



# EYEPOINT

## Clinical Trial / Research Standards Policy

EyePoint is committed to conducting well-designed, well-controlled and carefully monitored clinical trials with adherence to the highest ethical and quality standards. We value patient safety and protecting the rights and well-being of the participants in our clinical trials.

These are the principles in which we strive to meet, to deliver safe and effective treatments to the community for unmet medical needs:

- **Ethical Conduct** – EyePoint commits to adhering to ethical guidelines for conducting trials in an ethical manner. We strive to protect the safety, rights, dignity and well-being of the subjects. The interests of the subjects will be of the utmost priority over all other interests. All protocols are submitted to the FDA or applicable competent regulatory authorities as well as the Institutional Review Boards (IRB) / Ethics Committees (ECs) for approval before implementation. The safety of the clinical trial participants is routinely monitored and reported to IRBs / ECs and applicable regulatory authorities. EyePoint conducts reviews of safety data from clinical studies and reviews of side effects and technical complaints received on marketed products.
- **Regulatory and Applicable Guidelines** - EyePoint pledges to ensure compliance with all applicable industry guidelines, regulations, codes and standards. All EyePoint sponsored clinical trials are conducted in accordance with applicable laws and regulations including the Declaration of Helsinki, The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6 Guideline for Good Clinical Practice and The Belmont Report.
- **Transparency** – EyePoint strives to provide a high level of transparency through registration of all trials on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or other applicable registries prior to trial initiation in compliance with clinical trial disclosure requirements. Trial results are also disclosed on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or other applicable registries according to the requirements and timelines set forth by applicable regulatory clinical trial guidance.
- **Outsourced Trial Vendors** - EyePoint works closely with our Contract Research Organizations (CROs) and other vendors that participate in the preparation, conduct or analysis of clinical trials to ensure that our principles and standards are applied in all areas throughout the clinical trial process. We expect our vendors to adhere to these guidelines and we accomplish this by regular monitoring and quality checks of our outsourced obligations. Throughout the lifecycle of a clinical trial, we are conducting audits of vendors, regular meetings and reviews of their Standard Operating Procedures (SOPs).
- **Animal Welfare** – EyePoint recognizes the sensitivities with animal research and is committed to promoting and implementing the 3Rs (replacement, reduction and refinement) principles in conducting its search activities. While new insentient, ex vivo and in vitro methods are developed every day and contribute to reducing and, in some instances, replacing in vivo studies, their utility is limited. Animal studies are legally required and essential from a scientific perspective for assessing the safety and



efficacy of our products. EyePoint does not have a vivarium. Accordingly, all required animal research is conducted at U.S. based CROs who have policies ensuring humane and appropriate care of all animals, and a commitment to implementing the 3Rs. EyePoint expects CROs to ensure all animal studies are conducted in compliance with SOPs, all applicable laws (including Animal Welfare Act and Regulations) and the FDA Good Laboratory Practice Regulations (21 CFR Part 58).

- In addition to working closely with our CROs, EyePoint employs 3Rs in preclinical study design, where practical, by use of proper statistical methods for design of experiments, use of computer assisted modeling, use of in-vitro assays and use of in vivo CAM assay to replace the use of animals, combining studies to maximize the data available from a limited number of animals, reducing the number of animals used to achieve the objectives of the research and taking appropriate measures in the study design to avoid or mitigate any pain, suffering or distress that the animals might feel (including use of anesthesia and analgesia).

