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Overall Highlight

Development of iPSC regenerative medicine
(Age-related macular degeneration)

Future business direction

Expansion to 3D organ
(Liver)

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1. Company Overview

Company Roots

About Us	
Company Name	HEALIOS K.K.
Head Office	World Trade Center Building 15F 2-4-1 Hamamatsucho Minato-ku, Tokyo Japan 105-6115
Kobe Research Institution	Kobe KIMEC Center Building 9F 1-5-2 Minatojima-minamimachi Chuo-ku, Kobe Hyogo Japan 650-0047
Number of Employees	42 (As of end of September, 2015)
Major Share Holders	Sumitomo Dainippon Pharma Co., Ltd., NIKON CORPORATION, SHIBUYA CORPORATION, Shin Nippon Biomedical Laboratories, Ltd., tella, Inc., iPS Academia Japan, Inc.
Affiliated Company	SighRegen Co., Ltd. (Joint Venture with Sumitomo Dainippon Pharma Co., Ltd.)

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Company Roots

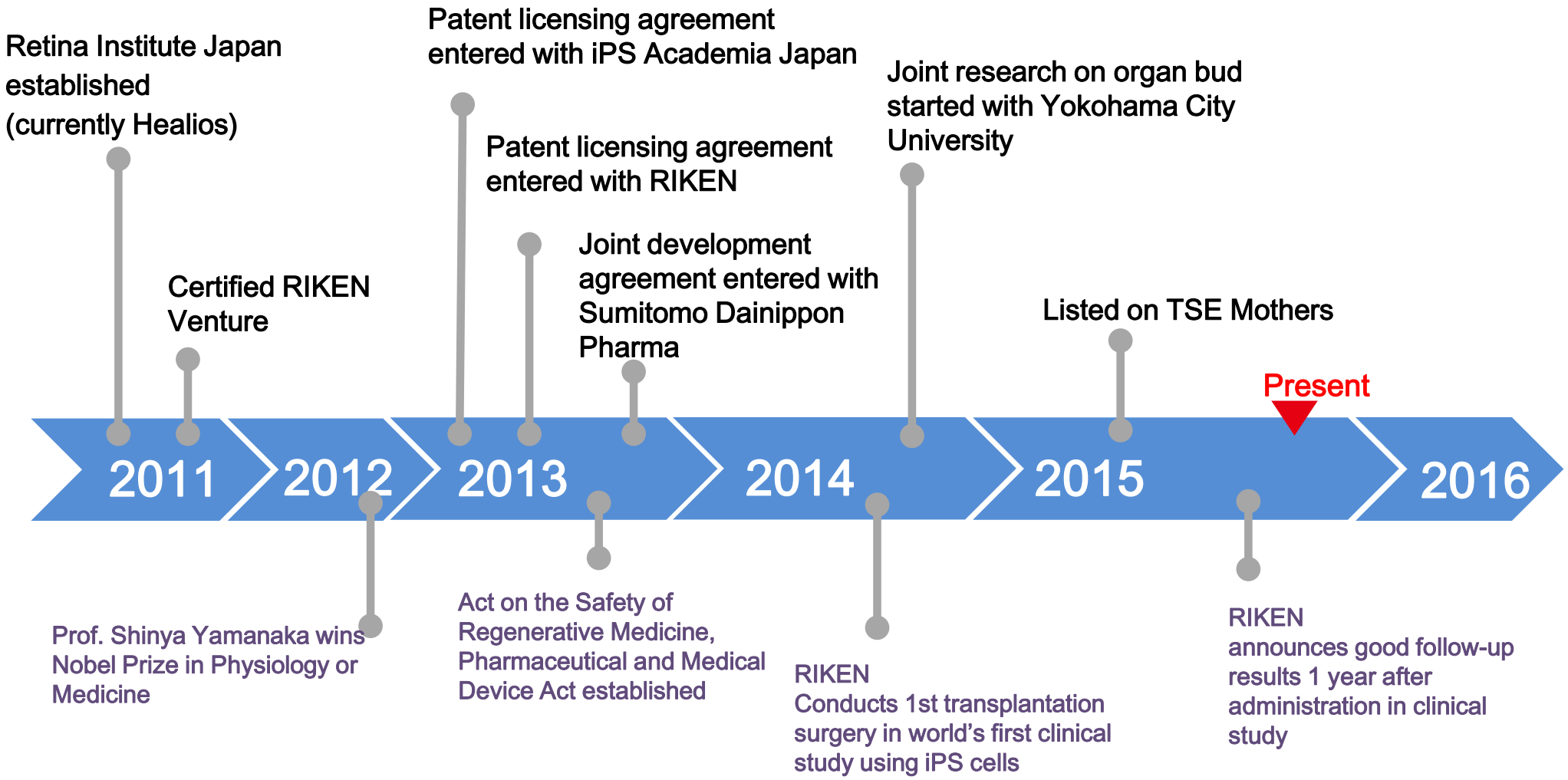
How it was founded

- Started business to establish treatments for age-related macular degeneration and determined to build up a pharmaceutical company which can provide treatments for intractable diseases.
- Founded Aqumen Biopharmaceuticals K.K. (later transferred business to Healios), succeeded in developing BBG250, entered into a contract with DORC, and started selling across Europe.
- Appraised by Institute of Physical and Chemical Research, including Dr. Masayo Takahashi, targeted the very first iPSC regenerative medicine based on iPS cells, which have the potential to be a complete cure for age-related macular degeneration, and I am responsible for putting retinal pigment epithelial cells to practical use.

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Company History and Social Trends

Pioneer of iPSC regenerative medicine development



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“To be the change in an ever evolving world through enrichment of living”

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Two Business Fields

Compound Medicine Field

▼ Ophthalmology Surgery Support Agent BBG250



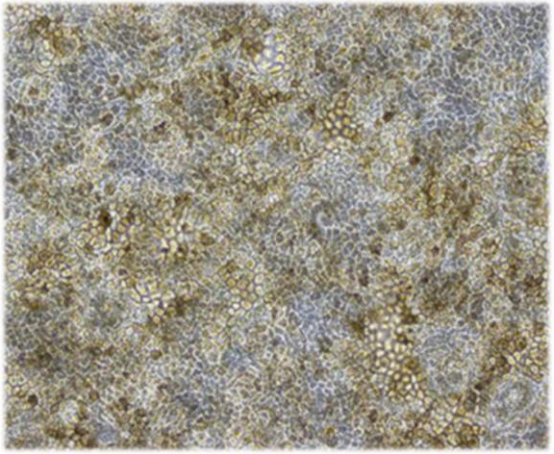
On Sale

- On sale in Europe
- Proceeded with treatments with business partners in Japan and America

iPSC Regenerative Medicine Field

▼ RPE cells originated from iPS cells





Under Development

- iPS cells → Produce normal RPE cells
- Replace the aged cells → Treat AMD

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Expanding Sales Area of Ophthalmology Surgery Support Agent BBG250

Further sales growth inside and outside EU



- Sales areas:
  Expands to **73 countries and regions** (As of October 2015)

- Total sales:
  Approx. **120,000 units** (FY2014 performance)

- **63.1%** of ophthalmologists in the world reply BBG250 to be the best among similar products.

(Source) ASRS 2013 Preferences and Trends Membership Survey

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2. Business Outline

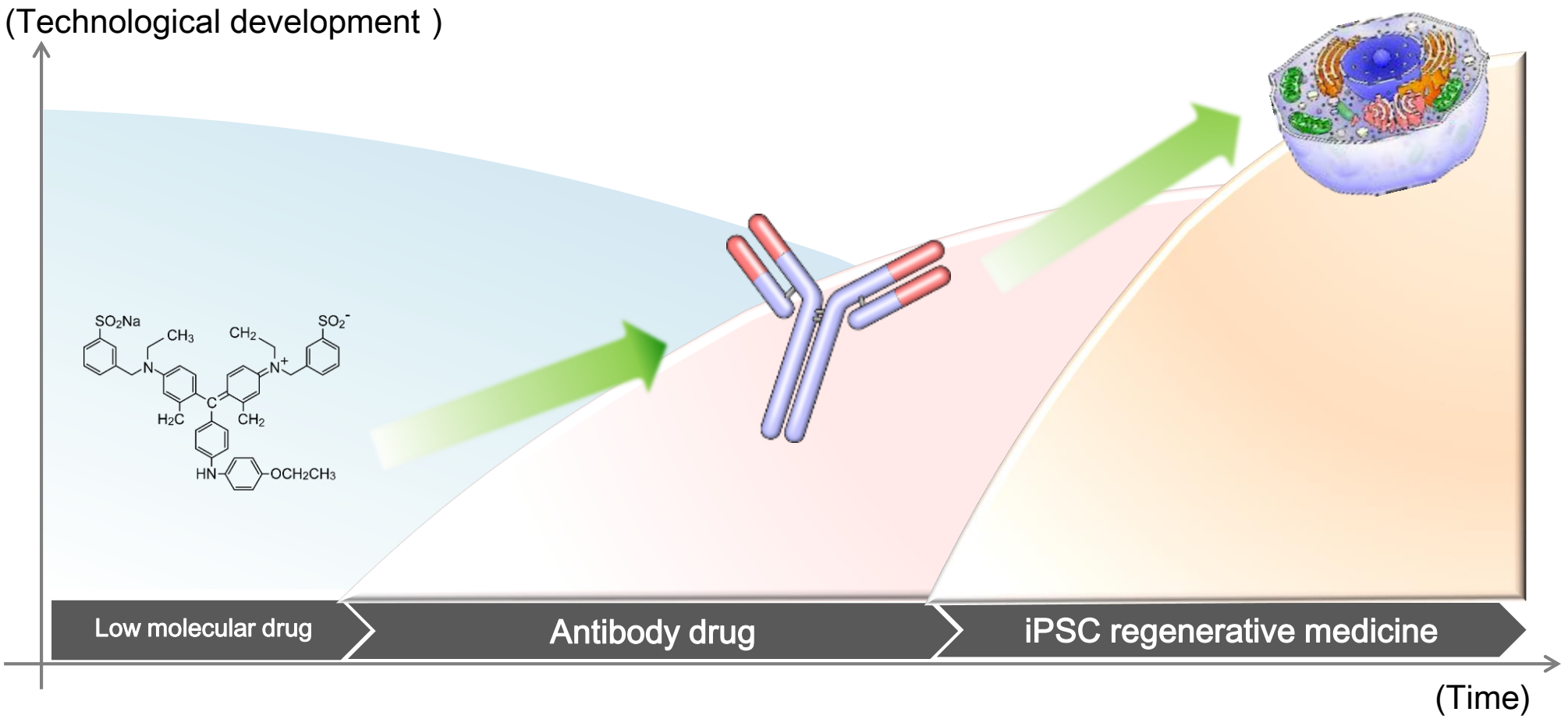
Step 1 Treat AMD (Age-Related Macular Degeneration) with iPS cells

Step 2 About AMD and Profitability of RPE Cell Medicine

Step 3 Strategy for Placing RPE Cell Medicine on the Market

Transition to iPSC Regenerative Medicine

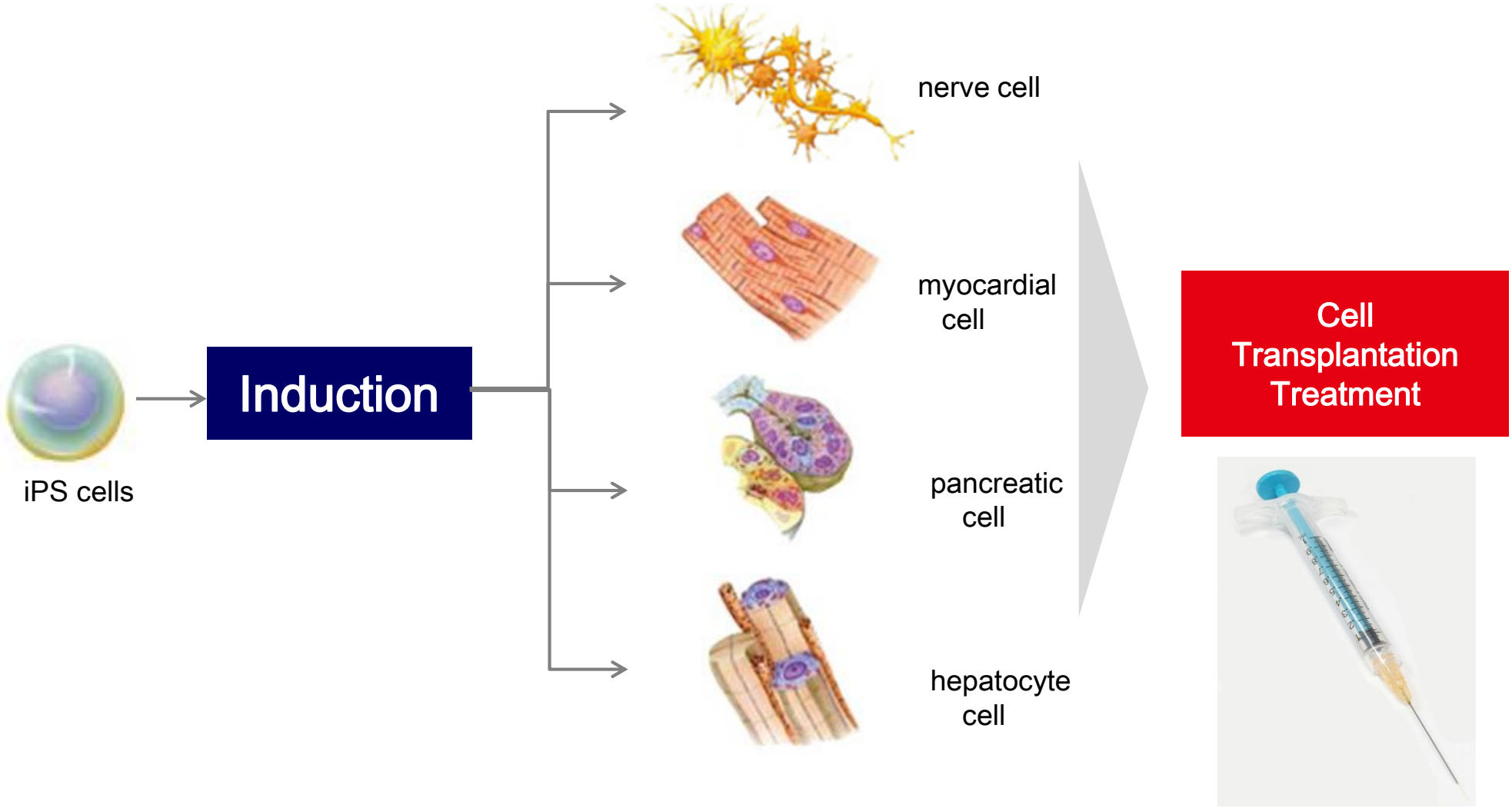
Technological development from low molecular drug to antibody drug, iPSC regenerative medicine, etc.



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Concept of iPSC Regenerative Medicine

Make “Regular Cells” from iPS Cells



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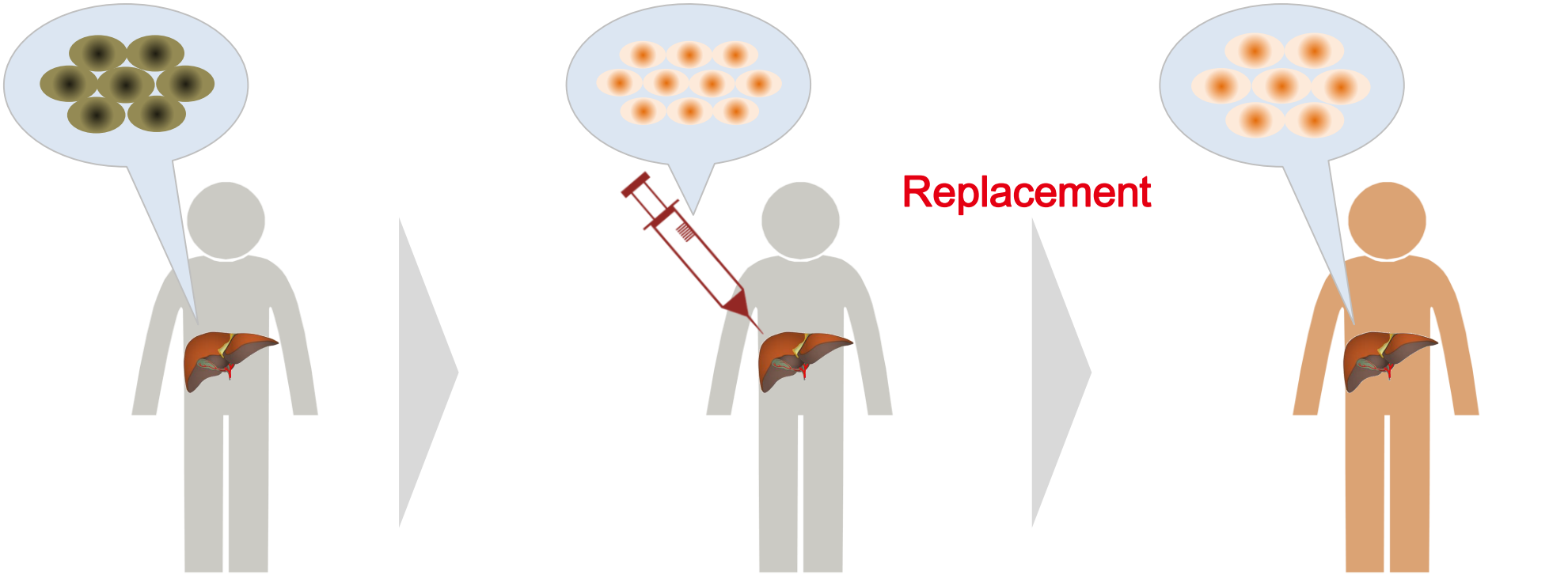
Mechanism of iPS Regenerative Medicine

Replace damaged cells with regular cells

Tissue (cells) Damaged by Aging, Disease or Accident

iPSC Regenerative Medicine
Target Cells made from iPS cells

Replace Damaged Tissue (cells) with regular cells



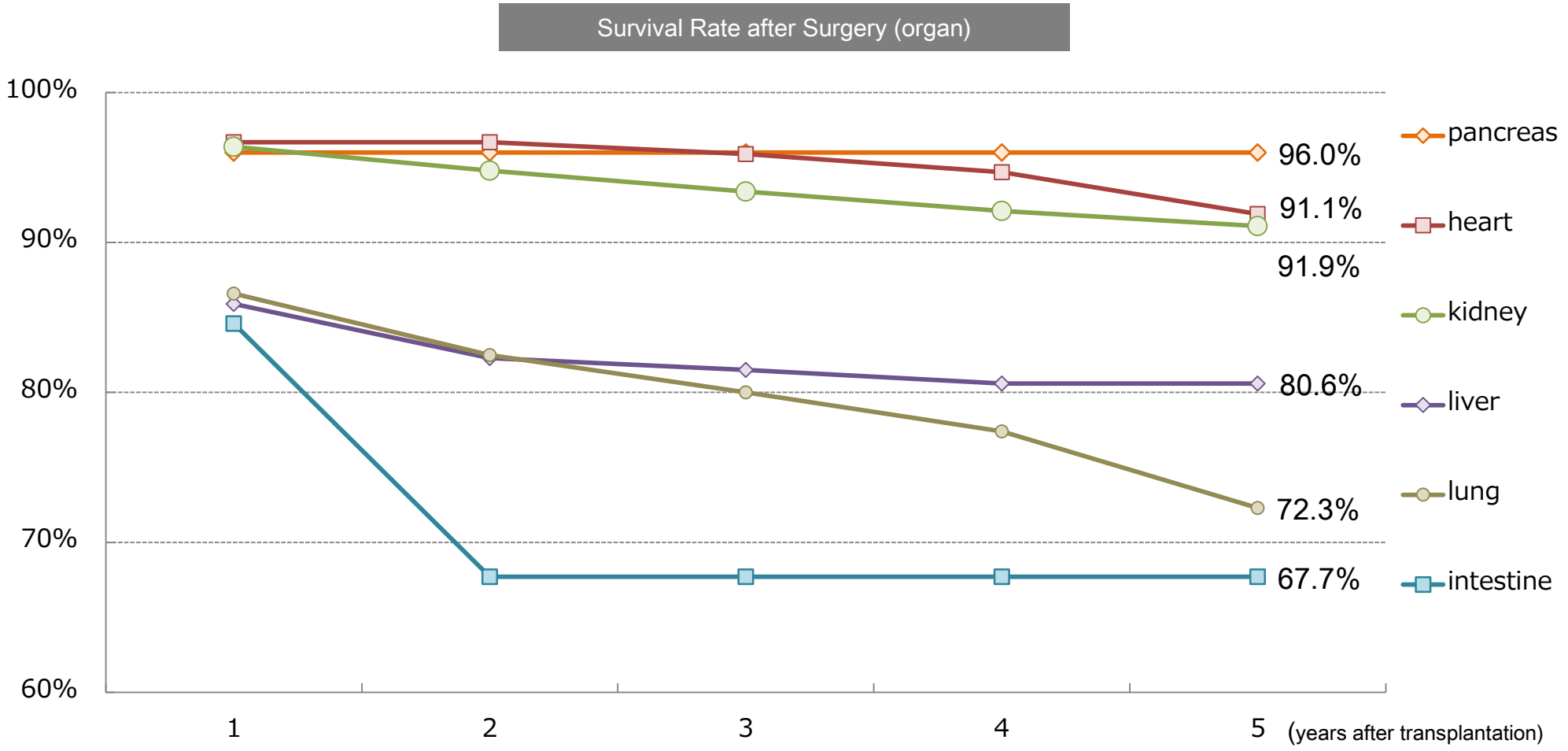
Patient

Recovery of Organ Function

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Success Rate of Organ Transplantation

High Possibility to Succeed with Development of Technological Innovation

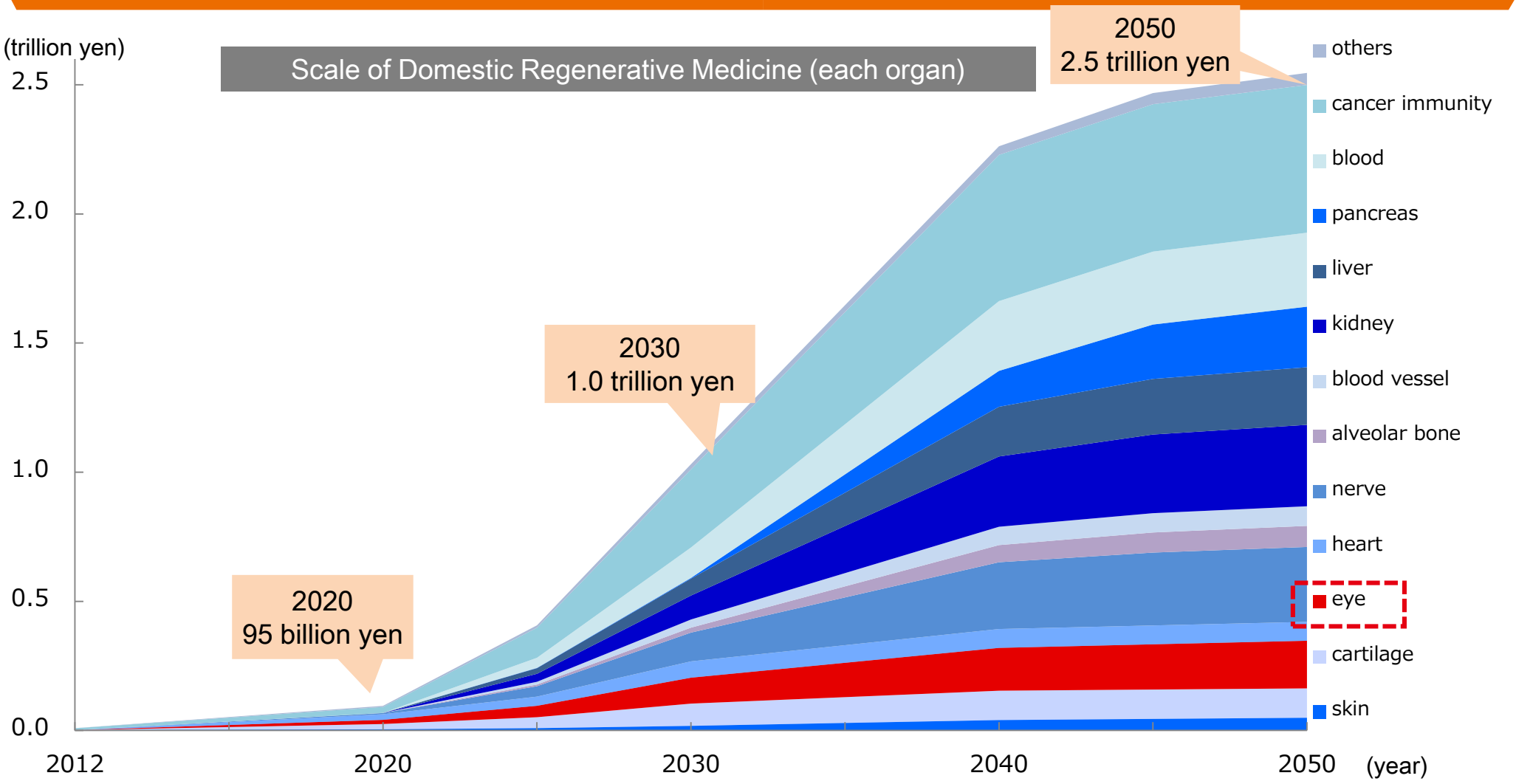


(note) the transplantations of heart, lung, liver, pancreas and intestine were performed by the end of March, 2014.
(note) the transplantation of kidney was performed by the end of December, 2015.
(source) The Ministry of Health, Labor and Welfare ”Report about Transplantations”

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Roadmap of Regenerative Medicine (including cell medicine)

It is expected that regenerative medicine will reach cartilage, eye, and internal organs



(source) the Ministry of Economy, Trade and Industry "report about industrialization and implementation of regenerative medicine"

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Aim toward Treatment of Age-Related Macular Degeneration (AMD) as a First Step

Example Symptoms of Age-Related Macular Degeneration





Aging of RPE (retinal pigment epithelial) cell is considered the cause.

(source) excerpted from homepage of Japanese Ophthalmological Soc.

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2. Business Outline

Step 1 Treat AMD (Age-Related Macular Degeneration) with iPS cells

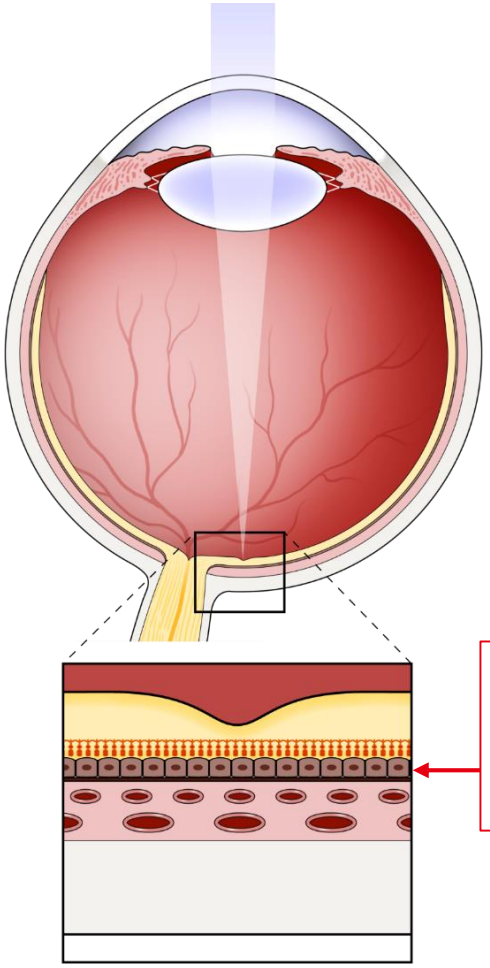
Step 2 About AMD and Profitability of RPE Cell Medicine

Step 3 Strategy for Placing RPE Cell Medicine on the Market

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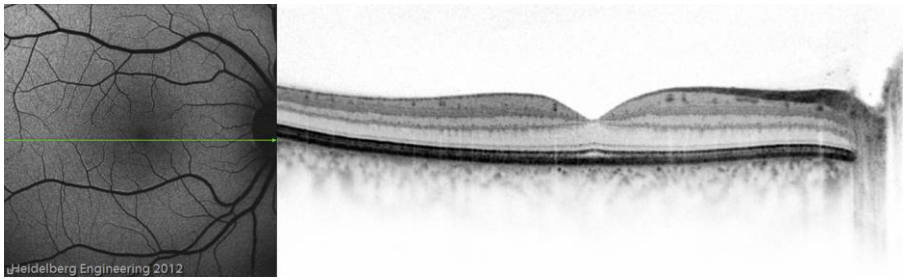
Explanation of AMD Pathological Condition

AMD causes RPE Cells to degenerate, which will damage functions

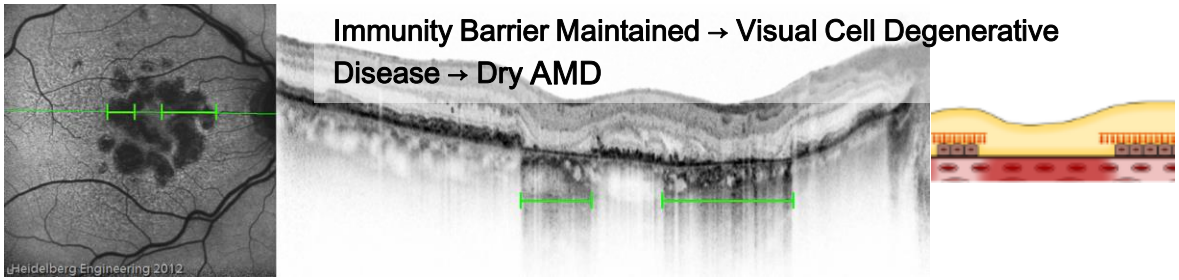


Retinal Pigment Epithelial Cell (RPE)

Regular Macular Part

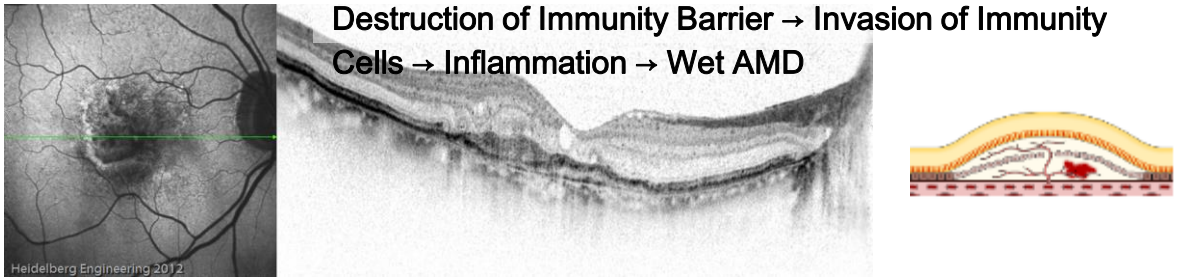


Developed Dry AMD



Immunity Barrier Maintained → Visual Cell Degenerative Disease → Dry AMD

Wet AMD

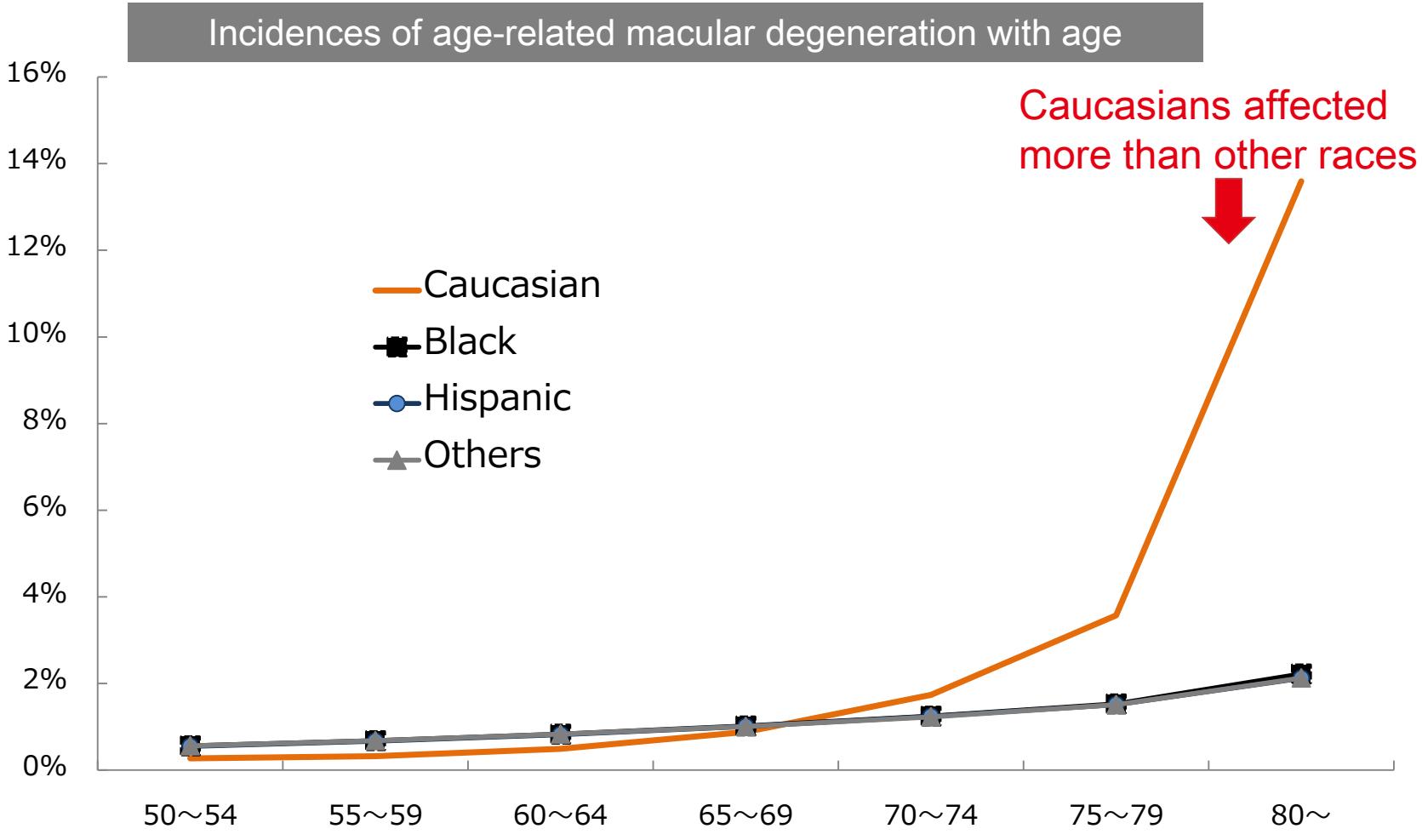


Destruction of Immunity Barrier → Invasion of Immunity Cells → Inflammation → Wet AMD

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Pathological Condition of AMD

AMD emerges with aging and is most prominent in caucasians

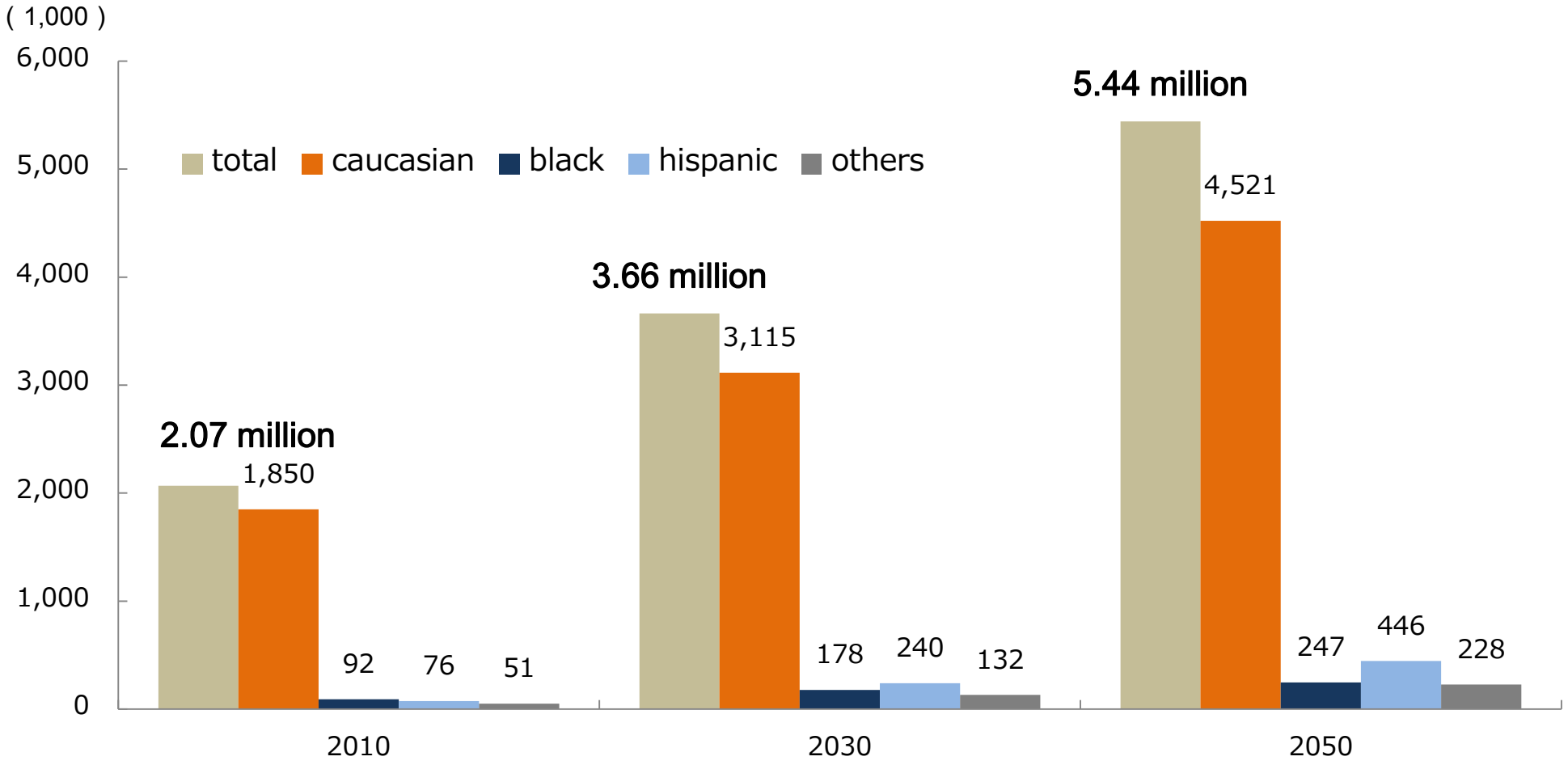


(source) National Eye Institute

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Estimated Number of AMD Future Patients in Serious Cases in US

Expected to Increase over Medium to Long Term as Society Ages



(source) National Eye Institute

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Number of AMD Patients

Number of both Wet and Dry patients (including mild cases)

	US	Japan	Others
The Number of AMD Patients	10,000,000	9,230,000	13,000,000
The Number of AMD Patients in Serious Cases	2,000,000	690,000	2,600,000-3,220,000
Wet-Patients in serious cases	1,000,000-1,500,000	630,000	1,300,000-1,950,000
Dry-Patients in serious cases	850,000-900,000	60,000	1,100,000-1,170,000

※According to research by Hisayama Kyushu University Graduate School of Medicine in Fukuoka (based on a comprehensive study), the total number of patients in Japan is calculated, estimating the total number of first-stage age-related macular degeneration and latter stage of age-related macular degeneration based on population statistics (2007) Also, the Disease Information Center announced that the number of patients suffering serious cases is approximately 690,000. The total number of patients in the US, which the National Institute reports, includes the total number of age-related macular degeneration patients in light cases and patients with visual field defects. Also, our company calculated the total number of Dry/Wet patients based on the incidence rates presented by AMDF (2010). Our company calculated the total number of patients in Europe based on incidence rates in each grade of European population statistics (2010)

※source: Prevalence of age-related maculopathy in older Europeans: the European Eye Study (EUREYE).Source: Arch Ophthalmol. 2006 Apr;124(4):529-35

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Market Scale of AMD

Annual Sales of Medicinal Treatments of Wet: 831.6 billion yen. No Medicine for Dry

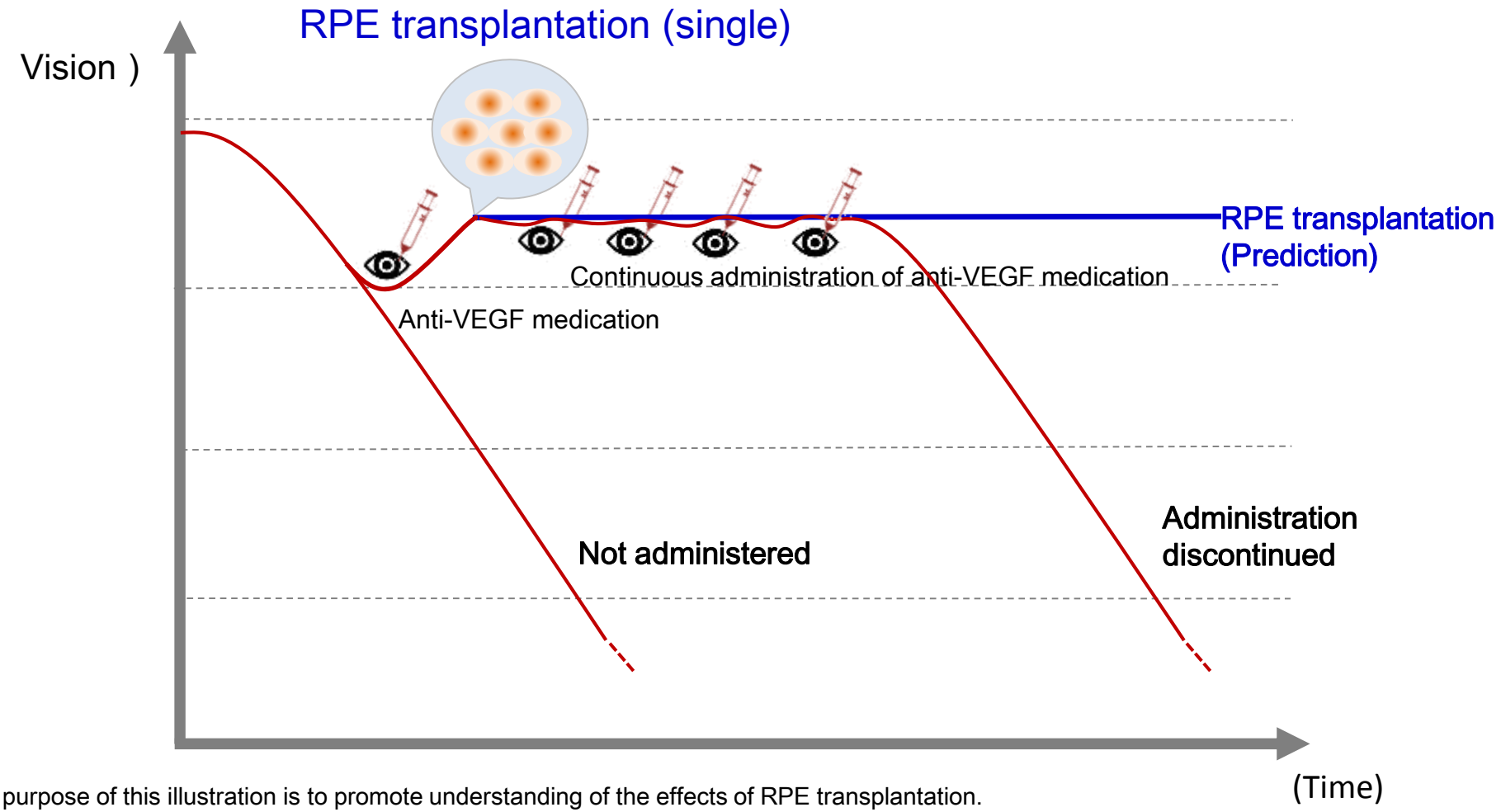
Condition	Medicine/Effect	Year	US	Japan	Others	Total
Wet	Anti-VEGF Medicine/ Restraint of New Blood Vessels	2013	363.6 billion yen	38.0 billion yen	294.7 billion yen	696.3 billion yen
		2014	414.1 billion yen	55.7 billion yen	361.8 billion yen	831.6 billion yen
Dry	No Medicine					

(source)Market scale was calculated using official materials from drug companies (Roche Diagnostic, Novartis, Regeneron,Bayer HealthCare, Santen Pharmaceutical Co., Ltd). Calculated using 2013 and 2014 fiscal year-end exchange rates.

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Changes in Vision

Good vision can be maintained with early treatment

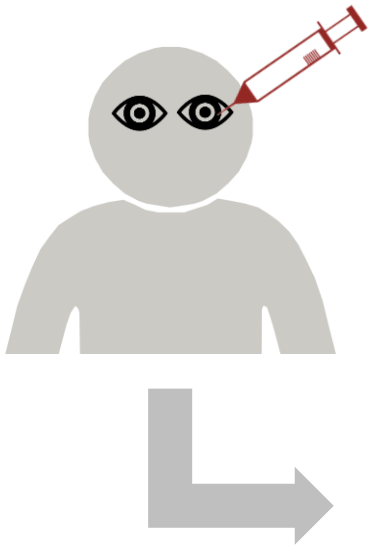


* The purpose of this illustration is to promote understanding of the effects of RPE transplantation.
Changes in vision with the administration of anti-VEGF medication are not the same as the above according to patient symptoms and administration frequency.

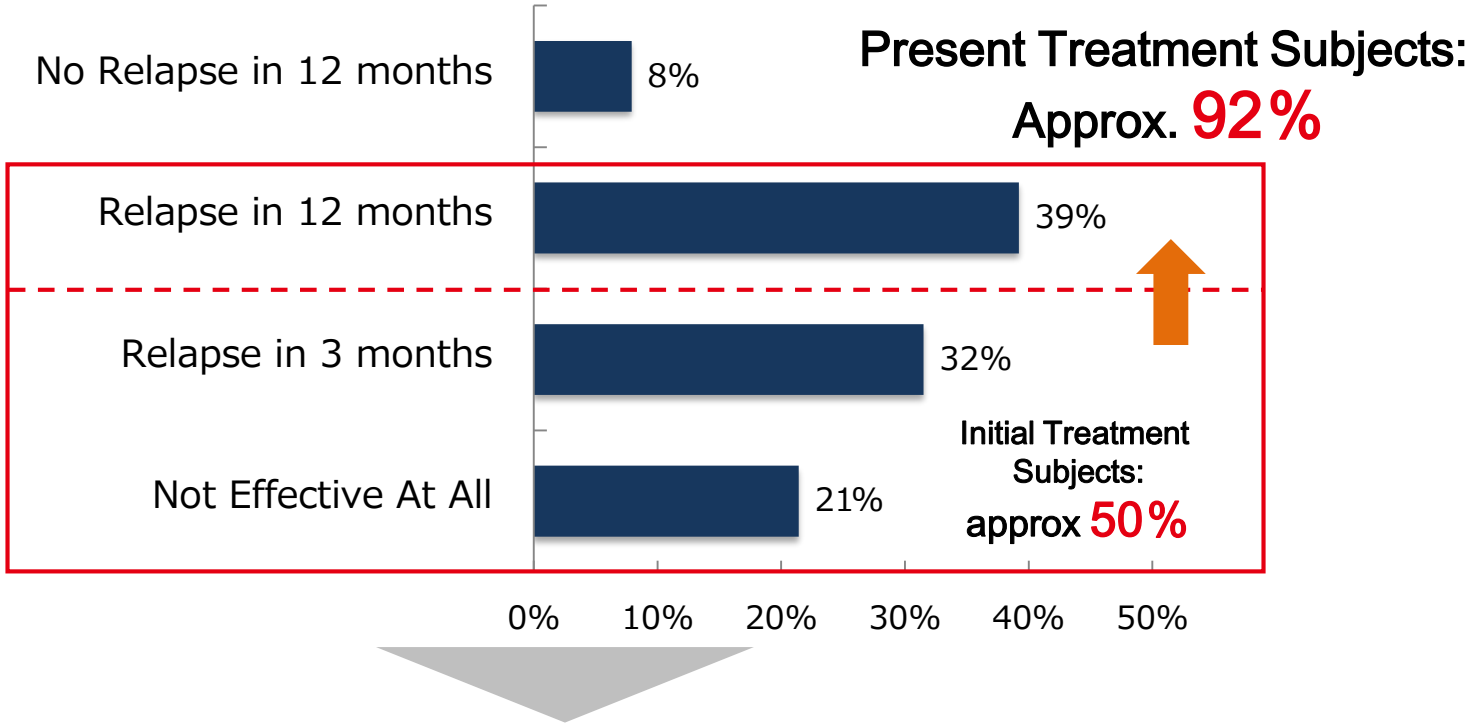
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Treatment Subjects for Wet AMD

Patients recurring within 1 Year, which is the case of approx. 92% of Wet AMD Patients, are the candidates for treatment.



Recurrence frequency after receiving anti-VEGF medication



Present Treatment Subjects: Approx. 92%

Initial Treatment Subjects: approx 50%

QOL of Continuously Medicated Patients is not High.

(source) 13th Annual Meeting of The Japanese Society for Regenerative Medicine March 19th Thurs, 12:00 ~ 12:50
Approach to Clinical Application of iPS cells Institute of Physical and Chemical Research, Mandai Michiko

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One-Year Follow-Up Results of World's First Clinical Study

Results of 1-Year follow-up assessed to be good

Clinical study

September 12, 2014: 1st transplantation
"Clinical Study on Autologous Transplantation of iPSC-Derived RPE Cell Sheets for Wet AMD"

Main follow-up report

- The results were good throughout the follow-up period, and the transplanted RPE cell sheets still survive as of now.
- No particular abnormality seen, such as tumorigenesis, etc. caused by the transplanted sheet.
- Postoperatively, vision, which tended to deteriorate before transplantation, turned to be maintained.
- Vision related QOL score improved postoperatively.

(Source) RIKEN　October 2, 2015 Press Release　http://www.riken.jp/pr/topics/2015/20151002_1/

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Anti-VEGF Medicine mostly Continues From the Beginning of the Treatment to Death

Annual Medical Expense

Unit Price of Anti-VEGF **170,000 yen** × Annual Recommended Medication Protocol **6 Times** = Annual Medical Expense **1,020,000 yen**

Estimate of Lifetime Medical Expense

On the Assumption of Average Life Span (Japan): 80years old (Male) / 86 years old (female)

		Estimate of Lifetime Medical Expense
Continuous Treatment for **50-year old Patient Onset** = approx. **30years**	× 1,020,000yen =	**Approx. 30,000,000 yen**
60-year old Patient Onset = approx. **20years**	× 1,020,000yen =	**Approx. 20,000,000 yen**

(source) Onset Data: National Eye Institute; Average Life Span: The Ministry of Health, Labor and Welfare; Annual Recommended Medication Protocol: Materials Presented by Institute of Physical and Chemical Research

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Drug Prices of Emerging Medicines and Medical Expenses are Very Costly

Examples



Autologous Cultured Epidermis "Jace"

1 piece: 300,000yen × Covered by Insurance until 40 pieces

= Total Amount for Treatment:

12,000,000 yen



Hemoglobinuria Medicine 「Soliris」

One Bottle: 570,000yen

Annual Total Amount: **approx. 45,000,000 yen**

(source) The Movement of Medical Technology involving Cost-Effectiveness/The Ministry of Health, Labor, and Welfare September 6, 2013

NHI price calculation method prospects

Cost accounting system

* The price of new drugs is basically calculated according to the prices of official articles with similar efficacy (price determination by comparable drug). However, if there are no appropriate similar official articles, required costs are added in the calculation of prices (cost accounting system).

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2. Business Outline

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Autologous and Allogeneic Transplantation

We Handle Cross-Regenerative Medical Treatment , with High Profit Margins

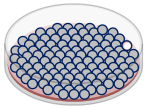
iPSC Regenerative Medicine
(Autologous)

Patient A

Cell Extraction

Cultivation Induction Formulation

Patient A



Transplant One's Own Cells

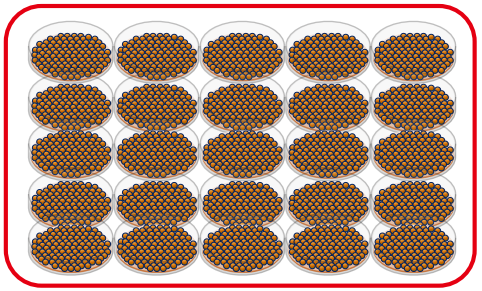
iPSC Regenerative Medicine
(Allogeneic)

Donor

Cell Extraction

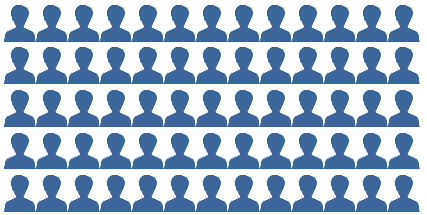
Cultivation Induction Formulation

Patient



Mass Production

High Profit

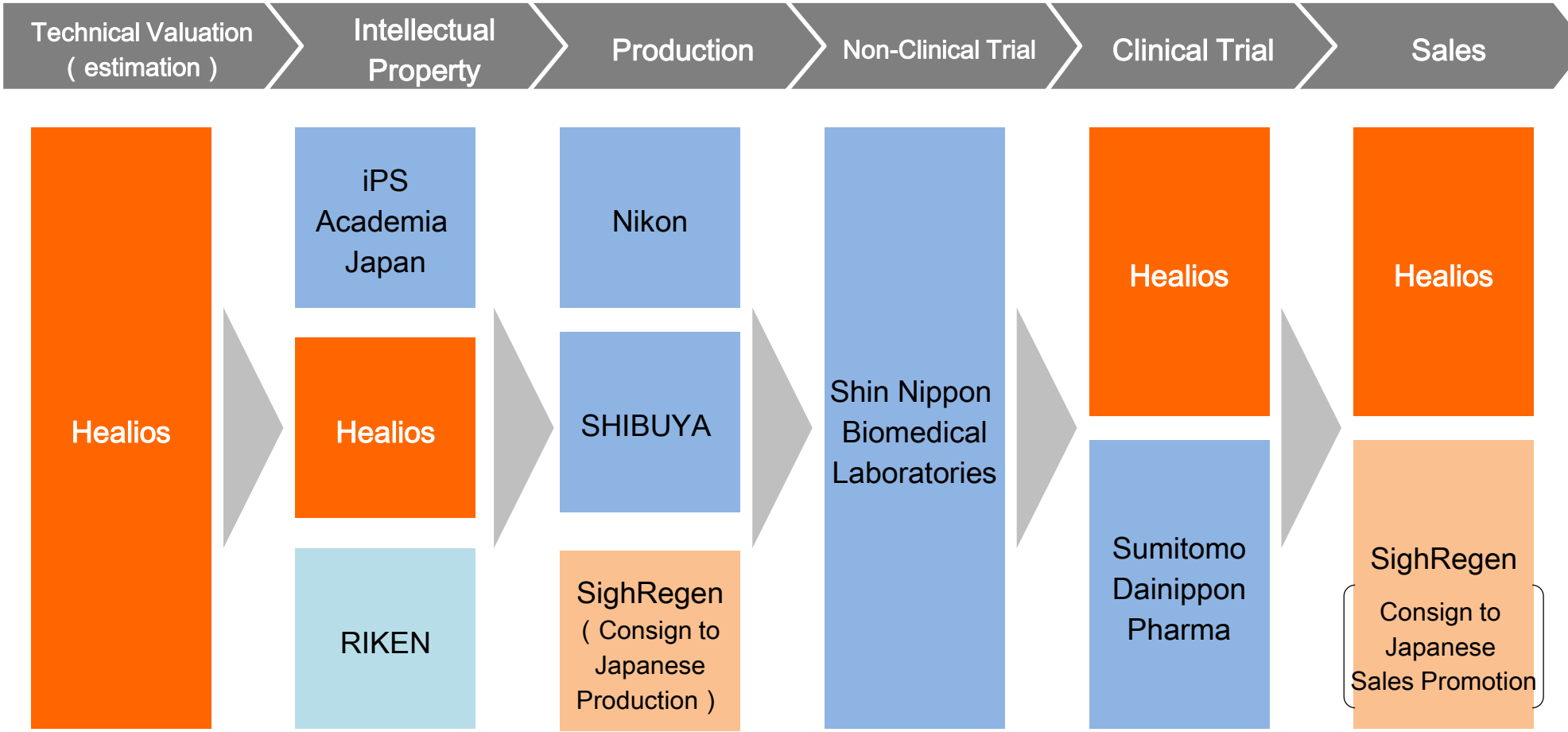


Transplant Other Cells

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Development System of RPE Cells

Built Up a Strong Partnership with Japanese Companies with Globally Leading Component Technology



(note) 1. ( ) Our Company's Stock Holders
2. SighRegen is a joint venture with Sumitomo Dainippon Pharma Co. Ltd, invested 50% each.

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Project System

Arranged Domestic Value Chain by Cooperation with Sumitomo Dainippon Pharma Co., Ltd

Development → Production → Marketing → Sales

Can Build Up Developing, Sales and Manufacturing in Japan

Development	Production	Marketing	Sales	
Healios 6.8 billion yen by Collaborative Development with Sumitomo Dainippon Pharma Co., Ltd	**SighRegen** (※) Secured Personnel Structure for Pharmaceutical Manufacturing	**SighRegen** Approved Sales Promotion	**Healios** Sales	Medical Institution

(※) Joint Venture with Sumitomo Dainippon Pharma Co., Ltd

Flexibly Examine Collaborative Development, Prioritizing Self-Manufactured Sales

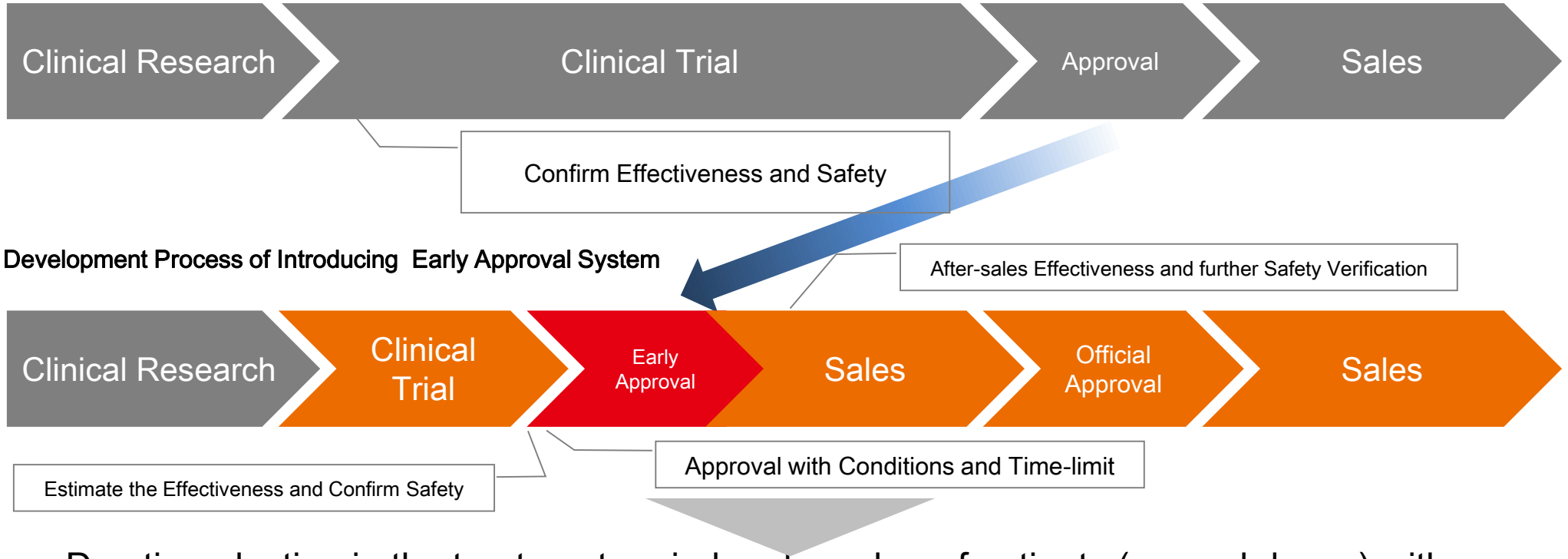
Development	Production	Marketing	Sales	
Healios Initial POC in Japan	**Healios** Contract Manufacturing to Lonza	**Under Consideration** (Under Consideration)	**Under Consideration** (Under Consideration)	Medical Institution

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Historical Alleviation of Regulations

Japanese Government Revises Regulations to Put Japan at the Forefront

Process of the Development So Far



- Drastic reduction in the treatment period and number of patients (several dozen) with 'Early Approval System. Insurance is listed at 'Early Approval' stage

* September 2015 Topics: Approval of regenerative medicine products, etc.

- **First conditional time-limited approval : "Heart Sheet" from Terumo**
- **First xenogeneic cell-based regenerative medicine and product approved in Japan: "Temcell HS Injection " from JCR Pharmaceuticals**

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Development Schedule

Japanese Clinical Trials ”in a short time +10 patients” with Conditional Approvals

Field	Development Code	Indication	Market	Pre-Clinical Test	Clinical Test	Apply-Approve	On the Market	Progress Status
iPSC Regenerative Medical Field	HLCR011	Wet AMD	Japan	→				Ongoing Pre-Clinical Test

Assuming to Start in 2017

Assuming Approval with Conditions in 2019

Current Clinical Trials “over a long time + hundreds of patients” (though rule may be revised in western markets)

Field	Development Code	Indication	Market	Pre-Clinical Test	Phase I Test	Phase II Test	Phase III Test	Apply-approve	On the Market	Progress Status
iPSC Regenerative Medical Field	HLCR012	Dry AMD	US	→						Getting Ready for cGMP Production
	HLCR012	Dry AMD	Europe	→						Global Trial Under Consideration based on US Phase III Trial

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Our Experienced Team for Development

Lineup to Develop in Japan, US, and Europe

Ophthalmology Expert



President & CEO

Tadahisa Kagimoto

- Succeeded in Developing BBG and Realized Sales in Europe

Expert in Age-related Macular Degeneration



Director Management of Development Field

Al Reaves

- Led global clinical programs for Visudyne and Lucentis (x-US)
- Innovated first clinical program for advanced Dry AMD

Experts in Immunosuppressant Development



Director of Laboratories in Kobe

Kouichi Tamura

- Astellas US Director of Laboratories
- Well-acquainted with Immunosuppressant Research



Outside Director

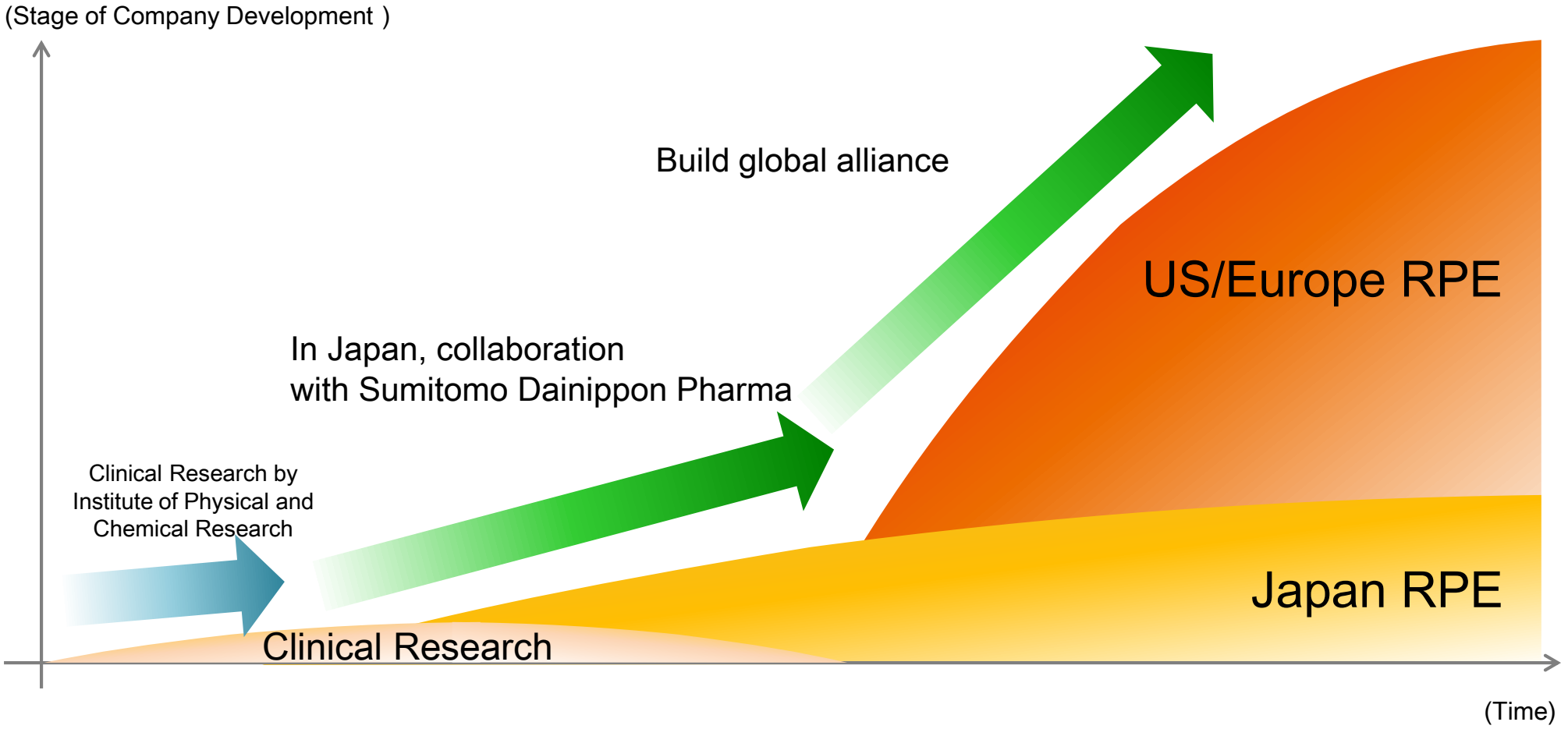
Michihisa Nishiyama

- Constructed Network for Tacrolimus Approval and Sales at Astellas in the US and Europe

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Deal with Development Risk

Ready to build global alliance



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3 ．Future Business Directions

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Future Business Directions Outline

Steadily proceed several pipelines focusing on the growth of the iPSC regenerative medicine area

iPSC Regenerative medicine	RPEs in Japan	Carry out research development activities for starting clinical studies in 2017. In particular, focus efforts on manufacturing preparations at manufacturing subcontractor SightRegen (venture firm established jointly by Healios and Sumitomo Dainippon Pharma).
	RPEs overseas	Optimize manufacturing process at manufacturing subcontractor. At the same time, actively review alliance with other companies.
	3D organs (Liver)	Jointly carry out clinical studies led by Yokohama City University, and also build pipelines based on metabolic liver diseases as indications. At the same time, actively consider alliance with other companies.
Peripheral business areas	New seeds	Review acquisition of new seeds which may further accelerate growth of iPSC regenerative medicine field.
Compounds	BBG	Apply for approval in Japan as more and more countries start selling the product.

Selective criteria	Technical synergistic effects with iPSC regenerative medicine area	Existing human resources can be used	Acquisition of approval at an early stage, increased profits

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Facilitating pipelines for practical application of 3D organs (liver)

iPSC Regenerative medicine	RPEs in Japan	Carry out research development activities for starting clinical studies in 2017. In particular, focus efforts on manufacturing preparations at manufacturing subcontractor SightRegen (venture firm established jointly by Healios and Sumitomo Dainippon Pharma).
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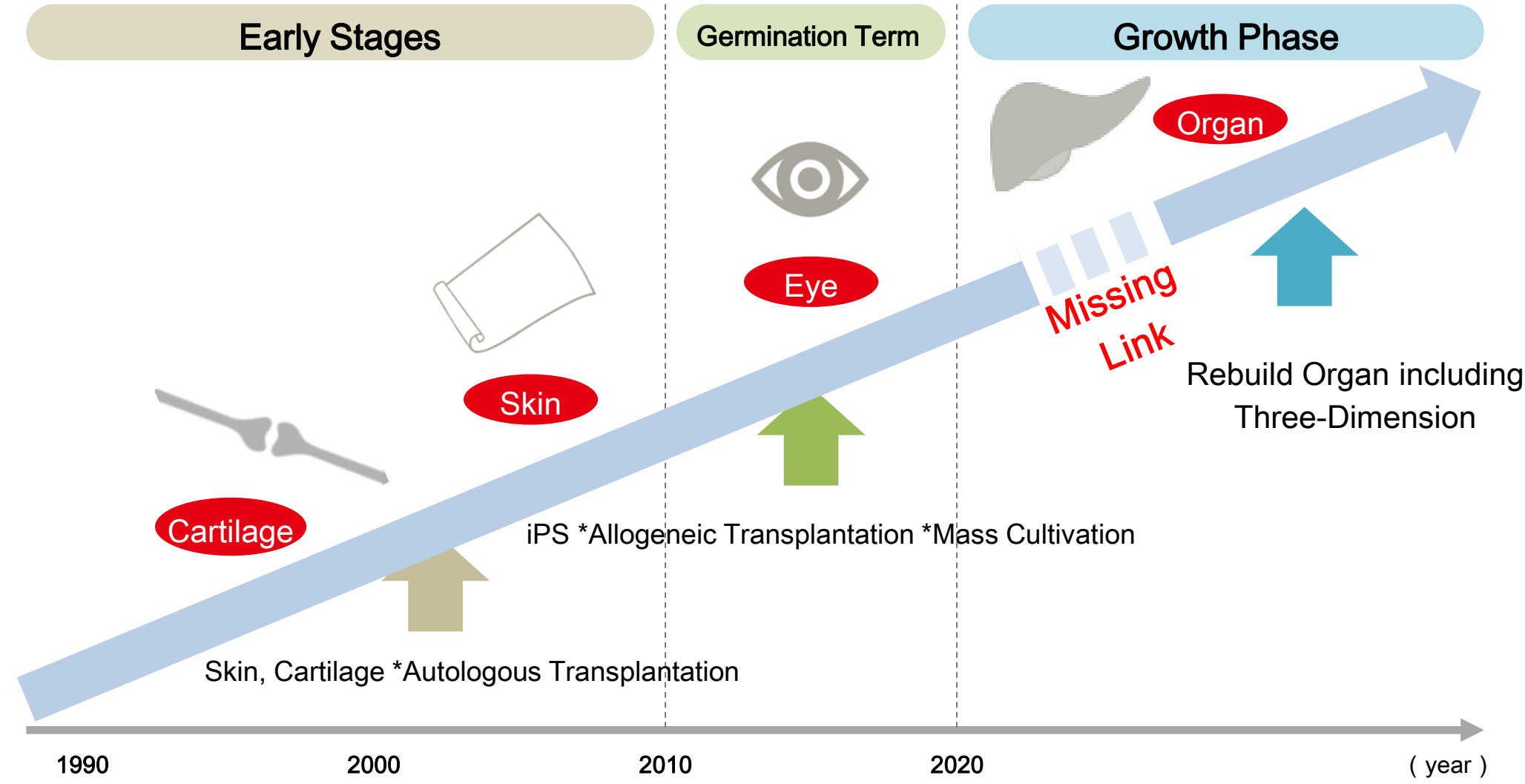
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4 ．Expansion to 3D Organs (Liver)

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Strategy From Now On

Further Expansion when Three-Dimensional Organs Become Possible

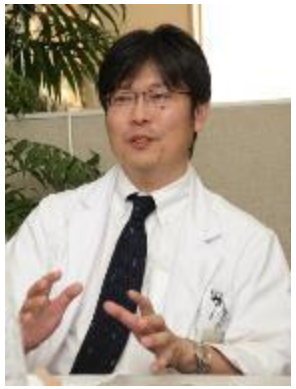


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Facilitating Pipelines in Liver Area

Department of Regenerative Medicine, Yokohama City University Graduate School of Medicine
Joint Research Agreement in Organ Regenerative Medicine

Leading authority of organ regeneration



Department of Regenerative Medicine, Yokohama City University Graduate School of Medicine
Prof. Hideki Taniguchi

1995 MD, PhD, University of Tsukuba Graduate School of Medical Sciences
University of Tsukuba Hospita
2002 Professor, Yokohama City University School of Medicine

2003-2008 Research Unit Leader (Concurrent post)
RIKEN Center for Developmental Biology

2003- Professor, Department of Regenerative Medicine, Yokohama City University Graduate School of Medicine (Main post)

Prominent researcher of human organ construction



Department of Regenerative Medicine, Yokohama City University Graduae School of Medicine
Associate Prof. Takanori Takebe

2009 Researcher, Scripps Research Institute (Chemical Department)
2011 MD, Medical Course, Yokohama City University School of Medicine
Assistant at the university at Department of Regenerative Medicine
2013-Present Associate Professor of Department of Regenerative Medicine, Yokohama City University School of Medicine (Main post)
2015 Associate Professor (Concurrent post)
Cincinnati Pediatric Hospital
Pediatric Digestive Organ Department

- July 2013 *Nature* article: World's First Case of Successfully Creating Functional Human Organ with Vascular Structure from iPS Cells
- December 2013 *Science* article: Chosen as "Science Breakthrough Of The Year" (Top 10 News in the World)
- Received 2014 Baelz Prize: Organ Regenerative Medicine: Paper by Prof. Taniguchi and Associate Prof. Takebe selected.

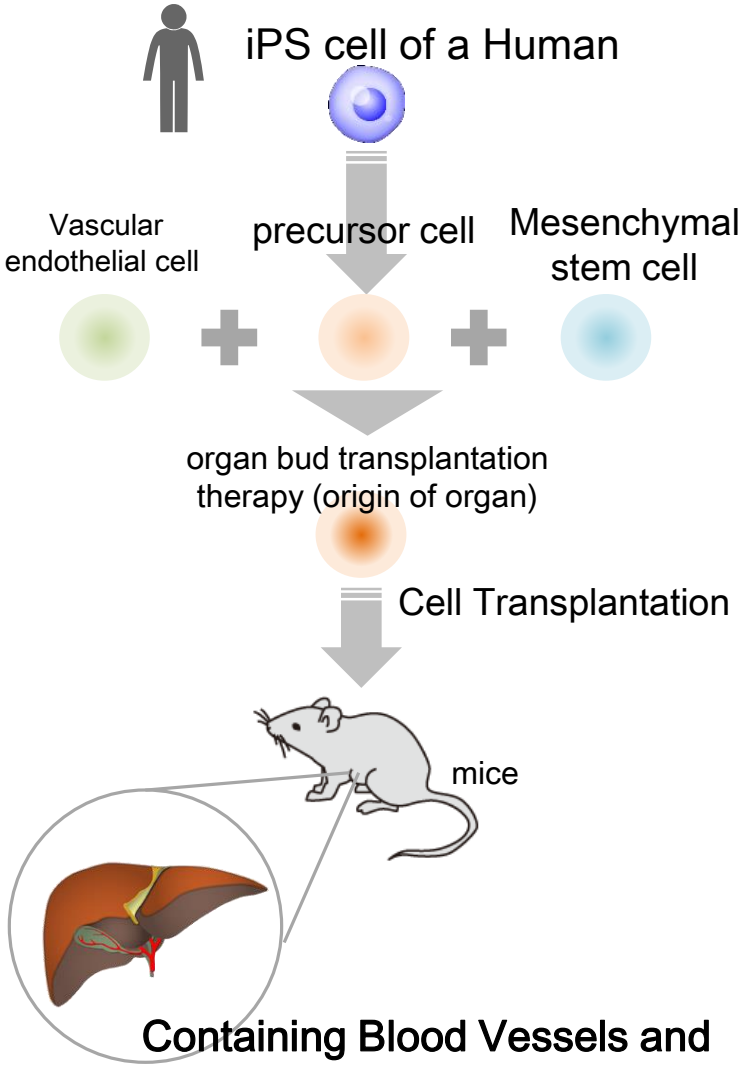
  * Traditional medical prize established in 1964 by Boehringer-Ingelheim with the purpose of deepening medical interchanges between Japan and Germany.

(Source) Compiled by Healios based on the "Department of Regenerative Medicine, Yokohama City University Graduate School of Medicine" website
http://www-user.yokohama-cu.ac.jp/~saisei/index.html

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Development Status of Three-Dimensional Organ

Successfully created liver organ bud by cocultivating 3 types of cells





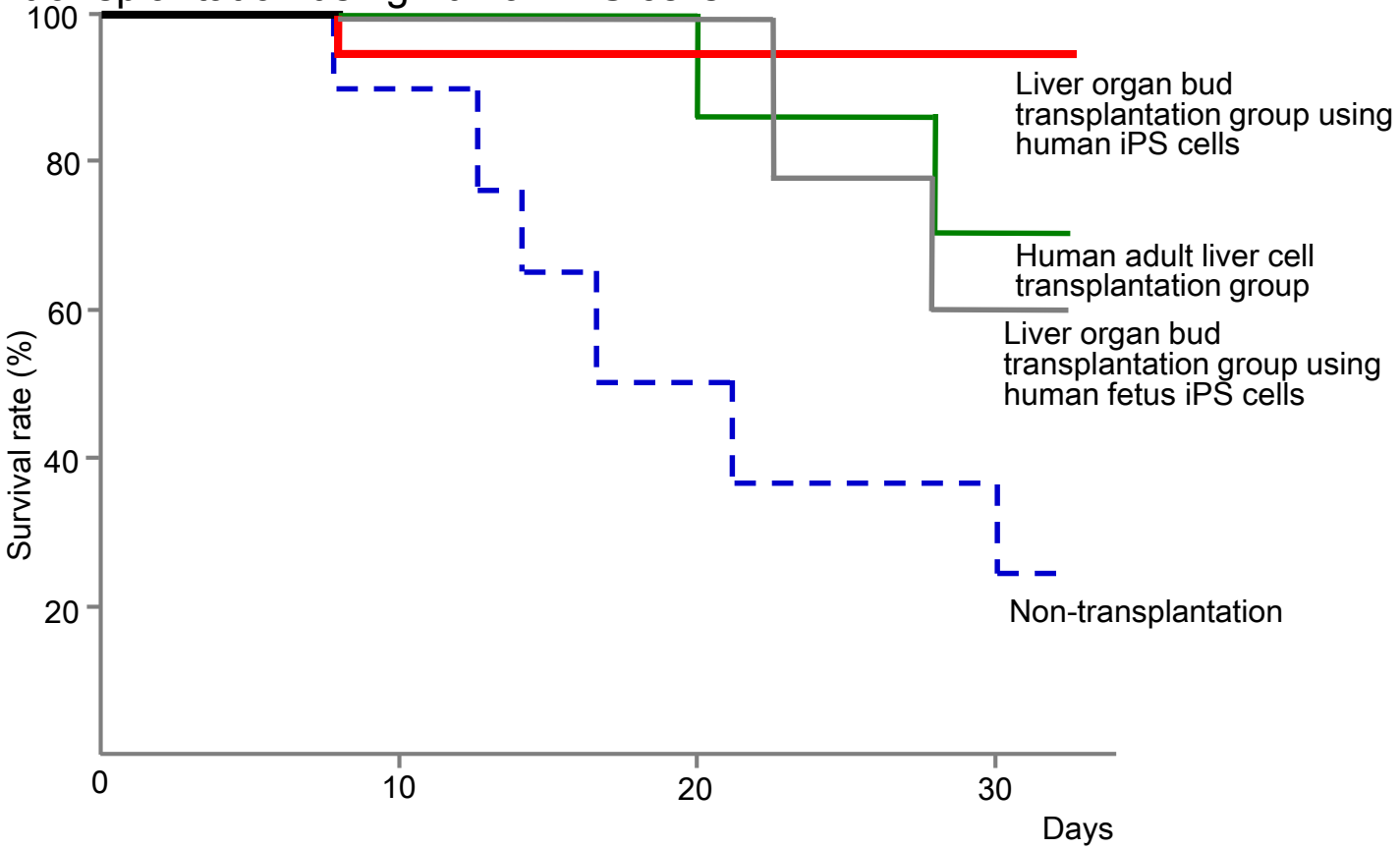
(Source) Japan Science and Technology Agency
Science News “Diverse Approaches in Regenerative Medicine from Cell to Tissue/Organ”
(Distributed October 3, 2013)
https://sciencechannel.jst.go.jp/M130001/detail/M130001005.html

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Survival Rate of Liver Failure Model Mouse

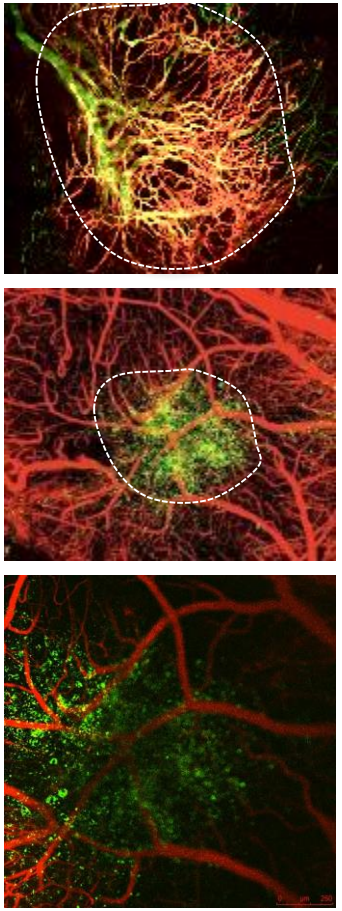
Survival rate improves significantly in transplantation experiments

Treatment effects of liver organ bud transplantation using human iPS cells



(Source) Adapted bu Healios from Takebe. T, et al. Nature, 499 (7459), (2013)

Process in which organ formed from organ bud links mouse ‘s vascular network autonomously



(Source) Takebe,T., et al.
Nature Protocols, 9, 396–409 (2014)

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Metabolic Liver Disease in Newborns

Yokohama City University planning to start clinical study in 2019

Target

Metabolic liver disease “urea cycle defect,” etc.

Urea cycle defect

Disease caused by congenital abnormality of enzyme functioning in metabolic pathway (urea cycle) which detoxifies ammonia in the liver and produces urea.

Present treatment

Presently, the only definitive treatment available is liver transplantation.

* Even patients with minor conditions require treatment combining food treatment and medication to lower ammonia levels throughout their lives.

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Marketability (Newborns Metabolic Liver Disease)

Estimated market size of metabolic liver disease in newborns

	US	Japan	Europe	Total
Number of patients (year)	Approx. 160	Approx. 30	Approx. 230	Approx. 420
Treatment costs (Annual) Enzyme replacement therapy	30–50 million yen			
Estimated annual market scale	5–8 billion yen	1–1.5 billion yen	6–11.5 billion yen	12–21 billion yen

* Number of patients and market size are estimated by Healios based on number of newborns, incidence rate.

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Expansion of Marketability (Alternative Treatment for Replacing Liver transplantation)

Prospecting R&D for alternative treatment for liver transplantation

	Liver transplantation			Total
	US	Japan	Europe	
Number of patients undergoing treatment (Annual)	Approx. 6,000	Approx. 400	Approx. 4,000	Approx. 10000
Number of patients on waiting list (Annual)	Approx. 15,000	Approx. 400	Approx. 4,000	Approx. 20000

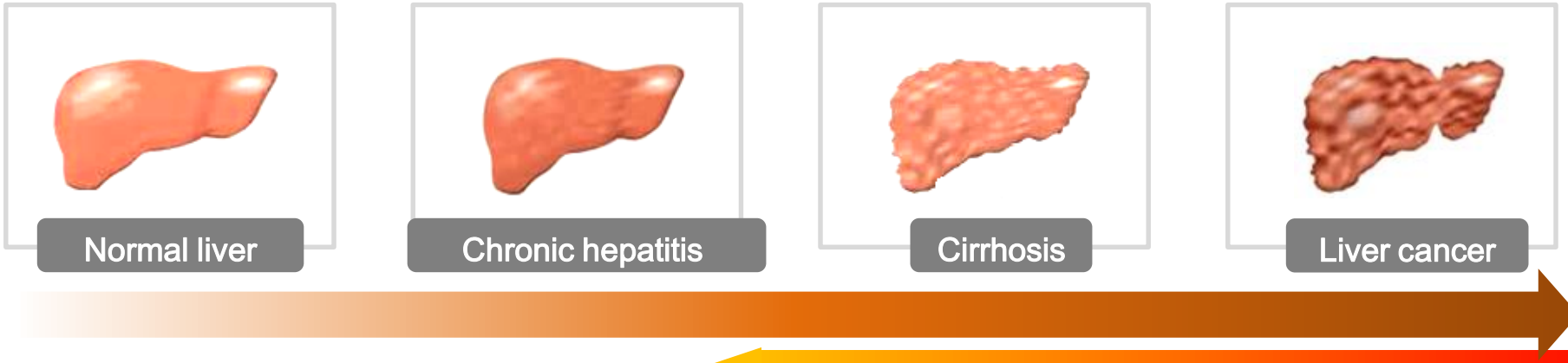
（Source）Compiled by Healios based on materials disclosed by Japanese Liver Transplantation Society, UNOS, Eurotransplan, UK Transplant, Agence de la biomédecine, and Scandia Transplant.

Liver disease drawing attention in future is cirrhosis

Estimated patients with cirrhosis in Japan: 400,000 to 500,000. About 56,000 receive treatment at medical facilities.
Annual deaths in Japan: 17,000 patients.

（Source）Patient Survey 2011 Liver Cancer White Paper 2015

Progress of liver disease



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Towards Practical Application of 3 D Organ (Liver)

Aiming for early realization of regenerative medicine for liver disease patients

Mass cell culture technologies

- Need to produce mass volume of cells compared to RPE
- Mass cell culture technique of GMP grade such as mesenchymal stem cell

Fundamental technologies

- Enter globally exclusive patent licensing agreement related to human organ bud construction
- Steadily promote joint research

Alliance

- Cell donor partners
- Joint development partners
- Distribution partners

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Acquired Three Competitive Advantages

Acquired Core Position in New Industries and Rapidly Advancing Further

Healios

Merit of Proceeding

Experience and Deep Understanding of Transplantation Treatment

- Knowledge on medical scene and applicable diseases = Unmet medical needs× Determine technological superiority surpassing existing treatments

Knowledge（Permission・Know-How about Cell Cultivation）

- Establish target cell line method
- Build up effective cultivation method at industrial level
- Understand regulations of different countries

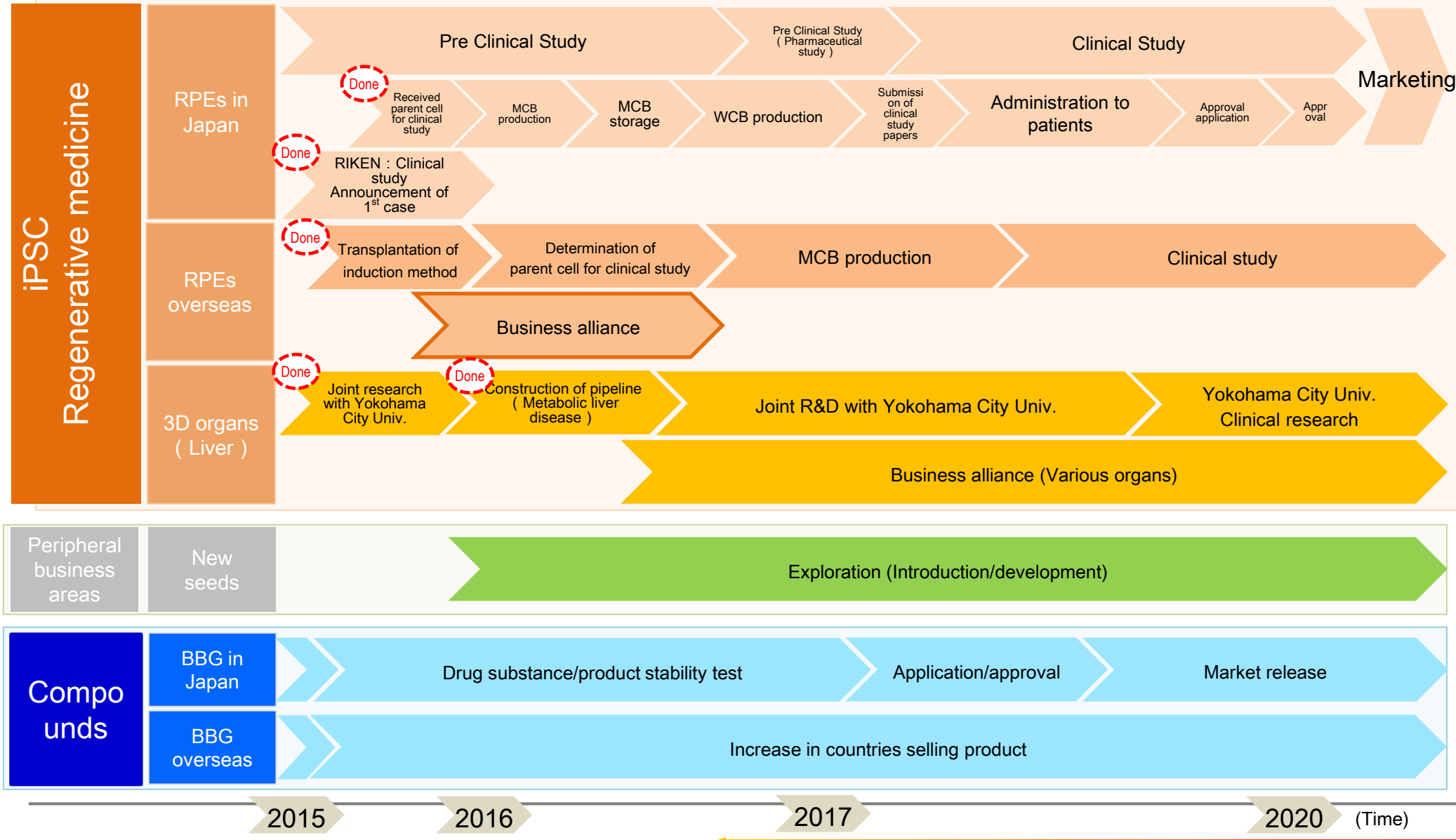
Manufacturing（Stable Manufacturing of Products）

- Promptly implement through alliance with partners
- Automated Culture Machine

To the World

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Summary of Main News Follow-Up



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5．Financial Highlights

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Statement of income

(Million yen)

	3Q FY2014	3Q FY2015			FY 2015	
			YoY change	Reasons for increase/decrease	Previous forecast	Revised forecast
Sales	259	76	▲183	Reaction to appropriating milestone income of 200 related to RPE cells products in precious period	73	95
Operating income	▲289	▲705	▲415	Sales dropped ▲183 (Above) R&D costs increased▲174	▲1,638	▲1,171
Ordinary income	▲192	▲611	▲419	-	▲1,588	▲1,063
Net income	▲198	▲582	▲383	-	▲1,591	▲1,033
R&D	201	375	+174	Reinforcement of development system (recruitment), promotion of R&D	986	692
Amortization of goodwill	75	75	-	-	100	100
Number of employees	27	42	+15	-	-	-

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Balance sheet

(Million yen/%)

		December 31, 2014		September 30, 2015	
				YoY change	Main reasons for increase/decrease
	Current assets	2,064 (65.1%)	9,604 (88.9%)	7,540	Cash and deposit +7,599
	Non-current assets	1,107 (34.9%)	1,194 (11.1%)	86	
Total assets		3,171 (100.0%)	10,799 (100.0%)	7,627	
	Current liabilities	475 (15.0%)	1,021 (9.5%)	545	
	Non-current liabilities	31 (1.0%)	30 (0.3%)	△0	
Total liabilities		507 (16.0%)	1,051 (9.7%)	544	
Total equity		2,664 (84.0%)	9,747 (90.3%)	7,082	Capital +3,846 Capital surplus +3,846 Earned surplus ▲582
Total assets		3,171 (100.0%)	10,799 (100.0%)	7,627	

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Appendix: Explanation of Terms

iPSC Regenerative Medicine

Form of treatment with human tissue equivalent functions produced by differentiating iPS cells.

Age-related Macular Degeneration (AMD)

Degeneration in the macula (located at the center of the eye) resulting from aging. Distortion and/or failure of vision can occur. This is roughly divided into two types: Wet and Dry

Retinal Pigment Epithelial Cells (RPE Cells)

Cells located in the outer retina responsible for the decomposition of nutrition and waste in the eye. AMD will develop from the aging of the RPE cells.

Autologous (Self) Transplantation

The culturing of cells taken from the patient's body and returned to the site of the disease. Suffers from problems with culture efficiency.

Allogeneic (Cross) Transplantation

Cultured cells taken from donors in advance and stored for future use. Large quantities can be cultured for the required purpose.

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Important Note on Future Events, etc.

Descriptions on future events, etc. in this document include Healios' assumptions, prospects, etc. based on information which could be acquired at the time this document was presented. For this reason, actual performance, development progress, etc. may differ from those described in this document according to the outcome of R&D in the future, the actions of regulatory authorities, etc. in the future, and uncertain/pending factors as of this point.

Also, this document contains information on regenerative medicine and medical equipment that are currently under development or already on the market. Such information is not intended for promoting advertising or providing medical advice.

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