How clinical trial software can be used to optimize clinical trials

Clinical trial software is used by CROs, biotechnology, and pharmaceutical companies to facilitate clinical trials from conception to finish. For example protocol management, CRF design, metadata management, and the collection, analysis, and submission of compliant clinical study data to regulatory authorities. The aim is to get quality clinical products to the market faster.

Companies are having to conduct multiple clinical trials at the same time. They've got to be efficient. And comply with industry regulations. They need to be able to see and manage their clinical trials effectively so they can improve inefficiencies in the process, and get the data they need. Full transparency is needed from start to finish. This is why there's been a move in the industry towards clinical trial software and cloud-based solutions.

Where is the industry now with clinical trial software?

The pharmaceutical industry has been slow to try new approaches and emerging software solutions. Its focus has been all about getting clinical products to the market.

Traditionally spreadsheets have been used to record and manage all the various aspects of clinical trials. That means there's a high risk of errors, not getting vital data, and for there to be bottlenecks in the process. So efficiency, compliance, and patient care have been compromised.

The industry is now recognizing that to stay ahead of competitors, technological cloud-based clinical trial software solutions are key for faster, more efficient clinical trials. And the FDA has been encouraging the use of cloud-based solutions to streamline the clinical trial process. The end goal is to have more effective medications and more personalized healthcare.

Types of clinical trial software

Clinical trial software encompasses many different types of software for different stages in the clinical trial process. Some of them include:

- Clinical Trial Management Systems (CTMS)
- Electronic Data Capture system (EDC)
- Integrated clinical study automation software

What is a CTMS?

A CTMS is an integrated cloud-based software platform that's used for the end-to-end management of clinical trials. They help companies improve the quality of their clinical products, reduce the time it takes to get a product to market and ensure compliance with industry standards and regulations. They're used to plan, track, and analyze clinical trials. And to find and manage participating patients, track their involvement in clinical trials, and manage finances.

CTMS are often used in conjunction with other clinical trial software that specializes in a specific area, such as EDC's and integrated clinical study automation software.

What is an EDC system?

It's an electronic system that lets users gather patient data during clinical trials. They typically have a user interface for users to enter data into electronic forms. Validation to check forms have been filled in accurately. And a reporting tool to let users analyze the data collected.

EDCs have been around since the 1990s and are improving all the time. Modern EDCs let you target specific patient profiles or study phases. Examples of modern features can include cloud data storage, role-based permissions, CRF designers, clinical data analytics, interactive dashboards, and electronic health record integration.

The main benefits of using an EDC system are that they increase data accuracy, speed up the data collection process, and reduce costs over the lifetime of a clinical trial.

What is meant by integrated clinical study automation software?

Clinical study automation software is an integrated cloud-based software that specializes in specific parts of a clinical trial. These types of systems vary and can cover areas such as CRF designers, metadata management, standards governance, data warehousing, statistical computing, and submission to regulatory authorities.

An example of this type of software is the Formedix clinical trial automation platform and clinical metadata repository. Our automated processes are streamlined for CRF design, data collection, tabulation, analysis, and submission. With CDISC compliance and validation built-in.

And as such, the focus of this blog is on clinical metadata repository features and automation of processes during a clinical study.

What is a clinical metadata repository?

It's a web-based, centralized, governance platform that lets organizations store and manage all of their metadata. A bit like a library, or a single source of truth.

Metadata can be stored in various stages of development. It can be updated, approved, and kept as organizational standards. Once approved, it can be reused across many studies. Examples of standardized metadata are CRFs, terminologies, datasets, and mappings.

The key drivers for using a clinical metadata repository are:

- Regulatory compliance.
- High data quality.
- Process efficiency.
- Reuse

Using a clinical metadata repository results in saved time, a reduced need for resources, and the ability to get quality products to the market quicker.

What are the main features of a clinical metadata repository?

A good quality clinical metadata repository should have the following features built-in.

Ability to find assets, standards, and studies easily

By storing your assets, standards, and studies in 1 place, it's easy for teams to search across all past and present metadata content. Stakeholders don't need to go looking for content or rely on others to provide it. It can be quickly and easily found.

User access control

You should be able to control all internal and external user access and assign roles to each individual. So for example, being able to assign view-only access to a particular user. And allowing another user to edit metadata content. Ideally, it should be possible to set access by standard or study thereby allowing specific users to edit particular standards and studies, but not allowing them to edit others.

Ability to reuse metadata content

Organizational standards are stored 'all in one place' in a clinical metadata repository. This includes metadata such as CRFs, mappings, edit checks, annotations, controlled terminology, datasets, and so on. All ready to reuse.

Reusing standardized content reduces manual errors, and increases consistency across studies. It helps to improve the overall quality of your study data. It's quick and easy to then reuse a piece of content and to update it to suit other study-specific requirements.

Impact analysis

Impact analysis is a key objective of clinical metadata repositories and should be built-in. It lets you see what upstream and downstream metadata and processes are affected if a particular change is made. Before you make that change.

Global traceability and reporting show where standards and study content is being used. For example, asset groups in other standards that use the same CRF. Or SDTM datasets that are mapped to the CRF.

Impact analysis puts you in a much better place to make informed decisions on whether a proposed change is worth making, or not.

Change management

There should be a way for team members to request changes to existing metadata content. It must be possible to edit, add, and retire metadata content. The change management process should record what the change is, why it's been requested, who made the change, who requested the change, when the change was requested, and when the change was made.

These changes should go through a well thought out governance process. See the example below.

Governance

Governance refers to the process that must be adhered to for any change to existing metadata content and organizational standards. Or for the creation of new metadata content. A governance process, or workflow, must be built in to make sure that changes are managed and dealt with effectively in a way that suits an organization's needs.

Being able to fully track metadata means that it's easier to see how to improve metadata management. Having governance means there's a fully traceable audit trail, the ability to do impact analysis, and the ability to see the flow of data through the system.

Versioning

A quality clinical metadata repository should allow versioning of internal standards across the organization. It should let you update and improve both study level standards and organizational standards. For example, you might want to have various versions of the same CRF for different purposes. And changes to a version of a CRF will have an impact on SDTM mappings and TLFs (tables, listings, and figures).

Built-in compliance and validation

Compliance and validation ensure that a clinical study meets the expectations of regulatory authorities. It should be built in from the start of a study, through to submission. So each part of the study should be tested against validation rules to make sure it stays compliant.

Integration

A clinical metadata repository should be able to let other external systems integrate with it. That could be with an organization's systems to allow them to upload data. Or it could be to integrate with a SAS based system for pushing and pulling data in different formats. Or to integrate with EDCs.

What is automation in clinical studies?

Automation simplifies processes for clinical studies, from study setup through to submission. It helps to speed studies up and to reduce human error by removing

manual processes. It makes it easier for companies to comply with regulatory standards and guidelines set out by regulatory authorities.

What are the benefits of clinical trial automation?

Here are the main benefits for organizations:

- Get clinical trials done faster.
- Improved metadata quality and consistency.
- Analyze data more quickly and effectively.
- Reduce overall costs.

Automated processes and clinical metadata repositories go hand in hand...

As discussed, a clinical metadata repository stores all your organizational standards in 1 place. Doing this means they are easily accessible and ready to use across all your studies. This enables auto-generation of study artifacts such as EDC, SDTM, and ADaM specifications.

Automation improves clinical trial efficiency and means your submission will be of better quality. Fewer resources are needed, and costs are saved.

Formedix clinical metadata repository and automation platform

Our off the shelf clinical trial automation software and clinical metadata repository is a fully integrated online platform for facilitating clinical trials.

In short, you can store metadata content and build studies quickly using automated workflows. It simplifies the study design process and there's no requirement for programming skills.

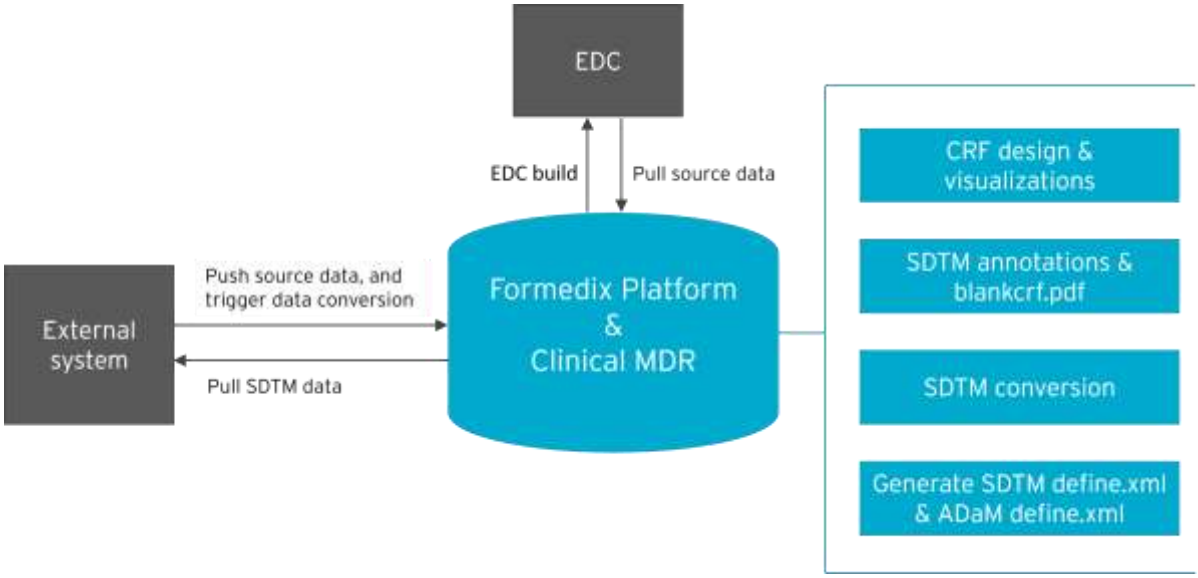
Our clinical metadata repository has all the desired features such as impact analysis, change management, and governance that were discussed earlier. And it has the necessary automated processes needed to generate the study artifacts required to make a submission to the FDA.

You can:

- Store and manage metadata, across the end-to-end life cycle of your studies. You can create metadata content from scratch, or upload your existing organizational standards.
- Manage your organizational standards, helping to increase data quality while decreasing downstream costs.
- Make validated CRF designs, EDC designs, and builds.
- Convert data to produce validated SDTM datasets.
- Create valid SDTM and ADaM define.xml files for submission.
- Use the APIs to integrate with external systems.

Automated processes in Formedix

The diagram below shows the Formedix platform integrating with other systems. It also shows the built-in automated processes on the right-hand side.



Here's a breakdown of our automated processes.

CRF Design and Visualizations

Formedix makes it quick and easy to make all the different metadata formats you need. You can see how your CRFs will look and how they'll work in your EDC system before you build it.

Here's a list of the different visualizations you can do:

- See what CRFs look like in your EDC – as you design CRFs in Formedix. And validate CRFs against the rules of your specific EDC.
- CRF specifications.
- Visit structure specifications.
- Edit check specifications.
- Mapping specifications.
- Submission ready annotated CRFs in PDF format.
- SAS XPT and SAS v9 clinical views.

You don't even need to be using an EDC system to do this. You can approve forms in Formedix before using an EDC system. You can decide later on which EDC system to use.

Generating annotated CRFs and blankcrf.pdf

Once you have your CRF designs in Formedix, it's easy to add annotations. Or if you have your CRFs standardized with annotations, that's even better! You can just reuse your annotations.

If you need to make changes, you can instantly preview them. Then when you're happy, it's just 1 click to get your submission ready annotated CRFs in PDF format.

Generate SDTM datasets from source data

Start by defining the mappings from your source data to your SDTM. Then you can pull data directly from your chosen EDC system to generate your SDTM datasets after you start collecting data.

Our platform supports all versions of CDISC standards and SDTM automation. We keep our platform updated in line with CDISC and NCI standards. That way your study designs and datasets are always regulatory compliant.

Generate SDTM and ADaM define.xmls

Once you've built your study and defined your datasets, it's just 1 click to generate your SDTM define.xml, and another click to generate your ADaM define.xml. If you need to create a define.pdf, that's just another click.

You can even generate define.xml from SAS XPT files or old legacy datasets. Learn more about our visual define.xml editor.

Integration

The Formedix platform lets you integrate with 7 leading EDCs. You can design your studies with all the features of the EDC you work with. You can see what your forms look like and how they'll work in your chosen EDC as you design them. When everything's finished, automatically build the EDC database with just 1 click.

You can also use our API to integrate with your own internal systems. That means you can set up automatic processes to push source data into Formedix and trigger a conversion. Then, pull the datasets back into your system from Formedix. You can also pull metadata in ODM and Define-XML formats.

Want to find out more?

If you want to find out a bit more about the Formedix clinical trial automation platform, you can take a look at our website.