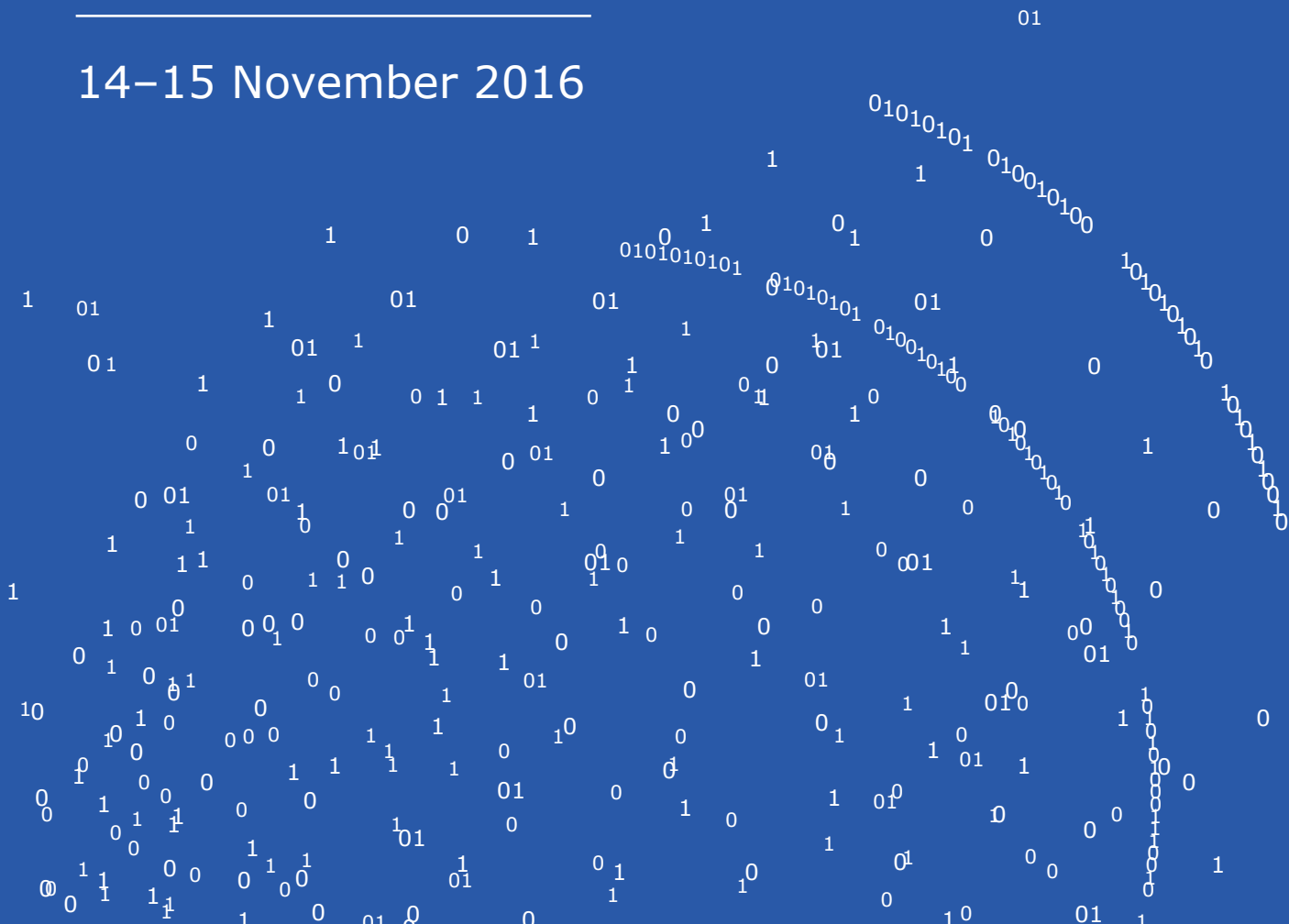
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Identifying opportunities for 'Big Data' in medicines development and regulatory science

14–15 November 2016



Background and objectives

Rapid developments in technology have resulted in the generation of vast volumes of data, creating new evidence which has the potential to add significantly to the way the benefit-risk of medicinal products is assessed over their entire life cycle.

While creating huge opportunities, it is recognised there are also significant challenges in the exploitation of these data. For example there is a fundamental need to establish appropriate access to the data, to understand their strengths and limitations and to apply new analytical methods to integrate and analyse the heterogeneous datasets in order to generate conclusions which contribute to regulatory decision making. Importantly, compliance with data protection legislation ensuring robust mechanisms to protect patient confidentiality is critical for securing patient trust.

It is important for the European Medicines Agency and the European Union Medicines Regulatory Network to gather information on the latest developments in the field of big data from the perspective of different stakeholders. This will begin to clarify how and when the multitude of data sources may contribute to medicinal product development, authorisation and surveillance.

This meeting brings together a group of individuals who can inform on the advances being made in this field and the opportunities for the application of big data in medicine.

Scope

This workshop will be of interest to all stakeholders involved in medicines development and regulatory science: health authorities; healthcare professionals; patient associations; regulators; pharmaceutical industry; academics; civil-society organisations; corporate decision-makers.

Sessions

Session 1 The Big Data Landscape

Session 2 Big Data meets Medicines Regulation: Which data and When?

Session 3 How do we transform Data into Knowledge to support decision making?

Session 4 Reconciling Big Data and Privacy: Legal safeguards for unleashing technological innovation

Session 5 Panel discussion: Brainstorming Big Data

Outputs

The workshop is being broadcast live via the website. Both a recording of the workshop and a written synopsis will be made publicly available.

Workshop venue: CCT Venue Plus, 195 Marsh Wall, South Quay, London

14 November 2016 – 1st floor, Spice Room

12:30	**Registration**		
	Coffee and biscuits		
13:30	**Welcome and Introduction**		
	Guido Rasi, Executive Director, European Medicines Agency (EMA)		**10'**
13:40	**Session 1: The Big Data Landscape**		
Chair:	**Jean Georges**, Alzheimer Europe	**setting the scene**	**5'**
Co-chair:	**Fergus Sweeney**, EMA		
	The Age of Big Data and the Power of Watson **Lisa Latts**, IBM Watson Health		**25'**
	Data Management in the Cloud - Lessons learned from Inside Google **Nico Gaviola**, Google Cloud Platform		**25'**
	Delivering Better Transport through Big Data Innovation **Lauren Sager Weinstein**, Transport for London		**25'**
	Discussion		**10'**
15:10	**Session 2: Big Data Meets Medicines Regulation: Which Data and When?**		
Chair:	**Luca Pani**, Italian Medicines Agency	**setting the scene**	**5'**
Co-chair:	**Alison Cave**, EMA		
	Biomedical Discovery through Data Mining and Data Science **Nicolas Tatonetti,** University of Columbia		**25'**
15:40	**Coffee break**		**30'**
16:10	**Session 2: Big Data Meets Medicines Regulation: Which Data and When?**		
	Enabling Precision Medicine and the Transformation of Healthcare Systems: Thoughts on Data and Technology Strategies **Brian Kelly**, Association of Clinical Research Organizations (ACRO)		**25'**

Integrating Pharmacogenomics into Decision Making 25'
Munir Pirmohamed, University of Liverpool

Identifying the Future Needs for Big Data in Medicines Regulation 25'
Hans Hillege, EMA Committee for Medicinal Products for Human Use

The Future: partly FAIR, partly Cloudy 25'
Barend Mons, European Science Cloud, Leiden University

Big Data: Current and Future Initiatives of the European Commission 25'
Roger Lim, European Commission DG SANTE

Leveraging Big Data for Better Health Outcomes: The Need for a Collaborative Space and Common Solutions 15'
Richard Bergstrom, European Federation of Pharmaceutical Industries and Associations (EFPIA)

18:30 End of day 1

18:30 Reception and dinner (venue restaurant)

Workshop venue: CCT Venue Plus, 195 Marsh Wall, South Quay, London

15 November 2016 – 1st floor, Spice Room

08:15	**Registration**	
	Coffee and biscuits	
08:45	**Session 3: How do we Transform Data into Knowledge to Support Decision Making?**	
Chair:	**Thomas Senderovitz**, Danish Medicines Agency **setting the scene**	**5'**
Co-chair:	**Paolo Alcini**, EMA	
Keynote:	**FDA Approaches to Analytical Challenges Posed by Big Data** **David Martin**, Food and Drug Administration	**30'**
	Case study: Large scale analytics for Electronic Health Records - OHDSI: Observational Health Data Sciences and Informatics **Patrick Ryan**, Observational Health Data Sciences and Informatics	**25'**
	Case study: Specific Challenges around data analytics for Social Media Data **Marcel Salathé**, École Polytechnique Fédérale de Lausanne	**25'**
	An Industry Perspective on Big Data **Bart Vannieuwenhuyse**, European Federation of Pharmaceutical Industries and Associations (EFPIA)	**25'**
	Discussion	**15'**
10:50	**Coffee break**	**25'**
11:15	**Session 4: Reconciling Big Data and Privacy: legal safeguards for unleashing technological innovation**	
Chair:	**Jon Snaedal**, World Medical Association **setting the scene**	**5'**
Co-chair:	**Alessandro Spina**, EMA	
	Big Data and the New EU Data Protection Regulation (GDPR) **Sophie Louveaux**, European Data Protection Supervisor	**25'**
	Mechanisms to Meet Privacy Requirements for Clinical Data Management in Large Observational and Experimental Studies **Ronald Brand**, University of Leiden	**25'**
	Ethical and Governance Aspects of Research Data: Experience from UK Biobank **Helene Hayman**, House of Lords, UK Biobank Ethics and Governance Council	**25'**
	Wacean. A patient-driven innovative tool for data capture **Julian Isla,** Dravet Syndrome Foundation	**25'**
	Discussion	**15'**

13:15	**Lunch (venue restaurant)**	**45'**

14:00 Session 5: Panel discussion: Brainstorming Big Data

***Moderator/Chair*: Pierre Meulien**, Innovative Medicines Initiative (IMI) **105'**

This session will debate the key questions raised during the meeting specifically in the context of medicines development and regulation

Panellists:

Ian Hudson, Medicines Healthcare and Product Regulatory Agency

Andrew Leach, European Bioinformatics Institute

Miriam Sturkenboom, Erasmus University Medical Center

Rob Hemmings, Medicines Healthcare and Product Regulatory Agency

Olaf Klungel, University of Utrecht

Stephen Evans, London School of Hygiene and Tropical Medicine

Thomas Senderovitz, Danish Medicines Agency

Hugo Hurts, Medicines Evaluation Board

Bart Vannieuwenhuyse, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Lisa Latts, IBM Watson Health

15:45 Closing remarks

Guido Rasi, EMA **15'**

16:00 End of workshop

List of speakers, co-chairs and panellists

Paolo Alcini	European Medicines Agency
Ronald Brand	Leiden University, Netherlands
Alison Cave	European Medicines Agency
Stephen Evans	London School of Hygiene and Tropical Medicine, United Kingdom
Nico Gaviola	Google Cloud Platform, United Kingdom
Jean Georges	Alzheimer Europe, Luxembourg
Baroness Helene Hayman	House of Lords, UK Biobank Ethics and Governance Council, United Kingdom
Robert Hemmings	Medicines and Healthcare products Regulatory Agency, United Kingdom
Hans Hillege	EMA Committee for Medicinal Products for Human Use, Medicines Evaluation Board, Netherlands
Ian Hudson	Medicines and Healthcare products Regulatory Agency, United Kingdom
Hugo Hurts	Medicines Evaluation Board, Netherlands
Julian Isla	Dravet Syndrome Foundation, Spain
Brian Kelly	Association of Clinical Research Organizations (ACRO) representative, United States of America
Olaf Klungel	University of Utrecht, Netherlands
Lisa Latts	IBM Watson Health, United States of America
Andrew Leach	European Bioinformatics Institute, United Kingdom
Roger Lim	European Commission DG SANTE, Belgium
Sophie Louveaux	European Data Protection Supervisor (EDPS), Belgium
David Martin	Food and Drug Administration, United States of America
Pierre Meulien	Innovative Medicines Initiative, Belgium
Barend Mons	European Science Cloud, Leiden University, Netherlands
Luca Pani	Italian Medicines Agency, Italy
Munir Pirmohamed	University of Liverpool, United Kingdom
Patrick Ryan	Observational Health Data Sciences and Informatics, United States of America
Richard Bergström	European Federation of Pharmaceutical Industries and Associations (EFPIA) representative, Belgium
Lauren Sager Weinstein	Transport for London, United Kingdom
Marcel Salathé	École Polytechnique Fédérale de Lausanne, Switzerland

Thomas Senderovitz	Danish Medicines Agency, Denmark
Jón Snædal	World Medical Association, Iceland
Alessandro Spina	European Medicines Agency
Miriam Sturkenboom	Erasmus University Medical Center, Netherlands
Fergus Sweeney	European Medicines Agency
Nicholas Tatonetti	Columbia University, United States of America
Bart Vannieuwenhuyse	European Federation of Pharmaceutical Industries and Associations (EFPIA) representative, Belgium

Workshop attendees

Speakers

Prof Guido Rasi

Executive Director, European Medicines Agency

Professor Guido Rasi began his second term as Executive Director of EMA on 16 November 2015. From November 2014 to mid-November 2015, Professor Guido Rasi served as EMA's Principal Adviser in Charge of Strategy. From November 2011 to November 2014 he was the Executive Director of the European Medicines Agency and a member of its Management Board in the three years prior to this. He was Director-General of the Italian Medicines Agency from 2008 to 2011 and member of the Management Board from 2004 and 2008. He was made full professor of microbiology at the University of Rome 'Tor Vergata' in 2008. From 2005 to 2008 he was Director of the Institute of Molecular Medicine of the National Research Council in Rome. From 1990 to 2005 Professor Rasi worked at the Institute for Experimental Medicine of the National Research Council, Italy. He had teaching and research experience at the University of California, Berkeley in 1999. Professor Rasi holds a degree in medicine and surgery, with specialisations in internal medicine, allergology and clinical immunology, from the University of Rome. From 1978 to 1990, he worked as a physician in hospital, research and private practice. He is author of more than 100 scientific publications. Prof Rasi was born in Padova, Italy and is married with two children.

Introduction and objectives of the workshop

I am delighted to be able to welcome you to this EMA workshop focused on identifying opportunities for Big Data in medicines development and regulatory science.

Big data is an area that is generating unprecedented interest and excitement across the globe. In the healthcare world, simultaneous technological advances in both basic science and information technology have led to the generation of datasets which offer tantalising promise for the future. We believe these new sources of evidence will complement traditional evidence, for example from randomised clinical trials, enabling better informed decisions, potentially transforming the way we regulate medicines. The challenge is to understand how to exploit these data and incorporate this thinking into regulatory practice. It is therefore timely that the regulatory community begins a conversation on the opportunities and challenges posed by these diverse datasets. This workshop contributes to that conversation with the objective of identifying the key opportunities and challenges.

I very much hope you enjoy the workshop and thank you in advance for all your contributions. Through our dialogue on big data I believe we can move closer to realising its potential for better health promotion and protection.

Lisa M. Latts, MD, MSPH, MBA, FACP

Deputy Chief Health Officer, IBM Watson Health

Dr Lisa Latts is the Deputy Chief Health Officer for IBM Watson Health. Her area of focus is using cognitive computing to improve value in healthcare delivery as well as quality improvement. Prior to this, she was the Principle of LML Health Solutions, and the Chief Medical Officer for the self-insured health plans at the University of California. Dr Latts also served as Vice President for Public Health Policy and Programs in Clinical Excellence with Anthem, Inc. (WellPoint,) where she was instrumental in developing many of their value based payment and delivery system reform initiatives such as the Patient Centered Medical Home, Pay for Performance, Centres of Excellence, and International Medical Tourism. Dr Latts is a national leader in health quality and health policy and is currently chair of the NCQA Standards Committee and co-chair of the Cost and Resource Use committee for the National Quality Forum. She is board certified in Internal Medicine. She received her MD from the University of Minnesota, an executive MBA from the University of Colorado's Leeds School of Business and a MSPH from the University of Colorado.

Presentation:

The Age of Big Data and the Power of Watson

Abstract:

The discussion will focus on the rapidly changing healthcare landscape and the opportunity to use "big data" analytics technology to develop innovative solutions in health care. The explosion of data, coupled with the increasing use of the 'Internet of Things' are paving the way for new advancements and insights into health and disease. Watson cognitive technology has the ability to understand, reason and learns and will provide opportunities to improve health, and personalize healthcare. Use cases where Watson technology can accelerate drug discovery and monitor drug safety and increase the personalization of medicine will be presented.

Key messages:

- It is impossible for humans in healthcare to keep up with the explosion of information.
- Big Data is here and can transform healthcare
- Cognitive technology understands, reasons and learns
- Big Data technology can be used to accelerate drug discovery
- Cognitive technologies can improve access to personalization of medicine.

Nico Gaviola

Head of Life Sciences and Healthcare UK, Google Cloud Platform

Nico Gaviola is the Head of Life Sciences and Healthcare for the Google Cloud Platform in the UK. In his role, he helps companies of all sizes tackle IT challenges by leveraging Google's IaaS, PaaS, Big Data and Machine learning services. Prior to Google, Nico spend 10 years in business development for leading SaaS providers across Europe, the Middle East and Africa region (EMEA).

Presentation:

Data Management in the Cloud - lessons learned from inside Google

Abstract:

Since its inception, Google's mission has always been to organise the world's information and make it universally accessible and useful. In order to accomplish this vision, Google engineers have had to create the framework for big data management and processing such as Mapreduce or BigTable. The Google Cloud Platform (GCP) is now making the same data services Google uses internally to power Search, Maps, YouTube, Gmail and Android available as managed services to the enterprise. These services are revolutionising the way companies can store, process and analyse their data and begin to apply machine learning.

Key messages:

- Google Research is behind many open source projects that led to the big data movement
- GCP data services are removing the friction enterprises face to access, query and analyse their data.

Ms Lauren Sager Weinstein

Head of Analytics, Transport for London

Lauren Sager Weinstein, Head of Analytics at Transport for London, has responsibility for the analysis of customer data, supporting operational and planning areas in delivery of services to TfL's customers. She joined TfL in 2002, where she has held a variety of roles- Senior Business Planner, Acting Head of Finance for London's Transport Museum, Chief of Staff to the Managing Director of Finance & Planning and the Head of Oyster Development. During her time at TfL, Lauren has worked on a number of projects: the establishment of TfL's first long-term funding package for infrastructure investment; the successful delivery of the London 2012 Olympic and Paralympic Games by providing analysis on travel patterns; the launch of contactless payment card acceptance on the TfL network; and the creation of TfL's ODX tool that provides a multi-modal picture of customer travel patterns. Originally from Washington, DC, USA, she has degrees from Princeton University and from the Harvard Kennedy School of Government.

Presentation:

Delivering better Transport through Big Data Innovation

Abstract:

Our purpose at TfL is to keep London working and growing and make life better. We must plan ahead to meet the challenges of a growing population, unlock economic development and growth and meet the rising expectations of our customers and users. Translating our vast amounts of data into intelligence to drive improvement helps us to do this. Millions of public transport and road journeys are made every day offering vast quantities of information. For example, there are nineteen million daily 'taps' captured through our ticketing system alone. We create 5.2 billion records through our 15,000 traffic signal loop detectors, and huge quantities of data from our other sensors and signals. This is combined with insight from customer surveys and social media to increase its practical application to plan services more efficiently and improve reliability. Information from our data tools informs our customers about travel options on the network, particularly during busy times or times of disruption. We also use our ticketing data to refund our customers when things go wrong on our services. For many years we have used rail station entry and exit data for network planning from touches in and out with Oyster and contactless payment cards. We can now tell where customers are leaving a bus (where no exit touch is required) through a Big Data tool combining bus location and ticketing to create origin and destination pairs. As a result, we have a comprehensive picture of travel patterns across rail and bus networks to improve network and interchange planning and review the impacts of closures or diversions. Our data tools help us to operate and maintain our network more efficiently. For example, we have started identify opportunities for predictive maintenance on Underground trains, and we have built a real-time operational big data tool that used by our Road traffic control centre. These initiatives help us run our complex transport network better. They also benefit our customers as every penny we make goes back into improving services for the people who rely on them every day.

Key messages:

- Focus on the right questions and the problems you face
- Operational Infrastructure generates data – consider your needs when investing in infrastructure
- Rapidly test through POCs and deliver tangible and incremental results

- Don't get lost in the weeds. Avoid data for data’s sake.

Nicholas P. Tatonetti

Herbert Irving Assistant Professor, Columbia University

Dr Nicholas Tatonetti is assistant professor of biomedical informatics in the Departments of Biomedical Informatics, Systems Biology, and Medicine and is Director of Clinical Informatics at the Herbert Irving Comprehensive Cancer Centre at Columbia University. He received his PhD from Stanford University where he focused on the development of novel statistical and computational methods for observational data mining. He applied these methods to drug safety surveillance where he discovered and validated new drug effects and interactions. His lab at Columbia is focused on expanding upon his previous work in detecting, explaining, and validating drug effects and drug interactions from large-scale observational data. Widely published in both clinical and bioinformatics, Dr Tatonetti is passionate about the integration of hospital data (stored in the electronic health records) and high-dimensional biological data (captured using next-generation sequencing, high-throughput screening, and other "omics" technologies). Dr Tatonetti has been featured by the New York Times, Genome Web, and Science Careers. His work has been picked up by the mainstream and scientific media and generated thousands of news articles.

Presentation:

Biomedical Discovery through Data Mining and Data Science

Abstract:

Observation is the starting point of discovery. Based on observations scientists form hypotheses that are then tested. In the information trillions of observations are being made and recorded every day – from online social interactions to the emergency room visit. With so much data available, generating hypotheses using a single scientist's mind is no longer sufficient. Data mining is about training algorithms to recognize patterns in enormous sets of data and automatically identify new hypotheses. In this talk, I will discuss how we use data mining algorithms to identify unexpected effects of drugs used singly and in combination with other drugs. Using integrative informatics methods, we are able to discover drug-drug interactions that no one considered possible before. Finally, I will demonstrate how to use simple and efficient laboratory experiments to validate these hypotheses. In many cases these experiments can be executed in high-throughput by robotic systems, with the ultimate goal of automating the scientific method.

Key messages:

- Health Data Science
- Discovery Mining
- Large-scale Statistical Analysis
- Machine Learning
- Adverse Drug Reactions.

Brian Kelly, M.D.

President, Payer and Provider Solutions, QuintilesIMS

Dr Brian Kelly joined Quintiles in 2012 to lead the company's Payer and Provider Solutions businesses. His focus for the last twenty years has been on using healthcare technology to improve clinical care and research. Prior to joining Quintiles, Dr Kelly served as the Head of Informatics and as the National Medical Director for Aetna's large commercial clients. From 2003 to 2008, he worked at Accenture focused on the application of healthcare technology. Dr Kelly is a former Navy neurologist and intensive care medicine specialist who was the Head of the Critical Care Medicine department and a staff neurologist at the Navy's flagship hospital in Bethesda, Maryland.

Presentation:

Enabling Precision Medicine and the Transformation of Healthcare Systems: Thoughts on Data and Technology Strategies

Abstract:

Over the past two decades, hospitals, integrated delivery systems and providers have invested billions of pounds in electronic health records. Despite this, few systems have effectively utilized these investments to optimize clinical outcomes and the value of the care delivered. As we increasingly develop the ability to target effective therapies to smaller populations through precision medicine, the ability to identify these different cohorts and measure a variety of clinical outcomes becomes critically important. To do this effectively, a variety of data sources are required. This session will describe approaches to developing the data and technology infrastructure at the health system level to enable precision medicine.

Key messages:

- A variety of data types are needed to enable precision medicine
- These data types include: Clinical data; Lab and genomics data; Imaging data; Sensor data; Patient reported data
- The amount and size of these data sets will require them to be collected in a cloud computing environment
- Hospital systems need a well thought out, systematic approach to developing the infrastructure to collect and analyse this data
- If done properly, this comprehensive data set can be used to drive insights and better clinical outcomes through both traditional analytics and machine learning.

Prof Sir Munir Pirmohamed

David Weatherall Chair of Medicine and NHS Chair of Pharmacogenetics

Professor Sir Munir Pirmohamed is currently David Weatherall Chair in Medicine at the University of Liverpool, and a Consultant Physician at the Royal Liverpool University Hospital. He is also the Associate Executive Pro Vice Chancellor for Clinical Research for the Faculty of Health and Life Sciences. He also holds the only NHS Chair of Pharmacogenetics in the UK, and is Director of the M.R.C. Centre for Drug Safety Sciences, Director of the Wolfson Centre for Personalised Medicine and Executive Director, Liverpool Health Partners. He was awarded a Knights Bachelor in the Queen's Birthday Honours list in 2015. He is also an inaugural NIHR Senior Investigator, and Fellow of the Academy of Medical Sciences in the UK. He is also a Commissioner on Human Medicines. His research focuses on personalised medicine in order to optimise drug efficacy and minimise toxicity, move discoveries from the lab to the clinic, and from clinic to application. He has authored over 380 peer-reviewed publications, and has a H-index of 78.

Presentation:

Integrating Pharmacogenomics into Decision Making

Abstract:

There has been increasing interest in pharmacogenomics since the completion of the human genome project. Indeed, pharmacogenomics is now regarded as one of the early wins as we enter the precision medicine era. However, there are numerous challenges in developing the evidence base to incorporate pharmacogenomics into regulatory decision making and ultimately into clinical practice in healthcare systems. For new drugs, where the biomarker is co-developed with the drug as a companion diagnostic, evidence of efficacy will have been generated through randomized controlled trials in targeted populations, leading to the licensing of the drug-diagnostic combination, and appropriate wording in the indication section of the SmPC. More difficult is the situation where a biomarker has been identified after the drug has already been licensed and in some cases may be off patent. In such situations, it may not be possible to conduct randomized controlled trials, but whether observational real-world data, even when replicated in different studies and populations, is acceptable is not clear. This may particularly be the case for serious adverse events where the only possibility of generating evidence may be through observational studies because of the rarity of the event. Further disconnect may occur when health technology assessment shows the use of a diagnostic to predict dose or choice of drug is cost-effective, yet the SmPC may only provide data on the biomarker for information. There is now also a trend to undertake pre-emptive genotyping and provide genetic information at the point of prescribing (in the same way as we have renal function tests available), but how such data and practice will need to be handled in terms of regulatory decision making is unclear.

Key messages:

- Pharmacogenomic data is present in about 10% of summary of product characteristics, but most of it is for information only, and not mandatory.
- The evidence to incorporate pharmacogenomics data will depend on the stage of the development of the drug.

- In the era of big data, and multiple biomarkers affecting drug response, what is regarded as evidence for inclusion will need to be re-considered as randomised trials may not always be possible
- A challenge for drug regulation will be to ensure there is some consistency with health technology assessments and clinical guidelines
- As more patients begin to have pharmacogenomic data, either from direct to consumer genetic testing companies, or in their medical records, it will not be possible to ignore the data, but how (or whether) this will be dealt with through regulation needs full debate.

Hans Hillege, MD, MSc, PhD

Member: EMA Committee for Medicinal Products for Human Use

Hans Hillege is a Professor in Cardiology and member of the European Committee of Human Medicinal Products (CHMP) on behalf of the Netherlands. His fields of specialization and research include cardiovascular epidemiology and the impact of extracardiac comorbidities with specific interest in the coexistence of cardiovascular and kidney disease, epidemiological models, clinical trials, evidence based medicine, regulatory science, medical decision-making and health information technology.

Presentation:

Identifying the Future Needs for Big Data in Medicines Regulation

Abstract:

Different initiatives are running within the regulatory environment to accommodate big data. The scientific assessment within the EMA of new products and the supervision of medicinal products of already authorized medicinal products is supported by different scientific committees like the CHMP, COMP, PRAC, PDCO, SAWP and CAT. In today's presentation a number of user cases will be discussed from the various committees, taking into account their specific task and responsibilities, where the use of big data could fulfil an important supportive role.

Key messages:

- Benefit Risk
- Evidence
- Precision medicine
- Real world data
- Data harmonization and sharing.

Prof Barend Mons

Professor in Bio-Semantics, Leiden University, Lead for European Science Cloud

Barend Mons is a molecular biologist by training (PhD Leiden University 1986). He spent over 15 years in malaria research in close collaboration with endemic countries. After that he gained experience in computer-assisted knowledge discovery, which is still his research focus. He spent time with the European Commission as a Seconded National Expert with the INCO-DC programme (1993-1996) and with the Netherlands Organisation for Scientific Research (NWO 1966-1999). Barend also co-founded several spin off companies. In 2000 he founded the biosemantics group in Rotterdam and later also in Leiden. Currently, Barend is Professor in Biosemantics at the Human Genetics department of Leiden University Medical Centre, is Head of Node for ELIXIR-NL at the Dutch Techcentre for Life Sciences, Integrator Life Sciences at the Netherlands eScience Centre, and board member of the Leiden Centre of Data Science. In 2014, Barend initiated the FAIR data initiative and in 2015, he was appointed Chair of the European Commission's High Level Expert Group for the “European Open Science Cloud”.

Presentation:

The Future: partly FAIR, partly Cloudy.

Abstract:

The “European Open Science Cloud” (EOSC) is meant to be a supporting expert infrastructure for Open Science. This presentation will cover the aspects of Open and Participatory Science in which community curation and annotation of data is the key and will on the joint responsibility for data stewardship in Open Science. The concepts of data in machine actionable format and the concept of FAIR (Findable, Accessible, Interoperable, and Re-usable) data and other Research Objects will be explained. Finally, Barend will outline the future developments of The Internet of FAIR data and Services enabling Social Machines in Science and how users and producers of data merge into a knowledge creation communities where man-machine interaction is key. Examples will be from his own field: Human Genetics.

Key messages:

- Community curation
- Annotation
- Data stewardship
- Open science for regulation.

Roger Lim

Policy officer, European Commission DG SANTE, Unit Cross-border healthcare and eHealth

Roger Lim is a Dutch seconded national expert working for the European Commission DG SANTE in the unit Cross-border healthcare and eHealth since February 2015. He is part of the eHealth team working on the interoperability of health systems across the EU for the benefit of the cross-border exchange of health data. In the team he is responsible for managing the eHealth Network, which was set up under the cross-border healthcare Directive as a voluntary network of EU Member States where strategic decisions on eHealth at EU-level are made. He is further responsible for the topic of Big Data and topics related to the long term sustainability of eHealth in EU. Before coming to the European Commission, he worked for 6 years for the Dutch Ministry of Health, Welfare and Sports at the Health Insurance Directorate. There he, among other things, worked on the implementation of the Cross-Border Healthcare Directive into national law, but also on the risk equalization model of the health insurance system. Roger studied Business Economics at the Haarlem Business School, Business Administration at Macquarie University in Sydney (Australia), and holds a Master degree in Strategic Management from the Rotterdam School of Management (Erasmus University).

Presentation:

Big Data: current and future initiatives of the European Commission

Abstract:

Big Data has the potential to increase better health outcomes by improving the prediction of epidemics, prevention, and treatment delivery. Big Data could also improve the sustainability of health systems. eHealth unlocks the potential of generating more valuable data through e.g. mHealth and other eHealth solutions, but also increases access to existing data repositories across the EU. The eHealth Action Plan 2012-2020 of the European Commission sets out the framework for EU policy actions in eHealth that facilitates the further uptake of Big Data in health through research and other activities. Furthermore, a study on Big Data in public health, telemedicine and healthcare provides policy recommendations that should bring focus to future activities.

Key messages:

- eHealth unlocks the potential of Big Data in health
- Through the eHealth Action Plan 2012-2020 the European Commission commits itself to address barriers for a wider uptake of eHealth in the EU
- The European Commission supports research in the field of Big Data in health through funding
- The European Commission has published initiatives under the Digital Single Market Strategy that could facilitate Big Data in health
- Future policy actions specifically on Big Data in health are yet to be developed.

Richard Bergström

Director General, European Federation of Pharmaceutical Industries and Associations

Richard Bergström has been the Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA) since April 2011. Previously he served for nine years as the Director-General of LIF, the Swedish Association of the Pharmaceutical Industry, following positions in Switzerland in regulatory affairs at the pharmaceutical companies Roche and Novartis. Mr Bergström was also appointed by the Swedish Government to the Board of the Karolinska Institute. He is a pharmacist by training, receiving his MScPharm degree from the University of Uppsala, Sweden in 1988.

Presentation:

Leveraging big data for better health outcomes: the need for a collaborative space and common solutions

Abstract:

Both structured everyday clinical data and more diverse "big data" will transform the development of new medicines, and their introduction into health systems. If data on patient results (real outcomes) are available, biopharmaceutical companies can move to a new business model, in which developers are paid for results as opposed to by tablet or vial. An infrastructure for tracking each patient for safety and effectiveness also opens new approaches for regulators, including the option to approve new promising medicines earlier. However, the biggest impact of "big data" may be in discovery and early stages of development: understanding disease and the underlying causes. Such understanding may result in a step-change in research productivity. In other words: "data sharing is the new normal".

Key messages:

- Everyone is very excited about use of big data to advance science and deliver better health outcomes
- Patient-generated and patient-held health data will enable new solutions to track safety and effectiveness in real time
- With a common focus on health outcomes, and the availability of everyday clinical data will enable companies to agree new payment models, paying for results
- Connecting the physical world (medicines) with the digital one, such as through serialisation and wearables, will "close the loop" and deliver big data sets of good quality.

David Martin, MD, MPH

FDA Liaison to the Reagan Udall Foundation IMEDS Program

Office of the Centre Director, Centre for Drug Evaluation and Research

David Martin, MD, MPH is assigned to the FDA Centre for Drug Evaluation and Research as the FDA Liaison to the Reagan Udall Foundation, Innovation in Medical Evidence Development and Surveillance program. He is facilitating a system for routine private-sector queries related to medical products using a distributed database approach modelled on the FDA's Sentinel system. As a former Branch Chief and Division Director in the FDA Centre for Biologics Evaluation and Research, he led analyses of spontaneous reports, formalized risk management planning, and played a key role in the development of the Sentinel system. Before joining the FDA, Dr Martin served in the U.S. Air Force as a flight and occupational medicine physician. He received his bachelor's degree at the Citadel, his medical degree at the Johns Hopkins University School of Medicine, and his master of public health degree at the Johns Hopkins University Bloomberg School of Public Health.

Presentation:

FDA Approaches to Analytical Challenges Posed by Big Data

Abstract:

Real World Evidence derived from Big Data should be fit for purpose. This requires careful framing of questions as well as critical review of the context surrounding data collection. FDA is promoting exploratory work to embed randomization into the delivery of clinical care, facilitate trial recruitment, and incorporate data provided by patients. The Sentinel Infrastructure is being expanded in order to improve its utility to FDA and support broader uses by other stakeholders including the private sector. Public input, pilot projects, and review activities will inform future draft FDA guidance regarding the ways that Real World Evidence can contribute to the assessment of safety and effectiveness in regulatory submissions.

Key messages:

- It is not enough merely to have data, even very large amounts of it. Data are best understood as raw measurements which become information when we add critical context about what is being measured. That information can then be analyzed and combined to yield evidence, which in turn, can be used to guide decision-making for scientific and clinical questions
- Real World Evidence derived from Big Data should be fit for purpose
- FDA is supporting the integration of real world clinical care and rigorous clinical research (including randomization and planned interventions) to help answer outstanding questions about the safe and effective use of medical products in a broad range of populations
- The Foundation for the FDA (Reagan-Udall Foundation) is enabling access to a system modeled on the Sentinel Infrastructure in order to provide other stakeholders including the private sector with a high quality Real World Evidence resource.
- Proposed Prescription Drug User Fee Act commitments for fiscal years 2018-2022 include public input as well as publication of draft guidance on how Real World Evidence can contribute to the assessment of safety and effectiveness in regulatory submissions.

Patrick Ryan, PhD

Senior Director and Head, Epidemiology Analytics Janssen Research and Development

Patrick Ryan, PhD is Senior Director of Epidemiology and the Head of Epidemiology Analytics at Janssen Research and Development, where he is leading efforts to develop and apply analysis methods to better understand the real-world effects of medical products. He is currently a collaborator in Observational Health Data Sciences and Informatics (OHDSI), a multi-stakeholder, interdisciplinary collaborative to create open-source solutions that bring out the value of observational health data through large-scale analytics. He served as a principal investigator of the Observational Medical Outcomes Partnership (OMOP), a public-private partnership chaired by the Food and Drug Administration, where he led methodological research to assess the appropriate use of observational health care data to identify and evaluate drug safety issues. Patrick has received his undergraduate degrees in Computer Science and Operations Research at Cornell University, Master of Engineering in Operations Research and Industrial Engineering at Cornell, and PhD in Pharmaceutical Outcomes and Policy from University of North Carolina at Chapel Hill.

Presentation:

Case study: Large scale analytics for Electronic Health Records - OHDSI: Observational Health Data Sciences and Informatics

Abstract:

Thousands of researchers around the world are attempting to use observational data, such as electronic health records and administrative claims, to generate evidence about disease natural history, treatment utilization, and the effects of medical interventions. But are we actually doing more harm than good? The Observational Health Data Sciences and Informatics (OHDSI) collaborative was established as open science community to learn, develop, and apply scientific best practices to the appropriate use of observational data. OHDSI's mission is to "improve health, by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care." In this talk, we will explore how the current practice in observational research is performing, and demonstrate how advances in empirical evaluations and large-scale analyses can improve the transparency, reproducibility and reliability of population-level effect estimation. We will also highlight how a community and the world's largest international network offers opportunities to advance the science of pharmacovigilance and medical product evaluation through methodological research, open-source development, and clinical evidence generation.

Key messages:

- Observational data, such as administrative claims and electronic health records, offer potential to expand our understanding of disease, treatment utilization, and the effects of medical interventions, but scientific best practices and empirical demonstrations of the credibility of observational evidence must be developed to realize that potential
- An open science approach to establishing community standards for harmonizing the structure and content of observational data, as well as development open-source tools to standardize analytics processes for clinical characterization, population-level effect estimation, and patient-level prediction highlight opportunities for scientific advancement in evidence generation, dissemination, and evaluation

- Large-scale analysis across observational data networks can simultaneously improve the transparency, efficiency, quality, and quantity of observational research and can generate evidence that can more meaningfully inform medical decision-making.

Prof Marcel Salathé

Associate Professor, School of Life Sciences & the School of Computer and communication Sciences at the EPFL - École Polytechnique Fédérale de Lausanne

Marcel Salathé is Associate Professor at the School of Life Sciences & the School of Computer and communication Sciences at the EPFL - **É**cole Polytechnique Fédérale de Lausanne. Marcel is a digital epidemiologist working at the interface of population biology, computational sciences / engineering, and the social sciences.

Presentation:

Case study: Specific Challenges around data analytics for Social Media Data

Abstract:

The growing social media use creates large amounts of data that can be mined for any purpose imaginable. Generally, the steps of data filtering, human data interpretation, and machine learning (natural language processing) are necessary in order to generate insights from the data. All of these pose considerable challenges, especially in a real-time context. I will discuss a few examples and will argue that unless machine learning development becomes part of routine public health, these new data sources will never be able to be leveraged for their full potential.

Key messages:

- Social media use is now ubiquitous and is poised to grow further both in volume and data variability
- The three steps of any social media analysis are filtering, human Inter-Ration, and machine learning.
- Proper filtering is the only step that requires traditional expertise, while human assessment can be done effectively using crowdsourcing
- Machine learning can assess huge amounts of data following the previous two steps.
- These processes need to become part of routing public health, otherwise only retrospective studies will be possible.

Bart Vannieuwenhuyse

Senior Director, Janssen R&D

In 1985, Bart joined Janssen Pharmaceutica as a clinical trial monitor. In the course of his career with Janssen, Bart has held a variety of marketing and sales positions, both at local operating company level (e.g. the Netherlands) and at international level. While in the Netherlands he was one of the pioneers that started “Healthy Solutions” a J&J daughter company that focused on developing integrated services in the healthcare field. Later, he was in the core team that developed the initial Customer Relationship Management (CRM) approach for Janssen EMEA. Between 1999 and 2003, Bart spent 4 years in the IM department of Janssen Pharmaceutica in the US, where he was responsible for the e-business initiatives and for the overall IM technical architecture. Bart joined the EMEA CRM Centre of Excellence in April 2003, where he prepared the CRM Roadmap for the short to mid-term. In 2009 Bart was instrumental in developing a new customer-orientation project for Janssen Europe. In 2011 Bart joined the Janssen R&D group to focus on external eHealth / Health Information projects with external partners. Currently, Bart is coordinator of the EMIF (European Medical Information Framework) project, an IMI (Innovative Medicine Initiative) funded project. Bart holds a MSc degree in Biology from the University of Ghent (Belgium) and a MBA/MBI degree from the Erasmus University Rotterdam (Netherlands).

Presentation:

An Industry Perspective on Big Data

Abstract:

Big data and the required advanced analytical methods to fully explore such data sets have a high potential value for life sciences industry in general. Opportunities to advance the current state of art exist all along the product life cycle. Where the initial applications are mainly in the discovery space, it is clear that there are also opportunities for clinical development (think adaptive trial designs and pragmatic trials) and in the pre-launch and post-launch tracking of product safety and effectiveness.

To take full advantage of these opportunities, a number of conditions have to be met. Clearly there could be patient / subject privacy challenges which have to be dealt with. Part of the solution here can be to develop a federated approach. Second, the necessary analytical skills (e.g. machine learning) and deep understanding of the data sets should be available.

Key messages:

- Big data offers opportunities along the full product life cycle
- Specific analytical skills and methods are required
- Analysis and approaches to big data need to take patient / subject privacy challenges into account
- Federated approaches can help to mitigate privacy challenges.

Sophie Louveaux

Head of Policy and Consultation, European Data Protection Supervisor

Sophie has been specialized in the area of data protection for over twenty years. Since October 2004 she has been a legal advisor to the European Data Protection Supervisor (EDPS). In her role at the EDPS, she has served the supervision team in ensuring compliance with the data protection Regulation (EC) 45/2001 in the EU institutions and bodies. She was responsible for coordinating EDPS relations with the Data Protection Officers of the EU institutions and bodies. She now leads a team in charge of examining the data protection and privacy impact of proposed new legislation and advising the EU legislator in this respect.

Presentation:

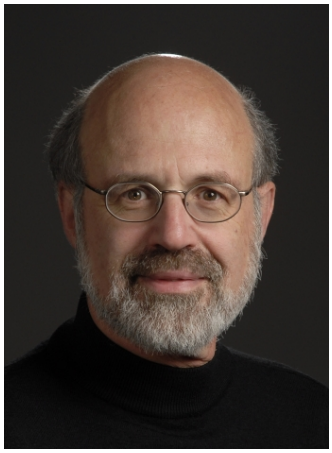
Big data and the new EU data protection Regulation (GDPR)

Abstract:

The use of big data in medical research, and in the healthcare industry in general, opens the way to unprecedented opportunities, whose reach remains difficult to determine. Additional data and information (including Real World Evidence) are useful for clinical trials, scientific research and customised healthcare. It is therefore undeniable that big data carries with it a large potential in terms of economic and social benefits. We should not however overlook that there are also risks of abuses and that ensuring compliance also has a cost. On the one hand, we see a scenario where, in order to facilitate scientific research and the healthcare business, compliance efforts are diluted or entirely overlooked and the burden of having an appropriate protection of personal data is put on the citizens. On the other hand, we have a different vision of the future and call upon the stakeholders with more knowledge and resources (research entities and industry) to adopt the safeguards necessary to protect personal data and empower citizens in an environment of growing complexity. Compliance has a cost. We believe, however, that this is an investment, a ticket to enter into an innovative field, where the use of personal data not only becomes more intensive, but is also supported by the confidence of patients and citizens in general. In this perspective, our presentation focuses on provisions in the new EU data protection framework that have a crucial role in the use of personal data for scientific and medical purposes. We refer to existing provisions, already present in the Data Protection Directive, as well as to new provisions (on privacy by design, profiling, etc.) that have filled gaps or consolidated existing practices. We welcome a thoughtful debate on these themes, in order to ensure that regulators and stakeholders engage in the same direction.

Key messages:

- The use of big data in medical research, and in the healthcare industry in general, opens the way to unprecedented opportunities, whose reach remains difficult to determine
- We should not however overlook that there are also risks of abuses and that ensuring compliance also has a cost
- Compliance with data protection rules however will enhance the confidence of patients and citizens in general
- The presentation will focus on provisions in the new EU data protection framework that have a crucial role in the use of personal data for scientific and medical purposes.



Prof Dr Ronald Brand

Biostatistician, Head section Advanced Data Management, department of Medical Statistics and BioInformatics, Leiden University Medical Hospital

Ronald Brand works at the Leiden University Medical Centre (LUMC) since 1980 as consulting biostatistician. He supported many PhD students and researchers in (inter)national research projects with the design and analysis of clinical trials and observational studies. He teaches post academic courses in statistics, has been a member of the LUMC Medical Ethical Committee for 20 years and is member of several DSMB's. He founded the section Advanced Data Management (ADM) within the department of Medical Statistics & BioInformatics where 25 employees design, build and maintain NEN7510 (ISO27001) certified infrastructures for single/multi-centre studies. The largest project is the European Society for Blood and Marrow Transplantation: he designed and hosts the European data base of all bone marrow transplants and supports European statistical analyses. Another research topic is the development of privacy enhancing methods (Real Time Encryption and Decryption). Ronald is professor of Good Research Data Management at the LUMC.

Presentation:

Mechanisms to meet privacy requirements for clinical data management in large observational and experimental studies

Abstract:

In this presentation I will show how a department of Medical Statistics, involved in the design, implementation, maintenance and analysis of hundreds of large (inter)national clinical trials, registries, cohort studies and hospital quality comparison studies, interprets and implements the requirements set forth by European and national privacy legislation. The emphasis will be on showing that our approach is practically feasible, relatively cheap and generalizable to other research areas. The "privacy by design" approach is driven by the principles of Necessity, Proportionality and Subsidiarity applied to the firm belief that data management should be approached from a biostatistical perspective and that researchers are morally obliged to maximize privacy protection, work according to FAIR principles and at the same time are indeed able to optimize the usability of the (follow-up) data being collected.

Key messages:

- "Privacy by Design" is nowadays truly affordable and relatively simple to apply in practice
- Real time encryption/decryption of personal identifiers has been proven to be feasible and capable of increasing trust among participants and collaborators
- Informed opt-out is in line with current European legislation and reduces bias in observational studies
- Encryption of national unique identifiers as a privacy enhancing method in research is crucial to collect research (follow-up) data spread over space and time without violation of (inter)national privacy legislation provided the encryption takes place at the source legally allowed to store the original identifier
- Necessity, Proportionality and Subsidiarity should be the leading and active principle in designing data registries with personal data.

Baroness Helene Hayman

Crossbench Peer, House of Lords

Chair, UK Biobank Ethics and Governance Council

Baroness Hayman has been a member of the House of Lords since 1996, and in 2006 became the first elected Lord Speaker. She has a wealth of experience in the health sector having served on medical ethics committees and governing bodies in the National Health Service as well as on health charities and regulators. She was first Chair of the Human Tissue Authority and is former Chair of Cancer Research UK. She is currently Chair of the board of Cambridge University Health Partners and the UK Biobank Ethics and Governance Council, a member of the General Medical Council and a trustee of Malaria Consortium and the Disasters Emergency Committee.

Presentation:

Ethical and governance aspects of research data: the case of UK biobank

Abstract:

Big data presents both opportunities and challenges for all of us working in healthcare and has been an issue for UK Biobank since its formation. This large prospective cohort study contains a vast amount of data relating to its 500,000 participants. This presentation will describe the ethical challenges faced by this international research resource, outlining its approach and novel governance arrangements.

Key messages:

- The rise of big data in the fields of science, medicine and health poses a challenge for ethics and governance. While the fundamental ethical principles remain valid their implementation in this new context must be considered
- UK Biobank contains a wealth of data on health outcomes, genotyping and biomarkers from 500,000 people. These data are made available to bona fide researchers with a view to improving the prevention, diagnosis and treatment of illness and promoting health throughout society for public benefit
- An independent Ethics and Governance Council was established in direct response to the broad model of consent adopted by UK Biobank and to the long term nature of the resource (recognising that there will be both foreseen and unforeseen challenges)
- Key issues addressed by the project include feedback of health information to participants and re-contact
- Robust governance and rigorous reflection can promote ethical research in the age of big data.

Julian Isla

CEO Dravet Syndrome Foundation

Julian Isla is chairman and founder of Dravet Syndrome Foundation. Dravet Syndrome Foundation is committed to find new treatment for Dravet Syndrome, an epileptic encephalopathy having long lasting seizures refractory to treatment as severe developmental delay as main symptoms. Julian is the father of Sergio, a young boy six years old who has Dravet Syndrome. Julian is software engineer by training and he works for Microsoft as full time employee. Despite not having a neuroscience or medical background he gained the skills to be part of the Orphan Drug Committee at European Medicines Agency (EMA) as a patient representative. Julian is also part of the Patient Advisory Council for Eurordis, the biggest organization of rare diseases in Europe. He is also ambassador of the Spanish Rare Diseases Federation and Chairman of the European Dravet Syndrome Federation.

Presentation:

Wacean. A patient-driven innovative tool for data capture

Abstract:

Digital transformation for medical care is critical. Most of medical records for patients are spread across different hospital and institutions. Health and IT industry have been trying to solve this problem creating standards and interoperability platforms but the problems are getting bigger rather than being solved. A health world divided in silos and data protection regulations are the key blockers for this consolidation data process. Dravet Syndrome Foundation is changing the way data is being captured putting the patient in the middle and focusing more on portability rather than interoperability. This presentation will focus on how patients are getting inpatients and how they changing the way we are doing medicine. Right here, right now.

Key messages:

- Interoperability or portability for data capture
- Inpatient patients involved on drug development
- Patient-driven innovation
- PROMs for creating medical evidence.

Chairs and co-chairs

Jean Georges

Executive Director, Alzheimer Europe

Before joining Alzheimer Europe as its first Executive Director in 1996, Jean Georges worked as a journalist for the European and International department of the Luxembourg newspaper "Tageblatt" and as a parliamentary assistant for Members of the Luxembourg and European Parliament. As Executive Director of Alzheimer Europe, Jean was in charge of the various projects of the organisation including the three-year European Commission financed "European Collaboration on Dementia – EuroCoDe" (2006—2008) project which brought together over 30 dementia experts from 20 European countries. He also represents the organisation in IMI, Horizon2020 and FP7 projects, such as PredictND, EPAD (European Prevention of Alzheimer's dementia) or EMIF (European Medical Information Framework). He has been liaising with various other European organisations and held a number of elected positions, such as Secretary General of the European Federation of Neurological Associations (2002-2004) or Vice-Chairperson of the European Patients' Forum (2007-2008). In 2005, he was appointed by the Council of Ministers and the European Parliament as one of two patient representatives to the Management Board of the European Medicines Agency (2005-2008).

Dr Fergus Sweeney

Head of Inspections, Human Medicines Pharmacovigilance and Committees Division, European Medicines Agency

Fergus Sweeney is Head of Inspections, Human Medicines Pharmacovigilance and Committees Division at the European Medicines Agency. The Division provides the organisational and operational support to the Agency's Human Scientific Committees in close collaboration with the elected chairs and nominated members. It is responsible for pharmacovigilance and epidemiology, including signal detection and management, monitoring of products on the market and providing leadership for the Agency's pharmacovigilance system. It ensures the coordination of inspections and good practice standards, coordinates incident management in the area of safety and quality of human medicines in liaison with the European medicines regulatory network and maintains close contact with international partners in the areas of inspection and pharmacovigilance in conjunction with the Agency's International Affairs function. The Division oversees the work of the EU NTC Training platform, whose mission is to ensure good scientific and regulatory practice is spread across the European medicines regulatory network.

Fergus joined the Agency in 1999 in the Inspection Sector and was appointed Head of Sector, Compliance and Inspections in May 2009. In August 2013 he was appointed Head of Division Inspections and Human Medicines Pharmacovigilance which became the Inspections, Human Medicines Pharmacovigilance and Committees Division in 2016. Fergus has a Degree in Physiology (Trinity College Dublin, Ireland, 1979), a Doctorat de Troisiéme Cycle in cancer biology (Université de Paris, 1982), and a PhD in Pharmacology (UCD, Ireland, 1986). Prior to joining the Agency he worked in industry from 1982 to 1999, covering phase I-IV clinical research, pharmacovigilance and laboratory activities, primarily in the field of quality assurance.

Luca Pani, M.D.

Director General, Italian Medicines Agency

Luca Pani, Medical Doctor, specialized in Psychiatry is an Expert in Pharmacology and Molecular Biology, and a Fellow of the National Research Council of Italy who has served as Director General of the Italian Medicines Agency (AIFA) from 2011 to Nov, 15th 2016, with CEO roles of both Regulator and Negotiator/Payer. Prof Pani is currently associated with the Faculty of the Department of Psychiatry and Behavioural Sciences at the University of Miami, School of Medicine. Luca Pani's professional trajectory has touched several areas of expertise from preclinical study to clinical activity as well as R&D of CNS drugs, along with his commitment to teaching on experimental and clinical cases. He has attended national and international regulatory activities for the European Union. During the past decade he has prepared, evaluated and coordinated vast research projects with strategic planning and partnerships collaborating with national and international research groups also by participating in international bodies and advisory committees worldwide both at the scientific and regulatory / HTA level. Luca Pani is Italian Member of the Committee for Human Medicine Products (CHMP); Member of the Scientific Advice Working Party (SAWP); participant of the Working Party on Central Nervous System (WPCNS) and he serves as Chair of the European Union Management Board Telematic Committee (EUMBTC) and Chair of the EU Network Pharmacovigilance Oversight Group for the European Medicines Agency (EMA) in London (UK). He is the author of over one hundred and fifty scientific publications, editor and author of several volumes and also a writer of successful leisure literature. He has attended more than 1000 conferences, seminars and national and international roundtables as an invited speaker.

Dr Alison Cave

Principal Scientific Administrator, European Medicines Agency

Alison Cave joined the European Medicines Agency in January 2016 as a Principal Scientific Administrator in the Pharmacovigilance and Epidemiology Department where she leads on developing mechanisms to increase capacity in the use of real world data in medicines regulation. She holds a BA Honours degree and PhD from the University of London and has over 20 years of academic research experience in the cardiovascular field including post-doctoral fellowships in US and London before joining King's College London where she was a Senior Lecturer. Prior to joining the EMA she was Head of Cellular, Developmental and Physiological Sciences at the Wellcome Trust and, prior to this, an Expert Scientific Assessor at the UK Medicines and HealthCare products Regulatory Agency.

Thomas Senderovitz

Director General, Danish Medicines Agency

Thomas Senderovitz took over as Director General of the Danish Medicines Agency on 1 April 2016. His career includes more than 15 years working intensively with medicinal products and he has held several senior positions in international biopharmaceutical companies (Ferring Pharmaceuticals, UCB Pharma, Grünenthal GmbH). Most recently, Thomas Senderovitz was a member of the management team of the global CRO (Contract Research Organisation) PAREXEL engaging in clinical research for pharmaceutical and biotechnological companies. Thomas Senderovitz previously worked at the Clinical Pharmacological Department at Bispebjerg Hospital in Copenhagen and was a medical secretary in the former Danish Medicines Agency.

Paolo Alcini

Head of Data Standardisation and Analytics Service, European Medicines Agency

Paolo Alcini has a master degree in Physics and he has been working for the European Medicines Agency since 2004. He is currently the Head of the Data Standardisation and Analytics Service. With his team, he is responsible (i) for the collection, management, quality assurance and analytics activities on Adverse Drug Reaction data (EudraVigilance) and Medicinal Product data (Art. 57), (ii) for the development of international data standards in liaison with international partners, (iii) for performing data analytics activities to support Best Evidence studies and (iv) for the EudraVigilance, Art. 57 and Medical Literature Monitoring (MLM) business/data processes.

Dr Jón Snædal

Professor in Geriatric Medicine, University Hospital in Reykjavik

World Medical Association

Jon graduated in medicine from University of Iceland in 1976. He did his specialisation in Internal Medicine and Geriatrics in Sweden but since 1985 he has been working at the University Hospital in Reykjavik, Iceland, Associate Professor since 2003 and full professor since 2012. He served as vice president of the Icelandic Medical Association in 1996-2004, during this time responsible for Nordic and International collaboration. He has served for two terms in the Council of the World Medical Association (WMA) being chair of the standing committee on Medical Ethics in 2003-2005 and President of the WMA in 2007-2008. Since 2012 he has been chairing the WMA working group on Health Databases and Biobanks forming a policy that is up for consideration for adoption at the WMA General Assembly in October 2016. His research has focused on Alzheimer´s disease, mostly in genetics and in establishing new methods for diagnosis.

Dr Alessandro Spina

Data Protection Officer, European Medicines Agency

Alessandro Spina is Data Protection Officer of the European Medicines Agency (EMA) and a member of its Legal Department. He is a dual qualified Italian and English lawyer (solicitor). Alessandro studied law at the University of Siena (JD), and at the University of Oxford (M.Jur.) He holds a PhD in Law and Economics from the University of Siena where he discussed a thesis on EU administrative law and regulation of pharmaceuticals. His interests are EU data protection law, pharmaceutical law and risk and behavioural regulation. He is a member of the editorial board of the European Journal of Risk Regulation and of the European Data Protection Law Review.

Chair and Moderator

Dr Pierre Meulien

Executive Director, Innovative Medicines Initiative (IMI)

Pierre Meulien is Executive Director of the Innovative Medicines Initiative (IMI), a €5 billion public-private partnership between the European Union and the European pharmaceutical industry. At IMI, he is responsible for the overall management of the programme, which is working to improve and accelerate the entire medicines development process by facilitating collaboration between the key players involved in health research, including universities, pharmaceutical and other companies, patient organisations, and medicines regulators. Dr Meulien joined IMI in September 2015. From 2010 to 2015, Dr Meulien was President and CEO of Genome Canada, where he raised significant funds for the organisation and oversaw the launch of novel projects and networks in the field of genomics-based technologies. Prior to that from 2007 to 2010, he was Chief Scientific Officer for Genome British Columbia. From 2002 to 2007, Dr Meulien served as founding CEO of the Dublin Molecular Medicine Centre (now Molecular Medicine Ireland), which linked medical schools and teaching hospitals in Dublin to build a critical mass in molecular medicine and translational research.

Panellists

Dr Ian Hudson

Chief Executive, Medicines Healthcare and Product Regulatory Agency

Dr Ian Hudson became Chief Executive of the Medicines and Healthcare products Regulatory Agency in September 2013. He is a physician who practised as a paediatrician for a number of years, before working in the pharmaceutical industry in clinical research and development between 1989 and 2001, when he joined the former MCA (Medicines Control Agency) as Director of the Licensing Division. Before being appointed as Chief Executive, Dr Hudson was the MHRA's Licensing Director, responsible for the majority of its medicines licensing activities. He was also the UK delegate to the Committee for Human Medicinal Products (CHMP) and was its vice-chairman from October 2012 to September 2013. He is qualified in medicine from University of London (London Hospital Medical School) and practiced predominantly in paediatrics after qualifying. His main research interest is neonatal haematology.

Dr Andrew R. Leach

Head of Chemistry Services, European Bioinformatics Institute

Andrew Leach studied Chemistry as an undergraduate and postgraduate at the University of Oxford. He was then an SERC/NATO fellow at the University of California, San Francisco, where he worked on the application of computational chemistry and simulation methods to biological systems. He returned to the University of Southampton and three years later joined Glaxo (now GlaxoSmithKline) Research and Development. During more than 20 years at GSK he was involved in the development and application of new platform capabilities for drug discovery in areas including computational chemistry and cheminformatics, fragment-based drug discovery, cardiovascular safety, proteomics and biological mass spectrometry. He also contributed to many therapeutic projects and led GSK's early Discovery portfolios against protease, ion channel and epigenetic targets. In 2016 Andrew moved to the European Bioinformatics Institute as Head of Chemistry Services where he is responsible for the EBI's resources in chemogenomics, molecular structure and metabolomics. He has more than 70 publications including widely-used textbooks on molecular modelling and chemoinformatics.

Prof Dr Miriam Sturkenboom

Erasmus University Medical Centre

Miriam Sturkenboom is professor in Observational Data Analysis at the department of Medical Informatics of the Erasmus University Medical Centre in the Netherlands. She has a PhD from the Faculty of Mathematics and Physics in Groningen (cum laude), a pharmacy degree and a Master in Epidemiology from the Harvard School of Public Health. Her research group focuses on knowledge discovery from data collected in routine health care to improve evidence on drug and vaccine safety and rare diseases. Her group has created national and most importantly international socio-technological infrastructures that allow for big data mining, pooling and analysis. These infrastructures have been tested and used as prototypes in many distributed networks in projects funded by the European Commission, the Innovative Medicines Initiative, the European Medicines Agency, ECDC, and also privately funded projects. She is past-president of the International Society of Pharmacoepidemiology and has more than 350 peer reviewed papers in the area of pharmacovigilance, pharmacoepidemiology and medical informatics.

Rob Hemmings

Medicines Healthcare and Product Regulatory Agency

Rob Hemmings has been with the Medicines and Healthcare products Regulatory Agency for 16 years and heads the group of medical statisticians and pharmacokineticists. Most of Rob's time is dedicated to work on behalf of the scientific committees that are hosted at the European Medicines Agency. Specifically: Rob is a member of the European Medicines Agency Committee for Medicinal Products for Human Use (CHMP), 'co-opted' for expertise in clinical trial methodology. Rob is also the chair of the CHMP's Scientific Advice Working Party (SAWP), a multi-disciplinary group providing scientific advice and protocol assistance to drug developers to facilitate access of medicinal products to patients by optimising research and development, reducing uncertainties in regulatory outcomes, and accelerating time to approval of a marketing authorisation application. Rob has a broad interest in all aspects of clinical trial design, statistical methodology and drug development as they relate to regulatory science.

Dr Olaf H. Klungel, PharmD

Professor of Pharmacoepidemiologic methods, University Medical Centre Utrecht

Olaf Klungel is chair of research and professor of pharmacoepidemiologic methods at the division of Pharmacoepidemiology & Clinical Pharmacology at the Utrecht Institute for Pharmaceutical Sciences. He was trained as a pharmacist and epidemiologist. His research focus is the development, improvement and evaluation of innovative methods to control for confounding in observational drug research. Performance of various study designs and methods to control for confounding has been thoroughly assessed in multiple EU databases and in simulation studies. He co-led the 'Framework for pharmacoepidemiology studies' program as part of the IMI-PROTECT project that was coordinated by EMA. He was involved in the establishment of several national research infrastructures for linkage and enrichment of routine health care data with biobank/cohort data to increase the validity and richness of data on drug exposure, disease outcomes, confounding and modifying (e.g. biomarkers) factors. He (co-)authored more than 250 scientific peer-reviewed papers, research reports and book chapters.

Prof Stephen JW Evans

Professor of Pharmacoepidemiology, London School of Hygiene and Tropical Medicine

Independent member of the Pharmacovigilance and Risk Assessment Committee of the European Medicines Agency

Prof Stephen JW Evans trained in physics and chemistry including a year in the US. He was both a student and staff at CERN, the European Organization for Nuclear Research (Geneva). Having worked in computing, he did the MSc in Medical Statistics at LSHTM (1977) and worked in statistics and computing at The London Hospital and Medical College for 25 years. He has also been at the UK Medicines Control Agency and briefly at Quintiles, where he mainly worked on the Bristol Royal Infirmary Inquiry. He is an independent Expert member of the Pharmacovigilance and Risk Assessment Committee at the EMA. Prof Evans was President of the International Society of Pharmacoepidemiology for 2010/2011 and a member of the WHO Global Advisory Committee on Vaccine Safety. His research interests have been in methods for studying drug safety and in their application to various areas of medical interest, including vaccines, antibiotics, drugs in pregnancy and Huntington's Disease.

Hugo Hurts

Executive Director, Medicines Evaluation Board

Dr Hurts is the Executive Director of the Dutch Medicines Evaluation Board (CBG-MEB) since 2014. Before this he was Director of the Department of Pharmaceutical Affairs and Medical Technology and Director of the Department of Health Insurances Ministry of Health, Welfare and Sport, Netherlands. He was a staff member of the so called Dekker Commission, advising Dutch government on health reform and scientific researcher/research assistant at the Dutch Institute for Research of Public Expenditure. Currently Dr Hurts is a member of the Management Board of the European Medicines Agency and a member of the organisation of Heads of Medicines Agencies. Dr Hurts has a degree in General Economics at Erasmus University, Rotterdam (1982) and he has frequent appearances as a speaker, panel member or chair at congresses, symposia and meetings in the Netherlands and in other countries.

Bart Vannieuwenhuyse

Senior Director, Janssen R&D

In 1985, Bart joined Janssen Pharmaceutica as a clinical trial monitor. In the course of his career with Janssen, Bart has held a variety of marketing and sales positions, both at local operating company level (e.g. the Netherlands) and at international level. While in the Netherlands he was one of the pioneers that started “Healthy Solutions” a J&J daughter company that focused on developing integrated services in the healthcare field. Later, he was in the core team that developed the initial Customer Relationship Management (CRM) approach for Janssen EMEA. Between 1999 and 2003, Bart spent 4 years in the IM department of Janssen Pharmaceutica in the US, where he was responsible for the e-business initiatives and for the overall IM technical architecture. Bart joined the EMEA CRM Centre of Excellence in April 2003, where he prepared the CRM Roadmap for the short to mid-term. In 2009 Bart was instrumental in developing a new customer-orientation project for Janssen Europe. In 2011 Bart joined the Janssen R&D group to focus on external eHealth / Health Information projects with external partners. Currently, Bart is coordinator of the EMIF (European Medical Information Framework) project, an IMI (Innovative Medicine Initiative) funded project. Bart holds a MSc degree in Biology from the University of Ghent (Belgium) and a MBA/MBI degree from the Erasmus University Rotterdam (Netherlands).

Lisa M. Latts, MD, MSPH, MBA, FACP

Deputy Chief Health Officer, IBM Watson Health

Dr Lisa Latts is the Deputy Chief Health Officer for IBM Watson Health. Her area of focus is using cognitive computing to improve value in healthcare delivery as well as quality improvement. Prior to this, she was the Principle of LML Health Solutions, and the Chief Medical Officer for the self-insured health plans at the University of California. Dr Latts also served as Vice President for Public Health Policy and Programs in Clinical Excellence with Anthem, Inc. (WellPoint,) where she was instrumental in developing many of their value based payment and delivery system reform initiatives such as the Patient Centered Medical Home, Pay for Performance, Centres of Excellence, and International Medical Tourism. Dr Latts is a national leader in health quality and health policy and is currently chair of the NCQA Standards Committee and co-chair of the Cost and Resource Use committee for the National Quality Forum. She is board certified in Internal Medicine. She received her MD from the University of Minnesota, an executive MBA from the University of Colorado's Leeds School of Business and a MSPH from the University of Colorado.

List of attendees

	First name	Last name	Position	Affiliation
1.	Jan Petter	Akselsen	Director Medicines Assessment and Evaluation	Norwegian Medicines Agency, Norway
2.	Paolo	Alcini	Head of Data Standardisation and Analytics Service	European Medicines Agency
3.	Enrica	Alteri	Head of Human Medicines R&D Support	European Medicines Agency
4.	Christelle	Anquez-Traxler, Dr	AESGP regulatory and scientific affairs manager	Association of the European Self-Medication Industry (AESGP), Belgium
5.	Peter	Arlett, Dr	Head of Pharmacovigilance and Epidemiology	European Medicines Agency
6.	Roberto	Ascione, Dr	CEO	Healthware International, Italy
7.	Martin	Atkinson	Scientific Officer	Joint Research Centre, European Commission
8.	Andrew	Barron	Vice President, Global Site Start-Up and Regulatory	INC Research - Association of Clinical Research Organizations (ACRO), United Kingdom
9.	Ahmed	Basa	Director of Regulatory Affairs, EMEA	Johnson & Johnson Consumer - Association of the European Self-Medication Industry (AESGP), United Kingdom
10.	Andrew	Bate, PhD	Senior Director, Epidemiology Group Lead, Analytics	Pfizer, United Kingdom
11.	Lauren	Becnel, Ph.D.	Senior Director	Biomedical Informatics & Alliances, CDISC, United States of America
12.	Bojana	Bellamy	President	Centre for Information Policy Leadership, United Kingdom
13.	Richard	Bergström	Director General	European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
14.	Paul	Blake	Medical Writer, Stakeholders and Communication Division	European Medicines Agency
15.	Stefan	Blixen-Finecke	Head of Planning, Architecture and Quality	European Medicines Agency
16.	Kamil	Blšák	IT specialist	State Institute for Drug Control, Slovakia
17.	Sergio	Bonini, MD, Professor	Expert on secondment	European Medicines Agency
18.	Ronald	Brand, Prof Dr	Biostatistician, Head section Advanced Data Management, Department of Medical Statistics and Bioinformatics	Leiden University Medical Hospital, Netherlands
19.	Niamh	Buckley	Pharmacovigilance assessor	Health Products Regulatory Authority, Ireland
20.	Gianmario	Candore, MSc	Data Scientist	European Medicines Agency
21.	Tiziana	Catarci, Prof Dr	Director ECONA Interuniversity Research Centre	Sapienza University of Roma, Italy
22.	Francesca	Cattarin	Health Policy Officer	Bureau Européen des Unions de Consommateurs (BEUC), Belgium
23.	Alison	Cave, Dr	Principal Scientific Administrator	European Medicines Agency
24.	Belén	Crespo Sánchez-Eznarriaga	Executive Director	Spanish Agency of Medicines and Medical Devices, Spain
25.	Andreja	Čufar, Dr	Director	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, Slovenia
26.	Corinne	de Vries, Prof	Head of Science and Innovation Support Office	European Medicines Agency
27.	Nikos	Dedes	Board Member	European AIDS Treatment Group (EATG), Belgium
28.	Sergio Bruno	de Oliveira Santana	Chief Information Officer	Farmoz - Medicines for Europe, Portugal
29.	Susanna	Del Signore	Director and Founder	BlueCompanion ltd, United Kingdom
30.	Roberto	Di Lauro, Prof	Scientific Attaché	Italian Embassy in London, Italy

	First name	Last name	Position	Affiliation
31.	Anikó	Dobi-Rózsa	Science and Technology Attaché	London Diplomatic Science Club, United Kingdom
32.	Iiro	Eerola	Scientific and Technical Project Officer	DG Research & Innovation Directorate E: Health Unit E2: Innovative and Personalised Medicine, European Commission
33.	Falk	Ehmann, MD, PhD	Science and Innovation Support	European Medicines Agency
34.	Hans-Georg	Eichler, Prof MD MsC	Senior Medical Officer	European Medicines Agency
35.	Jörg	Engelbergs, Dr	Scientific Assessor, Quality, Non-Clinic & Personalized Medicine	Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Germany
36.	Monica	Ensini, PhD	Newcastle University, seconded at EMA as National Expert	European Medicines Agency
37.	Malcolm	Evans	Head of Patient, Public and Stakeholder Engagement	Medicines and Healthcare products Regulatory Agency
38.	Giovanni	Ferretti, Dr	ICT Sector	Italian Medicines Agency, Italy
39.	Belinda	Foo Pei Qin	Regulatory Specialist	Health Sciences Authority, Singapore
40.	Nicolae	Fotin, MD	President	National Agency for Medicines and Medical Devices, Romania
41.	Barbara	Freischem	Executive Director	European Biopharmaceutical Enterprises (EBE), Belgium
42.	Zaide	Frias	Head of Human Medicines Evaluation Division	European Medicines Agency
43.	Christopher	Gadd	Head of Online and Corporate Design Service	European Medicines Agency
44.	Susana	Garcia Rodriguez	Health Project Officer	Organización de Consumidores y Usuarios, Spain, Bureau Européen des Unions de Consommateurs, Belgium
45.	Nico	Gaviola	Head of LifeSciences and Healthcare	Google Cloud Platform, United Kingdom
46.	Georgy	Genov	Head of Signal and Incident Management Service	European Medicines Agency
47.	Jean	Georges	Executive Director	Alzheimer Europe (AE), Luxembourg
48.	Iris	Goetz, MD MSc	Research Advisor Epidemiology, Global Health Outcomes	Eli Lilly - European Federation of Pharmaceutical Industries and Associations (EFPIA), United Kingdom
49.	Harald	Gschaidmeier, PhD	Economic Affairs and Outcome Research Director	Oncology Region Europe Novartis - European Biopharmaceutical Enterprises (EBE), Italy
50.	Olaf	H. Klungel, PharmD, PhD	Professor of Pharmacoepidemiologic methods	University Medical Centre Utrecht, Netherlands
51.	Elin Haf	Davies, Dr	CEO	Aparito Digital Health, United Kingdom
52.	Bernard	Hamelin	VP Medical Evidence Generation	Sanofi - European Federation of Pharmaceutical Industries and Associations (EFPIA), France
53.	Tan Siew	Har	Regulatory Consultant	Health Sciences Authority, Singapore
54.	Helene	Baroness Hayman	Crossbench Peer, UK Biobank Chair	House of Lords, UK Biobank Ethics and Governance Council, United Kingdom
55.	Marjo-Riitta	Helle, Dr	Director	Finnish Medicines Agency, Finland
56.	Robert James	Hemmings	Statistics and Pharmacokinetics Unit Manager	Medicines and Healthcare products Regulatory Agency, United Kingdom

	First name	Last name	Position	Affiliation
57.	Svens	Henkuzens	Director	State Agency of Medicines, Latvia
58.	Cesar	Hernandez Garcia	Head of Medicines for Human Use Department	Spanish Agency of Medicines and Medical Devices, Spain
59.	Jesús	Hernández Rivas, Prof	Professor of Medicine, Consultant, Head Molecular Cytogenetics Lab	Hospital Universitario de Salamanca, University of Salamanca, Spain
60.	Johann Lodewijk	Hillege, MD, MsC, PhD	Member of EMA Committee for Medicinal Products for Human Use	Medicines Evaluation Board, Netherlands
61.	Vicky	Hogan, Dr		Marketed Health Products Directorate, Health Products and Food Branch, Health Canada
62.	Ian	Hudson, Dr	Chief Executive	Medicines and Healthcare products Regulatory Agency, United Kingdom
63.	Ben	Hughes, Dr	Vice President	Real World Insights, QuintilesIMS, United Kingdom
64.	Wendy	Huisman	Qualified Person for Pharmacovigilance	TEVA – Medicines for Europe, Netherlands
65.	Anthony	Humphreys	Head of Scientific Committee Regulatory Science Strategy	European Medicines Agency
66.	Hugo	Hurts	Executive Director	Medicines Evaluation Board, Netherlands
67.	Julian	Isla	CEO	Dravet Syndrome Foundation, Spain
68.	Stephen	JW Evans, Prof.	Professor of Pharmacoepidemiology	London School of Hygiene and Tropical Medicine, United Kingdom
69.	Thomas	Kelley, Dr	Vice President, Business Development and Partnerships	International Consortium for Health Outcomes Measurement (ICHOM), United Kingdom
70.	Brian	Kelly, M.D.	President, Payer and Provider Solutions	QuintilesIMS - Association of Clinical Research Organizations (ACRO), United States of America
71.	Katrin	Kiisk	Deputy Director General	State Agency of Medicines, Estonia
72.	Ryan	Kilpatrick, PhD	Senior Director, Epidemiology	AbbVie - European Biopharmaceutical Enterprises (EBE), United States of America
73.	Otmar	Kloiber, Dr	Secretary General	World Medical Association International, France
74.	Evdokia	Korakianiti	Head of Procedure Management Department	European Medicines Agency
75.	Darko	Krnić, MD	Head of pharmacovigilance Department	Agency for medicinal products and medical devices - HALMED, Croatia
76.	Xavier	Kurz, Dr	Head of Surveillance and Epidemiology Service	European Medicines Agency
77.	Sandra	L. Kweder, MD	Deputy Director, Europe Office	Food and Drug Administration, United States of America
78.	Cordula	Landgraf, PharmD	Head of Networking Swissmedic	Swissmedic, Swiss Agency for Therapeutic Products, Switzerland
79.	Roger	Lim	Policy officer	DG SANTE, Unit Cross-border healthcare and eHealth, European Commission
80.	Sophie	Louveaux	Head of Policy and Consultation	European Data Protection Supervisor (EDPS), Belgium

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81.	Elizabeth	Madichie, Dr, CChem FRSC MTOPRA MCMI	Global Head of Regulatory Affairs	Pharmaceutical Product Development – Association of Clinical Research Organizations (ACRO), United Kingdom
82.	Amr	Makady, MSc.	Policy Advisor	The National Healthcare Institute (ZIN), The Netherlands
83.	David	Martin, MD, MPH	FDA Liaison to the Reagan Udall Foundation IMEDS program Office of the Centre, Director Centre for Drug Evaluation and Research	Food and Drug Administration, United States of America
84.	Keith	McDonald	Deputy Director, Licensing Division	Medicines and Healthcare products Regulatory Agency, United Kingdom
85.	Duccio	Medini, PhD	Head Data Science and Clinical Systems	GSK Vaccines R&D - Vaccines Europe, Italy
86.	Dirk	Mentzer, Dr, MD, PhD	Medical Doctor	Paul-Ehrlich-Institute, Germany
87.	Pierre	Meulien	Executive Director	Innovative Medicines Initiative (IMI), Belgium
88.	François	Meyer, MD	Advisor to the President, International Affairs	Haute Autorité de santé, France
89.	Miriam	Sturkenboom, Prof Dr	Professor of Analysis of Observational Data Departments of Medical Informatics and Epidemiology	Erasmus MC - University Medical Centre Rotterdam, Netherlands
90.	Barend	Mons, Prof	Professor in Biosemantics, Head of Node for ELIXIR- NL at the Dutch Techcentre for Life Sciences, Board Member of the Leiden Centre of Data Science	Leiden University Medical Centre, Netherlands
91.	Robert	Moss, hospital pharmacist	Director of Professional Development	European Association of Hospital Pharmacists (EAHP), Netherlands
92.	Isabelle	Moulon	Head of Public Engagement Department	European Medicines Agency
93.	Wilhelm (Willie)	Muehlhausen	Head of eClinical Innovation	ICON plc – Association of Clinical Research Organizations (ACRO), Ireland
94.	Joseph D. Jr.	Mumma	Vice President, eHealth Quality Assurance and Compliance Services	Bioclinica Inc. - Association of Clinical Research Organizations (ACRO), United States of America
95.	June	Munro Raine, Dr	Director of Vigilance and Risk Management	Medicines and Healthcare products Regulatory Agency, United Kingdom
96.	Flora	Musuamba Tshinanu, PharmD, PhD	Associate Professor, Assessor	Université de Limoges, France, Federal Agency for Medicines and Health Products, Belgium
97.	Ioannis	Natsis	Access to Medicines Policy Coordinator	European Public Health Alliance, Belgium
98.	Alexis	Nolte, Dr	Head of Information Management Division	European Medicines Agency
99.	Koenraad	Norga, Dr	Paediatric Oncology, Expert, Member of EMA Paediatric Committee and Committee for Medicinal Products for Human Use	Antwerp University Hospital, Federal Agency for Medicines and Health Products, Belgium
100.	Martin Erik	Nyeland	Special Advisor	Danish Medicines Agency, Denmark
101.	Jos	Olaerts	Scientific Administrator	European Medicines Agency
102.	Hans	Ovelgönne, Dr	Member of Scientific Staff	Medicines Evaluation Board, EMA Scientific Advice Working Party, EMA Committee for Advanced Therapies, Netherlands

	First name	Last name	Position	Affiliation
103.	Nicholas	P. Tatonetti	Herbert Irving Assistant Professor	Columbia University, United States of America
104.	Luca	Pani	Director General	Italian Medicines Agency, Italy
105.	Ellas (Elsa)	Papadopoulou	Legal Officer	European Commission
106.	Marisa	Papaluca, MD	Senior Scientific Advisor, Scientific Committees Regulatory Science Strategy	European Medicines Agency
107.	Markus	Paulmichl, MD	Professor	Paracelsus Medical University, Austria
108.	Marta	Pereira, PhD MSc	Research Manager	Bristol-Myers Squibb-European Federation of Pharmaceutical Industries and Associations (EFPIA), United Kingdom
109.	Frank	Pétavy	Head of Biostatistics and Methodology Support (ad interim), Specialised Scientific Disciplines Department	European Medicines Agency
110.	Marie-Helene	Pinheiro, Dr	Industry Stakeholder Liaison	European Medicines Agency
111.	Munir	Pirmohamed, Professor Sir	David Weatherall Chair of Medicine and NHS Chair of Pharmacogenetics	University of Liverpool, United Kingdom
112.	Fabio	Polverino	Legal Officer	European Data Protection Supervisor, Belgium
113.	Maria	Popova-Kiradjieva, MD PhD	Head of Pharmacovigilance and Clinical trials department	Bulgarian Drug Agency, Bulgaria
114.	Csilla	Pozsgay, MD	General Director	National Institute of Pharmacy and Nutrition, Hungary
115.	Andrew	R. Leach, Dr	Head of Chemistry Services	European Bioinformatic Institute (EBI), United Kingdom
116.	Guido	Rasi, Prof	Executive Director	European Medicines Agency
117.	Patrick	Ryan, PhD	Senior Director and Head, Epidemiology Analytics	Observational Health Data Sciences and Informatics (OHDSI), United States of America
118.	Lauren	Sager Weinstein	Head of Analytics	Transport for London, United Kingdom
119.	Michele	Sala	Legal Department	Italian Medicines Agency, Italy
120.	Marcel	Salathé, Prof	Associate Professor & Academic Director	EPFL, School of Life Sciences & School of Computer and Communications Sciences EPFL Extension School , Switzerland
121.	Ancel.la	Santos Quintano	Policy Advisor	Health Action International-Europe (HAI), Netherlands
122.	Mihaela	Savastre	Ad-Interim Head of Data Modelling and Warehouse	European Medicines Agency
123.	Roberto	Savona	Associate Professor of Financial Markets and Institutions, Department of Economics and Management	University of Brescia, Italy
124.	Elizabeth	Scanlan	Medical Writer, Stakeholders and Communication Division	European Medicines Agency
125.	Serena	Scollen, Dr	Head of Human Genomics and Translational Data	ELIXIR, United Kingdom
126.	Thomas	Senderovitz	Director General	Danish Medicines Agency, Denmark
127.	Bruno	Sepodes, PharmD MSc PhD	Professor of Pharmacology and Pharmacotherapy, Chair of EMA the Committee of Orphan Medicinal Products	University of Lisbon, Portugal

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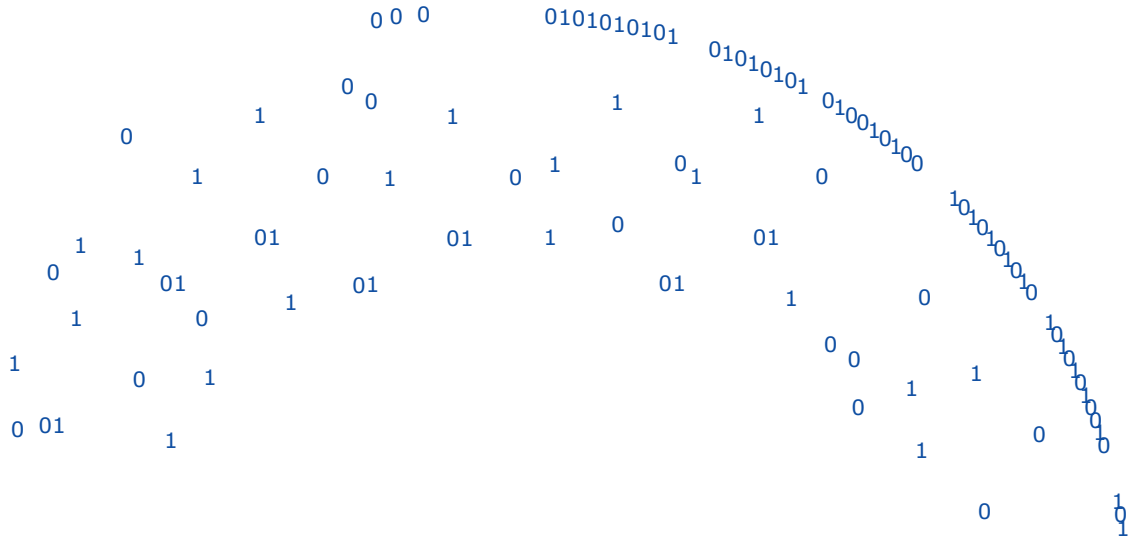
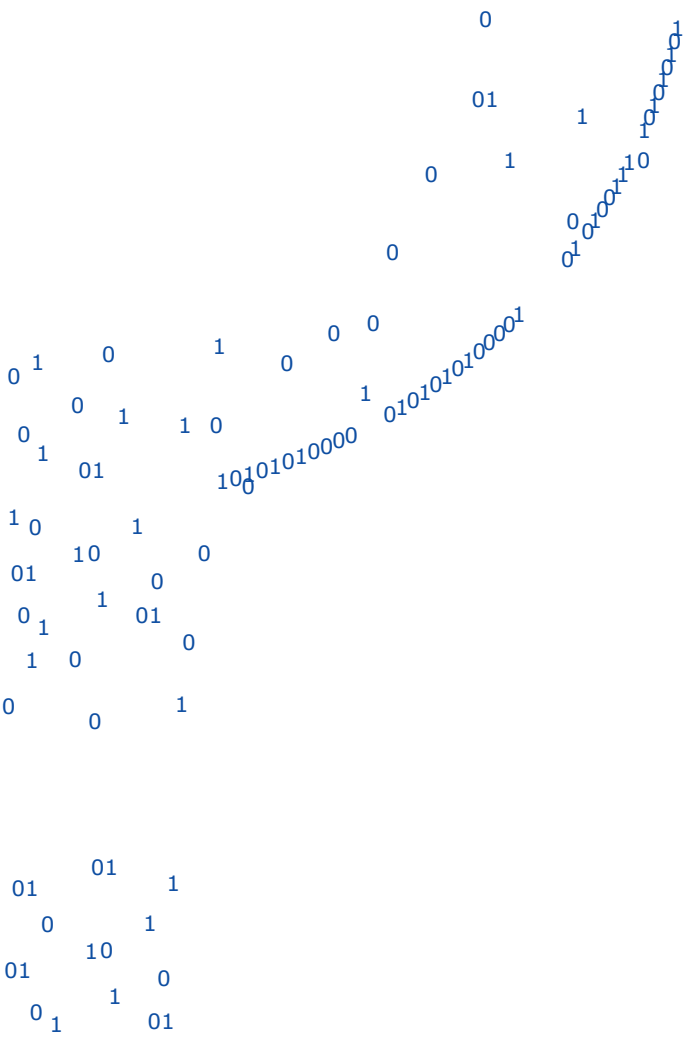
128.	Ivana	Silva	Scientific Administrator Stakeholders and Communication Division	European Medicines Agency
129.	Donald	Singer, Prof	Chair, Advisory Board FPM Member EACPT Executive Committee	Health Policy and Technology, Fellowship of Postgraduate Medicines (FPM), European Association for Clinical Pharmacology and Therapeutics (EACPT), United Kingdom
130.	Ine	Skottheim Rusten	Senior Advisor, Chair of EMA Modelling and Simulation Working Group	Norwegian Medicines Agency, Norway
131.	Jón	Snædal	Professor in Geriatric Medicine	University Hospital in Reykjavik, Iceland, World Medical Association
132.	Mike	Spencer	Head of Real World Evidence	Janssen-Cilag - Vaccines Europe, United Kingdom
133.	Alessandro	Spina, Dr	Data Protection Officer	European Medicines Agency
134.	Almath	Spooner, Dr	Pharmacovigilance and Risk Management Lead, Vice Chair of EMA Pharmacovigilance Risk Assessment Committee	The Health Products Regulatory Authority, Ireland
135.	Vikesh	Srivastava	Associate Director, Business Informatics Division	Resource Management and Operation Directorate, Health Canada
136.	Fergus	Sweeney, PhD	Head of Inspections, Human Medicines Pharmacovigilance and Committees	European Medicines Agency
137.	Rafal	Swierzewski, PhD	Consultant	European Cancer Patient Coalition (ECPC), Belgium
138.	Steven	Teerenstra, Dr	Biostatistician	Radboud University Medical Centre, Medicines Evaluation Board, Netherlands
139.	Andrew	Thomson	Statistician for the Biostatistics and Methodology Support Office, Specialised Scientific Disciplines Department	European Medicines Agency
140.	Boris	Thurisch, Dr	Head of Pharmacovigilance	German Pharmaceutical Industry Association, Germany
141.	Ura	Katsuaki	Review coordinator, General Affairs Division	Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, Japan
142.	Spiros	Vamvakas	Head of Scientific Advice Office	European Medicines Agency
143.	Bart	van der Sloot, mphil, llm	Senior researcher	Tilburg University, Netherlands
144.	Bert	van Nistelrooij, MSc BEng	Data scientist	The National Healthcare Institute (ZIN), Netherlands
145.	Peter	Van Reusel	Managing Director	Innovion, Belgium
146.	Bart	Vannieuwenhuyse	Senior Director	Janssen R&D - European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
147.	Richard	Veselý, MD	Head of the Rheumatology, Respiratory, Gastroenterology and Immunology Office Scientific and Regulatory Management Department	European Medicines Agency
148.	Marika	Vezzoli, PhD	Assistant Professor of Statistics, Department of Molecular and Translational Medicine	University of Brescia, Italy
149.	Giorgio	Visentin, Dr	Member of Executive Board	Csermeg, Italy

	First name	Last name	Position	Affiliation
150.	Maren	von Fritschen, Dr	Regulatory Affairs	European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), Belgium
151.	Stig	W. Omholt, Professor	Professor, Director of NTNU's cross-campus biotechnology programme	Norwegian University of Science and Technology (NTNU), Norway
152.	Judith	Wagner	Head of eHealth	FMH Swiss Medical Association, Switzerland
153.	Noel	Wathion	Deputy Executive Director	European Medicines Agency
154.	Christa	Wirthumer-Hoche, DI Dr	Head of the Austrian Medicines and Medical Devices Agency, Chair of EMA of the EMA-Management Board	Austrian Medicines and Medical Devices Agency, Austria
155.	Entela	Xoxi	Pharmacologist AIFA Registries	Italian Medicines Agency, Italy
156.	Gianluca	Zia	President	Caretek srl, Italy
157.	Jörg	Zinserling	Scientific Assessor Quality, Non-Clinic & Personalized Medicine	Paul-Ehrlich-Institut Federal Institute for Vaccines and Biomedicines, Germany



Practical infomation

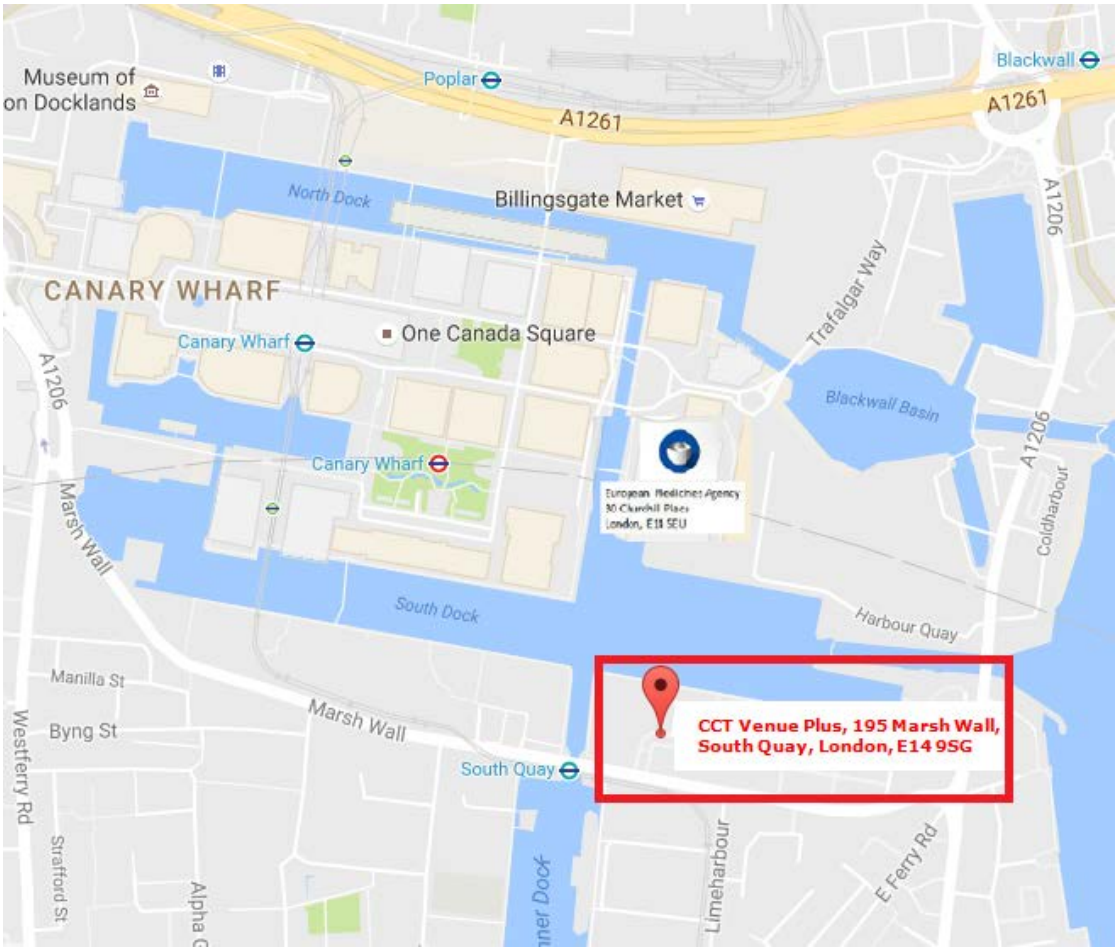


Venue

The workshop venue is the CCT Venue Plus, 195 Marsh Wall, South Quay, London, E14 9SG.

Lunch and dinner will also be served at this location

- By Docklands Light Railway (DLR)
  The workshop venue is a short walk from South Quay station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton.
- By Underground
  The nearest stop for the venue is Canary Wharf station on the Jubilee Line.
- By bus
  The venue is serviced by local bus numbers D6, D7, D8, 135 and 277.
- Plan your journey on TfL website



Entering the building

Upon arrival at the ground-floor reception, you will be guided to the 1st floor. Please make sure you have an ID or a bank card with your name for identification at registration

Physical disability

Let us know if you would like any specific help or information that would make your stay more comfortable. We will be very happy to help.

Registration

We advise you to arrive up to one hour before the start of the workshop (i.e. at 12:30) to allow sufficient time for registration and settling down. Registration will take place in the foyer on the 1st floor.

Meeting room

There is no seating plan in the room except for a number of reserved seats for the speakers, panellists and chairs of the workshop.

Presentations

We will not circulate printouts of speakers' presentations beforehand. However, you will be able to download the presentations from the workshop website approximately one week after the event.

Catering

Beverages and dinner will be provided on the 14th November and beverages and lunch on the 15th November for all delegates free of charge to allow opportunities for discussion and networking.

Media disclaimer

The Agency records or broadcasts a number of its meetings, including some virtual meetings. This is part of the Agency's commitment to the principle of transparency as enshrined in the Treaty on the European Union. By attending this meeting you consent to any recording or broadcast.

Live broadcast

The workshop will be live streamed. Please follow the link in Multimedia tab on the event page. No registration or password is required.

Individuals interested to tweet on this event are invited to use the hashtag #bigdata4medicines.

Workshop venue

CCT Venue Plus
195 Marsh Wall, South Quay

London, E14 9SG

Website
http://www.cctvenues.co.uk/venues/canary-wharf-south-quay

European Medicines Agency

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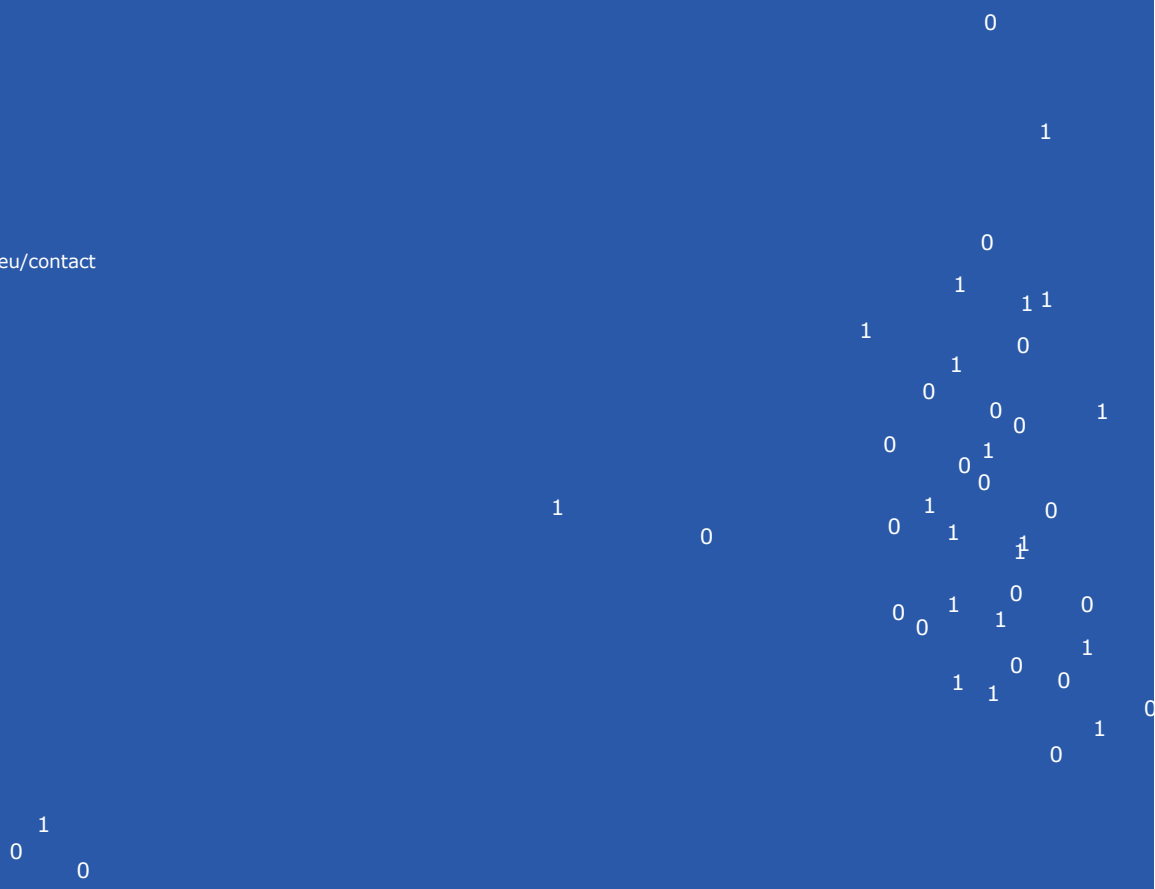

Identifying opportunities for 'Big Data' in medicines development and Regulatory Science
EMA/730119/2016
Inspections, Human Medicines Pharmacovigilance and Committees