

ISCA

NEWSLETTER



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MAY

2021





To mark the developing formation of this collaborative academic consortium a formal and distinctive name the International Stem Cell Alliance (ISCA) has been chosen after the earlier discussions in the partner meeting in January and an exchange meeting with ISSCR in March. Further information on the ISCA name and logo is listed on page 5 of this issue.

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Welcome

Welcome newly engaged partners



Prof Wataru Fujibuchi

Professor, Center for iPS Cell Research and Application (CiRA), Kyoto University, Japan.

Welcome NDA signatory

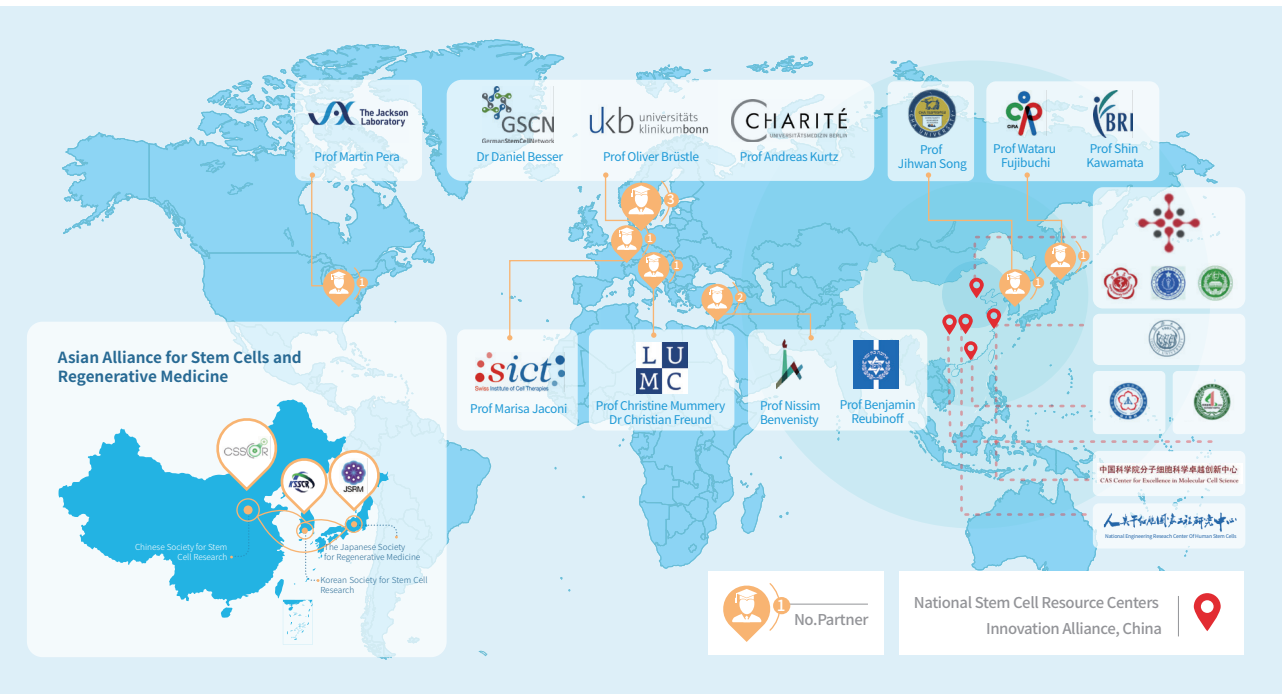


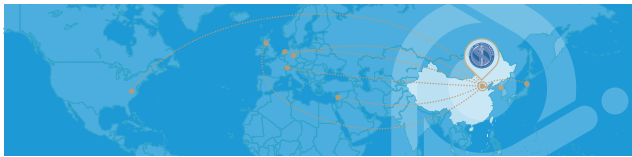
Prof Peter Andrews

Emeritus Professor, The University of Sheffield, UK.

January 2021 Partner Matrix

Each partner gave a presentation on their expertise, activities, and resources. A summarized partner matrix is summarized for partners' comments and feedback. We expect the developing partner matrix will provide opportunities for collaboration and become the leading workforce to drive the future advances in this exciting field. Please see detailed summary in Appendix 1.





Partner	Specialist local facilities/infrastructure
<p>Hebrew University of Jerusalem Prof Nissim Benvenisty</p>	<ul style="list-style-type: none"> -Biobank of haploid hESCs as a public service -Bioinformatics expertise for analysis of genetic changes
<p>German Stem Cell Network Dr Daniel Besser</p>	<ul style="list-style-type: none"> -PluriCore coordination of 23 hiPSC core labs in Germany/Europe
<p>University of Bonn Prof Oliver Brüstle</p>	<ul style="list-style-type: none"> -Life and Brain GmbH, focusing on PSC-based neural products and assays as well as automated cell culture and reprogramming (STEMCELLFACTORY) -Advanced tissue imaging and services
<p>Swiss Institute of Cell Therapies Prof Marisa Jaconi</p>	<ul style="list-style-type: none"> -Seven GMP manufacturing centers across Switzerland with allied clinical networks
<p>Fraunhofer-IBMT and Charité University Medicine Prof Andreas Kurtz</p>	<ul style="list-style-type: none"> -EBISC biobank and database www.ebisc.org -hPSCreg EC registry and database (EC) -Regenerative medicine manufacturing centre
<p>Leiden University Medical Centre Prof Christine Mummery, Dr Christian Freund</p>	<ul style="list-style-type: none"> -hiPSC and MPS Hotel: <ol style="list-style-type: none"> 1) hiPSC Biobank and gene editing service 2) Manufacture of microfluidic chambers and miniaturization for Emulate, AimBiotec and Mimetas platforms -NECSTGEN product development and GMP manufacture
<p>Jackson Laboratories Prof Martin Pera</p>	<ul style="list-style-type: none"> -Mouse and human genetic resources -Stem cell research mouse-models for preclinical safety and efficacy studies
<p>Hadassah hESC Research Centre Prof Benjamin Reubinoff</p>	<ul style="list-style-type: none"> -Large scale manufacture of hESC-derivative products -GMP accredited cell manufacturing facility with EU & USFDA compliant QA and regulatory platform for translation of hESCs to Phase III clinical trial
<p>CHA University Prof Jihwan Song</p>	<ul style="list-style-type: none"> -iPSC Bio iPSC manufacturing company -Korea HLA-Typed iPSC Banking (KHiB)

MEETING AND BRIEFING

March

Dialogue with ISSCR

The first exchange meeting between representatives of International Society for Stem Cell Research (ISSCR) and International Stem Cell Alliance (ISCA) was held at 9-10 pm on March 18th, 2021 (GMT+8). Prof Tongbiao Zhao gave a presentation to introduce the ISCA and explain the aim, partnership development, funding sources, special expertise, established projects, and primary outputs. In representation of ISSCR, Prof Christine Mummery and Keith Alm responded with a summary of ISSCR activities. The attendees agreed that the meeting had been very useful introductory dialogue for the two groups and would be the starting point to initiate future coordination and collaboration. ISSCR attendees encouraged ISCA membership to attend the upcoming 'Digital series' of online meetings and ISCA attendees welcomed ISSCR attendees to participate in open ISCA meetings.

It was also proposed to hold a face-to-face meeting in China when international pandemic controls allow.



ISCA name and logo

Upon the exchange meeting with ISSCR, the name for the network (initiated as Chinese International Stem Cell Network, CISCN) was accepted as International Stem Cell Alliance (ISCA).

April**First ISCA IP Advisory Meeting**

The first ISCA IP advisory meeting was held at 10-11 pm on April 7th, 2021 (GMT+8). A group of IP experts recommended by ISCA partners had provided detailed responses to the ISCA questionnaire on IP and licensing issues and participated in the meeting. A range of topics were discussed and the group helped to shape the direction for future discussion on key IP issues. A meeting summary has been circulated for comment by the discussion group and a proposal is being prepared for a further meeting later in the summer. Future contributions had been invited from the licensing groups of the UK Cell and Gene Therapy Catapult and the CiRA centre in Japan.

**April****Brief Report of PSConf 2021**

The Pluripotent Stem Cell Conference 2021 (PSConf 2021) was held April 21-26, 2021, held at the Institute for Stem Cell and Regeneration, Chinese Academy of Sciences and Beijing Institute for Stem Cell and Regenerative Medicine in Beijing, China. In response to COVID-19, restrictions PSConf was arranged with online formats to provide livestreaming and recording for a total of 136 delegates from

PSCConf 2021
International Symposium and Workshops on Development of hPSCs for Clinical Application
On-line & Off-line April 21st-26th, 2021

CO-HOSTS:
 Institute of Zoology, Chinese Academy of Sciences
 Institute for Stem Cell and Regeneration, Chinese Academy of Sciences
 Beijing Institute for Stem Cell and Regenerative Medicine

CO-ORGANIZERS:
 International Stem Cell Forum
 Chinese Society for Stem Cell Research
 National Stem Cell Resource Centers Innovation Alliance, China
 National Stem Cell Resource Center, China

IN COLLABORATION:
 Human Pluripotent Stem Cell Registry
 International Stem Cell Banking Initiative
 International Stem Cell Initiative

SUPPORTED BY:
 Chinese Academy of Sciences

23 countries registered at the conference website (<http://www.2021psconf.com/>). The theme of the conference was to identify the current gaps in knowledge and technology and priorities for future research in human pluripotent stem cell (hPSC)-based manufacturing. With this theme, the conference aimed to provide an opportunity to facilitate communications and promote development of this field.

International Symposium on Development of hPSCs for Clinical Application



Qi Zhou **China**
 Chinese Academy of Sciences



Baoyang Hu **China**
 IOZ / ISCR, CAS; Beijing Institute for Stem Cell and Regenerative Medicine



Christine Mummery **Netherlands**
 Leiden University



Peter Andrews **UK**
 University of Sheffield



Nissim Benvenisty **Israel**
 The Hebrew University of Jerusalem



Glyn Stacey **UK**
 Coordinator and Director, ISCBI



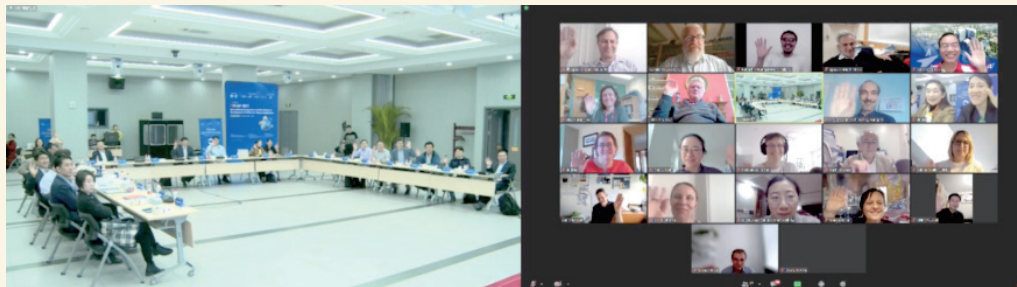
Bridging Session: Engaging Chinese Networks and International Groups (hPSCreg, ISCBI, ISCI)

The bridging session, organized on 21 April 2021, brought together the leadership of the Chinese Society for Stem Cell Research (CSSCR), National Stem Cell Resource Centers Innovation Alliance, the human Pluripotent Stem Cell Registry (hPSCreg), the International Stem Cell Banking Initiative (ISCBI) and the International Stem Cell Initiative (ISCI). All participants reaffirmed their commitment to synergize global efforts for the development of stem cell-derived products.

A draft statement was developed where key areas for further co-operation were highlighted, including:

- 1) standards development,
- 2) genetic stability and safety of stem cell-derived medicines,
- 3) international regulatory issues and best practice,
- 4) training initiatives for stem cell technology,
- 5) stem cell ethics and data sharing,
- 6) intellectual property and licensing for stem cell lines, culture systems, protocols and products.

This session aimed to foster international coordination in the abovementioned aspects and we envision that such joint efforts will drive the global agenda together to advance the frontiers in this exciting field.



Training Session

On April 22nd, a training session including international speakers was organized, with a total of 12 speakers from 8 countries including Korea, Singapore, China, Japan, Germany, UK, and France, providing training courses on cell differentiation and reprogramming, clinical application, standards development, AI-based data mining, stem cell ethics, etc. Around 70 trainees from different regions of China actively participated both onsite and virtually.



Panel Discussion on hPSC Manufacturing: Scale-up and Differentiation & Product Formulation and Release

More than 40 panelists from over 15 countries participated in workshops on human pluripotent hPSC manufacturing, featuring topics on scale-up and differentiation, and product formulation and release.

This meeting recognized key research priorities for hPSC manufacturing, including:

- 1) cell line genetic stability,
- 2) cell system interactions and relevant critical production parameters,
- 3) technical challenges in differentiation pathways and control measures,
- 4) bioreactor scale-up systems and cost-effective manufacturing processes,
- 5) effective tools and protocols for biopreservation and recovery,
- 6) safety of engineered cells,
- 7) tumorigenicity assays,
- 8) validation tools and effective critical quality attributes.

All delegates agreed that it was important to promote international coordination in setting global standards and felt the urgent need for collaborative effort.



Alex Zhang China
Zephyrm



Cedric Ghevaert UK
University of Cambridge



Jane Lebkowski USA
Regenerative Patch Technologies



Kapil Bharti USA
National Eye Institute / National Institutes of Health, USA



Benjamin Reubinoff Israel
Hadassah University Medical Center



Roger Barker UK
University of Cambridge



Patricia Murray UK
University of Liverpool



Shugo Tohyama Japan
Keio University



Jianchao Gao China
center for drug evaluation,
national medical products administration, china

Plans for ISCA Activities in Second-half of 2021

June 2021

Comments and Feedback on PSConf 2021

August/September 2021

ISCA Collaboration Discussions

December 2021

ISCA Session at CSSCR Annual Meeting

Appendix 1: Partner Matrix

Partner	Research projects and key activities	Specialist local facilities /infrastructure	Non-scientific activities
<p>Hebrew University of Jerusalem</p> <p>Prof Nissim Benvenisty</p> <p>http://benvenisty.huji.ac.il/</p>	<ul style="list-style-type: none"> -Derivation and application of haploid hESCs -Genomic stability and tumorigenicity studies including point mutations, chromosomal abnormality, epigenetic aberrations, and consequences of genetic manipulation -Disease modelling -Drug screening/discovery -Cell therapy, strategy to eliminate tumorigenic PSCs 	<ul style="list-style-type: none"> -Biobank of haploid hESCs as a public service -Bioinformatics expertise for analysis of genetic changes 	<p>Active on policy committees in Israel</p>
<p>German Stem Cell Network</p> <p>Dr Daniel Besser</p> <p>www.gscn.org</p>	<ul style="list-style-type: none"> -Supports harmonisation and standardisation in hiPSC research and translation - Provides a platform for science strategy (now funded by BIH) -EuroStemCell partner 	<ul style="list-style-type: none"> -7 Scientific and 7 strategy working groups including the German regulator PEI -PluriCore coordination of 23 hiPSC core labs in Germany/Europe -Outreach office 	<ul style="list-style-type: none"> -Teaching -Public engagement and information (30% activity) -Programme to deliver white papers on: 1) public funding of stem cell research–Germany in an international comparison, 2) translation–from stem cell to innovative therapy, and 3) organoids
<p>Institute for Reconstructive Neurobiology (University of Bonn)</p> <p>Prof Oliver Brüstle</p> <p>http://www.meb.uni-bonn.de/rnb/</p> <p>https://www.lifeand-brain.com</p>	<ul style="list-style-type: none"> -Neural cell biology Establishment of stable intermediate neural stem cell types, Standardized human neural cell cultures (2D & 3D) PSC pipeline 1) conventional differentiation with extrinsic factors, 2) forward programming, 3) cortical organoids, 4) cortical spheroids, 5) iPSC suspension cultures -Disease modelling, drug screening, and cell therapy -Impact of ageing on development -Neural transplantation -Translation to cell therapy -EuroStemCell partner 	<ul style="list-style-type: none"> -Life and Brain GmbH, a Translational Platform of the University of Bonn Medical Faculty and the University Hospital Bonn focusing on PSC-based neural products and assays as well as automated cell culture and reprogramming (STEMCELL-FACTORY) -Advanced tissue imaging and services 	<p>Initiated the StemCellNetwork North Rhine Westphalia (StemCellNetwork.NRW), one of the first networks in the global stem cell scene</p> <p>StemCellNetwork.NRW is permanently funded by the state of North Rhine Westphalia and covers biomedical, ethical and legal aspects; strong focus on supporting junior scientists</p> <p>https://www.stammzellen.nrw.de/en/</p>

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<p>Swiss Institute of Cell Therapies and University of Geneva</p> <p>Prof Marisa Jaconi</p> <p>www.swiss-ict.ch</p>	<ul style="list-style-type: none"> -Coordinated manufacturing network for novel cell therapies (current clinical trials for cartilage and muscle repair) -Contract manufacture for other parts of Europe 	<ul style="list-style-type: none"> -SICT is a private foundation of public interest with the goal of setting up public-private partnerships to accelerate clinical translation -7 GMP manufacturing centers across Switzerland with allied clinical networks 	<ul style="list-style-type: none"> -Swiss Stem Cell Network -Close coordination (M Janconi) with Swissmedic regulatory body
<p>Fraunhofer-IBMT and Charité University Medicine</p> <p>Prof Andreas Kurtz</p> <p>https://www.ibmt-fraunhofer.de/en.html</p> <p>https://www.charite.de/en/research/charite_research/research_foci/regenerative_therapies/</p>	<p>Biobanking focused on iPSC and iPSC-derivatives</p> <ul style="list-style-type: none"> -Charité group working on immunotherapies -Stem Cell data base development, tools for data management and access and relevant standards -Ethics avatar to assist in modelling approaches to management of personal data -EC funded projects: EBiSC, hPSCreg, Neuro GCT, EuroStemCell, Organoid ethics, hPSC clinical trial database 	<p>IBMT:</p> <ul style="list-style-type: none"> -EBiSC biobank and database www.ebisc.org -hPSCreg EC registry and database (EC) -Regenerative medicine manufacturing centre <p>Charité:</p> <p>GMP facility under construction</p>	<p>Member, European Group on Ethics in Science and New Technologies (EGE)</p>
<p>Leiden University Medical Centre</p> <p>Prof Christine Mummery</p> <p>Dr Christian Freund</p> <p>https://www.universiteitleiden.nl/en/medicine-lumc</p> <p>https://necstgen.com/</p>	<p>Generation of 220 hiPSC lines (86 ‘control’ and 134 disease hiPSCs) from urine, milk teeth stromal cells, skin, peripheral blood, hip tissue, nasal epithelium</p> <p>hiPSC gene editing including six modification techniques</p> <p>Protocol development for hiPSC-based manufacture and scaling of differentiated cell production</p>	<p>-hiPSC and MPS Hotel: 1) Training Hotel (Collaborations with PluriCore, Harvard core facilities, Dutch hiPSC core facilities). 2) hiPSC Biobank and gene editing service. 3) Manufacture of microfluidic chambers and miniaturization for Emulate, AimBiotec and Mimetas platforms</p> <p>-NECSTGEN product development and GMP manufacture (Vectors, cell and gene-based medicines)</p>	<ul style="list-style-type: none"> -hiPSC facility on manufacturing -Hotel R&D, teaching/training -GMP facility on translation and production -Active in ISSCR, EuroStemCell, Dutch Society of Stem Cell Research, EUROoCS



Partner	Research projects and key activities	Specialist local facilities /infrastructure	Non-scientific activities
<p>Jackson Laboratories Prof Martin Pera www.jax.org</p>	<ul style="list-style-type: none"> -The pluripotency-cell state transitions and modelling of human development -Genetic basis for individual differences in CNS regeneration -Modelling the genetic basis for AMD using biobanks -ISCI international project lead (M Pera) on genetic and epigenetic stability and variation in hPSCs coordinating with ISCBI and ISCF 	<ul style="list-style-type: none"> -Mouse and human genetic resources plus international provision of mouse strains at 3 US centres and a Shanghai collaborating distribution centre -Stem cell research mouse-models for preclinical safety and efficacy studies 	<ul style="list-style-type: none"> -M Pera: <i>Stem Cell Reports</i>, Editor-in-chief -JAX 1) Genetic research, 2) Support for stem cell research-mouse models for preclinical studies with branches in Maine, Connecticut, California, Shanghai, 3) Education courses and conferences
<p>Hadassah hESC Research Centre Prof Benjamin Reubinoff http://www.hadassah-med.com/</p>	<ul style="list-style-type: none"> -Generation of clinical-grade hESCs for manufacture of cell therapies since 2012 and feeder-free since 2017 -NIH-approved and registered at hPSCreg -Universal donor hESC lines -Large scale manufacture of hESC-derivative products 	<ul style="list-style-type: none"> -GMP accredited cell manufacturing facility with EU & USFDA compliant QA and regulatory platform for translation of hESCs to Phase III clinical trial -Clinical trials ongoing: HAD-C hESCs in use for diabetes, ALS (Phase I/II in Israel) and retinal degeneration (Phase I/II in Israel/US), spinal cord injury, CNS disorders 	<ul style="list-style-type: none"> Close interaction with the Israeli regulatory -Israeli Ministry of Health Stem Cell Forum (Consultant) -Israel Stem Cell Society: Founder, steering committee member, head of scientific committee -European Society of Human Reproduction and Embryology (ESHRE) -Stem Cell Special Interest Group Member -International Stem Cell Initiative (ISCI): Co-Chair of Ectodermal Differentiation Interest Group -Member of the Foundation Committee of Israel National Academy of Sciences -hPSCreg Israel National Representative



Partner	Research projects and key activities	Specialist local facilities /infrastructure	Non-scientific activities
<p>CHA University Prof Jihwan Song https://www.cha.ac.kr/en/</p>	<ul style="list-style-type: none"> -HLA-homozygous iPSC lines (KHiB) -Disease modelling: Huntingdon's Disease, Alzheimer's Disease 	<ul style="list-style-type: none"> -iPSC Bio iPSC manufacturing company -Korea HLA-Typed iPSC Banking (KHiB) 	<ul style="list-style-type: none"> -KSSCR President (next meeting Busan August 12-14, 2021) -Int J Stem Cells -Asian Alliance for Stem Cells and Regenerative Medicine -Director & Korean Representative, GAIT -ISSCR committees for international affairs, Asian engagement and clinical translation

Distributed to: all ISCN partners, and meeting delegates with NDA signatories.

⚠ Please keep all information confidential within the International Stem Cell Network.



Contact with the ISCN

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