Clinical Operations in Oncology Trials
West Coast 2018

The 5th Annual Clinical Operations in Oncology West Coast Conference

April 24th & 25th 2018
Burlingame, CA, USA

2018 Confirmed Speakers

Archana Sah, Therapeutic Area Leader, Oncology, Director Clinical Operations, **Genentech/Roche**
Dr Elise Brownell, EVP, Operations & Project Management, **Amarantus BioScience**
Jane Kreis, Program Training Officer, **FDA**
Sameena Sharif, COO, **QED Therapeutics**
Bonne Adams, Senior VP Clinical Operations, **Tracon Pharmaceuticals**
Deborah Collyar, President, **Patient Advocates In Research**
Bruce Keyt, PhD, Chief Scientific Officer, **IGM Biosciences, Inc**.
Mena Niakian, Global Director of Clinical Operations, **SanBio**
Skanda Goudar, MBA, Director, Clinical Operations, **Forty Seven Inc.**
Darlene Ebeling, Director, Operational Excellence, Clinical Operations, **Pharmacyclics**
Franco Davi, Senior Clinical Program Leader, **Genentech**
Len Rosenberg, Head Clinical Operations, **Beat AML**
Hilary Nelson, Senior Director, Clinical Development, **Parker Institute**
Sue Naim, Director, Clinical Operations, **Astex Pharmaceuticals**
Ashley T Head, Former Associate Director, Clinical Operations
Michael Cox, Associate Director, **FibroGen**
Darshita Patel, Clinical Trial Manager, **Spectrum Pharmaceuticals**
Surani Fernando, Editor, North America, **GlobalData**
Dale Posner, Senior Manager, Strategic Clinical Sourcing, **BeiGene**
Jennifer Brandl, Clinical Trial Manager**, Portola Pharmaceuticals**
Kalyan Obalampalli, Senior Clinical Trial Manager, **Pharmacyclics**
Pat Devitt, President, **Precision Oncology**
Brian Huber, Executive Director, Oncology, Strategic Development, **Premier Research**
Brian Dunton, Sr. Director, Regional Operations, **Bracket**
Rajneesh Patil, Senior Director, Global Head, Process Design & Analytics Clinical Operations, Centralized Monitoring Services, **IQVIA**
Natasa Rajicic, Senior Director, Strategic Consulting, **Cytel**
Amit Vasanji, PhD, Chief Technology Officer, Imaging, **ERT**
Julie Martin, M.Sc., MBA, Director, Clinical Operations, **Scimega Research**
Heather Hernandez, Director of Business Development, **Seeker Health**

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	Clinical Operations in Oncology Trials: Burlingame, CA **Day One | April 24th 2018**
7:45	Registration and Refreshments
8:20	Chair's Opening Remarks ***Sameena Sharif**, COO, **QED Therapeutics***
	Exploring Strategies for Patient Recruitment and Retention
8.30 **Agenda Highlight**	**KEYNOTE** **Oncology Clinical Trials: Sponsor Insights on oncology trial recruitment in a competitive landscape attracting both physicians and patients** • Highlighting strategies to develop the right study design to successfully compete for PI and site resources • Data driven decision making in operations to fully understand patient pool and pathways • Highlighting strategies for trial recruitment in a competitive landscape to make your trial stand out • Collaborating with Patient Advocacy Groups and Advocacy Boards to ensure the correct info is available online encouraging patient involvement **Archana Sah**, Therapeutic Area Leader, Oncology, Director, Clinical Operations, **Genentech**
9:00	**Mastering Operational Challenges in Precision Medicine** • Addressing complexities in early phase personalized medicine trials • Data streams for review of integrated data for informed decision-making • Dynamic adaptive designs and impacts on operational activities • Planning for proactive management of critical biomarker data • "Putting it all together" **Pat Devitt,** President, **Precision Oncology**
9:30	**Exploring the use of the internet and social media as patient engagement tools optimizing the recruitment process** • Pinpointing the new ERA in patient recruitment to leverage for your study • Highlighting the use of social and digital media to accelerate your clinical trial • Utilizing social media to be directly connected with specific patient populations enhancing recruitment

	• Improving quality of patients through additional vetting to maximize your efficiency in recruitment **Mena Niakian**, Global Director of Clinical Operations, **SanBio**
10:00	**Transforming the Oncology Drug Development Process** In light of ever-expanding drug development costs, it's imperative that we transform the oncology drug development process to bring innovative medicines to patients faster, at lower cost, and with a higher probability of clinical success. Innovation is resulting from the combination of achievements in precision medicine in oncology, coupled with the adaptability and flexibility of the FDA. Recent examples of innovation in oncology drug development include: • Fusion of drug development phases • Seamless design and expansion cohorts • Accelerated marketing approvals in Phase I • Pay for performance and value-based pricing in oncology **Brian Huber, Ph.D,** Executive Director, Oncology, Strategic Development, **Premier Research**
10:30	Morning Refreshments and Networking
11:00	**FDA 101: Discussing what to expect from a clinical trial from an FDA representative** • Highlighting the clinical investigator inspection process to identify what the FDA are looking for • Pinpointing clinical investigator inspection observation trends • Tips and final thoughts to develop a successful oncology clinical trial **Jane Kreis**, Program Training Officer, **FDA**
11:30	**Balancing clinical trial perspectives by involving patients in the protocol design phase of oncology trials** • Aligning goals and ensuring objectives are synchronised by sharing insights into our protocol processes with patients • Developing internal education strategies to reduce the perception that patient involvement slows down clinical development • Implementing patient-oriented improvements to increase engagement • Identifying strategies for translating patient experience into protocol design to ensure patient engagement and retention

	Deborah Collyar, President, **Patient Advocates In Research (PAIR)**
12:00	**How to best design your IRT system to support the complexity inherent to oncology trials** • Review of oncology studies' specificities from an IRT perspective • Discuss common challenges encountered with clinical studies, particularly in oncology • Propose solutions on building IRT systems specifically designed for oncology studies **Brian Dunton,** Sr. Director, Regional Operations, **Bracket**
12:30 Agenda Highlight	**PANEL DISCUSSION** **Should your clinical oncology outsourcing model be Functional, Full-Service, or Hybrid?** PANEL DISCUSSION • Evaluating your internal expertise to decide which processes to outsource ensuring you make the most of in-house capabilities • Advantages and challenges of Hybrid vs Full-Service outsourcing models to identify which is more suitable for your oncology study • Overcoming the barrier of vying for a CROs attention when they are dedicated to multiple studies • Ensuring you are attracting successful suppliers who will provide clinical and regulatory experts to work with you • Evaluating the risk of each outsourcing model to understand who is ultimately responsible for different aspects of the trial *Chair:* **Sameena Sharif**, COO, **QED Therapeutics** *Confirmed Panelists:* **Dr Elise Brownell,** Executive Vice President, Operations and Project Management**, Amarantus BioScience; Skanda Goudar,** Director, **Forty Seven; Darshita Patel,** Clinical Trial Manager, Spectrum **Pharmaceuticals**
1:15	Lunch and Networking
2:30	**CASE STUDY** **Discussing strategies to overcome recruitment and study start-up challenges with First-in-Man (FIM) studies** • Pinpointing timings associated with FIM trials to encourage efficiency with study application • Selecting appropriate geographical sites in an ever changing regulatory landscape to

	understand where best to situate your FIM trial • Exploring the regulatory side of FIM studies to efficiently move through the approval process • Tackling potential issues with protocol approval and lengthier timelines to promote a smooth transition through the study • Identifying methods to achieve flexibility in your FIM study allowing you to remain in control throughout **Bruce Keyt,** PhD, Chief Scientific Officer, **IGM Biosciences, Inc**
3:00	**Lessons Learned: Realizing the Risk-based Monitoring (RBM) impact on quality & patient safety in Oncology trials** • Identifying Oncology-specific risks to highlight processes and mitigate risk • Implementing optimal monitoring approaches for higher efficiencies and faster timelines • Technology and processes driving faster identification & resolution of site and patient issues **Rajneesh Patil**, Senior Director, Global Head, Process Design & Analytics Clinical Operations, Centralized Monitoring Services, **IQVIA** **Susana Nolley**, MPH, Associate Director, Clinical Project Management, Oncology Project Leadership, **IQVIA**
3:30 NEW for 2018	**INTERACTIVE SESSION** **Discussing the advantages and operational challenges associated with combination trials in oncology to improve efficiency and retention in your study** *This interactive session will allow the audience to identify benefits and challenges faced when planning or conducting combination oncology trials. Our chair for this session will write down the main barriers to achieving success and then the audience will brainstorm possible solutions to these. The main points to be addressed include:* • Identifying that in oncology a singular drug has limited ability to prolong survival therefore combination studies can hugely increase the chance of success • Exploring the challenges associated with combination trials such as safety reporting • Overcoming challenges with drug sourcing from a clinical operations point of view • Addressing best practices to ensure a high level of communication with the site throughout the trial to maintain precise data collection **Franco Davi**, Senior Clinical Program Leader, **Genentech**
4:00	**Proven Digital Media Campaigns to Accelerate Oncology Clinical Trials**

	• Understanding social and digital media opportunities, including Google, Facebook, and Instagram • Understanding compliance and controls for social media campaigns • Understanding how to build an effecting online pre-screener questionnaire • Reviewing oncology case studies of use of social media to accelerate clinical trial enrolment **Heather Hernandez,** Director of Business Development, **Seeker Health**
4:30	Afternoon Refreshments and Networking
	Considering the Benefits and Challenges of Technologies in Oncology Trials
5:00	**Discovering the use of Electronic Patient-Reported Outcomes (ePRO) for better quality and more concise results** • Pinpointing the advantages of utilizing ePRO in an oncology trial • Addressing the concerns associated with ePRO such as cost and compliance challenges due to lack of guidance • Considering the ease of use when selecting a device to reduce any extra patient burden • Identifying a strategy to provide high level customer support specific to your ePRO throughout the trial **Dale Posner**, Senior Manager, Strategic Clinical Sourcing, **BeiGene**
5:30	**Establishing strategies for vendor management to strengthen collaboration and achieve goals throughout your oncology trial** • Highlighting the specific requirements you need from your vendor during protocol design to ensure everyone is on the same page • Best practices for establishing good communications between both internal departments and vendors to minimize delays • Exploring successful strategies for active monitoring to allow for timely problem solving • Assessing vendor performance after your study to incorporate lessons learned into future projects **Ashley T Head,** Former Associate Director, Clinical Operations & Regulatory Affairs
6:00	Chair's Closing Remarks

	Clinical Operations in Oncology: Burlingame, CA **Day Two | April 25th 2018**
08:30	Registration and Refreshments
08:55	Chair's Opening Remarks ***Len Rosenberg**, Head Clinical Operations, **Beat AML***
9:00	**Speaker Hosted Roundtables** Interactive roundtable sessions offer a unique opportunity to come together with your peers to share best practice and develop solutions to critical challenges facing the industry as a whole. Hosted by industry experts and each focused on a single issue, roundtables are an exciting, interactive way to build your personal network and learn from the experience and expertise of others. Each roundtable session lasts for 45 minutes, and delegates may attend up to 2 roundtables**.**
RT 1	**Exploring best practices to help improve vendor selection within oncology studies** **Darlene Ebeling,** Director, Operational Excellence, Clinical Operations, **Pharmacyclics LLC, an Abbvie company**
RT 2	**Exploring adaptive designs to accelerate clinical development and increase success in oncology trials** **Surani Fernando,** Editor, North America, **GlobalData**
RT 3	**Discussing patient recruitment strategies for small to mid-sized companies** **Sue Naim,** Director, Clinical Operations, **Astex Pharmaceuticals**
RT 4	**Discussing most effective methods for patient engagement in oncology trials to improve patient-centricity and retention**

	Kalyan Obalampalli, Senior Clinical Trial Manager, **Pharmacyclics**
10:30	Morning Refreshments and Networking
	Discussing Patient Centricity and the Future of Oncology Trials
11:00	**CASE STUDY** **Navigating oncology clinical trials with partners and cooperative groups to increase the success of your development program** • Exploring the benefit of working with cooperative groups to enhance enrollment in rare tumor type trials • Discussing collaboration with NCI & CTEP cooperative groups and how to run trials efficiently • Partnering development by therapeutic area and by oncology indication and region • Using real life case study examples to explain the benefit of licensing products from large pharma **Bonne Adams,** Senior VP Clinical Operations, **Tracon Pharmaceutical**
11:30	**How to train your IO dragon: What should I be concerned about before commencing accrual and planning for analyses?** • My immune-oncology therapy may exhibit delayed clinical effect or have long-term survivors - Do I plan for patients/events accrual any differently than in the past? • I want to schedule an interim analysis – should I worry about a proper timing and how best to evaluate my options? • Particular to immune-oncology, what other issues should I be concerned about before commencing accrual and planning for analyses? **Natasa Rajicic**, Senior Director, Strategic Consulting, **Cytel**
12:00	**Introducing a New Master Trial Concept in AML** • The Beat AML trial takes a precision medicine approach, directing up to 10 potential treatment regimens by drug mutation matches • Measurably improve efficiencies in genomic screening for clinical trial entry, timelines for drug biomarker testing and opening new trial arms faster • Change the paradigm: LLS non-profit mission alignment with key clinical development stakeholders

	• Collaborations are key - alignment between pharma partners, FDA, third-party vendors, sites, labs, and other participants • Nimble deployment of novel e-clinical technologies to meet new Regulatory guidelines (ICH E6 R2) **Len Rosenberg**, Head Clinical Operations, **Beat AML**
12:30	Lunch and Networking
1:30	**Leveraging Technology to Manage Risk in Imaging Scoring Systems** In this discussion, we'll explore the comparative effectiveness of various tumor response assessment methods and examine the standard of care vs. computer-assisted response evaluation. • Identifying the significant number of oncologic scoring systems with complicated workflows and guidelines, and exploring which imaging system is the most appropriate for your protocol • Pinpointing how can you leverage technology to manage multiple scoring systems in one trial • Evaluating how technology can eliminate common errors, improve documentation and increase reader efficiency to improve trial outcomes and reduce costs **Amit Vasanji**, PhD, Chief Technology Officer, Imaging, **ERT**
2:00	**Exploring patient enrichment, patient centricity and a forward discussion in oncology trials to maintain a patient-centric approach** • Discussing strategies to design clinical trials to enrich for target patient populations • Evaluating the true statistics of patient participation in clinical trials • Facilitating availability while protecting patient safety and avoiding interference with drug development • Speculating on industry's role in expanded access programs **Jennifer Brandl**, Clinical Trial Manager, **Portola Pharmaceuticals**
2:30	**Geographic Expansion: Big risk or lost opportunity?** • Identifying and understanding your trial challenges and risks of study failure • Achieving enhanced trial performance via geographic expansion • Real-life Canadian case studies of what works • Effectively Integrating a Regionally Specialized CRO Team

	Julie Martin, M.Sc., MBA, Director, Clinical Operations, **Scimega Research**
3:00	Afternoon Refreshments and Networking
3:30	**Uncovering challenges associated with patient screening and recruitment to reduce study start-up delays and patient burden** • Outlining the patient screening process in your clinical trial to ensure the correct patient population is identified • Addressing the implications of multiple screening processes to reduce unnecessary costs and burden on patients • Identifying challenges with informed consent in oncology trials to ensure compliance • Exploring options for patient data for those incompatible in your clinical trial • Adopting the process of returning pre-screening data to physicians to enable quick identification for suitable trials for patients in the future **Hilary Nelson,** Senior Director, Clinical Development, **Parker Institute**
4:00 Agenda Highlight	**Exploring ways to manage oncology study budgets and budget negotiations effectively to ensure resources are allocated appropriately** • Pinpointing strategies for forecasting protocol design costs to improve efficiency • Educating sites on standard pricing to ensure smooth budget negotiations reducing significant delays • Promoting negotiation transparency to make sure everyone is on the same page and you remain within your budget • Setting reasonable timeframes for how long it may take for the site to respond so as not to put unnecessary demands on site personnel • Highlighting the importance of regulator communication with the executive committee and stakeholders to determine the resources required for the trial **Michael Cox**, Associate Director, **FibroGen, Inc.**
4:30	Chairman's summation and close of conference