CAPACITY REGISTRY

Policy for Access to and Sharing of Data

1. Introduction

CAPACITY is a Registry of patients with COVID-19 across Europe and has been established to answer questions on the role of cardiovascular disease in this pandemic. It is an extension of the Case Record Form (CRF) that was released by ISARIC (International Severe Acute Respiratory and Emerging Infection Consortium) and WHO (World Health Organization) in response to the emerging outbreak of COVID-19 (https://capacity-covid.eu/).

The aim of CAPACITY is to collect data regarding the cardiovascular history, diagnostic information and occurrence of cardiovascular complications in COVID-19 patients. By collecting this information in a standardized manner, CAPACITY can aid in providing more insight in (1) the incidence of cardiovascular complications in patients with COVID-19, and (2) the vulnerability and clinical course of COVID-19 in patients with an underlying cardiovascular disease.

This access policy presents three areas of guidance:
i) ethical principles;
ii) governance procedures; and
iii) practical procedures for access.

Together with existing legal frameworks, these three areas provide the ethical and legal framework and practical procedures to guide access to and use of Data. This policy is a binding document for Requesters, who are seeking access to Data from CAPACITY.

2. Definition of Terms

Data

The data to be collected - by the Site Party - as specified in the Protocol and the REDCap Codebook of CAPACITY shall be included in the Registry after Pseudonymisation.

Registry

The database containing all the Data of which the Coordinating Center (=UMC Utrecht, Utrecht, the Netherlands) acts as custodian. Any database rights shall be owned by Coordinating Center.

Site Party

Data Provider as described in “DATA TRANSFER AGREEMENT FOR CAPACITY REGISTRY”.

Requester

A qualified person requesting Data. Needs to be registered as specified in Step-1 and -2 of section 6.

Bona Fide Researcher

A researcher:

1. with an intention to generate new knowledge and understanding by using rigorous scientific methods;

2. with an intention to publish the research findings and share the Data in the scientific community, without restrictions and with minimal delay, for wider scientific and eventual public benefit; and

3. that shall comply with legal and ethical requirements or widely recognized good research practice; and

4. they have a bona fide research project: in practical terms, a research project or proposal that has been approved by a recognized funder, or a researcher that belongs to a research organization that has the capability to lead or participate in high quality, ethical research should normally be considered bona fide.

Data Transfer Agreement (DTA)

A contract between the Requester and CAPACITY specifying conditions under which Data are transferred to Requester.

Project Outcome

Can be published in the form research papers, patents, new therapies and other types of commonly acknowledged medical research achievements. This also includes a report on the use of Data.

Personal Data

'Personal data' means any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (GDPR Article 4.1).

Pseudonymisation

'Pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures to ensure that the personal data are not attributed to an identified or identifiable natural person (GDPR Article 4.5).

Data Access Committee

An independent committee with the mandate to review all applications for access to Data deriving from the conduct of CAPACITY. The Data Access Committee makes recommendations for approval and rejection of access requests. The composition of the Committee is specified in Section 8.

3. Legal Premise

All proceedings related to access and sharing must be compliant with national and European legislation such as the Directive 95/46/EC and, as of 28 May 2018, the EU General Data Protection Regulation and Code of Conduct (GDPR Article 40). The processing of Data must be compliant with the provisions of the consent procedure and/or decision of an ethical review board, and/or a data protection authority/officer if applicable. If none of the above is applicable, it must be compliant with national legislation.

4. Governing Ethical Principles

CAPACITY will facilitate and support access to Data from participating Site Parties according to the following principles:

1. Scientific integrity:
   Requesters and providers are expected to act in an honest and transparent manner and uphold the highest standards of quality in scientific research.
2. Responsibility and accountability:
   It is both the requesters' and providers' responsibility to ensure that they have read and understood the relevant CAPACITY policies and procedures (published on https://capacity-covid.eu/for-professionals/) and that they act in accordance with them.
3. Respect for responsible governance regarding data and research:
   Requesters and providers are expected to take the necessary precautions and safeguards to avoid Data breaches. This entails protecting their Data and putting in place state-of-the-art safety measures for data security.
4. Accessibility to research results:
   Requesters publish their research results open access in a timely manner.
5. Attribution of CAPACITY-COVID collaborative:
   The intellectual investment of investigators involved in the creation of CAPACITY is substantial, and should be acknowledged as CAPACITY-COVID collaborative. This should be specified in a Data Transfer Agreements (DTA) signed by Requester and Coordinating Center (=UMC Utrecht, Utrecht, the Netherlands) after approval of the Data Access Committee.
6. Respect for intellectual property:
   Sharing of Data needs to be performed in a way that protects intellectual property rights of the parties involved. It also needs to address the requirements of institutions and third-party funders.

7. Equity and inclusivity of users:
   Bona fide researchers who meet the relevant criteria should be granted access based on fair and non-discriminatory terms.
8. Reciprocity:
   Stewardship also implies giving something back. Feedback regarding general results should be channeled towards institutions and patients.
9. Confidentiality:
   CAPACITY shall treat all the access requests confidentially and will not use them for any purpose other than assessing the availability of the Data and access provisions.

5. Procedures Governing Access to and Use of Data

A. The data shall remain under the stewardship of the Site Parties as the original source, unless otherwise specified in a separate agreement. Each Site Party is a separate Data Access Group in REDCap where users at each site are only able to view Data from their own site.
B. Requests for access to Data issued by Requesters will be required to follow the request procedure for Data (see section 6).
C. The Data Access Committee approves or rejects data transfer to a Requester.
D. Each Site Party is responsible for the collection of the Data to guarantee the quality of collected data.
E. The Requester needs to ascertain that the requested Data provided are stored in a secure and operational facility accompanied by an appropriate access policy, including a description of who can access the facility and the time-period the requested Data are needed.
F. Transfer of requested Data for research purposes to Requester should always be governed by a Data Transfer Agreements (DTA). By signing the "DATA TRANSFER AGREEMENT FOR CAPACITY REGISTRY", the Site Parties mandate the Data Access Committee to coordinate and arrange the transfer of Data from the central REDCap database to the Requester.
G. Data can only be used for academic or industrial research purposes, depending on the legislation of the Member State or international organization: the usage and limitations need to be specified in the DTA with Requester.
H. Access will be cost-neutral for Requesters. It is possible that CAPACITY requires the Requester to partially or fully cover the costs incurred in providing Data. Cost aspects must be specified in the DTA.

6. Request Procedure for Access to Data via PODIUM

The basic framework governing the request procedure for accessing Data via the CAPACITY portal comprises the following steps.

Step 1: Registration of Requester

CAPACITY verifies the identity of each Requester and his/her institutional affiliation (employee status).

Step 2: Request of Data

A Requester files a request for access to data via Podium (https://podium.bbmri.nl). The digital request form must be filled in (see Annex 1 for questions on the digital request form). The Data Access Committee may request refinement of the request. In compliance with the governing ethical principles (section 4), the request is treated as confidential by the Data Access Committee. In case of identical research questions by two or more Requesters the Data Access Committee will bring Requesters together and encourages Requesters to jointly resubmit the research question.

Step 3: Access control & Data delivery

After receiving feedback from the Data Access Committee, the Requester follows up directly with the Data Access Committee in order to provide any additional information needed to assess whether access can be granted. As part of this process, the Data Access Committee must comply with the regulatory and ethical conditions (e.g., data protection regulations, assessment of compliance of informed consent with the approved/proposed project, assess whether the amount of extraditable data required is scientifically justified), assess the application on content and feasibility, prevent duplication and transfer liability to the Requester by using DTAs as deemed appropriate. The Data Access Committee decides whether Data are released for the project requested. Review by the Data Access Committee will take one (1) week. At approval the DTA will immediately be provided. This DTA needs to be executed before Data are released to the requester.

The Data Access Committee will coordinate the Data delivery. Data will be released in a digital research environment.

Step 4: Request completion notification

For each request obtained via Podium, where Step 3 has been completed, the Data Access Committee needs to be informed whether the request has been completed successfully. The Requester will initially have exclusive access to the requested dataset for a period of six (6) weeks to perform the analyses. After this period of six (6) weeks, the Requester reports the status of the analyses. If needed the analysis period can be extended. After request completion the Data Access Committee will publish the approved research question(s) on the CAPACITY website.

7. Publication and Authorship

A. Site Parties shall be free to use their own Data for their own internal teaching, (non-)commercial research, educational, clinical and publication purposes under their own title, without any reference to CAPACITY.
B. The design and main paper will be coordinated by the Data Access Committee of CAPACITY. In these two mentioned papers all involved researchers will be recognized in the author list, limited to one author per department per participating center. The questions that will be addressed in the main paper are mentioned on https://capacity-covid.eu.

C. Within three (3) months after accessing the dataset the Requester has the possibility to prepare material for public dissemination (e.g. publications, posters, presentations) based on a data delivery from CAPACITY. After three (3) months the 'exclusivity' of the data will be over. All material for public dissemination will be sent to the Coordinating Center and globally reviewed by the Data Access Committee.

D. Publications based on data delivery from CAPACITY will be in accordance with international recognized scientific and ethical standards concerning publications and authorship, including the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, established by the International Committee of Medical Journal Editors. Copyrights concerning Publications of the CATACITY remain with the authors of the Publication, regardless of any other provisions regarding intellectual property rights (see www.icmje.org).

E. For each publication resulting from a Data delivery of CAPACITY:
    a. the Data Access Committee will form a writing group on behalf of CAPACITY. This writing group is involved in the writing process and will be mentioned in the authors list.
    b. the CAPACITY-COVID collaborative will be mentioned as last author. In the acknowledgements every involved professional is mentioned. The acknowledgement section is provided by the Data Access Committee.

8. Open Access

Since COVID-19 is a public health emergency of international concern, there is an need on researchers to make any information available that might have value in combatting the crisis. The CAPACITY team therefore asks/requires researchers to make the results from the CAPACITY COVID registry immediately publicly available and help save lives.

We ask/require researchers using the CAPACITY data to:

- ✓ Make all peer-reviewed research publications relevant to the outbreak immediately open access, or freely available at least for the duration of the outbreak
- ✓ Make research findings available via preprint servers before journal publication, or via platforms that make papers openly accessible before peer review, with clear statements regarding the availability of underlying data
- ✓ Share research findings relevant to the outbreak immediately with the CAPACITY team upon journal submission.

9. The Data Access Committee

At the start of CAPACITY the Committee is composed by the following persons. During the extension of CAPACITY, the composition of the Committee may change depending on contribution.

Prof. Dr. F.W. Asselbergs, MD, University Medical Center Utrecht**,** The Netherlands / DCVA
Dr. R.G. Tieleman, MD, Martini Ziekenhuis Groningen, The Netherlands / DCVA
Prof. Dr. P. van der Harst, MD, University Medical Center Utrecht**,** The Netherlands UMCU
Dr. P. Smits, MD, board member Netherlands Heart Registration (NHR) /DCVA
Dr. L. Jewbali, MD, member Dutch Association for Cardiology (NVVC) / DCVA
Dr. H.J. Siebelink, MD, board member Dutch Association for Cardiology (NVVC) /DCVA
Dr. C.W. Jansen, senior advisor Dutch Association for Cardiology (NVVC) /DCVA
Prof. Dr. W. van Gilst, MD, scientific counselor Dutch Heart Foundation (DHF) / DCVA
Dr. J. Schaap, MD, board member Dutch Network for Cardiovascular Research (WCN) / DCVA
Dr. I. Schalkers, advisor patient participation Harteraad / DCVA
Dr. M. van Smeden, scientist Julius Center for Health Sciences and Primary Care, The Netherlands
Dr. J.F. Hermans-van Ast, manager Durrer Center at Netherlands Heart Institute (NL-HI) / DCVA

Annex 1: Questions on the Request form in PODIUM

Data Request Podium

- Title of research
- Organization(s)
- Search criteria (refer to variables in the codebook of CAPACITY)

Research Proposal

- Background
- Research Question(s)
- Hypothesis / Goals
- Methods

Principal Investigator Details

- Name
- Function
- Affiliation
- Email

Revisions:

10-04-2020	Version 1.1	Final version
29-04-2020	Version 1.2	- Deleted table 'timeline' in paragraph 7 - Added article 8 Open Access