

The Challenges and Opportunities in Conducting Real World Study in China

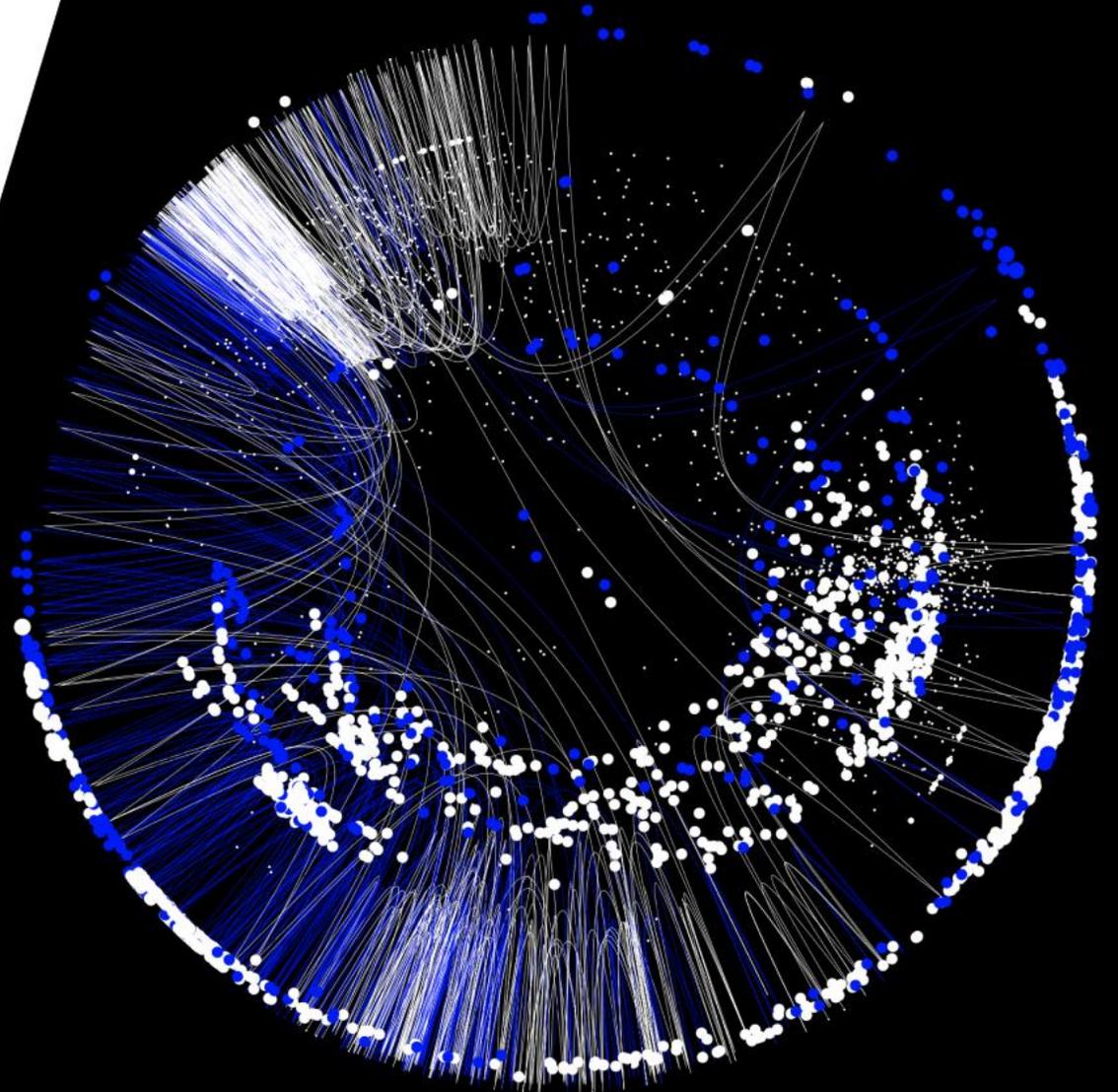
Prepared by:

Haijun Cao, M.D, PhD

Prepared for:

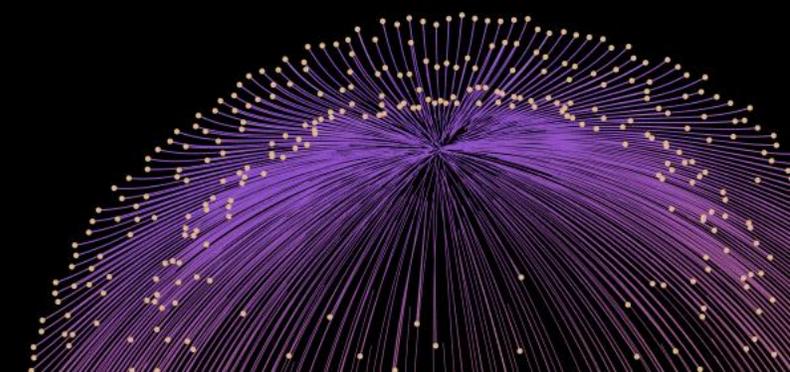
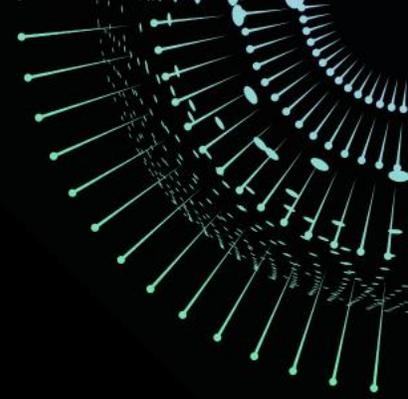
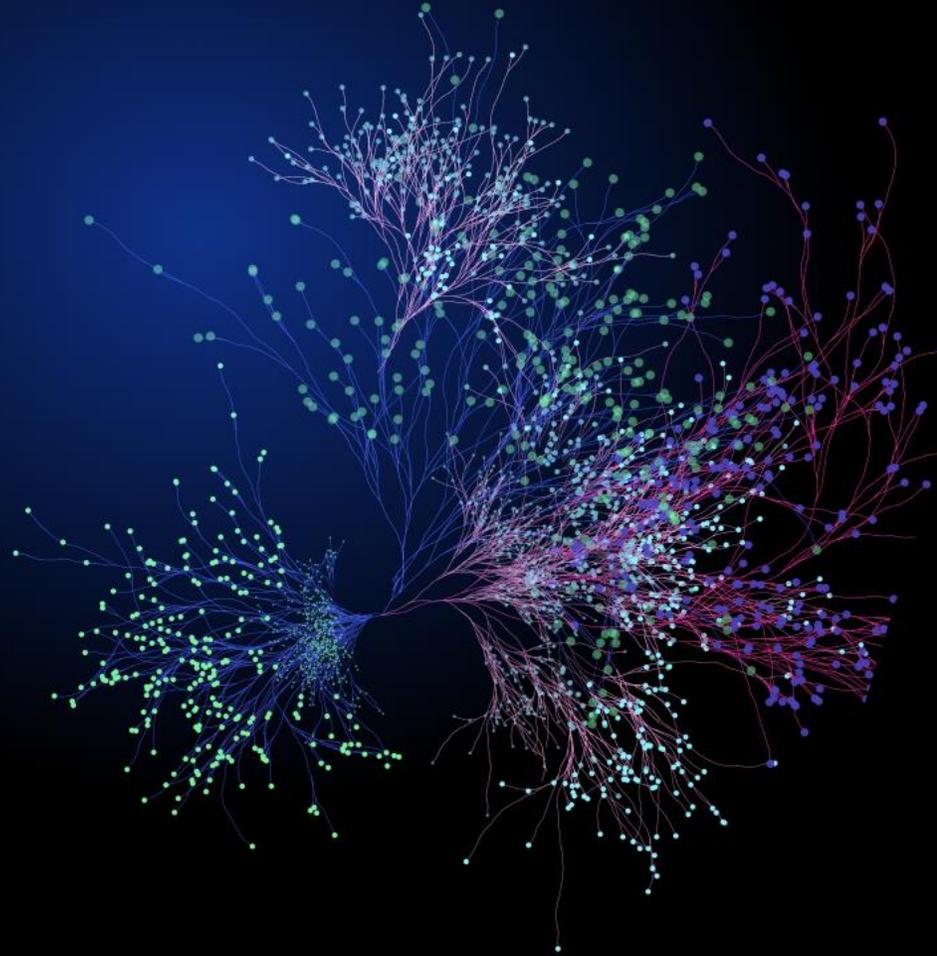
ISPOR Asia Pacific Summit

21 Sept 11:30-12:30pm (Korean time) 2022



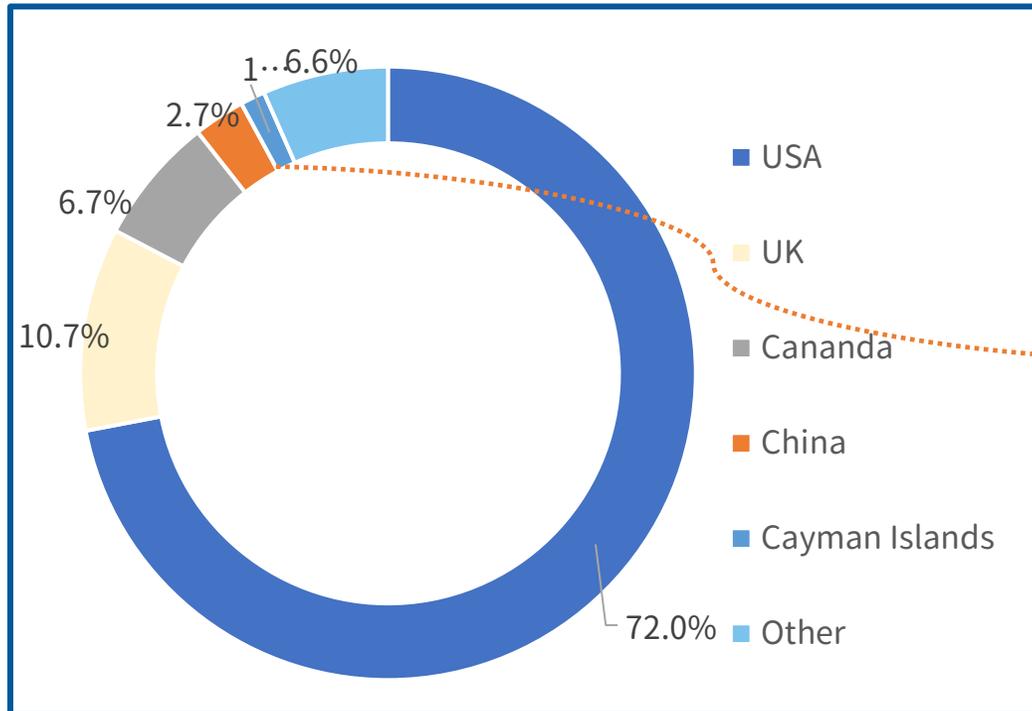
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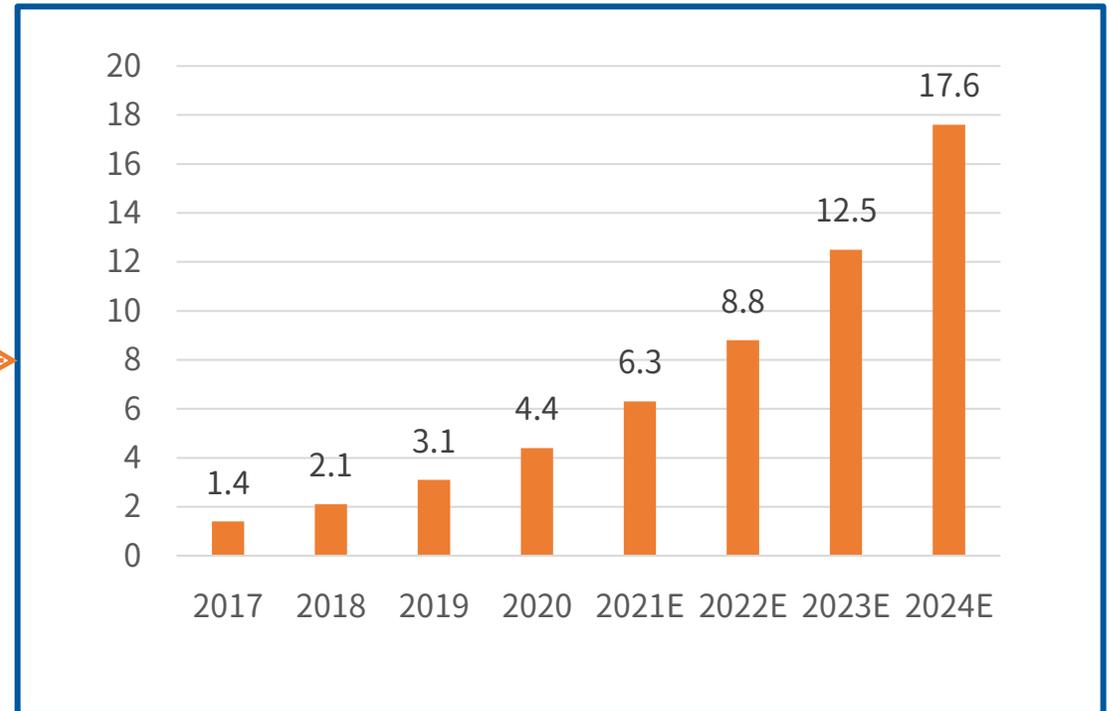


Growing investment in healthcare data-related companies boost RWS development in China

Distribution of RWD companies in the world



Total Investment of RWE in China (Billion Yuan)



Cornerstone of RWS start-up: EC and HGRAC

EC and HGRAC Regulatory development in China

Tentative Measure on the Management of Human Genetic Resource was issued, as the fundamental document on the use and protection of HGR in China

Measures on Ethical Guidelines on Biomedical Research Involving Human Subjects, released

Renewed the guideline on the application procedure of HGR use in international cooperative scientific researches

Regulations of the People's Republic of China on the Management of Human Genetic Resources issued, aimed protecting and using HGR effectively

HGRAC office further optimized the approval procedure and timeframe for HGR related international cooperative scientific researches

HGR related regulations incorporated into Biosecurity Law, elevating the protection of HGR to the level of national law

Jun. 1998

Oct. 2016

Oct. 2017

Jul. 2019

Aug. 2020

Apr. 2021

Ethnical committee (EC)

- Any institution conducting HGR related scientific studies is required to set ethnical committee, to guarantee the ethnic issues in studies
- Any studies involving HGR, including non-interventional retrospective studies, is required to pass the ethnical examination prior to the kickoff of the study
- Ethnical examination criteria includes the ethnic and scientific standard of the study design, the design of the consent form, fairness for the study subjects, etc.

Human Genetic Resource Administration of China (HGRAC)

- HGRAC operates under the Ministry of Science and Technology of PRC to regulate the use and protection of HGR in China

HGRAC process for RWS projects in China

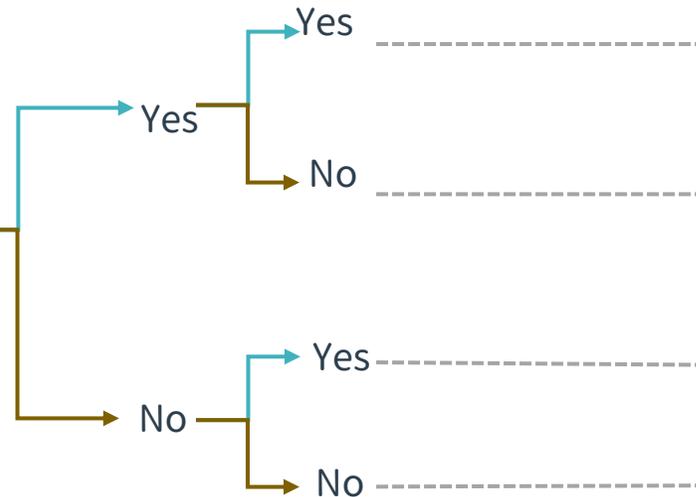
Starting

For research projects with international sponsorship

If meet any of the following:

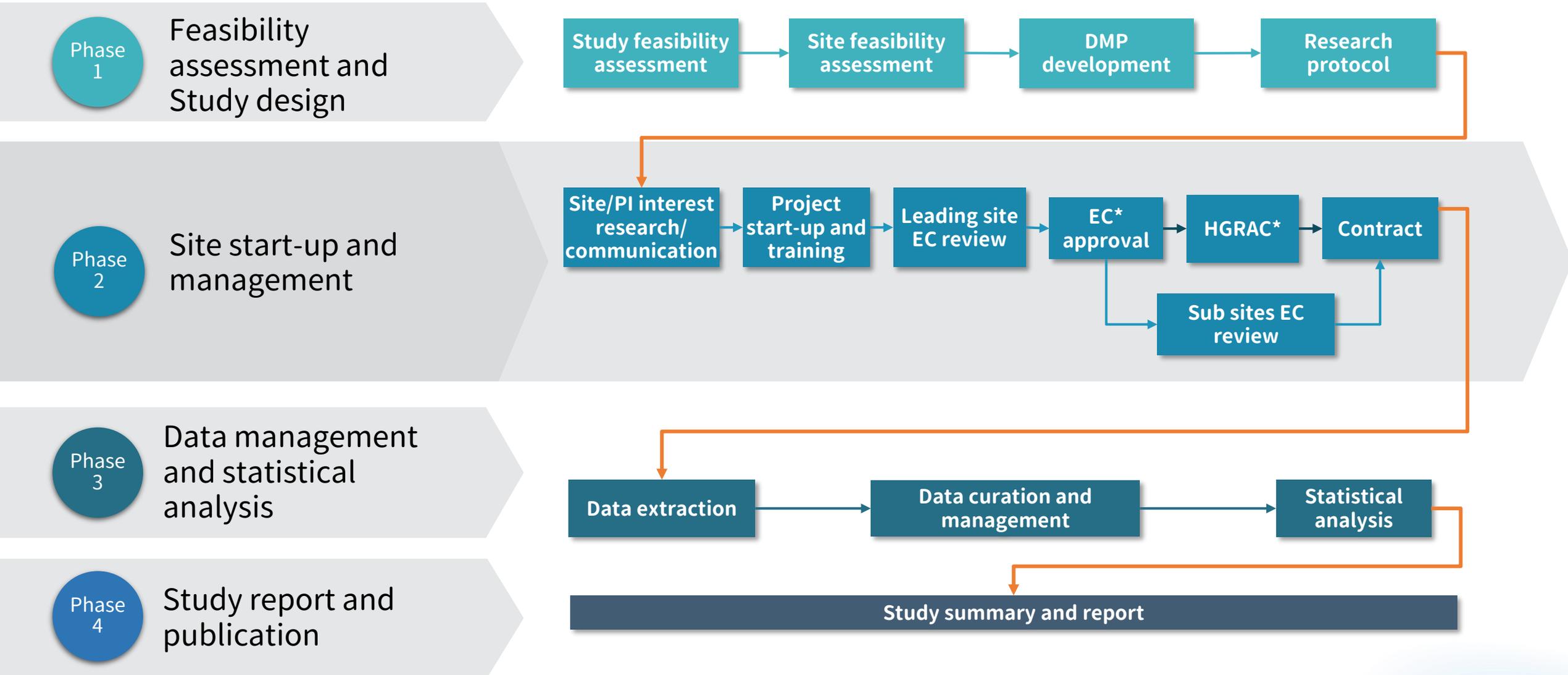
1. Sample size is greater than 500
2. Rare diseases
3. Special locations, family, or ethnicity

Publish on international journals or make results public to international use



| International collaboration review | Collection | External provision | Preservation |
|------------------------------------|------------|--------------------|--------------|
| ✓ | ✓ | ✓ | ✗ |
| ✓ | ✓ | ✗ | ✗ |
| ✓ | ✗ | ✓ | ✗ |
| ✓ | ✗ | ✗ | ✗ |

Site start-up and management to promote RWS execution in China

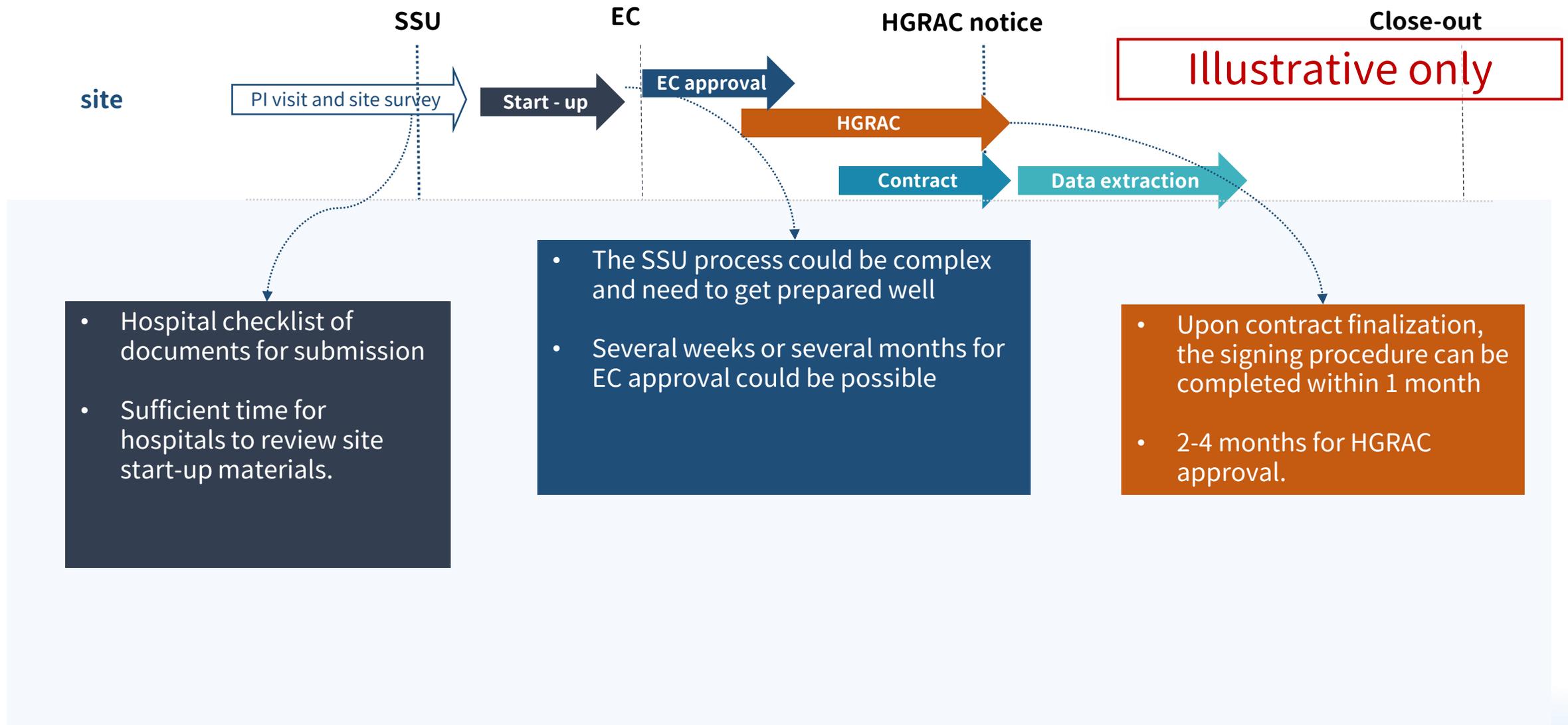


PI mapping and site selection

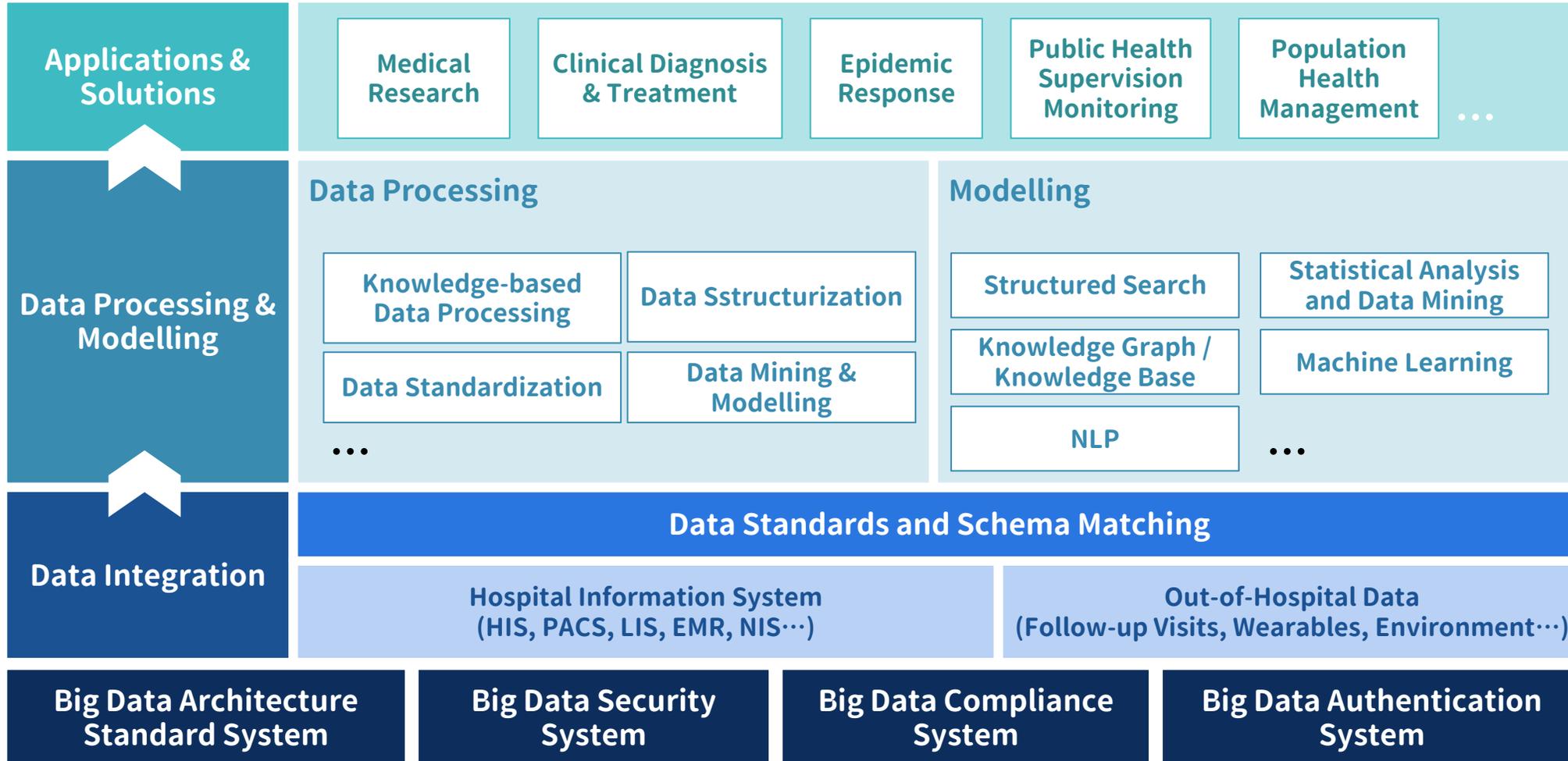


| Source | |
|----------|-------------------------------------|
| Research | Authors of guidelines and consensus |
| | Members of academic associations |
| | Conference speakers |
| | PIs of key competitors |

Rigorous SSU pre-planning to manage RWS operation



Solid and efficient technology provides opportunities for conducting RWS from different hospitals





Future considerations and actions to advance RWE in China

- Data authorization and compliance to obtain real world data is a huge challenge.
- Site start-up and management should follow the regulations of EC, HGRAC, and hospitals requirement, a big challenge for management of project timeline.
- Professionally qualified personnel and multi-background teams are required to manage hospital-based data and multi-source data collection and analysis.