A Coordinated Screening and Management System for Effective Large-Scale Literature Monitoring

MEETING PHARMACOVIGILANCE AND MEDICAL DEVICE POST-MARKET SURVEILLANCE REQUIREMENTS
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THE FUNDAMENTALS OF MONITORING LITERATURE

Monitoring literature for product citations would be an impossible task if not for modern research informatics solutions. Corporate, academic and government pharmaceutical and medical research facilities produce in excess of 20 terabytes of data per day. Even with only a fraction of this data making it into peer-reviewed journals and conference proceedings, without the support of dedicated informatics solutions, pharmacovigilance teams and researchers would need to spend incredible amounts of time sifting through heterogeneous data and cross-disciplinary reports before they could gain the required information. There would also be a real risk of missing important data due to the sheer volume of information to be reviewed.

The high volume of literature continually being published can pose significant problems without an effective literature screening and management solution – for example, effective pharmacovigilance and post-market surveillance of medical devices in critical areas, where any mention of a drug or medical device must be identified as soon as possible. Supporting medical affairs and strategic product development would be impossible without in-depth knowledge of how drugs and medical devices appear in the literature postmarket. Have there been any adverse events? Has anyone discovered a competitive strength or deficiency in the product? Has the product been used for applications other than those intended? These are questions that must be answered for your business to be successful.

Importantly, tracking and reporting adverse events is essential for regulatory compliance. The FDA has required registration of adverse events for over 30 years in addition to periodic reporting on the safety, effectiveness and reliability of drugs and medical devices, and new EU guidelines now mandate similar levels of detail in reports.

Insufficient literature monitoring is not solely a marketing and regulatory concern – it can have serious financial and reputational implications. The increasing number of high-profile safety-related drug withdrawals and the growing consumer expectations regarding drug safety have lent pharmacovigilance extra weight. In addition, the recent proliferation of high-technology medical devices that are intended for use by health care workers or patients has heightened concerns about the correct use and safety of medical devices.

An effective product literature screening and triage solution must meet all of these regulatory, marketing and strategic requirements.
HOW CAN LITERATURE SCREENING AND TRIAGE BE MOST EFFECTIVE

To function effectively, all types of biomedical literature must be covered. Pharmaceutical companies and medical device manufacturers cannot afford to miss any product mentions, so their literature screening solution must give access to more than just peer-reviewed journals. Conference abstracts and proceedings, preclinical and clinical trial documents, and patient and healthcare provider reports are all key documents in pharmacovigilance and medical device surveillance.

A comprehensive database alone will not make literature monitoring easy – effective literature screening and triage must support all of the following tasks:

- Monitoring adverse events
- Preparing drug and medical device safety reports
- Tracking company and competitor product information
- Monitoring the latest research and scientific trends
- Informing clinical trial design
- Assessing competitiveness of products
- Ensuring that the literature review process can be tracked in the event of an audit

This requires dedicated features to be integrated, including customizable alerts, RSS feeds and data export tools, as well as the possibility to integrate found data, customer reports and internally generated information in a single, user-friendly, taxonomically organized format.
EMBASE AND QUOSA – THE IDEAL PARTNERSHIP

Embase and QUOSA combine to form an ideal solution for pharmacovigilance, post-market medical device surveillance and product strategy planning. They cover all the required bases – from comprehensive literature access to user-friendly data management. Together, they allow research and information professionals to manage full-text information efficiently, with an unmatched functionality for literature screening, organization, archiving and sharing.

WHY CHOOSE EMBASE?

Embase provides high-quality, comprehensive biomedical information from an ever-growing database that already includes records from over 8,500 journals and 5,500 conferences from abstracts published in journals and journal supplements. Using the Emtree life science thesaurus, literature is indexed with terms including trade, generic and chemical names for drugs, and general and medical devices (e.g., endoscopes, catheters, prostheses) as well as several thousand terms for related medical procedures, (e.g. endoscopy, catheterization). This facilitates the retrieval of product data from a whole range of literature.

Embase supports customizable regular alerts that ensure critical mentions of products aren’t missed, no matter where they appear. Receiving alerts cuts down the amount of time spent on the enormous tasks of pharmacovigilance and medical device surveillance – the information comes to the information manager with userdefined regularity.

Importantly, new European guidelines specifically name Embase as one of the example sources that can be used to search biomedical literature.

WHY CHOOSE QUOSA?

QUOSA is a customizable literature management system that handles both full-text journal and conference content sourced from online literature databases (e.g., Embase) and content from internal libraries and patents. Acting as a central repository of product information, it can be accessed by the whole organization from desktops and mobile devices.

Crucially, QUOSA can automate the literature review and triage process. Articles can be tagged and indexed for proper storage and easy retrieval. Automatic screening and customizable alerts eliminate the need for manually informing the whole organization of new content. QUOSA informs users of new content according to their self-defined requirements.

QUOSA has proven to be a scalable solution that works for both small and large pharmaceutical and medical device manufacturers as well as academic and government institutions. Literature use is fully auditable to comply with regulatory requirements.
HOW DO EMBASE AND QUOSA FUNCTION TOGETHER
Together, Embase and QUOSA provide you with a comprehensive literature screening and management solution that lets you import full-text literature and excerpted data from the world’s most comprehensive biomedical journal and conference database and combine it with information from RSS feeds, internal reports, healthcare provider and patient reports, patents and so on.

Our professional services team advises on the integration of the Embase–QUOSA solution into organizational literature management workflows. The team members have extensive experience, which allows them to advise on best practices for literature management. This facilitates the development of sophisticated search strategies that are customized to particular aspects of pharmacovigilance and medical device surveillance.

The alert functions of Embase help information managers to collect all the data their research colleagues require. QUOSA then informs researchers throughout the organization about new literature that is relevant for their particular tasks.

Embase and QUOSA form a complete, tried-and-tested solution for pharmacovigilance and medical device surveillance – no other solution can match the comprehensive database and full support offered by this excellent combination.
REFERENCES


GET STARTED

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