

From Chaos To Clarity - How FAIR Data Principles Deliver Clinical Data Management And Analytics Success

Human beings are physiologically complex, as are the diseases and conditions that afflict them. Therefore, the more scientists understand the body's mechanisms, the more complex clinical trials become as pharmaceutical and biotechnology companies create innovative therapeutics to target disease and benefit the largest number of patients. During a trial, investigators must gather enormous amounts of data from each participant to ensure a drug's safety and efficacy. Traditionally, that information is collected at a trial site, but when DCTs, wearable devices, telehealth, and third-party labs are factored into the mix, data management becomes even more cumbersome.

Managing, aggregating, and cleaning these data points can be so time-consuming that little time is left to create invaluable clinical analytics and visualizations that drive study decisions. To improve data management and reduce manual labor and delays, companies should adhere to the FAIR principles that data are:

- Findable
- Accessible
- Interoperable
- Reusable





When optimized, FAIR empowers companies to spend less time managing data and more time understanding and applying it. A centralized analytics platform can deliver fast, flexible, and

scalable data preparation with safety, efficacy, and operational insights that empower companies to make quick decisions while safeguarding participants’ well-being.

What Is FAIR?

Too often, the FAIR standard is underutilized in the clinical trial space. The first principle, findable, indicates that data should be well-described, have persistent identifiers, and be searchable. Accessible means that the data, metadata, dictionaries, etc., are understandable to developers and computers. Analytic tools to search, aggregate and filter data use consistent metadata to generate useful results within and across clinical trials. Additionally, data are most accessible in a secure, user-friendly common space rather than scattered across various platforms. Interoperable data can be integrated and fully harmonized with other data rather than siloed using a formal, shared, broadly applicable language. Reusable denotes that the data have clear usage licenses and are associated with accurate information. It also means that users can easily look across and within studies, allowing investigators to compare information from similar trials.

Following these criteria engenders harmonization and avoids errors such as crucial information being included in the title of a trial but not its clinical database. For example, an oncology trial may study several types of tumors at once and indicate in its title which ones are under investigation. However, if the individual patient data does not also include their tumor type, then HCPs or investigators looking for patients in the study with specific tumor types would not be able to find them. Prioritizing FAIR means that data managers look for situations where data may be left out of the database and ensure that it is included. And when the data are merged, the responses appear in the same columns from the same data sources, creating accessibility that allows researchers to examine data across studies.

			
Findable	Accessible	Interoperable	Reusable
<ul style="list-style-type: none"> • Persistent & unique IDs • Indexing with metadata • Scalable technology 	<ul style="list-style-type: none"> • Role specific permissions • Accessible user interface • Integrated authentication 	<ul style="list-style-type: none"> • Flexible data model • Fully configurable • Controlled vocabulary 	<ul style="list-style-type: none"> • Consistent harmonization • Analysis ready datasets • Integrated analytics workflows
<p>F.A.I.R. data principles provide a framework to manage data Variety, Velocity, Volume, Veracity, & Value</p>			

When Should Companies Implement FAIR?

Industry best practices have FAIR principles in mind in the earliest planning stages of a clinical trial to meet regulatory approval. For instance, before a trial can begin, it must be approved by the FDA, which has stringent requirements for ethical trial design and participant demographics. FAIR data management demonstrates to the FDA or other regulatory bodies that the study will meet their requirements. Secondly, implementing these practices early on creates a consistency that can be applied to subsequent trials. For an initial trial, such as a first-in-human study, the best approach is to start by considering what data is needed at the end of the trial. If a company knows it needs X, Y, and Z data for approval submission, planning for that data from the beginning saves time and effort throughout the trial. Thus, companies can reverse-engineer their data management strategy and eliminate inefficiencies.

As a company develops subsequent trials, the reverse-engineering approach will speed up its study planning timelines because it continues to build on what it learned in previous trials. For example, Signals Clinical™ can map, load, access, harmonize, and standardize data for a Phase 1 trial, creating methodologies that can be applied to the same company's Phase 2 trial with only minor changes, significantly reducing workload. As an old saying goes, if you do something once, that's fine, but if you have to do it again, automate it.

How Does FAIR Ensure Safety And Efficacy?

Every clinical trial has a set of predicted outcomes regarding safety and efficacy. For instance, if a company is testing a cardiovascular drug, they expect patients to show no serious adverse effects while also enjoying improving the condition being targeted. However, the reality of clinical trials is that the human body is highly complex and often unpredictable, and the subject's comorbidities or other conditions may affect the drug's safety or efficacy. The adverse effect could be overlooked during a clinical trial if it is extremely rare. Therefore, the more data can be harmonized during the study, the more quickly companies can identify any potential problems with the drug.

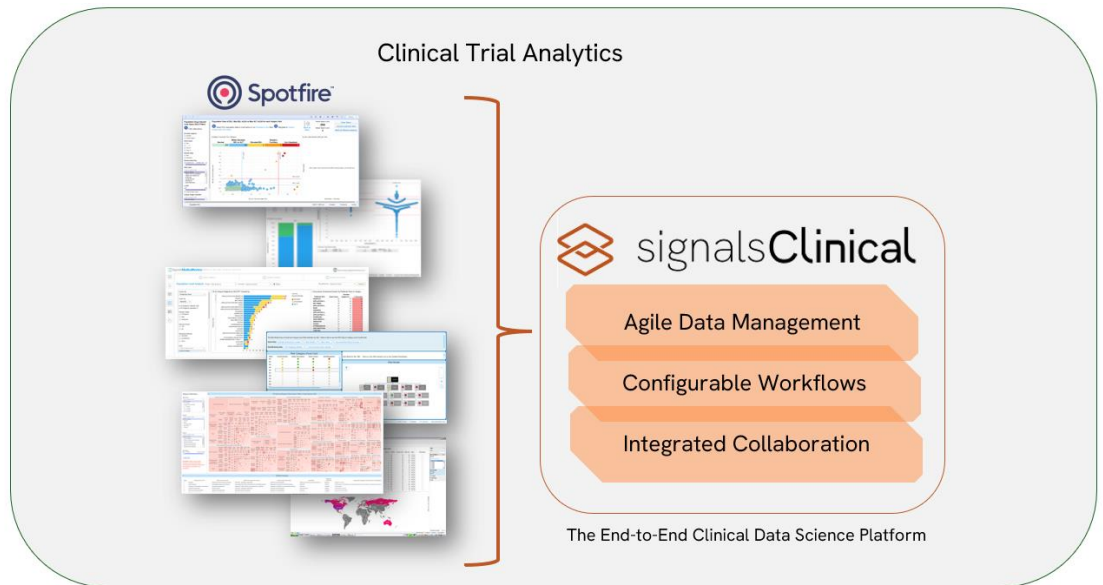
Although individuals have complex physiologies that intersect with demographic data and family history, clinical trial data is traditionally siloed into disparate categories, such as adverse events, demographics, vital signs, labs, diagnoses, etc. When data are siloed, they can't be thoroughly examined or applied to subsequent trials or indicate red flags that need attention. For instance, say, an adverse effect only applied to women over 50 from a specific demographic who also smoked. If each of those data points (woman, age, demographic, health history) were kept separate and never harmonized, then the risks to that specific group would be missed by investigators but could manifest in pharmacovigilance reports that lead to a therapeutic being pulled or re-labeled. Harmonizing throughout the study avoids those risks.

AI and machine learning (ML) allow companies to automate data harmonization by mapping data and cross-referencing information to identify red flags, such as the hypothetical example above. And as companies add new studies to the system, AI and ML become more efficient and

thorough. If AI and ML use “dirty” data, they will most likely identify some data issues but miss other data cleaning issues. By harmonizing data first, Signals Clinical™ uses AI and ML programs more effectively with each daily refresh to identify emerging data issues or scientific signals between related and comparable data. The analyzable data allow AI and ML to identify signals or issues that are meaningful and not just the result of missing protocol metadata information or differences in data sources.

How Can A Centralized Analytics Platform Create Harmonization?

Not all data are created equal, and large amounts of disorganized data create chaos. Chaotic, unharmonized data does not give companies the actionable insights that fully analyzable data can. Siloed data requires extensive work to integrate, increasing the risk of mistakes. Frequently, programmers find errors in the data that require the database to be unlocked after a study closes and cleaned again, creating delays. When the information is centrally located and analysis-ready, it meets compliance requirements and accelerates end-of-study timelines. Also, visualization tools that combine with data management, such as Spotfire’s platform integrating with Signals Clinical™, generate actionable reports that companies can use to more effectively manage their studies.



As a software-as-a-service clinical data science platform, Signals Clinical™ begins with the core concepts of accessibility, interoperability, standardization, harmonization, and reusability. It prepares analyzable information from day one of a clinical trial by generating harmonized and standardized data, with automated processes minimizing effort and maximizing the value of the data. Also, Signals Clinical™ has configurable workflows to support companies’ data

management, clinical data review, and study monitoring activities. It includes integrated collaboration capabilities so that when users query the system, it's captured and documented and can be referenced by study managers. The centralized platform accesses, loads, and maps the data to a consistent variable structure, standardizing and harmonizing them in the background. All data are kept in one cloud-based location and never siloed. When companies prioritize FAIR practices to plan their data management using centralized platforms like Signals Clinical™, they can avoid costly delays while conducting ethical, fully compliant clinical trials.

*To learn more about Signals Clinical™ please visit:
<https://revvitysignals.com/products/clinical-development/signals-clinical>*


About Revvity Signals

Revvity Signals Software Inc. is committed to delivering the most comprehensive suite of biopharmaceutical Research and Development software solutions that provide scientists and clinicians with the necessary tools to aggregate, search, mine, analyze, and visualize critical data, which leads to actionable insights in an automated, predictive, and scalable way.

Signals Clinical™ and our Spotfire® powered clinical data analytics solutions provide fast, flexible clinical data insights to inform and accelerate decisions in clinical development. Interactive visualizations and predictive analytics allow rapid clinical data exploration for proactive decision-making in near real-time. Revvity Signals supports clinical analytics workflows for clinical data review, medical review, clinical operations, risk-based monitoring, and pharmacovigilance.




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