

Glossary

TERM	DESCRIPTION
ADR	Adverse Drug Reaction
AE	Adverse Event
CAPA	Corrective and Preventative Actions
CASA	Civil Aviation Safety Authority
CI	Coordinating Investigator
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organisation
CTRA	Clinical Trial Research Agreement
CV	Curriculum Vitae
DCT	Decentralised Clinical Trials
DIL	Dear Investigator Letters
DSMB	Data and Safety Monitoring Board
DSURs	Development Safety Update Reports
EMR	Electronic Medical Record
E2E	End-to-End
GCP	Good Clinical Practice
HDEC	Health and Disability Ethics Committee
HRC	Health Research Council
IATA	International Air Transport Association
IB	Investigational Brochure
ICH	International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
IP	Investigational Product
IMD	Investigational Medicinal Device
IMP	Investigational Medicinal Product

Decentralised Clinical Trials NZ Glossary

TERM	DESCRIPTION
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
MEDSAFE	Medicines and Medical Devices Safety Authority
PI	Principal Investigator
PICF	Participant Information and Consent Form
PMS	Post Registration or Marketing Surveillance Study
PS	Primary Site
SAE	Serious Adverse Event
SCOTT	Standing Committee on Therapeutic Trials
SIV	Site Initiation Visit
SMF	Study Master File
SSA Form	Site Specific Assessment Form
SSI	Significant Safety Issue
SS	Satellite Site
SI	Sub Investigator
SUSAR	Suspected Unexpected Serious Adverse Reaction