NMVO ON-BOARDING PRESENTATION

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CONTENT

- General Information
- NMVO on-boarding & QA goals
- Cooperation Agreement with EMVO
- Process- & Technical on-boarding Assessment
- Quality Assurance
- Audit

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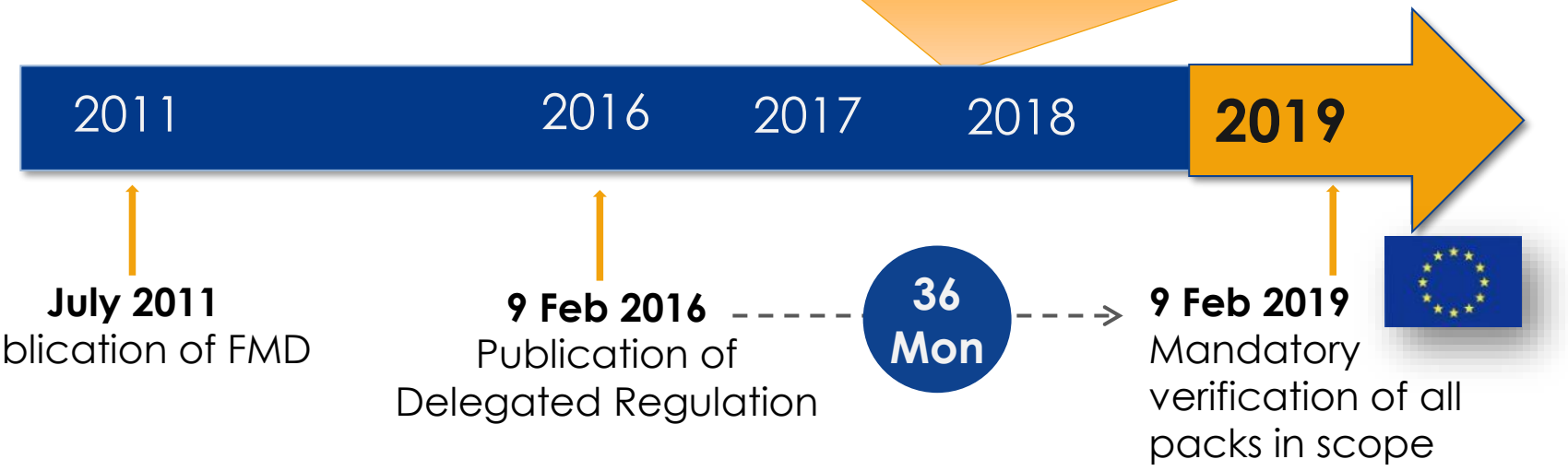
FMD LEGISLATION AND DELEGATED ACT

- **<u>Establish National Systems in 32 countries</u>**
- Connect approx. 2,000 On-boarding Partners (OBPs) to the EU Hub
- Connect many thousand Pharmacies and Wholesalers
- Serialise all affected pharmaceutical packs (10.5 bn)
- Derogation for Italy and Greece to comply before February 2025



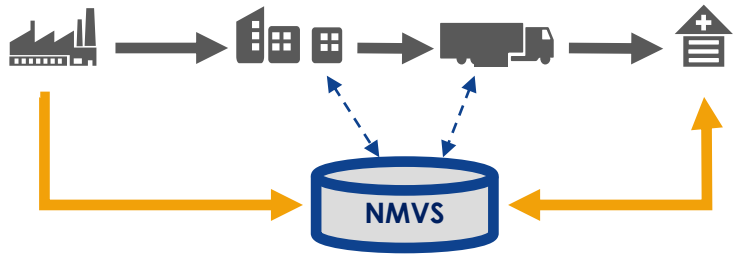
FMD: Falsified Medicines Directive

RESPONSIBILITIES OF THE SUPPLY CHAIN PARTNERS

Serialization by MAH

Risk based verification by Wholesalers

Verification and check-out at point of dispense



Safety features:

Code ('unique identifier')

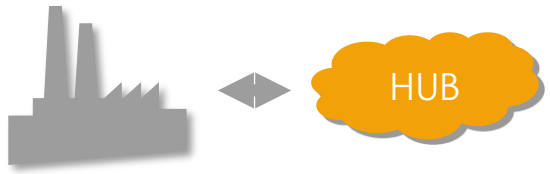
+

Tamper evidence

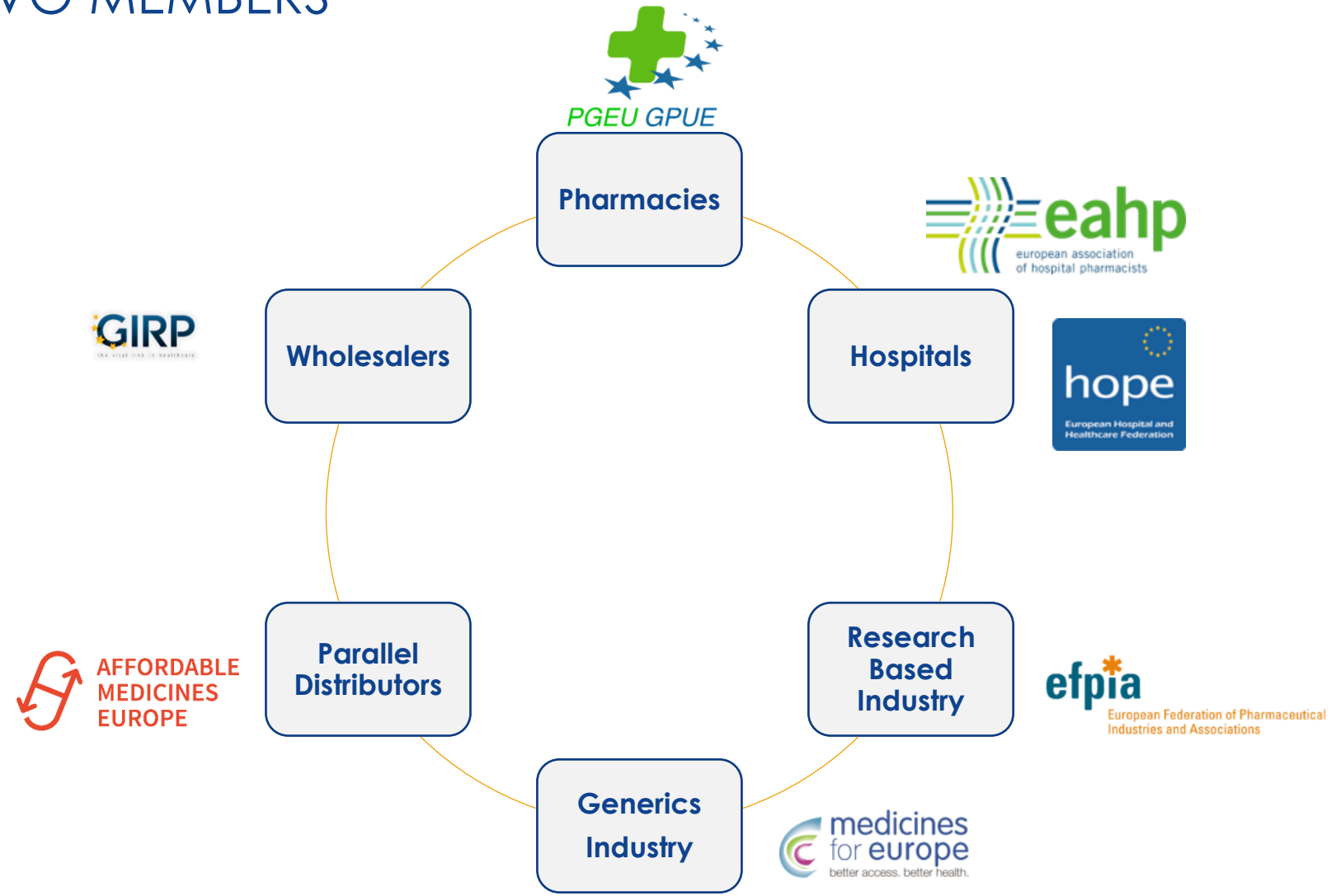
Product #:	09876543210982
S/N:	12345AZRQF1234567890
Batch:	A1C2E3G4I5
Expiry:	140531

System set up and Governance by MAH together with other stakeholders

Oversight by competent authorities



EMVO MEMBERS



EMVO BOARD OF DIRECTORS

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Affordable Medicines Europe

Vice-President:
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PGEU

Treasurer:
Adrian Van den Hoven
Medicines for Europe

Nathalie Moll
EFPIA

Monica Derecque-Pois
GIRP

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Quality Assurance Manager
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Quality Assurance Expert

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1st Line Support
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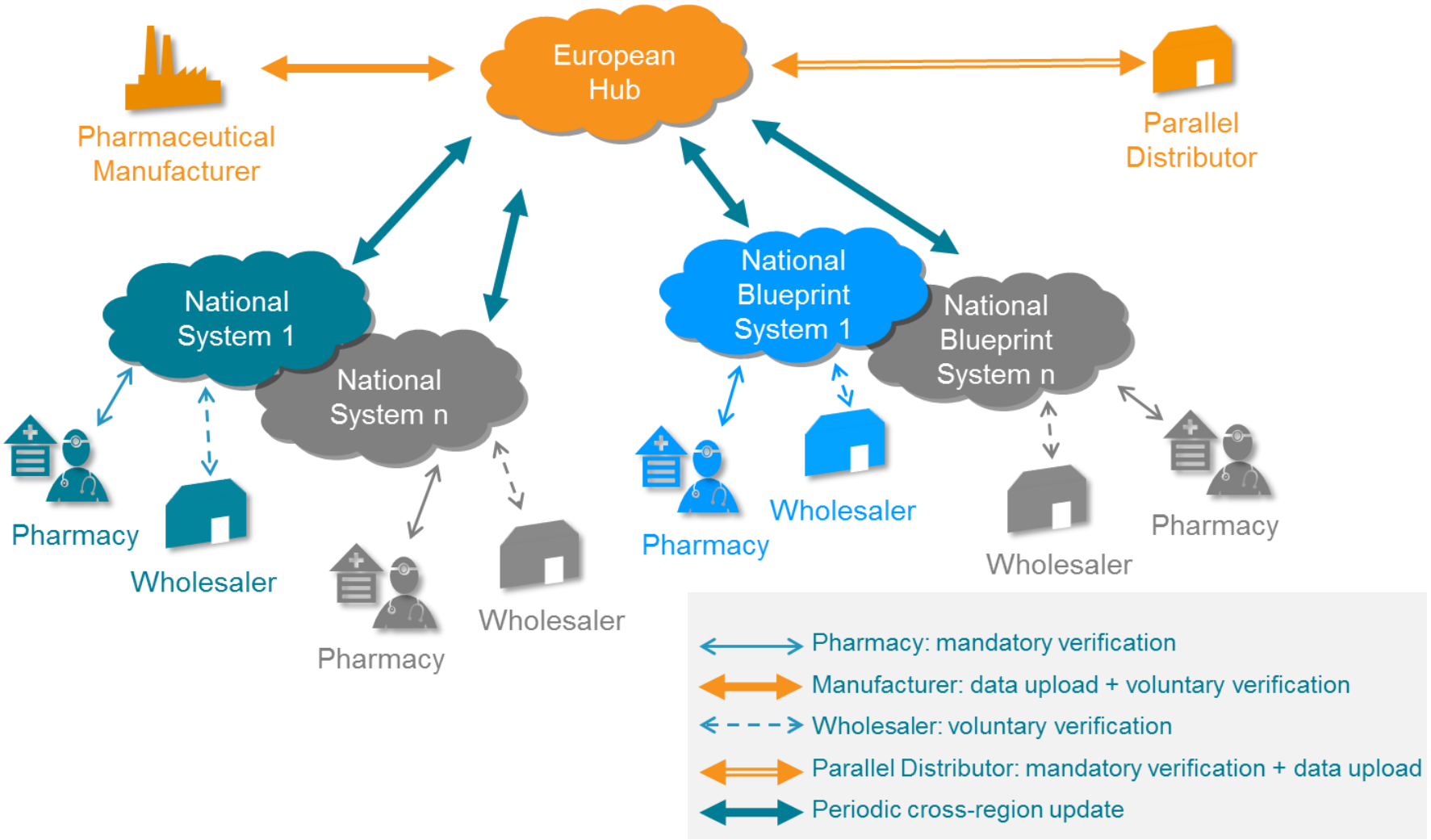
(Margarita Kabakchieva)

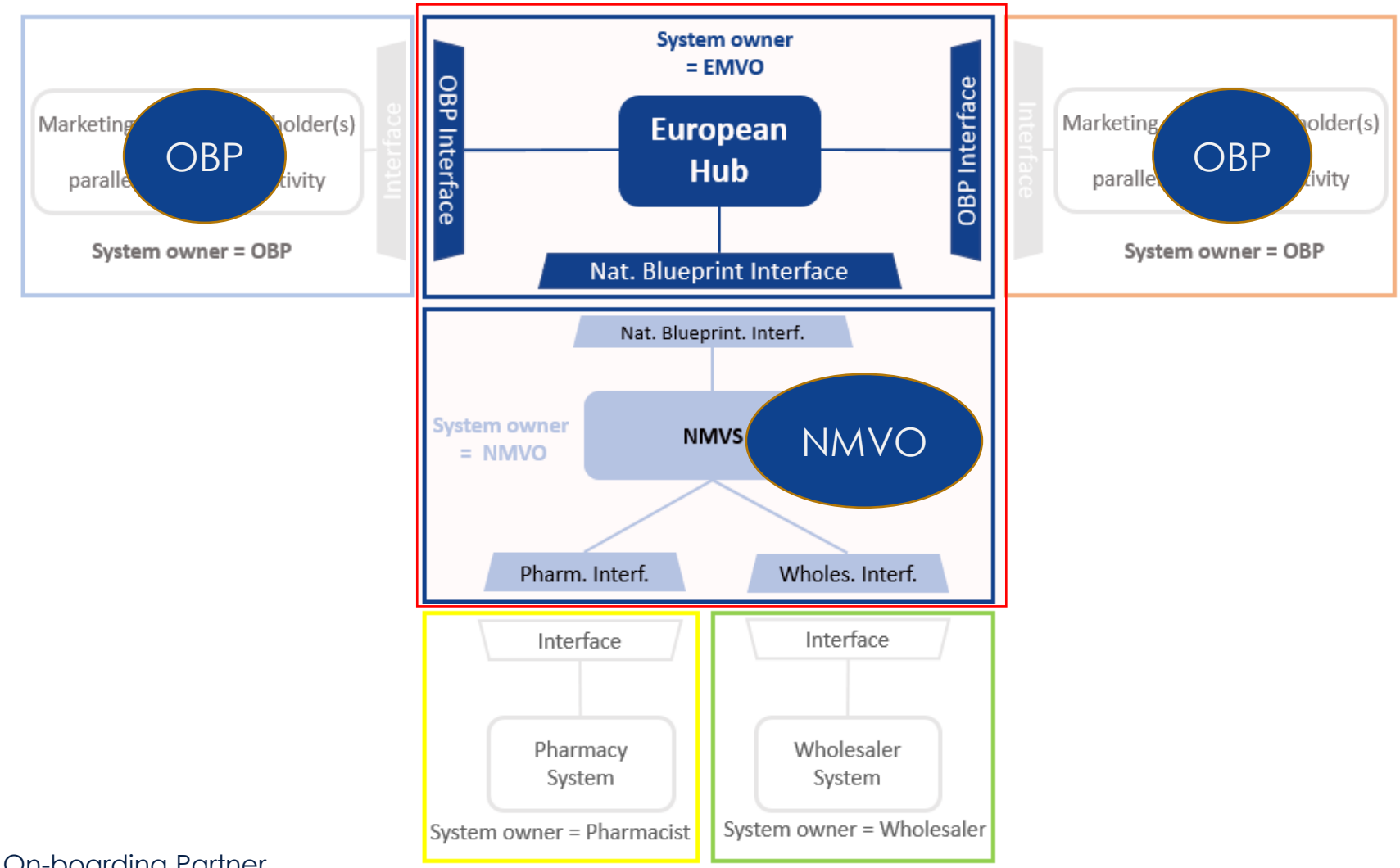
Project & Partner Expert
(Tracy Slosse)

Business & Partner Coordinator
(Camilla Casale)

SYSTEM LANDSCAPE I



SYSTEM LANDSCAPE II



OBP: On-boarding Partner
NMVS: National Medicines Verification System
NMVO: National Medicines Verification Organisation

emvo European Medicines Verification Organisation

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NMVO ON-BOARDING PROCESS

Implementation Phase

PRD Live

Operational Phase

Start

Contract with IT service provider signed after EMVO audited the IT Supplier (only if a non-existing blueprint supplier is used)

Contract NMVO - EMVO

Sign off the Cooperation Agreement

Process assessment

Part 1

- QMS processes assessed by EMVO
- Subscribe to a Customer Group or establish one in cooperation with the EU CCB (only if non-existing blueprint supplier is used)
- Training in EU CCB processes completed

=> Organisation ready

Technical on-boarding assessment

Part 2

- Initiate EU CCB Change- and Release Request
- System connection to EU Hub IQE
- UAT performed by NMVO
- IOT passed(only if a non-validated release is used)
- System connection to productive environment

=> System released for productive use

Ramp-up

- Controlled on-boarding of End-Users
- OBPs to upload PMD and PPD

BAU

Quality Assurance goals:

- QA person assigned
- Set-up QMS @ NMVO
- Ensure QMS @ IT service provider
- Ensure a validated NMVS

Operational QMS implemented

emvo European Medicines Verification Organisation

EMVO not involved **EMVO involved**

EMVS GOVERNANCE BODIES

Arvato Customer Group

SSR Customer Group

EMVO Customer Group

- EMVO Stakeholders
- EMVO Management

ARV CAB

(Arvato CG
Change Advisory Board)

SSR CAB

(Solidsoft CG
Change Advisory Board)

EMVO CAB

(EMVO CG
Change Advisory Board)

EU CCB

(EU Change Control Board)

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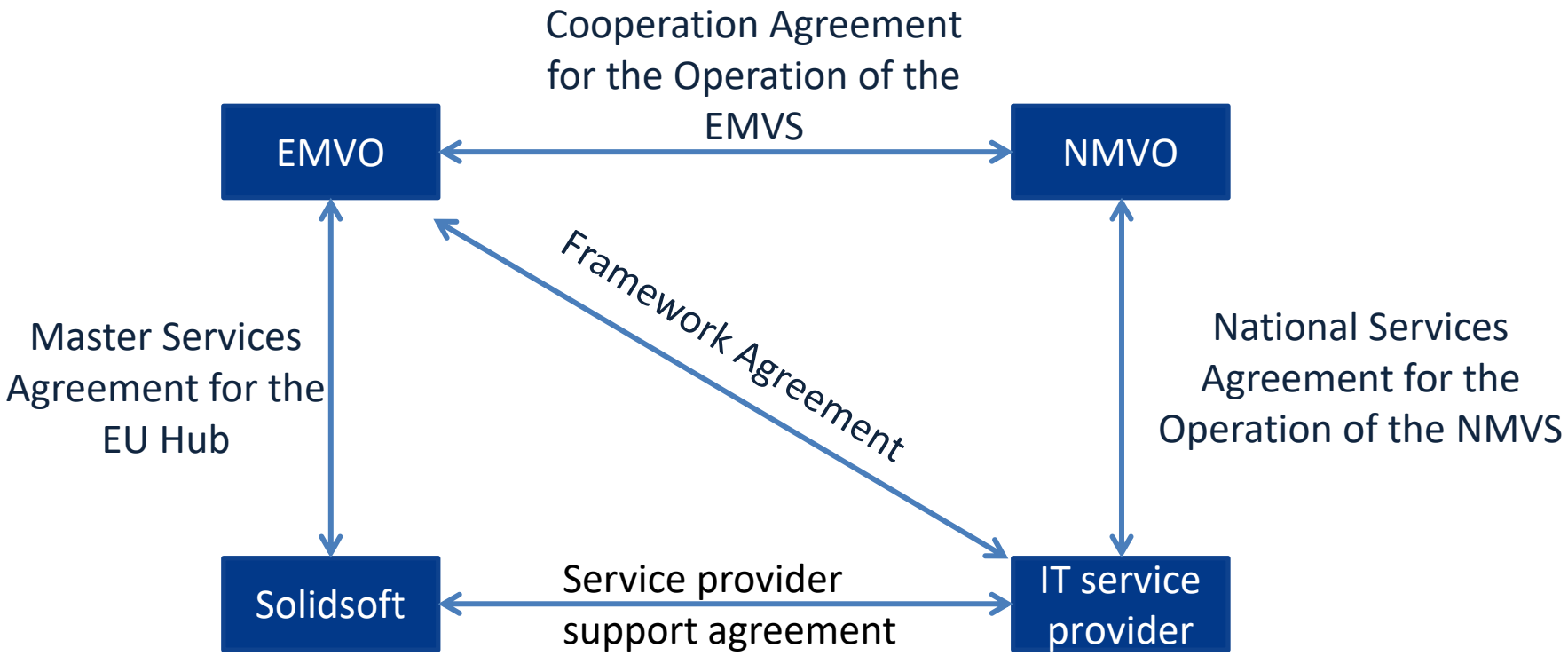
NATIONAL PREREQUISITES

- A National Medicines Verification System (**NMVS**) must be set up and managed by a non-profit legal entity (National Medicines Verification Organisation – **NMVO**) established by national stakeholders in accordance with Article 31 of the Delegated Regulation ("DR")
- The establishment of the NMVO requires **alignment** between all national stakeholders, contraction of **Articles of Association**, communication to the relevant **competent authority**(ies) etc. as per Article 37 of the DR.
- For an NMVO to connect is NMVS to the EU Hub, the NMVO* needs to enter into the **Cooperation Agreement for the Operation of the EMVS with EMVO**.

* And the NMVO's Affiliate (in case of a two-tier structure) that agrees to be bound jointly and severally with the (main) NMVO

CONTRACTUAL LANDSCAPE



EMVO: European Medicines Verification Organisation
Solidsoft: IT service provider for the implementation and operation of EU Hub
NMVO: National Medicines Verification Organisation
IT service provider: IT service provider of the NMVS (e.g. one of the Blueprint suppliers)

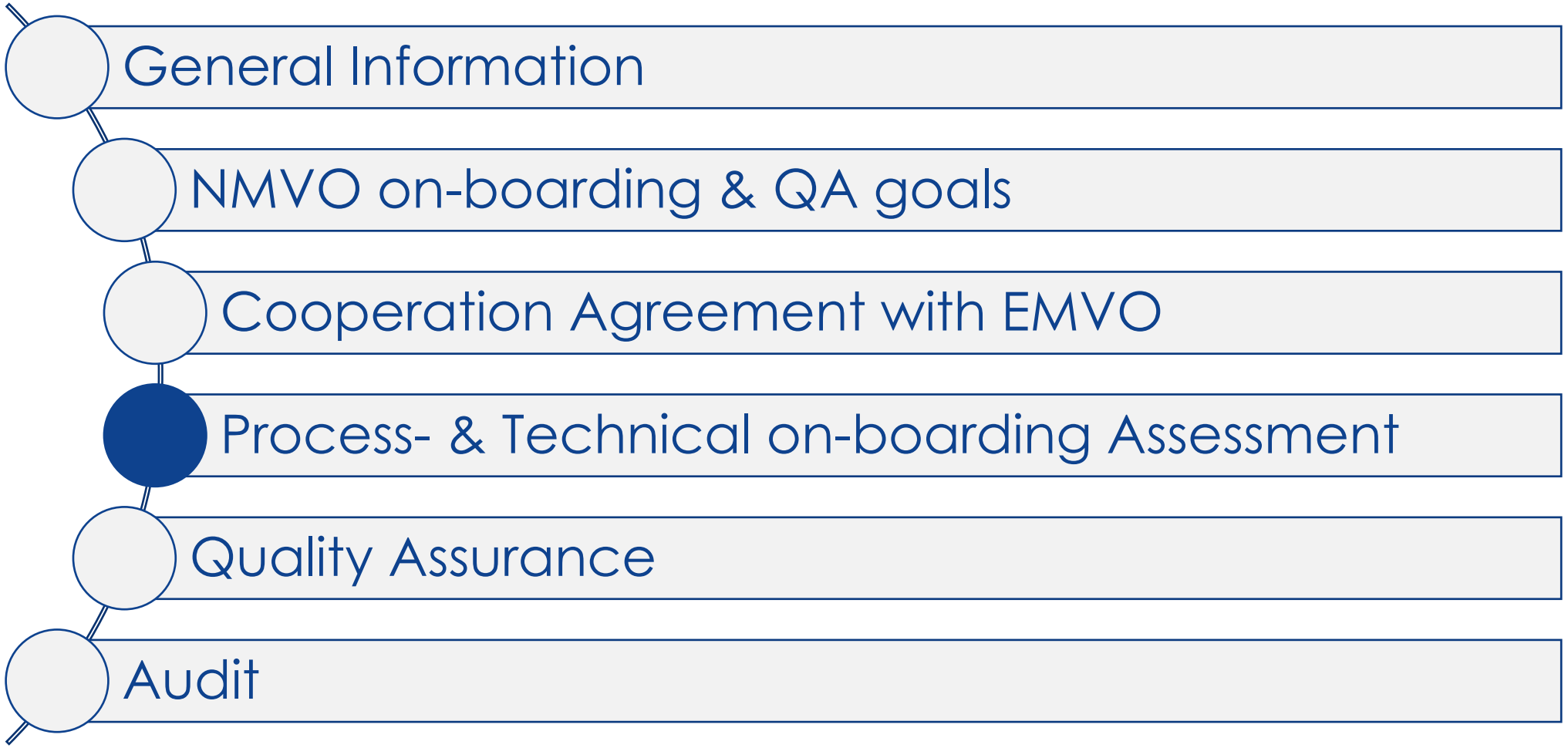
PURPOSE AND SUBJECT MATTER OF THE COOPERATION AGREEMENT

Cooperation between EMVO and the NMVO - including the mutual grant of rights that are necessary for:

- the operation and testing, where necessary, of the EMVS
- the connection between a NMVS and the EU Hub
- their use to transfer Data between the EU Hub and the NMVS

to enable the operation of the EMVS in order to allow End Users to verify the authenticity of medicinal products and the other use cases as set out in the EU Directive on Falsified Medicines and its Delegated Regulation and the EMVS URS.

CONTENT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PROCESS ASSESSMENT

Process assessment

- Part 1

- QMS processes assessed by EMVO
- Subscribe to a Customer Group or establish one in cooperation with the EU CCB (only if non-existing blueprint supplier is used)
- Training in EU CCB processes completed

- => Organisation ready

PROCESS ASSESSMENT (PART 1)

The process assessment part 1 will ensure that:

- The NMVO meets minimum expectations for:
  - Financial stability;
  - Information security management;
  - Roles and responsibilities;
  - End-user legitimacy check;
  - End-user On-boarding process;
  - Access management;
  - Incident management;
  - Change management.
  - See also onboarding guide (EMVO_00114)

- The NMVO is familiar with the EU CCB processes
- The NMVO is subscribed to a Customer Group
  - subscribe to a Customer Group

  or

  establish a Customer Group in cooperation with the EU CCB (if non-existing blueprint supplier is used)

- A Single Point of Contact (SPOC) is assigned

=> Organisation ready

PROCESS ASSESSMENT (PART 1)

Latest versions of :

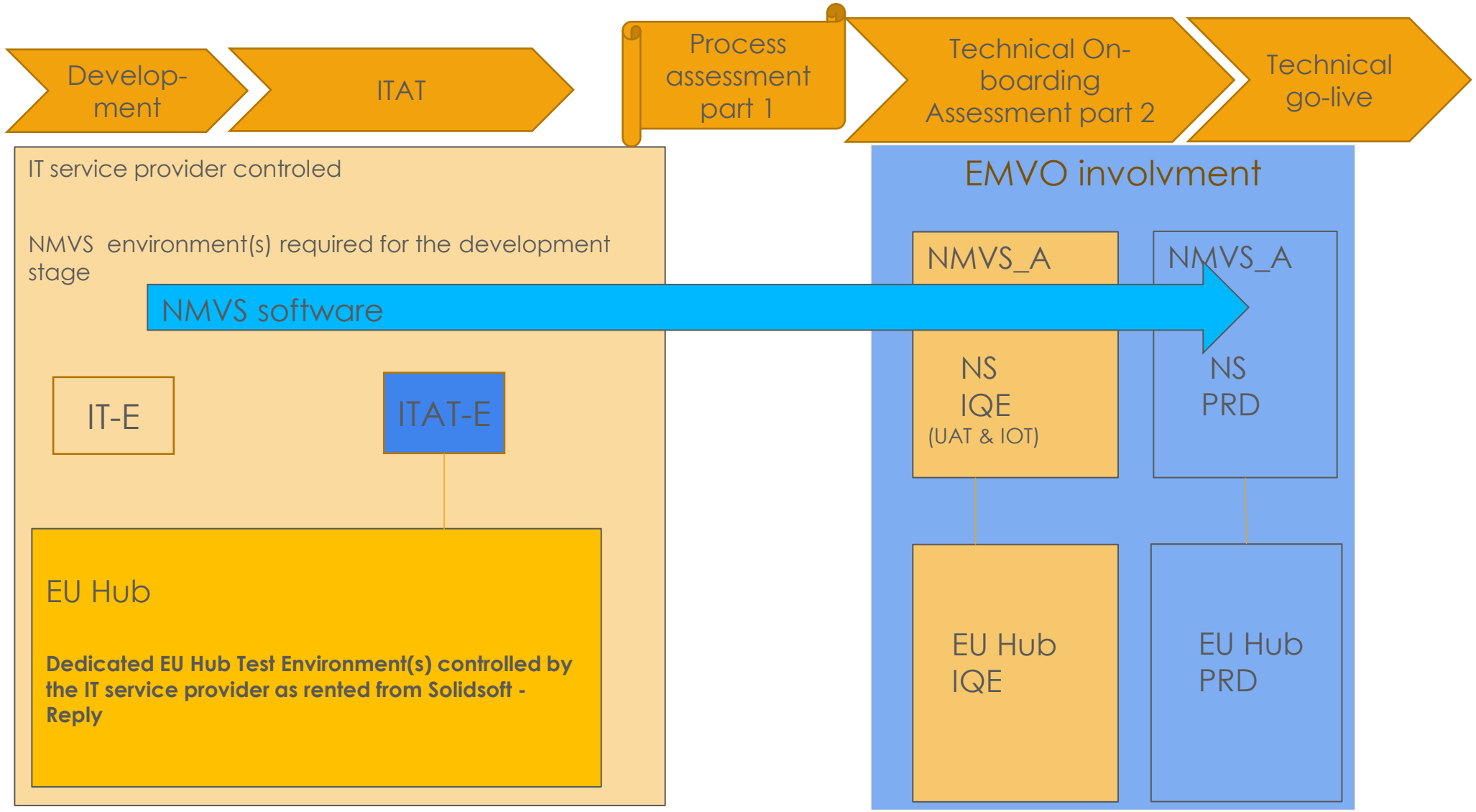
- Directive 2011/62/EU and Delegated Act
- Cooperation Agreement
- GAMP5: A Risk-Based Approach to Compliant GxP Computerized Systems
- Eudralex Volume 4 and applicable Annexes
- ISO/IEC 27001: Information security management systems
- ISO/IEC 27002: Code of practice for information security management

TECHNICAL ON-BOARDING ASSESSMENT

Technical on-boarding assessment

- Part 2
- Initiate EU CCB Change- and Release Request
- System connection to EU Hub IQE
- UAT performed by NMVO
- IOT passed (only if a non-validated release is used)
- System connection to productive environment
- => System released for productive use

NMVS: FROM DEVELOPMENT TO TECHNICAL GO-LIVE (V3.0)



TECHNICAL ON-BOARDING OF NMVS

- Starts after a positive process assessment part 1
- NMVS IQE will be connected to EU Hub IQE to execute the NMVS UAT / IOT
- Technical on-boarding assessment Part 2 (See next slide)
- NMVS PRD will be connected to EU Hub PRD

Note: Exchange of certificate information is identical for EU Hub IQE and EU Hub PRD

- NMVO creates CSR file
- Solidsoft signs CER certificate
- IT service provider to provide connection

TECHNICAL ON-BOARDING ASSESSMENT (PART 2)

- The NMVS is meeting the EMVS requirements
  - The UAT- test and IOT-report, external security audit and traceability matrix will act as input for the system assessment.
  - Both functional- and non-functional requirements are in scope.

ASSESSMENTS AND EXPENSES

As per Cooperation Agreement, the NMVO will :

- support these assessments with all reasonably necessary means.
- bear the costs of these assessments
  - All EMVO assessment efforts will be charged under Time & Material, including hours of staff/experts and travel expenses.
  - EMVO will provide a cost estimate to the NMVO in advance.

PLANNING OF PROCESS ASSESSMENT, AND TECHNICAL ON-BOARDING

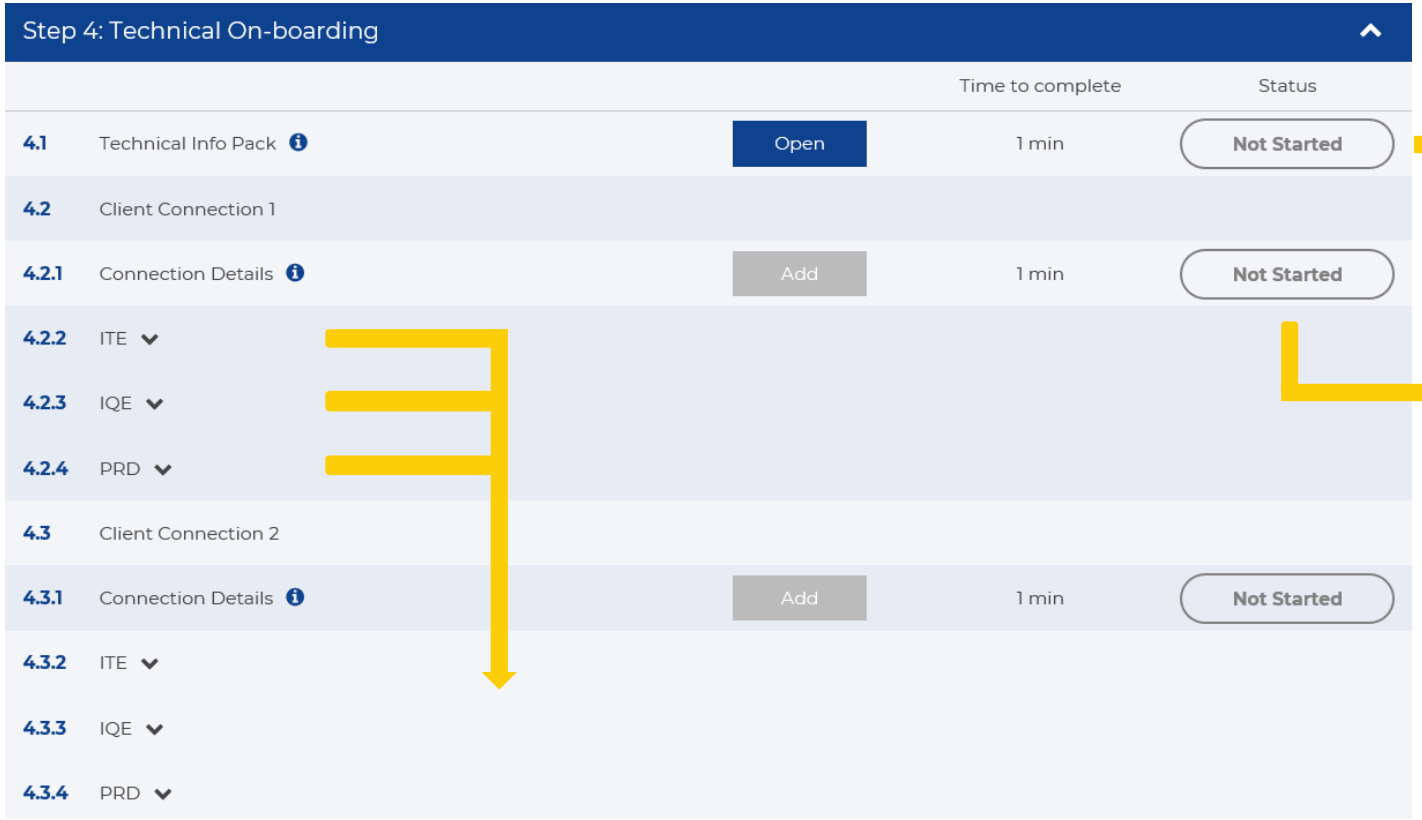
- Before the UAT/IOT, the NMVO has to:
  - Request the preferred UAT/IOT and Go-live timeslots
    1. Check the availabilities in the UAT/IOT planning
    2. Send the requested UAT/IOT and Go-live dates and the NMVO SPOC to helpdesk@emvo-medicines.eu
    3. EMVO will confirm the dates of the UAT/IOT
    4. Provide documentation for assessment part 1
- Planning constraints:
  - Resource availability
  - IOT team availability / IOT slots

Before UAT and the process assessment, the Cooperation Agreement has to be concluded between NMVO and EMVO

4. TECHNICAL ON-BOARDING

Trigger Step 4:
Approval of:
- Legitimacy Check Status
- Countershigned Participation Agreement
- Invoice Status

Note
If you make use of a Gateway Connection, the ITE environment is not necessary. Consequently, you can skip steps 4.2.2 and 4.3.2.



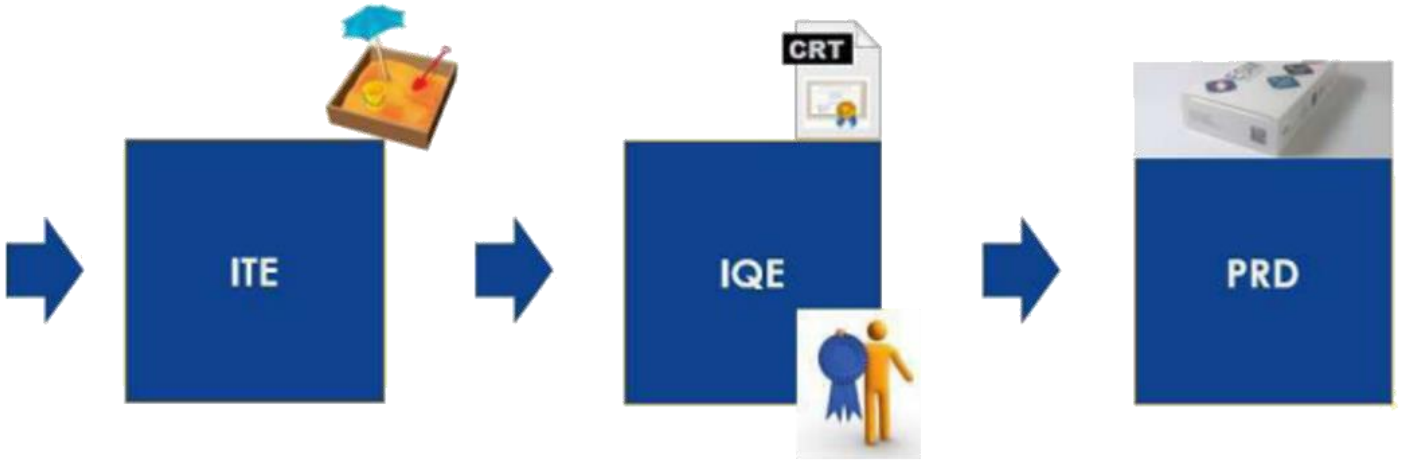
Status:
Not Started
Completed

Status:
Not started
Completed

STEPS FOR TECHNICAL ON-BOARDING

- **ITE** – can be used as a sandbox by the NMVOs to perform the first development of the connection and do a first integration test.
- When the NMVO is confident that his interface is ready for testing, they can request access to the **IQE** to execute tests from the test status metrics.
- After the NMVO passed the baseline tests, access will be granted for the PRD.

  Note: Only internal validated systems are allowed to send data into the EU Hub.



4.1 TECHNICAL INFO PACK

The Technical Info Pack is a package of several files to download. It contains the following information in their last available versions:

Documentation JAVA

- 20181 MAH SDK
- EMVS0787 - EMVS Java SDK Installation Instructions For OBPs

Documentation .NET

- EMVS0794 - EMVS OBPs .NET SDK Installation Guide
- C# SDK Code Sample
- .NET Callback

EMVO Gateway

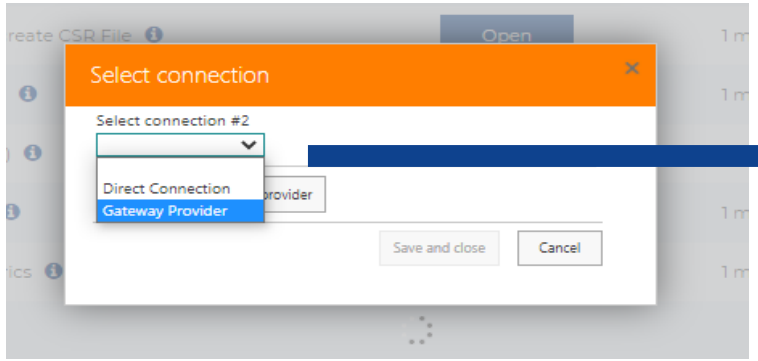
- EMVO_0038_EMVO Gateway User Manual

AMS

- AMS –HUB-insert Alert Tool
- AMS Qualification Plan and Report –Template
- AMS Qualification Booklet – Template
- AMS Pilot Report
- AMS On-boarding and Qualification Process
- EMVO-00549 – AMS Hub SDK (2)
- EMVO-00544 – AMS HUB API Specification
- EMVO-01393 – Alert Management System FAQ's v.1.0
- EMVO – 1376 – AMS User Manual V3.0
- AMS HUB DEMO – AMS Technical and Stakeholders Q&A
- AMS Technical Q&A
- EMVO-01057- AMS Access to ITE

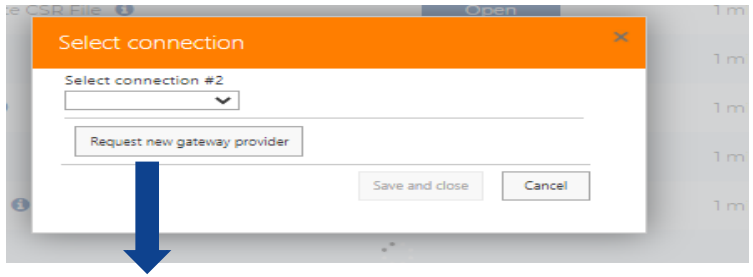
4.2.1 CONNECTION DETAILS

Note
This step is pre filled if you completed Step 1.3 of the OBP Portal already.



Drop-down menu listing the **registered* Connection Providers**. Making use of a registered Connection Provider allows the OBP to start immediately the tests in the Integrated Quality Environment (IQE).

***registered Connection Provider** is a provider which signed the License Agreement with EMVO and a Support Contract with SolidSoft.*



If the Connection Provider of your choice is not listed in the drop-down menu, please click the '*Request new gateway provider*' button to promote them.

4.2.3 IQE

Note
When the NMVO is confident that its interface is ready for testing, they can start testing in IQE for testing purpose.

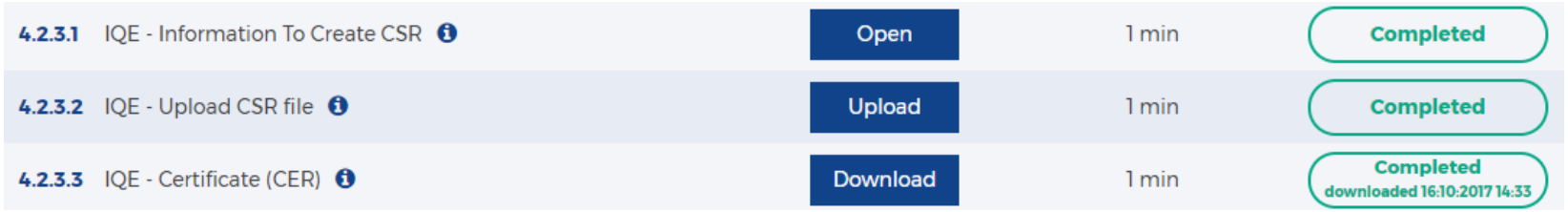
4.2.3.1	IQE - Information To Create CSR	Open	1 min	Completed
4.2.3.2	IQE - Upload CSR file	Upload	1 min	Completed
4.2.3.3	IQE - Certificate (CER)	Download	1 min	Completed downloaded 16:10:2017 14:33
4.2.3.4	IQE - Session Token	Request New	1 min	Available viewed 16:10:2017 14:36
4.2.3.5	IQE - Test Status Metrics	Open	1 min	In Progress

Info button will display the current Session Token

To review if your related transactions have been successfully processed in the EU Hub.

EMVO GATEWAY REQUEST

Note
This only applies if the NMVO would need access via the EMVO Gateway for testing purposes (IQE Only)

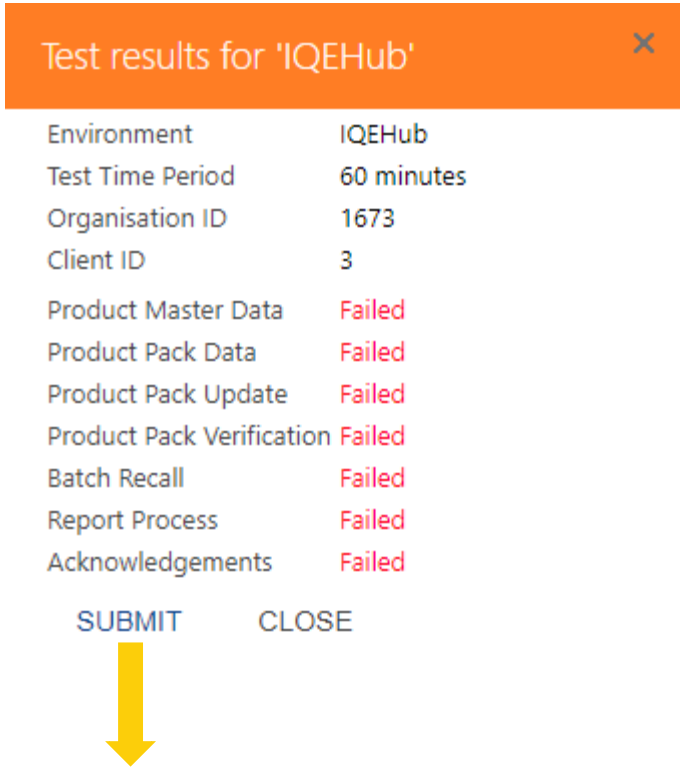


As soon as Step 4.2.3.3 is finished, the following information should be sent to the EMVO Helpdesk (helpdesk@emvo-medicines.eu).

- Environment (IQE)
- Tenant / Company Name
- SPOC Name
- SPOC Email

The credentials and URL will be sent through the following email: noreply@meliorsolutions.com (please be aware to check your Junk folder).

4.2.2.5 IQE - TEST STATUS METRICS



This will send the current Test Results for EMVO's approval. If Product Master Data, Product Pack Data and Product Pack Update tests are passed, EMVO will allow access to PRD.

Note 1

The NMVO should verify and submit the Test Results of all positive transactions **which are sent to the EU Hub in the last 30 minutes.** The number of successful tests need to be higher than for failed tests.

In case of failed tests, the NMVO should retry to upload the data and then contact the EMVO Helpdesk (helpdesk@emvo-medicines.eu) for further assistance.

When the transactions are passed, the NMVO should click the **Submit** button.

Note 2

By default all statuses are marked as '*failed*'. After passing and submitting the test results, statuses will reset to 'failed' after 30 minutes. Please await as EMVO has to approve your results.

4.2.4 PRD

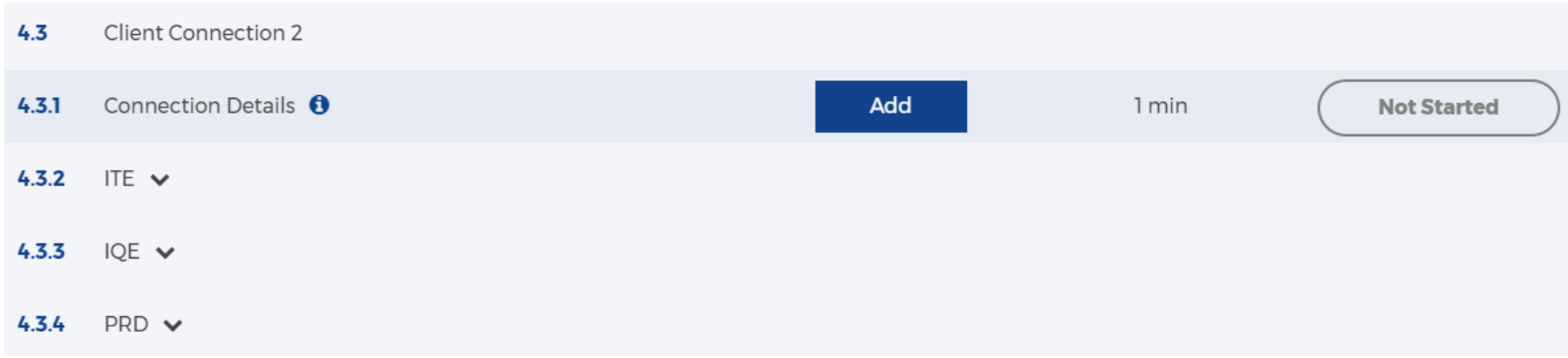
Note 1
We only allow validated systems to connect to the PRD environment.
It is a prerequisite to have an approved test result.

Note 2
The NMVO doesn't need to perform the Test Status Metrics in the PRD environment.

4.2.4.1	PRD - Information To Create CSR	Open	1 min	Not Started
4.2.4.2	PRD - Upload CSR file	Upload	1 min	Not Started
4.2.4.3	PRD - Certificate (CER)	Download	1 min	Not Started
4.2.4.4	PRD - Session Token	Request New	1 min	Not Started

4.3 CONNECTION 2

Optional
This step can be used in case the NMVO wants a second connection to the EU Hub. There is no difference with the Connection 1 and the NMVO can repeat the previous steps.



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QUALITY ASSURANCE

Quality Assurance goals

- QA person assigned
- Set-up QMS @ NMVO
- Ensure QMS @ IT service provider
- Ensure a validated NMVS

QUALITY ASSURANCE GOALS

- QA person assigned
  - Each system owner is responsible for the validation of his system
  - EMVO for the EU Hub
  - Each NMVO for its NMVS

QUALITY ASSURANCE GOALS

- Set-up QMS@NMVO
  - For Blueprint model based countries: EMVO provides QA templates free of charge
  - The tailoring of the QMS to the specific NMVO organisation is to be managed by the NMVO to fulfill the applicable Regulation & Best Practices:
    - Directive 2011/62/EU and Delegated Act;
    - GAMP5, A Risk-Based Approach to Compliant GxP Computerized Syst.;
    - Eudralex Volume 4 and applicable annexes (e.g. Annex 11;
    - ISO/IEC 27001: Information security management systems;
    - ISO/IEC 27002: Code of practice for information security management;
    - ISO/IEC 27005: Information security risk management;
    - ISO/IEC 38500: Information Technology Governance;
    - ISO/IEC 20000: IT service management.

QUALITY ASSURANCE GOALS

- ENSURE QMS @ IT SERVICE PROVIDER
  - Exact operating procedures to be agreed on NMVO level
  - IT service providers are to be audited by NMVO to ensure their QMS meets Quality expectations

QUALITY ASSURANCE GOALS

- Ensure a validated NMVS
  - NMVS is to be well-documented and tested

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AUDITS

Audits

- System Operation
- QMS implemented

AUDIT PURPOSE & OBJECTIVE

Purpose

- To verify that the NMVS, its system operation and support processes comply with:
  - EMVO quality standards
  - Regulation

Objectives

- To verify the capability to operate the system in a validated status
- Achieve high degree of confidence that NMVS will perform as intended
- Ensure QMS of IT service provider meets EMVO Quality expectations
- Ensure that NMVO complies with Article 31 of the DR and is financially stable

AUDIT APPLICABLE REGULATION & BEST PRACTICES

- Directive 2011/62/EU and Delegated Act
- Cooperation Agreement
- GAMP5: A Risk-Based Approach to Compliant GxP Computerized Systems
- Eudralex Volume 4 and applicable Annexes
- ISO/IEC 27001: Information security management systems
- ISO/IEC 27002: Code of practice for information security management

AUDIT FOCUS I.A.

- URS compliance
- System design and architecture compliance with DR
- Interface with EU Hub developed according to EMVS specification (EMVS URS & SDK)
- Data integrity, access and ownership
- Compliance of NMVO to Article 31 of the DR
- Risk assessments
- QMS procedures, incl. :
  - the on-boarding procedure for end-users (to ensure compliance with DR Article 37(b))
  - Legitimacy check of end-users & potentially manufacturers (if applicable)

AUDIT MINIMUM REQUIREMENTS TO QMS

QMS deliverable implemented
SOP template
Form Template
NMVO controlled document list
Document management
Validation policy
Validation plan template
Validation report template
User requirements specification template
Roles and Responsabilities
Risk management
Risk assessment template
Information security management
QMS manual
Initial system assessment template
Test management
Release and deployment management

QMS deliverable implemented
Change management
Change request template
Training management
Training registration form template
QMS Training requirements
Access management
Onboarding process
User requirements specification
Incident management
Incident investigation report template
CAPA management
CAPA Form
Audit management
Complaint management
Business continuity management