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SCIENCE MEDICINES HEALTH

# CTIS: functionalities and support for clinical trial sponsors, availability of clinical trial data to the public

Presented by Fia Westerholm on 21 September 2021
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# Disclaimer



The presenter does not have any conflict of interests.

The views expressed are those of the presenter.

# CTIS Benefits

With CTIS sponsors can:

- Apply for a clinical trial in up to 30 EU/EEA countries with a **single application**
- Facilitate involvement of trial participants by allowing **easy expansion of trials to other EU/EEA countries**
- **Collaborate across borders** for better results and knowledge sharing
- Ensure the EU/EEA remains an attractive location for **clinical research investment**
- Fulfil all **clinical trial publication requirements** with no additional effort

CTIS: harmonising the authorisation and supervision of clinical trials

# CTIS future users

The **future users of CTIS** include:

## Sponsors

Commercial: large pharmaceutical companies & CROs, SMEs

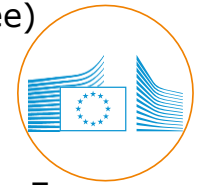
Academia

Will **input clinical trial data** in CTIS

## Authorities

Member States (NCA & ethics committee)

EMA



European Commission

Will **review clinical trial data** (MS/EMA) and create **Union Control Reports** (COM)

## Public

Public users (Healthcare professionals, patients, other)

Will **search for publicly available clinical trial data** in CTIS

# Two dedicated and secure workspaces and a public portal

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Sponsors: industry and academia

Marketing authorisation applicants

Member States *NCAs and ethics committees

European Commission

European Medicines Agency

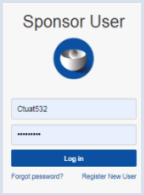
General public

*National competent authorities

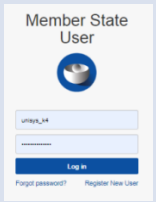
**secure access**

**open access**

sponsor workspace




authority workspace




**EU Portal**

EU CT Database

public website

Data accessible to the public

# Introduction to the common sponsor functionalities

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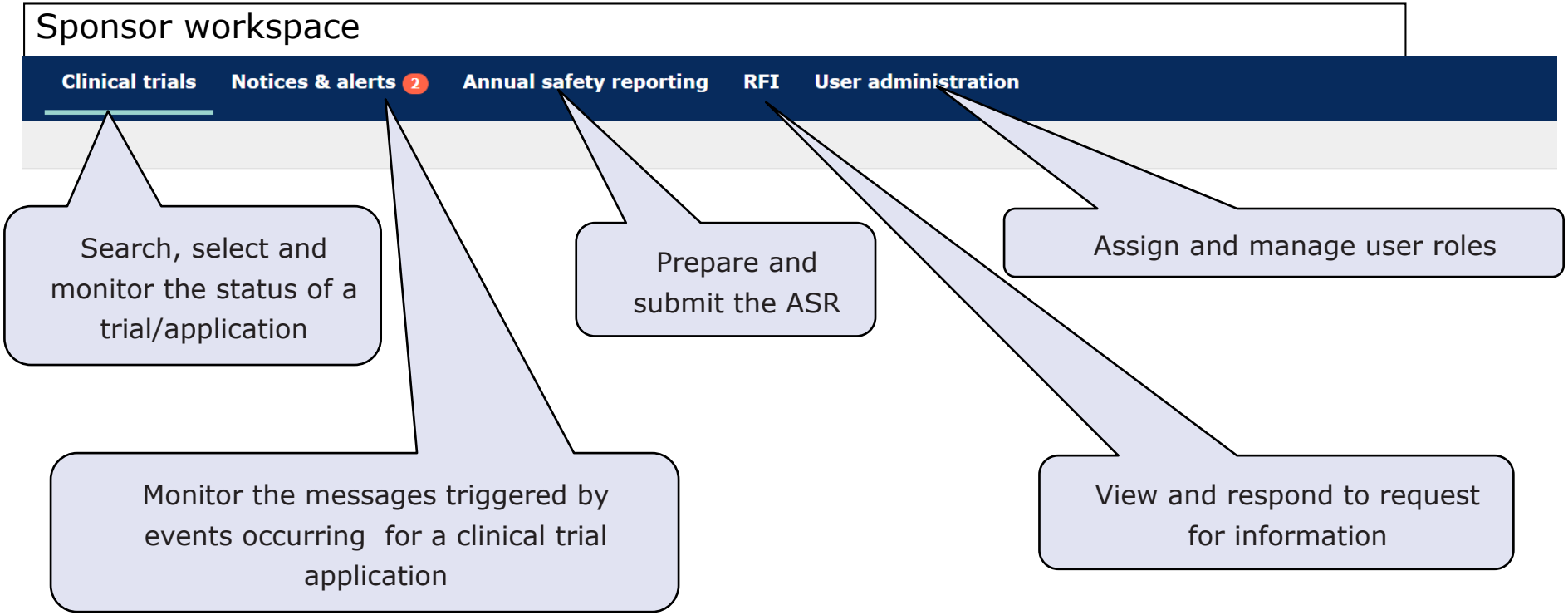
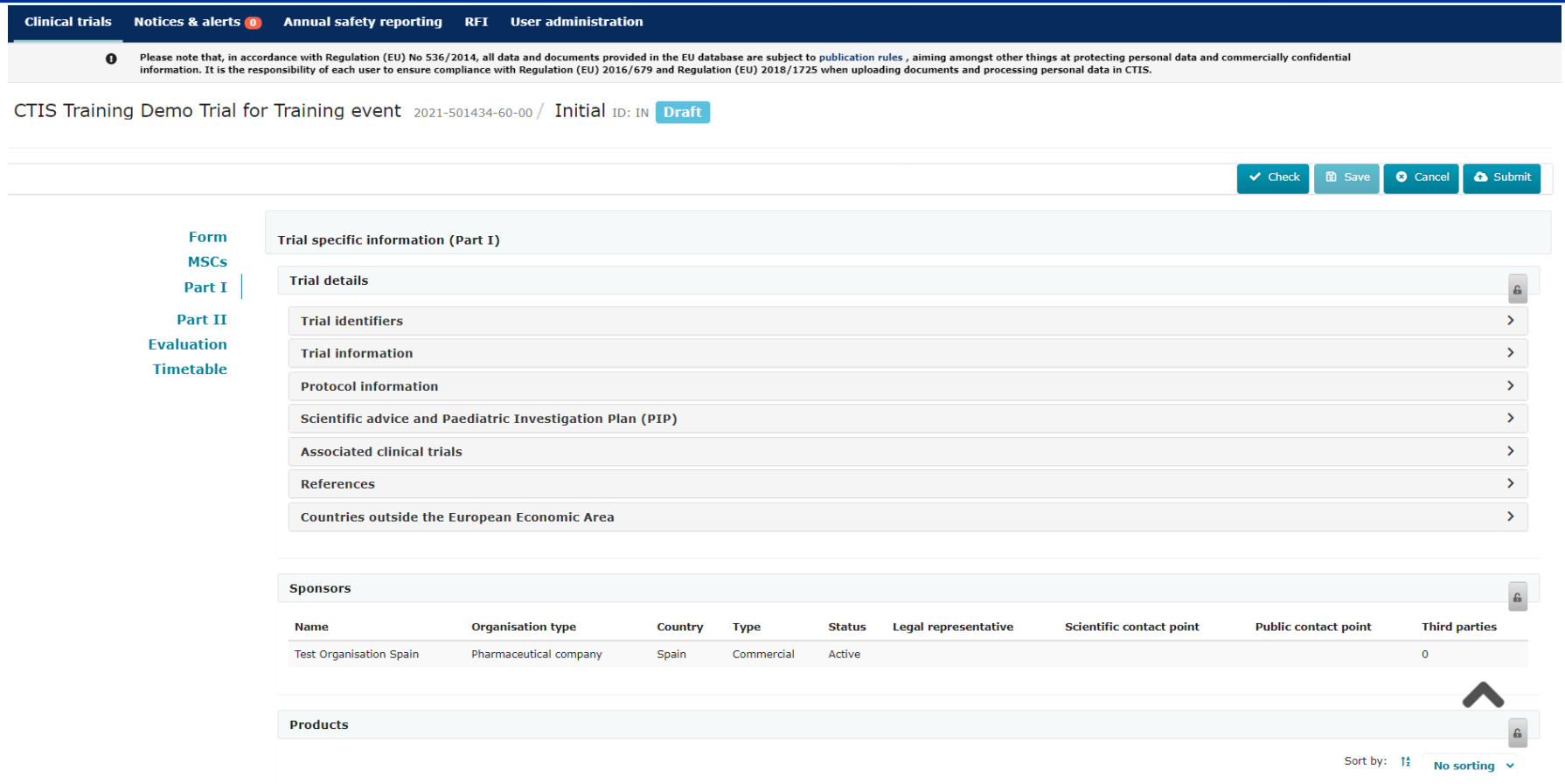
*CTIS offers these high-level functionalities to sponsors users. These are: Overview of Clinical Trials (search functionality), Notices & alerts, Annual Safety Reporting, Requests for Information and User administration.*



# A view of the sponsor functionalities in CTIS – Part I



# Legal basis for transparency in the Regulation (EU) No 536/2014

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The Regulation outlines the requirements for transparency in CTIS

Article 81(4):

*4. The EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified on any of the following grounds:*

*(a) protecting **personal data** in accordance with Regulation (EC) No 45/2001;*

*(b) protecting **commercially confidential information**, in particular through taking into account the status of the marketing authorisation for the medicinal product, unless there is an overriding public interest in disclosure;*

*(c) protecting **confidential communication** between Member States in relation to the preparation of the assessment report;*

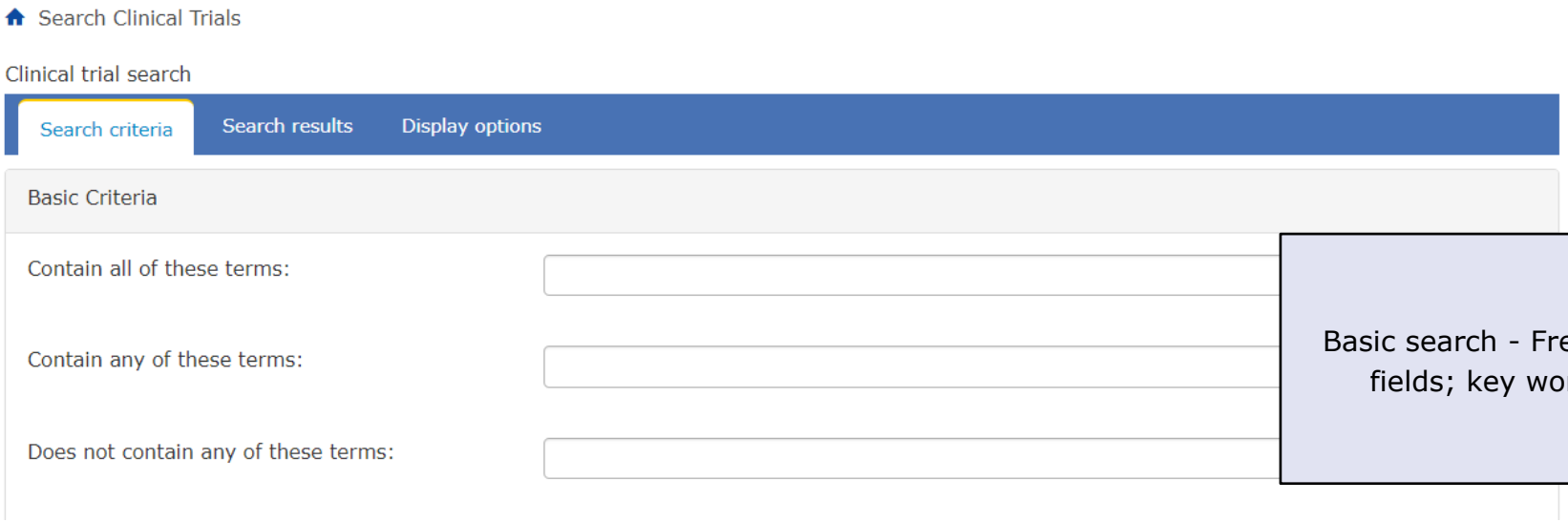
*(d) ensuring **effective supervision** of the conduct of a clinical trial by Member States*

# CTIS – Publication Aspects

- 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 some 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

# CTIS –public search for data

The data in CTIS will accumulate over time as sponsors submit their applications and results.
There is a basic search on free text and an advanced search with more options



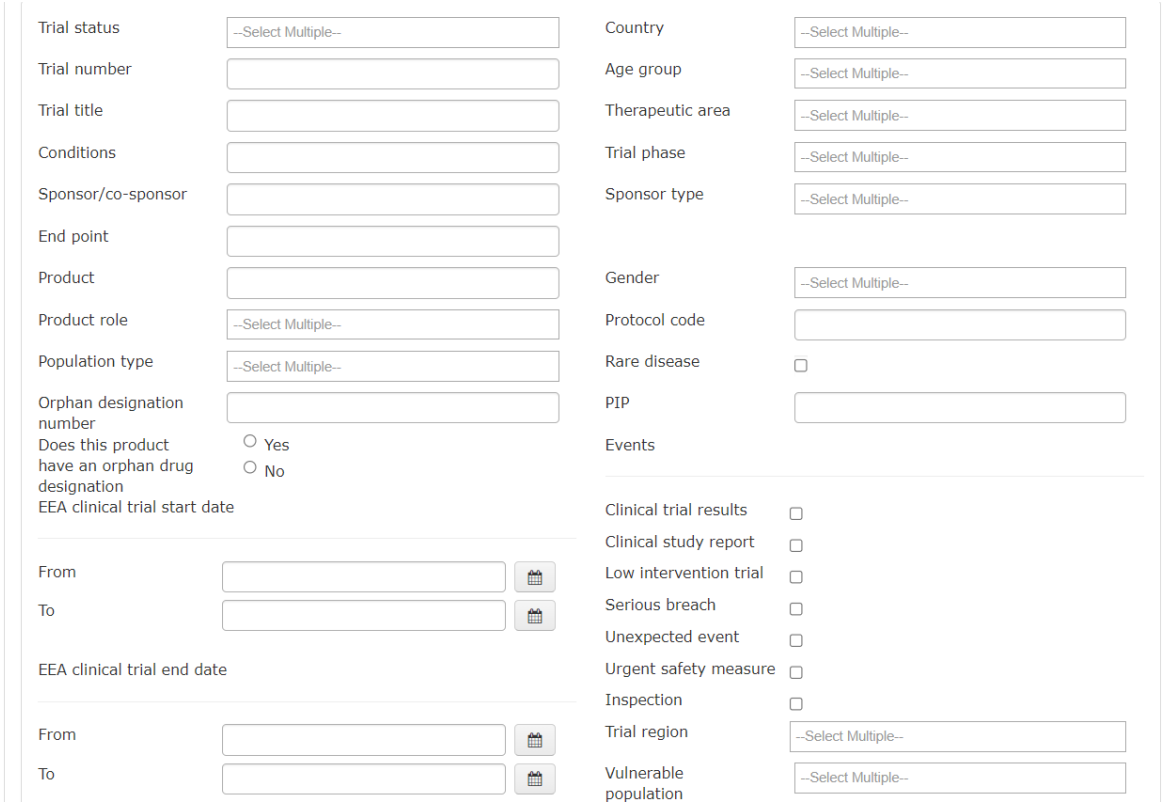

Basic search - Free text fields; key words

# CTIS – what the public will be able to search for - advanced

Options for search include elements of, e.g.:

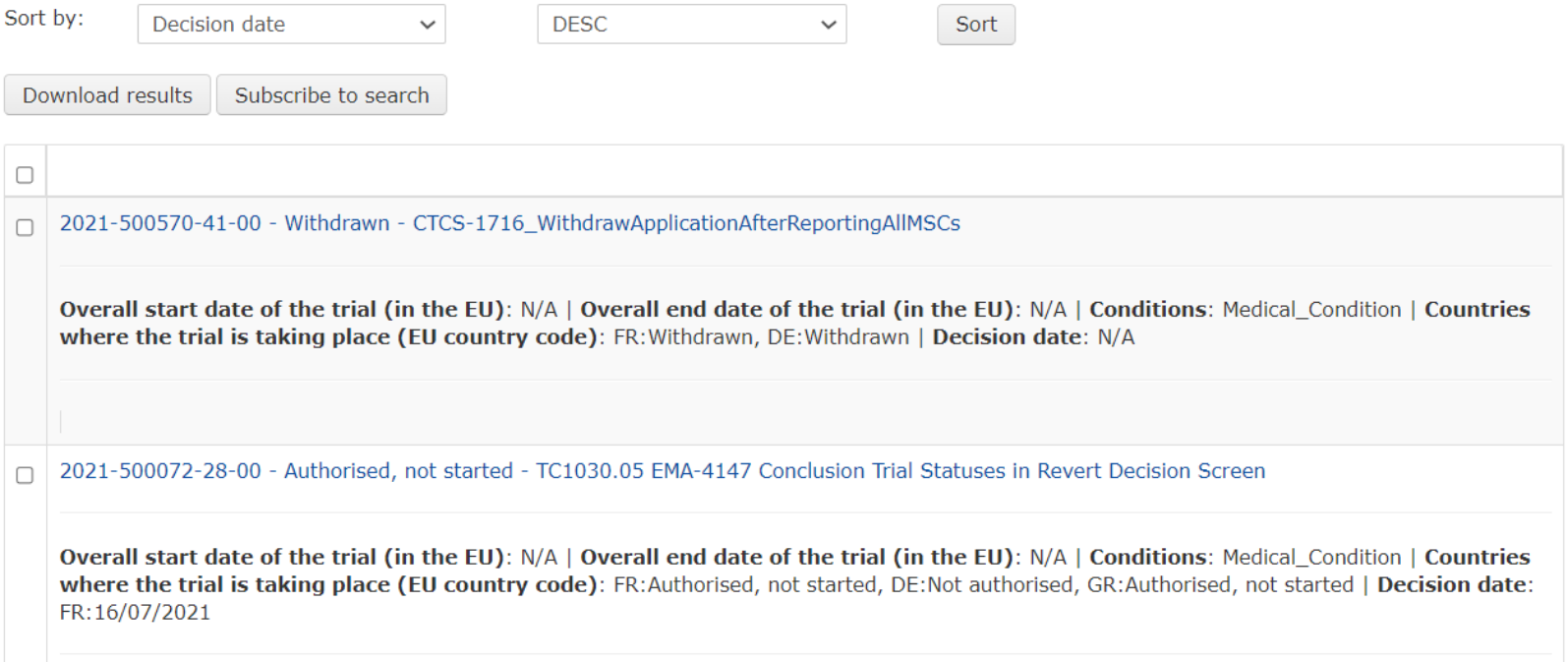
- Trial information
- Sponsor
- End point
- Therapeutic area
- Orphan status and number
- Rare disease status
- Paediatric trial (PIP)
- Trial phase
- Product
- Time ranges
- Trial events
- Country
- Age group
- Gender
- Vulnerable population

… etc



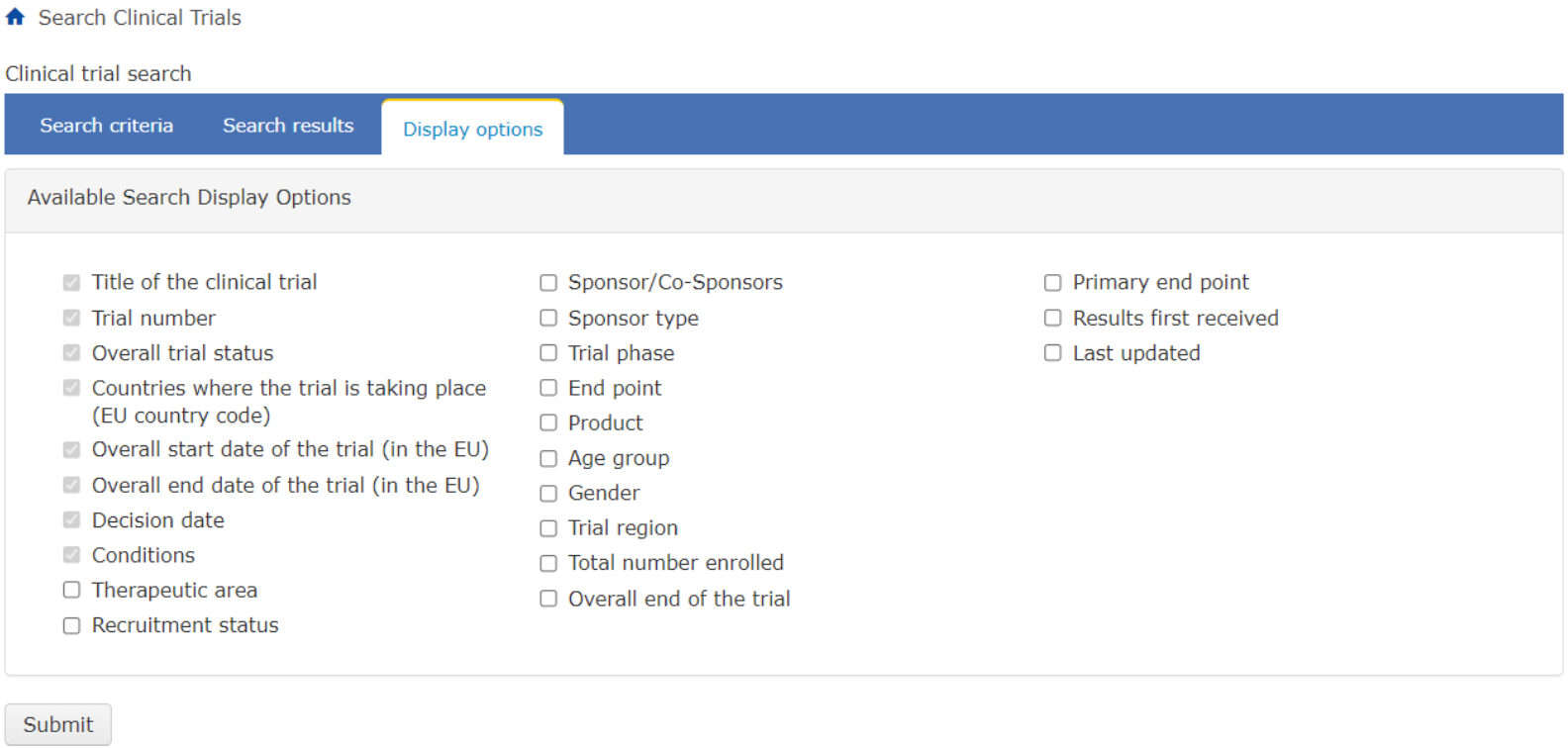
# CTIS –public search results

The results can be sorted, downloaded and a subscription to the search can be made.



# CTIS –display options of searches

It will also be possible to choose the type of data that will be displayed.



# What will not be made public

- Quality related information that include:
  - ❑ The IMPD quality
  - ❑ Scientific advice on quality
  - ❑ Quality related request of information (RFI) raised during the assessment
  - ❑ Quality Assessment reports (draft and final)
- Drafts of assessment reports;
- Versions of documents that are 'not for publication', which may include personal information identifying Member States experts, sponsor staff, MAH/applicant staff, as needed;
- Financial agreements between the sponsor and the investigator site;
- Any requests for information from MS to the sponsor and responses recorded outside of an assessment of an application

# CTIS Sponsor Support

| | |
|---|---|
| Engagement | Info events (recorded & published)<br>Collaborative approach |
| Online Training | Extensive online programme available<br>Sponsor Master Trainer programme |
| Online Support | EMA CTIS Sponsor Handbook<br>Supportive materials and references |
| Research community/SME | Targeted SME/academia trainings |
| EMA CTIS info | EMA CTIS Highlights Newsletters<br>(subscribe by writing to CT.Communication@ema.europa.eu) |

*All above are available on www.ema.europa.eu*

# Next open CTIS Information/Training Events for sponsors

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*Events are planned to help future CTIS users prepare for CTIS Go-Live.*
*Find on EMA events page (search e.g. "CTIS")*

## 26 October info event

**Target audience**
MS and sponsor end users

**Objectives**
- Ensure **awareness of CTIS** across the end-user base
- **Prepare users for the new way of working** with CTIS

Supported by DIA; fee applies

## 29 November training event

**Target audience**
SME/academia sponsors & end users

**Objectives**
- Ensure **awareness of CTIS** across the end-user base
- **Prepare SME/academia users** for the new way of working with CTIS

Open event, no fee

Thank you for your attention

## Further information

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# A view of the sponsor functionalities in CTIS – Part II

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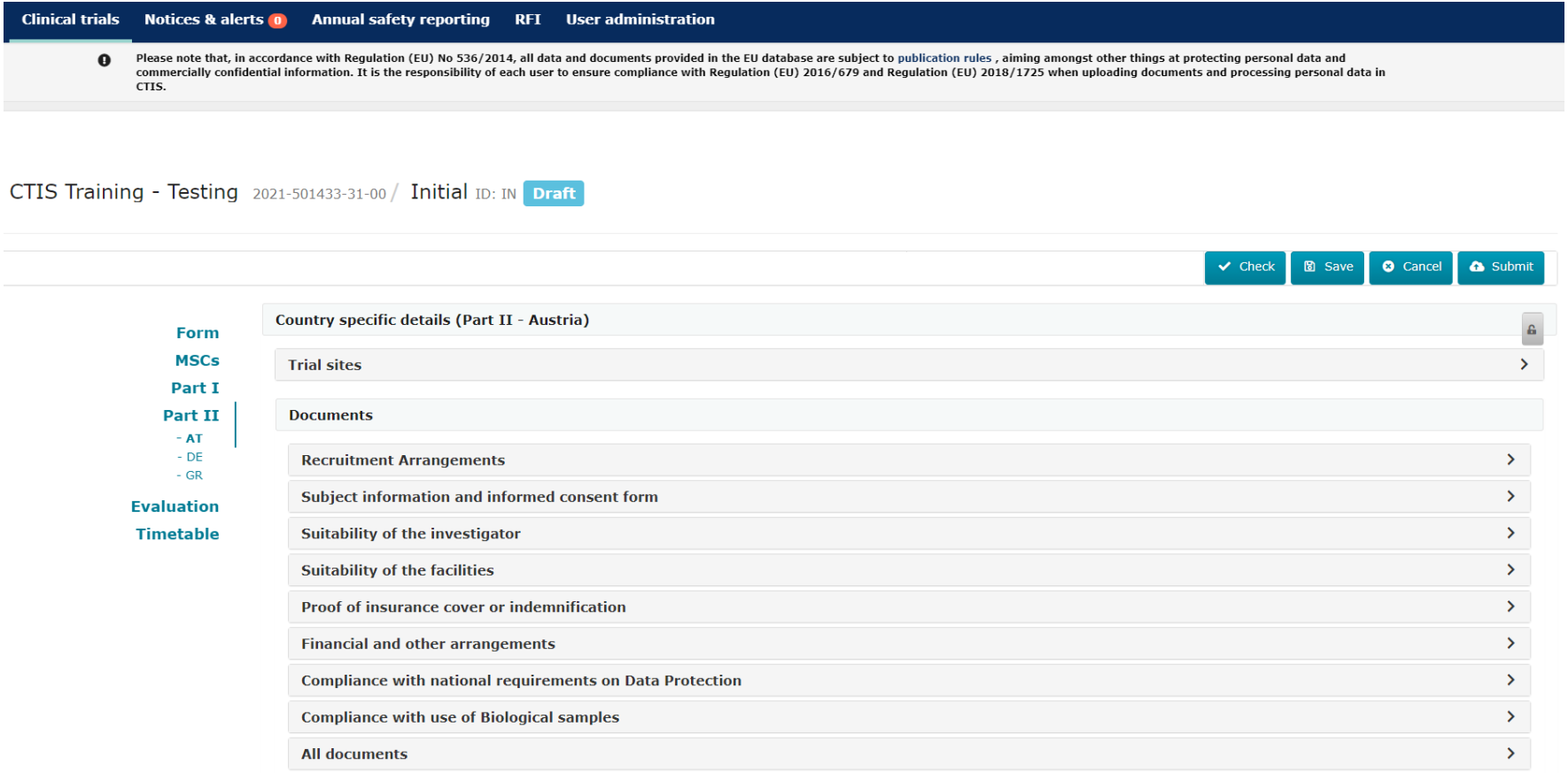

# Evaluation phases of an Initial Clinical trial application

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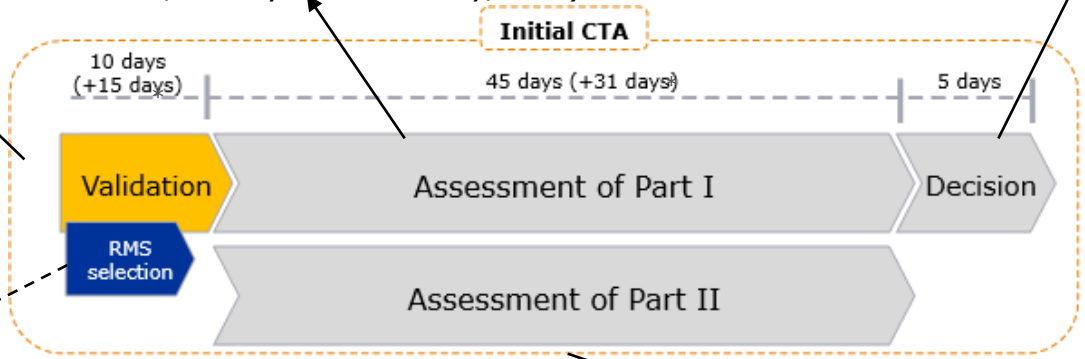
*The evaluation of an Initial application is structured in three phases: Validation, Assessment and Decision. MSCs generally have up to 60 days to complete the evaluation of an Initial application.*

Assessment of scientific documentation (protocol and medicinal product, Investigational Brochure, safety and efficacy, etc.).

Authorisation or non-authorisation of a CT.

Validation of the application (scope of the CT Regulation, completeness)




For multinational trial, a Reporting Member State (RMS) should be selected.

Assessment performed by each MSC on the aspects that are of a more national/local nature, (informed consent, the recruitment and compensation of patients, facilities and data protection)