myClin

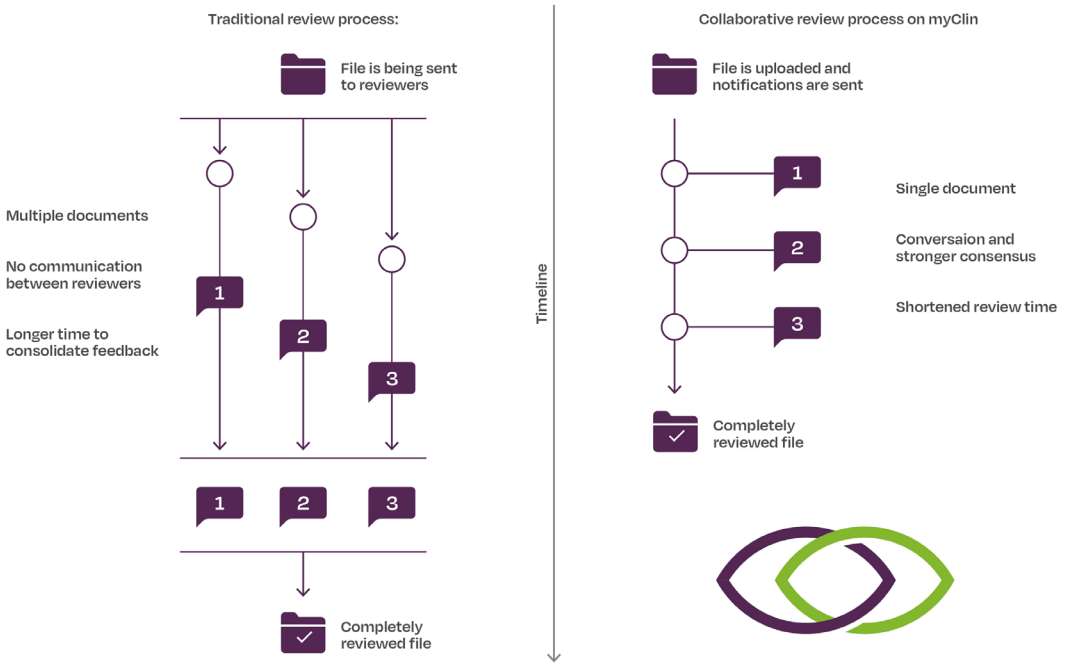
Streamline and Accelerate Protocol Development

Study protocols are blueprints that clinical researchers follow to conduct clinical studies. These are unarguably some of the most important documents in your studies, and consequently ones that require the most time and attention to prepare. Protocol writers need to gather information, submit questions to internal and external collaborators in the medical community, receive answers and incorporate their feedback while keeping all parties informed. Multiple versions of documents are often exchanged back-and-forth throughout this important and time-consuming phase.

Traditionally, when using email, draft versions are shared with multiple consultants and KOLs who make their comments in isolation from each other. The sponsor then reconciles the feedback to produce a new draft to be redistributed to the reviewers. It is only at this point that the reviewers get to see each other's comments and ideas – to which they now start responding, triggering further time consuming review/reconciliation cycles.

Collaborative Review Cycles

As a single and secure collaboration channel, the myClin platform can streamline and accelerate protocol development while keeping all parties in sync. On myClin, reviews occur in parallel with everybody seeing contributions from other team members. This dramatically shortens review cycles by allowing participants to work together and build a stronger consensus around the protocol.

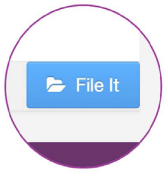


Enriched Communication and Improved Quality

According to myClin users, this process also enriches the team communication and sets the stage for cross-pollination and better ideas to emerge. The sponsors that already use myClin to facilitate this process report substantially improved protocol quality, identifying substantial implementation issues and opportunities for improved compliance before finalizing a protocol. Avoiding and reducing the need for protocol amendments is a major benefit achieved by this collaborative process.

When you engage in a dialog with investigational sites before the protocol is final, their input helps to reach a stronger consensus and approval from all parties, which has a strong positive impact on timelines down the road. This can save substantial amounts of time for training and project rollout which might otherwise get repeated after the first few patients are screened. It also paves the way for the lead investigators to become advocates for your protocol by the time of Investigator Meetings.

Communicating Protocol Amendments



Even when protocol development was done diligently, protocol amendments are common. Tufts (Tufts Center for the Study of Drug Development 2010 analysis of 3,596 amendments and 19,345 changes) data notes that 69% of all protocols have at least 1 amendment with 64% of all amendments coming after first patient, first dose. myClin helps disseminate protocol amendments to all sites and participating parties. myClin's "File it" feature lets you monitor which sites have reviewed the new document, who is up to speed or behind. Filing an item also adds it to a virtual study file for that site, easing the record keeping obligation for sites, and ensuring compliance and preparedness for audits.

> myClin enriches the team communication and sets the stage for better ideas to emerge

myClin is the leading Software as a Service (SaaS) platform for essential Clinical Trial Compliance and Oversight. It allows for secure document exchange between sites, sponsors and CROs, automatically tracked study communications, centralized and accelerated study training, and unique Compliance Scoring insights.

The myClin Compliance Score gives all study stakeholders the ability to identify and measure hidden study compliance gaps. You can track and improve the readership of essential study documents and the delivery of critical study updates and training. It provides clear and objective metrics for all stakeholders to stay inspection-ready and ensure continuous and contemporaneous oversight.

Since 2008 our mission has been to leverage technology to enhance oversight, compliance, engagement and collaboration in clinical trials. The team of clinical research veterans that created myClin brought deep experience delivering clinical operations services and building feature-rich eClinical systems. Since then, myClin has been used across all phases of research, in global bio-pharmaceutical and device studies with thousands of clinical users.

myClin is headquartered in Philadelphia, PA, with offices in the United Kingdom.