

## **Poster: Overview of the Pfizer Phase 1 Management System (P1MS)**

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### **ABSTRACT**

P1MS is an electronic data management system used in the Pfizer Clinic Research Units (PCRU) for Phase 1 studies. This poster describes the process surrounding P1MS from data collection to study reporting.

### **DATA COLLECTION > DATA EXTRACTION**

P1MS contains a database of potential candidates for phase 1 trials. The PCRUs apply the inclusion and exclusion criteria for new studies to find an applicable candidate population for a forthcoming study. This population is then invited to enter the trials. During the course of a clinical trial, data is collected at the PCRU and either automatically loaded (e.g. Blood pressure, ECG) or manually entered (e.g. Adverse Events) into a P1MS window.

### **DATA FLOW FOR P1MS STUDIES**

The PCRU send the lab sample data to the Central Labs to be assayed. The assayed data is then sent to a system called QUOVADX runs checks over the lab data and loads it up to P1MS. The pharmacokinetic sample data is sent to the assay group to be analysed, which is then uploaded to Oracle Clinical. The rest of the clinical trial data is captured at the time of the trial and uploaded manually or automatically into P1MS. Data checks are performed within P1MS and by the PCRU investigators. The P1MS data and PK data is extracted and clinical study report tables are generated using the Pfizer reporting system, CDARS.

### **DATA COLLECTION > DATA REVIEW**

The P1MS data can be accessed and reviewed by clinicians at any point during a study, using a simple database query in EXCEL. This information can feed into the planning of a new study.

### **CONCLUSION**

The main benefits of using P1MS are coordination of volunteer recruitment, management of the Phase 1 trials, instant electronic data collection, immediate real-time access of data and faster reporting times.

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### **CONTACT INFORMATION (HEADER 1)**

Your comments and questions are valued and encouraged. Contact the author at:

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