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*Tools & Techniques*

# Speedy clinical analysis

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**NextCode Health** is seeking to extract untapped value from the assets of deCode genetics by using sequencing data to improve clinical diagnoses. NextCode is focused on building its user base via partnerships with medical centers and universities.

**Amgen Inc.** acquired deCode genetics ehf in late 2012 for $415 million in cash because it wanted to use the Icelandic company's databases and data mining and computational expertise to identify and validate drug targets. However, Amgen said it was not interested in continuing to offer deCode's diagnostics and genomic screening services *(see BioCentury, Dec. 24, 2012)*.

As a result, NextCode debuted last October with a $15 million series A round from Polaris Partners and Arch Venture Partners and an exclusive, five-year license from Amgen to use the deCode genomics platform for sequence-based clinical diagnostic applications. Most members of NextCode's senior leadership team come from deCode.

The company is offering access to vast databases of genomic information, software for analyzing and interpreting sequencing data, as well as data storage and management services.

Co-Founder, President and CSO Jeffrey Gulcher, who was the former CSO of deCode, said the time was right to launch NextCode as the cost of sequencing has come down dramatically while the volume of sequencing data being generated has exploded.

He said NextCode is developing its genomics business in the diagnostics space in several ways. The company is growing its user base through partnerships that provide access to the company's system, and by offering web-based and data hosting services.

Gulcher said the company already has partnerships with dozens of universities and medical centers, including **Boston Children's Hospital**, **Newcastle University**, the **QIMR Berghofer Medical Research Institute** and **Saitama Medical University**.

NextCode also is focused on site installations of its system for partners. These installations could include building a local database to house the partner's data and/or setting up access to NextCode's software.

Eventually, NextCode aims to make its system and software tools generally available to the medical community.

While deCode had started a direct-to-consumer genetic testing business called deCODEme, Gulcher said NextCode wants to build up its core business in the clinical diagnostic segment and currently has no plans to pursue the DTC market.

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>
> **Thomas Caskey,**
> **Baylor College of Medicine**

## Fast and easy

While at least 12 companies offer sequencing data analysis and interpretation services, Gulcher said the speed and capabilities of NextCode's system outstrip the others. He attributed the speed to the company's Genomic Ordered Relational (GOR) database architecture and the decade-plus that has been invested in gathering population genomic data and building up the IT infrastructure needed to house, analyze and interpret its data.

The GOR architecture was developed at deCode and is optimized to handle genetic sequencing data. NextCode has access to the GOR architecture and the IT infrastructure through its license from Amgen and has been using them to build up its own database, called the NextCode Knowledge Base, and its suite of software tools.

NextCode's database contains publicly available as well as non-public sequencing datasets, including diagnostically relevant datasets from deCode's database.

Most NextCode partners provide their own sequencing data, but the company also offers clinical-grade genomic sequencing services through an undisclosed partner's CLIA-certified laboratory.

Once a patient's sequencing data are loaded into a GOR database, the information can be analyzed in the context of all other data contained within the NextCode Knowledge Base to extract useful information, such as candidate genetic

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mutations that could be responsible for a medical condition.

While it is possible to store large quantities of sequencing data in databases built with other relational database architectures, Gulcher said querying them could take days to weeks. In contrast, he said querying a GOR database takes seconds to minutes.

NextCode's clients can use the company's front-end software tools to query a GOR database. Many such tools are part of NextCode's Clinical Sequence Analyzer (CSA) system, which allows physicians to rapidly sift patient sequencing data to make a diagnosis and/or define disease risks.

Earlier this year, NextCode launched its Tumor Mutation Analyzer system to help identify oncogenic driver mutations by analyzing sequencing data from matched pairs of malignant and normal tissues.

Gulcher said the speed of NextCode's system means physicians could make a clinical diagnosis within minutes to hours once a patient's sequencing data are loaded into a GOR database. He said this speed makes it possible for physicians to address patient questions in the point-of-care setting.

Gulcher noted other genomics companies that quickly return query results do so with whole exome data sets, whereas NextCode's system uses whole genome datasets. He said the latter are more complex and several orders of magnitude larger than the former, so querying such data in non-GOR databases would take much longer.

Whole exome data sets could miss disease-linked mutations that occur outside of exomes.

NextCode also can simultaneously analyze sequencing data from multiple individuals — from a patient and both parents for example — to provide more accurate and thorough analyses.

Finally, as NextCode's software tools are web-based, the upfront costs to use the company's system and capabilities can be held down.

"With NextCode, there is no setup charge and no switching costs. Instead, we currently charge by volume of work and it is easy for our users to switch over to other systems or use our system in parallel with the other analysis tools and services that they are already using," said Gulcher.

Pankaj Agrawal, a staff neonatologist at Boston Children's and assistant professor of pediatrics at **Harvard Medical School**, has been using NextCode's system to identify the genetic cause of pediatric conditions that do not have an actual diagnosis. He said NextCode's tools have helped him identify mutations that could be responsible for his patients' conditions in at least seven cases.

Michael Kruer has been using NextCode's tools to identify mutations in genes that could be responsible for pediatric neurological conditions. Kruer is an assistant professor in the departments of pediatrics and neurosciences at the **Sanford School of Medicine of the University of South Dakota**.

"NextCode's system allows us to pick the filters we want to use to analyze our data and individually rank the importance of each filter. Their tools have allowed us to drill down to the candidate genes that are of interest to us," he said.

Kruer added: "The learning curve for NextCode's tools was surprisingly minimal and our group was able to get up to speed within a few days. They have pretty keen understanding of what we as users would want to look for and how we would want to use their software."

Thomas Caskey, a professor of molecular and human genetics at **Baylor College of Medicine**, said NextCode's system is the fastest he has seen and also has an interface that is easy for clinicians to use.

"NextCode's system also has a very good reporting format for its data that is really directed towards members of medical community," he said. "Right now, we get so much information from our CLIA lab sequencing data to the point where it is not very useful. NextCode's system has a very clear visual data reporting format that makes it easy for doctors to harvest the important information."

"Our CLIA lab is doing over 300 cases a month and we need to have speed, efficiency and accuracy when working with all the data it generates. Out of all the systems we've evaluated, NextCode's is the one that meets all those criteria," Caskey told BioCentury.

Gulcher said NextCode is generating revenue through its partnerships and said it expects to achieve positive cash flow in three years.

COMPANIES AND INSTITUTIONS MENTIONED

**Amgen Inc.** (NASDAQ:AMGN), Thousand Oaks, Calif.
**Baylor College of Medicine**, Houston, Texas
**Boston Children's Hospital**, Boston, Mass.
**Harvard Medical School**, Boston, Mass.
**Newcastle University**, Newcastle upon Tyne, U.K.
**NextCode Health**, Cambridge, Mass.
**QIMR Berghofer Medical Research Institute**, Brisbane, Australia
**Saitama Medical University**, Saitama, Japan
**Sanford School of Medicine of the University of South Dakota**, Sioux Falls, S.D.

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