vGenix Ai

vGenix safety

INTELLIGENT SAFETY PLATFORM

Safety intelligence that is trusted, connected, traceable and human-led.

THE CONTEXT

Safety data at a scale manual teams can't keep up with

EVERY DAY

≈4,800

ICSRs reach EudraVigilance, each on a 15- or 90-day reporting clock

2025 total ÷ 365

1.77M

ICSRs received in EudraVigilance in 2025

31.3M

ICSRs held, covering 17.9M cases

1,201

potential signals reviewed by EMA in 2025

22.5%

forecast yearly growth of AI in pharmacovigilance

Sources: EMA EudraVigilance Annual Report 2025 · Mordor Intelligence 2026

CHALLENGE TO SOLUTION

From fragmented to connected safety

WHERE PV BREAKS DOWN TODAY	HOW VGENIX AI ANSWERS IT
Manual, repetitive work Expert time goes to intake, data entry and formatting.	**Intelligent automation** AI handles intake, extraction and formatting; experts focus on review.
Fragmented tools Cases, literature, signals and reports in separate systems.	**One connected platform** One data model and workspace for every safety process.
Inconsistent decisions Classification and review vary across teams.	**Consistent decisions** Shared intelligence and guided workflows align review.
Traceability gaps Evidence and approvals hard to reconstruct at inspection.	**Built-in traceability** Every output keeps its source, decision history and approvals.

ACROSS ALL FIVE Case processing · Literature · Signals · Aggregate reports · Submission, with risk-based automation and humans in control

AI IN SAFETY

Why AI adoption in PV is hard, and how we solve it

THE CONCERN	THE VGENIX AI ANSWER
Regulatory Validating changing models; guidance still evolving	**Validated, controlled models** Validation packs and change control for every release, aligned to EMA, FDA and CIOMS principles
Trust Black-box outputs; missed or invented safety facts	**Source-linked, grounded AI** Every output cites its source and rationale; low-confidence results go to an expert
Data Unstructured, multilingual sources; accuracy drift	**Trusted data, monitored models** AI extraction, translation and MedDRA coding; drift tracked with alerts
Operations Oversight, legacy systems, privacy, proving value	**Built to fit your operation** Risk-based human review; Argus, ARISg, Veeva; encryption and residency; value dashboards

OUR FRAMEWORK

The S.A.F.E.T.Y. framework for Pharmacovigilance

S **Secure**
Privacy-by-design patient data protection

A **Auditable**
Explainable, traceable, inspection-ready decisions

F **Fit-for-purpose**
GxP-validated models, monitored for drift and bias

E **Expert-in-the-loop**
Risk-based human oversight at critical decisions

T **Trusted data**
Clean, standardised, integrated safety data

Y **Yield**
Measurable value in speed, quality and compliance

"AI you can trust, because patient safety comes first."

No Cheap Intelligence

Rich & Trusted Intelligence

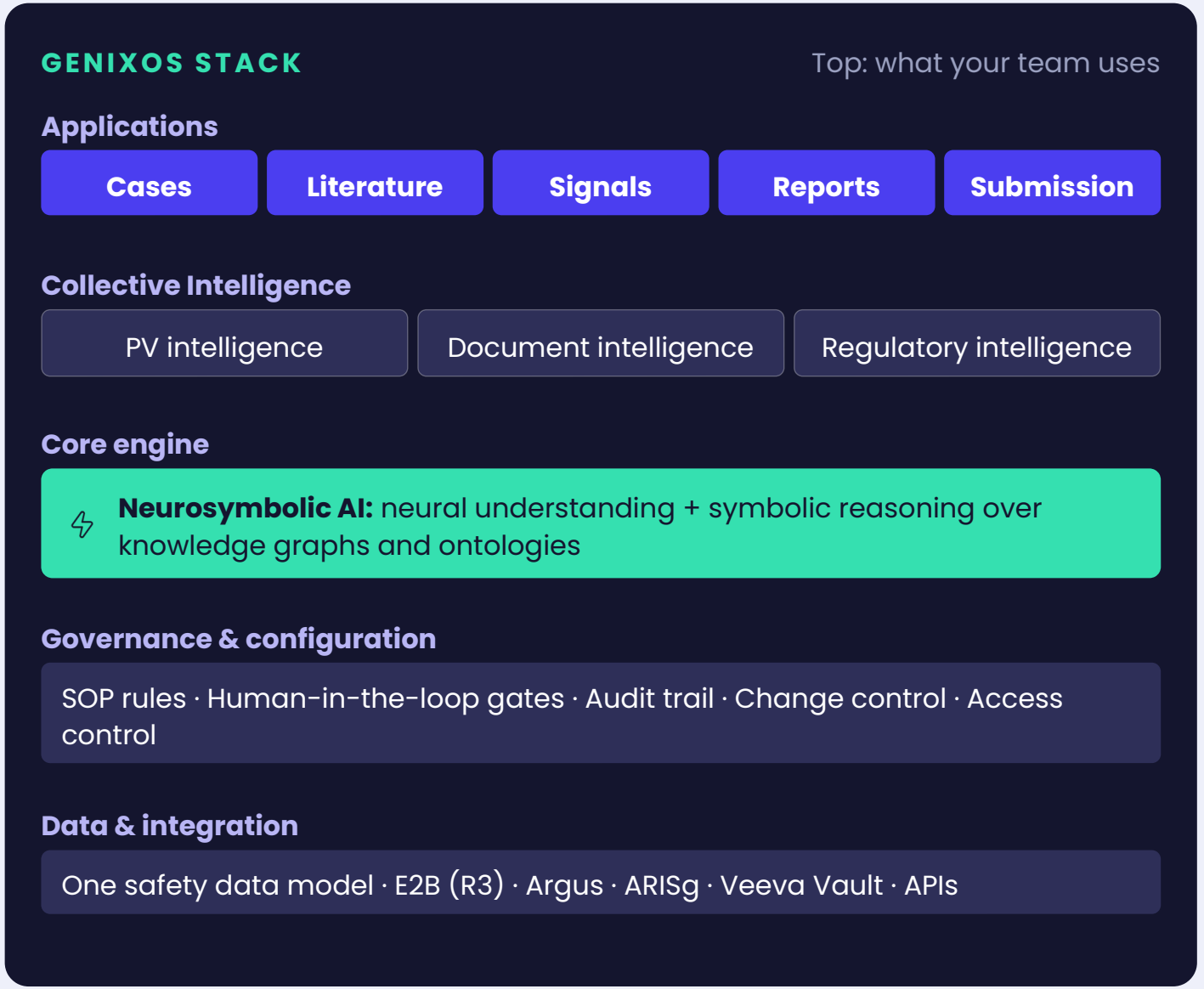
INTRODUCING

GenixOS

The operating system for safety intelligence

Not just AI-native, but neurosymbolic: neural AI reads every source, and symbolic AI checks each answer against your SOPs, the regulations and the knowledge graph.

- **Collective Intelligence:** every module learns together
- **SOP-native:** configured to how you work
- **Explainable:** every output traced to its source
- **Governed:** validated, versioned, audit-ready



HOW VGENIX AI THINKS

Collective Intelligence: one shared brain behind every module

LAYER 1
Module intelligence

Case Intelligence
Intake, triage, coding, causality support

Literature Intelligence
Screening, relevance, safety extraction

Signal Intelligence
Detection, validation, prioritisation

Report Intelligence
Compilation, narratives, tables

HOW IT WORKS
A continuous loop

01 Learn Each module captures decisions → **02 Share** Into one knowledge graph → **03 Reason** Neurosymbolic engine applies it → **04 Improve** Every module gets smarter

LAYER 2
Domain intelligence

Pharmacovigilance Intelligence
MedDRA, WHO Drug, safety concepts and clinical context

Document Intelligence
Reads forms, emails, PDFs, scans and E2B, in any language

Regulatory Intelligence
Agency rules, timelines, GVP and local requirements

FOUNDATION
Reasoning engine

Neurosymbolic AI engine
Neural language understanding + symbolic reasoning over knowledge graphs, ontologies and your SOP rules

Explainable · Grounded · Rule-consistent · Auditable

PLATFORM

One Platform for OMNIVIGILANCE

"Compliance First & AI Enabled."

DOMAINS	Medicinal products	Vaccines	Medical devices	Cosmetics	Nutrition	Veterinary medicine
SOURCES	Clinical trials	Spontaneous reports	Literature	Social media	Patient support programmes	OpenFDA / MedWatch
INGESTION	E2B (R3)	Excel / CSV	Database exports	Custom APIs	Duplicate detection	Multi-format intake
MODULES	**MODULE 01** **Intelligent case processing** Intake · triage · coding · QC · E2B (R3)	**MODULE 02** **Intelligent literature monitoring** Discovery · AI screening · extraction	**MODULE 03** **Intelligent signal detection** PRR / ROR · EBGM · prioritization	**MODULE 04** **Intelligent aggregate reports** Compilation · narratives · tracking		
GOVERNANCE	Enterprise SSO · Role-based access · Encryption at rest & in transit · Audit trails · Version & change control · AI governance · Human-in-the-loop					
OUTPUTS	E2B (R3) submissions	PSUR · PBRER · DSUR · PADER	Signal dashboards	Line listings & tables	Audit-ready archive	Excel / CSV · custom APIs

CONNECTS & DEPLOYS Oracle Argus · ARISg · Veeva Vault | Cloud / APIs · SaaS · On-premise · Hybrid | EU / US / UK / Canada residency

AI GOVERNANCE

AI does the work. Experts own the decisions.

AI AUTOMATES · SPEED AND SCALE

- Multi-channel intake
- Literature screening
- Extraction and coding
- Statistical signal detection
- Draft narratives and tables
- Duplicate detection

Human in the loop

EXPERTS DECIDE · JUDGEMENT AND CONTROL

- Medical review and causality
- QC and approvals
- Signal validation and prioritisation
- Benefit–risk interpretation
- Escalation of high-risk cases
- Final sign-off on submissions

PRINCIPLE The higher the scientific or regulatory consequence, the more explicit the human gate.

FIT FOR YOUR PURPOSE

Intelligence built on your SOPs, not a generic model

GENERIC AI

- ✕ One-size-fits-all rules
- ✕ Your team adapts to the tool
- ✕ Outputs don't match your SOPs

VGENIX AI

- ✓ Your rules, your conventions
- ✓ The platform adapts to your team
- ✓ Every output follows your SOPs

WHAT WE CONFIGURE FROM YOUR SOPS

Case rules
Validity, seriousness, expectedness, triage

Timelines & routing
Reporting clocks, allocation, distribution

Coding conventions
MedDRA, WHO Drug, your coding guidelines

Literature strategies
Search terms, sources, schedules

Signal thresholds
Methods, triggers, prioritisation

Templates & narratives
Report profiles, house style

Review gates & roles
Who reviews, approves and signs off

Local requirements
Country and agency-specific rules

HOW **Your SOPs** → **Map** → **Configure** → **Validate** → **Version-control**

END-TO-END AUTOMATION

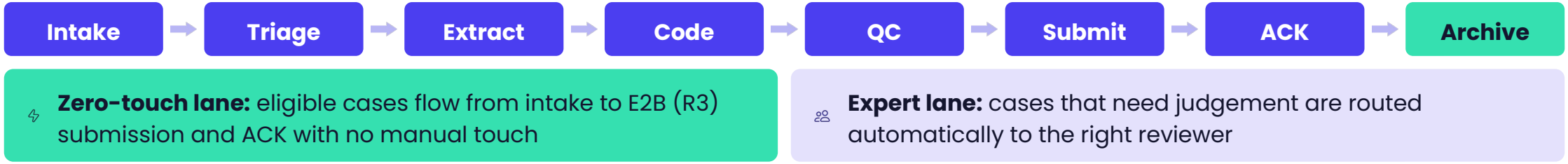
One true automation, from start to end

PARTIAL AUTOMATION

- ✕ Point tools automate one step at a time
- ✕ People re-key and hand off between systems
- ✕ Every case still needs manual touches

VGENIX AI: TRUE AUTOMATION

- ✓ Every step automated, in one continuous flow
- ✓ One platform and data model: no re-keying, no hand-offs
- ✓ Zero-touch processing for eligible cases



MEANINGFUL AUTOMATION Not islands of automation, but the whole case lifecycle in one automated flow

COMPLIANCE FIRST

Compliance designed in, not bolted on

COMPLIANCE FIRST

PV regulations

- ✓ EU GVP modules
- ✓ ICH E2B (R3)
- ✓ ICH E2D · E2C (R2)
- ✓ FDA 21 CFR 314.80 / 600.80

Computerised systems

- ✓ 21 CFR Part 11
- ✓ EU Annex 11
- ✓ GAMP 5 (risk-based validation)
- ✓ ALCOA+ data integrity

Data privacy & security

- ✓ GDPR
- ✓ HIPAA
- ✓ Encryption at rest & in transit
- ✓ EU / US / UK / Canada residency

AI governance

- ✓ CIOMS WG XIV on AI in PV
- ✓ EMA reflection paper on AI
- ✓ FDA AI · EU AI Act
- ✓ Model monitoring & drift control

BUILT-IN CONTROLS

Audit trails | **E-signatures** | **Role-based access** | **Validation packs** | **Change control** | **Version history**

Frameworks the platform is built to support · validation and regulatory responsibility agreed per implementation

WHY VGENIX AI

What sets vGenix Ai apart

1 Live end to end
Case to submission in one platform, live today

2 Neurosymbolic AI
Neural AI reads, symbolic AI checks the rules

3 Built on your SOPs
Configured, validated and versioned to how you work

4 Fits your landscape
Argus, ARISg, Veeva; SaaS, on-premise or hybrid

5 Every product type
Medicines, vaccines, devices, cosmetics and more

6 Proven on your data
Pilot results measured against your own baseline

"Live today, compliant by design, proven on your data."

Roadmap promises	Live, proven intelligence

USE CASES

What changes for a team like yours

ILLUSTRATIVE SCENARIO

PROFILE
Mid-size pharma, ~40,000 ICSRs a year, 3 regions

STARTING POINT
Manual intake, literature backlog, PBRERs built in spreadsheets

DEPLOYED
All four modules, cloud, connected to Argus

CASE PROCESSING
−60% 45 → 18 min
Handling time per non-serious case

ZERO-TOUCH
55% of eligible cases
Processed intake to ACK with no manual touch

LITERATURE
−65% 120 → 42 h / week
Screening effort, with zero backlog

AGGREGATE REPORTS
−50% 6 → 3 weeks
PBRER compilation, data lock to draft

SUBMISSION **92% → 99%**
first-pass E2B (R3) acceptance, with every ACK tracked

Illustrative figures for discussion, not client results · measured against baselines agreed per implementation

OUR COMMITMENTS

What we promise, and how we prove it.

GUARANTEED BY DESIGN · FROM DAY ONE

- 100% of actions in the audit trail
- 100% of AI outputs traced to source
- 100% of routing set by your SOPs
- Human sign-off wherever your SOP requires
- Every case tracked against its deadline
- No AI change outside change control

Your own data

PROVEN IN YOUR PILOT · TARGETS

- Case cycle time: ↓ [__]%
- Cost per case: ↓ [__]%
- Literature screening effort: ↓ [__]%
- On-time submission: ≥ [__]%
- Data-entry accuracy: ≥ [__]%
- Measured in a 6-week pilot

PROMISE Controls are guaranteed from day one. Outcomes are measured on your data, not just claimed.

GETTING STARTED

From kick-off to steady-state operations

DEPLOY YOUR WAY

Cloud / SaaS · On-Premise · Hybrid

DATA RESIDENCY

EU · US · UK · Canada

CONNECTS WITH

Argus · ARISg · Veeva Vault · E2B (R3) · APIs

PHASE 1

Scope & design

Modules, domains, workflows, data sources

PHASE 2

Configure & validate

Rules, thresholds, templates, human review gates

PHASE 3

Integrate & onboard

Systems, access controls, user training

PHASE 4

Go live & operate

Controlled release, dashboards, 24/7 support

PRINCIPLE Configure before you integrate; validate as you configure.

NEXT STEP

Intelligent safety should be one connected operation

Automate the work. Keep the decisions with your experts. Keep the evidence traceable.

sales@vgenix.ai

www.vgenix.ai

RECOMMENDED

6-week pilot on literature monitoring

Measured against baselines agreed up front, on your own data/requirements.

ALSO AVAILABLE

Capability walkthrough against your workflows

Configuration workshop

Deployment and integration scoping