

Facilitating the remote and effective management of contract research projects

A Q&A on the capabilities and value of the Arxspan Electronic Lab Notebook (ELN) for external project management

As the pharmaceutical industry's reliance on contract research organizations (CROs) increases, so too do requirements for effective project and data management. The global CRO market is estimated to be growing at a CAGR (compound annual growth rate) of 7.9%¹ as outsourcing, from drug discovery through to clinical trials continues to advance. Many CROs specialize in discrete activities with the result that multiple, geographically diverse players are now routinely involved in a single project. The effective management of CROs notably data management is therefore critical. Current restrictions on travel and meetings, along with globally variable levels of allowable activity, make these issues more important than ever.

Here Jeff Carter, Co-Founder and COO of Arxspan considers routinely asked questions associated with implementation of the Arxspan ELN for external project management, particularly with CROs. The aim is to help customers understand and evaluate the potential benefits of investing in the system.

What specific challenges does the use of an ELN address when it comes to CRO management?

The instantly tangible benefit of using an ELN for CRO management is that all the inputs and outputs to and from a project are recorded and stored, in real-time, in a consistent, searchable form. From one central interface all work with all CROs can be instigated and tracked and all incoming results curated. Collaborative working can be secure, aligned with regulatory requirements and highly productive.

Having the flexibility to work efficiently with a network of CROs makes it possible to take advantage of specialist services across the globe, to spread workload in line with resource limitations and/or to bring the talents of different groups to a specific problem. Effective communication - from work request to



delivery - is key, with incoming data management a recognized bottleneck for many. Establishing the architecture and processes to reliably and efficiently handle information exchange and data curation, for every step of a synthesis, experiment or assay, can be transformative.

Historically CROs have used paper-based reporting systems, often in combination with spreadsheeting tools; electronic work requests are routine as is regular pdf-based reporting. Some organizations still operate with these tools, but they typically generate decentralized information that is unsearchable; integration with in-house systems to import data to the customer tends to be cumbersome and labor-intensive.

To illustrate the commercial limitations of this approach consider the challenges for a company interested in selling a number of candidate drug molecules, developed via projects with one or more CROs. The sale relies on the robust transfer of intellectual property, on providing all the information and evidence associated with synthesis of the molecules, including structure, acceptable purity levels and any other essential assay data. In the absence of an ELN this is a substantial, manually-intensive information-gathering exercise that in the worst case could fail to realize the sale.

The issue of efficient data-sharing and its impact on the development and sale of intellectual property are primary motivations for investing in an ELN solution that can be installed by all the CROs that a company works with. Typically, a client chooses the ELN that best suits their requirements and then requests its usage as part of the contract for any new project, or with any new CRO provider. In this way a company can integrate and manage data from every partner, enhancing the productivity of each CRO/client relationship. Knowledge can be shared effectively within the organization, and externally

too, where required. This approach improves the quality and speed of data and knowledge transfer accelerating progress and easing regulatory compliance. Via these benefits ELNs typically deliver a substantial return on investment, predominantly in the form of savings in time and manual effort.

What is feasible via an ELN in terms of project and data management?

A modern ELN will allow you to submit a new request to a CRO, provide all the information the receiving scientist requires, monitor progress, and review, record and search (as required) all the experimental results associated with a specific molecule or project. More specifically, using an ELN makes it easy to:

- Initiate a project.
- Keep track of projects in progress with different CROs and assign new work more effectively.
- Securely store experimental results in one central repository, in experiments or projects, for future reference.
- Record and protect intellectual property.
- Access all the information associated with a synthesis, experiment or assay, including the source of raw materials, the transfer route of material from one synthesis step to another, structural details, spectra, assay data and/or specific notes related to the project.
- Register new materials - small molecules or biological compounds.
- Communicate, for example, to alert specific scientists to the requirement for new work, to highlight a problem or the availability of synthesized material.
- Maintain an up-to-date material inventory.
- Comply with regulatory standards.

How does Arxspan differ from other suppliers?

When it comes to buying an ELN there are two elements to consider: software and support. Arxspan was the first company to develop an ELN specifically designed for collaborative working with external agencies - academic institutions, joint ventures, and CROs. We've been working with customers for close to a decade now and that experience is evident in both our software and the support services wrapped around it.

Arxspan's integrated platform is a turn-key, cloud-based suite of applications incorporating ELN, Assay, Registration and Inventory modules. Delivered as a 100% web-browser, commercial off the shelf (COTS) solution it is a 'one-stop shop' for informatics, for chemistry and biology, offering all the functionality required for CRO collaboration, out of the box. Progressive, highly effective optimization is evident in the intuitive workflows; high cost-efficiency is under-pinned by a cloud-based approach. In contrast, with self-managed

internal server storage it is all too easy to end up with steadily rising costs - capital expenditure for new hardware and a growing IT team to manage it.

Arxspan products are supported by a team of PhD-level scientists, notably chemists and biologists, and feedback suggests this makes a major difference to customers. We understand the workflows associated with scientific research and we are experts in making them more effective. Those new to ELNs also benefit from our experience of how best to implement a new system to maximize buy-in and productivity, as rapidly as possible. We have both the product and the expertise to accelerate users through to productive ELN use, as quickly as possible.

How easy is it to implement?

As a true COTS solution, the Arxspan Workbook platform can be up and running for a new user, or at a new location, within hours, upto 24 hours maximum. All that is required is a web browser such as Internet Explorer, Google Chrome, Firefox or Safari running on any device with an internet connection. Tablets or other mobile devices are suitable as well as desktops and PCs running Windows, MacOS, Linux or similar.

Training is tailored to the requirements of the user but experience suggests that 30 – 45 minute context-based sessions from day one at progressively less frequent intervals is the most effective approach.

Beyond routine set-up Arxspan has an established track record of efficiently implementing more complex projects, notably integration with, or migration from, existing or legacy systems. Where the requirement is to move extensive quantities of information over to a new system, either internally or due to a use of an alternative ELN (or indeed no ELN), Arxspan can cost-effectively provide the resource required. Such projects typically result in faster implementation at lower cost, relative to internal resourcing.

Can I remove and add CROs easily? What security measures are in place?

New CROs can be given all the functionality required in under 24 hours (as described above). Equally importantly a CRO can be removed instantly from a specific project or the entire system, as required. In this event all legacy information and experimental data remain intact and accessible.

Security measures include the ability to afford users view-only, write-only or view-write to any part of the system. Customers can control information-sharing among named scientists within a CRO or across different organizations. Scientists within a CRO can sign off work as complete with internal management and witnessing as required. Arxspan

solutions are 21 CFR Part 11 compliant with a full audit trail in place for each project, complete with electronic signature and witnessing.

With respect to data storage, Arxspan uses industry-standard hosting and storage practices to store data securely on a private cloud infrastructure with regular back-up to a digitally and physically secure off-site location. In addition, customers can opt for weekly or monthly data back-ups of all stored data to a location of choice.

Are Arxspan products already used for CRO management? What does experience suggest?

CRO management was one of the primary motivations when we first developed the Arxspan platform and there is extensive evidence that it provides an optimal solution.

Experience suggests that customers find the Arxspan ELN highly effective for managing routine interactions with all external collaborators but particularly CROs. Rapid implementation and ease of use are standout features but support is undoubtedly a differentiating factor. When tackling complex issues, talking to a real expert can make a significant difference. This is particularly critical for bespoke projects, for example, where the goal is to efficiently integrate diverse or existing data management systems into an effective new solution. Our track record in tackling projects such as these provides confidence that we can deliver a cost-efficient solution regardless of the starting point.

¹<https://www.europeanpharmaceuticalreview.com/news/112382/global-cro-market-to-reach-71-7-billion-by-2024-says-research/>