Discussion of Essential Requirements (GSPRs) in CERs

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Which GSPRs should be included in the Conclusions section of a CER?

Analysis of Performance and Safety of a clinical device is practically the section where clinical data are analysed and discussed with respect to General Safety and Performance Requirements (GSPRs) outlined in Annex I of EU-MDR 2017/745.
However, this section should not be mistaken for a section that will only summarize the safety and performance and the acceptability of benefit-risk profile of the device.

Analysis of and conclusions on clinical data should include an assessment of compliance with **ALL** applicable GSPRs, i.e.

✓ GSPRs 1-9 should be discussed for all medical devices regardless of class:

- ❑ General Requirements on Safety
- ❑ General Requirements on Performance
- ❑ General Requirements on acceptability of Side-effects
- ❑ General Requirements on Acceptability of Benefit-Risk profile
- ❑ General Requirements on Labels and packaging

Generic discussion to be included in all CERs

✓ Adequacy of Instructions of Use (GSPR 23.4) should be discussed for classes where IFUs are required

✓ Discussion of specific Requirements should be discussed on a case-per-case scenario based on a given medical device, e.g.

- ❑ Requirements on devices incorporating phthalates (GSPR 10.4.3) or endocrine disruptors (GSPR 10.4.4)
- ❑ Requirements on devices incorporating materials of biological origin (GSPR 13)
- ❑ Requirements on devices emitting hazardous or potentially hazardous radiation (GSPR 16)
- ❑ Requirements on devices that incorporate electronic programmable systems (GSPR 17)
- ❑ Particular Requirements for active implantable devices (GSPR 19)

Do not forget to add a concluding statement for the sufficient substantiation of Clinical Benefits.
The clinical benefit(s) of the medical device, which will be included in the Instructions of Use (IFU) (where applicable), should be substantiated by:

- ❑ pre-clinical data (i.e. verification & validation testing),
- ❑ data generated and held by the Manufacturer based on their clinical and PMS program,
- ❑ device-specific data identified in the literature