Controversies about Genetic Databanks and their Commercialization: Is There More to Learn from deCODE Genetics?

Sirkka L. Jarvenpaa, University of Texas at Austin
M. Lynne Markus, Bentley University
Brigham also is burdened by debt from two big projects: a $510 million new building that opened last year, and a $335 million new software system that launched in 2015.
The island nation with the tiny population have just dumped one of the most esteemed football countries out of Euro 2016 but their feat is no upset - it's planned
Entrepreneurial company in Focus

Why are we still talking about deCODE? Why did deCODE succeed where other similar initiatives failed?
The deCODE Story

- Commercial startup proposed to build three linked databases for all Icelanders
  - Genetic, health, genealogical
  - Sell results/access to data to pharma companies
- Huge controversies for and against deCODE
  - Privacy concerns obscured the other concerns of health care providers and researchers
  - But public voted with their donations
- Legacy
  - Impressive research discoveries
  - Developed a technological software system considered a gold standard in genomic research
FEATURE

Iceland's Dilemma: Privacy Versus Progress

A small Icelandic startup has been granted a 12-year license to create and manage a database of the entire nation's medical and genetic records. Can it make medical history without violating patient privacy?

BURLINGTON, VT — July 19, 2000

Choppy IPO For deCode Genetics

BUSINESS

CAN DECODE, A BIOTECH STAR GONE BUST, COME BACK?

BY MARY CARMICHAEL ON 2/11/10 AT 7:00 PM
<table>
<thead>
<tr>
<th>YEAR</th>
<th>EVENT/ISSUE</th>
<th>Implications for deCODE (dC)</th>
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<tbody>
<tr>
<td>1996</td>
<td>$12 million from seven U.S. venture capital firms</td>
<td>Iceland’s first biotech firm born as “Delaware-based firm”</td>
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<td>1998</td>
<td>$200 million partnership with Roche</td>
<td>Broad publicity and potential revenue stream</td>
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<td>1998</td>
<td>Health database bill approved by Alpingi</td>
<td>Public-private partnership</td>
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<td>1998</td>
<td>Mannvernd, or “human protection” formed to rally against Health database bill</td>
<td>International backlash toward dC</td>
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<td>2000</td>
<td>Iceland’s Supreme Court overturns the Health database bill</td>
<td>Pivots from centralized public-private model to implement collaborative distributed approach.</td>
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<td>2000-2016</td>
<td>Runs research studies leveraging local physicians.</td>
<td>By 2002: “database now exists inside deCODE”</td>
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<td>2003</td>
<td>Partnerships with Merck and Bayer</td>
<td>Refine data and mining technologies</td>
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<td>2002-5</td>
<td>Acquires MediChen Life Sciences. Hires Pfizer talent for clinical trials</td>
<td>dC acquires downstream skills</td>
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<td>2003-6(?)</td>
<td>Three year IBM partnership</td>
<td>Advances software platform, Genetics Sequence Miner</td>
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<td>2009-2010</td>
<td>Files for bankruptcy and acquired by two VCs for $20 million</td>
<td>Downsizes from 750 people to 125 people</td>
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<td>2012</td>
<td>Acquired by Amgen for $450. Subsidiary NextCODE Health</td>
<td>Provides independence, stability and financial resources to focus on fundamental research</td>
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<td>2012</td>
<td>Legal request to apply computational methods to country’s genealogical records of all 280000 Icelanders (no consent)</td>
<td>Request declined by Icelandic supreme court: must obtain individuals and relative’s consent</td>
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<td>2014</td>
<td>Ramps up research studies; as many as 50 studies in parallel run with highest level of consent.</td>
<td>Publications accelerate. By 2014, claims to have published over 400 scientific papers.</td>
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<td>2015</td>
<td>Wuxi Pharmatech acquires exclusive license to NextCODE Health; Partners with UK’s 100,000 Genomes project</td>
<td>Road for global expansion intensifies</td>
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Global Partner Capabilities for Building Genome Platform
Local Partner Capabilities for Building Genome Platform

Groomed home grown data scientists and bioinformatics

**Alþingi, legislature of Iceland**

Partnerships with local physicians and future potential coauthors

120,000 Icelandic research volunteers

Iceland’s “gray market.”
THE GLOBAL PLATFORM FOR GENOMIC BIG DATA

Built over twenty years on the world’s largest collection of human genomes, our platform today powers the biggest and most innovative precision medicine efforts on four continents, including pioneering population-optimized genome tests and wellness products in China.

UK 100,000 Genome project

Qatar Genome Project
The eMERGE Network: A consortium of biorepositories linked to electronic medical records data for conducting genomic studies

Catherine A McCarty III, Rex L Chisholm, Christopher G Chute, Hrihcar J Kullo, Gail P Janéls, Eric B Larson, Rongling U. Daniel R Maisy, Marylyn D Itch RE, Dan M Roden, Jeffery P Struwing, Wendy A Wolf and the eMERGE Team

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Open Peer review reports

Abstract

Introduction

The eMERGE (electronic MEDical Records and GEnomics) Network is an NHGRI-supported consortium of five institutions to explore the utility of DNA repositories coupled to Electronic Medical Record (EMR) systems for advancing discovery in genome science. eMERGE also includes a special emphasis on the ethical, legal and social issues related to these endeavors.

What is the next chapter in deCODE story?

Partners’ $1.2b patient data system seen as key to future

Aims for one file per person, fewer errors
What can we learn from DeCode?

The value of technological software systems in governing?
- Data sharing
- Permissions
- Authentication
- Privacy
- Security

The role of technological software systems in changing research collaborations and translational medicine?

Broad implications from different technological software systems collaborating/competing?
- Commercial interests
- Research interests
- Benefit sharing for clinical purposes
- Lingering concerns about harms to individuals and populations