



# Regenerative Medicine in Healthcare Policy of the Abe Administration

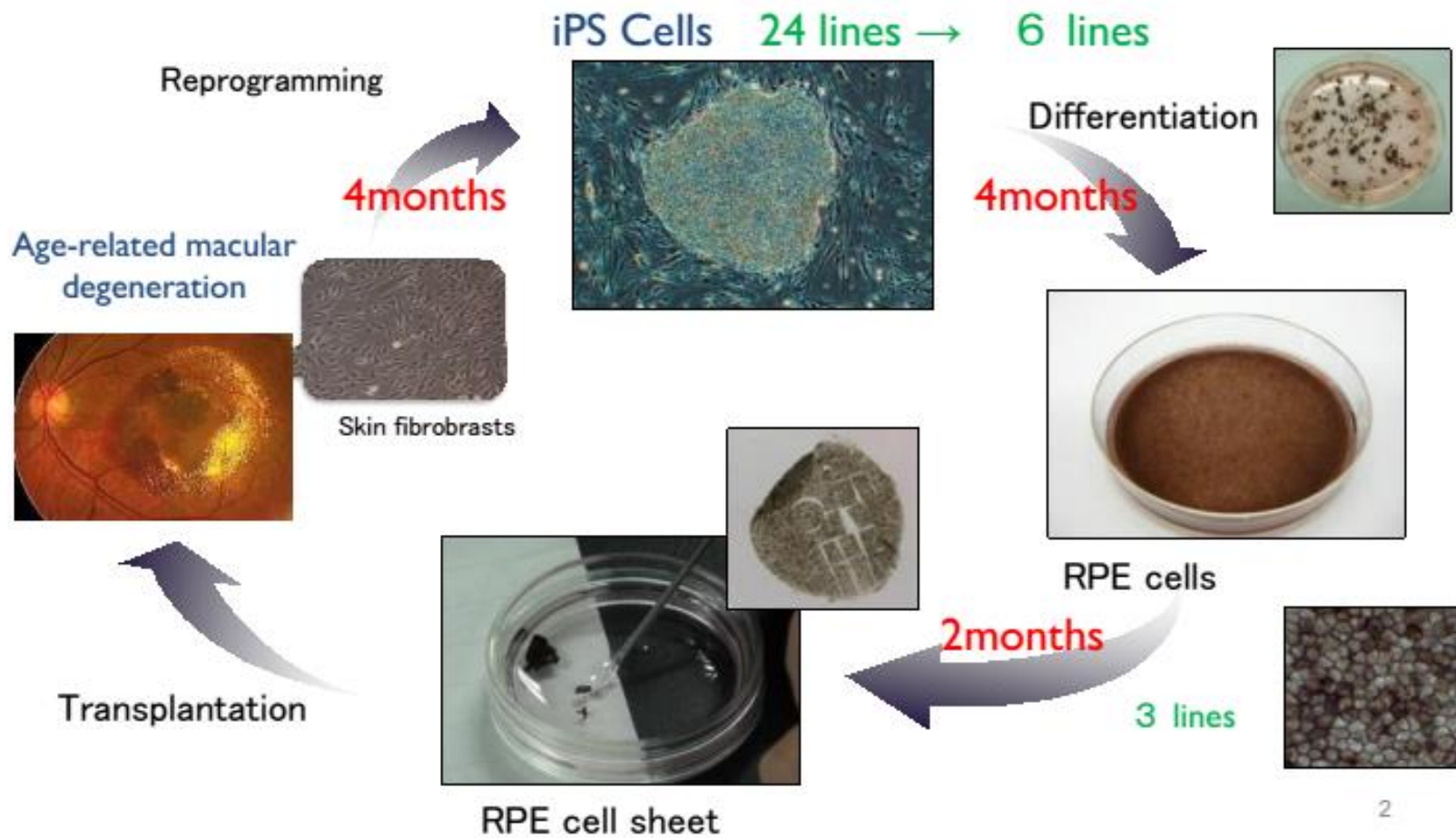
26 May 2015

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Director-General of the Office of Healthcare  
Policy



# The first transplant of RPE cell sheet in derived from iPS cells



# The main points of the Act on Promotion of Healthcare Industries and Advancement of Healthcare Technologies

Establishment of **the Headquarters of Healthcare Policy (HHP)** [Article 21 through 29]

## **The Healthcare Policy (Article 17)**

The Prime Minister shall seek a cabinet decision on the Healthcare Policy, which consists of the following points:

- ✓ Promotion of medical R&D, preparation of R&D environment, and dissemination of the results of R&D
- ✓ Creation and vitalization of new businesses and industries including export of Japanese healthcare systems and medical equipment

## **The Plan for Promotion of Medical R&D (Article 18)**

The HHP shall make the plan which shall include the following points:

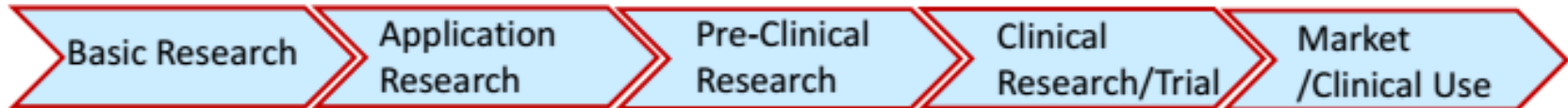
- ✓ Decision on important fields of medical R&D in which the Government should focus its resources
- ✓ Functions of the AMED that shall play core roles in implementation and in granting of medical R&D



The HHP shall propose a basic policy of the management of the business of the A-MED based on the Plan for Promotion of Medical R&D

Japan Agency for Medical  
Research and Development,  
independent administrative  
agency (AMED)

# Japan Agency for Medical Research and Development Agency (AMED)



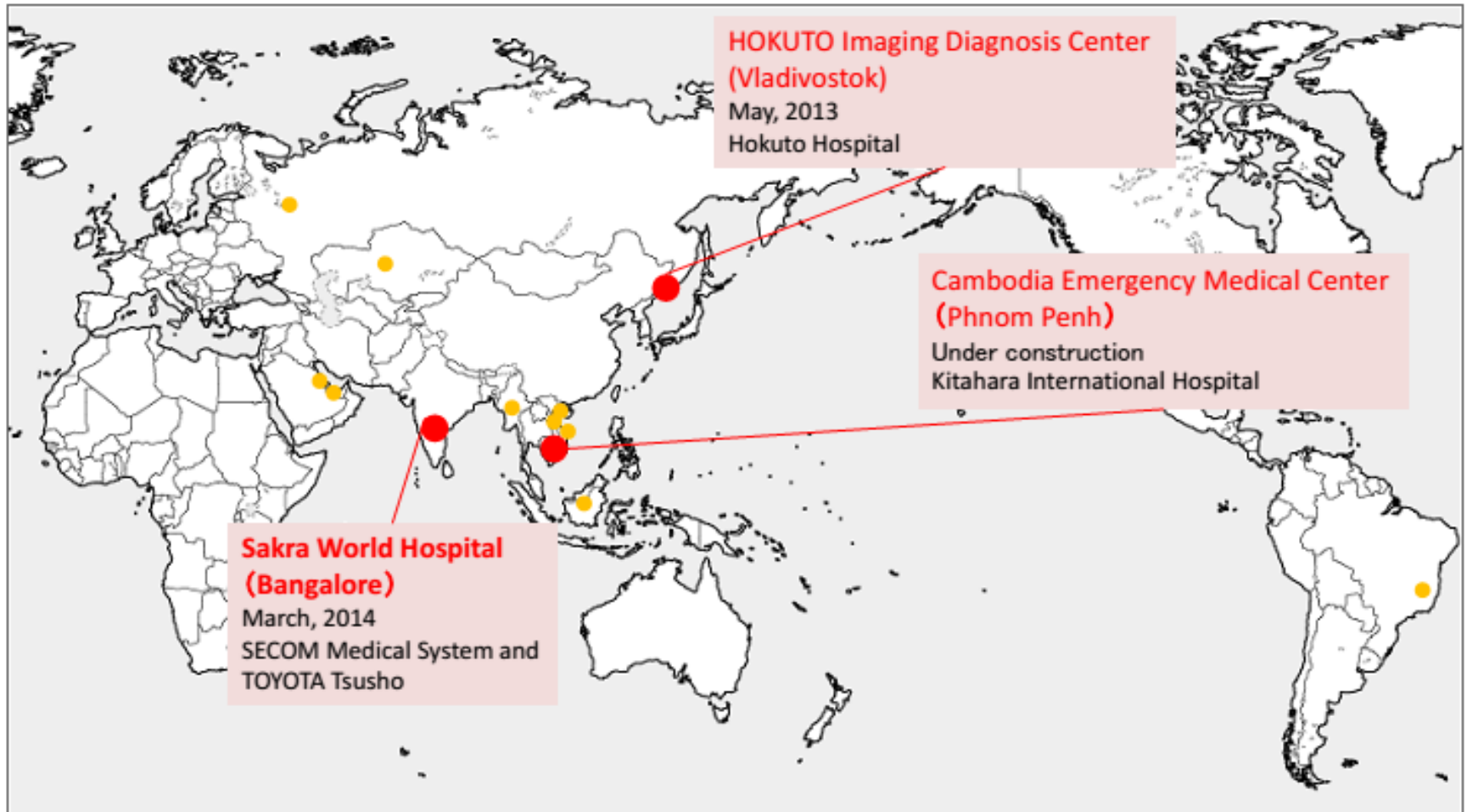
Promote and support medical R&D consecutively from basic research to clinical research/trial by funding

- ◆ Strong management of R&D program by PD, PO and etc.
- ◆ Improvement of the infrastructure for clinical research/trial
- ◆ Support for industrialization; bridging academia and industry
- ◆ Promotion of International strategy

9 Projects supported by 3 Ministries;

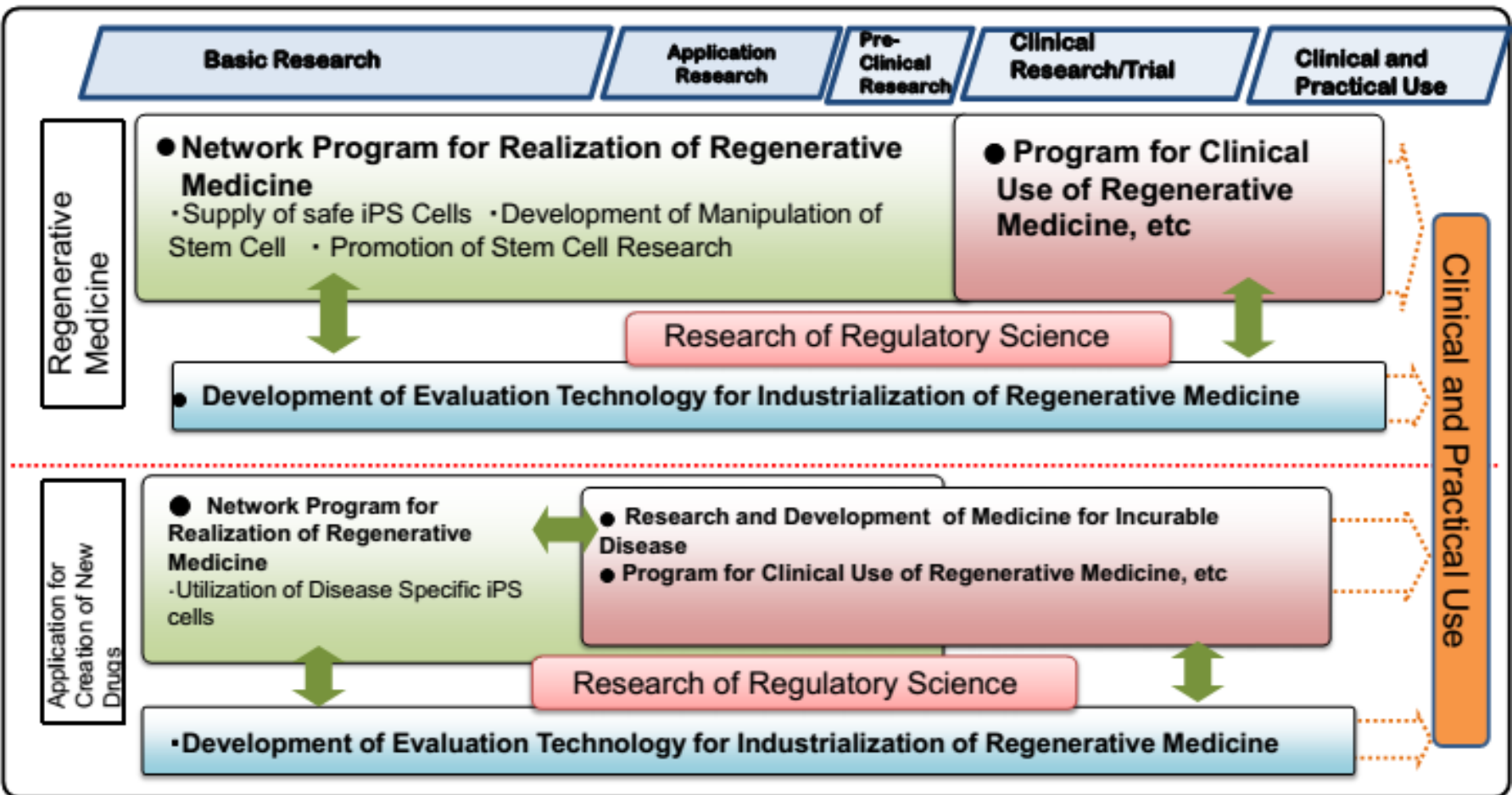
- ① Drug discovery
- ② Medical devices
- ③ Infrastructure of clinical research and trial
- ④ **Regenerative medicine**
- ⑤ Genomic Medicine
- ⑥ Cancer
- ⑦ Psychiatric and Neurological Disorders (Brain research)
- ⑧ Emerging and re-emerging infectious diseases
- ⑨ Intractable diseases

# Current Situation on International Center supported by Government of Japan



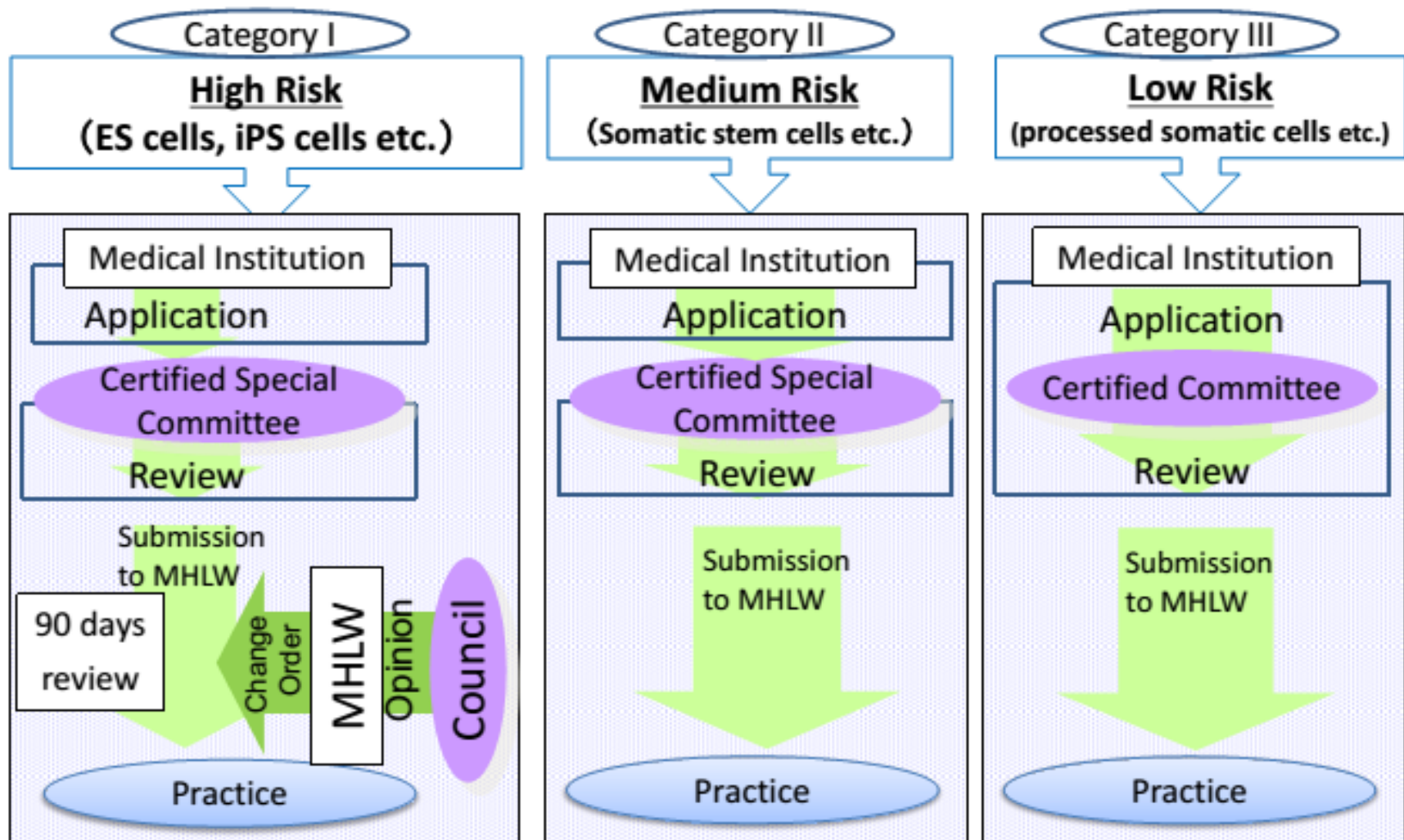
Other cases such as in Kazakhstan, Vietnam, Indonesia, Myanmar, Kuwait, Qatar, Brazil etc. are under consideration.

# Regenerative Medicine Highway Promoted by AMED



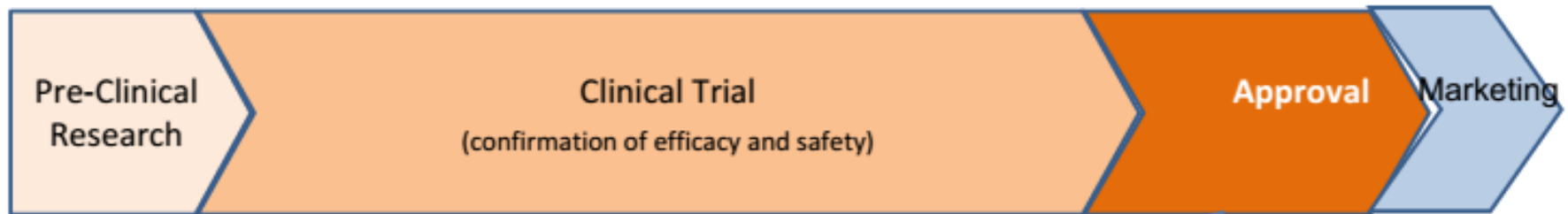
■ :MEXT. ■ :MHLW, ■ :METI

# Risk-based classification of regenerative medicine practice under the Act to Ensure the Safety of Regenerative Medicine

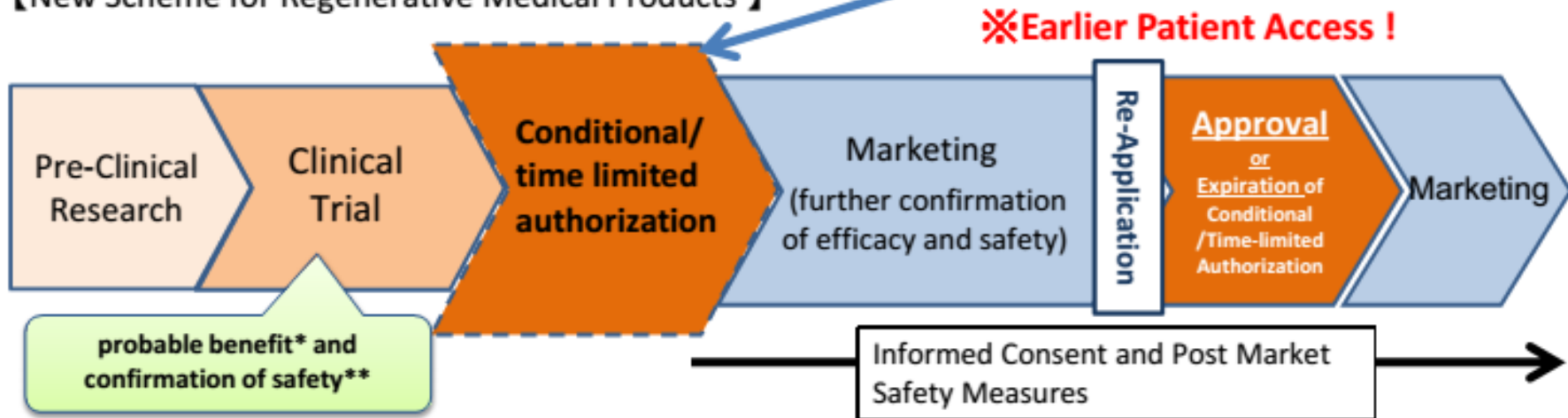


# New Approval System under the Pharmaceuticals and Medical Devices Act (PMD-Act)

## 【Traditional Approval Process】



## 【New Scheme for Regenerative Medical Products】



\* Probable benefit: Confirmation of efficacy with small patient population.

\*\* Safety: Evaluation of acute adverse events etc.



Thank you very much for your attention!