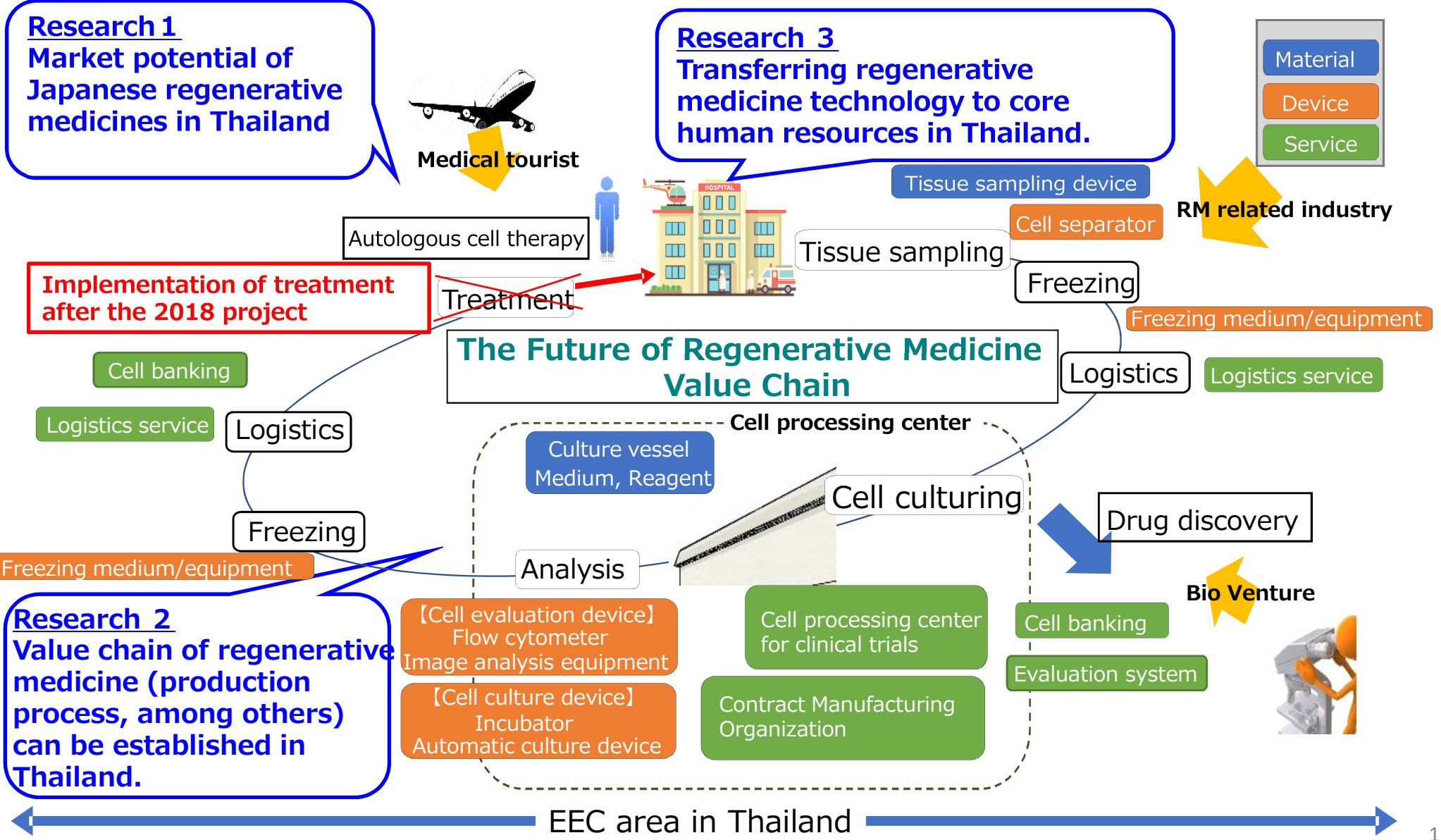


***Feasibility study of Regenerative Medicine  
Business in Thailand***

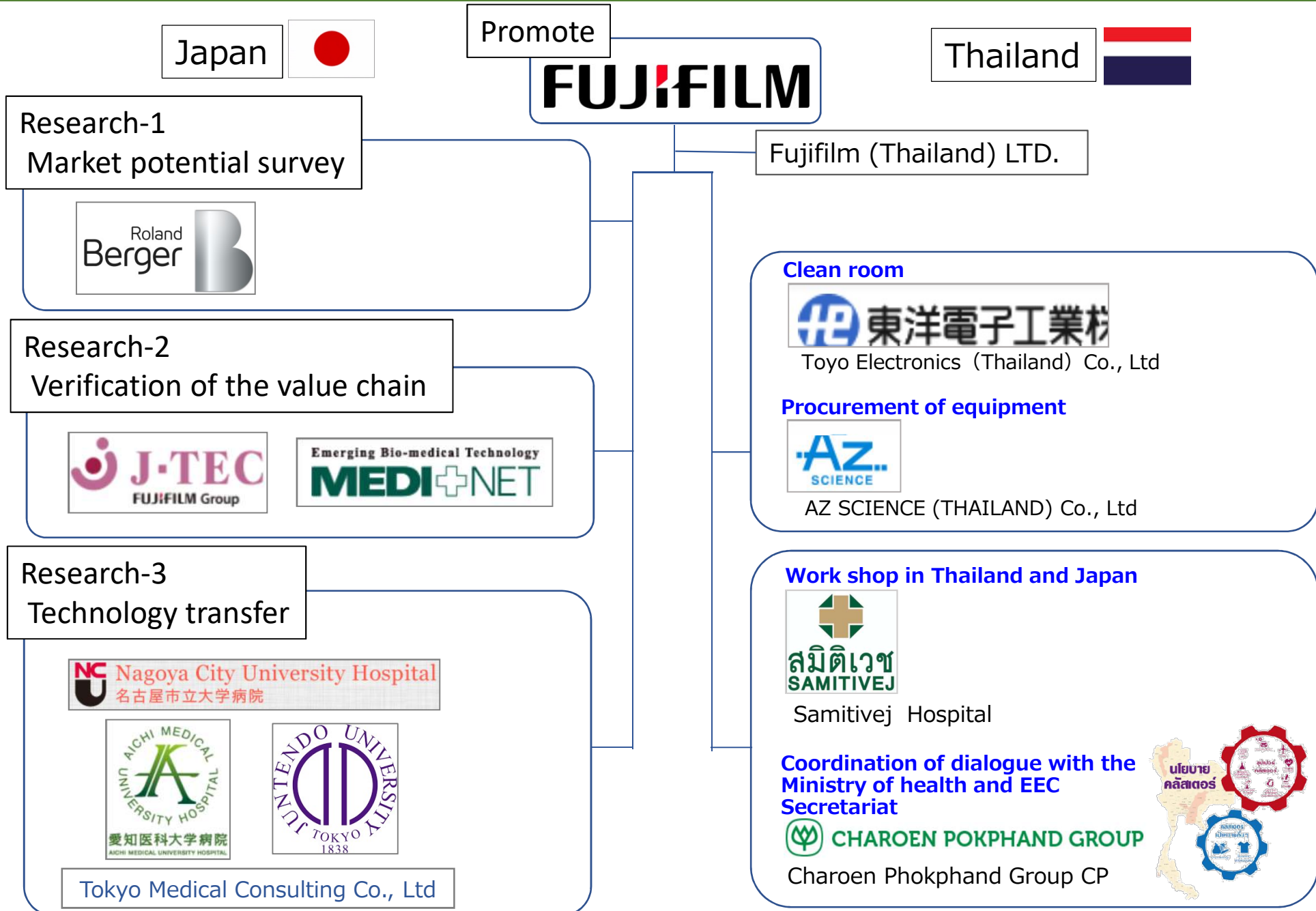
FUJIFILM Corporation  
Regenerative Medicine  
Business Division  
Dec 18<sup>th</sup>, 2018

# 1. Research conducted by FUJIFILM in Thailand in 2018

FUJIFILM examines the following three items to verify whether the Regenerative Medicine industry scheme implemented in Japan can be realized in Thailand.






## 2. Structure of the project



### 3. Research-1 Market potential survey

As a result of the market potential survey, we could confirm that there is enough marketability of regenerative medicines in Thailand.

		Situation in Japan	# of patient treated	CAGR	Potential # of pt. <sup>1)</sup>	Unmet needs
Joint Disease	Traumatic Cartilage Defect	Approved for regenerative medicine Reimbursement by health insurance	48,014	 10.0%	450 (7.0%)	> No treatment available to treat large-sized cartilage defect (> 4cm <sup>2</sup> )
	Osteochondritis Dissecans		12,005			
Skin Disease	Giant Congenital Nevus		3,500	 0.3%	100 (3.0%)	> Limited unmet needs as many standard options are already available  > Low taking rate and mismatch/cobblestoned surface for current surgery
	Cancer Immune Cell Therapy	Medical treatment at patient's own expense	436,936	 4.0%	700 (0.1%)	> NK-cell therapy is available, but there is no clear evidence of its outcome > High unmet needs of cancer treatment

1) Potential number of patients may change drastically, depending on the price setting; (xx%) stands for potential number of patients / # of patient treated

## 4. Research-2 Verification of the value chain

We rented a space and established a cell culturing test laboratory in a factory with high cleanliness levels, in Amata City Chonburi Industrial Estate.

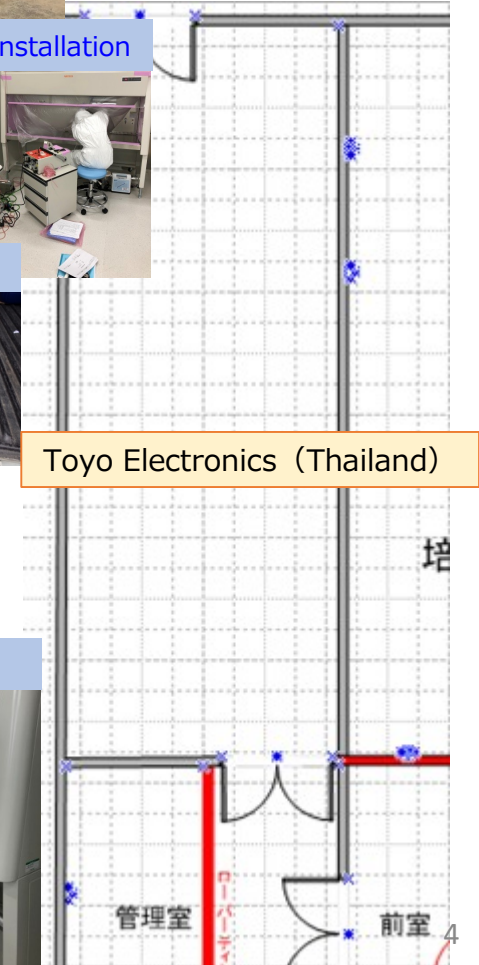
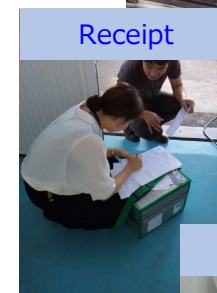
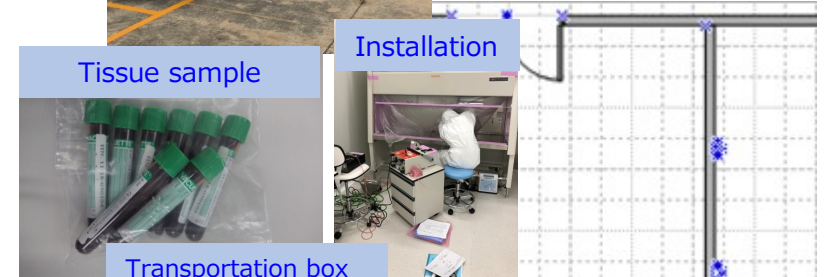
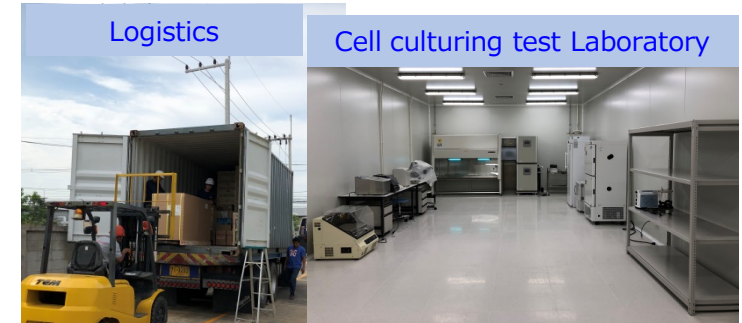
We confirm that overseas researchers can conduct research on cell culturing if necessary procedures are followed, such as taking approval from the Ethics Committee and National Research Council of Thailand (NRCT).

As a result of test culturing, the same performance and quality as in Japan could be confirmed.

→ We may have a good prospect to establish the value chain of regenerative medicine in Thailand.

### ◆ Schedule

Feb	Decide the location, equipment, and layout
Mar	Order the equipment and material
Apr	Install the equipment
May	Validation → Completed lab set up
June } Oct	Ethics committee & NRCT approval
Oct } Dec	Cultivate the cancer immune cell product and the autologous cultured cartilage → Check the performance and quality



## 5. Research-3 Technology transfer

We held workshops in Thailand and Japan in cooperation with the Samitivej Hospital.  
We could confirm that there is enough possibility to transfer the regenerative medicine technology from Japan to Thailand.

### □ in Thailand (1<sup>st</sup> step)

- Organized a workshop for sharing the current situation of RM treatment and regulations in Japan

- Requested a Japanese doctor to serve as a lecturer for this project.

June 26 Autologous Cultured Cartilage

Masataka Deie, M.D., Ph.D., Vice president of Aichi Medical University Hospital

July 17 Autologous Cultured Epidermis

Kazuhiro Toriyama, M.D., Ph.D., Professor of plastic and reconstructive surgery, Nagoya City Graduate School of Medicine

August 31 Periodontal Tissue Regeneration

Morikuni Tobita, D.D.S., Ph.D. Associate Professor, Juntendo University



### □ in Japan (2<sup>nd</sup> step)

- Held a meeting in the hospital and facility of the RM company (J-TEC) to observe the RM treatment.

- Invited doctors from Thailand for each product.

October 23 Autologous Cultured Epidermis surgery tour

Kazuhiro Toriyama, M.D., Ph.D. Professor of plastic and reconstructive surgery, Nagoya City Graduate School of Medicine

November 20 Autologous Cultured Cartilage surgery tour

Masataka Deie, M.D., Ph.D. Vice president of Aichi Medical University Hospital





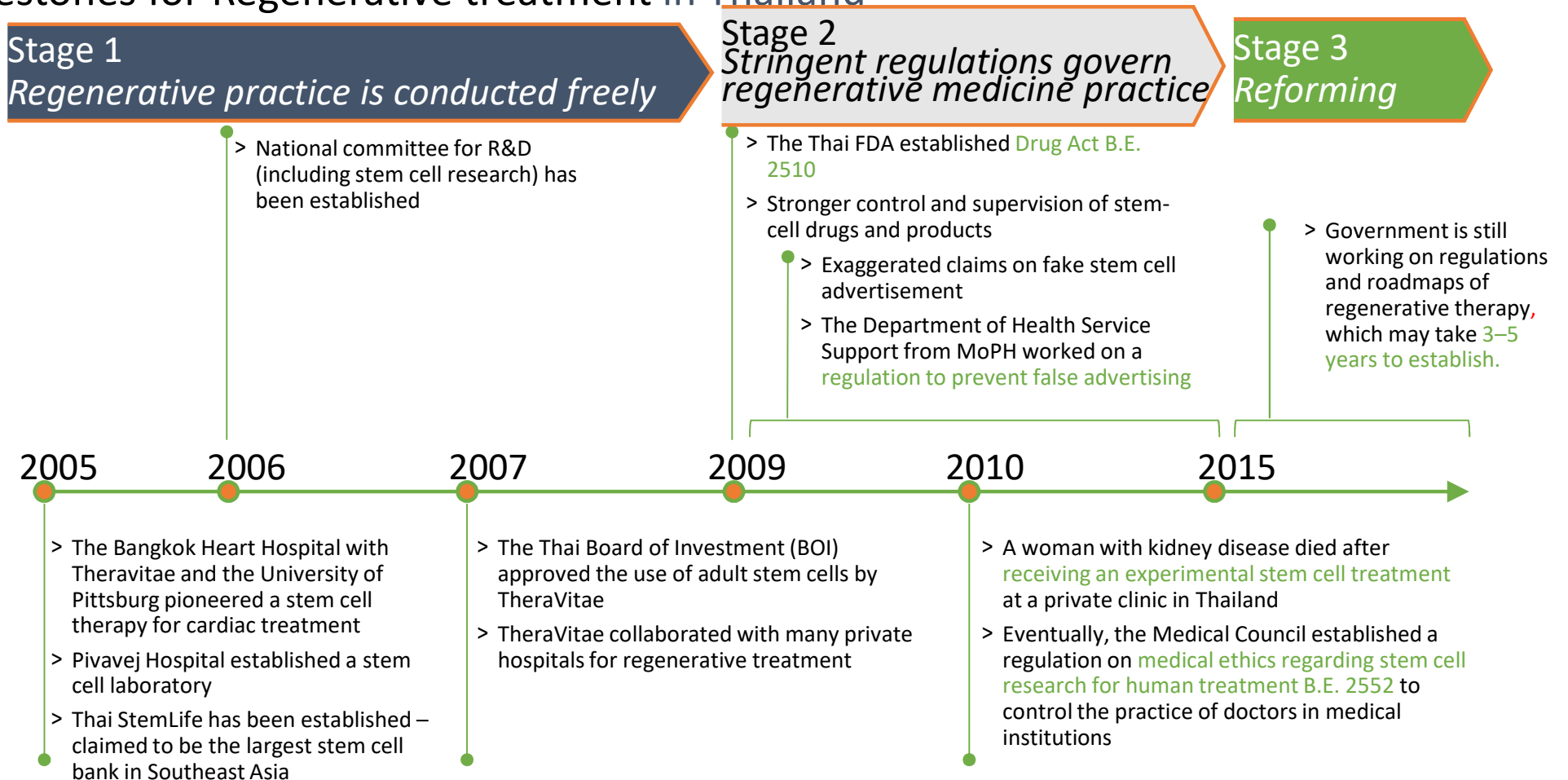
## 6. Regulations on Regenerative Medicine in Thailand

Since 2009, restrictions on the regenerative medicine practice in Thailand have increased. The government is working on the regulations and roadmap.

As per the latest information, Thai FDA provides the notification of “Advanced Therapy Medical Products”.

→We would recommend the Thai government to translate regulatory content into English.

### Milestones for Regenerative treatment in Thailand



## 7. Summary of the results and future prospects

### ◆ Results

Research	Result
Market potential in Thailand	Enough marketability of regenerative medicines in Thailand
Value chain of regenerative medicine	Good prospect to establish the value chain of regenerative medicine in Thailand.
Transfer of regenerative medicine technology	Enough possibility to transfer the regenerative medicine technology from Japan to Thailand.
Regulations	Further investigation required.

### ◆ Future prospects

- Through this project, we confirmed that Thailand is a very promising market for regenerative medicine.
- Meanwhile, it is necessary to conduct further investigations about regulations. Particularly, no regenerative medicine in Thailand has obtained an approval, under the current regulations. A high regulatory hurdle may hinder the commercialization of regenerative medicines.
- We would like to judge whether commercialization of Japanese Regenerative Medicine product is possible or not after verifying the above regulation.

**Please feel free to get in touch : [shusaku.matsuda@fujifilm.com](mailto:shusaku.matsuda@fujifilm.com)**