European Medicines Verification Organisation

EMVO's Blueprint Approach

BOGIN Symposium
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EMVO Commercial and Partner Management

European Association of Euro-Pharmaceutical Companies

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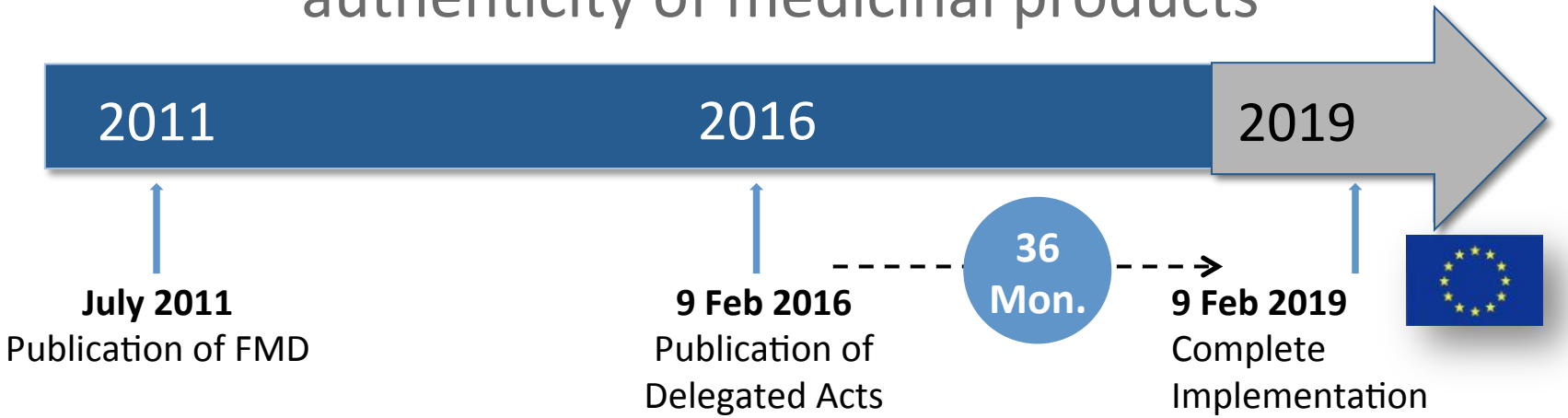
Implementation of Falsified Medicines Directive (FMD) must be final at 9/2 2019

- Objective Protection of patients from counterfeited medicines in the legal distribution chain
- Content Pan-European system to verify the authenticity of medicinal products



Non-compliance means X products can not be legally provided to patients

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Content

- EMVO and EMVS
- Blueprint Approach
- Company On Boarding to the HUB
- Program Status and Outlook

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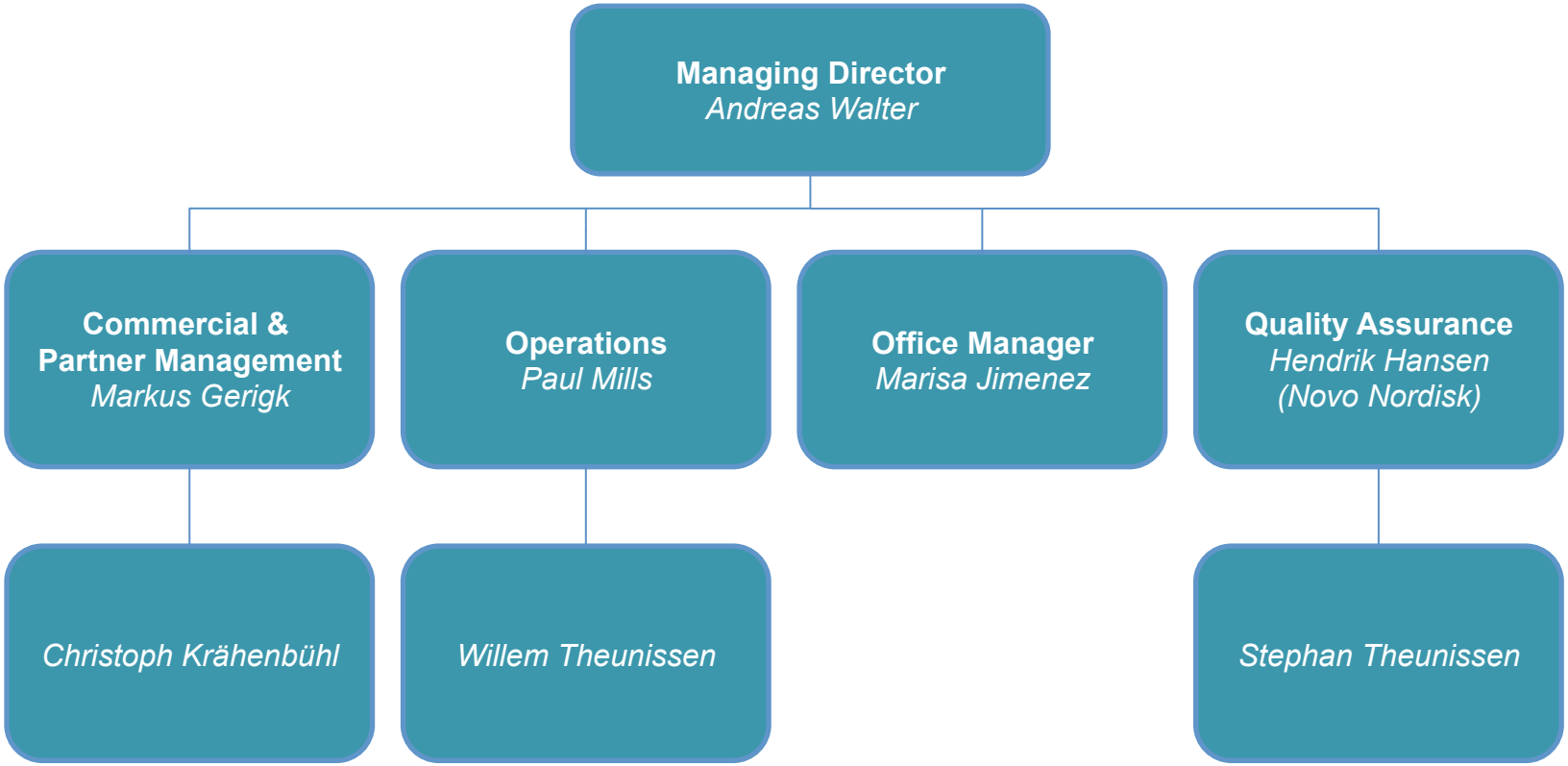
EMVO Organisation and Members



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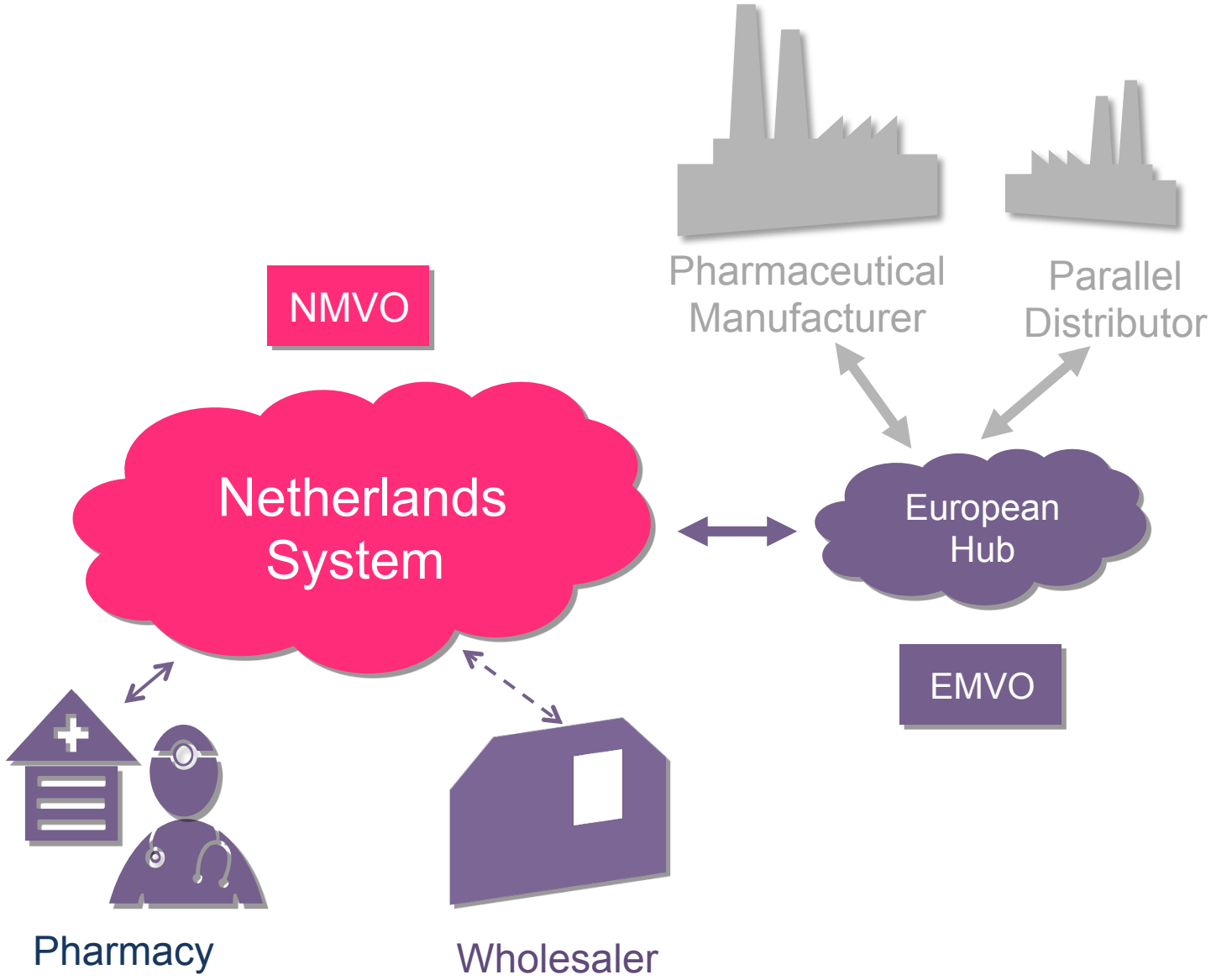
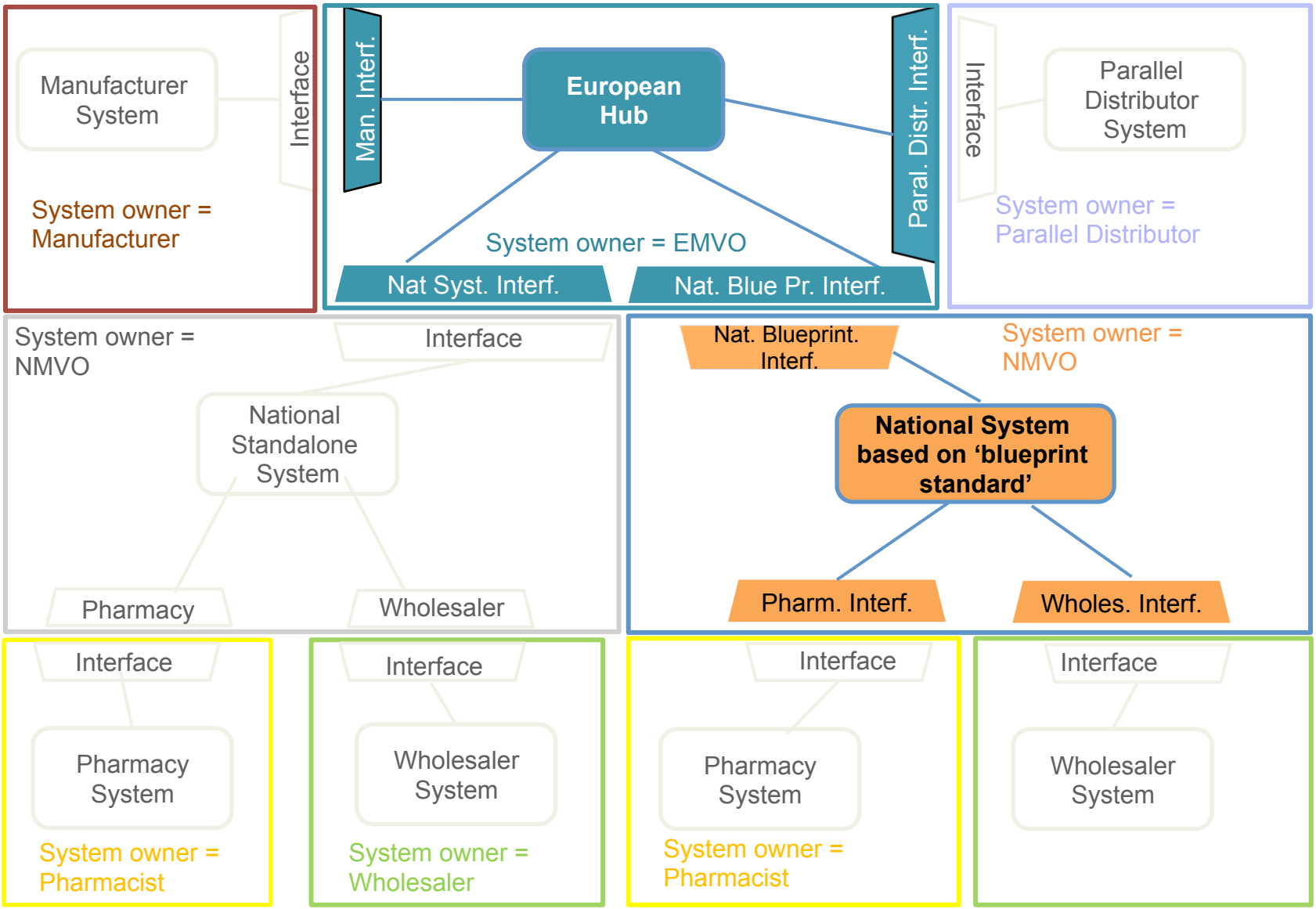
EMVS from National Perspective



System Landscape



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Motivation for Blueprint Approach

Mitigation of the following Risks

- Risk to fail technically
  - Functionality
  - Security
  - Quality
- Risk to fail in timeline
- Risk to fail financially

→ Preselection of Blueprint Service Providers

EMVOs Selection process

- assessment of the supplier's experience and capability to cooperate with EMVO and support in all EEA countries;
- comparison of total cost of ownership;
- evaluation of their respective technical proposals;
- check if EMVO will be entrusted the day-to-day management for NMVOs, if requested;
- comparison of contractual conditions, including ownership of related IP rights
- SWOT analysis of each candidate

Additional Blueprint Providers for National Systems

Due to the progressed timeline EMVOs criteria for any potential additional Blueprint Provider are

All criteria from the selection process

+

References of existing Systems in similar markets

Components of Blueprint Approach I

- National Systems are implemented and operated based on a “Blueprint standard” as defined in
  - the template of national Memorandum of Understanding
  - the template statutes of an NMVO
  - The EMVO User Requirement specifications (URS)
  - Requirements for the European Medicines Verification System (URS light), including the cost allocation Flat Fee Model

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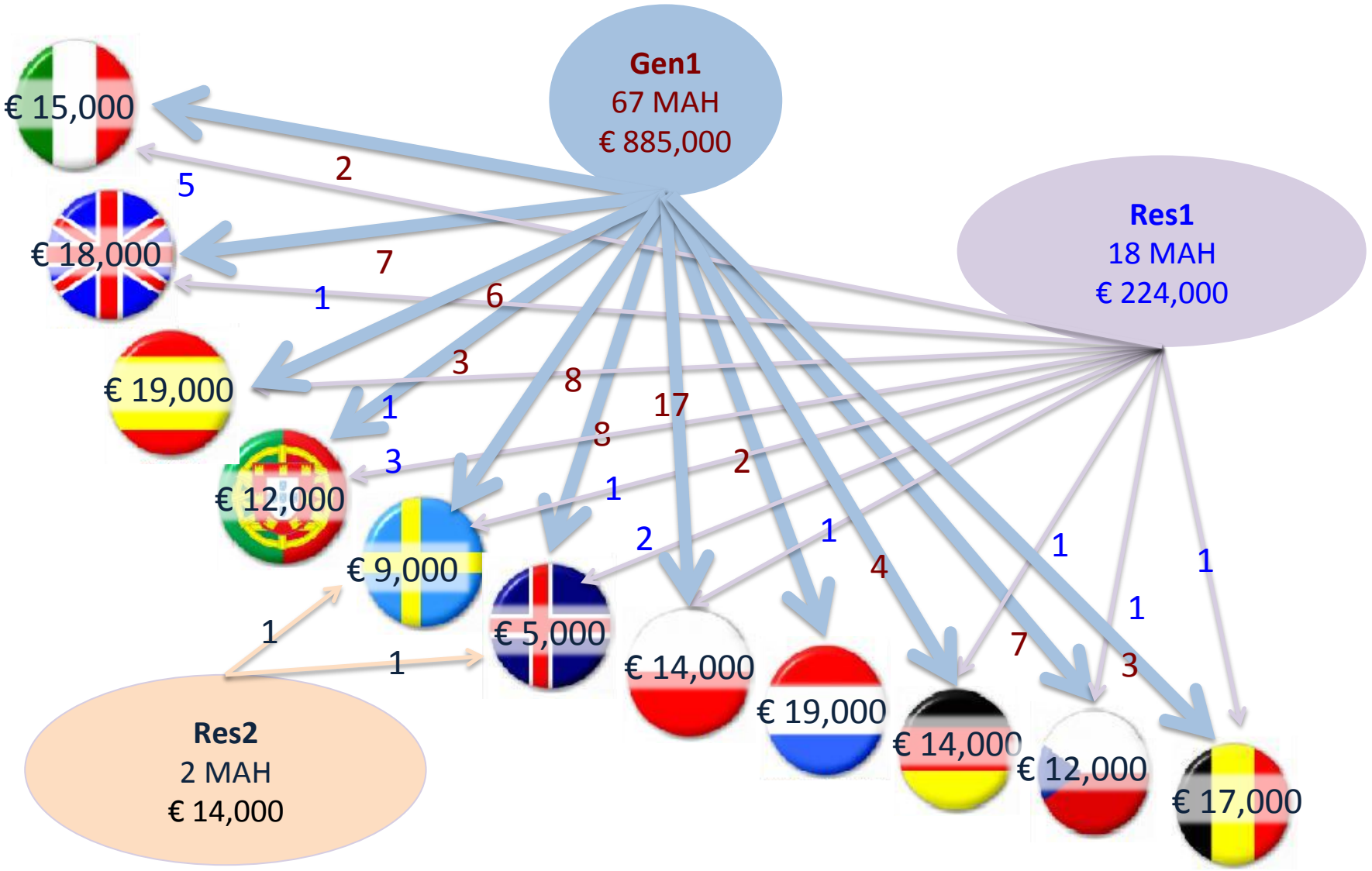
Components of Blueprint Approach II

- System operation is carried out by pre-qualified IT service providers.
- EMVO offers support to national stakeholders during the system deployment phase
- Management of National System operation can be partly outsourced to the EMVO to use synergies and for reducing management cost.

Illustration of Flat Fee Approach with estimated Fees



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Benefits Blueprint Approach

- Highest overall cost efficiency for building the EMVS
- Quick start for all countries with pre negotiated service contracts
- Guaranteed compliance with Delegated Regulation based on EMVO URS
- Highest security standards for national systems and HUB
- Minimal implementation, maintenance and service costs for the national systems

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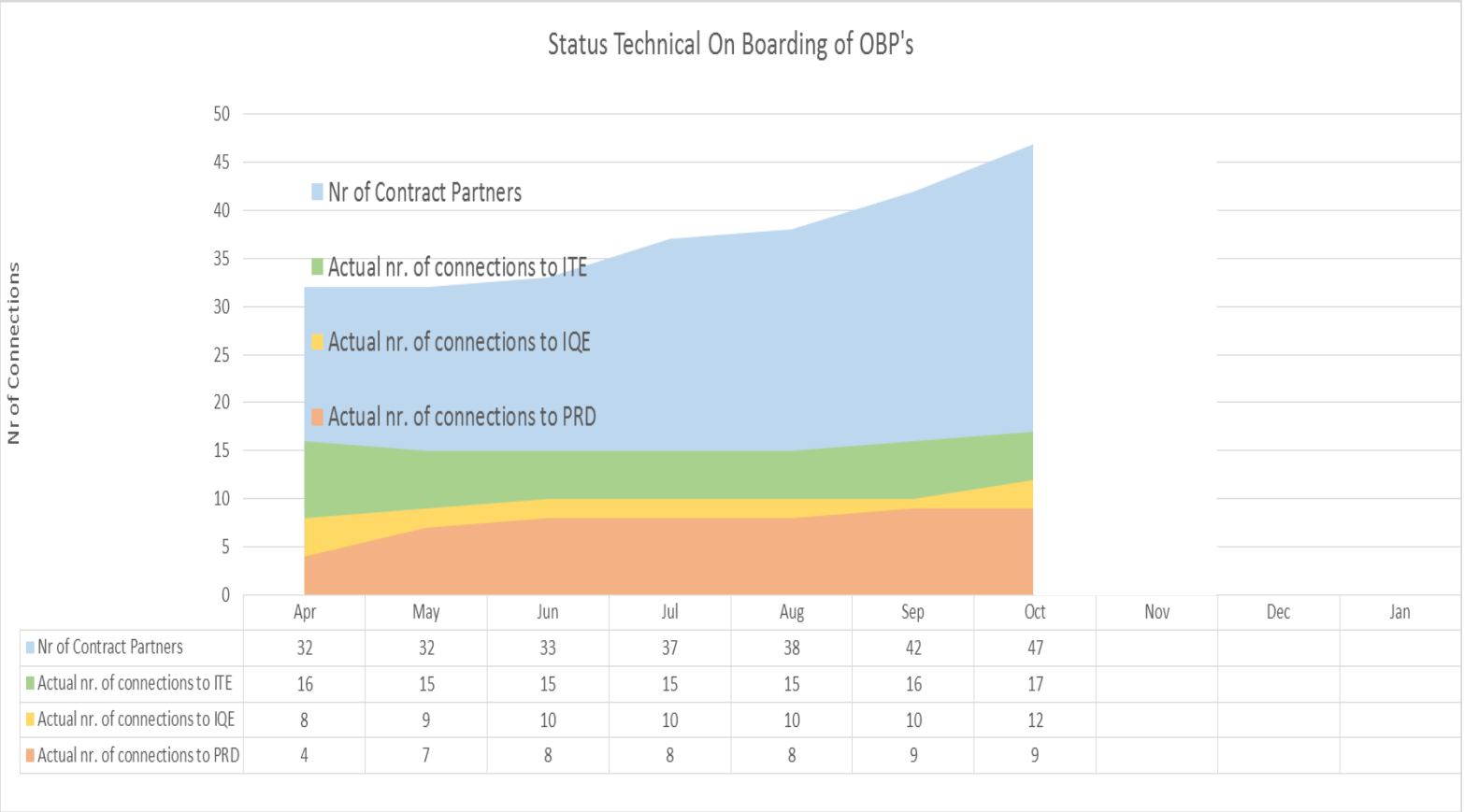
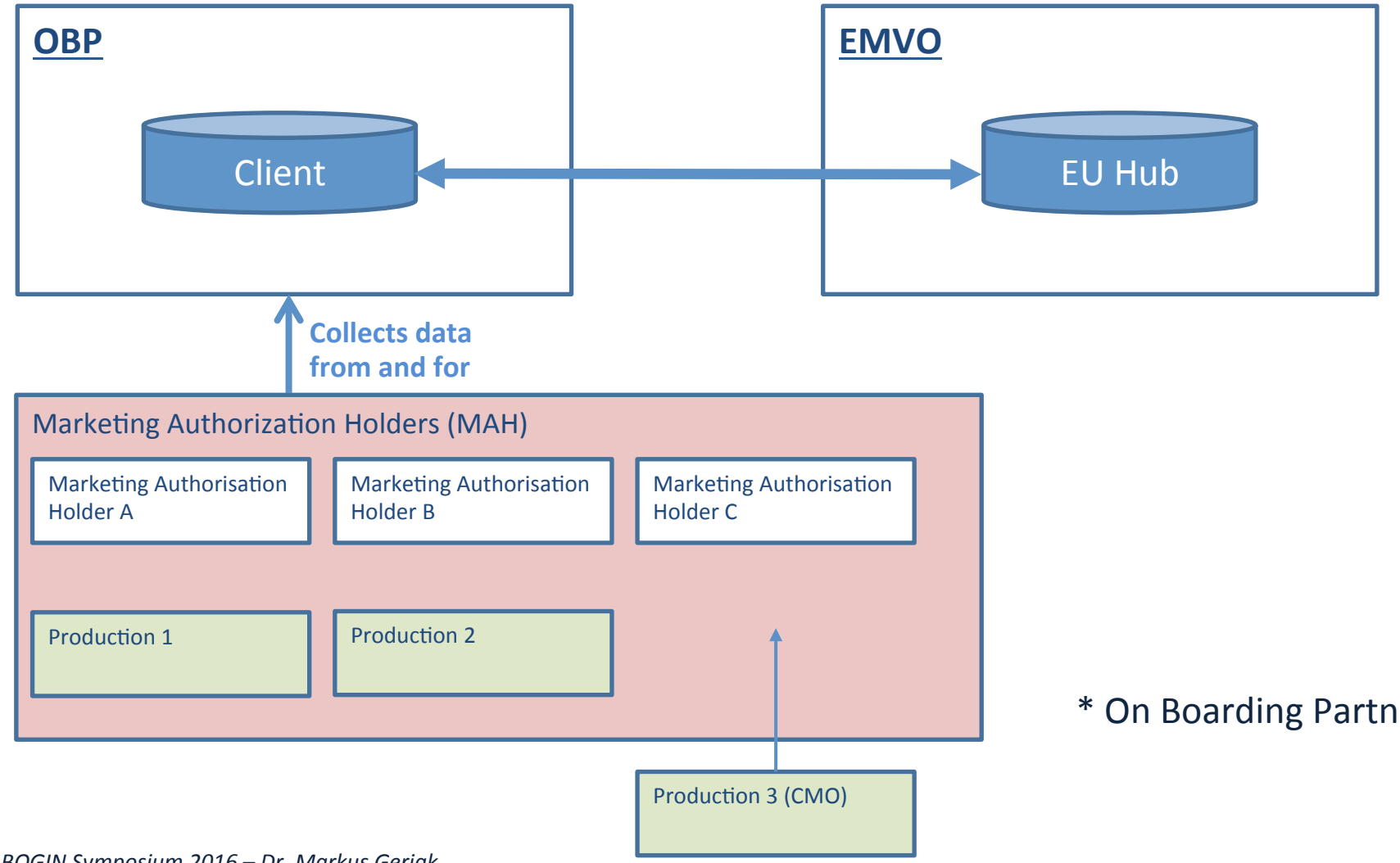
On Boarding Statistics



	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan
Nr of Contract Partners	32	32	33	37	38	42	47			
Actual nr. of connections to ITE	16	15	15	15	15	16	17			
Actual nr. of connections to IQE	8	9	10	10	10	10	12			
Actual nr. of connections to PRD	4	7	8	8	8	9	9			

ITE = Test Environment
IQE = Quality Environment
PRD = Productive Environment

Relationship OBP* and EMVO



* On Boarding Partner

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1. Non-Disclosure Agreement	2. Participation Agreement

- Covers **provisi** framework for **Confident** **be On** EMVO
  -
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  -
- Pur **partic** **g** project

No Contract Negotiation

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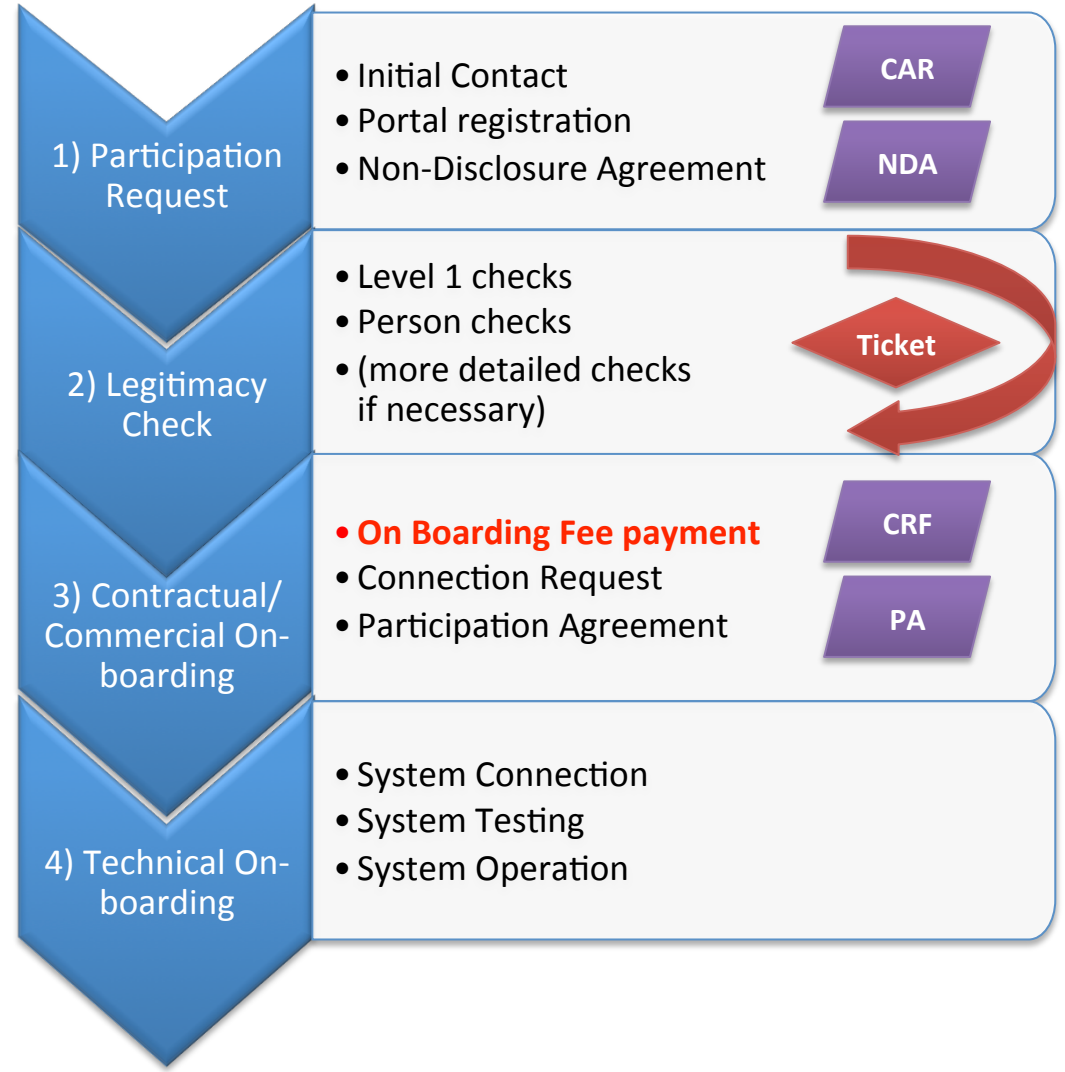
Managed and administered by the EMVO's Commercial and Partnership Management Team

Managed by the EMVO's Operations Team & Solidsoft Reply

*Managed by EMVO and supported by IMS**



*in negotiations

On Boarding Fee

One-Time Fee per OBP

	On-boarding Fee
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 €

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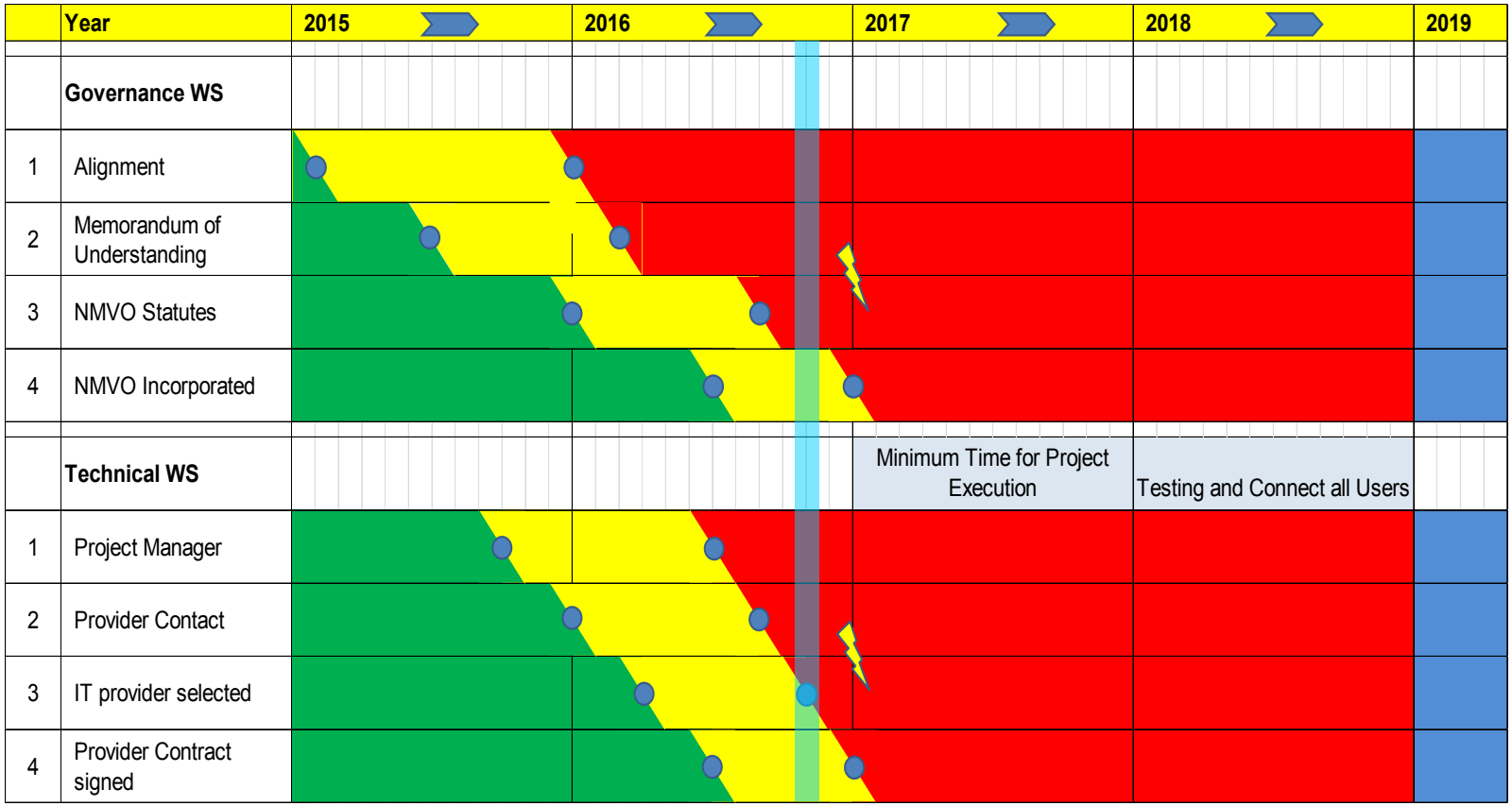
Reference Schedule Country Readiness



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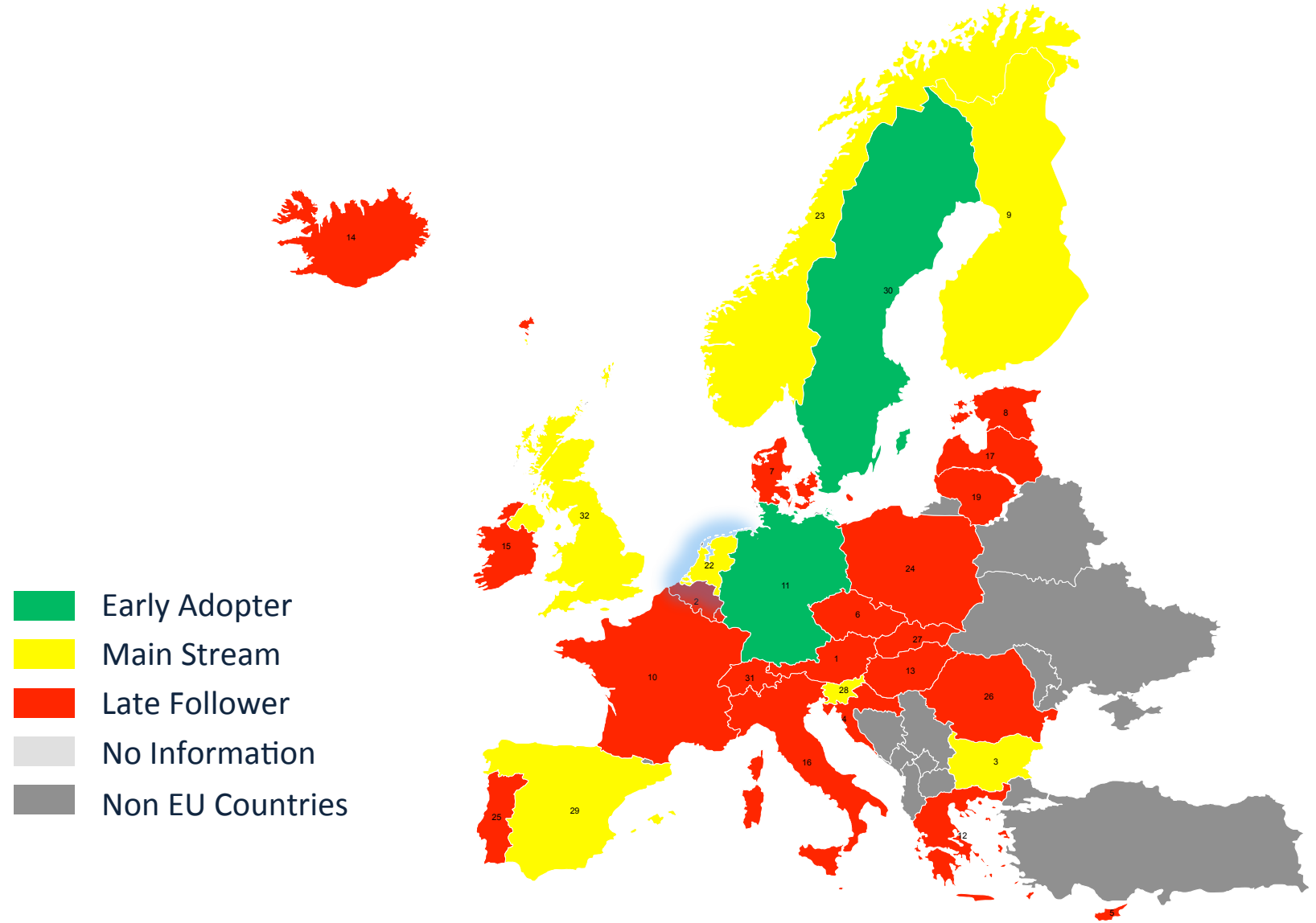
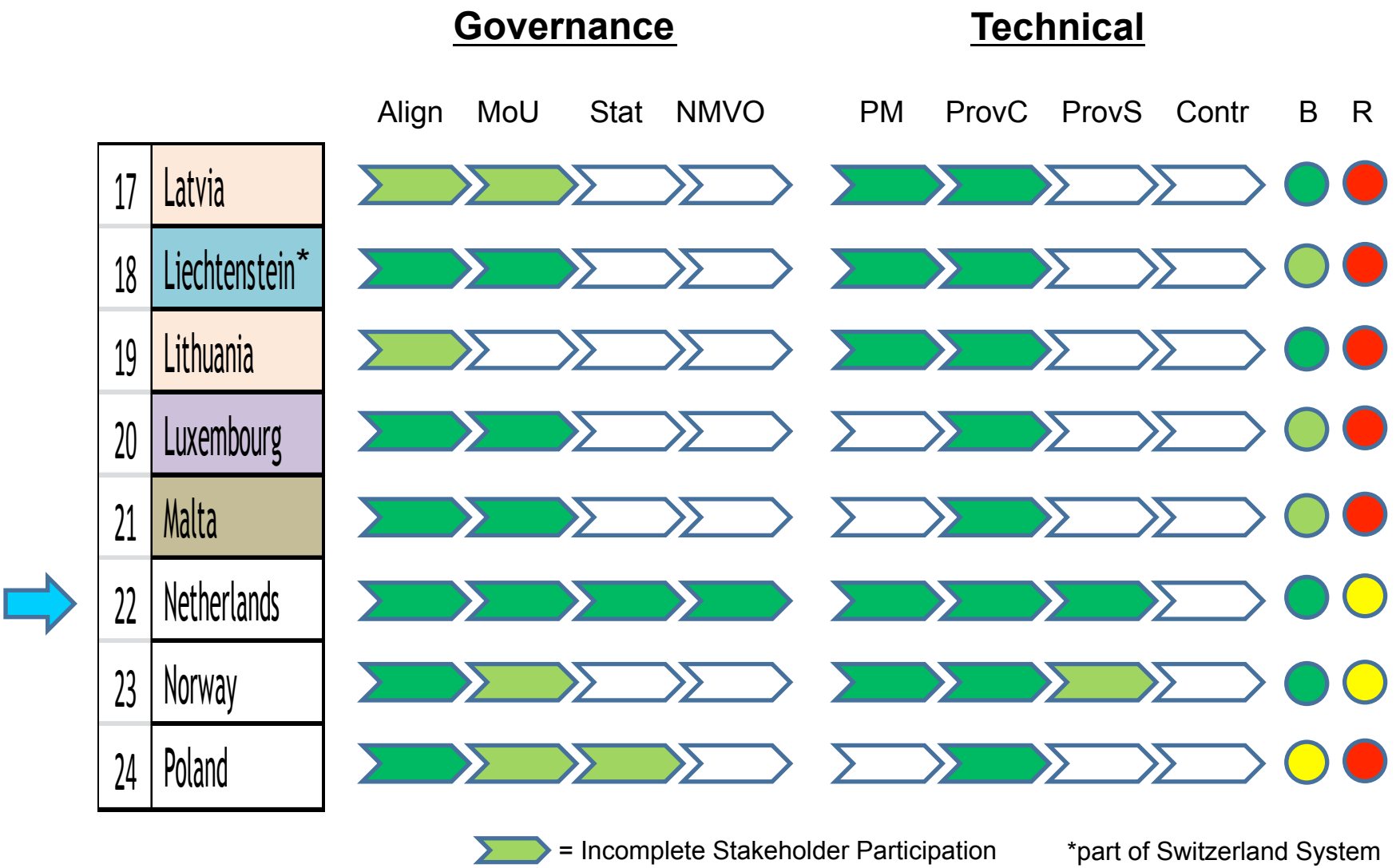
Executive Summary Country Readiness



Status per Country 17-24



EMVO Observations

- Program Progress
  - 7 NMVOs founded, 2 Contracts Signed
  - Majority of Countries progress and aim for Provider Contract in 2016

- To be improved
  - 2/3 of Countries are behind Schedule
  - Still 5 Countries did not start Technical Work Stream
  - Stakeholder alignment in MOU and Statutes not complete in several Countries (e.g. Pharmacies and Wholesalers not integrated in NMVO set up)

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Contact for On Boarding and general topics:

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Back Up

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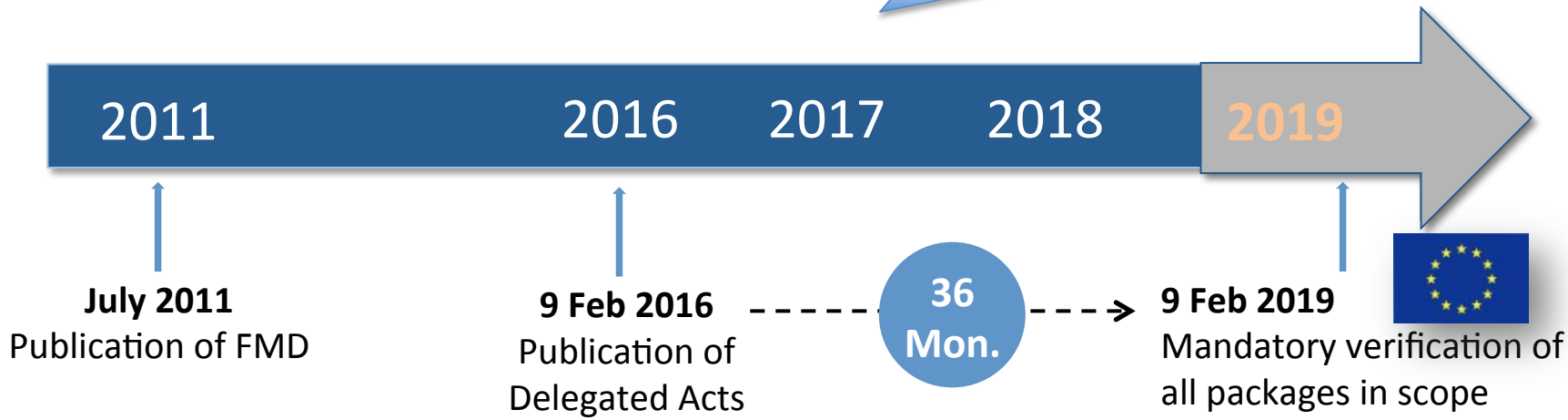
No Time to wait

- Connect appr 2500 manufacturers to the EU Hub
- Establish National Systems for 32 countries
- Connect many thousand Pharmacies and Wholesalers
- Serialise all pharmaceutical packages in scope (10.5 bn)



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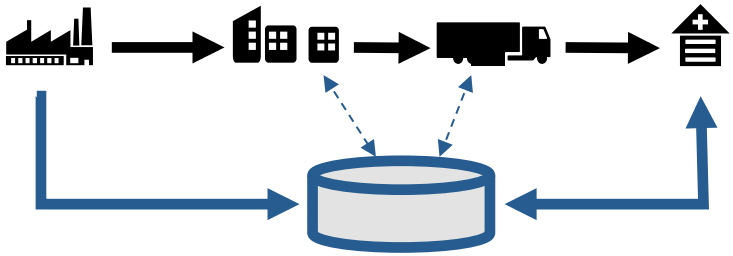
Serialization by manufacturer

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 governed by manufacturers and marketing auth. holders in consultation with other stakeholders. Oversight by competent authorities