

Clinical Evaluation of Class I Devices

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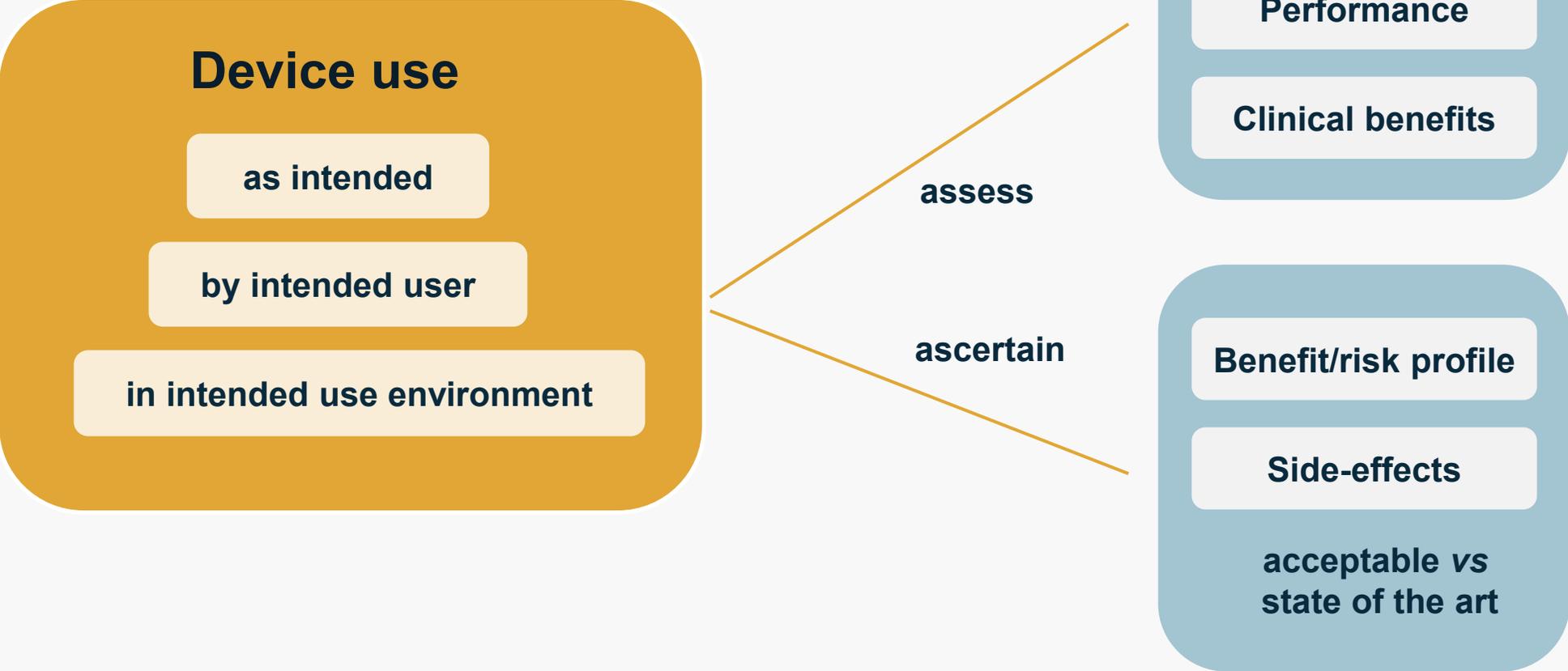
This presentation contains interpretations of the clinical evaluation requirements in the Medical Device Regulation* (MDR).

References to the full MDR text are provided at the bottom of the slides.

**Regulation (EU) 2017/745*

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Clinical Evaluation



Sufficient

Clinical Evidence

Clinical Evaluation Process



if needed

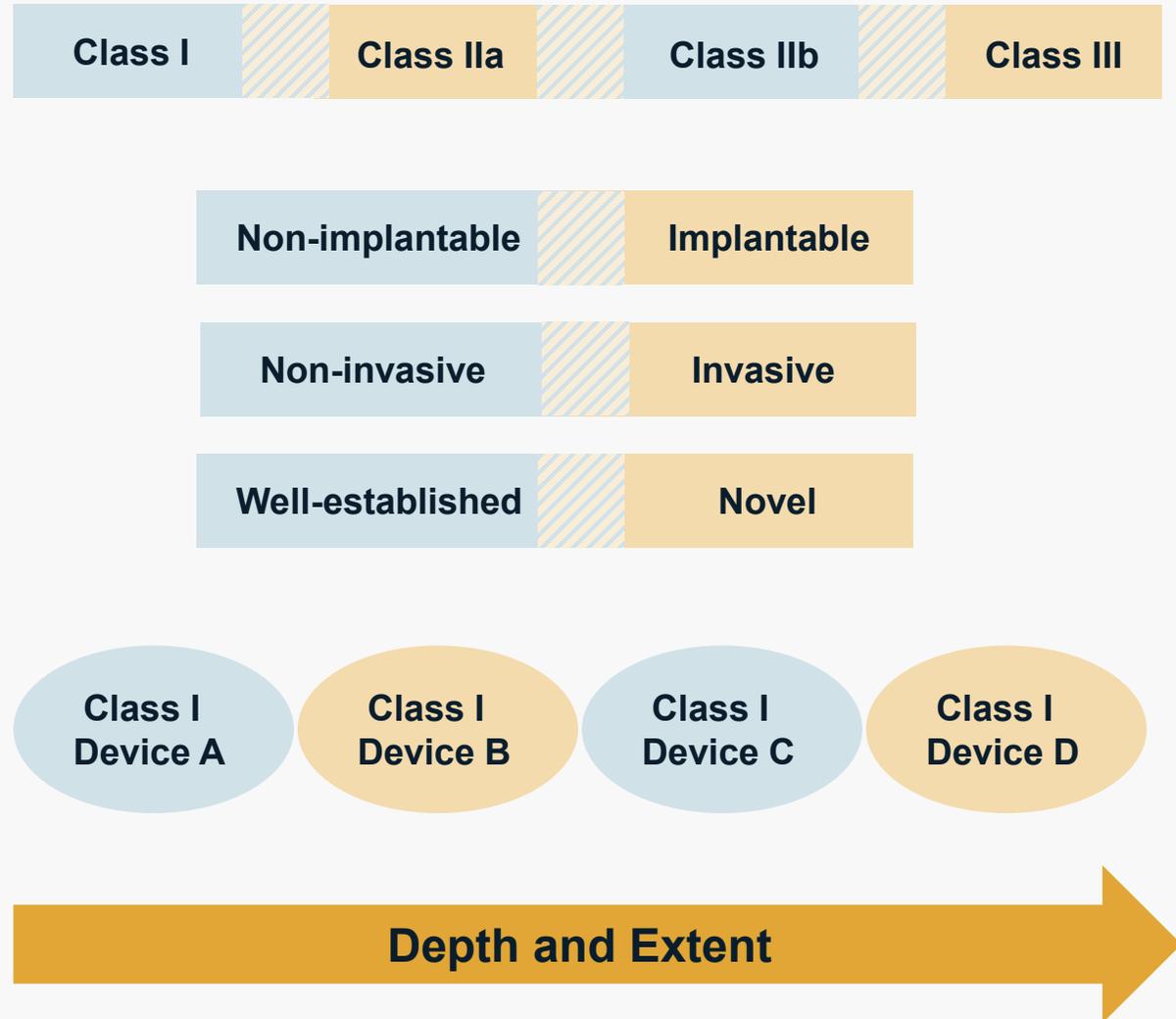
Clinical Evaluation

Required?

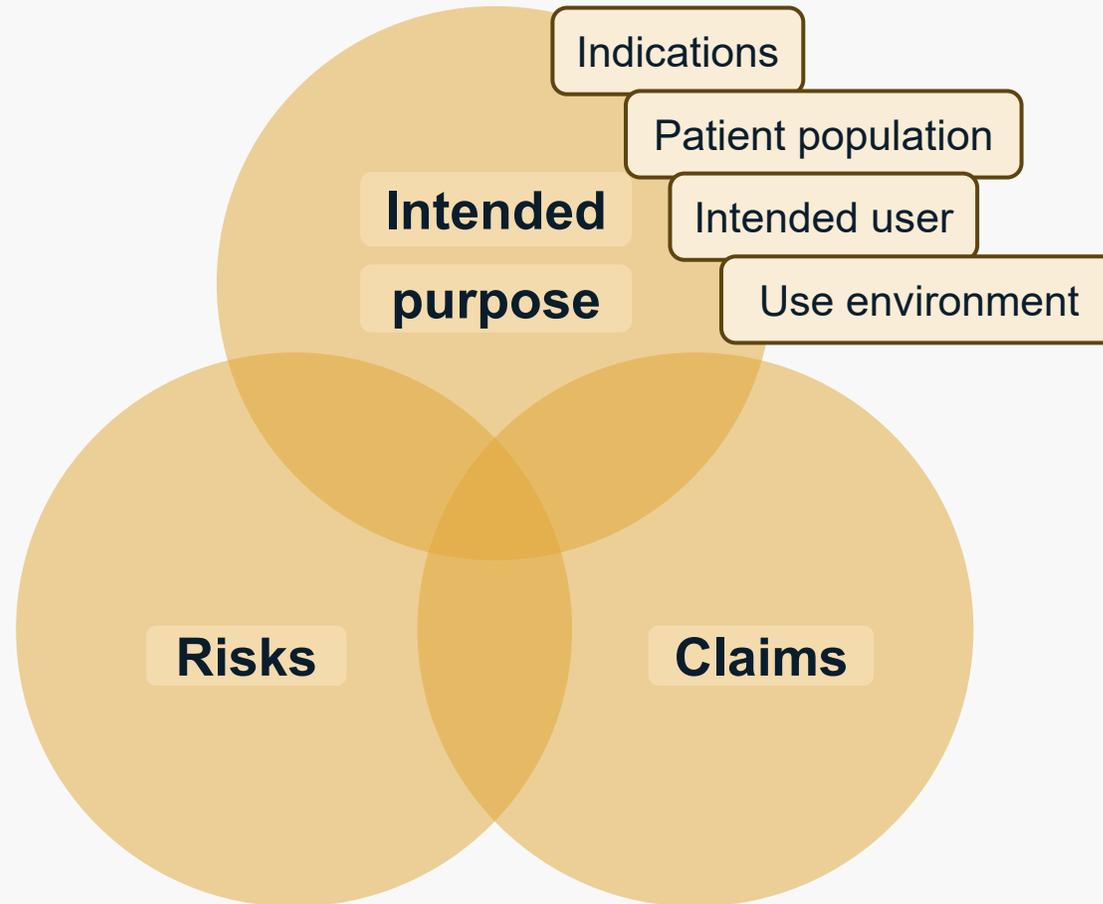
Yes

Adaptations possible?

Yes



How to decide depth and extent?



Clinical Investigation

Required?

No*

*Sufficient clinical
evidence is needed

A clinical investigation
may be required

A clinical investigation
is not always required



Clinical Data

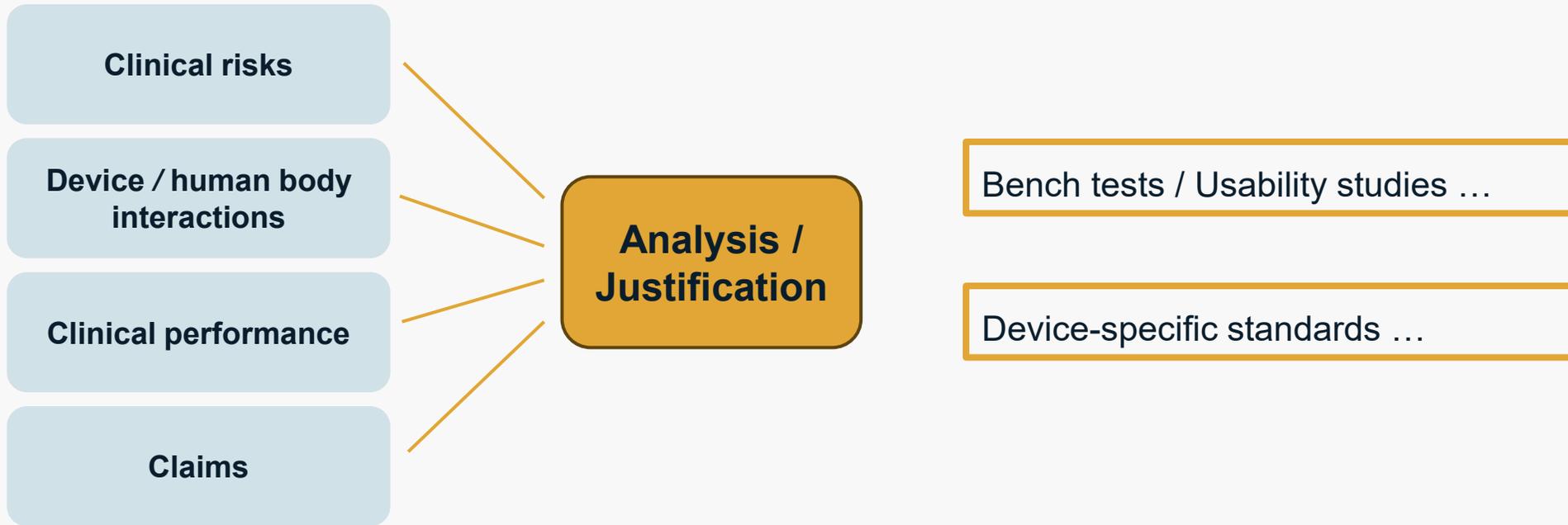
Required? As a general rule, yes

Adaptations possible? Yes

Information on safety or performance generated from the use of the device or an equivalent device

- Clinical investigations
- Scientific publications of clinical studies / clinical experience
- Post-market clinical-follow up / Post-market surveillance

**In exceptional cases, it is possible to CE-mark
a device without access to clinical data**



Literature Search

Required?

Yes

Adaptations possible?

Yes

Structured literature search is needed for all devices

State of the art

- Is there really a need?
- Alternatives?
- Benchmark devices?
- Guidelines?

Device under evaluation

- Clinical studies?
- Other clinical use?

Scientific literature – Device incidents – (Clinical trials)

Appraisal

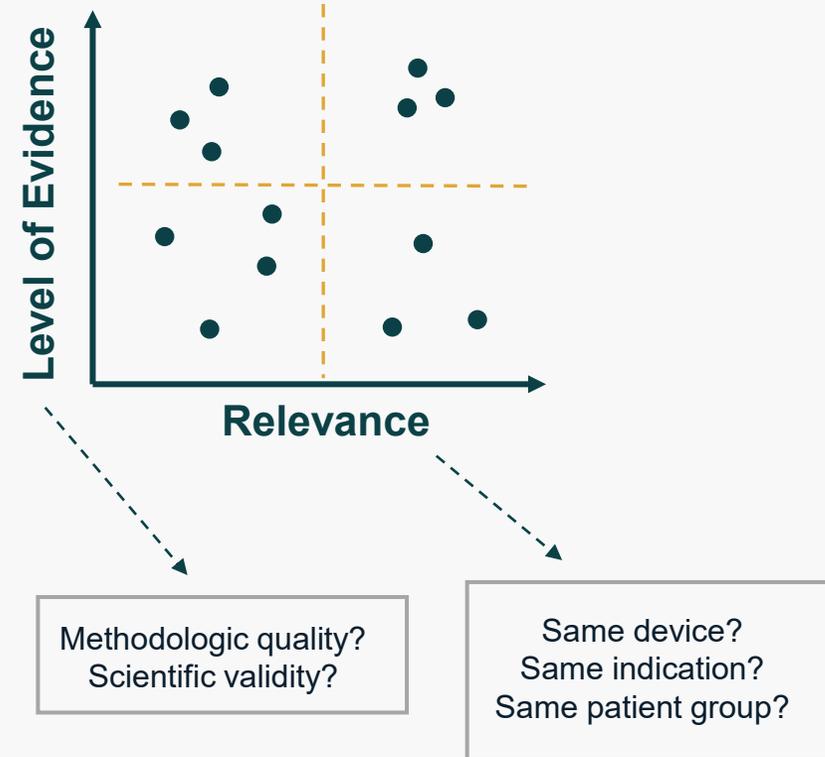
Required?

Yes

Adaptations possible?

Yes

- All clinical data are expected to be appraised:
 - scientific publications
 - clinical investigations
 - post-market data
- Quantitative vs Qualitative
- Scientific publications – systematic appraisal, pre-defined criteria

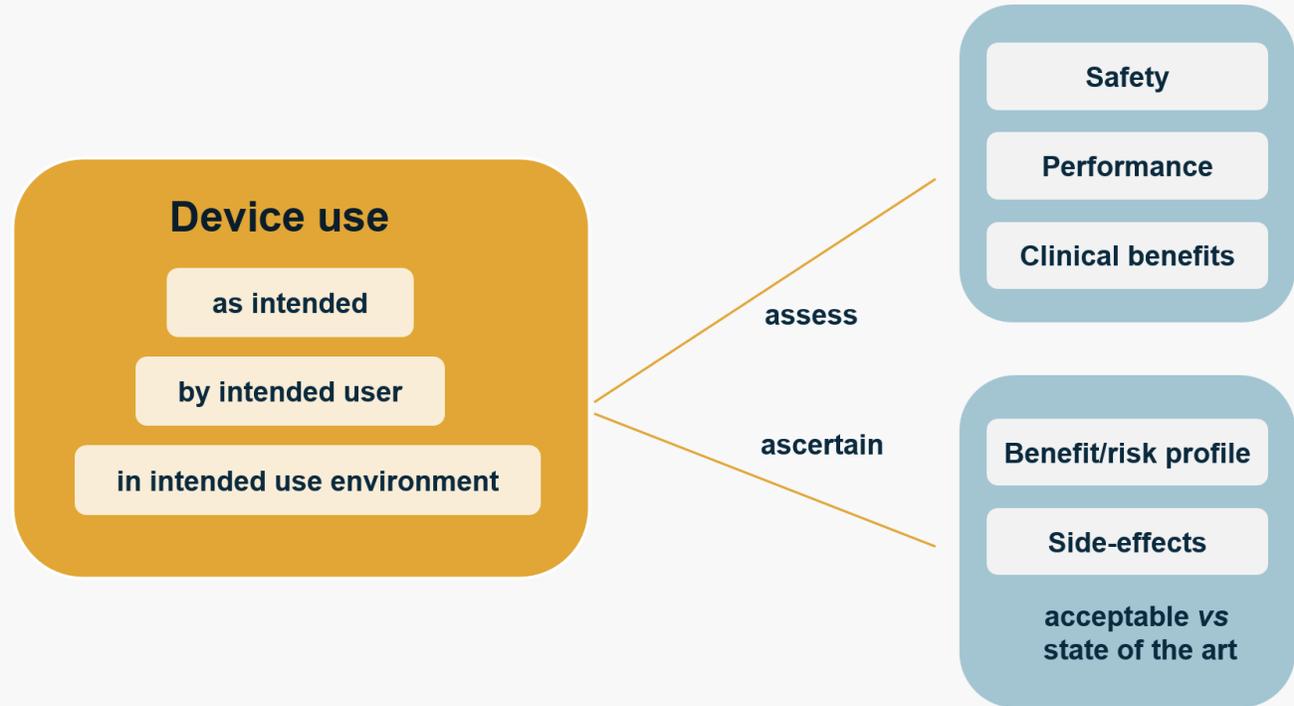


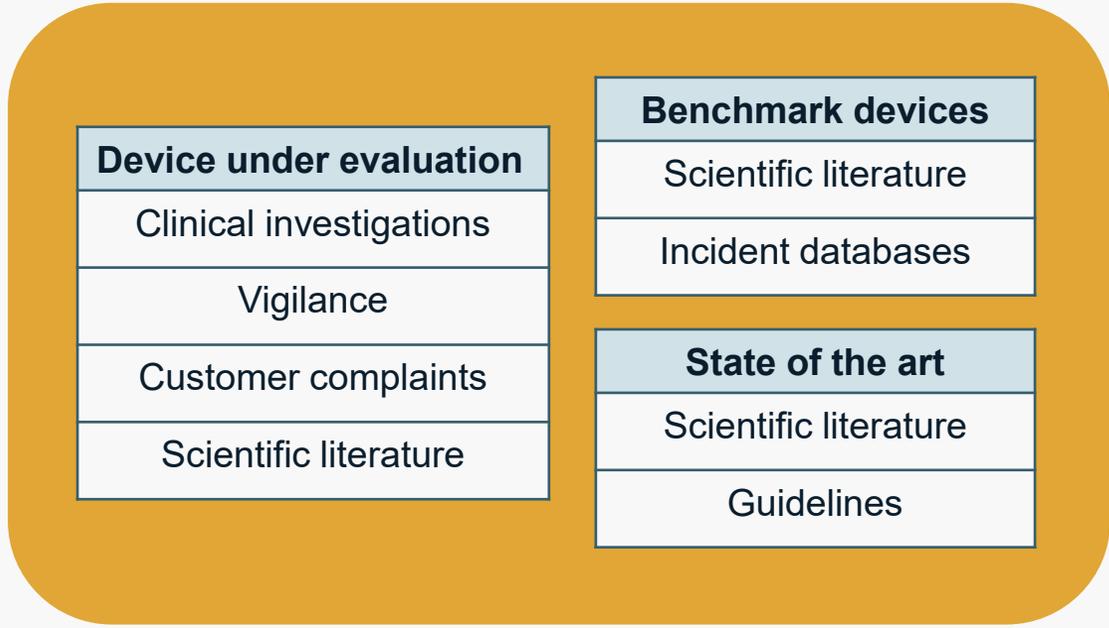


Analysis

Required? Yes

Adaptations possible? Yes





Safety

Performance

Clinical benefits

Claims

Side-effects

Benefit-risk ratio

Remember that state of the art may change over time

Clinical evaluation

All devices

**Sufficient clinical
evidence**

All devices

Clinical data

Most devices

Clinical investigation

Many devices

