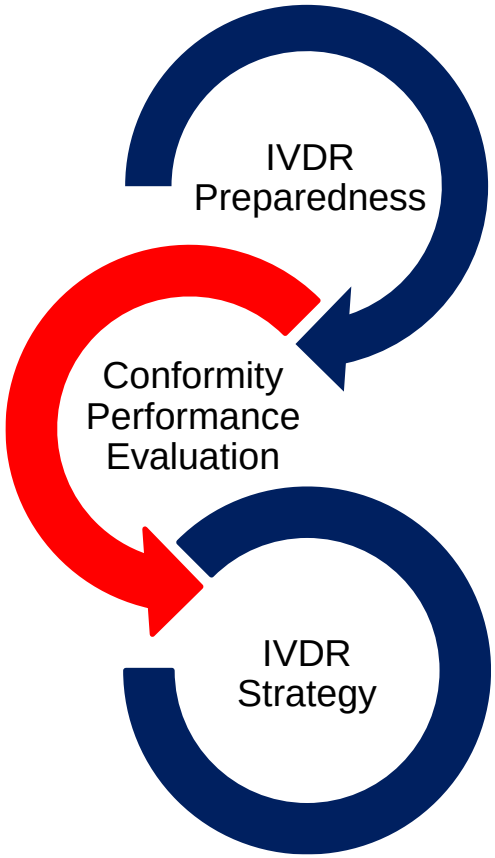


# In Vitro Diagnostics Regulation (IVDR) Consultancy & Services

Therawis
*Pharma | Diagnostics*

**In vitro diagnostics conformity assessment and performance evaluation according to IVDR 2017/746**

We support our clients to achieve conformity for their “in vitro diagnostic medical devices” (IVD) according to the IVD Regulation (EU) 2017/746 by

- developing the right strategies for the IVD
- getting prepared for IVDR conformity, and
- perform activities for performance evaluation and clinical evidence covering the three pillars scientific validity, analytical performance, and clinical performance for the device before (reference: IVDR Chapter VI “Clinical evidence, performance evaluation and performance studies) and after market entry (reference: IVDR Chapter VII “Post-market surveillance, vigilance and market surveillance) in compliance to the IVDR

## IVDR Preparedness

**Standard Operating Procedures (SOPs)** for IVD performance evaluation (Annex XIII of the IVDR)

**Evaluation and (gap) analysis** of clinical evidence covering State of the Art, scientific validity, analytical & clinical performance and assessment of benefit-risk ratio

**Development of essential performance plans** including
Performance Evaluation Plan,
Clinical Study Plan,
Post-Market Follow-Up Plan

## IVDR Strategy

**Development of intended purpose/intended use statements** including intended patient population

**Defining strategies to establish sufficient clinical performance and evidence for the device** including analytical & clinical performance requirements according to the General Safety and Performance Requirements (GPSRs, Annex I of the IVDR)

**Assessments of State of the Art (SOTA), scientific validity, clinical utility & medical risk** for your IVD device

# IVDR Conformity Performance Evaluation

**Creation and review of essential performance documentation**

Performance Evaluation Plan,
Scientific Validity Report,
Analytical Performance Report,
Clinical Performance Report,
Performance Evaluation Report,
Summary of Safety and Performance

**Systematic literature review**

comprising literature search methodology, search protocol, literature appraisal and report

**Planning and conducting clinical performance studies**
(retrospective/prospective studies)

**Activities for Post-Market Surveillance (PMS) and Post-Market Performance/Clinical Follow-Up (PMPF, PMCF)**

including post market clinical registry trials, periodic updates of PMS and PMPF reports

# Our Approach

**Strength**

In-depth expertise in IVDR regulation based on recast of > 20 IVD products, approved IVDs and feedback from regulatory authorities.
Multidisciplinary team combining the required knowledge, experience and strong track records.
High flexibility & motivation to support your project and to meet impending deadlines.

**Compliance**

Strictly working at the highest standard. Based on our internal QMS system we provide the quality and continuous training to ensure compliance with the evolving IVDR requirements.

**Dedication**

Diligent and focused to understand your needs and your project. Clear and transparent communication and high responsiveness.

# About Us

**Therawis Pharma/Diagnostics GmbH** is a privately held oncology/virology-specialized company with offices located in Munich, Germany, founded in April 2014. As part of the business we provide European-wide support in IVDR related services.

**The Therawis team**, individually with more than 20 years professional experience, possesses a significant track record in IVDR evaluation, assessment and documentation with > 20 IVD products for our clients in the last 3 years. The team is composed of professionals in science, analytical & clinical development, medical & clinical affairs and quality assurance.

# Contact

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