EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Key functionalities to protect personal data and CCI in CTIS

14 July 2022

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.

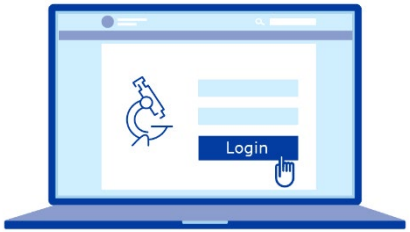
Content of the guidance document on protection of personal data and commercially confidential information (CCI) in CTIS

Guidance intends to provide clarification on:

- Introduction (chapter 1)
- CTIS functionalities implemented to allow protection of PD and CCI (chapter 2)
- Principles on protection of personal data (chapter 3)
- Principles on protection of CCI, also in relation to the use of deferrals (chapter 4)

The guidance document is published for public consultation until 08 September 2022:

CTIS public website & secure domains



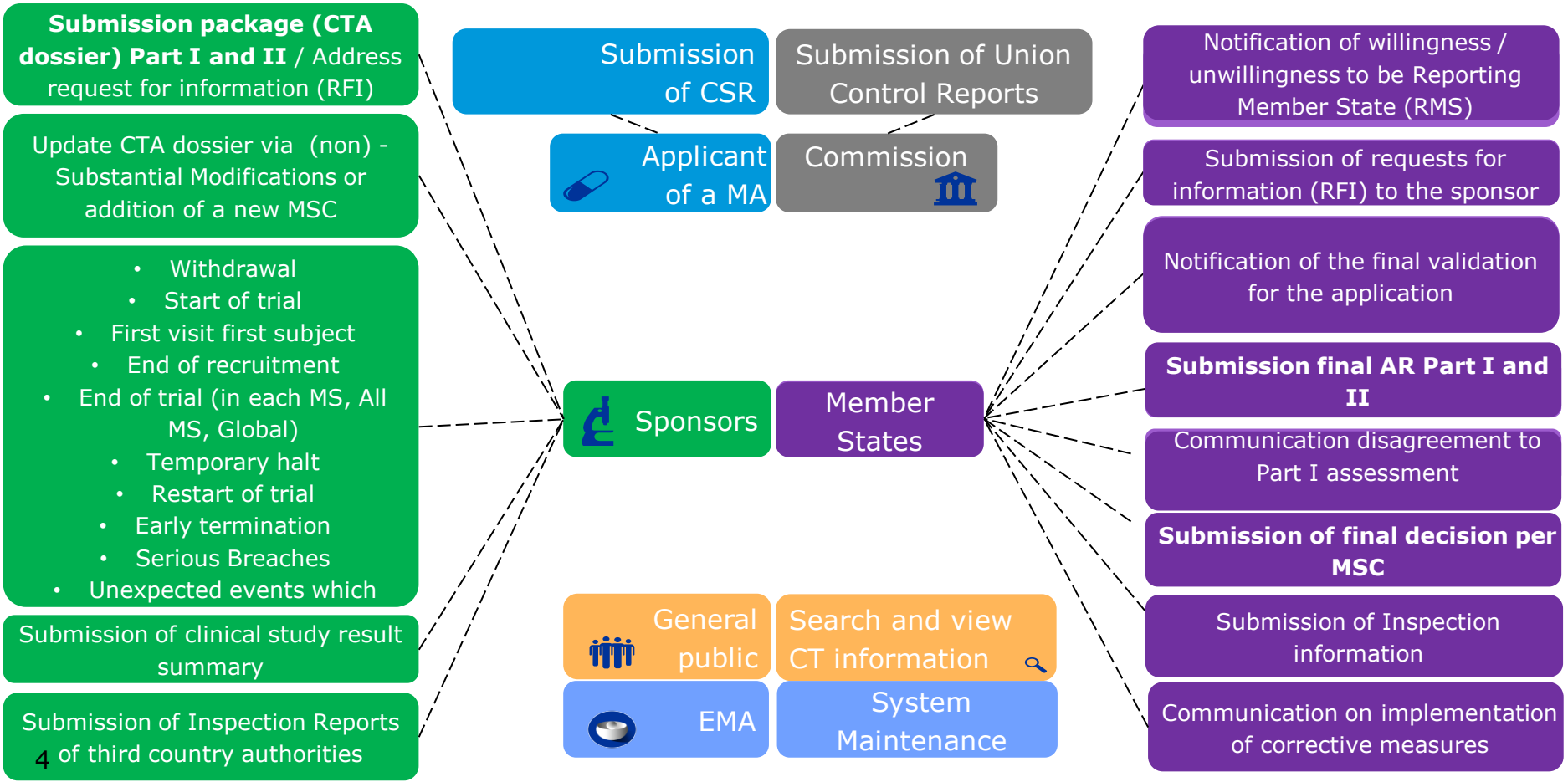
A **Sponsor workspace** where clinical trial sponsors, and the organisations that work with them, can apply for and manage a clinical trial in up to 30 EU/EEA countries

An **Authority workspace** for EU Member States, EEA countries and the European Commission to assess, authorise and oversee clinical trials

Secure access

A **public website** where anyone can search for information on clinical trials and find recruiting trials

Open access



Publication Rules in CTIS

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

"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;

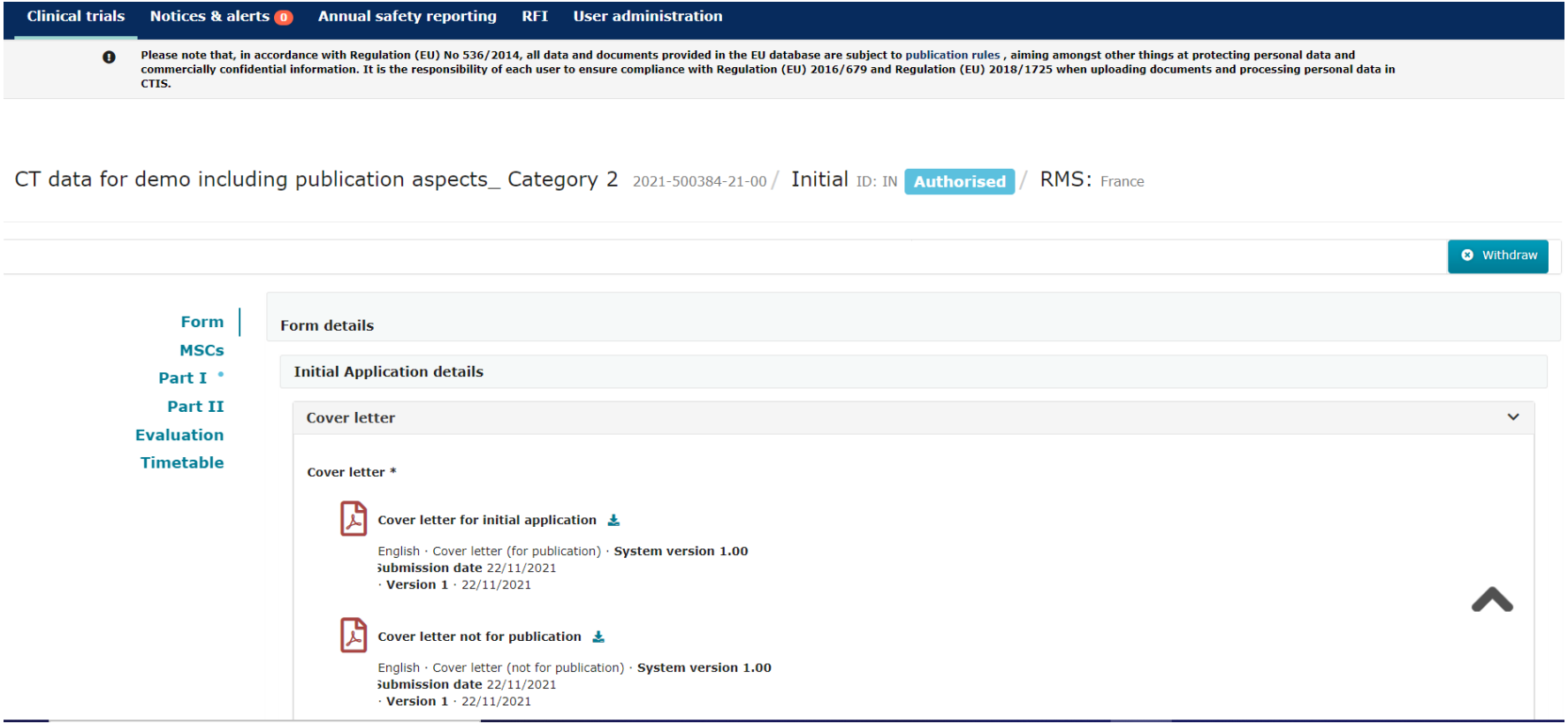
(c) protecting confidential communication between Member States in relation to the preparation of the assessment report;

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

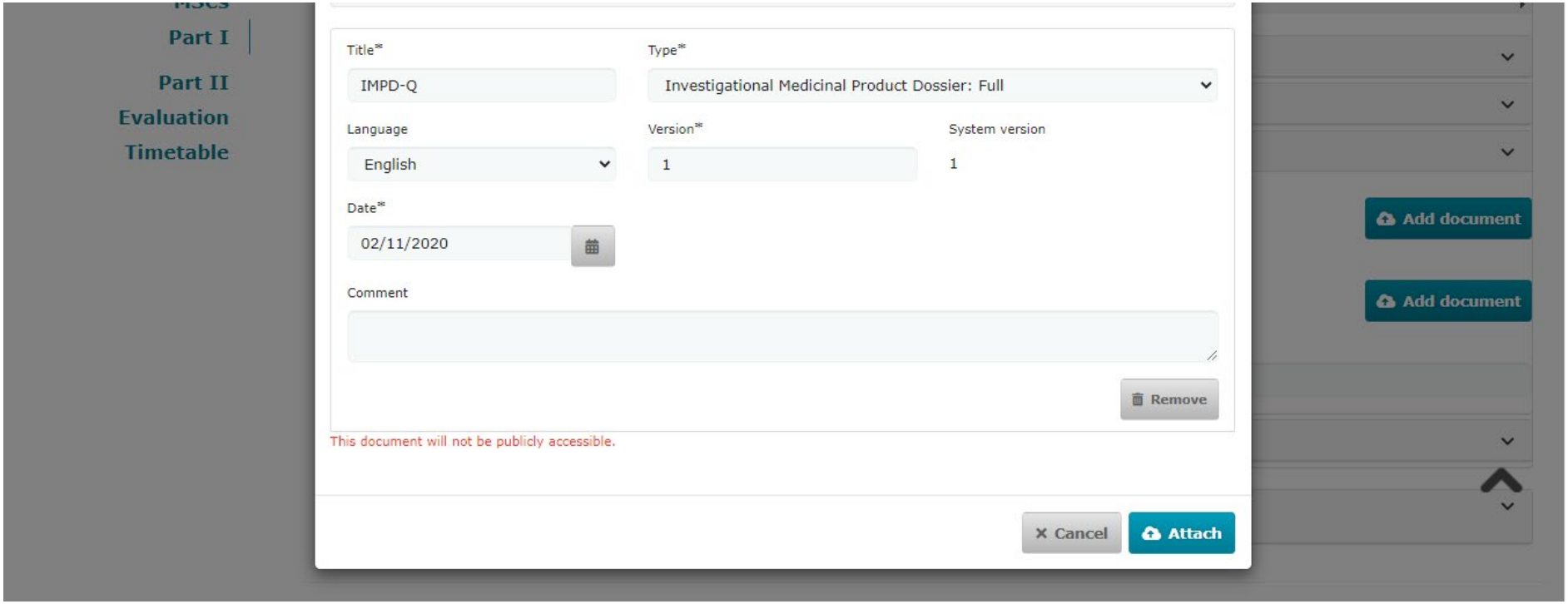
CTIS Joint Controllership Arrangement (JCA)

- **Protection of personal data** while using CTIS is the joint responsibility of:
  - EMA
  - European Commission
  - EU/EEA Member States
  - Commercial, non-commercial organisations and academia acting as sponsors of clinical trials and/or marketing authorisation applicants/holders
- Each party should ensure that personal data are treated according to the principles of the **GDPR** (for MS, sponsors, MAAs, MAHs) and **EUDPR** (for EMA and EC)
- A **Joint Controllership Arrangement (JCA)** has been created by the EC, EMA, EU/EEA Member States in consultation with representatives of industry associations, academia and learned societies.
- When accessing CTIS for the first time, users will be reminded of the contents of the JCA before they can progress with the use of CTIS.

Publication rules in CTIS



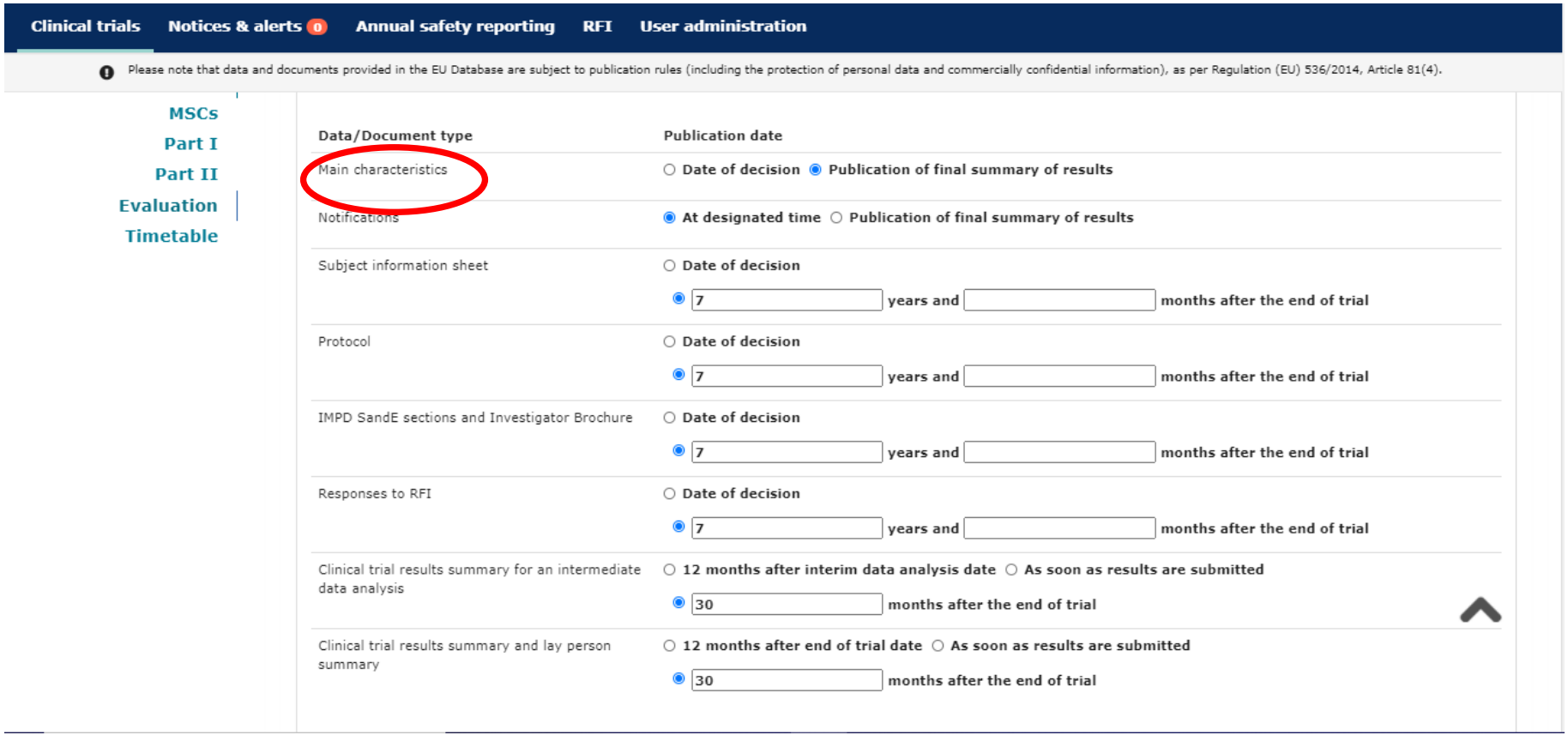
Publication rules in CTIS



- Only applications on which a **decision** (any decision) has been reached by the Member State Concerned will be made public;
- The default is always to make public at the first opportunity, e.g. time of decision;
- Data and documents in the CTIS will be made public, with few exceptions;
- 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 as defined in the appendix, on the disclosure **rules**, to the" Functional Specifications for the EU Portal and DB to be audited "

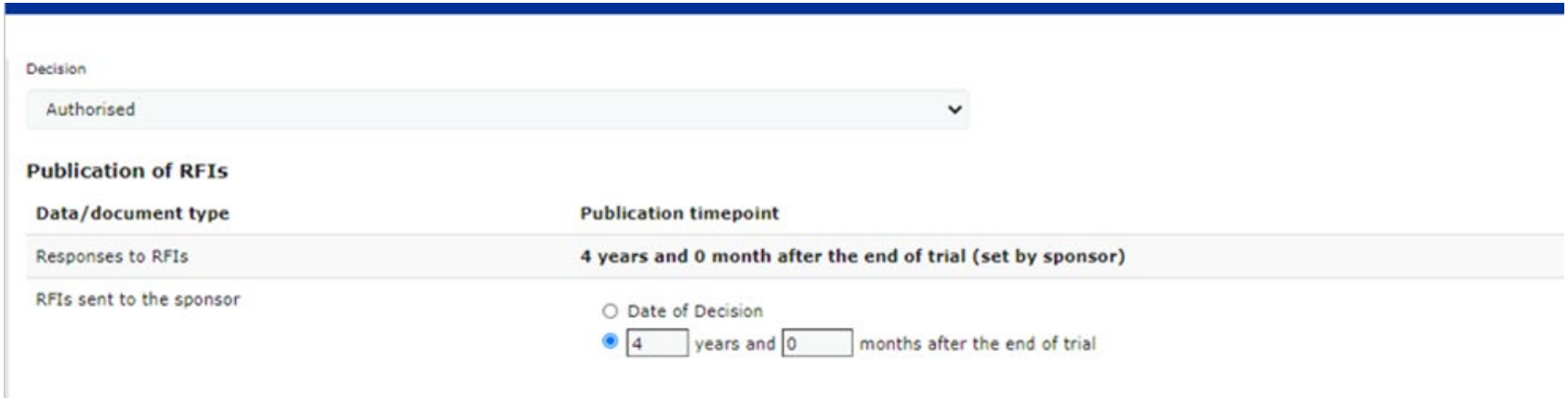
Actor	Grouping	Category 1 FIH, PK/PD, BE/BA, Bio similarity	Category 2 Phase II and III	Category 3 Phase IV
Sponsor	• Main Characteristics*	Publication of final **summary of results**		
Sponsor	• Notifications*	Publication of final **summary of results**		
Sponsor	• Subject information sheet	Up to **7 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 and Scientific Advice	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		

*not permitted if the trial includes paediatric population or it is part of a PIP



Deferral set by the Member States concerned

MSC can also set a deferral for Assessment Reports (part I and part II) and RFI at the time when they issue the decision



Publication rules in CTIS

- The use of a deferral is per trial
- The timing for deferrals is set by the sponsor at the time of initial application
- The Member States documents and the RFI raised to the sponsors can also be deferred
- It would be preferable to have alignment between the publication timelines of sponsor documents and MSC documents
- A document submitted in an application for which a decision has been issued, but not yet published because of deferral, cannot be modified in the context of that application

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;

Any questions?

Further information

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