

# Sources of Clinical Data for Clinical Evaluation Reports



## Sources of Clinical Data and rationale for their Use in a Clinical Evaluation Report

Type of Source	Applicable to State of the Art	Applicable to similar/benchmark devices	Applicable to device under evaluation
Peer-reviewed published literature	✓ <b>Note:</b> Priority to be given in meta-analyses, systematic reviews and reviews	✓	✓
Grey literature, including all non-peer reviewed sources	No	On a case per case scenario depending on data contribution suitability criteria set by the appraisal plan. <b>Note:</b> Typically, this source will provide low level of evidence. Use it wisely and always provide a rationale for the reason of inclusion	
Clinical Practice Guidelines/	✓ Clinical Practice Guidelines should always be thoroughly discussed in the SotA section as they collect and interpret safety and performance data for all alternative treatment options for a given medical field from a clinical perspective	No	No
Technical/ Standards Harmonised	No	No	✓
Expert opinion(s)	No	No	On a case per case scenario depending on data contribution suitability criteria set by the appraisal plan. <b>Note:</b> Typically, this source will provide low level of evidence. Use it wisely and always provide a rationale for the reason of inclusion
Risk management output	No	No	✓
Pre-clinical evaluation, including design verification/ bench testing and/or animal testing if applicable	Typically no, but it might be necessary to discuss pre-clinical data depending on intended medical field (e.g. biomechanical data)	✓ <b>Note:</b> Typically no but for some cases it might be necessary to retrieve and discuss them. i.e. when the basic function of the device is directly dependent on bench testing and will determine whether the device is performing its intended purpose	✓
Manufacturer PMS data (internal) <input type="checkbox"/> PMS reports <input type="checkbox"/> Complaints, CAPAs <input type="checkbox"/> PMCF Studies <input type="checkbox"/> Manufacturer's device registry	No	No	✓
Device registries	On a case per case scenario depending on data contribution suitability criteria set by the appraisal plan. <b>Note:</b> Typically, clinical data from device registries should be retrieved from literature	✓	✓
Clinical studies databases (ClinicalTrials.gov, clinicalregister.eu etc.)	On a case per case scenario depending on data contribution suitability criteria set by the appraisal plan. <b>Note:</b> Typically, clinical data from this source would be discussed in the device-specific data section or in the state of the art section discussing similar/benchmark devices if clinical data from other sources were deemed insufficient	✓	✓
Regulatory and vigilance databases including safety alerts and field corrective actions	On a case per case scenario depending on data contribution suitability criteria set by the appraisal plan. <b>Note:</b> Typically, clinical data from this source would be discussed in the PMS section of a CER and in the section discussing conformity with GSPRs	✓	<b>Tip:</b> Expand your searches in vigilance databases to similar/benchmark devices. This will provide you with safety info for the intended medical field as well! ✓

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