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STATE OF THE ART

Quick Guide to an EU MDR State of the Art Review

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Quick Guide

To an EU MDR State of the Art Review

What is state of the art?

The STATE-OF-THE-ART embodies what is currently and generally accepted as good practice in technology and medicine.

- Applicable standards and guidance documents.
- Information relating to the medical condition managed with the device and its natural course.
- Benchmark devices, and other devices and medical alternatives available to the target population.

Why do a state of the art literature review?

- A critical part of the new EU MDR process.
- A need to describe the clinical background and identify the current knowledge/state of the art in the corresponding medical field.
- Required to define acceptability criteria for the evaluation of the benefit/risk profile and of specific side-effects of the device under evaluation.

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Search key sites online:
Click to connect:

ECRI Trip PROSPERO CADTH Evidence Driven.

How to do a state of the art literature search?

- Use your indication and target population to help generate search terms.
- If possible, engage a librarian (for more information visit https://www.mlanet.org/).
- Use synonyms, singular/plural forms, verbal forms, adjectives, different spellings.
- Be aware of classification terms used by databases.
- Consider using Boolean search operators to broaden or narrow your search: 'AND', 'OR', 'NOT'.
- Consider using more than one database (e.g., Medline & Embase)
  Visit PubMed for a tutorial on conducting a search! (pubmed.ncbi.nlm.nih.gov)

Make sure to design your search to include narrative reviews, systematic reviews, meta-analyses, health technology assessments, and clinical practice guidelines!

Appraising your evidence!

What is critical appraisal?

Critical appraisal is the course of action for watchfully and systematically examining research to assess its reliability, value and relevance in order to direct professionals in their vital clinical decision making[1].

Did the clinical research study:

- Address a clearly focused research question?
- Use valid methods to address the research question?
- Have results that were clinically relevant?
- Have results that were applicable to your device and target population?

[1]Burls A. What is critical appraisal? London: Hayward Medical Communications; 2016. Available from: http://www.whatisseries.co.uk/what-is-critical-appraisal/

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Consider using the Appraisal criteria for Suitability and Data Contribution[2].
Consider using the OCEBM levels of evidence in your appraisal[3].

For more about appraisals click:

For appraising narrative reviews: SANRA, the Scale for the Assessment of Narrative Review Articles.

The appraisal plan for clinical research studies typically includes:

- Criteria for determining the methodological quality and the scientific validity of each data set.
- Criteria for determining the relevance to the clinical evaluation (relevance to the device and to the different aspects of its intended purpose).
- Criteria for weighting the contribution of each data set to the overall clinical evaluation.

The State of the Art report should include[4]:

- ☑ Identification of medical fields concerned/relevant medical conditions.
- ☑ Brief summary and justification of the literature search strategy applied for retrieval of information on current knowledge/the state of the art, including sources used, search questions, search terms, selection criteria applied to the output of the search, quality control measures, results, number and type of literature found to be pertinent.
- ☑ Appraisal criteria used.
- ☑ Applicable standards and guidance documents.
- ☑ Description, natural course and consequences of the medical conditions concerned. Whether there are different clinical forms, stages and severities of the conditions. Frequency in the general population, by age group, gender, ethnicity, familiar predispositions, genetic aspects.
- ☑ Description of available therapeutic/management/diagnostic options, historical context and developments, summary of advantages and disadvantages of the different options, benefit/risk profiles and limitations in relation to the different clinical forms, stages, and severities of the medical conditions and in relation to different target populations.

[2]For an example, refer to Appendix D of the GHTF SG5 document N2R8:2007 on Clinical Evaluation (Appendix D: A Possible Method of Appraisal)

[3]OCEBM Levels of Evidence Working Group. "The Oxford Levels of Evidence 2". Oxford Centre for Evidence-Based Medicine. https://www.cebm.net/index.aspx?o=5653

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The State of the Art report should include[4]:

- ☑ Description of the benefits and risks (nature, extent, probability, duration, frequency), acceptability of undesirable side-effects and other risks (including the nature, severity, probability and duration of acceptable harm).
- ☑ Hazards due to substances and technologies that could be relevant to the device under evaluation.
- ☑ The mechanisms of harm, clinical aspects of minimization and management of side effects and other risks.
- ☑ Types of users.
- ☑ Diverging opinions of professionals as to the use of the different medical options.
- ☑ Unmet medical needs.

Qualitative and quantitative analyses!

- ★ The methods available for analyzing clinical data generally are either qualitative or quantitative.
- ★ Depending on the nature of the medical device and the circumstances, it is likely that qualitative (i.e. descriptive) methods will need to be used for some devices.
- ★ Reliance on qualitative methods should be justified.
- ★ Generally, available clinical data such as numbers of incidents in the post market phase should be assessed quantitatively in relation to current knowledge/ the state of the art.

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[4]Guidelines on medical devices. Clinical evaluation: A guide for manufacturers and notified bodies under Directives 93/42/EEC and 90/385/EEC (MEDDEV 2.7/1 revision 4). 2016.