Clinical Trial Acronyms and Abbreviations

While conducting clinical trials, you will encounter a multitude of acronyms and abbreviations. Here is a list of some of the more common ones.

ADaM	Analysis Data Model (statistics standard)
ADE	Adverse Device Effect
ADR	Adverse Drug Reaction
AE	Adverse Event
AI	Associate Investigator
ALCOA	Attributable, Legible, Contemporaneous, Original, Accurate
ANZCTR	Australia and New Zealand Clinical Trials Registry
AR	Adverse Reaction
ARTG	Australian Register of Therapeutic Goods
ASR	Annual Safety Report
CAP	Consumer Advisory Panel
CAPA	Corrective and Preventative Action
CDA	Confidentiality Disclosure Agreement
CDASH	Clinical Data Acquisition Standards Harmonisation (statistics standard)
CDISC	Clinical Data Interchange Standards Consortium
CI	Chief-Investigator
CMO	Contract Manufacturing Organisation
COA	Clinical Outcome Assessments
Co-I	Co-Investigator
COV	Close-Out Visit
CPI	Coordinating Principal Investigator
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organisation
CSO	Contract Safety Organisation
CRN	Clinical Research Nurse
CSR	Clinical Study Report
CT	Clinical Trial
CTA	Clinical Trial Approval (scheme) – previously Clinical Trial Exemption (CTX)
CTAC(P)	Clinical Trials Advisory Committee (or Panel)
CTC	Clinical Trial Co-ordinator
CTCAE	Common Terminology Criteria for Adverse Events
CTMS	Clinical Trial Management System
CTN	Clinical Trial Notification (Scheme)
DAEN	Database of Adverse Event Notifications – medicines or devices
DCF	Data Correction Form
DCT	Decentralised Clinical Trial

DLT	Dose Limiting Toxicity
DM	Data Manager
DMP	Data Management Plan
DOA	Delegation of Authority
DSMC(B)	Data Safety Monitoring Committee (or Board)
DSUR	Development Safety Update Report
EC	Ethics Committee
eCOA	Electronic Clinical Outcome Assessments
eCRF	Electronic Case Report Form
eSource	Electronic Source Data
ED	Essential Documents
EDC	Electronic Data Capture
EMA	European Medicines Agency
EMR	Electronic Medical Record
EOS	End of Study
ePRO	Electronic Patient-Reported Outcomes
eTMF	Electronic Trial Master File
EU	European Union
EMR	Electronic Medical Records
FDA	Food and Drug Administration
FIH	First in Human
FPI	First Patient In
FPFV	First Patient First Visit
GCDMP	Good Clinical Data Management Practice
GCP	Good Clinical Practice
GDP	Good Documentation Practice
GDRP	General Data Protection Regulation
GLNR	Greater than Low Risk
GLP	Good Laboratory Practice
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practice
GVP	Good Pharmacovigilance Practice
HCP	Health Care Provider
HIPAA	Health Insurance Portability and Accountability Act
HREA	Human Research Ethics Application
HREC	Human Research Ethics Committee
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDMC	Independent Data Monitoring Committee
IIT	Investigator Initiated Trial
IP	Investigational Product
IMD	Investigational Medicinal Device
IMP	Investigational Medicinal Product

IMV	Interim Monitoring Visit
IND	Investigational New Drug
IVRS	Interactive Voice Recognition System
IRB	Institutional Review Board
ISF	Investigator Site File
LHD	Local Health District
LNR	Low and Negligible Risk
LOI	Letter of Intent
LPLV	Last Patient Last Visit
MD	Medical Device
MMP	Medical Monitoring Plan
MP	Monitoring Plan
MRI	Medical Resonance Imaging (scan)
MTA	Material Transfer Agreement
NCTGF	National Clinical Trials Governance Framework
NDA	New Drug Application
NIH	National Institutes of Health (US)
NMA	National Mutual Acceptance
NHMRC	National Health and Medical Research Council
OGTR	Office of Gene Technology Regulator
PHA	Public Health Act
PHI	Protected Health Information
PHO	Public Health Organisation
PI	Principal Investigator
PICF	Patient Information Sheet and Consent Form
PIS	Patient Information Sheet
PK	Pharmacokinetic
PD	Pharmacodynamic
PSQV	Pre-Study Qualification Visit
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
QOL	Quality of Life
QRM	Quality Risk Management
RA	Research Associate
RCA	Root Cause Analysis
RCT	Randomised controlled trial
RBM	Risk Based Monitoring
REGIS	Research Ethics and Governance Information System (NSW & ACT)
RGO	Research Governance Office
RWD(E)	Real World Data (or Evidence)
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Effect

SAR	Serious Adverse Reaction
SaMD	Software as a Medical Device
SC	Study Coordinator
SDTM	Study Data Tabulation Model (statistics standard)
SDV	Source Document Verification
SIV	Site Initiation Visit
SMP	Safety Monitoring Plan
SOA	Schedule of Assessments
SOC	Standard of Care
SOP	Standard Operating Procedure
SQV	Site Qualification Visit
Sub-I	Sub Investigator
SSI	Significant Safety Issue
SSU	Study Start Up
SSV	Site Selection Visit
SMF	Site Master File
SOP	Standard Operating Procedure
SSA (STE)	Site Specific Assessment (Research Governance application)
SUSAR	Serious Unexpected Suspected Adverse Reaction
TGA	Therapeutic Goods Administration
TLF	Tables, listings and figures (used in clinical study reports)
TMF	Trial Master File
Tx	Treatment
USADE	Unanticipated Serious Adverse Device Effect
UADR	Unexpected Adverse Drug Reaction
USM	Urgent Safety Measure
WHO	World Health Organization

Definitions for some of these acronyms, and other commonly used terms, can be found here: https://vcccalliance.org.au/research/clinical-trial-innovations/investigator-initiated-trials/glossary/

References

https://www.tga.gov.au/resources/acronyms-and-glossary-terms

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