GLOBAL CLINICAL SUPPLIES GROUP

EUROPEAN KNOWLEDGE FORUM 2024

MALTA | 15-17 Oct

GCSG 2024 European Knowledge Forum

Begins	Ends	Day 1 - Tuesday 15 October 2024	Location	Summary	Speaker
07:30	08:30	Bootcamp Registration Open	Registration Area		
08:00	16:30	Bootcamp: How to Plan & Implement an Expanded Access Program	Carthaginian I	Expanded Access, Named Patient, Compassionate Use... the names for the process are as varied as the options for supporting them. This interactive course will give an overview of expanded access as well as discuss relevant regulations and their impact on operational and strategic planning. Atttendees will be able to hear from subject matter experts with many years experience on best practices and important questions to ask when supporting these types of studies. Come to this boot camp to discuss the regulations for expanded access and how they impact your operational and strategic supply planning.	Gretchen Randlett (Eli Lilly) Graham Sidorowicz (BionicalEmas)
08:00	16:30	Bootcamp: Understanding the Essentials Of the Clinical Supply Chain	Roman	This class, geared towards people new to the world of clinical trial supplies, focuses on drug development and what goes into planning for and delivering a study drug for a clinical trial. Topics include: reasons behind Good Manufacturing Practices (cGMPs), phases of new drug development and approval, randomizing and blinding clinical trial materials, quality assurance & documentation, protocol interpretation, patient compliance, labeling, standard operating procedures (SOPs), stability, Good Distribution Practices (GDPs), returned drug accountability, and changing regulations in the European Union (EU) and rest of world (ROW). Attendees will hear a massive amount of information in a fun and interactive atmosphere.	Steve Jacobs (Global BioPharm Solutions) Richard Lambie (Lambda Pharma Consulting)
08:00	16:30	Bootcamp: Import / Export	Castillian III	This class is designed for clinical supply professionals who want to learn more than just the basics about shipping and distribution for global clinical trials. This seminar will cover trade compliance, international shipment workflow and clearance, Value Added Tax (VAT) and logistics supply chain partnerships to ensure success with international distribution.	Gavin Morgan (PCI) Melissa Brod (VAT IT)
08:00	16:30	Bootcamp: Mastering Clinical Supply Planning	Norman	Planning the clinical supply chain is a formidable task, full of challenges and complexities. With the variety of information to consider, external influences, and the inherent uncertainties of clinical trials, supply managers often find themselves under pressure to deliver a supply plan that is not only accurate but also highly efficient. This advanced one-day bootcamp is tailored for supply chain managers and planners familiar with the basics who would like to elevate their skills and knowledge. Together, we will address the main drivers of inefficiencies in clinical supply planning and navigate good practices to avoid them.	Alexis Davin Amaury Jeandrain (N-Side)
15:00	17:30	Registration Open	Registration Area		
15:00	17:30	Exhibitor Set Up	South/Bay Foyers & St George's		
16:00	16:30	Presenters / WS Facilitators Orientation	Registration Area	If you are speaking at a plenary session or facilitating one of our many workshops, plan to join this session to learn all the last-minute tips and tricks you'll need to be a success!	Bev Nicol Olivia Riordan Jasmine Ramtoolah
16:30	17:30	Vendor Showcase: Exploring Comparator Sourcing Strategies and Opportunities for Use within China - Hosted by Bionical Emas	Phoenician I&II	Are you looking to better understand the benefits and challenges of Central Sourcing vs. Local Sourcing models in China, and when to decide which sourcing strategy to use and the timelines associated? This session will cover the two models as well as delving into how accessible commercial products are for use in clinical trials in China. It will explore what the process is for accessing products locally: POA, trial disclosure, pricing differentiators, lead times and documents provided with products.	James Rowley
16:30	17:30	Vendor Showcase: Implementing Sustainable Sourcing Practices for Commercial Medicines in Your Clinical Trials - Hosted by Abacus Medicine	Castillian I&II	If you want to understand the commercial medicine supply chain inside out, then this session is for you! Topics covered will be predicting the future using data analytics, AI and market intelligence. Your hosts will talk through reviewing regularly, back-up & risk mitigation and will provide case studies that their audience can learn from.	Lucy Fox & Ian Hoban
16:30	17:30	Vendor Showcase: Navigating Regulatory Changes for Packaging & Labeling: Lessons Learned From the Transition to the EU Clinical Trial Regulation - Hosted by Clinigen	Carthaginian II	The transition from the Clinical Trial Directive to the EU Clinical Trial Regulation has created significant operational challenges for clinical trial supplies. This session will discuss Clinigen's proactive approach to managing the regulatory change for packaging and labelling to ensure seamless compliance. This included a comprehensive impact analysis, client education initiatives and tailored solutions to reduce complexity and avoid delays. You will learn best practices for navigating change and gain insight into how you can mitigate risk and maintain operational excellence.	Melany Pierad & Mathieu Denis
17:45	18:15	Start The Knowledge Forum Right! - Knowledge Forum Orientation	Spinola/St Julian's	Whether this is your first time attending or you are an 'old pro', plan to join us at the conference orientation to learn how you can make the most of your time at the GCSG 2024 European Knowledge Forum!	David Spillett & JP Kappelle
18:30	22:30	GCSG Meet & Greet Networking Event	Pavillion		

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Begins	Ends	Day 2 - Wednesday 16 October 2022		Location	Summary	Speaker
07:30	08:30	Registration Open Exhibitor Displays Open		Registration Area South/Bay Foyers & St George's		
08:00	08:30	Welcome & Opening Remarks - European GCSG Scholarship Announcement		Spinola/St Julian's		David Spillett & JP Kappelle
08:30	09:30	Patient Testimonial		Spinola/St Julian's	Dalia, a Senior Clinical Trial Manager at Janssen, has worked in clinical research since 2010. Diagnosed with breast cancer in 2022, she completed extensive treatment and joined a clinical trial in 2023. Dalia advocates for breast cancer awareness in younger people and collaborates with charities and media for campaigns.	Dalia Ismail
09:30	09:45	Room transfer				
09:45	10:45	Breakout Session 1	WS1: What to Consider When Getting into Cell & Gene Therapy	Phoenician I&II	This workshop will be a discussion focused on the challenges of cell and gene therapy. Key topics to be discussed will include CGT's patient orientation, temperature controlled logistics, site requirements, manufacturing challenges and aggressive timing.	Sue Lee (Hexagon Consulting) Alexandra Holtzen (AcnosPharma)
			WS3: Lessons Learned After 30 Years In Clinical Supplies	Carthaginian II	In 30 years, a lot could be learned in the clinical supply industry. This workshop will leverage SME's and participant's knowledge to provide solutions to the attendee's biggest issues and questions.	Steve Jacobs (Global BioPharm Solutions) Joe Iacabucci (Moderna)
			WS6: Using AI to Predict Enrollment & Forcasting	Roman	Clinical supply's greatest challenge is patient enrollment. It is the greatest cause of supply chain turmoil. This workshop will discuss how AI is being used to not only accelerate enrollment but to predict it and how those trends can be used by the clinical supply chain.	Cedric Druck (Trialzen) Mark Gribman (Medidata)
			WS15: Building Career Success (as YOU define it) & a Great Work-Life Balance	Castillian III	In this interactive workshop, participants are guided through self-reflection, share and develop insights and leave with an action they can take immediately, to progress their careers and positively impact their work life balance. The exercise is designed to benefit the individuals, the companies they work for, the customers they serve, and the family and friends they care about. In addition to enabling important self-reflection and action planning, the participants can take this approach back to the workplace to support conversations with their teams.	Julie Williams (Gatehouse Consulting)
			WS16: Understanding the Requirements & Challenges for Importer of Record (IoR)	Castillian I&II	Ever have an international shipment get delayed due to documentation issues? This workshop will discuss what the importer of record (IoR) does, along with various other document requirements that enable shipments between countries to occur smoothly.	Gavin Morgan (PCI) Melissa Brod (VATIT)
			WS18: Selection of Vendor Companies & Partnering with Internal Stakeholders During the Process	Norman	As the incidence of outsourcing the clinical supply chain has increased, understanding the value of clinical supply management using your vendor as a partner has become essential. This workshop will explore how to best utilize your vendor partner as a seamless part of your supply chain while utilizing internal stakeholder inputs to update your metrics.	Jonathan Pritchard (4G) Richard Lambie (Lambda Pharma Consulting) Tony Street (Orifarm)
10:45	11:00	Room transfer				
11:00	12:00	Breakout Session 2	WS2: Clinical Supply Chain Open Forum	Phoenician I&II	This forum will give attendees the opportunity to ask questions and get solutions to some of their current challenges within their clinical supply chains.	Ana-Zeralda Canala (DebioPharma) Victoria Parkinson (ClientPharma)
			WS8: Compare & Contrast the Diverse Types of Access (Compassionate Use, Off-label Access, Continued Access, Special License sales & Right-to-Try)	Castillian III	This session provides a broad overview of the diverse mechanisms to support patients' ability to access investigational drugs. In this workshop we will go over all these mechanisms which will enable you to successfully understand which is the best pathway based on the patient need. Topics covered will include compassionate use, off-label access, continued access, special license sales and right-to -try.	Gretchen Randlett (Eli Lilly) Graham Sidorowicz (BionicalEmas)
			WS9: How to Accomplish Drug Pooling in Europe	Carthaginian II	Supplying multiple clinical trials from a pooled inventory of material provides a number of advantages. This workshop will focus on the challenges of doing pooling of supplies in Europe as well as provide some solutions to accomplish the most pooling possible.	Paula Figueiredo (AlfaSigma) Mattia Scarafoni (Incyte) Abi Fakolujo (Incyte)
			WS10: QP Certification: Your Questions Answered	Norman	QP certification is often an area of confusion and misunderstanding in our complex industry. This session will provide you with an opportunity to have your questions answered by a Qualified Person.	Naomi Wilmer (ThermoFisher)
			WS13: Resources to Assist Patients in Identifying and Navigating Clinical Trials	Roman	This workshop will identify one of the largest challenges we have in the clinical trial industry - finding and enrolling patients. It will provide a different perspective to help understand how we can support patients in finding appropriate clinical trials to treat or cure many of the diseases from which they suffer today.	Fiona Gallaher (Cancer Patients Europe)
			WS17: Clinical Supply Stakeholder Management	Castillian I&II	Clinical Supply bridges the gap among many stakeholders (both internal and external). Clinical Supply is always being asked to expedite and be the most flexible amongst all the teams. This session will explore how cross-functional teams can collaborate effectively to develop a robust clinical supply strategy with accurate forecasting, strong vendor partnerships and smooth operational execution.	Nancy Morrone (Pfizer) Lyn McNeill (Almac)
12:00	13:15	Lunch (Restaurant) Exhibitor Displays Open (South/Bay Foyers & St George's)				
13:15	14:15	Breakout Session 3	WS4: Creating Clinical Trial Supply Success for Small Start-ups in a Sea of Giant Companies	Phoenician I&II	Clinical trial success is paramount to ensuring longevity, especially in a small start-up company. This session will aim to provide guidance on the processes to consider, whilst appreciating that this can grow as the company grows due to success.	Zayheda Khan (Oximio) Katy Ostertag-Johnson (Xerimis) Danielle Vasoncelos (Repare)
			WS5: What to Know & What to Avoid to Experience the Greatest Success When Sourcing Comparators	Carthaginian II	Comparator sourcing, a complex and challenging activity, is required to conduct the majority of clinical trials today. During this workshop we will discuss some of the key challenges of sourcing and procuring comparators and how to set yourself up for success..	Mark Johnson (Clinigen) Lorann Morse (Vir Biotechnology)
			WS11: Inspection Readiness Across the Pipeline	Castillian III	Instilling an inspection-ready culture in your operations groups is vital to success. Come to this session to discuss how to apply the 80-20 rule, prepare for inspections & get ready for the inspection room as well as learn about some key tools to help you stay calm, succeed and always be inspection-ready!	Christian Gauseoohl (Marken)
			WS12: Understanding EU Labelling Regulations	Castillian I&II	Awareness of labelling regulatory requirements across different agencies is critical for being a successful clinical trial supply professional. This workshop will discuss the labelling requirements in the EU that, when correctly implemented, allow you to avoid delays and supply chain disruptions.	Simon Morgan (Pfizer) Clive Balcombe (Pfizer)
			WS14: Navigating DTP - Stakeholder Perspectives & Challenges	Norman	DTP is a complex process with multiple stakeholders - patients, investigators, site staff, pharmacies, depots, Health Authorities, Ethics Committees and couriers to name a few. The GCSG DTP Team will lead a discussion about varied stakeholder perspectives, experiences and lessons learned (sponsors, vendors, etc.).	Henk Dietreren (Suvoda) Sarah Englert (ThermoFisher) Rima Darwiche (cplAustralia)

			WS16: Understanding the Requirements & Challenges for Importer of Record (IoR)	**Roman**	Ever have an international shipment get delayed due to documentation issues? This workshop will discuss what the importer of record (IoR) does, along with various other document requirements that enable shipments between countries to occur smoothly.	**Gavin Morgan (PCI)** **Melissa Brod (VATIT)**
14:15	**14:30**	**Room transfer**				
14:30	**15:30**	**Keynote Presentation**		**Spinola/St Julian's**	Dr. Helena Boschi is a renowned psychologist who applies brain science to the business world, offering tools to improve decision-making, innovation, and communication. For nearly three decades, she has advised multinational organizations on organizational behavior, leadership, and change management. Represented by Leading Authorities speakers bureau, she engages audiences with insights into brain function and practical tips for enhancing workplace performance and wellbeing. Dr. Boschi's research includes the impact of work-induced stress on brain function, detailed in her book "Why We Do What We Do." She is a member of the British Psychological Society.	**Helen Broschi**
15:30	**15:45**	**Closing Remarks**		**Spinola/St Julian's**		**David Spillett & JP Kappelle**
15:45	**17:30**	**Vendor Reception & PRIZE DRAWS!**		**South/Bay Foyers & St George's**		**Steve Jacobs & Richard Lambie**
17:30	**18:00**	**Personal Time**				
18:00	**18:30**	**Departure for GCSG Night Out at Hotel Reception**				
18:30	**23:59**	**GCSG Night Out sponsored by Alcura**				
22:30	**23:59**	**Departures to Hotel**				

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08:00	08:30	Registration Open- Exhibitor Displays Open		Registration Area South/Bay Foyers & St George's		
08:30	08:45	Welcome, Opening Remarks & Committee Recognition		Spinola/St Julian's		David Spillett & JP Kappelle
08:45	09:45	Plenary Presentation	Clinical Trial Trends	Spinola/St Julian's	There are several challenges impacting global clinical supply chains. In this session we cover key market trends including clinical trial starts funding, therapies, locations and sites and discuss the implications for clinical supply chains.	Carol Alexandra (IQVIA) Chris Armstrong (Thermo Fisher)
09:45	10:00	Room transfer				
10:00	11:00	Vendor Showcase: Acceleration to Market Through Innovation and Integration - Hosted by Thermo Fisher Scientific		Phoenician I&II	Learn how Thermo Fisher Scientific is helping you accelerate to market through two key areas: clinical trial innovation and CRO/CDMO integration. By introducing many market-leading innovative clinical trial services across our end-to-end suite of solutions as well as our integration of CRO and CDMO capabilities, Thermo Fisher has proven an industry differentiating ability to drive increased speed, efficiency, and flexibility in drug development. Hear from industry experts on how we've successfully executed in these two areas and how the combination of our innovation and integration efforts uniquely enables Thermo Fisher to support acceleration of your molecule to market.	Sarah Englert, Eric Deschamps & Luke Wilson
10:00	11:00	Vendor Showcase: Clinical Trial Logistics – Planning is Key! - Hosted by Marken		Castillian I&II	Types of Logistics, dependent on supply chain, study design - Depot to Depot; site to Depot, Direct to Patient Depot Strategy - how to select depots for optimising patient reach and cost control. Cold chain Packaging what to consider. Sustainability in logistics	Manishaa O'Brien
10:00	11:00	Vendor Showcase: Innovating in Forecasting & Planning – Deep Dive into a Freshly Released Planning Platform - Hosted by N-Side		Carthaginian II	Choosing a forecasting & planning tool – criteria, challenges & opportunities in our industry. Discover N-SIDE Lighthouse, a forecasting & planning solution for all trials and users. Navigate a live demo – build a trial in N-SIDE Lighthouse, create a supply and distribution plan and monitor an ongoing trial. Learn about the long-term vision of N-SIDE for its clinical supply chain solutions. At the end of the session, you may register for a hands-on experience during the conference.	Yoni Van den Branden & Laurent Verdickt
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			WS7: SMART Packaging for Adherence Measurement: Understanding the Impact on Supply Planning	Roman	Drug administration and compliance have always been a challenge. With the advent of SMART devices, this has become easier. This workshop will discuss how and why to integrate SMART technology into your supply chain to improve adherence	Paul Ingram (Consultant) Joanne Watters (Intelligent Device)
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15:30	15:45	Room transfer				
15:45	16:45	Plenary Presentation	Environmental Sustainability and the Supply of Medicines for use in Clinical Trials	Spinola/St George's	During this session we will take a broad look at environmental sustainability & , in terms of global impact, the biggest contributors. Looking at our industry's impact and how it's categorised, considering how you can measure impact for your own company and partners. Discussion on setting goals and measuring impact, we'll also review some real-world initiatives to achieve sustainability objectives, concluding with the practical, real-life requirements for your own businesses towards Environmental Sustainability goals	Mark Ware (Inceptua)
16:45	17:00	Closing Remarks, Survey Completion, Prize Draws		Spinola/St George's		David Spillett & JP Kappelle