1 PURPOSE

The purpose of this document is to provide an overview and explanation of key concepts used in NorCRIN SOPs

2 DEFINITIONS

ENGLISH	NORWEGIAN	ABBREVIATION	EXPLANATION
Advanced therapy	Avansert terapi	AT	Gene therapy, somatic cell therapy or tissue therapy. An investigatonal product based on advanced therapy is called ATIMP. Regulation (EC) No 1394/2007, Article 2.
Adverse Event	Uønsket medisinsk hendelse	AE	"Adverse event" means any untoward medical occurrence in a subject to whom a medicinal product is administered and which does not necessarily have a causal relationship with this treatment. Regulation (EU) No 536/2014, Article 2.
Adverse Reaction	Bivirkning	AR	A response to a medicinal product which is noxious and unintended. Directive 2001/83/EC.
Anatomical Therapeutic Chemical classification system	Anatomical Therapeutic Chemical classification system	ATC	International classification system for drugs
Annotated CRF	Annotert CRF	aCRF	A blank CRF with markings, or annotations, that coordinate each datapoint in the form with its corresponding dataset name. An annotated CRF communicates where the data collected for each Question is stored in the database Oracle ® Creating a study
Annual safety report	Årsrapport	ASR	Is part of the mandatory safety reporting. Regulation (EU) No 536/2014, art 43. The annual report should be sent on a DSUR format. ICH guideline E2F on development safety update report
Audit trail	Sporbarhet	---	Documentation that allows reconstruction of the course of events. ICH GCP 1.9.

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Authorised auxiliary medicinal product	Markedsført Tilleggslegemiddel	---	"Authorised auxiliary medicinal product" means a medicinal product authorised in accordance with Regulation (EC) No 726/2004 or in any Member State concerned in accordance with Directive 2001/83/EC, irrespective of changes to the labelling of the medicinal product, which is used as an auxiliary medicinal product; Regulation (EU) No 536/2014, Article 2.
Authorised investigational medicinal product	Markedsført utprøvingspreparat	---	"Authorised investigational medicinal product" means a medicinal product authorised in accordance with Regulation (EC) No 726/2004 or in any Member State concerned in accordance with Directive 2001/83/EC, irrespective of changes to the labelling of the medicinal product, which is used as an investigational medicinal product. Regulation (EU) No 536/2014, Article 2.
Auxiliary medicinal product	Tilleggslegemiddel		A drug to be used in a clinical trial and described in the protocol, but not as a drug under investigation (IMP).
Bias	Bias/skjevhet	---	Bias: used in statistical and empirical research when results or inferences systematically deviate from the true values. Bias may occur as a result of errors or inaccuracies in the sample of study subjects, choice of method of investigation or assessment of results. The Norwegian Large Encyclopaedia of Medicine
Blinding/ Masking	Blinding	---	A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s). ICH GCP 1.10.
Case Report Form	Case Report Form (datainnsamlingsskjema)	CRF eCRF	The case report form is the tool used by the sponsor of a clinical trial to collect data from each participating patient. All data on each patient participating in a clinical trial are held and/or documented in the CRF. Electronic CRFs are often referred to as eCRFs as they originally were made on paper.

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CE Marking	CE-merking	---	CE marking is an administrative marking that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA).
Clinical Study	Klinisk studie		"Clinical study" means any investigation in relation to humans intended: (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; (b) to identify any adverse reactions to one or more medicinal products; or (c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products; with the objective of ascertaining the safety and/or efficacy of those medicinal products. A clinical study that does not fulfil the definition of a clinical trial will **not** be subject to scientific and ethical review in accordance with Regulation (EU) No 536/2014, Article 2.
Clinical Trial	Klinisk (legemiddel) utprøving	CT	"Clinical trial" means a clinical study (see definition) which fulfils any of the following conditions: (a) the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned; (b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or (c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects. A clinical trial shall be subject to scientific and ethical review and shall be authorised in accordance with Regulation (EU) No 536/2014, Article 2.
Co-monitoring	Komonitorering	---	Monitoring together wih someone else as part of training.
Contract Research Organisation	CRO	CRO	A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions. ICH GCP 1.20.

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Coordinating Investiator	Koordinerende utprøver		An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre trial. ICH GCP 1.19.
Data entry	Datainnlegging	---	Adding data to the database, by punching, transfer or scanning data.
Data entry application	Data entry application	DEA	An application for entering data/information into a database.
Data entry instructions	Data entry instructions	DEI	Instructions for entering data into the database.
Data management documentation	Datahåndteringsdokumentasjon	DMD	All documentation that is part of data management, see SOP Data Management
Data management plan	Datahåndteringsplan	DMP	Plan that describes the quality control process of data from planning until closure, or publication, of clinical drug trial.
Data management rapport	Datahåndteringsrapport	DMP	Report that describes the quality control process of data from planning until closure, or publication, of clinical drug trial.
Data manager/data management	Datahåndterer	DM	Person responsible for the data entry application (DEA), validation, coding, export of data etc. according to the data management plan.
Data monitoring committee Data and safety monitoring board Monitorering committee	Datamonitoreringskomité	DMC/DSMB	An independent data-monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial. ICH GCP 1.25.
Database	Database	DB	A database is a collection of information that is organized so that it can be easily accessed, managed and updated.
De-identified see also Pseudonymisation	Avidentifisert se også Pseudonymisering	---	De-identifying is a procedure removing personally identifiable information fields within a record and replacing by one or more artificial identifiers, e.g. subject number in a clinical trial. This makes the person in the data record less identifiable while remaining suitable for data analysis and data processing. This process is under GDPR called pseudonymisation.

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Delegation log/ list	Delegeringslogg/liste	---	A list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties. ICH GCP 4.1.5.
Description of Manufacturing Process	Tilvirknings-dokumentasjon	---	Detailed Commission guidelines on good maufacturing practice for investigational medicinal products. Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials (europa.eu) Auxiliary Medicinal Products in Clinical Trials
Development Safety Update Report	Development Safety Update Report	DSUR	A common standard for periodic (annual) reporting on drugs under development (including marketed drugs that are under further study). ICH guideline E2F on development safety update report
Double dummy	Double dummy	---	A technique for retaining the blind when administering supplies in a clinical trial, when the two treatments cannot be made identical. Supplies are prepared for Treatment A (active and indistinguishable placebo) and for Treatment B (active and indistinguishable placebo). Subjects then take two sets of treatment; either A (active) and B (placebo), or A (placebo) and B (active). ICH E9 Note for Guidance on Statistical Principles for Clinical Trials
Double-blind	Dobbeltblind	---	A double-blind trial is one in which neither the subject nor any of the investigator or sponsor staff who are involved in the treatment or clinical evaluation of the subjects are aware of the treatment received. This includes anyone determining subject eligibility, evaluating endpoints, or assessing compliance with the protocol. This level of blinding is maintained throughout the conduct of the trial, and only when the data are cleaned to an acceptable

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			level of quality will appropriate personnel be unblinded. ICH E9 Note for Guidance on Statistical Principles for Clinical Trials
Early termination of a clinical trial	Tidlig avslutning av en klinisk utprøving	---	"Early termination of a clinical trial" means the premature end of a clinical trial due to any reason before the conditions specified in the protocol are complied with. Regulation (EU) No 536/2014, Article 2.
Electronic data capture system	Elektronisk datafangstløsning	EDCS	Electronic solution to collect subject data in a clinical trial.
Electronic data management system	Elektronisk datahåndteringssystem	EDMS	Software for organiseing and archiving docuements.
End of a clinical trial	Slutttidspunkt for en klinisk utprøving	---	"End of a clinical trial' means the last visit of the last subject, or at a later point in time as defined in the protocol. Regulation (EU) 536/2014, Article 2.
Essential documents	Essensielle dokumenter	---	Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. ICH GCP 1.23
EU application form	EU søknadsskjema	---	Application form to be completed and submitted for a clinical trial to regulatory authorities (e.g. DMP) and ethics committees (e.g. REK). Valid for all EU/EEC countries. Regulation (EU) No 536/2014, Article 16, Annex I and II.
EU CT number	EU utprøvingsnummer	---	A unique identifying number for a specific clinical trial in the EU database. Regulation (EU) No 536/2014, Article 81.
ICH country	ICH-land	---	An ICH country is a member of "The International Council for Harmonisation", e.g. Japan, US and EEC countries.
Identification and Enrollment Log	Deltagerliste Kodeliste/koblingsnøkkel	---	The identification log is a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any subject. The Enrollment log is used for documenting chronological enrolment of subjects in the trial

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			ICH GCP 8.3.21 og 8.3.22. The identification list is also called code-list or key-list.
Important Protocol Deviation	Vesentlig protokoll avvik	IPD	Important Protocol Deviation (IPD): A PD that may significantly impact the completeness, accuracy, and/or reliability of the study data or that may significantly affect a subject's rights, safety, or well-being. For example, enrolling patients that do not meet key eligibility criteria; incorrect administration of study drug; absence of source documents; failure in recording or incorrectly recording the primary efficacy variable(s).
Incapacitated subject	Deltagere uten samtykkekompetanse	---	A trial participant that of other reasons than being a minor, cannot consent to participation. Incapacitated subjects are, for example, elderly people with advanced dementia, mentally handicapped, coma patients or people with a severe psychological disorders.
Independent Ethics Committee in Norway	REK	IEC / REK	Regional Committee for medical and health realted reseatch ethics. Regionale komiteer for medisinsk og helsefaglig forskningsetikk.
Informed Consent Form	Informert samtykke/ samtykkeskjema	ICF	A written, dated and signed statement to participate in a clinical trial, given by a subject (or, where applicable, to their legally designated representatives). The statement must be given voluntary after being properly and fully informed. Regulation (EU) 536/2014, Article 29.
Inspection	Inspeksjon	---	The act by a competent authority of conducting an official review of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by the competent authority to be related to the clinical trial and that may be located at the clinical trial site, at the sponsor's and/or contract research organisation's facilities, or at other establishments which the competent authority sees fit to inspect. Regulation (EU) No 536/2014, Article 2.

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Intention-to-treat	Intention-to-treat	ITT	Comparison of treatment groups based on initial treatment assignment and not on the treatment eventually received.
Interim Analysis	Interimanalyse	---	An analysis of collected data before the trial has been completed. Are used for safety evaluations and to determine whether to continue, amend or stop the study. ICH GCP 1.25/1.32.
Investigational medicinal product	Utprøvingspreparat	IMP	"Investigational medicinal product" means a medicinal product which is being tested or used as a reference, including as a placebo, in a clinical trial. Regulation (EU) No 536/2014, Article 2.
Investigational Medicinal Product Dossier	Investigational Medicinal Product Dossier	IMPD	The IMPD shall give information on the quality of any investigational medicinal product, the manufacture and control of the investigational medicinal product, and data from non-clinical studies and from its clinical use. The SmPC valid at the time of application may be used as the IMPD if the investigational medicinal product is authorised. Regulation (EU) No 536/2014, Annex I, G.
Investigator	Utprøver	---	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. Regulation (EU) No 536/2014, Article 2.
Investigator's Brochure	Investigator's Brochure	IB	A compilation of the clinical and non-clinical data on the investigational medicinal product or products which are relevant to the study of the product or products in humans. Regulation (EU) No 536/2014, Article 2.
Legally designated representativ	Verge	---	"Legally designated representative" means a natural or legal person, authority or body which, according to the law of the Member State concerned, is empowered to give informed consent on behalf of a subject who is an incapacitated subject or a minor. Regulation (EU) No 536/2014, Article 2.

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			I Norway, next of kin according to pasient- og brukerrettighetsloven § 1-3 letter b.
Low-intervention clinical trial	Lav-intervensjon klinisk studie		"Low-intervention clinical trial" means a clinical trial which fulfils all of the following conditions: (a) the investigational medicinal products, excluding placebos, are authorised; (b) according to the protocol of the clinical trial, (i) the investigational medicinal products are used in accordance with the terms of the marketing authorisation; or (ii) the use of the investigational medicinal products is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products in any of the Member States concerned; and (c) the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned. Regulation (EU) No 536/2014, Article 2.
Manufacturing authorisation	Tilvirkertillatelse	---	Permission from the Norwegian Medicianes agency for production of specific drugs in specific production factories. Manufacturing authorisation is given according to the legemiddelloven and Forskrift om tilvirkning og import av legemidler.
Manufacturing of IMP	Tilvirkning av legemiddel	---	Must be conducted according to Good Manufacturing Practice for investigational medicinal products (GMP) and includes production, packaging, labelling re-labelling and release of drugs.
Medical dictionary for regulatory activities	MedDRA	MedDRA	Coding system for medical events.
Medical monitor and medical officer	Medisinsk monitor	MM/MO	Sponsor representative with authority to assess the safety aspects for a clinical trial.

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Member State concerned	Gjeldende medlemsland	---	Country in the EEC in which an application or substantial amendment for a clinical trial has been submitted. Regulation (EU) No 536/2014, Article 2.
Minor	Barn	---	A subject who is, according to the law of the Member State concerned, under the age of legal competence to give informed consent. Regulation (EU) No 536/2014, Article 2. In Norway this is 18 years for drug trials.
Monitor	Monitor	---	A person appointed by sponsor to verify that the rights, safety and well-being of subjects are protected, that the reported data are reliable and robust, and that the conduct of the clinical trial is in compliance with the requirements of the Regulation (EU) No 536/2014, Article 48.
Monitoring	Monitorering	---	The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s). ICH GCP 1.38.
Monitoring Plan	Monitoreringsplan	---	A written plan for the Extent and Nature of Monitoring of a clinical trial ICH GCP 5.18.3.
Monitoring Report	Monitoreringsrapport	---	A written report to the sponsor after each trial-site visit or trial-related communication. ICH GCP 5.18.6.
Normal clinical practice	Vanlig klinisk praksis	---	"Normal clinical practice" means the treatment regime typically followed to treat, prevent, or diagnose a disease or a disorder. Regulation (EU) No 536/2014, Article 2.
Not Important Deviation	Ikke-vesentlig avvik	NID	A protocol deviation with anticipated low impact on the study subjects rights, safety and/or well-being, or data integrity.
Patient reported outcome	Pasientrapporterte utfall	PROs	Results/events reported through questionnaires or other means to assess health and quality of life from the patient's perspective.

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Patient reported outcome measures	Pasientrapporterte utfallsmål	PROMs	Questionnaires or tools trial subjects complete that are used to assess aspects regarding health and quality of life.
Per protocol	Per protokoll	PP	A per protocol analysis is an analysis only including the data from the subjects who fully complied with the protocl.
Placebo	Placebo	---	Medical test product without any active ingredient, that looks and appears like the medical test product, “dummy treatment”. The Norwegian Large Encyclopaedia of Medicine EMA medical terms simplifier (europa.eu)
Prescribe	Forskrive	---	Decision made by authorised health personnel to initiate, continue or change individual treatment with a drug. Prescriptions should be recorded in the patient’s medical charts. FOR-2008-04-03 nr 320 § 3.
Prescriber	Rekvirent	---	Physical or legal person with authorisation to requisite or prescribe drug FOR-1998-04-27-455 § 1.3.
Principal Investigator	Hovedutprøver	HU/PI	An investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site. Regulation (EU) No 536/2014, Article 2.
Protocol	Protokoll	---	“Protocol” means a document that describes the objectives, design, methodology, statistical considerations and organisation of a clinical trial. The term “protocol” encompasses successive versions of the protocol and protocol modifications. Regulation (EU) No 536/2014, Article 2.
Protocol Deviation	Protokollavvik	PD	Any change, divergence or departure from the study design or procedures defined in the protocol.
Protocol Deviation Handling Plan	Handlingsplan for protokollavvik	PDHP	Study specific plan describing how deviations are to be detected, documented, reviewed, followed-up and closed. The plan may be a separate document or part of an excisting plan e.g. the protocol.
Protocol modification	Protokollendring og/ eller tillegg	---	A change to the trial protocol. A susbtantial Protocol modification is likely to have a substantial

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			impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial. Regulation (EU) No 536/2014, Artivcle 2.
Pseudonymisation	Pseudonymisering	---	*"…the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person."* Article 4, Regulation (EU) 2016/679, GDPR.
Quality assurance and quality control system	Elektronisk kvalitetssystem	EK-system	Electronic quality system where the institutions keep their internal routines.
Quality of Life Questionnaire	Livskvalitetsskjema, spørreskjema	QOL	Usually a validated standardised form/questionnaire for completion by the trial subject /guardian.
Queries (Data Request Form)	Queries	---	Questions to site regarding unclarities and missing data. E.g. missing data, error in CRF completion, unlogical and unexpected answers, too high or low values etc. Queries are usually entered in the eCRF or in a data clarification form.
Reconciliation	Rekonsiliering	---	Comparing two sets of records to check that data are in agreement.
Requisition	Rekvirering (resept/rekvisisjon)	---	Ordering a drug verbally, in writing or electronially by prescription or requisition. FOR-1998-04-27-455 § 1.3. Prescription is usually for a patient / study subject and a requisition for storage.
Serious Adverse Event / Serious Adverse Reaction	Alvorlig uønsket medisinsk hendelse eller alvorlig bivirkning	SAE/SAR	"Serious adverse event" means any untoward medical occurrence that at any dose: - requires inpatient hospitalisation or prolongation of existing hospitalization - results in persistent or significant disability or incapacity - results in a congenital anomaly or birth defect - is life-threatening - results in death A SAR is a SAE possible related to the study drug.

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			Regulation (EU) No 536/2014, Article 2.
Serious breach	Alvorlig avvik	---	A breach likely to affect to a significant degree the safety and rights of a subject or the reliability and robustness of the data generated in the clinical trial. Regulation (EU) No 536/2014, Article 52.
Single-blind	Enkeltblind	---	In a single-blind trial the investigator and/or his staff are aware of the treatment but the subject is not, or vice versa. ICH E9 Note for Guidance on Statistical Principles for Clinical Trials
Source Data	Kildedata	---	All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies). ICH GCP 1.51.
Source Data Verification	Kildedataverifisering	SDV	Checking the accuracy and completeness of the CRF entries, source documents and other trial related records against each other. ICH GCP 5.18.4 (m).
Source documents	Kildedokumenter	---	Original documents, data, and records (e.g. hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial. ICH GCP 1.52.

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Sponsor	Sponsor	---	"Sponsor" means an individual, company, institution or organisation which takes responsibility for the initiation, for the management and for setting up the financing of the clinical trial. Regulation (EU) No 536/2014, Article 2. Sponsor has an overarching responsibility for organising, conducting and reporting of the study. Sponsot must follow the sponsor requirements in ICH GCP chapter 5 and in regulation 536/2014.
Sponsor representative	Sponsors representant	---	Function in health institution delegated the tast to represent sponsor and usually also research responsible. The function is described in "roles and responsibilities" for clinical drug trials.Who holds the function may vary between institutions, it can be e.g. clinic directors or the research director.
Standard Operating Procedure	Prosedyre	SOP	Detailed, written instructions to achieve uniformity of the performance of a specific function. ICH GCP 1.55. Describes responsibility, delegation and who does what, when and how.
Start of a clinical trial	Starttidspunkt for en klinisk utprøving	---	"Start of a clinical trial" means the first act of recruitment of a potential subject for a specific clinical trial, unless defined differently in the protocol. Regulation (EU) No 536/2014, Article 2.
Subject	Deltager	---	Participant in a clinical drug trial.
Subject screening log	Screeningliste	---	To document identification of subjects who entered pre-trial screening. ICH GCP 8.3.20.
Substantial Modification	Vesentlig endring	---	"Substantial modification" means any change to any aspect of the clinical trial which is made after notification of a decision referred to in Articles 8, 14, 19, 20 or 23 and which is likely to have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial. Regulation (EU) No 536/2014, Article 2.

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Summary of Product Characteristics	Preparatomtale	SmPC	A document describing the properties and the officially approved conditions of use of a medicine. Summaries of product characteristics form the basis of information for healthcare professionals on how to use the medicine safely and effectively. EMA glossary
Suspected Unexpected Serious Adverse Reaction	Uventet alvorlig uønsket medisinsk bivirkning	SUSAR	Serious adverse reaction which is not covered by reference safety information, RSI. For academic studies reference docuements used are usually Investigator's Brochure or SmPC. Regulation (EU) No 536/2014, Article 2 and Annex III.
Suspension of a clinical trial	Avbrudd av en klinisk utprøving	---	Interruption of the conduct of a clinical trial. Regulation (EU) No 536/2014, Article 2.
Tables/listings/figures	Tabeller/lister/figurer	TLF	Different presentations of data in trial reports and/or publications.
Temporary halt of a clinical trial	Midlertidig stopp i en klinisk utprøving	---	"Temporary halt of a clinical trial" means an interruption not provided in the protocol of the conduct of a clinical trial by the sponsor with the intention of the sponsor to resume it. Regulation (EU) No 536/2014, Article 2.
The Norwegian Medical Products Agency Agency	Direktoratet for medisinske produkter	DMP/NoMA	Norwegian regulatory authority for medicines.
Trial Master File & Investigator Site File	Studiearkiv	TMFand ISF	The clinical trial master file shall at all times contain the essential documents relating to that clinical trial. TMF should be present at sponsor site and at each study site. The latter is referred to as Investigator Site File (ISF) or Investigator Study File. Regulation 536/2014 names both TMF and ISF for TMF. Regulation (EU) No 536/2014, Article 57. ICH GCP 8.
Trial site	Studiesenter	---	The location(s) where trial-related activities are actually conducted. E.g a hospital department. ICH GCP 1.59.
Unblinding	Avblinding	---	The disclosure of the identity of blinded products. Detailed Commission guidelines on good manufacturing practice for investigational medicinal products for human use, pursuant to the

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			second subparagraph of Article 63 (1) of Regulation (EU) No 536/2014.
User acceptance testing	User acceptance testing	AT	Last part of the testing of the DEA, where users are testing the application to ensure it works according to the specifications.
Vancouver recommendations ---	Vancouver-konvensjonen	---	Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals developed of International Committee of Medical Journal Editors (ICMJE). Includes pratical and ethical guidelines for authors, including compliance with the Declaration of Helsinki and approval from an independent Ethics Committee.