Health Institution Exemption – the easy way out?

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Agenda

- Health Institution (HI) Definition
- Health Institution *Exemption*
- Challenges with Implementation
- MDCG Q&A Responses
- Considerations for Pharma
- Key Takeaways
- Resources

‘Health Institution’ means an organization, the primary purpose of which is the care or treatment of patients or the promotion of public health

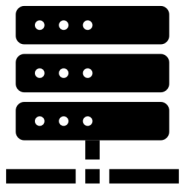
2017/746 Article 2 Definitions

''**Health institutions** should have the **possibility of manufacturing, modifying and using devices in-house** and thereby addressing, on a **non-industrial scale**, the **specific needs of target patient groups** which **cannot be met** at the appropriate level of performance **by an equivalent device available on the market**. In that context, it is appropriate to provide that certain rules of this Regulation, as regards devices manufactured and used only within health institutions, **including hospitals** as well **as institutions, such as laboratories** and public health institutes that support the health care system and/or **address patient needs**, but which do not treat or care for patients directly, should not apply, since the **aims of this Regulation would still be met** in a *proportionate* manner''

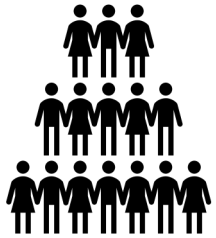
2017/746 Point 29 of the Legislation

Health Institutions must comply with all points of Article 5.5 & Annex 1 GSPRs

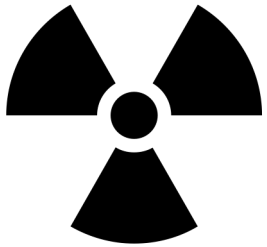
Laboratory Quality Management System



Manufacturing Documentation (UDI, IFU)



Justification for IVD use in specific patient population



General Safety & Performance Requirements (GSPRs)

Publicly Available Declarations

Health Institution Exemption

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QMS

- Demonstrate Compliance to Article 5.5 & GSPRs
- ISO15189 Compliant
- Identify, Generate & Appraise Data
- Traceable Manufacturing
- Monitoring, analysis and continuous improvement
- Communication with competent authorities

GSPRs

- Risk Management Plan
- Benefit – Risk Ratio
- State of the Art
- Post Market Surveillance
- Performance Characteristics – Analytical & Clinical
- Appropriate Labelling (UDI)
- IVD Instructions for Use (IFU)

Published / Available Data

- Published declaration of conformity to A.5.5 & GSPRs
- Market Assessment – Justification of IVD for specific patient population
- IVD Batch Details
- Performance Outcome
- Vigilance, Incidents & Corrective Actions

Challenges with Implementation

Assumption that Hospital Labs are exempt from IVDR

- Local Labs regularly used for fast TAT and ability to treat patients quickly
- World Leading expert Investigators develop novel LDTs that can support effective new drug development
- Limited Hospital resource or capacity to support IVDR Article 5.5 & Annex 1 requirements to qualify as a HI

Significant number of Central Labs used within Clinical Trials are outside of the EU

- Only Health Institutions in the European Union (EU) can be considered as exempt under IVDR
- No path for non-EU labs to use LDT's for medical decisions – IVD Clinical Performance Study required
- UK is not part of the EU & Switzerland currently has third country status – HI Exemption rules do not apply

Limited guidance on how Health Institutions can fully demonstrate compliance to IVDR

- Unlike CTR, Clinical Trial IVDs need to be assessed in all countries (until EUDAMED full functionality ~2027)
- HI's are advised to seek guidance from their local regulatory body on approval
- No clear guideline on how this local approval will be perceived across the EU

Medical Device Coordination Group Q&A on Interface between CTR & IVDR

3. Question: Can I use an in-house IVD in a clinical trial?

Answer: Yes. This remains possible.

With the exception of the **relevant general safety and performance requirements** set out in Annex I, the requirements of the IVDR shall not apply to devices manufactured and used **only within health institutions established in the Union**, provided that **all of the conditions of Article 5(5) are met**.

4. Question: Are all assays used in a clinical trial subject to the IVD legislation?

Answer: No, not all assays, **but those that fulfil the definition of an IVD are subject to the IVD legislation**. Such assays may have a **medical purpose within the clinical trial**, e.g. when they guide medical management decisions or follow-up (see Q6).

8. Question: Is a use in research sufficient justification for an assay to be defined as Research Use Only?

Answer: No. Where an assay, instrument, apparatus, appliance material or other article, including software is intended for research use only and is **assigned a medical purpose by the clinical trial sponsor** in the clinical trial protocol in a way that the assay **fulfils the definition of an IVD according to IVDR Article 2,** it becomes an IVD and can no longer be considered a research use only assay. It **becomes regulated under the IVDR** (see Q4-Q6).

13. Question: Which information needs to be provided in the clinical trial application for an in-house IVD?

Answer: In principle, in the case of in-house IVDs, the sponsor should provide the **name of the health institution** where the IVD is manufactured and used and **a link to their IVDR Art 5(f) declaration**. It is recommended to document this aspect in the harmonised template document . The IVD analysis must be carried out in **a laboratory complying with ISO15189,** or, where applicable, with national provisions, in line with IVDR Article 5(5)(c).

Considerations for Pharma

Risk vs. Benefit - Clinical Development Strategy - any IVD filing?

Lab Conformance

- Approved IVD on the market?
- HI Public Declaration?
- Appropriate QMS?
- Justification for use of Investigational IVD in the clinical trial?

- Include HI Declaration as part of the CTR submission
- Be clear you are using a qualified HI to complete Investigational IVD testing & provide sufficient justification for use of assay with patient population

Risk / Benefit

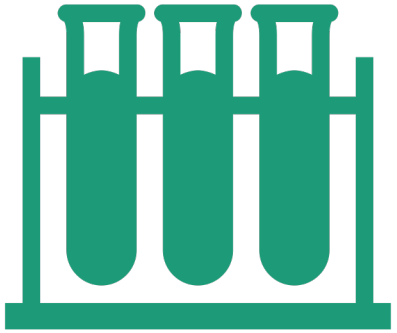
Market Analysis

HI Conformance

IVD Justification

Key Takeaways

All IVDs that result in patient medical decisions are in scope of IVDR



Lab Developed tests can only be run in Compliant Health Institutions

HI Exemption rules are outlined in 2017/746 Article 5.5 & Annex 1 GSPRs

Sponsors need to ensure selected IVDs can support their IMP Clinical Development Strategy

Resources

- MDCG Guidance on Health Institution Exemption
- Annex A - Public Declaration Template
- MDCG Q&A on Interface between CTR & IVDR
- European Commission - MDCG Guidance
- 2017/746 In Vitro Diagnostic Regulation

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