Clinical Research Boot Camp 2022

ITHS | Institute of Translational Health Sciences

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Wednesday, July 20th, 2022

How To Make The Transition From Investigator To Local PI For An Externally Sponsored Study

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Q&A

Have a question for the panel?

Ask via the Q&A function.

Want to send a message to only the hosts or panel? Use the **Chat** function.

Resources

Do you have a great resource to share?

Please post freely during the discussion or send us a direct message.

Feedback

We want to hear from you!

You will be redirected to a daily survey upon leaving Zoom.

Please click “Continue” when prompted.

Panelists:

Dr. Bonnie Ramsey (Moderator)

Endowed Professor in Cystic Fibrosis and Vice Chair for Research,
Department of Pediatrics, University of Washington School of Medicine

Kelley Branch, MD, MSc, FACC, FSCCT

Professor, Division of Cardiology
Director, Cardiovascular Clinical Trials Unit

Mignon Lee-Cheun Loh, MD

Professor and Division Chief, Pediatric Hematology, Oncology, BMT and Cellular Therapies,
Department of Pediatrics, UW School of Medicine
Director, Ben Towne Center for Cancer Research, Seattle Children's Research Institute

Filippo Milano, MD, PhD

Associate Professor, FHCRC and UW School of Medicine
Director. Cord Blood Transplant Program and Cellular Therapy Lab, FHCRC

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How does being a local PI for a large externally sponsored trial differ from being a local investigator?

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How does being a local PI for a large externally sponsored trial differ from being a local investigator?

- The Protocol is everything – Guidance, Instruction, Timeline, The Final Word.
  - Your opinion does not matter that much.

- Scrutiny of all your work is mandatory
  - Uniformity and adherence to protocol and Good Clinical Practices is required by sponsors

- Be aware of all regulatory steps for different trial structures

- Scrutinize trial coverage analysis - ensure staff doing coverage analysis understand what is research versus billable to avoid budget surprises

Did you have any formal training for this role before you began? If so, what was it, and how did it help?

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- Training in regulatory aspects both by specific courses and personal experiences.
- Learning how to dialogue with the FDA and the Sponsor
- Knowledge of SAEs report

Did you have a formal mentor for this role? If so, who was your mentor, and how did your mentor help?

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Did you have a formal mentor for this role? If so, who was your mentor, and how did your mentor help?

- Choosing a mentor with experience in running both investigator-initiated and sponsored clinical trial
- Establishing/Supporting connections with companies in the field of interest
- Utilization/Sharing of your mentor's clinical group (clinical coordinator, regulatory, etc.) to run your initial clinical trials

Did you have any surprises about the scope and amount of effort required after you started the work?

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Did you have any surprises about the scope and amount of effort required after you started the work?

- Paperwork and budgets are much more complicated – need experienced staff to help
- Laws of 3 and 2 – 3x as hard, 2x as expensive or 3x as expensive and 2X as hard
- Recruitment can be hard – under-promise and over-perform recruitment

Given your experience, what recommendations would you make to a less experienced colleague who would like to become a local PI for an externally sponsored study ?

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Given your experience, what recommendations would you make to a less experienced colleague who would like to become a work in local PI for an externally sponsored study ?

- Identification of the resources needed—and overestimate! It's never enough!
  - Industry studies are notoriously demanding, especially for filing for FDA or EMA approval.
  - Industry will be parsimonious about the budget.

- Teamwork building, covering all the needed aspects to run a clinical trial

- High involvement/interest in the clinical trial

Did you ever make a mistake in this role? If so, could you tell us more about it? Did you make any changes to avoid a recurrence? If so, what were they, and did they work?

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Did you ever make a mistake in this role? If so, could you tell us more about it? Did you make any changes to avoid a recurrence? If so, what were they, and did they work?

- Experience is needed to run any type of clinical trial. Consider conducting your first industry trial with a more experienced colleague.
- Mistakes will happen, importance of rapid recognition of them.
- Put in place preventive strategies to avoid recurrent mistakes:
- Corrective and Preventive Actions (CAPA). The purpose of the corrective and preventive action system is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence

How did you prepare yourself and build on your prior experience for this new role?

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How did you prepare yourself and build on your prior experience for this new role?

- Site PI is often an apprenticeship – little formal training available. Find experienced mentor and research coordinator, and possibly a research nurse
- Leveraged experience with recruitment and retention of participants. Utilized prior interactions with funding agencies to inform interactions with sponsors
- Creativity to solve problems needed, but within guardrails of the Protocol

Thanks for Joining

Resources

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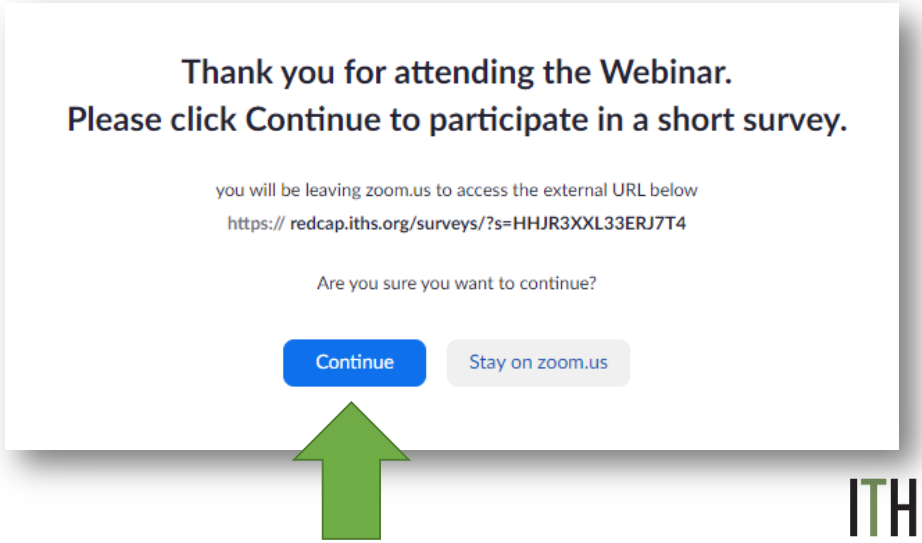

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