



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EudraCT Gateway Interface – NCA Guide

Guidance for NCA partners taking part in the EudraCT Gateway



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1. This document purpose

The purpose of this document is to give an overview of the interaction between NCAs and EudraCT via the Gateway.

2. System brief description

Gateway is the communication mechanism that will be used between the NCAs and EudraCT in order to allow the importing of CTAs, Amendments, IoCs, Reviews and Inspections is based on the admission that messages are represented by files.

Messages are exchanged between disparate systems (endpoints) and may represent either a straight-forward operation, initiated by an NCA, or a response to it produced by EudraCT.

Each message must encapsulate both a header, containing the necessary control fields required to track communication flow, and a body containing the payload. All information within a message should be described by a unique XSD, since all exchanged messages belong to the same protocol.

3. Communication Endpoints

The systems that are involved in the communication scheme are the following:

- Axway Gateway
- NCA's client system
- EudraCT communication subsystem

3.1. Axway Gateway

The Axway Gateway is a product used to transfer information between disparate platforms. It provides end-to-end monitoring and tracking of file movements. Finally, it offers a broad spectrum of security measures to protect against data loss and improve governance.

3.2. NCA Client System

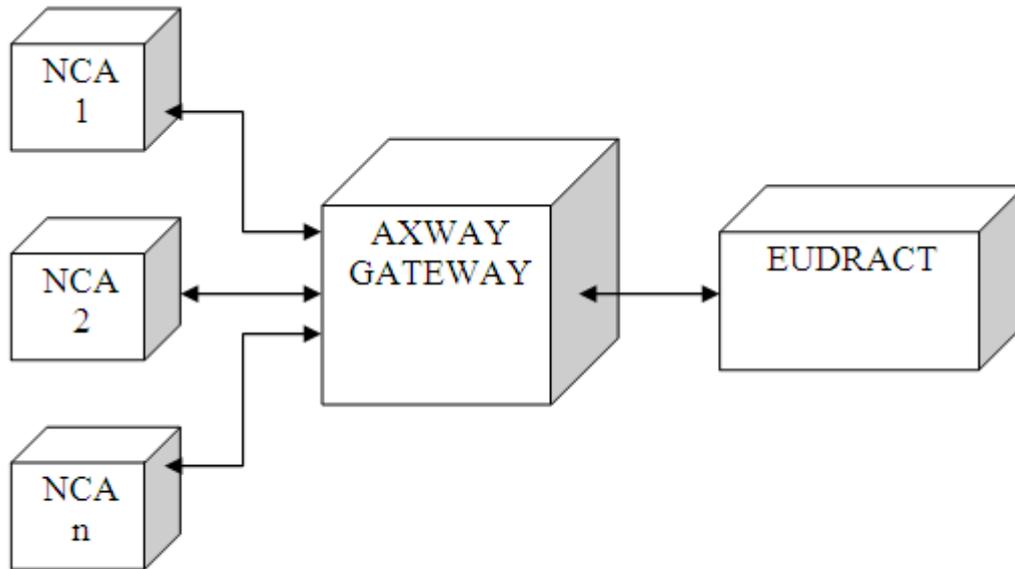
The NCA's client system will be responsible for preparing messages according to the relevant XSDs (which are available on the [EudraCT SECURE website](#)) and for generating a unique identifier for each message. A unique message identifier should be present in order to be able to identify messages at a later point in time, to allow the sending of multiple messages for the same entity (e.g. multiple messages for the same CTA) and to correlate the original message with the response produced by the EudraCT communication subsystem.

3.3. EudraCT

The EudraCT communication subsystem is responsible for performing business-wise validation of the messages as well as for importing the relevant entities in the EudraCT persistent storage. It will also be responsible for generating the response for each particular message that has been received. EudraCT should also generate unique message identifiers for its responses.

4. Communication Process

Message producers push messages to a pre-defined location within the Axway Gateway, which in turn routes them to the designated remote locations (inboxes) provided by consumers. Message-inboxes appear like file directories. Message recipients are responsible for polling their own inbox in order to retrieve and consume messages. The Axway Gateway is responsible for all communication mechanics. The following picture describes the communication scheme:

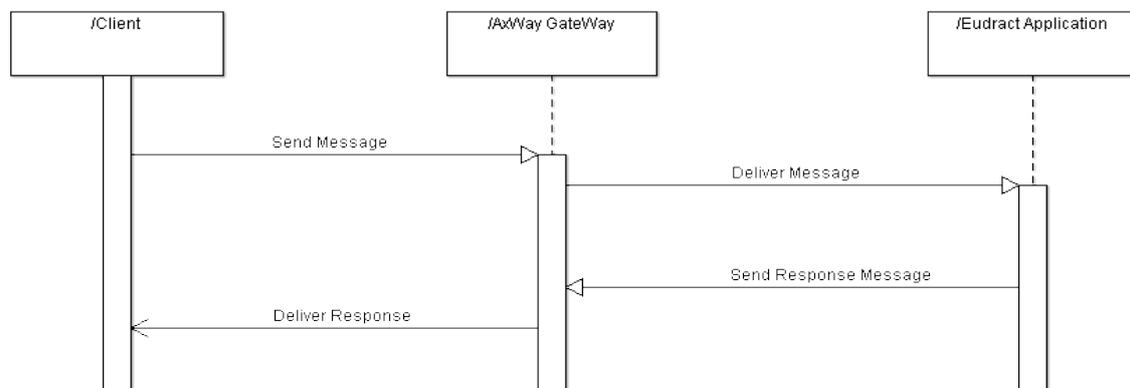


Picture 1: Communication parts

The basic design principles of the communication scheme described above are the following:

- An endpoint can only receive/send messages from/to the Axway Gateway.
- NCA client systems and EudraCT can be both message producers and consumers.

The following sequence diagram depicts a full successful communication cycle between an NCA and EudraCT, i.e. a message is sent by the NCA to EudraCT through the Axway Gateway and the response to this message is sent back by EudraCT to the NCA, again through the Axway Gateway:



Picture 1: Communication cycle

Under normal circumstances NCA client system will receive a response for a message within a short time period. In case such communication is broken, none of the parties involved will be notified further as there is no additional feedback mechanism over the lower level networking layer.

5. NCA

NCAs will be responsible for:

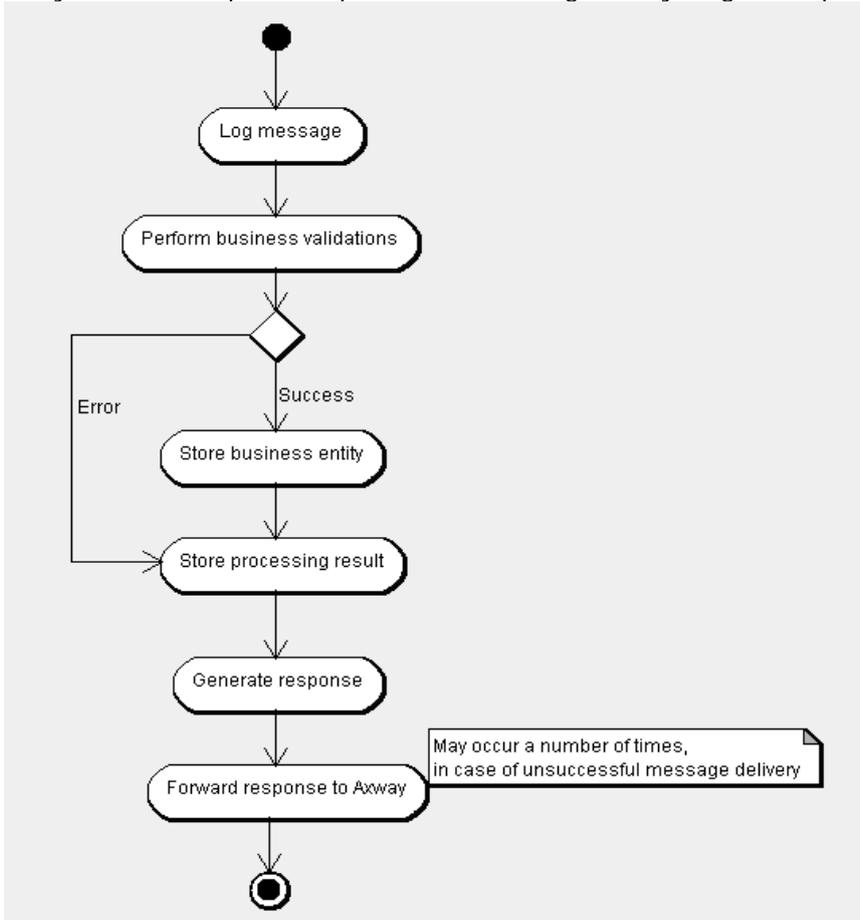
- Submitting zip files into the gateway inbox
- Checking the gateway outbox for relevant response files

6. EudraCT

EudraCT functionality can be described in general - without taking into account the specificities of particular business entities - by the following coarse-grained steps:

1. Gateway inbox folder will be monitored for any incoming message
2. Once the message is received, it is recorded in persistent storage for logging purposes.
3. Business-wise validation is performed.
4. If step 3 is a success, the corresponding business entity is recorded in EudraCT.
5. The result of message processing is stored in EudraCT persistent storage.
6. The response to the appropriate NCA client is prepared.
7. The response is being sent to Axway Gateway in order to be properly routed and delivered to the intended destination.

Step 2 is a complex state that depends on the nature of a particular business entity, and will be further analyzed in subsequent chapters. The following activity diagram depicts the above steps:



Picture 3: EudraCT message processing

7. Incoming Message Format

7.1. Main file XML format

The complete incoming message format is a thin wrapper around the existing message formats accepted by the EudraCT application via upload screen functionality.

On top level for each EudraCT message there is a message header and a message detail. The **message detail** is formed by the actual payload represented by the existing EudraCT message formats.

The **message header** represents an envelope with certain technical attributes, gateway sender/recipient identifiers, message formats, timestamps and other additional auxiliary information). There is also a concept of a transaction ID (a unique message transaction ID/sequence guaranteed to be unique by the sender) as well as a concept of "any" arbitrary information (within XML:ANYTYPE

element) to be communicated in a loopback from the sender and passed back to them within the response.

All the relevant schema definitions are published.

7.2. ZIP package format

EudraCT will support complete packages as a ZIP package format with the following conventions:

- There is one XML file corresponding to the actual business message as described above.
- There is an arbitrary number of attachments which are related to certain EudraCT section. The appropriate CTA section is marked as a starting prefix of the attached file.
- The ZIP file is also checked for correctness by the gateway file handler/validator along with the actual structural validation of the XML file.

For every file received from outside the sender shall receive an acknowledgement message back stating the main result as well as possible further details.

The following unified acknowledgement format is used to represent EudraCT response to the outside world (although it may be from various sources – file handler or main application).

On the top level it uses the same envelope with the same message header type as for the incoming files.

Within the response details section where the actual acknowledgement payload is there is a provision to report one clear global status of the whole workflow (either ACCEPTED, REJECTED or ACCEPTED-WITH-WARNINGS) plus a repeating group of any number of findings within a certain place of origin in certain message type.

If a CTA is processed via Gateway and has validation errors the acknowledgement message returns an ACCEPTED-ITH-WARNINGS acknowledgement and lists the validation errors in the message body.

7.3. Bulk Submission

NCA's may choose to submit files in one of the following two ways:

1. Updates to trials etc. will be submitted into the gateway in real time at the time of update in the local systems
2. Updates to trials will be submitted into the gateway in bulk in scheduled intervals

The following is applicable if the second approach is chosen:

If there is a requirement for EudraCT to process submitted files in a particular order then

- The filename for all incoming zip files should be prefixed with a sequence such as a timestamp of when the data was created/modified. The exact details of this format are yet to be confirmed.
- For instances where there are multiple submissions, EudraCT will process them in the sequential order of the filename.

This is important ensure the correct sequence of submissions where multiple updates for the same clinical trial may have been submitted to the gateway in bulk.