Is the regulatory engagement related to the development of an individual medical product?

**YES**

What type of medical product are you developing?

- **Drug**
- **Device**

**IND/NDA/BLA Pathway**
- Type B Meeting
- Type C Meeting

**IDE/510(k)/De Novo/PMA Pathway**
- Q-submission Program
- Determination Meeting
- Agreement Meeting
- Digital Health Center of Excellence

**Qualification**

- Critical Path Innovation Meeting (CPIM)
- Drug Development Tool (DDT) Qualification Programs
  - Clinical Outcome Assessment Qualification Program
  - Biomarker Qualification Program
  - ISTAND Pilot Program
- Medical Device Development Tools (MDDT) Program

**Improvement**

**MAA Pathway**
- Innovation Task Force Meeting
- Pre-submission meeting for Scientific Advice (or Protocol Assistance for Orphan Medicines)

**Conformity Assessment (CE Mark) Pathway**
- Notified Body Consultation
- Scientific Opinion (by Notified Body)

**Innovation Task Force (ITF) Briefing Meeting**

**Qualification Advice Meeting**
- For Letters of Support or Qualification Opinion

**NO**

What are you seeking advice about?

- Scientific Methodology or Technology*

*not qualification

**FDA**

**EMA**
Appendix: FDA Engagement Opportunity Overview

IND/NDA/BLA Pathways

- **Type B Meeting**
  - Potential Topics: Endpoint development strategy. Formal, intended for general advice on a planned submission (and could be binding).

- **Type C Meeting**
  - Potential Topics: Any topics not addressed in Type A (stalled product development) or Type B meetings; if concept of interest (COI) is acceptable; rationale for the context of use (COU), if DHT-measure is meaningful to patient; analytical and/or clinical validation results (including minimal clinically important difference [MCID]); risk evaluation and mitigation strategies; end of phase advice. Formal and could be binding.

IDE/510(k)/De Novo/PMA Pathway

- **Q-submission Program**
  - Potential topics: can vary, such as advice on investigational plan/protocol, general advice prior to submission of an IDE, 510(k), De Novo, or PMA. Less formal interaction.

- **Determination Meetings**
  - Potential Topics: determine the type of valid scientific evidence needed to demonstrate the device is effective for its intended use. Binding, specific to a single PMA program.

- **Agreement Meetings**
  - Potential Topics: agree on key parameters of the investigational plan and protocol. Binding, open to PMA and 510(k) programs.

- **Digital Health Center of Excellence**
  - For general digital health inquiries and advice on interpretation of digital health guidance documents and/or regulatory status of a digital health technology.

- **Critical Path Innovation Meeting (CPIM)**

- **Drug Development Tool (DDT) Qualification Programs**
  - Program to qualify a tool that sponsors can use in the development and evaluation of drugs; applicable to different drugs or diseases. DDT programs include submission of a letter of intent (LOI), followed by a qualification plan (QP), and then a full qualification package (FQP).
Potential Topics:

• pre-LOI meetings available on a case-by-case basis to help submitters understand the qualification process and offer suggestions on ways to optimize their submissions.

• LOI: concept of interest, context of use, description of the measure, unmet need for the instrument.

• QP: qualitative evidence, qualitative study protocol, qualitative results, interview guides, quantitative (statistical) analysis plan.

• FQP: QP documents, qualitative study protocol, qualitative results, interview guides, quantitative (statistical) analyses plan, results from quantitative analyses, datasets.

Medical Device Development Tools (MDDT) Program

• Program to qualify a tool that sponsors can use in the development and evaluation of medical devices; applicable to different devices or diseases.
Appendix: EMA Engagement Opportunity Overview

MAA Pathway

- Pre-submission meeting for Scientific Advice (or Protocol Assistance for Orphan Medicines)
  - Advice on best methods and study designs to generate robust evidence for a specific medicinal product in a clinic program.
  - Potential Topics: Endpoint development strategy, if COI is acceptable, rationale for the COU, if DHT measure is meaningful to patient, how the technology will provide clinically meaningful data; analytical and/or clinical validation results (including MCID); written advice, binding.

Conformity Assessment (CE Mark) Pathway

- Notified Body Consultation
  - If needed prior to CE Marking (EMA not involved).
  - Potential Topics: general advice on medical device development and scientific evidence necessary to demonstrate safety and performance.

- Scientific Opinion
  - Obtained by the Notified Body on behalf of the applicant for some medical devices (i.e. when devices are used with drugs).
  - Potential Topics: advice on scientific evidence necessary to demonstrate safety and performance for significant-risk devices.

Innovation Task Force (ITF) Briefing Meeting

- General advice on methodology or technology to enhance drug development; not binding.

Qualification Advice Meeting

- Advice on a methodology or technology to be used for pivotal trials (based on data from exploratory studies); applicable to different medicinal products or diseases.
  - Potential Topics: the methodology and its clinical usefulness, added benefits compared to traditional methods, whether the clinical measure taken with the technology is fit for the intended use in regulatory decision making (content validity, construct validity, reliability and sensitivity to change), generalizability and clinical applicability of the methodology.
  - Qualification Advice meeting may result in a Letter of Support (if further qualification is needed) and a Qualification Opinion may be sought (binding).

Interactions with Health Technology Assessment (HTA) bodies are out of scope of this document. HTA engagements may vary depending on the country.
REFERENCES


