

EMA Workshop

Users' feedback on CTIS use

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Clinical Trials Legislation Working Group

Scope: Review of new or updates of Clinical Trials related Legislation

Current: Guidance document on protection of personal data and CCI in CTIS

(due for comments 08 Sept 2022)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- 1 7 April 2022
- 2 EMA/212507/2021
- 3 European Medicines Agency

- 4 [DRAFT] Guidance document on how to approach the
- 5 protection of personal data and commercially confidential
- 6 information in documents uploaded and published in the
- 7 Clinical Trial Information System (CTIS)
- 8

Clinical Trials Legislation Working Group

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14 members

9 countries

CTIS Users feedback: Casus / Trial



Phase I, first in human, single-centre, randomized, double-blind, placebo-controlled, dose escalation study to assess safety, tolerability and immunogenicity after the administration of a single dose of hRVFV-4s vaccine in healthy adult subjects.

Financed with community money by the Coalition for Epidemic Preparedness Innovations (CEPI), with support from EU Horizon 2020 program, therefore;

- No deferral of publication of data and documents requested
- No redaction of Commercially Confidential Information

CTIS Users feedback:

Management of documents 'for publication' / 'not for publication'

Project team

- During submission and answering RFI: focus should be on the content and completeness of the submission
- Some documents needed to be done again after RFI

Proposed solution

- Sponsors to start taking this into account during the development of documents
- Add the (redacted) documents 'for publication' at a later stage during the application phase (at time of decision at the latest)

CTIS Users feedback:

Management of documents 'for publication' / 'not for publication'

CTL working group

- Example in the public space of CTIS discovered:

Proposed solution

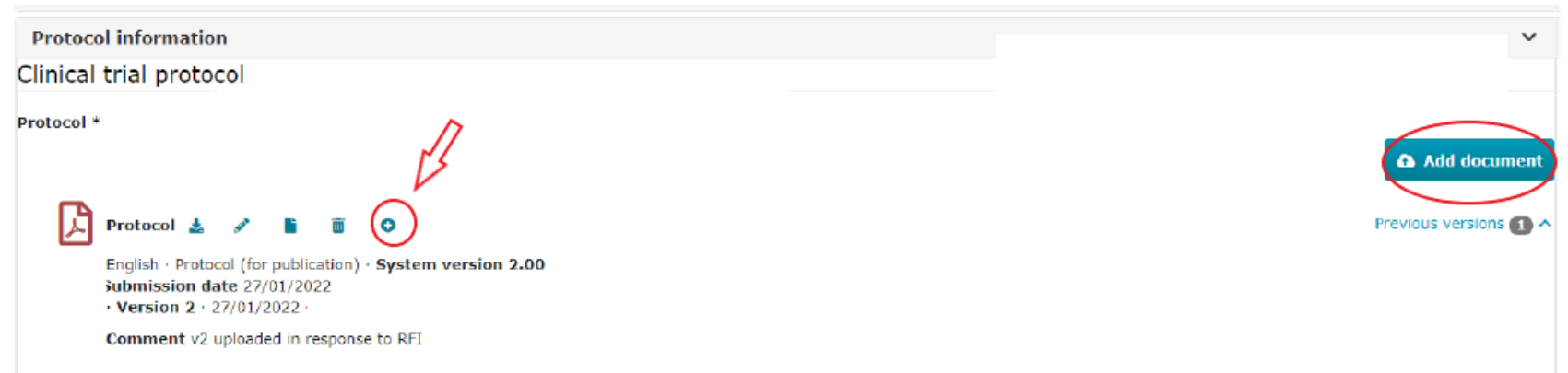
Attached documents	
Title	
CTA Cover Letter_heredERA_24Feb22_REDACTED	
CTA Cover Letter_heredERA_24Feb22	

The screenshot displays the 'Protocol information' section for a 'Clinical trial protocol'. Under the heading 'Protocol *', there is a document icon labeled 'Protocol' with several action icons: a download icon, an edit icon, a trash icon, and a plus icon. A red circle highlights the plus icon, with a red lightning bolt arrow pointing to it. To the right of the document list, there is a blue button labeled 'Add document' which is circled in red. Below this button, it says 'Previous versions 1' with an upward arrow icon. The document details below the icon list include: 'English · Protocol (for publication) · System version 2.00', 'Submission date 27/01/2022', 'Version 2 · 27/01/2022', and a comment: 'v2 uploaded in response to RFI'.

CTIS Users feedback:

Management of documents ‘for publication’ / ‘not for publication’

Proposed solution



- Update CTIS: make 2 different buttons “add document not for publication (instead of the + sign) and “add document for publication”
- Guidance document: annotate the figure and indicate that the “+” sign has to be clicked to add the “not for publication” version of a document

CTIS Users feedback:

Management of personal data in CTIS

Project team

- Redacting is time consuming

Proposed solution

- Add the (anonymised) documents 'for publication' at a later stage during the application phase (at time of decision at the latest)
- Redaction tool in CTIS

Thank You!