BIOVIA

3DEXPERIENCE®

DESIGN, LAUNCH AND MONITOR SCIENTIFIC STUDIES

BIOVIA STUDY DESIGN & TRACKING

Datasheet

Product Development is complex, especially in Life Sciences. It takes the testing of several million compounds through rigorous safety and efficacy studies to release a new commercial drug. Data shows that 20-30% of proposed medicines fail to advance due to improper, or incomplete study designs or product stability.

BIOVIA Study Design & Tracking provides the tools to design and manage multiple study types that are performed in your scientific laboratories. These include Stability, Process Validation and Formulation Optimization. Study Design & Tracking offers improved visibility of the experimental development and design process to the organization, minimizes the effort of defining independent study arms, and ensures that study design implementation is consistent, irrespective of the execution location. BIOVIA Study Design & Tracking App aims to bring a comprehensive and scientifically supported design guide to laboratory testing, associated with critical product development milestones, to enable testing of materials to comply with both regulatory and scientifically relevant criteria.

DASSAULT SYSTEMES

SCIENTIFIC STUDY MANAGEMENT CHALLENGES

Throughout product development, quality control, and product manufacturing, scientific studies are undertaken to test product stability, develop, optimize and validate methods, provide environmental monitoring, and determine excipient compatibility. In product development, the goal of a stability study is to determine the extent to which a product, specific formulation, or individual active ingredient stays intact over time and over a range of possible conditions. This provides the basis for expected product shelf life and expiry dates. In some cases the study will need to identify all possible degradation products and the pathways and mechanisms that yield any breakdown. This is a tremendous amount of work effort to design the investigations, track the testing, and generate the necessary reports.

In Pharmaceutical markets, there is a regulatory requirement to report the stability of product batches of every unique formulation, dosage strength, and packaging. This results in both a high volume of work effort and coordination to ensure timely completion within the published designs. The associated data volume and complexity creates a reporting risk to ensure all testing data is properly tracked, reviewed and within target specification limits. BIOVIA Study Design & Tracking provides data access and monitoring dashboards so responsible parties can see trends and actionable alerts before compliance becomes an issue reducing the risk of citations and fines that may result from failure to demonstrate compliance with specifications.

BIOVIA Study Design & Tracking provides the tools to efficiently design and manage the multiple study types that are performed in your scientific laboratories, streamlining workflows, reducing cycle times, and providing a comprehensive overview of all existing scientific studies.

BIOVIA STUDY DESIGN & TRACKING

BIOVIA Study Design & Tracking offers improved visibility of the experimental design (development) process to the organization. It minimizes the effort of defining the independent study arms by integrating the selection test criteria and parameters with your centralized library of approved recipes and/or test procedures. This ensures that each study design is implemented consistently, irrespective of where in the world the work is executed. Controls are in place to ensure study design approval follows an agreed lifecycle with appropriate management and electronic signatures, providing full traceability of author activities.

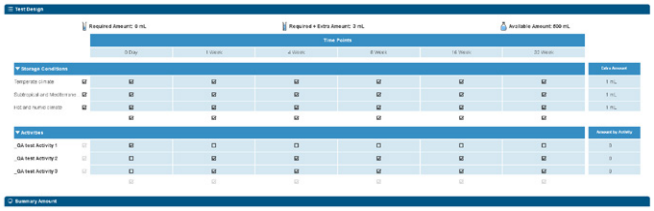

Figure 1: BIOVIA Study Design & Tracking

Study Design & Tracking integrates with BIOVIA Unified Lab to ensure that the materials and formulations tested have full traceability. Launching a study initiates a Task Plan with the necessary Tasks, Samples, and Result that will be used in the lab, linked to the target material. Using the tracking functionality, oversight of work progress is possible; allowing early identification of issues to facilitate mitigating actions and management of ongoing work in a study and portfolio.

Study Design & Tracking provides a graphical overview of the progress of the Study over the lifetime of the investigation ensuring the team is informed of specific test and timing details. Study Design & Tracking also uses the dynamic reporting engine provided by BIOVIA Pipeline Pilot to run a standard set of study reports and to allow customer specific reports to be configured.

CAPABILITIES

- Easy-to-use design and overview of scientific studies
- Incorporate multiple dimensions of Study Parameters, Time Intervals, and Test Plans
- Select Tests and Specifications to characterize the material
- Automatically generate a linked Task Plan in BIOVIA Unified Lab
- Visibility into study progress with a Monitoring page and included Standard and configurable Reports to meet your Study needs

With BIOVIA Study Design & Tracking, scientific studies are easier to design and manage across global R&D organizations, with full traceability and better insight into current operations for faster cycle times and improved decision-making.

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