

Mass Serialization and Traceability Implementation in the Pharma Industry



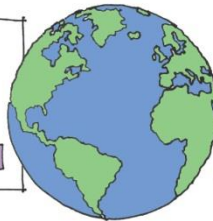
Keeping the Supply Chain Safe for Patients

DOING NOW WHAT
PATIENTS NEED NEXT



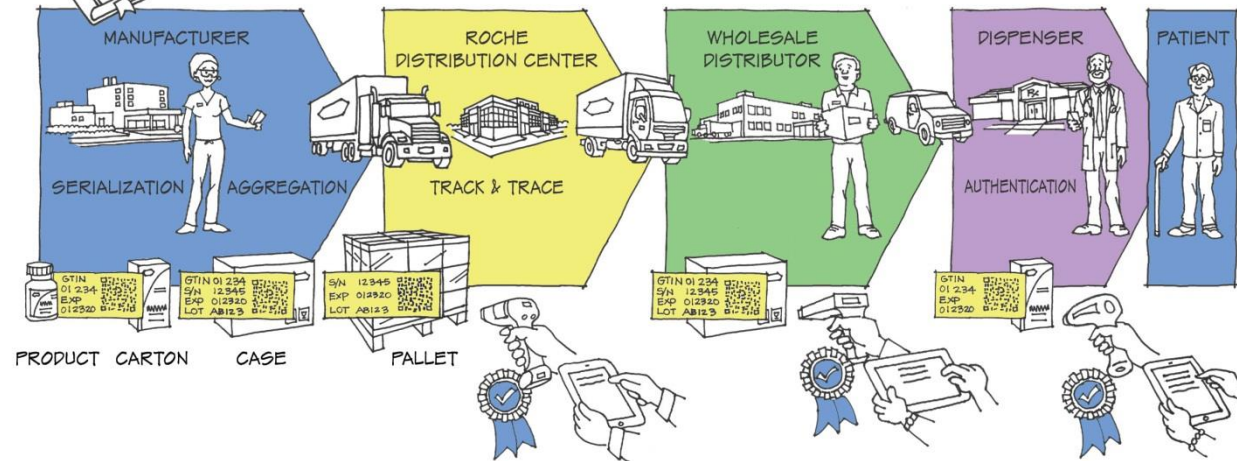
PATIENTS' RIGHTS:
• RIGHT PRODUCT
• RIGHT DOSE
• RIGHT TIME

• **Right Channel**



A Safe Supply Chain

1. ENHANCES PATIENT SAFETY
2. PROTECTS CORPORATE BRAND
3. IMPROVES E2E SUPPLY CHAIN VISIBILITY
4. ENHANCES RECALL EFFECTIVENESS
5. ADDITIONAL FUTURE BENEFITS



Mathieu Aman, Global Program Lead
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What drives the industry towards more “*traceability*”

Strategic thinking & a long-term vision required

Roche's roadmap

A few Take-home messages

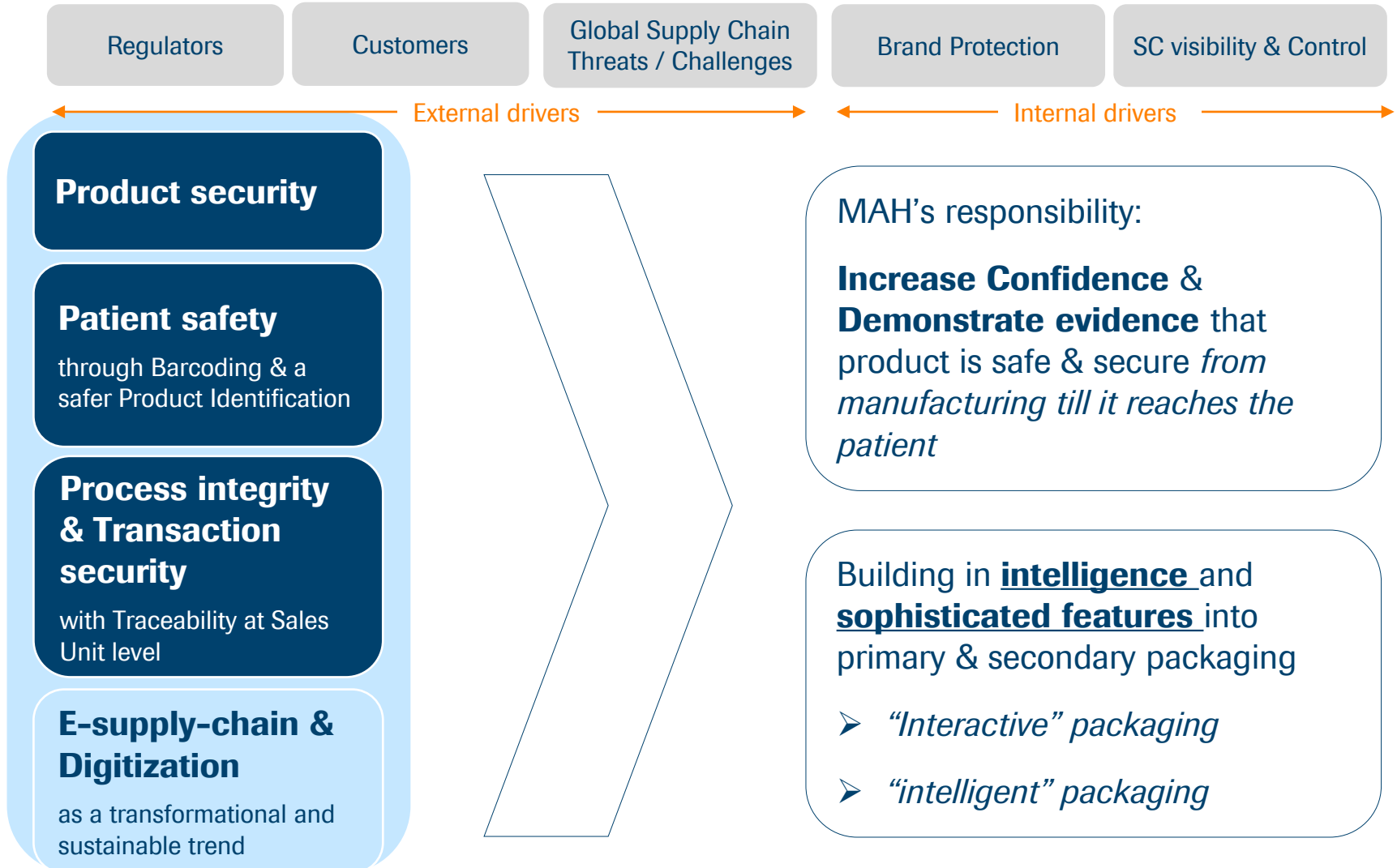
An ongoing focus towards more control & security in today's global Pharma Supply Chains

The Importance of Packaging is Increasing in Pharma



An ongoing focus towards more control & security in today's global Pharma Supply Chains

The Importance of Packaging is Increasing in Pharma



The outcome: the sales units gets unique and tamper-proof

A unique number to identify each single tamper-proof sales pack



Roche is global GS1 member

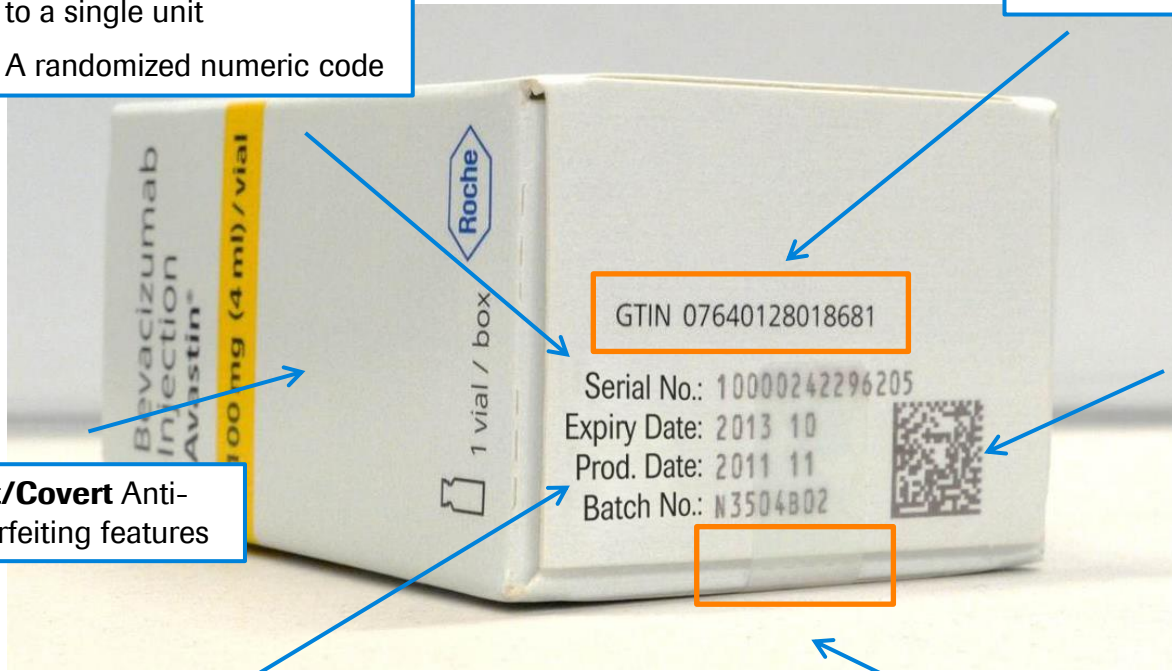
Level 1: 2D-CODING and SERIALIZATION

Serial Number new

- A unique number assigned to a single unit
- A randomized numeric code

Material Number new

GTIN / NTIN



Overt/Covert Anti-Counterfeiting features

Data Carrier new

Machine readable

Human Readable Information

Tamper Evidence

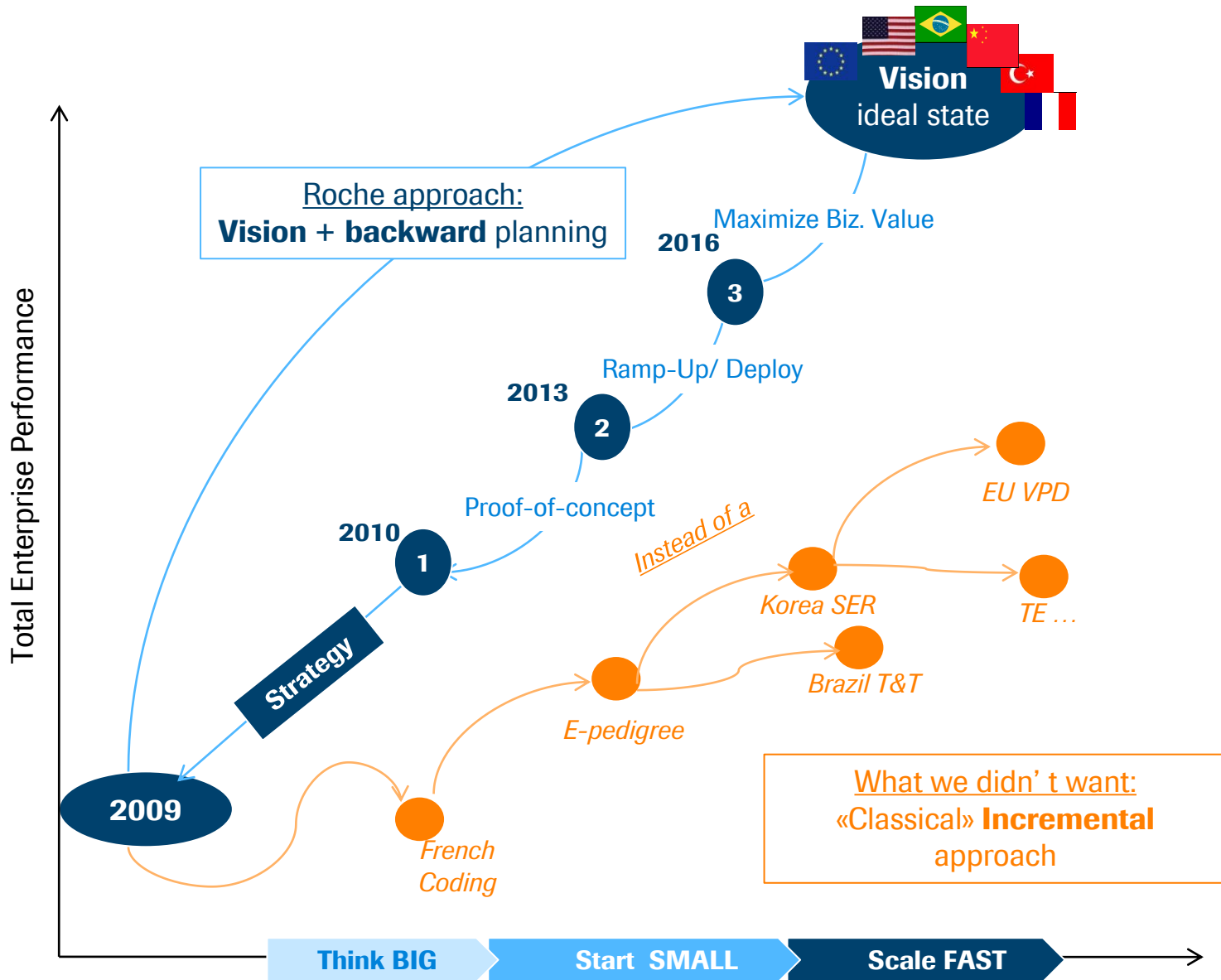
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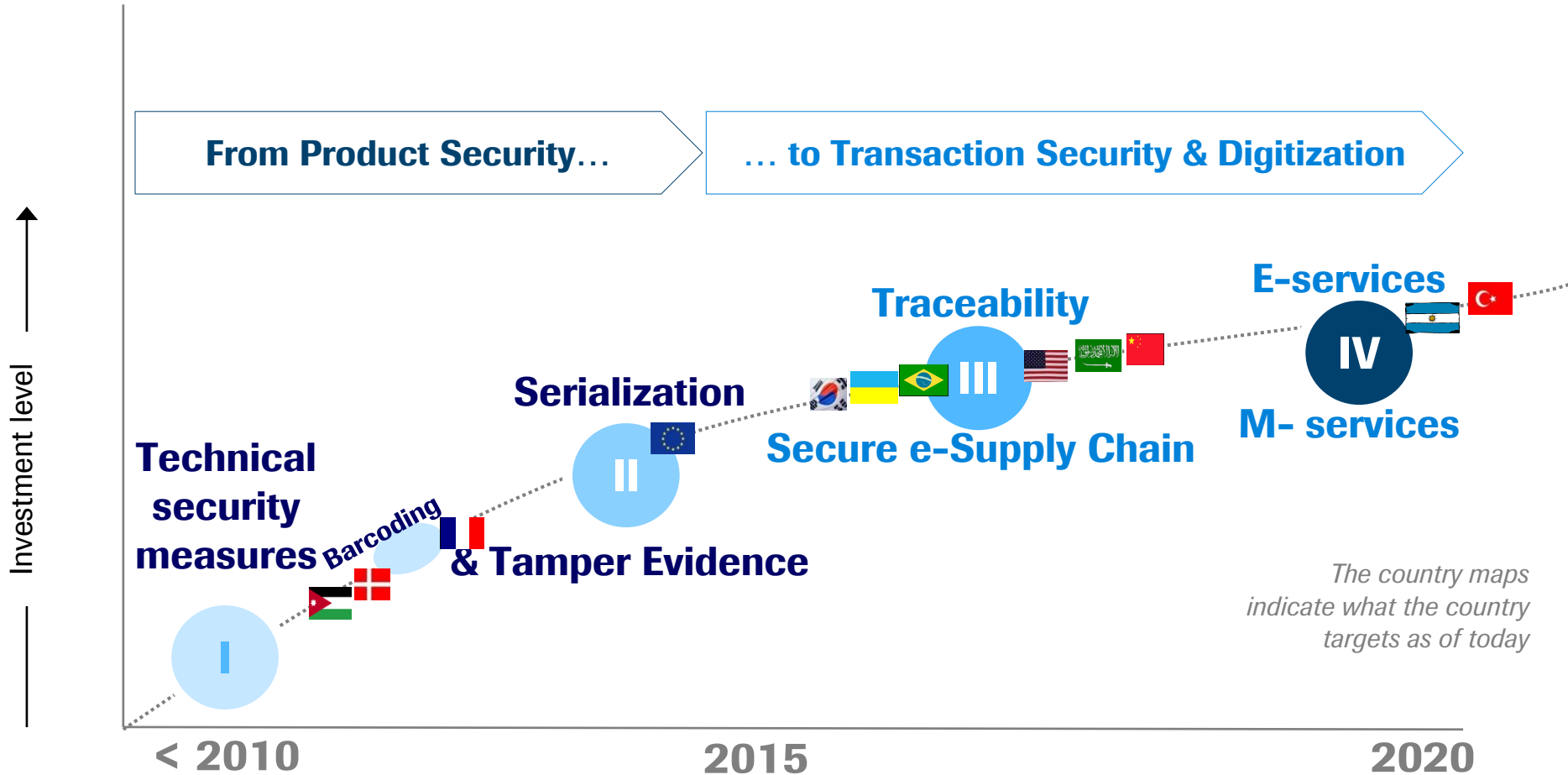
Strategic thinking & a long-term vision



Where do we see this journey going...



Do not focus on one specific requirement; Instead, put in perspective



Strategic thinking & a long-term vision

What our approach is from beginning

- A **cross functional global effort**
 - *ensure standardization, interoperability and integration*
 - *Strong global drive & close cooperation with local implementation teams / SME's*
 - *This is not only a technical project*

- Develop and implement an **adaptable/scalable** technical standard solution
 - *Co-develop with vendor*
 - *A constant mix of prototyping, conceptual design and operational implementation*

- Work **together** with other stakeholders
 - *authorities, standard bodies, associations, peers, trading partners, vendors...*

Accept the challenge as an **opportunity**

Success through a **collaborative approach**

What drives the industry towards more traceability

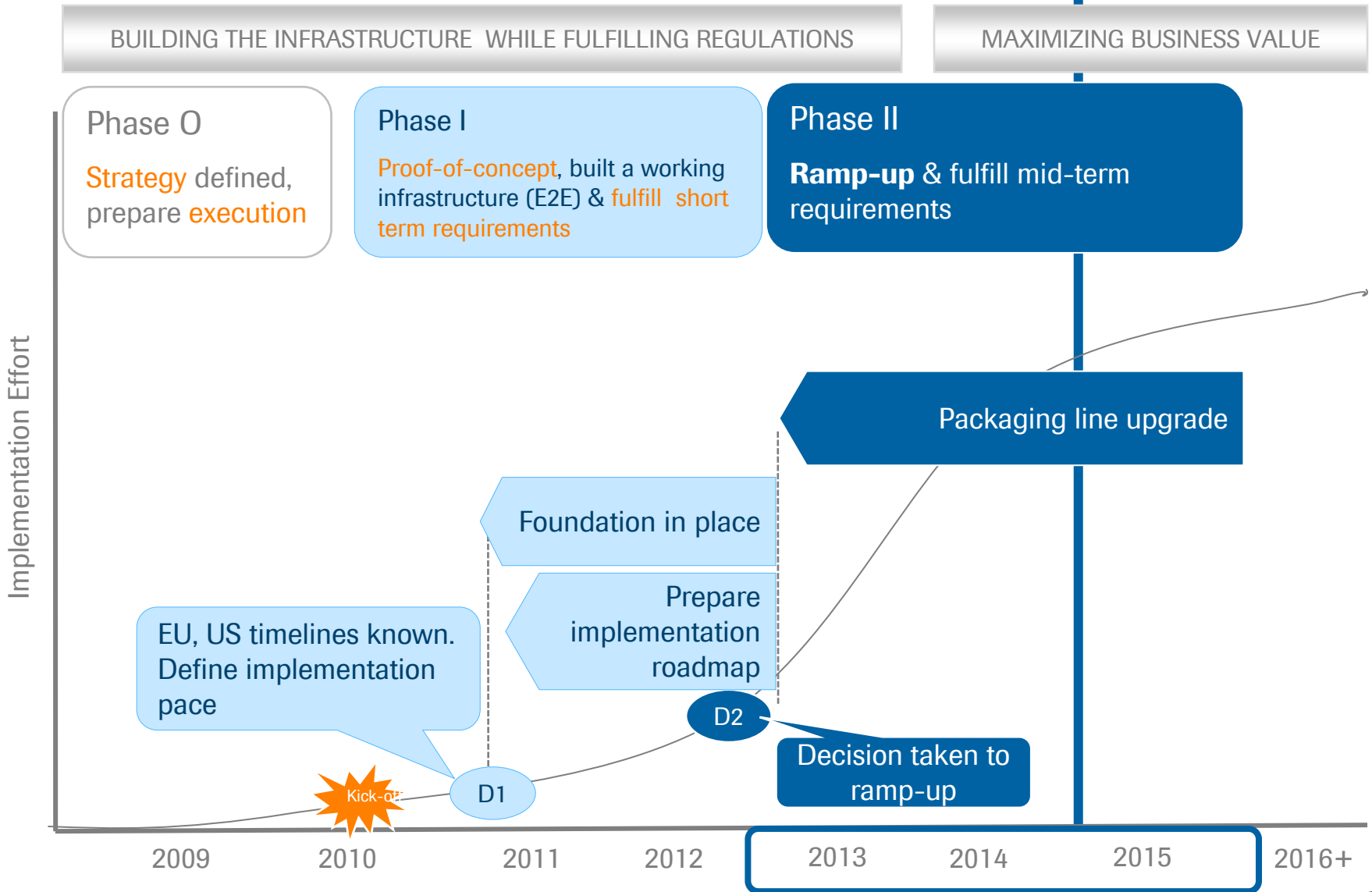
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A long term effort

We are here

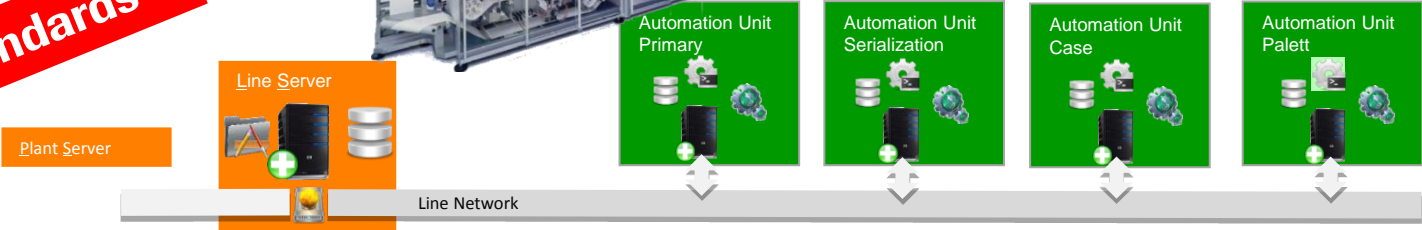


As a consequence, we have to upgrade all packaging lines and build a new IT-infrastructure *while ensuring continuous supply*

The “PHYSICAL WORLD”



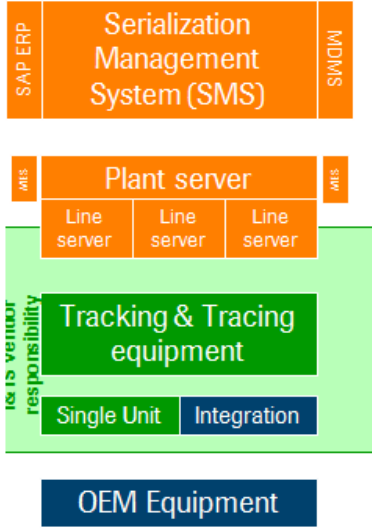
International standards !



The “DATA WORLD”

Interoperability !

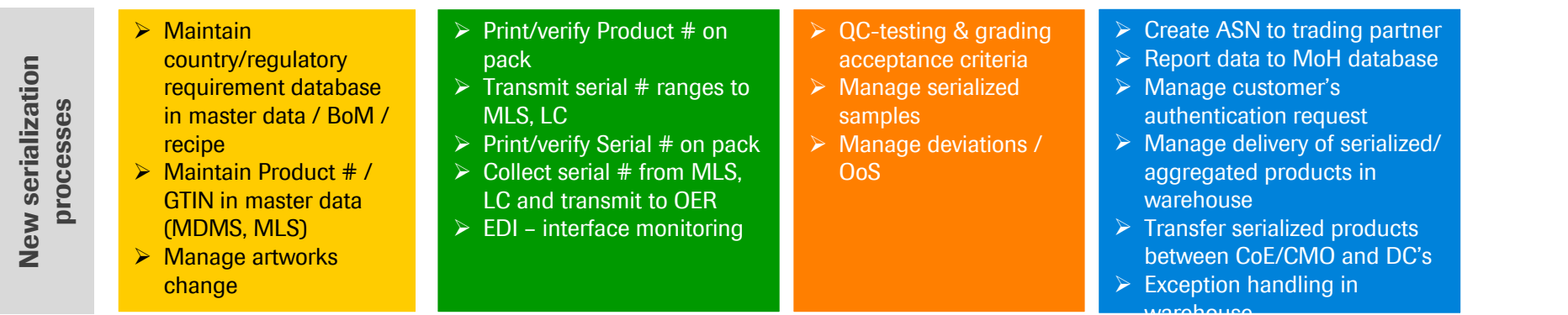
- Coordination of various vendors requiring strong and robust planning under consideration of capacity bottleneck at OEM vendors
- Regulatory developments with impact on program timelines
- Roche supply constraints



- Consider line/site switches
- Build bridging stocks in alignment between supply planning-site planning team
- Consider workarounds e.g. offline printing

It is not only about line upgrades & IT tools !

People & Functions are impacted, requiring a strong change management



Change management
the REAL challenge of the implementation of mass serialization

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Roche's roadmap

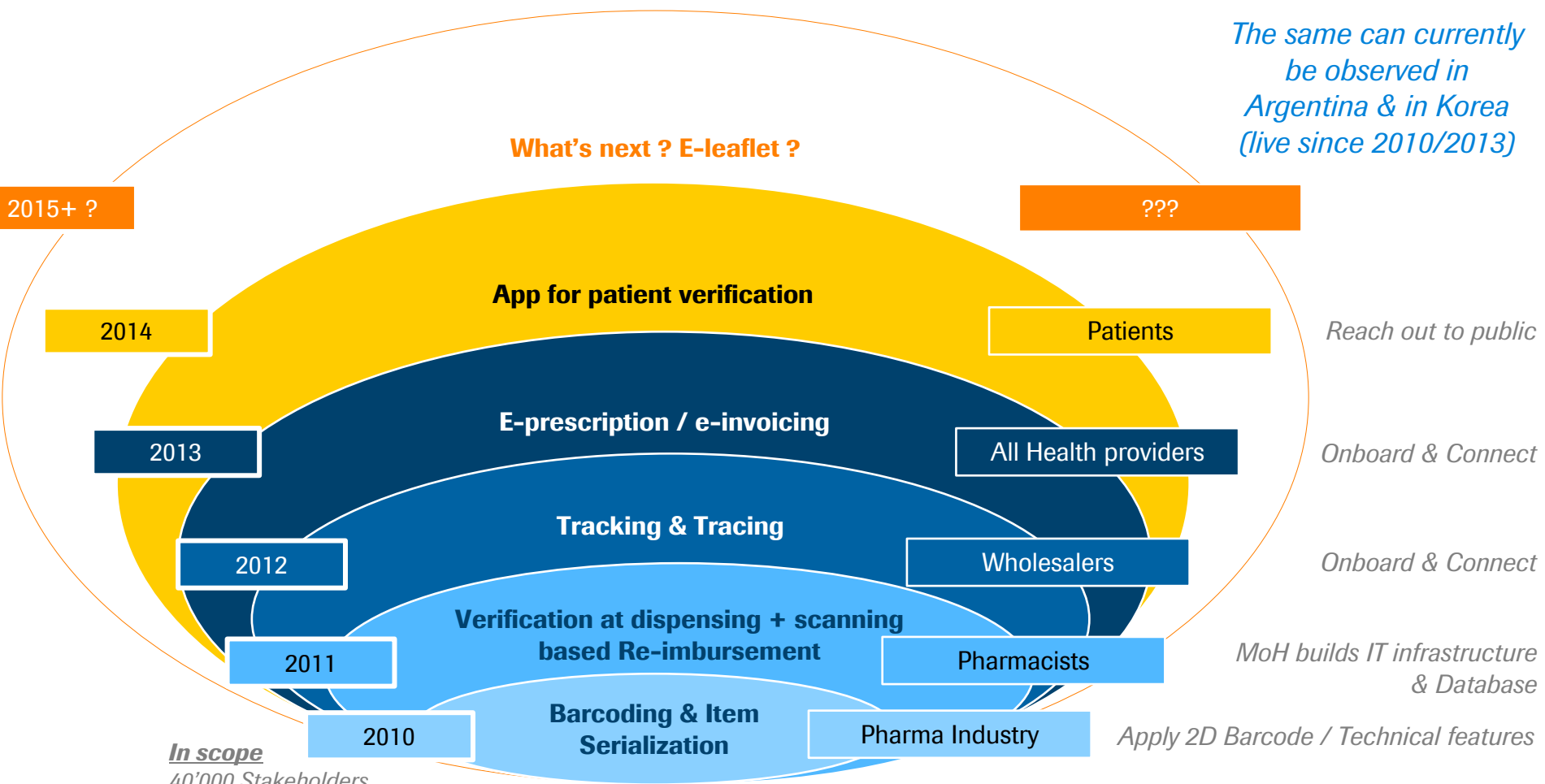
A few Take-home messages

Onboarding of HC actors by continuous scope extension



See the example of Turkey's implementation roadmap

The same can currently be observed in Argentina & in Korea (live since 2010/2013)



In scope

40'000 Stakeholders

- Hospitals
- Health Centers
- Family Physician Centers
- Pharmacies and Pharmacy Warehouses
- Manufacturers
- Importers
- Reimbursement Institutions

Figures & Facts today

Number of drug types in ITS: 18 900
 Number of drug units in ITS: 7 000 000 000
 Number of daily operations in ITS: 45 000 000
 Number of operations per second in ITS: 520
 Response time of system: < 1 sec
ROI in ONE YEAR!

Applying a 2D Barcode on the packs is just the beginning of the journey... and it's not only about Traceability

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Doing now what patients need next