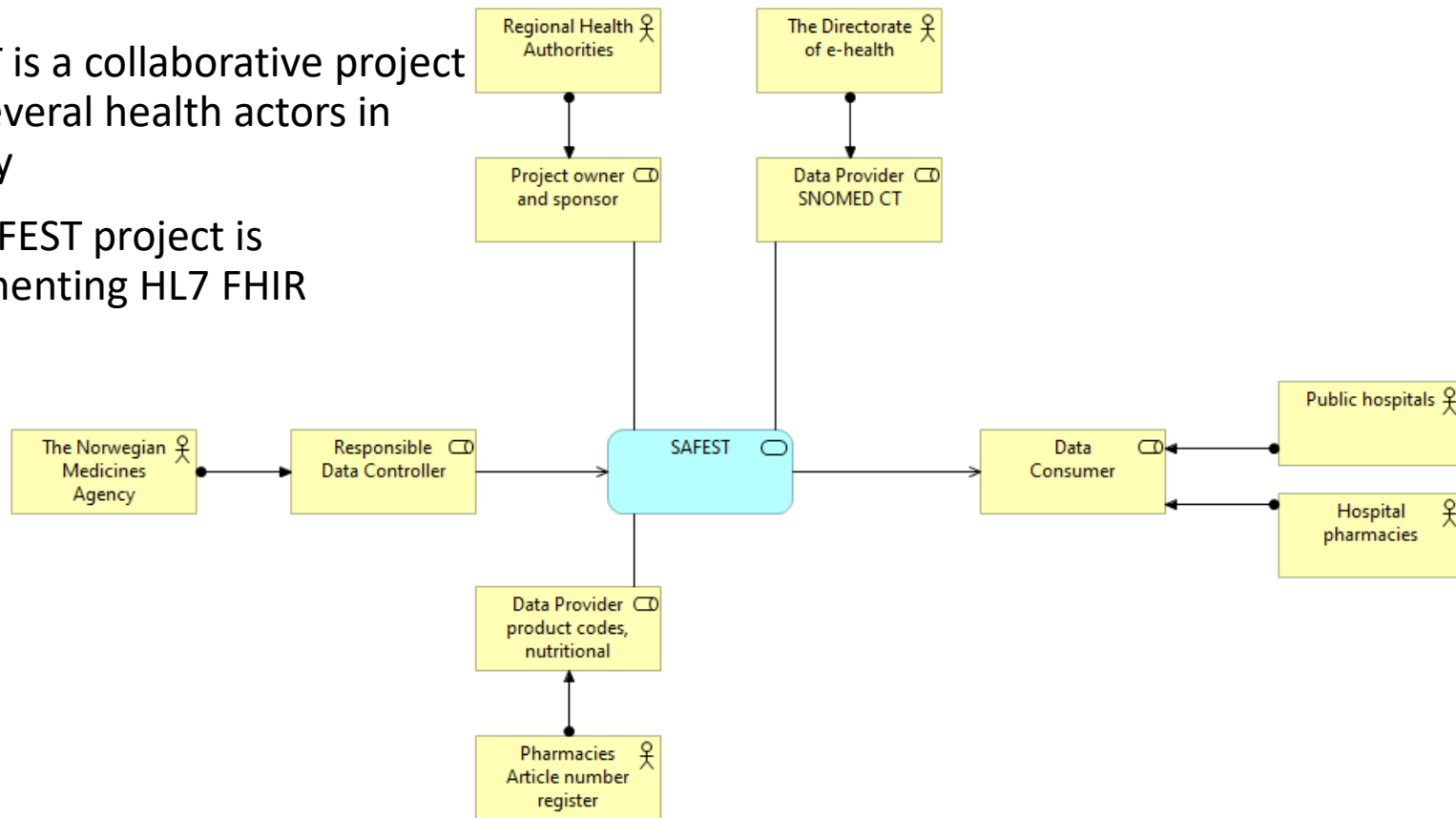# The Norwegian Medicines Agency's road towards ISO IDMP

- ❑ **Implementation of the HL7 FHIR**
- ❑ **Implementation of ISO IDMP**
- ❑ **Connection to EMA's SPOR databases**
- ❑ **Download and upload of authorized medicinal products**

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Implementation of HL7 FHIR

- SAFEST is a collaborative project with several health actors in Norway

- The SAFEST project is implementing HL7 FHIR


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Background for SAFEST project

Today The Norwegian Medicines Agency (NoMA) is providing data about medicinal products through the FEST xml message. Secondary health care needs

- Master data for exchange in clinical processes and IT-systems

- Data for ordination of active substance

- Package info, product codes and detailed data about, e.g., strength, dose form
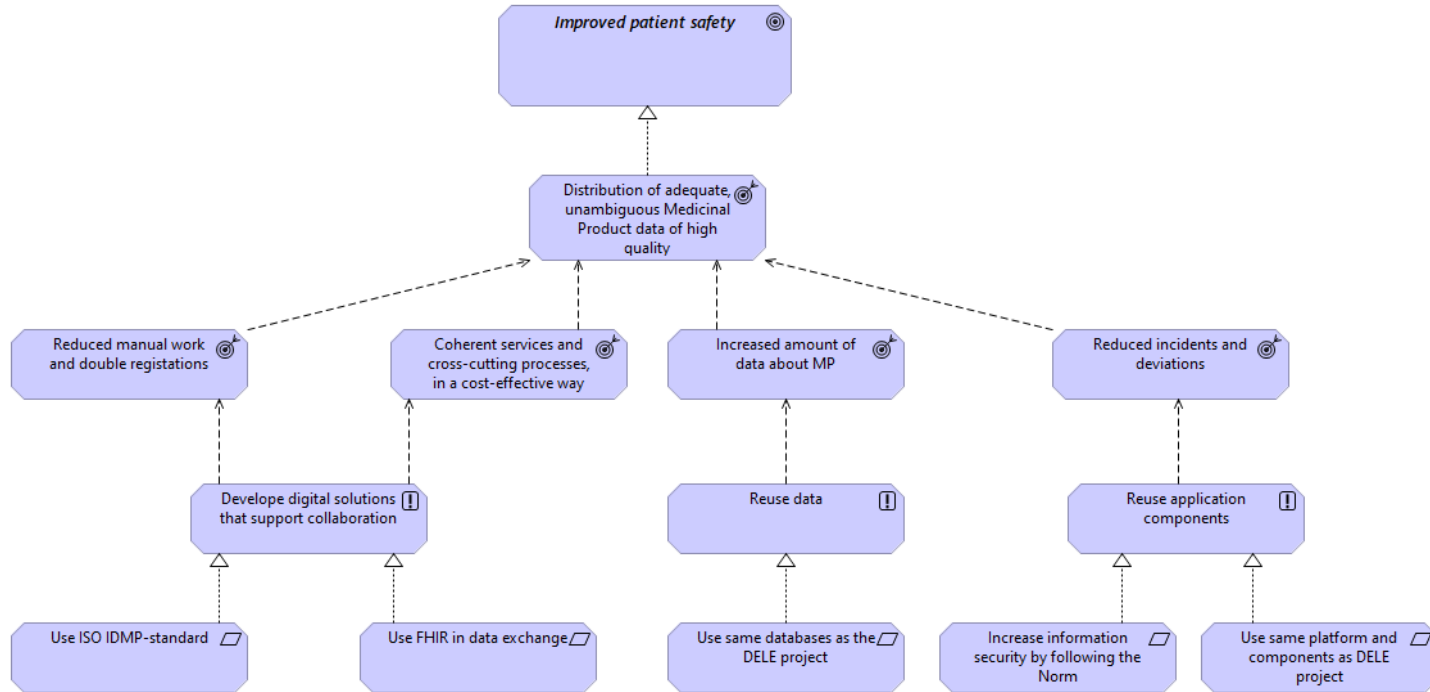
- Data on nutritional products
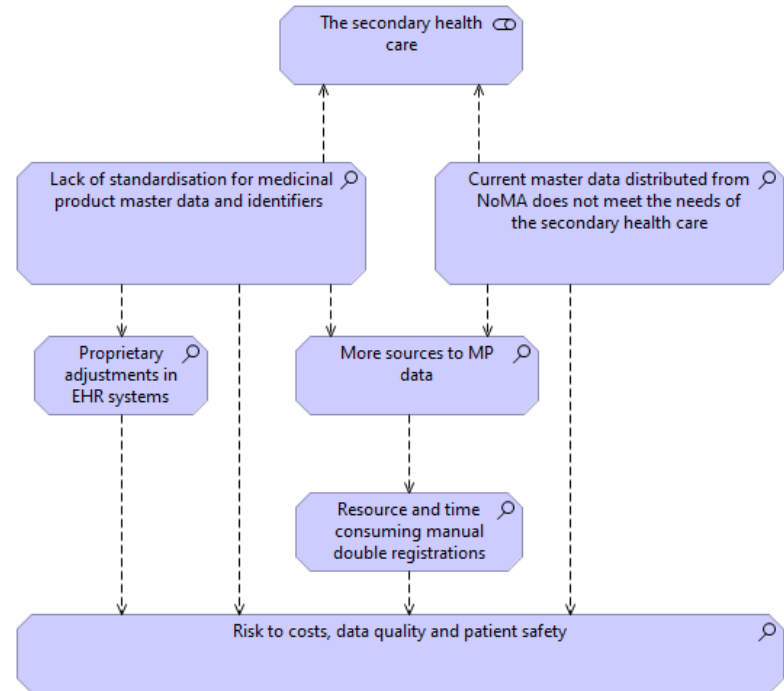
Motivational context for the SAFEST project
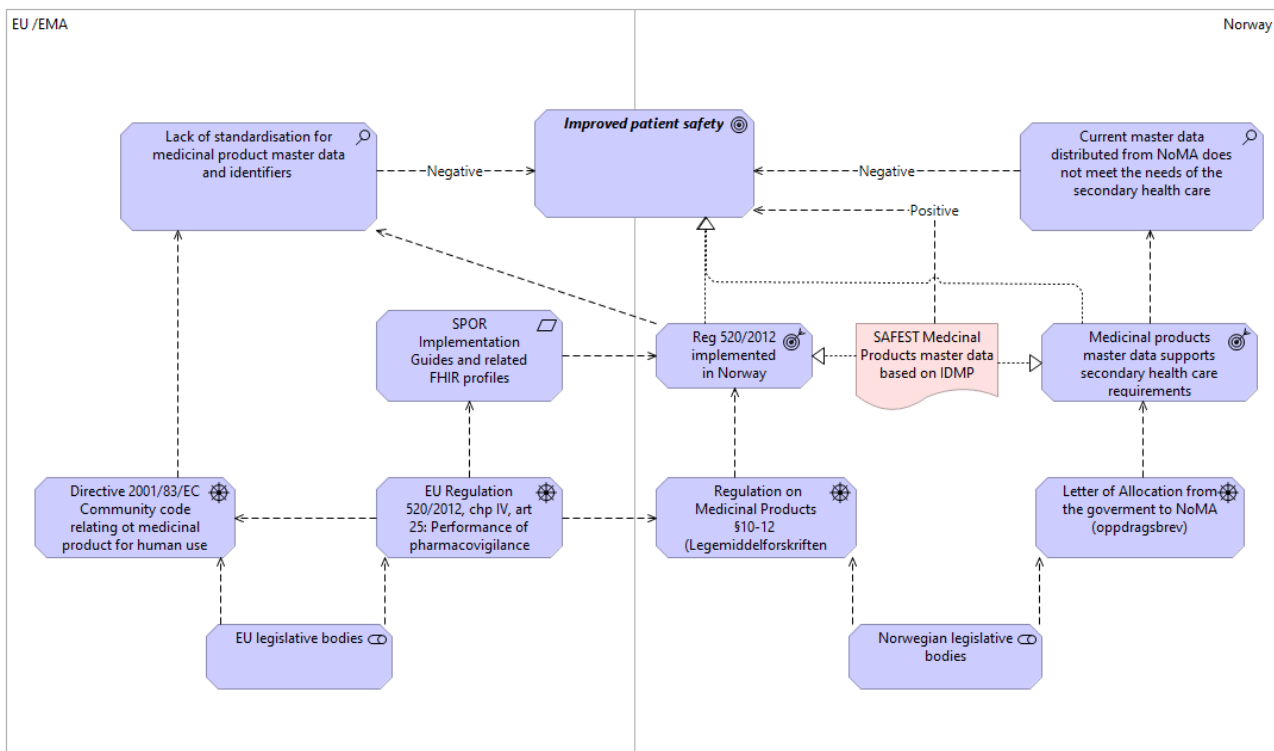
The vision is improved patient safety

by distribution of adequate, unambiguous, high-quality data about medicinal products

FHIR resources in SAFEST

- SAFEST aims to provide legacy data about medicinal products transformed directly to FHIR

- The first release in SAFEST focuses on the two primary resources: MedicinalProductDefinition & PackagedProductDefinition

- Upcoming release will add Manufactured- & AdministrableProductDefinition as well as Ingredient & SubstanceDefinition

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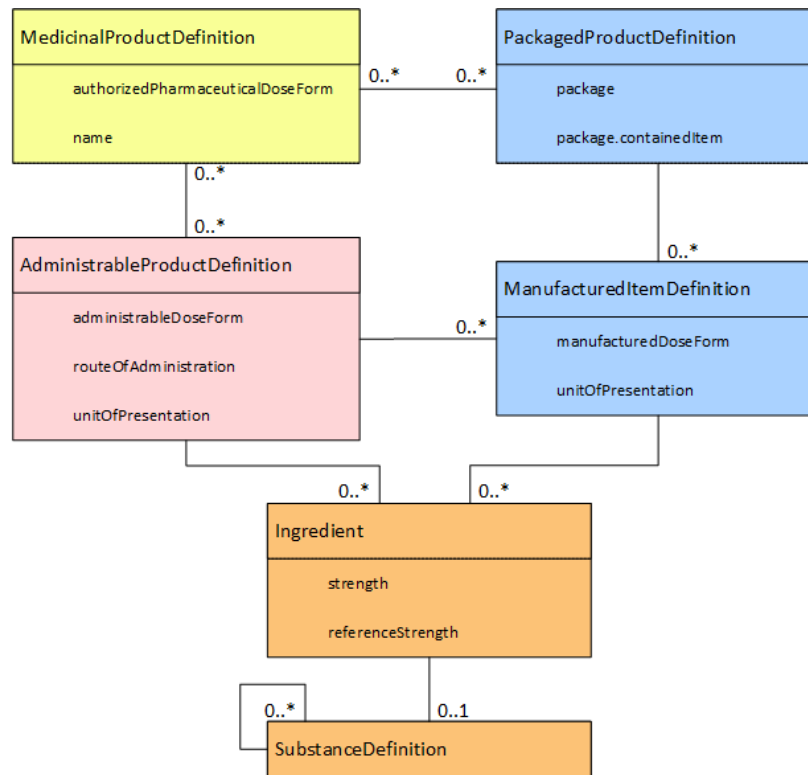
Functions in SAFEST

The SAFEST solution consists of three main functions/modules:
1. Data transfer
2. Quality improvement
3. Distribution
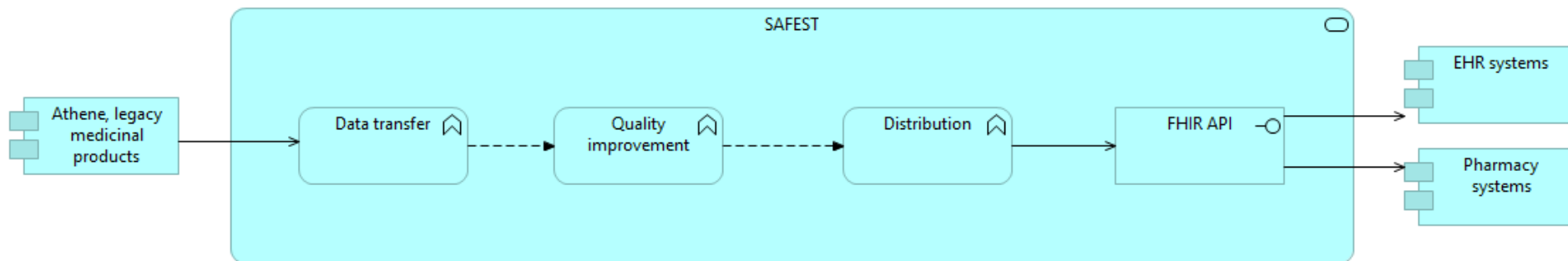
Transfer from on premise into cloud

1. The transfer function starts with an export of non-confidential data from the medicinal product database on premise
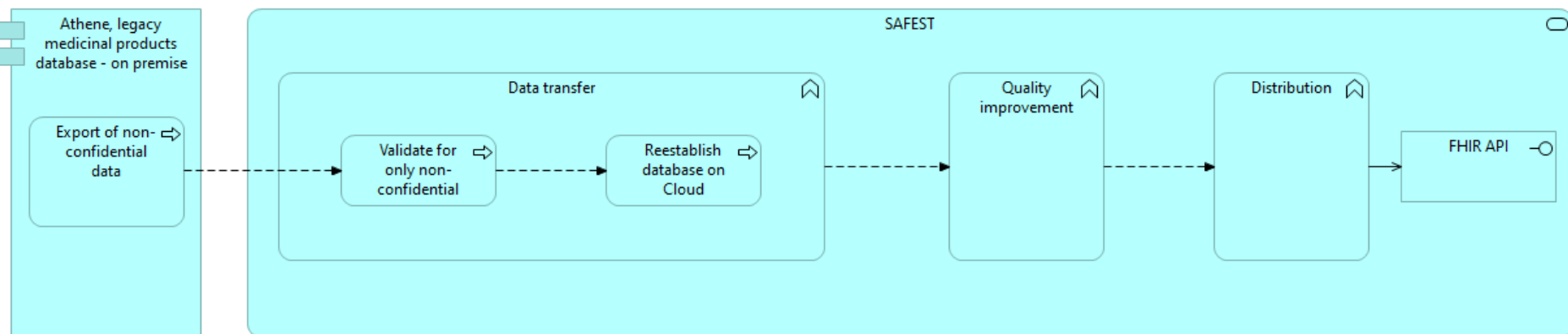2. The data is validated for only non-confidential data
3. The database is re-established in the cloud

Quality improvement

1. The quality improvement starts with a check for new version
2. Data are being enriched with product codes and package level
3. Data are transformed into FHIR format and structure
4. Data are validated
   a) If something is not according to the rules, the data is sent for manual quality control and mitigation
   b) If everything are according to the rules, the data is compiled and exported for distribution
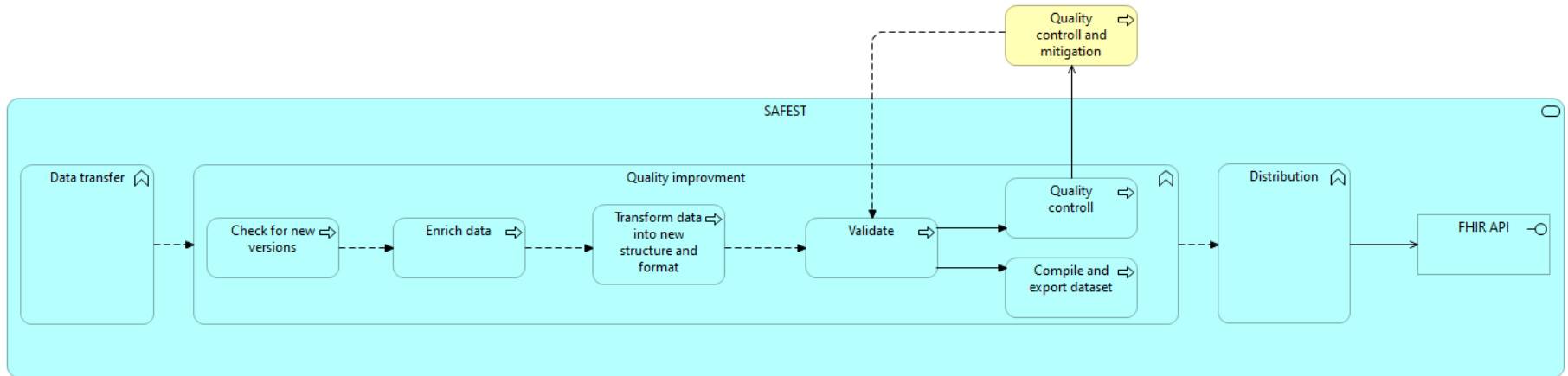
Distribution

1. The distribution starts with building the new dataset

2. The new dataset is published and back-uped

3. The previous dataset is retired
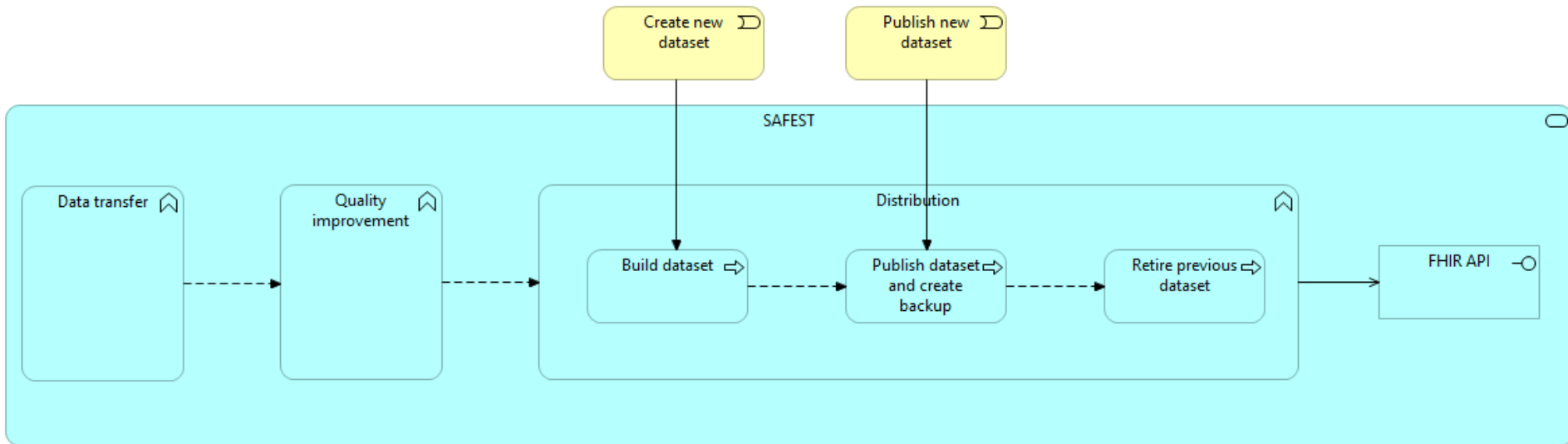
Technical platforms

- The Data Transfer module is served by MS Azure
- The Quality Improvement module with transformation to FHIR format and structure, is served by process pipelines in Sesam
- The Quality Control processes is handled through the GUI in MS Dynamics
- The Distribution module is served by MS Azure
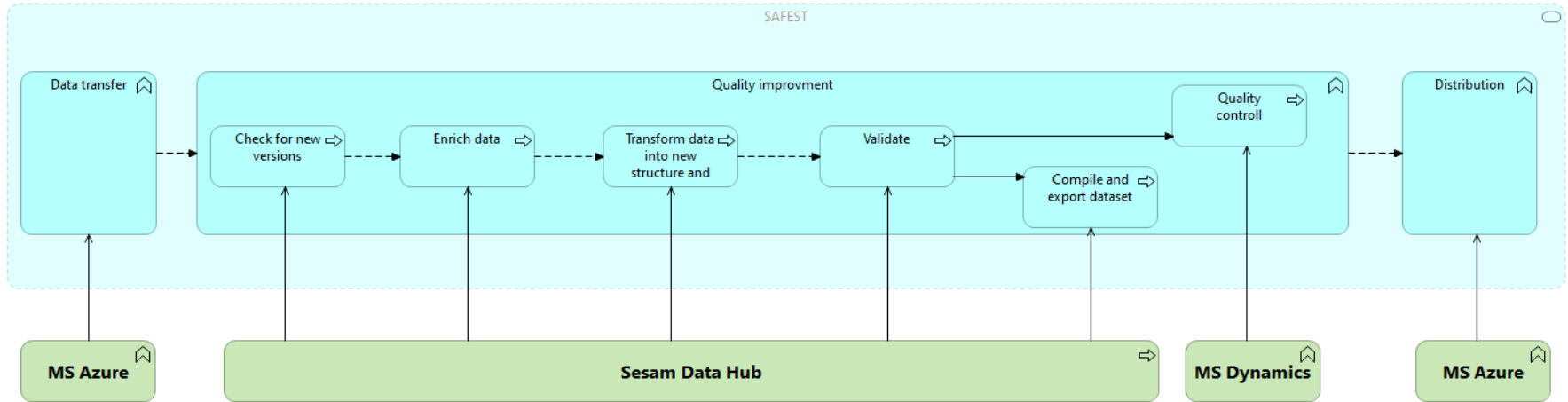
Implementation of the ISO IDMP standards

- NoMA's current on-premise application portfolio will be replaced by new developed applications for a Cloud solution, our project called DELE

- The Sesam data hub will serve the integration with EMA

- Governance of medicinal product's portfolio and case handling will be done in Dynamics and SharePoint

- Data about medicinal products will be distributed on FHIR through Sesam for clinical use

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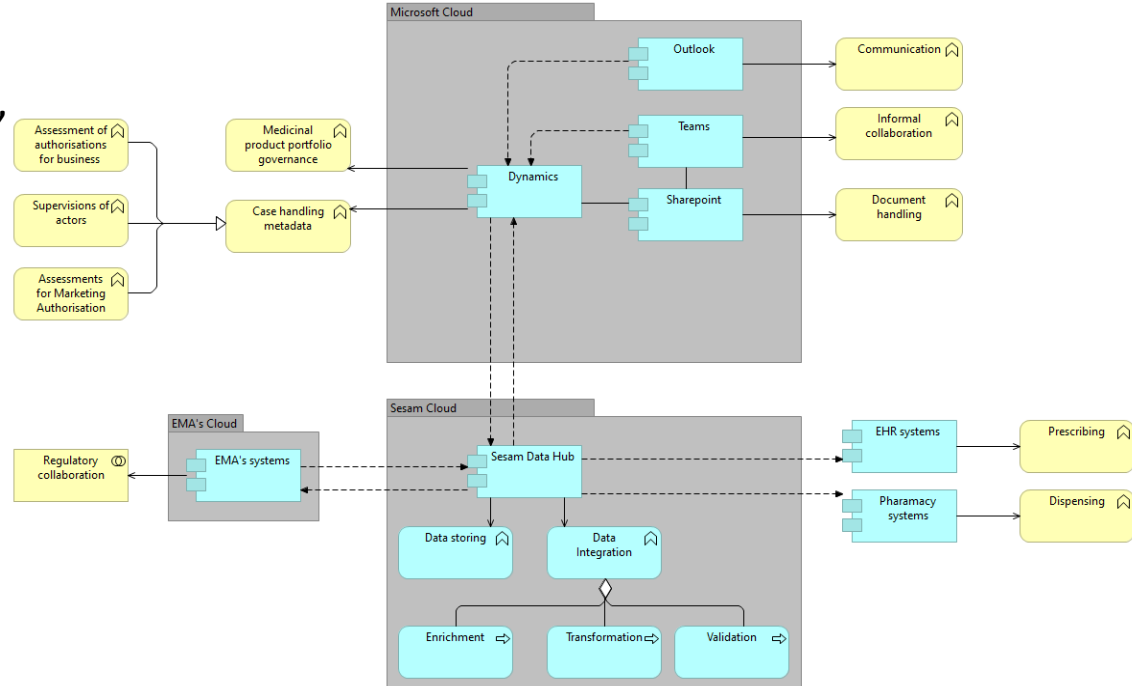
Migration of legacy data into IDMP structure
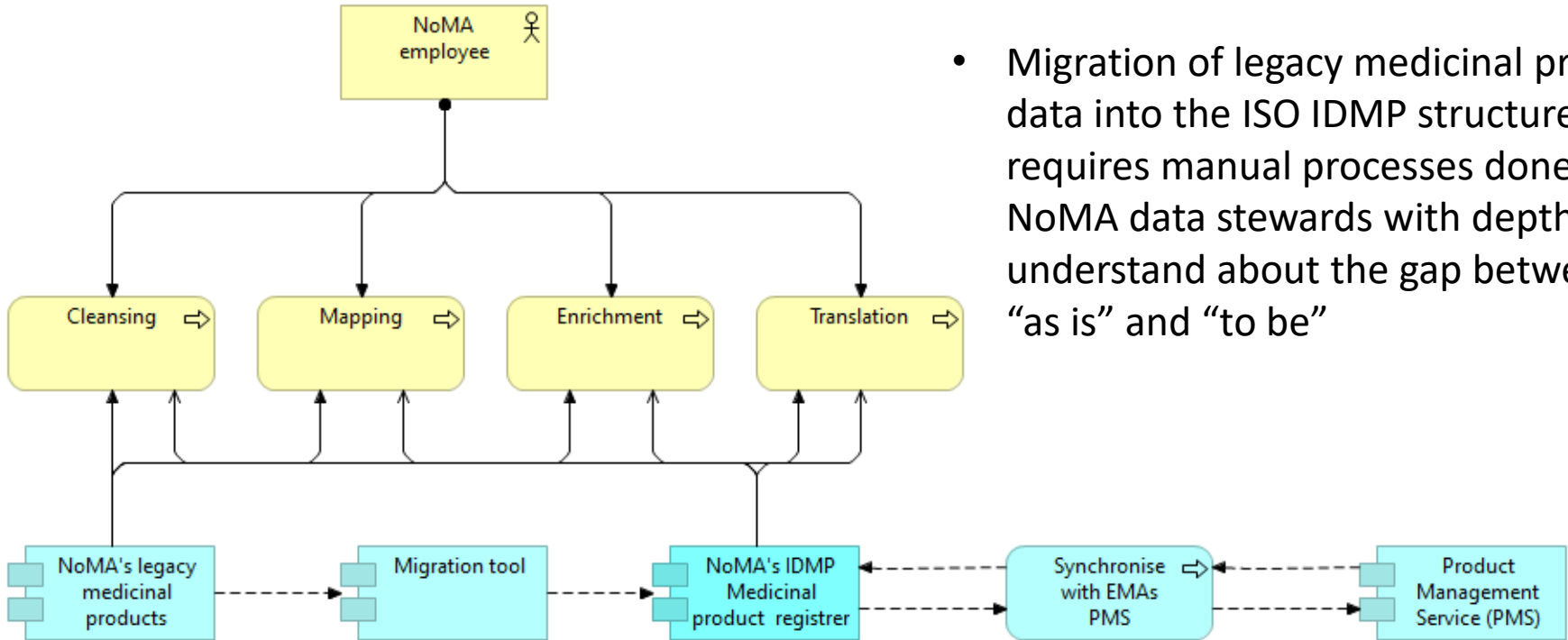
- Migration of legacy medicinal product data into the ISO IDMP structure requires manual processes done by NoMA data stewards with depth understand about the gap between "as is" and "to be"

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NoMA's national SPOR databases

NOMA will develop national databases for Substances, Products, Organisations, Referentials (national SPOR). The national SPOR will be served by the Dynamics platform.

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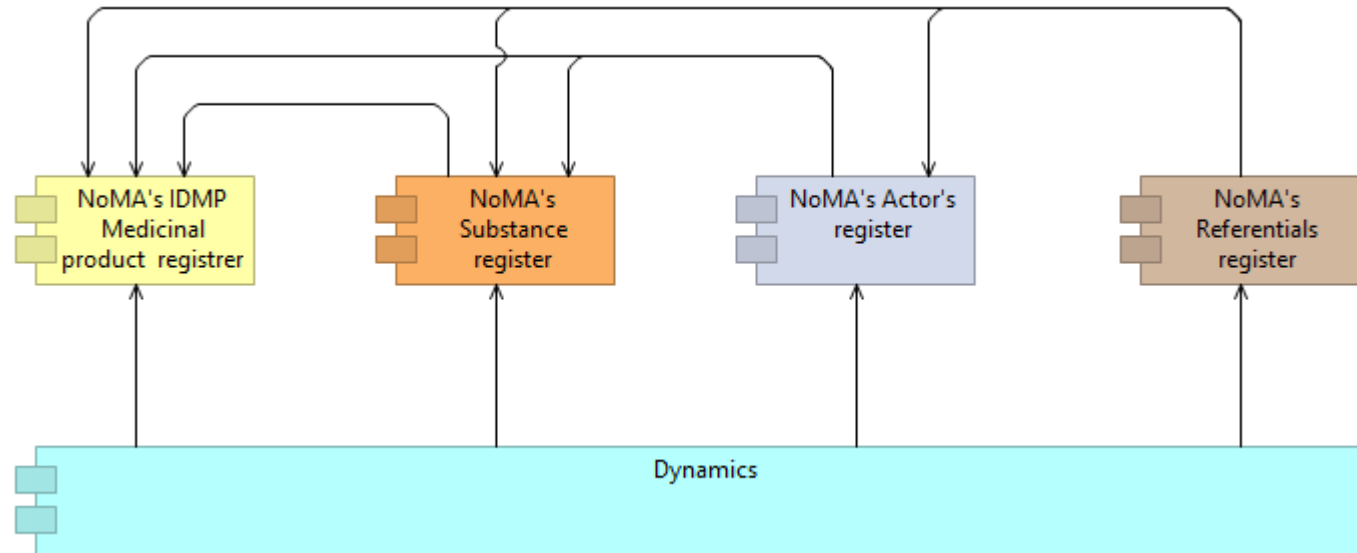
Use of EMA's SPOR data management services

- NoMA's national SPOR databases will synchronise with EMA's
- Data will be exchanged through FHIR
- Synchronising details will be decided later
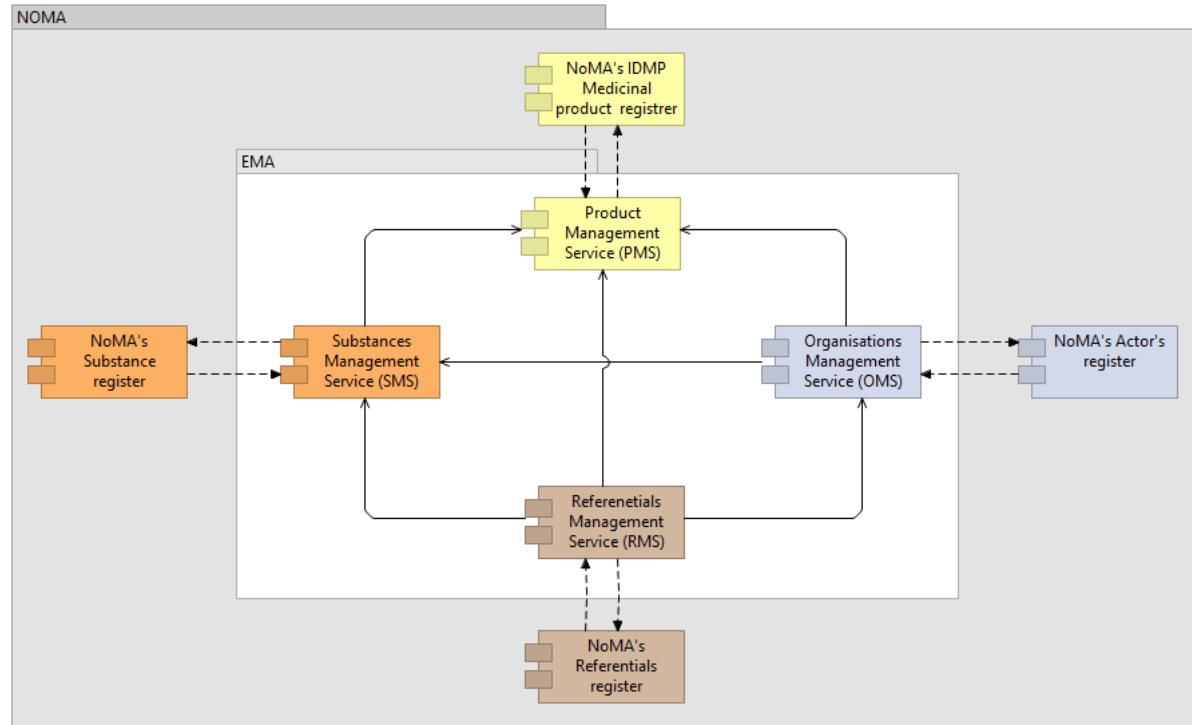
The steps towards a full ISO IDMP implementation

- Baseline - legacy systems
- NoMA's OMS with OrgID and LocID implemented
- NoMA's RMS with ListID and TermID implemented
- NoMAs SMS with SMSID implemented
- IDMP implemented in NoMA's PMS
- Exchange of data with EMA on FHIR
- Distribution of fully IDMP described Medicinal Product data

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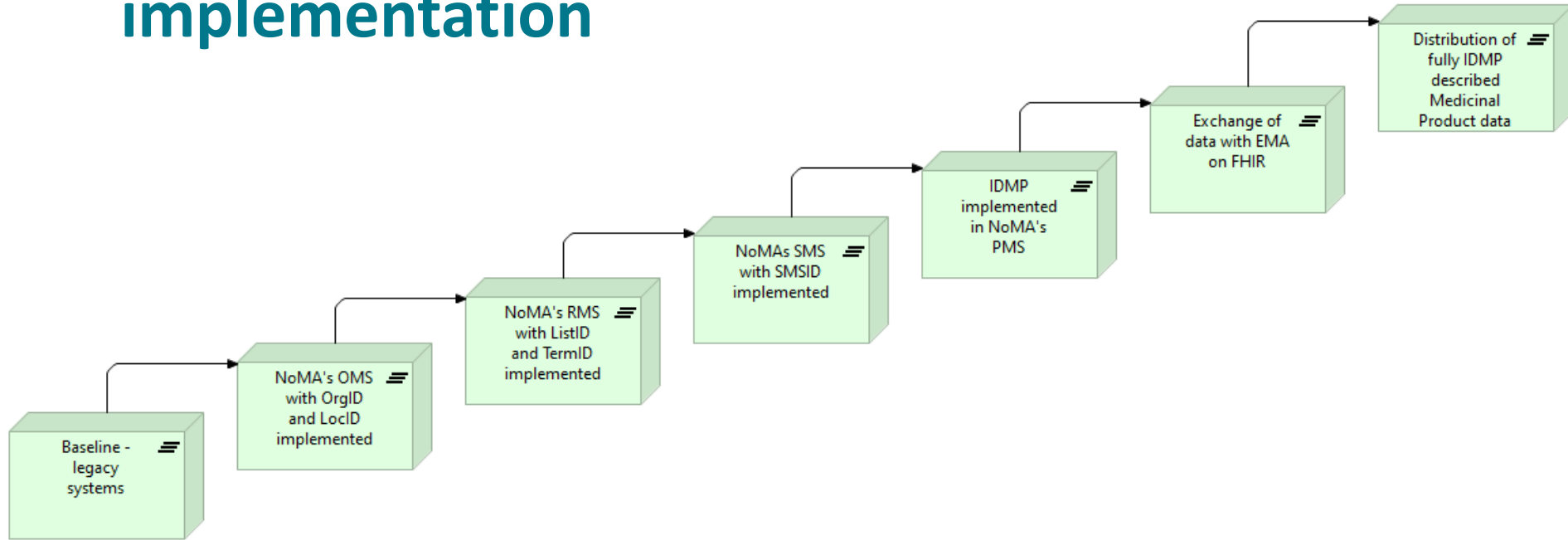
Work packages and deliveries to realise the ISO IDMP implementation and migration

Baseline - legacy systems

NoMA's OMS with OrgID and LocID implemented

NoMA's RMS with ListID and TermID implemented

NoMAs SMS with SMSID implemented

IDMP implemented in NoMA's PMS

Exchange of data with EMA on FHIR

Distribution of fully IDMP described Medicinal Product data

Process system Supervisions and Business auth

NoMA's Actor's Register

Referentials Register

Process system Marketing Auth. Assessment

Substance Register

Medicinal Product Register

FHIR integration with DADI

FHIR synchronising with EMA's SPOR

FHIR distribution of Medicinal Product data

Release 1 - Replace legacy system Supervisions and Business authorisation
- Develop new actor's register and process system Supervisions, business auth
- Migrate org. data from legacy system to systems and DB
- Cleansing and mapping organisation data

Release 2 - Replace legacy system Marketing Authorisation Assessment
- Develop new Referential register and prosess system MA assessments
- Import data from EMAs RMS
- Migrate data from legacy MA assessment system
- Translate RMS terms from EN to NO

Release 3 - Replace legacy system Medicinal Products
- Develop new Substance register and Medicinal product databases
- Migrate data from legacy medicinal product database
- Cleansing, mapping, enrichment and translation of data about substances
- Cleansing, mapping, enrichment of data about medicinal products

Release 4: Exchange of data with EMA on FHIR
- FHIR integration with DADI and receiving eAF on FHIR
- Develop synchronisation NoMA's SPOR with EMA's SPOR

Release5 : Distribution of Medicinal Product data on FHIR
- Transform Medicinal product IDMP data to FHIR
- Distribute Medicinal Product data on FHIR for Clinical Use

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