

English	Abbreviation	in Dutch	afkorting
ABR-form	ABR-form	Algemeen Beoordelings- en Registratieformulier	ABR-formulier
Adverse Event	AE	Adverse Event	AE
General Data Protection Regulation	GDPR (AVG)	Algemene Verordening Gegevensbescherming	AVG
Decree on central assessment of medical scientific research involving human subjects	Bbmo	Besluit centrale beoordeling medisch-wetenschappelijk onderzoek met mensen	Bbmo
Central Committee on Research Involving Human Subjects	CCMO	Centrale Commissie Mensgebonden Onderzoek	CCMO
Contract Research Organizations	CRO	Contract Research Organizations	CRO
Clinical Trial Agreement	CTA	Clinical Trial Agreement	CTA
Clinical Trial Directive	CTD	Clinical Trial Directive	CTD
Clinical Trial Regulation	CTR	Clinical Trial Regulation	CTR
Clinical Trials Information System	CTIS	Clinical Trials Information System	CTIS
Data Acquisition Tool	DAT	Data Acquisition Tool	DAT
Data Management Plan	DMP	Data Management Plan	DMP
Data and Safety Monitoring Board	DSMB	Data and Safety Monitoring Board	DSMB
Data Transfer Agreement	DTA	Data Transfer Agreement	DTA
Drug Accountability	DA	Drug Accountability	DA
Device Accountability	DA	Device Accountability	DA
Drug Accountability Log	DAL	Drug Accountability Log	DAL
(electronic) Case Report Form	(e)CRF	(elektronisch) Case Report Form	(e)CRF
Electronic Patient File	EPD	Elektronisch Patiëntendossier	EPD
European Medicines Agency	EMA	European Medicines Agency	EMA
Food and Drug Administration	FDA	Food and Drug Administration	FDA
Good Clinical Practice	GCP	Good Clinical Practice	GCP
Het Ministry of Health, Welfare and Sport	VWS	Het Ministerie van Volksgezondheid, Welzijn en Sport	VWS
Investigator's Brochure	IB	Investigator's Brochure	IB
Informed Consent	IC	Informed Consent	IC
Informed Consent Form	ICF	Informed Consent Form	ICF
Informed Consent Consultation	ICG	Informed Consent Gesprek	ICG
Investigational Medical Device Dossier	IMDD	Investigational Medical Device Dossier	IMDD
Investigational Medicinal Product	IMP	Investigational Medicinal Product	IMP
Investigational Medicinal Product Dossier	IMPD	Investigational Medicinal Product Dossier	IMPD
Intellectual Property	IP	Intellectual Property	IP
Investigation Product	IP	Investigational Product	IP
Investigator Site File	ISF	Investigator Site File	ISF
Medical Device Regulation	MDR	Medical Device Regulation	MDR
Medisch-Ethische Toetsingscommissie/Medical Research Ethics Committee	METC/MREC	Medisch-Ethische Toetsingscommissie	METC
The Netherlands Cancer Institute / Antoni van Leeuwenhoek	NKI/AvL	Nederlands Kanker Instituut / Antoni van Leeuwenhoek	NKI/AvL
Note to File	NtF	Note to File	NtF
The Netherlands Association of METCs	NVMETC	De Nederlandse Vereniging van METC's	NVMETC
Product Accountability	PA	Product Accountability	PA

Patient Information Form	PIF	proefpersoneninformatie	PIF
Reference Safety Information	RSI	Reference Safety Information	RSI
Regulatory Authorities	RA	Regulatory Authorities	RA
Executive Board	RvB	raad van bestuur	RvB
Serious Adverse Event	SAE	Serious Adverse Event	SAE
Source Data Verification	SDV	Source Data Verification	SDV
Standard Operating Procedure	SOP	Standard Operating Procedure	SOP
Association of top clinical teaching hospitals	STZ	Samenwerkende Topklinische opleidingsZiekenhuizen	STZ
Suspected Unexpected Serious Adverse Reaction	SUSAR	Suspected Unexpected Serious Adverse Reaction	SUSAR
Trial Master File	TMF	Trial Master File	TMF
University Medical Centre	UMC	Universitair Medisch Centrum	UMC
Site Suitability Declaration	VGO	Verklaring Geschiktheid Onderzoekinstelling	VGO
Medical Treatment Contracts Act	WGBO	Wet op de geneeskundige behandelingsovereenkomst	WGBO
World Health Organization	WHO	World Health Organization	WHO
Wet Medisch-Wetenschappelijk Onderzoek met mensen / Medical Research involving Human Subjects	WMO	Wet medisch-wetenschappelijk onderzoek met mensen	WMO

Other	in Dutch
assent	instemming
principal investigator	(lokale) hoofdonderzoeker
pilot study	pilot study
competent authority	bevoegde instantie
metadata	data over data
governance	het systeem dat toezicht en verantwoording in klinisch onderzoek waarborgt
reviewing authority	toetsende instantie
certified copy	gecertificeerde kopie
essential records	essentiële documenten
sponsor	verrichter (sponsor)
service provider	externe dienstverleners in klinische proeven
(possible) resesarch participant	(mogelijke) onderzoeksdeelnemer
investigator	onderzoeker
trial participant	onderzoeksdeelnemer
ICH-GCP Guideline	ICH-GCP richtlijn