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Blog

What Should a Clinical Metadata Repository Do?

Gilbert Hunter

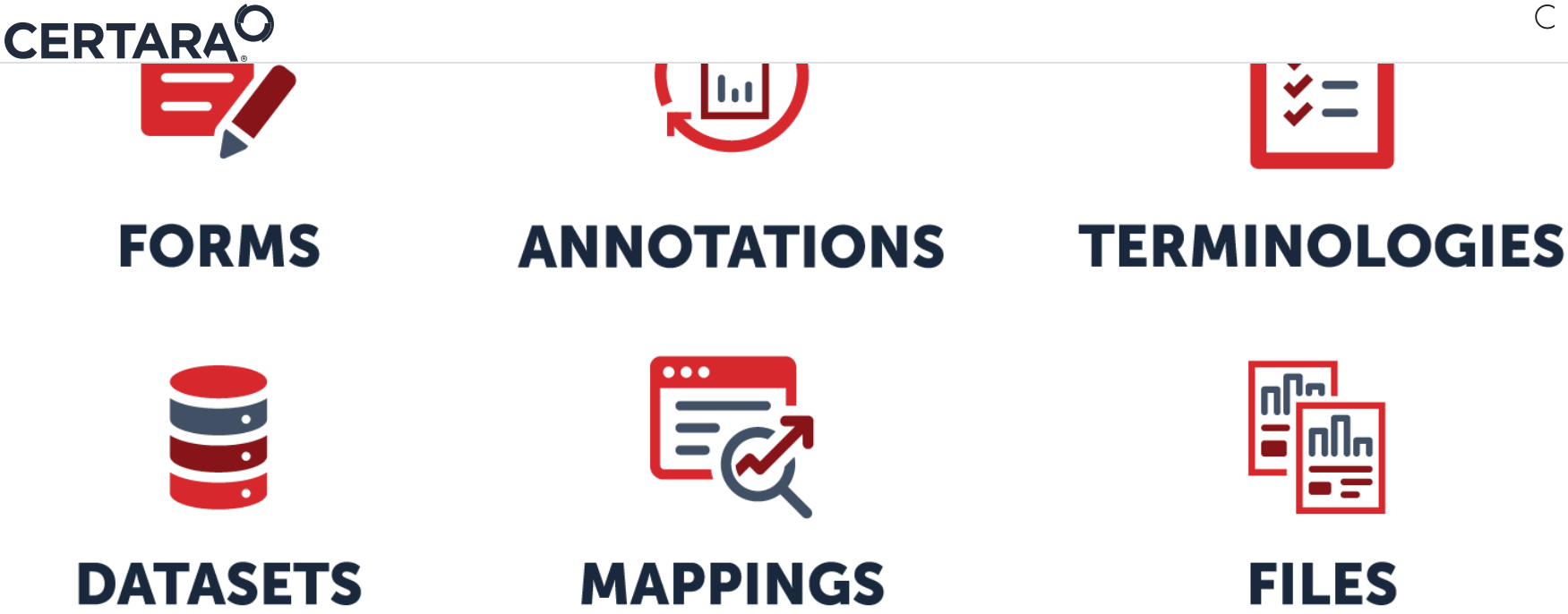
When clinical trial metadata is not managed efficiently, it can be unreliable, inconsistent, and outdated. Typically, metadata is stored over multiple locations, and is non-standardized. It can be difficult to find the correct forms to use, or the latest, approved internal standards to adhere to when collecting data. A clinical metadata repository can help overcome these problems.

What exactly is a clinical metadata repository?

A clinical metadata repository is a 'single source of truth': a centralized, reliable library of metadata assets such as forms, terminologies and datasets that are ready to use and reuse when you need them. By implementing a comprehensive clinical metadata repository, organizations can streamline their metadata management, improve submission data quality, get earlier data insights, and accelerate new drugs to market.

What is 'metadata' in clinical trials?

The term 'metadata' in clinical trials refers to the content that forms the building blocks of your clinical study, for example forms, annotations, terminologies, datasets, mapping and files. Metadata is 'data that describes data'. An example of metadata within a dataset would be a 'variable'. A 'variable' describes a particular measurement (e.g. height, age, weight) and how it should be



What are some of the key benefits of implementing a clinical metadata repository?

drug more quickly, ultimately improving patient outcomes.

- Easier collaboration

Efficient metadata management plays a crucial role in the process of drug discovery. With the increasing volume and complexity of clinical trial data, it is essential to have a centralized repository that enables you to share, reuse and standardize metadata. Standardization of metadata in clinical trials ensures consistency and accuracy in data interpretation, enabling easier collaboration among different stakeholders. It also allows you to compare data for different studies more easily.

What should you consider when choosing a clinical metadata repository?

It's not enough to simply find a clinical metadata repository and implement it. Different platforms have different capabilities, and not every offering will meet your requirements or enable you to maximize your clinical metadata management.

If the platform you're looking at doesn't meet some basic specifications, you could be wasting your time and money. So, what should you expect when it comes to choosing a clinical metadata repository?

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What are some additional features of a clinical metadata repository?

Beyond the list above, there are some additional features that could really make a difference to the performance of your clinical trials. We've identified four additional considerations for building successful clinical trials.

1. Visibility

It's really important to understand how content is used in your clinical trials. A metadata repository should provide clear visibility of:

- where your metadata is used
- how it's used
- how often it's used
- the impact of changing it (I know you mention this below but I think it should still be in the list

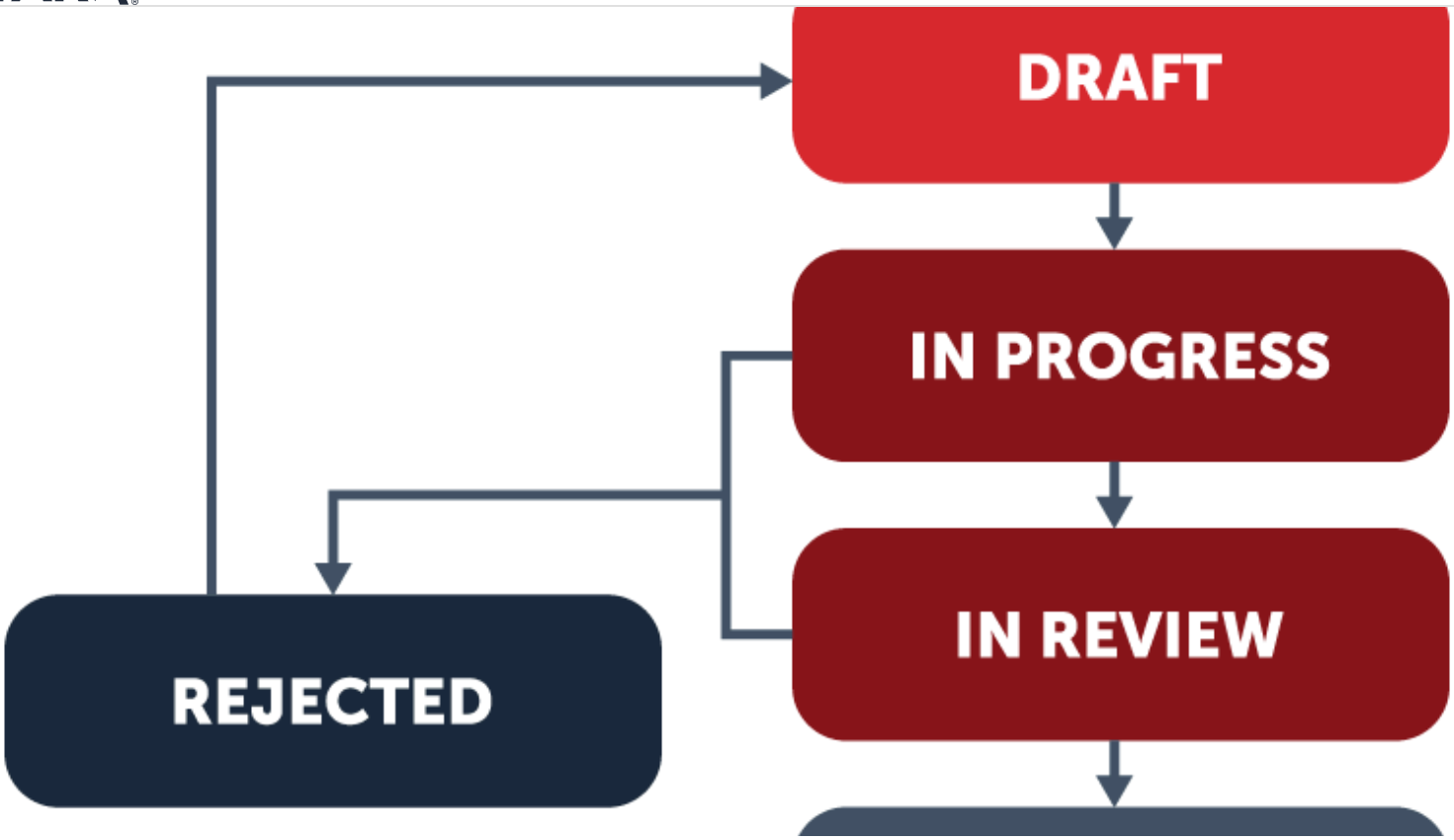
That way, when you have lots of change requests, you can easily see which ones you need to focus on.

If the content needs to be changed, you need to be able to see what the impact of those changes will be, so you can decide the

metadata, then, needs to be subject to a governance lifecycle.

Data governance refers to the processes and policies that govern the management, quality, and security of clinical data. It includes establishing data standards, defining data ownership and stewardship, and implementing data access controls. Effective data governance ensures that the clinical metadata repository is maintained and utilized in a consistent and secure manner.

Here's a simple example of a governance lifecycle:


DRAFT
IN PROGRESS
IN REVIEW
REJECTED

Governance is one of the most important features of a metadata repository. It helps you:

- Improve data quality
- Control and understand the workflow of content
- Assess the impact of change
- Develop robust organizational standards

With good governance, you can trust your metadata is accurate. And if your metadata is accurate, your data will be accurate too.

If you can see the detailed lifecycle of a standard, there's total transparency in your team, and you'll avoid regulatory non-compliance.

3. Collaboration

Collaboration allows a team of people, regardless of their role or location, to work together easily. For example, a group of people with different roles maintaining a set of global standards need to be able to collaborate on those standards without

Every clinical trial is different. For example, you might have to use different electronic data capture (EDC) systems for different studies, or even for different phases of one study. Having the ability to design studies and standards with specific EDC systems in mind, and the freedom to use multiple systems if required, makes building clinical trials much easier.

A clinical metadata repository with EDC integration lets you fully design your Case Report Forms (CRFs), including complex tasks like edit checks and conditions. You can see what your forms look like upfront, before you upload it to the EDC. You can carry out a simple review and approval process and you can generate specifications for review outside the system. Once you're happy with your CRFs, you can automatically build your EDC system, which saves time and money by removing manual interpretation of your specs. Overall, your studies will be higher quality and more consistent.

You should also consider whether you need other systems to be able to pull metadata from your chosen metadata repository, and push data to it. If your metadata repository has an API, your other systems can talk to it and make it the central hub for knowledge in your organization.

Customer Success Manager

Gilbert joined Formedix, now part of Certara, nearly ten years ago as a technical writer. The system knowledge he gained from content development, together with his existing customer service skills, marked him out for transition to the Professional Services (PS) team.

Gilbert has worked with the PS team for over four years, providing both CDISC-based training and software training, as well as support and consultancy services to Pharmaceutical, Biotechnology and Clinical Research Organizations. He helps organizations build studies faster and to a higher quality by making their clinical trial design and regulatory submissions far more efficient.

Today, as Customer Success Manager, Gilbert's focus is to ensure customers maximize the benefits they can achieve by overcoming their challenges and achieving their goals.

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- [ ] Building studies (CRFs, EDC build)
- [ ] Managing external data (non-CRF data)
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