



## Workshops

### 2019 European Knowledge Forum

Workshop	Title	Summary	Location
<b>Workshop # 1</b> Wednesday - Oct 23rd 10.15 - 11.15	Leveraging Social Media to enhance Clinical Trial Outcomes	Social media is having a paradigm shifting effect on clinical trials by facilitating cross-cutting, multi-directional communication among patient, advocate, researcher and clinician communities. This workshop will discuss the impact of social media on drug development and explore ways we can use it to increase patient enrollment, education, retention and compliance.	TBC
	The evolving regulatory landscape - including the impact of Brexit and The Clinical Trial Regulation 536/2014	Clinical supply chains are evolving in accordance with the potential implications of Brexit and The Clinical Trial Regulation. This workshop will provide an opportunity to discuss that evolution and get answers to your questions.	TBC
	Cell Gene Therapy Supply Chain Strategies	Over the course of the last decade, there has been an increased emphasis on research and development into cell, gene and immunotherapy treatments. We expect to see this therapeutic area grow exponentially in the future. Come to this workshop to learn about the strategies being employed for cell & gene therapies, their unique supply chain challenges and how to overcome them.	TBC
	How to partner with your clinical sites, a shared perspective from a site pharmacist and CMO	In our ever-evolving clinical development world, we are realizing the value of a site-centric approach to clinical trials and clinical supplies. This workshop will identify ways to better collaborate with clinical sites to enhance patient enrollment, improve patient retention throughout the clinical trial and decrease in clinical supply dosing and maintenance requirements	TBC
	Supply Chain Challenges when going into Emerging Markets	As clinical trials grow and more and more sites must be found to accelerate enrollment and trial completion, the use of emerging markets continues to grow. This workshop will explore the planning needed when entering into emerging markets, the challenges of flexing with new regulatory requirements that often occur and the best way to leverage your courier service partners to access these new countries.	TBC
	Compassionate / Expanded Access Use: Understanding Supply Chain Requirements, Planning and Forecasting	This interactive presentation will give an overview of expanded access and discuss new regulations and their impact on the planning and execution of Expanded Access Programs.	TBC
	Preparing for Regulatory Inspections	Regulatory inspections don't have to be a stressful situation. With the proper training, planning, technology and self-auditing programs in place they can be easier, faster and less stressful. This workshop will examine ways to ensure regulatory audits and inspections will be as smooth as possible while creating finding-free outcomes.	TBC

<b>Workshop # 2</b> Wednesday - Oct 23rd 11.30 - 12.30	<b>Linking Simulation to IRT</b>	Simulations, to identify the probable outcomes of trial enrollment which will impact the clinical supply chain, are the way of the near-term future. Linking the IRT to simulation software/systems can help predict clinical supply requirements while adjusting quickly to enrollment outcomes. In this workshop we will discuss the value of linking simulation to your IRT, how to demonstrate the value of doing it to Clinical Operations and the savings this linkage can create.	TBC
	<b>Strategies of Returns, Reconciliations and Destructions</b>	Returns and reconciliation have come under greater scrutiny as we get closer to complying with the clinical trial regulation. Performing the final reconciliation and disposition of material being returned from a clinical site is typically one of the most challenging aspects of clinical supplies because it requires a collaborative bridge between Clinical Operations and Clinical Supplies. In this workshop options for completing the return process and ways to reconcile the returns will be discussed.	TBC
	<b>Accelerating Enrolment, Improving Retention and Shortening Clinical Trials Using Direct to Patient Clinical Supply Chain Strategies</b>	Improving access to patient populations, accelerating recruitment, increasing patient retention and decreasing time to market are all reasons sponsors are exploring direct to patient clinical trial models. This workshop is designed to discuss ways to implement a direct to patient supply chain model.	TBC
<b>Workshop # 3</b> Wednesday - Oct 23rd 13.45 - 14.45	<b>Leveraging Social Media to enhance Clinical Trial Outcomes</b>	Social media is having a paradigm shifting effect on clinical trials by facilitating cross-cutting, multi-directional communication among patient, advocate, researcher and clinician communities. This workshop will discuss the impact of social media on drug development and explore ways we can use it to increase patient enrollment, education, retention and compliance.	TBC
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<b>Workshop</b>	<b>Title</b>	<b>Summary</b>	<b>Location</b>
	<b>Compassionate/Expanded Access Use: Understanding Supply Chain Requirements, Planning and Forecasting</b>	This interactive presentation will give an overview of expanded access and discuss new regulations and their impact on the planning and execution of Expanded Access Programs.	TBC
	<b>Preparing for Regulatory Inspections</b>	Regulatory inspections don't have to be a stressful situation. With the proper training, planning, technology and self-auditing programs in place they can be easier, faster and less stressful. This workshop will examine ways to ensure regulatory audits and inspections will be as smooth as possible while creating finding-free outcomes.	TBC

<b>Workshop # 4</b> Thursday - Oct 24th 10.15 - 11.15	Linking Simulation to IRT	Simulations, to identify the probable outcomes of trial enrollment which will impact the clinical supply chain, are the way of the near-term future. Linking the IRT to simulation software/systems can help predict clinical supply requirements while adjusting quickly to enrollment outcomes. In this workshop we will discuss the value of linking simulation to your IRT, how to demonstrate the value of doing it to Clinical Operations and the savings this linkage can create.	TBC
	Accelerating Enrolment, Improving Retention and Shortening Clinical Trials Using Direct to Patient Clinical Supply Chain Strategies	Improving access to patient populations, accelerating recruitment, increasing patient retention and decreasing time to market are all reasons sponsors are exploring direct to patient clinical trial models. This workshop is designed to discuss ways to implement a direct to patient supply chain model.	TBC
	Culture Of Accountability	In this session, we will discuss and define accountability and case studies will be provided to demonstrate techniques and concepts to instill a culture of accountability within your team.	TBC
<b>Workshop # 5</b> Thursday - Oct 24th 11.30 - 12.30	Compassionate/Expanded Access Use: Understanding Supply Chain Requirements, Planning and Forecasting	This interactive presentation will give an overview of expanded access and discuss new regulations and their impact on the planning and execution of Expanded Access Programs.	TBC
	How to partner with your clinical sites, a shared perspective from a site pharmacist and CMO	In our ever-evolving clinical development world, we are realizing the value of a site-centric approach to clinical trials and clinical supplies. This workshop will identify ways to better collaborate with clinical sites to enhance patient enrollment, improve patient retention throughout the clinical trial and decrease in clinical supply dosing and maintenance requirements	TBC
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