An EU-Canada joint infrastructure
for next-generation multi-Study Heart research

Deliverable 1.3

Comparative cross-mapping table detailing which participating cohorts are compliant with euCanSHare requirements

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Retrospective Cohorts Assessment Report

(Report on the interoperability assessment, November 2020)

Executive Summary

The Centre of Genomics and Policy has provided a holistic review of the consent materials, governance documentation, and data use permissions of 31 participating euCanSHare cohorts. The data use permissions inherent in the cohorts have been compared and principal barriers to ethico-legal interoperability have been identified. For each cohort, a standardized representation of the applicable ethico-legal permissions has been produced, both in a standardized ADA-M form and in a more traditional textual summary.

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1. Main Conclusions of Report

1. Context, Objectives and Steps of ADA-M Tables

The euCanSHare project aims to create a centralized, secure, and easy-to-use integrated platform for enhanced data sharing and analytics in cardiovascular research. The platform will provide a simple user interface for researchers and cohorts to facilitate the procedure of granting and managing credentials. To do so, the euCanSHare project will assess the use of blockchain technology and smart contracts to automate the assignment of credentials for access to research data**.** The ultimate aim of the euCanSHare project is to promote scientific discovery by facilitating researchers' access to data. Within this larger effort, the Centre of Genomics and Policy at McGill has been tasked with creating standardized profiles describing the access permissions inherent to each dataset.

To the above ends, euCanSHare called on Canadian and European research cohorts to pilot the approach. Approximately 32 cohorts are expected to be integrated to the platform (see the list in section 3 of this document). An assessment of existing cohorts (retrospective assessment) has been performed. This assessment has performed an analysis of the cohort consent forms, governance documents, and data access practices of each cohort. Further dialogue has been initiated with the Primary Investigators of each cohort to further refine and confirm the use conditions applicable to the data. The output of this assessment consists of standardized representations of the ethico-legal permissions and access conditions inherent in each cohort's data.

This retrospective cohort assessment has been completed using the Global Alliance for Genomics and Health (GA4GH) and International Rare Disease Research Consortium (IRDiRC) Automatable Discovery and Access Matrix (ADA-M). ADA-M provides a standardized way to represent consent and other conditions of use applicable to a given dataset, making such information unambiguous, computer-readable, and hence eventually available for digital communication, searching, and automation activities. The ADA-M serves as a checklist that allows existing regulatory information to be clearly and consistently portrayed, and/or searched and discovered. Such a mechanism can constitute the basis for increasingly automated data access procedures.

Research cohorts, which were not designed for and consented in a harmonized fashion, may be subject to differing conditions or limitations related to data discovery, access, or use. A rigorous analysis of consent materials and, where applicable, other cohort-related policy documents has been undertaken to identify and attribute any use conditions and restrictions relating to such datasets.

2. General observations and outcomes

The Centre of Genomics and Policy (CGP, McGill University) was tasked with creating the ADA-M profiles. As of now, we have received documents and information from **31 of the 32 cohorts** expected to participate in the euCanSHare project. In some instances, the consent materials are not available, or access to the data proceeds on an ethico-legal basis other than individual consent. This has been noted.

The ADA-M profiles have been integrated to the euCanSHare cohort browser and are thus available to researchers prior to requesting access to the data.

3. Preliminary observations

The documents provided to us by some of the cohorts are pictures of untranslated documents (in several languages), which we have not always been able to translate accurately. Due to the unofficial nature of the translations effected, our interpretation of the consent materials and governance policy documents may not always be entirely accurate.

Some cohorts (e.g. *SHIP*, *FINRISK*, and *NSHDS*) have different phases of data collection, which can create challenges in ensuring future interoperability, and ensuring that the conditions for permissive data reuse are consistent even within each cohort (ADA-M). First, we did not systematically receive the consent documents for all the different investigation periods. Second, the consent forms that we did receive are not always labelled with the relevant period of investigation. Cohort PIs have been contacted and have participated in ensuring that the standardized ADA-M profiles reflect the permissions inherent in each cohort. If the collection phases of a single cohort or multi-cohort study differ in their consent practices and data management practices, the data may be difficult to reuse interoperably.

In addition, some cohorts use different data access tiers, provide multiple consent options to research participants, or vary the conditions of data use or access across multiple instances of data collection. This makes it difficult to create an ADA-M profile with a single set of controls, requirements, and limitations common to all the datasets in that cohort. Instead, different ADA-M profiles have sometimes been produced for one same cohort.

Finally, for some cohorts the geographical or jurisdictional boundaries within which the data may be used are ambiguous or variable (e.g. *PRIME*, *NSHDS, KORA, ESTHER)*. For some cohorts, the permissible use conditions are vague or are subject to discretionary human interpretation on a contextual basis (e.g. *FINRISK*, *MATISS, Estonian Genome Project*). This has created challenges in creating standardized representations of the ethico-legal access conditions applicable to such cohorts. Coordination and dialogue with cohort PIs has nonetheless enabled us to create faithful representations of the ethico-legal permissions applicable to such cohorts.

4. Initial outcomes of the essential consent items for the use of data within euCanSHare

For each cohort identified, we assessed respective permissions for **(1) cardiovascular research, (2) international data sharing, and (3) access to cardiac imaging data for research purposes.**

Overall, many of the cohorts we assessed (e.g. *Barts Bioresource, UKBiobank, SHIP, FINRISK, Estonian Genome Project*) allow a broad range of research to be performed using the data. Based on our assessment, this would indicate that with appropriate ethics approvals, these cohorts would be interoperable once integrated to the euCanSHare platform. However, some other cohorts addressed, (e.g. *UKE Clinical Cohort Studies, HCHS*) have a more restrictive range of research permissions and do not allow data to be used for other purposes than those for which they were initially collected.

For some cohorts, international data sharing may either be prohibited (e.g. *MONICA Novosibirsk)* or permitted *(*e.g. *Barts Bioresource, UKBiobank, HCHS*). Certain cohorts allow international data sharing subject to highly unique conditions, such as direct research collaboration with the host university of medical institution (e.g. *SHIP*). Certain cohorts use highly unique approvals mechanisms that are discretionary or subject to the consideration of highly subjective criteria that can be difficult to automate or to translate into uniform profiles (e.g. *StenoCardia, UKE Clinical Cohort Studies*).

Furthermore, in some cases, access to cardiac imaging data for research purposes is permitted (e.g. *UKBiobank, SHIP, HCHS*). In other cases, cardiac imaging data was not collected at all (e.g. *FINRISK, Estonian Genome Project, Prospective Study of Myocardial Infarction*).

Finally, for some cohorts, data storage limitations may prevent the centralization of the data by researchers in a single platform or the direct release of the data to third parties. Federated approaches to data storage, where data and biological materials remain in separate locations and are accessed remotely, may be most appropriate to performing secondary research using such cohorts' datasets.

5. Cohorts

Cohorts	Documents received (Y/N/C)	ADA-M profile completed (Y/N/P)
Hamburg City Health Study (HCHS)	Yes	Yes
UKE Clinical Cohort Studies	Yes	Yes
Study of Health in Pomerania (SHIP)	Yes	Yes
UK Biobank	Yes	Yes
Barts BioResource	Yes	Yes
Alpha-Tocopherol Beta-Carotene Prevention	Yes	Yes
Estonian Genome Centre University of Tartu	Yes	Yes
The National FINRISK Study (FINRISK)	Yes	Yes
Glostrup Study / DAN-Monica	No	No
Kooperative Region Augsburg (KORA)	Yes	Yes
Moli-Sani Project	Yes	Yes
MONICA Brianza	Yes (Conditions accessed)	Yes
MONICA Catalonia	No	No
MONICA Rome	No (Under development)	No (Under development)
MONICA Friuli	Yes (Conditions accessed)	Yes
MONICA Kaunas	Yes	Yes
MONICA Northern Sweden Health and Disease Study (NSHDS)	Yes	Yes
MONICA Newcastle	No (RC destroyed)	No (RC destroyed)
MONICA Novosibirsk	Yes	No (under development)
MONICA Warsaw	No (RC unavailable)	No (RC unavailable)
Prospective Study of Myocardial Infarction (PRIME)	Yes	Yes
The Tromso Study	Yes	No (under development)
AtheroGene	Yes	Yes
StenoCardia	Yes	Yes
Malattie Aterosclerotiche Istituto Superiore di Sanita (MATISS)	Yes	Yes
Epidemiological Study on the Chances of Prevention, Early Detection and Optimized Therapy of Chronic Diseases in the Elderly Population (ESTHER)	Yes	Yes

PAMELA Arterial Pressure Study	No (No RC materials exist)	No (No RC materials exist)
CAHHM British Columbia Generations Projects	Yes	Yes
CAHHM Alberta's Tomorrow Project	Yes	Yes
CAHHM Ontario's Health Study	Yes	Yes
CAHHM CARTaGene	Yes	Yes
CAHHM Atlantic Partnership for Tomorrow's Health	Yes	Yes

Note: "RC" refers to the research consent documentation used in obtaining and documenting the informed consent of the research participants.

2. euCanSHare – Retrospective Cohorts Assessment Tables

1. Retrospective Cohort Assessment General Table

Goal: The euCanSHare project aims to create a **centralized, secure, and easy-to-use integrated platform** for enhanced data sharing and analytics in cardiovascular research. The platform will provide a simple user interface for researchers and cohorts to **facilitate the procedure of granting and managing credentials. To do so, the broader euCanSHare project is investigating the possibility of automated credentials assignment using blockchain technology and smart contracts. At McGill, we compared the permissions and restrictions applicable to the datasets of the project cohorts. We have prepared standardized ADA-M profiles describing these permissions and restrictions, so that the pilot blockchain platform can efficiently integrate them.**

	Principal Consent Items relevant to the interoperability of data within euCanSHare		
Retrospective Cohorts	**Does the cohort allow cardiovascular disease research?**	**Does the cohort allow international data sharing?**	**Does the cohort allow access to cardiac imaging data for research purposes?**
Alpha-Tocopherol Beta-Carotene Prevention (ATBC) Study			N/A (not collected)
AtheroGene			N/A (not collected)
Barts Bioresource			
CAHHM (Alberta's Tomorrow Project)			
CAHHM (Atlantic Alliance)			
CAHHM (CARTaGENE)			
CAHHM (British Columbia Generations Project)			
CAHHM (Ontario Health Study)			N/A (not collected)
Epidemiological Study on Chances of Prevention, Early Detection, and Optimized Therapy of Chronic Diseases in the Elderly Population (ESTHER)			
Estonian Genome Project (EGP)			N/A (not collected)
FINRISK*			N/A (not collected)
Hamburg City Health Study (HCHS)			
Kooperative Region Augsburg (KORA)			N/A (not collected)
Malattie Aterosclerotiche Istituto Superiore di Sanità (MATISS)			N/A (not collected)
MOLI-SANI Study			N/A (not collected)
MONICA Brianza			N/A (not collected)
MONICA Friuli and Friuli Studio Emostatico			N/A (not collected)
MONICA Kaunas			N/A (not collected)
MONICA Novosibirsk			N/A (not collected)
Northern Sweden Health and Disease Study (NSHDS)*			

Prospective Study of Myocardial Infarction (PRIME and PRIME COG)			N/A (not collected)
Study of Health in Pomerania (SHIP)			
StenoCardia			
UK Biobank			
UKE Clinical Cohort Studies (CCS)			
MONICA Warsaw†			
Newcastle MONICA Collaborating Centre (MCC)†			
PAMELA Arterial Pressure Study†			

† The consent materials for this study, except data and limited other materials are lost or otherwise unavailable.

	Consent language presents restrictions
	Consent language is ambiguous or unclear
	Consent language appears to meet this requirement, with qualifications
	Consent language appears to meet this requirement.
	It cannot be assessed due to a lack of documents and/or the absence of such information in the documents provided.

2. Retrospective Cohort Assessment Interoperability Analysis

Goal: The euCanSHare project aims to create a **centralized, secure, and easy-to-use integrated platform** for enhanced data sharing and analytics in cardiovascular research. The platform will provide a simple user interface for researchers and cohorts to **facilitate the procedure of granting and managing credentials. To do so, the broader euCanSHare project is investigating the possibility of automated credentials assignment using blockchain technology and smart contracts. At McGill, we have drafted a listed of potential consent elements and permissions management practices that can affect the interoperability of data and facilitate or preclude the centralization and automation of permissions management.**

The consent materials and data management practices of participating euCanSHare cohorts are compared with reference to such criteria.

The elements assessed are the following:

1. **Geographic or jurisdictional restrictions on data sharing**
2. **Restrictions on use based on categories of entities (hospitals, universities, etc.) or sector of activities (commercial, non-commercial)**
3. **Data reuse restricted to specific categories of research**
4. **Requirements to use data in direct collaboration with the institution having collected or provided the data**
5. **Different data permissions across each instance of collection**
6. **Different data permissions dependent on the consent choices of individual research participants**
7. **Requirement that the institution having collected or provided the data, or other specified institution, perform scientific, ethical approvals process, or data management directly**
8. **Data is collected and managed without the use of formal research consent materials**
9. **Data permissions are granted based on discretionary criteria that are difficult to automate**
10. **Limitations on participant recontact**
11. **Limitations on data linkage**

	Data governance practices forbid this activity or impose conditions that could act as significant barrier to data sharing.
	Data governance practices present such restriction
	Data governance practices silent to this issue
	Data governance practices impose limited restrictions or requirements
	Data governance practices do not present such restriction
	It cannot be assessed due to a lack of documents and/or the absence of such information in the documents provided.

Comparative Interoperability	Geographic or jurisdictional restrictions on data sharing	Entity-specific or sector-specific limitations	Collaboration requirements	Reuse restricted to specific categories of research	Different data permissions within cohort records based on participant choices	Specified institution performs permissions management	Consent material not available	Discretionary permissions management criteria	Limitations on participant recontact (for future research participation).	Limitations on data linkage
Alpha-Tocopherol, Beta-Carotene (ATBC) Cancer Prevention Study										
AtheroGene										
Barts Bioresource										
Canadian Alliance for Healthy Hearts and Minds (CAHHM) †										
Epidemiological Study on Chances of Prevention, Early Detection, and Optimized Therapy of Chronic Diseases in the Elderly Population (ESTHER)										
Estonian Genome Project (EGP)										
FINRISK										
Hamburg City Health Study (HCHS)										
Kooperative Region Augsburg (KORA)										
Malattie Aterosclerotiche Istituto Superiore di Sanità (MATISS)										
MOLI-SANI Study										
MONICA Brianza										
MONICA Friuli										
MONICA Kaunas										
MONICA Novosibirsk										
Northern Sweden Health and Disease Study (NSHDS) MONICA 1990, 1994, 1999										
Northern Sweden Health and Disease Study (NSHDS) MONICA 2004, 2009										
Northern Sweden Health and Disease Study (NSHDS) MONICA 2014										
Prospective Study of Myocardial Infarction										

(PRIME and PRIME COG)										
Study of Health in Pomerania (SHIP)										
StenoCardia										
UK Biobank										
UKE Clinical Cohort Studies (Clinical Data)										
UKE Clinical Cohort Studies (Genetic Data)										
MONICA Warsaw										
Newcastle MONICA Collaborating Centre (MCC)										
PAMELA Arterial Pressure Study										

† This cohort description comprises the following CAHHM collection waves: CAHHM (Alberta's Tomorrow Project), CAHHM (Atlantic Alliance), CAHHM (CARTaGENE), CAHHM (British Columbia Generations Project), CAHHM (Ontario Health Study).

The color scheme was established as follows.

Green generally means that the cohort's ADA-M profile explicitly states that no such restriction is applicable. In a subset of cases, a green description has been used if the ADA-M profile is silent to the issue, but the context implies that a lack of restriction can be presumed.

Orange generally means that the cohort's ADA-M profile explicitly asserts that restrictions of the described category are applicable to the dataset, but the textual description associated with the restriction establishes that such restriction is not a significant impediment to data sharing.

Yellow generally means the cohort's ADA-M profile is silent to the presence or absence of the concerned restriction.

Red generally means that the cohort's ADA-M profile imposes a strong restriction of the category described, and that the restriction can be considered an impediment to the centralization of the data, or to the free movement thereof.

Black generally means that the cohort's ADA-M profile categorically forbids the concerned activity, or that the concerned restriction is present and sufficiently strong to preclude most or all data sharing.

Grey means that it is impossible to know what the concerned restrictions are in the dataset, as the consent materials or other documents required to assess the issue are unavailable or are insufficiently detailed to provide the requisite information.

3. Ethico-Legal Data Use Condition Summaries

This section contains textual summaries of the ethico-legal data use permissions applicable to each listed euCanSHare cohort. The data use conditions described below reflect the permissions incorporated to the more technical ADA-M profiles. The Principal Investigators of each cohort have been granted the opportunity to consult and incorporate changes to the summary descriptions provided below, as well as to the ADA-M profiles themselves.

Name of the project	**Alpha-Tocopherol, Beta-Carotene Cancer Prevention (ATBC) Study**
Principal Investigator(s)	Satu Männistö (Finnish part); Demetrius Albanes (USA part)
Institution(s)/Sponsor(s)/Funder(s)	THL-Finnish Institute for Health and Welfare, Finland NCI-National Cancer Institute, USA Funders: THL and NCI from the 1980s to 2015
Study duration	1985-
Data conservation	THL Biobank
Data/Samples storage location	THL Biobank
Documents reviewed	Alpha-Tocopherol, Beta-Carotene Cancer Prevention (ATBC) Study Informed Consent Materials (setti_saate "ATBC_cover letter" and setti_suostumus "ATBC_consent")
Notes	
Profile Summary – Informed Consent Form	Data withdrawal: Withdrawal is possible without any further obligations. Data linkage: Data linkage at source to data from registries and hospitals where information is collected during the study. Data linkage requires the permission of registries. Other researcher obligations: Researchers are bound by absolute confidentiality. All information in the study is treated anonymously.

Name of the project	**AtheroGene**
Principal Investigator(s)	
Institution(s)/Sponsor(s)/Funder(s)	
Study duration	
Data conservation	
Data/Samples storage location	
Documents reviewed	AtheroGene Informed Consent Materials.
Notes	
Profile Summary – Informed Consent Form	**Data use conditions:**

	The data and biomaterial collected will be evaluated anonymously for scientific purposes Data can be accessed or transferred only once a submitted proposal is approved by the steering committee Data can be used for research and non-research purposes (i.e. clinical care, teaching purposes only once a submitted proposal is approved by the steering committee External researchers and other external data users can only use the AtheroGene data in collaboration with the AtheroGene Principal Investigators. **Research Participant Withdrawal:** Participation in this study is voluntary. Participants may revoke their consent at any time without giving information about the reasons, without this having a detrimental effect on the continuation of treatment. **Other Data Use Conditions:** Full compliance with federal data protection law will be ensured.

Name of the project	**Barts BioResource**
Principal Investigator(s)	
Institution(s)/Sponsor(s)/Funder(s)	William Harvey Research Institute
Study duration	Pilot phase: approximately 3 months. Extended Study: indefinitely with long-term follow-up via NHS Registries.
Data conservation	Data are stored for a period of up to 25 years. Biological samples are stored for a period of up to 10 years.
Data/Samples storage location	
Documents reviewed	• Data Protection Impact Assessment (DPIA) – Version 26 March 2019; • Barts BioResource Protocol – Version 9 1 – Final (2)7; • Patient Information Sheet (PIS) – Registry/Data and related Consent Form – Version 9 1 11-May-2017; • Patient Information Sheet (PIS) – Registry and biological sample(s) donation (Blood/Saliva/Urine) and related Consent Form – Version 9 1 11-May-2017; and

	• Patient Information Sheet (PIS) – Registry and sample(s) donation (Blood/saliva/urine and/or cardiovascular tissue sample) and related Consent Form – Version 9 1 11-May-2017.
Notes and additional documents required	• The Barts BioResource uses a controlled-access process, but also allows public access to some data. **Controlled-access:** - Available information and materials: anonymised medical information, including genetic information, as well as blood and tissues samples - Eligible purposes: research into diseases of the heart and circulation **Public access:** - Available information and materials: medical images and other medical data (with all personal details removed) - Eligible purposes: research, teaching, and education / research, teaching, and education of cardiovascular disease
Profile Summary	• Barts Bioresource data has three tiers of permissions. One for controlled access data, one for biological samples, and one for de-identified public access data. Unless otherwise stipulated, the limitations applicable to the use of controlled access data also apply to the use of biological samples. Controlled access data: • The use of samples and controlled access data is limited to universities, research institutes, commercial organizations or hospitals for research related to diseases of the heart and circulation. Such use can be for commercial or non-commercial purposes. • Access is governed by a formal approval procedure, and subject to a Material Transfer Agreement (MTA). • Granting researchers remote data access is the first choice if possible. If this is not possible, then data transfer should still be possible. • Direct clinical system access is not allowed to external researchers, only members of the core Barts BioResource research team as part of data curation

	that cannot be done outside clinical systems. • Data can be held for up to 25 years. If access to Barts BioResource data is withdrawn, data must be destroyed or made de-identified and inaccessible. • There is an obligation to return research results to the Barts BioResource for integration thereto. • Research publications must provide attribution to Barts BioResource. Research publications cannot contain identifiable participant data. • Barts BioResource must initiate recontact for future research participation. Biological samples: • Can be used in animal research. Cannot be used for research that involves reproductive cloning. Cannot be used for cloning experimentation. • Cannot be used for medical treatment of third parties. • Cannot be sold for commercial gain. • Biological samples will be held for 10 years, after which a decision will be made to keep the remaining samples or dispose of them. Public access data: • Research, education, teaching purposes. • Research, education, or teaching of cardiovascular disease.
Name of the project	**Canadian Alliance for Health Hearts and Minds**
Principal Investigator(s)	Sonia S Anand, Matthias Friedrich and Douglas Lee
Institution(s)/Sponsor(s)/Funder(s)	**Canadian Alliance for Healthy Hearts and Minds (CAHHM)**
Study duration	
Data conservation	
Data/Samples storage location	
Documents reviewed	**For all cohorts:** CANPATH Access Policy CANPATH Intellectual Property Policy CANPATH Publications Policy **Ontario Health Study Cohorts:** uOttawa Participant Informed Consent form – Alliance ICF v2: August 15, 2016 (EN) uOttawa Participant Informed Consent form – Alliance ICF v3: September 21, 2016 (EN) uOttawa Participant Informed Consent form – Alliance ICF v3: September 21, 2016 (FR)

	William Osler Health System Alliance-OHS Consent – General; Final 1.3: August 10, 2016 McMaster University Informed Consent to Participate in a Research Study Version 03 September 26, 2016 Western University Canada Consent to Participate in a Research Study ALLIANCE Version: July 15, 2015 Sunnybrook Health Sciences Centre Informed Consent to Participate in a Research Study Informed Consent Form Version 02 13 June 2014 St. Michaels Healthy Hearts and Minds Alliance (Canadian Alliance for Healthy Hearts and Minds) Main Consent Form, Version 13, October 7, 2016 **CARTAGENE Cohort:** Information and Consent Form no 2 for CAG-MRI Short v.23 29 Feb 2016 EN (incl. ICF no 3 addenda CAG-MRI Long 29 Feb 2016) Information and Consent Form no 2 for CAG-MRI Short v.23 29 Feb 2016 FR (incl. ICF no 3 addenda CAG-MRI Long 29 Feb 2016) Information and Consent Form no 1 for CAG-MRI Short v.23 29 Feb 2016 EN Information and Consent Form no 1 for CAG-MRI Short v.23 29 Feb 2016 FR **Atlantic Path Cohort:** Atlantic Path – Alliance – Consent to Take Part in a Research Study and Participant Information Form Version 3 2015/09/08 **British Columbia Generation Project:** Canadian Alliance for Healthy Hearts and Minds – Alliance BCGP Informed Consent Version Number 3.8 August 30th, 2016 **Alberta's Tomorrow Project:** University of Calgary – Alliance – Information and Consent Form September 20, 2016 Version 4.0
Notes	The Canadian Alliance for Healthy Hearts and Minds is in the process of finalizing a common data access procedure for all participants from the multiple cohorts and newly recruited participants through one common process that will be coordinated with CANPATH.
Profile Summary	The following conditions apply to the use of Alliance data generally:

	Geographic restrictions: National and international use. **Organisational requirements:** Public and private institutions that conduct scientific research can use the data. Use by law enforcement bodies or governmental agencies for purposes other than research projects aligned with CANPATH guiding principles is prohibited. **Application requirements:** Data access will be monitored and controlled by the CANPATH Data Access Oversight Committee (all CANPATH cohorts) and / or Ontario Health Study Access Committee (Ontario cohorts). In addition, other participating cohort (PURE and MHI Biobank) will oversee access to data from their participants in Alliance. Must provide approved research protocol (having received ethics approval), proof of scientific peer-review of research protocol (if applicable), approval by a Research Ethics Board, and 2-page CV of principal applicant. Must provide data and material access application form, and access renewal form where relevant. **Publication requirements:** Lay summaries of all approved projects will be published in the online registry. Results must be published in peer-reviewed publications. Cannot reidentify individuals or groups in publication. Attribution of Alliance, the participating cohorts and active contributors is required, and CANPATH should be informed of substantive changes to manuscripts. All publications and abstracts should be submitted to the Access Office at the same time as submission for publication to the journal or to a conference. Copy of final publication must be sent to the Access Office. **Access duration:** Limited to the period of time set out in the access agreement **Security requirements:** Must follow security practices and procedures in the access application form **Data destruction requirements:** Data must (generally) be destroyed.

	Intellectual property requirements: No IP claims on data are permitted, but IP claims can be made on subsequent innovations and downstream discoveries. Compliance with the OECD Guidelines for the licensing of genetic inventions is recommended. **Return of derived data:** Requirement to return derived data to CANPATH, which will be provided to researchers. **Requirements to report back regarding the use of accessed resources:** Annual progress report, final research report, unanticipated change report, and destruction report must be provided. **Collaboration requirements:** Co-authorship must be offered to one or more members of each of the cohorts whose data and/or samples are used and also potentially to CANPATH members. All co-authors must satisfy the ICMJE criteria. **Other requirements:** Compliance with the guiding principles of CANPATH is required. Research projects will be approved if scientifically sound, adequate resources exist to complete the research project, the need for the data is justified, and based on the value of the returned data, justification of the need for data and/or biosamples, the value of the returned data, and the scientific contribution of the research project.

	Esther
Principal Investigator(s)	Herman Brenner / Ben Schottker
Institution(s)/Sponsor(s)/Funder(s)	German Centre for Research on Ageing in Heidelberg
Study duration	
Data conservation	Unlimited period of time
Data/Samples storage location	
Documents reviewed	• Consent form
Notes	
Profile Summary	• Relates to anonymous samples, data, and questionnaire data. Data and sample permissions: • Commercial use is forbidden. • The stored samples may solely be used for scientific research into risk markers, and risk factors of chronic diseases (including genetic factors associated with the development and

	course of chronic diseases, such as cardiovascular diseases or cancer). Data linkage and recontact: • Recontact of participants by original project staff may occur for up to 21 years. • Information from the Saarland Cancer Registry may also be used for research into cancer and information on new diseases may be obtained from participants' attending physicians. Publication requirements: • Data must be published in anonymous form. Withdrawal: • Participants may withdraw and ask for the destruction of all data collected, and the destruction of their transferred materials and the laboratory results determined therefrom.

Name of the project	**Estonian Genome Project**
Principal Investigator(s)	
Institution(s)/Sponsor(s)/Funder(s)	University of Tartu
Study duration	
Data conservation	
Data/Samples storage location	
Documents reviewed	• Gene Donor Consent Form 2001; • Gene Donor Consent Form 2007; • Gene Donor Consent Form 2019; and • Authorization for storage and examination of tissue samples outside Estonia.
Notes	
Profile Summary	Three different sub-cohorts exist, with different associated permissions. An ADA-M profile tab has been created for each. The three tiers are datasets / samples associated with the 2001 consent materials; datasets / samples associated with the 2007 consent materials, and datasets / samples associated with the 2019 consent materials. 2001 Data / samples concerned: • Coded (anonymous) tissue samples, descriptions of state of health, descriptions of DNA Permissions: • Entities that can receive data include, but are not limited to, research and development institutions and commercial enterprises. The following research purposes are permissible (one or more must apply):

	• Genetic research, public health research, and statistical or other purposes in accordance with the law • Scientific and applied gene and health research to determine genes that influence disease. Research carried out with the help of the gene bank shall not be limited to the present scientific level. Limitations: • No one has the right to access the participant's data stored in the gene bank unless the data have been coded (anonymized). The chief processor of the Gene Bank may give out tissue samples, descriptions of DNA, and descriptions of the state of health from the Gene Bank only in coded form so that the identity of the gene donor remains unknown to the receiver of the data. 2007 Data / samples concerned: • Data on the health and genes of participants, blood samples. Includes coded descriptions of participant state of health and genealogy. Permissions: • Entities that can receive data include, but are not limited to, research and development institutions, and commercial enterprises. These entities may receive data about pseudonymous donors. The following research purposes are permissible (one or more must apply): • Statistical purposes • Public health research • Scientific and applied gene and health research • Research to determine the genes that influence the development of diseases. Research carried out with the help of the Gene Bank shall not be limited to the present scientific level. • Genetic research. Recontact / return of results: • The subject has a right not to be aware of their genetic data, hereditary characteristics, and genetic risks obtained as a result of genetic research. Limitations: • No one has the right to access the participant's data stored in the gene bank unless the data have been coded (anonymized). The chief processor of the Gene Bank may give out tissue samples, descriptions

	of DNA, and descriptions of the state of health from the Gene Bank only in coded form so that the identity of the gene donor remains unknown to the receiver of the data. 2019: Data / samples concerned: • Pseudonymized blood samples, description of DNA, description of state of health, genealogy. Permissions: • Entities that can receive data include, but are not limited to, research and development institutions and commercial enterprises. These entities may receive data about pseudonymous gene donors. The following research purposes are permissible (one or more must apply): • Use for a statistical purpose. • Scientific research or public health research. • Genetic research. • Research of the diseases of the gene donor. • Treatment of the diseases of the gene donor (clinical). Recontact / return of results: • The subject has the right not to know the results of the genetic research. Limitations: • The controller of the Gene bank may give out tissue samples, descriptions of DNA and descriptions of the state of health from the Gene Bank for research and development only in pseudonymized format so that the identity of the gene donor remains unknown to the recipient of the data. • Use of the Gene Bank for collection of evidence or surveillance in civil or criminal cases is forbidden.

Name of the project	FINRISK (Part of the Morgam Cohorts)
Principal Investigator(s)	
Institution(s)/Sponsor(s)/Funder(s)	Finnish Institute for Health and Welfare
Study duration	Data and samples will be used for research that will span years and even decades.
Data conservation	Stored at the Finnish Institute for Health and Welfare permanently.
Data/Samples storage location	Finnish Institute for Health and Welfare
Documents reviewed	• Consent Form / Name of study: FINRISK 2007 - National Health Survey; • Consent Form / Name of study: FINRISK 2007 – Glucose and Fat Metabolism; and • Notice to Subject National FINRISK 2012 Health Study.
Notes	• The same consent permissions are intended to apply to all cohorts. • Cohorts 01-03 are FINRISK cohorts with baseline examinations in 1982, 1987 and 1992. They have been described in the MORGAM manual : https://www.thl.fi/publications/morgam/cohorts/full/finland/fin-fina.htm At that time it was not yet customary to collect written consents for observational studies but the law on THL enables the use of these data for research purposes • At the moment, the national permission processes of sharing research data are being centralized and standardized in Finland. principle, the data are available through the THL biobank https://thl.fi/en/web/thl-biobank and/or through the office of Findata https://thl.fi/en/web/thlfi-en/statistics/data-and-services/data-permit-authority-findata according to the instructions given in their websites.
Profile Summary	**FINRISK 2007 National Health Survey**: Content: Questionnaires, physical examinations, test results. Purposes: • Research into cardiovascular diseases, diseases of the brain, cancer, diabetes, asthma, allergy, as well as the heredity of their risk factors. Data linkage: • Information concerning participants' health can be later obtained from various officials and registries kept by health service institutions. **FINRISK 2007 - Glucose and Fat Metabolism Study:** Content: Questionnaires, physical examinations, test results. Purposes : must be used for one or more of the following:

	• May be used for research related to the prevalence of diabetes and its risk factors in the Finnish population today. • To gather new data about the influence of food, exercise, and other lifestyle choices, as well as oral health and heredity on glucose and fat metabolism, weight and body build, as well as the onset of diabetes and metabolic syndrome. • Data may be used to research and develop methods for prevention and treatment of the most significant Finnish public health problems. • Blood test data may also be used to determine other factors related to glucose and fat metabolism, appetite, sleep, rhythm, and blood clotting and inflammation. Data linkage: • Can be linked to and used with the data of the FINRISK 2007 study. **FINRISK 2012 – Health Study:** Questionnaires, physical examinations, interviews, measurements, test results, blood sample and urine sample analysis, DNA tests. Purposes: Must be used for one or more of the following: • Changes of cardiovascular and other major chronic diseases and their risk factors in Finland • Cardiovascular and other major chronic diseases and their risk factors in Finland • Chronic diseases and their risk factors • Risk factors related to chronic diseases, such as smoking, eating habits, and exercise habits Data linkage / geographic limitations: • The study is connected to a larger project, which collects and compares health information fulfilling scientific criteria from different countries across Europe.

Name of the project	**Hamburg City Health Study**
Principal Investigator(s)	
Institution(s)/Sponsor(s)/Funder(s)	Department for General and Interventional Cardiology
Study duration	
Data conservation	
Data/Samples storage location	
Documents reviewed	• Study Protocol – Version 03_201700 • Patient Information Sheet Version 01.10.2018
Notes	
Profile Summary	Entities: • Can be passed on to academic and industrial cooperation partners.

	• Cooperation partners include institutions and companies within and outside the European Economic Area. • A list of companies is provided online, and the external companies may change if necessary. • Passing on to third parties takes place exclusively for research purposes and is pseudonymized. Purposes: One or more of the following research purposes must be met: • For the clarification of causes, factors and course of disease in cardiovascular diseases, internal, neurological, psychological, musculoskeletal, eye, tooth and skin diseases as well as cancer. Access procedures: • Only study personnel can access pseudonymised study databases and biomaterial database of the University Medical Center Hamburg Eppendorf. • Access by academic and industrial cooperation partners within and outside the EEA is contingent on participants agreeing to a consent option separate from research consent. Security measures: • Study databases use secure access which is only possible for study personnel. All databases use secure access, which requires registration and password. Samples are stored at the University Medical Center Hamburg Eppendorf. • Data transferred to third parties will be pseudonymised a second time. Database controls: • Study database data is primarily restricted to data quality control and statistic group and can be transferred to cooperation partners only with the permission of the steering committee. • Quality controlled study database (QCSD) and analysis / statistical database access is primarily restricted to the members of the data quality control and statistic group and can be transferred to cooperation partners only with the permission of the steering committee. Only for specific variables that had been requested and granted beforehand • Access to the genetic database is primarily restricted to the quality control and the statistic group.

	• Access to the sample management database is primarily restricted to the lab staff. • Access to the individual-related database is restricted to the recruitment team only. And is not linked to any research /study data. Only the data trustee can link all data Publication: • Publication in any form will require a majority approval by the steering committee. The publication has to be sent for approval to the steering committee before submission. • Publications of scientific results from the study will not allow conclusions to be drawn about the persons involved. • Identifiable data will not be published. • Anonymized data will be published in peer-reviewed journals, book chapters, as part of theses, reviews, scientific journals. Participant withdrawal: • Upon withdrawal, if biomaterials have been sent to external cooperation partners, the respective cooperation partner will be requested immediately by mail to destroy all biomaterials from this person and to send back a written confirmation of the successful destruction thereof. • The anonymized study data will remain in the study and can be further analyzed. Recontact / Return of results • Participants will not receive analysis results from blood or urine samples. If a participant requests their data, the data needs to be sent. • Participants will not receive results from cooperation partners. • Participants indicate preferences for return of genetic results in four tiers: (1) If there is a direct and prophylactic therapy for the findings (2) If there is currently no treatment for the finding (3) If the finding is without individual medical consequence for the participant, and therefore only a statistical statement (4) If the finding is without individual medical consequence, but there may be diseases in descendants / family members Reporting obligations: • After processing the analyzed data, these have to be imported into the study data base.

Name of the project	Kooperative Region Augsburg (KORA)
Principal Investigator(s)	
Institution(s)/Sponsor(s)/Funder(s)	
Study duration	
Data conservation	
Data/Samples storage location	
Documents reviewed	• KORA Unlabeled Informed Consent Form • KORA Consent Form 1999-2001 • General Terms and Conditions for Usage of Data and Biosamples of the KORA StudiesVersion:2017/07/24
Notes	
Profile Summary KORA (Kooperative Region Augsburg) ICF Materials FV_EV (Unlabeled Informed Consent Form)	KORA (Kooperative Region Augsburg) ICF Materials FV_EV (Unlabeled Informed Consent Form) Data concerned: General interview about the state of health and current medication; self completion sheet; blood pressure measurement; oral glucose tolerance test; ECG; measurement of height and weight; blood collection to determine blood values in this study; ultrasound of the thyroid gland; ultrasound of the carotid artery; Ankle-Arm-Index Measurement ; skin examination; urine delivery ; saliva sample measure of endothelial dysfunction; pulmonary function examination; output of an ECG card to derive ecg by telephone ; blood and dna sample and test results. Data permissions: Use by organizations (Unrestricted): Industry, foundations, K6 bodies, and government agencies can be involved in the formulation of evaluation targets Use for non-profit purpose is obligatory. Use for research purposes is obligatory. Approval and access conditions: The data set to be analyzed and/or the biosamples shall be put together in accordance with the specifications set out in the project agreement. Publication requirements and conditions: The applicant undertakes to use the citation style described in the project agreement in all publications. Different citation styles must, in exceptional cases, be

	approved by the KORA steering committee. Any queries may be addressed to the responsible scientist of KORA. Prior to submission, the manuscript must be authorized by the responsible scientist of KORA. Any manuscripts resulting from the data set to be analysed or the biosamples must, upon request and prior to submission, be shown to the KORA steering commitee. Furthermore, following publication, a printed or electronic version (PDF file) containing the application number (PV No.) must be sent to KORA or KORA-gen coordination unit. Timing and timeline restrictions: HMGU shall, during the set term of the Agreement, grant the applicant an exclusive right of use of the data for the purpose specified in the Agreement. The term is generally two years and can, upon request, be extended no more than twice, by one year respectively. After expiry of the right of use, the KORA steering committee shall consider the merits of the project. If there has been insufficient progress, the data made available to the applicant may be released within KORA and be passed on to other scientists by the KORA or KORA-gen coordination unit. For biosamples: Any unused biosamples must be returned to HMGU within three months of study completion but no later than upon expiry of the right of use. In any case, the biosamples must only be used for the research and test purposes agreed. Data security requirements: The dataset to be analysed will be handed over in pseudonymised form. The biosamples too are pseudonmyised. The applicant undertakes to refrain from any attempt at re-identification and to inform HGMU immediately if re-identification still is or might be possible. The dataset to be analysed shall be secured and archived at HGMU for at least 10 years. Data sets and analysis programs must be archived for at least ten years after publication of the results. To this end, the applicant undertakes to archive the data and analysis programs that have been used to produce the publication. Upon request, a copy of the program code must be sent to the KORA or KORA-gen coordination unit. Data withdrawal:

	There is a continuing right for participants to withdraw their consent in whole or in part, at any time and without reasons given. Data linkage: Linkage at source can be performed for required information from medical records regarding cardiovascular disease and used in anonymous form. Return of primary research results, return of material incidental findings, and recontact: Return of health-relevant primary research results and incidental findings may be performed by original research team. Recontact for participation in a future KORA study may be performed by original research team. Intellectual property and ownership: All rights, in particular ownership rights and industrial protection rights in the data of the datasets to be analysed and/or the biosamples shall remain vested in the respective data owners and/or owners of the biosamples according to the valid KORA coordination contracts. The applicant shall not apply for any property rights and, in particular, any patents for the KORA data, the biosamples or any other information or results obtained on the basis of the data or biosamples without the prior written consent of HMGU. Any invention resulting from the provision of the data and/or biosamples must immediately be reported to KORA. The parties involved shall jointly agree to determine the respective inventor's shares by duly taking into account the contribution made by providing the data and/or biosamples concerning the invention. All other decisions, in particular the registration or exploitation of a patent, shall be made after the inventor's shares have been determined. The applicant shall grant KORA and the respective data owners or the owners of the biosamples a free right of use for research, teaching, and non-commercial purposes. For biosamples: The biosamples are and shall remain, without exception and for an unlimited period of time, the property of HMGU. Reporting requirements: The applicant undertakes to inform the data owner of any potential errors noted by him in the data passed on to him or obtained from the biosamples or of any

	changes to the values e.g. through the setting of the detection limit or through imputation. The applicant undertakes to inform HMGU of any transformed variables that could be used for further analyses and, upon request, hand them over together with the respective documentation. For biosamples: The biosamples and the DNA shall be handed over to the laboratory or the genotyping centre specified in the project application. They shall undertake the analyses in the name and on account of the applicant. The applicant shall inform the participating scientists of HMGU of the results of all analyses performed and transfer all genotypes, laboratory parameters, and other data produced on the basis of the provided biosamples directly to the KORA or KORA-gen coordination unit. Fees levied: KORA may charge fees to cover its expenses. As, depending on requirements, the costs can vary, the level of fee shall be determined individually following a consultation with the KORA or KORA-gen coordination unit. Other conditions of use: The applicant undertakes to use the data and/or biosamples made available to him exclusively for the purpose and publication specified in the project application. The data and/or biosamples must neither be passed on to third parties nor be entered in freely accessible databases or biobanks. The use of the data and/or biosamples for commercial purposes shall be excluded. If the data and/or biosamples are to be used for another purpose or publication, a new project agreement must be submitted.
Profile Summary KORA (Kooperative Region Augsburg) ICF Materials 1999-2001.	Data concerned: General survey on the state of health, early diseases, lifestyle, health insurance. Blood pressure measurement, EKG, background of the eye (ocular fundus image), measurement of height and weight as well as the percentage of fat in the body, dermatological examination of pigment marks, blood sample collection and DNA collection. Data permissions: Use by organizations (Unrestricted):

	Government agencies, foundations, corporations and industry can perform research and formulate study targets. Use for non-profit purpose is obligatory. Use for research purposes is obligatory. Unrestricted use for biomedical research: Future research on xenobiotic enzyme systems, genes involved in the development of asthma, diabetes, cardiovascular diseases, and further examinations. Use for genetic research: Genetic testing and analysis may be performed for research purposes only. Use for disease-related research [Limited]: Limited to research on the hereditary causes of disease. Approval and access conditions: Research must be acceded to by a relevant research ethics committee. The data set to be analyzed and/or the biosamples shall be put together in accordance with the specifications set out in the project agreement. Publication requirements and conditions: The applicant undertakes to use the citation style described in the project agreement in all publications. Different citation styles must, in exceptional cases, be approved by the KORA steering committee. Any queries may be addressed to the responsible scientist of KORA. Prior to submission, the manuscript must be authorized by the responsible scientist of KORA. Any manuscripts resulting from the data set to be analysed or the biosamples must, upon request and prior to submission, be shown to the KORA steering commitee. Furthermore, following publication, a printed or electronic version (PDF file) containing the application number (PV No.) must be sent to KORA or KORA-gen coordination unit. Timing and timeline restrictions:

	HMGU shall, during the set term of the Agreement, grant the applicant an exclusive right of use of the data for the purpose specified in the Agreement. The term is generally two years and can, upon request, be extended no more than twice, by one year respectively. After expiry of the right of use, the KORA steering committee shall consider the merits of the project. If there has been insufficient progress, the data made available to the applicant may be released within KORA and be passed on to other scientists by the KORA or KORA-gen coordination unit. For biosamples: Any unused biosamples must be returned to HMGU within three months of study completion but no later than upon expiry of the right of use. In any case, the biosamples must only be used for the research and test purposes agreed. Data security requirements: The dataset to be analysed will be handed over in pseudonymised form. The biosamples too are pseudonmyised. The applicant undertakes to refrain from any attempt at re-identification and to inform HGMU immediately if re-identification still is or might be possible. The dataset to be analysed shall be secured and archived at HGMU for at least 10 years. Data sets and analysis programs must be archived for at least ten years after publication of the results. To this end, the applicant undertakes to archive the data and analysis programs that have been used to produce the publication. Upon request, a copy of the program code must be sent to the KORA or KORA-gen coordination unit. Data withdrawal: There is a continuing right for participants to withdraw their consent in whole or in part, at any time and without reasons given. Return of primary research results, return of material incidental findings, and recontact: Return of health-relevant primary research results and incidental findings may be performed by original research team, if research participants agree. Recontact for participation in a future KORA study may be performed by original research team. Intellectual property and ownership:

	All rights, in particular ownership rights and industrial protection rights in the data of the datasets to be analysed and/or the biosamples shall remain vested in the respective data owners and/or owners of the biosamples according to the valid KORA coordination contracts. The applicant shall not apply for any property rights and, in particular, any patents for the KORA data, the biosamples or any other information or results obtained on the basis of the data or biosamples without the prior written consent of HMGU. Any invention resulting from the provision of the data and/or biosamples must immediately be reported to KORA. The parties involved shall jointly agree to determine the respective inventor's shares by duly taking into account the contribution made by providing the data and/or biosamples concerning the invention. All other decisions, in particular the registration or exploitation of a patent, shall be made after the inventor's shares have been determined. The applicant shall grant KORA and the respective data owners or the owners of the biosamples a free right of use for research, teaching, and non-commercial purposes. For biosamples: The biosamples are and shall remain, without exception and for an unlimited period of time, the property of HMGU. Reporting requirements: The applicant undertakes to inform the data owner of any potential errors noted by him in the data passed on to him or obtained from the biosamples or of any changes to the values e.g. through the setting of the detection limit or through imputation. The applicant undertakes to inform HMGU of any transformed variables that could be used for further analyses and, upon request, hand them over together with the respective documentation. For biosamples: The biosamples and the DNA shall be handed over to the laboratory or the genotyping centre specified in the project application. They shall undertake the analyses in the name and on account of the applicant. The applicant shall inform the participating scientists of HMGU of the results of all analyses performed and transfer all genotypes, laboratory parameters, and other data produced on the basis of the provided biosamples directly to the KORA or KORA-gen coordination unit. Fees levied: KORA may charge fees to cover its expenses. As, depending on requirements, the costs can vary, the level of fee shall be determined individually following

	a consultation with the KORA or KORA-gen coordination unit. Other conditions of use: The applicant undertakes to use the data and/or biosamples made available to him exclusively for the purpose and publication specified in the project application. The data and/or biosamples must neither be passed on to third parties nor be entered in freely accessible databases or biobanks. The use of the data and/or biosamples for commercial purposes shall be excluded. If the data and/or biosamples are to be used for another purpose or publication, a new project agreement must be submitted.

Name of the project	**MATISS-Malattie ATerosclerotiche Istituto Superiore di Sanità**
Principal Investigator(s)	Luigi Palmieri and Chiara Donfrancesco
Institution(s)/Sponsor(s)/Funder(s)	Istituto Superiore di Sanità, Rome, Italy
Study duration	Recruitment: 1983-1996. Follow-up: from baseline visit up to 31/12/2004
Data conservation	As much as data are in use for research purposes, and 10 years thereafter
Data/Samples storage location	Department of Cardiovascular, Endocrine-metabolic Diseases and Aging, Istituto Superiore di Sanità, Rome, Italy
Documents reviewed	Informed Consent Form
Notes	
Profile Summary – Informed Consent Form	**Data sharing must be subject to the following conditions:** Data and samples can be communicated and disseminated to coronary and cerebrovascular institutions, as well as public and non-public institutions interested in the problems of cardiovascular diseases and their risk factors **Data use must be subject to the following conditions:** Statistical and collective results can be stored in databases and used for anonymous analysis, for study research, and publication purposes Research on the distribution of risk factors for cardiovascular diseases and coronary and cerebrovascular events **Publications must be subject to the following conditions:**

	Data in publications must be anonymous

Name of the project	**MOLI-SANI Study**
Principal Investigator(s)	Licia Iacovelli
Institution(s)/Sponsor(s)/Funder(s)	
Study duration	
Data conservation	
Data/Samples storage location	
Documents reviewed	MOLI-SANI Informed Consent Materials (ICF and Information Booklet)
Notes	
Profile Summary	Secondary data use: Research on the biochemical, genetic, behavioral and environmental risk factors of cancer and heart disease. Use of data in for-profit research is forbidden. Location of data storage: The samples and data are held in the Biobank of the Catholic University of Campobasso, and in other centralized Biobanks. Data storage duration: Indefinite storage of samples and data. Data security measures: Storage of data on computer and magnetic media, in anonymous and aggregated form. Conditions of participant withdrawal: Participant may withdraw at any time and without providing a reason. Samples and data will be destroyed. Information already processed for research and certain aggregated information will be retained. Data linkage: Participant has the option to consent to present and future data linkage at source of medical records to study data. Participant recontact: Participant may choose to consent to recontact for return of tests performed as part of research, may choose to be recontacted to learn about the health-related results of future research, and may choose to be recontacted for research follow-up. Other considerations:

	Data use conditions may differ across datasets based on the expressed consent preferences in the consent materials.

Name of the project	**MONICA-Brianza**
Principal Investigator(s)	Prof. Marco M Ferrario, prof. Giancarlo Cesana (former PI)
Institution(s)/Sponsor(s)/Funder(s)	Institution: Research Center in Epidemiology and Preventive Medicine – EPIMED Dept. of Medicine and Surgery, University of Insubria, Varese, Italy Past funders: Health Administration of the Lombardia Region (grants no. 17155/2004 and 10800/2009). Italian Ministry of Health (grant 2012/597)
Study duration	Recruitment: 1986-1993. Follow-up: from baseline visit up to 31/12/2008
Data conservation	Research Center in Epidemiology and Preventive Medicine – EPIMED Dept. of Medicine and Surgery University of Insubria, Varese, Italy Duration of data conservation: as much as data are in use for research purposes, and 10 years thereafter.
Data/Samples storage location	Research Center in Epidemiology and Preventive Medicine – EPIMED Dept. of Medicine and Surgery University of Insubria, Varese, Italy
Documents reviewed	Informed Consent Form
Notes	
Profile Summary – Informed Consent Form	**Data sharing must be subject to the following conditions:** Data and samples can be communicated and disseminated to coronary and cerebrovascular institutions, as well as public and non-public institutions interested in the problems of cardiovascular diseases and their risk factors **Data use must be subject to the following conditions:** Statistical and collective results can be stored in databases and used for anonymous analysis, for study research, and publication purposes Research on the distribution of risk factors for cardiovascular diseases and coronary and cerebrovascular events **Publications must be subject to the following conditions:**

	Data in publications must be anonymous

Name of the project	MONICA-Friuli and Friuli Studio Emostatico
Principal Investigator(s)	Prof. Giovanni Veronesi, dr. Diego Vanuzzo (former PI)
Institution(s)/Sponsor(s)/Funder(s)	Institution: Centre for Cardiovascular Prevention ASUI Udine, Udine Past funders: regional grants
Study duration	Recruitment: 1986-1996. Follow-up: from baseline visit up to 31/12/1998
Data conservation	Research Center in Epidemiology and Preventive Medicine – EPIMED Dept. of Medicine and Surgery University of Insubria, Varese, Italy Duration of data conservation: as much as data are in use for research purposes, and 10 years thereafter.
Data/Samples storage location	Research Center in Epidemiology and Preventive Medicine – EPIMED Dept. of Medicine and Surgery University of Insubria, Varese, Italy
Documents reviewed	Informed Consent Form
Notes	
Profile Summary – Informed Consent Form	**Data sharing must be subject to the following conditions:** Data and samples can be communicated and disseminated to coronary and cerebrovascular institutions, as well as public and non-public institutions interested in the problems of cardiovascular diseases and their risk factors **Data use must be subject to the following conditions:** Statistical and collective results can be stored in databases and used for anonymous analysis, for study research, and publication purposes Research on the distribution of risk factors for cardiovascular diseases and coronary and cerebrovascular events **Publications must be subject to the following conditions:** Data in publications must be anonymous

Name of the project	MONICA Kaunas
Principal Investigator(s)	
Institution(s)/Sponsor(s)/Funder(s)	
Study duration	
Data conservation	
Data/Samples storage location	
Documents reviewed	MONICA Kaunas Informed Consent Materials
Notes	
Profile Summary –	**Data Permissions:** Secondary data use is forbidden. Data can only be used by researchers of the study. **Publication:** Personal data cannot be published (i.e. identifiable data). **Withdrawal:** Participants can withdraw and their data will be destroyed. **Data linkage:** Linkage by study researchers of participant's study data to participant's hospital records and GP records. **Recontact:** Participants can be recontacted. **Samples:** Blood sample stored and used in future research projects of chronic diseases, which may include studies of genetic markers
Name of the project	**MONICA NOVOSIBIRSK**
Principal Investigator(s)	Yuri Nikitin, Sofia Malyutina
Institution(s)/Sponsor(s)/Funder(s)	Research Institute of Internal and Preventive Medicine - Branch of the Federal Research Center Institute of Cytology and Genetics, the Siberian Branch of the Russian Academy of Sciences
Study duration	1885-1996
Data conservation	
Data/Samples storage location	Research Institute of Internal and Preventive Medicine - Branch of the Federal Research Center Institute of Cytology and Genetics, the Siberian Branch of the Russian Academy of Sciences, Novosibirsk, Russia
Documents reviewed	Eastern European Cardiovascular Determinants Program (Novosibirsk Cohort) Informed Consent of the Survey Participant on the Eastern European Cardiovascular Determinants Program:

	Multicentre Cohort Study
Notes	
Profile Summary – MONICA Novosibirsk	Data sharing and secondary data use: Individual-level data are shared in the frame of MONICA/MORGAM collaboration and further development. Individual level data, by default, will not be shared with external researchers. Aggregated data for secondary use might be shared and is a subject of agreeing with the centre. Individual level data sharing might be considered in separate exceptional cases. Permissible purposes for research use of data: To monitor the state of health of the people, study the main causes of heart diseases and their relation to lifestyle, social and hereditary factors. Publication of data: Personal data cannot be published (i.e. identifiable data). Participant withdrawal: Participants can withdraw and their data will be destroyed. Data linkage: Linkage by study researchers of participant's study data to participant's hospital records and GP records. Participant recontact: Participants can be recontacted.

Name of the project	**Northern Sweden Health and Disease Study (NSHDS) (Part of the Morgam Cohorts)**
Principal Investigator(s)	
Institution(s)/Sponsor(s)/Funder(s)	UMEA University – The Biobank Research Unit
Study duration	
Data conservation	
Data/Samples storage location	
Documents reviewed	• Consent Forms assemblage document: - Statement of Consent MONICA 1990 - Statement of Consent MONICA 1994 - Consent Statement MONICA 1999 - Consent Statement MONICA 2004 - Consent Statement MONICA 2009 - Consent Statement MONICA 2014
Notes	
Profile Summary MONICA Cohort(s)	**MONICA 1990, 1994, 1999 Blood Samples:** Purposes: • For future disease prevention research

	Access conditions: • Research Ethics Committee approval required Return of results: • Participants will not receive any personal information on the analysis result. **MONICA 2004, 2009 Coded Blood Samples and Coded, De-identified Personal Data:** Conditions (all the following conditions must be met) Location conditions: • Use within national limits is unrestricted. Use in cooperation with international research groups is permitted where requirements are set at the corresponding level of protection of personal data that applies in Swedish Legislation. Entity conditions • Use by national research groups specializing in the research areas for the study (i.e. cardiovascular, diseases, cancer, diabetes, hereditary causes of disease emergence). Research purpose conditions: • One of the following purposes must be met: Research on diseases of people (cardiovascular diseases, cancer, diabetes, etc.). Research on hereditary causes of disease emergence. Research to study factors for: metabolism, inflammatory conditions, blood supply, diet, environmental pollution, heavy metals, dementia, stroke, brain disorders, tumor diseases, diabetes, atherosclerosis, heart disease. Access conditions: • Prior to each new research project, approval processes will be carried out by the regional ethics review board as well as by the MONICA project and the Medical Biobank's scientific expert groups. Return of results: • Personal response regarding research samples will not be provided to participants. **MONICA 2014 Coded blood and urine samples and coded analysis data, questionnaire data and health data:** Geographic restrictions: • National and international use is unrestricted. Permissions: Research on at least one of the following: Disease research:

	• Prevention, diagnosis and treatment of cardiovascular disease, diabetes and related diseases; • Atherosclerotic diseases such as heart attack, stroke and heart disease, other heart diseases, such as atrial fibrillation and flap, diabetes, and its precursors, • Obesity and disorders in metabolism, eating habits and diet, inflammation and clot formation, dementia and debilitating brain diseases, cancerous conditions, • The prevalence of infectious diseases and their association with cardiovascular disease, heavy metals and environmental pollution. • Research on hereditary / genetic causes of disease. Access conditions: • Prior to data or sample use, MONICA's steering group and an expert group must review the purpose and scientific value of the research project and approve the use of the samples. The samples and data may only be used for the purposes that the participant has approved and for which the EPN (Regional Ethics Review Board at Umea University) has given approval. • Participant recontact and EPN (Regional Ethics Review Board at Umea University) approval required for research outside scope of consent (i.e. outside of purposes listed above). Return of results: • No return of research sample results to participants. Data linkage: • For longitudinal research purposes, participants' research data can be linked to participant data in the health register of the healthcare system.

Name of the project	**PRIME Study (Prospective Study of Myocardial Infarction) (Part of the Morgam Cohorts)**
Principal Investigator(s)	PI Prof Frank Kee: Morgam PI Prof Gerard Linden: Prime Study follow up PI Dr Bernadette McGuiness: Prime Cognitive Study Study Admin - Ms Angela Mullan a.mullan@qub.ac.uk
Institution(s)/Sponsor(s)/Funder(s)	Department of Epidemiology & Public Health

Study duration	
Data conservation	
Data/Samples storage location	
Documents reviewed	• Fact Sheet (picture); • Prime Study Consent (Picture, one clause); and • Prime Study Consent (Picture, four clauses). • PRIME Baseline Screening Consent Form • PRIME Annual Follow-Up Protocol • PRIME Memory Study (PRIME COG) Protocol Outline Version 3 12/12/2017 • PRIME memory follow up (PRIME COG) Participant Consent Form Version 3 12/12/2017 • PRIME memory follow up (PRIME COG) Participant Consent Form Version 3 12/12/2017 • PRIME Internal Timeline and Information Sheet
Notes	The contents of the materials considered have been supplemented with additions made by the Principal Investigators and their personnel. The ADA-M Profiles address the following cohorts and successive waves of data collection: 1990 – 1991 – 1993 MONICA PRIME – Study Baseline 1993 – 1995 PRIME Study Follow up Questionnaire 1996 PRIME Study Questionnaire Follow Up 2 1998 1999 PRIME Study Questionnaire Follow Up 4 1999 PRIME Study Questionnaire Follow Up 5 2001 – 2003 PRIME Study Follow Up 6 2000 – 2001 & 2006 PRIME Study Rescreen 2003 PRIME Study Questionnaire Follow Up 6e 2007 PRIME Study Questionnaire Follow Up 7 2010 PRIME Study Questionnaire Follow Up 8 2015 PRIME Study Questionnaire Follow Up 9 2017 PRIME Cog Study Rescreen
Questions for Study PIs	
Permissions in data	Stored, anonymised data and blood samples can be analysed in future research studies for indicators of vascular disease risk, cognitive-related factors, or dental factors, or by other research groups. Includes investigation of possible relationship between factors such as gum disease and the bacteria in dental plaque and coronary heart disease or stroke. (Including Genetic Studies)

Conditions of use	Data will be kept strictly confidential as necessary under the Data Protection Act and will be stored securely on University & NHS premises. Information may be analysed by responsible individuals in the study team, Belfast Health and Social Care Trust, Queen's University Belfast, and regulatory authorities. Stored, anonymised data and blood samples can be analysed in future research studies for indicators of vascular disease risk, cognitive-related factors, or dental factors, or by other research groups. Includes investigation of possible relationship between factors such as gum disease and the bacteria in dental plaque and coronary heart disease or stroke. Access can be obtained by emailing PI directly to request data. Participants will not be identifiable in any data published. Samples already taken can be retained, but no further samples can be collected.

Name of the project	**Study of Health in Pomerania (SHIP) (Part of the Morgam Cohorts)**
Principal Investigator(s)	
Institution(s)/Sponsor(s)/Funder(s)	Institute for Community Medicine, University Medical Center Greifswald
Study duration	
Data conservation	
Data/Samples storage location	
Documents reviewed	• 01d_Teilnehmerinformation Version ST - 5.1 - 12.05.2016 (Participant Information)); • 05a_UZ_Einverständnisse_ST1 (Declaration of consent); • 05b_Abschlussgespräch_ST1 (Final Conference); • 06_Innere_Einverständnis (Internal Agreement); • 07a_MRT_Einverständnis (Agreement) • Einverstandnisse_Trend_20090207 (Declaration of consent); and • MAILship_trend_innen_a5Mai2010 (Participant Information).
Notes	• There are two distinct cohorts (SHIP and SHIP-TREND) spread across multiple investigation periods

	(SHIP-0, SHIP-1, SHIP-2 and SHIP-TREND-0, SHIP-TREND-1, among others). • An ADA-M Matrix was prepared both for the **SHIP** and **SHIP-TREND** periods of investigation. • Access to SHIP and SHIP-TREND data requires an application to be made through the online portal. Research collaboration with the Institute for Community Medicine is generally a mandatory prerequisite to data access.
Profile Summary	**SHIP and SHIP-TREND** **<u>Use of pseudonymized (coded) data, pseudonymised (coded) images and examination data:</u>** The following condition must be met to access data: **Geographic restrictions:** • EU without restrictions, outside case by case decision based on legal background **Entities:** • Data use for health research purposes according to conditions of the Research Network (Community Medicine) and if allowed by participant consent. • Commercial or non-commercial organizations related to health research, if permitted by participant **The following conditions must be met in using data:** • Approval from access committee required, generally preferring academic over commercial uses • Each data use contract is limited for 2-3 years, prolongation possible • Data storage in compliance with EU legal framework • Data must be deleted after permission expires **Recontact:** • SHIP is designed as a lifelong study, therefore recontact is possible for all consenting participants • Linkage only possible if consented by participant for the specific source. **Data linkage:** • No linkage outside the SHIP Core team **Publication:** • Only anonymized or aggregated data can be published **Intellectual property in resulting data:** • All data generated based on SHIP data belongs to the research network community medicine**.** **Reporting of research results:** • Reporting is enforced. • SHIP is open for national and international collaboration, but regulations of the research network community medicine provide a formal basis (Collaboration is a mandatory requirement).

	Costs and fees: • For biomaterials costs will be charged.

Name of the project	**StenoCardia**
Principal Investigator(s)	
Institution(s)/Sponsor(s)/Funder(s)	
Study duration	
Data conservation	
Data/Samples storage location	
Documents reviewed	stenoCardia Patient Information Form
Notes	
Profile Summary – Informed Consent Form	**Data use conditions:** Data and findings may be evaluated in anonymized form (without mentioning names) and used for scientific purposes. The collection, storage, and evaluation of study data is done in pseudonymized form (i.e. encrypted without giving name, address, initials, or similar). The data can be used for research purposes or non-research purposes (i.e. clinical care, teaching purposes, or quality assurance) only upon a submitted proposal is approved by the steering committee **Participant withdrawal:** Participants can withdraw consent in written and oral form without giving reasons and without disadvantages. Participants can, at any time, and without giving reasons, revoke their consent to participation without any disadvantages arising. **Participant recontact:** If clinically relevant findings are discovered, the patient or the patient's family doctor can be informed about the findings if the patient has agreed to such recontact.

Name of the project	**UK Biobank**
Principal Investigator(s)	
Institution(s)/Sponsor(s)/Funder(s)	UK Biobank Limited, a limited and charitable company funded by the Medical Research Council, Wellcome Trust, Department of Health, Scottish Executive and North West Regional Development Agency.
Study duration	Phase 1 pilot study (February-March 2005) / Integrated pilot study (March-June 2006)

Data conservation	The anticipated lifetime of UK Biobank is more than 20 years.
Data/Samples storage location	
Documents reviewed	• UK Biobank: Protocol for a large-scale prospective epidemiological resource – Version 21 March 2007; • UK Biobank Ethics and Governance Framework – Version 3.0, October 2007; • Access procedures: Application and review procedures for access to the UK Biobank Resource – Version 1.0, November 2011; • Material Transfer Agreement for data and/or samples – Version 1.2, 20th August 2012; • Collaborator Material Transfer Agreement for data and/or samples – Version 1.4, 17th May 2017; • UK Biobank / Data Management & Sharing Plan – December 2012; • UK Biobank data linkage/guidance notes; • UK Biobank Re-contact Procedures for Third-Party Researchers (version 2.0); • Access matters / Collaborations – 17th June 2017; • Access matters / the return to UK Biobank of derived variables (7 June 2016); • Return of Results Data / Guidance Note for Approved Projects (August 2017); • Access matters: Cloud Computing Policy; • UK Biobank imaging assessment visit: incidental findings; • Information Leaflet 31/04/2010; • Further Information Leaflet 7/15/09; • Information Leaflet UK Biobank Imaging Assessment Visit August 2018; • Information Leaflet UK Biobank Second Imaging Assessment Visit February 2019; and • Information Leaflet for Repeat Assessment Visit 26/03/2012.
Notes	
Profile Summary	Public access: • Open access data use is unrestricted For controlled data and sample access, the following obligations apply: • Controlled access data and samples are available for unrestricted research use. Cannot be used by insurance companies,

	employers, police, law enforcement, security services or lawyers, nor the relatives of research participants (absent a court order). • Approval from Biobank PI and access subcommittee is required for data/sample access. Requires ethics approval. Sometimes also requires scientific approval. • Researchers must enter into material transfer agreements for data and samples. Access is limited to the approved researchers listed, and the approved purposes. UKB approval is required to subcontract obligations. Monitoring obligations (audit) and penalties / future use restrictions are imposed for non-compliance. • UKB approval is required to subcontract obligations. Monitoring obligations (audit) and penalties / future use restrictions are imposed for non-compliance. • Access fees must be paid. Security measures (controlled access): • Biological materials (i.e. samples) must be retained in a secure location. Samples must be kept on the premises of the applicant specified in the application. Data must be retained in a secure network. • Cloud computing is allowed, but must be subject to a contract between the recipient organization (research institution, not researcher) and the cloud service provider. Certain requirements are imposed on researchers, and the contract must contain certain minimum features. Destruction and return (controlled access): • Researchers must destroy datasets on expiry or termination of agreement. • Researchers must destroy or return samples on expiry or termination of agreement. Researchers must destroy samples at the end of the research project. Data linkage and re-contact: • Re-contact is permitted, but must be initiated by UK Biobank. • Re-identification is prohibited. There is a procedure that must be followed by researchers in the case of inadvertent re-identification. • Data linkage is permitted across UK Biobank on approval. It must be proportionate, reasonable, technically feasible, compatible with UKB access procedures, and not unacceptably increase re-identification risk.

	Publication and reporting obligations: • Researchers must provide UK Biobank with an annual progress report and must provide UKB with copies of patents applicable to related inventions within 2 months of publication. • Researchers must disseminate results as widely and rapidly as possible, subject to ethics and confidentiality. Researchers cannot publish identifying data. Researchers must place research findings in the public domain. Must publish within 6 months of completion date. • Researchers must return data analysis, supporting information, and research results to UKB for inclusion in the Biobank within stipulated delays (earlier of 6 months of publication and 12 months of completion date). Researchers must report findings to UKB two weeks before publication, and advise UKB of any results reasonably anticipated to cause controversy or public attention. • Researchers must attribute UK Biobank in publications.

Name of the project	**UKE Clinical Cohort Studies Clinical Cohort Study (CCS)**
Principal Investigator(s)	
Institution(s)/Sponsor(s)/Funder(s)	University Heart and Vascular Centre UKE Hamburg
Study duration	
Data conservation	Indefinitely
Data/Samples storage location	
Documents reviewed	• Patient Information Version 03– 26.03.2018
Notes	
ADA-M Profile Summary	**<u>Clinical Cohort Data and Genetic Data:</u>** Geographic restrictions: • The transfer of data to other countries where an adequate level of data protection has not been established is only possible if appropriate safeguards are in place. Entities: • Entities permitted to use the data include, but are not limited to, academic and industrial partners at home and abroad. • Data are not passed on to unauthorized third parties (e.g. employers, insurance companies.) • Personal data is stored in separate databases from the examination and result data, and

	only the master data administrator has access to the personal data. Purposes: One or more of the following purposes must be met: Research into cardiovascular diseases and their associated diseases (e.g. lung, kidney and metabolic diseases). More specifically, research related to: • The identification of new risk factors for cardiovascular diseases. • Clarification of causes, factors and disease progression in cardiovascular diseases and their associated diseases such as lung, kidney and metabolic diseases. • Research and development of new diagnostic approaches and effective tests for the detection of cardiovascular diseases and their associated diseases such as lung, kidney and metabolic diseases, their severity and for the selection of appropriate therapies. • Research development of therapeutic approaches, drugs and therapies for the treatment of cardiovascular diseases and their associated diseases such as lung, kidney and metabolic diseases. Access procedures: • The use of data is controlled by special committees. • Only authorized persons have access to the pseudonymized data. • Genetic examination data / genetic analysis results are stored separately from other clinical data and personal data, and only certain authorized persons can merge genetic information with study data. Security measures: • Before data are passed on, they are pseudonymized again. • Access controls, computer security precautions, and data encryption techniques are used. Publication: • Publications of scientific results do not allow conclusions to be drawn about personal data. Participant withdrawal: • Participants can withdraw consent at any time. • Data will be deleted. Return of results and data linkage: • Participants will not receive information about the results of blood or urine tests, nor of tissue samples.

	• Participant sample data can be linked to the participant's clinical data. However, reidentification is prohibited and measures such as separate storage and multiple pseudonymization are used to protect identity and prevent reidentification. • Only certain authorized persons (master data administrator) can merge genetic information with the study data of a specific person. Reporting obligations: • The results of external evaluations are imported into the study database. **Samples:** Geographic restrictions: • The transfer of samples to other countries where an adequate level of data protection has not been established is only possible if appropriate safeguards are in place. Entities: • Entities permitted to use the samples include, but are not limited to, academic and industrial partners at home and abroad. • Samples are not passed on to unauthorized third parties (e.g. employers, insurance companies.) Purposes: One or more of the following purposes must be met: Research into cardiovascular diseases and their associated diseases (e.g. lung, kidney and metabolic diseases). More specifically, research related to: • The identification of new risk factors for cardiovascular diseases. • Clarification of causes, factors and disease progression in cardiovascular diseases and their associated diseases such as lung, kidney and metabolic diseases. • Research and development of new diagnostic approaches and effective tests for the detection of cardiovascular diseases and their associated diseases such as lung, kidney and metabolic diseases, their severity and for the selection of appropriate therapies. • Research development of therapeutic approaches, drugs and therapies for the treatment of cardiovascular diseases and their associated diseases such as lung, kidney and metabolic diseases. Access procedures: • The use of samples is controlled by special committees. • Only authorized persons have access to the pseudonymized samples.

	Security measures: • Before samples are passed on they are pseudonymized again. • Access controls, computer security precautions, and data encryption techniques are used (as appropriate). Participant withdrawal: • Each participant is free to arrange for the destruction of the samples, including any samples sent to cooperation partners, at any time. • Participant can withdraw consent, and object to further processing at any time. Data will be deleted. Return of results and data linkage: • A participant's sample data can be linked to that participant's clinical data. However, reidentification is prohibited and measures such as separate storage and multiple pseudonymization are used to protect identity and prevent reidentification. • Participants will not receive information about the results of blood or urine tests, nor of tissue samples Reporting obligations: • The results of external evaluations are imported into the study database.