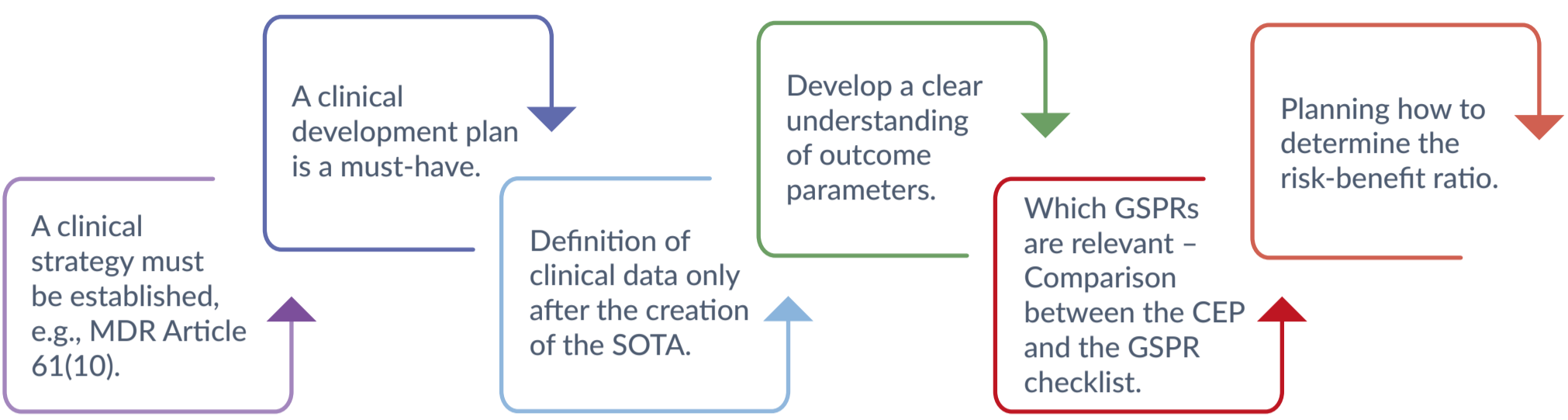
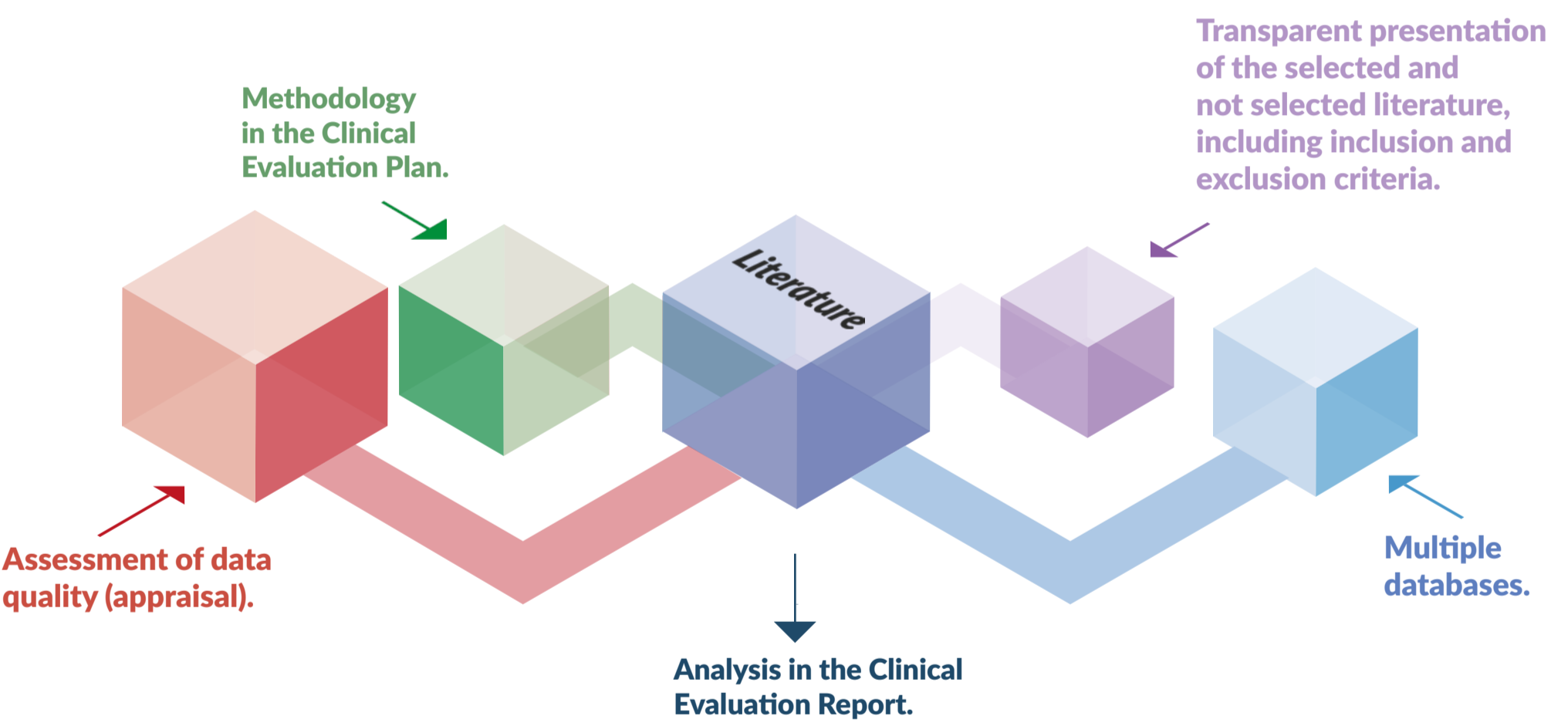


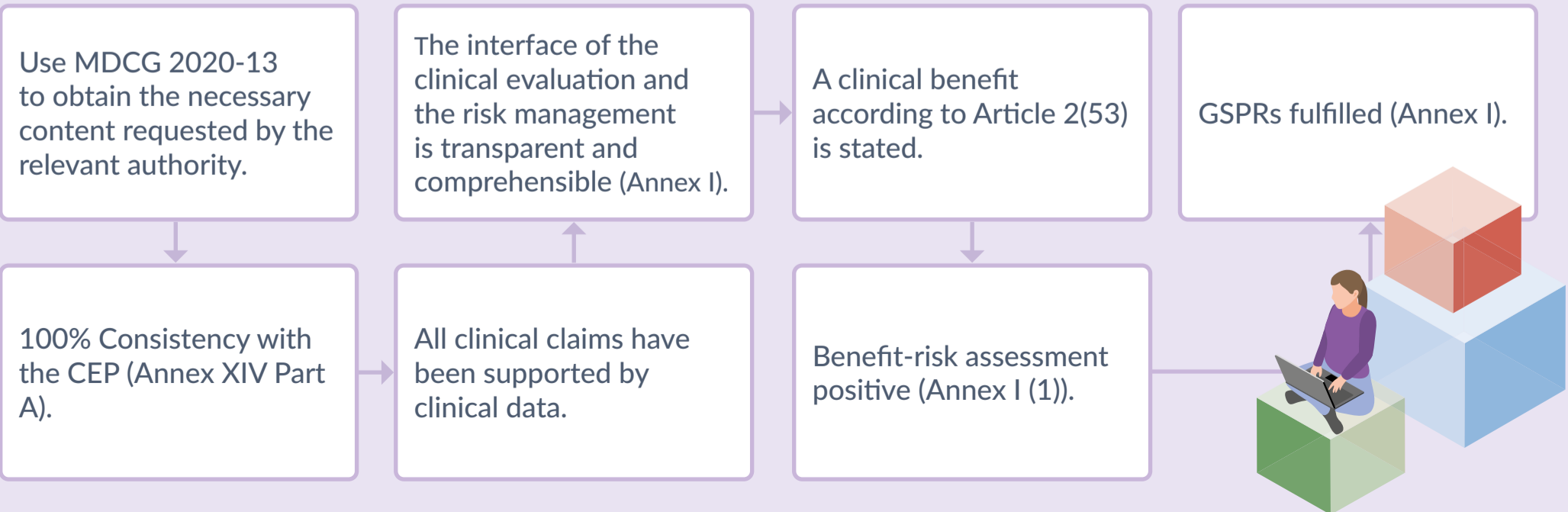
Clinical Evaluation Plan – CEP



Literature: Planning, selection, and evaluation

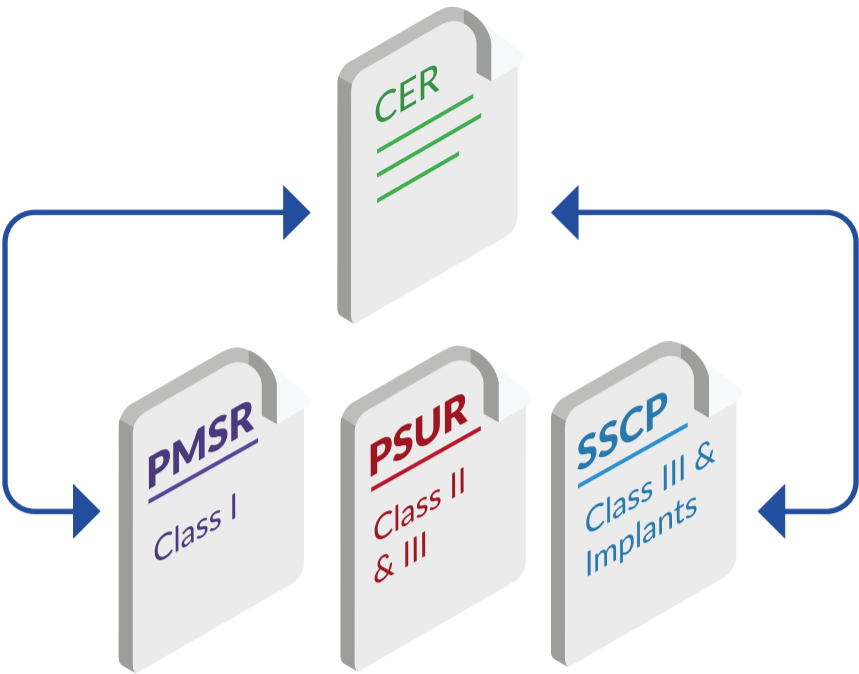


Clinical Evaluation Report – CER



PMSR / PSUR / PMCF

- ✓ Use Annex XIV Part B!
- ✓ Use MDCG 2020-7 and 2020-8 templates!
- ✓ Data are consistent with the CER.



SSCP

- ✓ The SSCP is primarily sourced from the clinical evaluation.
- ✓ The layperson section of the SSCP must undergo a readability test!
- ✓ Consider MDCG 2019-3!

Note:
Corrective and preventive actions are in accordance with the Clinical Evaluation Plan and the Clinical Evaluation Report.

PSUR

- ✓ Observe MDCG 2022-21
- ✓ Define Update Interval
- ✓ Sales figures and, if applicable, frequency of use must be considered!

Part of TD, available for NB and Authorities on request		sampling
Risk class and attribute of device	Update frequency	
Class IIb MD (other than implantable devices)	annually	
Class IIa MD (other than implantable devices)	biennially	
NB considers PSURs and update intervals during TD assessments und auditing (sampling)		

To be submitted to NB for review - via EUDAMED if available		100% review
Risk class and attribute of device	Update frequency	
Class III (including class III implantable devices)	biennially	
Class IIb implantable devices	annually	
Class IIa implantable devices	annually	
NB provides their „Evaluation of PSUR“ to Competent Authorities - via EUDAMED if available		