



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

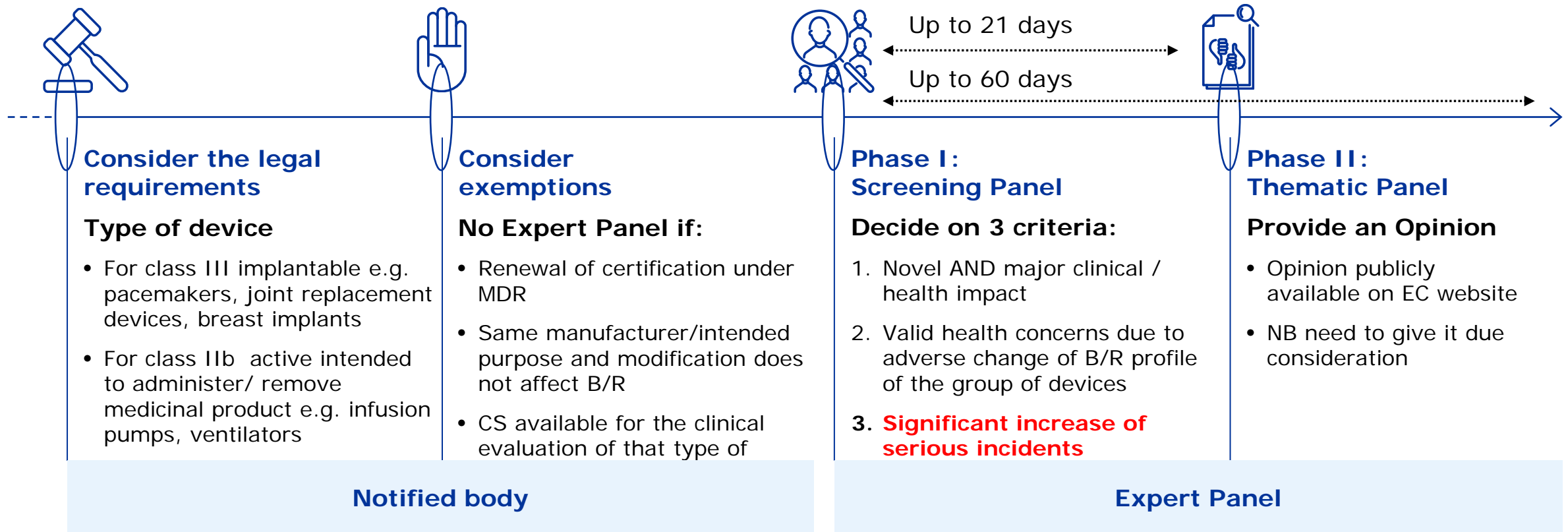
Overview of the screening criteria for the clinical evaluation consultation report (CECP)

CORE-MD Webinar: IT tools for regulatory science
5th December 2023

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Clinical Evaluation Consultation Procedure (CECP)

Provide an opinion on the notified bodies' assessment of the clinical evaluation of certain high-risk medical devices



Clinical Evaluation Consultation Procedure (CECP)

- All Class III implantable devices
- 10 Opinions delivered in total
 - 8 based on criterion 1 (clinical/health impact related to novelty aspects)
 - 2 based on criterion 2 (valid health concerns for a specific group/category of devices)

Thematic area	Number of opinions	Type of device
Circulatory system	5	- Transcatheter pulmonary valve - Transcatheter aortic valve - Transcatheter tricuspid valve replacement - Bioabsorbable stent (paediatric use) - Extravascular ICD
Orthopaedics, traumatology, rehabilitation, rheumatology	2	- Hip prosthesis - Shoulder prosthesis -> criterion 2
General and plastic surgery and dentistry	2	- Bone filler - Resorbable hernia surgical mesh -> criterion 2
Neurology	1	- Implantable neurostimulator
Total	10	