Clinical Operations, Supply Chain & Pharmacovigilance:

Insights from the Industry

CLINICALOPERATIONS

CLINICALTRIALSUPPLYCHAIN

PHARMACOVIGILANCE

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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 Clinical Trials and PV

The clinical sphere was arguably the area most hard-hit by Covid-19. With patient-facing roles and clinical interactions commonplace, experts here had to adapt and change far more than those in R&D, and possibly more than in manufacturing too. Whole projects and processes had to be rapidly altered to limit face-to-face interactions, and the problem of patient retention became a genuine fear.

But this year brought benefits, too. Decentralised trials, for a long time largely a hypothetical scenario, have been brought wholly to the fore as their utility skyrocketed. Hygiene and patient safety measures have become much more important. And brand new means of increasing patient engagement and retention have been deployed to ensure fear of contamination does not put patients off contributing to science.

This report will look at some of the highlights of the recent Clinical and PV event, 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 clinical trials and PV will change as the years roll on, and 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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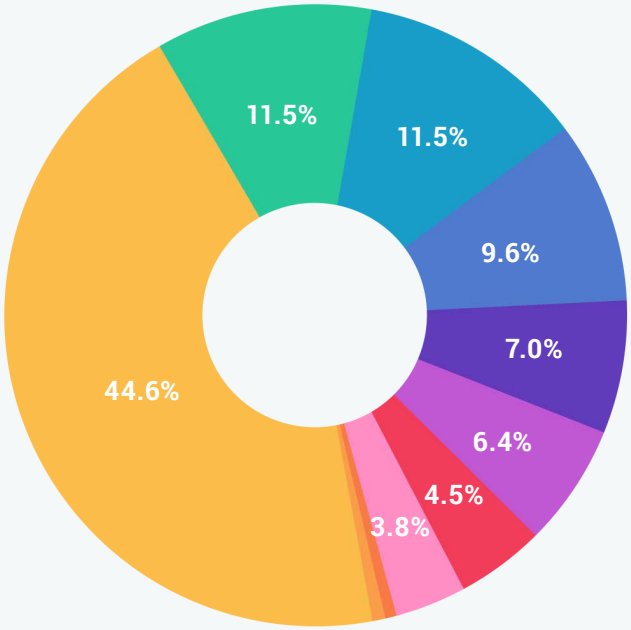


44.6% Director Level

11.5% Department Head

11.5% President / VP

9.6% C-Level

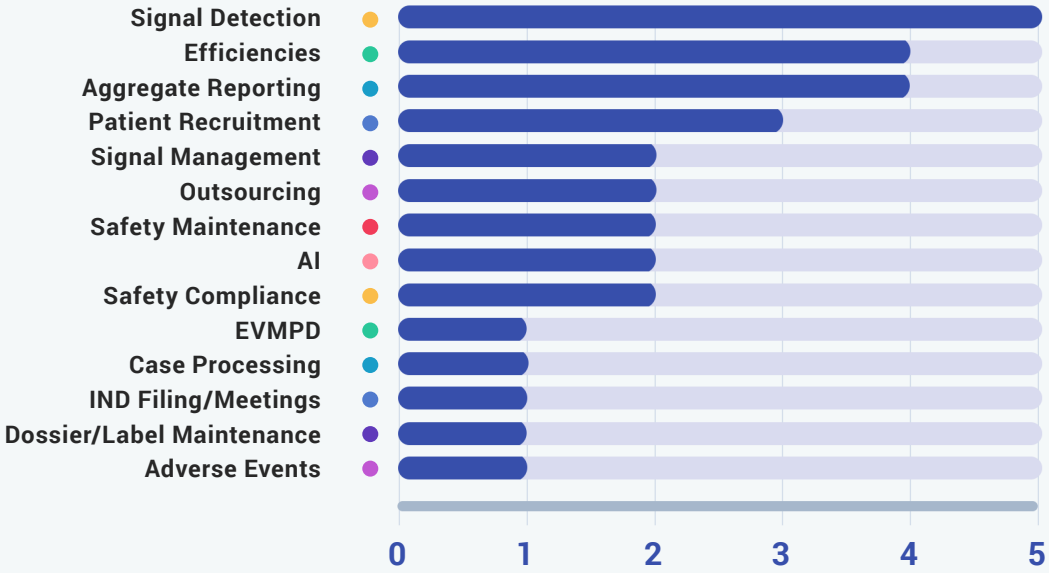
7.0% Team Lead

6.4% Manager

4.5% Scientist

3.8% Other

Key Investments



2020 Event Highlights

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How to better leverage the power of multiple disparate systems and access real-time data to make better informed decisions

In the Clinical Trial Supply track, a fascinating roundtable was chaired by **Joanne McCaigue, Director, DM and Programming / Statistical and Data Sciences at Poseida Therapeutics**, on leveraging multiple disparate systems and accessing real-time data to make better informed decisions.

The roundtable was framed around three central discussion topics: Strategically reviewing data with numerous data systems and sources; combining data sources to allow for efficient review and analysis, and tackling data review throughout a study to make data-based decisions in realtime.

Two polls were presented to the audience to enhance their discussion: the first asked how many data sources or systems, on average, are involved in delegates' current or recent studies. The second asked delegates whether they found navigating and making conclusions about all data for a study/program in real-time an easy task.

In their answers, the delegates made clear in the first poll that while one had more than ten data sources, most had between three and ten - still a considerable number to collect data from. In the second, they concluded that most did not find real-time conclusions an easy thing to do.

One delegate agreed that combining data sources to allow for efficient review and analysis is a challenge. This is increasingly so, they said, with most professionals needing to routinely look at data for a number of different reasons, including quality, safety and end-point adjudication. They said they needed data to also determine KPIs, all of which was difficult for a small company without robust internal resources. Another said that this is an issue in bigger companies as well, who often push such tasks onto CROs rather than investing in internal infrastructure.

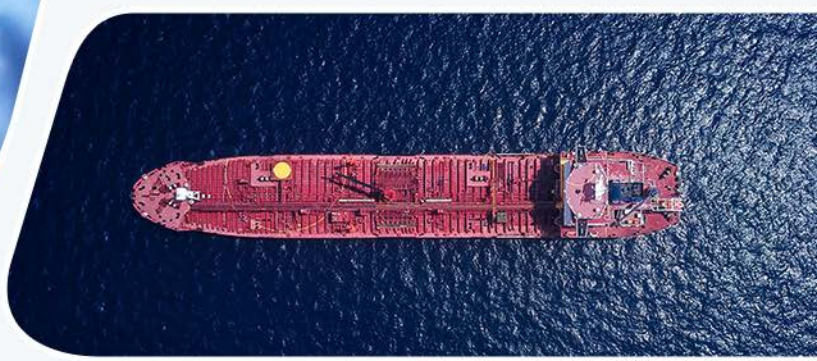
Another noted that their own company had tried to build in infrastructure to perform internal analysis and not rely on vendors, but this presented its own challenge, as did ensuring each of these systems interacted with one another correctly and worked efficiently.

It was agreed that it's hard to find an integration or analysis system that meets all of a company's needs: while some systems focus exclusively on risk management, others deal with the issue from a data or safety review perspective. One which crosses all disciplines without creating disparate datasets was rare.

One delegate noted that it is important when working on large trials with sponsors and thousands of patients across a number of countries to work as a team. All parties in the trial should work together to lay out dataflows, including how they sync between systems, to ensure the model is flexible and different data systems can be used. This communication and collaboration at all levels was vital to ensure a project worked well.

Another delegate pointed out their own key to success, which was to identify the highest-risk areas before a project began, and determine actions to be taken should the right indicators or targets be met, allowing data to be routinely viewed on those areas of highest risk. In this way, should an action be needed based on pre-set indication, the steps to be taken would already have been planned out, allowing for greater speed of reaction and flexibility.

Regarding the question of tackling data reviews to make decisions in real-time, one delegate working in decentralised trials said that they use a platform connecting trial sites, internal staff and patients together, with in-app messaging. These parties all communicated each day, with verification performed in-platform to alert patients should any adverse events be noticed. It was agreed that 2020 and the near future will heavily focus on integration, with real solutions set to appear shortly.



Adverse Events Analysis and COVID-19

In the Pharmacovigilance track, **Senior Medical Director of Immunology & Devices and Global Safety Lead at Shire Ashraf Youssef** gave an interesting roundtable looking at how AE analysis has changed in the wake of the COVID-19 pandemic.

He began by speaking about the currently-established guidelines: these included the FDA's recent guidance on COVID-19, which sets out that while companies should not in most cases delay the reporting of AEs due to the pandemic, exceptions are made for delaying reporting by up to six months. This only applies to certain products, however, and for companies who either have a specific reduction/absenteeism in their workforce or a sudden increase in AE frequency that they are unable to handle.

He also mentioned the EUA guidelines, which lets the FDA give permission for drugs that have been generally approved but not necessarily for a specific use, e.g. off-label use; and the EMA guidance on the matter.

Delegates suggested that in terms of the impact of the coronavirus on AE reporting, so far there had been limited changes to reporting processes. They were, however, looking ahead to a situation in which potentially billions of patients received a vaccine or drug for the virus: this could see a massive increase in AE reporting, which could strain not only individual companies but the whole industry.

The conversation then moved on to whether companies should test enrolling patients for Covi-19 symptoms - and, should they be found to test positive, whether to continue them in the study or terminate it early.

One delegate noted that while they were not screening for Covid-19 on enrollment, symptomatic patients would be tested: the decision would then be made on that outcome.

When questioned, most delegates suggested they had also not had to implement guidance rules to delay their AE reporting, as the majority of workers could function from homes rather than take time off; and few patients are yet on Covid medication, and as such AE reporting has not increased.

Key Delegate Challenges - 2020 and Beyond

Digitalisation / Data and Integration

The top challenge for experts over the next few years was, unsurprisingly, focused on digitalisation and integration of current systems and data. A huge problem across the board for pharma, a number of experts noted issues in particular around leveraging RWD for study design, using new technology to optimise data collection, and analysing multiple data types.

Signal Detection / Management

Signal detection, particularly in clinical trials, was the most specified challenge last year; it has fallen a place in 2020. Specific examples of challenges facing experts in the PV field included signal detection in development and improving signal detection in PV data.

Covid-19

Unsurprisingly, a number of delegates noted Covid-19 as one of the most difficult challenges faced. More disruptive than almost any other event in the last few decades, the coronavirus has reduced patient retention and trust, forced a total rewriting of clinical processes and made safety more vital than ever. With a potential return of the virus annually from here on, Covid-19 could give professionals enormous difficulties in the near future - but should also bring about great innovation.

Resources / Budget / Timeline

The fourth challenge mentioned for the years ahead was one not ranked highly in 2019: a number of delegates noted their difficulties managing time, resource and financial constraints, with specifics including time management and resource co-ordination, finding partners who could meet strict timelines and simply dealing with limited resources.

Regulatory

Issues around regulation were another problem experts face over the near future. Particular problems cited varied wildly, and included difficulties around global regulation; regulatory strategies for complex generics; and learning new requirements.

Key Delegate Challenges - 2020 and Beyond

Enrollment / Recruitment

Patient enrollment and recruitment was next on delegates' list of challenges for the coming future. This could well be linked to the Covid-19 outbreak, with patient recruitment made much more difficult by that event. Increasing patient access and the recruitment rate were specifically mentioned as expert difficulties.

Safety / AEs

Another issue probably linked with Covid, delegates mentioned the problem of ensuring safety increasing AE detection as high on their list for the coming years. Improving safety databases, ensuring patient safety compliance, and translation of the PD biomarker to safety in subsequent clinical studies were specified as major challenges for the times ahead.

Supply Operations / Distribution

Supply operations and drug distribution is another entry on the list of challenges not present in the 2019 survey. This year, delegates suggested that supply planning, improving the supply chain and distribution of cryopreserved products were among the major challenges they expect to still be facing in the near future.

PV

Lower down the list of challenges a number of delegates cited was the area of PV itself. Specifically, field experts mentioned PV in rare disease, cross-functional alignment within PV and applying emerging digital solutions to PV were all noted as difficulties facing those working within pharmacovigilance.

Outsourcing / CROs

Outsourcing and dealing with CROs was a final challenge mentioned by experts as having considerable impact in the next few years. Particularly, outsourcing of clinical supply management, finding the right CRO, and meeting experienced vendors were all difficulties that companies are having and will continue to have in the near future.

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.

Catherynne Cruz-Scheckner, Director Clinical Supplies at Ionis Pharma, also advocated for increased remote trials. She 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, the CFO 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 CFO noted the importance of increasing efficiencies in the near future, as there is an increasing sense of urgency to get new drugs to market.

Jessica Raiz, Senior Director Clinical Operations at Timber Pharma, 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.” She 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 revolutionize new medicines”. Catherynne Cruz-Scheckner agreed with this, noting that “AI will be revolutionary”. She 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

Jessica Raiz 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, she thought, though potentially with the trend towards less burdensome trials this could eventually be solved.

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