

New Era of Regenerative Medicine With New Legal Framework

March 2016

Bio-Industry Division

***Ministry of Economy, Trade and Industry (METI)
JAPAN***

To make drug, medical devices and regenerative medicine a leading industry

New agency, AMED, manages all of health and medical R&D projects to create a synergy effect among three ministries from this April.

Three main Ministries



Ministry of Education, Culture, Sports, Science and Technology

- Responsible for Education
- Promote basic research



Ministry of Economy, Trade and Industry

- Support company's activity
- Promote industrialization



Ministry of Health, Labor and Welfare

- Equip medical care system
- Grant approval of drug & medical devices

✓ Strategy
✓ Promotion Plan



Established on April, 2015

Japan Agency for Medical Research and Development

- Conduct concentrated R&D

Quick
High Quality
Low-Cost

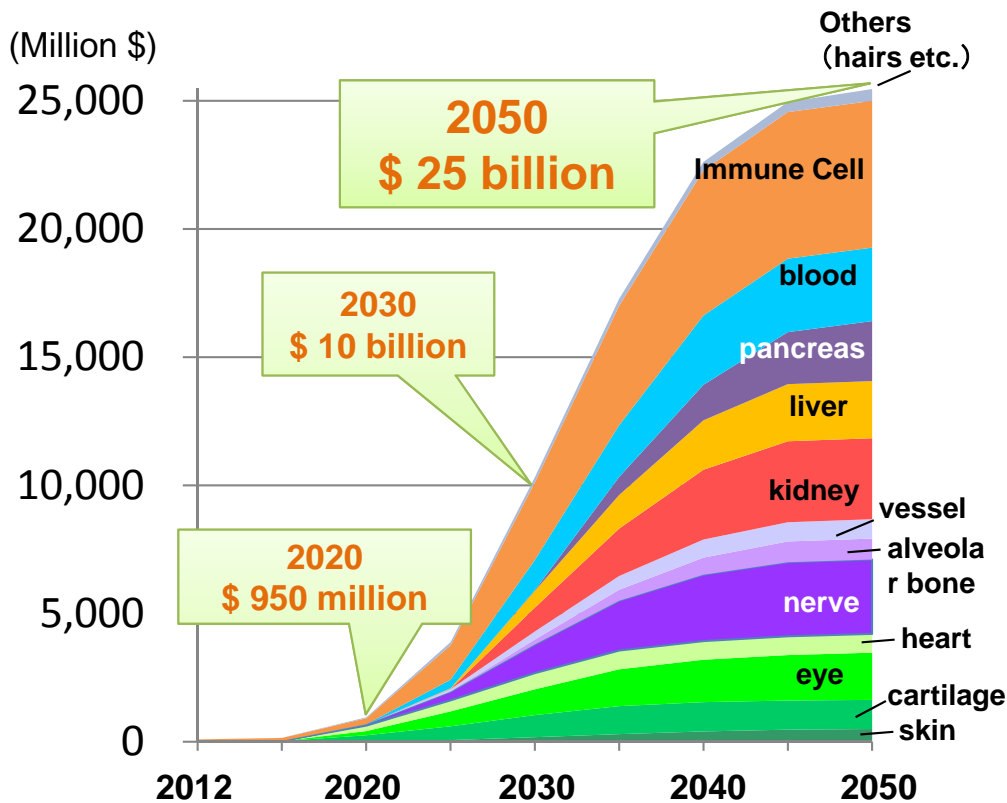


Estimated market size of regenerative medicine

Regenerative medicine market expands rapidly both in Japan and in the world.

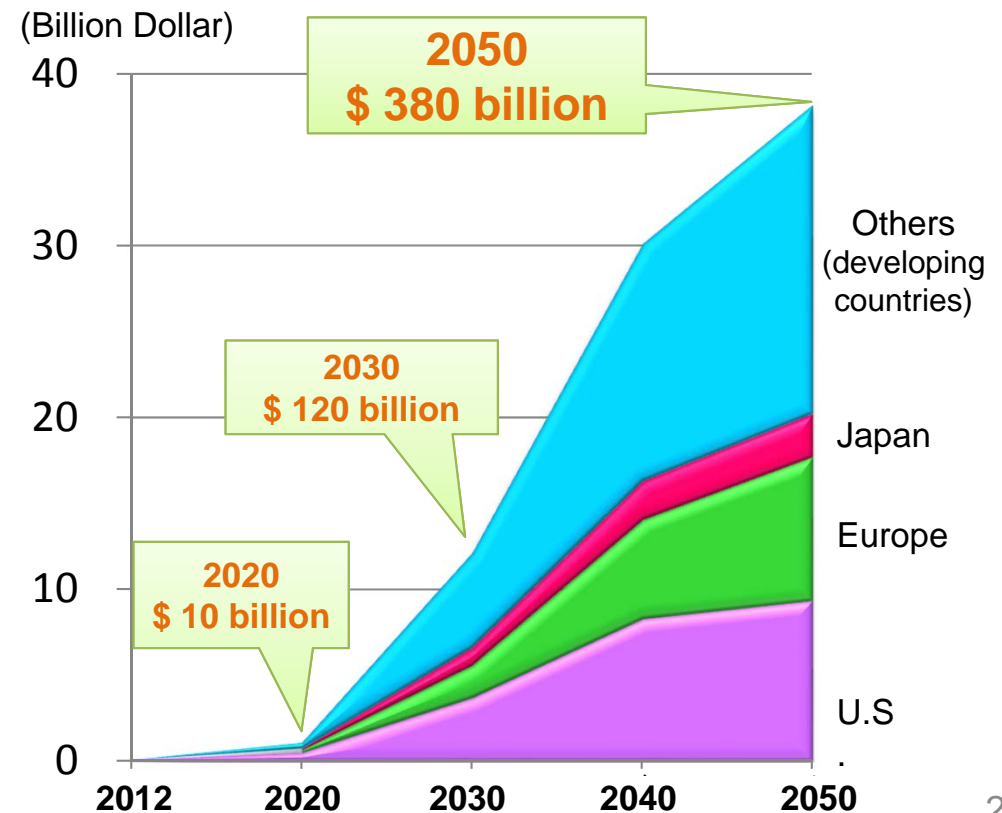
Japan

2012 2020 2030 2050
\$ 90mill. \$ 950mill. \$ 10bn. \$ 25bn.



Global

2012 2020 2030 2050
\$ 1bn. \$ 10bn. \$ 120bn \$ 380bn



Japanese government has revised the legislation to promote practical realization of regenerative medicine.

< for products distributed by companies >

Pharmaceuticals and Medical Devices Act

- ✓ **expedited approval system**

< for therapies under the control of medical institutions >

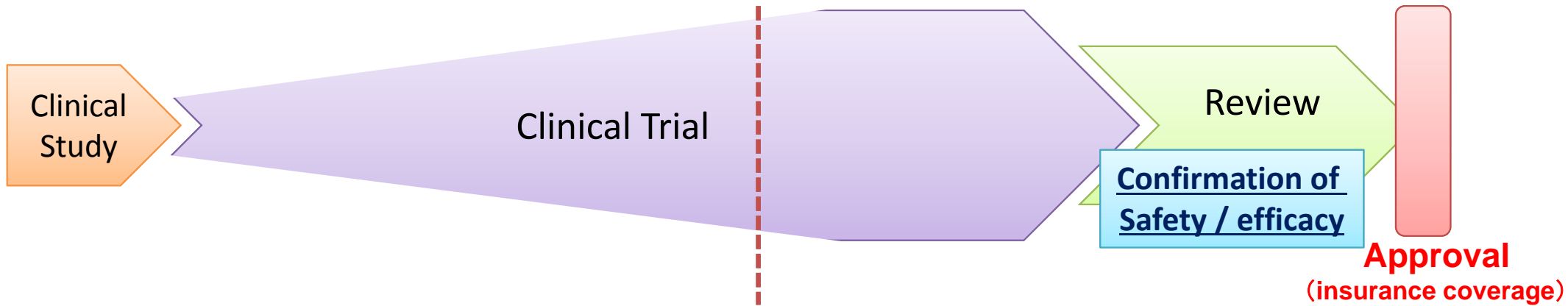
The Act on the Safety of Regenerative Medicine

- ✓ **licensing scheme for cell processing centers outside medical institutes**

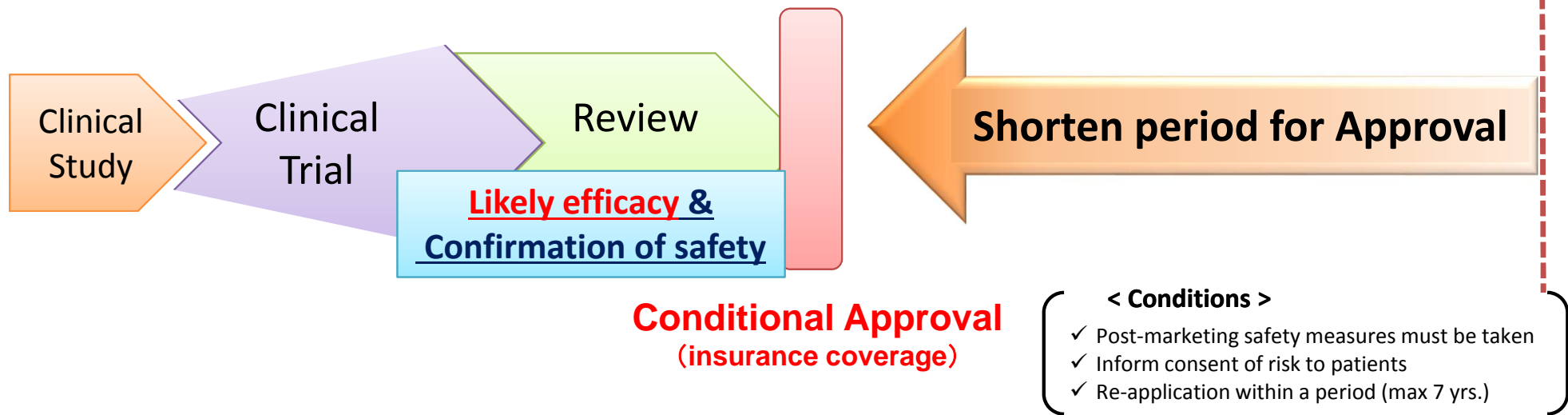
(enforced on November 2014)

New approval system helps companies launch regenerative medicine products quickly.

Former Approval process *without exclusive category for RM products until Nov. 2014*



New scheme *for regenerative medicine products from Nov. 2014*



Best country for application of regenerative medicine

Japan offers superior business environments.

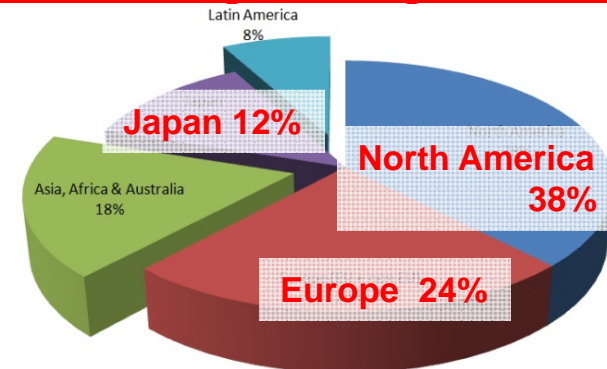
✓ Set National strategic special zones



Osaka Tokyo

Two national strategic special zones

✓ Second largest single market



World pharmaceutical market. IMS Health Market Prognosis, June 2013.

✓ High quality supporting industry



Automatically culturing apparatus

Emerging Bio-medical Technology
MEDI+NET



Cell manufacturing

✓ Top-level basic research

✓ High-quality clinical trials

✓ Fastest-aging nation

and more...

FIRM member companies

The number of FIRM* members is increasing rapidly.

14 (Jun. 2011) → 72 (Nov. 2013) → 109 (Dec. 2014) → 185 (Jan. 2016)

*FIRM: The Forum for Innovative Regenerative Medicine

Chemical & materials

Regenerative medicine & cellular therapy

Bio industry

Pharmaceutical

Transportation

Insurance

Machinery & device

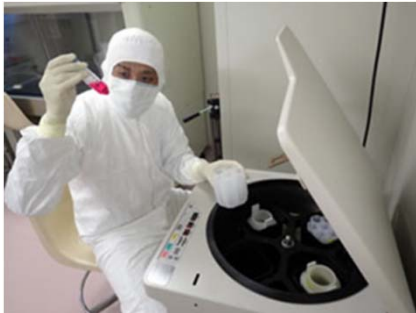
Consulting firm

Outcome(1) : Two new products were approved

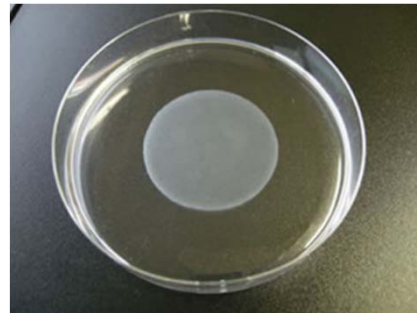
Japan approved two new products less than 1 year after introducing new laws.

Terumo Corporation autologous skeletal myoblast sheets

The sheets are cultured from a patient own muscle of thigh and transplanted to patient's heart under the open chest surgery to improve the patient's heart condition.



<Culturing cells>



<Skeletal myoblast sheet>

Conditional Approval

JCR Pharma. Corporation allogeneic mesenchymal stem cell-based product

It is a treatment of Acute GVHD, a severe complication arising from hematopoietic cell transplant



<The product>

(Regular) Approval

Approved by the Ministry of Health, Labour and Welfare at September 18, 2015

Point 1 : Shortened period until approval

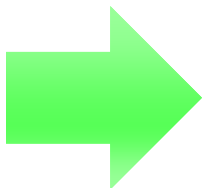
(before) 5 -8 years → (after) 3.5 years

× 1/2

Point 2 : Number of approved products

(before) 2 products → (after) + 2 products less than 1 year

× 2



Outcome(2) : Collaboration between Japan and others

Some foreign companies have already started collaboration businesses with Japanese companies.

Cell Manufacturing



- Produces functioning human cells, including iPS cells on an industrial scale
- Combining the technologies and knowhow to seek synergies and efficiency



- Cell and gene therapy contract manufacturing
- Established new facility in the Tokyo and Yokohama area

Clinical Trial



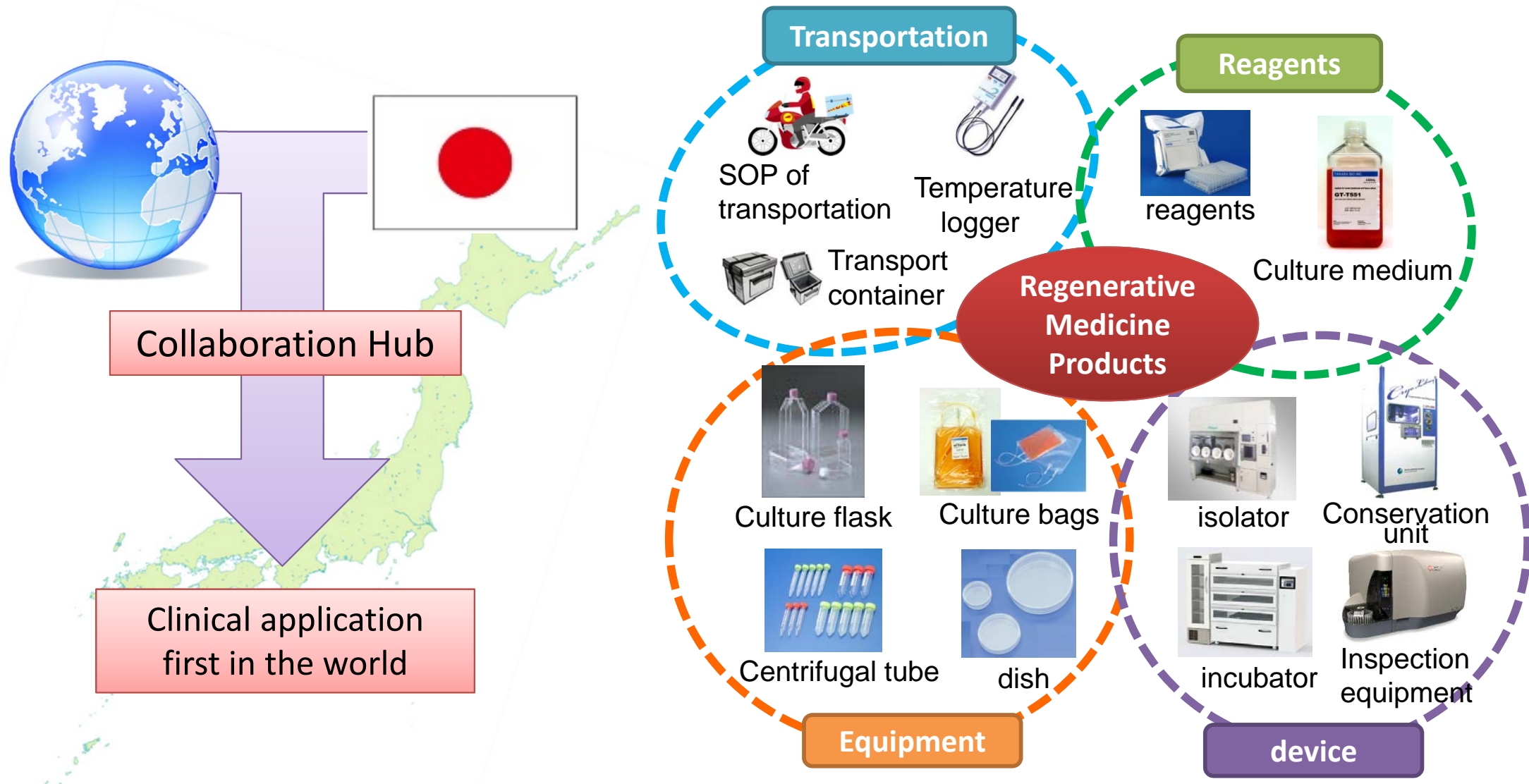
- Exclusive geographic license to use RepliCel's RCH-01 hair regeneration technology in Japan and Asian countries.
- Established new facility in Kobe



- Exclusively develops and commercializes MultiStem® cell therapy for ischemic stroke in Japan

Setting Common Standards for Regenerative Medicine INVEST JAPAN

Japan aims to be the world collaboration hub for regenerative medicine industry.



Subsidy Program for Global Innovation Centers

Subsidy Program for Global Innovation Centers Budget Amount: **1.0 billion JPY** (FY2015 Supplementary Budget)

➤ Target industries: Regenerative medicine and IoT (Internet of Things) (which are industries with high future growth potential)

➤ Target projects: Projects by foreign companies which collaborate with Japanese companies or other organizations

✓ Establishment of global innovation centers
(Costs for equipment and facility purchase, rent, construction, etc.)

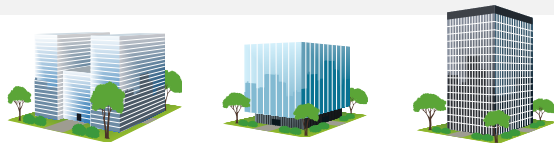
▶ **subsidy rate:1/3**

✓ Experimental studies
(Costs for researchers' employment, outsourcing, equipment, business trip, etc.)

▶ **subsidy rate:2/3**

✓ Feasibility studies (F/S)
(Costs for researchers' employment, outsourcing, business trip, etc.)

▶ **subsidy rate: 1/1**
(up to 10 million JPY)



Support

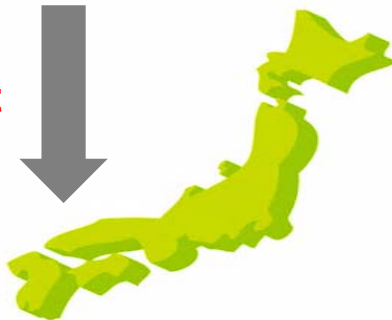
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✓ Target : Foreign companies who possess advanced technology/resources
(Corporate status in Japan is not necessary at the time of application)

✓ Target industries : Regenerative medicine/ IoT

✓ Target projects: Establishment of innovation centers, experimental studies, feasibility studies (F/S) with Japanese companies or other organizations

Investment



Expected Effects

✓ Making Japan a "high-value added hub" and "innovation base" for global value chains

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English HP: https://www.jetro.go.jp/en/invest/incentive_programs/info.html 10

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