IDS Led Medication Review at Screening to Support Eligibility Determination and Ensure Protocol Compliance and Subject Safety

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Abstract

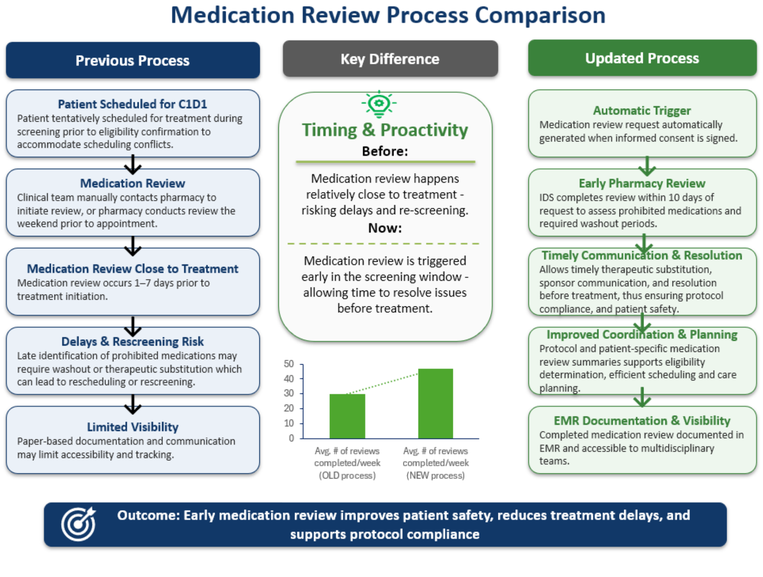
Protocols include guidance on concomitant and prohibited medications to ensure subject eligibility and safety during clinical trials. Timely and robust medication review is essential to ensure protocol compliance and subject safety. Investigational Drug Services (IDS) can provide vital support to clinical trial study teams through completion of medication reviews and assessment of drug-drug interactions with study medications. Under a previous process, IDS review occurred close to when the first dose was due, thus delaying identification of prohibited medications. This occasionally resulted in postponed or canceled appointments, missed screening windows, and the need for subject rescreening prior to treatment initiation.

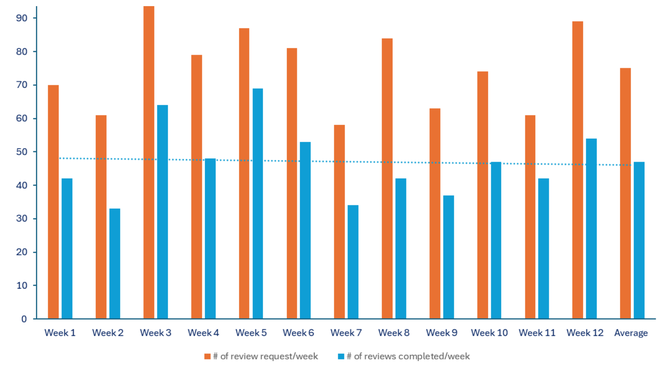
Introduction

Early medication review during the screening window allows sufficient time to identify concomitant medications that may be prohibited or require caution per study protocol. Conducting these assessments before treatment initiation enables appropriate therapeutic interventions, such as medication substitution, dose adjustment, or required washout periods, while minimizing disruption to patient care. Proactive review supports protocol compliance, enhances subject safety, and reduces the risk of treatment delays, canceled appointments, protocol deviations, or rescreening. Collaboration between IDS, study teams, and investigators is essential to facilitate timely communication and efficient resolution of medication-related eligibility concerns.

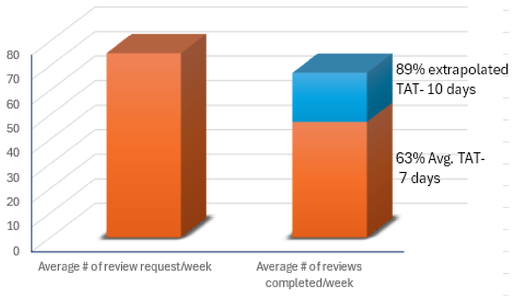
Methods

IDS collaborated with Information Technology (IT) and clinical trial teams to implement an automated workflow that notifies IDS when a subject signs research consent. When a Clinical Research Coordinator (CRC) enters a participation note in the electronic medical record (EMR), an alert is generated in the IDS message center, creating a centralized queue of enrolled research subjects. Standardized workflows, pharmacist training, and documentation practices were developed to ensure consistency in medication review and communication. Most clinical trials included a screening window of approximately 28 days. IDS completed comprehensive medication reviews within 10 days of notification and documented assessments in the EMR. Reviews included protocol-specific references for prohibited or cautionary medications, washout requirements, and potential drug interactions. When medication-related concerns were identified, IDS communicated recommendations to the Principal Investigator (PI) and CRC to facilitate therapeutic substitution, medication holds, sponsor consultation, or washout completion prior to treatment initiation. Weekly operational reports were developed to monitor consult volume, communication tracking, and medication review turnaround times.





12- Week Medication Review Turn Around Data



Weekly Average Medication Review Metrics

Outcomes

IDS interventions during the screening window enabled timely management of prohibited or cautionary medications (e.g., substitutions, holds, washouts, sponsor consultation), supporting protocol compliance, patient safety, continuity of care, and minimizing treatment delays. Ongoing medication reviews ensured continued alignment with protocol and safety requirements, while standardized workflows, training, documentation, and tracking systems established a consistent and efficient medication review process.

Based on a 12-week review:

- IDS received an average of 75 medication review notifications per week following subject consent and completed approximately 63% of reviews within a week, with projections indicating achievement of the 89% completion target within 10 days.
- During this 12-week period, approximately 160 significant interventions (~17%) were identified, guiding the study team in making protocol-compliant decisions during the screening window and helping prevent delays to treatment initiation.
- Implementation of the new medication review process resulted in improved efficiency, evidenced by an approximate 36% increase in average weekly medication reviews.

Lessons Learned and Future Directions

Several operational challenges were identified during implementation:

- Phase I clinical trials often require expedited medication review; however, the current workflow does not automatically identify or prioritize these studies, resulting in additional manual communication burden.
- In addition, medication review requests are automatically generated for all consented subjects, although not all trials require IDS involvement, creating unnecessary manual review and request removal processes.
- Staffing variability, including call-outs and fluctuations in patient care workload, also impacts medication review turnaround times.

Future optimization should focus on automated trial filtering, prioritization, and operational solutions to ensure consistent turnaround despite workload variability.

Leveraging technology for protocol- and patient-specific medication reviews, along with enhanced EMR integration and reporting, can further improve communication, multidisciplinary visibility, and timely interventions.

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