PHARMACOVIGILANCE

Insights from the Industry

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Introduction

Over the last two years, Pharmacovigilance has truly moved to the mainstream of the life science industry. With a public that has survived a pandemic and multiple health-related controversies, health literacy and drug safety awareness has risen exponentially. This has translated to a greater emphasis on ensuring not merely therapeutic efficacy, but also safety during the drug development cycle. The workload placed upon the existing pharmacovigilance infrastructure has therefore multiplied - and new technologies are needed to adjust to this new reality. Chief among these remains Natural Language Processing, which featured prominently in our Strategy Meetings in Boston and London.

The field also seeks to harness the potential presented by developments in real world evidence and novel risk minimization strategies, while new methods for signal management and case processing remain in everyone's minds. These and other trends were discussed at our meetings, in our unique roundtable discussions facilitated by world-renowned experts. The common theme in truly advancing the novel technologies that professionals are hoping will transform the field remains the need for breaking down barriers to collaboration and the fragmented landscape of the industry - which was also discussed at length. These and other topics will be touched upon in this report - which we hope you will enjoy reading.

The Editorial Team
Proventa International

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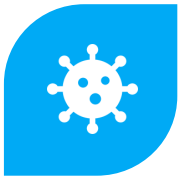
1 AI & Intelligent Automation

Professionals in pharmacovigilance are looking at ways to integrate AI technologies in their workflow, particularly for data entry regarding adverse event case reports. AI is expected to exponentially increase the bandwidth of data that can be dealt with, while lessening costs and shortening timelines. The most interest has been in Natural Language Processing (NLP) technology.

2 Data Harmonization and Integration

Related to exploiting novel technology, peers are concerned about the data landscape for drug safety and drug regulation. Training AI models will be a challenge, and improved data harmonization and integration across the industry will be required to develop models that are applicable throughout the field. Harmonization also promises to accelerate development in the field overall.



3 COVID-19

COVID-19 may not be as pressing a concern in 2022 as it was earlier in the pandemic, but the transformational impacts it has had on Pharmacovigilance cannot be understated. Peers seek to replicate regulatory and drug safety successes seen in COVID-related therapeutics, but also avoid the pitfalls and public controversies some of these, particularly vaccines, have suffered. Improving on the collaborative standards established to fight COVID, while also dealing with a more health literate public as a result of the pandemic are also urgent concerns.

4 Precision Medicine

Precision medicines, particularly immunotherapies and oncology therapeutics, introduce new complexities to the field of pharmacovigilance. Establishing safety guidelines and protocols appropriate for more targeted and precise treatments present new challenges - particularly as they require a precision approach in pharmacovigilance as well. Overcoming this challenge will be key to accelerating the growth of novel therapeutics.

5 Proactive Signal Detection

Proactive signal detection will be crucial in promoting quicker development lifecycles in pharma, and regulators are expecting more proactive efforts in the prediction of adverse events. While not yet mandatory, proactive signal monitoring is part of Good Vigilance Practice standards; many hope to integrate the use of AI and Machine Learning to improve adverse event prediction.

TOP 10 Challenges 2022: What Peers are Focusing on

6 Patient Centricity

Patient centricity is a concept that has been firmly established in pharmacological mainstream as a result of the pandemic. The same is true for pharmacovigilance. Partnering with patients for self-reporting, analysis and communication can not only save resources, but it can also build trust and improve patient retention - but navigating a way to do so without compromising results is a question many seek to address.

7 Process Improvement

Applying process improvement practices to pharmacovigilance is not a novel concept - having been floating around for the last few years. Continuously reviewing workflows and assessing the costs-to-benefit ratios of the overall process will be critical in ensuring the increased demands on pharmacovigilance stakeholders are met as efficiently as possible, and many companies seek answers in how to facilitate such improvements.

8 Real World Evidence

Real World Evidence promises new treasure troves of data for improving drug safety and taking advantage of novel, more complex biomarkers enabled by smarter technologies and wearables. Integrating signals from such data has the potential to deeply enhance good practices, but the raw amount of data produced can often be daunting.

9 Quality Improvement

Improving standards for pharmacovigilance is a never ending, continuous process. Many seek to integrate novel technologies, increased patient engagement, an abundance of data used in better ways to enhance the overall quality of their results - though the ways to do so are often difficult to implement.

10 Effective Regulatory and Industrial Collaboration

Collaboration remains key to overcoming all other challenges listed here - and overcoming silo mentalities will be pivotal in doing so. Many are also anxious to see increased dialogue with regulatory authorities, as well as increased levels of expertise on the regulatory side to ensure that public regulators can cope with the increased adoption of new technologies.

AI For Pharmacovigilance - Insights from PharmaFEATURES

As the industry develops more precise and complex drugs and treatments, the data generated regarding safety and adverse events, as well as individual case safety reports, also rises exponentially. Finding innovative and novel ways to handle the increased volumes of data is one of the challenges facing the wider field of pharmacovigilance. Cutting-edge technologies based on Artificial Intelligence (AI) promise to revolutionize how we handle this data, as well as overhaul the typical work and career paths for pharmacovigilance professionals. In this article, we will briefly explore the possible applications, and impacts, of increased AI adoption on pharmacovigilance.

The Nature of Pharmacovigilance

The building block of ensuring drug safety is the reporting and handling of Adverse Event (AE) reactions to treatments – these can be recorded from a diverse array of sources, such as patients presenting AEs in clinical trials or hospitals, or even reporting side effects on social media. The management of AEs involves a great deal of repetitive tasks – which can be well suited for AI to handle. These include multiple stages of the AE handling process: from the intake of reports, to patient followup, reviewing and reporting results to regulatory authorities.

While the processing of AEs may involve a great deal of repetitive, administrative tasks, it still requires significant decision-making capabilities in assessing each adverse event, which makes automating the process more challenging. AI with decision-making capabilities holds the potential to change this.

Applications of AI in Pharmacovigilance

Deep learning (DL), machine learning (ML) and natural language processing (NLP) models have been the aspects of AI that have been the most investigated for applications in pharmacovigilance so far. NLP remains particularly important in pharmacovigilance due to the variability of case reports for AEs – unlike other areas of the life sciences which may exhibit much more standardized terminology. Celgene, a Bristol-Myers Squibb subsidiary, developed ten cognitive services which scored over 75% in evaluating spontaneous individual case reports, which it hopes will enable a more proactive stance to drug safety. Celgene went to great lengths to reassure pharmacovigilance professionals that the models will support their decision-making, rather than replace them. This belies the worries that often come with AI taking over any processes that were previously carried out by humans, in any field.

Pfizer has also innovated a pilot study for the use of AI in AE case processing, limited to Italy. The study focused on extracting AE information from report document sources, as well as the use of databases rather than the direct and expensive annotation of source documents. The study confirmed the feasibility of AI in these applications, while also noting that larger training datasets would better improve quality. The pilot run by Pfizer only demonstrated the possibility of automating AE case processing rather than identifying cases for regulatory submission. While the pilot was successful in demonstrating how AI can support pharmacovigilance, further improvements will be needed for implementations that can carry out regulatory functions.

Regulatory Applications of AI

The implementation of AI in pharmacovigilance need not be limited to drug developers – regulators can also make extensive use of the technologies. For example, the American FDA is carrying out extensive work on machine learning models that can predict adverse events for new drugs based on post-market data for marketed drugs. This is done through the known safety profiles of previously approved drugs, using chemical similarity scores for the novel treatments.

Predicting AE profiles for novel drugs also holds promise for drug developers themselves; clinical trials often fail to capture the full breadth and depth of a drug's safety profile. However, current models remain somewhat limited in their capabilities to predict secondary AEs which do not have a well-characterized causative basis. Better target prediction and drug binding data will naturally improve any such model, providing more mechanisms of action to draw upon to predict effects.

Obstacles for Adoption

The key obstacles for further AI uptake in pharmacovigilance are similar to other areas of the life sciences. One of the defining features of AI, and ML in particular, is that it does not truly provide explanations or interpretations for its reasonings – often operating as a "black box". While this may be acceptable in other industries, healthcare decision-making must come with justifications – particularly when we consider that patients may have to provide their consent for their data to be used by AI.

This also shows the legal questions that greater adoption of AI will raise; questions of liability for wrong decisions and data management failures will need to be addressed, and regulators must establish frameworks within which AI technologies will operate in the field. Training new algorithms is also not without its difficulties – particularly when we consider the heterogeneity and fragmentation of AE and healthcare datasets that are needed to train them. Greater standardization and data sharing would enable further success in this area – although privacy and consent issues arise from data sharing, as well.

Pharmacovigilance also requires greater versatility than other applications that AI may be implemented in. While AI algorithms can excel at solving narrow problems, advancements will need to be made in their general capabilities before wider use of the technologies truly happens in vaccine and drug safety. This is particularly important when we consider the noisy and often randomly incomplete data that will be encountered in pharmacovigilance scenarios, although improvements in data collection and curation will likely alleviate some of this.

We see that AI holds deep potential for improving drug safety – not only through monitoring adverse events, but also predicting the safety profiles of novel drug candidates. While obstacles may be present on the path to adopting AI in pharmacovigilance, one could also see them as opportunities to rethink and modernize the field of pharmacovigilance as well. There is no longer much need to adhere to 20th century standards for individual case safety reports, or generate fragmented datasets.

Read more on the latest trends in the life sciences industry on **PharmaFEATURES**

TOP Investment Areas 2022

Proventa asked delegates at its events to speak about their investments for the coming year. Those surveyed emphasized the need to improve established processes, increase cost efficiencies, harness novel AI technologies, as well as facilitate more robust collaboration.

Signal Detection and Management

Peers are actively investing in novel ways for signal detection and the management of such signals, particularly in combination with new technologies and improved standards. The earlier signals are detected, the better they can be handled. Emphasis on post-market signal detection is also increasing. Lowering costs for the overall process is crucial, due to the increased demands placed upon the industry as regulators and the public raise their expectations.

Benefit-Risk Evaluation

Delegates remained concerned in finding the right balance between benefit and risk for each medicine - the ultimate goal of the pharmacovigilance field. Investing in new tools to better handle the process is high on the priority list, particularly as we see a growth in novel treatment modalities and an expansion in indications and therapeutic areas being handled - for which toxicity and tolerability profiles are not well established.

Adverse Event Reporting and Handling

Managing adverse events, the cornerstone of the industry, remains a crucial area of investment. As new methods arise to report adverse events - from novel technologies, self-reporting, to predicted adverse events, peers seek to improve their own methods for assessing and processing such data. Collaborating with partners who can aid in this endeavor remains important.

Consulting

Continuing the pattern seen in the post-COVID pharmacovigilance world, many delegates seek closer collaboration and advice on how to achieve it. This has led to an increased investment in consulting services and partners, as firms seek to better understand a drastically changed market landscape while tackling novel challenges.

Artificial Intelligence and Machine Learning

Natural Language Processing (NPL) technologies took up a lot of airtime in our own events, as peers hope to understand the new technologies and partners who can provide reliable models to suit their needs. Text mining and case report processing are two crucial applications of the technology. Machine Learning also remains relevant, particularly with regards to adverse event prediction.

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Real World Evidence

Delegates sought to understand how to best integrate Real World Evidence (RWE) and the technologies that help gather it through our own events, but also their own private endeavors - investing heavily in the subject as it firmly establishes itself in the mainstream of the clinical operations and pharmacovigilance space.

Medical Writing

The increased demands placed upon the pharmacovigilance industry have also seen a growth in the medical writing industry - as expected. More delegates report increased investment in medical writing, both in-house and towards dedicated communications agencies. This space is expected to grow, particularly as we see a more health literate public that demands improved medical communications.

Aggregate Reporting

Delegates report an increased emphasis on investing for improved aggregate reporting. While individual case reports remain important, aggregate reports provide more informative overviews and facilitate improved communication with regulators. Delegates seek to improve the expediency and efficiency with which aggregate reports are produced, particularly as aggregate reports remain crucial for high quality benefit-risk analyses.

Literature Screening

Literature screening can provide informed insights about compounds, or classes of compounds, with the vast scientific knowledge base available presenting a treasure trove of data for drug safety. However, delegates seek to invest in technologies that can make bigger literature analyses feasible - with technologies such as NLP being touted as the solution.

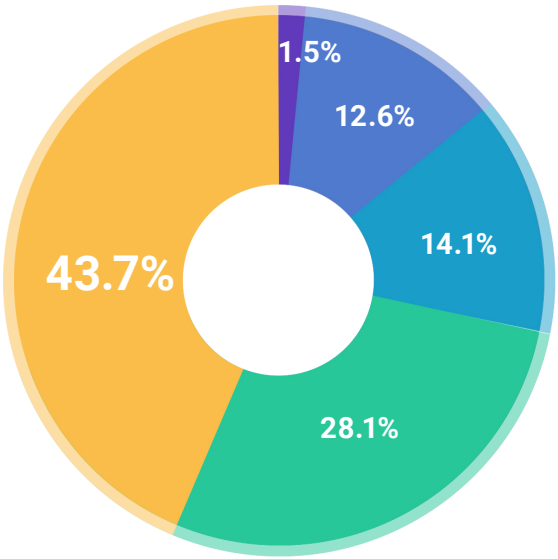
Safety Database

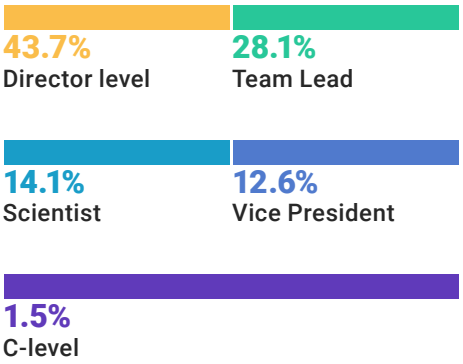
Delegates sought to invest in the latest and most robust safety database solutions, particularly ones that can keep up with regulatory requirements, data privacy and business regulation requirements. Establishing agile, adaptable solutions that anticipate forthcoming regulatory changes will be crucial as peers seek to navigate the changes.

Delegate Breakdown:

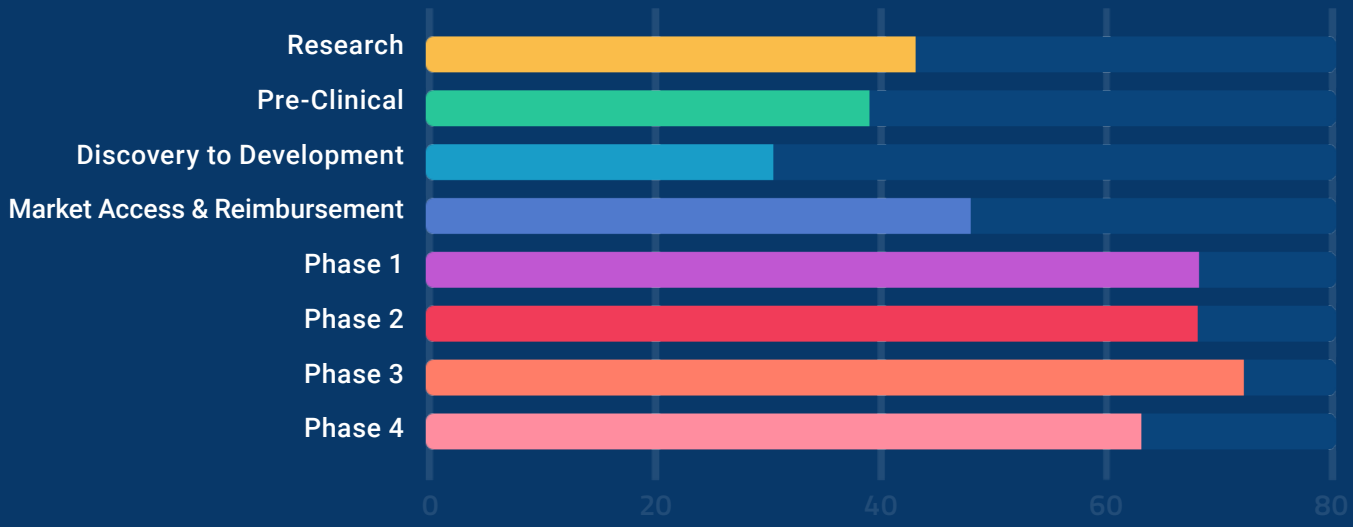
Attendees at Proventa's 2022 Strategy Meetings

2022 Atendee Breakdown

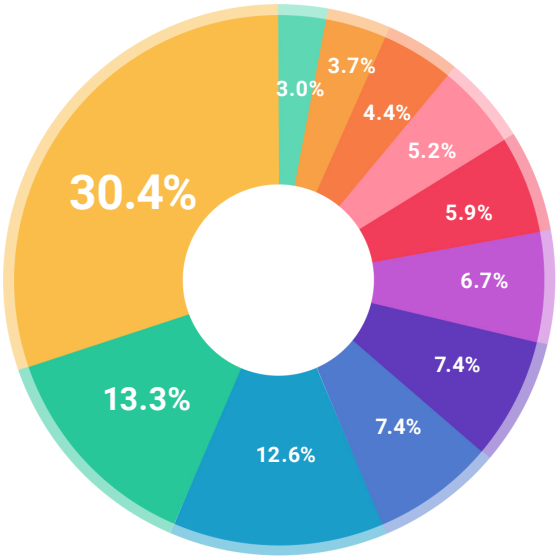




Drug Development Stages



Therapeutic Areas



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