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Clinical Operations

Insights from the Industry

CLINICALOPERATIONS

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Introduction

The COVID-19 pandemic brought extreme challenges and rapid innovation to the pharma and life science industries in equal measure. On one hand, recruitment faltered, clinical trials were forced to close to make way for vaccination testing and companies suffered as a great deal of research was put on the backburner to make way for new, critical areas.

On the other, these difficulties ushered in an almost unprecedented wave of new innovations and revolutions to procedures that have remained immobile for years. Changes in monitoring practices, a sudden and emphatic shift towards decentralised trials, and new technologies within AI and automation, have all been driven by the need for practical solutions to the COVID-19 threat.

Proventa's 2021 event on Clinical Operations examined these innovations in depth. From the impact of COVID on patient recruitment to discovering strategies to enhance integration of clinical genomics & precisions medicine in cancer therapy, the changing landscape of the clinic was discussed by experts in the field.

This report looks to provide greater information on the near future of both oncology and clinical fields: using data from our expert facilitators, it will discuss the top strategic challenges facing those who attended Proventa's event, as well as the major investments they will be making over the next 12 months. It will also show the quality of attendees at Proventa's event, and feature an article on an important issue in the field.

We hope this report proves engaging and useful,

Joshua Neil, *Editor*
Proventa International

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1 Patient enrollment / retention
Unsurprisingly, patient-related difficulties represented the top challenge faced by delegates this year. Those spoken to mentioned the need to recruit more patients generally, better identify and select patients, and recruit more patients when working in rare indications as some of the challenges they faced over the next few years.

2 COVID-19
COVID-19 was pointed to as the next greatest challenge industry experts are focusing on. Specifically, industry leaders mentioned challenges including the need to continue innovations developed during COVID beyond the pandemic; the backlog in obtaining supplies from vendors; and enrollment of infectious disease during COVID-19.

3 CROs & outsourcing
Outsourcing, a common challenge for clinical operations professionals, was another highly-rated problem for the coming few months. Experts surveyed spoke about whether to outsource infrastructure creation, the need to outsource clinical trials and determining overall outsourcing strategy as particular difficulties for the year ahead.

4 Virtual trials & remote
A natural product of the changes forced by COVID-19, the need for virtual trials was another challenge faced by delegates. Among other things, those spoken to mentioned challenges they faced included deciding whether to adapt to virtual trials versus ongoing traditional ones; going to virtual clinical trials for HCP-administered IP; and implementing virtual elements into the trial procedure.

5 Time, costs & resources
Another perennial issue, cost and resource challenges were mentioned by many experts at the event. Among other things, delegates mentioned the need for faster study start-up timelines, the need for data to be reported on time, and proper allocation of resources as problems to overcome.

TOP 10 Challenges 2021:
What Peers are Focusing on

6 Risk / RBM
Risk-related issues were another problem for several delegates, though lower down on the list than some other problems. Among other things, experts cited implementation of risk-based quality management, moving away from traditional methods of managing risk, and setting up a risk dashboard as challenges within their companies.

7 Regulation
Regulation was a further problem faced by delegates. Those surveyed cited finding the right regulatory pathways with innovative cost-effective designs; global regulation differences; and regulatory acceptance of new technologies as challenges to overcome in the coming years.

8 Data
Data was surprisingly low on the list for delegates surveyed, with challenges in this area including multiplicity of data sources, clinical data analytics and reporting, and the alignment of white space and clinical data.

9 Manufacturing & supply
Many delegates surveyed cited delays and issues around manufacturing and the supply chain as one of the crucial issues they were facing. Among other things, they mentioned packaging and labelling constraints, distribution outside the USA, and delivery of materials from suppliers as particular challenges they had come up against.

10 New technologies
Finally, AI and new technologies were another surprisingly low addition to some delegates' challenges. Problems to be overcome in the coming years included the introduction of AI technologies to workflow; digital technology in medical affairs; and regulatory acceptance of new technologies.

Performing Effective Vendor Oversight:

An Interview with

Dr Eyal Ron, MADASH

With outsourcing and selection of third-parties for joint work such a major issue in many pharma companies today, it is important to understand how best to qualify new vendors and ensure full oversight as work continues. Proventa spoke to **Dr Eyal S. Ron, Principal at MADASH**, about the best ways to revert poor cultures around outsourcing and how to ensure good vendor oversight post-COVID.

P Proventa: Tell us about your own work, and particularly your experience with vendor qualification and oversight?

E Eyal Ron: I largely work as Chief Technical Officer (CTO) of early-stage companies, usually in an acting capacity. I aid companies in setting up their infrastructure through virtual contract vendors. Part of this role is to select contract vendors which compliment the company itself. Every company has different needs and culture, and that's something one has to align with the vendor audit.

The other part of the acting CTO role is a physical audit with individuals at the CRO, meeting the people who the customer will work with and their facilities. It's vital to get a feel for the team on the other side of the outsourcing effort, and evaluate whether there is a synergy between the two partiels that will make the partnership successful.

P Do most companies have good processes in place for vendor oversight? Are there often cultural issues when seeking out vendors?

E It varies. I've seen companies where the founding team are certain of the right solution, and use an individual or company they know and like. This can often be a poor decision, and one I've had to correct in the past. Others select the cheapest vendor. Both cases are rarely the right option. That said, there isn't one system that works for all companies either.

E My goal when entering a company is to determine why they made the decisions they made, and whether the vendor is right for them - based on my experience. Sometimes a contract has already been signed, and you just have to run with the hand you are dealt. But sometimes you do have an opportunity to sit back, discuss and change course, and decide who will be the right vendor for that specific company. Though that certainly requires additional efforts on my part!

> **"Every company is forced to work with certain constraints, and the costs of outsourcing should never be massive."**

P **Are the decisions that need to be made affected by region - e.g. different regulations, client needs etc? Do you advise clients take region into account?**

E I have an international mindset - I don't think companies should select the vendors limited by region. If one could access a great vendor afar, there's no point in limiting the geographical region and missing out on their services. Today everything is much more international in terms of communication - if they're the best in class vendor and provide good services, they should be a potential option for outsourcing.

P **What are the key points a company should think about when choosing a vendor?**

E Quality of the vendor is extremely important, obviously, but in particular do they have expertise and excellence in the area you're looking for? In drug discovery, a company that is great in oncology could still be unprepared or less excellent in endocrinology. This doesn't mean they're a bad company, of course, but the area simply isn't their expertise. In that case, it is advisable not to use them for that purpose.

Culture is the next important point. Every vendor has a different culture. There are customers who are very organised and know what they want, and can dictate exactly their specifications and stick to them. Others are less clear, and need the vendor to be more flexible and change as they change their decisions. If the vendor is unable to accommodate this need for change, then they should look for another partner.

The last important point to bear in mind is cost. Every company is forced to work with certain constraints, and the costs of outsourcing should never be massive. Sometimes it is vital to set some requirements on the payment for completed work, e.g. paying in increments based on tranches attached to milestones (tranched financing), for example being clinic-ready. In this case the vendor must accept that they will only be paid when all necessities are met.

Obviously, all these constraints are independent of one another. But they all must be considered when finding a vendor, and at the end of the day they are all in one 'bucket' that goes towards finding the right vendor for you.

P How has vendor qualification and oversight changed during COVID-19? Will these changes remain, or revert to post-pandemic standards?

E Obviously, we haven't been able to do face-to-face meetings since March 2020. Neither side wanted to travel during the pandemic. The problem was and still is that not everyone accepted Zoom as a suitable, viable alternative. If you're one of those willing to go the Zoom route, you can have a very successful remote audit where the other side can still be met and spoken to. You can also have a functional tour of facilities using a camera on a phone, etc. Any procedures that need to be seen can be sent via computer drive.

Following the pandemic, I think we'll see a mixed bag of online and in-person audits and meetings. Remote work is going to be faster, cheaper and more easy for everyone involved. But many will still prefer the more traditional of meeting in person.

It's important to remember how much money can be saved with Zoom meetings. While obviously the time of the audit is the same in either case, companies will save two or three days of travel for an in-person audit, as well as the cost of travel and lodging.

P How will vendor identification and onboarding change in the next five years?

E The ability of vendors to accommodate their clients by remote interactions will improve, as some are not there yet. This will increase company efficiency, allowing companies to screen three or more vendors remotely and thus need to visit only one. The total removal of costly, challenging travel is difficult, however - I think it will not go away soon.

Further on, I see a need to standardise the process of selecting a vendor. Electronic systems will be able to screen vendors using data. With this, one would need to buy software that smaller companies simply cannot afford. It would be easier to identify the key elements that each vendor provides, and compare them directly against others more simply. We need an improvement in this - the ability to compare like for like, in a simple and swift manner.

> **"I don't think companies should select the vendors limited by region. If one could access a great vendor afar, there's no point in limiting the geographical region and missing out on their services."**

TOP 10
Delegate Investments for the Next 12 Months

Virtual trials
1

Perhaps unsurprisingly given the changes caused by COVID, virtual and hybridised trials were highest on the list of investments delegates are making over the next 12 months. Among other things, delegates specified they were investing to better consider patient-centricity, at-home labs, and to make trial participation easier.

Patient recruitment
2

Those delegates surveyed about their investments also mentioned the need for greater patient recruitment, hoping to invest in order to counter a difficulty in finding the right patients, as well as to meet recruitment targets as planned and expand their portfolio.

EDC / CTMS
3

A number of interviewees stated that they were investing in electronic data capture, and the related technology of clinical trial management systems. This was, among other things, being done to switch to a better EDC system; to ensure faster trial start-up; and integrate EDC solutions with risk-based monitoring systems.

Consulting
4

Consulting services were also a significant investment for a number of delegates. Those surveyed mentioned that they were doing so in the areas of monitoring, phase 2 and 3 studies, and for support of QMS building and inspection readiness, among other things.

ePRO / eCOA / eSOURCE
5

Electronic data capturing systems such as eCOA and eSOURCE were a significant investment for several pharma companies. Those investing in this space did so to better integrate real-time data collection, prepare for a post-COVID world, and ensure PRO implementation in their clinical trials.

TOP 10
Delegate Investments for the Next 12 Months

Patient engagement / retention
6

No surprise considering the importance of virtual trials and patient recruitment further up this list, patient engagement and retention was also a major investment of several delegates. Those interviewed spoke about meeting recruitment targets, working more with advocacy groups and ensuring patient retention particularly in virtual trials.

Site selection
7

Site selection was another area of investment for several delegates. Those spoken to discussed the need for investment to ensure internal ownership of site ID, and because of the twin problems of finding the right sites, and slow site selection and activation by CROs.

RWE
8

Those investing in RWE did so to support portfolio expansion and brand development; to increase enrollment; and to fulfil regulatory requirements.

Direct-to-patient
9

Direct-to-patient medicines were another area related to COVID that experts were putting money into. Those surveyed described COVID as the primary reason for their investment, discussing the need to enable remote CTs, expand on their experience from COVID and make trial participation easier.

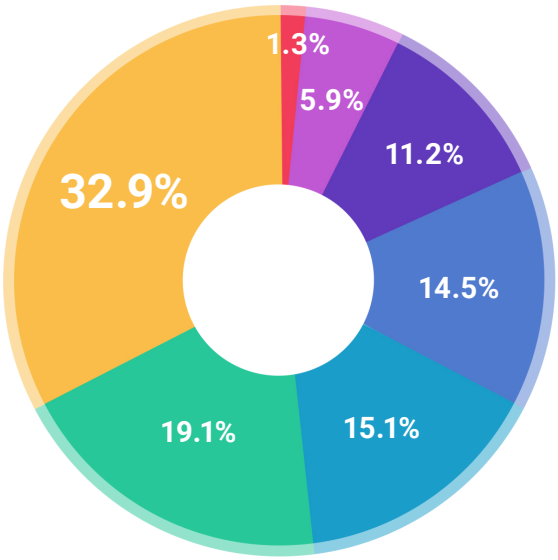
ETMF
10

Finally, investors spoke about electronic trial master file (ETMFs), another electronic filing system that has increased in popularity post-COVID. Among other things, investors were looking to ETMFs to ensure internal ownership of the technology; because they were curious to learn about the technology; and to ensure greater standardisation in business practices.

Delegate Breakdown:

Attendees at Proventa's 2021 Strategy Meetings

2021 Atendee Breakdown



32.9% Director level

19.1% Head

15.1% Manager

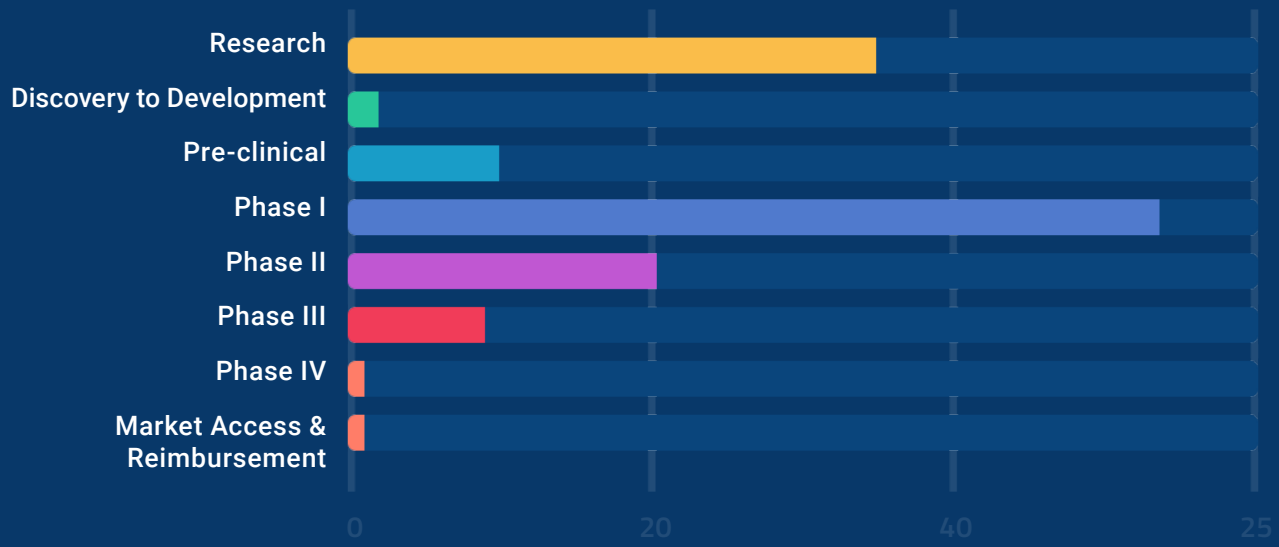
14.5% Team Lead

11.2% President / VP

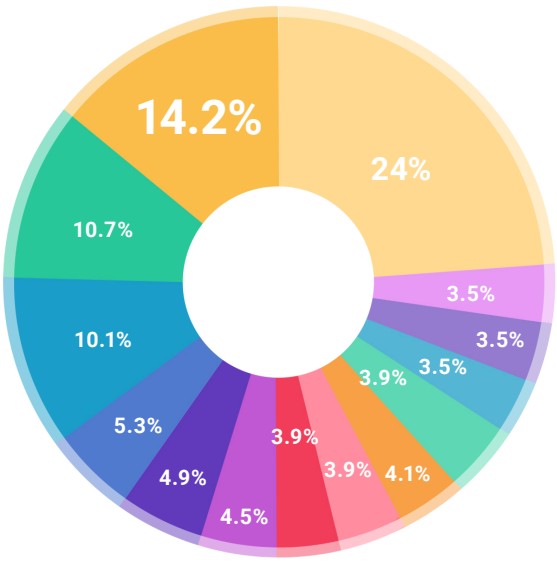
5.9% C-level

1.3% Scientist

Drug Development Stages



Therapeutic Areas



- Oncology
- Immunology
- Rare diseases
- CNS
- Cardiovascular
- Infectious diseases
- Inflammation
- Neurology
- Vaccines
- Metabolic diseases
- Haematology
- Dermatology
- Respiratory
- Other

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