Reporting-as-a-Service for pharmaceutical studies

studygen

up to data

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studygen

studygen raas (reporting-as-a-service) is a subscription-based solution that reduces the upfront implementation costs dramatically, thus generating immediate value. It increases lab efficiency and productivity by generating submission-ready approval documents in a matter of minutes. The solution implements full data integrity for the daily study process as a GxP compliant and validated system.

studygen raas is the newest member of our studygen product family (former iStudyReporter), a platform of report writing solutions for the pharmaceutical industry. It offers the same expertise and advantages to CROs and smaller research labs that it provided to the top pharmaceutical and biotech companies for streamlining processes and eliminating manual data reprocessing at an affordable cloud solution price.

studygen raas does not require any investment into hardware or additional internal resources and can be validated with minimal effort. The solution delivers preconfigured, compliant reports and SEND files by leveraging up to data's 30 years of experience in implementing bioanalytical reports.

Key benefits

- Optimized lab workflow for CROs and smaller labs
- Integrates with all systems and equipment for end-to-end data integrity
- Eliminates the need for LIMS, EXCEL or any other third-party tools
- Ready-to-use templates and SEND files
- In line with FDA, NMPA, EMA, and ICH rules and regulations
- Immediately available
- Zero invest in internal hardware or resources to maintain the system
- Minimal validation-effort following GAMP 5
- Fully validated, GxP compliant platform

Specifically designed to write study reports

studygen

A solution platform that delivers rapid time to market. Developed with leading pharmaceutical companies with the goal to automatically generate complex study reports and approval documents within a matter of minutes, simultaneously ensuring full data integrity. This makes our solution ideal for pre-clinical, clinical, and stability studies. Leading pharmaceutical companies and CROs worldwide bank on the studygen platform for its ability not only to automate processes, but also to safeguard seamless data collaboration and reporting.

Applications

studygen bioanalytic
For small or large molecules, ADA, and immunogenicity using any form of instrument software or LIMS. Export interface between submission report and CDISC SEND. Accesses data from multiple sources (from Excel to Sciex Analyst© Software and Thermo Fisher™ Watson LIMS™).

studygen stability
Based on LIMS (e.g. Thermo Scientific™ SampleManager LIMS, LabWare, LabVantage, SAP) with preconfigured, ready-to-use formats and reports including stability tables, shelf-life evaluations based on ICHQ1E, complex trend analysis, APR, and PQR.

studygen study archiving
Long-term archiving of study data in human-readable formats, including validation studies according to FDA Guidance for Industry: 21 CFR Part 11(11.10 (b) and 11.50).

studygen raas
Subscription-based regulatory reporting for pharmaceutical studies, designed with CROs and smaller reasearch labs in mind.

About up to data

We support laboratories in enhancing efficiency and using lesspaper. By providing flexible laboratory information management systems and highly specialized reporting tools, we deliver future-proof solutions for documenting and managing sensitive laboratory information in the pharmaceutical industry.

Our team of scientists, software engineers, and economists are highly familiar with customer tasks and processes, spanning everything from data capturing to finished reports, thus delivering solutions that map workflows from start to finish.

Whether you are working on the early stages of development for a new vaccine or performing stability studies to establish the shelf life of a product, we ensure that our solutions integrate seamlessly into your working environment and support your individual processes.

Partner

We maintain long-term partnerships and work with the best in the industry. This ensures that our solutions support the latest technologies and meet the individual requirements of our customers.

Compliance & Security

To map the complex process and increasing requirements, security and data integrity is essential for our customers who are following good scientific and laboratory practices. Our solutions are designed to meet the latest industry regulations such as GMP, ISO 17025 and FDA 21 CRF Part 11. Our quality management system is certified by DQS following the standard for DIN EN ISO 9001:2015.

up to data

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