3rd Investigator Initiated Trials Summit

Advance The Future of Healthcare Through Compliant Investigator-Led Research
November 13-14, 2023 | The Inn at Penn | Philadelphia, PA

Who Attends:

- Investigator Initiated Trials
- Risk Management
- Compliance
- Collaborative Research
- Scientific Communications
- Medical Affairs
- MSLs
- External Research, Partnerships and Collaborations
- Clinical Research, Clinical Operations Clinical Specialists, Clinical Trial Monitoring Clinical Outcomes and Publications
- Medical Research, Medical Writing, Medical Scientist, Medical Operations
- Grants
- Contract Management
- Health Economics and Outcomes Research
- Trials Managers
- Congress Operations
- Research Process and Infrastructure
- External Research
- Data Transparency
- Global IST Operations
- MA Study and ISR Operations
- Site Management
- Pre-Market Studies
- Post-Market Studies
- Scientific Research and Management
- Corporate Funding

Day 1 **Monday November 13th, 2023** **ALL TIMES ARE IN EST**	
8:00 AM	**Registration and Networking Breakfast**
8:45 AM	**Chairperson's Opening Remarks**
RE-IMAGINE THE IIT ROADMAP	
9:00 AM	**Combine Resources to Help Even the Smallest Patient Populations** Your organization is under high outside scrutiny – and your entire industry is often distrusted by the public. How is your company culture balancing the priorities of therapeutic success for at-risk patients and delivering higher financial returns?

	• Demonstrate the positive outcomes that can occur when the focus is on the patient • Create processes to combat inequities within trials and studies • Explain the benefits, both fiscal and moral, of dedication to patient success Debra Litwak, Sr. Director Global Medical Affairs, Investigator Initiated Trials & Compassionate Use Programs, BEIGENE
9:45 AM	**Highlight How "One-Man" Teams Can Still Make a Difference** In a small company, there may be only one person representing IITs. What is the best way they can continue to support their patient populations? • Detail the successes of small- or micro-sized teams • Discuss the advantage of partnering with smaller firms to eliminate excessive oversight and potential timeline delays • Showcase how influential smaller biotech firms are becoming in the IIT space Andrew Lanier, IST Program Leader, VERASTEM
10:30 AM	Networking Break
11:00 AM	**IIT 101: Map Effective Communication and Clear Definitions** The numerous terms at work in IITs can cause confusion, especially when academic institutions use different definitions than pharma. This session will minimize confusion and lead to a better understanding for all involved parties • Identify and consistently define key terms • Explore areas of inconsistency to avoid future confusion • Interact with fellow attendees to gain a better insight into areas of uncertainty Nami Pandit-Abid, Senior Director, Global Medical Affairs, Immunology, SANOFI GENZYME
11:45 AM	**Set and Achieve DEI Goals** Dedication to Diversity, Equity, and Inclusion is critical to creating equitable spaces for underserved populations. And it is increasingly necessary to ensure all R&D avenues are explored. • Discuss new avenues of engaging marginalized communities • Create effective protocols incorporating DEI initiatives in contract and budgetary exchanges • Examine processes that put ideas into actionable programs
12:30 PM	Lunch
1:45 PM	**Panel: Compare and Contrast Collaborative Studies vs. Traditional IITs/IIRs** Both Collaborative Studies and Traditional IITs/IIRs are part of your research toolkit. Though both have the same basis for collecting patient data, there are distinct pros and cons to each.

	• Convey the similarities and differences between the types of studies • Discuss the regulatory concerns raised by both types of studies • Highlight the main risk areas of each Swati Pradhan-Bhatt, Director, Global Scientific Affairs, ABBOTT LABRATORIES Krunal Desai, Associate Director, Scientific Communications, Clinical Development & Medical Affairs, BOEHRINGER INGELHEIM
2:30 PM	**Structure European Partnerships that will Have the Best Results** COVID shut the door on collaborating with international institutions, but these opportunities are at last returning. How can you be best prepared to restart European partnerships – better than ever? • Showcase the key factors in successful international study design • Outline partnerships and potential collaborators that provide access to deeper and more diverse patient pools • Recognize and prepare for the biggest global challenges
3:15 PM	Break
3:45 PM	**PANEL: Build and Maintain the Best Teams** With many qualified staff like nurses, MSLs, and Clinical Specialists pulled in the direction of COVID, the IIT world was hampered by this unavoidable staffing crisis. Now with things returning to normal, but staff still an issue, how do you know you're hiring not just the appropriate number of staff, but the right staff? • Present the space positively for prospective candidates • Capitalize on the strengths of current staffers to improve data outcomes • Understand the importance of a caring and understanding staff presence from all aspects of a study and trial Kaitlin Morrison, Director of UNC Lineberger Sponsored Clinical Research, UNC LINEBERGER COMPREHENSIVE CANCER CENTER Debra Litwak, Sr. Director Global Medical Affairs- Investigator Initiated Trials & Compassionate Use Programs, BEIGENE Sheila Waters, Medical Science Liaison, SECURABIO Colleen Lemoine, Oncology Clinical Specialist, SECURABIO
4:45 PM	**Day 1 Concludes**
Day 2 **Tuesday, November 14th, 2023** **ALL TIMES ARE IN EST**	
8:00 AM	**Registration and Networking Breakfast**

8:45 AM	**Chairperson's Recap of Day One**
IIT TECHNOLOGY: THE FUTURE IS NOW	
9:00 AM	**Address The Role of the MSL in Investigator Initiated Research** An IIT/IIR benefits tremendously from a well-traveled and experienced MSL, who may take on many roles within the trial. Better grasping MSL performance can lead to overall better study planning and outcomes. • Discuss the importance of proper engagement and oversight MSLs provide • Rely on MSLs to unite teams and functions • Ensure MSLs are prepared for timeline management Dave Maryanski, Medical Affairs Professional, SECURABIO
9:45 AM	**Promote Best Practices for Collaborating with a Site or Institution** Hear from an Institution Leader on how best to collaborate with sites and institutions and keep studies on effective timelines. Both sides need to communicate effectively and understand the importance of controlled urgency. • Realize the need to be a leading partner to sites and institutions • Reduce waiting periods during contract review and dimmish confusion • Provide positive collaboration Laura Seravalli, Scientific Leadership and Research Manager, MERCK
10:30 AM	Break
11:00 AM	**PANEL: Focus on Proper Contract and Budgetary Negotiations** Both Budgets and Contracts are considerable pain points in initializing studies and trials, with major impacts on timelines. Having a clear, concise, and understandable contract and a flexible but consistent budget template can help with start-up speed and help alleviate some of the common pressures that come with these negotiations • Discuss the proper and concise formats of contracts • Establish potential protocols to help collaborators have meaningful discussions surrounding contracts and trial budgets • Debate solutions to consistent contract and budget concerns with members of sites/institutions, pharma, and independent investigators Andrew Lanier, IST Program Leader, VERASTEM Rosanna Veggeberg, Director, Investigator Sponsored Research Unit, FOX CHASE CANCER CENTER Krista Vermillion, Investigator Initiated Trials Division Manager, VANDERBILT UNIVERSITY MEDICAL CENTER
11:45 AM	**Guarantee Processes are Up to Date and Compliant**

	With both the FDA and other regulatory bodies updating their compliance processes and guidelines, it can be hard to stay ahead of the curve. This consistent adjustment presents its own set of unique challenges and needs dedicated staff attention. • Explain latest FDA updates • Highlight upcoming changes to protocols and best practices • Provide guidance on fringe and other "grey area" topics that provide complex problems to trial and study leaders
12:30 PM	**Lunch**
1:30 PM	**INDEPENDENT DISCUSSION GROUPS** *Our facilitated, Interactive Discussion Groups (IDGs) optimize peer-to-peer learning by crowdsourcing solutions to common challenges surrounding developing and managing IIT programs. The connections you make through the IDGs will become your most valuable takeaways.* • Leverage AI and Data Libraries to Promote Published Findings • Working with Vendors for the Best ISS Portals • Cultivating the Value of Well-Trained Admins • Strategizing Rapid Response to Emergencies
2:30 PM	**Chairperson's Closing Remarks**
Conference Concludes	

SPEAKER FACULTY:

Andrew Lanier
Senior Manager of Medical Affairs
Verastem Oncology

J. Kaitlin Morrison, PhD
Executive Director, LCCC Clinical Research
UNC Lineberger Comprehensive Cancer Center

Krunal Desai
Associate Director, Scientific Communications, Clinical Development and Medical Affairs
Boehringer Ingelheim

Debra Litwak
Sr. Director Global Medical Affairs- Investigator Initiated Trials & Compassionate Use Programs
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Krista Vermillion
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Laura Seravalli
Scientific Leadership and Research Manager
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