

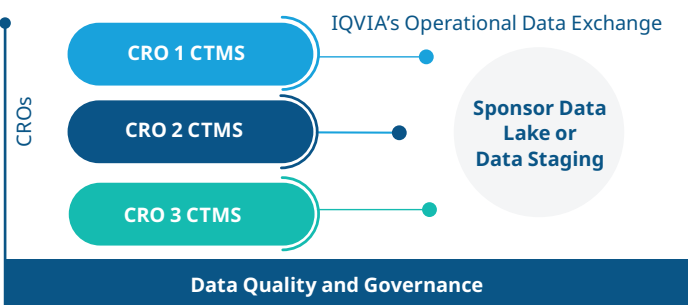
Operational Data Exchange Fact Sheet

Near real-time data availability for operational oversight and other workflows

The challenge

A recent IQVIA survey revealed that one third of the sponsors fully or partially outsource their clinical trials to several CROs. And although this model usually results in successfully taking a new product to market, there is a large set of data that is generated during the trials and, today, remain vastly siloed and very hard to combine in different systems that don't communicate with each other. Manual efforts are required for study teams to create real time reports related to enrollment, site start up and monitoring, data management and key milestones & metrics.

For example, you might have several CROs involved in your studies and every one of them is using their own CTMS. And you have your own CTMS, so how do you move the data from the CROs' CTMS to yours for a comprehensive trial portfolio oversight?



The solutions

IQVIA's Operational Data Exchange (ODE) enables automated methods to update Sponsor data lakes with operational data from any CRO and any trial and can be used for oversight visualization and trial management system updates in an easy-to-use format. Operational data from the exchange is available in near real-time and can be delivered via API, file sharing (CSV, XML), or Cloud-based data sharing capabilities.

Here is an example of all the operational data types that can be exchanged via the Operational Data Exchange:

Standard ODE Model

Address	Study
Account	
Account Address	
Contact	
Contact License	
Contact Address	
Study Milestone	
Study Country Milestone	Study Country
Study Country Metric by MO	
Site Account	Site
Site Address	
Site Contact	
Site Milestone	
Site Metric	
Site Visit	
Subject	
Subject Status	
Regulatory Submission	
Documents	
Documents Submissions	
Protocol Deviations	

Any additional entities and attributes beyond standard ODI offering can be included as a bespoke/custom need from customers.

Your benefits

IQVIA's Operational Data Exchanges can provide an easy-to-use solution to all the above challenges. Here is some examples of the value for sponsors that use Operational Data Exchange realized:

- The Standard Operational Data Exchange [SODE] is a service offering to extract data from IQVIA and other CRO's data assets and provide to sponsors as a data feed using CDAS platform on IQVIA's multi-tenant Environment
- Near real-time data availability for operational oversight and other workflows
- Operational trial data from any CRO and any trial available at your fingertips
- Improve the relationship between CROs and industry sponsors
- Easily configured to your requirements, without a need for custom coding
 - » Customizable to the unique needs of customers
 - » Easy to implement Data Quality rules
 - » Full auditability of data flow

- Flexible data model that supports your data and format needs
 - » Define your data validation rules and mappings
 - » Data exchange frequency can be accommodated based on your needs
- Secure and compliant data environment that supports GxP
- Currently supporting integrations with all major CTMS across customers (Siebel CTMS, Medidata, Impact, Veeva)

Our capabilities

Our Operational Data Exchange Capabilities include:

- **45** Specialists
- **30** active customers
- **750+** Study integrations in production

Click [here](#) to schedule a consultation about Operational Data Exchange and CDAS.