CASE STUDY

Lighting the Way

How Replior's Integrated UV Monitoring and ePRO Improves Patient Engagement in the Almirall AKtive Trial

Setting the Stage: Ultraviolet Index (UVI) Monitoring in the AKtive Study

In a Phase IV, three-year study, Almirall is evaluating the long-term safety of a topical treatment for patients with actinic keratosis. The study requires patients to report outcomes periodically and avoid sunlight or UV light exposure. Therefore, tracking participants' UV index (UVI) exposure is crucial to minimize the risks of overexposure, especially during the spring and summer seasons. Almirall wanted to provide patients with a wearable device option to measure UVI. This measurement is essential for raising awareness about the risks of excessive UV radiation exposure and for alerting them to adopt protective measures.

Enrollment began in November 2022, and the study is still ongoing. This case study focuses on the results obtained from the initial analysis.

Overcoming Engagement Barriers

While patient engagement and retention commonly challenge clinical trials, the AKtive study presented a unique hurdle due to the average participant age of 72. The technology solution needed to be both accessible and easy to use for participants and clinical site staff, ensuring optimal engagement and retention throughout the study.

Additionally, the wearable device needed to continuously monitor each participant's UV exposure and provide real-time feedback. This feedback alerts participants when they reach the maximum UV exposure level appropriate for their skin type.

Diego Herrera Egea, Director of Clinical Data & Digital Innovation at Almirall, explained, "The protocol required patients to avoid sun overexposure, which underscored the importance of continuously monitoring the UV exposure behavior of our participants over a long duration."

Replior's Integrated Solution for EffectiveUV Monitoring

Almirall chose Replior to provide an integrated patient data collection solution that includes the Trial Online ePRO mobile application and a wearable UV sensor from SunSense.

SunSense continuously monitors UVI, UVA, and UVB levels every 2 minutes — a crucial feature to prevent skin lesions caused by excessive sun exposure. The sensor is exceptionally lightweight at only 7g (0.25 oz), lighter than a paperclip, and compact with a diameter of just 24mm (approximately 0.95 inches), making it comfortable for participants to wear. Its battery lasts at least 250 to 300 days, after which the device is replaced.

The Trial Online ePRO system transmits data from the sensor to the participant's smartphone in real time via Bluetooth, and then uploads this data to the ePRO platform.

> "We selected the Replior solution because integrating the UV sensor with the study ePRO app simplified access and supported participant retention and engagement, while streamlining UV exposure monitoring for our study team."

- Diego Herrera Egea

To facilitate the rollout of the solution, Almirall and Replior prioritized training for site staff and the study team on the correct pairing, usage of the sensor device, and the ePRO app.

Enhancing Engagement: Gamification and Tailored Communications

The solution provides the study team with direct access to participants. Throughout the trial, Almirall has sent more than 200 tailored push messages to motivate and encourage participants, while also sharing educational content about the disease, the study, and best practices.

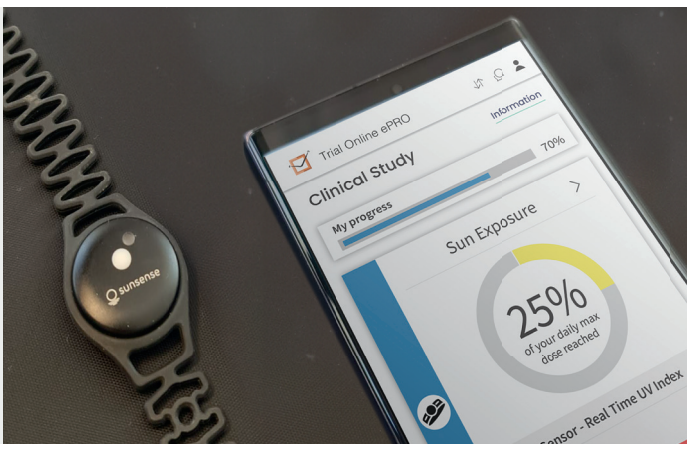
The ePRO app serves as a comprehensive resource hub for the AKtive study. Participants start their journey with an instructional video that shows how to pair the sensor device with their smartphones, easing this initial step. The journey continues with guided, step-by-step information provided through the ePRO app.

Gamification features like awards and badges are embedded in the ePRO to celebrate progress and task completion. As participants move forward in the study, they can track their progress within the app—viewing the time and effort invested, as well as what is needed to complete the study. The more they progress, the more they receive awards and badges, which not only celebrate but also motivate their continued engagement and compliance with the study requirements.

Educating patients using multimedia information is vital for maximizing the effectiveness of wearable tools. Multimedia resources, such as videos and infographics, enhance patient understanding not only of how to correctly use wearables and interpret their data, but also of their disease.

Technical data:

- Sensor: 285-360nm UV-index (erythemal weighted)
- Range ~5m (Bluetooth Low Energy)
- Android and iOS app interface
- Splashproof
- Attachment clip with rubberized grip



Additionally, weekly messages with tips remind patients to take protective measures. This comprehensive education ensures that patients are well informed, engaged, and more likely to comply with trial protocols, which ultimately contributes to more reliable and robust clinical outcomes.

“Engaging patients in clinical trials is crucial to retaining them in the study. Developing integrated mobile applications allows participants to send study data and receive multimedia content on their own smartphones, improving disease management and protocol adherence,” stated Mayely Sánchez, Senior Digital Data Scientist at Almirall.

Advancing Trial Success: The Impact of Integrated UV Monitoring

Over one year into the AKtive study, the Almirall study team has already observed significant findings regarding patient sun exposure behaviors, participant retention, and patient-reported outcomes compliance:

Enhanced Patient Compliance:

- **User-Friendly Interface:** Participants can check their individual sun exposure anytime through a user-friendly interface, aiding adherence to the recommended study thresholds and ensuring comprehensive data collection.
- **ePRO Compliance Rate:** The preliminary analysis reveals an impressive 91.7% compliance rate in patient- outcomes reported on the mobile app, strongly indicating that the study is on track to maintain high compliance through to its conclusion.

Improved Retention:

- **Qualitative Feedback:** Feedback indicates that the solution resonated well with patients. The seamless ePRO integration made UV monitoring feel integral rather than burdensome.
- **Engagement Tools:** Tailored push notifications, gamification elements like awards and badges, and educational videos and guides within the app kept participants motivated and well-informed.
- **UV Sensor Optionality and Retention:** Offering the UV sensor optionally resulted in a 95% retention rate among those who chose to use it.

Diego noted, "We needed to know if adding a UV sensor would bother the patients and increase dropout. We see that is not the case as 95% of the patients who actively use the UV sensor are still in the study."

About Replior and Trial Online

Replior specializes in integrated data collection solutions, combining hardware and software to collect both subjective and objective data, addressing common challenges in clinical trials. Modular and customizable, Trial Online meets the unique demands of each study while ensuring data accuracy and efficiency. To enhance patient retention and humanize the trial experience, Trial Online incorporates innovative gamification techniques, making participation more engaging. Our team is dedicated to continually evolving our solutions to meet the changing demands of clinical trials, working closely with customers to enhance data precision and patient engagement.

Contact us today to learn how Trial Online by Replior can be customized to meet specific endpoints and patient retention needs of your study.

www.replior.com info@replior.com