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Case Study #4

*Pharmacovigilance
Department Setup for Emerging and
Early-Stage Pharmaceutical Companies*



*Smarter today,
Safer tomorrow.*



Pharmacovigilance Department Setup for Emerging and Early-Stage Pharmaceutical Companies

How PharmaSoft helps small and emerging pharmaceutical companies build a compliant pharmacovigilance foundation before full commercialisation begins.





Supporting Market Entry With Structure From the Start

This case reflects small and emerging pharmaceutical companies, including organisations still in the marketing authorisation application stage, that need a compliant pharmacovigilance structure from the very beginning of their market entry journey.

- **Small & Emerging Companies**

Pharmaceutical companies at an early stage of market presence in Türkiye.

- **Application-Phase Organisations**

Companies currently in the marketing authorisation application process.

- **No In-House PV Department**

Organisations without a fully established internal pharmacovigilance function.

- **Early PV Readiness Needed**

A need for structured pharmacovigilance readiness in the Türkiye market from the outset.



Pharmacovigilance Starts Before Commercialisation

Pharmacovigilance responsibilities do not begin only after market launch. In Türkiye, important obligations already arise during the marketing authorisation application phase, requiring companies to demonstrate core readiness before a full internal department is in place.

At this stage, companies are already expected to demonstrate core pharmacovigilance readiness.





A Ready-Made PV Structure Replaced Early Internal Burden



Weekly Local Literature Screening

Routine local literature surveillance performed in line with pharmacovigilance obligations.



PV Department Setup & Management

Practical support for establishing and managing a compliant pharmacovigilance function.



Local PV Role Assignment

Guidance for defining local responsible roles in line with regulatory expectations.



Application-Stage PV Documentation

Support for pharmacovigilance system information and related documentation during application phases.



Pre- & Post-Market Entry Readiness

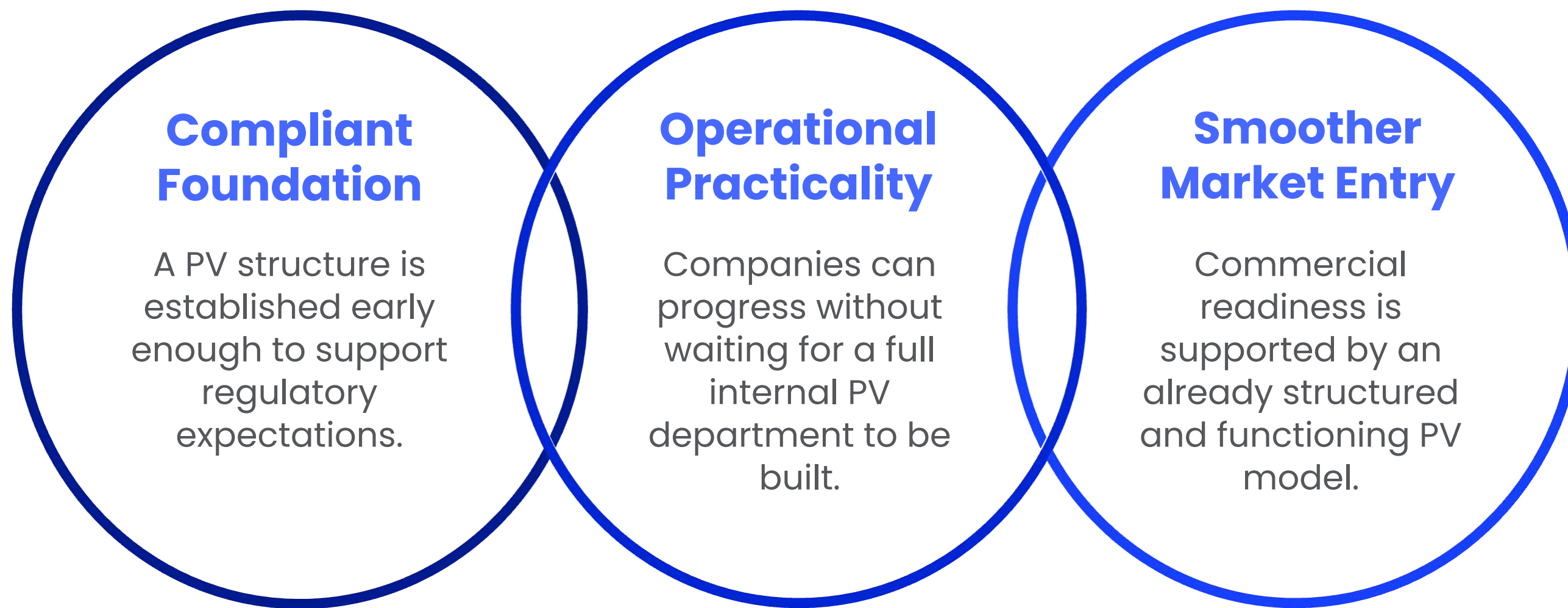
A practical PV framework supporting both application-stage needs and future commercial operations.

This model gives early-stage companies access to an established pharmacovigilance structure without building internal capacity prematurely.



Readiness Before Commercialisation

PharmaSoft enables early-stage and smaller pharmaceutical companies to build pharmacovigilance readiness before commercialisation, rather than reacting later under time pressure.





Key Takeaway

Early-Stage Support

PharmaSoft supports pharmaceutical companies from the earliest stages of market entry, including before full commercial operations begin.

Practical PV Infrastructure

Services include pharmacovigilance department support, literature screening, and regulatory-aligned PV operational setup.

Compliance Without Delay

Clients can establish pharmacovigilance readiness at the right time without waiting to build a full internal department first.

PharmaSoft helps emerging pharmaceutical companies enter the market with a more structured, compliant, and operationally ready pharmacovigilance foundation.



**Complex processes
need the right partner.**

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Pharmacovigilance



Regulatory Affairs



Digital Solutions



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