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The P4D Dashboard: A Platform for Monitoring Clinical Studies

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Abstract. The P4D (Personalized, Predictive, Precise & Preventive Medicine for Major Depression) dashboard (https://p4dashboard.vercel.app) is a web-based platform for monitoring and generating data-driven insights within a multi-site clinical depression study. Part of the broader P4D initiative, which aims to advance personalized medicine for depression through deep phenotyping, genotyping, and machine learning, the dashboard addresses the challenge of integrating heterogeneous data sources. Dynamic visualizations and interactive filtering methods enable users to define and explore sub-cohorts, facilitating the understanding of complex patterns and tailoring data views to their specific needs. The dashboard also summarizes key metrics, allowing real-time monitoring of the data collection and the generation of actionable reports. The P4D dashboard has successfully identified data irregularities, such as missing followup assessments due to early patient discharge and site-specific recruitment disparities, enabling timely interventions to enhance data quality. With its adaptable and scalable framework, the dashboard may be applied to other clinical cohort studies in the future.

Keywords. Clinical monitoring, interactive dashboard, depression, data integration, dynamic visualization**.**

1. Introduction

Clinical studies play a critical role in medical research to effectively illustrate outcomes or the natural progression of a disease or condition within a specified study population

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over time. As these studies proliferate, frequently encompassing numerous sites and substantial data volumes, the management and interpretation of this information become progressively demanding, with researchers needing to address challenges such as data consistency and quality assurance [1,2]. Dashboards have become vital tools in addressing these challenges. They allow researchers to monitor study progress, track patient-specific data, and identify information gaps by integrating data from multiple sources [3]. Beyond viewing data, interactive dashboards support filtering information, performance tracking, decision-making, data downloads for further analysis, and personalized views for individual patients, thereby providing deeper study insights [4]. These features are crucial in multi-site healthcare studies.

The P4D Dashboard was developed to address these needs of the multi-site cohort study "P4D—Personalized, Predictive, Precise & Preventive Medicine for Major Depression" (German Clinical Trial Register DRKS00032215 [5]), with ethical approval (10799_BO_S_2023) from all committees after protocol review. Recruitment is ongoing, with 244 of 1,000 target patients enrolled. The dashboard is being used for monitoring and ensuring progress towards the study goals. It is available online with synthetic data at https://p4dashboard.vercel.app/. The dashboard is based on insights from a cooperative design study [6]. It combines real-time tracking, filtering, and monitoring tools to provide a detailed overview of study data and derived metrics, including Polysomnography (PSG), Electroencephalography (EEG), Therapeutic Drug Monitoring (TDM), Cognitive Task Battery (CTB), genomic, Magnetic Resonance Imaging (MRI), and biobank data. Built on a flexible and scalable technology stack, the dashboard can adapt to complex study requirements. This paper describes the P4D Dashboard's design, key features, and its potential to support more informed decision-making in clinical studies.

2. Methods

System Architecture and Data Integration. The P4D dashboard leverages a scalable, modular architecture to manage multi-site cohort data. The front end uses Next.js [7] for responsiveness and rapid loading, with React Context API [8] ensuring data consistency. NextAuth [9] manages secure user authentication and role-based access. The backend features PostgreSQL [10] as the primary database, optimized for handling large, complex datasets, and Prisma for efficient data querying and schema management. D3.js [11] supports interactive visualizations, and the system is containerized with Docker [12] for consistency and scalability. APIs seamlessly integrate front-end and back-end, enabling real-time data access and interactivity (Fig. 1). The dashboard employs non-commercial, open-source software to ensure accessibility. The backbone of the P4D case management is the Marvin electronic Case Report Form (eCRF) software (XClinical), which records and links the clinical patient data to the other datasets, e.g., MRI and PSG. The dashboard builds upon the Marvin export and integrates these heterogeneous datasets through a standardized preprocessing pipeline: 1) Validation: checking raw data for anomalies and inconsistencies, 2) Standardization: harmonizing units, formats, and nomenclature, 3) Cleaning: resolving outliers and duplicates to improve quality, and 4) Alignment: synchronizing data with patient IDs and timestamps.

Design and Usability. User feedback significantly shaped the P4D dashboard. A cooperative, user-centric design approach was employed, focusing on iterative revisions based on stakeholder input and 39 heuristics. Early feedback on an initial prototype

identified the need for clearer visual cues, intuitive icons, and interactive components, which were implemented to enhance usability and engagement [6]. New pages tailored to distinct data types were added based on user requests. The MRI-QC [13] page was introduced to enable quality control of MRI data across sites. The genomic data page was added to track sequencing coverage, copy number variations (CNVs), single nucleotide polymorphisms (SNPs), and short tandem repeats (STRs) distributions. These pages, along with terminology updates in the Overview page, streamlined data monitoring and improved accessibility for researchers managing complex data.

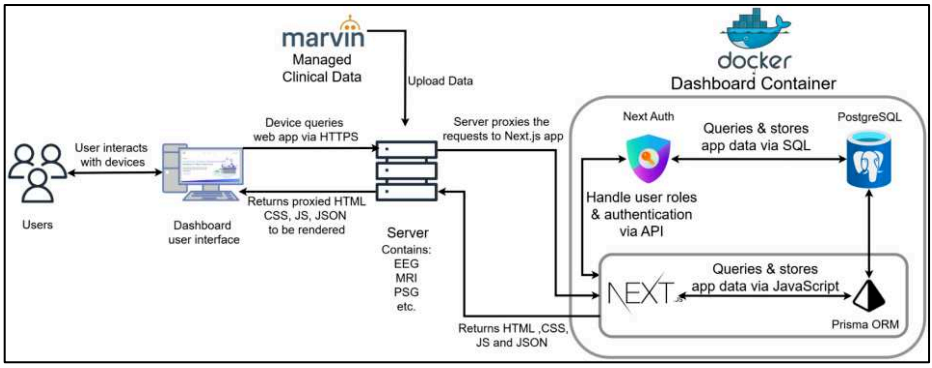

Figure 1. Architecture of the P4D dashboard - a platform for monitoring clinical studies.

3. Results

Interactive filtering and personalized analysis. Features like brushing, linking, and dynamic queries allow for focusing on sub-cohorts based on attributes like age, gender, key health parameters, and diagnosis codes (Fig. 2, left). For example, researchers can isolate patients of a certain sex and age by clicking the corresponding bars in the age-sex pyramid, causing an automatic highlighting of this sub-cohort in the other plots in the context of the entire cohort. The "Patient-specific" page (Fig. 2, right) provides detailed longitudinal data, including PSG metrics, MRI sequence availability, and other measures. These features facilitate individualized analyses, helping to uncover trends such as irregular followup schedules or deviations in health parameters that require intervention.

Figure 2.Interactive Filtering (Left) and Patient-Specific Page (Right).

Data completeness across sites. The Regularity page (Fig. 3) plays a critical role in monitoring data completeness. It provides an overview of total patient data for different modalities, such as EEG, MRI, and PSG, as well as counts for baseline and followup datasets. During its use, the page identified missing followup records for 77 EEG and 61 MRI acquisitions (red circles), e.g., due to early patient discharge. By tagging patients with incomplete data, researchers can coordinate with clinical site staff to identify reasons and improve adherence to study protocols and reduce missing data.

Figure 3. Regularity page summarizing data completeness.

Quality control for imaging and genomic data. The MRI-QC page has flagged inconsistencies in imaging metrics across sites, such as excessive patient movement in the MRI-scanner, prompting recalibrations that enhanced data standardization. Similarly, the genomic data page monitors sequencing coverage and tracks CNV, SNP, and STR distributions. While coverage is managed during preprocessing, the dashboard continuously verifies data integrity, and no outliers have been detected so far.

Streamlined sample and workflow management. The Biobank Administration page monitors SOP adherence for blood and saliva sample collection across all sites. It detected sites not complying with collection timelines, for prompt corrective actions.

Cohort-level insights. The "Overview" page summarizes the recruitment progress and followup statuses. Some of its plots integrate a history display that allows for comparing the current status to the previous dashboard update, thereby indicating (site-specific) changes. The page exposes site-specific disparities in gender distribution and patient inclusion. These insights guide recruitment strategies, ensuring a more balanced cohort.

4. Discussion

The P4D dashboard significantly enhances data management, identification of irregularities, and study coordination through its intuitive interface and targeted features. It proved essential in identifying data gaps, standardizing metrics, and streamlining workflows. By providing actionable insights and enabling timely interventions, it enhances data quality, solidifying its value for multi-site cohort studies. The dashboard effectively centralizes data and ensures consistency across sites, addressing emerging challenges. Features like the regularity page and patient-specific views improve data

accessibility, support decision-making, and enhance irregularities detection, such as missing follow-up assessments caused by early patient discharge. Using the dashboard in consortium meetings has been fostering collaboration and problem-solving. The dashboard can be readily adapted to other cohort studies managed with the widely used Marvin eCRF software. Future enhancements, including support for additional data types, predictive analytics, and automatic detection of deeper hidden errors in the data, could further improve study data quality and advance research outcomes.

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