CLINICAL TRIAL SUPPLY EAST COAST 2017

18TH-19TH OCTOBER 2017 | PRINCETON, NEW JERSEY

SPEAKING FACULTY

Reid Tonik, Director, Global Clinical Supply Chain, **Teva Pharmaceuticals**
Anthony Orosz, Assistant Director, Pharmaceutical, Health and Chemical Center of Excellence and Expertise, **US Customs and Border Protection**
Rey Bacchus, Clinical Trial Supply Manager, **Janssen R&D US**
Paul Larochelle, Senior Manager, Clinical Asset Planning, **Biogen**
Anthony Zuccarello, Associate Director, IRT and Global Clinical Supply Strategy, **Amicus Therapeutics**
Matthew Moyer, Director Clinical Supply Technology, **Merck**
Ken Kube, Associate Director, Global Clinical Supplies, **Merck**
Carla Reis, Senior Manager of IRT/Randomization, **Bristol-Myers Squibb**
David Green, Associate Director, Clinical Supply and Logistics**, Insmed Incorporated**
Tanya Momtahen, Vice President, Global Procurement, Scientific & Clinical**, Sanofi**
Brain Rogers, Packaging Project Management Head, **Sanofi**
Rocco Barone, Associate Director Operations, **TransCelerate BioPharma**
Frank Leu, Chief Executive Officer, **Novapeautics**
Steven Awad, Clinical Trial Supply Manager**, Janssen**
Sanjeev Luther, Chief Operating Officer, **Rafael Pharmaceuticals**
Nish Chudasama, Group Leader of Clinical Supply Chain Operations**, Bristol-Myers Squibb/TransCelerate**
Maryam Ahmadi, Senior Director of Pharmaceutical Science**, Achillion Pharmaceuticals**
Doug Meyer, Associate Director, Clinical Drug Supply**, Biogen**
Cara Sclafani, Supply Chain Head**, Pfizer**
Buz Hillman, Associate Director, Clinical Supply Systems**, Johnson and Johnson**
Carol Lee, Associate Director Clinical Drug Supply, Logistics, & IRT**, Regeneron Pharmaceuticals**
Mayo Pujols, Sr. Vice President, Technical Operations, **Advantix Inc**
Michael Schwartz, Director Quality Assurance**, Concert Pharmaceuticals**
Edoardo Madussi, EVP US, Key Accounts Manager, **Multipharma**
Tom Gottschalk, Executive Director, Business Development**, RxSolutions**
Jessica Deveau, Business Development Manager, **World Courier**
Dave Lecher, Business Development Executive, **PCI Clinical Services**
Mark Maurice, Senior Project Manager / Industrial Engineer**, Sensitech Inc. Professional Services**
Nikita Avdeev, Sr. Import/Export Manager**, IMP Logistics**

	Clinical Trial Supply East Coast 2017 | Princeton, New Jersey **Day One | October, 18th 2017**
7:45	Registration and refreshments
08:20	Chairman's opening remarks
08:30	**Partnering with manufacturers to minimize downstream regulatory and distribution concerns** • Highlighting the need to ensure ancillaries and comparators are blinded to ensure the fairness of trials • Emphasizing the need for blinding and global uniformity requirements in clinical trials • Exploring why not all manufactures are willing to supply comparators for clinical trials to establish an industry wide benchmark • Investigating ways through which large-scale manufacturers can enable clinical supply teams to customize their products for non-commercial usage • Presenting positive outcomes that arise from a lack of global uniformity and how this can benefit your trial **Mayo Pujols,** Sr. Vice President, Technical Operations, **Advantix Inc**
09:00	**Logistics: Navigating the Challenges of a Global Temperature Controlled Supply Chain** • Effectively managing the challenges of an expanding global temperature controlled supply chain • Exploring new trends in clinical trial design and how it impacts logistical considerations • Highlighting the evolution of large molecules/complex products and the need for a temperature control strategy • Pinpointing the increase of regulatory scrutiny and how pharma sponsors can stay ahead of the curve **Jessica Deveau**, Business Development Manager, **World Courier**
09:30	**Reaping rewards when overcoming comparator sourcing challenges** • Emphasizing the value of shared knowledge between pharmaceutical companies • Evaluating the pros and cons of outsourced versus internal comparator sourcing to understand which model is most effective for your company • Investigating scenarios through which comparator prices can be lowered to minimize over-head costs • Sharing strategies utilized by clinical trial teams to acquire blinded comparators for global trials • Outlining what current strategies the industry is undertaking to overcome disruptions to trial times and how to employ these in your own trials **Tanya Momtahen,** Vice President, Global Procurement, Scientific & Clinical**, Sanofi**

10:00	**New Tech or Old Process?** • Determining if new technology is needed to support standard clinical packaging process; discussing what we could be using versus the established standard practice • Comparing the benefits of new tech over current practices; highlight differences through examples • Unlocking who is going to pay for this and the costs of advancing technology **Dave Lecher**, Business Development Executive, **PCI Clinical Services**	
10:30	Morning refreshments and networking	
	Operational Stream	Technology Stream
11:00	**Transforming the Supply Chain for Comparator Medicines** • Understanding challenges associated with the traditional supply chain for Comparator Medicine sourcing • Examining how TransCelerate's Comparator Network presents a new operating model by creating a direct relationship between Innovators (Buyers) and Manufacturers • Describing direct implications and intangible benefits of the comparator network • Share value stories around cost savings, trial efficiencies, and collaboration from TransCelerate Member Companies' use of the network **Nish Chudasama,** Group Leader of Clinical Supply Chain Operations**, Bristol-Myers Squibb/TransCelerate**	**Discovering the practical benefits of e-labeling; how this technological innovation can expedite packaging and labeling timelines** • Exploring reasons driving the development of e-label technology to best understand its value for industry as a whole • Framing e-labels as a patient friendly solution instead of a cost cutting mechanism to guarantee regulatory buy-in • Comparing the value of e-labels versus traditional forms of labeling to emphasize their value for your supply chain planning • Investigating US and EU regulators ambivalence towards approving e-labels and understanding what can change this • Outlining cost saving opportunities associated with e-labels **Rocco Barone,** Associate Director Operations**, TransCelerate BioPharma**
11:30	**Changing the paradigm of the clinical study procurement and distribution process for medication and supplies** • Exploring existing challenges and difficulties with current supply processes to establish a new process • Analysing where the new process can provide benefit to gain the best results • Identifying what benefits the new process provides to clinical study procurement and distribution • Highlighting how the new process works to best	**Implementing technology with success in clinical supply management** • Evaluating the importance of change management for your clinical supplies • Reviewing the risk and reward associated with the implementation of these technologies • Outlining the benefits of partnering with new vendors versus growing existing relationships • Uncovering key lessons learned in implementing new technologies

	implement for your clinical trial **Tom Gottschalk**, Executive Director, Business Development**, RxSolutions**	• Determine whether phasing in new technology or "cutting the cord" to old technology is best for your organization **Paul Larochelle**, Senior Manager, Clinical Asset Planning Specialty Therapeutic Area, Clinical Drug Supply, **Biogen Corporation**
12:00	**Is your business operating model aligned with your clinical supply business strategy?** • Exploring the current operating model employed by your company • Investigating how this aligns with your business strategy and your stake holders requirements • Determining how to define your target operating model • Establishing ways to reach this point within your organization • Managing changes and developing a culture of continuous improvement **Doug Meyer**, Associate Director, Clinical Drug Supply, **Biogen**	**Safeguarding temperature controlled shipments; developing technologies to monitor temperature excursions in real time and ensure minimal drug loss** • Harnessing IRT technology to monitor temperature fluctuations throughout the shipping process and account for any damages • Designing systems which ensure all excursions can be identified by lot so to comply with Quality Assurance expectations • Addressing the need to improve controlled room temperature technologies given increasing regulatory demands in this area • Exploring ways to centralize data monitoring of temperature excursions between shipping companies and clinical supply teams • Investigating ways to adequately equip trial sites so these can carry out temperature monitoring and ensure drug maintenance **Frank Leu**, CEO, **Novapeautics**
12:30	Lunch and networking	
13:30	**Maximizing forecasting software capabilities to minimize overages and avoid costly overruns to your trials** • Learning which component of forecasting simulating software engages with to enable you to best understand the technology • Harnessing the power of historic data; learning how to use past experiences to improve forecasting accuracy and inform current studies • Emphasizing the need to develop responsive forecasting systems that react to fluctuations in the supply chain to ensure forecasting can adapt in real time • Harmonizing forecasting software with human hardware to improve its applicability	**Maximizing IRT's potential and outlining methods to ensure this technology delivers what is needed for you to carry out successful clinical trials** • Exploring key aspects to consider when selecting an IRT system • Defining key challenges when integrating IRT systems into your trials and ways to overcome these • Determining how IRT tools can interact with forecasting to accurately map drug supplies throughout the trail process • Establish internal protocols within clinical supply teams to ensure accurate data input and maximize IRT's effectiveness

		• Analyze how IRT systems are progressing from an atomized towards a global management system and what this means for your supply chain planning **Anthony Zuccarello,** Associate Director, IRT and Global Clinical Supply Strategy**, Amicus Therapeautics**
	Buz Hillman, Associate Director, Clinical Supply Systems, **Johnson and Johnson**	
14:00	**Discovering how to Balance the Risk and Cost of Controlled Room Temperature (CRT) Clinical Trial Shipments** • Examining why is developing stability data up front in the trial process a necessity? • Unpacking what risks are associated with clinical distribution without temperature protection? • Outlining if temperature excursions confound your clinical trial? • Considering how to effectively monitor your CRT trial shipments costs **Mark Maurice,** Senior Project Manager / Industrial Engineer**, Sensitech Inc. Professional Services**	**Session reserved for Braket**
14:30	**Uncovering what is driving supply outsourcing; how and why are traditionally in-house capabilities being externalized** • Investigating what major components of the supply chain are being outsourced across the industry to assess if there is an industry trend • Outlining what structural arrangements those who do not outsource have in place to enable them to carry this out and what others can learn from this • Exploring what underlying causes are driving industry towards a further reliance on Contract Manufacturing Organizations • Examining ways through which increased oversight because of greater levels of outsourcing can be streamlined given regulatory expectations to monitor vendor compliance • Assessing the implications that greater outsourcing will have upon sponsor-vendor relationships **David Green**, Associate Director, Clinical Supply and	**Exploring methods through which IRT technology can improve clinical supply logistics** • Pinpointing how IRT technology can be set up to improve your logistical planning • Exploring the benefits of creating your own in house IRT system versus using a base-line vendor model • Outlining ways IRT can better manager temperature excursions • Recognizing the value of IRT in clinical supply ordering and distribution • Emphasizing ways through which IRT systems can become more effective for your different trials **Carol Lee,** Associate Director Clinical Drug Supply,

	Logistics, **Insmed Incorporated**	Logistics, & IRT**, Regeneron Pharmaceuticals**
15:00	Afternoon refreshments and networking	
15:30	**Panel Discussion: Exploring ways clinical supplies teams and quality assurance Inspectors can work together to ensure trials run on time** • Aligning Quality Assurance considerations with Supply Chain protocols to minimize disruptions and backlogs in supply chain development • Enhancing knowledge of EU Qualified Person requirements so that industry can address these and prevent clinical trial delays • Investigating common problems faced by industry in their ability to comply with QA expectations and how to overcome these • Exploring ways to improve internal quality assurance knowledge to minimize outsourcing and reduce costs • Designing strategies to ensure communication between clinical supplies and quality assurance experts is improved **Michael Schwartz,** Director Quality Assurance**, Concert Pharmaceuticals**	**Exploring how working with preferred partners to establish development standards can improve your use of IRT** • Partnering with vendors to develop standardization for innovate IRT systems • Establishing standardization with reporting and notifications • Reducing overall development time • Highlighting how this can expedite timeframes • Developing standard integrations for reduction of costs and customizing fit for company use (ordering, outputting of data for other groups, data transfers to other departments) **Carla Reis**, Senior Manager of IRT/Randomization, **Bristol-Myers Squibb**
16:00	**Exploring the benefits of integration-focused import / export strategy in challenging regions.** • Understanding the limitations of country-specific approach to import / export processes • Emphasizing importance of IoR in the changing regulatory environment - Ukraine case study • Outlining the implications of the global import / export strategy on local practical requirements • Exploring time and cost savings of the global vs. local import / export strategy • Determining critical success factors of development and execution of long-term import / export planning **Nikita Avdeev,** Sr. Import/Export Manager**, IMP Logistics**	**Session reserved for Medidata**
16:30	**Integrating communication strategies across in-house and**	**Customizing current technologies to improve pharmaceutical supply chain management and improve**

	outsourcing teams to maximize efficiency and minimize trial overrun • Emphasizing the importance of ensuring in-house supply and operations teams share up-to date information so timelines are adhered to effectively • Modifying relationships with vendors to invest them in the clinical trial process and equate your success with theirs • Sharing successful communication strategies to ensure data is distributed effectively and improve industry's ability to react to unforeseen changes • Promoting better communication between supply trial teams to ensure sufficient drug is delivered to trial sites • Design systems which enable all parties involved to be notified of changes which affect the supply chain and enable these to react best **Paul Larochelle,** Senior Manager, Clinical Asset Planning**, Biogen**	**efficiency** • Harnessing mobile phone infrastructure to enable 24/7 management of your clinical supplies • Developing portable software systems which can enable patients to enrol on trials and ensure sufficient drug is delivered at trial sites • Creating platforms which improve delivery timeframes to remote drug sites and reduce delays to • Exploring increasing growth in wearable devices and what this means for your clinical trial supply management as a method to acquire • Recognizing how adopting new technologies can reduce overall trial costs and minimize growing financial pressures on industry **Rey Bacchus,** Clinical Trial Supply Manager**, Janssen**
17:00	Chairman's summation and close of conference	

	Clinical Trial Supply East Coast 2017 | Princeton, New Jersey **Day Two | October, 19th 2017**
08:15	Registration and refreshments
08:50	Chairman's opening remarks
09.00	**Enhancing border control knowledge to ensure your trial drugs reach their destination** • Understanding permit complexities in regards to the importing of trial drugs into the US and how to overcome this • Exploring what challenges arise as a result of carrying out global clinical trials and how to adequately prepare • Considering the advantages and disadvantages of manufacturing in one or multiple sites from an import/export perspective • Designing strategies to minimize holdups that arise from surprise FDA inspections **Anthony Orosz,** Assistant Director, Pharmaceutical, Health and Chemical Center of Excellence and Expertise, **US Customs and Border Protection**

09:30	**Session reserved for Multipharma** **Edoardo Madussi**, EVP US, Key Accounts Manager, **Multipharma**
10:00	**Strategies to optimize efficiencies while minimizing wastage and overages to reduce overall trial costs** • Addressing internal communication challenges between clinical supplies and operations teams to ensure efficient shipments and on-time delivery • Identifying potential sources of waste that organizations can manage • Examining key distribution metrics gathered across organizations such as aggregated studies and historic data to better assess what gets used, shipped and dispended • Promoting multi-user technology platforms to enable accurate information sharing across internal and external teams to minimize delays and improve reaction times to disruptions **Sanjeev Luther,** Chief Operating Officer**, Rafael Pharmaceuticals**
10.30	Morning refreshments and networking
11:00	**How moving to an open-office floor plan can kill collaboration** • Clinical Supply Chain's role in the pharma world is to facilitate communication. We are not lab scientists discovering new therapies or doctors treating patients. Our success depends, almost exclusively, on how well we communicate. • The goal in our recent office move was to design an office space which would increase job satisfaction, cooperation, collaboration, for everyone. • In some parts of the organization, it had the opposite effect we were hoping for. It resulted in more work-from-home desire, quieter halls, increased reliance on email/IM and less on phone/in-person. • In other parts of the organization, we designed differently and it worked. • At some point in your career, you may get the chance to design your group's office space. This presentation can help guide what'll work for a CSC-type organization. **Reid Tonik, Director,** Global Clinical Supply Chain**, Teva Pharmaceuticals**
11:30	**Mobile Health Technologies in Clinical Development: A Patient-Centric Approach** • Unpacking limitations of current clinical development paradigm • Adopting mobile health technologies to augment clinical data through at-home dosing and sampling • Demonstrating how dosing adherence devices and trial participant responses from 2 Merck pilot trials • Analyzing data considerations, including integration and reconciliation of data from devices • Presenting next steps, and ongoing joint industry/regulatory initiatives aimed at addressing these **Matthew Moyer**, Director Clinical Supply Technology, **Merck**
12:00	Lunch and networking

13:00	**Exploring what supply chain complexities arise from using biologics** • Investigating the impact tighter regulations regarding track and trace will have upon clinical supply chain management • Uncovering what measures clinical supply chain managers will be required to take to ensure they comply with new regulations and can continue using commercial products in their trials • Assessing the impact these guidelines will have upon clinical packaging and distribution timelines and what investment will be required to enable this • Discussing the need for serialization regulations by showcasing what systems are already in place to safeguard clinical trial supplies • Exploring 2-D Bar codes; what this means for your clinical trial supply **Brian Rogers,** Packaging Project Management Head**, Sanofi**
13:30	Afternoon refreshments and networking
14:00	**Speaker Hosted Roundtables** Interactive roundtable sessions offer a unique opportunity to come together with your peers to share best practice and develop solutions to critical challenges facing the industry as a whole. Hosted by industry experts and each focused on a single issue, roundtables are an exciting, interactive way to build your personal network and learn from the experience and expertise of others. Each roundtable session lasts for 30 minutes, and delegates may attend up to 2 roundtables
Roundtable 1	**Exploring the challenges of importing into the US and Europe** **Maryam Ahmadi,** Senior Director of Pharmaceutical Science, **Achillion Pharmaceuticals**
Roundtable 2	**Exploring the challenges of importing into the US and Latin America** **Ken Kube,** Associate Director – Global Clinical Supplies, **Merck**
Roundtable 3	**Sharing demand planning successes and failures** **Steven Awad**, Clinical Trial Supply Manager, **Janssen**
Roundtable 4	**Discussing the potential liberalization of the US pharmaceutical industry** **Cara Sclafani,** Supply Chain Lead**, Pfizer**
15:00	Chairman's summation and close of conference