



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Annex 3 to the eSubmission Roadmap on Transitioning to the mandatory use of the Common Repository for eCTD format Centralised Procedure submissions

Status and next steps

## 1. Background

The final adopted version of the [eSubmission Roadmap](#) was endorsed by the EU Telematics Management Board on the 1<sup>st</sup> of October 2014, and describes the current situation of eSubmission in the European Union and the issues that will be addressed in the near future. The roadmap includes a number of initiatives such as dossier formats, portal solutions and application forms. The roadmap also describes the mandatory use of the Common Repository for Centralised Procedure submissions in the human area. This outline of Stream VI describes the transitioning to the mandatory use of the Common Repository.

### Common Repository

The current [CAP Dossier Requirements](#) elaborates details on the requirements on dossier format and addresses for the provision of copies of the submission sequences sent to EMA for the Centralised Procedure applications/procedures. The Common Repository removes the need to provide each NCA with a copy of the submission by allowing all NCAs access to all eCTD format submissions received for all Human Centralised Procedure products. This means that the applicant/MAH will only send a submission to the EMA via eSubmission Gateway and this submission will be technically validated upon receipt and automatically uploaded to the EMA eCTD Review Tool (EURS) through which it will be made available in the Common Repository to all NCAs.

The NCAs have permanent and immediate access to search, view and download all submission sequences either using manual web interface or an automated API (Application Programming Interface).

The objective and vision is to reduce the administrative burden for Regulatory Authorities and Industry and to support the timely availability of the submissions within the network.

A stepwise approach has been developed to deliver the vision, as follows:

- Step 1: 1<sup>st</sup> of July 2015: Usage of the Common Repository is compulsory for all NCAs.
- Step 2: timing to be confirmed: The Common Repository will be extended to contain all submissions for the following **centralised procedures/EMA coordinated procedures**: Veterinary submissions, Referrals, Paediatric submissions, Scientific Advice submission and non-eCTD ASMF submissions. In this step, the Common Repository will be upgraded to host also NeeS and VNeS formats.

As a further step, the Common Repository will be merged with the PSUR Repository to further streamline the NCA access to all types of submissions

## 2. General Concepts

NCAs have two ways of downloading documentation from the CR:

- Download individual documents (using http protocol) Tool: Web User Interface (Browser)
- Download full dossier (using BitTorrent protocol) Tool: CR API Client

The Web User Interface is available to the NCAs via Eudranet. Two types of roles are available for access:

- Anonymous User, with rights to search, view and download individual documents
- Administrator with rights to search, view and download individual documents and full submissions.

The Web User Interface is compatible with LDAP and can therefore use the Eudra Common Directory user registry. In practice this means that the registered users of the Common Repository do not need a separate account to connect to the Common Repository but can use their Eudra user account.

The CR API client is available through Eudranet together with a JAVA based client tested and developed for automatic download by AEMPS. The client is also available sending an email to [edossier@aemps.es](mailto:edossier@aemps.es).

The Web User Interface is not intended to be an eCTD viewer. Investments for a separate eCTD viewer tool should not be needed as the CP submissions can be downloaded using an API Client and reviewed with National eCTD Review Tools. Each NCA should have its own eCTD viewer to review national and MRP/DCP eCTD submissions and it is foreseen that it is used also for centralised procedure dossiers when needed.

Working documents folders that are usually provided simultaneously with the eCTD submissions are planned to be made available via the CR at a later step. These are currently not available via the CR as they are outside of eCTD specification and hence provided outside the eCTD submission sequence. While solving this problem, EMA has set up an automated solution to forward email notifications with attached Word format working documents. The notifications are sent to the NCAs that have joined the Common Repository. Currently this system sends notifications for all CAP submissions uploaded in CR so NCAs may receive notifications about working documents for CAP submissions they have decided not to download. Use of functional mailbox for the receipt of notifications and word format working documents is recommended as this allows further (auto) forwarding of required messages and matching with downloaded dossiers within NCAs.

For further information please see the [Q&A document](#).

### **3. Operational aspects**

User and password requests can be addressed to [esubmission@ema.europa.eu](mailto:esubmission@ema.europa.eu). Up to 3 administrator users is recommended per NCA. The number of anonymous user is not limited per NCA. Administrators are authorized to manage NCA APIs and BitTorrent based download of sequences whereas anonymous users can only browse the CR and download single documents.

The CRMG (Common Repository Maintenance Group) collects and evaluates change requests and once approved coordinates their implementation and releasing into production. Change requests can be addressed to [eSub.changerequests@ema.europa.eu](mailto:eSub.changerequests@ema.europa.eu).

If a National Competent Authority downloads the submissions using the CR API it is useful to know that:

- Due to all downloaded sequences being eCTD, you can use the [eu-regional.xml](#). This file contains all the metadata needed to identify the submission and can be used to import the downloaded sequences automatically in your local repository.

- BitTorrent clients can be set up to move the submissions, once downloaded, to a different folder. This action can be used as a signal to know that the sequence has been completely downloaded.
- It is possible to access and download a single document via http using the relative path associated with the document in the eCTD backbone files eu-regional.xml or index.xml

#### **4. Benefits of using the Common Repository**

- Simplification of submission channels: All eCTD format Centralised Procedure submissions are sent via the eSubmission Gateway / Web Client removing the need to send separate copies to NCAs and hence reducing the number of submissions sent by the applicants/MAHs, thereby reducing time and costs related to submissions.
- One way of submission transmission: there will no longer be need to create CDs/DVDs as all submissions are sent through a portal.
- Reduction in the need to archive and store non-relevant submissions in the NCAs: The NCAs download and store only those submissions of which they wish to have local copies in their national systems (for majority of NCAs this means retrieving only dossiers for procedures where they are a Rapporteur or Co-Rapporteur).
- Continuous and immediate access to up-to-date centralised procedure dossiers by all NCAs
- Automated downloads from the Common Repository using an API can be scheduled removing need for manual access to the repository.
- All submissions are validated at the point of receipt before upload to the Common Repository.

#### **5. Availability of the Common Repository**

Common Repository was launched on the 28th of February 2014 and is now available to all NCAs via the Eudraportal. The list of NCAs receiving all Centralised Procedure submissions exclusive via the Common Repository is available and updated on the Common Repository webpage. The remaining NCAs should require copies of the submissions via CESP or on a CD/DVD as per the [Dossier Requirements](#) document until the 1<sup>st</sup> of July at the latest, when the use CR for human CAP procedures becomes mandatory.

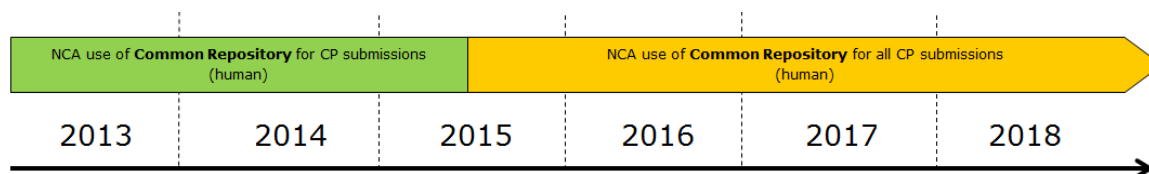
This list acts as an indicator to show National Competent Authorities receiving Centralised Procedure submissions via the Common Repository only. This indicator will be continuously updated until all NCAs have joined the system.

#### **6. Information about implementation**

The implementation towards the mandatory use of the Common Repository by the NCAs will be organised via existing change management activity ongoing within the EMA with close collaboration with the NCAs. The EMA project team would be pleased to receive your feedback and/or ideas to assist implementation.

## 6.1. Timelines

- **Step 1: 1st of July 2015:** Usage of the Common Repository is compulsory for all human medicines NCAs.
- **Step 2: timing to be confirmed:** Extend the use of the Common Repository to cover the following **centralised procedure dossiers/centrally coordinated procedures:** Veterinary submissions, Referrals, Paediatric submissions, Scientific Advice submission and non-eCTD ASMF submissions. . In this step the Common Repository will be upgraded to host also Nees and VNees formats.



## 6.2. Important milestones

Milestone	By
Project Request to deliver a release to solve any blocking issues preventing the use of the Common Repository by NCAs and a request to modify the Repository to allow use for all procedure types coordinated centrally.	February 2015
Work together with the NCAs to assist the adoption of the Repository in the remaining NCAs	January - June 2015
Publish updated CAP Dossier Requirements	1 <sup>st</sup> of July 2015
<b>Usage of Common Repository compulsory for NCAs</b>	<b>1st of July 2015</b>

## 6.3. Guidance Notes, useful links and contacts

- All information (direct or linked) will be made available under: [http://esubmission.ema.europa.eu/central\\_repository.HTML](http://esubmission.ema.europa.eu/central_repository.HTML)
- [The acceptable usage policy](#) defines a set of rules for the Common Repository users, which give direction how to use the CR system in an optimal way, leading to good system response times, high reliability and an efficient use of the available IT resources
- Relevant guidance and documents will be updated / created (user guidance, Q&A, workaround documents, etc...) and made available.
- One to one (TC) meetings with NCAs continue to be held during the transitional period to assist the remaining NCAs.
- If you have any questions regarding the Common Repository, please contact the EMA with your query: [esubmission@ema.europa.eu](mailto:esubmission@ema.europa.eu)