Fact Sheet

IQVIA TECHNOLOGIES

Navigating The Use of Controlled Substances in Clinical Trials Using IRT

Understanding DEA Form 222

Clinical trials that use controlled substances are generating promising results for a large number of indications, including treatment-resistant depression and epilepsy.

Sponsor organizations that want to use controlled substances in clinical studies must manage the associated regulatory and logistical requirements. This can be challenging for Emerging BioPharmas with smaller staffs and fewer resources. Regardless of size, every sponsor must use extreme care to meet geographic regulations for the use and distribution of controlled substances in studies.

Cenduit's leading team of experts in global regulatory compliance and quality build highly configurable and adaptable IRT systems that can easily manage the many requirements of using controlled substances – whether in the U.S., or any other country. Clients receive the confidence of consistent compliance for their supply chain, drug management, and dosing practices.

DEA REGULATIONS

In the U.S., the Controlled Substances Act (CSA) of 1970 defines five schedules of controlled substances, with the Drug Enforcement Administration (DEA) regulating transport and storage. The DEA requires that whenever a sponsor transfers controlled substances between locations in the U.S, the receiving party must have a DEA Form 222 and order the substances via a registered form (complete with unique reference).

Taking a consultative approach on the road to controlled substances in clinical trials

Trial design incorporating a controlled substance is a highly specific, complicated process that can take weeks or much longer. Our team's proven framework enables us to anticipate and design for change, and create the specifications for this type of study design in days.

Our Business Solutions and Project Management Team take a differentiated approach that begins with their initial client discussions (even prior to award). Through expertise and insights gained over hundreds of trials, our team makes detailed assessments to determine a potential solution, and establish feasibility within the available timeframe. During the quotation process, we sketch out the trial design and visualize the IRT workflows. With the added element of incorporating controlled substances, the team is able to create a design and provide clients with a comprehensive demonstration of what the final solution could look like, all before an award is confirmed.

When the study is awarded and formal design work begins, our design teams pride themselves in becoming the experts in the protocol for each study and its required processes (such as managing controlled substances, via DEA form 222). Once the study is live, Cenduit continues to apply our expertise and dedication to quality, to ensure the study runs without fault.

MINI CASE STUDY

IRT with a controlled substances study

Most clients prefer in-depth discussions about what they want from the study during the bidding process, before we begin the formal design phase. Occasionally, all that is available from the sponsor at this time is a very early draft protocol or short synopsis of the trial's goals. Either way, our experience enables Cenduit to provide personal support and the same consultative approach.

For one client using controlled substances in a study investigating inflammatory and fibrotic diseases, we went from initial concept to showing the client how their IRT system would work in just a few days – complete with sample wireframes and demonstrations to help visualize the workflow.

We delivered a system as a completed package – not in stages – and tailored to include DEA Form 222 registration and assignment processes.

The study has been operational for many months across multiple sites and geographies, and is successfully enabling a complex workflow without a single surprise for the client or Cenduit's support team.

Consultation and initial concepts

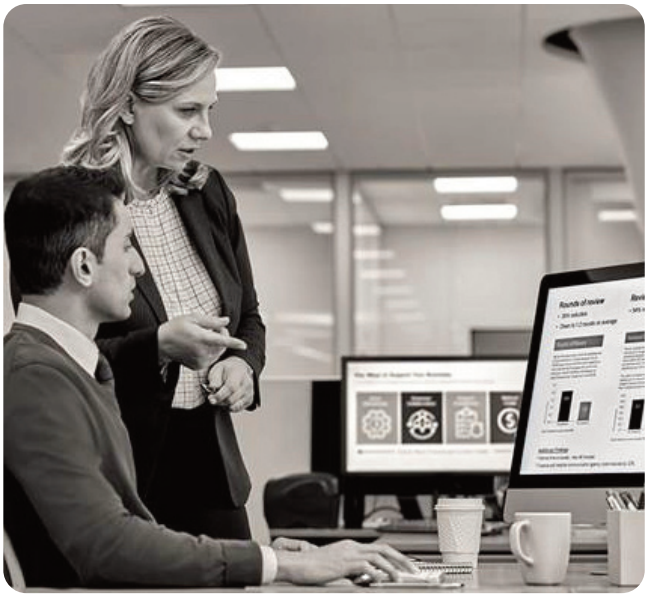
Sample wireframes and workflow demonstrations

Implementation across multiple sites and geographies

Designing in quality from the inside out

Clients and prospective clients often ask our teams for their advice and consultation on potential challenges presented by unique study designs. This is especially true for EBPs, where we consult in a way that serves almost as an extension of the client's own staff – many of our most experienced staff are within dedicated teams aligned to EBP clients.

Often, we ask our design Project Management colleagues worldwide for input on the most challenging study requests – such as the use of controlled substances – and the answers invariably illustrate our teams' passion to innovate and deliver quality solutions. It's the level of service that we believe you can only receive from an eClinical technology provider focused on IRT and associated eClinical technologies, consistently exploring new ways to research promising new treatment areas.



Contact us today, and let's start a conversation about how our team can help you ensure smooth operations and strict compliance in your organization's use of controlled substances for clinical programs.

CONTACT US

Toll Free (US & Canada): 877-253-3080

Global Direct Dial : +1 610-871-0150 | UK: +44 140 334 2316

www.iqvia.com/oct