

Science For A Better Life

# The German securPharm Initiative

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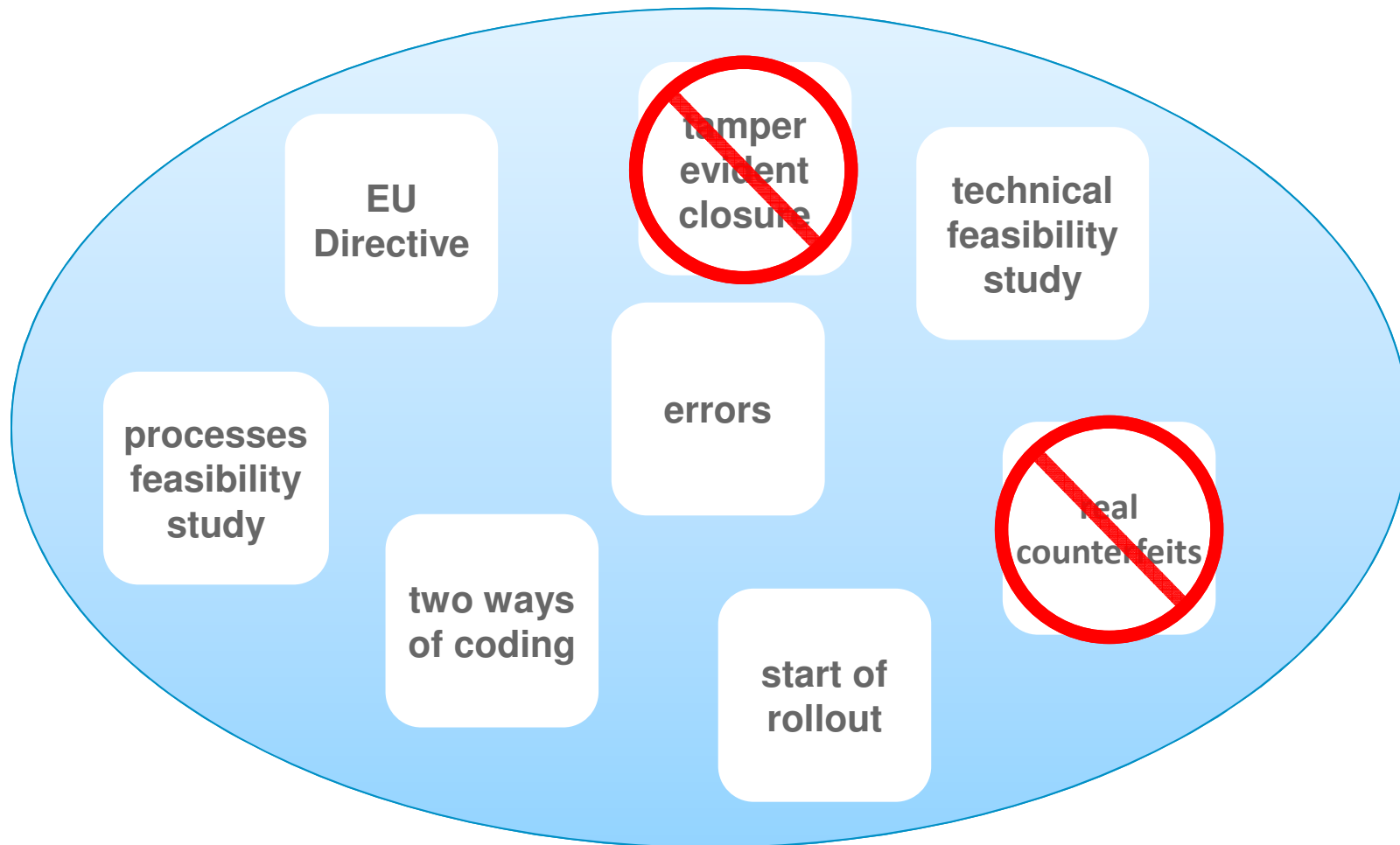


# securPharm - Stakeholders





# securPharm - Goals





# The occasion: EU-directive 2011/62/EU

L 174/74

EN

Official Journal of the European Union

1.7.2011

## DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 8 June 2011

amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114, and point (c) of Article 168(4), thereof,

Having regard to the proposal from the European Commission,

medicinal products from other illegal medicinal products, as well as from products infringing intellectual property rights. Furthermore, medicinal products with unintentional quality defects resulting from manufacturing or distribution errors should not be confused with falsified medicinal products. To ensure uniform application of this Directive, the terms 'active substance' and 'excipient' should also be defined.

+ 3 years delegated acts = 2014 + 3 years to fulfill the obligations = 2017



# Objective of the EU-directive

## Main objective

- Increase protection of patients against counterfeited drugs

## Approach

- Making counterfeits unprofitable

## Additional benefits

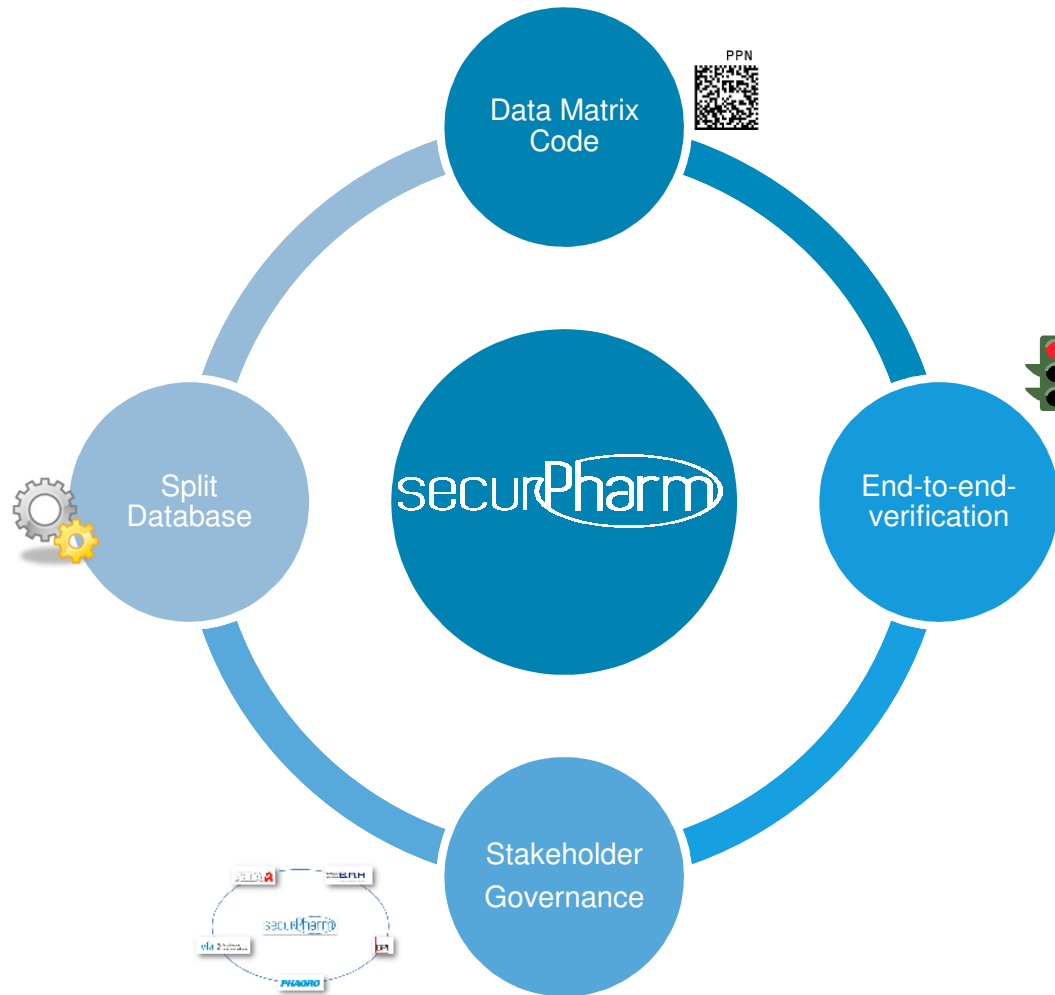
- Precise callbacks
- Optimized goods management with machine-readable product data
- Optional: Reimbursement



- Product number
- Batch number
- Expiry date
- Serial number

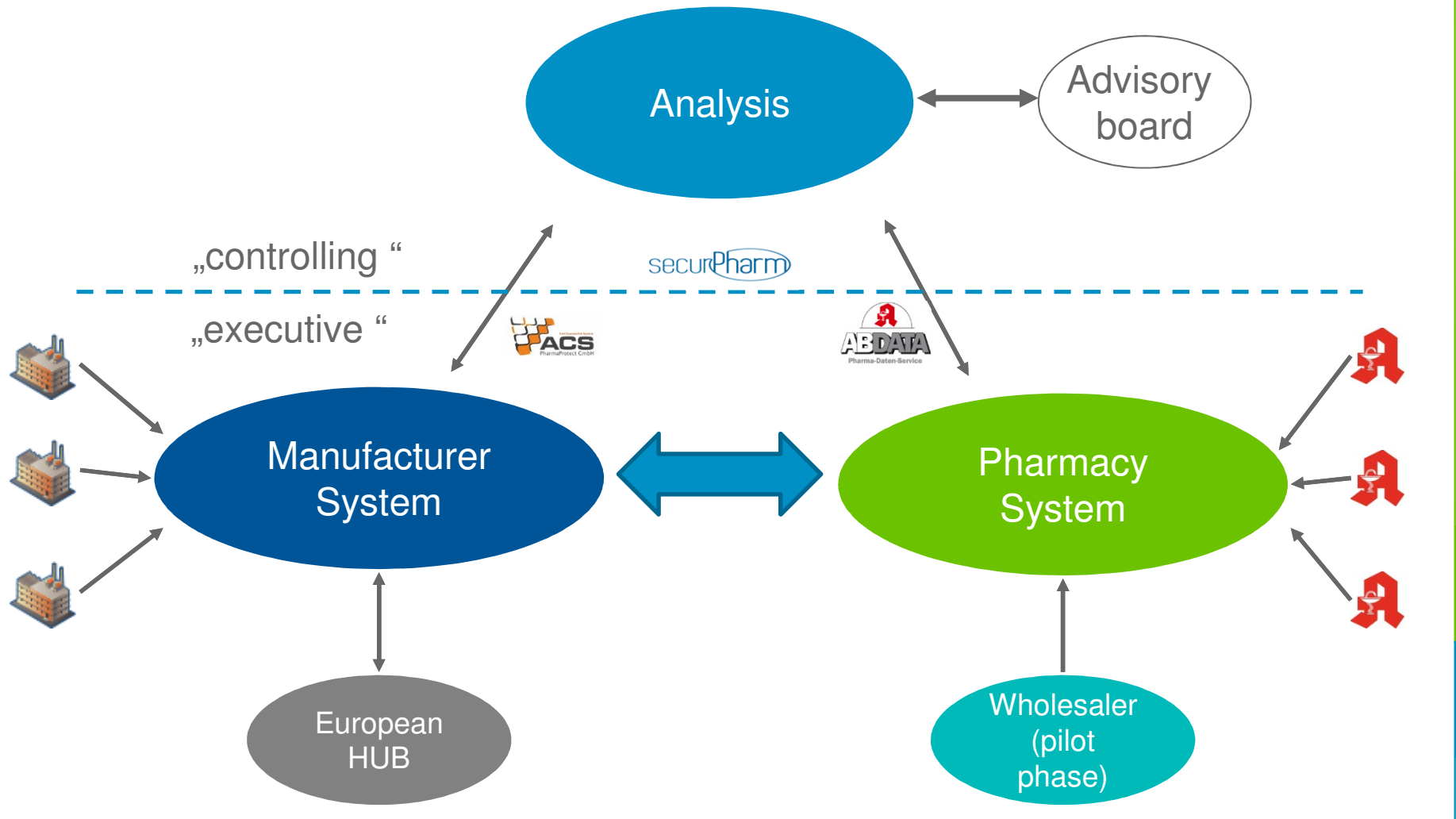


# securPharm - Concept



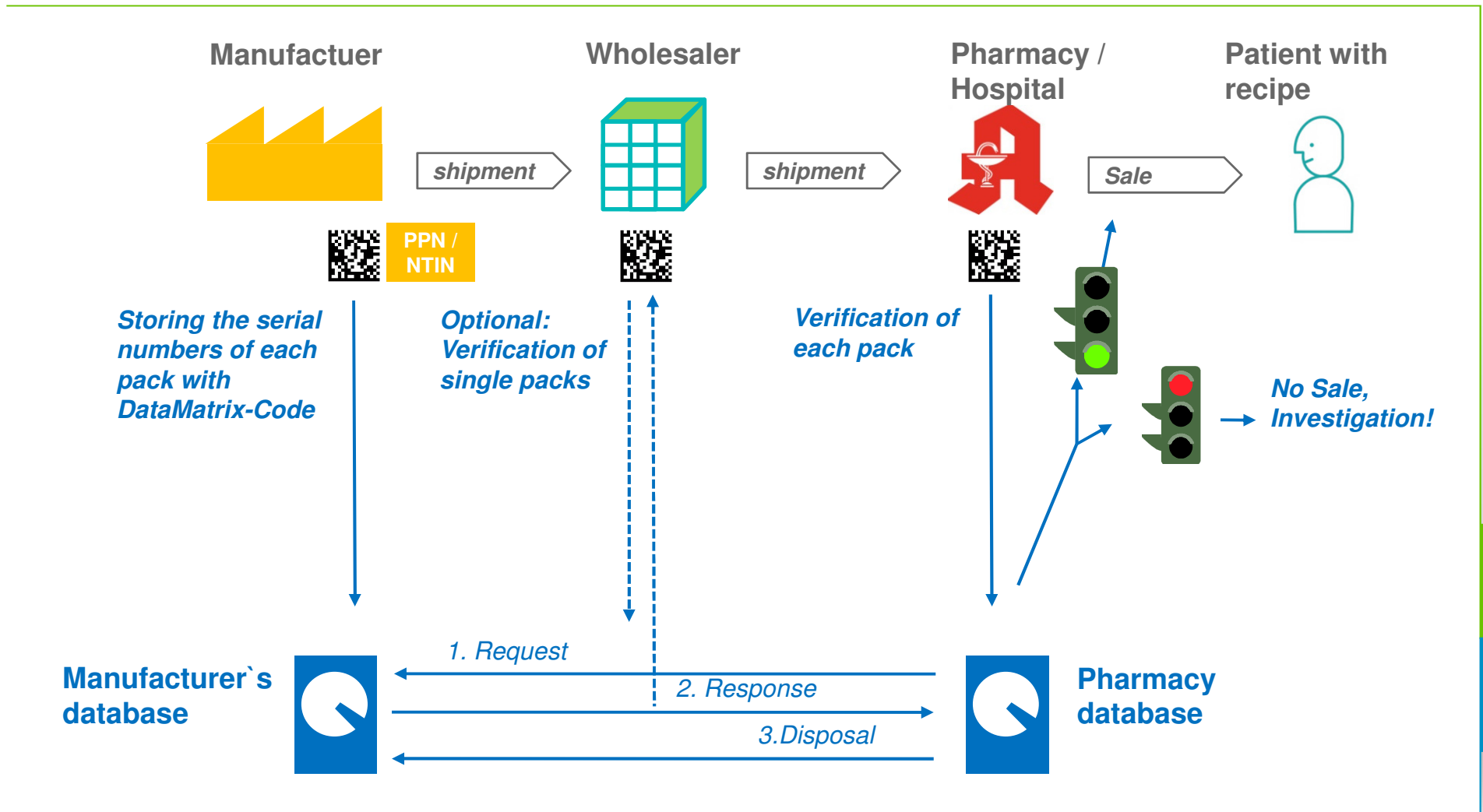


# Data Ownership





# securPharm - End-to-end-principle







# Coding with Data Matrix Code

Today	In plain text	Machine-readable
<b>PZN-7</b>	✓	✓
<b>Batch</b>	✓	
<b>Expiry-date</b>	✓	



Future	In plain text	Machine-readable
<b>PZN-8</b>	✓	✓
<b>Ser.Nr.</b>	?	✓
<b>Batch</b>	✓	✓
<b>Expiry-date</b>	✓	✓





# securPharm - Pilot Characteristics

- 21 manufacturers
- 90 products (different PZN)
- Period 1.1.2013 – 31.3.2013
- ~2.3 millionen packs
- Using PPN and NTIN

Manufacturer



- Integration into day-to-day business
- No directed distribution
- Every wholesaler supplies coded products
- Wholesaler checks code (optional)
- Connection to Pharmacy system

Wholesaler



- 200 – 300 Pharmacies
- Selection by software companies
- ~5 software companies with ~8 software products

Pharmacies



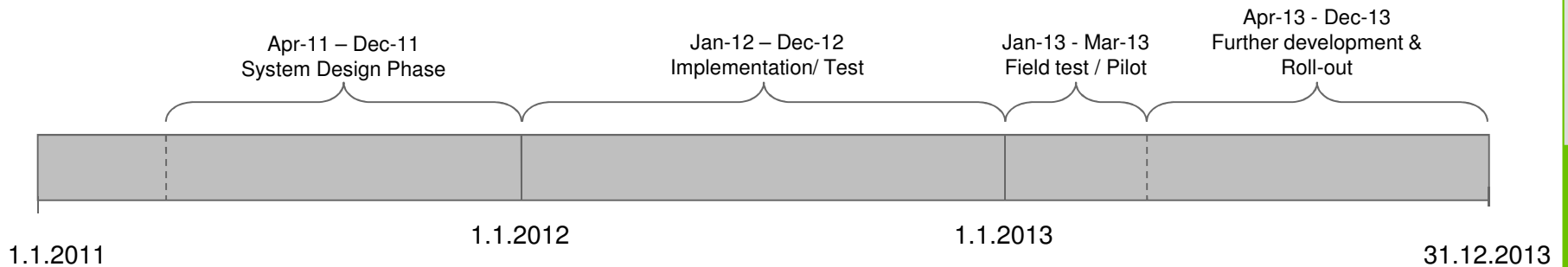
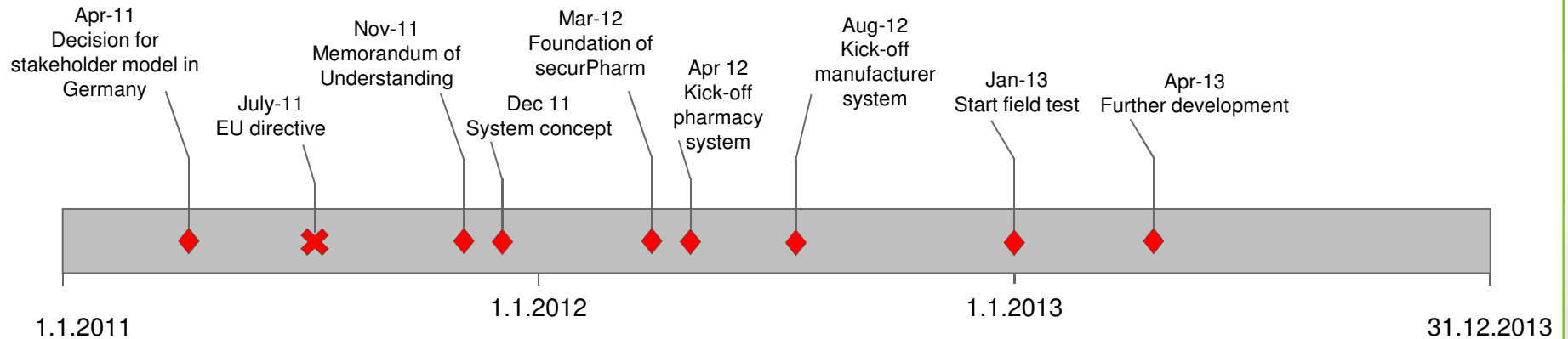
Heterogene technology

Heterogene responsibility

Real products



# Timeline



The field test is the start of the rollout!



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Thank you!



# Forward-Looking Statements

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