REGIONE DEL VENETO
ULSS7 PEDEMONTANA
Via dei Lotti, n. 40
36061 Bassano del Grappa (VI)
Codice fiscale e partita IVA 00913430245

N. 788 DEL 12/05/2023

DELIBERAZIONE
del

DIRETTORE GENERALE

Nominato con D.P.G.R. n. 26 del 26/02/2021

Coadiuvato dai sigg.:

DIRETTORE AMMINISTRATIVO dott.ssa MICHELA CONTE

DIRETTORE SANITARIO dr. ANTONIO DI CAPRIO

DIRETTORE DEI SERVIZI SOCIO – SANITARI dott. EDDI FREZZA

OGGETTO: AUTORIZZAZIONE ALLA CONDUZIONE DELLO STUDIO CLINICO NO-PROFIT "FIGHT RETINAL BLINDNESS PROJECT - LOTTA CONTRO LE PATOLOGIE MACULARI - REGISTRO FRB"

IL DIRETTORE GENERALE
DELL'AZIENDA ULSS 7 PEDEMONTANA
dott. Carlo Bramezza

Documento informatico firmato digitalmente ai sensi del D. Lgs n. 82/2005, del T.U. n. 445/2000 e norme collegate, il quale sostituisce il documento cartaceo e la firma autografa; il documento informatico è conservato digitalmente negli archivi informatici dell'Azienda.

Proponente: UOC AFFARI GENERALI
Anno Proposta: 2023 Numero Proposta: 813/23

Il Dirigente, Direttore dell'UOC Affari Generali, nonché Responsabile del procedimento, attesta che la presente proposta di deliberazione è stata regolarmente istruita nel rispetto della vigente normativa nazionale, regionale e regolamentare: f.to Cristiano Galizian

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Il Direttore dell'U.O.C. Affari Generali relaziona quanto segue.

Premesso che:

- con deliberazione n. 1477 del 05/08/2022 è stato approvato, in aggiornamento della disciplina aziendale regolata con la deliberazione n. 453 del 28/05/2014, il Regolamento aziendale sulla gestione delle sperimentazioni cliniche profit e no-profit, comprensivo anche della regolamentazione dei fondi per la gestione della ricerca con determinazione delle quote dei fondi stessi e fissazione dei criteri per l'attribuzione dei compensi;
- con deliberazione n. 1684 del 09/09/2022 sono stati aggiornati i componenti del Nucleo per la Ricerca Clinica Aziendale (N.R.C.) ai sensi della DGRV n. 2174 del 23/12/2016.

Considerato che:

- il sistema di valutazione delle sperimentazioni cliniche di medicinali per uso umano in Europa a partire dal 31/01/2023 è stato investito da notevoli cambiamenti procedurali, mediante la prevista piena applicazione del Regolamento Europeo in materia (EU) n. 536/2014;
- il predetto Regolamento (EU) infatti prevede la centralizzazione delle procedure di autorizzazione delle sperimentazioni cliniche e delle procedure amministrative attraverso un portale informatico unico a livello europeo;
- a livello nazionale è intervenuta la Legge n. 3 dell'11/01/2018 in materia di sperimentazione clinica e in data 7 febbraio 2023 sono stati pubblicati sulla Gazzetta Ufficiale, Serie Generale n. 31, quattro decreti del Ministro della Salute attuativi della Legge 3/12018, dalla cui entrata in vigore dipende la definitiva stabilizzazione del quadro regolatorio delle sperimentazioni cliniche in Italia, così come armonizzate a livello europeo dal Regolamento (UE) n. 536/2014;
- nelle more dell'attuazione dei predetti Decreti, si applica la disciplina aziendale in vigore che verrà rivista secondo quanto definito dalla Regione del Veneto con DGR n. 330 del 29 marzo 2023.

Rilevato che:

– con nota del 06/10/2022, ns. prot. 88733 dell'11/10/2022, il Prof. Alessandro Invernizzi - Professore del Dipartimento Oculistico dell'Università degli studi di Milano "Luigi Sacco" ha invitato questa Azienda a partecipare alla sperimentazione clinica dal titolo "*Fight Retinal Blindness Project – Lotta contro le patologie maculari – REGISTRO FRB"*

SCHEDA STUDIO CLINICO

Titolo	Autorizzazione alla conduzione dello studio clinico no-profit *"Fight Retinal Blindness Project – Lotta contro le patologie maculari – REGISTRO FRB"*
Codice Protocollo	Registro FRB!
Strutture interessate	U.O.C. Oculistica P.O. Bassano
Sperimentatore Principale	dr. Ezio Cappello – dirigente medico dell'U.O.C. Oculistica del P.O. Bassano
Co sperimentatori	Dott.sse Anna Mocellin, Luisa Russo e Sara

	Crecca - Ortottiste
Promotore	Department of Ophthalmology & Eye Health University of Sydney – Professor Mark Gillies
Centro Coordinatore	Università degli Studi di Milano "Luigi Sacco" – Prof. Alessandro Invernizzi

- è stato individuato, quale Responsabile dello studio presso questa Azienda, il dr. Ezio Cappello – Dirigente medico dell'U.O.C. di Oculistica del P.O. di Bassano;
- il dr. Ezio Cappello in data 16/03/2023, ns. prot 25050 del 22/03/2023, ha chiesto la valutazione e l'autorizzazione allo svolgimento dello studio di cui sopra, inviando l'apposito modulo di fattibilità e dichiarando che lo studio verrà condotto secondo la legislazione vigente in materia.

Tenuto conto che:

- il N.R.C. Aziendale, nella sua composizione prevista dalla deliberazione n. 1684 del 09/09/2022, in data 24/03/2023 ha attestato - considerata la regolarità della documentazione presentata dallo sperimentatore - la fattibilità locale della ricerca sopra citata;
- il N.R.C. ha trasmesso, con nota prot. 29333 del 04/04/2023, al Comitato Etico per le Sperimentazioni Cliniche della Provincia di Vicenza (CESC) la documentazione necessaria per acquisirne il relativo parere;
- il Comitato Etico per le sperimentazioni Cliniche della Provincia di Vicenza (CESC) in occasione della seduta del 12/04/2023, ns. prot. 37576 del 03/05/2023, ha espresso parere favorevole all'unanimità alla conduzione dello studio.

Considerato che:

- trattasi di uno studio osservazionale no-profit, internazionale con il coinvolgimento di pazienti con diagnosi di maculopatia che vengono trattati secondo normale pratica clinica;
- lo scopo del registro FRB è quello di raccogliere dati di *real life* di alta qualità con l'obiettivo di comprendere meglio le patologie della macula, l'efficacia dei trattamenti ad oggi disponibili, comprendere i pattern di trattamento evidenziando quelli che portino ai migliori risultati terapeutici e promuovere l'educazione del paziente;
- gli obiettivi primari del registro sono quelli di valutare l'efficacia clinica, il rapporto costo/efficacia e la sicurezza delle terapie esistenti e di quelle emergenti per il trattamento delle patologie della macula con il fine ultimo di individuare i trattamenti che garantiscono l'*outcome* migliore e riducano quindi l'incidenza di cecità legale.

Per quanto sopra, il Direttore dell'U.O.C. Affari Generali, propone di autorizzare lo studio clinico no-profit dal titolo *"Fight Retinal Blindness Project – Lotta contro le patologie maculari – REGISTRO FRB"* presso l'U.O.C. di Oculistica del P.O. di Bassano, con P.I. il dr. Ezio Cappello – dirigente medico della struttura citata

IL DIRETTORE GENERALE

Vista la relazione e la proposta del Responsabile del procedimento;

Dato atto che il responsabile del Servizio competente ha attestato l'avvenuta regolare istruttoria della pratica, in ordine alla compatibilità con la vigente legislazione statale, regionale e regolamentare;

Visti:

- il decreto ministeriale 15/07/1997;

- la circolare del Ministero della Salute 02/09/2002 n. 6;
- il D.lgs 24/06/2003, n. 211;
- il decreto ministeriale 17/12/2004;
- la DGRV 28/12/2006, n. 4430;
- il decreto ministeriale 12/05/2006;
- il D.lgs 6/11/2007, n. 200;
- il decreto ministeriale 21/12/2007;
- la determinazione AIFA 20/03/2008;
- la DRGV 07/10/2008, n. 2855;
- la Legge 08/11/2012, n. 189 – Decreto Balduzzi;
- il decreto del Ministero della Salute 08/02/2013;
- la DRGV 28/06/2013 n. 1066;
- il D.M. 30/11/2021

Acquisito il parere favorevole del Direttore Amministrativo, Sanitario e dei Servizi Socio-Sanitari, per quanto di rispettiva competenza

DELIBERA

1. di prendere atto che il Comitato Etico per le Sperimentazioni Cliniche della Provincia di Vicenza (CESC) in occasione della seduta del 12/04/2023 ha espresso parere favorevole in ordine alla conduzione dello studio clinico "*Fight Retinal Blindness Project – Lotta contro le patologie maculari – REGISTRO FRB"* la cui documentazione è conservata agli atti della Segreteria del NRC;
2. di autorizzare, per quanto in premessa illustrato, lo svolgimento del predetto studio no-profit presso questa Azienda, sotto la diretta Responsabilità del dr. Ezio Cappello, Dirigente medico dell'U.O.C. di Oculistica del P.O. Bassano, in collaborazione con le seguenti dott.sse: Anna Mocellin, Luisa Russo e Crecca Sara - Ortottiste – in servizio presso la struttura citata;
3. di dare atto che il dr. Ezio Cappello e i Co-sperimentatori sopra elencati sono autorizzati a svolgere l'attività di cui sopra durante l'attività istituzionale e che nessun compenso, come da regolamento aziendale sulle sperimentazioni – deliberazione n. 1477/2022, spetterà agli sperimentatori;
4. di dare atto che lo studio clinico dovrà essere eseguito secondo quanto previsto dal protocollo di studio, dalla normativa vigente in ambito di sperimentazioni e dalle norme di buona pratica clinica (GCP) che allegato alla presente deliberazione ne costituisco parte integrante e sostanziale;
5. di dare atto che ai sensi dell'art. 8 del Regolamento aziendale sulla gestione delle sperimentazioni cliniche (deliberazione n. 1477/2022):
   a) il Responsabile della Sperimentazione durante il corso dello studio è tenuto a comunicare al CESC, per il tramite del NRC, le informazioni necessarie a consentire il periodico aggiornamento sull'andamento della ricerca, ogni evento o reazione avversa, l'interruzione anticipata di uno studio, con l'indicazione dettagliata dei motivi e degli eventuali risultati parziali ottenuti;
   b) lo Sperimentatore si impegna a fornire annualmente al CESC un rapporto scritto sullo stato di avanzamento dello studio (monitoraggio periodico) e una relazione analitica alla conclusione dello studio e pubblicazione se previsto;
6. di dare atto che dall'esecuzione del predetto studio non deriverà nessun onere aggiuntivo di spesa in capo all'Azienda ULSS7 Pedemontana;
7. di dare atto che il presente provvedimento è soggetto a pubblicazione ai sensi dell'art. 23, lettera d)

del D.L.vo 14 marzo 2013 n. 33;

8. di dare atto che la presente deliberazione viene pubblicata all'albo del sito istituzionale dell'Azienda per 10 gg. continuativi, inviata contestualmente al Collegio Sindacale e diventa esecutiva il giorno stesso della sua pubblicazione come da norma regolamentare approvata con deliberazione n. 1386 del 22/07/2022.

4/30/2018

Save Sight Registries

Seeing Outcomes

PROTOCOL

Save Sight Registries
Seeing Outcomes

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Fight Retinal Blindness! (FRB!) Project

INTRODUCTION

Save Sight Registries (SSR) provide a scientific, web-based research platform for clinicians to conduct post-marketing observational studies by efficiently capturing high quality data from real life practice. SSR is one of the world's most advanced registries of real-world outcomes of the treatments of eye diseases listed in Diagram 1.

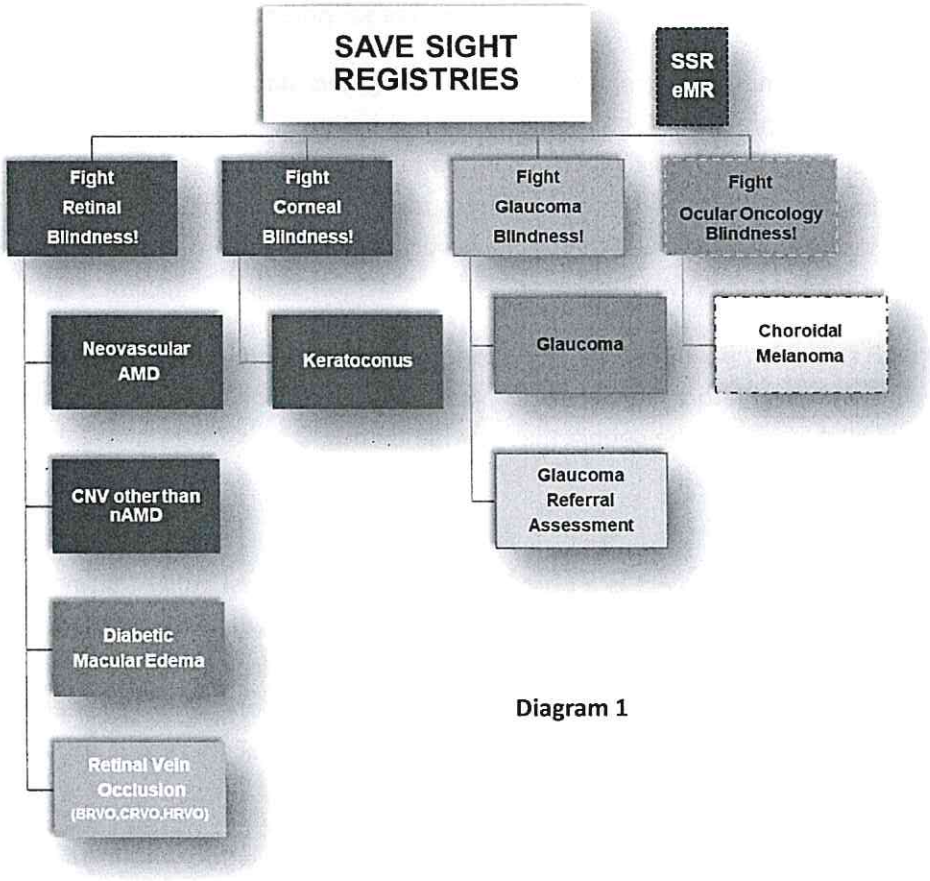


Diagram 1

This document outlines the operational principles of the FRB! Registry. These principles can also be found in the publication "Efficient Capture of High-Quality Data on Outcomes of Treatment for Macular Diseases, The Fight Retinal Blindness Project"[1] and the website for the Save Sight Registries and the Save Sight Institute.[2]

SSR is endorsed as the preferred scientific tool for the collection of the minimum dataset for Macular Degeneration by the Consortium of Heath Outcomes Measurements (ICHOM). Hence data collected

1 Save Sight Institute. Save Sight Registries. 2017. http://savesightregistries.org/.

2 Retina. 2014 Jan;34(1):188-95. doi: 10.1097/IAE.0b013e318296b271

though this platform has the potential to form the basis for the development of evidence based clinical management guidelines to assist clinicians improve patient care.

Successful implementation of the SSR to investigate and evaluate the clinical effectiveness, cost effectiveness and safety of current and emerging therapies will enable clinicians to develop strategies to reduce the incidence of ocular blindness at a global level, particularly as standardized data is collected across geographical borders.

Implementation of the FRB! System is expected to result in successful collaboration at scientific level to inform and deliver much needed research-driven evidence to drive improved care on a local and global scale. This collaboration will have significant impact on various stakeholders including clinicians, health policy makers, industry and patients by providing them with much needed information to facilitate addressing the increasing burden of AMD and other potentially blinding diseases.

Anonymous analyses and dissemination of the aggregated data are performed at all levels: international, national, practice, doctors and individual patients. The system enables clinicians to benchmark and continuously improve their own patient outcomes. It facilitates investigation and comparison of the clinical effectiveness and safety in routine clinical practice of emerging treatments for ocular diseases including the VEGF inhibitors, bevacizumab, ranibizumab and aflibercept, that are now available for neovascular AMD.

Compliance with strict European privacy regulations ensures, anonymity, security and accessibility of the data in line with regulatory requirements. Automatic accessibility of data, data analytics and outcomes are available only to the people that provide them.

BACKGROUND

The Fight Retinal Blindness! Project is a post-marketing observational study that has developed an innovative web-based software system to track long-term outcomes of AMD treatment. This scientific data collection system was developed by two key academics, Professor Mark Gillies from the Save Sight Institute at The University of Sydney, Australia, and Doctor Daniel Barthelmes from The University Hospital Zurich, Switzerland when it became evident that there was an unmet need for observational studies

Macular Degeneration affects over 30-50 million people around the world with its more severe form, nAMD, affecting approximately 1.3% of people over 50 years old. The proportion of visual impairment due to AMD has been found to vary between 40% in France [27], 39% in Germany [26], 36.3% in the Netherlands [25], 16.30% in the European North of Russia [29], and 14% in Bulgaria.[3]

Uptake and successful implementation of this scientific data collection system in both public and private centres in Australia, New Zealand, Switzerland, The Netherlands, France, Belgium and the United Kingdom has been encouraging since its introduction in 2006. The system is currently tracking over 8,536 patients, 10,859 eyes, 220,012 visits and 156,173 treatments in a completely anonymous

3 Epidemiology of Major Eye Diseases Leading to Blindness in Europe: A Literature Review Elena Prokofyeva Eberhart ZrennerOphthalmic Res 2012; 47:171–188
DOI: 10.1159/000329603

way dating back to 2007. This wealth of information provides valuable insights regarding different treatment approaches.

AIM

The aim of the FRB! Registry is to collect real world, high quality routine clinical data to better understand macular diseases, the effectiveness of new and existing treatments, highlight treatment patterns that lead to best patient outcomes and support patient education.

The primary goals of the registry are to investigate and evaluate the clinical effectiveness; cost effectiveness and safety of existing and emerging therapies for treatment of macular conditions, with the aim of identifying effective treatments that reduce the incidence of blindness.

DESIGN

The Fight Retinal Blindness! Registry was established in 2007. The robust web-based system forms the core structure for the Save Sight Registries database and interface. The SSR system is a structured system that uses observational study methods to systematically collect ocular data for specific ocular conditions to evaluate different dosing regimens for their safety and long-term effectiveness. The FRB! Registry systematically collects health-related data from a defined patient population) [4]

Participation in the registry is completely voluntary. Data will be collected prospectively during routine clinical practice and stored in the registry. Patients do not undergo additional tests or procedures that are outside of the standard of care.

Retrospective data entry is possible provided strict Retrospective Data Protocols are followed by those wishing entering data.

The collected data will be anonymously aggregated with data from other participants in the registry. The results may be used for scientific purposes including research, publications or presented at scientific meetings in a completely anonymous and aggregated manner.

STRUCTURE AND GOVERNANCE

An overarching International Steering Committee is supported by:

- Executive Committee, a Publishing Committee and User Groups.
- ***Country specific Steering Committees to ensure that research activities align with the aims and strategic direction of the Registry's overall aims. The Chair of this committee must be affiliated with a leading academic site or center of clinical excellence at the specific country, shall consider formalising an Advisory Committee and Working Groups as required in the future.***

The Project Advisory Committee and Working Groups report to the Steering Committee on progress, issues or recommendations as required.

4 Gliklich R, Dreyer N. Registries for Evaluating Patient Outcomes: A User's Guide. Agency Healthc Res Qual. 2007;2. doi: AHRQ Publication No. 07-EHC001-1.

ETHICAL AND REGULATORY REQUIREMENTS

All registries in Australia under the Save Sight Registries banner must be approved by local area health Human Research Ethics Committees (HREC). All private sites in Australia (i.e. private clinics/practices) are covered by an overarching Ethics approval issued by the Royal Australian and New Zealand College of Ophthalmology (Ref. nos. 16.09 and 50.14).

Users outside of Australia must be approved by the respective Human Research Ethics Committee of the concerned country. In some jurisdictions, countries may be able to obtain country-wide Ethics approval. Irrespective, it is the Site's responsibility to ensure they meet the regulatory and legal requirements for research purposes and that they have Ethics approval for the site.

If any Applicable Privacy Law, including but not limited to the the General Data Protection Regulation EU2016/679, requires that the patient give clear and unequivocal consent to the use of their Patient Data, all necessary patient consents must be executed at site level in accordance with the said requirements.

PATIENT CONSENT

Patient data is included in the Registry for research purposes according to SSR User Participation Agreement as well as each country's Human Research Ethics Committee, or equivalent, requirements.

Where Informed Patient Consent is required the patient must sign a consent form before data can be entered into the SSR System.

Patient Informed Consent must include information on:
Purpose of Study
Benefits and potential risks to patients must be communicates
Privacy and Confidentiality policies
Information about data transfer across international borders
Mode of data transfer - encryption and security of the data
Potential analyses, dissemination and sharing of anonymous data or results with third parties.

DATA COLLECTED

The FRB! registry captures data usually collected in routine clinical visits from patients receiving treatment for neovascular age-related macular degeneration (nAMD), CNV other than nAMD, Diabetic Macular Edema (DME) and Retinal Vein Occlusion (RVO).

Data is collected from participating clinicians (Users) both in public and in private institutions in Australia and internationally. Participants must agree to the Terms and Conditions as outlined in a User Participation Agreement with the University of Sydney. Where required Site Participation Agreement may also be required in line with local regulatory regulations, such as the General Data Protection Regulations (GDPR) in Europe.

Expansion of the database to other jurisdictions is possible provided that interested institutions agree to meet the legal requirements concerning the storage, protection, privacy and transfer of data and any requirements which may be applicable for the country concerned.

SOFTWARE AND SYSTEM DESIGN

The software used in the FRB! Registry consists of modules interacting with a core system. The core system provides a range of basic functions, which are used by each module for practice and patient data management.

Each module provides the User with the functionality to capture data for a specific purpose. The core system is modified and changed only under very specific circumstances, which have been approved by the Steering Committee.

Interested parties may commission the development of additional modules for other conditions which they can share with other users should they be interested.

Registered SSR can access the full scope of the software or request only modules that fit their needs.

MINIMUM DATASET

At patient level, the following personal details are collected:

- ✓ Year of birth
- ✓ Gender
- ✓ Ethnicity
- ✓ Postcode (collection of post code is not mandatory)

At eye level, the following variables are collected:

- ✓ Ocular conditions
- ✓ Previous AMD therapy
- ✓ Lesion size
- ✓ Angiography lesion type
- ✓ Visual Acuity (VA)
- ✓ Intra Ocular Pressure (IOP)
- ✓ Presence of Geographic Atrophy
- ✓ Presence of Sub retinal fibrosis
- ✓ Presence of Pigment epithelial detachment (PED)
- ✓ Choroidal neovascularization Activity (CNV)
- ✓ Type of AMD treatment administered
- ✓ Adverse events (including ocular procedures)
- ✓ Reason for treatment discontinuation (if applicable)

PATIENT RIGHTS

Patient have the rights accorded to data subjects under the applicable legal provisions, data protection and privacy laws, in particular:

- ✓ the right to request information as to whether data concerning them is being processed and to access such data;
- ✓ the right to have incorrect personal data corrected;

- ✓ the right to revoke their consent at any time, without stating their reasons, with the result that the data stored in the database are anonymised or are no longer used for research purposes.

DATA ACCESS AND VISIBILITY

The primary clinician ("primary doctor") can delegate authorities to assist with the data entry (for example, secondary treating clinicians and practice administrators). Unauthorized persons are denied access to the material.
There are different levels of password protected log-ins associated with varying data access and data visibility privileges. Control of the data remains with the treating doctor responsible for the patient's care.

Patient personal information will be handled in accordance GDPR. The information will be treated confidentially and only reviewed with the permission of the treating clinician.
Participating clinicians can withdraw their data from the database at any time, without providing a reason.

PASSWORDS

For security reasons, the SSR system automatically requests passwords be changed every 6 months. Logins and passwords are User-specific and not to shared.

SCIENTIFIC METHODOLOGY

The registry's standardized dataset is compliant with international measurement tools for health outcomes and enables current and emerging therapies to be evaluated for clinical efficacy, cost-effectiveness and safety.
Report analytics available to clinicians include:

- number of patients; number of visits; number of new patients
- number and type of treatments administered
- mean LogMAR Visual Acuity (VA)
- lesion-specific information such as lesion type, activity and size

BENEFITS FOR CLINICIANS AND PATIENTS

Benefits are delivered for patients and clinicians in various ways. The design of the system incorporates efficiencies to assist the dynamics of busy clinics and the increasing burden of the disease and of treatment.

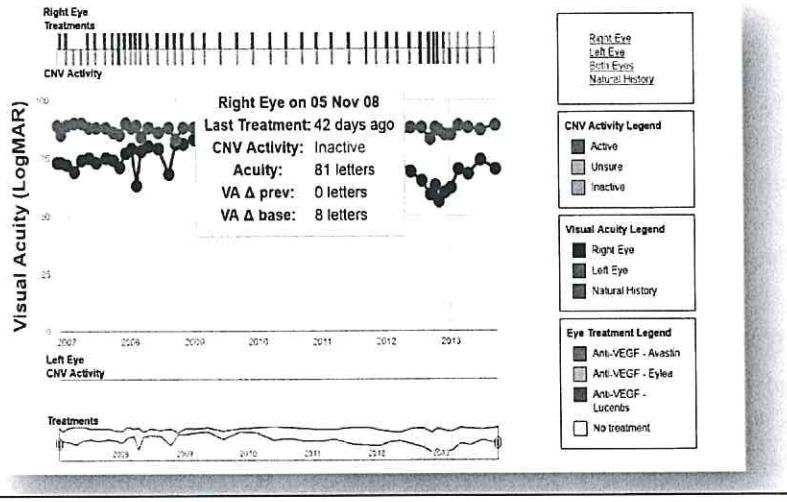
The system efficiently captures a core data set of fields with the first (Baseline) visit entered in under 30 seconds and Follow-up visits in approximately 15 seconds. All visits are registered with mandatory data fields with quality assurance measures (QA) to ensure data accuracy and completeness.

System features

The system is User friendly, efficient with in-built validation
Patient Graph
Individual patient's visual outcomes are graphed against treatment generating a powerful patient educational tool that quickly and seamlessly demonstrates the patient's own journey (see graph

below). Patients understand the consequences of various treatment approaches, and potentially, improve compliance.

It also efficiently generates clinically significant information for the physician, such as Treatment administered at a certain time point, variation of VA outcomes from visit to visit and from baseline. Summary details of lesion characteristics, number of days since last administered treatment are plotted on the graph for timely access to patient-specific data relevant to the management of the patient.



A graph of visual acuity over time is generated "on the fly", facilitating patient education as well as flow through the practice by reducing the time it takes for a doctor to gauge response to treatment over years

Reporting and Statistical Functionality

Reports can be anonymously generated by the practitioner based on their own data, providing difficult to obtain data on, per physician:

- ✓ Mean VA for own patients
- ✓ Total number of patients, visits eyes, new patients treated with in a pre-specified period.
- ✓ Total number and type of treatment administered during a pre-specified period
- ✓ Aggregate number of injections provided, used drugs, switch of drug (and its effectiveness) in all patients on several levels (see attached sample report)
- ✓ Longitudinal graphs anonymously comparing physician's own results to that of the rest FRB! cohort.

Data from individual practitioners can only be accessed by the practitioner

- ✓ The physician has complete control of their data.
- ✓ The physician may choose to use the system completely for their clinic's and patient's benefit and may chose not to join the global registry section of the Programme.
- ✓ The physician can delete their own data any time they wish to do so.

With agreed scientific collaboration, these outcomes can also be anonymously compared against overall patient aggregates at site, country and international level. The register would be able to compare different treatment strategies followed in different countries.

PRIVACY - ENCRYPTION AND STORAGE

Patients are assigned a unique code (identifier) by the User. This identifier can be any combination of letters and numbers. Users may utilize established patient identifiers to identify their own patients in the database when necessary.

The Identifier is used only identification purposes by the treating clinician and his support staff. This is not used or known by the SSR.

Anonymization of patient personal data is accomplished using a one-way encryption algorithm. No patient name or contact details are recorded in the registry database. All data transmissions between Users and the server are encrypted using 128-bit encryption (Secure Sockets Layer).

Anonymity of sites is also closely guarded. Individual clinicians can only see their ***own data*** and summary descriptive data from their own patients. Participants can withdraw their data from the database at any time, without providing a reason.

See Data Security Policy – ***Appendix A***

DURATION OF STORAGE

The registry is expected to continue indefinitely, therefore no termination date will be specified. If the registry is to be dissolved, data may be integrated into another registry provided that the specifications for data protection and privacy are met.

Where separate records (e.g. patient identification list) are required to be kept by the doctor on site, these are required to be kept during the registry and up to 15 years thereafter.

FUNDING

The Save Sight Institute is a not-for-profit entity. The Fight Retinal Blindness! Registry received start-up funding from The Eye Foundation in 2008 and has been successful in receiving competitive grants from the National Health & Medical Research Council (2010) and the Macular Disease Foundation (2016). The Registries have also been supported by Novartis and Bayer. All support is provided on a non-binding basis either as a research or educational grant

PUBLICATIONS

The FRB! project is committed to fulfilling its academic obligations and promoting dissemination of its findings. Since the development of the statistical functionality the Project has successfully published according to the FRB! Project Authorship and Scientific Publications Guidelines the following manuscripts based on the data entered into the system, with additional potential publications in the pipeline- Appendix B

SSR enables inclusive, collaborative, international scientific research.

APPENDIX A – DATA SECURITY POLICY

APPENDIX B - FRB! PUBLICATIONS