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SCIENCE MEDICINES HEALTH

Transparency – publication of clinical trial information contained in CTIS

SME and academia Clinical Trials Information System (CTIS) two-part training webinar

Presented by Laura Pioppo on 04 March 2021

An agency of the European Union

The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

CTIS User groups have dedicated workspaces

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Sponsors: industry and academia

Marketing authorisation applicants

Member States *NCAs and ethics committees

European Commission

European Medicines Agency

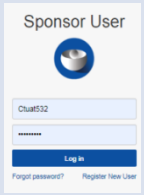
General public

*National competent authorities

secure access

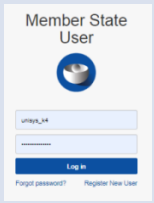
open access

sponsor workspace



EU Portal

authority workspace



public website

EU CT Database

Data accessible to the public

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

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Article 81(4) outlines the requirements for transparency in CTIS:

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

General principles for disclosure of CT information in CTIS

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- Only applications on which a **decision** (any decision) has been reached by the Member State Concerned will be made public;
- All data and documents in the CTIS 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 and MSC will have the chance to evaluate the proposal made by sponsor to defer the publication, as applicable;
- Deferral rules and maximum timelines to defer publication of data and documents will depend on the trial category [i.e. category 1 (phase I trials), category 2 (phase II and III trials) or category 3 (phase IV trials)] as defined in the appendix, on the disclosure **rules**, to the" Functional Specifications for the EU Portal and DB to be audited "

CTIS deferral rules of CT information, if not publish at the first opportunity

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Actor	Grouping	Category 1 FIH, PK/PD, BE/BA, Bio similarity	Category 2 Phase II and III	Category 3 Phase IV
Sponsor	• Main Characteristics	Publication of final **summary of results**		
Sponsor	• Notifications	Publication of final **summary of results**		
Sponsor	• Subject information sheet	Up to **7 years** after the end of the trial in EU/EEA	Up to **5 years** after the end of the trial in EU/EEA	
Sponsor	• Protocol	Up to **7 years** after the end of the trial in EU/EEA	Up to **5 years** after the end of the trial in EU/EEA	Publication of final **summary of results**
Sponsor	• IMPD S&E sections and Investigator Brochure	Up to **7 years** after the end of the trial in EU/EEA	Up to **5 years** after the end of the trial in EU/EEA	Publication of final **summary of results**
Sponsor	• Responses to RFI	Up to **7 years** after the end of the trial in EU/EEA	Up to **5 years** after the end of the trial in EU/EEA	Publication of final **summary of results**
Sponsor	• Clinical trial results summary for an intermediate data analysis	1. 12 months after interim analysis date 2. up to **30 months** after the end of the trial in the EU/EEA		
Sponsor	• Clinical trial results summary and lay person summary	1. 12 months after the end of trial date in the EU/EEA 2. Up to **30 months** after the end of trial in the EEA		

Extract from CTIS - Deferral rules for publication of category 1 trials

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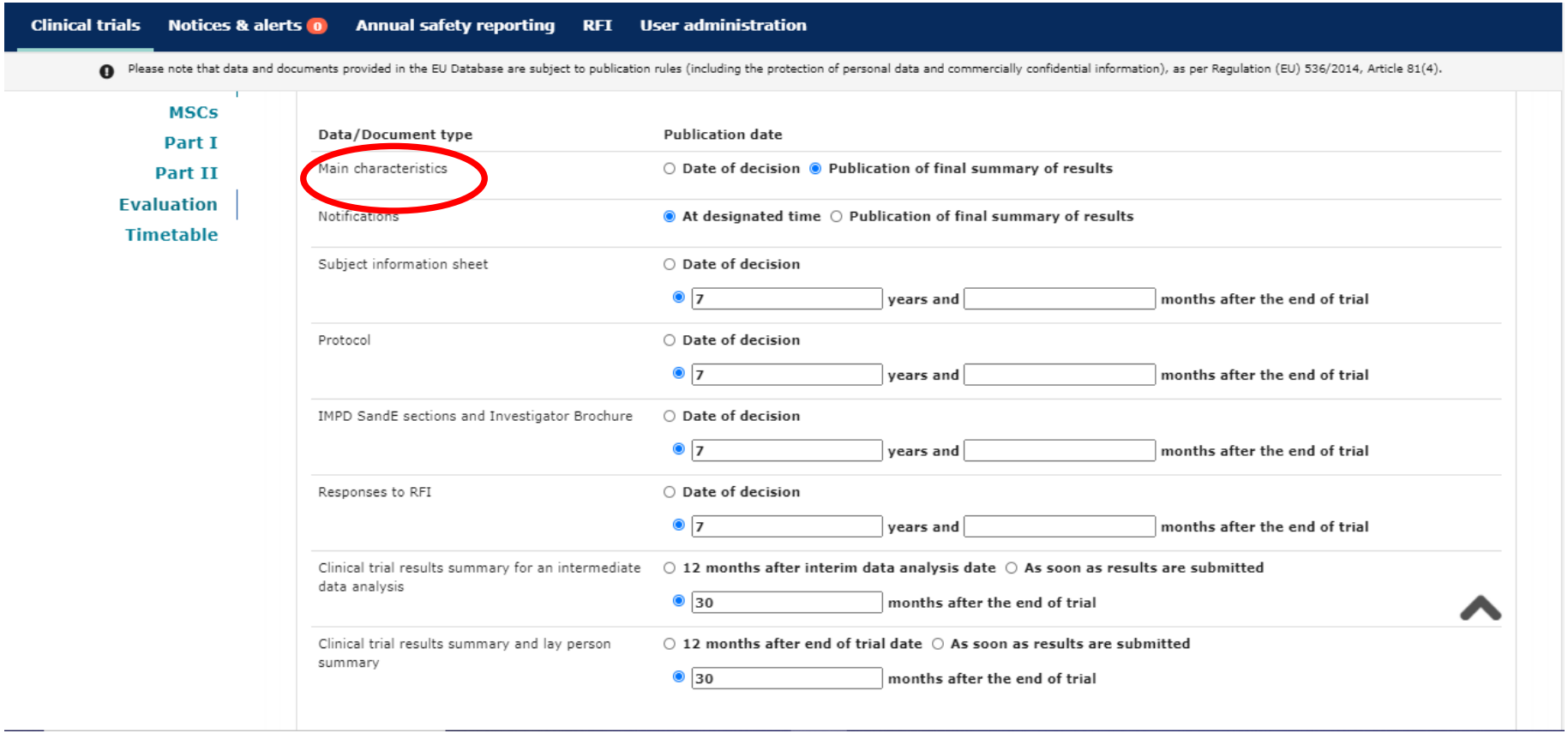

Sponsor data/documents that can be deferred for category 1 trials

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A **non-exhaustive** list of the clinical trial **main characteristics** for which publication can be deferred, include, but is not limited to:

- trial title,
- protocol code, trials design, therapeutic intent,
- main objective,
- secondary objective,
- endpoints,
- inclusion and exclusion criteria,
- treatment arms, treatment population and number of subjects,
- identification of the investigational medicinal products (IMPs).

*Of note, deferral of main characteristics is possible only for **category 1 trials.***

Fields always published, even in case of deferral

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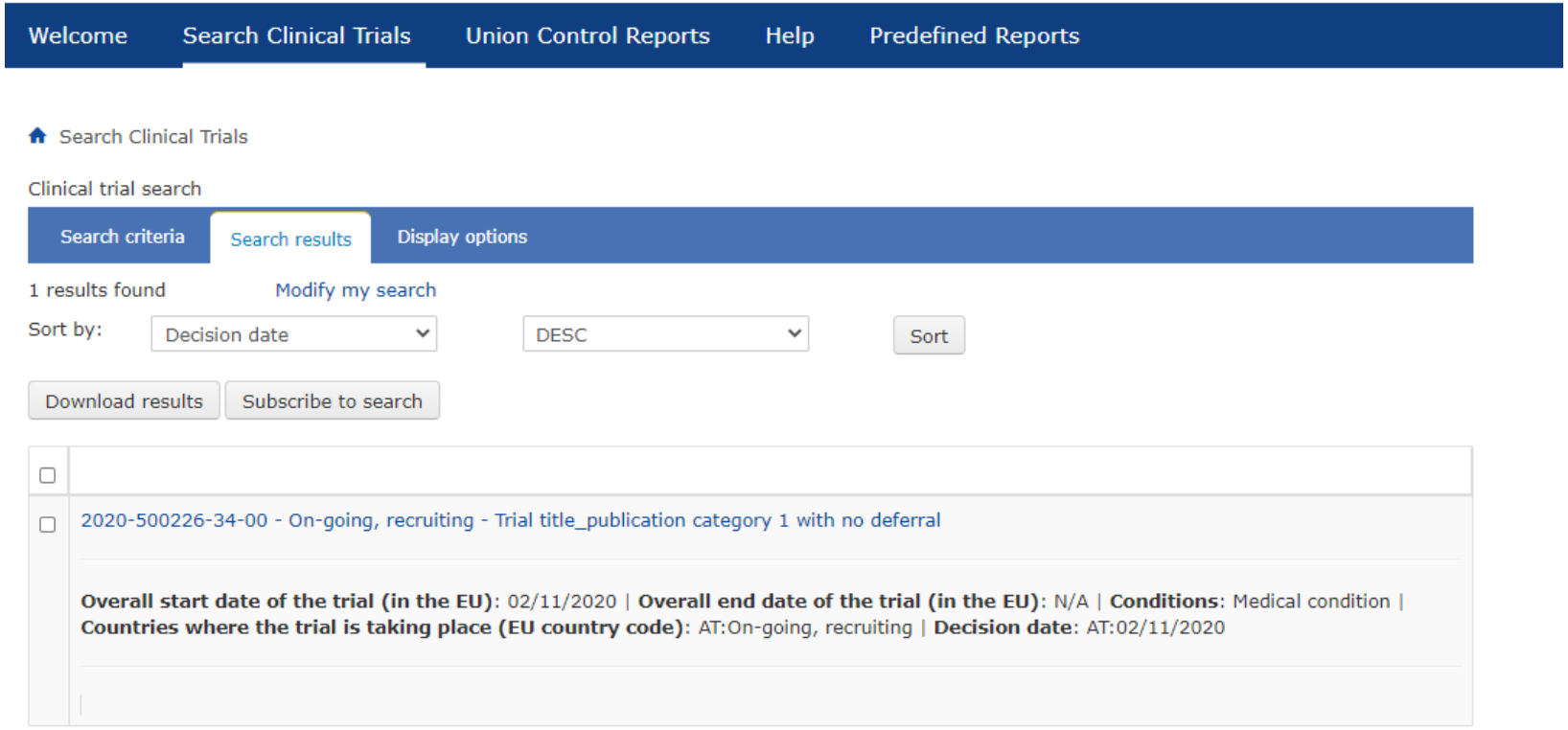
- EU Clinical Trial Number,
- Sponsor name and address,
- Nature of clinical trial (e.g. bioequivalence in 24 healthy volunteers),
- Decision outcome on the trial application and date of decision,
- Date of start of the trial,
- Dates of start and end of recruitment,
- Date of end of the trial in the Member State(s) in the EEA, and globally (including early termination of the trial),
- Principal Investigator Curriculum Vitae,
- Suitability of the facilities

Of note, these fields are always published at time of decision and ***regardless of trial category***

CTIS Public website: Category 1 with no deferral



CTIS Public website: Category 1 with no deferral

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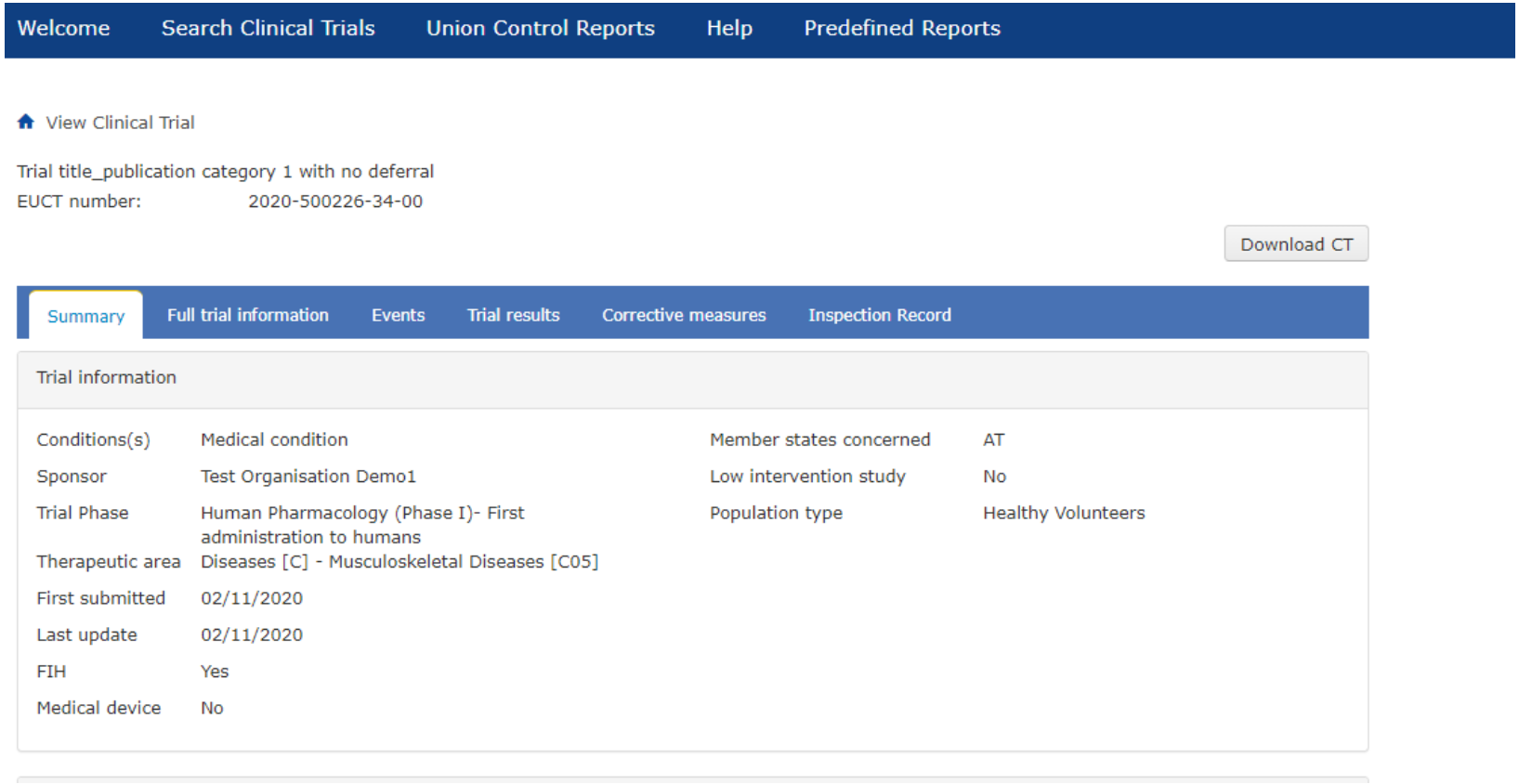
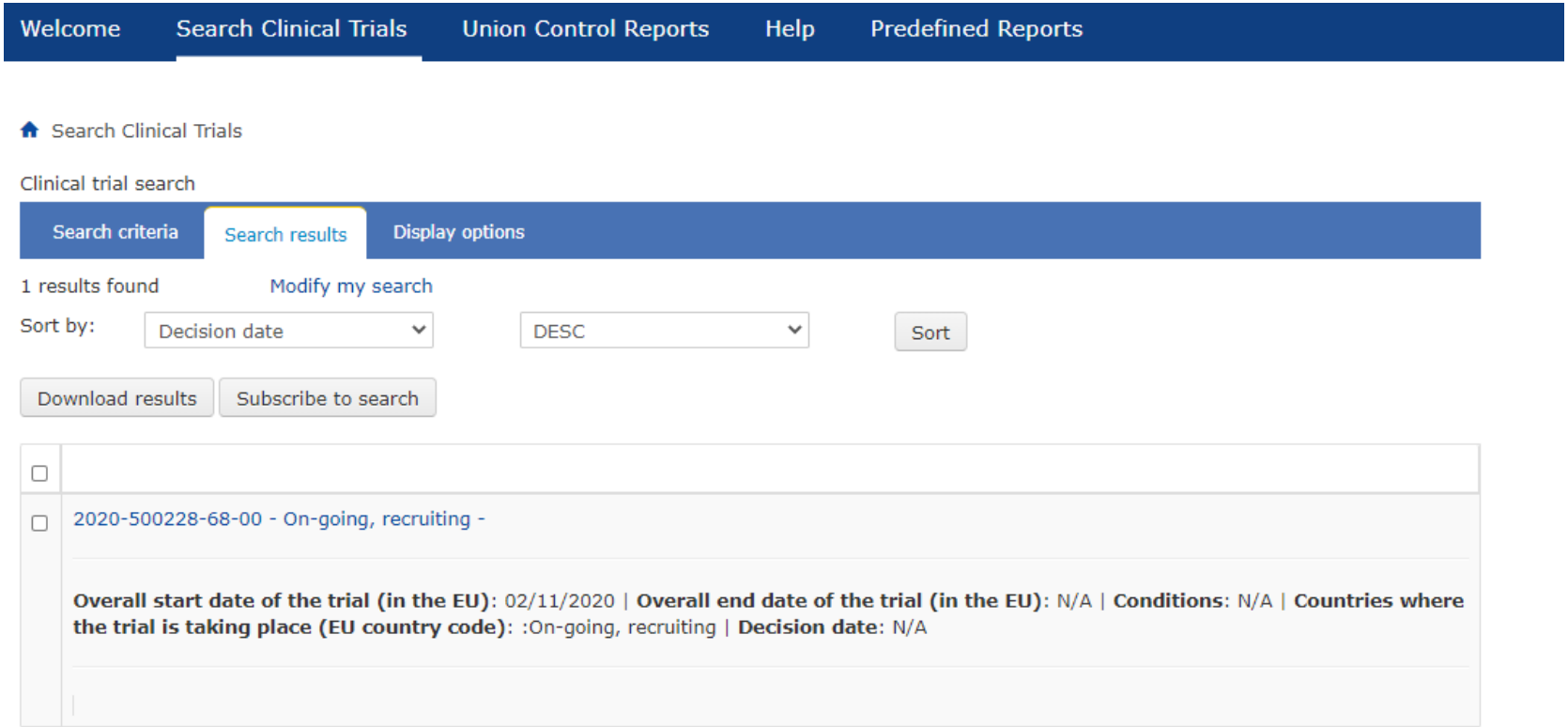
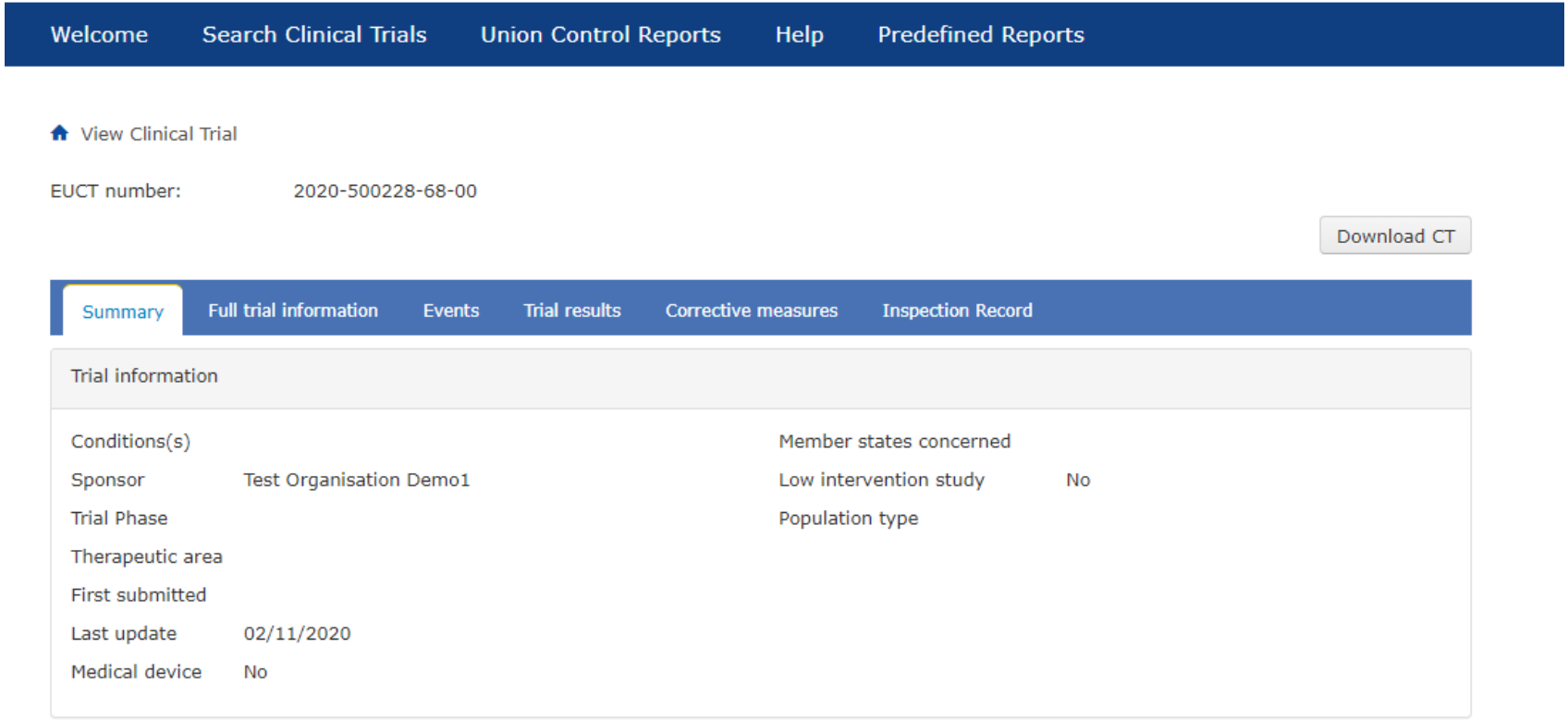


CTIS Public website: category 1 with deferral on main characteristics



CTIS Public website: category 1 with deferral on main characteristics



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)
- Draft assessment reports;
- Personal information identifying Member States experts, sponsor staff, MAH/applicant staff
- Financial agreements between the sponsor and the investigator site;

Examples of CTIS functionalities

How data confidentiality and data protection is enabled via CTIS

Upload a doc version for publication and not for publication, to protect personal data, as applicable

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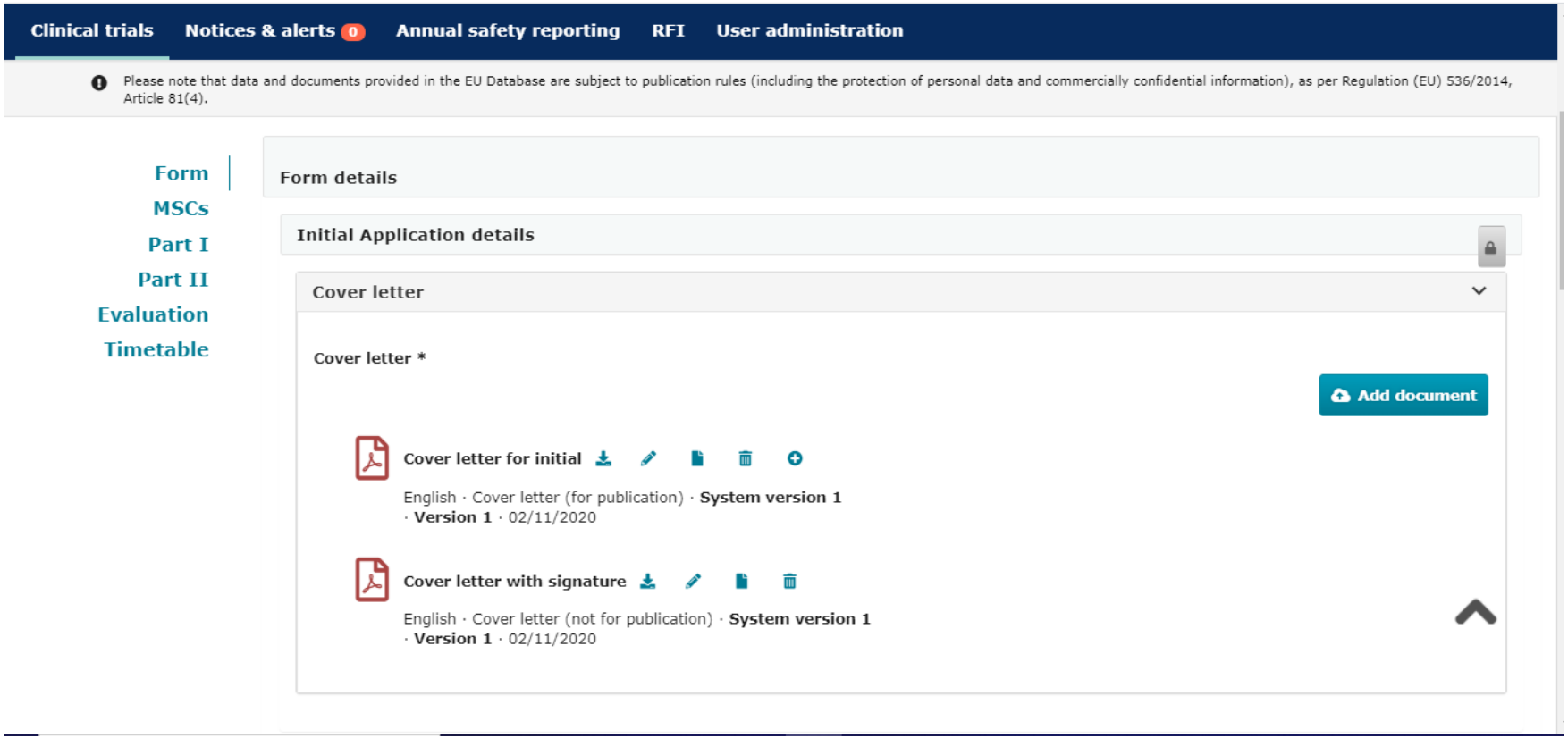
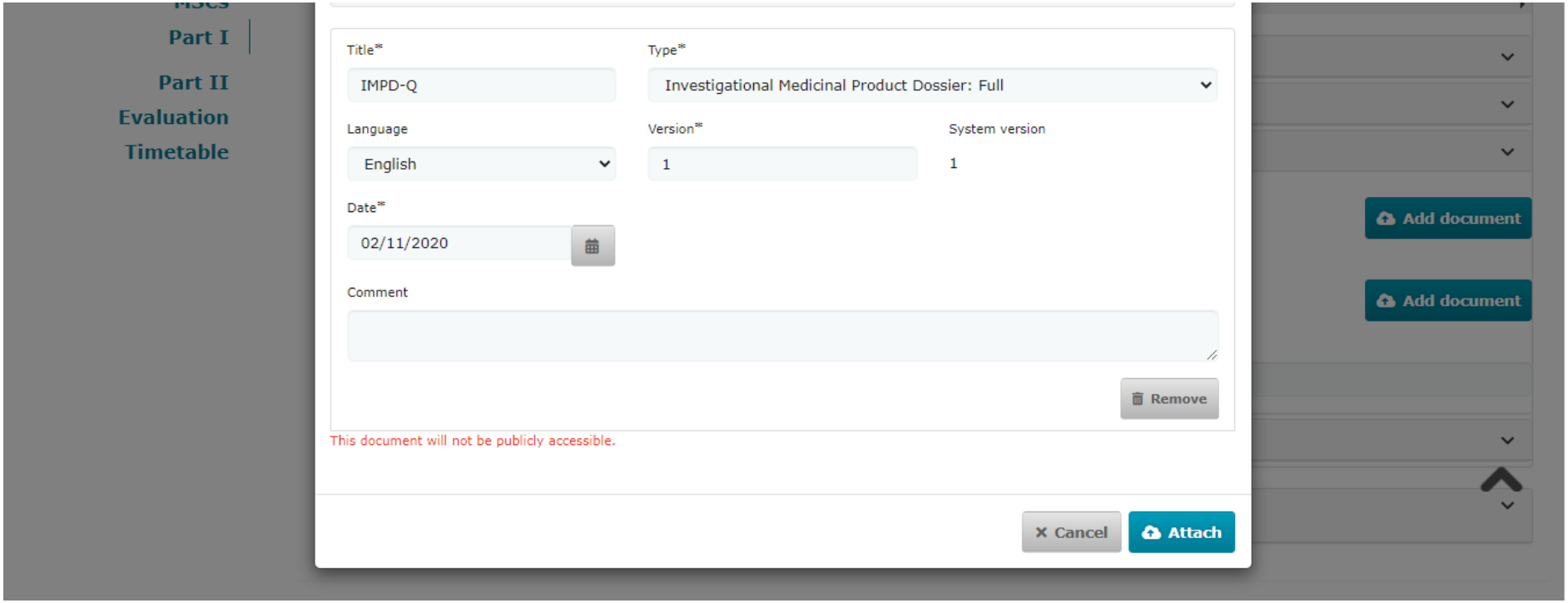
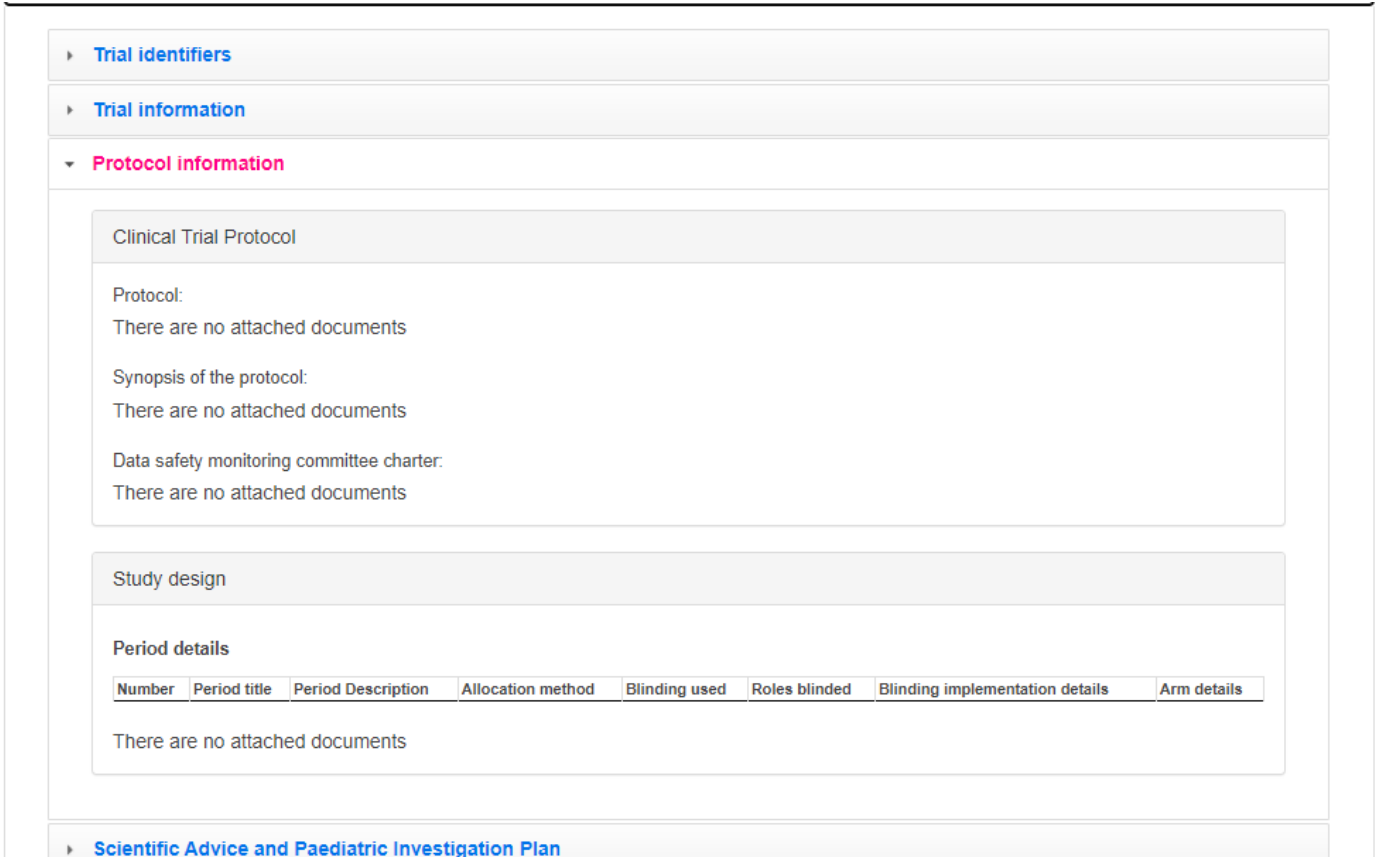


Some data/documents are never published



Deferral of some documents



Any questions?

Further information

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