CLINICAL TRIALS & ABBREVIATIONS

ADR: Adverse Drug Reaction.
AE: Adverse Event
AR: Adverse Reaction
BD: Business Development
CA: Competent Authority
CDMS: Clinical Data Management System
CO: Clinical Operations
COV: Close Out Visit
CPM: Clinical Project Manager
CRA: Clinical Research Associate
CRF: Case Report Form
CTA: Clinical Trial Assistant
CTD: Clinical Trials Directive
CTMS: Clinical Trial Management System.
DAF: Data Amendment Form
DBA: Database Administrator
DCF: Data Clarification Form
DM: Data Management
DMPM: Data Management Project Manager
DQF: Data Query Form
DSMB: Data Safety Monitoring Board
EC: European Commission
ECG: electrocardiogram
eCRF: electronic case report form
EDC: Electronic Data Capture
EMEA: European Medicines Evaluation Agency
EU: European Union.
EudraCT: European Clinical Trials Database
Eudravigilance: European Union Pharmacovigilance Database
EVCTM: Eudravigilance Clinical Trials Module
FDA: Food & Drug Administration (USA)
FL: Functional Lead.
GCP: Good Clinical Practice
GLP: Good Laboratory Practices
GMP: Good Manufacturing Practice
HMA: Head of Medical Affairs
IATA: International Air Transport Association
IB: Investigator's Brochure
ICF: Informed Consent Form
ICH: International Conference on Harmonisation
ICMJE: International Committee of Medical Journal Editors
IDB: Investigator's Drug Brochure
IDPCF: Investigator Data Protection Consent Form
IEC: Independent Ethics Committee
IMP: Investigational Medicinal Product
IND: Investigational New Drug
IP: Investigational Product
IRB: Institutional Review Board
ISF: Informatore Scientifico del Farmaco
IVRS: Interactive Voice Response System
KOM: Kick-Off Meeting
MA: Medical Affairs
MM: Medical Monitor
MW: Medical Writing
PI: Principal Investigator
PM: Project Manager
PRA: Pharmaceutical Research Associate
PSV: Pre-Study Visit
QA: Quality Assurance
QC: Quality Control
QP: Qualified Person
QR: Quality Review
SAE: Serious Adverse Event
SDV: Source Data Verification
SDR: Source Document Review
SIS: Subject Information Sheet
SIV: Site Initiation Visit
SMV: Site Monitoring Visit
SOP: Standard Operating Procedure
SOW: Scope of Work
SSAR: Suspected Serious Adverse Reaction
SSP: Study Specific Procedure
SUSAR: Suspected Unexpected Serious Adverse Reaction
WP: Working Procedure