Overview

• History of direct access genetics
• 23andMe Mission
• The Power of Engagement
Consumer Genetics: Historical Perspective

2007
- Launch of DeCode and 23andMe

2008
- SACGHS and Letters from the States
- 23andMe’s DTC genetic product named 2008 Time Invention of the Year

2010

2013
- FDA issues warning letter to 23andMe

2014
- HHS says that labs must give their data directly to patients, if requested
- 23andMe submits first 510(k) to FDA

2015
- 23andMe gets FDA authorization to market carrier status reports
- AMP and NSGC revise policy statement in support of DTC genetics
- President Obama announces Precision Medicine Initiative

“… the data suggest that consumer genomics does not provoke distress or inappropriate treatment.”


Regulation: The FDA is overcautious on consumer genomics

“The FDA believes that in many circumstances it is not necessary for consumers to go through a licensed practitioner to have direct access to their personal genetic information.”

Alberto Gutierrez, Ph.D., FDA director of the Office of In Vitro Diagnostics and Radiological Health
Tonight, I’m launching a new Precision Medicine Initiative to bring us closer to curing diseases like cancer and diabetes – and to give all of us access to the personalized information we need to keep ourselves and our families healthier.”

*President Barack Obama*

State of the Union Address, January 20, 2015
Our Mission:
To help people access, understand and benefit from the human genome.
How to engage people in health, wellness, and research: e-commerce meets healthcare

The most fascinating person you know is YOU.
Create an Engaging Consumer Experience

Reports
- Wellness
- Traits
- Carrier
- Ancestry

Tools
- Share & Compare
- Inheritance Tracing
- DNA Relatives

Research
- Surveys
- Communities
- Insights

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Trait Reports: How genetics works

Eyes

The eyes are said to be the windows to the soul. But did you know your genes are a window to your eyes? Although it’s not the only factor, your eye color is determined mostly by one gene.

Andy, you are likely to have light-colored eyes.

97% of customers who are genetically similar to you have blue, green, or light hazel eyes.

Your genetic likelihood

- Blue: 52%
- Greenish blue: 21%
- Green: 16%
- Light hazel: 8%
- Dark hazel: 2%
- Light brown: < 1%
- Dark brown: < 1%

European ancestry customers

- 30% Blue
- 13% Greenish blue
- 13% Green
- 13% Light hazel
- 12% Dark hazel
- 6% Light brown
- 14% Dark brown

About Eye Color

Eye color refers to the color of the iris, which can be blue, green, hazel, brown, or many shades in between.

Biology

Human eye color is primarily determined by the amount of a pigment called melanin in the iris. This is the same pigment that determines skin and hair color. Lighter-colored eyes have less of this pigment while darker eyes have more pigment.

Genetics

The OCA2 gene helps control the amount of melanin in the iris. A certain variant near this gene changes how active it is. In people with this variant, the OCA2 gene is less active, leading to less melanin in the iris.

Other factors

- History
- Lighting
- Heterochromia
Carrier Status* Reports

*C[Our tests] can be used to determine carrier status in adults from saliva collected using an FDA-cleared collection device (Oragene DX model OGD.500.001), but cannot determine if you have two copies of the genetic variant. Each test is most relevant for people of certain ethnicities. The tests are not intended to diagnose a disease, or tell you anything about your risk for developing a disease in the future. On their own, carrier status tests are not intended to tell you anything about the health of your fetus, or your newborn child’s risk of developing a particular disease later in life.
Tell me more about me: Ancestry Reports
Tools: Engage, understand, share

Overview
Use interactive tools to share, compare and discover more with friends and family.

Inheritance Tracing
Trace DNA through your close family, and see how different traits have traveled through generations.

Share and Compare
Share and compare your reports, and explore the genetic similarities and differences between you and family members.

DNA Relatives
Find and connect with new DNA relatives, and see specific DNA segments you share with them to fill in your family tree.
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You
- Prefers sweet taste
- Can taste bitter
- Earlobe attached
- Super taster
- Not lactose intolerant
- Blonde hair
- Blue eyes

Dad
- Prefers sweet taste
- Cannot taste bitter
- Earlobe attached
- Not a super taster
- Lactose intolerant
- Brown hair
- Blue eyes
Participatory Research Made Easy

How it works.

When you participate in our research, you can answer survey questions online, day or night. From your phone or laptop, for five minutes or fifty, your contribution is up to you.

By answering online survey questions and allowing researchers to combine your genetic data with millions of other data points, you can help drive scientific and medical discoveries.

The markers identified with **nearsightedness** were found in or near genes involved in:

- Eye size and development
- Regeneration of vitamin A (important for photoreceptors)
- Growth of retinal cells
- Neuron growth and function

[LEARN MORE]
The Power of Engagement
80% Consent to research

2M Phenotypic data points per week

>320M Phenotypic data points

- ✓ Genotype data
- ✓ Phenotype data
- ✓ Biobanked samples
- ✓ Longitudinal data
- ✓ Ability to re-contact

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Customer Demographics
<table>
<thead>
<tr>
<th>Condition</th>
<th>Confirmed Cases</th>
<th>Controls</th>
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</thead>
<tbody>
<tr>
<td>12,000 with Parkinson’s</td>
<td>706,000</td>
<td>686,000 non-e4 carriers</td>
</tr>
<tr>
<td>87,000 with asthma</td>
<td>437,000</td>
<td>647,000 controls</td>
</tr>
<tr>
<td>240,000 APOE e4 carriers</td>
<td>653,000</td>
<td>686,000 non-e4 carriers</td>
</tr>
<tr>
<td>34,000 with psoriasis</td>
<td>539,000</td>
<td>647,000 controls</td>
</tr>
<tr>
<td>77,000 with cancer</td>
<td>517,000</td>
<td>653,000 controls</td>
</tr>
<tr>
<td>188,000 with cardiovascular disease</td>
<td>707,000</td>
<td>539,000 controls</td>
</tr>
<tr>
<td>3,000 with colorectal cancer</td>
<td></td>
<td>707,000 controls</td>
</tr>
</tbody>
</table>
Yes we can. In a few hours we were able to find a similar association doing analysis using a cohort of about 45,000 women.
Results indicate that elastin could be key to more effective prevention and treatment of stretch marks.
Human Knock Outs
The best model organism to understand human disease is humans.

Profile
40 year-old, aerobics teacher, mother of two from Dallas, TX

Unusual Phenotype
LDL: 14 mg/dl (very low)

Mutation
PCSK9 homozygous mutant

5 PCSK9 Drugs in Development
“Anyone trying to replicate the 23andMe model by focusing only on the data, and neglecting the central focus on empowered, engaged patients, is likely to fail – and never understand why.”

— David Shaywitz, Forbes Magazine
The Power of Engagement

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23 pairs of chromosomes.
One unique you.