

Glossary

Acronyms, Abbreviations, and Initials

- AAAS** American Association for the Advancement of Science
- AAAB** American Association of Blood Banks
- ADA** Abbreviated Antibiotic Drug Application (FDA) (used primarily for generics)
- AAMC** Association of American Medical Colleges
- AAPP** American Academy of Pharmaceutical Physicians
- AAPS** American Association of Pharmaceutical Scientists
- ABPI** Association of the British Pharmaceutical Industry
- ACC** American College of Clinical Pharmacology
- ACDM** Association of Clinical Data Management (UK)
- ACIL** A national trade association representing independent, commercial scientific, and engineering firms (formerly the American Council of Independent Laboratories)
- 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 Institute of Clinical Research (UK)
- ACT** *Applied Clinical Trials* magazine
- ACTG** AIDS Clinical Trials Group (NIAID)
- ACTU** AIDS Clinical Trials Unit (NIH)
- ADaM** Analysis Dataset Model (CDISC)
- ADAMHA** Alcohol, Drug Abuse, and Mental Health Administration (no longer exists)
- 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; adverse experience
- ADROIT** 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)
- AICRC** Association of Independent Clinical Research Contractors (UK)
- AIDS** Acquired immune deficiency syndrome. *See also SIDA and HIV in acronym glossary.*
- ALCOA** attributable, legible, contemporaneous, original, accurate (dimensions of data quality)
- 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
- ARCS** Association of Regulatory & Clinical Scientists (Australia)
- ARENA** Applied Research Ethics National Association
- 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
- ASQ** American Society for Quality, formerly American Society for Quality Control
- AUC** area under the curve (statistics)
- AZT** zidovudine (HIV treatment)
- 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)

BGV 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

BSA body surface area

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

CAPRA Canadian Association of Pharmaceutical Regulatory Affairs

CAS Chemical Abstracts Service

CBER Center for Biologics Evaluation and Research (FDA)

CCI Committee on Clinical Investigations. *See also Ethics Committee box.*

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

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.*

CDC Centers for Disease Control and Prevention

CDER Center for Drug Evaluation and Research (FDA)

CDISC Clinical Data Interchange Standards Consortium (formerly a DIA special interest group called the Clinical Data Interchange Standards Committee)

CDM clinical data management

CDRH Center for Devices and Radiological Health (FDA)

CEN Comité Européen de Normalisation (European Committee for Standardization)

CEU continuing education unit

CF consent form

CFH Connecting for Health

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

Nuremberg Code—Directives for Human Experimentation

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Reprinted from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 181–182. Washington, D.C.: U.S. Government Printing Office, 1949.

cGMP current good manufacturing practices

CHI Consolidated Health Initiative (eGov)

CHR Committee on Human Research. *See also Ethics Committee box.*

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 Improvements 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

CNS central nervous system

COP CDISC operating process/procedure

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 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)

CRO contract research organization. *See also IPRO.*

CSDD Center for the Study of Drug Development

CSF Collaborative Standards Forum (CDISC)

CSM Committee on Safety of Medicines (UK)

CSO Consumer Safety Officer (FDA)

CSR clinical study report

CSU clinical supply unit

CT clinical trial

CTC clinical trial certificate (UK)

CTD common technical document

- CTEP** Clinical Therapeutics Evaluation Program (NCI)
- CTM** clinical trials materials
- CTX** clinical trial exemption (MCA)
- CV** curriculum vitae
- CVM** Center for Veterinary Medicine (FDA)
- DAWN** Drug Abuse Warning Network
- DD** Department of Drugs (Swedish regulatory agency)
- 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
- DHEW** Department of Health, Education and Welfare (U.S., now split into DHHS and Department of Education)
- 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)
- DoD** Department of Defense (U.S.)
- 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 and Safety Monitoring Board
- DSNP** development of standardized nomenclature project (FDA)
- 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 box*.
- EC** ethics committee. See also *Ethics Committee box*.
- 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.)
- EPCHIN** European Community Pharmaceutical Products Information Network
- eCRF** electronic case report form
- EDC** electronic data capture/collection
- EDI** electronic data interchange
- 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
- EIR** Establishment Inspection Report (FDA)
- ELA** Establishment License Application (FDA)
- EMA** European Agency for the Evaluation of Medicinal Products
- EMS** electronic mail service
- EMWA** European Medical Writers Association
- EORTC** European Organization for the Research and Treatment of Cancer
- EP** European Parliament
- EPAR** European Public Assessment Report
- EPO** European Patent Office
- EPRG** European Pharmacovigilance Research Group
- ER** Essential Requirements (EMA)
- 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
- EWG** expert working group
- FAQ** frequently asked questions
- Farindustria** The Association of Italian Pharmaceutical Manufacturers
- FD&C Act** Food, Drug, and Cosmetic Act (U.S.)
- FDA** Food and Drug Administration (U.S.)
- FDAMA** FDA Modernization Act
- FDLI** Food and Drug Law Institute
- FFPM** Fellow of the Faculty of Pharmaceutical Medicine (UK)
- 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** Federal-wide assurance
- GAO** General Accounting 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 practice
- GP** general practitioner; general practice (UK)

- GPMS** good postmarketing surveillance practice (Japan)
- GRAS** generally regarded as safe (foods)
- GXP** good [pharmaceutical] practice
- HCFA** Health Care Financing Administration; now renamed The Centers for Medicare & Medicaid Services.
- HEX** human experimentation committee. *See also Ethics Committee box.*
- HHS** Department of Health and Human Services (U.S., also called DHHS)
- HIMA** Health Industry Manufacturers Association
- HIMSS** Health Information and Management Systems Society
- HIPPA** Health Insurance Portability and Accountability Act
- HL7** Health Level 7 (a not-for-profit ANSI-accredited standards developing organization (SDO))
- HPB** Health Protection Branch, Laboratory Centre for Disease Control (Canada)
- HPLC** high performance liquid chromatography
- HSRC** human subjects review committee. *See also Ethics Committee box.*
- 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.*
- 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 Haemostases
- IEC** independent ethics committee. *See also Ethics Committee box.*
- IEEE** Institute of Electrical and Electronic Engineers, Inc.
- IFAPP** International Federation of Associations of Pharmaceutical Physicians
- IFPMA** International Federation of Pharmaceutical Manufacturers' Associations
- IG** Inspector General (HHS)
- IKS** Interkantonale Kontrollstelle für Heilmittel (Switzerland)
- IMP** investigational materials plan
- IND** Investigational New Drug application (FDA). *See also TIND*
- 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.*
- IRD** International Registration Document
- ISCB** International Society for Clinical Biostatistics
- ISDN** Integrated Services Digital Network
- ISO** International Organization for Standardization
- ISP** Internet service provider
- IT** information technology
- ITU-T** Telecommunication Standardization Sector of the International Telecommunications Union
- IVD** in vitro diagnostics
- IVR** interactive voice response (telephone technology)
- 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
- LREC** local research ethics committee (UK). *See also Ethics Committee box.*
- MA** marketing authorization
- MAA** Marketing application (EU)
- Mbps** millions of bits per second (data transmission)
- MCA** Medicines Control Agency (UK)
- 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)
- 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)
- MIAME** minimum information about a microarray experiment (standard for microarray data)
- MOH** Ministry of Health (UK, Canada, others)
- MOPH** Ministry of Public Health
- MOU** Memorandum of Understanding (an MOU between FDA and a regulatory agency in another country allows mutual recognition of inspections)

- MR** medical representative (Japan)
- MRA** medical research associate
- MREC** multicentre research ethics committee(UK). See also *Ethics Committee box*.
- 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.)
- NCCAM** National Center for Complementary and Alternative Medicine, formerly Office of Alternative Medicine (NIH)
- NCCTG** North Central Cancer Treatment Group (U.S.)
- NCDM** Nordic Clinical Data Management (Association)
- NCE** new chemical entity
- NCHGR** National Center for Human Genome Research (NIH)
- NCHS** National Center for Health Statistics (in CDC)
- NCI** National Cancer Institute (NIH)
- NCPDP** National Council for Prescription Drug Programs
- NCPIE** National Council on Patient Information and Education (Washington, DC)
- NCR** no carbon [paper] required
- NCRR** National Center for Research Resources (NIH)
- NCVIA** National Childhood Vaccine Injury Act (1986)
- NDA** New Drug Application (FDA)
- NDS** New Drug Submission (Canada's new drug application)
- NEFARMA** Dutch Association of the Innovative Pharmaceutical Industry
- NEI** National Eye Institute (NIH)
- NGO** nongovernmental organization
- NHI** National Health Insurance (Japan)
- 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)
- 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)
- NIDDK** National Institute of Diabetes and Digestive and Kidney Diseases (NIH)
- NIDR** National Institute of Dental Research (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** noninstitutional review board. See also *Ethics Committee box*.
- NLM** National Library of Medicine (NIH)
- NME** new molecular entity
- NOEL** No observable effect level [dose of an experimental drug given pre-clinically, that does not produce an observable toxicity]
- NRB** noninstitutional review board, also known as an independent review board. See also *Ethics Committee box*.
- NSCLC** non-small cell lung carcinoma
- NTP** National Toxicology Program
- OAI** Official action indicated (serious FDA post-inspection classification)
- OAM** See *NCCAM*
- ODAC** Oncologic Drugs Advisory Committee (U.S.)
- ODE** Office of Drug Evaluation (CDER now has five such offices: ODE I, II, III, IV, and V)
- ODM** Operational Data Model [CDISC]
- OGD** Office of Generic Drugs (CDER, formerly DGB)
- OGE** Office of Government Ethics (formerly part of Office of Personnel Management, separate executive branch in 1989)
- OHRP** Office for Human Research Protections
- OIG** Office of the Inspector General
- OJC** Office Journal of the European Union–C Series (Information)
- OJEC** Official Journal of the European Communities
- OJL** Office Journal of the European Union–L Series (Legislation)
- OMB** Office of Management and Budget (U.S.)
- 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 by Congress, Fall 1995)
- OTC** over-the-counter (refers to nonprescription drugs)
- PAB** Pharmaceutical Affairs Bureau (Japan)
- PAHO** Pan American Health Organization

PCC Poison Control Center	PRIM&R Public Responsibility in Medicine and Research (Boston, MA)	SAS Statistical Analysis System (commonly used statistical analysis package)	SME significant medical event
PCP Pneumocystis carinii pneumonia	PROG peer-review oversight group (NIH)	SATCM State Administration of Traditional Chinese Medicine (China)	SMO site management organization
PD pharmacodynamics	PSUR periodic safety update report	SBA summary basis of approval	SmPC Summary of Product Characteristics
PDA personal digital assistant (Palm Pilot, for example)	PTC Points to Consider	SC study coordinator. <i>See also</i> CRC, CCRC, SSC	SNDA Supplemental New Drug Application
PDF Portable Document Format	QA quality assurance	SCDM Society for Clinical Data Management (US)	SNIP Syndicat National de l'Industrie Pharmaceutique (France)
PDQ Physicians' Data Query (NCI-sponsored cancer trial registry)	QAU quality assurance unit	SCT Society for Clinical Trials	SNOMED Systematized Nomenclature of Medicine (a dictionary)
PDR Physicians' Desk Reference	QC quality control	SD standard deviation	SOCRA Society of Clinical Research Associates
PDUFA Prescription Drug User Fee Act (1992, U.S.)	QL quality of life	SDA State Drug Administration (China)	SOP standard operating procedure
PEM prescription event monitoring	QOL quality of life	SDM Submission Data Model (CDISC)	SPAC State Pharmaceutical Administration of China
PERI Pharmaceutical Education & Research Institute (not-for-profit division of PhRMA)	R&D research and development	SDO standards development organization	SPM Society of Pharmaceutical Medicine (UK)
PFT pulmonary function tests	RADAR Risk Assessment of Drugs—Analysis and Response	SDS Submission Domain Standards (CDISC)	SQA Society of Quality Assurance
PhRMA Pharmaceutical Research and Manufacturers of America (formerly PMA)	RAPS Regulatory Affairs Professionals Society	SDS submissions data standard	SQAP systems quality assurance plan
PHS Public Health Service (U.S.)	RCRIM Regulated Clinical Research and Information Management (HL7)	SE standard error (statistics)	SSC study site coordinator. <i>See also</i> CRC, CCRC, SC
PI principal investigator	RCT randomized clinical trial	SEA Single European Act of 1987	SSCT Swedish Society for Clinical Trials
PK pharmacokinetics	RDE remote data entry	SEER Surveillance, Epidemiology, and End Results program of the the National Cancer Institute that collects and publishes cancer incidence and survival data.	SSFA Società di Scienze Farmacologiche Applicate (Italy)
PKI public key infrastructure	RDRC Radioactive Drug Research Committee	SGML Standard Generalized Markup Language	STF study tagging file
PLA Product License Application (FDA)	REB research ethics board (Canada)	SIAC Special Interest Area Community (DIA)	STT short term tests
PMA Pre-Market Approval application (FDA)	RIM Reference Information Model (HL7)	SIG Special Interest Group (HL7)	SC study coordinator. <i>See clinical research coordinator.</i>
PMS postmarketing surveillance	RKI Robert-Koch-Institut, Bundesinstitut für Infektionskrankheiten und nicht-übertragbare Krankheiten (Federal Institute for Infectious and Non-communicable Diseases, Germany)	SLA service level agreement	SUA serious unexpected adverse event
PPI patient package insert	RL regulatory letter (FDA post-audit letter)	SMART Submission Management and Review Tracking (FDA)	SUD sudden unexpected death
PPO preferred provider organization; policy and procedure order	SAE serious adverse event		SWOG Southwest Oncology Group (U.S.)
PR partial response; pulse rate			

TC Technical Committee (HL7)

TCC Technical Coordinating Committee (CDISC)

TCP/IP Transmission Control Protocol/Internet Protocol

TESS treatment emergent signs and symptoms

TIND Treatment IND. See also *IND*

TK toxicokinetics

Tmax the time after dosing when C_{max} occurs

TMO trial management organization

URL uniform resource locator (address of a Web site)

USC United States Code (book of laws)

USDA Department of Agriculture (U.S.)

USP United States Pharmacopeia

VA Veterans Administration (officially, United States Department of Veterans Affairs)

VAERS Vaccine Adverse Event Reporting System

VAI Voluntary Action Indicated (FDA postaudit inspection classification)

VGDS Voluntary Genomic Data Submission

VPN virtual private network

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)

WRAIR Walter Reed Army Institute of Research (DoD)

WTO World Trade Organization

www World Wide Web

XML Extensible Markup Language

Applied Clinical Trials is your forum

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