SGS launches new consultancy services to transform and accelerate clinical trial submissions

GENEVA, SWITZERLAND, October 21, 2024 / EINPresswire.com/ -- SGS, the world's leading testing, inspection and certification company, has today launched its pioneering 'CDISC Open Rules Consultancy', a new service designed to transform and accelerate clinical trial submissions.

Pharmaceutical organizations worldwide face the critical yet complex task of achieving compliance with Clinical Data Interchange Standards Consortium (CDISC) standards and regulatory requirements. Implementing the innovative CDISC Open Rules is vital for success, but navigating these requirements can be challenging.

As an official CDISC Registered Solutions Provider (RSP), and a leader in the CDISC Open Rules open-source software project, SGS has unmatched expertise at the forefront of industry advancements. SGS recognizes how implementing CDISC Open Rules can revolutionize clinical research by enabling standardized, industry-wide validation of data packages.

The SGS consultancy team is led by Roman Radelicki, Head of Data Technology at SGS, alongside Data Management System and Process Managers, Marisa Wyckmans and Els Janssens. All have played a pivotal role in the development of the first CDISC Open Rules, with Els Janssens becoming the first authorized CDISC training facilitator for CDISC Open Rules.

Together with a growing team of specialists, the teams provide unparalleled knowledge and experience, supported by CDISC, SDTM, define.xml and ADaM certifications. This ensures that data management and statistical processes are not only compliant, but also efficient and optimized for regulatory submission.

Roman Radelicki, Head of Data Technology, said: "CDISC Open Rules are a major change for the industry, defining the future of data conformance. With SGS by your side, you can be certain your journey towards their implementation will be smooth and stress-free."

SGS's CDISC Open Rules Consultancy services guide users through every step of implementation

from initial consultation and strategic planning to full project execution and ongoing evaluation.

The benefits of implementing CDISC Open Rules within an organization include:

- Quality assurance: ensuring consistently high-quality data is ready for submission, reducing the risk of errors, time-consuming corrections and submission failures
- Compliance: helping with adherence to industry standards, regulatory requirements and company-specific rules
- 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; as well as supporting the creation of local rules to enable their exchange between stakeholders
- Efficiency: via automated data conformance checks using CDISC's executable rules and open-source execution engine to save time and resources
- Flexibility and adaptability: in-house implementation of the CDISC Open Rules Engine enables customization for the incorporation of company-defined rules and the ability to add further requirements

About SGS Clinical Research

SGS's biometrics team is committed to capturing, reviewing and analyzing all necessary trial data to the highest standards. They 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. Their data packages are fully aligned with the latest standards, ensuring clinical trial data is ready for regulatory submission. When you need to be sure, choose SGS.

About SGS
We are SGS – the world's leading testing, inspection and certification company. We are recognized as the global benchmark for sustainability, quality and integrity. Our 99,600 employees operate a network of 2,600 offices and laboratories around the world.

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