Virtual ISPOR Asia Pacific Summit 2022

W13: Evolving Dynamics of Reimbursement and Post Listing Accessibility of High-Priced Innovative Medicines

DISCUSSANTS

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Development and Perspectives on the high price-innovation medicine

Kun Zhao

China National Health Development Research Center

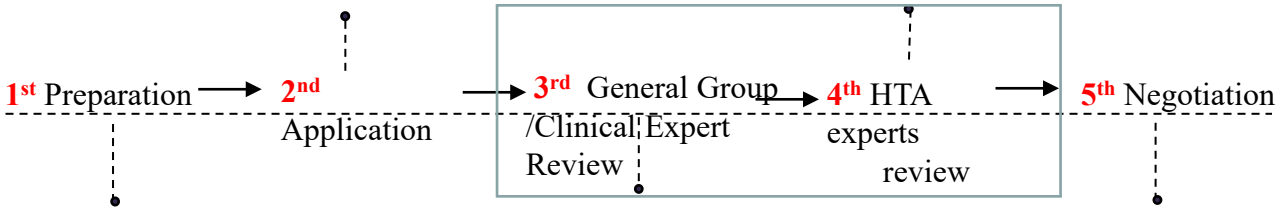
The process of NRDL on high price drugs

Aug-Sept

- Basic info submission;
- Review based on basic info.

Oct-Nov

- HTA info submission;
- Pricing based on HTA evidence;



July-Aug

- Formulate principles & procedure, appeal, revise and announce it
- Establish working groups & expert committees

Sept-Oct

- Topic selection by using MCDA
- Comparator selection
- Scoring the drugs selected according to clinical data

Nov-Dec

- Drug Price negotiation
- Results announcement
- Publish the updated NRDL.

NRDL=National Reimbursement Drug List 3

Perspective I： Assess the value on the high price drugs ---Re-HTA

Definition of innovative drugs

- **Patents for chemical structure or new addminsion route**
- **Drugs which figure out unmet needs**
- **Drugs which are brand new since**

Drugs Lists management in China

- National Reimbursement Drug List
- --PE+negotiation on prices

- National Essential Drug List
  --drug comprehensive evaluation for safety, effectiveness, economics, innovation, properness, and accessibility

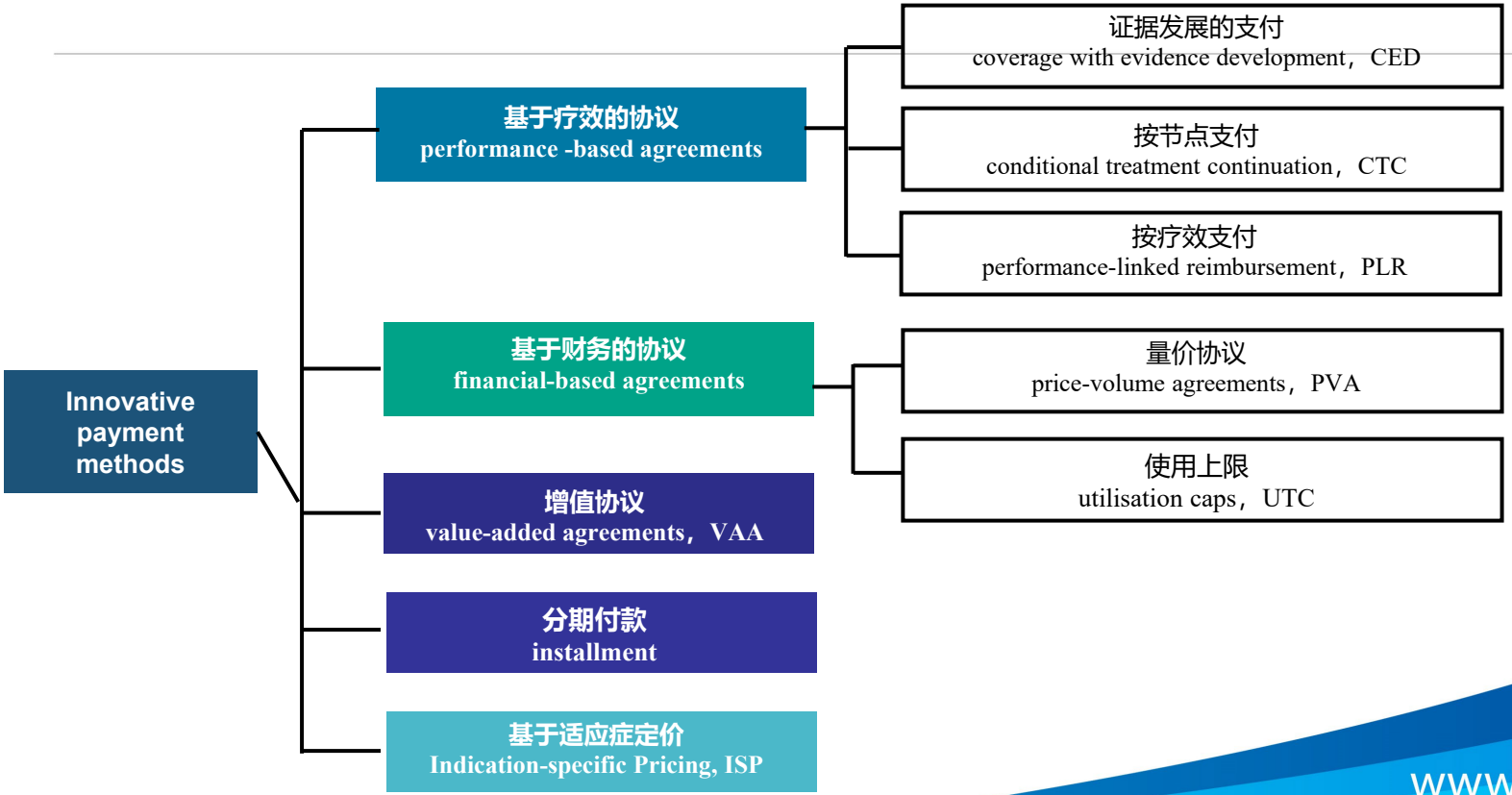
- Hospital Procurement List
  --Hospital drugs committee

Perspectives II： Pilot managed entry agreement

Innovative payment agreetments

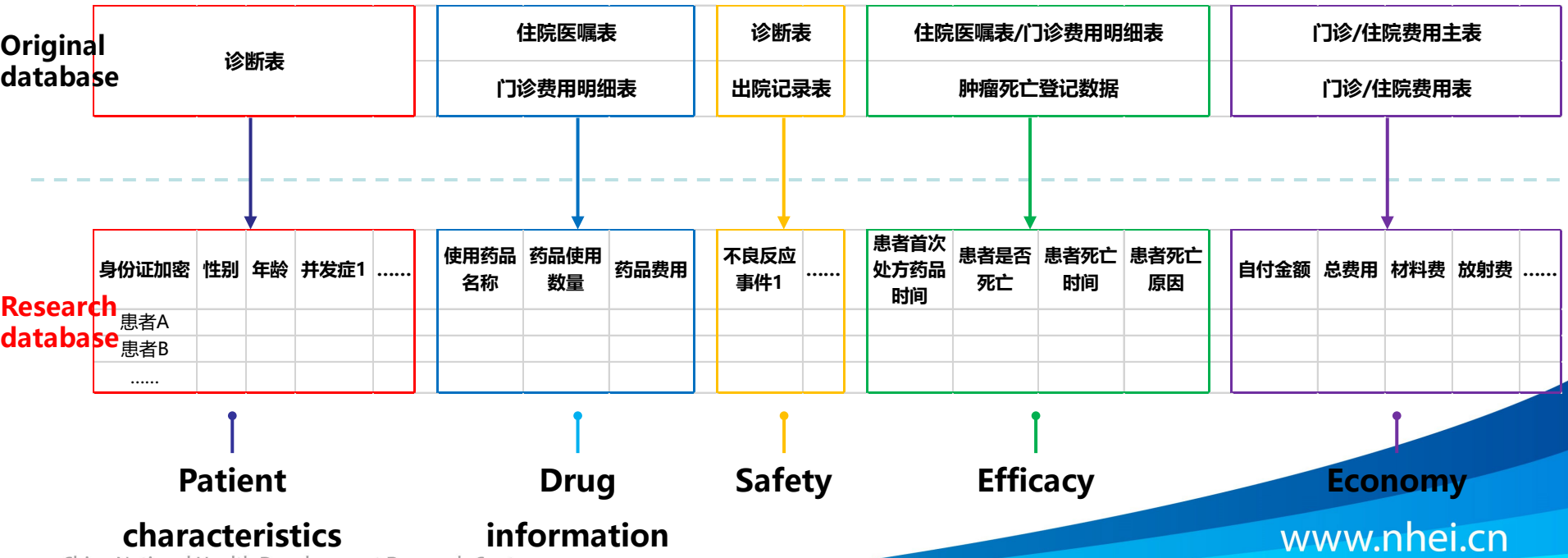
- risk-sharing agreements，RSAs
- patient access scheme，PAS
- managed entry agreements，MEAs
- pay for performance, PFP
- deeds of agreement
- ……

Main innovationve payment methods

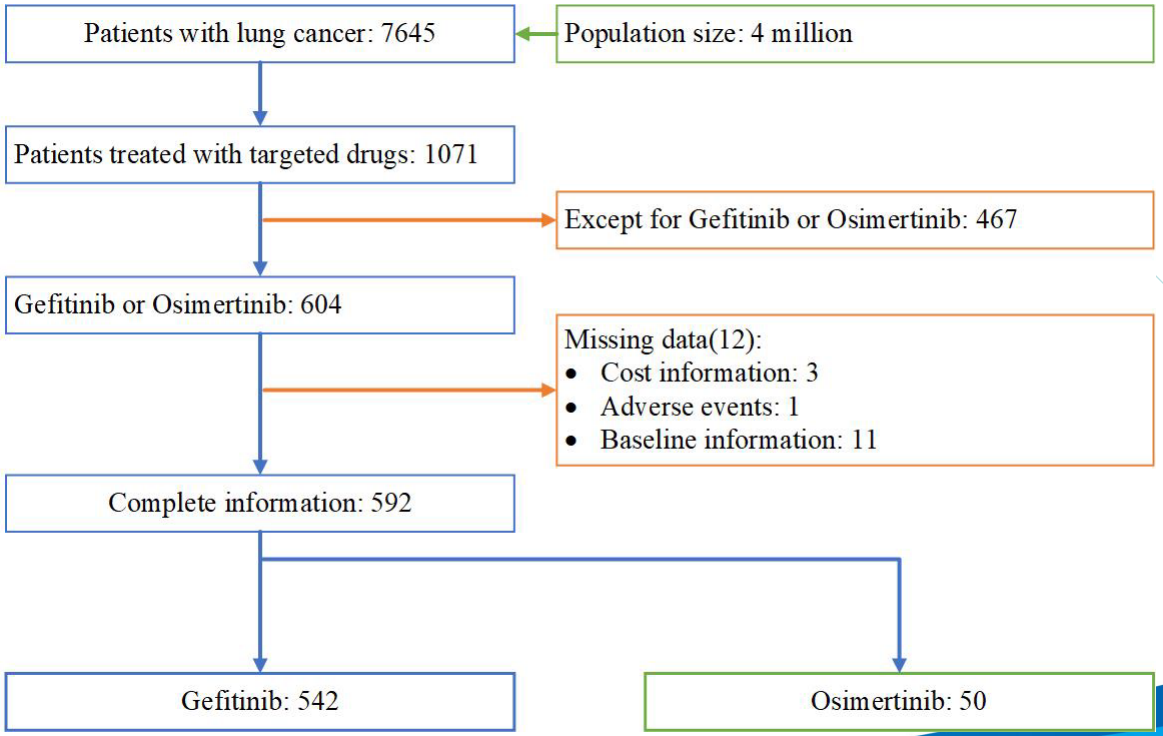


Perspectives III： RWD-HTA-based pricing

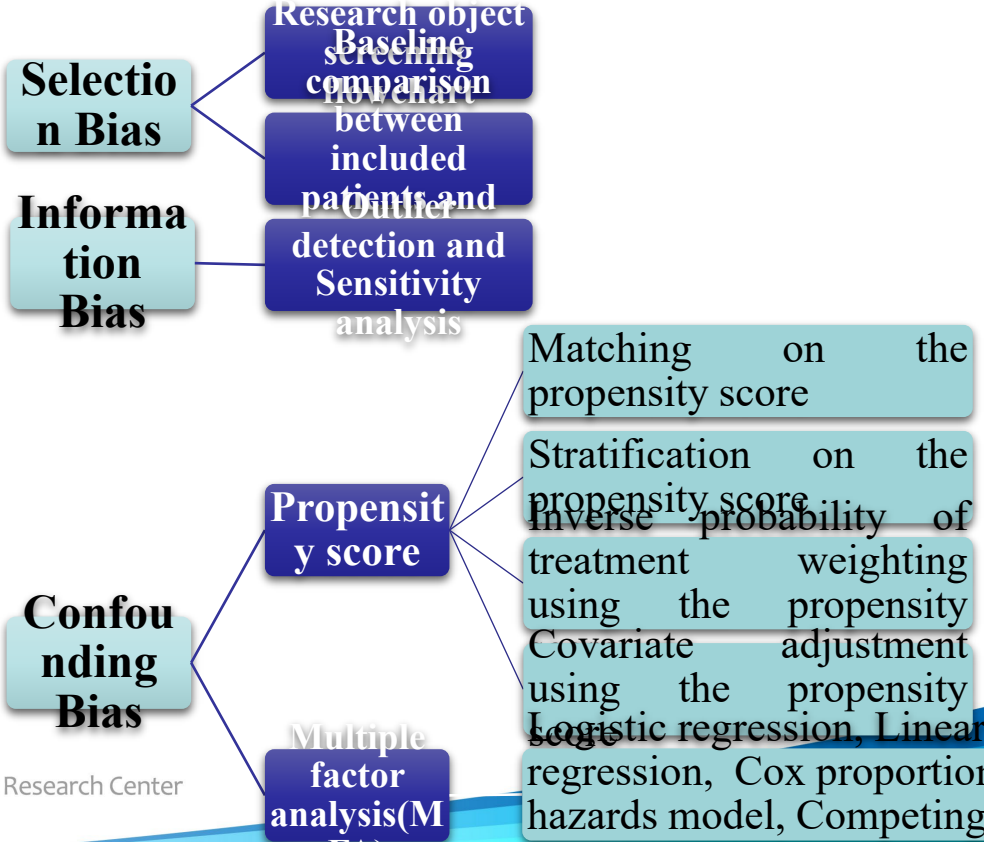
Database schema



Target population，data cleaning

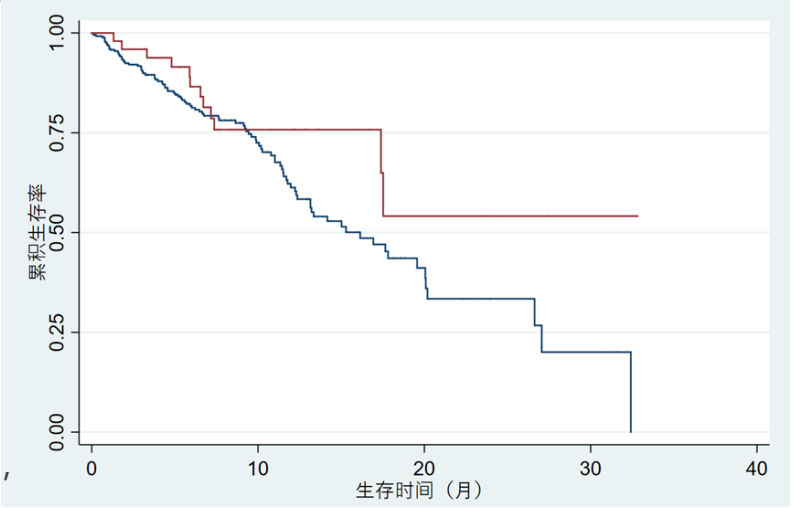


Bias control



Results of survival analysis

- **Survival rate:**
  - 1-year survival rate: 61.29% vs 75.77%
  - 2-year survival rate : 33.42% vs 54.12%
- **Median overall survival:**
  - Drug A: 16.14 months (95%CI: 13.15~20.05 months)
  - Drug B: NE, Q1: 17.39 months
- **Log-rank test:**
  - no statistical difference between the two groups ($\chi 2=2.99$, P=0.084)
- **Cox proportional hazards model:**
  - Drug B vs Drug A (HR=0.73,P=0.325)



Thank you！ ！ ！

Reimbursement and Clinical Accessibility of Innovative Medicines in China
中国创新药医保准入与临床可及性思考

Jiuhong Wu

Beijing Health Economics Association

Virtual ISPOR Asia Pacific Summit 2022
2022.09.21

Gearing Up for High Quality Development in China's Public Hospitals

中国公立医院高质量发展在推进

2022-09-21 WU JIUHONG

Challenges and issues facing medical institutes
医疗机构面临的问题与挑战：

China’s status quo and social and economics diversities across country

Differences in the level of medical development and technical capacities

Policies implementation and synergy across insurance and healthcare departments

Parallel development of DRG reform and quality improvement of medical institutes

Booming of innovative medicines and the combination usage of traditional and modern medicines

Subsidization level and co-payment pressure under the national reimbursement scheme and private insurance

……

The 1st Conference for the Reform of CHS-DRG/DIP Payment Method in China

第一届中国CHS-DRG/DIP支付方式改革大会

——«Three Year Action Plan for reform of DRG/DIP Payment Method»

By the end of 2024, DRG / Dip payment reform will be carried out in all overall planning areas across the country

Recent priorities of health insurance policy and reform
医保政策与改革近期重点

Three Year Action Plan for reform of DRG/DIP Payment Method
Digital information system to assess the performance of the Direct Settlement of Trans-Provincial patient Expenses
The perspective of resource integration and optimization, strategic purchase, and mutual benefit
Adjustment of the national reimbursement formulary and pricing negotiation of innovative medicines
Centralized procurement of high-value medical consumables
Improve eco-system of healthcare and fight fraud fund use and enhance safety of medical insurance funds
Promote the high-quality development of Chinese medical institutions

National Healthcare Security Administration (NHSA): 2022 adjustment of National Drug Catalogue for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance

国家医保局：《关于公示2022年国家基本医疗保险、工伤保险和生育保险药品目录调整通过初步形式审查的药品及相关信息的公告》

- **2022-09-06 NHSA released the Announcement of the list and information of medicines following preliminary evaluation:**
  - 537 applications from industry
  - 490 medicines
  - 344 medicines (70%) passed the preliminary assessment

Steady Development of Innovative Medicines in China

中国创新药稳步发展的现实

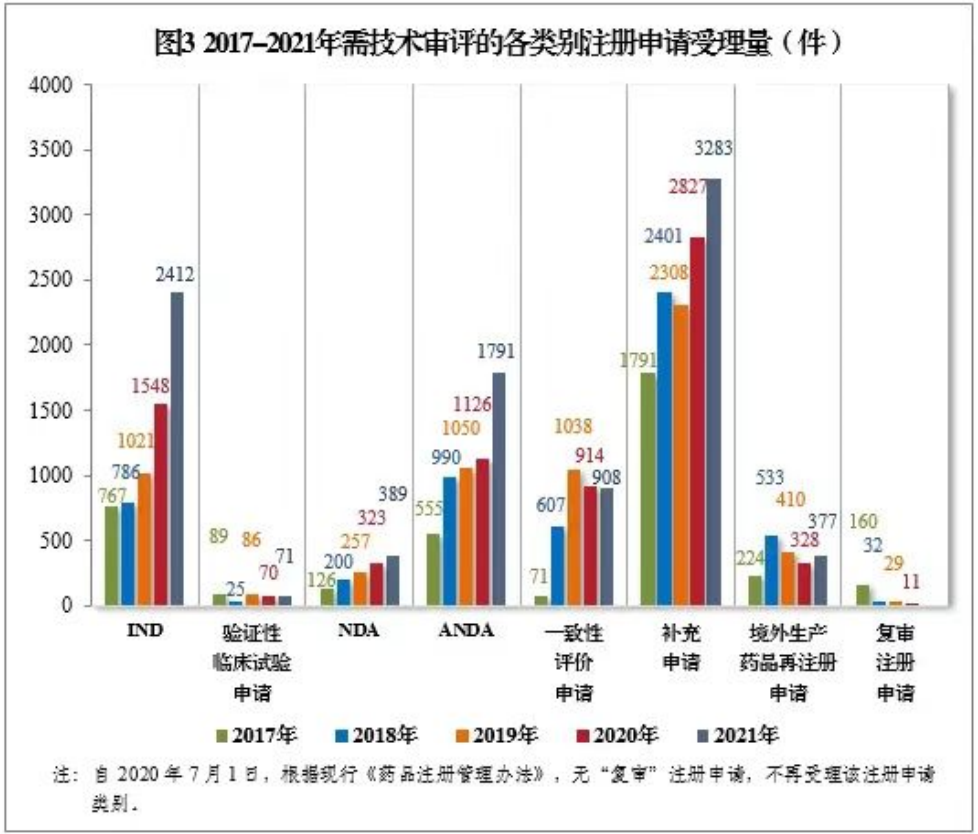
2022-09-21 WU JIUHONG

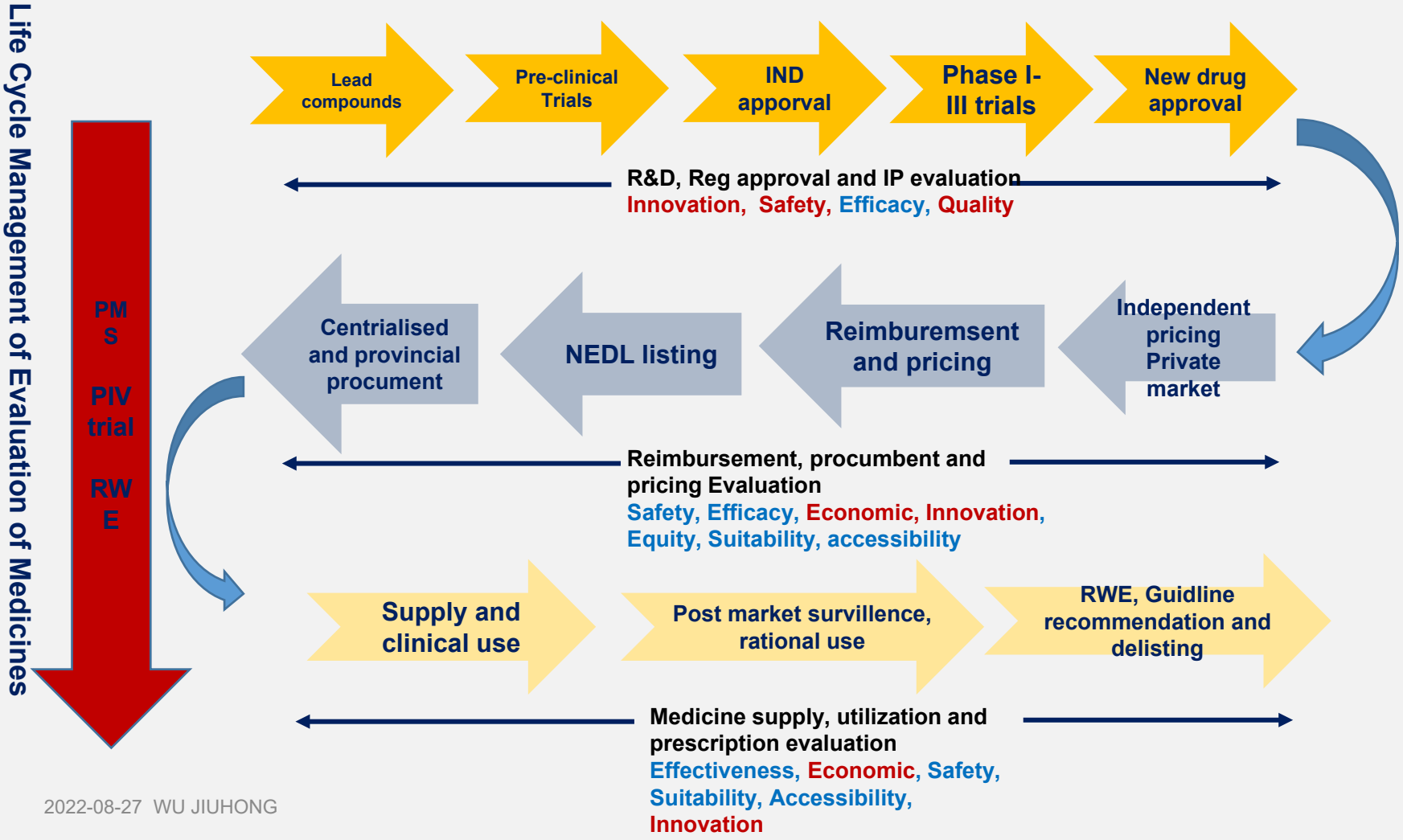
Trends in innovative medicines development in China
(CHEN Kaixian, Academician of the Chinese Academy of Sciences (CAS) 2021-2022)
中国创新药发展趋势（陈凯先院士 2021-2022）

National Medical Products Administration (NMPA)

Regulatory approval of new medicines

国家药监局新药注册审评进展




Life Cycle Management of Evaluation of Medicines
PM S
PIV trial
RW E
Lead compounds
Pre-clinical Trials
IND apporval
Phase I-III trials
New drug approval
R&D, Reg approval and IP evaluation
Innovation, Safety, Efficacy, Quality
Independent pricing Private market
Reimburemsent and pricing
NEDL listing
Centrialised and provincial procument
Reimbursement, procumbent and pricing Evaluation
Safety, Efficacy, Economic, Innovation,
Equity, Suitability, accessibility
Supply and clinical use
Post market survillence, rational use
RWE, Guidline recommendation and delisting
Medicine supply, utilization and prescription evaluation
Effectiveness, Economic, Safety,
Suitability, Accessibility,
Innovation

Quality Improvement and Advancement in Regulation

质量提升与监管的进步

2022-09-21 WU JIUHONG

National Medical Products Administration (NMPA): Guidelines of Clinical Value-Oriented Clinical Development for Anti-tumor Drugs
国家药监局发布：《以临床价值为导向的抗肿瘤药物临床研发指导原则》

Release date: July 2, 20210702 (implemented)

The purpose of the drug marketing is to address the patients needs – 'Clinical Value'

- **Implementing the clinical value-oriented and patient-centric R&D concept**
- **Rapid development of cancer drug R&D in China: patients has higher expectations on safety, treatment experiences, and quality of life**
- **Patient-oriented approach to cancer drug R&D: accelerate cancer drug development in China by directing resources to true innovation**

Perspectives on the new medicines evaluation
新药准入评价思考：

The challenges of accessibility of innovative medicines in China post reimbursement listing?
创新药准入与可及性在中国面临的困难?

- Restrictions on the hospital formulary (~1300 medicines, including 300 traditional medicines)
- ~30% co-payment for high-value innovative medicines
- Universal zero-markup drug policy in the hospital, high management cost for the high price medicines without subsidization
- Fast-track regulatory approval and reimbursement listing, limitation on the clinical data
- Dual-channel policy (direct-to-patient (DTP) pharmacies and hospital formularies) to promote innovation medicines, facing challenges
- Delisting mechanism is not in place to manage low performance medicines, high cost and high volume products etc.

The Future Value Increasement and Medical Advancement

未来价值提升与医疗进步

2022-09-21 WU JIUHONG

Health Insurance Coverage and Access, Value Based Healthcare(Top Level Design)
医保准入与价值医疗的制度建设（顶层设计）：

- Assessment system of medicines in the NRDL/NEDL
- Consensus on the HTA/PE guideline
- Government funded health technology research institutes
- Independent third-party evaluation organisations
- High quality HTA talents and capacities
- Transparent information platform and accessible datasets
- Formalized delisting mechanism

Opinion on the PE from hospital perspective
药物经济学医院视角的新思考

Hospital formulary

Optimise therapeutic options

- Establish evaluation standards and system
- Optimise the medicine utilization
- Fast-track health technology assessment and PE evaluation

Rational drug use /cost management

Align with payment method reform

- Implement DRG/DIP payment method reform
- RWE and outcomes research
- Medical records quality and compliance on the treatment guideline

Value Based Healthcare

High quality development of medical institutions

- Effectiveness/safety/innovation/accessibility/suitability/equity
- Perspective of value assessment?
- Hospital? Insurance fund? Patients? Industry?

Thank you!

Evolving Dynamics of Reimbursement and Post Listing Accessibility of High-Priced Innovative Medicines

Virtual ISPOR Summit - AP

Boxiong Tang, MD, PhD

Sept 21, 2022

Benefits from NRDL – From Pharmaceutical Perspectives

- Change from non-regular NRDL to annual NRDL negotiation
- Increasing innovation, manufacturers can reach patients in China sooner.
- Increased transparency of the process with some submission material being made public.
  - Openness for high priced therapies
- Greater transparency will likely move the process to be more uniform and help manufacturers understand the key drivers for access to the list.
- NHSA Continues Improving Foundation of NRDL's Success

https://remapconsulting.com/may-nrdl-china

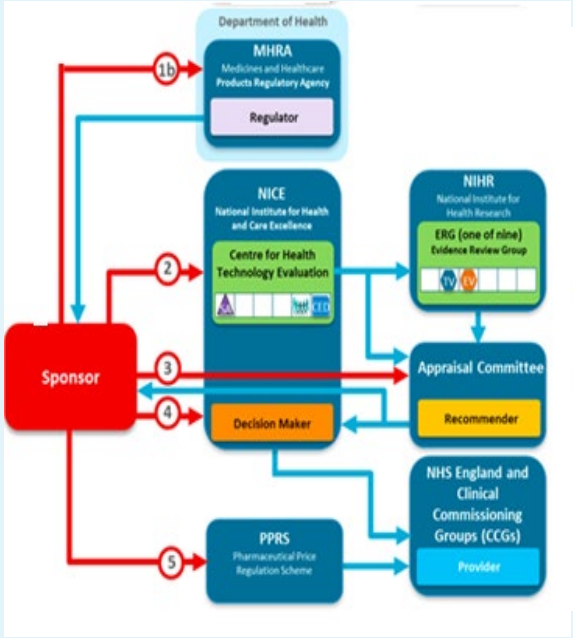
Drawbacks of being added to the NRDL

- Demands to lower the price of drugs. Manufacturers may need to make the decision whether the patient volume in China justifies the price reductions.
- This can also have implications for prices in other countries as the prices in China are public.
  - Multinational Companies Struggle to Strike a Deal with NHSA for Oncology Products
- Negotiated price can be subject to further price reductions if, for example, for additional indications.
- Price negotiations will occur every two years and can require large price cuts if a product wishes to stay listed.
  - Re-assessment of NRDL listed products that do not demonstrate strong efficacy results as expected
- Access to hospitals and pharmacies after NRDL

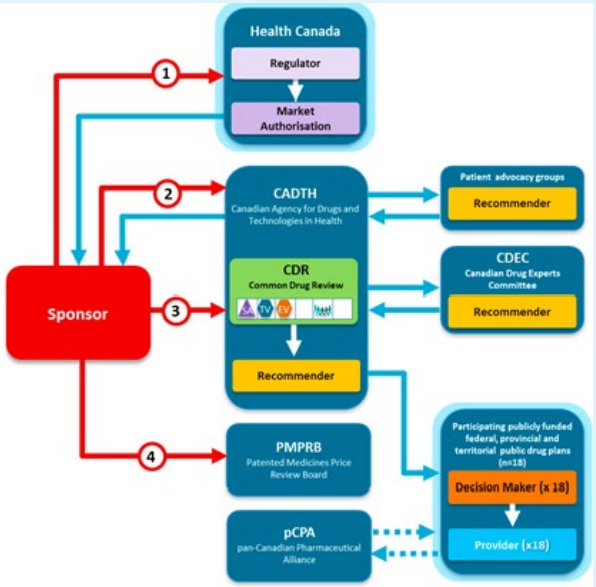
https://remapconsulting.com/may-nrdl-china

Lessons from Other Countries

England



Canada



China

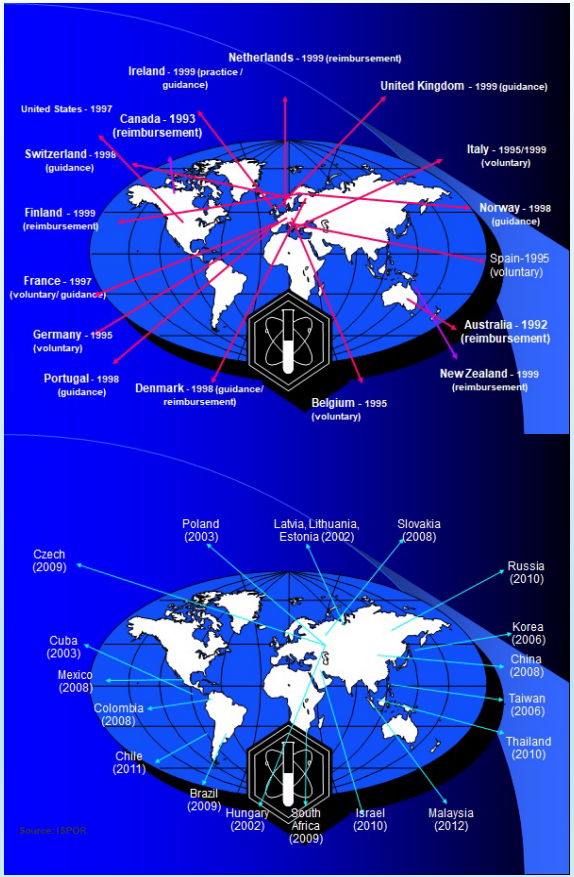
- -National Medical Products Administration (NMPA)
- -National Health Commission (NHC) - National Essential Drug List
- -National Healthcare Security Administration (NHSA) - NRDL

https://www.nice.org.uk/

Canadian Agency for Drugs and Technologies in Health (CADTH)

Clinical Pharmacy, Drug Information, Pharmacovigilance, Pharmacoeconomics and Clinical Research, 2019, Pages 313-320

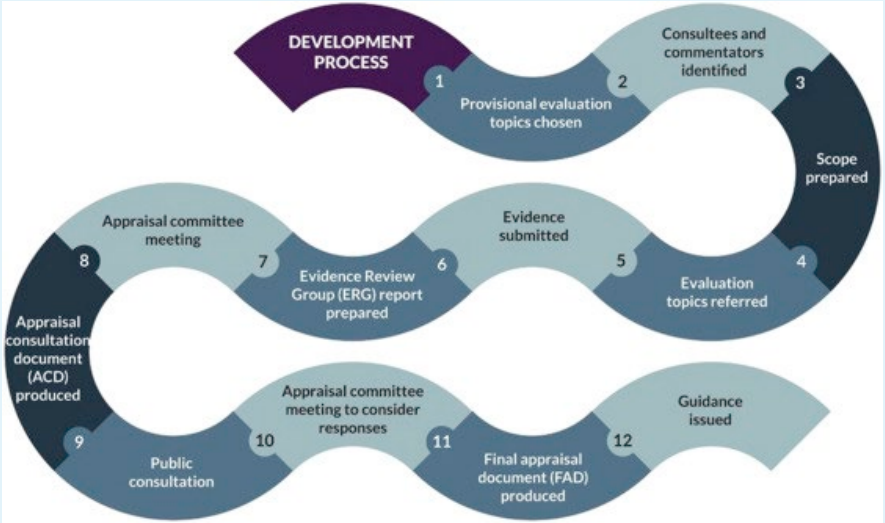
Reimbursement & HE Study Guideline



- HE guidelines for health economics research are similar across countries, the difference lies in the specific evaluation and implementation

- Examples:
  - The weight of clinical vs economic evidence
  - QALY vs other clinical indicators (LY, etc.)
  - Requirements for standard of care as comparators: standard treatment varies by country (based on clinical guidelines)
  - Comparative analysis: head-to-head clinical data vs indirect comparative methods
  - The need for indirect comparisons
  - Choice of Economic Model
  - Comprehensive literature: includes all information
  - The Importance of real-world evidence
  - Need for local data sources
  - Multiple factors, especially those non-economics considerations

Comparing UK HTA and China NRDL



Clinical Pharmacy, Drug Information, Pharmacovigilance, Pharmacoeconomics and Clinical Research, 2019, Pages 313-320

2021 timeline:

- Preparation (Jun-Jul)
- Application (Jul-Jun)
- Formal Review (Aug–Sept))
- Negotiation (Sept-Oct)
- Announcement (Oct-Nov)

https://remapconsulting.com/may-nrdl-china/

Conclusions

- NRDL expansion supports the ever-growing notion that China is becoming one of the most important markets for innovative therapies. However, challenges remain and as the rare disease and oncology space becomes more crowded year on year, manufacturers will need to strive for greater degrees of innovation and differentiation going forward.
- Collaborations among reimbursement authorities, academic experts, pharmaceutical companies – move toward to a value-based reimbursement
- Scientific evidence is a key saucerful factor
  - Pharmaceutical manufacturers should proactively prepare for evidence synthesis.
  - Health economic data, real-world evidence, and local data will provide support and facilitate value demonstration and effective pricing negotiation of innovative patent drugs.
  - International reference pricing (IRP) is an important reference to determine NRDL target prices
- Corporate reputation and image
    - Patient Access and Patient Focused Drug Development Programs