A Reporting Template for IVD Device's Clinical Performance Study

CPSP plan number and date corresponding to performance report:
Clinical Performance Study Report number:
Clinical Performance Study Report date:
Clinical Performance Study Report version:

Section A. Manufacturer contact details

REQUIREMENTS	COMMENTS/REMARKS
1. Legal manufacturer name:	
2. Address:	
3. SRN (if applicable):	
4. Person responsible for regulatory compliance:	
5. E-mail:	
6. Phone:	
7. Fax:	
8. Authorized representative (if applicable):	
i. Address:	
ii. Contact person:	
iii. E-mail:	
iv. Phone:	
v. Fax:	

Section B. In-vitro device description and specification

REQUIREMENTS	COMMENTS/REMARKS
1. Product or Trade name:	
2. Model and type:	
3. General description of the IVD:	
4. Intended purpose:	

© 2021 ComplianceQuest. All rights reserved. Confidential and Proprietary. Publishing of this content is not allowed without express permission from ComplianceQuest.

5. Intended user(s):	
6. Basic UDI-DI:	
7. Intended patient population:	
8. Indication(s):	
9. Contraindication(s):	
10. Warning(s):	
11. List of any accessories:	
12. Certificate number (if available):	
13. CND code(s):	
14. Class:	
15. Classification rule:	

Section C. Clinical performance study report

REQUIREMENTS	COMMENTS/REMARKS
A clinical performance study report, - signed by a medical practitioner or any other authorized person responsible, - shall contain documented information on the clinical performance study protocol plan, results and conclusions of the clinical performance study, including negative findings	
The results and conclusions shall be transparent, free of bias and clinically relevant	
The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents.	
The report shall also include, as appropriate, any protocol amendments or deviations, and data exclusions with the appropriate rationale.	

Other Performance Studies:
By analogy, the performance study report shall be documented for other performance studies than clinical performance studies.

© 2021 ComplianceQuest. All rights reserved. Confidential and Proprietary. Publishing of this content is not allowed without express permission from ComplianceQuest.

Revision history

Revision No.	Revision date	Description of change	Revised by

Reference:
REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU; ANNEX XIII Performance Evaluation, Performance Studies and Post-Market Performance Follow-Up; PART A Performance Evaluation and Performance Studies

DISCLAIMER: This document neither creates nor confers any rights towards any person or organization and does not enforce to abide by the content. It is only intended to support organization(s) or individual(s) referring this document to understand the requirements of Clinical Performance Study plan and report related to IVD. The simple usage does not automatically imply fulfilment of any regulation. Please refer the applicable regulation for complete detail.

Doc. CQCLINICAL-07 Ver1.0, eff. September 21st, 2021

About ComplianceQuest

ComplianceQuest is an award winning, **100% cloud based Next Generation AI-Powered Enterprise Clinical, Quality, Health and Safety Management Solution (QHSE)** natively built and run on the **Salesforce platform**. Our unified and connected solutions help companies of all sizes deliver quality products and services in the safest, most sustainable way by mitigating risk, problems, and inefficiencies while protecting customers, patients, employees, suppliers and brand.

For more information, or to request a demo with a ComplianceQuest expert, contact ComplianceQuest today.

Visit www.compliancequest.com • **Email us at marketing@compliancequest.com** • Call us at 408-458-8343

© 2021 ComplianceQuest. All rights reserved. Confidential and Proprietary. Publishing of this content is not allowed without express permission from ComplianceQuest.