

## **A Process for the People: Updating Oral Medication Compliance Policy, Guidelines, and Tools**

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### **1. Background**

With all the complexities of oral medication studies, including variable dosages, ramp-up periods, interval dosing, multiple medications, and dose holds or reductions, it is increasingly complicated for patients to remain compliant, even with their best efforts.

In 2016, our Division implemented a policy and tool to aid non-clinicians in assessing patient compliance with oral medications. While our Education Team has been continuously training new staff on the importance of patient compliance and how to assess this compliance, we had not re-evaluated our policy and tools, or provided formal refresher training to existing staff.

After reviewing the results of approximately 60 quality assurance (QA) audits, we learned that the existing tools and policy developed were misunderstood and misused. There was frequent miscommunication between clinic coordinators completing medication compliance forms and data coordinators entering data into Electronic Data Capture (EDC) systems. The forms were not completed consistently and the process for notification was not always followed.

### **2. Goals**

Through reframing our approach to oral medication compliance we hoped to accomplish the following:

- Evaluate and update our policy to provide clarity to sponsors and staff
- Provide updated tools and guidelines that are more clear, concise, and functional in a clinic setting
- Re-educate coordinators on the importance of compliance and provide real-life examples
- Establish an open line of communication, allowing coordinators to bring complex problems to light
- Minimize repeat issues with patient compliance
- Decrease the number of findings on QA audits related to the completion of the oral medication compliance form

### **3. Solutions and Methods**

We held focus group meetings to gather insight from coordinators involved in assessing oral medication compliance. We reviewed specific examples of problems coordinators faced with these studies to establish a framework of what was working and what wasn't. In addition, we looped in pharmacy, management, and education specialists to provide a comprehensive approach.

### **4. Outcomes**

This plan is still in its implementation phase. Thus far, we have developed an updated policy, comprehensive guidelines, clear and practical resources, and an education plan to share with staff.

## **5. Lessons Learned**

With all the complexities of running a clinical research trial, many individuals play a part in patient compliance with oral medications. It is important to obtain their perspective and feedback when developing or updating policies, rather than excluding these individuals in favor of exclusively management level decision-making.

Seeking input from multiple perspectives, including pharmacists, inpatient staff, clinic coordinators, and data coordinators has led to more comprehensive set of guidelines.

Using real life examples was key to developing impactful staff tools. Piloting new tools with actual protocols generated questions we had not considered, and led to a more thorough set of guidelines. One standard tool cannot address every possible scenario. Instead, address complex issues through education, customizable guidelines and tools, and communication across roles.

Having input from the staff on the ground leads to increased staff buy-in, and provides an incentive to use the tools they contributed to.