



myClin



NEKTAR®

How Nektar Used myClin To Transform Study Team And Sites Collaboration

Summary

- Deeply integrated study team across 13 collaborating organizations.
- Stronger communication with solicited and unsolicited feedback for a more effective operational plan and a better protocol.
- Highly engaged sites exceeded enrollment targets despite delayed start – attributable to stronger engagement between the sponsor, CRO and study site staff that was enabled by the myClin platform.

Challenge

Nektar Therapeutics is a biopharmaceutical company engaged in developing a proprietary pipeline of drug candidates for several therapeutic areas including oncology, pain, anti-infective, anti-viral, and immunology.

Nektar used the myClin platform across their portfolio from Phase I through III. This case study describes a multi-site phase III clinical program for chronic pain. This complex clinical program required the collaboration of 13 organizations including the sponsor, the CRO, vendors and 55 clinical sites.

Early on, the management team sought to reduce silos between the diverse organizations to create a collaborative, unified team operating under a single philosophy: *Protect the patients and endpoints, optimize site and patient experience, execute with an adaptive learning approach, and deliver an analysis-ready dataset and an inspection-ready file.*

Solution

To fulfil this objective, Nektar relied on myClin as a novel solution to:

- Engage and motivate all team members
- Manage communication and ensure consistent messaging and common understanding
- Aid the transmission of information among team members and across organizations

They put the sponsor team, the CRO, and all the vendors on the myClin platform in order for them to share documents, training, news items, and important study milestones – making them available for filing, reviews and comments. myClin offers a single, trackable communication channel that organizes team communications and automatically documents it in a secure, central and regulatory compliant manner.

Once the core study team was aligned, the platform was expanded to include all the staff at the clinical trial sites. The channels were used to support site activation, training, study correspondence and provide remote monitoring of the content published for inclusion in investigator site files.

Activities supported by myClin include:

- Protocol development
- Study planning
- Investigator meeting preparation and delivery
- Site training
- Site engagement

myClin helped **strengthen and unify the team culture** by drastically reducing low value, repetitive emails – it countered faceless communication by helping people engage with their fellow team members improving the study conduct. As an extremely easy to use collaboration platform, the sponsor found that the myClin platform fostered a productive and efficient review process. myClin works partly by the novel application of social media concepts – connecting team members in an intuitive way. It increased the team engagement and produced more effectively integrated and concise documents that crossed typical vendor boundaries.

zzz-Study Team - SUMMIT - Nektar Therapeutics

The screenshot shows a document interface on the myClin platform. At the top, it indicates 'Version 1.10' and a 'Download (1.19 MB) Current Version' button. The document title is 'Essential Documents Review Checklist', created by Kelsie Stephen on 09 December 2014 12:11 PM and modified by Tara Whalen on 26 February 2015 1:32 PM. The main text of the document discusses a merge of feedback from regulatory groups and Nektar's approval, mentioning GCP/ICH and FDA guidelines. It details requirements for section 1572 and CV requirements, and notes an update to the document on 08 Jan 15. Below the text is a small icon of a document. On the right side, there is a 'COMMENTS' section with a 'Toggle Filing Details' button. Three comments are visible: Eileen Daniel's comment about updating the document and removing local laboratory sections; Erin Elman's reply to Eileen; and Tara Whalen's comment asking a question about including a local lab in section 1572.

Example of a study document and comments on myClin.

Results

myClin helped the team shift from a paper environment to digital delivery, find new ways to facilitate site training, new ways to document and demonstrate oversight of study conduct.

“We discovered that we were capturing more input and ideas along the way” explains John Silowsky, Senior Director, Clinical Operation at Nektar Therapeutics. “There was a sense of opportunity to brainstorm and share ideas. It took the team to another level on how they approach working together.”