



**XI.**

**CLINICAL EVIDENCE -- IVDR**

Under IVDR Clinical Evidence -- Article 56

2(36) 'clinical evidence' means clinical data and performance evaluation results, pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer.

<b>Clinical Evidence</b>	Scientific Validity	<ul style="list-style-type: none"> <li>● Association of an analyte to a clinical condition or physiological state</li> <li>● From literature or may need to be established for companion diagnostics or novel analytes</li> </ul>
	Analytical Performance	<ul style="list-style-type: none"> <li>● Ability of an IVD medical device to correctly detect and measure a particular analyte</li> </ul>
	Clinical Performance	<ul style="list-style-type: none"> <li>● Ability to yield results that relate to a particular clinical condition or physiological state for the intended use and in accordance with the target population or the intended user</li> </ul>

**References**

- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical --IVDR Clinical Evidence -- Article 56

**CLINICAL EVIDENCE -- IVDR Fundamentals and Readiness Training Course**

- CLINICAL EVIDENCE - Basic Terms and Concepts
- Back Ground Applicable Regulation & Guidance Standards
- Content of CLINICAL EVIDENCE
- Implementation of CLINICAL EVIDENCE

**Our services:**

**D. CLINICAL EVIDENCE -- IVDR Training for Medical Device Companies**

This training is conducted on-sites. The training session tailored to the needs of your organization regarding this sub-system.

**E. CLINICAL EVIDENCE -- IVDR auditing and compilation for Medical Device Companies**

We provide internal auditing services which allow for an independent review of this part of your quality system. We can support compilation of clinical evidence for your devices.

**F. CLINICAL EVIDENCE -- IVDR - System Implementation Consulting and maintenance**

Gap analysis, design solution (custom made system), standard operating procedures, implementation, training, verification of effectiveness, and follow up.