Category: Quality Assurance – Work in Progress

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

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1. Background

Protocols include information on concomitant medications, including prohibited medications to guide providers to assess subject eligibility and ensure ongoing subject safety during the trial. For most investigational medications, the guidance is offered in the form of specific drugs, doses or drug class. Investigational Drug Services (IDS) can provide vital support to clinical trial study teams and patients by assisting with the medication review and assessing drug-drug interactions with investigational medications. Timely and robust medication review ensures protocol compliance and subject safety. At our site, IDS used to complete medication review prior to the first dose, however this delayed intervention would either lead to instances where prohibited medications were identified in subject profile and there was insufficient time to align with the washout period prior to the first dose, this would either lead to delayed or cancelled appointments or subject being out of the screening window and requiring to be rescreened prior to starting treatment.

2. Goals

Provide medication review assessment earlier in the screening window to allow for appropriate therapeutic intervention, either substitution or washout prior to starting treatment to ensure protocol compliance and avoid delays on the day of treatment.

3. Solutions and Methods

IDS worked with Information Technology (IT) and clinical trial teams to establish a workflow which automated notification to IDS when a subject signed the research consent. When a subject sign consent and the clinical research coordinators place a participation note in the electronic medical record (EMR), an alert is sent to the IDS message center, which is essentially a queue of research subjects that have signed consent to participate in a trial. Most trials have a screening window of 28 days; IDS completes its thorough medication review within 10 days of receiving notification and will document their assessment in the EMR. If any medication related recommendation, either caution or prohibited, then IDS will send additional communication to the Principal Investigator (PI) and Clinical Research Coordinator (CRC) to follow up with subject and sponsor as necessary.

4. Outcomes

The upstream intervention by IDS gives the study team sufficient time within the screening window to inform the subject to either hold or substitute the identified medication or communicate with sponsor. This leads to reduced delays on the day of treatment, ensures subject safety, protocol compliance and resolution is achieved within the screening window. IDS also provides continuous medication review to ensure that any new prescribed medications continue to follow the protocol recommendations.

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5. Lessons Learned and Future Directions

Resources were developed and standardized training was developed to ensure all pharmacists were following the standardized format for medication review, documentation and communication. Process had to include a way to identify when communication was sent with IDS recommendations to follow up and ensure resolved prior to first dose. IDS has developed a weekly report that captures the metrics, including number of messages received and turnaround times for the medication review. The future goal is to incorporate technology to provide protocol and subject specific medication review.