Clinical Trial Supply
East Coast

GlobalData.

ARENA
INTERNATIONAL EVENTS GROUP

Clinical Trial Supply East Coast 2023

Sheraton Valley Forge, King of Prussia, PA, USA

11th-12th October 2023

www.arena-international.com/ctseastcoast/

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Covering all things CTS from reducing timelines and streamlining processes to handling clinical supplies in a decentralized trial world. Our expert panel will deliver case studies, thought leadership pieces, interactive panels and roundtable discussions.

Clinical Trial Supply East Coast offers opportunities for both learning and networking with peers from across the CTS sphere, via informal networking breaks and lunches, as well as a relaxed drinks reception at the end of Day 1.

2023 Speakers

- **Ian Hoban,** Business Development Director, **Abacus Medicine**
- **Jason Bellman,** Manager, Clinical Supply Chain Systems, **Apellis Pharma**
- **Yves Dethier,** Drug Supply Chain Expert and Business Leader, **Boostcode**
- **Haneen Mazahreh-Boivert,** Senior Director Global Clinical Supply, **Boston Pharmaceuticals**
- **Susan Marlin,** President and Chief Executive Officer, **Clinical Trials Ontario**
- **Milena Izmirlieva,** Head of Health Economics and Market Access Research and Analysis, **GlobalData**
- **Simi Nischal,** Senior Director, Digital, Data and Analytics, Clinical Supply Chain, **GSK**
- **Linda Nichols,** Director, Study Start Up and Optimization, **GSK**
- **Blake Edward Wilson,** Partner (FDA Regulatory), **Hogan Lovells**
- **Francesco Santo,** Associate Director, Global Clinical Supply Chain, **HUYABIO International**
- **Michelle Novak,** Regional Director, Business Development, **Inceptua**
- **Dawn Wright,** Director Global Supply Chain, **Incyte**
- **Ronald Schaefer,** Senior Principal, **International Air Transport Association**
- **Paul F. Hughes,** Director, Randomization and Trial Supply Management, **Janssen**
- **Shawn Gehen,** Former Clinical Trial Supply Chain Manager, **Merck**
- **Kim Buchanan,** Associate Director, Clinical Supplies Quality (CSQ) Operations and Technology, **Merck**
- **Ram Raju,** Senior Vice President and Community Health Investment Officer, **Northwell Health**
- **David Sokoloff,** Senior Director, Global Logistics and Materials Management, **Novavax**
- **Amaury Jeandrain,** Senior Director, Solutions Engineering and Partnerships, **N-Side**
- **Loïc Struyf,** Associate Director, Head of Customer Success, **N-Side**
- **Ginelle Andrews,** Director Commercial Product Sourcing Strategy, **Pfizer**

Join our new CTS community on LinkedIn

#CTSEC23 | @ArenaIntPharma

- **Lindsey Marshall,** Director, Clinical Drug Supply, **Regeneron**
- **Jen Horonjeff,** Chief Executive Officer, **Savvy Cooperative**
- **Vatsala Sadasivan,** Global Operations Excellence Lead R&D, **Sanofi**
- **Paul Larochelle,** Director, Global Clinical Supply Chain, **Takeda**
- **Tyler Wilson,** Global Clinical Supply Chain Fellow, **Takeda**
- **Tom Gottschalk,** Senior Director, Business Development, **TrialCard**
- **Mary Zhang,** National Account Manager, **US Customs and Border Protection**
- **Elliot N. Ortiz,** Chief Agriculture Specialist, Area Port of Philadelphia, **US Customs and Border Protection**
- **Jennifer Fenwick,** Senior Manager, Personalized Supply Chain, **World Courier**

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DAY ONE – 11TH OCTOBER 2023

7:30am	**Registration and refreshments**
8:25am	**Chairperson's opening remarks** **Milena Izmirlieva,** Head of Health Economics and Market Access Research and Analysis, **GlobalData**
8:30am	**Revolutionizing clinical trial supply chains with data driven systems** • How data driven systems in clinical supply chains can lead to enhancing efficiency, accelerating trial timelines, and putting patients first • Automating data management for efficient supply chain operations • Enhancing and streamlining supply chain operations with AI and other data driven technologies **David Sokoloff,** Senior Director, Global Logistics and Materials Management, **Novavax**
9:00am	**Re-imagining planning for a best-in-class supply chain performance** *Planning serves as the brain of the supply chain, orchestrating various activities and KPIs that profoundly impact its overall performance. Waste, cost, risk, shortages, CO2 emissions, bottlenecks, and workload are all outcomes tied to carefully planned operations. But today's challenges are changing the paradigm of our supply chains. Join our talk to learn:* • The current challenges that will force us to revolutionize our supply chain • How GSK is re-imagining the role of clinical supply planner and its place in enabling an ambitious R&D • How planning is increasingly important at all stages of the trial lifecycle • At any given time, how to always remain with the optimal supply chain strategy **Amaury Jeandrain,** Senior Director, Solutions Engineering and Partnerships, **N-Side** **Linda Nichols,** Director, Study Start Up and Optimization, **GSK** **Loïc Struyf,** Associate Director, Head of Customer Success, **N-Side**
9:30am	**PANEL DISCUSSION: Navigating uncertainty: strategies for enhancing supply chain security in times of geopolitical and economic instability** • Assessing site selection in times of geopolitical tensions and uncertainty • Managing the impact of high inflation rates on the Medicare Part D Program • Enhancing supply chain security by understanding global socio-economic dynamics **MODERATOR:** **Milena Izmirlieva,** Head of Health Economics and Market Access Research and Analysis, **GlobalData** **PANELLISTS:** **Ram Raju,** Senior Vice President and Community Health Investment Officer, **Northwell Health** **David Sokoloff,** Senior Director, Global Logistics and Materials Management, **Novavax**
10:00am	**Reserved for 4G Clinical**
10:30am	**Morning refreshments and networking**

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	STREAM A: Clinical Supply Logistics and Operations *Chair:* **Milena Izmirlieva,** Head of Health Economics and Market Access Research and Analysis, **GlobalData**	STREAM B: Clinical Supply Technology and Innovation *Chair:* **Paul Larochelle,** Director, Global Clinical Supply Chain, **Takeda**
11:15am	**CEIV Pharma: raising the standard of pharmaceutical logistics** • Risks and potential gaps in cold chain when transporting temperature-sensitive drugs by air • How IATA's standards and certification can improve handling of pharmaceutical cargo, ensuring compliance with regulations • Benefits of participating in IATA's CEIV Pharma program: how this can help you establish and maintain shipment integrity • Engage in the process of a simplified audit solution against clear standard criteria and provide constructive feedback on IATA's proposed solution **Ronald Schaefer,** Senior Principal, **International Air Transport Association**	**PANEL DISCUSSION: Analyzing the opportunities offered by effective use of IRT** • Key considerations when choosing an IRT vendor: what questions should you be asking? • How to leverage your IRT systems effectively to get the most out of your technology • Incorporating data-driven technology such as AI and machine learning to maximize efficiency of your IRT systems • Understanding the key advantages and disadvantages of new IRT systems • Practical takeaways and lessons learned when it comes to using new IRT systems **PANELLISTS:** **Simi Nischal,** Senior Director, Digital, Data and Analytics, Clinical Supply Chain, **GSK** **Shawn Gehen,** Former Clinical Trial Supply Chain Manager, **Merck** **Jason Bellman,** Manager, Clinical Supply Chain Systems, **Apellis Pharma** Senior representative, **N-Side**
11:45am	**Clinical trial logistics: evolving supply models and new therapies highlight emerging trends** *Decentralized trial logistics:* • The role of DTP in maximizing benefits of DCT • Overcoming DTP complexities *Emergence of cell and gene therapies* • Unique logistics considerations for CGTs • Ensuring quality through technology solutions **Jennifer Fenwick,** Senior Manager, Personalized Supply Chain, **World Courier**	**Re-imagining IRT for modern clinical development** • The vast majority of clinical studies are being run on technology that is over 10 years old, which limits the ability to innovate and optimally support modern trials • IRT can become a driver of innovation and not a constraint when advances in the broader technology landscape are applied to allow for more flexible solutions • Deliver scalable, robust, and future-proof IRT solutions by applying lessons learned from other industries • Examples include: A.I.-enabled datasets, no-code study deployment, automated excursion reviews, rapid prototyping, reduced (or removed) need for change orders, and ability to adapt to unforeseen challenges **Evan Hahn,** Senior Vice President, IRT Solutions, **YPrime**

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12:15pm	**Impact of drug pooling and just-in-time manufacturing on the clinical supply chain and related technologies** **Dawn Wright,** Director Global Supply Chain, **Incyte**	**Revolutionizing clinical trial supply chains with Patient-Centric Hybrid Trials (PHTs) and Direct-to-Patient models** • Designing clinical trials with patient needs at the center by leveraging hybrid trial models for supply chain efficiency and success • Investing in patient-centric methodologies to prioritize patient needs and preferences for optimal clinical trial supply chain outcomes • Empowering patients for clinical trial supply chain success: personalizing logistics, delivering human content, providing data access, and engaging patients in innovative ways. **Vatsala Sadasivan,** Global Operations Excellence Lead R&D, **Sanofi**
12:45pm	**Reserved for Inceptua** **Michelle Novak,** Regional Director, Business Development, **Inceptua**	**Drug supply management: ensure supply safety while generating huge savings** • Challenges and opportunities in the drug supply chain management • Best practices • Expected skills in clinical supply • Communication framework • Success stories **Yves Dethier,** Drug Supply Chain Expert and Business Leader, **Boostcode**
1:15pm	**Lunch and networking**	
2:30pm	**Assessing sourcing models to determine the optimal sourcing strategy** • Overview of different sourcing models • Assessing options to determine optimal strategies • Working in a wholly outsourcing model: maintaining a strong supplier base **Ginelle Andrews,** Director Commercial Product Sourcing Strategy, **Pfizer**	**CASE STUDY: Implementing an effective IRT system into your clinical trial supply chain** • Choosing an IRT vendor that works for you: key considerations and factors in supplier choice • Overcoming challenges around implementation and use of a new IRT system • What do you need from your IRT system: measuring benefits and increased efficiency **Paul F. Hughes,** Director, Randomization and Trial Supply Management, **Janssen**

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3:00pm	**Innovative processes to better address today's trial dynamics** • Supply chain efficiency: why do extra work and spend more money than necessary? • Payment process efficient: leverage an existing workflow process that sites use everyday • Understanding the total value a vendor can provide • Select a vendor that can demonstrate its total value (and make you look good in the eyes of your company) **Tom Gottschalk,** Senior Director, Business Development, **TrialCard**	**Reserved for event sponsor**
3:30pm	**Enhanced communication methods: building rapport between clinical supply groups and partners** • Enhancing communication methods and tools to foster effective communication between global clinical supply groups and their partners • Building rapport through collaborative efforts to strengthen relationships • Establishing feedback mechanisms to provide a continuous loop of communication, allowing for ongoing improvement and increased understanding between stakeholders **Haneen Mazahreh-Boivert,** Senior Director, Global Clinical Supply, **Boston Pharmaceuticals**	**CASE STUDY: Digital display labels transforming the clinical supply chain** • Decreases turnaround timelines, increases flexibility and efficiency of scarce IMP inventory benefiting sponsors and study site personnel • Driving enhanced safety, understanding, and compliance for patients and clinical sites, enabled by immediate updates of IMP information and IMP label content • Leveraging technology enabling a more robust IMP data management, tracking of contents/changes as required by cGMP for patients, for clinical sites and for health authorities **Kim Buchanan,** Associate Director, Clinical Supplies Quality (CSQ) Operations and Technology, **Merck**
4:00pm	**Afternoon refreshments and networking**	
4:20pm	**EXHIBITION APPLE PRIZE DRAW** *Visit our exhibitors' booths throughout the day and collect stamps in order to enter our Prize Draw and be in for a chance of winning Apple devices or Amazon vouchers. The Prize Draw will take place in the Exhibition Hall and you will need to be physically present to be eligible for a prize. Make sure you don't miss out!*	

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Clinical Trial Supply East Coast

Sheraton Valley Forge, King of Prussia 11th-12th October 2023

4:30pm	**INTERACTIVE DISCUSSION SESSION: Overcoming roadblocks in comparator sourcing and vendor management** • Accessing supply: ensuring your supply chain is robust and planning timelines to avoid delays • Managing regulatory hurdles when importing comparators from overseas • Working efficiently with vendors when sourcing comparators for your clinical trial • What to consider in order to ensure your comparator sourcing processes meet cost and waste targets **SESSION HOST:** **Lindsey Marshall,** Director Clinical Drug Supply, **Regeneron**	**INTERACTIVE DISCUSSION SESSION: Building the bench: developing robust training programs for new clinical supplies professionals** • Training and inducting staff with technology and systems in order to ensure a smooth transition • The importance of your staff when it comes to supply chain efficiency: why you need to avoid overlooking this • Ensuring your new staff training programs are as effective as possible: what should you consider? **SESSION HOSTS:** **Paul Larochelle,** Director, Global Clinical Supply Chain, **Takeda** **Tyler Wilson,** Global Clinical Supply Chain Fellow, **Takeda**
5:00pm	**A toolkit for sourcing commercial medicines for your clinical trials** • Introduction to Abacus Medicine Pharma Services • Expect the unexpected • When to take action • Tools to minimize the risk of disruption **Ian Hoban,** Business Development Director, **Abacus Medicine**	**Reserved for event sponsor**
5:30pm	**Chairperson's closing remarks and networking drinks** **Milena Izmirlieva,** Head of Health Economics and Market Access Research and Analysis, **GlobalData**	

DAY TWO – 12th OCTOBER 2023

8:00am	**Registration and refreshments**	
	STREAM A: Clinical Supply Logistics and Operations *Chair:* **Milena Izmirlieva,** Head of Health Economics and Market Access Research and Analysis, **GlobalData**	**STREAM B: Clinical Supply Technology and Innovation** *Chair:* **Amaury Jeandrain,** Senior Director, Solutions Engineering and Partnerships, **N-Side**

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9:00am	**The improving clinical trials environment in Canada** • Harnessing unique assets to sustain Canada's role as a medical research and health innovation hub • Raising numerous interesting and difficult policy questions related to Canadian and US collaboration when addressing 'extraordinary' needs of rare disease patients • Clinical innovation as a means to cultivate supportive conditions for improved care for rare patients in Canada • Using scientific knowledge to improve patient impact and system receptivity **Susan Marlin,** President and Chief Executive Officer, **Clinical Trials Ontario**	**Revolutionizing clinical trial supply management with AI powered IRT forecasting and optimization** • Improving the efficiency and agility of clinical trial supply management through the use of AI-powered IRT forecasting • Optimizing the allocation of clinical trial supplies across sites and reducing waste by using advanced AI algorithms to forecast IRT needs • Leveraging real-time data and machine learning to enhance IRT forecasting accuracy and improve supply chain resilience in clinical trials **Shawn Gehen,** Clinical Demand Planning Manager (Contractor), **Seagen**
9:30am	**PANEL DISCUSSION: Pain points in the clinical supply chain: overcoming common challenges and hurdles to improve efficiency** • Using technology to mitigate against risk of changing supply and demand • Shipping internationally outside of the US: common hurdles and how to overcome these • The changing regulatory environment in the US and how to ensure you stay up to date with new regulations **MODERATOR:** **Milena Izmirlieva,** Head of Health Economics and Market Access Research and Analysis, **GlobalData** **PANELLISTS:** **Dawn Wright,** Director Global Supply Chain, **Incyte** **Ronald Schaefer,** Senior Principal, **International Air Transport Association** **Lindsey Marshall,** Director Clinical Drug Supply, **Regeneron**	**PANEL DISCUSSION: Considerations when designing a direct-to-patient distribution model for your clinical supply chain** • Benefits to patients of direct-to-patient models: how can DTP make clinical trials more accessible? • Where are the benefits and disadvantages of DTP from a patient perspective? • Implementing a DTP strategy that works for your clinical study • Understanding how DTP can optimize supply chain flexibility for clinical trials • The regulatory environment surrounding DCT and DTP in the US: what you need to be aware of **MODERATOR:** **Amaury Jeandrain,** Senior Director, Solutions Engineering and Partnerships, **N-Side** **PANELLISTS:** **Blake Edward Wilson,** Partner (FDA Regulatory), **Hogan Lovells** **Vatsala Sadasivan,** Global Operations Excellence Lead R&D, **Sanofi** **Jen Horonjeff,** Chief Executive Officer, **Savvy Cooperative** **Jennifer Fenwick,** Senior Manager, Personalized Supply Chain, **World Courier**
10:15am	**Morning refreshments and networking**	

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11:00am	**Driving successful clinical trials with complex supply chains** • Identifying and implementing continuous improvements in the supply chain: where are the main opportunities for higher efficiency? • Understanding additional needs of more complex supply chains and how to meet these • Taking advantage of new technology and systems in order to streamline and maximize the efficiency of your clinical supply chain **Francesco Santo,** Associate Director, Global Clinical Supply Chain, **HUYABIO International**	**Reserved for** **Elliot N. Ortiz,** Chief Agriculture Specialist, Area Port of Philadelphia, **US Customs and Border Protection**
11:30pm	**Ensuring financial sustainability in the pharmaceutical industry: strategies for pricing, reimbursement, and cost containment** • Evaluating pricing strategies for pharmaceutical products in light of changing market dynamics and reimbursement policies: ensuring financial sustainability for both payers and pharma sponsors • Navigating complex policy landscapes and balancing the needs of patients, providers, and payers when determining drug prices and reimbursement rates • Mitigating the risk of drug shortages, inflation pressure and economic uncertainty by modifying cost-containment measures and exploring alternative payment models for medicines **Milena Izmirlieva,** Head of Health Economics and Market Access Research and Analysis, **GlobalData**	**PANEL DISCUSSION: Considerations and best practice for working effectively with clinical supply technology vendors and partners** • The importance of integrated systems with CMOs: how much integration is useful? • Considerations when choosing technology partners in order to facilitate a strong partnership • Remote communications: best practice for selecting and working with partners when working remotely **MODERATOR:** **Amaury Jeandrain,** Senior Director, Solutions Engineering and Partnerships, **N-Side** **PANELLISTS:** **Susan Marlin,** President and Chief Executive Officer, **Clinical Trials Ontario** **Simi Nischal,** Senior Director, Digital, Data and Analytics, Clinical Supply Chain, **GSK**
12:00pm	**Lunch and networking**	
1:15pm	**Optimizing clinical trial supply chain efficiency through CTPAT/Trade Compliance** • Ensuring compliance with CBP regulations: a discussion of PHC-CEE, the benefits of joining the CTPAT Trade Compliance (TC) program and how to become eligible • Strengthening supply chain security and reducing the risk of delays at the border: understanding the CBP's expectations of importers and how the CTPAT TC program can support you • Enhancing the efficiency of clinical trial supply management: how participation in the CTPAT TC program can streamline import processes and lead to timely and cost-effective delivery **Mary Zhang,** National Account Manager, **US Customs and Border Protection**	

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1:45pm	**Revolutionizing clinical trials with accelerating clinical evidence models: enhancing efficiency, collaboration, and patient access** • Implementing a novel approach for drug approvals with accelerated approval pathway to streamline processes • Enhancing collaboration between the FDA and CMS in developing new payment methods for drugs approved via accelerated approval to promote the completion of confirmatory trials • Improving patient access to post-market safety and efficacy data by utilizing the Accelerating Clinical Evidence model, leading to better healthcare outcomes and cost savings **Blake Edward Wilson,** Partner (FDA Regulatory), **Hogan Lovells**
2:15pm	**PANEL DISCUSSION: Advancing diversity, equity, and inclusion in clinical trial supply chain management: best practices and future directions** • Designing for diversity: strategies for inclusive clinical trial supply chain management • Increasing vaccine awareness and acceptance through inclusive clinical trials • Addressing genetic differences and promoting equity in clinical trial supply management • Developing cultural competence in clinical trial supply chain management to ensure equity and inclusion **MODERATOR**: **Milena Izmirlieva,** Head of Health Economics and Market Access Research and Analysis, **GlobalData** **PANELLISTS:** **Ram Raju,** Senior Vice President and Community Health Investment Officer, **Northwell Health** **Jen Horonjeff,** Chief Executive Officer, **Savvy Cooperative**
3:00pm	**Afternoon refreshments and networking**
3:20pm	**EXHIBITION APPLE PRIZE DRAW** *Visit our exhibitors' booths throughout the day and collect stamps in order to enter our Prize Draw and be in for a chance of winning Apple devices or Amazon vouchers. The Prize Draw will take place in the Exhibition Hall and you will need to be physically present to be eligible for a prize. Make sure you don't miss out!*
3:30pm	**SPEAKER HOSTED ROUNDTABLE DISCUSSIONS** *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 clinical supply chain 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.*
	ROUNDTABLE 1: Planning for a smooth import/export at the border: considerations when working with CBP **Mary Zhang,** National Account Manager, **US Customs and Border Protection**
	ROUNDTABLE 2: Ensuring regulatory compliance in clinical trial supply: best practices and guidelines
	ROUNDTABLE 3: Navigating inflation and economic uncertainty: clinical supply chain considerations **Milena Izmirlieva,** Head of Health Economics and Market Access Research and Analysis, **GlobalData**
4:30pm	**End of conference**

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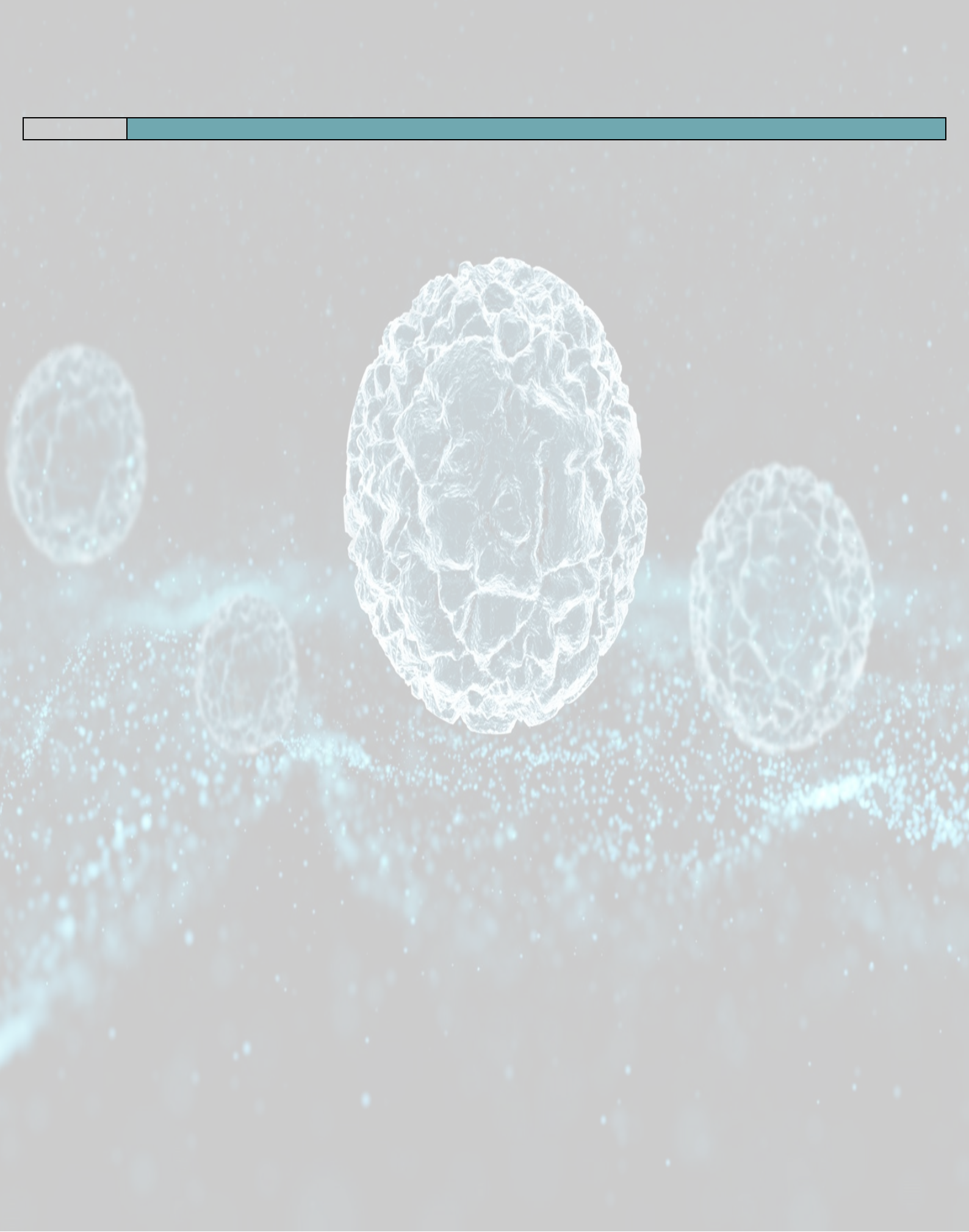

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