Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MediWales & BIVDA: Diagnostics Industry Update

July 2015


CHANGE

The Future …

2015
Luxembourgish Presidency
Trilogue negotiations

2016
Dutch Presidency
Publication of final Regulations
(entry into force)

2017
UDI for Class D

2018

2019
MD Regulation
(date of application)

2020
UDI for Class B and C

2021
IVD Regulation (date of application)

2022
UDI for Class A

Anticipated changes (1)

- Risk-based classification rules
- Clinical evidence & clinical investigation
- ‘In-house’ exemption
- Companion diagnostics
- Notified bodies

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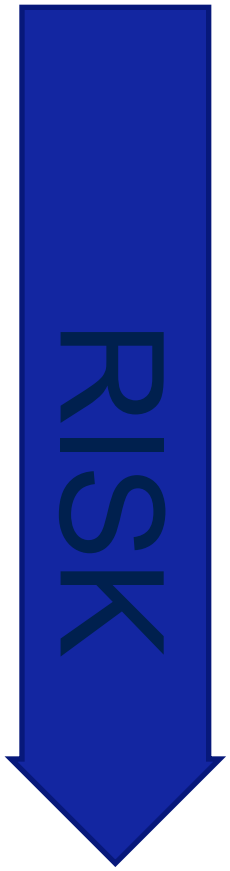
Classification

CLASS	RISK LEVEL
A	Low individual risk and Low public health risk
B	Moderate individual risk and/or Low public health risk
C	High individual risk and/or Moderate public health risk
D	High individual risk and High public health risk



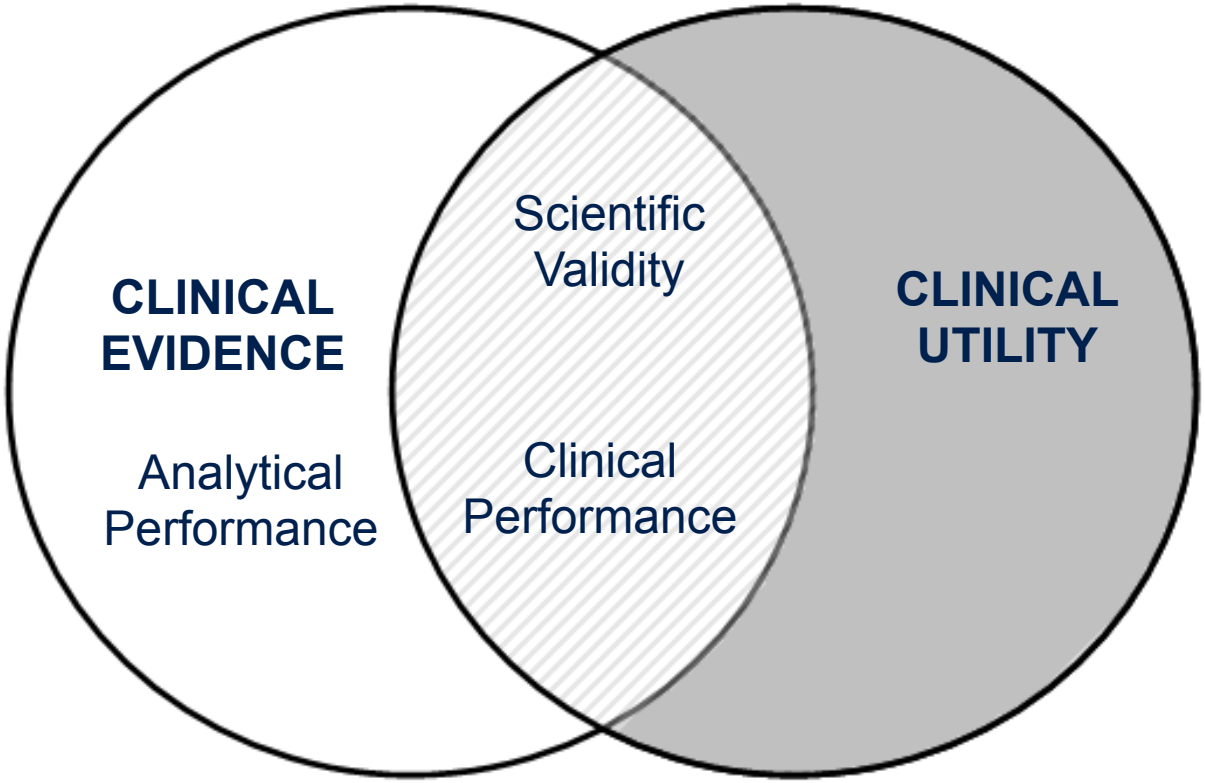
Clinical Evidence - Terminology

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

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

Clinical performance: the ability of an IVD to give results that are related to the clinical condition/ physiological state in the target population and intended user

Clinical evidence vs clinical utility



Clinical performance studies

General requirements on all studies when gathering data to support CE marking

Specific requirements (including competent authority approval) for

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

The ‘in-house’ exemption

Currently – blanket exemption for all IVDs manufactured and used within same health institution

Proposal:

- single quality management system
- accreditation to ISO 15189
- vigilance reporting
- Class A and B vs Class C and D?

Companion Diagnostics

Risk classification

Definition

Premarket scrutiny

Codevelopment

Notified Bodies

NB Reassessment

Joint audits of NB

Unannounced audits by NB

Anticipated changes (2)

- Qualified person
- UDI
- Common Specifications
- Economic Operators
- Two tier CE marking

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Coming up next…

Working Party to discuss outstanding technical issues and agree recitals (delayed from Tuesday)

Trialogue discussions after summer recess

MHRA preparing detailed plan for UK implementation of new Regulations, to be presented to stakeholders for discussion in September

Thank You!

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