The Regenerative Medicine National Consortium

RMNC

JSRM

The Regenerative Medicine National Consortium (RMNC) aims to achieve an environment of open innovation in the social implementation of regenerative medicine. This is done by taking knowledge and experience relating to clinical research and clinical trials on regenerative medicine that has been developed in leading research institutions in Japan and structuring it as shared knowledge that can be ↗ utilized by all research institutions and companies. Reducing the barriers to entry in regenerative medicine research and development, which is still in the process of widespread adoption, will accelerate patient access to novel treatments. The RMNC consists of the following six modules, and the results are available to domestic and overseas research institutions and companies.

Office for National Consortium, JSRM
nc@jsrm.jp

1 Clinical Research Support Module

Research institutions with advanced knowledge such as precedent cases act as consultants for resolving various bottlenecks in clinical research and clinical trials. We support not only wet tasks but also dry tasks such as paperwork, and approximately half of our clients are companies. In FY2016–2022, we worked on over 110 projects, of which over 60 have achieved goals such as stage-ups. We cover a wide range of phases, from basic stem cell technology to allogeneic cell supply chains, development strategy using organoids, ES cell regulatory compliance, ELSI and pre-clinical/clinical research on children, problems related to ethical review in Japan, and coordination with regulatory authorities (PMDA). >

2 Human Resource Development Module

We provide educational programs for all stakeholders involved in regenerative medicine. We have published textbooks that comprehensively cover the entire scope of regenerative medicine, and we have also developed content such as video teaching materials and E-learning content that visually convey the practice of cell culture operations for cell culture engineers. Several of these products are also available in English and Chinese. Additionally, we have established a system for certifying doctors, cell culture technicians, and CPF managers. This system can be used as a standard when patients select medical institutions or when medical institutions and companies recruit human resources. >

3 Academia–Industry Collaboration Module

We seek to achieve an ecosystem that integrates various elemental technologies such as cell collection, culture processing, storage, and transportation, which are necessary for the development of regenerative medicine products, by promoting scientific discussion of each process and publishing regulatory policy recommendations based on these discussions. Additionally, regenerative medicine-related intellectual property has the potential to include special intellectual property not only for the content of the final product but also for the entire production and supply process. Therefore, we provide information on the acquisition, development, management, and utilization of intellectual property at seminars and other events. >

4 Public and Patient Involvement Module

We seek to promote social acceptance of regenerative medicine, which is a new medical technology, by not only disseminating information unilaterally to the general public but also by holding interactive events with patients and citizens. We are also working on risk communication in order to curb excessive expectations regarding regenerative medicine and the spread of treatment choices based on objective judgment. >

5 International Collaboration Module

JSRM has established partnership agreements with institutions related to regenerative medicine worldwide such as academic societies, industrialization support organizations, and think tanks, and has promoted collaboration for the social implementation of international regenerative medicine beyond the exchange of research results. Through international conferences, we widely disseminate information on conditional and time-limited approval under the Pharmaceuticals and Medical Devices Act as well as clinical applications of iPS cells. >

6 Appropriateness Assessment Module

We use real-world evidence in order to evaluate whether clinical research conducted at research institutions and private practice conducted at private clinics have sufficient safety and effectiveness. For treatments that have a certain number of cases, we are building patient registries using data that ensure pharmaceutical quality and verification of whether the treatments are considered scientifically appropriate. In the future, we will conduct demonstration experiments with the aim of creating a system in which private insurance can cover treatment methods that have been evaluated as being appropriate. –