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The Cycle of Service: Clinical Trials Through the VA

By Michael Winer, PhD

Clinical Trials (CTs) are considered the pinnacle of medical evidence, as recognized by the Oxford Centre for Evidence-based Medicine, England. A lot goes into CT operations: planning, conducting, and then analyzing the data, as well as budgeting labor, materiel, and fringe costs. A given CT could conceivably involve hundreds of study personnel and external reviewers; sometimes thousands of patients will enroll. Given that CTs are generally conceived with the aim of changing medical practice, it should be expected that payers, federal regulatory agencies, professional organizations, and patients all be brought to the table at appropriate junctures so that the study has maximum impact. CTs are big; they are important—and they can be intimidating. But more than any single product, service, or provider, a CT has the potential to gather stakeholders in a unified effort to answer a high-value question.

Perhaps the greatest challenge facing would-be trialists in O&P is the more individualized nature of O&P research: Are there enough patients to enable a large-scale study? The answer may well be yes. Approximately 185,000 amputations occur per year in the United States; with estimates of 65–80 percent being lower-limb amputations; the prevalence of limb loss is expected to double between 2005 and 2050.1

If O&P is going to evolve along with others in the allied health fields, it is going to need to develop a trials culture. Partners with this expertise are already in place in the U.S. Department of Veterans Affairs (VA) Cooperative Studies Program (CSP). CSP is embedded within the VA healthcare system and is designed to advance the health and care of veterans through cooperative research studies that produce innovative and effective solutions to veteran and national healthcare problems. For 70 years, CSP has been a national and international leader in clinical research, with publications in top medical journals, informing topics as varied as infectious diseases and robotic rehabilitation.2 On multiple occasions, CSP has partnered with the VA’s rehabilitation research and development community to advance priority technologies that include development and testing of robotic upper-limb prosthetic systems as part of the U.S. Food and Drug Administration approval process for commercialization. Now may be the best time to build on this history of cooperative research by starting a clinical trial.

CSP continually welcomes study ideas and encourages innovative research that will improve veterans’ quality of life. CSP has a clinical research infrastructure that provides funding to VA clinician investigators, but many projects thrive on CSP’s ability to collaborate with external partners who share mutual goals; there are mechanisms by which private providers can work within a CSP study. Many veterans are looking for ways to continue their service, and they view participation in CTs as a way to help fellow veterans, or to blaze a trail for the younger generation; many find appeal in the notion that their participation in VA research will improve healthcare locally and internationally. Given that the initial lower-limb amputation rate ranges from two to ten per 1,000,3 the VA—serving nearly nine million veterans per year—knows there may be many veterans who would benefit from prosthetics-based CTs. Now is the time for us to work cooperatively to bring CTs to O&P.

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