White Paper

Regulatory Submission

Simplifying the Regulatory Submission Process with a Modern CTMS

Converging technologies in the clinical trials space are improving efficiencies on most fronts of the clinical research process. Gaps remain, however, and if we as an industry are to drive further efficiencies in clinical development, we must rethink our processes and our technology in a more modern context. Through direct work with a focus group composed of representatives from many divisions of the industry, the product development team at *DATATRAK* reached the conclusion that regulatory submission, among other operations of interest, remained largely unassisted by the current ecosystem of clinical technology. Working in collaboration with industry representatives, this group explored the value that pulling the regulatory submission process into a modern Clinical Trial Management System (CTMS) could have, and devised a purpose-built solution to address that need. This chapter seeks to discuss the ways in which collaboration with industry professionals resulted in a CTMS platform that drives efficiency and value in the regulatory submissions through:

Highlights

- The power of technology can be harnessed to simplify the regulatory submission process
- Modern technology delivers actionable data to improve workflows, reduce human error, and provide greater trial team efficiency.

- **Reusability – The elimination of redundancy:** Modern technologies that are purpose-built should seek to identify the constituent parts of the workflows they support with the intent to **provide reusability**. By identifying the most common elements in a process and modularizing them, the most common steps, particularly in the clinical trials space, can often be eliminated. The elimination of redundancy is among the simplest ways to drive efficiency with technology.

- **Reduction of human error:** A platform designed to support the enterprise should also inherently **reduce user error and the associated risk**. By bringing one's processes into a technological system that is specifically designed to support them, the tasks and procedures involved should necessarily become more intuitive and easy to complete. By pulling human processes into a more human-friendly environment the chance of mistakes made due to complexity decline. Additionally, once the decision has been made to bring these user-executed tasks into a platform, the software can then be employed to check and correct user errors as they happen. By getting out ahead of the problem, the potential for downstream impact of human error can be substantially reduced.

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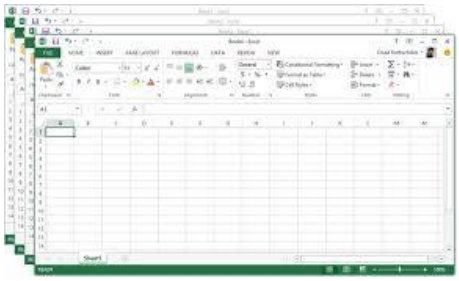
- **Making new workflows available:** A modern software solution should not simply improve your existing workflows; it should also make new workflows available. The **onboarding process should be simple, quick, and designed with your current processes in mind.** The solution should allow users to **perform their usual tasks more efficiently** while at the same time offering new ways to complete them.

- **Delivering actionable data:** Ultimately a platform like a CTMS should deliver more actionable data in all things. The simple act of bringing a process into the technology should render the data it yields more usable than before, allowing it to be more quickly aggregated, analyzed, and acted upon. In the end, this is the greatest value driver for technology because it creates value where it previously did not exist.

Design Challenges



After consulting our user group, we found that the vast majority of institutions making regulatory submissions were handling these procedures with in-house, proprietary solutions often consisting of Excel spreadsheets in disparate formats. Those that did employ specialized technology for the management of regulatory submissions found it to be outdated and inadequate for addressing their needs.

A solution was needed that had the flexibility necessary to integrate easily with the current workflows of potential users despite the fact that their existing methods were largely incompatible with one another. Additionally, the process by which users moved data into and out of the system had to be non-technical. A core design philosophy at *DATATRAK* is that any technology should be built specifically for those who use it. In the context of regulatory submissions and our CTMS platform, this meant that it had to be accessible to Clinical Operations personnel as well as anyone who might be responsible for handling ClinOps data. The commonality here was that the target users were non-technical and needed a solution that would not require the aid of coders. The solution had to be interface driven.

This solution in *UX CTMS 360*™ is the structure we call a Requirement Set. It is an easily configured interface object that can be used to store documents and meta information surrounding those documents that are relevant to a particular regulatory submission. We allow users to do this using a simplified Excel template. Users can choose from a menu of data collection formats in this template and easily prototype a Requirement Set. By utilizing the same document format in which nearly all users

are currently collecting their regulatory tracking information, the onboarding process is simplified as most of the existing data and data collection structures can be moved into the system with a simple copy and paste action.

Reusability Built In

With this tool in hand, users can set about pursuing the goal of reusability. Using *DATATRAK*'s proprietary Manager Framework, a repository of regulatory bodies or authorities can be built out, from Local Ethics Committees to Ministries of Health. Within each, users may define regulatory categories based on attributes like therapeutic area or phase of the trial and begin populating them with the most common sets of regulatory requirements required in a submission to that body, in that type of trial. The next step is to use this repository to easily import the desired requirements and reuse them to speed the process of study setup.

Most regulatory submissions are highly standardized in a given type of trial. Once these requirements are part of a user's repository, these standard requirements can be imported into any new trial in *UX CTMS 360* with the click of a button. Once this backbone structure is built out, the platform can then begin to enhance the data collection process and the analysis of its results.

Reducing Human Error

By having a single location for the entry of submissions data, the odds of user error necessarily decline. It eliminates the need to handle numerous individual documents in varying formats by providing an interface designed for the capture of all regulatory tracking data across the enterprise. Features like date checks and alerts can ensure data consistency at the point of data entry. This eliminates the time involved in someone identifying the problem later down the line and requesting a change, not to mention any impact that errors in this ancillary data would have on study startup timelines.

Redundant data entry can be sharply curtailed by the introduction of shared requirement sets. Within *UX CTMS 360*, a requirement set can be defined as shared across regulatory bodies within a study. This means that as files are uploaded or information is entered regarding that regulatory requirement, it is simultaneously updated by the system in every location it should be. What's more, these relationships can be standardized by defining them beforehand in the repository. In doing so, these associated requirement sets can be imported easily, with their intended relationship already

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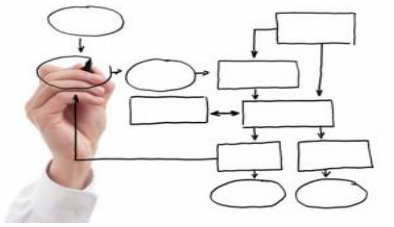
defined. Everywhere that repetitive processes exist, a supporting platform should attempt to compartmentalize those tasks in a way that allows them to be reused rather than re-executed.

Enable New Workflows



By utilizing Excel as the format for bringing data in and out of the system, we can easily allow users to import or export data stored in Requirement Sets in the same format. This eases the transition towards managing regulatory processes from within the CTMS by allowing data to be easily copied from existing spreadsheets into CTMS structures. The simplicity with which data can be moved allows for additional, actionable workflows. By exporting the data contained in requirement sets, the users can continue working with Excel. The contents of the user's local copy can be easily imported back into *UX CTMS 360* where it can be tracked and verified.

Incorporating regulatory tracking into a CTMS can also offer improved document control. In *UX CTMS 360*, every document uploaded to a requirement set is stored in the File Manager. From the File Manager, documents can be accessed from a central, logically arranged file structure. Once documents are stored in the File Manager, they gain the benefit of version control, allowing users to view both current and historical versions of the same regulatory document. Additionally, audits provide users with more oversight of the changes occurring in the document, granting visibility of who made changes and at what time.

Actionable Data

Ultimately bringing all this unmanaged data into the CTMS renders it more actionable. By allowing users to construct and track submissions packages in a high-level manager, they can, at a glance, locate items that are lagging behind timelines. Powerful cross-study managers and submissions reports allow users to compile and assess data from across the entire enterprise in a similar fashion. Rendering data more interpretable allows the right decisions to be made in less time, reducing downstream impacts on timelines and costs.

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The scale of the clinical trials industry means that even small gains in efficiency can have profound implications for the organization and ultimately the patients they serve.

Leveraging the unifying trend of technology in the digital clinical space, we can drive down costs and improve efficiencies by

- ✓ eliminating redundancy,
- ✓ reducing user error,
- ✓ improving workflows,
- ✓ delivering actionable data that provides meaningful insight.

A modern approach to clinical trial management systems harnesses the power of technology to simplify the regulatory submission process. To see how a modern CTMS solution can simplify your trials, contact us at Marketing@Datatrak.com or visit us online at www.Datatrak.com.