Medizin im Grünen

WHITEPAPER

Decision Tree for Preclinical Evidence

Three-Stage Decision Tree for Medical Devices · EU MDR & FDA

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PHASE 0 - Feasibility & Bench Assessment

- **Content:** Literature review, initial ISO 10993 assessment, technical bench testing, risk assessment, and evidence gap analysis
- **Result:** Overview of available versus missing evidence and recommendation for next development steps

Concept not feasible → **Stop or Re-design**

Fundamental safety concerns, unsuitable materials, or no feasible regulatory pathway identified

Evidence Sufficient → **Potential submission / Conformity assessment**

May be sufficient on a case-by-case basis for low-risk devices with sufficient supporting date

Data gaps identified, concept feasible

PHASE 1 - Pilot Animal Study

- **Content:** In-vivo proof of concept, model validation, protocol optimization, and initial safety data
- **Result:** Validated animal model, optimized protocol, and supporting data for Q-Submission and study planning

Safety signals / model- related issues → **Re-design and return to Phase 0**

Unclear tissue response, endpoints not achievable, or inadequate animal model

Pilot successful — GLP study potentially not be required → **Submission with bench and pilot data**

Pilot successful + submission pathway requires GLP data

PHASE 2 - GLP / Regulatory Study

- **Content:** Definitive safety data generated under Study Director oversight, with independent QA, comprehensive pathology, and statistically justified study design
- **Result:** GLP-compliant final report ready for technical documentation and premarket submission

Regulatory Submission

510(k), PMA, IDE, De Novo, CE conformity assessment

Note: This overview is intended as a general schematic framework and does not represent a complete regulatory decision pathway.

MiG
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MiG - Services

We are a specialized preclinical CRO for medical device companies, focused on in-vivo studies designed for regulatory submission readiness.

- Preclinical study planning and evidence strategy: from Phase 0 scoping to GLP-compliant submission
- In vivo studies using large and small animal models, integrated histopathology, and complete QA documentation
- Regulatory interoperability as a design principle: GSPR mapping, MDR Annex II, FDA 21 CFR Part 58

Contact us – in 30 minutes, we´ll clarify what your project needs for the next phase.

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