

Medical Technology Leadership Forum

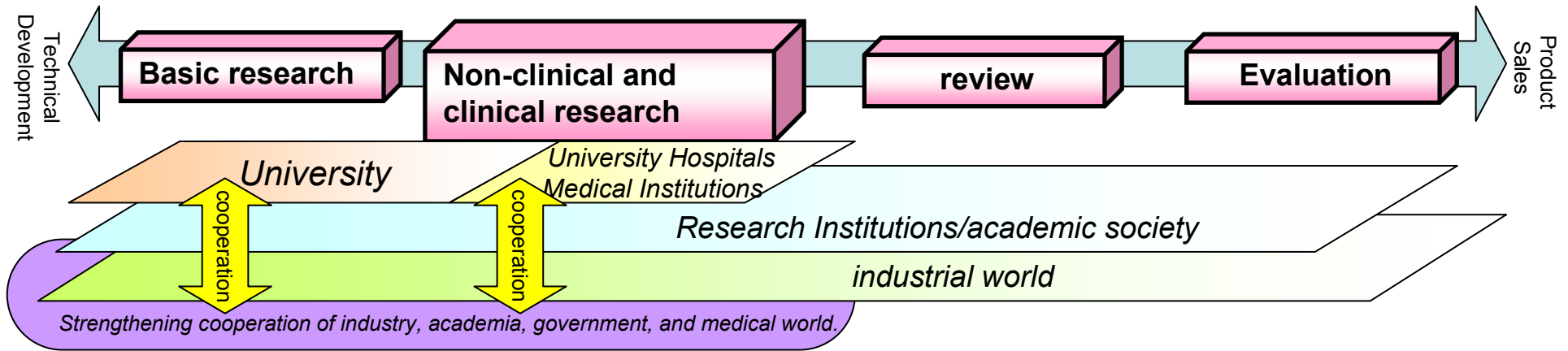
Challenges to Patient Access and Potential Market and Regulatory Solutions

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Key Messages

1. Failure of the policies to promote technical development:
It is difficult to commoditize even a successful case of a technical development.
→ A comprehensive package of policies that accommodates the entire length of the process from development assistance to commoditization for advanced technology is necessary.
2. As for the Pharmaceutical Affairs Law, it is important that the applying for the review process (approval and licenses) has the knowledge of the items to be reviewed beforehand.
3. In order to elevate incentive for businesses to develop new products, it is important to properly assess social and economic values of the medical device.

METI's view toward promotion for installment of medical devices



(Key Points)	Concentrated investment on key fields	Combination of research and clinical practice	Speeding up the review process	Evaluation of the economic efficiency of medical devices
	<p>Joint researches with other ministries</p> <p>Increasing topics</p> <ul style="list-style-type: none"> -Intelligent operation system -Molecular imaging system -DDS type cancer treatment system 	<p>Promotion of "translational research", a level of research between basic study and clinical research.</p> <p>- Promotion of researches that would bridge the gap between basic study to clinical practice.</p>	<p>Guideline to clarify the items in review process.</p>	<p>Guideline which contributes to appropriate evaluation of medical devices.</p>
(Measures)				

Establishing assessment guideline for medical equipment

Fields of technology that would progress in the next generation (examples)

- Artificial heart
- Robot surgery system
- Artificial sight system
- Medical devices which will contribute to regenerative medicine
 - :cultured myocardia
 - :cultured corneal
- Biological affinity implant
- DDS

Select about 5 fields based on technical possibility and needs

Guideline for assessment criteria

- Devices adaptable to next-generation technology

- Safety
- Efficacy
- Quality

Company: Promotion of developmental efficiency

PMDA: Speeding up the review process

Speedy application to clinical practice

Clinical trial/ counseling before application



Establishing assessment guideline for medical devices

Pharmaceutical Affairs Law states the review (approval and licenses) of medical devices is to be conducted from the viewpoint of efficacy and safety. However, because there are no prior examples for new devices, it is difficult for the applying for review to see what items will be targeted for inspection.

In order to speed up the development for medical devices as well as the review process, we are working in collaboration with MHLW since 2005 to establish a guideline which clarifies the inspection focuses.

Target fields for which the guideline will be established	Device that are to be inspected this year
Custom-made Medical Diagnostic Equipment	DNA chips
Surgical Navigation	Surgical robot
Body implant material	Biological affinity implant
Active implantable medical devices	Sophisticated artificial heart system
Regenerative medicine	Cell sheet

Establishing socioeconomic assessment guideline for medical devices

【Background】

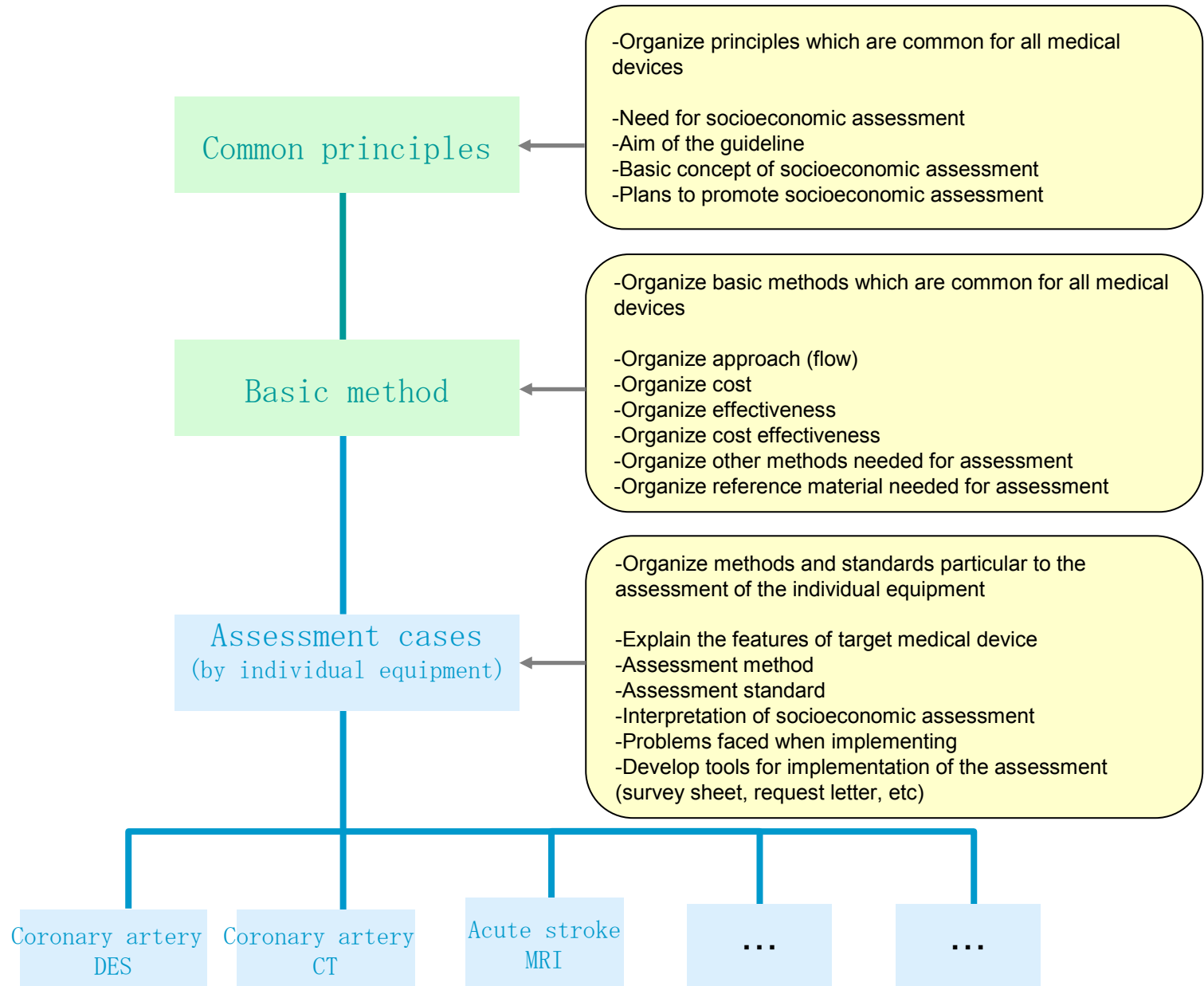
- In order to elevate incentive for businesses to develop new medical devices, it's important to conduct the logical socioeconomic assessment of advanced medical devices at the end of the R&D process.



【Aim】

- To organize and examine the socioeconomic assessment of medical devices which would contribute to the advancement of the industry.
- To organize and examine while taking in the technical features of the medical devices, the fields (targets) for which the socioeconomic assessment should be applied, and also the basic concepts of assessment methods and standards.
- To organize and examine the basic conditions of the system needed to permeate the adaptation of the socioeconomic assessment for medical devices.

Preliminary draft for socioeconomic assessment guideline



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Thank you !!!

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Project for Advanced Wellness Program

- **Health insurance, health consultation industry, fitness industry, and many others participate in the empirical project.**
 - The system which proves individuals' behavior modification is measured. By measuring cost effectiveness, later advancement of health consultation is improved.
 - Health data from various household health measurement equipments and health data which is used as unified standardization are developed. Information base for understanding individual health condition is structured.

