

# Acronyms, Abbreviations, and Initials

## Version 8.0

**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 Health Care Policy Research (NIH)

**AHIC** American Health Information Community. A US government-chartered 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 (HITS/P)

**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

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

**caBIG** Cancer Biomedical Informatics Grid

**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)

**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 Information 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 Organisations 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 (U.S.)

**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.*

**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 "seesweeey."

**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

**DD** Department of Drugs (Swedish regulatory agency)

**DDF** Data Definition File

**DDI** drug–drug interaction

**DEA** Drug Enforcement Administration (U.S.)

**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 (U.S.)

**DHTML** Dynamic HTML (IT)

**DIA** Drug Information Association

**DICOM** Digital Imaging and Communications in Medicine

**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 (U.S.)

**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

**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)

**EMEA** European Medicines Agency

**EMWA** European Medical Writers Association

**EORTC** European Organisation 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 (EMEA)

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

**eRX** electronic prescribing

**eSDI** electronic Source Data Interchange

**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 (U.S.)

**FDA** Food and Drug Administration (U.S.)

**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

**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 (U.S.)

**FTP** File Transfer Protocol

**FWA** Federalwide Assurance

**GAO** Government Accountability Office (U.S. 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** Health Care 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 (U.S., 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

**IBC** 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 Harmonisation 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 CDHRH 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, U.S.)

**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—Système 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)

**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 (EMEA, 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 (U.S.)

**NBAC** National Bioethics Advisory Commission (U.S.)

**NCA** national competent authority

**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.*

**ODAC** Oncologic Drugs Advisory Committee (U.S.)

**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 (U.S.)

**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 (U.S.)

**OTA** Office of Technology Assessment (U.S., 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

**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, U.S.)

**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 (U.S.)

- PI** principal investigator
- PIM** product information management (a system introduced by the EMEA)
- 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)
- 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)
- 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 nicht-übertragbare 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.*
- SAE** serious adverse event
- SADR** suspected adverse drug reaction (FDA)
- 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)
- SGML** Standard Generalized Markup Language
- 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)
- SoCRA** Society of Clinical Research Associates
- SOP** standard operating procedure
- SPAC** State Pharmaceutical Administration of China
- SPC** summary of product characteristics. *See also* *SmPC*.
- 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
- SWOG** Southwest Oncology Group (U.S.)
- 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
- 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 Web site)
- USAN** United States Adopted Name
- USC** United States Code (book of laws)
- USDA** U.S. 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)
- VA** Veterans Administration (officially, U.S. 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