

From Bench to Bedside: Secondary Use of Health Data for Precision Medicine

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Science
Translational
Medicine



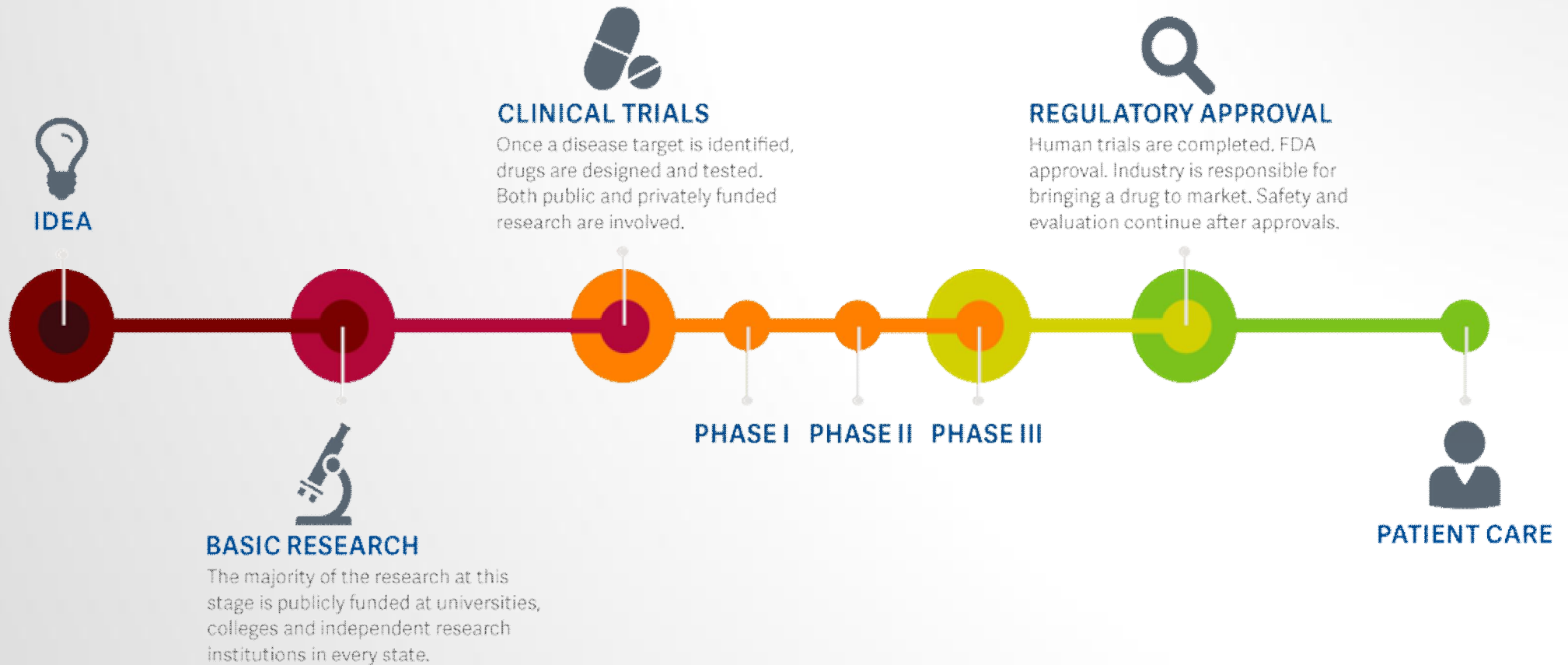
“ Translational research includes two areas of translation. One (T1) is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation (T2) concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.”

National Institutes of Health (NIH). Definitions under Subsection 1 (Research Objectives), Section I (Funding Opportunity Description), Part II (Full Text of Announcement), of RFA-RM-07-007: Institutional Clinical and Translational Science Award (U54) Mar2007

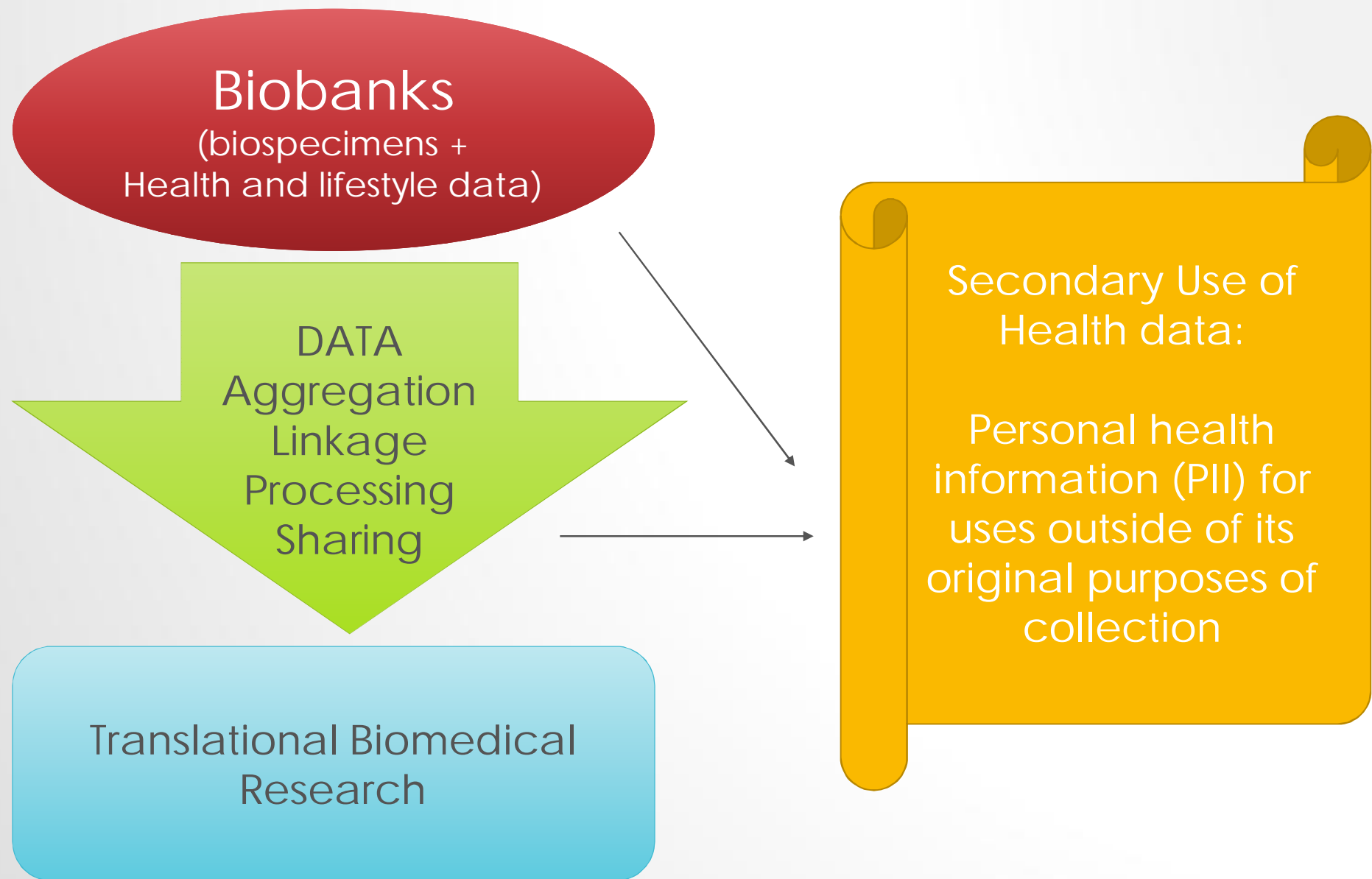
1. DISCOVERY

2. DEVELOPMENT

3. DELIVERY



[source: www.researchamerica.org](http://www.researchamerica.org)





Biobank Infrastructure for the 21st Century - Learning from Taiwan



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Introduction

The Taiwan government is committed to making Taiwan "The Biomed-Tech Island". This involves three major efforts:

- Taiwan Biobank Project
- National Health Information Project (NHIP)
- Clinical Trial Research

The Taiwan BioBank Project is

- a national effort that will integrate and synergize the public health, biotech, pharmaceutical and healthcare industries in an effort to deliver better healthcare for the Taiwanese people.

The project's goals are:

- To understand descriptive epidemiological features and to obtain background risk profiles of common diseases in Taiwan.
- To explore gene-risk factor/gene-gene interactions associated with common diseases.
- To establish essential bio-informatic networks of Biobanks, leading to the development of Bio-IT.
- To explore critical issues related to ethnic, legal, and social issues (ELSI) of genomic medicine and develop solutions for these concerns.

Why is Taiwan ideal for a BioBank effort?

- Relatively Genetically Homogeneous Population.
- High-Quality Medical Care Service.
- Nationwide Health Insurance System.
- Advanced instruments and platforms for clinical diagnosis, genetic and micro-array analysis, biological sample storage, and cell line preservation.
- Strong experience on IT hardware & software development.
- Extensive Logistics Network throughout Taiwan.



What is the Project's Scope and Current Status

Pilot study: January 2006 – December 2009

Size of Participants: 15,000

Expected cohort: 200,000

Participants:

Residents of:

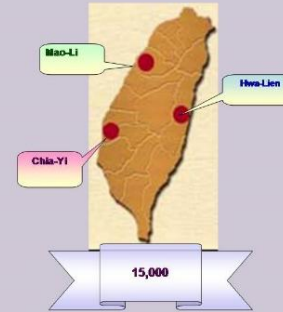
- Mao-Li Country (Fukien & Hukka & Mainland)
- Chia-Yi City (Fukien & Mainland)
- Hwa-Lien Country (Indigenous & Fukien & Mainland)

Aged 40 to 70

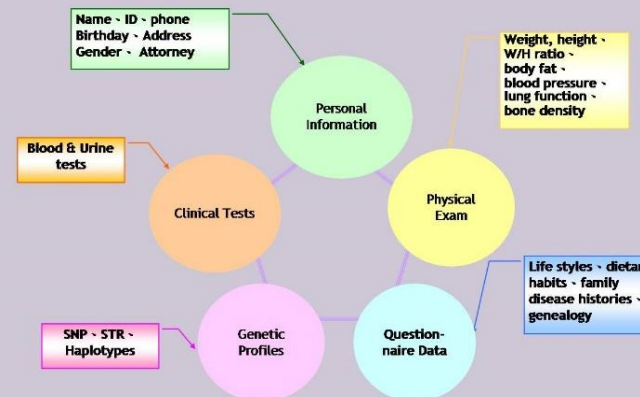
Volunteer

Current Focus:

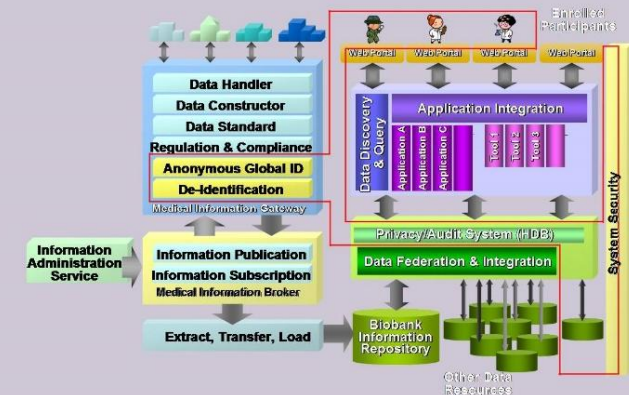
IT Platform Development.



Data Stored in the Taiwan Biobank



Taiwan Biobank Solution Architecture



Summary of Conclusions

- The Taiwan Biobank provides an amazing leap forward in the enablement of the medical research.
- The commitment from the government, perfect suitability of the country of Taiwan and the leveraging of state-of-the art technology to address the privacy and interoperability concerns makes a solid foundation for significant breakthrough in healthcare research, while allaying public fears.
- The establishment of a comprehensive and secure IT infrastructure that provides integrated tools, services and reliable management of information assets in support of Taiwan Biobank is a significant milestone for the healthcare community.
- The fact that the platform will address the privacy and security issues, raised by the public, and be compliant with policies, standards, and guidelines recommended by Taiwan's Information Technology Advisory Board (ITAB) provides the world with a safe model for biobank construction and use.

Features of Taiwan Biobank

- Biomedical Technology Island Plan (2004): (for health and wealth)
- Funded by the Ministry of Health (around NTD 7,000 millions)
- A prospective population cohort; target 200,000 (healthy population) + 100,000 (affiliated with 13 hospitals, disease samples)
- Executive agency: Institute of Biomedical Sciences (IBMS), Academia Sinica
- To know the causes of diseases (pharmacogenomics -> precision medicine)
- Governance Frameworks
 - Dual Track Governance: IRB + EGC (not only “ a critical friend”)
 - Guidelinesà Human Biobank Management Act (2010)
 - Personal Data Protection Act (data linkage?)
- IRB: disease samples (data merge: secondary use of data): re-consent? (not yet approved)

Secondary Use of Health Data

- As electronic health records (EHR) are adopted as the standard for clinical practice, new sources of detailed information will be created.
- Aggregated health data provide value to a broad range of research, quality, public health and commercial applications (used for non-clinical applications)
- Yet, **access** and **use** of health data pose complex ethical, legal, technical and economic challenges
- E.g., buying and selling of non-anonymized patient and provider data by the medical industry but carried out without explicit consent from patients or physicians

National Health Insurance Database

- NHI Model: mandatory insurance
- Universal coverage
- Enrolment rate: 99% (population: 23 million)
- National Health Insurance Act: the purpose of collection: insurance claims
- Data include
 - (i) personal data: ID no. name, DOB, type of work, insured salary
 - (ii) medical data: inpatient/outpatient visit data, length, branch of medicine, diagnosis, prescription, treatment, fee, etc



A Recent Pending Lawsuit in Taiwan

- Taiwan Association for Human Rights (TAHR) vs. National Health Insurance Administration (NHIA)
- **Background:** 8 plaintiffs claimed for withdraw their national health insurance data from the NHIA (data controller) when they knew that the NHIA sold their personal data (barcoded names & ID, but BOD and prescription info are still available) to the National Health Research Institute (NHRI) for academic research purposes. And, NHRI then sold the data to pharmaceutical companies for academic or non-academic research purposes.
- **Issues:**
 - (i) Non-personally identifiable information (PII)?
 - (ii) Under PDA in Taiwan-- if it is not PII, then no need to have consent
 - (iii) no opt-out allowed? (obstacle to research?)
- **Pending Decisions:**
 - Taipei Local Administrative Court: NHIA won; based on PDA in Taiwan
 - Taipei High Administrative Court: referred back

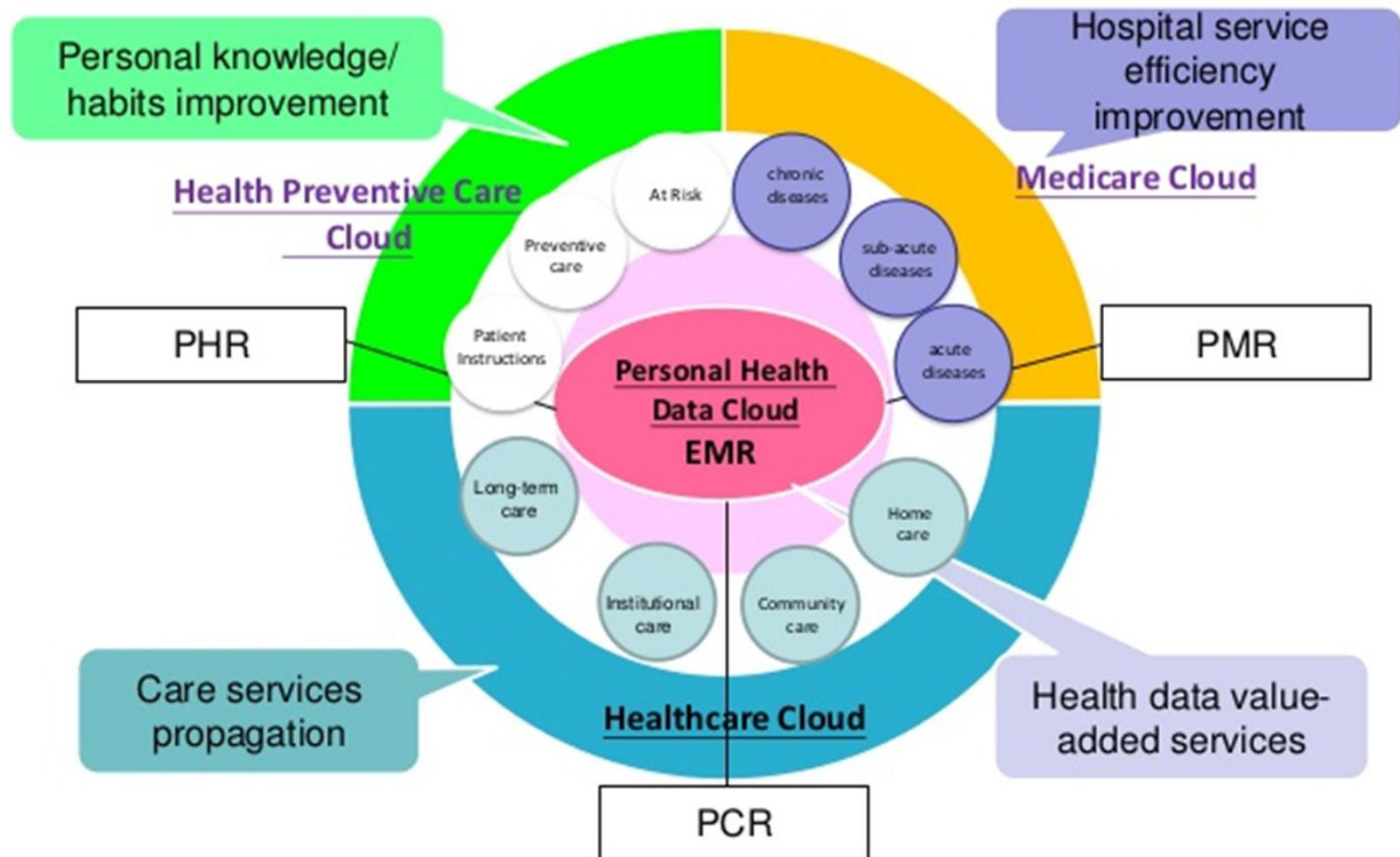
Laws on consent and data sharing

| Human Subjects Research Act | Biobank Management Act | Personal Data Protection Act |
|--|---|---|
| <ul style="list-style-type: none">- project specific consent- Re-consent needed for future research | <ul style="list-style-type: none">- broad consent- Re-consent usually not needed | Without consent, If the personal information is processed or provided by the information provider in a way that it would not lead to the identification of a certain person |

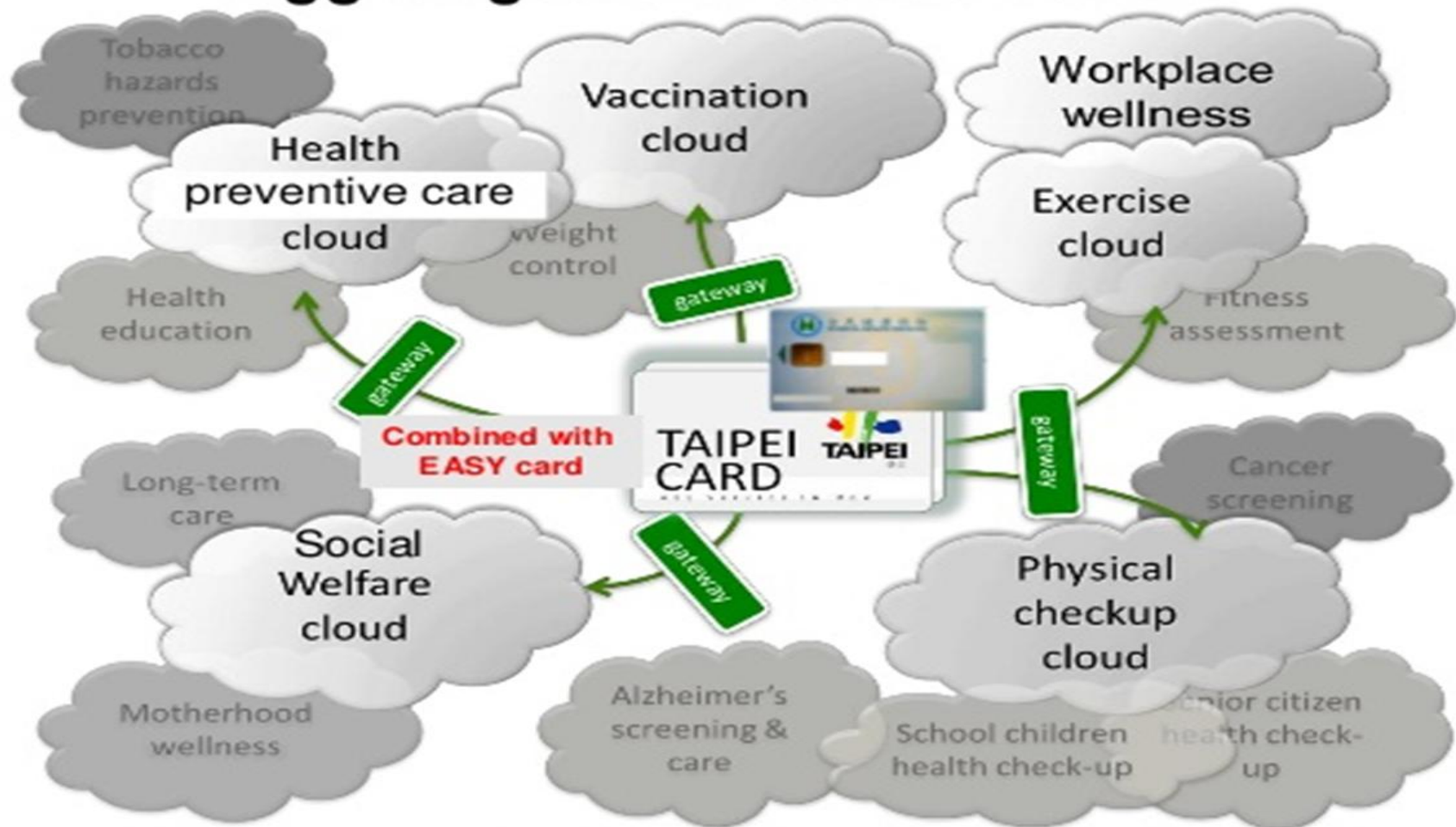
Secondary use of data

Big data challenge ??

Health Cloud Planning in Taiwan



Taipei Health Card / National Health Insurance IC Card Triggering Health Cloud Services



Proposing an Innovative Data Sharing Model

- A specific law for the release and use of health data from the National Health Database?
- Current Privacy Frameworks
 - anonymized or de-identification (data centric approach)
 - HIPPA (remove identifiers); Differential Privacy (adding noises)
- Community-based data sharing model
 - members are also data curators (data subject approach)
 - they are entitled to decide how they would like their data to be used
 - transparency, notification, self-governance, accountability
 - privacy impact assessment
 - ex: rare disease groups

Thank you for your attention!

