CLINICAL OPERATIONS IN ONCOLOGY TRIALS EAST COAST 2023

11th-12th July 2023

Boston, **Massachusetts**

www.arena-international.com/event/oncologyeastcoast/

SPEAKERS

Ekatherina Goryachikov, Vice President, Head of Clinical Operations, **Adicet Bio**

Judyth Zahora, Senior Director, Global Quality Systems and Process Improvement, **Agenus Bio**

Michelle Joseph, Associate Director, Data Management, **Alkermes**

Chris Adams, Chief Executive Officer, **Andarix**

Anand Merchant, Clinical Information Science Associate Director, Information Practice, Late Oncology, **AstraZeneca**

Len Rosenberg, Head, Clinical Operations, **Beat AML**

Leticia Tarilonte, Former Executive Director, Clinical Operations, **Black Diamond Therapeutics**

Cory Burke, Executive Director, Head of Biometrics and Data Management, **Black Diamond Therapeutics**

Fatima Scipione, Vice President, Global Patient Affairs, **Blueprint Medicines**

Dawn Kaminski, Vice President, Business Development Operations, **eClinical Solutions**

Ruth Subach, Vice President, Clinical Development and Operations, **Fujifilm Pharmaceuticals**

David Sherris, Chief Executive Officer, **GenAdam Therapeutics**

Tatiana Kolesnikova, Director, Oncology and Hematology, **GlobalData**

Humphrey Gardner, Chief Medical Officer, **Harbour Biomed**

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Leonella Seeley, Associate Director of Vendor Management and Operations, **Karyopharm Therapeutics**

Andrea Bottkova, Director, Vendor and Contracts Management, **Karyopharm Therapeutics**

Mundayat Jyoti Reddy, Executive Masters in Emergency & Disaster Management, Medical Science Liaison, **LAPIX Therapeutics**

Maria de Assis, Senior Director, Clinical Operations, **OriCell Therapeutics**

Bob Bauer, Director, Operational Strategy, **Precision for Medicine**

Loan Vuong, Senior Clinical Trial Manager, **Pyxis Oncology**

Rick Patt, MD, Co-Founder and Director, Medical and Scientific Affairs, **RadMD**

Galyna Ganieva, MBA, Clinical Study Lead, Development Operations and Portfolio Management, **Regeneron**

George Naumov, Chief Operating Officer, **RS Oncology**

Giovanni Abbadessa, Vice President, Head, Oncology Early Development, **Sanofi**

Rachel Nering, Head, Early Stage Oncology, R&D Clinical Science and Operations, **Sanofi**

Julie Martin, Chief Executive Officer, **Scimega Research**

Alice Drumheller, Vice President, Clinical Operations, **Salubris Bio**

Jim Palma, Executive Director, **TargetCancer Foundation**

Sara Musalli-Lee, Associate Director, Clinical Operations, **Tessa Therapeutics**

Tom Gottschalk, Vice President, Business Development, **TrialCard**

Debora Barton, Chief Medical Officer, **TScan Therapeutics**

Abigail S Dirks, Research Data Analyst, **Tufts Center for the Study of Drug Development, Tufts University School of Medicine**

Sarah R Anderson, Executive Director, Oncology Strategy Lead, **Worldwide Clinical Trials**

Ashley Finan, Senior Director, Portfolio Management, **YPrime**

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Clinical Operations in Oncology Trials East Coast

DAY 1 – Tuesday 11th July 2023

8:00am	**Registration and refreshments**
8:50am	**Chairperson's opening remarks** **Tatiana Kolesnikova,** Director, Oncology and Hematology, **GlobalData**
9:00am	**OPENING KEYNOTE PRESENTATION: Patient experience in oncology trials: lessons learned from a patient advocacy-driven, decentralized clinical trial** • How easy and accessible are oncology trials to patients, and where are the main hurdles? • What do pharma and biotech sponsors need to be doing in order to ensure a reduced burden on patients participating in clinical trials? • Decentralized clinical trials: and what are the benefits and challenges of incorporating elements of decentralization into your clinical trial from a patient perspective? **Jim Palma,** Executive Director, **TargetCancer Foundation**
9:30am	**Diversifying your site and patient population in the local community setting** • Advantages of local community sites in oncology studies • Diverse patient populations • Leveraging your CRO's strategic site partnerships with local community hospitals • Expanding the advanced clinical trial offering and awareness • Easing the financial burden of local clinical trials vs travel to large hospitals **Sarah R Anderson,** Executive Director, Oncology Strategy Lead, **Worldwide Clinical Trials**
10:00am	**PANEL DISCUSSION: Navigating the perfect storm as a small biotech company: what you need to know to succeed** • The impact of FDA Project Optimus, the financial crisis and the Inflation Reduction Act on oncology clinical trials in the US, particularly for early stage trials • How macro-political and economic issues affect clinical trials and mitigating risk surrounding this • Cutting costs and maximizing resources: the financial consequences of the storm on small biotech organizations • Understanding the changing regulatory environment for oncology trials in 2023 • Keeping the patient at the center of changes to clinical trials: navigating the storm while minimizing patient impact **MODERATOR:** **Chris Adams,** Chief Executive Officer, **Andarix** **PANELLISTS:** **Giovanni Abbadessa,** Vice President, Head, Oncology Early Development, **Sanofi** **Sara Musalli-Lee,** Associate Director, Clinical Operations, **Tessa Therapeutics** **Andrea Bottkova,** Director, Vendor and Contracts Management, **Karyopharm Therapeutics** **Loan Vuong,** Senior Clinical Trial Manager, **Pyxis Oncology**

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10:30am	**Getting hard feasibility data: how to do it** • How do you access current, hard feasibility data? • Does your CRO have a stable, permanent clinical team with trial legacy capability and expertise in your domain? • Are your sites and vendors audit proof, and how can you enhance continuous improvement by formally adopting Lean? • Are you confident your CRO has the capacity to achieve your study milestones on or before deadline? • Is your CRO independent, does it act like a SMO with a dedicated site network, and is it well-rounded in regard to systems, with a collaborative vendor team of specialized expertise to support your program? **Julie Martin,** Chief Executive Officer, **Scimega Research**	
11:00am	**Morning refreshments and networking**	
	STREAM A: Clinical Operations	**STREAM B: Clinical Technology and Innovation**
	Chair: **Tatiana Kolesnikova,** Director, Oncology and Hematology, **GlobalData**	*Chair:* **Chris Adams,** Chief Executive Officer, **Andarix**
11:30am	**A SITE PERSPECTIVE: How can sponsors support sites in order to minimize workload and enhance performance?** • What can sponsors change internally in order to reduce burden on sites which are stretched for resources? • Adapting processes for sites: creative solutions to be more efficient • Making processes less complicated and more straightforward for sites without compromising reliability • Where are pharma and biotech companies falling short and what more can be done to relieve pressure on sites? **Abigail S Dirks,** Research Data Analyst, **Tufts Center for the Study of Drug Development, Tufts University School of Medicine**	**Innovating and introducing new technology while ensuring patients remain at the heart of your clinical trial** • Ensuring that any new technology is for the benefit of the patient: the importance of involving the patient voice and advocacy groups in innovation • Where are the main difficulties for patients when participating in a clinical trial, and what technology is available in order to make this easier? • Decentralized and remote elements of clinical trials: what can be done remotely to ease the burden on patients? **Leticia Tarilonte,** Former Executive Director, Clinical Operations, **Black Diamond Therapeutics**
12:00pm	**Decentralized clinical trials in oncology in the post-COVID era** • Introduction to decentralized clinical trials (DCTs) in oncology • Unique challenges in oncology clinical trials • Regulatory support and initiatives • Benefits of decentralized clinical trials in oncology • Future perspectives and opportunities **Bob Bauer,** Director, Operational Strategy, **Precision for Medicine**	**eCOA data collection solutions for the unique needs of oncology studies** • Oncology trials and the need for flexibility • Addressing patient fatigue • Easing questionnaire response burden • Solving for logistical complexities **Ashley Finan,** Senior Director, Portfolio Management, **YPrime**

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<table>
<tr><td>12:30pm</td><td>PANEL DISCUSSION: Looking beyond the USA, which regions offer the best opportunities for early phase oncology trials?
With the regulatory and political storm hitting the US, is it best to look abroad for clinical trial opportunities or to stay in the US?
Pros and cons of running trials in the US vs looking at international options
Assessing opportunities for early stage trials in Africa, Latin America, Europe, Asia and Australia: which offers the best alternative for early stage oncology trials?
Which regions are most cost-effective and straightforward to set up an early stage clinical trial in?
The impact of European harmonization regulations on running Phase 1 trials in Europe
What are the advantages and benefits of keeping trials purely in the US?
<u>MODERATOR:</u>
Giovanni Abbadessa, Vice President, Head, Oncology Early Development, Sanofi

<u>PANELLISTS:</u>
Ekatherina Goryachikov, Vice President, Head of Clinical Operations, Adicet Bio
Sara Musalli-Lee, Associate Director, Clinical Operations, Tessa Therapeutics
Maria de Assis, Senior Director, Clinical Operations, OriCell Therapeutics</td><td>Assessing opportunities for innovation in oncology trials: what barriers are present?
Creating an internal culture of innovation to foster adoption of new technology and ideas
What technology is available to make life easier for sponsors, sites and patients alike?
Regulatory barriers to new technology and innovation: what do you need to know?
Len Rosenberg, Head, Clinical Operations, Beat AML</td></tr>
<tr><td>1:00pm</td><td>Running up that hill: accelerate cycle times and reach patients faster with elluminate
Learn how elluminate and eClinical's biometrics services deliver:
Operational insights across numerous data sources that provides definitive answers and analytics on enrollment, protocol compliance and safety
Improved study oversight with a holistic view of risk across all data sources
50 out-of-the-box visualizations to support cross-study analysis for deeper insights with self-service access to clinical and operational analytics
Increased productivity across data management, medical monitoring, clinical operations, clinical programming and statistical analysis roles
Dawn Kaminski, Vice President, Business Development Operations, eClinical Solutions</td></tr>
<tr><td>1:15pm</td><td colspan="2">Lunch and networking</td></tr>
</table>

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2:15pm	**Real world evidence: is this key to accelerating approval processes for oncology trials?** • Tapping into the full potential of real world evidence and incorporating this into your oncology trial • Barriers to adopting RWE: how to address and overcome these • Navigating regulations in the USA in relation to the use of real world evidence in oncology trials **Fatima Scipione,** Vice President, Global Patient Affairs, **Blueprint Medicines**	**Capturing data from wearables and remote monitoring for early phase oncology studies** • Drawing additional data from wearables to support your clinical study: what new opportunities are there? • Shifting from on-site monitoring to hybrid and decentralized approaches: benefits and challenges • Remote monitoring as a method to minimize site workload and increase patient retention **Michelle Joseph,** Associate Director, Data Management, **Alkermes**
2:45pm	**Imaging considerations for early phase oncology trials: what you need, and what you don't** • Image analyses beyond RECIST to better detect signals • What to do with site/central discordant results • How early phase reviews should differ from Ph2/3 • Getting the most out of standard of care imaging **Rick Patt, MD,** Co-Founder and Director, Medical and Scientific Affairs, **RadMD**	**Study design: best practice for increasing your chances of success** • Striking a balance in inclusion and exclusion criteria in order to maximize recruitment without compromising data • Designing objectives and endpoints for an oncology trial: should you be considering surrogate endpoints? • With protocol changes far more common in oncology trials, how do you incorporate flexibility from the outset? • Involving patients and advocacy groups in study design for oncology trials **Anand Merchant,** Clinical Information Science Associate Director, Information Practice, Late Oncology, **AstraZeneca**
3:15pm	**CASE STUDY: Learnings and best practice when running a CAR-T clinical trial in oncology** • The regulatory environment surrounding CAR-T trials in oncology: what do you need to know from a regulatory perspective in order to run a successful trial? • Practicalities of running a CAR-T trial in the US and key considerations • Reducing and mitigating against risks in a CAR-T oncology trial from an operational perspective **Ekatherina Goryachikov,** Vice President, Head of Clinical Operations, **Adicet Bio**	**PANEL DISCUSSION: Innovating your data management processes when running an oncology trial** • How is data management and data capture evolving, and how can you be most efficient in using this? • Making processes easier for sites from a data management perspective: what tools are available? • Overcoming obstacles in order to ensure data is captured and processed in a timely manner **MODERATOR:** **Chris Adams,** Chief Executive Officer, **Andarix** **PANELLISTS:** **Michelle Joseph,** Associate Director, Data Management, **Alkermes** **Cory Burke,** Executive Director, Head of Biometrics and Data Management, **Black Diamond Therapeutics**

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3:45pm	**Afternoon refreshments and networking**
4:15pm	**Key considerations when choosing vendors and partners as a small oncology biotech** • How specialized should your CRO be in your therapeutic area: is this the most important factor? • As a small biotech, what are the benefits of working with a large global CRO vs a small specialized organization? • Working with and collaborating with multiple vendors: considerations and best practice **Leonella Seeley,** Associate Director of Vendor Management and Operations, **Karyopharm Therapeutics**
4:45pm	**Innovative processes to better address today's oncology trial dynamics** • Supply chain efficiency: why do extra work and spend more money than necessary? • Payment process efficiency: leverage an existing workflow process that sites use everyday • Understanding the total value a vendor can provide: select a vendor that can demonstrate its total value **Tom Gottschalk,** Vice President, Business Development, **TrialCard**
5:15pm	**CLOSING PANEL DISCUSSION: CRO oversight as a pharma or biotech sponsor company: how involved do you need to be?** • Balancing degrees of oversight with CROs and partners: how often should you check in? • Working with CROs in a remote environment and fostering a strong relationship virtually • Ensuring you, your vendors and other partners are aligned under one shared goal: best practice in achieving this • Achieving a balance to avoid micromanaging CROs • Considerations for building efficient working practices with your vendors and partners, and the importance of choosing the right vendors for your clinical trial **MODERATOR:** **Tatiana Kolesnikova,** Director, Oncology and Hematology, **GlobalData** **PANELLISTS:** **Cory Burke,** Executive Director, Head of Biometrics and Data Management, **Black Diamond Therapeutics** **Leonella Seeley,** Associate Director of Vendor Management and Operations, **Karyopharm Therapeutics** **Mundayat Jyoti Reddy,** Executive Masters in Emergency & Disaster Management, Medical Science Liaison, **LAPIX Therapeutics** **Ruth Subach,** Vice President, Clinical Development and Operations, **Fujifilm Pharmaceuticals**
6:00pm	**Chairperson's closing remarks** **Tatiana Kolesnikova,** Director, Oncology and Hematology, **GlobalData**

END OF DAY 1 AND NETWORKING DRINKS

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Clinical Operations in Oncology Trials East Coast 2023 DAY 2 – Wednesday 12th July 2023	
8:00am	**Registration and refreshments**
8:50am	**Chairperson's opening remarks** **Tatiana Kolesnikova,** Director, Oncology and Hematology, **GlobalData**
9:00am	**PROBLEM-SOLVING ROUNDTABLE DISCUSSIONS** *During the roundtable discussion session, the conference hall will be divided into four 'zones'. Delegates can choose which zone they would like to join. Each zone will be led by a table moderator and will focus on a different challenge within oncology clinical trials. After 45 minutes, delegates will have the opportunity to swap and choose a different table, and each roundtable will run twice.*
	ROUNDTABLE 1: Considerations when running clinical trials for rare forms of cancer **George Naumov,** Chief Operating Officer, **RS Oncology**
	ROUNDTABLE 2: Preparing data and documents for regulatory submissions: are you ready? **Humphrey Gardner,** Chief Medical Officer, **Harbour Biomed**
	ROUNDTABLE 3: Overcoming challenges in clinical development of cell and gene therapies **Rachel Nering,** Head, Early Stage Oncology, R&D Clinical Science and Operations, **Sanofi**
	ROUNDTABLE 4: Choosing vendors and partners as a small oncology biotech company: key considerations **Alice Drumheller,** Vice President, Clinical Operations, **Salubris Bio**
	ROUNDTABLE 5: Cell therapies for solid tumors **Debora Barton,** Chief Medical Officer, **TScan Therapeutics**
10:30am	**Morning refreshments and networking**

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11:00am	**PANEL DISCUSSION: Innovation and oncology clinical trials: where are the main opportunities in 2023 and beyond?** • Why is oncology typically slower to adopt new technology and innovate in other therapeutic areas? • Understanding patient needs for oncology trials: how can new technology support patients to make participation in trials easier? • Decentralized trials and oncology: will it ever be possible to have a fully decentralized oncology trial? • What elements of decentralization have or should be incorporated in oncology trials? • Assessing new technologies and processes for 2023 and 2024: where are the key areas for opportunity? **MODERATOR:** **Len Rosenberg,** Head, Clinical Operations, **Beat AML** **PANELLISTS:** **Fatima Scipione,** Vice President, Global Patient Affairs, **Blueprint Medicines** **Rachel Nering,** Head, Early Stage Oncology, R&D Clinical Science and Operations, **Sanofi**
11:45am	**The importance of diversity and inclusion in oncology trials and best practice in how to achieve this** • Working with patient advocacy groups in order to reach out to more patients and increase diversity • Improving accessibility to clinical trials: how to engage patients who would not normally participate in clinical trials • How having a diverse patient population can increase reliability of data and results from clinical trials **Rachel Nering,** Head, Early Stage Oncology, R&D Clinical Science and Operations, **Sanofi**
12:15pm	**Lunch, networking and prize draw!**
1:30pm	**Gene therapy: what's new in delivering therapeutics in oncology?** • An overview of new challenges and opportunities in oncology gene therapy • What's on the horizon for 2023 and 2024? • Learnings and key takeaways from preparing for and running gene therapy clinical trials **David Sherris,** Chief Executive Officer, **GenAdam Therapeutics**
2:00pm	**An overview of trends and themes in the clinical trial and healthcare industry in 2023: what's new for oncology trials?** *We welcome Tatiana Kolesnikova from GlobalData to present her research into trends and themes in the clinical trial industry, and what companies need to do to stay ahead of the curve. Join this presentation to hear what has changed since the pandemic, what's new in 2023, and what to watch out for in 2024.* **Tatiana Kolesnikova,** Director, Oncology and Hematology, **GlobalData**
2:30pm	**Chairperson's closing remarks** **Tatiana Kolesnikova,** Director, Oncology and Hematology, **GlobalData**

END OF CONFERENCE

Additional topic suggestions:

Understanding the regulatory environment in the USA for expedited drug approvals in oncology

- Expedited pathways for oncology programs: strategies for managing these from a regulatory point of view
- Analysing how the FDA's regulatory framework is evolving and what this means for trial sponsors
- Outlining the FDA's established and pilot programs and what different pathways are available for oncology companies
- Advice on early planning and a solid regulatory strategy to get your drug to patients quicker

Sourcing funding and investment for your clinical trial in an unstable global economy

- In the current financial climate, how can your reduce trial costs while maintaining effectiveness and efficiency?
- How can you ensure your trial is attractive to investors?
- Raising funding for your trial without compromising on quality and design

Oncology and rare diseases: regulatory and operational consideration when running a study for rare forms of cancer

- What additional challenges are created in clinical research when dealing with rare diseases and orphan drugs?
- Navigating regulatory submissions when dealing with limited data sets
- Designing a trial model for a rare cancer trial that is flexible and appropriate for your patients in order to maximize enrolment and retention

Best practice in engaging sites with new technology

- With sites typically stretched for resources and understaffed, how can you best incorporate new technology to reduce the burden on sites?
- Considering the impact of new technology on sites: ensuring new systems are user friendly and easy to adapt to
- Collaborating with and training sites on new systems in order to ensure staff are confident with processes

Innovating your patient enrolment campaign: how to maximize enrolment for oncology studies

- How have patient recruitment tactics changed since 2019 (before COVID-19 hit)?
- Using virtual and remote approaches to enrolling patients in oncology clinical studies
- Incorporating the use of electronic health records in your recruitment campaign: what challenges are there?