Booth A18

Website: www.medpace.com
Email: m.vanhaaren@medpace.com
Contact: Mandy van Haaren

Medpace is a full-service global Clinical Research Organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Headquartered in Cincinnati, Ohio, Medpace employs approximately 2,500 people across 35 countries.

Moravia IT s.r.o. ..... Booth B14

Website: www.moravia.com
Email: renatak@moravia.com
Contact: Renata Keprtova

Moravia Life Sciences is a global translation services provider that helps bring your product to international markets and satisfy local regulatory requirements. Founded in 1990, we're triple ISO-certified and rank among the top language services providers globally. We're Life Sciences translation experts offering translation in over 170 languages.

mt-g medical translation GmbH & Co. KG ..... Booth E17

Website: www.mt-g.com
Email: info@mt-g.com
Contact: Szilvia Bíró

As a language service provider, we specialise exclusively in medical and pharmaceutical translations in the following areas: medical technology, global regulatory affairs, clinical studies, marketing and communications as well as dentistry and dental technology. The range of services we offer covers the entire translation workflow. The language portfolio currently comprises more than 60 languages with around 600 language pairs.

MyMedsandMe Ltd. ..... Booth F12

Website: www.mymedsandme.com
Email: andy.watson@mymedsandme.com / chris.beverley@mymedsandme.com
Contact: Andy Watson / Chris Beverley

MyMeds&Me is a leading SaaS provider of web-based adverse event and product quality capture solutions for life sciences. Client companies see efficiency & effectiveness benefits by rapidly accessing more complete safety data for the earliest detection of safety or quality issues. Learn more about our multi-lingual web-based Reportum® solution today.

NDA Group AB ..... Booth C10

Website: www.ndareg.com
Email: anna.perrin@ndareg.com
Contact: Anna Perrin

NDA is a world leading drug development consultancy. We streamline the global process to accelerate patient access to important medical therapies. Our experts are leaders in clinical and regulatory drug development, payer strategy and High-stakes meeting preparation. NDA supported over 40% of the new medicinal products approved in the EU 2013-2016.

NHS Research Scotland ..... Booth G1

Website: www.nrs.org.uk
Email: communications@nrs.org.uk
Contact: Steven Burke

NRS promotes and supports excellence in clinical and translational research in Scotland so patients benefit from new and better treatments. Formed through a partnership of Scottish NHS Boards and the Chief Scientist Office (CSO) of Scottish Government, we work to ensure that NHS Scotland provides the best environment to support clinical research.

NNIT ..... Booth C17-C19

Website: www.nnit.com
Email: nnitcontact@nnit.com

«NNIT is an international consultancy in the development, implementation, validation and operation of IT for the life sciences industry.

We create value for our clients by treating their IT as if it were our own and, of course, we meet the industry's strictest requirements for quality.»

EXHIBITOR DIRECTORY

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Nordtext ..... Booth C4

Website: www.nordtext.com
Email: info@nordtext.com
Contact: Gunita Aboltina

Nordtext is an ISO certified translation agency specializing in language solutions for life sciences companies. Our core expertise is written translation from and into Scandinavian, Baltic and Eastern European languages.

Onix Life Sciences Ltd ..... Booth F10

Website: http://www.onixls.com
Email: jc@onixls.com
Contact: Mrs Jasbir Chohan

ONIX offers eCTD Submission Services to the pharmaceutical industry. ONIX eSubmission services include eCTD regulatory strategy, project and life-cycle management, PDF/MS word publishing, compilation of eCTD/NeeS applications, technical validation and submission to the Health Authorities.

Oracle Health Sciences ..... Booth C6

Website: www.oracle.com/healthsciences
Email: kate.andrews@oracle.com
Contact: Kate Andrews

Oracle Health Sciences is a leading strategic software solutions provider to Life Sciences & Healthcare. We are helping to transform clinical R&D from pipeline to patient through innovative cloud and mHealth solutions that improve patient outcomes and safety, increase pipeline performance, and optimize clinical development efficiency. Companies worldwide rely on us to develop and bring life-improving therapies to patients faster, while reducing the cost and risk of clinical research.

Patients Direct ..... Booth D10

Website: www.patientsdirect.org
Email: angela@patientsdirect.org
Contact: Angela Scott-Henderson

Patients Direct facilitate the twin ambitions of Pharma's desire to be 'patient centric' with patients' desire to be more involved in healthcare decisions by combining expertise in recording patient outcomes with powerful recruitment algorithms, ensuring that our surveys are patient friendly with scientific rigour and representative populations.

Paul-Ehrlich-Institut ..... Booth G14

Website: www.pei.de
Email: Bettina.Ziegele@pei.de
Contact: Bettina Ziegele

The PEI is the Federal Institute for Vaccines and Biomedicines in Germany. It is responsible for the approval of clinical trials, the processing of applications for marketing authorisation and applications of national and European procedures. The innovation office of the PEI provides regulatory and scientific advice to support early development of biomedicines.

Pharmaceuticals and Medical Devices Agency ..... Booth B13

Website: www.pmda.go.jp/english/index.html
Email: fukushi-tamami@pmda.go.jp
Contact: Dr. Tamami Fukushi

PMDA is a Japanese regulatory agency tasked with protecting and improving public health through three major services: product review, post-marketing safety measures, and offering relief to adverse drug reaction victims. PMDA considers patient welfare, and works to serve the public and contribute to global harmonization while maintaining trust, cutting-edge experience and expertise, and transparency.

PharmaLex SAS ..... Booth F28

Website: http://www.pharmalex.com/
Email: sophie.guillaume@pharmalex.com
Contact: Sophie Guillaume

PharmaLex is a leading specialist provider for regulatory affairs, pharmacovigilance and development consulting & scientific affairs. Our more than 500 specialists in 22 offices are dedicated to guiding you through regulatory approval processes. We have a proven track record - with more than 25,000 successful projects for over 550 clients.

Pharmathen S.A. ..... Booth B16

Website: www.pharmathen.com
Email: edova@pharmathen.com
Contact: Evangelia Dova

Pharmathen, located in Athens, Greece, was founded in 1969. With 3 state-of-the-art R&D laboratories, Pharmathen's core business is the out-licensing of complex generics & advanced pharmaceutical technologies to pharma companies globally. Over & above, Pharmathen aspire to deliver top-class pharmacovigilance services safeguarding regulatory compliance & market presence for clients' products.

Pilgrim Quality Solutions ..... Booth B18

Email: sandy.carson@pilgrimquality.com
Contact: Sandy Carson

Pilgrim Quality Solutions is the leader in quality compliance management software and services for Life Sciences, helping companies worldwide achieve quality system compliance and pass regulatory audits. Our cloud-based and on-premise solutions include in-the-box best practice workflows, document and process management, dashboards, electronic signatures, audit trails, and automated validation

Pope Woodhead ..... Booth C16

Website: www.popewoodhead.com
Email: laura.waite@popewoodhead.com
Contact: Laura Waite

Pope Woodhead, a Huron company, provides strategic advisory & integrated solutions to the life sciences industry. We are dedicated to helping our clients innovate within a highly regulated, complex, global market place. Our core offerings include benefit-risk drug safety, commercialisation, and organisation and digital enablement.

EXHIBITOR DIRECTORY

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PQE ..... Booth B2

Website: www.pqe.eu
Email: info@pqe.eu
Contact: Francesco Amorosi

«PQE is a complete quality solution provider operating in the life science industry since 1998. Thanks to the 16 offices worldwide from Japan to USA, we can rapidly support you anywhere you require in the following areas:

- Data Integrity Assurance & CSV,
- Qualification & Engineering,
- Compliance,
- Regulatory Affairs,
- Third Party Auditing.»

PrimeVigilance Limited ..... Booth E7

Website: www.primevigilance.com
Email: florence.denance.habek@primevigilance.com
Contact: Florence Denance Habek

PrimeVigilance is focused on providing high quality pharmacovigilance and medical information services. We have proven expertise and the international presence to assure clients that patients and products will be adequately protected. We have over 300 experienced PV and MI professionals across our 5 offices in Europe and the USA.

ProductLife Group ..... Booth C21

Website: www.productlifegroup.com
Email: SSchmitt@productlife-group.com
Contact: Sebastien Schmitt

ProductLife Group specialises in helping international life sciences organisations more effectively get their products and therapies to market by providing those clients with functional support across all of the regulated stages of the product life cycle—from development to launch, to postmarketing. Visit ProductLife Group at www.ProductLifeGroup.com

Promedim Ltd ..... Booth G10

Website: www.promedim.com
Email: hugh.devine@promedim.com
Contact: Hugh Devine

Promedim are a fully validated medical monitoring solution that ensure 24/7 real time coverage and reporting of physician availability delivered through a combination of in-house and Promedim medics, our dedicated control centre and the Promedim24 software App that provides access to our secure document repository for protocols and related material.

Prudentia Group ..... Booth E16

Website: www.prudentia-grp.com
Email: info@prudentia-grp.com
Contact: Krishna Patel

Prudentia provides pharmacovigilance management and technology consulting services to the pharmaceutical and medical device industries. We advise companies on processes and technologies in support of clinical and post marketing safety and surveillance. We provide technology solutions to enhance Safety.

Real Life Sciences ..... Booth C1

Website: realstaffing.com
Email: t.way@sthree.com
Contact: Thomas Way

Real Life Sciences is a specialist, global recruitment partner, leading the field in Pharma, Biotech and Medical Devices recruitment. Our customers are at the heart of everything we do. We work hard to understand our clients' objectives and our candidates' motivations so we can match the right people to your company.

Regulatory Pharma Net ..... Booth D6

Website: www.regulatorypharmanet.com
Email: a.falezza@regulatorypharmanet.com
Contact: Dr Anita Falezza

Regulatory Pharma Net (RPN) offers regulatory affairs, drug development, pharmacovigilance services, P&R and market access. RPN is partner of many pharmaceutical companies, managing hundreds of multitask projects, on a worldwide scale.

Rephine Limited ..... Booth B21

Website: http://rephine.com/
Email: vma@rephine.com
Contact: Viktoria Angelova

Rephine is one of the leading pharmaceutical consultancies & provides services to the pharmaceutical, medical device and biotechnology industry worldwide. Rephine is a specialist in GMP&GCP compliance, providing consultancy & auditing services. Rephine has conducted a 1000 GMP&GCP audits & has a library of 150 audit reports available for purchase.

SG Research International ..... Booth B4

Website: www.sgrintl.com
Email: sgilbride@sgrintl.com
Contact: Stephen Gilbride

«SG Research International (SGRI) with offices in Wyckoff, NJ and Beijing, China was founded in 2006 and is owned and managed by Stephen Gilbride. He has more than twenty years of experience in the Pharmaceutical Industry and holds a Master's Degree in Drug Regulatory Affairs.

SGRI has a talent network of seasoned and regionally-based GxP auditors with backgrounds in the Global Pharmaceutical and Biotech Industries as well as with Regulatory Authorities.

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SEC Recruitment Ltd ..... Booth A16

Website: www.secrecruitment.com
Email: info@secrecruitment.com
Contact: Chris Howard

At SEC we're proud to be one of Europe's leading talent acquisition specialists for Contract Research Organisations (CRO), pharmaceutical and other life science businesses and when you choose to work with us, you'll be working with a company who lives by the values of trust, honesty, integrity and commitment. Call us today and let us help you with your staffing requirements.

SQN - Syne qua non ..... Booth F11

Website: http://www.synequanon.com/
Email: Karen.grover@synequanon.com
Contact: Karen Grover

SQN was founded in 1996 and is one of the largest functional biometrics suppliers in Europe providing global pharma, biotech, medical device and animal health partners with innovative, cost effective development services in data management, EDC systems, statistics, project management, quality management, consultancy audits, medical writing and electronic data preparation and submission including ISS/ISE.

Stefanini ..... Booth C14

Website: www.stefanini.com / www.integron.com
Email: Denis.Reynders@stefanini.com or emea.stefanini.com
Contact: Mr. Denis Reynders

Stefanini is a global player with 22000+ staff and $1.2bn+ sales annually. Stefanini has offered eHealth support services since 2000, bringing multi-lingual support services (24+ languages) to more than 250,000 global eClinical end-users on a variety of platforms. Stefanini has a partnership with Integron (IoT Managed Services). Integron offers kitting, configuration, cellular and logistics services.

Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) ..... Booth A3

Website: http://www.scopejointaction.eu/
Email: Scope@mhra.gsi.gov.uk and Louise.Loughlin@mhra.gsi.gov.uk
Contact: Louise Loughlin

Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) was aimed to help medicine regulators operate pharmacovigilance systems to EU legislative requirements. Regulators have worked together and delivered recommendations, guidance, learning materials and other tools to improve the skills and capability in the PV network.

Synchrogenix ..... Booth C22

Website: www.synchrogenix.com
Email: kirra.sponenberg@synchrogenix.com
Contact: Kirra Sponenberg

Synchrogenix is a global medical and regulatory writing consultancy. We partner with pharmaceutical and biotechnology companies to support the critical tasks of data interpretation, message development, and submission leadership. Synchrogenix develops documents on behalf of sponsor organizations for submission to regulatory agencies and lay audiences worldwide.

Synevo Central Labs ..... Booth E1

Contact: Michal Dysko

Synevo Central Labs is the largest wholly-owned, fully-harmonized and GCLP accredited network of central laboratories in Europe dedicated exclusively to support clinical trials. Synevo Central Labs supports global clinical trials through globally-harmonized network of partner central labs located all over the world.

Tarius A/S ..... Booth E12

Website: www.tarius.com
Email: max@tarius.com
Contact: Michael Axelsen

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The Regulatory Affairs Company™ ..... Booth G6

Website: http://www.theregulatoryaffairscompany.com/
Email: Audrey_jamieson@theclinicaltrialcompany.com
Contact: Audrey Jamieson

The Regulatory Affairs CompanyTM is the division of The TCTC GroupTM, a full service global specialist Clinical Contract Research Organization, that is comprehensively experienced in providing global regulatory consultancy and medical writing services to pharmaceutical and device companies and assisting them meet their legislative requirements.

ThreeWire, Inc. ..... Booth C9

Website: www.threewire.com
Email: bgould@threewire.com
Contact: Bruce K. Gould

ThreeWire is a patient recruitment, enrollment, retention and management provider focused on accelerating patient recruitment and enrollment for the medical device, pharmaceutical and biotech industries. Our customized programs provide valuable solutions for sponsors, CROs, sites and patients in North America, Latin America, Europe and Middle East.

EXHIBITOR DIRECTORY

SUMMARIES PROVIDED BY EXHIBITING COMPANY AS OF 20 MARCH 2017

Tissue Solutions Ltd ..... Booth F24

Website: www.tissue-solutions.com
Email: Derek@tissue-solutions.com
Contact: Dr Derek McFerran

Tissue Solutions Ltd is an ISO 9001:2015 accredited provider of high quality human biomaterials for pre-clinical research and discovery biomarker research. We have a global network of more than 120 ethically approved sources of biosamples. We support projects by providing reliable access to high quality, highly annotated biomaterials fit for purpose and tailored to individual needs. Tissue Solutions also holds a Research Tissue Bank Licence in the UK.

TRAC - The Regulatory Affairs Consultancy ..... Booth D7

Website: www.tracservices.co.uk
Email: hello@tracservices.co.uk
Contact: Harriet Wills

Do you need to increase the people in your regulatory affairs team? Outsource a project? Launch a new product in other countries? Obtain a Marketing Authorisation for a new product? 85% of our business is from returning customers; confident with our individual, innovative, quality and friendly service. We are refreshingly different. Tempted?

TransPerfect ..... Booth D4

Website: www.transperfect.com
Email: tscott@transperfect.com
Contact: Terra Scott

TransPerfect Life Sciences specialises in supporting global development and commercialisation of drugs, treatments and devices designed to improve and save lives. Our comprehensive solutions include eTMF and eClinical technologies, paper TMF migration, pharmacovigilance and safety solutions, translation and language services, and call centre support. With offices in over 90 cities worldwide, TransPerfect is the ideal partner to ensure that your global launch makes a global impact.

Trilogy Writing & Consulting..... Booth D14

Email: evija.kuemmel@trilogywriting.com
Contcact: Evija Kuemmel

At Trilogy, medical writing is our passion. As specialists in clinical regulatory documentation, we provide a service that is more than just writing. Our writers are integral parts of our clients' teams. We proactively plan, coordinate and write clinical documents to meet aggressive timelines, with a readability that reduces the time for approval.

UNIVERSAL MEDICA ..... Booth E6

Website: www.universalmedica.com
Email: rafi.mardachti@universalmedica.com
Contact: Rafi Mardachti

Universal Medica is a Global Contract Services Organization which offers a full range of services including Medical Information, Medical Communication, Crisis Management and Communication, Pharmacovigilance and Risk Management, Real-World Evidence and Market Access.

Uppsala Monitoring Centre ..... Booth E13

Website: www.who-umc.org
Email: Info@who-umc.org
Contact: Anna Mattsson (at location), Anette Sahlin (UMC coordinator)

Uppsala Monitoring Centre is a non-profit foundation and centre for international service and scientific research. Our vision is a world where all patients and health professionals make wise therapeutic decisions in their use of medicines. Our mission is to support and promote patient safety through effective global pharmacovigilance practice.

Veeva Systems UK Limited ..... Booth B22

Website: www.veeva.eu
Email: laura.garrido@veeva.com
Contact: Laura Garrido

Veeva Systems Inc. is a leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva has more than 500customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. For more information, visitwww.veeva.com/eu.

Veristat ..... Booth D12

Website: www.veristat.com
Email: marketing@veristat.com
Contact: Andrew Bowen

Veristat is a full-service consultative CRO that is committed to partnering with clients to advance their therapies through the clinical development and regulatory submission process. Ultimately, we guide biopharmaceutical firms to market success so that their therapies become available to improve and save people's lives.

Xendo B.V. & Sofus Regulatory Affairs AB..... Booth C20

Website: www.xendo.com & www.sofus.se
Email: info@xendo.com
Contact: Nick Veringmeier (Xendo)
Lovisa Rosenquist (Sofus)

«Xendo is a leading consultancy and project management organisation in the fields of (bio)pharmaceutical products, medical devices and healthcare.

Together with the recently acquired Sofus Regulatory Affairs, over 220 experienced and highly educated professionals offer their expertise ranging from strategic advice and project management to auditing, operational support and training.»

EuroMeeting Glasgow 2017
SESSION OVERVIEW

	Theme 1	Theme 2	Theme 3	Theme 4	Theme 5
	Globalisation – What are the Current Successes and Challenges?	Innovation – What are the Key Success Factors?	Current Challenges in Clinical Research	eHealth/Big Data/Master- and Reference Data Management	Pharmacovigilance
Wednesday, 29 March 2017					
09:00-10:30	UK Satellite Session - Hall 2 | IMI Session - Hall 1				
09:00-12:30	Short Courses - See Final Programme page 14 to 17				
11:00-12:30	Regulatory Town Hall Meeting - Lomond				
14:00-15:30	Opening Plenary Session - Clyde Auditorium				
Session 1 16:30-18:00	Session 0101 Global Dossier for Clinical Development	Session 0201 Creating a Framework for Innovation I: Incentives and Regulatory Frameworks	Session 0301/0601 Benefit/Risk Communication: Towards a Patient-Centred Approach	Session 0401 Innovation through eHealth Data	Session 0501 Global Pharmacovigilance and Risk Management in 2025
	Boisdale	Forth	Lomond	Dochart	Hall 1
Thursday, 30 March 2017					
09:00-10:30	DIAmond SESSIONS DIAmond Session 1: Major Regulatory Challenges Enabling Decision Making for Early Patient Access				
	Lomond				
Session 2 11:00-12:30	Session 0102 Update of PMDA Activities	Session 0202 Creating a Framework for Innovation II: Infrastructure and Collaborations	Session 0302 EU Clinical Trial Regulation and Its Implications	Session 0402 Best Solutions for Master Data Management	Session 0502 Social Media Analytics for Safety Monitoring and Comunication
	Boisdale	Carron	Hall 5	Dochart	Hall 1
Session 3 14:00-15:30	Session 0103 Quality Standards across the Globe - Evolution and Enforcement	Session 0203 Leveraging Information beyond Randomised Clinical Trials: How Real World Data Can Contribute to Decision-Making	Session 0303 Immunogenicity Assessment – Risk-Based Approaches	Session 0403 EU Telematics beyond Cost and Timelines	Session 0503 How Optimal Regulatory Decision Making Relies on Excellent Regulatory Science
	Boisdale	Hall 5	Carron	Dochart	Hall 1
Session 4 16:00-17:30	Session 0104 Vaccine Pandemic Preparedness - New Approaches	Session 0204 Do Payers and Patients Have a Role in Supporting Innovation?	Session 0304 GCP Inspection Findings and the Benefit-Risk Balance	Session 0404 Interoperability: Avoiding Babylonian Confusion	Session 0504/0904 Patient Leaflets, Educational Materials and Patients - How to Increase Their Effectiveness in the Real World *16:00-17:45*
	Boisdale	Hall 5	Carron	Dochart	Lomond
Friday, 31 March 2017					
09:00-10:30	DIAmond SESSIONS DIAmond Session 3: Global Regulatory Convergence				
	Lomond				
Session 5 11:00-12:30	Session 0105 Impacts of Trade Negotiations for Regulator and Industry Cooperation	Session 0205 Creating a Favourable Environment for Advanced Therapy Medicinal Products (ATMPs)	Session 0305 Translational Research: Transition between Research and Development Phases, Applied Clinical Biomarkers	Session 0405 From Inventive Ideas to Implemented Innovation	Sesison 0505 Eudravigilance, The New ICH E2B(R3) ICSR and the EU Telematics Programme- How to Prepare for Change
	Boisdale	Hall 5	Carron	Dochart	Hall 1
13:30-14:30	Conference Insights and Outcomes - Rapid Fire Session				
	Lomond				

EuroMeeting Glasgow 2017

SESSION OVERVIEW

Theme 6	Theme 7	Theme 8	Theme 9	Theme 10	
Regulatory Science	Medical Devices and Combination Products	HTA, Value and Access	Information on Medicines, Medical Writing and Dossier Generation	Special Populations	Hot Topics/Stand Alone Sessions
Wednesday, 29 March 2017					
UK Satellite Session - Hall 2 | IMI Session - Hall 1					
Short Courses - See Final Programme page 14 to 17					
Regulatory Town Hall Meeting - Lomond					
Opening Plenary Session - Clyde Auditorium					
Session 0301/0601 Benefit/Risk Communication: Towards a Patient-Centred Approach	Session 0701 Keynote Session: Headlines of the New EU MDR & EU IVDR	Session 0801 Adaptive Approaches and Patient Access	Session 0901 Information on Medicines for Lay Audiences	Session 1001 10 Years On: Has the Paediatric Regulation Achieved its Aims?	Session 1101 The Evolving Role of Clinical Biomarkers and Biobanking in Today's Search for Innovative Cure
Lomond	Seminar Suite	Carron	Alsh 2	Alsh 1	Hall 2
Thursday, 30 March 2017					
DIAmond SESSIONS DIAmond Session 2: Current Trends and Solutions in Global Clinical Operations					
Hall 1					
Session 0602/0902 EMA's Policy 70: Opportunities, Challenges and Measuring Success	Session 0702 Consultations for Combination Products and Substance-Based Medical Devices	Session 0802 Value Demonstration Planning for Pharmaceutical Companies to Support Pricing and Reimbursement	Session 0602/0902 EMA's Policy 70: Opportunities, Challenges and Measuring Success	Session 1002 Optimising the Development of Paediatric Medicines Therapeutic Target	Session 1102 Market Access Roundtable Update: Financing of Therapeutics in Europe – Beyond Traditional Approaches
Lomond	Seminar Suite	Alsh 2	Lomond	Alsh 1	Hall 2
Session 0603/1003 The Future of the EU Orphan Drug Network	Session 0703 Balancing Clinical Evaluations versus Clinical Studies	Session 0803 Real World Evidence for the Future	Session 0903 Making Submission Documents Transparency- Ready: Challenges, Approaches, and Best Practices	Session 0603/1003 The Future of the EU Orphan Drug Network	Session 1103 Brexit - Where Are We Now?
Lomond	Seminar Suite	Alsh 1	Alsh 2	Lomond	Hall 2
Session 0604 Early Access Tools: 10 Years Experience and Lessons Learned with Conditional MAs in the EU	Session 0704 Post-Market Surveillance and Vigilance – Globalisation and Data Pooling	Session 0804 The Patient at the Centre of Adaptive Approaches	Session 0504/0904 Patient Leaflets, Educational Materials and Patients- How to Increase Their Effectiveness in the Real World *16:00-17:45*	Session 1004 Conducting Trials in Hard-to-Reach Populations: Adolescents, Pregnant Women and Older People	Session 1104 Real World Evidence in Pharmacovigilance - Making the Most of the Data
Hall 1	Seminar Suite	Alsh 2	Lomond	Alsh 1	Hall 2
Friday, 31 March 2017					
DIAmond SESSIONS DIAmond Session 4: Clinical Development Partnering 2.0					
Hall 1					
Session 0605 The 3R's: Reinvigorating, Repurposing and Reclassification	Session 0705 IVD and Companion Diagnostics in the Era of Personalised Medicines	Session 0805 The Pillars of Decision Making: Regulators, HTAs, Payers/Budget Holders	Session 0905 The Importance of Good Communication in Risk Management		Session 1105 ICMRA - A Global Coalition of Medicines Regulators
Lomond	Seminar Suite	Alsh 1	Alsh 2		Hall 2
Conference Insights and Outcomes - Rapid Fire Session					
Lomond					

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