INFO SHEET

FORTREA PATIENT SAFETY SOLUTIONS (PSS)

End-to-end solutions in clinical trials, device and post-approval patient safety and pharmacovigilance (PV) services

Fortrea is your strategic collaborator, with decades of experience actively embracing your culture and driving your mission. At Fortrea Patient Safety Solutions (PSS), we streamline clinical safety management, delivering efficiency, consistency and compliance across all studies. You benefit from our holistic, fit-for-purpose solutions, enabling your data-driven development decisions. Fortrea PSS strives to be your one-stop solution provider from discovery to commercialization and beyond.

Why choose Fortrea PSS?

- Integrated Clinical Trial Signal Management (CTSM)—Proactive risk identification and mitigation
- End-to-end safety oversight—Tailored CT and pharmacovigilance strategies
- Dedicated safety professionals—Global regulatory intelligence acumen
- Data-driven insights—Metrics driven analytics for informed decision-making
- Mature team for smooth project delivery, customization and tailoring
- Global resource pool brings local proficiency
- Best practices/Lessons Learned incorporated
- Inspection readiness and audit support
- Seamless set-up, scale up with future focus
- Comprehensive safety technology provider

Experience Summary	
Total PV experience (years)	32+
Total PV clientele	150+
PV team including safety professionals	1,900+
Safety writing & risk management clientele	40+
Signal management clientele	15+
Annual cases processing volumes	900,000
Periodic safety reports authored	2,200
Annual call handling	100,000+
Type of safety reports	PADERs, PBRERs, CARs, PSURs, IND AR, RMP, DSURs, SBR
Type of signal detection	70% on single product; 30% across portfolio
Signal detection report types	90% periodic (3-6 monthly); 10% ad-hoc

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Advantages of collaborating with Fortrea for multiple studies

Managing your portfolio with Fortrea PSS enables efficiency and consistent delivery across all your studies.

Dedicated portfolio lead: Your studies are overseen by a dedicated Safety Portfolio Lead, delivering consistency and quality and one point of contact for seamless coordination.

Safety database: Fortrea Safety database allows for an unlimited number of studies, both clinical trial and post approval. Scalable, integrated system solutions optimizing budgets, faster timelines—streamlined workflows for quicker safety reporting and submissions.

Universal safety management plan—dedicated teams.

Customized safety solutions—for studies of any scale and complexity.

Regulatory and compliance support—proactive global regulatory alignment.

Real-time safety monitoring—continuous oversight for data integrity.

Training and consultation—empowering teams with safety best practices.

Submission efficiencies.

Quality focus.

What else can we offer?

Safety single service studies: Proven success managing studies where only safety services are outsourced to Fortrea Patient Safety.

Transition/rescue studies: History of success in transitioning ongoing studies and programs, at all phases and stages, to Fortrea Patient Safety.

FDA reporting: Comprehensive support for FDA safety submissions.

Biotech specialist: Experience with companies' first product to market, expanding geographies and subsequent launches with various options for deliveries and phased-approached, to suit unique needs.

EAP studies: Skillset extends to Expanded Access Program studies.

Clinical signal detection process: Proficient in advanced methodologies for detecting clinical signals.

Adjudication services: Offering includes robust adjudication processes for clinical trials.

Device studies: Providing specialized services for medical device studies.

Regulatory intelligence: Our dedicated regulatory intelligence team actively tracks and monitors regulatory intelligence for over 100 countries.

Post-approval safety services: We deliver ongoing safety monitoring and reporting post-approval.

LEARN MORE at fortrea.com

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