INDUSTRY

Life Sciences & Healthcare

CHALLENGES

Adverse events (AEs) cases arrive at volume through multiple channels in multiple formats

Human assessment of Individual Case Safety Reports (ICSRs) is inefficient, error-prone, and expensive

Stringent reporting regulations for safety issues and adverse events cannot be missed

KEY BENEFITS

Automated ICSR intake by data integration from all safety channels

Enables reliable, timely adherence to regulatory Safety/PV requirements

Safety/PV data made available quickly and more efficiently

Safety and Pharmacovigilance (PV)

UNIVERSAL CAPTURE AND REPORTING OF PV DATA

SUMMARY

The realm of Pharmacovigilance (PV), the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem is driven by data. Adverse events can be reported in a variety of ways from multiple sources, including formal Individual Case Safety Reports (ICSR), fax, email, PDFs, scripts from call centers, clinician reports, and even social media.

The reports arrive at volume, often in incompatible and unstructured formats: and there is the constant pressure to satisfy stringent, time-based regulatory reporting requirements for serious adverse events (SAE).

Anzo enables rapid, on-demand, self-service access to comprehensive adverse events reports and data to meet regulatory reporting requirements and to answer outcomes and treatment questions.

THE CHALLENGE

Simply managing safety/PV data flow itself is a major challenge, and this is compounded by the need to rapidly and efficiently detect, extract and assess the meaning and impact of an adverse event report.

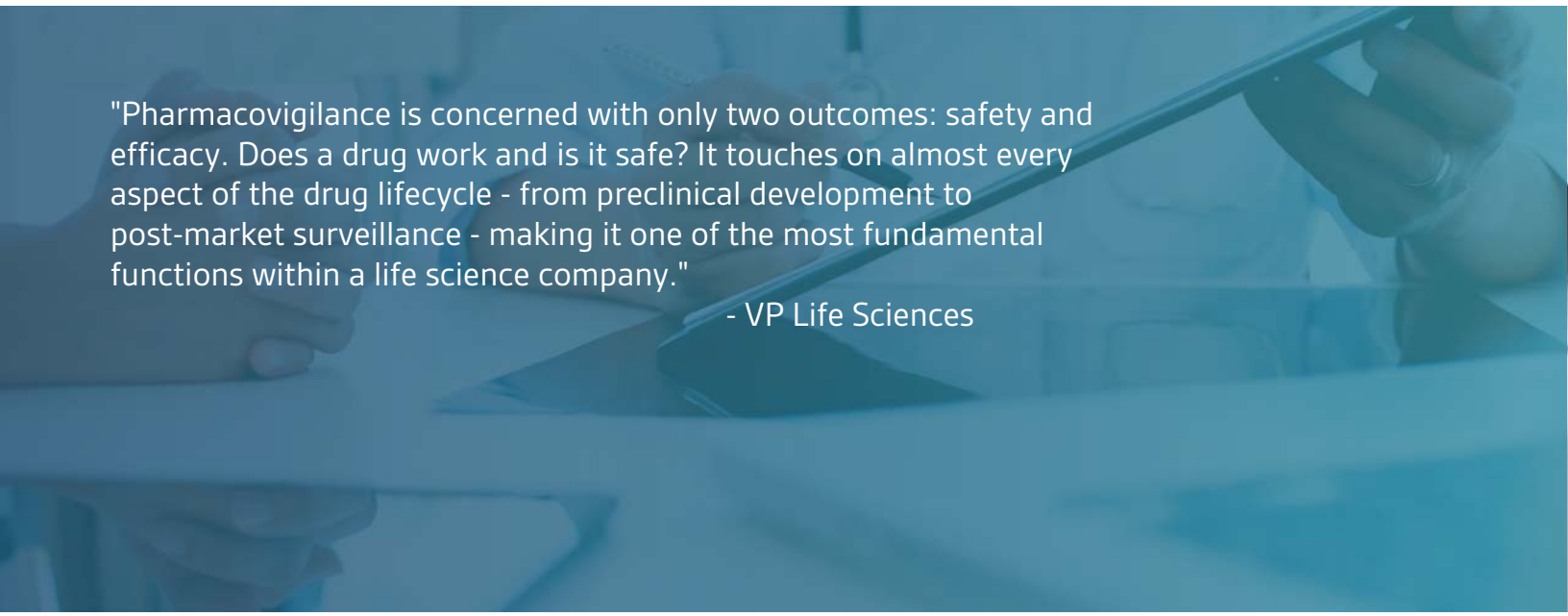
Human assessment is used in many cases. A top-20 pharma company reports employing 500+ SMEs to review incoming safety/PV reports – but this is clearly not scalable, and not 100% reliable. Added to the data management and assessment challenge, is the regulatory requirement to report SAEs to multiple regulatory agencies within strictly mandated timelines. There can be no margin for error as the risks and repercussions of failure are too high.

Traditional data indexing and searching techniques with safety/PV data are just not feasible when complete accuracy is a must, and time is of the essence. The crucial warning signals of an adverse event that need to be linked together could be buried in an unformatted clinician note and a series of call center entries, each in their own impenetrable data silo. Timely access to this safety/PV data is crucial – and in some circumstances a patient health imperative.

THE SOLUTION

Anzo® enables safety and PV staff to flexibly search, navigate, correlate, and analyze all the incoming safety/PV reports, including structured and unstructured data locked away in clinical trial reports, ICSRs, AE call center entries, clinician reports and even social media, for faster insights and accurate, rapid reporting. Anzo automatically integrates source documents, files and other content, whether standards-based or not, and creates a semantic layer driven knowledge graph that categorizes and harmonizes the meaning and relationships of every safety and PV information asset.

Anzo enables the understanding of safety/PV data, operates with unmatched speed at big data scale, uses open standards and provides robust security. Safety and PVI analysts in life science companies are relieved from manually reading and assessing incoming reports and can focus on using Anzo-derived safety/PV data to research better, safer healthcare outcomes. Anzo-derived safety/PV data offers substantial time-savings over using traditional assessment and searching techniques to locate, analyze and report disparate data, and the ability to ask previously unanswerable questions, so that businesses can gain faster, better insights.



"Pharmacovigilance is concerned with only two outcomes: safety and efficacy. Does a drug work and is it safe? It touches on almost every aspect of the drug lifecycle - from preclinical development to post-market surveillance - making it one of the most fundamental functions within a life science company."

- VP Life Sciences

ABOUT CAMBRIDGE SEMANTICS

Cambridge Semantics Inc., is a big data management and enterprise analytics software company that offers a universal semantic layer to connect and bring meaning to all enterprise data. Its software, Anzo®, allows IT departments and their business users to semantically link, analyze and manage diverse data whether internal or external, structured or unstructured, with speed, at big data scale and at the fraction of the implementation costs of using traditional approaches.

Cambridge Semantics is based in Boston, Massachusetts. For more information, visit www.cambridgesemantics.com or follow us on: