12th Annual Clinical Trials in Oncology West Coast 2025

14th – 15th May 2025 Burlingame, California, USA

Event website

2025 Speakers

Abhijit Ramachandran, Director, Clinical Development Operations – Oncology**, Corcept Therapeutics**
Anthony Fermin, Clinical Program Director**, Genentech**
Bobby Asem, Associate Director, ClinOps**, Bluejay Therapeutics**
Cecilia Tran Muchowski, Senior Director, Site Alliances**, Genmab**
Christian Apfel, Chairman & CEO**, SageMedic Corp**
Cynthia C. Obiozor, Physician, Oncology Clinical Research Medical Director**, Amgen**
David Larwood, CEO**, Valley Fever**
David Tsai, Associate Director, Project Management**, Scribe Therapeutics**
Daniela Vecchio, Director, Clinical Development**, Olema Oncology**
Deepa Arora, Director**, AJNA Therapeutics**
Edward Owen, Therapeutic Area Director, Oncology, Early Clinical Development, **Genentech**
Feng Wang-Johanning, CEO**, SunnyBay Biotech**
Gary Johanning, CSO**, SunnyBay Biotech**
Gay Crawford, Founding Chair/Emeritus Member, Patient and Family Advisory Council at Stanford Health Care South Bay Cancer Center
Irene Soto, Clinical Operations Expert
Jennifer Willert, Global Clinical Development Medical Director (CDMD), **Novartis Cell and Gene/Hematology**
John Gouws, VP Finance**, Alumis**
John McAdory, Vice President, Clinical Operations**, CG Oncology**
Kumar Gadamasetti, CEO**, Certum Bio**
Lloryn Hubbard, Director Clinical Trial Diversity and Patient Voice**, Daiichi Sankyo**
Meghan McKenzie, Director of Health Equity and Clinical Research**, Genentech, Inclusion and Belonging Office**
Mukhtar Ahmed, Director, Project & Portfolio Strategy**, Greenstone Biosciences**
Rabindra Shivnaraine, Director, Drug Discovery**, Greenstone Biosciences**
Sarah Hamirani, Portfolio Director**, AbbVie**
Sarah Schiltz, Board Chair, **Cancer CAREpoint**/ Board Director, **Blue Faery**/ Patient Advocate, **NCI/NHI**/ Consumer Reviewer, **DoD, CDMRP**
Steve Warner, Senior Vice President, Head of Translational Research & Medicine – Oncology, **Sumitomo Pharma America**
Tatiana Kolesnikova, Director, Oncology and Hematology**, GlobalData**

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CLINICAL TRIALS IN ONCOLOGY WEST COAST

14 – 15 MAY | BURLINGAME, CA

Wenjing Wang, Associate Director - Associate Principal Scientist**, Merck**
Keya Watkins, Senior Vice-President**, Catalyst Clinical Research**
Bin Pan, Executive Director, Operational Strategy**, Ergomed**
Emily McInturf, Director, Feasibility**, PSI CRO**
Jim Eamma, Executive Director, Therapeutic Strategy**,** Oncology, **Worldwide Clinical Trials**
Julie Martin, President & CEO**, Scimega**
Karen Benson, Director, Regulatory Strategy Consulting**, ICON**
Kohkan Shamsi, MD, PhD, Co-founder, Vice President of Medical and Scientific Affairs**, RadMD**
Sandra Shpilberg, CEO & Co-founder**, Adnexi**

Clinical Trials in Oncology West Coast

DAY 1 – Wednesday 14th May 2025

8:00am	**Registration and refreshments**
8:20am	**Chairperson's opening remarks** ***Chair: Keya Watkins, Senior Vice-President, Catalyst Clinical Research***
8:30am	**KEYNOTE: Developing resilient clinical trials: Lessons learned in CAR-T for ped-young adult and adult oncology trials** • Working with both cooperative groups and biotechs in a harmonious way • How to streamline processes and improve trial design • Avoiding pitfalls which can have lasting global impacts • Setting up trials for offsite patients and ensuring remote data can be obtained ***Jennifer Willert, Global Clinical Development Medical Director (CDMD), Novartis Cell and Gene/Hematology***
9:00am	**Joined at the Hip – Regulatory implications of the new Joint Clinical Assessment (JCA) regime** • Understanding how we got here • Coordinating JCA in parallel to MAA • How to adapt your oncology strategy to JCA • What's next for JCA ***Karen Benson, Director, Regulatory Strategy Consulting, ICON***
9:30am	**PANEL DISCUSSION: Where is the oncology clinical trial industry headed in 2025?** • Navigating new regulations around clinical trials smoothly and successfully • Predictions for how the global markets will impact US studies • The impact of artificial intelligence: how far can we expect to move forward in the next 12 months? • Patient centricity in clinical trials: how can burden be reduced in order to make trials easier for patients to participate in? ***Chair: Keya Watkins, Senior Vice-President, Catalyst Clinical Research***

CLINICAL TRIALS IN ONCOLOGY WEST COAST

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	Panelists: Anthony Fermin, Clinical Program Director, Genentech ***Jennifer Willert, Global Clinical Development Medical Director (CDMD), Novartis Cell and Gene/Hematology*** ***Steve Warner, Senior Vice President, Head of Translational Research & Medicine – Oncology, Sumitomo Pharma America***	
10:00am	**Global virtual clinical trial supplies: The benefits of implementing a virtual supply strategy for commercially available medications and ancillary supplies** • Optimize employ effort • Minimize waste and risk • Appreciate significant savings • Sustainably friendly ***Robbie Hill, Director of Business Development, Mercalis***	
10:30am	**Morning refreshments and networking sponsored by Aixial LOGO**	
	STREAM A: Clinical Operations **Chair: Keya Watkins, Senior Vice-President, Catalyst Clinical Research**	**STREAM B: Patient Recruitment and Engagement** **Chair: Sarah Schiltz, Board Chair, Cancer CAREpoint/ Board Director, Blue Faery/ Patient Advocate, NCI/NHI/ Consumer Reviewer, DoD, CDMRP**
11:00am	**Strengthening the Sponsor-Site partnership: A path to a successful clinical trial: How collaboration and trust drive clinical trial success** • Understanding site processes and expectations to reduce delays in site initiation, activation, and screening for potential patients • Championing collaborative sites for a streamlined trial • Can we ever be appropriately equipped for adverse effects with off-site testing? ***Daniela Vecchio, Director, Clinical Development, Olema Oncology***	**Improving clinical trial representation to increase access to trials** • Sharing best practices for recruiting and integrating populations that are not well represented in oncology trials • Lessons from Advancing Inclusive Research Site Alliance collaborations • What strategies that pharma/biotech and vendor companies can design and support to help sites reach a more diverse patient population ***Meghan McKenzie, Director of Health Equity and Clinical Research, Genentech, Inclusion and Belonging Office***
11:30am	**How to measurably increase operational efficiency in clinical trials** • Identify and eliminate operational inefficiencies that cause bottlenecks in clinical trials • Organize, implement and maintain the coordination between investigators and study teams, sponsors, and other key operational partners to conserve resources and time to accelerate progress in cancer research	**The value of hope** • Research and development initiatives have long acknowledged that patient participation in clinical research is driven by "hope for a cure" as a key incentive • Patient reported outcomes, subgroup analyses, "exit" interviews at study conclusions, help contextualize the value of trial data within a scientific, clinical, and humanistic framework

	• Implement continuous examination and optimization ***Julie Martin, President & CEO, Scimega***	• Within oncology indications particularly, selective patient targeting, innovative trial designs to accelerate approval, and assessments that reflect how patients "feel, function or survive" are highlighted as distinguishing characteristics. ***Jim Eamma, Executive Director, Therapeutic Strategy, Oncology, Worldwide Clinical Trials***
12:00pm	**FIRESIDE CHAT: The pursuit of success: Driving your drug from the bench to bedside** • Defining what do we do well and what could be improved – EU vs US focus • Planning and preparation within oncology drug trials – focus on phase 2/3 • Choosing the right trial designs for rare disease studies • How to achieve a successful launch by building appropriate phase 3 ***Chair: Keya Watkins, Senior Vice-President, Catalyst Clinical Research*** ***Kumar Gadamasetti, CEO, Certum Bio***	**Clinical trial representation and how it intersects with patient-centric approaches and inclusive trial designs** • **The need for broad representation**: The importance of ensuring that clinical trials include a wide range of patient populations to improve the applicability and validity of results across all demographic groups. This approach helps reflect real-world conditions and ensures treatments are safe and effective for everyone. • **Patient-centric trial design**: Focusing on designing trials with a patient-first approach, considering their needs, preferences, and challenges to improve engagement and outcomes. • **Inclusive trial design**: Exploring strategies for creating accessible trials, such as flexible locations, culturally sensitive recruitment, and remote monitoring, to ensure participation from diverse groups. • **Intersectionality and health outcomes**: Examining how diversity, patient-centric approaches, and inclusive design intersect to improve trial relevance, reduce healthcare disparities, and enhance the generalizability of results. ***Cynthia C. Obiozor, Physician, Oncology Clinical Research Medical Director, Amgen***
12:30pm	**TECHNOLOGY SPOTLIGHT: Innovative Digital Opinion Leaders identification with Adnexi to improve trial awareness** • Understand the reliance of both patients and doctors alike on online resources for trial and disease awareness. • Learn about a new technology solution to search for Digital Opinion Leaders sharing content online about the therapeutic area	**SESSION SPONSOR: Enhancing patient centricity in oncology trials – A 360º site support model** • Oncology trials are growing in complexity, both in design and execution. • Precision medicine is leading to hyper-fractionated patient populations in biomarker-driven studies. • Sponsors and CROs must evolve their operating models to enhance patient centricity in this shifting landscape.

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- Discover how to identify and track Digital Opinion Leaders across all social and online platforms
- Plan how to engage Digital Opinion Leaders in trial awareness

Sandra Shpilberg, CEO & Co-founder, Adnexi

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- This session presents a 360° Site Support model that puts patients at the center — with proven success in oncology trials.

Bin Pan, Executive Director, Operational Strategy, Ergomed

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<tr><td>12:45pm</td><td colspan="2">Lunch and networking</td></tr>
<tr><td>2:00pm</td><td>

From protocol problems to powerful partnerships: The soft skills behind hard data

- Chronicles of a site whisperer: Unlocking underperforming trials through connection
- Front-loading focus: Proactive engagement for study success
- Partnership greenhouse: Cultivating strong site relationships
- Safety net navigator: Why escalation pathways matter

David Tsai, Associate Director, Project Management, Scribe Therapeutics

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PANEL DISCUSSION: Innovatively progressing patient-centric oncology trials in 2025

- The evolving ecosystem of cancer research: adapting trial design amid political and economic shifts
- Strategies for advancing patient-centric trials in 2025, focusing on innovative approaches to enhance trial design and execution
- Streamlining and improving patient involvement, communication, and the simplification of processes in trials to minimize patient burden
- Sharing best practices to foster an engaged patient journey, ensuring patient retention throughout the trial process
- Translating technology to tangible outcomes: What are the latest innovative technologies helping patients throughout the trial

Chair: Sarah Sarah Schiltz, Board Chair, Cancer CAREpoint/ Board Director, Blue Faery/ Patient Advocate, NCI/NHI/ Consumer Reviewer, DoD, CDMRP

Panelists: Gay Crawford, Founding Chair/Emeritus Member, Patient and Family Advisory Council at Stanford Health Care South Bay Cancer Center

Lloryn Hubbard, Director Clinical Trial Diversity and Patient Voice, Daiichi Sankyo

Meghan McKenzie, Director of Health Equity and Clinical Research, Genentech, Inclusion and Belonging Office

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FIRESIDE CHAT: Solving challenges for operational excellence in early-phase oncology trials

- Navigate new regulatory requirements and complex study designs with larger sample sizes and a broader global footprint
- Implement country and site selection strategies that optimize FPI/LPI milestones
- Manage the complexities of enrollment, cohort management, safety review, and trial logistics across multiple regions
- Maintain a patient-centric approach to optimize study coordination and to benefit patients

Chair: Keya Watkins, Senior Vice-President, Catalyst Clinical Research

John McAdory, Vice President, Clinical Operations, CG Oncology

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FDA regulations in decentralized clinical trials

- An overview of the FDA's latest guidelines and requirements for DCTs, highlighting key aspects such as the integration of digital health technologies, remote monitoring, and the

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PATIENT VOICE: My Story: How clinical trials have impacted my life (breast cancer at 31, lymphoma and eye disease)

- Why clinical trials matter for patients
- My Experience in Clinical Trials

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	adherence to Good Clinical Practice (GCP) principles, as well as ensuring innovative trials maintain the highest standards of safety, efficacy, and data integrity. • Discussion of the FDA's collaborative efforts with other regulatory bodies, promoting harmonized standards and facilitating global acceptance of DCT methodologies. • Adhering to the FDA's comprehensive regulatory requirements so sponsors can navigate the complexities of DCTs and contribute to the evolution of clinical trials and the accelerated development of innovative medical treatments ***Wenjing Wang, Associate Director - Associate Principle Scientist, Merck***	• Importance of media, personal stories, outreach • Lessons learned ***Gay Crawford, Founding Chair/Emeritus Member, Patient and Family Advisory Council at Stanford Health Care South Bay Cancer Center***
3:30pm	**Afternoon refreshments and networking**	
4:00pm	**Ensuring regulatory compliance for expedited drug approvals in oncology in the USA** • Expediting: Fast track, Breakthrough therapy, Accelerated approval, Priority review, RMAT • Key considerations: Clinical evidence, surrogate endpoints, post-approval requirements • Major health policy concerns around support for developing new oncology drugs • Cost, access, regulation, public funding, balancing innovation with long-term care ***David Larwood, CEO, Valley Fever***	**Functional precision oncology to increase clinical trial success rates** • **The Patient Selection Problem**: Current biomarker-based strategies identify <30% of likely responders, leading to high failure rates and inefficient trial designs. • **The SAGE Oncotest Advantage**: A best-in-class ex vivo functional profiling platform that tests patient-derived tumor cells directly against the investigational drug to identify true responders. • **Smarter Trial Design**: Incorporating functional profiling to enrich responders into the study, thereby reducing required sample size while increasing clinical trial success rates. ***Christian Apfel, Chairman & CEO, SageMedic Corp***
4:30pm	**CLOSING KEYNOTE: Driving great decision making: A perspective from a finance fanboy** • Perils of a less-optimal decision setup • Setting the stage for decision prep • Always bring them choices - scenarios for the win • Sticking the landing with clear decisions and documentation ***John Gouws, VP Finance, Alumis***	**CLOSING KEYNOTE: Integrating patient perspectives to reduce patient burden and enhancing early oncology trial designs** • Empowering study teams with methodologies to integrate patient perspectives in study protocols • Transformative case study on how patient insights reshaped an oncology trial ***Sarah Hamirani, Portfolio Director, AbbVie***

5:00pm	**Chairperson's closing remarks**
END OF DAY 1 AND NETWORKING DRINKS	

Clinical Trials in Oncology West Coast

DAY 2 – Thursday 15th May 2025

8:00am	**Registration and refreshments**	
8:50am	**Chairperson's opening remarks** **Chair: Keya Watkins, Senior Vice-President, Catalyst Clinical Research**	
9:00am	**Interactive Speaker-Hosted Roundtable Discussions** 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. Each discussion will be led by a table moderator and will focus on a different challenge within oncology clinical trials. Roundtables are an exciting, interactive way to build your personal network and learn from the experience and expertise of others. After 30 minutes, delegates will have the opportunity to swap and choose a different table, and each roundtable will run twice.	
	Roundtable 1	**Measuring success by assessing the effectiveness of your patient enrollment strategy** Hosted by Irene Soto, Clinical Operations Expert
	Roundtable 2	**Advantages and challenges of conducting multi-regional clinical trials in oncology** Hosted by Deepa Arora, Director, AJNA Therapeutics
	Roundtable 3	**Fine-tuning the site-sponsor partnership** Hosted by Cecilia Tran Muchowski, Senior Director, Site Alliances, Genmab
	Roundtable 4	**Bringing innovation to clinical trials** Hosted by Bobby Asem, Associate Director, ClinOps, Bluejay Therapeutics
10:00am	**Morning refreshments and networking**	
10:30am	**KEYNOTE: How to align financial incentives between CROs and biotechs so that both sides win** • Fine-tuning the partnership and incentivizing CROs to be more thoughtful in proposals • Reconsidering PM involvement and responsibilities • Encouraging data system investment • Building better budgets on the known ***Abhijit Ramachandran, Director, Clinical Development Operations – Oncology, Corcept Therapeutics***	
11:00am	**The Full Picture: RECIST PLUS**	

	Dr Shamsi will explore the evolution of oncology imaging, the limitations of RECIST 1.1, and how additional measurements can enhance early-phase decision-making and late-phase efficacy confirmation in clinical trials. • The evolution of oncology clinical trials since RECIST 1.1 • The impact of immunotherapies, cell therapies, cancer vaccines, and ADCs • RECIST Plus – enhanced features that integrate volumetric and radiological parameters for a more comprehensive analysis ***Kohkan Shamsi, MD, PhD, Co-founder, Vice President of Medical and Scientific Affairs, RadMD***
11:30am	**Clinical Trial Decarbonization: The beginning our journey to NetZero** • Measuring clinical trial carbon emission footprints • Identifying emissions hotspots and decarbonization initiatives • Aligning with key partners (e.g. CRO, Central Lab) • Incentivizing the organization ***Edward Owen, Therapeutic Area Director, Oncology, Early Clinical Development, Genentech***
12:00pm	**PANEL DISCUSSION: How innovation has involved that will shape the future of clinical research in oncology** • Assessing the value of innovation in oncology trials: sharing best practice on engaging sites with new technology • Leveraging the latest technologies to enhance patient experience • Training sites and staff on new systems to maximize the benefits of the latest technology and streamline processes • Assessing the efficiency and success of pragmatic trials for more patient-centered approaches: do they work for oncology? ***Chair: Keya Watkins, Senior Vice-President, Catalyst Clinical Research*** ***Panelists: Abhijit Ramachandran, Director, Clinical Development Operations – Oncology, Corcept Therapeutics*** ***Edward Owen, Therapeutic Area Director, Oncology, Early Clinical Development, Genentech*** ***Steve Warner, Senior Vice President, Head of Translational Research & Medicine – Oncology, Sumitomo Pharma America***
12:30pm	**Lunch and networking**
1:30pm	**New alternate methods for clinical trials: Discussion of the use of human induced pluripotent stem cells for drug development** • Overview of recent regulatory shifts (FDA Modernization Act 2.0, April 2025 FDA policy) enabling non-animal methods for oncology IND submissions. • Addressing tumor heterogeneity and efficacy challenges through isogenic iPSC-derived tumor models engineered with specific mutations (e.g., KRAS, TP53, EGFR) using CRISPR/Cas9, enabling precise assessment of variant effects. • Utilizing human induced pluripotent stem cells (iPSCs) for predictive toxicology (e.g., CARTOX assays) and disease modeling to enhance safety assessments and clinical trial efficiency, particularly in small molecule and antibody-based therapies.

	• Employing differentiated iPSC-derived healthy tissue models (e.g., cardiomyocytes, hepatocytes, neurons) to evaluate off-tumor/on-target toxicities in CAR-T therapies, mitigating risks of unintended tissue damage. • Operational considerations, validation strategies, and practical lessons from developing scalable iPSC biobanks supporting New Approach Methodologies (NAMs) in oncology drug development. ***Rabindra Shivnaraine, Director, Drug Discovery, Greenstone Biosciences*** ***Mukhtar Ahmed, Director, Project & Portfolio Strategy, Greenstone Biosciences***
2:00pm	**PSI's VISIONAL: Enhancing Feasibility & Enrollment Predictions with GenAI** • **GenAI-Driven Protocol & Enrollment Predictions**: Explore how PSI integrates GenAI for protocol similarity searches and enrollment rate predictions, improving accuracy and efficiency in clinical trial planning. • **Expanded Data for Global Feasibility Insights:** Learn how VISIONAL™ incorporates three new data sources to enhance site performance analysis and offer insights across 56 countries, supporting better decision-making. • **Faster Trial Planning & Budgeting:** Discover how VISIONAL™ enables sponsors to quickly generate multi-country feasibility scenarios and budgets in under 30 minutes, streamlining the planning process. ***Emily McInturf, Director, Feasibility, PSI CRO***
2:30pm	**The role of Medical Monitor in ensuring protocol compliance and patient safety in oncology clinical trials** • Medical Monitors serve as the primary communication bridge between the study team, investigators, and regulatory bodies & play a critical role in ensuring protocol compliance and protecting patient safety in oncology trials. • Proactive oversight by a Medical Monitor assures trial integrity, regulatory adherence, and overall study success, making them a key pillar in the execution of high-quality clinical research. • Medical Monitors facilitate discussions on trial updates including emerging safety concerns, and protocol clarifications, ensuring smooth trial execution. • A Medical Monitor's expertise in crisis management is crucial in responding to unexpected safety signals or high rates of SAEs, helping to guide decision-making for patient safety and trial continuation. ***Deepa Arora, Director, AJNA Therapeutics***
3:00pm	**Afternoon break, networking and prize draw** **Visit our exhibitors' booths throughout the day and collect stamps in order to enter our prize draw and be in for a chance of winning Apple products or Amazon vouchers. Return your card by 3:15pm on May 15th. The draw will take place at 3:20pm on May 15th in the Exhibition Hall.** **Make sure you don't miss out!**
3:30pm	**The ongoing road to clinical trials from a startup perspective: Bench to bedside with a novel pan-cancer target** • Human endogenous retrovirus (HERV) sequences comprise 8% of the total human genome DNA, and they entered the genome between 10 and 50 million years ago • HERVs are unique tumor targets that are overexpressed in more than 80% of solid tumors, but not in normal tissues • SunnyBay Biotech has developed therapeutics targeting the HERV-K supergroup of HERVs

	• Our approach for moving novel HERV-K therapeutic antibody-drug conjugates (ADCs), which reduce tumor growth, inhibit metastasis, and prolong survival in murine models of breast and lung cancers, from the lab into the clinic will be discussed ***Gary Johanning, CSO, SunnyBay Biotech*** ***Feng Wang-Johanning, CEO, SunnyBay Biotech***
4:00pm	**The clinical trial landscape of cell therapies in oncology** • Cell therapies market landscape - current and future • Key industry trends • Industry forecast ***Tatiana Kolesnikova, Director, Oncology and Hematology, GlobalData***
4:30pm	**Chairperson's closing remarks** **Chair: Keya Watkins, Senior Vice-President, Catalyst Clinical Research**
END OF CONFERENCE	