A European Cancer Image Platform Linked to Biological and Health Data for Next-Generation Artificial Intelligence and Precision Medicine in Oncology

D1.2 Glossary on common definitions across EU privacy and data security laws (V1.0)

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Version log

Issue Date	Version	Involved	Comments
11/17/2021	V0.0	Michaela Th. Mayrhofer (BBMRI), Ilaria Collussi (BBMRI), Irene Schlünder (TMF)	Draft conceptualised
6/12/2021	V0.1	Ilaria Collussi (BBMRI)	Draft content finalised
13/12/2021	V1.0	Michaela Th. Mayrhofer (BBMRI)	V1.0 draft & sent to WP1
14/12/2021	V1.0	Nicolás, Pilar (UPV/EHU)	Inclusion of additional keywords, recommendation link to data governance.
17/12/2021	V1.0	Michaela Th. Mayrhofer (BBMRI)	Version 1.0 final submitted. Feedback specified in next steps.
17/12/2021	V1.0	Isabell Tributsch (UB), Karim Lekadir (UB)	Reviewed last version

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Methodology

The glossary on common definitions across EU privacy and data security laws for EuCanImage builds on the latest draft version of the draft glossary for the Code of Conduct for Health Research (http://code-of-conduct-for-health-research.eu). The initiative is spearheaded by BBMRI-ERIC and aims to 'translate' GDPR provisions into practice and simplify its interpretation through a code of conduct under GDPR Art. 40/41. The draft glossary benefiting from findings from previous projects such as CORBEL, ADOPT BBMRI-ERIC, Do-It and especially the inkind contributions from legal experts from BBMRI, EFPIA and ECRIN. The latest version of the glossary of the Code of Conduct for Health Research of 6. December 2021 was enlarged by BBMRI experts (listed above as authors of the deliverable) of EuCanImage and circulated within WP1 experts (listed above as contributors) of EuCanImage for comments.

The final edited document (V1.0) is submitted as Deliverable 1.2 to the Commission services after publication on Zenodo (10.5281/zenodo.5789057). Ultimately, the glossary will serve EuCanImage and the Code of Conduct initiative aiming towards further clarity and harmonisation.

Glossary V1.0

TERM	DEFINITION	REFERENCE
Adverse Event	"Any untoward medical occurrence in a patient or clinical investigation subject administered with a pharmaceutical product, but which does not necessarily have a causal relationship with the intervention. An adverse event (AE) can therefore be any unfavourable and unintended clinical sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product"	ICH Harmonised Tripartite Guideline for Good Clinical Practice E6 (R1), 10th June 1996
Aggregate Data	**"**Statistical data about several individuals that has been combined to show general trends or values without identifying individuals within the data."	EMA External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use, 20 September 2017
Anonymisation	The process of rendering personal data anonymous in such a manner that the data subject is not or no longer identifiable.	Adapted from Recital 26, EU GDPR
Anonymised or anonymous data	Data where the individual is not or no longer identifiable	Adapted from Article 29 Data Protection Working Party, Opinion 05/2014 on Anonymisation Techniques, 10 April 2014.

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Audit	"A systematic and independent examination of trial related activities and documents related to a process of an organisation to determine whether activities were conducted, and the data were recorded, analysed and accurately reported according to the standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable policies and regulatory requirement(s)"	ICH Good Clinical Practice Glossary
Biobank (including biomaterial bank, sample bank, tissue bank, sample collection)	A collection of biological material and the associated data and information stored in an organised system, for a population or a subset of a population, for research purposes.	Adapted from OECD, Creation and Governance of Human Genetic Research Databases, 2009
Case Report Form (CRF)	A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant.	Adapted from ICH Good Clinical Practice Glossary;
Clinical Monitor	The individual responsible for 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).	Adapted from ICH Good Clinical Practice Glossary
Clinical Study	"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."	Art. 2(2)(1) of the Clinical Trials Regulation 536/2014
Clinical Trial	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;	Art. 2(2)(2) of the Clinical Trials Regulation 536/2014

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	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."	
Coding	"Substituting a code for personally identifying information in such a way that linkage is only possible through a key"	Biobank Lexicon, P3G Consortium
Confidentiality	"The ethical and legal obligation of an individual or organisation to safeguard data or information by controlling access as authorised by law or by the data donor."	Data sharing lexicon, Global Alliance for Genomics & Health.
Conflict of Interest	"Connections or interests (personal, social, financial or professional) that influence or, are perceived to influence, professional integrity and independence"	Biobank Lexicon, P3G Consortium
Consent, data in general	"Any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she by statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.''	Art 4(11) GDPR
Custodian	**"Entity responsible for managing the biobank, including control over its release, use and access as well as sample/information destruction. Custodianship does not necessarily equate with ownership over the biobank contents"**	Biobank Lexicon, P3G Consortium
Data Access Committee	"A committee that reviews and authorises applications for data access and use"	Data sharing lexicon, Global Alliance for Genomics & Health.
Data Breach	"The unauthorised collection, access, use, disclosure or release of data."	Data sharing lexicon, Global Alliance for Genomics & Health.
Data concerning health	"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."	Art. 4(15), GDPR
Data Controller	"The natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific	Art. 4(7) of the GDPR

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	criteria for its nomination may be provided for by Union or Member State law"	
Data Linkage	"The process by which records representing the same entity or individual are linked across multiple data sources."	Data sharing lexicon, Global Alliance for Genomics & Health.
Data Protection Impact Assessment	An assessment of the impact of the envisaged processing operations on the protection of personal data.	Adapted from Art 35, GDPR
Data Processor	"A natural or legal person, public authority, agency or any other body which processes personal data on behalf of the controller."	Art 4(6) GDPR
Data Protection Officer (DPO)	The individual assigned with the tasks stated in art. 39 GDPR, which: • Inform and advise the controller and processor • Monitor compliance with GDPR • Cooperate with supervisory Authority.	Adapted from Art 39.1 GDPR
Data Quality	The "degree to which a set of inherent characteristics of data fulfils requirements".	ISO 8000-2:2017 on Data quality —
Data or Material Transfer Agreement	A binding legal agreement between the provider and the recipient of data or materials that sets forth conditions for transfer, use and disclosure.	Data sharing lexicon, Global Alliance for Genomics & Health.
Data Subject	An identified or identifiable natural person whose personal data is being processed	Adapted from Art 4(1) and Art. 4(2) GDPR
De-identification	"The removal or alteration of any data/attributes that identifies an individual or could, foreseeably, identify an individual in the future."	Data sharing lexicon, Global Alliance for Genomics & Health.
Disclosure	"The act of releasing identifying information to unauthorised third parties"	Administrative Data Research Network Glossary
Disclosure Risk	"The probability of confidential information being revealed about an individual."	Data sharing lexicon, Global Alliance for Genomics & Health.
Epidemiology	"The study of the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems."	WHO Definition: http://www.who.int/topics/epidemiology/en/
Ethics Committee	"An independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions (for the purposes of this Regulation), taking into account the views of laypersons, in particular patients or patients' organisations".	Art 2(11), Clinical Trials Regulations

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General Data Protection Regulation	Regulation laying "down rules relating to the protection of natural persons with regard to the processing of personal data and rules relating to the free movement of personal data."	Art 1.1, GDPR
Genetic Counselling	''The process of helping people understand and adapt to the medical, psychological and familial implications of genetic contributions to disease.''	Resta, Robert & Biesecker, Barbara & Bennett, Robin & Blum, Sandra & Hahn, Susan & Strecker, Michelle & Williams, Janet. (2006). A New Definition of Genetic Counseling: National Society of Genetic Counselors' Task Force Report. Journal of genetic counseling. 15. 77-83. 10.1007/s10897-005-9014-3.
Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.	Adapted from the EMA Guideline for Good Clinical Practice E6(R2), 1 December 2016
Individual level data	The individual data separately recorded for each research participant.	Adapted from European Medicines Agency Policy on publication of clinical data for medicinal products for human use EMA/240810/2013, 2 October 2014
Information Security Management System (ISMS)	"A systematic approach for establishing, implementing, operating, monitoring, reviewing, maintaining, and improving an organisation's information security to achieve business objectives."	ISO27000:2018 Information technology — Security techniques — Information security management systems — Overview and vocabulary
Intervention, Clinical Trial	''A process or action that is the focus of a clinical study"	ClinicalTrials.gov (Glossary of Common Site Terms)
Interventional Study	"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."	Art 2.2(2) Clinical Trials Regulation
Investigator	"Individual responsible for the conduct of a clinical trial at a clinical trial site''	Art 2.2(15), Clinical Trials Regulation
Medical Confidentiality	The ethical and legal obligation of a health care professional or organisation to safeguard data or information by	Adapted from Data sharing lexicon, Global Alliance for Genomics & Health Available at:

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	controlling access as authorised by law or by the data donor.	https://genomicsandhealth.org/files/public/GA4GH_DataSharingLexicon_Mar15. pdf
Monitoring	"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 Good Clinical Practice Glossary
Multi-centre study	**"**A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.''	ICH Good Clinical Practice Glossary
Material or Data Transfer Agreement	**"**A binding legal agreement between the provider and the recipient of data or materials that sets forth conditions of transfer, use and disclosure."	Data sharing lexicon, Global Alliance for Genomics & Health
Observational study	''A type of clinical study in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to a specific interventions/treatment''	ClinicalTrials.gov (Glossary of Common Site Terms)
Personal data	"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."	Art. 4 (1) of the GDPR
Personal data breach	"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."	Art. 4 (1) of the GDPR
Principal Investigator (PI)	''An investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site''	Art 2.2(16) Clinical Trials Regulation
Pseudonymisation (coding)	"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, as long as such additional information is kept separately and subject to technical and organisational	Art. 4 (5) GDPR

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	measures to ensure non-attribution to an identified or identifiable person."	
Re-identification	"The act of associating specific information within a dataset with an individual."	Data sharing lexicon, Global Alliance for Genomics & Health
Sensitive data	''…personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation''	Art.9 (1) GDPR
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".	EMA, Good clinical practice, Guideline for good clinical practice E6(R2), 1 December 2016, EMA/CHMP/ICH/135/1995
Sponsor	**"**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.''	Art. 2.2(14) Clinical Trials Regulation
Standard Operating Procedure (SOP)	**"**Detailed, written instructions to achieve uniformity of the performance of a specific function''	EMA, Good clinical practice, Guideline for good clinical practice E6(R2), 1 December 2016, EMA/CHMP/ICH/135/1995
Study Protocol	"A document that describes the objectives, design, methodology, statistical considerations and organisation of a clinical trial."	Art 2.2(22) Clinical Trials Regulation
Supervisory Authority (data protection authority)	"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."	Data sharing lexicon, Global Alliance for Genomics & Health
Trial Master File	**"…**at all times contain the essential documents relating to that clinical trial which allow verification of the conduct of a clinical trial and the quality of the data generated, taking into account all characteristics of the clinical trial, including in particular whether the clinical trial is a low-intervention clinical trial."	Art 57 Clinical Trials Regulations
Trusted Third Party	"An individual or organization that safeguards access to information linking individuals to their data and bio-specimens.''	Data sharing lexicon, Global Alliance for Genomics & Health

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Next Steps

V2.0 will enlarge on terms related particularly to the project's needs on "imaging data"; "data access", "data transfer", "data catalogue", "data platform" etc and available on Zenodo in its latest version.

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