

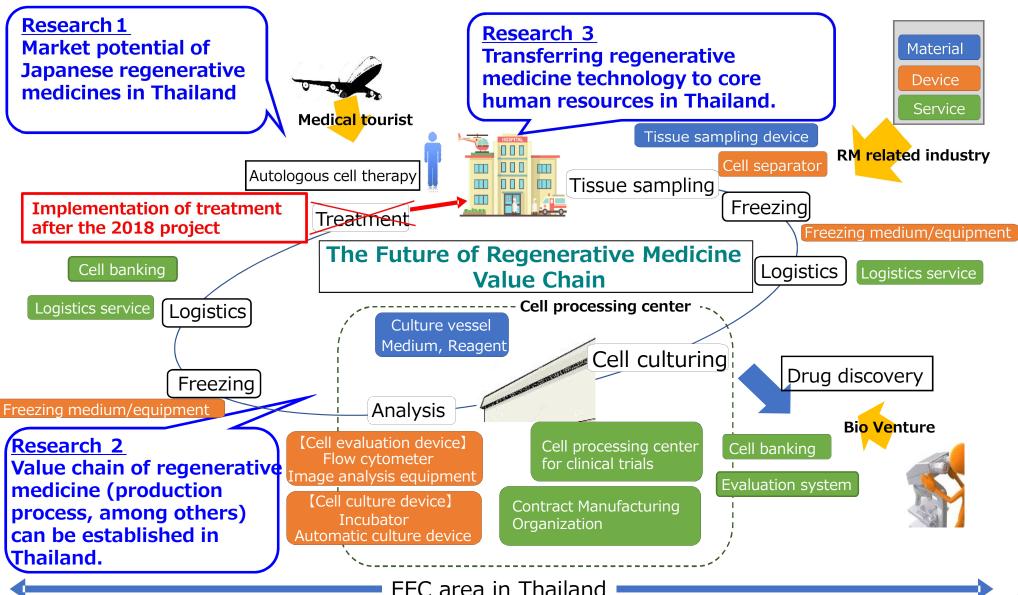
Feasibility study of Regenerative Medicine Business in Thailand

FUJIFILM Corporation
Regenerative Medicine
Business Division
Dec 18th, 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



Promote Japan Research-1 Market potential survey Roland Berger Research-2 Verification of the value chain Emerging Bio-medical Technology **FUJIFILM Group** Research-3 Technology transfer Nagoya City University Hospital 名古屋市立大学病院

FUJIFILM

Thailand

Fujifilm (Thailand) LTD.

Clean room



Toyo Electronics (Thailand) Co., Ltd

Procurement of equipment



AZ SCIENCE (THAILAND) Co., Ltd

Work shop in Thailand and Japan



Samitivej Hospital

Coordination of dialogue with the Ministry of health and EEC Secretariat



Charoen Phokphand Group CP

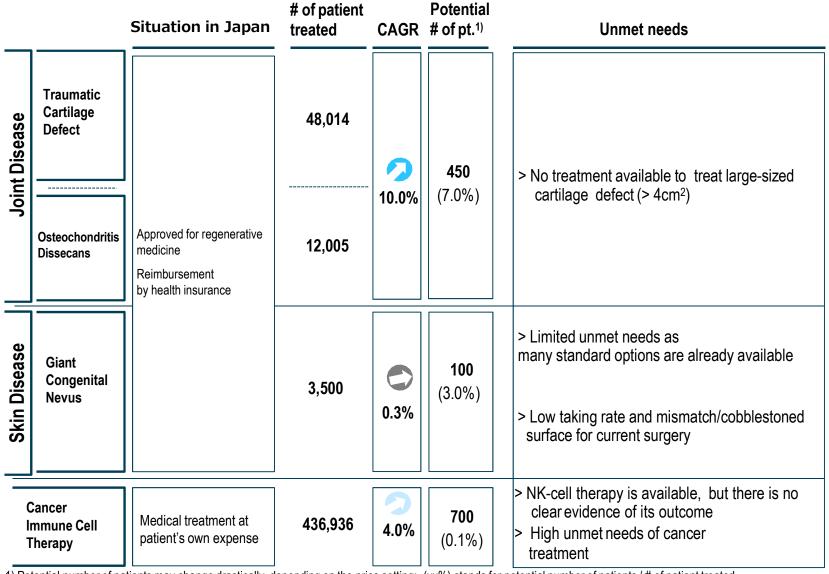


Tokyo Medical Consulting Co., Ltd

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.



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.

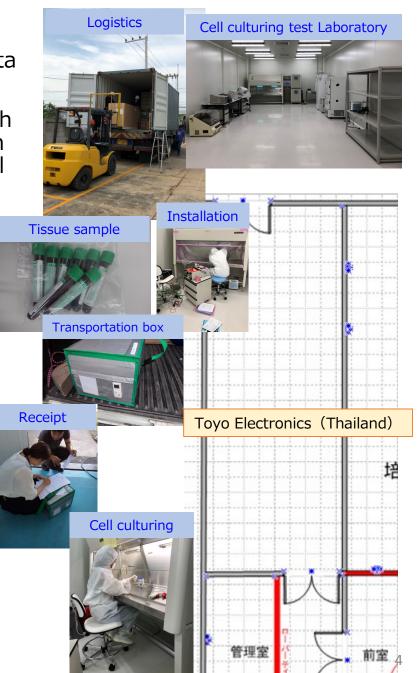
We confirm that overseas researchers can conduct research on cell culturing if necessary procedures are followed, such as taking approval from the Ethics Committee and National Research Council of Thailand (NRCT).

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 \rightarrow Completed lab set up
June \$ Oct	Ethics committee & NRCT approval
Oct	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.

\Box in Thailand (1st 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.
 - Autologous Cultured Cartilage

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

Autologous Cultured Epidermis July 17

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

\Box in Japan (2nd 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 Stage 2 Stringent regulations govern regenerative medicine practice Stage 1 Stage 3 Regenerative practice is conducted freely Reforming > The Thai FDA established Drug Act B.E. > National committee for R&D 2510 (including stem cell research) has been established > Stronger control and supervision of stemcell drugs and products > Government is still working on regulations > Exaggerated claims on fake stem cell and roadmaps of advertisement regenerative therapy. > The Department of Health Service which may take 3–5 Support from MoPH worked on a vears to establish. regulation to prevent false advertising 2006 2009 2015 2005 2007 2010 > The Bangkok Heart Hospital with > The Thai Board of Investment (BOI) > A woman with kidney disease died after Theravitae and the University of approved the use of adult stem cells by receiving an experimental stem cell treatment Pittsburg pioneered a stem cell TheraVitae at a private clinic in Thailand therapy for cardiac treatment > TheraVitae collaborated with many private > Eventually, the Medical Council established a regulation on medical ethics regarding stem cell > Pivavej Hospital established a stem hospitals for regenerative treatment cell laboratory research for human treatment B.E. 2552 to control the practice of doctors in medical > Thai StemLife has been established institutions claimed to be the largest stem cell

bank in Southeast Asia
Source: Desktop research, Roland Berger

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.

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