

Glossary

Acronyms, Abbreviations, and Initials

- AAAS** American Association for the Advancement of Science
- AABB** American Association of Blood Banks
- 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
- ACCP** American College of Clinical Pharmacology
- ACIL** a national trade association representing independent, commercial scientific, and engineering firms (formerly the American Council of Independent Laboratories)
- ACRA** Associate Commissioner for Regulatory Affairs (FDA)
- ACRO** Association of Clinical Research Organizations
- ACRP** Association of Clinical Research Professionals, formerly Associates in Clinical Pharmacology (ACP)
- ACRPI** now ICR, the Institute of Clinical Research (UK)
- ACT** *Applied Clinical Trials* magazine
- ACTG** AIDS Clinical Trials Group (NIAID)
- ACTU** AIDS Clinical Trials Unit (NIH)
- ADAS** Alzheimer's Disease Assessment Scale
- ADAS COG** Alzheimer's Disease Assessment Scale, Cognitive Subscale
- 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
- AEGIS** ADROIT Electronically Generated Information Service
- AERS** Adverse Event Reporting System (FDA)
- AFCR** *See AFMR*
- AFMR** American Federation for Medical Research, formerly the American Federation for Clinical Research (AFCR)
- AHA** Area Health Authority (UK)
- AHCPR** Agency for Health Care Policy Research (NIH)
- AICRC** Association of Independent Clinical Research Contractors (UK)
- AMA** American Medical Association
- AMC** academic medical center
- AmFAR** American Foundation for AIDS Research
- AMG** Arzneimittelgesetz (German Drug Law)
- AMI** acute myocardial infarction
- ANDA** Abbreviated New Drug Application (for a generic drug)
- ANOVA** analysis of variance (statistics)
- AOAC** Association of Official Analytical Chemists
- APB** Association Pharmaceutique Belge (Belgium)
- AphA** American Pharmaceutical Association
- API** active pharmaceutical ingredient
- ARENA** Applied Research Ethics National Association
- ARO** academic research organization
- ASAP** administrative systems automation project (FDA)
- ASCH** 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)
- 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
- BSA** body surface area
- CA** Competent Authority (regulatory body charged with monitoring compliance with European Union member state national statutes and regulations)
- CAD** coronary artery disease
- CAPRA** Canadian Association of Pharmaceutical Regulatory Affairs
- CAS** Chemical Abstracts Service
- CBCTN** Community Based Clinical Trials Network
- CBER** Center for Biologics Evaluation and Research (FDA)
- CCI** Committee on Clinical Investigations. *See also CCPPRB, CHR, CPHS, CRB, EAB, EC, HEX, IEC, IRB, LREC, MREC, NIRB, REB*
- CCPPRB** Comité Consultative pour la Protection des Personnes dans les Recherches Biomédicales (France). *See also CCI, CHR, CPHS, CRB, EAB, EC, HEX, IEC, IRB, LREC, MREC, NIRB, REB*
- CCRA** Certified Clinical Research Associate. ACRP certification of monitors.
- CCRP** Certified Clinical Research Professional. SoCRA certification of coordinators, monitors, and other research professionals.
- CCRC** Certified Clinical Research Coordinator. Certification issued to clinical coordinators by ACRP
- CDC** Centers for Disease Control and Prevention (Atlanta, GA)
- CDER** Center for Drug Evaluation and Research (FDA)
- CDISC** Clinical Data Interchange Standards Committee (DIA)
- CDM** clinical data management
- CDRH** Center for Devices and Radiological Health (FDA)
- CEU** continuing education unit
- CF** consent form
- CFR** *Code of Federal Regulations* (cited in ACT by title and part; 21 CFR 50, for example, indicates Title 21, Part 50 on the protection of human subjects)
- cGMP** current good manufacturing practices
- CHR** committee on human research. *See also CCI, CCPPRB, CPHS, CRB, EAB, EC, HEX, IEC, IRB, LREC, MREC, NIRB, REB*
- 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
- 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
- CSM** Committee on Safety of Medicines (UK)
- CSR** clinical study report
- CSU** clinical supply unit
- CT** clinical trial
- CTC** clinical trial certificate (UK)
- 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)
- DGD** Now OGD (formerly CBER's Division of Generic Drugs)
- 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
- 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)
- DRG** Division of Research Grants (NIH); Diagnosis Related Groups
- 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 (for electronic interchange)
- EAB** advisory board. *See also CCI, CCPPRB, CHR, CPHS, CRB, EC, HEX, IEC, IRB, LREC, MREC, NIRB, REB*
- EAB** Editorial Advisory Board (*Applied Clinical Trials*)
- EC** ethics committee. *See also CCI, CCPPRB, CHR, CPHS, CRB, EAB, HEX, IEC, IRB, LREC, MREC, NIRB, REB*
- EC** European Commission (in documents older than the mid-1980s, EC may mean European Community)
- ECJ** European Court of Justice
- ECOG** Eastern Cooperative Oncology Group (U.S.)
- ECPHIN** European Community Pharmaceutical Products Information Network
- ECU** European Currency Unit
- EDC** electronic data capture
- 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)
- EMEA** European Agency for the Evaluation of Medicinal Products
- EMS** electronic mail service
- EORTC** European Organisation 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 (EMEA)
- ESRA** European Society of Regulatory Affairs
- ESTRI** Electronic Standards for the Transfer of Regulatory Information (M2)
- EU** European Union
- EUDDRA** European Union Drug Regulatory Authorities
- EWG** expert working group
- FAQ** frequently asked questions (IT)
- 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 practices
- GP** general practitioner; general practice (UK)
- GPMS** good postmarketing surveillance practice (Japan)
- GRAS** generally regarded as safe (foods)
- GXP** good [pharmaceutical] practice
- HARTS** Hoechst Adverse Reaction Terminology System
- HCFA** Health Care Financing Administration (HHS)
- HEX** human experimentation committee
- HHS** Department of Health and Human Services (U.S., also called DHHS)
- HIMA** Health Industry Manufacturers Association
- HL7** Health Level 7 (clinical data interchange)
- HPB** Health Protection Branch, Laboratory Centre for Disease Control (Canada)
- HPLC** high performance liquid chromatography
- HSRC** human subjects review committee
- HTML** Hypertext Markup Language (IT)
- HTTP** hypertext transfer protocol (IT)
- IB** investigator's brochure
- IC** informed consent
- ICD9** International Classification of Diseases, 9th revision. *See also MedDRA*

- ICF** informed consent form
- 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
- ICS report** integrated
- IDDM** insulin-dependent diabetes mellitus
- IEC** independent ethics committee
- IEEE** The 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 CCI, CCPPRB, CHR, CPHS, CRB, EAB, EC, HEX, IEC, LREC, MREC, NIRB, REB*
- 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 device; in vitro diagnostics
- IVF** in vitro fertilization
- IVF/ET** in vitro fertilization/embryo transfer
- IVR** interactive voice response (telephone technology)
- JCAHO** Joint Commission on Accreditation of Healthcare Organizations
- JCPT** *Journal of Clinical Pharmacology and Therapeutics*
- JCRDD** *Journal of Clinical Research and Drug Development*
- JCRP** *Journal of Clinical Research and Pharmacoepidemiology*
- JMA** Japan Medical Association
- JPMA** Japan Pharmaceutical Manufacturers Association
- Kbps** thousands of bits per second (data transmission)
- KS** Kaposi's sarcoma
- LAN** local area network (IT)
- LIF** Swedish Pharmaceutical Industry Association
- LKP** Leiter der klinischen Prüfung, under the German Drug Law, the physician who is head of clinical testing
- LOA** letter of agreement
- LREC** local research ethics committee(UK). *See also CCI, CCPPRB, CHR, CPHS, CRB, EAB, EC, HEX, IEC, IRB, MREC, NIRB, REB*
- MA** marketing authorization
- Mbps** millions of bits per second (data transmission)
- MCA** Medicines Control Agency (UK)
- MDR** Medical Device Reporting
- MECU** million ECU
- MEDDRA** *Medical Dictionary for Drug Regulatory Affairs*
- 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
- MHW** Ministry of Health and Welfare (Koseisho, Japan's drug regulatory agency)
- 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 CCI, CCPPRB, CHR, CPHS, CRB, EAB, EC, HEX, IEC, IRB, LREC, NRB, REB*
- 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 postinspection 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.)
- 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)
- 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 Study (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)
- NIAD** 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)
- NIHES** 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
- NLM** National Library of Medicine (NIH)
- NME** new molecular entity
- NRB** noninstitutional review board, also known as an independent review board. *See*

also *CCI, CCPPRB, CHR, CPHS, CRB, EAB, EC, HEX, IEC, IRB, LREC, MREC, REB*

NSCLC non-small cell lung carcinoma

OAI Official Action Indicated (serious FDA postinspection classification)

OAM See *NCCAM*

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

ODE Office of Drug Evaluation (CDER now has five such offices: ODE I, II, III, IV, and V)

OGD Office of Generic Drugs (CDER, formerly DGB)

OGI 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)

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 (abolished by U.S. Congress, fall 1995)

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

PAB Pharmaceutical Affairs Bureau (Japan)

PAHO Pan American Health Organization

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.)

PEM prescription event monitoring

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

PFT pulmonary function tests

PhRMA Pharmaceutical Research and Manufacturers of America (formerly PMA)

PHS Public Health Service (U.S.)

PI principal investigator

PK pharmacokinetics

PKI public key infrastructure (IT)

PLA Product License Application (FDA)

PMA Pre-Market Approval application (FDA)

PMS postmarketing surveillance

PPI patient package insert

PPO preferred provider organization; policy and procedure order

PR public relations

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

PROG peer-review oversight group (NIH)

PSUR periodic safety update report

PTC Points to Consider

QA quality assurance

QAU quality assurance unit

QC quality control

QL quality of life

QOL quality of life

R&D research and development

R&TD research and technological development

RADAR Risk Assessment of Drugs—Analysis and Response

RAPS Regulatory Affairs Professionals Society

RCT randomized clinical trial

RDE remote data entry

RDRRC Radioactive Drug Research Committee

REB research ethics board (Canada). See also *CCI, CCPPRB, CHR, CPPHS, CRB, EAB, EC, HEX, IEC, IRB, LREC, MREC, NRB*

RKI Robert-Koch-Institut, Bundesinstitut für Infektionskrankheiten und nich-

übertragbare Krankheiten (Federal Institute for Infectious and Non-communicable Diseases, Germany)

RL regulatory letter (FDA post-audit letter)

SAE serious adverse event

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*

SCT Society for Clinical Trials

SD standard deviation

SDA State Drug Administration (China)

SE standard error (statistics)

SEA Single European Act of 1987

SEER Surveillance, Epidemiology, and End Results (Registry of NCI)

SGML Standard Generalized Markup Language (IT)

SLA service level agreement

SMART Submission Management and Review Tracking (FDA)

SME significant medical event

SMO site management organization

SmPC Summary of Product Characteristics

SNDA Supplemental New Drug Application

SNIP Syndicat National de l'Industrie Pharmaceutique (France)

SNOMED *Systematized Nomenclature of Medicine* (a dictionary)

SoCRA Society of Clinical Research Associates

SOP standard operating procedure

SPAC State Pharmaceutical Administration of China

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)

SSM skin surface microscopy

STD sexually transmitted disease

STT short term tests

SUD sudden unexpected death

SWOG Southwest Oncology Group (U.S.)

TB tuberculosis

TCP/IP Transmission Control Protocol/Internet Protocol

TESS treatment emergent signs and symptoms

TIND Treatment IND. See also *IND*

TK toxicokinetics

t_{max} the time after dosing when C_{max} occurs

TMO trial management organization

UK United Kingdom

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)

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 (IT) □