Acronyms, Abbreviations, and Initials

Version 9.0

AAAS American Association for the Advancement of Science

AABB American Association of Blood Banks

AADA Abbreviated Antibiotic Drug Application (FDA) (used primarily for generics)

AAMC Association of American Medical Colleges

AAPS American Association of Pharmaceutical Scientists

ABPI Association of the British Pharmaceutical Industry

ACCP American College of Clinical Pharmacology

ACDM Association for Clinical Data Management (UK)

ACE angiotensin-converting enzyme

ACIL A national trade association representing independent, commercial scientific, and engineering firms

ACPU Association of Clinical Pharmacology Units

ACRA Associate Commissioner for Regulatory Affairs (FDA)

ACRP Association of Clinical Research Professionals (formerly Associates in Clinical Pharmacology, ACP)

ACRPI Changed its name to ICR—Institute of Clinical Research (UK)

ACT *Applied Clinical Trials* magazine

ACTG AIDS Clinical Trials Group (NIAID)

ACTU AIDS Clinical Trials Unit (NIH)

ADaM Analysis Data Model (a CDISC standard)

ADE Adverse Drug Event; Adverse Drug Effect

ADME absorption, distribution, metabolism, and excretion (used to describe pharmacokinetic processes)

ADR adverse drug reaction

AE adverse event

AEGIS ADROIT Electronically Generated Information Service, a subscription service that provides subscribing organizations with access to adverse drug reaction data from the Medicines Control Agency's ADROIT (Adverse Drug Reaction On-line Information Tracking) database

AERS Adverse Event Reporting System (FDA)

AFMR American Federation for Medical Research, formerly the American Federation for Clinical Research (AFCR)

AHA American Heart Association

AHCPR Agency for Healthcare Policy Research (NIH)

AHIC American Health Information Community. A US government-charted commission providing input and recommendations to HHS on how to make health records digital and interoperable, and assure the privacy and security of those records (HITSP)

AICRC Association of Independent Clinical Research Contractors (UK)

AIDS acquired immune deficiency syndrome, acquired immunodeficiency syndrome

ALCOA attributable, legible, contemporaneous, original, accurate (dimensions of data integrity)

am ante meridian, morning (12:00 midnight thru 11:59:59)

AMA American Medical Association

AMC antibody-mediated cytotoxicity

AmFAR American Foundation for AIDS Research

AMG Arzneimittelgesetz (German Drug Law)

AMWA American Medical Writers Association

ANDA Abbreviated New Drug Application (for a generic drug)

ANOVA analysis of variance (statistics)

ANSI American National Standards Institute

AOAC Association of Official Analytical Chemists

APB Association Pharmaceutique Belge (Belgium)

APhA American Pharmacists Association

API active pharmaceutical ingredient

APPI Academy of Pharmaceutical Physicians and Investigators

ARCS Association of Regulatory & Clinical Scientists (Australia)

ARO academic research organization

ASAP administrative systems automation project (FDA)

ASCII American Standard Code for Information Interchange (computer files)

ASCPT American Society for Clinical Pharmacology and Therapeutics

ASP application service provider delivering a computer application via the www

ASQ American Society for Quality, formerly American Society for Quality Control

ATC Anatomic-Therapeutic-Chemical Coding dictionary

AUC area under the curve (statistics)

BARQA British Association of Research Quality Assurance

BCE beneficial clinical event

BDPA Bureau of Drug Policy and Administration (China)

BEUC European Bureau of Consumer Unions

BfArM Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices, Germany)

BGA Bundesgesundheitsamt (Federal health office; former German public health agency)

BGVV Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin (Federal Institute for Health Protection of Consumers and Veterinary Medicine, Germany)

BIO Biotechnology Industry Organization

BIRA British Institute of Regulatory Affairs

BLA Biologics License Application (FDA)

BPI Bundesverband der Pharmazeutischen Industrie EV (Germany)

BrAPP British Association of Pharmaceutical Physicians

BRIDG Biomedical Research Integrated Domain Group

BSA body surface area

C3C China CDISC Coordinating Committee

CA Competent Authority (regulatory body charged with monitoring compliance with European Union member state national statutes and regulations)

caBIG Cancer Biomedical Informatics Grid

caCORE Cancer Common Ontologic Resource Environment

caDSR Cancer Data Standards Repository and toolset maintained by NCI

CAPRA Canadian Association of Professional Pharmaceutical Regulatory Affairs (also ACPR Association canadienne des professionnels en réglementation)

CAS Chemical Abstracts Service

CBER Center for Biologics Evaluation and Research (FDA)

CBIIT Center for Biomedical Informatics and Information Technology

CCI Committee on Clinical Investigations. *See also Ethics Committee box in the Glossary.*

CCPPRB Comité Consultative pour la Protection des Personnes dans les Recherches Biomédicales (France). *See also Ethics Committee box in the Glossary.*

CCRA Certified Clinical Research Associate. Certification issued to monitors by ACRP.

CCRC Certified Clinical Research Coordinator. Certification issued to clinical coordinators by ACRP.

CCRP Certified Clinical Research Professional. SoCRA certification of coordinators, monitors, and other research professionals

CCSI Company Core Safety Information

CDA Clinical Document Architecture (HL7)

CDASH Clinical Data Acquisition Standards Harmonization (a 2006 CDISC initiative)

CDC Centers for Disease Control and Prevention

CDE common data element

CDER Center for Drug Evaluation and Research (FDA)

CDISC Clinical Data Interchange Standards Consortium

CDM clinical data management

CDMS clinical data management system

CDRH Center for Devices and Radiological Health (FDA)

CEN Comité Européen de Normalisation (European Committee for Standardization)

CEU Continuing Education Unit

CF consent form

CFR Code of Federal Regulations (usually cited by title and part; for example, Title 21, Part 211 is shown as 21 CFR 211)

cGMP current good manufacturing practices

CHI Consolidated Health Informatics. CHI began as an eGov initiative to establish a portfolio of existing health information interoperability standards (health vocabulary and messaging) enabling all agencies in the federal health enterprise to "speak the same language" based on common enterprise-wide business and information technology architectures. CHI is currently managed under the Office of the National Coordinator for Health Informational Technology's (ONC) Federal Health Architecture (FHA) Program Management Office. Ref: The United States Health Information Knowledgebase [USHIK]. (HITSP)

CHR Committee on Human Research. *See also Ethics Committee box in the Glossary.*

CIC clinical imaging center

CIOMS Council for International Organizations of Medical Sciences (postapproval international ADR reporting, UK)

CIP Certified IRB Professional

CIS Commonwealth of Independent States

CLIA Clinical Laboratory Improvement Amendments

Cmax concentration maximum; used in pharmacokinetics and bioequivalence to indicate maximum plasma concentration for a drug

CMC chemistry, manufacturing, and control

CME Continuing Medical Education

CMS Centers for Medicare & Medicaid Services

CNS central nervous system

CONSORT Consolidated Standards of Reporting Trials

COP CDISC Operating Process/Procedure

CORE CDISC Operational Roadmap Environment (CDISC)

COSTART Coding Symbols for a Thesaurus of Adverse Reaction Terms. *See also MedDRA.*

CPHS Committee for the Protection of Human Subjects

CPMP Committee for Proprietary Medicinal Products (EU)

CPSC Consumer Product Safety Commission (US)

CRA clinical research associate. *See also CCRA.*

CRADA Cooperative Research And Development Agreement (with US Government entities such as FDA or NIH)

CRB case record book

CRB Central Review Board

CRC clinical research coordinator. *See also CCRC, SC, SSC.*

CRF case report form (sometimes case record form)

CRIX Clinical Research Information Exchange

CRO contract research organization. *See also IPRO.*

CRT Case Report Tabulation

CSDD Center for the Study of Drug Development (Tufts)

CSF Collaborative Standards Forum (CDISC)

CSF cerebrospinal fluid

CSF colony stimulating factor

CSM Committee on Safety of Medicines (UK)

CSO Consumer Safety Officer (FDA)

CSR clinical study report

CSU clinical supply unit

CSUICI (replaces CSUCT) Computerized Systems Used In Clinical Investigations. NOTE: usually pronounced "seesweecy."

CT clinical trial

CTA Clinical Trial Agreement

CTC Clinical Trial Certificate (UK)

CTCAE Common Terminology Criterion for Adverse Events. Standard terminology developed to report adverse events occurring in cancer clinical trials. CTCAE are used in study adverse event summaries and Investigational New Drug (IND) reports to the Food and Drug Administration. The CTCAE contain a grading scale for each adverse event term representing the severity of the event. (NCI)

CTD Common Technical Document

CTEP Cancer Therapy Evaluation Program

CTM clinical trials materials

CTX Clinical Trial Exemption (MCA)

CUI common unique identifier. A code used in the Enterprise Vocabulary System (EVS) to link a particular concept across one or more terms.

CV curriculum vitae

CVM Center for Veterinary Medicine (FDA)

DAWN Drug Abuse Warning Network

DCGI Drugs Controller General of India (Indian regulatory authority)

DD Department of Drugs (Swedish regulatory agency)

DDF Data Definition File

DDI drug–drug interaction

DEA Drug Enforcement Administration (US)

DEN Drug Experience Network

DES Data Encryption Standard

DESI Drug Efficacy Study Implementation notice (FDA, to evaluate drugs in use before 1962)

DGPharMed Deutsche Gesellschaft für Pharmazeutische Medizin (German Society of Pharmaceutical Medicine), formerly FÄPI

DHHS Department of Health and Human Services (US)

DHTML Dynamic HTML (IT)

DIA Drug Information Association

DIBD Development International Birth Date. Analogous to the International Birth Date (IBD) for a PSUR, defined as the date of first marketing approval, worldwide. [Ref: ICH E2F – Development Safety Update Report]

DICOM Digital Imaging and Communications in Medicine

DITA Darwin Information Typing Architecture

DLT dose-limiting toxicity

DMB Data Management Biomedical (France)

DPC-PTR Act Drug Price Competition and Patent Term Restoration Act of 1984 (also Waxman-Hatch or Hatch-Waxman bill)

DSI Division of Scientific Investigations (FDA)

DSM Diagnostic and Statistical Manual (of the American Psychiatric Association)

DSMB data safety monitoring board

DSNP Development of Standardized Nomenclature Project (FDA)

DST daylight saving time

DSTU Draft Standard for Trial Use. *See HL7 definition*.

DSUR Development Safety Update Report (ICH)

DTC direct-to-consumer (drug advertising)

DTD Document Type Definition (XML)

E3C European CDISC Coordinating Committee

EAB Editorial Advisory Board (*Applied Clinical Trials*)

EAB Ethical Advisory Board. *See also Ethics Committee in the Glossary.*

EC ethics committee. *See also Ethics Committee in the Glossary.*

EC European Commission (in documents older than the mid-1980s, EC may mean European Community)

ECG electrocardiogram

ECG European CDISC Group

ECJ European Court of Justice

ECOG Eastern Cooperative Oncology Group (US)

ECPHIN European Community Pharmaceutical Information Network

eCRF electronic case report form

ECRIN European Clinical Research Infrastructures Network

eCTD electronic common technical document

EDC electronic data capture/collection

EDI electronic data interchange

eDT Electronic Data Transfer

eDMS electronic data management system

EDR electronic document room. NOTE: The EDR is an extension of the e-Submissions central document room. A check is performed on each submission sent to the EDR for file formats used and the integrity of bookmarks and hypertext links.

EEC European Economic Community, now EU; some regulatory documents still have EEC document numbers.

EFGCP European Forum for Good Clinical Practice

EFPIA European Federation of Pharmaceutical Industries and Associations

EFTA European Free Trade Association

eHR electronic health record

EIR Establishment Inspection Report (FDA)

ELA Establishment License Application (FDA)

EMA European Medicines Agency

EMWA European Medical Writers Association

EORTC European Organization for Research and Treatment of Cancer

EP European Parliament

EPAR European Public Assessment Report

EPO European Patent Office; erythropoietin

EPRG European Pharmacovigilance Research Group

ER Essential Requirements (EMA)

ERSR electronic regulatory submissions and review (FDA's e-Submissions processing group)

eRX electronic prescribing

eSDI electronic Source Data Interchange

eSR Electronic Source Record. (*see eSource*)

ESRA European Society of Regulatory Affairs

ESTRI Electronic Standards for the Transfer of Regulatory Information (ICH)

EU European Union

EUDRA European Union Drug Regulatory Authorities

EudraCT European Union clinical trials database

EVS Enterprise Vocabulary Services (National Cancer Institute)

EWG expert working group

FAQ frequently asked questions

Farmindustria The Association of Italian Pharmaceutical Manufacturers

FD&C Act Food, Drug, and Cosmetic Act (US)

FDA Food and Drug Administration (US)

FDAAA Food and Drug Administration Amendment Act (pronounced fedaahh or fedah-ah)

FDAMA FDA Modernization Act

FDLI Food and Drug Law Institute

FFPM Fellow of the Faculty of Pharmaceutical Medicine (UK)

FIPS Federal Information Processing Standards

FISMA Federal Information Security Management Act

FRCP Fellow of the Royal College of Physicians, sometimes followed by a place name—for example, FRCP (Edin.)—that indicates a university medical school

FTC Federal Trade Commission (US)

FTP File Transfer Protocol

FWA Federalwide Assurance

GAO Government Accountability Office (US government)

GBP good business practice

Gbps gigabits, or billions of bits per second (data transmission)

GCP good clinical practice

GCRP good clinical research practice

GLP good laboratory practice

GMP good manufacturing practices

GMT Greenwich mean time. *See UTC.*

GP general practitioner; general practice (UK)

GPMS good postmarketing surveillance practice (Japan)

GRAS generally regarded as safe (foods)

GRP good review practice (CDER)

GXP good (pharmaceutical) practice

HA health authority (UK)

HCFA Healthcare Financing Administration; now renamed The Centers for Medicare & Medicaid Services (CMS)

HEX Human Experimentation Committee. *See also Ethics Committee box in the Glossary.*

HHS Department of Health and Human Services (US, also called DHHS)

HIE Health Information Exchange. The mobilization of healthcare information electronically across organizations within a region or community. HIE provides the capability to electronically move clinical information between disparate healthcare information systems, while maintaining the meaning of the information being exchanged. The goal of HIE is to facilitate access to, and retrieval of, clinical data to provide safer, more timely, efficient, effective, equitable, and patient-centered care. (HITSP)

HIMA Health Industry Manufacturers Association

HIMSS Healthcare Information and Management Systems Society (pronounced hymns)

HIPAA Health Insurance Portability and Accountability Act

HIT health information technology

HITSP Health Information Technology Standards Panel (pronounced hitspee)

HL7 Health Level 7 (a not-for-profit ANSI-accredited standards developing/development organization [SDO])

HPB Health Protection Branch, Laboratory Centre for Disease Control (Canada); has been superseded by Health Canada

HPLC high performance liquid chromatography

HSRC Human Subjects Review Committee. *See also Ethics Committee box in the Glossary*.

HTML Hypertext Markup Language

HTTP Hypertext Transfer Protocol

I3C India CDISC Coordinating Committee

IAB Industry Advisory Board (for CDISC)

IB investigator's brochure

IC informed consent

ICD9 International Classification of Diseases, 9th revision. *See also MedDRA*.

ICF informed consent form

ICG India CDISC Group

ICH International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

ICR Institute of Clinical Research (formerly ACRPI, Association for Clinical Research in the Pharmaceutical Industry, UK)

ICSR individual case safety report

ICTH International Committee on Thrombosis and Haemostasis

ICTRP International Clinical Trials Registry Platform (WHO)

IDE Investigational Device Exemption Application to CDRH to get permission for investigational device testing in clinical trials

IEC independent ethics committee. *See also Ethics Committee box in the Glossary.*

IEEE Institute of Electrical and Electronic Engineers, Inc.

IFAPP International Federation of Associations of Pharmaceutical Physicians

IFPMA International Federation of Pharmaceutical Manufacturers and Associations

IG Inspector General (HHS)

IHE Integrating the Healthcare Enterprise (an international standards organization)

IHI Institute for Healthcare Improvement

IKS Interkantonale Kontrollstelle für Heilmittel (Switzerland)

IMI Innovative Medicines Initiative (European Commission)

IMP investigational medicinal product; investigational materials plan

IMPD Investigational Medicinal Product Dossier (EUDRA)

IND Investigational New Drug application (FDA). *See also TIND.*

INN International Nonproprietary Name

IOM Institute of Medicine (National Academy of Science, US)

IPRO independent pharmaceutical research organization. *See also CRO.*

IRB institutional review board; independent review board. *See also Ethics Committee box in the Glossary.*

IRD international registration document

IS International System of Units (may also be referred to as SI—Systéme Internationale)

ISCB International Society for Clinical Biostatistics

ISDN Integrated Services Digital Network

ISO International Organization for Standardization

ISOQOL International Society for Quality of Life Research

ISP Internet service provider

IT information technology

ITU-T International Telecommunication Union—Telecommunication Standardization Sector

IUPAC International Union of Pure and Applied Chemistry

IVD in vitro diagnostics

IVRS interactive voice response system

J3C Japan CDISC Coordinating Committee

JCAHO Joint Commission on Accreditation of Healthcare Organizations

JCG Japan CDISC Group

JMA Japan Medical Association

JPMA Japan Pharmaceutical Manufacturers Association

Kbps kilobits, or thousands of bits per second (data transmission)

KFDA Korean Food and Drug Administration

LAB Laboratory Data Model (CDISC)

LAN local area network

LIF Swedish Pharmaceutical Industry Association

LKP Leiter der Klinischen Prüfung

LOA letter of agreement

LOINC logical observations, identifiers, names, and codes

LREC local research ethics committee (UK). *See also Ethics Committee box in the Glossary.*

MA marketing authorization

MAA Marketing Authorisation Application (EMA, EU)

MAH Marketing Authorisation Holder (EU)

MaPP Manual of Policies and Procedures (CDER)

Mbps megabits, millions of bits per second (data transmission)

MDR medical device reporting

MedDRA Medical Dictionary for Regulatory Activities (new global standard medical terminology designed to supersede other terminologies used in the medical product development process, including COSTART, ICD9, and others)

MedID Medicinal Product Identifier

MEDLARS Medical Literature Analysis and Retrieval System

MEFA Association of the Danish Pharmaceutical Industry

MEP Member of the European Parliament

MHLW Ministry of Health, Labor and Welfare (Japan)

MHRA Medicines and Healthcare products Regulatory Agency (UK)

MIAME minimum information about a microarray experiment (standard for microarray data)

MOH Ministry of Health (UK, Canada, others)

MOPH Ministry of Public Health (Thailand, Yemen, others)

MOU memorandum of understanding (an MOU between FDA and a regulatory agency in another country allows mutual recognition of inspections)

MPR Medical Products Agency (Swedish Regulatory Agency)

MR Medical Representative (Japan)

MRA medical research associate

MREC Multicentre Research Ethics Committee (UK). *See also Ethics Committee in the Glossary.*

MRI magnetic resonance imaging

MTD maximum tolerated dose

MVP master validation plan

NABR National Association for Biomedical Research

NAF Notice of Adverse Findings (FDA postaudit letter)

NAI No Action Indicated (most favorable FDA post-inspection classification)

NAS new active substance (UK)

NAS–NRC National Academy of Sciences–National Research Council (US)

NBAC National Bioethics Advisory Commission (US)

NCA national competent authority

NCI National Cancer Institute (National Institutes of Health, USA)

NCICB National Cancer Institute Center for Bioinformatics

NEFARMA Dutch Association of the Innovative Pharmaceutical Industry

NEI National Eye Institute (NIH)

NGO nongovernmental organization

NHI National Health Insurance (Japan)

NHIN National Health Information Network

NHLBI National Heart, Lung, and Blood Institute (NIH)

NHS National Health Service (UK)

NIA National Institute on Aging (NIH)

NIAAA National Institute on Alcohol Abuse and Alcoholism (NIH)

NIAID National Institute of Allergies and Infectious Diseases (NIH)

NIAMS National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIH)

NIBIB National Institute of Biomedical Imaging and Bioengineering

NICHD National Institute of Child Health and Human Development (NIH)

NIDA National Institute on Drug Abuse (NIH)

NIDCD National Institute on Deafness and Other Communication Disorders (NIH)

NIDCR National Institute of Dental and Craniofacial Research (NIH)

NIDDK National Institute of Diabetes and Digestive and Kidney Diseases (NIH)

NIEHS National Institute of Environmental Health Sciences (NIH)

NIGMS National Institute of General Medical Sciences (NIH)

NIH National Institutes of Health (DHHS)

NIMH National Institute of Mental Health (NIH)

NINDS National Institute of Neurological Disorders & Stroke (NIH)

NINR National Institute of Nursing Research (NIH)

NIRB See NRB. *See also Ethics Committee, Independent IRB in the Glossary.*

NLM National Library of Medicine (NIH)

NME new molecular entity

NOAEL no observed adverse effect level (IUPAC)

NOEL no observable effect level (dose of an experimental drug given preclinically that does not produce an observable toxicity)

NRB noninstitutional review board, also known as an independent review board. *See also Ethics Committee in the Glossary, NIRB.*

NSCLC non-small cell lung carcinoma

NTP National Toxicology Program

OAI Official Action Indicated (serious FDA postinspection classification)

OAM *See NCCAM.*

OASIS Open Accessible Space Information System

ODAC Oncologic Drugs Advisory Committee (US)

ODE Office of Drug Evaluation

ODM Operational Data Model (CDISC)

OGD Office of Generic Drugs (CDER, formerly DGB)

OGE Office of Government Ethics

OHITA Office of Health Information Technology Adoption (ONCHIT)

OHRP Office for Human Research Protections (pronounced O-harp)

OIG Office of the Inspector General

OIS Office of Interoperability and Standards

OJC Official Journal of the European Union–C Series (Information)

OJEC Official Journal of the European Communities

OJL Official Journal of the European Union–L Series (Legislation)

OMB Office of Management and Budget (US)

ONCHIT Office of the National Coordinator for Health Information Technology (HIMSS)

OPR Office of Policy and Research

OPRR Office for Protection from Research Risks (predecessor to OHRP)

OSHA Occupational Safety & Health Administration (US)

OTA Office of Technology Assessment (US, abolished 1995)

OTC over-the-counter (refers to nonprescription drugs)

PAB Pharmaceutical Affairs Bureau (Japan)

PAHO Pan American Health Organization

PCC Poison Control Center

PCP pneumocystis carinii pneumonia. (The older name pneumocystis carinii—which now only applies to the pneumocystis variant that occurs in animals—is still in common usage. As a result, pneumocystis pneumonia (PCP) is also known as pneumocystis jiroveci[i] pneumonia

PD pharmacodynamics

PDA personal digital assistant (Palm Pilot, for example)

PDF portable document format

PDQ Physicians' Data Query (NCI-sponsored cancer trial registry)

PDR Physicians' Desk Reference

PDUFA Prescription Drug User Fee Act (1992, US)

PDUFA IV Prescription Drug User Fee Act (FDA)

PEM prescription event monitoring

PERI Pharmaceutical Education & Research Institute (not-for-profit division of PhRMA)

PFT pulmonary function test

PGT pharmacogenetics

PGX pharmacogenomics

PhPID pharmaceutical product identifier

PhRMA Pharmaceutical Research and Manufacturers of America

PHS Public Health Service (US)

PI principal investigator

PIM product information management (a system introduced by the EMA)

PK pharmacokinetics

PKI public key infrastructure

PLA Product License Application (FDA)

pm post meridian, evening (12 noon thru 23:59:59)

PMA Premarket Approval application (FDA)

PMDA Pharmaceutical and Medical Devices Agency (Japanese regulatory authority)

PMS postmarketing surveillance

PPI Patient Package Insert

PPO preferred provider organization; policy and procedure order

PR partial response; pulse rate

PRG Protocol Representation Group (CDISC)

PRIM&R Public Responsibility in Medicine and Research (Boston, MA)

PRM Protocol Reference Model

PRO patient-reported outcome

PROG Peer-Review Oversight Group (NIH)

PROMIS Patient Reported Outcomes Measurement Information Systems (pronounced promise)

PSUR periodic safety update report

PTC points to consider

PV pharmacovigilance

QA quality assurance

QAU quality assurance unit

QC quality control

QL quality of life

QOL quality of life (also QoL)

R&D research and development

RADAR risk assessment of drugs–analysis and response

RAPS Regulatory Affairs Professionals Society

RCRIM Regulated Clinical Research Information Management, a technical committee of HL7 with responsibility for developing technical standards for the exchange and management of health research information to be submitted to regulatory authority(ies)

RCT randomized clinical trial

RDE remote data entry

RDRC Radioactive Drug Research Committee (FDA)

REB research ethics board (Canada)

REMS Risk Evaluation and Mitigation Strategy

RFD retrieve form for data capture

RFP request for proposal

RHIO Regional Health Information Organization. A group of organizations with a business stake in improving the quality, safety and efficiency of healthcare delivery. RHIOs are the building blocks of the proposed National Health Information Network (NHIN) initiative

RIM Reference Information Model (HL7)

RKI Robert-Koch-Institut, Bundesinstitut für Infektionskrankheiten und nichtübertragbare Krankheiten (Federal Institute for Infectious and Noncommunicable Diseases, Germany)

RL Regulatory Letter (FDA—postaudit letter)

RPS Regulated Product Submission (HL7 RCRIM)

SACHRP Secretary's Advisory Committee on Human Protection. *See also OHRP*.

SADR suspected adverse drug reaction (FDA)

SAE serious adverse event

SAFE Secure Access for Everyone

SAS Statistical Analysis System (commonly used statistical analysis package)

SATCM State Administration of Traditional Chinese Medicine (China)

SBA Summary Basis of Approval

SC study coordinator. *See also CRC, CCRC, SSC.*

SCDM Society for Clinical Data Management

SCT Society for Clinical Trials

SD standard deviation (statistics)

SDA State Drug Administration (China)

SDM Submission Data Model (CDISC)

SDO standards development organization

SDS Submission Data Standards (CDISC)

SDTM Study Data Tabulation Model (CDISC)

SDV source document (data) verification

SE standard error (statistics)

SEA Single European Act of 1987

SEER Surveillance, Epidemiology, and End Results program (National Cancer Institute)

SEND Standard for the Exchange of Nonclinical Data. NOTE: The focus of the SEND Team is on data collected from animal toxicology studies. (CDISC)

SFDA State Food and Drug Administration (Chinese regulatory authority)

SGML Standard Generalized Markup Language

SHARE Shared Health and Research Electronic Library

SIAC Special Interest Area Community (DIA)

SIG Special Interest Group (HL7)

SLA service level agreement

SMART Submission Management and Review Tracking (FDA)

SME significant medical event

SMO site management organization

SmPC summary of product characteristics. *See also SPC.*

SNDA Supplemental New Drug Application

SNIP Syndicat National de l'Industrie Pharmaceutique (France)

SNOMED Systematized Nomenclature of Medicine. A structured nomenclature and classification of the terminology used in human and veterinary medicine developed by the College of Pathologists and American Veterinary Medical Association. Terms are applied to one of eleven independent systematized modules.

SOAP simple object access protocol (a W3C XML initiative)

SOC System Organ Class (MedDRA)

SoCRA Society of Clinical Research Associates

SOP standard operating procedure

SPAC State Pharmaceutical Administration of China

SPC summary of product characteristics. *See also SmPC.*

SPIRIT *Standard Protocol Items for Randomized Trials (CONSORT for protocols)*

SPL Structured Product Labeling (HL7, FDA)

SPM Society of Pharmaceutical Medicine (UK)

SQA Society of Quality Assurance

SQAP systems quality assurance plan

SSC study site coordinator. *See also CRC, CCRC, SC.*

SSCT Swedish Society for Clinical Trials

SSFA Società di Scienze Farmacologiche Applicate (Italy)

STF study tagging file

STT short term test

SUAE serious unexpected adverse event

SUD sudden unexpected death

SUSAR Suspected Unexpected Serious Adverse Reaction

SWOG Southwest Oncology Group (US)

TAC Technical Advisory Committee (CDISC)

TC Technical Committee (HL7)

TCC Technical Coordinating Committee (CDISC)

TCP/IP Transmission Control Protocol/Internet Protocol

TermID Controlled Vocabulary Term Identifier

TESS treatment-emergent signs and symptoms

TGA Therapeutic Goods Administration (Australian regulatory authority)

TIND treatment IND. *See also IND.*

TK toxicokinetics

Tmax the time after dosing when Cmax occurs

TMO trial management organization

UMT universal mean time (also known as Greenwich mean time). *See UTC.*

URL uniform resource locator (address of a website)

USAN United States Adopted Name

USC United States Code (book of laws)

USDA US Department of Agriculture

USP United States Pharmacopeia

UST user site testing. *Synonym for UAT (user acceptance testing)*

UT universal time (also known as Greenwich mean time). *See UTC.*

UTC coordinated universal time (international standard since 1972)

UUID Universally Unique Identifier

VA Veterans Administration (officially, US Department of Veterans Affairs)

VAERS Vaccine Adverse Event Reporting System

VAI Voluntary Action Indicated (FDA postaudit inspection classification)

VCDE vocabularies and common data elements (caBIG)

VGDS voluntary genomic data submission

VPN virtual private network

W3C World Wide Web Consortium

WAN wide area network

WHO World Health Organization

WHOART World Health Organization Adverse Reaction Terminology

WL Warning Letter (most serious FDA postaudit letter, demands immediate action within 15 days)

WR written request

WRAIR Walter Reed Army Institute of Research (DoD)

WTO World Trade Organization

WWW World Wide Web

XML eXtensible Markup Language