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CASE STUDY

Using ideaPoint to Manage Investigator Initiated Studies at Abbott Nutrition

PROFILE

Abbott Nutrition, a division of Abbott Laboratories, manufactures and sells pediatric and adult nutritional products, including Similac® infant formulas, PediaSure® for children, and Ensure® for adults.

Abbott Laboratories is a publicly traded Fortune 500 company (NYSE: ABT) with $20+ billion in revenue and 74,000 employees.

"Our products encircle life, from newborns to aging adults, from nutrition and diagnostics through medical care and pharmaceutical therapy."

"We sustain success—for our business and the people we serve—by staying true to key tenets upon which our company was founded over a century ago: innovative care and a desire to make a meaningful difference in all that we do."

- Excerpts from Abbott's "Who We Are" mission statement

The Problem: Managing Investigator Initiated Studies

Pharmaceutical medical device and life sciences companies are often interested in supporting innovative research related to their products by providing assistance through an Investigator Initiated Study, or IIS. (See footer.)

Participating in an IIS poses unique challenges for a potential sponsoring organization since they are not permitted to actively solicit these types of relationships, must ensure proposals meet their guidelines, and are required to manage the relationship and track mutual obligations post-approval.

Abbott Nutrition faced a number of difficulties related to their IIS program:

- There were numerous ways to submit a proposal (via email, handing a paper version to a medical liaison, postal mail, through an online submission form) which made it difficult to review, approve and track them.
- The process for reviewing and making decisions about the proposals operated on an inconsistent timeline. This resulted in "approval fire drills" during which the review committee was brought together for ad hoc meetings in order to provide timely decisions.
- Investigators did not have a direct view into the process and were unable to easily follow the progress of their proposal.

Once studies were approved, Abbott Nutrition had more than one approach to tracking all studies and their results which made it difficult to provide audit reports in a timely manner thus satisfying a key regulatory requirement.

What is an Investigator Initiated Study?

An Investigator Initiated Study (IIS), also known as an Investigator Initiated Trial (IIT), is a research project which is designed and led by an independent investigator or institution who independently approaches a pharmaceutical, medical device or life sciences company and requests assistance: financial, product, intellectual.

A study may be preclinical or clinical, outcomes or disease-state. While companies are permitted to support investigators via an IIS, they cannot actively approach or solicit participation in the study. An IIS must be truly independent of the company, initiated and run by the investigator who, often along with their institution, serves as the study sponsor.

Abbott Nutrition ultimately sought a system and process which could solve these critical needs:

- Centralized submission: The distributed submission process resulted in items falling through the cracks, fire-drills needed to vet proposals in a timely manner, and lack of transparency both internally and with the investigators who submitted the request.

- Reporting: Once a request was approved, there was no easy way to report on the progress of a particular study, nor to follow-up with investigators.

- Standardized process: The process they had in place was very manual, high touch, and at times ad hoc. Critical information was being captured and stored, but it was not in a format which made reporting easy.

The Solution: A Single System to Manage the Process End-To-End

Abbott Nutrition was able to address these challenges through a mix of process improvements and implementing the appropriate technical solution. By creating and enforcing a submission process which required that all proposals be entered via a standard submission portal, and systematizing the review and approval process, they were able to gain control over the pre-approval stages of the program. Once a proposal was approved, the team continued to use the central portal to communicate with investigators while also keeping internal stakeholders

The Results

- Abbott Nutrition receives **more than 60 proposals a year through a centralized submission portal**. Each submission is assigned to a nutrition scientist for triage, and more than half of them are reviewed by the full Nutrition Review Committee. The full process typically takes less than a month to complete.

- **Only electronic submissions are accepted**. Abbott Nutrition has eliminated the need for paper submissions. This was a major cultural shift.

- **A happy medium between high tech and high touch**. Due to the technology, during the review process, investigators can see the status of their proposal online. But, Abbott also uses this process as an effective way to engage with investigators, reaching out directly whether or not the application is approved.

- The team is able to **quickly pull reports** that assure compliance with regulatory requirements

- According to historic benchmarking, approximately **one third of IIS projects resulted in some type of publication**. With the improved tracking and reporting, Abbott Nutrition expects to establish an updated baseline for this success metric, and follow it over time.

Best Practices: Managing Investigator Initiated Studies

How was Abbott Nutrition able to refine and rejigger their approach to managing IIS? They identified some key areas of improvement, understanding that changes in these areas would have a ripple effect throughout the process. Some of the steps they took when operationalizing this program:

- **Single Submission Process:** Investigators can only submit a proposal electronically, through a centralized portal. Previously, proposals might have been submitted via email or on paper, then routed to the appropriate person for review (hopefully). The IIS team at Abbott Nutrition revamped the process itself so that only proposals submitted through the portal would be accepted for review. To ensure broad exposure for the submission portal, its address is included on many pages of the Abbott Nutrition website (in the footer), and medical liaisons also promote the site, should an investigator want to create a proposal. Culturally, the biggest change was moving from a process which allowed paper submissions to one which only allowed them electronically. This one change enabled many of the other best practices that follow.

• **Predictable Process:** Instituting a single, standard process for reviewing and approving proposals eliminated the need for fire drills and ad hoc review meetings. When a proposal is received via the portal, it is assigned to a nutrition scientist who serves as its internal sponsor. The internal sponsor conducts an initial assessment of the submission, adds their notes to the submission, which triggers whether it is ready to be reviewed by the full scientific evaluation committee.

The Committee meets monthly, and its cross-discipline membership consists of representatives from key groups (e.g. Medical Director(s), Clinical Science, Clinical Ops, Regulatory, Legal, Safety, etc.). This group is responsible for determining whether a proposal should be approved, conditionally approved or declined. Most often, proposals are sconditionally approved, pending the need to address potential issues. The initial review is focused on the scientific merits of the proposal; once the science is approved, fiscal approval is required from a core group of 3 or 4 senior executives.

This entire process, including routing and approvals, is managed from the single centralized system.

• **Defined Areas of Focus / Clearly defined evaluation criteria.** Abbott Nutrition defined five evaluation criteria for all submissions:

- Scientific Merit
- Ethical Considerations
- Legitimate Need
- Abbott's Strategy
- Fair Market Value

These criteria are used to make a determination about the proposal, and are also embedded within the submission form to increase the likelihood that a proposal is complete and will meet the threshold required for approval.

• **Technology's Great, but the Human Element Matters.** Abbott Nutrition views each submission as an opportunity to reach out to the investigator directly and form a relationship. Although the technology allows them to send electronic updates and solicit follow-up info exclusively electronically, they prioritize the relationship over possible technical efficiency.

• **Single System of Record.** Along with creating a single process, having a single system of record has simplified their approach to managing submissions and subsequently managing the studies and relationships with investigators. Even when there are actions which happen outside of the system, such as conversations or follow-up communication, the results must be put back into the system before the proposal can proceed.

• **A Small Part of A Day Job.** This process is only a small part of what reviewers do, so when the system was put in place they wanted to ensure it was easy to follow, and that the system prompted users to do their next step. And, in the case of important but tedious tasks, such as generating Quarterly Status Reports for the Executive Management Team, using this system has streamlined the process of compiling that report and assessing the data.

• **Culture Change.** The team wanted to manage all submissions within a single system, so each proposal had to be submitted in the same way and in the same format. One consequence: submissions made on paper would no longer be accepted, which was a departure from how it had always been done. In order to enforce this change, the team took a hard line, refusing any non-electronic submissions, no exceptions. The upside is that by managing proposals and studies electronically, they have greater visibility into each individual study and into the program as a whole. That said, the team remains conscious that relationships supercede technology; they did not want to entirely weed out any personal interactions in this process.

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How ideaPoint Supported Abbott Nutrition's IIS program

To operationalize the program, Abbott Nutrition wanted a software platform to capture the submissions, facilitate multiple review processes and ultimately enable them to be transparent with the process itself.

Abbott Nutrition chose to utilize the ideaPoint platform since it met their selection criteria:

- **Online Idea Submission:** The ideaPoint platforms serves as the single system of record which is universally available to both internal and external stakeholders. Abbott Nutrition has a custom submission form through which the proposal is submitted. The page itself leads investigators through the process of submitting their request. The form is web-based, so any investigator worldwide is able to access it and submit their proposal.

- **Custom Workflow:** Abbott Nutrition created a custom workflow within ideaPoint to simplify the review process. The system was also implemented so that it could support the parts of the process which happened outside of the system itself (conversations, meetings, status updates).

- **Submission Tracking:** All submissions were captured and tracked in a single central system so administrators were able to monitor the status of each submission and ensure it was reviewed in a timely manner. In the past, this process was done via email and a sharepoint database which was extremely cumbersome and error prone.

- **Relationship Management:** Because the system captures all proposals, whether approved or not, the team is able to maintain contact with all of the investigators who have sought assistance. For approved proposals, the systems also serves as an auditable record of the interactions which have taken place between Abbott Nutrition and Investigators.

- **Study Management:** Once a study has been approved, the ideaPoint system enables Abbott Nutrition administrators to track the studies' progress. Specifically, it enables them to validate the outcome of each study, facilitating longer term longitudinal tracking and trend analysis while giving them the capability to benchmark the program's overall efficacy.

In Summary

ideaPoint is a foundational component of Abbott Nutrition's IIS program. Through ideaPoint, Abbott Nutrition:

- Managed ideas and submissions in a single repository which allowed them to quickly scale the program.

- Captured submissions then quickly and systematically evaluated them while also keeping track of where they were in the review pipeline, thus providing increased transparency.

- Automatically routed submissions to the appropriate reviewers to ensure timely triage and decision-making.

- Easily reported on the status of each submission, and on the program overall.

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