European Medicines Verification Organisation

European Hub Manufacturer On-Boarding and Legitimacy Check Process

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European Association of Euro-Pharmaceutical Companies

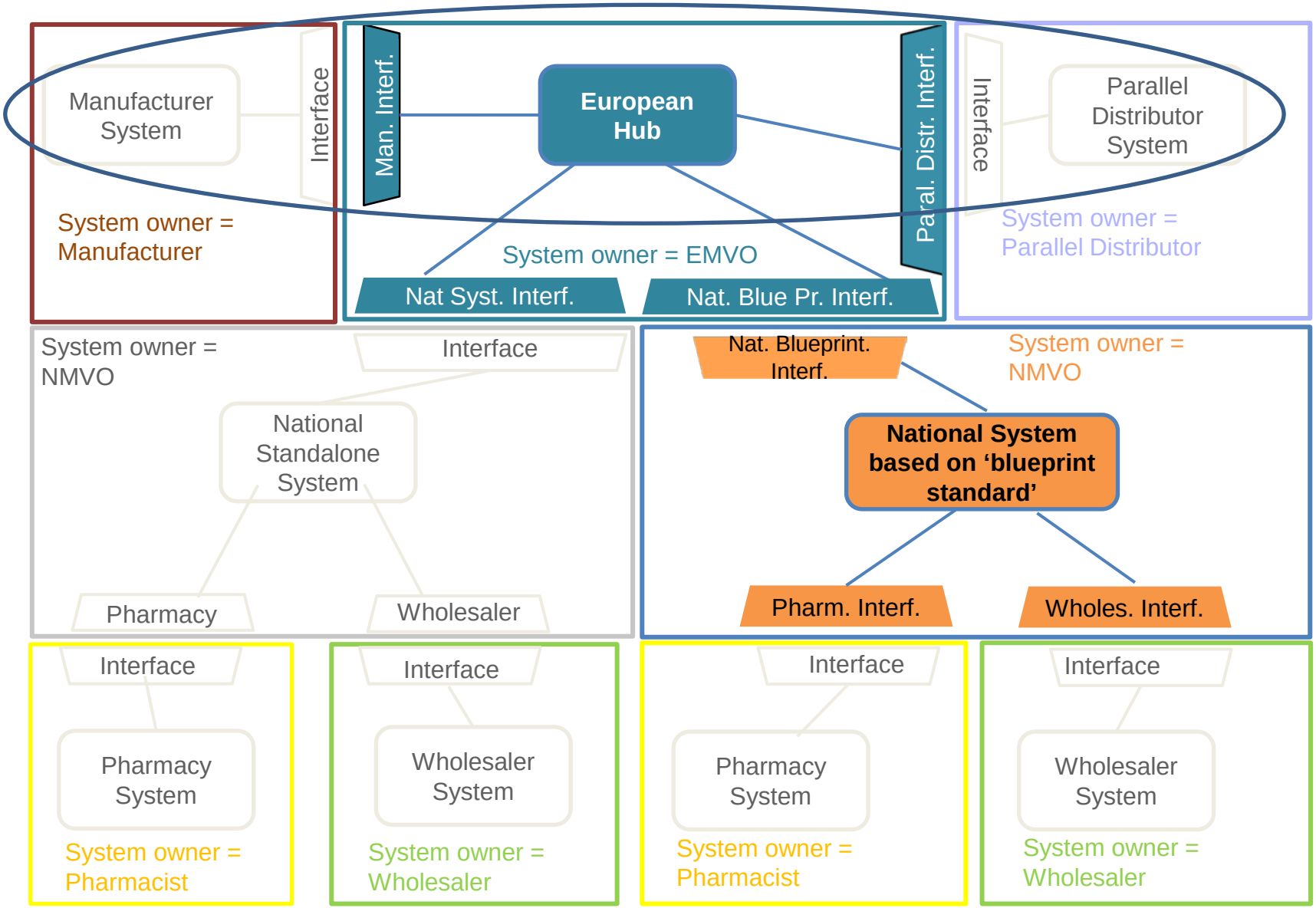
medicines for europe
better access. better health.

efpia
European Federation of Pharmaceutical Industries and Associations

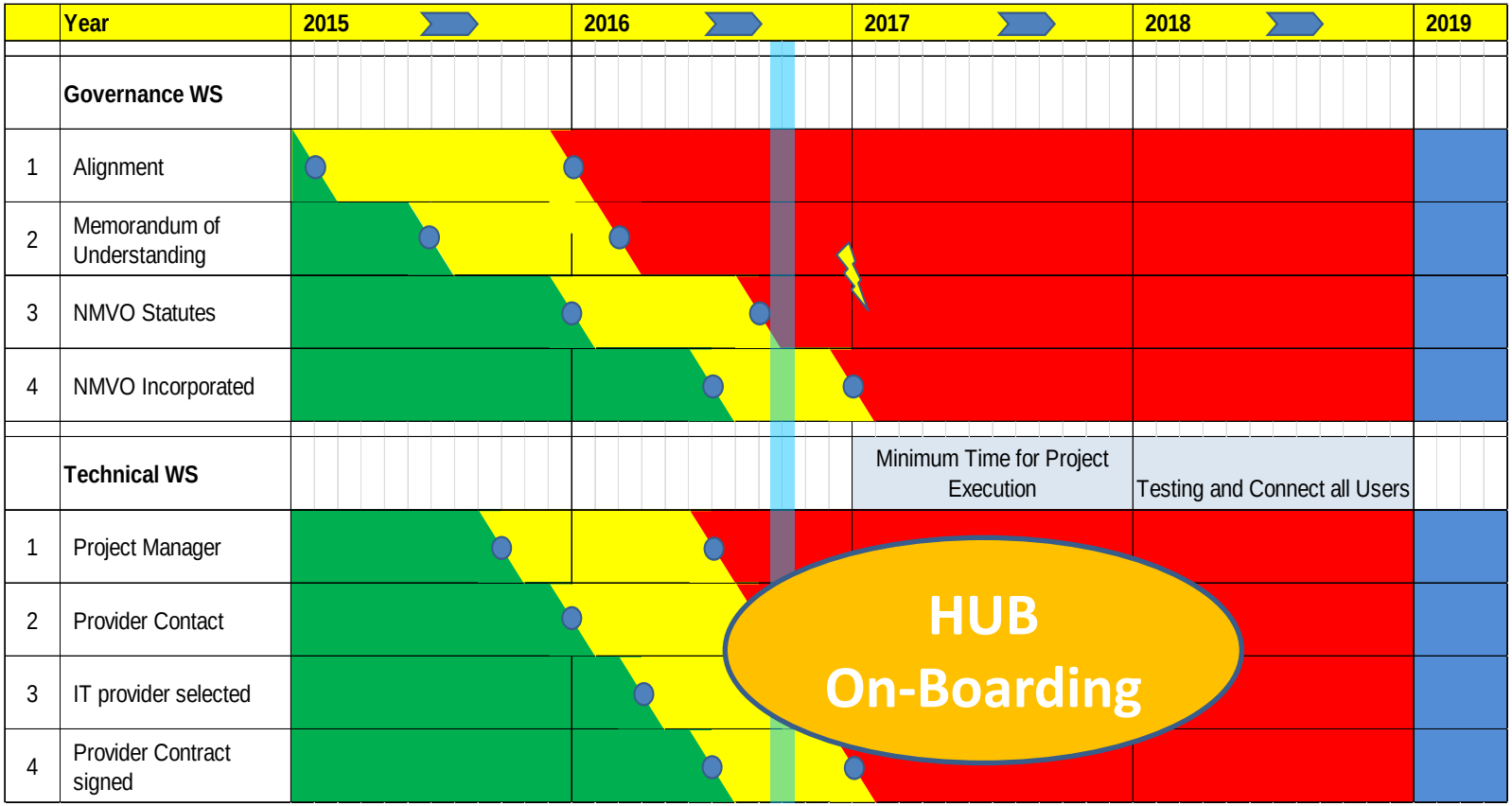
GIRP
the vital link in healthcare

PGEU GPUE
Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

System Landscape



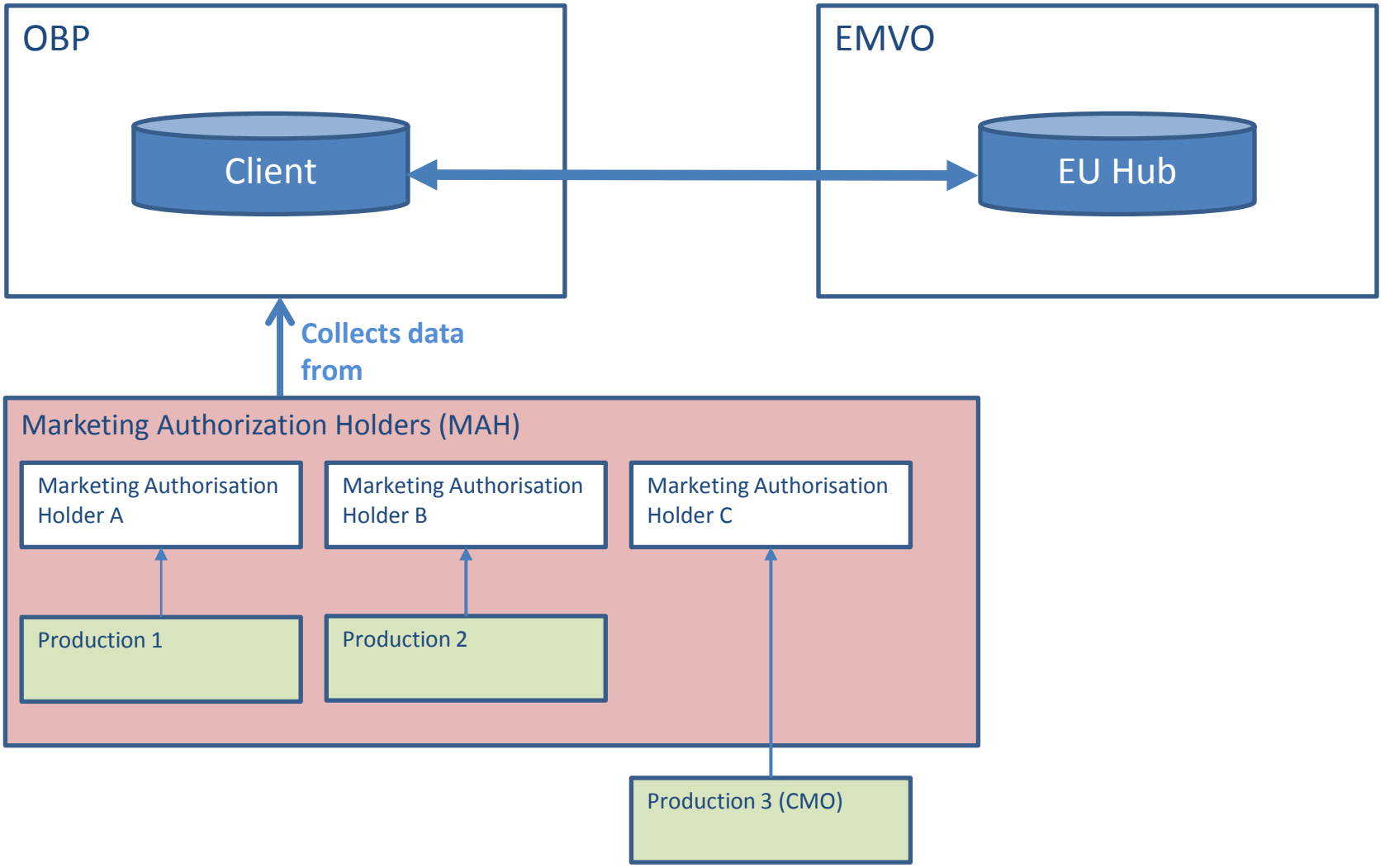
Reference Time Schedule for NMVS Implementation



Terminology

CAR	Corporate Authorisation Request	Initial document where a potential OBP (On-boarding Partner) submits details about: • the Company and Company structure • the Person (Requester) • all Marketing Authorisations (in EEA markets) • list of main products
	Client	Source from which data is sent by an organisation to the EU Hub
	Connection Pack	Pack, provided by Solidsoft-Reply with the technical details (Environment certificates & API endpoints), required to set up a connection to an EU Hub environment
	Connection Type	• Direct: when data is sent from a Client directly to EU Hub • Gateway: when data is sent from a Client to a Gateway provider, who sends the data through to the EU Hub
CRF	Connection Request Form	Technical details
NDA	Non-Disclosure Agreement	NDA: • Protects EMVO (technical information)
OBP	On Boarding Partner	Manfacturer or Parallel Distributor who will on board to the EU Hub
PA	Participation Agreement	Contractual on-boarding
SDK	Software Development Kit	Pack of information consisting of SDK (Code Samples + documentation), Certification Test Plan, Certification Test Cases and Certification Test Checklist

Relationship OBP and EMVO



Purpose and Context

The European Hub is the central element of the European Medicines Verification System infrastructure required by the EU-FMD.

It is to the European Hub that the data that forms the critical element of the point-of-dispense verification concept is uploaded, namely:

- For every Medicinal Product: Product master data
- For each individual sales pack of medicines: Unique Identifier

Any incorrect or fraudulent data uploaded will severely affect the medicines verification process and seriously undermine the trust in the system and Europe-wide process.

It is therefore critical that:

- the access to the European Hub for the upload of these critical data is tightly controlled and that
- the Legitimacy of any party requesting access to the European Hub is established through a rigorously administered process.

Overall approach

- Controlled by EMVO but partly outsourced to specialised 3rd Party
- Checks for a corporation requesting to become an OBP (Onboarding Partner) take a risk-based approach, with multiple levels (optional)
- Process initiated on EMVO self-service portal
- Workflow between EMVO and 3rd Party based on ticketing system
- Audit Trail for each decision: Why it was taken, by whom, when, based on what information
- Roll-out will be phased: Process will initially be mainly manual > semi-automatic > automatic (where appropriate)

On-boarding Process – To Be

Managed and administered by the EMVO's Commercial and Partnership Management Team

Managed by the EMVO's Operations Team & Solidsoft Reply

Managed by EMVO and supported by IMS

1) Participation Request

- Initial Contact
- Portal registration
- Non-Disclosure Agreement

CAR

NDA

2) Legitimacy Check

- Level 1 checks
- Person checks
- (more detailed checks if necessary)

Ticket

3) Contractual/ Commercial On-boarding

- Registration fee payment
- Connection Request
- Participation Agreement

CRF

PA

4) Technical On-boarding

- System Connection
- System Testing
- System Operation

Contractual On Boarding

1. Non-Disclosure Agreement

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

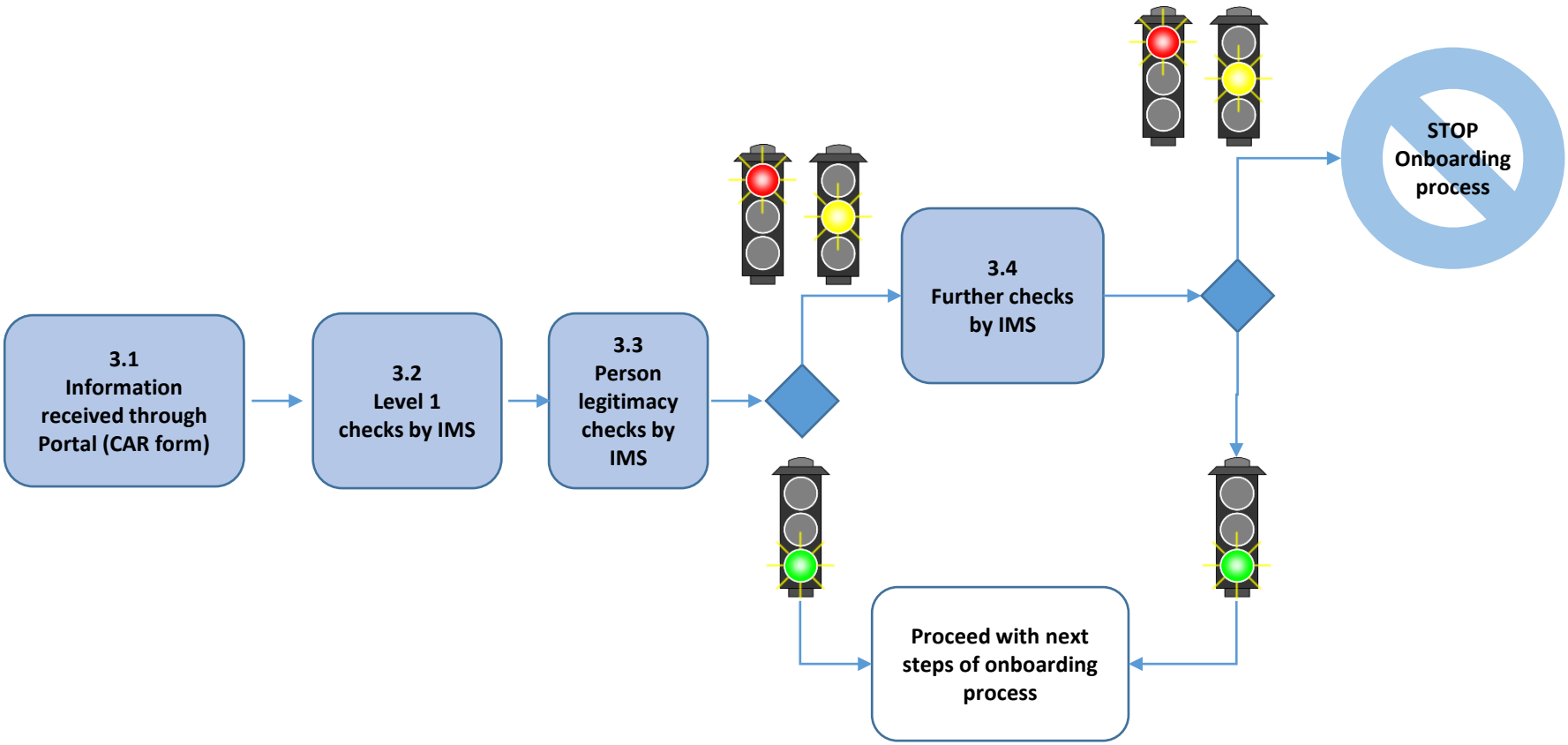
2. Participation Agreement

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

Checks for legitimacy

1. Is the organisation requesting access an established and **legitimate business**?
2. Is the organisation requesting access a **pharmaceutical "manufacturer"** as defined for EMVO purposes that is entitled to access the European Hub?
3. Is the person making the access request **entitled to make this request** on behalf of the organisation?
4. Is the request a **duplicate** (i.e. an organisation already covered or registered for example duplicate request? Erroneous request by subsidiary of a registered parent/group organisation)?
5. Are there **any other causes for concern** about giving this organisation access?

Legitimacy Check Process steps



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Summary / Conclusions

- ✓ EMVO is in the final stages of establishing a thorough and robust legitimacy check process
- ✓ The process will be controlled by EMVO but will leverage what a specialised IMS can provide
- ✓ Checks for a corporation requesting to become an OBP (Onboarding Partner) will take a risk-based approach
- ✓ There will be an Audit Trail for each decision: Why it was taken, by whom, when, based on what information
- ✓ Phased roll-out will commence in October 2016

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