EMVO On-Boarding

How to connect to the EU Hub?

Info Pack V.2.0

3 May 2017

> **Please check**
>
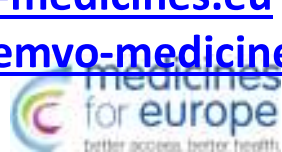> **https://www.emvo-medicines.eu/**
>
> **for the latest version of this presentation and the On-boarding Guideline.**

European Medicines Verification Organisation (EMVO)

www.emvo-medicines.eu

helpdesk@emvo-medicines.eu

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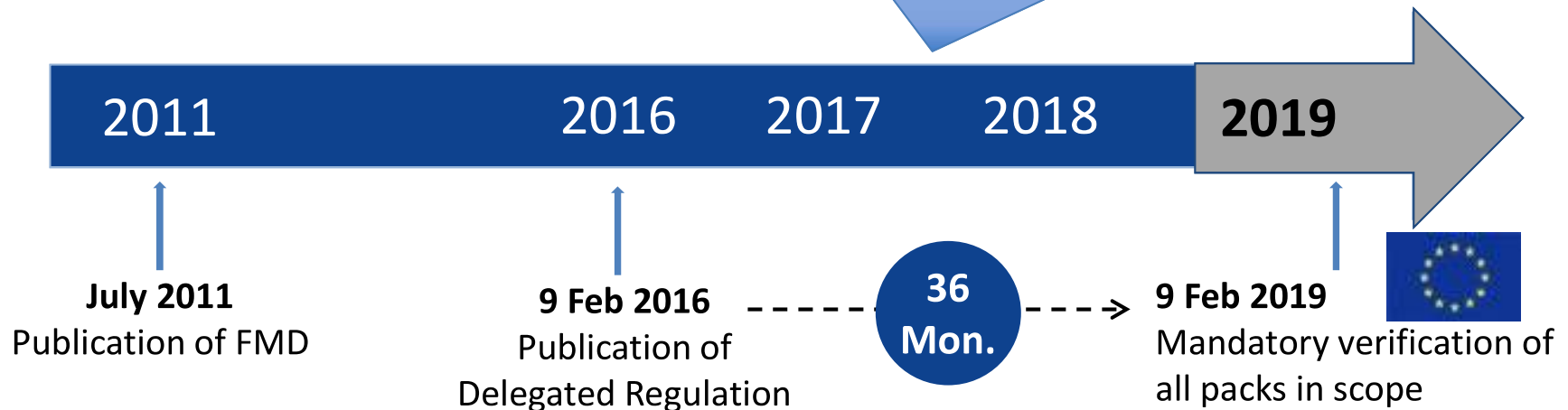
General Information

How does the On-Boarding work?

General Information

How does the On-Boarding work?

FMD Legislation and Delegated Act

- **Connect approx. 2,500 On-boarding Partners (OBPs) to the EU Hub**
- Establish National Systems in 32 countries
- Connect many thousand Pharmacies and Wholesalers
- Serialise all affected pharmaceutical packs (10.5 bn)

2011	2016	2017	2018	**2019**

July 2011
Publication of FMD

9 Feb 2016
Publication of
Delegated Regulation

36 Mon.

9 Feb 2019
Mandatory verification of
all packs in scope

~ 700 days remain

FMD: Falsified Medicines Directive

European Medicines Verification Organisation

Serialization by MAH

Risk based verification by Wholesalers

Verification and check-out at point of dispense
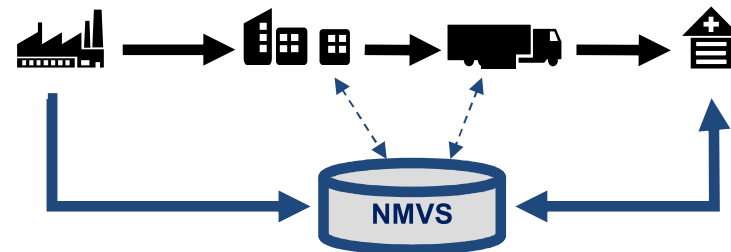
Safety features:

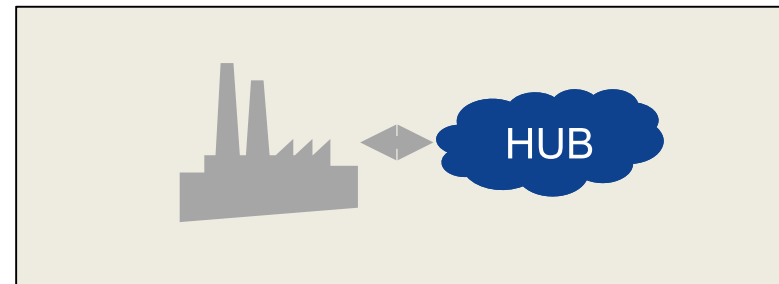**Code ('unique identifier')**

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Tamper evidence

System set up and Governance by MAH together with other stakeholders

Oversight by competent authorities

NMVS

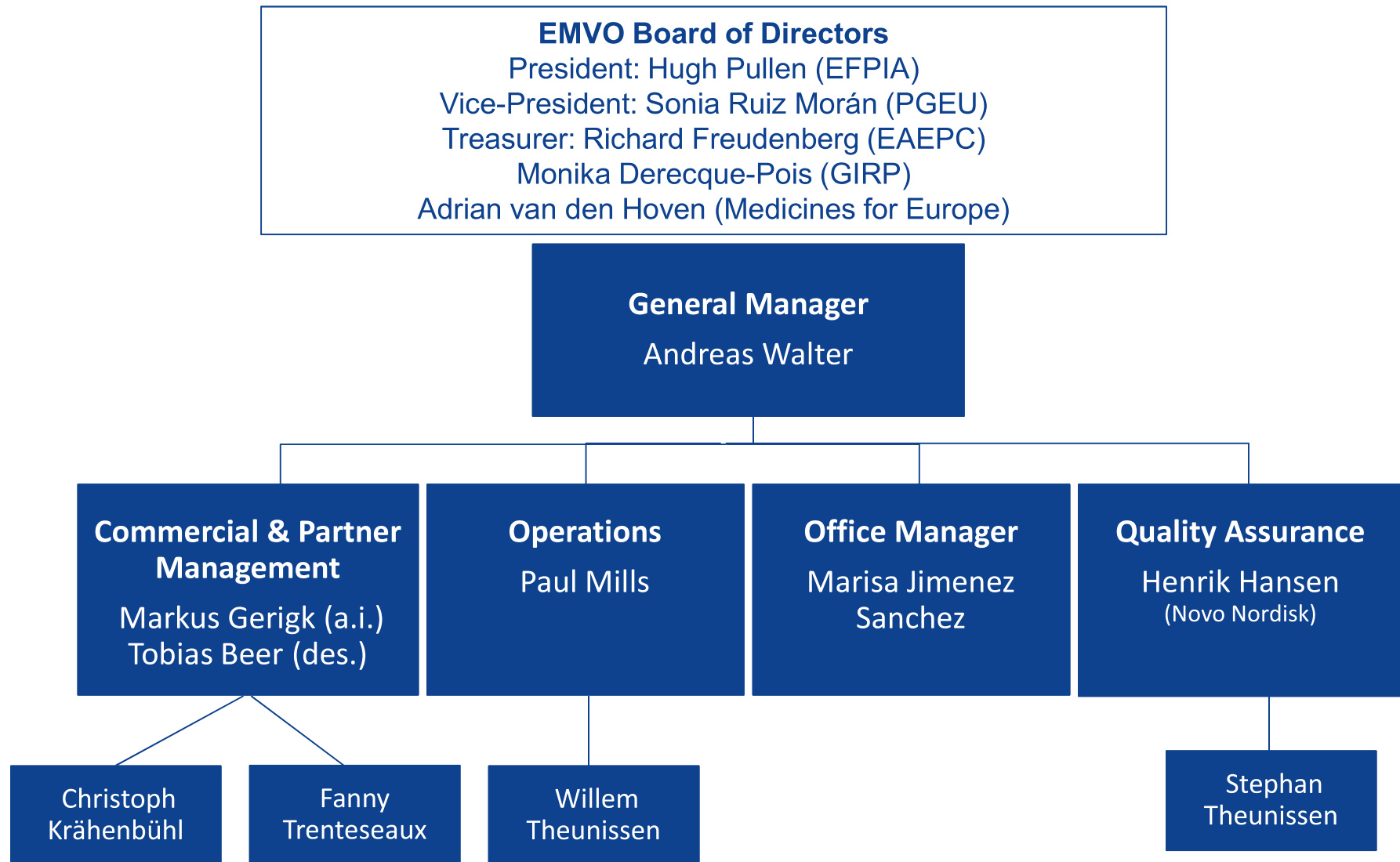|	
Product #:	09876543210982
S/N:	12345AZRQF1234567890
Batch:	A1C2E3G4I5
Expiry:	140531

HUB

EMVO Foundation Members

Organisational chart

EMVO Board of Directors
President: Hugh Pullen (EFPIA)
Vice-President: Sonia Ruiz Morán (PGEU)
Treasurer: Richard Freudenberg (EAEPC)
Monika Derecque-Pois (GIRP)
Adrian van den Hoven (Medicines for Europe)

General Manager

Andreas Walter

Commercial & Partner Management

Markus Gerigk (a.i.)
Tobias Beer (des.)

Operations

Paul Mills

Office Manager

Marisa Jimenez Sanchez

Quality Assurance

Henrik Hansen
(Novo Nordisk)

Christoph Krähenbühl

Fanny Trenteseaux

Willem Theunissen

Stephan Theunissen

OBP: On-boarding Partner
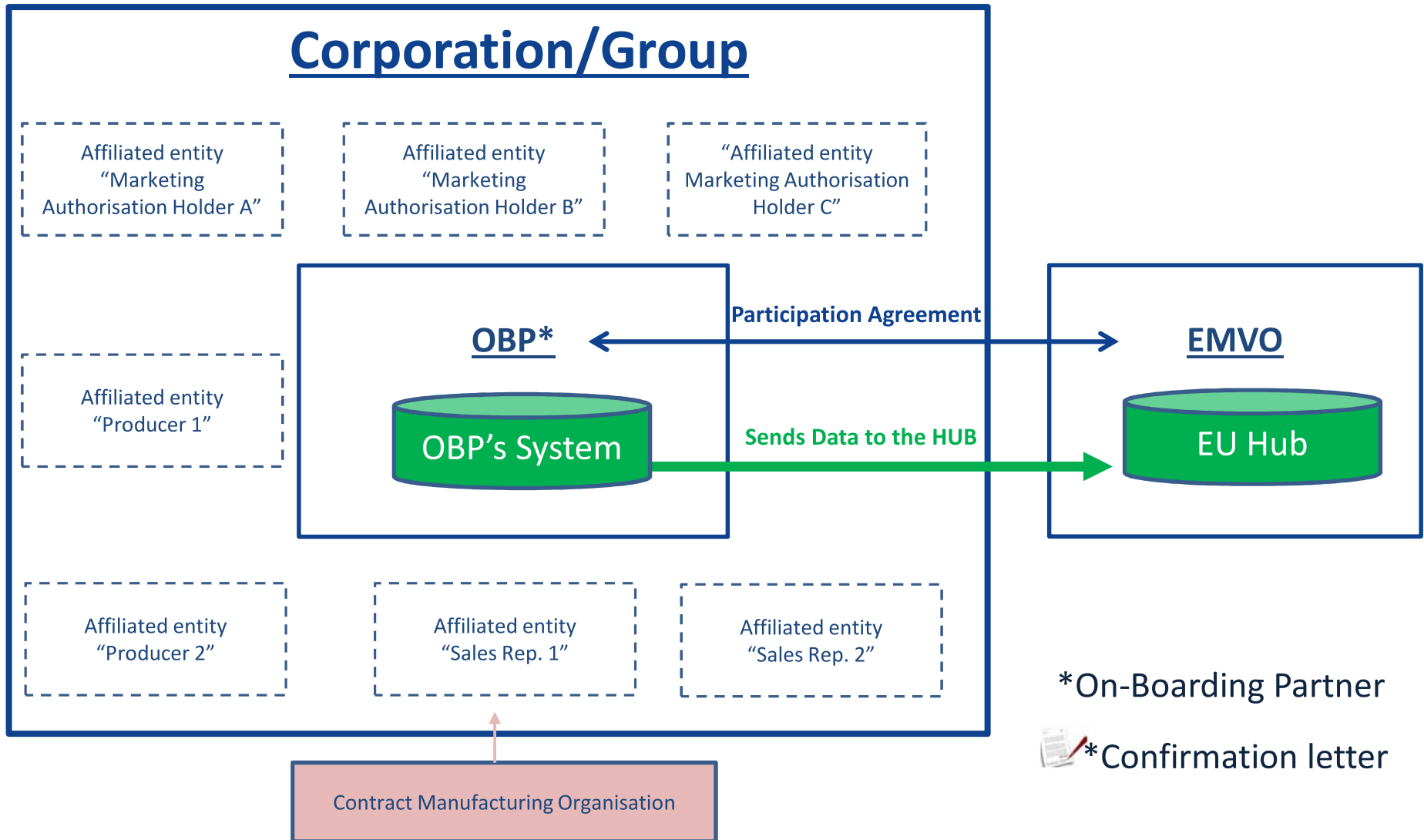**NMVS:** National Medicines Verification System
NMVO: National Medicines Verification Organisation
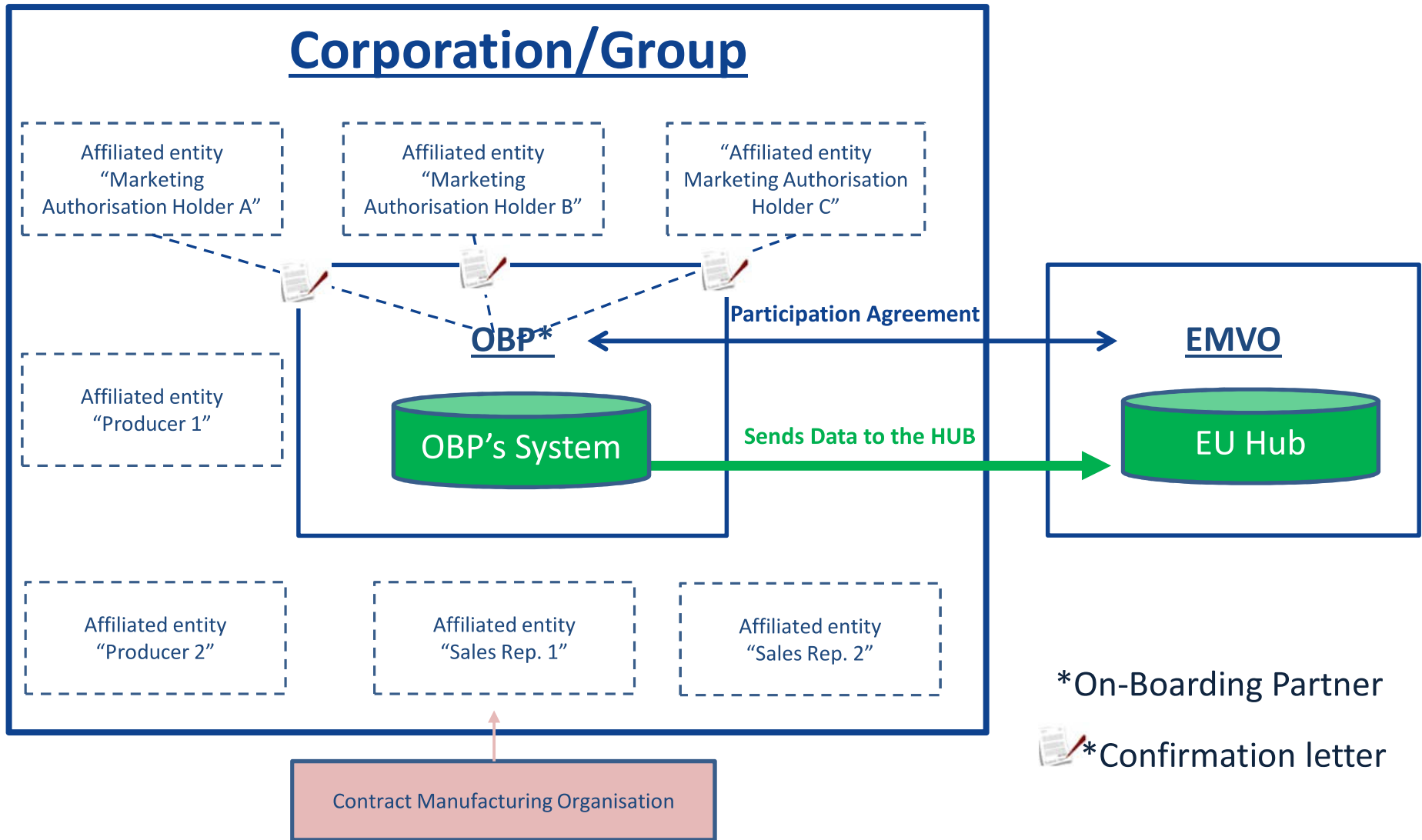
What is an "OBP"?

❑ OBP means **O**n-**B**oarding **P**artner and is the contracting party of EMVO and concludes the non-disclosure agreement (NDA) and participation agreement (PA).

❑ The OBP is legally authorized to sign on behalf of a MAH/a group of MAHs.

❑ The OBP has to be affiliated (*) to a MAH/a group of MAHs

(*) 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).
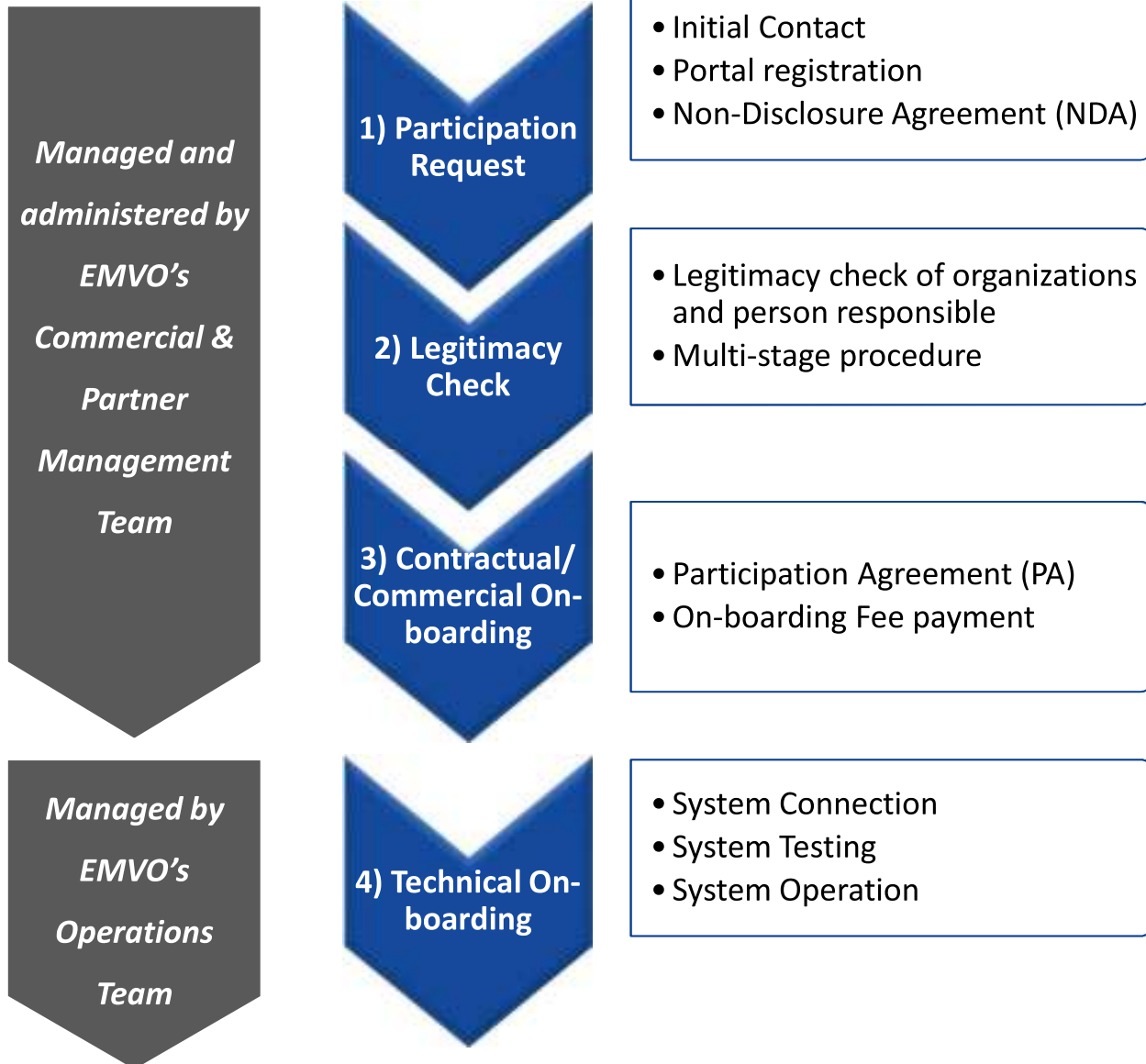
Relationship OBP* and EMVO

Corporation/Group

Affiliated entity "Marketing Authorisation Holder A"

Affiliated entity "Marketing Authorisation Holder B"

"Affiliated entity Marketing Authorisation Holder C"

Affiliated entity "Producer 1"

OBP*

OBP's System

Participation Agreement

EMVO

EU Hub

Sends Data to the HUB

Affiliated entity "Producer 2"

Affiliated entity "Sales Rep. 1"

Affiliated entity "Sales Rep. 2"

Contract Manufacturing Organisation

*On-Boarding Partner

*Confirmation letter

12

Relationship OBP* and EMVO

Corporation/Group

Affiliated entity "Marketing Authorisation Holder A"

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"Affiliated entity Marketing Authorisation Holder C"

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Sends Data to the HUB

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Affiliated entity "Producer 2"

Affiliated entity "Sales Rep. 1"

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Contract Manufacturing Organisation

*On-Boarding Partner

*Confirmation letter

On-Boarding Process

Managed and administered by EMVO's Commercial & Partner Management Team

1) Participation Request

- Initial Contact
- Portal registration
- Non-Disclosure Agreement (NDA)

2) Legitimacy Check

- Legitimacy check of organizations and person responsible
- Multi-stage procedure

3) Contractual/ Commercial On-boarding

- Participation Agreement (PA)
- On-boarding Fee payment

Managed by EMVO's Operations Team

4) Technical On-boarding

- System Connection
- System Testing
- System Operation

OBP Contracts with EMVO

1. Non-Disclosure Agreement (NDA)

- Covers **provision of Confidential Information** by EMVO, e.g. on
  - European Hub
  - Gateway
- Purpose: **Assessment of participation** in the EMVS project

2. Participation Agreement (PA)

- Contractual framework for **participation in the On-boarding project**, e.g.
  - Use of Gateway
  - Interface development
  - Connect to the HUB
  - SDK
- Purpose: **Execution of Technical On-Boarding**

OBP Contracts with EMVO

1. Non-Disclosure Agreement (NDA)	2. Participation Agreement (PA)

- Covers **provisi...** ...l framework for **Confident...** ...**the On-** EMVO... ...g.

  - ▪ ...
  - ▪ ...nt

- Pu... **parti...** ...ng project...

No Contract Negotiation

One-Time Fee per OBP

OBPs with more than 12 MAHs in Europe	20,000 €
OBPs with 6 to12 MAHs in Europe	10,000 €
OBPs with 3 to 5 MAHs in Europe	8,000 €
OBPs with 2 MAHs in Europe	6,000 €
OBPs with 1 MAH in Europe	3,000 €

On-Boarding Contract Landscape

EMVO ←— Participation Agreement —→ OBP

Frame Contract
HUB

License Agreement

Service Contract

Solidsoft ←— Support Contract —→ OBP CP
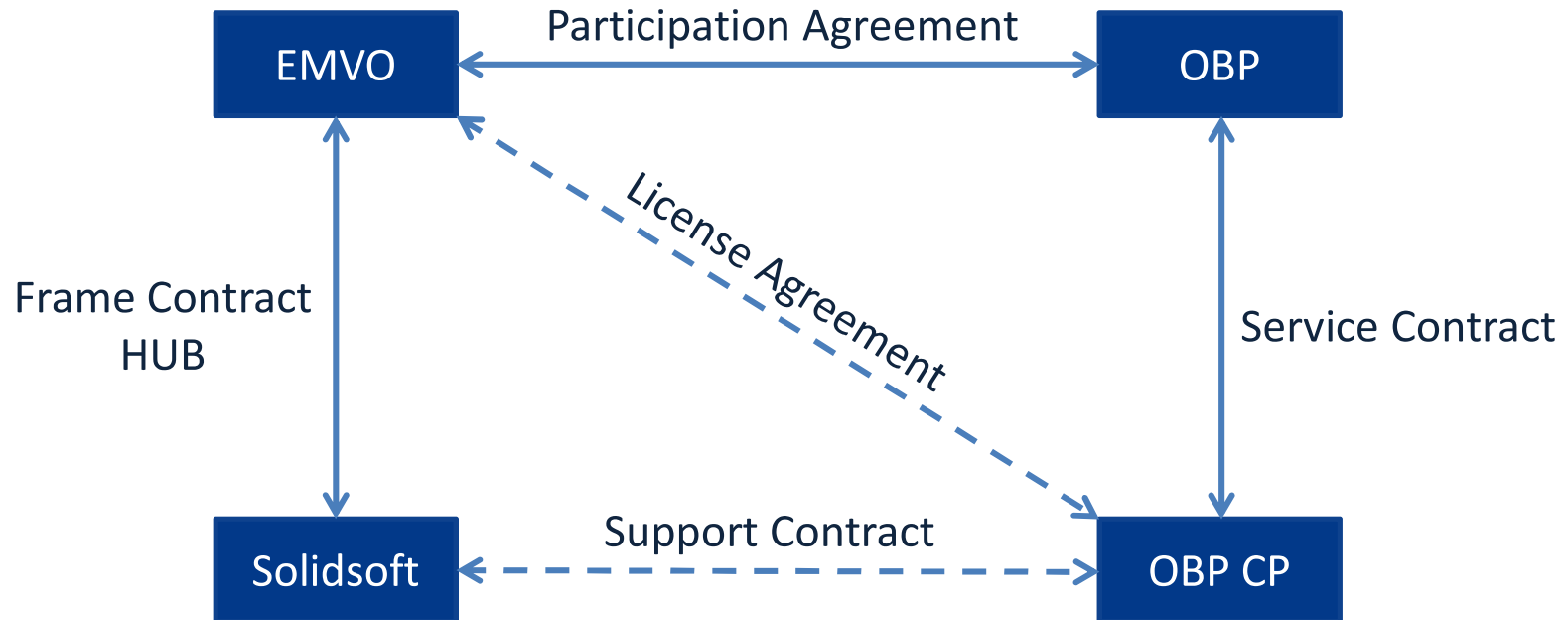
EMVO: European Medicines Verification Organization
Solidsoft: IT Service Provider for implementation and operation of European HUB
OBP: On-Boarding Partner
OBP CP: IT Service Provider
  - Gateway connection
  - Direct connection

Technical On-boarding

❑ Starts when Participation Agreement is signed by EMVO

❑ OBPs will connect their system sequentially to:

- the ITE environment to develop an interface

- the IQE environment to certify the interface

- The PRD environment to use the interface

❑ OBPs can choose to connect via

- a Direct connection (data send from OBP's system straight to EU Hub)

- a Gateway connection (Data sent first to a Gateway Provider. The Gateway Provider sends it through to the EU Hub

EU Hub Environments

ITE

IQE

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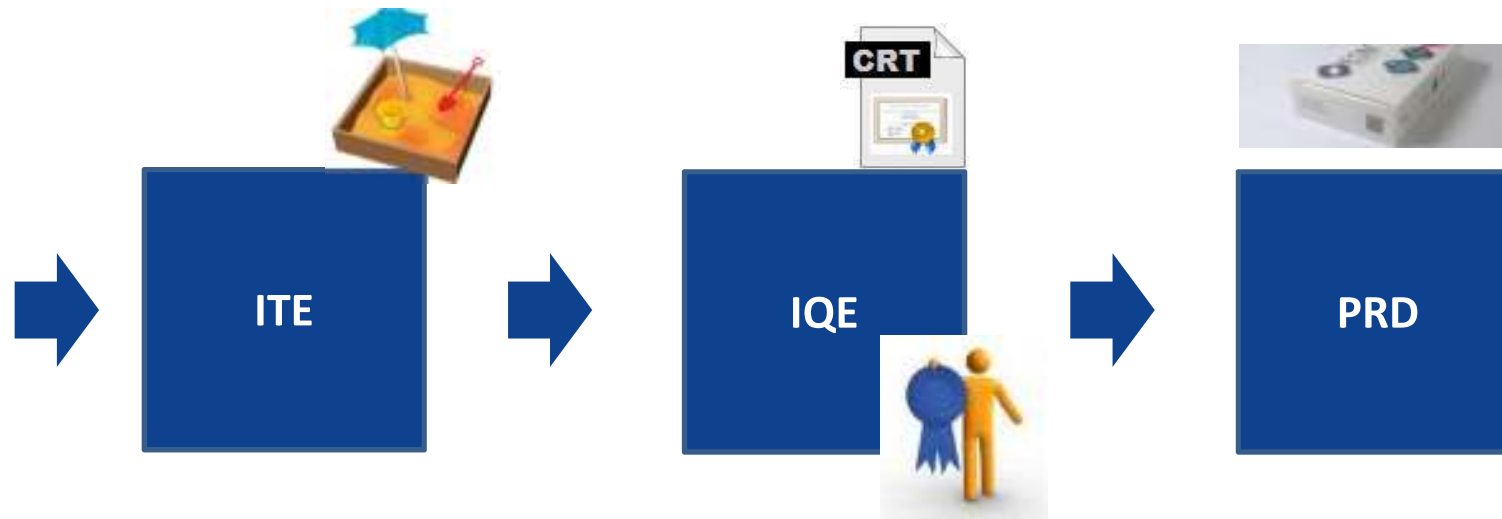
ITE environment
- Integrated Test Environment
- Used as sandbox by multiple OBP's
- Integration testing of OBP's connection

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

PRD environment
- Productive Environment
- Validated environment

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

Connection Types

EU Hub

OBP A Hub Connection 2

OBP B Hub Connection

OBP C Hub Connection

OBP A Hub Connection 1

Gateway Provider X

Gateway Provider Y

OBP A Gateway Connection

OBP B Gateway Connection

OBP C Gateway Connection

OBP A

OBP's System a

OBP B

OBP's System b

OBP C

OBP's System c
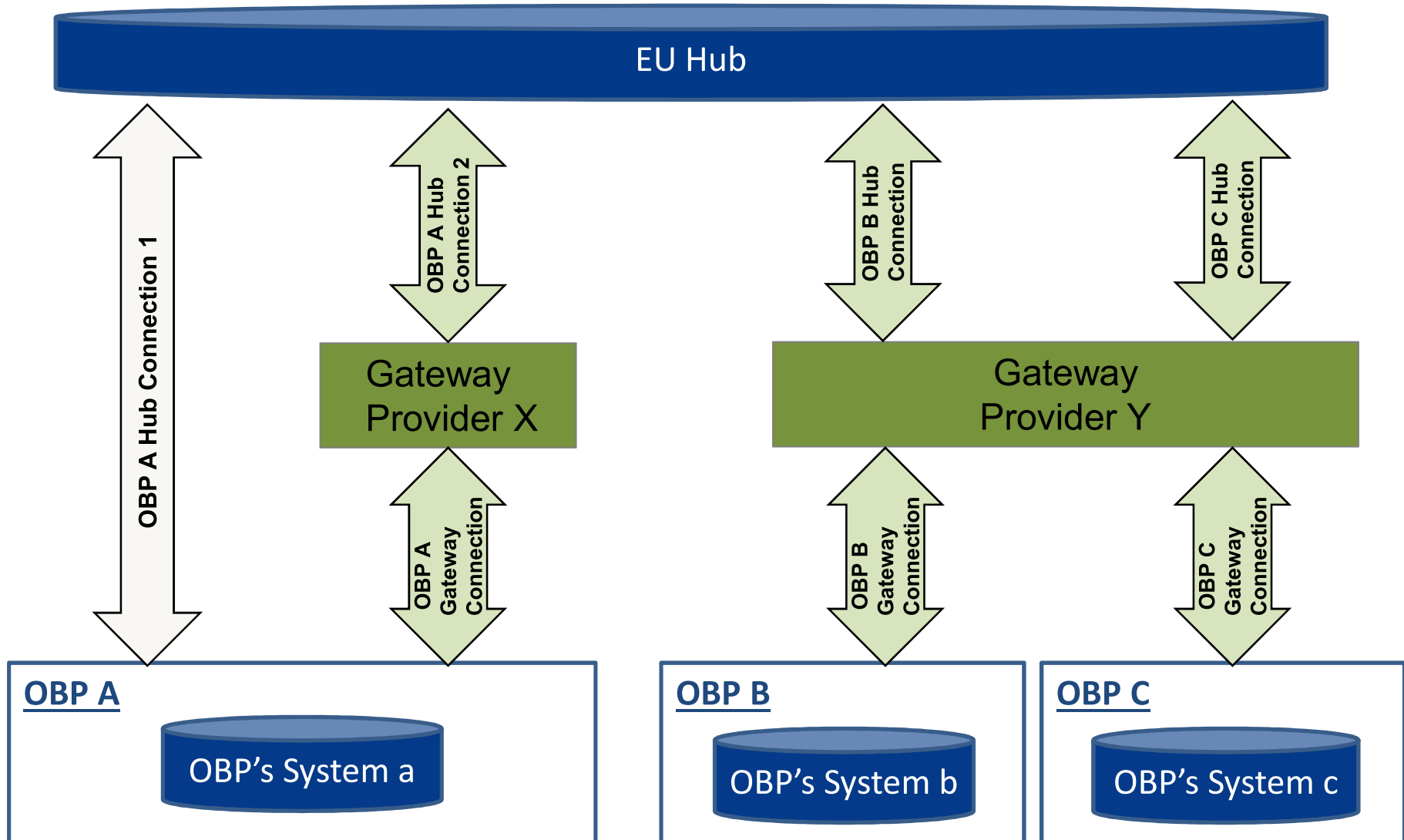
What is an OBP Gateway Provider?

- ❑ A third-party contractor engaged by the OBP, who assists in whole or part of with the **development, implementation, provision, use and/or operation** of the OBP interface to the EU Hub via a Gateway Connection

- ❑ Every OBP Gateway Provider has to be promoted by at least one OBP in the On-boarding Process

- ❑ EMVO validates and approves the proposed Gateway Providers

General Information

How does the On-Boarding work?

General Information

How does the On-Boarding work?

Prerequisite to on-board
> 2.500 MAHs/Parallel Distributors

User-friendly
web-based portal
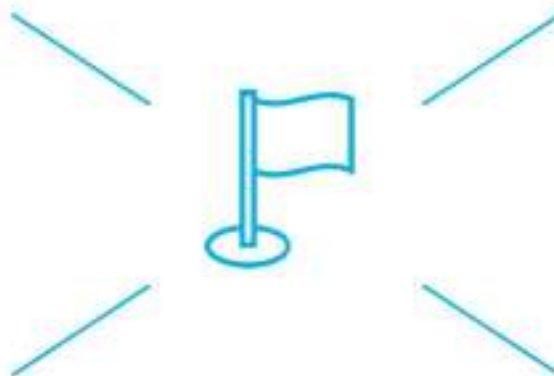
Decrease EMVO's
response time

Starting point/ trigger
for legitimacy check

How does the On-Boarding work?

On Boarding Partner Portal
(Support software to guide OBPs to connect with the EU Hub)

How to request to participate

1. Via website – link

2. Fill in User + Company details

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

On-Boarding Partner Portal

Step 1: Provide Initial Information

Step 2: Non-Disclosure Agreement

Step 3: Participation Agreement + Detailed information

Step 4: Approvals

Step 5: Technical On Boarding

Step 1: Provide Initial Information

Trigger step 1:
Successful Request to Participate

To add or modify the requested information

Estimated time to complete

Status:
Not Started
In Progress
Complete

Step 1: Provide initial information

			Time to complete	Status
1.1	Company information ℹ	Add	5-7 min	Not Started
1.2	Authorised representative information ℹ	Add	5-7 min	Not Started
1.3	Pre-technical Connection Information ℹ	Add	5-7 min	

Step 2: Non-disclosure agreement

Step 3: Detailed information and participation agreement

Step 4: Approvals

Step 5: Technical onboarding

1.1 Company Information

Please provide all the necessary/mandatory **information of your Company** which will be used for the legitimacy check

1.2 Authorised Representative

Please provide all the necessary/mandatory **information of the Authorised representative** which will be used for the legitimacy check

Note:
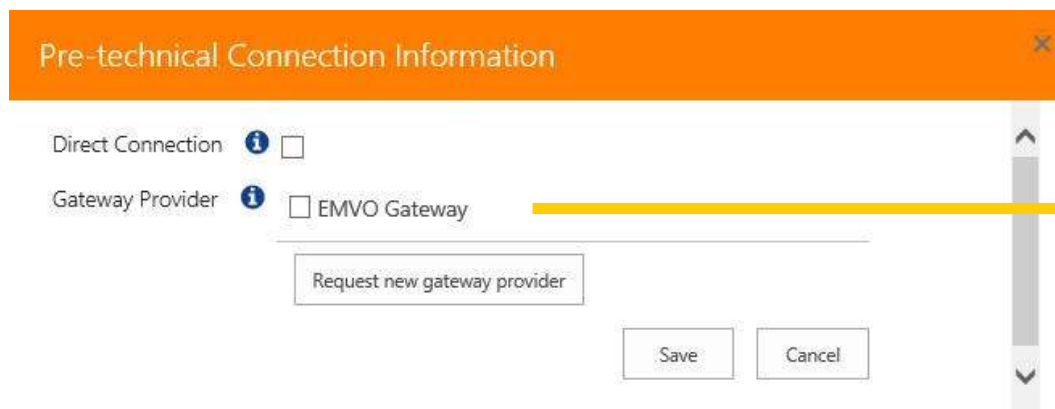The Authorised Representative will be the person who need to sign the Participation Agreement and the Non-Disclosure Agreement

Obligated for the legitimacy check

Action:
A prefilled NDA will be generated

1.3 Connection Provider Information

Optional:
This field can be used to provide us info concerning the desired
Connection to the EU Hub (if already known at this stage)

List with Certified * Gateway Providers which allows the OBP to start immediately the mini-certification test in the Integrated Quality Environment (IQE)

Note:
We only allow 2 connection per OBP

* Certified Gateway Provider is a provider which for a first OBP already passed the full certification test of the Gateway of this Gateway Provider

On-Boarding Partner Portal

Step 1: Provide Initial Information

Step 2: Non-Disclosure Agreement

Step 3: Participation Agreement + Detailed information

Step 4: Approvals

Step 5: Technical On Boarding

Step 2: Non-Disclosure Agreement

Trigger step 2:
- Company information available
- Authorised Representative Information available

View and Download prefilled Non-Disclosure Agreement

Upload signed Non-Disclosure Agreement

Status:
Not Started
Available

Status:
Not Started
Awaiting Approval
Approved
Rejected

	Step 1: Provide initial information	Complete				⌄

	Step 2: Non-disclosure agreement					⌃
				Time to complete	Status	
2.1	Non-disclosure agreement ⓘ		View Download	1 min	Available	
2.2	Upload signed non-disclosure agreement ⓘ		Upload PDF	1 min	Not Started	
2.3	Two hardcopies sent to EMVO ⓘ			21 days		

	Step 3: Detailed information and participation agreement	⌄

	Step 4: Approvals	⌄

	Step 5: Technical onboarding	⌄

Status:
No Status
Awaiting hardcopy
Send back on
xx:xx:xxxx

On-Boarding Partner Portal

Step 1: Provide Initial Information

Step 2: Non-Disclosure Agreement

Step 3: Participation Agreement + Detailed information

Step 4: Approvals

Step 5: Technical On Boarding

Trigger step 3:
- EMVO approved the signed Non-Disclosure Agreement

Dowload General Info Pack

Add or Modify requested information

Status:
Not Started
Available

Status:
Not Started
Completed

Status:
Not Started
Available

Status:
Not Started
Awaiting Approval
Approved
Rejected

			Time to complete	Status
Step 1: Provide initial information	Complete			
Step 2: Non-disclosure agreement	Complete			
Step 3: Detailed information and participation agreement				
3.1	General info pack	Open		Available
3.2	Single point of contact information	Modify	5-7 min	Complete
3.3	Participation Agreement	View Download	1 min	Available
3.4	Upload Signed Participation Agreement	Upload PDF	1 min	Awaiting approval
3.5	Invoicing information	Add	5-7 min	Not Started
3.6	Additional company information	Add	5-7 min	Not started
3.7	MAH and product information	Add	60 min	Not started
Step 4: Approvals				
Step 5: Technical onboarding				

Step 3: Detailed information and Participation Agreement

View and Download prefilled Participation Agreement

Upload signed Participation Agreement

			Time to complete	Status
Step 1: Provide initial information	Complete			
Step 2: Non-disclosure agreement	Complete			
Step 3: Detailed information and participation agreement				
3.1	General info pack	Open		Available
3.2	Single point of contact information	Modify	5-7 min	Complete
3.3	Participation Agreement	View Download	1 min	Available
3.4	Upload Signed Participation Agreement	Upload PDF	1 min	Awaiting approval
3.5	Invoicing information	Add	5-7 min	Not Started
3.6	Additional company information	Add	5-7 min	Not started
3.7	MAH and product information	Add	60 min	Not started
Step 4: Approvals				
Step 5: Technical onboarding				

Status:
Not Started
Completed

38

3.1 General Info Pack

In the **General info Pack** the OBP can find some General Information

3.2 Single point of contact

Please provide all the necessary/mandatory **information of the Single point of contact** which will be used to generate the Participation Agreement

Note:
The Single point of contact will be confirmed by the Authorized Representative in the Participation Agreement to be the responsible for providing all the required information in the OBP Portal for the On-boarding of the OBP

Action:
A prefilled Participation Agreement will be generated

3.5 Invoicing information

Please provide all the necessary/mandatory **invoicing information** to where we can address the Invoicing form

On-Boarding Partner Portal

Step 1: Provide Initial Information

Step 2: Non-Disclosure Agreement

Step 3: Participation Agreement + Detailed information

Step 4: Approvals

Step 5: Technical On Boarding

Step 4: Approvals

Trigger step 4:
- Step 3 completed

Status:
Not Started
Passed
Failed

Status:
Not Started
Awaiting harcopy
Sent back on
xx:xx:xxxx

Step 1: Provide initial information	Complete	
Step 2: Non-disclosure agreement	Complete	
Step 3: Detailed information and participation agreement		

Step 4: Approvals		
---	Time to complete	Status
4.1 Legitimacy check status ℹ	14 days	
4.2 Countersigned Participation Agreement send back to OBP ℹ	21 days	
4.3 Invoice status ℹ		

| Step 5: Technical onboarding | | |

Status:
No Status
Awaiting payment
Payment received

On-Boarding Partner Portal

Step 1: Provide Initial Information

Step 2: Non-Disclosure Agreement

Step 3: Participation Agreement + Detailed information

Step 4: Approvals

Step 5: Technical On Boarding

**The Technical On-boarding process
will be described in future
 versions of this presentation**

Sign-off page

Authored by:

Willem Theunissen		
Author	Signature	Date

Approved by:

Tobias Beer		
Commercial & Partner Manager	Signature	Date

Revision History:

Version Date	Version	Author	Reason For Changes
18/04/2017	V1.0	Stephan Theunissen	Initial Document
3/5/2017	V2.0	Willem Theunissen	adapted: Slide 15: SDK moved to PA Slide 19: Client adapted to OBP's system

Sign-off page

Authored by:

Willem Theunissen		3/05/17
Author	Signature	Date

Approved by:

Tobias Beer		3/05/17
Commercial & Partner Manager	Signature	Date