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U.S. Healthcare- Related Data and China's Biotechnology Industry

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June 17, 2021

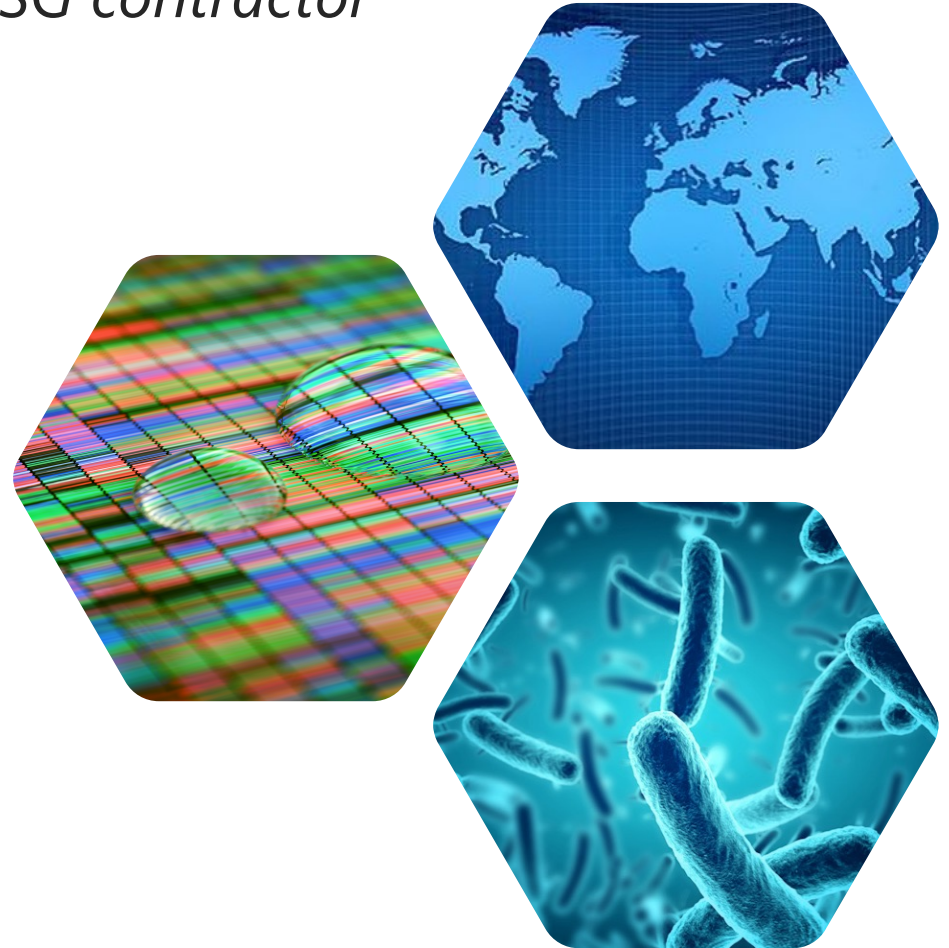


Gryphon Scientific

Research and consulting firm and USG contractor

Data Analytics Risk Assessment
Policy Analysis
Training and Exercise

Emergency Preparedness
Biosecurity
CBRN Defense
International Science Engagement





China's Biotechnology Development

The Role of U.S. and Other Foreign Engagement

- U.S.-China Economic Security and Review Commission
- Directed by USCC to assess:



State of China's biotechnology sector



Role of foreign firms and technologies



Chinese investment in U.S. biotechnology



China's biotech partnerships and research institutes in the U.S.



China's access to U.S. healthcare-related data.





Growth in Biotechnology



China \$5-6 billion
U.S. \$120 billion

Biologics and other medical technologies

Genomics and precision medicine



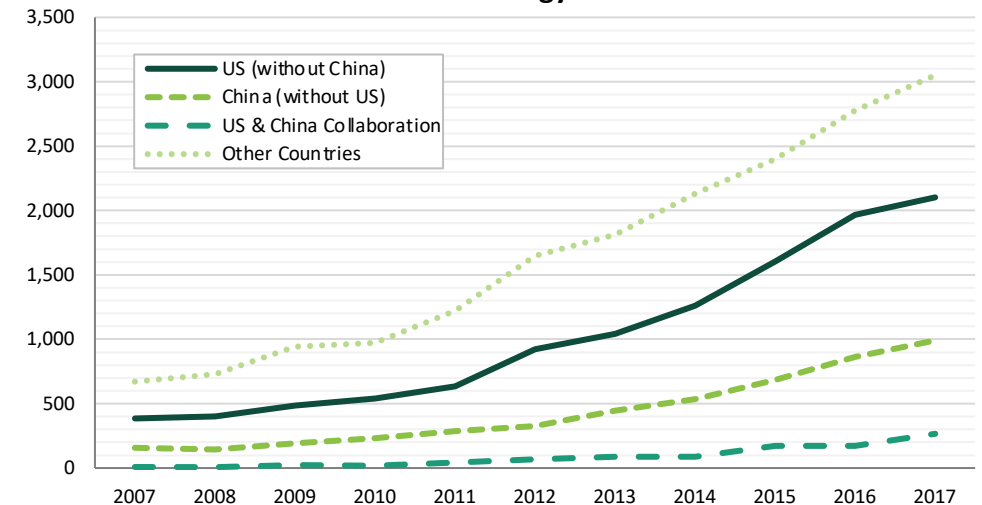
China \$8 billion
U.S. \$110 billion

Genetically modified (GM) crops

Industrial biotech and synthetic biology

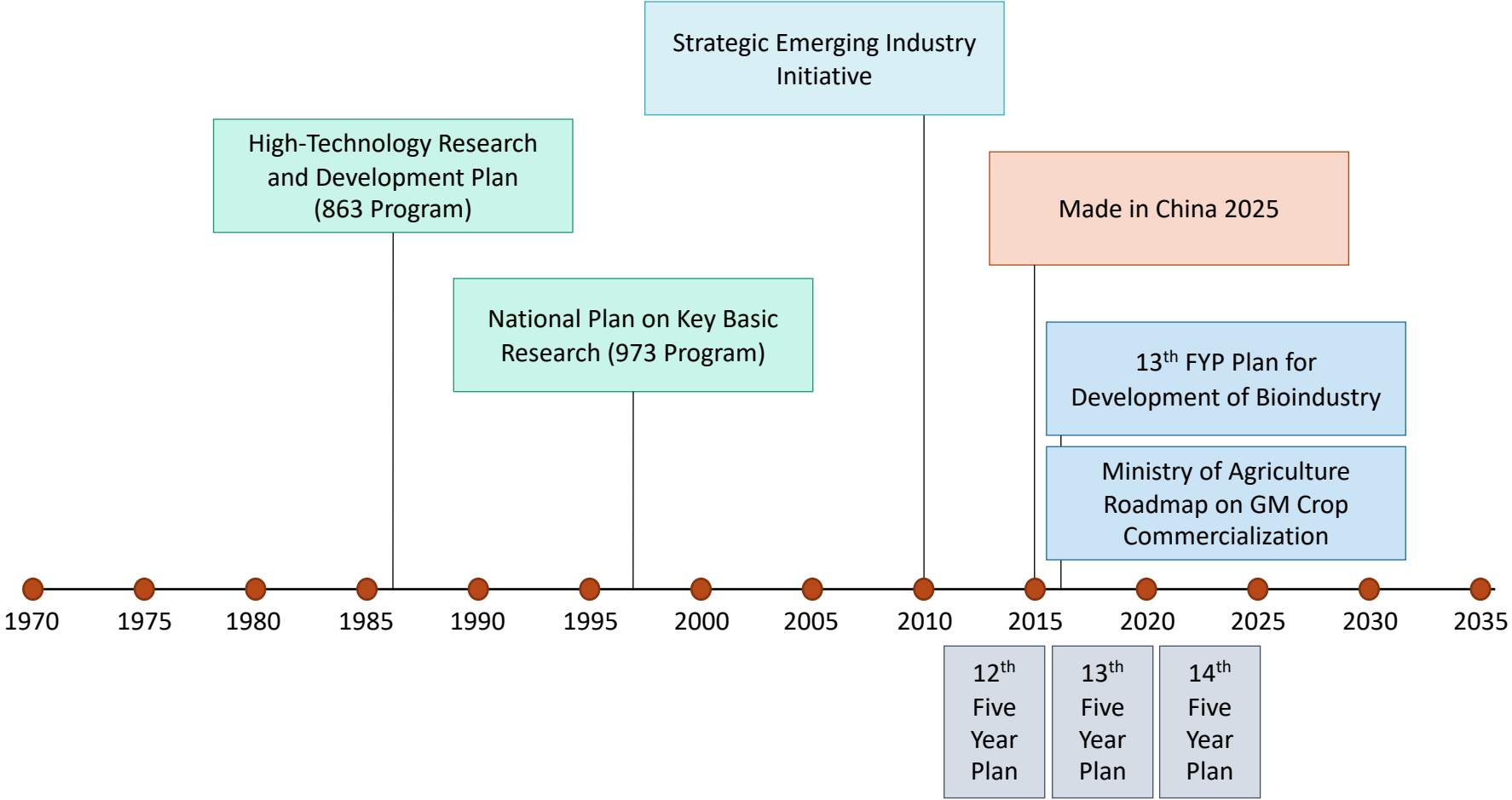


Annual Biotechnology Publications





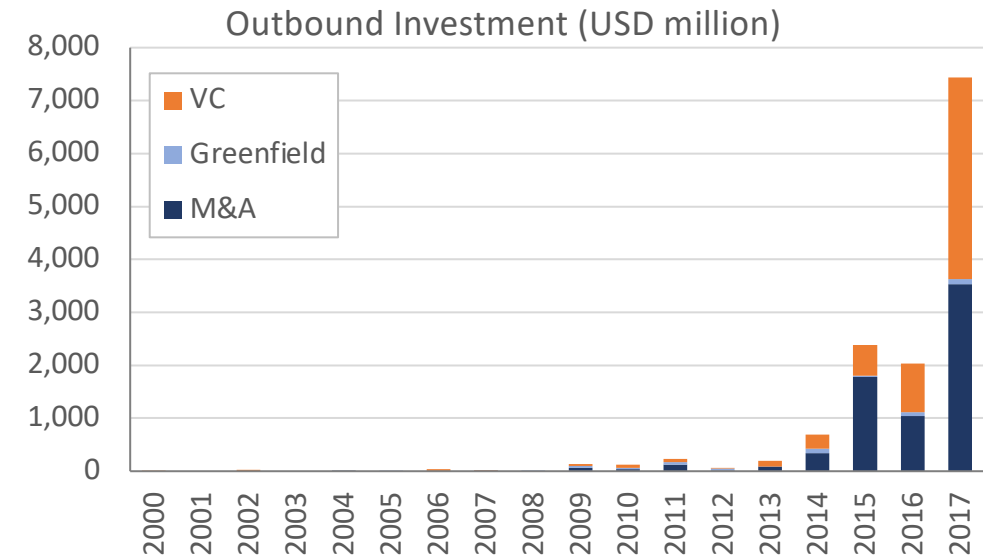
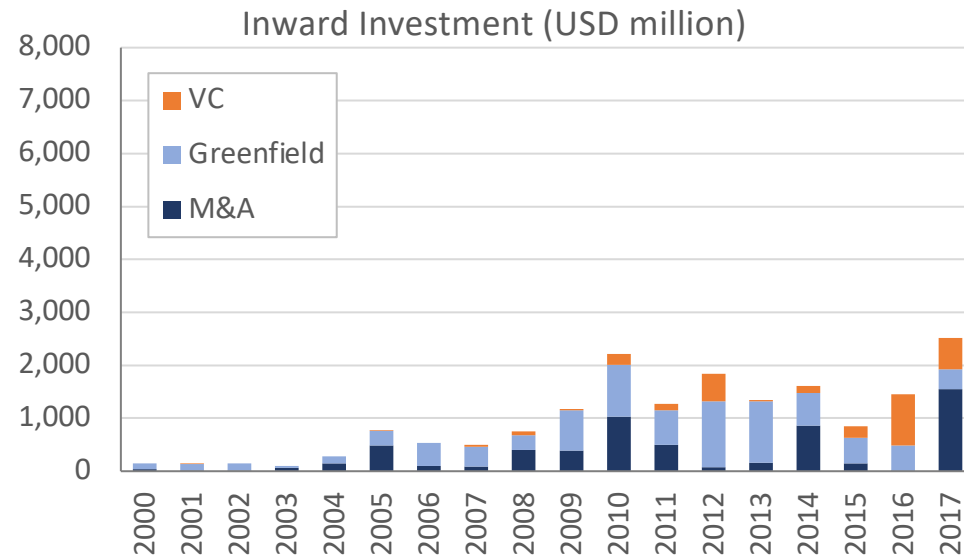
Key Policies





Foreign Investment in China's Biotech

- Inward investment increased starting in early/mid-2000s
- Outbound investments strong since 2015

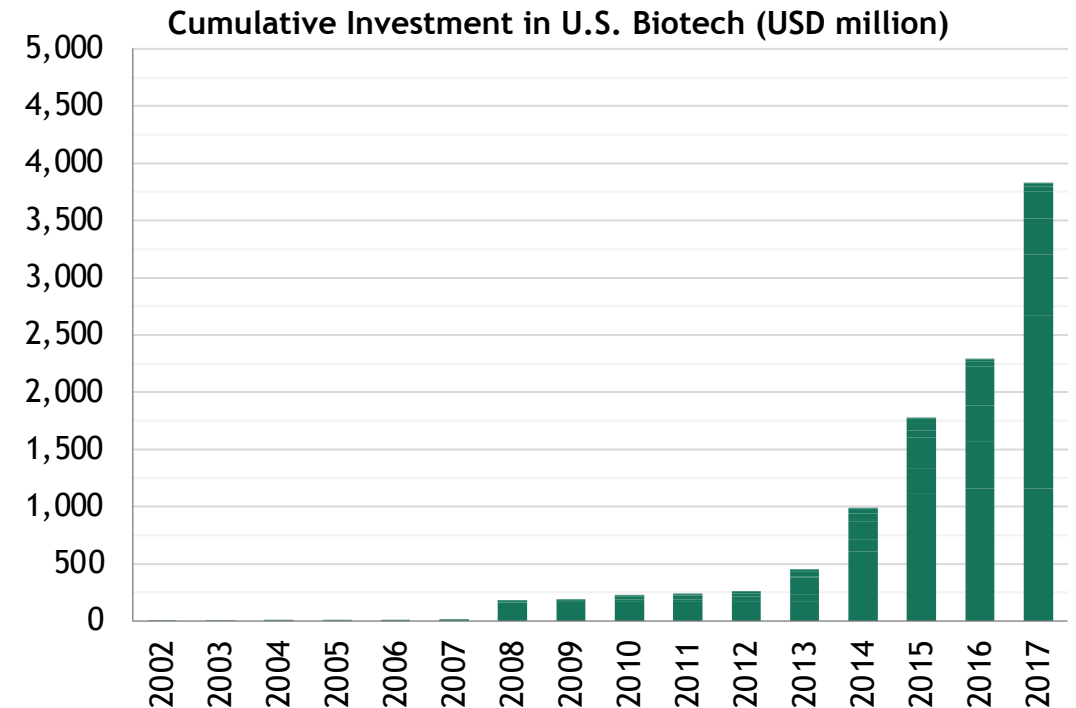
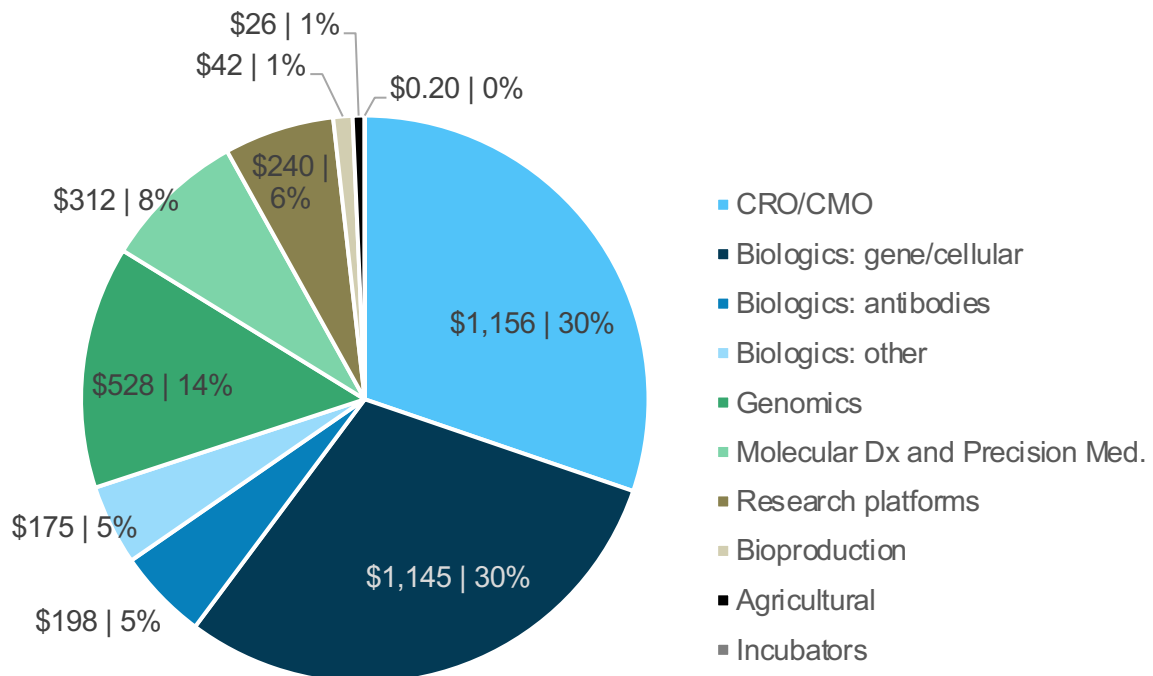


Source: Rhodium Group



Chinese Investment in U.S. Biotech 2000-2017

- \$3.8 billion total
 - 2% of Chinese investment in U.S.





Major Players in Genomic/Biomedical Data



China's #1 DNA sequencing and genomics company

Provides sequencing systems, service, molecular diagnostics

World's largest sequencing capacity



WuXi AppTec leading global CRO

Clinical research, biologics, genomics, pharmaceuticals

WuXi Genomics →
WuXi NextCODE →
Genuity Science



Founded 2015 by Jun Wang

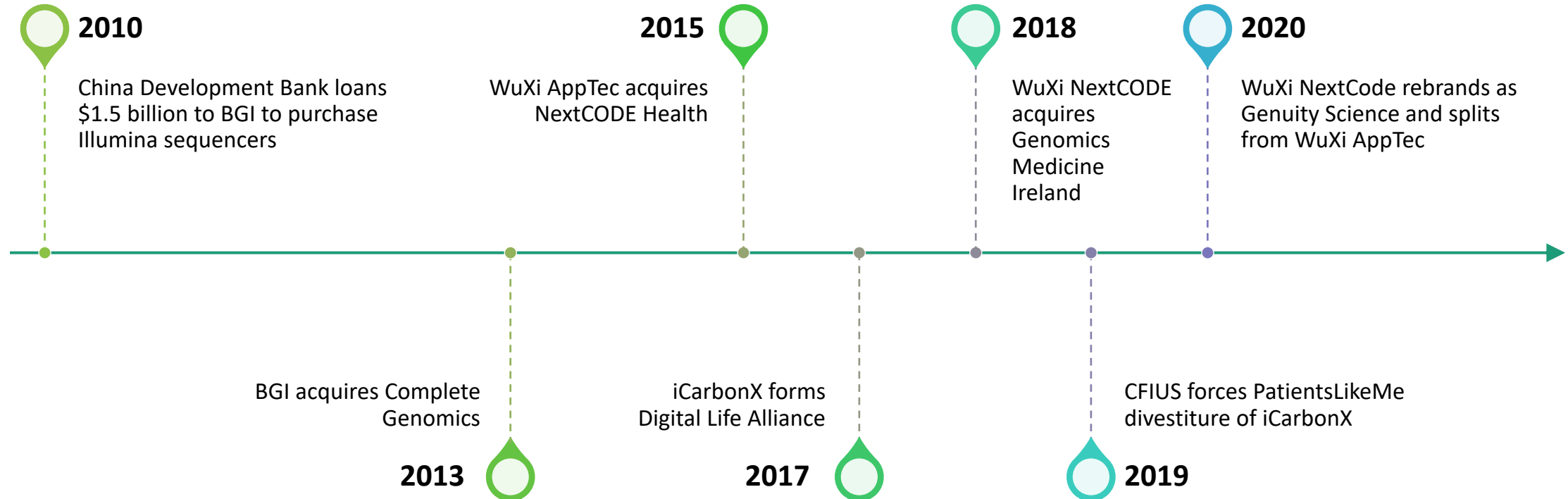
Combines AI and genomics

Digital Life Alliance



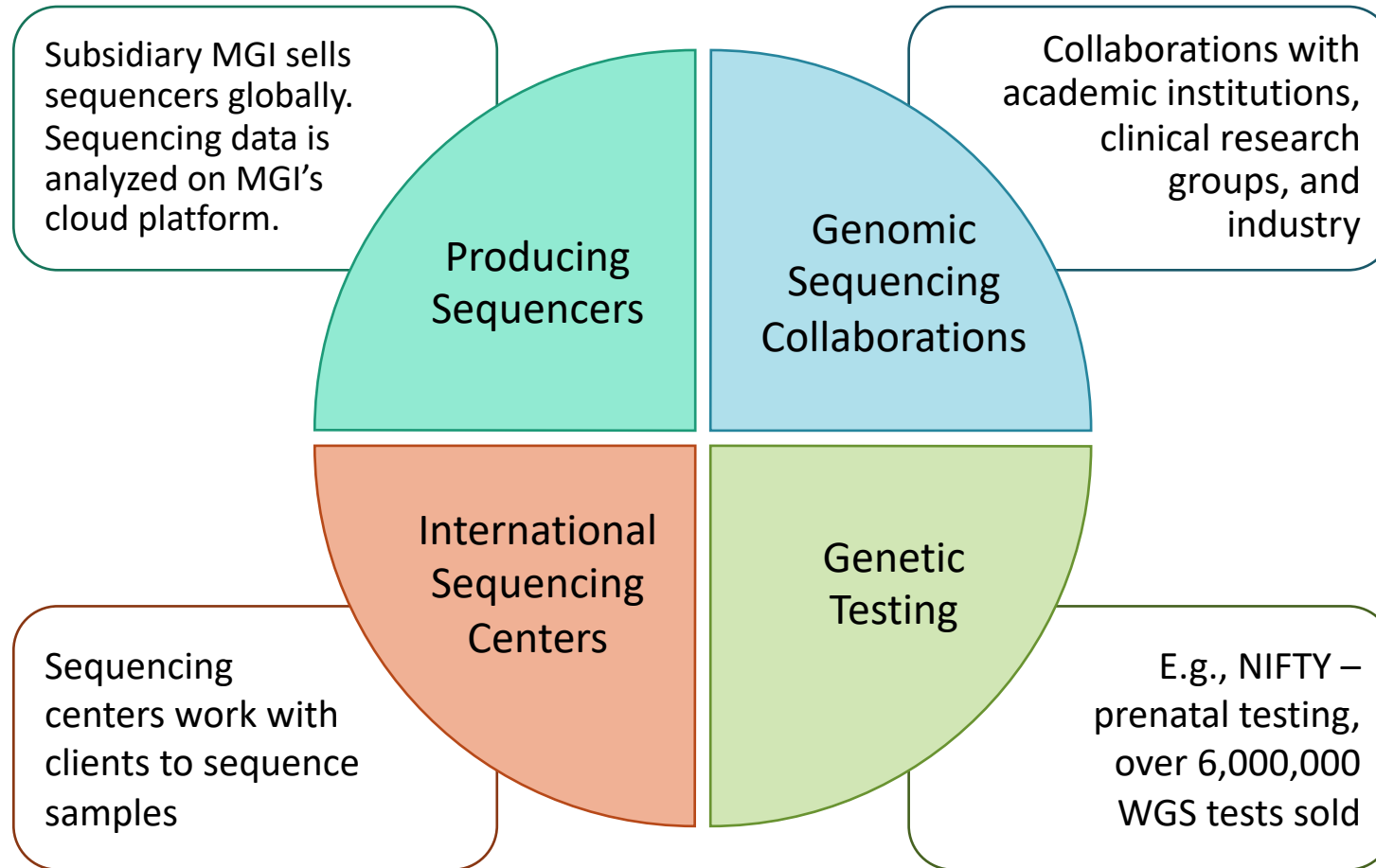


Genomics and Health Data Developments in China





How Does BGI access genomic data?





Encouraging open access as a way to gain data

Giga Science Press

Publishing arm of BGI

- Open access journals
- Platform for data sharing – including genomic data

China National Genebank

Repository of genetic information funded by the Chinese government

- Bioinformatics data center and living biobank
- CNGB has had collaborations with over 100 global organizations on over 600 projects.

Data Sharing Alliances

Alliances promote sharing of genomic data between research institutions

- Global Alliance 4 Genomics and Health (GA4GH)
- International Rare Disease Research Consortium (IRDiRC)
- International Cancer Genome Consortium (ICGC)



WuXi Partnerships for Precision Medicine in the Cloud



- Partner to combine WuXi and Google's genomic analysis tools
- Cloud HealthCare API
 - Electronic Health Records of numerous hospital systems
 - Biometric data from medical devices, wearables, etc
 - De-identified data is shared to non-privileged parties



- WuXi NextCODE and Huawei partner for China Precision Medicine Initiative



Incubators and Research Centers in U.S.

Incubators

- QBIC (Boston)
- Cumberland Emerging Technologies (Nashville)
- CUBIC (Houston/Texas Medical Center)

R&D Centers

- QLB Biotherapeutics (Boston)
- VcanBio USA (Boston)
- Luye Boston R&D Center (Boston)
- Sihuan Pharmaceutical (SF Bay Area)
- Novogene (Sacramento/UC Davis)
- Genetron Health Technologies (Research Triangle Park, NC)



Image credit: Houston Chronicle

- cancer immunotherapy
- cancer immunotherapy
- cancer immunotherapy
- cancer immunotherapy
- genome sequencing center
- molecular diagnostics

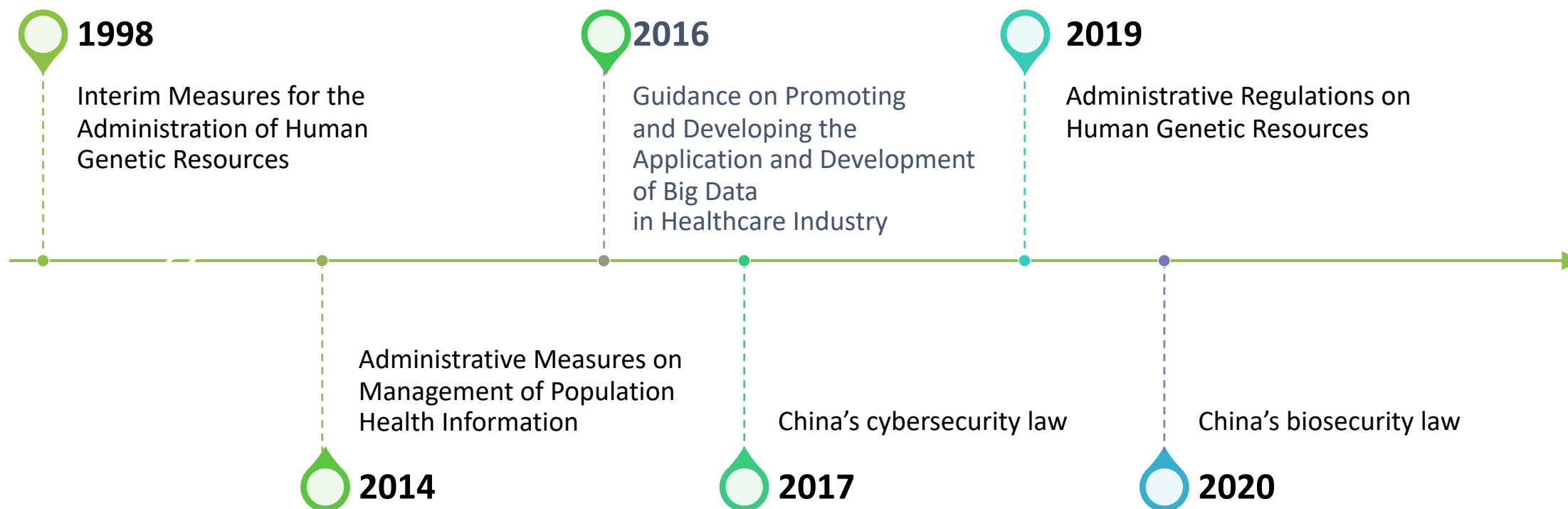


Molecular Diagnostics or Other Genetic Testing Companies with CLIA/CAP Accreditation

US with Chinese presence	Chinese with US presence	Chinese
Cancer Genetics, Inc.	Kingmed Center for Clinical Lab Co., Ltd.	3DMed Clinical Laboratory, Inc.
Fulgent Genetics	Kingmed Diagnostics (Shanghai)	Adicon Clinical Laboratories
Illumina Clinical Services Laboratory	WuXi AppTec	Chengdu Gaoxin-Daan Medical Laboratory Co., Ltd.
Veritas Genetics	WuXi NextCODE Genomics	Genetron Health (Beijing) Co., Ltd.
ACM Global Central Lab China Pte. Ltd.	Novogene	Guangzhou DAAN
AccuraGen		Nanjing Shihe Jiyin Biotech, Inc.
Hangzhou Veritas		Shanghai Daan Med Laboratory
Q Squared Solutions (Beijing) Co., Ltd.		Shanghai Dian Medical Testing Lab
		Shanghai Liwen Diagnostics
		Teddy Clinical Research Laboratory



Data Laws and Developments in China





Interim Measures for the Administration of Human Genetic Resources (1998)

- China's foundational policy on protection of genetic data
- For "efficiently protecting and rationally utilizing human genetic resources in the People's Republic of China."

Sampling, collecting, trading or exporting of human genetic resources performed in China is subject to government approval

Only a Chinese entity may apply for permit

All collaborations involving genetic data must be approved by the China Administration of Human Genetic Resources



Administrative Measures on Management of Population Health Information (2014)

Prohibits export of personal information by health organizations

Mandates the domestic storage of medical information

Includes individual medical records and aggregated or derivative data*

* Potentially even if de-identified

* Under HIPAA, de-identified PHI may be shared, and aggregated data are not considered PHI



Cybersecurity Law (2017)

Identifies three types of data that may not be stored overseas :

Personal data (PII/PHI)

Sensitive personal data (misuse would endanger the health/safety)

Important data related to **national interests or economic or national security**.

Cross-border transfer of personal data is prohibited



Administrative Regulations on Human Genetic Resources (2019)

- More stringent than Interim Measures

Foreign parties may not sample/maintain HGR in China or provide overseas

Foreign parties must conduct HGR research with Chinese institutions

Subject to application to MOST

Research may not jeopardize China's public health, national security or social and public interests.

- 2020 Biosecurity Law strengthens these provisions



Non-Reciprocal Data Sharing

- U.S. – HIPAA

- Protects patient privacy and confidentiality, not data
- No controls on who can access data (or where)
- Unenforceable outside U.S. borders
- Personal health data (e.g., for ancestry) can be exempt



- EU – GDPR

- Specifically includes genetic and biometric data
- Cross-border sharing is regulated – whitelisted countries
- Anonymized data exempt



Risks of Data Access

- Privacy
- Economic security
 - Competition
 - U.S. dependence on China
- Data Protection vs. Innovation
 - U.S. law favors research and innovation over patient data protection
 - Chinese and EU-style laws could slow innovation in the U.S.





Policy Approaches

1. Awareness raising and Federal guidance for international collaborations
 - a) Understanding risks
 - b) Structuring partnerships and data sharing agreements
 - c) Sharing best practices
2. Enhance measures to protect personal data on U.S. citizens
 - a) Comprehensive approach, not piecemeal
3. Enhance cybersecurity measures

U.S. needs to define what we want long-term outcomes of new laws to be at a high level before diving into the specifics.

GDPR and Chinese laws may or may not be compatible with US values and ethics.



THANK YOU

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