EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Follow-up discussion on Horizon Scanning activities

EMA – Payer Community meeting, 18 June 2019

Presented by Michael Berntgen
Head of Product Development Scientific Support Department

# Topics to be addressed

1/ Experience with providing updates on evaluation activities to TISP

2/ Information on clinical studies - current and future

3/ Feedback from tendering a drug pipeline database

# Information provided for TISP activities

As part of EUnetHTA's Topic Identification, Selection and Prioritisation activities (TISP), EMA was invited to provide processable data on regulatory evaluation activities

Data fields of interest were jointly identified, based on published information, and EXCEL agreed as submission format

- Prospective milestones need to be established by the recipient, based on general knowledge about regulatory processes
- First submission with data cut off 1st March 2019, second with data cut off 1st May 2019

Fine-tuning of the report based on experience (focus on products in the first phase of the evaluation due to relevance for TISP activities)

# Clinical trial information: the current EU CTR


Art. 11 of Directive 2001/20/EC (Eudralex website)
https://ec.europa.eu/health/documents/eudralex/vol-10_en

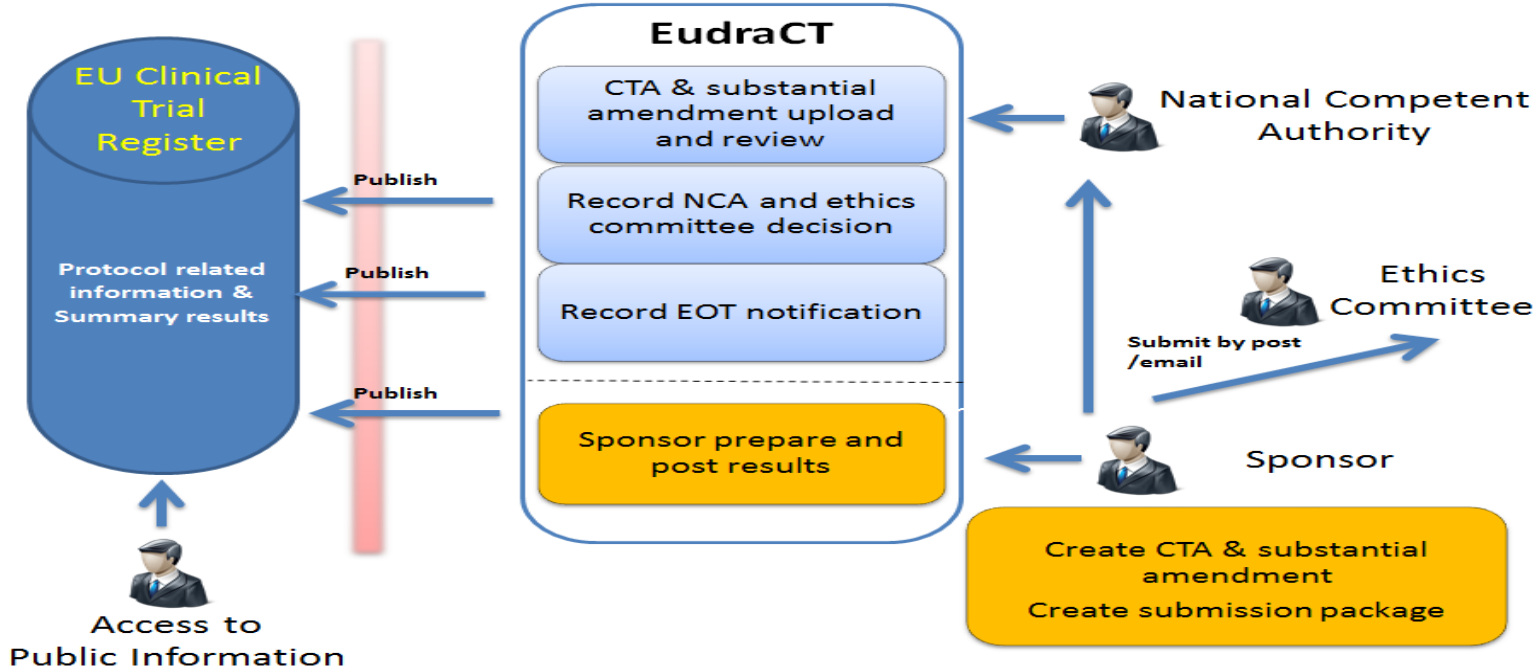

EudraCT: database used by NCAs (National Competent Authorities) to legally approve CT applications submitted by sponsors and by paediatric-investigation-plan Addressees (launched in May 2004)


Only accessible to the Competent Authorities, European Commission and EMA

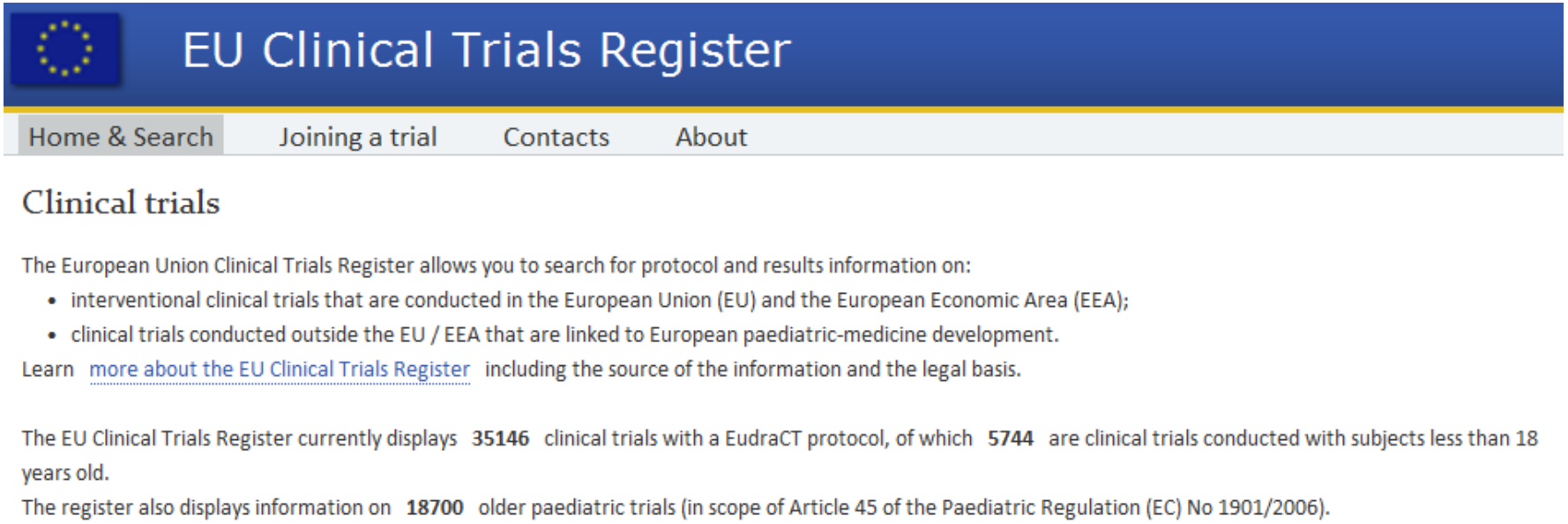

Since October 2013 sponsors can log in to prepare and post the structured results of approved interventional CTs


Public access: a subset of this data is made available through the EU Clinical Trials Register (EU CTR) launched in March 2011

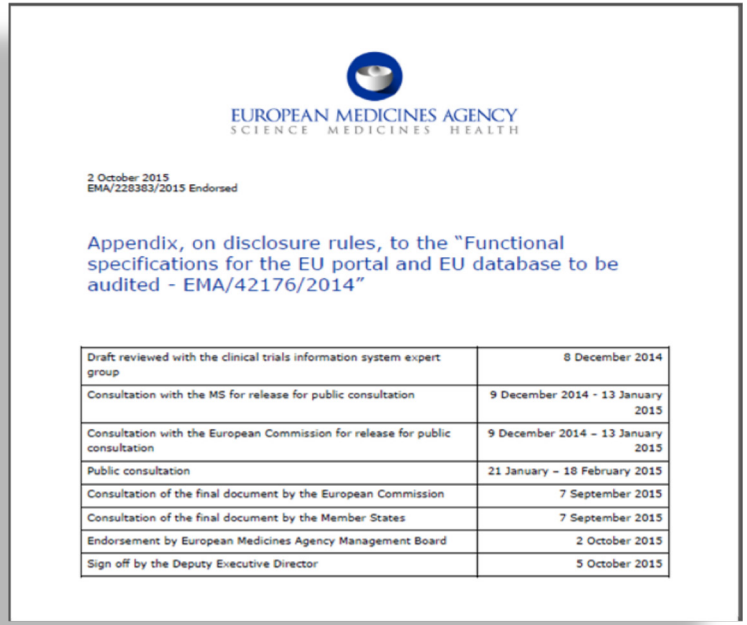
# Overview of actors



# https://www.clinicaltrialsregister.eu



# Clinical trial information: the future EU database



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 October 2015
EMA/228383/2015 Endorsed

Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014"

| | |
|---|---|
| Draft reviewed with the clinical trials information system expert group | 8 December 2014 |
| Consultation with the MS for release for public consultation | 9 December 2014 - 13 January 2015 |
| Consultation with the European Commission for release for public consultation | 9 December 2014 – 13 January 2015 |
| Public consultation | 21 January – 18 February 2015 |
| Consultation of the final document by the European Commission | 7 September 2015 |
| Consultation of the final document by the Member States | 7 September 2015 |
| Endorsement by European Medicines Agency Management Board | 2 October 2015 |
| Sign off by the Deputy Executive Director | 5 October 2015 |

Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014"

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/10/WC500195084.pdf

# Tender for a drug pipeline database

EMA activities are informed by drug pipeline information from a database subject to a tender

A new tender has recently be completed; the technical specification can be found here

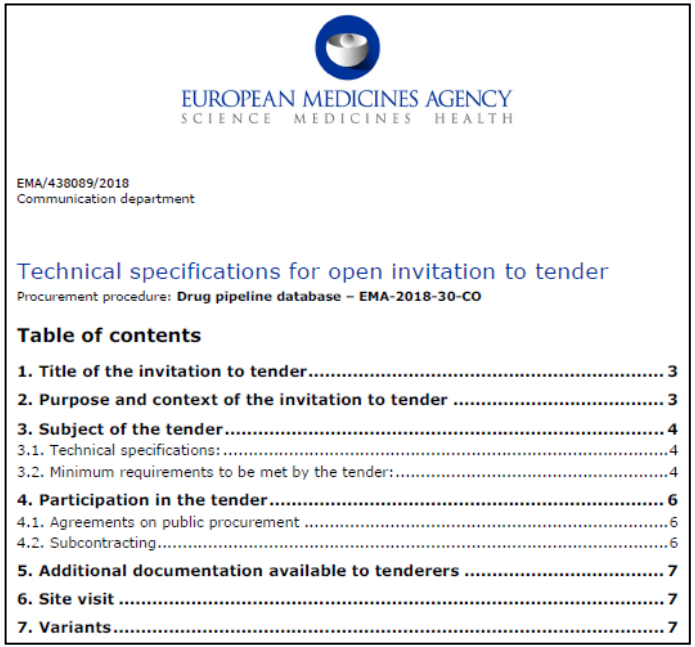
- current, comprehensive and complete drug databases to provide information of the medicines and medical devices for human use
- to inform the assessment and monitoring of these products by the Agency and to support its work forecast
- for abstracted adverse reaction reports to find and/or evaluate adverse reactions of medicines for human use licensed in the EEA

# Tender for a drug pipeline database

Important elements of learning include:

- terminology for disease classification
- products in scope (eg use of "all")
- balancing information capacity vs constantly

Next step: possibility to share experience with the selection and the use of the drug pipeline database



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/438089/2018
Communication department

Technical specifications for open invitation to tender

Procurement procedure: **Drug pipeline database – EMA-2018-30-CO**

**Table of contents**

# Thank you for your attention

## Further information

Michael.Berntgen@ema.europa.eu

**Temporary visiting address** Spark building • Orlyplein 24 • 1043 DP Amsterdam • The Netherlands
**For deliveries** refer to www.ema.europa.eu/how-to-find-us
**Send us a question** via www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Follow us on **@EMA_News**