The essence of EU MDR

and its key consequences

Gert Bos

Short overview

Objectives in legislative reform

- **Consistently high level of health & safety protection for EU citizens**
- **Free and fair trade of medical devices throughout the EU**
- **Adaption to significant technological & scientific progress in the sector over last 2 decades**

Objectives in legislative reform – reachable?

- **Consistently high level of health & safety protection for EU citizens**

  Sufficient clinical data; biocomp/tox, transparency/labeling

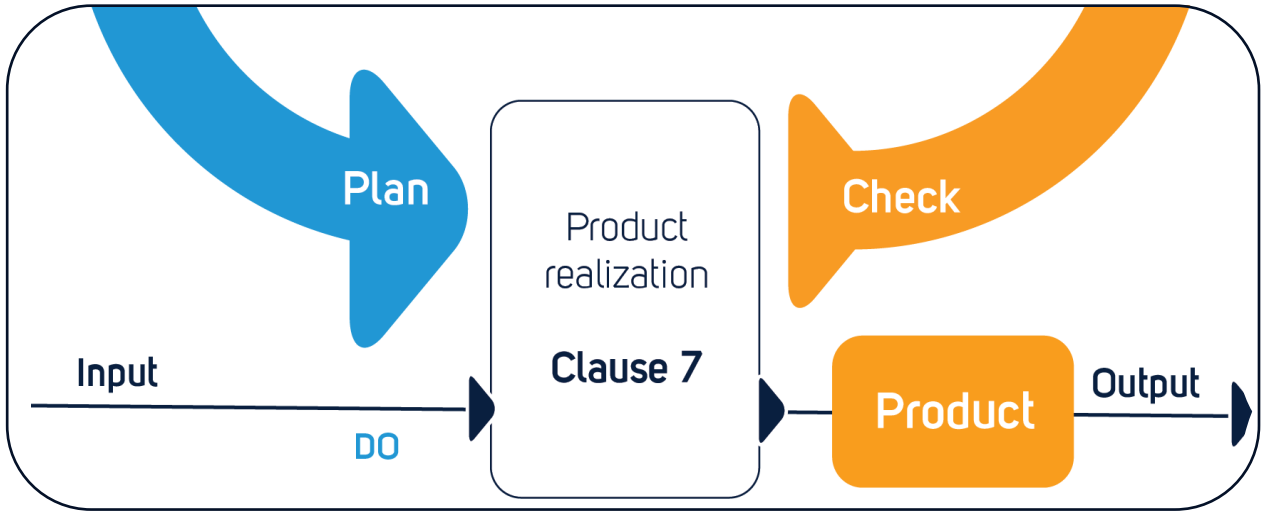
- **Free and fair trade of medical devices throughout the EU**

  Economic Operator enhancement (incl. sponsor); liability

- **Adaption to significant technological & scientific progress in the sector over last 2 decades**

  State of the art; real world evidence; common specifications

All stakeholder involvement – safety proven to public

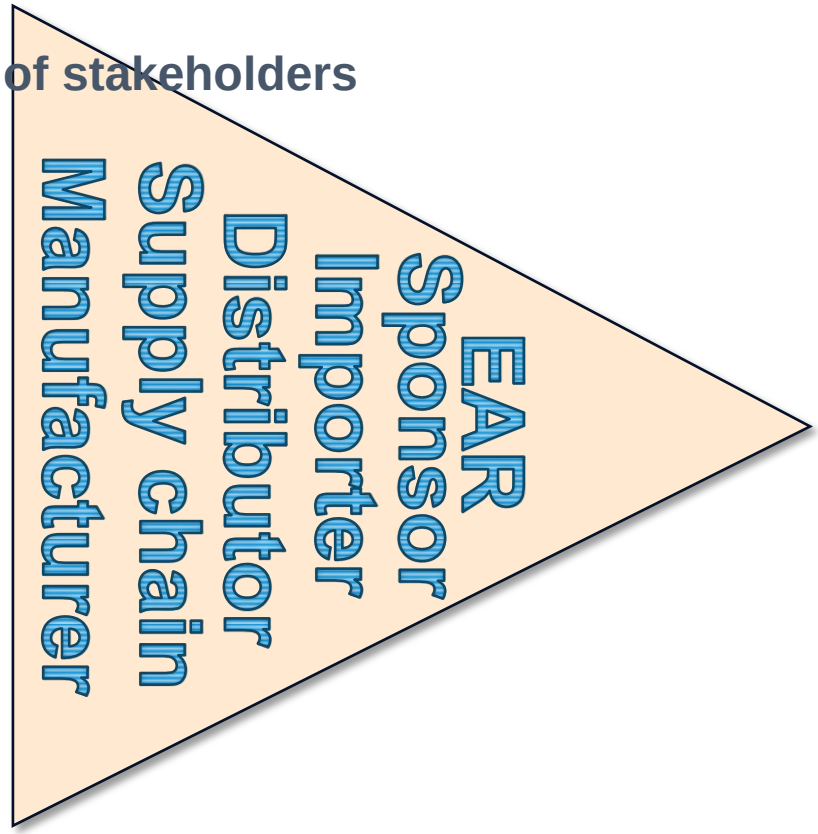


EUDAMED

2 years delay….

Rights and responsibilities of stakeholders

LiABiLiTy



Traceability

Continuous improvement moving into regulatory affairs

QMS & pdca

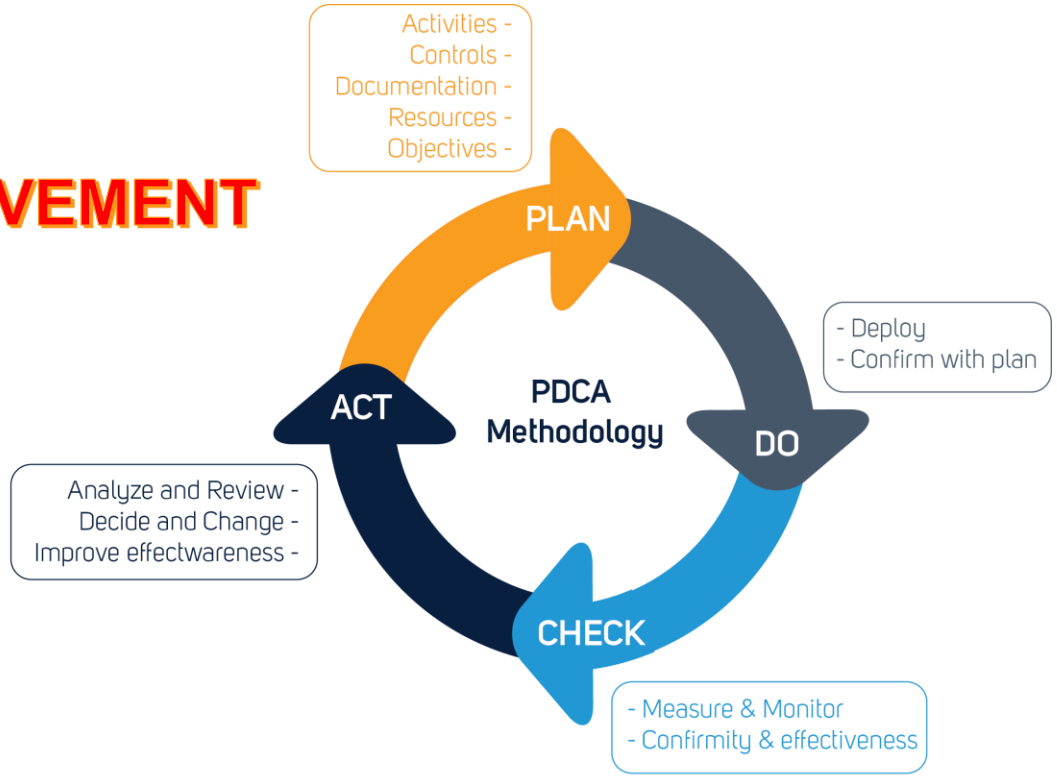
Trend analysis

Hazardous substances
Phthalates
CMR

COMMON SPECIFICATIONS

CONTINOUS IMPROVEMENT

PMS
PMCF



.....the practical approach

Compliance-driven oversight – rapid drift of expectations

COMMON SPECIFICATIONS

EU DAMED

Reclassification

II
V

NBs

Suspension
& recalls

Empowerment

LiABiLiTy

MDCG

Scrutiny

Supply chain
Manufacturer

EAR

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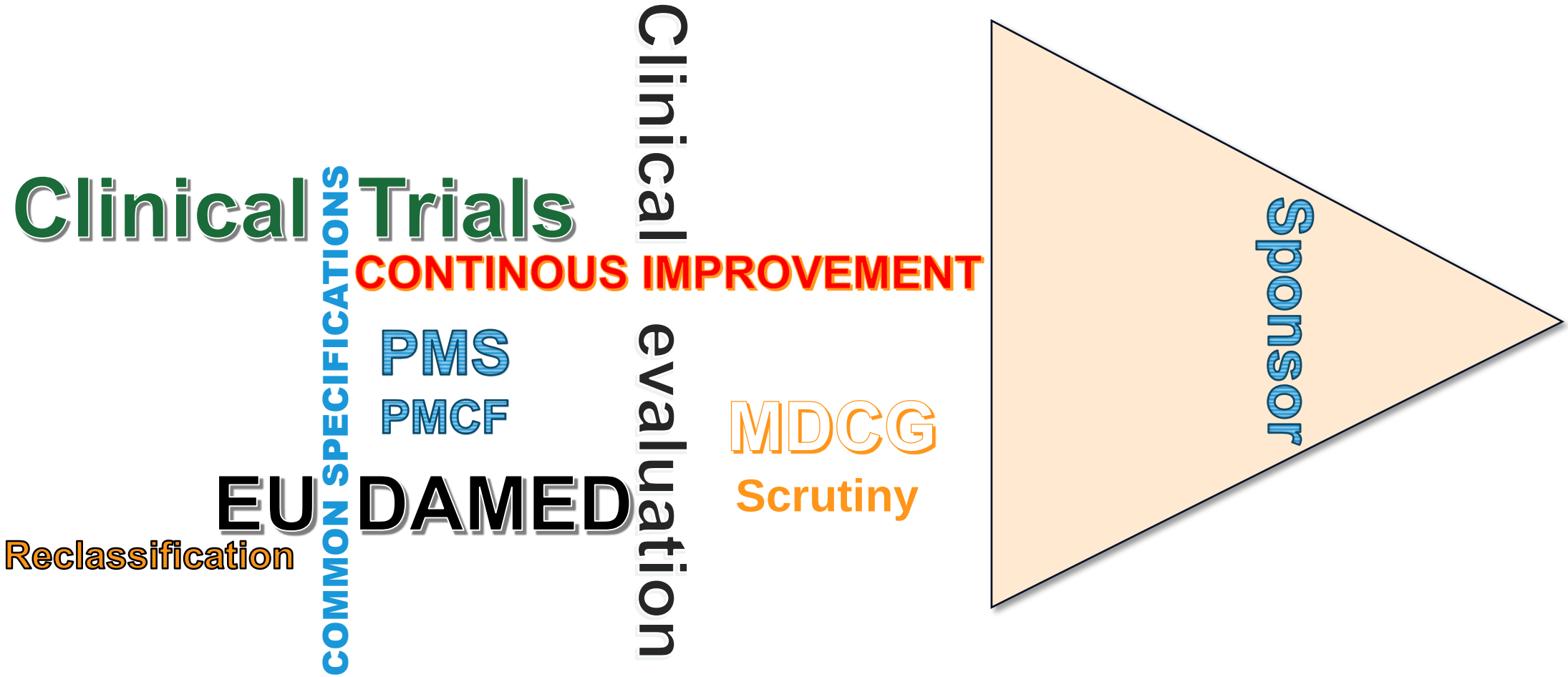
The essence in Clinical Data – what is sufficient?



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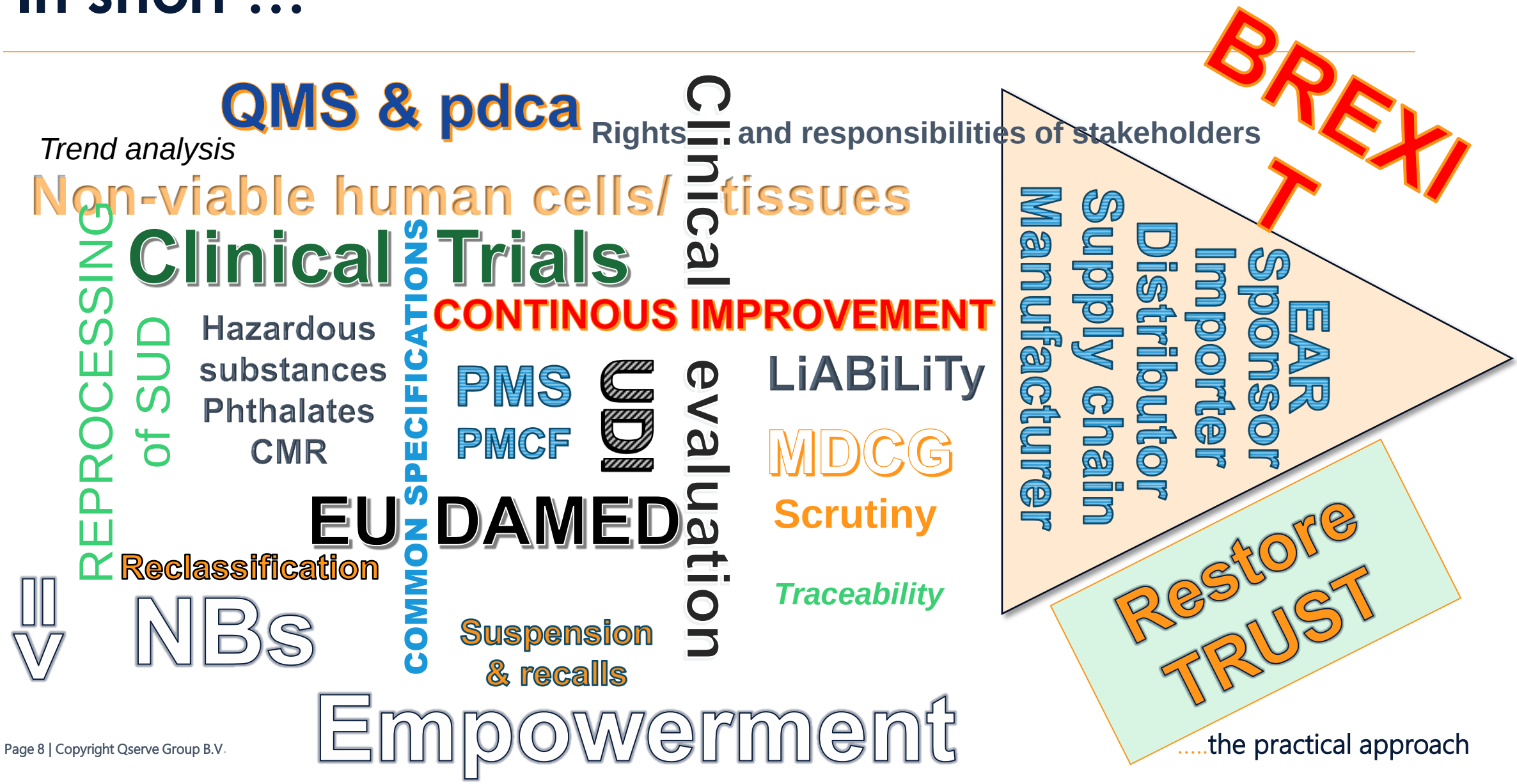
In short …


QMS & pdca
Trend analysis
Rights and responsibilities of stakeholders
Clinical evaluation
Non-viable human cells/ tissues
REPROCESSING of SUD
Clinical Trials
COMMON SPECIFICATIONS
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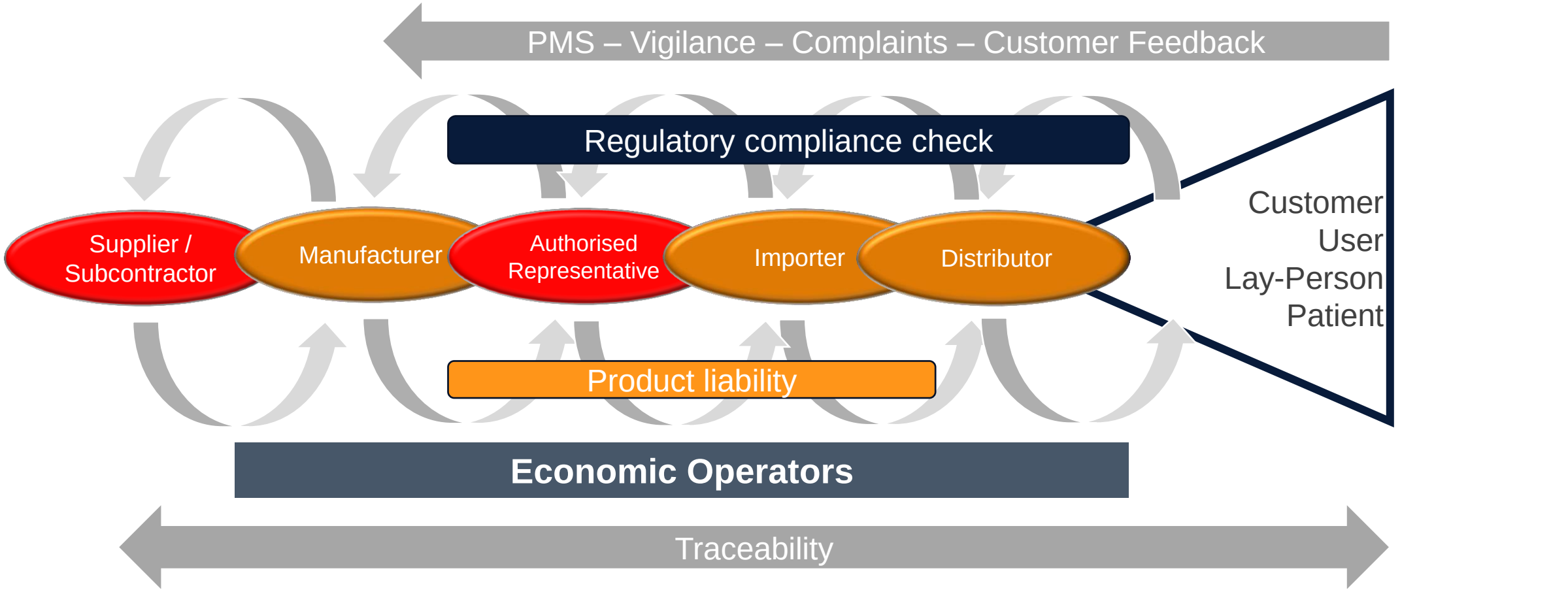
BREXIT
EAR
Sponsor
Importer
Distributor
Supply chain
Manufacturer
Restore TRUST

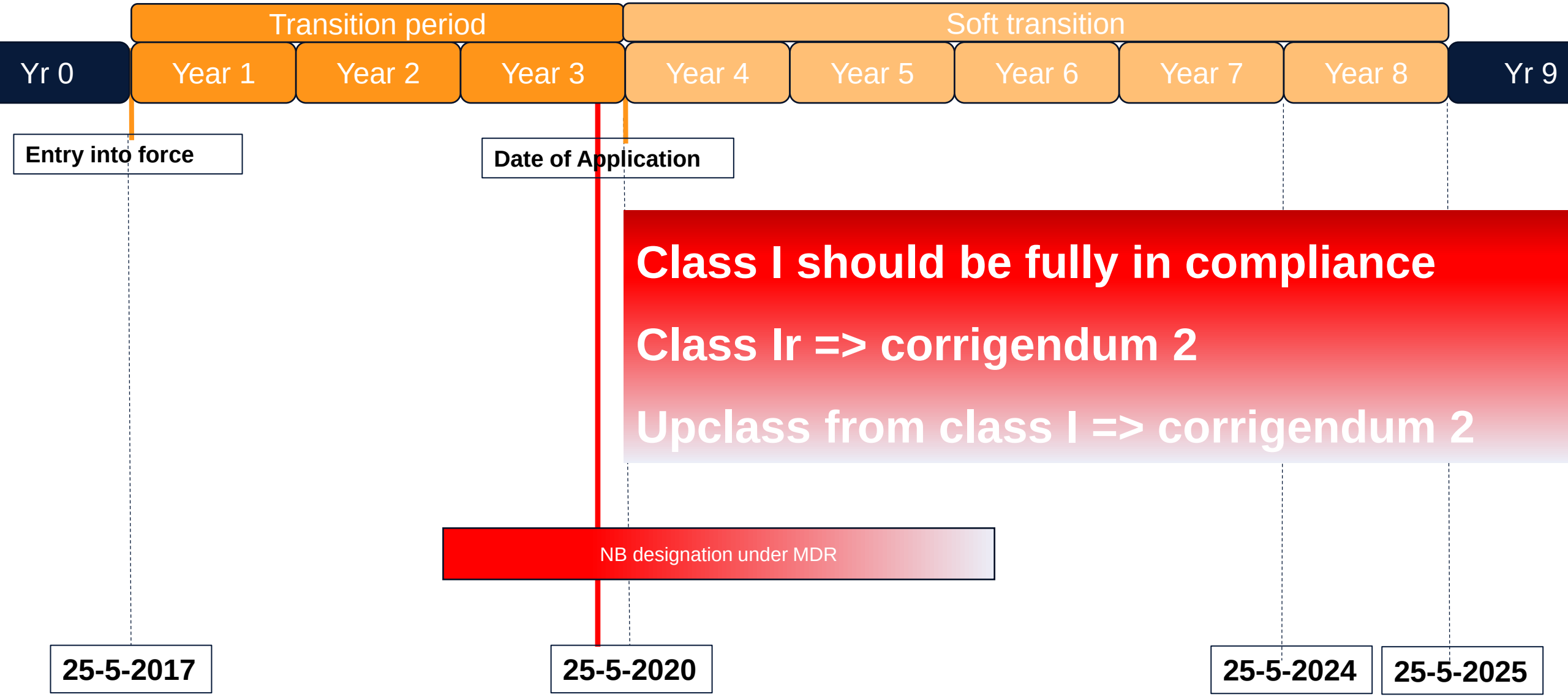
Addressing the whole Supply Chain & its Economic Operators



OBL/OEM

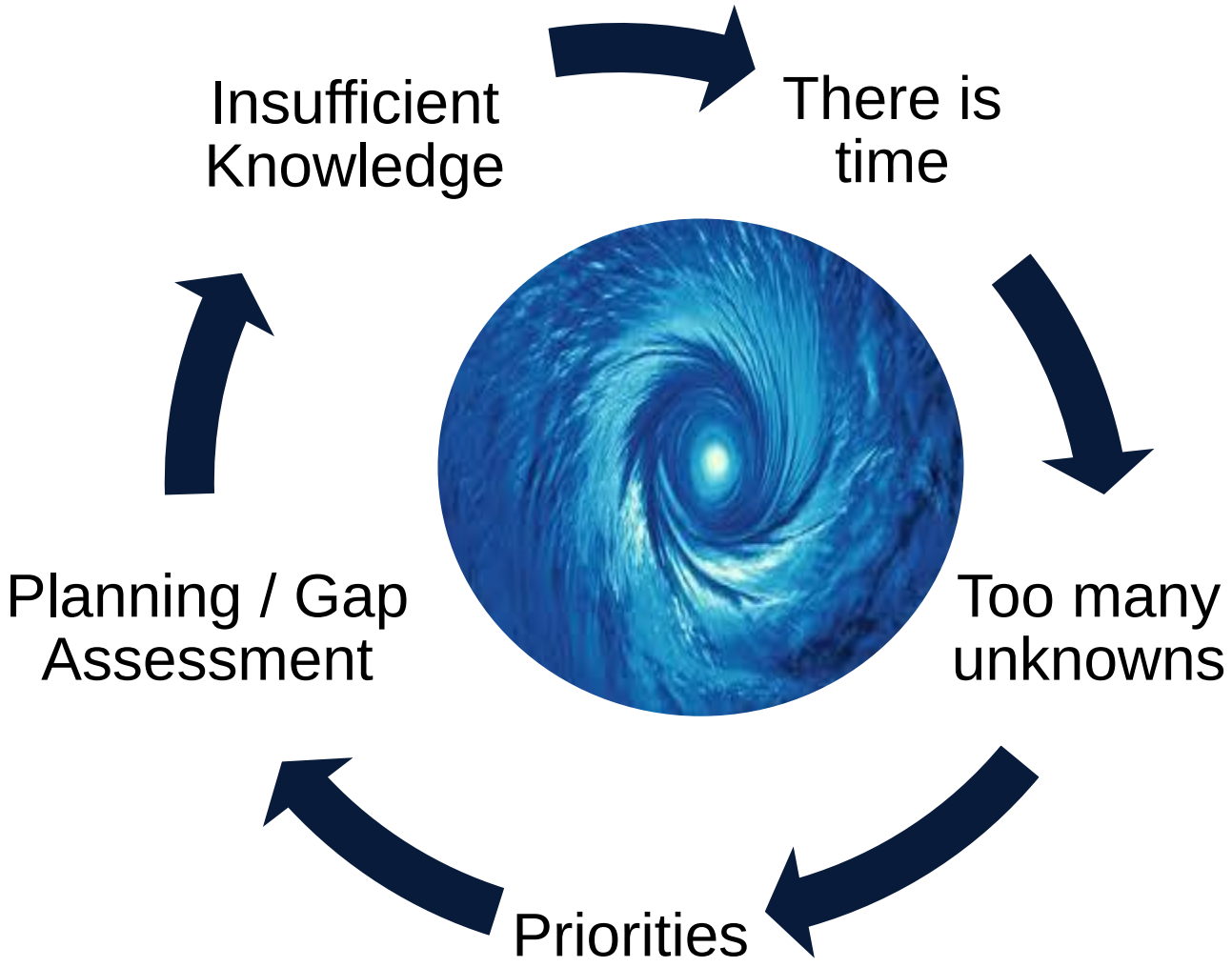
Transition details and timelines

***From DoA of MDR, NO significant changes and PMS, Vigilance EO requirements of MDR to be met**



The Buzzwords… - status 5 march 2020

Vortex of Inertia



Growing body of high level guidance

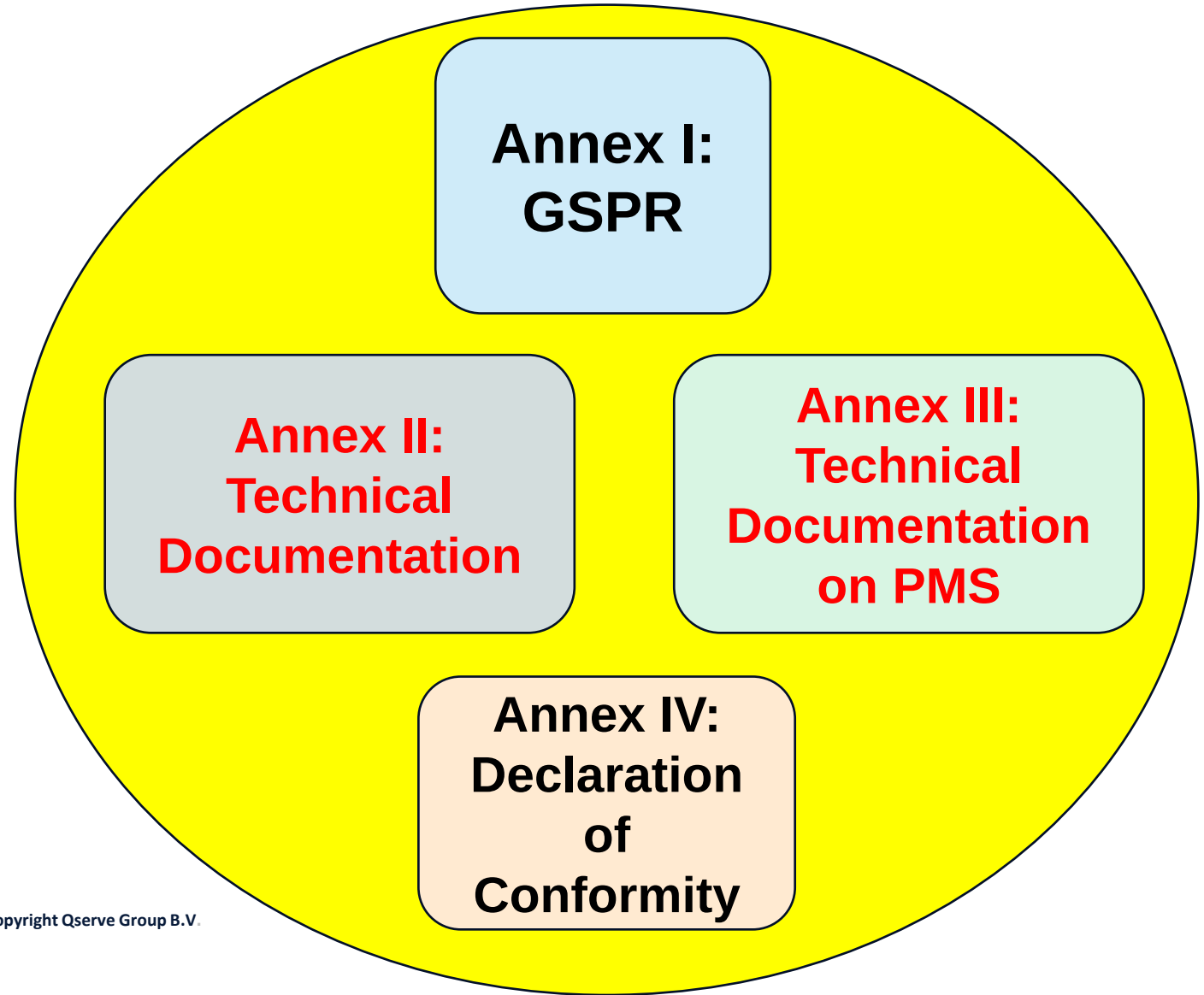
- **30 documents finished**
  - 14 on Notified Body designation
  - 9 on UDI details
  - 2 on EUDAMED
  - 1 on clinical - SSCP
  - 1 on software – classification
  - PRRC
  - Implant card
  - Pre-CE clinical evaluation consultation

- **Additional guidance planned (‘19/’20/?)**
  - 6 (2/1/3) on Notified Body oversight
  - 1 (1) on standardisation
  - 11 (8/3) on clinical
  - 3 (3) on PMS
  - 4 (1/2/1) on MS by authority
  - 2 (2) on borderline
  - 2 (1/1) on software
  - 4 (2/2) on UDI
  - 1 (1) on MDSAP
  - 6 (1/5) on IVDR
  - 6 (2/4) on nomenclature
  - 1 (1) on annex XVI

- Panic ?
- Chaos ?

Do not wait, get it done !

Practically speaking……



and….
QMS update

Technical Documentation

MDR	Information
• Article 5(2): Placing on the market and putting into service • Article 10(8): General Obligations of Manufacturers • Article 11(3b): Authorized Representative • Article 15(3b): Person Responsible	• All devices shall meet GSPR Annex I • Retention time 10 years/15 for implantable • Verify the DoC and TechDoc per appropriate conformity assessment procedure • Responsible for TechDoc and the DoC
• Article 27(7): UDI	• TechDoc keep up to date list of UDI's assigned
• Article 45: Notified Body review • Article 52: Conformity Assessment Procedure	• NB Authorities shall review of NB assessments of TechDoc • Route dictates specifics of TechDoc

Retention Period:
Keep TD available for the competent authorities for at least 10 years after the last device has been placed on the market.
In the case of implantable devices15 years.

Technical Documentation

MDR	Information
• Article 61: Clinical Evaluation • Annex XIV: Clinical Evaluation and PMCF	• Confirmation of GSPR per Annex I
Article 83: Post-market surveillance system Article 84: Post-market surveillance plan Article 85: Post-market surveillance report Article 86: Periodic safety update report Article 87: Reporting of serious incidents and FSCA Article 88: Trend Reporting	Updates from PMS, PMS Plan, PSUR, trend reporting
• Annex II: Technical Documentation • Annex III: Technical Documentation on PMS	• Detailed requirements on contents of technical documentation

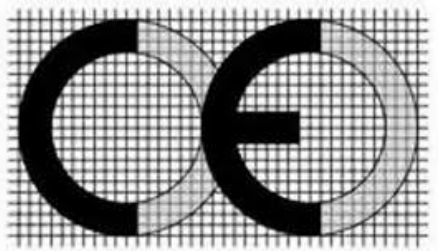
Be clear on claims

- **Claims**
- **Intended use**
- **Intended purpose**

“what you can prove, you can get certified”

- **Validation protocols & reports**
  - plan, do, check, act (PDCA)

- **Pre-market**
- **Post market**



(PMS, PMCF)

Article 83 (3) PMS data shall be used to…

a) Update benefit/risk determination and improve risk management.
b) Update design and manufacturing information (IFU and labelling).
c) Update clinical evaluation.
d) Update Summary of Safety and Clinical Performance (SSCP) as described in Article 32 for Class III and Implantable devices.
e) Identify preventative, corrective or field safety corrective actions.
f) Identify options to improve usability, performance and safety.
g) Contribute to PMS of other devices.
h) Detect and report trends.

- The technical documentation shall be updated accordingly.

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Thank you for your attention

Qserve Group

Gert.bos@qservegroup.com

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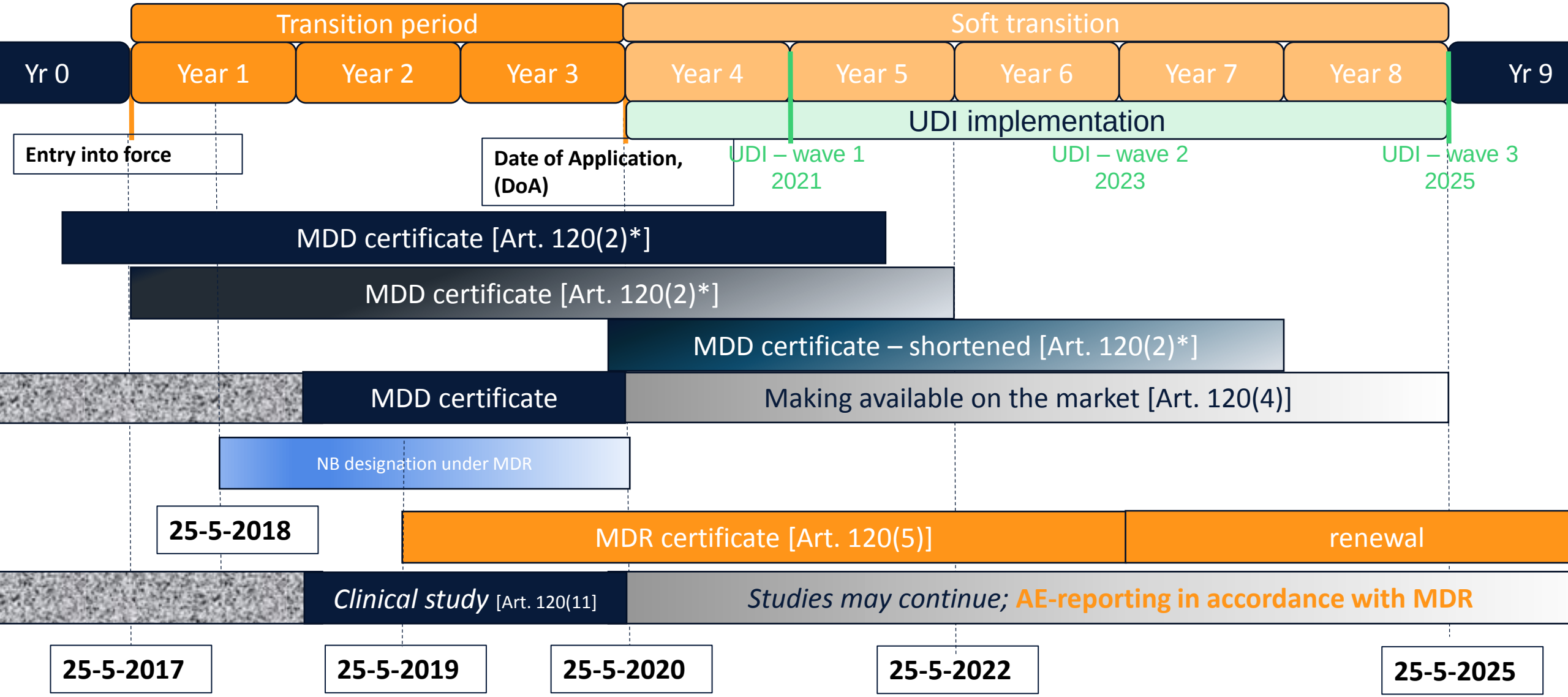

Transition details and timelines MDR