Two Approaches to Developing Clinical Trialists

South Carolina Clinical & Translational Research Institute (SCCTR) & North Carolina Translational & Clinical Sciences Institute (NC TraCS)

SCCTR MUSC Contributors – Diana Lee-Chavarría, Amanda Fortelney, Signe Denmark, Stephanie Gentilin, Clare Tyson, Royce Sampson, Tammy Loucks, Patrick Flume, Marc Chimowitz, Tanya Turan

UNC Contributors – John Buse, Nicholas Shaheen, Andrea Carnegie, Laura Viera, Catherine Barnes

Introduction

Robust clinical trials are a vital component of conducting research at academic medical centers, and it is important to have a diversity of clinical trials and a qualified pipeline of clinical trialists at such institutions.

Establishing a clinical trials portfolio and building a qualified study team requires dedicated effort on the part of local site principal investigators (PIs).

Rationale

Establishing a clinical trials portfolio at health centers provides:

- patients the opportunity to participate in the development of state-of-the-art therapeutics
- academic and leadership opportunities for site PIs

Clinical productivity goals that drive health care provider reimbursement may be a barrier to engagement in academic activities, including leading clinical trials.

To address this barrier, SCTR and NC TraCS initiated new programs with College of Medicine and Cancer Center investments to provide 10% protected time for 12 months to develop four clinical trialists per year. These programs include protected time for new trialists, training, consultations, mentoring, and other resources. A separate “bootcamp” was also developed at each institution to provide high-level overviews of clinical trial PI responsibilities.

Appreciating that other CTSAs may face similar challenges, we share our approaches to clinical trialist development and preliminary data from these innovative educational programs.

Potential Impacts

- expand pipeline of local site investigators
- increase breadth and depth of clinical trial opportunities at the department and organizational levels
- reinforce good clinical practices related to trial selection, initiation, and management

MUSC Clinical Trialist Training Program (CTTP)

Inaugural Cohort, July 2021-2022

CTTP bootcamp participants and selected evaluation results

- 58 Registrants
- 39-45 attendees/session
- 48% early career, 63% not served as PI on a clinical trial
- Overall evaluation – 71% responded

UNC-CH Clinical Trialist Training Program (CTTP)

Inaugural Cohort, July 2021-2022

The UNC-CH CTTP is a one-year program to develop new clinical trialists at UNC-CH. Applicants must:
- 1) hold a full-time clinical faculty appointment in the UNC SOM at the rank of Associate Professor or lower at time of award
- 2) have a clinical doctoral degree
- 3) be board certified in their specialty

Application materials included letters from the applicant and the applicant’s department chair or division chief and a current curriculum vitae.

By the end of the CTTP, selected investigators (scholars) should engage in new clinical research that will generate a continued salary support (at least 10%) and cover research costs of the trial; and develop a clinical trial portfolio with sustained 10% salary support for at least 3 years after the program.

UNC-CH Clinical Trialist Training Bootcamp

August 4th, 11th, 18th and 25th

UNC-CH held a Clinical Trialist Training Bootcamp, required for CTTP scholars but also open to other UNC-CH investigators. Sessions were virtual and 2 hours in length, once weekly for 4 weeks.

Overall Bootcamp Evaluation (Across All 4 Sessions)

- NC TRaCS and other Services & Resources
- Research Feasibility
- Budget Preparation
- Contract Review
- IRB Application
- Managing a Study Team

Bootcamp Topics Included:

- PI Responsibilities
- Participant Recruitment
- Informed Consent
- Protocol Adherence
- Adverse Events and Protocol Deviations
- Site Visits

Registration for the bootcamp was limited to 30 in order to encourage participant engagement via the virtual platform. Priority registration was given to CTTP applicants who were not selected as CTTP scholars.