



Modern and Real-World Study Oversight with myClin

The Reality of Oversight as a GCP Requirement

The term "Sponsor Oversight" has slowly crept into the vernacular of Clinical Research and Development but, make no mistake, the requirement for Oversight is all around us. The Medicines and Healthcare Products Regulatory Agency (MHRA) Guide to GCP makes no fewer than 169 references to "oversight".

The call for documentation or evidence is a consistent and repeated theme across many regulatory publications. The updated ICH E6 (R2) Addendum, adopted by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) last year, reinforces this trend setting out clear expectations that:

"The sponsor should ensure oversight of any trial-related duties and functions carried out on it's behalf."

Source: ICH GCP E6 (R2), 5.2.1 & 5.2.2

The new addendum ICH GCP E6 (R2) introduced 26 new items concentrated in the areas of sponsor and investigator responsibilities. For example, it assigns to the investigator the generation of documentation to be available "upon request", moving requirements toward a more real-world and real-time clinical research oversight. As ICH E6 (R2) Addendum becomes the standard expected by inspectors worldwide how confident are you that you're documenting your study oversight activity in a compliant way?

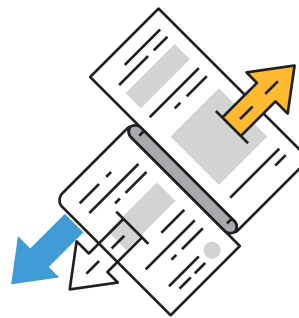
This paper provides a modern definition of oversight and what it involves, and illustrates how the myClin platform builds a strong oversight directly within your study team communication and collaboration channels.

Principles of Oversight and Common Inspection Findings

The conceptual principles of Oversight are:

- The sponsor retains accountability
- Oversight methods should be defined in advance
- Oversight is a continuous activity
- Oversight should aim to identify leading rather than lagging indicators
- Address issues that arise (with an audit trail)
- Oversight conducted must be clearly & contemporaneously documented and retained in the TMF

Source: Jeanette Dixon, Biogen – EU Clinical Quality Oversight Forum 2017 ([ExL Events](#))



The list of typical recent inspection findings related on this topic will be familiar to many:

- TMF doesn't hold the RFP and related outsourcing/contracting records. In other words, the record of vendor assessment prior to award - often not considered trial data.
- Lots of use of SharePoint - one person's organizational file structure is not another person's organizational file structure
- No evidence of contemporaneous oversight
- No earlier versions, or audit trail, of electronic trackers, e.g. spreadsheets
- Incomplete training records because they get split across organizations
- Difficult to track when participants were actively involved in the study; tracking staff turnover at the sites, CRA team, study team, etc

Source: Joy Eldridge, AZ -- EU Clinical Quality Oversight Forum 2017 ([ExL Events](#))

Streamline, Centralize and Automate Oversight

Oversight activity needs to be documented on a continuous basis as clinical studies proceed through planning, execution and closeout. It is almost as though regulators are seeking evidence of the stream of consciousness of a clinical study from inception to conclusions.

CREATE A TRAIL OF DATA

It is apparent that the outcome of the study isn't the only interest of regulators. They are just as interested in the path the entire team took to generate the results. It's not possible to collect all decisions made and processes followed during a clinical trial but a concentrated effort needs to be maintained to ensure that sufficient data points are captured along the way to "recreate the scene". This requires a disciplined and consistent approach to capturing/recording information about the studies along the way.

DOCUMENT YOUR STEPS

Documenting Oversight in practical terms can start by being as simple as taking effective minutes of weekly meetings and tracking the corresponding issues. Straightforward as that sounds, important tasks like these can be pushed aside when recruitment lags or when problems are identified and the study team scrambles to provide a fix. It's easy to push aside meetings and "chores" to focus on solving problems. While important (and sometimes exciting) to solve problems, remember to bring a scribe along the way to "record" what was done and why. To what extent do our current processes and systems support the continuous and automatic collection of oversight evidence?

CENTRALIZE AND AUTOMATE TRACKING

Centralizing collection of trial information and making that information visible to anyone/everyone on the study team enables oversight.

Enter myClin and the "File It" button. Posting content on a myClin study channel records who accessed documents and when they did it (via the "File It" button). Simultaneously, these posts become a "living TMF" for the sites and study team.

"Regulators are just as interested in the path the team took to generate results as in the outcome of the study"



Tweet



Share

Personalized Knowledge Feed
myClin presents each study team member with a personalized knowledge feed that centralizes the latest posts for their clinical study.





Trackable Sharing & Filing
Users hit "File It" for new posts once they have read and understood announcements, training, or documents. They can also post comments and questions so you can easily clarify each piece of information for the whole team.

Audit-Ready Study Files
By nature, study correspondence, training, events, and updates relevant to each site are recorded on myClin. It's all there and accessible at all times.

Real-Time Trial Oversight
myClin provides your team with secure, central, and personalized access to essential information and documents relevant to your study, and a communication channel to ask important questions and receive answers faster.

Clear regulations describe that documentation demonstrating that the site or study team member is meeting regulatory requirements must be maintained and be able to be accessed in real time, not retrospectively. The File It feature helps monitors and study team members assess the level of engagement and attention research sites are paying to your important clinical research trial and, more importantly, point out members who are not picking up their messages. Reaching out to sites who have not hit "File It" is a ripe opportunity to evaluate overall engagement and interest in the study (as well as fulfilling oversight requirements that require sponsors to ensure that research sites have the proper skills, qualifications and training to compliantly execute a trial).

myClin study team membership reports shows who was active in on the project within a given period of time. Study team membership in myClin serves as source to justify who gains access to other electronic systems (EDC, IxRS, central services portals, etc). Control of who was on and when they were on the study and the systems they accessed all demonstrate adequate sponsor oversight.

Key Contacts Member Directory Investigator Sites		
Search		
Name	Role	Contact Information
 Adam Wood VP, Business Development at myClin Clinical Research LLC Local time: 1:10 PM Last login: 25 minutes ago		myClin Clinical Research LLC 118 Church Street, Philadelphia, Pennsylvania, 19106 adam.wood@myclin.com +44 77 7082 5669
 Albin Rehn at Karolinska University Hospital Local time: 12:10 PM Last login: 14 days ago	Investigator (primary)	Karolinska University Hospital Karolinska vägen, Söna, Stockholm, 171 76 adam.wood+albin@myclin.com +46 78 13 266 90
 Anke Nortamo Data Manager at Data Magik Local time: 12:10 PM Last login: 3 days ago		Data Magik Laburnum House, East Grimstead, Salisbury, SP5 3RT adam.wood+dm@myclin.com +44 1722 712972
 Axel Stojkovic at Karolinska University Hospital Local time: 12:10 PM Last login: 16 days ago	Coordinator (nurse)	Karolinska University Hospital Karolinska University Campus, Stockholm, 45678 adam.wood+axel@myclin.com +46 78 569 45 58

The Trial Master File as the Stream of Consciousness for your Studies

The move to a living Trial Master File continues to accelerate and inspector expectations match this level of acceleration. This acceleration easily lends itself to the use of automated technologies. These days, inspectors are well versed in analyzing TMF meta data and content, e.g. to review when material was posted to the TMF. A red flag is raised when they see a surge of material submissions in the days and weeks immediately prior to their visit, instead of a naturalistic pattern that showed the researchers accessing and using information when they needed it in real time, instead of weeks, months or years after the activity. These surges provide a clear indication that oversight activity was not quite as continuous and ongoing as GCP demands.

In this way, the TMF is becoming the stream of consciousness for your study. Many clinical developers know that and are improving efforts to get study activity evidence loaded. But so often it is hard to bring together material from the many vendors and sites that are the participants in so many of our studies.

Wouldn't it be good to have a tool that all study stakeholders can access to funnel content into the TMF on a timely and contemporaneous basis? Automatically documenting our everyday study delivery activity? The myClin Clinical Trial Knowledge Platform can do this.

myClin's Role in Quality Management

Jonathan Rowe is responsible for the performance oversight of Pfizer's Good Clinical Practice (GCP) Quality Management System. He articulated 13 components of a GCP QMS:

The 13 Components of a GCP Quality Management System



Source: Jonathan Rowe, Pfizer – EU Clinical Quality Oversight Forum 2017 ([ExL Events](#))

As illustrated myClin substantially fulfils 6 of these components – and touches some of the others as well. myClin is a unique solution – partly email on regulatory steroids; partly a portal but without the pain and inflexibility; it is a communication and compliance platform that automatically documents your oversight activity, organizes that content into TMF ready form while stretching across all your study stakeholders.

myClin is the leading Clinical Trial Knowledge Platform, offering a transformative collaboration channel and the most documented, data-driven clinical trial oversight. The company's mission is to leverage technology to enhance participation, engagement, collaboration, and compliance in clinical trials. The team of clinical research veterans that created myClin in 2008 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 San Francisco, CA, and the UK.