State of the Art and EU-MDR /IVDR

State of the Art ⇒ noun
VS.
State-of-the-art ⇒ adjective

STATE OF THE ART
≠
STANDARDS OF CARE

✓12 mentions in EU-MDR
✓20 mentions in EU-IVDR
✓ 0 definitions

State of the Art is **NOT**

- The most innovative
- The most technologically advanced
- The most expensive
- The most frequently used
- The less ‘’dangerous’’ (use-associated risks)

State of the Art is bounded by
-intended use
-medical field

State of the Art and EU-MDR /IVDR

ISO 14971, 2019

Developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience

Note 1 to entry: The state of the art embodies what is currently and generally accepted as good practice in technology and medicine. The state of the art does not necessarily imply the most technologically advanced solution. The state of the art described here is sometimes referred to as the “generally acknowledged state of the art.

Taken from ISO/IEC Guide 63:2019, 3.18

MDCG 2020-6, according to IMDRF/GRRP WG/N47

Developed stage of current technical capability and/or accepted clinical practice in regard to products, processes and patient management, based on the relevant consolidated findings of science, technology and experience’.

Note: The state of the art embodies what is currently and generally accepted as good practice in technology and medicine. The state of the art does not necessarily imply the most technologically advanced solution. The state of the art described here is sometimes referred to as the “generally acknowledged state of the art.

MEDDEV 2.7.1. rev4

Includes applicable standards and guidance documents, data that relate to benchmark devices, other devices, critical components and medical alternatives or to the specific medical conditions and patient populations intended to be managed with the device. The data are typically needed in order to - describe the clinical background and identify the current knowledge/ state of the art in the corresponding medical field, - identify potential clinical hazards (including hazards due to substances and technologies, manufacturing procedures and impurity profiles), - justify the validity of criteria used for the demonstration of equivalence (if equivalence is claimed), - justify the validity of surrogate endpoints (if surrogate endpoints are used). [...] A review of the current knowledge/ the state of the art needed for the proper conduct of the appraisal and analysis of the clinical data of the device under evaluation and the equivalent device (i.e. applicable standards and guidance documents, information on the medical conditions that are relevant to the clinical evaluation, therapeutic/ management/ diagnostic options available for the intended patient population, etc.)

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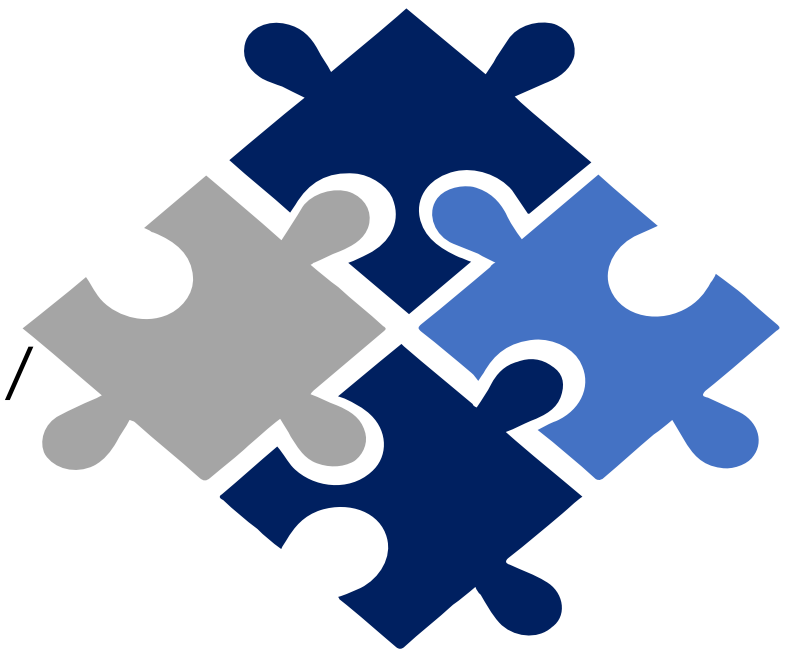
State of the Art is expected to

- ❑ Frame the device in scope within the intended medical field AND respective alternative treatment options
- ❑ Define safety and performance endpoints to be used for the assessment of clinical data in all relevant CER sections (including PMS + literature + RM)
- ❑ Provide evidence for the assessment of risk management data
- ❑ Provide criteria AND evidence for the acceptability of benefit-risk profile
- ❑ Explain/corroborate equivalence criteria

Sources of data for State of the Art

- ❑ Literature databases
- ❑ Manufacturer documentation (own device AND similar /benchmark / equivalent devices)
- ❑ Applicable Standards
- ❑ Up-to-date Guidelines applicable to the intended medical field
- ❑ External vigilance data



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Evnia
To Strive · To Seek · To Find

Steps for a comprehensive development of State of the Art

- ❑ Formulate the research questions to reflect the aspects to be discussed (see previous page). Find the balance point between sensitivity and specificity

Note: *Increasing search sensitivity tends to reduce specificity (search precision)*

- ❑ Divide searches into concepts (e.g. use PICO model)
- ❑ Select databases and build a rationale for the selection
- ❑ Identify search terms and keywords. Combine concepts with Boolean operators (OR, AND, NOT) and proximity operators (near /next) to build your final algorithm
- ❑ Include additional search options, e.g. filters such as dates of search, truncation, wildcards and build a rationale for the selection
- ❑ Implement searches (you may need to run a few pilot searches to optimize results)
- ❑ Manage the retrieved results with reference management software
- ❑ Appraise search results based on data contribution, data suitability and levels of evidence

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What to discuss in the State of the Art section of a CER

- ❑ Identification and historical perspective of the intended medical field
- ❑ Identification and discussion of the intended medical condition (pathophysiology, clinical manifestations, epidemiology etc.)
- ❑ Applicable Standards and Guidelines
- ❑ Alternative treatments options for the Intended Use

(available options / available technologies : benefit-risk profiles and their acceptability, harms, management of side effects and risk mitigation approaches; diverging opinions related to available treatment options)

- ❑ Similar/ benchmark devices: technical features, available clinical data, benefit-risk profile and its acceptability
- ❑ Intended users
- ❑ Unmet clinical needs on the intended medical field / intended use