



• Metadata Assisted Programming Services (MAPS)

*Navigate the world of metadata
and streamline clinical
programming using AI*

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Sanofi "All in AI"

"Our ambition is to become the first pharma company powered by artificial intelligence at scale, giving our people tools and technologies that focus on insights and allow them to make better everyday decisions. The use of artificial intelligence and data science already support our teams' efforts in areas such as accelerating drug discovery, enhanced clinical trial design, and improving manufacturing and supply of medicines and vaccines. We have just scratched the surface as to how we embrace these disruptive technologies to achieve our ambition of transforming the practice of medicine", Paul Hudson, CEO of Sanofi.

AI in Manufacturing and Supply: Sanofi has digitized its quality assessment processes and implemented AI-enabled yield optimization solutions that help optimize the usage of raw materials and support cost efficiency. Adopting plai has enabled the prediction of 80% of low inventory positions.

AI in mRNA Research: Sanofi uses AI to select lipid nanoparticles essential for the delivery of mRNA vaccines, reducing the time required for this process from months to days.

plai, a company-wide AI-powered "everything app": plai collects internal company data across various functions to deliver real-time data interactions, insights, and enable scenario planning for decision-makers in the company.

AI in Clinical Operations: Digital tools and insights from plai are used to improve the design and execution of clinical trials, including the selection of trial sites that can increase the representation of underrepresented communities in clinical research.

AI in Drug Discovery and Clinical Research: AI and data science are being used to accelerate drug discovery, enhance clinical trial design, and improve the manufacturing and supply of medicines and vaccines. Sanofi has multiple AI programs in clinical research to cut the time, improve outcomes, and automate time-consuming activities. AI has also improved potential target identification in therapeutic areas like immunology, oncology, or neurology by 20% to 30%.

Sanofi's approach to AI

Improving the outcomes
and experiences of our
patients, employees, and
align to Sanofi's core
values

Responsible AI governance within a five-pillar framework



Automate

Repetitive
Tedious
Error-prone



Improve

Efficiency
Productivity



Insights

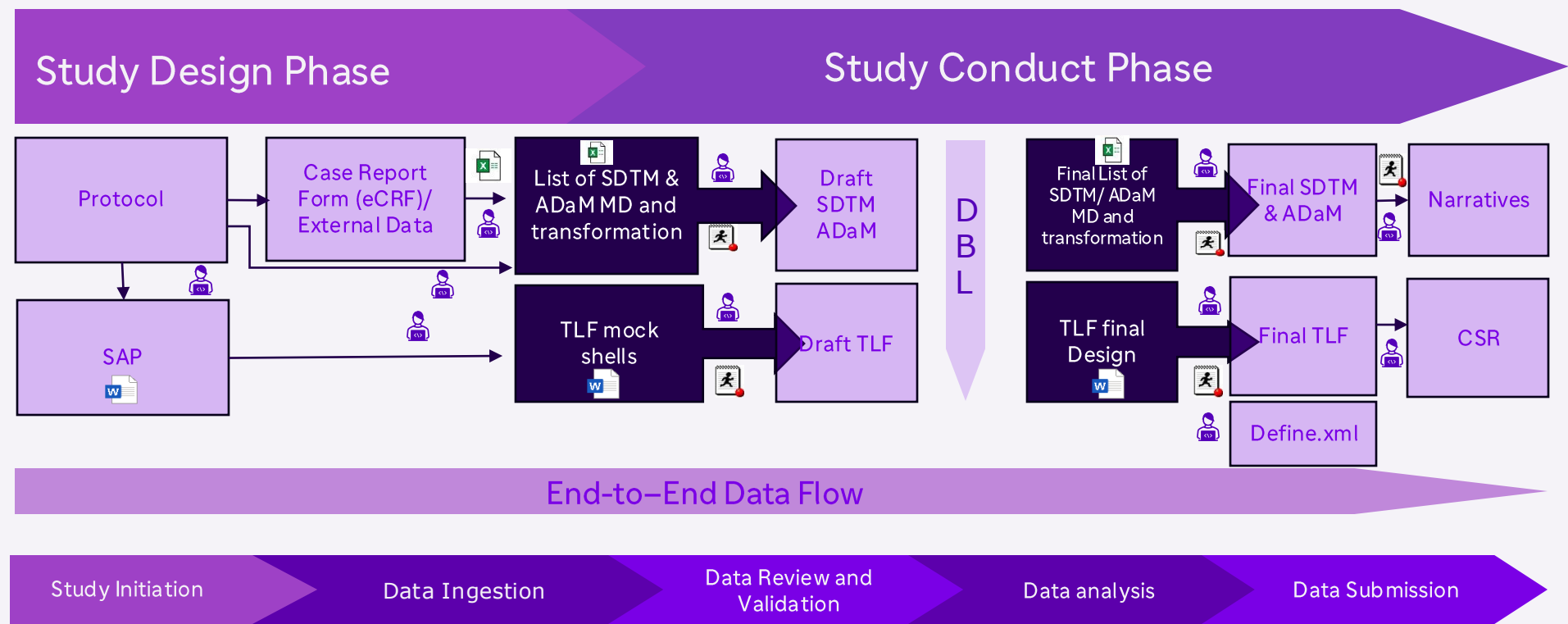
Data
Simulations
Complex
problems
Risks



Generate

Solutions
New Ideas
Decisions
Predictions

Opportunities to accelerate from data acquisition to submission through automation, GenAI and ML, enhancing efficiency, productivity and decision making



MAPS

Metadata Assisted Programming Services

MAPS: Metadata Assisted Programming Services

Navigate the world of metadata and streamline clinical programming

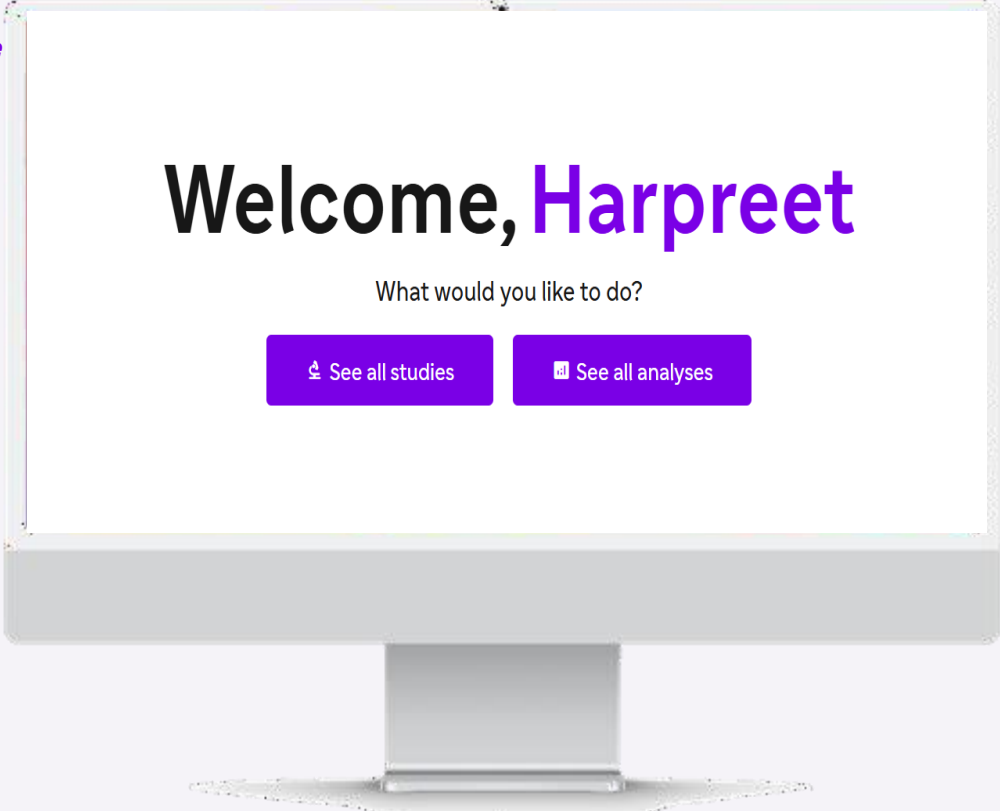
Vision

Enable clinical programming teams to focus on **high-value tasks**.

Mission

Eliminate **manual, error-prone tasks**, ensuring regulatory compliance, fostering **collaboration** across studies and teams, and driving **metadata-driven** preparation for all studies, all domain.

In addition, semi-automated mapping and assisted **code generation** of draft R programs for SDTM, ADaM, and TLF deliverable will support non-efficacy data preparation.

A computer monitor with a silver frame and stand. The screen is white and displays a welcome message. The text 'Welcome, Harpreet' is centered, with 'Harpreet' in purple. Below it, the text 'What would you like to do?' is centered. There are two purple buttons with white text: 'See all studies' with a magnifying glass icon and 'See all analyses' with a document icon.

Welcome, Harpreet

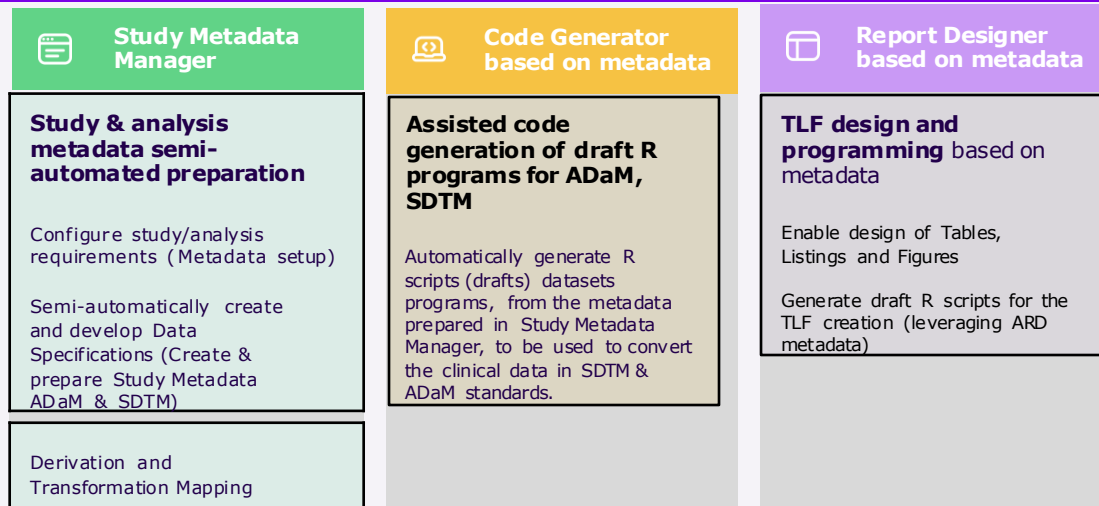
What would you like to do?

 See all studies

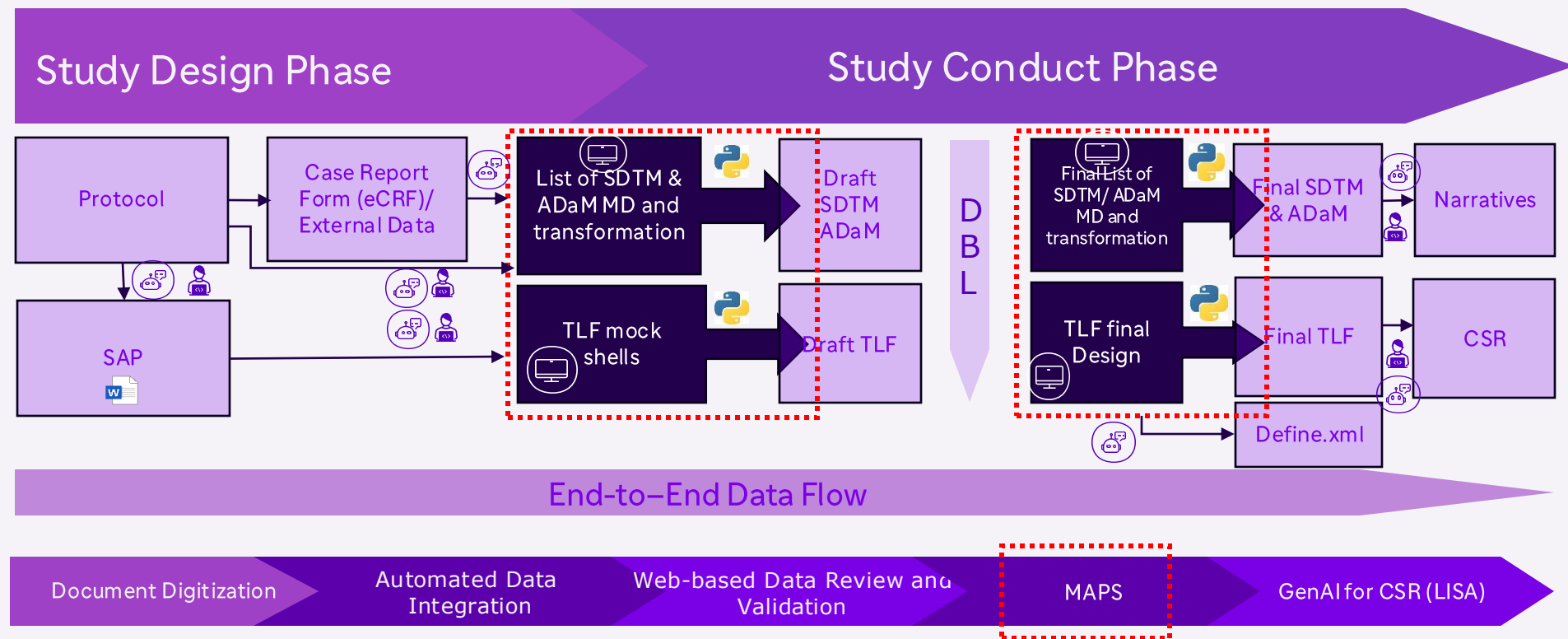
 See all analyses

Components of MAPS

MAPS offers a **unique opportunity to transform clinical statistical programming & gain efficiency** by simplifying and automating existing manual process



MAPS in Digital and Automation Workflow



Metadata Assisted Programming Services (MAPS) in Sanofi clinical ecosystem

1 Inputs from digital sources

Input 1

Study Protocol

- Reuse information for the study setup
- Connection with Digitized protocol*

Input 2

Study aCRF, CRF guidelines, SDS, FTS

- For SDTM preparation reference
- Connection with RAVE and centralized MD repository*

Input 3

Statistical Analysis Plan

- Reuse information for the study setup
- Connection with Digitized SAP*

Input 4

Sanofi Standard MD for clin. Data References

- Global Standard Metadata
- Including Standard Derivation Functions
- SDTM pseudo code (non efficacy only)
- ADaM pseudo code (non efficacy as a start)
- ARD/TLF

Connection with centralized MD repository

2

Prepare SDTM & ADaM Metadata, mapping & transformation

MAPS



Study and analysis Metadata preparation



Code Generator based on metadata



TLF design and programming based on TLF metadata

Input 5

Study "sister"

- Re-use from previous SDTM and ADaM MD that are already stored in MAPS

3

Generate data

eWISE

- Receive Metadata in the appropriate format
- Receive draft and adjust programs
- Run programs to generate SDTM, ADaM, TLF

4

Prepare Clinical Reports

LISA + GenAI CSR

- Author Prot., SAP, Narratives, CSR..
- ...

Non-Rule-based Code Generator: Generative AI assisted code generation

Code Generator

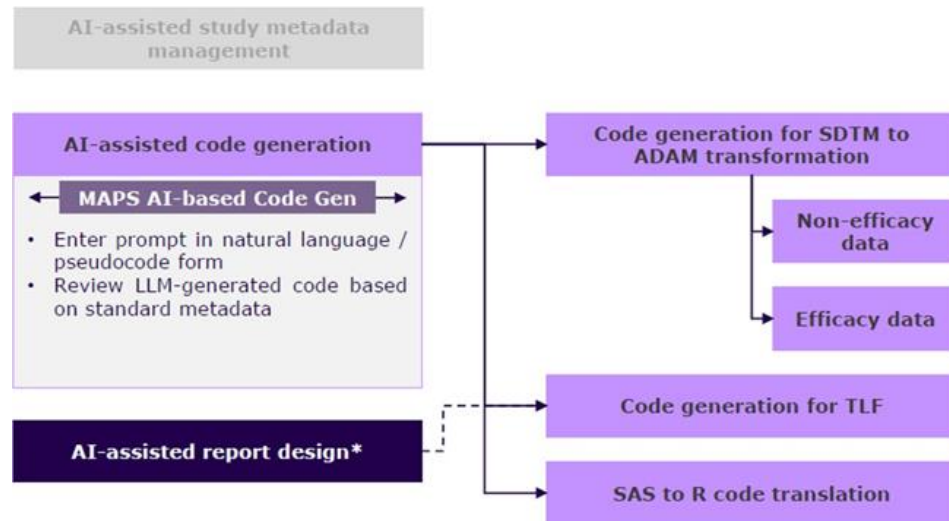
Move from template-based to **semi-automated clinical statistical programming**



GenAI can be applied for enhancing Code Generator scope

Report Designer

Integrate **TLF design and programming** with metadata



*Tables, listings, & figures can be generated with LLMs

Benefits of MAPS

WITHOUT MAPS

- **Manual / repetitive** work
- Difficulties for **collaboration**
- **Time consuming** steps (e.g. Silos in information flow)
- **Risk on quality**
- **Time-consuming, error-prone** work
- Clinical metadata **references** not integrated

WITH MAPS

- **Centralized, user-friendly** user interface
 - Easy, **semi-automated** metadata selection & **Adaptation**
 - **Gain efficiency** working with Web Interface & Database instead of Excel.
 - Crosschecks and warnings.
 - **Benefit** from **historical/ongoing** studies
 - **Ease navigation** in Global/Study Metadata
 - **Leverage use of SDTM & ADaM Standards**
 - More transparency
 - **Semi-automated** metadata mapping /- assisted programming
 - *Audit trails*

Thank
you

sanofi

