North American Spinal Cord Injury Consortium

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

Introduction to research and development

New medical products, including medicines and medical devices, follow step-by-step research and development processes that are required by government officials to protect the public from products that are unsafe or do not work.

These government officials, called "regulators," must approve or clear new drugs or therapeutic medical devices before companies are allowed to market them. Until that happens, these products are considered experimental.

Throughout the research and development process, called "R&D" for short, scientists, companies that make drugs and devices, and regulators are faced with complicated decisions. These include:

- What characteristics the drug or device should have
- How to design studies to test the product
- How to measure safety and efficacy
- When to keep going and when to stop, and
- How to weigh the health benefits a product provides against its side effects or risks.

Research advocates can help scientists, companies, and regulators make those decisions in ways that reflect what is important to the SCI community.

In this module you will learn about:

- The R&D processes for drugs and devices.
- Who the decision-makers are, and how they approach decision-making.
- How basic research creates the foundation for drug and device R&D.
- How research advocates can help throughout the R&D process.