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Novartis launches FocalView app, providing opportunity for patients to participate in ophthalmology clinical trials from home

- *FocalView is a first-of-its-kind app designed to modernize ophthalmic clinical trials, making them more accessible and flexible*
- *Using patients' self-recorded measurements, FocalView aims to enable more sensitive trial endpoints and more accurate patient-reported outcomes*
- *Using the Apple ResearchKit platform, Novartis is making FocalView vision tests freely available to the scientific community*

Basel, April 25, 2018 – Novartis announced the launch of its FocalView app, an ophthalmic digital research platform created with ResearchKit. FocalView aims to allow researchers to track disease progression by collecting real-time, self-reported data directly from consenting patients. By adapting the design of clinical trials to suit the daily routine of patients, the app may reduce barriers to participation, leading to a more nuanced understanding of ophthalmic diseases and potentially accelerating the development of novel treatments.

Data capture in traditional ophthalmic clinical trials can be inflexible and infrequent, making it difficult for researchers to monitor patients' disease activity and capture real-world patient experiences. FocalView aims to help patients complete various assessments, gaining feedback on their visual function, including any changes over time. At the same time, the app could provide researchers with a greater volume of real-world, patient-reported data, creating more flexible and accessible clinical trial designs.

“Because patients with eye diseases are often not as mobile, FocalView has the potential to offer tremendous benefit for the ophthalmic community and for researchers looking to develop better treatments for these patients,” said Dr. Mark Bullimore, Medical Advisor for the creation of FocalView and Dean of the Southern California College of Optometry, Marshall B. Ketchum University. “Collating validated patient-reported outcomes in clinical trial research is no longer a nice-to-have. This kind of data is fast becoming a critical element of research and development, because it offers a better reflection of real-world patient experiences, fosters better patient compliance and provides researchers with richer and more accurate data points.”

FocalView will be tested in a prospective, non-interventional study to evaluate the app's efficacy and usability in assessing visual function. These measurements include visual acuity and contrast sensitivity. Researchers will in turn assess ease of use, level of enrollment and the ability to obtain important documentation for future clinical trial research, such as informed consent. In the next phase, the app will be validated against traditional visual testing that takes place within conventional clinical settings.

“Optimizing digital technology in research and development, particularly in ophthalmic disease, could have a marked impact on the quality of the data we capture,” said Bertrand Bodson, Novartis Chief Digital Officer. “We believe apps like FocalView, which we've made

freely available to the research community on an open-source platform, can help accelerate the development of treatments and bring them to the patients who need them most.”

FocalView is now available for download from the App Store in the US. Consent to contribute to research data will be required before a user can interact with the tool. Novartis is planning to launch in additional markets in the future.

About Novartis in ophthalmology

Novartis is a leading ophthalmology company, with therapies that treat both front and back of the eye disorders, including retina diseases, glaucoma, dry eye and other external eye diseases. In 2016, approximately 200 million patients worldwide were treated with Novartis ophthalmic products.

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About Novartis

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2017, the Group achieved net sales of USD 49.1 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 124,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit <http://www.novartis.com>.

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