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Transforming regulatory activities with AI

8 May 2025

Yves Jacob

Head Regulatory Europe

"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."

Paul Hudson
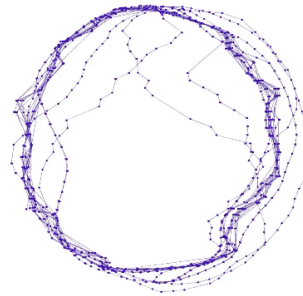**CEO Sanofi**
(June 2023)

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Becoming the first biopharma company *powered by AI at-scale*

Ai

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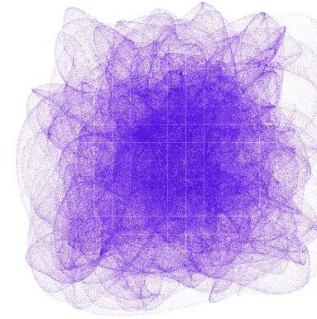To achieve our ambition, *we're building on 3 pillars:*

1 *Expert AI*

Competitive Edge

Apply massive computing power, machine learning and trained algorithms to optimize drug development and complex manufacturing processes.
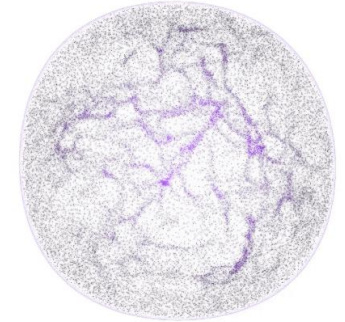
2 *Snackable AI*

Plai

Easy-to-use and interpret AI for daily workflow to make better decisions and allocate resources more efficiently.
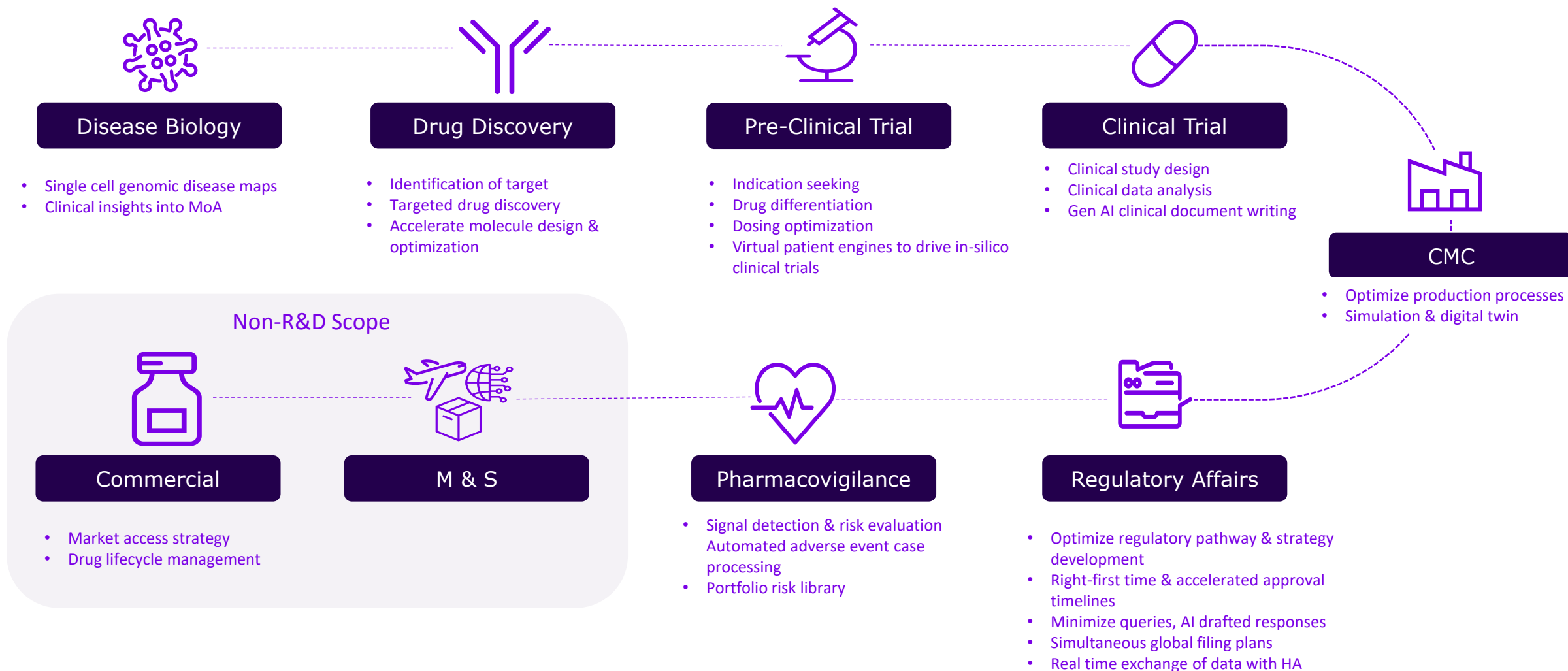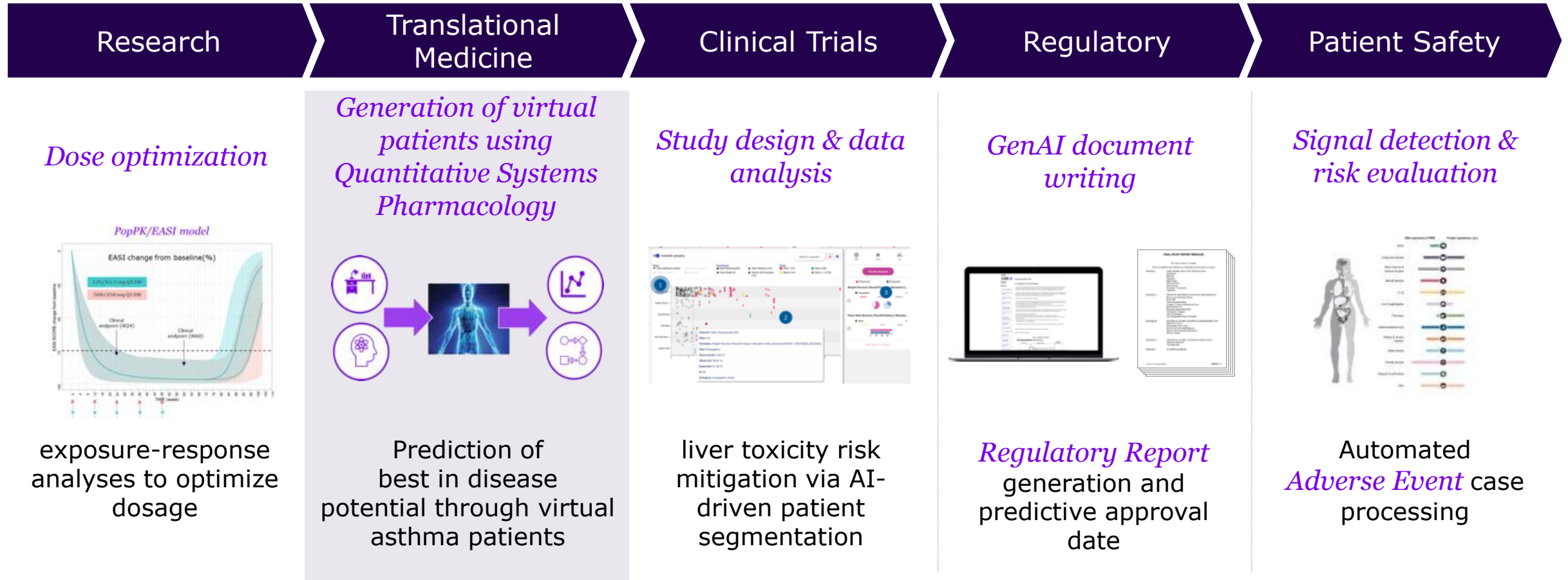
3 *Generative AI*

Company-Wide

A subset of AI that specializes in learning patterns from existing data to generate entirely new content to improve productivity.

AI-Powered R&D Organization Across The Value Chain

Disease Biology
- Single cell genomic disease maps
- Clinical insights into MoA

Drug Discovery
- Identification of target
- Targeted drug discovery
- Accelerate molecule design & optimization

Pre-Clinical Trial
- Indication seeking
- Drug differentiation
- Dosing optimization
- Virtual patient engines to drive in-silico clinical trials

Clinical Trial
- Clinical study design
- Clinical data analysis
- Gen AI clinical document writing

CMC
- Optimize production processes
- Simulation & digital twin

Non-R&D Scope

Commercial
- Market access strategy
- Drug lifecycle management

M & S

Pharmacovigilance
- Signal detection & risk evaluation
- Automated adverse event case processing
- Portfolio risk library

Regulatory Affairs
- Optimize regulatory pathway & strategy development
- Right-first time & accelerated approval timelines
- Minimize queries, AI drafted responses
- Simultaneous global filing plans
- Real time exchange of data with HA

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IQVIA · Clarivate · veeva · Power BI · plai. · iPORT · Accumulus synergy

Leading digital/AI capabilities to *enhance* R&D productivity

Research	Translational Medicine	Clinical Trials	Regulatory	Patient Safety

Research

Dose optimization

PopPK/EASI model

EASI change from baseline(%)

exposure-response analyses to optimize dosage

Translational Medicine

Generation of virtual patients using Quantitative Systems Pharmacology

Prediction of best in disease potential through virtual asthma patients

Clinical Trials

Study design & data analysis

liver toxicity risk mitigation via AI-driven patient segmentation

Regulatory

GenAI document writing

Regulatory Report generation and predictive approval date

Patient Safety

Signal detection & risk evaluation

Automated *Adverse Event* case processing

CTD content generation | *Interest for Regulatory affairs*

Use Case Clinical Study Reports

70%

Final version of content generated in **10 minutes or less**

35-65%

Writing **time efficiencies** on tested document sections

- Enhance *Efficiency*
- *Accelerate* draft document creation
- *Improve* consistency
- *Inform* decision making
- *Automate* Repetitive Tasks

Example: CSR authoring

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AI to *facilitate Common Technical Documents* generation starting with Health Authority Questions

- ✓ *Leverage a 100K+ HAQ database* to capitalize on previous similar queries

- ✓ *Facilitate analysis* of large datasets providing valuable insights that can *inform decision-making* processes

- ✓ *Simplify* authoring process

- ✓ *Assist* document drafting with full Human oversight
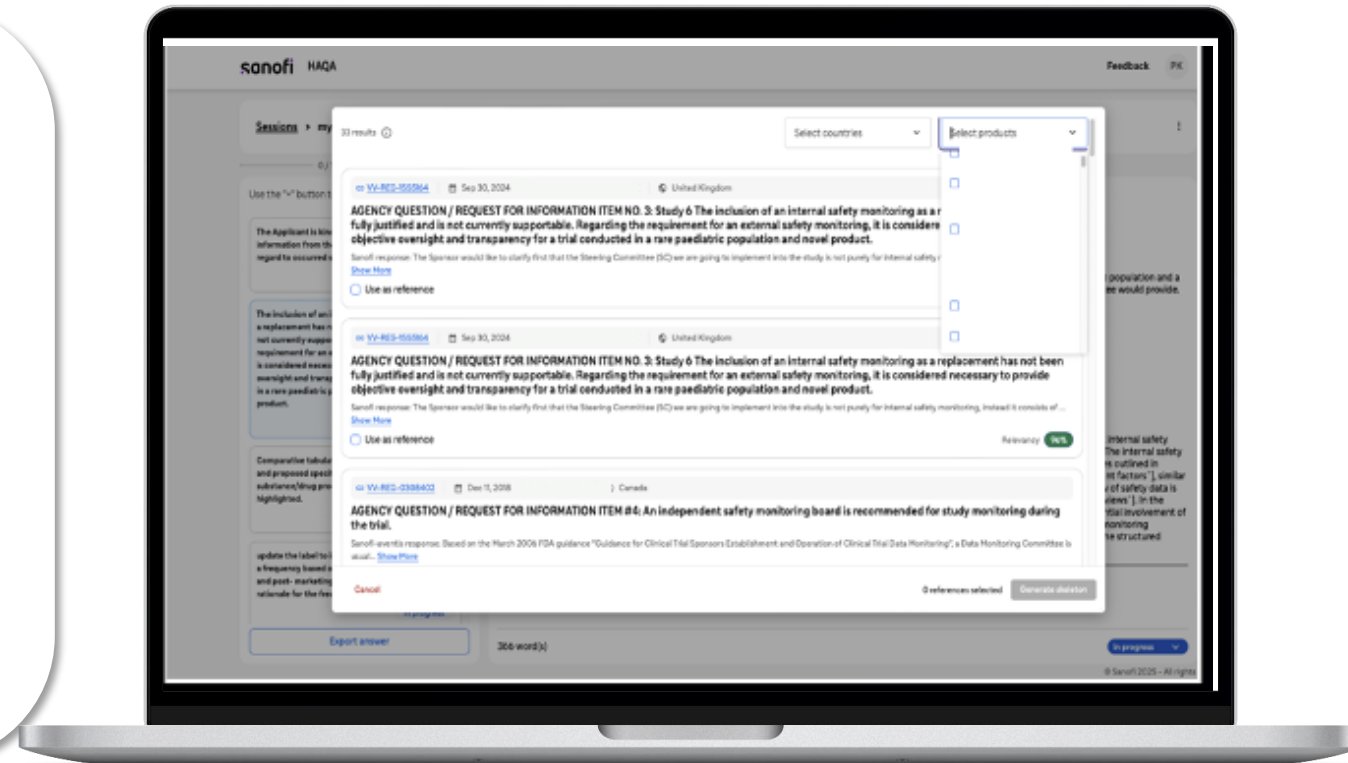
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AI translation | *OneTranslate*

Artificial Intelligence

Leverages AI, machine learning, and Sanofi translation memory

Self-Service Translation

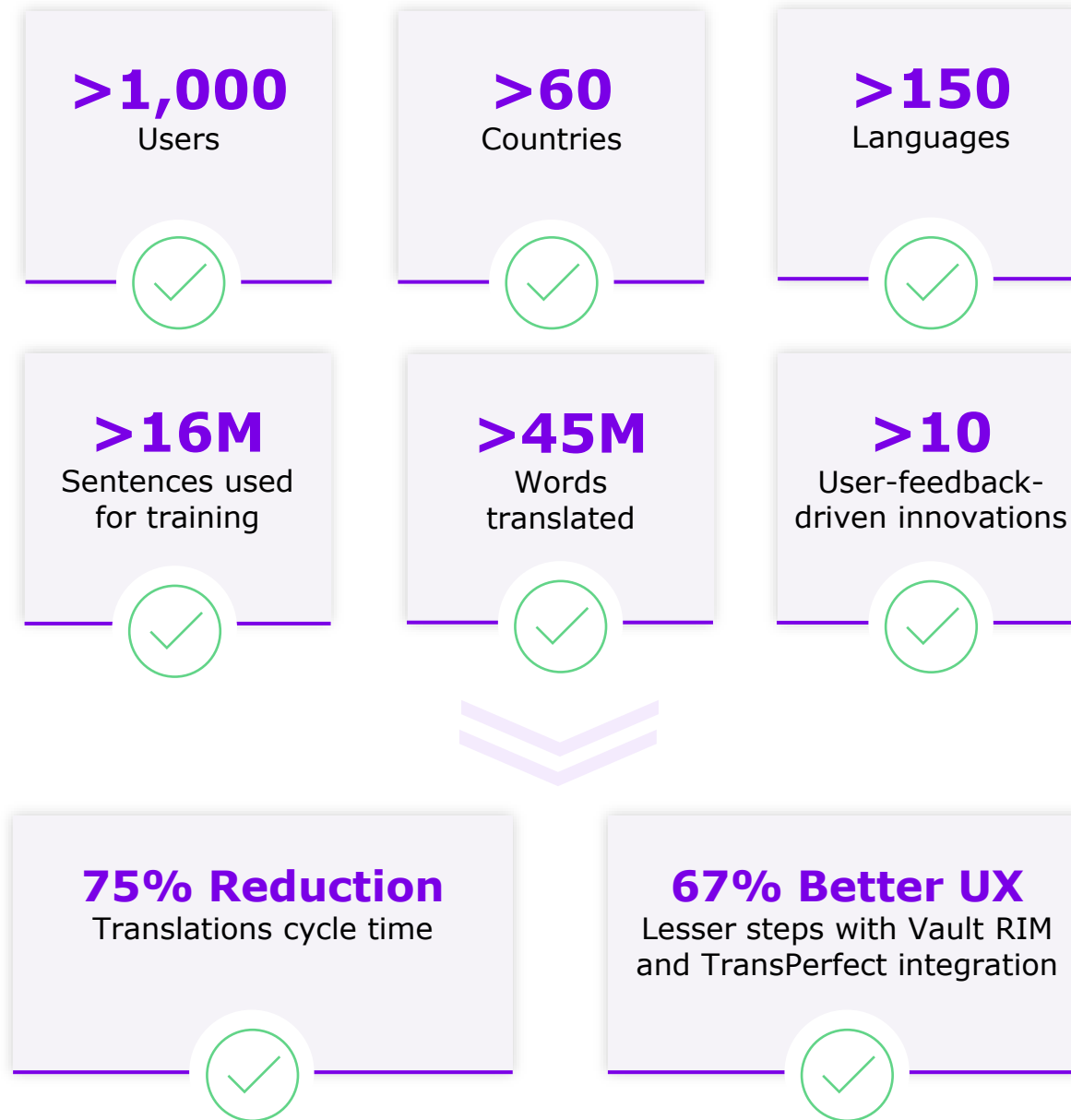End-user initiates translation and performs machine translation quality checks

Continuous Improvement

Updates implemented based on user feedback for emerging innovation and improvement

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Achievements

OneTranslate

>1,000
Users

>60
Countries

>150
Languages

>16M
Sentences used
for training

>45M
Words
translated

>10
User-feedback-
driven innovations

75% Reduction
Translations cycle time

67% Better UX
Lesser steps with Vault RIM
and TransPerfect integration

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Product Quality Review

Current lead time: **~130 hours per PQR**

| Manual | Data collection | Content drafting and formatting, data analysis, review & closure | Final review & Approval |

With GenAIR: **~15-45 hours per PQR** (~65-85% efficiency)
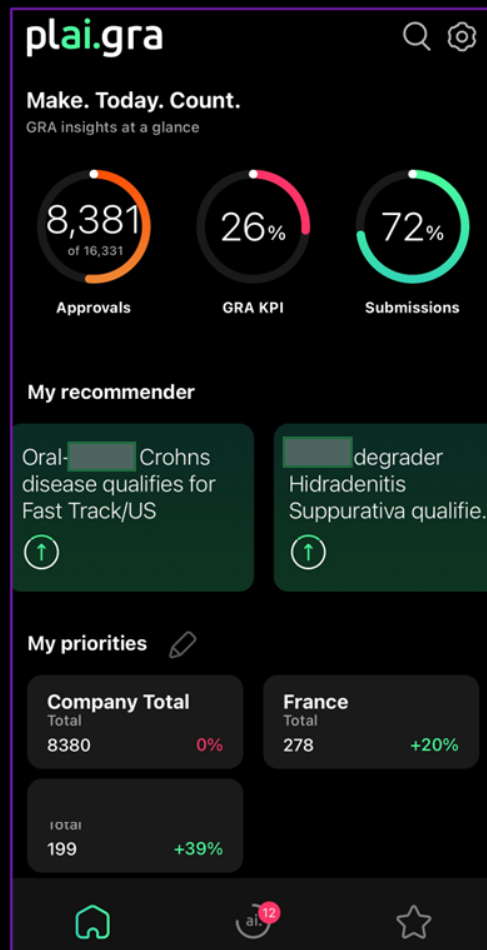
| GenAIR | Automated data collection, content drafting and data analyses | Review focused on key analyses and insights generation, where human expertise is required |

5min

Note: time efficiencies demonstrated during first GenAI trial on PoC Dec. 2023

Plai : Interest for Regulatory affairs

plai.gra

Make. Today. Count.
GRA insights at a glance

8,381 of 16,331 — Approvals
26% — GRA KPI
72% — Submissions

My recommender

Oral-████ Crohns disease qualifies for Fast Track/US

████degrader Hidradenitis Suppurativa qualifie...

My priorities ✎

Company Total		France	
Total		Total	
8380	0%	278	+20%

Total			
199	+39%		

Recommendations
From strategy to ops

Predictions
Near real-time

360° view
Across Sanofi

Portfolio
Simulations

Enhancing
Decision making & planning

+1bn data *points correlated into Plai*

- AI-generated recommendations to identify opportunities for regulatory strategy acceleration
- Predict HA approval
- Improve planning out of stock prediction to inform shortage notifications
- Inform strategy and timelines based on historical data
- Democratize our data to unlock our potential

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# Employee experience | *Interest for Regulatory affairs*

- Copilot MS365
- AI concierge in your pocket to empower employee with a personalized experience to ease their day to day
- Easily retrieve information within your company
- Leverage GenAI capabilities to facilitate your everyday work

Save time spent on mundane tasks to focus on the strategic value
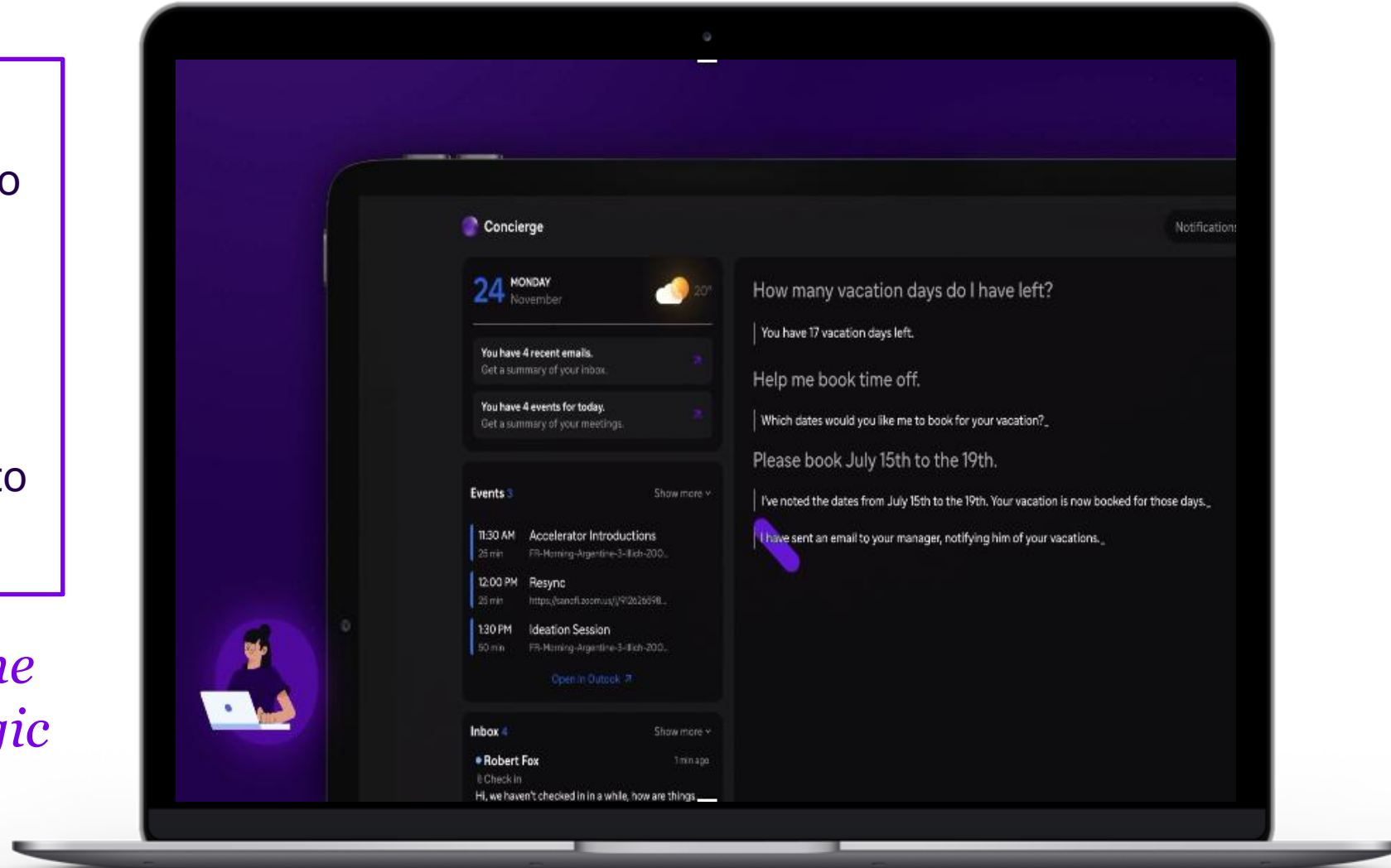
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Responsible AI at Sanofi for Everyone (RAISE)
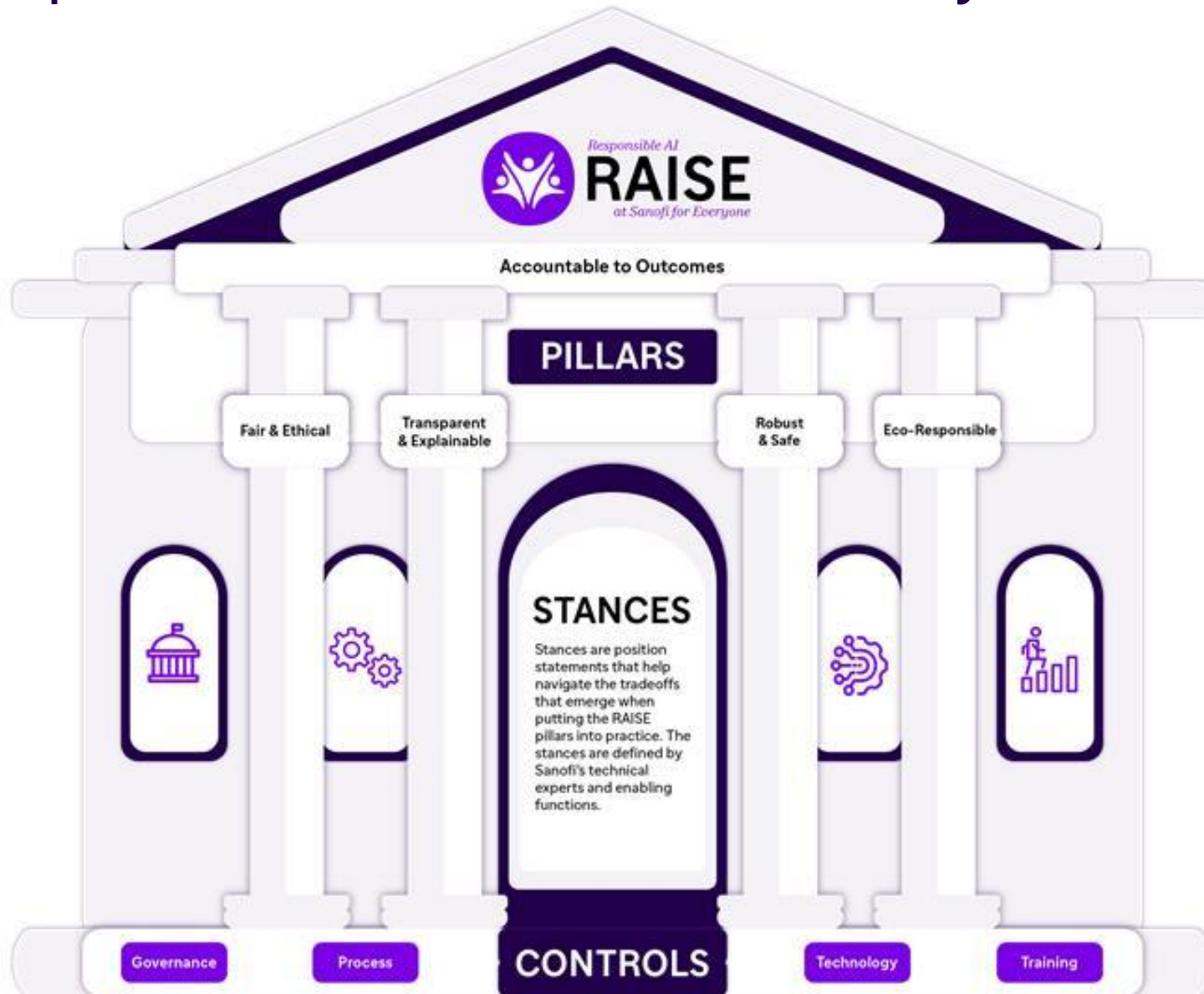
All of our projects follow our Responsible AI policy to ensure they meet our moral & ethical standards and protect our people, patients and customers.

Robust **governance and accountability framework**, with a mission to enable Sanofi to be the first AI-powered biopharma company at scale by **mitigating AI-related risks**

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Achieving Success Through Ambitious Goals and Organizational Engagement

We must rethink and adapt our processes as we pioneer the early stages of GenAI.

Rethink the process
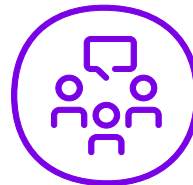Take advantage of GenAI capabilities

Build new skills
Investing early in employee growth

Data is key
AI is only as powerful as the data you give it

Change ready mindset
Foster a culture of innovation and adaptability

Continuous improvement
Constantly evolving technologies

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Thank you

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