EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CT Regulation: EMA role

Presented by: Anabela Marcal
Head of Compliance and Inspection Department

CT Regulation: the EMA role

- Deliver the IT platforms needed for the implementation as required by Regulation

- Coordination of cooperation between MS concerned on EU and third country inspections of clinical trials

Legal basis - Art 80 EU Portal

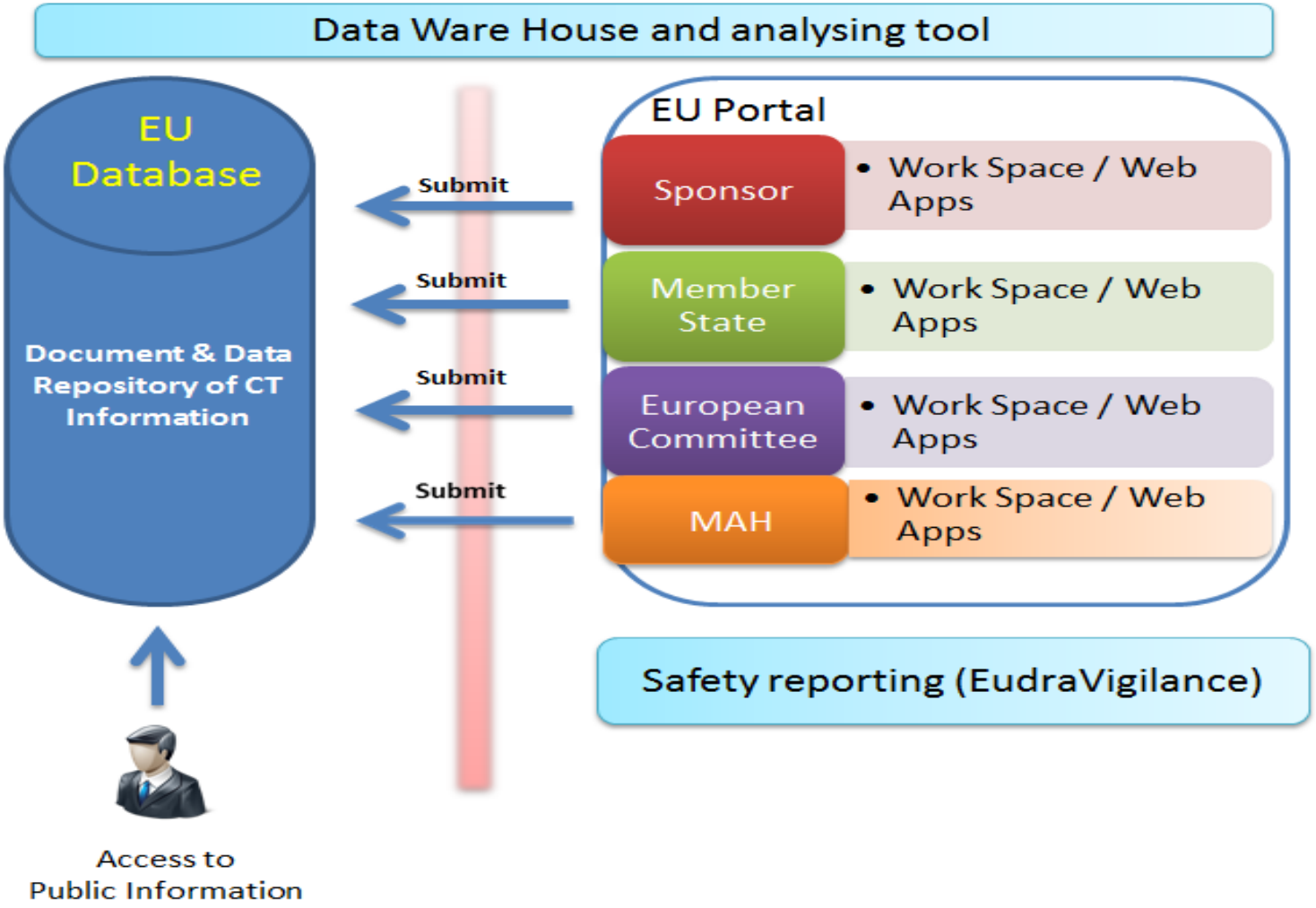
"The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a ***portal at Union level*** *as a single entry point for the submission of data and information relating to clinical trials in accordance with this Regulation. The EU Portal shall be technically advanced and user friendly so as to avoid unnecessary work.*

Data and information submitted through the EU portal shall be stored in the EU Database."

Legal basis - Art 81 EU Database

"The Agency shall, in collaboration with the Member States and the Commission, ***set up and maintain a EU database*** *at Union level. The Agency shall be considered to be the controller of the EU database and shall be responsible for avoiding unnecessary duplication between the EU database and the EudraCT and Eudravigilance databases."*

Clinical trial systems



Legal basis - Article 82
Functionality of the EU portal and EU database

"The Agency shall, in collaboration with the Member States and the Commission draw up the ***functional specifications*** *for the EU portal and the EU database, together with the* ***timeframe for their implementation****."*

Legal basis - Article 82
Functionality of the EU portal and EU database

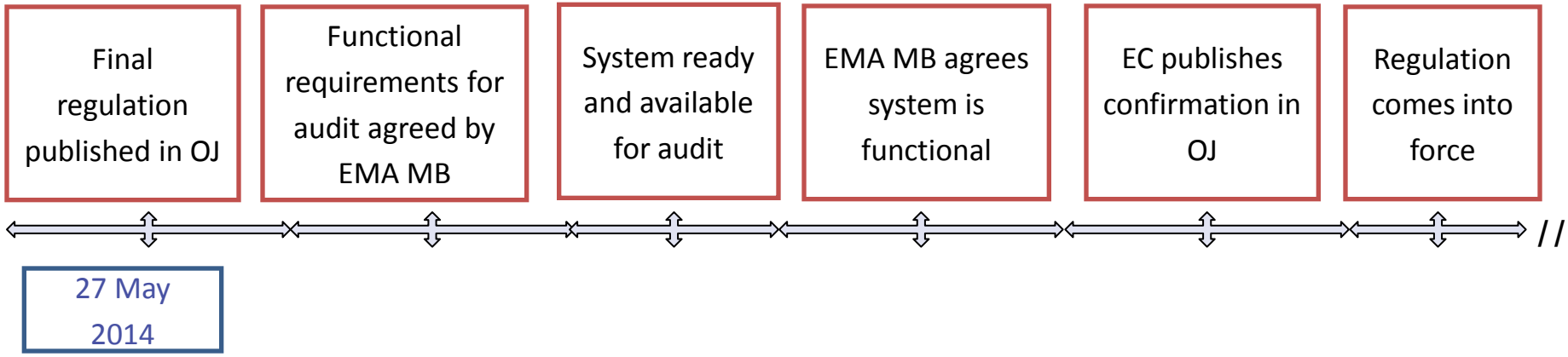
*"The Management Board of the Agency shall, on the basis of an **independent audit**, confirm to the Commission when the EU portal and the EU database have achieved full functionality and meet the functional specifications drawn up pursuant to the third paragraph.*

*The **Commission shall**, when it is satisfied that the Union portal and database achieved full functionality, **publish a notice** to that effect in the Official Journal of the European Union."*

CT regulation timelines – key milestones

- CT regulation published in the OJ: 27 May 2014
- EMA to agree the functional specifications with Member States and the European Commission
- EMA to prepare the detail requirements for the system
- **EMA to liaise with the relevant stakeholders for contribute / feedback on the systems to be developed**
- Functionality of EU portal and Database to be audited
- EMA MB agrees system is functional
- EC publishes confirmation in OJ
- **Regulation comes into force no earlier than 2 years after its publication**

CT regulation key milestones



The regulation will come into force no earlier than 2 years after publication in the OJ (27 May 2016 at the earliest)

CT regulation timelines: transitional provisions

Transitional provisions:

Clinical trials (CTA data) can continue to be managed through EudraCT for a limited period of time (for up to 1 year after implementation) unless the sponsor has opted to submit the clinical trial dossier to the EU database once it is launched.

CT regulation implementation: interaction with stakeholders

EMA will liaise with the relevant stakeholders for feedback on the functionalities of systems to be developed:

EU CT Information System Expert Group with Stakeholders
25-Jun
30-Sep
24-Oct
27-Nov