

### **Short List of Commonly Used Acronyms in Clinical Research**

700U	Statement of Economic Interest
ACRP	Association of Clinical Research Professionals
AE	Adverse Event
ADR	Adverse Drug Reaction
AMA	American Medical Association
BID	Twice Daily
BIND	Biological IND
CAP	College of American Pathologists
CBCTN	Community Based Clinical Trials Network
CBER	Center for Biologics Evaluation and Research (FDA)
CCRA	Certified Clinical Research Associate (ACRP)
CCRC	Certified Clinical Research Coordinator (ACRP)
CCRC	CTSC Clinical Research Center
CCRP	Certified Clinical Research Professional (SoCRA)
CDA	Confidential Disclosure Agreement
CDC	Center for Disease Control
CDER	Center for Drug Evaluation and Research (FDA)
CDRH	Center for Devices and Radiological Health (FDA)
CF	Consent Form
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CME	Continuing Medical Education
CP	Compliance Program (FDA)
COI	Conflict of Interest
CRA	Clinical Research Associate

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CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Clinical Research Organization
CT	Clinical Trial
CTA	Clinical Trial Agreement
CS	Clinically Significant
CSA	Clinical Service Agreement
CTSC	Clinical and Translational Science Center
CV	Curriculum Vitae
DCF	Data Correction Form / Data Clarification Form
DEA	Drug Enforcement Agency (law enforcement division of FDA)
DHHS	Department of Health & Human Services
DOS	Description of Study
EAB	Ethical Advisory Board (similar to IRB, used by other nations)
EDC	Electronic Data Capture
FDA	Food and Drug Administration
FDA-482	Notice of Inspection
FDA-483	Notice of Adverse Findings in an Inspection
FDA-1572	FDA Form for New Drug Application
FDA-1572	FDA Form for Statement of Investigator
FDA-SRS	Spontaneous Reporting System of the FDA
FDCA	Food, Drug, and Cosmetic Act
FOIA	Freedom of Information Act
FTC	Federal Trade Commission (has primary responsibility for non-prescription advertising while the FDA has responsibility for prescription drug advertising)
GCP	Good Clinical Practice
GDA	Global Disclosure Agreement
GLP	Good Laboratory Practice

GMP	Good Manufacturing Practice
HIPAA	Health Insurance Portability and Accountability Act
HHS	Health and Human Services (Department of)
HMO	Health Maintenance Organization
IACUC	Institutional Animal Care and Use Committee (IRB for animal use)
IB	Investigator's Brochure
ICD-9	International Classification of Disease Codes, 9 <sup>th</sup> revision
ICD-9-CM	International Classification of Disease Codes, 9 <sup>th</sup> revision-Clinical Modification
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IDB	Investigational Drug Brochure
IDE	Investigational Device Exemption
IDS	Investigational Drug Service (pharmacy)
INAD	Investigational New Animal Drug (FDA)
IND	Investigational New Drug
IRB	Institutional Review Board
JCAHO	Joint Commission of Accreditation of Health Care Organizations
LOA	Letter of Agreement
MDR	Medical Device Reporting
MOU	Memoranda of Understanding
MRA	Medical Research Associate
NAI	No Action Indication (most favorable post-FDA inspection classification)
NCI	National Cancer Institute
NCS	Not Clinically Significant
NDA	New Drug Application
NHLBI	National Heart, Lung, and Blood Institute
NIAID	National Institute of Allergy and Infectious Diseases

NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NKA	No Known Allergies
OAI	Official Action Indicated (serious post-FDA inspection classification)
OHRP	Office for Human Research Protection
OSHA	Occupational Safety and Health Administration
OTC	Over-the-counter (non-prescription drugs)
OVCR	Office of the Vice Chancellor for Research
PCC	Poison Control Center
PD	Pharmacodynamics
PDQ	Physician's Data Query (NCI sponsored cancer trial registry)
PDR	Physician's Desk Reference
PE	Physical Examination
PHI	Protected Health Information
PI	Package Insert
PI	Principal Investigator
PK	Pharmacokinetics
PLA	Product License Application (when seeking commercialization of a biologic)
PMA	Pre-Market Approval (when seeking commercialization of a device)
PO	By Mouth
PPE	Personal Protective Equipment
PPI	Patient Package Inserts
PPO	Preferred Provider Organization
PRN	As Needed
QA	Quality Assurance
QC	Quality Control
QD	Every day

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QID	Four Times a Day
QOL	Quality of Life
R&D	Research and Development
RDE	Remote Data Entry
RL	Regulatory Letter (post-FDA audit letter)
Rx.	Prescription
SAE	Serious Adverse Event
SC	Study Coordinator
SD	Source Document
SMO	Site Management Organization
SoCRA	Society of Clinical Research Associates
SOM	School of Medicine
SOP	Standard Operating Procedure
SRA	Staff Research Associate
TID	Three Times a Day
UNK	Unknown
USP	U.S. Pharmacopeia
VA	United States Department of Veterans Affairs
VAI	Voluntary Action Indicated (post-FDA audit inspection classification)
VS	Vital Signs
WHO	World Health Organization
WL	Warning Letter (most serious of post-FDA audit letter, demands immediate action within 15 days)