

Quadrant Biosciences Awarded \$2.3M NIH Grant to Develop Rapid Saliva Test for Concussion in Children

Novel, minimally invasive biomarker to predict duration and character of concussions

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Quadrant Biosciences Inc., a developer of epigenetic diagnostic technologies, has been awarded a \$2.3M Fast Track (Phase I/II combined) STTR grant from the National Institutes of Health ("NIH")

to develop an objective, saliva-based diagnostic tool for detecting concussion in children and adolescents. The grant will support research to further refine a saliva diagnostic test previously developed by Quadrant Biosciences, Penn State Medical Center and Upstate Medical University, with the objective of improving care for school-aged children and young adults who are particularly vulnerable to head injuries and their potential lasting effects. Quadrant will be partnering with Penn State, SUNY Buffalo, SUNY Upstate, Arkansas Children's, and Children's Hospital of Michigan in this study.

More than 2 million children and adolescents experience concussions each year. Despite the prevalence of the injury, there are few clinically valid methods for pediatric concussion diagnosis or prognosis. As a result, there is great value in an objective biomarker that is not only accurate, but easily collected and measured.

"Currently, the diagnosis of concussion relies largely on subjective symptom reports from patients," explains Steven Hicks, MD, Ph.D., FAAP, Associate Professor of Pediatrics, Penn State Hershey Medical Center and one of the principal investigators in this study. "The lack of objective tools for concussion assessment is problematic because symptom reports can be manipulated to expedite, or delay return to activities. As a result, studies have shown that concussion is often



under-diagnosed.”

In an effort to address the need for objective tools, Quadrant Biosciences has been working the past several years with researchers from Penn State Medical Center and SUNY Upstate Medical University to explore the use of saliva biomarkers to diagnose concussion. The findings of Quadrant’s earlier research, published in the Journal of the American Medical Association Pediatrics in 2018, identified a panel of small, non-coding molecules in the saliva called microRNA (miRNA) that act as a "molecular signature" to not only diagnose concussion, but predict the duration and character of concussion symptoms.

As a result of this novel research, the National Institute Of Neurological Disorders And Stroke of the National Institutes of Health has awarded Quadrant Biosciences funding to further refine their molecular test. Specifically, the study objectives are to definitively ascertain that a concussion has occurred, predict the length and type of symptoms, and then use that data to improve and personalize care for children and young adults who have had a concussion. According to Dr. Hicks, “with that knowledge physicians could make more informed decisions about how long to hold a child out of sports, whether starting more aggressive medication regimens might be warranted, or whether involving a concussion specialist might be appropriate. Anytime we can use accurate, objective measures to guide medical care, I think that represents an opportunity to improve concussion treatment.”

In Phase I of the awarded grant, Quadrant will advance development of their diagnostic test by establishing a rapid, accurate method for quantifying these saliva biomarkers. This will drastically reduce sample processing time from days to hours, opening the door for point-of-care diagnostics, and moving one step closer to the coveted sideline or battlefield test. In Phase II, Quadrant will validate the diagnostic algorithm and its ability to distinguish mTBI from medical conditions with overlapping symptomatology, such as chronic headaches, clinical depression, ADHD, exercise-related fatigue, and orthopedic injury.

The study, a partnership with SUNY Upstate, SUNY Buffalo, Arkansas Children's, Children's Hospital of Michigan, and Penn State Medical Centers, will enroll 2500 adolescents and young adults with either a formal diagnosis of an mTBI or an overlapping medical condition. One of the study investigators, Usha Sethuraman, MD, a pediatric emergency medicine physician from the Children's Hospital of Michigan, explains why this study is so important. “I believe the proposed salivary molecular biomarker test will yield a minimally invasive, rapid and specific biomarker that can aid in predicting severe concussion in children with minor TBI.”

Ryan C. Kwong, MD, MPH, Assistant Professor in the Department of Pediatrics at the University of Arkansas College of Medicine, and one of Dr Sethuraman’s colleagues on the study concurs. “Since there are no current modalities that aid clinicians in identifying and prognosticating severe concussion, this biomarker will serve as a novel and important tool in the Emergency Department.”

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About Quadrant Biosciences

Quadrant Biosciences is a life science company involved in the development of functional assessments and epigenetic diagnostic solutions for large-scale health issues. The company has entered into collaborative research relationships with a number of institutions including SUNY Upstate Medical University and Penn State University to explore and develop novel biomarker technologies with a focus on Autism Spectrum Disorder, concussion, and Parkinson's Disease. Quadrant Biosciences also participates in the Start-up NY program, a New York State economic development program.

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