Clinical Trial Supply Europe

NH Milano Congress Centre, Italy

15th-16th March 2023

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'Achieving true supply chain agility in response to increasingly complex trial demands'

2023 edition of the Clinical Trial Supply Europe conference will be hosted in Milan, where pharma, large and small, alongside biotechs will have the opportunity to discuss, debate and consider new technologies and processes to streamline supply chain operations.

2023 Speakers

- **Margaret Radford,** Unlicensed Medicine Services Manager, **Almac**
- **Marcus Wajngarten,** Senior Director, Home Supply, **AstraZeneca**
- **Sam Mulligan,** Digital Lead, Clinical Manufacturing and Supply, **AstraZeneca**
- **Laura Gibbons,** Director of Business Strategy and Portfolio Management, **AstraZeneca**
- **Alexandru Marineac,** International Logistics Manager**, Audubon Biosciences**
- **Marcel Walraven,** Key Account Director, **Biocair**
- **Gary Cunnington,** Global Leader Clinical Trial Supplies Business Consultancy, **Boehringer Ingelheim**
- **Philip Oyewale Babatunde Olabode,** Senior Manager, Supply Chain and Logistics, **Bristol Myers Squibb**
- **Stefan Dürr,** Senior Director, Client Delivery, **Cenduit IRT, an IQVIA business, Head of Drug Supply Center of Excellence**
- **Ilaria Rondinone,** Senior Clinical Supply Lead, **Chiesi Group**
- **Vanessa Dekou,** Managing Director, **CSI**
- **Chiranth Hulgur,** Senior Manager Clinical Supply Chain Data and Analytics, **CSL Behring**
- **Ulrich Mengel,** Associate Director, CTS Business Operations, **CSL Behring**
- **Camillo Rossi,** Associate Director, Clinical Trial Material Logistics, **Eli Lilly and Company**
- **Edo Madussi,** Managing Director, **Euromed Pharma**
- **Paula Figueiredo,** Clinical Supplies Leader, **Galapagos**
- **Dr Kamal Amin,** Head of Clinical Supplies Management, **Galderma**
- **Daniel Fitzgerald,** Director, Clinical Supplies, **Galecto Inc**
- **Urtė Fultinavičiūtė,** Healthcare Reporter, Clinical Trials Arena, **GlobalData Healthcare**
- **Ruth Barbero,** Associate Director Global Clinical Supply Chain, **Incyte**
- **Niklas Mattson,** Director, Comparator Management, **MSD**
- **Jasmin Hellwig,** Associate Director Vendor Relationship Management, **MSD**
- **Amaury Jeandrain,** Senior Director, Solutions Engineering and Partnerships, **N-Side**

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- **Diana Cocora,** Senior Supply Chain Manager, **Akamis Bio**
- **Roel van der Heijde,** Facilitator and Trainer, **Rotterdam and Patient Experience Association**
- **Arnaud Dourlens,** Head of Clinical Trial Supply, **Sanofi**
- **Landry Giardina,** Global Head of Clinical Supply Chain Operations Innovation and Technology, **Sanofi**
- **Henk Dieteren,** Clinical Supply Chain Solutions Consultant, **Suvoda**
- **Thomas Thoma,** Head Managed Access Programs, CTS/GHT/SR, **Teva Pharmaceuticals**
- **Hadar Shaked,** Clinical Supply Project Manager, **Teva Pharmaceuticals**
- **Brendan Krause,** Head of International, **Uber Health**
- **Révérien Uwacu,** Clinical Trial Supply Manager, **UCB**
- **Sean Smith,** Biological Threat Exclusion Co-Ordinator**, US Customs and Border Protection**

DAY ONE – WEDNESDAY, 15TH MARCH 2023

7:30	**Registration and refreshments**
8:20	**Chairperson's opening remarks** **Vanessa Dekou,** Managing Director, **CSI**
8:30	**Opening keynote on healthcare and digitalization** **Brendan Krause,** Head of International, **Uber Health**
9:00	**Reserved for Suvoda**
9:30	**Transforming our supply chain by investing in key capabilities: processes, people and digital** • Developing a new strategy to build a leading supply organisation capable of dealing with an ever increasing and complex portfolio • How a digital transformation will enable significant business value in terms of increasing efficiency and driving down waste **Sam Mulligan,** Digital Lead, Clinical Manufacturing and Supply, **AstraZeneca** **Laura Gibbons,** Director of Business Strategy and Portfolio Management, **AstraZeneca**
10:00	**Reserved for** **Edo Madussi,** Managing Director, **Euromed Pharma**
10:30	**Morning refreshments and networking**

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	STREAM A: Clinical Supply Logistics and Operations	STREAM B: Clinical Supply Technology and Innovation
	Chair: **Vanessa Dekou,** Managing Director, **CSI**	*Chair:* **Amaury Jeandrain,** Senior Director, Solutions Engineering and Partnerships, **N-Side**
11:15	**Forecasting and demand planning in the supply chain: preparing for uncertainty** • Ensuring flexibility in your budget supply strategy to cater for unexpected situations • Demand planning when there is uncertainty around patient enrolment: the importance of communicating with your clinical operations team • Learnings from the COVID-19 pandemic and the Russia-Ukraine conflict in terms of managing clinical supply in times of uncertainty **Ruth Barbero,** Associate Director Global Clinical Supply Chain, **Incyte**	**PANEL DISCUSSION: Uncovering new trends and technological advancements for the European clinical supply chain: what's new for 2023?** • Considerations for clinical supply chains in Europe for 2023: how have Brexit, the Russia-Ukraine conflict, and other factors impacted trial supply? • An overview of emerging technologies and processes to support clinical supply chains in Europe • How the Clinical Trial Regulation and other regulatory factors are impacting European clinical supply chains • Opportunities created by data-driven technologies such as AI and machine learning for clinical supply chains • Linking everything back to the patient: how new clinical supply technology will benefit patients in clinical trials **MODERATOR:** **Amaury Jeandrain,** Senior Director, Solutions Engineering and Partnerships, **N-Side** **PANELLISTS:** **Roel van der Heijde,** Facilitator and Trainer, **Rotterdam and Patient Experience Association** **Arnaud Dourlens,** Head of Clinical Trial Supply, **Sanofi**
11:45	**Reserved for Berlinger**	**Reserved for N-Side**

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12:15	**Getting your pharmaceutical products seamlessly into the US: what you need to know** • Breaking down all that you need to know about CBP and other agency importation requirements to facilitate clinical supply shipments • Receive detailed information on how to correctly declare biological products at the US border (Ports of Entry) • Discover which biological products may have transportation restrictions that must be factored into your clinical supply chain strategy • Review case examples of non-compliant shipments **Sean Smith,** Biological Threat Exclusion Co-ordinator, **US Customs and Border Protection**	**CASE STUDY: 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? • Implementing a DTP strategy that works for your clinical study • Understanding how DTP can optimise supply chain flexibility for clinical trials **Révérien Uwacu,** Clinical Trial Supply Manager, **UCB**
12:45	**Reserved for Almac** **Margaret Radford,** Unlicensed Medicine Services Manager, **Almac**	**Reserved for Medidata**
13:15	**Lunch and networking**	
14:30	**Effective strategies for sourcing comparators and placebos** • Accessing supply: ensuring your supply chain is robust and planning timelines to avoid delays • Managing regulatory hurdles when importing comparators from overseas • What to consider in order to ensure your comparator sourcing processes meet cost and waste targets **Niklas Mattson,** Director, Comparator Management, **MSD**	**PANEL DISCUSSION: Making a success of direct-to-patient for your clinical trials** • Considerations when designing a DTP strategy • Navigating regulatory frameworks, both in Europe and beyond • Identifying vendors and partners in order to deliver DTP successfully • Understanding the benefits of DTP from a patient perspective and the importance of this • Overcoming common pitfalls and hurdles in DTP **MODERATOR:** **Amaury Jeandrain,** Senior Director, Solutions Engineering and Partnerships, **N-Side** **PANELLISTS:** **Daniel Fitzgerald,** Director, Clinical Supplies, **Galecto Inc** **Révérien Uwacu,** Clinical Trial Supply Manager, **UCB** **Marcus Wajngarten,** Senior Director, Home Supply, **AstraZeneca**

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15:00	**Holistic approach to effective clinical trial supply strategies: beyond comparator sourcing** • Biosimilar and generic product benefits and regulatory framework • Competitive advantage: Bolar exemption in practice • Why science and not wholesale mindset should drive your approach **Vanessa Dekou,** Managing Director, **CSI**	**Reserved for 4G Clinical**
15:30	**PANEL DISCUSSION: Running your clinical trial internationally: overcoming logistical challenges to maximise supply chain efficiency** • Regulatory considerations when shipping across borders, both within Europe and cross-continent • Shipping biologics cross-border: what you need to know, and how to prepare in advance for this • How geopolitical factors have influenced clinical supply chains in Europe and how to mitigate the impact of this • Assessing the benefits of air, sea, road and rail as methods of transporting drugs around Europe **MODERATOR:** **Vanessa Dekou,** Managing Director, **CSI** **PANELLISTS:** **Camillo Rossi,** Associate Director, Clinical Trial Material Logistics, **Eli Lilly and Company** **Alexandru Marineac,** International Logistics Manager, **Audubon Biosciences**	**How clinical trial supply managers can reduce the patient burden from a fear reduction perspective** • Understanding where patient concerns lie when participating in clinical trials and what pharma companies can do to mitigate against these • Aiming to reduce the burden of trial participation on patients as much as possible: where are pharma companies falling short? • What more needs to be done when it comes to patient accessibility for clinical trials? • The benefits of systems like direct-to-patient for increasing patient accessibility for clinical trials **Roel van der Heijde,** Facilitator and Trainer, **Rotterdam and Patient Experience Association**
16:00	**Afternoon refreshments and networking**	
16:30	**Supply chain efficiency and data driven performance** • Using technology to improve your systems while remaining cost-effective • Best practice in ensuring your supply chain is as efficient as possible • Measuring supply chain KPIs and identifying areas of weakness **Landry Giardina,** Global Head of Clinical Supply Chain Operations Innovation and Technology, **Sanofi**	**Incorporating technology to increase clinical supply chain efficiency** • Assessing emerging technologies: what is available for improving supply chain efficiency? • How effective use of data and data management tools can help streamline your supply chain • Training staff and logistics partners on up to date technology: overcoming hurdles surrounding this **Philip Oyewale Babatunde Olabode,** Senior Manager, Supply Chain and Logistics, **Bristol Myers Squibb**

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17:00	**Reserved for Abacus Medicine**	**Reserved for IQVIA** **Stefan Dürr,** Senior Director, Client Delivery, **Cenduit IRT, an IQVIA business, Head of Drug Supply Center of Excellence**
17:30	**IMP during the Ukrainian conflict: an inspiring story of humanity** • A case study of how Galapagos kept their clinical supplies running in Ukraine this year • Crisis management: key takeaways in keeping supply chains running smoothly during times of crisis • Learnings from disruption to European supply chains as a fallout of the Russia-Ukraine conflict **Paula Figueiredo,** Clinical Supplies Leader, **Galapagos**	
18:00	**Chairperson's closing remarks** **Vanessa Dekou,** Managing Director, **CSI**	

END OF DAY 1 AND NETWORKING DRINKS

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DAY TWO – THURSDAY 16TH MARCH 2023

8:00	**Registration and refreshments**	
8:50	**Chairperson's opening remarks** **Vanessa Dekou,** Managing Director, **CSI**	
	STREAM A: Clinical Supply Logistics and Operations	**STREAM B: Clinical Supply Technology and Innovation**
	Chair: **Vanessa Dekou,** Managing Director, **CSI**	*Chair:* **Amaury Jeandrain,** Senior Director, Solutions Engineering and Partnerships, **N-Side**
9:00	**Choosing a manufacturing partner: what to consider when selecting a CMO** • Preparing for a clinical trial: choosing the right CMO to manufacture your product • Balancing cost with quality when selecting a CMO • Understanding increasing complexity in clinical setup with different CMOs and shared sponsoring • Ensuring the best setup to work constructively with your CMO • Handling expectations and getting the relationship right **Diana Cocora,** Senior Supply Chain Manager, **Akamis Bio**	**PANEL DISCUSSION: Automation in clinical supply chains: what level of automation can you incorporate?** • Analysing cost vs benefit of automation in supply chains: at what point does automation become cost effective? • Understanding risks associated with automating supply chains • How IRT and simulation system capabilities can help manage supply chains automatically **MODERATOR:** **Amaury Jeandrain,** Senior Director, Solutions Engineering and Partnerships, **N-Side** **PANELLISTS:** **Dr Kamal Amin,** Head of Clinical Supplies Management, **Galderma** **Camillo Rossi,** Associate Director, Clinical Trial Material Logistics, **Eli Lilly and Company**
9:30	**Reserved for Biocair** **Marcel Walraven,** Key Account Director, **Biocair**	**Reserved for Calyx**

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10:00	**Harnessing the benefits of e-labelling: accelerating packaging and labelling processes through technological innovation** • E-labelling as a patient friendly solution • Emphasizing the value of e-labelling for your supply chain planning: overcoming the expiration date hurdle • Navigating the risks and the rewards; considering costs, timelines, contingency plans and patient safety • Understanding the drive behind the development of e-label technology: success stories vs lessons learned **Gary Cunnington,** Global Leader Clinical Trial Supplies Business Consultancy, **Boehringer Ingelheim**	**FIRESIDE CHAT: The clinical to commercial transition in packaging: managing and aligning different prime directives** • Choosing packaging options when taking your drug from a clinical trial to market: an overview of key considerations to take into account • Should we be designing packing for trial drugs with commercialisation in mind? • Communicating effectively with your commercial department: how to ensure design of the best possible commercial packaging **INTERVIEWER: Amaury Jeandrain,** Senior Director, Solutions Engineering and Partnerships, **N-Side** **INTERVIEWEE: Thomas Thoma,** Head Managed Access Programs, CTS/GHT/SR, **Teva**
10:30	**Reserved for TSS**	**Reserved for Parexel**
11:00	**Morning refreshments and networking**	
11:30	**PANEL DISCUSSION: Operational agility: the importance of maintaining flexibility in your clinical supply chain** • With trials more and more complex, how do you ensure supply chain operations are agile and flexible? • What can we do to be as flexible as possible to handle changes in demand, particularly when shipping internationally? • Ensuring you are prepared for a crisis: what the pandemic has taught us about being prepared for every eventuality **MODERATOR:** **Vanessa Dekou,** Managing Director, **CSI** **PANELLISTS:** **Niklas Mattson,** Director, Comparator Management, **MSD** **Henk Dieteren,** Clinical Supply Chain Solutions Consultant, **Suvoda** Senior representative, **Medidata**	
12:00	**Reserved for DHL**	

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12:30	**Vendor management: the importance of aligning vendors and sponsors under one shared goal to deliver your trial** • Handling vendors when working remotely: tips for fostering a strong relationship virtually • How much oversight do you need to have over your vendors and partners, and how involved should you be in the process? • Overcoming challenges involved when working with multiple vendors in order to ensure everyone's goals are in line **Jasmin Hellwig,** Associate Director Vendor Relationship Management, **MSD**
13:00	**CASE STUDY: Incorporating e-labelling into your clinical trial supply processes** • Navigating regulatory hurdles around e-labelling, in particular the new Clinical Trial Regulation • How e-labelling can improve the patient experience and thus engagement and retention in trials • Using e-labels as a way to increase efficiency and reduce costs: where are the main benefits and opportunities? **Hadar Shaked,** Clinical Supply Project Manager, **Teva Pharmaceuticals**
13:30	**Lunch and networking**
14:30	**PROBLEM-SOLVING ROUNDTABLE DISCUSSIONS** *During the roundtable discussion session, the conference hall will be divided into two 'zones'. Delegates can choose which zone they would like to join. Each zone will be led by a table moderator and will focus on a different challenge within clinical trial supply. After 45 minutes, delegates will have the opportunity to swap and choose a different table, and each roundtable will run twice.*
	ROUNDTABLE 1: Selecting vendors and partners for your supply chain: key considerations **Ilaria Rondinone,** Senior Clinical Supply Lead, **Chiesi Group**
	ROUNDTABLE 2: Usage of internal systems for outsourced manufacturing steps **Chiranth Hulgur,** Senior Manager Clinical Supply Chain Data and Analytics, **CSL Behring**
	ROUNDTABLE 3: Forecasting the unexpected: how to handle unforeseen circumstances to reduce impact to clinical supply chains **Ruth Barbero,** Associate Director Global Clinical Supply Chain, **Incyte**
	ROUNDTABLE 4: The pros and cons of just in time labelling: what to consider when adopting this as a strategy **Dr Kamal Amin,** Head of Clinical Supplies Management, **Galderma**
	ROUNDTABLE 5: End2End visibility in clinical trial supply **Ulrich Mengel,** Associate Director, CTS Business Operations, **CSL Behring**

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16:00	**Chairperson's closing remarks** **Vanessa Dekou,** Managing Director, **CSI**

END OF CONFERENCE

Additional topic suggestions:

An analysis of 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 both within and outside Europe: common hurdles and how to overcome these
- The changing regulatory environment in Europe and how to ensure you stay up to date with new regulations

CASE STUDY: Learnings from operating a clinical supply chain for stem cell therapy

- Overcoming common supply chain challenges for stem cell therapy
- Stem cell therapy supply chains in 2023: what's new, and what should you consider for your trial?
- An overview of the stem cell therapy clinical trial landscape: new technology and advances

Improving your supply chain risk management strategies

- Preparing for the unexpected: building contingency protocols in from the beginning of a trial
- Planning for unforeseen events and incorporating this into your risk management strategy: what the pandemic has taught us
- Incorporating risk assessment into project management plans in order to be better prepared for every eventuality

EXPERT INSIGHTS: Understanding the new Clinical Trial Regulation and the impact of this on clinical supply chains

- An update on the Clinical Trial Regulation: what do you need to do to ensure you are prepared?
- How will processes change, and what should you take into account when designing protocols?
- Ensuring your interpretation of the Clinical Trial Regulation is accurate and up to date

Tracking and serialisation: how new systems can benefit your clinical supply chain

- Comparing serialisation and tracking systems in Europe, the US and beyond
- Integrating multiple systems to ensure real-time tracking of drug shipments
- Understanding the regulatory environment surrounding tracking and serialisation

Interactive response technology as a tool to reduce risk and optimise supply chain strategy

- Utilising IRT reporting and functionality for demand and supply planning
- Demand forecasting for clinical sites and IRT inventory management
- Understand regulatory compliance requirements for using IRT processes in your supply chain
- Make the most of your IRT system to track your product during shipment and patient distribution to maintain control over your clinical study

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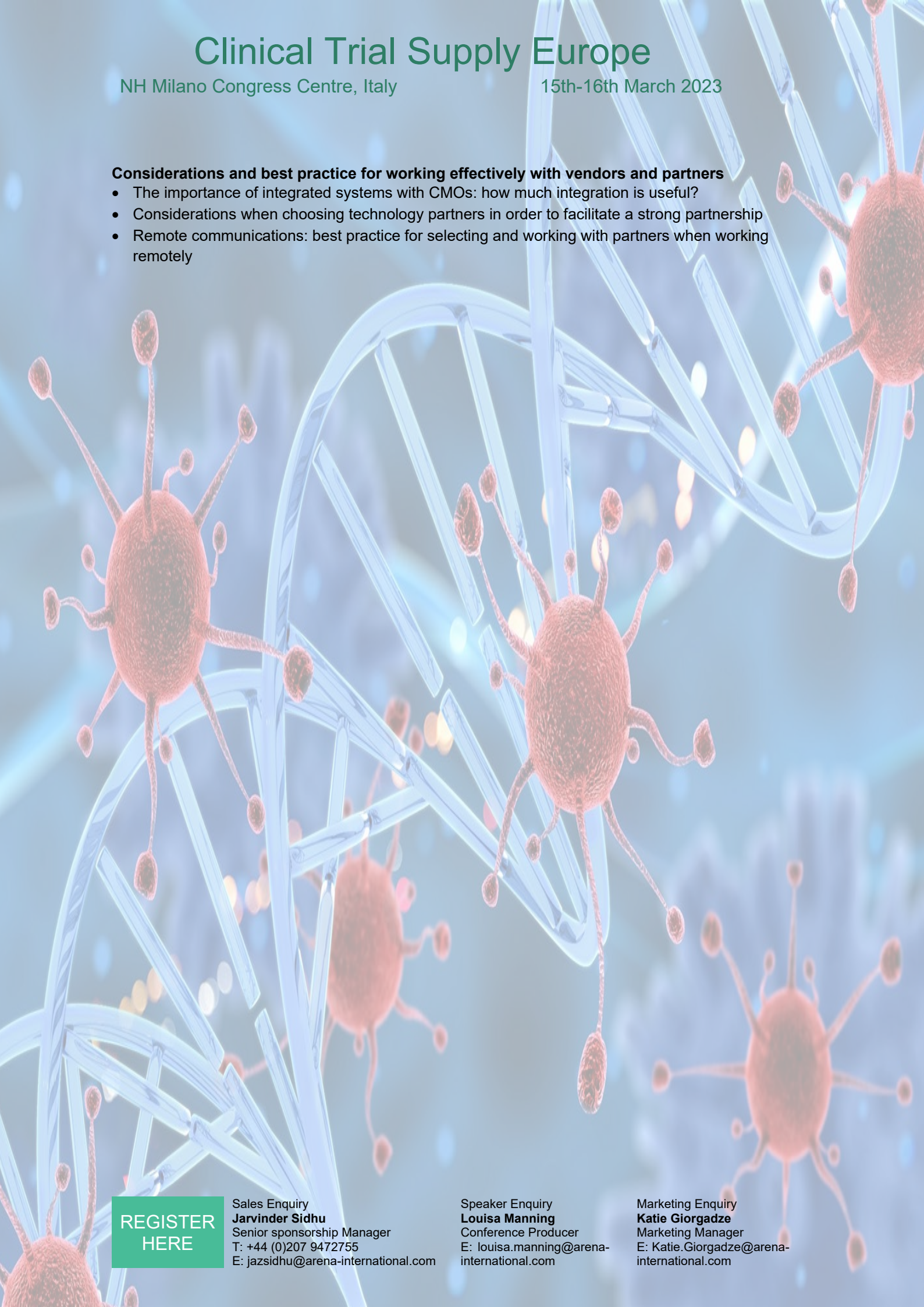
Considerations and best practice for working effectively with vendors and partners

- 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



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