EU CT Portal and Database

SME Info day – The New Clinical Trials Regulation

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Clinical & Non-clinical Compliance, European Medicines Agency

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Systems to implement the new regulation

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

The EMA is working collaboratively to develop systems to implement the regulation

- **STAKEHOLDERS**
  - Sponsors
  - CROs
  - Health Care Professionals
  - Patient Representatives

**STAKEHOLDERS**

**EUROPEAN COMMISSION**

**EUROPEAN MEDICINES AGENCY**

**MEMBER STATES & ETHICS COMMITTEES**
This diagram depicts the To-Be system architecture for the clinical trial systems:

Sponsors (Industry + Academia) → Member States (NCA + Ethics Committee) → EMA → Applicant of MA → EU Comm. → General public

Symbol Key:
- User access service
- Interface
- Portal / website
- Databases

Future MDM solution

Initial production version

Safety Portal

Safety databases

EVCTM ASR Repository

Reports

Reports (Sponsor)

EU portal and database – business context view

Legend:
- XEVMPD
- SPO
- Informatica

The EU Portal and Database

6
Activities in the system

- Submit application (CTA dossier) / Address request for information
- Update of Clinical Trial information (re non substantial modifications)
- Submit notifications:
  - Start of trial
  - First visit first subject
  - End of recruitment
  - End of trial (in each MS, All MS, Global)
  - Temporary halt & restart
  - Serious Breach, Unexpected event, urgent safety measure
  - Inspection from third country inspectorate
- Submission of clinical study result (summary and lay person summary)
- Notification of willingness to be RMS (part I) / Decision on RMS
- Submission of requests for information
- Notification of the final validation (initial, additional MS or Substantial Modification)
- Submission final conclusion to Part I and Part II
- Final single decision notification
- Submission Inspection Information
- Communication disagreement to part 1 assessment
- Communication on implementation of corrective measures
- Search and view CT information
- System Maintenance
- General public
- EMA
- Member States
- Sponsors
## High level system overview

**Submission Workspace** for Sponsors

<table>
<thead>
<tr>
<th>Clinical Trials Overview and Search</th>
<th>Requests for information &amp; notices</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Search for trials I have access to</td>
<td>• See formal or informal requests for information from Member States and respond</td>
</tr>
<tr>
<td>• See current state of my trials</td>
<td>• See deadlines for requests</td>
</tr>
<tr>
<td>• Select and initiate new trials / change trials</td>
<td>• See all alerts and notices for all my trials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CT Application Dossier</th>
<th>Sponsor User management</th>
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<tbody>
<tr>
<td>• Complete application dossier to create a new trial (initial application)</td>
<td>• Self register on to the Portal</td>
</tr>
<tr>
<td>• Update an existing trial already authorised and create substantial modification application or additional MSC application</td>
<td>• Assign roles to users including administrators</td>
</tr>
<tr>
<td>• Provide notifications for authorised trial.</td>
<td>• Invite users to access trial</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Documents</th>
<th>System interfaces</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Upload documents to the clinical trial application</td>
<td>• Import clinical trial application into the portal</td>
</tr>
<tr>
<td>• Ability to mass upload documents</td>
<td>• Submit notifications to the CT portal</td>
</tr>
<tr>
<td>• Ability to copy documents from an existing trial</td>
<td>• Submit results to a clinical trial</td>
</tr>
<tr>
<td>• Ability to version control uploaded documents</td>
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</table>
### 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

**Public website** for the public, EMA and MSCs

<table>
<thead>
<tr>
<th><strong>Entry site</strong></th>
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<tbody>
<tr>
<td>• News, announcements, scheduled downtimes</td>
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<tr>
<td>• View publicly available statistics on clinical trials registered in the EU Database</td>
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<tr>
<td>• Available in all official languages of the European</td>
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<table>
<thead>
<tr>
<th><strong>Public Search</strong></th>
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<tbody>
<tr>
<td>• Search for keywords and filter results</td>
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<tr>
<td>• Find public clinical trials (the same portal also contains pro active publications, medicinal products, articles,...)</td>
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</table>

<table>
<thead>
<tr>
<th><strong>Public Clinical Trial Data</strong></th>
<th></th>
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<tbody>
<tr>
<td>• Go into the detail of a clinical trial</td>
<td></td>
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<tr>
<td>• Download trial information and documents</td>
<td></td>
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<tr>
<td>• View and download predefined reports</td>
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<table>
<thead>
<tr>
<th><strong>Content Management (EMA)</strong></th>
<th></th>
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<tbody>
<tr>
<td>• Go into the detail of a clinical trial</td>
<td></td>
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<tr>
<td>• Download trial information and documents</td>
<td></td>
</tr>
<tr>
<td>• Publish clinical trail data</td>
<td></td>
</tr>
<tr>
<td>• Remove clinical trial data from public view</td>
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</tbody>
</table>
Pre-population of 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

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

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

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

<table>
<thead>
<tr>
<th></th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
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<tbody>
<tr>
<td>Q4</td>
<td></td>
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<td>Auditable Release (V4)</td>
<td>Production Release (V1)</td>
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<tr>
<td>Q1</td>
<td></td>
<td></td>
<td></td>
<td>PCLR (V2)</td>
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<tr>
<td>Q2</td>
<td></td>
<td></td>
<td></td>
<td>PCLR (V3)</td>
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<tr>
<td>Q3</td>
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<td>Q4</td>
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<td>Q4</td>
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</table>

**System build**
- Iteration 1
- Iteration 2
- Iteration 3
- Iteration 4
- Iteration 5
- Iteration 6
- Iteration 7
- Iteration 8
- Iteration 9
- Iteration 10
- Iteration 11
- Iteration 12
- Iteration 13
- Iteration 14

**UAT**
- UAT 1
- UAT 2
- UAT 3
- UAT 4
- UAT 5
- UAT 6
- UAT 7
- UAT 8
- UAT 9
- UAT 10
- UAT continues

**Milestones**
- Appendix on disclosure rules endorsed by MB - Oct ‘15
- Project delivery timeframe endorsed by MB - Dec ‘15
- Interface specifications shared with MS - Jan ‘17
- Interface delivered (Agency side) - Q3 ‘17
- Audit endorsed by MB - Dec ‘17
- Audit completed - Nov ‘17
- Production Version completed - Jul ‘18
- EC notice - Mar ‘18
- Regulation applies - Oct ‘18
- Project closure - Q3 ‘19

**Other IT**
- Use Case Specification
- Requirements Management
  - Production data provisioning
  - MS integration testing
  - Develop auditor manual
  - Develop user manual for V1
  - Update user manual for V2 and V3
  - Develop training quick guides & demo videos
  - Finalise
  - Hold training webinars

**Change mgmt.**
- Start of new IT framework contract
- Period since last update

**Key**
- Auditable release
- Production release V1
- PCLR release V1
- PCLR release V2 & V3
- Maintenance release
- Audit
- Training
- Milestone
EU portal and database - key milestones

1. Audit
   ~ Aug – Nov 2017

2. European Commission Notice
   ~ Mar 2018

3. System goes live & Regulation Applies
   ~ Oct 2018
UAT (User Acceptance Testing)

- 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
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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