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Module 2 – Understanding the Research Process and R&D Decision Making

Understanding Medical Device R&D

While all new drugs and biologics follow the same basic R&D pathway, there are several different development pathways for medical devices. Medical devices are defined as products that are used to diagnose, prevent, or treat health conditions that *do not* work through a chemical action in the body.

It is a broad category of products that include things like tongue depressors and surgical gloves, wheelchairs, x-ray machines, and devices that are surgically implanted in people.

Regulators use risk-based classification systems to determine the regulatory requirements for medical devices. Details vary by country. The classification systems and class requirements are generally based on what the device will be used for, how invasive it is, how long it will be used, and the risks and potential harms associated with its use.

FDA, for example, classify devices into 3 categories.

- Class I devices, such as tongue depressors and surgical gloves, have the simplest design and almost no likelihood of causing an injury or illness from their use.
- Class II devices, such as x-ray machines, cardiac monitors, and powered wheelchairs, have more complex designs, and their use presents minimal risk of causing injury or illness.
- Class III devices are very complex, and are intended to support or sustain human life; as a result, they are capable of posing substantial risks. Examples include cerebral stimulators and heart valves.

Most medical devices used to treat health conditions, including SCI, are considered Class II or Class III devices.

FDA requires all three classes of medical devices have to comply with a basic set of regulations, sometimes called “general controls.” General controls establish minimum requirements for device manufacturing methods, product quality, accurate labeling, and registration with regulatory authorities.

Most Class II devices have to meet additional requirements before they can be marketed. In the U.S., most Class II devices are approved using FDA’s 510(k) pathway. This pathway requires evidence that the new device is “substantially equivalent” in use, design, materials, labeling,

and other characteristics, to an existing device, called a “predicate device.” Only 10-15% of 510(k) applications require clinical data.

The highest-risk Class II devices, plus all Class III devices, *do* require clinical data. These devices also require a full marketing application called a PMA, or Premarket Approval, before they can be marketed.

For medical devices that require clinical trials, the R&D process is similar to the drug development pathway, but with some key differences.

The first step is called discovery and ideation, and involves determining the characteristics that a medical device needs to have to treat an injury or illness. Just like drug discovery, this process relies heavily on knowledge developed through basic research.

The next step is to create a prototype of the device that can enter preclinical development. The prototype may be refined and retested in animal models many times during this stage.

If the device will be tested in clinical trials, the sponsor must first submit an application regulators. All the protections for study participants – including IRBs, informed consent, and safety monitoring – also apply to clinical trials of medical devices. However, clinical trials for medical devices are different from drug trials in several ways.

Typically, there are two stages instead of three: feasibility testing and pivotal testing. Feasibility studies are usually required to assess safety and basic efficacy before a pivotal study. Typically, only one pivotal study that demonstrates safety and efficacy is required.

Device trials also tend to be smaller than drug trials.

Even though the development pathway for medical devices and drugs are different, medical device sponsors and regulators face many of the same decisions about product design, study design, and benefit-risk trade-offs. And just like in drug development, advocates can help companies and regulators make better decisions.

Advocates can help medical device companies and regulators understand what medical needs are most important, and provide advice on how to design devices that people will want and be able to use. When clinical studies are required, advocates can help ensure that people will want and be able to participate. Advocates also can advise developers and regulators on what benefit and risk trade-offs are acceptable, and which are not.