ePRISM ABBREVIATIONS

For further reference: gcp_spt000003 Pharma R&D Glossary
Acronyms are however permanently changing.
The list will be regularly adapted.

Roles/Functions:

APTS	Affiliate Process and Training Services (PA)
BEML	Biomarker Experimental Medicine Leader
BM	Business Manager
Biostat	Biostatistician
Business Owner	Business Owner
BOM	Biosample Operations Manager
CDP/CDC	Clinical Data Programmer
CDSL	Clinical Demand and Supply Leader
CIT	Core Inspection Team
ClinOPs	Clinical Operations representative
COL	Clinical Operations Leader (pRED)
COL-A	Clinical Operations Leader - Alliances (pRED)
CP	Clinical Pharmacologist
CPL	Clinical Program Leader (gRED)
CPSS	Clinical Pharmacologist Science Specialist
CRA	Clinical Research Associate (gRED)
CRO	Clinical Research Organization
CrSL	Clinical Research Study Leader
CrSM	Clinical Research Study Manager
CrTAC	Clinical Research Training & Accounts Coordinator (pRED)
CS	Clinical Scientist
CSA	Clinical Study Associate
CSL	Clinical Study Leader
CSM	Clinical Study Manager
CTA	Clinical Trial Associate
CTM	Clinical Trial Monitor (also Monitor)
CUC	Compassionate Use Coordinator
DAS	Data Acquisition Specialist
DM	Data Manager
DS	Drug Safety
EC	Ethics Committee
GCDL	Global Clinical Distribution Leader
GIG	Global Inspections Group
GPPS	Global Pharma Procurement Scientific Sourcing
GSA	Global Study Associate (PD)

GSL	Global Study Leader (PD)
GSM	Global Study Manager (PD)
GSS	Global Site Service (gRED)
GTC	Global Trial Coordinator (PD)
HR	Human Resource
IC	Inspection Contact
ICTM	International Clinical Trial Manager (GMA)
IML	International Medical Leader (GMA) replaced by IMD
IMD	International Medical Director (GMA) replaces IML
IT	Information Technology
LS/LSR	Lead Scientific Responsible
MD	Medical Director
Medical Admin	Medical Administrator
MM	Medical Manager
MW	Medical Writer
OPL	Operations Program Leader (PD)
PDQA	Pharma Development Quality Assurance
PAC	Protocol/Product Approval Committee
PET	Protocol Execution Team (gRED only)
PETL	Protocol Execution Team Lead (gRED only)
PM	Project Manager
PTDQ-EK	Pharma Technical Development Quality – Europe Kaiseraugst
PTDQ-EG or PTS or PTQG	Pharma Technical Development Quality – Europe Global
(PTQP	Old abbreviation in Pharma Technical Operations)
(PTQX-D	Old abbreviation in Pharma Technical Operations: external group)
(PTDQ-U	Old abbreviation in Pharma Technical Operations: organization in the USA)
QA	Quality Assurance
QC	Quality Coordinator
QP	Qualified Person
Reg	Regulatory Representative
RM	Resource Manager
Safety O	Safety Operations
Safety S	Safety Science
SDM	Study Data Manager
SL	Study Leader
Snr BOM	See BOM
SMT	Study Management Team
SMTL	Study Management Team Leader
SPA	Statistics Programmer
SS	Study Stat.
SSG	Scientific Sourcing Group
Supply	Supply
Stats/STATS	Statistician (also Biostat used)
TML	Translational Medicines Leader (pRED)
TPS	Training, Process & Systems
Vendor (DM)	Vendor (Data Manger)

Bodies/Systems:

CLARA	Clinical Drug Supply Application
CTP	Clinical Trial Portal
CTMS	Clinical Trial Monitoring System
CTP	Clinical Trial Portal
DCM	Data Collection Module
DDE	Database Development and Extraction
DSMB	Data Safety Monitoring Board
ECs	Ethics Committee
EDC	Electronic Data Capture
eCRF	electronic Case Report Form
ePRO	electronic Patient Reported Outcome
FDA	Federal Drug Authority
GDM	Generic Data Model
iDMC	independent Data Monitoring Committee
IDSMB	Independent Data Safety Monitoring Board
IEC	Independent Ethics Committee
IRB	Institutional Review Board
INDSR	Investigational New Drug Safety Report
IRB	Institutional Review Board
IXRS	Interactive Voice and Web Response System
MACRO	Roche Electronic Data Capture (EDC) used for eCRF
PhV/PV	Pharmacovigilance
RAVE	Medidata Rave validated system for EDC
SW	Shareweb
TP	Touchpoint

Documents/Others:

AE	Adverse Events
BIMO	**BI**oresearch **MO**nitoring inspection
BMP	Biosample Management Plan
CAPA	Corrective Action Preventive Action
CD	Controlled Document
CDP	Clinical Development Plan
CDS	Core Data Sheet
CSR	Clinical Study Report
CV	Curriculum Vitae
DLR	Data Listing Review
DMP	Data Management Plan
DSB	Database Specification Document
DSUR	Development Safety Update Report
GCP	Good Clinical Practice
GUI	Guideline
HA	Health Authority
IB	Investigator Brochure
ICSR	Individual Case Safety Reporting
iDRP	integrated Data Review Plan
IMP	Investigational Medicinal Products
INDSR	Investigational New Drug Safety Report
INF	Issues notification forms
JD	Job Description
MTSA	Master Technology and Services Agreement
NDA	New Drug Application
PMA	Premarket Approval Application
PV	Protocol Violation
RESP	Regulatory Ethics and Submission Plan
RFP	Request For Proposal
SAE	Serious Adverse Events
SDV	Source Document Verification
SLACS	Study Logic and Check Specifications Document
SOW	Scope of Work
SPC	Summary of Product Characteristics
SSR	Six monthly SUSAR Report
SUSAR	Suspected Unexpected Serious Adverse Reactions
TMF	Trial Master File
TMP	Trial Monitoring Plan
UAT	User Acceptance Test
WKD	Working Document (GNE)