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Boot Camp 1	Essentials of Clinical Supply (B)	Beginner	Clinical Supplies	This beginner level class is geared toward people new to the clinical trial supplies world and focuses on drug development as well as planning for and delivering a study drug for clinical trial. Topics will include: history of Good Manufacturing Practices (cGMPs), phases of drug development and approval, randomizing and blinding clinical materials, quality assurance and documentation, protocol interpretation, labeling, SOPs, Good Distribution Practices (GDPs), drug accountability, and current regulations. Attendees will obtain a massive amount of information in a fun and interactive atmosphere.
Boot Camp 2	Clinical Supplies Shipping and Distribution: Far Beyond the Fundamentals (I)	Intermediate	Distribution	This intermediate level interactive bootcamp provides a comprehensive introduction to the key concepts and practical considerations of international trade, focusing on import/export regulations, trade compliance and Value-Added Tax (VAT) implications. Participants will explore customs requirements, documentation, compliance obligations, and strategies to manage costs and mitigate risks. Through real-world examples, discussions, and hands-on exercises, attendees will gain the knowledge needed to navigate global supply operations effectively and ensure regulatory compliance across multiple markets.
Boot Camp 3	Understanding the Deeper Capabilities of IRT Systems (A)	Advanced	IRT	This advanced level hands-on bootcamp is designed for participants with intermediate IRT experience who want to deepen their understanding of advanced system capabilities in clinical trial management. Attendees will explore complex scenarios including adaptive trial designs, randomization algorithms, kit management, site resupply, and real-time data analytics. Through interactive exercises, case studies, and team discussions, participants will gain practical skills to highly optimize IRT setups, ensuring compliance, and improving operational efficiency in complex clinical trials.
Boot Camp 4 - Part 1	Artificial Intelligence (AI) Foundations (B)	Beginner	Technology - AI	This beginner level half-day boot camp will provide a comprehensive introduction to the world of AI, tracing its evolution from theory in the 1950s to the machine learning and generative models available today. Participants will explore the major classes of AI, their distinguishing features, and where each is most effectively applied — particularly within the context of Pharma R&D and the Clinical Trial Supply Chain. Through real-life examples, open discussions, and small exercises, the group will examine AI's current capabilities, its potential to optimize clinical operations, and the ethical and operational risks involved. A hands-on team project will challenge participants to design and defend an AI solution, emphasizing the importance of strategic framing, stakeholder alignment, and responsible implementation. The program will conclude with shared reflections and key takeaways to guide future AI initiatives. Attendees should bring a laptop and be prepared for an interactive session using light weight AI tools.
Boot Camp 4 - Part 2	Artificial Intelligence (AI) A Hands-On Session for Experienced Users (I)	Intermediate	Technology - AI	This intermediate level half-day Bootcamp introduces participants to essential AI concepts tailored for the clinical trial industry emphasizing data security and privacy. Attendees will gain hands-on experience with AI tools to enhance efficiency and learn strategies for ethical and secure AI use in clinical settings. Through interactive sessions and real-world examples, participants will leave equipped to implement AI responsibly in their work.
Plenary 1	Key Challenges in Transitioning from Clinical to Commercial: Bridging the Gap to Launch Readiness (I)	Intermediate	Clinical Supplies	This intermediate level plenary will guide you through the critical transition from clinical phase to commercial launch. Participants will leave with a deeper understanding of the activities & requirements of moving from clinical development to commercialization, including timeline, quality, production, stakeholder, logistical and artwork and serialization differences.
Plenary 2	Company Strategies for Patient Centricity (I)	Intermediate	Patient Centricity	This intermediate level plenary examines how companies are embedding patient-centric principles into their clinical development strategy. Participants will explore approaches to engage patients meaningfully throughout the trial lifecycle, including communication, trial design, support programs, and feedback integration. The session highlights successful case studies and practical tools companies use to prioritize patient needs, improve experience, and foster trust with current and future trial participants.

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Plenary 3	The Evolution of AI and Its Impact on the Clinical Supply Chain (I)	Intermediate	Technology - AI	This intermediate level plenary explores how artificial intelligence (AI) is transforming the clinical supply chain—from forecasting and planning to real-time monitoring and risk mitigation. Participants will examine the evolution of AI tools, machine learning algorithms, and predictive analytics, and how they are being applied to optimize supply chain efficiency, reduce waste, and improve patient service levels. Real-world use cases will highlight AI's current capabilities and future potential in reshaping supply operations across the clinical trial lifecycle.
L01	How Quality and Regulations Shape Clinical Trial Ancillary Supply (B)	Beginner	Ancillaries	The Clinical Trial Ancillary Supply Chain (CTASC) is diverse and complex, with performance that can directly impact trial timelines and patient outcomes. This beginner level lecture will provide critical insights into how proactive collaboration with Quality and Regulatory partners strengthens supply chain performance, mitigates risks, and supports successful trial execution.
L02	Emerging Markets: Setting Up Cell & Gene Therapy Trials & Launch Strategies (A)	Advanced	CGT	This advanced level lecture will explore the unique challenges encountered during trial setup and product launch for Cell and Gene Therapies in emerging markets. Participants will gain insights into key lessons learned, effective planning considerations, and proven collaboration strategies. High-level case studies will highlight impactful best practices, tactics, and tools to ensure successful execution in these complex and evolving environments.
L03	Forecasting or Simulation? Choosing the Right Approach (A)	Advanced	Clinical Supply Planning	This advanced level lecture will explore the differences between forecasting and simulation techniques within clinical trials and supply chain management. Participants will learn how to select the most appropriate approach based on project objectives, understand the strengths and limitations of each method, and review practical applications through case studies demonstrating their effectiveness.
L04	Developing IRT UAT Scripts (A)	Advanced	IRT	Test scripts for User Acceptance Testing (UAT) are a critical tool to ensure the IRT has been built correctly and is in compliance with user requirement specifications (URS). The industry best practice is to generate your own test scripts. This advanced level lecture will cover industry expectations for test planning, execution, documentation and managing change control.
L05	Designing the IRT to Prevent Accidental Unblinding (I)	Intermediate	IRT	Protecting study integrity starts with safeguarding the blind. This intermediate level interactive lecture will examine how IRT configuration can inadvertently lead to unblinding. Through real-world examples, attendees will learn to identify potential vulnerabilities and implement practical strategies to prevent accidental unblinding—ensuring your study remains robust from start to finish.
L06	Regulatory Submissions Best Practices for Clinical Trials (A)	Advanced	Quality/ Regulatory	This advanced level lecture provides a practical guide to regulatory submission strategies that drive clinical trial success worldwide. Participants will learn how to prepare high-quality regulatory packages, navigate region-specific requirements, and avoid common pitfalls that cause delays or rejections. The session covers best practices in dossier planning, document management, cross-functional coordination, and effective use of electronic submission platforms such as the eCTD.
L07	Introduction to Digital Supply Networks (A)	Advanced	Technology	This advanced level lecture provides a foundational overview of Digital Supply Networks (DSNs) and their transformative potential for the clinical supply chain. Unlike traditional linear models, DSNs enable dynamic, real-time data flow across interconnected nodes—driving agility, transparency, and informed decision-making. Participants will explore the key technologies behind DSNs (such as IoT, AI, and cloud platforms), their application in clinical development, and how to begin transitioning from a traditional supply chain to a digitally connected platform.

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L08	Implementing a Control Tower for Real-Time Executive Dashboards and Actionable Insights (A)	Advanced	Technology	This advanced level session explores how a Control Tower aggregates data across multiple source systems to provide real-time dashboards and actionable insights. In clinical operations, it serves as a centralized, data-driven command center, enhancing visibility, streamlining trial supply planning, and enabling proactive decision-making. Attendees will gain a strategic perspective on how adopting a Control Tower model can drive innovation and deliver tangible operational benefits in clinical supply chain management.
L09	Case Study: Using AI and Advanced Analytics to Optimize a Large Phase 3 Global Trial (I)	Intermediate	Technology - AI	This intermediate level session examines how AI and advanced analytics streamlined clinical supply planning and execution for a complex Phase 3 trial spanning multiple countries. By implementing predictive algorithms for demand forecasting, site resupply, and risk mitigation, the sponsor gained real-time insights to manage variable enrollment rates and sensitive cold-chain requirements. Attendees will learn how these technologies helped prevent overages, reduce wastage, and ensure on-time patient dosing across all geographies.
WS01	Clinical Supplies: Trials and Tribulations (I)	Intermediate	Clinical Supply Planning	This intermediate level workshop will provide a forum to share challenging situations that the attendees have experienced with the clinical supply chain. The attendees will bring stories that everyone can learn from and then the group will address them by providing possible solutions that everyone can use.
WS02	Global Distribution: Real-World Challenges & Solutions (I)	Intermediate	Distribution	This intermediate level interactive workshop explores the complexities of global distribution in clinical supply chains, focusing on real-world challenges and practical solutions. The attendees will bring examples of common pain points such as regulatory hurdles, customs clearance, temperature control, and coordination across multiple regions that the group can learn from.
WS03	Import/Export and Distribution Challenges in Emerging Markets (I)	Intermediate	Distribution	This intermediate level workshop provides an in-depth look at the unique import/export and distribution challenges faced in emerging markets. Participants will explore regulatory complexities, customs requirements, infrastructure limitations, and logistical hurdles specific to these regions. Through case studies and interactive discussions, attendees will learn practical strategies to navigate these obstacles, ensuring efficient and compliant clinical supply delivery. This session is designed for supply chain managers, logistics professionals, and clinical operations teams working or planning to work in emerging markets.
WS04	VAT and IOR Considerations in Clinical Supply Chains (I)	Intermediate	Distribution	This intermediate level workshop will focus on the critical aspects of Value Added Tax (VAT) and Importer of Record (IOR) considerations in clinical supply chains. Participants will learn about the regulatory requirements and best practices for managing VAT and IOR in the context of clinical trials. The session will cover strategies to ensure compliance, optimize cost management, and streamline logistics. Attendees will gain insights into the complexities of international clinical supply chains and how to navigate these challenges effectively.
WS05	Temperature Excursion Considerations for Comparator Product Sourcing (I)	Intermediate	Distribution	This intermediate level workshop will help clinical supply professionals proactively identify and mitigate temperature excursions for comparator products used in clinical trials.
WS06	Elements of a Biotech Mindset: Driving Agility, Innovation, and Ownership in Clinical Supplies (I)	Intermediate	Industry	This workshop will explore how to build a highly functioning partnership that empowers individuals across both organizations to operate with speed, adaptability, cross-functional collaboration, and entrepreneurial ownership—regardless of company size.

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WS07	Navigating the Complexities of Packaging and Labeling for Investigator-Sponsored Trials (ISTs) (I)	Intermediate	Packaging	This intermediate level workshop explores the unique complexities and common pitfalls in managing packaging and labeling for ISTs, including navigating country-specific regulations, GMP compliance, and timelines when sponsors are academic institutions or individual investigators. Participants will leave with practical tools, risk mitigation strategies, and collaboration models to better support ISTs without compromising quality or regulatory integrity.
WS08	Real-World Strategies for successful Clinical Supply Vendor Transitions (I)	Intermediate	Relationships	Vendor transitions in the clinical supply space—whether due to performance, scalability, or strategic alignment—are highly complex and high-risk if not managed carefully. This intermediate level workshop provides real-world strategies for planning and executing successful transitions between clinical supply vendors, including depots, packaging providers, IRT vendors, and logistics partners. Participants will explore change management tactics, risk mitigation plans, stakeholder communication, and regulatory considerations through practical examples and peer discussion.
WS09	Universal Ancillary Procurement vs Local Sourcing (I)	Intermediate	Ancillaries	Join us for an insightful intermediate level workshop that explores the strategic decision-making process between universal ancillary procurement and local sourcing. This intermediate level session will delve into the benefits and challenges of each approach, examining factors such as cost efficiency, supply chain reliability, sustainability, and community impact.
WS10	Middle East & North Africa (MENA) - Strategy and Requirements	Beginner	Clinical Supplies	This beginner level session will cover the unique aspects of conducting clinical trials in MENA countries, including regulatory landscapes, cultural considerations, patient recruitment strategies, and logistical challenges.
WS11	Managing Controlled Substances in Global Clinical Trials (B)	Beginner	Clinical Supplies	This beginner level workshop will provide an overview of the varying requirements for managing controlled drugs across multiple countries.
WS12	Optimizing Direct-to-Patient Distribution: Addressing Barriers for Sustainable Trial Integration (A)	Advanced	Clinical Supplies	This advanced level session explores actionable strategies to enhance the feasibility of Direct-to-Patient (DTP) distribution in clinical trials. Drawing on Tufts & GCSG Impact Summary insights, we'll examine key challenges—technical support gaps, delivery logistics, and scheduling inefficiencies—and discussion solutions to improve site and patient experiences. Attendees will leave with a roadmap for maintaining DTP as a viable and patient-centric trial model.
WS13	Clinical Trial Supplies for Orphan Indications & Rare Disease Trials (I)	Intermediate	Clinical Supplies	This intermediate level workshop will provide a deeper understanding of the challenges of orphan indication and rare disease trials. Attendees will explore critical requirements for rare disease studies, such as smaller patient numbers and commensurate supplies, greater geographic representation and timelines.
WS14	Drug Accountability and Destruction at Study Closeout (I)	Intermediate	Close Out	This intermediate level workshop will provide a comprehensive overview of the critical processes involved in drug accountability and destruction at the closeout of clinical studies. Participants will learn about regulatory requirements, best practices for tracking and documenting drug usage, and methods for the safe and compliant destruction of unused investigational products. The session will also cover common challenges and solutions to ensure a smooth and efficient study closeout.

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WS15	Comparators: Sponsor and Vendor Collaboration (B)	Beginner	Comparators	This beginner level workshop will address the critical aspects of sourcing comparators for clinical trials. Participants will learn about common mistakes in comparator sourcing and strategies to mitigate risks associated with these choices. The session will explore the impact of comparator selection on the entire clinical supply chain, including labelling operations. Additionally, attendees will gain insights into effective communication practices between sponsors and vendors to ensure smooth operations.
WS16	Centrally-Sourced European Comparator Challenges: Supplies & Labeling Insights (I)	Intermediate	Comparators	In this intermediate level session attendees will discuss the nuances of supplying commercial materials in clinical trials conducted in Europe. Topics to include the requirements for using non-EU sourced drugs, the impact of changing the source country and the timelines involved.
WS17	Latin America (LATAM) Importation Challenges and Considerations (B)	Beginner	Distribution	This beginner level session will provide an awareness of the regulatory requirements across different agencies to enable successful clinical supply planning. Discussion will include an overview of the regulatory requirements for Latin American countries for labeling and distribution.
WS18	Import/Export Essentials (B)	Beginner	Distribution	This beginner level workshop will provide the attendees with a step-by-step interactive overview of what goes into shipping clinical supplies from shipping request to site/depot delivery. Key areas of focus will be on understanding regulatory requirements, developing risk management strategies and optimizing logistics and supply chain efficiency for international shipments.
WS19	Temperature Monitoring & Managing Excursions Throughout the Drug Lifecycle (B)	Beginner	Distribution	This beginner level workshop will identify best practices for monitoring temperatures and manage excursions throughout the entire drug lifecycle, from manufacturing to distribution and storage. New tools and techniques will be discussed which will enable excursion data to be tracked against stability data to allow rapid adjudication. Open discussions will provide a forum to explore the latest innovations and ways to manage cumulative data to assess total time out of temperature to avoid replacing supplies at the site.
WS20	Introduction to Expanded Access Program (B)	Beginner	EAR	This beginner level workshop will explore the primary challenges in expanded access (EA): Ethics, Supply Planning and Regulatory. Real-life scenarios (failures and successes) will be shared , highlighting how these experts navigated the obstacles.
WS21	Introduction to Good Clinical Practices (GCP) (B)	Beginner	Industry	Good Clinical Practices (GCP) are what our key stakeholders in Clinical Operations/Clinical Development are required to follow. It's important that clinical supply chain professionals understand GCPs as patient requirements should always be a consideration when packaging and labeling clinical supplies. This beginner level workshop will review GCPs and how the differe from GMPs, as well as how they are involved in drug development and the site.
WS22	Innovative Label Strategies to Overcome Regulatory Hurdles (I)	Intermediate	Labels	In this intermediate level workshop we will discuss some of the more common label regulatory hurdles and delays that may happen. The attendees will explore new and innovative ways to avoid or mitigate these regulatory delays.

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WS23	Blinding in Clinical Trials (B)	Beginner	Packaging	This beginner level workshop provides a comprehensive overview of blinding in clinical trials, focusing on its critical role in minimizing bias and ensuring data integrity. Participants will learn about various blinding methods (single, double, and triple blinding), practical implementation challenges, and strategies to maintain blinding throughout the study. The session also covers regulatory expectations and real-world scenarios where blinding may be compromised. Designed for clinical operations, study managers, and quality assurance professionals, this workshop equips attendees with the knowledge to design and manage effective blinding processes.
WS24	Best Ways to Handle Stress in Leadership (B)	Beginner	People	In this beginner level workshop the facilitators will provide strategies to turn stress into success in any situation. After taking a stress self assessment, attendees will learn mental calming techniques that can interrupt intensely stressful mental escalations as well as ways to be an empathetic and calming leader in times of stress.
WS25	Clarifying Roles and Responsibilities through RACIs (B)	Beginner	People	Knowing everyone's role & responsibilities is an essential requirement for successful teams. This beginner level workshop will provide an overview and process methods for deploying a RACI (Responsible, Accountable, Consulted, Informed) chart in support of those outcomes.
WS26	Best Practices in Clinical GMP QA (B)	Beginner	Quality/Regulatory	This beginner level workshop will provide a comprehensive overview of best practices in Good Manufacturing Practice (GMP) Quality Assurance (QA) for clinical trials. Participants will learn about the essential principles of GMP, regulatory requirements, and the critical role of QA in ensuring the safety and efficacy of clinical trial materials. The session will cover strategies for implementing robust QA systems, conducting effective audits, managing quality risks and mitigation strategies.
WS27	Qualified Person (QP) Declarations & Release – Overview (B)	Beginner	Quality/Regulatory	QP declarations and certification and release requirements vary more than they should. This can affect timelines and stakeholder satisfaction. This beginner level workshop will discuss what is absolutely required as inputs to get QP certifications and declarations within expected timelines.
WS28	Pharmacy Manual in Clinical Trials: Purpose and Scope (B)	Beginner	Quality/Regulatory	The Pharmacy Manual is an integral document for conducting a clinical trial that provides critical study information and guidance to positively influence site GxP compliance. This beginner level session will discuss best industry practice for pharmacy manuals, components and aspects that allow sites to comply with ICH E6(r3).
WS29	Clinical Trial Start-Up Best Practices: Avoiding Delays and Ensuring Readiness (B)	Beginner	Trial Start Up	This beginner level workshop explores best practices for clinical supplies to support studies before and during clinical trial start-up. Participants will learn how to create a comprehensive clinical supply start-up plan, collaborate effectively with CMC teams, and identify key timeline deliverables to ensure sites are adequately stocked. Through real-world examples and actionable tools, attendees will gain strategies to identify and mitigate risks, coordinate efficiently with clinical stakeholders, and ensure clinical supplies arrive on time and are stored and managed correctly throughout the study.
WS30	Navigating Child-Resistant and Repackaging Strategies in the EU (I)	Intermediate	Packaging	This intermediate level workshop delves into the regulatory requirements and practical considerations for implementing child-resistant packaging and repackaging of clinical supplies within the European Union. Participants will explore EU-specific regulations and labeling requirement. The session will also cover challenges and best practices for repackaging clinical materials while ensuring compliance and maintaining product integrity.