Afkortingen STZ-Kwaliteitshandboek SOPs

AE	Adverse Event
ABR	Algemeen Beoordeling en Registratie formulier
AIMDD	Active Implantable Medical Devices Directive
AR	Adverse Reaction
AVG	Algemene Verordening Gegevensbescherming
BI	Bevoegde Instantie
BROK	Basiscursus Regelgeving & Organisatie voor Klinisch onderzoekers
CBG	College van Beoordeling Geneesmiddelen
CE	Conformité Européenne
CCMO	Centrale Commissie Mensgebonden Onderzoek
CEP	Clinical Evaluation Plan
CIP	Clinical Investigation Plan
CRF	Case Report Form
CTIS	Clinical Trials Information System (van de EMA)
CTR	Clinical Trial Regulation
CV	Curriculum Vitae
DCRF	Dutch Clinical Research Foundation
DD	Device Deficiency
DMP	Data Management Plan
DSMB	Data Safety Monitoring Board= IDMC, Independent Data-Monitoring Committee
EMA	European Medicines Agency
EU	European Union
EudraCT	European Union Drug Regulating Authorities Clinical Trials
FU	Follow up
GCP	Good Clinical Practice
GMP	Good Manufactural Practice
IB	Investigator's Brochure
ICH	International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use
ICTRP	International Clinical Trials Registry Platform
IDMC	Independent Data-Monitoring Committee = DSMB, Data Safety Monitoring Board

Samenwerkende Topklinische Ziekenhuizen

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IGJ	Inspectie Gezondheidszorg en Jeugd
IMDD	Investigational Medical Device Dossier
IMPD	Investigational Medicinal Product Dossier
IP	Intellectual Property
ISF	Investigator Site File
LB	Landelijke Bureau (van de CCMO)
MDD	Medical Devices Directive
MDR	Medical Device Regulation
MEB	Medicine Evaluation Board
METC	Medisch Ethische Toetsingscommissie
NWMO	Niet WMO-plichtig
PI	Principal Investigator
PIF	Proefpersoneninformatie
PMCF	Post Marketing Clinical Follow-up
RCT	Randomised Clinical Trial
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
SPC	Summary of Product Characteristics (Officiële productinfomatie IB-tekst)
STED	Summary TEchnical Documentation
STZ	Samenwerkende Topklinische opleidingsZiekenhuizen
SUSAR	Suspected Unexpected Serious Adverse Reaction
TC	Toetsende Commissie
TMF	Trial Master File
TTP	Trusted Third Party
VGO	Verklaring Geschiktheid Onderzoeksinstelling
WBP	Wet Bescherming Persoonsgegevens
WMO	Wet Medisch-wetenschappelijk Onderzoek met mensen