



PharmaSoft

Let Us Take Care!



DRUG
SAFETY



REGULATORY
EXCELLENCE



SMART
TECHNOLOGY



STRONG
PARTNERSHIPS



DATA DRIVEN
INSIGHTS

Case Study #5

*Building a Scalable
Pharmacovigilance Technology
Ecosystem with Validated
In-House Platforms*



*Smarter today,
Safer tomorrow.*



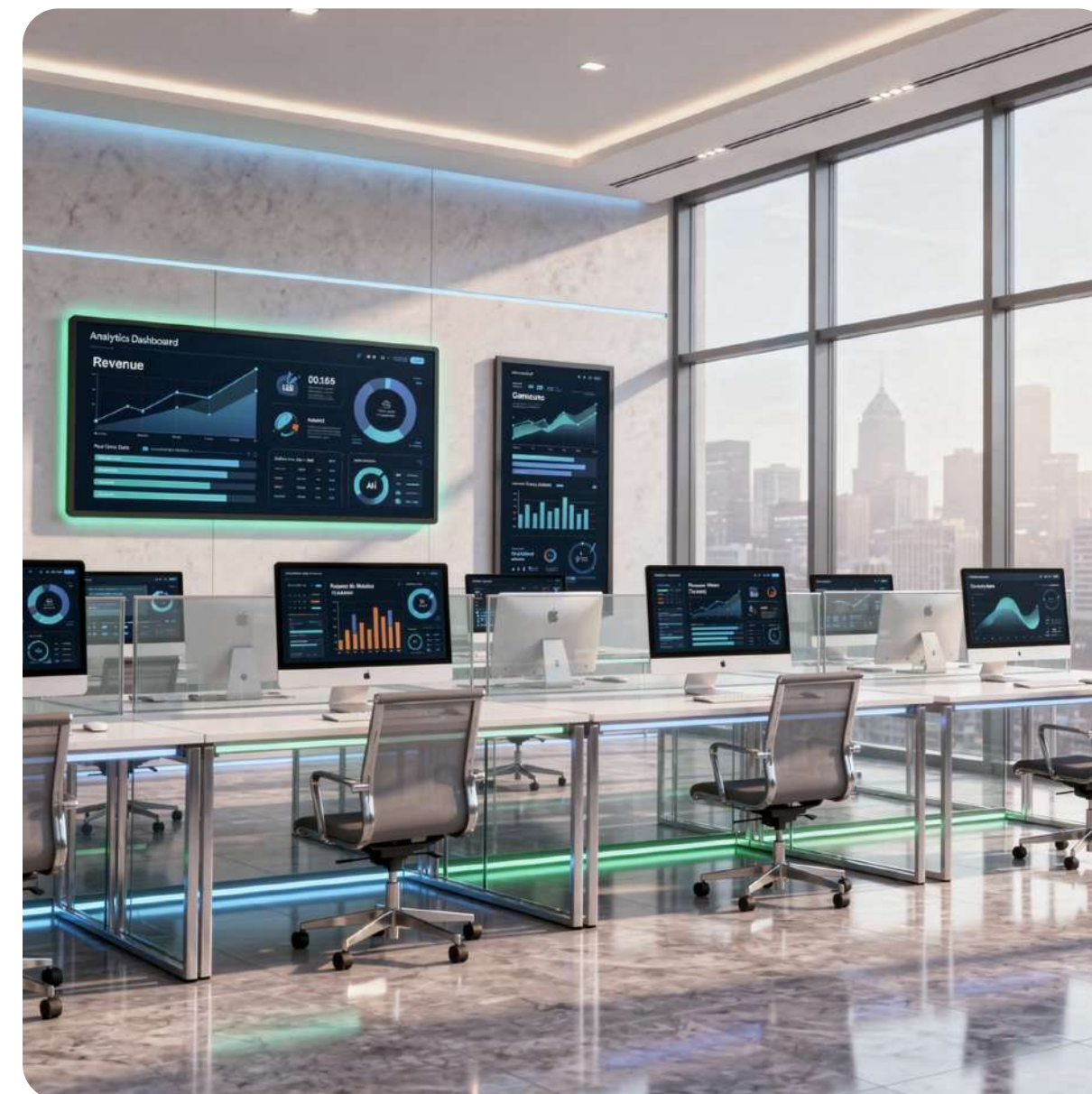
CASE STUDY

PHARMASOFT SUITE

PV TECHNOLOGY

Building a Scalable Pharmacovigilance Technology Ecosystem with Validated In-House Platforms

How PharmaSoft supports pharmaceutical companies with validated, sector-specific digital infrastructure for pharmacovigilance operations.





Built in Practice, Not in Theory



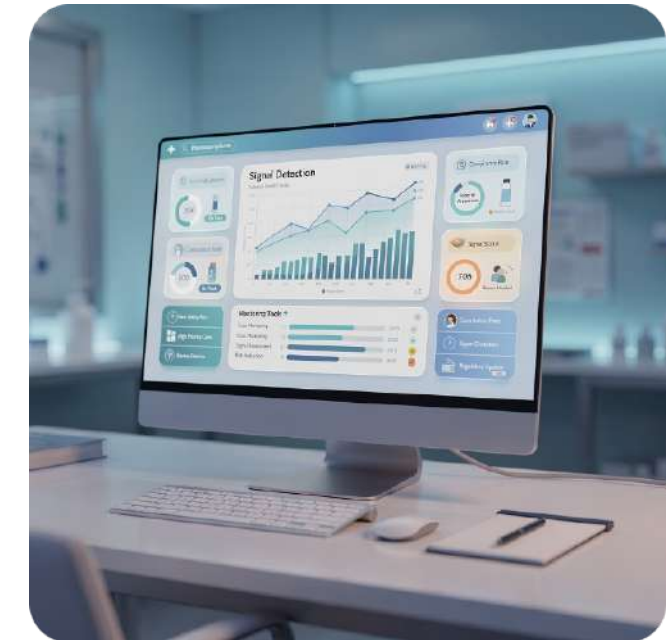
Real-World Application

PharmaSoft's technology ecosystem was not developed in isolation. It was shaped through first-hand operational use in real pharmacovigilance practice, addressing the day-to-day needs of companies.



CEO-Led Development

Developed from 2015 onward under the expert perspective of **MSc. Pharm. R. Ayşe Çetin**, PharmaSoft's CEO, the platforms were continuously refined as QPPV-led tools.



Purpose-Built, Not Adapted

The suite was intentionally built for pharmacovigilance, not adapted from generic software, ensuring deep alignment with industry requirements and regulatory demands.



Who This Is Built For

This case reflects pharmaceutical companies seeking validated, sector-specific digital tools for pharmacovigilance operations, whether as external service clients or as independent in-house teams.

Service Clients

Companies receiving PV services through PharmaSoft.

In-House Teams

Companies managing pharmacovigilance internally.

Digital Infrastructure Need

A need for validated, sector-specific PV systems.

Shared Technology Base

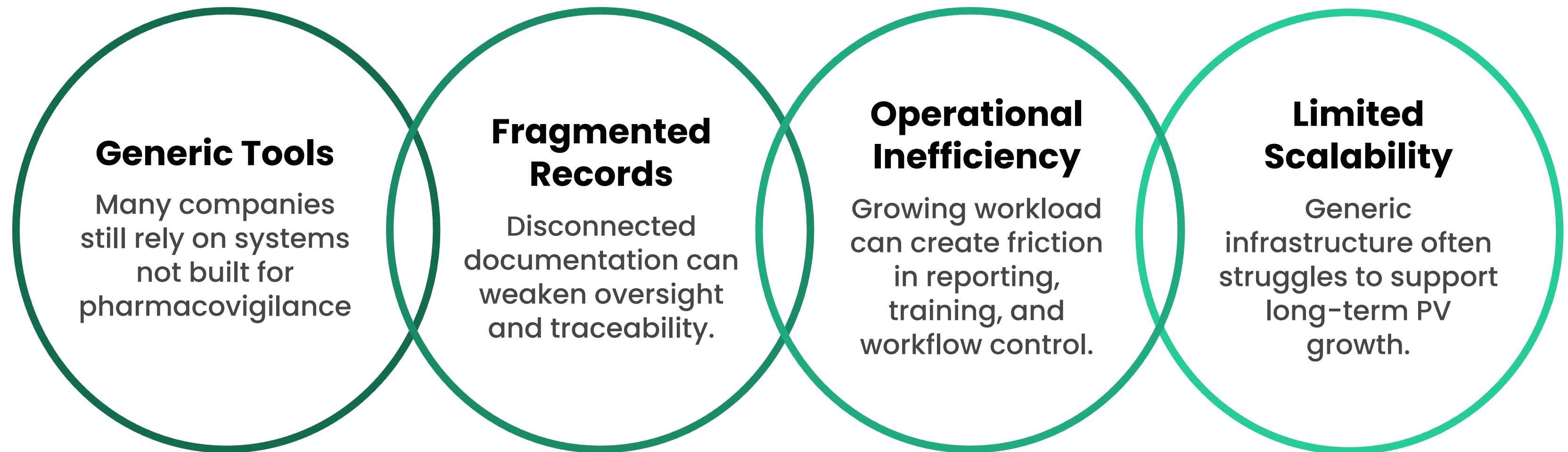
Infrastructure that supports multiple operating models.

Specialized PV technology for both managed and independent use models.



Strong PV Requires Strong Systems

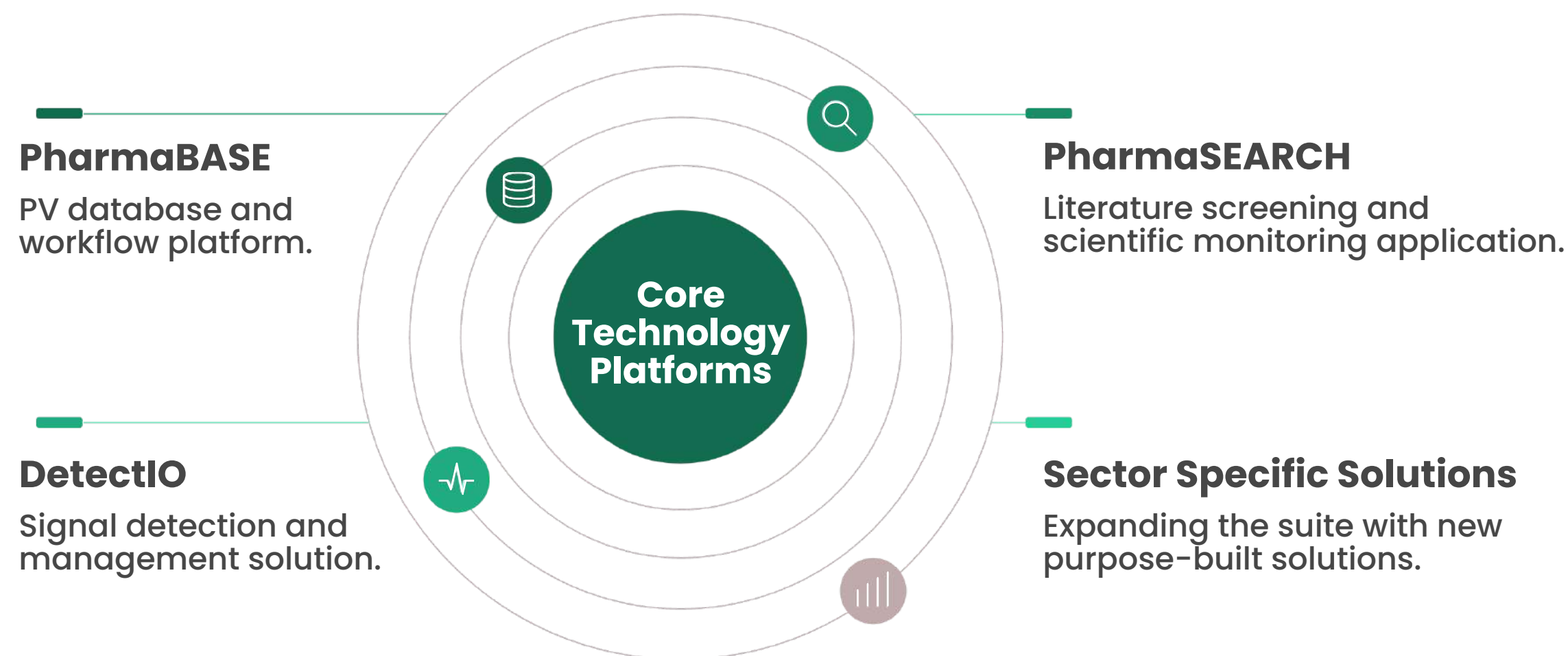
Pharmacovigilance requires not only professional expertise but also systems that are structured, traceable, specialized, and suited to regulated workflows.





PharmaSoft Suite: A Validated In-House Technology

Under the PharmaSoft Suite, PharmaSoft has developed its own validated, web-based applications specifically for the pharmaceutical sector.



A specialized digital ecosystem built around real pharmacovigilance operations.



Three Core Platforms. One Integrated Suite.



PharmaBASE

A 14-module pharmacovigilance platform designed to manage the full PV function in one validated, traceable environment. Once a QPPV works within PharmaBASE, no additional tool is needed for core PV operations. Its all-in-one structure supports case processing, documentation, oversight, and stronger inspection readiness.



PharmaSEARCH

A dedicated literature screening and scientific monitoring application powered by Türkiye's most comprehensive local medical literature database. Its client-specific interface gives users easy access to screening details, ADR information notes, and reconciliation records directly within the system, supporting a structured and auditable workflow.



DetectIO

A machine learning-powered signal detection and management solution trained on approximately 15 million ICSRs. Built for medical and pharmacovigilance experts, it identifies potential signals in alignment with EMA reporting formats and turns complex safety data into enriched, graphically supported insights.



Designed for Different Service Models

These platforms support both companies that outsource pharmacovigilance services to PharmaSoft and companies that manage their own internal departments but require specialized digital infrastructure.

SaaS Model

Cloud-based access with validated infrastructure managed by PharmaSoft.

On-Premise Model

Deployment within the client's own IT environment for greater internal control.

Hybrid Model

A flexible setup combining client-side control with PharmaSoft-supported infrastructure and expertise.



Technology Already in Active Use

PharmaSoft's technology ecosystem already supports a broad client base across different service models.

20+

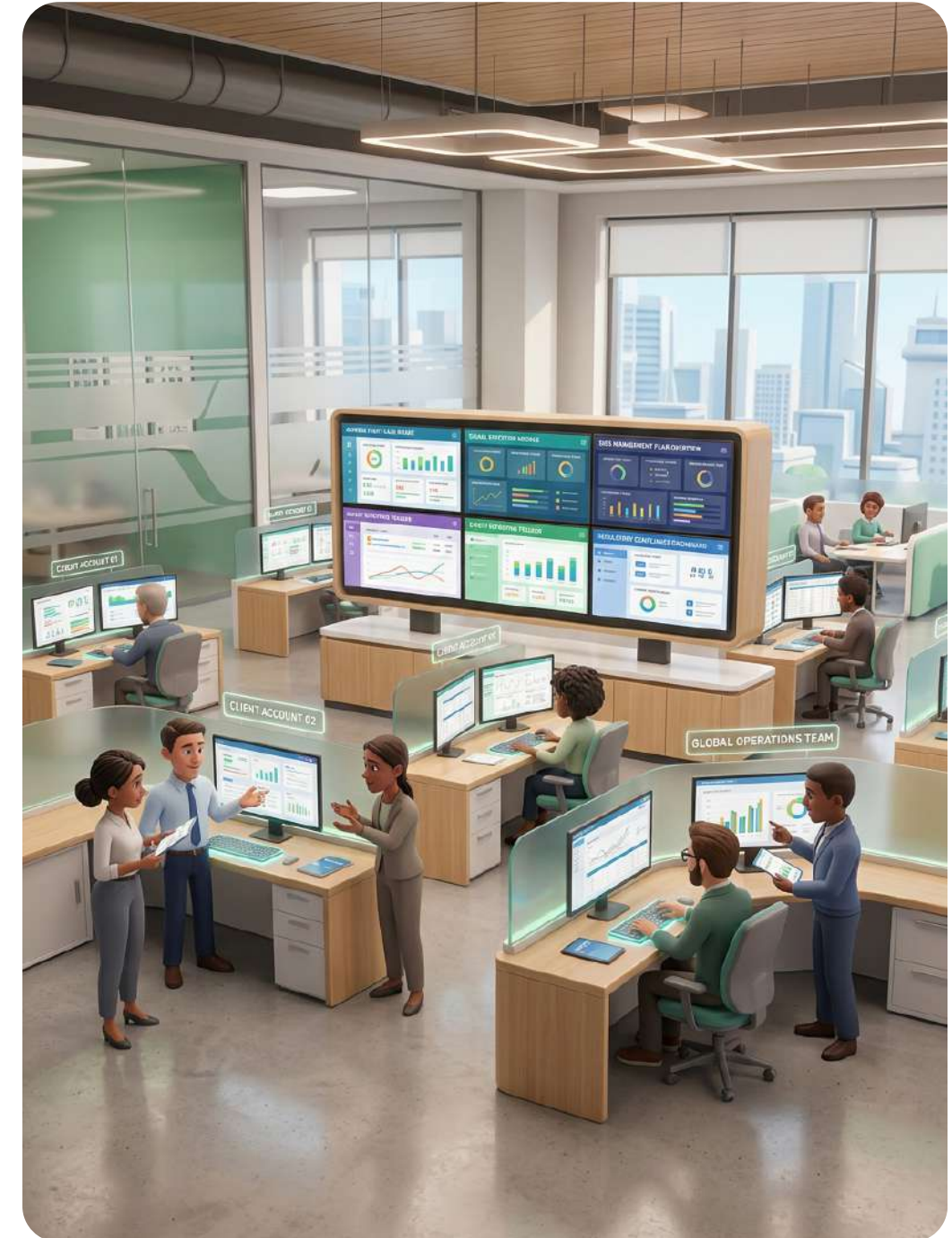
Software Clients

More than 20 pharmaceutical companies with internal departments actively use PharmaBASE under a monthly rental model.

~100

Service Clients

Approximately 100 companies receiving pharmacovigilance department services also operate through PharmaBASE.





What This Technology Enables

PharmaSoft provides specialized PV technology built around real operational needs.



Structured Workflows

More control across daily PV processes.



Validated Platforms

Web-based systems built for regulated use.



Purpose-Built Design

Designed for PV, not generic software.



Flexible Access

Available in both service and software models.



Scalable Operations

Supports sustainable growth over time.



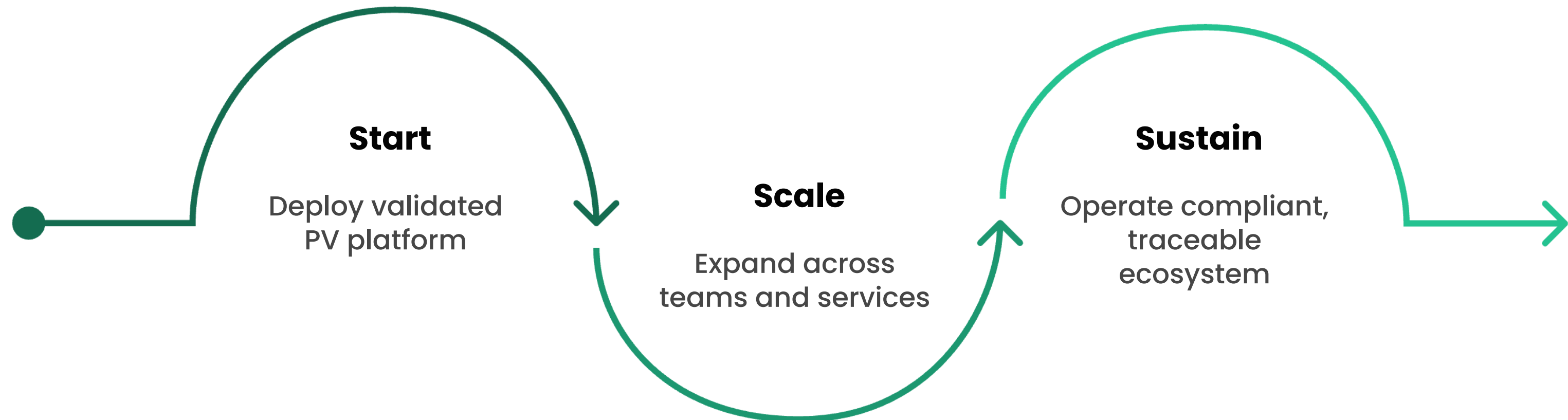
Audit Readiness

Helps maintain clearer, inspection-ready records.



A Model Built to Grow With You

PharmaSoft's ecosystem supports pharmaceutical companies at every stage of operational maturity, from initial platform deployment to long-term, enterprise-wide PV infrastructure.





A Growing Ecosystem Backed by Sector Expertise

PharmaSoft has built a growing pharmacovigilance technology ecosystem that supports both outsourced and in-house client models.

This gives pharmaceutical companies access to specialized digital infrastructure backed by practical sector expertise.





**Complex processes
need the right partner.**

Let Us Take Care!



Pharmacovigilance



Regulatory Affairs



Digital Solutions



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