Clinical Operations, Supply Chain & Pharmacovigilance:

Insights from the Industry

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Introduction

There are few years in living memory as disruptive and uncertain as 2020 has been. While this is true of almost every sector, the events field has seen unprecedented change in how events are held and how operations will be conducted in the future.

Proventa International was among the companies spearheading this innovation, utilising its trademark versatility to ensure that none of its important meetings were cancelled and its mission was carried out. Moving fully online, Proventa was able to facilitate connections and host expert, sector-critical discussions that would otherwise have been missed.

Despite the unforeseen challenges 2020 brought, Proventa's meetings were as successful as always, bringing together top-tier industry experts to talk through challenges and innovations with one another, make new connections and take back brand new information to their companies. Whatever challenges the rest of the year brings, those who attended the online meetings will be able to face them fully prepared and as informed as possible.

The Future of CTSC, ClinOps and PV

The clinical sector was one of the hardest hit by the COVID-19 pandemic: with huge patient drop-out rates in most countries and outdated processes in many companies that were found wanting, frank discussions about the future of the field were paramount. The roundtables held by Proventa this year took advantage of this, discussing among other things optimising patient recruitment through digital health and RWE; utilising eCOA, ePRO & eSOURCE to improve protocol compliance and minimise errors by patients on entry point; and harnessing AI in utilisation and management of RWD.

From AI in case processing to virtual trial technology to direct-to-patient technologies, Proventa's 2020 events looked at some of the most relevant and important changes in the field today, with leading experts offering their insights and thoughts to those who were there.

This report will look at some of the highlights of the recent Clinical Trial Supply Chain, Clinical Operations and Pharmacovigilance events, but will also go further: it will explore what delegates are investing in right now, and look ahead to the next five years in the field: how delegates are being affected by the turbulence of Covid-19.

We hope you enjoy this report, and look forward to seeing you at our events next year,

Joshua Neil, ***Editor***
Proventa International

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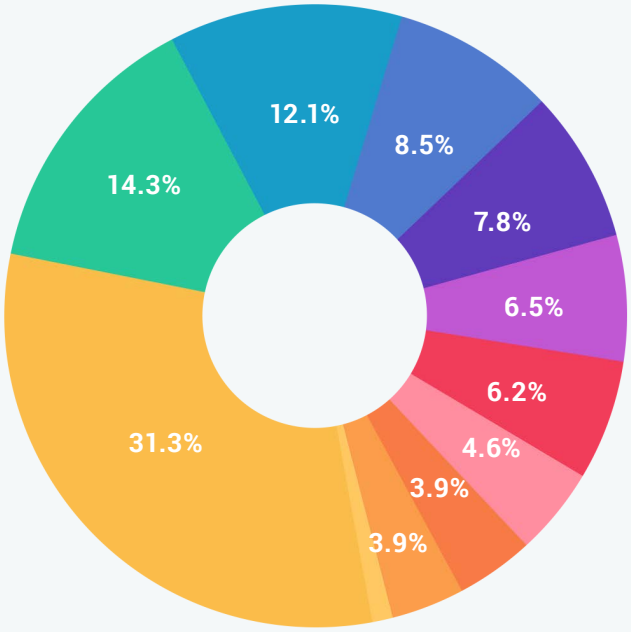

31.3% Director Level

14.3% Department Head

12.1% Manager

8.5% President / VP

7.8% Team Lead

6.5% Scientist

6.2% PV Specialist

4.6% C-Level

3.9% CT Specialist

3.9% Other

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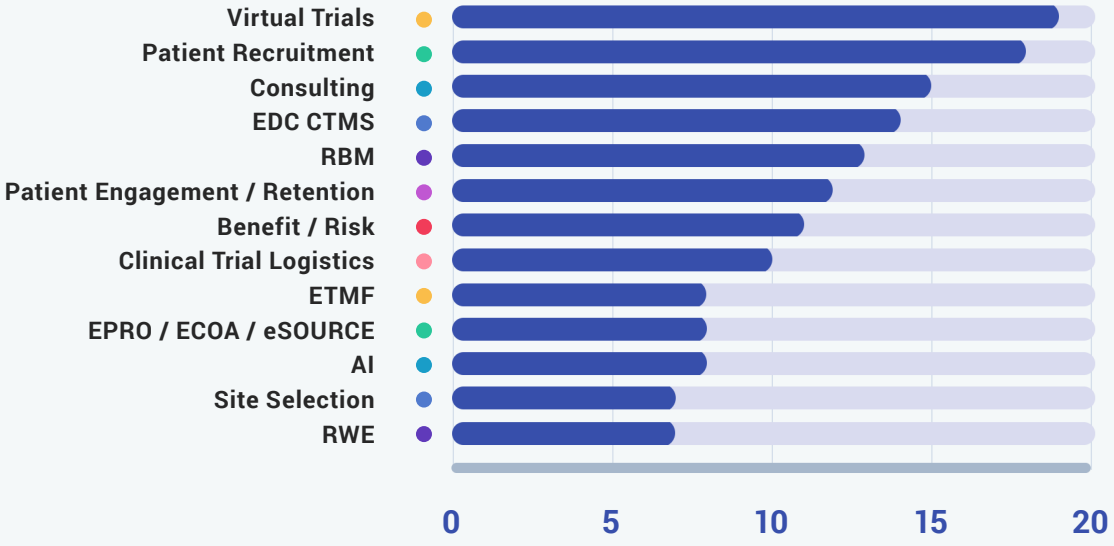
Key Investments



2020 Delegate Breakdown

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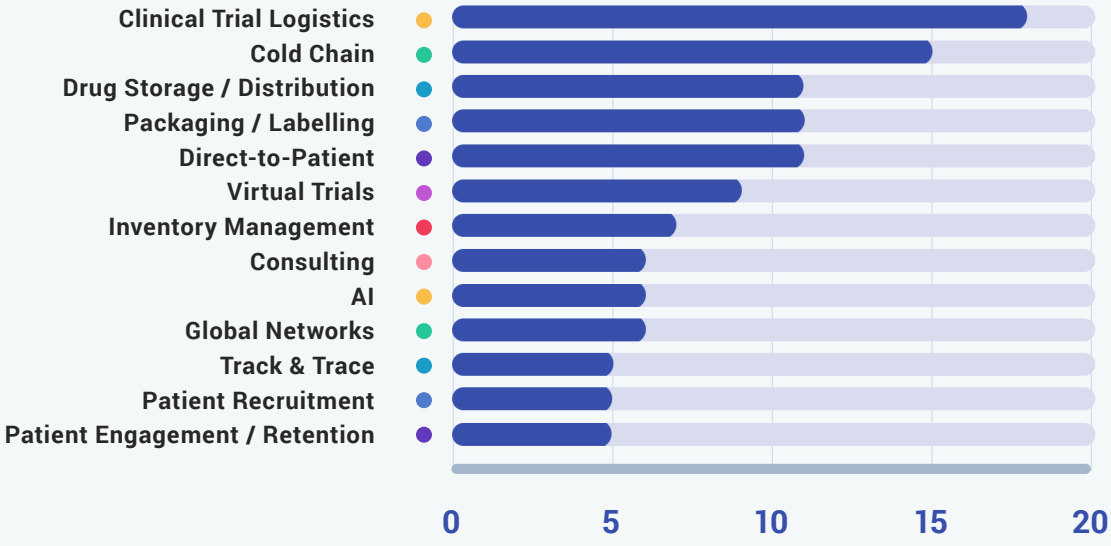
Key Investments



PHARMACOVIGILANCE

Key Investments

2020 Event Highlights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PV - Risk Management of the Future: The New Normal

One of the most interesting roundtables during the PV event looked at the 'new normal' of risk management, and was facilitated by **Avinash Kakade, SGM, Global Head of Pharmacovigilance at Lupin Global**.

A number of questions arose in the initial discussion held by delegates. When asking whether risk management would remain the same, one expert pointed out that compliance and safety will still remain the main element to focus on. But further issues were raised around how adverse events will be handled when patients can't come to centres.

The conversation then moved onto the question of AI and automation, and whether these new technologies could really help with core risk management.

One delegate noted that the main challenge would be legislation keeping up with the new technology. She said that without this legislation, compliance effectiveness would be difficult to measure.

This was largely agreed upon, with another professional mentioning that there must be a period of harmonisation first to ensure greatest flexibility and guidance before any AI is fully implemented.

Delegates agreed that AI is certainly coming, but possibly in ways that professionals would not even notice. These technologies could be part of case and signal management, and even the way pharma experts communicate with other disciplines, within or without the company.

One delegate said they had been working with automation to ensure workflows are more seamless and efficient. They said that from a risk mitigation standpoint, it's always been important in terms of how experts can integrate AI into existing workflows and systems that stakeholders are using. The conversation moved on to electronic health records: commercial teams have been using them for a while now for quick messaging, but it is yet unknown how to leverage this for risk mitigation, and to ensure that practitioners receive key information they need to use products safely.

The challenges here are that different vendors offering this technology do not use a common approach, and that not all stakeholders use the same tools.

Another delegate pointed out that it is difficult currently to operationalise this new technology and ensure consistent usage. Should regulators pilot it for companies, and not have a requirement that pharma must be responsible for ensuring safety, that could be a way forward, they said. AI could be useful in triage stages in this case, though in pharmacovigilance and risk management patient speech could be too nuanced for AI to fully understand in certain issues.

Another delegate disagreed: for early case processing and initial triage, they said, reading a case entirely created by AI doesn't make sense: the AI narrative doesn't provide good information. This delegate though it was hard to believe AI will become reliable enough for signal detection / risk management any time soon, though perhaps within 20 years it could be a reality.

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Clinical Operations: Clinical Research in the Time of COVID-19

During the clinical events, an extremely engaging discussion on clinical research during the global pandemic was facilitated by **Kylie Gyertson, Head of Cancer Clinical Trials at NHS Foundation Trust**.

Before the roundtable began, Kylie gave a brief description of the current scenario: she pointed to the massive drop-off of recruits noted around the world since April 2020, with a 45-90% reduction in some countries. While this has improved, dropping to 40% in the UK since August 2020, she noted that the NHS has closed its doors to research and routine care for fear of being overwhelmed. This meant great deal of non-COVID research was stopped. Those trials still open had to align with clinical services, and do all they could to avoid having patients travel to hospitals.

This meant however, that teams were given all the tools they needed to work from home, when traditionally these methods weren't available - this was a huge leap forward in thinking.

One delegate pointed out that many trial sponsors were habitual in nature, and used what had worked for them in the past. The expert thought because of this, there would be a swift return to this line of thinking after the pandemic ended. He hoped, however, that there would perhaps be slow sea changes, with a lot of the latest technology and products able to be delivered to homes. He thought the industry may push forwards with a more hybrid model.

Another thought along a similar track: that while there would be a return to a norm of habituation, it would still incorporate the new ideas and technologies which have appeared during the pandemic. All delegates agreed that flexibility is highly useful for their work, and that stakeholders may move towards a greater portfolio of risk.

A problem raised about codifying this new technology into practices is that as it develops, there are no firm ideas about who owns those technologies and processes: because of this, no-one is willing or able to bring them firmly into the company.

The discussion ended with a conversation about how the new vaccine will be taken: given that many vaccines are around 50-70% effective, it was argued that early promising results could have clouded the public's opinion of what 'good' means in vaccine production, and that a 50% effectiveness rate - which is seen largely as a 'good' result for vaccines - could be taken to mean ineffectiveness by a misunderstanding general public.

It was agreed that knowledge gaps do exist, with the public not understanding a majority of what is required in vaccine production. They agreed that the industry should better educate the general populace on vaccine steps, in an understandable and concise manner.

Key Delegate Challenges - 2020 and Beyond

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COVID-19

Unsurprisingly, the greatest challenge facing clinical operations delegates in the foreseeable future is the COVID-19 pandemic. Those surveyed mentioned outsourcing post-COVID-19, the impact of the coronavirus on clinical trials, and trial recruitment during COVID as specific difficulties to be overcome in the near future.

Virtual and Remote

Related to the above, virtual and remote working was another high-priority challenge facing most of the delegates attending Proventa's event. Among other things, delegates pointed to the organisation of at-home clinical trials, effective remote monitoring and remote auditing as central challenges they are facing.

Supply Chain Management

Managing the supply chain was, expectedly, another challenge mentioned by most delegates surveyed. Those attending spoke about supply agility, transparency and real-time demand-driven supply and the coronavirus' impact on the overall supply chain from MAKE - storage - delivery.

Patient Recruitment and Retention

Naturally, recruitment and retention of patients was relevant to a number of those working within clinical trials. Delegates attending mentioned patient engagement and recruitment, reaching all necessary patients, and engaging patients digitally as major issues they are dealing with.

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Partnerships and Outsourcing

Working with third parties was another recurring challenge mentioned in the survey. Delegates spoke about finding the right partners, engaging with CRO resources, and creating an effective outsourcing model and strategy, among other things.

Clinical Trials

Another unsurprising challenge faced by many was in the day-to-day running of clinical trials. Delegates spoke about issues with running at-home clinical trials, the impact of COVID-19 on trials they were running, trial recruitment during the pandemic, and finding ENT clinics with enough bandwidth to participate in clinical trials and their normal routine patient visits.

Data and RWE

As with almost every area of the pharma sector, clinical operations experts suffered from a number of challenges relating to data in their work. Those attending the events discussed challenges involving integrating data systems for risk-based monitoring, handling of data integrity in the digitalised world, and assimilation of data.

Staffing and Expertise

Training staff, hiring the right internal resources and coming up with better hiring strategies were all challenges mentioned by delegates relating to staffing and expertise.

Cost and Resources

Lower on the clinical operations list than on some other event surveys, the burden of funding and resources was still a point mentioned by a number of delegates. Those surveyed spoke about finding cost-effective contract services, cost containment, and cost-effective innovation, among other challenges.

Regulation

Finally, regulation came up a number of times among those surveyed. Challenges raised included the burden of regulatory requirements, audits and inspections, and a better understanding of systems and compliance within clinical operations.

Key Delegate Challenges - 2020 and Beyond

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COVID-19

Once again, COVID-19 proved the most important issue with CTSC experts attending the Proventa event. Experts pointed out the coronavirus' effect on materials and logistics, as well as the problem of numerous delays because of the pandemic, were some of the most pressing challenges.

Partnerships and Outsource

The problem of working with third parties came up much more frequently in clinical supply chains than in the operation of clinical trials event; delegates mentioned a range of issues including finding logistics partners who are able to fulfil service on a global scale, determining the best consultant and CMOs to use, and improving relationships with vendors.

Cost and Resources

The difficulties of funding and resources were also considerably more important for CTSC delegates than those in the Clinical Operations event. Within this sector, professionals mentioned challenges for the near future including finding cost-effective contract services, and the need for greater investment.

Remote and Virtual Operations

Remote operations were slightly less important to CTSC delegates, though still one of the most pressing concerns they face. Among other concerns, delegates mentioned the difficulties of running virtual trials, resolving logistics issues regarding direct-to-patient, and remote auditing.

Staffing and Expertise

The problem of internal resources was also an issue for many CTSC delegates. Those surveyed mentioned issues with recruiting expertise, finding key researchers for new indications, and the integration of other companies as smoothly and efficiently as possible.

New Technology and AI

New technology, including AI, was also an important factor for many delegates. Those surveyed said that particular challenges in this regard included incorporating new technologies into their campus, implementation of machine learning, and technology for chain of custody.

Regulation

Regulation was another, though lower-down, concern for a number of delegates. Process changes, regulatory filings, customs clearance and regulatory development and economic conditions were challenges the experts thought they would face for at least the next few years.

Data and RWE

Data was a challenge that ranked surprisingly low on many CTSC experts' listings. Despite this, there were a number of particular challenges to be found in this area, including finding a study temperature data management system that would provide better sponsor oversight of temperature data, handling of data integrity in the digitalised world, and the availability of good data to optimise physical flows especially for P2P businesses.

Key Delegate Challenges - 2020 and Beyond

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Signal Detection/Management

Unsurprisingly, signal detection and management were the most important challenge for most PV experts surveyed. Among other things, delegates mentioned signal detection in COVID-19, finding one source for signalling, and leveraging AI to improve signal detection and evaluation as challenges to be faced in the years to come.

COVID-19

As with almost every sector in pharma right now, the COVID-19 pandemic was a major challenge that affected almost every PV expert questioned. Specific challenges mentioned included outsourcing in a post-COVID world, the impact of COVID on clinical trials, CT continuation during the pandemic and the coronavirus' impact on the overall supply chain from MAKE - storage - delivery.

Cost and Resources

Funding and resources were another significant issue for those in the PV industry. Among other things, delegates mentioned finding cost-effective contract services, finding operational resources, and the PV costs for low adverse events.

Partnerships and Outsourcing

Working with third parties was another major challenge for the years ahead, according to a number of delegates. Specific issues included outsourcing PV services with limited budget, vendor oversight, and outsourcing post-COVID-19.

Data and RWE

Data was a considerable challenge for a number of delegates. Using data across platforms, data mining, big databases and the reliance on a CRO to maintain the company's safety database were all mentioned as issues for the years to come.

New Technology and AI

New technology was a focus of a number of PV professionals. Specific challenges for the years ahead included technology deployment for drug development, AI technology in PV case processing, and governance of AI.

Regulation

Regulation is another area with several challenges for PV experts. Specific mentions of this topic related to changing regulations, increased regulatory requirements for renewal approval of old products, and keeping teams abreast of the new developments in regulations.

Safety

Related to the above, concerns from a number of those surveyed naturally revolved around patient safety. Specific mentions around safety related to, among other things, the quality of safety reporting by site, the magnitude of safety reporting in the next five years, and ensuring patient safety in general.

Clinical Trials

Finally, clinical trials themselves were mentioned as a major PV challenge. Delegates specifically mentioned global trials in the COVID-19 pandemic, safety monitoring in trials at home, and general clinical trial management.

A Look Ahead:
Clinical Trials and PV Over the Next 5 Years

While key investments of our leading delegates are a useful indicator of what is most important to industry professionals both now and in the immediate future, their scope and importance only extends so far ahead. To look further - to the next five years in Clinical Trials and PV, for instance - Proventa asked its facilitators about their expectations for the near future, and how the field will have changed in the run-up to 2025.

COVID-19 and Safety (remote monitoring)

One delegate, a chief science officer at a leading company, noted that safety issues are some of the most important today. They noted that even after the vaccines for the current pandemic are approved, the situation will never be as it was before. Because of this, they advocated remote clinical monitoring as an important aspect of clinical studies right now, due to vitally increasing safety and increasing clinical trial efficiency.

Another delegate spoken to advocated for increased remote trials. They noted that both telemedicine and remote visits are gaining greater importance and relevance right now, and that it would be likely they persist beyond that given their effectiveness and convenience, and that hopefully the coming years will see more user-friendly technologies patients can use for such decentralised visits.

Despite the importance of safety in the post-COVID world, they also noted that speed for roll-out of new COVID-19 vaccines was something suffering from a certain degree of hype at present.

Efficiencies and Costs

The CSO noted the importance of increasing efficiencies in the near future, as there is an increasing sense of urgency to get new drugs to market.

A director of clinical operations, on the other hand, thought that while there are always new technologies for streamlining data, merging information and creating other efficiencies, they would not soon be revolutionising the field: “Trials have largely run the same for years and due to the complex nature of trials globally. Any shift from the normal paradigm is highly unlikely- it’s just too risky, and many in the industry and at the site level are hesitant to stray too far from what they know.” They did, however, note costs as a major problem today, and one which would hopefully improve in the future.

AI

The CFO pointed out AI as one of the most promising aspects of current drug development: “Digital integration of clinical trial data can feed into the trend that may revolutionise new medicines”. A further delegate agreed with this, noting that “AI will be revolutionary”. They said that apps, on the other hand, have yet to live up to their promise, and could well be an example of industry hype.

Patient Recruitment/ Identification

An expert attending the event noted that patient recruitment and identification are some of the most important aspects of clinical trials right now, as one of the biggest challenges facing professionals. This would continue to be the case over the next five years, they thought, though potentially with the trend towards less burdensome trials this could eventually be solved.

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GET IN TOUCH

info@proventainternational.com

UK: +44 (0)20 3314 0100
US: +1 (617) 614 0377

www.proventainternational.com