Acronyms, Abbreviations, and Initials

Version 7.0

**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

**AHCCP** Agency for Health Care Policy Research (NIH)

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

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

**ALCOA** attributable, legible, contemporaneous, original, accurate (dimensions of data integrity)

**am** ante meridian, morning (12:00 midnight thru 11:59:59)
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 Initiative (eGov)

CHR  Committee on Human Research. See also Ethics Committee box in the Glossary.

CIC  clinical imaging center

CIOMS  Council for International Organisations of Medical Sciences (postapproval international ADR reporting, UK)

CIP  Certified IRB Professional

CIS  Commonwealth of Independent States

CLIA  Clinical Laboratory Improvement Amendments

Cmax  concentration maximum; used in pharmacokinetics and bioequivalence to indicate maximum plasma concentration for a drug

CMC  chemistry, manufacturing, and control

CME  Continuing Medical Education

CMS  Centers for Medicare & Medicaid Services

CNS  central nervous system

CONSORT  Consolidated Standards of Reporting Trials

COP  CDISC Operating Process/Procedure

CORE  CDISC Operational Roadmap Environment (CDISC)

COSTART  Coding Symbols for a Thesaurus of Adverse Reaction Terms. See also MedDRA.

CPHS  Committee for the Protection of Human Subjects

CPMP  Committee for Proprietary Medicinal Products (EU)

CPSC  Consumer Product Safety Commission (U.S.)

CRA  clinical research associate. See also CCRA.

CRADA  Cooperative Research And Development Agreement (with US Government entities such as FDA or NIH)

CRB  case record book

CRB  Central Review Board

CRC  clinical research coordinator. See also CCCR, SC, SSC.

CRF  case report form (sometimes case record form)

CRJX  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 “seesweecy.”

CT  clinical trial

CTA  Clinical Trial Agreement

CTC  Clinical Trial Certificate (UK)

CTD  Common Technical Document

CTEP  Cancer Therapy Evaluation Program

CTM  clinical trials materials

CTX  Clinical Trial Exemption (MCA)

CUI  common unique identifier. A code used in the Enterprise Vocabulary System (EVS) to link a particular concept across one or more terms.

CV  curriculum vitae

CVM  Center for Veterinary Medicine (FDA)

DAWN  Drug Abuse Warning Network

DD  Department of Drugs (Swedish regulatory agency)

DDF  Data Definition File

DDI  drug–drug interaction

DEA  Drug Enforcement Administration (U.S.)

DEN  Drug Experience Network

DES  Data Encryption Standard

DESI  Drug Efficacy Study Implementation notice (FDA, to evaluate drugs in use before 1962)

DGPharMed  Deutsche Gesellschaft für Pharmazeutische Medizin (German Society of Pharmaceutical Medicine), formerly FAPi

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-PT Act  Drug Price Competition and Patent Term Restoration Act of 1984 (also Waxman-Hatch or Hatch-Waxman bill)

DSI  Division of Scientific Investigations (FDA)

DSM  Diagnostic and Statistical Manual (of the American Psychiatric Association)

DSMB  data safety monitoring board
DSNP  Development of Standardized Nomenclature Project (FDA)

DST  daylight saving time

DSTU  Draft Standard for Trial Use. See HL7 definition.

DSUR  Development Safety Update Report (ICH)

DTC  direct-to-consumer (drug advertising)

DTD  Document Type Definition (XML)

DSTU  Draft Standard for Trial Use

DSUR  Development Safety Update Report (ICH)

DTC  direct-to-consumer (drug advertising)

EDC  electronic data capture/collection

EDI  electronic data interchange

eDMIS  electronic data management system

EDR  electronic document room. NOTE: The EDR is an extension of the e-Submissions central document room. A check is performed on each submission sent to the EDR for file formats used and the integrity of bookmarks and hypertext links.

EEC  European Economic Community, now EU; some regulatory documents still have EEC document numbers.

EFGCP  European Forum for Good Clinical Practice

EFPIA  European Federation of Pharmaceutical Industries and Associations

EFTA  European Free Trade Association

eHR  electronic health record

EIR  Establishment Inspection Report (FDA)

ELA  Establishment License Application (FDA)

EMWA  European Medical Writers Association

EO2C  European Organisation for Research and Treatment of Cancer

EP  European Parliament

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)

EWG  expert working group

FAQ  frequently asked questions

Farmindustria  The Association of Italian Pharmaceutical Manufacturers

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

FDA  Food and Drug Administration (U.S.)

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

FDAMA  FDA Modernization Act

FDLI  Food and Drug Law Institute

FFPM  Fellow of the Faculty of Pharmaceutical Medicine (UK)

FIPS  Federal Information Processing Standards

FRCP  Fellow of the Royal College of Physicians, sometimes followed by a place name—for example, FRCP (Edin.)—that indicates a university medical school

FTC  Federal Trade Commission (U.S.)

FTP  File Transfer Protocol

FWA  Federalwide Assurance

GAO  Government Accountability Office (U.S. government)

GBP  good business practice

Gbps  gigabits, or billions of bits per second (data transmission)

GCP  good clinical practice

GCRP  good clinical research practice

GCP  good clinical practice
GLP  good laboratory practice
GMP  good manufacturing practices
GMT  Greenwich mean time. See UTC.
GP  general practitioner; general practice (UK)
GPMS  good postmarketing surveillance practice (Japan)
GRAS  generally regarded as safe (foods)
GRP  good review practice (CDER)
GXP  good (pharmaceutical) practice
HA  health authority (UK)
HCFA  Health Care Financing Administration; now renamed The Centers for Medicare & Medicaid Services (CMS).
HEX  Human Experimentation Committee. See also Ethics Committee box in the Glossary.
HHS  Department of Health and Human Services (U.S., also called DHHS)
HIE  health information exchange
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 (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
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.
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.
IFAPP  International Federation of Associations of Pharmaceutical Physicians
IFPMA  International Federation of Pharmaceutical Manufacturers and Associations
IFPRO  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 International)
ISCB  International Society for Clinical Biostatistics
ISDN  Integrated Services Digital Network
ISO  International Organization for Standardization
ISQOL  International Society for Quality of Life Research
ISP  Internet service provider
**NIDCD** National Institute on Deafness and Other Communication Disorders (NIH)

**NIDCR** National Institute of Dental and Craniofacial Research (NIH)

**NIDDK** National Institute of Diabetes and Digestive and Kidney Diseases (NIH)

**NIEHS** National Institute of Environmental Health Sciences (NIH)

**NIGMS** National Institute of General Medical Sciences (NIH)

**NIH** National Institutes of Health (DHHS)

**NIMH** National Institute of Mental Health (NIH)

**NINDS** National Institute of Neurological Disorders & Stroke (NIH)

**NINR** National Institute of Nursing Research (NIH)

**NIRB** See NRB. See also Ethics Committee, Independent IRB in the Glossary.

**NLM** National Library of Medicine (NIH)

**NME** new molecular entity

**NOAEL** no observed adverse effect level (IUPAC)

**NOEL** no observable effect level (dose of an experimental drug given preclinically that does not produce an observable toxicity)

**NRB** noninstitutional review board, also known as an independent review board. See also Ethics Committee in the Glossary. NIRB.

**NSCLC** non-small cell lung carcinoma

**NTP** National Toxicology Program

**OAI** Official Action Indicated (serious FDA postinspection classification)

**OAM** See NCCAM.

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

**ODE** Office of Drug Evaluation

**ODM** Operational Data Model (CDISC)

**OGD** Office of Generic Drugs (CDER, formerly DGB)

**OGE** Office of Government Ethics

**OHITA** Office of Health Information Technology Adoption (ONCHIT)

**OHRP** Office for Human Research Protections (pronounced O-harp)

**OPR** Office of Policy and Research

**OPRR** Office for Protection from Research Risks (predecessor to OHRP)

**OSHA** Occupational Safety & Health Administration (U.S.)

**OTA** Office of Technology Assessment (U.S., abolished 1995)

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

**PAB** Pharmaceutical Affairs Bureau (Japan)

**PAC** Pan American Health Organization

**PCP** pneumocystis carinii pneumonia

**PK** pharmacokinetics

**PKI** public key infrastructure

**PMA** Premarket Approval application (FDA)

**PDUFA** Prescription Drug User Fee Act (1992, U.S.)

**PDUFA IV** Prescription Drug User Fee Act (FDA)

**PEM** prescription event monitoring

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

**PFT** pulmonary function test

**PGT** pharmacogenetics

**PGX** pharmacogenomics

**PhPID** pharmaceutical product identifier

**PhRMA** Pharmaceutical Research and Manufacturers of America

**PHS** Public Health Service (U.S.)

**PI** principal investigator

**PIM** product information management (a system introduced by the EMEA)

**PK** pharmacokinetics

**PKI** public key infrastructure

**PLA** Product License Application (FDA)

**pm** post meridian, evening (12 noon thru 23:59:59)
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>PMS</td>
<td>postmarketing surveillance</td>
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<tr>
<td>PPI</td>
<td>Patient Package Insert</td>
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<tr>
<td>PPO</td>
<td>preferred provider organization; policy and procedure order</td>
</tr>
<tr>
<td>PR</td>
<td>partial response; pulse rate</td>
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<tr>
<td>PRG</td>
<td>Protocol Representation Group (CDISC)</td>
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<tr>
<td>PRIM&amp;R</td>
<td>Public Responsibility in Medicine and Research (Boston, MA)</td>
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<tr>
<td>PRO</td>
<td>patient-reported outcome</td>
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<tr>
<td>PROG</td>
<td>Peer-Review Oversight Group (NIH)</td>
</tr>
<tr>
<td>PROMIS</td>
<td>Patient Reported Outcomes Measurement Information Systems (pronounced promise)</td>
</tr>
<tr>
<td>PSUR</td>
<td>periodic safety update report</td>
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<tr>
<td>PTC</td>
<td>points to consider</td>
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<tr>
<td>PV</td>
<td>pharmacovigilance</td>
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<tr>
<td>QA</td>
<td>quality assurance</td>
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<tr>
<td>QAU</td>
<td>quality assurance unit</td>
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<tr>
<td>QC</td>
<td>quality control</td>
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<tr>
<td>QL</td>
<td>quality of life</td>
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<tr>
<td>QOL</td>
<td>quality of life (also QoL)</td>
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<tr>
<td>R&amp;D</td>
<td>research and development</td>
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<tr>
<td>RADAR</td>
<td>risk assessment of drugs—analysis and response</td>
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<tr>
<td>RAPS</td>
<td>Regulatory Affairs Professionals Society</td>
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<tr>
<td>RCRIM</td>
<td>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)</td>
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<tr>
<td>RCT</td>
<td>randomized clinical trial</td>
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<td>RFP</td>
<td>request for proposal</td>
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<tr>
<td>RHIO</td>
<td>regional health information organization</td>
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<tr>
<td>RIM</td>
<td>Reference Information Model (HL7)</td>
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<td>RKI</td>
<td>Robert-Koch-Institut, Bundesinstitut für Infektionskrankheiten und nichtübertragbare Krankheiten (Federal Institute for Infectious and Noncommunicable Diseases, Germany)</td>
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<tr>
<td>RFS</td>
<td>retrieve form for data capture</td>
</tr>
<tr>
<td>RPS</td>
<td>Regulated Product Submission (HL7 RCRIM)</td>
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<tr>
<td>SADR</td>
<td>suspected adverse drug reaction (FDA)</td>
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<tr>
<td>SAR</td>
<td>Serious ADR Reporting (1977)</td>
</tr>
<tr>
<td>SAS</td>
<td>Statistical Analysis System (commonly used statistical analysis package)</td>
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<tr>
<td>SATCM</td>
<td>State Administration of Traditional Chinese Medicine (China)</td>
</tr>
<tr>
<td>SBA</td>
<td>Summary Basis of Approval</td>
</tr>
<tr>
<td>SC</td>
<td>study coordinator. See also CRC, CCRC, SSC.</td>
</tr>
<tr>
<td>SCDM</td>
<td>Society for Clinical Data Management</td>
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<tr>
<td>SCT</td>
<td>Society for Clinical Trials</td>
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<tr>
<td>SD</td>
<td>standard deviation (statistics)</td>
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<tr>
<td>SDA</td>
<td>State Drug Administration (China)</td>
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<tr>
<td>SDM</td>
<td>Submission Data Model (CDISC)</td>
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<tr>
<td>SDO</td>
<td>standards development organization</td>
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<tr>
<td>SDS</td>
<td>Submission Data Standards (CDISC)</td>
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<tr>
<td>SDTM</td>
<td>Study Data Tabulation Model (CDISC)</td>
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<tr>
<td>SDV</td>
<td>source document (data) verification</td>
</tr>
<tr>
<td>SE</td>
<td>standard error (statistics)</td>
</tr>
<tr>
<td>SEA</td>
<td>Single European Act of 1987</td>
</tr>
<tr>
<td>SEER</td>
<td>Surveillance, Epidemiology, and End Results program (National Cancer Institute)</td>
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<tr>
<td>SEND</td>
<td>Standard for the Exchange of Nonclinical</td>
</tr>
</tbody>
</table>
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 dictionary)

**SOAP** simple object access protocol (a W3C XML initiative)

**SoCRA** Society of Clinical Research Associates

**SOP** standard operating procedure

**SPAC** State Pharmaceutical Administration of China

**SPC** summary of product characteristics. See also SmPC.

**SPL** Structured Product Labeling (HL7, FDA)

**SPM** Society of Pharmaceutical Medicine (UK)

**SQA** Society of Quality Assurance

**SQAP** systems quality assurance plan

**SSC** study site coordinator. See also CRC, CCRC, SC.

**SSCT** Swedish Society for Clinical Trials

**SSFA** Società di Scienze Farmacologiche Applicate (Italy)

**STF** study tagging file

**STT** short term test

**SUAE** serious unexpected adverse event

**SUD** sudden unexpected death

**SWOG** Southwest Oncology Group (U.S.)

**TAC** Technical Advisory Committee (CDISC)

**TC** Technical Committee (HL7)

**TCC** Technical Coordinating Committee (CDISC)

**TCP/IP** Transmission Control Protocol/Internet Protocol

**TermID** Controlled Vocabulary Term Identifier

**TESS** treatment-emergent signs and symptoms

**TIND** treatment IND. See also IND.

**TK** toxicokinetics

**Tmax** the time after dosing when Cmax occurs

**TMO** trial management organization

**UMT** universal mean time (also known as Greenwich mean time). See UTC.

**URL** uniform resource locator (address of a Web site)

**USAN** United States Adopted Name

**USC** United States Code (book of laws)

**USDA** U.S. Department of Agriculture

**USP** United States Pharmacopeia

**UST** user site testing. *Synonym for UAT (user acceptance testing)*

**UT** universal time (also known as Greenwich mean time). See UTC.

**UTC** coordinated universal time (international standard since 1972)

**VA** Veterans Administration (officially, U.S. Department of Veterans Affairs)

**VAERS** Vaccine Adverse Event Reporting System

**VAI** Voluntary Action Indicated (FDA postaudit inspection classification)

**VCDE** vocabularies and common data elements (caBIG)

**VPN** virtual private network

**W3C** World Wide Web Consortium

**WAN** wide area network

**WHO** World Health Organization

**WHOART** World Health Organization Adverse Reaction Terminology

**WL** Warning Letter (most serious FDA postaudit letter, demands immediate action within 15 days)

**WR** written request

**WRAIR** Walter Reed Army Institute of Research (DoD)

**WTO** World Trade Organization

**WWW** World Wide Web

**XML** eXtensible Markup Language