



Frequently Asked Questions (FAQs)

What is Sanford Imagenetics?

Sanford Imagenetics is a comprehensive new program of Sanford Health that fully integrates genetics with internal medicine, creating a first-of-its-kind model for exceptionally high-quality and innovative primary care for adults.

With Sanford Imagenetics, Sanford's MD clinical geneticists, genetic counselors and diagnostic clinical genetics laboratories will work hand in hand with the organization's primary care internal medicine physicians. Patients will experience improved health outcomes, a higher overall quality of care and a greater understanding of current or future health conditions through in-depth evaluation of family history and targeted genetic testing. For example, Sanford Imagenetics will help physicians translate a patient's genetic information, obtained through a simple blood draw, in order to prescribe certain medications with even more precision.

Education is also a critical component of Sanford Imagenetics. As the health care industry as a whole moves to place greater emphasis on genomics in the everyday care of patients, the demand for qualified professionals at Sanford and elsewhere in the region will increase. Sanford Imagenetics has partnered with the Sanford School of Medicine of the University of South Dakota, as well as Augustana College, to offer scholarships and develop new academic programs that train the next generation of doctors, nurses and scientists in genomic medicine.

Sanford Imagenetics was established thanks to a generous gift of \$125 million from Denny Sanford.

How will Imagenetics be implemented at Sanford Health?

Sanford Health has long recognized the impact genetics can have on the diagnosis and treatment of certain health conditions. For example, Sanford Women's, Edith Sanford Breast Cancer and Sanford Children's already consider genetic evaluation and genetic testing to be an essential part of clinical practice and will continue to do so going forward.

Sanford Imagenetics expands on this approach by further incorporating clinical genetics into the everyday practice of primary care for adults, allowing for more precise prescription of medications, screening for and management of chronic disorders.

Sanford Health leadership, physicians and genetic staff are currently finalizing how Sanford Imagenetics will be implemented within its clinics. For example, Sanford Health expects to begin offering the initial DNA analyses for a broad panel of pharmacogenetic screening tests from a blood draw in the spring of 2014. Sanford Health internal medicine physicians or their clinics will communicate with patients as these services become available. Patients will not, however, need to switch physicians in order to participate in the program. All Sanford physicians can access the resources and expertise of Sanford Imagenetics.

Sanford Imagenetics will be further applied through these key elements:

CLINICAL CARE:

- Later this year, Sanford Imagenetics will offer adult patients in Sanford's general internal medicine practices the opportunity to undergo genetic counseling for familial disorders as well as precise genetic testing (when indicated) from a simple blood draw.
- This genetic information will add to the information Sanford's internal medicine physicians already consider in the care of their patients, leading to the practice of precision medicine.
- Sanford Health internal medicine physicians will also offer a broad battery of genetic testing about how drugs are metabolized to their patients, allowing them to customize prescriptions. For example, this information will improve a physician's ability to prescribe the right medication, at the right dose, at the right time, with the fewest side effects for drugs such as statins and blood thinners, as well as medications used to treat anxiety and depression.

FACILITIES:

- As a part of this initiative, Sanford Health will also have dedicated facilities in all major markets to accommodate implementation of this new program throughout the enterprise. Depending on the region, these facilities would house the internal medicine practice, genetic counselors, medical geneticists, research, education, and lab services.

WORKFORCE DEVELOPMENT:

- Sanford Imagenetics has formed initial partnerships with area colleges and universities to develop new academic programs that train the next generation of doctors, nurses and scientists in genomic medicine.
- These initial partnerships include:
 - Training in genetics in the internal medicine residency program at the Sanford School of Medicine of the University of South Dakota.
 - Opportunities for medical students and residents interested in genomic medicine through scholarships, residencies and fellowships for post-MD students.
 - Training and scholarship support for the next generation of non-MD genetics health care professionals (i.e. genetic counselors, genomic nurses, bioinformaticians) through new and innovative undergraduate and graduate degree programs developed in collaboration with Augustana College and, potentially, other area colleges and universities.

RECRUITMENT:

- Sanford Health has already begun recruiting the best in the field of genetics and genomics to support Sanford Imagenetics. This includes:
 - Recruitment of star quality physicians throughout the enterprise, including an internist/geneticist clinical leader, doubly-boarded in internal medicine and clinical genetics, who will spearhead the enterprise clinical initiative.
 - Recruitment of nationally-known research leader to spearhead the Sanford Research expansion under Imagenetics.
 - Recruitment of an enterprise clinical genomics bioethicist to become part of the internal medicine genomics team.
 - Expansion of the genetics workforce throughout the entire Sanford Health system, including MD geneticists, PhD clinical laboratory geneticists and genetic counselors.

RESEARCH:

- Through Sanford Imagenetics, Sanford Health will develop rigorous research programs to define:
 - The genomic markers most successful in predicting and managing the chronic disorders of adult life cared for by our general internists
 - Outcomes research to evaluate the effectiveness of this approach
 - In-depth bioinformatics research to interpret complicated biological data from whole genome sequencing.

How is Sanford Imagenetics unique?

Sanford Imagenetics is the first identified program in the nation to fully integrate genetic medicine into internal medicine. Although dietitians, social workers and pharmacists sometimes function as team members within an internal medicine office, there are currently no organizations that similarly embed genetics health care professionals into a primary care practice.

What is internal medicine?

Internal medicine physicians care for adult patients by diagnosing and managing complex health issues such as diabetes and high blood pressure. The origins of the specialty of internal medicine were in the early 20th century in the United States; internists were the first physicians to incorporate the scientific method into medical practice.

Sanford's internal medicine physicians provide general primary health care for patients 18 years of age and older. Sanford Health's internal medicine program includes more than 170 physicians trained in internal medicine locations, offering internal medicine primary care services at more than 40 clinic locations.

How will a person be tested for drug metabolism or disease predisposition?

Using a simple blood draw, a person's DNA is placed on a glass slide or 'chip' from where it is clinically analyzed. The interpretation of the genetic information from this chip is then stored securely in a patient's private electronic medical record.

What is the 'chip'?

Simply, the chip is a genetic test, whereby hundreds or thousands of genetic markers are simultaneously evaluated. DNA from a patient is applied to a slide or 'chip' with thousands of wells that contain known pieces of DNA.

Initially, this chip analysis will be used to uncover how a patient metabolizes more than 400 different medications. Later chips will be used to predict disease predisposition. Interpretation of the genetic information is then uploaded to a patient's private electronic health record and the chips are destroyed.

The chip is an important aspect of Sanford Imagenetics, as it will allow Sanford's internal medicine physicians the ability to be proactive in treating patients and will enable them to prescribe the right medication at the right dose at the right time. Such precision in care means fewer adverse drug reactions and a higher overall quality of care for patients.

There is not one single chip, but a variety of chips designed to complete specific analysis. For example, one chip will be used to identify how well a patient may or may not react to a certain medication. Another chip would analysis specific aspects of a patient's DNA to predict their risk for developing breast cancer.

What are some examples of how the information from the pharmacogenomics chip could change a patient's care plan?

Much like physicians consider a patient's age, weight, family history and lifestyle when prescribing medications or treatments, access to information about a patient's genetic makeup provided by the chip will provide yet another source of personalized data to physicians for more precise care. As such, two patients with the same diagnosis might receive different dosages of the same prescription or different prescriptions altogether.

Take clopidogrel, for example. Known more widely by its brand name, Plavix®, this medication is sometimes prescribed to prevent platelets in the blood from sticking together and forming clots that could cause heart attack or stroke. This medication, like many others, is metabolized differently in each patient depending on genetics. The CYP2C19 gene contains "instructions" for the body to make an enzyme needed to metabolize this drug and others and different variations of this gene can predict how a person may react to clopidogrel. If a patient has reduced activity in the CYP2C19 gene, he or she is unlikely to benefit from this drug at all and may even see increased risk for heart attack and stroke. Alternately, a patient with increased activity in this gene is more likely to process the medication more quickly, which can have its benefits but also puts the patient at higher risk for bleeding.

The chip will contain information that sheds light on genetic variations such as this, enabling physicians to prescribe medication that is safe and effective for a particular individual from the get go instead of relying on trial and error which could result in potentially dangerous adverse effects on the patient.

Where will the test be analyzed?

In-house genetic testing is essential for a robust program as it allows for rapid processing and readily available expertise in translating the findings. Sanford Health is home to two clinical genetics and genomics laboratories. Both labs will be further developed and expanded because of this gift.

- *Sanford Clinical Cytogenetics Laboratory.* This is an existing CLIA certified clinical laboratory that uses the entire array of molecular cytogenetics tools in patient care. This technology is currently used extensively in pediatrics, obstetrics and oncology.
- *Sanford Clinical Molecular Genetics Laboratory.* This newly developed laboratory will provide clinically actionable genetic information to physicians. The lab will provide single-gene sequencing, whole exome sequencing and targeted mutation analysis in oncology and selected single gene disorders in adults and children. This lab is currently seeking CLIA certification.

What is a CLIA certified lab?

Clinical Laboratory Improvement Amendments (CLIA) of 1988 are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States. The CLIA Program sets standards and issues certificates for clinical laboratory testing. Sanford Health currently has the only CLIA certified genetics laboratory in North and South Dakota.

How will patient information be used? Is this information secure?

Participation in Sanford Imagenetics is completely voluntary. All information obtained about a patient's genetic makeup is protected under HIPAA and stored in secure electronic medical records. Patients can also agree to provide a DNA sample to the Sanford Biobank for additional research as genetic testing evolves, but that is not done without the patient's prior consent.

How much will the test cost a patient?

The cost of genetic counseling and genetic testing will depend upon a patient's insurance coverage. Out of pocket costs for genetic laboratory testing can range from \$200 to \$3,000 depending on the test.

How does Sanford Health currently integrate genetics into health care?

Sanford Health has a long-standing history of providing comprehensive genetic health care to the region. A number of Sanford specialty providers, including physicians with Edith Sanford Breast Cancer, Sanford Children's, Sanford Women's and other areas, already consider genetics evaluation an important part of treating patients with specific illnesses and will continue to do so going forward.

Sanford Health already has an experienced team of genetic counselors, MD clinical geneticists and PhD laboratory geneticists throughout its system who provide these innovative genetic services to patients. For example, in collaboration with the South Dakota Department of Health, Sanford's genetics team provides unique genetics outreach clinics throughout South Dakota.

Through Imagenetics, the Sanford Health internal medicine practice will become the "hub" for genetics at Sanford, although they will not be the only area to apply genetics in patient care. Internal medicine physicians will also work with other primary care providers who identify patients whose care would be improved through genetic analysis.

Why is Sanford Health investing in genomics?

Sanford Health is investing in genomics because it's what's right for patients. Genetic information is becoming critical in patient care. Each individual has a unique genetic makeup and these individual genes play a role in determining a person's risk for different diseases and their response to various medications or treatments. For example, some medicines that work well for some people do not work well for others and may even cause serious problems.

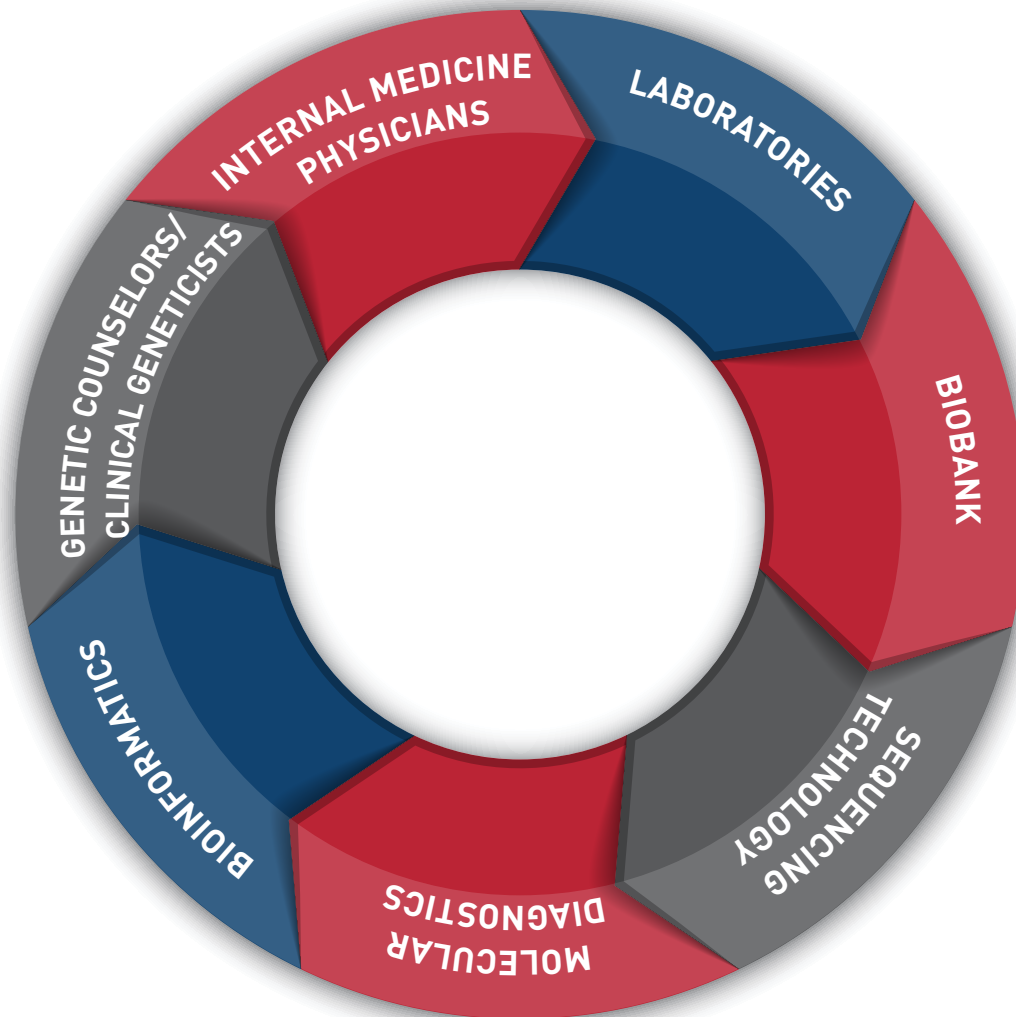
Genetic information gathered through Imagenetics can lead to precise treatment and care plans for each individual patient. Understanding this information and how it can be applied is the future of health care worldwide.

How much has Denny Sanford given Sanford Health?

Denny Sanford is the pre-eminent healthcare philanthropist in the world. Including this \$125 million gift, Denny has entrusted Sanford Health with now nearly \$1 billion to achieve the organization's vision of improving the human condition through exceptional care, delivery and innovation.

SANFORD IMAGENETICS:

COMPREHENSIVE CAPABILITIES IN GENETICS AND GENOMIC MEDICINE



- **INTERNAL MEDICINE PHYSICIANS:** More than 170 physicians trained in internal medicine, delivering primary care at more than 40 clinic locations.
- **LABORATORIES:** CLIA certified clinical cytogenetics and clinical molecular genetics laboratories to process advanced genetic analysis that can be applied directly to patient care.
- **BIOBANK:** The region's only state-of-the-art BioBank, which serves as a repository for thousands of blood and tissue samples.
- **SEQUENCING TECHNOLOGY:** The latest DNA sequencing technology including Sanger Sequencing, Life Technologies' Ion Semiconductor Sequencing and Illumina HiSeq 2500.
- **MOLECULAR DIAGNOSTICS:** Molecular diagnostic capabilities to analyze biological markers in patients' DNA to diagnose disease and identify the most effective therapies and treatments.
- **BIOINFORMATICS:** An advanced Bioinformatics core to store and analyze genetic data, helping uncover the ways in which our genes impact our health.
- **GENETIC COUNSELORS/CLINICAL GENETICISTS:** Seven genetic counselors and five MD clinical geneticists consulting with patients, recommending advanced genetic analysis and partnering with physicians to interpret test results.



LEARN MORE AT SANFORDHEALTH.ORG/IMAGENETICS