

European Society of Ophthalmology



Submit completed abstract to the Secretariat

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European Leadership Development Program Class of 2017-2019 Project Abstract

The European Society of Ophthalmology requests a brief abstract of the project that each EuLDP participants has worked on during the program. The compiled abstracts will be included on the SOE website and will be given to incoming EuLDP classes as background material. Please e-mail your abstract to E-mail: secretariat@soevision.org

*Please include the headings if appropriate: **Title, Purpose, Methods, Results and Conclusion***

Title of Project: Development of an ophthalmic regulatory intelligence and outcomes network

The regulation of ophthalmic medications is a key public health priority, enabling patients to be confident that the ophthalmic medicines they receive are both safe and have a robust evidence base of clinical efficacy. Regulation of ophthalmic products across Europe, in common with all medicinal products, is overseen by the European Medicines Agency (EMA) in conjunction with the national Competent Authorities, who base approval decisions on benefit-risk assessments of the submitted efficacy and safety dossiers.

Regulators may additionally call upon a number expert advisory groups to provide specialist input on wide-ranging topics across therapeutic and other areas from biological agents, pharmacokinetics and biostatistics. With an increase in the number and complexity of novel ophthalmic products and new ophthalmic indications for existing biological, biosimilar, cell- and gene-therapy agents, specialist input from clinical, scientific, regulatory and public-health stakeholders is critical to overcome considerable regulatory challenges for future approvals of novel medicines.

The aim of this project is to establish and develop a specialist ophthalmic network of professionals with interest and expertise in clinical development and regulatory requirements, with a view to maintaining a current and forward-looking view on the ophthalmic regulatory landscape. Such a network represents an opportunity for expert consideration of novel regulatory approaches, standard-setting and benchmarks for ophthalmic products, and may provide the EMA and competent authorities with an option to refer for authoritative specialist input.

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