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SHARING EXPERTISE

B.BRAUN TRACK AND TRACE INITIATIVES

AFRICAN GS1 HEALTHCARE CONFERENCE

Collins Agoro

Addis Ababa, Ethiopia

Introduction

Name: Collins Agoro

Title: Project engineering manager ,
Serialization & Traceability

Company: B. Braun Melsungen AG, Germany

Role: Traceability law implementation EU, Asia, Middle East & Africa

AGENDA

1. Company Information
2. Motivation
3. Legal requirements
4. Case study (EU-FMD)
5. Conclusion

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COMPANY INFORMATION

B. BRAUN MELSUNGEN AG

We stand for these values.

Innovation

We create innovations by exchanging knowledge with the users of our products and let this knowledge flow into the development process.

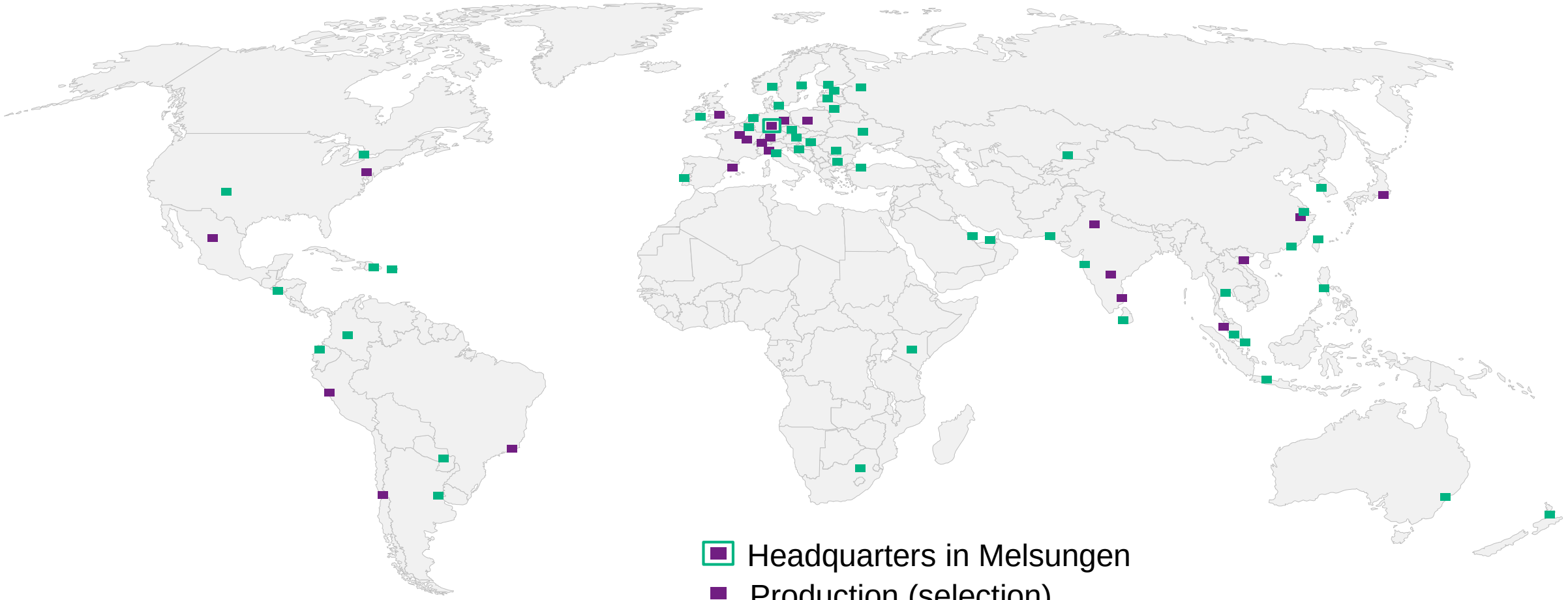
Efficiency

We use modern technologies and help hospitals with our innovative products and services to improve their process efficiency.

Sustainability

We live sustainability through our commitment to people, the environment and different cultures – in each region in which we are operating.

We have subsidiaries in 64 countries.



Our customers value the benefits provided by B. Braun

We produce more than 5,000 products and 120,000 articles.

B. BRAUN AT A GLANCE

SALES

6,788.9

€ MILLION

61,583

EMPLOYEES

INVESTMENTS

969.2 EUR million

239

CORPORATE SOCIAL RESPONSIBILITY PROJECTS

64

COUNTRIES

RESEARCH AND DEVELOPMENT ACTIVITIES

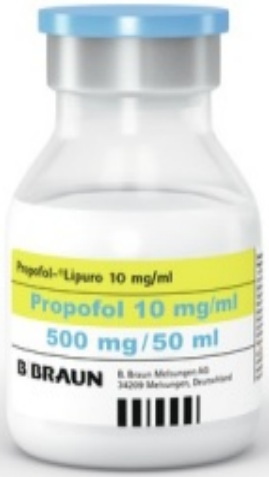
352.0 EUR million

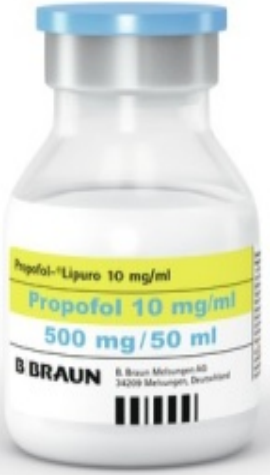
MOTIVATION

WHY IS TRACK & TRACE NECESSARY?

One of these medicines is fake…..

Can you tell which?





UNPREDICTABILITY

Are counterfeited drugs produced under GMP conditions?

→ NO

RISK

Trading with counterfeited drugs: a profitable business

UNVERIFIABLE

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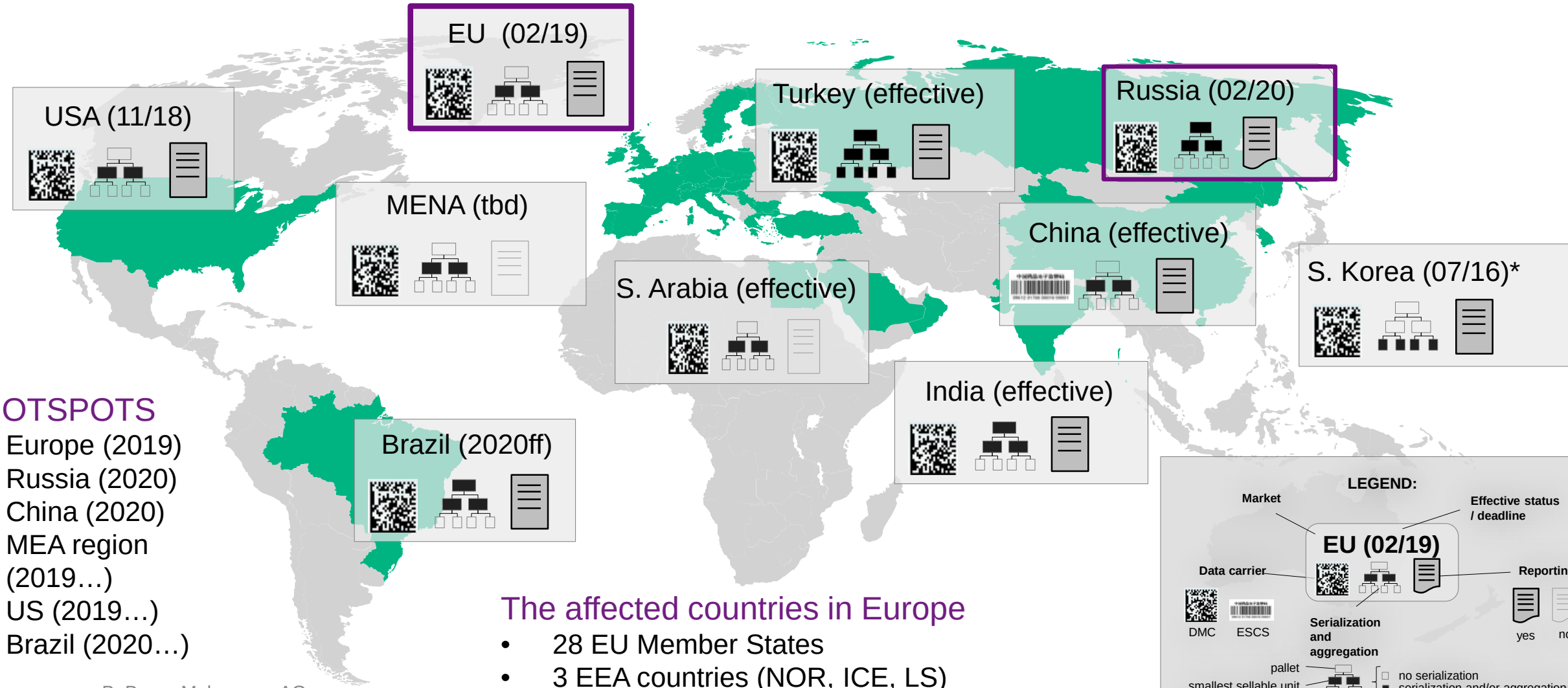
LEGAL REQUIREMENTS

DEVELOPMENT OF TRACK & TRACE LEGISLATIONS

Overview of main T&T legislations and deadlines affecting B. Braun



HOTSPOTS

- Europe (2019)
- Russia (2020)
- China (2020)
- MEA region (2019…)
- US (2019…)
- Brazil (2020…)

The affected countries in Europe

- 28 EU Member States
- 3 EEA countries (NOR, ICE, LS)
- Italy & Greece have 3 more years to implement

T&T at B. Braun

3 DIVISIONS

Hospital Care
Homecare
Dialysis

DEPARTMENTS

ALL

LINES

> 45

PRODUCTION SITES

> 13

EU-COUNTRIES INVOLVED

ALL

ARTICLES AFFECTED IN EUROPE

Prescription / Black list

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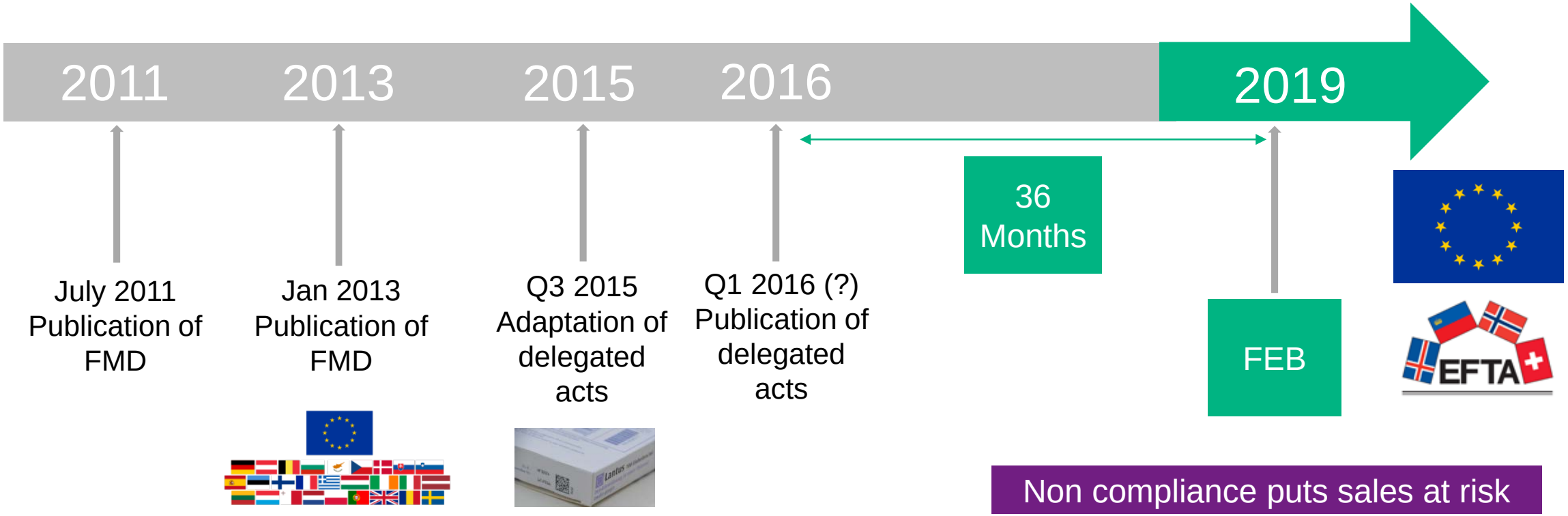
CASE STUDY

THE EUROPEAN FALSIFIED MEDICINES DIRECTIVE (EU 161/2016)

Overview of EU-Falsified medicine directive

Protecting patients from falsified medicines in the legal supply chain – FMD 2011/62/EU



T&T EU FMD – the „End-to-end“ verification system

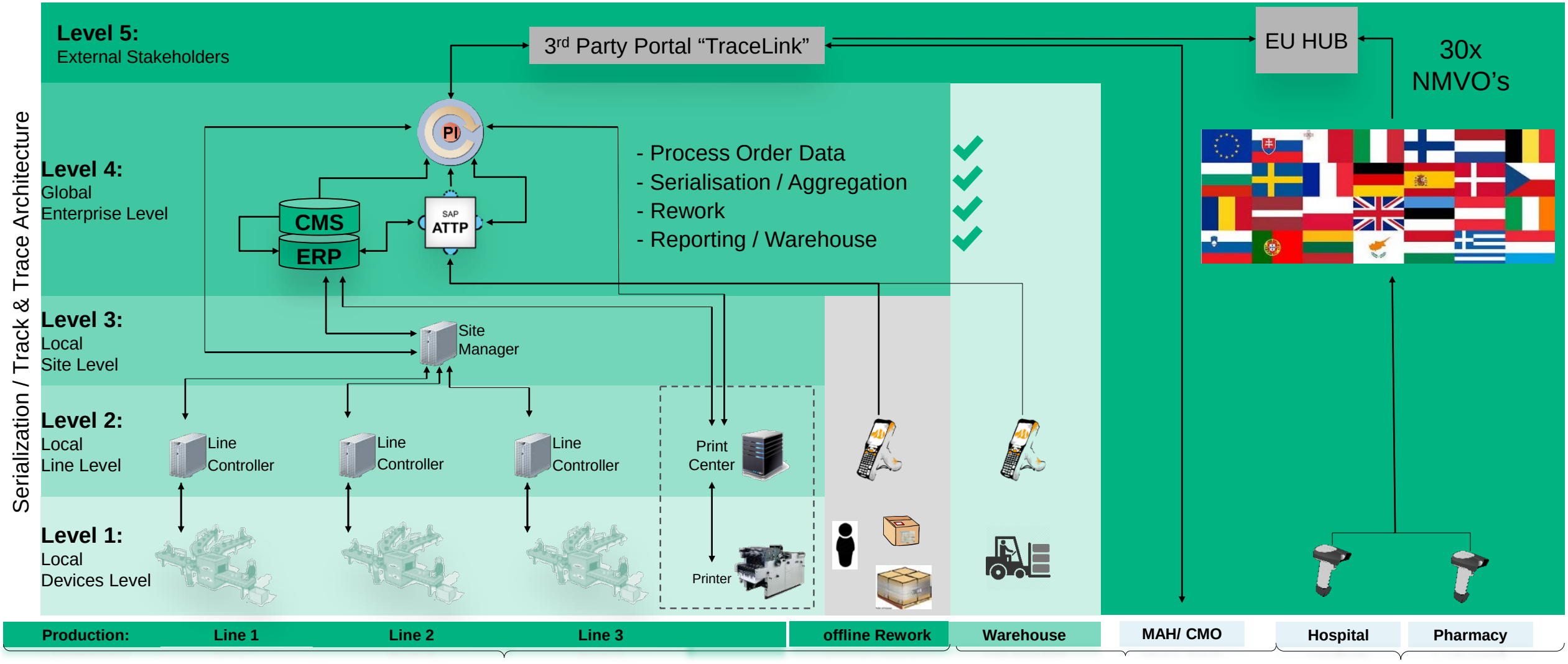
SAFETY FEATURES

1. Serialization of packs with (UI) unique identifier
2. Anti-tampering device (ATD)

REPORTING

3. Upload and maintain status of (UI) in the EU HUB

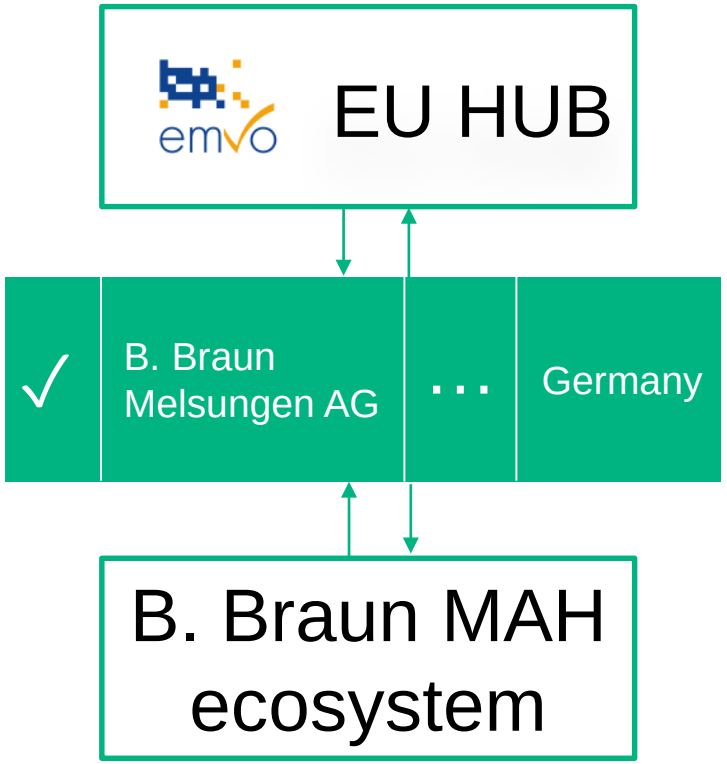
B. Braun T&T architectural strategy



EMVO: EU-HUB Onboarding

Administrative onboarding

Technical onboarding

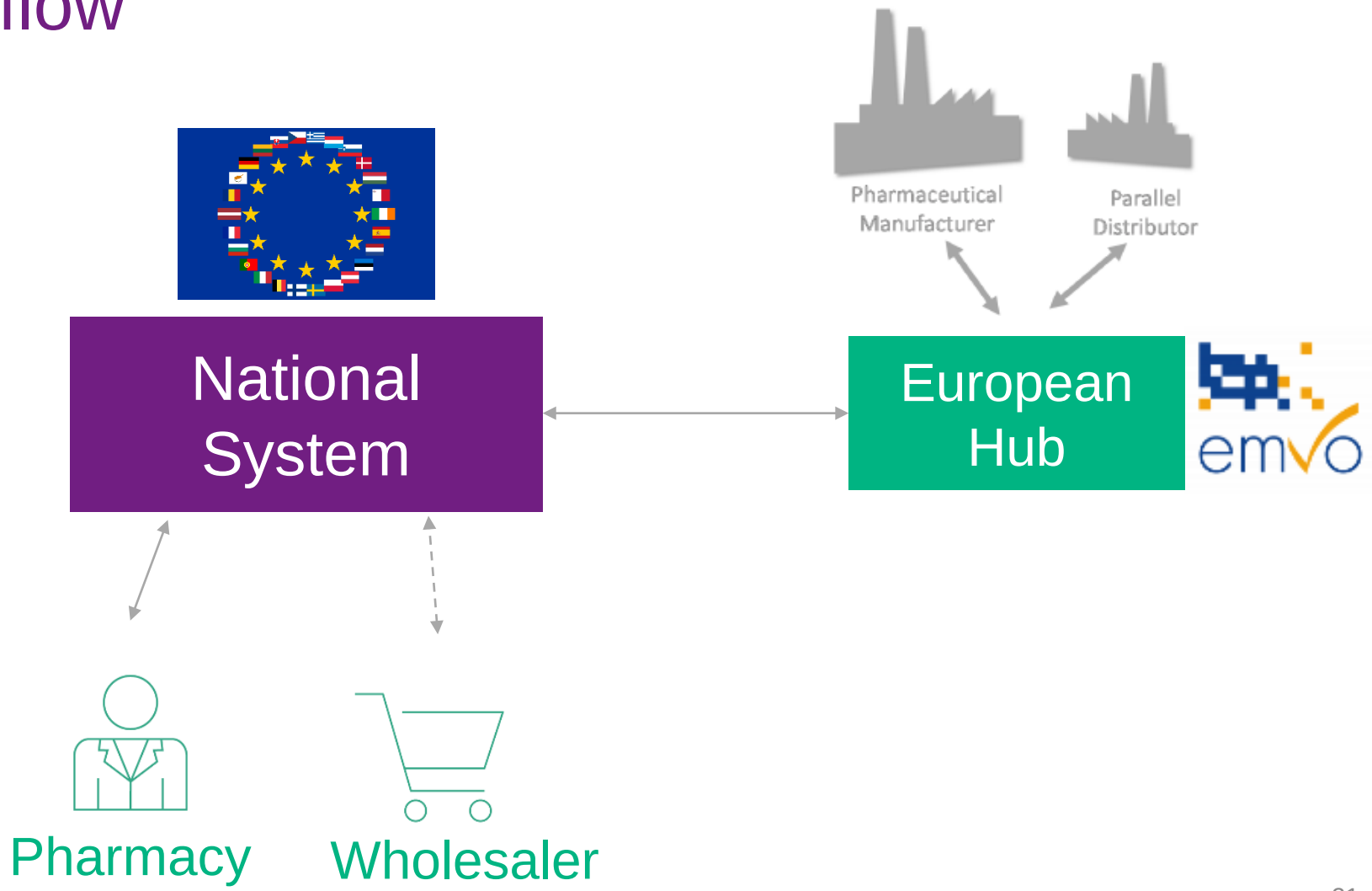


Main MAH (Onboarding Partner)

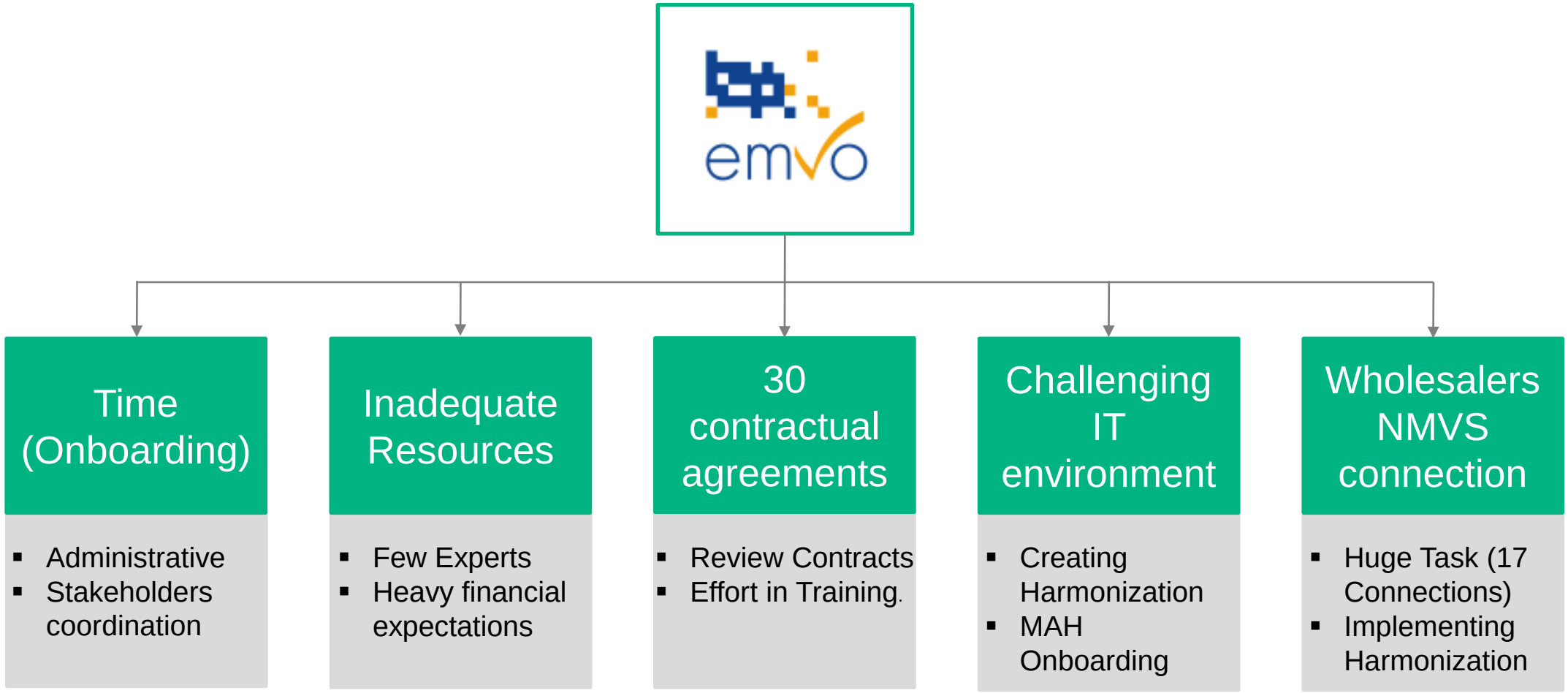
National medicine verification organisation

Onboarding workflow

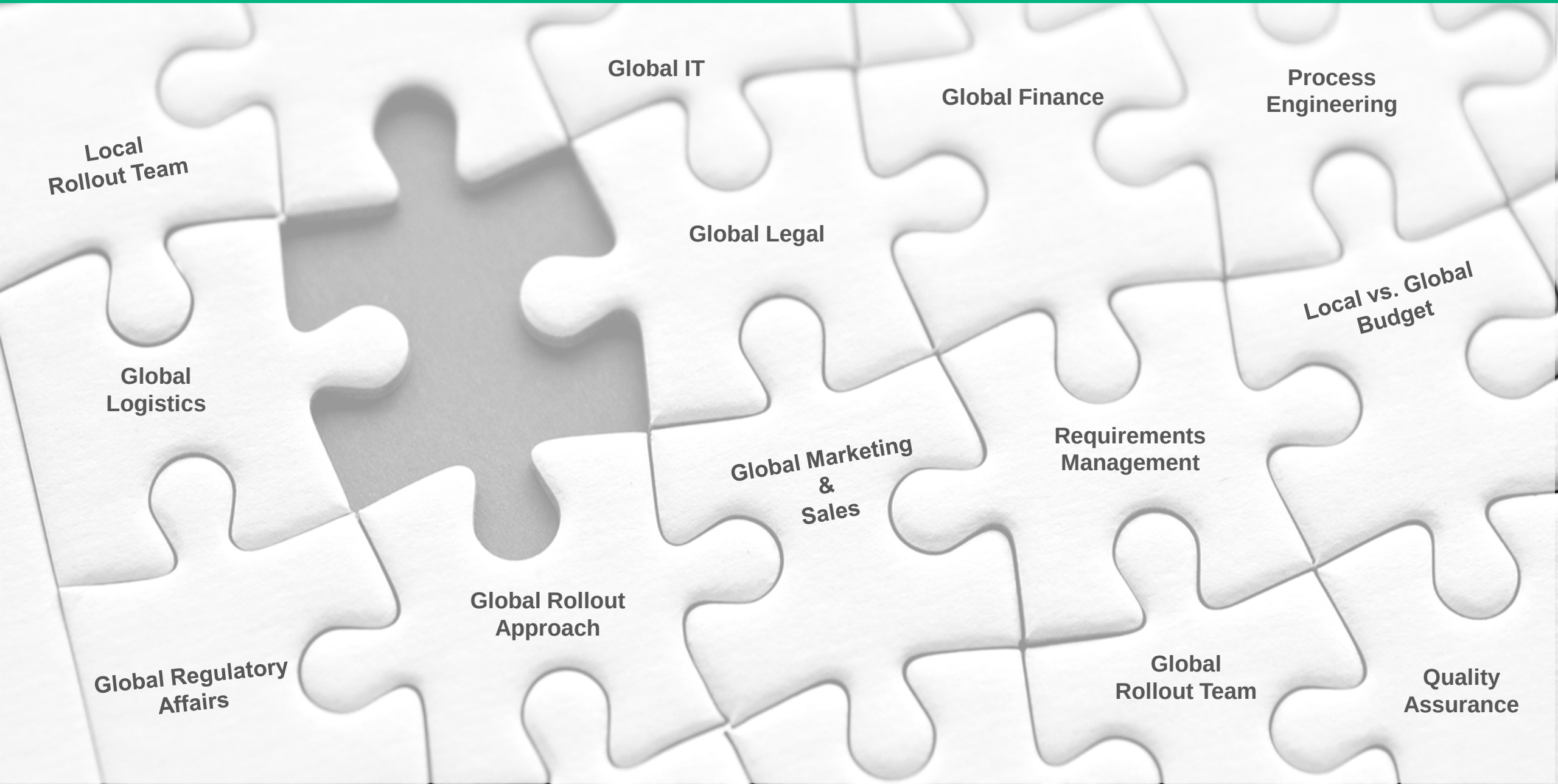
- Contract Released
- Legal Review
- Contract Signed
- One time Fee-Paid
- Technical Connection



Challenges of EU-FMD implementation



Conclusion-Interconnectivity is the key



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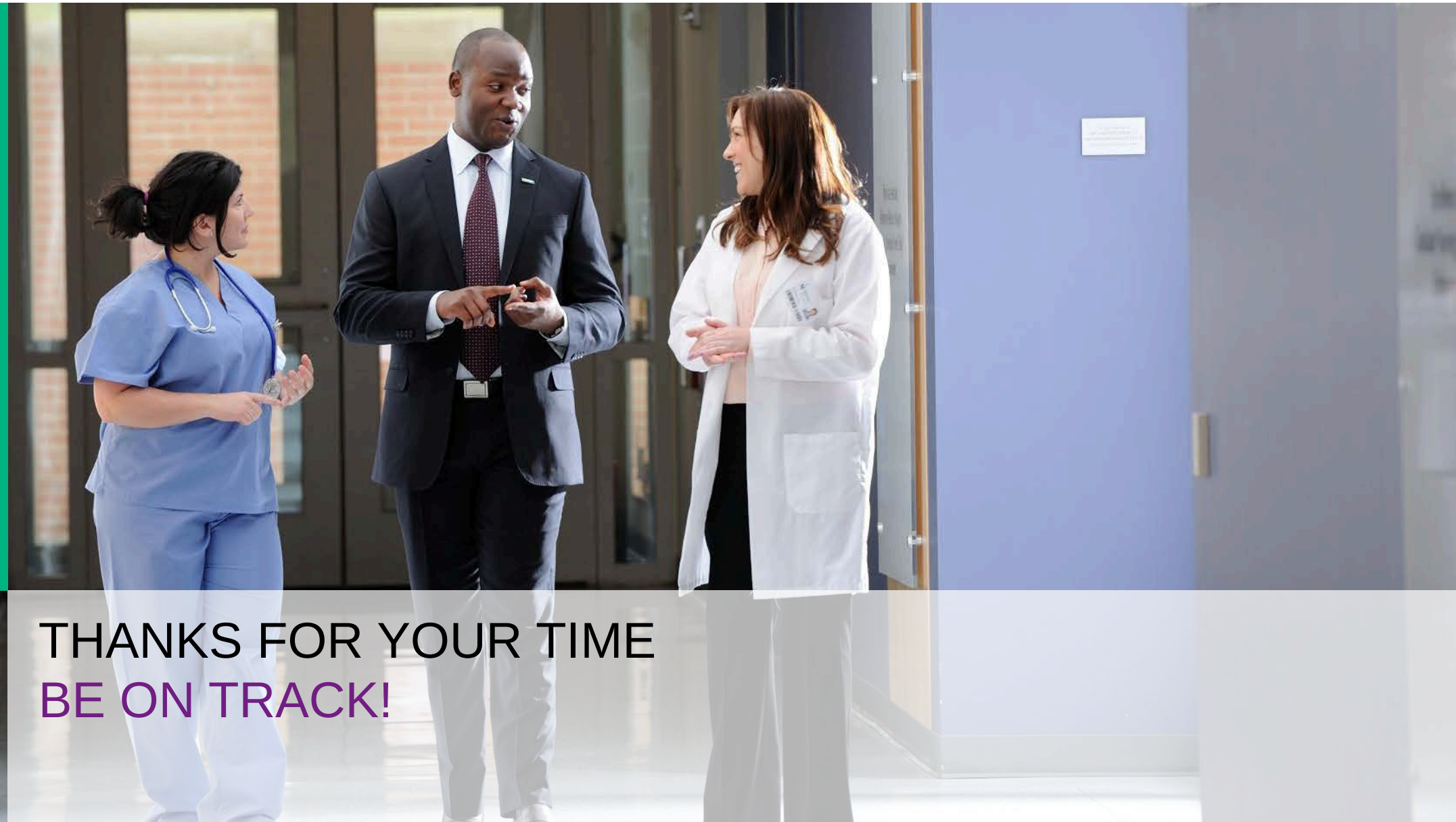

THANKS FOR YOUR TIME
BE ON TRACK!