

**FOR IMMEDIATE RELEASE**

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**NAVIGENICS PROPOSES STANDARDS FOR PERSONAL GENOMICS SERVICES,  
COUPLED WITH PROSPECTIVE OUTCOMES STUDIES, TO SAFEGUARD  
CONSUMERS**

*Company acts to 'ensure the integrity of this critical step toward personalized health care'*

Redwood Shores, Calif. – April 8, 2008 – Navigenics, a personalized genetic health services company, today announced that it will develop a set of industry standards for consumer genomic testing services, and that it will seek broad, multi-stakeholder input and endorsement of these or similar criteria. Further, the company announced it will also support prospective health outcomes studies, involving leading medical centers and other partners, designed to examine the impact that consumer access to personal genetic information has on behaviors and health outcomes.

The Navigenics Health Compass service, officially launched today, uses genotyping, coupled with the latest research findings on genetic associations with an initial set of 18 common medical conditions, to provide a personalized genetic assessment to its members. The assessment comes with 24/7 access to a Genetic Counselor to help understand results, and is designed to be part of an ongoing process to help individuals and their professional health advisors apply the information to improve health. In addition, members have access to information on preventive measures and clinical research focused on avoiding or delaying the onset of these health conditions.

The company will present and solicit input on its proposed criteria from multiple stakeholders, among other subjects related to direct-to-consumer genetic testing, at a conference now being planned for later this year in collaboration with the Personalized Medicine Coalition.

“The Personalized Medicine Coalition looks forward to this conference to explore key issues including the development of standards regarding direct-to-consumer genetic testing,” says Edward Abrahams, Ph.D., executive director of the Personalized Medicine Coalition. “This type of service represents the public’s first major exposure to the significance of personalized medicine.”

Over time, as the science continues to evolve and expand, new conditions will be added and new findings relevant to the initial 18 conditions will be incorporated into member profiles to

ensure they have the most accurate and up-to-date picture of their genetic predispositions and what they can do to optimize their health.

“Much has been said and written about the potential of putting personal genetic information in the hands of consumers,” says Dr. David Agus, Navigenics co-founder, board member and clinical advisory board chair. “We’re convinced we’ve developed a service that maximizes the potential for the latest genetic information to positively impact behavior and accurately inform health decisions -- and in the process improve health across the population, one person at a time.”

The company’s proposed standards for personal genomic services will include commitments to 10 specific criteria for performance, service and quality, including:

1. **Validity** – of genetic association, epidemiological and clinical information provided through the service and used to determine predispositions for included health conditions
2. **Accuracy and quality** – of testing, with all samples processed in a reputable CLIA-certified lab and in accordance with state and federal regulation, with guaranteed analytical accuracy of 99 percent or more, and with a “100 percent call rate” guarantee
3. **Clinical relevance** – of information provided, using only genetic risk factors that show consistent effect sizes in multiple sample populations of the same ethnicity; with supporting information vetted by a team of experienced, clinically trained reviewers; and with content screened or provided by leading medical institutions or reputable, independent content providers
4. **Actionability** – associated with conditions included in the service, to ensure that the promise of improved outcomes over time can be met, or that at a minimum there is valid clinical or scientific information available to demonstrate an ability to prevent, delay or enhance treatment options for an included health condition
5. **Access to genetic counseling** – to ensure that each individual can speak directly to a counselor, at their convenience, to understand the implications of their particular profile, and that they can have access to continued counsel over time as new findings or information may change or expand their particular genetic predispositions
6. **Security and privacy** – to ensure that only the individual member has access to their particular profile, and has complete control over granting access to others; operating in a manner consistent with HIPAA regulations; and using the latest measures to protect and safeguard all member data, at a level at least consistent with what leading financial institutions use
7. **Ownership of genetic information** – to acknowledge each member’s right to access their own genetic information and record
8. **Physician education and engagement** – to sponsor and ensure physician access to relevant genomics-focused continuing medical education; to incorporate specific tools

into the service that enable physicians direct access to general information on latest advancements in genomics; and to enable members to share specific, personal genetic information with health professionals in a productive way, should they choose to do so

**9. Transparency** – regarding relative applicability, limitations and specificity of genetic risk information, as well as assuring that personal or aggregated genetic information will never be shared without the full knowledge and consent of each individual member

**10. Measurement** – to assess the impact of the service on health outcomes over time, and member response and experiences with the service in the near and long term

“The science is advancing at a rapid pace, and that’s very exciting not just for researchers, but for all of us who can ultimately benefit from the application of these findings,” says Dietrich Stephan, Ph.D., a genetic researcher and co-founder and chief scientific officer of Navigenics. “But with that advancement comes a serious responsibility to ensure the integrity of this critical step toward personalized health care. We know that if we don’t do it right, we could set things back quite a bit – which is why it’s important for us and others to be clear about what we will be accountable for.”

In addition to developing and adopting proposed standards, the company will be participating in research initiatives aimed at measuring the actual impact of genetic risk information on consumer behavior and related health outcomes over time.

The first such study, announced this week, is a Mayo Clinic study examining how patients understand and utilize information provided by a Navigenics personalized genetic risk assessment. The research also addresses 1) physicians’ understanding of predictive genetic risk assessment and 2) the impact of such information on preventive health decision making. Titled “A Proof of Principle Trial of Communication to Patients Receiving Predictive Genetic Risk Assessment,” the study begins in April 2008 and runs through September 2009. The study is funded jointly by Navigenics and Mayo Clinic.

### **About Navigenics**

Navigenics, Inc. is a privately held company based in Redwood Shores, Calif. The company was founded by David Agus, M.D. and Dietrich Stephan, Ph.D., with the goal of improving health outcomes in individuals across the population. Navigenics educates and empowers customers with knowledge of their genetic predispositions, and then motivates them to act on the information to prevent the onset of disease, achieve earlier diagnosis, appropriately manage disease or otherwise lessen its impact. Navigenics’ lead investors are Kleiner Perkins Caufield and Byers, Sequoia Capital and MDV-Mohr Davidow Ventures. More information is at [www.navigenics.com](http://www.navigenics.com).

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