Explanatory note to flowchart to determine which IVDR article is applicable and if MREC approval is needed for the performance study.

1. Is the study a performance study as defined in the IVDR? In other words; Will the study establish or confirm the analytical or clinical performance of an IVD? Will this study determine whether the IVD can correctly detect or measure a particular analyte (analytical performance)? Will this study determine whether the IVD yields results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended purpose (clinical performance)?

2. Post-market performance follow-up (PMPF) studies are performed with IVDs that do have a valid CE-mark and are used as part of the standard of care of the patients. PMPF studies will be commissioned by the manufacturer of an IVD and be part of the performance evaluation plan to generate additional evidence on the clinical performance of the IVD (Annex XIII of the IVDR).

3. PMPF studies in which subjects are submitted to additional invasive or burdensome procedures compared to the standard of care are subject to article 70.1 of the IVDR. PMPF 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 IVDR and outside the scope of the WMO and are considered nWMO studies.

4. Performance studies that involve companion diagnostics are subject to chapter VI of the IVDR. Companion diagnostics are IVDs which are essential for the safe and effective use of a corresponding medicinal product. Please note that in addition to the IVDR also the EU clinical trial regulation 536/2014 can be applicable for the corresponding medicinal product.

5. Left-over samples are archived samples or samples that would otherwise be discarded. When the performance study with a companion diagnostic only uses such left-over samples, there is no MREC or CCMO approval needed for this performance study based on article 58.2 of the IVDR. However, MREC approval based on other legislation (CTR) can be required. Based on the IVDR the study should comply with articles 56 and 57 and a notification to the competent authority (CCMO for the Netherlands) is needed.

6. Surgically invasive sample taking for the sole purpose of the performance study means taking a sample by penetration inside the body through the surface of the body, including mucous membranes of body orifices. This includes venous and capillary blood draws.

7. When the results of the IVD might have an effect on the clinical care of a subject as described in the protocol, the performance study falls within the scope article 58 of the IVDR and MREC or CCMO approval is needed.

8. If the performance study involves additional invasive procedures or other risks for the subject in addition to normal clinical practice, the performance study is subject to article 58 of the IVDR and MREC approval is needed.

Performance studies that do not fall within the scope of article 58 of the IVDR, do not need an MREC or CCMO approval based on the IVDR. These performance studies should comply with certain IVDR articles (including 56 and 57) and should be conducted in accordance with the general data protection regulation 2016/679 (GDPR).