



European Medicines
Verification Organisation



European Federation of Pharmaceutical
Industries and Associations



PGEU GPUE

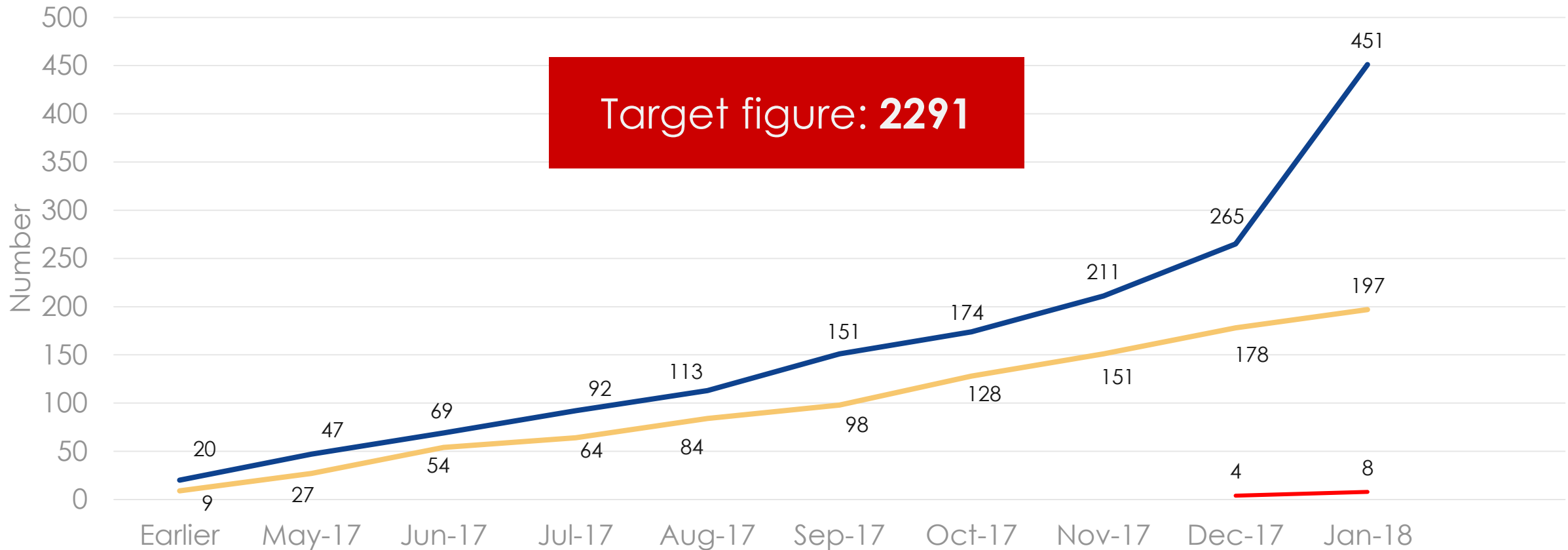


OBP ALREADY REGISTERED WITHIN THE HUB: EMVO'S ON-BOARDING PROCESS

OSMR CONFERENCE
9TH FEBRUARY 2018

Andreas Walter
(General Manager)
European Medicines Verification Organisation

STATUS ON-BOARDING



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

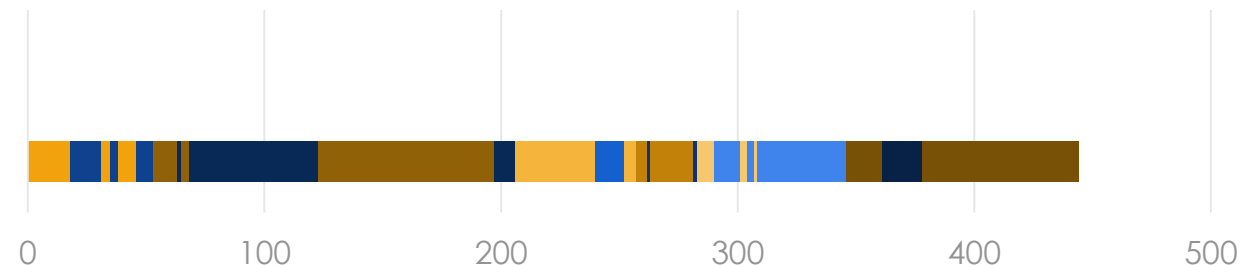
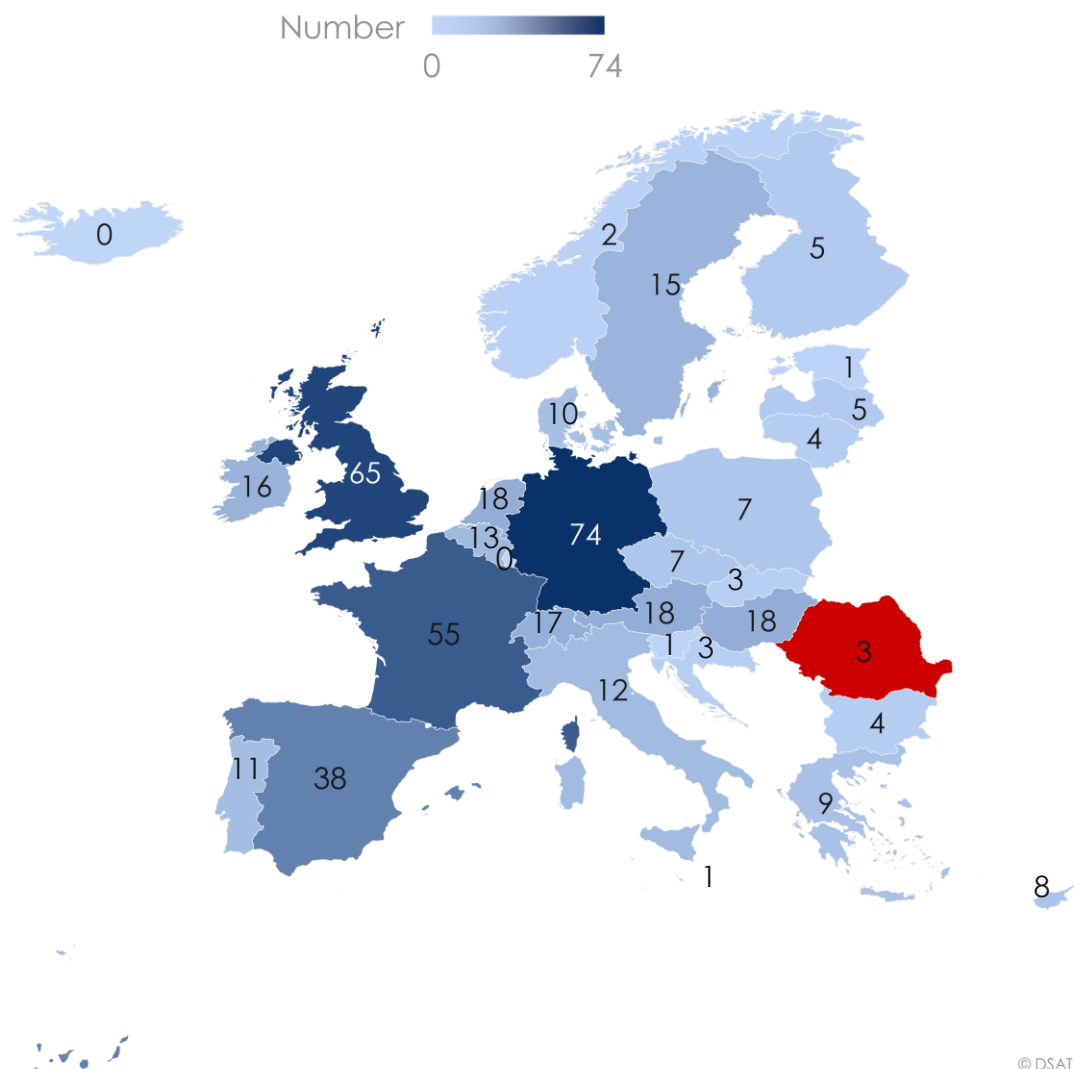
— Legitimacy check passed

— OBPs connected to Hub V2 (PRD)

09 February 2018

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SIGNED PARTICIPATION AGREEMENT BY OBPs PER COUNTRY



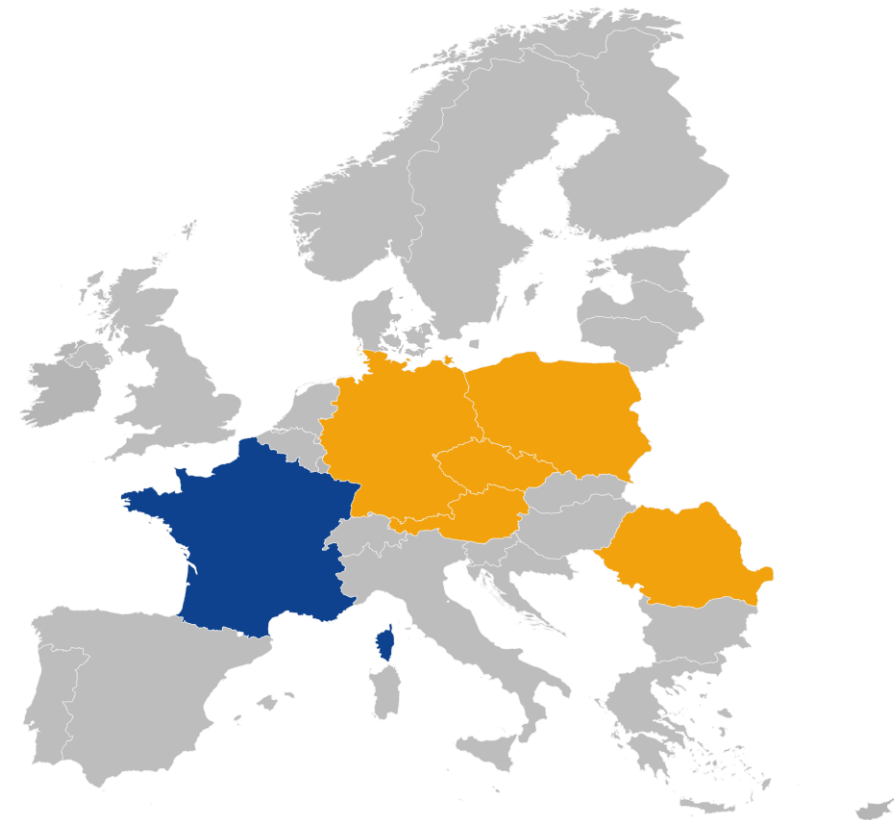
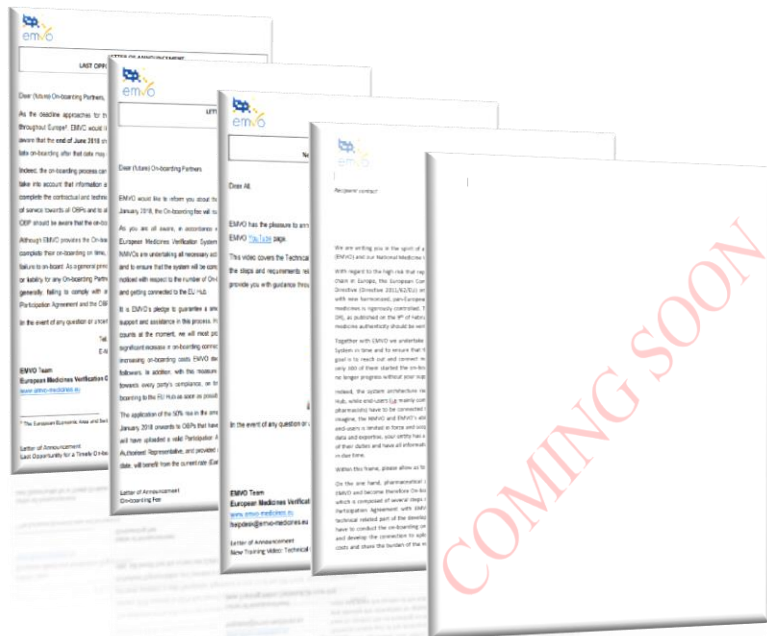
- | | | | |
|------------|-----------------|---------------|---------------|
| ■ Austria | ■ Belgium | ■ Bulgaria | ■ Croatia |
| ■ Cyprus | ■ CZ | ■ Denmark | ■ Estonia |
| ■ Finland | ■ France | ■ Germany | ■ Greece |
| ■ Hungary | ■ Iceland | ■ Ireland | ■ Italy |
| ■ Latvia | ■ Liechtenstein | ■ Lithuania | ■ Luxembourg |
| ■ Malta | ■ Monaco | ■ Netherlands | ■ Norway |
| ■ Poland | ■ Portugal | ■ Romania | ■ Slovakia |
| ■ Slovenia | ■ Spain | ■ Sweden | ■ Switzerland |
| ■ UK | | | |

Additional PA signed by OBPs in non-european countries:

- | | |
|---|--------|
|  | 2 OBPs |
|  | 4 OBPs |

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AWARENESS CAMPAIGN



- Attended workshops
- Attended NMVO workshops
- Upcoming workshops in the next months

15th December 2017 - On-boarding Fee rise by 50%

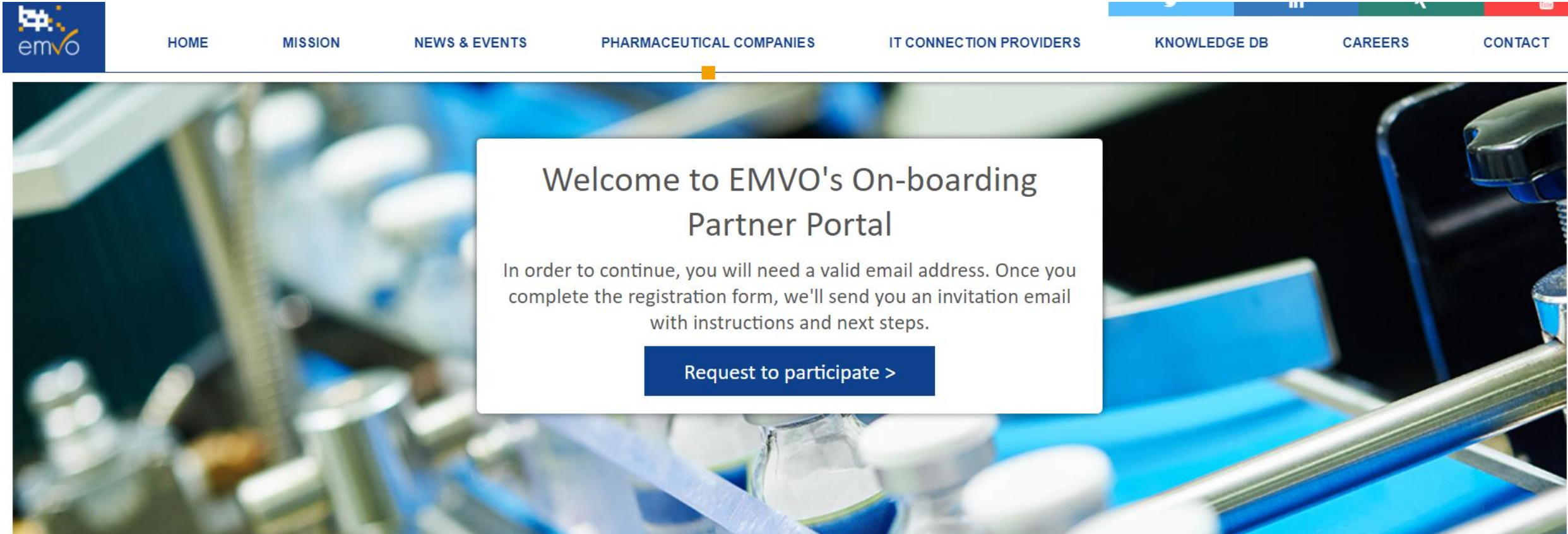
12th January 2018 - Last Opportunity for a timely On-boarding (June 2018)

TO BE SENT OUT: EMVO Notice to future On-boarding Partners

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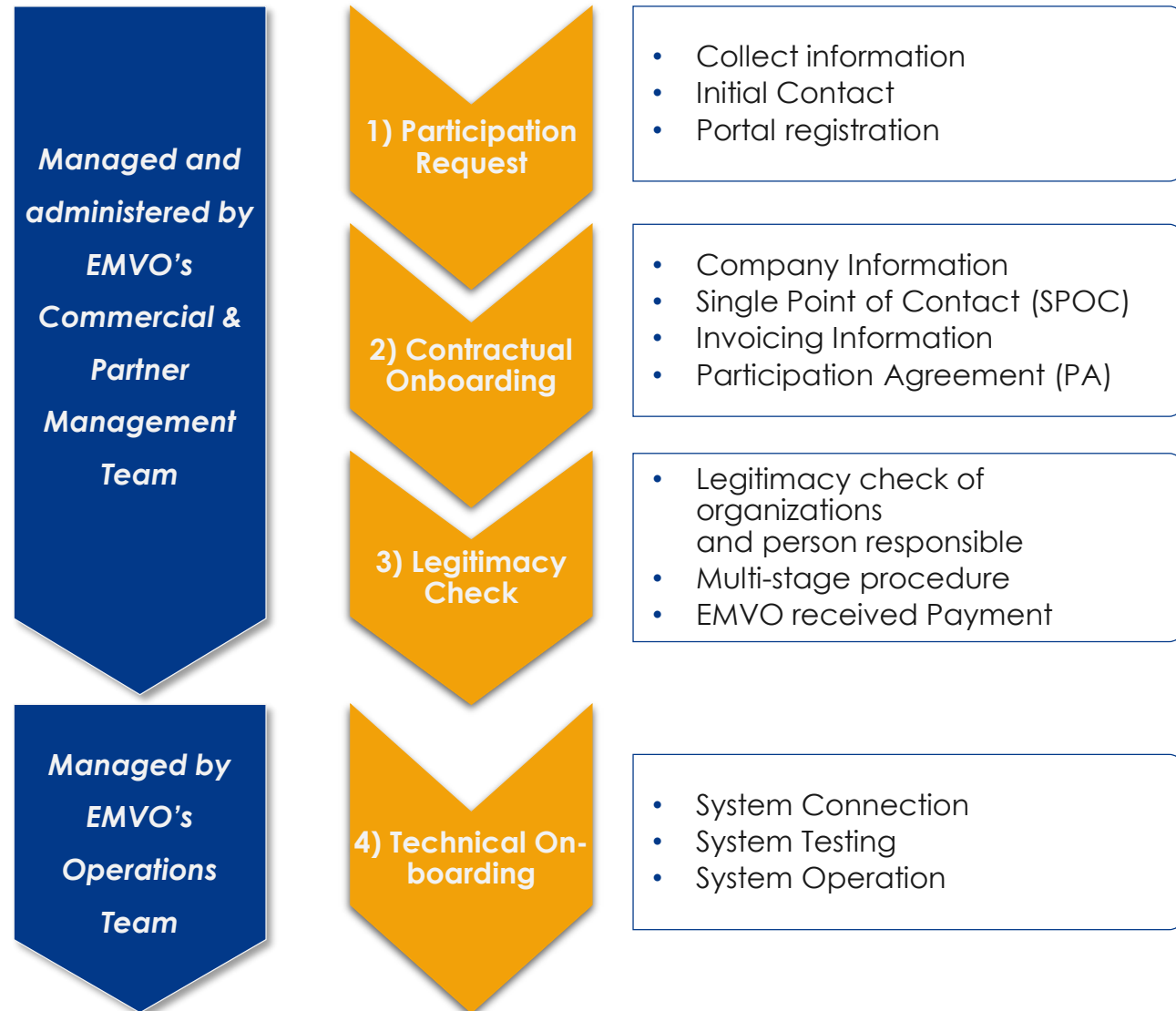
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HOW DOES THE ON-BOARDING WORK?



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

ON-BOARDING PROCESS

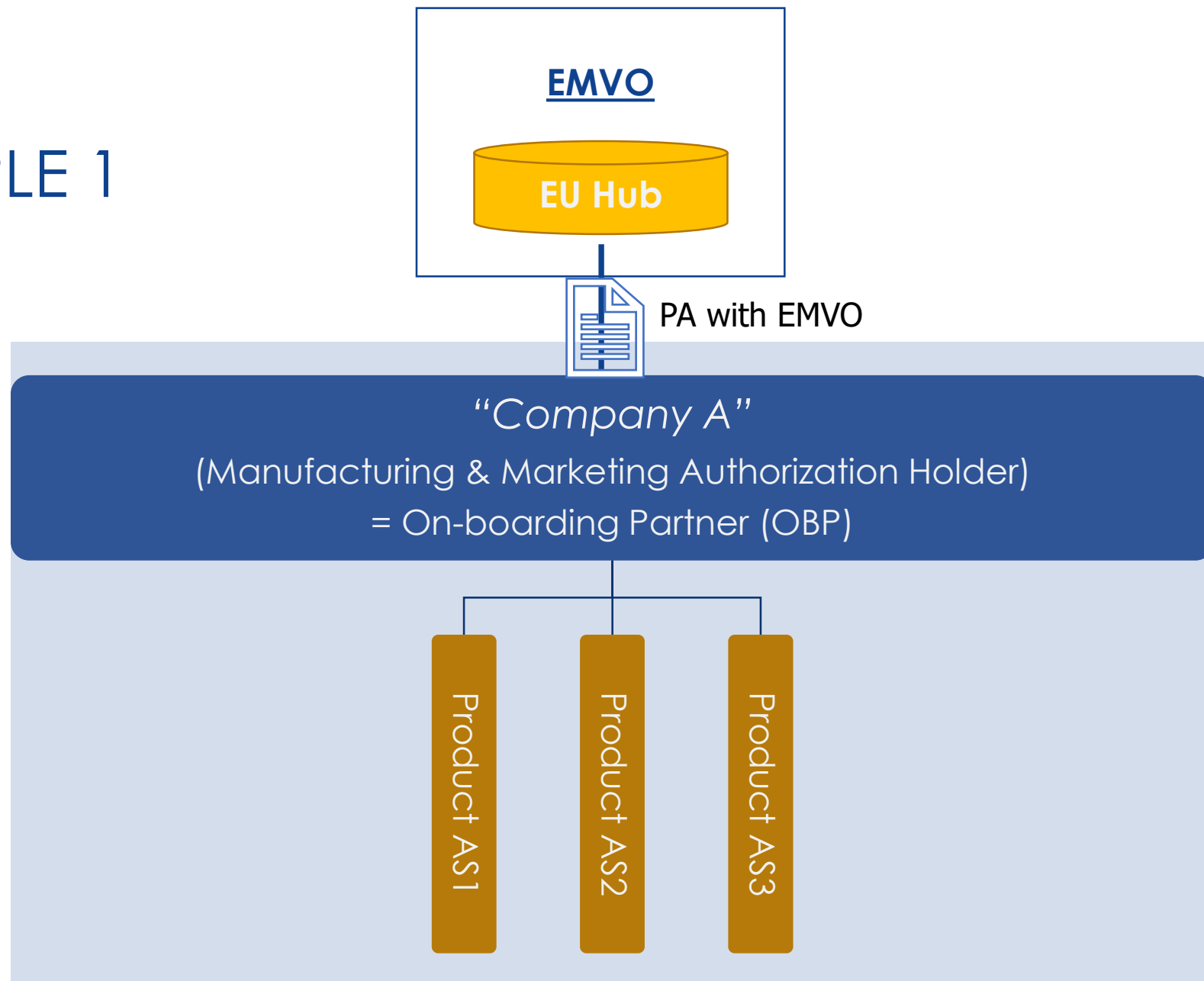


WHAT IS AN “OBP”?

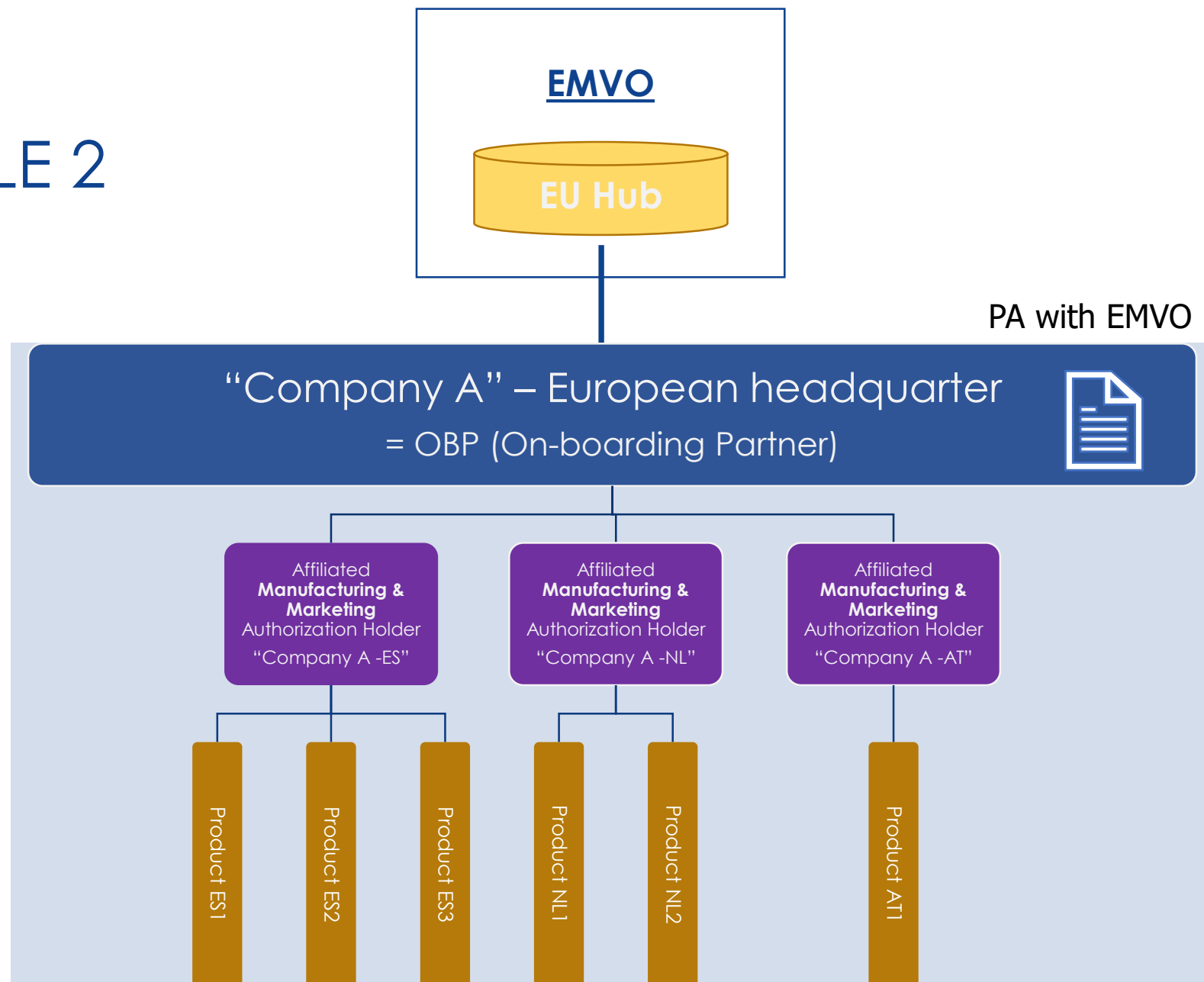
- OBP means **On-Boarding Partner**. The OBP is the contracting party of EMVO; it concludes the Non-Disclosure Agreement (NDA) and Participation Agreement (PA).
- The OBP **represents the Marketing Authorization Holders (MAH)** it will upload data for in the European Hub. It has therefore to be legally authorized to conclude contracts on behalf of a MAH/a group of MAHs.
- The OBP has to be **affiliated (*) to a MAH/a group of MAHs**
- The OBP should be located in the European Economic Area.

(*) 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).

EXAMPLE 1



EXAMPLE 2



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?

ON-BOARDING PARTNER PORTAL

Step 1: Provide Initial Information

Step 2: Participation Agreement + Detailed information

Step 3: Approvals

Step 4: 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

Step 1: Provide initial information				
			Time to complete	Status
1.1	Company information ⓘ	Add	5-7 min	Not Started
1.2	Authorised representative information ⓘ	Add	5-7 min	Not Started
1.3	Pre-technical Connection Information ⓘ	Add	5-7 min	

Status:
Not Started
In Progress
Complete

ON-BOARDING PARTNER PORTAL

Step 1: Provide Initial Information

Step 2: Participation Agreement + Detailed information

Step 3: Approvals

Step 4: Technical On Boarding

STEP 2: DETAILED INFORMATION AND PARTICIPATION AGREEMENT

Trigger step 2:

Successful Initial Information and Authorise Representative copy of proof

Download
General
Info Pack

Status:

Not Started
Completed

Step 2: Detailed information and participation agreement				
			Time to complete	Status
2.1	General info pack	Open		
2.2	Single point of contact information	Add	5-7 min	Not Started
2.3	Participation Agreement		1 min	
2.4	Upload Signed Participation Agreement	Upload PDF	1 min	Not Started
2.5	Invoicing Information Form	View Download	5 min	Available
2.6	Upload Invoicing Information Form	Upload PDF	1 min	Not Started
2.7	MAH and product information	Add	60 min	Not Started

View and Download
prefilled Participation
Agreement (PA)

Status:

Not Started
Awaiting Approval
Approved
Rejected

Status:

Not Started
Completed

A sample of the PA is available on our website in its download section.

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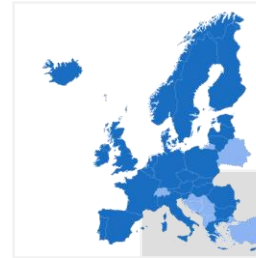
SYSTEM COSTS

EMVO ON-BOARDING / NMVO CONTRACTING



EMVO On-boarding

- Participation Agreement 
- One-time On-boarding Fee (table) 
- Contracting partner : OBP 



NMVO Contracting

- Contract in place 
- Annual fee (flat fee model) 
- Contracting partner : MAH 

ON-BOARDING PARTNER PORTAL

Step 1: Provide Initial Information

Step 2: Participation Agreement + Detailed information

Step 3: Approvals

Step 4: Technical On Boarding

STEP 3: APPROVALS

Trigger step 3:

Step 2 completed and confirm button pressed.

Step 1: Provide initial information		Complete	▼
Step 2: Detailed information and participation agreement		Complete	▼
Step 3: Approvals		Complete	▼
		Time to complete	Status
3.1	Legitimacy check status ⓘ	15 days	In Progress
3.2	Countersigned Participation Agreement send back to OBP ⓘ View	21 days	Awaiting Hardcopy
3.3	Invoice status ⓘ		Awaiting payment
Step 4: Technical onboarding			▼

Status:

Not Started

Passed

Failed

Status:

Not Started

Awaiting hardcopy

Sent back on
xx:xx:xxxx

Status:

No Status

Awaiting

payment

Payment

received

EMVO ON-BOARDING FEE FROM 15TH JANUARY 2018

	Early bird On-Boarding fee	From the 15 th January 2018	From the 15 th June 2018
		+50%	+50%
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

ON-BOARDING PARTNER PORTAL

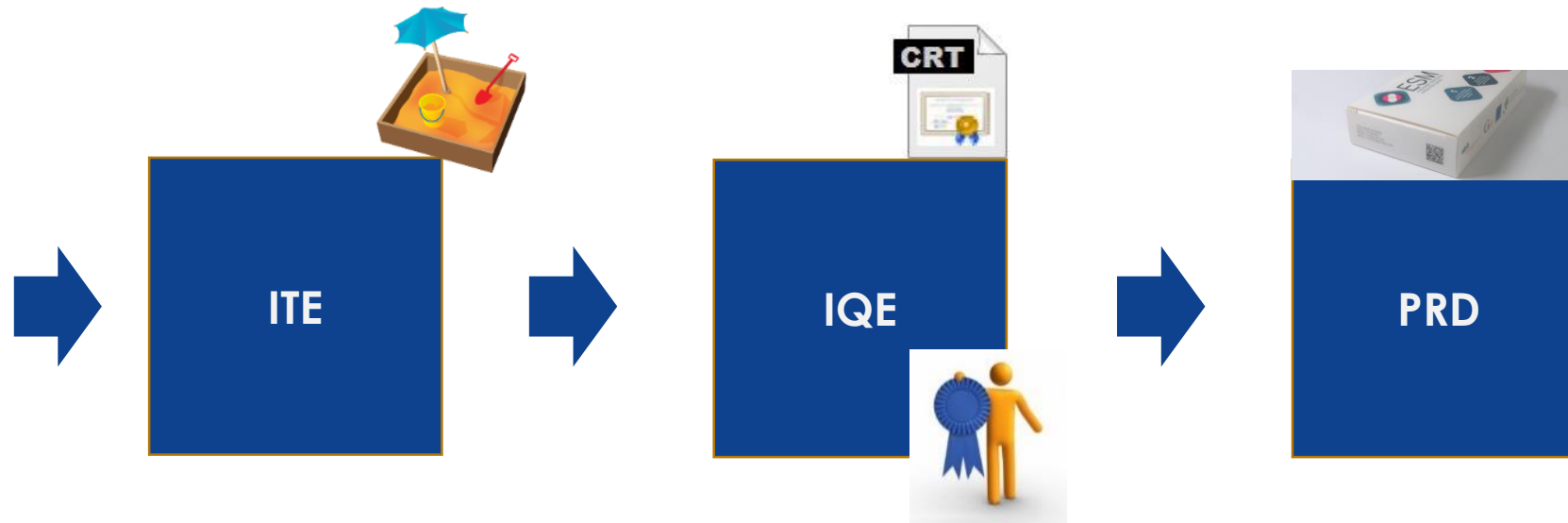
Step 1: Provide Initial Information

Step 2: Participation Agreement + Detailed information

Step 3: Approvals

Step 4: Technical On Boarding

EU HUB ENVIRONMENTS



ITE environment

- Integrated **T**est Environment
- Used as sandbox by multiple OBP's
- Integration testing of OBP's connection

IQE environment

- Integrated **Q**uality 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



Tel. Helpdesk: +372 611 90 44
E-Mail: helpdesk@emvo-medicines.eu

BACKUP

OBP CONTRACT WITH EMVO

The Participant Agreement (PA)

- Contractual framework for the project, e.g.
- Includes a Confidential
- Purpose of the project

**NO
CONTRACT
NEGOTIATION**