ITHS Clinical Research Boot Camp 2022

AGENDA

Week One

July 18–July 22

Monday, July 18, 12–1pm PDT

HOW TO GET STARTED AS AN INVESTIGATOR IN AN EXTERNALLY SPONSORED STUDY

Panel members will describe their initial experience as investigators in clinical trials, including how well their prior training prepared them for the new role, whether they encountered any surprises, and how they managed unfamiliar responsibilities.

Tuesday, July 19, 12–1pm PDT

HOW TO MAKE BEST USE OF MONITORS AND COORDINATORS

Panel members representing investigators and staff will discuss best practices in meeting regulatory requirements through training, early identification of problems and implementation of corrective action plans.

Wednesday, July 20, 12–1pm PDT

HOW TO MAKE THE TRANSITION FROM INVESTIGATOR TO LOCAL PI FOR AN EXTERNALLY SPONSORED STUDY

Panel members will discuss how they identified and developed a specific area of expertise that offered a career opportunity as a clinical investigator. They will also discuss how they prepared themselves to assume responsibilities as a PI and learned how to manage a study team.

Thursday, July 21, 12–1pm PDT

HOW TO LAUNCH AND CONDUCT AN INVESTIGATOR-INITIATED TRIAL WITH OR WITHOUT PHARMA SUPPORT

Panel members will discuss how they have designed clinical trials and obtained the necessary financial support to complete the study successfully. Supply of the investigational product for these studies is a key consideration, often requiring support from a pharmaceutical manufacturer.

Friday, July 22, 12–1pm PDT

HOW TO NAVIGATE AN IND APPLICATION AND TRIAL UNDER FDA OVERSIGHT

Panel members will explain when and why FDA oversight through an IND is necessary. They will highlight FDA guidance documents that explain the expectations that come with an IND and how they apply in an academic setting.

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Week Two

July 25–July 29

Monday, July 25, 12–1pm PDT

HOW TO NAVIGATE THE START-UP PROCESS: TIPS FOR EFFICIENCY FROM PROFESSIONALS

The clinical trial start-up process is notoriously complex at any institution. Panel members will discuss how they have founds ways to anticipate problems and improve efficiency, especially in situations where they do not have full control.

Tuesday, July 26, 12–1pm PDT

IF WE BUILD IT, WILL THEY COME? STRATEGIES FOR RECRUITMENT

Panel members will discuss how they estimate the numbers of subjects who fulfill both the inclusion and exclusion criteria for a study. An equally important consideration is the proportion of eligible subjects who would be willing to participate in the study based on the anticipated benefits balanced by burdens of participation.

Wednesday, July 27, 12–1pm PDT

CAN WE AFFORD TO DO THIS STUDY? HOW TO PREPARE AND EVALUATE A BUDGET

Panel members will discuss how they estimate costs of coordinator effort, data collection and reporting, and financial management. They will offer tips on how to account for costs associated with protocol revisions, monitoring visits and unexpected sponsor or CRO requirements. They will also explain how they negotiate the contract with the sponsor or CRO so as to avoid a deficit.

Thursday, July 28, 12–1pm PDT

ROLES, RESPONSIBILITIES AND RELATIONSHIPS: HOW DO WE WORK IN TEAMS?

Panel members will discuss the allocation of responsibilities across team members according to their training. They will explain how they communicate expectations and accountability and how they devise contingency plans for changes in staffing.

Friday, July 29, 12–1pm PDT

CAN WE REALLY DO THIS STUDY? HOW TO READ A CLINICAL TRIAL PROTOCOL

Panel members will discuss how they determine whether a protocol is a good fit for the team and how easily the work could be accommodated within existing clinical practices and capabilities at our center.

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