ONCOLOGY

2020: A LOOK AHEAD

Part of Proventa International's U.S. Oncology Strategy Meeting 2019 Le Méridien, Cambridge, MA - 18 November 2019

ATTENDEE STATISTICS - WHO WENT AND WHAT THEY'RE INVESTING IN

HIGHLIGHTS FROM ALL OUR TRACKS THIS YEAR

TOP STRATEGIC CHALLENGES FOR ONCOLOGY, 2020 AND BEYOND

AN EXPERT LOOK AT THE NEXT FIVE YEARS IN ONCOLOGY

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INTRODUCTION

Proventa's 2019 U.S. Oncology Strategy Meeting featured the hallmarks of all Proventa's other successful events: suppliers and delegates enjoyed the unique approach of its roundtable discussions, in which the facilitator simply leads and organises the gathering and the delegates themselves provide the discussion amongst themselves, as well as the fantastic venue in the Cambridge Le Méridien and the fantastic networking opportunities throughout the day.

Discussions at the event included a look at some of the biggest challenges in the field, in biomarker discovery, in genomics, in immuno-oncology and in checkpoint inhibitors.

THIS REPORT: THE FUTURE OF ONCOLOGY

This report looks not only at the discussions and conclusions of the event but more importantly discusses the future of the whole oncology area: in addition to highlights from the event and statistics on attending delegates, the report will focus on the next five years within the oncology 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 and variety 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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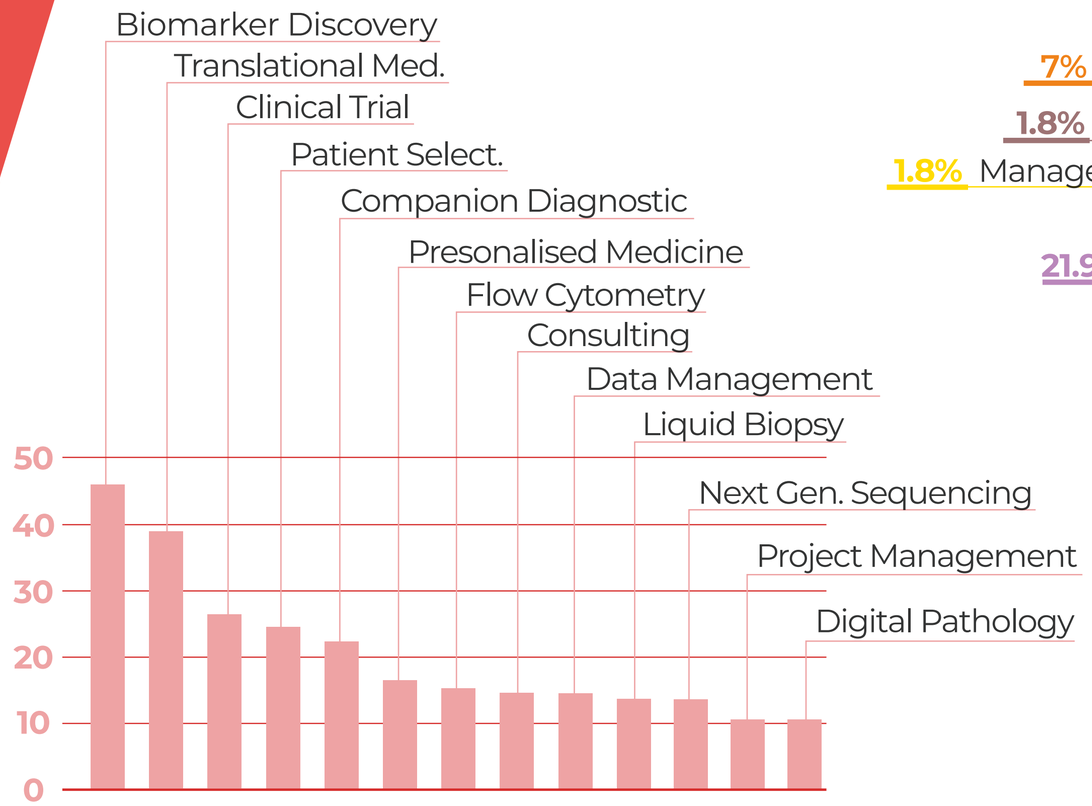
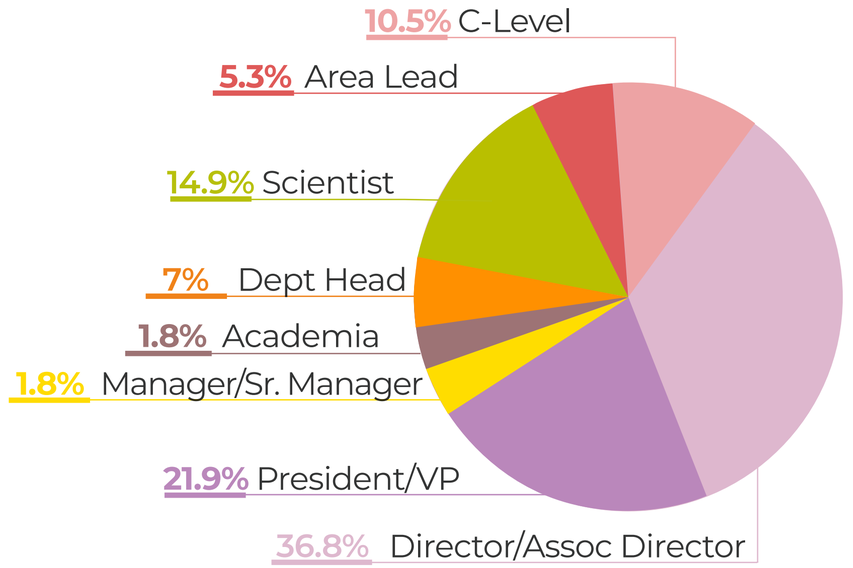
2019 DELEGATES BIGGEST INVESTMENTS



2019 ATTENDEE BREAKDOWN



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2 EVENT HIGHLIGHTS

The U.S. 2019 Oncology Strategy Meeting saw engaging roundtables across six main tracks, with everyone who attended finding something of use. The tracks were: biomarker discovery; genomics; clinical trials; immuno-oncology; personalised/precision medicine; and checkpoint inhibitors.

BIOMARKER DISCOVERY

The biomarker discovery track began with a discussion on gaining confidence in predictive biomarkers and best practice in the field, with Tina Garyantes of Linnaeus Therapeutics facilitating. This was followed by Dan Edelstein of Sysmex Inostics speaking about accurate plasma biomarker detection for clinical trials and clinical practice, and why sensitivity matters.

After lunch, a discussion entitled: “Beyond genomics for biomarker discovery - metabolic profiling” was facilitated by Alex Buko, of Human Metabolome Technologies. The track ended with Kevin Leach of Spring Bank Pharmaceuticals leading a roundtable on how to provide more sensitive ways to detect changes related to disease and discovering novel biomarkers.

CLINICAL TRIALS

The first session in the clinical trials track related to expanding clinical trial eligibility criteria, so as to allow patients with comorbidities to participate in clinical trials for cancer drugs, and was facilitated by Eva Gallagher of Agios Pharmaceuticals.

This was followed by a roundtable on transforming decision-making in early clinical development, with MD Aiden Flynn of Exploristics facilitating. The talk began with a discussion on what information experts seek out at the beginning of clinical development, to best inform trial design. One individual said they immediately talk to key opinion leaders, which works very well - it helps to exactly understand standard of care in clinical areas, and allows you to learn what is and is not possible. This helps both with operational and strategic need on unmet medical needs. Other answers to the question included:

- patient data for assays - you could have the perfect biomarker, but this information will aid in understanding how it works in the clinic
- checking out the dynamic opinions of the FDA: some requirements change and are longer valid when entering a clinical trial; it helps in not putting effort into fulfilling a requirement that is no longer actually needed
- observing preclinical data to find the right doses

The conversation then moved on to which study designs are considered in early work, e.g. standard or alternative. One delegate brought up that such alternative designs were often not viable for big companies, who stick to tried formulas: often only smaller companies with innovative business heads can attempt them.

Next, it was asked when a statistician should be engaged in the process: the answer was as soon as possible, often externally. The process was noted to cause some frustration for biostatisticians, however, as often almost all of the process has already been decided at their on-boarding.

After this talk, the track’s next roundtable focused on flexible clinical trial design protocols, particularly regarding their principles and regulatory perspectives, led by EMD Serono’s Fabio Valentini. The track ended with an engaging conversation about CROs and sponsors tapping into patient-centric models to improve trial recruitment and retention.

IMMUNO-ONCOLOGY

The first talk of the IO track regarded trends shaping and driving future IO development, run by TESARO’s VP and Development Program Lead Mohan Bala. The discussion began with a number of difficult questions: how can positive survival data be translated into success in phase 3? Is failure of an agent more often due to the agents or due to the trial?

It was noted that the operation of clinical trials and how they're run has a bigger impact on studies than people realise. Many aspects of the operation can have a high impact on patient survivability, for example how long to keep patients on a drug, when to discontinue the trial, and patient selection. A delegate added, however, that the FDA does have excellent guidance on when to keep patients on trials and drugs.

The conversation then moved on to using steroids to control IO adverse effects, and whether they might reduce efficacy - it was concluded that there was no strong evidence to show that.

After this, Philippe Mourere of Ultivue delivered a roundtable on converting biopharma research into effective immunotherapies through actionable biomarker programs; another discussed pairing the right drugs and technologies with immunotherapies, as facilitated by David Sherris, CEO of GenAdam Therapeutics.

The track ended with a roundtable on costimulatory molecules for immunological activation and therapeutic intervention, delivered ably by Lorena Lerner of Oncorus.

GENOMICS

The genomics track began with Transcode Therapeutics' VP R&D, Oliver Steinbach, and his discussion on genomics and bioinformatics combined, looking particularly at revolutionising the healthcare system by developing customised and personalised medicine.

After lunch, Frank Slack of Harvard University ended the track with a discussion on developing and using the polygenic risk score to enable the generation of and access to more genomic and quality phenotypic data.

PERSONALISED/PRECISION MEDICINE

The personalised/precision medicine track began with a conversation around accelerating research in precision medicine through meta-analysis, transcriptome data analysis and RNA-Seq data analysis, run by Transcode Therapeutics' Oliver Steinbach. Following this, Tyler Hulett of CDI Laboratories Inc. spoke with others on the antigen-specific revolution, and whether it is possible that patient antibodies hold the answers to some of precision medicine's biggest challenges.

The track's final talk of the day involved a discussion around ways to reduce overspending on prescription and pharmaceutical research, as well as in precision medicine. Charlie Pak, Syros Pharmaceuticals' VP of New Product Planning, began the discussion by debating at what point companies bring in a commercial aspect to their processes.

The delegates agreed that often companies differ a lot in where they decide to bring in a commercial aspect: in small companies, it largely happens in phase 2, when drugs become "pivotal". It was agreed that companies must conduct an "opportunity assessment" to determine the commercial aspect of value versus interest regarding biomarkers.

Delegates also noted that, from a commercial point of view, there should not just be a drive for the "most patients". Instead, companies must run figures and set up trial criteria based singularly on the level of response. Luckily, companies can get a proxy number of patients fairly easily, and decide how many patients they need from this.

Another point raised was that it is vital to create an internal reason why you will have a commercial advantage: if not, it is not worth continuing a trial.

The final topic raised in the conversation was regarding cell and gene therapy, and its viability. One delegate noted that it was being actively tested, though lots of complexity remained around reimbursement.

CHECKPOINT INHIBITORS

The track on checkpoint inhibitors began with a meta-analysis on the efficacy of PD-1 or PD-L1 inhibitors and PD-L1 expression status in cancer, facilitated by Jonathan Pachter of Verastem Oncology. The second talk in the track was led by TESARO's Martin Huber, and focused on targeting the SIRPA gene to control myeloid-derived suppressor cells and tumour-associated macrophages.

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3 KEY DELEGATE CHALLENGES

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 prior to our 2019 event, 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

BIOMARKER DISCOVERY

By far the biggest challenge for surveyed delegates proved to be biomarker discovery: when asked, experts mentioned that they had concerns around identification and analysis of biomarkers generally, as well as ensuring data quality around biomarkers and biomarker assay validation.

PATIENT SELECTION

Patient selection was another significant challenge for those within the oncology space, with experts noting that industry challenges in the area included enrolment, stratification, patient diagnostics and getting inexperienced patients to trial.

IMMUNO-ONCOLOGY

The fledgling IO space also proved a major challenge for oncology experts looking to the near future. Specific worries about IO were many and varied, but some particular concerns included CAR-T decisions, precision medicine in IO, IO biomarkers and resistance to IO therapies.

CLINICAL TRIALS

Issues around the varied clinical trial phases are a continuing challenge for experts in the oncology field, with challenges including difficulties around multiple phase 1 trials; design and execution of trials; improving the design of trials; and indication selection.

COSTS AND RESOURCES

Limitations of cost and resource are a continuing challenge in all areas of the pharmaceutical area, and Proventa's surveyed proved that the oncology field is not spared these difficulties. Among other things, experts cited resource prioritisation and modelling as two challenges they perceive in the years ahead.

HIRING AND TRAINING STAFF

As with all areas in the life sciences, hiring and training skilled and efficient staff is a difficulty few have solved yet. The surveyed experts noted particular challenges looking for individuals with both a bioinformatics and oncologically-trained background.

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DATA

Data analysis, quality of data, general data integration and issues around privacy were some of the many concerns experts had around data for the years to come. Others mentioned involved development of new analysis strategies, the integration of F.A.I.R. data and the applications of real-world evidence and big data.

OUTSOURCING AND PARTNERSHIPS

While concerns were raised about external collaborations with either paid third parties or with other pharma enterprises, the issue posed less of an immediate challenge in oncology, it seemed, compared with some of the other areas Proventa surveyed. Nevertheless, experts did mention concerns around new models for outsourcing, impactful collaborations with other pharma giants, and finding the right partner for a CDx assay.

IND FILING

The last difficulty mentioned by a significant amount of experts involved filing Investigational New Drug applications. Experts noted concerns involving comparability studies of pre-IND to IND work, preparation for IND applications, and the initiation of IND-enabling studies.

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EXPERT OPINION ON THE FUTURE OF ONCOLOGY

More than some other fields within the pharmaceutical space, the oncology field moves and evolves rapidly. The highly innovative field has seen huge changes in the last few years, which seem to show no signs of abating - and companies have noted this, with giants including Merck and AstraZeneca moving further into the space most recently.

With CAR-T and immuno-oncologic therapies only just beginning to show their full potential, oncology is a space with a huge amount of promise. To better understand the most innovative oncologic areas over the coming years, we spoke to experts and facilitators at the Proventa event to find out which topics will be the ones to watch.

BIOMARKERS AND PERSONALISED MEDICINE

A VP in molecular biology mentioned biomarkers as an important topic for the next few years, with further research set to give a more detailed understanding of patient response. She said it would fit the trend that “not one size of treatment fits all”, especially in immuno-oncology. This would lead to further discussions around how patients are treated, and better rational designs in combination trials.

Another facilitator argued that the first step in precision medicine was to nail down the meaning of the term, saying the precise idea of it isn’t sharp yet.

One delegate, a vice president in non-clinical and translational research, stressed that the challenge still remained around cost: what is the patient willing to pay for? In addition to this, once personalised medicine is instituted, how does one pay for and charge for personalised medicine? These are some of the questions that remain to be determined as the push to precision and personalised medicines continues to advance.

ONCOLYTIC DRUGS

Several facilitators mentioned oncolytic drugs as a promising innovation, with a number of forward-thinking companies mentioned as working in this area. One noted that more and more fields with increasingly limited options will begin working with oncolytic drugs, as is currently the case in rare disease.

DATA INTEGRATION AND ANALYSIS

One facilitator, a VP of research and development, said that one of the big innovations over the next five years will be improvements in data analytics and data integration, for example integrating genomics, medical imaging, medical history, lifestyle and variable sensors.

DATA COMPANIES ENTERING HEALTHCARE

The same facilitator mentioned that the future of oncology could well be dominated by unexpected companies in data analytics, storage and retrieval, for example Oracle, Google and S.A.P. He said that while currently such companies are missing clinical expertise and contacts, they have the money to buy it in. These companies, with their ability to handle large datastreams and analytics well, could be major competitors in the near future.

NEW COLLABORATION MODELS

One facilitator said that given cost pressure, industry must in the near future find new collaboration models. He noted that the current model is to attempt to bring everything in-house, providing significant investment and infrastructure, but hoped that in future joint clearing houses could be created for data, where data is input and companies could then use it for their own purposes.

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