INNOVATION IS THE KEY.
SUSTAINABILITY LEADS THE WAY.

BNN Innovation Support - Regulatory

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BNN Innovation Support Team

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BNN Services

GO-COMPLIANT

Regulatory Advice and Operational guidance and implementation for **(nano)pharmaceuticals and MD/IVD.**

GO-SUSTAINABLE

Design & create safe and sustainable innovative materials, processes, and products following the **SSbD principles**

GO-SMARTER

Through optimal training…**SSbD, regulatory** and **business aspects**, and **optimize the innovation process**

GO-2-MARKET

Combining our knowledge of **technology and business fields**, innovation practices and **strategic guidance**

GO-BEYOND

Link you with an extensive **network of partners** to address any data gaps that arise and ensure steady progress towards your objectives

Opportunities for Collaborating

Regulatory Service…Overview

Members of Association - Synergies

BNN has complemented its existing services with regulatory support

- Consulting
- Public funding programs (Partners or External providers)

Scope

- Products - Drugs (chemicals-biologics)/Medical Devices
- Stage - from preclinical to market
- Condition - no limitation (oncology, neurodegenerative, rare, etc.)
- Region - EU (central/national). US limited activity
- Spectrum - involvement of external experts for specific matters

Strong Expertise

Regulatory Service… Briefly

Drugs

Strategic

- Regulatory Roadmap
- Gap Analysis
- Regular Support

Operational/Strategic

- Interactions Regulators (EMA/National; FDA)
- Orphan Drug Designation
- Paediatric Investigational Plan
- Due Diligence

Medical Devices/In Vitro Diagnostics

Strategic

- Regulatory Roadmap
- Gap Analysis
- Regular Support
- Product qualification/classification
- Standards Identification

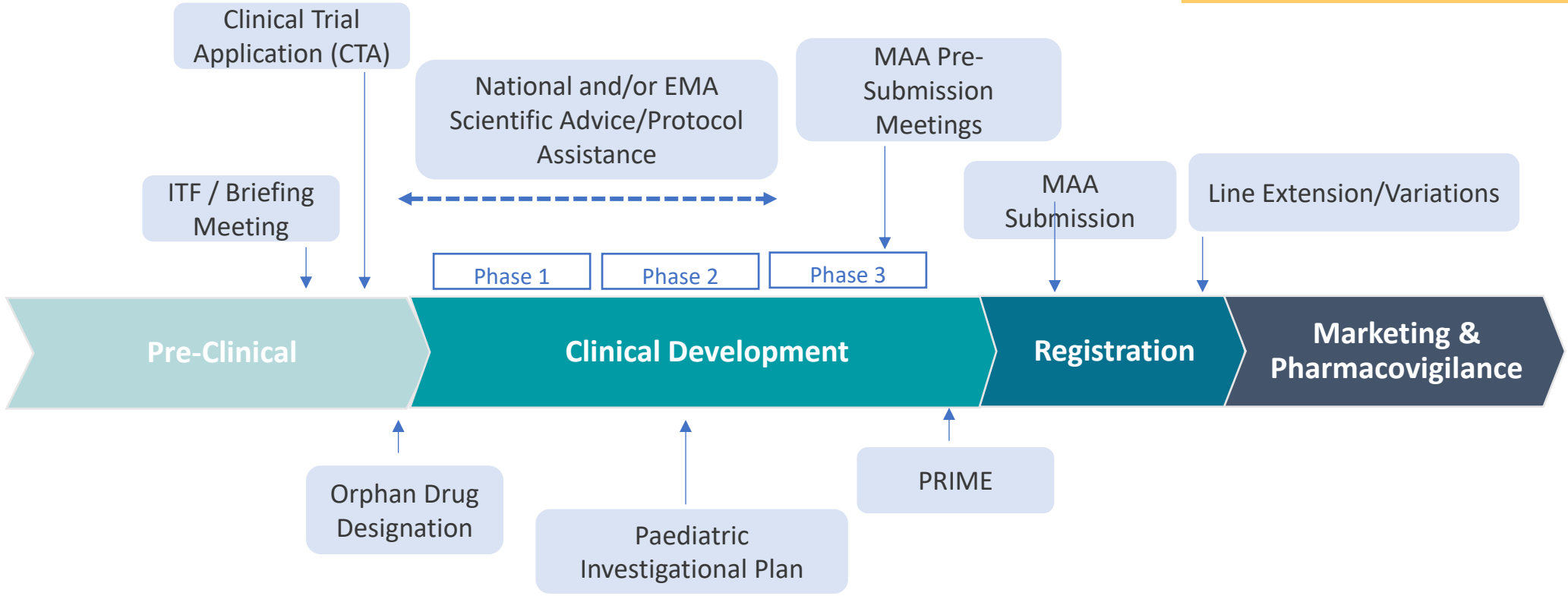
Operational/Strategic

- Submission management, Interactions with FDA: Pre-sub, 510(k), De Novo, PMA, IDE)
- EU NB selection
- EU technical documentation preparation
- Due Diligence

Strategies to add value to product

Regulatory Interactions in EU

- Certainty – Investors
- Validation – Cost and Timelines
- Pathway definition

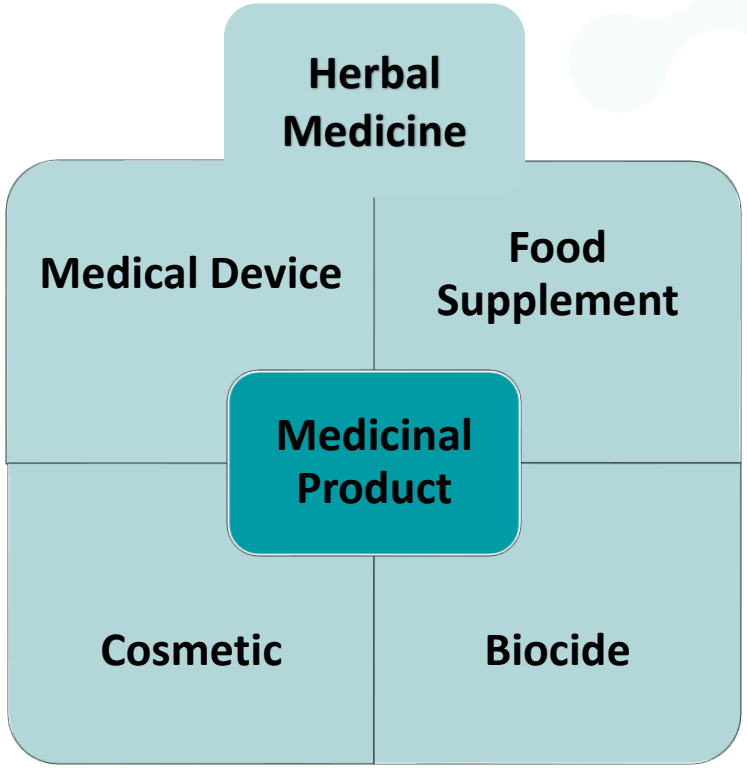


ITF: Innovative task-force; MAA: Marketing Authorization Application; PRIME: Priority Medicines Review

First thing to Clarify

Categorization of Medical Technologies

- Category determine regulatory requirements and Reg. interlocutors
- Straight forward/Not straight forward/Borderline
- Category based on:
  - Nature of the product
  - Intended use
  - MoA
  - Administration/Application
- Borderline – Halfway between different categories, not easy categorization
- Possibility to combine categories – Combination Products, e.x.
  - Patches for transdermal drug delivery
  - Catheters coated with heparin

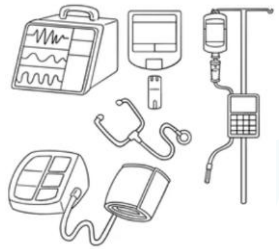


Six major categories

Product Category

Medical Device

Well-being devices?



Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
- *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
- *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*

*and which **does not achieve its principal intended action by pharmacological, immunological or metabolic** means, in or on the human body, but which may be assisted in its function by such means.*

Regulation EU 2017/745 and 2017/746

Product Category

Medicinal Product

A substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a ***pharmacological, immunological or metabolic action****.* Directive 2001/83/EC

Combination Products

Medicine +	Medical Device =	Regulated as **Medicine** (Patches for transdermal drug delivery
Medicine +	Medical Device =	Regulated as **Medical Device** (Catheters coated with heparin)

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