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Module 3 – Addressing Historical Challenges in SCI Research

Challenges for Sponsors of SCI Clinical Trials

Clinical trials in SCI also have unique challenges relative to other health conditions. One of the biggest is finding enough people to agree to join a study.

The relative rarity of spinal cord injuries makes it hard to find participants. Any one hospital or center may not see a patient with an SCI for months or more.

Expanding a study to include more hospitals may not help. For one thing, not every hospital has the research staff and the capabilities to participate in a clinical trial in SCI. Even those that do require special training to do SCI assessments.

Jim Hamer – Just expanding the number of centers does not always equate to faster enrollment. Um, or even getting, you know, the concern of ensuring you have staff, um, and assessors that are familiar with what you're doing. They may be great nurses but they're not great at doing research if they're not as familiar as other centers.

In addition, the more sites a trial sponsor opens, the more the trial costs, even if the new sites enroll few or even no participants.

Jim Hamer – For every center that we have to begin contract negotiations and we finalize many of those institutes require large or potentially large upfront dollars for preparing the contract, preparing the regulatory submission to either the local IRB or to a central IRB, which is an institutional review board that has to be obtained before the study can move at that center. So those added costs, um, as well as overhead costs that many budgets have nowadays all keep adding on.

The difficulty enrolling participants into trials is compounded by the wide variation in the way SCI can affect individuals, even when their level of injury and other characteristics are similar. In a small trial with few participants, one or two who recover better or worse than expected can sway the results of the whole study.

To prevent that, SCI trials need more participants than other conditions where outcomes are less varied or more predictable.

Research advocates have an important role to play in increasing participation in clinical trials. Advocates can raise awareness of the opportunity to participate in trials to the community. They also can help remove barriers to participation by helping researchers design studies that

are less burdensome to people with SCI and their caregivers. We'll talk more about that in the next video.

In acute SCI, meaning within the first several days of the injury, there are additional challenges. Acute trials often require participants to be treated very soon after injury, because that is when acute therapies are most likely to have a benefit.

In reality, rapid treatment with an experimental intervention may not be possible for people who need life-saving emergency treatment first.

Another challenge in the acute setting is that people who have experienced a traumatic injury may not be able to consent to participate in a trial, and a legal representative may not be available to consent on their behalf.

It is also harder to measure whether a new treatment improves function in acute SCI, because most people who have an SCI will experience some amount of spontaneous recovery within the months following an injury.

We know that the location and severity of injury are factors that influence how much function will return, but even two people with very similar injuries can experience very different amounts of spontaneous recovery and on very different timelines.

This means that in acute SCI, it is hard to tell if someone who improves in a clinical trial is benefitting from a treatment or just improving on their own, unless the improvement is very large. More subtle changes in function that could represent big changes in independence and daily activity often are not measured, in part because reliable measures haven't been validated.

Working with researchers and regulators, research advocates can help guide the identification of measures that are meaningful to the SCI community.

In the chronic setting, there is a larger pool of people living with the condition. However, trials in the chronic setting can be more affected by issues that make it hard for individuals living with SCI to join or stay in a study.

We'll talk about those in the next video.