



Accelerating TFL- and Standard-Compliant Data Generation Through Automation with AI-Enabled Algorithms

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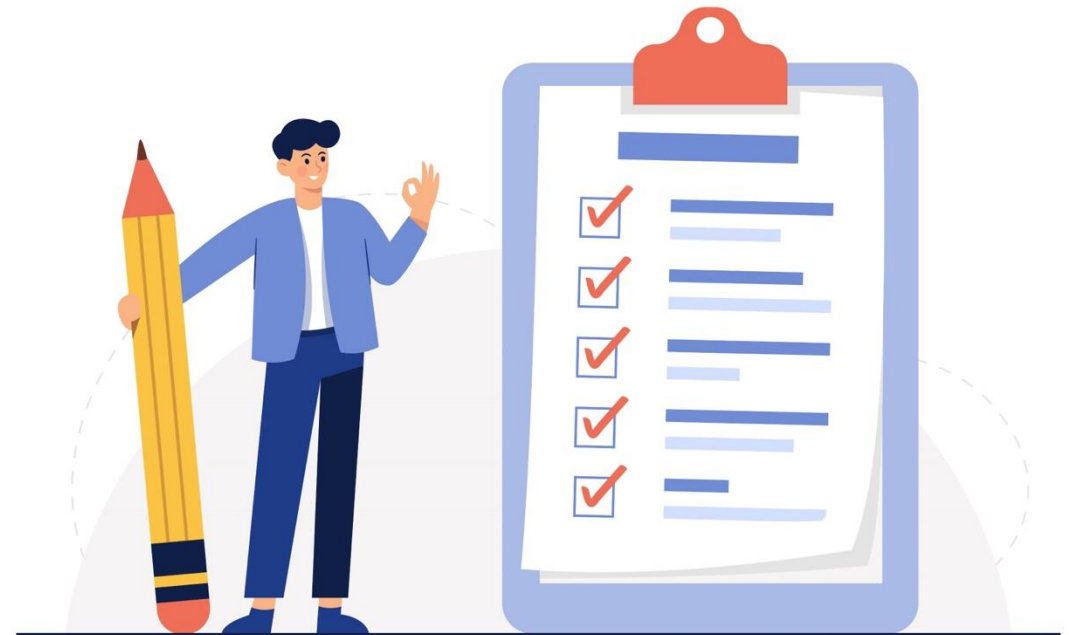
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Agenda

- **Current Approach and Challenges**
- **Advantages of Open-Source Technology**
- **Automation**
 - Mapping
 - Re-usability of Mappings
 - Mockshell Creation
 - TLF Generation
 - Manual Approach Vs Automation
 - Auto-Code Generation
 - Predefined and User Specific Transformations
- **AI Algorithms**
 - Why
 - Benefits
- **Multiple Refreshes**
- **Impact Analysis**
- **Quality, Time and Cost**



Current Approach and Challenges

Manual Approach



Time-Intensive

Frequent Updates

Inconsistence

Tedious

Error-Prone

Limited Scalability

High Skilled Resources

Advantages of Automation and Open-Source Technology



CUSTOMIZATION



SCALABILITY



INTEROPERABILITY

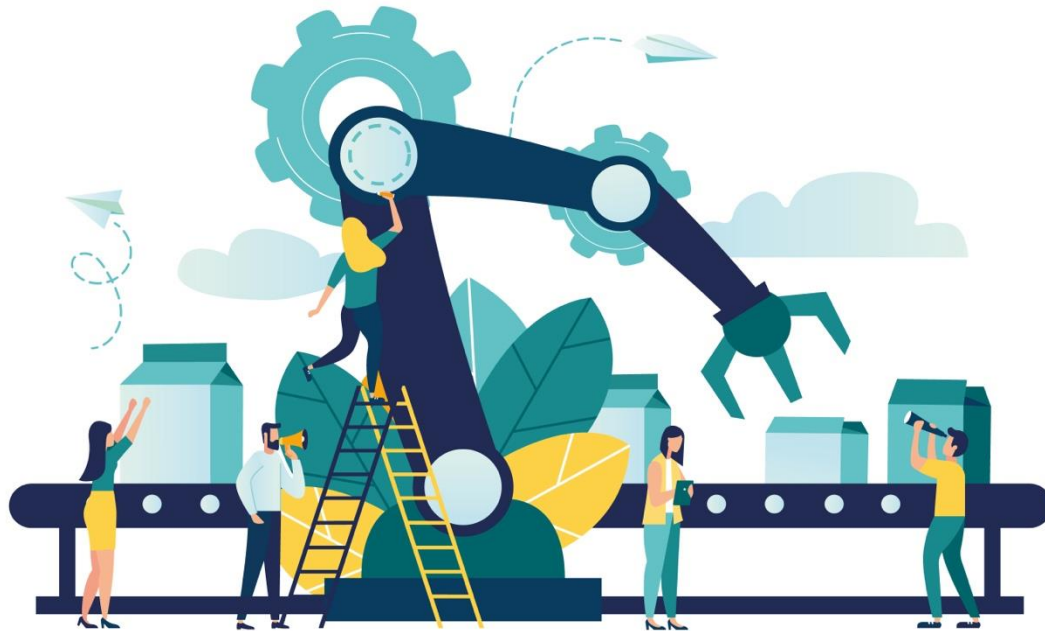


COST



TRANSPARENCY

Automation



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Efficiency

Accuracy

Consistency

Compliance

Cost-Effective

Flexibility

Scalability

Automation: Mapping

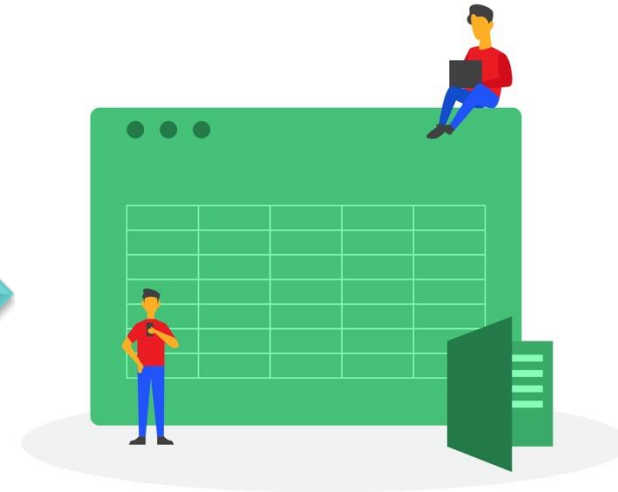
DATA SOURCE



MAPPING SCENARIOS

- Copy/Rename
- Concatenate/Split
- Transformation
- Attribute or Format Change
- Code List/Controlled Terminology
- Derivation

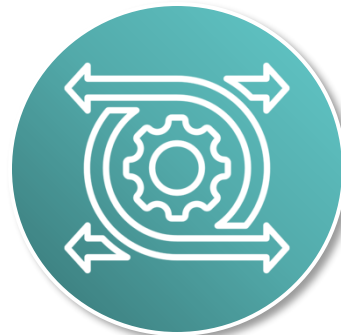
MAPPING SPECIFICATION



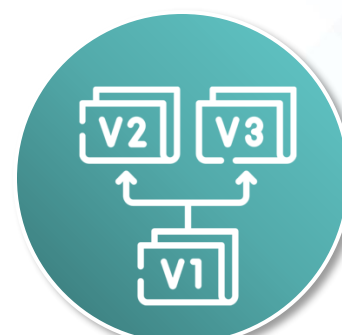
Automation: Re-usability of Mappings



STANDARDIZATION



FLEXIBILITY



VERSIONING



CONSISTENCY



VALIDATION

Automation: Mockshell Creation

Overall Design:

Disclosure Statement: This is a double-blind, parallel group intervention study.

Intervention Model: Parallel group

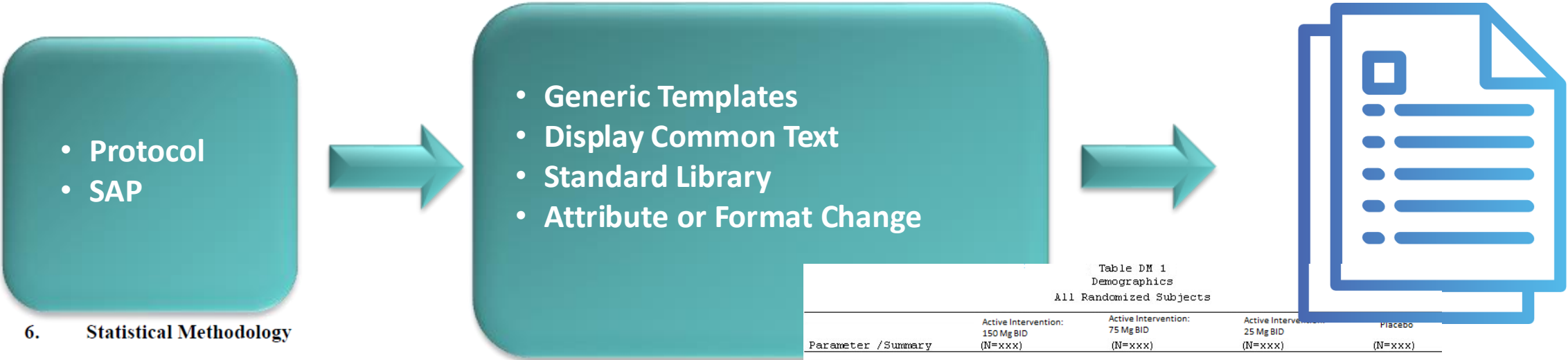
Primary Purpose: Treatment

Number of Arms: 4 arms including

- Active intervention: 150 mg BID
- Active intervention: 75 mg BID
- Active intervention: 25 mg BID
- Placebo

MOCKSHELL DESIGN

MOCKSHELLS



6. Statistical Methodology

6.1 Population characteristics

6.1.1 Demographics and Baseline Characteristics

The following demographic data and baseline characteristics will be summarized:

- Age at baseline (years);
- Age category (<60 vs ≥60 years; <65 vs ≥65 years);
- Sex (male vs. female)
- Race and ethnicity;
- Height (cm);
- Weight (kg) at baseline;

Table DM 1 Demographics All Randomized Subjects				
Parameter / Summary	Active Intervention: 150 Mg BID (N=xxx)	Active Intervention: 75 Mg BID (N=xxx)	Active Intervention: 25 Mg BID (N=xxx)	Placebo (N=xxx)
Age (year)				
n	xxx	xxx	xxx	xxx
mean (SD)	xx (x)	xx (x)	xx (x)	xx (x)
median	xxx	xxx	xxx	xxx
range	(xxx, xx)	(xxx, xx)	(xxx, xx)	(xxx, xx)
Sex				
Male	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Female	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Race				
Caucasian	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Black	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Hispanic	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Asian	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Other	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Height (cm)				
n	xxx	xxx	xxx	xxx
mean (SD)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
median	xxx	xxx	xxx	xxx
range	(xxx, xxx)	(xxx, xxx)	(xxx, xxx)	(xxx, xxx)

Automation: TLF Generation

SOURCE



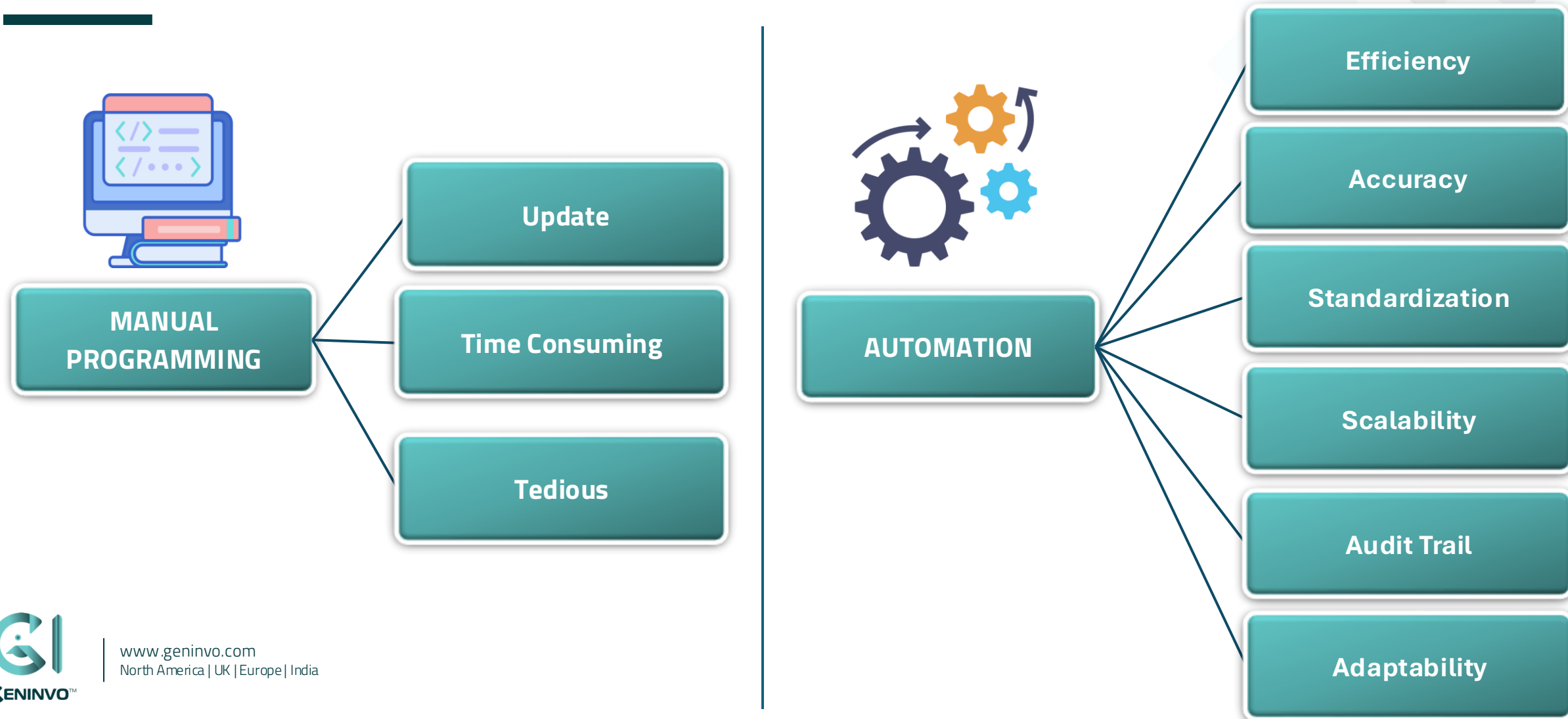
TLF SETUP

- General Settings
- Analysis Populations
- List of Planned Outputs
- Output Selection
- Auto populate the required variables/values from ADAM based on Mockshell
- Customization option
- Code Repository

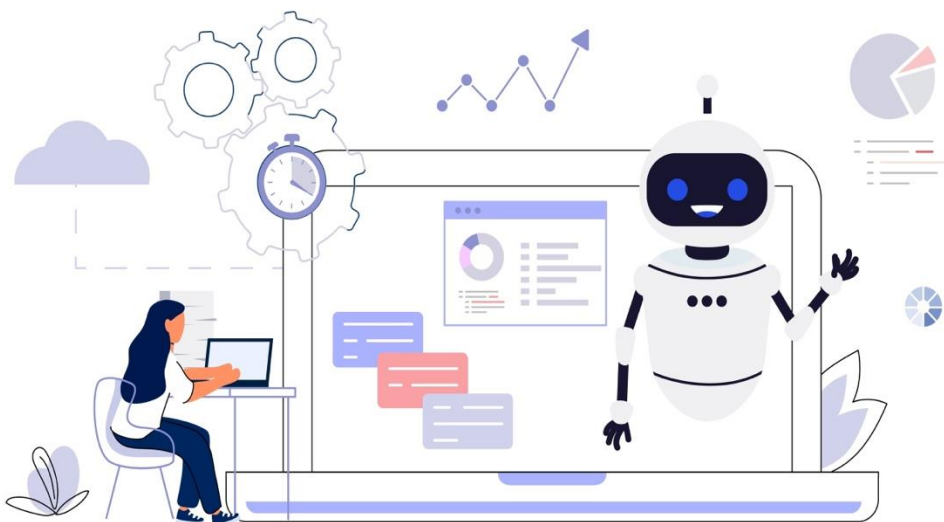
TLF OUTPUT



Manual Approach Vs Automation



Automation: Auto-Code Generation



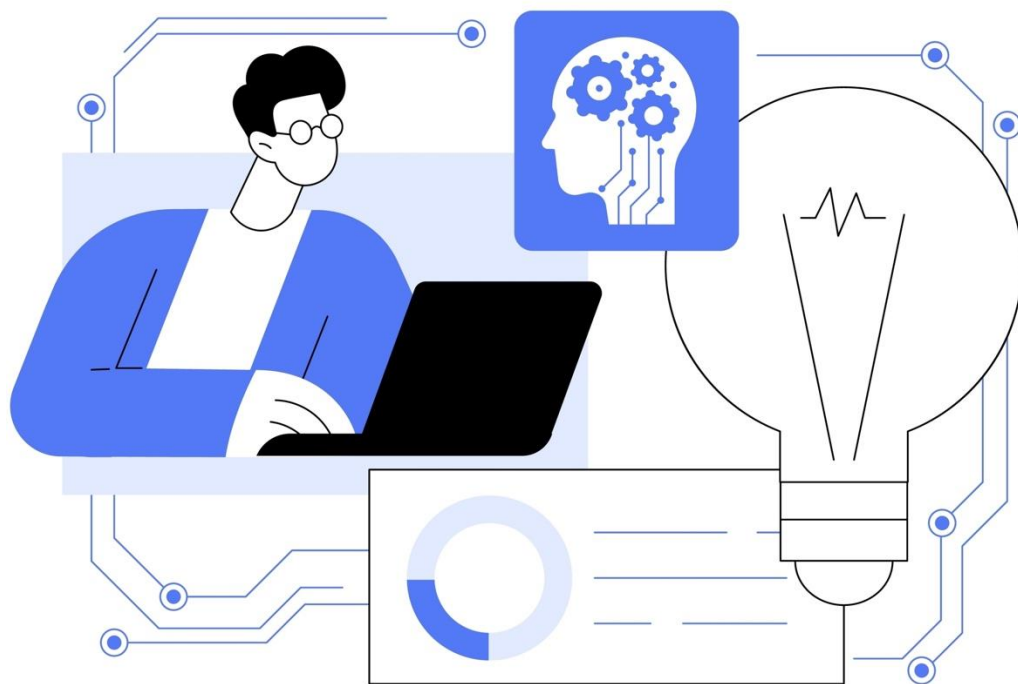
- It is very important in clinical trials to re-produce the reports such tables, listings and figures (TLFs) as and when required.
- Automation allows us to generate and store not only the reports but codes as well.
- We can automate code generation in R to streamline the workflows and reduce manual effort.
- Imagine you are performing the activities by clicking the buttons and codes are being generated along with the desired reports.

Automation: Predefined and User Specific Transformations



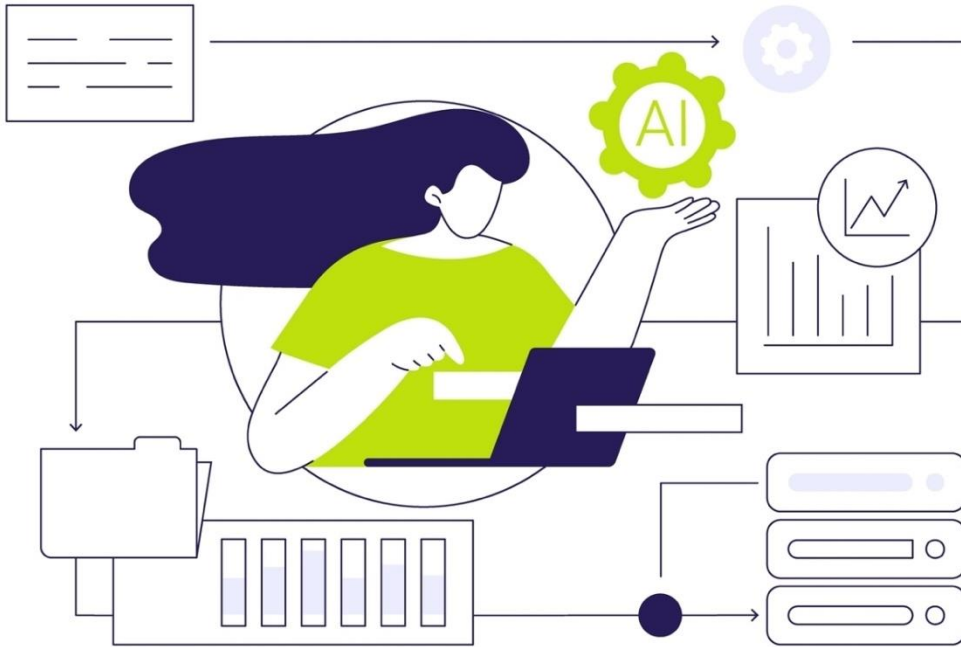
- R functions benefit from the vast ecosystem of R packages, which provide additional functionality for data manipulation, statistical analysis, visualization, etc
- R functions can interact with data stored in various formats (e.g., data frames, matrices, lists) and can easily integrate with external data sources using R packages
- User can use built-in function for certain tasks and to transform the data or for term standardization user can define their own function to perform specific transformations.

AI Algorithms: Why



- We know data transformation and mapping process requires many manual efforts such understanding raw data, creating mapping specification, writing macros/programs, checking on the status.
- Integrating AI into standard and analysis datasets generation processes offers numerous benefits, including improved efficiency, data quality, scalability, and decision support, ultimately accelerating the drug development lifecycle and improving patient outcomes.

AI Algorithms: Benefits



Speed & Efficiency

Skills & Resources Reduction

Accuracy & Consistency

Data Quality Improvement

Flexibility & Adaptability

Risk Reduction

Insights & Decision Support

Scalability

Multiple Refreshes



Validation & Compliance

Version Control

Data Mapping & Transformation

Quality Assurance

Monitoring

Establish DM Procedures



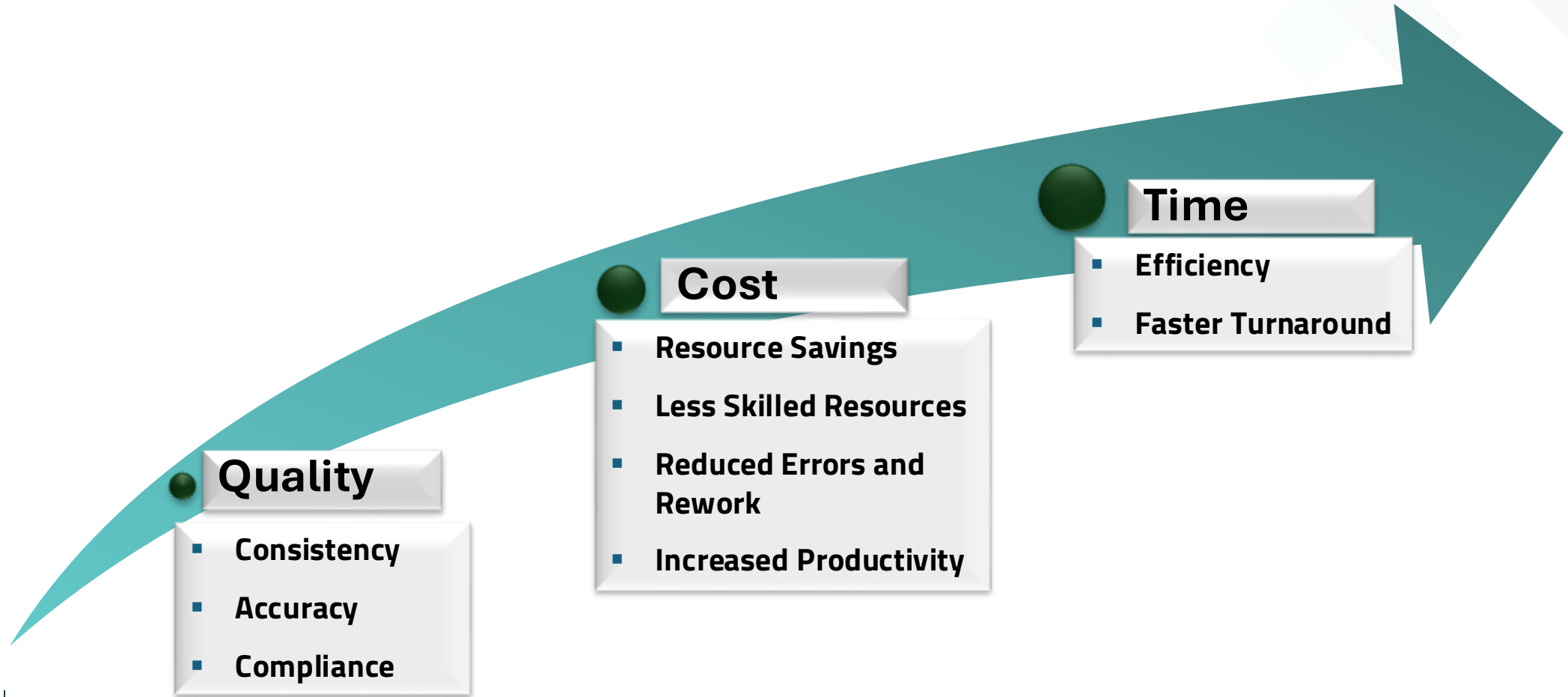
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Impact Analysis

- Identify Data Changes
- Assess Mapping Impact
- Review Mapping Specifications
- Evaluate Datasets
- Consider Downstream Processes
- Update Documentation
- Communicate Findings
- Implement Changes
- Validate Changes



Quality, Cost, and Time





Ideas
Delivered
Intuitively

Thank You!

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