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Blur Software Demonstration

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Abstract

Greater transparency in clinical trials has been a hot topic for several years now. Tools that support the de-identification of clinical trial data are essential in delivering anonymised data with a high level of usability quickly. This presentation will demonstrate with the use of Blur how the de-identification process can be completed with no SAS knowledge using our point and click interface. Templates can cut the time required for DE identification by up to 70%. Rules developed by Phuse and Transcelerate can quickly be applied and edited. The project system allows you to manage many de-identification efforts, including staff allocation and progress. A secure export facility with audit trail requires two electronic signatures from both a de-identifier and a reviewer. de-identified data can be delivered in several formats including sas7bdat and CSV files. A report of exactly what rules have been applied to what columns accompanies exported data.

Introduction

Biopharmaceutical companies have been de-identifying data on a small scale for years, but the era of clinical trial data transparency has changed the rules. The need to share clinical trial data with external collaborators (like independent researchers) and internal partners (like modelling, exploration and marketing teams) has never been greater. As data sharing needs accelerate in terms of volume and urgency, the old ways of delivering de-identified data are no longer practical. Blur, developed by d-Wise, is the industry-leading solution for delivering de-identified clinical trial data and protecting patient privacy.

Blur reduces the cost and eff ort of de-identifying data from individual trials, and brings scalability to the clinical trials de-identification process

• For any given trial, reduce de-identification delivery costs by 70% compared to current industry best practices.

• For trials based on industry standards (like CDISC SDTM), reduce de-identification delivery costs by 90%.

• Bring outsourced work back in-house, and control unpredictability regarding costs and delivery timelines.

Blur is designed specifically for the de-identification of clinical trial data – with built-in capabilities for clinical data structures, workflow and de-identification rules.

• Blur provides native support for all expected clinical trial data types.

• SAS data sets and transport fi les.

• CDISC (SDTM and ADaM) structures.

• Non-standardised data.

• Blur integrates the expected “do-er/reviewer” clinical trial data transformation process into the solution workflow.

• Blur has been developed to accommodate established and emerging de-identification rules, such as the TransCelerate and PhUSE working group recommendations.

• Blur provides an audit trail of project de-identification activities.

Blur is an off -the-shelf software solution, developed by industry experts, that requires far less internal development, maintenance and support than SAS based macros and programs.

• Internally-developed macros are time-consuming to develop and a distraction from the operational business of executing clinical trials. Pharmaceutical companies need to focus on core competencies and “buy” rather than “build”.

• Maintenance of macros is a very low priority and expensive activity. This creates stale tools that will not readily be adapted to emerging de-identification rules or business requests.

• Customers who adopt Blur will benefit from industry best practices.

Key Features of Blur

Application-driven data de-identification

- Overall reduction in cost in terms of time and eff ort to de-identify data.
- Hard-to-resource and costly SAS programmers are not required, enabling use of lower cost alternative resources.
- Risk reduction through menu-driven de-identification functionality and avoidance of coding and syntax challenges.
- Reduced validation and maintenance eff orts decrease total cost of ownership when compared to alternative approaches (like SAS macros).

Integrated workflow and controls

- Workflow automates manual industry business practices to deliver high quality data while reducing cost.
- Summary report provides valuable information for downstream data consumers and automates internal documentation.
- Specialized controls reduce risk by preventing the distribution of non-de-identified data.
- Audit trail provides de-identification history to address quality and control questions.

Rapid replication for new de-identification projects

- Similarly structured projects can be de-identified in a small fraction of the time as the initial project.
- Successfully completed projects serve as the starting point for new projects, ensuring high-quality deliverables.
- Support for internal, CDISC and evolving data standards ensures flexibility in meeting project-specific de-identification needs.

Designed for clinical trials

- Alignment with emerging de-identification guidelines from PhUSE, TransCelerate and across the industry provides out-of-the-box expected de-identification capabilities.
- Data restructuring prior to de-identification is not required, reducing complexity and cost of de-identification processes.
- Native support for reading and writing SAS data sets.

Blur allows you to selectively de-identify data within horizontal or vertical data sets, this allows you to both de-identify a subset within a single dataset or subset a group of patients across multiple datasets.

Blur can be shipped with existing templates developed by PhUSE and TransCelerate. Templates can be created from scratch or, current ones can be copied and edited in order to best need a companies' needs

Blur comes with built in capabilities that allow you to look at the original data, how it stands once it has been de identified and a comparison tool to show you what has changed and how.

Blur has an integrated workflow system that allows one to see who is working on what project, how much of that project is complete and what templates they have applied in order to let them complete their work. There are electronic signatures for handing off work to be reviewed and then further exported.

About d-Wise

d-Wise is a technology leader with the expertise to empower organizations to resolve their business optimization challenges, helping them rapidly harness and leverage data, systems and processes to gain competitive advantage. With offices in the US and UK, d-Wise offers product, service and consulting solutions that help clients implement robust, reliable, and compliant data infrastructures that are optimized for analytics and decision support. d-Wise has over a decade of experience tailoring data warehousing and standards solutions to meet the foundational data needs of their clients.

Conclusion

Blur will reduce the de-identification process of clinical trial data when used with templates by up to 70%. It's project management system will allow you to manage de-identification efforts on the largest scale. Its electronic signature sign-off system means you have an audit trail of who did exactly what with time stamps, and who reviewed that effort before agreeing that it has been done properly. Due to the fact that no SAS knowledge is required, this will free up scarce SAS resources to work on other tasks.

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