Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Developing diagnostics – the regulatory picture

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Today’s talk

- A little about the MHRA
- The regulatory process for IVDs
- Changes on the horizon
  - Clinical evidence & performance evaluation
  - ‘In-house’ development of diagnostics
- Q&A

About the MHRA

Executive Agency

- Government Trading Fund and an Executive Agency of the Department of Health and Social Care

Size

- Around 1300 staff, with a total budget of approximately £160 million

Medicines & Healthcare products Regulatory Agency

CPRD

Clinical Practice Research Datalink

- NHS observational data and interventional research service
- Jointly funded by NIHR and MHRA
- Anonymised data
- Observational research studies: links between things like diet, or family history, and particular illnesses
- Clinical trials: UK/pan-EU

NIBSC

National Institute for Biological Standards and Control

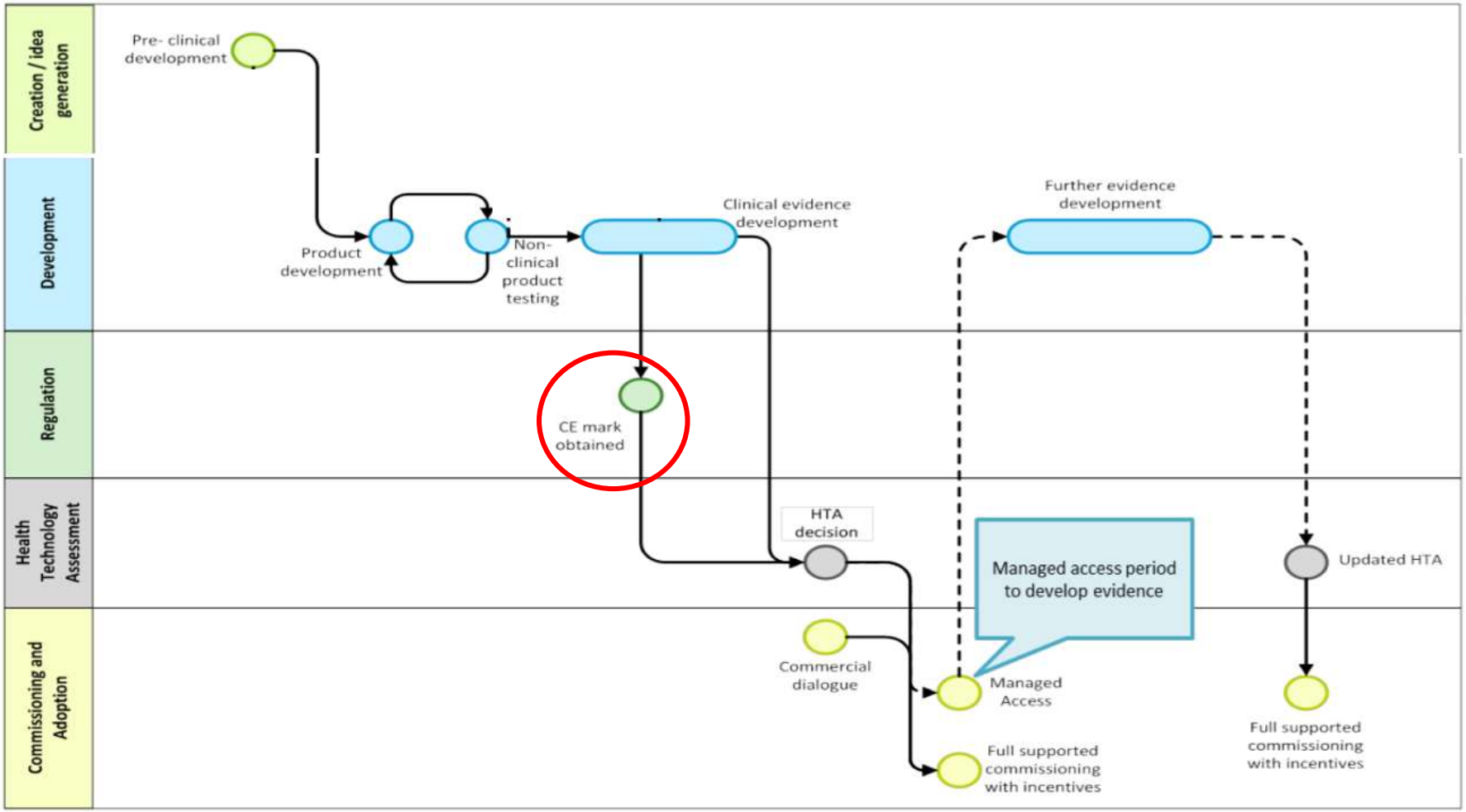
- Standardization and control of biological medicines
- Over 90% of international biological standards
- UK's Official Medicines Control Laboratory for biological medicines
- Research
- Close relationship with WHO
- WHO collaborating center for polio, influenza and HIV

MHRA

Medicines and Healthcare Products Regulatory Agency

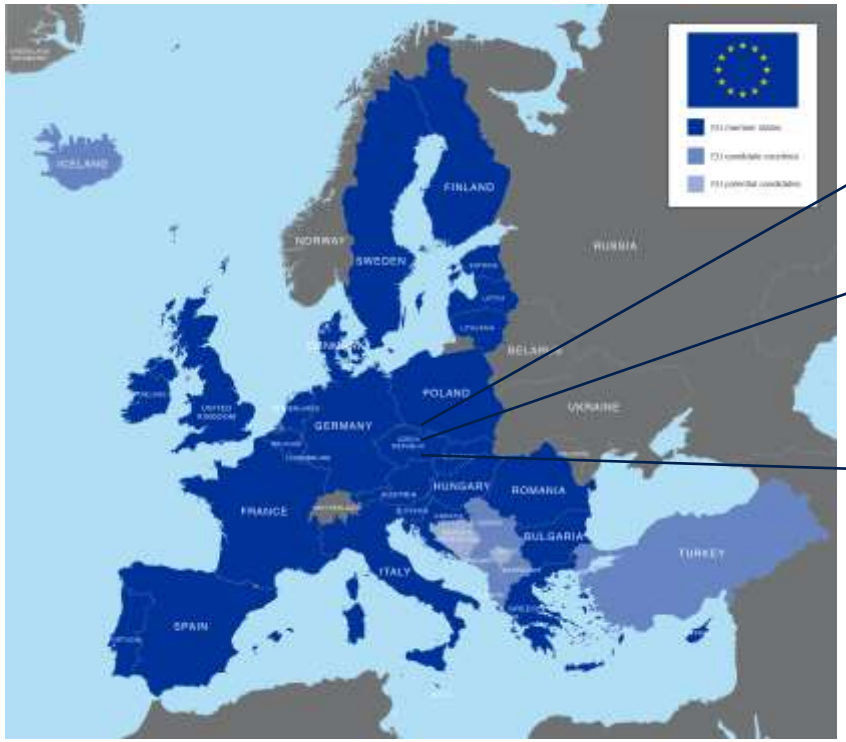
- regulation of medicines: quality, safety, efficacy
- Medical devices: overseeing the UK Notified Bodies
- Operating vigilance systems
- Blood and blood products
- Quality surveillance system
- regulating clinical trials
- British Pharmacopoeia

Regulation in the bigger picture



Medical devices legislation

- Legislation – three EU Directives

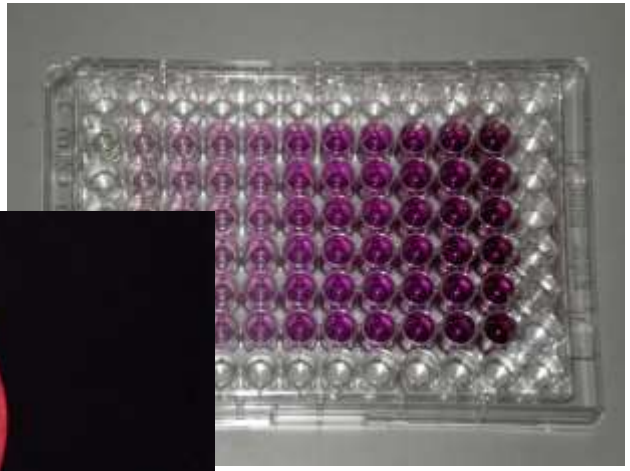


Medical Devices Directive

Active Implantable Medical Devices Directive

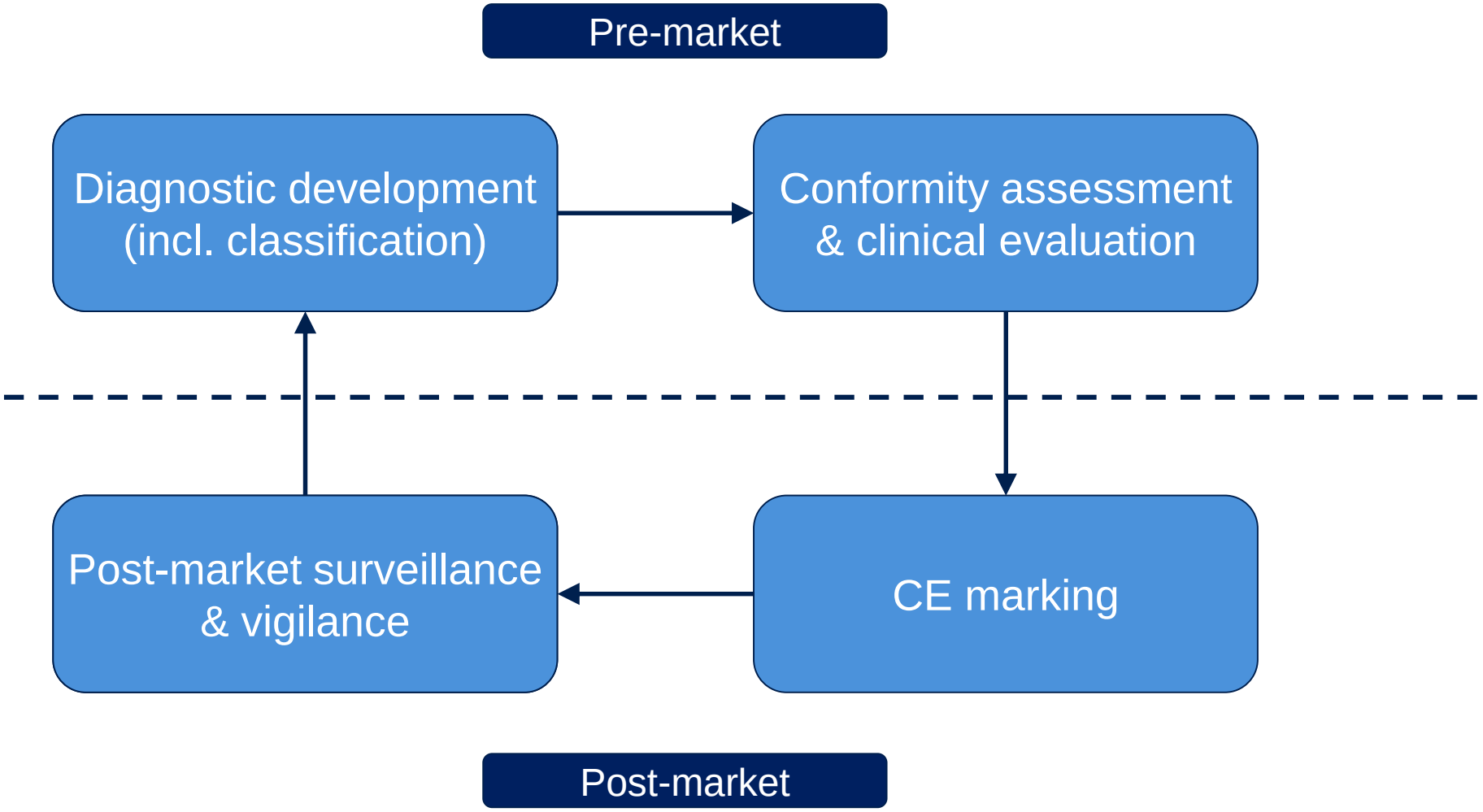
In-Vitro Diagnostic Devices Directive

What's an IVD?

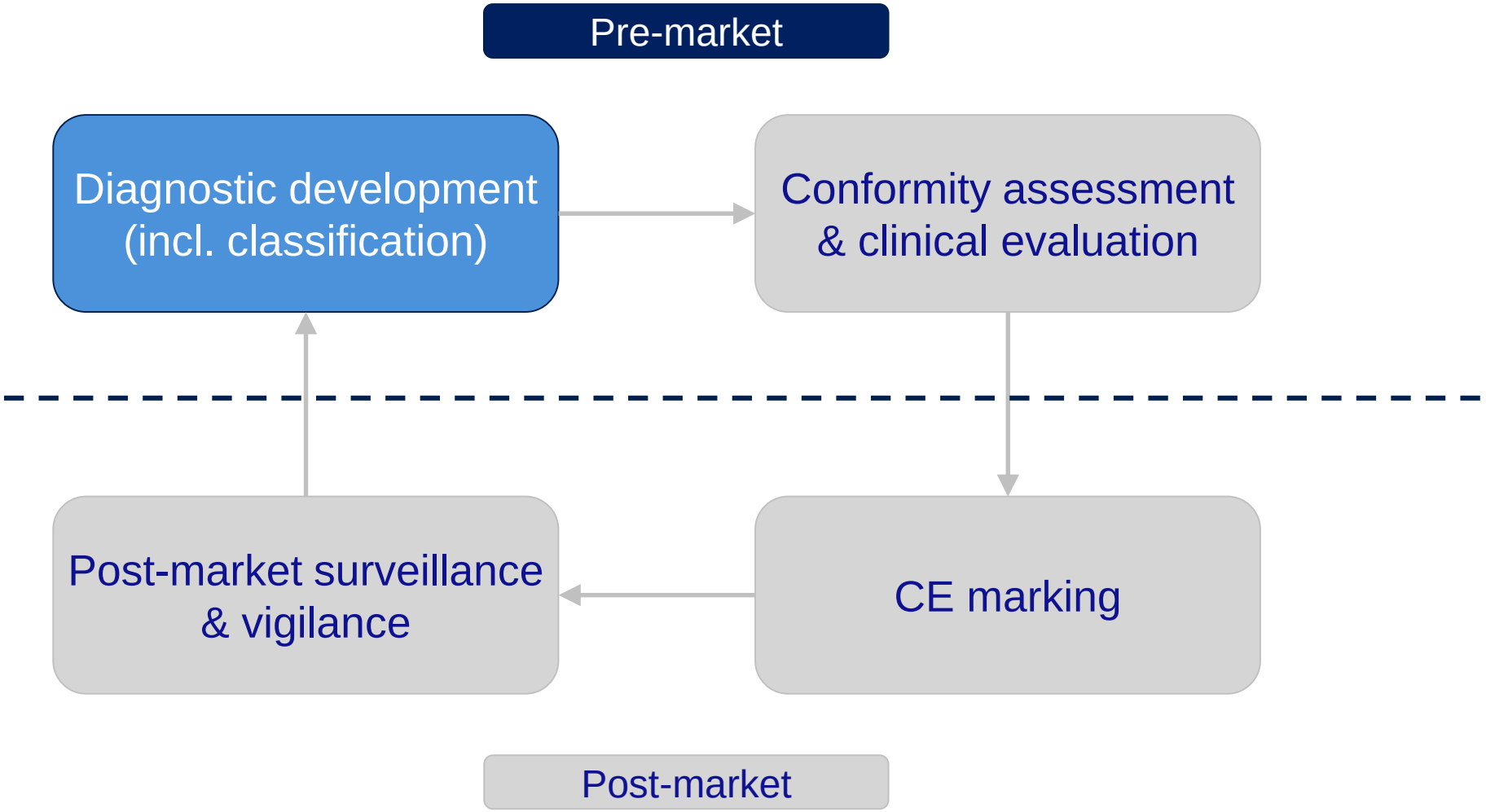



Rocket science is for kids
Bioinformatics is for scientists

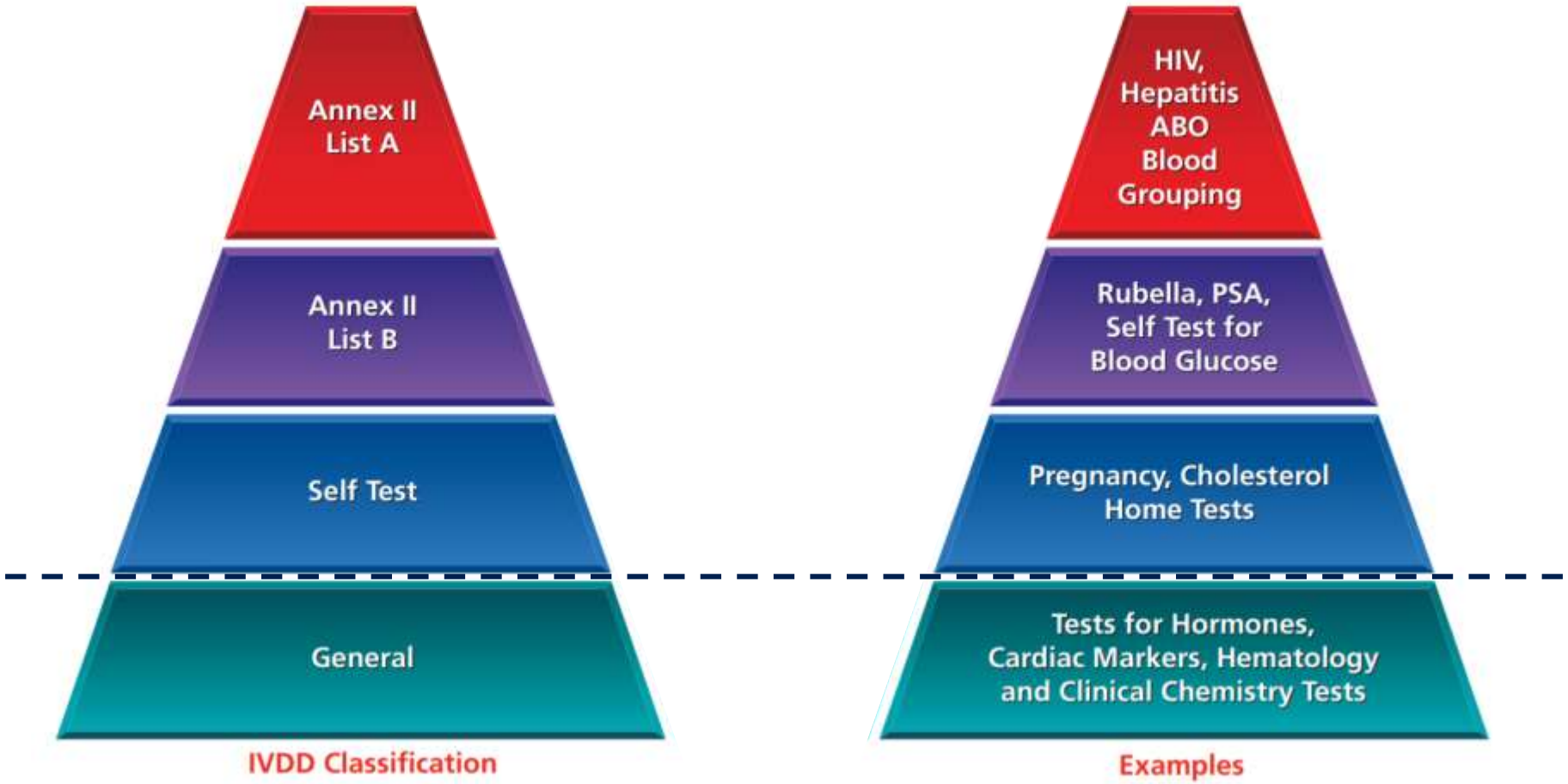
The regulatory cycle



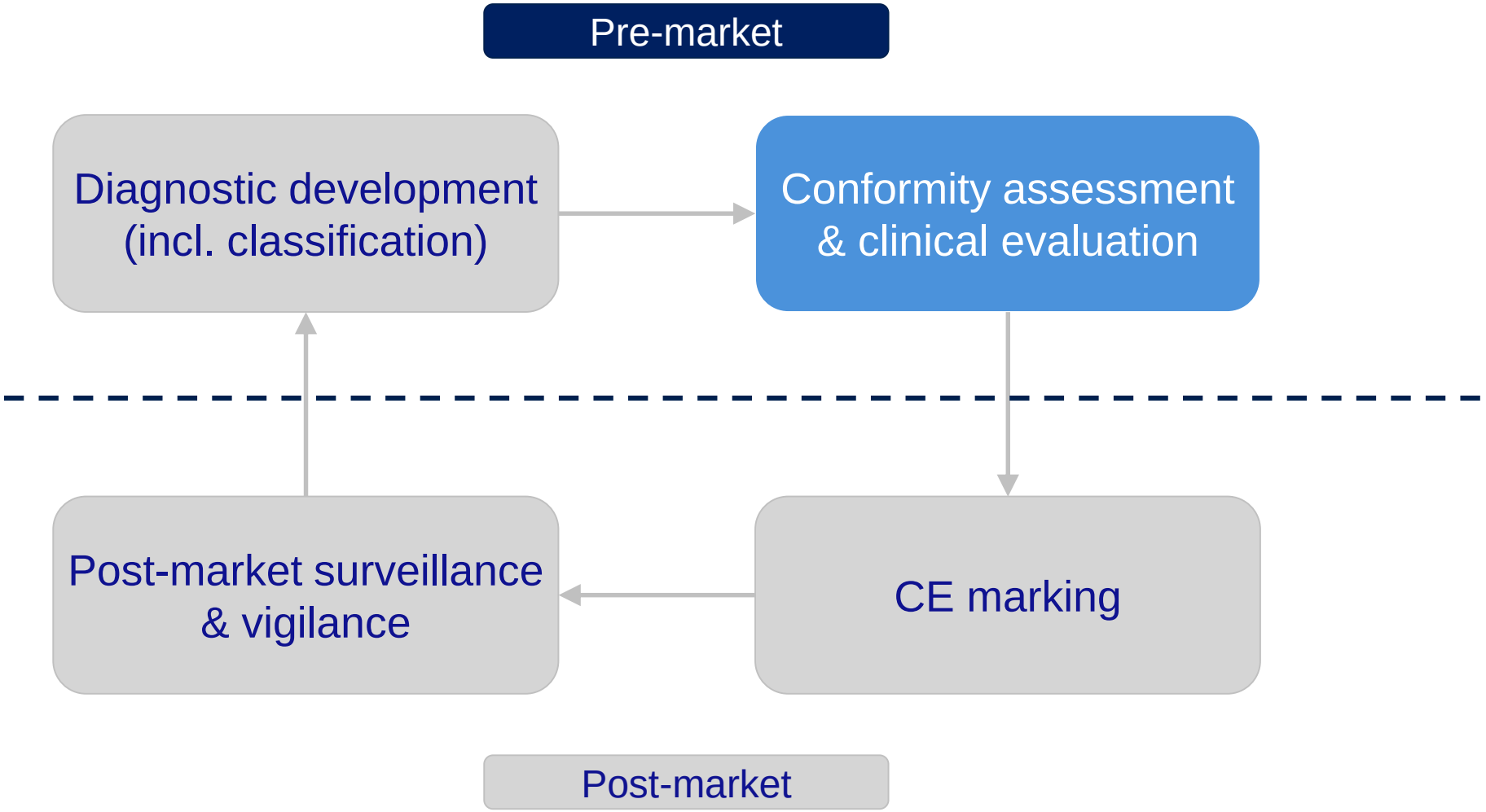
Classification



Classification - IVDs



Conformity assessment

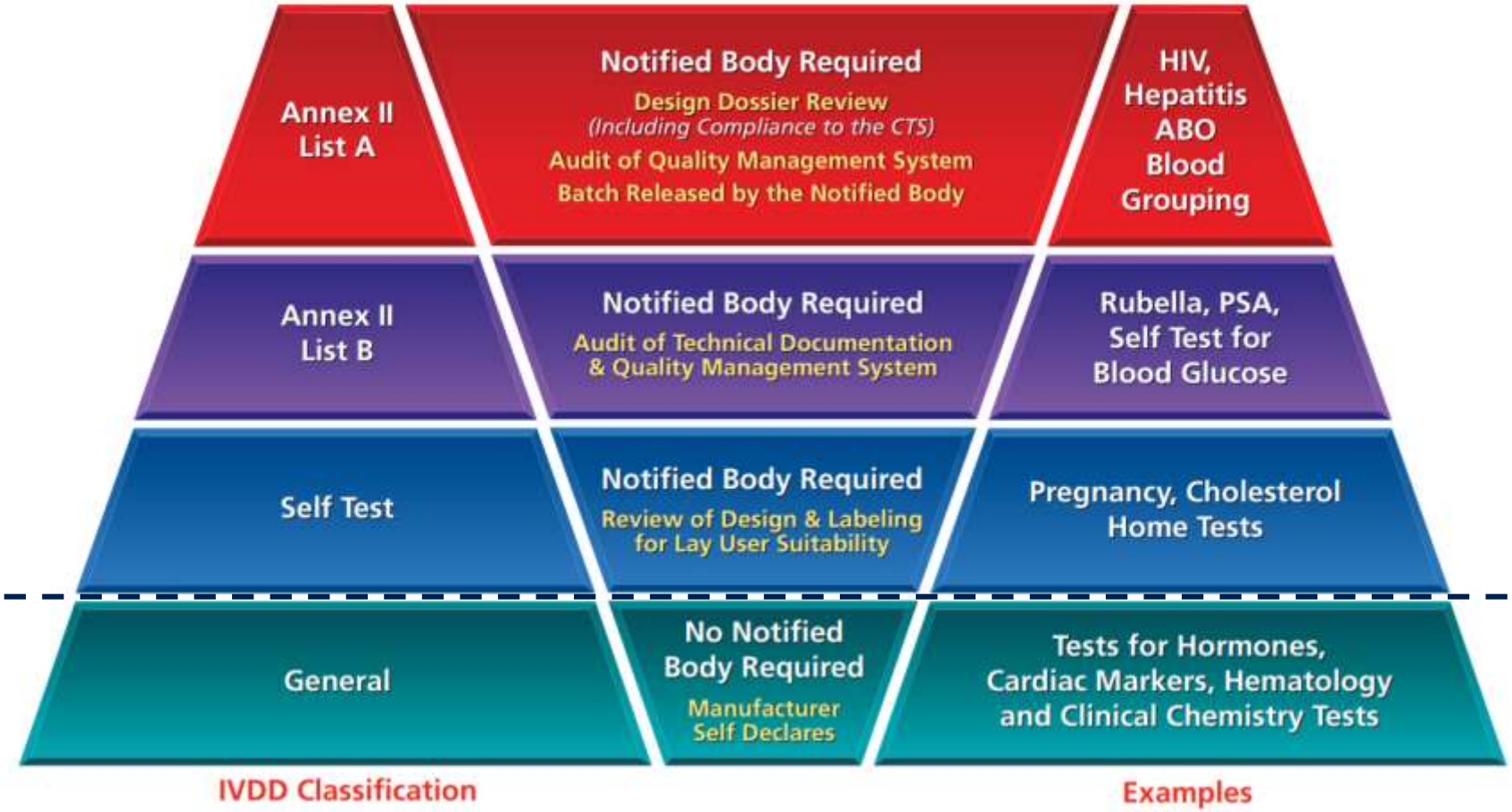


Conformity assessment

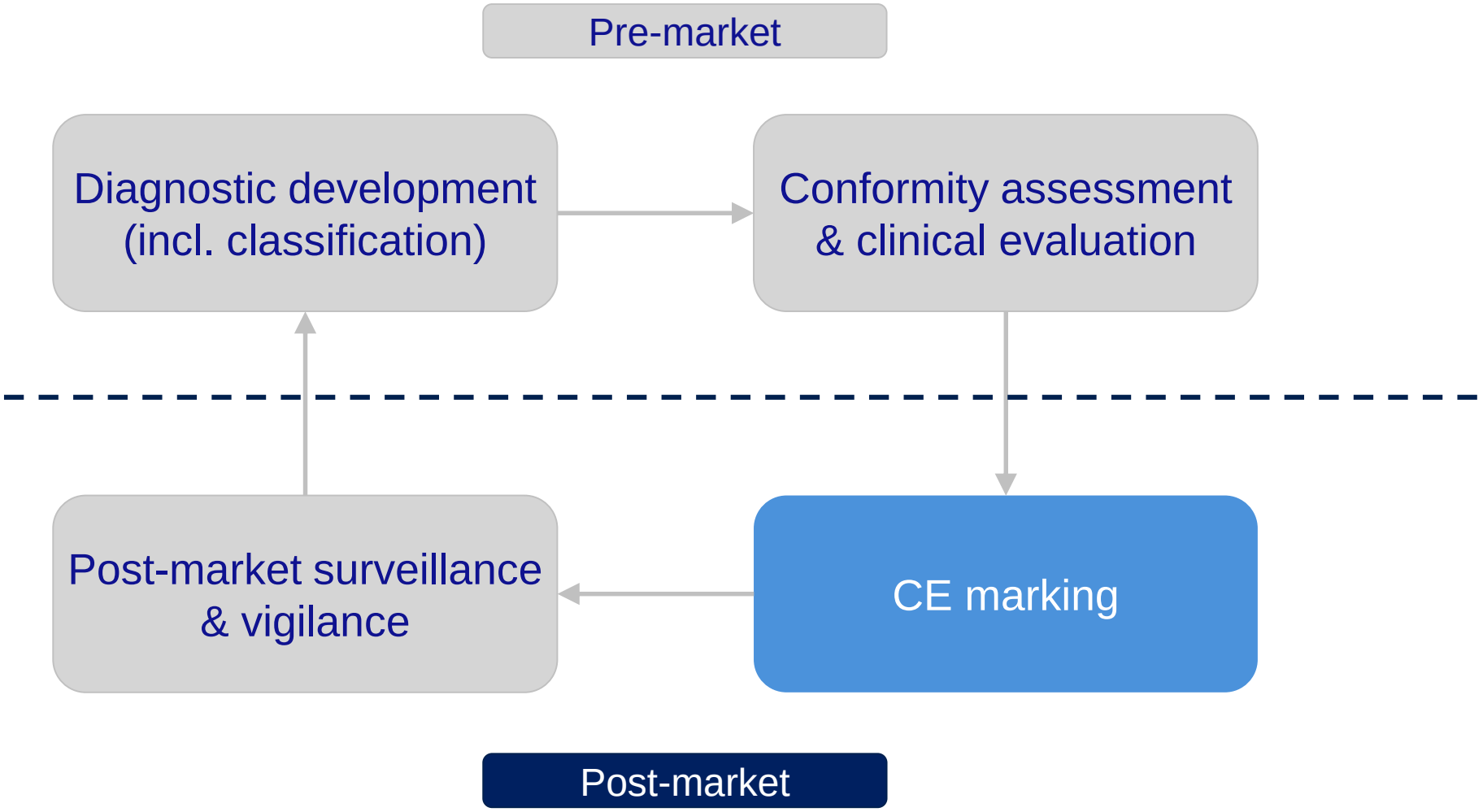
- Directives set out **‘essential requirements’** that manufacturers must meet
  - ✓ Benefits must outweigh risks and achieve the claimed performance
  - ✓ Analytical & diagnostic sensitivity
  - ✓ Analytical & diagnostic specificity
  - ✓ Accuracy
  - ✓ Repeatability
  - ✓ Reproducibility
- Manufacturer prepares technical documentation to demonstrate conformity with essential requirements
- Use of harmonised standards

Notified bodies

Notified body involvement



CE marking


Pre-market
Diagnostic development (incl. classification)
Conformity assessment & clinical evaluation
Post-market surveillance & vigilance
CE marking
Post-market

CE marking

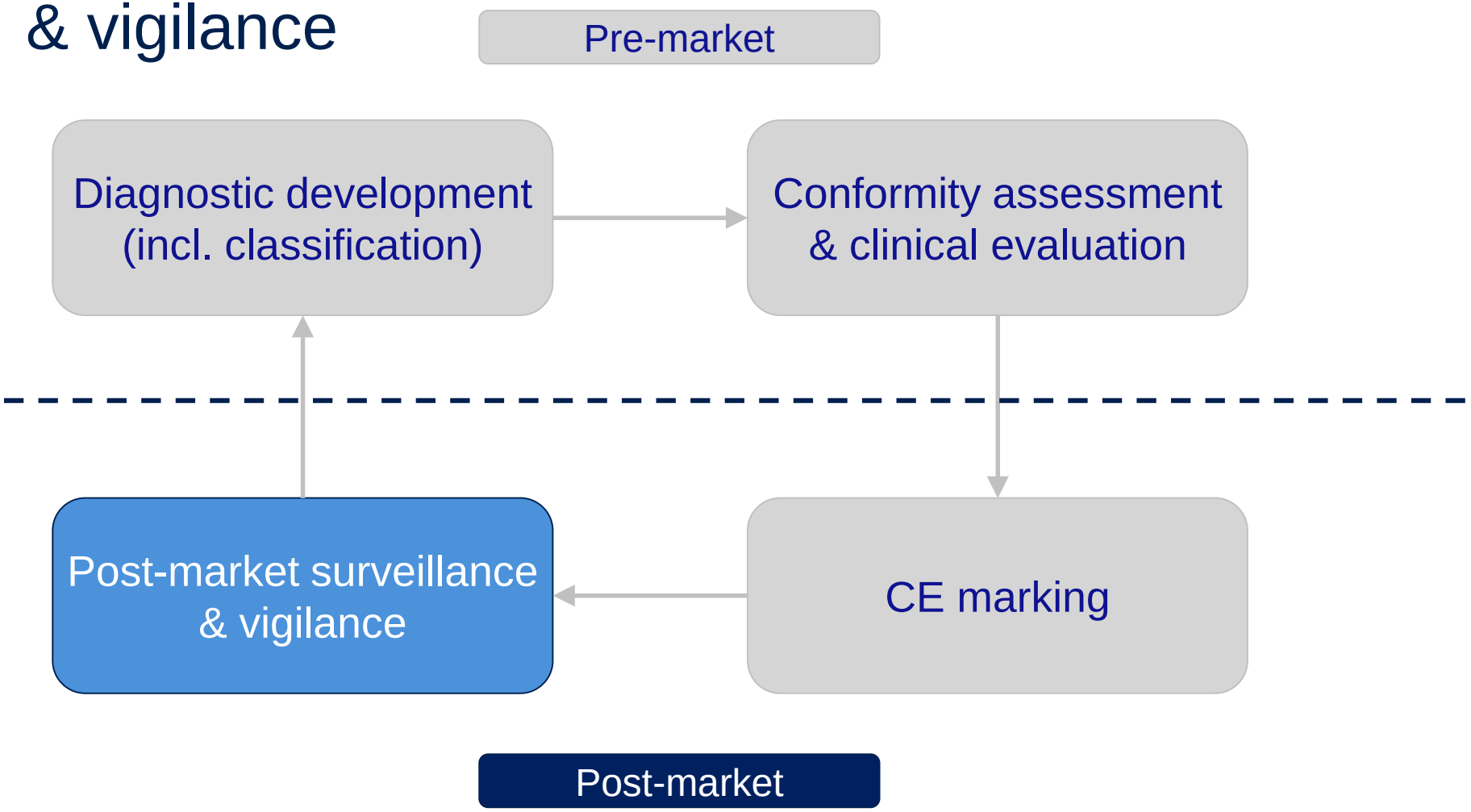
• Following successful conformity assessment, a manufacturer draws up a **declaration of conformity** and places a CE mark on the device – can be marketed anywhere in the EU

• CE mark not unique to medical devices

• ‘New Legislative Framework’ sets out common approach across a number of products sectors

• **But** standards involved vary substantially

Post-market surveillance & vigilance



Post-market surveillance & vigilance

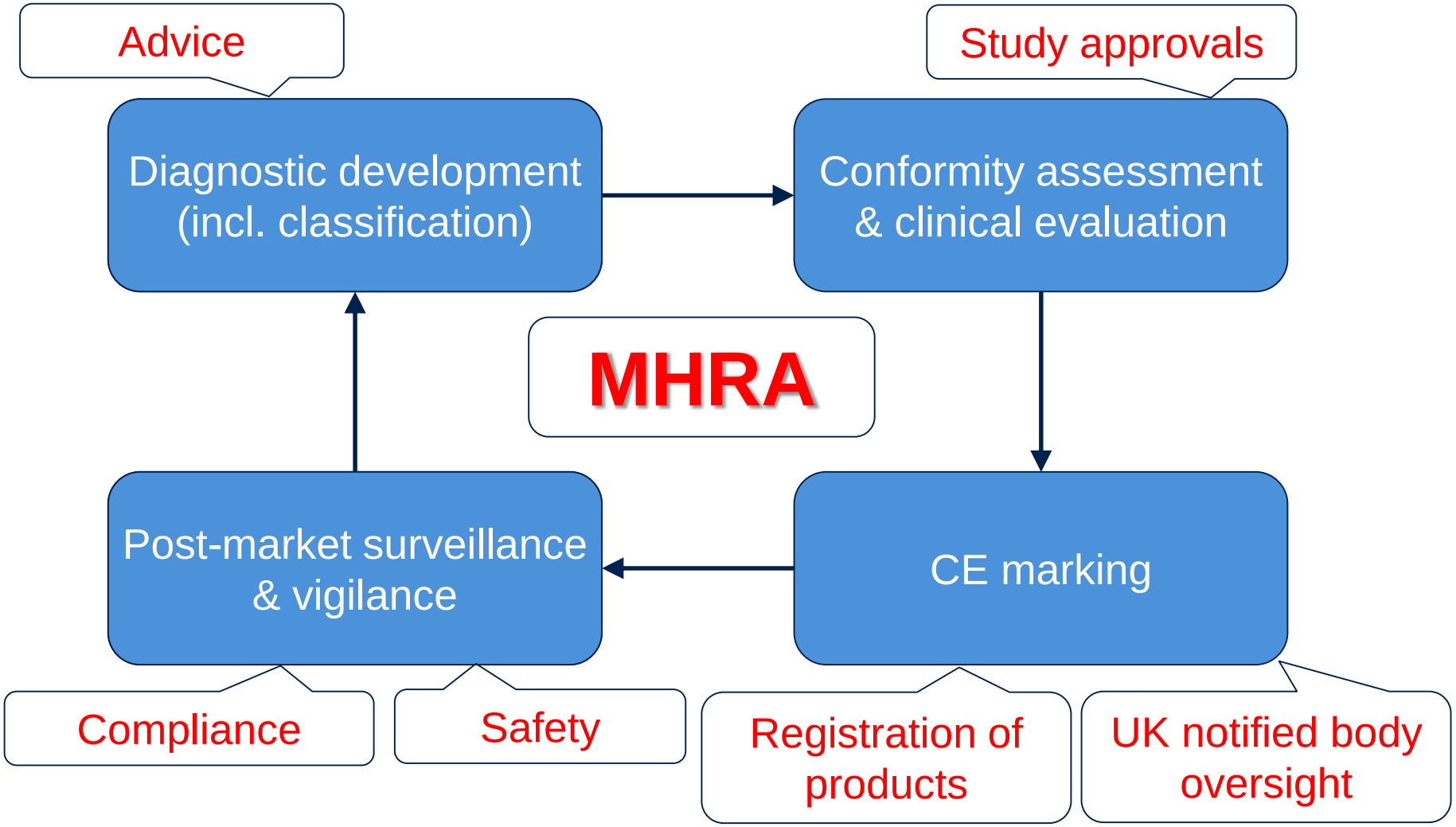
Post-market surveillance – preventative/proactive

- ensure ongoing performance of device – appropriate/risk benefit balance
- inform development of future iterations of the device

Vigilance – reactive

- reporting of serious incidents
- voluntary & mandatory reporting

MHRA – our role



Exciting times

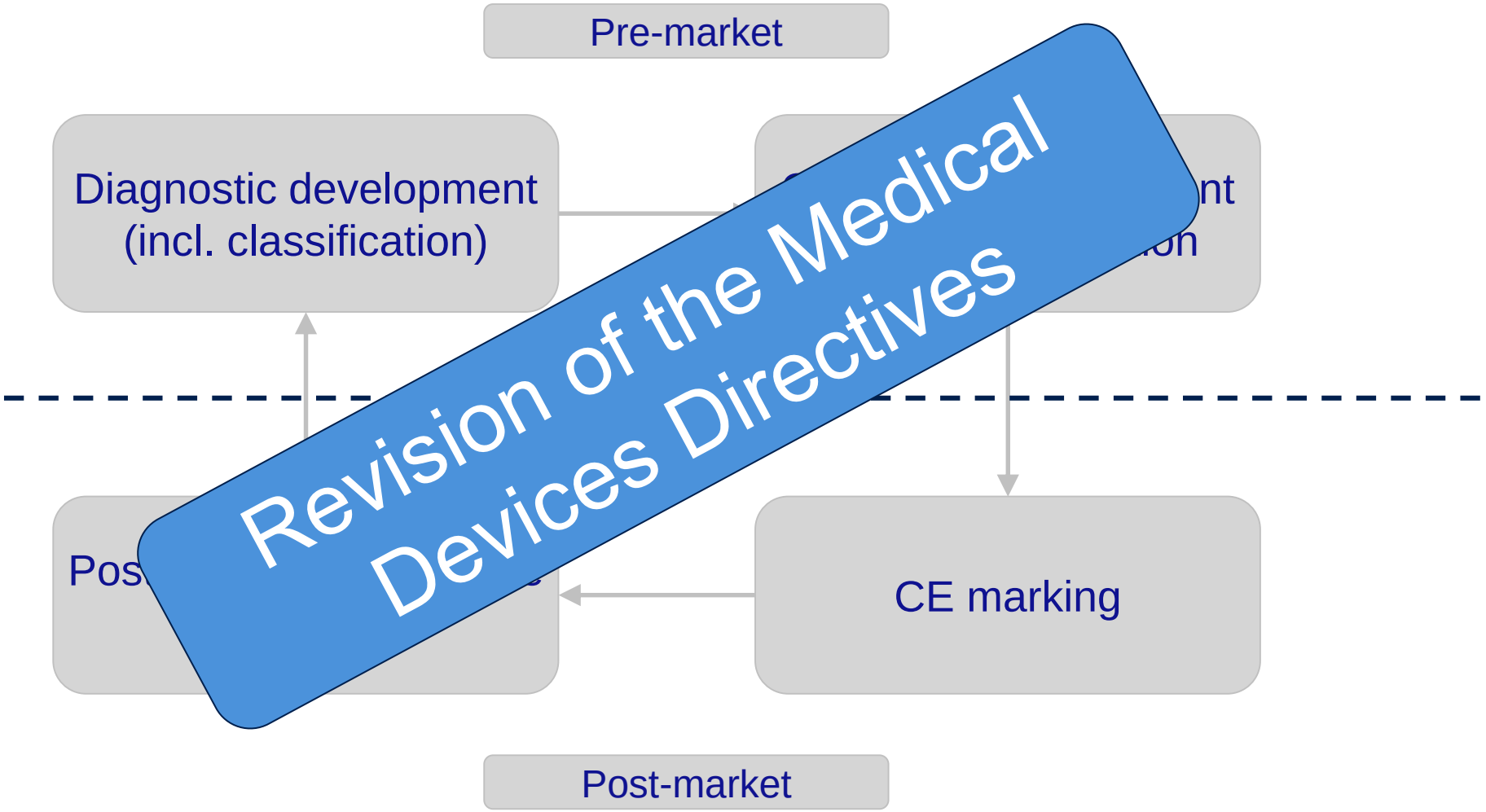
Medtech patents overtake transport as UK's biggest technology field

RSS Print

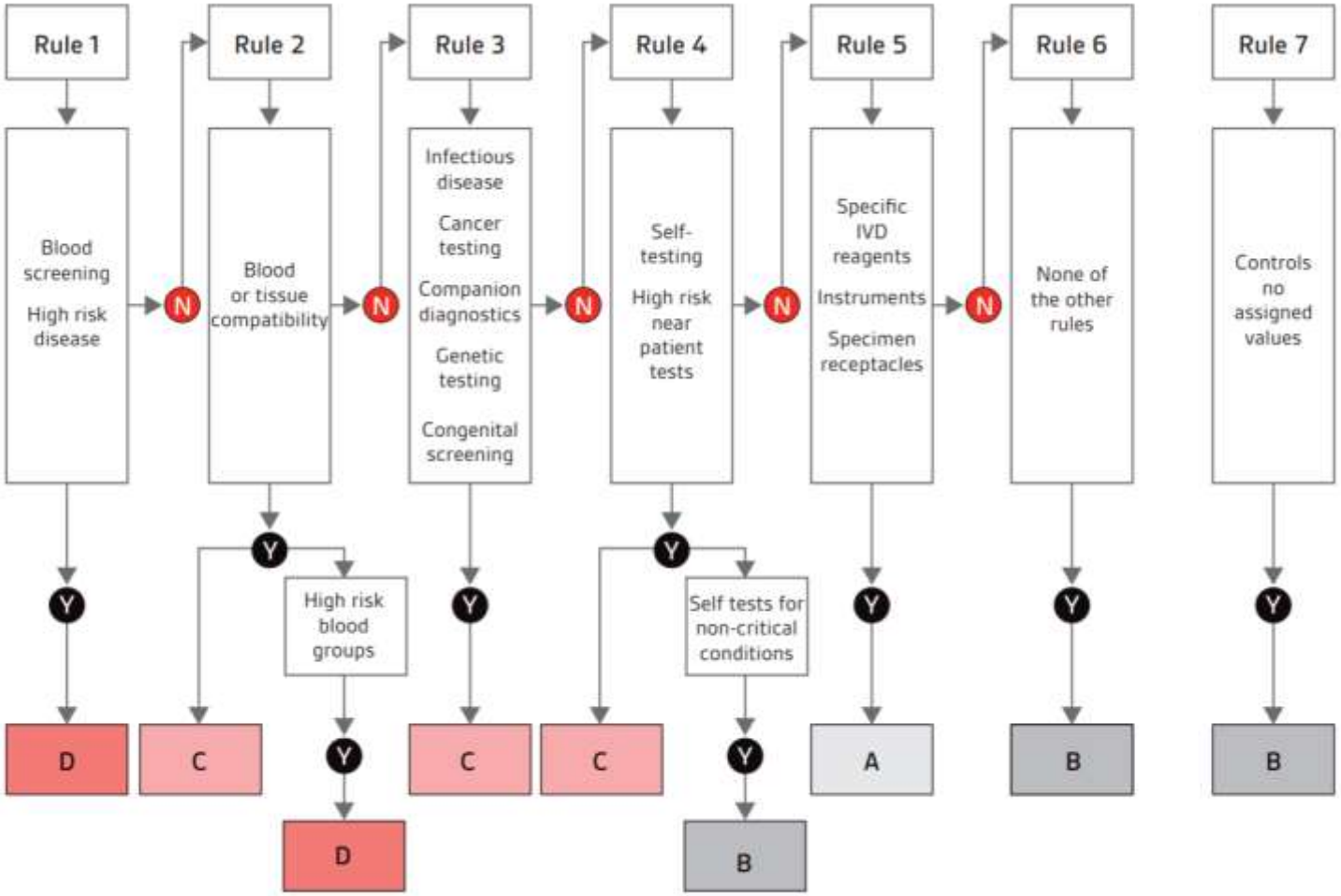
European patents for medical technology from the UK increased by 7.1% in 2017, overtaking transport as the UK's major technology field.

The figure comes from the European Patent Office's (EPO) annual report, which highlights the number of patents filed across Europe in 2017.

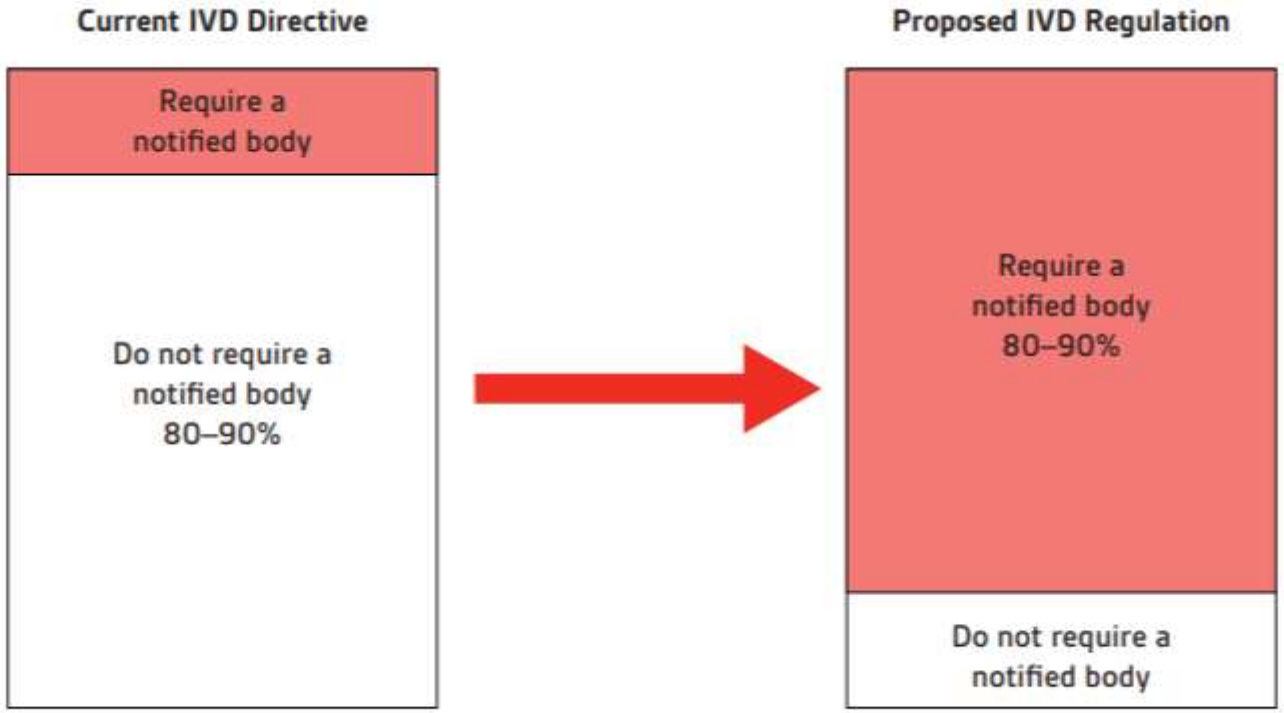
More exciting times



New classification rules



The quantum leap



Clinical evidence

“Confirmation of conformity with relevant general safety and performance requirements shall be based on scientific validity, analytical and clinical performance data providing sufficient clinical evidence.

“The manufacturer shall specify and justify the level of the clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

“To that end, manufacturers shall plan, conduct and document a performance evaluation.”

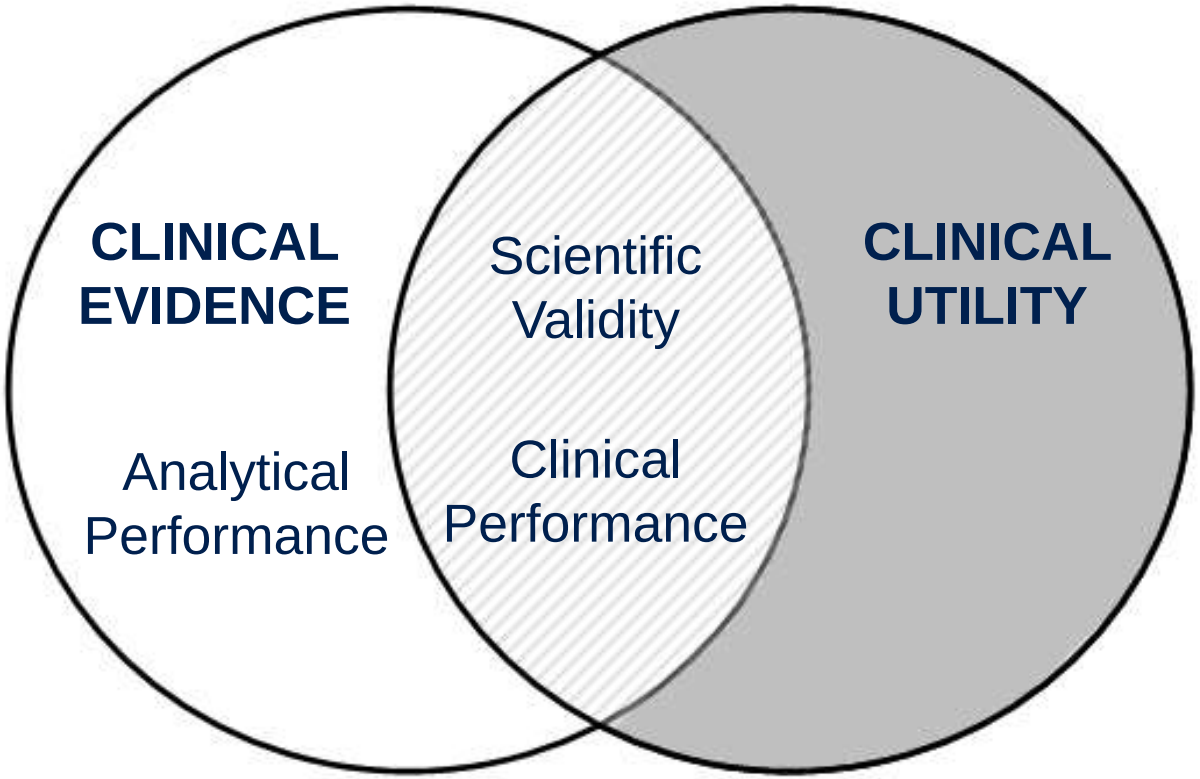
Terminology

Scientific validity: the association of an analyte to a clinical condition or a physiological state

Analytical performance: the ability of an IVD to correctly detect or measure a particular analyte

Clinical performance: the ability of an IVD to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with target population and intended user

Clinical evidence vs clinical utility



So…

All IVDs will need a new performance **evaluation**, which must be updated throughout the lifecycle of the product

Not all IVDs will need a new performance **study**

Performance studies

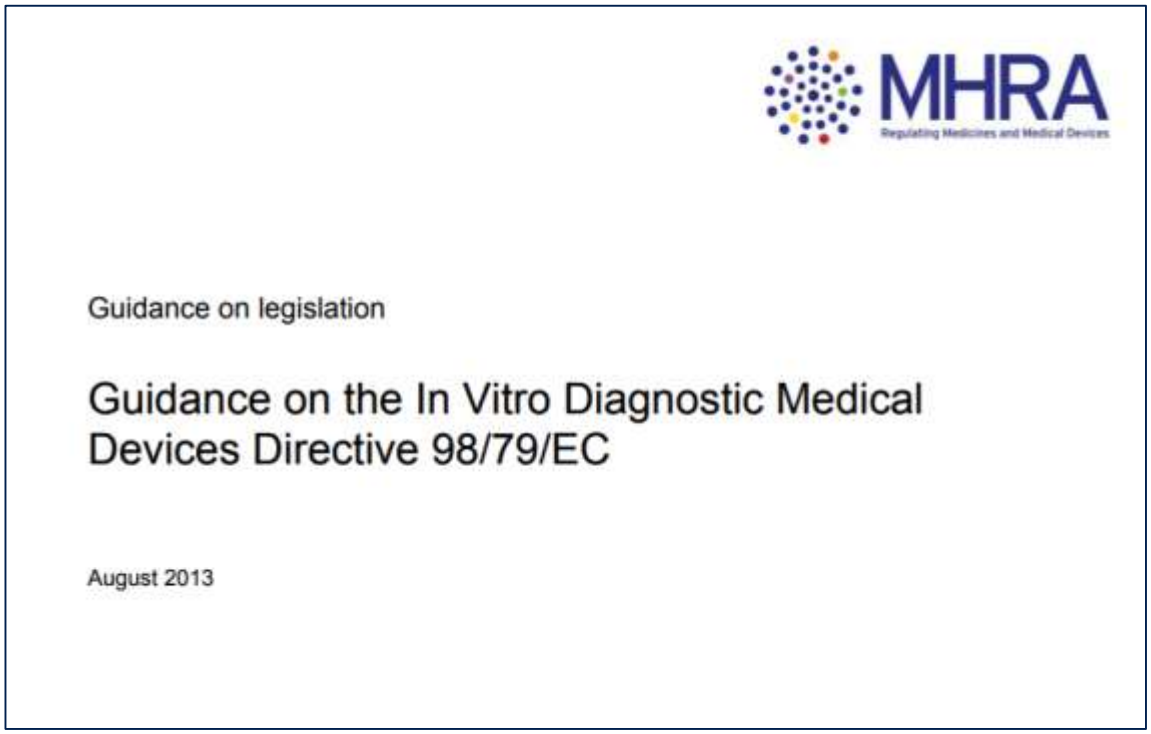
New concept – when gathering data to support CE marking

General requirements on all studies

Specific requirements – including competent authority approval – on:

- ‘interventional’ studies – affecting patient management decisions; and
- studies that involve invasive procedures or other risks for patients.

Health Institution Exemption

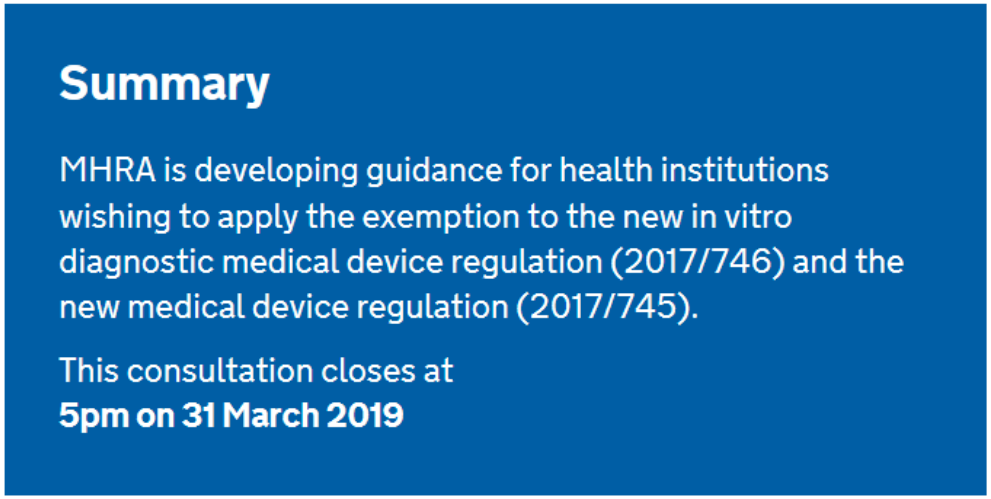


"Devices w… …l by health in… …only on their own patients ('in-house manu… …requirements of the Medical Devices Re… …2002

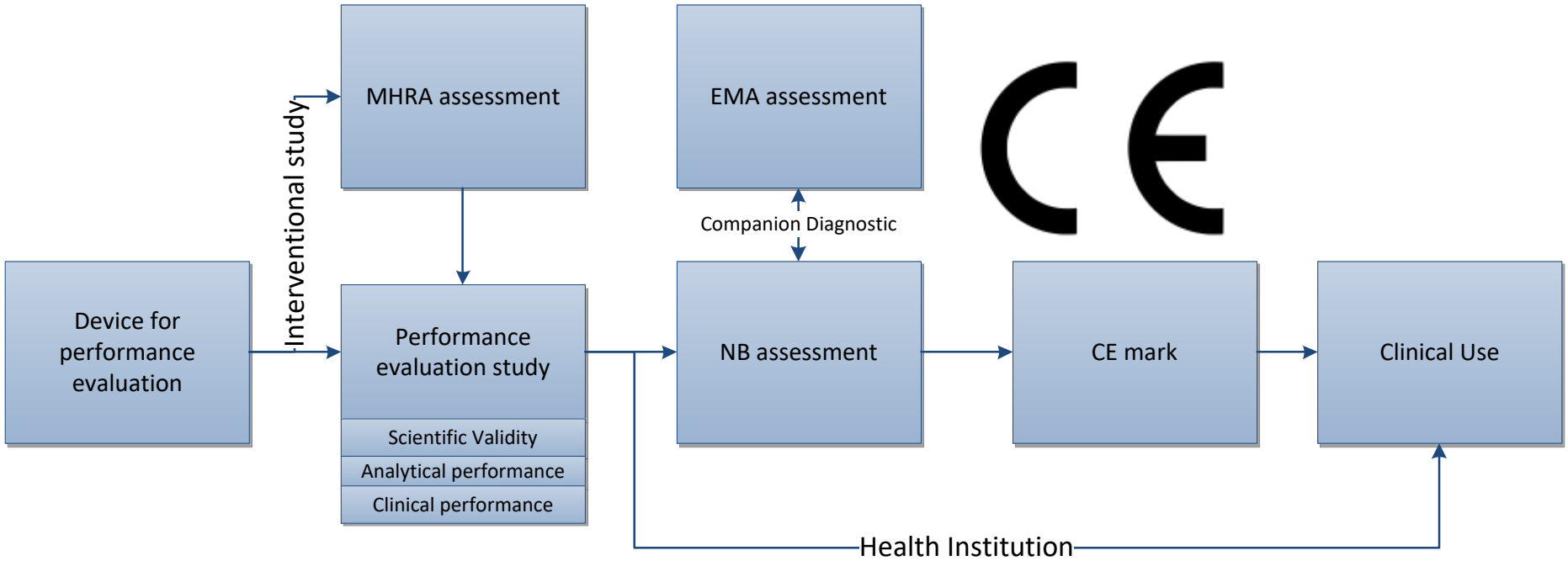
Health Institution Exemption

Exemption for devices used in the same health institution as they are made *or modified* provided:

- The exemption is justified
- An appropriate quality system is in place
- Some information is made publicly available
- The device meets all relevant GSPR
- (additional documentation requirements for some IVDs)



In summary…


MHRA assessment
EMA assessment
Interventional study
Companion Diagnostic
Device for performance evaluation
Performance evaluation study
Scientific Validity
Analytical performance
Clinical performance
NB assessment
CE mark
Clinical Use
Health Institution

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Thank you

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