exl pharma

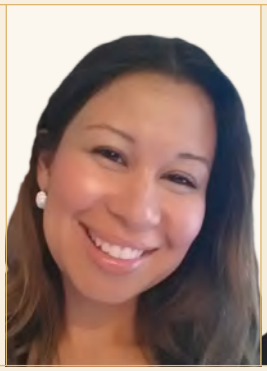
2nd

Clinical Trial Financial Management SUMMIT

Decrease overall variance between forecasted and actual clinical trial costs through better gross forecasting, managing outsourced partners, reducing delays and budgeting appropriately

April 4–5, 2018 // Sonesta Hotel // Philadelphia, PA

FEATURED SPEAKERS



Débora S. Araujo
Associate Director, Site Budget and Payments Site Enablement
BOEHRINGER INGELHEIM PHARMACEUTICALS

Richard Brand
CFO
BEYONDSPRING

Jonathan Cohen
Executive Director, Business Operations
REGENERON PHARMACEUTICALS

Jeff Kingsley
CEO
IACT Health

Jinyong Oh
Head of Finance, Global R&D Operations
JOHNSON & JOHNSON

Kim Zahan
Director Finance
GLAXOSMITHKLINE

Special Focuses for 2018

- Analyze operational and financial trial data to calculate country-level cost metrics by therapy area
- Navigate the difficulties of working with site investigators to accurately project patient enrollment rates
- Deliberate on how to keep up to date with legislation and requirements changes
- Improve negotiation strategies to benefit all stakeholders involved
- Emphasize on interdepartmental support to bolster harmonization and decrease variance
- Focus on ways to harness innovation and run trials that are more attractive to sites, more engaging for patients, and less of a financial burden on the sponsor
- Understand how the site level template can be utilized to build a forecast for total investigator grants

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Dear Colleague,

Developing procedures for budgeting and financial accruals is a challenge the industry is dealing with around clinical trials. Each organization has a budget that is unique and difficult to predict and manage. Protocol amendments, the number of participating sites, monitoring strategies, and misalliances all drive costs up. It is critical to find reliable partners and tools to effectively plan for future challenges.

Establishing the difference between a realistic forecast and approved spending can be difficult. Fluctuations in trial forecasts from quarter to quarter make funding requests challenging but well-formed teams, systems, tools, and processes can help.

ExL Events is proud to bring you the 2nd Clinical Trial Financial Management Summit. Over the course of two days, a bright lineup of industry professionals will discuss the difficulties surrounding clinical forecasting and budgeting.

Attend educational sessions on data management, new technologies, timeline expectations, improved internal department functions, contract accuracy and accountability, vendor selection, outsourcing, budgeting for remote trials and much more. Join us for this exciting program and discover how to improve financial planning, budgeting, and communication, which will reduce the burden of cost and lead to more accurate and efficient trials.

I look forward to welcoming you to Philadelphia this spring!

Sincerely,

Megan Heburn

Director, Conference Production
mheburn@exlevents.com

WHO SHOULD ATTEND

This conference is designed for representatives from pharmaceutical, medical device, biotechnology, and clinical research organizations with responsibilities in the following areas:

- Clinical Finance
- Clinical Strategic Planning
- Budget Management
- Contracting
- Outsourcing
- R&D Budget and Finance
- Finance
- Trial Management
- Clinical Program/Protocol Management
- Clinical Operations/Research
- Study Management
- Clinical Project Management
- Study/Protocol Management

This conference is also of interest to:

- Clinical Trial Forecasting and Financial Service Providers
- Clinical Research Organizations
- Consultants
- Vendor Management Service Providers

VENUE INFORMATION

Sonesta Philadelphia Rittenhouse Square
1800 Market St, | Philadelphia, PA 19103

To make reservations, please call 1-800-SONESTA and request the negotiated rate for **ExL's April Meetings** You may also make reservations online using the following weblink: http://bit.ly/2AhLpGF. The group rate is available until **March 13, 2018**. Please book your room early, as rooms available at this rate are limited.

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SPONSORSHIP AND EXHIBITION OPPORTUNITIES

Do you want to spread the word about your organization's solutions and services to potential clients attending this event? Take advantage of the opportunity to exhibit, underwrite an educational session, host a networking event or distribute promotional items to attendees. ExL Events will work closely with you to customize a package that will suit all of your needs.

Wednesday, April 4, 2018

8:30 Registration and Continental Breakfast

9:30 Chairperson's Opening Remarks

Importance of an Accurate Timeline

9:45 **Review the Importance of an Accurate Timeline to Minimize Costly Delays**

- Examine the financial impact of a timeline shift that includes the current year, a five-year plan and the life of a study
- Bolster communication between clinical and R&D finance teams to ensure timelines are realistic
- Forecast long-term expectations and set short-term goals to create achievable benchmarks
- Address slowdowns and strategies to resolve them in a timely fashion

Richard Brand, *CFO,* **BEYONDSPRING INC.**

Budgeting/Contracting Strategies

10:30 **Keys to Developing an Accurate Prediction Model**

- Navigate financial forecasting throughout the life of a study
- Develop study specifications to provide enhanced cost estimates
- Work with site investigators to accurately project patient enrollment rates, along with the correct timelines it would take to achieve such numbers
- Highlight the importance of utilizing scenarios

Jonathan Cohen, *Executive Director, Business Operations,* **REGENERON PHARMACEUTICALS**

11:15 Networking Break

11:45 **Explore Why Oncology Studies Finish Late and Over Budget - Sponsor and Site Perspective**

- Discuss Budget development and negotiations with comments from both sides of the table
- Challenges with enrolling the right patients according to a study timeline
- Improve your communication to investigators, patients and all site staff to keep your study top-of-mind
- Use realistic protocol inclusion/exclusion criteria

12:30 Luncheon

1:30 **Develop Advanced Budgeting Strategies to Manage Clinical Trials**

- Construct a budget and contract that allow flexibility
- Control costs through budget negotiations with CROs
- Learn strategies to manage and negotiate budgets with study sites
- Discuss and analyze issues related to budgets and contracts

Débora S. Araujo, *Associate Director, Site Budget and Payments, Site Enablement — Clinical Operations,* **BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.**

2:15 **Grant Forecasting: New Approaches to Predicting Clinical Trial Costs**

- Discuss why CROs should provide grant forecasting as a service to produce more accurate projections and to give their customers greater visibility
- Explore how to continually evaluate study payments, patient enrollment, and site contract costs to adjust projections and find opportunities to simplify trial processes
- Investigate enrollment risks, undisclosed site contract costs, and other factors that can drive up site payments
- Assess cost variances in real time to get a clear, data-driven picture of the trial's cost trajectory and support efficient re-forecasting

James Sacchetta, *Manager, Technical Operations,* **PREMIER RESEARCH**

3:00 Networking Break

3:30 **Ensure Trial Designs Include the Collection of the Data Required for U.S. Sunshine Act Reporting As Well As European (EFPIA) Reporting**

- Discuss the constraining disclosures and reporting of payments made directly or indirectly to HCOs/HCPs
- Examine if your clinical organization knows who is a covered recipient for
- Check that your vendor's financial data is correct and determine how accurate it is
- Deliberate on how to keep up to date with changes in legislation and requirements

Kim Zahan, *Director Finance,* **GLAXOSMITHKLINE**

4:15 Day One Concludes

"This is the best financial conference I've been to." **—MERCK**

Thursday, April 5, 2018

8:00 Continental Breakfast

9:00 Chairperson's Recap of Day One

Working With Sites and CROs

9:15 **Industry Overview of Critical Necessities and Potential Improvement Methods**

- Discuss prioritization strategies and how to best align them with corporate goals
- Analyze methods of allocating resources as efficiently as possible
- Focus on interdepartmental support to bolster harmonization and decrease variance

Jinyong Oh, *Senior Director, Head of Finance, Global Pharm R&D Operations,* **JOHNSON & JOHNSON**

10:00 **Develop a Novel Process to Improve Clinical Trial Sourcing**

- Discuss the steps Mallinckrodt Pharmaceuticals has taken to advance their Clinical Trial Sourcing
- Examine how an iterative sourcing process with advanced templates can lead to securing a more accurate budget and faster timeline
- Focus on ways to harness this innovation and run trials that are more attractive to sites, more engaging for patients, and less of a financial risk for the sponsor

Crystal Wilmesherr, *Senior Category Manager, Science and Technology Services, Specialty Generics,* **MALLINCKRODT PHARMACEUTICALS**

11:00 Networking Break

11:30 **Forecast the Overall Budget of a Clinical Trial**

- Process to manage study team and functional areas, and presentation of estimate at internal committee(s)
- Prepare for internal budget approvals such as start-up funding, gated decisions, and full study approval
- Strategic planning for estimates from CRO, Ancillary Vendors, Drug Supply, and Investigator Grants

Victor Lucariello, *Business Analytics,* **CELGENE CORPORATION**

12:15 Luncheon

1:15 **Integrate Capabilities to Provide a Centralized Approach and User Experience for Investigators Budget and Payment Process**

- Implement a centralized investigator payment process and system across all studies and geographies
- Ensure consistent site budget and contract terms across CROs executing clinical trials
- Explore processes and technologies to streamline site budget negotiations and contracts

Tara Dubois, *Head of Clinical Trial Cost Management,* **PFIZER**

Phil Paone, *Director of Site Budgets and Contracts,* **PFIZER**

2:15 **Panel Discussion: Financial Management From the Perspectives of Sponsors, CROs and Sites**

- Discuss the issues that arise from contract modeling with external partners
- Approach the dynamic of risk sharing and how it can affect clinical trial financials in the long run
- Address setting accountability benchmarks during the contract
- Improve negotiation strategies to benefit all stakeholders involved

Moderator:

Jim Kremidas, *Executive Director,* **ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS**

Panelists:

Victor Lucariello, *Business Analytics,* **CELGENE CORPORATION**

Jeff Kingsley, *CEO,* **IACT HEALTH**

Utilizing the Best Tools Internally and Externally

3:15 **Understand How to Budget for Digital and Remote Clinical Trials**

- Integrate capabilities to provide a centralized approach
- Forecast resource consumption in the adaptive monitoring space
- Use of predictive analytics to identifying patterns harnessing existing data

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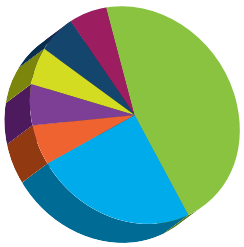
4:00 Conference Concludes

2017 Audience Breakdown

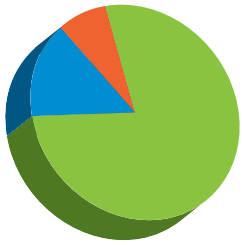
DEPARTMENT OF PHARMA, BIOTECH AND MED DEVICE PARTICIPANTS

- 46% Finance
- 24% Contracts and Budgets
- 6% Outsourcing
- 6% Lab Manager
- 6% R&D
- 6% Clinical Monitoring
- 6% Other



COMPANY TYPE

- 77% Pharma
- 15% Biotech/Med Device
- 8% Hospital



REGISTRATION
to register CLICK HERE or

Call: 201 871 0474
fax: 253 663 7224
email: register@pmaconference.com/
web: http://pmaconference.com/
Mail: POB 2303 Falls Church Va 22042

Registration Fees for Attending ExL's 2rd Clinical Trial Financial Management Summit

EARLY BIRD PRICING — *Register by Friday, February 16, 2018*

Conference	$1,895

STANDARD PRICING — *Register After Friday, February 16, 2018*

Conference	$2,095

ONSITE PRICING

Conference	$2,295

Questions? Comments?

Do you have a question or comment that you would like addressed at this event? Would you like to get involved as a speaker or discussion leader?

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Registration

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Please Note: There will be an administrative charge of $300 to substitute, exchange and/or replace attendance badges with a colleague within five business days of any ExL conference.

CANCELLATION AND REFUND POLICY: If you cancel your registration for an upcoming ExL event, the following policies apply, derived from the Start Date of the event:

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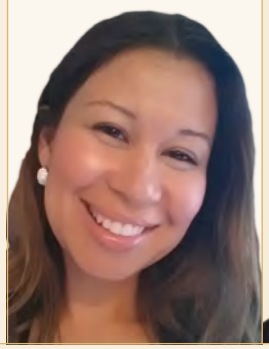

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❑ YES! Register me for this conference!

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