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GROUP

Improved Disclosure Clearance at a Top Tier Pharma Company: A Case Study

Part 1: The need for a 'simpler, better way'

In 2011 this top 15 pharmaceutical company identified a need to improve what had become an unwieldy and complicated process for approving material for external disclosure. The revised process would be required to cover a variety of publication-related and other scientific materials. The goals were to simplify the process and to 'push down' decision making authority in the organization, while still ensuring the correct people were involved in providing advice, making decisions about information release, and kept appropriately informed along the way. Previously, those submitting a request for document release had been able to assign reviewers and decision makers at their own discretion, and the company considered that this process was "getting out of hand", putting them at risk, and needed to change. The company looked at the available proprietary tools that might support this process improvement, and then initiated, but subsequently abandoned one such tool. This system was "a bear to use", and "people would need to set aside an afternoon just to submit one disclosure." The system was found to place additional burdens on users that the company regarded as unacceptable and wanted to rectify. For example, completion of several hours of training was essential to learn how to navigate the system prior to use – which was found to be not very practical if first use of the system happened to be for an urgent disclosure approval. In addition, the internal support team would frequently get requests for 'hand holding' through aspects of the system that were not intuitive.

Another perceived weakness was that this tool allowed users to "just let things hang" – with the result that tasks could sometimes be overdue by weeks. Following adoption of Datavision™ by the company's publications team, a decision was made to further align with Envision as a supplier, through the implementation of their disclosure clearance software, Clear. Future integration of these two Envision systems was also an attractive prospect.

"It was a very collaborative venture."

Several planning sessions were held between Envision and the company to determine how intended process changes and technical requirements could be best accommodated within Clear. The company team also reported that, in the crucial early stages of implementation, they had "unbelievable access" to the Envision team – which was considered ultimately to be a key factor in the successful launch of the system. Another factor that contributed to successful roll-out was a sequence of focus groups, held with representation from across the research, product development, and commercialization functions. Participants included multiple stakeholders from across several sites, and encompassed team members likely to play both submitter and reviewer roles once Clear was launched. These focus groups worked with the system, in simulated but realistic scenarios, and provided feedback on adaptations that would bring the system fully in line with the company's needs. All participants found this process very valuable, and the company acknowledged the advantages gained by taking Clear to potential users at this pre-launch stage.

From contracting to full roll-out, the implementation of Clear in this company took approximately 9 months.

"Envision's participation was not from the perspective of a vendor, it was from the perspective of a partner."

"The team were very engaged and questioning, in a very helpful sense."

"The questions asked, and insights into the process, made it a seamless experience."

For more information, or to arrange a demo, please contact:
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Part 2: Reaping the benefits

The company has identified three key benefits since the system was launched in mid-2012.

1. The submission, review, and approval process is much simpler and faster

"The Q&A wizard ..." that supports the submission and review process and determines the appropriate workflow

"...has worked remarkably well. A complex workflow system backs this up, but the front end is pretty simple."

"Credit to the Envision tech team for helping us think that through and ensuring that the advisors and decision makers are informed"

The company team responsible for the implementation received many positive anecdotal reports on the speed, performance, and intuitiveness of the system. For example, the time involved in completing a disclosure was reported as "light years ahead of where it used to be." The average time from submission to decision was reduced to approximately 4 days, whereas previously "it could take weeks to push a disclosure through the system."

2. Senior executives have observed much greater transparency in the decision making process

Senior management have a clearer understanding of the advisor and decision maker roles, and the inputs that each have in the process. The responsibility matrix feature of Clear has proven easily adjustable to ensure that the system aligns the correct people to review the correct disclosures.

3. The system has supported better protection of intellectual property

Clear allows for a check on potential patent registration- and protection-related implications of disclosures through legal review, including those relevant to existing alliance partnerships. (It can also facilitate third-party access to the system to further assist the process in this latter case).

"Pharma development is a very complex environment. Once something moves out of a particular area, people remain curious as to what transpires with an asset. Being informed remains valuable."

"This is very much part of that translational R&D effort."

In addition to these benefits, one original goal of the company had been to establish a 'zero requirement for training', and this has been successfully achieved. A 'Quick Reference Guide' and other tools were developed for submitters and reviewers, and for administrative assistants using the system on behalf of others; but these tools have been rarely used in practice – reinforcing the intuitive nature of the system.

Clear has also supported the company's philosophy of working towards 'translational R&D', where visibility and feedback occurs throughout the drug development process; for example, where information from clinical research can feed back into earlier stage research. By automatically informing key individuals of information relevant to their areas of interest and responsibility, the system has prompted conversations that might otherwise not have occurred.

Looking to the future

The company has identified a key role within the Envision team – the Business Analyst – as essential to the ongoing successful implementation of Clear. This key go-to Envision team member is adept at translating the client's needs into the required system solutions as the use of Clear evolves and expands. The Business Analyst will likely remain important in this particular case, as the company considers Clear for other areas where review and approval processes require support. One such area is public affairs, where press releases and similar documents currently go through an email-driven review process.

The company's old process and system were burdensome and, as a result, there had been no desire to look at applying them more broadly within the company. Now, with Clear in place, the company is eager to identify process improvements that might be made in other areas. One particular interest may be the potential application of Clear to enhance processes where there is a requirement for an audit trail: "The audit part of the system is pretty powerful. When needed, it's easy to get to that information." So, with its ease of implementation and intuitive functionality, Clear is perceived as a solution that could help address other process challenges into the future.

In conclusion, this company reports that Envision's Clear has "... made a pretty complex process relatively simple from the user's perspective – one of the keys to the success of the system."