TRIALSCOPE DISCLOSE
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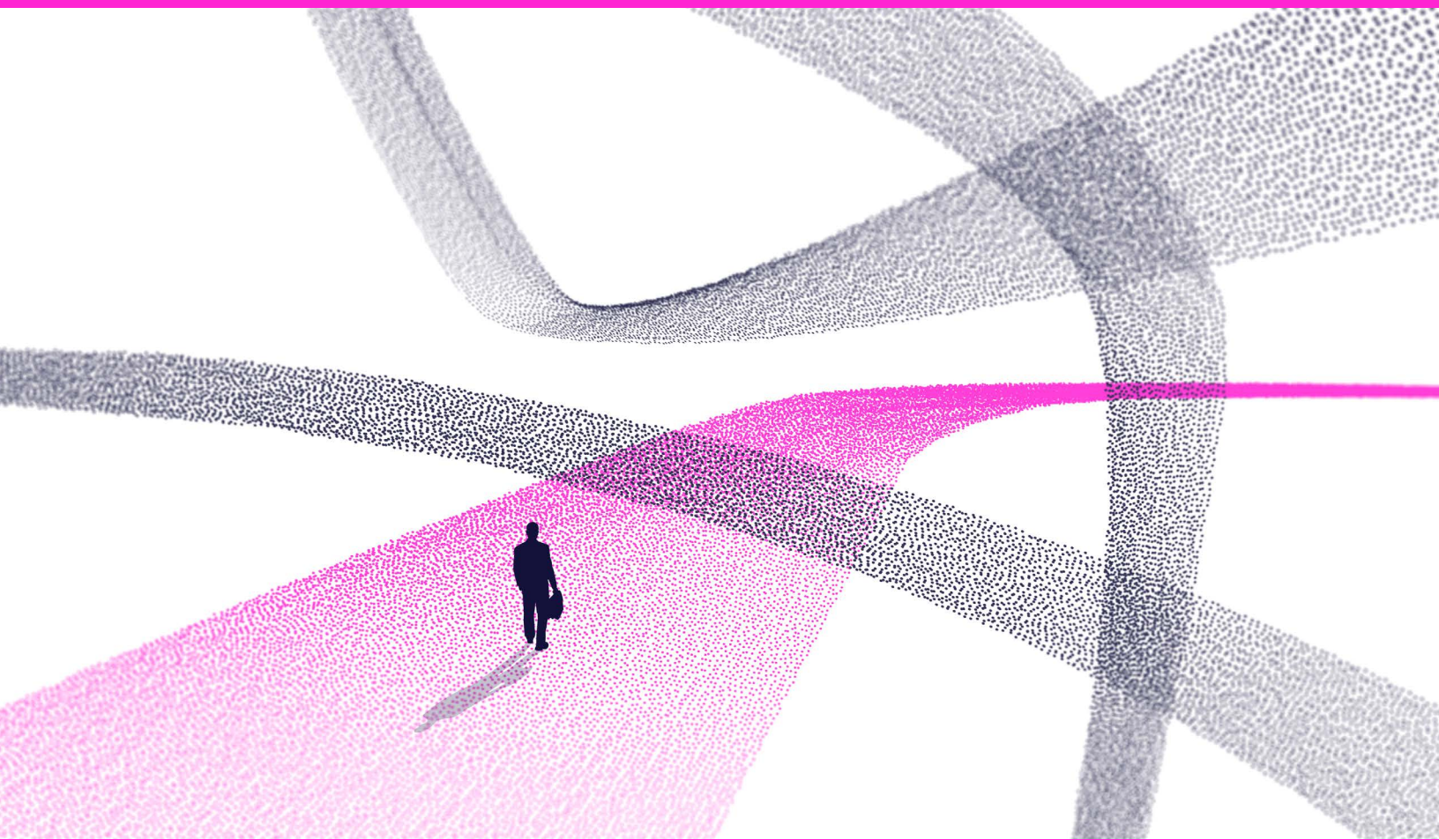
Use Case

Precision in Practice: Unlocking Efficiency with TrialScope Disclose: Core Data

January 2024



Situation

The pharmaceutical landscape is ever evolving, marked by stringent regulatory requirements and the increasing need for transparency.

In this challenging environment, a leading pharmaceutical company, navigating a complex portfolio of global clinical trials, encountered bottlenecks in its disclosure process. Data entry across multiple registries led to inefficiencies, inconsistencies, and increased scrutiny from regulatory authorities. The trial sponsor sought a solution to streamline its disclosure process while ensuring data accuracy and compliance.

Fragmented data entry processes across different platforms resulted in duplicated efforts, raised questions from stakeholders, and posed challenges in maintaining the harmonization of disclosed information. With the pressure to adhere to strict timelines, the company recognized the need for a comprehensive solution.

Against this backdrop, the pharmaceutical company sought an innovative approach, leading it to explore the capabilities of TrialScope Disclose: Core Data. The scenario demanded a solution to unify its disclosure processes, establish a single source of truth for data entry, and enhance the overall efficiency and quality of clinical trial disclosure.

Solution

1 Prepare study disclosure content

- Initiate the study disclosure process by accessing the centralized content repository
- Collect and compile relevant study information required for disclosure across multiple global registries (e.g., CTgov, jRCT, CTIS, EudraCT)
- Utilize the platform to view disclosure content specifically tailored for each global registry
- Navigate seamlessly among different registry views to ensure accurate representation and alignment with registry-specific formatting

2 Edit content for global registry requirements

- Manage and edit disclosure content directly within the centralized system
- Adhere to global registry requirements, making necessary adjustments to ensure compliance and accuracy

3 Review and comment on disclosure content

- Access a unified interface for reviewing and commenting on disclosure content
- Facilitate collaboration among stakeholders, enabling real-time feedback and efficient communication in one centralized location

4 Approve content selection

- Select the appropriate content for approval, considering global and local requirements
- Navigate through a user-friendly interface to streamline the selection process for the right internal approvers

5 Submit content to registries

- Create registry submissions directly from the centralized content repository
- Utilize the system to generate accurate and compliant submissions for each global registry, minimizing the risk of errors during the submission process

Added Value

Innovative and Unified Platform

TrialScope Disclose addressed the challenge of fragmented data entry by introducing Core Data — a centralized, user-friendly form tailored for simplified trial data input. This unified registry submission platform allowed the company to seamlessly enter all essential trial data using a comprehensive single form. The result was a streamlined process that eliminated navigation complexities and significantly reduced the risk of errors.

Validated single source of truth for data accuracy

Core Data served as a validated single source of truth for data collection and review. This not only ensured unwavering consistency across diverse global registries but also mitigated the risk of discrepancies. The result was enhanced confidence in the accuracy and completeness of the disclosed information.

Consistency and quality assurance across registries

The centralized approach of TrialScope Disclose: Core Data minimized inconsistencies in data entry, elevating the overall quality of disclosed information. The solution presented standardized datasets across diverse global registries, meeting and surpassing the stringent requirements of regulatory bodies. This ensured a coherent representation of the company's clinical trials, bolstering compliance and data accuracy.

Reduction in stakeholder queries with comprehensive data submission

TrialScope Disclose: Core Data's standardized and comprehensive data submission approach led to a notable reduction in queries from stakeholders. The clear and consistent representation of data streamlined communication channels, fostering a more efficient and harmonious disclosure process. Stakeholders experienced a reduction in uncertainties, strengthening relationships.

Efficient elimination of duplications enhances accuracy

Designed to efficiently eliminate duplications in data entry and review, TrialScope Disclose: Core Data resulted in a unified dataset across various registries, minimizing the risk of errors and ensuring an efficient, accurate disclosure process. This meticulous approach elevated the company's precision in data management, contributing to operational excellence in clinical trial disclosure.

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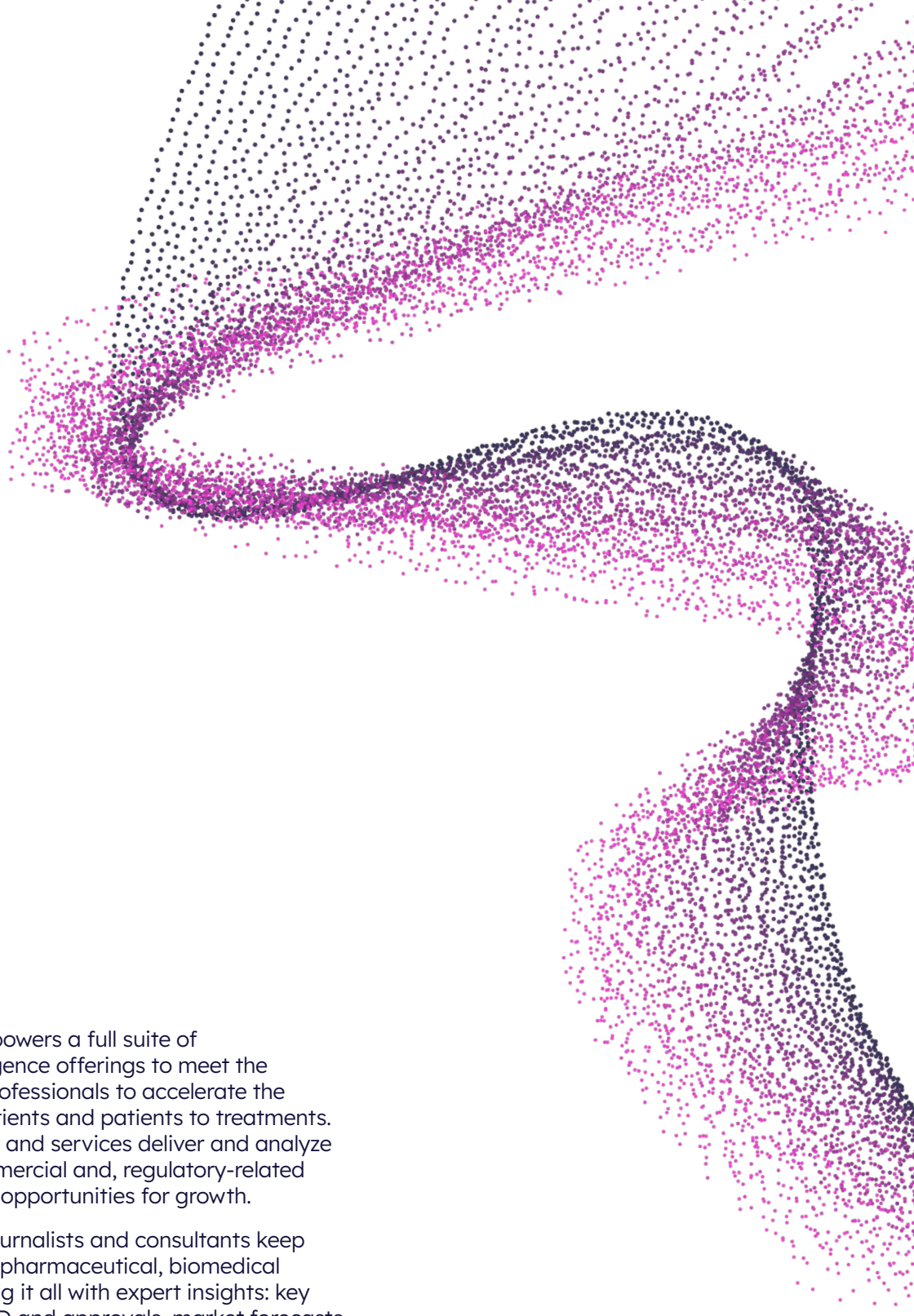

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