Clinical evidence generation for high-risk orthopaedic medical devices under MDR

THE NOTIFIED BODY AND EARLY FEASIBILITY STUDIES

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Harmonised Approach to Early Feasibility Studies for Medical Devices in the European Union Symposium

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Presentation Overview

- Overview of Clinical Evaluation Assessments
- The Clinical Development Plan
- Consultation on Clinical Development Strategy
- Harmonised Approach & Structured Dialogue
- Conclusions

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Purpose of a Clinical Evaluation

Article 61(1) of the EU Medical Devices Regulation (EU) 2017/745)

Confirmation of conformity with relevant general safety and performance requirements set out in Annex I under the normal conditions of the intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk- ratio referred to in Sections 1 and 8 of Annex I, shall be based on clinical data providing sufficient clinical evidence, including where applicable relevant data as referred to in Annex III.

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The Clinical Development Plan (CDP)

The Requirement (MDR 2017/245)

ANNEX XIV

CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

PART A

CLINICAL EVALUATION

1. To plan, continuously conduct and document a clinical evaluation, manufacturers shall:

(a) establish and update a clinical evaluation plan, which shall include at least:

— **a clinical development plan** indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF as referred to in Part B of this Annex with an indication of milestones and a description of potential acceptance criteria;

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The Clinical Development Plan (CDP)

The CDP defines how you will collect sufficient clinical data for later clinical evaluation.

Key Components

- Prospective Patients

Prospective Patients

Performance Profile

- Intended Clinical Benefit
- Patient Population
- Intended Purpose
- Indications (stage/severity)
- Intended User Groups

Safety profile

- Identify known safety concerns with the patient population
- Identify contraindications, warnings, precautions
- Identify potential off-label use

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The Clinical Development Plan (CDP)

The CDP defines how you will collect sufficient clinical data for later clinical evaluation.

Key Components

- Scientific Rationale for Development

Scientific Rationale for Development

- **Unmet clinical needs/expansion of clinical indications**
- Limitations of current therapies/diagnostics
- Drug/Device Interaction

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The Clinical Development Plan (CDP)

The CDP defines how you will collect sufficient clinical data for later clinical evaluation.

Key Components

- Commercial Rationale for Development

Commercial Rationale for Development

- **Unmet market needs/Unmet clinical needs**
- Market size assumption and projections
- International considerations
- Competitive situation
- Resources Available

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The Clinical Development Plan (CDP)

The CDP defines how you will collect sufficient clinical data for later clinical evaluation.

Key Components

- Clinical Data/investigations

Clinical Data/Investigations

- Study Design
- Devices identified – think accessories, instrumentation
- Patient population/numbers
- Objectives and Endpoints
- Follow-up and Intervals
- Study Locations

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The Clinical Development Plan (CDP)

The CDP is a blue print of the entire clinical research strategy of a medical device defining the pathway to operational plans

Key Components

- Strategic Planning

Strategic Planning

- Milestones
- Decisions and actions (e.g. what is outcomes are not reached, repeat EFS)
- Longer term plans (PMCF), Expansion of Indications
- Market Access (controlled roll out?)
- Risk assessment & contingency plans
- Regulatory aspects (Article 61(2) Voluntary Consultation, Clinical Evaluation Consultation Procedure)

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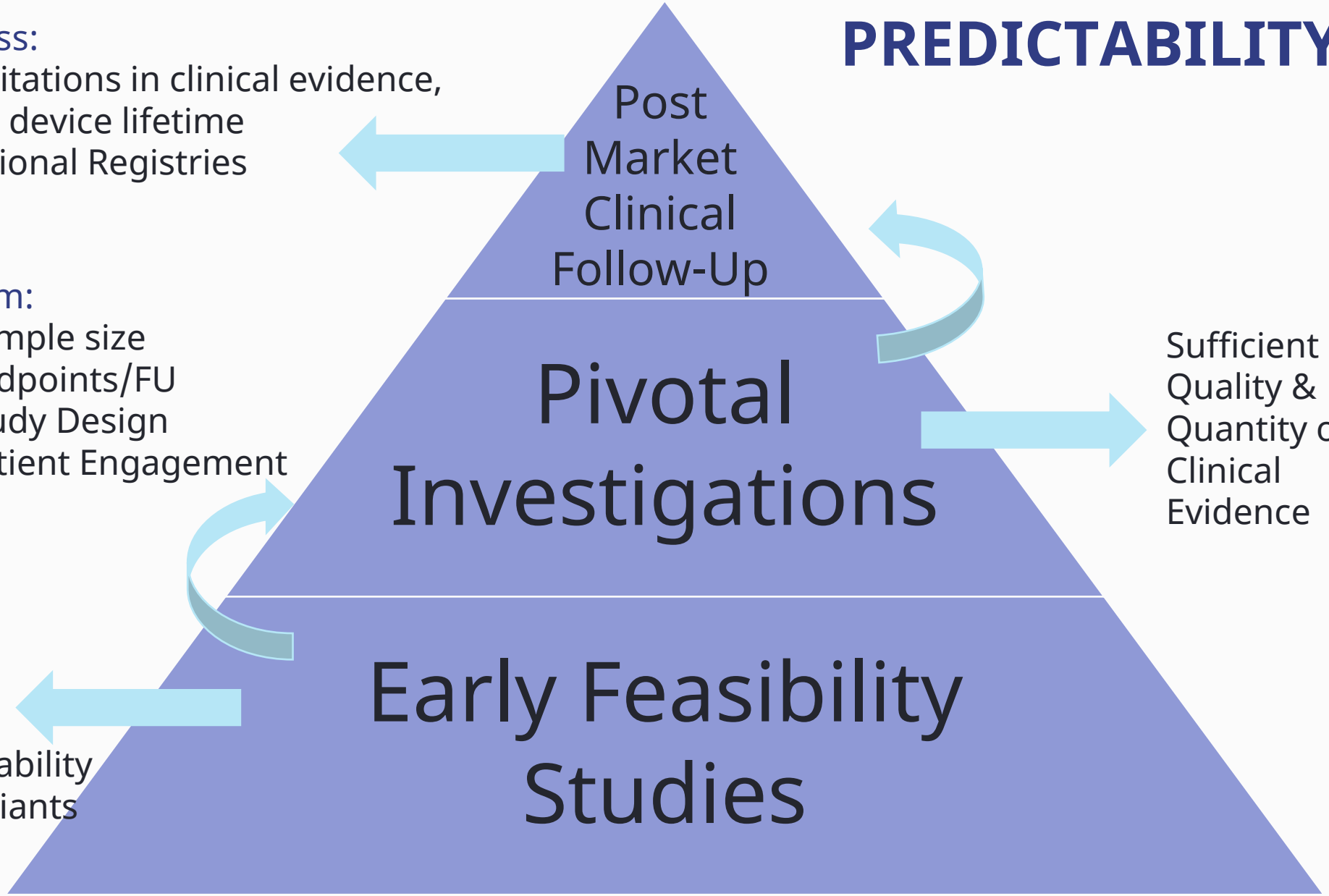
PREDICTABILITY

Address:
- Limitations in clinical evidence, e.g. device lifetime
- National Registries

Inform:
- Sample size
- Endpoints/FU
- Study Design
- Patient Engagement

Confirm:
- Intended Purpose
- Indications
- Patient Population
- Intended Users/Usability
- **Device Design**/Variants
- **Potential Risks**



Sufficient Quality & Quantity of Clinical Evidence

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Consultation on Clinical Development Strategy

MDR Article 61 (2)

Medical device expert panels were established under the EU MDR to provide expert opinion on high-risk medical devices.

2. For all class III devices and for the class IIb devices referred to in point (b) of Article 54(1), the manufacturer may, prior to its clinical evaluation and/or investigation, consult an expert panel as referred to in Article 106, with the aim of reviewing the manufacturer's intended clinical development strategy and proposals for clinical investigation. The manufacturer shall give due consideration to the views expressed by the expert panel. Such consideration shall be documented in the clinical evaluation report referred to in paragraph 12 of this Article.

The manufacturer may not invoke any rights to the views expressed by the expert panel with regard to any future conformity assessment procedure.

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Impact of a Harmonised Approach

Predictability in the regulatory process is crucial to the effective planning of clinical activities and resources.

Structured Dialogue and a Harmonised Approach

Structured Dialogue

MDCG 2019-6 Section I.6.3 outlines discussion topics that can be undertaken as part of structured dialogue. These would rarely include EFS, as structured dialogue is usually undertaken much later in the regulatory pathway.

Harmonised Approach

A harmonised approach to EFS will allow improved predictability for manufacturers and reassurance for notified bodies that early evidence generation is robust and scientifically sound, forming a foundation for the pivotal clinical data on which the clinical evaluation is based.

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Conclusions

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- Early feasibility studies are carried out early in the regulatory pathway but form the foundation of sufficient clinical evidence
- Robust early feasibility studies, early engagement with regulators and a harmonised approach provide confidence in the clinical evidence, predictability for manufacturers, maximise resources and improve patient safety
- The Clinical Development Plan is an MDR requirement and should describe progression from exploratory investigations, such as early feasibility studies, feasibility and pilot studies to confirmatory investigations, such as pivotal investigations and PMCF Investigations

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