MakroCare
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IVDR: Clinical/Performance Documentation requirements

For IVDR depending on the risk classification (A, B, C or D), Documentation demonstrating good clinical practices through documentation is imperative. Some of the below may not apply to you if you products are lower risk class mainly A or B.

No.	Documentation	Purpose or Comment
01	Ethics committee notification, correspondence and opinion/approval	Gives evidence that a qualified, independent ethics committee has reviewed the clinical performance study and is maintaining oversight
02	Reports of adverse events, adverse device effects and device deficiencies	Documents the occurrence and resolution of adverse events, adverse device effects and device deficiencies
03	Sample of approved informed consent forms, where used, information for the subjects and advertisements, including translations and amendments, if made	Gives evidence of the content of the informed consent forms and of the information provided to the subject during the clinical performance study
04	Evidence of informed consent	Verifies that informed consent has been given. This document should remain only at the site
05	Documentation of principal investigator's adequate qualifications (updated if there is a new principal investigator)	Identifies the principal investigator
06	Documentation of roles and responsibilities of principal investigator and key members of study site team at each study site	Documents the attribution of responsibilities, with signature, title, and responsibilities in the clinical performance study
07	Records of qualification of key members of the study site team: (updated as necessary for new members)	Identifies the key members of the study site team
08	Investigator brochure, and a record of amendments, if applicable	Describes the IVD medical device under investigation, including instructions for use
09	Clinical Performance Study Protocol (CPSP)	Describes the clinical performance study design and procedures
10	Monitoring documentation	Provides evidence that adequate monitoring has taken place includes: › Monitoring plan › Site monitoring documentation › Names and qualifications of monitor(s), updated when necessary
11	Shipping records and accountability records for IVD medical devices under investigation	Verifies physical possession of devices, ensures integrity of device. Reconciles with sponsor's shipping and receipt Records
12	Records of specimen accountability and specimen integrity	Ensure accountability of all the specimens during the steps of the study

13	List of study site(s)	Site(s) conducting the study with site names and addresses
14	Documentation of IVD medical device under investigation return or disposal, where applicable	Documents the proper disposal of bio hazardous materials or other materials that require special disposal
15	Regulatory authority notification, correspondence and approval (where applicable)	Verifies information provided to regulatory authorities. Confirms notification or approval
16	Data collection tools	This can take the form of data collection form, instrument printouts, Case Report Forms (CRF). Blank set to evidence the content of data being collected
17	Study sample log	Record required information for all specimens in the study
18	Maintenance and calibration records of equipment if relevant to the clinical performance study	Documents equipment maintenance and calibration, any changes of equipment and continuous maintenance and calibration throughout the clinical performance study
19	Documentation of study site selection	Verifies that qualifications of investigator and study site have been reviewed
20	Signed agreement between principal investigator(s)/study site(s) and sponsor	Demonstrates understanding of each party's respective responsibilities
21	Signed agreements between sponsors and third parties, e.g. contract re- search organization, core laboratories	Demonstrates understanding of each party's responsibilities
22	Disclosures of conflicts of interest, updated as necessary	Documentation of conflicts of interest, e.g. financial
23	Sample of labeling attached to IVD medical device under investigation	Confirms appropriate labeling
24	Documentation of clinical performance study initiation	Verifies that investigator and study site team have been trained to device use and CPSP conformity
25	Financial agreements, if separate from agreements on responsibilities	Provides evidence of financial arrangements between investigator/study site and sponsor (can be kept separate from other site files)
26	Documentation of training	Provides evidence of training as specified in the relevant clauses of this document.
27	Correspondence related to the clinical performance study, including emails, letters, meeting notes and phone reports	This does not have to be in paper form
28	Notification of clinical performance study close-out to the ethics committee and/or regulatory authority by principal investigators or sponsor, where required	
29	Clinical performance study report	
30	CRFs amendments	Gives evidence of any changes, additions, or corrections made to CRFs after data were initially recorded
31	CRFs, fully executed	Evidences what data were collected and that their authenticity has been verified by principal investigator
32	Decoding procedures for blinded/ masked clinical performance studies, where applicable	Ensures in case of medical emergency that decoding can occur
33	Evidence of insurance, when applicable	Gives evidence that compensation to subject(s) for clinical performance study-related injuries will be available
34	Description of randomization for randomized clinical performance studies	Verifies that randomization has been followed. Depending on the design of the clinical performance study, the list might not be available at the study site for blinded/masked clinical performance studies