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Annual Report

[2022] – 1st January to 31st December 2022

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This document was produced for review by the European Alliance for Vision Research and Ophthalmology (EU EYE), Belgium.

THE ORGANISATION

The EU EYE constituency comprises of ophthalmological societies representing over 9,000 medical specialists active in clinical medicine, research, education and training in 100 countries.
The EU EYE works towards building a respected forum which brings medicine, science, education and advocacy together and is accessible to all – citizens, decision makers, research and healthcare workforce.

EU-EYE Full Members

- European Society of Cataract and Refractive Surgeons **ESCRS**
- European Society of Retina Specialists **EURETINA**
- European Glaucoma Society **EGS**
- European Association for Vision and Eye Research **EVER**
- European Eye Bank Association **EEBA**
- European Society of Cornea and Ocular Surface Disease Specialists **EuCornea**
- European Association for the Study of Diabetes/Ophthalmology Section **EASDec**
- European Paediatric Ophthalmological **EPOS**
- European Vision Institute **EVI**
- European Vision Clinical Research network **EVICR.net**

EU-EYE Associate Members

- COST Action CA18116 Aniridia network **Aniridia-Net.eu**

EU-EYE Board

Carlo Traverso	President/EGS Representative
Paul Rosen	Vice-President / ESCRS Representative
Jesper Hjortdal	Secretary / EEBA Representative
Tunde Peto	Treasurer / EASDec Representative
Giuseppe Querques	Board Member / EURETINA Representative
Massimo Nicolò	Board Member / EURETINA co-opt Representative
Marcela Votruba	Board Member / EVER Representative
Marie-José Tassignon	Board Member / ESCRS Representative
José Güell	Board Member / EuCornea Representative
Darius Hildebrand	Board Member / EPOS Representative
Hendrik Scholl	Board Member / EVI & EVICR.net Representative

General Assembly Representatives

Current Board Members represent their individual organisations at the General Assembly. Associate member Aniridia-Net is represented by Neil Lagali.

EU-EYE Objectives

We advocate for people-centred eye health care and have an ongoing commitment to the integration of research priorities, policies and strategies in eye health at European level.

Our varied portfolio of activities aim to open up the space for the patient empowerment process and the creation of new translational and fundamental research networks in our discipline.

ACRONYMS AND ABBREVIATIONS

ACT-EU	Accelerating Clinical Trials in the EU
ESC	European Society of Cardiology
CLEO	Council of Lived Experience in Ophthalmology
EDQM	European Directorate for the Quality of Medicines & HealthCare
EHDS	European Health Data Space
EMA	European Medicines Agency
ESFRI	European Strategy Forum on Research Infrastructures
FAIR	Findable, accessible, interoperable, and reliable
HCP POG	Healthcare Professionals Policy Officer Group
HCPWP	Healthcare Professionals Working Party
HPP	Health Policy Platform
IRD	Inherited Retinal Dystrophies
COMP	Committee on Orphan Medicinal Products
MEP	Member of European Parliament
PCWP	Patients and Consumers Working Party
RWD	Real World Data
TaSHI	Empowering EU health policies on Task SHIfting
YIO	Yearbook of International Organisations

Summary

In 2022 the organisation was awarded full membership to the HPCWP by the EMA with parallel participation in the HCP POG and co-led the academic work stream carried out by the Drafting group on surrogate endpoints and new ways of conducting clinical trials together with the ESC. Input was provided on the challenges and priorities in ophthalmology regarding registries & RWD; biosimilars; patient experience data; environmental risk-assessment of medicines; shortages in ocular medicines; medicines for special populations including frail and older people; people with rare diseases; and children. Regulatory work with the EMA included the Data Quality Framework workshop and the regulatory reflection of COMP on IRDs, the latter leading to the amended policy on orphan designations for inherited retinal dystrophies.

The EU EYE participated in the ESFRI Stakeholders Forum launch, the TaSHI project on medical desserts and joined the discussions of the EHDS Alliance. Submission to key public consultations covered among others: Data Standardisation Strategy; Driving

Licence Directive; Product Liability and AI Tools; ACT-EU; Interchangeability of biosimilars. Engagement continued with the TRANSFORM Alliance MEP Interest Group with a panelist at the launch of the Charter in the European Parliament and with input on training needs in ATMPs in paediatrics; and the ATMPs under the Hospital Exemption in EU.

Other key achievements were coordinating support for eye patients for the EMA and clinical expertise to 5th edition of EDQM Stakeholder consultation of the Guide to the quality and safety of tissues and cells for human application.

External and internal individual inquiries on policy, applications and other matters have increased further compared to the previous year. Compared to 2021, a rising number of countries accessed the website; the overall website traffic was increased by around 40% with the UK showing 300% increase in first time users.

EU EYE Activities 2022

1. General Organisation

In 2022 the EU EYE renewed its entry in the EU Transparency Register; it retained the entries in the Yearbook of International Organisations (YIO)[1] and the Horizon2020 Galahad site[2]; and it continued as a registered user of the Health Policy Platform (HPP) of the European Commission. In autumn 2022 the organisation attended the launch of the European Strategy Forum on Research Infrastructures (ESFRI) Stakeholders Forum Platform as a registered stakeholder; and the TaSHI[3] project with considerable input to the Roadmap on medical desserts.

The EU EYE expanded its presence in other stakeholder forums and alliances, notably:

- attendance to the EUnetHTA stakeholder meetings was followed by an application to HTA Stakeholder Network; outcome is expected in 2023;
- the EHDS Alliance, an informal alliance providing targeted input on the challenges of the implementation of the European Health Data Space and led by Sarah Collen, the European Association of Urology: the EU EYE was a signatory to the joint statement sent to the European Parliament and participated in a number of policy discussion organised by the EHDS Alliance on the impact of EHDS on data sharing in healthcare delivery; how it regulates the Electronic Health Record systems, and its potential to ensure that the FAIR principle is applied on health data.

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[1] YIO is a comprehensive database of intergovernmental (IGOs) and international non-governmental organizations (INGOs) worldwide; published in English and Chinese

[2] Galahad is an initiative of the Photonics Public Private Partnership supported by Photonics 21; its primary objective is to improve screening and basic diagnostics for glaucoma.

[3] TaSHI is one of the "Health Workforce Projects Cluster", the ongoing projects evolving from SEPEN EU Health Workforce network, the EU Joint Action on Support for the health workforce planning and forecasting expert network

The EU EYE Working Group (WG-CLEO), which was established in August 2021[4], continued the discussion on operational factors of the Council of Lived Experience in Ophthalmology (CLEO) and began to recruit patients willing to join the pilot. The launch of CLEO is expected in early 2024.

Aiming to increase its visibility among the ophthalmology community, the EU EYE manned a booth at EURETINA, Hamburg 2022. Visitors inquired about the EU EYE's work and show willingness to assist the efforts at EU level. This is the first time the EU EYE participated formally in an event of one of its members thanks to the generosity of the EURETINA. Work has also started on setting up an Internal Communications Group to improve awareness among the greater ophthalmology community about policy developments through timely alerts and a series of briefings focussing on emerging concerns of patients, healthcare professionals in ophthalmic practices and researchers.

The EU EYE's social media profile (https://twitter.com/EUEYENews) has doubled its followers whereas the website was accessed by 89 countries, an increase of about 29% compared to 2021. An overall increase of just under 40% was also observed in the number of first time users with the UK showing the most prominent increase at just over 300% compared to the previous year.

2 ADVOCACY

In 2022 the advocacy efforts of the EU EYE were strengthened by the following external experts:

Stefano Ferrari
Head of Research & Development · Fondazione Banca degli Occhi del Veneto O.n.l.u.s.

Tomas Bro
Member of the advisory board to the Swedish Transport Authority (Transport Styrelsen)

José María Pérez y Pérez
Representative of the Spanish Society of Ophthalmology to the General Directorate of Traffic, Spain and also Head of the Spanish Ergo-ophthalmology Society.

Susana Duch
Representative of the Healthcare Services sector of the Barcelona Chamber of Commerce through the Condal Institute of Ophthalmology.

[4] The WG-CLEO aims to set a loose basis for CLEO, propose inclusion criteria and short-term tasks and provide support when needed. Once CLEO is formed, its members will decide an appropriate organisational structure (formal or informal); refine concepts involved; and generate solutions for the expansion of CLEO. It is hoped that CLEO will address existing gaps in policy for all eye diseases such as lack of awareness about the challenges patients and their carers face (available therapies, reimbursement, etc); improve communications with citizens regarding eye health; and integrate in research the needs, perspectives and expectations of different groups as far as it is possible (age, ethnic, groups including vulnerable populations such as children, elderly etc).

Elba Agustí Rovira
Barcelona Tissue Bank, Barcelona, Spain

Bert Van den Bogerd
University of Antwerp, Belgium.

The section below lists the various activities per EU institutions and agencies.

European Medicines Agency

In December 2022 the EU EYE was awarded full membership to the HPCWP of the EMA for the mandate 2023-2025 with Dominique Brémond-Gignac and Mor Dickman as the clinical representatives to the working meetings.
The EU EYE strengthened its participation in the Healthcare Professionals Policy Officers' Group (HCP POG) of EMA by undertaking the co-leading of the academic stream on surrogate endpoints and new ways of conducting clinical trials together with the European Society of Cardiology.

European Parliament

The EU EYE secured its presence in the launch of the Charter of TRANSFORM ALLIANCE MEP Interest Group[5] with Mor Dickman as a panelist in the European Parliament in October 2022. The launch can be viewed at: The Charter with Charter with Solutions to Enable Safe and Timely Patient Access to Advanced Therapies in Europe.
Throughout the year, Dominique Brémond-Gignac ensured a consistent representation of the needs of rare ocular diseases in briefings to French politicians and in a series of policy events and workshops organised by the TRANSFORM Alliance and entitled 'Mind the Gap! How to Pave the Way to Access to Authorized ATMPs for Patients in Europe' in March; and 'FIT FOR ATMPs? Creating an EU Regulatory Framework that works for Transformative Therapies' in June.
The EU EYE attended also the events entitled 'Future of the ATMPs in Europe', organised by the Alliance for Regenerative Medicine' and 'Geographic atrophy as an unmet medical need in the field of ophthalmology' organised by the RPP group.

[5] The European Alliance for Transformative Therapies (TRANSFORM) is a multi-stakeholder Alliance that connects Members of the European Parliament (MEPs) and policy-makers with patient groups, medical experts and associations, scientists, researchers, industry actors, networks and other relevant stakeholders.

Public consultations, hearings and events

Engagement continued with the consultation and decision making process of the EU institutions and its agencies through participation in the following:

Consultations of the European Commission

- Roadmap on Medical Desserts
- Product Liability and AI Tools;
- D4.4 Outcomes (Endpoints) (EUnetHTA)
- Driving Licence Directive

Proactive communication was also undertaken with DG SANTE (Health and Food Safety) Unit B4 on the concerns of the ophthalmology community regarding implementation of Hospital Exemption.

Consultations, workshops and events of the European Medicines Agency

- ACT-EU/priorities;
- Interchangeability of biosimilars;
- Decision-making ecosystem;
- Platform trials;
- Data quality Framework (workshop)
- Informing on shortages of medicines due to Ukraine crisis;
- Qualification procedure, novel endpoints, achromatopsia;
- DARWIN and the EHDS Multistakeholder workshop on EMA's extended mandate;
- Regulatory Framework on Orphan Drugs for Rare Diseases;
- ICH harmonised guidelines on Quality Risk management;
- Data standardisation Strategy;
- Draft ICH guideline E11A on pediatric extrapolation;
- Big Data Stakeholder Forum;
- Patient experience data (workshop);
- Biosimilars multistakeholder workshop