FORUM

Abkürzungsverzeichnis Projektmanagement Klinische Forschung

A

ADR	Adverse Drug Reaction
AE	Adverse Event
AMG	Arzneimittelgesetz
AMS	Arzneimittelsicherheit
ATMP	Arzneimittel für neuartige Therapien
ATP	According-To-Protocol
AWB	Anwendungsbeobachtung

B

BDM	Bid Defense Meeting
BE	Bioequivalence
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
BfS	Bundesamt für Strahlenschutz
BOB	Bundesoberbehörde

C

CA	Competent Authority
CAPA	Corrective and Preventive Actions
CCI	Commercial Confidential Information
CDA	Confidential Disclosure Agreement
CFR	Code of Federal Regulations
CHMP	Committee for Medicinal Products for Human Use
cMS	Concerned Member State
COL	Clinical Operations Leader
CONSORT	Consolidated Standards of Reporting Trials
CPI	Cost Performance Index
CRA	Clinical Research Associate
(e)CRF	(electronic) Case Report Form
CRO	Clinical Research Organisation
CSAT	Customer Satisfaction Score

CSM	Centralized Statistical Monitoring
CSR	Clinical Study Report
CT	Clinical Trial
CTA	Clinical Trial Application
CTD	Clinical Trials Directive
CTIS	Clinical Trials Information System
CTMS	Clinical Trial Management System
CTR	Clinical Trials Regulation
CTQ	Critical to Quality
CV	Cost Variance

D

DAT	Data Acquisition Tool
DBL	Data Base Lock
DM	Data Management/Data Manager
DMP	Data Management Plan
DMS	Datenmanagement System
DSGVO	Europäische Datenschutzgrundverordnung
DSMB	Data Safety Monitoring Board

E

EC	Ethics Committee
EDC	Electronic Data Capture
EFPIA	European Federation of Pharmaceutical Industries and Associations
EHDS	Electronic Health Data Space
EK	Ethikkommission
EMA	European Medicines Agency
ePRO	electronic Patient Reported Outcomes
EU	Europäische Union
EU-CTR	European Clinical Trials Regulation
EUDRA	European Union Drug Regulatory Authorities
EVM	Earned Value Management

F

FDA	Food and Drug Administration
F&E	Forschung und Entwicklung
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
FTE	Full-time equivalent
FU	Follow-up
FY	Financial Year
F2F	Face to face

G

GAMP 5	Leitfaden zur „Good Automated Manufacturing Practice”
GCLP	Good Clinical Laboratory Practice
GCP	Good Clinical Practice
GDNG	Gesundheitsdatennutzungsgesetz
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GOÄ	Gebührenordnung für Ärzte
GPM	Global Project Manager
GVP	Good Pharmacovigilance Practice

H

HTA	Health Technology Assessment

I

IB	Investigator’s Brochure/Prüferinformation
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
IRB	Institutional Review Board
ISF	Investigator Site File
ITT	Intention to treat
IVD	In-vitro-Diagnostika

K

KKS	Koordinierungszentrum für klinische Studien
KOL	Key Opinion Leader
KPI	Key Performance Indicator
KQI	Key Quality Indicator
KRI	Key Risk Indicator

L

LPI	Last patient in
LPO	Last patient out
LSLV	Last subject last visit

M

MA	Medical Advisor
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MD(R)	Medical Device (Regulation)
MedDRA	Medical Dictionary for Regulatory Activities
MFG	Medizinforschungsgesetz
MREC	Medical Research and Ethics Committee
MHLW	Ministry of Health, Labour and Welfare (Japanisches Ministerium für Gesundheit, Arbeit und Sozialwesen)
MHRA	Medicines and Healthcare Products Regulatory Agency (UK)
MoH	Ministry of Health
MOL	Medical Operations Leader
MPDG	Medizinprodukterecht-Durchführungsgesetz
MREC	Multicentre Research Ethics Committee
MS	Member State
MSA	Master Service Agreement
MSC	Member State Concerned

N

NCA	National Competent Authorities
NCT	National Clinical Trial/Nationales Centrum für Tumorerkrankungen
NIS	Nicht-interventionelle Studie
NNT	Number needed to treat
NW	Nebenwirkung

P

PASS	Post Authorisation Safety Study
PAES	Post Authorisation Efficacy Study
PC	Planned Costs
PD	Pharmakodynamik

PDCA	Plan Do Check Act
PDCO	Paediatric Committee
PEI	Paul-Ehrlich-Institut (Deutschland)
PI	Principle Investigator
PIP	Paediatric Investigation Plan
PK	Pharmakokinetik
PL	Project Leader
PM	Project Manager
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PMI	Project Management Institute
PoC	Proof of Concept
PP	Per protocol
PPD	Protected Personal Data
PQL	Project Quality Leader
PSUR	Periodic Safety Update Report
pU	pharmazeutischer Unternehmer
PV	Pharmakovigilanz

Q

QA	Quality Assurance
QbD	Quality by Design
QC	Quality Control
QM(S)	Quality Management (System)
QoL	Quality of Life
QTL	Quality Tolerance Limit
QVR	Qualification Visit Report

R

RA	Regulatory Affairs
RACI	Responsible, Accountable, Consult, Inform
RACT	Risk Assessment and Categorization Tool
RBM	Risk-based Monitoring

RBQM	Risk-based Quality Management
RCA	Root Cause Analysis
R&D	Research and Development
REC	Research Ethics Committee
REG	Regulatory Manager
RFI	Request for Information
RFP	Request for Proposal
RMP	Risk Management Plan
rMS	Reporting Member State
RP	Regierungspräsidium
RPN	Risk Priority Number
RRR	Relative Risk Reduction

S

SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SDV	Source Data Verification
SG	Stage Gate
SIV	Site Initiation Visit
SMO	Site Management Organisation
SOP	Standard Operating Procedure
SPI	Schedule Performance Index
SUE	Schwerwiegendes Unerwünschtes Ereignis
SUSAR	Suspected Unexpected Serious Adverse Reaction
SV	Schedule Variance
SWISSMEDIC	Schweizerisches Heilmittelinstitut
SWOT	Strengths, Weaknesses, Opportunities, Threats

T

(e)TMF	(electronic) Trial Master File

U

UAW	Unerwünschte Arzneimittelwirkung
UE	Unerwünschtes Ereignis

V

VO	Verordnung

W

WBS	Work Breakdown Structure
WHO	Weltgesundheitsorganisation
WP	Work Package
WW	Wechselwirkung

Z

ZLG	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZKS	Zentrum für Klinische Studien

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