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BASKET & UMBRELLA TRAILS FOR ONCOLOGY
New Trial Designs and Innovative Approaches to Grow Scientific Knowledge and Tailor Treatments to More Patients
October 17-18, 2018 | Philadelphia 201 Hotel | Philadelphia, PA

Collaborate with pharmaceutical manufacturers, government agencies, non-profits, research centers and patient advocacy groups to master emerging complex trial protocols

INSIGHTS FROM GROUND-BREAKING BASKET AND UMBRELLA TRIALS
Lung-MAP • NCI-MATCH • NCI-COG • ALCHEMIST • Beat AML
DART • I-SPY • MIDAS • VIKTORY • BATTLE

- Discover how cross-industry collaborations can be leveraged as a tool to promote buy-in for new trial formats
- Develop multi-site and multi-manufacturer agreements that are seamless and promote stakeholder confidence
- Dramatically shorten trial timelines in phase III trials
- Explore regulator data standards and ensure that the data created from your organization’s basket and umbrella trials meets expectations
- Master statistical methodologies to ensure efficient and effective trial protocols
- Resolve challenges of multiple indications, such as random high bias leading to false positives

Insights From Ground-Breaking Basket and Umbrella Trials
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REGISTER BY AUGUST 17, 2018 AND SAVE $300!
Basket and umbrella trials have emerged as a potential solution to many of the headaches of failed clinical trials such as high startup costs, narrow patient pools, investigator bandwidth and regulatory approval. These next generation trial protocols serve as a tool to provide broad patient pools and rigorous clinical testing, but adoption is not a simple path. CBI’S Basket and Umbrella Trials for Oncology convenes the key stakeholders looking at adoption to share strategies to quickly overcome these hurdles and foster adoption.
DAY ONE
Wednesday, October 17, 2018

7:30  
Registration and Continental Breakfast

8:30  
Chairman’s Welcome and Opening Remarks
Robert Beckman, M.D., Professor of Oncology and of Biostatistics, Bioinformatics, and Biomathematics, Georgetown University

Navigate Trial Agreements and Planning in Complex Adaptive Trials

8:45  
Gain Cutting Edge Strategies to Design a Confirmatory Basket Trial
- Discuss the core principals of protocol design for confirmatory basket studies
- Resolve challenges of multiple indications, such as random high bias leading to false positives
- Mitigate the risks of false negatives due to pooling of indications
- Be aware of special issues involving biomarker assays and tissue acquisition
Robert Beckman, M.D., Professor of Oncology and of Biostatistics, Bioinformatics and Biomathematics, Georgetown University

9:30  
Lung-MAP, DART and LEAP
Ensure Contracts and Agreements in Basket and Umbrella Trials Align with Regulatory Expectations
- Discuss lessons learned in gaining regulatory approval for major studies
- Align trial support from multiple companies to utilization of one centralized filing system
- Uncover strategies to gain approval to file single regulatory IND
- Promote consistent and accurate regulatory filings
Dana Sparks, Director of Operations and Protocols, SWOG

10:15  
Networking and Refreshment Break

10:45  
Does the Test Drug Work: Perspectives on Basket Trials and Beyond
- Introduce the current landscape of immuno-oncology and the role of basket trial in this field.
- Discuss the motivating example of Keytruda’s approval in MSI-H or dMMR basket trial and what’ next.
- Barriers between the current statistical approaches and practical considerations in early oncology development.
- How to use statistical strategy to improve power for detecting an effective drug.
Cai (Iris) Wu, Senior Scientist in Biostatistics, Merck

11:30  
Implementation of a Novel Platform Trial Design in Pediatric Rare Tumors — Key Learnings and Questions
- Evaluate structural and analytical methodology in platform protocol design

12:15  
Networking Luncheon

Master Intricate Protocol Design and Manage Novel Biomarker Data

1:15  
MIDAS
Novel Bayesian Adaptive Designs for Basket Trials
- Discuss fundamental issues of response heterogeneity across disease types that serve as barriers to efficient basket trials
- Describe novel Bayesian adaptive designs that address the heterogeneity issue and render adaptive information borrowing across disease types
- Significantly improve statistical power to identify effective treatments, remove ineffective treatments, reduce costs and adhere to ethical considerations
- Dramatically shorten trial timelines in phase III trials
Ying Yuan, Professor, Department of Biostatistics, University of Texas MD Anderson Cancer Center

2:00  
Using IRT to Implement Bayesian Futility Analysis in Basket Trials
- Understand the importance of patient flow in precision medicine studies
- Develop techniques and solutions to speed the overall process of screening, identification and assignment to improve trial design and timelines
- Explore the need for molecular tumor boards and biomarker algorithm techniques for patient assignment
- Improve and maintain database records to ensure patients have rapid access to future trials
- Examine the importance of longitudinal pharmacodynamic assessments (solid and liquid biopsies)
Erica Jonas, Associate Director, Services Delivery, Suvoda
Feng Zhou, Principal Biostatistician, Biostatistics, Incyte

2:45  
Networking & Refreshment Break
Master the Design Stage for Basket and Platform Trials to Ensure Smooth Implementation

• Gain an overview of the pros and cons of utilizing platform and basket methodologies
• Evaluate strategies to create consistent protocols to streamline trial planning
• Uncover potential issues you may run into when planning and developing protocols and planning for basket and platform trials
• Discuss methods to determine a drug’s appropriateness for emerging trial methodologies

Wenqiong Xue, Principal Biostatistician, Boehringer Ingelheim

Best Practices in Working with Federal Entities in Basket and Umbrella Trials

I-SPY

Manage Federal and Private Partnerships End-to-End for Basket and Umbrella Trials

• Explore an overview of the public and private sector contributors to developing cancer clinical trials
• Discuss lessons learned from major adaptive trial platforms from Lung-MAP to I-SPY
• Development oversight of multi-stakeholder contracts, logistics, and funding
• Align with patients, advocates, non-profits and other contributing third parties

Stacey Adam, Director – Cancer, Foundation for the National Institutes of Health (FNIH)

Networking, Wine and Cheese Reception

immediately following the final session on day one

JOIN US!
9:45  Networking and Refreshment Break

Manage Biostatistics and Data Challenges in Basket and Umbrella Trials

10:15  Evaluate Receptor Expression with Advanced Imaging and Screening for Basket Trials
- Determine if a potential oncology patient is expressing the correct receptors to assert a positive match to your basket trial
- Identify patient populations who’s gene expression indicated an affirmative match for effective therapy
- Develop clear thresholds for expression to determine what constitutes a successful match
- Validate receptor expression with advanced imaging
  Chris Adams, Chief Executive Officer, Andarix

10:45  WHY BASKET AND UMBRELLA TRIALS NOW?
Industry adoption of Basket and Umbrella trial protocols has dramatically exploded since 2012 with close to half the industry adopting these formats in less than a decade!

Are you keeping pace with your competitors?

11:00  BATTLE
Utilize Technology to Address Statistical Design Challenges in Basket Trials
- Evaluate the methods statisticians currently utilize to handle type I and II error rate controls
- Learn to sufficiently demonstrate control of false positive findings to regulators
- Examine how statistical simulation can be used as a tool to overcome statistical design challenges
- Measure the statistical efficiency gained from basket trials vs traditional approaches
  Alex Liu, Clinical Statistician, Bayer

11:45  Beat AML
Streamline Umbrella Trials for Narrow Patient Pools and Short Screening Timelines
- Measurably improve efficiencies in genomic screening for clinical trial entry, timelines for drug biomarker testing and opening new trial arms faster
- Align a broad spectrum of collaborators including: FDA, labs, vendors, sites, and labs to one unified master protocol
- Treat patients through a personalized medicine approach, expanding potential regimens through drug mutation matches increasing effectiveness of treatment
- Master deployment of novel e-clinical technologies to improve data collection and execution of clinical programs
  Len Rosenberg, Ph.D., RPh, Head Clinical Operations, Leukemia & Lymphoma Society

12:00  Chairperson’s Closing Remarks
Robert Beckman, M.D., Professor of Oncology and of Biostatistics, Bioinformatics, and Biomathematics, Georgetown University

12:45  Close of Conference
Basket and Umbrella Trials for Oncology

**VENUE:**

Philadelphia 201 Hotel  
(Formerly Sheraton Philadelphia Downtown)  
201 North 17th Street  
Philadelphia, PA 19103  
Phone Reservations: (800) 325-3535  
Hotel Direct Line: (215) 448-2000

**ACCOMMODATIONS:**

To receive CBI’s special discounted hotel rate online or by phone, please go to:
- Online: [www.cbinet.com/basket-umbrella-trials](http://www.cbinet.com/basket-umbrella-trials)
- Phone reservations: (800) 325-3535 and mention CBI’s Basket and Umbrella Trials

**Book Now!** The Sheraton Philadelphia Downtown is accepting reservations on a space and rate availability basis. Rooms are limited, so please book early. All travel arrangements subject to availability.

**PLEASE NOTE:** All hotel reservations for this conference should be booked directly with the hotel. CBI does not use Housing Bureaus and none are authorized to call on our behalf.

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*Register by August 17, 2018 and SAVE $300.* Fee includes continental breakfast, lunch, wine and cheese reception, refreshments and conference documentation. Credit Card (Visa, MC, AMEX, Discover) or checks accepted. Please make checks (in U.S. funds drawn on a U.S. bank) payable to: CBI. (No personal checks accepted.) PLEASE NOTE: All advertised discounts are taken from the full, Standard Rate.

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ANY QUESTIONS OR TO REGISTER CONTACT:

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