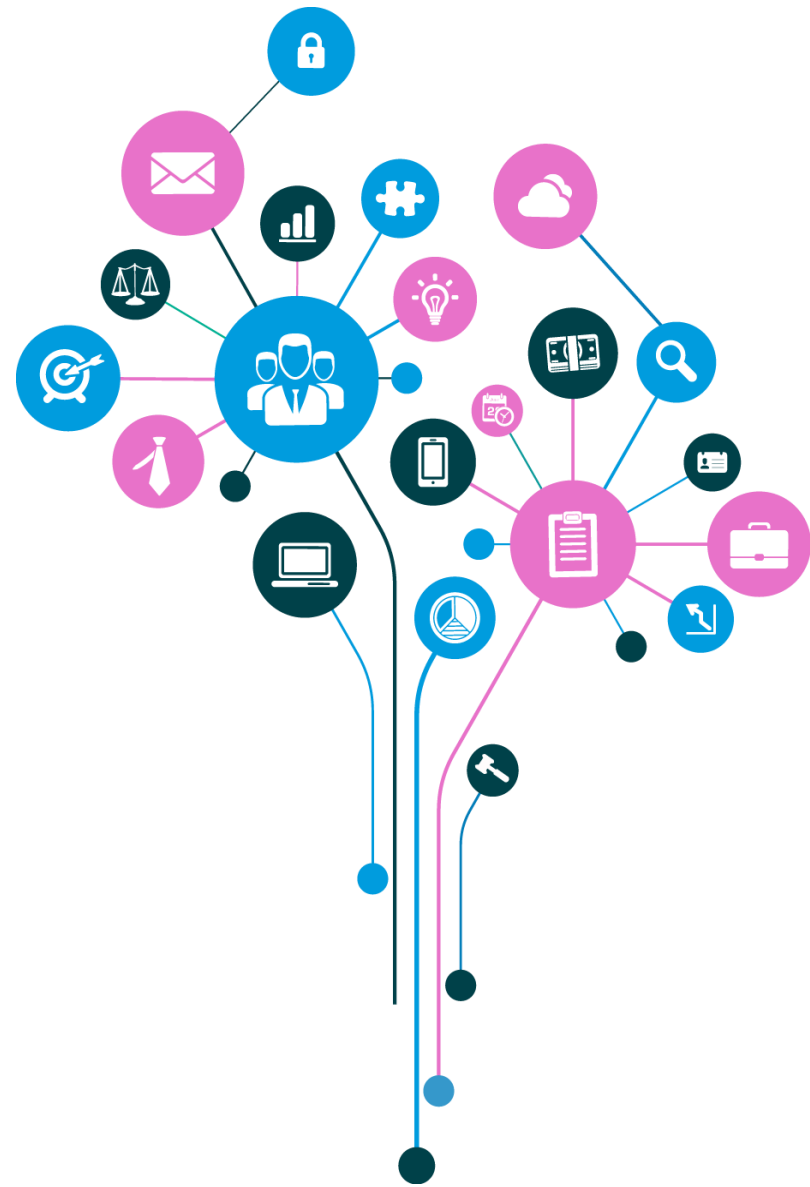# Íslenska lyfjaauðkenniskerfið

Mark Usher
Solidsoft Reply
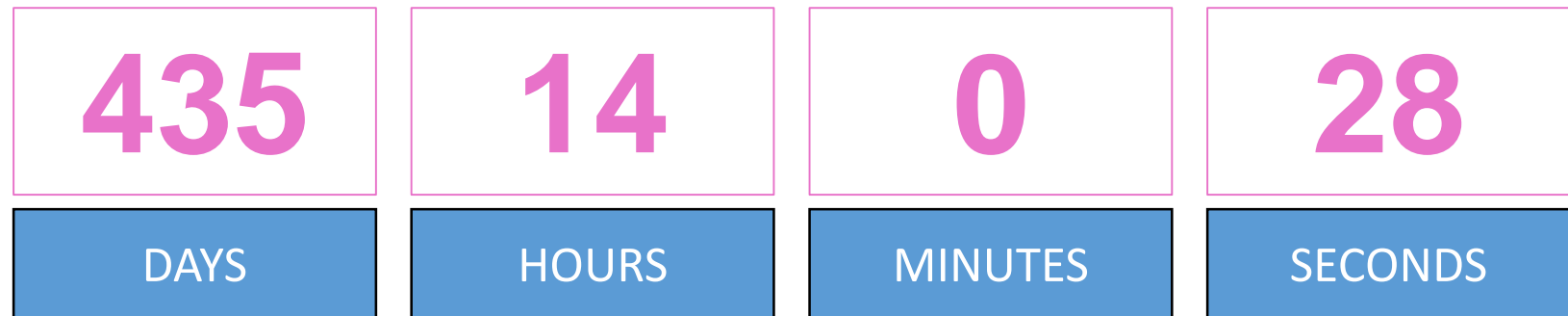
Falsified Medicines Directive

Delegated Regulation to the FMD 2011/62/EU comes into force on:

9 February 2019

435	14	0	28
DAYS	HOURS	MINUTES	SECONDS

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Obligatory Safety Features

Anti-tamper device + Unique Identifier

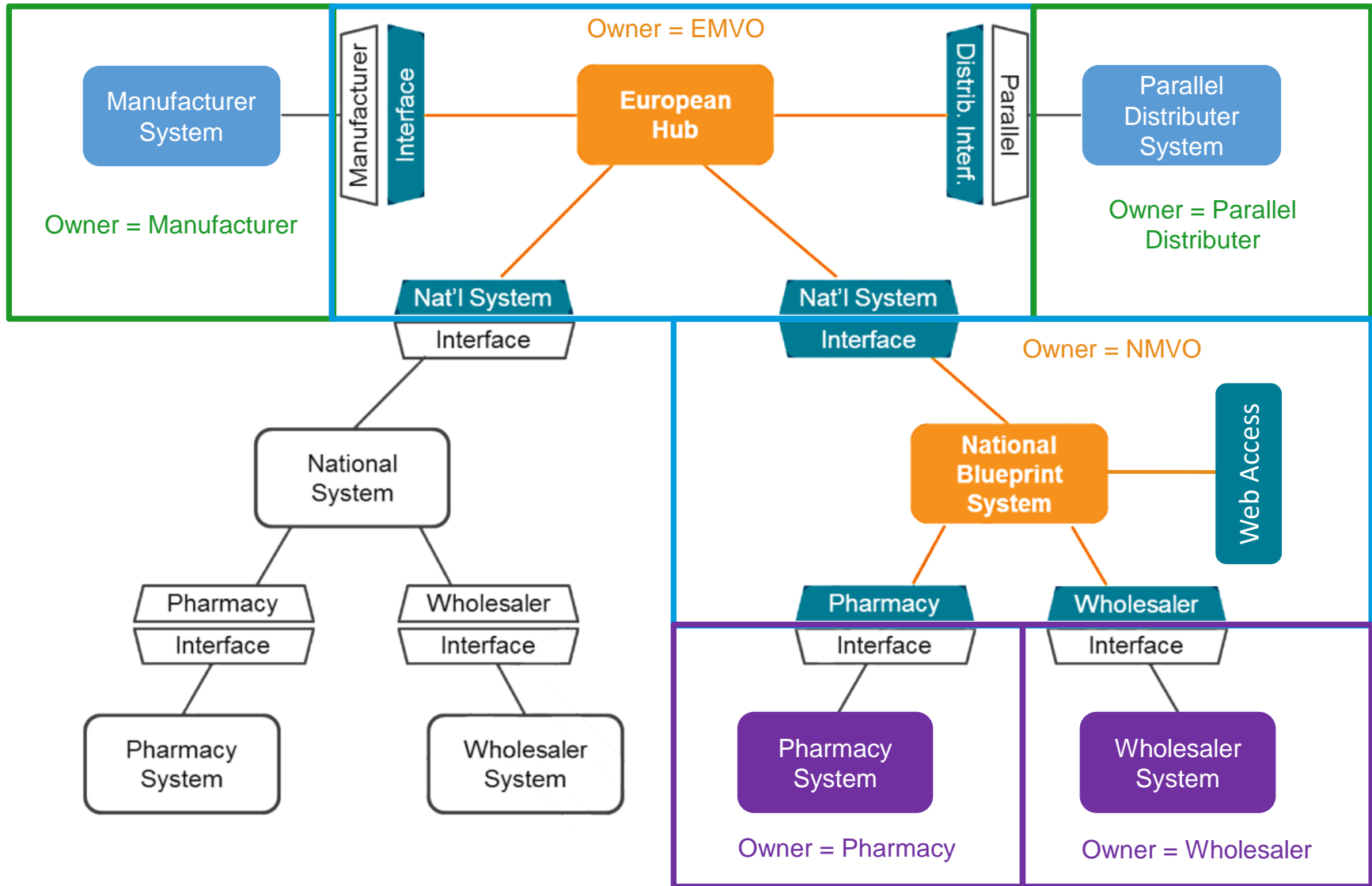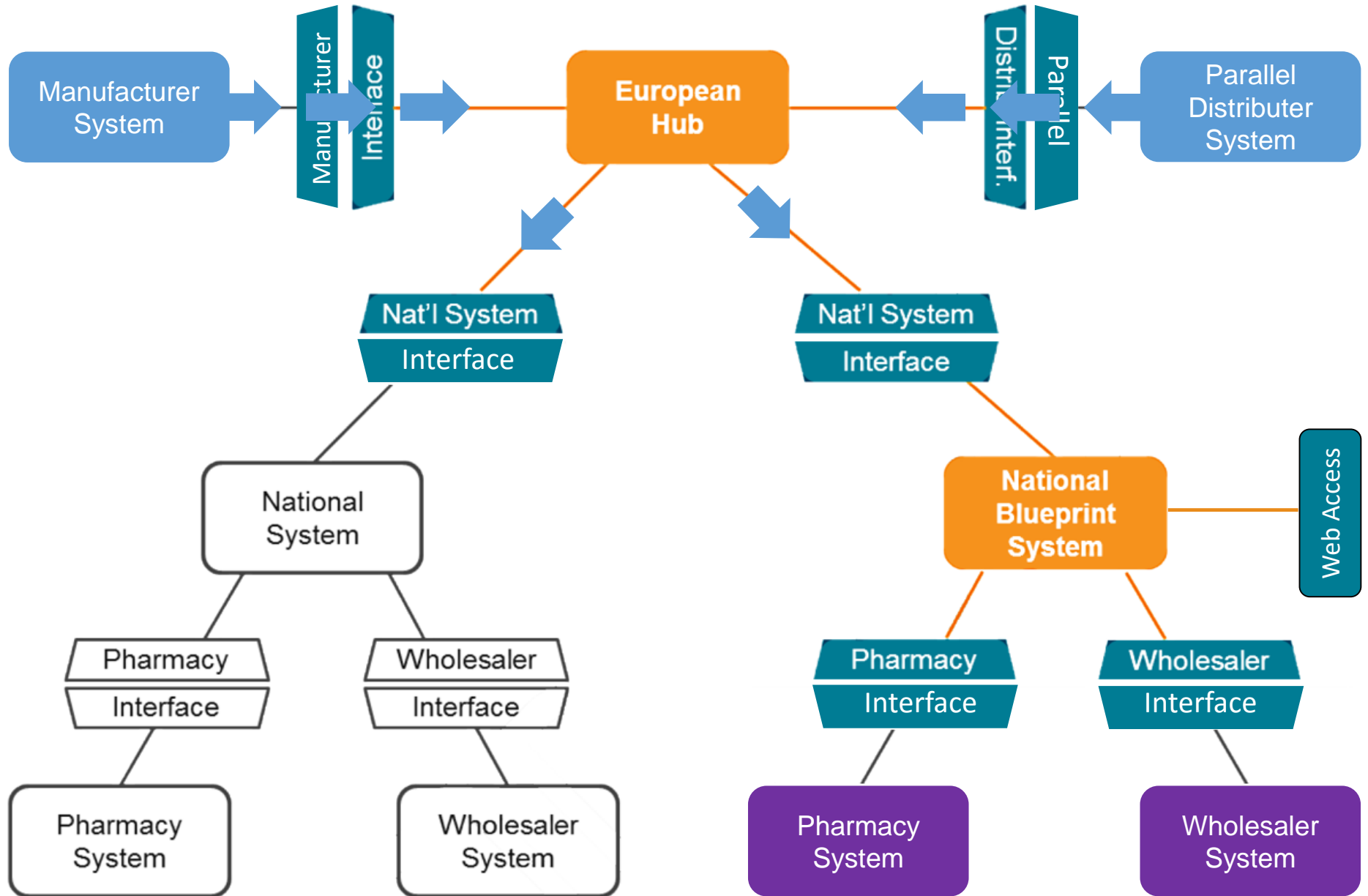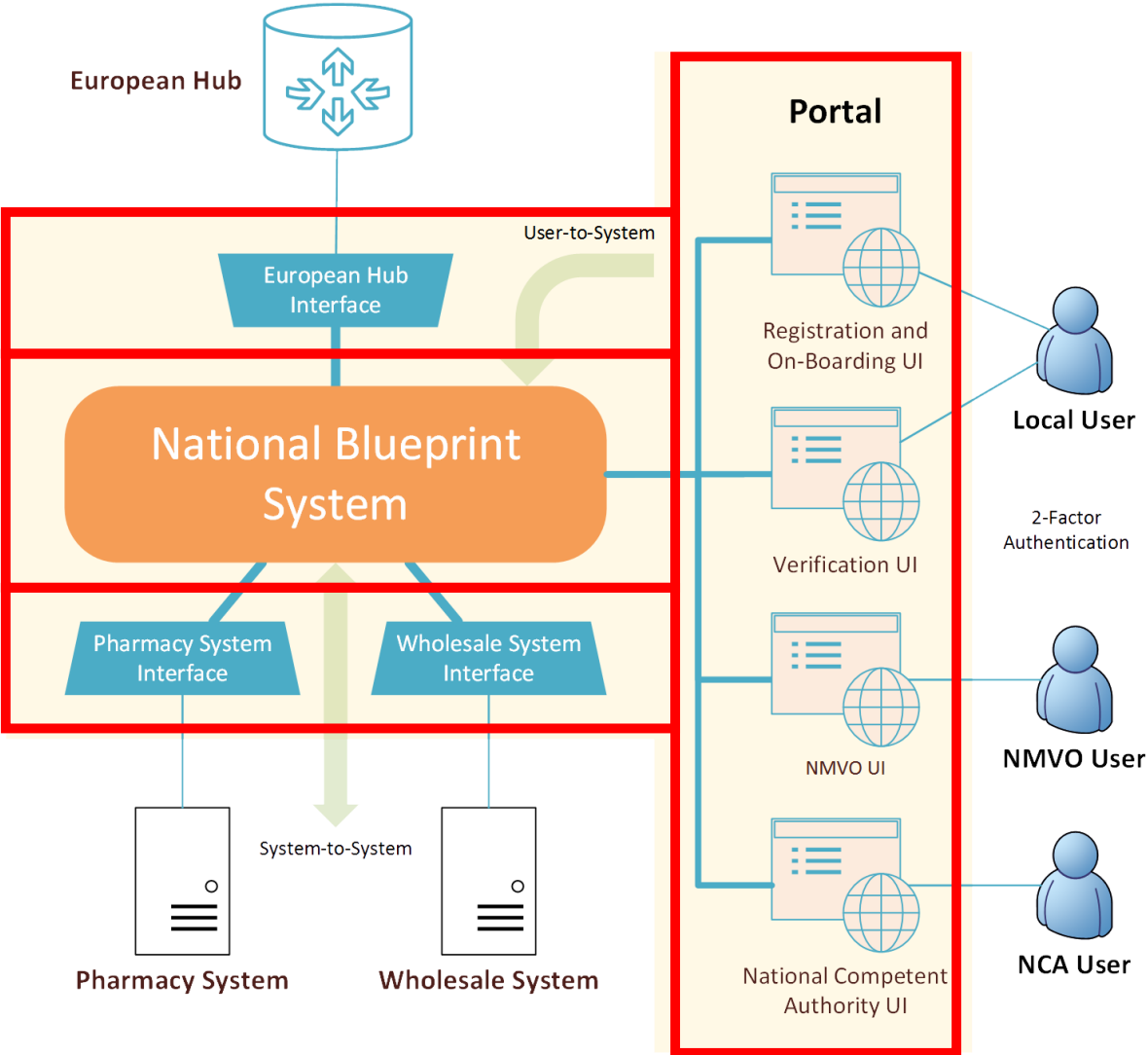|	
Product Code:	The product code
Serial Number:	Serial number of the pack.
Batch Number:	The batch (or lot) number
Expiry Date:	The batch expiry date.
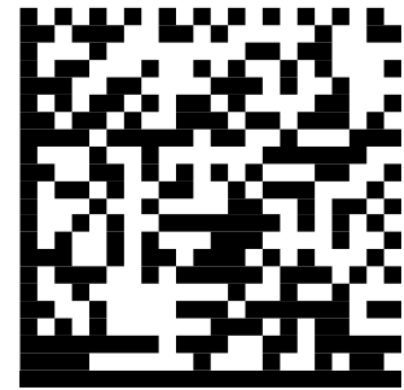
EMVS Components

Data Flow (Normal Operation)

National Blueprint System Scope

Precisely meets the requirements of the FMD & Delegated Regulation

- Connection to the European Hub

- Data Repository and Processing Engine

- Interfaces for Pharmacies and Wholesalers

- Portal

  - Integrated on-boarding portal for Pharmacies and Wholesalers

  - Web-based emergency Verification Portal

  - NMVO Administration and Reporting Portal
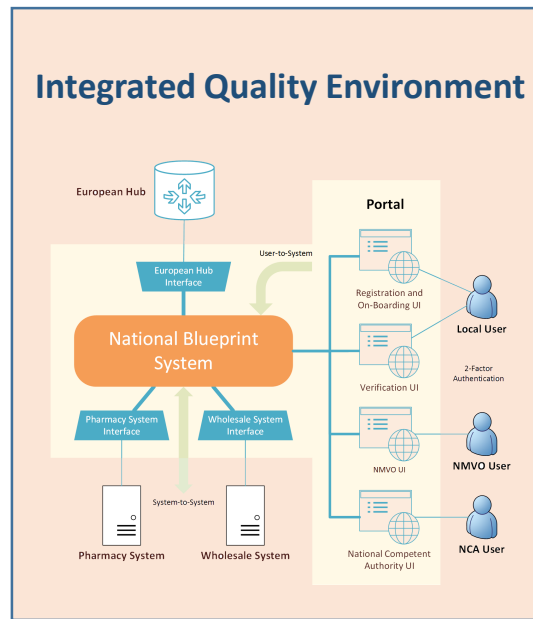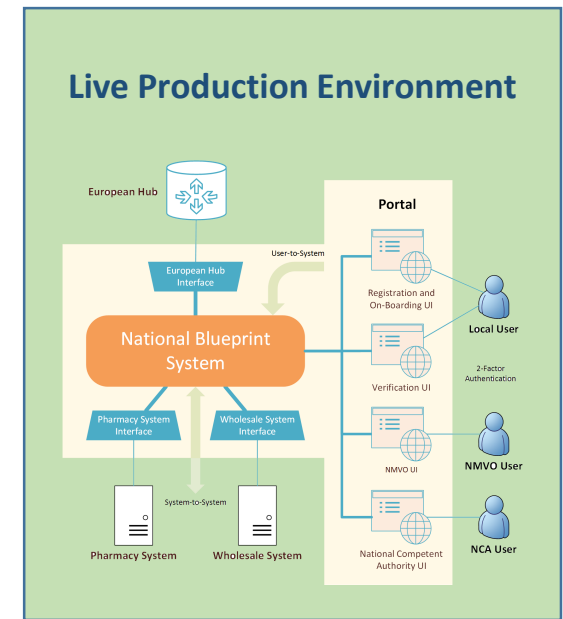
  - NCA Portal

Environments

ITE   IQE   PRD

Integrated Test Environment   Integrated Quality Environment   Live Production Environment
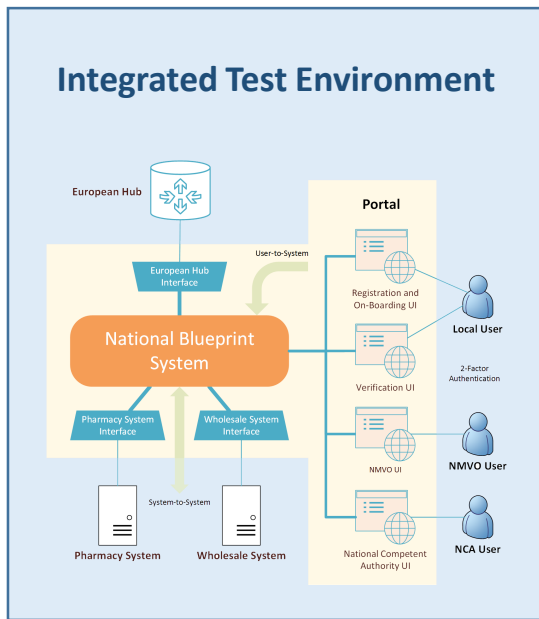
1X   2X   1X

Clear Route to Implementation

Set-up	Pilot	Ramp-up	FOC
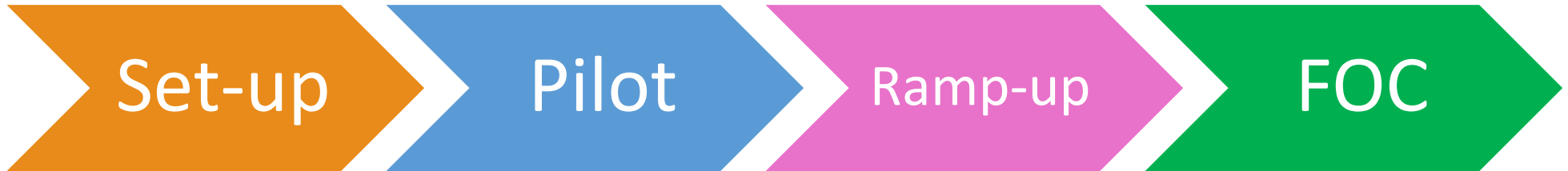
Project Management

Governance, Compliance, Contracts

NMVO Setup and Operation

System Set-up

Pharmacy / Wholesaler On-boarding

Manufacturers / Parallel Distributers On-boarding

Service Desk

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High Level Project Plan
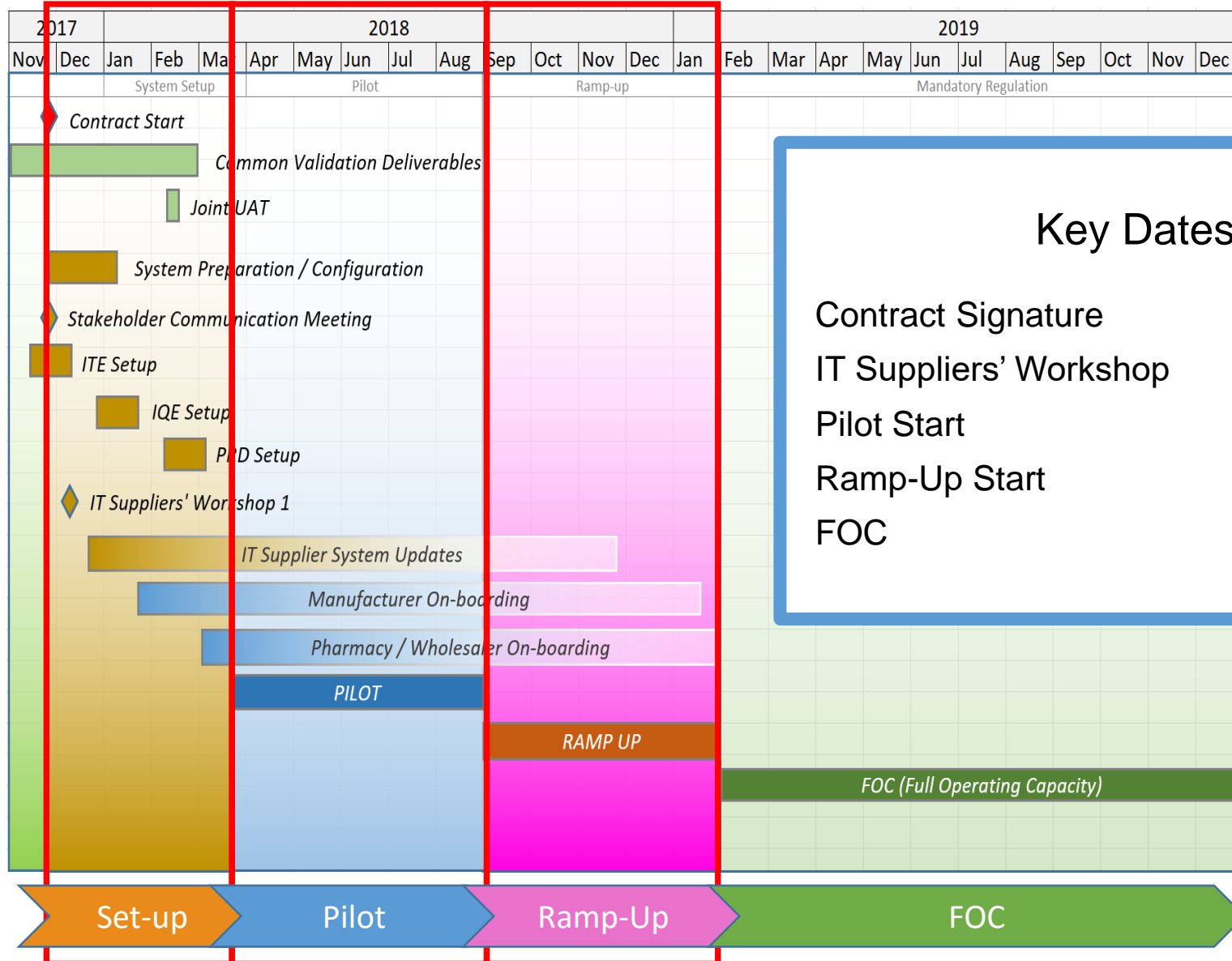
Community of Solidsoft Reply NMVOs

Lyfjaauðkenni	Iceland	🇮🇸	✓	ICEMVO LYFJAAUÐKENNI
IMVO	Ireland	🇮🇪	✓	IMVO IRISH MEDICINES VERIFICATION ORGANISATION
DMVO	Denmark	🇩🇰	✓	DMVO Dansk Medicin Verifikation Organisation
ZAPAZ	Slovenia	🇸🇮	✓	ZAPAZ
LtMVO	Lithuania	🇱🇹	✓	NVVO NACIONALINĖ VAISTŲ VERIFIKACIJOS ORGANIZACIJA
BgMVO	Bulgaria	🇧🇬	✓	Българска организация за верификация на лекарствата
NOOL	Czech Republic	🇨🇿	✓	Národní organizace pro ověřování pravosti léčiv
eVIS	Sweden	🇸🇪	✓	e-VIS e-Verifikation i Sverige
HOPAL	Croatia	🇭🇷	**STC**	
NMVO	TBA (within 2 weeks)		**STC**	
NMVO	TBA			
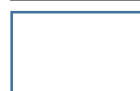
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Community Leveraging

The Community of Solidsoft Reply NMVOs has established 3 joint working groups:

- Project Management
- Technical
- Quality

- These working groups have agreed a common approach to the generation of Processes and Validation Deliverables

- EMVO have confirmed they will accept a common document set (leveraged documents)

- Future Solidsoft Reply NMVO customers are welcome to join the existing customer community and leverage work performed to date

Sharing experience for the benefit of all

Thank You

435	14	0	28
DAYS	HOURS	MINUTES	SECONDS