



European Medicines Verification Organisation



European Federation of Pharmaceutical Industries and Associations



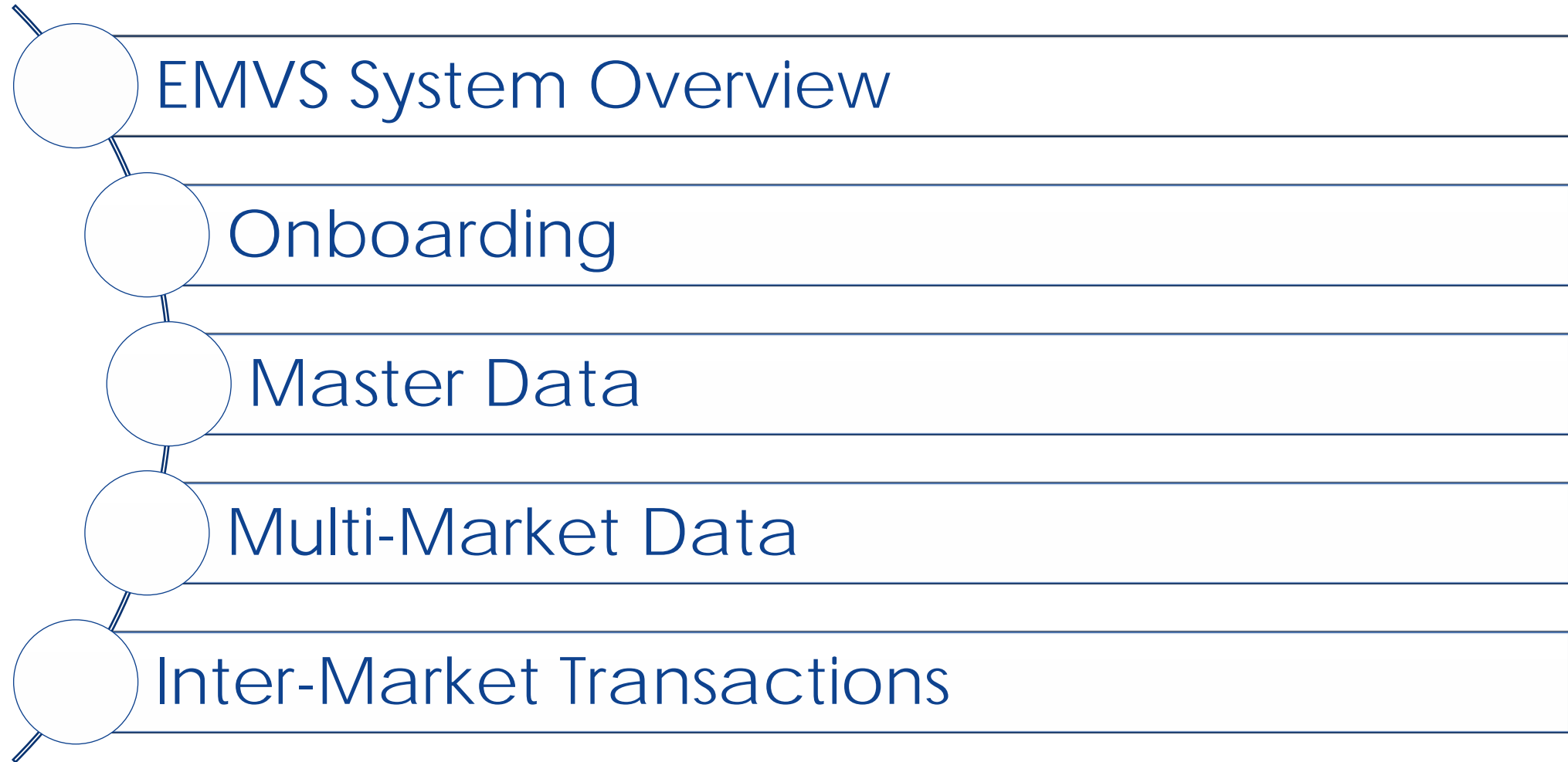
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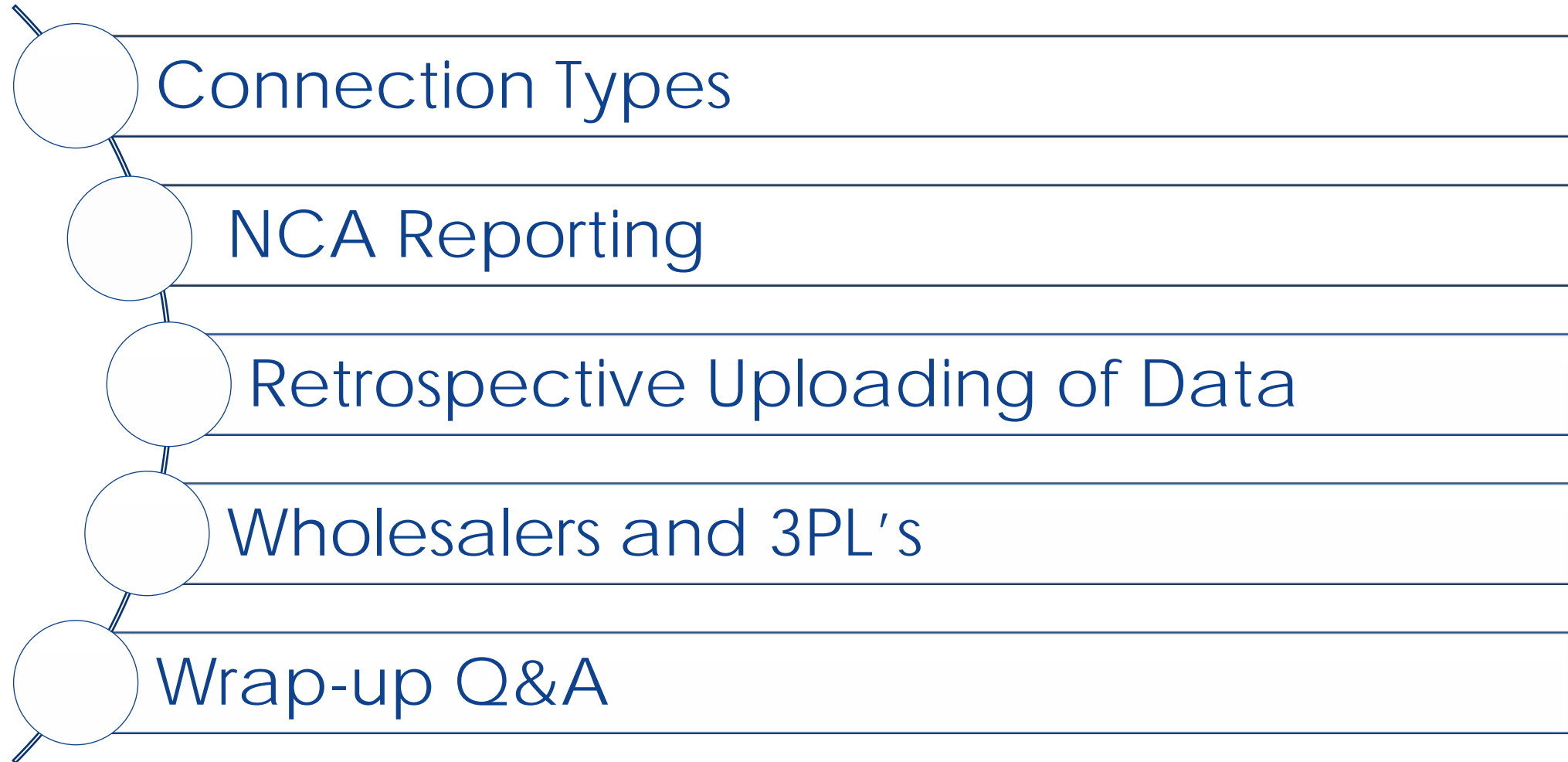
FIMVO OBP WORKSHOP

Paul Mills - EMVO

AGENDA I



AGENDA II



SESSION GUIDELINES

- Questions while I talk are great – helps with the flow
 - I might ask to delay a response if it's coming up in a later slide.
- Happy if you want to ask about things not directly covered – make use of having me here.
- Please remember that we are all learning.
 - There is a specification for EMVS (the infamous URS)
 - Reality says that a system of this size and scope is unlikely to be 100% described as we need in the URS – so we adapt when needed.
 - I'm here to learn as much as you are.

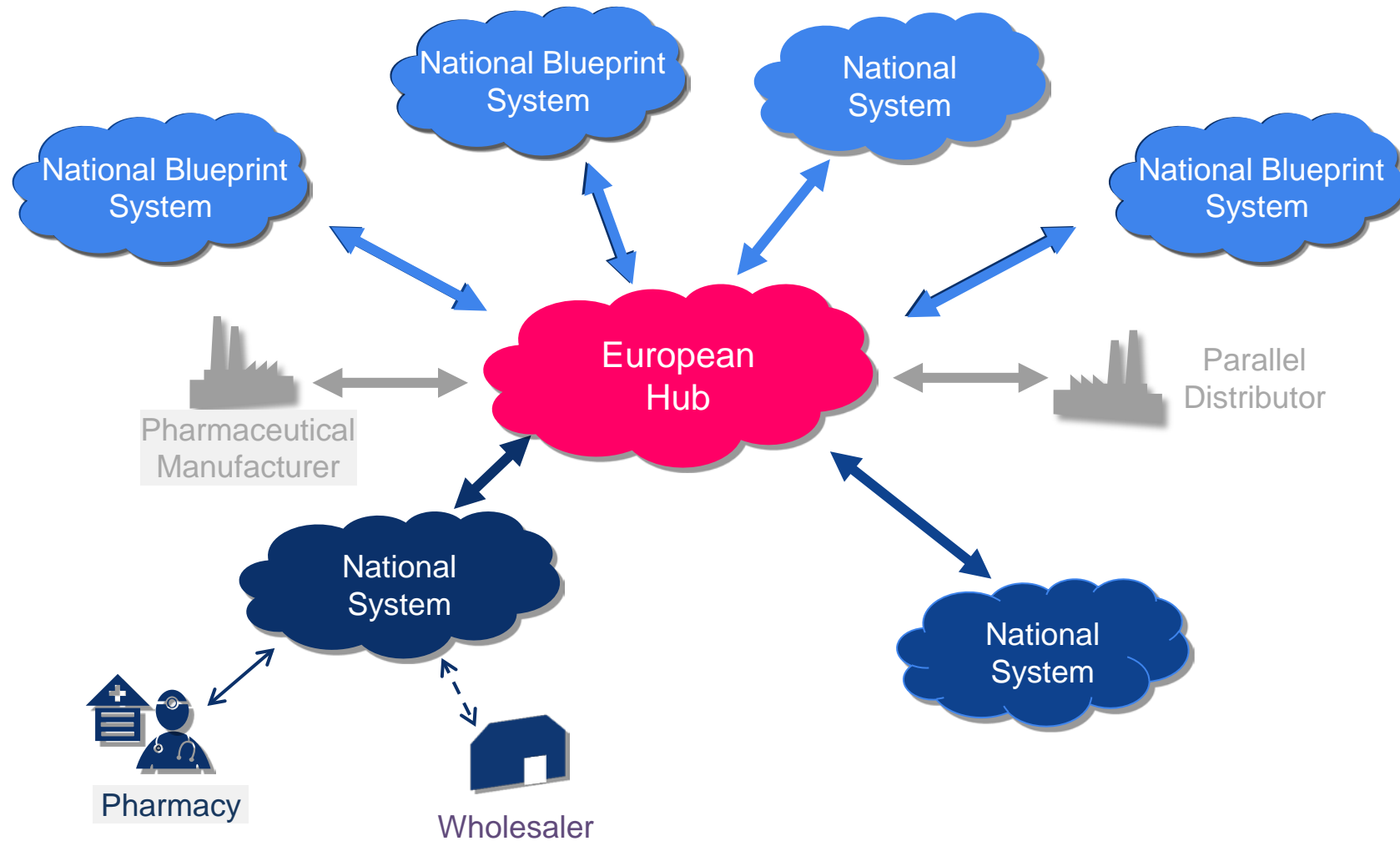
EMVS OVERVIEW

- EMVS is a DISTRIBUTED IT system.
- At its heart is the European Hub
 - All On-Boarding Partners (OBP's) (e.g. MAH's or MFR's) for original packs and Parallel Distribution connect to the Hub.
 - The Hub distributes data received from OBP's to the National Medicines Verification System's (NMVS).
 - The Hub manages 'Alerts' received from NMVS's and sends them to the relevant OBP.
 - The Hub manages parallel trade reconciliation.
 - The Hub handles Multi-Market Pack (MMP) data and the market synchronisation of decommissioning. It also handles cross-border verification/decommissioning known as Inter-Market Transactions (IMT)
 - The Hub saves each OBP having to connect to each trading market individually – it's a 'single point of connection'.

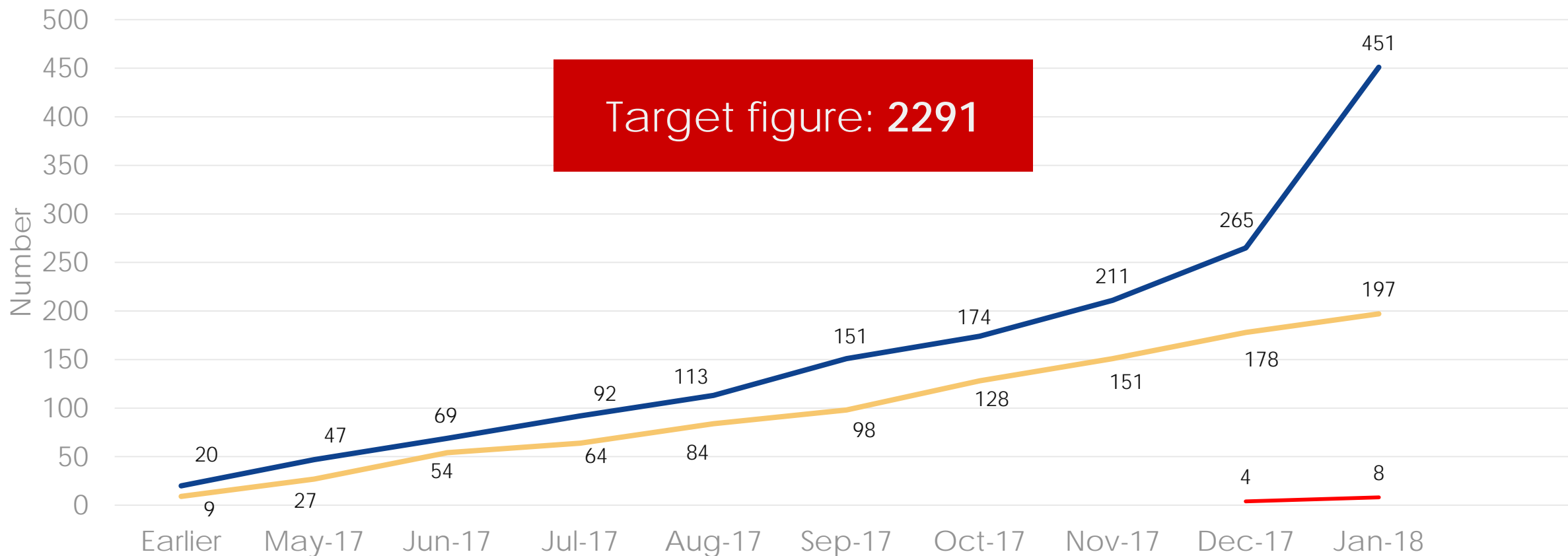
EMVS OVERVIEW

- Surrounding the Hub are NMVS's – one per market.
 - The NMVS's are the systems that Wholesale, Persons Authorised to Supply (PATS) and Hospitals connect to.
 - The NMVS undertakes the verification and decommissioning activities (the Hub doesn't hold the pack data).
 - For MMP's – each NMVS informs the Hub of the transaction and the Hub synchronises the other NMVS's where the same data is held.
 - For out of market enquires, the NMVS asks the Hub to find the market from which a decommission or verification enquiry can be satisfied.
 - The NMVS also creates most of the reports required for the local NCA (some may be generated by the Hub upon request)

EMVS OVERVIEW



ON-BOARDING – CURRENT STATUS



Target figure: 2291

OBPs in PRD: Biogen International GmbH – Bayer AG – Amgen Europe BV – F. Hoffmann La Roche Ltd – Janssen Pharmaceutica NV – UXA farma – Naturland Magyarország Terelo es Kereskedelmi Kft – Almus Pharmaceuticals Limited

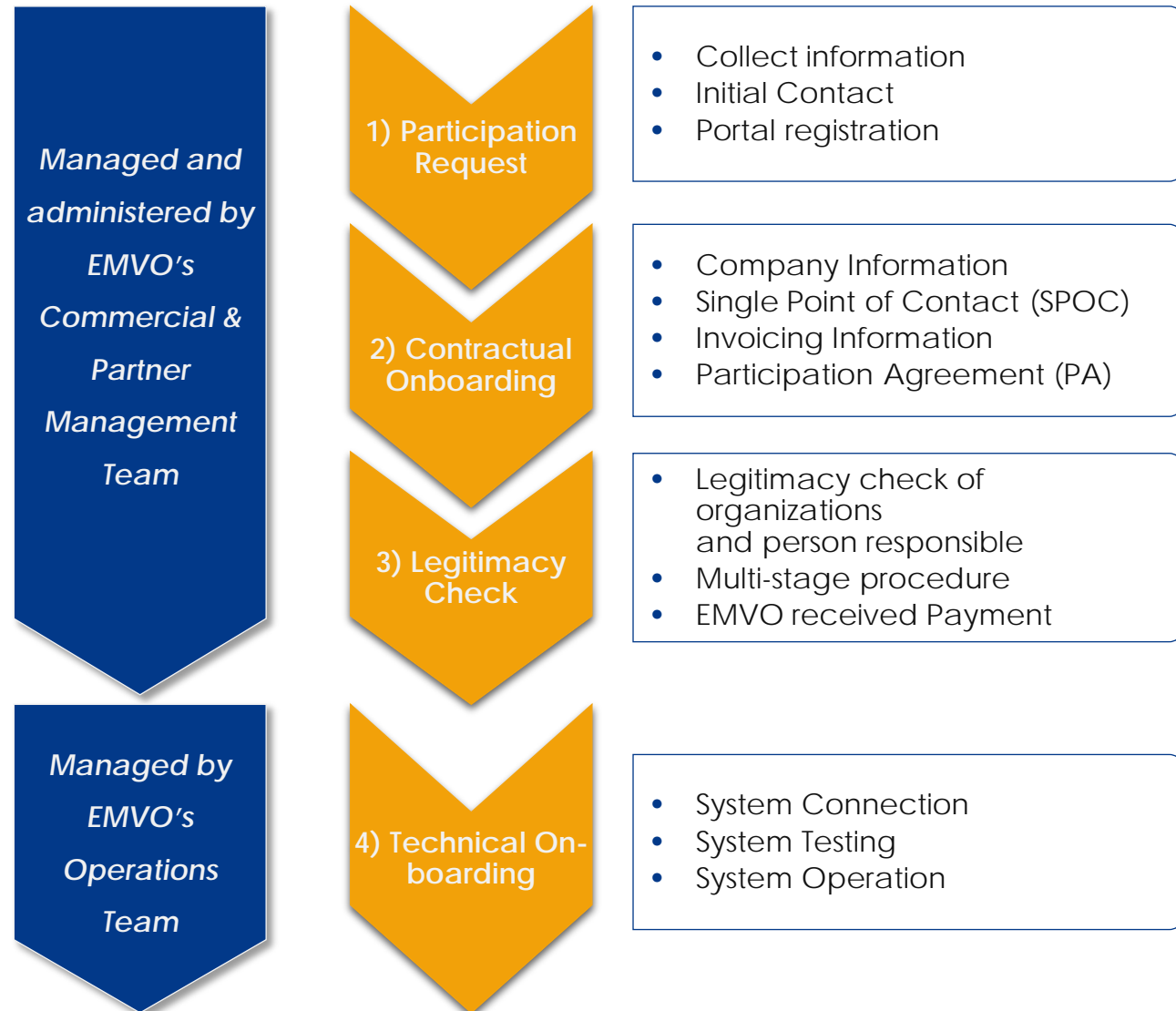
- Signed Participation Agreements
- Legitimacy check passed
- OBPs connected to Hub V2 (PRD)

WHAT IS AN "OBP"?

- OBP means **On-Boarding Partner**. The OBP is the contracting party of EMVO; it concludes the Participation Agreement (PA).
- The OBP **represents the Marketing Authorization Holders (MAH)** on behalf of which it will upload data for in the European Hub. It has therefore to be legally authorized to conclude contracts on behalf of a MAH/a group of MAHs.
- The OBP has to be **affiliated (*) to the MAH(s)** on behalf of which it will upload data in the European Hub.
- The OBP should be located in the European Economic Area.
- **The OBP can only upload product data for:**
 - its affiliated MAH's – the responsibility for upload vests in the OBP who can delegate to the MAH if wanted.
 - a manufacturer as long as the marketing authorization of the related products lies within the OBP corporation. It's for the OBP to work out how to interface local QP's and RP's with the uploading process.

(*) Affiliate shall mean, in relation to a Party, any other person affiliated with such Party within the meaning of Article 11 of the Belgian Code of Companies (it being understood, for the avoidance of doubt, that the definition set out in said Article 11 is agreed to also apply to non-Belgian persons).

ON-BOARDING PROCESS



ON-BOARDING FEE

In order to support the On-boarding costs, EMVO will charge the OBP a One-Time Fee. The applicable On-boarding fee that will be invoiced to the OBP depends on the following elements:

- The number of MAHs in Europe (European Economic Area and Switzerland) the OBP represents
- The timing when the OBP uploads a valid Participation Agreement on the OBP Portal.

	Early bird On-Boarding fee	From the 15 th January 2018	From the 15 th June 2018
OBP with >12 MAHs	€20.000	€30.000	€45.000
OBP with 6-12 MAHs	€10.000	€15.000	€22.500
OBP with 3-5 MAHs	€8.000	€12.000	€18.000
OBP with 2 MAHs	€6.000	€9.000	€13.500
OBP with 1 MAH	€3.000	€4.500	€6.750

NB: Please note that EMVO reserves its right to potentially apply an additional rise of the On-boarding fee in 2018.

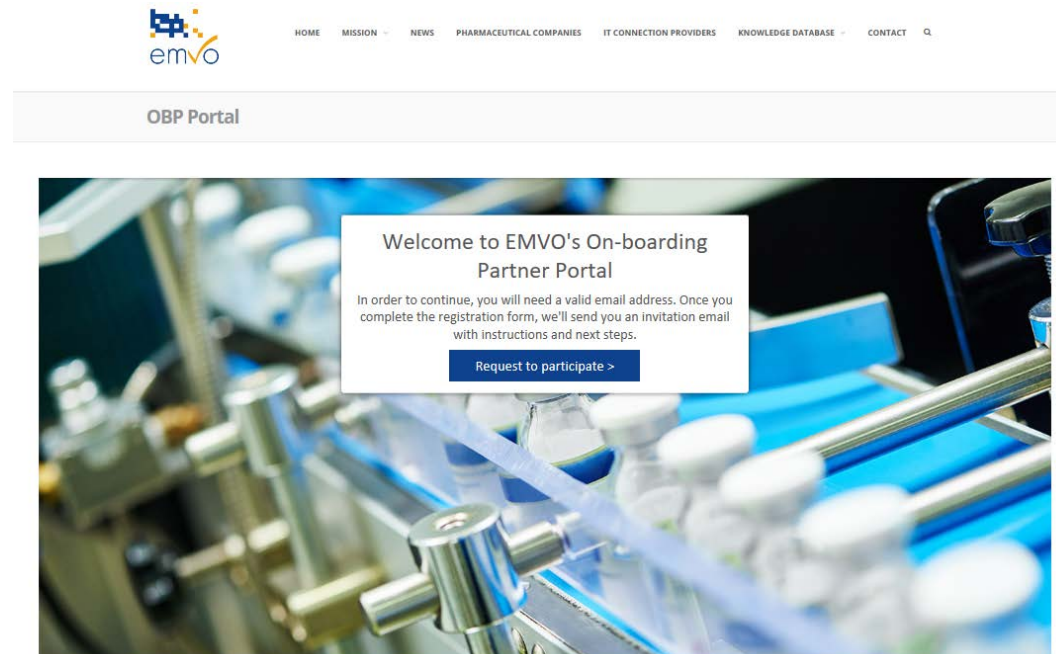
HOW DOES THE ON-BOARDING WORK?

On-boarding Partner Portal

(Support software to guide the OBPs through the requirements to connect to the EU Hub)

<https://emvo-medicines.eu/pharmaceutical-companies/obp-portal/>

Linked directly from the EMVO Website.



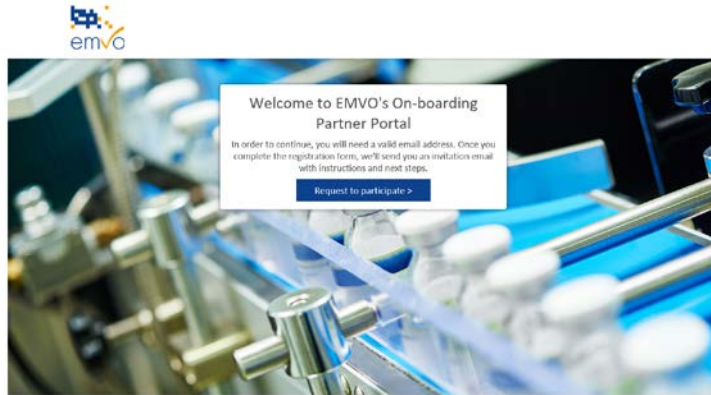
HOW TO SPEED UP THE PROCESS RIGHT FROM THE START?

Collect Information:

1. Visit EMVO **Download Section**
2. Visit EMVO **Knowledge Data Base**
3. Who will be the **On-Boarding Partner**?
4. What is my Company Registration number and VAT number?
5. Who can and will be the **Authorized Representative**?
6. Who can and will be the **Single Point of Contact**?
7. How many **MAHs** does the OBP represent?

HOW TO REQUEST TO PARTICIPATE

1. Via website – [link](#)



2. Fill in User + Company details

The screenshot shows the EMVO logo at the top left. The form title is "Request to participate". It is divided into two sections: "User details" and "Company details".

User details:

- First Name: [text input]
- Last Name: [text input]
- e-mail: [text input]

Company details:

- Company Name: [text input]
- Country of Registration: [text input]
- VAT Number: [text input]
- Type of Organisation:
 - Marketing Authorisation Holders (MAH) with Parallel Distribution activity
 - Marketing Authorisation Holders (MAH) without Parallel Distribution activity

Below the form, a note reads: "Once your request is submitted, we will create a secure area within the EMVO On-boarding Partner Portal for you in order to upload on-boarding related information like company information, contact details, product information, a non-disclosure agreement (NDA) and a participation agreement (PA)." At the bottom is a blue "Submit >" button.

3. You'll be directed to the confirmation screen

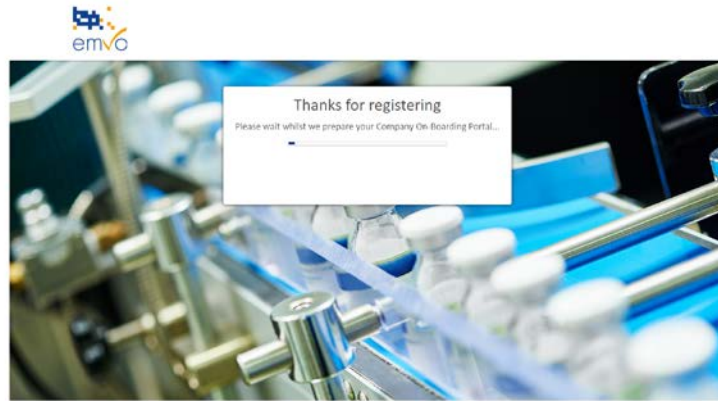


4. Check your email to validate your account

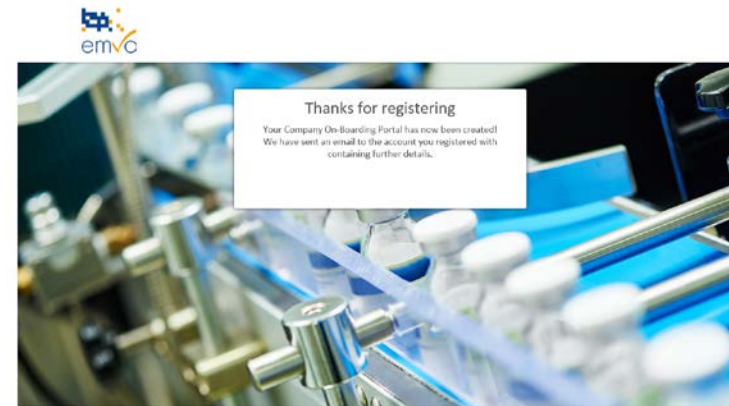


HOW TO REQUEST TO PARTICIPATE

5. Your company portal will be created



6. Your company portal is created



7. Follow the instructions in your email to login to your Company portal



8. Your Company portal is ready to On board



TECHNICAL ON-BOARDING

			Time to complete	Status
Step 1: Provide initial information			Complete	▼
Step 2: Detailed information and participation agreement			Complete	▼
Step 3: Approvals			Complete	▼
Step 4: Technical onboarding				▲
4.1	Technical InfoPack ⓘ	Open	1 min	Completed
4.2	Client Connection 1			
4.2.1	Connection Details ⓘ	Add	1 min	Not Started
4.2.2	ITE ▼			
4.2.3	IQE ▼			
4.2.4	PRD ▼			
4.3	Client Connection 2			

Trigger step 4:

- Step 3 completed

Note:
If you make use of a Gateway Connection, step 4.2.2 (ITE) is optional

Status:
Not Started
Completed

Status:
Not started
Completed

Access sub-steps

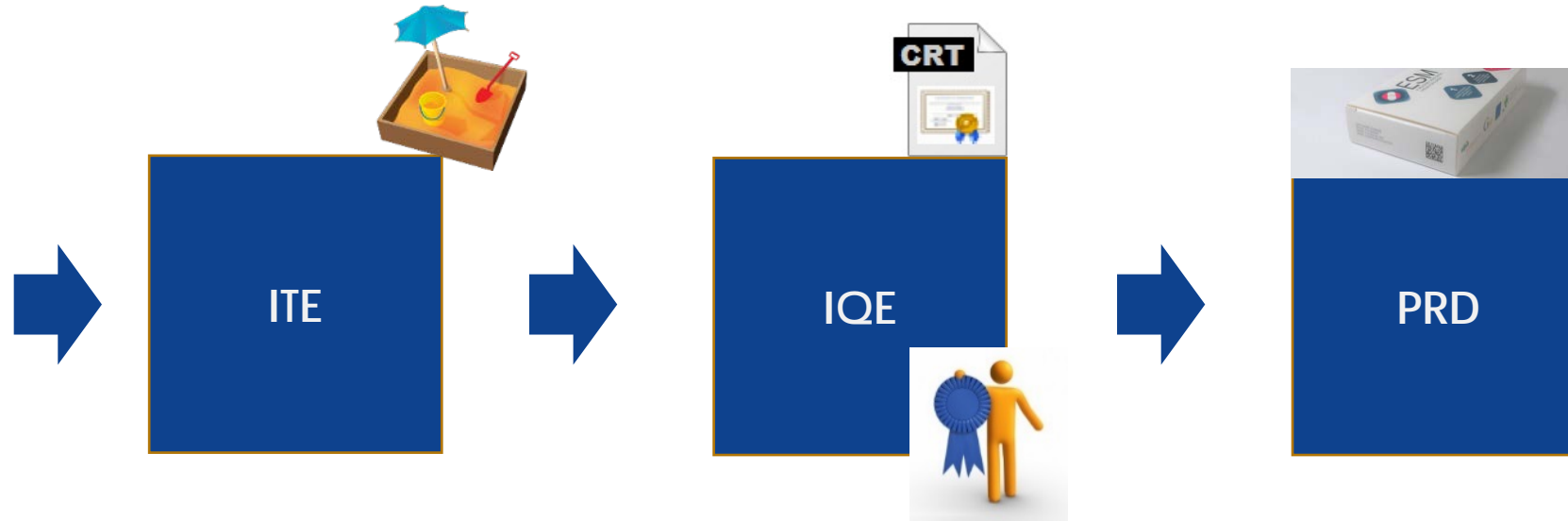
Access sub-steps

4.1 TECHNICAL INFO PACK

The Technical Info Pack contains the following information in their last available versions:

1. Documentation .NET
 - .Net Callback Service
 - .Net Hub 2.0 SDK
 - EMVS0794 - EMVS OBPs .NET SDK Installation Guide
2. Documentation JAVA
 - EMVS0787 - EMVS Java SDK Installation Instructions For OBPs
 - EMVS Java SDK_MAH_Hub_2
3. On Boarding Steps |
 - EMVO_0077_OBP On-boarding Guideline
 - EMVO_0086_OBP On-Boarding Presentation
 - EMVO_0117_Creating CSR Files
 - EMVS0714 - EMVS SDK for OBPs
 - EMVS0789 - EMVS SDK Quick Start Guide For OBPs

EU HUB ENVIRONMENTS



ITE environment

- Integrated Test Environment
- Used as sandbox by multiple OBP's
- Integration testing of OBP's connection

IQE environment

- Integrated Quality Environment
- Used for Quality- & Certification testing by multiple OBP's
- Validated environment

PRD environment

- Productive Environment
- Validated environment

ITE: Integration Quality Environment
IQE: Integration Quality Environment
PRD: Productive Environment

EMVS DATA

- Master Data

- The 'stuff' that describes the product/SKU and that defines which markets it will be sold.

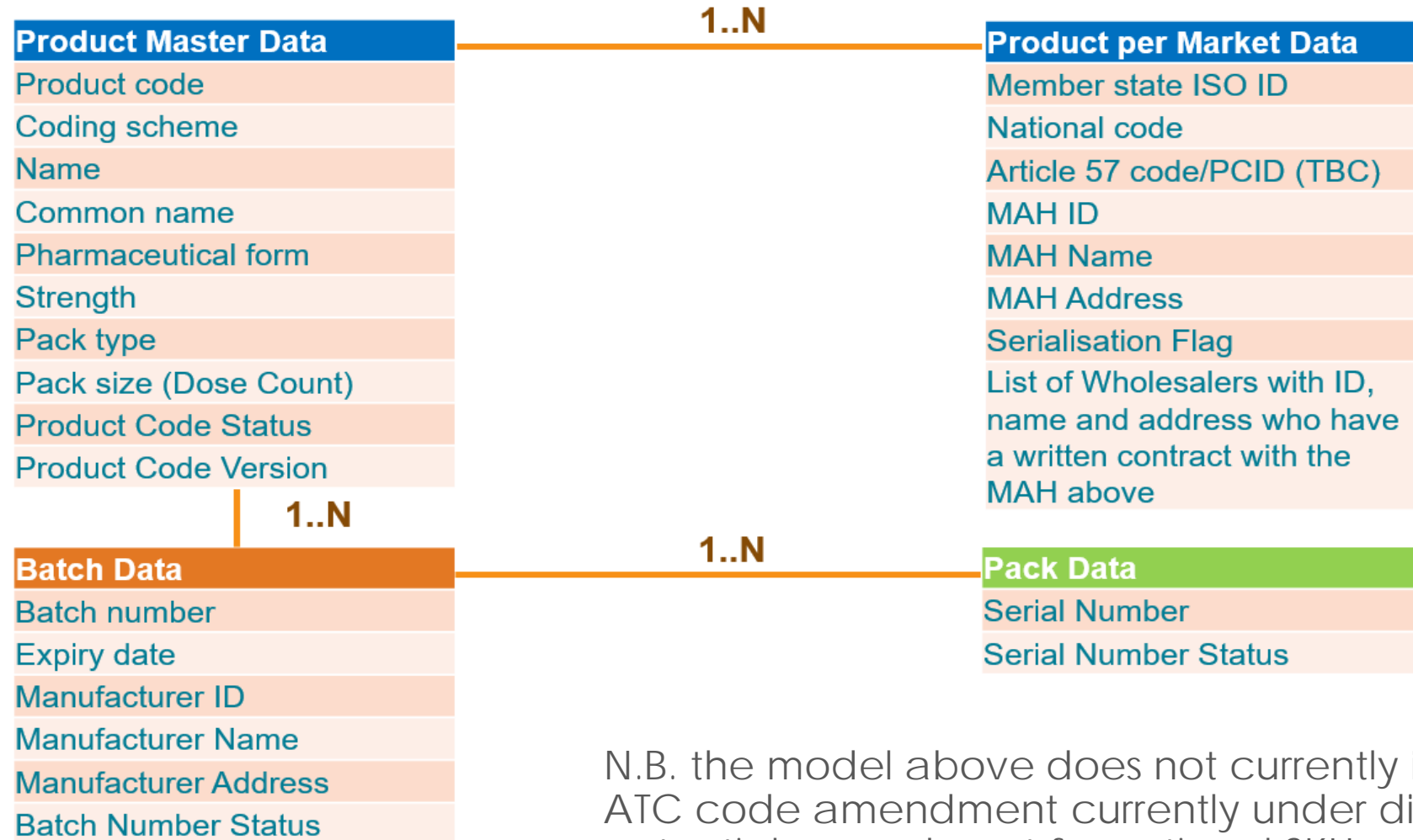
- Batch Data

- The batch header (Batch ID and Expiry) and MFR details and the serial ID's.

- Parallel Distribution

- Treated as an OBP except
- Batch data creates reconciliation stores in the Hub holding the decommissioned serial ID's, the product and batch codes and the number of doses decommissioned
- Newly commissioned product/packs are then linked to the stores.

EMVS DATA CONTENT



N.B. the model above does not currently include the ATC code amendment currently under discussion nor any potential amendment for national SKU naming.

EMVS DATA

- Contracted Wholesalers
 - See Article 33 (h).
 - These are the wholesalers (most likely 3PL's) with whom you have a written contract to store and distribute (note nothing is said about selling!)
 - Likely to be a very short list for most products
 - This isn't a list of all the stakeholders that handle/sell your product.
- A reasonable source of guidance regarding Master Data can be found on the EMVO website.
 - https://emvo-medicines.eu/new/wp-content/uploads/EMVO_0122_EMVS-Master-Data-Guide.pdf
 - Document due for revision to include IDMP (SPOR) mapping information and EMVO Gateway element name mapping.

MULTI-MARKET PRODUCT

- EMVS supports OBP's sending data to multiple markets in one single transaction.
- The NMVS and Hub maintain the synchronisation of packs spread across these markets
- The Hub allows for batch recall to be targeted by market (or multiple markets) for MMP's
- The Hub handles product withdrawal for MMP's in one single message (similar to batch recall).
- All responses from multiple markets are reported to the OBP in a manner that is easy to decipher.

MULTI-MARKET PRODUCT

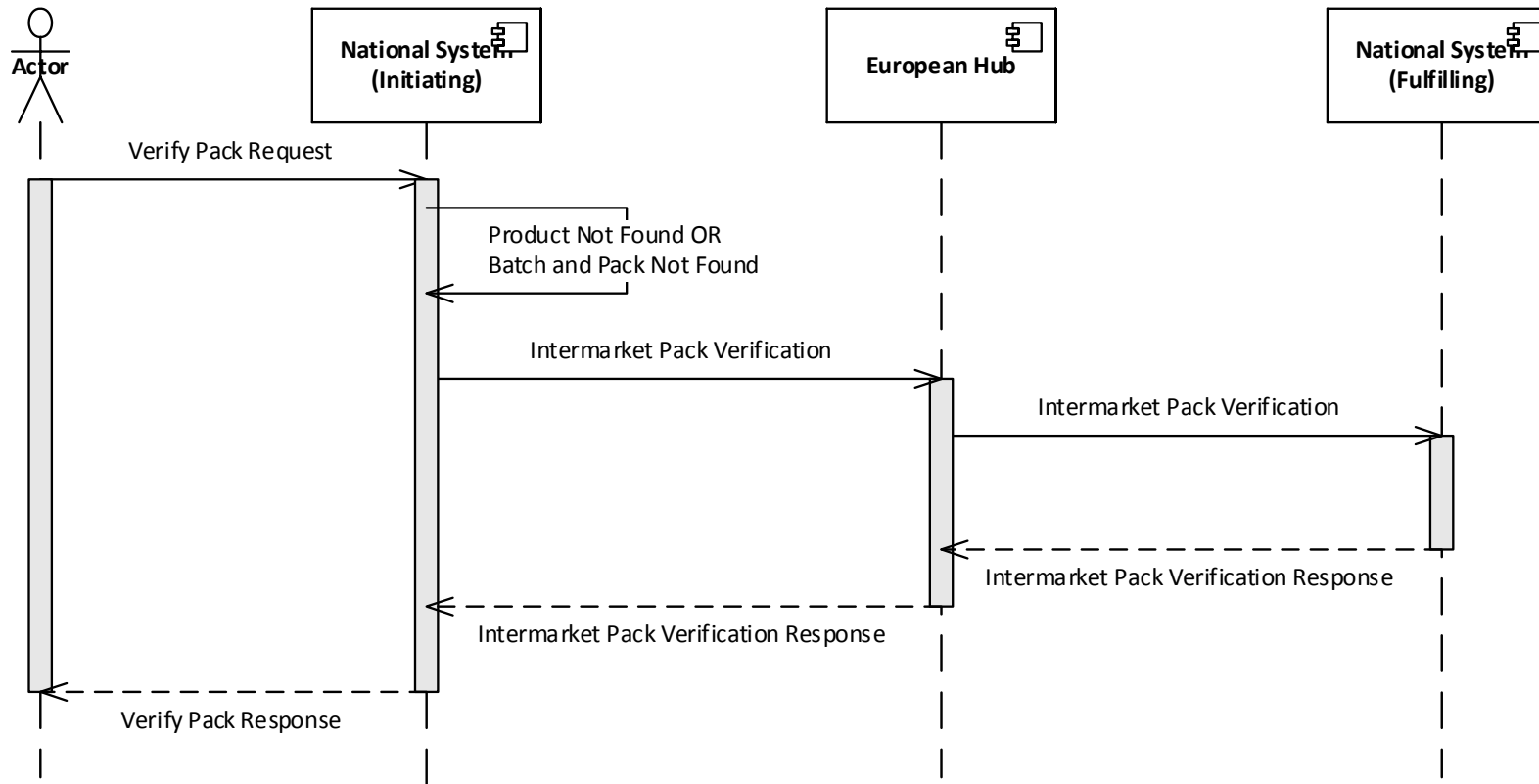
- Let's step through a three market MMP process
 - Assume the OBP has loaded the data and the Hub has sent it to all three markets.
 - A pack is decommissioned in Market A successfully
 - Market A sends a notification to the Hub that pack xyz of product abc, batch 123 has been decommissioned to a state S.
 - The Hub checks the master data for product abc, batch 123 and determines the markets of intended sale.
 - The Hub sends a decommission request to the NMVS's in markets B and C (not A because it knows that was the source)
 - Markets B and C set the pack state for pack xyz of product abc, batch 123 to S and confirm the successful update to the Hub
 - Hub confirms the update to the NMVS in market A

INTER-MARKET TRANSACTIONS

- These are transactions that are initiated when a pack is scanned in a market where it was not destined to be sold by the OBP/MAH.
- Reasons this might happen include:
 - Compassionate use (special licence) packs.
 - Packs that are legally used on a market but sourced from another (e.g. Luxembourg uses packs from BE, FR and DE in original condition).
 - Packs that really shouldn't be there!
- How does it work?

INTER-MARKET TRANSACTIONS

- IMT Data Flow (Verification Shown)



DATA TO BE SENT

- From the initiating NMVS to the Hub and Hub to the fulfilment NMVS we need data to be sent:
 - Product Code & Product Code Scheme (mandatory)
 - Product Batch Number (mandatory)
 - Pack Serial Number (mandatory)
 - Batch Expiry Date (optional)
 - The New Pack State (mandatory)
 - The Originating Location Code (mandatory)

INTER-MARKET TRANSACTION IN PRACTICE

- Now let's scan a pack the NMVS doesn't know
 - User scans a medicinal pack.
 - Details from the scan are transferred to the NMVS (national medicines verification system).
 - The NMVS "looks-up" the pack status using the data transferred.
 - The NMVS fails to find the product -> Inter-market Transaction
 - The NMVS finds the product but not the batch -> Inter-market Transaction
 - The NMVS finds the product & batch but not the pack -> the NMVS rejects the transaction, responds to the user and raises an alert.
 - Regardless of the outcome, the NMVS writes an audit log for the transaction.

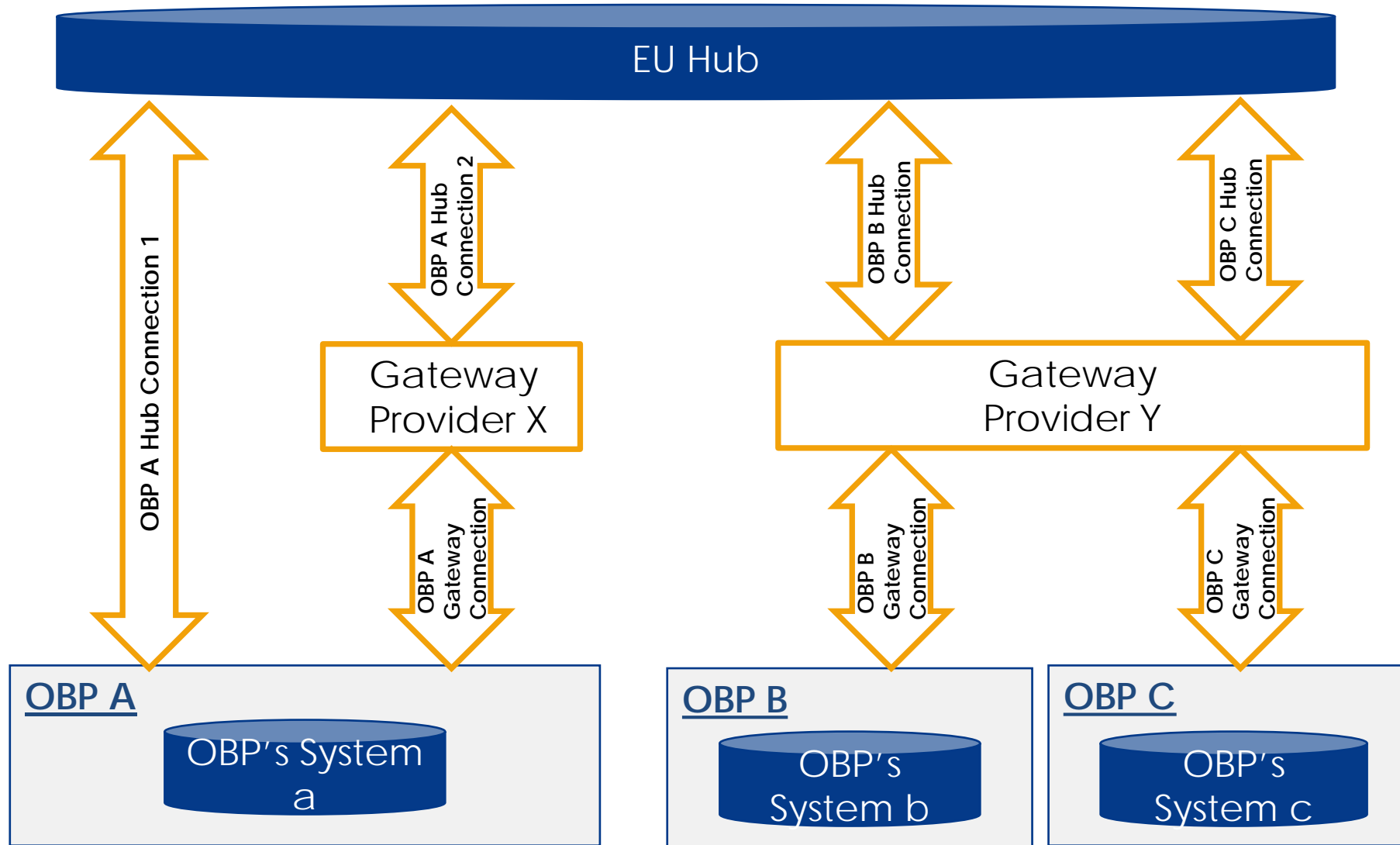
REVERSAL

- The same process as the original transaction but:
 - The NMVS for the “market of intended sale” will now check that the criteria defined in Delegated Regulation Article 13 specifically:
 - Reversed within 10 days following the original decommission
 - Pack has not expired or been placed under recall, withdrawn, destroyed or stolen and;
 - The reversal is performed by a person within the same premises as the person who originally decommissioned the pack (unique identifier)
 - As such it is vital that the NMVS which undertook the original decommission knows who undertook the original decommission (i.e. the Client ID and Market ID combination) and when they did it.

OBP CONNECTIONS

- When onboarding OBP's have the choice of direct connections or gateway connections,
 - Direct
 - These are connections made directly from an in-house/on-premise system like an ERP or stock management system. e.g. SAP ATTP.
 - These connections rely on the provider configuring the system to work for the client and not using a common connection provision.
 - Gateway
 - Here the system supplier is providing a common service to many OBP's and in general, these systems are not on-premise but cloud-based.
 - Examples would include the EMVO Gateway, Tracelink etc.
 - The key is that the connection used to the Hub is 'common' to all OBP's using the system suppliers product and thus, EMVO have a higher expectation that the connection is reliable and unchanged from last use.

CONNECTION TYPES



NCA REPORTING AND ACCESS

o Summary:

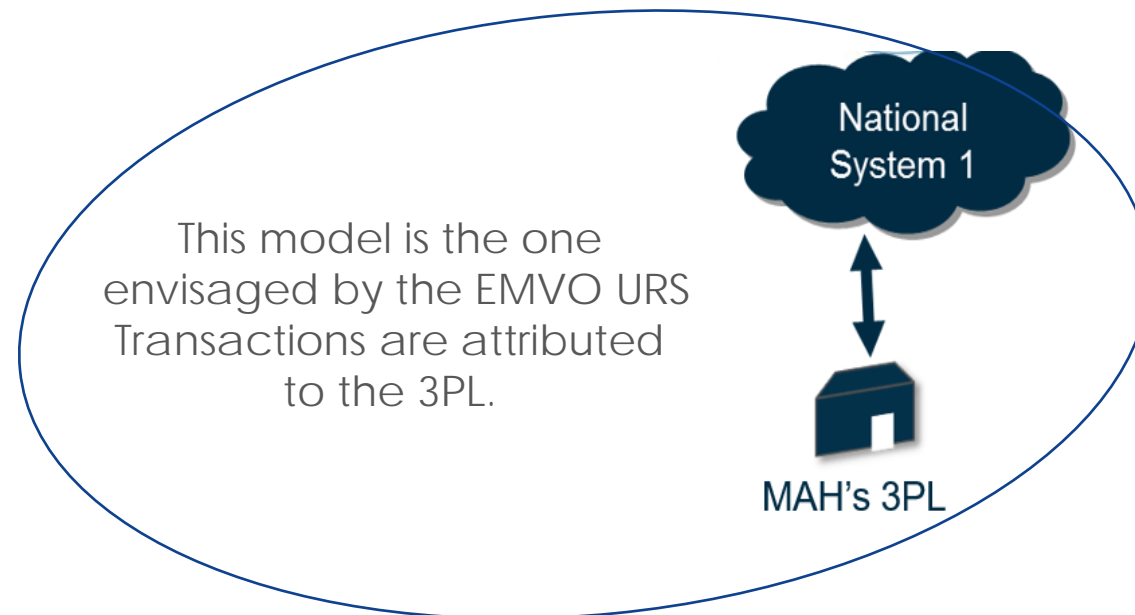
- EMVO are working together with the NCA WG 2 lead by Spain
- Nearing the end of a lengthy process to define and agree a standard set of reports to be provided by each NMVS for the local market NCA.
- The reports cover access and data for:
 - Supervision
 - Investigation
 - Reimbursement
 - Pharmacovigilance
- Some reports require data from the European Hub – how this is provided has to be decided.
- Hopefully not all reports will be mandated by Feb 2019 as resources at the IT providers will probably not allow this to occur.
- Reports will be prioritised.

RETROSPECTIVE DATA UPLOADING

- Only important for multi-market product or if serialised product is placed on a market before the NMVS is live and productive.
- The idea here is to upload data for serialised product as the sales market(s) come online potentially after physical product has been shipped and consumed.
- As an OBP you do this to:
 - Make the serialised product data available in the NMVS where you sell.
 - To avoid being deluged with false negative alerts (which will happen if the product data doesn't exist – the EMVS will consider your packs as potentially falsified).
- Retrospectively uploaded data will, by definition, have pack status indications that are wrong – because stock will have been used before being decommissioned.

WHOLESALE – 3PL'S

- Wholesalers and 3PL's connect to the NMVS and not the Hub at least that's how the URS envisaged it.



WHOLESALE – 3PL'S

- Alternative connection strategies include:

