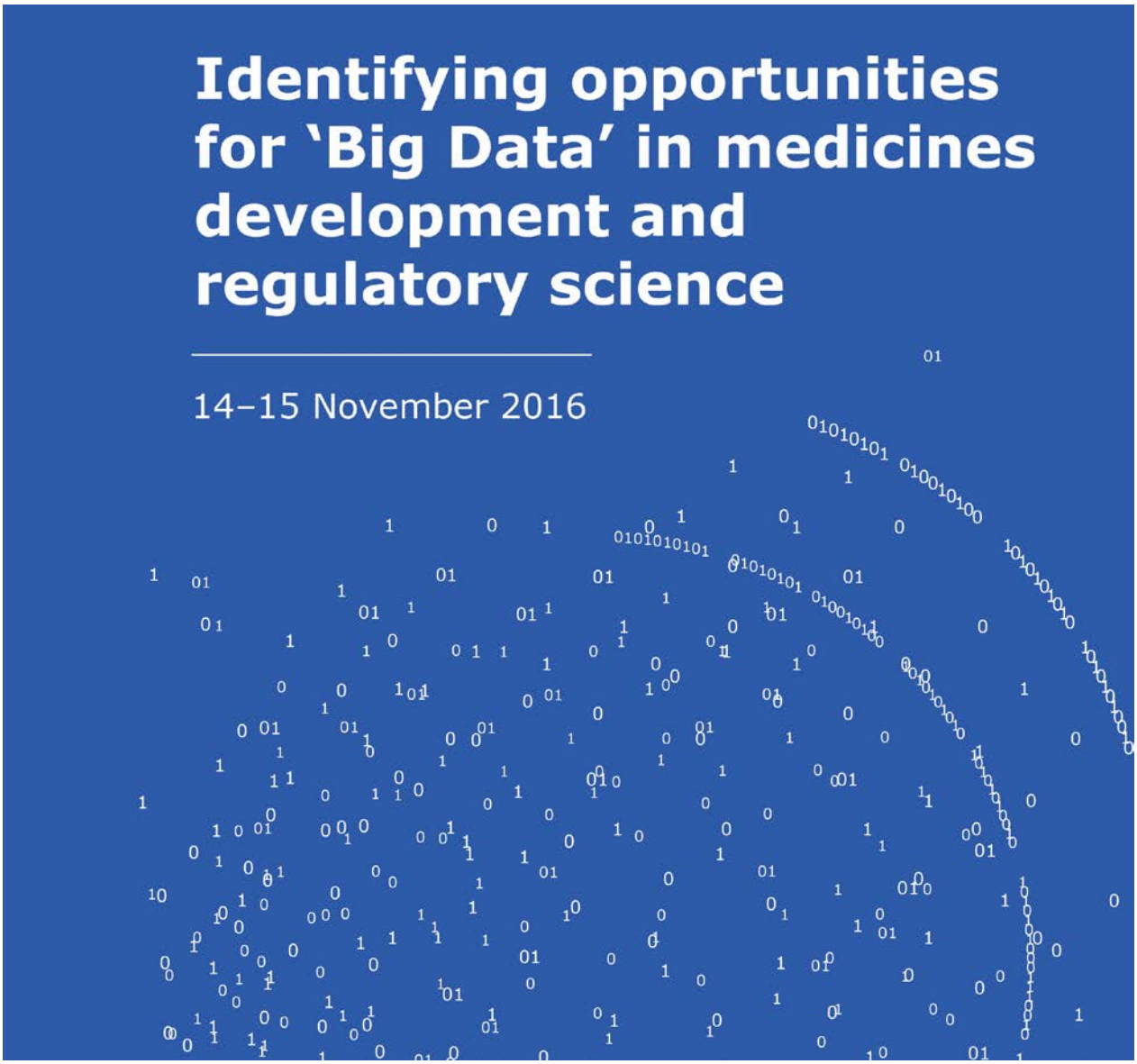
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 November 2016
EMA/707605/2016
Inspections, Human Medicines Pharmacovigilance and Committees Division

Workshop final programme



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 Sweeny**, 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
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, College ter Beoordeling van Geneesmiddelen, 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

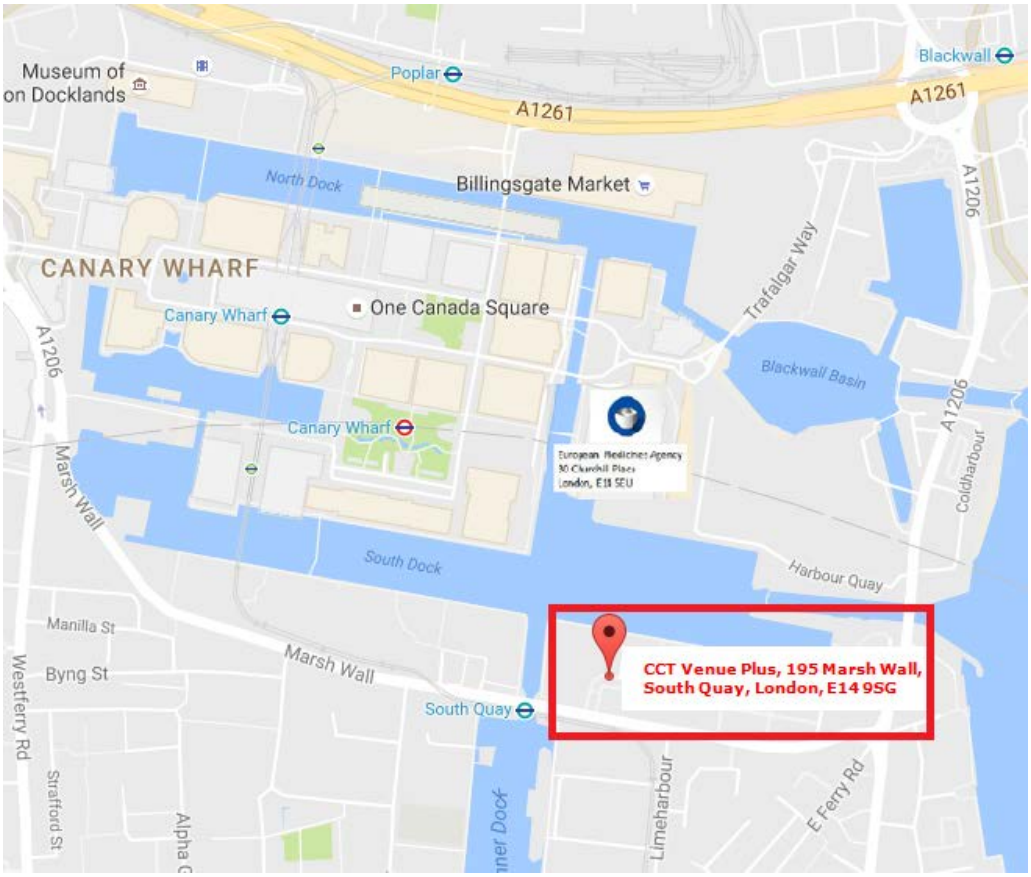
Lauren Sager Weinstein	Transport for London, United Kingdom
Marcel Salathé	École Polytechnique Fédérale de Lausanne, Switzerland
Thomas Senderovitz	Danish Medicines Agency, Denmark
Jón Snædal	World Medical Association, Iceland
Alessandro Spina	European Medicines Agency
Miriam Sturkenboom	Erasmus University 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

Practical information

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