

# Meta VCI Map Membership and Principles of Collaboration

Version 2.2, 25 September 2018

## Preamble

**Meta VCI Map** is a collaboration of independent consortia and research groups from around the world working together to perform **Meta**-analyses on strategic lesion locations for vascular cognitive impairment (**VCI**) using lesion-symptom **Mapping**. In addition, Meta VCI Map can support other types of pooled analyses on vascular lesion patterns.

This document offers an overview of membership guidelines and principles of collaboration for Meta VCI Map. The purpose of this document is to provide the ground rules for researchers who wish to collaborate within the Meta VCI Map framework. Note that this is not a data sharing agreement. Additional data sharing agreement(s) can be drawn up for the purpose of individual projects. Guidelines for data governance and sharing are provided in this document (see section IV below).

## I. Guiding Principles

The collaboration is based on certain values and a shared consensus about governance and sharing and analyses of data. These are outlined below:

**A. Trust.** Any collaborative agreement is fundamentally based on a sense of mutual trust and respect among the participating groups. At times members may disagree with each other on a specific issue but this should not erode the fundamental sense of trust and respect. Participation in the collaboration is contingent on each group affirming this fundamental basis.

**B. Confidentiality.** Findings and results generated by the collaborative efforts of the group will be treated on a confidential basis and cannot be used in grant applications or papers without the prior consent of the scientists involved.

**C. Open communication among members.** All decisions and activities will be conducted in an open way. This is best accomplished through clear, regular and open communication among all the participating groups, either by in-person meetings, phone, or by email. Each principal investigator (PI) of the individual consortia or groups which comprise Meta VCI Map is responsible for communicating to members of his/her own consortium or group.

**D. Timeliness of activities/research.** There is a commitment to adhere to reasonable timelines in reviewing analytic plans, carrying out analyses, sending summary statistics to the common server and publishing papers.

**E. Use of individual consortium's own data in research studies outside Meta VCI Map.** There is general agreement that individual consortia or groups are able to analyze any data they themselves have collected. No review of such research projects is necessary.

**F. All parties to the collaboration benefit.** The first and foremost benefit of the Meta VCI Map collaboration will be the ability to perform large-scale lesion-symptom Mapping studies that can overcome previous limitations regarding study sample size and lesion coverage in the brain. The investigators may also benefit through other direct and indirect benefits. There is a clear recognition that for this collaboration to go ahead, any decisions that are made must attempt to provide mutual benefit for all those involved in Meta VCI Map, not just those directly responsible for a particular discovery.

## II. Meta VCI Map Membership

Meta VCI Map has evolved from collaborations in the VCI research field, such as STRIVE, MetaCOHORTS and HARNESS. Where these previous initiatives focused on standardization of terminology and techniques, Meta VCI Map will involve actual collaborative research projects, combining clinical and imaging data.

Independent consortia and groups are invited to join the Meta VCI Map collaboration. Membership is open to all project groups or consortia who are interested and are willing to share suitable data. In order for a project group or consortium to become a member of Meta VCI Map, interested parties should:

- 1) Submit their request to join Meta VCI Map to the Steering Committee (SC). This request should be accompanied by a summary of the nature of the data that may be shared, such as cohort type and size, imaging modalities, neuropsychological data, availability of preprocessed lesion Maps, and previous publications on the cohort.
- 2) Submit a signed copy of the “Meta VCI Map Membership and Principles of Collaboration” document to the SC.

Applications will be reviewed by the secretary and presented to the SC. If the available dataset is indeed suitable for the Meta VCI Map framework, membership will be granted.

Membership of Meta VCI Map allows researchers to perform research projects within the Meta VCI Map framework, but members do not have any formal obligations. Membership only implies the willingness to share data, but does not require the actual submission of data. Data is only shared in the context of specific Meta VCI Map projects. Members can actively initiate or join such research projects.

### **III. Consortium Structure**

**A. Steering Committee.** The Meta VCI Map consortium forms an overarching structure to support specific research projects. The Steering Committee (SC) is responsible for making decisions and resolving conflicts regarding the consortium, including organization, priorities, collaborative projects, working group management, and new membership requests. The SC consists of one or two representatives of member groups and consortia who have participated in one or more specific Meta VCI Map projects (see section III-D below), and as such have contributed data to that project. Member groups themselves will decide who will represent them on the SC. SC members will represent the interests and scientific expertise of their own groups and consortia.

**B. Executive Committee.** A small Executive Committee (EC) is appointed through the SC. The EC is responsible for dealing with day-to-day management responsibilities for Meta VCI Map on behalf of the SC. The EC consists of the Meta VCI Map consortium chair, a secretary and other appointed representatives as needed.

**C. Working Groups.** Meta VCI Map will form working groups in different areas of expertise. These groups will provide technical support to the consortium and to individual projects on a task-driven basis. Focus is on technique development, implementation, technical support and quality control, or legal aspects, not so much with policy or governance. A data analysis working group and a data storage/management working group have been installed. Other working groups might be initiated as Meta VCI Map further develops. Participants in working groups will be selected based on interest and expertise. Not every individual member group needs to be represented in the working groups. The working groups will primarily consist of individuals with hands-on technical experience.

**D. Project Groups.** Each individual project will be managed by its own project group. Meta VCI Map supports projects executed by project groups that work on specific project proposals. Proposals can be submitted to the SC by the envisioned project group chair. The SC will evaluate whether the project fits within the framework of Meta VCI Map, and can provide comments and suggestions on the project proposal. After approval by the SC, Meta VCI Map members can be formally invited to join the specific project. Individual members can then decide themselves whether to join a specific project and share their data in that project.

A project group generally consists of a maximum of four members from the center(s) leading and executing the project (including the project chair) and up to two members from each other participating center. Project groups can make an appeal to the SC and/or working groups if they require advice or assistance at any point during the project.

**E. Communication.** The EC will distribute newsletters and organize telephone conferences with the SC to discuss consortium governance, progress of projects, new project proposals and membership requests. The working groups and project groups will have regularly scheduled meetings at their own initiative, and report the results to the Meta VCI Map SC.

## **IV. Data Governance and Sharing**

Meta VCI Map supports and encourages sharing data as much as possible, while strictly adhering to Institutional Review Board (IRB) regulations and protecting human subjects. The main principle is that ownership of the provided data will always remain with the contributing consortia or group. Data is shared and used on a project-by-project basis. After approval of a project by the SC, individual members can decide whether or not they wish to contribute data to that particular project. Data that is being used in a specific ongoing project will be accessible to the project group only. Details are outlined below.

### **A. General principles of data ownership and sharing**

- 1) Data are owned by the group that has generated the data.
- 2) Data will exclusively be used on a per-project basis and for the purpose outlined in a written project proposal that has been approved by the SC.
- 3) The use of data in a particular project requires prior written agreement by all parties providing data for this specific project. This agreement specifies where the data will be stored and who will have access.
- 4) Data will not be further distributed to other parties without prior approval by the party providing the data.
- 5) Once project data has been used in a publication, this data cannot be fully withdrawn from the dataset by the party originally providing the data, as this would interfere with guidelines on traceability of data in published research.
- 6) Each partner is fully responsible for the quality of the data it provides, and that data is provided in agreement with all local guidelines at the site of the data provider.
- 7) The “data storage and management working group” of Meta VCI Map is responsible for harmonization of individual datasets according to Meta VCI Map standards.

### **B. Open access catalogue for overview purposes**

An overview of the nature of the data (i.e. not the actual data) that a consortium member can contribute will be included in open access catalogues, including the Meta VCI Map website ([www.metavcimap.org](http://www.metavcimap.org)), online study registries, and publications including the design article, after approval from the SC and the contributing member.

### **C. Project-specific data sharing agreements**

Data will be shared on a project-by-project basis, which means that each project will require individual data sharing agreements between the participating consortia and groups. Data sharing procedures and regulations differ between countries and research centers, and also depend on the exact nature of the data. Therefore it is not feasible to provide an all-encompassing contract for usage within the Meta VCI Map consortium framework. Legal documents and other formal requirements will depend on local regulations of the participating centers, and on the provided data.

The project group chair is responsible for preparing the data transfer agreements and coordinating the actual data transfer for the project, thereby ensuring adherence to the local regulations of each submitting and receiving centers.

To support this process, a standard format for the data sharing and publication agreement is provided by the Meta VCI Map consortium, which is formulated to comply with European Union privacy guidelines. This document can be modified to fit the requirements for individual data providers and data recipients.

### **D. Data storage**

Depending on the level of data pre-processing performed by member groups, imaging data can be shared with project groups in different formats (e.g. anonymized MRI scans without any preselection of sequences; lesion Maps only). Project groups are responsible for secure storage and (pre-)processing of data, and are encouraged to make an appeal to the expertise of the various Meta VCI Map working groups for technical support.

## **E. Sharing summary statistics within Meta VCI Map**

All data and results shared pre-publication are confidential and cannot be used for further analysis without approval from the owner of the data.

## **F. Sharing summary statistics outside of Meta VCI Map**

Summary statistics may not be shared outside of Meta VCI Map without prior approval from the project group and explicit agreement of the responsible PIs.

## **V. Authorship**

For projects, the project group is responsible for assigning authorships, under guidance of the project chair. The chair or project members may seek advice from the Meta VCI Map SC or EC.

Qualification as an author will follow typical academic criteria. To qualify as an author, an individual will need to contribute to study design, and/or study execution, and/or preparation of results for publication, and/or drafting/revision of the manuscript. Each group will determine who should be an author for a particular publication and the group will be asked to describe the contribution by each author nominated.

## **A. Consortium publications in Meta VCI Map**

Publications on the Meta VCI Map consortium (i.e. not project-based) will be handled by the EC, in communication with the SC. The main author list will typically include the PIs of each Meta VCI Map member group and consortium, and any other investigators who have significantly participated in developing or analyzing the content of the publication. Considering the growing number of Meta VCI Map members, publications will typically have multiple equal co-authors.

## **B. Project publications in Meta VCI Map**

For project publications, the main author will include investigators who have significantly participated in developing and analyzing the data in the manuscript related to a specific project. These will typically include the members of the project-specific group, with one or two additional authors from each of the studies/consortia that contributed the data to the project.

Meta VCI Map recognizes projects are driven by more than one person, thus publications will often have multiple co-authors. The members also will work to promote young investigators and encourage their leadership and place as first authors.

For all studies performed within the Meta VCI Map framework, the contribution of Meta VCI Map consortium should be acknowledged in any and all oral and written presentations, disclosures, publications, and patents resulting from any and all analysis of data received through Meta VCI Map.

## **VI. Chairmanship of Meta VCI Map**

These principles of collaboration for Meta VCI Map have been set up in January, 2018. Geert Jan Biessels, from the UMC Utrecht, is the founding chairman of Meta VCI Map. To ensure sustainability of the program in the start-up phase this chairmanship is for three years. From January 1, 2021, the chairmanship of Meta VCI Map will be reviewed by the SC on a yearly basis. The chair will serve a term of one year but an individual can serve more than one term if the SC wishes. The choice of chairmanship will be taken via a vote of all SC members. Responsibilities of the chairman include:

- 1) Chairing the Executive Committee, distributing newsletters and organizing telephone conferences on a regular basis .
- 2) Producing minutes within 3 days following each Steering Committee teleconference;
- 3) Scheduling ad hoc meetings and calls as needed.

Date: 25 September 2018

## **Acknowledgement**

This document was adapted from the MEGASTROKE Membership and Principles of Collaboration (version 13-11-2015) document to fit the purpose of Meta VCI Map.

**Memorandum of Understanding for membership of the Meta VCI Map consortium**

The undersigned parties to this Memorandum of Understanding (MuO) agree to the terms of membership and collaboration of the Meta VCI Map consortium as stipulated in the "Meta VCI Map Membership and Principles of Collaboration" (version 2.2, September 2018) document.

This MoU is signed by a scientific representative of the study cohort or consortium indicated below, and by the Chair of the Meta VCI Map consortium. With this signature the representative indicates that he/she has mandate to represent the named study cohort or consortium scientifically within Meta VCI Map. Meta VCI Map will communicate to the named study cohort or consortium primarily through this representative.

Name study/cohort/consortium:

Name institution:

Name representative:

E-mail:

This MoU is at-will and will remain in effect until modified or terminated by either party.

Signed by:

**Representative of the study cohort or consortium**

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Date: \_\_\_\_\_

**Chair Steering Committee Meta VCI Map**

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Date: \_\_\_\_\_