Position of the European Alliance for Vision Research and Ophthalmology (EU EYE)

on

European Open Science Cloud

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European Innovation Partnership on Active and Healthy Ageing

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Executive Summary

The European Alliance for Vision Research and Ophthalmology (EU EYE) is a non-profit pan European advocacy group. We draw from the experience of our ophthalmology community across Europe to provide a forum for the integration of research priorities, policies and strategies in eye healthcare and vision research.

The EU EYE applauds the move towards Open Science and the implementation of European Open Science Cloud (EOSC) and anticipates huge implications for medical research. Data accessibility has the potential to improve transparency and reproducibility of research including a more fair attribution of credit to data originators. Such ambitious initiative must therefore focus on fraud detection and monitoring of data quality, including validation, accuracy and reliability. The EU-EYE pledges to assist the EOSC efforts by initiating work in data sharing among the ophthalmology community as complementary to its ongoing work as a partner of the European Innovation Partnership on Active Healthy Ageing. The management of health data in a cloud environment remains however a serious concern and the EU EYE calls the European Commission to:

- pay attention to the risk of creating 'sharing inequalities' as a result of variations in funding at national level and in approaches to open data of different disciplines ranging from attitudes towards sharing to organisational differences in depositing and storing data;
- strengthen the representation of the medical community within the Open Science Policy Platform to address in a systemic manner the diversity in open data needs in medicine;
- recognise the contribution of existing localised efforts to the progress of the EOSC project by providing the space for knowledge and experience sharing;
- enlisting the help of professional societies and associations in bringing about a paradigm shift and culture change towards data sharing;
- provide incentive structures and recognition of practices regarding data sharing and re-use for governments, funders and scientific communities including a European accreditation system of the data originators at instances of data reuse in the wild;
- integrate the notion of data trajectories to track data reuse as a evaluation of the EOSC and as enabler for a European accreditation system of the data originators;
- assign shared responsibility for compliance with data protection rules between cloud users and cloud providers;
- provide clarity in accountability for data processing;
- integrate guidelines for data security tools and measures for users against unauthorised data access, theft or leak as a condition for access;
- provide clear guidance on data transfer beyond EU borders.

A pledge towards the European Open Science Cloud realisation

The European Alliance for vision Research and Ophthalmology (EU EYE) is a non-profit pan European advocacy group. We provide a forum for the integration of research priorities, policies and strategies in eye healthcare and vision research drawing from the experience of our ophthalmology community across Europe. As a partner to the European Innovation Partnership on Active Healthy Ageing, we demonstrate our continuous commitment to improve public health through an ongoing effort to integrate research priorities, policies and strategies in eye health.

This paper presents the collective views of our member societies.

The EU EYE applauds the move towards Open Science and the implementation of EOSC and anticipates huge implications for medical research. Data accessibility has the potential to improve transparency and reproducibility of research including a more fair attribution of credit to data originators. Such ambitious initiative must therefore ensure a strong focus on control of data quality, which includes validation, accuracy, reliability and must integrate the necessary steps to minimize the risk of fraudulent data.

The essence of our alliance is to advance interdependence while recognizing members' independence. The EU EYE is therefore willing to work together with the European Commission and the key stakeholders in the process of building the EOSC by mediating between high and bottom-up actions and forging a shared vision for the EOSC of the ophthalmology community . We can tap to our potential as an alliance to cut across groups to cause fundamental shifts and help researchers to interact beyond established disciplinary or institutional silos.

The EU-EYE believes that only collaborative efforts will bring fruition in such ambitious work. While our alliance is voicing our concerns on certain aspects of the project, we are also prepared to contribute in whichever way we can to make European Open Science a reality and more specifically by undertaking the following:

- assist in the bottom-up motivation for researchers to share data through targeted awareness activities within the ophthalmology research community

- assist in the formulation of incentive structures for academics, industry and public services to share their data, and improve data management training, literacy and data stewardship skills;

- assisting in the establishment of clear standards and repositories in vision research and ophthalmology;

- creating initiatives in vision science and ophthalmology to credit authors for the sharing and reuse of their data and for advancing common standards;

- getting existing ophthalmic data infrastructures to agree on protocols that make at least some of their data findable, accessible, interoperable and reusable (FAIR).

- promoting and implementing cultural change in order to make the FAIR-principles a working standard in ophthalmology research and to reform reward systems in a way that evaluation of research careers fully acknowledges Open Science activities

- Assisting in the identification of the training needs specific to medical research to inform efforts such as GO-TRAIN

- promoting the integration of Open Science training into academic medical curricula.

- engage the vision research and ophthalmology community to prepare formal codes of conduct that would set out — in simple language — what can and cannot be done.

- assist in the cross-regional cooperation efforts (such as the NIH Commons) to build an Internet of FAIR Data and Services

- assist in transatlantic efforts with our association to World eye societies and the American eye societies ensuring that duplication of efforts will be prevented while identifying needed standards or community-generated use cases.

Our concerns regarding the current efforts of European Open Science Cloud

EOSC and the medical community

Science has long become multidisciplinary and interdisciplinary activity. In the last few years science is increasingly branching out to collaborative policy design activities whether with upstream or downstream policy actors. A transition to open science cannot depend solely on policy statements, voluntary action or academic departments. The technical infrastructure can be built. However the social acceptance of such technology may lag behind and aspects of data sharing may take a while to develop. 'Top down' or 'bottom up' initiatives are not sufficient in an effort that has already recognised that its success depends on a cultural shift regarding data sharing. Enlisting help from the middle can speed up the much needed Culture Change for Open Access. The Commission can legitimize new cross-cutting entities that catalyse sharing such as professional societies and alliances like the EU EYE.

Our alliance of ophthalmology subspecialties recognizes and promotes mutual benefits while appreciating the diversity brought by the separate characteristics of each member society. The EU EYE is therefore well placed in understanding the inherent complexities in data sharing in the medical field. Each medical specialty has their own technical specifications needs and methods; differing terminology; data structure and classification systems. Moreover the numerous subspecialties in each area create a plethora of primary and secondary research fields in basic science such as drug development and disease management such as care protocols and health outcomes. The landscape becomes more complex when one considers the even more granular unique areas of expertise in public health such as disease registries or co-designing public services and research projects with the citizens as end users. Such complexity demands a systemic manner in addressing the diversity in open data needs in medicine. The EU EYE feels that the representation of the medical community could be strengthened within the Open Science Policy Platform otherwise the Open Science Cloud may not consider adequately the specifics of data on disease management (therapeutic interventions and associated health outcomes) generated by hospitals and other clinical settings across the EU.

The EU EYE believes that the European Commission can speed up the implementation of EOSC by tapping into existing efforts and pilot schemes in many European countries. We call therefore for recognition of localised efforts in the progress of the EOSC project and asks the European Commission to provide the space for knowledge and experience sharing as to what works and what does not.

A sustainable EOSC

The EU EYE recognises that such ambitious plan can emerge only with European leadership and the collaboration of all stakeholders - Member States, research teams, laboratories, academic departments, professional societies, science funders, publishers. The EU EYE raises however its concern around the two basic assumptions on which the move towards Open Science is based:

1. the investment of the EU will be matched at 'local' level by national funders and private sources through innovative business models;

2. the proposed technical system will be used widely once it is build.

Sustainability in open data initiatives require:

- a proper calculation of true costs of data openness;
- a paradigm shift and culture change towards data sharing;
- data stewardship training programmes that are able to address disciplinary needs in research data management.

Maintaining and updating technologically a host platform for data is expensive, as are data validation and curation. At a time when most public funding agencies have limited resources taking responsibility for a new infrastructure will be slow particularly as dedicated subject-specific data management is required. The Commission has estimated that the implementation effort of the European Cloud initiative will cost about €6.7 billion of which €2 billion will come from Horizon 2020 funding with the rest of €4.7 billion to be covered by public and private investment over 5 years. Expectations that universities and research performing organisations could come forward as data hosts will only result in limited diffusion of common data standards and curation as development of institutional repositories is isolated.
Tangible support from governments and national funders must therefore be secured rather than assumed particularly if the culture shift towards data sharing is to be achieved and the current proprietary norm for data from collection to publication is to be abandoned.

The EU EYE is particularly concerned about the risk of 'sharing inequalities' as a result of not only variations in funding at national level but also in approaches to open data of different disciplines and the organisational differences in depositing and storing research data. For example the nature of genomic data have demanded a long-term focus on data ownership with adequate provisions for the deposition and storage of research data in life sciences. Smaller disciplines may not have developed adequate standards. Furthermore different proprietary access conditions operating for different disciplines often hinder true openness e.g. restrictions on what data can be made available with time lags between data generation and data access. Some disciplines may have an advantage rendered by

the nature of the discipline itself but such factors create inevitably inequalities of data access among disciplines. Such inequalities will prevent the growth of some disciplines which is required if their data are to be integrated in the greater infrastructure. 'Uneven' growth of disciplines will have an impact on multidisciplinary and interdisciplinary research.

EOSC and Public Health

The EOSC must also service the ordinary citizens, not just the researchers. Improving population health outcomes does not come only from new breakthrough research but also from the continuous assessment of existing therapeutic interventions and emerging ones. The EOSC must therefore integrate public health data and consider existing initiatives and quality databases organised by medical disciplines across Europe such as the EUREQUO (European Registry of Quality Outcomes for Cataract and Refractive Surgery; http://www.eurequo.org/) and the recently launched pan-European registry on corneal transplantation, the ECCTR (European Cornea and Cell Transplant Registry, www.ecctr.org); both funded by the Health programme of the European Union.

Although the data extracted from such registries are very general, their large number is important in epidemiological approaches and in reducing the impact of inadvertent errors. Interoperability with the future platforms is therefore crucial for the continuation of valuable databases as means for auditing therapeutic interventions and for ensuring efficiency of public spending.

The ophthalmology community alone contributes and uses regularly the EUREQUO, a database of 2.5 million cataract surgeries since 2008. The EUREQUO enables better knowledge of indications for surgery and offers a tool for clinical improvement work based on the patients' outcome as the patient-reported outcome being linked to clinical data encourages surgeons to make audit adjustment to their techniques and improve their results. Similarly, the ECCTR aims to evolve to an EU web-based registry and network for academics, health professionals and public authorities to assess and verify the safety quality and efficacy of corneal transplantation.

Accreditation for data originators as part of the evaluation of EOSC

The EU EYE believes that the research community would benefit if the EOSC integrates also the notion of data trajectories as it is essential to track reuse of published data both for the evaluation of the EOSC and as an incentive for data sharing by enabling the accreditation of the data originators at instances of data reuse in the wild. Such capability in the technical elements of connectivity, hardware, repositories, data formats and APIs should be integrated in the research agenda as the design of accurate models to explore the creating, collecting, and using Data Trajectory DTs systematically across a large number of data reuse instances, in the wild must address the issues encountered in tracking reuse of published data for transitive credit attribution:

- data consumers have no obligation to acknowledge their primary source of data;
- consumers are less likely to record reuse in any systematic way.

- credit management is complicated when ROs are only partially reused, as this violates the assumption that ROs are atomic data entities.

EOSC and General Data Protection Regulation (GDPR)

It is hoped that the European Open Science Cloud will improve efficiency in all sectors as data will become available to the scientific community, public administrations and businesses. However personal data in a cloud environment and in particularly health personal data must not be compromised for the goals of 'data-enabled science'.

The ophthalmology community warns against the unethical exploitation of data. The principles of purpose limitation and storage limitation are subject to derogation when a scientific purpose is present. Such legislative exceptions can be interpreted and applied narrowly as in the case of dataset mining exercise under alleged scientific purposes with subsequent reselling of personal data for commercial use.

The traditional data user - data provider relationship, where the former gives directives followed by the latter, is no longer adequate in a complex cloud environment.
Under the GDPR the mandatory principle privacy-by-design ensures that data security must be embedded in the design at the early stage of design and not as an afterthought. It will be difficult to monitor the position and use of data in the cloud infrastructure as circulation increases and it will be even more difficult to ensure that the multiple cloud users have adequate data security tools against unauthorised data access, theft or leak.

Data will inevitably move beyond the borders of the European Union and they may become subject to different data protection rules. Article 3 of the GDPR makes it clear what rules apply when the processing of personal data takes place in the Union with either the data user or the cloud provider being established in the European Union but it is not clear whether this tool is sufficient or how it can be implemented when neither the cloud user nor the cloud provider are established in the EU.

It is therefore not sufficient for personal data protection to only define the purposes of data usage but also:

- the infrastructure design to support it
- what rules will determine how data will move within the infrastructure and how far

The EU EYE calls therefore the European Commission to:

- clarify the funding process of such initiative process of managing competing and common interests of the stakeholders and in particularly in relation to the funding of such initiative.

- formulate an appropriate research data funding model for the integration of research data management in research project with adequate and supplementary funding for such action;
- strengthen the representation of the medical field within platforms such as the Open Science Policy Platform;
- create ownership in the process of building the EOSC by guaranteeing interoperability with existing projects and providing platforms for dialogue and knowledge sharing with existing efforts and pilot schemes
- ensure a technical system that is flexible to take into account emerging needs and practices and concurrently manages the diversity in technical norms of a diverse scientific community;
- establish clear rules of engagement for access to the EOSC and internationally effective guiding governance including the adoption of a set of terms to address differences in understanding and reduce time and costs in access negotiations;
- clarify the role of not-for-profit repositories and commercial data platforms in such efforts including restrictions on using such data platforms;
- include in the research agenda also models for ascribing credit to data originators and to monitor systematically reuse of published data for transitive credit attribution across a large number of data reuse instances, in the wild.
- provide incentives and support for the uptake of research data management (training, literacy and data stewardship skills) in existing projects
- support the growth of existing data repositories and shared cloud-computing facilities to adopt the required research data management practices;
- identify existing models of good platforms for data sharing and encourage upscaling of such efforts;
- formulate and disseminate widely guidelines for best practice for the creation, storage, publication and dissemination of large data sets, including recommended file formats and data repositories.
- ensure a technical system with enough flexibility to adapt to emerging needs and practices
- increase awareness among researchers regarding the existence and value of EOSC
- provide incentive structures and recognition of practices regarding data sharing and re-use for governments, funders and scientific communities;
- integrate the training of the data stewards in the education aims of the European Pillar of Social Rights;
- recognised the shared responsibility for compliance with data protection rules between cloud users and cloud providers
- bring clarity in accountability for data processing;
- integrate in the EOSC work also guidelines for data security tools and measures for users against unauthorised data access, theft or leak as a condition for access
- provide clear guidance on data transfer beyond EU borders