QUICK REFERENCE GUIDE TO PROCESSES FOR INTERACTING WITH THE US FOOD AND DRUG ADMINISTRATION (FDA) REGARDING NOVEL ENDPOINT DEVELOPMENT

DEVICE TRIALS

The process for interacting with the Center for Devices and Radiological Health (CDRH) at the FDA when developing a therapeutic medical device is described in a formal guidance document and a draft guidance:

1. **Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff**.[1]

   The interactions described in this guidance are applicable to sponsors seeking FDA feedback on potential novel endpoints for use in an investigational device exemption (IDE) trial.

2. **Medical Device Development Tools - Draft Guidance for Industry, Tool Developers, and Food and Drug Administration Staff**.[2]

   This draft guidance provides information for stakeholders seeking FDA input on a tool that medical device sponsors can use in the development and evaluation of medical devices.

DRUG TRIALS

There are three potential regulatory pathways for engaging with the Center for Drug Evaluation and Research (CDER) at FDA:

1. **The Investigational New Drug (IND)[3]/New Drug Application (NDA)[4]/Biologics License Application (BLA) pathway[5]**

   The IND/NDA/BLA process, the traditional and most commonly used pathway for engaging with CDER, is specific to individual drug development programs where drug sponsors can seek FDA feedback on potential novel endpoints.

2. **The Clinical Outcome Assessment (COA) Qualification Program[6]**

   The newer Drug Development Tools (DDT) COA Qualification pathway is outside of an individual drug development program. Intended to advance the development of novel outcome assessments, it provides developers the opportunity to collaborate with FDA throughout endpoint development, ultimately resulting in potential qualification of the COA instrument.

3. **Critical Path Innovation Meetings (CPIM)[7]**

   The CPIM pathway is another regulatory mechanism that is outside an individual drug development program. Its purpose is to discuss a methodology or technology proposed by the meeting requester and for CDER to provide general advice on how this methodology or technology might enhance drug development. This could include novel technologies used to capture or derive novel endpoints.

REFERENCES

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