INNOVATION EWHA

# F4: Exploring New Frameworks for Real-World Evidence (RWE) Best Practices in Asia Pacific: Korea

ISPOR Annual Conference May 18, 2021

Jeonghoon Ahn
Department of Health Convergence



이화여자대학교
EWHA WOMANS UNIVERSITY

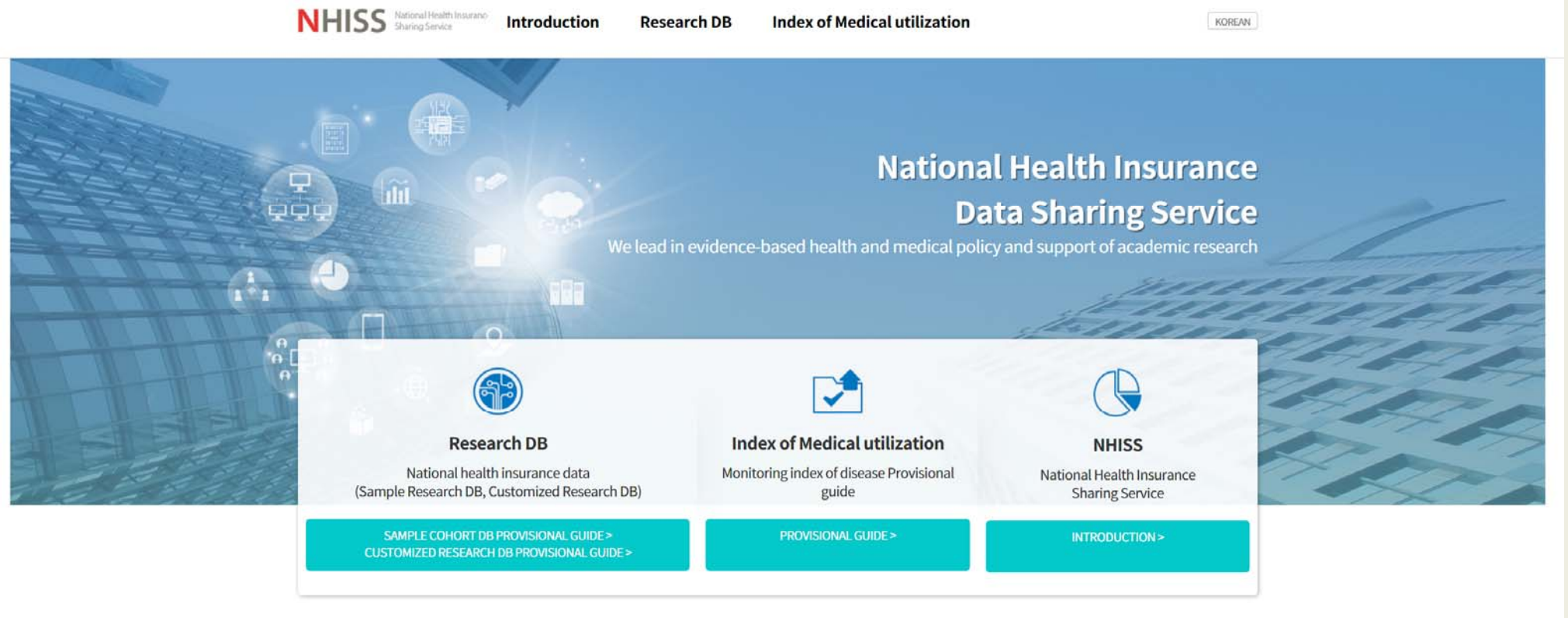
# Real World Evidences in Korea

- **National Health Insurance Claims data**
  - Sample cohort data: NHIS or HIRA
  - Customized data from the whole claims : NHIS or HIRA
- **Clinical research data**
  - Various public agencies fund clinical research using prospective registries and retrospective data: NECA, KCDC, NCI, KHIDI and many others
- **Hospital Electronic Medical Records**
- **Others**
  - Post Market Surveillance (PMS) data, Korean Adverse Event Reporting System (KAERS) data
  - Performance based risk sharing agreements data
  - Post reimbursement evaluation (Newly emerging concept in Korea)

# HIRA Sample Cohorts

| Data | Descriptions |
|---|---|
| Inpatients sample data data (HIRA-NIS) | 2009-2016 about a million patients (13%)<br>2017- about 0.75 million patients (10%)<br>Includes 1% outpatients (400K) except the 2016 sample |
| All patients sample data (HIRA-NPS) | 2009-2016 about 1.4 million (3%)<br>2017- about 1.45 million (3%) |
| Elderly patients sample sample data (HIRA-APS) | 2009-2016 about a million ≥65 years old (20%)<br>2017- about 0.7 million ≥65 years old (10%) |
| Young patients sample sample data (HIRA-PPS) PPS) | 2009-2016 about 1.1 million <20 years old (10%)<br>2017- about a million <20 years old (10%) |

# NHIS Claims Data for Research

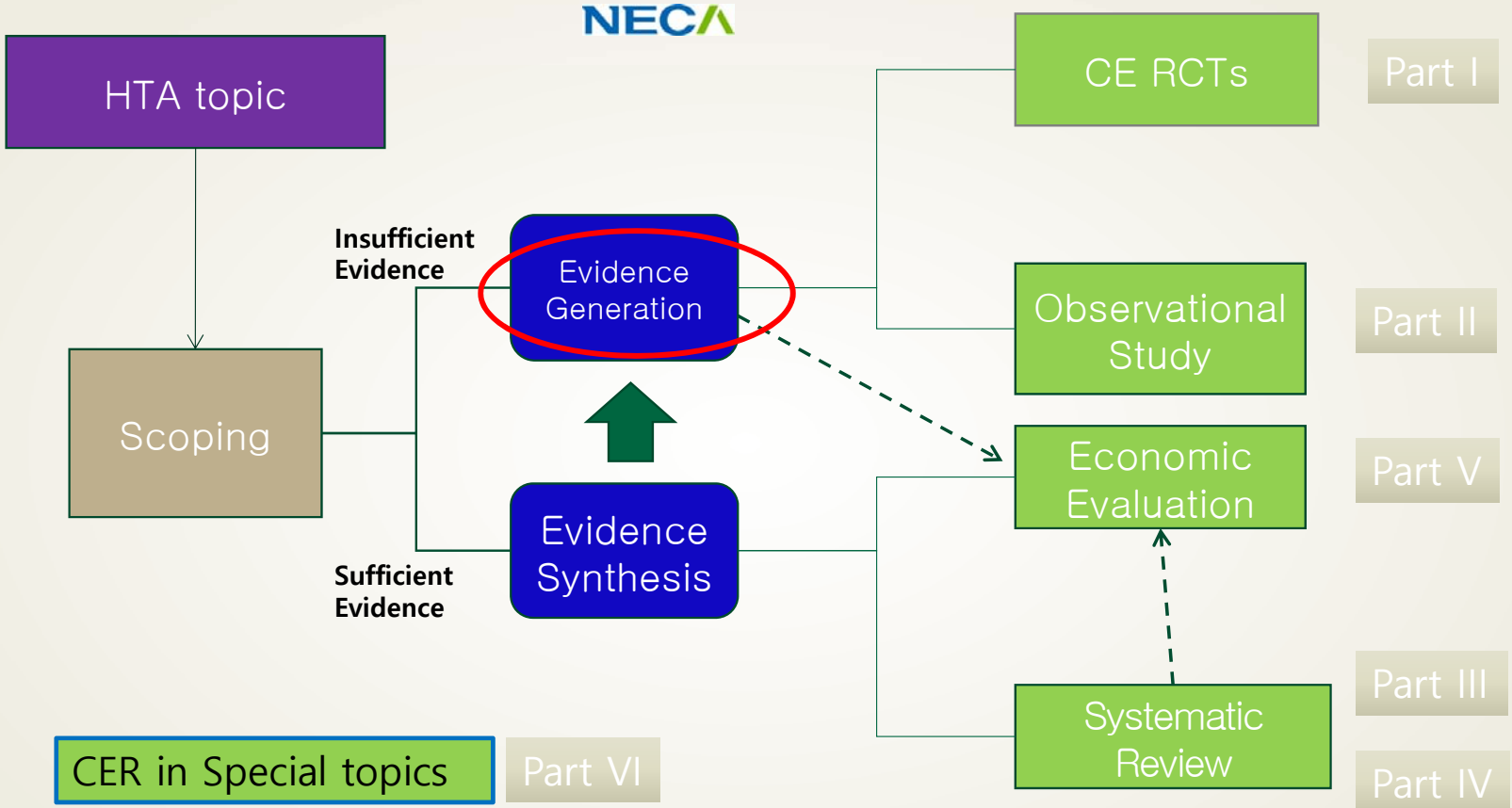



https://nhiss.nhis.or.kr/bd/ab/bdaba000eng.do

# Real World Evidence Uses in Korea

- **Public funded research**
  - Public agencies and ministry funded research
  - Can be linked with decision making
- **Private industry funded research**
  - Industry funded research such as dossier preparation
  - Limited access to available data: HIRA sample cohorts are at least available
- **Internal decision making**
  - HIRA and NHIS provide data for their internal use or for ministry

# NECA HTA Research Framework



# Korean System: Institutions

| | Drugs | Medical Devices | Diagnostics and Procedures |
|---|---|---|---|
| HTA research (reports published) | National Evidence-based healthcare Collaborating Agency (NECA) | National Evidence-based healthcare Collaborating Agency (NECA) | National Evidence-based healthcare Collaborating Agency (NECA) |
| Approval | Korean Food and Drug Administration (KFDA) | Korean Food and Drug Administration (KFDA) | Committee for New Health Technology Assessment (CNHTA) |
| Review and Recommendation | Health Insurance Review and Assessment Services (HIRA) | Health Insurance Review and Assessment Services (HIRA) | Health Insurance Review and Assessment Services (HIRA) |
| | National Health Insurance Corporation (NHIS)* | | |
| Decision Making | Ministry Of Health and Welfare (MOHW) | Ministry Of Health and Welfare (MOHW) | Ministry Of Health and Welfare (MOHW) |

HTA report linked to CnHTA decisions

DREC

*For drugs, HIRA does dossier review and NHIS does price negotiation

From Ahn et al. 2012. Social Values and Healthcare Priority Setting in Korea. *Journal of Health Organization and Management* 26(3):343-350

# Some High Cost Drugs on Risk Sharing Agreement (RSA) in Korea

- **Korean RSA is limited to only the drugs meet eligibility**
- **Eligibility of Korean RSA**
  - **Anticancer drug which is non-substitutable or non-equivalent drug exists**
  - **Drugs for life threatening rare disease**
  - **Other drugs designateded by the Drug Reimbursement Evaluation Committee (DREC)**
    - **considering disease severity, social impact, and other impact on healthcare**

# Risk Sharing can be a Solution

- **Just like many other countries, risk sharing scheme can be a solution to deal with access issue to a high cost drugs in Korea**
- **Financial risk sharing contracts such as maximum budget cap type or refund type are popular in many countries because it can restrict budget impact effectively**
  - **RSA in Korea is working as hidden discounts on high priced drugs in certain categories**
- **RSA is a tool to overcome International Reference Pricing (IRP)**
  - **Korean drug price (maximum allowable price) is published online**
  - **Countries referencing the Korean drug price are increasing and it is likely to have a negative impact on Korean patient access to the innovative medicine**
  - **RSA results in higher published price which may help overcoming IRP**

INNOVATION EWHA

# Post-reimbursement Evaluation: Just a proposal

# Current Stand Off

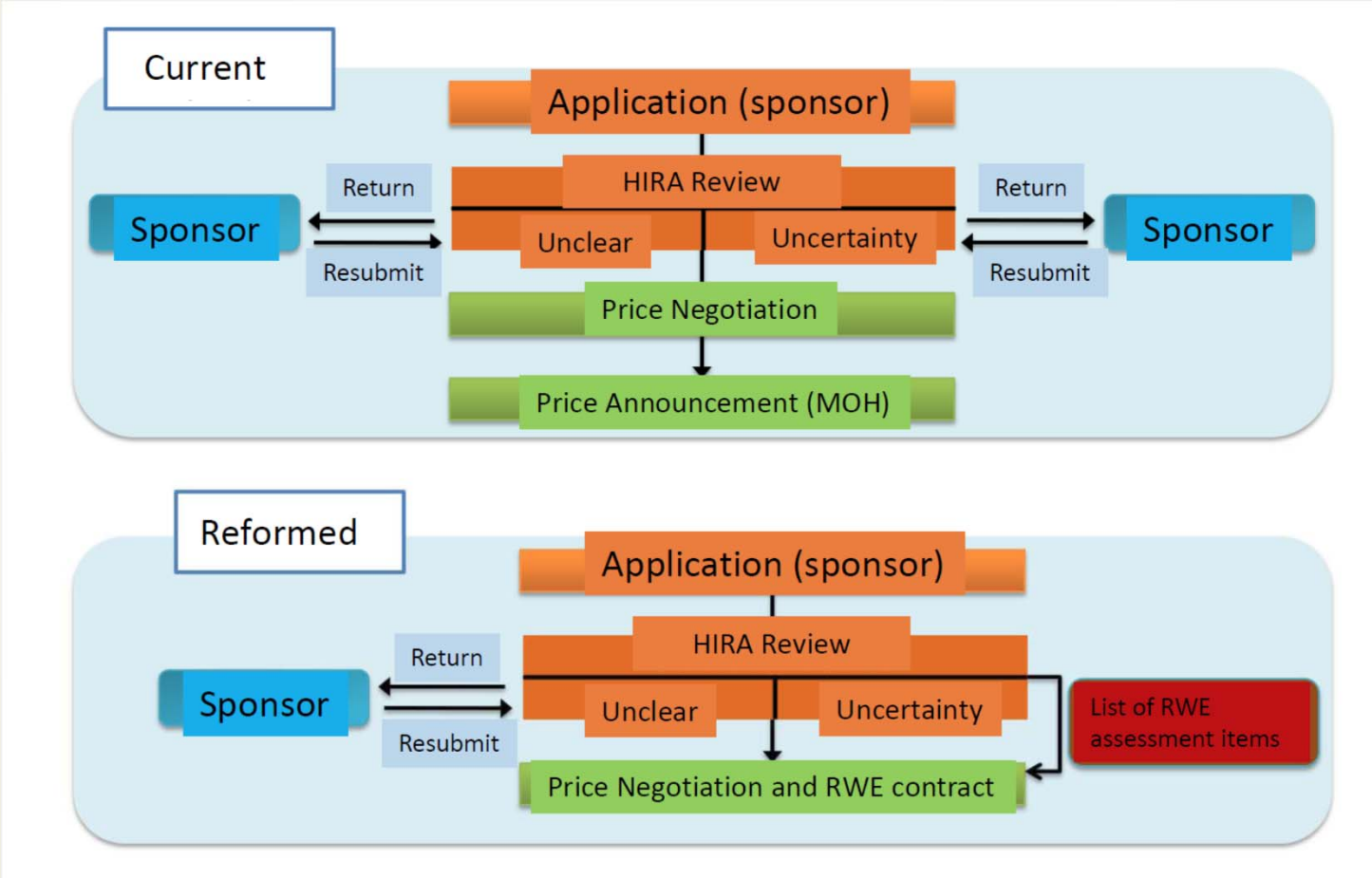
- **Current Korean system lacks evaluation of effectiveness of drugs after reimbursement decisions**
  - Once the reimbursement is decided by dossier submitted by the sponsor company, no further evaluation usually imposed
  - Issues such as uncertainties in effectiveness cannot be reflected in the value of innovative high cost drugs efficiently under the current system
- **On the other hand, most sponsor companies complain the review process of dossier**
  - Too lengthy (HIRA time clock starts only after a complete submission)
  - HIRA's revision requests sometimes demand non-existing evidence such as effectiveness of new drug in Korean population
  - Uncertainty = price cut

# Proposed Solution

- **Introducing a new system of post reimbursement evaluation on high cost drugs**
  - A research group is formed and sponsored by the NIHS (payer)
  - Prospective data collection to generate the Real World Evidence (RWE) in Korea
  - The collected RWE will be compared to the efficacy data in the original dossier
  - If significant discrepancy is found, the cost effectiveness model in the original dossier will be updated by the RWE and consequently a new price will be proposed
- **Taking this new system is voluntary and combined in the pricing contract between the NHIS and the sponsor company (may be with a volume cap)**
  - One incentive for the company side will be potentially reduced period of review on dossier since most uncertainties can be forwarded to the new system of evaluation
  - Another incentive will be potentially a higher price initially (but subject to adjustment after the evaluation) which can lead to higher pricing in the countries referencing Korean drug prices

# Post-reimbursement Evaluation

This is a proposed scheme to the payer and it is not officially introduced yet




RWE: Real World Evidence

# Thank you!

E-mail: ahnjeonghoon@ewha.ac.kr