



Abkürzungsverzeichnis Projektmanagement Klinische Forschung

A

| | |
|------|--------------------------------------|
| AE | Adverse Event |
| AMG | Arzneimittelgesetz |
| ATMP | Arzneimittel für neuartige Therapien |

B

| | |
|-------|---|
| BDM | Bid Defense Meeting |
| BfArM | Bundesinstitut für Arzneimittel und Medizinprodukte |
| BS | Biostatistics |

C

| | |
|--------|---|
| CA | Competent Authority |
| CAPA | Corrective And Preventive Actions |
| CDA | Confidential Disclosure Agreement |
| CFR | Code of Federal Regulations |
| COL | Clinical Operations Leader |
| CRA | Clinical Research Associate |
| (e)CRF | (electronic) Case Report Form CROClinical Research Organisation |
| CTMS | Clinical Trial Management System |
| CTA | Clinical Trial Application |
| CSR | Clinical Study Report |
| CTIMP | Clinical Trial of an Investigational Medicinal Product |
| CTIS | Clinical Trials Information System |
| CV | Curriculum vitae |

D

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|------|------------------------------|
| DCF | Data Clarification Form |
| DM | Data Management |
| DOL | Data Operations Leader |
| DSMB | Data Safety Monitoring Board |

E

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|----------|-----------------------------------|
| EC | Ethics Committee |
| EDC | Electronic Data Capture |
| EMA/EMEA | European Medicines Agency |
| EU-CTR | European Clinical Trials Register |

F

| | |
|------|------------------------------|
| FDA | Food and Drug Administration |
| FIH | First in Human |
| FIM | First in Man |
| FPI | First patient in |
| FPO | First patient out |
| FSFV | First subject first visit |
| FTE | Full-time equivalent |
| F2F | Face to face |

G

| | |
|-------|---|
| GCP | Good Clinical Practice |
| GCP-V | Verordnung über die Anwendung der Guten Klinischen Praxis bei der Durchführung von klinischen Prüfungen mit Arzneimitteln zur Anwendung am Menschen |
| GOÄ | Gebührenordnung für Ärzte |

I

| | |
|------|---|
| IB | Investigator's Brochure |
| ICF | Informed Consent Form |
| ICH | International Conference on Harmonisation |
| IEC | Independent Ethics Committee |
| IMP | Investigational Medicinal Product |
| IMPD | Investigational Medicinal Product Dossier |
| IND | Investigational New Drug |
| INDA | Investigational New Drug Application |
| IP | Investigational Product |
| IRB | Institutional Review Board |
| ISF | Investigator Site File |
| IVD | In-vitro-Diagnostika |
| IVR | Interactive Voice Response |
| IWRS | Interactive Web Response System |

K - L

| | |
|---------------|-------------------------|
| KPI | Key Performance |
| Indicator LEC | Local Ethics Committee |
| LPI | Last patient in |
| LPO | Last patient out |
| LSLV | Last subject last visit |

M - N

| | |
|------|---|
| MD | Medical Device |
| MREC | Medical Research and Ethics Committee |
| MHRA | Medicines and Healthcare Products Regulatory Agency |
| MoH | Ministry of Health |
| MOL | Medical Operations Leader |
| MPG | Medizinproduktegesetz |
| MREC | Multicentre Research Ethics Committee |

P

| | |
|-----------------|------------------------|
| PEI | Paul-Ehrlich-Institut |
| PI | Principle |
| Investigator PL | Project Leader |
| PM | Project Manager |
| PoC | Proof of Concept |
| PQL | Project Quality Leader |

Q

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

R

| | |
|-----|---------------------------|
| R&D | Research and Development |
| REC | Research Ethics Committee |
| REG | Regulatory Manager |
| RFI | Request for information |
| RFP | Request for proposal |
| RMP | Risk Management Plan |

S

| | |
|-------|---|
| SAE | Serious Adverse Event |
| SDV | Source Data Verification |
| SIV | Site Initiation Visit |
| SOP | Standard Operating Procedure |
| SUSAR | Suspected Unexpected Serious Adverse Reaction |

T

| | |
|-----|------------------------------|
| TC | Telephone conference |
| TLF | Tables, listings and figures |
| TMF | Trial Master File |

V - W

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|-----|--------------------------|
| VAS | Visual Analogue Scale |
| WBS | Work Breakdown Structure |

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