



For Immediate Release

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## **Warfarin Study with Iverson Genetics Receives CMS Approval**

*Morehouse School of Medicine and Iverson Genetics partner in first-of-its-kind study to test how genetic information can help predict patient response and improve safety of world's leading anti-blood clotting drug*

ATLANTA – Morehouse School of Medicine and Iverson Genetic Diagnostics recently announced that its WARFARIN Clinical Study has received approval from Centers for Medicare & Medicaid Services (CMS). The two-year (2) study will assess the impact of genetic information in calculating doses and the changes in the rate of adverse events when initiating Warfarin drug therapy. These changes will be compared against doses initiated without genetic data.

Iverson Genetic Diagnostic's CEO Dean Sproles noted, "The CMS approval of the WARFARIN Study is evidence of the growing role of genetics in helping doctors to develop optimal individual treatments for their patients. In the case of warfarin, it is our hope that the data from this study contributes to making the future use of this vital drug safer, and less costly."

The specific CMS approval is for a clinical study under Coverage with Evidence Development (CED) and will cover pharmacogenetic testing of CYP2C9 or VKORC1 alleles to predict warfarin responsiveness.

The WARFARIN Study is being led by Principal Investigator Elizabeth Ofili, MD, MPH, Director of the Clinical Research Center, Chief of Cardiology and Associate Dean for Clinical Research at Morehouse School of Medicine in Atlanta.

"Warfarin is an essential drug for preventing blood clots, but the adverse event rates need to be lowered," added Dr. Ofili. "This study should help us understand how to use each patient's genetic information to deliver a safer and more effective dose."

Warfarin is a commonly used anticoagulant (blood thinner) and is most commonly known by the brand name of Coumadin®. The dosage and administration of warfarin must be individualized for each patient according to his or her response to the drug. Currently, these individual responses are evaluated on a trial-and-error basis.

Today, more than 2 million patients are prescribed warfarin in the United States each year. One (1) to five (5) percent experience a major bleeding event. The annual cost associated with warfarin complications is estimated to be \$1.1 billion. Researchers have identified two specific genes, VKORC1 and CYP2C9 that contribute up to 60 percent of individual patient variations in response to using warfarin. The WARFARIN Study will evaluate changes in side-effects such as



major hemorrhagic or thromboembolic events when using genetic information to determine individualized warfarin dosages.

“Given how many patients take warfarin and the relatively high rates of adverse events we see, it’s critical to find out if genetic information can help physicians tailor the doses of warfarin they prescribe to each patient and reduce the chances of a major bleed,” said Morehouse School of Medicine president Dr. John E. Maupin, Jr.

Tests are administered when doctors collect a saliva swab from the patient’s mouth. This sample is then forwarded to the newly developed Iverson Genetic Diagnostics lab on the campus of Morehouse School of Medicine in Atlanta. Test results are provided to the doctor within about 24 hours.

The WARFARIN Study Steering Committee is accepting clinical sites interested in participation. Please visit [www.warfarinstudy.org](http://www.warfarinstudy.org) to obtain updated information about participation and progress.

#### **About Morehouse School of Medicine**

Morehouse School of Medicine (MSM), located in Atlanta, Georgia, was founded in 1975 as the Medical Education Program at Morehouse College. In 1981, Morehouse School of Medicine became an independently chartered institution and the first minority medical school established at a Historically Black College and University in the 20<sup>th</sup> century. MSM is among the nation’s leading educators of primary care physicians, and was recently recognized as the top institution among US medical schools for its social mission. Our faculty and alumni are noted in their fields for excellence in teaching, research and public policy. MSM physicians are known in the community for exceptional, culturally appropriate patient care. MSM recognizes that the elimination of health disparities requires a paradigm shift to healthcare that is personalized, predictive, pre-emptive, and preventive. The Clinical Research Center (CRC) at MSM will provide a biorepository for the WARFARIN study. The CRC is supported by the NIH’s National Center for Research Resources through its Research Centers in Minority Institutions (RCMI) program. MSM is also a partner in the NIH funded Atlanta Clinical and Translational Science Institute (ACTSI), a three (3) institution partnership that includes Emory University and Georgia Institute of Technology. For more information about Morehouse School of Medicine, visit ([www.msm.edu](http://www.msm.edu)).

#### **About Iverson Genetics Diagnostics**

Iverson Genetic Diagnostics is a leader in making actionable genetic information readily available to physicians in everyday practice. The mission of Iverson Genetic Diagnostics is to provide physicians with clinically relevant gene-based information to optimize therapy and enhance personal wellness for their patients. Through its gene-based health and treatment profiles, the company provides physicians with actionable genetic information to optimize clinical decision-making and patient care. Iverson Genetic Diagnostics is headquartered in the Seattle suburb of Bothell, Washington where it maintains CLIA and CAP certified genetic testing laboratories. In addition, the company operates two specialty-specific genetic testing labs through university relationships in Georgia and South Carolina. For more information, visit [www.IversonGenetics.com](http://www.IversonGenetics.com).

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