

Organisations: Reports from subgroup

EU ISO IDMP Task Force meeting
25 September 2015

1. Progress report on subgroup activities
2. Phase I implementation of the operating model
3. Next steps

Work continued after summer break covering the following key items:

- Logical Data model
- Multi lingual support on organisation data
- Versioning of organisation records
- Definition of EU_Org_ID
- User management to request organisation registration/updates

Logical Data model (**work in progress**):

- Support for multi-level organisation classification
 - E.g. Higher Level = Industry/Pharma company, Sub_Level = SME, Lower Sub_Level = Micro, Small or Medium, etc.
 - Still to define the levels of classification to implement by business
- EU_Org_ID assignment on the address level
 - The uniqueness of the ID to be based on the combination for unique organisation and address.
 - An organisation can have multiple sites/addresses
- Associations between organisations; organisations & individuals; between individuals is possible
 - E.g. A person linked to a Sponsor or MAH, linkage between two organisations after a previous split, etc.
- Support for hierarchies amongst organisations

Multi lingual support on organisation data (**work in progress**):

- The group agreed with supporting organisation data in 'English' only
- What does 'English' mean?
 - Key elements to consider: Organisation name, Organisation address, City, County/State/Region and Country.
 - Agreed that Country can be stored only in English.
 - Agreed that address will have to be accepted and stored in local/national language
 - Debating whether organisation name, city and County/State/Region should be accepted always in English (as preferred) but stored also in local/national language
- In principle, terminology used should be in Latin characters
 - Support for additional characters particular to EU national languages but not in Cyrillic and Greek
- Search functionality for organisations to follow the above principles

Versioning of organisation records (**work in progress**):

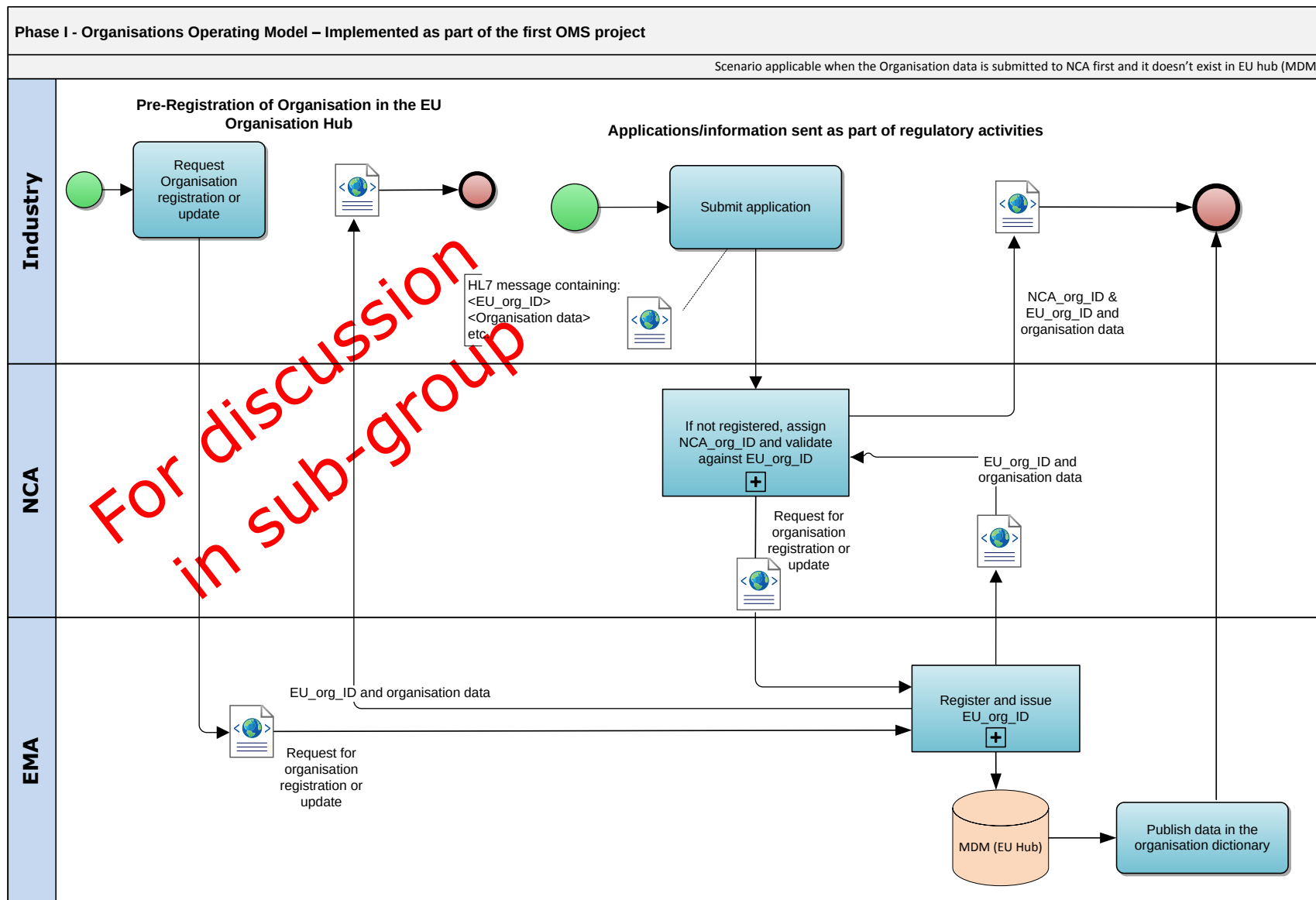
- Multiple versions to be stored against the same EU_Org_ID
- Questions on what is exposed to users (web UI/API interface)
 - For browse & search in dictionary, only current version?
 - For download and export of dictionary, all versions?

EU_Org_ID definition (**work in progress**):

- Identifying all business scenarios which may trigger changes to Organisation data
- Define business rules/criteria to issue new EU_Org_ID or create a new version of existing ID.
- Define EU_Org_ID composition and format

User Management (**work in progress**):

- Agreed that requesters for organisation registration/updates should be authenticated and controlled
- Implementation of a 'Super/Administrative User'
 - Must be linked to a Sponsor, MA applicant or MAH
 - This user is validated/authenticated by EMA
 - They validate/assign access to other users linked to the same organisation on a self-service approach
 - All these users can then send requests for organisation registration/updates
 - Requests for organisation registration and updates based on authenticated users
- A large number of users (super users) will need to be created at the beginning – how not yet defined.



- Conclude current discussions with a decision
- Start discussions on the implementation approach for the operating model
- Test the operating model to implement in this project with sample data/real scenarios (use cases)
- Analyse possibilities to obtain manufacturers data from additional sources to EudraGMDP e.g. EU national Agencies, FDA, EDQM, etc.