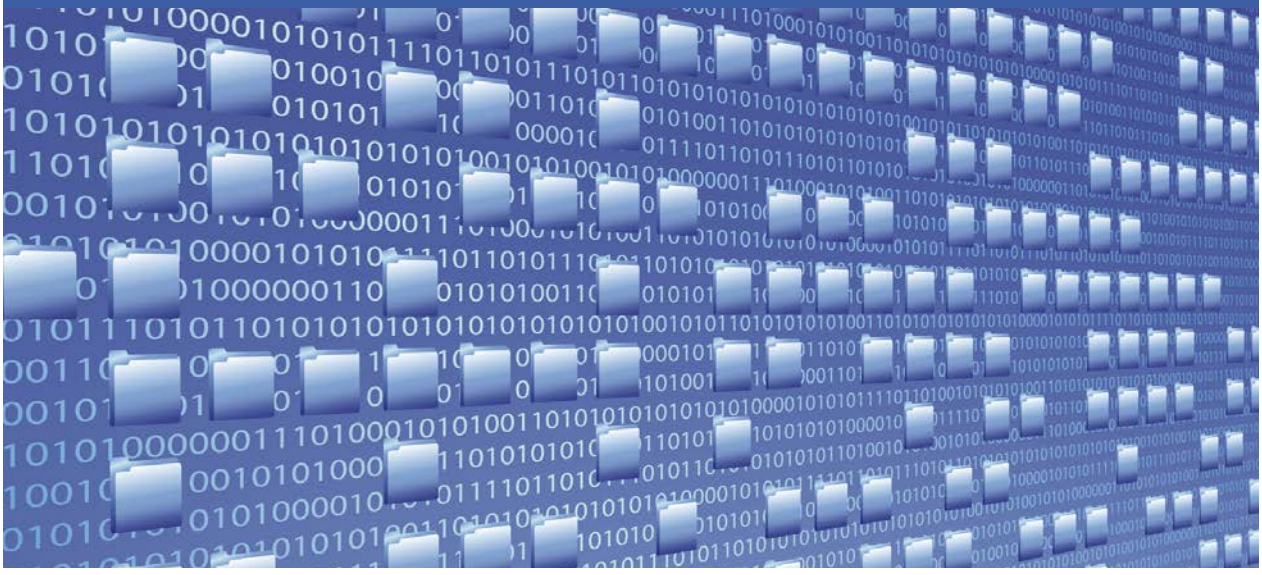
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 December 2017
EMA/550682/2017

A Common Data Model for Europe? – Why? Which? How?

11-12 December 2017
European Medicines Agency, London, United Kingdom



30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

Objectives and outputs

Objectives: To define the opportunities and challenges around implementation of a common data model in Europe to support regulatory decision making for human use.

Output: Proposals for guiding principles for the development of Common Data model in Europe including key criteria for validation in the context of regulatory decision making.

Programme details

Monday, 11 December 2017

12:30	**Registration**	
13:00	**Welcome and introduction**	
	Peter Arlett, EMA	***5'***
	Drivers for the Common Data Model – meeting objectives	
	Alison Cave, EMA	***10'***
13:15	**Session 1: A Common Data Model – Why?**	
	Chair: **Peter Arlett,** EMA	
	Use of real world data pre-authorisation – what can it answer?	
13.15	**Peter Mol,** CBG-MEB, NL	***20'***
13.35	***What do I want to know? – A regulatory perspective***	
	June Raine, MHRA, UK	***20'***
13.55	***FDA Experience with Sentinel Common Data Model – addressing data sufficiency***	
	Michael D. Nguyen, FDA, US	***30'***
14.25	***Strengths and limitations of a common data approach***	
	Patrick Ryan, Janssen Research and Development	***20'***
14.45	***Questions and discussion***	***15'***
15:00	**Coffee break**	
15:20	**Session 2: A Common Data Model – Which?**	
	Chair: **Xavier Kurz,** EMA	
15.20	***Overview of the Sentinel common data model***	
	Jeff Brown, Harvard Pilgrim Health Care Institute, US	***25'***
15.45	***PCORnet: challenges in applying the Sentinel Common Data Model to electronic medical records***	
	Lesley H. Curtis, Duke University, US	***20'***

16.05	***Overview of the OMOP common data model*** **Peter Rijnbeek,** Erasmus University Medical Center, NL	***25'***
16.30	***Challenges faced by Europe in implementing a CDM*** **Olaf Klungel,** Utrecht University, NL	***35'***
17.05	***Case study: Challenges faced by EMIF in utilising the OMOP CDM*** **Johan van der Lei,** Erasmus University Medical Center, NL	***30'***
17.35	***Comparing the use of Sentinel and OMOP CDMs for Drug Safety - Implications for European Data*** **Andrew Bate,** Pfizer, UK	***30'***
18.05	***Questions and discussion***	***25'***

18:30 **End of Day 1**

Tuesday, 12 December 2017

08:30 **Session 3: Validation of CDM - What is needed for regulatory decision making?**

Chair: **Stephen J. W. Evans**, LSHTM, UK

08.30 ***Sentinel CDM – the validation approach***
Jeff Brown, Harvard Pilgrim Health Care Institute, US ***30'***

09.00 ***OMOP CDM – the validation approach***
Jon Duke, Georgia Tech Research Institute, US ***30'***

09.30 ***CNODES CDM Pilot – the challenge of transforming data***
Robert W. Platt, McGill University, CA ***30'***

10.00 ***A Regulatory Approach to Validation of the CDM***
Jim Slattery, EMA ***30'***

10.30 ***Panel session*** ***40'***

11:10 **Coffee break**

11:30 **Session 4: Solutions for Europe: what is needed?**

Chair: **Alison Cave**, EMA

Group 1: What are the specific European barriers and challenges in applying a CDM?
Moderator: **Rosa Gini,** ARS, IT ***60'***

Group 2: How do you operationalise a CDM network?
Moderator: **Miriam Sturkenboom,** UMC Utrecht, NL ***60'***

Group 3: What are the key criteria necessary for validation of a CDM in Europe?
Moderator: **Stephen J. W. Evans,** LSHTM, UK ***60'***

Group 4: What are the key design choices of a CDM which influence the range of regulatory questions that can be addressed?
Moderator: **Niklas Noren,** WHO-UMC, SE ***60'***

12.30 Lunch

13:30 Session 4 continued: Solutions for Europe: what is needed?

13.30 ***Continue in groups to agree a Summary of the Groups' conclusions/recommendations*** ***30'***

14.00 ***Feedback from Group 1***
Moderator: **Rosa Gini,** ARS, IT ***15'***

14.15 ***Feedback from Group 2***
Moderator: **Miriam Sturkenboom,** UMC Utrecht, NL ***15'***

14.30 ***Feedback from Group 3***
Moderator: **Stephen J. W. Evans,** LSHTM, UK ***15'***

14.45 ***Feedback from Group 4***
Moderator: **Niklas Noren,** WHO-UMC, SE ***15'***

15.00 ***Discussion to agree*** ***45'***

- key criteria for validation of the Common Data Model and
- identification of areas of potential regulatory applicability

15:45 Closing remarks

Fergus Sweeney, EMA

16:00 End of Meeting

Practical information

Venue

The European Medicines Agency can be reached:

- **By Underground**
  The nearest stop for Churchill Place is Canary Wharf station on the Jubilee Line. From East exit (NB. This is the closest exit to 30 Churchill Place): exit the station and turn left into Upper Bank Street, turn right at Canada Square and continue straight into Churchill Place.

- **By Docklands Light Railway (DLR)**
  The Agency is a short walk from Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton. Exit into The South Colonnade, turn left towards Canada Square continuing straight into Churchill Place.

- **By car**

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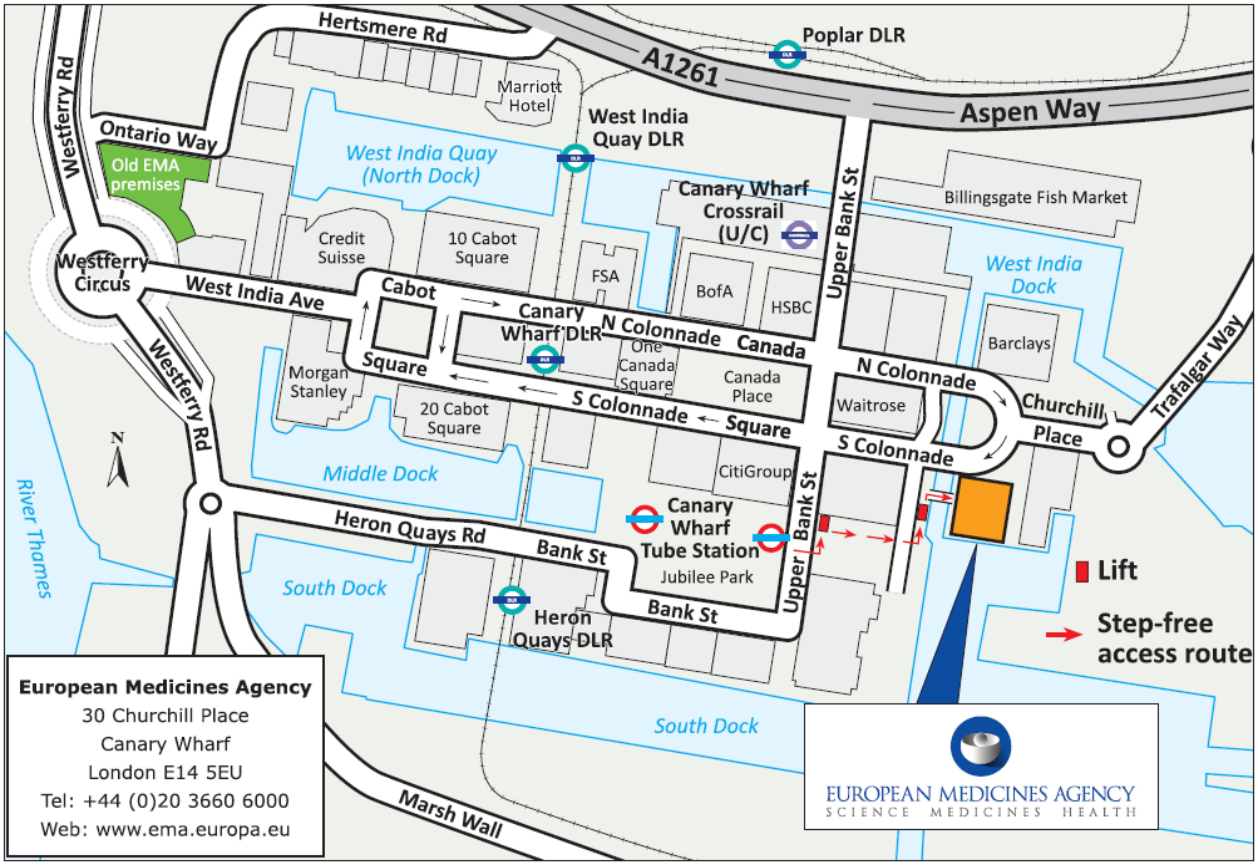
  http://www.canarywharf.com/aboutus/The-Estate/Travel-/Roads--Parking/

Map



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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 strongly advise you to arrive up to 30 minutes before the start of the workshop, to allow you time for registration and settling down.

Meeting room

You will be able to sit wherever you wish; note that the only reserved seats are for the speakers, panellists and organisers of the workshop.

Wi-Fi access & Laptop computers

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Conference venue and secretariat

European Medicines Agency
30 Churchill Place, Canary Wharf
London E14 5EU, United Kingdom
Telephone +44 (0)20 3660 7259 | **Facsimile** +44 (0)20 3660 5550
E-mail jolanta.palepsaitiene@ema.europa.eu | **Website** www.ema.europa.eu