



PROVENTA
INTERNATIONAL

Clinical Operations & Oncology Insights from the Industry

 CLINICAL OPERATIONS

 ONCOLOGY

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 and Oncology examined these innovations in depth. From the impact of COVID on patient recruitment to discovering strategies to enhance integration of clinical genomics & precision 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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TOP
10

Challenges 2021: What Peers are Focusing on



1 Time, costs and resources

Limited resources and time restrictions were counted as the highest strategic challenges for many delegates spoken to, with specific examples including pricing, limitations with global resources, and other budgetary constraints. This challenge was likely heavily affected by COVID-19, with supply chain hold-ups and wide-scale trial closures a global concern.



2 CROs and outsourcing

Outsourcing and partnership was the second most mentioned challenge presented in Proventa's survey. Specific challenges mentioned by delegates included finding the 'right' CROs that can perform well in a single continent and then expand to multiple continents; CRO management; and building external vendor data management.



3 Patient enrollment and retention

A further challenge presented by the onset of COVID, patient enrollment and retention was another challenge which has risen significantly over previous surveys. Finding the right patient populations, enrolling oncology patients in a competitive landscape for anti-TIGIT molecules, and embedding patient-centric approaches into clinical trials were all difficulties mentioned by delegates in Proventa's survey.



4 New technologies

Always high on the list, new and innovative technologies fell a few spaces this year - possibly due to complications of COVID that bring other challenges to the fore. Specific challenges cited by delegates included acquisition of AI and disruptive technologies; staying on top of new novel technologies; and using innovative technologies to increase efficiency.



5 Regulation

Regulation was another challenge still reasonably high on most delegates' lists. Specifically cited challenges included the impact of new regulations, the quality landscape, and developing a fast-to-market clinical development plan that balances the regulators' and payers' needs.

TOP
10

Challenges 2021: What Peers are Focusing on



6 COVID-19

Unsurprisingly, COVID-19 was one of the greatest challenges many delegates faced. The pandemic was a contributing factor to many of the other challenges on this list, but in particular facilitators and delegates mentioned the COVID-related supply shortages; preparations and contingency plans that needed to be put in place; and the impact of COVID on enrollment as difficulties they have faced over the past year.



7 Risk and RBM

Risk-based issues were another challenge faced by delegates, although lower on the list than many others faced this last year. Those surveyed spoke about, among other things, risk mitigation at the early developmental stage, implementing RBM and having a focus on risk in general.



8 Sites

Sites were another challenge lower on the list this year, with experts surveyed complaining about site identification, start-up and staffing as some of the particular issues they face in this regard.



9 Talent and staff

Finally, delegates pointed to staffing and expert recruitment as a trouble they have faced this past year. Among other things, they pointed to staffing start-ups, retaining talent and finding the right individuals for the job as difficulties at this point in time.



10 Data

Lower down than might otherwise have been expected, data was the last of the top ten challenges facing those delegates surveyed by Proventa. Among other things, those asked said that issues in this regard centred around integration and dealing with increased loads of data in trials, in part due to the increase in wearable technologies.

The Importance of Data Innovations for the Future of Oncology Trials:

An Interview with



Sashka Dimitrievska

Some of the largest changes happening in the clinical trial space are being seen in oncology. Oncology is a perfectly poised therapeutic area for rapid uptake of innovation, both by way of breadth of drug design innovations, rapidly developing trials (often bypassing Phase 2 altogether) and very large number of ongoing trials and fluid financial investments – these make this therapeutic area ideal for changes. From specific innovations such as use of molecularly targeted agents for immunotherapies to broad changes in thinking, it is clear the oncology trial space will be radically different in the coming decade. We spoke to **Sashka Dimitrievska, Global Head for Oncology IP Clinical Insights at AstraZeneca**, for her thoughts on the future of clinical trials in oncology.



P Proventa: Can you give us a brief introduction to your background and current activities?

S Sashka Dimitrievska: I head up a global organisation at AstraZeneca, called Information Practice. It's an unusual department in big pharma as it manages late-stage drug development processes by focusing on generating value from internal and external data and information. We have a lot of both, especially in oncology, and our portfolio at AstraZeneca is a multi-billion dollar portfolio across IO, oncology and haematology, and we work across all three.

I've been at AstraZeneca since 2017. Prior to that I was at Alexion Pharma working in strategy and BD, before moving to the commercial side in marketing. I have a PhD in bioengineering and an MBA from Yale University.

P What is the most exciting oncological area in oncology you're currently working on?

S It's an interesting time for oncology, from many perspectives. For one, the industry is rapidly maturing its understanding of cancer and oncology itself. We now no longer think of it as just one disease, but instead as many thousands of different diseases. That's really opened up a whole field of translational medicine, diagnostics, understanding the patient, patient segmentation, targeting patients better, personalising the medicine they receive even further. That's translating a lot into what we're seeing in therapeutics.



S By way of clinical trial design, which is where I sit, we're becoming a lot more specific about which patients we're targeting and how we're targeting them, so we can become more preventative, and we can intervene with cancer earlier. There's a shift now to start earlier into the disease and into the diagnostic and be smarter.

And the last piece that's really interesting in cancer regards the historic 'swimming lanes' in oncology. Whether you were working on checkpoint inhibitors, or chemotherapeutics, or surgical interventions, there were clear siloes in place. They're very broken up now, and we're looking at many more combinations. We're also looking at them now more open-mindedly and creatively across IO, onc and hemes. So the real-world evidence and data we're generating out of cancer now, beyond just trials and the commercial aspect, is becoming a lot more important. We used it for submissions for the first time this past year. And that's just because we're entering a new phase where we have a much better understanding scientifically, and better tools to diagnose this and intervene earlier.

P Are silos still an issue in this field? What is the next big challenge to overcome them?

S Well currently, a haematologist doesn't necessarily interact with an oncology surgeon specialist very often, for example. Obviously in primary care, and in the real world, those conversations and ways of thinking are certainly present. But in the research space, we're seeing more and more bleed-over and therapeutics coming in – the haematology space, for example, with CAR-T and therapeutics – and being applied elsewhere. We're seeing creative learning from different spaces – solid tumours into liquid, for example – and diagnostics and precision medicine, all bleed into one another. I think we're on the cusp of that journey, but I don't know if we're really seeing the proof of it yet. I think the next big challenge will be in cancer, generally speaking, and value-add is going to come out of the better use of data.

Currently, the data and information is there, but in such large quantities that when you try to weed through it all it's overwhelming, and it's impossible to gain insight or clarity. So the new tools we're developing so I think it'll be around all these other tools we're using around data that will be very helpful. When looking at past trends and trajectories and then future trends and trajectories.

“..the industry is rapidly maturing its understanding of cancer and oncology itself. We now no longer think of it as just one disease, but instead as many thousands of different diseases.”

P What currently are the best tools to make this data more manageable? Of course AI / machine learning area major talking point right now: is this the best way to wrangle big data?

S The pharma industry as a whole is lagging behind the usage of data compared with other industries. Right now we're playing catch-up, but I'm hoping we'll see pharma leapfrog over those other areas because we're seeing a lot of investments into healthcare to make AI and ML better.

AI/ML can really help with this data problem. There are many more connections and inferences that can be made. We have working drugs that have mechanisms of action in certain patient populations, that may have efficacies in other places we're not naturally thinking of. By way of benchmarking, smarter AIs and ML connections are helping us get there.

So AI and ML are certainly one of the main ways we're overcoming this data. But I do think we'll see a lot of usage out of real-world data and evidence as well.

“AI/ML can really help with this data problem. There are many more connections and inferences that can be made.”

P How have precision / personalised medicine been affected by COVID? Have they seen a rapid advancement?

S COVID-19 has forced us all to become better at selecting patients, sites and therapeutics. The virus depleted hospitals of patients in the first two quarters of 2020, and without patients you can't run trials. That's already a very competitive space. COVID has, in an agile way, shown how we can get better at identifying patients, and how to think more broadly and creatively. From a clinical operations standpoint, we all have preferred sites and regions or preferred partners, and we've had to expand beyond that into other markets and get creative. I think COVID's given us a lot of learning points that will be carried on in other aspects, too. So certainly, personalised medicine has leapfrogged because of COVID.

P Are there any other innovations or new technologies not yet mentioned which you think will radically change the area?

S There are many schools of thought on this. Some think the next generations of gene therapies will create a huge change, some think preventative oncology, and I do think all these things will come to play eventually and have an impact. But in the shorter-term, in the next decade, I think we'll see major shifts in oncology around better diagnostics, better liquid diagnostics, better patient identification, better targeting of therapeutics, and simply starting treatment earlier on cancer. I think those will see big changes occur soon.

TOP 10

Delegate Investments for the Next 12 Months

EDC / CTMS

1



The majority of delegates surveyed mentioned that their primary investment in 2021 revolved around electronic data capture (EDC) and clinical trial management system (CTMS) technology. Individuals specified they were looking into trial databases, improved oversight of the trials, and improving efficiencies in their organisations.

Patient recruitment

2



Following EDC/CTMS', the need to invest in patient recruitment was the highest investment for the next 12 months. Delegates spoke about improving patient relationships, finding new solutions and moving towards patient-centricity in all clinical trials as some of the investments they are aiming to achieve in 2022.

RWE

3



Real-world evidence (RWE) was another investment cited by many of those surveyed as critical for the coming year. Field experts mentioned that they were investing in RWE, among other things, to increase patient enrollment, to supplement data for labelling and reimbursement, and improve commercial launches.

ETMF

4



As with EDCs and CTMS', the electronic trial master file (ETMF) was another heavy investment area for experts within the clinical operations and oncology spaces. Among other things, delegates wished to invest in order to expand outside the USA; improve new studies and decide whether to bring TMFs in-house.

Consulting

5



A number of those surveyed mentioned consulting services as a significant investment for 2021/2022, pointing to the need for a greater market presence and for clinical operations support as some of the points that have driven this trend.

TOP 10

Delegate Investments for the Next 12 Months

RBM

6



Risk-based monitoring (RBM) was another highly invested-in topic within clinical operations and oncology, those attending Proventa's event revealed. Among other things, Investment in this subject came from a need for greater compliance and efficiency, as well as a general desire to implement innovative RBM strategies in a company.

Virtual trials

7



A natural consequence of the damage caused by COVID-19, virtual trial investment rose sharply over previous years. Among other things, delegates were hoping to improve efficiency of trials, increase patient enrollment, and invest in decentralised trials to reach uninsured or underinsured patient populations.

AI

8



Surprisingly, AI was low down on the list of investments for the coming year. Despite this a number of delegates did mention it as one of their top priorities for 2022, with mentions of AI investment in order to increase speed and accelerate clinical trials.

Site selection

9



Site selection was at the lower end of investments for 2022, though still mentioned by a number of those surveyed. Among other things, delegates specified the need to quickly start phase 1 trials, ensuring rapid site startup and improving staff education as reasons for investing in this area.

Direct-to-patient

10

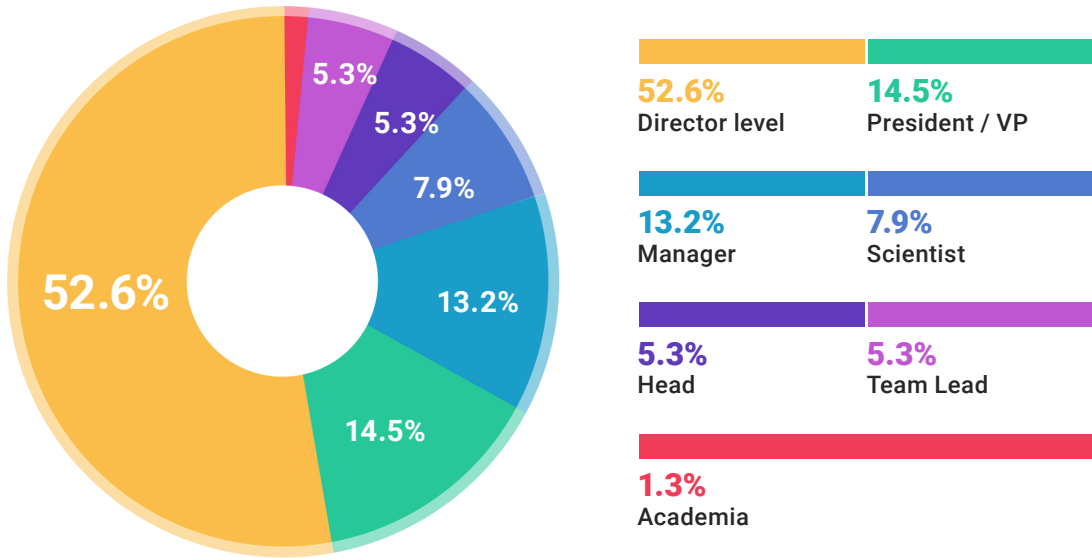


Direct-to-patient was the last of the top ten investments as mentioned by delegates. Those surveyed mentioned that they were investing in direct-to-patient technologies in relation to oncology, improving company efficiencies, and overcoming COVID.

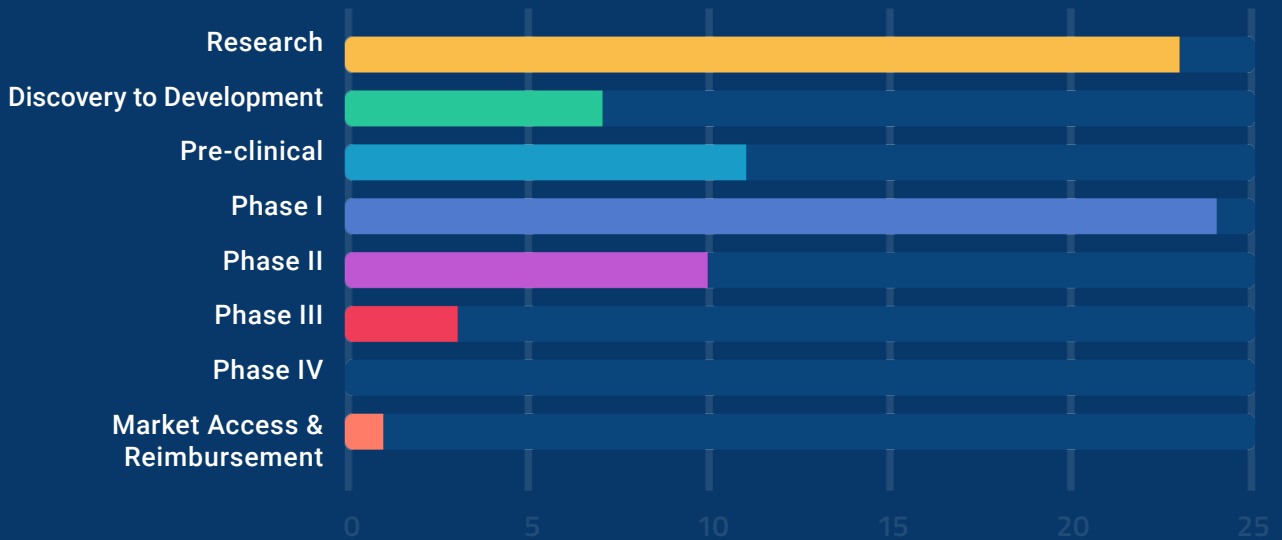
Delegate Breakdown:

Attendees at Proventa's 2021 Strategy Meetings

2021 Attendee Breakdown



Delegate's drug Development Phase



Therapeutic Areas

