

CellSeed Inc.

Fiscal 2024 First-Half Earnings

Results Presentation



- Company Profile

- Financial Summary Second Quarter of Fiscal

Year Ending December 31, 2024

- Progress of each business

Established May, 2001  
Core competence Cell Sheet Engineering based on Temperature Responsive Polymers  
Listed Tokyo Stock Exchange Growth (7776)

### Head Office

15F (East Wing) Telecom Center Building  
2-5-10, Aomi, Koto-ku, Tokyo

### Cell Processing Center

Telecom Center Building 6F  
Total Floor Area 763 m<sup>2</sup>  
**(Facility Number:FA3160008)**

### Aomi Cell Cultureware Innovation Center

Time 24 Building, 4-32,  
Aomi 2-chome, Koto-ku, Tokyo

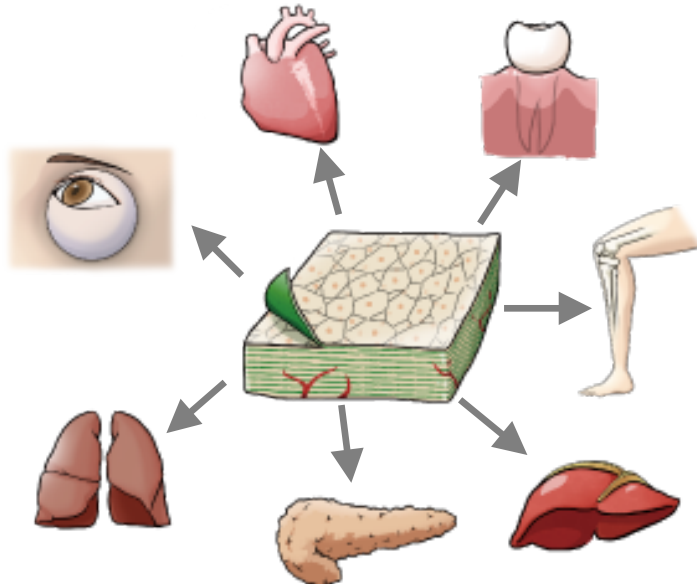


## Mission

We take the initiative of contributing to global health care in the valuable and innovative field of regenerative medicine.

### Regenerative Medical Products Business

- Commercialization of Cell Sheet Therapies



### Regenerative Medicine Supporting Business

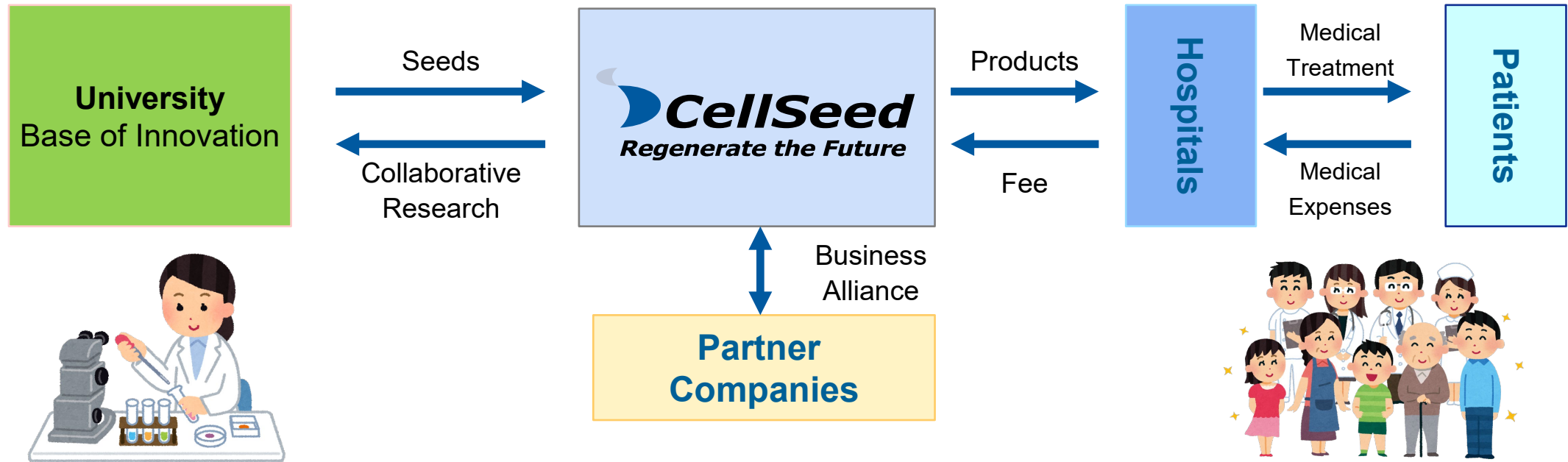
- Intelligent Culture Ware as Research Tools



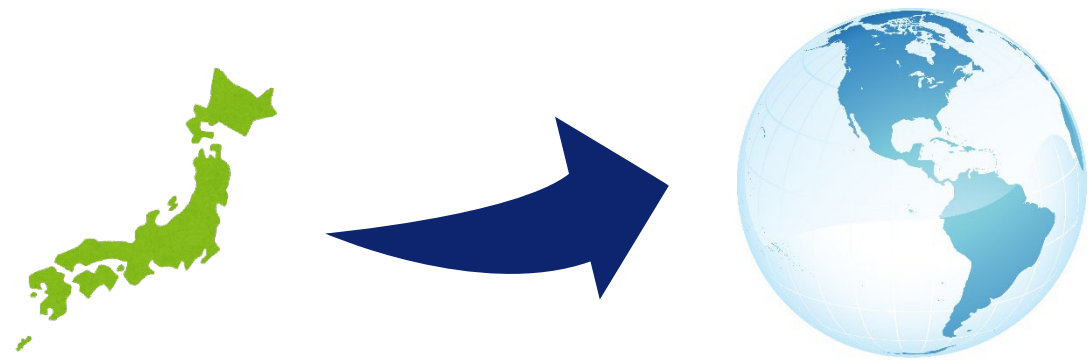
- Contract Manufacturing Services • Consulting



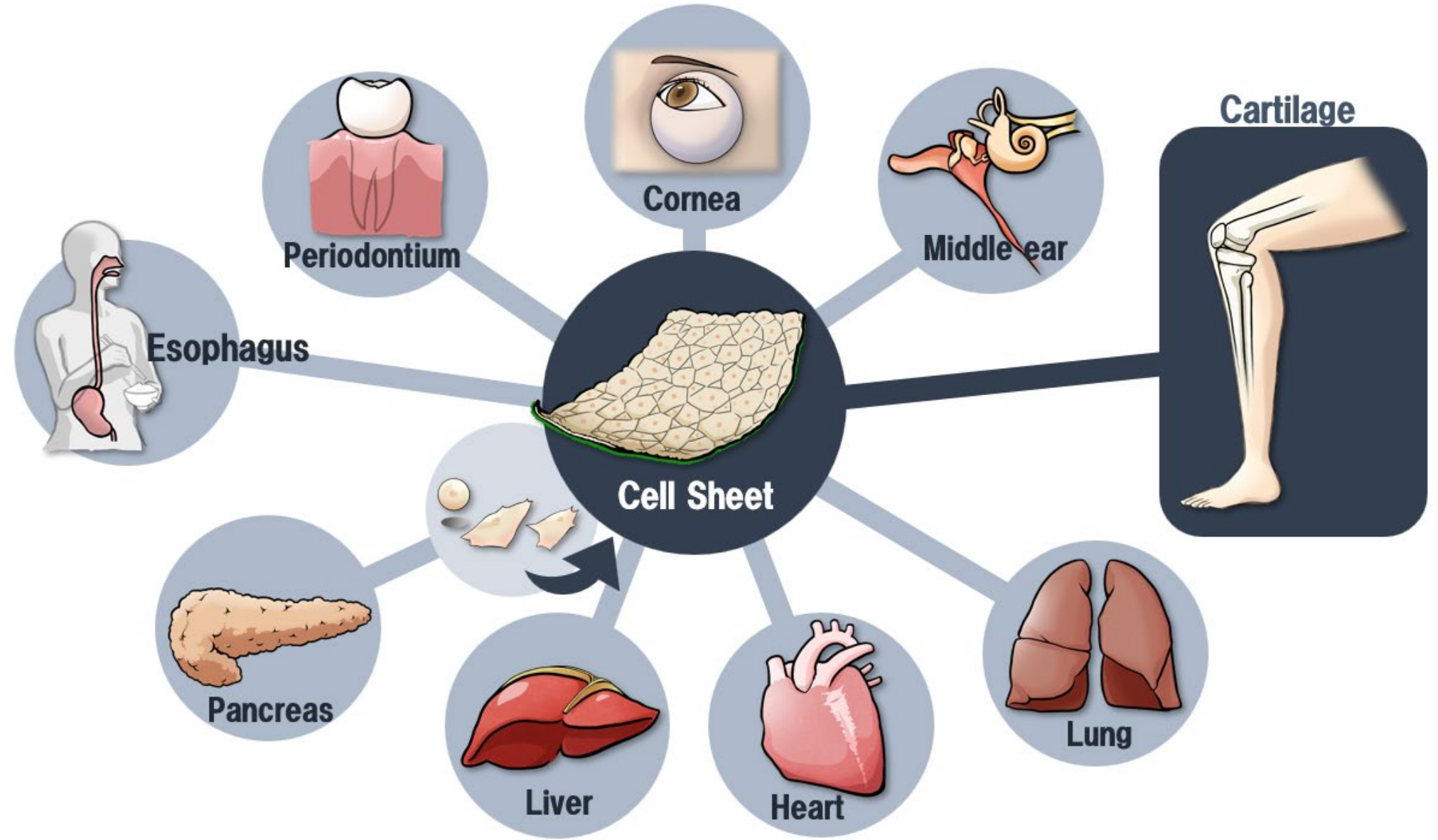
# Our Business Model



Delivering the technology developed at a university and developed at a venture to patients as soon as possible.



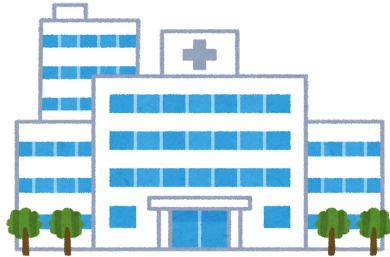




# New law related to regenerative medicine, enforced in 2014

## Act on the Safety of Regenerative Medicine

Law for regulating regenerative medicine, etc. performed **on the responsibility of a medical doctor**



Classified into Classes 1 to 3, according to risk.  
Medical institutions submit plans for regenerative medicine.  
Evaluation by the certified committee for regenerative medicine, etc.

Medical treatment not covered by health insurance

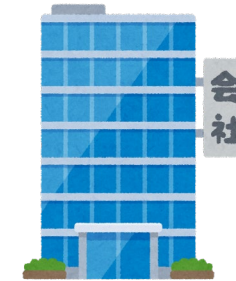
Clinical research

Advanced medical care

Over 5,000 plans for regenerative medicine

Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

Law for regulating products for regenerative medicine, etc. manufactured and sold by **enterprises**



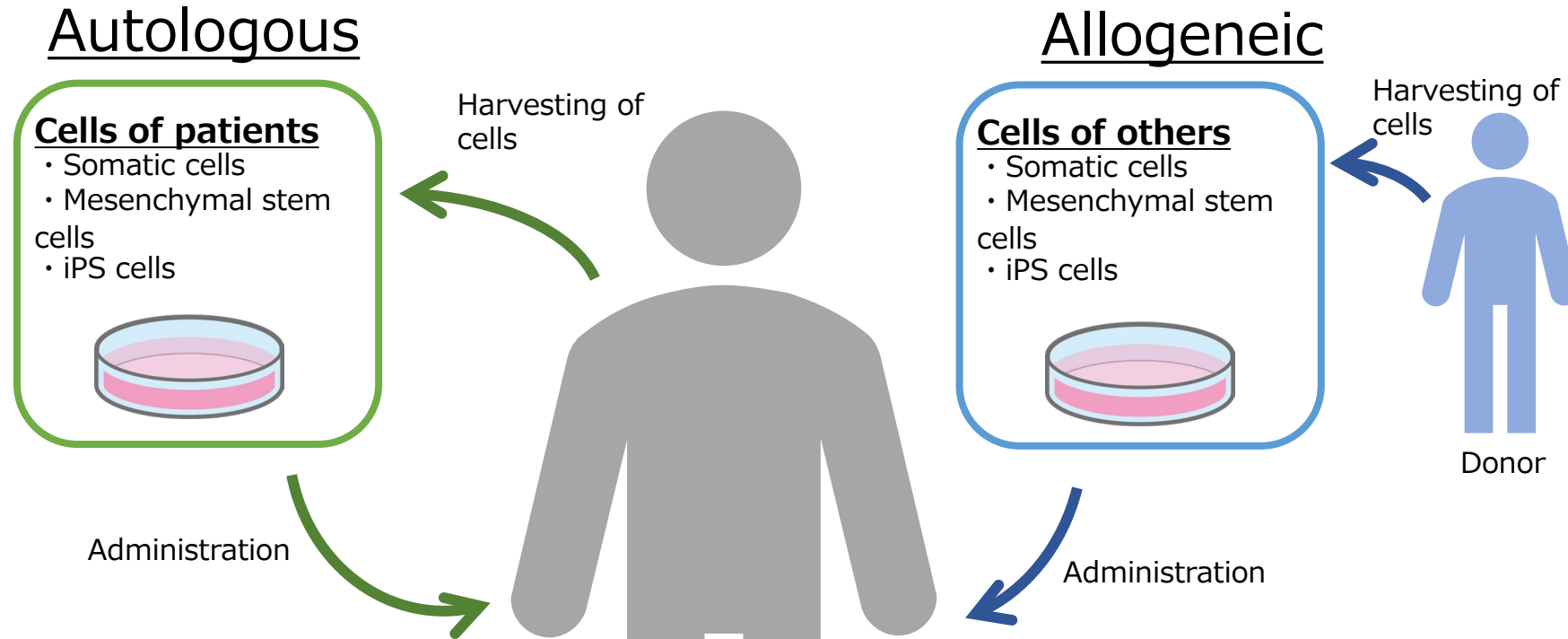
Clinical trials conducted by enterprises  
Clinical trials led by medical doctors



Approved as products  
Covered by health insurance

Twenty products have been approved so far.

# Sources of cells used for regenerative medicine



## Merits

- Free from rejection response

## Demerits

- Only after a treatment is determined, cells are harvested and cultured. Accordingly, it takes time to start administration.

## Merits

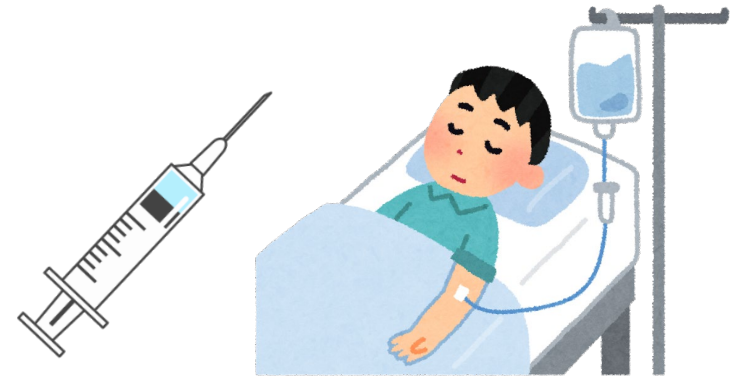
- It is unnecessary to harvest cells from patients.
- It is possible to stock cells and store cultured cells.

## Demerits

- Rejection response may occur.



- To directly administer or implant a product to a target area for regeneration by surgery or with an endoscope
- To administer a product to the entire body via blood vessels by injection or intravenous drip



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# Half-year financial summary FY 12/2024

	First Half of the FY2024 (January 2024 - June 2024)			First Half of the FY2023 (January 2023 - June 2023)
	Amount (Millions of yen)	Change from Previous Period (Millions of yen)	Change from Previous Period (%)	Amount (Millions of yen)
<b>Sales</b>	76	9	13.9	66
<b>Operating profit</b>	△464	△104	—	△359
<b>Ordinary profit</b>	△463	△96	—	△366
<b>Net profit</b>	△474	△110	—	△363

## Full-year earnings forecast for the term ending December 2024

	Sales	Operating profit	Ordinary profit	Net profit
<b>Full year</b>	170	△920	△920	△940

# Topics (cumulative 2<sup>nd</sup> quarter of FY 12/2024)

- The sales of cultureware increased from the previous year, because we received a healthy number of orders from an overseas agency (Thermo Fisher).
- In the commissioned regenerative medicine business, we recorded sales from one case like in the previous year in the first half of FY 2024. From the second half, we are expected to record sales from multiple cases.
- For allogeneic cartilage cell sheets, we signed contracts with facilities for clinical trials, and these facilities are currently developing systems to perform surgeries.
- We are negotiating for concluding contracts for business alliance and collaborative development with multiple companies.
- We are dealing with the lawsuit filed by MetaTech in a calm manner.

# Completion of exercise of the 24<sup>th</sup> share acquisition right distributed through the allocation to third parties

The exercise of the 24<sup>th</sup> share acquisition right was completed, and then **we procured a total of about 1.95 billion yen.**

	Issuance of the 24 <sup>th</sup> share acquisition right with a provision for revising the strike price
<b>Date of issuance</b>	June 5, 2023
<b>Number of share acquisition rights</b>	69,000
<b>Number of dilutive shares (maximum dilution rate)</b>	6,900,000 (24.95% with respect to the number of outstanding shares as of March 31, 2023)
<b>Exercise period</b>	June 6, 2023 to June 12, 2025
<b>Issuance method</b>	Third-party allocation to Barclays Bank
<b>Revision of the strike price</b>	Revised to the amount equivalent to 96% of the closing price on the trading date preceding the date of notification of a request for exercise
<b>Date of completion of exercise</b>	July 1, 2024
<b>Purposes of use of funds</b>	① R&D ② Business operation



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## UpCell®

This cultureware maintains the physiological activity of cells and retains a high level of antigen proteins on the cell surface while serving as a cell culture dish for the recovery of the cell sheet.



## RepCell®

In addition to the same characteristics as those of UpCell®, this cultureware allows for the recovery of cells in a single cell or small colonies using the surface grid wall.



## HydroCell®

Using proprietary technology, nano-surface design, super-hydrophilic polymers are fixed to the surface of this cultureware, which forms spheroids of iPS cells and cancer cells.

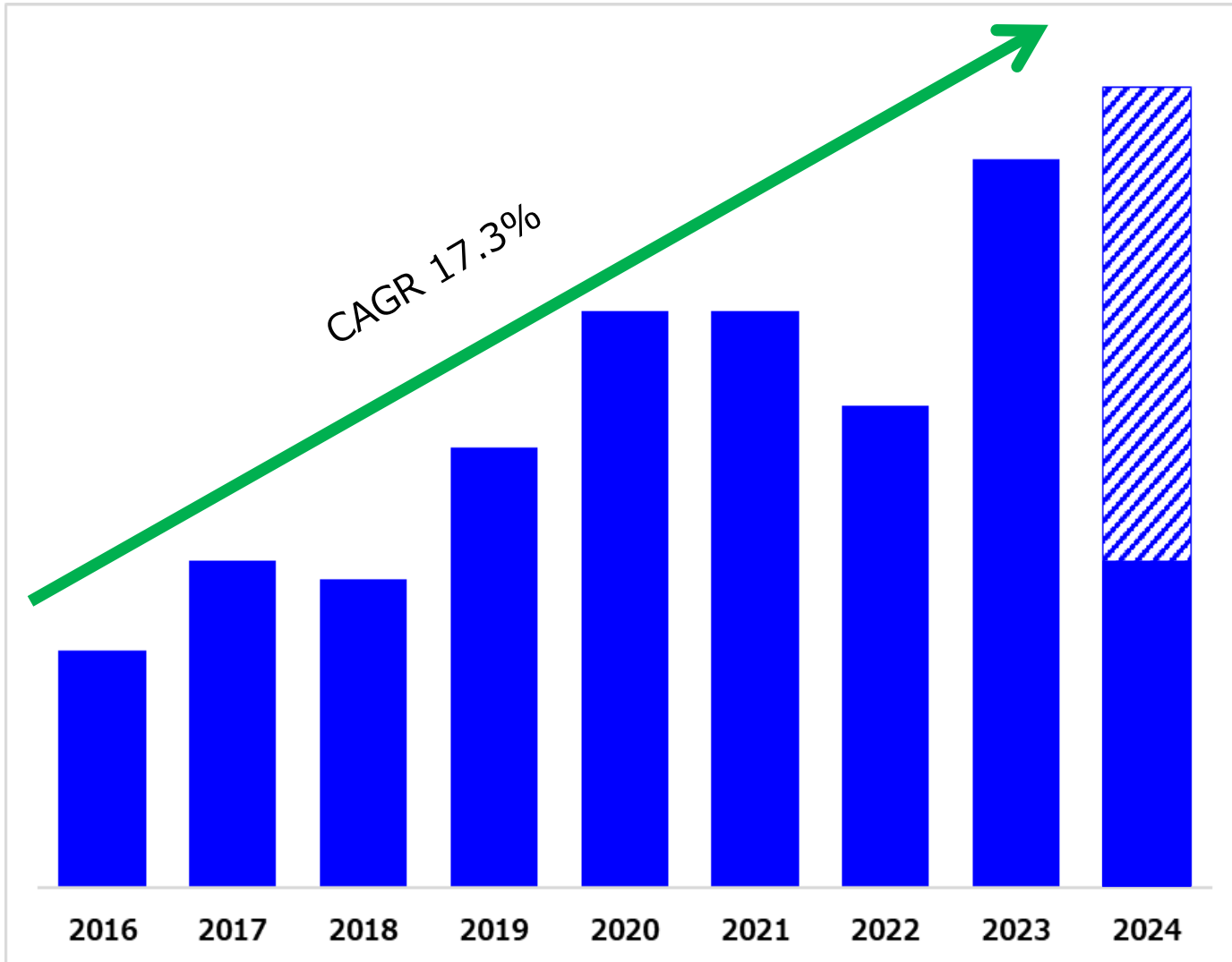


## cellZscope

This is a type of cultureware that is most suitable for research into the effect of drugs and poisons for the evaluation of cell layer barrier functions.



# Variation in sales of the cell cultureware business



- Sales grew threefold in the past 7 years.
- In 2023, **overseas sales increased significantly.**
- In FY 12/2023, **sales hit a record high.**

**In the first half of FY 12/2024**  
**We received a healthy number of orders from an overseas agency (Thermo Fisher).**



**Sales increased from the previous year.**

## Regenerative medicine outside Japan: Trends of fundamental research, clinical study, and therapy

There are an increasing number of treatments for cancer, allergy, and immunity disorder and treatments using stem cells.

## Major purposes of overseas UpCell users:

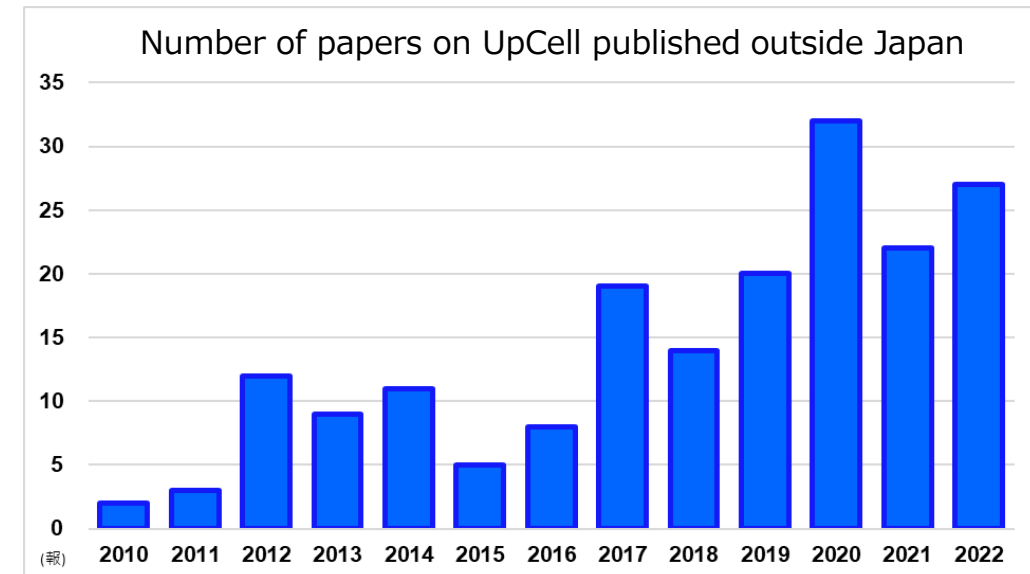
Culture and collection of a large number of cells >>> Manufacturing of cell sheets



## Merit of cell culture with UpCell

Cells can be collected without damaging them.

Start of development of products suited for culture and collection of a large number of cells in 2020: UpCell Flask

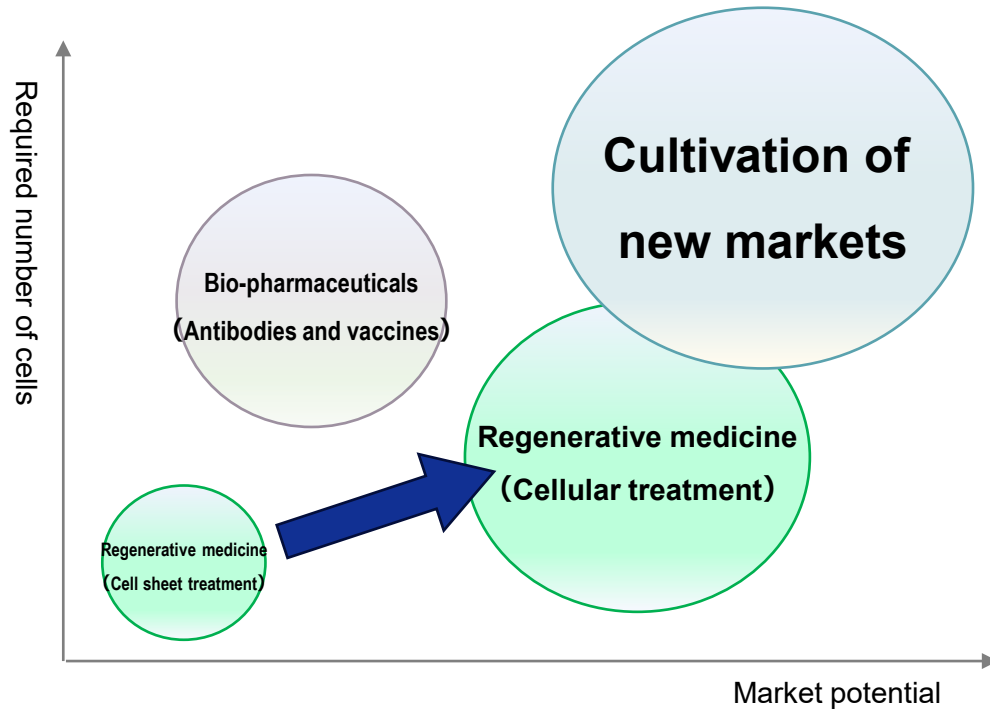


## Need for technology to culture cells in large quantities

- Biopharmaceutical manufacturing
- Manufacturing cells for use in immunotherapy
- Development of cellular foods such as cultured meat



## Possibility of market expansion



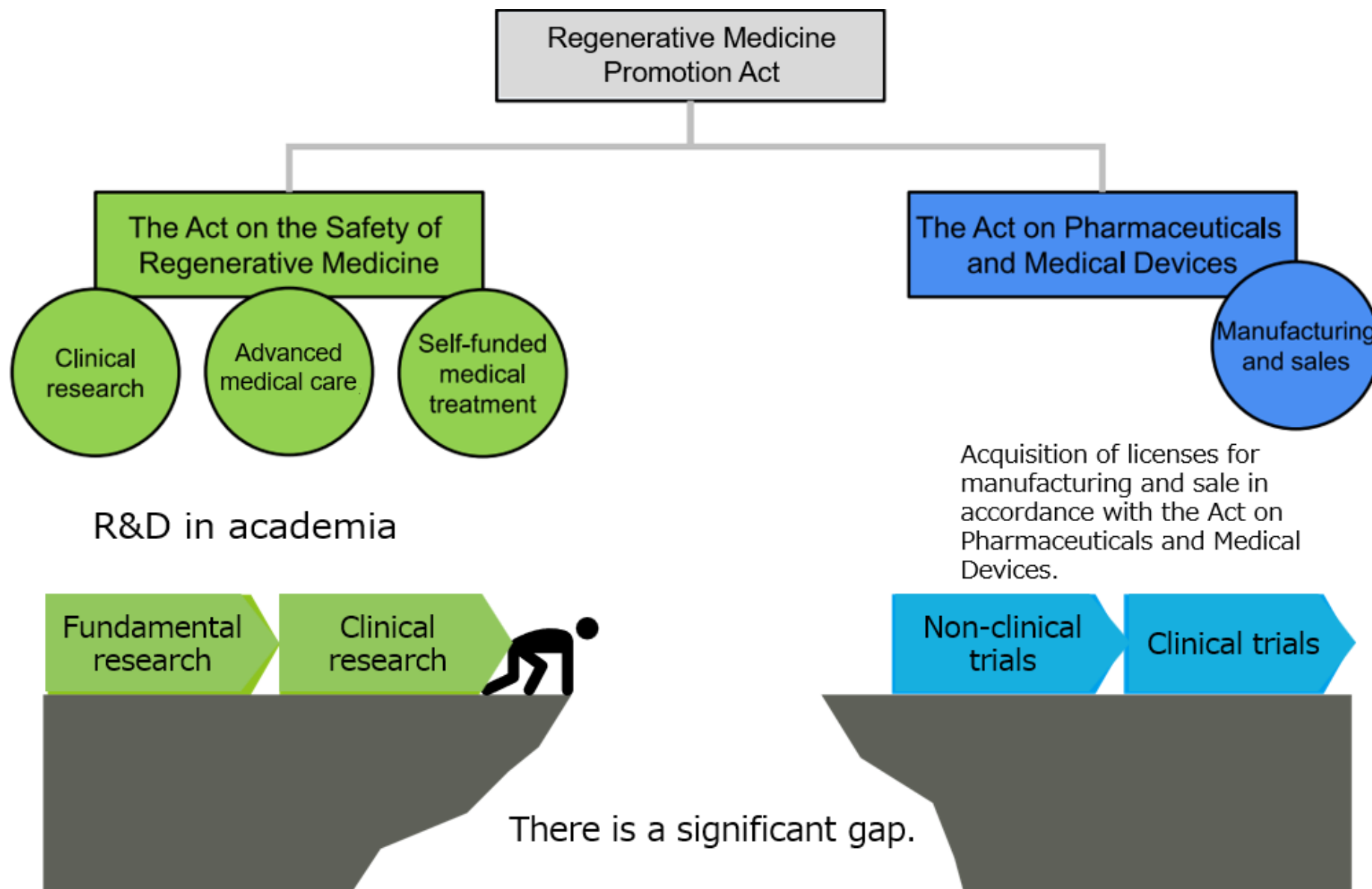
Temperature-responsive cell cultureware

**Reference info: Forecast for the global market of regenerative medicine 2025/2030/2035**  
(100 million yen)  
Tissue transplantation (cell sheets); 812/895/885  
Cell transplantation (cell therapy); 13,476/24,695/36,033  
**Source:** Survey on the market of regenerative medicine and gene therapy in fiscal 2019  
Arthur D. Little Japan Final Report, P144

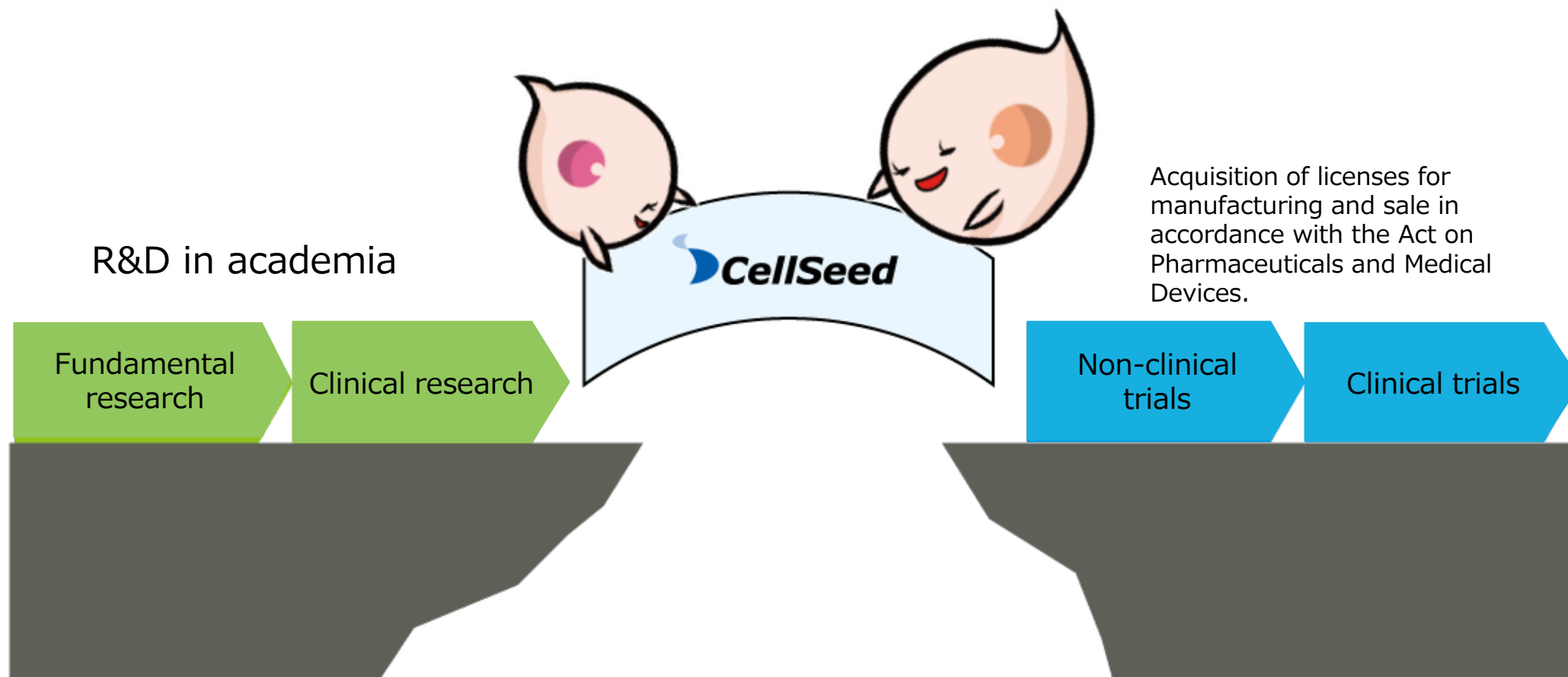
**Reference info: Forecast for sales of bio-pharmaceutical products 2020** (100 million yen)  
2020; 300,000  
**Source:** Issues in the bio-pharmaceutical industry and suggestions for further development  
Japan Pharmaceutical Manufacturers Association, Office of Pharmaceutical Industry Research, Research  
Paper, No.71, P8



# Regenerative medicine supporting business: Regenerative medicine consignment services



## Serving as a bridge to deliver regenerative medicine to patients by solving problems with academia and closing the gap



CellSeed aims to contribute to the provision of regenerative medicine to patients by offering the service of undertaking regenerative medicine projects.

1

## Development of Manufacturing Methods and Contract Manufacturing for Cell Sheet Products

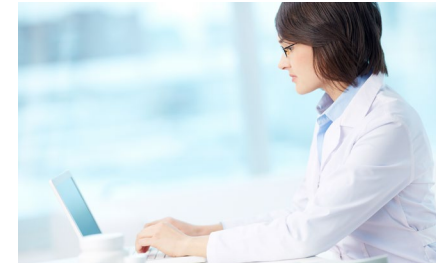
- Development of cell sheet manufacturing methods
- Contract manufacturing of cell sheet products
- Quality testing of cell sheets, etc.



2

## Facility Management and Application Support

- Support for preparing and submitting applications
- Support for document creation/consulting
- Support for operation and maintenance of facilities equipment/management system, etc.



3

## Training of Cell Culturing Technicians

- Cell sheet culturing training
- Cell sheet harvesting training, etc.

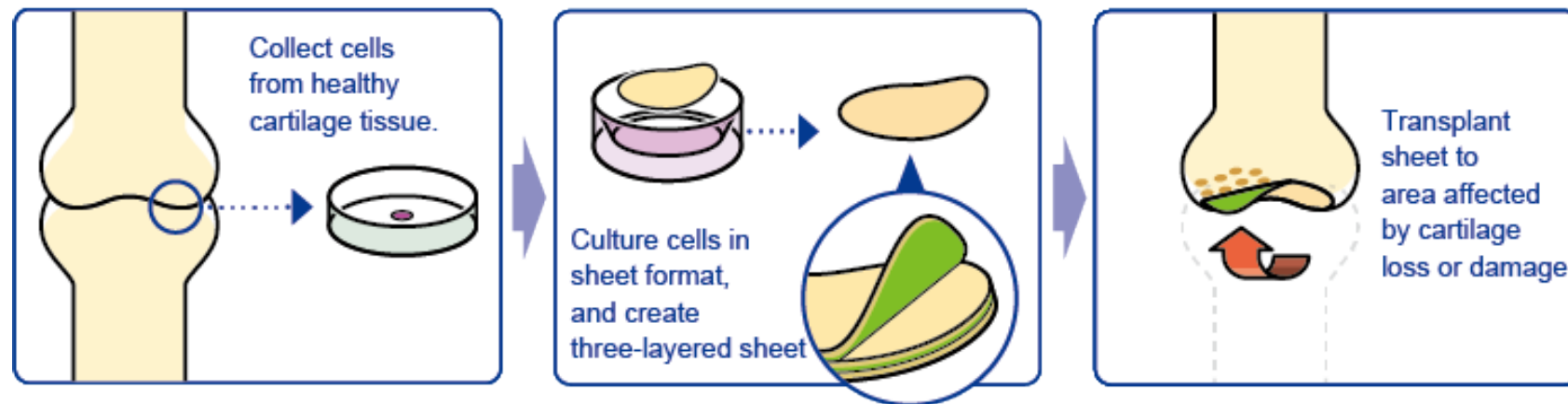


## Cell Processing Center

- The permission to manufacture specific processed cells (facility No. FA3160008 , March 2017)
- The permission to manufacture products for regenerative medicine (October 2018 )

## Major commissioned project results

- Autologous cartilage cell sheets
  - Contract manufacturing of autologous chondrocyte sheets for the Advanced Medical Care B program conducted by Tokai University.



- Pediatric autologous epithelium cell sheet

# Background for development of allogeneic cartilage cell sheets (CLS2901C)

## ■ Knee osteoarthritis (OA)

- Due to the aging of the population, the number of patients is projected to increase.
- There is no definitive treatment method.



Number of potential patients:  
About 30 million  
(in Japan)



Number of people  
with symptoms:  
About 10 million  
(in Japan)



Professor Masato  
Sato of Tokai  
University



In clinical research, good results  
were observed in all of 10 cases.

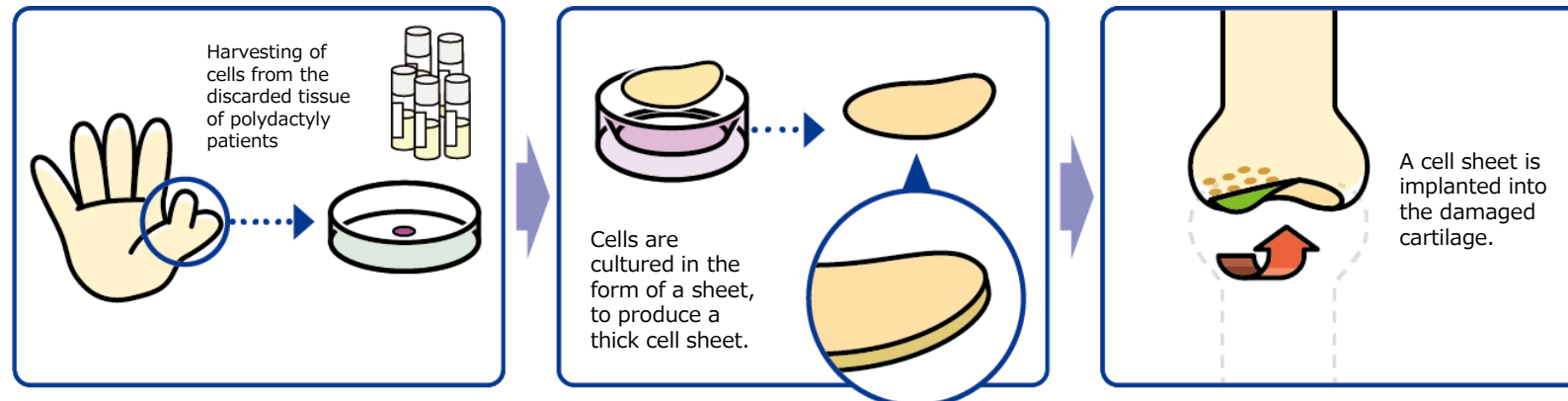


Transfer of technologies



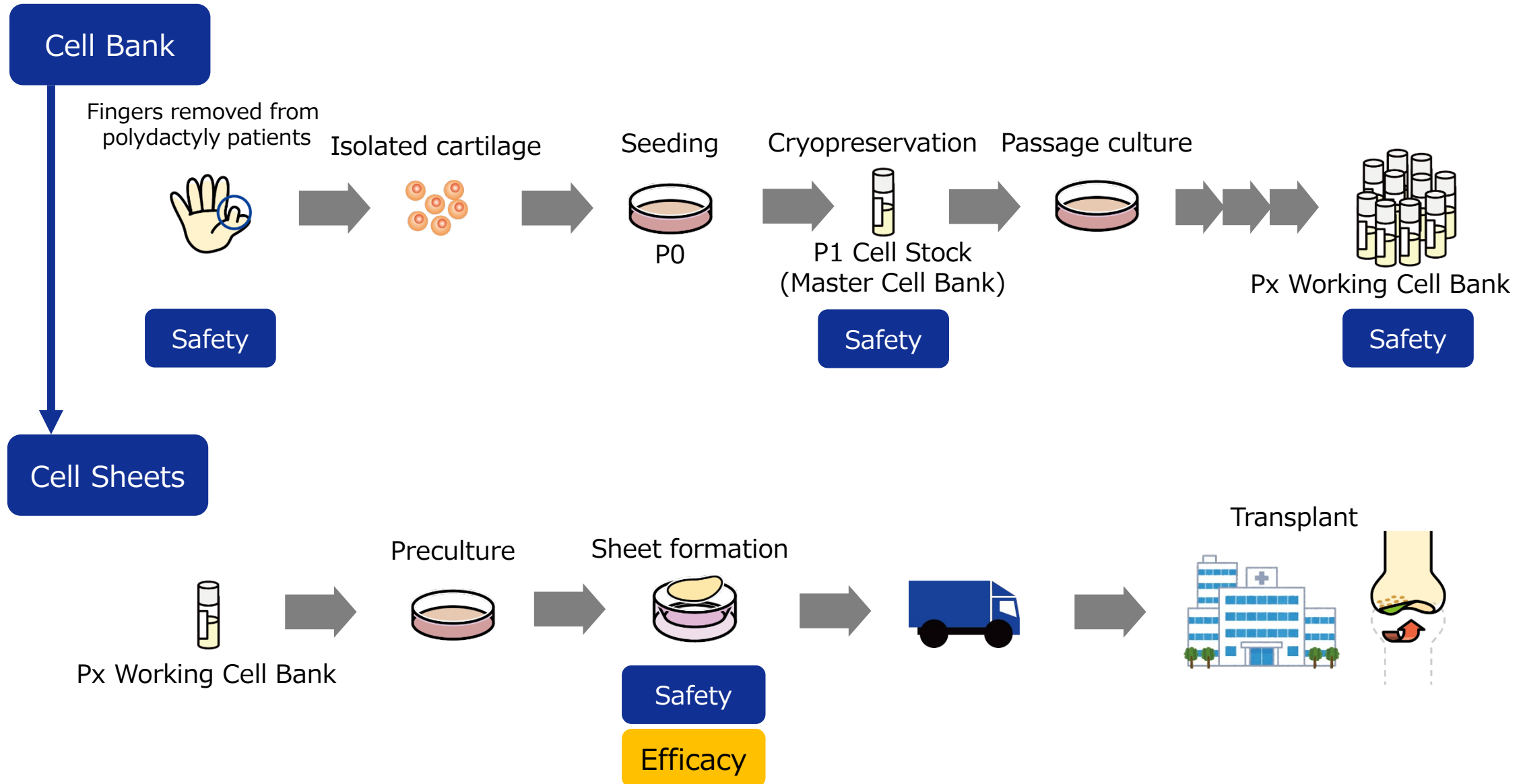
Development as products for  
regenerative medicine, etc.

## ■ Allogeneic cartilage cell sheets

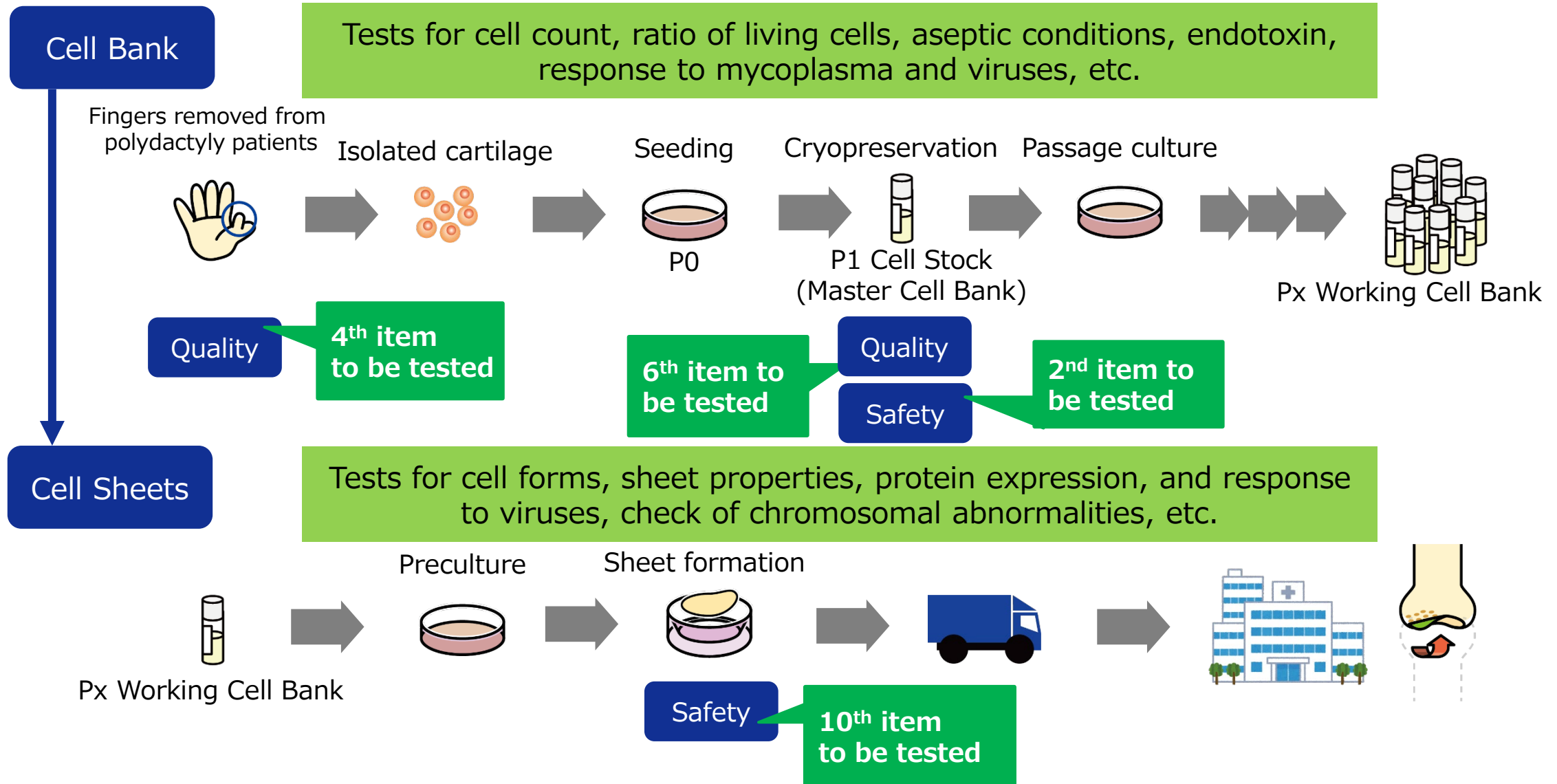




# Manufacturing process of allogeneic cartilage cell sheets (CLS2901C)

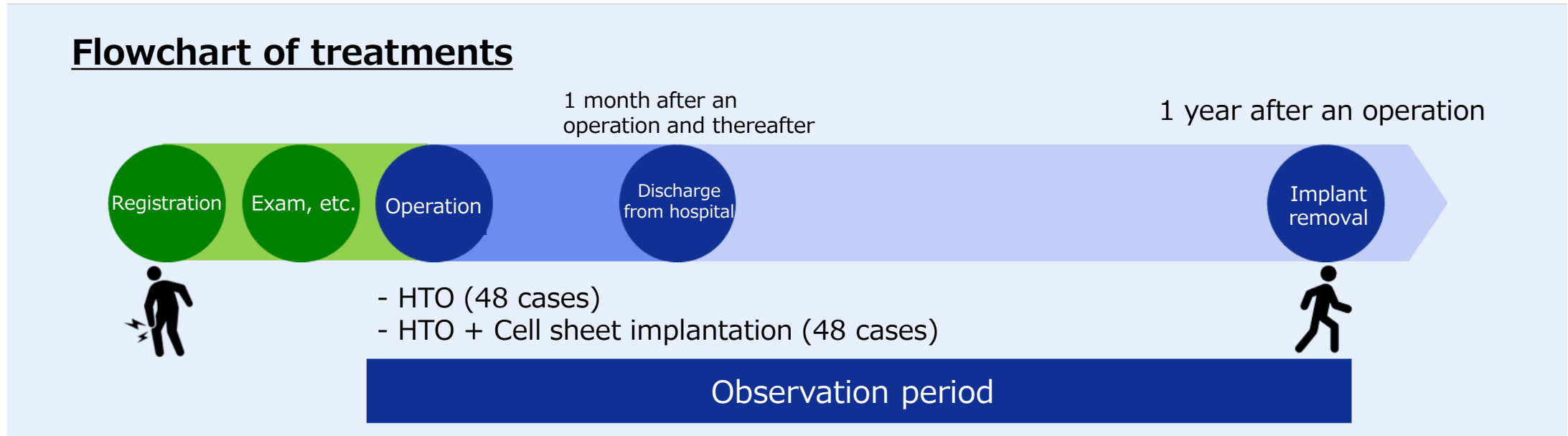


# Quality test items for cell banks and cell sheets



# Third-phase test of allogeneic cartilage cell sheets

Subjects: patients with knee osteoarthritis who should undergo high tibial osteotomy (HTO)



Five facilities where the test will be conducted: Tokai University Hospital, Yokohama Sekishinkai Hospital, Ebina General Hospital, Juntendo University Hospital, and Yokohama City University Hospital

Currently, we are developing systems for performing operations at each facility for clinical trials.

- In response to the application for the following U.S. patent related to allogeneic cartilage cell sheets, a decision to grant a patent has been made.
  - U.S. patent application No. 17/729,608
  - Title of the invention: a cultured cell sheet for tissue regeneration, and methods for producing and using it
- This is an outcome of research into allogeneic cartilage cell sheets conducted in collaboration with Tokai University.

**The Japan Society for Immunology (poster presentation and corporate exhibition; Mar. 28-30, 2024)**

**The Japanese Society for Regenerative Medicine (luncheon, poster, and corporate exhibition; Mar. 28-30, 2024)**

**The Pharmaceutical Society of Japan (corporate exhibition; Mar. 28-30, 2024)**

**Japanese Research Group on Knee Osteotomy and Joint Preservation (hosting special lectures and a luncheon seminar; Apr. 19, 2024)**

**Regenerative Medicine EXPO Tokyo (participation in special lectures and a round-table Talk; Jun. 26-28, 2024)**

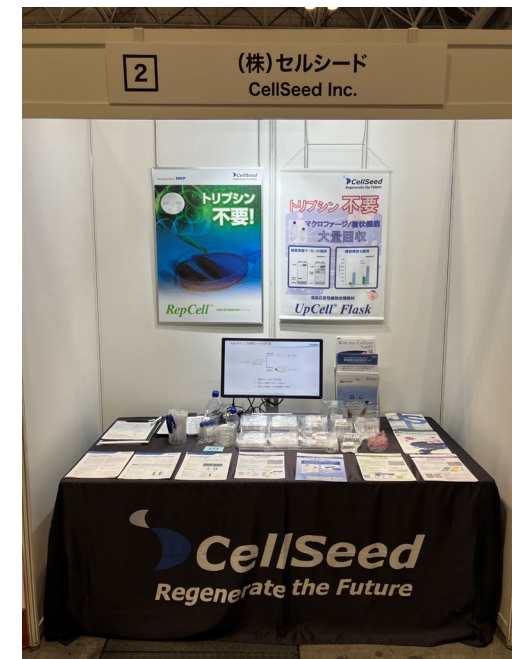
**ISSCR (The International Society for Stem Cell Research) (poster presentation; Jul. 10-13, 2024)**

**Regenerative Medicine JAPAN (corporate exhibition; Oct. 9-11, 2024)**

**The Japanese Biochemical Society (poster presentation and corporate exhibition; Nov. 6-8, 2024)**

**The Molecular Biology Society of Japan (poster presentation and corporate exhibition; Nov. 27-29, 2024)**

**The Japan Society for Immunology (poster presentation and corporate exhibition; Dec. 3-5, 2024)**



Exhibition booth at a conference



# Participation in academic conferences, etc.

- Congress of the Japanese Society for Regenerative Medicine  
Date: Thursday, March 21 to Saturday, March 23  
Place: Toki Messe (Niigata)
  - Corporate exhibition
  - Co-hosted academic seminar



第23回日本再生医療学会総会  
The 23rd Congress of the Japanese Society for Regenerative Medicine

CellSeed  
Regenerate the Future

共催学術セミナー22(ランチオン)/SES-22  
**変形性膝関節症治療のゲームチェンジャー**  
～軟骨細胞シートによる再生医療の最前線～

プログラム

- 1 「細胞シート移植による変形性膝関節症の再生医療の実現」  
佐藤 正人 先生 (東海大学医学部医学科外科学系整形外科学 教授)
- 2 「軟骨細胞シートを患者さんへ」  
橋本 せつ子 (株式会社セルシード 代表取締役社長)  
座長：松尾 純子 (株式会社セルシード)

日時  
**3/23(土)**  
11:20 ~ 12:10

会場  
第3会場  
朱鷺メッセ 3F  
中会議室 301

■本セミナーは整理券制です。  
■配布場所：朱鷺メッセ 2F アトリウム  
■配布時間等は HP をご確認ください。

共催：第23回日本再生医療学会総会 / 株式会社セルシード

## 🇯🇵 Japanese Research Group on Knee Osteotomy and Joint Preservation

Date: Friday, April 19 to Saturday, April 20

Place: Rexam Hall (Takamatsu)

- Co-hosting lectures for citizens



第3回日本Knee Osteotomy and Joint Preservation研究会 特別講演1

## 市民公開講座

参加無料  
事前申込制



### 細胞シートが拓く ひざ関節症の再生医療

4/19 **金** 13:40~14:40  
(開場 13:30)

**会場** レクザムホール(香川県民ホール)小ホール  
〒760-0030 香川県高松市玉藻町9-10

**座長** 安田 和則先生(八木整形外科病院 名誉教授)

**演者** 佐藤 正人先生(東海大学医学部医学科外科学系整形外科学 教授)

参加希望の方は、こちらから  
お申込みください



問い合わせ先:株式会社JTB 高松支店  
TEL 087-851-3055



CellSeed  
Regenerate the Future  
共催:株式会社セルシード



# Participation in academic conferences, etc.

## ● Regenerative Medicine EXPO

Date: Wednesday, June 26, 2024; 14:00 to 15:00

Place: Tokyo Big Sight

### ■ Special lecture 2 at Regenerative Medicine EXPO

Round-table talk: regarding regulations on all phases from clinical trials to after-sales care for products for regenerative medicine, etc.





# We will participate in Regenerative Medicine JAPAN

Date: Wednesday, October 9 to Friday, October 11, 2024

Venue: Pacifico Yokohama

◆ Exhibition booth: Booth No. R-24

◆ Presentation

Date: Thursday, October 10; 15:40 to 15:50

Place: Regenerative Medicine Stage

Presenter: Chikako Sato, Head of Cell Sheet Business Division





In 2025, we plan to hold the 4<sup>th</sup> Cell Sheet Engineering Innovation Forum!

We will inform you of details as soon as they are determined.





This presentation is made by CellSeed Inc. solely for the disclosure of the financial statements, and not published for the purpose of soliciting sales or purchases of securities in Japan and any other regions.