The Target Operating Model

How shall we get data into PMS?

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Need progress on several fronts

1. Get clarity from HMA/EMA MB/EU Commission on the level of ambition for what processes/business processes they are expecting to use PMS/UPD data for
2. Come up with a proposal for a solution to provide the information quality needed to support the business processes

1 - Need to take questions to the HMA/EMA MB

- What business processes are we expecting the PMS/UPD to support?
- What data quality is needed in the PMS/UPD to support these processes?
- Probably two times to these boards
  - first time general information
  - second time with a more concrete porposal based on business processes with proposals for budget, timelines etc

Who will take this to the HMA/EMA MB?

- Need somebody to lead taking this to HMA/EMA MB
- Need to gather support from (N)CAs & Industry during this process

Veterinary legislation pushes us

- NVR (New Veterinary Regulation) defines a number of business cases for a Union Product Database (UPD)
- UPD has more explicit Business Use Cases/Requirements than for the human Art 57
- Includes support for sales data, support for pharmacovigilance, support for variations that do not require assessment, support for cascade use of products, etc
- Details about business requirements are still being worked on – deadline end of August

2 - Assuming better quality is needed

- The QC/Art 57 process does not give us the data quality we want and it costs EMA a lot to check the data against the SmPC
  - not suitable for e-prescriptions/e-health
  - not suitable for cross-border product identifaction
  - not suitable for regulatory/ROG purposes
- We need to get data into PMS via a process that can ensure better data quality

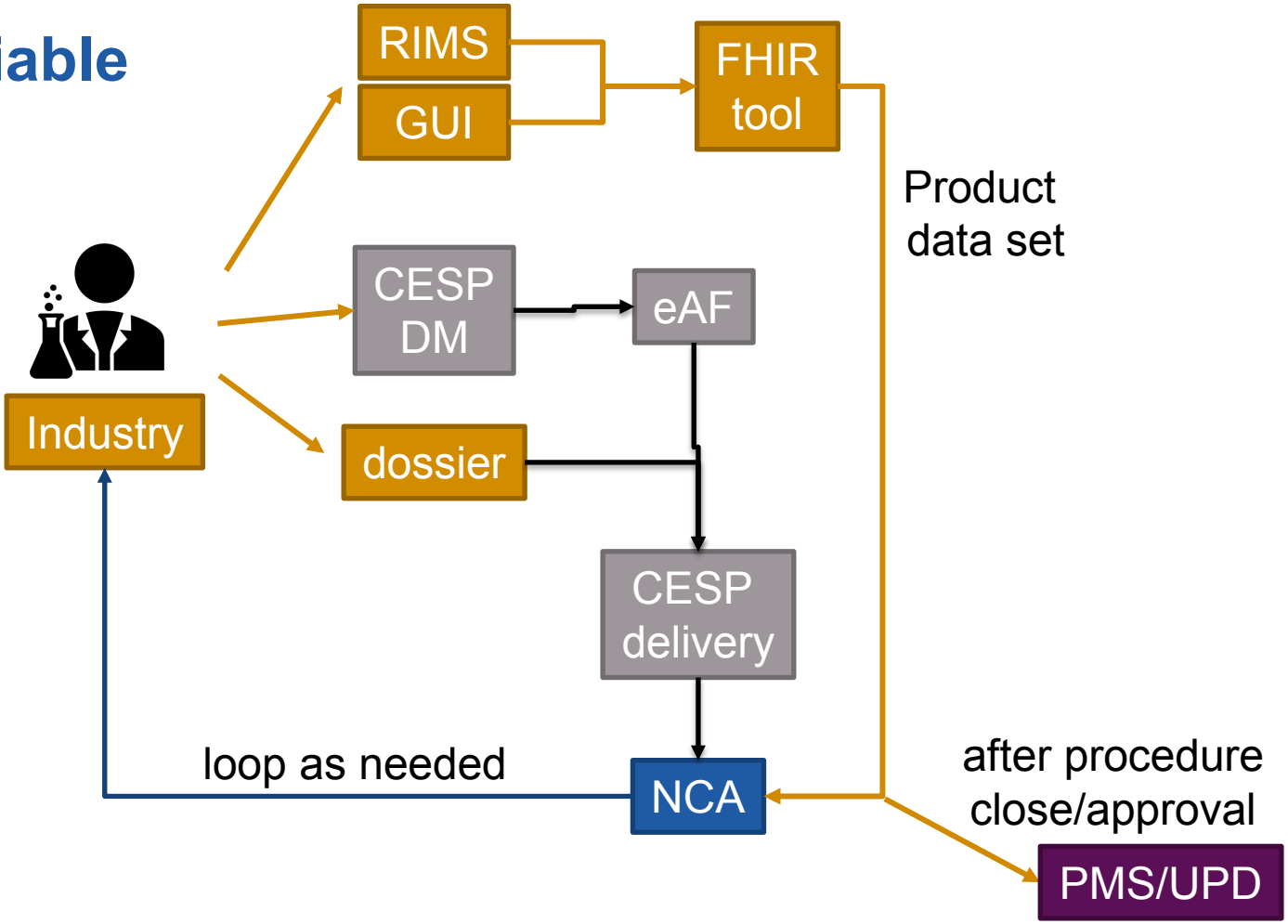
Need to include the (N)CAs in the data quality loop

- Include checking the data during the process so that, by the end of the procedure, an electronic version of the data that has been quality checked by the NCA
- Need a tool to support this process

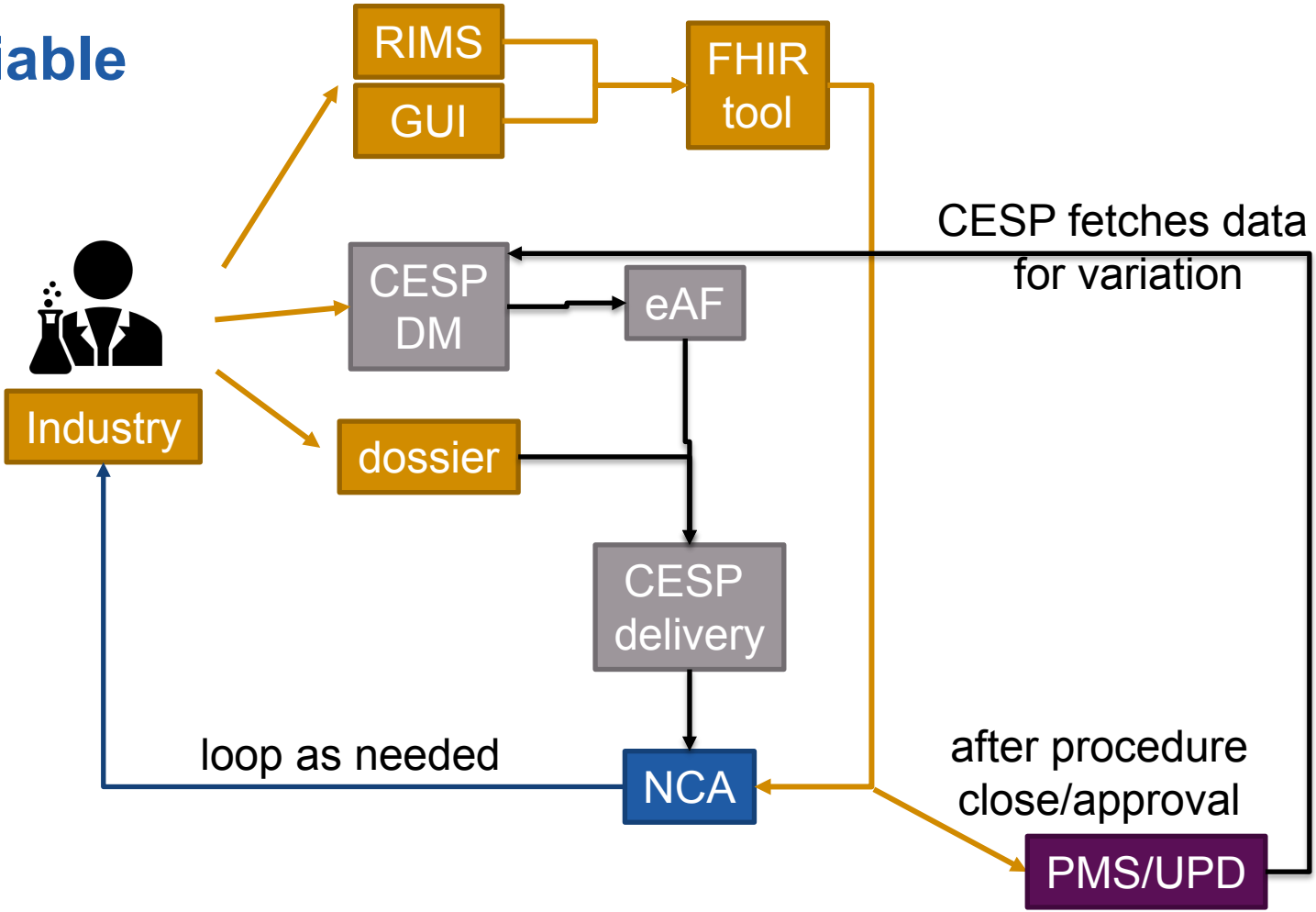
Two proposals for tools

- A: From Industry – Minimum Viable Product proposal
  - have a separate tool that is FHIR comptabile and create a full Iteration 1 dataset and submit the data to the NCAs along with the eAF/CESP dataset
- B: From NCAs (TOM proposal):
  - expanding the CESP dataset module that is under construction now to support this processes

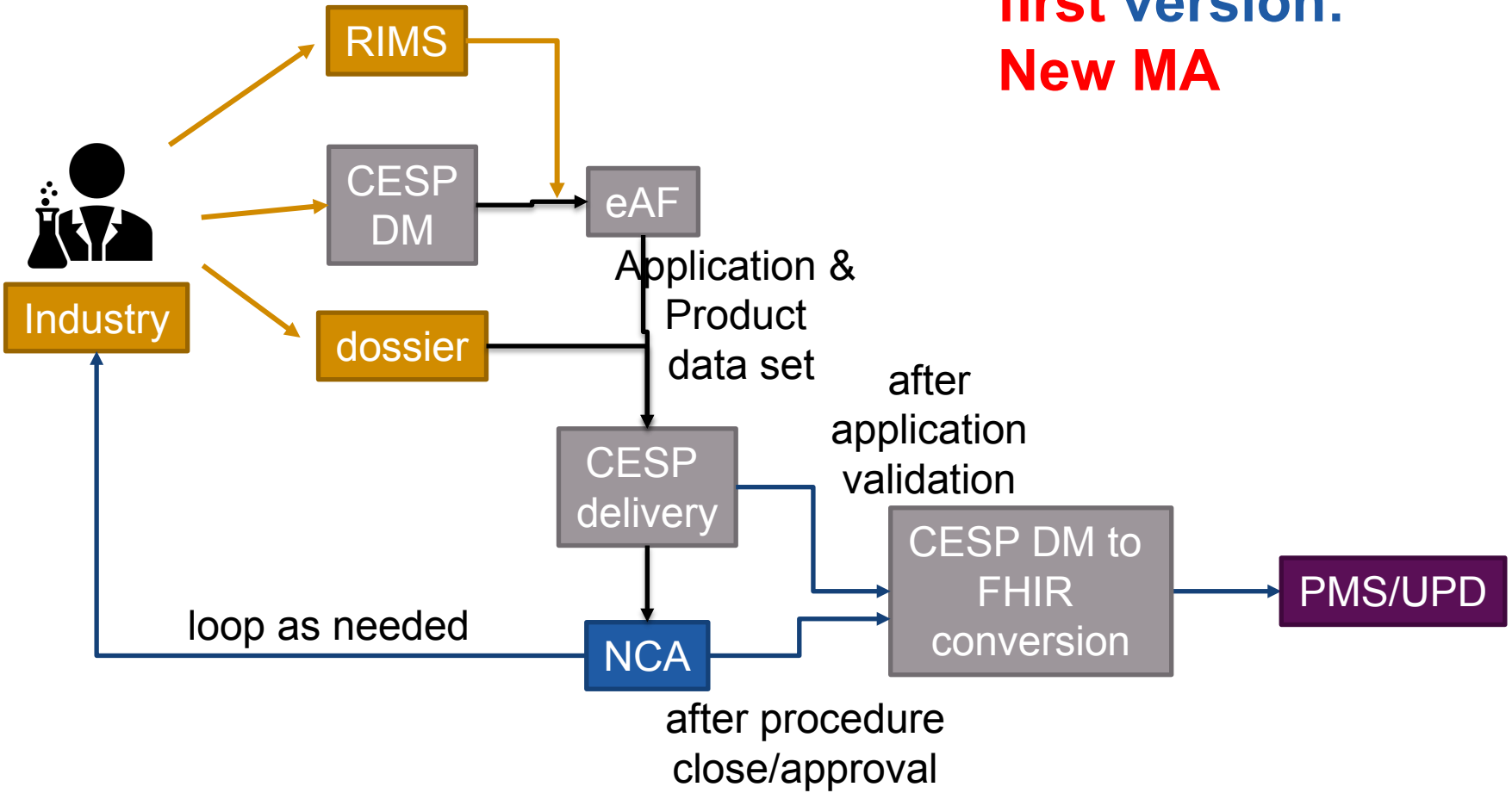
A: Industry – Minimum Viable Product: New MA



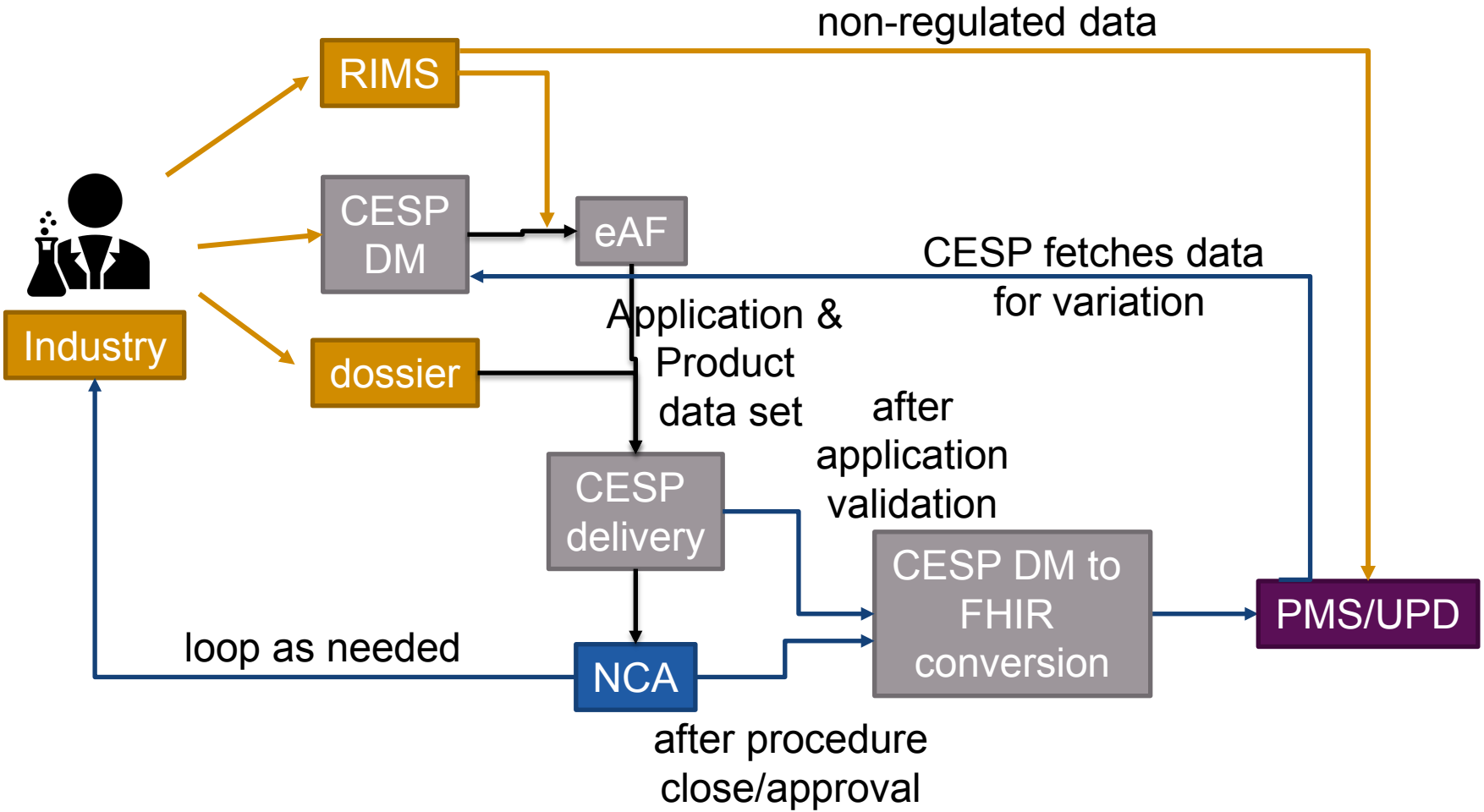
A: Industry – Minimum Viable Product: Variations



B: NCA – CESP DM first version: New MA



B: NCA – CESP DM second version: Variations/Additions



A: Industry – Minimum Viable Product

Pros

- Not dependent on CESP delivery and timeframe
- FHIR message from the beginning
- Could be used to submit non-regulated information (sales, availability, QPPV, etc)
- Industry responsibility for tool?

Cons

- Two product data sets – one in eAF, one from FHIR tool
- Tool has not started to be developed
  - multiple data sets need to be developed: new human, new vet, variations, parallel trade/import, etc
- NCAs need to look at two data sets and compare with Module 3
- NCAs potentially receive two data deliveries for one application procedure
- How do we ensure that the data set submitted from the FHIR tool is exactly what the NCAs have approved

B: NCA TOM based on CESP DM version 1

Pros

- Tool already under development
- Tool for comparison of two data set version already in scope
- No extra tool to train on and maintain
- NCAs only need to compare one data set to Module 3
- Common process for human and vet

Cons

- Uncertain financing and delivery time frame
- Data in new XML-format, not FHIR
- Data set not complete
  - QC/Art 57 process will be needed for data missing in data set
- No variation form in development yet
- Variation eAF based on present form has little structured data – new concept for form needed
- Tool needed to submit non-regulated data – CESP?
  - QPPV, sales, availability etc

QC/Art 57 process when there is a tool

- Will still be needed regardless of the tool but more limited in scope
  - less data to do check in the quality control process
  - in case some NCAs do not do the quality control during the process
    - same QC/Art 57 process for these products as if there was no tool

If we have no tool

- Use the existing QC/Art 57
- No change in data quality

Next steps?