Adaptive Governance for Precision Medicine in China

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I. Evolution of governance regime

Innovation Paradigm	The Most Relevant Systems	The Most Active Actors	Main Governance Issues Identified
Paradigm 1 • genetic engineering • medical genetics	• domestic clinical and health system • domestic research system	• national legislature • national regulatory authorities	• human gene patent
Paradigm 2 • genetic sequencing • human genome project	• international research community	• governmental funding agencies • foundations • IGOs, INGOs	• open access of human genome database
Paradigm3 • genome-wide association study	• international research community • the public	• governmental funding agencies • ethical committees	• balance between personal data protection and data open access
Paradigm4 • clinical sequencing test • precision medicine	• domestic healthcare system • research community • commercial system	• national legislature • national regulatory authorities • IGOs, INGOs	• combination of clinical data and large-scale genomic data

Summary

- Science/technology development in precision medicine area determines the scope of stakeholders; there are many important policy issues discussed by stakeholders;
- However, it is the most active players in the pool of stakeholders who often define the policy agenda;
- The final **governing regime** is often the result of a path-dependent process rather than the outcome of a well planned/scientifically analyzed process;
- The challenge, then, is to pay attention to not only the technology development, but also to the policy actors and processes.

II. Adaptive Governance in China: a case

Clinical genetic services in recent years:

-The health administrative department at the provincial level approved the establishment of med labs which can provide genetic test service;

-Those med labs were under management as clinical labs. The methods they use and the service they provide must meet MOH regulations.

(Regulations on the Administration of Clinical Laboratories In Medical Institutions, 2006; Basic Principles of the Med Lab (Trial), 2009)

Critical event: in February of 2014, NHFPC&CFDA jointly called off all clinical genetic services in China.

Reason: sequencing products and technologies for clinical services were unregistered. The emerging market was without proper regulation.

- *“ Sequencing related products and technology have evolved from laboratory research to clinical service……”*
- *“ In order to guarantee sequencing diagnosis products and services are safe and effective, and to strengthen the management of medical technology clinical application……”* (Announcement of NHFPC&CFDA, Feb 2014)

New Arrangement (see graph below)

- CFDA: in charge of examination and approval of clinical sequencing diagnostic products **(**sequencers and its diagnostic kits, software, etc.**)**
- NHFPC: in charge of clinical application management of genetic sequencing technology, and select pilot units of clinical services.

After Calling Off

Application → **Assessment** → **Management**

Medical institutions with the qualification can apply the permission to the health administrative department at the provincial level

NHFPC organizes the assessment of the application with the help of CMA, NCCL & Prenatal diagnosis technology experts

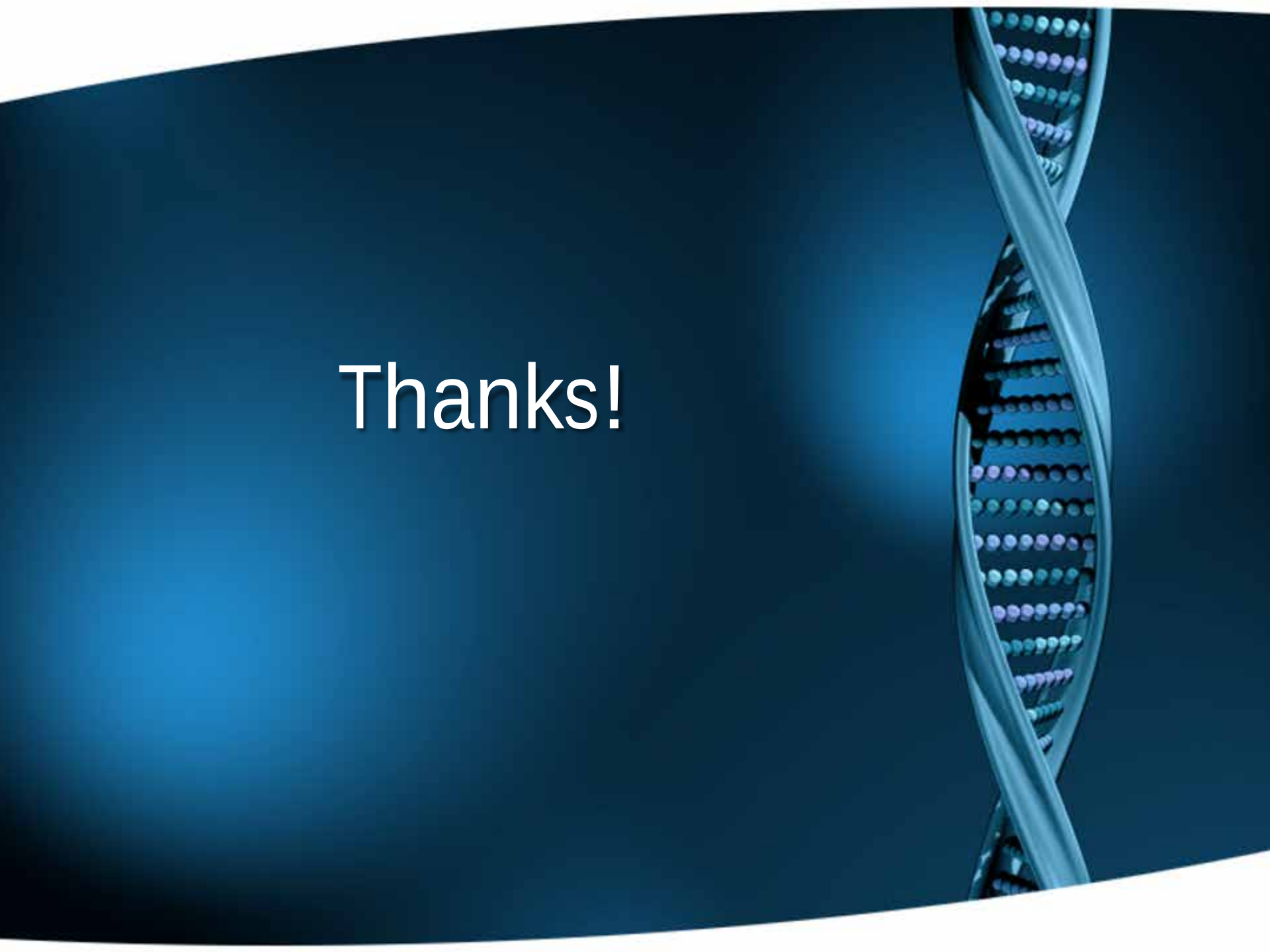
NHFPC publishes the lists of the Pilot Units of the High-throughput /Cancer Gene Detection Technology in the Area of Clinical Application

Follow-up events

Date	Government agencies	Actions
Feb, 2014	NHFPC&CFDA	Called off all clinical genetic services in China
2014-2015	CFDA	Approved next generation sequencing diagnostic products of several companies (sequencers and its diagnostic kits)
Dec, 2014	NHFPC	Approved 109 pilot institutions for NIPT clinical genetic services
Apr, 2015	NHFPC	Approved 20 pilot institutions for tumor clinical genetic services

Issues need further attention

- (1) Issues for further consideration
- Privacy protection for personal data
- Genomic and clinical data sharing
- Public education and trust building
- (2) adaptive regulation in the Chinese context
  - Innovation and regulation—different government agencies are in charge of different aspects of technology development. How to coordinate/balance innovation and regulation?
  - Government and the market relations—one way regulation of government on industry? Can industry play a more active role?
  - Central and local relationships—local experiments=>generate problems; centralization=>stifles innovation; decentralization=>more problems…
  - Policy capacity—adaptive regulation and policy learning requires a policy capacity often do not exist in local governments in China.


Thanks!