



Agentic AI in Pharmacovigilance: From Task Automation to Unified Data Intelligence

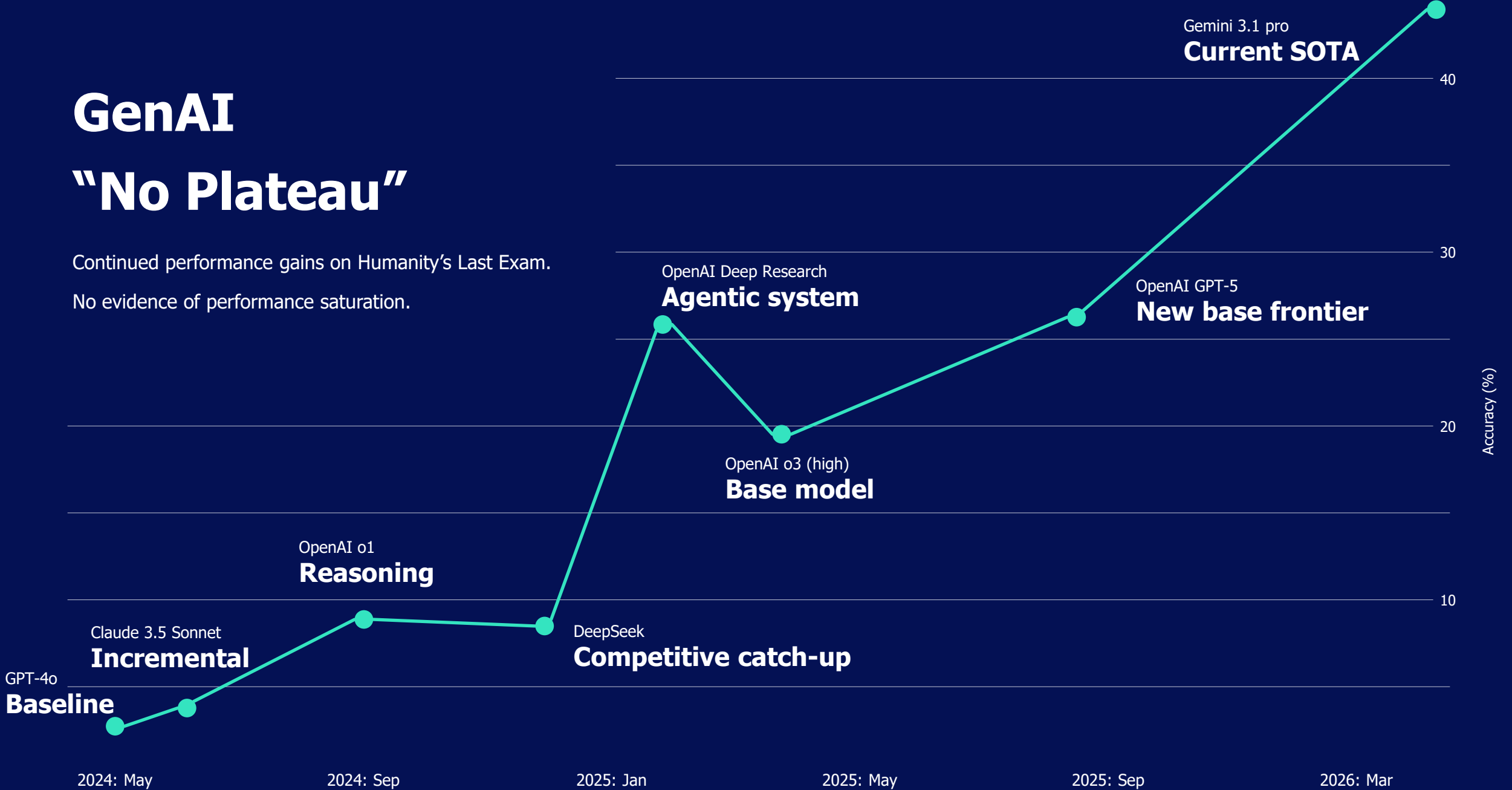
Antoine de La Gardette

Director Product Management, AI, ArisGlobal

GenAI

“No Plateau”

Continued performance gains on Humanity’s Last Exam.
No evidence of performance saturation.



GPT-5.2 Just Solved a 30-Year Math Problem

Jan 12, 2026



Terence Tao

@tao@mathstodon.xyz

Recently, the application of AI tools to Erdos problems passed a milestone: an Erdos problem ([#728 erdosproblems.com/728](#)) was solved more or less autonomously by AI (after some feedback from an initial attempt), in the spirit of the problem (as reconstructed by the Erdos problem website community), with the result (to the best of our knowledge) not replicated in existing literature

Terence Tao

2024: “Mediocre, but not completely incompetent graduate students.”

2025: “Better at certain types of high-level math reasoning, but lacking creativity and making subtle mistakes.”

2026: “The technology is opening up a **different ‘way of doing mathematics.’**”

Where Innovation Meets Reality

**Foundational
Operating System**

LifeSphere Safety & Medical Affairs Suite

Reporter

Lit Intelligence

Advanced Intake

MultiVigilance

Medical Information

Business Intelligence

Advanced Signals

LifeSphere Regulatory & Quality Suite

RIM

Product Compliance

QMS

Labeling

Documents

Submissions

← **SaaS Transformation 2018 – 2023** →

Where Innovation Meets Reality

NavaX
AI Operationalized
GenAI 2023 | Agentic AI 2025

Advanced AI in Safety

Dynamic Data Extraction

MedDRA Coding Agent

Narrative Generation

Advanced AI in Regulatory

HA Interactions

Regulatory Intelligence

Foundational
Operating System

LifeSphere Safety & Medical Affairs Suite

Reporter

Lit Intelligence

Advanced Intake

MultiVigilance

Medical Information

Business Intelligence

Advanced Signals

LifeSphere Regulatory & Quality Suite

RIM

Product Compliance

QMS

Labeling

Documents

Submissions

← SaaS Transformation 2018 – 2023 →

Where Innovation Meets Reality

NavaX
AI Operationalized
GenAI 2023 | Agentic AI 2025

Advanced AI in Safety

Dynamic Data Extraction

MedDRA Coding Agent

Translation

Narrative Generation

Distribution Agents

Signals Agents

Advanced AI in Regulatory

HA Interactions

Intelligence Agents

Regulatory Intelligence

Foundational
Operating System

LifeSphere Safety & Medical Affairs Suite

Reporter

Lit Intelligence

Advanced Intake

MultiVigilance

Medical Information

Business Intelligence

Advanced Signals

LifeSphere Regulatory & Quality Suite

RIM

Product Compliance

QMS

Labeling

Documents

Submissions

← SaaS Transformation 2018 – 2023 →

NavaX Strategic Horizons

Horizon 1

Delivering Now

Automation

GenAI

Horizon 2

Launching Next

Decision Intelligence

AgenticAI

Horizon 3

Shaping the future

X-Domain Intelligence

Beyond platform, beyond data

NavaX Horizon 1

EVOLVING TOWARDS
AGENTIC

CAPABILITY LAYER

AUTOMATION

EXTRACTION

Retrieves data
from diverse sources

GENERATION

Creates narratives
from data

INTERPRETATION

Understands
complex data

ACTION

Executes chains of
tasks

AUGMENTATION LAYER

MULTI-MODAL - Integrates different data types

MULTI-LINGUAL - Integrates different human languages

NavaX Translation

Key Features

- **Partnership with TransPerfect** - industry-leading translation
- **Instantly detects** and routes non-English forms for certified translation
- **Pharma-specific** models and human linguists for quality and compliance
- **Seamless API integration** - translated forms flow back automatically
- **Available July 2026**



Time Spent Managing Translation

Average time spent per case

Activity	Without NavaX Translation	With NavaX Translation
Export Content for Translation	30 Mins	0 Mins
Managing Translation Process	1 Hour	
In-Country Translation & Review	3 Hours	
Import to NavaX	30 Mins	

MedDRA Coding Agent

Key Features

- **>90% accuracy**
Industry-leading performance, validated in real-world PV operations
- **>80% efficiency gains**
Dramatically reduces reviewer workload and manual effort
- **Agentic AI**
Context-aware, autonomous, learns and adapts to coding goals and evolving medical terminology
- **Available April 2026**



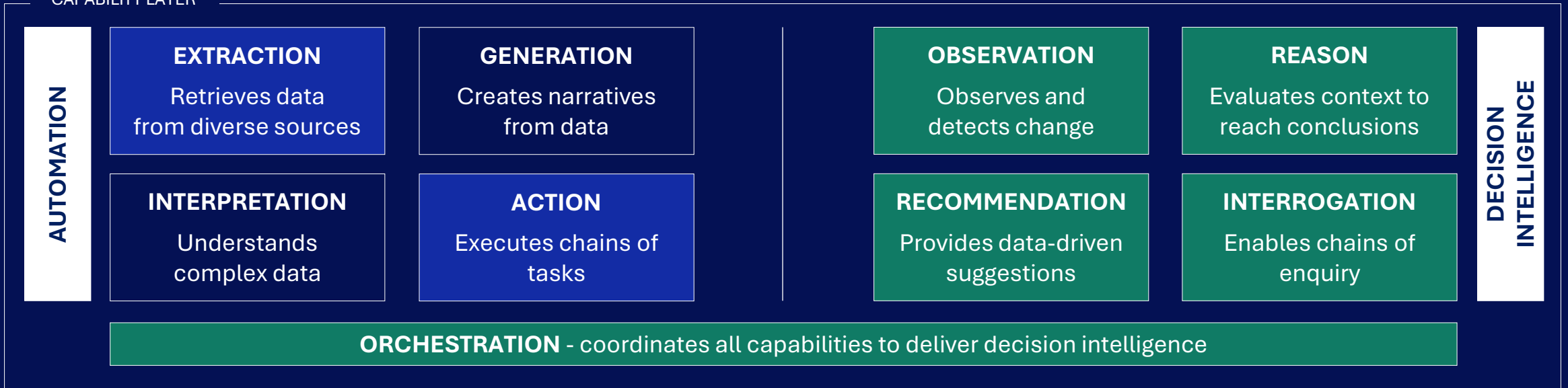
First-of-its-kind Agentic AI in Pharmacovigilance

NavaX Horizon 2

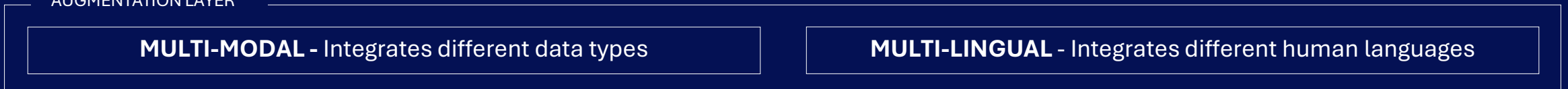
EVOLVING TOWARDS
AGENTIC

AGENTIC
BY DESIGN

CAPABILITY LAYER



AUGMENTATION LAYER



NavaX Agents

Key Features

- **Connects Safety & Regulatory verticals** - agentic orchestration bridges domains for unified workflow and insights
- **Multi-agent system** – agents work across both verticals
- **Agents also deployed against Horizon 1 challenges** - e.g., quality control, reducing human QC effort and strengthening audit trails
- **BYO Agent** - designed for seamless integration with customer and third-party specialised agents



Private Preview
Opens Apr 2026

What It Solves For

- **Misalignment** between regulatory requirements or PV Agreements and distribution rules lead to missed or over submissions
- **Compliance** risk if misalignment is not identified and resolved quickly
- **Time consuming** manual effort in reviewing regional regulations in multiple languages
- **Change management** and documentation gaps lead to inspection and audit findings
- **Rule configuration** is manual and time consuming

DISTRIBUTION AGENTS

What It Solves For

- **Fragmented**, siloed data reviews
- Signal detection is **reactive and late**
- **Manual data extraction**, analysis and interpretation **is time consuming**
- **Signal evaluation reports** take significant time
- **Limited real-time decision support**

SIGNAL
SIGNALS
AGENTS

What It Solves For

- **Dispersed sources** of regulatory rules across global markets
- **Time consuming** analysis of regulations in multiple languages
- **Late adoption** of regulatory requirement changes
- **Inconsistencies** between regulatory data and content
- **Extensive** regulatory submission compliance reviews
- **Deficiencies** from Health Authorities
- **Disconnected** change management and documentation updates lead to inspection and audit findings

INTELLIGENCE AGENTS

NavaX Horizon 3

Where Innovation Meets Reality

**XDI
2026**

NavaX Data-Intelligence

XDI is ArisGlobal's system-agnostic Data-Intelligence Cortex - our newest advancement, focused on transforming regulated life-sciences data into continuous, explainable, decision-grade intelligence across all domains.

**NavaX
AI Operationalized**
GenAI 2023 | Agentic AI 2025

Advanced AI in Safety

Dynamic Data Extraction

Translation

Distribution Agents

MedDRA Coding Agent

Narrative Generation

Signals Agents

Advanced AI in Regulatory

HA Interactions

Intelligence Agents

Regulatory Intelligence

**Foundational
Operating System**

LifeSphere Safety & Medical Affairs Suite

Reporter

Lit Intelligence

Advanced Intake

MultiVigilance

Medical Information

Business Intelligence

Advanced Signals

LifeSphere Regulatory & Quality Suite

RIM

Product Compliance

QMS

Labeling

Documents

Submissions

← **SaaS Transformation 2018 – 2023** →

XDI Goes Beyond

- **Beyond Platform**
Intelligence goes to the data
- wherever it lives.
- **Beyond Data**
The next leap is federating meaning, not
just federating data.
- **Cross-Domain Intelligence**
Risk, quality, and compliance decisions
confident and explainable at scale.
- **Industry-Shaping**
Enabled by NavaX's Horizon 1 and 2
capabilities to unlock
meaning-aware intelligence.

The logo for XDI (Cross-Domain Intelligence) is displayed in large, white, bold, sans-serif capital letters. The letters 'X', 'D', and 'I' are significantly larger than the 'X' and 'D' in the word 'XDI'. A small 'TM' trademark symbol is positioned to the upper right of the final 'I'. The logo is set against a dark blue background with a subtle geometric pattern of overlapping triangles.

Automation ROI today

Agentic ROI tomorrow

Efficiency

FTE / cycle-time reduction (TAMS)

Agentic Lift

efficiency & quality (amplified)

Quality

accuracy, precision, recall, F1 score

Intelligence ROI

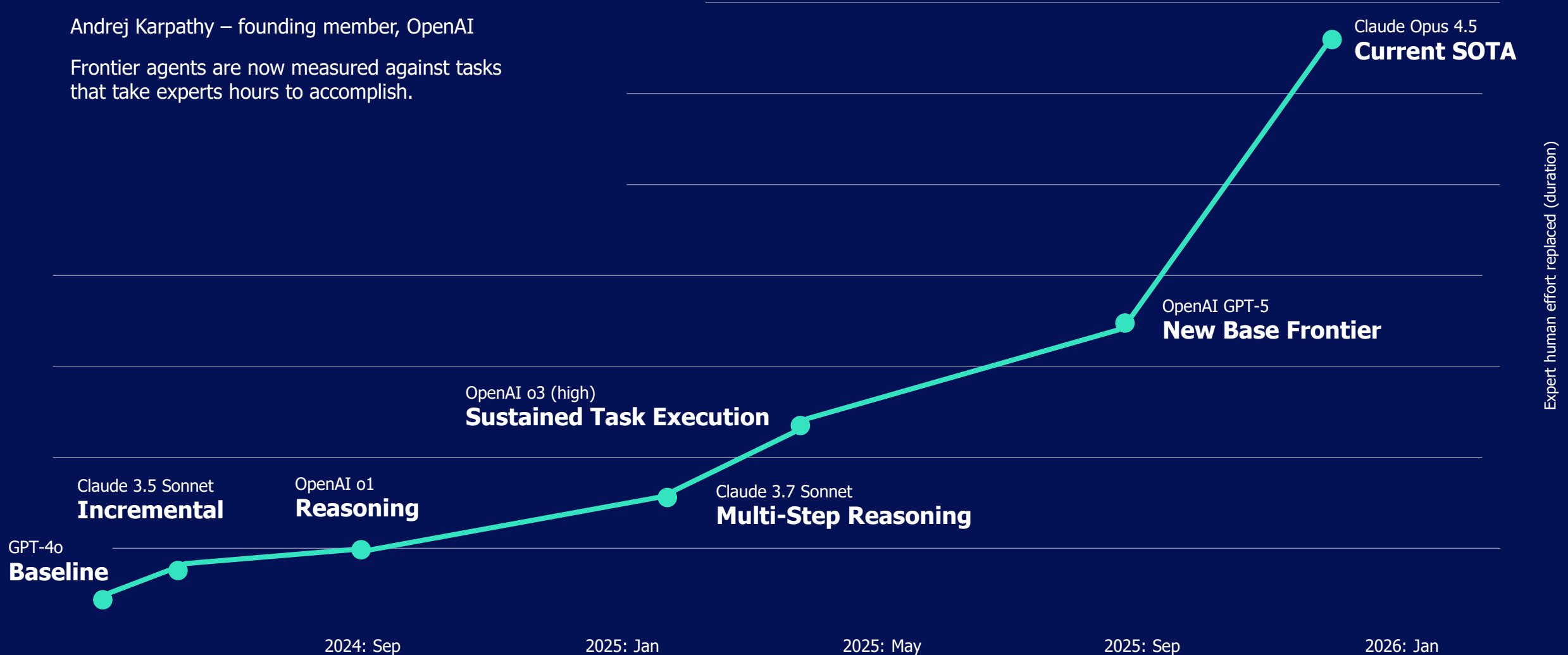
resource optimisation, decision time

Metrics are both **proof** and **catalyst** – value is captured when organisations use them to drive change, scale adoption, and capture **sustainable bottom-line impact**

"The Decade of Agents"

Andrej Karpathy – founding member, OpenAI

Frontier agents are now measured against tasks that take experts hours to accomplish.



**Value is created when
teams of experts stop doing
the wrong kind of work**

Trust by Design

- **Law & public commitments**
AI laws and cross-industry commitments (e.g. AI Pact)
- **Life sciences expectations**
Regulators, industry bodies, and customer standards converge
- **Governance & controls**
Policies, controls, auditability across the AI lifecycle
- **Execution in practice**
NavaX AI governance embedded in day-to-day delivery

