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Clinical Protocol Management with Deviation Summarization

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Public

Purpose statement

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Summary

As clinical trials become more complex, managing protocol deviations efficiently is key to ensuring data integrity and compliance. When deviation records in Siebel Clinical Trial Management Systems (CTMS) are entered in free-text fields, they often become verbose and difficult to manage. To address this, a Generative AI-based solution is proposed that parses and summarizes protocol deviation records. This system presents the summarized information to the user for review and editing, ensuring accuracy and clarity. Once finalized, the summary is automatically applied to the parent protocol record, reducing manual input and improving overall protocol management efficiency. This approach leverages AI to streamline the process and ensure precise documentation.

Overview

In Clinical Trial Management Systems (CTMS), managing protocol deviations can be a challenging and labor-intensive process. Detailed deviation descriptions and multiple records often result in verbose entries that are difficult to interpret and summarize. Introducing a Generative AI-based solution for protocol deviation summarization significantly streamlines this process, enhancing clarity and efficiency.

For example, when protocol deviation records are entered into the CTMS, the Clinical Research Associate (CRA) may need to go through the entire older deviation records for the same Protocol record which is very time consuming. But using this system the CRA can click on "Generate Summary" button in the protocol deviation records list applet, Gen AI model parses through the detailed descriptions of each Protocol Deviation, identifies key points, and generates a concise summary. This summary is then presented to the user for review and editing, allowing for interactive refinement. Once approved, the final summary is stamped onto the parent protocol record, ensuring seamless integration with minimal manual intervention.

A practical use case is seen in large-scale clinical trials, where numerous deviation records can hinder efficient management. The system analyses these records, extracting actionable insights and summarizing them in a user-friendly format. This reduces the time spent on manual reviews and ensures that protocol records remain accurate and up-to-date.

By automating the summarization of protocol deviations and integrating AI-driven insights, this solution improves productivity, ensures consistency in record management, and enhances the overall efficiency of clinical trial workflows.

Challenges in Protocol Management

Managing protocol deviations effectively poses several challenges, including verbose descriptions, multiple deviation records, and difficulty in maintaining accurate summaries. These inefficiencies can lead to miscommunication, increased manual effort, and compliance risks in clinical trial workflows. A Generative AI-based summarization solution addresses these issues by parsing detailed deviation records, generating concise summaries, and integrating them seamlessly into protocol management systems. This innovative approach reduces manual workload, ensures consistency in documentation, and improves overall trial efficiency.

How it works

A new button is added to the Protocol Deviation List applet within the CTMS interface. When clicked, this button collects all the descriptions of the records from the Protocol Deviation list. These records are then sent to the OCI AI framework's Generative AI Service, which processes the data to generate a detailed and concise summary.
Once the summary is generated, a popup window is displayed, allowing the user to review and edit the summary as needed. After the user finalizes the summary, it is saved and automatically applied to the parent protocol record, ensuring seamless integration and reducing manual effort in protocol management.

Benefits

1. **Streamlined Protocol Management:** By automating the summarization of verbose protocol deviation records, the system reduces manual effort, allowing clinical teams to save time and focus on critical trial activities.

2. **Enhanced Data Accuracy**: The AI-powered summarization ensures that only accurate and relevant details are captured, minimizing errors and inconsistencies across protocol documentation.

3. **Improved User Efficiency**: With an intuitive review and editing interface, users can quickly refine and approve summaries, ensuring a seamless workflow and reducing cognitive load.

Conclusion

Managing verbose protocol deviation records in Siebel CTMS can be challenging and time-consuming. By leveraging a Generative AI-based solution, this process becomes streamlined and efficient. The AI automatically parses all protocol deviation records, generates a concise summary, and allows users to review and refine it before saving it to the parent protocol record. This innovative approach ensures accuracy, reduces manual effort, and enhances productivity maintaining high-quality documentation standards.

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