



# Please join us For Lunch & Learn

## The Nuts and Bolts of Early Clinical Research

Mike Di Spirito, MSc, Director, Clinical Pharmacology & Pharmacometrics

- Designing your First in Human Trial
- Assessing ADME and Absolute Bioavailability with Radiolabeled Drug
- Measuring Drug Interactions
- Evaluating Hepatic and Renal Insufficiency

### Event Details

**Date:** Tuesday,  
August 13, 2019

**Time:** 11:30-12:00: Arrival/Networking  
12:00-13:00: Presentation/Lunch

**Venue:** **UF Innovate**  
**Sid Martin Biotech**  
12085 Research Drive  
Alachua, FL 32615

## About The Speaker



### Mike Di Spirito, MSc | Director, Clinical Pharmacology & Pharmacometrics

Mike is the Director of Clinical Pharmacology & Pharmacometrics at Celerion. He is leading a team of 30 scientists developing study designs and trial protocols in early clinical research, creating statistical analysis plans and conducting pharmacokinetic and pharmacodynamic analyses. Over the last 20 years at Celerion and its legacy companies, Mike has worked on hundreds of NDA-enabling studies: First in Human SAN/MAD, Radiolabeled ADME mass balance, Drug-drug interactions, Hepatic and Renal insufficiency, TQT, Microdosing, Microtracer, Bioavailability, Bioequivalence, Food-effect, and First in Patient signal effects.

## About The Host



**Celerion**, a full-service, early clinical CRO, is the leader in accelerating development for Phase I-III. We enable our clients to make timely decision with expert advice and high-quality data through our unique combination of medical expertise, clinical operations experience and scientific excellence. Celerion uses our experience, agility and innovation to help clients get their drug to market faster so they can start making a difference in people's lives.

To access our unique insights for successful drug development, please visit: [www.celerion.com](http://www.celerion.com)

Space is limited. **Please RSVP** to Chad Pollio, Director of Business Development at [Chad.Pollio@celerion.com](mailto:Chad.Pollio@celerion.com) by **Fri, Aug 9, 2019**.