SPOTLIGHT

The cornerstone of clinical trial success: selecting seasoned CDMOs and IRT vendors

Selecting the right contract development and manufacturing organisation (CDMO) and interactive response technology (IRT) vendors is crucial for clinical trial success, as these partners significantly impact patient safety and data integrity. This article will demonstrate how experienced CDMOs and IRT vendors provide invaluable expertise, anticipate challenges, and ensure smooth trial operations through proactive collaboration and comprehensive support

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It takes an average of ten to 12 years before a promising new drug candidate goes through preclinical and clinical drug trials, and marketing authorisation can be obtained.[1] At critical turning points, clinical trial sponsors and investigators have crucial decisions to make regarding how to operationalise a trial and, with patient safety and data collection on the line, which technology vendors they can trust in full confidence.

In the complex clinical trials ecosystem, choosing the right contract development and manufacturing organisation (CDMO) and interactive response technology (IRT), or randomisation and trial supply management (RTSM) vendors, is about far more than the mere outsourcing of tasks. The technology vendors that a sponsor engages with will have significant impact on patient safety and, ultimately, whether the trial generates meaningful data.

Key considerations for choosing clinical trial vendors

First and foremost, it is important for clinical trial sponsors to choose CDMO and IRT vendors comprised of seasoned team members who have been through it all – preferably from both the vendor and sponsor standpoints of running a clinical trial – and, as a result, have learned to proactively anticipate the unexpected.

Among the most important resources a CDMO can place behind a clinical trial is a dedicated team of experienced contract clinical supply managers (CSMs). Tapping into expertise diverse backgrounds in areas such as quality assurance, chemistry, supply chain management, formulation development, toxicology and clinical trial software, CSMs determine exactly how much drug will be needed throughout the trial – which, ideally, is the least amount possible to fulfil the trial without creating much surplus. CSMs also anticipate which sites the therapeutic supply must reach at various times, and what can be executed expediently when supply must be moved to keep pace with trial participants' dosing needs.

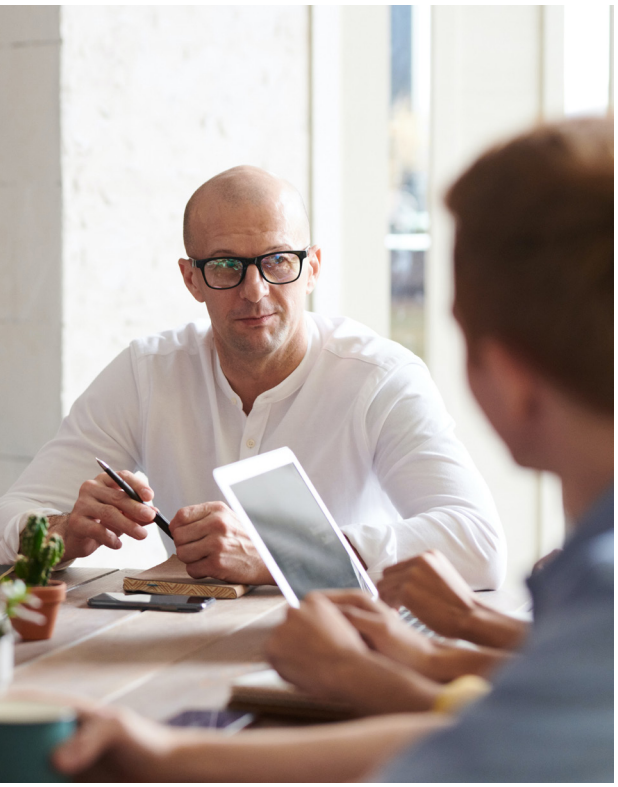
CSMs are essentially a sturdy bridge and strong glue, connecting and coalescing the clinical operations and development teams, tailoring the unique needs of each clinical trial before enrolment begins and at every pivotal point during the study.

Among other attributes, CSMs must be flexible – available to assist sponsors however they are needed – ensuring a clinical trial is conducted smoothly and efficiently.

IRT systems: handle patient screening and randomisation; manage patient interactions; oversee drug supply and data flow throughout the trial; securely protect sensitive data;

enable regulatory compliance; and provide preset and ad hoc reports for real time data visibility. IRT systems are the software backbone of clinical trials, and must be fit for purpose and designed to accommodate the unique protocol and operational needs of each clinical trial. How well an IRT is tailored to each trial will directly affect data integrity and patient safety. Optimally, IRT systems also ensure the highest efficiency when it comes to drug logistics, achieving the highest possible waste reduction, lowest carbon footprint and most efficient use of budget.

When sponsors are looking for an IRT vendor, they want to work with a vendor that has extensive expertise, resources and people. Best-in-class IRT partners provide invaluable guidance on clinical trial supply logistics, drug supply optimisation and technology set-up specific to the sponsor's protocol for the trial's full lifespan. IRT services teams are an especially valuable resource for sponsors. Comprised of both protocol and technology experts, IRT study teams leverage their deep functional expertise to streamline processes and make informed decisions throughout the trial. Their knowledge of the sponsors' specific protocols helps the trial adhere to the required standards and guidelines, minimising errors and delays. Their holistic understanding of the trial process allows them to anticipate challenges and proactively address issues. IRT study teams help drive data accuracy, cost reduction and trial outcomes. When a CDMO and IRT vendor team up to provide seamless support for a clinical trial, we see the best success stories.



Selecting a CDMO and IRT vendor with proven history of successful collaboration

IRT vendors collaborating with CSMs can be highly effective in determining the user requirements specification (URS) for IRT systems and performing user acceptance testing (UAT).

A proficient IRT system gives clinical supply managers the ability to tightly control the movement of drug supply, making updates in real time to change expiration dates or release lots as needed, for example.

IRT systems can also handle updates throughout the trial without tangling up data on the back end; upon the trial's completion, statisticians must be able to analyse which patient was administered which medication and the precise dosage taken. This requires a system that can easily keep track of dynamic data; it is far more difficult to trace data after the fact, a challenge that potentially leads to data gaps and strains the analysis of study data.

When CSMs and IRT teams proactively offer their solutions to customers as partners, they are best-positioned to support clinical trial sponsors and contract research organisations (CROs), guide UAT and, ultimately, enable an exemplary clinical trial experience.

By working together from day one, partnered CSMs and IRT teams are primed and prepared to respond rapidly to real-world situations – drug shortages, natural disasters, geopolitical conflicts and more. As representatives and advocates for their customers, CSMs and IRT teams help ensure clinical trials keep running without disruption, that patients don't have any interruptions to the dosing they critically need and that clinicians are protected from being accidentally unblinded when changes arise.

For example, right from project inception, savvy CSMs can work with the project manager at a CRO to create enrolment projections that inform proper set up of packaging and distribution and allow CSMs and IRT teams to precisely prepare for how much drug supply will be needed across various trial sites, countries and geographies.

Tight teamwork between CSMs and IRT teams takes practice

Collaborations between CSMs and IRT teams are especially important, particularly when unforeseen challenges arise. One example would be when a trial enrolment exceeds the forecast, which sometimes can be significant and lead to logistical issues around drug supply. In this instance, managing such overages requires tight teamwork and a plan. PCI and Suvoda have had multiple experiences of managing such challenges with very practical steps that are tried and tested coming into play. These include the addition of specific weekly meetings with the clinical trial sponsor to discuss the screening and enrolment numbers, to pinpoint where the drug is needed. After updating the supply parameter settings in the IRT system, PCI and Suvoda are able to square off where and when the drug is required with existing inventory, accelerated manufacturing, and orchestrated packaging and distribution logistics. In each of these instances, ultimately,

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through partnership working, the supply strategy parameters were able to be adjusted at key granular levels and meet the supply demands of such excessive enrolment without slowing down the trial process. Most importantly: no patient was incorrectly dosed or even missed a visit. CSMs and IRT teams make all this happen because they themselves are unblinded – allowing them to see all information within an IRT. IRT systems are built to ensure clinicians, or any member of the sponsor's study team, can't see anything they shouldn't. This is especially beneficial when trial designs change during the study – for instance, when dosing guidelines are updated, or adverse reactions are reported. With minimal delay, CSM and IRT teams working in tandem accommodate updates without compromising patient safety or trial integrity.

Choosing vendors that have a strong track record of collaboration can help to avoid issues or disconnects by ensuring both the CSM and IRT teams are working within the same standards. Being synced up on small items such as the use of titles, headers and vernacular within the IRT system help avoid confusion. PCI and Suvoda have seen how a mutually agreed-upon set of standards can prevent mistakes from occurring.

Vendors that have walked in a sponsor's shoes

Team members at PCI and Suvoda leverage a wealth of knowledge gained from diverse roles in the clinical industry, including some with experience on the sponsor side, in their current vendor positions. This ability to clearly see both sides of the coin has made PCI and Suvoda teams better at assessing and mitigating risks in the clinical supply chain, preventing issues before and during a clinical trial, forecasting what challenges might crop up, and tackling concerns before they turn into problems.

When PCI and Suvoda team up to provide all-in-one support for clinical trials, there are distinct advantages: enabling compliance with good manufacturing practice (GMP) and good clinical practice (GCP); anticipating the impact of temperature excursions on drug supply; managing movement of drug from depot to site according to actual patient enrolment timelines; and responding to issues in real time by making any necessary modifications to the IRT system.

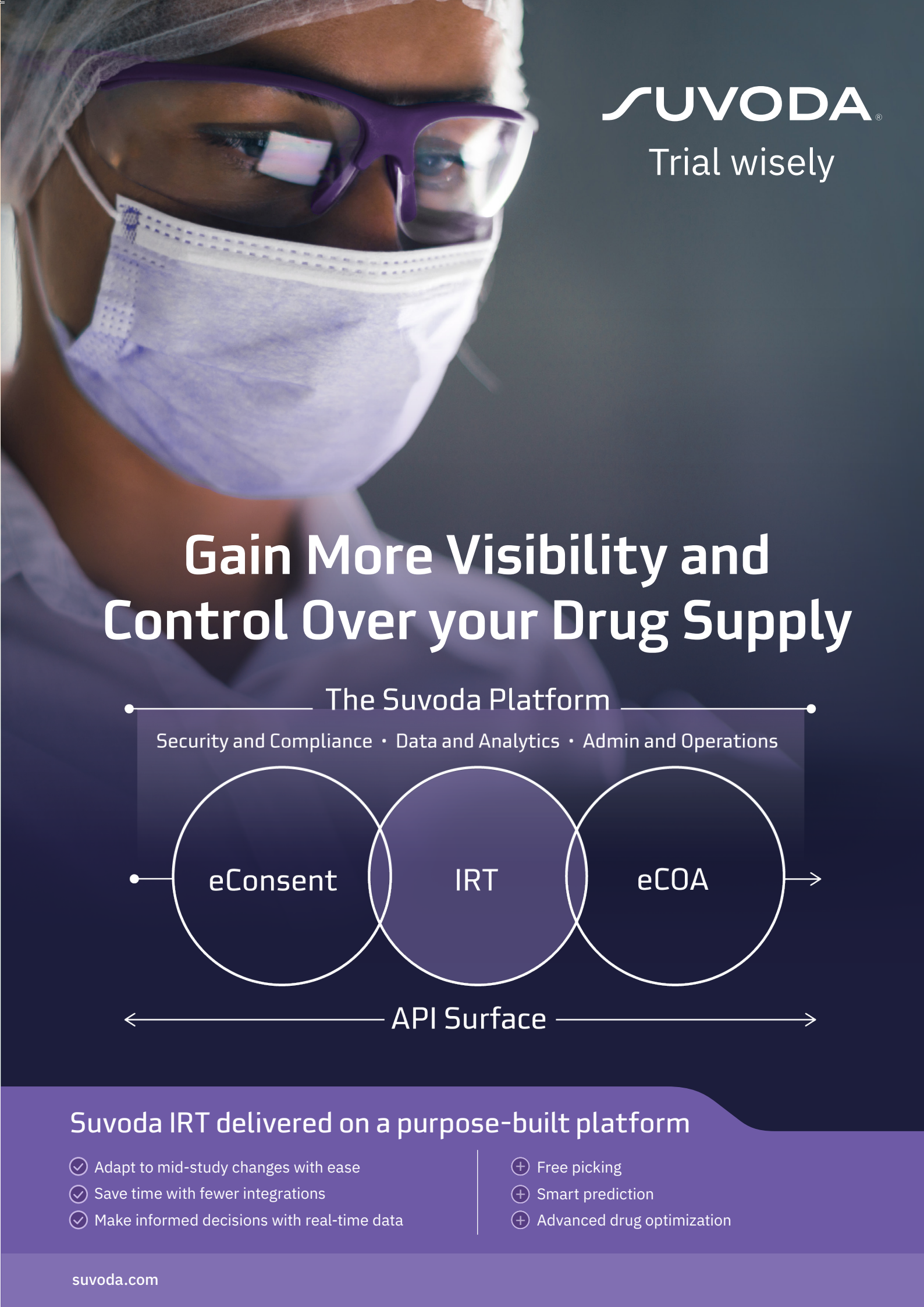
Partnered technology vendors like PCI and Suvoda, backed by extensive experience and knowledge, play a pivotal role in enhancing clinical trial outcomes, the development of emerging drugs and therapeutics, ultimately delivering new treatment options to millions of patients in need.

Reference:

1. *Visit: ncbi.nlm.nih.gov/pmc/articles/PMC1299137/*

Henk Dieteren, Clinical Supply Chain Solutions consultant, has been assisting **Suvoda** with his knowledge in various areas of clinical trial supply management since October 2020. Prior to joining Suvoda, Henk co-founded the clinical supply chain department at Grünenthal GmbH in Aachen, Germany, and served as associate director of this department for ten years. Henk then moved to BioNTech SE in Mainz, Germany, where he assumed the role of senior investigational medicinal product manager. Henk is an innovative expert in IRT, temperature excursion management and direct-to-patient logistics, and is a member of the DtP sub-team of the GCSG Regulatory e-Team.

Ed Groleau is senior director of Clinical Supply Chains. He has over 30 years of experience in pharmaceutical drug development on both the pharma and vendor sides. The first half of his career was spent in various laboratories from analytical method development, to solid state characterisation and polymorph screening, to stress degradation and chemical characterisation. He left the labs and moved into clinical supplies in 2003, providing all aspects of CSM support to maintain clinical programmes. He joined **PCI** in 2018 and became senior director of PCI's Supply Management And Readiness Team (SMART).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