e-verification of Pharmaceuticals

- what will it mean for the pharmaceutical industry?

Information session 2016-10-28

The implementation project team

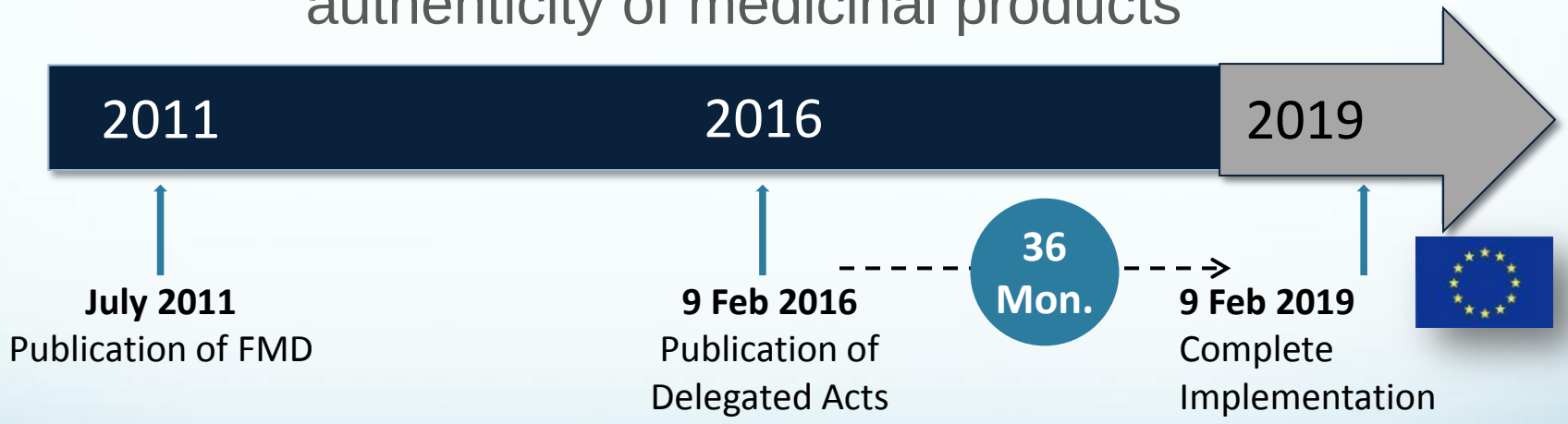
Solidsoft Reply Ltd

Introduction

- Formal implementation project established March 2015
- Steering group and two working groups; technical and governance
- Participants from LIF, FGL, LH, SvAF and LDF in all groups
- Two major milestones reached in June 2016:
  - The mandatory governance organisation, e-VIS was formed
  - The system provider, Solidsoft Reply, was selected
- Sweden is well placed to meet the legal requirements:
  - Experience from the Swedish Pilot 2009-2010
  - Advanced infrastructure and collaborative climate

Implementation of Falsified Medicines Directive (FMD) required Feb 2019

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



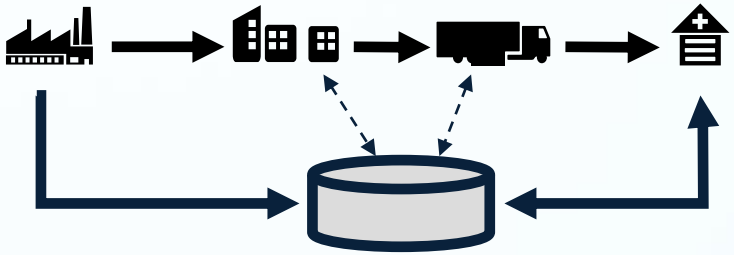
Non-compliance puts sales at risk

The Delegated *Regulation* mandates rules for medicines verification

Serialization by manufacturer

Risk based verification by Wholesalers

Verification and check-out at point of dispense



Safety features:

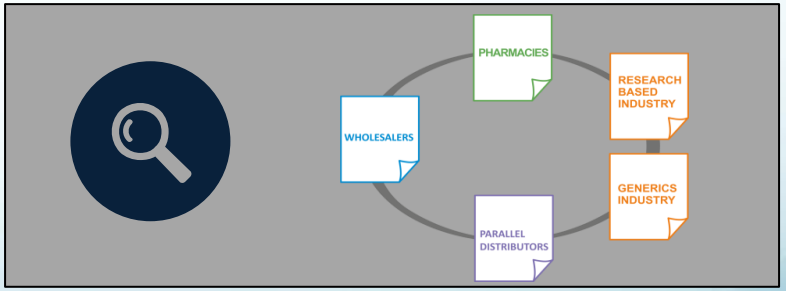
Code ('unique identifier')

+

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



e-VIS (e-verifikation i Sverige)

- Association
- Statutes
  - Membership by constituency
  - Two categories; Full membership and associated membership
  - Full membership is required for voting/veto and a seat on the Board
  - Veto rights for the industry regarding key decisions about the National system they are mandated to set up, run and pay for

e-VIS

- We have 5 constituencies participating in the project
- Only 4 are members of e-VIS (all have Full Membership)
- The Pharmacy Association has chosen to remain outside e-VIS due to principal reasons
- e-VIS Board will make all the formal decisions, but…
- A ”consultation group” (includes the Pharmacy Association) will discuss all information and intended decisions

Government contacts

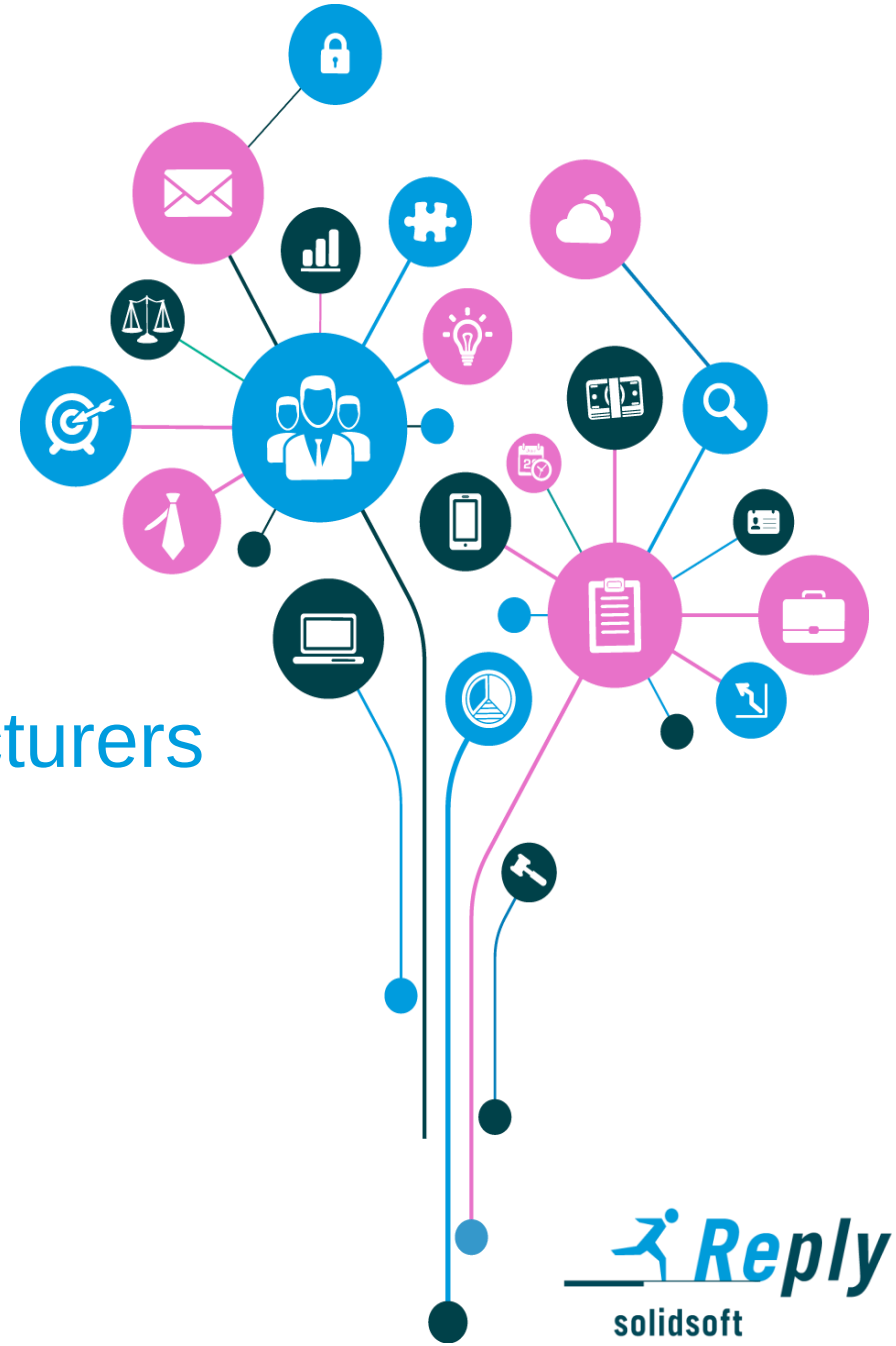
Competent authority – Medical Products Agency

- Have been kept informed over the past few years
- Formal consultation with MPA in June
  - A few adjustments to e-VIS statutes to allow for their participation should they decide so
- Legal review of the Delegated Regulation and possible need for further adjustments of the Swedish law is ongoing with both MPA and Ministry
  - **Verification/decommissioning for hospitals** needs to be clarified – the ambition is to avoid this burden/cost on health care personnel if at all possible – Key for setting up the system
  - **Decommissioning of Vaccines** is a big concern – there are some 4000+ places where vaccines are given….

EMVS and the European Hub

An Overview for Manufacturers and Parallel Distributors

Charles Young



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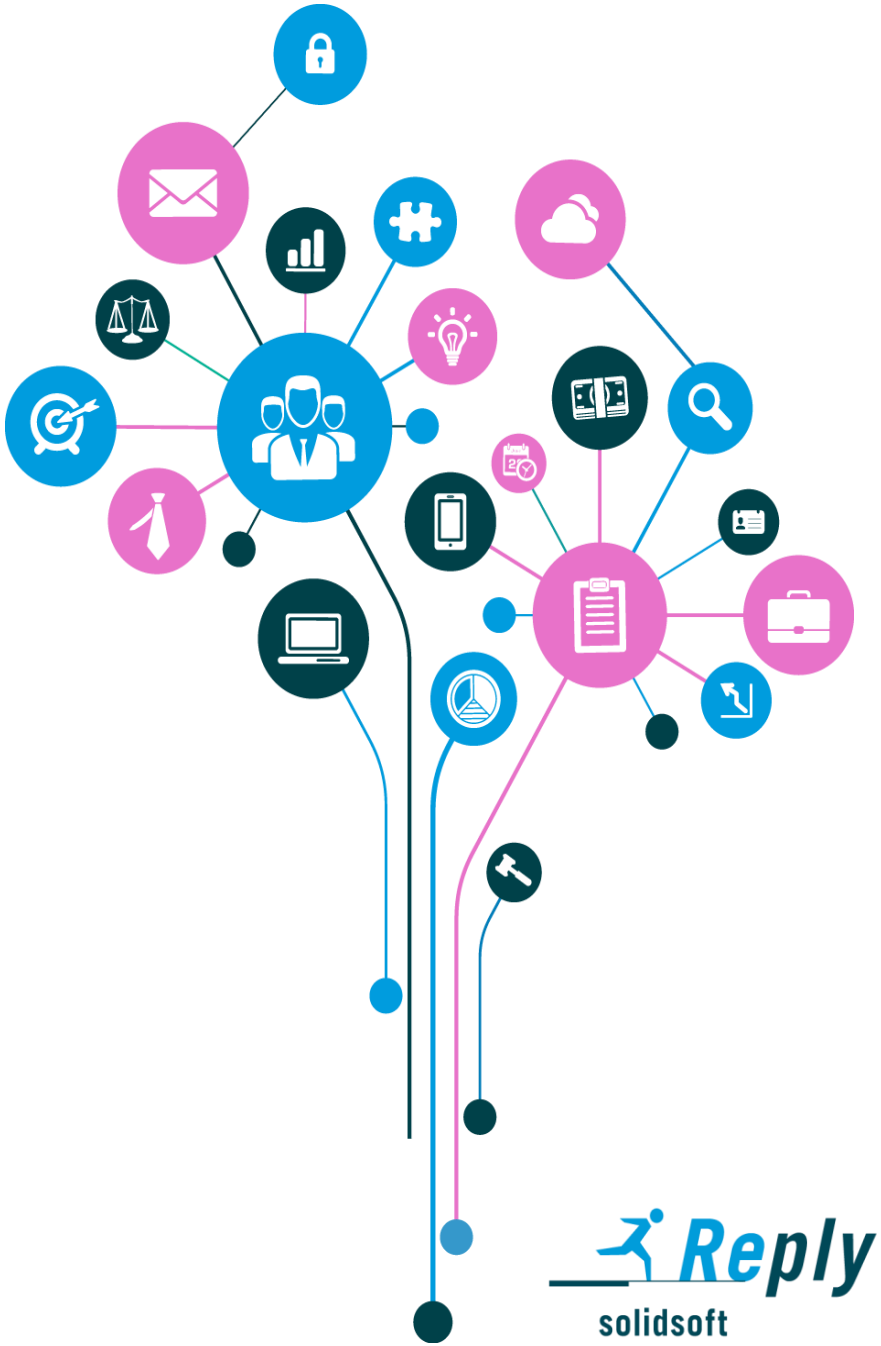
EMVS Overview



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European Medicines Verification System

Distribution of product and pack data to markets

Verification at the point of dispense

Additional Verification in the supply chain

Product and pack data upload from MAHs and PDs

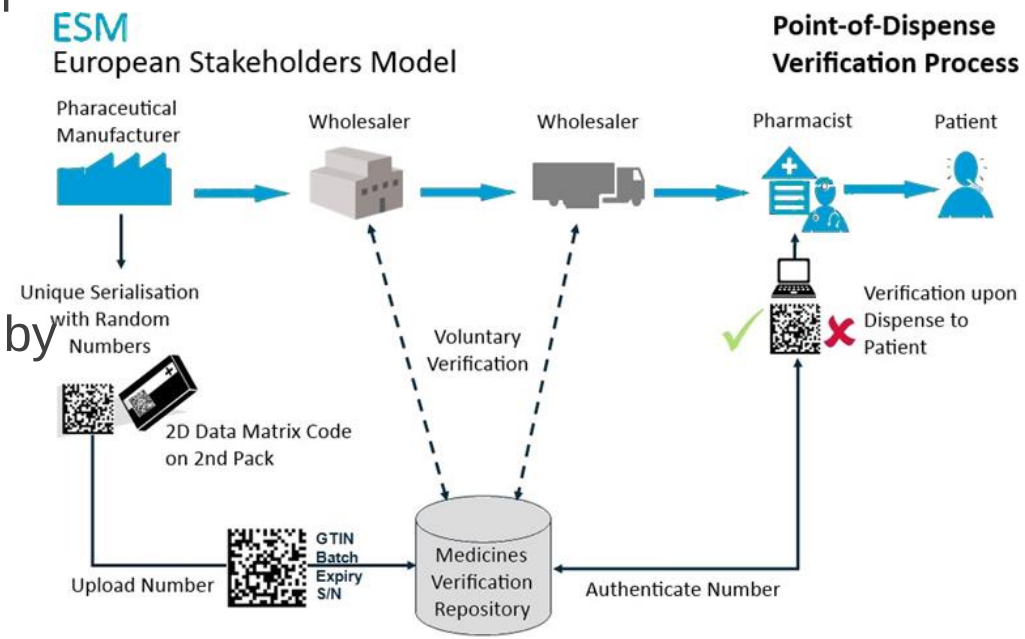
Repacking

Multi-market packs

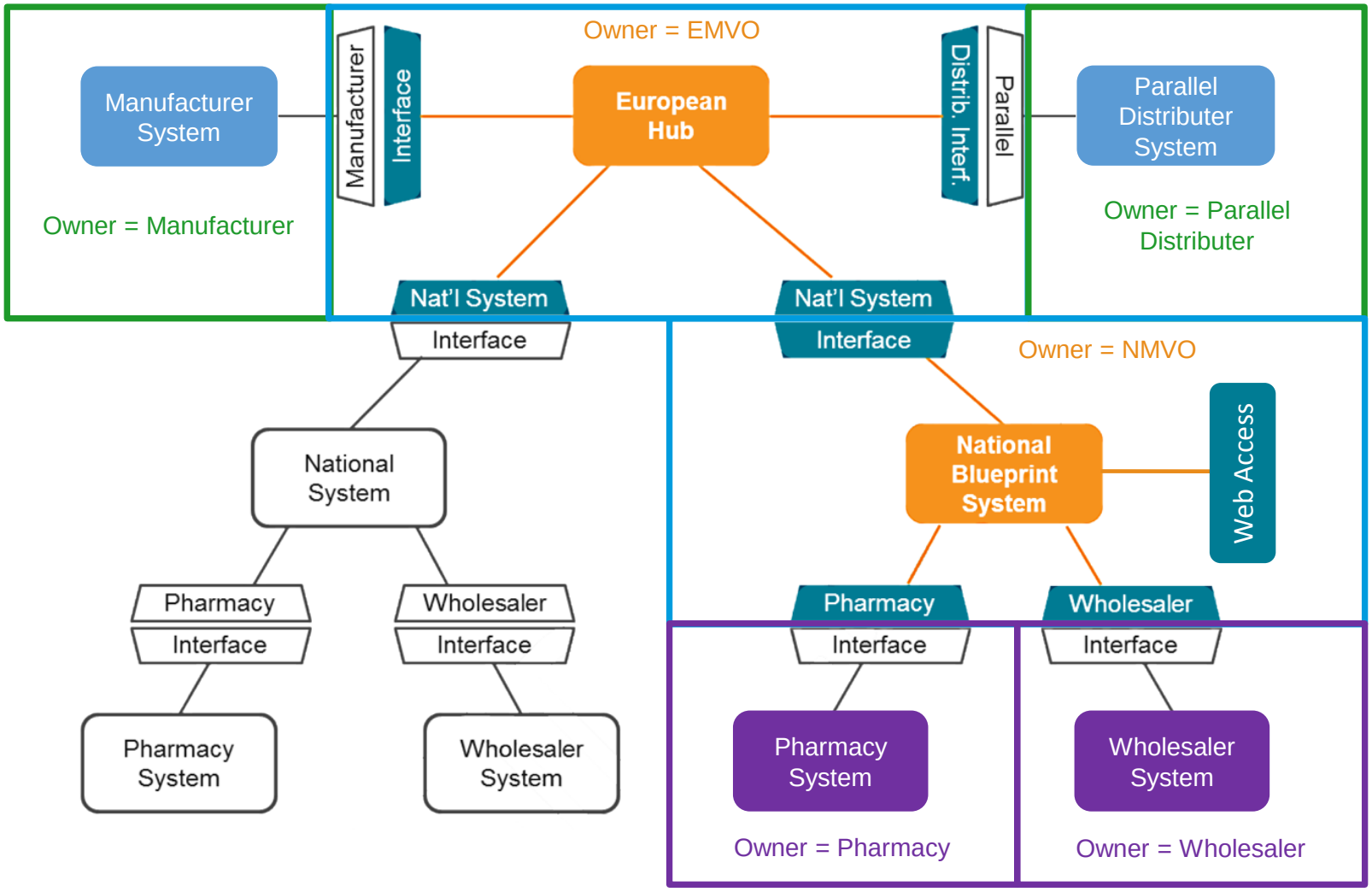
Notifications, alerts and reports

Verification, and decommissioning by pharmacies and wholesalers

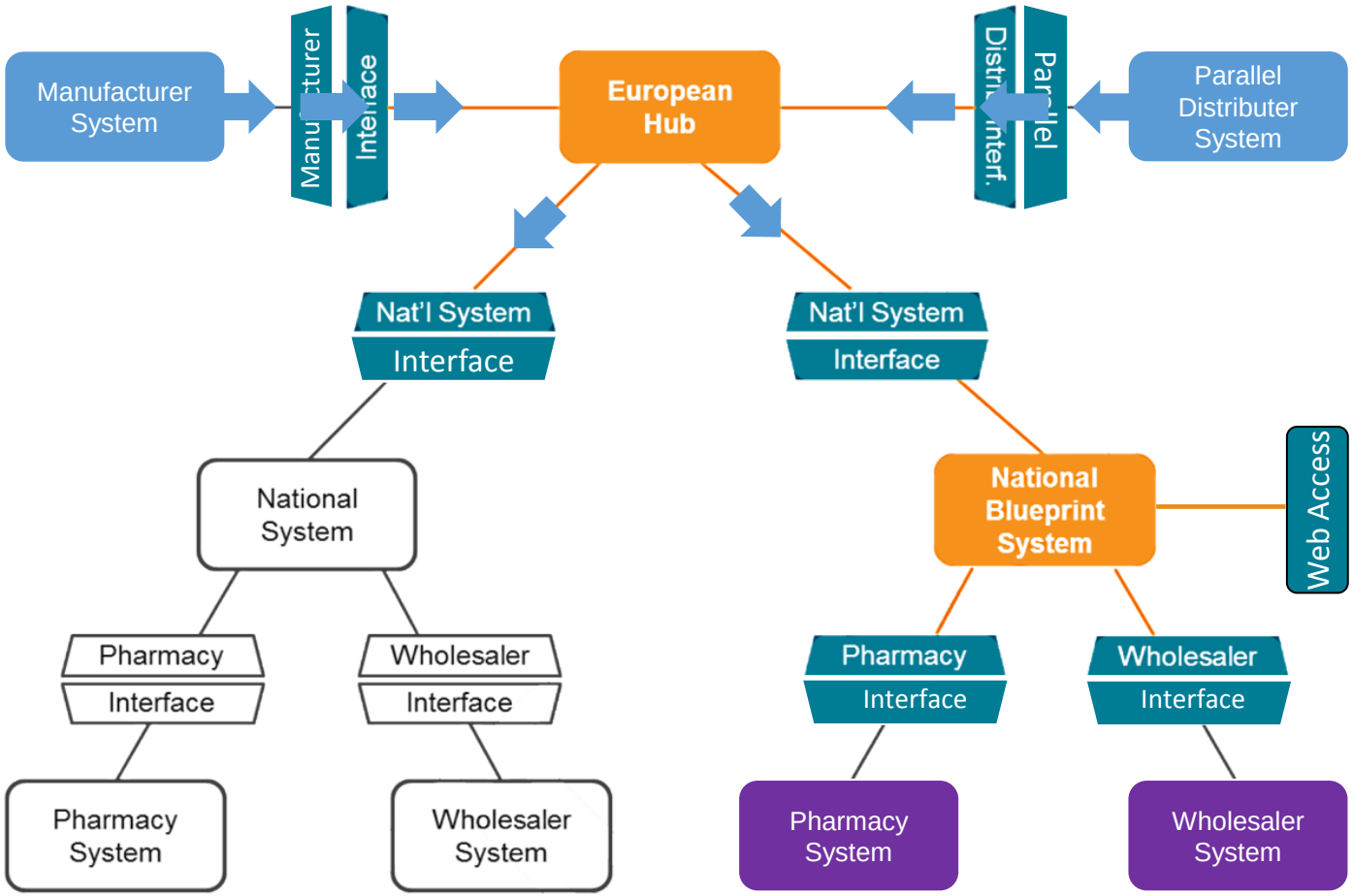
Supply to public (dispense) by pharmacies



EMVS Components

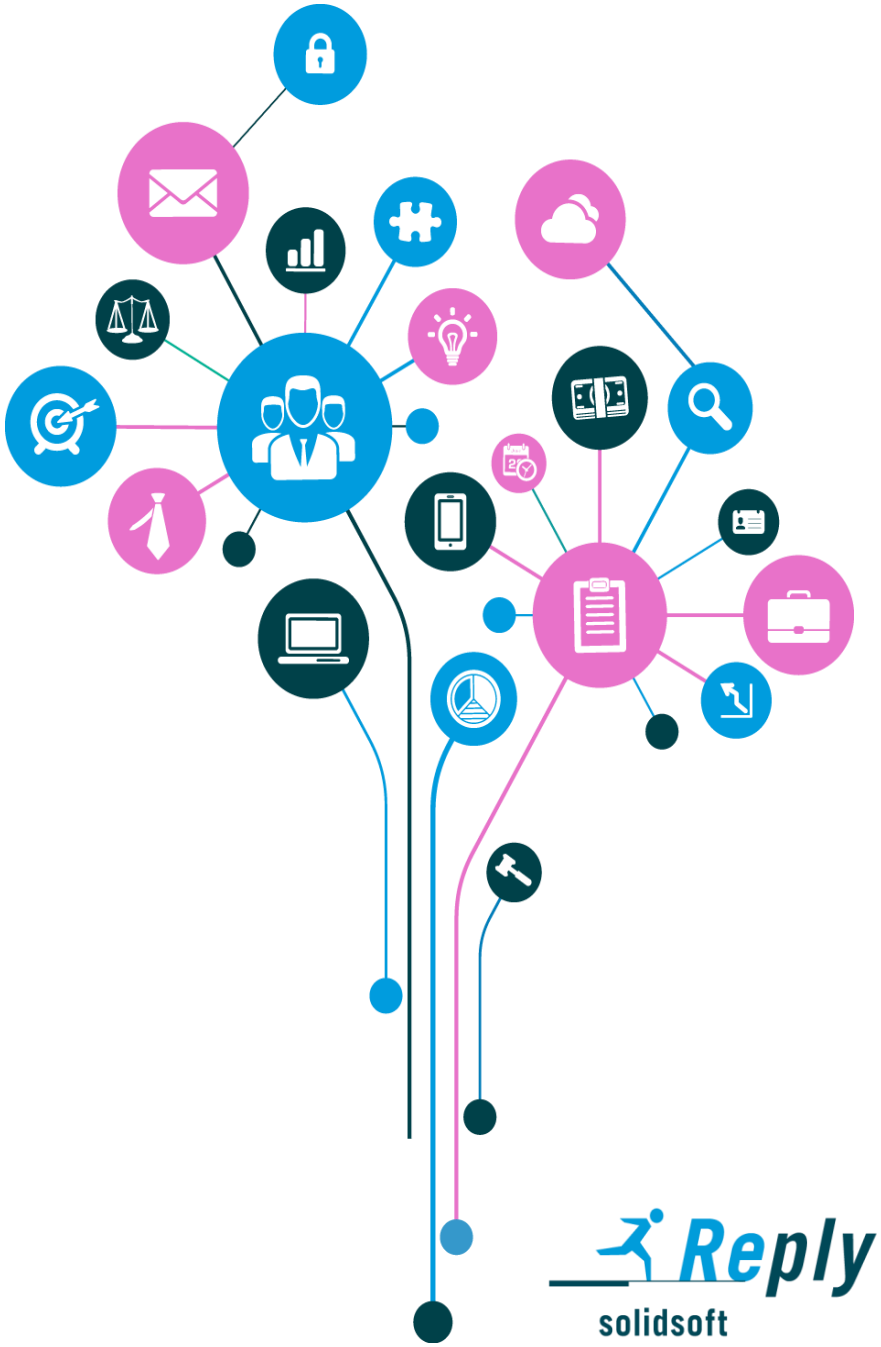


Data Flow (Normal Operation)



European Hub Capabilities

For Pharmacies and Wholesalers/Distributors



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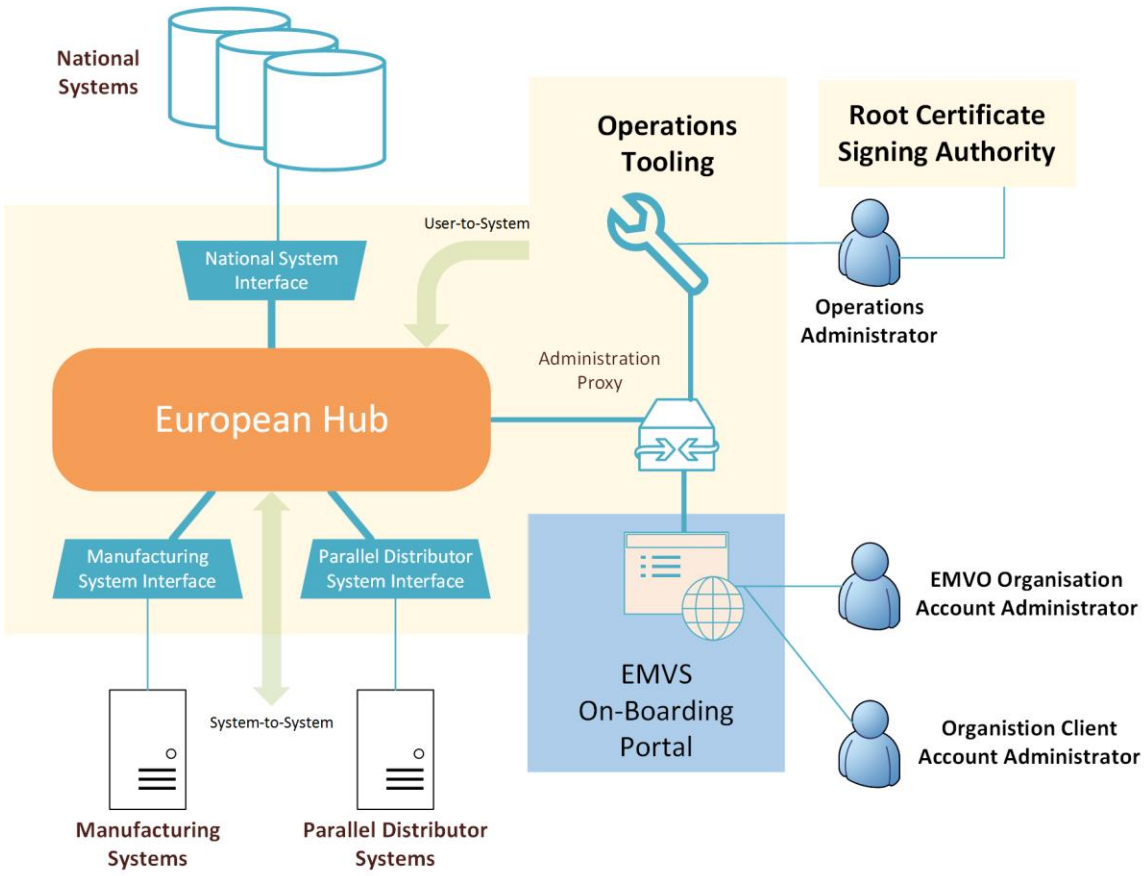
European System Scope



Precisely meets the EMVS and Delegated Regulation requirements

EMVO implements on-boarding portal for Manufacturers and Wholesalers

Operations Management Support

Root Certificate Signing Authority

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Meets EMVO's Requirements

Use Cases	Primary Stakeholder(s)
• Master Data Upload • Product Pack Data Upload • Recall Batch • Withdraw Product • Request Report	Manufacturing Authorisation Holder (MAH)
• Verify Single / Bulk of Pack(s)	Pharmacist, Wholesaler, MAH
• Dispense Pack • Re-Introduce Dispensed Pack	Pharmacist (Wholesaler)
• Decommission Single / Bulk of Pack(s) • Undo Decommission Single / Bulk of Pack(s)	Pharmacist, Wholesaler, MAH
• Export Bulk of Packs from EU • Undo Export Bulk of Packs from EU	Wholesaler MAH

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Data

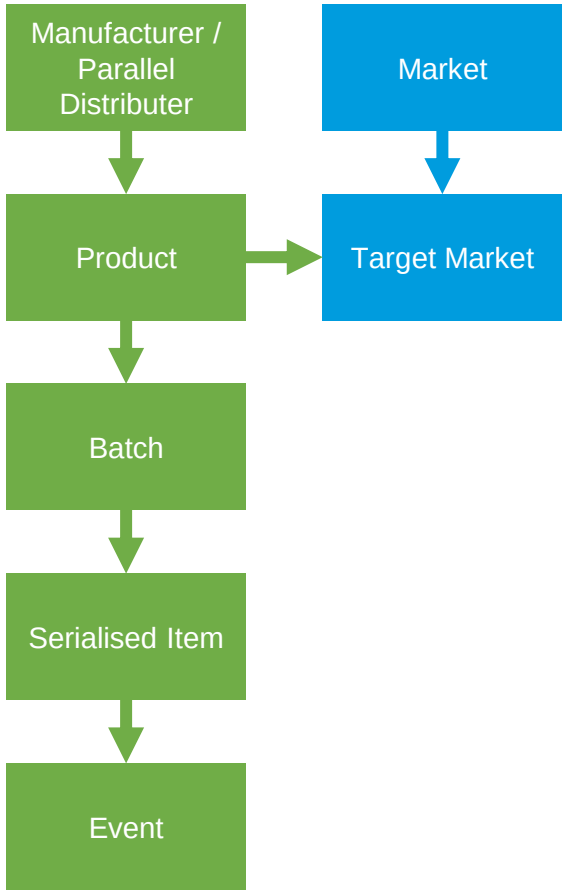
Each Manufacturer / PD provides many Products

Each Product is produced in many Batches

Each Batch contains many Serialised Items

Each Serialised Item has many Events recorded

Each Product is licenced to be sold in one or multiple Markets



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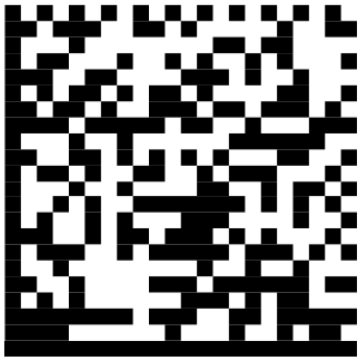
Pack Identifiers

Product Code Scheme: Product Code Coding scheme (GTIN or PPN)

Product Code:	The product code
Serial Number:	Serial number of the pack.
Batch Number:	The batch (or lot) number for the set of product packs being created or update
Expiry Date:	The batch expiry date.



Multi-Market Support
NTINs
Reimbursement - NHRNs

Human-Readable Representation
Anti-Tamper Device

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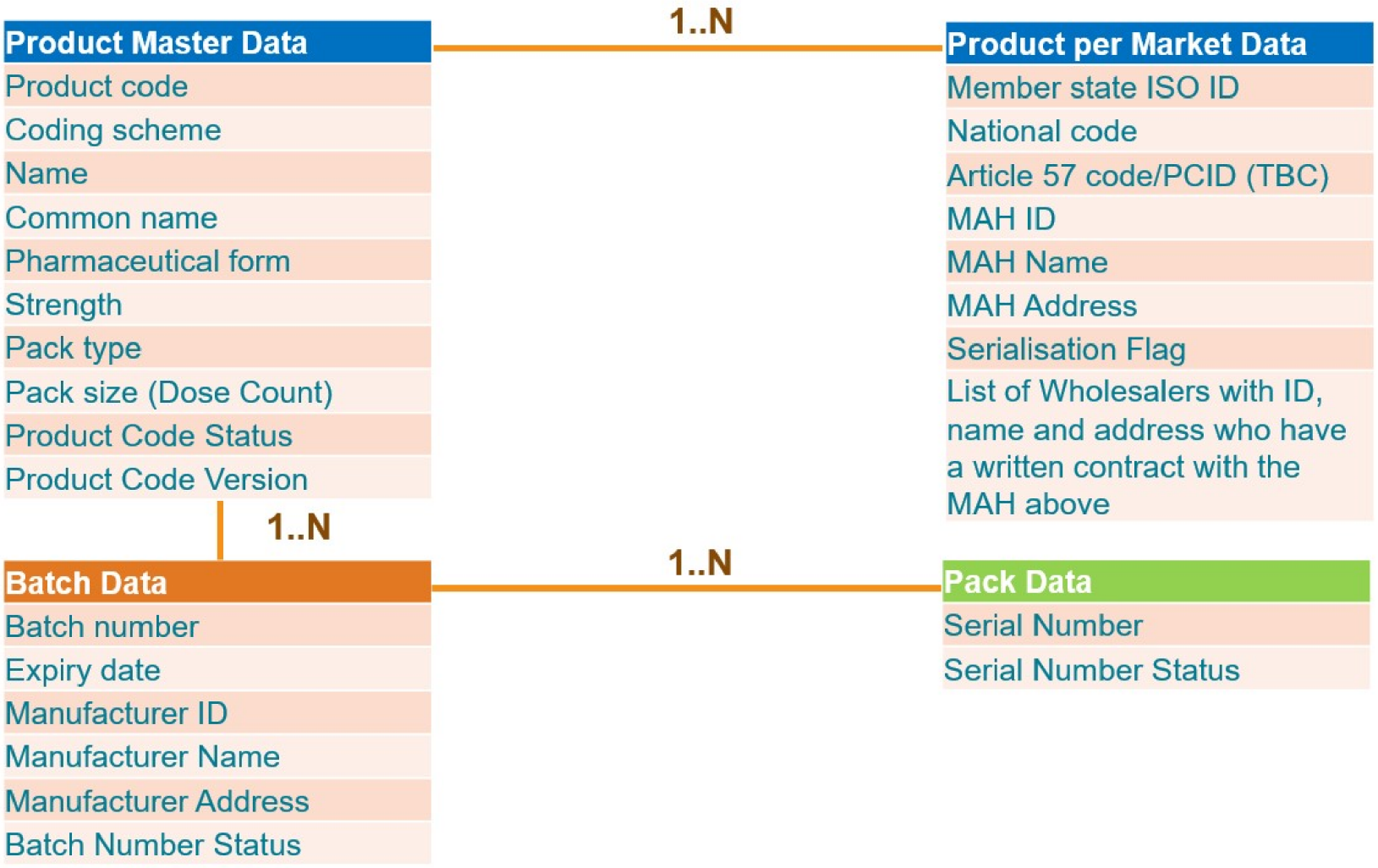
Product, Batch and Pack Data



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European Hub Features

Fully managed service operation

Cloud Hosted

Full operated and monitored

Maintained

Full Disaster Recovery

Self-service On-Boarding

Technical Help Desk

SDK including:

Full Technical Documentation

Working code sample (including store & forward)

Class Libraries & other code artefacts

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Integration Strategy

Software Development Kit

Documentation and Guidance

Code Examples (Java, C#)

Working example of store & forward

Tools and libraries

Development Portal

Development hub

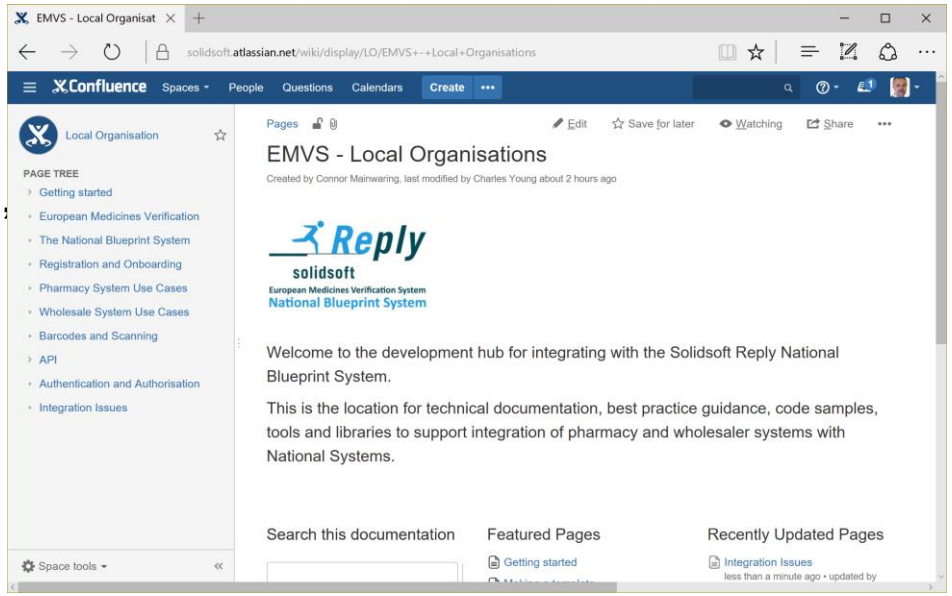
Will evolve to capture ‘lessons learned’

best practice, etc.

Sign NDA for access

Helpdesk

Technical support



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Implementation Approach

Set-up

Create System Environments

Agree Scenario Processes / publish guidelines / Training

Identify Pilot Participants (invite only)

Work with ISV's to enable integration

Engage with MAHs / Parallel Distributers

Pilot

Register participants

Start On-boarding participants

Prove Use Cases / Scenarios

Review / Amend Processes

Ramp-up

Open system to all stakeholders

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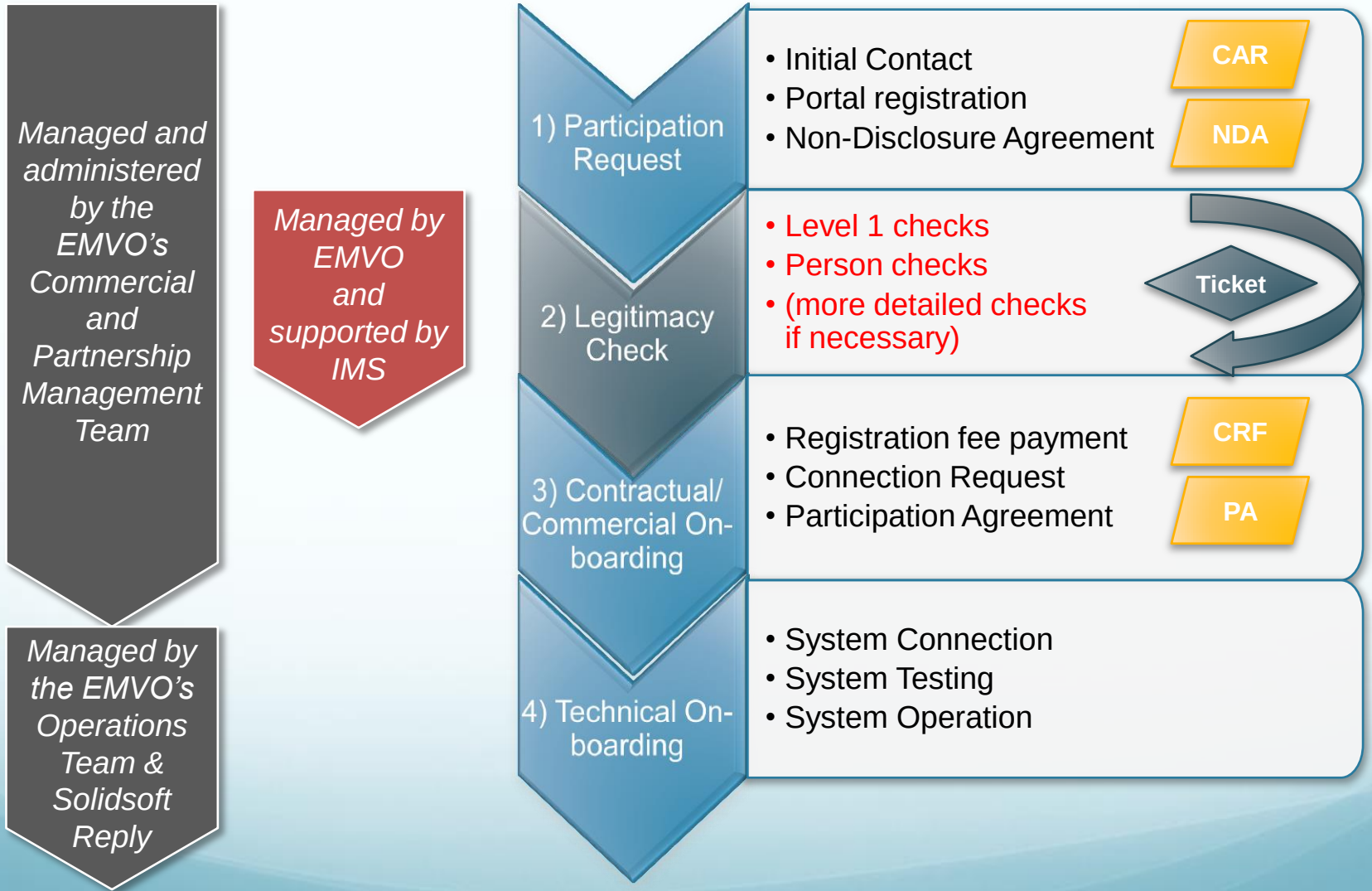
On-boarding Process – To Be



Contractual On Boarding

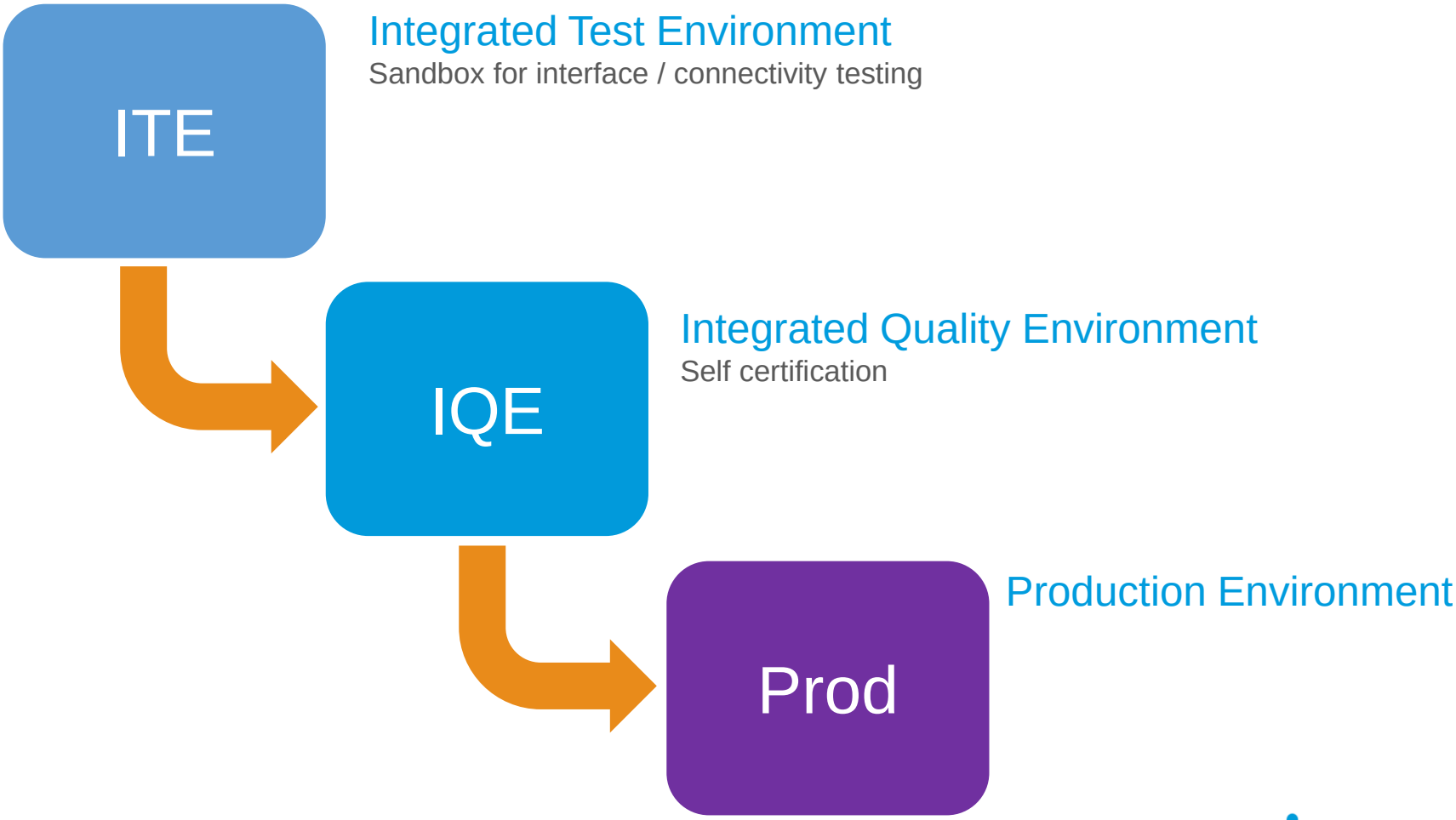
1. Non-Disclosure Agreement

- 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**

Environments



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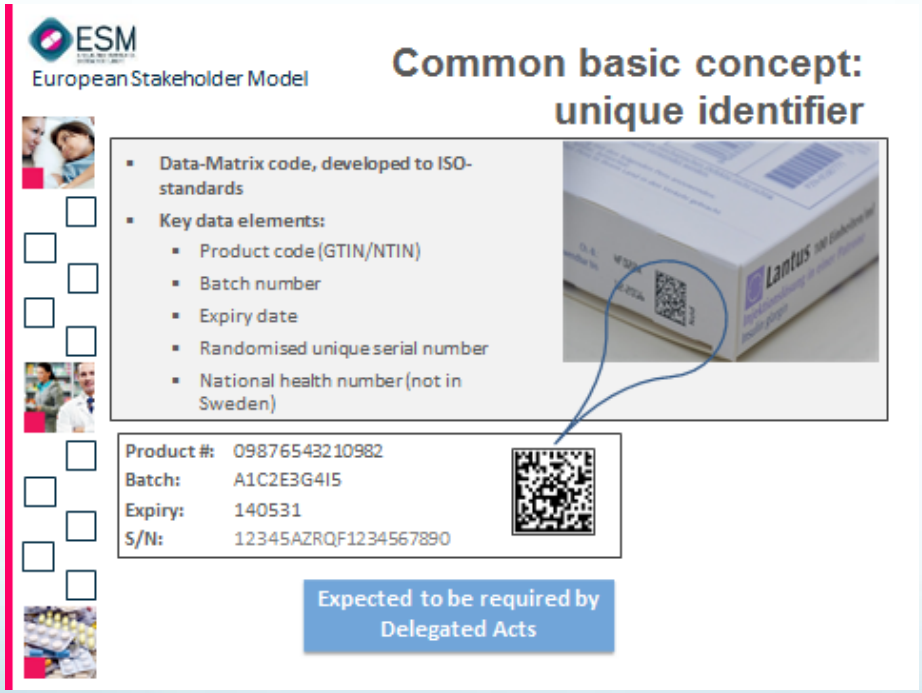
Coffee break

Codes and coding schemes

- 2D Data Matrix is to be used



Labelling of packages

- Medical Products Agency

https://lakemedelsverket.se/english/All-news/NYHETER-2016/Requirements-regarding-safety-features-for-packages-for-medicinal-products/

- CMDh and EMA

- Marketing authorization holders for the concerned Swedish medicinal products shall follow the guidelines published by CMDh and EMA with the purpose to update the labelling and the QRD-template.

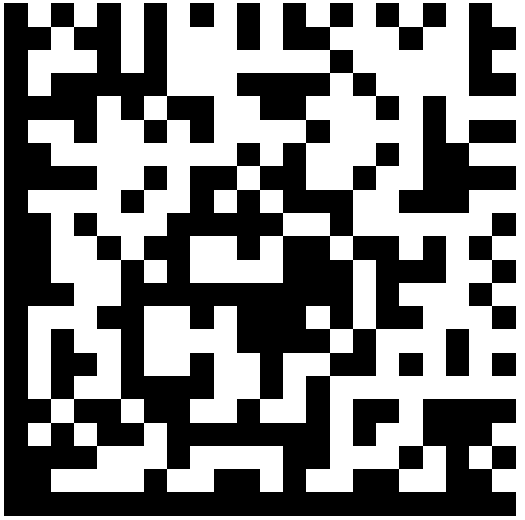
NTIN to GTIN

- Currently NTIN, which is not always unique, is used instead of GTIN for pharmaceuticals in the Nordic countries. In other markets, many pharmaceutical companies already use GTIN.
- Since the format of NTIN and GTIN is the same, it is technically possible to replace the current NTIN with a GTIN.
- To change all NTINs into GTINs will take a long time. The implementation of GTIN could therefore, if necessary, be phased.
- The Vnr will continue to be printed on all packages.
- Articles with a Vnr only used in one Nordic country can be changed at any time, as long as the systems using the NTINs can handle more than one GTIN.
- For articles with common Nordic Vnrs the change must be synchronized in the Nordic countries.

Why change to GTIN?

- e-verification will need unique NTIN/GTIN.
- To be able to distinguish the different packages a unique identity on the package level will be needed (GTIN/unique NTIN).
- There is no connection between the different packages and the serial number. The serial number is not enough to identify the different packages.
- Thus - the combination of the serial number and the GTIN/unique NTIN will identify a pack

Difference 2D and QR



GS1 DataMatrix

QR-kod

QR -code

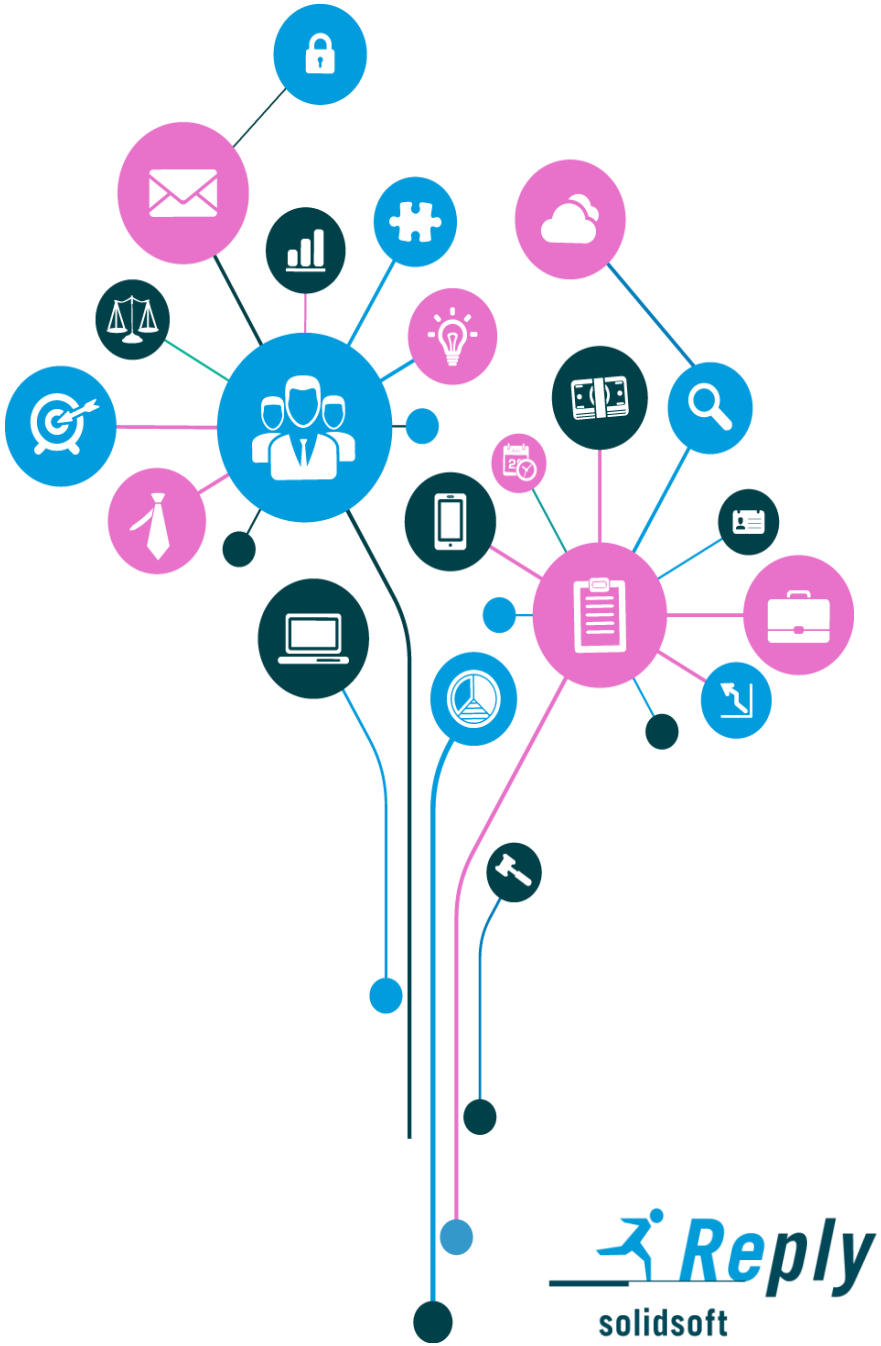
- Bestämmelser från CMDh
- http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/About_CMDh/Contact_with_Representatives_Organisations/Meeting_w._IPs_May_2014/CMDh_Position_paper_on_QR_codes.pdf
- Bestämmelser från EMA
- http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2015/07/WC500190405.pdf

Useful links

- Vnrwiki http://wiki.vnr.fi/?page_id=36

- Kurser på GS1- http://www.gs1.se/sv/borja-har/Utbildningar/
- GS1 kan anordna specialanpassade kurser - http://www.gs1.se/sv/Kom-igang/Utbildningar/gs1-skraddarsytt/

Pilot



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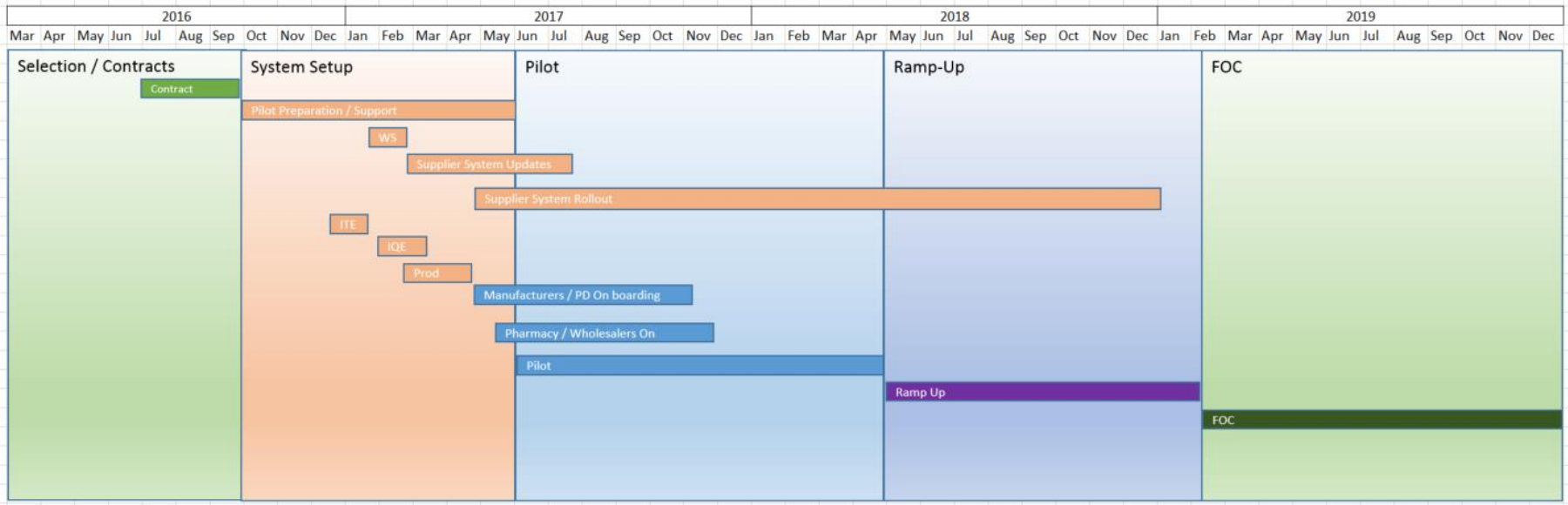
High Level Project Plan

28 Months



8 Months

11Months

9 Months

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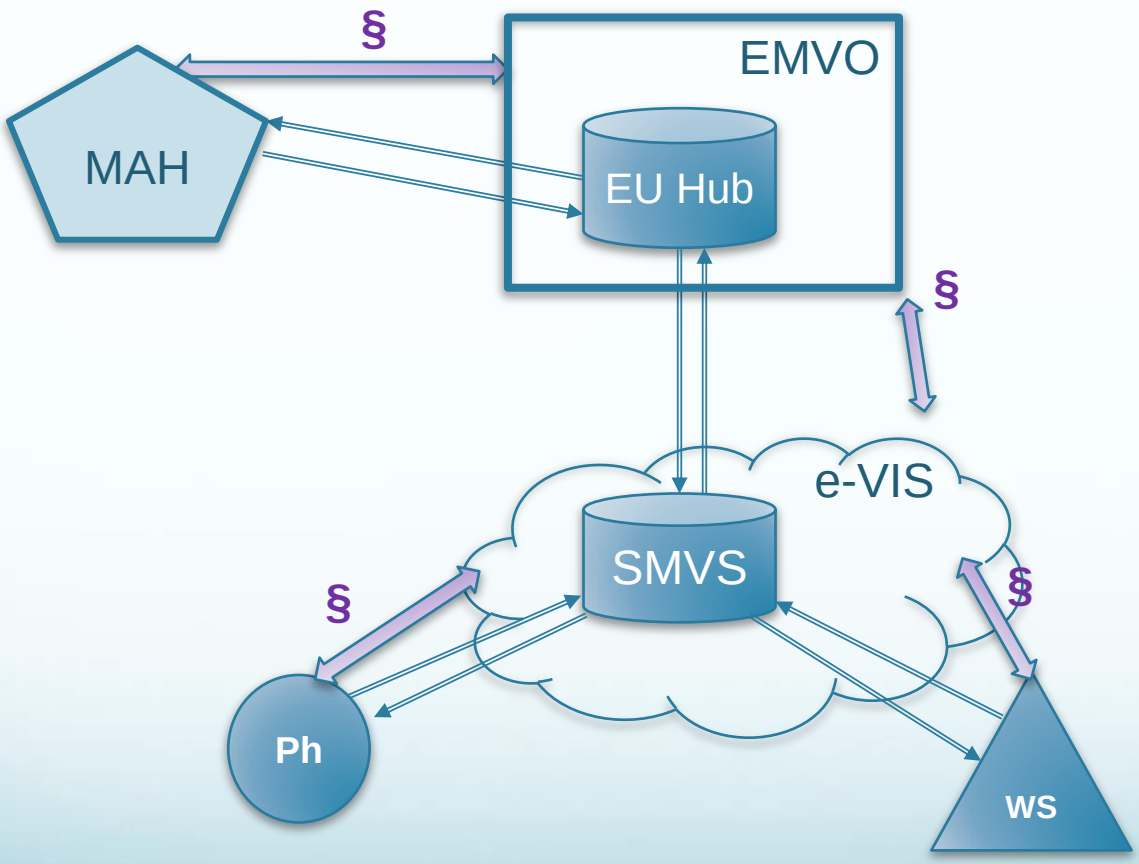
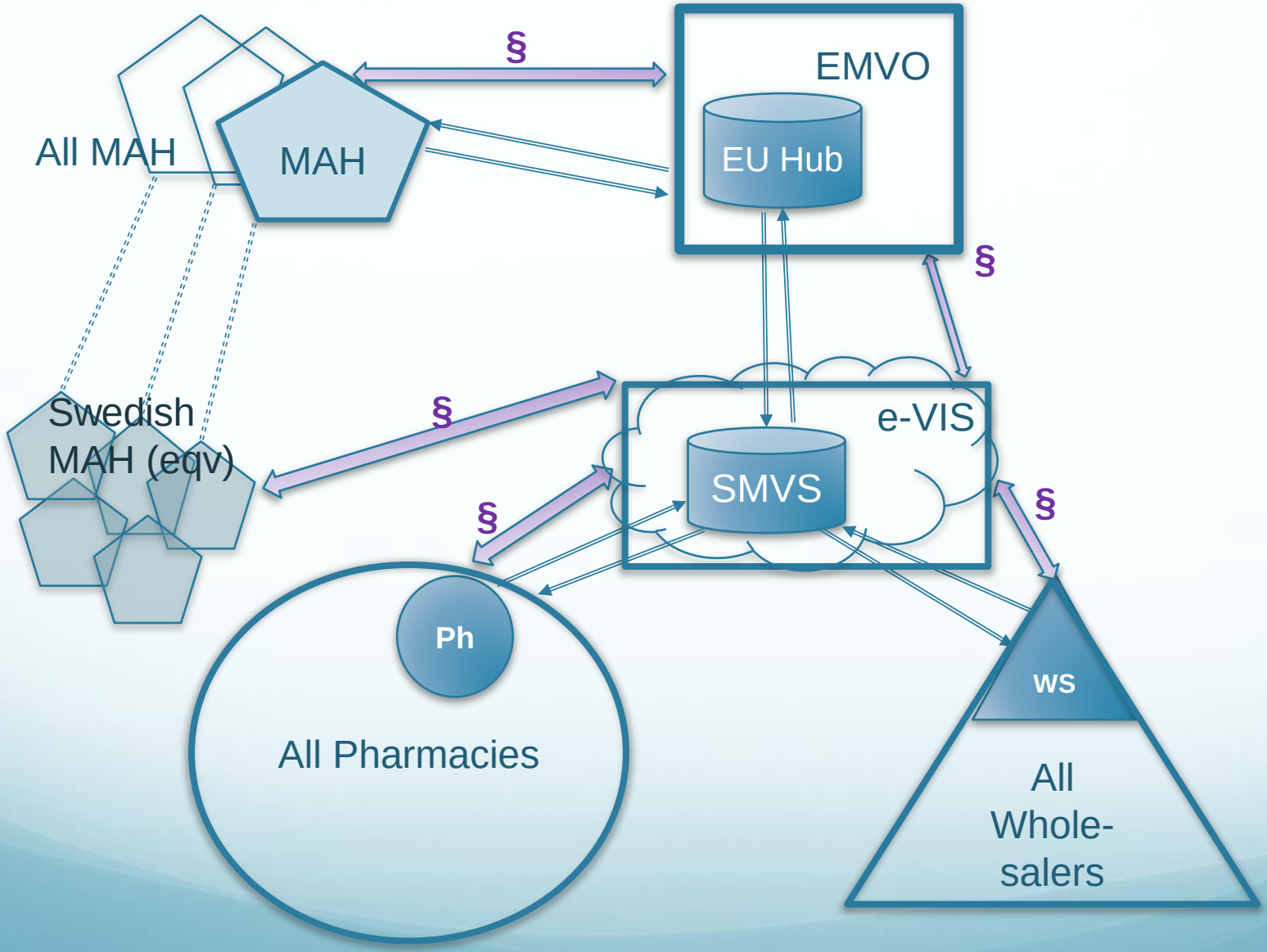
What is the “Pilot”?

A limited, well controlled implementation of the total system



What is endpoint and what happens then?

Ramp up to full implementation

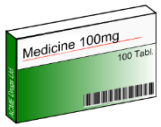
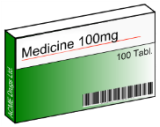
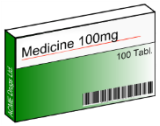


Prerequisites to start the Pilot

- A number of Pharmacies and Distributors are ready:
  - IT systems adapted and connected to Swedish system
  - Personnel trained
- Serialised packs available in a sufficient number
  - MAH with high volume products on the Swedish market have serialised these and uploaded to the EU Hub
- SOPs/instructions for events affecting more than one actor have been developed to a final draft
  - In particular exceptions occurring when verifying or decommissioning packs

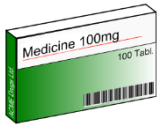
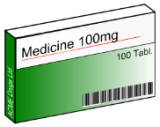
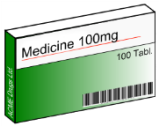
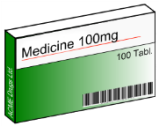
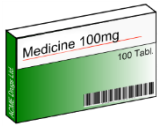
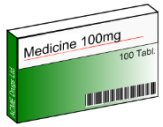
Processes/Guidelines/SOP:s

Use cases, status and exceptions

Manuf., PD	Manuf., PD	Manuf., PD	Manuf., PD, Wholesaler, Ph.	Manuf., PD, Wholesaler, Ph.
Master Data Upload X	**Product Pack Data Upload** X	**Recall Batch** X	**Request Report** X	**Verify Pack.** X
				
	Available	**Recalled**		**No status change**
	Repacked (PD)			

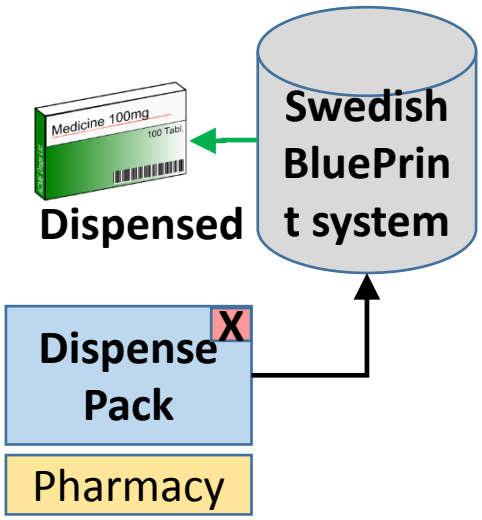
Use case
Executed by
Exception

Use cases & exceptions to be described in instructions/ Standard Operating Procedures

					
Dispensed	**Available**	**Decommissioned**	**Available**	**Exported**	**Available**
Dispense Pack X	**Re-Introduce Dispensed Pack** X	**Decommission Pack** X	**Undo Decommission Pack** X	**Export Pack from EU** X	**Undo Export Pack from EU** X
Pharmacy	Pharmacy	Manuf., PD, Wholesaler, Ph.	Manuf., PD, Wholesaler, Ph.	Wholesaler	Wholesaler

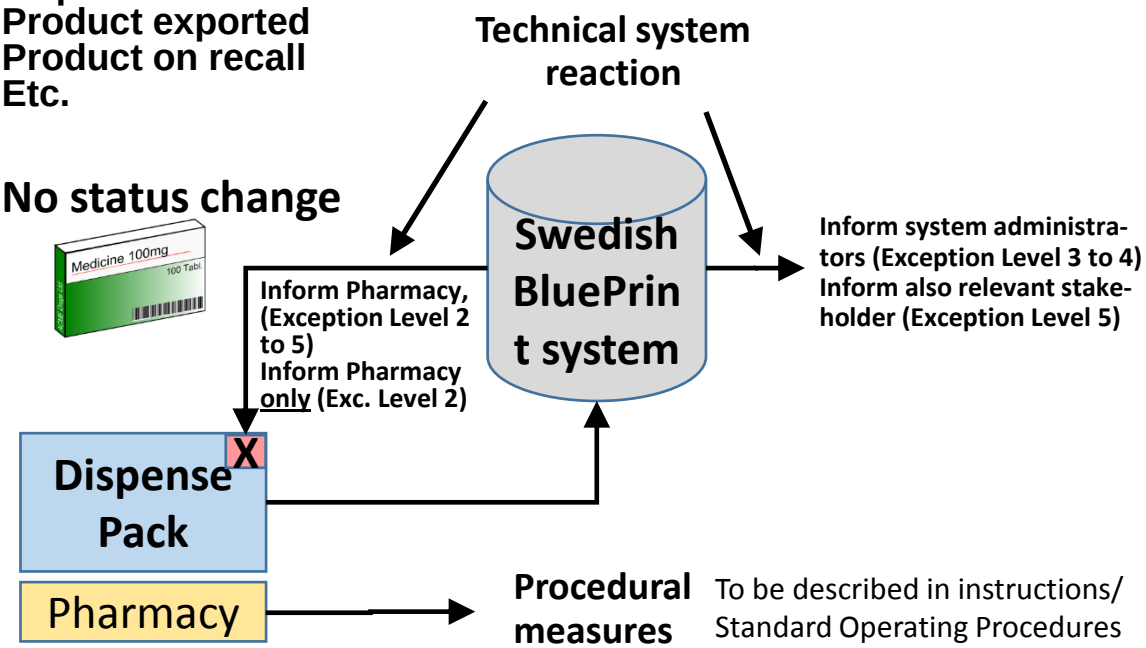
Use case example, ”Dispense Pack”

Normal case



Exception

- Pack already dispensed
- Product exported
- Product on recall
- Etc.

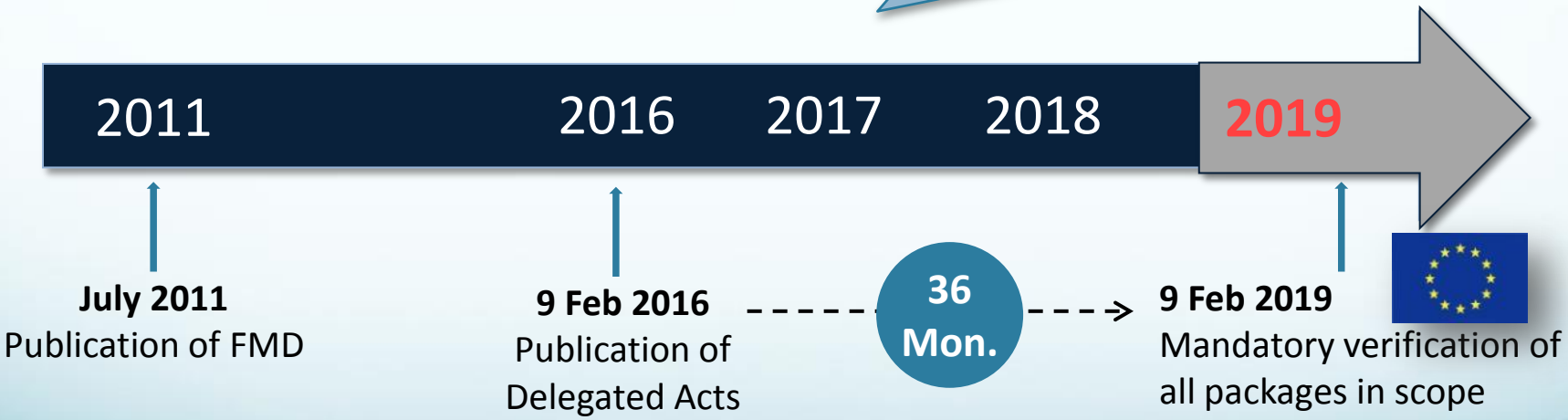


Actions needed

- Prepare for serialisation of packs:
  - Unique product codes, serial numbers, encoding and printing
  - IT system adaption
  - Artwork changes and regulatory submissions
- On-boarding to the EU Hub
  - Contractual process – define who is the on-boarding partner
  - Technical process - decide focal point for uploading
- Start to serialise some high volume product for the Swedish market to support the pilot
  - Provide input to the governance; processes, SOP:s, training etc
- Plan for the full implementation to be ready well ahead of Feb 2019

Implementation timelines – no time to loose!

- 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)

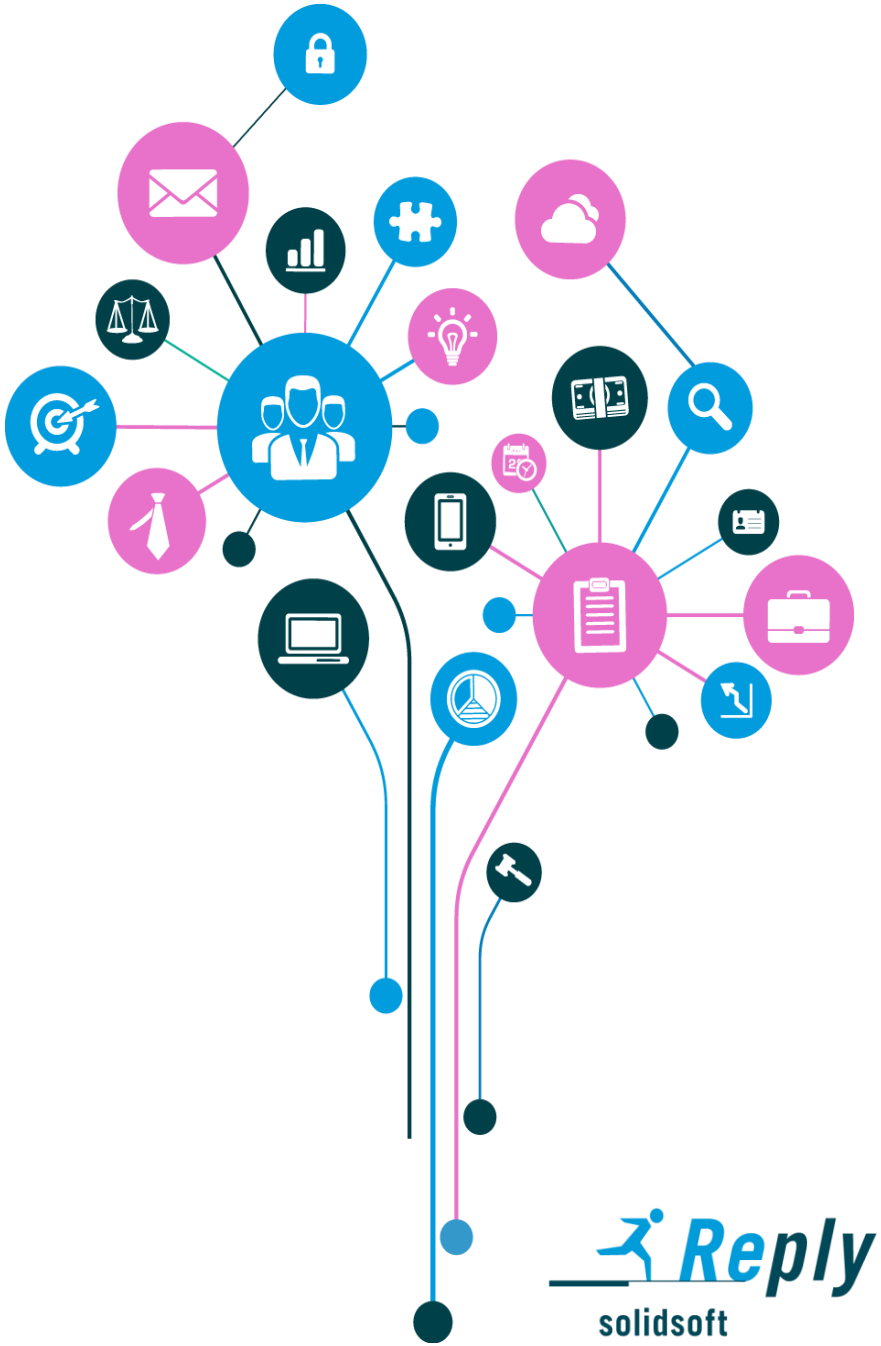


Access to information

- EMVO HUB on-boarding webinars
  - https://youtu.be/jrObT4r0CRw
  - Contact via helpdesk@emvo-medicines.eu
  - Connection request forms from connection@emvo-medicines.eu
- Implementation project Q&A version 1 available now http://www.lif.se/grundfakta/e-verifikation/
- Solidsoft Reply: Charles Young, c.young@reply.eu

  +44 (0)1256 375700
- e-VIS web page planned to be available early 2017

Questions?



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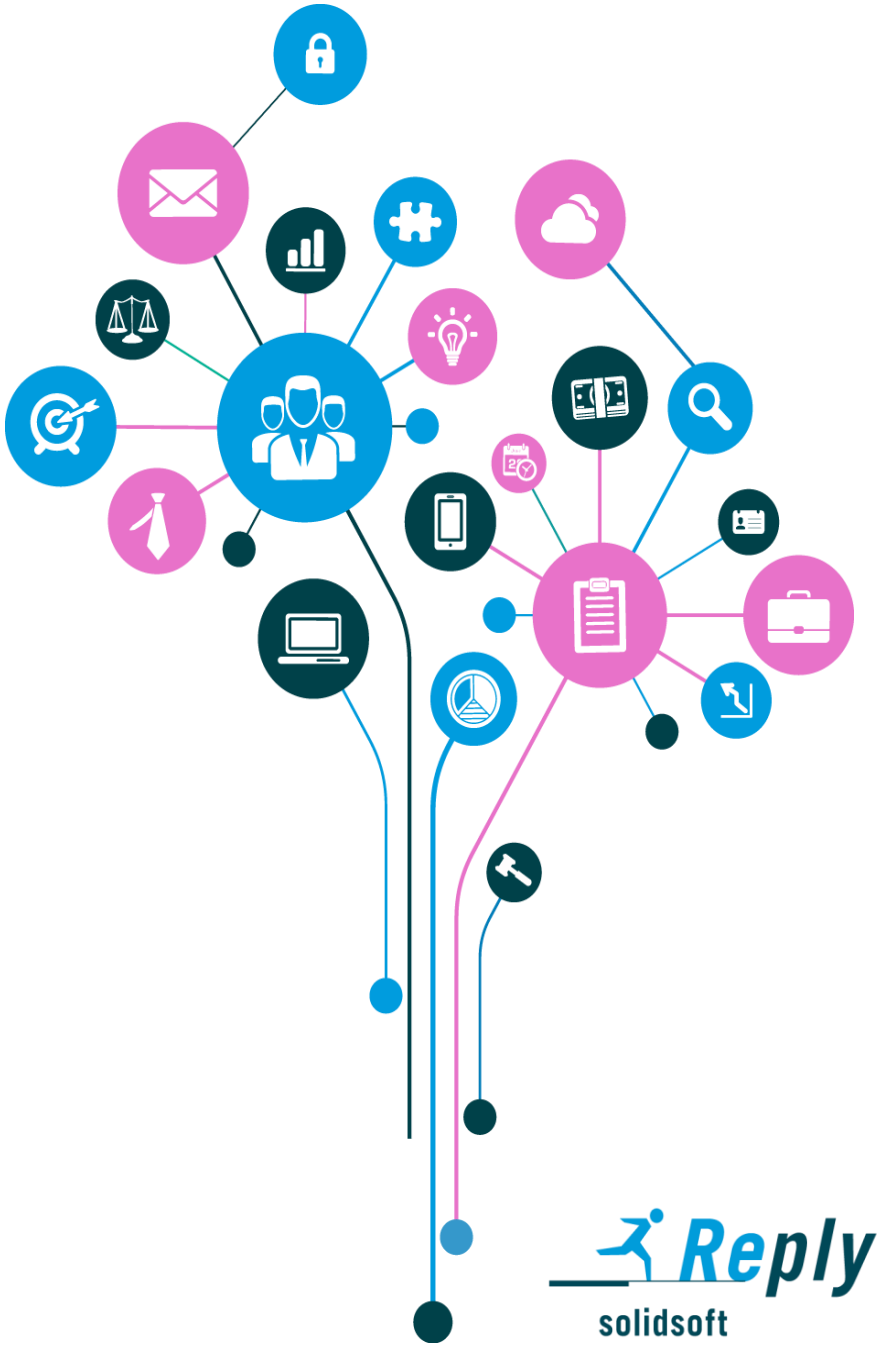
Thank You



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