DIA

Master Protocol Workshop

November 8-9 | Spire | 750 First Street NE, Washington, DC 20002

PROGRAM COMMITTEE

Scott Berry, PhD
President and Senior Statistical Scientist
Berry Consultants

Abby Bronson, MBA
Senior Vice President of Research Strategy
Parent Project Muscular Dystrophy

Daniel Millar, MBA
Senior Director, Strategic Business Transformation, Quantitative Sciences
Janssen Research & Development, LLC

Craig Lipset, MBA
Head of Clinical Innovation, Global Product Development
Pfizer

PROGRAM ADVISOR

Lisa Lavange, PhD
Professor and Associate Chair, Department of Biostatistics
UNC

Overview

The modernization of clinical trials is driven by the need to address important clinical questions more efficiently while decreasing costs. Master protocols (MAPs), including basket, umbrella, and platform trials, provide a method to answer multiple questions in one overall trial structure. Although MAPs require increased planning efforts and coordination, they provide an opportunity to efficiently address a broader set of objectives than would be possible in an independent trial. DIA's new Master Protocol Workshop will examine the common features and the advantages and limitations of different types of MAPs, along with lessons learned from recent master protocol clinical trials such as LUNG-MAP, I-SPY 2, EPAD, DIAN-TU, and others. Experts will discuss best practices for master protocol study design, collaboration - including navigating public-private partnerships and international considerations, and operationalization.

Highlights

- An in-depth look at ISPY2 and EPAD
- Discussions on various design features within a platform trial including randomization, blinding, treatment comparisons, and more
- Explore best practices for operationalizing master protocols and how master protocols impact internal stakeholders' processes
- Networking Reception at the conclusion of day one to continue the conversation and make connections

Intended Audience

Professionals involved in:

- Clinical Research and Development
- Study and Protocol Design
- Biostatistics
- Regulatory Affairs
- Clinical Operations
- Clinical Data Management
- Project Management
- Strategic Planning
- Oncology, Immunology, CNS, Rare Disease therapeutic areas

All Sessions will be in the VUE Meeting Room

DAY ONE | THURSDAY, NOVEMBER 8

11:30AM-5:30PM	Registration
12:45-1:00PM	**Welcome and Opening Remarks**
1:00-1:30PM	Keynote Address
1:30-2:30PM	**Session 1:** Landscape Overview
2:30-3:00PM	Refreshment and Networking Break
3:00-4:00PM	**Session 2:** An In-Depth Look at ISPY 2
4:00-5:00PM	**Session 3:** An In-Depth Look at EPAD
5:00-5:30PM	Q&A Discussion
5:30-6:30PM	Networking Reception

DAY TWO | FRIDAY, NOVEMBER 9

7:30AM-4:00PM	Registration
7:45-8:00AM	Continental Breakfast and Networking
8:00-10:00AM	**Session 4:** Collaboration with Stakeholders
10:00-10:30AM	Refreshment and Networking Break
10:30AM-12:30PM	**Session 5:** Study Design Considerations and Innovative Trials Designs
12:30-1:30PM	Luncheon and Networking
1:30-3:30PM	**Session 6:** Operational Considerations
3:30-4:00PM	Closing Remarks

Learning Objectives

At the conclusion of this workshop participants should be able to:

- Discuss the concepts, benefits, and efficiencies of utilizing master protocols in clinical trial design
- Identify the collaborations needed to successfully design, fund, and execute a master protocol including incentives and challenges for each stakeholder group
- Describe current trials utilizing master protocols and the strategic, design, and operational aspects of each
- Explain key considerations in planning, coordination and regulatory compliance when adopting master protocols

Continuing Education Credit

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This session is designated for up to 10.5 contact hours or 1.05 continuing education units (CEU's). Type of Activity: Knowledge

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Continuing Education Credit Allocation

Day One: 4 contact hours or .4 CEUs, UAN: 0286-0000-18-077-L04-P

Day Two: 6.5 contact hours or .65 CEUs, UAN: 0286-0000-18-078-L04-P

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DAY ONE | THURSDAY, NOVEMBER 8

11:30AM-5:30PM — **Registration**

12:45-1:00PM — **Welcome and Opening Remarks**

1:00-1:30PM — **Keynote Address**

Lisa Lavange, PhD, Professor and Associate Chair, Department of Biostatistics, UNC

1:30-2:30PM — **Session 1:** Landscape Overview

Session Co-Chairs
Abby Bronson, MBA, Senior Vice President of Research Strategy, Parent Project Muscular Dystrophy

Craig Lipset, MBA, Head of Clinical Innovation, Global Product Development, Pfizer

Explore the overall concept of a master protocol and the differences between the different types: umbrella, basket, and platform, by examining ongoing and planned trials. This landscape overview will also discuss the benefits/efficiencies that master protocols can bring to each stakeholder involved in the clinical trial ecosystem: clinicians, regulators, sponsors, and patients.

Scott Berry, PhD, President and Senior Statistical Scientist, Berry Consultants LLC

2:30-3:00PM — **Refreshment and Networking Break**

3:00-4:00PM — **Session 2:** An In-Depth Look at ISPY 2

Session Co-Chairs
Scott Berry, PhD, President and Senior Statistical Scientist, Berry Consultants

Daniel Millar, MBA, Senior Director, Strategic Business Transformation, Quantitative Sciences, Janssen Research & Development, LLC

Get and in-depth look at ISPY2, an exploratory-phase platform trial designed to investigate new treatments for biomarker-identified subtypes of early-stage breast cancer in the context of neoadjuvant therapy.

Donald A Berry, PhD, Professor, Department of Biostatistics, M.D. Anderson Cancer Center, Senior Statistical Scientist, Berry Consultants

4:00-5:00PM — **Session 3:** An In-Depth Look at EPAD

Session Co-Chairs
Scott Berry, PhD, President and Senior Statistical Scientist, Berry Consultants

Daniel Millar, MBA, Senior Director, Strategic Business Transformation, Quantitative Sciences, Janssen Research & Development, LLC

The I-Spy2 trial helped create the platform trial. It has had an amazing record of success and innovation. EPAD is an IMI sponsored phase II platform trial in Alzheimer's disease and has the potential to change the course of Alzheimer's with the innovative platform trial. Each of these trials will be presented and discussed in-depth both from a design, operation, and strategy perspective.

Gary J. Romano, Director, Clinical Research, Johnson & Johnson Prd.

Mark Fitzgerald, PhD, Statistical Scientist, Berry Consultants LLC

5:00-5:30PM — **Q&A Discussion**

5:30-6:30PM — **Networking Reception**

DAY TWO | FRIDAY, NOVEMBER 9

7:30AM-4:00PM — **Registration**

7:45-8:00AM — **Continental Breakfast and Networking**

8:00-10:00AM — **Session 4:** Collaboration with Stakeholders

Session Co-Chairs
Abby Bronson, MBA, Senior Vice President of Research Strategy, Parent Project Muscular Dystrophy

Daniel Millar, MBA, Senior Director, Strategic Business Transformation, Quantitative Sciences, Janssen Research & Development, LLC

Master protocols promise transformational efficiencies for drug developers while addressing shortcomings of traditional clinical trials which leave clinical trial patients underserved and society waiting for new therapies despite considerable investment. This session explores the importance of stakeholder collaboration to enable evolving the clinical development paradigm and realizing the promised benefits of master protocols. Examples will highlight where stakeholders' interests align well and where potential tensions must be managed actively through collaboration.

Abby Bronson, MBA, Senior Vice President of Research Strategy, Parent Project Muscular Dystrophy

Daniel Millar, MBA, Senior Director, Strategic Business Transformation, Quantitative Sciences, Janssen Research & Development, LLC

Victoria Manax Rutson, MD, Chief Medical Officer, Pancreatic Cancer Action Network

Amy Burd, PhD, Vice President, Research Strategy, Leukemia & Lymphoma Society

Gideon M. Blumenthal, MD, Deputy Director Oncology Center of Excellence, OHOP, OND, CDER, FDA

10:00-10:30AM — **Refreshment and Networking Break**

10:30AM-12:30PM — **Session 5:** Study Design Considerations and Innovative Trials Designs

Session Chair
Scott Berry, PhD, President and Senior Statistical Scientist, Berry Consultants

With multiple treatment arms within the same protocol, there is a great potential for innovative trial design features in order to enhance the learnings of the master protocol. Different design features within a platform trial will be discussed including randomization, blinding, treatment comparisons, sharing of controls, longitudinal modeling, and personalizing treatment.

Roger J. Lewis, MD, PhD, Professor of Medicine, Department of Emergency Medicine, Harbor UCLA Medical Center

Karen Lynn Price, PhD, MA, Senior Research Advisor, Eli Lilly and Company

Dionne Price, PhD, Acting Deputy Director, Office of Biostatistics, OTS, CDER, FDA

12:30-1:30PM — **Luncheon and Networking**

1:30-3:30PM — **Session 6:** Operational Considerations

Session Chair
Craig Lipset, MBA, Head of Clinical Innovation, Global Product Development, Pfizer

Daniel Millar, MBA, Senior Director, Strategic Business Transformation, Quantitative Sciences
Janssen Research & Development, LLC

Getting a master protocol trial started may seem daunting. How do you go from an impressive theoretical design to a tangible trial? How do you convince internal stakeholders that it will be operationally feasible within your constraints? This session will explore best practices for master protocol operationalization. Experienced industry colleagues will share their insights on setting up and operating master protocols, including assessment of internal capabilities and practical approaches to resolving common problems. An interactive expert panel and time for question and answer will round out the session.

Meredith Buxton, PhD, MPH, Director, Clinical Trial Strategy, Berry Consultants, LLC

Karen Xia, PhD, Director, Johnson & Johnson

Panelists
Moderator: Daniel Millar, MBA, Senior Director, Strategic Business Transformation, Quantitative Sciences Janssen Research & Development, LLC

Meredith Buxton, PhD, MPH, Director, Clinical Trial Strategy, Berry Consultants, LLC

Karen Xia, PhD, Director, Johnson & Johnson

Victoria Manax Rutson, MD, Chief Medical Officer, Pancreatic Cancer Action Network

Lisa Lavange, PhD, Professor and Associate Chair, Department of Biostatistics, UNC

3:30-4:00PM — **Closing Remarks**

Janet Woodcock, MD, Director, Center for Drug Evaluation and Research (CDER), FDA

4:00PM — **Workshop Adjourned**