Overview

The need
The Baim Institute wanted to improve the efficiency of their manual, paper-based endpoint adjudication process.

The solution
The Baim Institute incorporated the digital power of IBM Clinical Development’s endpoint adjudication module.

The benefit
The Baim Institute cut their adjudication timeline by an average of 30 percent and strengthened their relationships with sponsors.

“Before IBM Clinical Development, we had very highly regarded endpoint adjudication processes, but we were still performing many tasks in a manual fashion... with the IBM Clinical Development endpoint adjudication module, we’ve cut our timeline by an average of 30 percent.”

Michelle Escarfullery
Business Manager, Clinical Review and Safety, The Baim Institute for Clinical Research.

Baim Institute for Clinical Research

IBM Clinical Development helps cut endpoint adjudication timeline's by 30 percent

The Baim Institute for Clinical Research, a world-renowned academic research organization, expanded its endpoint adjudication services—and reduced the timeline to complete the process by an average of 30 percent²—by implementing IBM® Clinical Development, a multi-faceted, cloud-based clinical trials solution from IBM Watson Health.

The crucial role of endpoints in clinical trial management

An endpoint is an event in or a result of a clinical trial that helps measure whether the treatment under investigation is safe and/or effective. Events such as an increase or decrease in symptoms, improvements in quality of life, or even serious adverse outcomes such as a heart attack or stroke can be considered endpoints.
Researchers have to compile and ship multiple boxes filled with three-ring binders (each holding hundreds of pages of data) to Clinical Events Committee (CEC) members. Once the CEC can schedule a meeting (often several meetings) to review the data, the notebooks then have to be boxed up and shipped back to the research team for follow up. Communication between the researchers and adjudicators is often engaged and disjointed, and the lag time between steps in this traditional process can be long.

How long? Consider this: In a paper-based system it’s not uncommon that a single exchange between an investigator’s data manager (DM) and members of a CEC (for example to receive adjudication queries, resolve them, and return them for updates) takes at least five days—usually more. And nowhere is the old maxim “time is money” more applicable than in clinical research. According to the National Institutes of Health, the number of registered trials since 2000 has increased nearly 30-fold to more than 170,000.

Developing a drug now costs more than $1 billion, and each day a trial is delayed costs a sponsor $8 million. The FDA estimates roughly 94 percent of studies experience delays, and nearly three out of four are delayed by more than one month. When you factor in the cost of the delays produced by paper-based adjudication, it is clear there has to be a better way.

Harnessing benefits from a digital revolution

With electronic endpoint adjudication that same process can be completed much more quickly (think days, not weeks). It’s no wonder that the industry is embracing electronic endpoint adjudication. As an October 2015 call for input in Applied Clinical Trials put it, “the emerging field of Endpoint Adjudication is relatively new and is rapidly gaining traction.”

Historically, the manual, paper-based endpoint-adjudication process has been time-consuming, resource-intensive and inefficient. When endpoints are captured in clinical studies, an independent, objective group of experts (typically named an Endpoint Assessment, Event Adjudication or Clinical Events Committee) is often engaged to review the outcomes data and provide their assessments. Did the treatment under investigation cause this result? Why or why not? Were protocol-specified criteria achieved?

Endpoint Adjudication (EA) by a single entity, one not influenced by others in the research study, is typically considered an essential part of a clinical trial because it helps reduce variation in the interpretation of outcomes and events—a benefit that can be especially helpful during regulatory agency review.

Traditional endpoint adjudication: taxing, tedious and time-consuming

Historically, the manual, paper-based endpoint-adjudication process has been time-consuming, resource-intensive and inefficient.
While electronic endpoint adjudication is a new or relatively new concept to some researchers, IBM Clinical Development clients like The Baim Institute have been capitalizing on the many advantages it offers for several years. The introduction of the online Endpoint Adjudication Module from IBM Clinical Development has proven to be a powerful asset to organizations like The Baim Institute.

The Endpoint Adjudication Module allows users to create a digital, paperless workflow for adjudicating study endpoints. It gives all stakeholders on-demand access to the study data, documents and adjudication determinations based on their roles and permissions. It also compiles a “digital dossier” of all required endpoint details and source documents that can be shared online.

Endpoint Adjudication Module helps users streamline key workflows, including paired consensus, parallel review, expert review and direct-to-committee needs. To help speed the review process, the module automates several critical tasks such as document redaction (users can upload documents and perform all markup and redaction simultaneously), checklists (events can be coordinated on demand, and auto alerts can be established), and document translation (documents can be translated from one language to another without having to exit the system).

“The Baim Institute for Clinical Research cut timeline by an average of 30 percent.”

After incorporating the IBM Clinical Development Endpoint Adjudication module during 2015, The Baim Institute began to realize gains in the speed and efficiency of their adjudication process.

“Before IBM Clinical Development, we had very highly regarded endpoint adjudication processes, but we were still performing many tasks in a manual fashion,” says Michelle Escarfullery, business manager for Clinical Review and Safety with The Baim Institute for Clinical Research. With the IBM Clinical Development Endpoint Adjudication Module, we’ve cut our timeline by an average of 30 percent.”

According to Mr. Escarfullery, the flexibility of the Endpoint Adjudication Module was a key factor in The Baim Institute’s selection of IBM Clinical Development from Watson Health. “Number one, we needed an option that would let us tailor aspects of the workflow to our needs, and IBM Clinical Development fit that perfectly,” Mr. Escarfullery said. “For example, we can now easily modify adjudication forms to match the needs of specific studies. Our ability through the module to customize eCRF [electronic case report form] pages means that our team can collect source documents and translate them into multiple languages in one central location.”

Elaine Catapane, The Baim Institute’s director of Clinical Review and Safety, echoed this perspective and highlighted another advantage of the IBM Clinical Development platform and IBM Clinical Development Endpoint Adjudication for the organization: worldwide access to key study data. “Because we conduct studies around the world, having a cloud-based database empowers us and our partners to work in a truly unified global workplace.”

“Because we conduct studies around the world, having a cloud-based database empowers us and our partners to work in a truly unified global workplace.”

Elaine Catapane
Director of Clinical Review and Safety,
The Baim Institute for Clinical Research

About The Baim Institute for Clinical Research
The Baim Institute for Clinical Research is a leading, not-for-profit academic research organization that delivers insight, innovation and leadership in today’s dynamic research environment. The Baim Institute collaborates with some of the world’s most highly respected researchers from renowned institutions to help advance health and quality of life around the world.

The Baim Institute has gained notoriety for the design and execution of clinical trials for first-in-class medical devices. Examples include trials for the first approved drug-eluting stent, and the first approved transcatheter mitral valve repair device. In addition, The Baim Institute recently sponsored and completed the DAPT study, a large, FDA-mandated study that enrolled over 25,000 subjects, evaluating the use of dual antiplatelet therapy after stent implantation.

In April 2015, IBM launched IBM Watson Health and the Watson Health Cloud platform. The new unit will work with doctors, researchers and insurers to help them innovate by surfacing insights from the massive amount of personal health data being created and shared daily. The Watson Health Cloud can mask patient identities and allow for information to be shared and combined with a dynamic and constantly growing aggregated view of clinical, research and social health data.

For more information on IBM Watson Health, visit: ibm.com/watsonhealth.

Footnotes


