Overview of documents to be submitted for IVD performance studies

	Standard research file IVD performance studies	Article 58/ 70.2	Article 70.1	Comments
A1	Cover letter	✓	✓	See A1. Cover letter template.
A2	Authorisation from the sponsor	✓	✓	(If applicable)
A2	Authorisation from legal representative EU if sponsor does not hold offices within EU	✓	✓	(If applicable)
B1	ABR form	✓	✓	You are required to complete the ABR form in ToetsingOnline.
B1a	Eudamed form	✓	✓	You are required to submit the Eudamed form while the Eudamed portal is not yet available.
C1	Protocol (Clinical Performance Study Plan)	✓	✓	
C2	Protocol amendments	✓	✓	(If applicable)
D1	Investigator's Brochure (IB)	✓	✓	Article 70.1: Investigator's Brochure or Instruction for use.
D2	Technical documentation	✓		An IMDD for IVD performance studies is under construction.
D2	EU declaration of conformity		✓	
D2	Instructions for use		✓	
D4	Manufacturer's statement on safety and performance of the medical device	✓		See Annex XIV, section 4.1 of the IVDR.
E1 / E2	Subject information sheet and informed consent form subjects	✓	✓	
E3	Promotional materials subjects	✓	✓	(If applicable)
E4	Other informational materials			(If applicable)

		✓	✓	
E5	Newsletters or letters with study results	✓	✓	(If applicable)
F1	Questionnaires	✓	✓	(If applicable)
F2	Patient diaries	✓	✓	(If applicable)
F3	Patient cards	✓	✓	(If applicable)
F4	Other	✓	✓	(If applicable)
G1	Insurance certificate for WMO research	✓	✓	
G2	Proof of coverage	✓	✓	
H1	CV independent expert			An independent expert (WMO article 9) is not mandatory for performance studies falling within the scope of the IVDR.
H2	CV coordinating investigator	✓	✓	(If applicable)
I1	List of participating centres	✓	✓	
I2	Research declaration or Site Suitability Declaration	✓	✓	
I3	CVs principal investigators	✓	✓	
I4	Other information per participating centre	✓	✓	(If applicable)
J1	Financial compensation for subjects	✓	✓	Only applicable when the information in the ABR form is not sufficient.
J2	Financial compensation for investigators and participating centres	✓	✓	Only applicable when the information in the ABR form is not sufficient.
K1	Recommendations other authorities	✓	✓	Such as: expert panel, notified body, registration authority (FDA).

K2	Assessment other EU Member States	✓	✓	(If applicable)
K3	Clinical trial agreements	✓	✓	
K4	Scientific publications	✓	✓	(If applicable)
K5	Data Safety Monitoring Board (DSMB)	✓	✓	(If applicable)
K6	Other information	✓	✓	(If applicable)
K7	Performance Evaluation Plan (PEP)	✓	✓	Relevant details or a reference to section of the PEP, the complete CEP.
K8	Description of the processing of personal data	✓	✓	See IVDR, annex XIV, section 4.5. You may mention the procedure in the protocol or in a separate document.