



PharmaSoft

Let Us Take Care!



DRUG
SAFETY



REGULATORY
EXCELLENCE



SMART
TECHNOLOGY



STRONG
PARTNERSHIPS



DATA DRIVEN
INSIGHTS

Case Study #6

*Project-Based Pharmacovigilance,
Regulatory, and Scientific Support
for In-House Teams*



*Smarter today,
Safer tomorrow.*



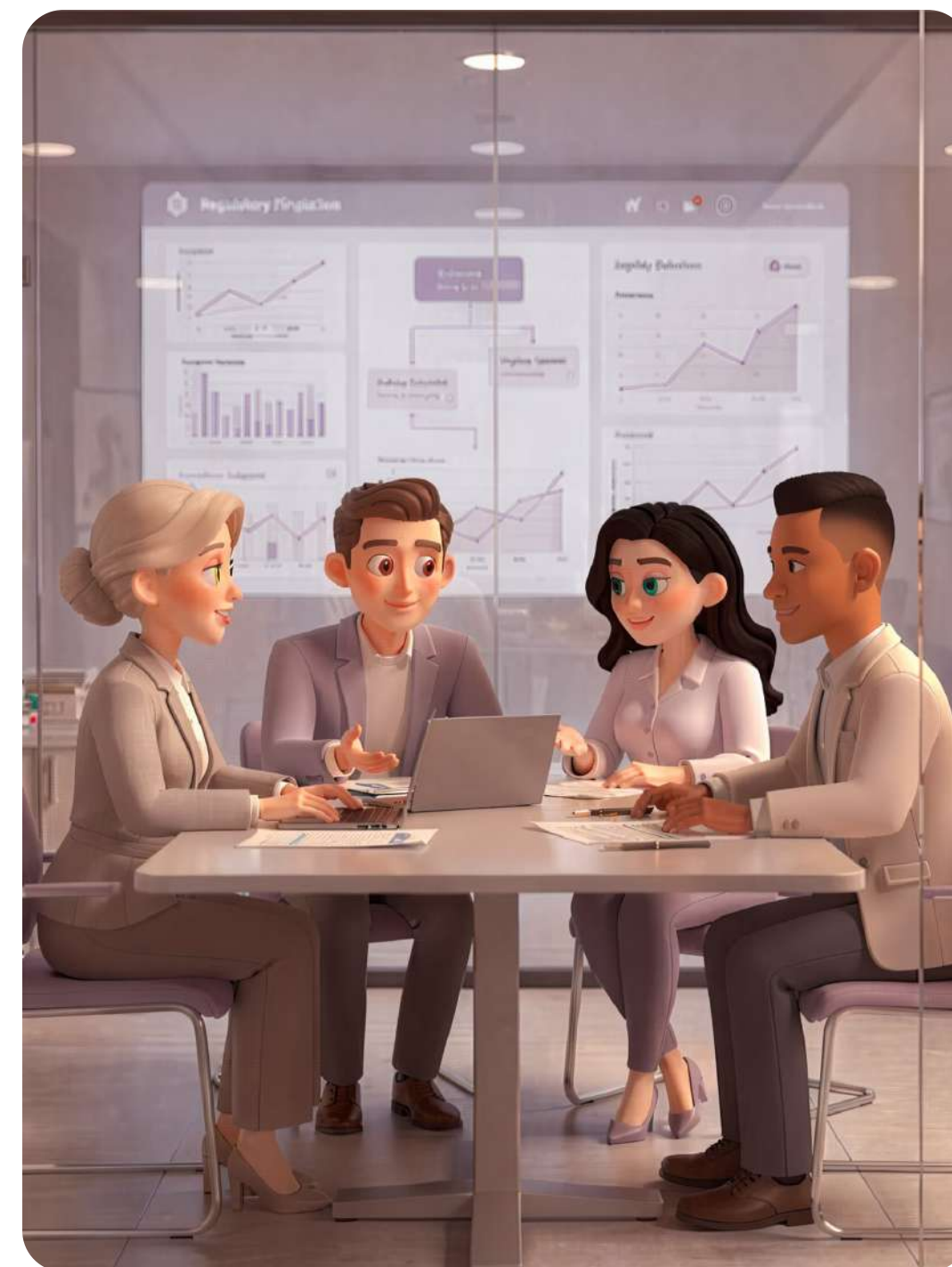
CASE STUDY

IN-HOUSE PV TEAMS

PROJECT-BASED SUPPORT

Project-Based Pharmacovigilance, Regulatory, and Scientific Support for In-House Teams

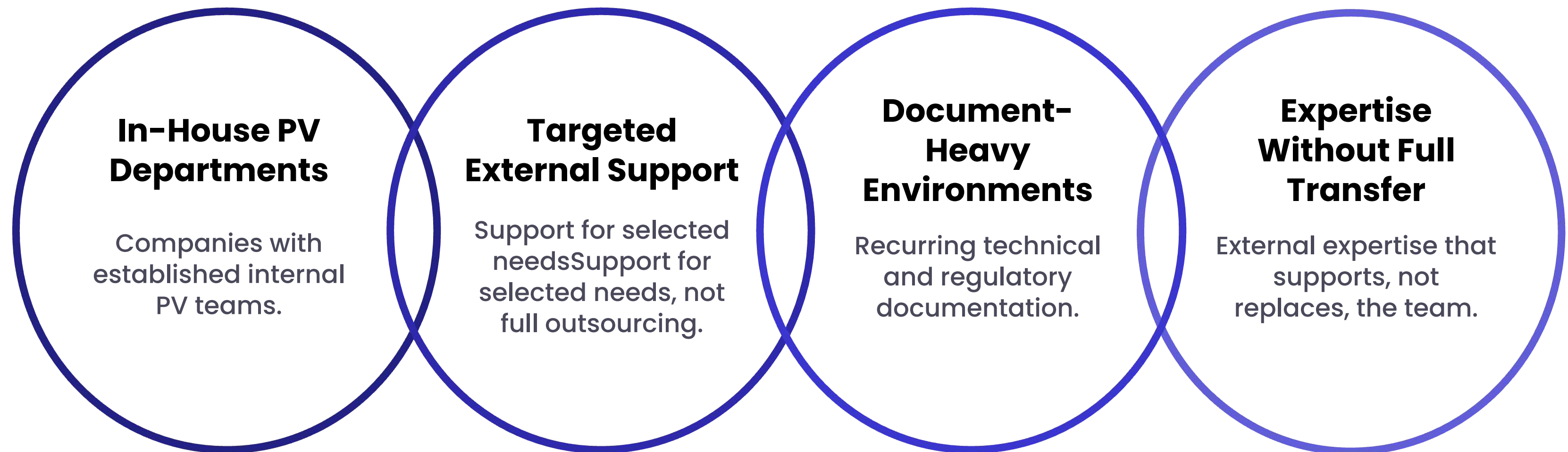
How PharmaSoft supports pharmaceutical companies with internal pharmacovigilance departments through targeted external expertise and specialist project support.





A Specialist Model for In-House Teams

This case reflects pharmaceutical companies with in-house pharmacovigilance teams that need targeted external support for specialised or workload-intensive activities. The need is support, not full outsourcing.



Internal ownership, external specialist support where it matters most.



Not Every Need Requires Full Outsourcing

Many pharmaceutical companies manage pharmacovigilance internally but still require external support for specialized and project-based needs across pharmacovigilance and regulatory affairs.

Specialised Deliverables

Certain outputs, such as PSURs, PBRERs, RMPs, and expert reports, require precise specialist handling.

Document-Heavy Projects

Dossiers, recurring reports, and scientific documentation can place significant pressure on internal capacity.

Flexible Support Needs

Some organizations need external support for selected activities without outsourcing the full function.

Cross-Functional Complexity

Project needs may extend across pharmacovigilance, regulatory, scientific, and training-related areas.



Specialist Support Across Key Workstreams

PharmaSoft's specialist support seamlessly integrates with your in-house pharmacovigilance and regulatory teams, covering a wide range of activities to manage peak workloads, deliver complex documents, and ensure ongoing compliance.

Pharmacovigilance & Safety

- Weekly literature screening
- Preparation of PYRDR, PSUR, PBRER, RMP, FSAD, and PSMF documents
- Medical device vigilance services
- Cosmetovigilance services

Scientific & Technical Documentation

- Addendum to Clinical Overview (AddCo) reports
- PDE and CTD expert report preparation
- CTD dossier preparation

Regulatory Affairs Support

- Local regulatory affairs & licensing services
- Variation submissions & renewal applications
- Post-approval maintenance & product registration

Training & Development

- Pharmacovigilance & regulatory affairs training programmes
- Specialised sector webinars
- Education initiatives via PharmaSoft ACADEMY



PharmaSoft ACADEMY: Targeted Education Initiatives

Through PharmaSoft ACADEMY, we empower pharmaceutical professionals with essential knowledge and skills, offering a range of specialised training programmes and platforms for collaborative learning.



**Pharmacovigilance
Trainings**



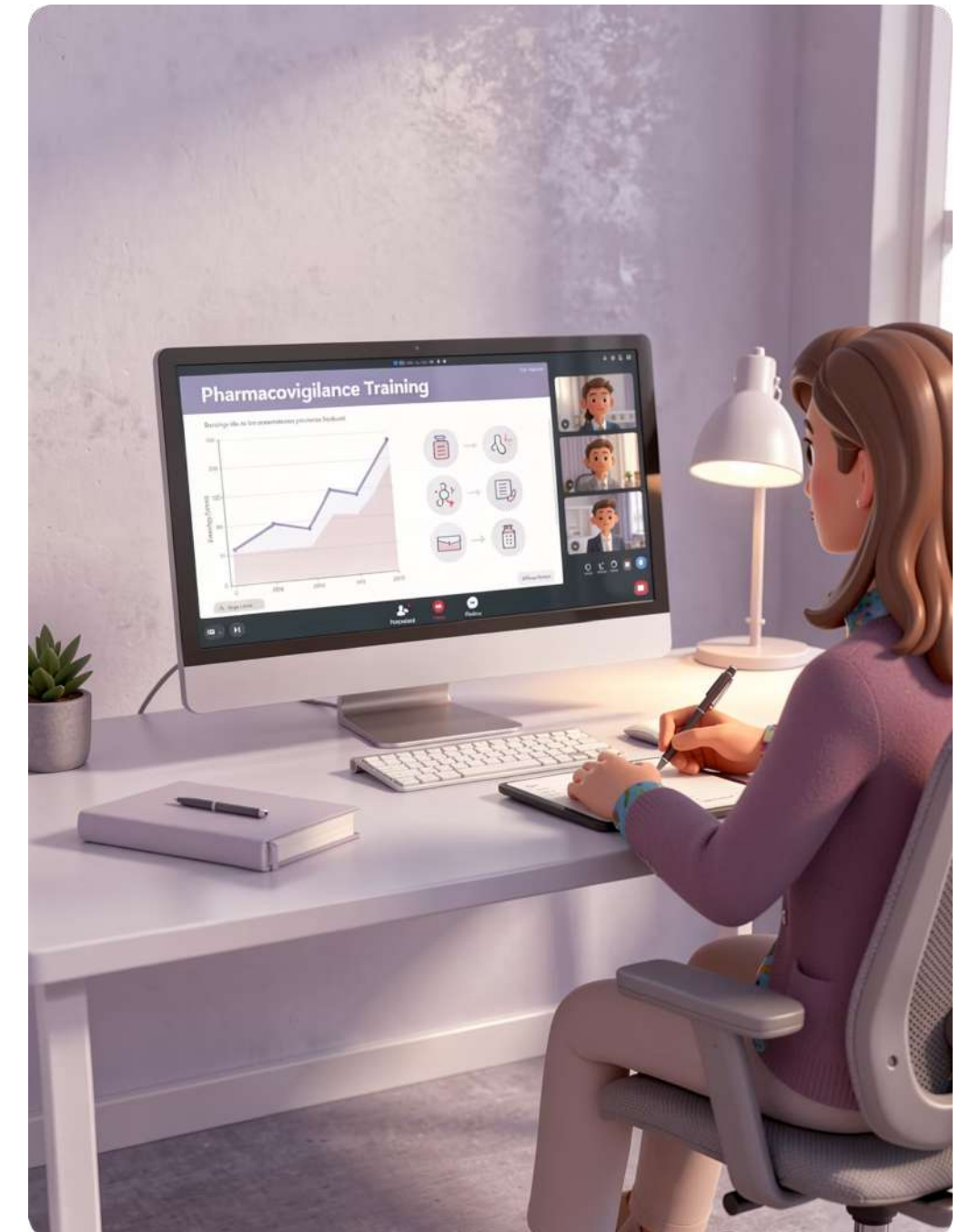
**Regulatory Affairs
Trainings**



**Specialised Sector
Webinars**



**Industry Education
Initiatives**



Impact

Local Community



Improving Access to MedDRA Training in Türkiye

PharmaSoft's commitment extends beyond direct client services, fostering growth within the broader pharmaceutical community.

2024 & 2026 MedDRA Istanbul

Contributed as host and co-host to MedDRA training events in Istanbul.

Wider Access

Bringing accredited MedDRA training closer to local participants.

Local Industry Benefit

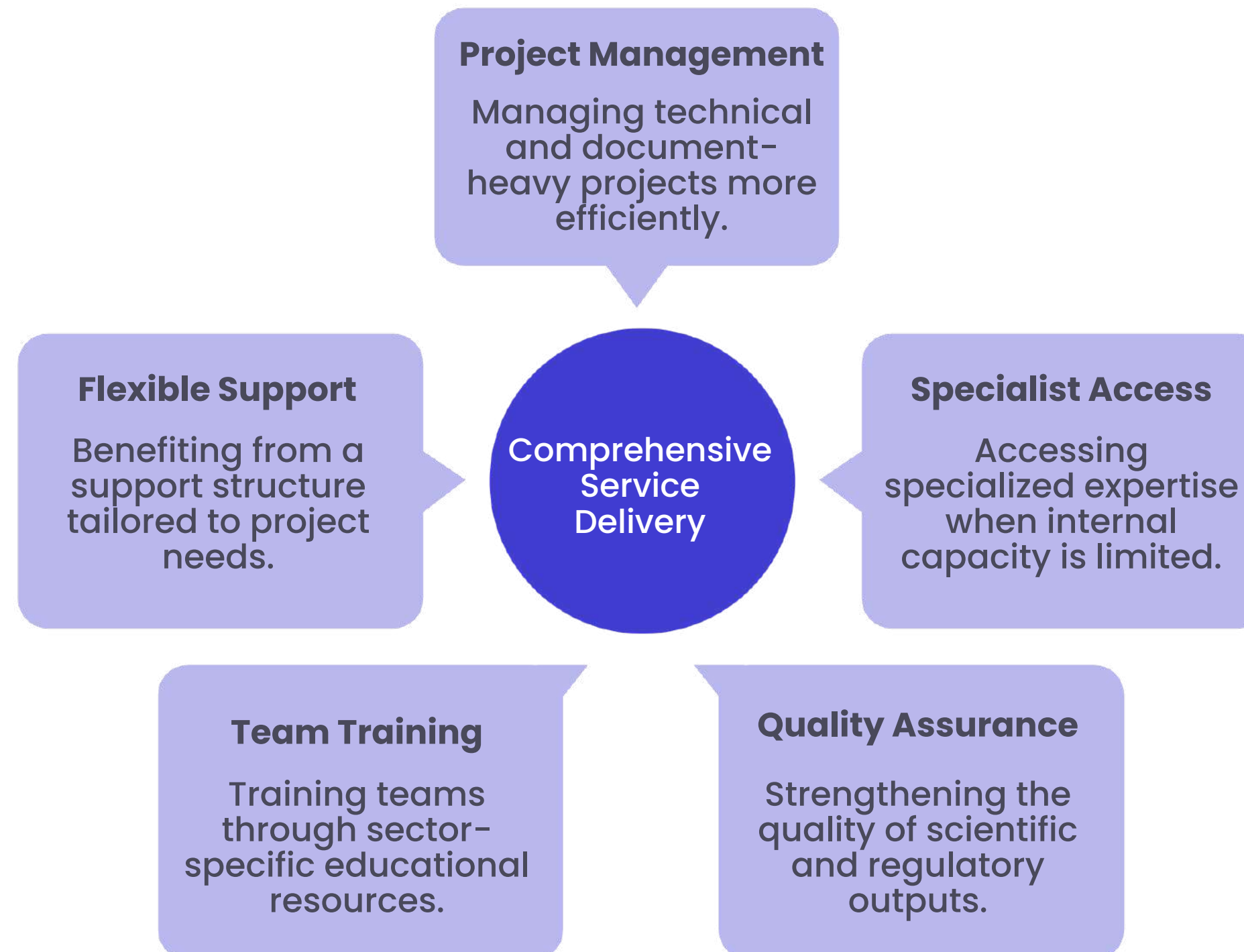
Contributing to sector knowledge beyond individual client work.

This initiative not only upskills local professionals but also demonstrates a sustainable model for industry education and development.



A Specialist Extension of the Internal Team

Companies gained access to specialized support exactly where it was needed, without outsourcing the full department.





PharmaSoft acts as a specialist extension of internal teams, combining in-house stability with expert external support.



Companies retain internal ownership while gaining access to specialised support where added expertise or capacity is needed.



Specialist Support Without Full Outsourcing

In-House Teams Remain Central

Internal teams stay in place, strengthened by targeted specialist support.

Project-Based Specialist Support

Support is delivered for selected scientific, regulatory, reporting, and training needs.

Expertise Without Full Outsourcing

Clients gain specialist support without transferring the full department function.

PharmaSoft strengthens in-house pharmacovigilance teams through flexible, project-based scientific, regulatory, and training support, tailored to real operational needs, delivered with specialist rigour.

Specialized expertise, without full departmental outsourcing.



**Complex processes
need the right partner.**

Let Us Take Care!



Pharmacovigilance



Regulatory Affairs



Digital Solutions



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