WORLDWIDE CLINICAL TRIALS

IN PARTNERSHIP WITH:

PROVENTA INTERNATIONAL

VIRTUAL BOARDROOM

ONLY 25 PLACES AVAILABLE

OCT 12

10am EST

Thursday

Moving Beyond The MTD: FDA Project Optimus Impact on European Drug Development

In the rapidly evolving world of clinical oncology drug development, therapies are becoming safer, patients are living longer, but dose optimization is becoming harder. The FDA's shift towards early phase dose optimization is fundamentally changing how clinical trial programs are designed, managed, and run. This shift requires more time, more patients, and more costs for sponsors who are looking to further develop their asset. European drug developers must be cognizant of these new regulatory requirements to preserve opportunities for global commercialization.

This boardroom will help you:

- Understand FDA Oncology Center of Excellence Special Projects
- Manage the FDA's new Project Optimus requirements from a medical, scientific, and operational perspective
- Plan a strategy to evaluate the efficacy of a wider range of doses in your early development programs

General Agenda

- 21st Century Cures Act and Oncology Center of Excellence (OCE)
- Recent FDA OCE Projects
- Focused discussion regarding Project Optimus
  - What it is and what are the goals
  - FDA expectations
  - Medical, scientific and operational support

SPEAKERS

Matt Cooper, PhD, *Executive Director, Therapeutic Strategy Lead, Oncology,* **Worldwide Clinical Trials**

Matt Cooper is the Executive Director, Therapeutic Strategy Lead, Oncology and has 25 years of experience in the life science industry conducting clinical trials across all phases. His experience spans roles at sponsors, sites, and the NHS, and he has extensive experience in site management and expanded use of oncology therapies. He is passionate about building effective relationships between industry stakeholders to drive innovation and patient access.

Matthew Confeld, *Assistant Director, Clinical Research Methodology,* **Worldwide Clinical Trials**

Matthew Confeld is the Assistant Director, Clinical Research Methodology, and has 10+ years of experience in pharmaceutical science. His experience spans preclinical drug development of environment responsive nanoparticles for various solid tumor indications, serves as a translational advisor to a National Institute of Health center of biologic research in pancreatic cancer, and has extensive experience in pharmacy including clinical pharmacogenomics for a large healthcare system and specialty pharmacy management. He provides consulting-like services to sponsors across phases of development from preclinical through NDA.

About Worldwide Clinical Trial

Worldwide Clinical Trials is a global, midsize contract research organization (CRO) that provides top-performing bioanalytical and Phase I-IV clinical development services to the biotechnology and pharmaceutical industries. Founded in 1986 by physicians committed to advancing medical science, our full-service clinical experience ranges from early phase and bioanalytical sciences through late phase studies, post approval, and real-world evidence. Major therapeutic areas of focus include cardiovascular, metabolic, neuroscience, oncology, and rare diseases. Operating in 60+ countries with offices in North and South America, Eastern and Western Europe, and Asia, Worldwide is powered by its more than 3,000 employee experts.
For more information, please visit www.worldwide.com or connect with us on Twitter, LinkedIn, Facebook, and Instagram.

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