TRINZO

IVDR Acronyms Guide

What Do They Mean?

The IVDR Acronyms Guide

To help you navigate the daunting process of implementing the requirements of the IVD Regulation, we have compiled a glossary of the most commonly used acronyms, terms and definitions.

This glossary is not only intended to aid understanding of terms within the regulation itself, but also those which frequently arise in guidance documents, whitepapers, presentations, and other relevant material.

Keep this guide with you anywhere you go, to help you make sense of the regulation when you need it most.

ACRONYMS LIST - IN ALPHABETICAL ORDER

A

AIDC Automatic identification and data capture (related to UDI)

Technology used to automatically capture data includes barcodes, smart cards, biometrics, and RFID.

APR: Analytical Performance Report

A document containing the evidence of a device's ability to detect or measure a particular analyte using parameters such as accuracy, sensitivity, and specificity. All of the parameters that must be considered can be found in Annex I Chapter 2 Section 9.1(a) of the IVDR.

B

BRA: Benefit Risk Analysis

The analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose when used in accordance with the intended purpose given by the manufacturer.

C

CA: Conformity Assessment / Competent Authority

The process demonstrating whether the requirements of the IVDR relating to a device have been fulfilled.

A governmental body responsible for transposing regulatory requirements into national legislation.

CAPA: Corrective and Preventative Action

A process belonging to a QMS whereby problems are investigated and measures put in place to prevent nonconformities or recurrence of an identified issue.

CFS: Certificate of Free Sale

A document used in the registration of a device in a non-EU country intended to demonstrate that a device is compliant with EU requirements and that it is free to be sold on the EU market.

CLP: Classification Labelling and Packaging [of substances and mixtures]

A regulation ensuring that the hazards presented by chemicals are clearly communicated to users in the European Union via appropriate labelling.

CMR: Carcinogenic Mutagenic or Toxic to Reproduction

Substances which are carcinogenic, mutagenic, or toxic to reproduction.

CS: Common Specification

A set of technical and/or clinical requirements other than a standard that provides a means of complying with the legal obligations applicable to a device, process, or system.

CPSP: Clinical Performance Study Plan

A document defining the rationale, objectives, design, and proposed analysis methodology, monitoring, conduct, and record-keeping of the clinical performance study according to Annex XIII Section 2.3.2 of the IVDR.

CPSR: Clinical Performance Study Report

Approved documented information on the results and conclusions of a clinical performance study according to the CPSP, including any negative findings.

D

DoA: Date of Application

The date the regulation enters into force.

DoC: Declaration of Conformity

A document that states that the IVDR requirements have been fulfilled. It must be continuously updated by the manufacturer and must contain at a minimum the information set out in Annex IV of the IVDR.

E

ECHA: European Chemicals Agency

An EU agency that implements the EU's chemicals legislation to protect health and the environment.

EMA: European Medicines Agency

A decentralised agency of the European Union (EU) responsible for the scientific evaluation, supervision, and safety monitoring of medicines in the EU.

EMDN: European Medical Device Nomenclature

An alphanumeric structure established by the European Commission and used for registration of devices in Eudamed.

EUAR: European Authorised Representative

Any natural or legal person established within the EU who has received and accepted a written mandate from a manufacturer located outside the EU to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under IVDR.

EUDAMED: European Database on Medical Devices

A database developed by the European Commission to facilitate compliance with European medical device regulations.

F

FSCA: Field Safety Corrective Action

Corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market.

FSN: Field Safety Notice

A communication sent by a manufacturer to users or customers in relation to a field safety corrective action.

G

GSPR: General Safety and Performance Requirements

A set of minimal requirements which all in vitro diagnostic devices must meet where applicable, found in Annex I of the In Vitro Diagnostic Device regulation.

GTIN: Global Trade Item Number

The globally unique identification number allocated to identify a trade item.

H

HRI: Human Readable Interpretation (related to UDI)

A legible interpretation of the data characters encoded in the UDI carrier.

I

IFU: Instructions for Use

The information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken.

M

MDCG: Medical Device Coordination Group

A group composed of persons designated by the Member States based on their role and expertise in the field of in vitro diagnostic devices and/or medical devices. Established to fulfil the tasks conferred on it by IVDR and by Regulation (EU) 2017/745 of the European Parliament and of the Council to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of the Regulations.

N

NB: Notified Body

A notified body is a conformity assessment body designated in accordance with an applicable regulation.

P

PEP: Performance Evaluation Plan

A document which specifies the characteristics and the performance of the device and the process and criteria applied to generate the necessary clinical evidence. At a minimum, it should include the elements of Annex XIII Part A Section 1.1 of the IVDR.

PER: Performance Evaluation Report

An overall report including the scientific validity report, the analytical performance report, the clinical performance report, and an assessment of those reports allowing demonstration of the clinical evidence.

PMS: Post-Market Surveillance

All activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market, or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.

PMPF: Post-Market Performance Follow-Up

A continuous process that updates the performance evaluation.

PMSP: Post-Market Surveillance Plan

A systematic plan of the processes that are put in place to ensure the continued safety and performance of a product after it has been released to the market.

PMSR: Post-Market Surveillance Report

A report that is required for class A and B devices summarising the results and conclusions of the post-market surveillance data gathered via the activities outlined in the post-market surveillance plan.

PRRC: Person Responsible for Regulatory Compliance

A person or people appointed by a manufacturer or authorised representative responsible for ensuring that the applicable regulatory requirements of the regulation are met.

PSR: Periodic Summary Reports

Used for serious incidents occurring with the same device or device types as an alternative to individual serious incident reports. This option can only be used when certain criteria are met and on agreement with the applicable competent authorities.

PSUR: Periodic Safety Update Report

A summary of the results and conclusions of the analyses of the post-market surveillance data for class C and D devices gathered as a result of the post-market surveillance plan, together with a rationale and description of any preventive and corrective actions taken.

Q

QA: Quality Assurance

A systematic process that ensures that a product meets predefined standards.

QMS: Quality Management System

A system that formally documents any procedures, processes, records, and responsibilities that a company puts in place to ensure that their quality policies and objectives are achieved and continuously monitored and improved upon where possible.

R

RA: Regulatory Affairs

A profession/department responsible for ensuring that compliance to applicable regulations, directives, and standards is achieved by a company within a regulated industry.

RBA: Risk Benefit Analysis

The analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose when used in accordance with the intended purpose given by the manufacturer.

REACH: Registration Evaluation Authorisation and Restriction of Chemicals

A regulation that aims to improve the protection of human health and the environment from the risks that can be posed by chemicals.

RFID: Radio Frequency Identification

A technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object for the purpose of identification.

RMF: Risk Management File

A file made up of any records, files, or documentation produced during a risk management process.

RMP: Risk Management Plan

A document which defines the approach that will be taken to assess, analyse, and manage any identified or foreseeable risks to the applicable device.

RMR: Risk Management Report

A document containing the outcome and summary of the activities described in the RMP, including information on the benefit-risk analysis.

S

SD: Standard Deviation

A measurement of the variation in a set of values.

SDS: Safety Data Sheet

A document containing information on certain substances, the hazards they pose, and any applicable storage or handling instructions.

SIN: Single Identification Number

Eudamed numbers generated for clinical evaluation trial identification.

SOTA: State of the Art

The generally accepted good practice in technology and medicine and not necessarily the most technically advanced solution.

SRN: Single Registration Number

A number issued to a manufacturer, authorised representative, or importer required to access Eudamed to fulfil the applicable economic operator responsibilities.

SSP: Summary of Safety and Performance

A publicly available document required for class C and D devices intended to provide information on safety and performance to any intended users.

STED: Summary Technical Documentation

A format by which to present technical documentation, established to encourage harmonisation among different countries.

SVR: Scientific Validity Report

A document which describes the association of an analyte to a specific clinical condition.

U

UDI: Unique Device Identifier

A series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.

(B)UDI: (Basic) Unique Device Identifier

The primary identifier of a device model. It is assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in technical documentation, certificates, and EU declarations of conformity. A single Basic UDI-DI can connect several devices that share the same risk classification, intended use, and design and manufacturing requirements.

UDI-DI: Unique Device Identifier – Device Identifier

A series of numeric or alphanumeric characters that identifies the labeller and the specific version or model of a device.

UDI-PI: Unique Device Identifier – Production Identifier

A series of numeric or alphanumeric characters that is a variable portion of a UDI identifying, for example, lot/batch/serial numbers, an expiration date, or a manufacturing date.

V

V&V: Verification and Validation

The results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the IVDR requirements.

Support for every IVD class, every step of the way

Trinzo can provide expertise for projects of all sizes:

Gap Assessments

- Device Classification as per IVDR (Classes A, B, C, D)
- IVDR Readiness Audits and Mock Audits
- Technical Documentation
- QMS development and implementation
- Clinical Evidence Gap Assessment
- Response to NB Feedback

Global Registrations

- UDI and Labeling Requirements Technical File Creation
- Review support
- ROW Submission Strategies
- CE-Mark Submission Strategies

Medical Writing

- Performance Evaluation Plan (PEP)
- Performance Evaluation Report (PER) Scientific Validity Report (SVR)
- Analytical Performance Report (APR) Clinical Performance Report (CPR)
- Post-Market Performance Follow-Up Plan (PMPF) IVDR Post-Market Surveillance (PMS) Plans
- Standard Operating Procedures (SOPs)

IVDR Training

- Public courses (Virtual & On-Site)
- Bespoke training (Virtual & On-Site)

Schedule a free consultation:

Phone:
Call us at **+353 (0) 91 394 804** to speak directly with our customer support team and schedule your consultation.

Email:
Send an email to info@trinzo.com with your preferred time, and our team will promptly confirm your appointment.

TRINZO

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