



# CDISC Open Rules Consultancy

Health Inspired,  
Quality Driven.

**SGS**

# About SGS Clinical Research

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Our biometrics team is committed to ensuring all necessary trial data is captured, reviewed and analyzed to the highest standards. We focus on maintaining high-quality data, meticulously adhering to rules set by ICH-GCP, CDISC and regulatory agencies like the FDA, EMA, MHRA and PMDA, to guarantee all global requirements are met. Our data packages are fully aligned with the latest data standards, ensuring your clinical trial data is ready for regulatory submissions. When you need to be sure, choose SGS.

Beyond meeting today's standards, we are shaping tomorrow's. We stand at the forefront of industry advances, actively participating in new initiatives like the CDISC Open Rules project to define the future of data conformance.

“ Our involvement with CDISC Open Rules exemplifies our proactive approach to shaping standards that ensure robust data integrity and compliance.”

**ROMAN RADELICKI**  
HEAD OF DATA TECHNOLOGY, SGS



# About CDISC Open Rules

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CDISC Open Rules includes open-source software developed by CDISC that incorporates executable data conformance rules, which are part of the Foundational Standards. These rules provide clear instructions enabling the industry to validate data packages in alignment with CDISC foundational standards and regulatory requirements.

At SGS, we strongly believe that the CDISC Open Rules project is transforming the clinical research industry, providing greater quality assurance, compliance, efficiency and interoperability.

```
17 # @param @context the context
18 # @return the result
19 # @example
20 attr_reader :observations
21
22 # Internal: Create a new result
23 #
24 # @param @experiment the Experiment this result is for
25 # @param @observations an Array of Observations, in experimental order
26 # @param @control the control Observation
27 #
28 def initialize(experiment, observations = [], control = nil)
29   @experiment = experiment
30   @observations = observations
31   @control = control
32   @candidates = observations - [control]
33   evaluate_candidates
34
35   freeze
36 end
37
38 # Public: the experiment's context
39 def context
40   @experiment.context
41 end
```



## Quality assurance

CDISC Open Rules ensures you have consistently high-quality data ready for submission, reducing the risk of errors, time-consuming corrections and submission failures.

## Compliance

CDISC Open Rules helps with adherence to industry standards, regulatory requirements & company-specific rules, thereby minimizing the risk of non-compliance. These CDISC data conformance rules act as a single source of truth when ensuring standard and regulatory compliance.

## Interoperability

The CDISC Library offers a comprehensive set of application programming interfaces (APIs) for accessing the CDISC conformance rules and the CDISC Open Rules Engine (CORE) offers

a command line interface (CLI)/API, facilitating seamless integration with existing clinical data systems. Additionally, CDISC Open Rules supports the creation of local rules and enables their exchange between stakeholders.

## Efficiency

Automate data conformance checks using CDISC's executable rules and open-source execution engine to save time and resources. Standard conformance rules are always kept up to date with the latest industry standards.

## Flexibility and adaptability

In-house implementation of the CDISC Open Rules system, assisted by SGS, enables customization tailored to your needs. Incorporate company-defined rules for a variety of data structures and maintain the ability to add further requirements as required.


# Consultancy services

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We are your comprehensive guide to mastering CDISC Open Rules, offering a suite of consultancy services customized to your needs, from expert advice and project scoping to implementation and resource support.

Let us support you every step of the way.



A woman with a long braid, wearing a white t-shirt and a long olive-green cardigan, stands in a modern office. She is holding a tablet and smiling. In the foreground, the back of a person's head and shoulders is visible, and another person is sitting in the background holding a folder. The office has wooden shelves with plants.

“ With SGS by your side, switching to the new CDISC Open Rules is smooth and stress-free. We'll make sure your data meets the required standards. ”

**ELS JANSSENS**  
DATA MANAGEMENT SYSTEM AND  
PROCESS MANAGER, SGS

# Your roadmap to CDISC Open Rules adoption



## EVALUATION

Regular status updates and strategic evaluation

## PROJECT EXECUTION

Start and execute project according to agreements

## PROJECT SCOPE

Agree on services, budget and timelines

## STRATEGIC PLANNING

Gap analysis, preparing project proposal

## INITIAL CONSULTATION

Understanding your needs and processes



## Initial consultation

Begin your joint CDISC Open Rules implementation journey with a comprehensive consultation focused on mapping your needs. Through detailed questioning, we gain deep insights into your existing processes and goals.

## Strategic planning

SGS's experts then analyze the collected data, conduct gap analysis, and formulate a strategic plan with fully customized solutions to facilitate seamless integration of the CDISC Open Rules. Our main objective is the efficient enhancing of your data compliance.

## Project scope

We present our proposed strategic plan, outlining each project step, consultancy services and estimated budget. The plan is then revised based on your feedback, establishing timelines and the scope of work.

## Project execution

We promptly begin implementing the CDISC Open Rules project.

## Evaluation

We regularly evaluate progress throughout the project to ensure we stay on track. These periodic assessments support an agile approach, allowing flexibility and adaptation. This strategy lets us accommodate changes in your needs, project scope, and evolutions within the industry.

## SGS's CDISC Open Rules project execution packages



### SGS-led project

Our project manager leads the CDISC Open Rules implementation project, developing the CDISC conformance rules, which are independently validated by an expert.



### Client-led project

You manage the project and we provide additional resource support to assist with CDISC Open Rules implementation, depending on the project's scope.



## Hybrid

We lead the CDISC Open Rules implementation project in collaboration with your team, ensuring the same packages as outlined in the SGS-led project package are applied.



## Expert consultancy

While we are not directly involved in the CDISC Open Rules implementation project, we can provide consultation should you encounter issues or have questions. Leveraging our experience and expertise, we assist in facilitating a smoother implementation process.

# Why SGS

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Team up with SGS for CDISC Open Rules implementation and enjoy a variety of benefits, including seamless transition to these open-source tools through our comprehensive suite of services.

## Expert guidance

As an early adopter of the CDISC Open Rules , our knowledge and expertise is officially recognized by CDISC.

## Comprehensive services

From project scoping and expert advice to project implementation and resource support, we offer a wide range of services tailored to your specific needs.

## Quality assurance

Our focus on high-quality data and strict adherence to industry standards ensures your data meets all compliance requirements and is ready for submission.

## Efficiency

Our expertise with the CDISC Open Rules helps streamline your processes, saving you time and resources.

## Innovation

As pioneers in the field, we are at the forefront of industry developments, enabling you to stay ahead of the curve.

## Reliability

With a proven track record and commitment to customer satisfaction, you can trust us to deliver on our promises.

“ As pioneers in developing the CDISC Open Rules, we've invested significant time and expertise in perfecting these rules. Let SGS simplify your implementation process to ensure a smooth transition. ”

**MARISA WYCKMANS**  
DATA MANAGEMENT SYSTEM AND  
PROCESS MANAGER, SGS





# Our CDISC Open Rules experts

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At SGS, our dedicated team has been deeply involved in the development of the CDISC data conformance rules. Two of our data management experts are integral to this process, participating in the CDISC Open Rules project from the very start. They bring a wealth of knowledge and expertise, while actively cultivating these skills within a growing team of specialists.

But our strengths do not stop there. Our data technology team provides robust support throughout implementation, ensuring a smooth transition to CDISC Open Rules. This blend of experienced professionals and strong technical backing ensure we are well-prepared to guide you through every aspect of CDISC Open Rules implementation.

## Meet Els Janssens

### DATA MANAGEMENT SYSTEM AND PROCESS MANAGER, SGS

Els is authorized to deliver comprehensive CDISC Open Rules hands-on implementation training sessions, which are available for subscription through the CDISC website. Her role as a CDISC training facilitator underscores our deep commitment to promoting industry best practices and ensuring compliance with global regulatory standards.



# Health Science

Health Inspired,  
Quality Driven.



## Contact us



[clinicalresearch@sgs.com](mailto:clinicalresearch@sgs.com)



[sgs.com/healthscience](https://sgs.com/healthscience)



[sgs.com/healthcommunity](https://sgs.com/healthcommunity)

**SGS**

When you need to be sure