



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Introduction to the Clinical Trials Information System (CTIS)

Enpr-EMA- 28th September

Presented by:
Ana Rodriguez, CTIS Deputy Programme Manager

An agency of the European Union



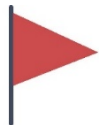


Disclaimer

These PowerPoint slides are copyright of the European Medicines Agency. Reproduction is permitted provided the source is acknowledged.

The presenter does not have any conflict of interests.

The views expressed are those of the presenter.



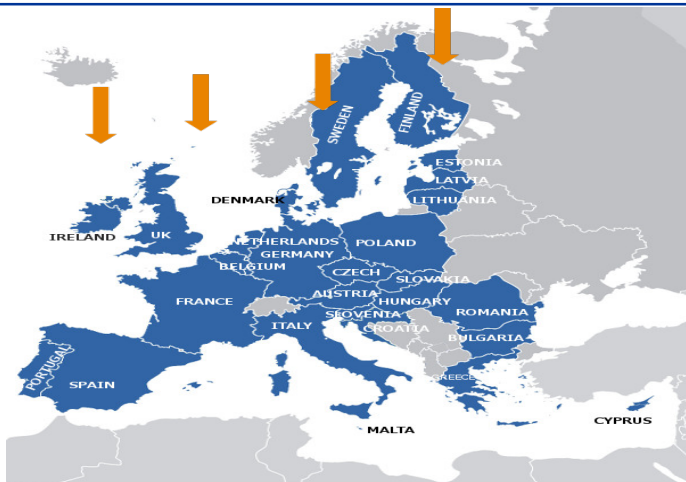
- **CTR and CTIS Benefits for sponsors**
- CTIS high-level system overview and actors
- CTIS User Management
- Sponsor Workspace functionalities
- Transparency rules
- Public module
- CTIS Sponsor support
- CTR Application and transition period
- Next steps

Directive (since 01/05/04)

versus

Regulation (from 31/01/22)

Implemented in national laws



First attempt to harmonise processes and requirements for CT authorizations;

Introduction of the e- application Form

Directly applicable

Objectives of new CTR

- [To protect](#) the rights, safety, dignity and well-being of subjects and the reliability and robustness of the data generated in the CT;
- [To foster innovation](#) and simplify the clinical trial application process, in particular for multistate trials;
- [To increase transparency](#), keeping the balance between protecting public health and fostering the innovation capacity of European medical research while recognising the legitimate economic interests of the sponsors.
- **Overall objective: Make EU attractive for R&D.**

CTIS is the business tool of the **Clinical Trials Regulation**.
CTIS **harmonises the submission, assessment and supervision of clinical trials.**



Public health

Facilitates large-scale trials to address key health issues (COVID, EU Beating Cancer plan...)



Research and innovation

Enables knowledge sharing and expert collaboration.

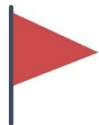


Investment in research

Ensures the EU/EEA remains an attractive clinical research hub globally.

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

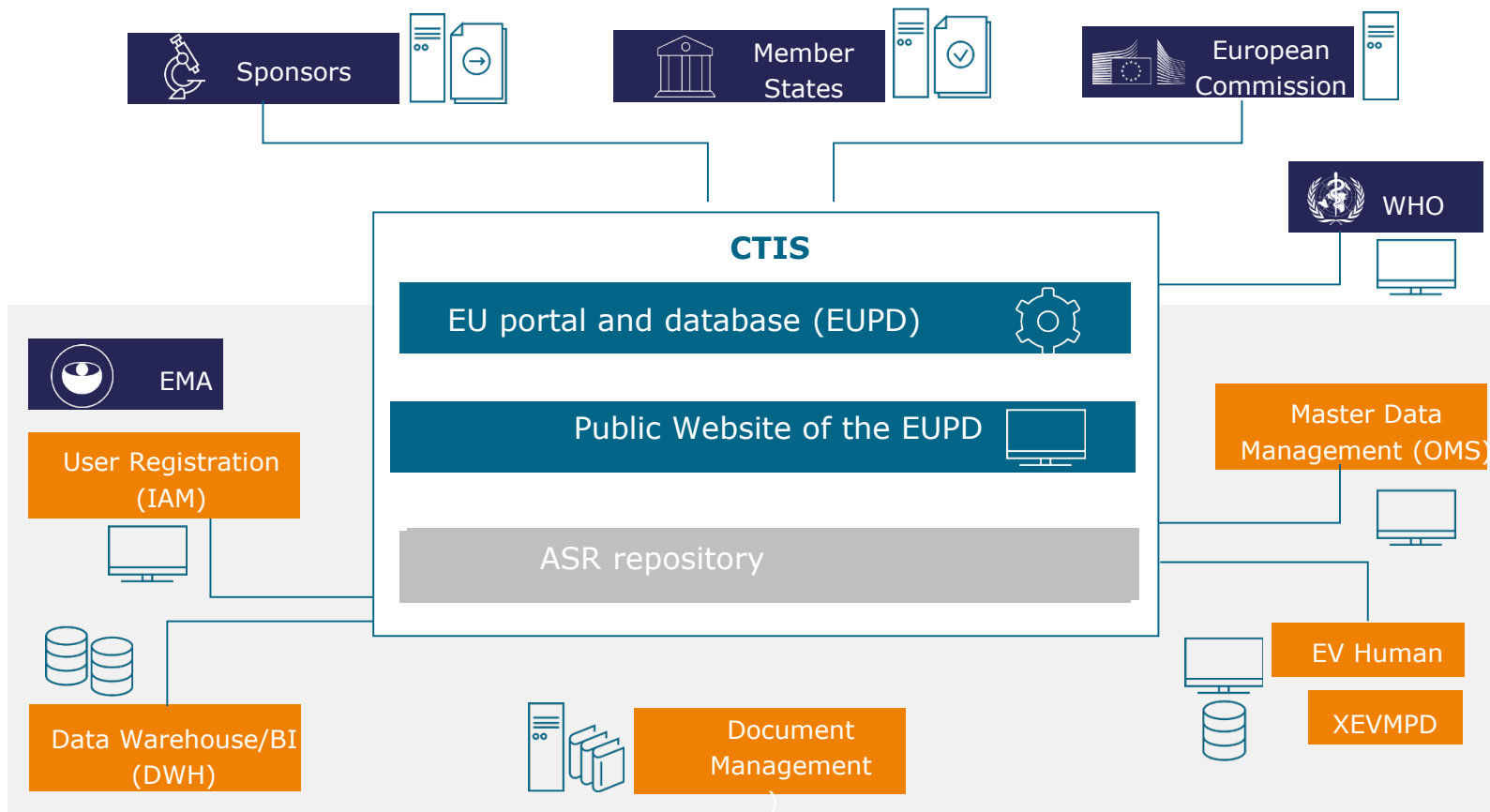


- CTR and CTIS Benefits for sponsors
- **CTIS high-level system overview and actors**
- CTIS User Management
- Sponsor Workspace functionalities
- Transparency rules
- Public module
- CTIS Sponsor support
- CTR Application and transition period
- Next steps

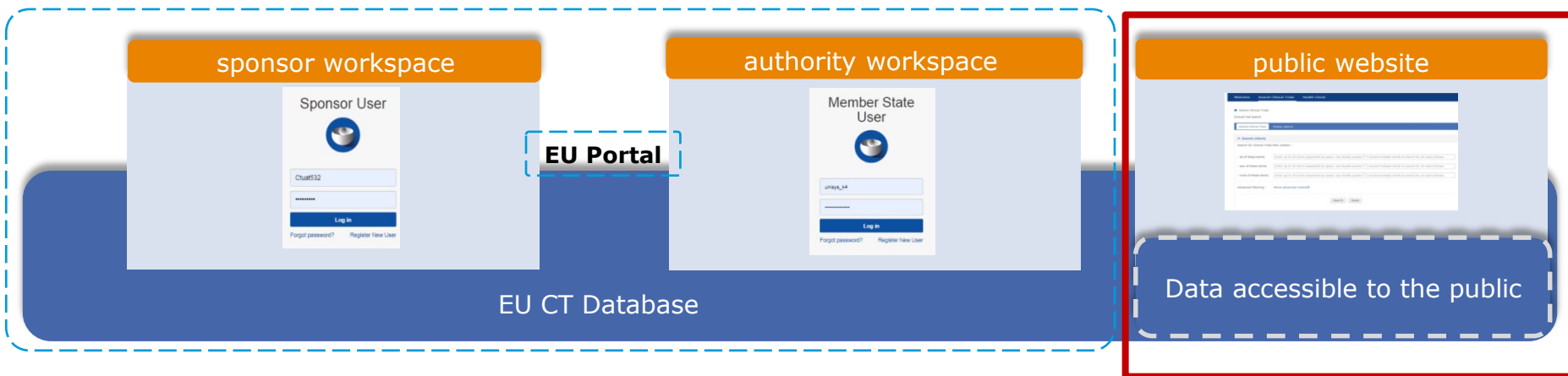
CTIS high level overview and interactions with other systems



EUROPEAN MEDICINES AGENCY



Two dedicated and secure workspaces and a public portal



Sponsors/MAH



Commercial: large pharmaceutical companies & CROs, SMEs



Academia



MAH

Will **input clinical trial data** (CTA, notifications, summary of results, CSR etc) in CTIS

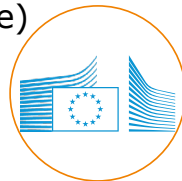
Authorities



Member States (NCA & ethics committee)



EMA



European Commission

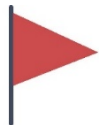
Will **review clinical trial data** (MS/EMA) (Assessment Reports, corrective measures etc.) and create **Union Control Reports** (COM)

Public



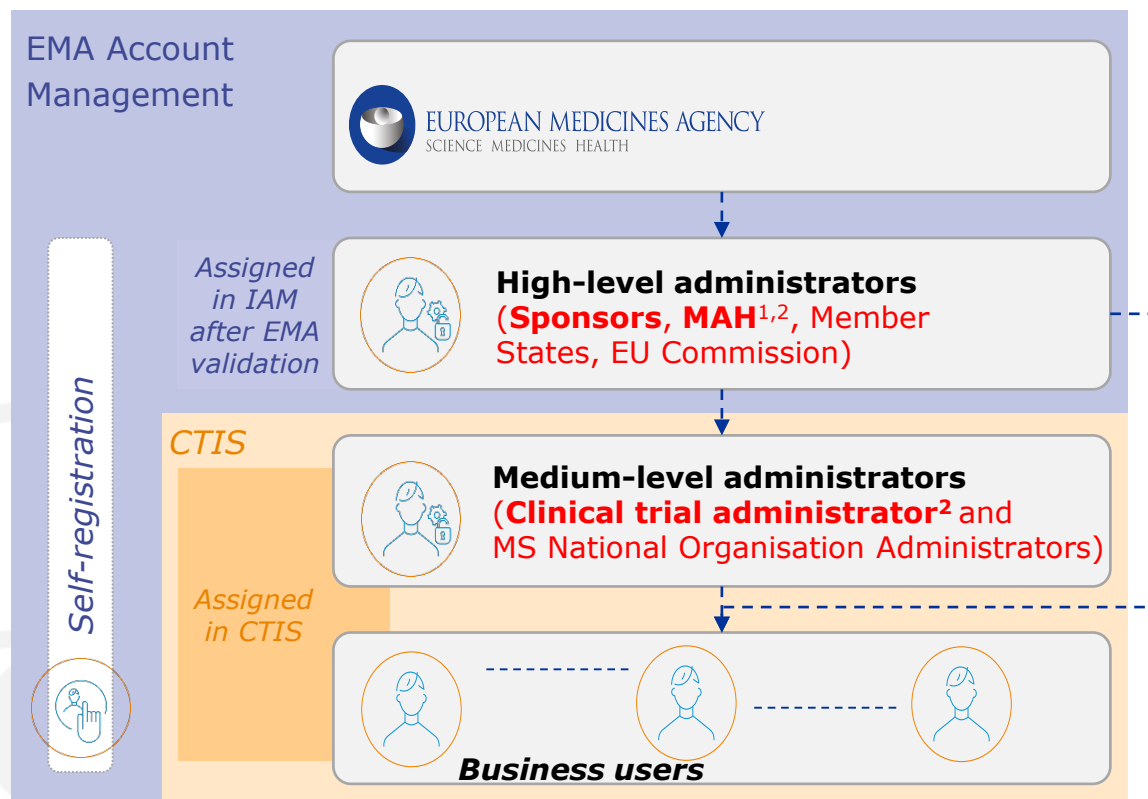
Public users (Healthcare professionals, patients, other)

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



- CTR and CTIS Benefits
- CTIS high-level system overview and actors
- **CTIS User Management**
- Sponsor Workspace functionalities
- Transparency rules
- Public module
- CTIS Sponsor support
- CTR Application and transition period
- Next steps

- **User management** is a set of features and capabilities that enable CTIS administrators to **manage user access** to CTs through role assignment as well as for each user to manage their **own roles/profiles**
- **Only users previously self-registered** in the EMA Account Management system can be assigned with CTIS roles
- The CTIS User Management follows a **hierarchical approach**
- The CTIS **administrator roles** (Sponsor, MSs, EC, MAH, EMA) are the ones responsible to manage users through the CTIS user management functionality
- **More than one user administrator** per organization or per CT is possible in CTIS
- **The CTIS users** will have **access** to the CT system functions **according to their business role**, so the system will display the appropriate data and also the appropriate activities for them
- The **profile of a user** can be built by combining roles



A structured top-down approach is used to maintain the integrity of the system:

Administrator Roles

- Assign new role/CT access
- Amend role/CT access
- Revoke role/CT access
- Approve/reject user requests for a role (*only applicable to sponsor users*)

Business roles

- Role allocated to perform CT related activities in the system

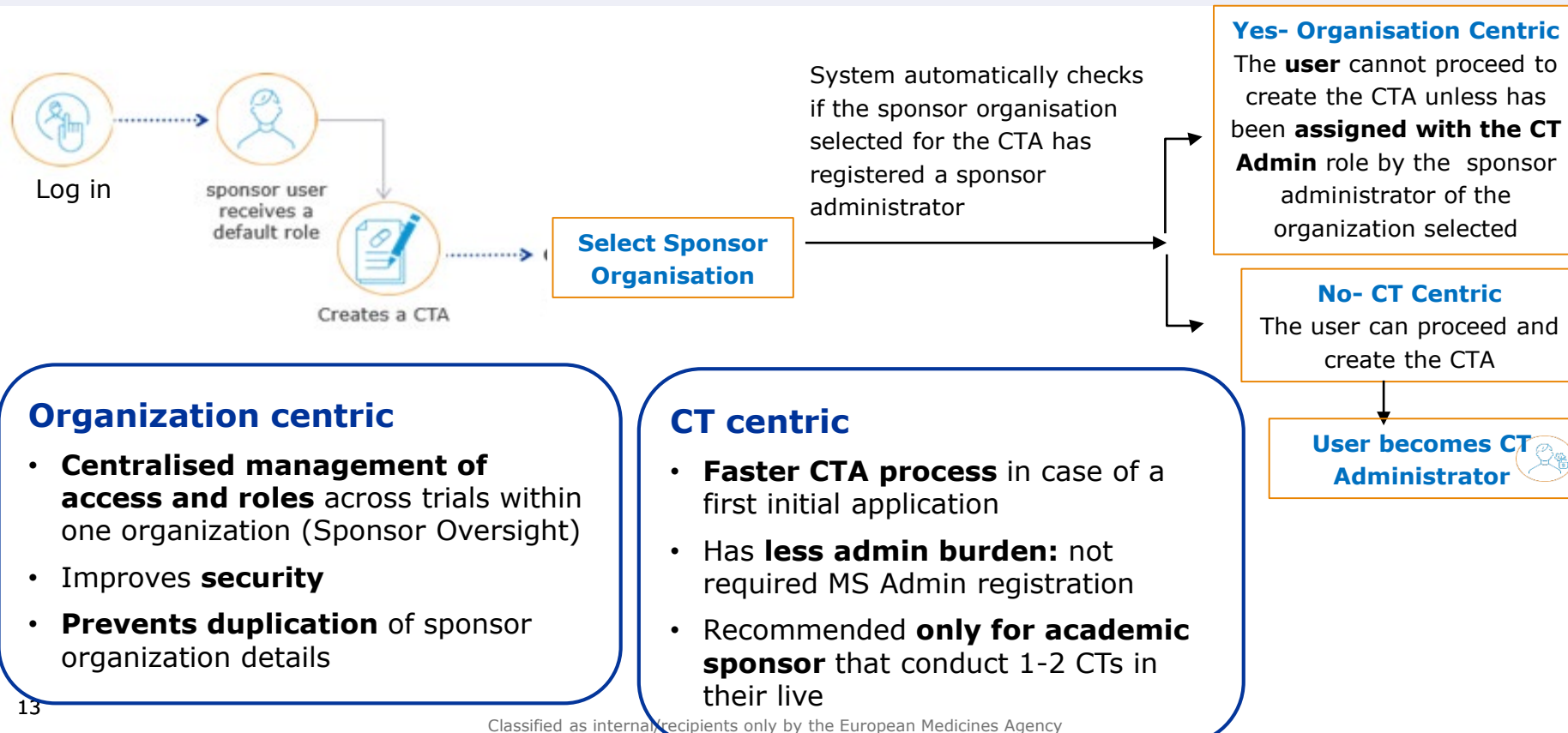
- 1 The MAH role is the only high level administrator role that will be assigned in CTIS by the EMA Administrator
- 2 These roles have also mapped the permissions of business roles: able to perform CT actions in CTIS on top of user administration

Organisation centric vs trial-centric approach



EUROPEAN MEDICINES AGENCY

Two user management approaches in CTIS for the sponsor group of users. They **are automatically applied by the system** based on whether there is an Sponsor Administrator registered in the EMA account management system



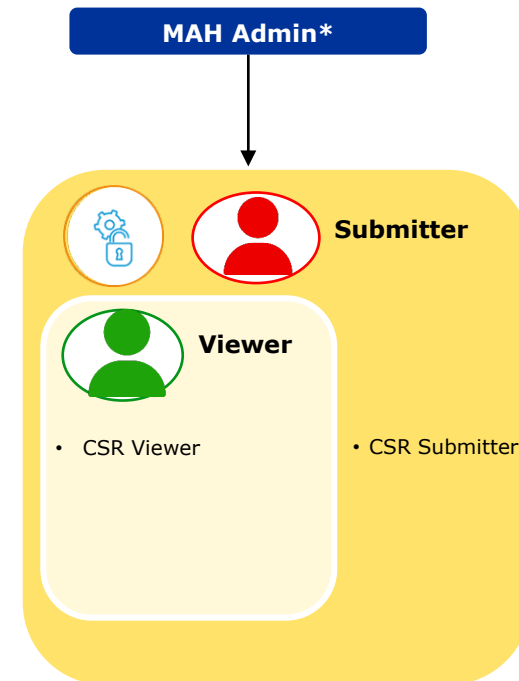
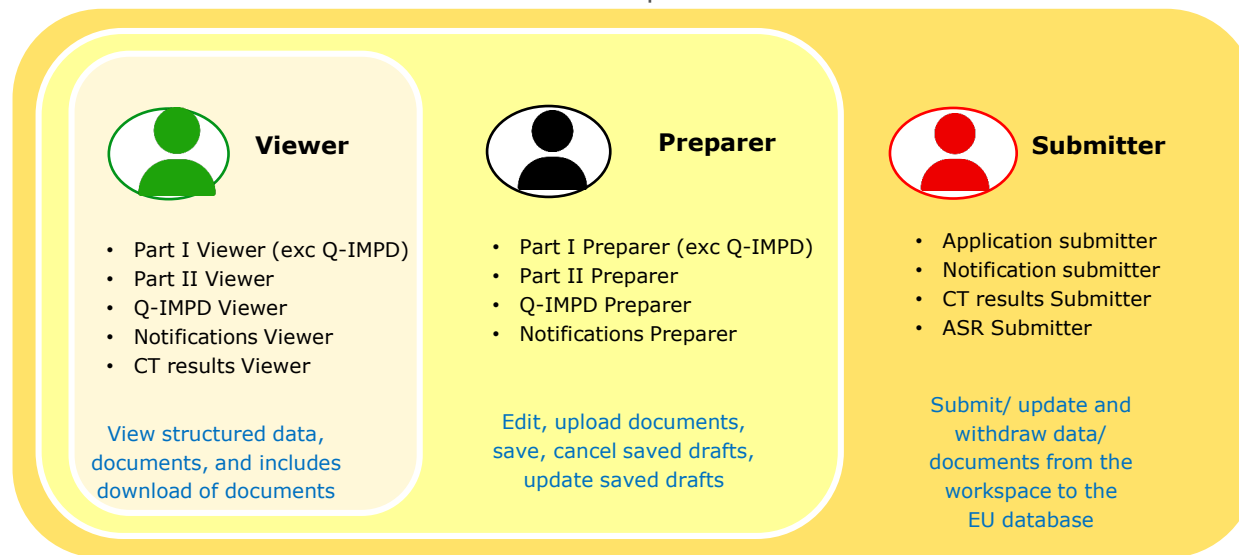


The Sponsors workspace comprises **15 roles business roles and 3 administrator roles** (including Sponsor Admin, CT Admin and MAH Admin):

Administrator roles

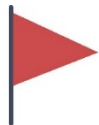


Business roles



***Marketing Authorisation applicants/holders (MAH):** user group within the sponsor workspace that is responsible for managing CSRs.

NOTE: A role can be assigned with the scope "all trials" or "specific trials". In the last case the administrator has to indicate the trial for which the user will have access



- CTR and CTIS Benefits for sponsors
- CTIS high-level system overview and actors
- CTIS User Management
- **Sponsor Workspace functionalities**
- Transparency rules
- Public module
- CTIS Sponsor support
- CTR Application and transition period
- Next steps

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.

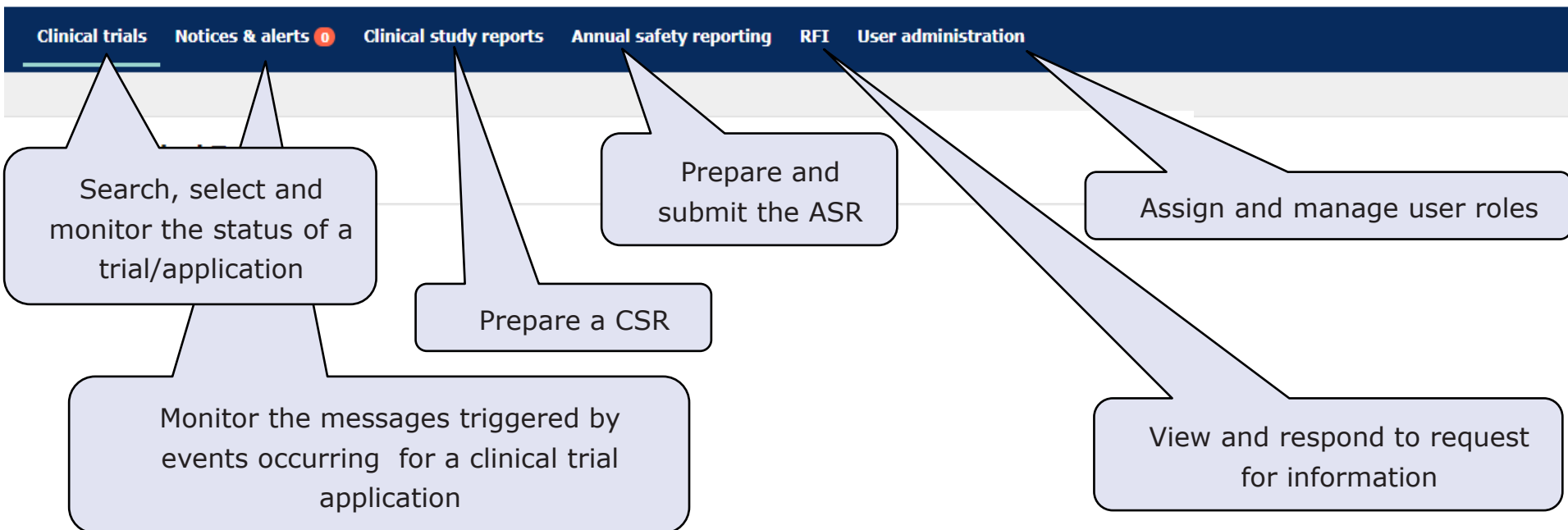
Clinical trials

The tabs displayed will depend on the user profile i.e. roles assigned to the user

UAT CT



EN



Clinical Trials

Enter EU CT number or use advanced search

SEARCH

Trial Advanced Search +

Advance search

Application Advanced Search +

Overall Trial Status: Add Status	Application status: Add Application Status	Title: Add Trial Title
Condition: Add Condition	Sponsor: Add Sponsor	Active substance: Add Active substance
Product name: Add Product		Route of administration: Add Route
Therapeutic area: Add Therapeutic Area	Planned dates covered: Add Member status	Reporting Member State: Add Reporting Member state
Evaluation process: Add Evaluation process	Submission date: dd/mm/yyyy	Validation date: dd/mm/yyyy
Reporting date: dd/mm/yyyy	Decision date: dd/mm/yyyy	Application type: Add Application Type
First CT submission date: dd/mm/yyyy	Max Disengagement: ☐	Product Code: Add Product Code

CLEAR SEARCH

New Trial

Search Results

Showing 1 - 10 of 200 items

1 of 20 pages

1 2 3 ... 20

Sort by:

Submitted

Download Trials

Click EU number to navigate to the trial

Download Trials

2021-000010-28-22
Trial title: CTX-11107 OH: Check working mechanism of corrective measures list

Details

EMA	EMA	Condition	Sponsor/Con-sponsor	Product	Submission date
07 (Pending)	08 (Pending)	01	National Veterinary Institute, National Research Institute for Biological Sciences, Research Institute for Biological Sciences	Enzyme 10 mg, oral solution, generic product	
08 (Pending)	09 (Pending)	02		ETHNOC, 100 mg, oral solution, generic product	
09 (Pending)	10 (Pending)	03		3901-000010-28-22, 10 mg, oral solution, generic product	
		04		3901-000010-28-22, 10 mg, oral solution, generic product	

Trial List

Please note that, in accordance with Regulation (EU) No 536/2014, all data and documents provided in the EU database are subject to publication rules, aiming amongst other things at protecting personal data and commercially confidential information. It is the responsibility of each user to ensure compliance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 when uploading documents and processing personal data in CTIS.

Download + CREATE

NCG testing do not touch

Authorised 2021-502041-15-00 RMS: France

Summary

Full Trial Information

Notifications

Trial results

Corrective measures

Ad Hoc assessments

Users

TRIAL INFORMATION

Sponsor

Trial phase

Therapeutic area

Medical device



and Pregnancy Complications (C13)

Member states concerned

AT - FR

Medical conditions

Premature delivery

Low intervention study

No

Population type

Patients (Pregnant women)

Start of trial

22/09/2021

IMP

Expand all

Flucloxacillin 250mg Capsules

OVERALL TRIAL STATUS

Member State

Overall Trial Status

First decision date

Start of trial

End of trial

Recruitment start date

AT

Authorised



21/09/2021

22/09/2021

FR

Suspended



APPLICATION AND NON-SUBSTANTIAL MODIFICATION

Type

ID

Parts

MSCs

Submission date

Decision date

Initial

[IN](#)

Part I & Part II

AT(Authorised with condition)

21/09/2021

21/09/2021

+ INFO

Within each trial, the tabs displayed will depend on the user profile i.e. roles assigned to the user

Click to navigate to the Application

CT Application Dossier structure



EUROPEAN MEDICINES AGENCY

[Clinical trials](#) [Notices & alerts](#) [Clinical study reports](#) [Annual safety reporting](#) [RFI](#) [User administration](#)

Please note that, in accordance with Regulation (EU) No 536/2014, all data and documents provided in the EU database are subject to publication rules, aiming amongst other things at protecting personal data and commercially confidential information. It is the responsibility of each user to ensure compliance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 when uploading documents and processing personal data in CTIS.

NCG testing do not touch 2021-502041-15-00 / Initial ID: IN **Authorised** / RMS: France

Form

Copy

Form

MSCs

Part I *

Part II

Evaluation

Timetable

Form details

Initial Application details

Cover letter

Proof of payment of fee

France

Proof of Payment

No document available

Austria

Proof of Payment

No document available

Deferral publication dates

Deferral of clinical trial information

Short title / Trial category *

Category 2

Justification for trial category / Trial category *

Justification for trial category

CT Application Dossier structure

[Clinical trials](#) [Notices & alerts](#) [Annual safety reporting](#) [RFI](#) [User administration](#)

Please note that data and documents provided in the EU Database are subject to publication rules, which take into account the need to protect personal data and commercially confidential information. Once available, a redacted version of the documents will be made publicly available in accordance with these rules.

Group B-Mono 01- CMS AT- 14-Oct- An Open Phase III Trial of MK-3475 (Pemb... 2019-500291-28-00 / Initial ID: IN [Draft](#)

MSCs

[✓ Check](#) [📁 Save](#) [⌂ Cancel](#) [📤 Submit](#)

[Form](#)
[MSCs](#)
[Part I](#)
[Part II](#)
[Evaluation](#)
[Timetable](#)

Member states concerned

Member states concerned	Reporting Member State	First submissions date	Subjects	Actions
Austria	Ⓢ		10	🗑
Belgium	Ⓢ		13	🗑

[+ Add member states](#)

Countries outside the European Economic Area

Argentina
Australia
China
Colombia
Japan
Mexico
New Zealand

Rest of the world subjects*

Estimated total population for the trial

EEA subjects
23
Rest of the world subjects*
10
Total subjects
33



CT Application Dossier structure



EUROPEAN MEDICINES AGENCY

[Clinical trials](#) [Notices & alerts](#) [Annual safety reporting](#) [RFI](#) [User administration](#)

[Clinical trials](#) [Notices & alerts](#) [Annual safety reporting](#) [RFI](#) [User administration](#)

Please note that data and documents provided in the EU Database are subject to publication rules, which take into account the need to protect personal data and commercially confidential information. Once available, a redacted version of the documents will be made publicly available in accordance with these rules.

Please note that data and documents provided in the EU Database are subject to publication rules, which take into account the need to protect personal data and commercially confidential information. Once available, a redacted version of the documents will be made publicly available in accordance with these rules.

Group B-Mono 01- CMS AT- 14-Oct- An Open Phase III Trial of MK-3475 (Pemb... 2019-500291-28-00 / Initial ID: IN Draft

Part I

Trial information

✓ Check @ Save 0 Cancel 0 St

Trial specific information (Part I)

Trial details

Trial identifiers

Trial information

Protocol information

Scientific advice and Paediatric Investigation Plan (PIP)

Associated clinical trials

References

Countries outside the European Economic Area

Sponsors

Sponsors

Name	Organisation type	Country	Type	Status	Legal representative	Scientific contact point	Public contact point	Third parties
Pierre Fabre Iberica S.A.	Pharmaceutical company	Spain	Commercial	Active		John AA	John AA	0

Contact point for union*

Organisation name	Address
Pierre Fabre Iberica S.A.	Edificio Marina Village, Calle Ramon Trias Fargas 7-11
Address line 1*	Address line 2
Edificio Marina Village	Calle Ramon Trias Fargas 7-11
Address line 3	Address line 4

Products

Products

EU MP number	Marketing authorisation number	Product authorisation	Product name	Pharmaceutical form	Strength	Sponsors product code	Active substance name	EU substance number	ATC Name	ATC Code	ATC Level	Sponsors other substance code	Active substance descriptive name	Type
PRD-4232786	EU/1/15/1024/002	AUTHORISED	Kaytruda 25 mg/ml	Solution for	25 mg/ml	MK-3475	Pembrolizumab	SUB167136	-	L01XC18	5			Product

Documents

Documents

Part 1



Protocol version 2 vs 1_Track changes

Version 1 - 18/10/2019 - English - Protocol

Comments: In response to RFI



Protocol version 2

Version 2 - 18/10/2019 - English - Protocol

Comments: In response to RFI



20191014-MON01_Cover_Redacted

Version 1 - 14/10/2019 - English - Redacted Cover Letter



Protocol version 1

Version 1 - 14/10/2019 - English - Protocol

CT Application Dossier structure

[Clinical trials](#) [Notices & alerts](#) [Annual safety reporting](#) [RFI](#) [User administration](#)

 Please note that data and documents provided in the EU Database are subject to publication rules, which take into account the need to protect personal data and commercially confidential information. Once available, a redacted version of the documents will be made publicly available in accordance with these rules.

Group B-Mono 01- CMS AT- 14-Oct- An Open Phase III Trial of MK-3475 (Pemb... 2019-500291-28-00 / Initial ID: IN [Draft](#)

Part II

[✓ Check](#) [📁 Save](#) [⌂ Cancel](#) [📤 Submit](#)

[Form](#)

[MSCs](#)

[Part I](#)

[Part II](#)

[- AT](#)

[- BE](#)

[Evaluation](#)

[Timetable](#)

Country specific details (Part II - AT)

Trial sites

Documents

Recruitment Arrangements

Subject information and informed consent form

Suitability of the investigator

Suitability of the facilities

Proof of insurance cover or indemnification

Financial and other arrangements

Proof of payment of fee

Compliance with national requirements on Data Protection

Compliance with use of Biological samples

All documents



Evaluation section

CG testing do not touch 2021-2024-1-15-00 / Initial ID: 2N Authorised / RMS: France

Evaluation

Validation

Form
MSCs
Part I *
Part II *
Evaluation
Timetable

RFI 1
Conclusion

Assessment Part I

RFI 2
Conclusion
Intended Disagreements

Assessment Part II

AT
RFI 3
Conclusion

FR
RFI 4
Conclusion

Decision

Part I Disagreements

ASSESSMENT OVERVIEW

MSCs	Validation	Assessment Part I	Assessment Part II	Decision	+ info
AUSTRIA			Acceptable (21/06/2021)	Authorized with condition (21/06/2021)	+
FRANCE	Valid (21/06/2021)	Acceptable (21/06/2021)	Acceptable (21/06/2021)		+

Form
MSCs
Part I
Part II
Evaluation
Timetable

~~Winter clock stop~~

- The winter clock also is enabled.

Timetable

- All tasks / events are shown in European Central Time (CET).
- Please note that the due dates for tasks in the future are indicative and might get updated.
- After the RMS has been selected, all projected tasks / events will be updated based on the RMS calendar.
- Part II assessment project timeline is based on each respective MSC calendar

Legend

Filter

Time Filter

Daily

Including Validation Phase RPT: ☐

Including Assessment Phase RPT: ☐

Name

12/1113/1114/1115/1116/1117/1118/1119/120/121/122/123/124/125/126/127/128/129/130/11/1/2 2/12 3/12 4/12 5/12 6/12 7/12 8/12 9/12 10/1211/1312/1313/1314/1315/1316/1317/1318/1319/1220/1221/1222/1223/1224/1225/1226/1227/1228/1229/1330/1/

Application submission

3. [Download the PDF](#)

Validation

▼ Select RMS

[v Agree R](#)

2.2.2. Conclusions

➤ Conclusion

Part I

Conclusion

1000

Part II

Portugal

▼ Concludi

100

Germany

▼ Conclusions

Decision

100

Portugal

Germany

Arrec RMS (Predicted)

Subjekt: ...

Submit Part I conclusion (Projected)

Submit Part II conclusion (Projected)

Submit Part II conclusion (Predicted)

Notices & Alerts

Notices & alerts

Default and advance Search

Enter EU CT ID or ASR ID (Business Keys) or use advanced search.

SEARCH

Advanced Search +

☐ Notices ☐ Alerts ☒ Both

Title of the Notice/Alert

Add Title

Message of the Notice/Alert

Add Message

Received

From

To

Sponsor

Add Source type

Active Substance

Product Name

ATC Code

saMS

Add Member states

RMS

Add Member states

Assessing MS

Add Member states

CLEAR SEARCH

Showing 1 - 9 of 9 items

1 of 1 pages

Sort by:

Received

New! 9

All 11467

Notice No active Conclusion to Part II submitted	Ref number	Source type	Evaluation process	Received	IMP	RMS	Sponsor
The Initial has no active conclusion recorded for Part II for Austria.	2021-501814-41-00	Initial	Assess part II	24/09/2021	APPROVAL 300 MG TABLETS	Austria	Panpharma
Notice No active Conclusion to Part II submitted	Ref number	Source type	Evaluation process	Received	IMP	RMS	Sponsor
The Initial has no active conclusion recorded for Part II for France.	2021-501747-41-00	Initial	Assess part II	24/09/2021	APPROVAL 300 MG TABLETS	France	Panpharma
Notice No active Conclusion to Part II submitted	Ref number	Source type	Evaluation process	Received	IMP	RMS	Sponsor
The Initial has no active conclusion recorded for Part II for France.	2021-501758-21-00	Initial	Assess part II	24/09/2021	APPROVAL 300 MG TABLETS	France	Panpharma

N&A List

Request for Information (RFI)

Default and advance Search

RFI

Enter EUCT, RFI, Ad hoc assessment, corrective measure IDs or use advanced search

SEARCH

Advanced Search +

MSC

Source type

Add Source type

Status

Due date

Response Date

Submit Date

CLEAR SEARCH

Showing 1 - 10 of 522 items

1 of 53 pages

< 1 2 3 ... 53 >

Sort by: 

No sorting



RFI-ASR-2021-00232-001

Pending ASR-2021-00232

IMP1: APPROVEL 300 MG TABLETS · IRBESARTAN

MSC

Australia

Source type

Assess ASR

Evaluation process

Submitted

20/09/2021

Responded

Due

04/10/2021

RFI-CT-2021-502028-65-00-IN-003 IN

Pending CT-2021-502028-65-00

Title: MPA_210916_SD Henning&Björn (Full Title)

IMP1: Candesartan Pensa 32 mg comprimé · CANDESARTAN CILEXETIL

MSC

Sweden

Source type

Initial

Evaluation process

Assess part II

Submitted

21/09/2021

Responded

Due

04/10/2021

RFI-CT-2021-502013-25-00-IN-004 IN

Pending CT-2021-502013-25-00

MSC

Australia

Source type

Initial

Evaluation process

Assess part I

Submitted

17/09/2021

Responded

Due

29/09/2021

RFI List

Administration of users

Default and advance Search

Enter EU CT ID or ASR ID or use advanced search

SEARCH

Advanced search ▾

Search Results

Showing 1 - 10 of 17 items

1 of 2 pages

< 1 2 >

Sort by: 📄

User Id ▾

✓ Approve

🚫 Reject

↺ Revoke

ASSIGN NEW ROLE

unisis_i1 | uat.ct17@ext.ema.europa.eu

approved

Scope: All trials

Employer:

Organisation name: Pierre Fabre Iberica S.A.

Organisation Id: ORG-100003995

Role:
Sponsor Admin

Creation date:
04/10/2019

Assesment date:
04/10/2019

Authorised from:
04/10/2019

Authorised to:

EU CT Number:

ctuat386 | uat.ct574@ext.ema.europa.eu

approved

Scope: All trials

Employer:

Organisation name:

Organisation Id: ORG-100003995

Role:
CT Admin

Creation date:
11/10/2019

Assesment date:
11/10/2019

Authorised from:
11/10/2019

Authorised to:

EU CT Number:

AMEND

ctuat389 | uat.ct577@ext.ema.europa.eu

approved

Scope: All trials

EU CT Number:

Role:
Application Submitter

Creation date:
11/10/2019

Assesment date:
11/10/2019

Authorised from:
11/10/2019

Authorised to:

User List

Clinical trials

UAT CT |  | EN 

[Clinical trials](#) [Notices & alerts](#) [Annual safety reporting](#) [RFI](#) [User administration](#)

Annual safety reports

Advanced search 

Search results

No results

 NEW ASR

Default and advance Search

Click to create new ASR

Screen to create ASR

Clinical trials

UAT CT |  | EN 

[Clinical trials](#) [Notices & alerts](#) [Annual safety reporting](#) [RFI](#) [User administration](#)

Submit ASR

 CLEAR  CHECK  CANCEL

1

Sponsor information

2

Clinical Trial detail

3

ASR reporting period details

4

Supporting documents and submit

Expand all 

Step 1

Sponsor information

Step 2

Clinical Trial Detail

Step 3

ASR Reporting Period details

Step 4

Supporting Documents and Submit

Clinical trials

UAT CT | | EN ▼

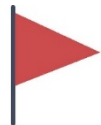
Clinical trials **Notices & alerts** **Clinical study reports** **Annual safety reporting** **RPI** **User administration**

Please note that, in accordance with Regulation (EU) No 536/2014, all data and documents provided in the EU database are subject to publication rules, aiming amongst other things at protecting personal data and commercially confidential information. It is the responsibility of each user to ensure compliance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 when uploading documents and processing personal data in CTIS.

Search

EU CT Number: Trial title: Status:
 MAA procedure outcome: Procedure number (MAA reference ID): Submission date:

EU CT number	Trial title	Procedure number:	Procedure outcome	Submission date:	Status	Actions
2021-501768-14-00	Clinical Trial for CTC5-16135 - DO NOT TOUCH	BE0123456	MA granted	18/08/2021	Submitted	
2021-501072-28-00	CTC5-8640 - TUC015.VMU.02 - Validation of screen MU015.02 ASR Submission	EMEA/H/C/112312/312	MA granted	06/08/2021	Submitted	
2021-501072-28-00	CTC5-8640 - TUC015.VMU.02 - Validation of screen MU015.02 ASR Submission	EMEA/H/C/213213/123	MA granted	06/08/2021	Withdrawn	
2021-500375-23-00	Maria 04 test in progress do not touch	EMEA/H/C/111111/111	MA granted	26/07/2021	Submitted	
2021-501717-23-00	CTC5-20734 Public Portal Download does not contain all data and documents (Template #)	EMEA/H/C/501717/230	MA granted	23/07/2021	Submitted	
2021-501604-19-00	Maria 08 test in progress do not touch - Pplication submitter	123456789	MA granted	19/07/2021	Submitted	
2021-500012-11-00	CTC5-11175 Check document handling when an application is copied:	XFstafAS	MA granted	07/07/2021	Withdrawn	
2021-501549-33-00	MARIA do not touch 2 - Extended	123456	MA granted	05/07/2021	Withdrawn	
2021-501412-41-00	TC1089: CTC5-18490 Publication of Inspection Record (MAA Inspection)	EMEA/H/C/111111/111	Procedure for MA completed	18/06/2021	Submitted	
2021-501408-23-00	TC1089: CTC5-18490 Publication of Inspection Record (MAA Inspection)	EMEA/H/C/111111/111	Procedure for MA completed	18/06/2021	Submitted	
2021-501335-13-00	TC1046.09 E2E: Download Clinical Study Report	EMEA/H/C/111111/111	MA granted	17/06/2021	Submitted	
2021-500911-35-00	TC1046.09 E2E: Download Clinical Study Report	EMEA/H/C/111111/111	MA granted	16/06/2021	Submitted	
2021-500704-29-00	TC1046.08 E2E: View Clinical Study Report	EMEA/H/C/111111/111	MA granted	15/06/2021	Submitted	
2021-500703-74-00	TC1046.07: View Clinical Study Report - Negative	EMEA/H/C/111111/111	MA granted	15/06/2021	Submitted	
2021-500381-22-00	[Extended User Testing] - Public portal - to test information "test %*#@) ~ Do not touch	EMEA/H/C/222222/333	MA granted	15/06/2021	Withdrawn	



- CTR and CTIS Benefits
- CTIS high-level system overview and actors
- User Management
- Sponsor Workspace functionalities
- **Transparency rules**
- Public module
- CTIS Sponsor support
- CTR Application and transition period
- Next steps



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 October 2015
BMA/228363/2015 Endorsed

Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014"

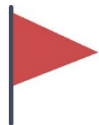
Draft reviewed with the clinical trials information system expert group	8 December 2014
Consultation with the MS for release for public consultation	9 December 2014 - 13 January 2015
Consultation with the European Commission for release for public consultation	9 December 2014 - 13 January 2015
Public consultation	21 January - 18 February 2015
Consultation of the final document by the European Commission	7 September 2015
Consultation of the final document by the Member States	7 September 2015
Endorsement by European Medicines Agency Management Board	2 October 2015
Sign off by the Deputy Executive Director	5 October 2015

- Article 81(4) of Regulation (EU) No. 536/2014: EU database publically accessible by default, with exceptions 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
- Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014"- General principles
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/10/WC500195084.pdf



- The same rules apply whether the sponsor is a pharmaceutical company, academic research group or other type of organisation;
- Only applications on which a decision has been reached will be made public;
- Public registration of trials at their start including all information needed for patients who may wish to participate in therapeutic or preventive trials;
- All data and documents in the system will be made public except for manufacturing/quality information, details of financial agreements between sponsors and investigators, and specified personal data;
- The default is always to make public at the first opportunity;
- The rules depend on the IMPs used in a trial and how they are used;
- Depending on the category of trial Sponsors have options to defer the timing of publication of specific data/documents up to a maximum time limit (see background slides as reference);
- The use of deferrals will be monitored and should not exceed what is really needed.

- 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



- CTR and CTIS Benefits
- CTIS high-level system overview and actors
- User Management
- Sponsor Workspace functionalities
- Transparency rules
- **Public module**
- CTIS Sponsor support
- CTR Application and transition period
- Next steps

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

[🏠 Search Clinical Trials](#)

Clinical trial search

Search criteria

Search results

Display options

Basic Criteria

Contain all of these terms:

Contain any of these terms:

Does not contain any of these terms:

Basic search - Free text fields; key words

Public Module – 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

Trial status	--Select Multiple--	Country	--Select Multiple--
Trial number		Age group	--Select Multiple--
Trial title		Therapeutic area	--Select Multiple--
Conditions		Trial phase	--Select Multiple--
Sponsor/co-sponsor		Sponsor type	--Select Multiple--
End point			
Product		Gender	--Select Multiple--
Product role	--Select Multiple--	Protocol code	
Population type	--Select Multiple--	Rare disease	☐
Orphan designation number		PIP	
Does this product have an orphan drug designation	☐ Yes ☐ No	Events	
EEA clinical trial start date			
From		Clinical trial results	☐
To		Clinical study report	☐
		Low intervention trial	☐
		Serious breach	☐
		Unexpected event	☐
		Urgent safety measure	☐
		Inspection	☐
EEA clinical trial end date		Trial region	--Select Multiple--
From		Vulnerable population	--Select Multiple--
To			

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

Sort by: Decision date DESC Sort

Download results Subscribe to search

☐	
☐	2021-500570-41-00 - Withdrawn - CTCS-1716_WithdrawApplicationAfterReportingAllMSCs Overall start date of the trial (in the EU): N/A Overall end date of the trial (in the EU): N/A Conditions: Medical_Condition Countries where the trial is taking place (EU country code): FR:Withdrawn, DE:Withdrawn Decision date: N/A
☐	2021-500072-28-00 - Authorised, not started - TC1030.05 EMA-4147 Conclusion Trial Statuses in Revert Decision Screen Overall start date of the trial (in the EU): N/A Overall end date of the trial (in the EU): N/A Conditions: Medical_Condition Countries where the trial is taking place (EU country code): FR:Authorised, not started, DE:Not authorised, GR:Authorised, not started Decision date: FR:16/07/2021

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

[🏠 Search Clinical Trials](#)

Clinical trial search

Search criteria

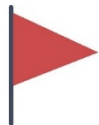
Search results

Display options

Available Search Display Options

- | | | |
|---|---|---|
| ☒ Title of the clinical trial | ☐ Sponsor/Co-Sponsors | ☐ Primary end point |
| ☒ Trial number | ☐ Sponsor type | ☐ Results first received |
| ☒ Overall trial status | ☐ Trial phase | ☐ Last updated |
| ☒ Countries where the trial is taking place (EU country code) | ☐ End point | |
| ☒ Overall start date of the trial (in the EU) | ☐ Product | |
| ☒ Overall end date of the trial (in the EU) | ☐ Age group | |
| ☒ Decision date | ☐ Gender | |
| ☒ Conditions | ☐ Trial region | |
| ☐ Therapeutic area | ☐ Total number enrolled | |
| ☐ Recruitment status | ☐ Overall end of the trial | |

Submit



- CTR and CTIS Benefits
- CTIS high-level system overview and actors
- User Management
- Sponsor Workspace functionalities
- Transparency rules
- Public module
- **CTIS Sponsor support**
- CTR Application and transition period
- Next steps



Engagement

[Info events](#) (recorded & published)

Collaborative approach



Online Training

[Extensive online programme available](#)

Sponsor Master Trainer programme



Online Support

[EMA CTIS Sponsor Handbook](#)

[Supportive materials and references](#)



Research community/SME

[Targeted SME/academia trainings](#)



EMA CTIS info

[EMA CTIS Highlights Newsletters](#)

(subscribe by writing to CT.Communication@ema.europa.eu)



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



*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

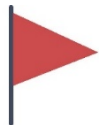
Target audience

SME/academia sponsors & end users

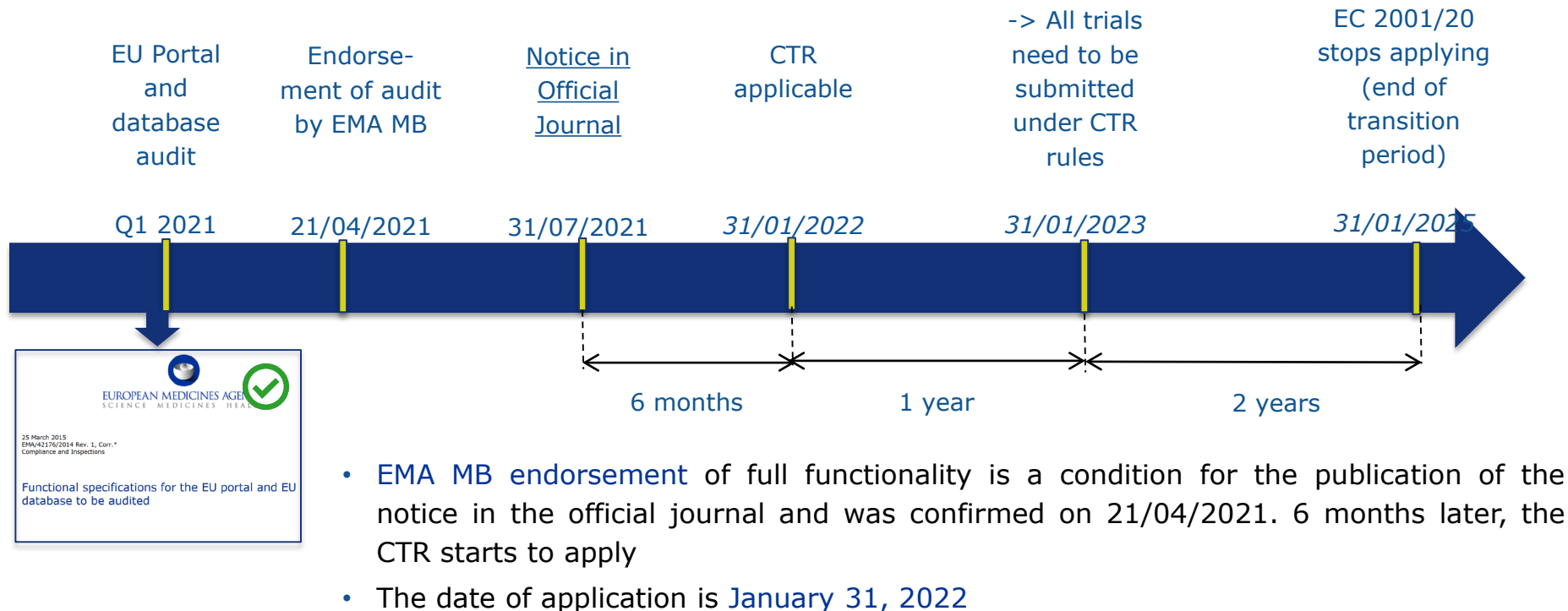
Objectives

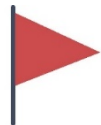
- Ensure **awareness of CTIS** across the end-user base
- **Prepare SME/academia users** for the new way of working with CTIS

Open event, no fee



- CTR and CTIS Benefits
- CTIS high-level system overview and actors
- User Management
- Sponsor Workspace functionalities
- Transparency rules
- Public module
- CTIS Sponsor support
- **CTR Application and transition period**
- Next steps





- CTR and CTIS Benefits
- CTIS high-level system overview and actors
- User Management
- Sponsor Workspace functionalities
- Transparency rules
- Public module
- CTIS Sponsor support
- CTR Application and transition period
- **Next steps**

Clinical Trials Information System - CTIS



- *Focus:*
 - *Ensure quality and stability of CTIS*
 - *Deliver CTIS for go-live*
 - *Put effort now into preparing for CTIS Go Live*
- *Get ready:*
 - *Define functions and processes embedding CTIS*
 - *Nominate the Administrator (if applicable)*
 - *Define the form of your organisations*
 - *Choose the people to work with CTIS, train the people implement the processes*
- *Countdown has started:*
 - **Go Live 31 January 2022**



Thank you for your attention

Further information

Ana.Rodriguez@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

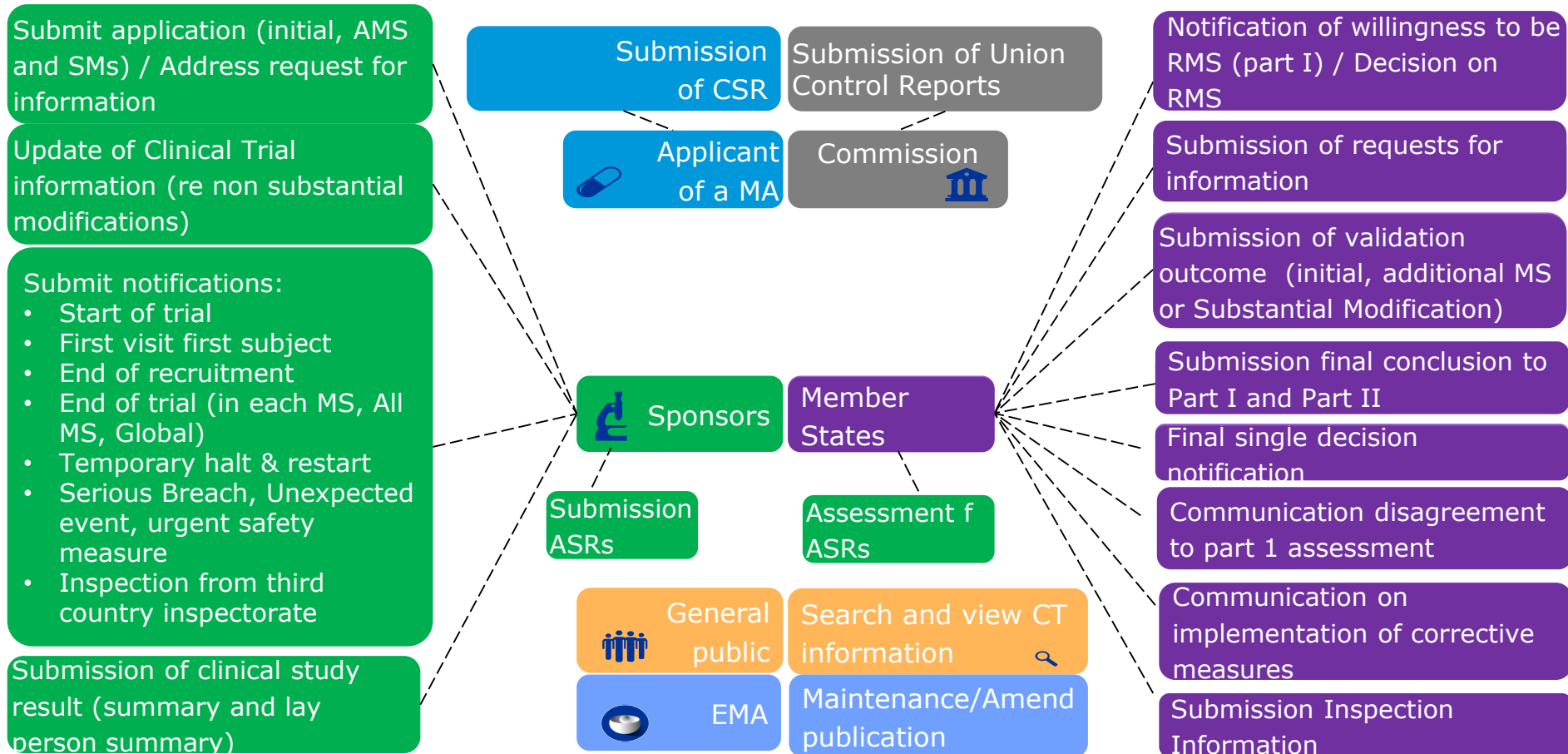
Telephone +31 (0)88 781 6000

Send us a question Go to www.ema.europa.eu/contact

Follow us on  **@EMA_News**

CTIS- Actors and activities in the CTIS system

EUROPEAN MEDICINES AGENCY



**OPTIONS FOR DEFERRALS**

		CATEGORY 1	CATEGORY 2	CATEGORY 3
Main Characteristics of the trial		For a subset of information and up to the time the CT Results Summary is posted (Justification)	No deferral	No deferral
Trial related documents	Subject Information sheet	Up to the time of MA using this trial or up to 7 years after the end of the trial, whichever is earlier	Up to the time of MA using this trial or up to 5 years after the end of the trial, whichever is earlier	No deferral
	Protocol	As above	As above	Up to the time the CT Results Summary is posted (usually 12 months after the end of the trial in the EU)
Product related Documents	IB	As above	As above	As above
	IMPd, S&E	As above	As above	As above
Assessors documents /data	Request for information	MS decides but takes into account the exceptions of the legislation and the deferral time proposed by the sponsor		No deferral
	AR (I & II)			
	Conditions			

OPTIONS FOR DEFERRALS

		CATEGORY 1	CATEGORY 2	CATEGORY 3
Substantial modifications		Deferral possible only for changes or additions to data/documents not yet made public because of the legal deadline is not reached or a deferral was requested. Publication will take place when the legal deadline is reached or deferral deadline expires.		
Notifications	Unexpected events, urgent safety measures	Up to the time when summary results are posted - except for early terminations for reasons involving subject safety or if Corrective measures (Justification)	No deferral	No deferral
Clinical Trials Summary Results	Scientific Summary	Up to 18 months after the due date for the publication of the summary of results (usually 12 months after the end of the trial unless article 37(4) applies/or 6 months for paediatric CTs according to the Paediatric Regulation) (Justification)	No deferral	No deferral
	Lay person	As above	No deferral	No deferral
Clinical Study Report		No deferral	No deferral	No deferral

OPTIONS FOR DEFERRALS

		CATEGORY 1	CATEGORY 2	CATEGORY 3
Supervisory measures	Serious Breaches	If the sponsor requested a deferral up to the time of publication of summary results the same will apply here.	No deferral	No deferral
	Inspections Reports (EU)	As above		
	Inspections Reports (by third country CA)	As above		
	Union Controls	As above		
	Corrective Measures	No deferral		