



>>> Moving from a manual, labour-intensive process to an automated, secure collaborative document review system proves a huge success, right from the start

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When implementing PleaseReview, there was virtually no set up except knowing who was going to be set up on the system and the training was easy because PleaseReview is really intuitive for people to use.

Business overview

Amarin Corporation is a clinical-stage biopharmaceutical company focused on improving the treatment of cardiovascular disease, capitalizing on their expertise in the field of lipid science and the known therapeutic benefits of essential fatty acids. Amarin is a publicly-traded company headquartered in Dublin, Ireland, with research and development based out of Mystic Connecticut, USA. Amarin's lead product candidate has recently completed two Phase 3 clinical trials, reporting positive results for both.

Conducting clinical trials is an extremely document intensive process, with all departments involved in the creation and subsequent review of documents particularly related to submissions, such as protocols, reports, memos, certifications, contracts, quality agreements and clinical investigator agreements. By early 2009, Amarin was actively looking for a solution that could simplify and speed up this process, especially as the Phase 3 trials had received FDA approval to proceed.

The challenge

Amarin previously circulated documents for review by email as attachments, or distributed hard copies for manual editing and review. However, there was the constant concern that document confidentiality could be compromised. A key deciding factor in their search for a review solution, was the ability to provide secure remote access to documents. Additionally, managing reviewer comments was a challenge that was both extremely frustrating and time consuming, as Peggy Berry, Vice President and Head of Quality & Regulatory Affairs states, "... collating, duplicating, and wading through so many comments from so many people- it seemed to go on forever."



We use PleaseReview across the company as it maintains document confidentiality and it makes it far quicker for authors to collate and reconcile comments, saving us all so much time.

The solution

Amarin opted for PleaseTech's private cloud solution as a cost effective and hassle-free way to access PleaseReview. As there was virtually no set up involved (except for some customization and administrative tasks) and only minimal training, PleaseReview's implementation was totally painless. PleaseReview is used throughout the organization, including regulatory, quality, CMC, clinical, medical and non-clinical departments as well as by project management and business development. Its success is based on its functionality, its ease of use and the assurance that document confidentiality is maintained by providing reviewers secure access to the documents both within and outside the corporate firewall.

Peggy no longer has to manage review comments manually: "with PleaseReview, all comments are made on a single draft of the document, and as every reviewer can see comments from other reviewers there are no duplications and if they disagree, they can indicate that within the comments. It is all so much more civilized and everyone gets to really collaborate on the review".

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