



Please join us for Celerion's Clinical Discussion Forum Dinner

Current Trends in First-in-Human Study Design and Conduct

Gayane Machkalyan, PhD, Protocol Design and Development Scientist II
Staci McDonald, Executive Director of Scientific Clinical Operations

This topic explores ideas about FIH trial design such as sentinel dosing, adaptive design, realistic I/E criteria, exploratory endpoints and biomarkers, flexible protocol language, interim PK analysis, CQt and special populations.

As a CRO, we pool this information from the many protocols that we write or review and within the context of current regulatory FDA guidance. We will also discuss new thoughts affecting clinical trial supply and demands on your CRO pharmacy.

Event Details

Date: Wednesday,
August 7, 2019

Time: 5:30pm-6:00pm:
Arrival/Drink Reception
6:00pm-6:15pm:
Seating
6:15pm-8:00pm:
Presentation/Dinner

Venue: Arterra (Marriott Del Mar)
11966 El Camino Real
San Diego, CA 92130
1.858.369.6032

RSVP

Space is limited. **Please RSVP** to Stephanie Hagen,
Senior Director of Business Development
at stephanie.hagen@celerion.com by **Fri, Aug 2, 2019.**