The Challenges and Opportunities in Conducting Real World Study in China

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

Reference: CB Insights China. 生物医药领域的真实世界数据行业报告2021

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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 Ethnical 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

**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

*All policy are available at [中国政府网_中央人民政府门户网站](www.gov.cn)
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

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<th>Preservation</th>
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Site start-up and management to promote RWS execution in China

Phase 1: Feasibility assessment and Study design
- Study feasibility assessment
- Site feasibility assessment
- DMP development
- Research protocol

Phase 2: Site start-up and management
- Site/PI interest
- Research/communication
- Project start-up and training
- Leading site EC review
- EC* approval
- HGRAC*
- Contract
- Sub sites EC review

Phase 3: Data management and statistical analysis
- Data extraction
- Data curation and management
- Statistical analysis

Phase 4: Study report and publication
- Study summary and report

EC: Ethics Committee; HGRAC: Human Genetic Resources Administration of China
PI mapping and site selection

50% - Research project related
- Sample size
- Operation risk

35% - Principal Investigator
- Members of academic associations
- Authors of guidelines and consensus
- Publications
- Hospital titles

15% - Hospital and Department
- Overall rank of hospital
- Rank of oncology department
- Research capacity
- Oncology department capacity

Source

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<th>Research</th>
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<td>PIs of key competitors</td>
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Rigorous SSU pre-planning to manage RWS operation

- **SSU**
  - PI visit and site survey

- **EC**
  - Start-up
  - EC approval

- **HGRAC**
  - Contract
  - Data extraction

- **Close-out**
  - Illustrative only

- **Hospital checklist of documents for submission**
- **Sufficient time for hospitals to review site start-up materials.**

- **The SSU process could be complex and need to get prepared well**
- **Several weeks or several months for EC approval could be possible**

- **Upon contract finalization, the signing procedure can be completed within 1 month**
- **2-4 months for HGRAC approval.**
Solid and efficient technology provides opportunities for conducting RWS from different hospitals.

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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.