COMMONLY USED ABBREVIATIONS AND TERMS in CLINCAL TRIALS

Abbreviation	Definition
ADR	Adverse Drug Reaction
AE	Adverse Event
AUC	Area Under the Curve
BLA	Biologic Licensing Application
BUN	Blood Urea Nitrogen
CAP	College of American Pathologists
CBER	Center for Biologics Evaluation and Research (FDA)
CDER	Center for Drug Evaluation and Research (FDA)
CDRH	Center for Devices and Radiological Health (FDA)
CFR	Code of Federal Regulations
CI	Confidence Interval
CLIA	Clinical Laboratory Improvements Amendments
C_{max}	Maximum Plasma Concentration
C_{min}	Minimum Plasma Concentration
CNT	Consented but Not Treated
Cr	Serum Creatinine
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organization
CT	Computed Tomography
CTA	Clinical Trials Agreement
CTC	Circulating Tumor Cell Count
CTCAE	Common Terminology Criteria for Adverse Events
CYP	Cytochrome P450
DAR	Drug or Device Accountability Records
DHEA	Dihydroepiandrosterone
DLT	Dose Limiting Toxicity
DNA	Deoxyribonucleic Acid
DSMB	Data Safety Monitoring Board
DSMP	Data Safety Monitoring Plan

EC	Ethics Committee
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group (Used to determine Performance Status)
EDC	Electronic Data Capture
EMEA	European Agency for the Evaluation of Medicinal Products
FDA	Food and Drug Administration
FWA number	Federal Wide Assurance number (number assigned to IRB)
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
HAQ	Health Assessment Questionnaire
HDE	Humanitarian Device Exemption (must be in place to use a HUD)
HUD	Humanitarian Use Device (for less than 4, 000 subjects)
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IC_{50}	Inhibitory Concentration 50%
IDE	Investigational Device Exemption
IEC	Independent Ethics Committee
IND	Investigational New Drug
IRB	Institutional Review Board
ISR	Injection Site Reaction
ITT	Intent-to-Treat
IVRS	Interactive Voice Recognition System
K_i	Inhibition Constant
LDH	Lactate Dehydrogenase
MDR	Medical Device Reporting
MedDRA	Medical Dictionary for Regulatory Activities
mmHg	Millimeters of Mercury
MOS	Medical Outcomes Study
MTD	Maximum Tolerated Dose
NDA	New Drug Application

NSR	Non-Significant Risk (usually refers to device research)
OHRP	Office for Human Research Protection
PD	Pharmacodynamics
PFS	Progression-Free Survival
PI	Principal Investigator
PK	Pharmacokinetic
PMA	Pre- Market Approval
PMS	Post Marketing Surveillance
prn	As Needed
QOL	Quality of Life
QTcF	QT Interval Corrected by the Fridericia Correction Formula
RECIST	Response Evaluation Criteria in Solid Tumors (Oncology)
SAE	Serious Adverse Event
SD	Standard Deviation
SDV	Source Document Verification
SEM	Standard Error for the Mean
SEV	Site Evaluation Visit
SIV	Site Initiation Visit
SR	Significant Risk (usually refers to device research)
Tbili	Total Bilirubin
TK	Toxicokinetics
$t_{1/2}$	Half-Life
TTP	Time To Progression
WBC	White Blood Cell Count
WHO	World Health Organization
WMA	World Medical Association