Acronyms, Abbreviations, and Initials

Version 4.0

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 of 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 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

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)

AFCR *See AFMR.*

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

ALCOA Attributable, Legible, Contemporaneous, Original, Accurate (dimensions of data integrity)

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)

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

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)

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 in the Glossary.*

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

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

CDA Clinical Document Architecture

CDC Centers for Disease Control and Prevention

CDER Center for Drug Evaluation and Research (FDA)

CDISC Clinical Data Interchange Standards Consortium

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. *See also Informed Consent Form – ICF.*

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 Initiative (eGov)

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

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

CMMS Centers for Medicare & Medicaid Services

CNS Central Nervous System

CONSORT Consolidated Standards of Reporting Trials

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 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)

CRO Contract Research Organization. *See also IPRO.*

CSDD Center for the Study of Drug Development

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

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)

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)

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 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 Products Information Network

eCRF electronic Case Report Form

eCTD electronic Common Technical Document

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

eHR electronic Health Record

EIR Establishment Inspection Report (FDA)

ELA Establishment License Application (FDA)

EMEA 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 (EMEA)

eRX electronic Prescribing

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

Farmindustria 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 (CMMS).

HEX Human Experimentation Committee. *See also Ethics Committee in the Glossary.*

HHS Department of Health and Human Services (U.S., also called DHHS)

HIMA Health Industry Manufacturers Association

HIMSS Health Information and Management Systems Society

HIPAA Health Insurance Portability and Accountability Act

HIT Healthcare Information Technology

HL7 Health Level 7 (a not-for-profit ANSI-accredited standards developing 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 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 Haemostases

IEC Independent Ethics Committee. *See also Ethics Committee 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' Associations

IG Inspector General (HHS)

IKS Interkantonale Kontrollstelle für Heilmittel (Switzerland)

IMP Investigational Materials Plan

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 in the Glossary.*

IRD International Registration Document

IS International System of Units (may also be referred to as SI – Systéme Internationale)

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

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

LOINC Logical Observations, Identifiers, Names, and Codes

LREC Local Research Ethics Committee (UK). *See also Ethics Committee in the Glossary.*

MA Marketing Authorization

MAA Marketing Authorisation Application (EU)

MAH Marketing Authorization Holder (EU)

Mbps megabits, 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)

MedID Medicinal Product Identifier

MEDLARS Medical Literature Analysis and Retrieval System

MEFA Association of the Danish Pharmaceutical Industry

MEP Member of the European Parliament

MHLW Ministry of Health, Labor and Welfare (Japan)

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)

MPR Medical Products Agency (Swedish Regulatory Agency)

MR Medical Representative (Japan)

MRA Medical Research Associate

MREC Multicentre Research Ethics Committee (UK). *See also Ethics Committee in the Glossary.*

MRI Magnetic Resonance Imaging

MTD Maximum Tolerated Dose

MVP Master Validation Plan

NABR National Association for Biomedical Research

NAF Notice of Adverse Findings (FDA post-audit 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)

NHIH National Healthcare Information Network

NHLBI National Heart, Lung, and Blood Institute (NIH)

NHS National Health Service (UK)

NIA National Institute on Aging (NIH)

NIAAA National Institute on Alcohol Abuse and Alcoholism (NIH)

NIAID National Institute of Allergies and Infectious Diseases (NIH)

NIAMS National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIH)

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, Independent IRB in the Glossary.*

NLM National Library of Medicine (NIH)

NME New Molecular Entity

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 post-inspection 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

OHRP Office for Human Research Protections

OIG Office of the Inspector General

OIS Office of Interoperability and Standards

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.)

ONC Office of the national Coordinator for Health Information Technology

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)

PAHO Pan American Health Organization

PCC Poison Control Center

PCP Pneumocystis carinii pneumonia

PD pharmacodynamics

PDA Personal Digital Assistant (Palm Pilot(r), 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

PhPID Pharmaceutical Product Identifier

PhRMA Pharmaceutical Research and Manufacturers of America (formerly PMA)

PHS Public Health Service (U.S.)

PI Principal Investigator

PK pharmacokinetics

PKI Public Key Infrastructure

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 Partial Response; Pulse Rate

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 (also QoL)

R&D Research and Development

RADAR Risk Assessment of Drugs-Analysis and Response

RAPS Regulatory Affairs Professionals Society

RCRIM Regulated Clinical Research and Information Management (HL7)

RCT Randomized Clinical Trial

RDE Remote Data Entry

RDRC Radioactive Drug Research Committee

REB Research Ethics Board (Canada)

RHIO Regional Health Information Organization

RIM Reference Information Model (HL7)

RKI Robert-Koch-Institut, Bundesinstitut für Infektionskrankheiten und nichtübertragbare Krankheiten (Federal Institute for Infectious and 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.

SCDM Society for Clinical Data Management (U.S.)

SCT Society for Clinical Trials

SD Standard Deviation (statistics)

SDA State Drug Administration (China)

SDM Submission Data Model (CDISC)

SDO Standards Development Organization

SDS Submission Data Standards (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)

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 SPC.*

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

SPC Summary of Product Characteristics. *See also SmPC.*

Nuremberg Code—Directive 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, over-reaching, 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.

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)

SDTM Subject Data Tabulation Model

SPL Structured Product Labeling

STF Study Tagging File

STT Short Term Tests

SUA Serious Unexpected Adverse event

SUD Sudden Unexpected Death

SWOG Southwest Oncology Group (U.S.)

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

URL Uniform Resource Locator (address of a Web site)

USAN United States Adopted Name

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 post-audit 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