

Personalized Medicine under China Privacy Rules: Opportunities and Challenges

Sino-EU PerMed
Stakeholders' Workshop
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Privacy Regulatory Framework in China

SINO-EU PerMed has been granted for funding through the current EU Framework Programme for Research and Innovation 'Horizon 2020' under grant agreement no 874556



Critical Differences of Data Regulation Between EU and China

Dedicated DPA v multiple agencies

- GDPR: dedicated data protection authority with sufficient expertise and independence
- China data regime: multiple agencies with overlapped, blurred and sometimes broken boundaries of jurisdictions. Enforcement may not be consistent across agencies and regions.

One GDPR v layered rules

- GDPR: one pillar law supported by EDPB and EDPS guidelines and local laws that are consistent with GDPR
- China data regime: layered rules in different legal hierarchies with multiple rules at each level

PII v all data

- GDPR: PII only
- China data regime: PII + important data + state core data + state secret

Complicated legal consequences

- GDPR: mainly pecuniary fine
- China data regime: fine, suspension/revocation of licenses, criminal liabilities at both corporate and individual levels, debarment from professional jobs and senior management, tainted social credits, civil damages, etc.

Multiple Supervisory Agencies with Blurred Jurisdictions

Cooper
in Perso

Headed by President Xi & in charge of coordinating and deciding on national security strategies

National Security Commission of the CPC



Cyberspace Administration of China (CAC, lead agency)

- Overall planning of cybersecurity at state level
- Establishment of state-level cybersecurity guidelines
- Cross-departmental coordination
- Internet content regulation

Ministry of Industry and Information Technology (MIIT)

- Supervision of network infrastructure security and user protection
- Telecommunications industry regulation (incl. ICP/IDC/ISP/CDN/IRCS licenses, etc.)
- Supervision of cybersecurity of connected cars and industry network

Ministry of Public Security (MPS)

- Critical information infrastructure registration
- Multi-level protection scheme (MLPS) administration
- Investigation of cyber crimes

Industry Regulators

Health Care, Drug & Science
NHC, NMPA, MOST

Finance
PBC, CBIRC, CSRC

Commerce & Trade
SAMR, MOFCOM

...

Three Pillar Laws & Layered Implementing Rules

Three Pillar Laws

Law	Legislation Package	Online/Offline	PII/Non-PII	Regulatory Focuses
Data Security Law ("DSL")	National security	Online + Offline	PII + Non-PII	National security, public interest and fundamental data regulatory framework
Cybersecurity Law ("CSL")	Cyber regulation	Online	PII + Non-PII	Security of information infrastructures and facilities
Personal Information Protection Law ("PIPL")	PII protection	Online + Offline	PII	Data rights and interests of individuals

Layered Implementing Rules

- **Judicial interpretations**, e.g.: those regarding PII protection, cyber crimes and facial recognition
- **Regulations**, e.g.: Guiding Opinions of the General Office of the State Council on Promoting and Regulating the Application and Development of Big Data on Health and Medical Treatment
- **Departmental rules**, e.g.: Administrative Measures on Standards, Security and Services of National Healthcare Big Data, Administrative Measures for Clinical Research Projects Conducted by Medical and Health Institutions, etc.
- **National standards & guidelines**, e.g.: Personal Information Security Specification (PISS), Guidelines on the Prevention of Ethical and Security Risks from Artificial Intelligence, Guide for Health Data Security, etc.

More under way with fast pace...

Dual Liabilities at Corporate & Individual Levels

Corporate Liabilities



Hefty fines

(up to RMB 50 M or 5% of proceeding year's revenue)



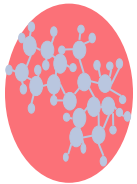
Suspension of business



Cease and desist



Blacklisting re cross-border data transfer



Criminal liabilities



Civil liabilities

(incl. public interest lawsuit lodged by prosecutors)



Revocation of licenses/ Take down of websites



Tainted social credit

Individual Liabilities

Fines

Debarment from professional jobs and senior management positions

Civil liability

Tainted social credit

Criminal liability

Opportunities Provided to PerMed Stake Holders

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Cooperation between China and Europe
in Personalised Medicine

14th Five-Year Plan (2021-2025)
for Medicine Industry
Development Plan (2021)

· To develop chemical medicine for precision treatment purposes

14th Five-Year Plan (2021-2025)
for National Clinical Special
Capability Building Plan (2021)

· To encourage innovation in precision medicine...artificial intelligence, biomedicine...try to make breakthroughs in key sectors

Guiding Opinions of the
General Office of the State
Council on Promoting and
Regulating the Application and
Development of Big Data on
Health and Medical Treatment
Departmental rules (2016)

· To promote precision medicine technology development...innovate pharmaceutical R&D data aggregation and sharing mechanism...

Shandong Provincial
Government General Office
Implementing Opinions on
Promoting and Normalizing
Big Data Application and
Development in Health Sector
(2017)

· To promote precision medicine technology development...strengthen clinical and R&D data resource integration and sharing by replying on provincial resources in medical research...

Guizhou Provincial
Government General Office
Implementing Opinions on
Promoting and Normalizing
Big Data Application and
Development in Health Sector
(2017)

· To promote precision medicine technology development...encourage hospitals and research institutions to conduct data aggregation, mining and application...

Encouragement from The Top: Data Regulation Angle

Personal Information Protection Law



Article 1 This Law is enacted in accordance with the Constitution to protect the rights and interests of personal information, regulate the processing of personal information and **promote the reasonable use of personal information.**

Data Security Law



Article 1 This Law is enacted in order to regulate data processing activities, guarantee data security, **promote the development and utilization of data**, protect the legitimate rights and interests of individuals and organizations, and safeguard the sovereignty, security and developmental interests of the State.

Challenges Facing PerMed Stake Holders

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Stringent Regulation throughout Data Life Cycle: Privacy Protection Angle

Informed & separate consent on collection

- Sensitive personal information (e.g.: genetic information, health data, EHR): **separate consent based on full transparency**
- Human genetic resources: **written consent**

Restriction on use of health data

- Ex ante **DPIA**
- **In-scope data usage only**, otherwise will have to seek new consent
- **Prohibition** on human genetic data processing by **foreign** organizations, individuals and institutions established or controlled by them

Limitation on redisclosure without the consent

- **Informed & separate consent** on data sharing/publicity
- Data protection agreement

Cross-border data transfer

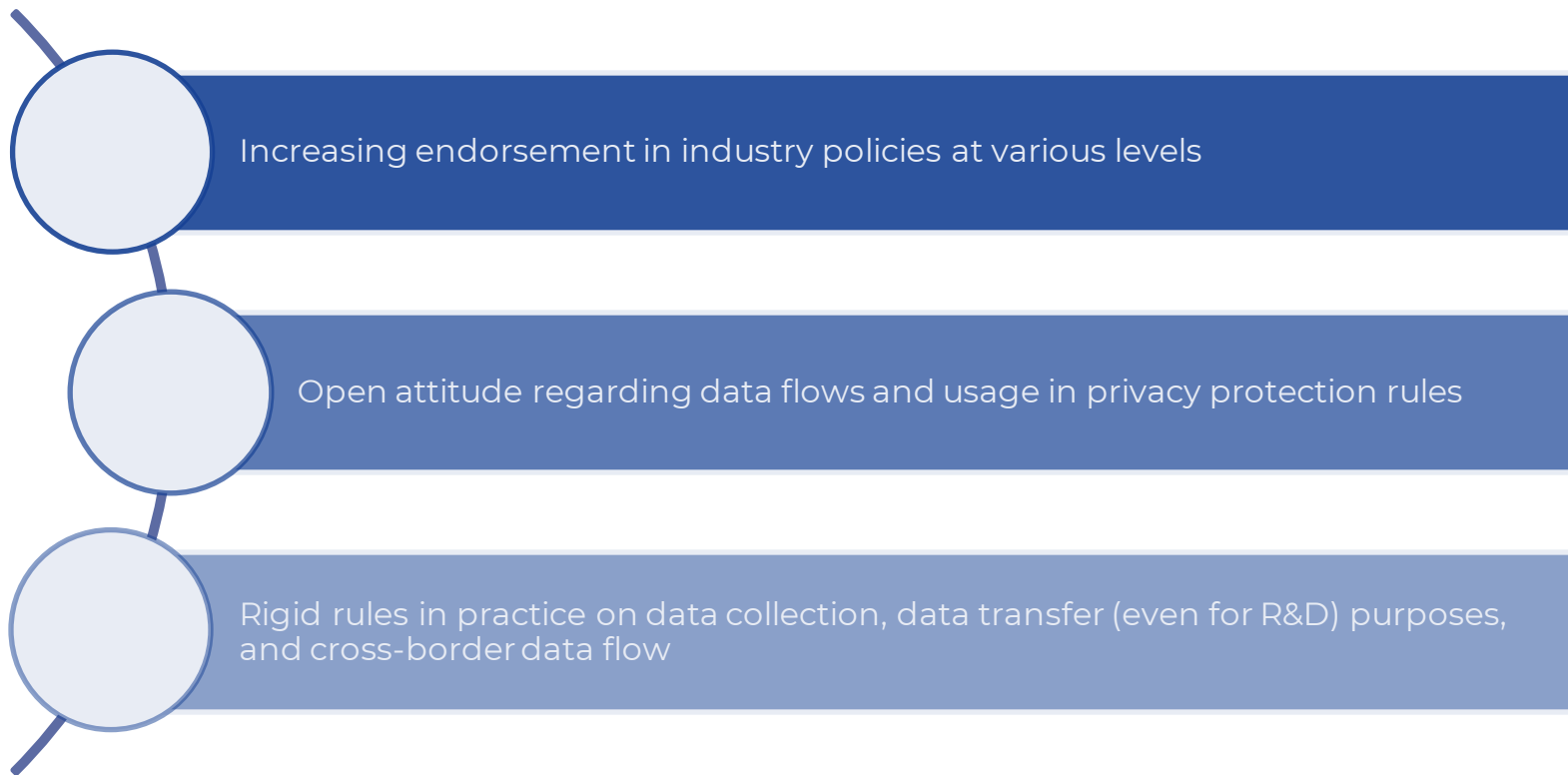
- **Informed & separate consent**
- Prior **self-security assessment**
- Prior **government assessment and approval** for critical information infrastructure operators and data controllers who process data exceeding a certain threshold
- Human genetic resources: prior government filing and approval

Outlook & Open Suggestions

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Outlook: Bright Prospects with Twists and Turns





Learn from the EU (such as EU Data Act) to promote data transfer for personalized medicine purposes and beyond

Enhance Sino-EU policy conversation and create reciprocal treatment regarding sensitive (esp.genetic) information cross-border transfer

Exchange knowledges and experiences about privacy computing technologies and data classification to promote layered data sharing mechanism

Thank you for your attention

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