Clinical trials on medicinal products that include as an integral part a device component

Depending of the type and regulatory status of the device component, the following information/documents need to be submitted in the eDok folder “21 MEP” as part of the CTA:

MD-component is CE-marked

When the device component provided is available as a physically separate entity, it is sometimes CE-marked (e.g. a CE-marked empty syringe). Only the following information is then needed:

- Information on the conformity of the MD (declaration of conformity, if applicable the conformity assessment certificate issued by a notified body)
- CE-marked instructions for use (check whether in line with the use in the trial)

MD-component is not CE-marked

- As part of the Investigator's brochure or as a separate document the information in accordance with Regulation (EU) 2017/745 (section 2 in chapter II of annex XV) that describe aspects pertaining to the General safety and performance requirements (GSPR).
  For example drawings or pictures showing the elements of the finished product; information describing how the product is actuated; whether the same MD-component is already used in the market, for which medicinal substance, name of the product, whether the intended user groups are comparable; whether innovative elements are being used and how they have been tested pre-clinically, e.g. for usability by the intended population; summaries of preclinical tests that have been conducted, for example on delivery of the correct dosage to the patient, variations, why the variations of the applied dosage are acceptable for the medicinal substance and the indication that is foreseen in this study, on foreseeable stress, alterations under foreseeable non optimal storage and use conditions, their consequences (depends on the intended user population and the conditions/ the location at the time of use), sterility, biological safety, shelf life, etc.; summaries of previous clinical experience (if any).
- Instructions for use, if not included in the investigator's brochure
- GSPR matrix and list of standards (you can find templates in the annex of the European guidance document MDCG 2021-08)

CE-marked MD-component used off-label

- Instead of a complete IB, the following information can be submitted: Information concerning the original on-label use *(declaration of conformity, if applicable the conformity assessment certificate issued by a notified body, CE-marked instructions for use);* information on off-label use *(description of the differences between the conventional use and the new use in the trial, risk analysis of the new intended use in the trial and resulting safety measures, summary of any completed preclinical studies on the new use, any clinical experience on the new use, instruction for use for the new use, other information relating to the new use)*
- Instead of a complete GSPR matrix and list of standards, the following can be submitted: a statement on which and how general safety and performance requirements are affected by the new off-label use.