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 Healthcare Policy Research (NIH)

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

**AICRC** Association of Independent Clinical Research Contractors (UK)

**AIDS** acquired immune deficiency syndrome, acquired immunodeficiency syndrome

**AICRC** Association of Independent Clinical Research Contractors (UK)

**AICR** attributed, 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)
ACRONYMS, ABBREVIATIONS, AND INITIALS

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 tooslset maintained by NCI
CAPRA  Canadian Association of Professional Pharmaceutical Regulatory Affairs (also ACPR Association canadienne des professionnels en réglementation)
CCRP  Certified Clinical Research Professional. SoCRA certification of coordinators, monitors, and other research professionals
CCSI  Company Core Safety Information
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
CDA  Clinical Document Architecture (HL7)
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
CEU  Continuing Education Unit
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
CEN  Comité Européen de Normalisation (European Committee for Standardization)
CEU  Continuing Education Unit
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.
CPCS  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 “seesweecky.”
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
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)
DS  Department of Drugs (Swedish regulatory agency)
DS-certifiable  Drug certification
DSI  Division of Scientific Investigations (FDA)
DMPA  Depo-Provera
DSMB  data safety monitoring board
DSNP  Development of Standardized Nomenclature Project (FDA)
DST  daylight saving time
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)
DSO  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
DSU  clinical supply unit
DSUICI  (replaces CSUCT) Computerized Systems Used In Clinical Investigations. NOTE: usually pronounced “seesweecky.”
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
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)
DSO  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
DSU  clinical supply unit
DSUICI  (replaces CSUCT) Computerized Systems Used In Clinical Investigations. NOTE: usually pronounced “seesweecky.”
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
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)
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-Submis-
sions 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 Organisa-
tion for Research and Treat-
ment 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

EudraCT  European Union
clinical trials database

EudraCT  European Union
clinical trials database

EVS  Enterprise Vocabulary
Services (National Cancer
Institute)

ER  Essential Requirements
(EMEA)

ER  Essential Requirements
(EMEA)

EWS  expert working group

FAQ  frequently asked
questions

Farmindustria  The Associ-
ation of Italian Pharmaceuti-
cal Manufacturers

F&D&C Act  Food, Drug, and
Cosmetic Act (U.S.)

FDA  Food and Drug Admin-
istration (U.S.)

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

FDAMA  FDA Moderniza-
tion 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 Commis-
sion (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

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)

GP  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)

HEIE  Health Information Exchange. The mobilization of healthcare information electronically across organizations within a region or community. HEIE 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 HEIE 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

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 CDRH to get permission for investigational device testing in clinical trials

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

IEEE  Institute of Electrical and Electronic Engineers, Inc.

IFAPP  International Federation of Associations of Pharmaceutical Physicians

IFPMA  International Federation of Pharmaceutical Manufacturers and Associations

IG  Inspector General (HHS)

IHE  Integrating the Healthcare Enterprise (an international standards organization)

IHI  Institute for Healthcare Improvement

IKS  Interkantonale Kontrollstelle für Heilmittel (Switzerland)

IMI  Innovative Medicines Initiative (European Commission)

IMP  investigational medicinal product; investigational materials plan

IMPD  Investigational Medicinal Product Dossier (EUDRA)

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

INN  International Nonproprietary Name

IOM  Institute of Medicine (National Academy of Science, 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)
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISCB</td>
<td>International Society for Clinical Biostatistics</td>
</tr>
<tr>
<td>ISDN</td>
<td>Integrated Services Digital Network</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
</tr>
<tr>
<td>ISOQOL</td>
<td>International Society for Quality of Life Research</td>
</tr>
<tr>
<td>ISP</td>
<td>Internet service provider</td>
</tr>
<tr>
<td>IT</td>
<td>Information technology</td>
</tr>
<tr>
<td>ITU-T</td>
<td>International Telecommunication Union—Telecommunication Standardization Sector</td>
</tr>
<tr>
<td>IUPAC</td>
<td>International Union of Pure and Applied Chemistry</td>
</tr>
<tr>
<td>IVD</td>
<td>In vitro diagnostics</td>
</tr>
<tr>
<td>IVRS</td>
<td>Interactive voice response system</td>
</tr>
<tr>
<td>J3C</td>
<td>Japan CDISC Coordinating Committee</td>
</tr>
<tr>
<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organizations</td>
</tr>
<tr>
<td>JCG</td>
<td>Japan CDISC Group</td>
</tr>
<tr>
<td>JMA</td>
<td>Japan Medical Association</td>
</tr>
<tr>
<td>JPMA</td>
<td>Japan Pharmaceutical Manufacturers Association</td>
</tr>
<tr>
<td>Kbps</td>
<td>Kilobits, or thousands of bits per second (data transmission)</td>
</tr>
<tr>
<td>LAB</td>
<td>Laboratory Data Model (CDISC)</td>
</tr>
<tr>
<td>LAN</td>
<td>Local area network</td>
</tr>
<tr>
<td>LIF</td>
<td>Swedish Pharmaceutical Industry Association</td>
</tr>
<tr>
<td>LKP</td>
<td>Leiter der Klinischen Prüfung</td>
</tr>
<tr>
<td>LOA</td>
<td>Letter of agreement</td>
</tr>
<tr>
<td>LOINC</td>
<td>Logical observations, identifiers, names, and codes</td>
</tr>
<tr>
<td>LREC</td>
<td>Local research ethics committee (UK). See also Ethics Committee box in the Glossary</td>
</tr>
<tr>
<td>MA</td>
<td>Marketing authorization</td>
</tr>
<tr>
<td>MAA</td>
<td>Marketing Authorization Application (EMEA, EU)</td>
</tr>
<tr>
<td>MAH</td>
<td>Marketing Authorization Holder (EU)</td>
</tr>
<tr>
<td>MAPP</td>
<td>Manual of Policies and Procedures (CDER)</td>
</tr>
<tr>
<td>Mbps</td>
<td>Megabits, millions of bits per second (data transmission)</td>
</tr>
<tr>
<td>MDR</td>
<td>Medical device reporting</td>
</tr>
<tr>
<td>MedDRA</td>
<td>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)</td>
</tr>
<tr>
<td>MedID</td>
<td>Medicinal Product Identifier</td>
</tr>
<tr>
<td>MEFA</td>
<td>Association of the Danish Pharmaceutical Industry</td>
</tr>
<tr>
<td>MEP</td>
<td>Member of the European Parliament</td>
</tr>
<tr>
<td>MHLW</td>
<td>Ministry of Health, Labor and Welfare (Japan)</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines and Healthcare products Regulatory Agency (UK)</td>
</tr>
<tr>
<td>MIAME</td>
<td>Minimum information about a microarray experiment (standard for microarray data)</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health (UK, Canada, others)</td>
</tr>
<tr>
<td>MOPH</td>
<td>Ministry of Public Health (Thailand, Yemen, others)</td>
</tr>
<tr>
<td>MOU</td>
<td>Memorandum of Understanding (an MOU between FDA and a regulatory agency in another country allows mutual recognition of inspections)</td>
</tr>
<tr>
<td>MPR</td>
<td>Medical Products Agency (Swedish Regulatory Agency)</td>
</tr>
<tr>
<td>MR</td>
<td>Medical Representative (Japan)</td>
</tr>
<tr>
<td>MRA</td>
<td>Medical research associate</td>
</tr>
<tr>
<td>MREC</td>
<td>Multicentre Research Ethics Committee (UK). See also Ethics Committee in the Glossary.</td>
</tr>
<tr>
<td>MRI</td>
<td>Magnetic resonance imaging</td>
</tr>
<tr>
<td>MTD</td>
<td>Maximum tolerated dose</td>
</tr>
<tr>
<td>MVP</td>
<td>Master validation plan</td>
</tr>
<tr>
<td>NABR</td>
<td>National Association for Biomedical Research</td>
</tr>
<tr>
<td>NAF</td>
<td>Notice of Adverse Findings (FDA postaudit letter)</td>
</tr>
<tr>
<td>NAI</td>
<td>No Action Indicated (most favorable FDA post-inspection classification)</td>
</tr>
<tr>
<td>NAS</td>
<td>New active substance (UK)</td>
</tr>
<tr>
<td>NAS–NRC</td>
<td>National Academy of Sciences—National Research Council (U.S.)</td>
</tr>
<tr>
<td>NBAC</td>
<td>National Bioethics Advisory Commission (U.S.)</td>
</tr>
<tr>
<td>NCA</td>
<td>National competent authority</td>
</tr>
<tr>
<td>NEFARMA</td>
<td>Dutch Association of the Innovative Pharmaceutical Industry</td>
</tr>
<tr>
<td>NEI</td>
<td>National Eye Institute (NIH)</td>
</tr>
<tr>
<td>NGO</td>
<td>Nongovernmental organization</td>
</tr>
<tr>
<td>NHI</td>
<td>National Health Insurance (Japan)</td>
</tr>
<tr>
<td>NHIN</td>
<td>National Health Information Network</td>
</tr>
<tr>
<td>NHLBI</td>
<td>National Heart, Lung, and Blood Institute (NIH)</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service (UK)</td>
</tr>
<tr>
<td>NIA</td>
<td>National Institute on Aging (NIH)</td>
</tr>
<tr>
<td>NIAAA</td>
<td>National Institute on Alcohol Abuse and Alcoholism (NIH)</td>
</tr>
</tbody>
</table>
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)

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

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.

RHIO Regional Health Information Organization.

RHIOS are the building blocks of the proposed National Health Information Network (NHIN) initiative

RLS 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)

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 SmPC.

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

TID  the time after dosing when Cmax occurs

TK  toxicokinetics

SMO  site management organization

SPC  summary of product characteristics. See also SmPC.

TESS  treatment-emergent signs and symptoms

TIND  treatment IND. See also IND.

UAT  user acceptance testing

UTC  coordinated universal time (international standard since 1972)

WHOART  World Health Organization Adverse Reaction Terminology

WHO  World Health Organization

WTO  World Trade Organization

WWW  World Wide Web

W3C  World Wide Web Consortium

XML  eXtensible Markup Language