Written comments on the revision of EUnetHTA's methodological guideline of process of information retrieval

Ecker + Ecker GmbH, a healthcare consultancy based in Germany with strong expertise in the early benefit assessment, is welcoming the effort by the EUnetHTA to provide a framework that allows for a structured and evidence-focused HTA process. The development and constant evaluation of the according methodology is key for a standardized and unbiased development of HTA documents.

The "Process of information retrieval for systematic reviews and health technology assessments on clinical effectiveness" document, as of August 2019 in version 2.0, is an essential guideline that meets the criteria for a systematic research process, leading to the identification of the accessible information in its entirety and thus allowing the evidence-based assessment of the identified data set.

While the guideline in its current form is of high quality in general, we identified several aspects that should be addressed before the finalized version 2.0 is published. They are described in detail below.

Major: Citing the "European Medicines Agency – Clinical data" website

- In line 825 ff., the guideline is citing the "European Medicines Agency – Clinical data" website as an appropriate source for regulatory documents including clinical study reports. While this may be the case in general, the publication of new clinical data is currently suspended due to the relocation of the agency to the Netherlands. No date has yet been communicated by when the EMA will resume the publication of new clinical data.
- Therefore, the website in its current state is not a reliable source for regulatory documents and should be treated as such. We propose the following wording instead (changes highlighted in red):
  - → "In addition, EMA introduced Policy 0070 on data transparency, which became effective in October 2016 [197,198]. Regulatory documents, including CSRs on all drugs submitted for approval, have since been available on the Agency´s website "European Medicines Agency – Clinical data" [199]. However, publication of clinical data is temporarily suspended and the database is currently not up to date."

Minor: Flawed reference

- Reference 148 is flawed.
- The cited link to the German Clinical Trials Register is invalid. Instead, the following URL should be cited: https://www.drks.de/drks_web/
- Furthermore, the DRKS is now associated with the German Institute of Medical Documentation and Information (DIMDI), not the University of Freiburg.

Linguistic: Formatting of tables

- For tables, captions should be placed above the table, not below.
- In general, the formatting of the tables in the document is not consistent. Most of the tables are not numbered. Some headings are bold, some are not. One table features a gray background, the others do not. A consistent formatting increases readability and orientation within the document.

The guideline is available here:
https://www.eunethta.eu/the-public-consultation-of-the-revision-of-the-methodological-guideline-process-of-information-retrieval-for-systematic-reviews-and-health-technology-assessments-on-clinical-effectiveness/

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