

Accelerating Clinical Data Flow from Protocol to Submission

Shafi Chowdhury and Subash Sadanandan

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Introduction : End-to-End Approach



Clinical trials have traditionally relied on manual processes, leading to inefficiencies and delays. Next-generation solutions powered by AI and automation transform this process, providing significant advantages

Traditional Approach

- Define key terms from protocol manually.
- Manually set up data management (DM) structure.
- Partial automation for Study Data Tabulation Model (SDTM).
- Develop Statistical Analysis Plan (SAP) manually.
- Define and program Analysis Data Model (ADaM) and Tables, Listings, and Figures (TLFs) manually.

New Approach (AI-Driven)

- AI reads protocols to:
 - Set up DM structures.
 - Develop partial SAP.
 - Generate table of contents (ToC) for TLFs.
- AI determines ADaM requirements and partially generates ADaM datasets and TLFs.
- The system automatically generates SDTM datasets.
- Manual effort limited to completing ADaM datasets and TLFs.





The Clinical Trial Landscape: A Sea of Challenges

- **Data Silos and Interoperability:** Fragmented data across systems slows access and integration, hindering collaboration.
- **Data Quality and Validation:** Errors from manual processing compromise data reliability, requiring costly corrections.
- **Statistical Analysis & Reporting Bottlenecks:** Slow data transformation and reporting delay critical milestones.
- **Regulatory Compliance & Audit Readiness:** Meeting evolving standards and maintaining documentation adds significant burden.
- **Resource Constraints and Budget Pressures:** Limited resources increase inefficiencies and operational costs.

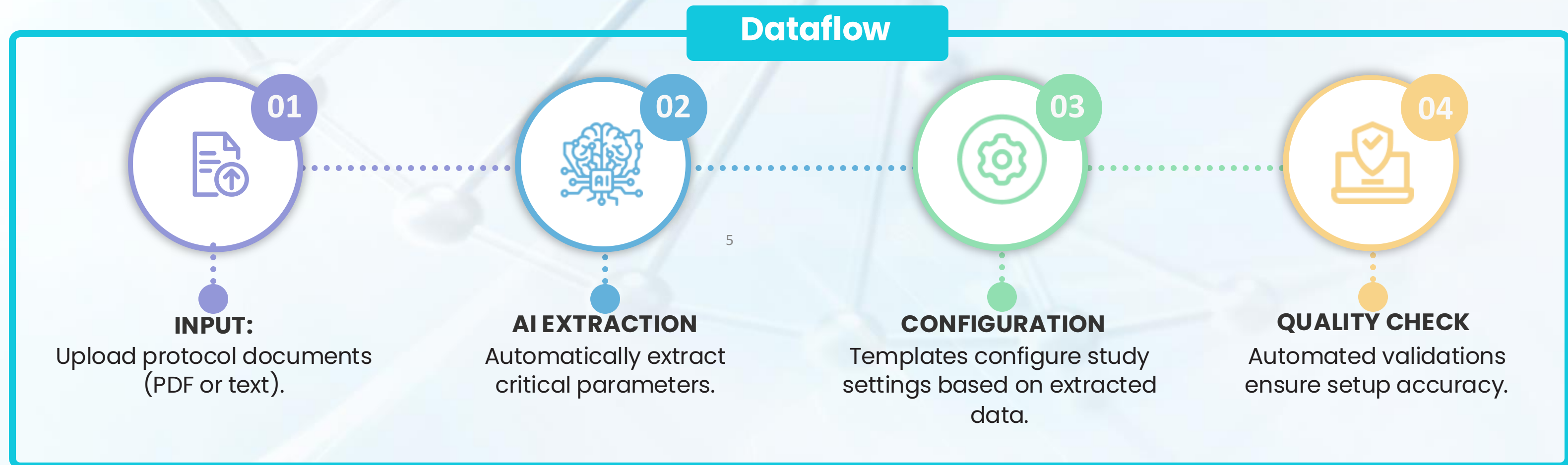
These challenges can lead to delays, increased costs, and potentially jeopardize your trial's success.



AI and Automation Tasks and Challenges

Protocol Data Extraction for Automated Study Onboarding

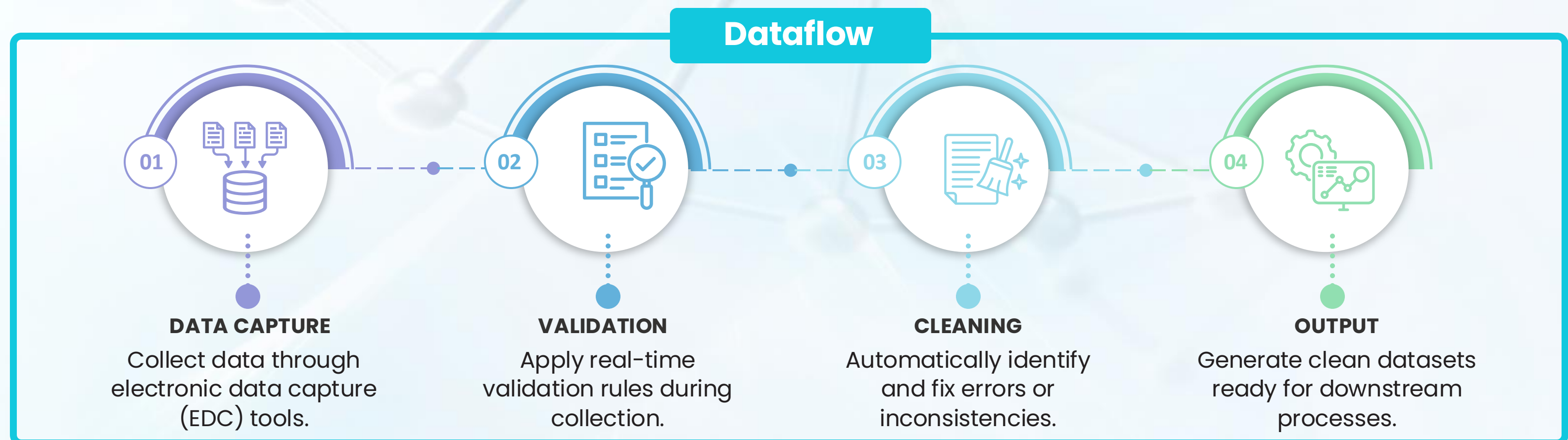
- AI driven data extraction – Inc./Excl. criteria, study schedules, etc.
- Template based setup – for consistency easy customisation



AI and Automation Tasks and Challenges

Real-Time Data Collection and Automated Cleaning

- **Challenges:**
 - Ensuring data quality and identifying inconsistencies require significant manual effort.
- **Automated Solution:**
 - Real-time validation during data entry minimizes errors.
 - Automated cleaning resolves inconsistencies and tracks data lineage for compliance.
- **Benefits:**
 - Generates clean, regulatory-ready datasets with minimal manual intervention.
 - Improves data accuracy and reduces turnaround time.



AI and Automation Tasks and Challenges

Automated Study Scheduling

Challenges:

Traditional scheduling is inflexible and resource-intensive.

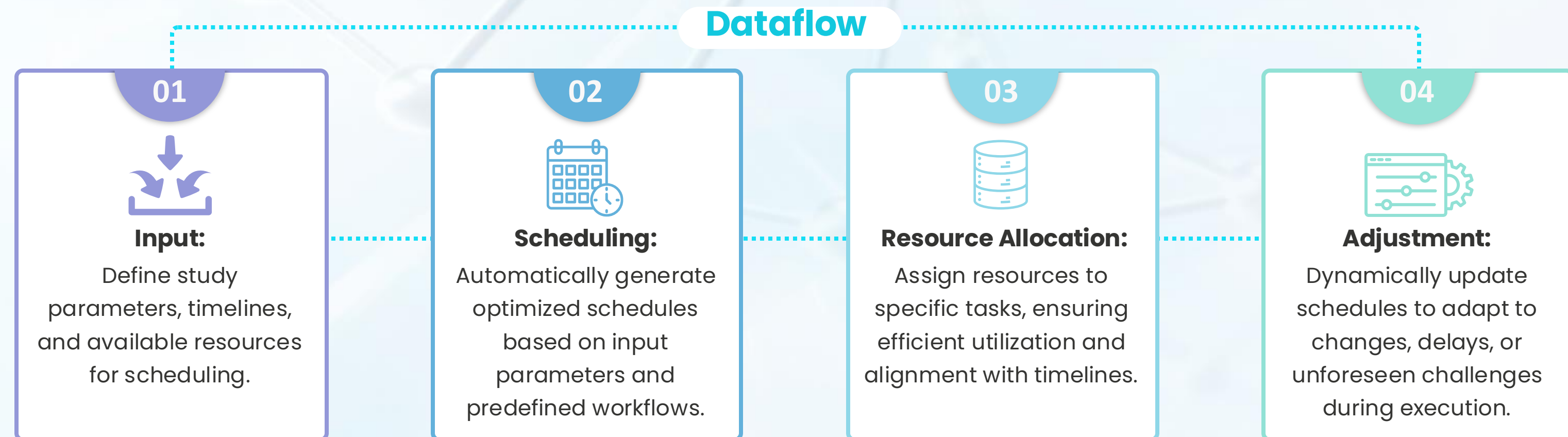
Automated Solution:

Generates timelines based on predefined parameters, reducing manual input.
Enables real-time updates to schedules without disrupting workflows.

Benefits:

Improves resource allocation.

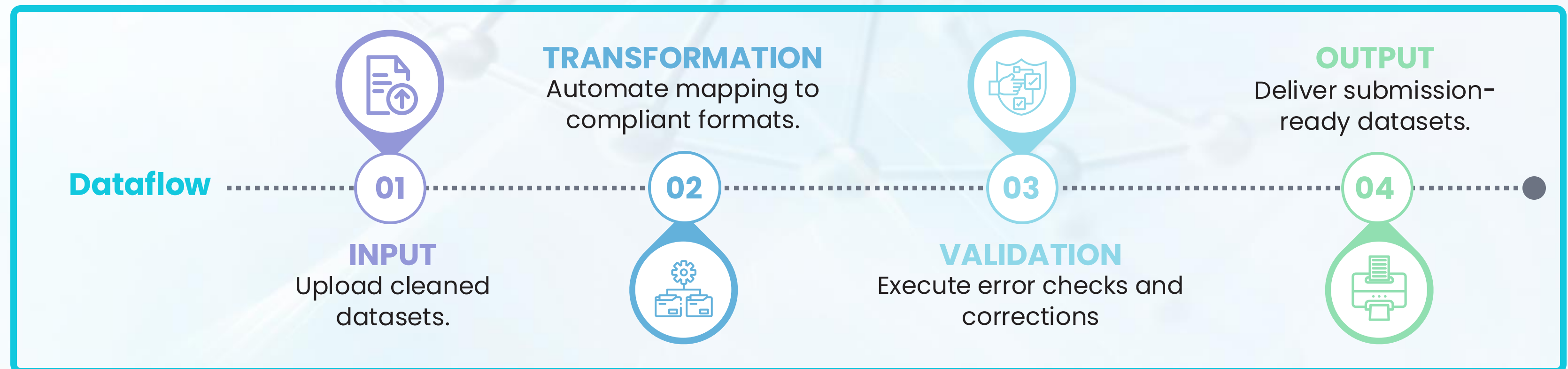
Minimizes delays and ensures timely completion of study milestones.



AI and Automation Tasks and Challenges

Standards-Compliant Data Transformation

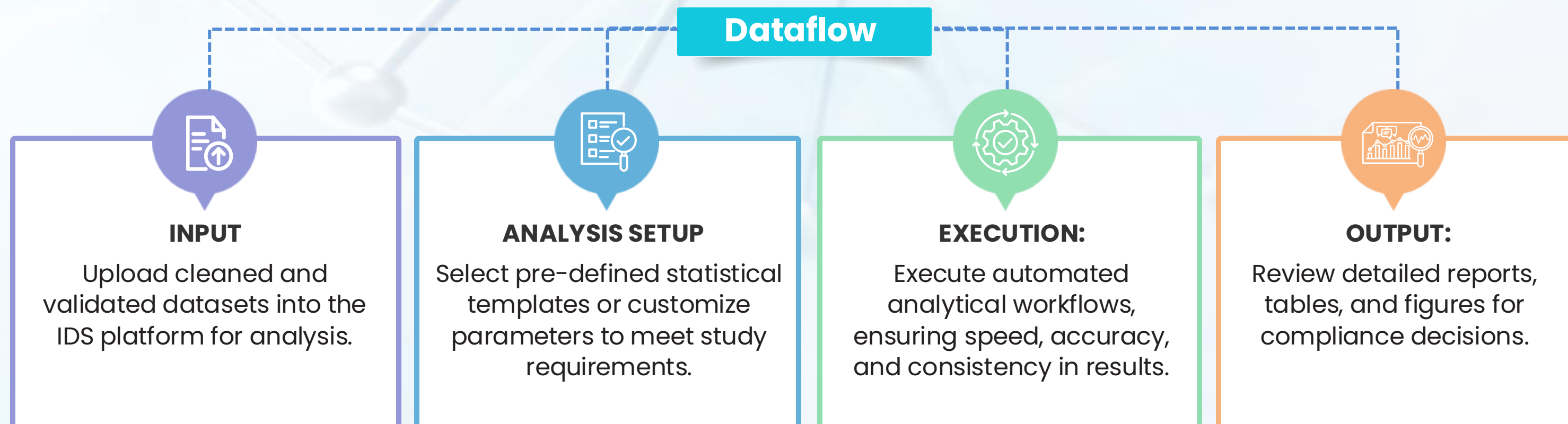
- **Challenges:**
 - Mapping data to CDISC standards (SDTM, ADaM) is resource-heavy and prone to errors.
- **Automated Solution:**
 - AI leverages pre-configured templates for mapping and transforming data.
 - Integrates HL7 FHIR for interoperability.
- **Benefits:**
 - Ensures compliance with regulatory standards.
 - Provides audit-ready datasets with validated data lineage.



AI and Automation Tasks and Challenges

Automated Statistical Analysis

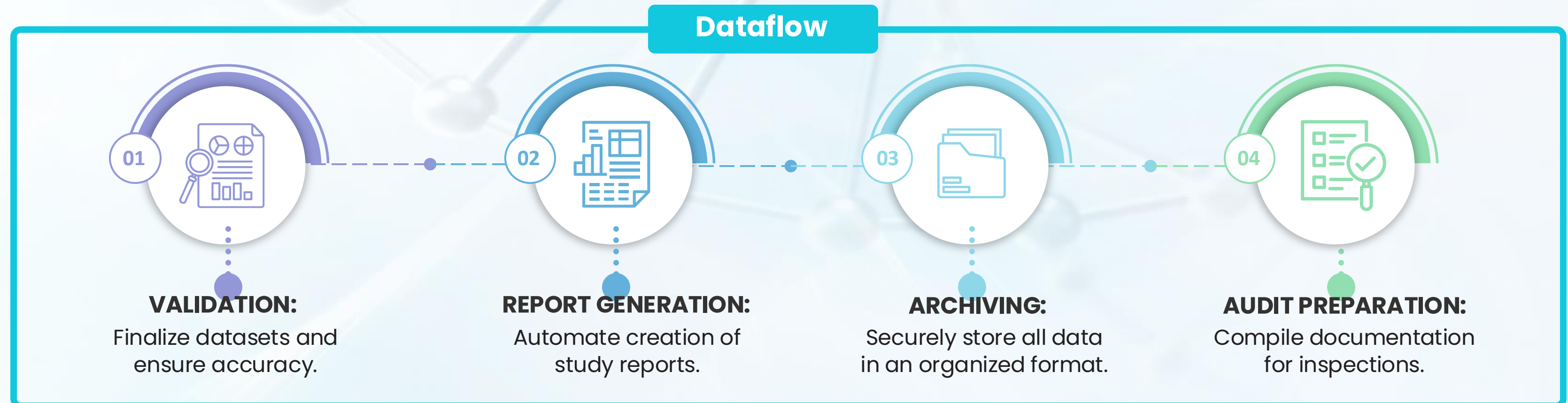
- **Challenges:**
 - Statistical analyses and reporting are time-consuming and error-prone.
- **AI-Powered Solution:**
 - Predefined templates for regression, survival analysis, and ANOVA.
 - Seamless integration with tools like R and SAS.
- **Benefits:**
 - Generates tables, listings, and figures (TLFs) automatically for regulatory submissions.
 - Enhances accuracy while saving time.



AI and Automation Tasks and Challenges

Streamlined Study Closeout Processes

- **Challenges:**
 - Finalizing studies is often delayed due to fragmented workflows and lack of integration.
- **Automated Solution:**
 - Automatically compiles final study reports.
 - Archives data securely for regulatory compliance and audit readiness.
- **Benefits:**
 - Ensures smooth study completion.
 - Reduces audit preparation time and costs.



End-to-End Automation Workflow

Study Onboarding:
AI-driven protocol extraction, template-based setup.



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Real-time Data Collection & Cleaning:
Automated validation, data cleansing, and lineage tracking, adhering to HL7 FHIR standards for interoperability.

Data Transformation:
Effortless conversion to CDISC SDTM/ADaM.

03



04



Study Scheduling:
Optimized timelines, dynamic rescheduling, and resource allocation.

Statistical Analysis:
Pre-built templates, integration with R/SAS, and automated report generation.

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Seamless Study Closeout:
Automated archiving, report compilation, and audit-ready documentation.





Expected Benefits

Benefits of Automation in Clinical Trials



✓ Time Savings:

- Accelerates study onboarding and setup.
- Speeds up CDISC-compliant dataset generation.
- Enhances the production of SAPs and TLFs.

✓ Improved Accuracy:

- Reduces errors with automated error detection and consistency checks.
- Reusable templates ensure quality and consistency across projects.

✓ Cost Efficiency:

- Streamlines workflows, reducing the need for large teams and manual tasks.
- Cuts operational expenses through automation.



Conclusion

- Automation is no longer a future aspiration; it's the present reality driving success in clinical trials.
- By adopting AI-driven solutions, organizations can overcome inefficiencies and deliver life-changing therapies faster.
- Embrace automation to unlock the full potential of your clinical trial processes.



Thank you

Shafi Chowdhury

shafi@shaficonsultancy.com

Subash Sadanandan

subashs@data-matica.com

