

## Module 3 – Addressing Historical Challenges in SCI Research

### Introduction to Challenges in SCI Research

In the previous module, we discussed the research and development pathways that all new drugs, biologics, and medical devices must go through before they can be approved for use by the public.

We described how the step-by-step process slowly builds knowledge about a new drug or device, and how challenging it is for sponsors and regulators to make decisions along the way, before they have all the information they would like.

In SCI, there are additional factors that create special challenges in R&D. These include the many different ways a spinal cord can be injured and the wide variety of effects an SCI can have on different people, which makes it difficult to determine the effects of a therapy in the real world.

The rarity of spinal cord injuries compared with more common conditions and the demands of emergency care following a traumatic SCI also present logistical challenges for clinical trials.

Even the care of animal models during discovery and preclinical research presents special demands that are different from those in research concerning other health conditions.

Understanding the challenges that are unique to SCI research can help a research advocate anticipate barriers that could prevent a clinical trial from succeeding and propose suggestions that can support the translation of basic research into clinical research, and guidelines for rehabilitation and healthcare.

In this module you will learn:

- Some of the reasons it is difficult to translate scientific discoveries about SCI from mouse and rat studies into successful human clinical trials.
- Factors that make it difficult to conduct and complete clinical trials in SCI.
- Factors that make it difficult for people with an SCI and their caregivers to participate in clinical trials.

Ways that research advocates can help researchers anticipate and solve some of these challenges.