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SCIENCE MEDICINES HEALTH

Overview of the Clinical Trials Information System (CTIS)

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What is the Clinical Trial Information System - CTIS?

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CTIS will become the single entry point for clinical trials data submission and supervision in the EU. It encompasses the EU portal and database for clinical trials established in the Clinical Trial Regulation.

CTIS will support the **harmonisation of the submission and assessment processes** of clinical trials conducted in the EU.

CTIS will be equipped with a set of functionalities supporting the **day-to-day business processes** of Member States and sponsors throughout the life cycle of a clinical trial, including **the following capabilities:**

Collaboration tools

Workload capabilities

User management

Document management and reporting

Introduction to CTIS workspaces and the public website

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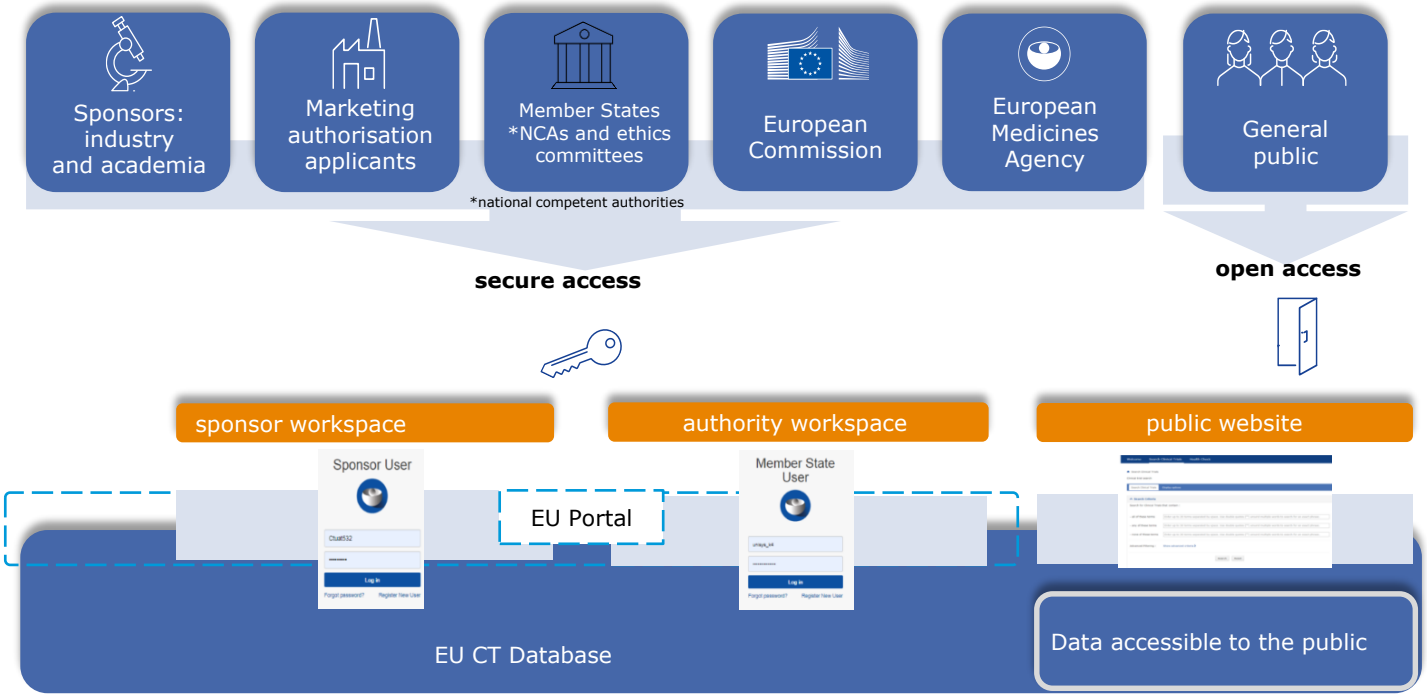
CTIS is composed of two workspaces with secured and restricted access for sponsors and authorities, and a public website openly accessible to the general public. Information stored in CTIS will be made publicly available via this website, unless exempted from publication rules under the CT Regulation.



Introduction to CTIS workspaces

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Two workspaces with restricted access are available to Member States, the European Commission and sponsors to enable them to perform their specific tasks regarding clinical trials, in addition to general functionalities available to all (CT searches, user management, etc.).

Authority workspace

Supporting the activities of Member States and the European Commission in **assessing**, **authorising** and **overseeing** clinical trials

Sponsor workspace

Assisting sponsors in **preparing and compiling data** on clinical trials to submit to the system for assessment by Member States. It will also cover **submission of events** happening during the trial life cycle.

CTIS environment - interactions with other systems

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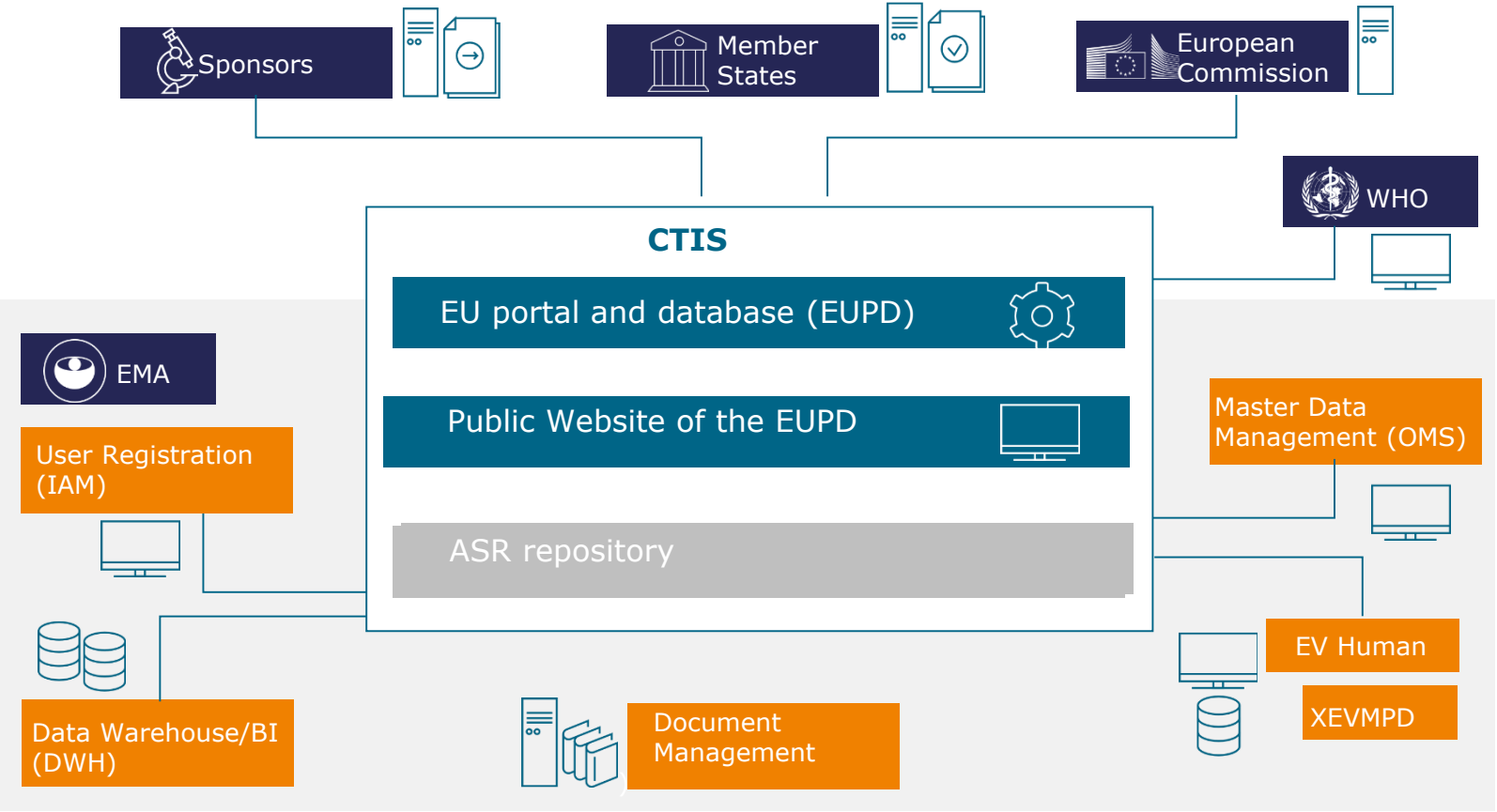

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EU Portal and Database (EU PD) part of CTIS

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Submission package (CTA dossier) Part I and II / Address request for information (RFI)

Update CTA dossier via (non) - Substantial Modifications or addition of a new MSC

- Withdrawal
- Start of trial
- First visit first subject
- End of recruitment
- End of trial (in each MS, All MS, Global)
- Temporary halt
- Restart of trial
- Early termination
- Serious Breaches
- Unexpected events which

Submission of clinical study result summary

Submission of Inspection Reports of third country authorities

Submission of CSR

Submission of Union Control Reports

Applicant of a MA

Commission

Sponsors

Member States

General public

Search and view CT information

EMA

System Maintenance

Notification of willingness / unwillingness to be Reporting Member State (RMS)

Submission of requests for information (RFI) to the sponsor

Notification of the final validation for the application

Submission final AR Part I and II

Communication disagreement to Part I assessment

Submission of final decision per MSC

Submission of Inspection information

Communication on implementation of corrective measures

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CTA dossier content and evaluation steps

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Validation 10d

Part I - Coordinated assessment (45d /+ 31d)

- **Is it a low-interventional CT**?
- **Benefits vs. risks** for subjects, including relevance of CT, reliability and robustness of data
- **Manufacturing and importation** for IMP
- **Labelling requirements**
- **Investigator's Brochure.**

26 days - RMS | Initial AR | 12 days - MSC | 7 days - RMS

Part II - National evaluation (45d /+ 31d)

- **Informed consent**, subject **recruitment**, **data protection**
- **Reward/compensation** investigators/subjects
- **Suitability of investigators and of trial sites**
- **Damage compensation**
- Collection/storage/**use of biological samples**.

Decision 5d

Notification of single decision by MSC sent to sponsor through the EU Portal

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CTIS common functionalities

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*CTIS displays **four main common functionalities** to the two main user groups (i.e. sponsors and authorities). These are: Overview of clinical trials, Notices & alerts, User management, Annual Safety Reporting.*

Overview of Clinical Trials

Allows users to **search, select and view** a clinical trial, and to monitor the status and information of clinical trials are stored in CTIS.

Notices & Alerts

Allows users to **monitor the messages** triggered by events that have occurred during the lifecycle of a clinical trial in which they are involved.

User management

Allows users with an **administrator** role to **manage the roles & permissions** of registered users that belong to their organisation or Member State.

Annual safety reporting

Allows sponsors to submit the **annual reports on the safety status** of their trials, and to have them assessed by Member States.

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EU Portal and Database – Publication Aspects

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

- EU database publicly 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 MSs.*

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EU Portal and Database – Publication Aspects

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- Data and documents of an application that is 'under evaluation' will not be made public, unless there is an overriding public interest;
- Only applications on which a **decision** has been reached will be made public;
- All data and documents in the system will be made public with few exceptions;
- The default is always to make public at the first opportunity, e.g. time of decision;
- Sponsors have options to defer the timing of publication of specific data/documents via the deferral mechanism
- Deferral will be part of CTA submission and, therefore, subject to the approval of the Member States Concerned

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What will not be made public

- Quality related information that include:
  - ❑ The IMPD quality
  - ❑ Quality related request of information (RFI) raised during the assessment
  - ❑ Quality Assessment reports (draft and final)
- Any draft assessment reports;
- Versions of documents that are **not for publication,** which may include personal information identifying Member States experts, sponsor staff, MAH/applicant staff
- Financial agreements between the sponsor and the investigator site;

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Any questions?

Further information

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