

average review time for a full board review decreased from at least three months to approximately thirty days. The IRB Module alone increased the satisfaction of faculty and research administrators by 14.3 percent. This increase in researcher satisfaction was a good beginning and as they were increasingly satisfied, so were the sponsors. Sponsors were able to receive real time information about the status of the study review from the research staff.

The first phase was successful, but it was very important to remain focused and continue to find electronic solutions to improve the approval process timeline. Research Affairs had already centralized research administration into one physical location; however, each process used by Research Affairs still needed to be addressed and improved in a separate fashion. These separate processes or systems often led to confusion and frustration for both internal and external customers. In order to decrease these frustrations, as well as the approval timeline, it was decided to decrease as many system redundancies as possible. To this end the RRP Team developed Study-Centered Research Management™.

This concept uses the plasticity of the Click Commerce product and the research experience of research administrators. The RRP Team created the Master Project* concept, connecting the current installation of the IRB Module with modules planned for the future. The Master Project* allows certain key information fields of a project to be completed and retained for all other modules; self-populating required fields where appropriate. This eliminates the need for data to be entered repetitiously. Most importantly the Master Project* allows one administrative entry point for the entire research project, and provides a space for monitoring the progress, or lack of progress, of each project.

With the Master Project* successfully implemented, it was decided to plan the installation of the Grants and Contacts Module. Two years prior to the initial planning for the RRP, Rush had developed a coverage analysis process which outlined all items and services required to conduct a clinical research project following Medicare's Clinical Trial Policy and National Coverage Determination. All studies conducted at Rush require a

Coverage Analysis prior to any other review. Thus all other modules, including the IRB, are dependent on this particular process. Early in the planning of the Click implementation it was decided to proceed with the IRB module first since this was already developed by Click. We would continue coverage analysis on paper until the Grants and Contracts Module implementation was initiated and completed. At the time Click Commerce did not have a coverage analysis process and utilized the Rush format to design their system. The Grants and Contracts Module also provides a system-to-system application for the electronic submission of federal grant applications through grants.gov. The installation of the Grants and Contracts Module, including the Coverage Analysis Module, was completed earlier this year and has allowed Rush to process compliant industry contracts more quickly and efficiently, as well as provide a transparent permanent electronic record.

Determining an accurate price for research procedures and services was an issue causing a delay in initiating an industry sponsored clinical trial. The RRP Team decided to create a new integrated pricing structure for all studies conducted at Rush. The negotiated Medicare rates were used as the ground floor for the integrated pricing and were increased based on the competitive market values for these procedures and services. The integrated price includes both the price for the procedure or service along with the applicable professional fee. The integrated pricing schedule has been posted in the RRP by CPT code and is readily available to Principal Investigators and research administrators when drafting a budget for an industry sponsored trial. The integrated pricing strategy not only allows clinical departments to draft budgets more quickly, thereby opening enrollment on studies faster, but also creates a margin in the research fund which can be used to cover costs which are incurred yet may not be billable to the sponsor.

Presently we are actively involved in the build out of the Clinical Trials Participant Tracking Module (CTPT Module). This new module will allow Rush to track each study participant as they progress from screening to completion of the clinical trial within the RRP. The grid that is created for each participant is coded not only to record the cost of each service and

procedure provided under the protocol, but also records whether the industry sponsor, a third party insurer or the subject should be billed for the item and the amount they should be billed. This billing information for each study is taken from the grid in the Coverage Analysis Module. The CTPT Module will allow the user to produce billings to send to industry sponsors and track outstanding invoices through an accounts receivable system. The CTPT Module is expected to go live at the end of September, 2009.

Once the CTPT Module is installed, we plan to develop integration between the RRP and the Rush EPIC electronic medical records system. This connection will allow an automatic feed of medical data for each study participant and research details to the clinical setting. This data sharing will also facilitate the rapid execution of sponsored agreements, increase study and billing compliance and improve the ability to conduct Phase I and II studies. Future plans also include implementation of the Conflict of Interest Module and an Effort Reporting Module.

Future plans also include the ongoing improvement and evaluation of the new research systems while keeping the maximum three month study implementation target in view. As Rush meets this target, it is anticipated that many of the issues of industry sponsored research will have been resolved.

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