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Efficient solutions for Stability Studies

iSTUDYREPORTER Stability

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 stability 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 LIMS and supporting systems (e.g. SAS, Batch Management, ad hoc reports…) to the final document. Due to the nature of this process the final document 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 Stability dramatically increases efficiency by delivering submission documents (e.g. NDA/ANDA, Annual Report or APR/PQR) through an automated process, directly interfacing with LIMS data.

THE FUTURE OF STUDY REPORTING

iStudyReporter enables the Life Science Industry to

- cut down the time-to-market by introducing lean and cross system processes for the management of the entire relevant study data
- speed up and simplify the study report creation process to release valuable time to core tasks
- completely automate report processes while integrating the full set of data representation, such as tables, graphs, and statistical analysis based on ICH Stability Guidelines
- accelerate the submission process by making use of HL7 eStability compliant data files
- seamlessly integrate to the existing heterogeneous IT environment

up to data
professional services GmbH
Schornsheimer Chaussee 7
55286 Woerrstadt
Germany

Phone: +49 (0) 6732 – 9490 – 0
Fax: +49 (0) 6732 – 9490 – 94
e_contact@uptodata.de
www.uptodata.com

EFFICIENCT

iStudyReporter Stability delivers automated regulatory reports based on any Stability-LIMS within 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 complex stability study reports for approval are available within minutes and laboratory resources will be used in an optimal way.

The solution has been developed specifically for Life Science Industry based on ICH Guidance Q1, including shelf-life analysis, trending prediction as well as the HL7 eStability compliant data files optimized for an accelerated submission process.

FLEXIBLE

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.

The creation of reports for "On-Going" stability studies is a matter of minutes and can be made available as soon as initial data is entered in LIMS leveraging the progressive reporting approach.

iStudyReporter Stability 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 (products, batches, etc.) 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 Stability 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**