



# SAFEGUARDING THE BIOECONOMY

AMAZING PROMISE

EMERGING CHALLENGES

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Edward H. You

Supervisory Special Agent

Federal Bureau of Investigation

Weapons of Mass Destruction Directorate

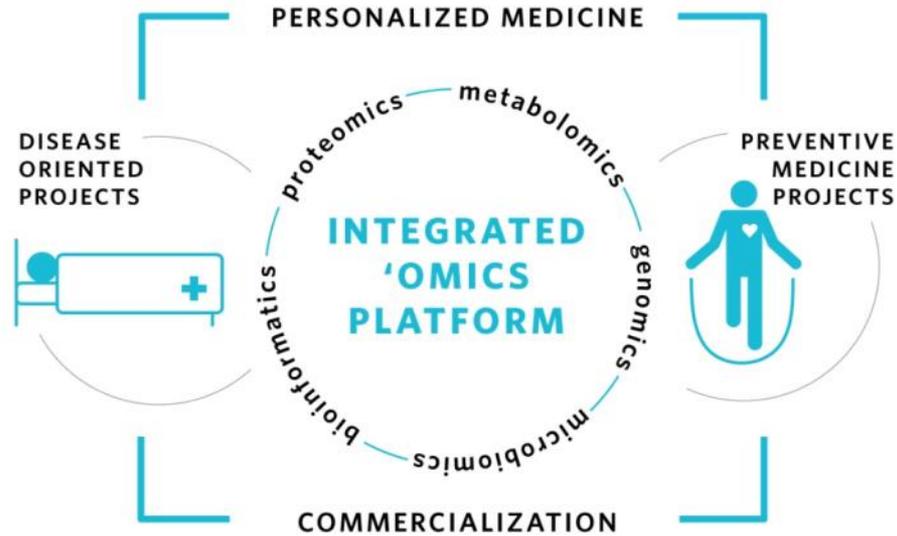
Liaison Officer

Office of National Security

U.S. Department of Health and Human Services

# “PRECISION/PERSONALIZED” MEDICINE

## Data is the New Oil



<http://lsi.ubc.ca/our-vision/personalized-medicine/projects/>



<http://www.telegraph.co.uk/finance/newsbysector/mediatechnologyandtelecoms/electronics/10540860/Fitbit-in-push-to-lead-the-wearable-tech-boom.html>



# 23andMe Pulls Off Massive Crowdsourced Depression Study

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MIT  
Technology  
Review

- by Antonio Regalado
- August 1, 2016

A scientific expedition into the DNA of more than **450,000 customers** of gene-testing company 23andMe has uncovered the first major trove of genetic clues to the cause of depression.

The study, the largest of its kind, detected 15 regions of human genome linked to a higher risk of struggling with serious depression.



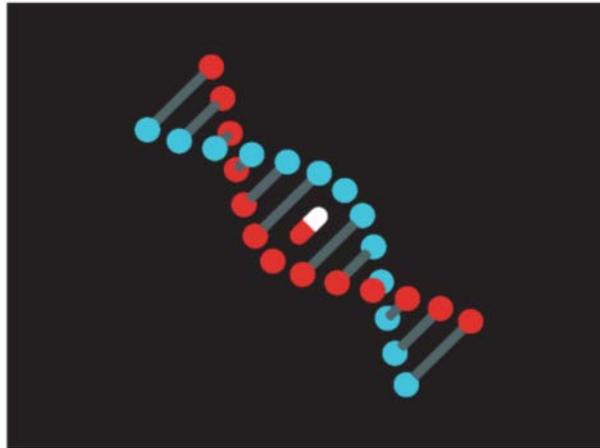
<https://www.technologyreview.com/s/602052/23andme-pulls-off-massive-crowdsourced-depression-study/>



**WIRED**

August 3, 2018

# 23ANDME'S PHARMA DEALS HAVE BEEN THE PLAN ALL ALONG



23andMe gets is an ever-expanding supply of valuable ***behavioral, health, and genetic information*** from the 80 percent of its customers who consent to having their data used for research.

GlaxoSmithKline, is gaining exclusive rights to mine 23andMe's customer data for drug targets (\$300 million investment).



# Your medical record is worth more to hackers than your credit card

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- Community Health Systems Inc., 4.5 million patient records (Aug. 2014)
- Anthem Blue Cross, 80 million patient records (Jan. 2015)
- Premera Blue Cross, 11 million patient records (Mar. 2015)\*
- UCLA Health System, 4.5 million patient records (Jul. 2015)\*



<http://www.reuters.com/article/us-cybersecurity-hospitals-idUSKCN0HJ21120140924>



# Another Day, Another Health Insurance Hack Affecting 11 Million People

By Lily Hay Newman



Premiera Blue Cross said that names, birthdays, email addresses, physical addresses, telephone numbers, Social Security numbers, member IDs, bank account information, **medical information, and insurance claims** may all have been exposed in the breach.

[www.slate.com/blogs/future\\_tense/2015/03/18/premera\\_blue\\_cross\\_health\\_insurer\\_hacked\\_11\\_million\\_financial\\_and\\_medical.html](http://www.slate.com/blogs/future_tense/2015/03/18/premera_blue_cross_health_insurer_hacked_11_million_financial_and_medical.html)



# China Doubles Down on the Double Helix

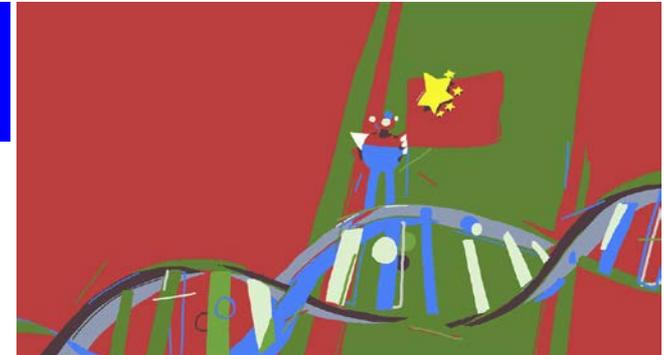
## KEY PLAYERS IN GENOMICS IN CHINA

COMPANY	HEADQUARTERS	FOUNDED	MAIN PRODUCTS
<b>Annoroad Genomics</b>	Beijing	2012	Genome sequencing, liquid biopsy tests, noninvasive prenatal testing, and direct-to-consumer tests that reveal cancer risks
<b>Berry Genomics</b>	Beijing	2010	Noninvasive prenatal testing, exome sequencing, and direct-to-consumer tests that reveal cancer risks
<b>BGI</b>	Shenzhen	1999	Genome sequencing; also manufactures a sequencer
<b>CloudHealth Genomics</b>	Shanghai	2014	Genome sequencing, "liquid biopsy" blood tests for cancer, and direct-to-consumer tests that can reveal a child's ability to absorb certain nutrients
<b>Gene+</b>	Beijing	2015	Direct-to-consumer tests that reveal cancer risks and genomic sequencing of tumors to help cancer doctors develop personalized treatment plans
<b>Haplox</b>	Shenzhen	2014	Liquid biopsy tests and direct-to-consumer tests that reveal cancer risks
<b>Mega Genomics</b>	Beijing	2016	Genome sequencing and direct-to-consumer tests that reveal cancer risks and tolerance of certain medications
<b>Novogene</b>	Beijing	2011	Genome sequencing and liquid biopsy tests
<b>WuXi NextCode</b>	Cambridge, Massachusetts*	2013	Genome sequencing, cloud storage for genomic data, and a genomic database that helps scientists research variation across population groups
<b>Yang Zi Investment Group</b>	Nanjing	2016	State-owned investment group that built a sequencing center

\* originally a spinoff of Iceland's Decode Genetics, acquired by Shanghai-based WuXi AppTech in 2015.



Nov. 2, 2017



About 30 percent of the world's sequencing machines were in China as of 2015, but the country has been gearing up to increase its share.

In 2016, the state-owned Yang Zi Investment Group built a sequencing center in Nanjing that's capable of sequencing the genomes of **400,000 to 500,000 people a year.**



# BGI is granted patent in 16 countries for non-invasive prenatal genetic test technology

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**October 10, 2014**, Shenzhen, China-- The European Patent Office has issued patent number for invention to BGI for its independently researched non-invasive prenatal genetic test (NIPT) technology. The patent is effective in 15 member countries including England, Belgium, Spain, Slovenia, Hungary, Sweden, Turkey, Switzerland, Italy, France, Denmark, Germany, Czech Republic, Poland and Romania

As of August, 2014, BGI Dx, a subsidiary unit of BGI, has provided non-invasive prenatal genetic testing services via its NIFTY® test to ***nearly 400,000 pregnant women worldwide.***



[www.eurekalert.org/pub\\_releases/2014-10/bs-big101014.php](http://www.eurekalert.org/pub_releases/2014-10/bs-big101014.php)



# Genomic Analyses from Non-invasive Prenatal Testing Reveal Genetic Associations, Patterns of Viral Infections, and Chinese Population History

Cell

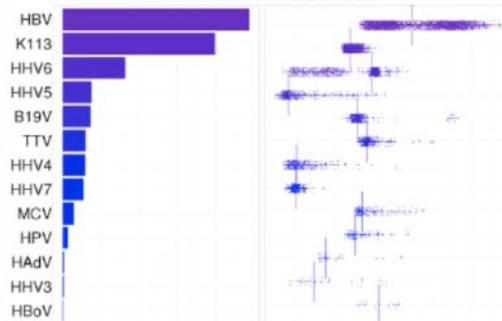
VOLUME 175, ISSUE 2, P347-359.E14, OCTOBER 04, 2018

## GWAS discoveries



141,431 NIPT Chinese participants

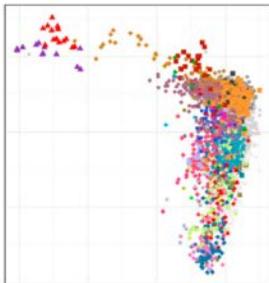
## Plasma virome



Prevalence and abundance

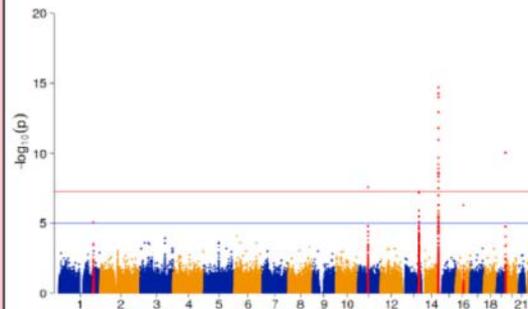
- Genome sequencing from low-pass noninvasive prenatal testing samples
- GWAS of 141,431 low-pass genomes reveals 16 unknown genetic associations
- Patterns of clinically relevant viral infection in maternal plasma
- Insights into the genetic structure and history of the Chinese population

## Population structure



Minorities and Han Chinese

## Genetic adaptation



Multiple loci under selection



**The New York Times**

Feb. 21, 2019

# China Uses DNA to Track Its People, With the Help of American Expertise

The Chinese authorities turned to a Massachusetts company and a prominent Yale researcher as they built an enormous system of surveillance and control.

In Xinjiang, in northwestern China, the program was known as “Physicals for All.”

From 2016 to 2017, nearly 36 million people took part in it, according to Xinhua, China’s official news agency. The authorities collected DNA samples, images of irises and other personal data, according to Uighurs and human rights groups.



# China Access to U.S. Genomic Data

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## WuXi Healthcare Invests In US Genomics Testmaker 23andMe

Oct. 21, 2015

WuXi Healthcare Ventures, the investment arm of WuXi PharmaTech, participated in the \$115 million E financing of California's 23andMe. 23andMe offers a \$199 direct-to-consumer saliva DNA test. According to one report, the test is a loss leader for the company, which is more interested in developing a genomics database than selling tests. About 80% of 23andMe's customers -- about 100 million people -- allow the company to include their DNA reports (anonymously) in a genomic database.

[www.biospace.com/News/wuxi-healthcare-invests-in-us-genomics-testmaker/396011](http://www.biospace.com/News/wuxi-healthcare-invests-in-us-genomics-testmaker/396011)

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## WuXi NextCode Sequencing Facility Receives CAP Accreditation

Feb 23, 2016

NEW YORK (GenomeWeb) –WuXi AppTec subsidiary WuXi NextCode said today that its sequencing facility in Shanghai, China has been accredited by the College of American Pathologists.

The company also said that the Shanghai lab is the first such lab in China to be licensed by the State of California, allowing the company to process samples from the state. WuXi NextCode is also the only sequencing facility in China with CLIA certification from the US Centers for Medicare and Medicaid, the company said.

[www.genomeweb.com/sequencing-technology/wuxi-nextcode-sequencing-facility-receives-cap-accreditation](http://www.genomeweb.com/sequencing-technology/wuxi-nextcode-sequencing-facility-receives-cap-accreditation)



# WuXi to build dedicated vaccine facility, but who's the client?

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FiercePharma

May 21, 2019



WuXi Biologics says it will build a dedicated facility to manufacture a commercial vaccine product for a client in a contract that should produce \$150 million a year for 20 years. It just didn't identify the client.

The Chinese CDMO announced WuXi Vaccines will build a vaccine manufacturing facility that will be able to handle substance and drug product manufacturing and will include quality control labs. It said it has estimated the value of the 20-year manufacturing contract at more than \$3 billion.



# BGI And Huawei Collaborate To Build Big Data Storage For Genomics

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 **BioSpace**® Sep. 21, 2015

BGI signed an agreement with Huawei Technology, a Shenzhen networking and telecom equipment maker, to develop big data storage systems for genomic research.

[www.biospace.com/News/bgi-and-huawei-collaborate-to-build-big-data/392057](http://www.biospace.com/News/bgi-and-huawei-collaborate-to-build-big-data/392057)



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## WuXi NextCODE, Huawei Launch Precision Medicine Cloud for China

**Bio-IT World** May 24, 2016

WuXi AppTec and Huawei launched the China Precision Medicine Cloud today. The two companies hope the platform will support the **Chinese government's Precision Medicine Initiative**, and link researchers across China through a **secure nationwide network**.

[www.bio-itworld.com/2016/5/24/wuxi-nextcode-huawei-launch-precision-medicine-cloud-china.aspx](http://www.bio-itworld.com/2016/5/24/wuxi-nextcode-huawei-launch-precision-medicine-cloud-china.aspx)

**WuXiNextCODE**  
Leading Genomics



# Huawei and Philips will collaborate on a new cloud-based healthcare solution



Oct 26, 2017

Huawei and Philips signed an MOU to build a new, cloud-based healthcare solution for deployment in China.

The project is now looking towards a future where cloud and machine-learning will digitalize and disrupt the healthcare vertical with unprecedented speed and reach.

- Increase patient accessibility
- Increase use of wearable technologies
- Reduce workload in diagnostics
- Increase analytics capabilities and information sharing



**PHILIPS**  
Healthcare



# DLA Selects Philips Healthcare Unit for \$450M Patient Monitoring Tech Supply Contract

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**GOVCON** WIRE

April 1, 2019



Philips' healthcare business has won a potential 10-year, \$450M contract with the Defense Logistics Agency to provide patient monitoring systems, accessories and training services to U.S. service branches and federal civilian agencies.

The base period of performance runs through March 28, 2024, and work could extend by five more years if all options are exercised.

[www.govconwire.com/2019/04/dla-selects-philips-healthcare-unit-for-450m-patient-monitoring-tech-supply-contract/](http://www.govconwire.com/2019/04/dla-selects-philips-healthcare-unit-for-450m-patient-monitoring-tech-supply-contract/)



# China Clamps Down on Foreign Use of Chinese Genetic Material and Data

**TheScientist**  
EXPLORING LIFE, INSPIRING INNOVATION

Jun. 17, 2019



The state council order contains 46 articles restricting the use and storage of any materials from China that contain human genomes, including organs and cells, as well as data derived from those sources.

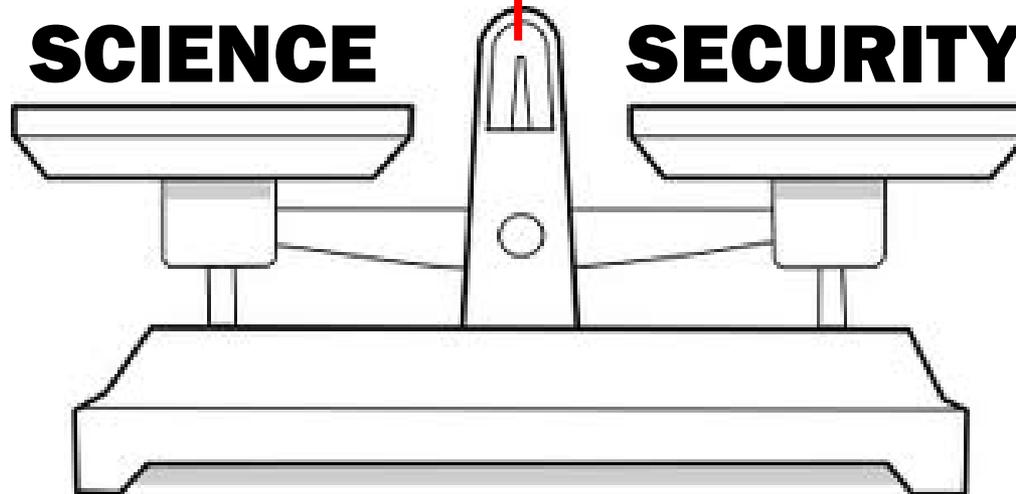
Article 21 states that foreign organizations that use the materials must abide by Chinese law and work in cooperation with Chinese institutes.

Article 24 says that all data and patents derived from such a collaboration must be shared with the Chinese institution.

[www.the-scientist.com/news-opinion/china-clamps-down-on-foreign-use-of-chinese-genetic-material-and-data-66016](http://www.the-scientist.com/news-opinion/china-clamps-down-on-foreign-use-of-chinese-genetic-material-and-data-66016)

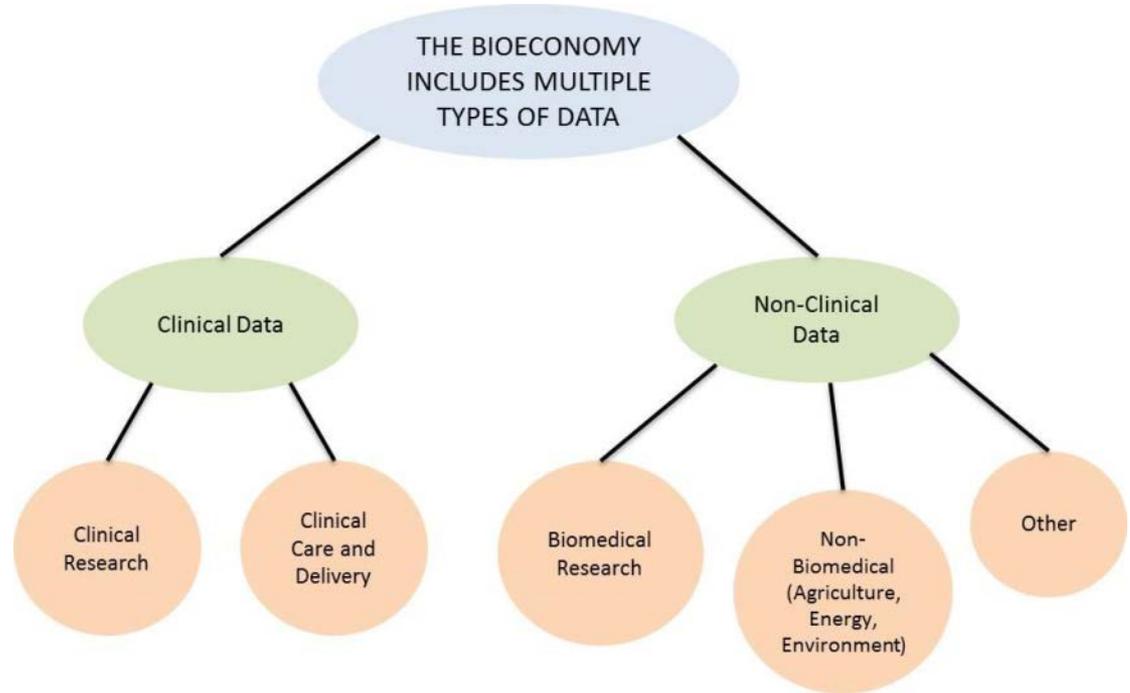
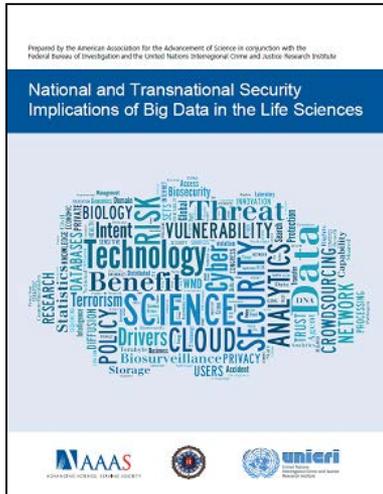


**NATIONAL  
SECURITY**

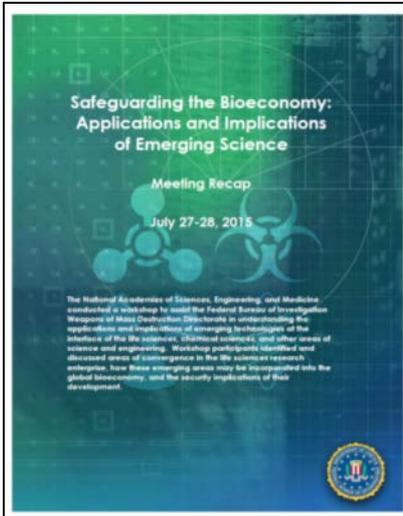


# FBI Safeguarding the Bioeconomy Awareness Raising

2014



2016



## Future Challenges

- Scoping the bioeconomy
- Broad, holistic assessment of the biological threat/vulnerability
- Development of countermeasures and policies to further grow and safeguard the bioeconomy

[www.ibpforum.org/resource/national-and-transnational-security-implications-big-data-life-sciences-0f](http://www.ibpforum.org/resource/national-and-transnational-security-implications-big-data-life-sciences-0f)

[www.ibpforum.org/resource/safeguarding-bioeconomy-iii-securing-life-sciences-data-meeting-recap](http://www.ibpforum.org/resource/safeguarding-bioeconomy-iii-securing-life-sciences-data-meeting-recap)



# CFIUS forces PatientsLikeMe into fire-sale booting Chinese investor

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Apr 4, 2019



- In 2017, the start-up raised \$100 million and sold a majority stake to Shenzhen-based iCarbonX, which was started by genomic scientist Jun Wang and is backed by Chinese giant Tencent.
- PatientsLikeMe sold a majority stake to China's iCarbonX in 2017 so it could take advantage of the Chinese company's deep technology.
- The Trump administration is now forcing a divestiture following a review by the Committee on Foreign Investment in the United States (CFIUS).



# Senators Want to Know If CMS Paid China-Linked Companies for Genetic Testing

Nextgov

June 11, 2019



Sens. Marco Rubio and Chuck Grassley want more information on how the Centers for Medicare and Medicaid Services (CMS) is protecting Americans' genomic data from foreign entities.

- Determine whether CMS considers national security risks when determining whether payments are permissible.
- Develop recommendations to CMS and Congress regarding how to mitigate national security risks related to CMS payments associated with Americans' genomic data

***“Taxpayers cover the costs of CMS payments. Accordingly, they have every right to know if their money has gone to entities connected to the Chinese government.”***

[www.nextgov.com/cybersecurity/2019/06/senators-want-know-if-cms-paid-china-linked-companies-genetic-testing/157641/](http://www.nextgov.com/cybersecurity/2019/06/senators-want-know-if-cms-paid-china-linked-companies-genetic-testing/157641/)



# Pentagon Leaders Tell Troops to Stop Using Mail-In Genealogy DNA Kits

**Military.com** Dec. 27, 2019

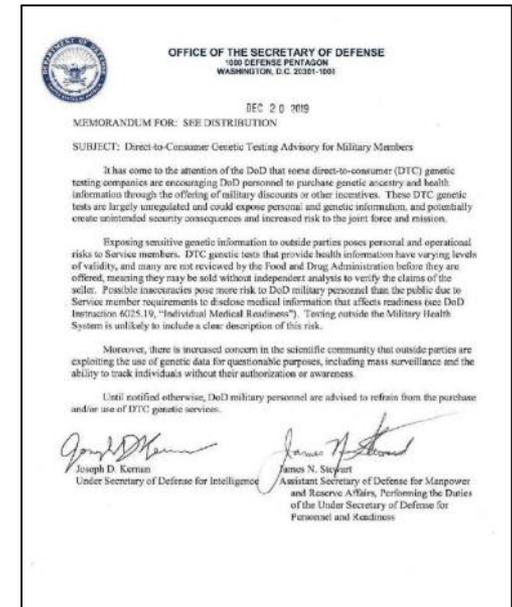
U.S. troops are being advised to steer clear of popular genetic-testing kits over what Pentagon leaders say is a growing concern that the personal information could be exploited or tracked.



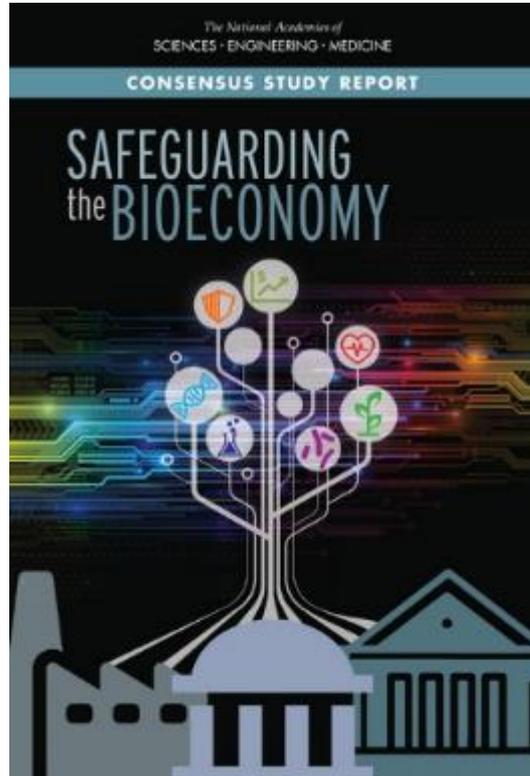
Testing performed by DTC companies may or may not provide reliable, accurate results.

“Increased concern in the scientific community that outside parties are exploiting the use of the genetic data for questionable purposes.”

“Mass surveillance and the ability to track individuals without their authorization or awareness.”



# National Academies of Science Safeguarding the Bioeconomy



Jan. 14, 2020

- Division on Earth and Life Studies  
Health and Medicine Division
- Division on Engineering and Physical Sciences
- Board on Life Sciences
- Board on Agriculture and Natural Resources
- Board on Science, Technology, and Economic Policy
- Board on Health Sciences Policy
- Forum on Cyber Resilience
- Committee on Safeguarding the Bioeconomy

While the United States has been a leader in advancements in the biological sciences, other countries are also actively investing in and expanding their capabilities in this area. Maintaining competitiveness in the bioeconomy is key to maintaining the economic health and security of the United States and other nations.



# 2019 Novel Coronavirus Outbreak

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## As Coronavirus Numbers Rise, C.D.C. Testing Comes Under Fire

Mar. 4, 2020

Federal health officials botched an initial diagnostic test and restricted widespread screening.

The Centers for Disease Control and Prevention botched its first attempt to mass produce a diagnostic test kit, a discovery made only after officials had shipped hundreds of kits to state laboratories.



# 2019 Novel Coronavirus Outbreak

Jan. 29, 2020

## BGI Sequencer, Coronavirus Molecular Assays Granted Emergency Use Approval in China

[www.genomeweb.com/regulatory-news-fda-approvals/bgi-sequencer-coronavirus-molecular-assays-granted-emergency-use#.Xjta6WhKiUk](http://www.genomeweb.com/regulatory-news-fda-approvals/bgi-sequencer-coronavirus-molecular-assays-granted-emergency-use#.Xjta6WhKiUk)



Jan. 30, 2020

## Ares Genetics Collaborates With BGI on Coronavirus Testing in Europe

BGI and MGI will now work with their long-term strategic partner Ares Genetics in Europe to make the 2019-nCoV testing portfolio available to public health institutions and hospitals for outbreak monitoring, infection control, and epidemiology.

[www.genomeweb.com/business-news/ares-genetics-collaborates-bgi-coronavirus-testing-europe#.Xjtdh2hKiUk](http://www.genomeweb.com/business-news/ares-genetics-collaborates-bgi-coronavirus-testing-europe#.Xjtdh2hKiUk)

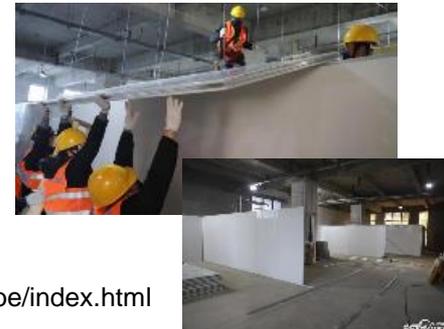


Feb. 3, 2020

## Wuhan: Pathogen biosafety lab built in five days

The construction officially started on February 1 by **BGI Genomics** in Wuhan. After completion on February 5, the lab will greatly increase the speed of realizing the 10,000 novel coronavirus cases needed per day so that suspected infections can be eliminated or confirmed as soon as possible.

[news.cgtn.com/news/2020-02-03/Wuhan-Pathogen-biosafety-lab-built-in-five-days-NMXIZI3wbe/index.html](http://news.cgtn.com/news/2020-02-03/Wuhan-Pathogen-biosafety-lab-built-in-five-days-NMXIZI3wbe/index.html)



# BGI Coronavirus Molecular Diagnostic Test Earns CE Mark

Mar. 2, 2020

BGI said late on Friday that its Real-Time Fluorescent RT-PCR kit for detecting SARS-CoV-2 (also known as 2019-nCoV) has received **CE-IVD** marking and is now **commercially available in markets recognizing the designation**.

[www.genomeweb.com/pcr/bgi-coronavirus-molecular-diagnostic-test-garners-ce-mark#.XmEDsahKiUk](http://www.genomeweb.com/pcr/bgi-coronavirus-molecular-diagnostic-test-garners-ce-mark#.XmEDsahKiUk)



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## BGI Genomics, Intel, Lenovo Form COVID-19 Research Alliance

Mar. 4, 2020

Through the alliance, Intel and Lenovo will provide BGI Genomics with computational and genomic analysis technologies as well as technical expertise, to advance its studies into COVID-19 virulence, transmission patterns, and host-pathogen interactions.

This research will help BGI Genomics' efforts to optimize COVID-19 diagnostic kits and identify potential drug targets, the companies said.

[www.genomeweb.com/infectious-disease/bgi-genomics-intel-lenovo-form-covid-19-research-alliance#.XmEEUahKiUk](http://www.genomeweb.com/infectious-disease/bgi-genomics-intel-lenovo-form-covid-19-research-alliance#.XmEEUahKiUk)



# WuXi hits the gas on coronavirus antibody development

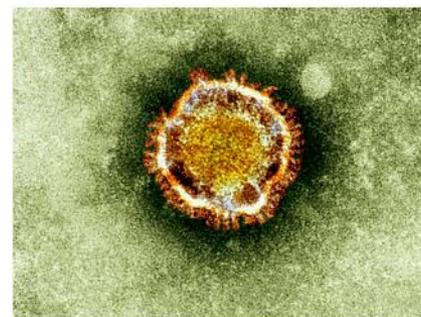
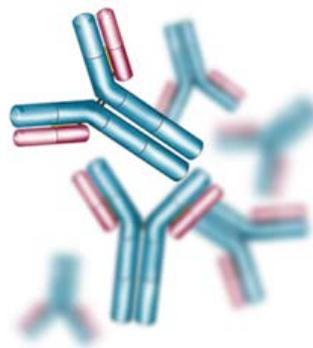
the **pharma**letter  
Up to date news for the Pharmaceutical and Biotechnology industries

Jan. 29, 2020



Shanghai, China-based WuXi Biologics says it has increased efforts in enabling the development of multiple neutralizing antibodies for the current outbreak of a novel coronavirus (2019-nCoV), centered in Wuhan, China.

Compared with the ***traditional timeline of 12 to 18 months***, all studies from DNA to IND could hopefully be completed in **4-5 months** while maintaining high quality. This way we can provide effective and timely interventions for the disease caused by 2019-nCoV.

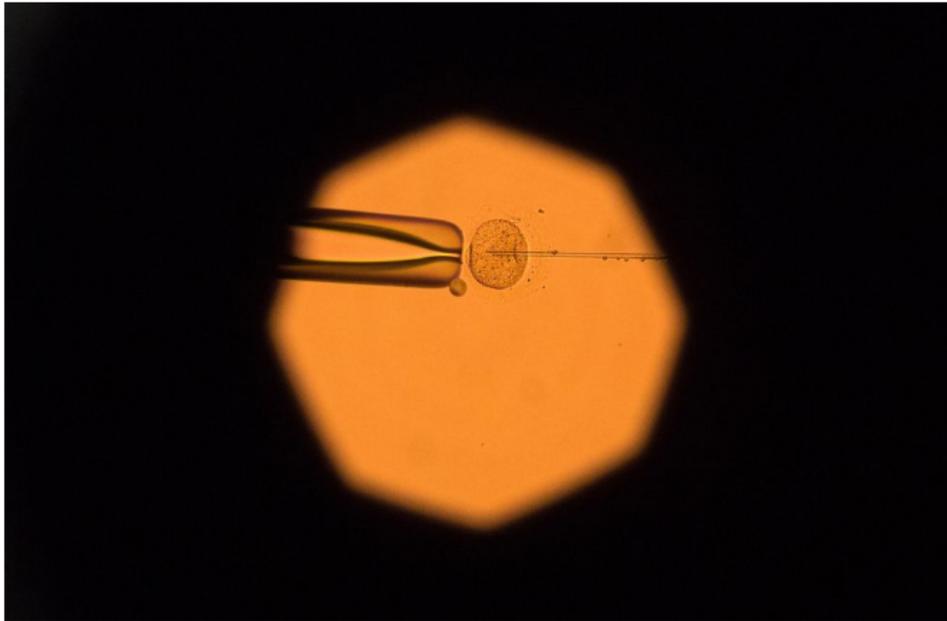


Prognosis

# Future of Genetically Modified Babies May Lie in Putin's Hands

By [Stepan Kravchenko](#)

September 29, 2019, 12:00 AM EDT



An image from an electron microscope shows oocyte manipulation. *Photographer: Andrey Rudakov/Bloomberg*



[www.bloomberg.com/news/articles/2019-09-29/future-of-genetically-modified-babies-may-lie-in-putin-s-hands](http://www.bloomberg.com/news/articles/2019-09-29/future-of-genetically-modified-babies-may-lie-in-putin-s-hands)



A vertical decorative bar on the left side of the slide, featuring a green-to-blue gradient background with a grid pattern. It contains several semi-transparent icons: a molecular structure, a biohazard symbol, a radiation symbol, and an atomic model. 

**THANK YOU**

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