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**
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**
Sean Walsh, Senior Director Supply Chain **Advantix Inc**
Michael Schwartz, Director Quality Assurance**, Concert Pharmaceuticals**
Paul Larochelle, Senior Manager, Clinical Asset Planning, **Biogen**
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**
Bart Nicholson, Associate Director Client Services, **Bracket**
Justin Roller, VP Technology Innovation, **Cubixx Solutions, an AmerisourceBergen company**
Christine Matakovich, Lead Product Manager**, Medidata Solutions**
Evan Hahn, Principal, Balance RTSM, **Medidata Solutions**

	Clinical Trial Supply East Coast 2017 | Princeton, New Jersey **Day One | October, 18th 2017**
7:45	**Registration and refreshments**
8:20	**Chairman's opening remarks** **Reid Tonik, Director, Global Clinical Supply Chain, Teva Pharmaceuticals**
8:30	**Partnering with contract manufacturers and research organizations to minimize downstream regulatory and distribution concerns** • Deterring opportunities for contract manufacturers and research organizations to support sponsor clinical supply teams in executing complex • Understanding needs and expectations of each of the customers in the clinical supply chain from the patient to the healthcare provider to the regulatory authorities • Ensuring that all supplies are proactively managed in complex global clinical trials including not only the investigational product but also ancillary supplies and comparators • Identifying and mitigate risks associated with supplying global clinical trials including managing the dynamic clinical trial design **Sean Walsh, Senior Director Supply Chain, Advaxis**
9:00	**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**
9:30	**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	**Overcoming Challenges of In-Home Clinical Trials** While in-home trials can address participation issues and provide added convenience and support for patients, they come with their own set of risks. Several challenges include: • Improving improper medication storage, particularly when temperature monitoring and control is paramount • Managing access to caregivers and patients only, and ensuring that medications are secure from unauthorized persons, including children and visitors • Investigating high shipping and storage costs for sensitive medications to reduce costs • Ensuring adherence, especially when it is the patient's responsibility to know when and how to take the medication • Collecting and integrating data when the information is decentralized to have control over all the study data in real-time **Dustin Roller, Vice President Technology Innovation, Cubixx Solutions, an AmerisourceBergen company**	
10:45	**Morning refreshments and networking**	
	Operational stream	**Technology stream**
11:30	**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 • Sharing value stories around cost savings, trial efficiencies, and collaboration from TransCelerate Member Companies' use of the network	**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

	Nish Chudasama, Group Leader of Clinical Supply Chain Operations, Bristol-Myers Squibb/TransCelerate	**Rocco Barone, Associate Director Operations, TransCelerate BioPharma**
12:00	**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 • Analyzing 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 implement for your clinical trial **Tom Gottschalk, Executive Director, Business Development, RxSolutions™**	**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 • 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**
12:30	**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, Chief Executive Officer, Novapeautics**
1:00	**Lunch and networking**	

2:15	**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 **Buz Hillman, Associate Director, Clinical Supply Systems, Johnson & Johnson**	**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 Therapeutics**
2:45	**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 Professional Services**	**RTSM + CSM = RCSM: the best of both worlds to streamline your clinical trials** • Combining the power of IRT (RTSM) and supply chain management solution (CSM); enabling Biopharmaceutical companies to shave time and cost off clinical trials implementation • Forecasting within IRT; how this technology is a solution which fits all sizes, biotech and large pharma alike, to minimize drug wastage • Streamlining IRT supply management to avoid data and system functionalities duplication • Advancing Cold chain management: Aggregating Longitudinal Dataset allowing for true temperature monitoring and greater trial safety **Bart Nicholson, Associate Director Client Services, Bracket**
3:15	**Panel Discussion: Exploring ways clinical supplies and quality assurance teams can work together to ensure trials run on time** • Aligning Quality Assurance considerations with Supply Chain protocols to minimize disruptions	**Exploring how working with preferred partners to establish development standards can improve your use of IRT** • Partnering with vendors to develop

	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** **David Green, Associate Director, Clinical Supply and Logistics, Insmed Incorporated**	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**
3:45	**Afternoon refreshments and networking**	
4:15	**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, Senior Import/Export Manager, IMP Logistics**	**Simplifying drug Pooling to enable complex drug development** • Practically integrating inventory pooling across supply chain to improve efficiencies and reduce costs • Reviewing how to innovatively pool drugs both on site and at depots when carrying out trials • Implementing complex and adaptive designs to decrease costs and shorten timelines while improving treatment for patients • Automating and pooling ancillary supplies across the organization • Overcoming Operational Opposition **Christine Matakovich**, Lead Product Manager **, Medidata Solutions** **Evan Hahn,** Principal, Balance RTSM, **Medidata Solutions**
4:45	**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	**Customizing current technologies to improve pharmaceutical supply chain management and improve efficiency** • Harnessing mobile phone infrastructure to enable 24/7 management of your clinical supplies

	• 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 Logistics, Insmed Incorporated**	• Developing portable software systems which can enable patients to enroll 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**
5:15	**Chairman's summation and close of conference** **Reid Tonik, Director, Global Clinical Supply Chain, Teva Pharmaceuticals**	

	Clinical Trial Supply East Coast 2017 | Princeton, New Jersey **Day Two | October, 19th 2017**
8:15	**Registration and refreshments**
8:50	**Chairman's opening remarks** **Reid Tonik, Director, Global Clinical Supply Chain, Teva Pharmaceuticals**
9.00	**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	**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**
10:00	**Survey: Assessing the current and future state of clinical trial supplies** **Ben VanderPlas, Global Product Manager, Sonoco ThermoSafe**
10.15	**Morning refreshments and networking**
10:45	**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**
11:15	**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**

11:45	**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**
12:15	**Lunch and networking**
1:15	**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 45 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	**Potential impacts of the health care debate on the pharmaceutical industry in America** **Cara Sclafani, Supply Chain Lead, Pfizer**
3:00	**Chairman's summation and close of conference** **Reid Tonik, Director, Global Clinical Supply Chain, Teva Pharmaceuticals**