EMA/301319/2012
10 August 2015

Common Repository

Acceptable Usage Policy

Table of Contents

1 Background

The Common Repository (CR) system has been established to identify an effective way to provide access for National Competent Authorities to Centralised Procedure application dossiers (initial MAA and post-authorisation activities) for human medicines, veterinary applications in NeeS format, all types of referral procedures, and certain other document types that support pharmacovigilance activities.

The Common Repository is being implemented in a phased approach. Release 1 focuses on Centralised Procedure submissions for human medicines in eCTD format. Further software releases of the CR solution will also include additional procedure and document types. This document only refers to processes and rules which shall be implemented for Release 1. However, it is the intention to update the usage policy for later releases as required.

2 Objective of the Acceptable Usage Policy

The objective of the acceptable usage policy (AUP) is to create 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. The AUP will be updated as required. As an example, some of the rules might be revised after the extended support phase in case they turn out to be overcautious.

3 Description of the Service Provided

3.1 Common Repository – Modes of Operation

The implementation of the Common Repository project will create a solution which allows for 2 main modes of operation: the Application Programming Interface and the Web User Interface.

3.1.1 Application Programming Interface (API)

The API is based on the concept that NCAs will build a copy of the EMA's Common Repository within their national Repository. This national copy may contain 100% of EMA's Common Repository files, but it may also contain only a subset of the centrally held information.

NCAs using the API will have a local IT system that is able to connect to the CR and automatically download predefined categories of sequences.

It is expected that the some of the National Competent Authorities that have decided to operate using the API, will select a start date and will create at that start date a complete national copy of all the CR information which shall be maintained in its national repositories.

Once the initial copy has been created, NCAs will then be able to regularly automatically download information about any new eCTD submission which has been sent to the EMA as part of the Centralised Procedure. In order to maintain their national CR copy, NCAs will choose which of the new Centralised Procedure submission shall be downloaded into their national environment. Where there is no business or legal requirement to keep all the sequences in the national repository, they may decide not to download all, but only a limited number of the recently submitted eCTD sequences.

The EMA has provided the NCAs with the description of an open application programmable interface (API) (see document "CR API Specifications") to the Common Repository for searching, downloading and browsing/viewing. This API will be accessible for all the NCAs (more than 30) via Eudranet.

This mode of operation is also known as the "Automatic mode".

3.1.2 Web User Interface

The second mode of operation is the Web User Interface. With this mode NCAs have the possibility to manually search and browse through all the dossiers stored in the EMAs Common Repository and view single files (size limitations may apply) as required.

This mode of operation is also known as the "Interactive mode".

Note that this user interface is not intended to replace the reviewing tools used by NCAs as the Web User Interface does not display the links between sequences.

3.2 Typical Scenarios of Usage of the Common Repository

The results of a few surveys related to the Common Repository, in which most NCAs have participated, suggest three main scenarios of usage of the Common Repository to fulfil the needs of the European Medicinal Regulatory Network:

3.2.1 NCA participates in Centralised Procedure marketing authorisation applications

The NCA has been appointed as Rapporteur, Co-Rapporteur, or Peer Reviewer for a Centralised Marketing Authorisation Procedure and is continuously involved in the assessment process for a specific product.

- In this case the NCA potentially needs at any time of the process access to the entire lifecycle of submissions for these products (including the most recent submissions).

- Therefore the NCA will regularly query the Common Repository if new submissions for certain Centrally Authorised Products have arrived.

- If a submission for a centrally authorised product, where the NCA is involved in the marketing authorisation process, has arrived, the NCA will request to download it to be able to store it subsequently in its national repository.

3.2.2 NCA has to fulfil a legal national requirement to keep all Centralised Procedure dossiers on national territory.

- This category is determined by the legal requirement to maintain a full (100%) copy of all Centralised Procedure submissions on national territory.

- As the EMA maintains in its Common Repository the entire lifecycle of all the submissions for all centrally authorised products, giving National Competent Authorities unrestricted access for downloading creates the possibility to comply with this national legal requirement in a very efficient way. The NCA needs to query at regular intervals which new eCTD sequences have been sent and download continuously each single submission from the Common Repository. The downloaded files will then be stored in the national copy of the CR. As a consequence the national CR copy will contain 100% of the centrally available information.

3.2.3 NCA is not directly involved in the assessment process of the majority of Centralised Procedure marketing authorisation applications and has no legal obligation to keep Centralised Procedure dossiers on national territory.

- However, the NCA needs for other purposes (secondary review, research, reporting, monitoring, etc.) to access certain dossiers of centrally authorised products.

- In this case the NCA can search the content of the EMA's Common Repository and open files for viewing as required.

3.3 Service Provided by the EMA

1.1. The EMA will make available an API to allow automated searching and downloading of sequences and dossiers as specified in document "CR API Specifications".

1.2. The EMA will make available a user interface to allow manual searching and browsing through all the dossiers stored in the EMAs Common Repository and view individual files.

1.3. The EMA shall provide this service during EMA working hours with the quality of service applicable for all Eudra systems. Outside of this time period, the service shall be available on a best-effort basis. This is similar to the service provided for other EU Telematics systems such as EudraLink and EudraVigilance.

1.4. During EMA working hours, up to 20% maximum of the available bandwidth is reserved for downloading information from the CR.

1.5. Outside of EMA working hours, up to 80% maximum of the available bandwidth is reserved for downloading information from the CR.

1.6. The current version of the Common Repository is strictly eCTD-compliant. The eCTD standard does not allow MS Word documents. As this format is sometimes used during the evaluation processes to exchange "working documents", there is a need to send these documents separately. The Common Repository can automatically send these to a specified email address. Considering the confidentiality of these docs, only EudraNet email addresses (xyz@eudra.org) should be used.

4 Rules

The following rules apply for users of the Common Repository:

1. Agencies which are involved in many centralised marketing authorisation procedures, are advised to use the API.

2. A submission, submission sequence or a dossier shall only be downloaded once. Multiple downloads of the same file must be avoided to protect the interest of other Common Repository users, who also need access to this central database with limited access capacity.

3. The file size of files which can be opened in the Web User Interface as unregistered (anonymous) user will initially be limited to 100 Mbytes, which is the maximum file size recommendation of an eCTD submission. Note that there is no such limitation when downloading files using the user interface as a registered user or using the API in automatic mode.

4. Once the initial population of a national repository has taken place, re-synchronization of entire national repository with the source repository over the network must be avoided. It is understood that there will be, very exceptionally, situations where a re-synchronisation of the entire repository will be required. If so, contact the EMA IT Service Desk to investigate the most efficient mechanism to make that possible.

5. The EudraNet Security Policy applies to all Common Repository users (because they are accessing the Common Repository over EudraNet).

6. Up to three Administrative Registered Users will be made available per NCA. If more are required, contact the EMA IT Service Desk to investigate the most efficient mechanism to make that possible.

7. Every NCA should strive to have at any point in time not more than three concurrent users (i.e. connected users (administrator or anonymous) in parallel actively interacting with the system by e.g. launching a query. Note that "concurrent" does not refer to the number of users simultaneously connected to the web user interface or in the process of defining a query or looking at query results.)

8. It is the responsibility of every NCA to make sure that the content of the mailbox used for receiving notifications and "working documents" is managed so at any point in time there is sufficient free space to receive the emails.

5 Definitions, Acronyms, and Abbreviations

Additional definitions, acronyms, and abbreviations:

EURS: European Review System

eCTD: electronic Common Technical Document

CR: Common Repository

NR: National Repository

NCA: National Competent Authority

EMA: European Medicines Agency

ECD: Eudra Common Directory

Eudra: European Union Drug Regulatory Authorities

EMRN: European Medicines Regulatory Network

VPN: A virtual private network (VPN) is a secure network that uses primarily public telecommunication infrastructures, such as the Internet, to provide remote offices an access to a central organizational network. There are two types of VPNs; remote access VPNs and site to site VPNs. Remote access VPNs are for individual users who are not in a fixed location – remote or roaming users. Site to site VPNs are for multiple users in a fixed location – like regional offices. EudraNet is a site to site VPN

6 Document Information

6.1 Referenced Documents

Doc ID	Title	Link
EMA/98215/2012	CR Solution Vision	https://docs.eudra.org/webtop/drl/objectId/090142b281c69b75
	EudraNet Security Policy	Link to document on EudraPortal
	CR API Specifications	
	Eudra Systems Service Level Agreement	

6.2 Document history

Version	Who	Date	What
1.0	TM	07-05-12	First Draft for internal review
1.3	TM	21-05-12	Amended draft version for internal review
1.5	TM	12-06-12	Amended version consolidating comments from internal review
1.8	TM	28-06-12	Amended version consolidating additional comments
01.09	OS	14 Jan 13	Updated and completed For review by Team
01.10	NB	17 Jan 13	Replaced download mode with API and view mode with Web User Interface as per the published Q&A document.
01.12	CEE JSI	24 Feb 14	Reviewed and merged by OS
01.13	OS	20 Mar 14	Integrated feedback received from NCAs
01.17	OS	25 Mar 14	Typos
01.18	OS	27 Apr 14	Accepted all tracked changes Final version
01.19	OS	04 Aug 14	Updated point 6 to reflect that the latest version allows more than one Admin user.
01.20	OS	14 Apr 15	Updated to reflect that the system is live and will be mandatory from 01 Jul 15.