PATIENT SAFETY, INCLUDING PHARMACOVIGILANCE (PV)

Delivering efficient, technology-driven patient safety solutions.

Effective and efficient end-to-end patient safety solutions

With an integrated, global safety team of over 2,700 across 20 delivery centers, we provide end-to-end safety solutions that span the entire product life cycle of drugs, medical devices, combination products and vaccines from clinical phases through commercialization. Automation systems help drive increased operational efficiencies across the continuum, while 32+ years of experience and best practices provide quality and regulatory compliance.

Identifying risks and new safety signals while meeting regulatory requirements

At Fortrea, we strive to be more than just a partner. Our safety services support clients of all sizes, from small and medium-sized biotechs to large pharmaceutical companies. This is indicative of our ability to customize solutions for each clients' needs.

Fortrea's integrated safety team is strategically located at 20+ delivery centers around the world. Their expertise exists across multiple geographies to ensure the support of regulatory requirements for over 150 safety clients.

Over the past four years, we have achieved compliance metrics over 99%, which are supported by a strong history of both client audits and regulatory inspections.

Over 1 million cases were processed in 2021 alone, and Fortrea has not only achieved this through process efficiencies, but also through innovative automation technologies.

50+
Audits and regulatory inspections with no critical findings (past 7 years)

2,700+
Safety team of experienced professionals in 20 global offices

32+
Years of safety experience and best practices to ensure quality and regulatory compliance

99.5%
Regulatory compliance metrics (past 4 years)

Flexible patient safety solutions including single or full services in clinical and post-marketing

Our science and data is always inspired by patients. As a true "end-to-end" safety services provider, Fortrea offers both clinical and post-marketing safety services to support specific client needs — as a full safety service provider or with selected services to compliment a client's current safety team.

Current service offerings span medical contact centers, case processing, medical review, aggregate reporting and safety surveillance. When needs expand, Fortrea can adapt with experienced transition teams, allowing clients to focus on critical tasks.

Fortrea

Delivering more efficient safety operations through innovation, automation and artificial intelligence

At Fortrea, we are driven to deliver with urgency. Our team meets client needs and improves efficiencies with end-to-end safety solutions that include pharmacovigilance systems management and solutions, innovation and automation, and qualified persons for pharmacovigilance (QPPV) services for clients located in the European Union.

These additional offerings within safety can provide clients with efficiencies that are based on their unique situations. Technology options span from hosting a safety database through to automation for larger volumes and are just a few of the options we offer our clients.

Single or full safety services — clinical and/or post-marketing

Medical Contact Center	Case Processing	Medical Review	Aggregate Reporting	Safety Surveillance
AE reports	Triage/duplicate check	Medical triage and review of ICSRs/SAEs/ SUSARs	DSUR	IND safety rule
Medical information	Data entry - MedDRA coding - Narrative writing	Analysis of similar events (AoSE)	IND AR	Safety assessment committee
Product complaints	Pier review	Investigator communications as required	Clinical overviews	Active clinical surveillance and post-approval safety studies (PASS)
	Case validation and lock	Medical review of clinical trial safety data	Addendum to clinical overview	Risk management strategies including RMPs, REMS
	Submissions	Medical review of aggregate reports	Integrated safety summaries	Regulatory communications
	Literature monitoring and review	Signal detection	PADER/PSUR/PBRER/ CAR	
	Product complaints		Support with regulatory responses	

Meeting client needs and improving efficiencies with end-to-end safety solutions

PV Systems Management & Solutions	Innovation and Automation	QPPV Services for EU
Oracle® Argus Enterprise	Basic processing automation	QPPV support, deputy SPPV support
Systems integration & customization	Attended & unattended bots	Local responsible person for PV
Safety cloud services	Robotic process automation	Regulatory communications
Database migration & support	Integrated case management	Dossier submissions (PSMF, RMP, etc.)
Business intelligence & analytics	Cognitive automation	
Gateway implementation	Signal management tools	
Contact center hosting	Artificial intelligence	
	Literature process automation	

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