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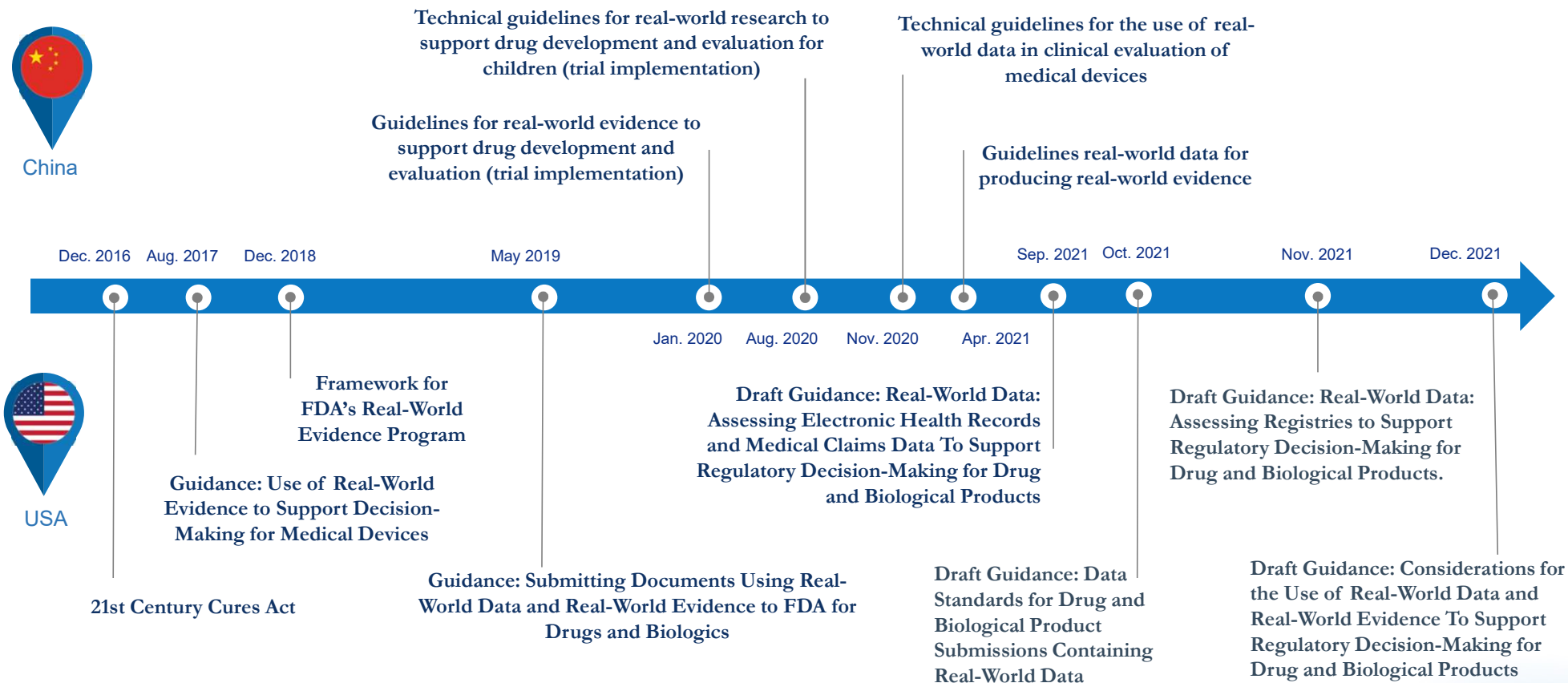
Registries in China: Guidelines, Trends and New Technologies

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Evolving Regulatory Environment to Encourage the Use of RWE



Registries in China

General characteristics

- Most registries in China, especially those with large sample sizes are developed according to disease or condition
- Large number of registries in cancer, cardiovascular and metabolic area

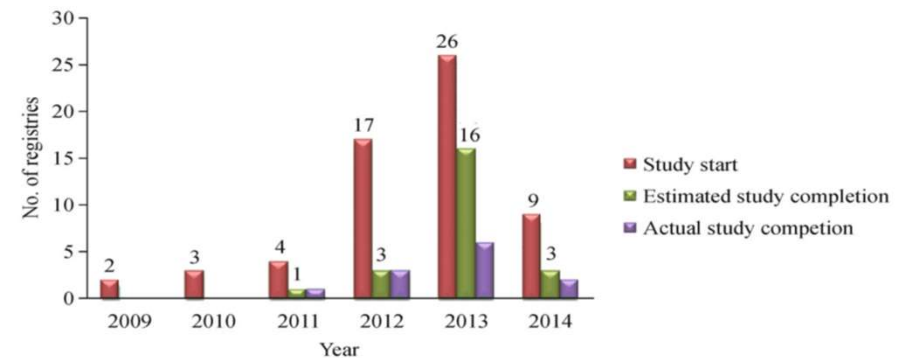
Purpose

- To obtain epidemiological features
- Drug and device registries are developed for surveillance
- Hospitals and universities are generally the main parties that develop registries
- Only a few registries are developed by the government and some professional associations in China

Reference:

1. Zhang, Yang, et al. "Current situation and challenge of registry in China." *Frontiers of Medicine* 8.3 (2014): 294-299.

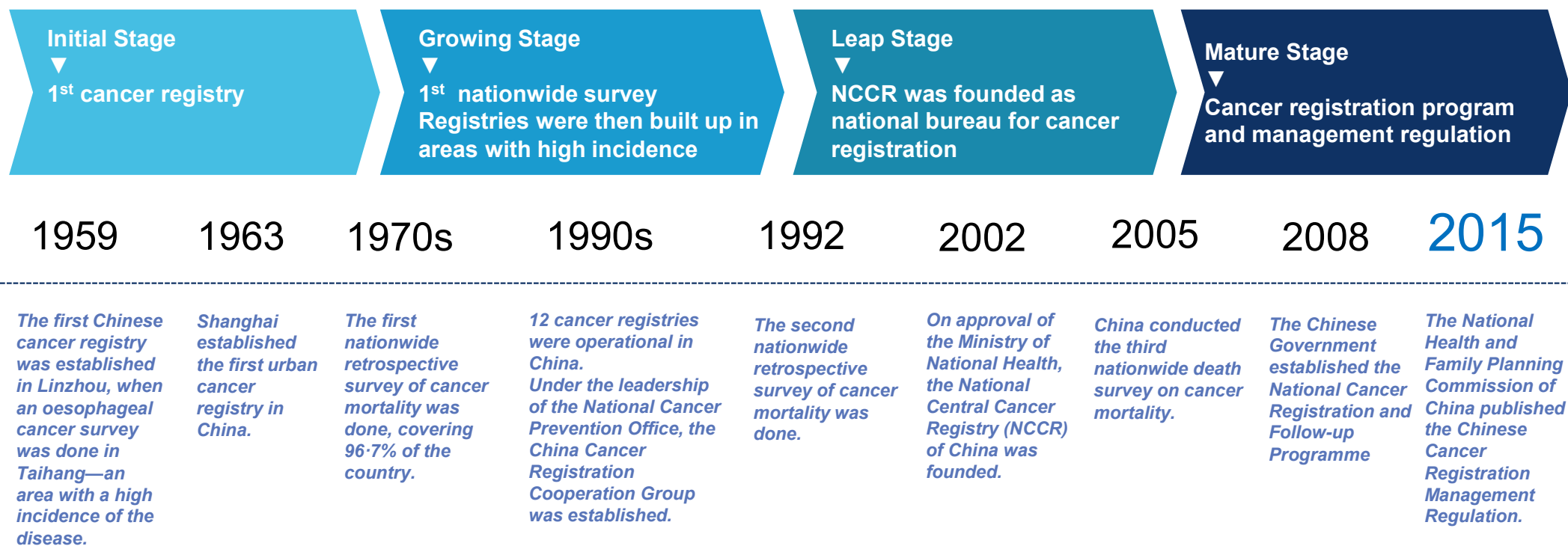
Trend



Challenges

- Variation of quality.
- Fragmentation and heterogeneity, limiting their general applicability
- Challenges on data sharing

Development of Cancer Registration in China



Reference:

1. Wei, Wenqiang, et al. "Cancer registration in China and its role in cancer prevention and control." *The Lancet Oncology* 21.7 (2020): e342-e349.
2. Chen, W. Q. "Establishing and perfecting of cancer registration system in China." *China Cancer* 20.1 (2011): 7-9.

The National Central Cancer Registry (NCCR)

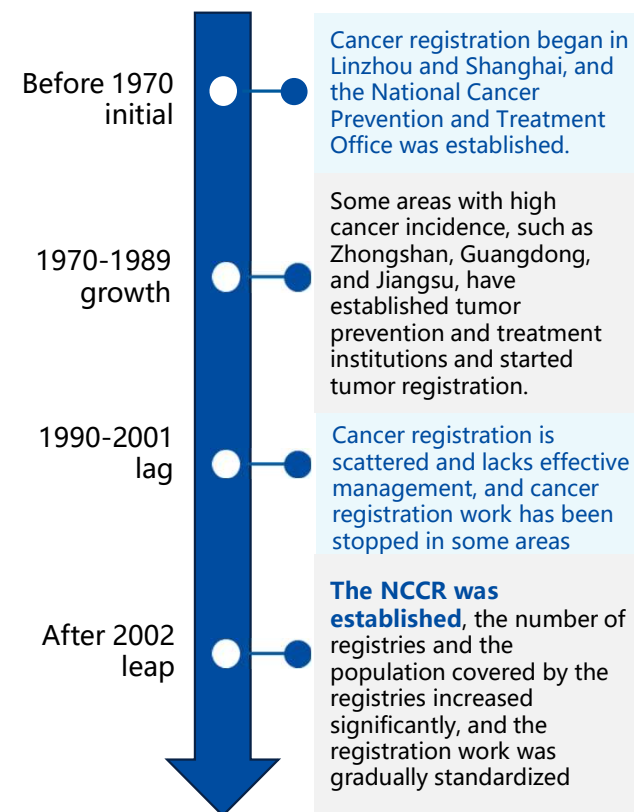


国家癌症防控平台
NATIONAL CANCER PREVENTION AND CONTROL NETWORK

The NCCR is the professional department of the National Cancer Center that undertakes the national cancer registration work

- Responsibility: Undertake the specific work of national tumor registration——clearly stipulated in the 2015 *Measures for the Administration of Cancer Registration*
- Achievement:
 1. Established a national cancer information release mechanism, and issue the Annual Report of China Cancer Registry every year.
 2. Basically established the professional and technical team of tumor registration at the national, provincial and registries levels. At present, there are nearly 5000 cancer registration staff at all levels in the country.
 3. Master the law of cancer epidemiology in China
 4. Clarify the standard system of tumor registration
 - In 2004, NCCR published the *Guiding for Chinese Cancer Registration*
 - In 2021, NCCR formulates and publishes *Standard for Dataset of Cancer Registration in China*
 - In 2020, the construction of China Cancer Registration platform (nccr.org.cn) was completed and officially put into use. At present, there are 54028 registration agencies, and the total number of cancer incidence cards entered and imported exceeds 11.53 million

History of development



By Mar 2019, there were 574 cancer registries in China, covering a population of about 438 million, accounting for about 31.5% of the Chinese population

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Reference:

1.陈万青, 梁智恒, 岑惠珊,等. 中国肿瘤登记现况及发展[J]. 中国医学前沿杂志: 电子版, 2016, 8(7):5.

National Rare Diseases Registry System (NRDRS)

NRDRS

<https://www.nrdrs.org.cn/>

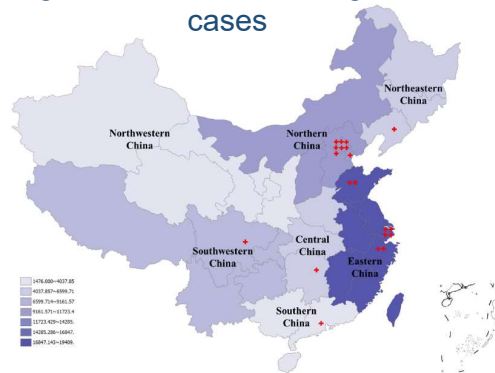
- In 2016, Peking Union Medical College Hospital (PUMCH) was selected as the lead institution to build the first national rare disease registry (National Rare Diseases Registry System of China; NRDRS), as part of the "Rare Diseases Cohort Study" funded under the nation's "13th Five-Year Plan" (2016–2020), in the "Key Research & Development Program – Precision Medicine Initiative".



Nationwide, multi-center, rare disease registration platform covering multiple diseases

As of Dec, 2021, researchers from 85 cooperative units from 28 provinces, municipalities and autonomous regions in China have registered cases based on the NRDRS platform. Cases involving **171 kinds of rare diseases**. **188 clinical research cohorts** have been established and **68,137 cases** have been registered, of which 13617 have registered biological sample information and 16114 have registered survival status and / or follow-up information.

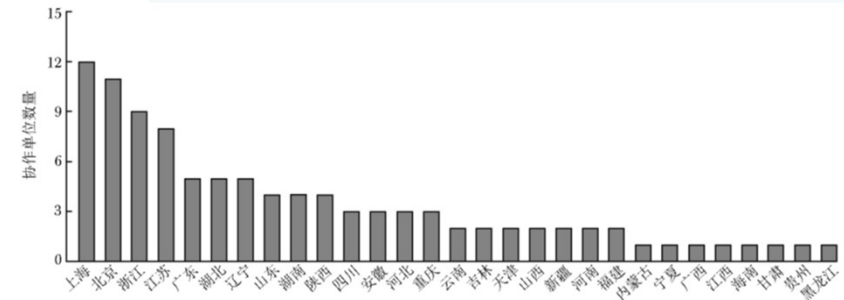
Regional distribution of registered cases



The main application of the NRDRS

As an important infrastructure for clinical diagnosis, treatment and scientific research of rare diseases in China, NRDRS can solve a variety of scientific problems related to rare diseases:

- ✓ Support clinical research and natural history research on rare diseases
- ✓ Support epidemiological research on rare diseases
- ✓ Conduct clinical trials based on registration
- ✓ Set up scientific comparison based on registration
- ✓ Support post-marketing monitoring of medical products
- ✓ The research team has also produced a large number of research results based on the NRDRS platform. As of December 2021, a total of 345 Chinese and English academic papers have been published.



Regional distribution of DRDRS collaboration units

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Reference:

- Guo, Jian, et al. "National Rare Diseases Registry System (NRDRS): China's first nation-wide rare diseases demographic analyses." *Orphanet journal of rare diseases* 16.1 (2021): 1-7
- 郭健, et al. "中国国家罕见病注册系统建设及应用." *罕见病研究* 1.1 (2022): 7-12..
- Peng Liu, et al. "Innovation in Informatics to Improve Clinical Care and Drug Accessibility for Rare Diseases in China." *Frontiers in Pharmacology*, 2021.

System Architecture and Administration of the NRDRS

Characteristics of rare disease data

- Cover a wide variety of rare disease areas;
- Registry data from the complex and various real-world clinical setting;
- Data captured longitudinally;
- Mainly are stock data;
- Data standardization extremely challenging.

Architecture of the registry system

Underline architecture

"Six horizontal and two vertical" system architecture

- "Six horizontal" refers to six levels
- "Two vertical" refers to establishing the standard operation procedures and the operation safety system

Administration

Multi-dimensional real-time monitoring and statistical functions

- List of registered disease categories (sorted by the number of real-time registered cases)
- Distribution map of registered cases (updated in real time)
- Case Statistics
- User Management
- hospital management
- group management
- Form management

Data quality control and platform administration procedures

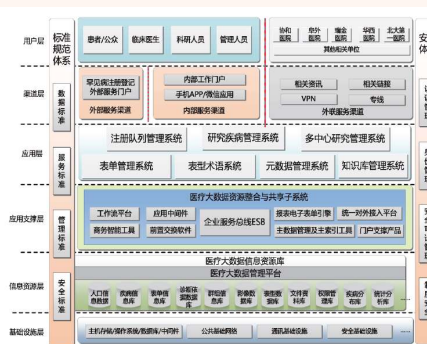


Figure 1 NRDRS platform architecture

Data Quality Control

Developed quality control strategies and research technical standards for rare disease cohort studies.

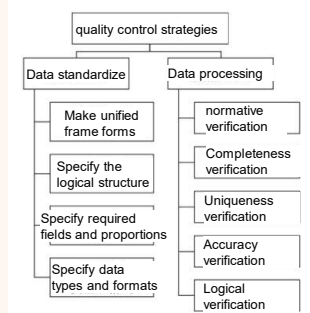


Figure 2 NRDRS platform quality control strategies

Platform administration procedures

The platform management team has gradually established three sets of management processes for users, forms and groups:

- Implement the "recommendation-review system" for new users
- The platform management team stipulates that only researcher users can create new disease forms, and new forms are created using the "application-review system"
- The NRDRS research group (hereinafter referred to as the "group") refers to a multi-center research team established on the platform by multiple medical research institutions to jointly study one/kind of rare diseases.

Platform accessibility

In order to facilitate researchers' work, in addition to the registry disease cohort function, the NRDRS platform has established a series of auxiliary functions, including:

- 1) The first batch of rare disease catalogues and disease definitions;
- 2) Rare disease cohort research project case statistics weekly report;
- 3) Academic papers published based on the NRDRS cohort;
- 4) Rare disease knowledge base link

The NRDRS platform management team gradually improves platform functions and strengthens data quality control from three aspects: optimizing the underlying framework and management functions of the registration system; Strengthen data quality control and promote data standardization from multiple links; establish a standardized process for platform management

Reference:

1. Guo, Jian, et al. "National rare diseases registry system of china: optimizing system architecture and enhancing data quality." *China Digit Med* 16.1 (2021): 17-22.

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Trend of Registry Development



Optimization and development of existing platforms



Enhancing the quality of registries

Sample size and quality assurance requirements, recruitment and supervision of providers, etc.



Explore some innovative methods and measures to maintain the long-term and stable operation of the system

For example, the NRDRS database can be docked with the existing national health insurance database, national hospital quality monitoring database and other conventional monitoring databases, and the routine monitoring information can be used to collect and supplement the long-term outcome data of patients with rare diseases.



Optimize the management system of disease information collection and unify the form content to the maximum extent



Interfacing registries and electronic health records

Most of China's registry sponsors are hospitals. The number of hospital-based registries with electronic health records (EHRs) is increasing along with the increase in population and the standardization of EHRs. However, data exchange accuracy in software-as-service may be an obstacle.



Data sharing is a key factor to further enhance the value of the database



Sharing and allocating benefits

Consider an effective system design and establishing a set of benefits with incentive mechanisms.



More registries to be developed

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Developing multicenter registry and linking registry data

closely and constantly monitors for common technical issues and the usage of resources

Construction of online registration database of Chinese asthma patients started in Guangzhou

China News Service, Guangzhou, March 1



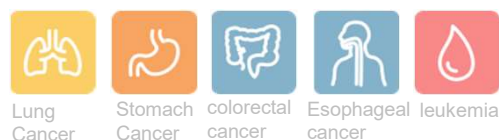
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1. 郭健, et al. "中国国家罕见病注册系统建设及应用." 罕见病研究 1.1 (2022): 7-12.
2. Zhang, Yang, et al. "Current situation and challenge of registry in China." Frontiers of Medicine 8.3 (2014): 294-299.

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Overview of HLT's scientific research collaboration platform

A、System Data Dictionary: 40+ diseases CRF



Build with disease experts

Specific disease registry
construction experience

Direct drag and drop access

Standard value range
Can be modified directly based on the
form



Drag and drop & click double interaction



Automatic calculation



Single and double column display



Value range, value type settings



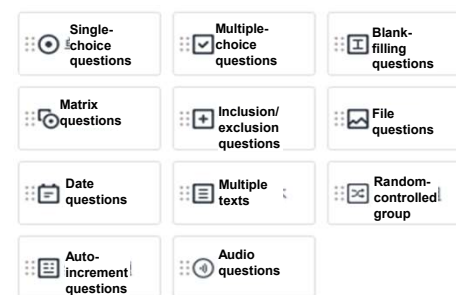
Support CRF template multiplexing



Hide fields using display logic

Research Plan Design-flexible eCRF

B、Custom question type: support 11 question types



Matrix questions

Question design that conforms to
traditional paper methods

Group auto-increment questions

Flexible data collection for different research
objects



Thank You!

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