Deloitte.

News Release

'Hearts of Athletes' Research Study Launches to Understand Effects of COVID-19 Using Innovative Digital Platform From Deloitte With Support From the Joel Cornette Foundation

Deloitte's ConvergeHEALTH MyPath for Clinical digital platform on AWS will transform the participants' clinical trial experience during the remote study, and contribute to the success and efficiency of the data collection

NEW YORK, Aug. 9, 2021 — The Hearts of Athletes study which has generous support from The Joel Cornette Foundation, is now open and recruiting participants at the Duke Heart Center. Powered by Deloitte's ConvergeHEALTH MyPath for Clinical, which runs on AWS, the study is encouraging athletes both with and without COVID-19 to take part in the study. Securely collecting data will help clinicians identify the prevalence of COVID-19-related heart inflammation among top-level athletes and then establish the associated symptoms and clinical features to support timely and accurate diagnosis.

The Joel Cornette Foundation was established to honor Butler University basketball star Joel Cornette who died tragically of a heart attack in 2016. "To carry on Joel's legacy, we have a responsibility and opportunity to improve lives and create opportunities for those in need," said Christi Cornette, executive director of The Joel Cornette Foundation based in Cincinnati, Ohio. "A key part of our mission is to develop, support and provide guidance to underserved youth through education and community but also wellness. We're honored to support the Duke Hearts of Athletes study because it truly supports this mission and we hope our involvement helps raise awareness and financial support for this important study."

Deloitte's ConvergeHEALTH MyPath for Clinical platform is helping researchers meet their objectives by leveraging a novel digital clinical trial approach including innovative recruitment, enrollment, retention and event ascertainment strategies all in one unified digital user experience. This novel approach, which does not require the athlete to be on-site at a medical facility, will help increase patient engagement and adherence, recruit a more geographically dispersed and diverse pool of study participants and enable investigators to conduct faster, more informed analysis.

"This study will enable us to enroll a population of young adults that prefer to engage on digital platforms and have travel limitations due to the pandemic," said study lead Dr. Manesh Patel, chief of Cardiology at Duke University School of Medicine. "This approach has the potential to allow patients to participate from wherever they are, have a better experience and helps the physicians, investigators and others involved in the study collaborate and respond more quickly. It could also give us the tools and a template for future studies."

Why now

To date the scientific community has lacked a large "library" with data on the hearts of individuals who have performed at the highest levels of athletic competition. Additionally, once an athlete has finished competing at the highest levels of their sport, there is little understanding and guidance on the management and medical care of the cardiovascular system in these athletes. This problem has only been exacerbated with COVID-19, which has posed an unprecedented public health challenge and is believed to impact the heart. Recent studies have identified inflammation of the heart – termed myocarditis – as a

possible side effect of COVID-19. For young adults, student athletes, and others without known cardiovascular disease, the true incidence of myocardial involvement after COVID-19 infection and the rate of detection via different testing modalities is not known. This has led to differential testing programs for athletes as part of a return to athletics around the United States.

How it will work

As part of an innovative "direct to patient" clinical trial model, athletes from across the U.S. can self-identify and download the iOS-based Hearts of Athletes app built on the MyPath platform to learn more about the study and decide if they would like to participate. As part of that decision, they will be presented with clear information about the study and have the ability to consent directly in the platform. Once enrolled in the study, participants with and without COVID-19 will use their mobile devices to provide health information securely, like symptoms and other patient reported outcomes, by answering survey questions daily for 30 days. In addition, participants will consent to their de-identified cardiac images to be sent to the Duke Heart Center for a blinded analysis. NCAA collegiate athletes, professional athletes, or Olympic athletes (18 or older) are eligible for the study.

The objectives of the study are to:

1. Determine the rate of COVID-19 myocarditis in athletes. This will be determined based on an independent blindly assessed cardiovascular work up including a standard CMR with contrast.
2. Characterize the clinical features associated with COVID-19 myocarditis.
3. Determine the sensitivity of upstream data (symptoms, clinical features, ECG and echocardiogram) for the identification of COVID-19 myocarditis. Develop models that predict COVID-19 myocarditis.

"Studies like Duke's Hearts of Athletes program are critical for understanding the implications of diseases like COVID-19, but also the overall cardiovascular implications of athlete behavior," said Brett Davis, principal and Global Assets leader, Deloitte Consulting LLP. "By taking this innovative decentralized digital trial approach, and hosting it on AWS, Duke is able to reach a broader and more diverse set of patients quicker, deliver a better experience for trial participants, as well as collect richer data by enabling patients to self-report through a convenient mobile experience."

About MyPath for Clinical

MyPath for Clinical is a modular, patient-centric platform that can help accelerate the execution of digital clinical trials by taking a holistic approach to connect clinical trial participants, investigators and clinical research associates. It leverages modern cloud, mobile and connected medical device technologies to address three core industry challenges: patient recruitment; patient engagement to drive retention; and protocol management. It enables:

- Personalized digital patient engagement with guidance and support along the clinical trial lifecycle with enhanced direct connectivity to investigators and patient communities.
- Improved patient experience through direct patient data collection as well as a growing ecosystem of connected devices.
- Integration of data across multiple inputs, leveraging AWS with integrated analytics and reporting capabilities.
- Support for digitally enabled novel virtual clinical trial designs across multiple geographies.
- Advanced consent management to enable the secure collection of robust real-world datasets for future clinical development.

- Support for the development of digital therapeutics leveraging a common patient platform and architecture.

MyPath for Clinical lays the foundation for digitizing clinical trials while enhancing patient and investigator engagement by providing education and resources; medication tracking and appointment management; symptom tracking; patient reported outcomes and surveys; and data visualization for patients. It also supports investigators by providing direct connectivity while organizing patient data into helpful dashboards. This improves the experience for patients and investigators, and enables research teams to generate new insights and provide better patient support while in a trial.

"Since our launch in 2014, ConvergeHEALTH has been singularly focused on building innovative new digital experience and data platforms that support the shift to value based, personalized health care," said Chris Zant, principal Deloitte Consulting LLP and general manager of ConvergeHEALTH. "In today's digital age, decentralized clinical trials represent a step change opportunity to not only advance our understanding of human health and disease but also make clinical trials more efficient and patient centric."

For more information please visit: The Duke Heart Center; The Joel Cornette Foundation; ConvergeHEALTH MyPath for Clinical. The Joel Cornette Foundation is hosting the second annual JCF Golf Outing on August 9. All funds raised through the tournament will support the Hearts of Athletes study. To donate please click here.

About Deloitte

Deloitte provides industry-leading audit, consulting, tax and advisory services to many of the world's most admired brands, including nearly 90% of the Fortune 500® and more than 7,000 private companies. Our people come together for the greater good and work across the industry sectors that drive and shape today's marketplace — delivering measurable and lasting results that help reinforce public trust in our capital markets, inspire clients to see challenges as opportunities to transform and thrive, and help lead the way toward a stronger economy and a healthier society. Deloitte is proud to be part of the largest global professional services network serving our clients in the markets that are most important to them. Building upon more than 175 years of service, our network of member firms spans more than 150 countries and territories. Learn how Deloitte's more than 330,000 people worldwide connect for impact at www.deloitte.com.

###

Contact

Lauren Dolezal
Public Relations
Deloitte Services LP
+1 516 220 0366
ldolezal@deloitte.com