ON the DEVELOPMENT PATHWAY
Communications with the FDA

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SUCCESSFULLY INTERACTING with the US FDA

- Increasing the quality of a **sponsor's interactions** with the FDA can greatly improve the chances for a **new drug** or **new device** to successfully navigate the **FDA regulatory maze.**

- Getting a **new** medical product onto the US marketplace involves a complex series of steps, not least of which is **convincing the FDA** that you as the sponsor have met the **regulatory standard** for that type of device or drug.

- Twenty years ago the usual path for finding out whether the FDA agreed with a sponsor that the product should be allowed to be marketed in the US was to simply submit a marketing application for and wait the requisite the official response.

SUCCESSFULLY INTERACTING with the US FDA

- Nowadays, for the **most successful companies**, interacting with the FDA occurs at an **earlier stage**, and the nature of these interactions will, to a large extent, shape how successful a sponsor is at their **ultimate goal -** marketing approval or clearance for their medical product.

SUCCESSFULLY INTERACTING with the US FDA

Because FDA has the advantage of viewing **the spectrum of drug / device development across sponsors**, **indications**, and **drug classes**, FDA is able to communicate advice to sponsors with that expertise in mind, while upholding commercial confidentiality

SUCCESSFULLY INTERACTING with the US FDA

- FDA's **stated philosophy** that "**timely interactive communication** with Sponsors during drug or device development is a **core activity to help achieve our mission** to facilitate the conduct of **efficient and effective drug / device development programs**, which can enhance public health by making new safe and effective drugs available to the American public in a timely manner."

- In recent public statements, FDA has noted that "**Sponsors who avail themselves of the opportunity to meet with FDA early in development have substantially reduced the time from the start of human testing—when FDA first becomes involved—until marketing approval**."

SUCCESSFULLY INTERACTING with the US FDA

For instance, companies that meet early with FDA during drug development have experienced a **median product development time reduction** of **1.4 years** and upwards of **2.1 years for orphan drugs**.

Thus, increased communication during drug development ultimately will **reduce time to market** and **speed** the availability of important new therapies to patients.

Pre – IND , Pre – IDE ,

- These interactions fall under the broad umbrella of what is known as the pre-IDE pre-IND programme.

- **In 1996, it was originally created to describe** the informal interactions that could take place before a sponsor officially submitted an IDE, or an IND application to gain permission to conduct a clinical study of their investigational device / drug in the US, in order to better understand the FDA's expectations for the eventual IDE; IND (**First in Human Clinical Trial**).

- The name pre-IDE; pre-IND has evolved to become a term of art since its inception, and now **serves as the mechanism for interacting with the FDA** for several other purposes.

Pre – IND , Pre – IDE ,

- As defined by the Food and Drug Administration (FDA), an IND, or **Investigational New Drug application**, is a request for authorization from the FDA to **administer an investigational drug or biological product to humans.**

- An IDE, or **Investigational Device Exemption**, allows an investigational device to be used in a clinical study to collect safety and effectiveness data required to support a premarket approval (PMA) application or a premarket notification [510(k)] submission to the FDA.

Pre – IND , Pre – IDE ,

- To discuss the scope and design of a sponsor’s next planned clinical study
  Sample size,
  study design,
  endpoints,
  statistical considerations
- Safety Monitoring
- Product development and production for the first in human use

Kinds of Meetings – Medical Devices

- Scientific Meeting/**Prior to proof of concept animal studies**
- Early Collaboration Meetings (Agreement and/or Determination)
- Pre-IDE Meeting/Post-feasibility/Pre-Pivotal Study Meeting
- Informal Pre-IDE Meetings
- Other Device Meetings
  - Pre-PMA Meeting
  - 100-Day PMA Meetings
  - Post-deficiency letter for 510(k) or PMA
  - Appeal of final decision on PMA, 510(k), IDE disapproval
- Advisory Committee Meeting

Kinds of Meetings – Drugs and Biologics

- Drugs and Therapeutic Biologics
  - Pre-clinical Research Meeting
  - Pre-IND Meeting
  - End of Phase 2/Pre-Phase 3 Meeting
  - Clinical Hold Meetings
  - Pre-NDA Meeting
  - Advisory Committee Meeting
  - End of Review Conference
  - Refusal to File Conference
  - Pre-NDA Supplement Meeting

Opportunities to Interact with the FDA

- Today **Many Opportunities** exist to interact with FDA throughout the **medical product life cycle (and not only before (PRE) research start)**

Conclusion

- Establishing a **good** working relationship and **open communication** with the FDA is essential to the development of any regulated product.

THANK YOU

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