up to data — Successful reporting for bioanalytical studies

iSTUDYREPORTER Bioanalytics

Life Science Industry today is facing the challenge to develop new drugs and substances in short and even shorter time frames. Increasing the efficiency of research and development processes is the most promising approach to achieve the goal of reduced time-to-market and reduced costs.

In particular the creation of bioanalytical study reports for submission today is tedious and time consuming. It requires a severe amount of manual processing. Most information in these reports has to be copied manually from data management Systems (e.g. Thermo Fisher Watson™ LIMS) and supporting systems such as ELN, SDMS to the final document. Due to the nature of this process the final report has to be doubled-checked to guarantee the accuracy of data, resulting in a laborious workflow that binds expensive resources inefficiently.

The introduction of iStudyReporter Bioanalytics dramatically increases efficiency by delivering submission documents (e.g. Tox-, Analytical-, Validation Report) through an automated process, directly interfacing with LIMS data.

AT A GLANCE

- Automated “out of the box” regulatory reporting
- Comprehensive set of bioanalytical standard tables
- MS Word as a target application including protected table technology, graphs, statistical calculation and multi analyte tables
- Scientific amendment can be included easily
- Validated data transfer from bioanalytical data management systems; Thermo Watson LIMS access as a standard interface
- No manual steps, no transcription error, no data cross-check
- Traceability secured through eSigs and audit trails
- Seamless integration in IT Infrastructure and Document Management System
- CDISC compliant exports
- ABSciex Analyst© Software Interface to easily integrate Chromatograms
- Human Readable Report Archiving options

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EFFICIENCT

iStudyReporter Bioanalytics delivers automated regulatory reports based on a bioanalytical data management system in a matter of minutes.

By making use of iStudyReporter almost all manual activities, including the time-consuming recheck, are eliminated and thus, the processing time is reduced dramatically.

As a result tox-, analytic- and validation study reports for submission are available within minutes; laboratory resources will be used in an optimal way.

An integrated interface to ABSciex Analyst© Software allows the embedding of relevant chromatograms into the final WORD report as protected graphics. These can be selected flexibly as necessary per report.

To ensure consistency between the submission report and the CDISC "Standard for Exchange of Nonclinical Data" (SEND) an export interface is provided.

iStudyReporter Bioanalytics can deliver a human readable study archiving mechanism, strictly based on regulatory authority requirements allowing long term data access and processing without special knowledge or access to the Watson software.

FLEXIBILE

By providing an easy to use wizard, all aspects of the report purpose are defined at creation time (e.g. specification to use). The report is based on customer defined Microsoft Word templates that meet the demands of regulatory guidelines and the clients Corporate Identity.

The solution ensures a valid transfer of data to Microsoft Word and ensures integrity by protecting data sections against unintentional changes – but allows manual amendments.

iStudyReporter Bioanalytics fits to any given IT environment due to its innovative RemoteCollector technology. Established systems like LIMS, ELN, SAP, SDMS, legacy systems etc. can be integrated and linked to each other, addressing common issues using the integrated Master-Data Management functionalities. As a result the final report can seamlessly represent data from multiple systems.

INTUITIVE

The application is designed similar to the Microsoft Windows Explorer in order to guarantee an intuitive handling of reports. The ability to create an individual structure based on report properties ensures that this will fit to any personal need.

An easy to use wizard supports the definition of the specific content and intuitively guides the user through the creation process.

iStudyReporter relies on the established Microsoft Office Suite. This allows leveraging established operations, which ensures a high user acceptance and a reduction of training effort for any new user.

PRODUCTIVE

Each report created with iStudyReporter is reproducible, well-established document management functionalities, such as versioning, audit trails and eSigs, ensure that any information item on the report is easily traceable to its origin. Unintended changes will be fully eliminated.

An integrated "Document Life-Cycle" guarantees that business and QA demands for the document review; finalization and approval workflow can be mapped easily.

EXPERIENCED

up to data represents an experienced and innovative IT software provider with a strong focus on companies in the Life Sciences, delivering services and products for more than 20 years now.

iStudyReporter Bioanalytics has been developed in close cooperation with global pharmaceutical companies taking market-specific requirements into account.

Thus, many of the leading enterprises around the world rely on the iStudyReporter product family.

For further information on this product family and up to data please visit: **www.uptodata.com**