EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical Trial Safety Reporting requirements

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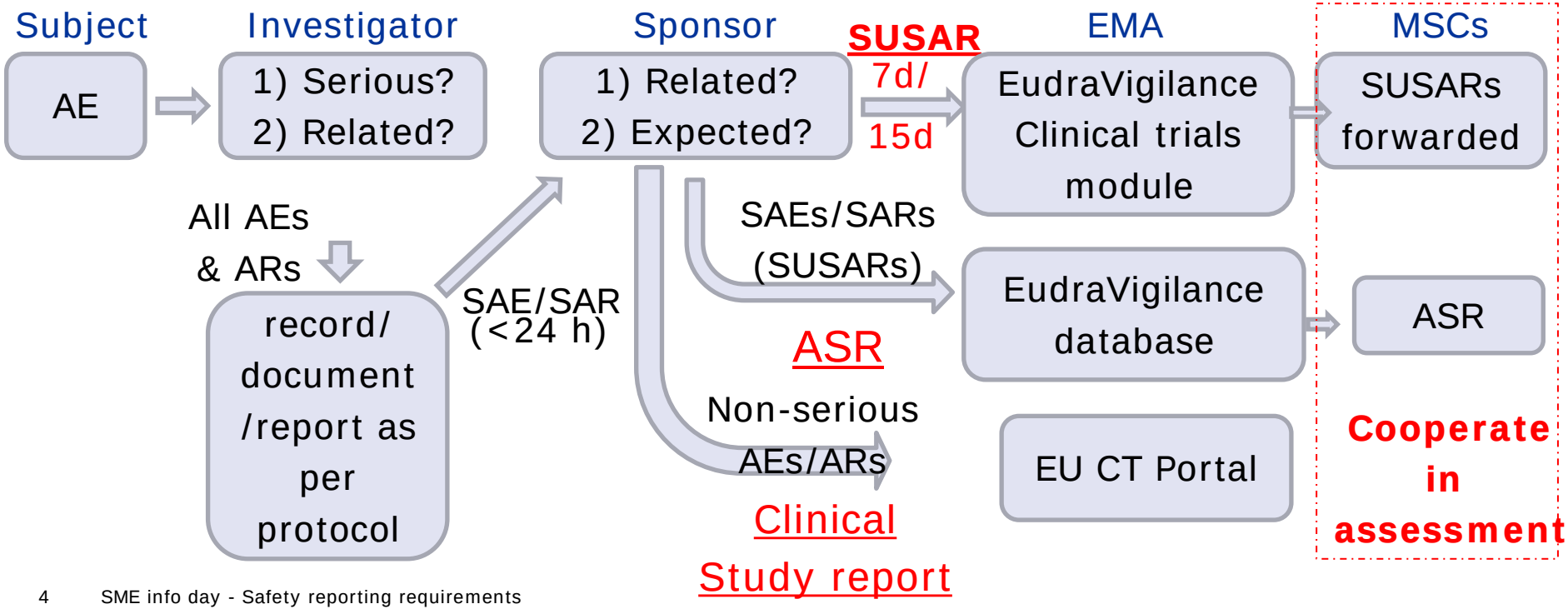
Presented by Sophia Mylona
Clinical & Non-clinical Compliance , European Medicines Agency

Article	Regulation (EU) No. 536/2014 EU Portal and database
Art 40	***Electronic database for safety reporting*** *The European Medicines Agency…shall* ***set up and maintain an electronic database for the reporting*** *provided in Articles 42* (i.e. SUSARs) *and 43* (i.e. Annual Safety Report). *That database shall be a module of …(the* ***EudraVigilance Database****).* *The Agency shall, in collaboration with Member States, develop a standard* ***web-based structured form*** *for the reporting by sponsors to the database referred to in paragraph 1 of suspected unexpected serious adverse reactions.*
Art 42	*The sponsor of a clinical trial performed in at least one Member State shall report electronically and without delay to the database referred to in Article 40(1) all relevant information about the following* ***suspected unexpected serious adverse reactions*** *(…).*

Article	Regulation (EU) No. 536/2014 EU Portal and database
Art 43	1. *Regarding investigational medicinal products other than placebo, the sponsor shall submit annually through the database referred to in Article 40(1) to the Agency a report on the safety of each investigational medicinal product used in a clinical trial for which it is the sponsor.* 2. *In the case of a clinical trial involving **the use of more than one** investigational medicinal product, the sponsor may, if provided for in the protocol, submit **a single safety report** on all investigational medicinal products used in that clinical trial.* 3. *The annual report referred to in paragraph 1 shall only contain **aggregate** and **anonymised** data.* 4. *The obligation referred to in paragraph 1 **starts with the first authorisation** of a clinical trial in accordance with this Regulation. It ends with the end of the last clinical trial conducted by the sponsor with the investigational medicinal product.*

Article	Regulation (EU) No. 536/2014 EU Portal and database
Art 44	*1.The Agency shall, by electronic means, forward to the Member States concerned the information reported in accordance with Article 42 and 43.* *2.**Member States shall cooperate in assessing the information reported in accordance with Articles 42 and 43.** The Commission may, by means of implementing acts, set up and modify the rules on such cooperation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(2).* *3.The responsible ethics committee shall be involved in the assessment of the information referred to in paragraphs 1 and 2, if it has been provided for in the law of the Member State concerned.*

What changes with Regulation (EU) No. 536/2014 ?
Clinical Trial safety reporting requirements similar



How will Member States cooperate for safety assessments?

- Work-sharing;
- Safety assessment member state (saMS) proposed to lead and provide recommendations to RMS and MSC;
- Clinical Trials Facilitation Group to define the process and develop guidance.

EU portal and database project – business context view

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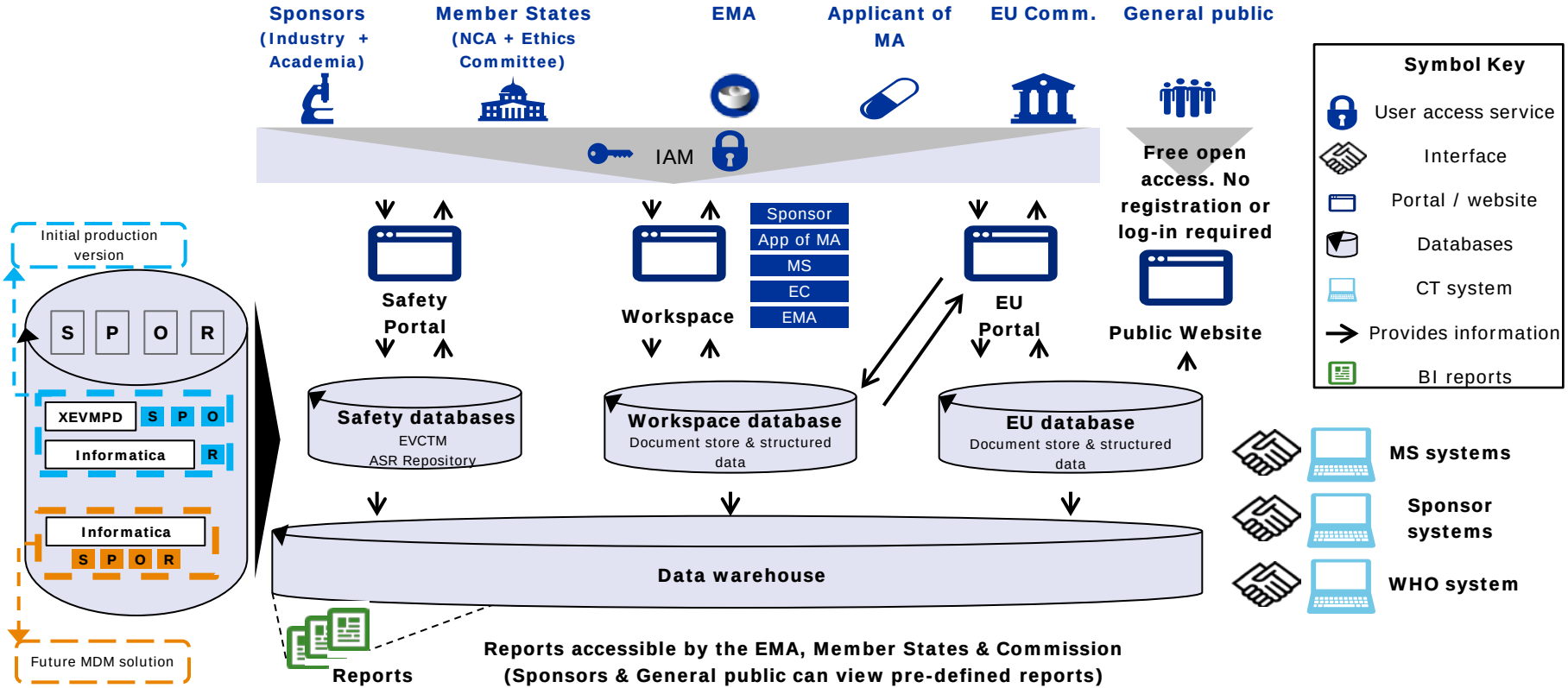
This diagram depicts the To-Be system architecture for the clinical trial systems:



Subgroup H (Industry and MS representatives)

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Working on system requirements for safety reporting

- Annual Safety Reporting (ASR) submission and assessment
  - Submission of reports by the sponsors of the clinical trials
  - Assignment of saMS
  - Assessment by the MSs including:
    - Recording of comments by the MSs
    - Collation of comments by the saMS
    - Request for information
- SUSAR reporting, rerouting and assessment
  - Reporting of SUSARs via the new EudraVigilance system
  - Re-routing of SUSARs to the MSs based on CT number and active ingredient
  - Assessment of SUSARs by the MSs
- Data analysis and BI
  - No requirements in the legislation. Scope to be agreed and limited to essential reporting

Clinical Trials Overall Programme Timeline

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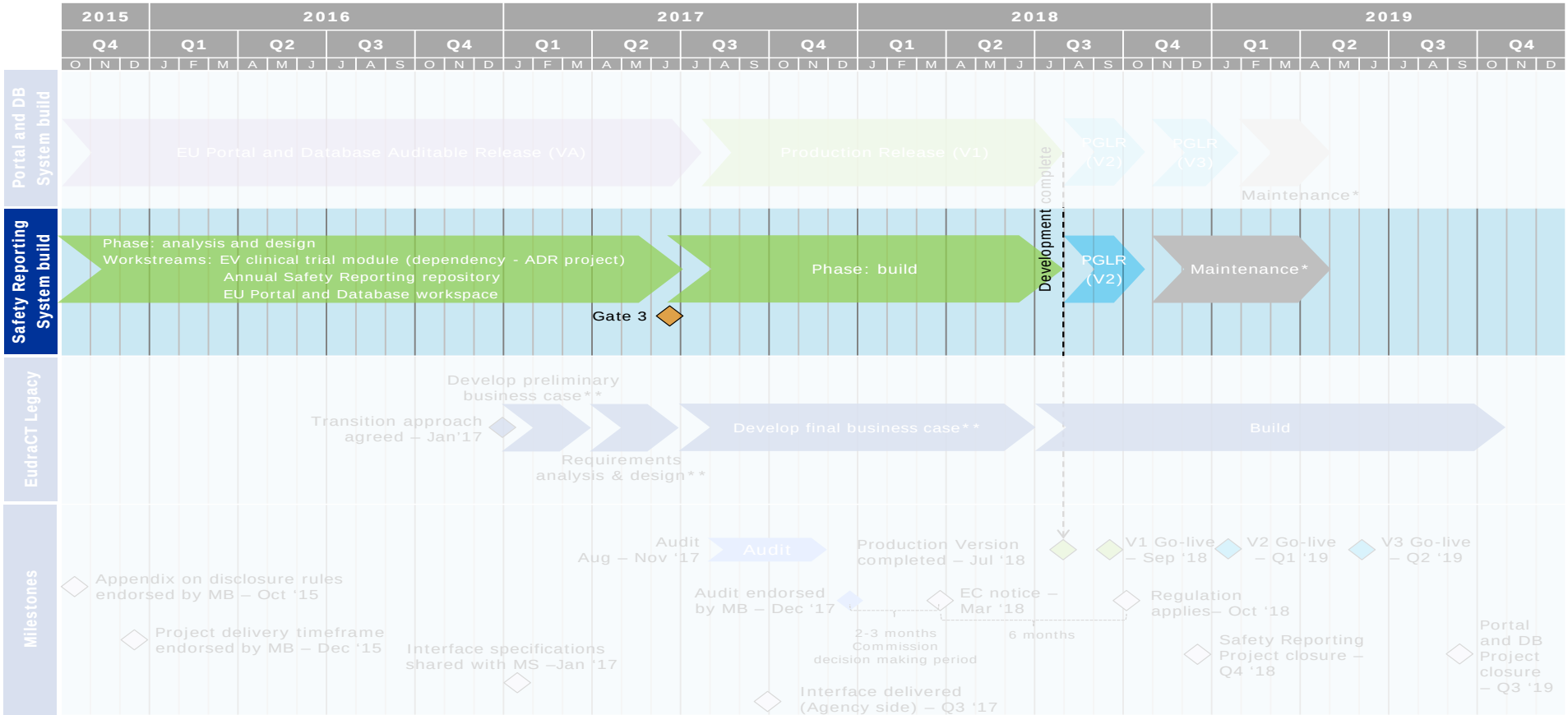

* Activity continues

** Dependency on decision measures agreed by the Commission

Thank you for your attention

Further information

Contact E-mail:
Pedro.Oliveira@ema.europa.eu
Sophia.Mylona@ema.europa.eu
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
Send a question via our website www.ema.europa.eu/contact

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