Explanatory note to flow chart to determine which MDR article is applicable to the clinical investigation

1. Whether or not the device already bears a valid CE marking as a medical device is crucial to the classification of the investigation. The CE certificate of the medical device or the declaration of conformity for class I medical devices can be consulted to answer this question.

2. The instructions for use of a medical device must contain the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate.

3. When the clinical investigation is conducted for conformity assessment purposes, either for a new device (MDR article 62) or to expand the intended purpose (MDR article 74.2), the envisioned aim is to market the device as a medical device under the MDR. The conditions that apply to MDR article 62 and MDR article 74.2 clinical investigations are the same. All investigations that are/will be part of the clinical evaluation plan (article 61 and annex XIV.A of the MDR) are considered to be conducted for conformity purposes. Therefore, early feasibility investigations can fall in the category of MDR article 62 clinical investigations.

4. Post-market clinical follow-up (PMCF) studies will be commissioned by the manufacturer of a medical device and be a part of the PMCF plan (annex XIV.B of the MDR). The medical devices in a PMCF investigation are used as part of the standard of care of the patients.

5. PMCF studies are considered PMCF investigations if the subjects are submitted to additional procedures compared to the standard of care and those procedures are invasive or burdensome. For these PMCF investigations, article 74.1 of the MDR applies. PMCF studies which are non-interventional, for instance clinical data are obtained by file research and no additional invasive or burdensome procedures compared to standard of care are applied, fall outside the scope of chapter VI of the MDR and outside the scope of the Medical Research Involving Human Subjects Act (WMO) and are considered non-WMO studies.

6. If the clinical investigation is not done for conformity assessment purposes and is also not part of the PMCF of the manufacturer it will be subject to article 82 of the MDR if the participants are subjected to procedures or are required to follow certain rules of behaviour in addition to normal clinical practice. In that case, also some articles of the WMO will apply.