

## COMMONLY-USED ABBREVIATIONS AND ACRONYMS FOR RESEARCH COORDINATORS

AABB	American Association of Blood Banks
AADA	Abbreviated Antibiotic Drug Application
AAPS	American Association of Pharmaceutical Scientists
Ab	Antibody
ABEP	Auditory Brainstem-Evoked Potential
ABPI	Association of British Pharmaceutical Industries
AC	Before Meals
ACE	Adverse Clinical Event
ACIL	American Council of Independent Laboratories
ACRA	Associate Commissioner of Regulatory Affairs (FDA)
ACRP	Association of Clinical Research Professionals
ACRPI	Association for Clinical Research in the Pharmaceutical Industry (United Kingdom)
ACT	Applied Clinical Trials (industry journal)
AD	Alzheimer's Disease
AD	Antidepressant
ADAMHA	Alcohol, Drug Abuse and Mental Health Administration
ADAS	Alzheimer's Disease Assessment Scale
ADE	Adverse Drug Event
ADME	Absorption, Distribution, Metabolism, and Excretion (criteria affecting activity of a drug within an organism)
ADR	Adverse Drug Reaction
AE	Adverse Event
AED	Antiepileptic Drugs
AHRQ	Agency for Healthcare Research and Quality
AIDS	Acquired Immunodeficiency Syndrome

AKA	Above-the-Knee Amputation
ALT	Alanine Aminotransferase (formerly SGPT, liver enzyme)
AMA	American Medical Association, American Management Association, against medical advice
AmFAR	American Foundation for AIDS Research
AMG	West Germany Drug Law (Germany's equivalent to Food, Drug and Cosmetic Act)
AMI	Acute Myocardial Infarction
ANDA	Abbreviated New Drug Application (used for generics)
AOACI	Association of Official Analytical Chemists International
APHIS	Animal and Plant Health Inspection Service (USDA)
ARC	AIDS-Related Complex
ARDS	Adult Respiratory Distress Syndrome
ASCPT	American Society for Clinical Pharmacology and Therapeutics
AST	Aspartate Aminotransferase (also known as SGOT, liver enzyme)
ATF	Bureau of Alcohol, Tobacco and Firearms (US Department of Justice)
AZT	Zidovudine (HIV treatment)
BAER	Brainstem Auditory-Evoked Potential
BCE	Beneficial Clinical Event
BEUC	European Consumers' Organisation
BGA	Bundesgesundheitsamt (Germany's equivalent to FDA)
BID	Twice a Day
BIND	Biological IND
BKA	Below-the-Knee Amputation
BMI	Body Mass Index
BMR	Basal metabolic rate
BP	Blood Pressure
BPAD	Bipolar Affective Disorder

BPM	Beats per Minute
BSA	Body Surface Area
BSN	Bachelor of Science in Nursing
BUN	Blood Urea Nitrogen
C & S	Culture and Sensitivity Test (for bacteria)
Ca	Calcium
CA	Carcinoma
CAD	Coronary Artery Disease
CANDA	Computer-Assisted New Drug Application
CAPLA	Computer-Assisted Product License Application
CAPRA	Canadian Association of Pharmaceutical Regulatory Affairs
CBC	Complete Blood Count
CBCTN	Community-Based Clinical Trials Network
CBER	Center for Biologics Evaluation and Research (FDA)
CBF	Cerebral Blood Flow
CC	Chief Complaint
CDD	Canadian Drugs Directorate
CCRA	Certified Clinical Research Associate
CCRC	Certified Clinical Research Coordinator
CDC	Centers for Disease Control
CDER	Center for Drug Evaluation and Research (FDA)
CDRH	Center for Devices and Radiological Health (FDA)
CEN	Committee for European Normalization
CEU	Continuing Education Units
CFR	Code of Federal Regulations
CFSAN	Center of Food Safety and Applied Nutrition (FDA)
CHD	Coronary Heart Disease

CHF	Congestive Heart Failure
CHI	Closed Head Injury
CIOMS	Council for International Organizations of Medical Sciences (post-approval international ADR)
CIR	Cosmetic Ingredient Review (FDA)
CK or CPK	Serum Creatine Kinase or Creatine Phosphokinase
Cl	Serum or Plasma Chloride
CLIA	Clinical Laboratory Improvement Amendments
CMC	Chemistry and Manufacturing Controls (FDA)
CMDRH	Center for Medical Devices and Radiological Health (FDA)
CME	Continuing Medical Education
CMG	Cystometrogram
CNS	Central Nervous System
COSTART	Coding Symbols for Thesaurus of Adverse Reaction Terms (FDA)
CP	Compliance Program (FDA)
CPMP	Committee for Proprietary Medicinal Products
CPR	Cardiopulmonary Resuscitation
CPSC	Consumer Product Safety Commission
CRA	Clinical Research Associate
CRADA	Cooperative Research and Development Agreements (between government agencies and industry)
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Clinical Research Organization
CSDD	Center for the Study of Drug Development
CSF	Cerebral Spinal Fluid
CSM	Commission on Safety of Medicines (United Kingdom)
CT	Clinical Trial

CT	Computed Tomography
CTM	Clinical Trial Material
CV	Curriculum Vitae
CVA	Cerebrovascular Accident
CVM	Center for Veterinary Medicine (FDA)
CXR	Chest X-Ray
DAWN	Drug Abuse Warning Network
DB	Double Blind
DBM	Division of Bioresearch Monitoring, CDRH, FDA
DCF	Data Correction Form/Data Clarification Form
DD	Department of Drugs (Sweden's equivalent to the FDA)
DEA	Drug Enforcement Administration (law enforcement division of FDA)
DEN	Drug Experience Network
DHHS	Department of Health & Human Services
DIA	Drug Information Association
DJD	Degenerative Joint Disease
dl.	Deciliter
DNR	Do Not Resuscitate
DOD	Department of Defense
DOT	Department of Transportation
DPC-PTR	Drug Price Competition and Patent Term Restoration Act of 1984
DRG	Diagnosis-Related Groups
DSI	Division of Scientific Investigations (FDA)
DSM	Diagnostic and Statistical Manual
DUR	Drug Use Review
Dx.	Diagnosis
EAB	Ethical Advisory Board (similar to IRB, used by other nations)

ECG	Electrocardiogram
ECU	European Currency Unit
ED	Erectile Dysfunction
EEC	European Economic Community
EEG	Electroencephalogram
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFTA	European Free Trade Association
EIR	Establishment Inspection Report (provides a detailed account of the FDA inspection)
EKG	Electrocardiogram
ELA	Establishment License Application
EMG	Electromyogram
EMS	Electronic Mail Service
ENDA	Electronic NDA
ENT	Ear, Nose, and Throat
EO	Executive Order
EORTC	European Organization for Research and Treatment of Cancer
EOS	End of Study
EPA	Environmental Protection Agency
EPI	Expanded Programme in Immunization (WHO program)
EPL	Effective Patent Life
ETT	Exercise Tolerance Test
EUP	Experimental Use Permit (for animal research, obtained from EPA)
EURODIAB	European Concerted Action on the Epidemiology of Diabetes
FACA	Federal Advisory Committee Act, 1972
FAX	Facsimile
FBS	Fasting Blood Sugar

FCC	Federal Communications Commission
FCCSET	Federal Coordinating Council for Science, Engineering and Technology
FDA	Food and Drug Administration
FDA-482	Notice of Inspection
FDA-483	Notice of Adverse Findings in an Inspection
FDA-1572	FDA Form for Statement of Investigator
FDA-SRS	Spontaneous Reporting System of the FDA
FDCA	Food, Drug, and Cosmetic Act
FDLI	Food and Drug Law Institute
FMD	Field Management Directives (FDA)
FOIA	Freedom of Information Act
FP	Family Practice
FR	Federal Register
FSIS	Food Safety and Inspection Service (USDA)
FTC	Federal Trade Commission (has primary responsibility for non-prescription advertising while the FDA has responsibility for prescription drug advertising)
FUO	Fever of unknown origin
Fx.	Fracture
g	Gram
GAO	General Accounting Office
GATT	General Agreement of Tariffs and Trade
GCP	Good Clinical Practices
GFR	Glomerular Filtration Rate
GI	Gastrointestinal
GIB	Gastrointestinal Bleed
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice

GP	General Practice Physician
GRAS	Generally Recognized as Safe (salt, hydrogen peroxide, etc.)
GRE	Generally Recognized as Effective
GTN	Nitroglycerin
GU	Genitourinary
HAI	Health Action International
HAZCOM	Hazardous Communication (EPA)
HAZMAT	Hazardous Materials (EPA)
Hb	Hemoglobin
HCFA	Health Care Financing Administration
HCO <sub>3</sub>	Serum or Plasma Bicarbonate
Hct	Hematocrit
Hg	Mercury
Hgb	Hemoglobin
HHS	Health and Human Services (Department of )
HIV	Human Immunodeficiency Virus
HMO	Health Maintenance Organization
HPB	Health Protection Branch (Canada's equivalent to the FDA)
HRG	Health Research Group
HRRC	Human Research Review Committee
HRSA	Health Resources and Services Administration
HS	At Hour of Sleep
HTN	Hypertension
Hx.	History
IACUC	Institutional Animal Care and Use Committee (IRB for animal research)
IB	Investigator's Brochure
ICD9	International Classification of Disease Codes, 9th Revision



ICD-9-CM	International Classification of Disease Codes, 9th Revision-Clinical Modification
ICH	International Conference on Harmonisation
ICTH	International Committee on Thrombosis and Haemostases
ID	Identification or Intradermal
IDB	Investigational Drug Brochure
IDE	Investigational Device Exemption
IDR	Idiosyncratic Drug Reaction
IM	Internal Medicine or Intramuscular
INAD	Investigational New Animal Drug (FDA)
IND	Investigational New Drug (Application)
IPCS	International Program for Chemical Safety
IPEMC	International Commission for Protection Against Mutagens and Carcinogens
IPRA	International Product Registration Application
IPRD	International Product Registration Document
IRB	Institutional Review Board
IRG	Initial Review Groups
ISO	International Organization for Standardization
ISPE	International Society for Pharmacoepidemiology
IT	Information Technology
IV	Intravenous
IVD	In Vitro Diagnostic (test that works on a body fluid sample)
IVDA	Intravenous Drug Abuse
IVF	In Vitro Fertilization
IVF/ET	In Vitro Fertilization/Embryo Transfer
IVP	Intravenous Pyelography
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
JPMA	Japan Pharmaceutical Manufacturers Association
K	Serum or Plasma Potassium
kg	Kilogram
Kilo	Kilogram
KS	Kaposi's sarcoma
LASER	Light Amplification by Stimulated Emission of Radiation
lb	Pound
LD	Linked Databases
LDH	Lactate Dehydrogenase
LOA	Letter of Agreement
LOC	Level of Concern
LTF	Liver Function Tests
MCA	Medicines Control Agency (a division of United Kingdom's equivalent to the FDA)
MCV	Mean Corpuscular Volume
MD	Medicines Division (United Kingdom's equivalent to the FDA)
MDD	Manic Depressive Disorder
MDI	Metered Dose Inhaler
MDR	Medical Device Reporting
MEDLARS	Medical Literature Analysis and Retrieval System
MHW	Ministry of Health and Welfare (Japan's equivalent to the FDA)
ml	Milliliter
mm	Millimeter
MMSE	Mini-Mental Status Exam (Folstein Test)

MOU	Memoranda of Understanding
MRA	Medical Research Associate
MRI	Magnetic Resonance Imaging
MS	Multiple Sclerosis
MTD	Maximum Tolerated Dose
MVP	Mitral Valve Prolapse
Na	Serum or Plasma Sodium
NA	Not Available, Not Applicable
NACH	National Advisory Health Council
NAF	Notice of Adverse Findings (post-FDA audit letter)
NAI	No Action Indication (most favorable post-FDA inspection classification)
NAS-NRC	National Academy of Sciences - National Research Council
NCE	New Chemical Entity
NCHS	National Center for Health Statistics (part of CDC)
NCI	National Cancer Institute
NCS	Not Clinically Significant
NCTR	National Center for Toxicological Research (FDA)
NCV	Nerve Conduction Velocities
NCVIA	National Childhood Vaccine Injury Act (1986)
ND	Not Done
NDA	New Drug Application
NDS	New Drug Study (Canada's equivalent of NDA)
NHLBI	National Heart, Lung, and Blood Institute
NHW	National Health and Welfare Department (Canada's equivalent of DHHS)
NIAID	National Institute of Allergy and Infections Disease
NIDA	National Institute of Drug Abuse
NIH	National Institutes of Health

NKA	No Known Allergies
NLEA	Nutrition Labeling and Education Act (1990)
NME	New Molecular Entity
NMR	Nuclear Magnetic Resonance
NPI	Neuropsychiatric Inventory
NPO	Nothing By Mouth
NRB	Non-Institutional Review Board
NRC	Nuclear Regulatory Commission
NS	Not Clinically Significant
NSAID	Nonsteroidal Anti-Inflammatory Drug
NSR	Normal Sinus Rhythm
NTP	National Toxicology Program
OAI	Official Action Indicated (serious post-FDA inspection classification)
OB-GYN	Obstetrics-Gynecology
OBRR	Office of Blood Research and Review (FDA)
°C	Temperature in Centigrade
OD	Right Eye
ODB	Observational Database
ODE	Office of Drug Evaluation (in FDA's CDER)
OE	Office of Enforcement (FDA)
OECD	Organization for Economic Cooperation and Development (international)
°F	Temperature in Fahrenheit
OGD	Office of Generic Drugs (FDA)
OHA	Office of Health Affairs (FDA)
OHRP	Office for Human Research Protections
OMB	Office of Management and Budget
OPD/SC	Office of Professional Development and Staff College (FDA)

ORA	Office of Regulatory Affairs (FDA)
ORO	Office of Regional Operations (FDA)
OS	Left Eye
Os	Opening
OSHA	Occupational Safety and Health Administration
OTA	Office of Technology Assessment (part of Patents and Trademarks)
OTC	Over-the-Counter (nonprescription drugs)
OU	Both Eyes
Oz	Ounce
PA	Posterior-Anterior
PaCO <sub>2</sub>	Arterial CO <sub>2</sub>
PaO <sub>2</sub>	Arterial O <sub>2</sub>
PAR	Post-Approval Research (significant for approval of AIDS drugs)
PCC	Poison Control Center
PCP	Pneumocystis Carinii Pneumonia
PD	Parkinson's Disease
PD	Pharmacodynamics
PDQ	Physician's Data Query (NCI-sponsored cancer trial registry)
PDR	Physician's Desk Reference
PE	Physical Examination or Pulmonary Embolus
PET	Positron Emission Topography
PFT	Pulmonary Function Tests
PhRMA	Pharmaceutical Research and Manufacturers of America
PHS	Public Health Service
PI	Package Insert
PI	Principal Investigator
PID	Pelvic Inflammatory Disease

PK	Pharmacokinetics
PLA	Product License Application (when seeking commercialization of a biologic)
PMA	Pre-Market Approval (when seeking commercialization of a device)
PMI	Point of Maximum Impulse
PMS	Premenstrual Syndrome
PMS	Post-Marketing Surveillance
PO	By Mouth
PPE	Personal Protective Equipment (EPA)
PPI	Patient Package Inserts
PPO	Policy and Procedure Order
PPO	Preferred Provider Organization
PR	Pulse Rate
PR interval	An ECG interval
PRIM & R	Public Responsibility in Medicine and Research (nonprofit agency)
PRN	As Needed
PT	Prothrombin Time
PTT	Partial Thromboplastin Time
PUD	Peptic Ulcer Disease
PVD	Peripheral Vascular Disease
QA	Quality Assurance
QAU	Quality Assurance Unit
QC	Quality Control
QD	Every Day
QI	Quality Improvement
QID	Four Times a Day

QNS	Quantity Not Sufficient
QOD	Every Other Day
QOL	Quality of Life
R & D	Research and Development
RADAR	Risk Assessment of Drugs - Analysis and Response
RAPS	Regulatory Affairs Professional Society
RBC	Red Blood Count
RCT	Randomized Controlled Trial
RDE	Remote Data Entry
RDRRC	Radioactive Drug Research Committee
RIND	Reversible Ischemic Neurological Deficit
RL	Regulatory Letter (post-FDA audit letter)
RUG	Resource Utilization Group
Rx	Prescription
SAE	Serious Adverse Event
SAH	Subarachnoid Hemorrhage
SC or SQ	Subcutaneous
SC	Study Coordinator
SD	Source Document
SD	Standard Deviation
SDAT	Senile Dementia of the Alzheimer's Type
SE	Standard Error
SEA	Single European Act of 1987
SEER	Surveillance, Epidemiology, and End Results (Registry of NCI)
SMDA	Safe Medical Devices Act (1990)
SME	Significant Medical Event
SMO	Site Management Organization

SNDA	Supplemental NDA
SOB	Shortness of Breath
SOP	Standard Operating Procedure
SSM	Skin Surface Microscopy
STD	Sexually Transmitted Disease
STT	Short Term Tests
SUD	Sudden Unexpected Death
Sx.	Symptom
TIA	Transient Ischemic Attack
TID	Three Times a Day
TIND	Treatment IND
TK	Toxicokinetics
TMO	Trial Management Organization
TNG	Nitroglycerin
TQM	Total Quality Management
UA	Urinalysis
UKCCR	United Kingdom Coordinating Committee on Cancer Research
UNESCO	United Nations Educational Science and Cultural Organization
UNK	Unknown
URI	Upper Respiratory Infection
USDA	United States Department of Agriculture
USP	U.S. Pharmacopeia
UTI	Urinary Tract Infection
VA	United States Department of Veterans Affairs
VAI	Voluntary Action Indicated (post-FDA audit inspection classification)
VER	Visual Evoked Response
VS	Vital Signs



WBC	White Blood Count
WHO	World Health Organization
WL	Warning Letter (most serious of post-FDA audit letter, demands immediate action within 15 days)
WNL	Within Normal Limits