



SOFTWARE

CRO Data Workflow Strategies

A Look at How the Bruker's Arxspan ELN Security Model Can Make Data Capture from External Resources (CROs) Secure and Simple

Innovation with Integrity

Introduction

Today many scientific R&D organizations are turning to partnerships to enhance their own workforce. An excellent example is the relationship between Pfizer and BioNTech. This collaboration has led to the fastest vaccine development in history.¹ For years many organizations from small biotech's to large pharma companies have utilized contract research organizations (CROs) to speed up their pipelines.² Working with CROs provides many advantages to organizations. The ability to scale teams to fit short-term and long-term project needs can allow organizations to be more agile. Outsourcing non-core activities allows them to focus internally on strategic scientific expertise CRO's can provide instrument services that allow companies to reduce the cost of these analyses. They can also provide a larger array of instrument options than many companies would have internally.

When working with a CRO there are some key factors to consider:

- How will you capture the data generated from this partnership?
- How will you ensure data can easily be accessed by your CRO but protected?
- How will you handle this data when the partnership ends?

Software as a Service (SaaS) ELN platforms have evolved to fill these important needs, and many do check off most of the boxes. Gone are the days of shipping servers around the globe or maintaining complex and costly infrastructure. These platforms allow real time access, from anywhere, to your data in a secure environment. Arxspan's ELN platform was developed from the ground up with all these features and more in mind.

Deploy Quickly & Securely

Arxspan's cloud based ELN requires only an internet connection and a device that can run a web browser. An organization can add and remove access to its private data quickly, easily, and securely. Administrators have complete control over the system. There are multiple flexible options for authentication; access is secured and controlled by your organization. Users can quickly and easily be added or removed from the system as needed. Turnover cost and overhead are reduced with simple-to-reassign notebooks and projects, it takes minutes not days to accommodate staff changes.

Arxspan's group permission model is designed to isolate data and scientists' access to that data within the system. You can design access layers that allow your internal R&D team to collaborate directly with the CRO researchers or separate them as if using two systems. All your company's data assets are housed under a secure customizable umbrella. Using the Arxspan system prevents costly and error prone data transfers or the complexity and risks of searching for data across multiple systems.

Simple Global Deployment

Working with a CRO in Asia? Arxspan offers multiple language options for the user interface and free user training with your deployment, in your partner's local language. The platform is so easy to use that the average scientist requires only a single 1-hour training session to begin using the platform. Your CRO can work within the product in the comfort of their own language allowing for easier adoption and higher compliance. All menus are translated by native speakers and controlled on the individual user level allowing each user to select their own language preferences.

Effective Local Support

Arxspan employs native speakers on their support staff for all supported languages. This allows them to respond to users' inquiries in their native language. Users in any time zone can receive support quickly and efficiently. The current average time to receive a real human response is less than 1 hour with a 2 hour guarantee 24/5. Arxspan support staff are trained in all aspects of the product, allowing them to assist everyone from the CRO user to the primary Administrator. Each has a degree in a scientific discipline to understand your needs from a scientific perspective. No more escalation through multiple layers of service to get an answer or the assistance you need.

Customer ELN Strategies For Working With CROs

Below are two real world examples of solutions designed for clients using the Arxspan solution.

Client 1

Profile: Mid-sized Biotech, epigenetic research, 3 CRO partners, multiple time zones

In the case of this customer, each CRO partner is set up as a separate group.

The CROs generate experimental data and place it in notebooks shared only within that group (e.g., scientists in CRO-1 have a notebook only shared with colleagues in CRO-1). Notebooks from all three groups are linked to an overarching project that is only visible to internal scientists.

Client 1 uses a combination of the ELN's groups, explicit notebook sharing settings, and projects to aggregate all their external research. The result is centralized data for a specific target without risking exposure of internal data or CRO data to the wrong party.

These settings are controlled entirely by the client and were configured by the client requiring no Arxspan custom configuration or support to maintain.

Client 2

Profile: Small pharma company, targeted immunotherapy research, 1 CRO, 2 time zones

This client houses internally generated data alongside CRO generated data in the Arxspan ELN.

The data is partitioned by placing all users in isolated groups. The company gives access to an isolated project. This project links to all work performed by the CRO. The CRO can only see the data in this project. The project is then included within a larger internal project shared only with the internal scientists. This data structure allows the seamless transfer of data to the internal scientist in real time. All data is grouped in one centralized location.

This system masks the primary project and target names from the CRO without requiring internal users to memorize complicated project mapping. The client requires no vendor support to maintain this system, it is defined and controlled entirely on the client side.

Get Started

With worldwide support and implementation teams, Arxspan can deploy ELN configurations and packages to any CRO partner quickly and securely. Arxspan works with their clients to create long-lasting partnerships. Adding a new CRO? Need a consultation on your current project layout? Arxspan experts are always available to assist and advise on your ELN needs. The world of scientific research is fast paced and constantly changing. As a technology company, Arxspan understands this and will be there at each juncture as your company grows and matures.

Arxspan's solution removes costly middleware, large IT teams, and data transfer delays that create barriers to worldwide scientific collaboration. With Bruker's Arxspan one-stop solution you can partner and share data across the globe, in real time, shared access to your secure data assets.

References:

1. Kim, Y.C., Dema, B. & Reyes-Sandoval, A. COVID-19 vaccines: breaking record times to first-in-human trials. *npj Vaccines* 5, 34 (2020). <https://doi.org/10.1038/s41541-020-0188-3>
2. Landhuis, Ester. *Nature* 556, 263-265 (2018) <https://www.nature.com/articles/d41586-018-04163-8>

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