PHARMACOVIGILANCE

REGULATORY AFFAIRS

2020 : A LOOK AHEAD

Part of Proventa International's U.S. PV and Regulatory Affairs Strategy Meeting 2019 Le Méridien, Cambridge, MA - 20,21 November 2019

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

HIGHLIGHTS FROM ALL OUR TRACKS THIS YEAR

TOP STRATEGIC CHALLENGES FOR PV & REG AFFAIRS, 2020 AND BEYOND

AN EXPERT LOOK AT THE NEXT FIVE YEARS IN PV & REG AFFAIRS

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INTRODUCTION

Proventa's complimentary meetings around pharmacovigilance on one hand and regulatory affairs on the other have now concluded for another year. Both events were huge successes, providing delegates with a valuable and unique roundtable format to discuss key challenges and solutions with their peers as well as a perfect space to network and connect with other experts and leading figures in their industry,

Talk topics in both events focused on real, cutting-edge issues in the pharma space. In Proventa's PV event, experts discussed the solutions presented by the growing fields of AI and innovative technology, while in Regulatory Affairs topics included RIM and data management, change control and labelling.

THE FUTURE OF PV AND REGULATORY AFFAIRS

Highlights of the recent events are only one part of this report's objective. In writing this we also hope to provide even more useful material that looks at the future of the two sectors, with information not only on what our delegates are currently investing in but expert opinion from facilitators at our recent events discussing how the two areas will develop over the next five years.

There is a wealth and variety of information packed into the pages of this report: we hope you find them of interest and use, and enjoy your time reading.

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1.1 DELEGATES BREAKDOWN
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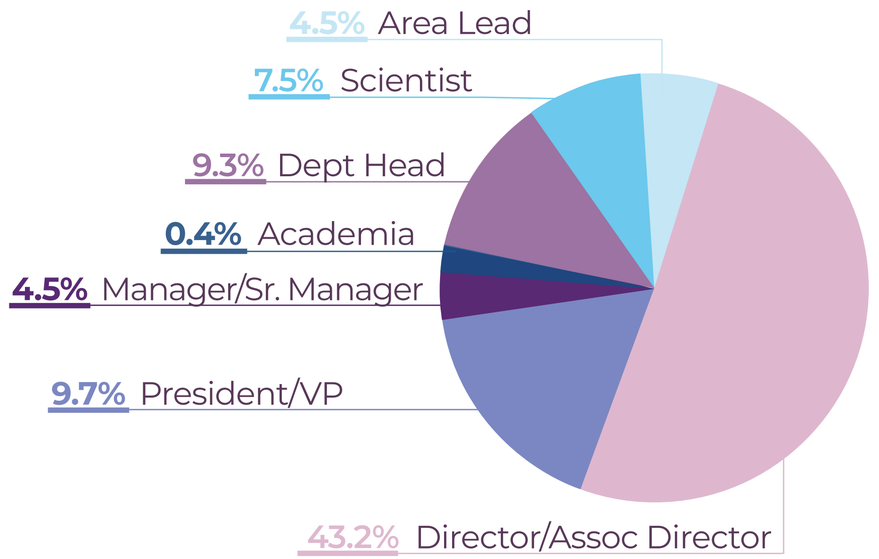
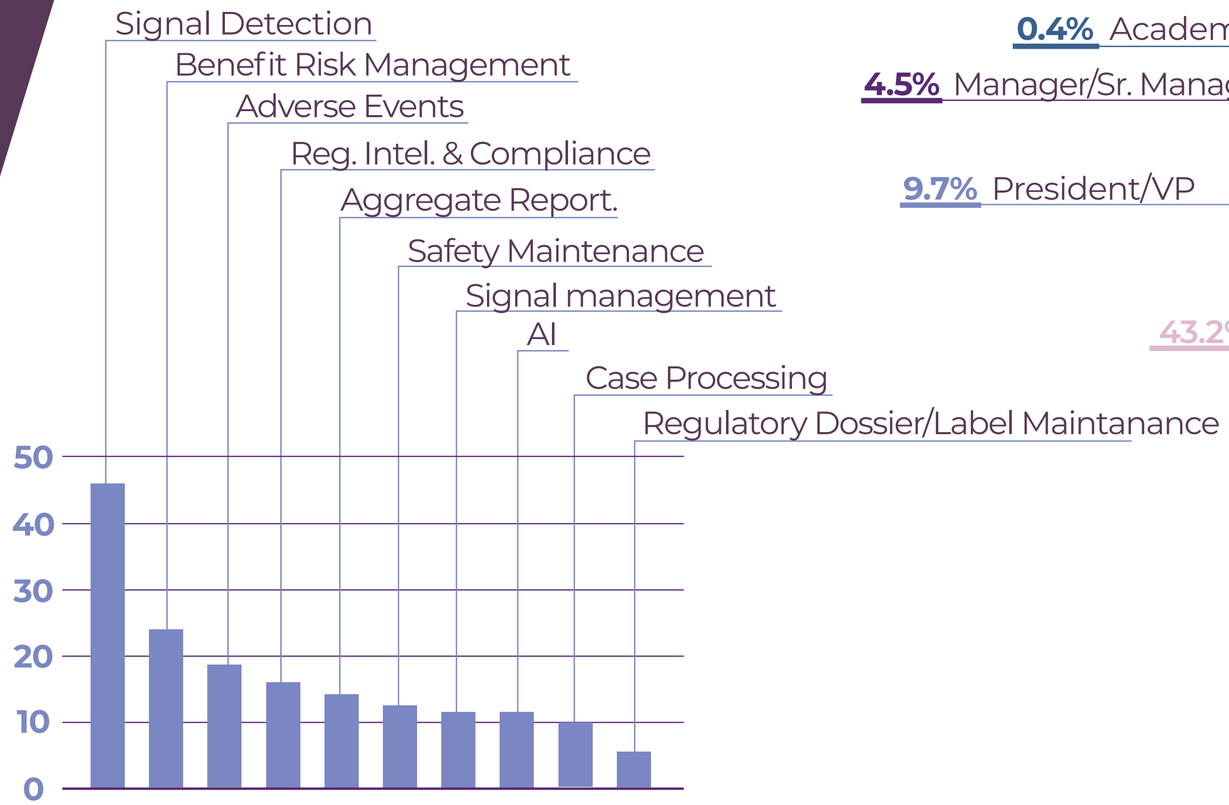
2019 ATTENDEE BREAKDOWN



2019 DELEGATES BIGGEST INVESTMENTS



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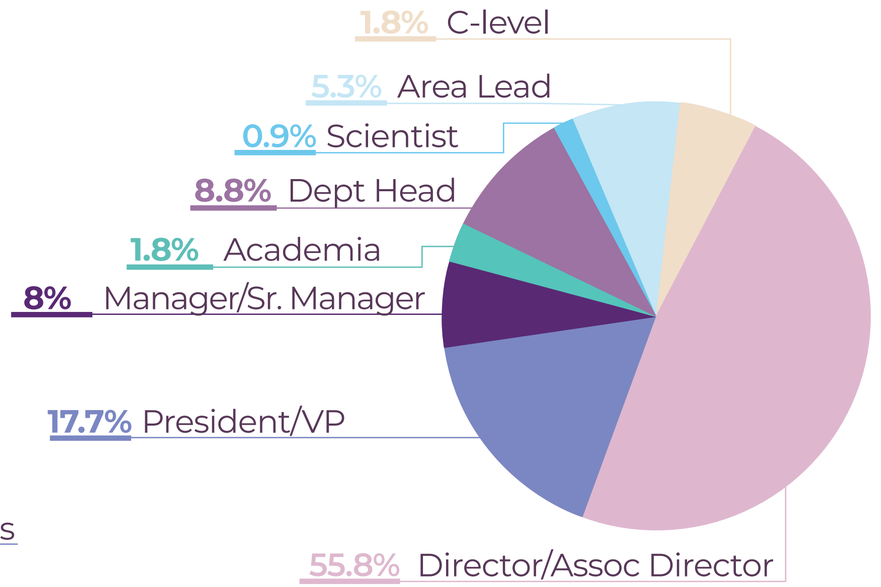
1.2 DELEGATES BREAKDOWN
REGULATORY AFFAIRS

2019 ATTENDEE BREAKDOWN



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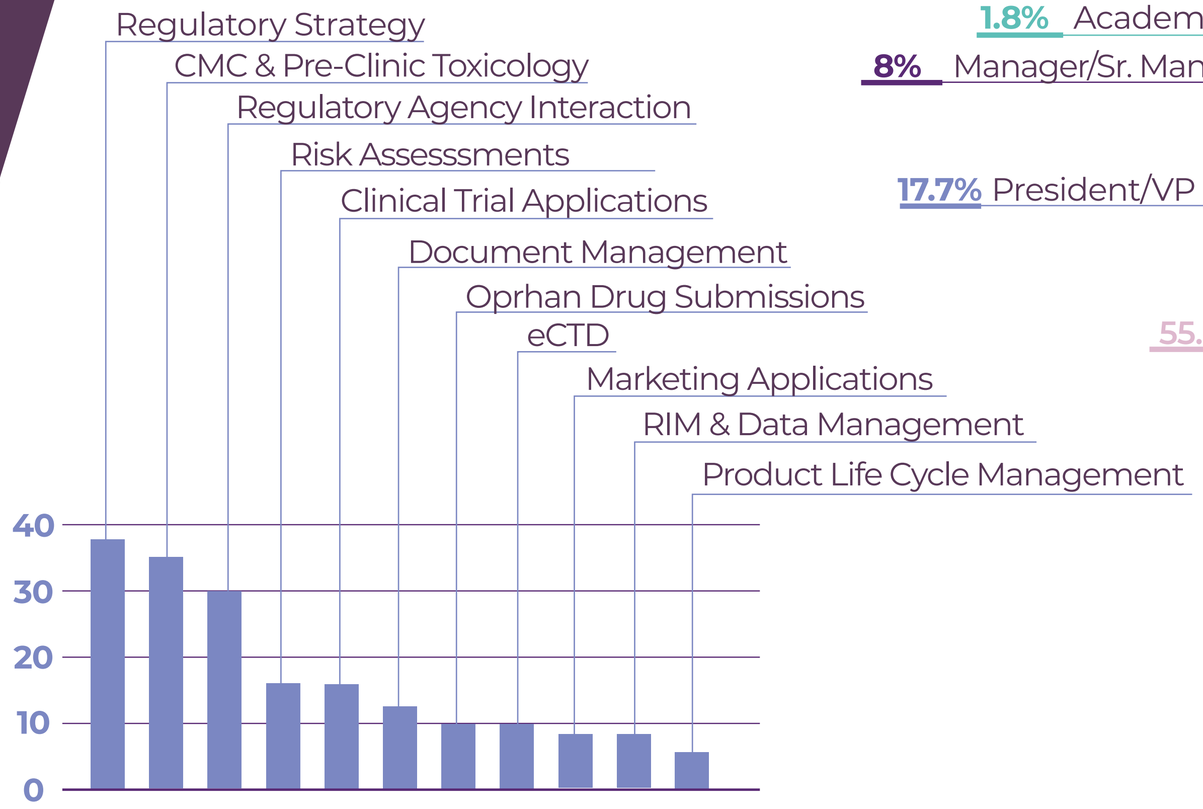

2 KEY DELEGATE CHALLENGES

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 PHARMACOVIGILANCE CHALLENGES - 2020 AND BEYOND

SIGNAL DETECTION

Signal detection, particularly in clinical trials, was by far the most pressing challenge facing delegates surveyed. Specific examples of challenges facing experts in the PV field included establishing a signaling process, signal detection in development and improving signal detection in PV data.

RISK MANAGEMENT

Risk management was another area widely agreed on as a significant challenge within the industry, with delegates citing more specific challenges including risk management plan optimisation, application of the principles of risk management and building a benefit-risk management framework.

SAFETY

Safety database optimisation, oversight of the safety compliance process, better understanding safety information as it comes in and improvements in the quality of safety analysis were all set out by surveyed individuals as considerable challenges for the near future.

REGULATORY/COMPLIANCE

On a related note, wider regulatory issues were also regarded as a considerable challenge by many in the PV industry. General regulatory strategy, an understanding of the regulatory landscape, submission of documents and safety regulations in China were all cited as being considerations for the coming years, with few yet having the solutions to satisfactorily solve them.

STAFF HIRING AND TRAINING

General recruitment of skilled individuals and the problem of changing staff were two issues cited by experts around hiring and training employees. Retention seemed a particular issue that had raised concerns for a number of experts.

AI AND NEW TECHNOLOGIES

A number of experts when surveyed mentioned the need for AI, machine learning and automation in the near future. Despite this, new and innovative technology seemed a less pressing issue in the area of pharmacovigilance than it has in many other areas, such as bioinformatics or medicinal chemistry, with fewer delegates overall citing the issue as a major challenge in the years ahead.

AGGREGATING REPORTS

Report aggregation was a challenge cited by several of those surveyed, with particular mention of improving the aggregate reporting process.

QUALITY CONTROL

Finally, several delegates noted that quality was a further concern for the near future, particularly around quality assurance, improvements in the quality of safety analyses and ensuring quality in case reports.

MAJOR REGULATORY AFFAIRS CHALLENGES - 2020 AND BEYOND

STRATEGY

Overall strategy was cited as the most important challenge of the upcoming few years, according to surveyed delegates: effective strategic implementation, efficient global regulatory strategy - particularly around due diligence for complex programs - and general digital strategy were all cited as particular challenges facing experts in the years ahead.

CMC

CMC-related issues were also one of the top challenges for the next few years, delegates agreed. Specific parts of the area causing difficulty included CMC dossier global updates, requirements for expedited approvals, challenges of CMC in biological product and lifecycle management of CMC.

IND APPLICATIONS

As with many other areas, Investigational New Drug (IND) applications are causing a number of issues within the regulatory affairs field, and seem set to continue for the foreseeable future. Specific mentions by delegates included: pre-IND strategy, IND amendments for gene therapy product, and developing successful IND applications to support FIP.

REGULATORY REQUIREMENTS

Requirements from regulators were a challenge for a number of delegates surveyed, with multiple overlapping regulatory requirements, regulatory harmonisation for pharmaceutical products in ASEAN, and regulatory agency interactions all mentioned as particular difficulties for the foreseeable future.

OUTSOURCING AND PARTNERSHIPS

While outsourcing to third parties and partnerships with other pharmaceutical companies was named as a difficulty for a number of delegates, it was mentioned less than in several other surveys undertaken by Proventa: it seems delegation to external companies has less impact in the regulatory space than in more clinical areas. Nevertheless, partner management and interactions with CROs were mentioned several times as areas that will continue to pose a challenge over the next few years.

QUALITY

The need for improvements in quality culture, assessment, systems and assurance came up several times in the course of the survey, suggesting another challenge that delegates will have to face in the years ahead. Quality issues at CMOs were also pointed out as a difficulty faced by pharmaceutical experts.

END OF PHASE 2

The most difficult part of the clinical pipeline from a regulatory perspective was, for most delegates questioned, the end of phase 2 and the beginning of late-stage clinical trials: this was mentioned numerous times as a specific challenge facing those attending Proventa's regulatory affairs meeting. Clinical efficiency and safety were mentioned as further trial challenges, as was globalisation of clinical studies and interruptions in clinical and commercial supply.

NDA PLANNING

Planning for the FDA's New Drug Application (NDA) process was a considerable challenge for several delegates, who pointed out pre-NDA meetings, supplemental NDA submissions, NDAs for drugs with novel MOAs and ensuring preparation of NDA CMC sections as particular areas of difficulty.

AI AND INNOVATIVE TECHNOLOGIES

AI and other new innovative technologies were also a challenge that saw less mention than might be expected: nevertheless, the area did come up as a major topic for the next few years in regulatory affairs, with delegates specifying AI and digital technologies in clinical trials and the legal challenges of AI as issues to be aware of.

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3 A LOOK AHEAD

EXPERT OPINION ON THE FUTURE OF ONCOLOGY

EXPERT OPINION ON THE FUTURE OF PHARMACOVIGILANCE & REGULATORY AFFAIRS

Adverse drug reactions make up around 7% of all hospital admissions in the US, with half of these thought to be avoidable. Due to increasing pressures on the pharmacovigilance sector to analyse information more swiftly, report patient reactions more accurately and cover greater areas more efficiently, much must change in the coming years in order to meet targets and ensure as many patients are kept safe as possible.

Issues remain that must first be overcome. Many companies are at present allocating greater spend to processing data rather than analysing it, with the processing of this adverse event data costing more in both money and resource requirements, and becoming less sustainable, with each month that passes.

AI and automatic processing of data are generally seen as the solution to these issues, allowing companies to produce more clear and specific reports of safety problems and intervene more quickly where patient safety is threatened. Such tools will also hopefully encourage greater transparency in the industry, and decreases costs by half.

To find out more about the future of PV and Reg Affairs, we spoke to some of the expert facilitators at Proventa's two recent strategy meetings, to hear their thoughts on the technologies and processes that will change the field over the next five years.

REGULATORY OPERATIONS

A major point of interest within regulatory operations, one facilitator said, was in regulatory information management. This has in recent times moved from task-based management, e,g, publishing and performing activities, to a more strategy-based operational system.

GLOBALISATION

One expert, a head of regulatory affairs and quality assurance, noted that an increasing trend is companies expanding their scope to become more global: many are looking to streamline their development process and easily implement reforms to better move to the global stage.

This drive for globalisation naturally affects different-sized companies differently, she said. Most large companies are already ready for globalisation, as they start out with that mindset. It varies with medium-sized companies, with many focused at the moment only on the U.S., but looking to change slowly in the next few years. Globalisation is a problem for most small companies, she said, who may want to grow but lack the fiscal and human resources to do so, having instead to choose their battles. It still benefits them, however, to understand how taking such a step could be valuable to their company.

OPTIMISATION AND PRICING REFORM

The facilitator said that one of the biggest challenges and potential changes in the years ahead will revolve around optimising inefficient systems and reforming drug prices. Both internally and from regulators, pharmaceutical companies face a great deal of pressure to optimise and respond to regulatory changes.

She noted that the U.S. will possibly move away from the current free-for-all charging system, with reforms set to have a major impact on industry. Should such reforms go through, companies may have to make a decision about which areas they want to stay in, and on whether or not to pursue certain development pathways.

She warned it is currently uncertain how the reforms will fall, but added the effect will be markedly different for large and small companies, as well as for different development areas. Innovative drug programs, such as gene therapies, have a very small pricing margin: reforms will hit these areas hard. In other areas, companies often argue they charge so much because they're paying for failures, and only taking risks in such areas because they can make that money back should they find a success. With less incentive to take risks post-reform, many companies will stop working in risk-heavy areas like Alzheimer's.

This change would eventually cause a pendulum shift, however, as regulators currently do for orphan drugs: exceptions would be made for areas now lacking in research and development, ensuring a continuation of some research into cures there.

BIG DATA

One facilitator suggested a major focus of the near future will be the gathering and utilisation of big data, and the rapid validation of that data, helpful particularly with the training of and experimentation around AI using binary language and elements of quantum computing.

To facilitate this change, the delegate suggested that professionals would need to become more accurate with how they use and analyse data, though this is changing now.

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