# Optimizing Clinical Trial Agreements for Effective Trial Management

**WHEN:** Wednesday, May 9th - 9:00 a.m. to 1:00 p.m. (8:30 a.m. coffee/registration)
**WHERE (NEW ADDRESS):** South San Francisco Conference Center (Baden A)
255 South Airport Boulevard, South San Francisco, CA 94080

CLSA
California Life Sciences Association

## Who Should Attend

Clinical Development, Clinical Operations and Legal Staff

## What We'll Discuss

How to leverage your CRO's capabilities - Set up an efficient contracting process
Address key issues in clinical trial agreements - Manage ex-US clinical trial considerations

### Speakers from Faber Daeufer & Itrato PC

**Isabelle DeBear**
**Founding Director, Contracts Specialists**

**Jon Linden**
**Principal**

**Greg Ikonen**
**Principal, Moderator**

### JOIN US AT NOON FOR A SPECIAL LUNCH PRESENTATION

Clinical Trial expert Ian Nisbet will discuss the advantages and incentives for conducting clinical trials in Australia

**Ian Nisbet, BSc, PhD**
**Partner, Afandin**

**CLICK HERE** to register
Please register by May 2nd

faber

*attorney advertising - prior results do not guarantee a similar outcome*

# JOIN US for this half-day seminar designed to help biotech companies to avoid costly pitfalls in clinical trial agreements and optimize the value of their CROs.

Negotiating clinical site agreements is complex, with various CROs, different agreements and multiple legal and regulatory issues. With funding and resource constraints, it is a challenge to get studies up and running quickly while protecting intellectual property rights, meeting regulatory requirements, establishing liability protections, and fulfilling commitments to partners and funders.

This seminar will provide practical, real-world tools to help companies efficiently navigate hurdles and anticipate common issues in negotiating clinical trial agreements and addressing trial-related challenges.

# THE AGENDA

| | |
|---|---|
| 8:30 a.m. | Coffee/Registration |
| 9:00 a.m. | **How Best to Leverage the Capabilities of Your CRO**<br>Not all CROs are equal. Some are good at some things and not as good at others. Ensure that the people you hire are doing the jobs they are qualified to do and preserve your flexibility to evolve the relationship as circumstances change. |
| 9:30 a.m. | **What Types of Agreements (Forms and Clauses) Are Needed**<br>Even the simplest study requires forms for confidential disclosure agreements, site agreements and informed consents. More complicated trials, especially trials involving ex-U.S. sites, can require considerably more. Standard CRO agreements often bulge with boilerplate, which can bog down negotiations, and are designed as "one form fits all." We will show you how to think about the key issues for your study, and how to develop contract templates that address those priorities. |
| 10:15 a.m. | Coffee Break |
| 10:30 a.m. | **Setting Up an Efficient Contracting Process**<br>We will discuss how to create a contracting process tailored for your trial, product and company – one that balances the need to protect your company with the goal of completing contracts quickly. Key topics: determining who will negotiate site agreements; who will be responsible for review of contracts in negotiations; whether the sponsor is a party to the site agreements; and who signs the agreements. |
| 11:00 a.m. | **Special Considerations for Ex-US Studies**<br>We will show you how to plan for different regulatory and legal requirements that vary from country to country. Key topics: GDPR and other data protection laws, legal representative requirements and managing negotiation timelines. |
| 12:00 p.m. | **Lunch & Learn**<br>Over lunch, the conversation will continue with remarks from Ian Nisbet, PhD, an expert on clinical trials in Australia, who will discuss advantages and incentives available for conducting clinical trials in Australia, including significant R&D rebates available to small biotech companies conducting trials there.<br>You will also have opportunities to talk one-on-one with the presenters and raise any additional issues you would like to discuss. |

faber

# THE SPEAKERS

**Isabelle DeBear, Founding Director, Contracts Specialists**
**Faber Daeufer & Itrato PC**

Isabelle is the founder and director of the Contracts Specialists group and brings over 30 years of specialized contracts management and negotiation experience to Faber clients, with an emphasis on multi-national clinical studies. Her vast experience across wide-ranging types of companies in the industry gives her a uniquely well-rounded perspective and understanding of the day-to-day contracting needs of the biopharmaceutical industry. Prior to founding the Contracts Specialist group at Faber, Isabelle worked as a Contracts Manager at Parexel International (a global CRO), Cytomed (a small startup company), and Genetics Institute (acquired by Wyeth Pharmaceuticals) and as Associated Director of Contracts Administration at Millennium Pharmaceuticals prior to its acquisition by Takeda.

Isabelle received a B.A., *magna cum laude*, from Adelphi University and a Paralegal Certificate with a specialty in Corporate Law from Adelphi University.

**Jon Linden, Principal**
**Faber Daeufer & Itrato PC**

Jon is a Principal at Faber Daeufer & Itrato PC with over 25 years' experience handling complex research and development, manufacturing and product licensing collaborations, transactions and agreements in the life sciences and technology industries. Jon helps manage Faber's clinical trial practice, supervising contracts specialists and other attorneys providing transactional support for clients' international clinical trials. Prior to joining Faber, Jon was Senior Counsel at Millennium Pharmaceuticals, Deputy General Counsel at Brookstone Inc. and Product Counsel at Apple Computer (now Apple Inc.).

Jon received a J.D., with Distinction, from Stanford Law School and an A.B., *magna cum laude* with Honors, from Brown University.

**Greg Ikonen, Principal**
**Faber Daeufer & Itrato PC**

Greg is a Principal at Faber Daeufer & Itrato PC and head of the firm's Northern California office. He has over 20 years' experience advising biotech companies on corporate and complex transactional matters, including structuring and negotiating strategic R&D collaborations, board governance issues, corporate financings and intellectual property matters.

Prior to joining the firm, Greg was CEO of Mendel Biotechnology, Inc., where he led the successful sale of its operating business and subsequently led the team after the acquisition in building out its microbial platform and development of new microbial products. During his tenure at Mendel, Greg also served as Senior Vice President, Corporate Development and General Counsel. Before his industry experience, Greg was a partner at Venture Law Group and Heller Ehrman.

Greg received a J.D., *cum laude*, from Harvard Law School and a B.S. in Chemical Engineering from the University of Michigan.

**Ian Nisbet, BSc, PhD - Partner**
**Afandin**

Ian has over 30 years of product development, business development and project management experience in the biotechnology sector, both in Australia and the United States. He has worked at an executive or board level with companies developing products across a range of therapeutic areas (including oncology, inflammatory disease, diabetes, Alzheimer's Disease) and modalities (including small molecules, antibodies, cellular therapies and vaccines). He played a leadership role in the development of two FDA-approved oncology drugs: VELCADEÒ (bortezimib) and SYNRIBOÒ (omacetaxine).

Ian currently serves as Corporate Advisor to Cartherics Pty Ltd, CEO of Cancure Pty Ltd and Chair of VivaZome Pty Ltd. He also acts as a director or advisor to several biotechnology companies, including three US companies undertaking product development in Australia. Over the past decade, Ian has worked with five US companies which, between them, have undertaken six clinical trials in Australia.

Ian received his BSc in microbiology and biochemistry from the University of Melbourne and his PhD in molecular biology from Monash University. He is also a graduate of the Advanced Management Program from the Melbourne Business School at the University of Melbourne and is a member of the Australian Institute of Company Directors.

faber