



How to embed a national system in a European context

Peter Krug

2. securPharm European Conference
on the Falsified Medicines Directive

Frankfurt, Thursday, July 23, 2015



Objective 3: to ensure interoperability of the repository system, free movement of medicines and supervision by the competent authorities

- Policy option 3/1: Establishment and management by stakeholders with supervision by the relevant competent authorities
- Policy option 3/2: Establishment and management by a public authority at EU level
- Policy option 3/3: Establishment and management by public authorities at national level

Health and
Consumers

Source: Patrizia Tosetti European Commission



Impact Assessment – Outcome (III)

Objective 3: to ensure interoperability of the repository system, free movement of medicines and supervision by the competent authorities

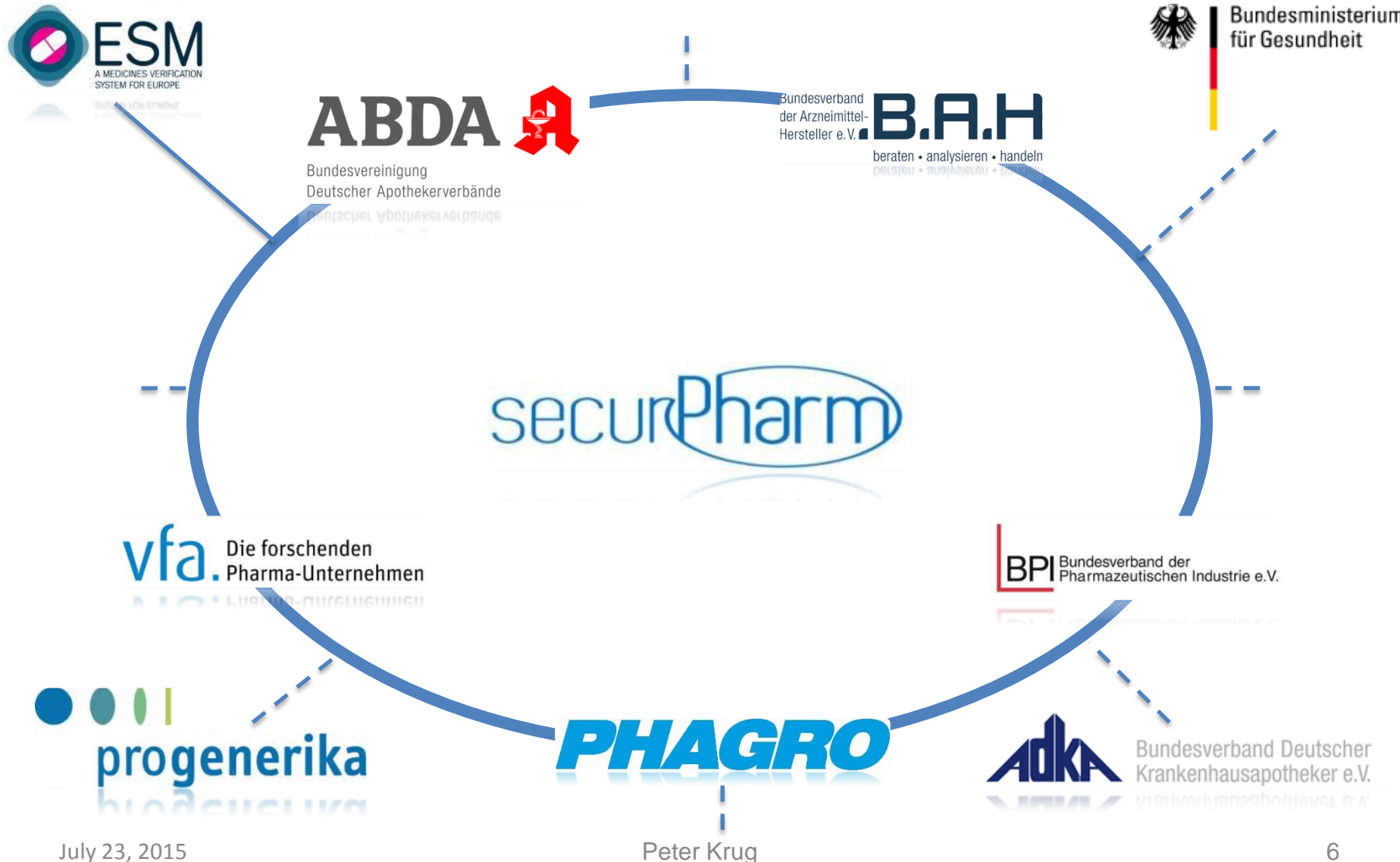
Selected option: Establishment and management by stakeholders with supervision by the relevant competent authorities

Source: Patrizia Tosetti European Commission

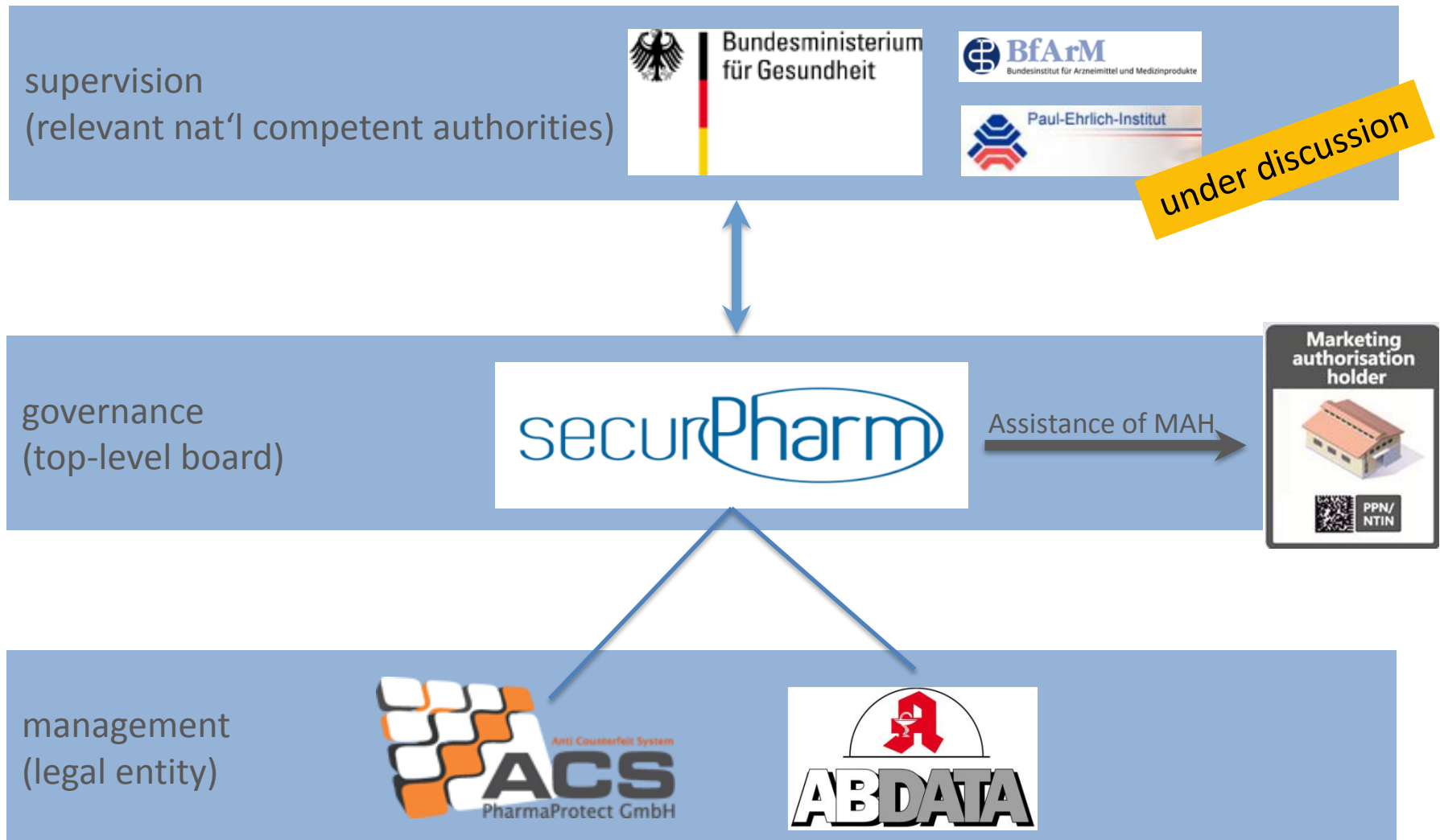


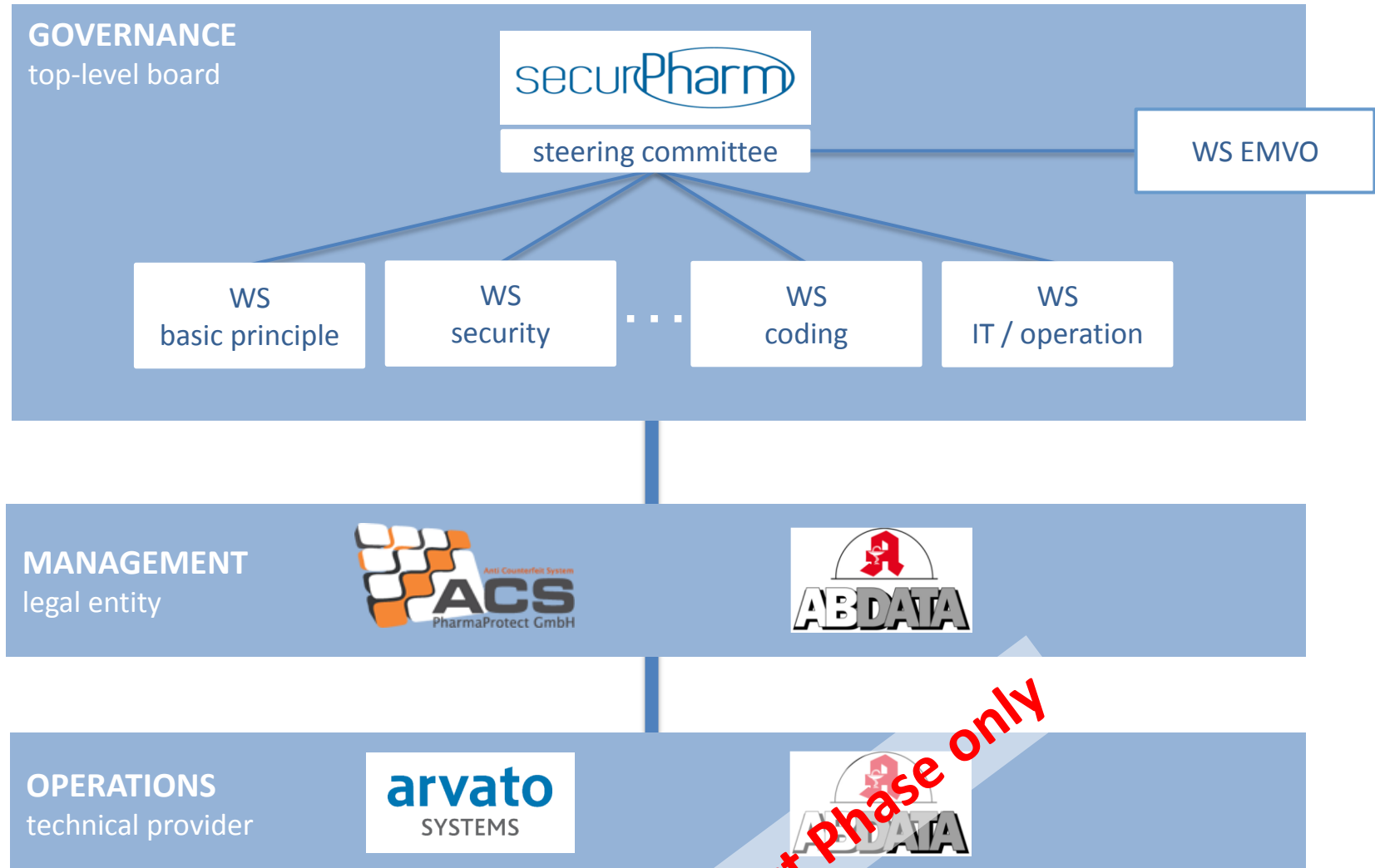


Stakeholders & Partners



Vision of access & supervision

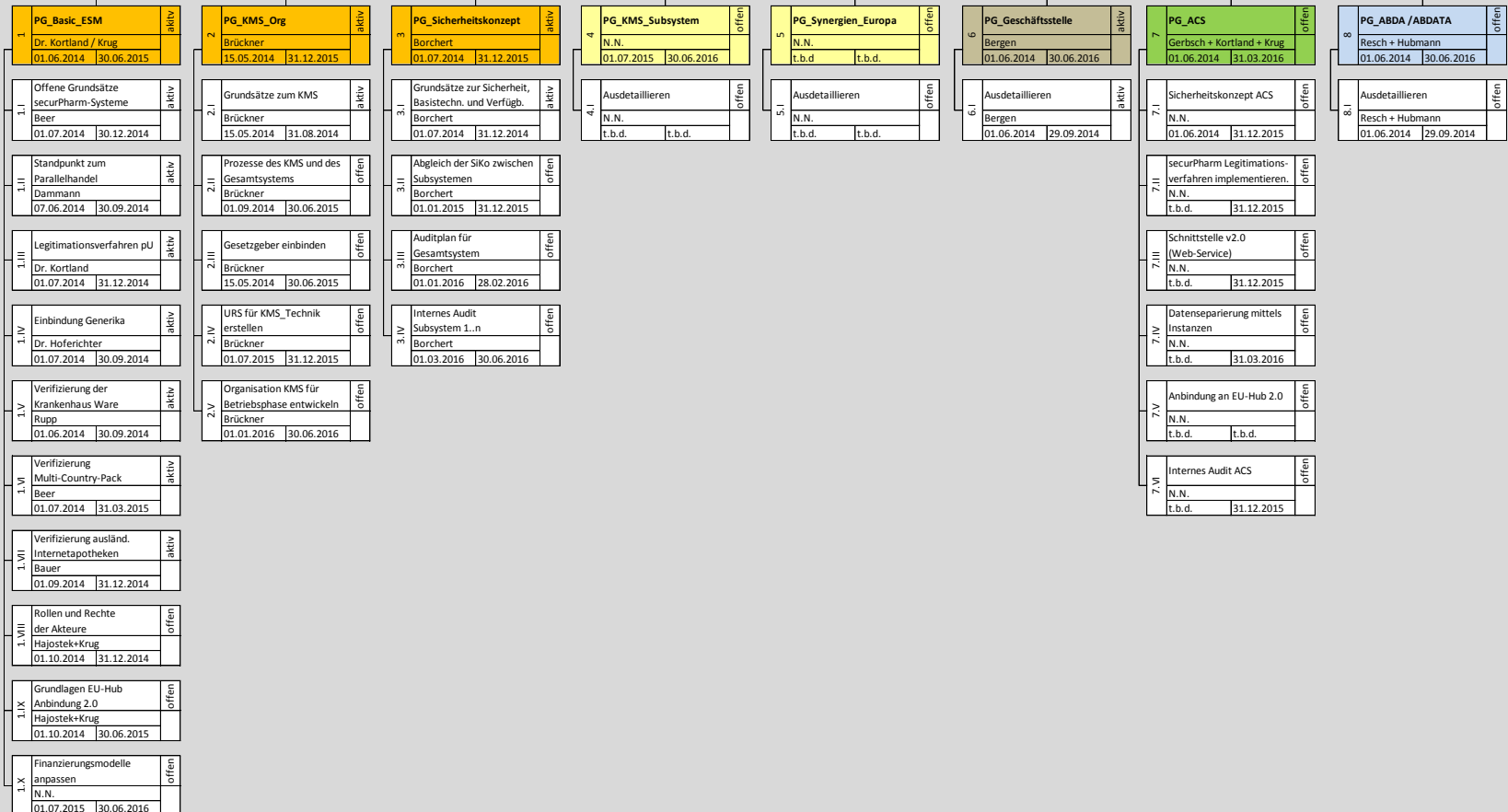


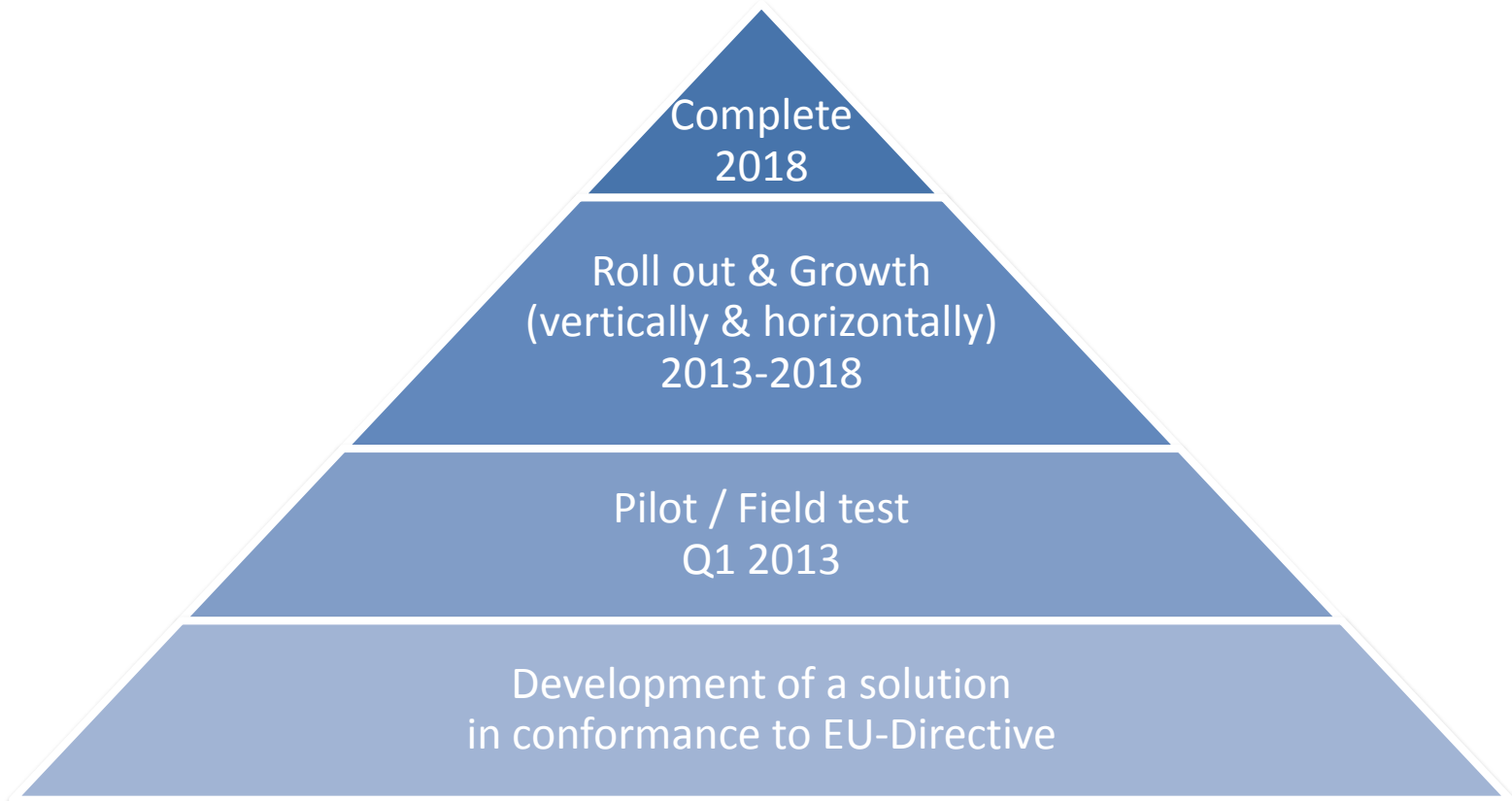


Work streams

Anmerkung
Dies ist eine vereinfachte Darstellung zu Demonstrationszwecken

Phase Ausbau und technische Erprobung
Lenkungsausschuss
01.06.2014 30.06.2016





Vertically Growth: Include additional groups (e.g. hospital pharmacies, European Hub, nat'l competent authorities etc.)

Horizontal Growth: More products, more MAH, more pharmacies etc.

How securPharm implements the FMD

1st

- created a stakeholder group
- memorandum of understanding



2nd

- common goals and rules for collaboration
- securPharm e.V. (non-profit organization)



3rd

- checked national prerequisites
- master data already available (IFA)
- product code (PZN) integrated in coding system



4th

- selected IT service provider
- data protection by separate data bases



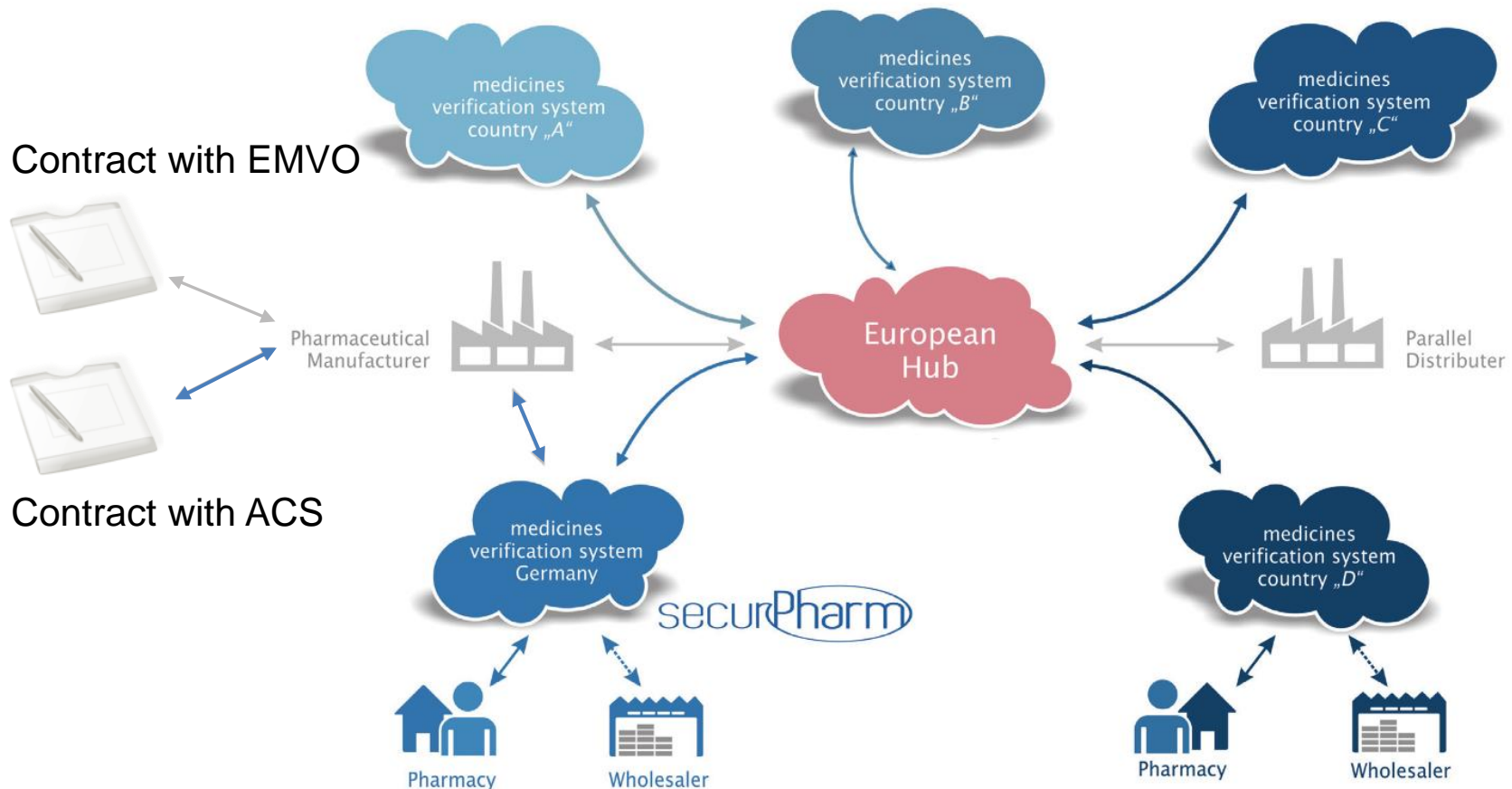
5th

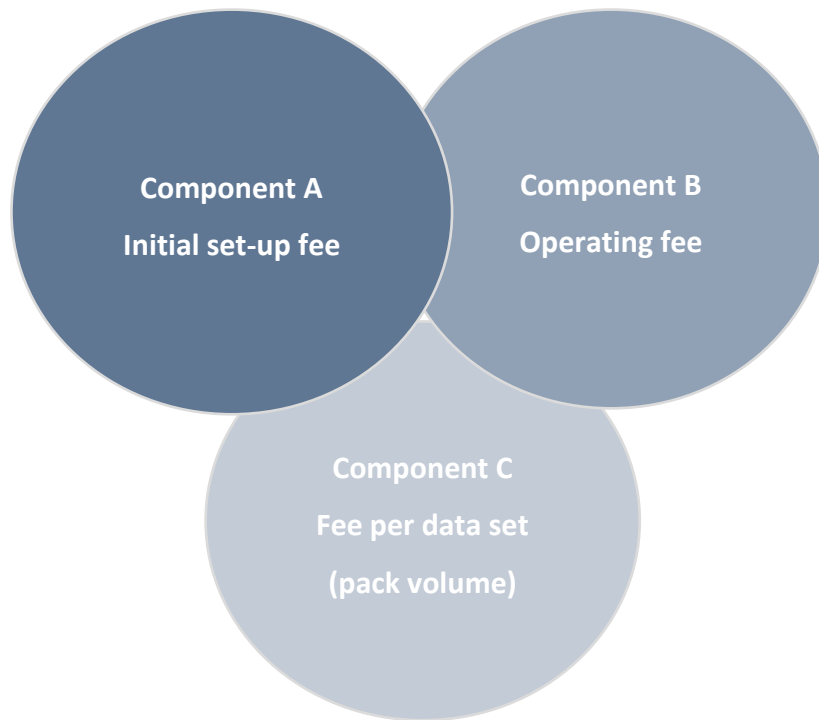
- learning from experience
- expand system for market phase
- optimize operation



securPharm

Pan-European architecture: design for interoperability and efficiency

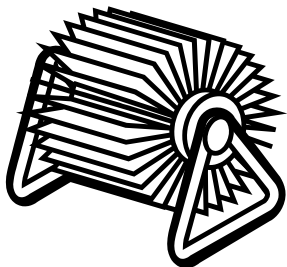




- **Initial set-up fee**
(increase in stepwise fashion by 2018)
- **Operating fee**
(degressively scaled, which means that the operating fee will decrease with an increasing number of new users)
- **Fee per data set (pack volume)**
(degressively scaled, i.e. with an increasing number of packs provided by a pharmaceutical company the costs will decrease)



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