OCT & CTS Israel

GlobalData.

ARENA INTERNATIONAL EVENTS GROUP

Outsourcing in Clinical Trials & Clinical Trial Supply Israel

Tel Aviv, Israel

6th-7th February 2023

www.arena-international.com/octisrael

REGISTER HERE

The Clinical Outsourcing & Supply Israel conference is returning to Tel Aviv, Israel in February 2023. The conference focuses on providing delegates with practical takeaways and solutions to their most current operational, outsourcing and supply challenges in clinical trials, this event is not to be missed.

In 2023, 250+ clinical experts will gather to learn from others and plan for the impact trends can have on the way we internally and externally operate as well as manage supply chains. This conference will be a platform to forge and find new partnerships, provide alternative solutions to your outsourcing and supply chain challenges and give you the opportunity to define an end-to-end clinical strategy.

2023 Speakers

Yigal Aviv, Patient and Healthcare experience lead, **Pfizer**
Amir Zaher, Head of Department, **Ministry of Health Israel**
Tali Schaffer, Executive Director Clinical Affairs, **ELGAN Pharma**
Sean Smith, Biological Threat Exclusion Coordinator (BTEC), **U.S. Customs and Border Protection**
Adam Pitt, Biological Threat Exclusion Coordinator (BTEC), **U.S. Customs and Border Protection**
Hadas Friedman, VP QA/RA and Clinical Affairs, **Pharma Two B**
Uri Heiman, Clinical Development Director, **Laminate Medical Technologies**
Boaz Barak, Assistant Professor, **Tel Aviv University**
Efrat Hartog-David, Ph.D, VP of Regulatory Affairs and Quality Assurance, **MeMed Diagnostics**
Julio Burman, Patient Advocate and Vice-president of **ELPA, European Liver Patient association**
Rochelle Pakier, Associate Manager, CTA**, TEVA**
Mor Buchshtav, Director of Clinical & Regulatory Affairs, **Medasense Biometrics**
Giora Sharf- Patient advocate, Founder: **Israeli CML Patients Organization, Halil Haor- home of blood cancer patients, global CML advocates network**
Illana Gozes, PhD, Professor Emerita of Clinical Biochemistry/Chief Scientific Officer, **Tel Aviv University/ATED Therapeutics Ltd.**
Boaz Albo, Director, Medical Cannabis Treatment & Clinical Research Center, **Sheba Medical Center**
Liat Ben David, Director of Clinical Trials Operations & Ethics Committee (regulatory), **Tel Aviv Medical Center**
Hilla Debby, Clinical Director, **IceCure Medical**
Nitsan Halevy, Chief Medical Officer, **Pluri-Biotech**
Anat Naschitz, Creator, **9xc;** venture partner, **OrbiMed**
Maayan Tsur, Director of Operations, **Neuroderm, Mitsubishi Tanabe Pharma**
Edith Dekel, Senior Director Clinical Operations, **Karyopharm Therapeutics**
Nina Hershkowitz, Global Training & Patient Education Sr. Manager, **Neuroderm**
Sonia Ben Hamida, PhD, Head of Special Cargo, **International Air Transport Association (IATA)**
Tami Rachmilewitz, Chief Medical Officer, **BioLineRX**
Jessica Marer, Sr. Manager, Smart Planning – Innovative Medicine, **Teva Pharmaceuticals**

Join our new OCT community on LinkedIn

#OCTIsrael #CTSIsrael #OCTCTSIsrael | @ArenaIntPharma

Luba Vitkin Katz, Clinical Trials Manager, **Corneat**
Eti Lavi, Head of Global Clinical Operations, **Neuroderm**
Yael Genosar, Associate Director of Clinical Supply Chain, **OPKO Biologics**
Elvira Suniega-Tolentino, Clinical Project Manager Team Lead (Asia), **Nestlé**
Lionel Philippe, Clinical Supply Manager, **Nestlé**
Rich Bennett, Senior Director, Therapeutic Strategy Lead**,** Neuroscience, **Worldwide Clinical Trials**
Paul Finney, Senior Strategic Services Account Manager, **Medidata**
Sascha Sonnenberg, Vice President Global Business Development & Country Head Germany, **SanaClis**

Outsourcing in Clinical Trials & Clinical Trial Supply Israel

Tel Aviv, Israel 6th-7th February 2023

DAY ONE – MONDAY 6TH FEBRUARY 2023

08:00	**REGISTRATION AND REFRESHMENTS**
08:50	Chair's Opening Remarks **Tali Schaffer,** Executive Director Clinical Affairs, **ELGAN Pharma**
9:00	**"Your Avatar Doctor Will Be with You Shortly"** • Considering whether the health care sector and pharmaceutical companies should think about the Metaverse as an Ecosystem? • Exploring how the Metaverse is expected to imminently impact patient relationships within health care • Investigating what plans for Physicians and touch bases will look like in a decade from now? • Focusing on how the Metaverse and Web 3.0 will affect the future of Decentralized Clinical Trials **Yigal Aviv,** *Patient and Healthcare experience lead,* ***Pfizer***
09:30	**Transformational Relationships: How a consultative approach from a CRO could add value to your development program** • How to unlock the full power of your CRO partner • How a CRO partner helps you navigate the interface between science and operations – and why that improves your study • Why early engagement can be a key to your study's success

REGISTER HERE

Sales Enquiry
Ben Lloyd-Davies
Head of Sponsorship Sales
T: +44 (0)207 9472755
E: BenLloyd-Davies@arena-international.com

Speaker Enquiry
Maya Hudson
Senior Conference Producer
E: Maya.Hudson@arena-international.com

Marketing Enquiry
Katie Giorgadze
Marketing Manager
E: Katie.Giorgadze@arena-international.com

	Rich Bennett, *Senior Director, Therapeutic Strategy Lead, Neuroscience,* ***Worldwide Clinical Trials***	
10:00	**PANEL** **Key Components of Successful Clinical Trials to Ensure Study Success** • Efficient utilisation of resources • Risk prevention vs issue management • Effective communication and transparency to minimise unforeseen issues • Learning from failure and celebrating successes Moderator: **Tali Schaffer**, *Executive Director Clinical Affairs,* ***ELGAN Pharma*** Panellists **Eti Lavi,** *Head of Global Clinical Operations,* ***Neuroderm*** **Rich Bennett,** Senior Director, Therapeutic Strategy Lead, **Neuroscience, Worldwide Clinical** **Luba Vitkin Katz**, *Clinical Trials Manager,* ***Corneat*** **Rochelle Pakier,** Associate Manager, CTA, Innovative Medicine, **Teva Pharmaceuticals**	
10:45	**COFFEE BREAK**	
	Outsourcing in Clinical Trials **Chair:** Tali Schaffer, Executive Director Clinical Affairs, ELGAN Pharma	**Clinical Trial Supply** **Chair:** Efrat Hartog-David, Ph.D, VP of Regulatory Affairs and Quality Assurance MeMed Diagnostics
11:15	**Using Real World Data in your clinical development program** • How real-world data can inform clinical trial planning • Highlights of regulatory guidelines for the use of real-world data in clinical development • How can real-world data add value in the clinical development process **Nitsan Halevy**, *Chief Medical Officer,* ***Pluri-Biotech***	**KEYNOTE** **Q&A Discussion: Explore importing and exporting requirements for biological materials and how preparation is everything in the modern world** • Important steps to take to help expedite the clearance of biological materials. • Case studies of inspections: when it really goes wrong and how to tackle it • Discover resources and contacts available to help facilitate your imports, especially time-sensitive/temperature dependent shipments, at U.S. ports of entry

REGISTER HERE

Sales Enquiry
Ben Lloyd-Davies
Head of Sponsorship Sales
T: +44 (0)207 9472755
E: BenLloyd-Davies@arena-international.com

Speaker Enquiry
Maya Hudson
Senior Conference Producer
E: Maya.Hudson@arena-international.com

Marketing Enquiry
Katie Giorgadze
Marketing Manager
E: Katie.Giorgadze@arena-international.com

		• Highlighting the key takeaways for ensuring a smooth inspection as we look to the future **Sean Smith,** *Biological Threat Exclusion Coordinator (BTEC),* ***U.S. Customs and Border Protection*** **Adam Pitt,** *Biological Threat Exclusion Coordinator (BTEC),* ***U.S. Customs and Border Protection***
11:45	**Data Management in Emerging Medical Device and Biotech** • **Corneat**: Introduction, products, studies, company status. **Medidata** Introduction • Site Coordinator perspective: Rave EDC as an end user Sponsor perspective: • Data capture for emerging companies • How emerging companies can "own" their DM processes • Adoption of new technology - Interpreting a protocol into an eCRF • Interactive build process - for sponsor and DB builder **Paul Finney**, *Senior Strategic Services Account Manager,* ***Medidata*** **Luba Vitkin Katz**, *Clinical Trials Manager,* ***Corneat***	**Clinical Trials 2023 and beyond – What do we need to consider preparing a robust and flexible supply chain?** • Expected and unexpected challenges when planning your clinical trial/clinical supply chain. • Innovations leading to an increased patient adherence and engagement. • Examples that can help you building a flexible and robust supply chain **Sascha Sonnenberg,** Vice President Global Business Development & Country Head Germany, **SanaClis**
12:15	**Decentralised Clinical Trials** **Decentralised solutions throughout the lifecycle of a clinical trial - do they add quality?** • Looking into the stakeholders roles • Outlining the challenges to operators and discuss alternatives and mitigations • Connecting the dots between Decentralized Clinical Trials and quality	**Temperature Controlled Airfreight Global Logistics for Clinical Trials** • Can standards and certifications improve the quality of temperature-controlled air cargo shipments? • How is risk management performed for ramp/tarmac operations? • How does the audit process work in the air cargo supply chain? **Sonia Ben Hamida, PhD,** *Head of Special Cargo,* ***International Air Transport Association (IATA)***

REGISTER HERE

Sales Enquiry
Ben Lloyd-Davies
Head of Sponsorship Sales
T: +44 (0)207 9472755
E: BenLloyd-Davies@arena-international.com

Speaker Enquiry
Maya Hudson
Senior Conference Producer
E: Maya.Hudson@arena-international.com

Marketing Enquiry
Katie Giorgadze
Marketing Manager
E: Katie.Giorgadze@arena-international.com

	Liat Ben David, *Director of Clinical Trials Operations & Ethics Committee,* ***Tel Aviv Sourasky Medical Center***	
12:45	**LUNCH BREAK** The exhibition will feature a varied line-up of innovative technologies to support the Israeli life sciences sector. No matter your job function you'll find providers to meet your needs; we'll be showcasing new solutions for trial operations, supply and beyond to give you a comprehensive suite of solutions to maximise trial success.	
14:00	**Regulation requirements for applying cannabis-based clinical trials in Israel** • Development of the medical cannabis field in Israel - from the ground-breaking research of Prof. Mechoulam to the present day • Review of cannabis innovation, research and development in Israel • Identifying the unique requirements need to be implemented to receive a license to conduct a cannabis-based clinical trial **Dr Tamir Gedo,** *former CEO,* ***BOL Pharma***	**Blinding in Clinical studies – Why, How, and related challenges** • Protecting against bias; *a deeper understanding* • To Blind or not to Blind? • Addressing challenges associated with blinding **Tami Rachmilewitz, MD,** *Chief Medical Officer,* ***BioLineRX***
14:30	FIRESIDE CHAT **Focusing on the importance of Diversity & Inclusion in clinical trials** *Diversity matters because inclusion, trust and equity matter for pharma. When developing therapies and medications, pharmaceutical and life sciences companies are tasked with designing products for a diverse range of patients and care providers. We will be discussing how to ensure diversity in clinical trials for the future of global health.* ***Moderator: Tali Schaffer,*** Executive Director Clinical Affairs, **ELGAN Pharma**	**PANEL DISCUSSION** **Safeguarding the Supply Chain Landscape Post Covid and Through Challenging Political Environments** • Managing supply timelines to not delay your study • Recognising the limited economic environment; shipment and the release of products • Investigating various Air transits to decrease timelines and outgoings • Addressing the political challenges which are affecting your supply chain

REGISTER HERE

Sales Enquiry
Ben Lloyd-Davies
Head of Sponsorship Sales
T: +44 (0)207 9472755
E: BenLloyd-Davies@arena-international.com

Speaker Enquiry
Maya Hudson
Senior Conference Producer
E: Maya.Hudson@arena-international.com

Marketing Enquiry
Katie Giorgadze
Marketing Manager
E: Katie.Giorgadze@arena-international.com

	Jessica Marer, *Sr. Manager, Smart Planning – Innovative Medicine,* ***Teva Pharmaceuticals***	• Discussing the lack of personnel in supply chain post pandemic **Moderator: Lionel Philippe, PhD**, *Clinical Supply Manager,* ***Nestlé*** **Panellists:** **Sonia Ben Hamida, PhD,** *Head of Special Cargo,* ***International Air Transport Association (IATA)*** **Illana Gozes, PhD,** *Professor Emerita of Clinical Biochemistry/Chief Scientific Officer,* ***Tel Aviv University/ ATED Therapeutics Ltd.*** **Yael Genosar,** *Associate Director of Clinical Supply Chain,* ***OPKO Biologics*** **Sascha Sonnenberg,** *Vice President Global Business Development & Country Head Germany,* ***SanaClis***
15:00	**COFFEE BREAK**	
15:30	**Fundraising and venture Capitals – how to best promote and raise funding for your study** • Understanding what VCs are looking for to give your study the best possibility of success • Pinpointing key components when compiling your proposal • Promoting the niche selling points to best showcase your study **Anat Naschitz,** *Creator at* ***9xc****; venture partner at* ***OrbiMed***	**Managing clinical vendors during a global crisis period** • Identifying gaps and risks in the vendors performance impacting the clinical study • Developing organizational awareness to global trends which influence the vendors performance (e.g., The Great Resignation) • Establishing internal and external mitigation plans to minimize the impact on ongoing studies **Maayan Tsur,** *Director of Operations,* ***Neuroderm, Mitsubishi Tanabe Pharma***
16:00	**Patient engagement in R&D Clinical Trials** • Discussing the personal experiences of the patient • Understanding the patient's perspective • Defining 'patient centricity'	**Running your clinical trial internationally: overcoming logistical challenges to maximize supply chain efficiency** • Managing the supply chain to improve the effectiveness of the process

REGISTER HERE

Sales Enquiry
Ben Lloyd-Davies
Head of Sponsorship Sales
T: +44 (0)207 9472755
E: BenLloyd-Davies@arena-international.com

Speaker Enquiry
Maya Hudson
Senior Conference Producer
E: Maya.Hudson@arena-international.com

Marketing Enquiry
Katie Giorgadze
Marketing Manager
E: Katie.Giorgadze@arena-international.com

	Giora Sharf- Patient advocate, Founder: **Israeli CML Patients Organization, Halil Haor- home of blood cancer patients, global CML advocates network**	• Risk based assessment on supply chain optimization, outsourcing strategy and logistics **Lionel Philippe, PhD,** *Clinical Supply Manager,* ***Nestlé***
16:30	**Chair's closing remarks**	**Chair's closing remark**

Outsourcing in Clinical Trials & Clinical Trial Supply Israel

Tel Aviv, Israel, 6th-7th February 2023

DAY TWO – TUESDAY 7TH FEBRUARY 2023

8:00	**REGISTRATION AND REFRESHMENTS**
09:00	**ROUNDTABLE DISCUSSIONS** Roundtables offer delegates the opportunity to delve into a topic or issue and unpack this in a thoughtful and constructive manner. Each host is a subject matter expert in their field and comes prepared with questions which will allow attendees the chance to debate and discuss in detail. Each session lasts 45 minutes and delegates will be able to attend 2 sessions
Roundtable 1	***Complexity of Randomised Controlled Trial's in Geriatric Population*** ***Amir Zaher,*** *Head of pharmacy geriatric department,* ***Ministry of Health Israel***
Roundtable 2	***Clinical Trial Educators, how to make the impossible, possible!*** **Nina Hershkowitz,** *Global Training & Patient Education Sr. Manager,* ***Neuroderm***
Roundtable 3	**How to find your perfect CRO** **Edith Dekel,** *Senior Director Clinical Operations,* ***Karyopharm Therapeutics***

REGISTER HERE

Sales Enquiry
Ben Lloyd-Davies
Head of Sponsorship Sales
T: +44 (0)207 9472755
E: BenLloyd-Davies@arena-international.com

Speaker Enquiry
Maya Hudson
Senior Conference Producer
E: Maya.Hudson@arena-international.com

Marketing Enquiry
Katie Giorgadze
Marketing Manager
E: Katie.Giorgadze@arena-international.com

Roundtable 4	**Q&A Session with U.S. Customs and Border Protection – Here to help with any questions you may have about how to import or export biological materials to or from the U.S.** ***Sean Smith,*** *Biological Threat Exclusion Coordinator (BTEC),* ***U.S. Customs and Border Protection*** ***Adam Pitt,*** *Biological Threat Exclusion Coordinator (BTEC),* ***U.S. Customs and Border Protection***	
10:30	**COFFEE BREAK**	
	Outsourcing in Clinical Trials **Chair:** Tali Schaffer, Executive Director Clinical Affairs, ELGAN Pharma	**Medical Devices** **Chair:** Elvira Suniega-Tolentino, Clinical Project Manager Team Lead (Asia), Nestlé
11:00	**Strategies for Country and Site Selection;** ***enhancing one's knowledgebase for the best move forward*** • Robust feasibility for clinical trials; from protocol design to country & site selection • Access to sites and site selection within Israel to refrain from going elsewhere • Analysing various countries to indicate the best options for site selection • Understanding new landscapes from a legislative perspective **Tali Schaffer,** Executive Director Clinical Affairs, **ELGAN Pharma**	 **Preparing the foundation of your regulatory plan in order to build a successful study** • Focusing on FDA Regulations • Delving into the new EU MDR Regulations • Conflicting advisory opinions and how to manage this **Mor Buchshtav,** *Director of Clinical & Regulatory Affairs,* ***Medasense Biometrics***
11:30	**Drug-drug combinations - study design and conduct: the P2B001 experience** • Study design, multiple arms vs study complexity • Compliance with written/unwritten US and EU regulatory requirements • Running a Parkinson's study during the COVID pandemic, our experience • Study results **Hadas Friedman,** *VP QA/RA and Clinical Affairs,* ***Pharma Two B***	**Creating Value once your product goes to market: Gathering, analysing, and creating relevant products of real-world use of medical device** • Data gathering: Sources, challenges, and tips • Creating relevant knowledge: data analysis in light of various internal and external costumers • How knowledge gained through your real-world clinical experience can provide benefits to your company: IFU, SOPs, Training, Marketing and Sales

REGISTER HERE

Sales Enquiry
Ben Lloyd-Davies
Head of Sponsorship Sales
T: +44 (0)207 9472755
E: BenLloyd-Davies@arena-international.com

Speaker Enquiry
Maya Hudson
Senior Conference Producer
E: Maya.Hudson@arena-international.com

Marketing Enquiry
Katie Giorgadze
Marketing Manager
E: Katie.Giorgadze@arena-international.com

		Uri Heiman, *Clinical Development Director,* ***Laminate Medical Technologies***
12:00	**LUNCH BREAK** The exhibition will feature a varied line-up of innovative technologies to support the Israeli life sciences sector. No matter your job function you'll find providers to meet your needs; we'll be showcasing new solutions for trial operations, supply and beyond to give you a comprehensive suite of solutions to maximise trial success.	
13:00	**From bench to bedside: taking a drug from the lab to a clinic to treat Williams Syndrome** • Natural history studies and preparing for a rare disease trial • Assessing unmet needs and long-term outcomes for orphan drugs in situations with no alternative treatments • Identifying endpoints when there is no precedence or pre-existing treatment for a rare or ultra-rare disease **Boaz Barak,** *Assistant Professor,* ***Tel Aviv University***	**Investigator initiated studies** • Definition and what makes a successful IIS trial? • What role does the company play • Providing examples of both the advantages and challenges • key points to remember **Hilla Debby,** *Clinical Director,* ***IceCure Medical***
13:30	**Development of therapeutics to neurodevelopmental/neurodegenerative disorders: Davunetide as a case study focusing on the most recent advances and scientific discoveries** • Developing therapeutics for rare diseases: the case of the ADNP syndrome and Davunetide • Exploring the tools, technologies and data management techniques used to streamline the process • Pitfalls encountered and how they were overcome • Advice on vendor negotiation and management – how to ensure you are working with a partner who can cater to your specific trial needs	**IVDR; how our diagnostic companies are addressing the increased regulatory requirements in the EU?** • Requirements for IVD clinical performance studies: what has changed? • Legacy products: how can we continue to market legacy products? • Introducing new products to the market: how are we going to adapt and address the new requirements? **Efrat Hartog-David, Ph.D,** *VP of Regulatory Affairs and Quality Assurance* ***MeMed Diagnostics***

REGISTER HERE

Sales Enquiry
Ben Lloyd-Davies
Head of Sponsorship Sales
T: +44 (0)207 9472755
E: BenLloyd-Davies@arena-international.com

Speaker Enquiry
Maya Hudson
Senior Conference Producer
E: Maya.Hudson@arena-international.com

Marketing Enquiry
Katie Giorgadze
Marketing Manager
E: Katie.Giorgadze@arena-international.com

	Illana Gozes, *Professor of Clinical Biochemistry/Chief Science Officer,* ***Tel Aviv University/ ATED Therapeutics Ltd.***	
14:00	**Building clinical trials with the perspective of the patients in mind*; exploring patient collaboration and the benefits it can bring to the sponsor and the patient*** • Discussing the collaboration that has to exist between all parties (patients, coordinators, doctors) in order to have a successful trial • Importance of good communication to the patients and how this can streamline trial timelines • Exploring how patients could, and should, be influencing decisions and the R&D process • Highlighting the importance of patient collaboration during COVID **Julio Burman,** *Patient Advocate and Vice-president of* ***ELPA: European Liver Patient association***	
14:30	**Chair's summary and close of conference**	

REGISTER HERE

Sales Enquiry
Ben Lloyd-Davies
Head of Sponsorship Sales
T: +44 (0)207 9472755
E: BenLloyd-Davies@arena-international.com

Speaker Enquiry
Maya Hudson
Senior Conference Producer
E: Maya.Hudson@arena-international.com

Marketing Enquiry
Katie Giorgadze
Marketing Manager
E: Katie.Giorgadze@arena-international.com