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SCIENCE MEDICINES HEALTH

EU CT Portal and Database

SME Info day – The New Clinical Trials Regulation

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Systems to implement the new regulation

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EU PORTAL AND DATABASE

- **Single EU entry point** for clinical trial applications
- Enables **supervision at EU level**, including inspections
- Provides **workspace collaboration** tools, workflow and document management capabilities
- Provides **publicly available** information

EUDRACT LEGACY

- Delivers **transition** between the current and new systems

Regulation (EU) No. 536/2014

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- **Single EU portal and database to support:**
  - One application dossier for each clinical trial or modification
  - Coordinated approach to clinical trial assessment, authorisation and supervision
  - Transparency of clinical trial information

- **One application dossier (e-dossier) :**
  - Part I common to all Member State Concerned (MSC)
  - Specific country part II (for each MSC)
  - A single decision in each MSC (scientific & ethical review)
  - 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

- **Simplifications for Sponsors, for EU/EEA Member State:**

- Uniform procedure in EU: whether single or multi- country clinical trials (CT)

- Communication hub: Electronically by Portal

- Unique clinical trial number

- 1 Contact per CT part I: Reporting Member State (RMS)

- 1 Common assessment (part I) by all concerned MS together

- 1 Decision per MS (Part I + II)

- 1 Fee per MS (if applicable)

The EU Portal and Database: System functionality overview

Collaborative working

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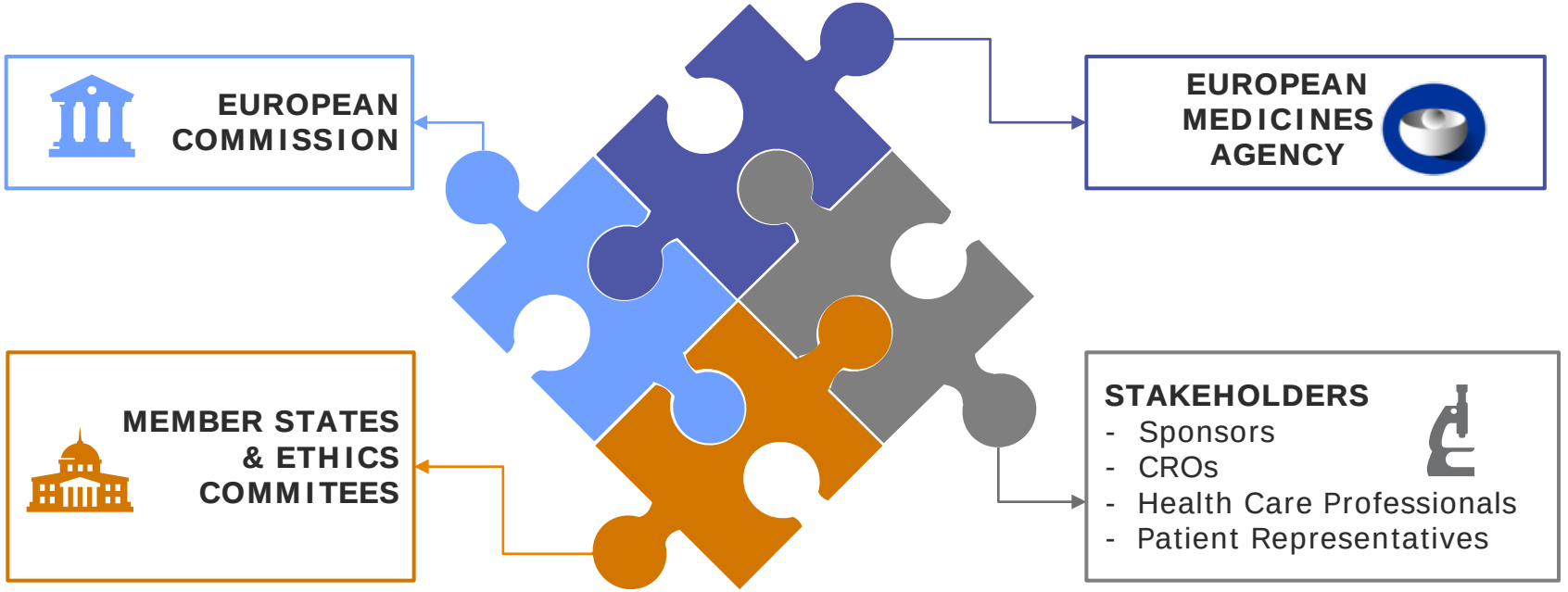
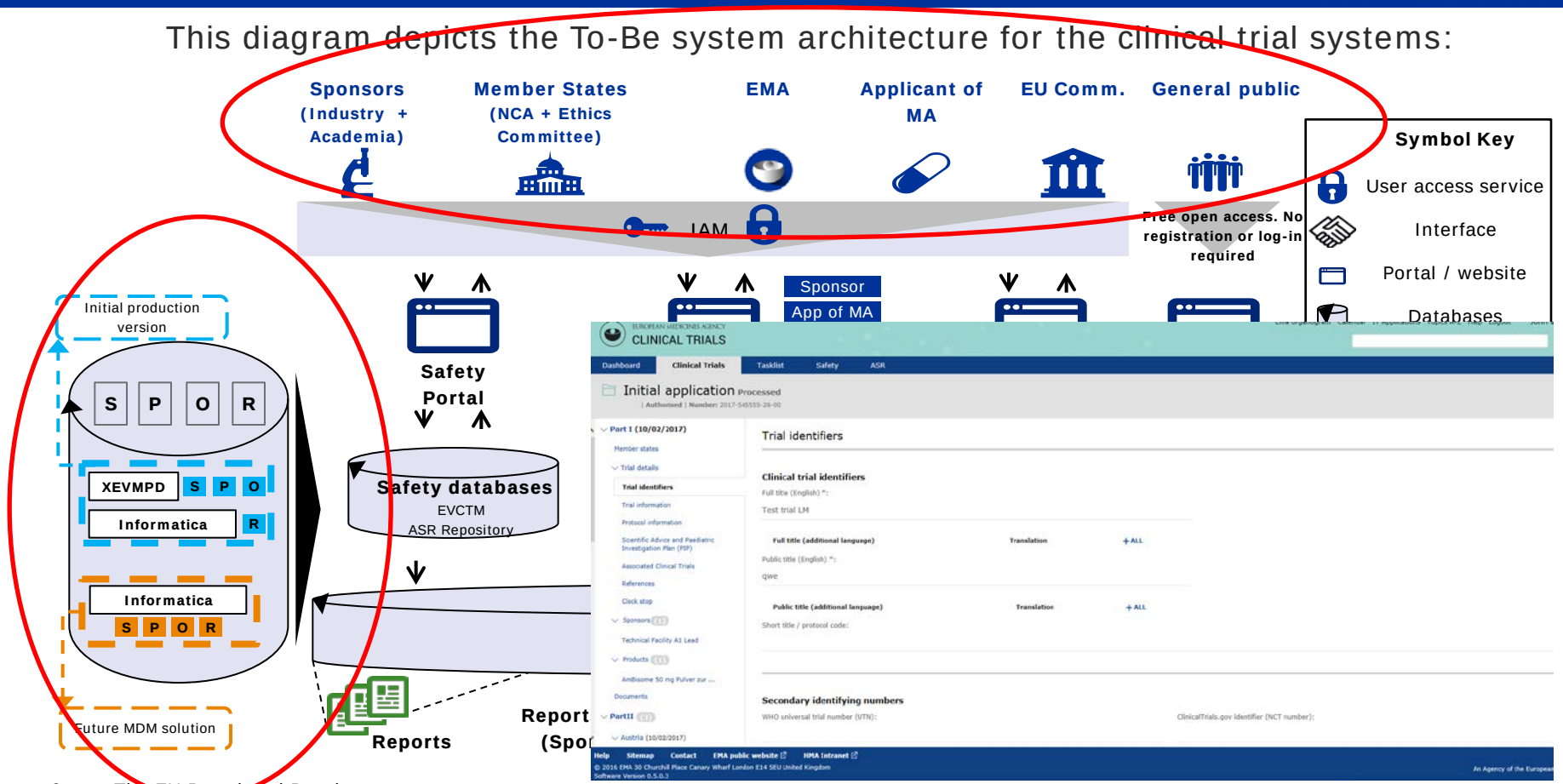
The EMA is working collaboratively



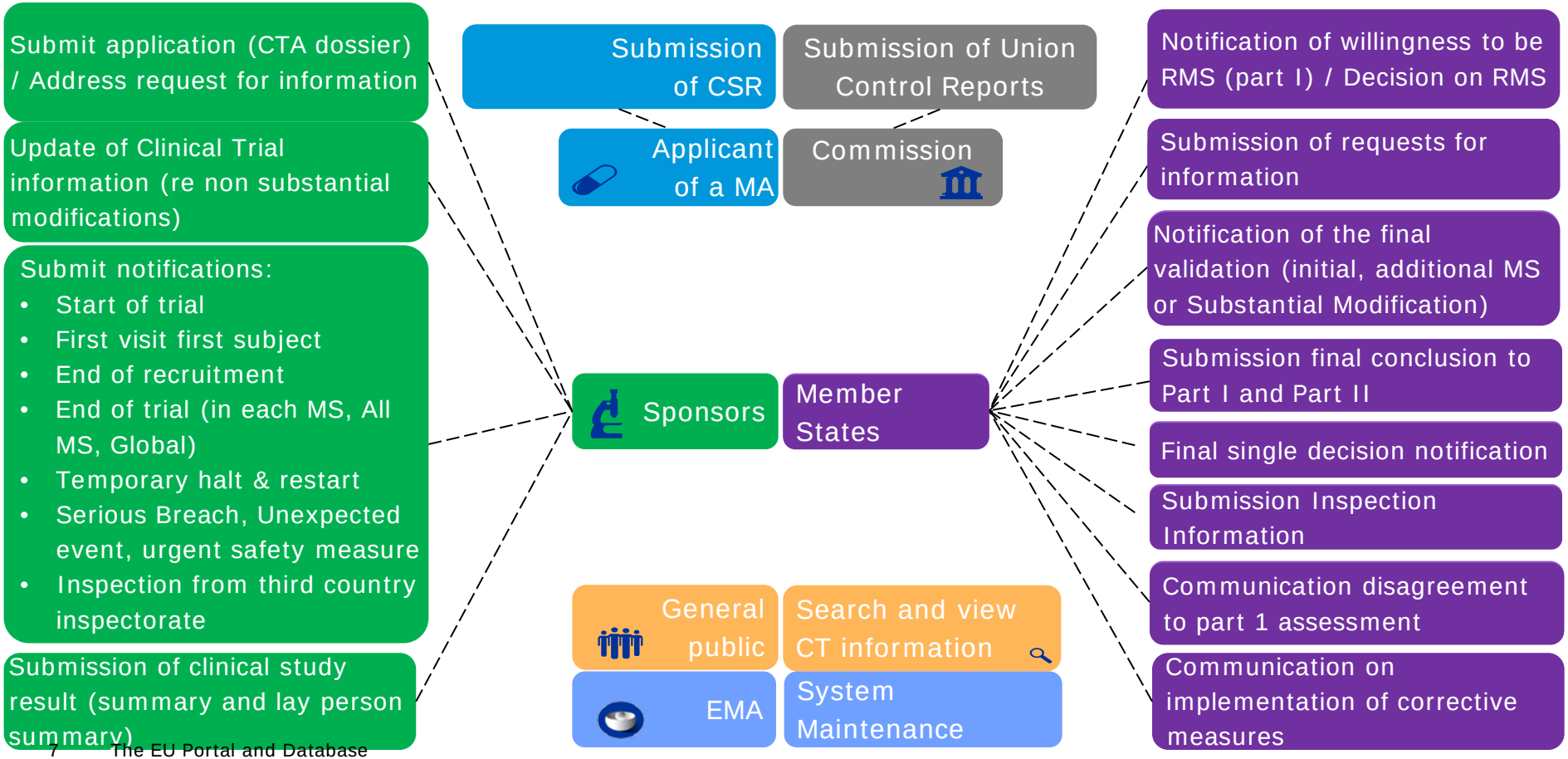
to develop systems to implement the regulation

EU portal and database – business context view

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



Activities in the system



High level system overview

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Submission Workspace *for Sponsors*

Clinical Trials Overview and Search

- Search for trials I have access to
- See current state of my trials
- Select and initiate new trials / change trials

CT Application Dossier

- Complete application dossier to create a new trial (initial application)
- Update an existing trial already authorised and create substantial modification application or additional MSC application
- Provide notifications for authorised trial.

Documents

- Upload documents to the clinical trial application
- Ability to mass upload documents
- Ability to copy documents from an existing trial
- Ability to version control uploaded documents

Requests for information & notices

- See formal or informal requests for information from Member States and respond
- See deadlines for requests
- See all alerts and notices for all my trials

Sponsor User management

- Self register on to the Portal
- Assign roles to users including administrators
- Invite users to access trial

System interfaces

- Import clinical trial application into the portal
- Submit notifications to the CT portal
- Submit results to a clinical trial

High level system overview

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Authority Workspace *for Member States*

Clinical trial overview & search

- A search for all clinical trials (documents are restricted to MSC)

Clinical trial detail

- An overview of one trial including: the application dossier, including structured data and documents, status, timetable, associated tasks, version history
- Ability to collaborate on national considerations on Parts I and II
- Formal or informal Request for Information to the sponsor
- Ability to supervise and issue corrective measure

Tasks

- Task-specific forms relating to the activities of Member States (select RMS, document considerations, make a decision, etc.)
- Ability to open the details of the clinical trial dossier
- Delegate Task, Create subtask and involve more people from this MSC (e.g. ethics committee)

Documents

- Download documents and data submitted by the sponsor
- Upload documents (e.g. assessment reports)

Task list

- Provides an overview of all tasks to be done by me or my group with deadline
- Users will be notified of new tasks via alerts upon login
- Able to open a specific item to see the task details

Inspection

- Record and upload inspection records inspections linked to sites and clinical trials

Member States user management

- Member State (MS) Administrator for each MS
- The MS Administrator to assign access to national NCA and Ethics Committee administrators
- National CA and Ethics Committee administrators are responsible for managing their user base

System interfaces

- A REST Service interface (CRUD) is used for all entities. The majority will be exposed in the EudraNet for MSCs to consume. Examples: Read trial, upload data and structured data relating to trials, etc.

High level system overview

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Public website *for the public, EMA and MSCs*

Entry site

- News, announcements, scheduled downtimes
- View publicly available statistics on clinical trials registered in the EU Database
- Available in all official languages of the European

Public Search

- Search for keywords and filter results
- Find public clinical trials (the same portal also contains pro active publications, medicinal products, articles,…)

Public Clinical Trial Data

- Go into the detail of a clinical trial
- Download trial information and documents
- View and download predefined reports

Content Management (EMA)

- Go into the detail of a clinical trial
- Download trial information and documents
- Publish clinical trail data
- Remove clinical trial data from public view

Pre-population of data

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Master Data

SPOR (Substance, Product, Organisation, referential) data in the Clinical Trial (CT) Application is selected/populated from master data stores:

- S: Substance management system
- P: Medicinal Product Dictionary (including Substances)
- O: Organisation management system
- R: Referentials

Summary Results

Trial data from the CTA is used to pre-populate summary results data structures where applicable

Document generation

Standard document output can be pre-populated with CTA and CT data where applicable

User management

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Member States and EC	Organisation-based access	MS and European Commission manage their user organisations (e.g. Ethics Committees), user administrators, who in turn can manage users and assign roles
Sponsors	Organisation-based access	Sponsors can formally register their organisations and appoint administrators, who then in turn can manage users, assign roles and access to clinical trials. This approach will be encouraged.
Sponsors	Trial-centric access	Sponsors can choose to limit access management to a trial-centric approach only, without the need to register the organisation, but will then not have the advantages of that.

EU portal and database – data standardisation

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WHO

WHO ICTRP standard will be fully met, and data provided to the ICTRP by the EU database

NIH
(clinicaltrials.gov)

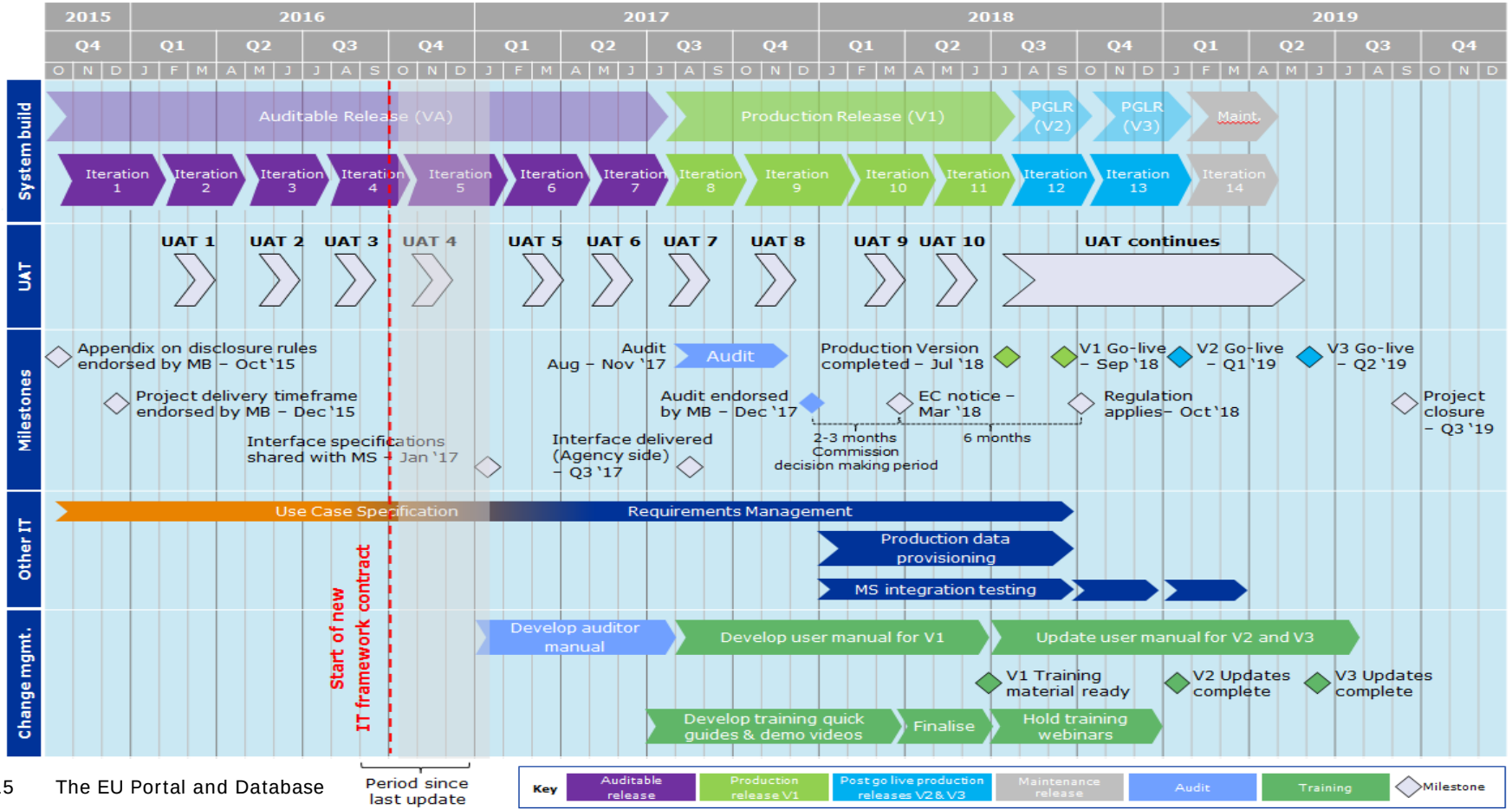
Collaboration and discussion on the anticipated changes to the data model (focusing on protocol / results) to ensure convergence and alignment where the same elements are used in both US and EU systems

CDISC

Collaboration on clinical trial registration including study design data model, and in due course on results model

Status of Development & User Acceptance Testing

EU portal and database - project timeline



EU portal and database - key milestones

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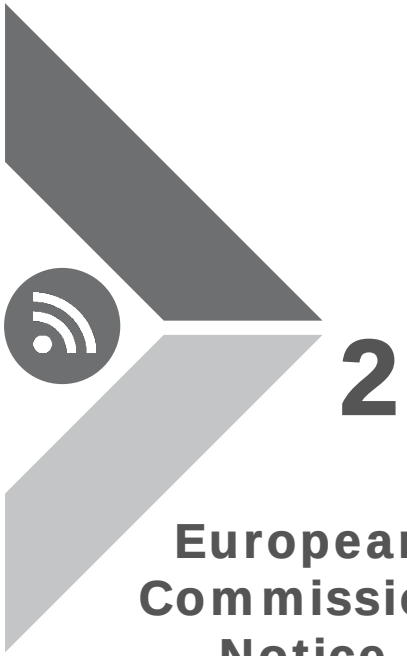
Audit

~ Aug – Nov 2017



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European Commission Notice

~ Mar 2018

3

System goes live & Regulation Applies

~Oct 2018

UAT (User Acceptance Testing)

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- UAT verifies the system has the **right features** (business functions and the system flow against business requirements)
- Other IT test types verify the system has **no significant bugs** and are carried out prior to UAT
- UAT is planned every **three months** (once per iteration)
- Each UAT is carried out **remotely** during a fixed period
- All Member States and wide range of stakeholders can participate using remote access

Demonstration

https://vimeopro.com/user13777322/uat-4-video-guides-sponsors

- Preparation of an application dossier for the initial application

Thank you for your attention

Further information

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