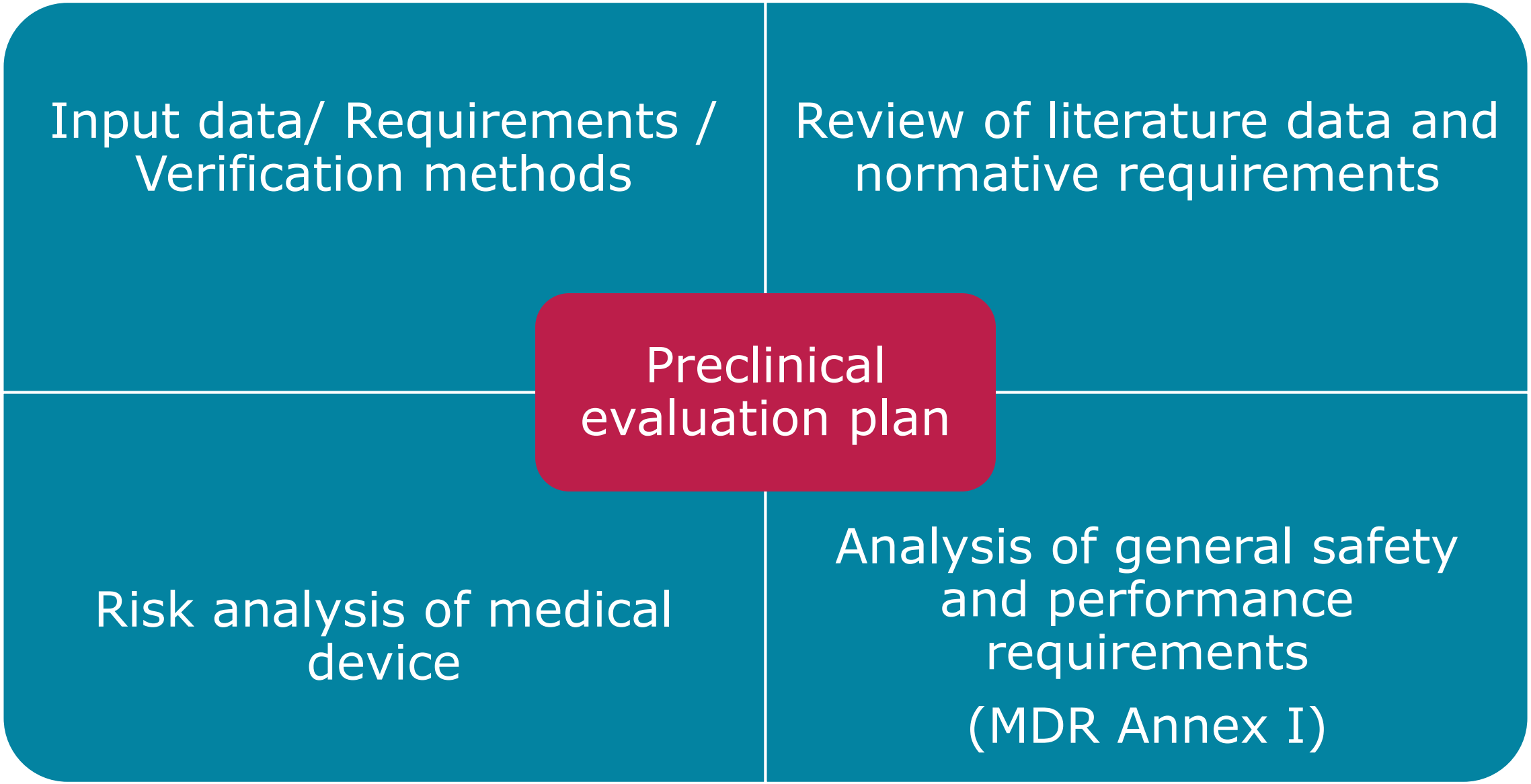
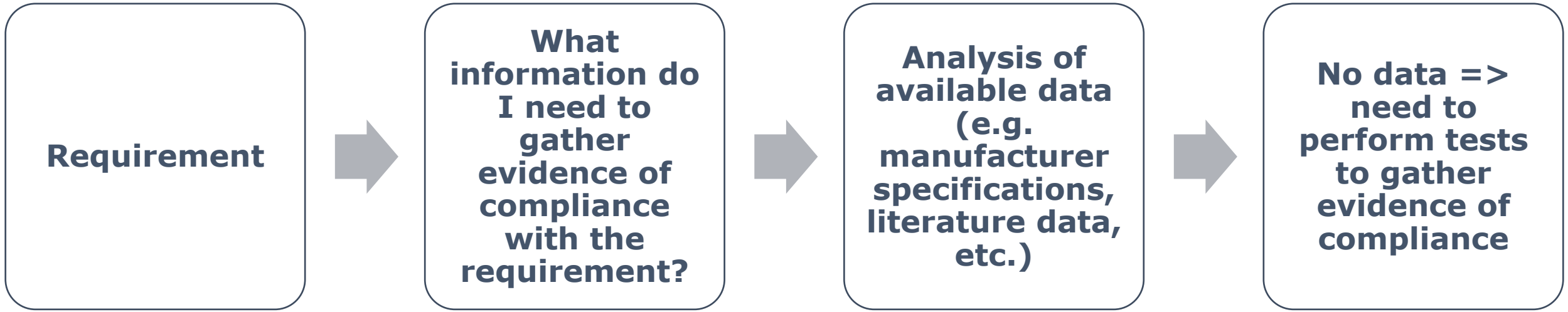
Preclinical & Biological Evaluation of Medical Device

DevGoMed



DevGoMed

Analysis of general safety and performance requirements – MDR Annex I



DevGoMed

List of tests for the preclinical evaluation

- ✓ Tests necessary to verify the initial assumptions for a medical device (device verification)
- ✓ Tests necessary to demonstrate compliance with the general requirements for the safety and performance of the product (product verification and validation)
- ✓ Tests determined on the basis of the product risk analysis performed
- ✓ Normative required tests for a given type of product

DevGoMed

Verification & Validation – EN-ISO 13485:2016 requirements

Verification

Confirmation that the output meets the input (product conforms to specification)

Validation

Confirmation that the product meets the requirements for a specific application or intended use

DevGoMed

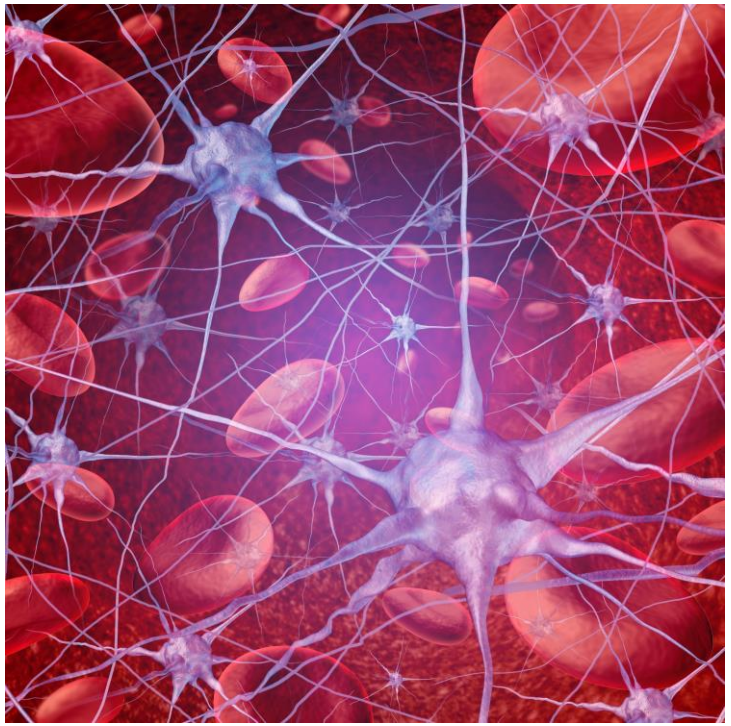
Biological safety of the device

- the **compatibility** between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, **absorption, distribution, metabolism** and **excretion**

Biocompatybility evaluation (ISO 10993)

Including the assessment of the impact of materials and substances contained in the product on the functioning of the body:

- Risk analysis of the way the product is used



DevGoMed

Biological risk management

DevGoMed

Categorization of medical device in accordance with ISO 10993-1

Nature of body contact

Body contact duration

Categorization by nature of body contact

- Non - contacting medical devices
- Surface – contacting medical devices
- Externally communicating medical devices
- Implant medical devices

DevGoMed

Categorization by duration of contact

A – Limited exposure	B – Prolonged exposure	C – Long-term exposure
< 24h	**>24h < 30d**	**> 30d**

Complete contact time with the body

DevGoMed

- Physical and chemical information
- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity
- Pyrogenicity
- Acute systemic toxicity
- Subacute toxicity
- Sub-chronic toxicity
- Chronic toxicity
- Implantation effects
- Hemocompatibility
- Genotoxicity
- Carcinogenicity
- Reproductive / Developmental Toxicity
- Degradation

DevGoMed