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A New Approach to Visualize Adverse Events

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ABSTRACT

The life sciences sector is witnessing a paradigm shift driven by emerging technologies that enhance data management and reporting. Among these, advanced data visualization, graph databases, and metadata-driven approaches are at the forefront, offering innovative solutions for handling complex datasets.

Integrating adverse event data from various sources and standardizing it with established medical terminologies improves data accuracy. Graph databases are pivotal in this process, enabling efficient modeling and visualization of complex relationships between data points. They enhance decision-making through advanced relationship mapping, contributing to better patient safety and regulatory compliance. These methods boost operational efficiency and the overall effectiveness of clinical trials.

This presentation will explore the advantages of graph databases, emphasizing their role in modernizing data management and visualization in the life sciences sector. It will demonstrate how graph databases improve the integration and interpretation of complex datasets for enhanced pharmacovigilance and research.

INTRODUCTION

The monitoring and interpretation of Adverse Events (AEs) play a critical role in ensuring patient safety and regulatory compliance in the pharmaceutical and life sciences industries. However, traditional tabular methods often fail to capture the complex relationships between AEs, treatments, and patient factors, making it difficult to identify emerging safety signals.

This paper explores the use of graph-based visualization to transform how AEs are understood and tracked. By leveraging property graphs, which structure data into nodes and edges, organizations can gain a more comprehensive and intuitive view of AE patterns. This approach enables trend identification, improved signal detection, and predictive modeling, ultimately strengthening pharmacovigilance and regulatory reporting.

Furthermore, integrating Standardized MedDRA Queries (SMQ) and FDA Medical Queries (FMQ) with safety databases and preparing structured Development Safety Update Reports (DSURs) creates new opportunities for data-driven decision-making.

This paper explores a systematic approach to analyzing adverse events using graph databases, focusing on the following key areas:

INVENTORY AND DISTRIBUTION

A comprehensive understanding of Adverse Events (AEs) requires an evaluation of their occurrence across different parameters. This includes assessing frequency to determine how often a particular AE manifests, severity to classify events based on their impact on patient health, and distribution across System Organ Classes (SOCs) to identify patterns within specific physiological systems. Additionally, variations in AE occurrence across patient subgroups, such as age, gender, and comorbidities, provide deeper insights into population-specific safety concerns.

TEMPORAL ANALYSIS

Tracking the progression of AEs over time is essential for understanding safety trends and predicting potential risks. By filtering for specific Preferred Terms (PTs), researchers can focus on well-defined adverse events. Evaluating the seriousness of AEs and their relationship to treatment timelines enables the identification of emerging safety signals, ensuring timely intervention. This time-based exploration offers a dynamic perspective on the evolution of safety concerns in clinical trials.

CORRELATIONS WITH MEDICATIONS AND BIOMARKERS

Understanding the relationship between AEs and other clinical parameters is critical for identifying potential risk factors. Graph-based methods facilitate the detection of co-occurrences between AEs and specific medications, helping to establish causal relationships. Additionally, examining abnormal lab values and biomarker fluctuations in relation to AEs can uncover hidden predispositions, leading to improved risk stratification and patient management.

PATIENT-CENTRIC INSIGHTS

A patient-centered approach to AE monitoring enables a more personalized understanding of safety profiles. Utilizing patient timelines allows for tracking AE occurrences in relation to drug administration, providing context for causality assessments. Panels and holon data further enhance this perspective by integrating multiple sources of patient information, offering a holistic view of individual safety risks. Longitudinal analysis supports monitoring of AEs over multiple treatment cycles, ensuring a proactive approach to risk mitigation.

SUBGROUP MONITORING AND COHORT ANALYSIS

Detecting safety concerns within specific populations requires targeted subgroup analysis. Logical filters such as AND/OR/NOT functions enable researchers to isolate particular patient cohorts, facilitating comparisons between treatment and control groups. Identifying emerging trends within high-risk subpopulations supports a data-driven approach to patient safety and regulatory decision-making.

INTEGRATION WITH SAFETY DATABASES

AEs do not exist in isolation; integrating safety databases enhances contextual understanding and supports regulatory compliance. Standardized MedDRA Queries (SMQ) and FDA Medical Queries (FMQ) streamline AE detection by leveraging predefined query sets. Incorporating broader safety data, including predispositions and co-existing conditions, ensures a comprehensive evaluation of potential risks. These insights are essential for structured regulatory reporting, including the preparation of Development Safety Update Reports (DSURs).

CONCLUSION

Graph-based approaches are revolutionizing adverse event (AE) evaluation, reshaping pharmacovigilance and clinical safety monitoring. By unlocking powerful data visualization techniques, researchers and regulators can spot hidden patterns, track trends, and integrate diverse safety data with ease. This cutting-edge method strengthens AE monitoring, providing a more comprehensive view of patient safety. As clinical trials and post-marketing surveillance evolve, graph-based solutions offer a scalable, efficient way to ensure safety and improve decision-making in clinical environments.

REFERENCES

1. New Approach to Graph Databases, A. Berg, C. Dahlbo, H. Drews, PP05 PHUSE EU Connect 2018
2. The Potential Power of Data, E. Kelty, C. Dahlbo, ET22 PHUSE US Connect 2024
3. Reflective Logic in a Graph Database, C. Dahlbo, E. Kelty, PP05 PHUSE US Connect 2022
4. Graph vs Table – A Complex Question, C. Dahlbo, E. Kelty, PP05 PHUSE EU Connect 2023

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