Joint research for a healthier future

GERMAN NATIONAL COHORT

USE AND ACCESS POLICY

OF THE NAKO E. V. FOR THE GERMAN NATIONAL COHORT (NAKO)

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Federal Ministry of Research, Technology and Space

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Disclaimer: This document is a translation of the original German text. In the event of any discrepancies or ambiguities, the German version shall prevail.

PREAMBLE

This Use and Access Policy regulates the responsible management of Data and Biosamples collected within the framework of the German National Cohort (NAKO).

The German National Cohort (NAKO) is a multidisciplinary, population-based, prospective cohort study in Germany. Since 2014, more than 205,000 randomly selected individuals (participants) have been medically examined and surveyed about their lifestyle habits at 18 study centres. The aim of the study is to investigate the frequency and causes of common diseases such as cancer, diabetes and cardiovascular disease, to identify risk factors and to identify ways of effective prevention and early detection.

The study is being conducted by the NAKO e. V. association, supported by 26 institutions and financed by funds from the German Federal Ministry of Research, Technology and Space (BMFTR), the Helmholtz Association and the participating federal states. (www.nako.de)

§1 BASIS OF USE

1.1 Purpose of the policy

This Use and Access Policy governs the transparent, statutory and scientifically appropriate Use of Data collected and Biosamples obtained by NAKO e. V. for research purposes. The Use is subject to constitutionally protected freedom of research, data protection and the legitimate interests of participants in the protection of their personal rights.

1.2 Legal basis

(1) The basis for any collection, processing and Use of Data, as well as any extraction, further processing, analysis and evaluation of Biosamples is the informed consent of the participants concerned in accordance with the signed declaration of consent. This forms the legal and ethical basis for the collection, storage, processing and transfer to authorised Users (see p. 11 for definition). Use is permitted solely in strict accordance with this Use and Access Policy. The collection, processing and Use of certain Data (e.g. secondary data) is furthermore carried out on the basis of statutory provisions or contractual agreements.

(2) Upon conclusion of the Agreement for Use/Access, the User shall be granted, in accordance with this Use and Access Policy, a simple, revocable, non-exclusive and non-transferable right to Use the Data and, where applicable, Biosamples. This right is limited in time and territory, restricted to the duration and purposes of the Agreement for Use/Access, and may only be sublicensed with the prior consent of NAKO e. V., provided that the Data and Biosamples are used solely for purposes consistent with the objectives of NAKO e. V. and do not prejudice its interests.

(3) An ethics approval has been obtained for the German National Cohort (NAKO), covering the collection of Data and Biosamples as well as the disclosure of Data to third parties for the research purposes specified therein.

(4) The Use of NAKO Data shall be the sole responsibility of the Users, in full compliance with the Agreement for Use/Access and the Use and Access Policy. Accordingly, it is incumbent upon the Users to ascertain whether additional ethical approvals are required for their intended Use of the Data. NAKO e. V. reserves the right to request application-specific ethical approval for particularly sensitive data, biosamples or research questions.

(5) In the event of withdrawal of consent by participants or cessation of the conditions on the basis of which the data may be collected, passed on or used, the data concerned and, where applicable, Biosamples shall be permanently excluded from future use in scientific projects.

(6) In all other respects, the relevant statutory provisions shall apply, in particular the data protection regulations at state, federal and EU level, copyright and patent law, as well as other relevant legal and ethical regulations. The guidelines on good scientific practice, in accordance with the principles of research ethics and integrity, shall likewise apply.

1.3 Procedure for Use

(1) Any Use of Data and Biosamples within the meaning of the Use and Access Policy requires the submission of a Use/Access Application. Such application shall undergo the procedure set out in this Use and Access Policy. Upon approval of the application, an Agreement of Use/Access shall be concluded between all Users and NAKO e. V.

(2) Incoming applications shall be reviewed by a Use and Access Committee (UAC) established by the General Assembly. The UAC assesses whether the proposed Use is consistent with the objectives and purpose of NAKO e. V., evaluates organisational and scientific aspects, and issues a recommendation to the General Assembly to approve or reject the application. The UAC may consult additional experts during the review process. For applications involving Biosamples, the opinion of a Biosample Panel, likewise established by the General Assembly, shall be sought. The UAC shall be supported in its review by the Transfer Office, Research Data Management and Central Quality Management.

1.4 General principles for the Use of Data and Biosamples

(1) Use is permitted exclusively for health-related research projects that are consistent with the objectives of the German National Cohort (NAKO) and are expected to generate significant scientific merit.

(2) Data and/or Biosamples Provided may be used solely for the purpose requested and approved, and only until the expiry of the authorised Period of Use. All requirements and conditions set out in the authorisation must be strictly observed.

(3) The personal rights of participants must be protected at all times. Only pseudonymised or anonymised Data may be used, and under no circumstances may any attempt be made to re-identify participants. Strict technical and organisational precautions shall be implemented to prevent any possibility of drawing conclusions about individuals. The transfer or linkage of Data to other data sources is permitted only with express authorisation and in full compliance with all applicable data protection regulations. Personally identifiable data (such as names, addresses, etc.) shall remain exclusively with the authorised units of NAKO e. V. and shall not be disclosed to third parties.

(4) The scientific objectives, methodology and intended publications must be fully disclosed. All results must be published in accordance with the Publication Policy of NAKO e. V.

(5) Imaging Data from NAKO may only be used in scientific publications and media reports in such a manner that re-identification of the persons concerned is impossible. Users bear sole responsibility for ensuring that published imaging data does not allow conclusions to be drawn about the identity of individual persons and that it complies with data protection regulations. In the case of media reports, the NAKO press office must be informed via presse@nako.de prior to publication.

(6) Commercial intentions must be disclosed when submitting the application and will be taken into account during the assessment and contract drafting process. If such intentions arise during or after completion of the research project, they must be reported to the transfer office immediately and require separate approval and a contractual basis.

(7) No claim to financial support or other funding or support from the NAKO e. V. may be derived from access to or the transfer of Data and Biosamples.

§2 APPLICATION PROCEDURE

2.1 Principles for the application procedure

(1) Universities, private and public research institutions, and research-based companies (Users) are eligible to apply.

(2) The Use of Data and Biosamples requires the submission of an application, approval by NAKO e. V. and the conclusion of a Use/Access Agreement.

(3) Contact for questions regarding the application process: transfer office (transfer@nako.de).

2.2 Form of the application

Data and Biosamples can only be requested via the web portal of the transfer office at NAKO e. V. (www.nako.de/transferhub). The application form provided there must be completed in full.

2.3 Content of the application

The Use/Access Application must contain at least the following information:

Information about the User; project title; project participants; summary project description; intended Period of Use; project objectives; scientific background; justification of feasibility; resources available for implementation (material and human); details on the type/quantity of Data/Biosamples; biological sample parameters, case numbers, justification, analysis method, project plan, if applicable; participation of third-party funding providers; industrial collaborations; GDPR compliance.

2.4 Application review

2.4.1 Use/Access Applications

(1) The applications received are forwarded to the Use and Access Committee (UAC), which meets at regular intervals and as required to ensure the timely processing of Use/Access Applications. Subject-matter experts may be consulted during the deliberations. The work of the UAC is supported by the transfer office, research data management and central quality management, which conduct preliminary checks on individual criteria and provide the results to the UAC for review.

(2) The UAC shall examine applications in accordance with the following criteria:

a) Identity of the applicants;
b) Affiliation with an institution located within the EEA, or in a country subject to an adequacy decision, or in a country where appropriate safeguards can be established;
c) Participation of industrial companies;
d) Availability of a sufficient pool of Data and Biosamples;
e) Assessment and decision/recommendation, involving experts if necessary, as to whether the planned Results Data should be submitted to NAKO e. V. and whether Data and/or Biosamples should be provided in two stages;
f) Review and management when requesting Data with restricted Use;
g) Verification of whether applicants have previously violated the Use and Access Policy or whether they are eligible to apply;
h) Assessment of the consistency of the planned Use with the objectives and purpose of the German National Cohort (NAKO) and the scientific questions addressed by the study, as well as compliance with the participants' declarations of informed consent;
i) Conclusiveness of the scientific justification for the project described (scientific concept including case number justification and analysis strategy);
j) Compliance with legal and ethical standards and with the provisions of this Use and Access Policy;
k) Correspondence between the Data and Biosamples requested in the Use and Access Application and the planned evaluations or analyses;
l) Achievability of the objectives of the evaluations or analyses with the resources described in the application (feasibility assessment).

2.4.2 Additional regulations for applications involving Biosamples

(1) NAKO stores Biosamples either centrally or decentrally. Central storage locations include the Central Biorepository and the Tumour Tissue Bank. Decentralised storage locations are the biological sample storage facilities at the NAKO study centres and member institutions.

(2) Applications for the Use of decentralised Biosamples require the prior express consent of the study centres or member institutions responsible for the collection or storage of the respective samples. In all other respects, the provisions set out in section 2.4.1 apply.

(3) Applications for the Use of centrally stored Biosamples shall be submitted to the Biosample Panel, which meets regularly and as required, prior to the UAC review referred to in 2.4.1.

(4) The Biosample Panel shall submit to the UAC, for its review of the applications referred to in paragraph 3, an opinion on the following criteria:

a) Availability of Biosamples;
b) Sample characteristics and sample size: Due to the large scope of the German National Cohort (NAKO) and its study design, preference will be given to applications that make optimal use of the breadth and depth of phenotyping, such as projects that examine as many participants or specific subgroups (e.g. MRI participants) as possible using a methodology at one or more points in time;
c) Projects with a smaller number of cases: these usually only receive Biosamples from participants for whom a minimum amount of Biosamples is still available.
d) Projects seeking to examine large control samples from NAKO for studies involving external cases and pilot studies aimed at developing new standardised procedures shall only be accepted were a particular and duly justified interest exists;
e) Quality-assured and well-documented methods:
a. Justification, quality and documentation of the planned method: Planned analysis methods must be well documented and the planned protocols must be submitted for review upon request;
b. A high degree of standardisation has priority, e.g. in the OMICs analysis.
f) For OMICs applications: assessment of the requirements relating to data infrastructure and data volume for storing the results;
g) Evaluation of competing requests and, where applicable, determination of specifications for outsourcing priority;
h) Requests for Biosamples of the highest quality: these are examined most closely and, if necessary, additional justifications will be requested;
i) Optimal use of aliquots: As a general principle, the smallest possible quantity of sample material should be utilised. Where aliquoting is necessary, the Biosample Panel shall issue a recommendation regarding the location for aliquoting and the handling of any residual samples.

(5) The final decision on the recommendation to the Board of Directors shall rest with the UAC.

2.5 Decision on the application

(1) After reviewing the application, the UAC will electronically transmit one of the following recommendations to the transfer office:

a) Approval of the application;
b) Rejection of the application;
c) Revision of the application.

(2) Any rejection or request for revision must be justified, and any required conditions or modifications must be specified. If the UAC considers a revision of the application to be appropriate, the applicants will receive a corresponding request from the transfer office. Upon resubmission, the UAC shall review the application anew and, if appropriate, recommend approval.

(3) Where the Use of Biosamples is approved, the UAC may request that applicants collaborate with another Project or carry out the Project at a later date if this would enable a more efficient Use of Biosamples.

(4) The transfer office shall submit to the Board of Directors all applications recommended for approval or rejection, and the Board shall render its decision without delay on the basis of the UAC's recommendation.

(5) In the event of rejection, applicants shall be informed of the reasons for the rejection.

(6) Upon approval, all parties involved in the German National Cohort (NAKO) (Board of Directors, members of NAKO e. V., coordinators of the infrastructure and competence units, module managers and spokespersons for the expert groups and their deputies) will be informed electronically. Such notification shall include, at a minimum, the names and institutional affiliations of all (co-)applicants, the title and duration of the Project and a project summary.

(7) Following approval of the Board of Directors, the transfer office shall execute the contractual agreement and authorise the transfer of Data and/or Biosamples.

(8) Once the Data and/or Biosamples have been made available, approved projects shall be published

on the NAKO TransferHub, together with their current project status (ongoing or completed) and the following details: project title, summary, keywords, project management, participating institutions, date of approval and, where applicable, date of completion

2.6 Refusal to approve Use

(1) Approval of Use may be refused irrespective of the Project's eligibility for approval if the Project Management or other Project Participants have culpably breached this Use and Access Policy to a significant degree in a previous case.

(2) A significant breach is deemed to exist in particular if

a) the rights of use under § 1.2 have been disregarded,
b) prior use exceeded the scope permitted under § 1.4,
c) the reporting obligations under § 4 have not been fulfilled,
d) the Results Data were not made available in accordance with § 4 or
e) the Publication Policy was violated.

2.7 Use/Access Agreement

The provision of Data and, where applicable, Biosamples following approval of the application is subject to the conclusion of a Use/Access Agreement, to which the relevant application shall be appended.

§ 3 TRANSFER OF DATA AND BIOSAMPLES

(1) Following the conclusion of the Use/Access Agreement, the requested Data will be compiled into one or more datasets and made available to Users via the TransferHub in pseudonymised or anonymised form, or sent to them.

(2) In individual cases, e.g. in relation to imaging data (MRI, 3D echo), Biosamples or geocoordinates, NAKO e. V. may stipulate a two-stage data/sample provision process (see section 2.4.1 (2) e). Under this procedure, only those data components required for the generation of the Results Data shall initially be transferred (e.g. Biosamples, DICOM images, geocoordinates, basic data). Once the generated Results Data has been delivered to the transfer point, the remaining requested data components shall subsequently be provided.

(3) In addition to the provisions under § 1 and 2, the following provisions apply to the transfer of Biosamples:

a) The Transfer Unit or Central Biorepository shall, either during the review conducted by the Biosample Panel or on the basis of the Use/Access Agreement, determine the selection of the participants and the Biosamples to be outsourced.
b) The transfer/shipment of Biosamples is carried out by the Central Biorepository, the decentralised biosample storage facilities or the tumour tissue bank. Biosamples are only transferred/shipped to the recipients or laboratory personnel specified in the Use/Access Agreement.

3.1 Costs and fees

Fees for costs incurred for the provision of Data and Biosamples may be charged.

3.2 Transport

Users shall bear the costs of any necessary transport of Data on physical data carriers. They shall be responsible for arranging the transport and, where required, the return of Biosamples, or for commissioning a suitably qualified and certified transport company at their own expense and under their sole responsibility.

3.3 Subsequent changes to the Use and Access Application

(1) The following additions or changes to an application can be requested via the TransferHub ticket system after the requested Data and/or Biosamples have already been provided:

- Additional Data related to the subject matter of the original application;
- Extension of the Period of Use;
- Inclusion of additional co-applicants;
- Inclusion of additional persons working for the Users;
- Change of (co-)project manager, provided that this person belongs to the same User.

(2) For all changes/additions exceeding those set out in (1), a follow-up application must be submitted, which shall be decided upon by the Board of Directors in accordance with Section 2.5 (4) and which requires a contractual basis.

§ 4 RIGHTS AND OBLIGATIONS DURING AND AFTER USE

(1) NAKO e. V. may request an interim report; such a report shall be mandatory if the Period of Use is extended. If no publication has been produced, a final report must be submitted.

(2) Users shall notify NAKO e. V. of all publications arising from the Project. The publications themselves, together with the applicable regulations, shall be governed by the Use/Access Agreement and, additionally, by the Publication Policy.

(3) Upon expiry of the contractually agreed Project Term, the Data, Biosamples and results provided may no longer be used by the Users.

(4) Users shall submit their Results Data, evaluation programmes and Metadata to NAKO e. V. no later than twelve months after the conclusion of the project. NAKO e. V. shall determine their inclusion in the research database and may, at its discretion, waive the requirement for submission.

(5) Users may reapply for the Results Data they have submitted to the association for the purpose of a new project.

(6) The responsibility for storing the Results Data in accordance with the principles of good scientific practice shall rest with the Users.

(7) All Data provided and Results Data must be erased once the purpose of Use no longer applies (or, where relevant, upon expiry of the retention period); Users themselves shall be responsible for this in accordance with Article 26 GDPR.

(8) The original Users shall be informed when their Results Data are used by other Users. The latter are obliged to observe the principles of good scientific practice when using this data. The obligation to provide information shall apply only for the duration specified in the Use/Access Agreement.

(9) Further details are set out in the Use/Access Agreement

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ANNEX – DEFINITIONS OF TERMS

The following definitions are arranged in such a way that concrete entities and facts are listed first. These are followed by role terms, which are characterised by the fact that they can be filled by different actors in the individual concrete usage procedures.

For the purposes of this Use and Access Policy governing the exchange of Data and, where applicable, Biosamples within the framework of the German National Cohort (NAKO), the following terms have the meanings set out below:

Anonymised Data: Data from which all personal characteristics have been removed or altered in such a way that it is impossible to identify the data subject either directly or indirectly. Re-identification is impossible.

Biosample Panel (role in the use procedure): a committee set up specifically to review applications for the Use of Biosamples, which advises the Use and Access Committee (UAC) (see UAC Rules of Procedure).

Biosamples: All Biosamples obtained from participants in the German National Cohort (NAKO) or provided by participants and stored in the NAKO's Biosample repositories (central and decentralised). These include, for example, serum, plasma, urine, saliva and tissue samples, as well as Biosamples obtained from these, such as blood components and DNA. For Biosamples from Level 3 projects, the Level 3 regulations apply in principle, unless reference is made there to the validity of the Use and Access Policy.

Central Biorepository (role in the use procedure): the central biobank of the German National Cohort (NAKO) at Helmholtz Zentrum München, which operates the NAKO laboratory information management system and checks the availability of the Biosamples requested for projects as part of the selection process. Once commissioned by the transfer office, it is responsible for transferring the centrally stored Biosamples to the recipients named in the application.

Co-Applicant (role in the use procedure): All persons additionally named in a Use/Access Application. These persons may co-sign the application but may not submit it. Co-applicants will only receive Data if they are named as Data Recipients in the Use/Access Application and a Use/Access Agreement has been concluded with their institution.

Co-Project Management (role in the use procedure): A natural person who works for an institution receiving Data and/or samples and who performs central coordination tasks in relation to NAKO e. V. in connection with the preparation and implementation of the Use/Access Agreement and the Use/Access Project.

Contractual Partner: the legal persons who enter into a Use/Access Agreement with the NAKO e. V. Each Contractual Partner must provide the Transfer Unit with the name of one or more authorised signatories to sign the agreement.

Data: the personal Data from the various parts of the German National Cohort (NAKO) (e.g. interviews, examinations, measurement results of Bio Samples, images, secondary data and register data, Results Data from previous Projects).

Data/Biosamples Provided: all data and/or Biosamples provided by NAKO e. V. to a User from the various parts of the German National Cohort (NAKO) (e.g. surveys, examinations, measurement results from biological samples, images, secondary and registry data, Results Data from previous projects, Biosamples, e.g. serum, plasma, urine, saliva and tissue samples, as well as Biosamples obtained from these, such as blood components and DNA), regardless of whether they are personal data and/or samples.

Decentral Biosample Repository (role in the use procedure): the Biosample storage facilities, where some of the Biosamples collected are stored decentrally under the responsibility of the respective study centre conducting the collection. The bio samples and their storage temperature are documented in the NAKO laboratory information management system. Removals, transfers and withdrawals of decentralised samples are documented in the NAKO laboratory information management system by the decentralised Biosample storage facility or facilities in a timely manner.

Independent Trust Centre (ITC) (role in the use procedure): the responsible body that stores and processes NAKO's personally identifiable data centrally and separately from medical data. For data

collection purposes, ITC stores the assignment of pseudonyms to participants and manages the declarations of consent, including documentation of changes to consent in the event of revocation.

Integration Centre (role in the use procedure): the body responsible for storing and processing the medical data of NAKO participants. The Integration Centre manages the Metadata (data dictionary) for all data elements/variables and integrates the Results Data into the Research Database.

Level 3 Project: a project that goes beyond the regular German National Cohort (NAKO) examination programme, which usefully supplements and expands the German National Cohort's (NAKO) scientific programme with additional examination aspects, questionnaires or Biosample collections.

Main Applicant (role in the use procedure): the person who prepares and submits the Use/Access Application and normally handles Project Management.

Metadata: non-personal Data describing processes, variables, categories and the like.

NAKO TransferHub: the Transfer Unit's web portal via www.nako.de/transferhub. The TransferHub provides information for potential applicants and, via personal access accounts, enables the electronic submission of applications and the tracking of the entire application and usage process by the respective parties involved.

Period of Use: the period during which the approved Use of Data and/or Biosamples is permitted. The Period of Use begins with the provision of the Data and, if applicable, Biosamples, and ends after the expiry of the period specified in the application. After this period, any further use or storage of the Data and Biosamples Provided is prohibited, unless an explicit extension has been approved.

Personal Data: are those within the meaning of Article 4(1) of the General Data Protection Regulation (GDPR).

Project: A project that is consistent with the objectives of the German National Cohort (NAKO), for which NAKO Data and, if applicable, Biosamples are to be used, and which is described in the application. The Use/Access Project is limited in time and is financed by the applicant.

Project Management (role in the use procedure): A natural person who works for the applicant institution and who performs central coordination tasks in relation to NAKO e. V. in connection with the preparation and implementation of the licence agreement and the licence project.

Project management for L3 projects (role in the utilisation process): A natural person who works for the applicant institution or is employed by another institution as a (co-)applicant. This person works in an institution that receives Data and/or samples and performs central coordination tasks in connection with the preparation and implementation of the Level 3 project.

Project Participants (role in the use procedure): all persons involved in a project as Main Applicants, Co-applicants, Data Recipients and, if applicable, Biosample Recipients, and their staff.

Project Term: covers all phases of the project, from provision, Data and Biosample Use, evaluation and reporting (publication) to the transfer of Results Data.

Pseudonymised Data: Data in which identifying characteristics have been replaced by a pseudonym so that the data subject cannot be directly identified without separately stored additional information. Re-identification is only possible with this additional information.

Research Database: NAKO's central database for long-term storage of all generally quality-assured data and files (e.g. medical device files, MRI images) as well as secondary data. The research database is operated by the Integration Centre and queried by TransferHub for data compilation.

Results Data: all personal data obtained in the context of Use of Data and from the analysis of Biosamples. These are variables derived from the Data Provided (e.g. categories, scores and indices).

Results Data from L3 projects: Results data is all information and derived variables obtained from Data and, where applicable, Biosamples within the scope of a Level 3 project and suitable for further evaluation. These include, for example, new variables generated from Data such as categories, scores and indices, as well as analytes, markers, etc. measured from Biosamples.

Study Database: NAKO's central database for primary data collection. The data is initially raw data, which is quality-assured where possible and transferred to the research database before being used by NAKO. The study database is operated by NAKO's Integration Centre.

Transfer Unit (role in the use procedure): the body responsible for the entire process of providing Data and Biosamples for scientific evaluation. It coordinates procedures, monitors compliance with deadlines for use, reports, publication notifications, and operates the application management system. Contact for scientists and general enquiries: transfer@nako.de.

Tumour Tissue Bank (role in the use procedure): the NAKO tissue bank, which is affiliated with the National Centre for Tumour Diseases (NCT) in Heidelberg. This offers centralised, quality-assured storage and processing of tissue samples from participants with relevant tumour diseases, which are transferred from pathology departments throughout Germany to the NAKO tumour tissue bank in Heidelberg, where they are stored centrally.

Use and Access Committee (UAC) (role in the use procedure): a committee established to assist the Board of Directors in reviewing applications for the transfer of Data and Biosamples (see UAC Rules of Procedure).

Use of Biosamples: the transfer, storage, processing, pooling and scientific analysis of Biosamples in accordance with the Agreement for Use/Access.

Use of data: any inspection or processing, in particular the statistical evaluation, of personal Data of the German National Cohort (NAKO) for scientific projects, publications, lectures or for preparation of further statistical evaluations in accordance with an Agreement for Use/Access.

Use/Access Agreement: Document regulating all essential points relating to the Use of Data and, where applicable, Biosamples. The conclusion of a Use/Access Agreement is a prerequisite for the start of a Use/Access Project.

Use/Access Application: Formal application describing the planned scientific Use of NAKO Data and Biosamples. It includes information on the research objectives, the planned methods and the scientific justification for the Use of Data and Biosamples. An application must be submitted via the application portal and, once approved, becomes part of the Use/Access Agreement.

User (role in the use procedure): a legal person who is involved in the Use/Access Project and becomes a Contractual Partner of the NAKO e. V. by legally entering into the Use/Access Agreement (e.g. a university institution as a body with legal capacity for a legally dependent institution or another dependent scientific institution).

Work Results: All non-personal results (whether protectable by intellectual property rights or not), including reports and documents, methods and/or procedures created on the basis of the Data and, where applicable, Biosamples provided for Use (e.g. data, findings on substances and organisms, know-how, inventions, copyright-protected results, software).