

Conference Abstracts

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Digital Phenotyping Using Wearable Actigraphy and Electronic Patient-Reported Outcomes to Advance Precision Monitoring in Early-Phase Oncology Trials

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Abstract

Background

Early-phase oncology trials rely on clinician-reported adverse events and performance status assessments to evaluate treatment tolerability. However, these measures are episodic, subject to interobserver variability, and may underestimate patients' symptom burden. Continuous digital monitoring using wearable sensors and electronic patient-reported outcomes (ePROs) offers an opportunity to generate objective, longitudinal digital biomarkers that may improve toxicity assessment and support precision oncology.

Methods

We designed a prospective, single-arm pilot study evaluating the feasibility of integrating smartwatch-derived actigraphy and weekly ePROs into Phase I oncology clinical trials at the Cleveland Clinic Novel Therapeutics Clinic. Thirty adults enrolled in early-phase trials will wear a smartwatch for four weeks while completing weekly PRO-CTCAE questionnaires through a custom mobile application. The primary endpoint is feasibility, defined as median smartwatch wear time of ≥ 12 hours/day and completion of $\geq 80\%$ of scheduled ePRO assessments. Secondary endpoints include

agreement between clinician- and patient-reported toxicities, time to first grade ≥ 1 adverse event, and user experience. Exploratory analyses will evaluate longitudinal changes in activity, sleep, gait, heart rate, and heart rate variability as potential digital biomarkers associated with treatment toxicity, dose modification, disease progression, and trial discontinuation using repeated-measures statistics and machine learning approaches.

Results

Enrollment is ongoing. We anticipate demonstrating the feasibility of integrating continuous wearable monitoring and ePRO collection into early-phase oncology trials while characterizing the concordance between clinician- and patient-reported toxicities and identifying preliminary digital phenotypes associated with treatment-related functional decline.

Conclusion

This study establishes a scalable platform for continuous digital phenotyping in early-phase oncology trials. Integration of wearable-derived physiologic data with patient-reported outcomes may enable development of AI-driven digital biomarkers for earlier detection of toxicity, improved characterization of treatment

tolerability, and more individualized monitoring in precision oncology.

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