Appendix 2: Glossary

	Terms	Definition	Source	Remarks
1.	(**Data**) **sharing**	Granting access to data to another party irrespective of the way access in granted		Data can be shared in various ways. Access to the database of the controller can be granted through on-site research, for instance via the 'data shield method' where in short questions come to the controller and results will be fed-back to the recipient, data can be transferred to another party or can be shared between data provider and data recipients on a common platform to analyse the data.
2.	**(Data) sharing agreement**	A binding legal agreement between the provider and the recipient of data that sets forth conditions for data.	Adapted from Data sharing lexicon, Global Alliance for Genomics & Health Available at: https://genomicsandhealth.org/files/public/GA4GH_DataSharingLexicon_Mar15.pdf Accessed May 11, 2017	This new term is introduced as the traditional data transfer is more and more replaced by new terms such as data sharing.
3.	**(Data) transfer**	Sharing of data in such a way that the data will be embedded in the data system of the recipient.		If personal data are being transferred, the recipient will become the data controller.

	Terms	Definition	Source	Remarks
4	**(Data) Transfer Agreement (DTA)**	A binding legal agreement between the provider and the recipient of data that sets forth conditions of transfer, use and disclosure of data sent to the recipient	Small adaptation of the Data sharing lexicon, Global Alliance for Genomics & Health https://genomicsandhealth.org/files/public/GA4GH_DataSharingLexicon_Mar15.pdf	
5.	**Secondary use**	Using data in a way that differ from the original purpose for which they were generated or collected.	Data sharing lexicon, Global Alliance for Genomics & Health Available at: https://genomicsandhealth.org/files/public/GA4GH_DataSharingLexicon_Mar15.pdf Accessed May 11, 2017	Secondary use of data for research is as such not considered incompatible under the GDPR art. 6.1.
5.	**Further use**	Synonymous to secondary use.		
6.	**Further use or secondary use of clinical trial data**	Using subject data outside the protocol of the clinical trial exclusively for scientific purposes.	Regulation 537/2014 EU, Article 28	The scientific research making use of the data outside the protocol of the clinical trial shall be conducted in accordance with the applicable law on data protection. (Article 28)

	Terms	Definition	Source	Remarks
7.	**Personal data**	Means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.	Definitions General Data Protection Regulation (EU) 016/679 (GDPR), Recital 27	GDPR does not apply to anonymous data or personal data of deceased persons. However, Member States may provide for rules regarding the processing of data of deceased persons.
8.	**Individual level data**	The individual data separately recorded for each research participant. Does not say anything about the legal status of the data, in other words whether they are personal data of anonymous data.	After European Medicines Agency Policy on publication of clinical data for medicinal products for human use EMA/240810/2013 Available at: http://www.ema.europa.eu/ema/ Accessed May 11, 2017	If the data records are (indirectly) identifiable they will be personal data. They can also be anonymised data.
9.	**Data concerning health**	Means personal data related to the physical or mental health of an individual, including the provision of health care services, which reveal information about his or her health status.	GDPR, article 4.15.	
10.	**Aggregate data**	Contrary of Individual Level Data. Does not say anything about the legal status of the data.		

	Terms	Definition	Source	Remarks
11.	**Metadata**	Data that describe other data.	Data sharing lexicon, Global Alliance for Genomics & Health Available at: https://genomicsandhealth.org/files/public/GA4GH_DataSharingLexicon_Mar15.pdf Accessed May 11, 2017	
12.	**Source data (clinical trials)**	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)	E6(R1) Good clinical practice, Finalized Guideline May 1996 Available at: http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html	

	Terms	Definition	Source	Remarks
13.	**Anonymisation**	The process of rendering personal data into anonymous data	GDPR, Recital 26 (penultimate sentence)	See also the following document: *Opinion 05/2014 on Anonymisation Techniques* : In brief, anonymisation must be 'irreversible' for anyone. It should also be mentioned that the EMA uses a different definition: The process of rendering data into a form which does not identify individuals and where identification is not likely to take place. The EU Court of Justice adopted a more nuanced view in a recent case. For instance, the Court of Justice of the European Union (CJEU) gave a positive response to the question of whether " *a dynamic IP address registered by an online media services provider when a person accesses a website that the provider makes accessible to the public constitutes personal data*" (CJEU, 19 October 2016, C-582/14: *Patrick Breyer v Bundesrepublik Deutschland*). Available at: http://curia.europa.eu/. This view could very well lead to a more nuanced view on anonymisation as well, as anonymous data is meant to be the result of anonymisation.

	Terms	Definition	Source	Remarks
14.	**Anonymised or anonymous data**	Data where the subject is not or no longer identifiable.	Not as such mentioned in the GDPR	The law does not distinguish between anonymised data or data which are anonymous from the start. It is the result which counts. See for more information also the following document: *Opinion 05/2014 on Anonymisation Techniques*
15.	**Pseudonymisation**	The processing of personal data in such a way that the 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 subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable person.	GDPR, Article 4. 5	Pseudonymisation here discusses a way of rendering data which are personal data less identifiable. This definition differs substantially form that in ISO/TS 25237:2008 where pseudonymisation is described as a means to arrive at linkable but anonymous data. **ISO/TS 25237:2008**: Pseudonymization: "*particular type of anonymization that both removes the association with a data subject and adds an association between a particular set of characteristics relating to the data subject and one or more pseudonyms"*
16.	**De - identification**	The removal or alteration of any data that identifies an individual or could, foreseeably, identify an individual in the future.	Data sharing lexicon, Global Alliance for Genomics & Health Available at: https://genomicsandhealth.org/files/public/GA4GH_DataSharingLexicon_Mar15.pdf Accessed May 11, 2017	

	Terms	Definition	Source	Remarks
17.	**Re-identification**	The act of associating specific data or information within a dataset with an individual.	Data sharing lexicon, Global Alliance for Genomics & Health Available at: https://genomicsandhealth.org/files/public/GA4GH_DataSharingLexicon_Mar15.pdf	
18.	**Personal data breach**	Means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed.	GDPR, See Article 4.12	This definition is broader than that of the lexicon of the Global Alliance. It also encompasses a breach on the integrity and the availability of the data.
19.	**(Data) controller**	The natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data.	GDPR, See Art. 4.5	The controller can be a natural or legal person or body recognised in law. Data controllers must ensure that any processing of personal data for which they are responsible complies with the law.
20.	**Supervisory Authority (data protection)**	The public authority (or authorities) in a given jurisdiction responsible for monitoring the application of law and administrative measures adopted pursuant to data privacy, data protection and data security.	After Data sharing lexicon, Global Alliance for Genomics & Health Available at: https://genomicsandhealth.org/files/public/GA4GH_DataSharingLexicon_Mar15.pdf Accessed May 11, 2017	This is the general definition. The GDPR states: an independent public authority which is established by a Member State pursuant to Article 51 (art. 4(21)), e.g. the CNIL in France or ICO in the UK. NB: in other realms of regulation there are other 'supervisory authorities' such as in health protection.

	Terms	Definition	Source	Remarks
21.	**(Data) generator**	Natural or legal person who generates information, that has not existed before such as results of analysis or research, e.g. laboratory, test or survey values. In the context. In the context of clinical trials 'data generators' means the trialists and other study personnel that conceive of the study, and then plan, manage, monitor, analyse and publish it.	New term	The term is introduced as there is a need to describe the entity which is at the basis of information which will be used in research. Plays a role in credits to this source or in IP discussions.
22.	**(Data) processor**	A natural or legal person, public authority, agency or any other body which processes personal data on behalf of the controller.	GDPR, See Article 4.6	Under the GDPR has certain responsibilities for compliance with the GDPR as well.
23.	**(Data) user**	A natural person who has been authorised to access the data.		Not everybody under the controller's responsibility can use the data. This has to be organised internally by the controller in a nuanced way, giving access only to certain authorised users
24.	**(Data) Protection Officer**	The person assigned with the tasks as mentioned in art. 39 GDPR, in sum: • Inform and advise the controller and processor • Monitor compliance with GDPR • Cooperate with supervisory authority	GDPR, See Section 4, Article 39	The designation of a DPO is obligatory in the context of research with sensitive data.
25.	**(Data) provider**	The data controller who grants access to the data to an another party or transfers data (or tissue) to another party (data sharing).		The provider and recipient will be mentioned in the Data Transfer Agreement. See the Global Alliance lexicon

	Terms	Definition	Source	Remarks
26.	**(Data) recipient**	The legal entity which has been granted access to the data that will be transferred.		The legal person can delegate to natural persons. Under GDPR definitions: definition of (personal data) recipient: 'recipient' means a natural or legal person, public authority, agency or another body, to which the personal data are disclosed, whether a third party or not. However, public authorities which may receive personal data in the framework of a particular inquiry in accordance with Union or Member State law shall not be regarded as recipients; the processing of those data by those public authorities shall be in compliance with the applicable data protection rules according to the purposes of the processing;
27.	**(Data) producer**	Synonymous to data generator.		
28.	**(Data) steward**	An entity appointed by the data controller for assuring the quality, integrity, and access arrangements of data and metadata in a manner that is consistent with applicable law, institutional policy, and individual consent.	After Data sharing lexicon, Global Alliance for Genomics & Health Available at: https://genomicsandhealth.org/files/public/GA4GH_DataSharingLexicon_Mar15.pdf Accessed May 11, 2017	This term is not a legal term but used by many research organisations for a specific function which can also be executed by a committee. The Data Protection Officer will be responsible for adherence with data protection legislation. The role of steward or custodian is additional to this function.

	Terms	Definition	Source	Remarks
29.	**(Data) custodian**	Equates to data steward		
30.	**Non-interventional study** (EU clinical trials on medicines)	'Non-interventional study' means a clinical study other than a clinical trial	Regulation 537/2014 EU, Art. 2.4	This definition applies in the context of clinical trials on medicine.
31.	**Intervention**	A process or action that is the focus of a clinical study. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include non-invasive approaches, such as surveys, education, and interviews.	ClinicalTrials.gov (Glossary of Common Site Terms) Available at: https://clinicaltrials.gov/ct2/about-studies/glossary Accessed May 11, 2017	
32.	**Interventional study** (EU clinical trials on medicines)	Means a clinical study 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.	REGULATION (EU) No 536/2014, See Article 2 and Definitions	This definition applies in the context of clinical trials on medicine. Alternative definition: INTERVENTIONAL STUDY (or Clinical Trial) A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions **Source**: Clinicaltrials.gov, Glossary of Common site terms; Available at: https://clinicaltrials.gov/ct2/about-studies/glossary

	Terms	Definition	Source	Remarks
33.	**Clinical study (pharma, medicinal products)** **(EU legislation)**	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.	REGULATION (EU) No 536/2014, See Art. 2.2.1	Regulation 536/2014 does not contain rules about clinical studies which are not also clinical trials. For clinical studies, data protection legislation will apply, in addition to possible national legislation and institutional policies. Obviously, there are also clinical studies which do not primarily focus on medicinal products such as those about surgical interventions
34.	**Clinical trial (WHO)**	Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.	**World Health Organisation** Available at: http://www.who.int/ictrp/en/ Accessed May 11, 2017	WHO provides a broader definition of clinical trials. This definition covers all types of interventional biomedical research. According to WHO, this definition includes also Phase I to Phase IV trials.

	Terms	Definition	Source	Remarks
35	**Non-commercial clinical trials (OECD)**	Clinical studies initiated and driven by academic investigators for non-commercial purposes – are usually driven by pressing public health needs and scientific opportunities – which do not offer a strong business case to private companies.	OECD Global Science Forum, Facilitating International Cooperation in Non-Commercial Clinical Trials, OCTOBER 2011: pp 39 Available at: http://www.oecd.org/sti/sci-tech/globalscienceforumreports.htm Accessed May 11, 2017	
36.	**Commercial trial**	A clinical trial is commercial when it does not meet all the requirements set out under the definition of 'non-commercial-trial'.		
37.	**Investigator-driven clinical trials** (IDCT)	Clinical trials that are instigated by academic researchers and are aimed at acquiring scientific knowledge and evidence to improve patient care.	European Science Foundation, Forward Look, Investigator-Driven Clinical Trials, pp 2 Available at: http://archives.esf.org/fileadmin/Public_documents/Publications/IDCT.pdf Accessed May 11, 2017	
38.	**Research participant**	An individual about whom a researcher obtains data for research purposes	New term	We chose a very broad definition. It does not state *how* the data are obtained. This can range from an interventional study to 'further use' of anonymised data.

	Terms	Definition	Source	Remarks
39.	**Subject (clinical trial)**	An individual who participates in a clinical trial, either as recipient of an investigational medicinal product or as a control;	Clinical trials - Regulation EU No 536/2014 Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf	
40.	**Confidentiality**	The legal, contractual or ethical obligation to prevent disclosure to individual's other than those who are authorised.		Confidentiality can follow from data protection regulation or common law but also from contractual agreements about commercial information.
41.	**Consent (data in general)**	Any freely given, specific, informed and unambiguous indication of the data subject's agreement to the processing of personal data relating to him or her.	GDPR, Art. 4.11	
42.	**Explicit consent (sensitive data)**	Consent by a clear affirmative action. E.g. written statement, including by electronic means, or an oral statement. This could include ticking a box when visiting an internet website, choosing technical settings for information society services or another statement or conduct which clearly indicates in this context the data subject's acceptance of the proposed processing of his or her personal data. (GDPR, Recital 32)	GDPR, 9.2.a, Recital 32	According to GDPR, silence, pre-ticked boxes or inactivity should not constitute consent. However, the implementation of these provisions may vary from one country to another.

	Terms	Definition	Source	Remarks
43.	**Broad consent**	Consent to secondary use of individual level data for further research purposes.		Broad consent is not forbidden under GDPR provided that conditions for a lawful consent are met.
44.	**Informed consent** (clinical **study**)	A subject's free and voluntary expression of his or her willingness to participate in a particular clinical study, after having been informed of all aspects of the study that are relevant to the subject's decision to participate or, in the case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical trial	After REGULATION (EU) No 536/2014, Art. 2.21	
45.	**Data linking**	Matching and combining data from multiple databases	ISO/TS 25237:2008(en) Health informatics — Pseudonymization Available at: *https://www.iso.org/standard/42807.html* Accessed May 11, 2017	
46.	**Data Privacy Impact Assessment**	An assessment of the impact of the envisaged processing operations on the protection of personal data.	GDPR, art. 81.1	Article 38.7 contains more details about the DPIA. It must be assumed that each new biomedical research project requires a DPIA.
47.	**ISMS**	Information Management Security System.		Required by ISO 27001 and follows from GDPR as well.
48.	**PIA**	See Data Privacy Impact Assessment		