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CLINICAL TRIAL SUPPLY CHAIN 2020 A LOOK AHEAD

PART OF PROVENTA INTERNATIONAL'S EU CLINICAL TRIAL SUPPLY CHAIN STRATEGY MEETING 2019

ATTENDEE STATISTICS WHO WENT AND WHAT THEY'RE INVESTING IN

HIGHLIGHTS FROM ALL OUR TRACKS

THE TOP STRATEGIC CHALLENGES FOR CTSC, 2020 AND BEYOND

AN EXPERT LOOK AT THE NEXT FIVE YEARS IN CTSC

INTRODUCTION
2019 AND BEYOND

Proventa's 2019 EU Clinical Trial Supply Chain (CTSC) Strategy Meeting featured the hallmarks of all Proventa's successful events: suppliers and delegates enjoyed the unique approach of its roundtable discussions, in which the delegates themselves provide the discussion, as well as the exceptional venue in the Zurich Airport Radisson Blu and the networking opportunities throughout the day.

Discussions at the event included optimising drug supply chain using IVRS/IWRS forecasting technology; the value of E-label technology to accelerate the timeliness packaging and labeling; and a fascinating discussion on how to improve the sustainability of temperature-controlled supply chains by better using circular temperature-controlled packaging systems and providers.

This Report: The Future of CTSC

This report looks not only at the discussions and conclusions of the event but more importantly discusses the future of the whole CTSC area: in addition to highlights from the event and statistics on attending delegates, the report will focus on the next five years within the clinical trial supply chain space, with insights from experts and facilitators present at the event, and discuss what delegates from some of the biggest names in pharma are investing in as we speak.

There is a wealth of information packed into the pages of this report: we hope you find them of interest, and enjoy reading through these pages.

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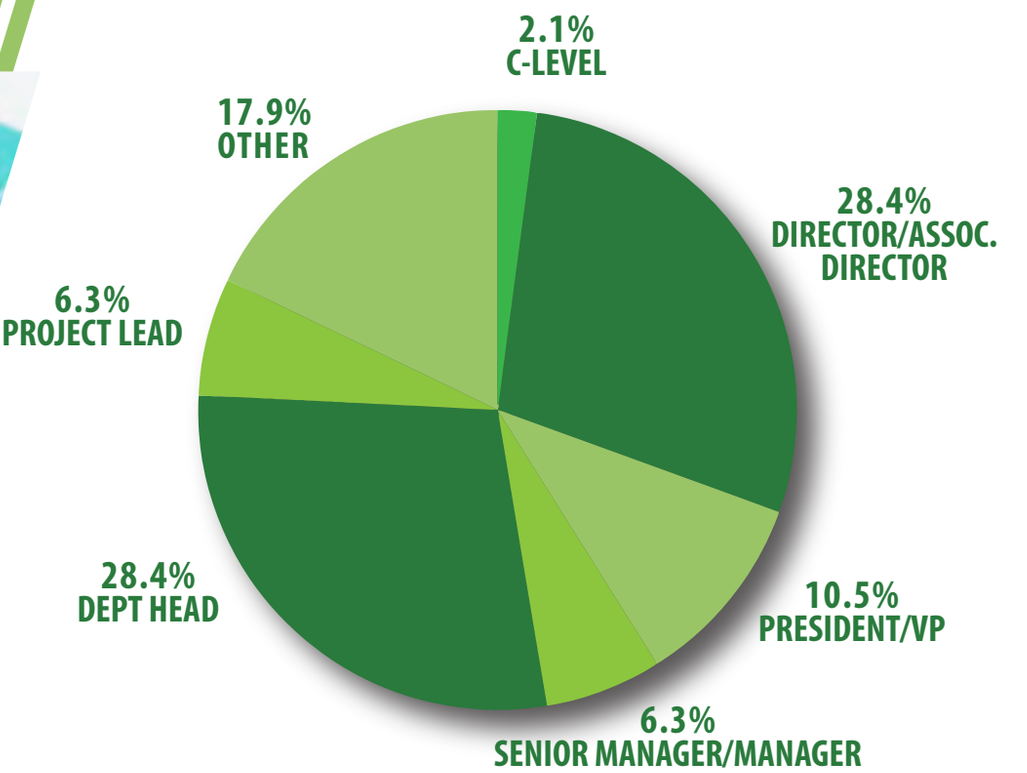
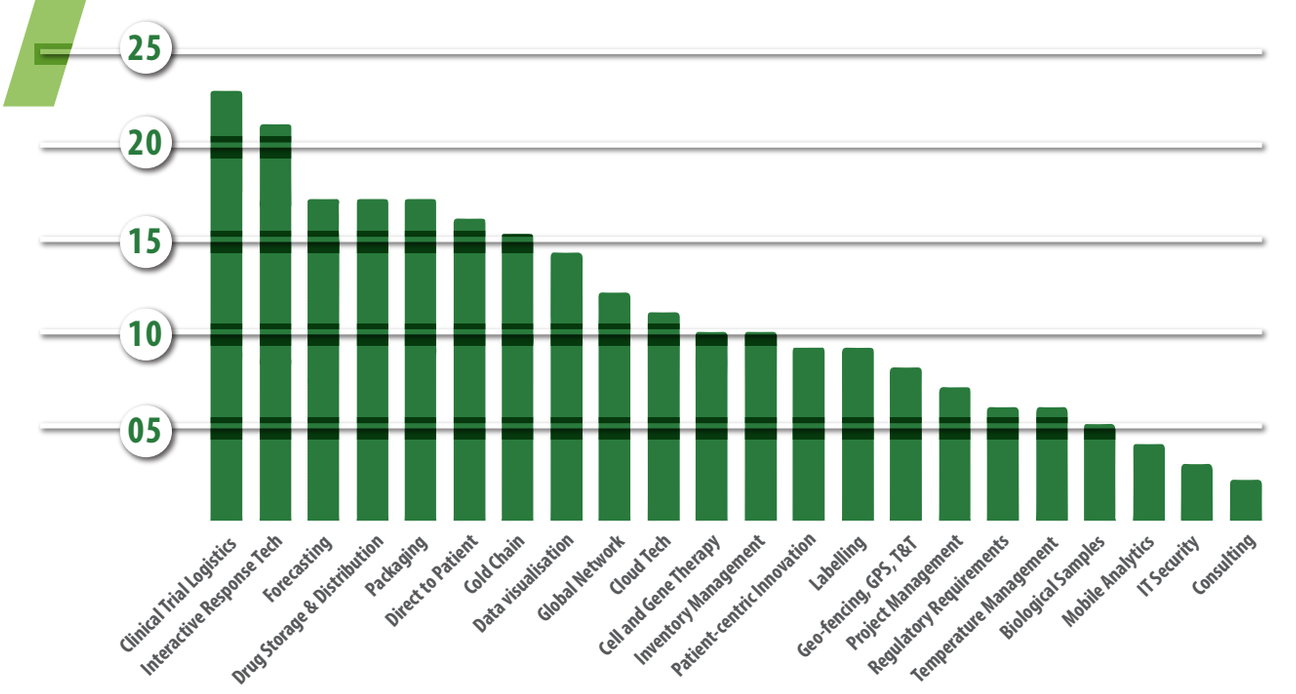
The Statistics: 2019 Attendee Breakdown





2019 Event Highlights

The 2019 Clinical Trial Supply Chain Strategy Meeting saw four high-quality tracks covering almost all delegates' areas and interests. The four tracks were: global networks and direct-to-patient; technology; storage & distribution; and finally IRT & packaging & labelling.

Global Networks and Direct-to-Patient

The track on global networks and direct-to-patient began with a roundtable by Wilhelm Scigalla of Oculis, which examined comparator sourcing for global trials, in particular single sourcing versus decentralised. After a short break, the track then returned with a roundtable on whether digitalisation can reduce the temperature excursion process to just a few seconds. Facilitated by Nina Nilsson and Hanna Söderström, both of TSS, this roundtable also discussed whether the internet of things could allow end-to-end visibility of product stability through the course of a clinical trial.

After lunch, Annette Schneidereit-Hanke of CSM facilitated a meeting on adopting direct-to-patient methods in clinical trials, before the track concluded with a roundtable by Raul Gerber of Novartis in which delegates discussed data security and privacy through a patient-centric approach.

2019 Event Highlights

Technology

The day's technology track began with a roundtable by Andy Evans, Vice President of Clinical Manufacturing and Supply at AstraZeneca, on optimising drug supply chains using IVRS/IWRS forecasting technology. The roundtable was focused specifically on what forecasting is being used for, what was being optimised in the supply chains, and the tools and technology which could help with this optimisation process.

Beginning with the statement that pharma companies should always assume a forecast is wrong, the roundtable discussed the benefits of real-time data versus continuous updating, though in both cases it was noted that end-to-end transparency remained elusive.

The financial aspect of forecasting was determined to be less important in forecasting, particularly on the clinical side, relegated largely to whether more or less was spent than intended. The question did arise over whether governance was becoming increasingly interested in clinical supply chain finance, but so far it appears too soon to draw a firm conclusion.

The roundtable ended with an interesting discussion on regulatory pressures, and whether rules preventing companies sharing data with one another were stopping AI and machine learning systems from becoming truly effective.

Over the rest of the track, N-Side's Head of Consulting Group, Sébastien Coppe, led a roundtable on real-time monitoring of the single source of truth for end-to-end clinical supply chains, after which Dario Cogo of Novartis discussed Blockchain and the internet of things, and how they could be used to mitigate the absence of internal and external visibility in the supply chain.

2019 Event Highlights

Storage & Distribution

The storage & distribution track began after the strategy meeting's first break period with a discussion on improving the sustainability of temperature-controlled supply chains with circular temperature-controlled packaging systems and providers, facilitated by Paul Terry of PeliBiothermal.

The roundtable began with a discussion on the importance of implementing increased sustainability into the process: depending on the values of the company, and on the business case that could be made, it was argued that sustainability is at least worth thinking about, with considerations also made for total cost of ownership of this change end-to-end.

The need for secondary packaging was then discussed, with delegates weighing the pro points of protection and better temperature control against the use of extra material and transportation of empty space. It was suggested that high-cost packaging could diminish in usefulness as cold chain logistics in airports and other areas became better, though ultimately the question came down to how much risk pharma companies were willing to take with their products.

The roundtable moved on to discuss whether re-use is a burden or an opportunity, to what extent quality processes limit reuse and finally sustainability in direct-to-patient supply, including a speculation on how much data is actually needed from the patient.

The track ended with an engaging talk on optimisation of clinical storage facilitated by Paul Viggers and Kevin Williams of PCI Pharma Service, and a final discussion around whether complex protocols impede supply chain efficiency and increase company costs.

2019 Event Highlights

Interactive Response Technology (IRT) & Packaging & Labelling

Luisa Freitas dos Santos, VP of Global Clinical Supply Chain (R&D) at GSK, facilitated the IRT & Packaging & Labelling track's first roundtable on enhancing integration of enrollment data and inventory to reduce wastage rates through IRT software; she was followed by an excellent discussion on dangerous goods packaging by Maarten De Gryze and Walter Myttenaere, both of vendor The Pack.

The third roundtable of the track was facilitated by Dario Cogo, Global Head of Supply Chain and Clinical supply at Novartis. It focused on the value of e-label technology to accelerate the timeliness of packaging and labelling, and started with the firm conclusion that e-labels are definitely a game-changer in the clinical supply chain, providing endless possibilities, particularly from a patient safety perspective.

Topics discussed in the roundtable included determining how e-labels can best be defined; exactly what is applicable and doable before exploring e-labelling; and whether a dual approach, focusing on implementing both digital and physical aspects into a label, was viable. While no consensus was reached there, the delegates did agree that health authorities were generally open to new ideas and proposals, as long as a strong case was put forward.

The track ended strongly with a talk on IRT requirements, pros and cons, delivered by Oculis' Wilhelm Scigalla.

Key Delegate Challenges 2020 and Beyond

One of the most important resources available to any senior figure in biotech or pharmaceuticals is an understanding not only of the field at present but where the field is going, and the key obstacles that any company in the sector faces.

Proventa International surveyed a number of major players in the field, using expert opinion and insider knowledge to uncover out of the many obstacles on the horizon the major challenges to overcome in the next few years.

Major Challenges 2020 and Beyond

Supply chain and drug delivery

Unsurprisingly, supply chain-specific challenges dominated the thoughts of many delegates in the survey. Areas particularly mentioned included cold chain supplies, the clinical supply chain and supply planning, and supply network optimisation.

Organisational changes and growth

Wider organisational change was another one of the key challenges presented by several delegates, citing organisational redesign and general transformation as key in the coming year.

Optimising / streamlining processes

Following on from these company-wide organisational changes, many of those surveyed mentioned the optimisation and streamlining of day-to-day processes, with network, OPEX and distribution singled out as particularly crucial areas in need of optimisation.

New Technology and AI

As with almost every sector, a critical challenge in the year ahead for CTSC experts was getting to grips with automation, AI and other new technologies: the Cloud and interactive response technologies were also mentioned as key challenges.

Key Delegate Challenges

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Key Delegate Challenges 2020 and Beyond

Direct to patient

Direct to patient models are at the forefront of many pharma companies' minds, and the coming year will see several delegates focusing on overcoming challenges with the model and integrating it into their current processes.

Clinical trials

Delegates mentioned a number of areas within clinical trials as potential challenges for the future, including issues around clinical trial logistics, forecasting and drug supplies, as well as incentive programs, implementation and expansion.

Time and costs

Both time and cost challenges were brought up by delegates, with major challenges largely relating to delivering clinical trial material on time, reducing agreement review timeframes, reducing lead times and cost efficiency.

Labelling

Labelling generation and automation were both mentioned as key issues for the coming year by delegates, with just under half of those surveyed suggesting that labelling was a key investment area for them.

A Look Ahead: Expert Opinion on the Future of Clinical Trial Supply Chain

The logistical and supply chain needs of clinical trials are highly complex, with potential failure points across the entire length of the chain: from cold chain issues to manufacturing delays to shipment problems to varying regulations in hundreds of different countries.

Currently, the task of ensuring that an ordered and safe supply chain is running correctly is a laborious and uncertain one, which desperately requires solutions around visibility, integration and knowledge in order to better ensure drugs reach patients who need them.

During our strategy meeting we spoke to several CTSC experts about the future of the sector, asking where they see CTSC going in five years and which technologies and processes will come to the fore in the near future.

A View of the Sector

A VP of Clinical Manufacturing suggested that the sector should be looked at through three "lenses" in order to receive a full picture: first, the technological side, which has already been much-discussed; second, discussions around business process and ways of working, which featured heavily on the Proventa CTSC agenda this year; and finally staff and training, including which capabilities and staff skills are needed for the future, an area equally as vital as the other two but which is often overlooked.

Direct-to-Patient

He suggested that one of the most important topics for the next five years of CTSC would be direct-to-patient delivery, due to the varied limitations of the current models for this, depending on area or location. He thought this area would grow considerably in the next five years, with potential leaps ahead in how patients could be monitored or data collected from them on a therapy area-specific basis.

A Look Ahead: Expert Opinion on the Future of Clinical Trial Supply Chain

Digital

The facilitator also noted digitalisation as an important future trend, speculating on how the power of digitalisation could be leveraged and how best to control insights and information on the supply chain.

One Global Head of Supply Chain supply agreed that new technological advances would lead much of the innovation in CTSC in the near future - including e-labelling, blockchain, and use of big data to predict and improve forecasting - but warned that early adoption of such new technology would be slow to come about, with a high cost and no clear business case or guaranteed return on investment.

Fundamental Improvements

One director at a leading shipping vendor, on the other hand, thought that new and innovative technology may be a distraction from improving the fundamental processes within the supply chain network. He argued that newer improvements to tracking or live-streaming data can only go so far in terms of useful additional information; and that adding such technology to a fundamentally flawed system will not in the end improve the system, and will still leave room for failures.

Integration Development

The director also suggested that another much-needed change that may appear in the next five to ten years would be integration of the different elements of the supply chain process, including bodies like pharmaceutical companies, distributors, and cold chain specialists. This integration could be partly technologically-based, such as ensuring supply chains are optimised for a particular thermal profile as defined by the pharma company, or through simply data sharing and ensuring better network communication between companies.

This would ensure responsibility for an item would be carried throughout the supply chain, with each body ensuring it had both the skills and technology to safely see the item to the next stage of the chain. This would make the whole process more collaborative, rather than transactional, increase transparency and ensure greater peace of mind for the pharmaceutical company transporting its product.

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