Global Research Consortium

Choroidal Vascularity Index Grid (CVIgrid)

Study Handbook

Last updated: 10/05/2019

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Table of Contents

1.1 **Project Overview** **3**
1.2 What is CVI? 3
1.3 Why CVIgrid? 3
1.4 Collaborators 4
2.1 **Key Members** **5**
2.2 Principle investigator 5
2.3 Advisory board 5
2.4 Administrative Team 5
2.5 Web platform administrator 5
2.6 Registering as a member 5
3.1 **Institutional Review Board Approval** **6**
3.2 Institutional Review and Ethics Approval 6
3.3 Data security 6
3.4 Disclaimer 6
4.1 **Authorship Policy** **7**
4.2 Primary manuscripts 7
4.3 Proposed studies 7
5.1 **Meeting Presentation Policy** **8**
5.2 Abstracts 8
5.3 Conference presentation authorship policy 8
6.1 **Data Entry** **8**
6.2 Inclusion and exclusion criteria 8
6.3 The CVIgrid Data System 9
6.4 Data confidentiality 9
6.5 Standard anonymization of patient data 9
6.6 Link to the CVIgrid web-based platform 9
6.7 Uploading OCT images 12
Annexure 1: Frequently Asked Questions **13**
Annexure 2: Ethics approval letter **13**
Annexure 3: Handbook acknowledgement **13**

1.0 Project overview

1.1 What is CVI?

The choroid is an intricate, highly vascular organ affected by a multitude of ocular and systemic diseases. Detailed structural analysis of the choroid using reliable parameters has tremendous implications in unveiling the pathomechanisms and understanding the progression of various ophthalmic pathologies, for both research and clinical purposes.

Studying the choroid is a tedious process, particularly due to its physical inaccessibility and complex angioarchitecture. Histopathological studies have established our fundamental knowledge by successfully delineating the various choroid layers, but the usage of post-mortem samples brought about limitations such as fixation induced shrinkage/artefacts and the inability to analyze longitudinal changes in vivo. The development of techniques such as fundus fluorescein angiography and indocyanine green angiography have provided clinicians with a means to study choroidal structure in living patients. However, angiography is an invasive procedure with dye related complications and operator dependency, rendering it less favorable as a research tool. With the advent of optical coherence tomography (OCT), a fast and non-invasive imaging modality with high resolution, we are now able to visualize cross sectional choroidal anatomy in real time. Researchers have attempted to achieve reproducible quantification of choroidal structure on OCT images, using biomarkers such as 'choroidal thickness' (CT), but the results have been inconsistent.[1-6]

Our group has developed a new biomarker named 'choroidal vascularity index' (CVI), defined as the ratio of total vascular luminal area (LA) to total choroidal area (TCA), computed by segmenting and binarizing OCT images using the public domain software, Fiji Image J (http://imageJ.nih.gov/ij/). A detailed protocol can be found in our previous studies.[7] CVI provides specific information about the choroidal vasculature and is believed to be more accurate and repeatable. Since its proposal in the letter to the editor of American Journal of Ophthalmology in 2016, CVI has become a widely accepted research tool, with consistent findings leading to over 30 publications in peer reviewed journals. CVI has the potential as a practical tool for monitoring, diagnosing and prognosticating ocular diseases, with significant implications on clinicians' therapeutic decision making.

1.2 Why CVIgrid?

Our group aims to validate CVI as a clinical parameter through longitudinal studies with large samples sizes, hence impacting current practice in patient care. Despite applaudable progress, the study of CVI is still in its infancy, and the lack of a common platform connecting researchers globally has slowed us down. Currently, OCT images/study data are shared via dropbox, and research ideas via email, both of which are inefficient when multiple international collaborators are on board. In addition, with limited publicity, potential collaborators only learn about CVI through conferences and journal publications.

CVIgrid is a global research consortium established in 2018, bringing together institutions worldwide, to validate CVI and produce more high impact publications through multi-national collaborative studies. The website for CVIgrid (cvigrid.org) will serve as an OCT image and data sharing portal, as well as a platform to initiate and collaborate in new projects. The site will be assessible to all, with restricted content (OCT images, annonymized patient data, study protocol) secured and only visible to registered members participating in the study. Regular updates on the progress of CVI research will also be made via CVIgrid.org and consortium meetings (skype/conference).

The current protocol for CVI is simple but relies on manual labor, which limits our efficiency in analysing large sample sizes. Automated algorithms have been proposed by our group and Vupparaboina et al, both of which await further improvements and modifications.[8,9] We hope fill up the current technical gap by obtaining more robust data through CVIgrid. to perfect our algorithm. We envision a software that is capable of generating CVI data readily, and incorporate that into commercially available OCT machines.

1.3 Investigators (as of 10th May 2019)

Country	Institution	Member *site principle investigator bolded*
Argentina	Consultorios Oftalmológicos Benisek Ascarza - Buenos Aires (COBA)	**Assistant Professor Andrés Manuel Rousselot Ascarza**
Australia	School of Optometry and Vision Science, University of New South Wales – Sydney (UNSW)	**Dr. Lisa Nivison-Smith**
	Sydney Eye Hospital, Sydney, Australia	**Prof Peter McCluskey**
Hong Kong	Chinese University of Hong Kong (CUHK)	**Assistant Professor Cheung Yim Lui Carol**
India	Advanced eye center, PGIMER – Chandigarh (PGIMER)	**Professor Vishali Gupta** Assistant Professor Mohit Dogra Dr. Simar Rajan Singh Dr. Aniruddha Agarwal
	Aditya Jyot Eye Hospital, Mumbai (AJEH)	**Prof Dr S Natarajan**
	Aravind Eye Hospital – Madurai (AEH)	**Professor Ramasamy Kim** Dr. Chitaranjan Mishra
	Dr. Shroff's Charity Eye Hospital – New Delhi (SCEH)	**Dr. Manisha Agarwal**
	Drishti Eye Institute – Dehradun (DEI)	**Dr. Saurabh Luthra**
	Narayana Netralaya, Bangalore (NN)	Dr Chaitra Jayadev
	Sankara Netralaya, Medical Research Foundation, Chennai (SN)	**Dr. Parveen Sen**
	Sankara Deva Netralaya - Guwahati (SDNG)	**Dr. Dipankar Das** Dr. Aavnish Upadhaya
	Shroff Eye Centre - New Delhi (SEC)	**Dr. Daraius Schroff** Dr Cyrus Shroff
Italy	Azienda Ospedaliera Santa Maria Nuova di Reggio Emilia	**Dr. Luca Cimino**
	Luigi Sacco Hospital, University of Milan – Milan (LSH)	**Assistant Professor Alessandro Invernizzi**
	University of Florence – Florence (UOF)	**Dr. Lucia Finocchio**
Japan	Kagawa University – Takamatsu (KU)	**Associate Professor Chieko Shiragami**
Korea	Inje University College of Medicine, Hyundae Paik Hospital – Gimhae (IUCM)	**Associate Professor Min Hee Suh**
Nepal	Birat Eye Hospital, Biratnagar	**Dr Anadi Khatri**
Singapore	Khoo Teck Puat Hospital (KTPH)	**Dr. Lekha Gopal** Dr Neelam Kumari
	Tan Tock Seng Hospital (TTSH)	**Adjunct Associate Professor Rupesh Agrawal** Dr. Wei Xin Mrs. Neha Khandelwal Mr. Ding Jianbin
Slovenia	Eye Hospital, University Clinical Centre Ljubljana, Slovenia	**Dr Alenka Lavric**
Switzerland	University Hospital Bern - Bern (UHB)	**Associate Professor Marion Munk**
UK	Moorfields Eye Hospital - London (MEH)	**Dr Carlos Pavesio**
USA	Byers Eye Institute, Stanford Health Centre (BEI)	**Dr Mohammed Hassan** Dr. Sarakshi Mahajan

Figure 1. Table of collaborators based on country and institution. Principle investigator of respective sites are bolded.

2.0 Key members

2.1 Principle investigator (PI)

Head PI - Dr Rupesh Agrawal.
Site PI – Bolded in figure 1.

The head PI of CVIgrid is the chief administrator and spokesperson of this research consortium. Overseeing all projects under CVIgrid, he will be in charge of approving pending project proposals, collaboration offer, manuscript submission, conference abstract submission, and new membership application. Should the policies of CVIgrid be violated, he reserves the right to take reject/terminate projects, erase data, and remove any members.

The site PIs are the chief spokespersons for the individual institutions. They will be responsible for obtaining respective institutional ethics approval, initiating projects approved by their own institution, accepting collaboration offer from other institutions. They will be responsible in ensuring that all data uploaded strictly abide by the policies of CVIgrid.

2.2Advisory board

Independent advisory board: will guide the study team about different projects. The advisory board will not be directly involved in any specific projects and will be mainly guiding the team about the set up of the platform, review the projects and guide the CVIgrid team about the projects.

A/P Adrian Koh – Singapore
Honorary Clinical A/P. Timothy Lai – Hong Kong
Dr. Pearse Keane – UK
Prof. Quan Dong Nguyen – USA

Role – to guide the study team about feasibility of different projects and advise the team about the specific pitfalls in the automated CVI tool.

2.3 Administrative team

Mr. Ding Jianbin – Singapore
Dr. Ilaria Testi – Italy
Ms. Neha Khandelwal – Singapore
Dr. Simar Rajan Singh – India
Dr. Wei Xin – Singapore

The administrative team will assist the head PI in all his duties. The team will coordinate CVIgrid meetings, update consortium progress (webpage, new members, new projects/publications/presentations), take charge of research project/ethics/grant application (Singapore only). The team will assist collaborators in image/data analysis and manuscript writing. The team reserves the right to review any project proposals/data/image uploads and will inform head PI & site PIs should they observe any violation of CVIgrid policies.

2.3 Web platform administrator

The CVIgrid.org web platform is developed by PLAYON a software development company based in Bangalore, India . The platform will be managed by the CVIgrid administrative team. The data is protected by secure authentication and role based access system delivered on a secure network using https. Uploaders are responsible for their own actions and annonymization of patient data is compulsory.

2.4 Registering as a member

Members are to first log in as visitors or using their Google account, and request to be a member via the collaborate function. Members are to fill in necessary profile information in detail. Following which an email of notification will be sent to cvi.grid@gmail.com.

Information will be reviewed by head PI, who will then decide whether to grant membership access to the applicant. Following which, an email will be sent to the applicant to inform him/her about the outcome.

On subsequent login with Google Plus account, membership privilege will permit the person to access the GRID to propose and offer collaboration in new projects.

3.0 Institutional Review Board Approval

3.1 Institutional review and ethics approval

The CVIgrid protocol requires all participating sites to obtain approval from their local Institute review boards (IRB) and/or equivalent ethics review boards prior to project proposal. Each site shall provide a final copy of the ethics approval to respective site PI and head PI (Associate Professor Rupesh Agrawal) before commencement of data uploading via email. The relevant documents also have to be uploaded onto CVIgrid portal, both during project proposal & data uploading. Where the local IRB dictates that no ethics clearance is required for retrospective data entry, a letter has to be obtained from the local IRB and provided to the CVIgrid team for record purposes. Ethics approvals are to include the same project title for all centers, to explicitly mention the usage for collaborative study in CVIgrid and contain the CVIgrid webpage link.

3.2 Data securtiy

The data on cvugrid.org will be secured using the following mechanism

1. Authentication:
Public Access: contains only the data about CVI and CVIGrid platform that is public domain and can be shared with everyone. This information is by website administrators
Member Access: The platform is authenticated using the member google account or username / password for that user that allows access to the Grid functionality.

Users can be deactivated by Administrators. Deactivated users will not be able to login into the platform.

2. Role Based Access:
The functionality of the platform is restricted to the role based access. The system roles are Super User, Member and Visitor,
A Administrators will have Super User access and be able to manage website content, institute and member details, publications, awards and be able to approve / reject project proposals

Members would be able to Propose a project and after the Administrator accepts the project they will have access specific to their role (explained below)
Visitors : Have only read only access to public area of the platform.
Project specific roles:
Every project will also have role-based access and following are the roles within a project.

Owner: Has access to upload documents, upload images, do CVI Analysis, post comments and manage roles of members of the project
Contributor: Has access to upload images for analysis and post comments.
Reader: Can only view images and analysis and post comments
Rejected: No access to this project.

3. Network Security
The communication between user web browser and cvigrid.org platform would be over secure https using 256-bit encryption.

The data involved shall be managed in accordance with legal regulations and all agreements made with the relevant IRB by the site PI. The online web-based data platform used in the CVIgrid study is HIPAA compliant. All data entered will be encrypted and will be accessible by the head PI and administrative team. Data will be erased/blocked from assess if deemed to breach patient confidentiality/CVIgrid policy.

All ongoing projects will be listed under the 'CVIgrid' tab under 'choroidal vascularity index' page and will only be assessible to official members of CVIgrid. Members will only be able to view 'abstract/brief project proposal', 'name of initiating institution'. Members can offer to collaborate for specific projects, for which they will be granted access to data once approved by site PI & head PI. Data for each project will be accessible by the site PIs and site members of proposing and collaborating institutions.

No patient identifiers (e.g. name, national identification number, date of birth) or sensitive information (e.g. HIV status) should be entered in the online web database. The data entry personnel of each participating centre will be responsible for anonymising the information entered and images uploaded. All data at each site location should be stored in password-protected medium or kept secure under lock and key. Any online data/images downloaded will be stored in a secure password protected desktop at Tan Tock Seng Hospital (TTSH).

For more information about patient confidentially and ethics approval, please see Annexure 1: "Frequently Asked Questions (FAQ)" or contact Mr. Ding Jianbin.

3.3 Disclaimer

By participating in this study, all site PIs have confirmed that:

Ethics approval for conducting the study in their centre(s) has been obtained from their respective Institutional Review Boards (IRB), Domain Specific Review Boards (DSRB), and other relevant ethics review boards and/or the equivalent.

All data entered are correct and legitimate. The site PIs may be contacted for verifications of data entry if discrepancies are detected during data audits.

Data entry personnel of each participating center are responsible for anonymizing data entered according to the study protocol and will not enter data that contains any patient identifiers.
The CVIgrid head PI and administrative team will not be held responsible for any errors in data entry or any non-anonymised data.

The head PI will have access to the data entered beyond the study period for research purposes and data can be shared with third-party statisticians for complex data analysis. Likewise, site PIs will have access to their respective site data.

4.0 Authorship policy

The authorship style for all papers will be the Modified Conventional style (named authors for the study group, e.g. Jones, Smith and Johnson, "for the CVIgrid"). The entire study group (defined as CVIgrid collaborators involved in data collection and analysis) will be acknowledged in primary papers. The head PI and CVIgrid administrative team will maintain a credit roster updated periodically for this purpose.

4.1 Primary manuscripts

Depending on journal, primary manuscripts (review article) will ideally list all members as contributing authors and head PI as first and corresponding author. In scenario of limited co-authorship, primary manuscripts will have all CVIgrid participating members listed as contributing authors under the CVIgrid as per ICMJE guidelines.

For other primary manuscripts (large collaborative study), the head PI and site PIs will be the named authors in the manuscripts. Depending on the contribution from the CVIgrid members to data collection, data analysis and/or manuscript preparation, members will be assigned as first author and added as named authors to manuscripts, subject to target journals' authorship criteria and instructions. Contributing study team members not included in a named manuscript will be acknowledged in the manuscript as members of the CVIgrid. The names of all the participating centres will also be acknowledged in primary manuscripts.

The biostatistician(s) conducting the analysis may also be included as a co-author. Other co-authors may be included following approval by the head PI and relevant site PIs.

4.2 Proposed studies

Studies proposed by any center via the site PI, but has to be approved by the head PI. It is anticipated that approval typically will be granted, after which the study details will be uploaded onto the CVIgrid portal and open for collaboration offers. To ensure continuous progress, the manuscript must be submitted within six months of completed data collection. There are no limitations on who may serve as the first author (e.g. PI, fellow, resident, another faculty member).

Proposed studies from different centers with similar objective will be encouraged to collaborate, with a joint first authorship between the two centers with the most significant contribution based on data quantity, analysis, and manuscript preparation. The corresponding authors will be the site PIs from the top two contributing centers. In situation of conflict and inability to decipher the degree of contribution, the head PI will be listed as the corresponding author.

Unless CVI protocol is issued and granted usage by the head PI, all data analysis will be completed by the CVIgrid administrative team and the relevant personnel will be listed a contributing author.

In greater detail, named authors will include: the primary writer (first author), the statistician (if applicable), the site PI and head PI (corresponding authors), members of participating centres, and the CVIgrid study group (as per ICMJE guidelines). Additional authors may be named with approval of the head and site PI when appropriate. Unless agreed otherwise, the "senior author" (listed last in the named authors list) will be primarily responsible for ensuring the quality and completion of the project. The specific authorship plan will be proposed at the time of proposal of the manuscript by the first author, based on the anticipated extent of contribution of each author, and is subject to approval by the PIs based on the aforementioned guidelines. Before journal submission, co-authors will have two weeks to respond with their suggestions and sign-off authorship documents. Failure to respond will lead to omission from authorship and acknowledged as contributors.

5.0 Meeting presentation policy

5.1 Abstracts

Abstracts must be circulated at least 2 weeks ahead of submission for co-authors' review. Co-authors may either return comments or may indicate approval of the submission by not returning comments. Abstracts should not be submitted unless the following requirements are met: 1) Completed final tables and figures; 2) Completed draft manuscript (outlined Discussion is acceptable)

5.2 Conference presentation authorship

Some conferences may restrict the number of authors credited in conference abstracts. If so, author names may be omitted in the abstract and instead acknowledged as members of the CVIgrid in order to meet the conference guidelines. However, all authors must be acknowledged in the talk or poster as contributing authors and members of the CVIgrid.

Note: Consult the site/head PI regarding authorship order prior to circulating abstracts.

6.0 Data entry

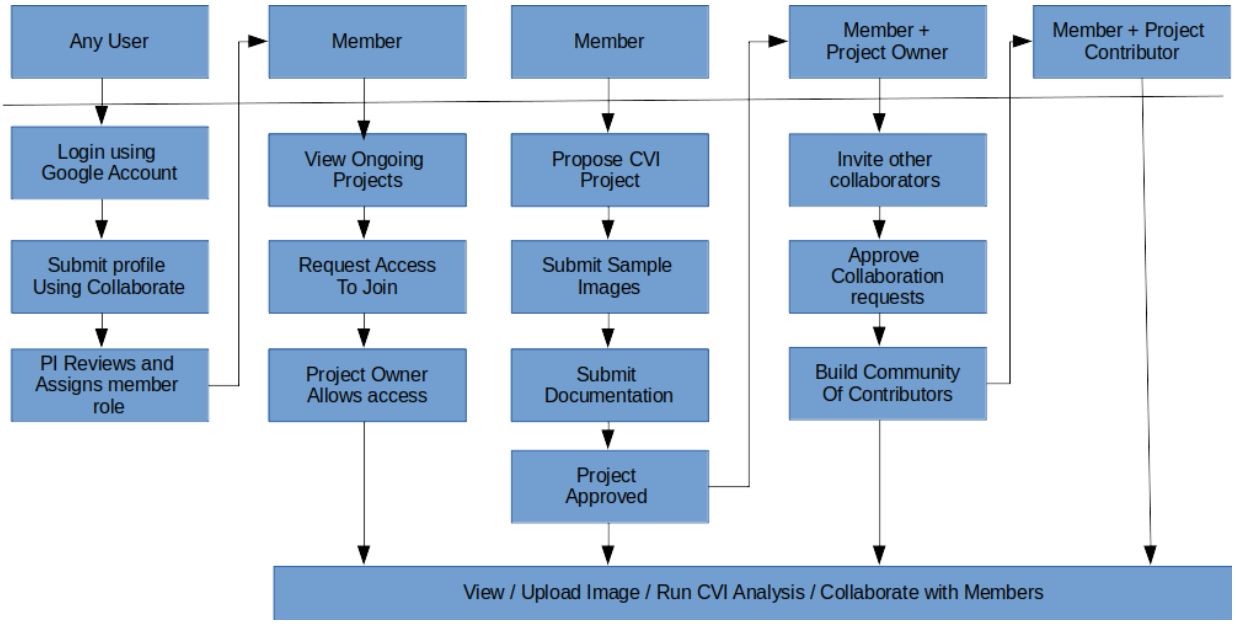
6.1 Inclusion and exclusion criteria

No fixed criteria, follow as stated in respective proposed studies.

6.2 The CVIgrid data system

The CVIgrid online image and data portal hosted on Amazon Web Services Cloud Platform and will be the main repository of data.

The site PI is to first propose a project via the 'propose new project' button under 'GRID' and key in all relevant details, including brief overview of project, institutional ethics approval, and sample OCT images. After review by head PI, access will be granted to upload attach word/pdf format of project proposal, institution and ethics approval, and OCT images, via 'choroidal vascularity index' tab. Excel format anonymized patient data will not be uploaded to the webpage and hence will not be available for download by any party.



Uploaders and site PIs are responsible in ensuring anonymized data is being uploaded. CVIgrid head principle investigator (A/P Rupesh Agrawal) and all administrators shall not be responsible for any breach of personal data protection act by any CVIgrid members. All members of CVIgrid are to agree to this handbook's contents prior to being approved as official member, and granted privilege to propose and upload any projects.

Please contact Mr. Ding Jianbin (dingjianbin97@gmail.com) for any queries regarding data entry.

6.3 Data confidentiality

All data/images shall not contain any patient identifiers or sensitive information. The data entry personnel of each site will be responsible for anonymising the patient's data. Only head PI (A/P Rupesh Agrawal), administrative team can access all the data in the system. The CVIgrid administrative team and head PI reserve the rights to remove any data deemed to breach patient confidentiality.

6.4 Standard anonymization of patient data

Patients are to be numbered with prefix of institution name in short form (refer to figure 1 i.e. Tan Tock Seng Hospital as TTSH) and given a specific identification/serial numbers (i.e. 1, 2, 3, 4). Hence a random patient from Tan Tock Seng Hospital should only be identified in the study as TTSH1, with no patient name, social security number, NRIC, or date of birth. All other medical conditions unrelated to the study must not be included as well.

For each eye, it will be labelled as 'LE' for left eye and 'RE' for right eye. Hence the OCT image of

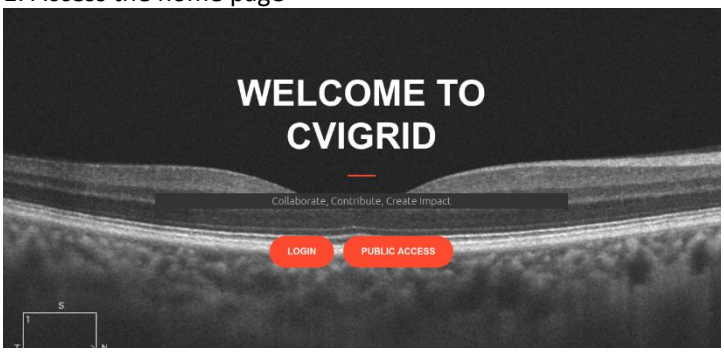
the right eye of patient TTSH1 will be titled TTSH1_RE. If there are follow-ups for the study, then the image should be titled TTSH1_RE_visit1, and changing to visit2, visit3 accordingly. Same changes are to be made in corresponding excel data file as well. Excel data file must not be uploaded onto the portal at any point of time. Only to be sent via email to head PI (A/P Rupesh Agrawal).

6.5 Link to the CVIgrid online portal

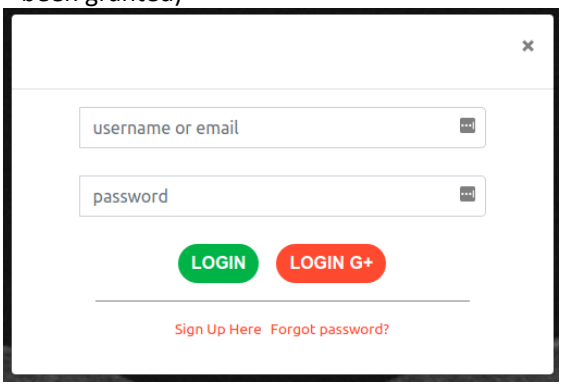
www.cvigrid.org

6.6Using the CVIgrid online portal

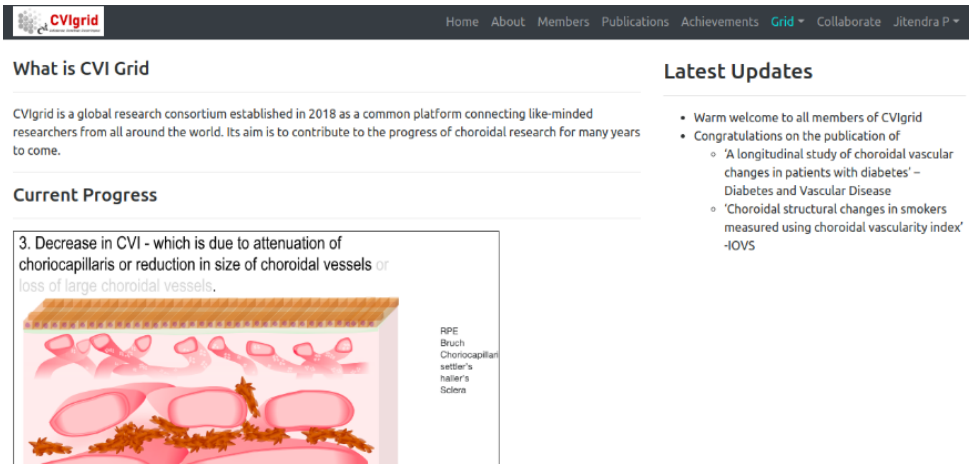
1. Access the home page



2. Click Login to get to the following popup window, login with google plus account (after membership has been granted)

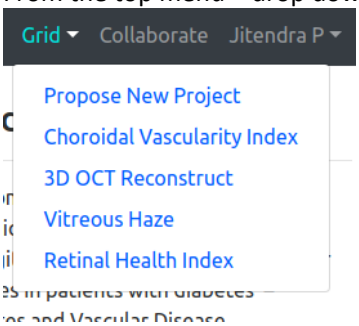


3. The following will be the landing Page

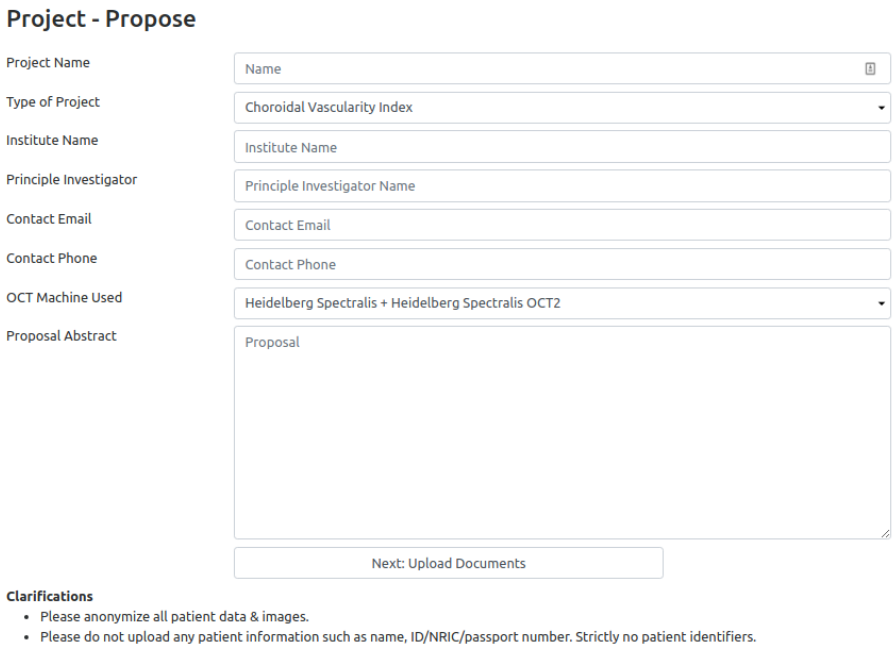


4. Propose a Project

From the top menu – drop down on Grid. Click propose new project

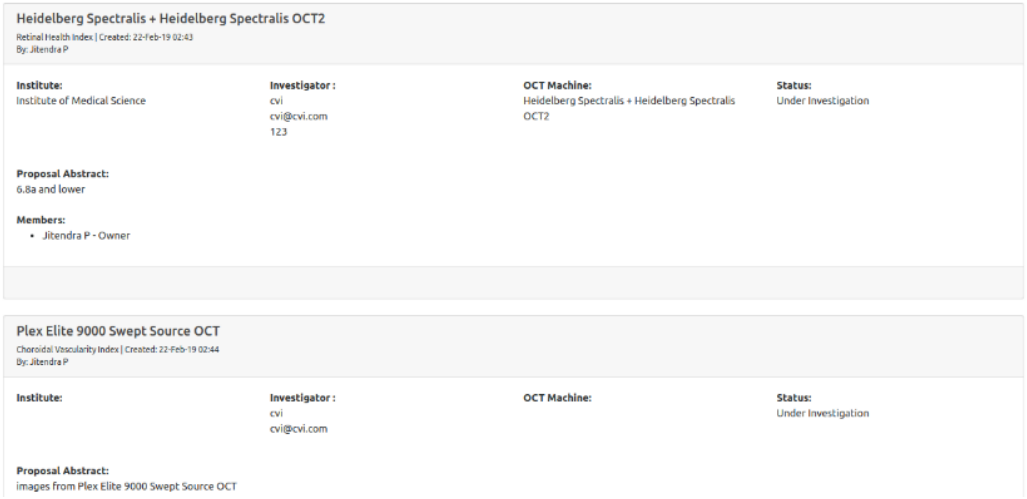


5. Fill-up the following form and upload the required documents. When all documents are reviewed, the project will be approved. Following such you will be allowed to uploaded images, study protocol, institutional ethics approval and other documents. Please anonymize image to mask any patient information.

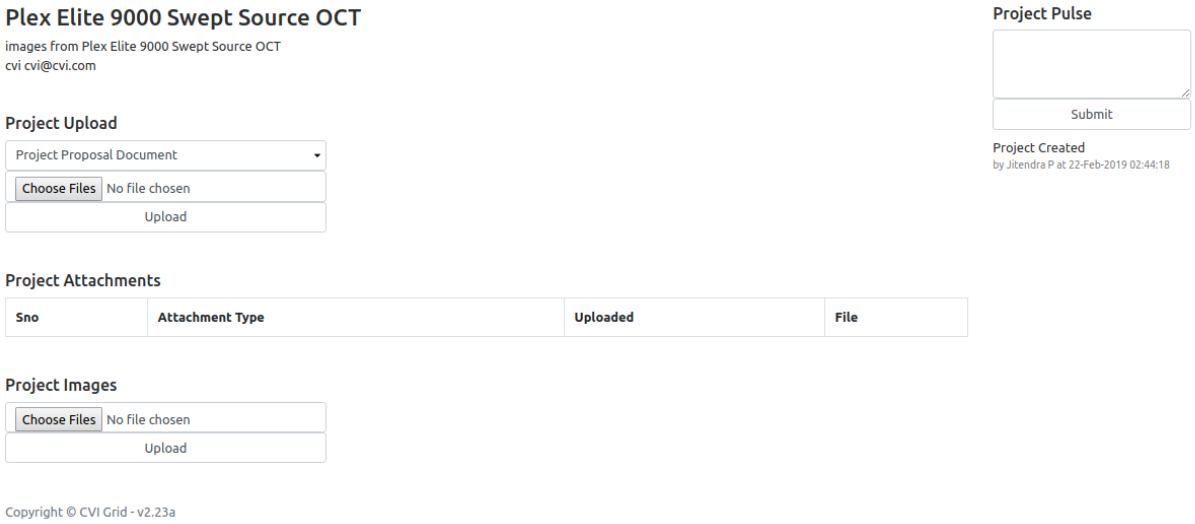


6. Participating in an ongoing project

Click on Choroidal Vascularity Index from the Grid Menu to see the list on ongoing projects, you may view available project details and comment to offer collaboration.



7. To upload your own data after approval. Click on your project name in the project list, and upload all necessary documents/data/images. Excel data sheet shall not be uploaded onto portal.



Annexure 1: Frequently Asked Questions

1. What is the cloud platform being used for this project?

The cloud platform used is Amazon Web Service (AWS) Cloud Platform.

2. Will all data be de-identified?

Yes. Patient identifiers will not be collected (such as name, social security number, date of birth etc.). The data entry personnel will be responsible for anonymizing the patient's identity on both OCT image and excel data sheet.

3. How is the data secured/encrypted?

CVIGrid.org uses TLS 1.2/SSL encryption and is access over https for all the functionalities. The data and the

platform are hosted securely on Amazon Web Services cloud.

4. What are the risks to patients in this study?

Depending on the proposed study. But CVI analysis itself does not inflict any physical harm on the patient.

5. Who are the study subjects?

Depending on the proposed study. Generally, CVIgrid studies can include any patient with OCT images taken.

Annexure 3: Handbook Acknowledgement

Disclaimer

CVIgrid head PI and administrators shall not be held responsible for any abuse of system, or upload of non-anonymized patient data that breaches personal data protection act. All members are to be responsible for their own actions and uploading of content. All members are to strictly protect patient confidentiality, by avoiding the sharing of any patient identifiers.

By signing the document in Annexure 2, you agree with all statement and clause stated in this document, including the disclaimer. You will be responsible for your own actions of uploading, CVIgrid administrators and head PI shall not be responsible for any events and their consequences. **I have read and agree to the guidelines stated in this CVIgrid Handbook. I will maintain confidentiality of this agreement and projects. Upon signing of this handbook, I agree to have my signature transferred to a master document for documentation. The content of this handbook is consistent between the signed and master document.**

SN	Name	Country	Signature	Date
1	A/P Adrian Koh	Singapore		
2	Dr Alenka Lavric	Slovenia		
3	Adj Asst/P Alessandro Invernizzi	Italy		
4	Dr Anadi Khatri	Nepal		
5	Asst/Prof Andrés Rousselot	Argentina		
6	Dr. Aniruddha Agarwal	India		
7	Dr. Awanish Upadhaya	India		
8	Dr Carlos Pavesio	UK		
9	Asst/P Cheung Yim Lui Carol	Hong Kong		
10	Dr Chaitra Jayadev	India		
11	A/P Chieko Shiragami	Japan		
12	Dr. Chitaranjan Mishra	India		
13	Dr Cyrus Shroff	India		
14	Dr. Daraius Shroff	India		

15	Mr. Ding Jianbin	Singapore		
16	Dr. Dipankar Das	India		
17	Dr Ilaria Testi	Italy		
18	Dr. Lehka Gopal	Singapore		
19	Dr. Lisa Nivison-Smith	Australia		
20	Dr. Luca Cimino	Italy		
21	Dr. Lucia Finocchio	Italy		
22	Dr. Manisha Agarwal	India		
23	A/P Marion Munk	Switzerland		
24	A/P Min Hee Suh	Korea		
25	Asst/P Mohit Dogra	India		
26	Dr Neelam Kumari	Singapore		
27	Mrs. Neha Khandelwal	Singapore		
28	Dr. Pearse Keane	UK		
29	Prof Peter McCluskey	Australia		
30	Dr. Parveen Sen	India		
31	Prof Quan Dong Nguyen	USA		
32	Prof Ramasamy Kim	India		
33	Adj A/P Rupesh Agrawal	Singapore		
34	Prof S Natarajan	India		
35	Dr. Sarakshi Mahajan	USA		
36	Dr. Saurabh Luthra	India		
37	Dr. Simar Rajan Singh	India		
38	Honorary Clinical A/P Timothy Lai	Hong Kong		
39	Prof Vishali Gupta	India		
40	Dr. Wei Xin	Singapore		

*Name of new members will be added accordingly. Signatures will be obtained after potential members agree to the policies and clauses in this document.

References

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