GBA KEY2COMPLIANCE

Abbreviations used in Clinical Development

Abbreviation	Definition	1 (2)
ADE	Adverse Device Effect	
AE	Adverse Event	
CA	Competent Authority	
CDM	Clinical Data Manager	
CF	Clean File	
CI	Clinical Investigation	
CIP	Clinical Investigation Plan	
CIR	Clinical Investigation Report	
COV	Close-Out Visit	
CPM	Clinical Project Manager	
CPS	Clinical Performance Study	
CPSP	Clinical Performance Study Plan	
CPSR	Clinical Performance Study Report	
CRA	Clinical Research Associate	
CRO	Contract Research Organization	
CSM	Clinical Safety Manager	
CRF	Case Report Form	
CTA	Clinical Trial Agreement	
DBL	Database Lock	
DD	Device Deficiency	
DM	Data Management	
DMP	Data Management Plan	
EC	Ethics Committee	
eCRF	Electronic Case Report Form	
EDC	Electronic Data Capture	
GSP	Good Study Practice	
eTMF	electronic Trial Master File	

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Abbreviation	Definition	2 (2)
GCP	Good Clinical Practice	
IB	Investigator's Brochure	
ICF	Informed Consent Form	
ICH-GCP	International Conference on Harmonization – Good Clinical Practice	
IFU	Instructions for Use	
IMD	Investigational Medical Device	
ISF	Investigator Site File	
ISO	International Organization for Standardization	
IVDR	In Vitro Diagnostic Device Regulation	
MM	Medical Monitor	
MP	Monitoring Plan	
MV	Monitoring Visit	
PI	Principal Investigator	
PSV	Pre-Study Visit	
QA	Quality Assurance	
QC	Quality Control	
RBM	Risk Based Monitoring	
SAE	Serious Adverse Event	
SC	Study Coordinator	
SDV	Source Data Verification	
SIV	Site Initiation Visit	
SM	Safety Management	
SMP	Safety Management Plan	
SN	Study Nurse	
SOP	Standard Operating Procedure	
Sub-Inv	Sub-Investigator	
TMF	Trial Master File	
USADE	Unanticipated Serious Adverse Device Effect	