Swiss Medtech - Regulatory Aspects

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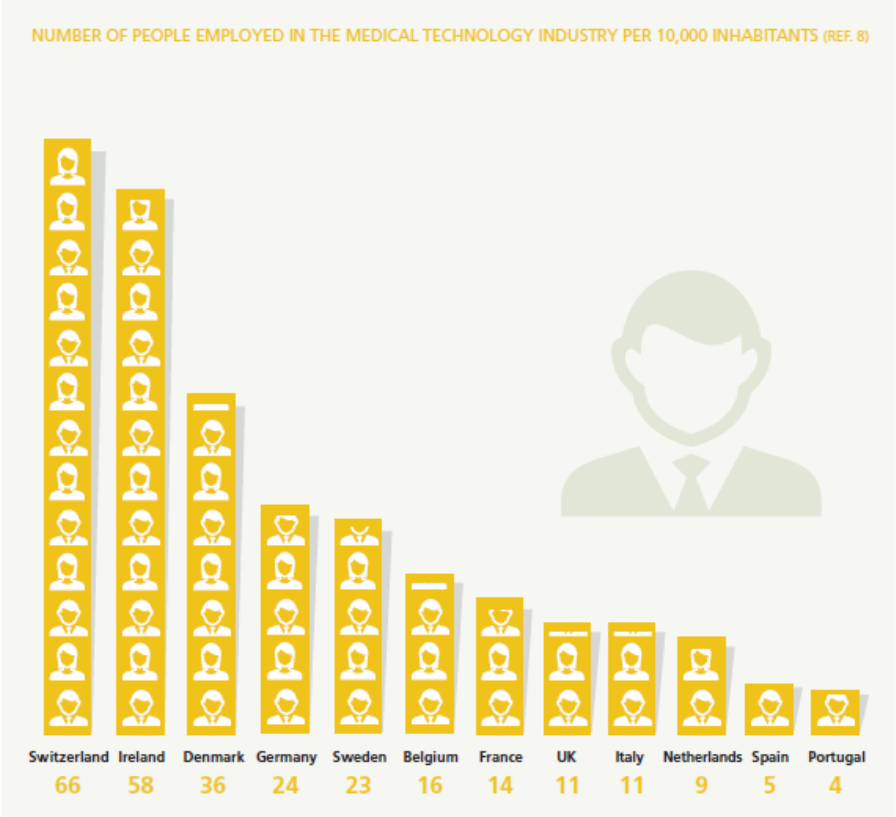
Swiss Medtech

Swiss Medtech*

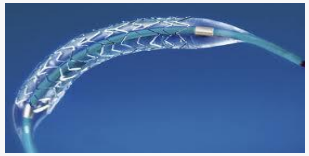
- 1350 companies
- 14.1 CHF Billion turnover
- 54’500 employees
- Up to 30% of turnover spent on R&D
- Strong collaboration with universities
- Support from CTI
- Highly qualified professionals
- Swiss labor law
- Taxation
- Swissness
- Same regulatory framework as EU due to mutual recognition agreement
  - **Devices manufactured and CE-marked in Switzerland can be marketed in EU without need for further regulatory activities & approval** CE



*Swiss Medtech Report 2016

**Europe Medtech Report 2016

What is a Combination Product? Device or Drug?

Medtech			
Pharma			
Combination products Device or Drug?			

Are Devices and Drugs Very Different?

Device Definition (Dir 93/42/EC)

Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of

> **Diagnosis, prevention, monitoring, treatment, alleviation of disease** …….

and **which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means** but which may be assisted in its function by such means

- ***Must have a medical purpose***
- ***Must be for use on humans***

Drug Definition (2001/83/EC)

Any substance or combination of substances presented as having properties for **treating or preventing disease in** human beings; or

Any substance or combination of substances which may be used in or administered to human beings either with a view to **r**estoring, correcting or modifying physiological functions **by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis**

- ***Must have a medical purpose***
- ***It can be used on humans as well as animals***

Classification

Device & IVD

Device: risk-based categorization

1. Class I (lowest risk)
2. Class II a and IIb
3. Class III (highest risk)

IVD: list-based categorization

- List A
- List B
- IVDs for self-testing
- General IVDs

Safety & Performance & Risk-Benefit

Drug

Risk based approach

- to some extent: novel or off-patent
- considerations to allow early access to innovative drugs

Quality & Efficay & Safety & Benefit-Risk

Who Decides the Product is Safe and Can be Marketed?

Device*

- Manufacturer and depending on risk Notifid Body (Private organization)
- CE-Mark: Switzerland = EU (Mutual Recogntion Agreement)

Drug

- Health authority or EU Commission (Government organization)
- Approval Switzerland ≠ EU (**no** Mutual Recognition Agreement)

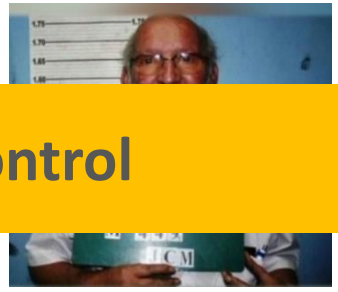
* New Approach Directive, ultimate responsibility with manufacturer

PERFECT

?

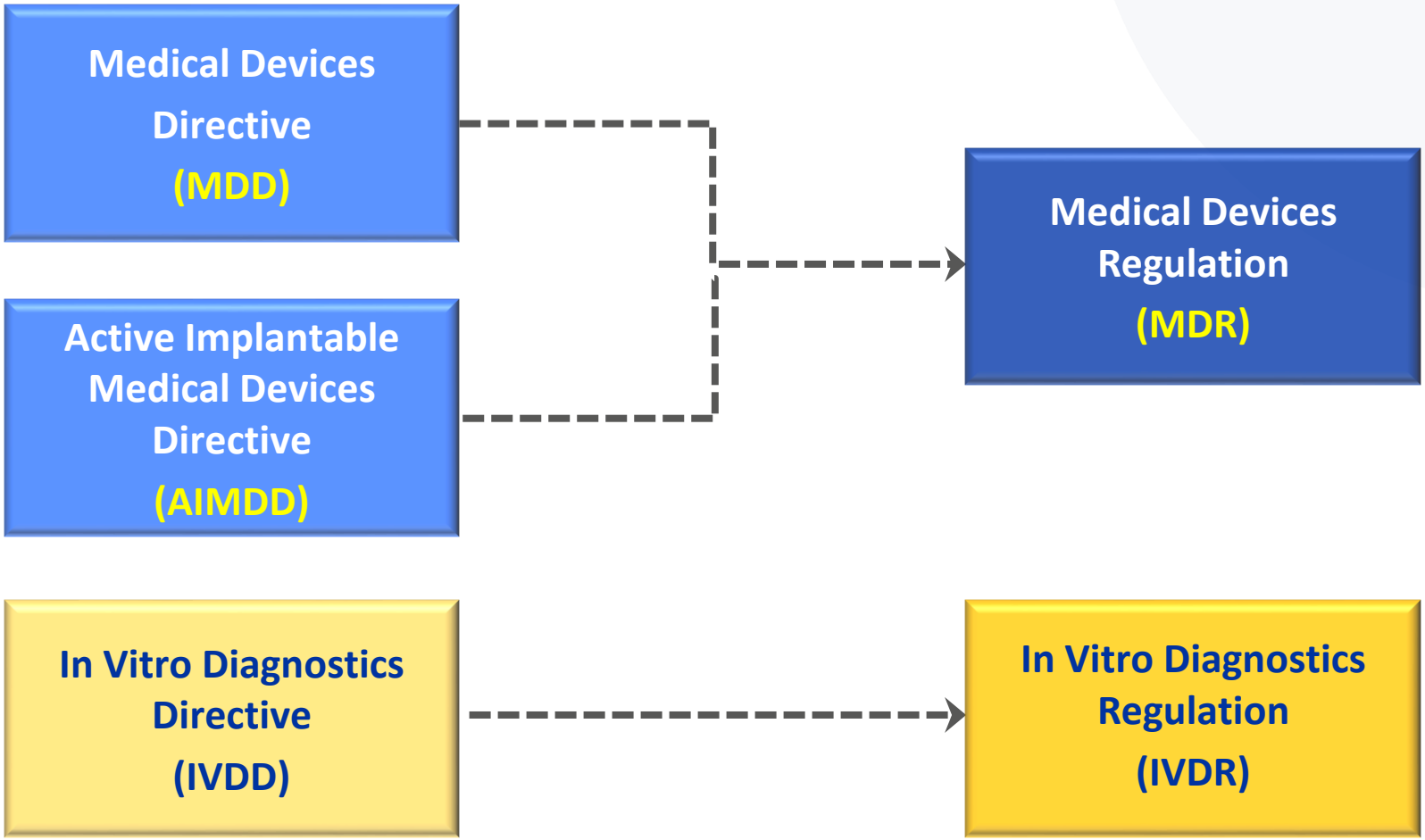
Drivers for Change to EU MD Law

- The European legislation is over 20 years old: The number of Member States in the EU has more than doubled
- Substantial technical and healthcare developments
  - Home healthcare,
  - eHealth and mHealth,
  - Companion diagnostics,
  - Device/drug combinations etc.



Trust → Control

Upcoming Changes in EU Medtech Law



Key Changes of the MDR

Main points

Updated scope

- Added devices with no intended medical purpose (e.g. aesthetic devices) . Substance-based devices
- Added non-viable human tissue products . Devices intended to administer a medicinal product (under certain conditions)

No pre-market approval

- Manufacturer continues to have the final responsibility

New expert bodies

- Medical Device Coordination Group (MDCG)
- Expert panels and laboratorise

Notified bodies

- Strengthened role in assessing manufacturers
- Conduct unannounced audits
- Stronger supervision by authorities

Clinical evidence

- Reinforced rules for clinical evidence for medical devices

Scrutiny mechanism

Scrutiny mechanism for high risk devices

- Notified bodies to consult MDCG
- Expert panels may also be involved

Qualified person

- Qualified person responsible for ensuring regulatory compliance

Increased transparency

- Registration of clinical investigations Eudamed
- Summary of safety & performance for class III and implantable devices published

Better traceability

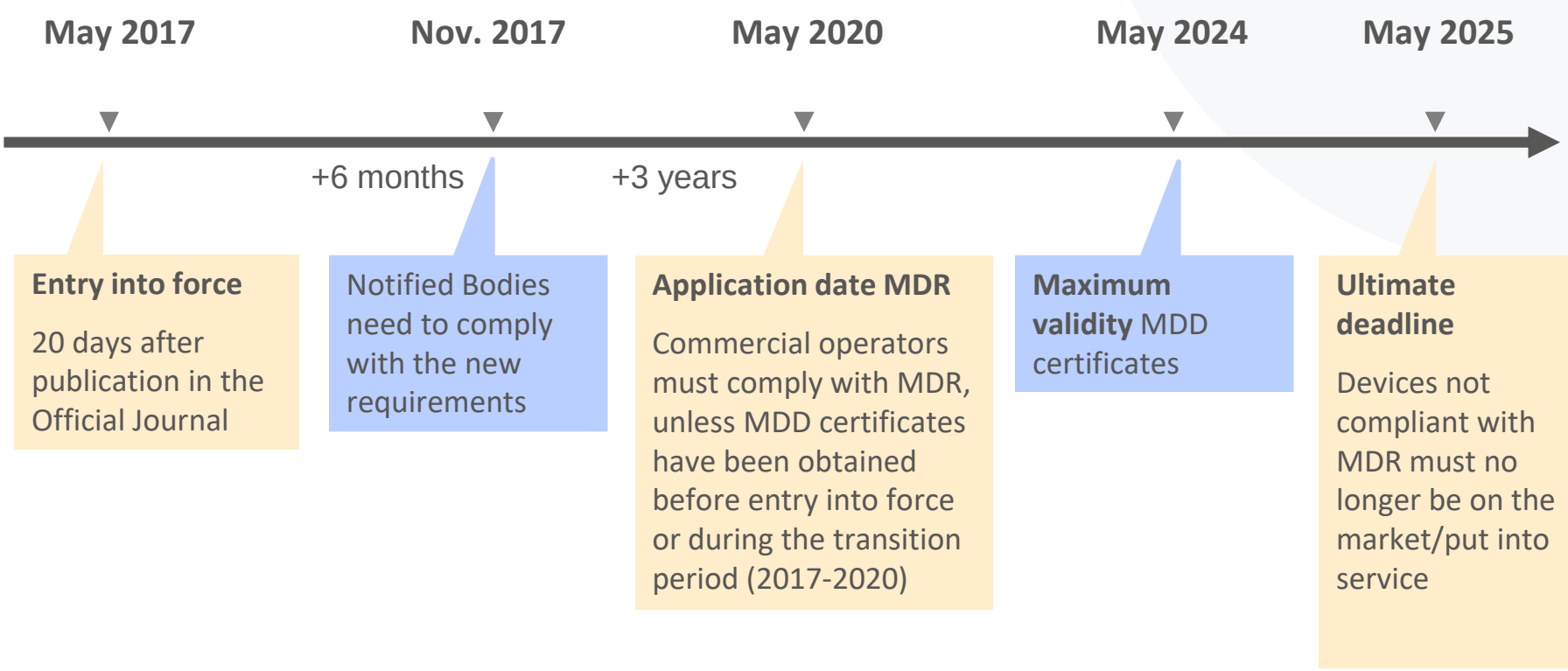
Unique device identification (UDI) system to

- Enhance post-market safety
- Reduce medical errors & counterfeiting

Vigilance and market surveillance

- PSUR for Class IIa, IIb and III
- Manufacturers report serious incidents and corrective actions to Eudamed

MDR: Key Timelines



Introduction to EU IVD law

IVDR: the new classification scheme

IVDD: 'list based' (in order of increasing risk)

- General IVDs
- IVDs for self-testing
- Annex II List B
- Annex II List A

IVDR: 'risk-based'

Class	Risk level		Examples
A	Patient – Low	Public – Low	Clinical chemistry analyser
B	Patient – Moderate	Public – Low	Urine test strips
C	Patient – High	Public – Moderate	Companion diagnostics
D	Patient – High	Public – High	HIV testing

Key Changes of the IVDR

Main points

Updated scope

- Applies to all IVDs and their accessories . Riaks based classification: Class A, B, C and D
- New definitions and rules for: companion diagnostics (CDx), in-house tests, kits, single use IVDs, distance sales

No pre-market approval

- Manufacturer continues to have the final responsibility

New expert bodies

- Medical Device Coordination Group (MDCG)
- Expert panels and laboratory
- EMA & National Competent Authorities

Notified bodies

- Strengthened role in assessing manufacturers
- Conduct unannounced audits
- Stronger supervision by authorities

Clinical evidence

- Clarification of performance indicators
- Clinical evidence throughout the lifecycle
- Performance Evaluation Report (PER)

Scrutiny mechanism

- Involvement of EMA & National Competent Authority for CDx
- Expert Panel involved for Class D IVDs

Qualified person

- Qualified person responsible for ensuring regulatory compliance

Increased transparency

- Registration of clinical performance studies in Eudamed
- Public transparency of data from clinical performance studies, and of class C & D

Better traceability

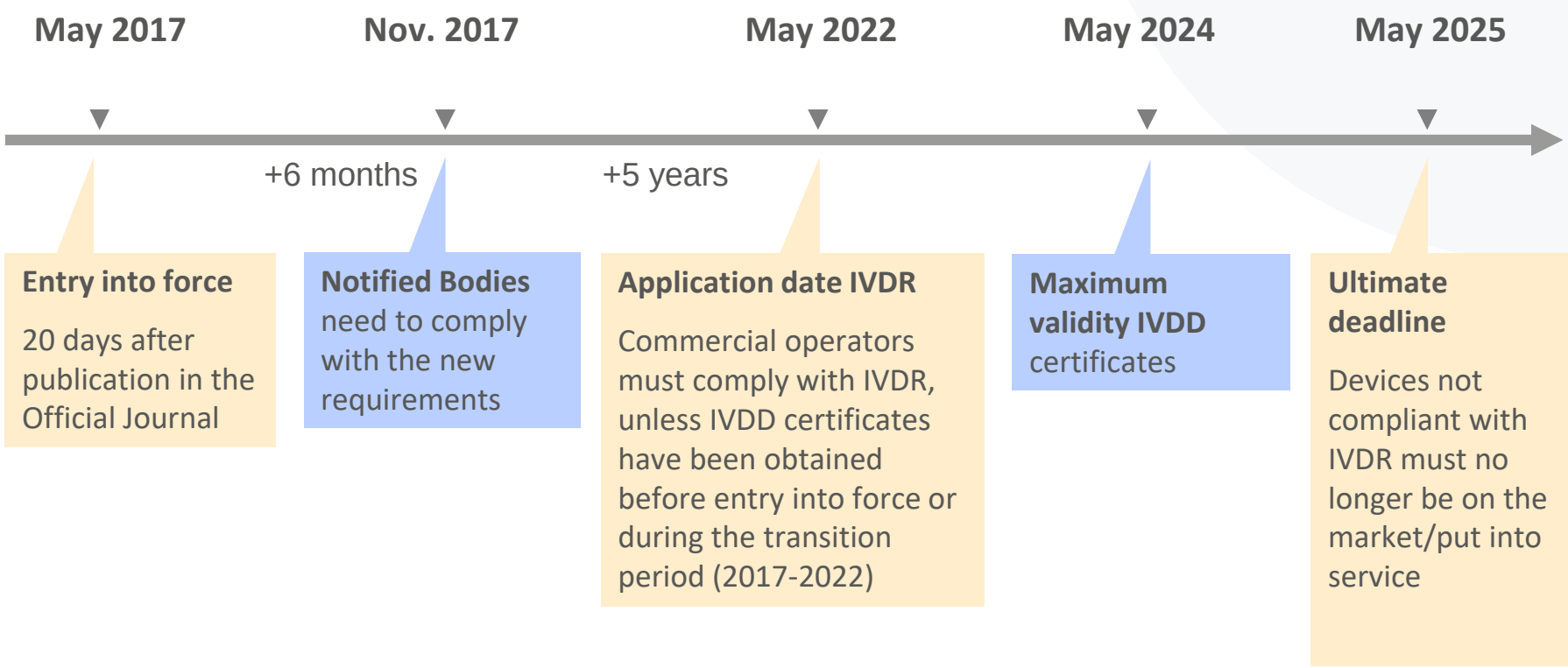
Unique device identification (UDI) system to

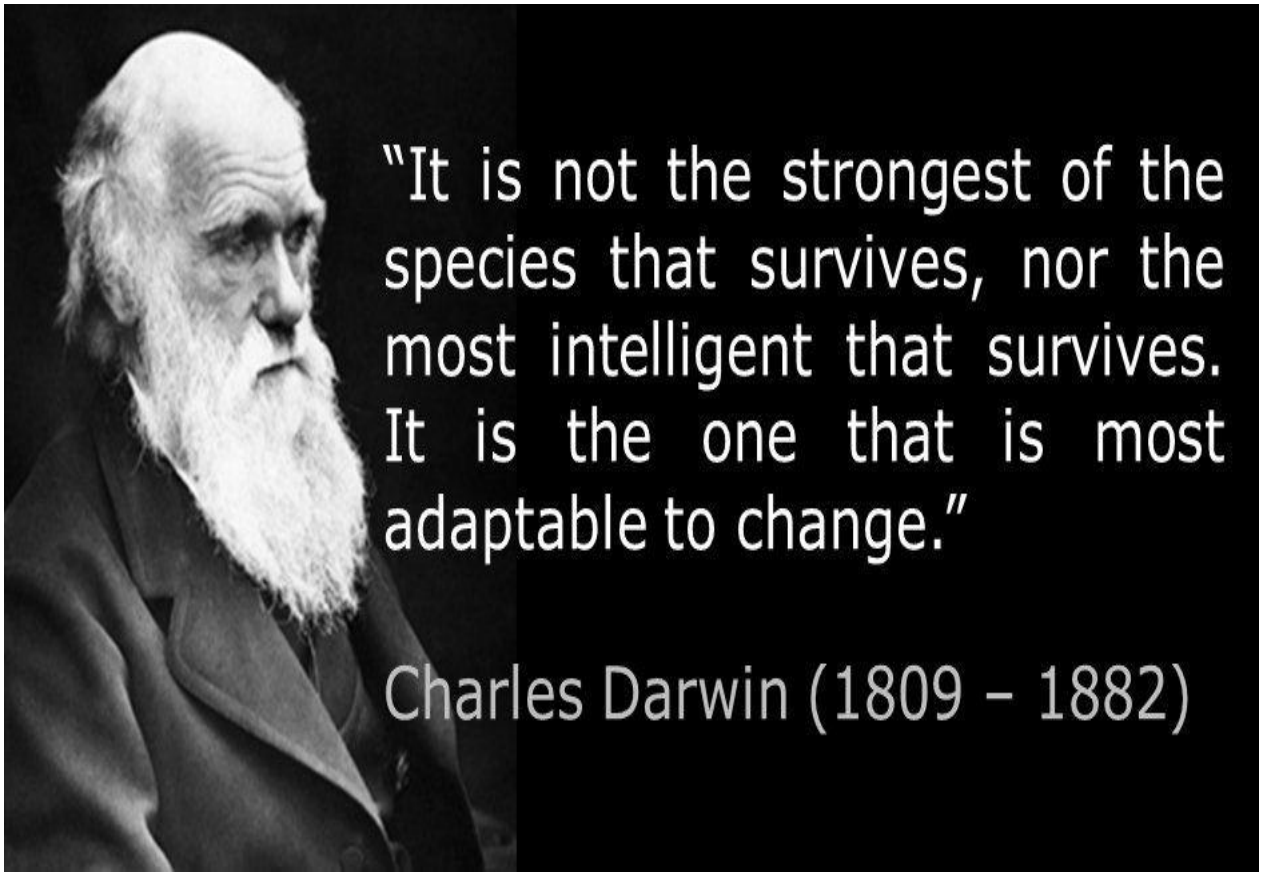
- Enhance post-market safety
- Reduce medical errors & counterfeiting

Vigilance and market surveillance

- PSUR for Class C and D
- Manufacturers report serious incidents and corrective actions to Eudamed

IVDR: Key Timelines





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