

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

Module Summary

Here are the key points from Module 2 – Understanding the Research Process and R&D Decision Making:

- The drug and device R&D pathways are designed to protect people from harm while we build knowledge about a new treatment.
- For sponsors and regulators, the R&D process presents a series of difficult decisions and trade-offs that often have to be made before they know everything they would like to know.
- SCI research advocates can help improve R&D decision-making by:
 - Informing sponsors and regulators about the SCI community's unmet needs.
 - Communicating the SCI community's expectations of benefit and tolerance for risk.
 - Advising on medical product characteristics, administration, and packaging.
 - Identifying and helping reduce barriers to participation in clinical trials.
 - Commenting on regulations and guidance documents, testifying at public hearings about drug development, and serving on advisory committees.
- Basic research about what happens when the spinal cord is injured and translational research on how to stop, slow, or reverse damage are the essential starting point for drug and device R&D.
- Research advocates can help advance basic and translational research by:
 - Identifying the scientific questions that are most relevant to the SCI community
 - Explaining what medical problems need to be understood and solved
 - Thinking through how basic and translational research might be applied during R&D or in healthcare
 - Ensuring that basic and translational research is useful to the SCI community