

Acronym/Abbreviation/Initial	Long Name/Description
A&WC	adequate and well-controlled
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
AAS	American Association for the Advancement of Science
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	American Council of Independent Laboratories. 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)
ACT	Applied Clinical Trials magazine
ACTG	AIDS Clinical Trials Group (NIAID)
ACTU	AIDS Clinical Trials Unit (NIH)
ADaM	Analysis Data Model (CDISC)
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
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
AICRC	Association of Independent Clinical Research Contractors (UK)
AIDS	acquired immune deficiency syndrome, acquired immunodeficiency syndrome
ALCOA	attributable, legible, contemporaneous, original, accurate
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)
AMP	authorised medicinal product (ISO 11615:2017, 3.1.60)
AMWA	American Medical Writers Association
ANDA	abbreviated new drug application (FDA) (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 (pharmacokinetics)
AxMP	auxiliary medicinal product (ISO 11615:2017, 3.1.60)
BARQA	British Association of Research Quality Assurance
BCE	beneficial clinical event
BDPA	Bureau of Drug Policy and Administration (China)
BEST	Biologics Effectiveness and Safety System (US FDA, CBER); Biomarkers, EndpointS, and other Tools (Taxonomy Resource, US)
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)
BID	<i>bis in die</i> (twice a day)
BIO	Biotechnology Innovation Organization
BIRA	British Institute of Regulatory Affairs
BLA	biologics license application (FDA)
BrAP	British Association of Pharmaceutical Physicians
BRIDG	Biomedical Research Integrated Domain Group
BSA	body surface area
C3C	China CDISC Coordinating Committee
CA	Competent Authority (EU)
caBIG	cancer biomedical informatics grid
caCORE	cancer common ontologic resource environment
caDSR	cancer data standards registry and repository. A toolset maintained by NCI.
CAS	Chemical Abstracts Service
CBER	Center for Biologics Evaluation and Research (FDA)
CBIIT	Center for Biomedical Informatics and Information Technology (NCI)
CCPPRB	Comité Consultative pour la Protection des Personnes dans les Recherches Biomédicales
CCRA	certified clinical research associate
CCRC	certified clinical research coordinator
CCRP	certified clinical research professional
CCSI	company core safety information
CDA	clinical document architecture (HL7)
CDASH	Clinical Data Acquisition Standards Harmonization
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
CHR	Committee on Human Research
CIC	clinical imaging center
CIOMS	Council for International Organizations of Medical Sciences
CIP	certified IRB professional
CIS	Commonwealth of Independent States
CLIA	clinical laboratory improvement amendments
ClinRO	clinician-reported outcome
Cmax	concentration maximum
CMC	chemistry, manufacturing, and control
CME	continuing medical education
CMS	Centers for Medicare & Medicaid Services (formerly Healthcare Financing Administration); Concerned Member State
CNS	central nervous system
COA	clinical outcome assessment
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.
COU	context of use
COVID-19	Coronavirus disease 2019
CPHS	Committee for the Protection of Human Subjects
CPMP	Committee for Proprietary Medicinal Products (EU)
CPSC	Consumer Product Safety Commission (US)
CR	Complete Response (in oncology)
CRA	clinical research associate
CRADA	Cooperative Research And Development Agreement (with US Government entities such as FDA or NIH)
CRB	case record book; central review board
CRC	clinical research coordinator
CRF	case report form; case record form
CRIX	clinical research information exchange
CRO	contract research organization
CRT	case report tabulation
CSDD	Center for the Study of Drug Development (Tufts)
CSF	cerebrospinal fluid; collaborative standards forum (CDISC); colony stimulating factor
CSM	Committee on Safety of Medicines (UK)
CSO	Consumer Safety Officer (FDA)
CSR	clinical study report
CSU	clinical supply unit
CSUICI	Computerized Systems Used In Clinical Investigations (replaced CSUCT). NOTE: usually pronounced "seesweecy."

CT	clinical trial; computerized tomography
CTA	clinical trial agreement
CTC	clinical trial certificate (UK)
CTCAE	Common Terminology Criterion for Adverse Events
CTD	common technical document
CTEP	Cancer Therapy Evaluation Program
CTM	clinical trial material
CTX	clinical trial exemption (MCA)
CUI	common unique identifier
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
DDT	drug development tool (FDA-NIH BEST Resource)
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
DICOM	Digital Imaging and Communications in Medicine
DIMs	domain information models
DITA	Darwin Information Typing Architecture
DLT	dose-limiting toxicity
DMB	Data Management Biomedical (France)
DNA	deoxyribonucleic acid
DPC-PTR	Drug Price Competition and Patent Term Restoration Act of 1984 (also Waxman-Hatch or Hatch-Waxman bill)
DRE	disease-related event
DSI	Division of Scientific Investigations (FDA)
DSM	Diagnostic and Statistical Manual (American Psychiatric Association)
DSMB	data safety monitoring board
DSMC	Data and Safety Monitoring Committee
DSNP	Development of Standardized Nomenclature Project (FDA)
DST	daylight saving time
DSUR	development safety update report (ICH)
DTC	direct-to-consumer (drug advertising)
DTD	document type definition coordinating committee
E3C	European CDISC coordinating committee
EAB	ethical advisory board
EC	European Commission; European Community (in documents older than the mid-1980s); ethics committee
EC <sub>50</sub>	half maximal effective concentration
ECG	electrocardiogram; European CDISC group

ECJ	European Court of Justice
eCOA	electronic clinical outcome assessment
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
eDMS	electronic data management system
EDR	electronic document room
eDT	electronic data transfer
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
EMEA	European Medicines Evaluation Agency (Predecessor to the EMA)
EMWA	European Medical Writers Association
EOP2A	end-of-phase 2A
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
ePRO	electronic patient-reported outcome
ER	essential requirements (EMA)
ERSR	electronic regulatory submissions and review (FDA's e-Submissions processing group)
eRX	electronic prescribing
eSDI	electronic source data interchange
ESG	electronic submission gateway (FDA)
eSR	electronic source record. See eSource.
ESRA	European Society of Regulatory Affairs
eSRF	electronic source report form
ESTRI	Electronic Standards for the Transfer of Regulatory Information (ICH)
EU	European Union
EU CTR	Clinical trials - Regulation EU No 536/2014
EUA	emergency use authorization
EUDRA	European Union Drug Regulatory Authorities
EudraCT	European Union clinical trials database
EVS	Enterprise Vocabulary Services (National Cancer Institute)
EWG	expert working group
FAERS	FDA adverse event reporting system
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)

FDA	Food and Drug Administration Amendment Act
FDAMA	FDA Modernization Act (pronounced fedahma)
FDLI	Food and Drug Law Institute
FFPM	Fellow of the Faculty of Pharmaceutical Medicine (UK)
FHIR	fast healthcare interoperability resources (an HL7 resource)
FIPS	federal information processing standards
FISMA	Federal Information Security Management Act
FRCP	Fellow of the Royal College of Physicians
FTC	Federal Trade Commission (US)
FTP	file transfer protocol
FWA	federalwide assurance
GBP	good business practice
Gbps	gigabits per second (billions of bits per second in data transmission) NOTE: GBps stands for gigabytes per second (an 8 fold difference).
GCP	good clinical practice
GCRP	good clinical research practice
GDPR	General Data Protection Regulation
GLP	good laboratory practice
GMP	good manufacturing practice
GMT	Greenwich Mean Time. Compare to UTC. See also UMT and UT.
GP	general practitioner
GPMS	good postmarketing surveillance practice (Japan)
GPVP	good pharmacovigilance practice
GRAS	generally regarded as safe
GRP	good review practice (CDER)
GXP	Good (X) Practices
HA	health authority (UK)
HD	high dose; high definition
HEOR	health economics and outcomes research
HEX	human experimentation committee
HHS	Department of Health and Human Services (US, also called DHHS)
HIE	Health Information Exchange
HIMA	Health Industry Manufacturers Association
HIMSS	Healthcare Information and Management Systems Society (pronounced hymns)
HIPA	Health Insurance Portability and Accountability Act
HIT	health information technology
HITSP	Health Information Technology Standards Panel (pronounced hitspee)
HL7	Health Level 7
HPB	Health Protection Branch (Laboratory Centre for Disease Control (Canada); has been superseded by Health Canada)
HPLC	high performance liquid chromatography
HRQoL	health-related quality of life
HSRC	human subjects review committee
HTML	hypertext markup language
HTTP	hypertext transfer protocol
I3C	India CDISC Coordinating Committee
IB	investigator's brochure
IBD	international birth date
IC	informed consent

ICD	International Classification of Diseases NOTE: Followed by a number indicating the version. E.g., ICD9 and ICD10. See also MedDRA.
ICF	informed consent form
ICG	India CDISC Group
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMJE	International Committee of Medical Journal Editors
ICR	Institute of Clinical Research (formerly Association for Clinical Research in the Pharmaceutical Industry, ACRPI, UK)
ICSR	individual case safety report
ICTH	International Committee on Thrombosis and Haemostasis
ICTRP	International Clinical Trials Registry Platform (WHO)
ICU	intensive care unit
IDE	investigational device exemption application to CDRH to get permission for investigational device testing in clinical trials.
IEC	independent ethics committee
IEEEEE	Institute of Electrical and Electronic Engineers, Inc.
IFAP	International Federation of Associations of Pharmaceutical Physicians
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IG	Inspector General (HHS)
IHE	Integrating the Healthcare Enterprise
IHI	Institute for Healthcare Improvement
IKS	Interkantonale Kontrollstelle für Heilmittel (Switzerland)
IMI	Innovative Medicines Initiative (European Commission)
IMP	investigational medicinal product
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)
IRB	institutional review board; independent review board
IRD	international registration document
IS	International System of Units (may also be referred to as 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
KASA	Knowledge-aided Assessment & Structured Application (a new FDA pharmaceutical quality assessment system)
Kbps	kilobits per second (thousands of bits per second in data transmission) NOTE: KBps stands for kilobytes per second (an 8 fold difference)

KFDA	Korean Food and Drug Administration
LAB	laboratory data model (CDISC)
LAN	local area network
LAR	Legally Authorized Representative
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)
MA	marketing authorization
MAA	marketing authorisation application (EMA, EU)
MAH	Marketing Authorisation Holder (EU)
MaPP	Manual of Policies and Procedures (CDER)
Mbps	megabits per second, (millions of bits per second in data transmission) NOTE: MBps stands for megabytes per second (an 8 fold difference).
MCM	medical countermeasure
MDR	medical device reporting
MDSAP	medical device single audit program
MedDRA	Medical Dictionary for Regulatory Activities
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)
MIC <sub>50</sub>	minimum inhibitory concentration required to inhibit the growth of 50% of organisms
MOA	mechanism of action
MOH	Ministry of Health (UK, Canada, others)
MOPH	Ministry of Public Health (Thailand, Yemen, others)
MOU	memorandum of understanding
MPDT	medical product development tool (FDA-NIH BEST Resource)
MPID	medicinal product identifier
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
MRP	mutual recognition procedure
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 postinspection 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
NCE	New Chemical Entity
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)
NEST	National Evaluation System for Health Technology (US)
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)
NIMP	Non-Investigational Medicinal Product
NINDS	National Institute of Neurological Disorders & Stroke (NIH)
NINR	National Institute of Nursing Research (NIH)
NIRB	Non-Institutional Review Board. See NRB. See also Ethics Committee, Independent.
NIST	National Institute of Standards and Technology
NLM	National Library of Medicine (NIH)
NME	new molecular entity
NME	New Molecular Entity
NOAEL	no observed adverse effect level (IUPAC)
NOEL	no observable effect level
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)
OASIS	open accessible space information system
ObsRO	observer-reported outcome
ODAC	Oncologic Drugs Advisory Committee (US)
ODE	Office of Drug Evaluation
ODM	operational data model (CDISC)
OGD	Office of Generic Drugs (formerly DBG, CDER)
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
OIQ	outcome instrument qualification
OIS	Office of Interoperability and Standards
OJEC	Official Journal of the European Communities

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)
OTC	over-the-counter (refers to nonprescription drugs)
PAB	Pharmaceutical Affairs Bureau (Japan)
PADER/PAER	periodic adverse drug experience report
PAHO	Pan American Health Organization
PBRER	periodic benefit-risk evaluation report
PCC	poison control center
PD	pharmacodynamics
PD	Progressive Disease (in oncology)
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
PerfO	performance outcome
PFT	pulmonary function test
PGT	pharmacogenetics
PGX	pharmacogenomics
PHE	public health emergency
PHI	protected health information
PhPID	pharmaceutical product identifier
PhRMA	Pharmaceutical Research and Manufacturers of America
PHS	Public Health Service (US)
PI	principal investigator
PII	personally identifiable information
PIM	product information management
PK	pharmacokinetics
PKI	public key infrastructure
PLA	product license application (FDA)
PLSP	plain language summary of publications
pm	post meridian, evening (12 noon thru 23:59:59)
PMA	premarket approval application (FDA)
PMDA	Pharmaceutical and Medical Devices Agency and Medical Devices Agency (Japanese regulatory authority)
PMS	postmarketing surveillance
PO	<i>per os</i> (by mouth)
PPD	protected personal data
PPI	patient package insert
PPO	preferred provider organization; policy and procedure order
PR	Partial Response (in oncology)
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
PSUR	periodic safety update report
PTC	points to consider

PV	pharmacovigilance
QA	quality assurance
QAU	quality assurance unit
QC	quality control
QD	<i>quaque die</i> (once a day)
QID	<i>quater in die</i> (four times a day)
QL	quality of life
QOL	quality of life (also QoL)
QRS	questionnaires, ratings and scales
R&D	research and development
RADAR	risk assessment of drugs—analysis and response
RAPS	Regulatory Affairs Professionals Society
RBM	risk based monitoring
RCRIM	Regulated Clinical Research Information Management
RCT	randomized controlled trial; randomized clinical trial
RDE	remote data entry
RDF	resource description framework
RDRC	Radioactive Drug Research Committee (FDA)
REB	research ethics board (Canada)
RECIST	Response Evaluation Criteria in Solid Tumors
REMS	risk evaluation and mitigation strategy
RFD	retrieve form for data capture
RFP	request for proposal
RHIO	Regional Health Information Organization
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)
RMAT	Regenerative Medicine Advanced Therapy
RMP	risk management plan
RMS	reference member state
RMT	Regenerative Medicine Therapy
RNA	ribonucleic acid
ROA	route of administration
RPS	Regulated Product Submission (HL7 RCRIM)
RR	relative risk
RSI	reference safety information
RWD	Real-World Data
RWE	Real-World Evidence
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
SaMD	software as a medical device
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus-2 (novel coronavirus causing COVID-19 disease)
SAS	statistical analysis system
SATCM	State Administration of Traditional Chinese Medicine (China)
SBA	summary basis of approval
SC	study coordinator
SCDM	Society for Clinical Data Management

SCT	Society for Clinical Trials
SD	standard deviation (statistics)
SD	Stable Disease (in oncology)
SDA	State Drug Administration (China)
SDM	submission data model (CDISC)
SDO	Standards Development Organization
SDS	submission data standards (CDISC)
SDSP	Study Data Standardization Plan
SDTM	study data tabulation model (CDISC)
SDTMIG	study data tabulation model implementation guide
SDV	source document verification; source data verification
SE	standard error (statistics)
SEA	Single European Act of 1987
SEER	Surveillance, Epidemiology, and End Results program (NCI)
SEND	standard for the exchange of nonclinical data
SFDA	State Food and Drug Administration (Chinese regulatory authority)
SGML	standard generalized markup language
SHARE	shared health and research electronic library (CDISC)
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
SoA	schedule of activities
SOAP	simple object access protocol (a W3C XML initiative)
SOC	System Organ Class (MedDRA); standard of care
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
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	time to maximum plasma concentration; time to maximum effect (drugs)
TMO	trial management organization
UAT	User Acceptance Testing
UCUM	Unified Code for Units of Measure
UMT	universal mean time (also known as Greenwich Mean Time and Universal Time). Compare to UTC.
URL	uniform resource locator
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
UT	universal time (also known as Greenwich Mean Time and Universal Mean Time). Compare to UTC.
UTC	coordinated universal time
UUID	universally unique identifier
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
WHODRUG/WHO-DRL	World Health Organization drug reference list
WL	warning letter (most serious FDA postaudit letter)
WOCBP	woman of childbearing potential
WR	written request
WRAIR	Walter Reed Army Institute of Research (DoD)
WTO	World Trade Organization
WWW	world wide web
XML	extensible markup language