DIA

Innovative Trial Designs Conference

Meeting November 3-4 | Tysons Corner, VA

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Overview

Celebrating its 5th year, DIA's Innovative Trial Designs Conference (previously titled Master Protocols and Complex Innovative Design) will bring together a truly multidisciplinary group of experts in clinical trial planning, execution, and analysis.

Contribute your perspective and discuss both the common and unique challenges and opportunities for innovation to meet the patient's needs through protocol design.

Event Goals and Offerings

- Discuss industry perspectives on innovations in clinical trials
- Address daily challenges with implementing and adopting innovative designs
- Seek collaborative solutions with a truly multidisciplinary group of experts
- Examine the growing body of knowledge, experience, and resources to better meet patient needs
- Evaluate real case examples of different types of innovative trials

Why You Can't Miss It

- Advance innovative regulatory science in clinical trial operations
- Develop strong partnerships with stakeholders to aid development of digital technologies
- Increase trials efficiency to clinical drug development and operations
- Provide framework for productive patient engagement
- Increase overall efficiency for productive and successful outcomes

Who Should Attend

Join all-stage professionals from every corner of the vast innovative trial designs industry and related fields:

- eClinical/Clinical Data Management
- Strategic Planning
- Good Clinical Practice
- Patient Engagement
- Research & Development
- Rare, Orphan Diseases
- Statistics and Data Science

Schedule At-A-Glance

All times listed are in EST

DAY ONE | THURSDAY, NOVEMBER 3

7:00AM-4:30PM	**Conference Registration**	Regency Ballroom Foyer
7:00-8:00AM	**Networking Breakfast**	Regency Ballroom A
8:00-8:15AM	**Welcoming Remarks**	Regency Ballroom BC
8:15-9:15AM	**Keynote:** Motivation for Clinical Trial Innovations, Keynote address by **Roger J. Lewis, MD, PhD**, Professor, Department of Emergency Medicine, Harbor-UCLA Medical Center and Senior Medical Scientist, Berry Consultants, LLC	Regency Ballroom BC
9:20-10:35AM	**Session 1:** Landscape and Emerging Innovations within Clinical Trials	Regency Ballroom BC
10:35-11:05AM	**Refreshment and Networking Break**	Regency Ballroom A
11:05AM-12:20PM	**Session 2:** Case Examples with Platform and Umbrella Trial Designs	Regency Ballroom BC
12:20-1:20PM	**Networking Luncheon**	Regency Ballroom A
1:20-2:35PM	**Session 3:** Diversity, Equity, and Inclusion in Innovative Clinical Trial Designs	Regency Ballroom BC
2:35-3:05PM	**Refreshment and Networking Break**	Regency Ballroom A
3:05-4:20PM	**Session 4:** Innovative Trial Designs with Information Borrowing Including Basket Trials	Regency Ballroom BC
4:20-5:20PM	**Networking Reception**	Regency Ballroom A

DAY TWO | FRIDAY, NOVEMBER 4

7:30AM-3:20PM	**Conference Registration**	Regency Ballroom Foyer
7:30-8:30AM	**Networking Breakfast**	Regency Ballroom A
8:30-9:45AM	**Session 5**: Operational Challenges and Best Practices in Implementing Innovative Clinical Trials	Regency Ballroom BC
9:50-11:05AM	**Session 6:** Tool Sets and Methodologies for Complex Innovative Designs	Regency Ballroom BC
11:05-11:35AM	**Refreshment and Networking Break**	Regency Ballroom A
11:35AM-12:50PM	**Session 7:** Utilization of Real-World Data (RWD) and Real-World Evidence (RWE) in Clinical Trials	Regency Ballroom BC
12:50-1:50PM	**Networking Luncheon**	Regency Ballroom A
1:50-3:05PM	**Session 8:** Regulatory Landscape of Innovative Trial Designs	Regency Ballroom BC
3:05-3:20PM	**Closing Remarks**	Regency Ballroom BC
3:20-3:20PM	**Conference Adjourns**	

Learning Objectives

At the conclusion of this conference, participants should be able to:

- Identify the advantages and disadvantages of platform and umbrella trial designs
- Assess the feasibility of implementing platform and umbrella trial designs in future clinical trials
- Discuss operational considerations of platform and umbrella trials
- Define the recent FDA guidance documents on clinical trial population diversity
- Discuss new technologies and innovative trial designs that could potentially enhance trial population diversity
- Obtain information from case examples to avoid potential pitfalls
- Share a roadmap for the documentation and operationalization of innovative clinical trials
- Discuss operational challenges and provide an explanation of available tools
- Present suggested best practices and lessons learned for the future trial development
- Apply machine learning into the drug development processes
- Calculate the Probability of Success using Bayesian methodology
- Recognize opportunities to use data more effectively
- Determine types of Real-World Evidence (RWE) and RWD which could augment-by-design decentralized or adaptive clinical trial designs during study start and execution
- Connect sources of patient data or community data to Electronic Data Capture (EDC) or Clinical Data Repository (CDR) for on-study deployment, emphasizing the value of Real-time data acquisition and processing
- Evaluate data security and privacy, and identify barriers to uploading RWD back to patient's Electronic Medical Records (EMR) or patient accessible dashboards to enhance routine patient care and engage patients in the clinical trial

Continuing Education Credits

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November 3 Day 1: Innovative Trial Designs Conference: 6 contact hours or .6 CEUs Type of Activity: Knowledge, 0286-0000-22-095-L04-P

November 4 Day 2: Innovative Trial Designs Conference: 5 contact hours or .5 CEUs Type of Activity: Knowledge, 0286-0000-22-096-L04-P

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Disclosure statements are included with each speaker's biographical sketch.

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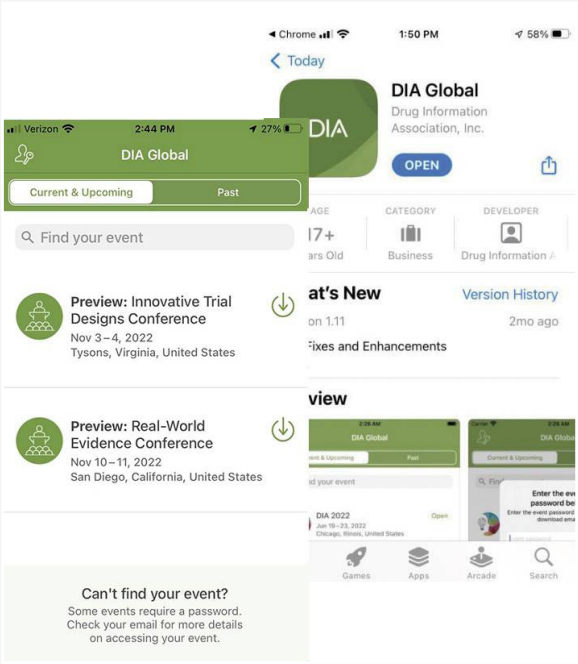

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