

CiRA Foundation Activity Report



Message from
Representative
Director of CiRA_F

Bridging laboratory results to clinical results

In April 2020, we began the CiRA Foundation, and we are now celebrating our first anniversary. I would like to express my heartfelt gratitude to all of you for your continued support.

Fourteen years have passed since the announcement of human iPS cells. The Center for iPS Cell Research and Application (CiRA), Kyoto University, has been acting as a "bridge" to transfer technologies for iPS cell production and quality evaluation to industry. However, because CiRA is part of a university and therefore founded as an educational and research institution, its activities are restricted.

The Foundation has taken over the responsibility of the "bridge" from CiRA and continues working to achieve its mission of providing top iPS cell technologies at affordable prices. To assist research institutions and companies, we provide iPS cells for regenerative medicine free of charge to non-profit institutions and at a low price to for-profit institutions. Furthermore, we will contribute to the realization of regenerative medicine by developing

automated cell manufacturing technologies and by sharing versatile technologies and information with companies.

We are just starting our journey on the road to the practical application of iPS cells. Thanks to the efforts of many researchers, clinical trials have begun to verify the safety and efficacy of several iPS cell products. Our work will help commence even more clinical trials. We look forward to your continued support and cooperation.



Shinya YAMANAKA
Representative Director

Anniversary

CiRA_F's 1st Anniversary

<https://www.youtube.com/watch?v=7yUPGlsBS5M&t=236s>



On April 23, 2021, we held an online session to recognize our anniversary and to express our gratitude. Thank you very much to everyone who participated in the event.

Lecture content

- ① The significance of the CiRA Foundation and Future of iPS cells
Speaker : Shinya YAMANAKA, Representative Director
- ② Why we need your support
Speaker : Fumitaka WATANABE, Philanthropy Office Leader

On the day, we also welcomed questions and comments from participants.

Due to time constraints, we were not able to answer all of the questions, but we had a great opportunity to understand people's interests in our work and on iPS cells in general.

It was also a great surprise to receive questionnaire responses from more than 80% of participants after the session. Many included messages of support to the Foundation. These messages have been shared with our staff members, and we thank all those who wrote them.

We will continue to regularly send out information about our work in accordance with our mission, "Walking with patients to lead society".

News

Activities of CiRA_F

January 2021



Obtained a manufacturing license based on the PMD Act

CiRA_F has obtained a manufacturing license (general category) for regenerative medicine products based on the Pharmaceutical Affairs and Medical Devices Act (PMD Act) in Japan. By obtaining this license, we can expand the range of collaborations with companies and contribute to the regenerative medicine industry.

February 2021



Basic agreement with Thyas for the manufacturing of iPS cell-derived T cells

CiRA_F has signed a basic agreement for the manufacturing of autologous regenerated T cells by Thyas. Joint research with Thyas for the my iPS Project to produce autologous regenerated T cells has also started.

March 2021



Began accepting applications for the free provision of iPS cells made from convalescent COVID-19 patients

The collaboration team to the left has established iPS cells from the peripheral blood of patients who have recovered from SARS-CoV-2 infection. These iPS cell lines are being distributed free of charge to companies and research institutes for the study of COVID-19, such as the onset mechanism.

April 2021



Platelets derived from the CiRA Foundation iPS Cell Stock enter an industry-led clinical trial

Evaluation of the clinical trial plan has been completed. This project is in collaboration with Megakaryon Corporation, Kyoto University Hospital, and the Center for iPS Cell Research and Application (CiRA), Kyoto University. CiRA_F is responsible for the manufacturing, the non-clinical safety evaluation, and the quality assessment of human iPS cell-derived platelets.

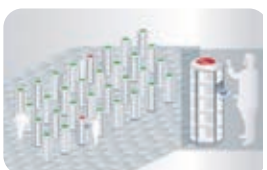
May 2021



First shipment of our iPS cell stock to an overseas partner

Our iPS cell stock arrived at CHA University, South Korea, safely at the end of May this year. We also plan to provide HLA-homozygous iPS cell stock to Novo Nordisk, which is a global pharmaceutical company headquartered in Denmark.

July 2021



A base facility for the my iPS Project has been selected

We have decided to locate the base facility for the my iPS Project in Osaka. For more details on the project, please see "The Present and Future of iPS Cells" on page 4. The facility will be open to the public, donors, and visitors from research institutes, etc. We hope that it will not only be a place where people can learn about iPS cells, but also a place to disseminate information to young people who aspire to become researchers in the future.

*In addition to the above news, we are working with many companies and organizations on donations. Thank you very much for your cooperation.

Principles

The Four Guiding Principles of the Foundation

In January 2021, CiRA_F announced four guidelines.
These guidelines serve our work every day.



MISSION

Walking with patients to lead society

We understand that to be a leader in medical technology, we must be always developing our technology. But our most important motivation is the patient.

Thus, to us, development is not simply pushing technology forward. It is standing with patients and understanding their needs. This is our mission.

PHILOSOPHY

Top iPS cell technologies at affordable prices

To bring iPS cells to the clinic as quickly as possible, we will bring technologies for cell manufacturing and quality control to industry.

As technology develops, so will we.

By collecting and sharing information on research and development, we will raise the quality, lower the cost, and ultimately advance clinical applications.

VALUES

People are our driving force

Why do we do this work? Because of people. These people include, of course, patients, but their families too. They also include our partners who hold our passion and ideals.

If it were only us, it would be easy to give up. But because people are our driving force, we devote ourselves to raising the quality of iPS cells at affordable prices and acting as a bridge to industry.

CODE of CONDUCT

To advance, to appreciate, to share

We believe the goals of our employees and our partners are the same: to provide high quality iPS cells at affordable prices. Because we share the same purpose, we recognize the importance of advancing each other's skills, appreciating each other's roles, and sharing each other's accomplishments. With priority to the patients, we will take on our challenges.

Topics

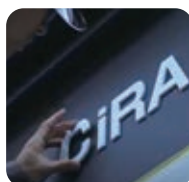
Milestones to date

April 1, 2020.

CiRA_F started its activities with 83 people reassigned from CiRA and 5 new hires.

Due to the spread of COVID-19 infection, we had to cancel the unveiling ceremony that we prepared for this day.

As a separate entity from Kyoto University, we had to establish new employment rules, launch our website, and make other changes, all of which required a concerted effort by our staff.



In order to handle a large amount of important research and manufacturing data, the creation of a network system was also critical at

the time of inception.

We received support from a number of companies to prepare the system so that we could start operating about 100 computer terminals within a preparation time of five months, including the conceptualization.

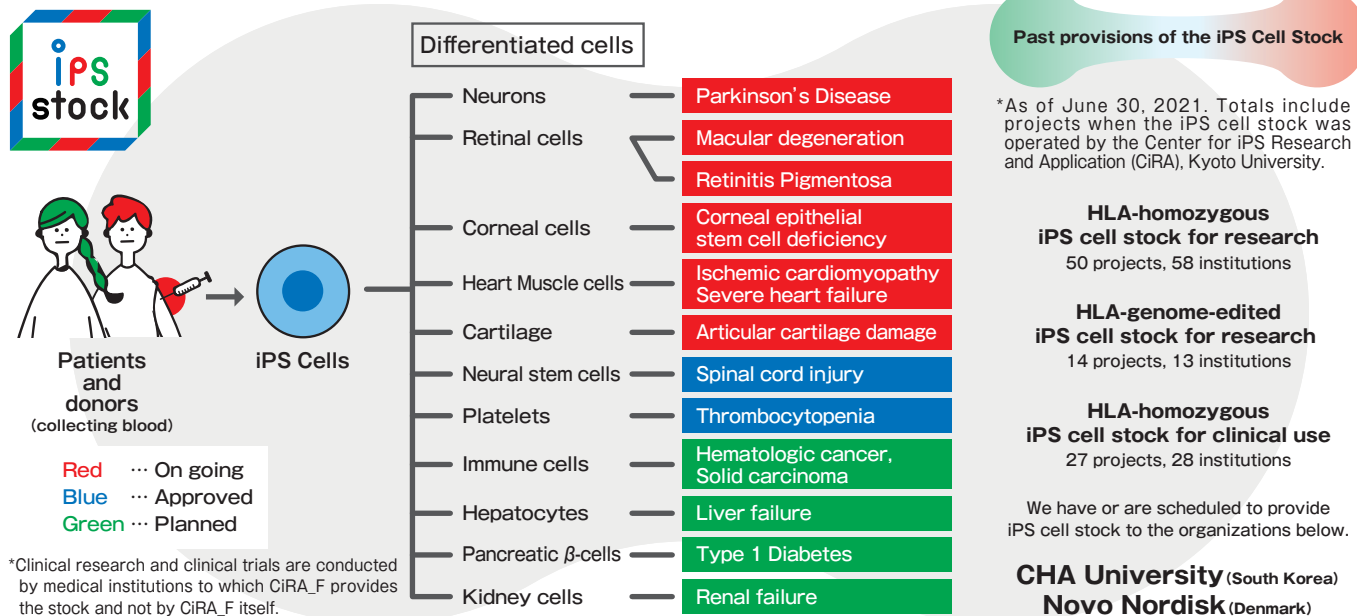


Our growth and activities are because of the cooperation of many people every day. We hope that you will continue to support us in our efforts.

Project

Clinical research and clinical trials using the iPS cell stock

Clinical research and clinical trials using the CiRA_F iPS cell stock are being conducted for various diseases and disorders. A list of diseases and the cell types made from the iPS cell stock used to study them are given below. All iPS cells are reprogrammed blood cells.

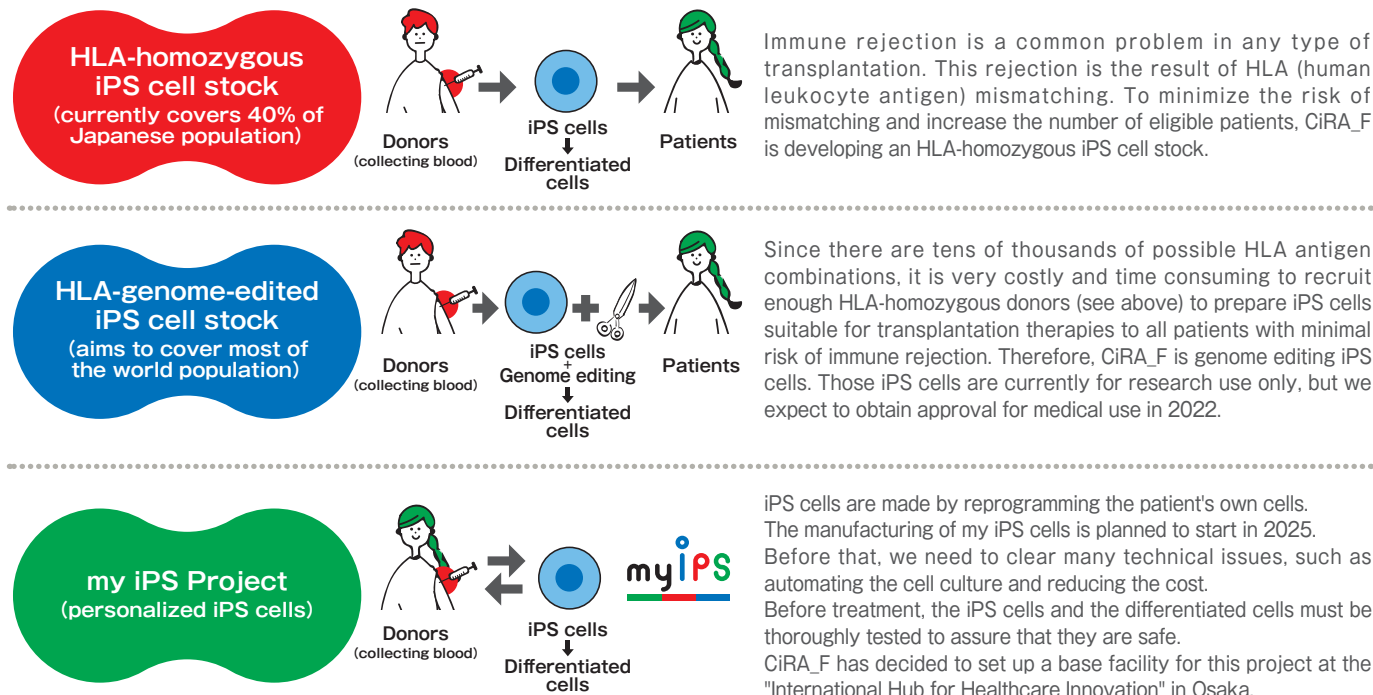


*Clinical research and clinical trials are conducted by medical institutions to which CiRA_F provides the stock and not by CiRA_F itself.

Future

The Present and Future of iPS Cells

Below are current projects at CiRA_F.



*When actually used to treat patients, iPS cells must be differentiated beforehand.

