The industry-leading solution for delivering de-identified clinical trial data and documents, and protecting patient privacy

d-wise

www.d-wise.com/blur

Developed by life science experts, for clinical trials

Blur, developed by d-Wise, is the industry-leading solution for de-identification of clinical trial data, safeguarding patient privacy and honoring informed consent.

The biopharmaceutical industry is transforming rapidly. With these changes has come an increased call for transparency surrounding clinical trials. As companies strive to make clinical trial data more readily available, whether internally within their organization, or externally to the general public, they must first de-identify all patient-level data.

As data-sharing needs accelerate in terms of volume and urgency, the old ways of delivering de-identified data are no longer adequate.

De-identification support for clinical trials

Blur is an application-based software solution that reduces the cost and effort of de-identifying data from individual trials. Blur brings scalability to the clinical trial de-identification process, and allows previously outsourced work to be performed in-house, allowing organizations to control the costs associated with unpredictable delivery timelines.

- *For any given trial, reduce de-id delivery costs by 70%*
- *For trials based on industry standards, (CDISC SDTM, etc.), reduce de-id delivery costs by 90%*

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.

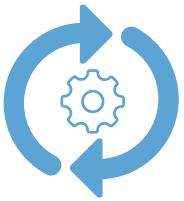
Blur provides native support for all expected clinical trial data types, including SAS data sets and transport files, CDISC (SDTM and ADaM) structures, and non-standardized data. The software has been developed to accommodate established and emerging de-identification rules, such as the TransCelerate and PhUSE working group recommendations. Blur also integrates the “doer/reviewer” clinical trial data transformation process into the solution workflow and provides an audit trail of all project de-identification activities.

Blur is an off-the-shelf software solution 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 then “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.

Key Features of Blur

Integrated workflow and controls



- Built-in workflow to ensure that integrated review and sign-off processes are included in every data delivery - high-quality data while reducing cost
- Summary report provides valuable information for approved 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

Protecting privacy, reducing costs

- Overall reduction in cost in terms of time and effort to de-identify data
- Data restructuring prior to de-identification is not required, reducing complexity and cost of de-identification processes
- Reduced validation and maintenance efforts decrease total cost of ownership when compared to alternative approaches

Application-driven data de-identification

- SAS programmers are not required, enabling the use of easier-to-resource and lower cost alternatives
- Risk reduction through menu-driven functionality and avoidance of coding and syntax challenges

Rapid replication for new de-identification projects

- Similarly structured projects can be de-identified in a fraction of the time it took for the initial project
- Successfully completed projects can 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
- Native support for reading and writing SAS data sets

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Enabling Transparency

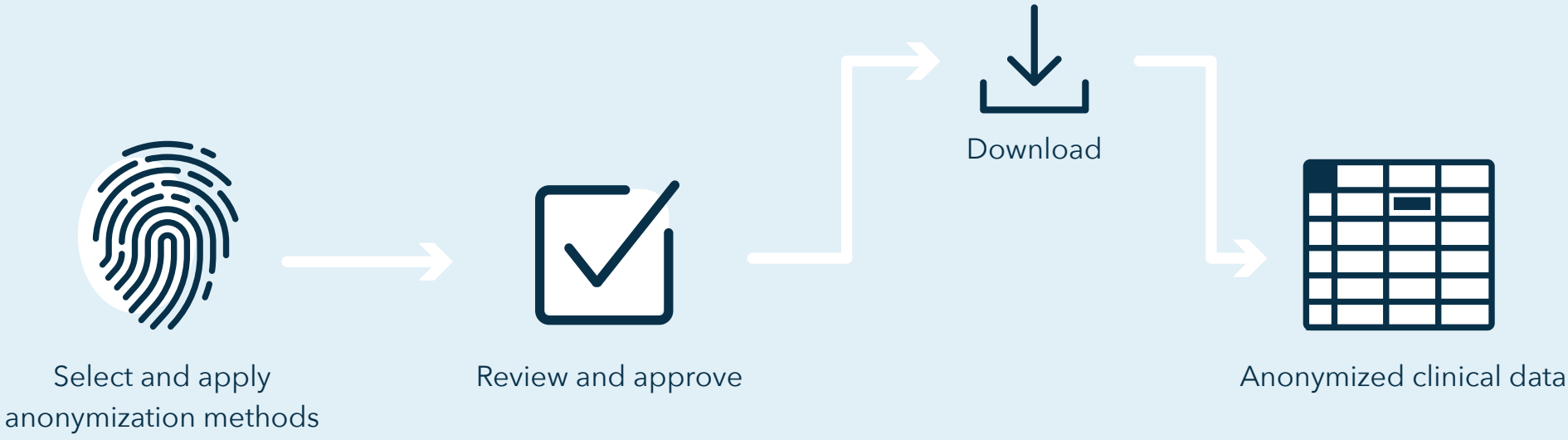
Data Anonymization

Risk Management

CSR Anonymization

Data Anonymization

- Role-based workflow for data de-identification lifecycle
- Templates to enable rapid replication between projects
- Anonymization methods aligned with industry best practices
- Reusable subject key mappings



Risk Management

- Measure re-identification risk of de-identified data
- Select identifiers to create equivalence classes
- Align risk assessment to release scenario
- Risk simulator to accelerate achieving target re-identification risk

Select identifiers

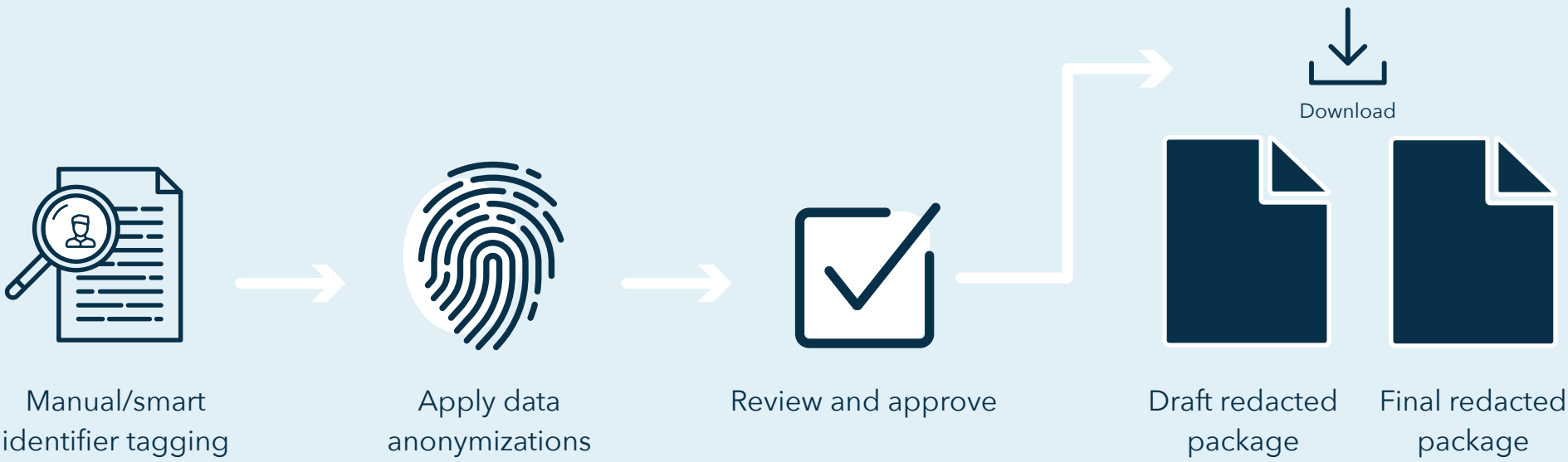
Align to release scenario

Interactively adjust to achieve targeted risk

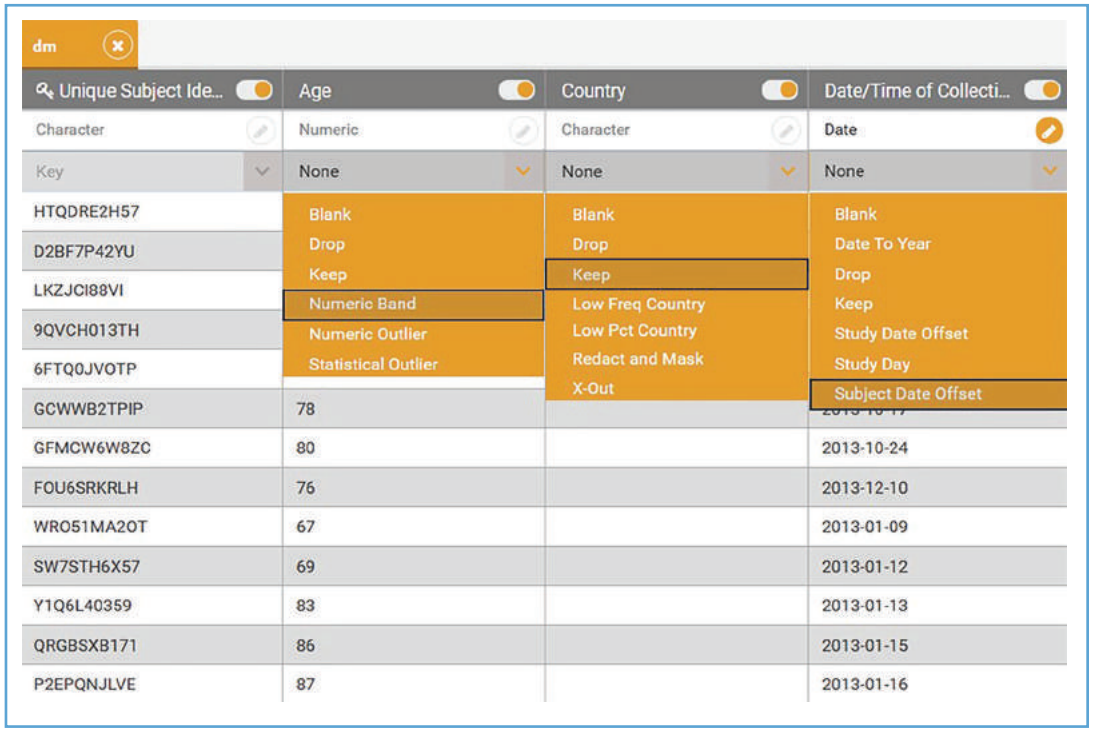
Risk quantified

CSR Anonymization

- Role-based workflow for CSR anonymization/policy 0070 lifecycle
- Support for automated and manual anonymization candidate text identification
- Apply anonymization consistently in CSRs and data
- Produce draft and final redacted package



Application View

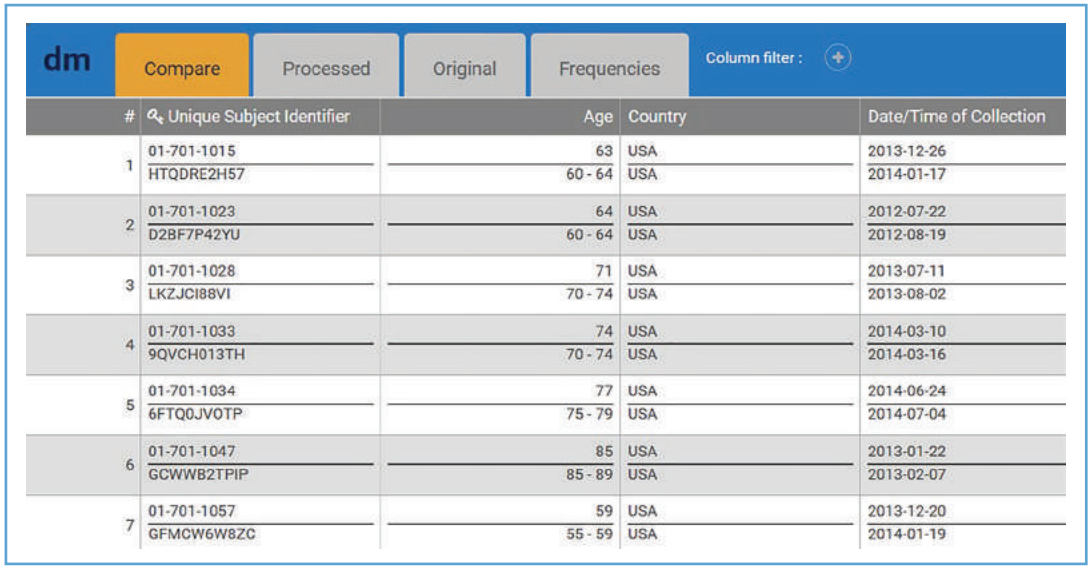


Data-specific Rules

Blur enables the user to apply various rules, (orange), to different data variables, (dark grey), within the application. This feature allows for the categorical customization of each de-identification effort, depending on data type.

In-app Comprehensive Data View

Blur's in-app data view allows users to view and compare the original source data and the data once it has been anonymized as they proceed through the de-identification process, as opposed to opening each data set in SAS.



CASE STUDY:
AstraZeneca's ongoing de-identification efforts using Blur

Client Scope

At AstraZeneca, non-regulatory research using clinical information was an area of increasing interest and importance for both internal and external research communities. It was becoming essential to be able to share clinical research data while still meeting the industry's obligation to protect the confidentiality of research patients. AstraZeneca determined that they needed to dramatically increase their ability to de-identify patient-level clinical trial data for both data sharing and transparency activities.

Challenges

AstraZeneca wasn't new to the de-identification process, but the augmented volume, complexity, and visibility of delivering de-identified data created new-found urgency. One-off and manual programming approaches were no longer a sustainable strategy for de-identification efforts because of the time, cost, and resources (technical programmers, review/QC personnel, software scripts, and ongoing maintenance and validation activities), that are required.

Solutions

AstraZeneca licensed the Blur de-identification solution from d-Wise to accelerate and operationalize patient-level de-identification activities.

Benefits realized by client

Blur enabled AstraZeneca to reduce costs and the increase efficiency of their de-identification process, protecting patient privacy and adhering to industry data standards.

Users of varying technical abilities can comprehensively de-identify clinical trial data without the need for informational technology or programming expertise, greatly expanding the pool of resources that can be called on to de-identify clinical trial data.

The solution supports a broad set of clinical trial de-identification rules, and has been designed to accommodate new rules and variables as industry de-identification strategies evolve.

"As we expand the availability and sharing of our patient-level clinical trial data to support the improvement of healthcare, we decided to streamline our processes further. d-Wise's software solution will help us to achieve this in a way that continues to safeguard the quality of the data."

– James Armbrust, AstraZeneca
Head, Clinical Trial Transparency & Disclosure

Systematize the transparency lifecycle to accelerate delivery, increase quality, understand risk, and share confidently.

Blur Use Cases

- Voluntary disclosure
- Policy 0070 compliance
- Structured & unstructured data
- Risk mitigation
- Data De-identification
- Data Anonymization
- Secondary use, both internal and external
- Journal publication

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