International Globe and Adnexal Trauma Epidemiology Study (IGATES)

Study Handbook Version 3.0

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Link to the IGATES platform: https://igates.oculartrauma.com

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1.0 PROJECT OVERVIEW

1.1 WHAT IS THE PURPOSE OF IGATES?

Traumatic eye and facial injuries encompass a significant proportion of all patients presenting to emergency departments[1]. Ocular trauma is associated with considerable morbidity and healthcare-associated costs[2,3]. The ability to predict and anticipate outcomes in patients with ocular trauma is critical to developing eye injury prevention strategies and appropriate treatment plans, as well as to advise and counsel patients.

The Birmingham Eye Trauma Terminology System (BETTS) and Ocular Trauma Score (OTS) have been widely adopted internationally since they were published and remain the benchmark for classification of ocular trauma. Whilst the current OTS has significantly contributed to reducing the ambiguity about classification and assisted the prediction of outcomes for most open globe trauma, there remain some limitations and controversies.

This includes the exclusion of adnexal injuries from the score. Further examples include whether the significance accorded to presenting VA is justifiable, and whether RAPD is an absolute biomarker for the patient's final visual outcome. First developed in early nineties, it is not known if BETTS and OTS accurately reflect current state of art trauma practice and outcome. In clinical practice, the BETTS and OTS classifications can be difficult as not all data is collected. We aim to build on the valuable aspects of the existing BETTS and OTS to build a more robust model incorporating a wider range of relevant markers relating to the outcome.

The primary aim of the International Globe and Adnexal Trauma Epidemiology Study (IGATES) is to use cloud computing and big data analytics to develop a prognostic classification system for ocular trauma through international collaboration. This score will serve to develop strategies to prevent ocular trauma and mitigate its consequences. Using big data analytics, cloud computing and machine learning, we aim to propose robust model incorporating a wider range of relevant markers relating to the outcome.

Specifically, we aim to:

    i.   Identify the factors affecting the outcome of open globe and adnexal injury (ophthalmic trauma).

    ii.   Develop a revised prognostic classification system for ophthalmic trauma.

    iii.   Conduct a large multicentre retrospective review of ophthalmic trauma utilising the revised "Ophthalmic Trauma Score" (OTS-2).

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[1] Yadav K, Cowan E, Wall S, Gennis P. Orbital fracture clinical decision rule development: burden of disease and use of a mandatory electronic survey instrument. Acad Emerg Med 18:313-316, 2011.

[2] Ko MJ, Morris CK, Kim JW, et al. Orbital fractures: national inpatient trends and complications. Ophthal Plast Reconstr Surg 29:298-303, 2013.

[3] Beshay N, Keay L, Watson SL, et al. The epidemiology of Open Globe Injuries presenting to a tertiary referral eye hospital in Australia. Injury; 2017. 48(7);1348-54.

1.2 IGATES PHASES

IGATES will compromise of **three** distinct phases:

PHASE 1: CREATION OF THE IGATES REGISTRY

Phase 1 will involve the collection of multicentre data on first contact information of patients presenting with ophthalmic trauma using the IGATES platform.

PHASE 2: IGATES-1

IGATES-1 will be a *retrospective cohort study*. The focus of this study will be on the collection of data over a 24-month period of patients presenting with ocular trauma between 2000-2020 at participating centres. Data analysis will be conducted in the following 6 months. The findings from IGATES-1 will be used to design key elements of the Ophthalmic Trauma Score (OTS-2), which will be validated in the a prospective study in next phase, IGATES-2.

PHASE 3: IGATES-2

IGATES-2 will be a *retrospective and prospective longitudinal study*. This study will provide extensive data relating to the factors affecting the outcome of open globe injury and repair. IGATES-2 will collect the data of patients with ophthalmic trauma for a 5-year period from commencement. It is anticipated to provide the largest data set of outcomes from globe and adnexal trauma from centres internationally to date.

1.3 COLLABORATING ORGANISATIONS

IGATES is a collaborative effort by the Asia Pacific Ophthalmic Trauma Society (APOTS), International Society of Ocular Trauma (ISOT), Chinese Ocular Trauma Society (COTS), Ocular Trauma Society of India (OTSI), PAN American Association of Ocular Trauma, All India Ophthalmological Society and American Society of Ophthalmic Trauma.

SITE COLLABORATORS

Argentina: Dr. Andrés Rousselot

Australia: Ms. Annette Hoskin

Southern India: Dr. Kim Ramasamy, Dr Chitaranjan Mishra, Dr. Chaitra Jayadev, Dr. Giridhar Anantharaman, Dr. Vanashree Nair, Dr. Apoorva Ayachit

Northern India: Prof. Namrata Sharma, Dr. Shakeen Singh, Dr. Ashok Grover

Central India: Prof. Rekha Khandelwal, Dr. Alok Sen

China: Prof. Feng Yun

East India: Dr. Kasturi Bhattacharjee, Dr Vatsalya

West India: Prof. Mehul Shah, Prof. S Natarajan

Columbia: Dr. Hugo H Ocampo

Indonesia: Dr. Yunia Irawati, Dr. Shanti F Boesoirie

Iran: Dr. Mohammad Soleimani

Malaysia: A/Prof. Tengku Ain Kamalden

Mexico: Dr. José Dalma

Nepal: Dr. Eli Pradhan, Dr. Anadi Khatri, Dr Meenu Chaudhary

Singapore: Prof. Gangadhara Sundar, A/Prof. Rupesh Agrawal

Thailand: Prof. Paisan Ruamviboonsuk

USA: Prof. Ferenc Kuhn, Prof. Prem S. Subramanian, Col. Mark Reynolds, Prof Fasika Woretta, Dr Grant Justin, LTC Marcus Colyer

2.0 KEY PARTICIPANTS

2.1 STUDY MENTORS:

Prof. Ferenc Kuhn, USA

Prof. Hua Yan, China

Prof. S Natarajan, India

Prof. Prof Prem Subramanian, USA

Prof. Gangadhara Sundar, Singapore

2.2 STEERING COMMITTEE:

A/Prof. Rupesh Agrawal, Singapore

Ms. Annette Hoskin, Australia

A/Prof. Fasika Woreta, United States

Dr. Parveen Sen, India

Dr. Andrés Rousselot, Argentina

Prof. Stephanie Watson, Australia

Dr. Kim Ramasamy, India

Dr. Yunia Irawati, Indonesia

Dr. Tengku Ain Kamalden, Malaysia

Dr. Eli Pradhan, Nepal

2.3 WEB PLATFORM AND BIG-DATA PROTOCOL ADMINISTRATORS:

Mr. Sean Ng, Singapore

Dr. Rebecca Low, Singapore

Mr. Dhananjay Raje, India

3.0 INSTITUTIONAL REVIEW BOARD APPROVAL

3.1 INSTITUTIONAL REVIEW AND ETHICS APPROVAL

The IGATES protocol requires all participating sites to obtain approval from their local Institute review boards (IRB) and/or equivalent ethics review boards prior to the usage of data for research purposes. Each site shall provide a final copy of the ethics approval to A/Prof. Rupesh Agrawal. However, you may begin uploading data prior to obtaining ethics approval and/or signing the IGATES agreement. However, during the period prior to ethics approval and/or signing of the IGATES agreement, the data that you have uploaded cannot be used for research purposes. Where the local IRB dictates that ethics clearance is not required for retrospective data entry, a letter has to be obtained from the local IRB and provided to the IGATES team for record purposes. It is required that the ethics approval include the same title for all centres and contain the IGATES web-based data aggregation platform link.

3.2 DATA SECURITY

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 IGATES study is HIPAA compliant. All data entered will be encrypted and will only be accessible by the steering committee. 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. All data involved at each site location should be stored in password-protected medium or kept secure under lock and key.

For more information about patient confidentially and ethics approval, please see Annexure 1: "Frequently Asked Questions (FAQ)" or contact the support team at: **support@oculartrauma.com**

3.3 DISCLAIMER

By participating in this study, all site principal investigators (PI) have confirmed that:

1. 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.

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

3. Data entry personnel of each participating centre are responsible for the data quality and for anonymising data entered, according to the study protocol, and will ensure that no data is entered (including images) that contain patient identifiers.

4. The steering committee will not be held responsible for any errors in data entry or any non-anonymised data.

5. The steering committee will have access to the data entered beyond the study period for research purposes and data will be shared with third-party statisticians for complex data analysis.

4.0 AUTHORSHIP POLICY

4.1 PRIMARY MANUSCRIPTS

Primary manuscripts (primary reports of the epidemiology, clinical features, mortality, incidence of complications, and outcomes) will have all the IGATES participating members listed as contributing authors under the IGATES group as per ICMJE guidelines.

Key members from the Steering Committee members (based on contribution) will be the named authors in the manuscripts. Dr. Rebecca Low, Mr. Sean Ng or Ms. Annette Hoskin (based on contribution) will be the default first authors and A/Prof Rupesh Agrawal will be the lead corresponding author. Depending on the contribution from the members of the IGATES group to data collection, data analysis and/or manuscript preparation, members will be added as named authors to manuscripts, subject to the 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 IGATES group. The names of all the participating centres will also be acknowledged in primary manuscripts.

Any participating centre can approach the Steering Committee to lead the authorship as first author or corresponding author of any additional proposed manuscript utilising the complete database. The biostatistician(s) conducting the analysis may also be included as a co-author. Other co-authors may be included following approval by the Steering Committee.

4.2 SECONDARY MANUSCRIPTS

Secondary manuscripts shall be considered as manuscripts containing single site or country data. Other ("secondary") manuscripts can be initiated by any centre. There are no limitations on who may serve as first author for a secondary manuscript (e.g., a core investigator, a fellow, a resident, another faculty member). Non-primary manuscripts must be proposed and approved by the study Steering Committee. It is anticipated that approval typically will be granted, but that going through the approval process will avoid duplication of effort, will facilitate allocation of (limited) central resources (e.g., biostatistician support) to individual projects, and may improve the quality of the proposed design of the analysis to be conducted. After approval to write a manuscript is obtained, the manuscript must be submitted within twelve months, or approval to write the manuscript may be revoked, at the discretion of the Steering Committee.

Named authors will include: the primary writer of the manuscript (first author), the statistician conducting the analysis for the paper (if applicable), the lead PI of the participating centre (corresponding author), members from the Steering Committee based on contribution and the IGATES study group (as per ICMJE guidelines). Additional authors may be named with approval of the Steering Committee when appropriate. Unless agreed otherwise, the "senior author" (listed last in the named authors list) will be the person who takes on primary responsibility for assuring the quality and completion of the project. Usually, this person will be the sponsor, but another could fulfill this role when appropriate. 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 to the manuscript, and is subject to

approval by the Steering Committee based on the guidelines above. At the time the manuscript is circulated for final approval, co-authors will have two weeks to respond with their suggestions and sign-off authorship documents. Those who do not respond will be omitted from authorship for that manuscript and acknowledged as contributors.

IGATES imposes no restriction upon a centre's reporting of its own data. Each centre may conduct chart review studies in the same manner as if they were not participating in the IGATES project. Any site may request data contributed from the site to the IGATES platform to be provided back to the centre for the study team to report its own data. Data will be returned in excel format within 2 weeks of receipt of this email request.

5.0 MEETING PRESENTATION POLICY

5.1 ABSTRACTS

Abstracts must be circulated to all co-authors at least 2 weeks ahead of submission so that they have an opportunity to comment before submission. 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) Final tables and figures are completed; 2) Draft manuscript is completed (outlined Discussion is acceptable).

5.2 CONFERENCE PRESENTATION AUTHORSHIP POLICY:

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 IGATES group in order to meet the guidelines and instructions of the conference. However, all authors must be acknowledged in the talk or poster as members of the IGATES group and contributing authors to the study.

Note: Consult the study PI regarding authorship order prior to circulating abstracts.

6.0 DATA ENTRY

6.1 INCLUSION AND EXCLUSION CRITERIA

Criteria	Details
Inclusion	The study will include all patients with a history of eye trauma, presenting: • For retrospective: from year 2000 onwards • For prospective: within the current or previous month
Exclusion	There are no specific exclusion criteria.

6.2 IGATES PLATFORM

Data will be collected on the IGATES platform, which can be found at the following link: https://igates.oculartrauma.com. The platform collects data regarding patient demographics, injury details", baseline variables, findings at follow-up visits and the final anatomical and visual outcome. If you would like to upload photographs, scans or documents of the patient onto the platform, you may also do so. This method of computerised data collection will help eliminate heterogeneity of data between the participating centres. Records on the patient registry can be saved and revisited at any time on the site itself.

The IGATES team will provide training sessions on the entering of data to all participating users. If at any point you have any doubts, you may refer to "IGATES Platform Guide" below for a pictorial guide on how to enter data into the system, or direct questions to us at support@oculartrauma.com. Random audits will be undertaken to ensure quality of the data, and the site investigator will be contacted if any revisions regarding the data are required.

6.3 DATA CONFIDENTIALITY

All data entered into the IGATES patient registry should not contain any patient identifiers or sensitive information. The data entry personnel of each site will be responsible for anoymising patients' data.

The user's access to the Patient Registry on IGATES depends on the account type:

- **Normal Users** will only be able to view and access the records that they uploaded onto the patient registry.
- **Site Administrators** will be able to view and access all records uploaded by users from their centre. You will not be able to view records uploaded by users from other centres unless a request has been made and permission sought.
- The **Site Super-administrator** will be able to view and access all records uploaded to the Patient Registry.

6.4 IGATES PATIENT CODE AND SEARCH INDEX ID

The **Search Index ID** is a safety feature of the IGATES platform designed to protect the platform from potential data leaks. When you create a new entry on the Patient Registry, the IGATES platform will automatically create a **Patient Code**, such as the one below:

Example of auto-generated Patient Code on IGATES	Type of Study: P = Prospective R = Retrospective	→ P0022-0002 ←	Number of Entry

Site ID

However, you are highly encouraged the create a **separate Search Index ID** and archive the actual patient identifiers with the search index ID on a **separate excel chart** on a password-protected computer in your institute.

Please **do not include patient identifiers within the Search Index ID (**for example, but not limited to, details such as their names, dates or birth or personal identification number). You may include patient initials in the Search Index ID, but this practice is not encouraged. Please also avoid using your centre's actual hospital record number of the patient.

The Search Index ID may be up to 12 characters long. An example of what you can set your Search Index ID as is: TTSH_0001

IGATES: FREQUENTLY ASKED QUESTIONS

1. WILL ALL DATA BE DE-IDENTIFIED ON IGATES?

Yes. Personal identifiable data will not be collected on the IGATES platform (such as name, social security number, date of birth etc.). The data entry personnel will be responsible for anonymizing the patient's identity by assigning a "Search Index ID" to the patient.

2. WHAT TYPE OF DATA WILL BE COLLECTED?

The data collected will include demographic details, circumstances and mechanism of injury, object causing injury, laterality, type of open globe injury, type of adnexal or orbital injury, clinical findings, investigations, treatment and surgical interventions, complications, and visual outcome. Clinical images will also be collected in some cases. Follow-up data will be collected for a period of 24 months following injury. For patients with bilateral eye injury, data will only be collected for the more severely injured eye, defined as the eye with the worse visual acuity at presentation. Clinical findings at presentation include details of the cornea, sclera, iris, lens, vitreous, retina, choroid and optic nerve. Details related to adnexal and orbital injuries will also be recorded. These include lid lacerations, lacrimal drainage apparatus involvement, extra ocular muscle involvement, orbital wall fracture, infraorbital paresthesia and Hertel's measurement. Involvement of the central visual axis and time taken from injury to presentation is recorded. Follow-up variables includes BCVA, number and type of surgeries done and clinical examination findings. Investigations include ultrasound B-scan, electro-diagnostics, ultrasound biomicroscopy, X-ray of face/orbit, and CT or MRI face/orbit/brain. These investigations help confirm the presence or absence of intraocular foreign bodies, posterior segment pathology that could not be visualized on slit-lamp biomicroscopy and other orbital and non-ophthalmic injuries.

The main dependent variable representing visual outcome is the final best corrected visual acuity (BCVA) which is taken at the latest follow up the patient attended, in the absence of any new injury or unrelated ocular/ophthalmic condition.

3. HOW ARE GLOBE INJURIES CLASSIFIED IN OUR STUDY?

The classification for type of open globe or closed globe injury is in accordance with the Birmingham Eye Trauma Terminology System (BETTS).

Open globe injuries involving full thickness wound of the eye are classified into rupture or laceration (penetrating, perforating or intraocular foreign body).

Closed globe injuries not involving full thickness wound of the eye are classified into contusion or lamellar laceration.

4. HOW WILL THE STATISTICAL ANALYSIS BE DONE?

Analysis of data will be performed after the period of data collection. Our statisticians will employ sophisticated statistical tools and machine learning tools to create the OTS-2. Initial statistical analysis will involve descriptive statistics (frequencies, mean, median, mode, standard deviation), univariate and multivariate analysis and survival analysis with the dependent variable being the final best corrected visual acuity (BCVA).

5. WHEN MAY I START UPLOADING DATA ONTO IGATES? DO I HAVE TO WAIT FOR ETHICS APPROVAL BEFORE I CAN BEGIN UPLOADING DATA?

You may begin to upload data onto the IGATES platform before the ethics approval has been given and before the agreement has been made.

During the period before the ethics approval and agreement are done, IGATES users will not be allowed to access or extract the data that you have uploaded.

6. IS THE UPLOADING OF IMAGES MANDATORY?

The uploading of clinical photographs, diagrams or documents are not mandatory but supplementary.

7. FOR PATIENTS THAT FALL UNDER THE PROSPECTIVE GROUP, ARE THERE ANY PROTOCOLS THAT ONE SHOULD FOLLOW IN TERMS OF WHEN TO FOLLOW-UP?

There is no fixed protocol for how patients should be followed up.

8. WHAT TYPES OF EYE INJURIES MAY I UPLOAD ONTO IGATES?

The details of patients with all kinds of ocular trauma (e.g., open globe, closed globe chemical injury etc.) can be uploaded onto IGATES.

9. IF A PATIENT WHO COMES IN WITH ENDOPHTHALMITIS AND A HISTORY OF OCULAR TRAUMA ONE OR TWO MONTHS AGO, SHOULD WE CATEGORIZE THIS PATIENT AS A RETROSPECTIVE OR PROSPECTIVE CASE?

Prospective. You should categorize a patient in the prospective group as long as the patient has presented to you in the current or previous month.

10. MANY OCULAR TRAUMA PATIENTS PRESENT IN EMERGENCY SITUATIONS. AS SUCH, SOME PATIENTS MAY NOT GET WORKED UP THOROUGHLY AND AS A RESULT THERE MAY BE SOME DATA POINTS LEFT EMPTY. WILL THIS BE AN ISSUE FOR DATA QUALITY?

It is understandable that sometimes one may not be able to comprehensively fill up all data points in an emergency setting.
You may select the "Not assessed" option first if the situation is time urgent.
Later on, when the patient is more stable and you are able to assess them, you have the option of going back to edit the record and fill in missing data points.
Even if certain data points are missing in records, we can analyse the records with incomplete data separately. Therefore, it is still very useful to upload the records of these patients.

11. IS THERE A MAXIMUM NUMBER OF USERS THAT SITE ADMINISTRATORS CAN REGISTER ON IGATES?

No, there is no maximum number of users.

12. WHAT SHOULD I DO IF I HAD ENTERED WRONG DETAILS WHEN REGISTERING A NEW USER? (APPLIES TO SITE ADMINISTRATORS ONLY)

You will have to create a new account and notify the IGATES administrators at "support@oculartrauma.com" that you had made an error. This is so the administrator can help to disable the account where the wrong details had been entered.
There is currently no way for IGATES administrators to delete accounts. This is for accountability purposes as IGATES requires a comprehensive list of all accounts created if there is ever a case of a data leak.

13. DO I NEED TO TAKE PATIENT CONSENT BEFORE UPLOADING THEIR RECORDS ONTO IGATES?

This differs between patients categorized as retrospective or prospective.
For the retrospective group, consent is usually not required to be taken.
For the prospective group, it depends on your local ethics board if consent is required.
We will be releasing an IGATES consent form that you may use to take consent from patients categorized in the prospective group.

14. IS ATTENDING THE IGATES TRAINING SESSION MANDATORY?

Yes. Members are required to undergo a training session before they are able to upload data onto the patient registry. This is to ensure the quality of data entered.
A certificate of completion will be awarded to members who have undergone the training session.

IGATES PLATFORM GUIDE

ACCESSING THE PLATFORM

1. Go to link https://igates.oculartrauma.com
2. Click onto "Login"

3. Sign in using your provided username and password.

FORGOT PASSWORD FUNCTION

- If you had forgotten your password, you may click on the "Forgot Password" function on the login page.
- You will be directed to enter your email address, to which the

SITE ADMINISTRATORS

- The principal investigators (PI) for each centre will be given a "Site Administrator" account. You will be able to assign new users through your Site Administrator account.
- Site Administrators are also able to disable users' accounts if the user is no longer needing it.

ASSIGNING NEW USERS USING YOUR ADMIN ACCOUNT

1. Click on "Admin" and then "User"
2. Click on "Create New"
3. Enter the following details:
   a. User/Name email
   b. Name
   c. Site
   d. Role

SELECTION OF STUDY TYPE

- When selecting the type of patient record to be created, you may select either "Retrospective" or "Prospective" (see picture below).
- For prospective entries, you will only be able to select either the current or last month for the "Month/Year of Presentation". Patients that presented before this duration should be regarded as a retrospective entry.

SEARCH INDEX ID

- The Search Index ID is a safety feature of the IGATES platform designed to protect the platform from potential data leaks.
- When you create a new entry on the Patient Registry, the IGATES platform will automatically create a Patient Code, such as the one below.

- However, you are highly encouraged the create a separate Search Index ID and archive the actual patient identifiers with the search index ID on a separate excel chart on a password-protected computer in your institute.
- Please do not include patient identifiers within the Search Index ID (for example, but not limited to, details such as their names, dates or birth or personal identification number).
- You may include patient initials in the Search Index ID, but this practice is not encouraged.
- Please also avoid using your centre's actual hospital record number of the patient.
- The Search Index ID may be up to 12 characters long.
- An example of what you can set your Search Index ID as is: TTSH_0001

MANDATORY FIELDS

- Mandatory fields are marked with an "*" (example below).
- You will need to fill up all mandatory fields before you are able to save the page and proceed to the next.

P0022-0002

Last Updated by seanngms@gmail.com at 18-Apr-21 04:43

Presented:	Patient:	Eye:

Show more / less

Search Index ID *

P0022-0002

Please archive the actual patient identifiers with the search index ID on a separate excel chart on a password-protected computer in your institute

Gender *

● Male ○ Female

Age *

60 years ▾

Duration (hours) from time of injury to time of presentation

5 ⌄

Month/Year of Presentation *

March-2021

SAVE FUNCTION

- It is important to click on the "Save" button before proceeding onto the next page.
- If you do not click "Save" before proceeding, the data that you had entered on the page will be lost.

Make a selection of the Race *

Asian ▾

Sub Race (Asia) *

Chinese ▾

Significant Past Medical History *

○ Yes ● No ○ Unknown

Significant Past Ocular History *

○ Yes ● No ○ Unknown

Save

IGATES Data Collection Form – Version 1.1

SEARCH FUNCTION

- If you wish to retrieve a particular record, you may find it using the search function (see box below).
- You may utilize either the Search Index ID that you created or the platform's automatically generated Patient ID in order to find the record.

Patient Registry

Search 🔍   + Create New

1-13 of 13 records

- Using the search bar, you may search the following, or a combination of the following parameters:
  - Patient Code
  - Search Index ID
  - Race
  - Date of Presentation
  - Mechanism Type
  - Mechanism Object
  - Type of Injury OS/OD
  - Open Globe Type OS/OD
  - Closed Globe Type OS/OD
  - Zone of Injury OS/OD
  - BCVA OS/OD
- To search a combination of parameters, simply enter a space in between the two parameters (example seen below).

IGATES Ophthalmic Trauma Registry
International Globe & Adnexal Trauma Epidemiology Study

Home   Admin ▾   Sean Ng 👤 ▾

Patient Registry

metal zone 1 🔍   + Create New

1-13 of 13 records

EXTENSION BOXES

- You will notice that throughout the platform, extension boxes may appear if you click "Yes" on some questions (see arrow below).
- This is so that more specific data can be entered into the registry.
- If the extension box includes tick boxes (such as in the example below), you may select more than one option if required.

Significant Past Medical History *

◉ Yes   ○ No   ○ Unknown

Medical Hitory
Tick all that apply

☑ Diabetes

☑ Hypertension

☐ Blood dyscrasias

☐ Other ✓

INDICATOR FOR COMPLETION OF PAGE

- After you have completed all mandatory fields within a page and press "Save", the marker beside the page menu will turn green (example below).
- If you have not yet completed a page, the marker will remain red.

"EYE NOT ASSESSED" FUNCTION

- When you click the "Baseline" page, you will notice that the default option selected will be the "normal" option. This is designed to make it easier for the filling as forms as you will only need to actively change options for areas where pathology is found.

- If you did not assess a particular parameter, you may select the "Not Assessed" option for that individual parameter.
- However, if you had not assessed an entire eye (e.g., right eye), you may click on the "Eye Not Assessed" button (see arrow below) at the top of the column. This will change the selected option for all parameters for that eye to "Not Assessed".
- If you wish to return all options back to normal, simply click the ""Eye Not Assessed" button again to do so.

DEFINITIONS OF DIFFERENT OPTIONS IN "BASELINE" PAGE

- Not assessed: Examination was not done and hence you were not able to comment on that particular finding.
- Not able to Assess: Examination was attempted but you were not able to comment on the particular finding due to certain limitations. For example, you attempted to assess the cornea for corneal injury but was not able to visualize it properly due to severe eyelid swelling.
- Unknown: Finding not recorded in the file, or history not available.

OPEN GLOBE ZONES IMAGE POP-UP FUNCTION

- When entering data in the "baseline" page for an open globe injury, you may notice a red information icon in the "Open Globe Zones" section. Hover your cursor over the icon for the image of the different zones to appear.

Open Globe Type *

Perforating ▾

Open Globe Zones ⓘ

Injury Zone *

Not Assessed ▾

Patient underwent Surgery *

○ Yes   ● No   ○ Unknown

Open Globe Type *

Perforating ▾

Open Globe Zones ⓘ

ZONES
I 🟨
II 🟥
III 🟦

Zones for open globe injury. Zone I, wound involves only cornea. Zone II, wound extends into anterior 5 mm of sclera. Zone III, wound involves sclera extending more than 5 mm from the limbus.

I.   Cornea and limbus
II.   Limbus to 5 mm posterior into sclera
III. Posterior to 5 mm from the limbus

AUTOMATED BETTS OCULAR TRAUMA SCORE AND VISUAL ACUITY PROGNOSIS CALCULATOR

IGATES Ophthalmic Trauma Registry
International Globe & Adnexal Trauma Epidemiology Study

P0022-0006

Last Updated by seanngms@gmail.com at 24-Apr-21 08:32

Presented:	Patient:	Eye:
March-2021	Female 17 years	Left

Click here for Summary Page with Calculated BETTS OTS and VA Prognosis

Search Index ID *

P0022-0006

Please archive the actual patient identifiers with the search index ID on a separate excel chart on a password-protected computer in your institute

Gender *
○ Male   ● Female

Age *
17 years ▾

Month/Year of Presentation *
March-2021

After completing the pages for demographics, injury details and baseline, you may click on the "Show more/less" to access the automated BETTS Ocular Trauma Score and Visual Acuity Prognosis Calculator.

IGATES Ophthalmic Trauma Registry
International Globe & Adnexal Trauma Epidemiology Study

P0022-0006

Last Updated by seanngms@gmail.com at 24-Apr-21 08:32

Presented: March-2021	Patient: Female 17 years	Eye: Left

Click here for Summary Page with Calculated BETTS OTS and VA Prognosis

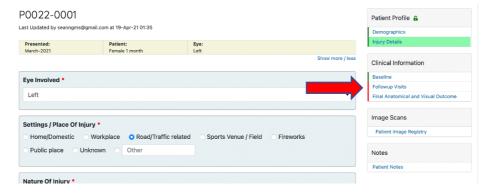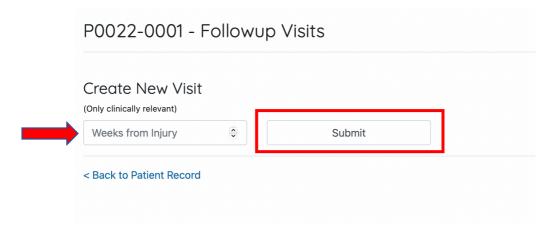| Injury Classification LE
Open Globe Injury
Type:IOFB
Grade:BCVA 20/25 (6/7.5)
Pupil (RAPD): Yes
Zone Zone 1
Mechanism: Sharp Wood | Treatment LE
Primary globe
repair,IOFB
removal | BETTS Ocular Trauma Score (OTS) - LE
1. Eye Left, BCVA 20/25 (6/7.5), Score: 10
2. Globe rupture Score: 0
3. Endophthalmitis Score: 0
4. Perforating Score: 0
5. Retinal Detachment Score: 0
6. RAPD Score: -10
Total OTS: 90 | **6months VA Probability**
NPL   1%
HM   2%
1/200-19/200   2%
20/200-20/50   21%
>=20/40   74% |

Search Index ID *

P0022-0006

Please archive the actual patient identifiers with the search index ID on a separate excel chart on a password-protected computer in your institute

The IGATES platform provides you with a summary of the case, and automatically calculates both the BETTS Ocular Trauma Score and the Visual Acuity Prognosis based on your entered data.
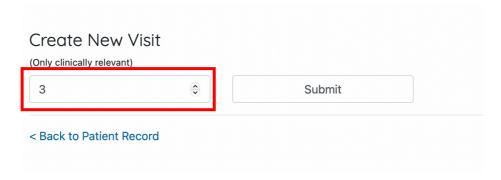

FOLLOW-UP VISITS

- You can upload details regarding follow-up visits onto the IGATES platform as well. To do so, start by clicking on the "Followup Visits" page (see arrow below).

P0022-0001
Last Updated by seanngms@gmail.com at 19-Apr-21 01:35

Presented: March-2021	Patient: Female 1 month	Eye: Left

Show more / less

Eye Involved *

Left

Settings / Place Of Injury *

○ Home/Domestic   ○ Workplace   ● Road/Traffic related   ○ Sports Venue / Field   ○ Fireworks
○ Public place   ○ Unknown   ○ Other

Nature Of Injury *

Patient Profile 🔒

Demographics
Injury Details

Clinical Information

Baseline
Followup Visits
Final Anatomical and Visual Outcome

Image Scans
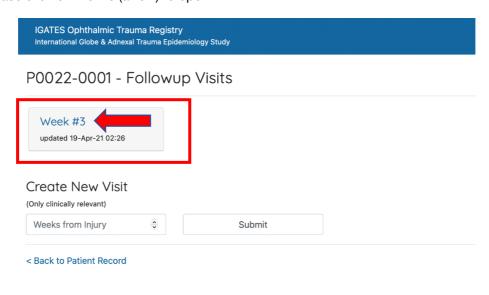
Patient Image Registry

Notes

Patient Notes

- This will bring you to the page below.
- Follow-up visits that are included should only be those that are clinically relevant.
- Although the IGATES platform allows you to add an unlimited number of follow-up visits, you are strongly encouraged to keep to a maximum number of four.
- To create a new visit, enter the number of weeks you are seeing the patient since their injury (arrow) and click submit (box).
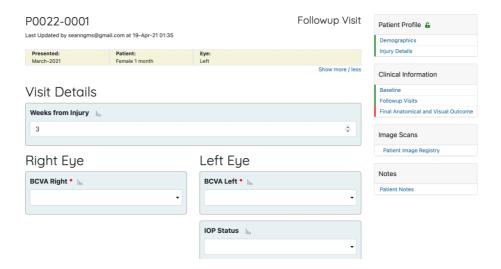
P0022-0001 - Followup Visits

Create New Visit
(Only clinically relevant)

- In this example, we are submitting the number of weeks from injury as "3" (see box below).

Create New Visit
(Only clinically relevant)

- After submission, you should see the file for the respective follow-up visit appear at the top half of the screen (box).
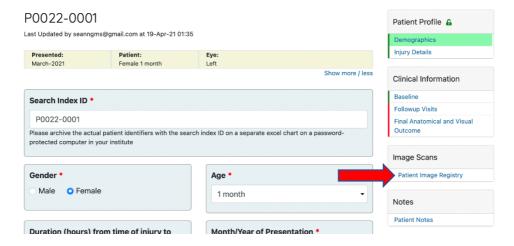- Please click on the file (arrow) to open it.

- After opening the page, you may enter all the relevant details accordingly.
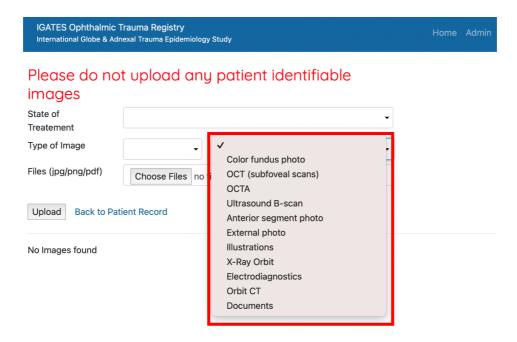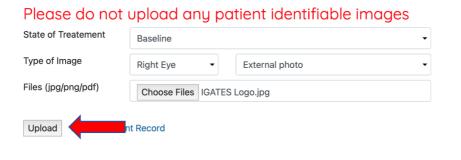
PATIENT IMAGE REGISTRY

- You may upload files such as clinical photographs, scans, illustrations or documents of the patient onto the IGATES platform through the Patient Image Registry (see arrow below).
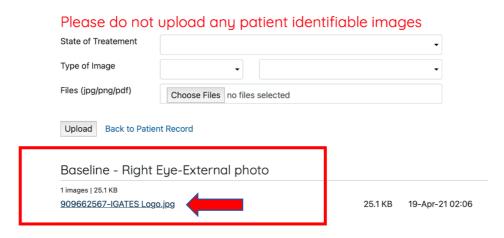

- The types of files that may be uploaded onto the Registry are shown below.
- When uploading files, please avoid uploading patient identifiers that can be seen within the file. If patient identifiers are found on the file, please ensure you crop or blur those areas out before uploading it.

- Once you input the various fields and select your document, click "Upload" (see arrow below)

- After clicking upload, your file will be shown at the bottom half of the page (see box below). The file will be labeled with the inputs that you had entered previously. For example, this file has been labelled as "Baseline – Right Eye – External Photo).
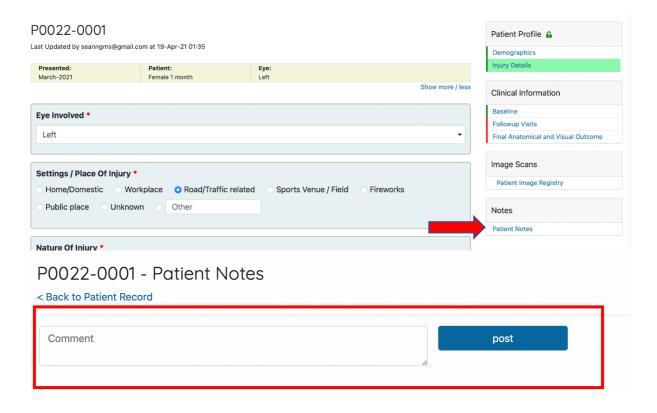- You may then click on the file's link (see arrow below) to open it up.

- You will be brought to the page below after clicking the file's link.
- In this page, you may input Comments and Key Findings of the file. You may also choose to delete the image if you had selected the wrong file or if you no longer want to keep it.
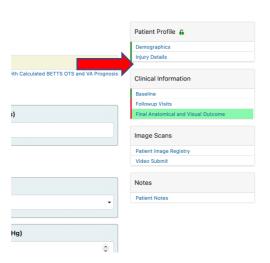
IGATES Logo.jpg
19-Apr-21 02:06 | 25.1 KB

Go Back Prev Next

Comments & Key Findings

[ ] post

Image Uploaded
seanngms@gmail.com 19-Apr-21 02:06
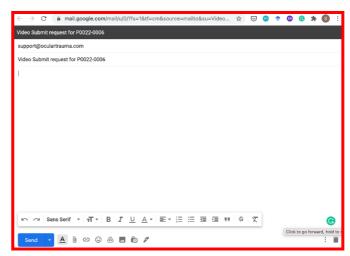
Delete

PATIENT NOTES

- Under the Patient Notes page (see arrow below), you may enter any specific free text write up regarding the patient that you feel was not covered in the form but is still clinically relevant to the case.

P0022-0001

Last Updated by seanngms@gmail.com at 19-Apr-21 01:35

Presented:	Patient:	Eye:
March-2021	Female 1 month	Left

Show more / less

Eye Involved *

Left

Settings / Place Of Injury *

○ Home/Domestic ○ Workplace ● Road/Traffic related ○ Sports Venue / Field ○ Fireworks
○ Public place ○ Unknown ○ Other

Nature Of Injury *

Patient Profile 🔒

Demographics
Injury Details

Clinical Information

Baseline
Followup Visits
Final Anatomical and Visual Outcome

Image Scans

Patient Image Registry

Notes

Patient Notes

P0022-0001 - Patient Notes

< Back to Patient Record

Comment

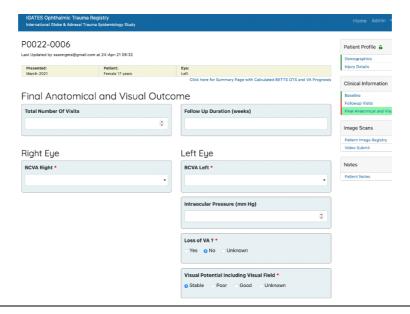post

30

UPLOADING OF VIDEOS

- If you are interested in submitting a video (e.g., video of clinical findings, surgical video), you may click the "Video Submit" tab (see arrow below).
- As we currently do not have a function allowing users to individually upload videos directly onto the IGATES platform, users will have to contact the IGATES team to do so.
- Clicking on the "Video Submit" tab will lead you to an email pop-up (see box below).
- The respective Patient Code (e.g., P0022-0006 in the example below) will automatically be inserted into the Email Subject Title, and you may then email the IGATES team to express your interest in uploading the video.
- We will then correspond with you and help you upload the video onto the IGATES platform.

FINAL ANATOMICAL AND VISUAL OUTCOME

- Before you discharge the patient from your care, please fill in the "Final Anatomical and Visual Outcome" page (seen below).

LOCKING AND ARCHIVING OF RECORDS

- After you are done filling in all the details (e.g., once you have filled in the Final Anatomical and Visual Outcome page for the patient), you may choose to lock and archive the record.
- The Lock and Archiving functions are safety features designed to prevent the editing or manipulation of patient data.
- After successfully entering the data for the "Demographics" and "Injury Details" pages, you will notice a "Lock" button appear next to the Patient Profile (see arrow below).
- Click the lock button to lock the patient entry. The button will turn red upon successfully locking the document (see example below).

- After locking your entry, only your Site Administrator will be able to unlock the data if edits need to be made.
- Once you have locked the entry, an "Archive Record" button will appear at the bottom of the screen (see arrow below).

Significant Past Ocular History *

○ Yes ● No ○ Unknown

| Save | Print | Archive Record |

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- After you have fully completed a record and no longer need to access it, your site administrator may also "Archive" the record. Once again, only the Site Administrator will be able unarchive the record.
- All activity involving the locking, unlocking, archiving or unarchiving of records will be tracked on the platform (under the patient notes page) to allow for the monitoring of suspicious activity.

DATA OWNERSHIP AND EXPORT FUNCTION

- The data that you have uploaded onto the site belongs to you.
- If at any point of time you wish to extract your data to write a manuscript, you may do so. There will be an export function where you can extract the data into an Excel sheet.
- If another centre would like to use data that your centre has uploaded onto the IGATES platform for a study, your permission will be sought before any data is shared.
- If IGATES uses pooled data (which includes data from your centre) for analysis in a study, your centre will be included in the list of contributing centres if a manuscript is published.

CREATION OF PROJECTS FROM PLATFORM DATA

- If you wish to use the IGATES platform's pooled data to start new projects, you may click on the "Share your idea" tab at the bottom of the screen on the IGATES platform (see box below).

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Contact Us | Submit Feedback | Share your Idea | FAQs

- This will lead you to an email pop-up, through which you can share this idea to the IGATES team through support@oculartrauma.com.
- Following which, permission will be requested from the various centres for the usage of their centre's data.

CREATION OF ADDITIONAL EXTENSION PAGES: INCLUSION OF ADDITIONAL PARAMETERS FOR SPECIFIC CONDITIONS

- If you would like to create Extension Pages to include more parameters eg specific types of injuries or circumstances, you are highly encouraged to do so.
- For example, if you would like to create an additional page specially for injuries of the macular, where you can add additional parameters not already included on the IGATES platform, please once again share this with the IGATES team using the "Share your idea" tab (see box below).
- We will then get into contact with you on how you may go about creating this page.

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Contact Us | Submit Feedback   Share your Idea   FAQs