



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The EU portal and database

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An agency of the European Union





Table of contents

- Legal basis
- CT programme
- EU portal and database
- Transparency
- Key message





Legal basis – Regulation (EU) No 536/2014

- ❑ **Article 80** in relation to the set up of a **portal at Union level** as a single entry point for the submission of data and information relating to clinical trials;
- ❑ **Article 81** in relation to the set up and maintenance of **a EU database at Union level**. The Agency shall be considered to be the controller of the EU database;
- ❑ **Article 81(4)** The EU database shall be **publicly accessible** unless, for all or part of the data and information contained therein, confidentiality is justified based on a set of grounds



Legal basis

- ❑ **Article 82** defines that the Agency shall draw up the **functional specifications** for the EU portal and the EU database, together with the timeframe for their implementation;
- ❑ **Article 84** defines that the Agency shall support the functioning of the cooperation of the Member States (...) by **maintaining and updating the EU portal** and the EU **database** in accordance with the experience acquired during the implementation of this Regulation.

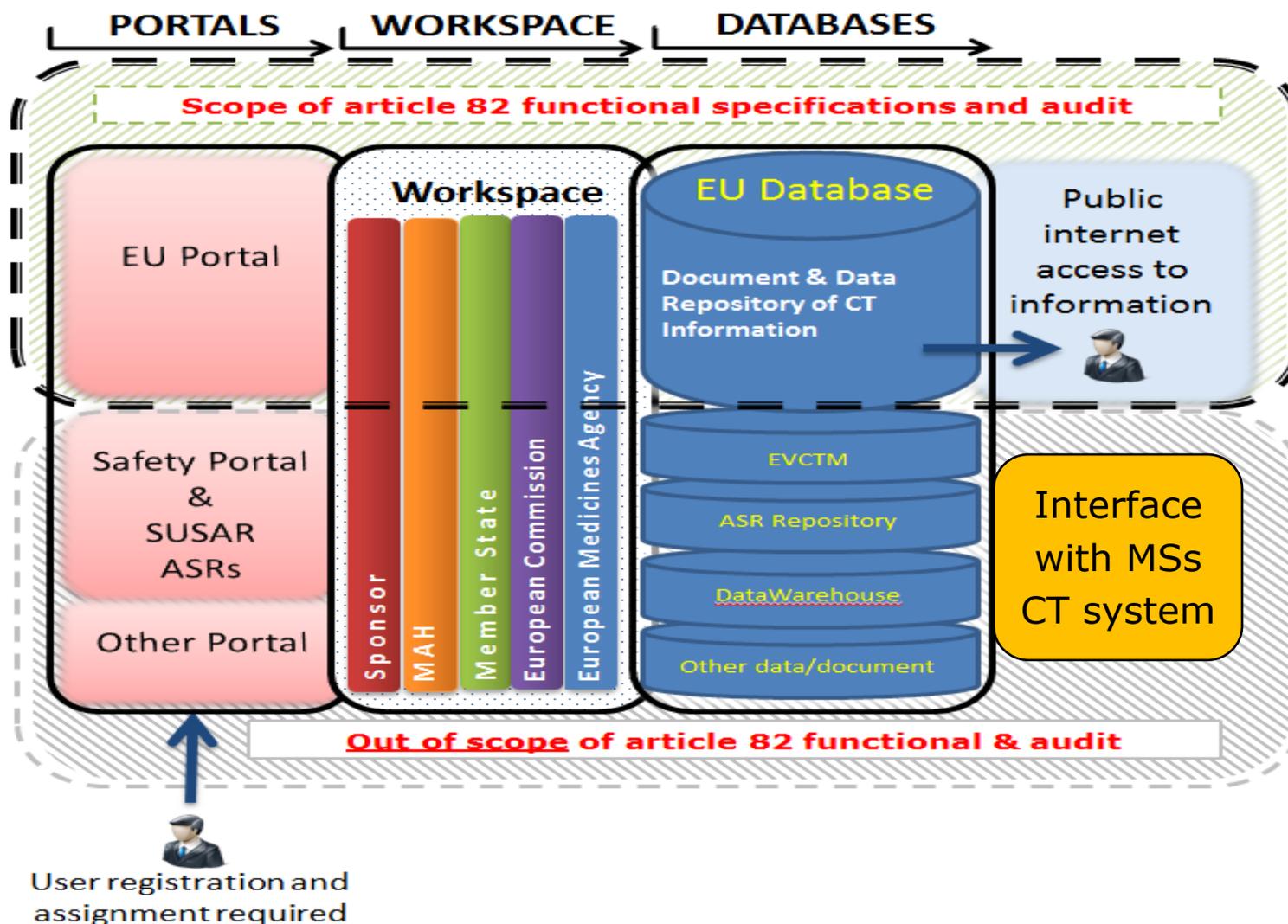


CT Programme



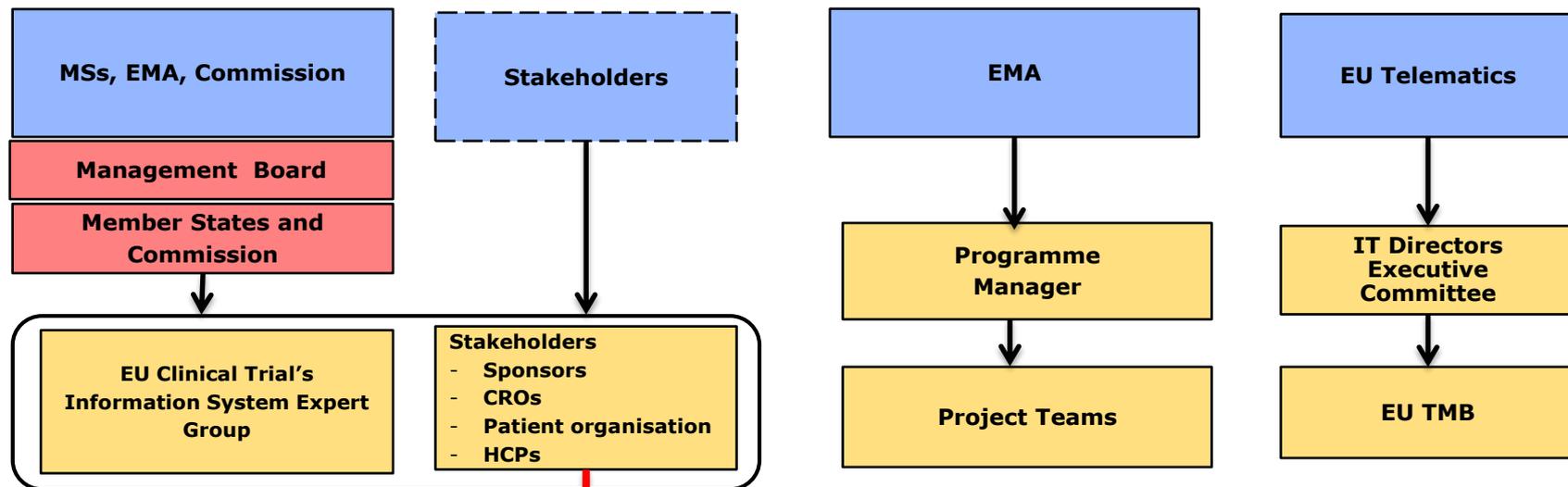


Medium level view





Programme governance



**Meetings four times per year
(first meeting took place on 25th of June 2014)**

**Regular Meetings
(with stakeholders starting in October 2014)**

- Sponsor driven activities
- Member state driven activities
- User management
- Provision to public
- Inspections
- EU control
- Clinical trial safety reporting



EU portal and database





Single EU portal and database

One clinical trial application form and supporting dossier for:

- One or more Member States, to cover all regulatory and ethics elements to be assessed;
- Public registration of the trial, and its subsequent updates, including the necessary elements of international registration at WHO ICTRP portal;
- Providing the trial design elements to support subsequent entry and publication of the summary of results;
- EU trial number – one per trial;
- EU numbers to identify products and substances to underpin linking and aggregation of information on IMPs.

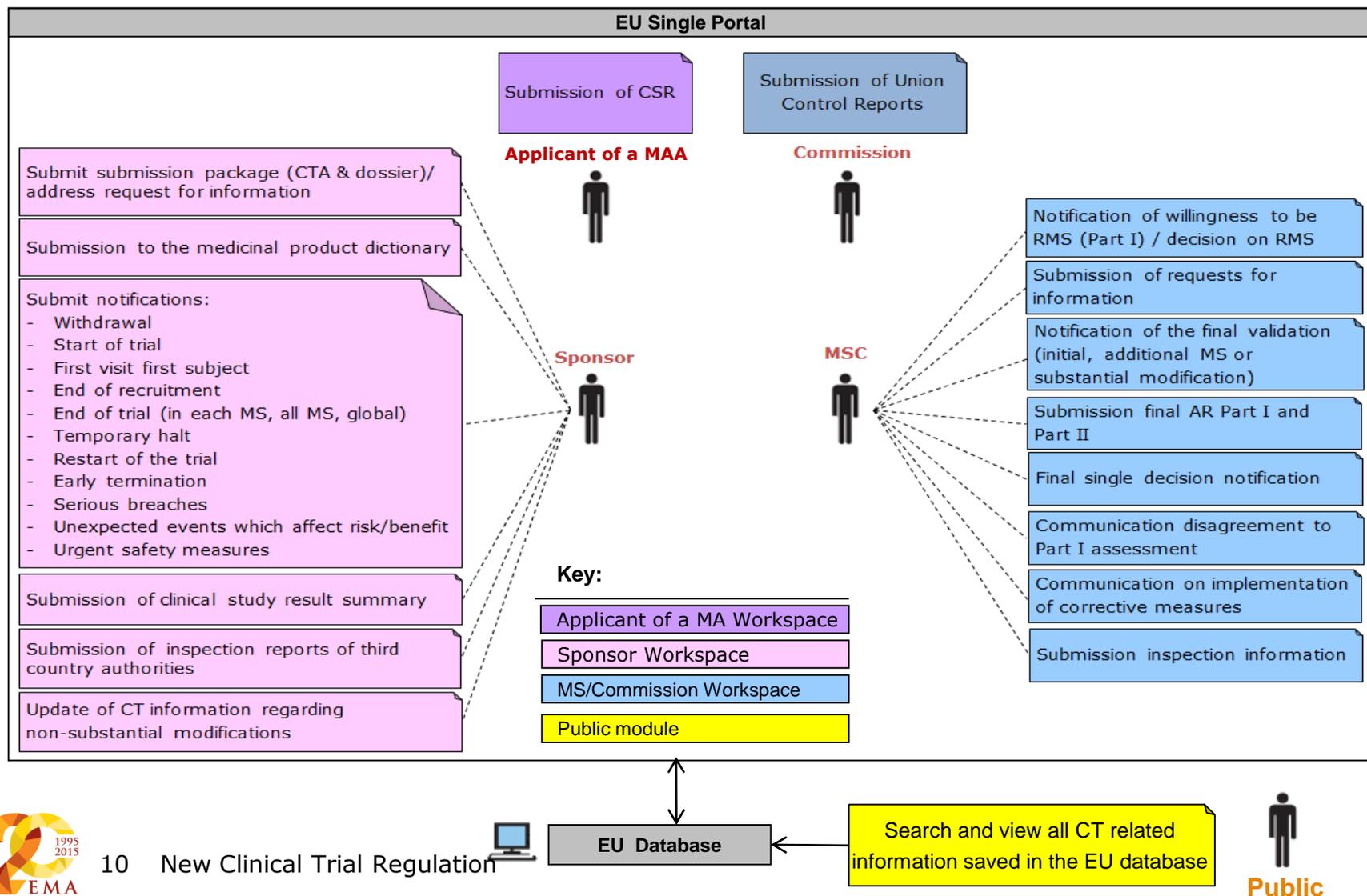


Authorisation procedure

- Part I – including joint assessment for trial in more than one MS (role of the RMS) + Part II national part;
- Single assessment of Part I with single set of questions and responses and single outcome, regardless of the number of MS involved (1-28);
- Combines and consolidates best expertise of the MSs involved;
- Strictly defined timelines;
- Ethics committees involved in the assessment of parts I and II, as applicable, according to the law of the MS concerned;
- Single decision per MS (including regulatory and ethics review) in line with coordinated assessment of Part I;

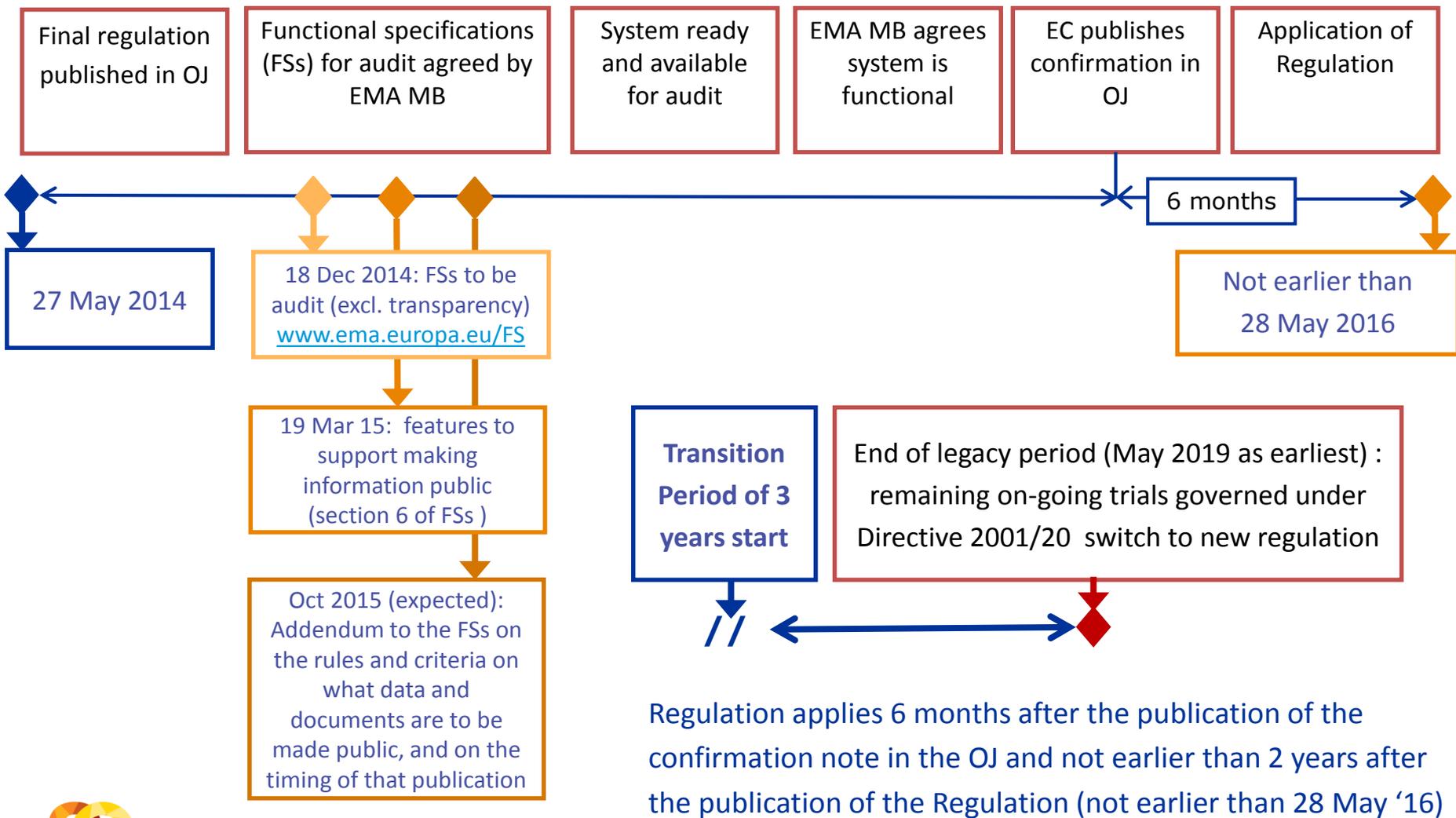


EU portal and EU database: "To be" process





CT regulation timelines/key milestones





Transparency





Addendum on transparency: Functional Specifications to be audited

- “Functional specifications for the EU portal and EU database to be audited” final published 19 December 2014;
- “Draft proposal for an addendum, on transparency, to the 'functional specifications for the EU portal and EU database to be audited” ;
- Public consultation from 21 January 2015 – 18 February 2015;
- Seek stakeholders’ views on the application of these exceptions set out in article 81(4) of the Regulation.



Transparency legal requirements: Clinical Trials Regulation

Article 81(4) of Regulation (EU) No. 536/2014

- EU database publically accessible by default, with exceptions justified on any of the following grounds:
 - Protection of personal data;
 - Protection of commercially confidential information in particular taking into account the MA status of the medicinal product, unless there is an overriding public interest in disclosure;
 - Protecting confidential communication between MS in relation to the preparation of the assessment report;
 - Ensuring effective supervision of the conduct of a clinical trial by MSs.



Transparency legal requirements: Clinical Trials Regulation

Strike the right balance between:

- Respecting patients' and doctors' needs and the public's entitlement to extensive and timely information about clinical trials;
and developers' and researchers' need to protect their investments;
- A balanced approach is needed to protect public health and also foster the innovation capacity of European medical research.



Clinical Trials Regulation: public disclosure of information

- Is there a trial in which I could participate?
- What was the outcome of the trial I did participate in?
- What trials were the basis of the marketing authorisation, what were their results?
- What is known about the medicine I am taking/prescribing?
- Can we review the data used to support the marketing authorisation?
- Has the trial we are designing already been conducted? Were there problems with similar trials?



What is being made public (currently under discussion):

- *At the time of decision on the trial:*
 - Main characteristics of the trial (clinical trial application form - a structured synopsis of the clinical trial protocol) – similar to what appears in EU CTR and WHO ICTRP or clinicaltrials.gov
 - Information on all EU investigator sites
 - Conclusion on the assessment of Part I of the trial
 - Decision on the trial including reasons for refusal if the trial is not authorised (or where applicable the reason for its withdrawal)
 - Start of the trial



What is being made public (currently under discussion):

- *During the trial:*
 - First visit of the first subject in each MS concerned
 - Substantial modification
 - Temporary halt or early termination
 - End of recruitment in each MS concerned
 - End of the trial
 - Other information/events during (some) trials (inspections, safety measures, serious breaches ...)
- **12 months** after the end of the trial:
 - summary clinical trial results and lay summary
- **30 days** after completion of the Marketing Authorisation process (whatever the outcome):
 - the clinical study report for trials authorised under the new Regulation and included thereafter in a MA dossier



Clinical Trials Regulation: public disclosure of information

- Access to individual patient data – out of scope of legislation
- Timing of release of details of category 1 trials may be deferred until 12 months after the trial (and published with the summary results)
- Deferral of publication of study specific documents and/or product specific documents (IB, IMPD S and E section)
- Publication of trial *results* – no proposal to delay or defer
- Scope of CCI definition/ balance with overriding public interest



Clinical Trials Regulation: public disclosure of information

- Publication of investigators' details (names, CVs) in accordance with EU data protection legislation
- Publication of MSs experts/inspectors' names not foreseen
- Selection of the proposal for the publication/timelines of study/product specific information for IMPs without a MA
- Redaction and harmonization of the end of procedure in relation to inspection, serious breaches and unexpected events/ urgent safety measures.



Addendum on transparency

Management Board has already endorsed on 19 March 2015 the “Draft revision of section 6 of the “Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014” setting out features to support making information public.”

Next steps

1. Revise the rules on transparency by EMA in close collaboration with the MSs and the EC, i.e. the choices to be made following the consultation.
2. Present the agreed rules for endorsement in the October 2015 (expected) to Management Board once agreed by MS and EC.



Key message

- Single submission for authorisation of a clinical trial to National Competent Authority & Ethics Committee and for public registration (primary register of clinical trials);
- Facilitate cooperation among MSCs in assessing a request for authorization of a clinical trial;
- One single decision per Member State;
- Public data and information about medicines, their development and authorisation:
 - To generate trust – information is available
 - To build confidence – I understand what is happening
 - To empower – knowledge enables decision-making



Thank you for your attention

Further information

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