FORUM

# Abbreviation list Clinical Research

# A

| | |
|---|---|
| AE | Adverse Event |
| ACRP | Association of Clinical Research Professionals |
| ADME | Absorption, Distribution, Metabolism, and Excretion |
| ADR | Adverse Drug Reaction |
| ALCOA++ | Data Integrity Principles in Clinical Trials (GCP) according to ICH E6(R3); Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available, Traceable |
| AMG | German Medicines Act (Arzneimittelgesetz, Germany) |
| API | Active Pharmaceutical Ingredient |
| ASR | Annual Safety Report |
| ATMP | Advanced Therapy Medicinal Products |
| ATP | According-To-Protocol |

# B

| | |
|---|---|
| BA | Bioavailability |
| BE | Bioequivalence |
| BfArM | Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, Germany) |
| BfS | Federal Office for Radiation Protection (Bundesamt für Strahlenschutz, Germany) |
| BMG | Federal Ministry of Health (Bundesministerium für Gesundheit, Germany) |
| BOB | Federal Higher Authority (Bundesoberbehörde, Germany) |

# C

| | |
|---|---|
| CA | Competent Authority |
| CAPA | Corrective and Preventive Actions |
| CCI | Commercial Confidential Information |
| CDA | Confidential Disclosure Agreement |
| CDASH | Clinical Data Acquisition Standard Harmonization |

| | |
|---|---|
| CDISC | Clinical Data Interchange Standards Consortium |
| CDM | Clinical Data Management |
| CDP | Clinical Development Plan |
| CFR | Code of Federal Regulations (USA) |
| CHMP | Committee for Medicinal Products for Human Use |
| cMS | Concerned Member State |
| COL | Clinical Operations Leader |
| CONSORT | Consolidated Standards of Reporting Trials |
| CRA | Clinical Research Associate |
| (e)CRF | (electronic) Case Report Form |
| CRO | Clinical Research Organisation |
| CT | Clinical Trial |
| CTMS | Clinical Trial Management System |
| CTA | Clinical Trial Agreement |
| CTA | Clinical Trial Assistant |
| CTCAE | Common Terminology Criteria for Adverse Events |
| CTD | Clinical Trials Directive |
| CTIS | Clinical Trials Information System |
| CTO | Clinical Trials Office |
| CTR | Clinical Trials Regulation |
| CRC | Clinical Research Coordinator |
| CSR | Clinical Study Report |

# D

| | |
|---|---|
| DBL | Data Base Lock |
| DCF | Data Clarification Form |
| DDI | Drug-Drug Interaction |
| DIA | Drug Information Association |
| DIR | Directive |
| DM | Data Manager |
| DMP | Data Management Plan |
| DSMB | Data Safety Monitoring Board |
| DSUR | Development Safety Update Report |
| DVP | Data Validation Plan |

# E

| | |
|---|---|
| EBM | Evidence Based Medicine |
| EC | Ethics Committee |
| EDC | Electronic Data Capture |
| EEA | European Economic Area |
| EFPIA | European Federation of Pharmaceutical Industries and Associations |
| EHDS | European Health Data Space |
| EHR | Electronic Health Record |
| EMA | European Medicines Agency |
| ePRO | electronic Patient Reported Outcomes |
| EU | European Union |
| EU-CTR | European Clinical Trials Regulation |
| EUDRA | European Union Drug Regulatory Authorities |

# F

| | |
|---|---|
| FDA | Food and Drug Administration (USA) |
| FIH | First in Human |
| FIM | First in Man |
| FMEA | Failure Mode and Effects Analysis |
| FPI | First patient in |
| FPFV | First patient first visit |
| FPO | First patient out |
| FSFV | First subject first visit |
| FU | Follow-up |

# G

| | |
|---|---|
| GAMP 5 | Good Automated Manufacturing Practice |
| GCLP | Good Clinical Laboratory Practice |
| GCP | Good Clinical Practice |
| GDNG | Health Data Use Act (Gesundheitsdatennutzungsgesetz, Germany) |
| GDPR | General Data Protection Regulation |

| | |
|---|---|
| GEP | Good Epidemiological Practice |
| GLP | Good Laboratory Practice |
| GMP | Good Manufacturing Practice |
| GVP | Good Pharmacovigilance Practice |

# H

| | |
|---|---|
| HAS | French National Authority for Health (France) |
| HTA | Health Technology Assessment |

# I

| | |
|---|---|
| IB | Investigator’s Brochure |
| ICF | Informed Consent Form |
| ICH | International Council for Harmonisation |
| ICSR | Individual Case Safety Report |
| IDMP | Independent Data Monitoring Committee |
| IEC | Independent Ethics Committee |
| IIT | Investigator Initiated Trial |
| IMP | Investigational Medicinal Product |
| IMPD | Investigational Medicinal Product Dossier |
| IND | Investigational New Drug |
| INDA | Investigational New Drug Application |
| IP | Investigational Product |
| IQWiG | Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, Germany) |
| IRB | Institutional Review Board |
| ISF | Investigator Site File |
| ITT | Intention to treat |
| IVD | In Vitro Diagnostics |
| IVR | Interactive Voice Response |
| IWRS | Interactive Web Response System |

# K

| | |
|---|---|
| KOL | Key Opinion Leader |
| KPI | Key Performance Indicator |

# L

| | |
|---|---|
| LAR | Legally Authorized Representative |
| LEC | Local Ethics Committee |
| LPI | Last patient in |
| LPO | Last patient out |
| LSLV | Last subject last visit |
| LTFU | Long Term Follow Up |

# M

| | |
|---|---|
| MA | Medical Advisor |
| MAA | Marketing Authorisation Application |
| MAH | Marketing Authorisation Holder |
| MABEL | Minimal Anticipated Biological Effect Level |
| MARB | Minimal Additional Risk or Burden |
| MD | Medical Device |
| MedDRA | Medical Dictionary for Regulatory Activities |
| MFG | Medical Research Act (Medizinforschungsgesetz, Germany) |
| MREC | Medical Research and Ethics Committee |
| MHLW | Ministry of Health, Labour and Welfare (Japan) |
| MHRA | Medicines and Healthcare Products Regulatory Agency (UK) |
| MoH | Ministry of Health |
| MOL | Medical Operations Leader |
| MPDG | Medical Devices Implementation Act (Medizinprodukterecht-Durchführungsgesetz, Germany) |
| MREC | Multicentre Research Ethics Committee |
| MS | Member State |
| MSC | Member State Concerned |

# N

| | |
|---|---|
| NCA | National Competent Authorities |
| NCI | National Cancer Institute |
| NCT | National Clinical Trial |
| NDA | New Drug Application |
| NIS | Non-interventional Study |
| NNT | Number needed to treat |
| NOAEL | No Observed Adverse Effect Level |

# P

| | |
|---|---|
| PASS | Post Authorisation Safety Study |
| PAES | Post Authorisation Efficacy Study |
| PD | Pharmacodynamics |
| PDCA | Plan Do Check Act |
| PDCO | Paediatric Committee |
| PEI | Paul-Ehrlich-Institut (Germany) |
| PI | Principle Investigator |
| PIP | Paediatric Investigation Plan |
| PK | Pharmacokinetics |
| PL | Project Leader |
| PM | Project Manager |
| PMDA | Pharmaceuticals and Medical Devices Agency (Japan) |
| PoC | Proof of Concept |
| PP | Per protocol |
| PPD | Protected Personal Data |
| PQL | Project Quality Leader |
| PSMF | Pharmacovigilance System Master File |
| PSUR | Periodic Safety Update Report |
| PV | Pharmacovigilance |

# Q

| | |
|---|---|
| QA | Quality Assurance |
| Q&A | Questions and Answers |
| QC | Quality Control |
| QM | Quality Management |
| QMS | Quality Management System |
| QoL | Quality of Life |
| QVR | Qualification Visit Report |

# R

| | |
|---|---|
| R&D | Research and Development |
| RA | Regulatory Affairs |
| RBQM | Risk-Based Quality Management |
| RCT | Randomized Controlled Trial |
| REC | Research Ethics Committee |
| REG | Regulation |
| RFI | Request for Information |
| RFP | Request for Proposal |
| RMP | Risk Management Plan |
| rMS | Reporting Member State |
| RRR | Relative Risk Reduction |
| RWD | Real World Data |
| RWE | Real World Evidence |

# S

| | |
|---|---|
| SAE | Serious Adverse Event |
| SAP | Statistical Analysis Plan |
| SDTM | Study Data Tabulation Model |
| SDR | Source Data Review |
| SDV | Source Data Verification |
| SIF | Site Investigator File |

| | |
|---|---|
| SIV | Site Initiation Visit |
| SMO | Site Management Organisation |
| SOP | Standard Operating Procedure |
| STROBE | Strengthening the Reporting of Observational Studies in Epidemiology |
| SUSAR | Suspected Unexpected Serious Adverse Reaction |
| SVT | Subject Visit Template |
| SWISSMEDIC | Swiss Agency for Therapeutic Products (Switzerland) |

# U

| | |
|---|---|
| UADE | Unanticipated Adverse Device Effects |
| UADR | Unexpected Adverse Drug Reaction |

# T

| | |
|---|---|
| (e)TMF | (electronic) Trial Master File |

# V

| | |
|---|---|
| VAS | Visual Analogue Scale |

# W

| | |
|---|---|
| WBS | Work Breakdown Structure |
| WHO | World Health Organisation |

# Z

| | |
|---|---|
| ZLG | Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, Germany) |

## Other offers

### Pharma & Healthcare Seminars

We offer tailored training solutions for the entire healthcare industry. Our training programmes are meticulously designed and based on thorough research and educational principles.
Our certification to ISO 9001 and ISO 21001 standard is a guarantee that we deliver to the highest quality.
More information

### e-Learning – Click and learn

FORUM Institut provides flexible training solutions and quality e-learning courses.
You decide for yourself when and where to learn. Test now.

### In-house seminars – Tailored solutions

All our seminars are also perfect for in-house training.
Request a personalised quotation now.

FORUM · Institut für Management GmbH · Vangerowstraße 18 · 69115 Heidelberg · Germany
Phone: +49 6221 500-500 · Fax: +49 6221 500-555 · www.forum-institut.com