

Generation of Evidence for unproven practices in Korea

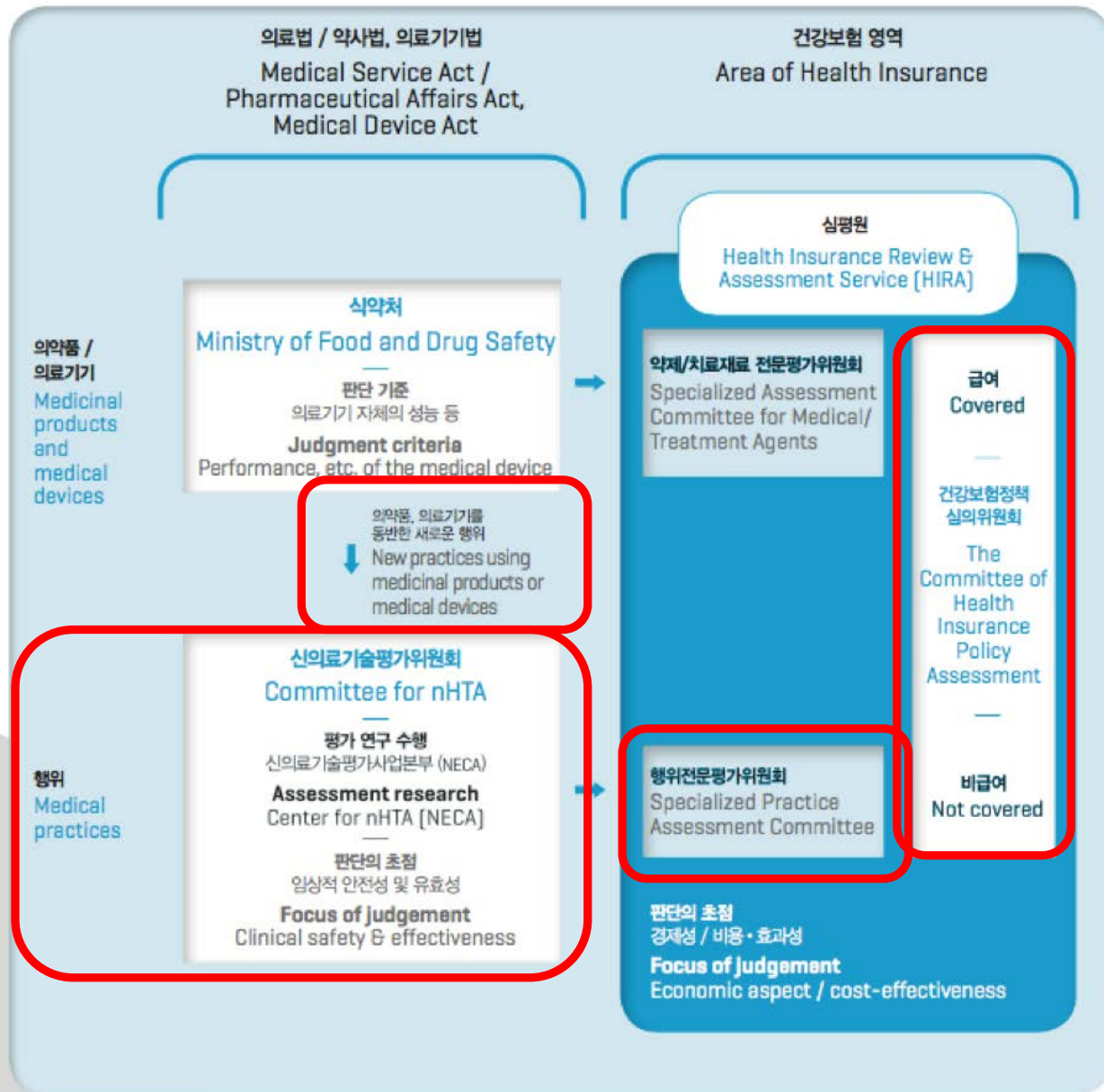
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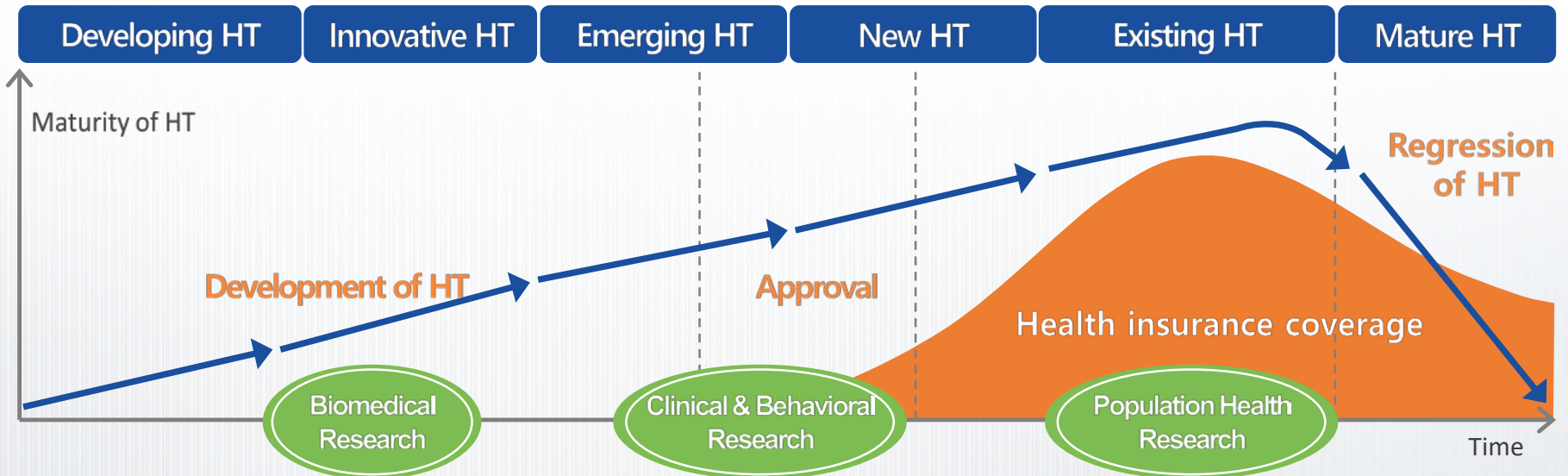
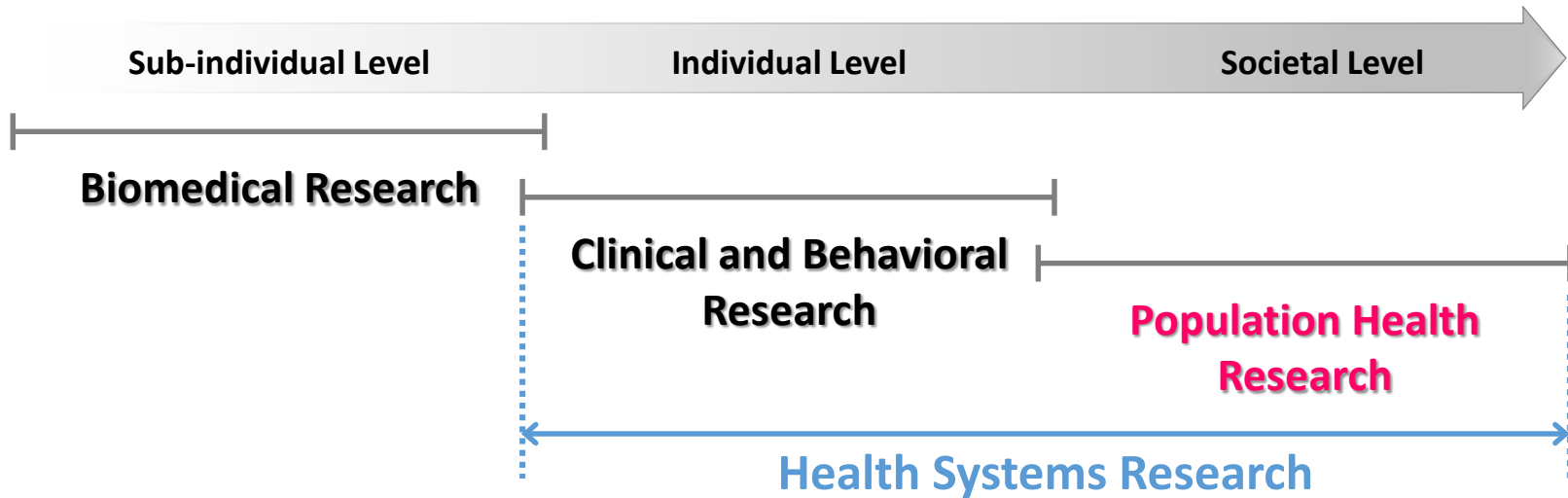
Introduction to Korean healthcare system

- ❖ Single-payer national health insurance (NHI) system for all people since 1999
- ❖ NHI (97.1% in 2016), Medical Aid (2.9% in 2016), and long-term care insurance
- ❖ Benefits coverage rate of NHI, 63.2% in 2016
- ❖ Pres. Moon's healthcare plan in Aug. 2017
 - ✓ Expand universal coverage over the next 5 years (~70%): full coverage for all medically essential services
 - ✓ Invest more than \$ 26.4 billion
 - ✓ Introduction of “preliminary benefits system” (reassessment in 3 to 5 years)
 - ✓ Strengthen Health Technology Assessment (HTA): amendment of Medical Law

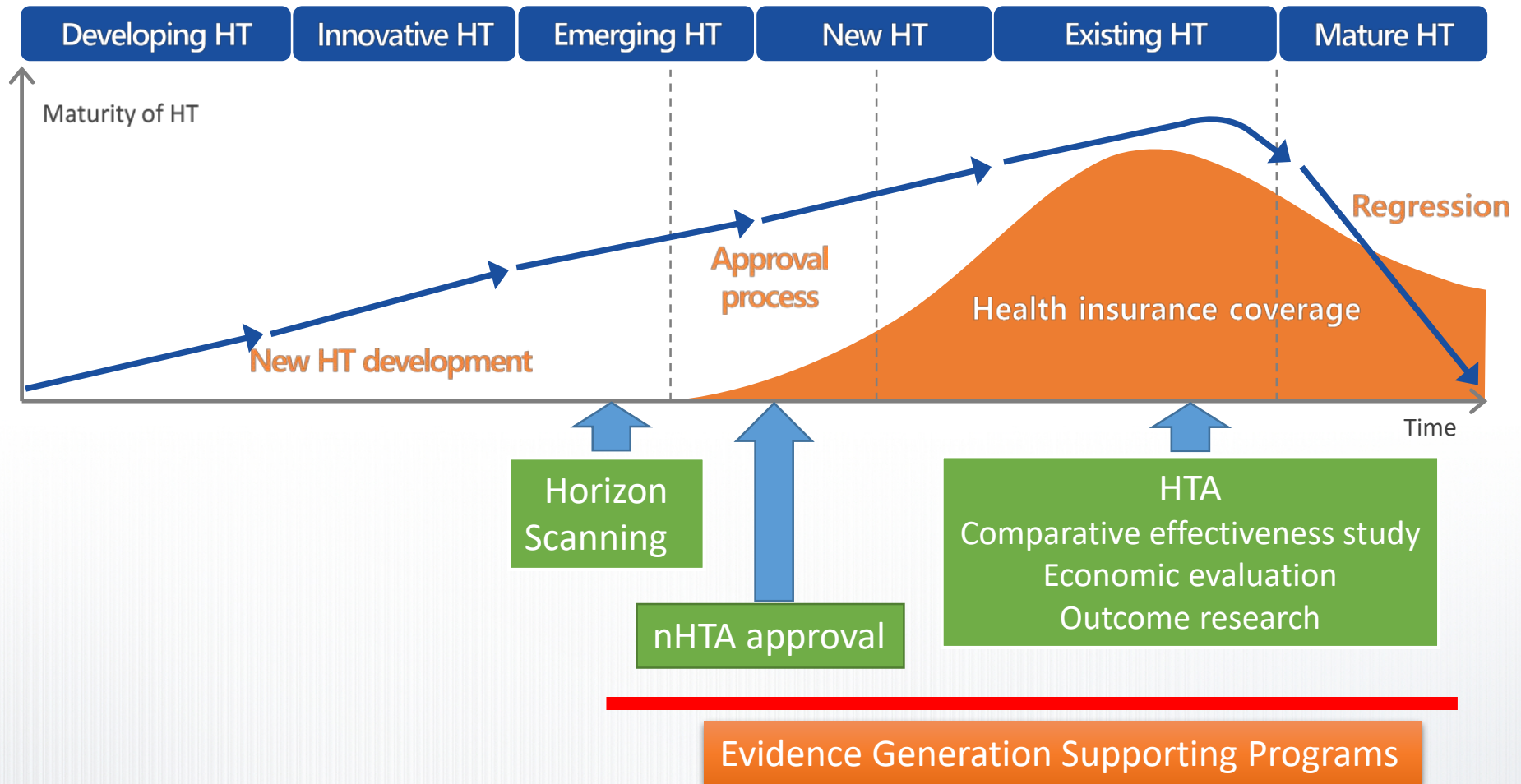
Process for introduction of pharmaceuticals, devices, and procedures



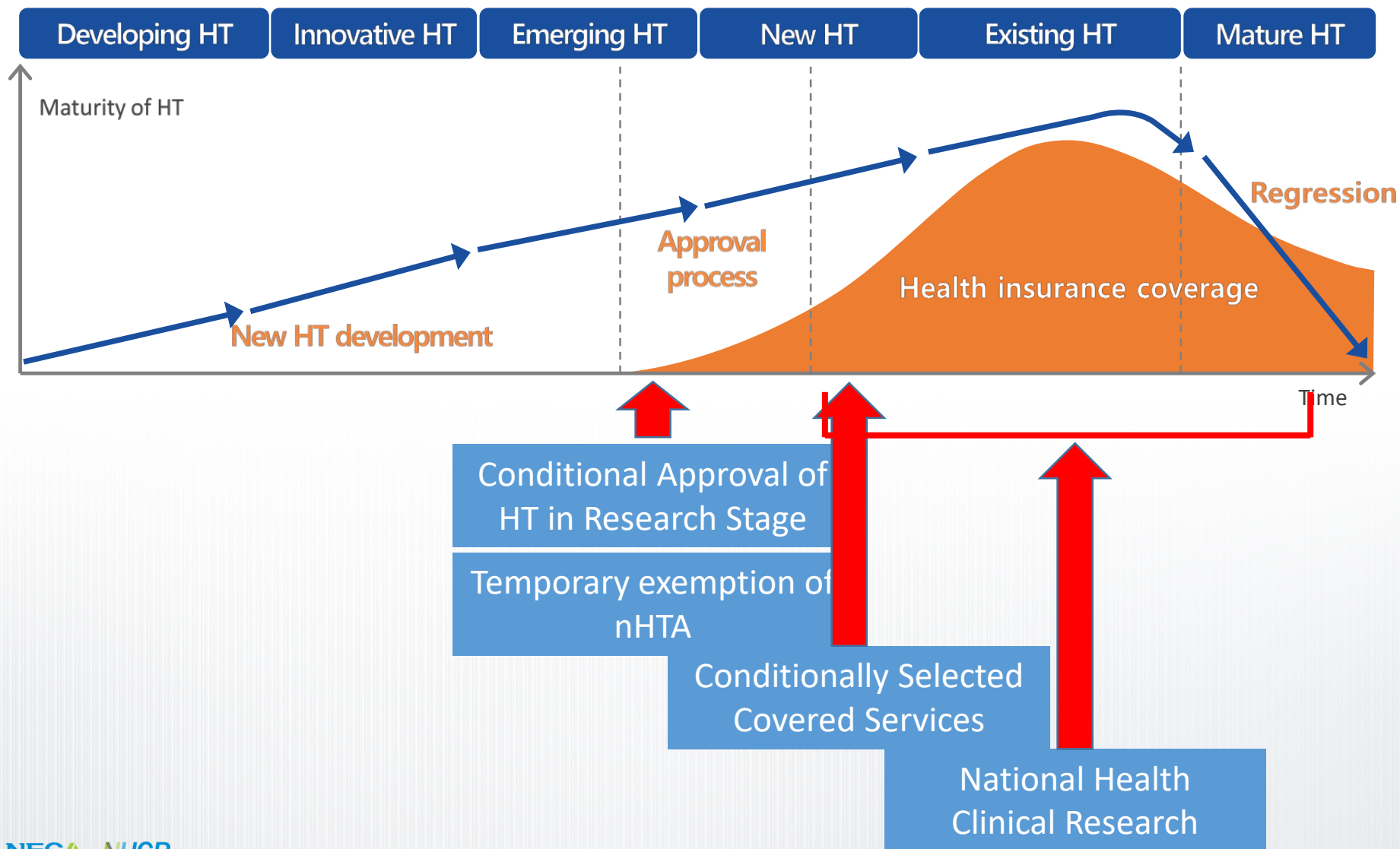
Life cycle of Health Technologies



Life cycle of Health Technologies



Evidence Generation Supporting Programs




Evidence Generation Supporting Programs in Korea

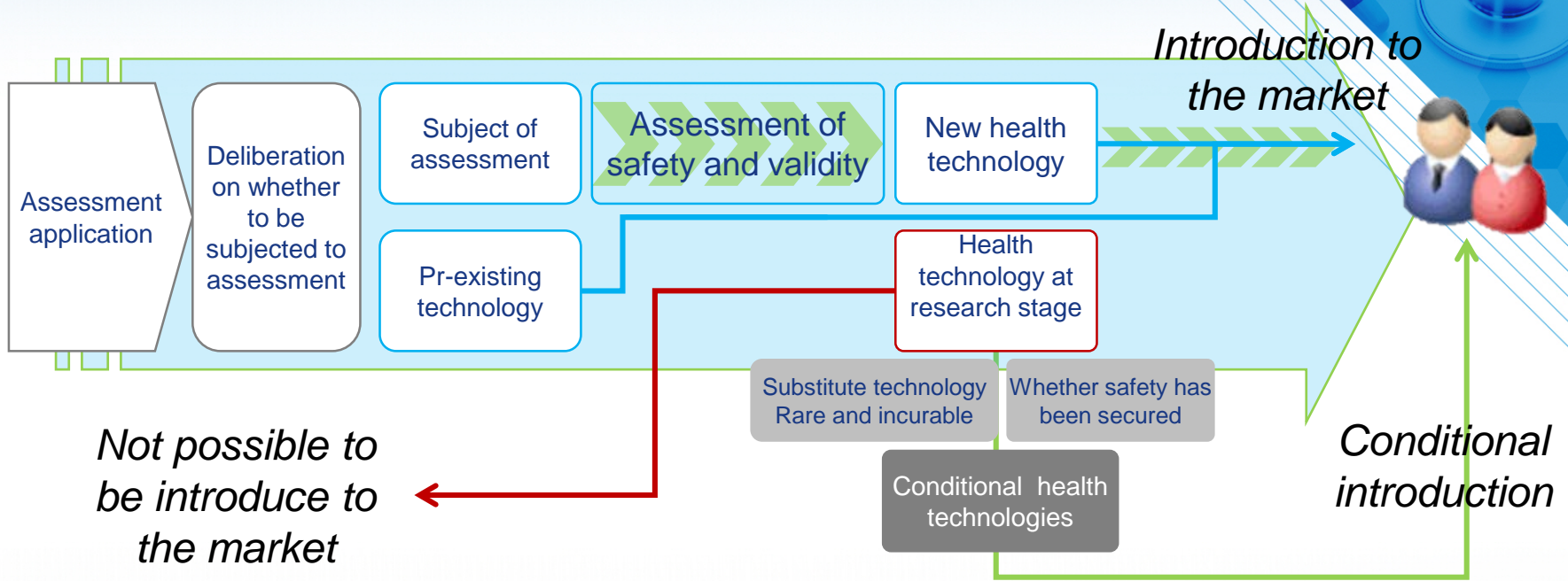
- ❖ Conditional Approval of Health Technology in Research stage
 - Pre-market supporting program
 - Procedures which fails to prove their effectiveness to pass nHTA approval, therefore in Research Stage judged by nHTA committee
 - Performed as a clinical research with mandatory clinical data collection
 - Government fund supporting operation of research
 - CRO, CRA, eCRF....
 - Participated patient should pay 100% amount for the procedures
 - 3 year plan and re-assessment for nHTA



< CONDITIONAL APPROVAL OF HT IN RESEARCH STAGE >

“Conditional Approval System” for Conditional introduction of HT in research stage to support evidence generation for safety and effectiveness





- ✓ Allow utilization of selected class II-b technology for rare and severe diseases
- ✓ Utilize in selected medical institutions for a prescribed period of time

Class II-b technologies in research stage:
Urgently needed to be adopted in the clinical field due to no alternative way for rare diseases and low possibility of abuse

	Committee for Conditional Approval	NECA	Participating Hospital
Role	<ul style="list-style-type: none"> •Application review •Approval of application (Duration, Precedure definition, participating institution. •Monitoring •Audit •Review of intermediary and final results. •Approval of final result report. 	<ul style="list-style-type: none"> • Administrative support of cCA • Development and management of e-CRF • Process Management : Acquisition and analysis of results • Re-evaluation of HTA 	<ul style="list-style-type: none"> • IRB approval • Practice of conditionally approved HT • Preparation and report of e-CRF • Report of Intermediary and final results.

- * Committee for Conditional Approval:
 - subcommittee of Committee of nHTA
 - Composed of 10 fixed and 10 flexible members

Conditional Approval System of Health Technology

No.	Health Technology (period)	Hospital number	Reg rate(%)	Total support cost USD	Cost* /patient USD
1	Therapeutic Use of Autologous Peripheral Blood Stem Cell in Myocardial Infarction '14.10.1.~'17.9.30.	3	25.9 (57/220)	289,590	5,080
2	Autologous Platelet Rich Plasma Application '14.10.1.~'17.9.30.	5	63.9 (234/366)	715,042	3,361
3	Irreversible Electroporation for Pancreatic Cancer '15.9.1.~'18.8.31.	2	15.0 (15/100)	215,292	14,352
4	C-11-methionine Positron Emission Tomography/ Computed Tomography (PET/CT) '16.8.1.~'19.7.31.	1	72.0 (36/50)	82,520	2,292
5	Intravitreal Autologous Platelet Concentrate Injection '16.11.1.~19.10.31.	6	20.6 (20/97)	303,272	15,164
6	Autologous Bone Marrow Stem Cell Treatment in Diabetic patient with Critical Limb Ischemia '18.1.1.~ 20.12.31.	3	0	81,819	0

*CRC, CRA salary etc.

Evidence Generation Supporting Programs in Korea

❖ Temporary Exemption of nHTA

- Procedures involved with newly MFDS (Korean FDA) approved medical devices
- Requirement for nHTA approval is exempted for a year
- Procedures are not covered by health insurance
- nHTA application is mandatory after 1 year evidence generation period.

Temporary Exemption of nHTA

No	Health Technology
1	Non-invasive Continuous Measurements of Respiration State
2	Retinal Prosthesis Implantation Procedure for Retinitis Pigmentosa patient
3	rhBMP-2 mixed Autogenous Tooth derived Bone Graft

Evidence Generation Supporting Programs in Korea

❖ Conditionally Selected Covered Services

- Procedures with low evidence and high impact on health system
- Performed as clinical practice with mandatory data collection
- Copayment rate is 50 ~ 80%
- Can be performed in selected hospitals
- Similar to Coverage with Evidence Development program in USA

Procedure listing system of Korea

Procedure List for Health Insurance

Covered Services

- CS with copayment (5 ~ 30%)
- Selected CS with higher copayment (50 ~ 80%)
 - ✓ Re-assessment after 3 to 5 years of practice
 - ✓ Selected CS
 - ✓ **Conditionally Selected CS**

Approved in selected hospitals with clinical data collection

Uncovered Services

- Listed services with 100% copayment

Procedure	Copay	Starting date	Evaluation date
Transcatheter Aortic Valve Replacement	80%	2015. 6. 1.	Late 2018
Percutaneous Left Atrial Appendage Closure	80%	2017. 3. 1.	2020
NGS Oncogene Panel Test	50%	2017. 3. 1.	2020



Thank you

NECA
한국보건의료연구원

NHCR
국민건강임상연구 코디네이팅센터

