

Enhancing Productivity: Utilizing the ONBASE Application and Pharmacist Created Order Sets to Streamline the Trial Launch Process

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1. Background

In the last year the University of Texas Health Science Center has experienced a substantial increase in the volume of clinical trials being submitted to the IRB, with each protocol requiring onboarding and EMR protocol validation. As a result, the process for protocol activation required restructuring to increase productivity and decrease time spent on order set approval. After breaking down each step in the workflow, two key processes were found to be the major contributors to inefficiency and errors:

- non-clinical staff developing medication order sets requiring multiple revisions by pharmacy
- using email to transmit and store trial related documents

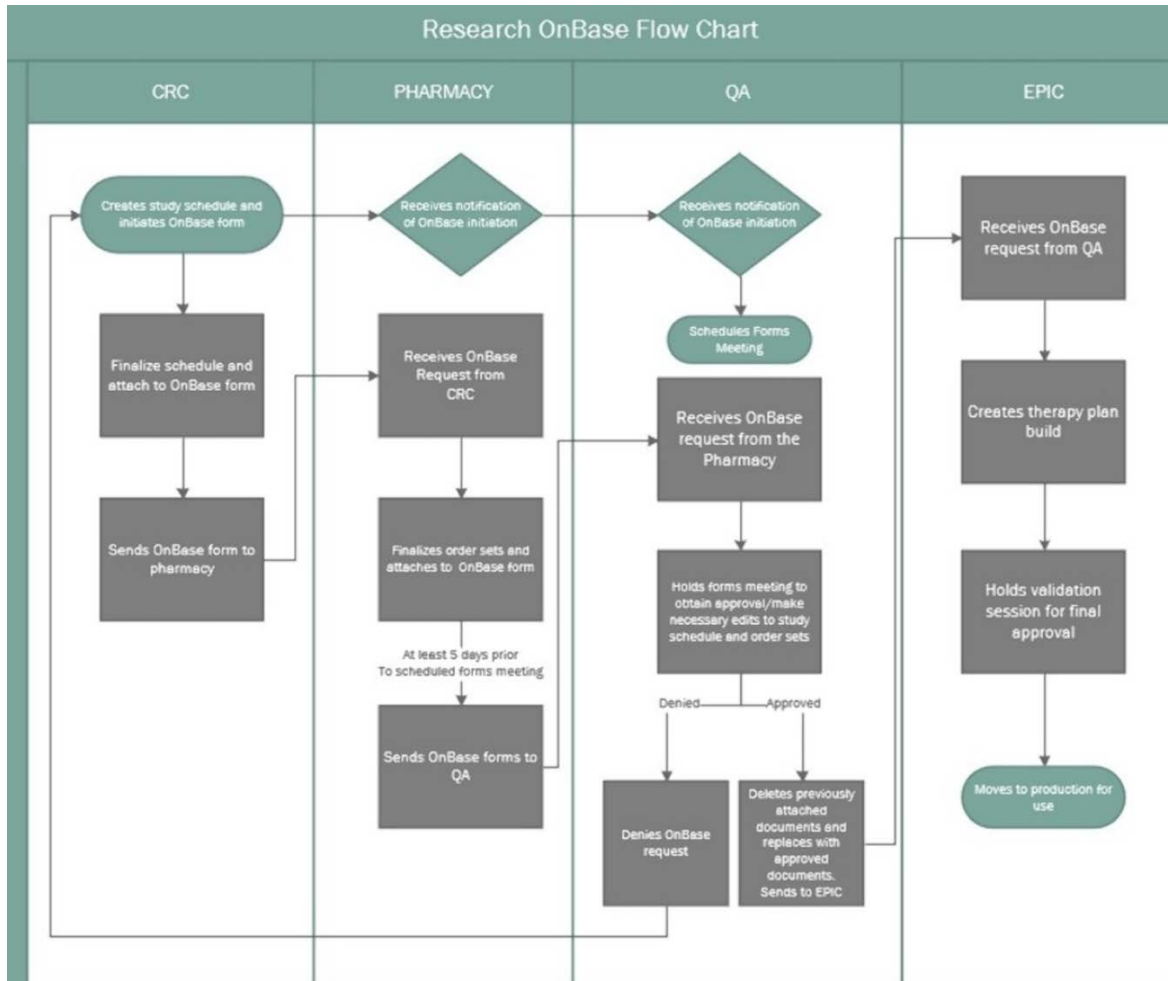
The strategy was to remove these practices and replace them with more constructive means of communication and order development.

2. Goals

- Decrease time from IRB approval to protocol activation
- Reduce errors during order set development
- Improve ease of process and overall staff satisfaction

3. Solutions and Methods

A committee including members from Quality assurance, the Investigational Drug Section, and Clinical Research team convened to establish a streamlined workflow for trial activation. The first task was to transition order set development from research coordinators to a dedicated research pharmacist. This allowed an individual with medication expertise to review protocols and build more precise medication order sets. An order template was created and required to be used for all protocol builds; this assured consistency and reduced errors caused by varying order form appearance and omission of critical information. The second step was to shift the management of all trial build requests and supporting documents to a single, trackable database. The application OnBase was selected for its ability to build a customized environment based on our desired workflow (flow chart attached). The application underwent testing to ensure all required information was captured and that the forms functioned properly prior to implementation.



4. Outcomes

The new process went live January 8th, 2020. Data collection to assess efficiency is still on-going; however, four protocol activations have been completed under the new workflow. When compared to data from 34 studies initiated in 2019, the average time from order form submission to protocol activation has dropped by 23% (35 to 27 days). In addition, time from order form submission to approval has decreased by 60% (15 to 6 days). This suggests that pharmacist created order sets require less revisions, and thus, result in faster approval times. We expect that as we continue to refine the process and collect additional metrics, we will be able to show a significant reduction in time from IRB approval to activation. A survey was conducted to assess staff satisfaction in the areas of efficiency, time consumption, error reduction, and submission ease. All areas scored 4.8/5 (5 being significantly better) except for error reduction, which scored a 4.5/5.

5. Lessons Learned

We learned that metric tracking is crucial in assessing the performance of process improvement measures. Historically this information wasn't adequately documented or pursued. In the future, Onbase use will be expanded to capture and provide automated metrics that will be reviewed on a quarterly basis to further improve the process.