

AIM - Business Process

1 - Introduction

This "Business Process" template shows the main processes contained in a module.

The diagrams notation is based upon BPMN, only a handful of elements are presented to simplify the diagram.

2 - Purpose

This purpose of this document is to provide an overview of the main processes of a specific module.

This high level representation is intended for stakeholders to be able to picture the scope and complexity of the system.

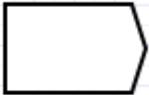


3 - Scope






We opted to provide business processes and their detailed descriptions by module.

MDR EUDAMED consists of several modules including:

Module	Code
Actor Registration	ACT
User Management	AIM
Device	UDID
Notified Bodies & Certificates	CRF
Vigilance	VGL
Clinical Investigation / Performance Study	CIPS
Market Surveillance	MSU

4 - Diagram legend

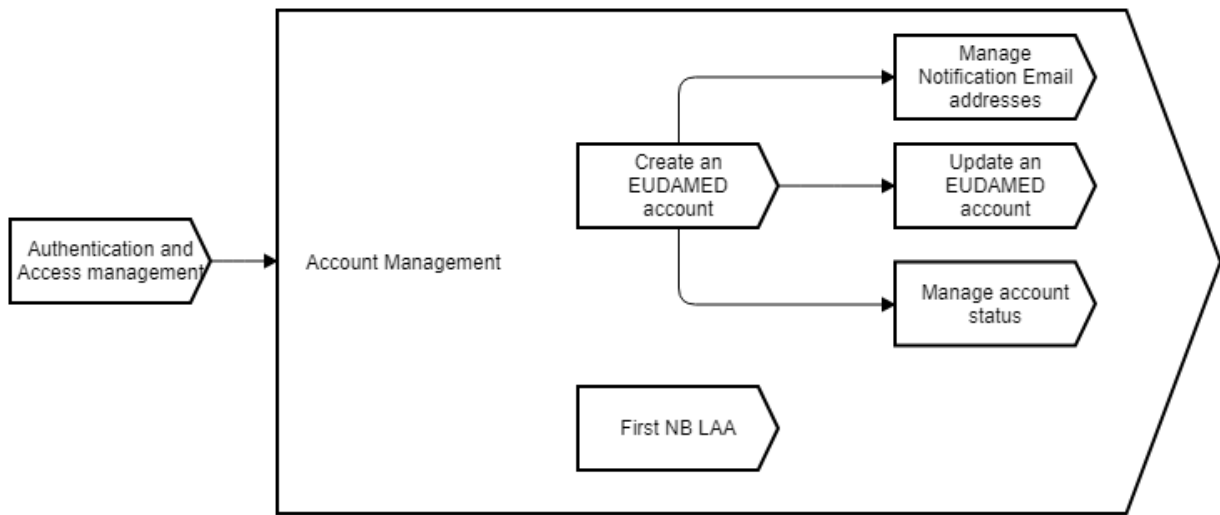
Symbol	Name	Meaning
	Process	Represents a collection of tasks performed by actors of EUDAMED
	Swimlane / Actor type	This boundary box shows the tasks a specific actor can perform for a given process.
	Start event	A black circle indicates a start event. A swimlane can contain multiple start event.

	Sequence flow	The order of the process is indicated by these arrows.
	Message flow	
	End event	A double filled circle indicated the end of a process.
	Notification system task	An envelope icon indicates a system task who will create and send out notifications.
	Task	A square box represents an interaction between an actor and the EUDAMED IT system.

5 - Acronyms

Term	Description
EC	European Commission
MF	Manufacturer
CA	Competent Authority
EO	Economic Operator (AR, MF, IM, SPPP)
AR	Authorised Representative
IM	Importer
Art	Article from the regulation
NB	Notified Body
SPPP	System or Procedure Pack Producer
M2M	Machine to Machine (Web Services)
LAA	Local Actor Administrator
LUA	Local User Administrator

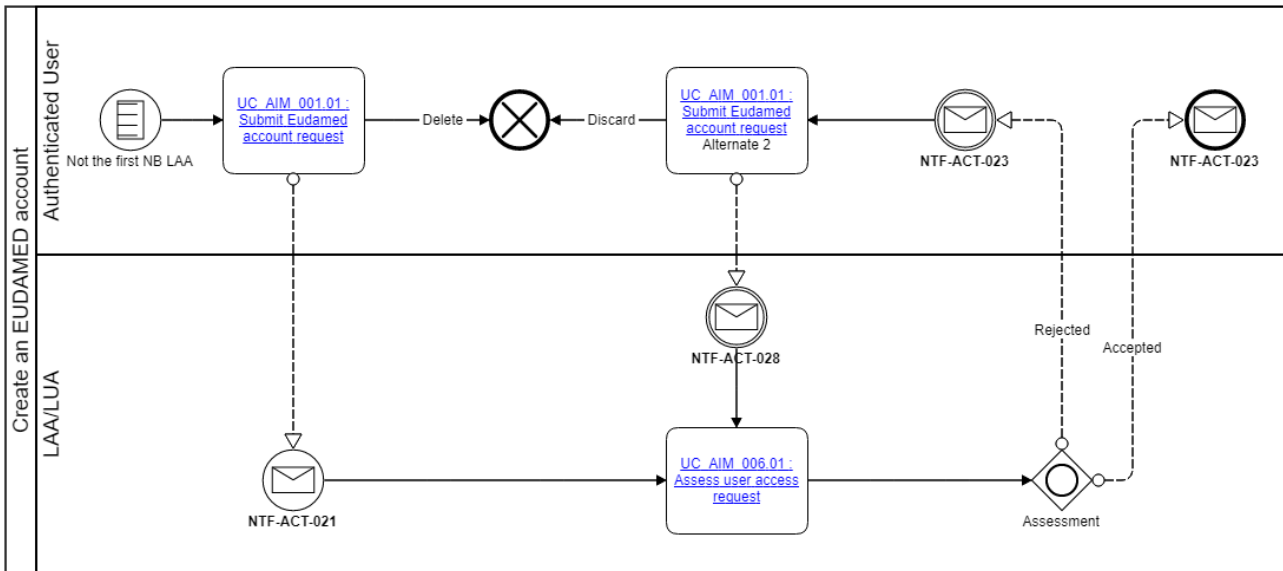
6 - AIM Process overview



(First NB LAA shall not be included in release 0.1)

6.1 - EUDAMED account management

6.1.1 - Create a EUDAMED account



This process consists of the following activities:

1. A user working for a registered Actor requests the creation of a EUDAMED account for this actor
2. A user of this actor with Local User Administrator rights (i.e. having the Local Actor Administrator or the Local User Administrator profile) assesses the request

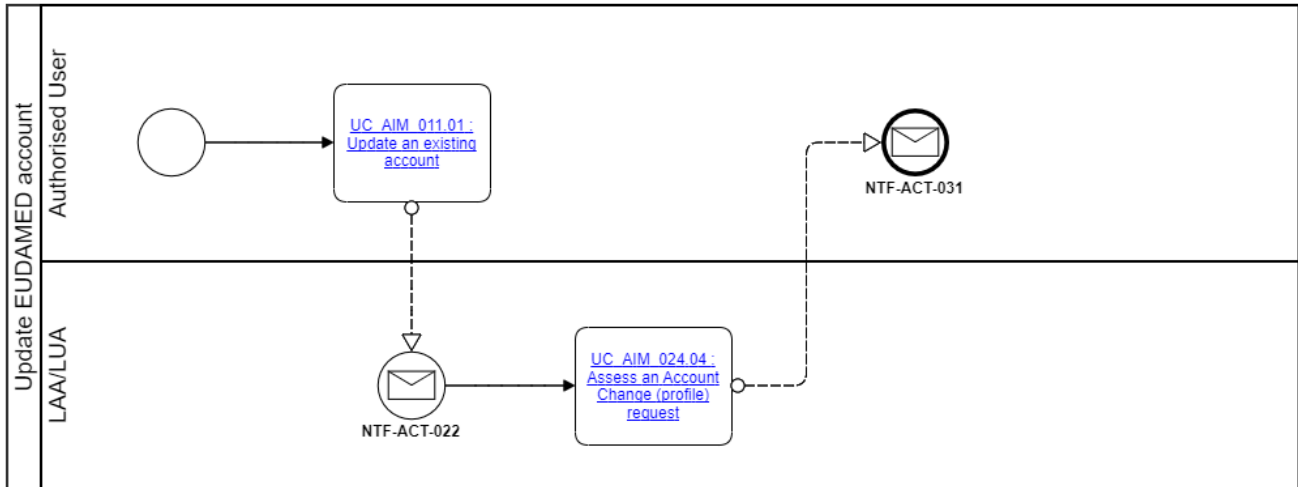
In the advent of a positive assessment:

1. EUDAMED creates the account, enabling the requesting user to perform activities on behalf of that actor
2. The user activates the EUDAMED account by accepting the User Rights and Obligations disclaimer on first access

In the advent of a negative assessment:

1. The requestor is informed about the negative assessment, so can take actions to correct or discard this EUDAMED account request

6.1.2 - Update a EUDAMED account



This process consists of the following activities:

1. The user (Account owner) submits a Change Account request
2. A user of this Actor with Local User Administrator rights (i.e. having the Local Actor Administrator or the Local User Administrator profile) assesses the request

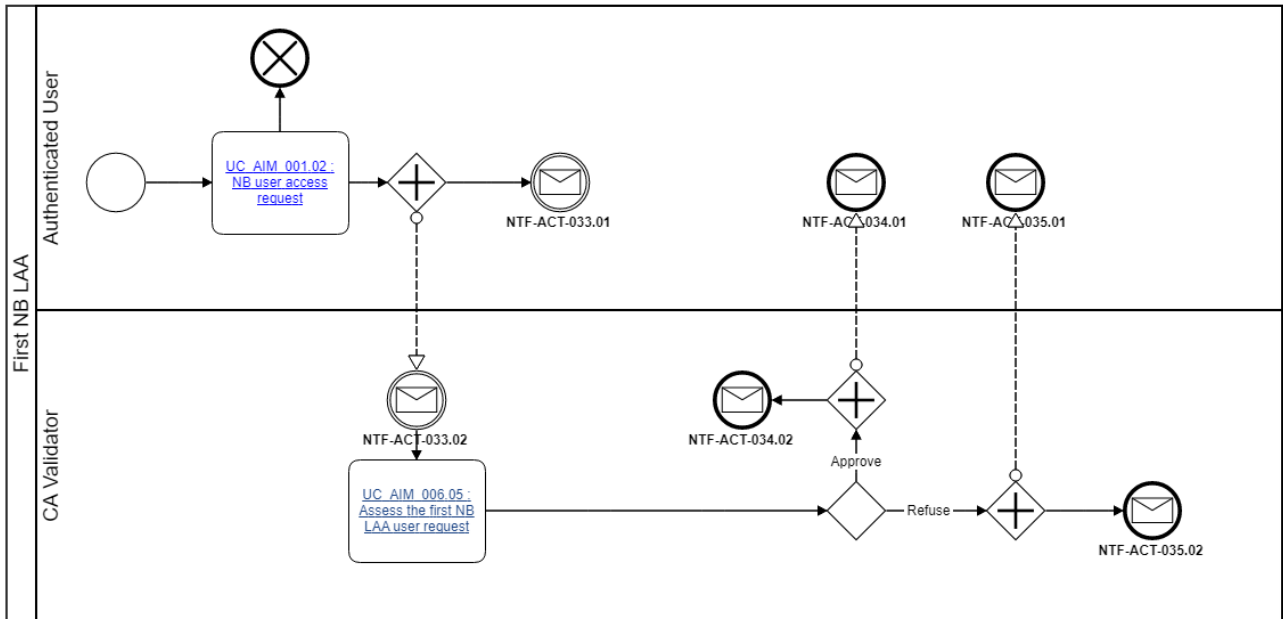
In the advent of a positive assessment, EUDAMED updates the account.

6.1.3 - Manage EUDAMED account status

This process consists of the following activities:

- LAA/LUA
 - Suspend an Account (this will not be included in Release 0.1)
 - Reactivate an Account (this will not be included in Release 0.1)
 - Terminate an Account
 - Resume an Account (this will not be included in Release 0.1)
 - Manage user access to a specific CI/PS (this will not be included in Release 0.1)
- Authorised User
 - Suspend my Account (this will not be included in Release 0.1)
 - Suspend all my Accounts (this will not be included in Release 0.1)
 - Terminate my Account (this will not be included in Release 0.1)
 - Terminate all my Accounts (this will not be included in Release 0.1)
 - Resume my Account (this will not be included in Release 0.1)
 - Resume all my Accounts (this will not be included in Release 0.1)
- EC
 - Terminate a EUDAMED account (this will not be included in Release 0.1)

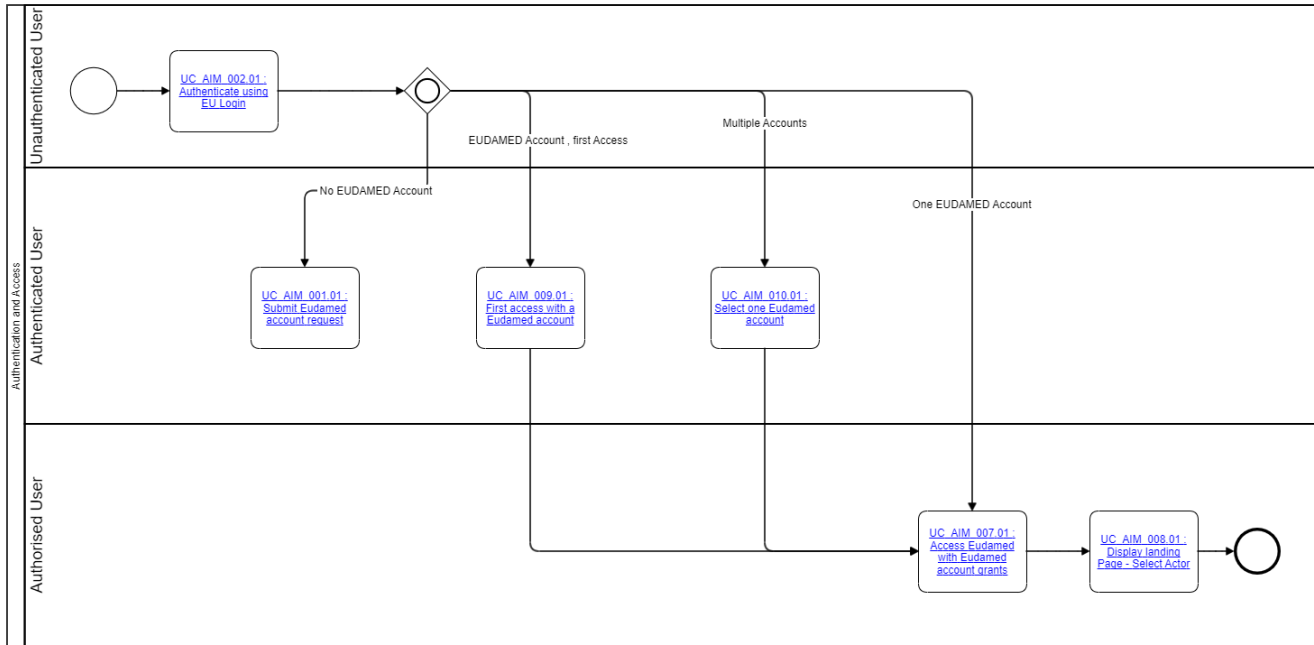
6.1.4 First NB LAA



This process consists of the following activities (this will not be included in Release 0.1):

- NB User access request
- Assess the first NB LAA user request
The CA validator in EUDAMED will be selected based on the Designated Authority relationship the Notified Body has in NANDO.

6.2 - Authentication and access management



This process consists of the following activities:

1. Users with an EU Login account enter their credentials in order to start a working session in EUDAMED
2. Unauthorised users can request a EUDAMED account request
3. Users with multiple EUDAMED accounts can specify the actor they are currently working for
4. Accept the user rights and obligations (after the first access)
5. Based on the profiles assigned to a EUDAMED account, as well as on the actor this account is for, EUDAMED grants the appropriate access rights to the user currently working for this actor
6. User gains access to a dashboard associated with the connected EUDAMED user account