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Exploration of a Digital Solution for Protocol Deviation Management in Clinical Trials Based on Microsoft Power Platform

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ABSTRACT

With the increasing scale and complexity of clinical trials, efficient management and compliant review of Protocol Deviations have become crucial for ensuring data quality and subject safety. Traditional review processes suffer from delayed data updates, inefficient team collaboration, and scattered, difficult-to-trace review records. This study designed and implemented a digital Protocol Deviation review solution based on Microsoft Power Platform, innovatively integrating automated data processing, multi-dimensional visualization analysis, online collaborative review, and comprehensive audit trail functionality. Through the coordinated application of Power BI, Power Apps, and Power Automate, this solution achieved end-to-end digitalization, standardization, and traceable management of Deviation data. Preliminary validation results indicate that this approach shows significant potential in improving review efficiency, enhancing compliance, and optimizing risk management, providing an innovative paradigm and implementation pathway for the digital transformation of clinical trial data management.

INTRODUCTION

Timely identification, accurate review, and standardized management of Protocol Deviations are essential for maintaining compliance and data integrity in clinical research. The growing scale and complexity of multicenter and international clinical trials have resulted in a substantial increase in both the volume and intricacy of Protocol Deviations. Traditional review processes—relying on SAS or R analysis and distribution via email or documents—are increasingly insufficient to meet the demands for efficient, real-time, and compliant management. Such methods often result in prolonged data feedback cycles, information loss, limited traceability, and fragmented communication, which severely restrict effective closed-loop management and risk control.

To address these issues, there is an increasing need for an integrated, highly automated, and intelligent Deviation management platform that enables end-to-end digitalization and traceability. While current solutions—including EDC (Electronic Data Capture) system modules, CTMS (Clinical Trial Management System) deviation management, and custom tracking systems—provide certain functionalities, they often face limitations such as lack of integration, limited scalability, and high customization costs. This is especially evident in multicenter, international trial settings that require real-time data, multi-role collaboration, and compliance traceability.

Microsoft Power Platform, as a low-code integration platform, provides new opportunities to tackle these challenges. With its components—Power BI, Power Apps, and Power Automate—the platform supports data integration, visualization, process automation, and team collaboration. In this exploratory study, we designed and implemented a prototype digital Protocol Deviation review solution using Microsoft Power Platform. This paper presents the design rationale, functional implementation, and preliminary validation of the solution, and discusses its potential advantages and implications for improving data quality, compliance, and collaborative efficiency in clinical trial management.

METHODS

SYSTEM ARCHITECTURE DESIGN

The Protocol Deviation management system designed in this study is based on a lifecycle management concept, constructing five core functional modules that form a complete closed loop from data generation to decision support. The system architecture is shown in Figure 1, with the following module functions:

- Data Processing Layer: Utilizes statistical tools such as SAS or R to automatically identify and determine Deviations according to preset rules. Outputs structured data containing key information such as subject ID, site, visit, Deviation type, severity, occurrence time, and description, ensuring data standardization and consistency.

- Data Management and Sharing Layer: Automatically uploads processed data to SharePoint List, enabling centralized storage, permission management, version control, and efficient retrieval. Supports association with original data, facilitating parallel operations and data synchronization for multi-center, multi-role teams.

- Visualization Analysis Layer: Builds multi-dimensional, interactive Deviation dashboards through Power BI connected to SharePoint data sources. Supports dynamic analysis, trend tracking, and anomaly alerts by country, site, time, type, severity, and other dimensions, enabling management to monitor Deviation distribution, processing progress, and risk points in real-time.

- Collaboration and Review Layer: Developed on Power Apps, this layer supports online collaborative review, multi-role comments, and comprehensive audit trail functionality. The system records all review activities and data changes, ensuring transparency, compliance, and integrity of the review process.

- Automated Notification and Process Layer: Uses Power Automate to monitor key events (such as new Deviation creation, status changes, review comment submission) in real-time, automatically sending email message reminders to relevant personnel.

The current implementation is at the prototype stage and has been validated using simulated data in controlled scenarios.

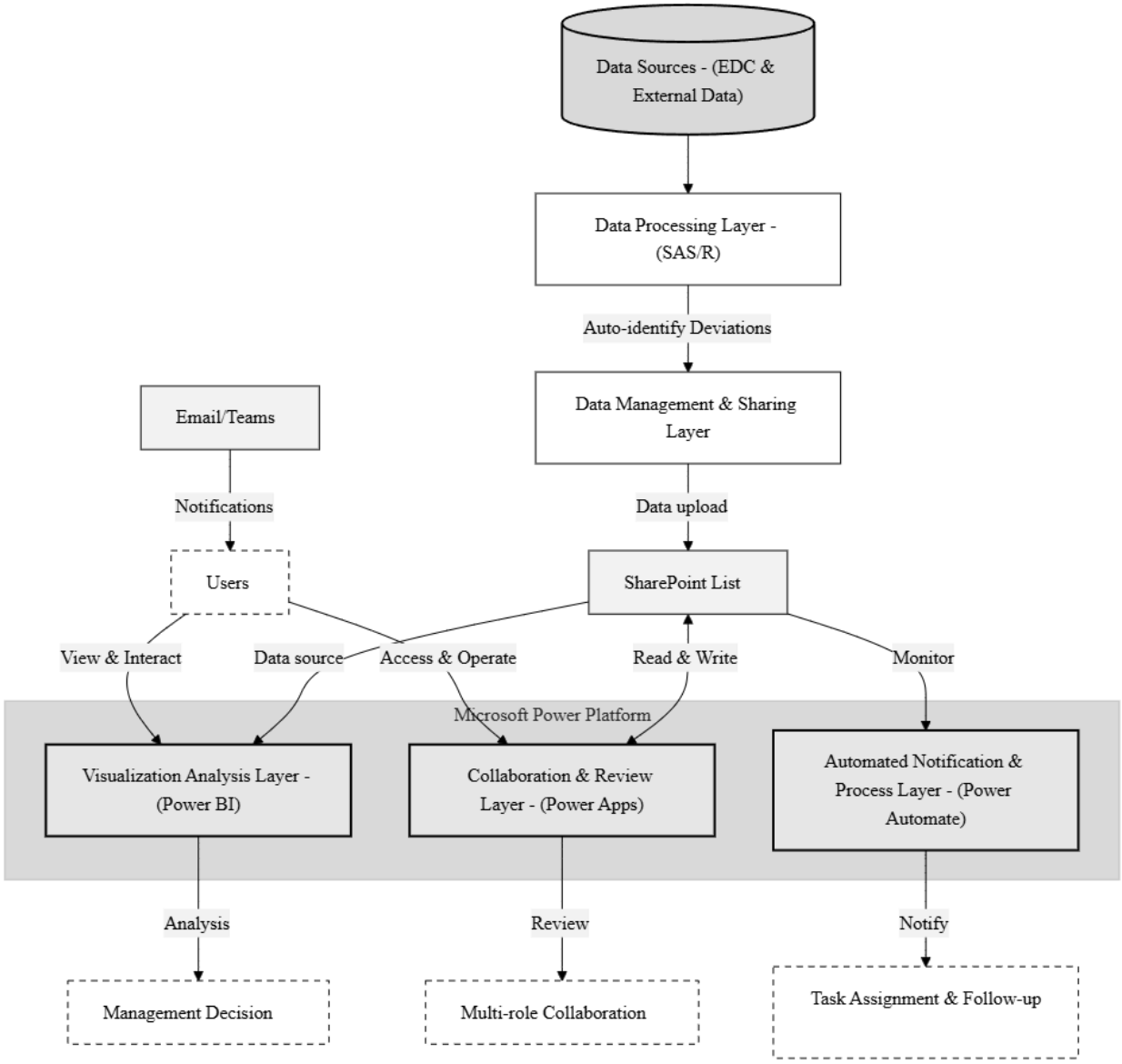

Figure 1. System Architecture of the Protocol Deviation Management Platform

KEY FUNCTIONALITY IMPLEMENTATION

DEVIATION DATA STANDARDIZATION AND INTEGRATION

Combining international standards such as CDISC (Clinical Data Interchange Standards Consortium), the platform uses SAS or R programming to generate Deviation information with standardized fields. This study selected SharePoint List as the initial data storage solution, primarily considering its deployment convenience, seamless integration with Power Platform, and flexible permission management. SharePoint List supports multi-version data management, granular permissions (such as read-only, edit, approval), historical tracking, and batch import or export, meeting the concurrent processing requirements of multi-center, multi-role teams.

MULTI-DIMENSIONAL VISUALIZATION AND INTELLIGENT RISK MONITORING

The Power BI dashboard provides comprehensive visualization analysis capabilities for Protocol Deviations (as shown in Figure 2). The system employs diverse chart display methods: Gauge Charts intuitively display Deviation review completion rates, Donut Charts present the distribution proportions of different review statuses, and Bar Charts show comparisons of various protocol deviation terms.

Utilizing filtering, drill-down analysis, and conditional formatting highlights, management can quickly grasp key indicators: total Deviations, number reviewed, and distribution patterns. An intelligent color scheme automatically highlights high-risk Deviations in prominent red, facilitating rapid identification of potential issues. The platform supports multi-dimensional interactive filtering, allowing users to perform precise filtering and in-depth analysis based on region, review status, Deviation severity, and other conditions, enabling quick location and prioritization of risk points.

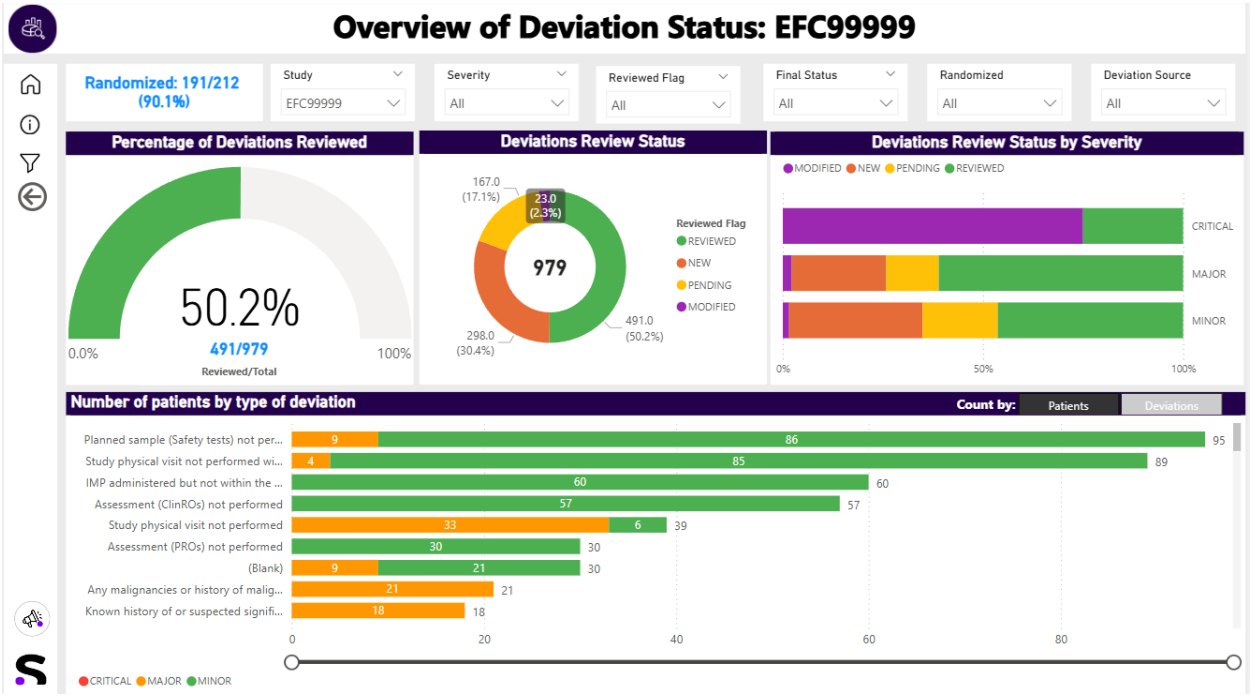

Figure 2. Multi-dimensional Visualization Dashboard for Protocol Deviation Analysis

COLLABORATIVE REVIEW

The Power Apps platform implements full lifecycle management of Deviations (as shown in Figure 3). The system, based on Model-driven application design, has built a complete application framework including review processes, role permissions, and audit trails. Reviewers can comment online, provide additional information, update status, and assign follow-up actions, with all operations and timestamps automatically recorded, ensuring process compliance and data traceability.

For example, when program checks identify that a subject did not complete the I-RODS assessment at Visit 6/Week 12/DB, the data manager can record preliminary analysis results in the system and mark it as "Needs Investigation"; the CRA can subsequently add specific findings from on-site verification, supplement details about the affected situation and deviation cause (such as "subject left early due to personal emergency"), and update the status to "Confirmed"; the medical monitor can then assess the impact of this deviation on data integrity and assign follow-up actions to the research site (such as "retrain on I-RODS assessment procedures before the next visit"). Throughout the process, comments, status changes, and action assignments are recorded in real-time by the system, forming a complete decision chain and accountability trail.

The system supports multi-role collaboration (such as Clinical Research Associate (CRA), Data Manager (DM), Safety Medical Monitor (SMM), etc.), with permissions that can be refined to field and functional module levels, ensuring data security. Additionally, biostatisticians can assess the potential impact of such deviations on overall study results, project managers can develop comprehensive action plans based on various opinions, and QA specialists can ensure the entire review process complies with GCP and relevant regulatory requirements

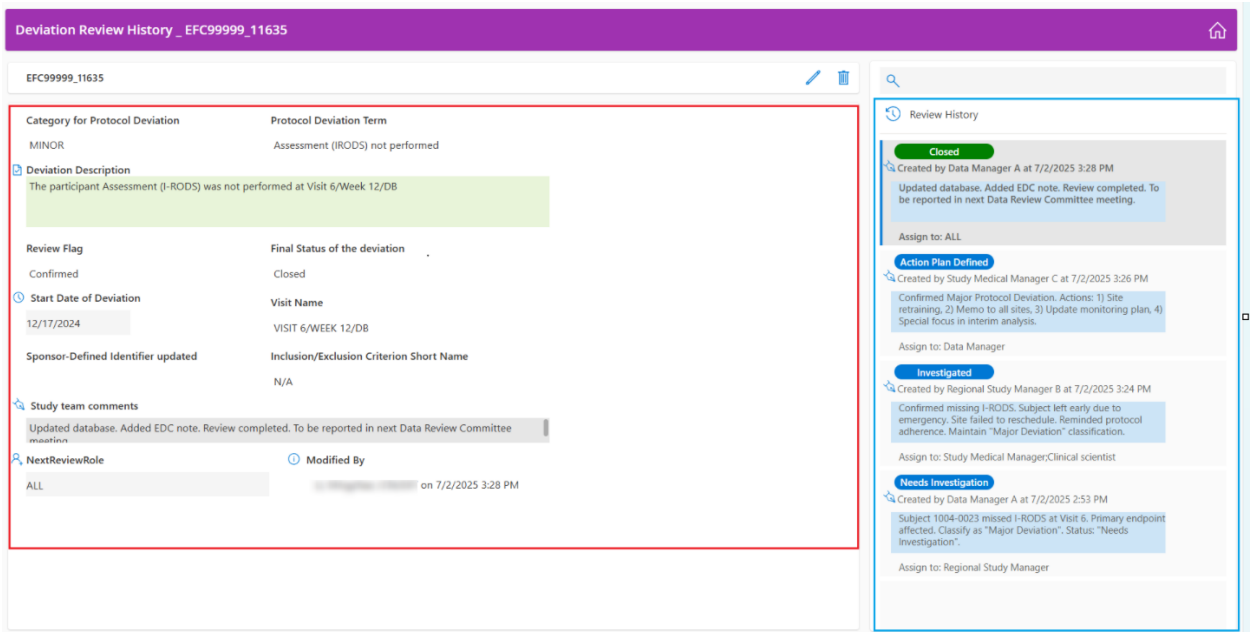

Figure 3: Collaborative Review Process Flow in Power Apps

AUTOMATED NOTIFICATIONS AND PROCESS MANAGEMENT

Power Automate triggers automated workflows based on Deviation creation, status changes, comment additions, etc., sending reminders to relevant personnel to prevent omissions and delays (as shown in Figure 4). Additionally, it can generate regular reports of unprocessed Deviations, automatically reporting to management, improving process closure rates and transparency. The system integrates with Teams, Outlook, and other tools, enabling multi-channel message delivery.

Figure 4: Automated Notification Workflow using Power Automate

PERMISSION SECURITY AND AUDIT TRAIL

This study implemented comprehensive permission management and audit trail mechanisms to ensure the system meets the strict compliance requirements of clinical trials. For permission control, the system assigns permissions based on roles, such as CRAs only accessing Deviation records for their responsible sites, while project managers can view data for all sites. The permission matrix design covers common clinical trial roles and supports customized roles and permission combinations, adapting to different organizational management needs.

For audit trails, the system records detailed user operations through custom audit functionality developed in Power Apps, including who accessed which records when, what review activities were performed, which fields were modified, and what decisions were made (as shown in Figure 5). These custom audit logs support multi-dimensional queries and report generation, meeting the strict compliance requirements of clinical trials. Additionally, SharePoint List, as the underlying data storage, provides built-in version history functionality, automatically recording the change history of each record, forming a dual audit guarantee.

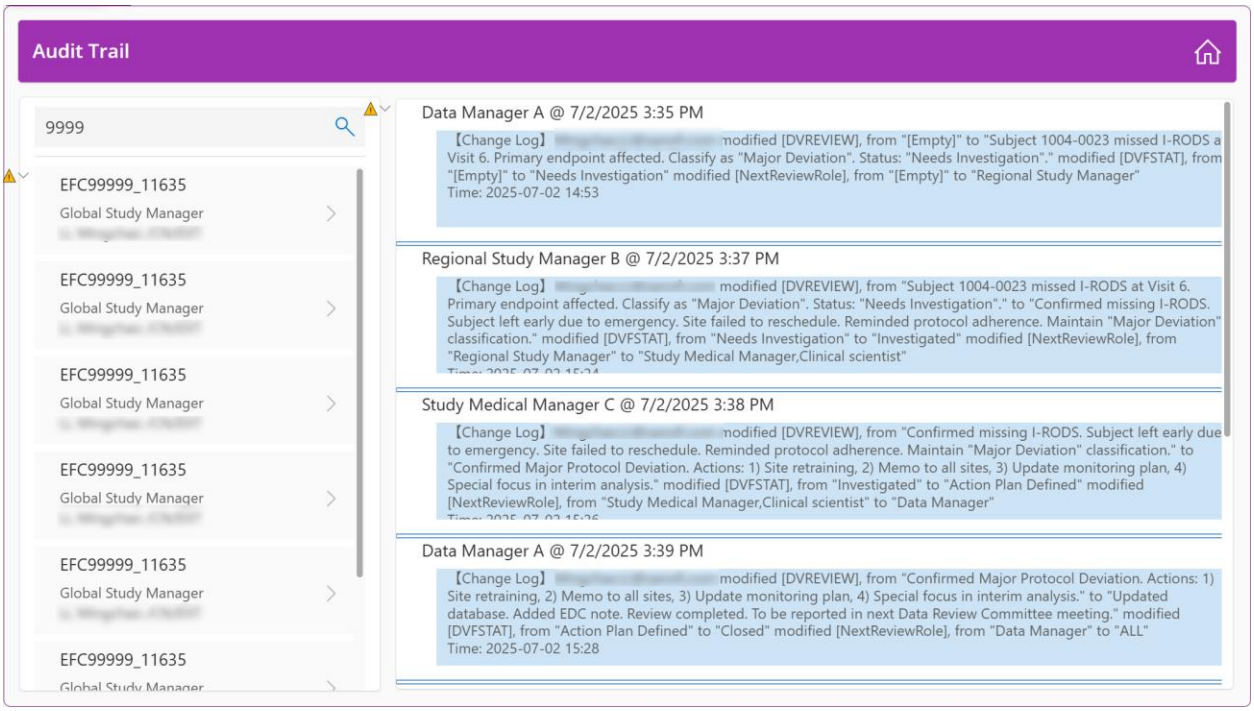

Figure 5: Audit Trail and Permission Management Interface

RESULTS

The system was preliminarily validated using simulated data and a limited user environment. Results indicate that the protocol deviation management system based on Microsoft Power Platform performs well in visualization analysis, collaborative review, compliance tracking, and automated notifications. The multi-dimensional analysis capabilities of Power BI help managers monitor the distribution, trends, and risk points of deviations in real time, while high-risk deviations can be quickly identified. The online review platform developed on Power Apps supports real-time, multi-role collaboration, enabling reviewers to conveniently share information and exchange opinions, significantly improving review efficiency. The audit trail functionality comprehensively records user operations, ensuring process transparency and traceability and meeting compliance requirements. The automated notification mechanism enhances team communication efficiency and reduces the risk of information omission.

Initial user feedback indicates that the platform's intuitive interface and automation features effectively reduce the burden of manual processing. In simulated multi-center scenarios, the system's collaboration and real-time notification features significantly improved information sharing and decision-making efficiency between teams. It should be noted that this validation was mainly based on simulated data and limited user testing. Further expansion to actual clinical trial environments is planned.

DISCUSSION

This study applied Microsoft Power Platform to protocol deviation management, providing an exploratory approach for the digital transformation of clinical data management. Although this study is still in the exploratory and prototype stage, the system shows the following potential advantages:

ADVANTAGES:

1. Integrated solution: Combines data processing, visualization analysis, collaborative review, and automated notifications, providing comprehensive support for Deviation management.

2. Flexibility and scalability: The low-code platform characteristics enable the system to quickly adapt to different project requirements.

3. Compliance assurance: Built-in audit trail and permission management functions meet strict regulatory requirements.

4. Real-time collaboration: Enables multi-role online review and decision-making, significantly improving team efficiency

LIMITATIONS AND FUTURE IMPROVEMENT DIRECTIONS:

1. Data storage expansion: As mentioned in Section 2.2.1, the current SharePoint List storage solution is suitable for initial validation, but large-scale deployment may require migration to higher-performance database solutions such as Dataverse or Azure SQL.

2. Advanced analytical capabilities: Consider introducing machine learning algorithms to enhance Deviation pattern recognition and risk prediction capabilities.

3. System integration: Future exploration of deep integration with EDC, CTMS, and other systems to achieve more comprehensive clinical trial data management.

CONCLUSION

The digital Protocol Deviation review solution developed in this study, based on Microsoft Power Platform and integrating the functionalities of Power BI, Power Apps, and Power Automate, provides a feasible pathway for the digital transformation of Deviation management processes Preliminary validation with simulated data and limited users indicates that the platform has certain potential for improving review efficiency, ensuring data quality, and strengthening risk control.

This low-code platform-based solution is not only applicable to Protocol Deviation management but also provides innovative ideas for other aspects of clinical trial data management. As the system is further optimized and functionality expanded, it has the potential to make important contributions to improving the overall quality and efficiency of clinical trials.

Future research will focus on evaluating the application of the system in actual clinical trials and exploring the integration of more intelligent functionalities, such as automated Deviation classification and risk assessment. With further optimization and functional expansion of the system, it has the potential to make significant contributions to improving the overall quality and efficiency of clinical trials.

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