Appendix

to the Site Suitability Template CTR

Supplementary information for combined studies in the following cases:

- Combination of a clinical trial on a medicinal product for human use (Regulation (EU) No. 536/2014) and a performance study according to Art 58 para. 2 (Regulation (EU) 2017/746) with a companion diagnostic (CDx).
- Combination of a clinical trial on a medicinal product for human use (Regulation (EU) No. 536/2014) and a performance study according to Art 58 (1) Regulation (EU) 2017/746 with an in vitro diagnostic (IVD).

1. General information regarding the performance study

EUDAMED No.	
Title of the performance study, if different from the title of the CTR study.	
Protocol No., if different from the CTR study.	
Sponsor, if different from the sponsor in the CTR study.	

2. Information on the laboratory, if the companion diagnostic (CDx) is only applied there and if the laboratory is within the scope of the MPDG

Name and address of the laboratory:	
Proof of the laboratory's suitability (e.g. DAkkS accreditation certificate, proof of compliance with ISO 15189)	
Name of the person responsible for the application of the IVD (CDx) in the laborator.	
Indication of the professional qualification of the person responsible for the application of the IVD (CDx) in the laboratory.	

3. Qualification of the investigators conducting the performance study (Annex XIV Chapter I, 1.13. IVDR in conjunction with § 30 MPDG)

NOTE:

In contrast to clinical trials on medicinal products, the MPDG stipulates for performance studies with IVDs that not only the head of the clinical trial (LKP) and one investigator must be notified by name and assessed by the EC, but also all other investigators involved at the trial site. Since the "members of the investigating team" do not have to be named according to the CTR, but all investigators at the trial site must be named for the performance study, the registered investigators in the drug trial and in the performance study are therefore often not congruent.
Investigators are physicians - but also persons according to Section 30 (3) MPDG without medical or dental qualifications - who are responsible for the conduct of the clinical trial or performance study.
(""investigator" means an individual responsible for the conduct of a performance study at a performance study site", Art. 2 (48) IVDR).
Investigators according to the performance study definition are therefore all persons who carry out or are responsible for activities in the context of the performance study: these are in particular the collection of blood or tissue samples required for the performance study, conducting the informed consent process, the inclusion and exclusion of the trial participants and the application of the in vitro diagnostic (including the use of a CDx to be tested in a German laboratory) as well as the utilisation of the results.

4. Details of the investigators*

This section must be completed **by all investigators as described above.**

(1) Curriculum vitae

Surname: ..... First name: .....

Date of birth: ..... Title: kä.....

Current Professional activity: .....

(2) Investigators declarations

I hereby declare that

(a) **I have experience in the field of application of the product to be tested.**

(Justification, where the experience in the area of application of the IVD to be tested results from. If the IVD is not used directly by the investigator him- or herself, it is sufficient to declare that there is experience with the indication in context of the pharmaceutical clinical trial.)

(b) **I am familiar with the protocol or the evaluation plan and the investigator's brochure.**

(c) **I will involve in the above-mentioned performance study**

- ☐ no persons dependent on me or the sponsor.
- ☐ the following persons named below who are dependent on me or the sponsor.

Involved persons dependent on me or the sponsor:

(d) **I have been trained and instructed in the use of the device under investigation** or will be trained and instructed during the initiation visit (not applicable if the IVD is not directly used by the investigators themselves).

(e) **I am familiar with the fundamentals of medical device law, the legal and scientific principles of clinical trials, performance studies or other clinical investigations***.

Place, date

signature of the investigator

* To prove this knowledge, the relevant training certificates must be submitted in accordance with the Guidelines of the Association of Medical Ethics Committees in Germany.

* For the responsible persons applying the IVD (CDx) in a German laboratory, the proof of regulatory knowledge is limited to the knowledge relevant to their role in the laboratory. This procedure has been coordinated with the Fachexpertengruppe 3 bei der Zentralstelle der Länder (ZLG) (Expert Group 3 of the ZLG).

This knowledge includes the investigator's obligations, as well as knowledge of reporting requirements and vigilance (§§ 62 ff MPDG). The Sponsor is responsible for providing this specific regulatory knowledge, which can take place during the initiation visit. The knowledge transfer must be declared and this sponsor`s declaration must be attached in the appendix.