PHARMACOVIGILANCE GLOSSARY

S/N	ABBREVIATION	MEANING
1	ADR	Adverse Drug Reaction
2	AE	Adverse Event
3	aRMMs	Additional Risk Minimization Measures
4	Briefing Book	A briefing book is a document prepared to provide comprehensive information about the safety profile of a drug or medical product.
5	CCDS	Company Core Data Sheet
6	CIOMS	Council for International Organizations of Medical Sciences
7	CRO	Contract Research Organization
8	cRMP	Core Risk Management Plan
9	cSBRA	Core Structural Benefit Risk Assessment
10	CSR	Clinical Study Report
11	DMEC	Data Monitoring and Ethics Committee
12	DMPK	Drug Metabolism and Pharmacokinetics
13	Dossier	A dossier typically refers to a collection of documents compiled to provide

		detailed information about a medicinal product.
14	DSUR	Development Safety Update Report
15	FDA	U.S. Food and Drug Administration
16	GCP	Good Clinical Practice
17	IB	Investigator's Brochure
18	ICF	Informed Consent Form
19	ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
20	IND	Investigational New Drug
21	MAH	Marketing Authorization Holder
22	MedDRA	Medical Dictionary for Regulatory Activities
23	NDA	New Drug Application
24	REMS/ETASU	Risk Evaluation Mitigation Strategy/ Element to Assure Safe Use
25	PADER	Periodic Adverse Drug Experience Report
26	PBRER/PSUR	Periodic Benefit Risk Evaluation Report/Periodic Safety Update Report

27	PD	Pharmacodynamics
28	PK	Pharmacokinetics
29	PMS	Post-Marketing Surveillance
30	PRAC Request	Pharmacovigilance Risk Assessment Committee Request
31	Protocol	A protocol refers to a document that outlines the plan and procedures for conducting a specific pharmacovigilance activity or study.
32	RTQ/RFI	Request for Quotation/Request for Information.
33	QPPV	Qualified Person Responsible for Pharmacovigilance
34	SAE	Serious Adverse Event
35	SOP	Standard Operating Procedure
36	SPC	Summary of Product Characteristics
37	SUSAR	Suspected Unexpected Serious Adverse Reaction
38	TSR	Targeted Spontaneous Reporting
39	TEAE	Treatment-Emergent Adverse Event