

The Ora EyeCup™

The Ora EyeCup™ technology powered by SDC Capture strengthens the quality of ophthalmic clinical studies, offering a comprehensive solution for capturing patient data and enhancing the overall research process. The user-friendly system captures high-quality clinical data and improves the likelihood of clinical study success.

- The Ora EyeCup™ broadens your company's data collection landscape both inside and outside of the clinic to reduce variability and produce more robust and higher quality data.
- The Ora EyeCup™ has been validated by Ora as a secondary endpoint in the US, Europe, and Latin America.
- Use of the Ora EyeCup™ increases the number of data points obtained in a clinical trial in a shorter timeframe, bringing therapies to market more quickly and efficiently.

The revolutionary Ora EyeCup™ system was developed with precise 3-D printing enabling it to comfortably enclose the subject's eye.. Either at home or in the clinic, the Ora EyeCup™ captures high-resolution images and diary entries, which can be uploaded to a web-based platform¹. In short, the Ora EyeCup™ allows:



①

Mobile, real-time data collection, including detailed imaging and patient symptom tracking.

②

All data (images and questionnaire responses) are time-stamped and quickly uploaded to a HIPAA compliant cloud where it is stored and managed for analysis.

③

Artificial Intelligence (AI)-powered image analyses for precise clinical assessments of ocular redness, tear film stability, and corneal health.

④

Intrinsic compliance assurance time stamped diary for symptom tracking and drop dosing.

⑤

Enhanced protocol adherence and the power to accelerate study timelines.

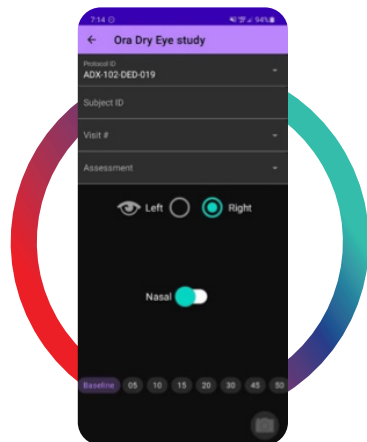
More data. Deeper insights.

The power of the Ora EyeCup™ technology is undeniable and has been shown to capture high-quality photos 98% of the time and can record adverse events on the ocular surface².



100% Customizable

Each Ora EyeCup™ study is custom designed for the sponsor. This includes treatment reminders, symptom tracking details, imaging requirements, and post-capture analyses that meet specific needs for your therapeutic program.



Powerful clinical metrics

The Ora EyeCup™ allows a hybrid approach to gathering more comprehensive, precise data under daily environmental stressors. An artificial intelligence algorithm reads the images and provides an objective measurement of ocular redness based upon a validated grading scale.

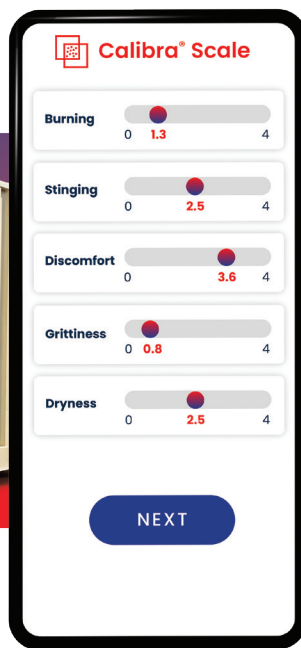
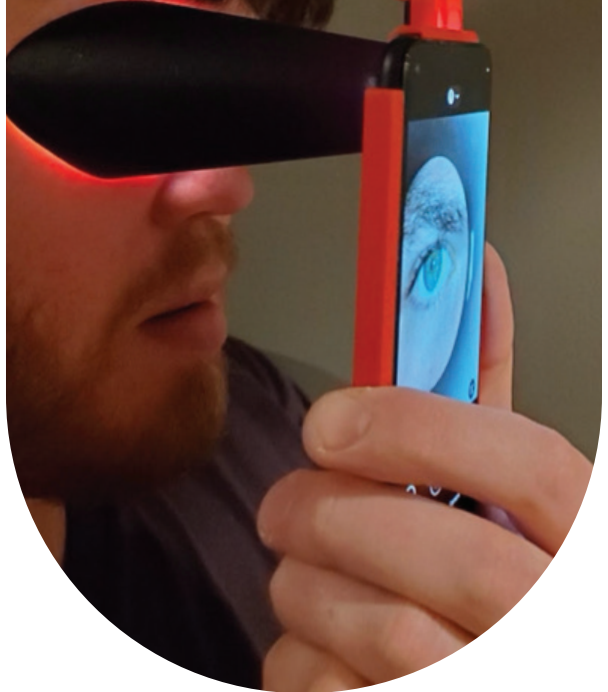


Robust patient feedback & symptom tracker

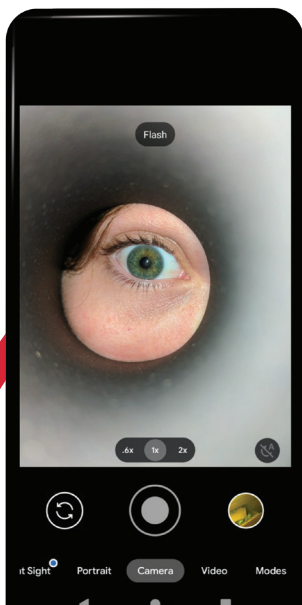
An intrinsic reminder system for a patient's therapy regimen ensures increased compliance. Built in auditory prompts for patients to input their symptoms into e-diaries and to take photos post-drop pre- and post-drop to enhance the study accuracy.

The Ora EyeCup™ was designed to make data capture easy & streamlined.

Whether at home, in-clinic, or in an environmental chamber, you're able to assess signs and symptoms in real-time as they're happening.



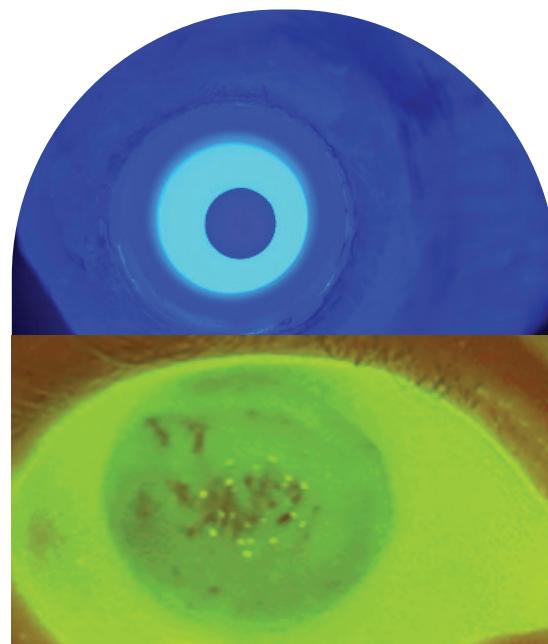
The Ora EyeCup™ enables patient in-clinic self-data collection during environmental stress trials, including the Ora CAE® and the Ora BioCube®.



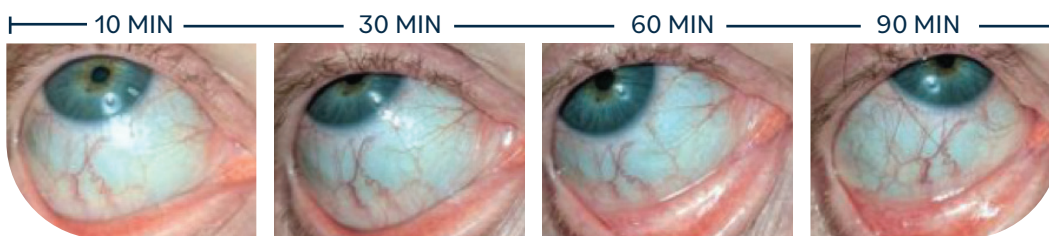
The Ora EyeCup™ controls both light and distance optimization to capture clear and consistent images.

The Ora EyeCup™ broadens your company’s data collection landscape both inside and out of the clinic to reduce variability and produce more robust and higher quality data. In summary, the Ora EyeCup™ technology will:

- Increase the number of data points obtained in a clinical trial in a shorter timeframe, bringing therapies to market more quickly and efficiently.
- Captures real-world impacts of investigative therapies on ocular health, signs and symptoms.
- Utilizes validated and automated custom grading software to enhance experimental accuracy when conducting a clinical study.



Top: Ora EyeCup™ adapted with blue filter for fluorescein detection. Above: Fluorescein image of the eye showing tear film break up (dark patches)



Left: Patient captured images depicting ocular redness with Ora EyeCup™ during 90-minute exposure in the Ora mobile Allergen BioCube®

Future capabilities of the Ora EyeCup™

AI measurement capabilities for clinical patient eye drop compliance. Utilizing the lower lash matting and detecting droplets in the lashes and face, Ora AI will be able to recognize if an eyedrop was administered with the EyeCup™ in a single image with 80% accuracy.

Sources

1. Ethan Bensinger, John David Rodriguez, Maurice Marquis, Kevin Dieter, Igor Sinyak, Mark B Abelson; Capturing Tear Film Stability with the Ocular Protection Index (OPI) acquired with Ora EyeCup Phone. Invest. Ophthalmol. Vis. Sci. 2022;63(7):1559 – A0284.
2. Igor Sinyak, Ethan Bensinger, Maurice Marquis, John David Rodriguez, Mark B Abelson; Reliability of Redness Imaging with the Ora EyeCup Phone. Invest. Ophthalmol. Vis. Sci. 2022;63(7):1562 – A0287.
3. Maurice Marquis, Mark B Abelson, John David Rodriguez, Ethan Bensinger, Igor Sinyak; Patient self acquired photos with the Ora Eyephone compared to self reported eye redness in mobile biocube. Invest. Ophthalmol. Vis. Sci. 2022;63(7):1561 – A0286.



Ora is a global full-service ophthalmic drug and device development firm with vast capabilities through all steps of clinical research, including preclinical, clinical, CMC & regulatory, and patient and site evaluations. Through Ora’s 40+ years of experience, the company has assisted in bringing more than 85 products to market. Ora’s team of experts utilizes global regulatory strategies, integrated research operations, and extensive site and patient engagement to accelerate product development in anterior and posterior segment, as well as ophthalmic devices.