EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

A European Common Data Model? Why? Which and How?

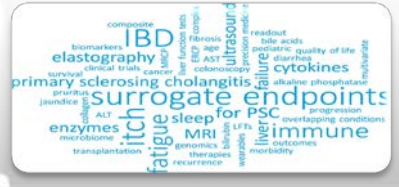
Dr Alison Cave,
Principal Scientific Administrator,
Pharmacovigilance and Epidemiology Department
European Medicines Agency

Why?..... What is the need and why now?

EUROPEAN MEDICINES AGENCY

Unknown **generalisability** of clinical trial results to normal clinical practice and lack of information in **high risk** groups demands new approaches to gather complementary evidence

Rapidly evolving scientific landscape enabling increasing patient stratification, driving **innovative medicinal approaches** and fuelling new possibilities for **rare diseases** but often results in **smaller, focused and shorter** RCTs or presents situations where a RCT is **not feasible**



A need for validation of shorter term surrogate endpoints with long term beneficial outcomes

Increasing data availability coupled with **technological advances** which offer new possibilities to store, mine and analyse data across multiple datasources

Enhanced Evidence Generation

Identify missing data / gaps

Support targeted and planned data collection

Highlight possible EU data sources

Sup
deve
am
of a

Life Cycle of a Medicine

Direct need for EU wide clinical data

Drug

Disease prevalence / epidemiology

Current clinical practice

Ap

Scientific Advice
PRIME
COMP

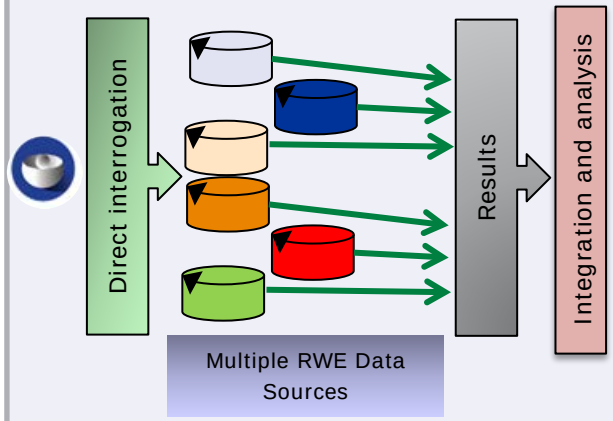
COMP
PDCO
CAT

CHMP
PRAC

Access to RWE

EUROPEAN MEDICINES AGENCY

Direct Access



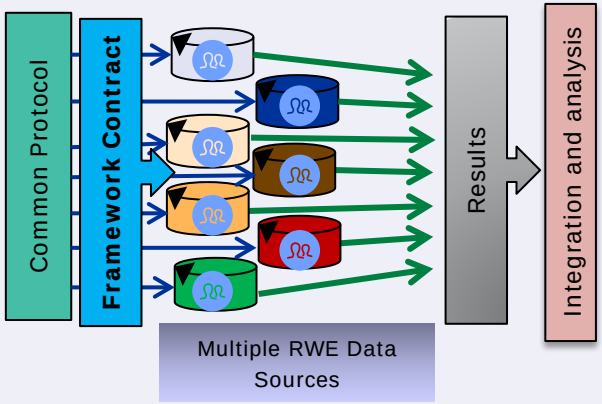
Advantages:

- EMA has direct access to 3 datasources which enables quick queries and in house studies to be run
- Enables collaborative studies to be performed with the EU network

Limitations:

- Need for internal resources
- Limited geographical coverage
- Collaborative studies can be slow

Indirect Access
Common Protocol



Advantages:

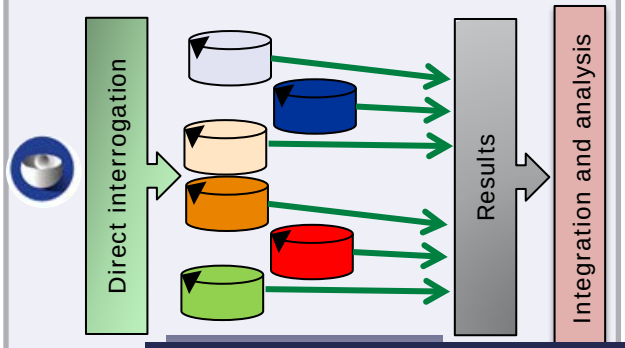
- More willingness to participate because there is no transfer of data
- Access to expertise
- Staged implementation

EMA-funded studies	N databases	N countries
A/H1N1 pandemic vaccines and pregnancy outcomes	1	1
Impact of risk minimisation in patients treated with rosiglitazone-containing products	2	2
Isotretinoin and the effectiveness of the Pregnancy Prevention Programme in Europe	5	3
Patterns and determinants of use of oral contraceptives in the EU	5	3
Monitoring the effectiveness of risk minimisation in patients treated with pioglitazone-containing products	3	3
Risk of cardiac valve disorders associated with the use of biphosphonates	6	3
Association between anxiolytic or hypnotic drugs and total mortality	2	2
Metformin use in renal impairment	2	2
Study of regulatory communication and risk awareness following the Article 31 referral of Combined Hormonal Contraceptives in relation to thromboembolism	n/a	6
Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU	9	6
Study of utilisation of Combined Hormonal Contraceptives in Europe	3	3
Anti-microbial resistance: choice of therapeutic interventions and outcomes for the treatment of infections caused by MDR Gram negative pathogens	4	1
Methods and data sources for determining long-term effects of drug exposure during pregnancy, with application to antiepileptic medicines	n/a	28
Impact of EU label changes for systemic diclofenac products: post-referral prescribing trends	4	3
Impact of EU label changes for hydroxyzine products: post-referral prescribing trends	4	3

EMA access to RWE?

EUROPEAN MEDICINES AGENCY

Direct Access



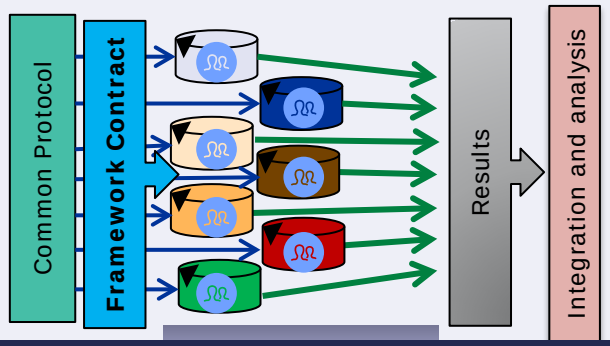
Advantages:

- EMA has direct access to 3 datasources which enables quick queries and in house studies to be run
- Enables collaborative studies to be performed with the EU network

Limitations:

- Need for internal resources
- Limited geographical coverage
- Collaborative studies can be slow

Indirect Access Common Protocol



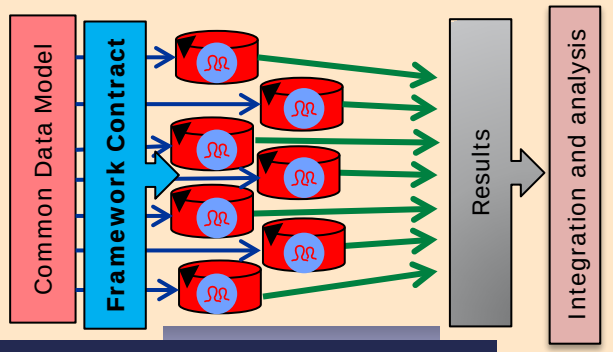
Advantages:

- More willingness to participate because there is no transfer of data
- Access to expertise
- Staged implementation

Limitations:

- Slower process for studies to be run
- Potential lack of interest from partners to participate in regulatory questions

Indirect Access Common Data



Advantages:

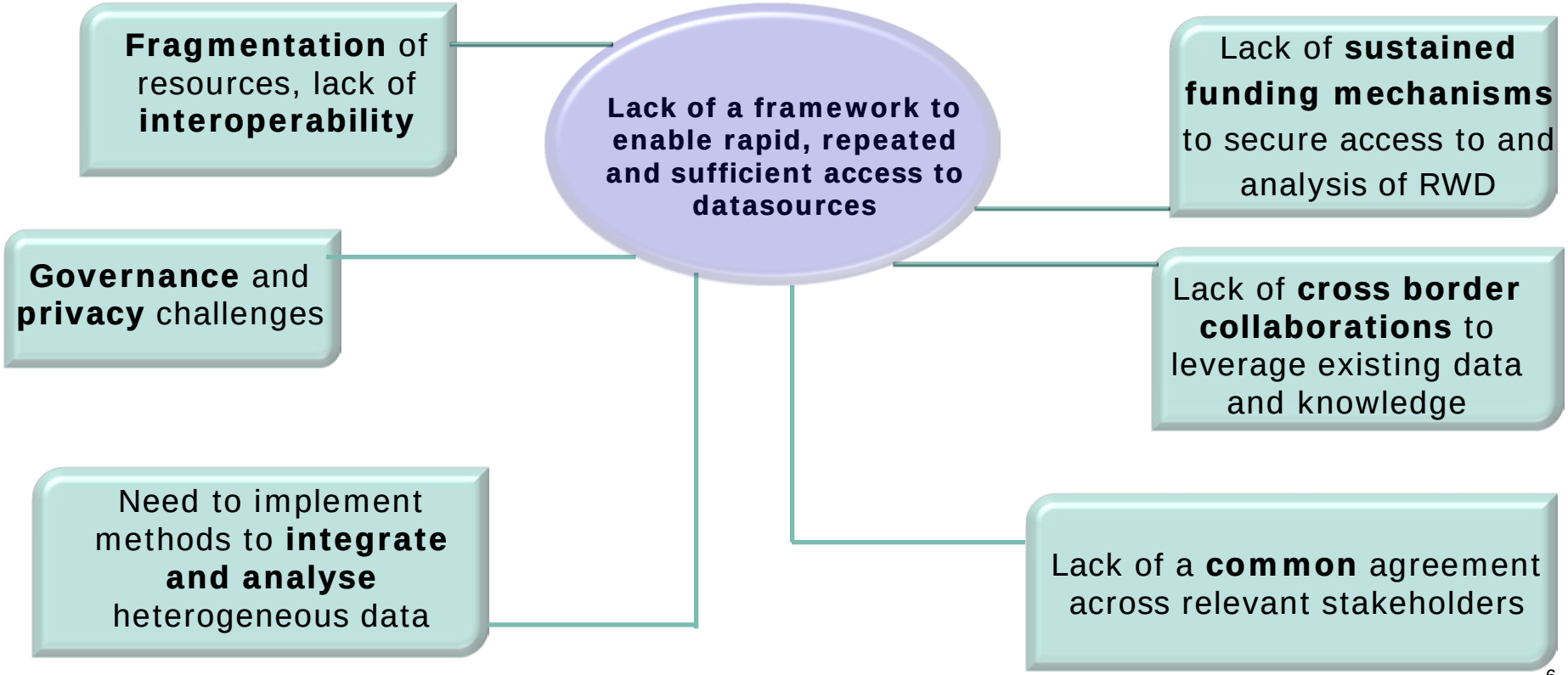
- More willingness to participate because there is no transfer of data
- Access to expertise
- Staged implementation
- **Fast**

Limitations:

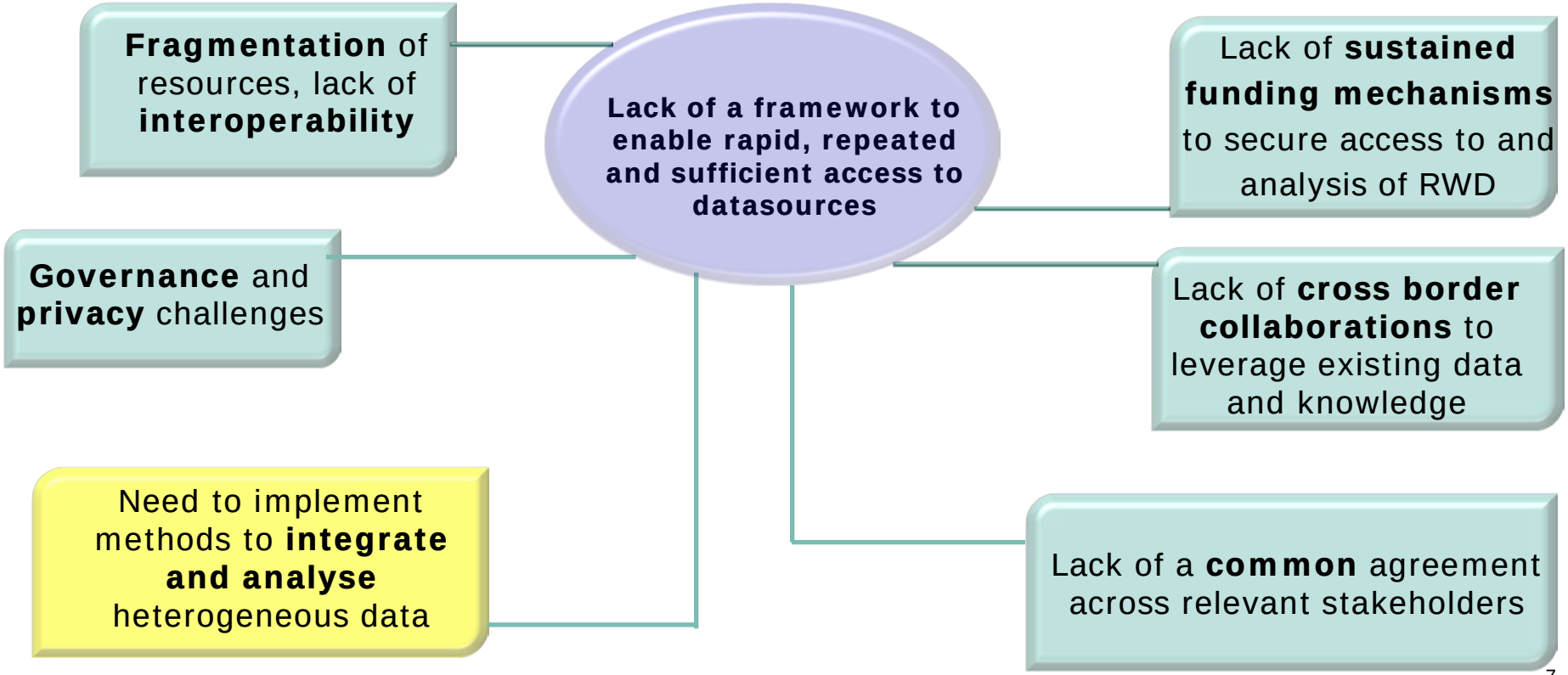
- Upfront resource investment
- Potential loss of information in transfer to CDM
- Need for validation of model

No one solution – a hybrid approach will be required

What is the problem?



What is the problem?



Multiple Approaches

Vaccine Safety Datalink (VSD)

This meeting explores just one possible approach

The Common Data Model

A common data model can be defined as a mechanism by which the raw data are standardised to a common structure, format and terminology independently from any particular study in order to allow a combined analysis across several databases/datasets. Standardisation of structure and content allows the use of standardised applications, tools and methods across the data to answer a wide range of questions.

Sentinel Initiative

OHDSI
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

Motivation

- To establish access to a **maintained** set of healthcare databases which are able to provide answers to **multiple** regulatory questions.
- To **accelerate** response times.
- To aid **clear documentation** of the methodological process.
- To aid **interpretation** of heterogeneous results.

Is a common data model the solution for Europe?

How can we manage but exploit the heterogeneity in data across Europe?

How do we balance flexibility with speed?

How do we validate the data transformation?

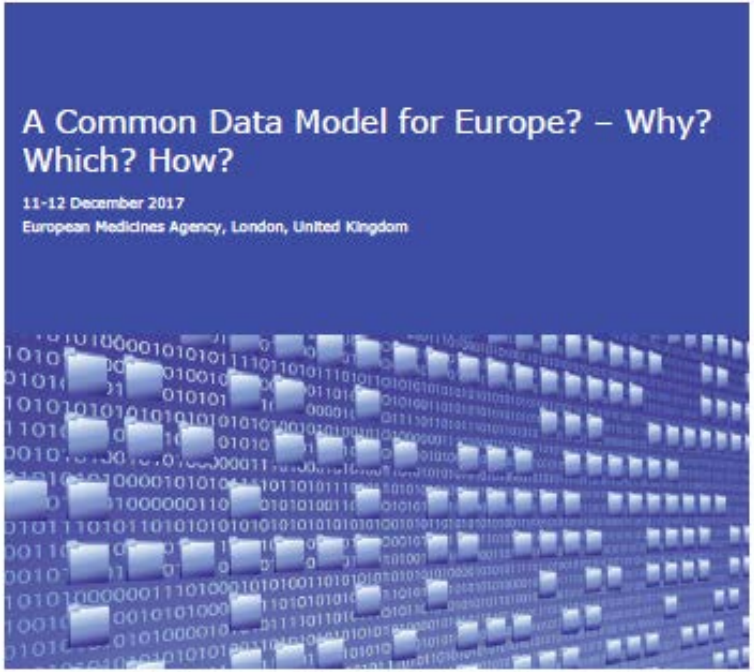
What are the key criteria for validation?

How do build a operationalise a network?

How do we ensure the expertise of all stakeholders is incorporated?

How do we build a sustainable system?

What are the key design choices of a CDM which influence data sufficiency?

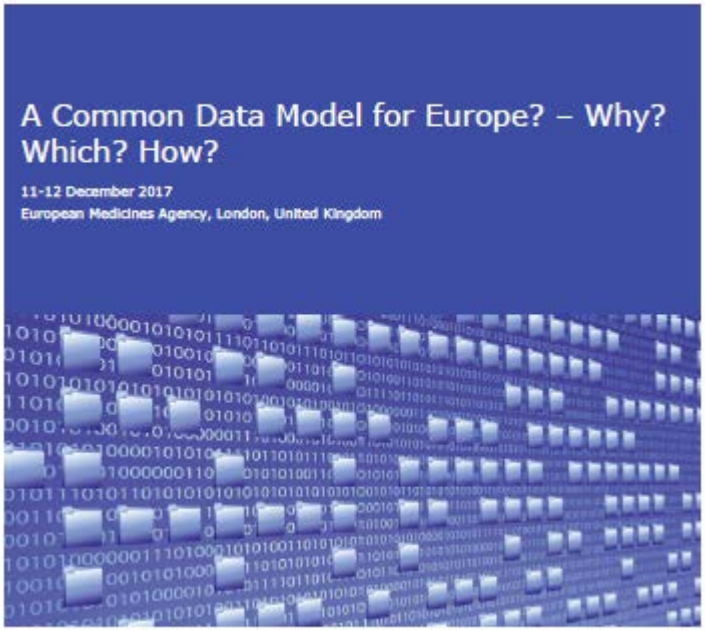


Objectives:

To define the **opportunities and challenges** around implementation of a common data model in Europe to support regulatory decision making.

Output:

To **propose guiding principles** for the development of Common Data model in Europe including **key criteria for validation** in the context of regulatory decision making.



Session 1: A Common Data Model – Why?
Session 2: A Common Data – Which?
Session 3: Validation of CDM - What is needed for regulatory decision making?
Session 4: Solutions for Europe: what is needed?

Group 1: What are the specific European barriers and challenges in applying a CDM?
Group 2: How do you operationalise a CDM network?
Group 3: What are the key criteria necessary for validation of a CDM in Europe?
Group 4: What are the key design choices of a CDM which influence the range of regulatory questions that can be addressed?

Thank you for your attention!

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Further questions: alison.cave@ema.europa.eu

Follow us on **@EMA_News**