EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Functioning of the EU portal and the database

7th Nordic Conference on clinical trials- 18th November

Presented by:
Ana Rodriguez, Head Clinical and Non-clinical Compliance

Contents

- Implementation of the CT Regulation: EMA role
- New Delivery Model
- Clinical Trials Information System
  - Actors
  - Business context view
  - User Management hierarchy
  - Sponsor Workspace
  - MS Workspace
- Training of the CTIS User Community
- Summary and status- highlights

Implementation of the CT Regulation EU 537/2014: EMA Role

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CTIS SYSTEM

EU PORTAL AND DATABASE

(Art. 80, 81, 82 and 84)

- **Single EU entry point** for clinical trial applications (**e-dossier**)
- Enables **supervision at EU level**, including inspections
- Provides **workspace collaboration** tools, capabilities for **coordinated assessment** between Member State Concerned
- One single decision per Member State Concerned
- Provides **publicly available** information

SAFETY REPORTING

(Art. 40 to 44)

- **Upgrade of EudraVigilance** clinical trial module for the electronic **reporting of SUSARs**
- Delivers an Annual safety reports (ASRs) repository

EUDRACT LEGACY

(Art. 98)

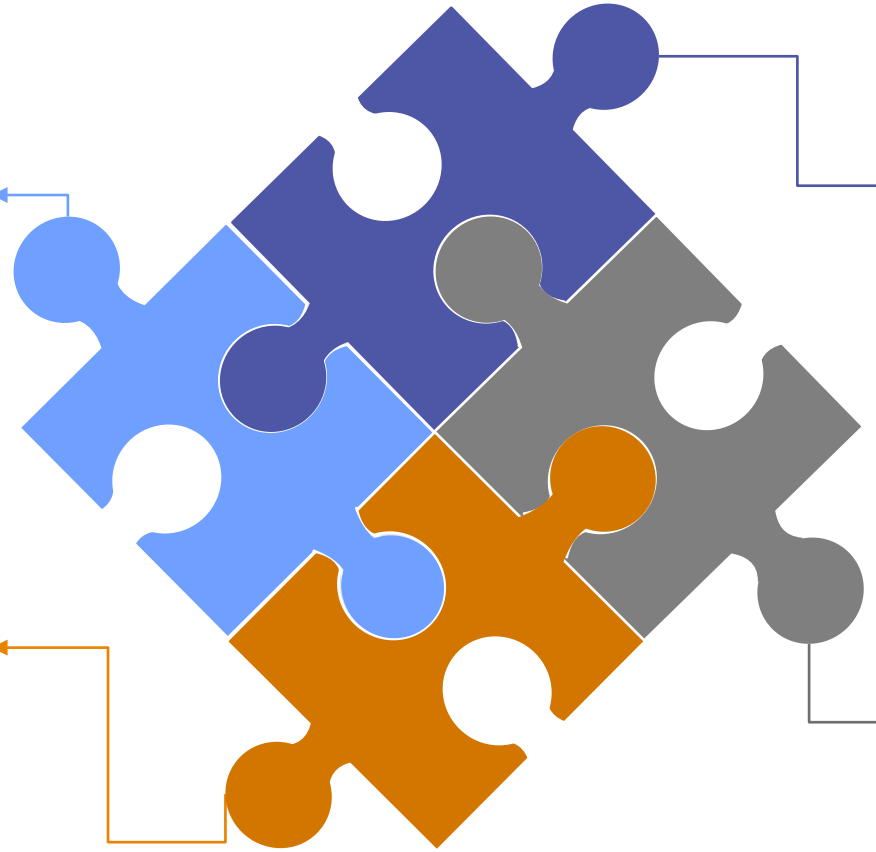
- Delivers **transition** between the current and new systems

Collaborative working

The EMA is working collaboratively

EUROPEAN COMMISSION

EUROPEAN MEDICINES AGENCY



MEMBER STATES & ETHICS COMMITEES

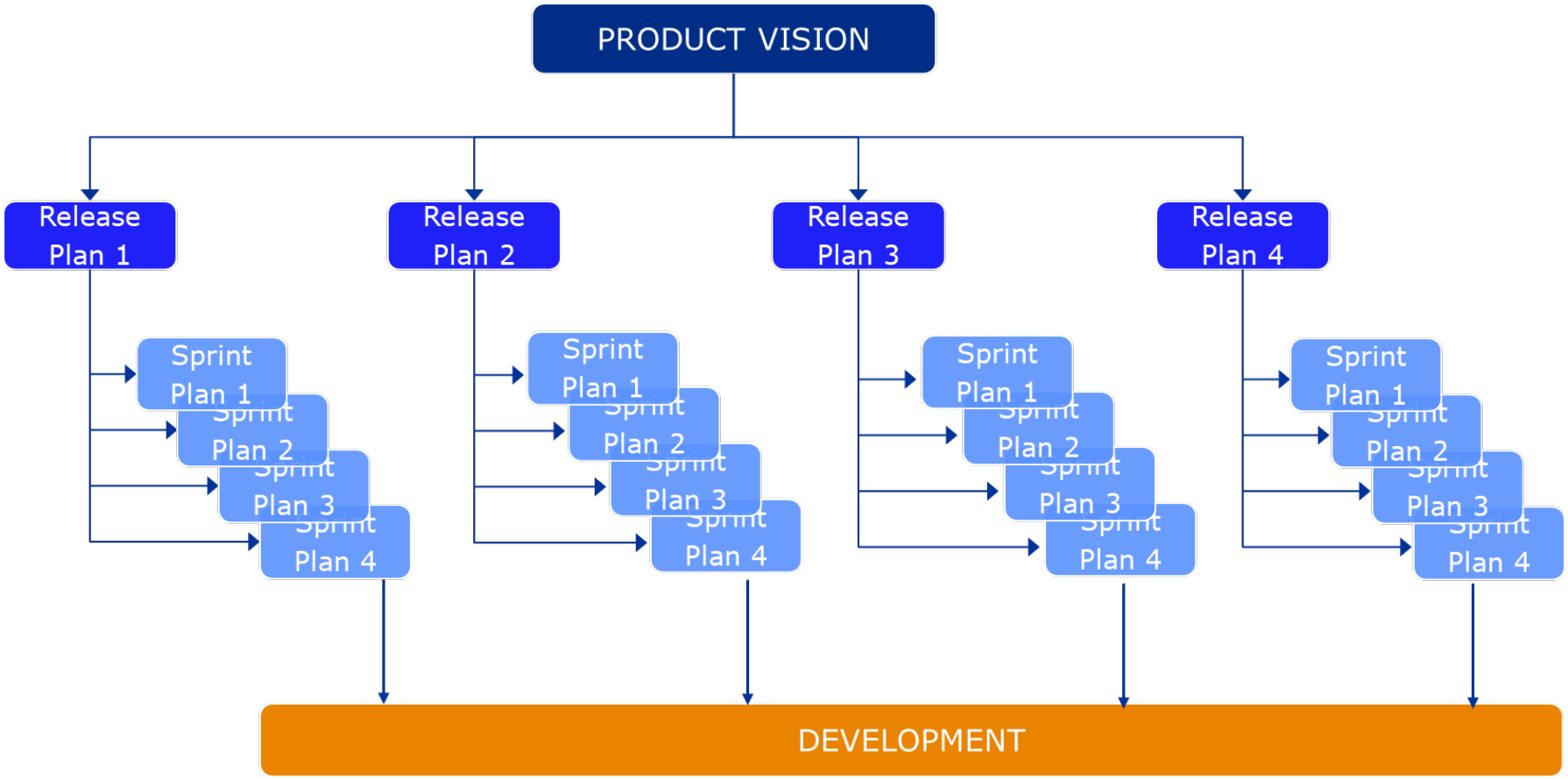
STAKEHOLDERS

- Sponsors
- CROs
- Health Care Professionals
- Patient Representatives

systems developed to implement the regulation

New Delivery Model – Approach

The new delivery model takes a top-down approach for the definition, planning and development of the requirements.



Decision making level

The **Product Vision** is the document setting-up the key objectives for the following release planning cycle *(yearly)*

Strategic

The **Release Plan** describes the specific goals of each release, the functionalities to be addressed and the KPIs *(quarterly)*

Tactic

The **Sprint Plan** gathers the relevant requirements from the backlog and organises them in different Sprints *(regularly)*

Operational

JIRA *will be used as the tool for documenting all phases of the delivery model*

New Delivery Model- Product Vision Milestones

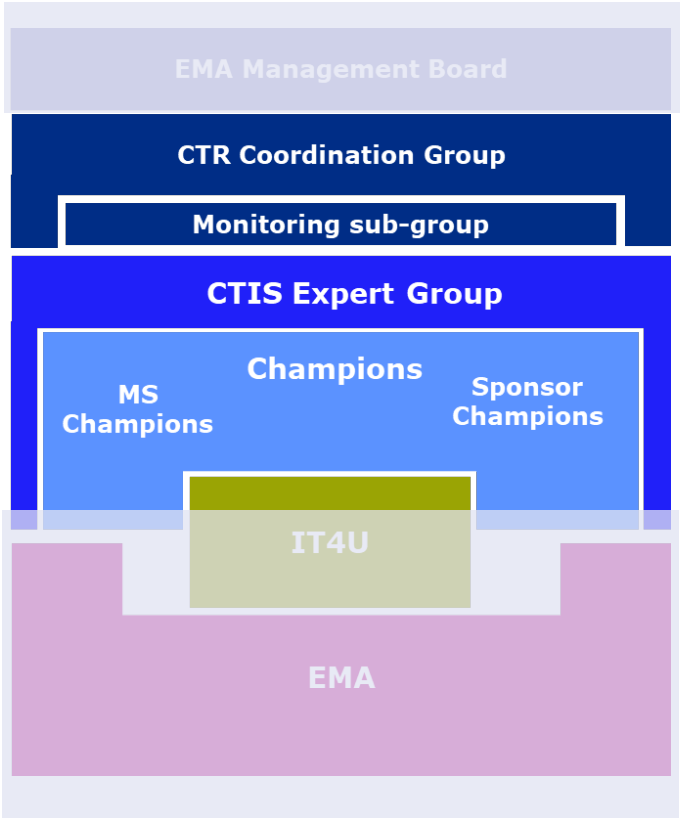
Sets the direction for CTIS system and its delivery over time focusing on the milestones:

Milestone	Scope
Milestone 1: Audit	Good enough state Fit to provide the defined functionality (functional specifications/CT Regulation) Support day to day oversight Support access by the general public (disclosure rules)
Milestone 2: Go-Live	Fully combine the safety reporting module & EU portal/EU database components Deliver enhanced functionalities for sponsors and MS focusing on oversight, cooperation and MS supervision
Milestone 3: After Go-Live	Deliver enhanced features to the public register of clinical trials Improve MS cooperation Improve interoperability (API, integration with SPOR)

Provides confidence in the development of features allocated to future releases beyond the audit or Go-Live.

New Delivery Model- CTIS Governance

*Business users will participate along **three levels of decision-making**:* Strategic, Tactical and Operational



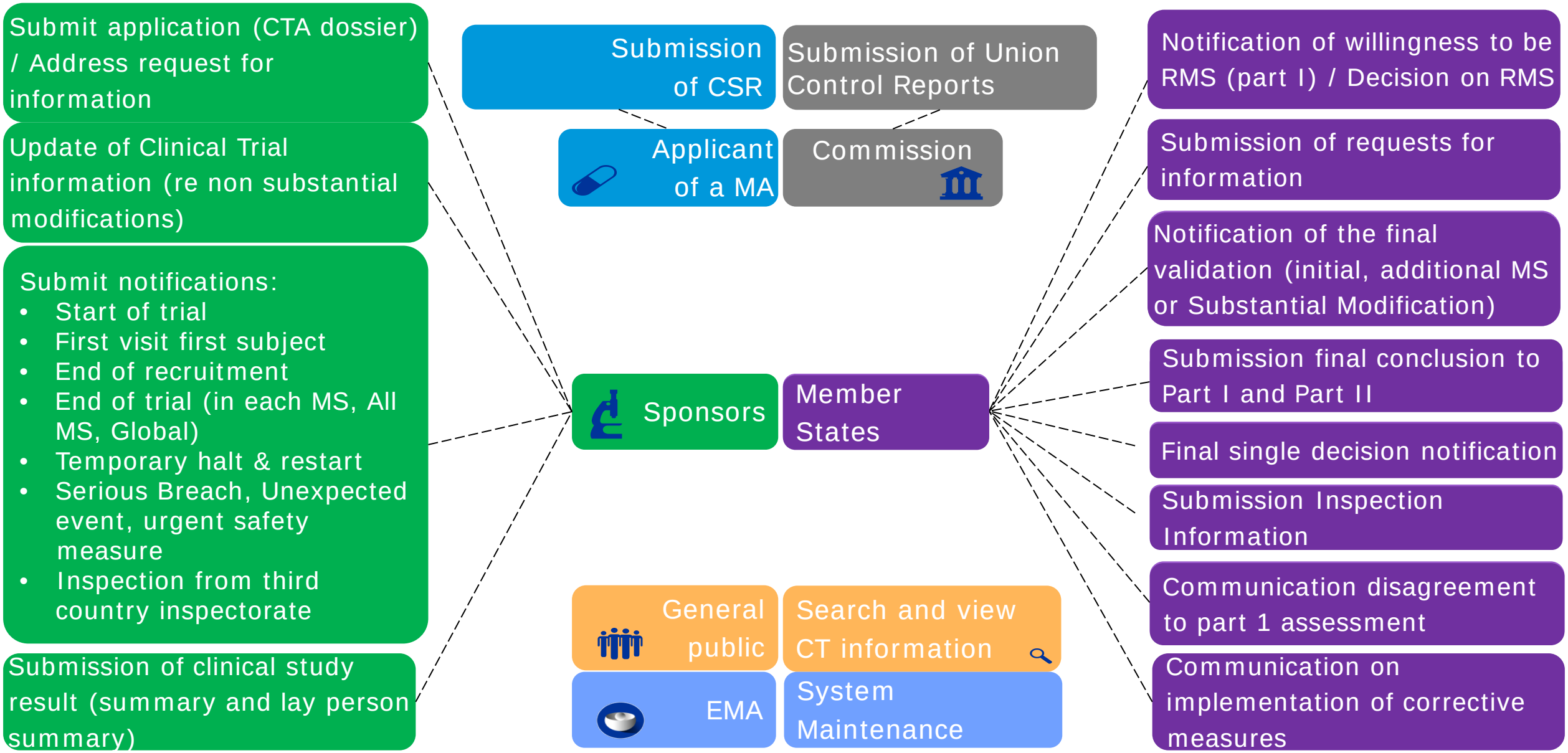
Decision-making level	Purpose	Frequency
Strategic	Define the **Product Vision**	Annual meeting
	Validate the **Release Plan**	Quarterly meeting
Tactical	Plan & scope the **releases (Release Plan)**	Quarterly meeting
Operational	**Prioritise, clarify** and **validate** requirements and development outputs	Very regular interactions

Top-down approach

Product Owners

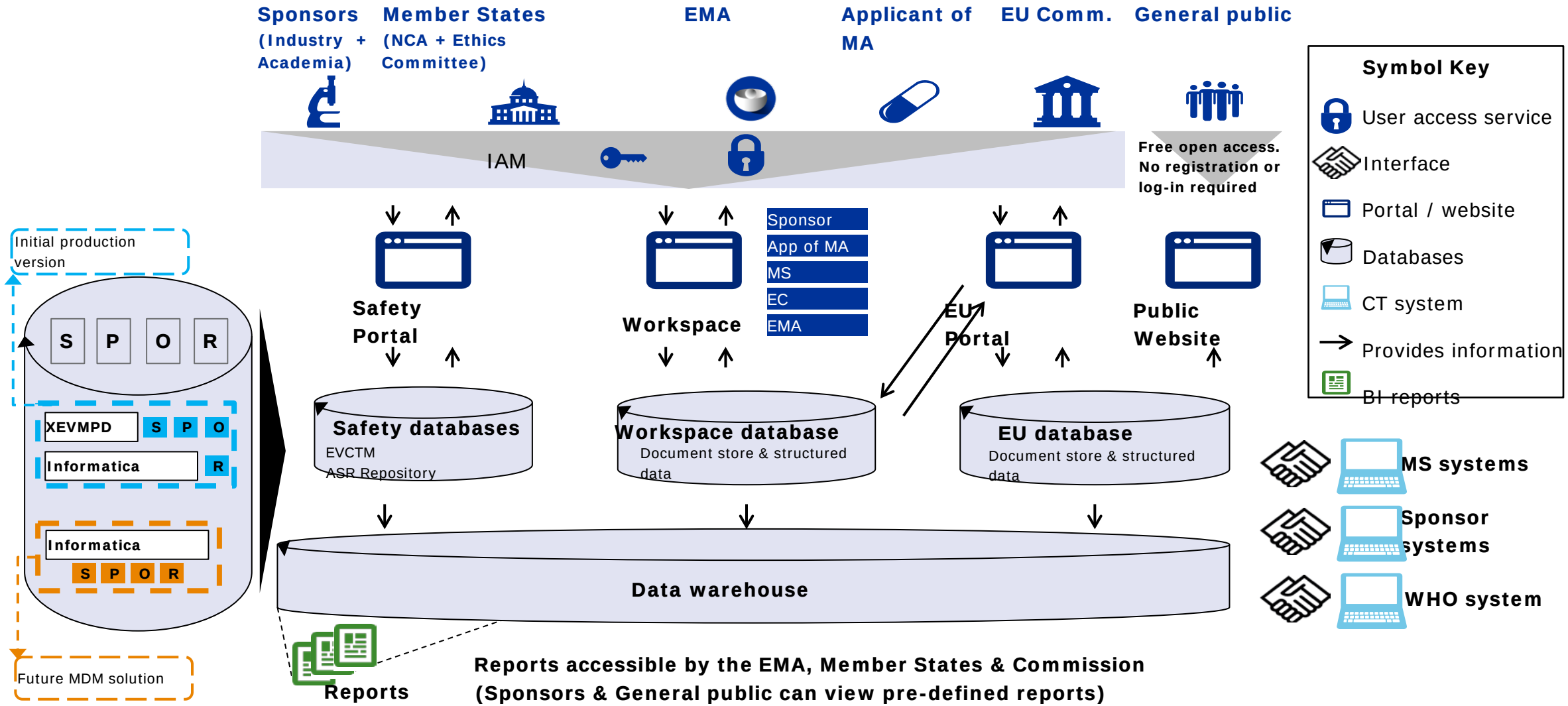
The Product Owners are business users highly involved in all phases of the Delivery Model. They provide **direct input** regarding existing and expected CTIS functionality, consolidating the Expert Group' opinions. They are the **main source for business requirements** and participate in all business validation sessions.

CTIS- Actors and activities in the system



CTIS– business context view

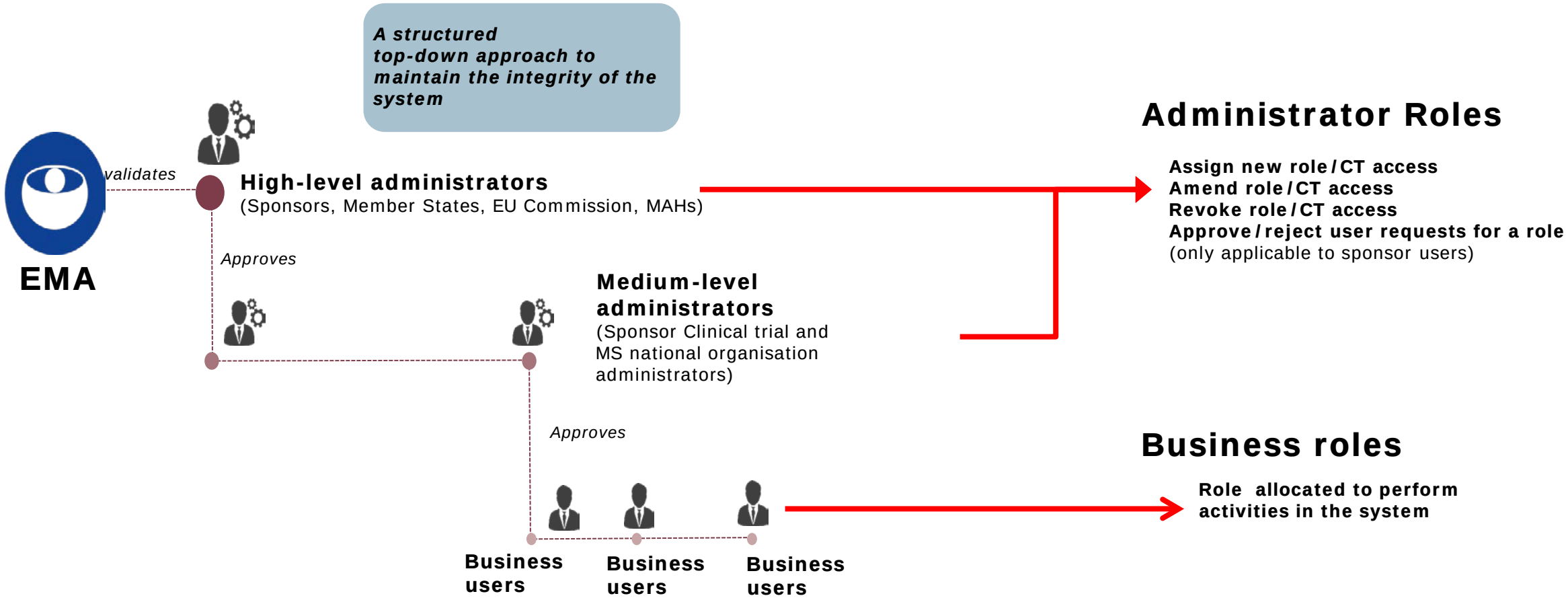
This diagram depicts the To-Be system architecture for the clinical trial systems:



9

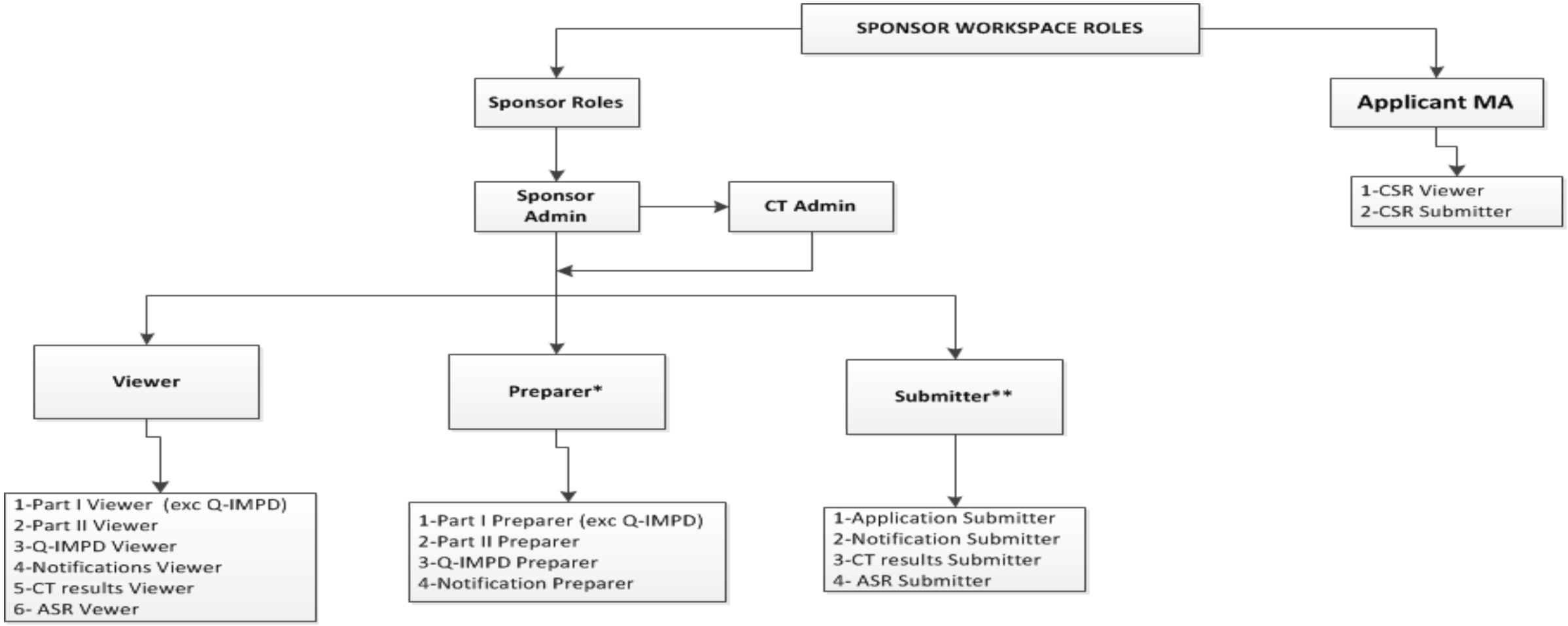
CTIS - User management hierarchy

- All users must self-registered in the EMA IAM (Identity and Access Management) system before they can access the EU Portal & EU Database.
- EMA will validate high level user administrators nominated by the sponsor (sponsor administrator), MS (MS administrator), European Commission (EC administrator) and applicant of a Marketing Authorization (MAH administrator)



CTIS- SPONSOR WORKSPACE

CTIS - sponsor workspace roles



* Preparers are also viewers

** Submitters are also preparer and viewers

CTIS – Sponsor workspace

CTIS- Sponsor Workspace Features

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Sponsors Workspace

Confidential work area where Sponsors can prepare and compile data and information to submit via the EU portal to the EU database as well as access already submitted data for their Trials.

My CTs Overview & Search

- Search for trials I have access to
- Trials current status overview
- Access CT Application Dossier
- Submit new Applications

My Requests for Information

- See formal or informal requests for information from Member States and respond
- See deadlines for responses
- Prepare responses to RFI

My Notices & Alerts

- See all alerts and notices for all my trials
- Get reminders for important deadlines

CT Application Dossier

- View detailed application dossier (data and documents)
- Manage my Trial (Complete application dossier for new / updated trial ,issue Notifications etc)
- Download data and documents

User Management

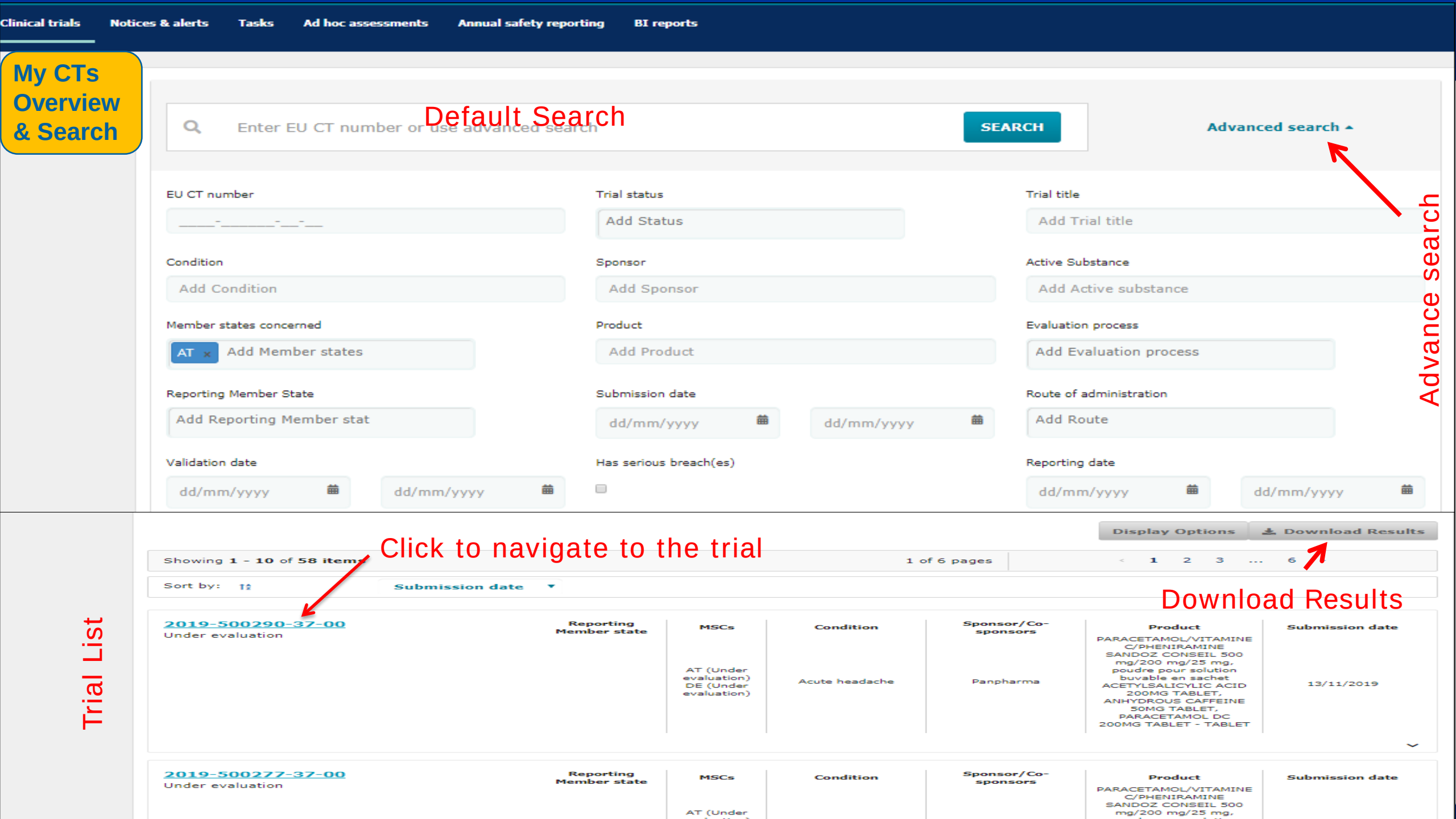
- Invite users to access trials
- Assign roles to users for trials
- 2 different approaches: Organisation Centric vs CT centric

Annual Safety Reporting (ASR)

- Create and submit ASR
- Reply to RFI

Sponsors Interface

- Imports CT Applications, Notifications and Trial Results to the Sponsor Workspace


Clinical trials
Notices & alerts
Tasks
Ad hoc assessments
Annual safety reporting
BI reports
My CTs Overview & Search
Default Search
Enter EU CT number or use advanced search
SEARCH
Advanced search
Advance search
EU CT number
Trial status
Add Status
Trial title
Add Trial title
Condition
Add Condition
Sponsor
Add Sponsor
Active Substance
Add Active substance
Member states concerned
AT
Add Member states
Product
Add Product
Evaluation process
Add Evaluation process
Reporting Member State
Add Reporting Member stat
Submission date
dd/mm/yyyy
Route of administration
Add Route
Validation date
Has serious breach(es)
Reporting date
Trial List
Click to navigate to the trial
Display Options
Download Results
Showing 1 - 10 of 58 items
1 of 6 pages
1 2 3 ... 6
Sort by:
Submission date
2019-500290-37-00
Under evaluation
Reporting Member state
MSCs
AT (Under evaluation)
DE (Under evaluation)
Condition
Acute headache
Sponsor/Co-sponsors
Panpharma
Product
PARACETAMOL/VITAMINE C/PHENIRAMINE SANDOZ CONSEIL 500 mg/200 mg/25 mg, poudre pour solution buvable en sachet
ACETYLSALICYLIC ACID 200MG TABLET, ANHYDROUS CAFFEINE 50MG TABLET, PARACETAMOL DC 200MG TABLET - TABLET
Submission date
13/11/2019
2019-500277-37-00
Under evaluation
Reporting Member state
MSCs
Condition
Sponsor/Co-sponsors
Product
PARACETAMOL/VITAMINE C/PHENIRAMINE SANDOZ CONSEIL 500 mg/200 mg/25 mg,
Submission date

CT Application Dossier

Group B–Mono 01– CMS AT– 14-Oct- An Open Phase III Trial of MK-3475 (Pembrolizumab) ATMP in Head and...

Pending 2019-500291-28-00 **Proposed RMS:** Austria

+ Create

Summary | Full Trial Information | Notifications | Trial results | Corrective measures | Users | Amend

TRIAL INFORMATION

Sponsor	[redacted]	**Member states concerned**	AT · BE
Trial phase	Therapeutic confirmatory (Phase III)	**Medical conditions**	Head and neck cancer
Therapeutic area	Diseases [C] - Cancer [C04]	**Low intervention study**	No
Medical device	No	**Population type**	Vulnerable populations (Women using contraceptives)

IMP

Expand all

▼ KEYTRUDA 25 mg/mL concentrate for solution for infusion

TRIAL STATUS

Member State	Trial status	First decision date	Start of trial	End of trial	Recruitment start date
AT	Pending				
BE	Pending				

APPLICATIONS

Click to navigate to the Application

Type	ID	Parts	MSCs	Submission date	Decision date
Initial	IN	Part I	AT (Draft)		

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 I

Check | Save | Cancel | Submit

Form
MSCs
Part I
Part II
Evaluation
Timetable

Trial specific information (Part I)

Trial details — Trial information

- 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: Pierre Fabre Iberica S.A.

Address: Edificio Marina Village, Calle Ramon Trias Fargas 7-11

Address line 1*: Edificio Marina Village

Address line 2: Calle Ramon Trias Fargas 7-11

Address line 3

Address line 4

Post code

https://euctis-audit.ema.europa.eu/ct-sponsor-services/

MSCs
Part I
Part II
Evaluation
Timetable

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	Sponsc substa code
PRD4323786	EU/1/15/1024/002	AUTHORISED	Keytruda 25 mg/ml concentrate for solution for infusion	Solution for infusion	25 mg/ml	MK-3475	Pembrolizumab	SUB167136	-	L01XC18	5	

Documents — Documents

Part 1

Protocol version 2 vs 1_Track changes
Version 1 · 18/10/2019 · English · Protocol
Comment: In response to RFI

Protocol version 2
Version 2 · 18/10/2019 · English · Protocol
Comment: In response to RFI

20191014-MONO1_Cover_Redacted
Version 1 · 14/10/2019 · English · Redacted Cover Letter

Protocol version 1
Version 1 · 14/10/2019 · English · Protocol

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 | Subm

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

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

Form

Check | Save | Cancel

Form
MSCs
Part I
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Timetable

Transparency Rules re deferrals https://www.ema.europa.eu/en/documents/other/appendix-disclosure-rules-functional-specifications-eu-portal-eu-database-be-

Form details

Initial Application details

Cover letter

Deferral publication dates

Deferral request section

Deferral of clinical trial information

The trial does not include paediatric subjects. If the trial is changed to be listed in a PIP or to include paediatric subjects, then Main Characteristics, Notifications and Summary of Results associated with this trial will be published at the date of decisi on the trial.

Short title / Trial category *

Category 3

Justification for trial category / Trial category *

TrialCategory Justification

Data/Document type	Publication date
Protocol	Date of decision / Publication of final summary of results
IMPD SandE sections and Investigator Brochure	Date of decision / Publication of final summary of results

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

Form
MSCs
Part I
Part II
Evaluation
Timetable

Member states concerned

+ Add membe

Member states concerned	Reporting Member State	First submissions date	Subjects	Actions
Austria	◉		10	
Belgium	○		13	

Countries outside the European Economic Area

- Argentina
- Australia
- China
- Colombia
- Japan
- Mexico
- New Zealand

Rest of the world subjects*

10

Estimated total population for the trial

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

Evaluation (example of an authorised trial)

Form
MSCs
Part I
Part II
Evaluation
Timetable

Evaluation

Validation

Validation

RFI 0

Conclusion

Assessment Part I

Assessment Part I

RFI 1

Conclusion

Disagreements

Assessment Part II

Assessment Part II

DE

RFI 1

Conclusion

Decision

Decision

MSC decisions

MSC	Date	Decision	Part II conclusion	Tacit decision	Justification	+All
Germany	17/10/2019	Authorised	Acceptable			+

Timetable (example of a trial under evaluation)

Withdraw | Copy

Form
MSCs
Part I
Part II
Evaluation
Timetable

Timeline

Winter clock stop

- The winter clock stop 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

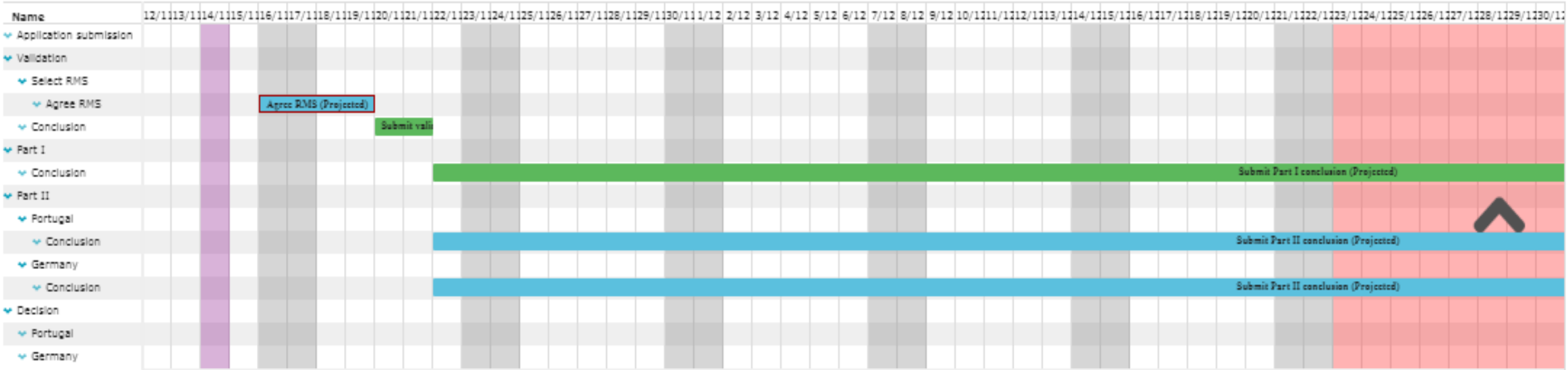
Legend
Concerns MSC
Concerns RMS
Concerns sponsor
Weekends
Winter clock stop days
Today's date

Filter

Time Filter: Daily

Including Validation Phase RFI:

Including Assessment Phase RFI:



My Notices & Alerts

Notice/Alert List

Default and advance Search

Notices & alerts 0

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

SEARCH

Advanced search

Showing **1 - 10** of **143 items** | 1 of 15 pages | ‹ 1 2 3 ... 15 ›

Sort by: Received

Notice **RMS Selected**

Germany has been selected as the RMS for the trial.

Ref number	Evaluation process	Received	IMP	RMS	Sponsor
2019-500285-30-00		14/11/2019	KEYTRUDA 25 mg/mL concentrate for solution for infusion Methotrexate Hospira 100 mg/ml injekční roztok Sterile Saline Solution (0.9%) Methotrexate Hospira 25 mg/ml injekční roztok	Germany	Pierre Fabre Iberica S.A.

Notice **RFI sent to sponsor**

An RFI has been sent by Germany for the Initial application, Assess Part I .

Ref number	Evaluation process	Received	IMP	RMS	Sponsor
2019-500286-79-00		14/11/2019	KEYTRUDA 25 mg/mL concentrate for solution for infusion Methotrexate Hospira 25 mg/ml injekční roztok	Germany	Pierre Fabre Iberica S.A.

Alert **Response to RFI due**

There are 2 days remaining to respond to the RFI sent by Germany as part of the assess Part I process. Failure to respond in time will result in the application becoming lapsed.

Ref number	Evaluation process	Received	IMP	RMS	Sponsor
2019-500286-79-00		14/11/2019	KEYTRUDA 25 mg/mL concentrate for solution for infusion Methotrexate Hospira 25 mg/ml injekční roztok	Germany	Pierre Fabre Iberica S.A.

My Requests for Information

RFI List

Default and advance Search

RFI

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

SEARCH

Advanced search

Showing **1 - 10** of **32 items**

1 of 4 pages

‹ 1 2 3 4 ›

Sort by: No sorting

	MSC	Application type	Evaluation process	Submitted	Responded	Due
RFI-106 Pending CT-2019-500175-86-02	Germany		Corrective Measure	11/11/2019		18/11/2019
RFI-90 Pending CT-2019-500215-17-00	Belgium	Initial	Assess part II	24/10/2019		05/11/2019
RFI-79 Pending CT-2019-500215-17-00	Belgium	Initial	Assess part II	23/10/2019		04/11/2019
RFI-82 Pending CT-2019-500215-17-00	Belgium	Initial	Assess part II	23/10/2019		01/11/2019
RFI-81 Responded PT-0000000001	Portugal		Ad hoc assessment	23/10/2019	24/10/2019	09/11/2019
RFI-94 Responded CT-2019-500173-36-00	Germany	Additional MSC	Assess part II	25/10/2019	25/10/2019	06/11/2019
RFI-87	MSC	Application type	Evaluation process	Submitted	Responded	Due

Administration of users

User Management

Default and advance Search

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

unisys_i1 | uat.ct17@ext.ema.europa.eu

approved

EU CT Number:

Scope: All trials

Employer:

Organisation name:

Organisation Id: ORG-100003995

Role:	Creation date:	Assesment date:	Authorised from:	Authorised to:
Sponsor Admin	04/10/2019	04/10/2019	04/10/2019	

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

approved

EU CT Number:

Scope: All trials

Employer:

Organisation name:

Organisation Id: ORG-100003995

Role:	Creation date:	Assesment date:	Authorised from:	Authorised to:
CT Admin	11/10/2019	11/10/2019	11/10/2019	

AMEND

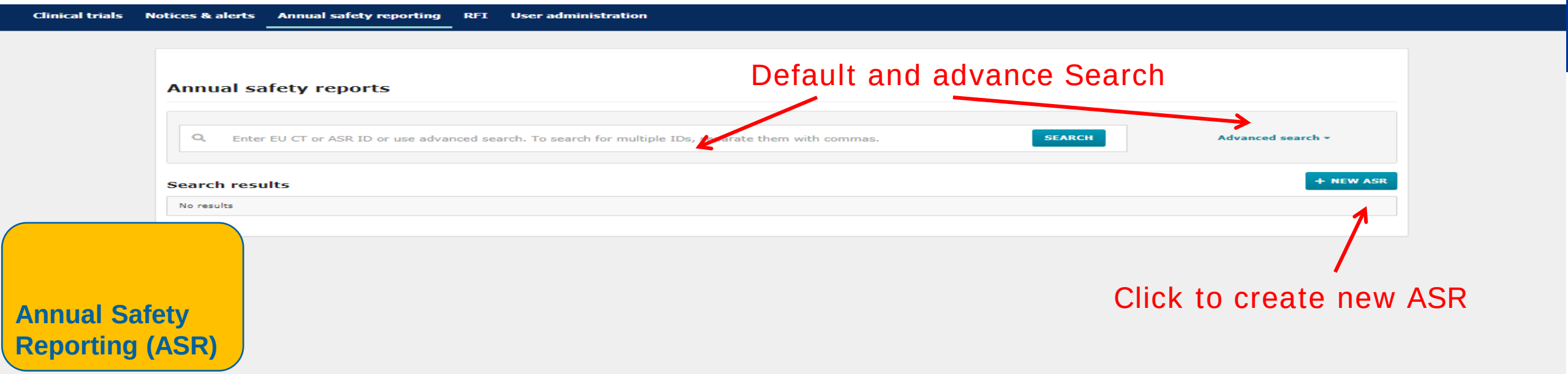
ctuat389 | uat.ct577@ext.ema.europa.eu

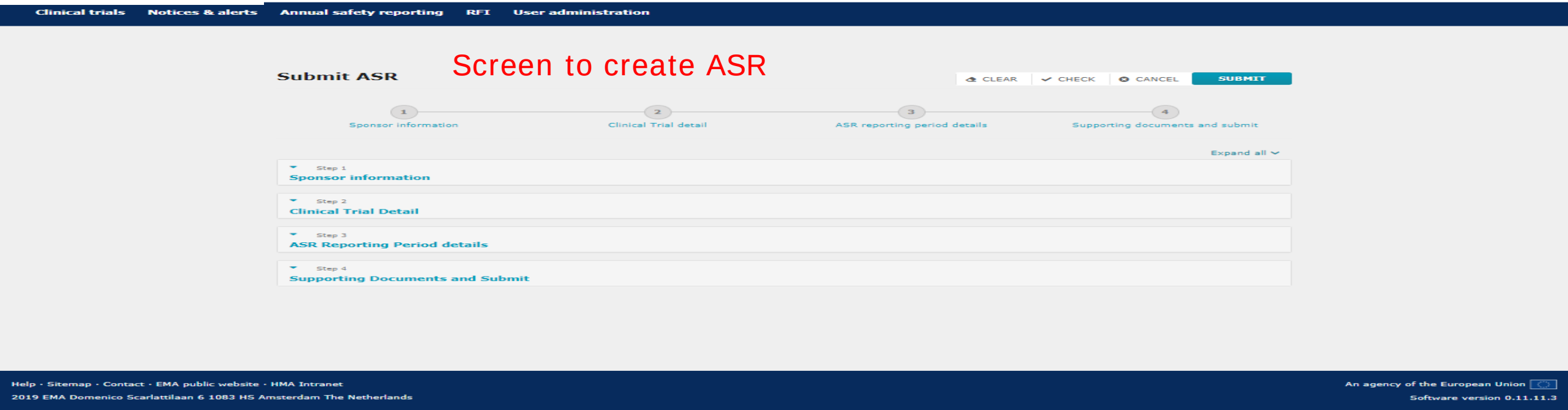
approved

EU CT Number:

Scope: All trials

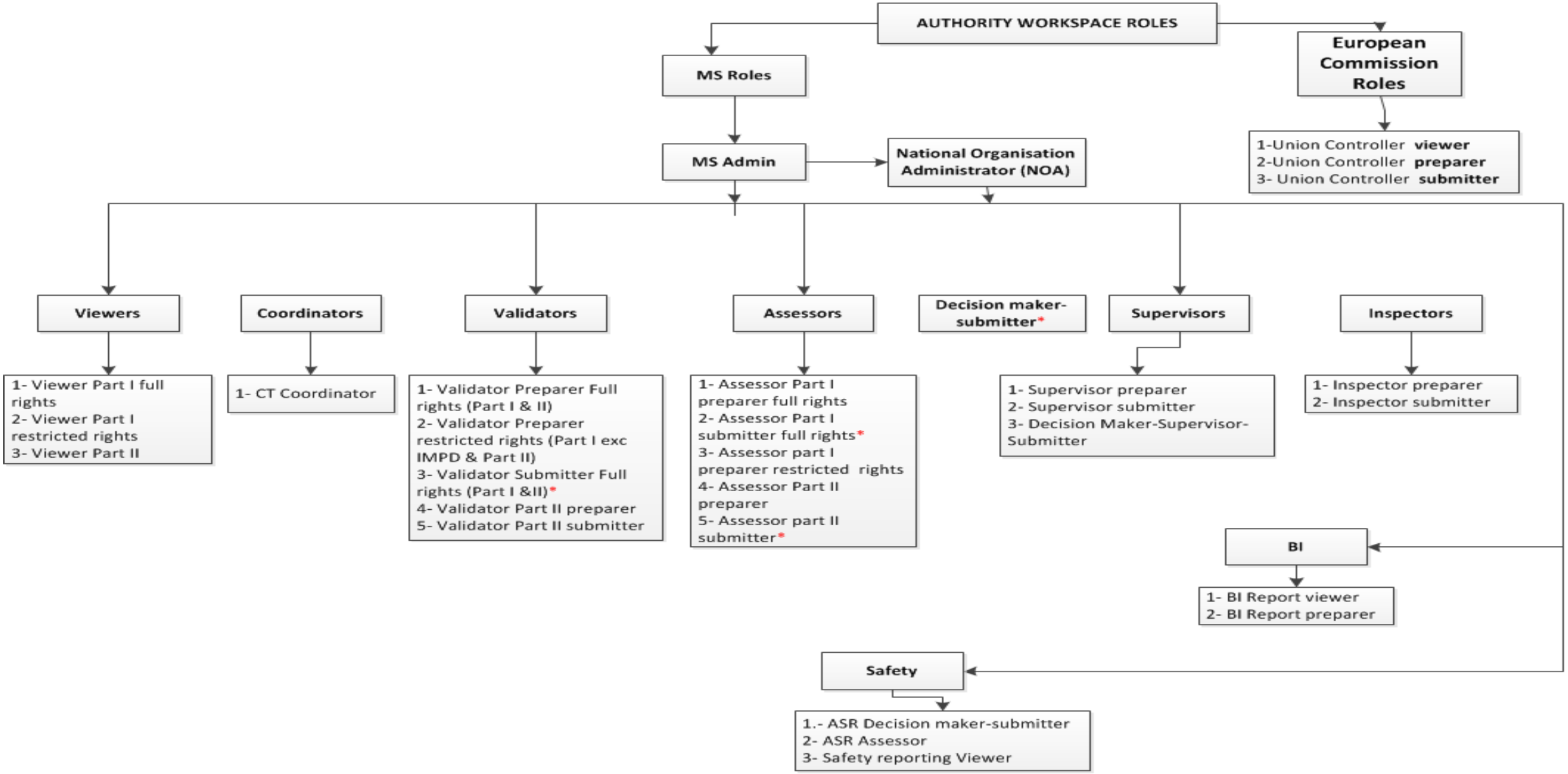
Role:	Creation date:	Assesment date:	Authorised from:	Authorised to:
Application Submitter	11/10/2019	11/10/2019	11/10/2019	


Clinical trials
Notices & alerts
Annual safety reporting
RFI
User administration
Annual safety reports
Default and advance Search
Enter EU CT or ASR ID or use advanced search. To search for multiple IDs, separate them with commas.
SEARCH
Advanced search
Search results
+ NEW ASR
No results
Annual Safety Reporting (ASR)
Click to create new ASR

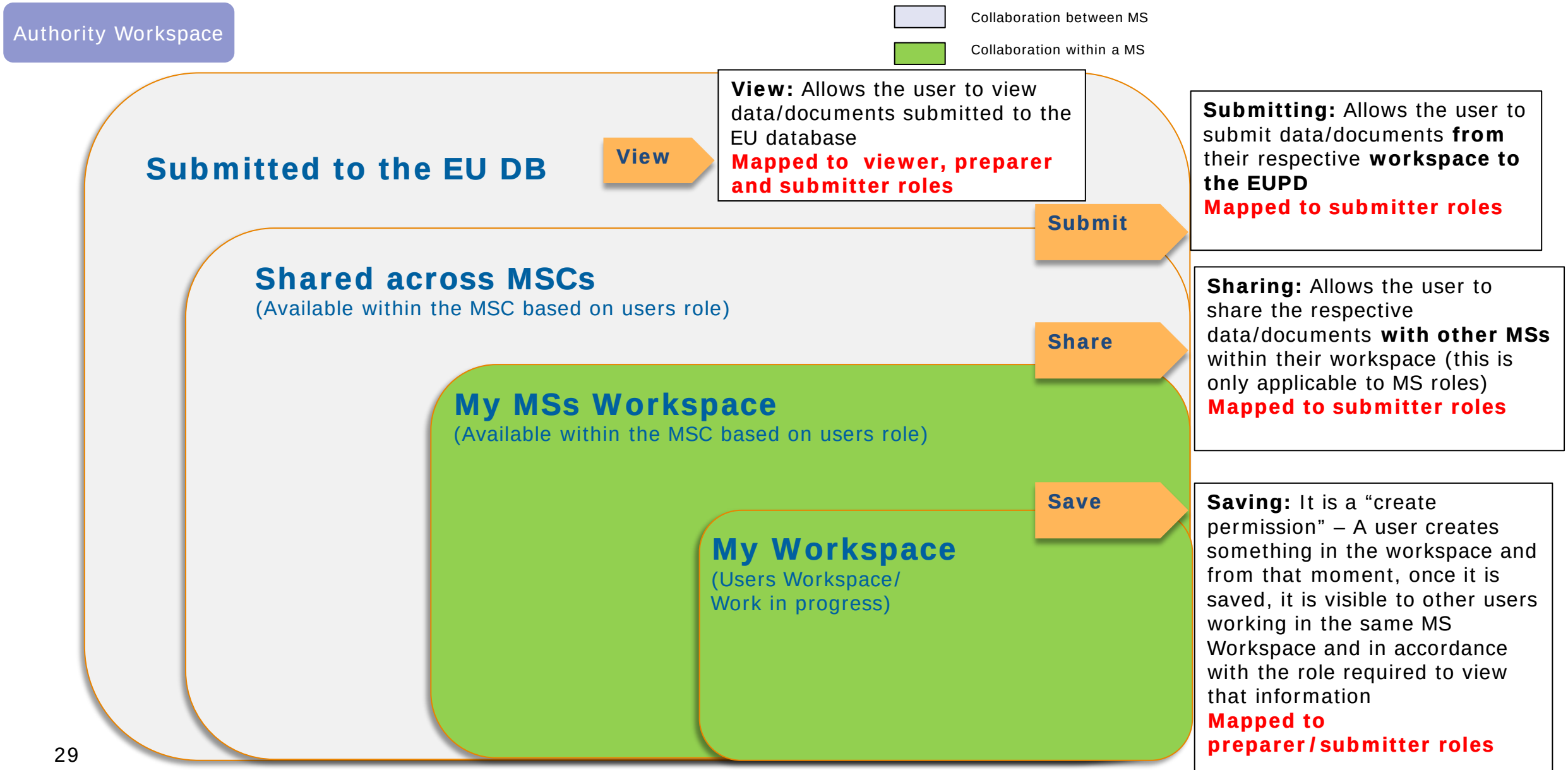

UAT CT
EN
Clinical trials
Notices & alerts
Annual safety reporting
RFI
User administration
Submit ASR
Screen to create ASR
CLEAR
CHECK
CANCEL
SUBMIT
1
Sponsor information
2
Clinical Trial detail
3
ASR reporting period details
4
Supporting documents and submit
Expand all
Step 1
Sponsor information
Step 2
Clinical Trial Detail
Step 3
ASR Reporting Period details
Step 4
Supporting Documents and Submit
Help · Sitemap · Contact · EMA public website · HMA Intranet
2019 EMA Domenico Scarlattilaan 6 1083 HS Amsterdam The Netherlands
An agency of the European Union
Software version 0.11.11.3

CTIS- AUTHORITY WORKSPACE

CTIS - Authority workspace roles



CTIS - Authority workspace- collaboration area



CTIS- Authority Workspace Features

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Authority Workspace

Supports all activities of MSs throughout the evaluation of a clinical trial application as well as the collaboration between Member States and allows Authority users to retrieve all necessary structured data and documents for Clinical Trials.

CTs Overview & Search

- Search for trials
- Access CT data and document is restricted to user role and the MSs role for the Trial (MS, MSC, RMS)

CT Application Dossier

- Trial overview including: the application dossier, medicinal product, documents, evaluation information/status, timetable, list of SUSARs, associated tasks, version history
- Option to start a MS notification (e.g. corrective measure)

My Notices & Alerts

- See all alerts and notices for all my trials
- Get reminders for important deadlines

My Tasklist

- Overview of tasks related to the evaluation phase designated for the user group (Role) or individual user with all deadlines
- Allows task management and coordination
- Task-specific forms relating to the activities of MS (e.g. select RMS, document considerations etc.)
- Seamless navigation to CT dossier

CT Supervision: Ad Hoc Assessment

- Search for ad hoc assessments
- Ad hoc assessment information and outcomes

CTIS- Authority Workspace Features

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Authority Workspace

Supports all activities of MSs throughout the evaluation of a clinical trial application as well as the collaboration between Member States and allows Authority users to retrieve all necessary structured data and documents for Clinical Trials.

Annual Safety Reporting (ASR)

- Prepare and submit ASR assessment
- Create and assess RFI

BI Reports

- Access to predefined BI reports
- Create and view ah-hoc reports

Inspections Planning/ Reports

- Overview of planned inspections for sites and CTs
- Create new inspections and clinical trials and upload inspection reports

Union Control Reports

- Submit and view union control reports

User Management

- Invite users to access trials
- Assign roles to users for trials
- Appointed MS Administrators are responsible for assigning access to national NCA and Ethics Committee administrators
- National NCA and Ethics Committee administrators are responsible for managing their user base

MSs Interface

- A REST Service interface (CRUD) is used for all entities.
- Allows to read CT structured data and documents and to submit Assessment reports

My Tasklist

Default and advance Search

Enter EU CT ID or ASR ID or use advanced search.

SEARCH

Advanced search

My group

Showing **1 - 10** of **77 items** 1 of 8 pages ‹ 1 2 3 ... 8 ›

Sort by: Due Date

Task List

Submit Part II Conclusion
Pending 2019-500267-33-00
RMS: | Application and Non-SM type: INITIAL | Sponsor/Co-sponsors: Panpharma | Evaluation process: | Due: 13/01/2020 | Remaining days: 59 | Assignee:
IMP1: ACETYLSALICYLIC ACID 200MG TABLET, ANHYDROUS CAFFEINE 50MG TABLET, PARACETAMOL DC 200MG TABLET - TABLET · ACETYLSALICYLIC ACID, ANHYDROUS CAFFEINE

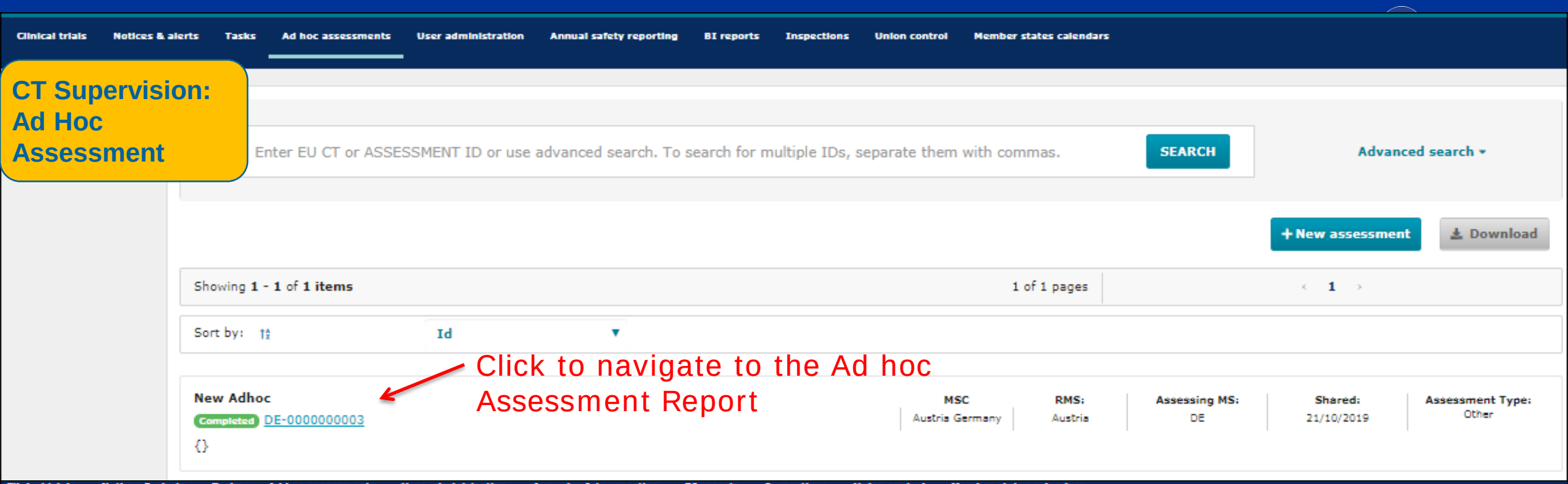
Submit Part I Conclusion
Pending 2019-500254-19-00
RMS: AUSTRIA | Application and Non-SM type: INITIAL | Sponsor/Co-sponsors: Panpharma | Evaluation process: | Due: 10/01/2020 | Remaining days: 56 | Assignee:
IMP1: ACETYLSALICYLIC ACID 200MG TABLET, ANHYDROUS CAFFEINE 50MG TABLET, PARACETAMOL DC 200MG TABLET - TABLET · ACETYLSALICYLIC ACID, ANHYDROUS CAFFEINE

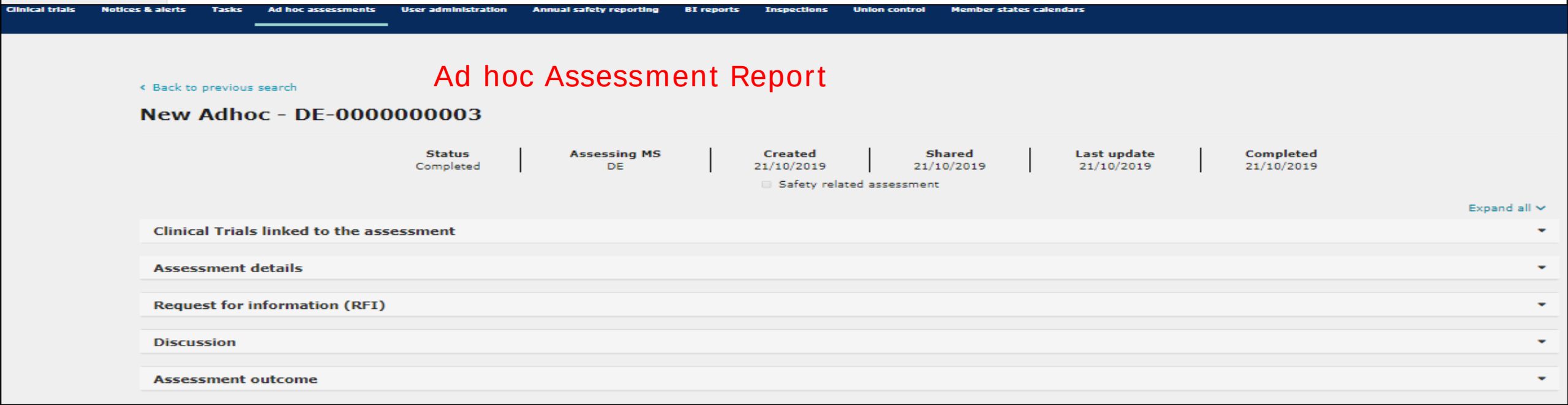
Document Considerations Assess Part I
Pending 2019-500254-19-00
RMS: AUSTRIA | Application and Non-SM type: INITIAL | Sponsor/Co-sponsors: Panpharma | Evaluation process: | Due: 08/01/2020 | Remaining days: 54 | Assignee:
IMP1: ACETYLSALICYLIC ACID 200MG TABLET, ANHYDROUS CAFFEINE 50MG TABLET, PARACETAMOL DC 200MG TABLET - TABLET · ACETYLSALICYLIC ACID, ANHYDROUS CAFFEINE

Document Considerations Assess Part I
Pending 2019-500267-33-00
RMS: AUSTRIA | Application and Non-SM type: INITIAL | Sponsor/Co-sponsors: Panpharma | Evaluation process: | Due: 08/01/2020 | Remaining days: 54 | Assignee:
IMP1: ACETYLSALICYLIC ACID 200MG TABLET, ANHYDROUS CAFFEINE 50MG TABLET, PARACETAMOL DC 200MG TABLET - TABLET · ACETYLSALICYLIC ACID, ANHYDROUS CAFFEINE

Submit Part II Conclusion
RMS: | Application and Non-SM type: | Sponsor/Co-sponsors: | Evaluation process: | Due: | Remaining days: | Assignee:

CT Supervision: Ad Hoc Assessment





Inspections Planning/ Reports

Inspections

Record ID or search using the advanced search

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Advanced search

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+ NEW INSPECTION

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Sort by: Inspection ID

	MSCs:	Site type:	Organisation name:	Organisation address:	Organisation country:	Start date:	End date:
INS|10|01 Planned **Record ID:** INS|10	Italy, Austria	Sponsor (commercial)		Via Dei Sette Santi 3	Italy	26/11/2019	28/11/2019
INS|09|01 Planned **Record ID:** INS|09	Germany, Italy	Clinical facility BE/BA		Kalendegatan 25	Sweden	01/11/2019	02/11/2019
INS|08|01 Planned **Record ID:** INS|08	Austria	Sponsor (commercial)		General-Arnold-Strasse 6	Austria	09/01/2020	18/01/2020

Clinical trials | Notices & alerts | Tasks | Ad hoc assessments | User administration | Annual safety reporting | BI reports | Inspections | Union control | Member states calendars

Union Control Reports

Plans / Programmes

ID	Type	Start date	End date	Share date	Status	Actions
UCP-2019-0002	Plan for Union Controls in Member States	19/10/2019	25/10/2019	18/10/2019	Removed	

« 1 »

1 -1 of1

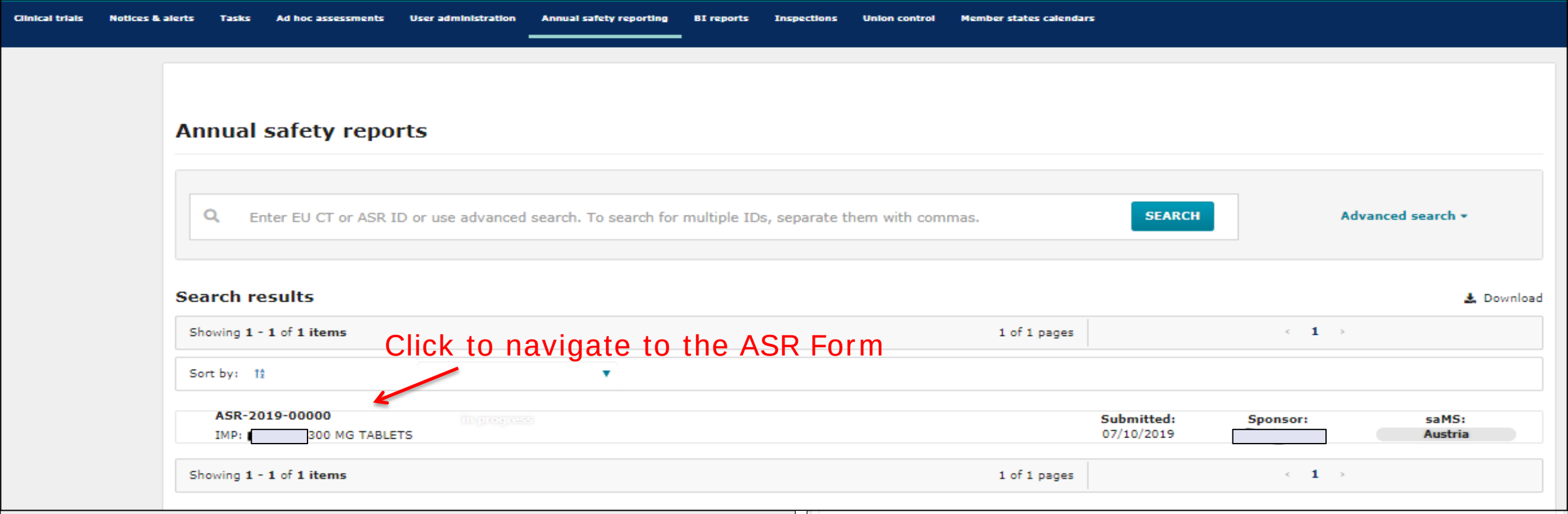
Reports

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.**

ID	EC's internal ID	Country	Start date	End date	Submission date	Status	Actions

« 1 »

1 -0 of0


Clinical trials
Notices & alerts
Tasks
Ad hoc assessments
User administration
Annual safety reporting
BI reports
Inspections
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Annual safety reports
Enter EU CT or ASR ID or use advanced search. To search for multiple IDs, separate them with commas.
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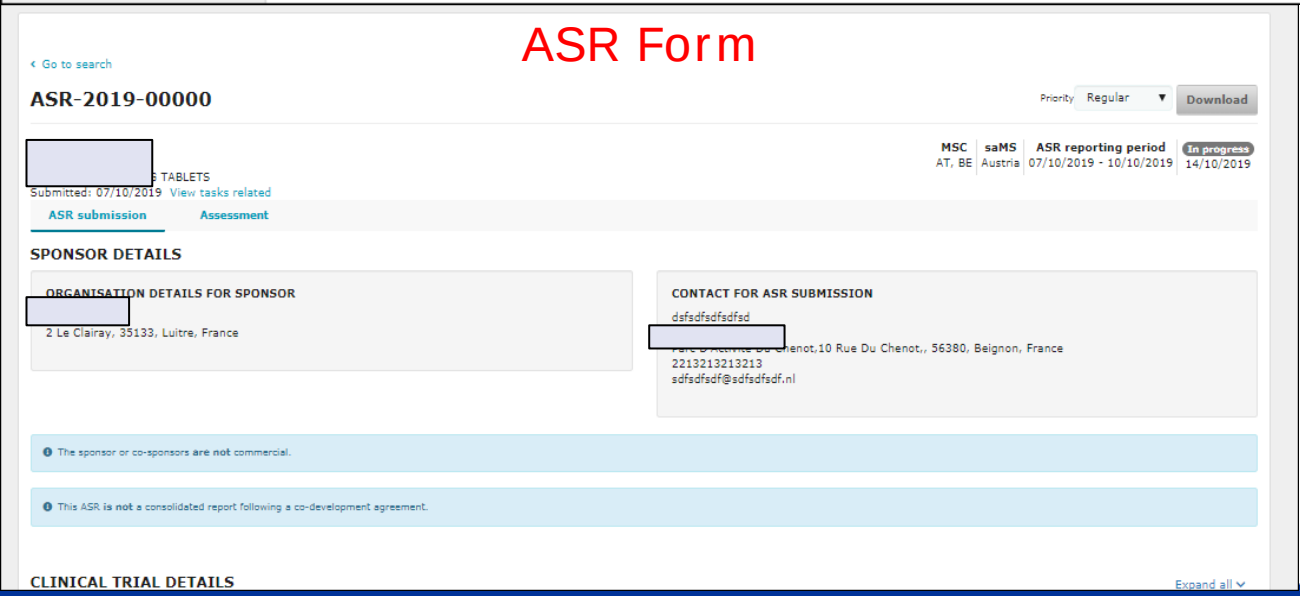
1 of 1 pages
1
Click to navigate to the ASR Form
Sort by:
ASR-2019-00000
IMP: [redacted]300 MG TABLETS
Submitted:
07/10/2019
Sponsor:
saMS:
Austria
Showing 1 - 1 of 1 items
1 of 1 pages
1


ASR Form
Go to search
ASR-2019-00000
Priority
Regular
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MSC
AT, BE
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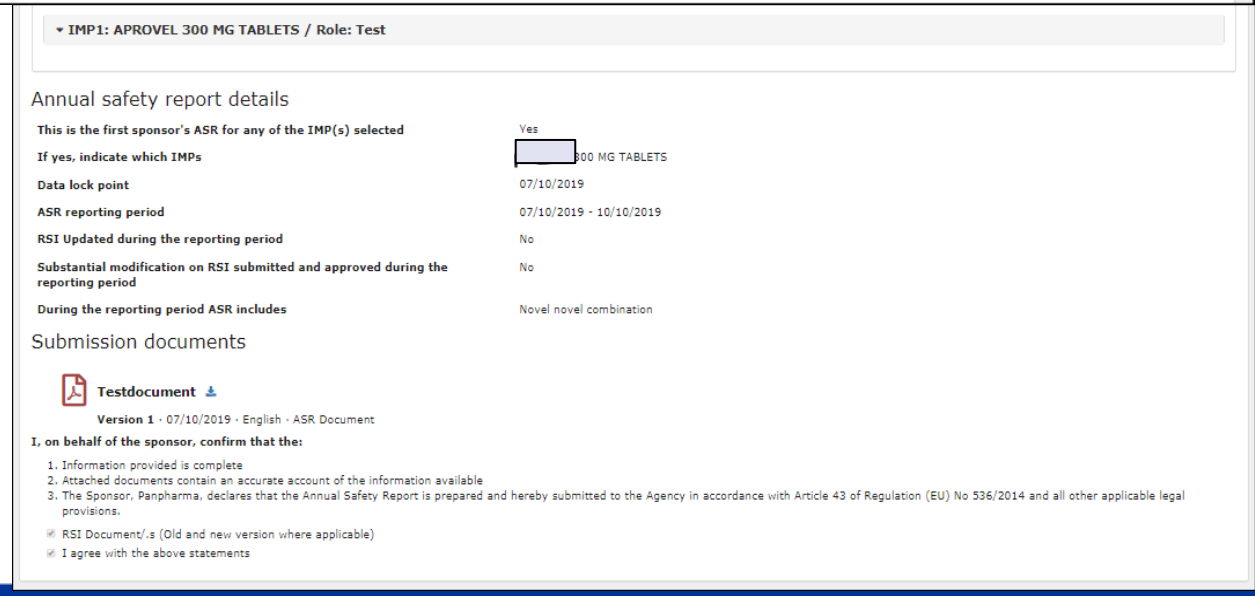
Austria
ASR reporting period
07/10/2019 - 10/10/2019
In progress
14/10/2019
[redacted] TABLETS
Submitted: 07/10/2019
View tasks related
ASR submission
Assessment
SPONSOR DETAILS
ORGANISATION DETAILS FOR SPONSOR
[redacted]
2 Le Clairay, 35133, Luitre, France
CONTACT FOR ASR SUBMISSION
dsfsdfsdfsdfsd
[redacted]
2213213213213
sdfsdfsdf@sdfsdfsdf.nl
The sponsor or co-sponsors are not commercial.
This ASR is not a consolidated report following a co-development agreement.
CLINICAL TRIAL DETAILS
Expand all


IMP1: APROVEL 300 MG TABLETS / Role: Test
Annual safety report details
This is the first sponsor's ASR for any of the IMP(s) selected
Yes
If yes, indicate which IMPs
[redacted]300 MG TABLETS
Data lock point
07/10/2019
ASR reporting period
07/10/2019 - 10/10/2019
RSI Updated during the reporting period
No
Substantial modification on RSI submitted and approved during the reporting period
No
During the reporting period ASR includes
Novel novel combination
Submission documents
Testdocument
Version 1 · 07/10/2019 · English · ASR Document
I, on behalf of the sponsor, confirm that the:
1. Information provided is complete
2. Attached documents contain an accurate account of the information available
3. The Sponsor, Panpharma, declares that the Annual Safety Report is prepared and hereby submitted to the Agency in accordance with Article 43 of Regulation (EU) No 536/2014 and all other applicable legal provisions.
RSI Document/.s (Old and new version where applicable)
I agree with the above statements

Training of the CTIS User Community- principles

- The main pathway for all users will be based on but not exclusive to online materials and events.
- A train-the-trainer approach including face-to-face trainings will develop superusers at Member State level
- Access to information on training and materials for all users will be through EMA website (www.ema.europa.eu)
- In case of questions, you are welcome to contact us through CT.Training@ema.europa.eu

User Manuals *will provide detailed instructions on all aspects of the system for all users.*

Short demo videos (5 – 10 minutes) *will be tailored to a specific task or sub-task which can be completed on the system, categorised by user group and split according to the business process they relate to*

Quick guides *training will be built into CTIS to provide the user with instant access to the relevant sections of the user manual for the task they are completing within the system*

In-system information *training will be built into CTIS to provide the user with instant access to the relevant sections of the user manual for the task they are completing within the system*

Dedicated training webinars *will be targeted at user groups and will be based around a specific set of processes and act as a forum for question and answers*

Summary and status- highlights

- The New Delivery Model has been gradually being implemented and is being monitored based on defined KPIs
- The first step was the merge of the EU portal and database (R0.7) with safety reporting system (R0.9) (CTIS system)
- The Product Vision adopted in May drives on the priorities to be considered in the release planning for each of the three milestones described (Audit, Go-live and after Go-live), considering the current status of the system as shown today
- Development continues as planned:
  - Release 11- sprint 13 is the one currently under development
  - Release 12 plan (Sprints 14 – 16) was presented for endorsement to the Expert Group in October
- MSs and Sponsors (end users) are highly involved in all phases of the Delivery Model via de Product Owners, who are working in very close collaboration with EMA and the development team
- MSs and Sponsors Product Owners have recently performed an end to end testing of the system (operational assessment) to identify the current gap in the system to pass the audit and achieve go-live
- The outcome of the operational assessment will help to provide projections for the audit date and plan
- The training strategy will be implemented considering the delivery plan.

Main Goal: collaboration, quality of the research, transparency and better patient outcome

Any questions?

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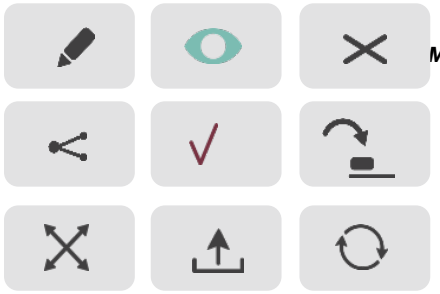
BACKGROUND SLIDES

CTIS- Permissions and roles

Permissions

example



Mix and match

Roles

example

Administrators

Coordinator

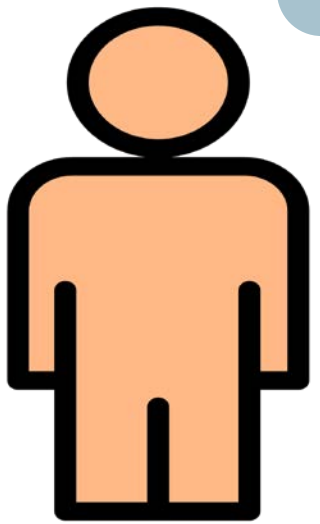
Business Roles (validator, assessor, supervisor etc)

- Viewer
- Preparer
- Submitter

Roles will be created by grouping respective permissions

Assign roles to people

Registered Users



A flexible system that can be adapted in the near future

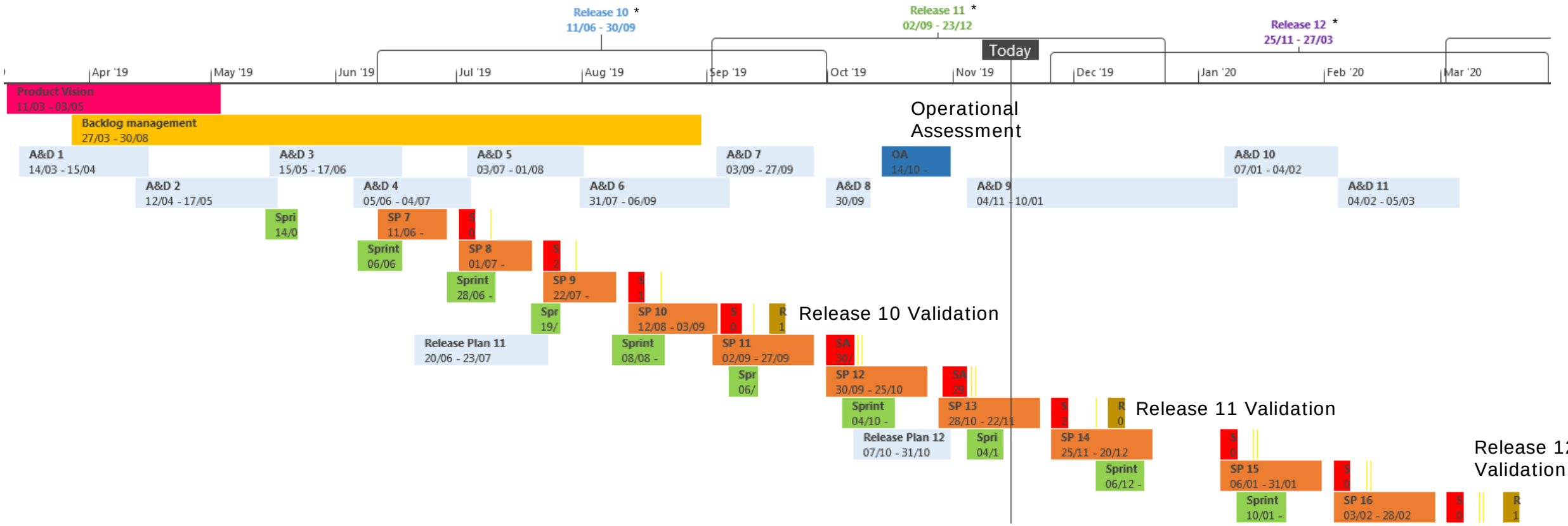
Each user can be assigned one or more roles to allow him/her to execute relevant actions in the system

View | **Create** | **Delete** | **Share** | **Assign/release task**

Submit | **Update** | **Withdrawal** | **Assign roles/trials**

Calendar overview

The project is in Release 11 and the 2nd Sprint has finished. The project team is working on planning Sprint 14. Release 12 plan was endorsed by the Expert Group. The development of Sprint 13 started as planned. The Operational Assessment has completed and the feedback is consolidated.



* Release 10 is comprised of 4 sprints: from 7 to 10
* Release 11 is comprised of 3 sprints: from 11 to 13
* Release 12 is comprised of 3 sprints: from 14 to 16