

**International Stem Cell Banking Initiative (ISCBI)
Annual Report for the year ending 30th September 2022**



International Stem Cell Banking Initiative

**Annual Report and Financial Statement For the Year
Ending 30th September 2022**

Company number: 10915388

International Stem Cell Banking Initiative (ISCBI) Annual Report for the year ending 30th September 2022



The Board of Directors presents its directors' report and financial statement for the year ended 30th September 2022.

Reference and Administrative Information:

Organisation Name:	International Stem Cell Banking Initiative
Company registration number:	10915388
Registered Office and operational address:	The Old Toll House 31 Loxhore Cottages, Loxhore, Barnstaple, Devon, United Kingdom, EX31 4ST

Board of Directors:

Director and Chair	Dr Glyn Stacey
Director	Dr Andreas Kurtz
Director	Dr Rosario Isasi
Secretary	Mrs Jenny Nelder

Accountant:

Curnow and Co Ltd, 31 Loxhore Cottages, Loxhore, Barnstaple, EX31 4ST, UK

Contents:

1. Our Aims and Objectives
 - 1.1 Purposes and Aims
 - 1.2 Ensuring our work delivers our aims
 - 1.3 How our activities deliver public benefit
 - 1.4 Who used and benefited from our services?
2. Financial Review
 - 2.1 Principal Funding Sources
 - 2.2 Reserves policy
 - 2.3 Plans for Future Periods
3. Structure, Governance and Management
 - 3.1 Governing Document
 - 3.2 Board of Directors/Organisational Structure
 - 3.3 Risk management
 - 3.4 Responsibilities of the Board of Directors
4. Statement of Financial Activities

1. ISCBI Aims and objectives

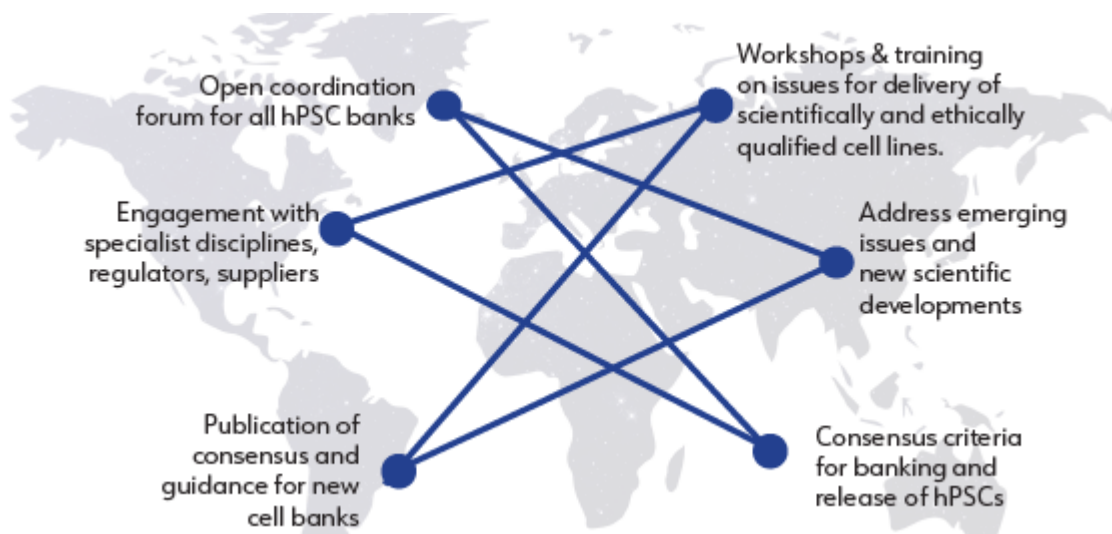
1.1 Purposes and Aims

Our purpose is to create and develop a global network of stem cell banks, both by coordinating existing pluripotent stem cell banks and also supporting those who are setting up new stem cell resource centres.

The ISCBI membership includes more than 200 specialist stem cell scientists and other experts from stem cell banks, stem cell societies, academia, industry and regulatory bodies, from more than 28 countries. It is managed by the ISCBI Executive Board. ISCBI has an independent Steering Group which advises the ISCBI Executive Board and drives the organisation of annual meetings and workshops. The international Steering Group is comprised of leading experts in stem cell banking from more than 13 countries and its membership was most recently updated in November 2020 (see below).

The ISCBI is an open community and welcomes new-comers interested in establishing and developing stem cell resources for local, national and international use. The guiding principles for the development of ISCBI have been:

- Diversity:
 - To bring together stem cell biobanks supporting diverse applications
 - To engage diverse expertise and knowledge: stem cell biobanks, leading stem cell research groups, scientific societies, regulators, industry, funders and policy groups
- Inclusivity:
 - Promoting equal access to meetings to all stakeholders and countries
 - Ensuring that every country has a voice.



1.2 Ensuring our work delivers our aims

We review our aims, objectives and activities each year. This review looks at what we achieved and the outcomes of our work in the previous 12 months. The review looks at the success of each key activity and the benefits they have brought to those groups of people we are set up to help. The review also helps us ensure our aim, objectives and activities remained focused on our stated purposes. In particular, the Directors consider how planned activities will contribute to the aims and objectives they have set.

Our main objectives for the year were focused on re-establishing regular face to face meetings as the world emerged from the Covid-19 pandemic which obviously impacted all membership countries but some disproportionately more than others. We also began to explore opportunities to expand our impact in the training of scientists to operate stem cell banks which can create the building blocks for translational activity in new medical, diagnostic and research tools based on human pluripotent stem cells. The strategies we used to meet these objectives included:

- Engaging with and contributing to high level stem cell educational programmes
- Securing funding for bursaries to enable attendance of stem cell workers from LMIC countries at ISCBI workshops and other international educational opportunities.
- Publication of scientific consensus developed at ISCBI workshops
- Providing a programme of ongoing webinars to educate, inform and connect stem cell bank staff around the world.
- Coordination with other international networks and initiatives and development of collaborative workshops with other stem cell and related organisations.

1.3 How our activities deliver public benefit

Our main activities and who we try to help are described below. All our activities focussed on improving communication between stem cell resource centres to promote development of consensus on best practice and its dissemination. Thus, ISCBI activities contribute to public benefit by:

- Providing advice and guidance to enhance the consistency, quality and safety of stem cell lines available for research and product development
- Directly supporting educational opportunities for stem cell workers
- Enhancing public educational materials on stem cells

Specifically in 2021-2022, the ISCBI was invited to provide expert feedback on the ISSCR standards for best practices in the use of stem cell cultures, at ISCBI's first post-pandemic face to face meeting in San Francisco 18 June 2022. The ISSCR formally acknowledged that this standard built on the extensive work performed by ISCBI and others in the area of stem cell line quality. In addition, the webinar on gene-edited hPSCs (see 1.4, ii)) cast new light on the quality requirements for such cell types, further educational webinars on donor and cell line data management were planned and discussion from the last pre-pandemic ISCBI meeting on cost of goods for stem cell banking was published (see 1.4, v)).

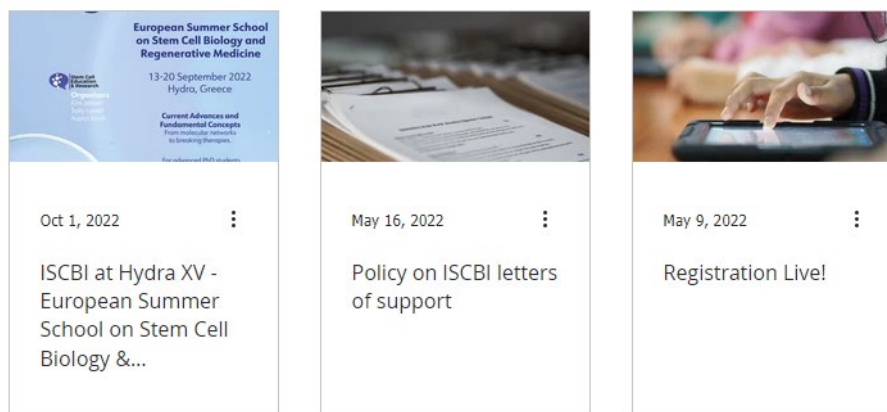
1.4 Who used and benefited from our services?



2022 was a relatively quiet post-pandemic for ISCBI as organisations were tentatively re-engaging with normal activities. However, it was important to maintain the activity and profile of ISCBI amongst the community as it became reactivated.

(i) Newsletters/bulletins

ISCBI sent regular digital newsletters and bulletins to our mailing list subscribers publicising webinar activities, relaunch of face to face meetings and highlighting new publications. Over 290 people are subscribed to our mailing list.



(ii) Webinars

New Technologies and Quality Control for Gene Edited hPSCs, 17th May 2022. This webinar, run in collaboration with the COREdinates organisation (www.coredinates.org), explored the challenge of generating high quality gene-edited hPSCs and revealed how complex this can be and the challenges that remain to assure that edited cell lines reflect their genome of origin. Important lessons for characterisation of gene-edited iPSCs intended for international distribution were discussed. In particular, the lack of effective and efficient means of determining off-target effects was recognised and further discussion was proposed for future discussion amongst the COREdinates group. A link for the video recording from the meeting was circulated to the ISCBI and COREdinates communities.

In 2022 plans were also laid out for a data management webinar series, as part of a developing collaboration between ISCBI, hPSCreg (the European Commission database for hPSCs) and the Chinese National Stem, Cell Resource Centre in Beijing. Links to recordings from these webinars will be made available on request and a publication of the proceedings will be prepared in 2023.

(iii) ISCBI/ISCI Meeting 2022, 19th June 2022

The ISSCR invited ISCBI feedback on the first ISSCR Standard on basic best practices for stem cell culture. Following an open dissemination session run by ISSCR, ISCBI ran a workshop comprising its community membership to give its feedback on the standards. ISSCR officials attended to capture this input. ISCBI Steering Group members Tenneille Ludwig and Glyn Stacey chaired this ISSCR activity. The ISSCR 'standard' will be published in 2023.

(iv) European Summer School on Stem Cell Biology and Regenerative Medicine

In September 2022 ISCBI sponsored the European Summer School on Stem Cell Biology and Regenerative Medicine. It is the only European course on stem cell research aimed specifically at PhD students and post-doctoral workers. It offers a unique training and networking environment for high quality students from around the world. In 2022 there were 65 students from 15 countries (54 PhD students, 11 post-doctoral researchers) and 22 faculty. The tried-and-tested summer school programme provides intensive theoretical training with emphasis on critical analysis of contemporary issues in stem cell biology and regenerative medicine, plus sessions on ethics, public engagement and entrepreneurship. Glyn Stacey attended the course on behalf of ISCBI and presented a poster about the ISCBI as well as a talk entitled "Stem Cell Banking: supporting the research community". Glyn also participated in discussion sessions, Q&A's and provided one-to-one advice for students throughout the week.



(v) 2022 Publications:

Perspectives on the cost of goods for hPSC banks for manufacture of cell therapies.

Kim JH, Kawase E, Bharti K, Karnieli O, Arakawa Y, Stacey G.

NPJ Regen Med. 2022 Sep 29;7(1):54.

DOI: <https://doi.org/10.1038/s41536-022-00242-7>

PMID: 36175440; PMCID: PMC9522845.

Summary: The 'Cost of Goods' for preparation of stem cell banks has been a topic of interest in the cell therapy manufacturing community. This paper sought to provide a better understanding of the basis for determining 'cost of goods' and focused on examples of stem cell banks in different geographical regions. The paper highlighted critical elements of the actual costs of goods. It also identified the diversity of organisations providing biobanks of hPSCs including for product development and the impact this can have on how CoGs are calculated.

Biobanking of human pluripotent stem cells in China.

Stacey GN, Hao J (2022)

Cell Prolif. First published: 02 June 2022.

DOI: <https://doi.org/10.1111/cpr.13180>

ISCBI members were also invited to engage in other international cell culture initiatives including the revision of Good Cell and tissue Culture Practice and a new ISO standard for mouse and human hPSC biobanking:

Guidance Document on Good Cell and Tissue Culture Practice 2.0 (GCCP 2.0).

Pamies, David; Leist, Marcel; Coecke, Sandra et al.

ALTEX, Vol. 39, No. 1, 2022, p. 30-70. (2022)

DOI: <https://doi.org/10.14573/altex.2111011>

ISO 24603:2022

Biotechnology — Biobanking — Requirements for human and mouse pluripotent stem cells

<https://www.iso.org/standard/79046.html>

ISCBI director Glyn Stacey was senior author on the publication of GCCP 2.0 he steering group for a new guidance document on Good Cell and tissue Practice which covered all core aspects in the original GCCP document by Coecke et al. (2005) and extended guidance to setting acceptance criteria in quality control, 3D and Micro physiological systems and use of hPSCs. This document now forms an appendix to the OECD guidance on development of in vitro methods for safety testing (GIVMP, 2018).

GIVMP REF : OECD (2018)

Guidance Document on Good In Vitro Method Practices (GIVIMP)

OECD Series on Testing and Assessment, No. 286, OECD Publishing, Paris

DOI: <https://doi.org/10.1787/9789264304796-en>.

2. Financial Review

Against the backdrop of limited resources and insecurities over funding during the pandemic period, it has continued to be difficult to plan or develop services. Nevertheless, with the aid of reserves from pre-pandemic years (£35,367) and some highly valued ongoing sponsorship from FBRI and Takara totalling £3000, ISCBI still had a positive financial outcome for the period with a net decrease in funds of only £5,714.

2.1 Principal Funding Sources

The principal funding sources for the our organisation in 2022 were:

- FBRI and Takara
- Other previous sponsors have expressed an interest in funding ISCBI in 2023.

2.2 Reserves Policy

The Board of Directors has examined the organisation's requirements for reserves in light of the main risks to the organisation. It has established a policy whereby the unrestricted funds not committed should be between 3 and 6 months of the expenditure as a minimum. Predicted expenditure for FY 2022/2023 is £12,000 and therefore the target for FY2022/2023 is £24,000 in general funds.

The reserves are needed to meet the working capital requirements of the organisation and the Board of Directors are confident that at this level they would be able to continue the current activities of the organisation even in the event of a significant drop in funding.

The prediction for sponsorship income in 2022/2023 is £8000.

Predicted expenditure in 2022/2023 is £18,000

- £6000 - company administration costs.
- £4500 - June 2023 Boston ISCBI meeting
- £3500 - September 2023 summer school support
- £2000 - meetings and events
- £1000 - bursaries
- £1000 - general running costs

The present level of reserves available to the organisation are £29,635 therefore falls comfortably within this target level.

2.3 Plans for Future Periods

The organisation plans to continue the activities outlined above and further developments in the forthcoming years subject to satisfactory funding arrangements. Plans are also being developed to work on:

- Two bursaries of €500 each to enable individuals to attend meetings such as the ISSCR or similar.

- A webinar series on donor and stem cell line data management (see 1.4)
- A training course in India on best practice in the use of hPSCs

In addition, the ISCBI is in the process of setting up a not-for-profit company called “International Stem Cell Biobanking Initiative” which will assist with running the finances more efficiently and will enable the organisation to open an independent bank account which has not been possible with the current company structure. It is hoped the not-for-profit organisation will be established with effect from mid-2023.

3. Structure, Governance and Management

3.1 Governing Document

The organisation is a limited company, incorporated on 14 August 2017. The company was established under a Memorandum of Association which established the objects and powers of the charitable company and is governed under its Articles of Association. In the event of the company being wound up members are required to contribute an amount not exceeding £3.

3.2 Board of Directors/Organisational Structure

The ISCBI has a Board of Directors of 4 members who meet quarterly and are responsible for the strategic direction and policy. At present the Committee has three members from a variety of professional backgrounds relevant to the work of the organization who are Directors of the Company. The Secretary also sits on the Committee but has no voting rights and is not a company director.

A scheme of delegation is in place and day to day responsibility for the provision of administrative services rest with the Secretary. The Chair is responsible for ensuring that the organisation delivers the services specified and that key performance indicators are met.

The Chair receives a small annual income from the company in recognition of the work performed. The other two company Directors give their time voluntarily. The Secretary is paid against invoices for administrative time.

Any expenses reclaimed from the company are set out in the accounts.

3.3 Risk Management

The Board of Directors has conducted a review of the major risks to which the organisation is exposed (primarily sponsorship income and reputation). A risk register will be established in 2023 and will be updated at least annually.

3.4 Responsibilities of the Board of Directors

Company law requires the Board of Directors to prepare financial statements for each financial year which give a true and fair view of the state of the affairs of the company as at the balance sheet date and of its incoming resources and application of resources, including income and

expenditure, for the financial year. In preparing those financial statements, the Board of Directors should follow best practice and:

- select suitable accounting policies and then apply them consistently;
- make judgements and estimates that are reasonable and prudent; and
- prepare the financial statements on the going concern basis unless it is not appropriate to assume that the company will continue on that basis.

The Board of Directors is responsible for maintaining proper accounting records which disclose with reasonable accuracy at any time the financial position of the company and to enable them to ensure that the financial statements comply with the Companies Act 1985. The Board of Directors is also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

3.5 Accountant

Curnow and Co Ltd were re-appointed as the company's accountants during the year and have expressed their willingness to continue in that capacity. This report has been prepared in accordance with the special provisions of Part VII of the Companies Act 1985 relating to small entities. Approved by the Board of Directors on 27/04/2023 and signed on its behalf by Glyn Stacey

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International Stem Cell Banking Initiative
Statement of Financial Activities (including Income & Expenditure Account) for the year ended 30 September 2022

	FY 2021/2022 (£)	FY 2020/2021 (£)
Current assets	35,090	37,191
Current liabilities	-4,242	-1,224
Accruals and deferred income	-1,213	-600
Net assets	29,635	35,367
Capital and reserves	29,635	35,367

Income and Expenditure in FY 2021-2022

Category	Item	2022 (£)	Description	Total (£)
Income	Sales	3,000	Sponsorship from FBRI & Takara	3,000
Expenses	Administration expenses	-3,000	Sponsorship of 2022 SCER Stem Cell Summer School	-9,956
		-12	Printing, post and stationery	
		-1,121	IT costs	
		-4,251	Travel & subsistence	
		-1,038	Admin support	
		-14	Bank charges	
		-13	General expenses	
Taxation	Corporation tax	1,224	Corporation tax adjustment from FY 2020-2021	1,224
			Profit/Loss in FY 2021-2022	-6,956

Current assets/Liabilities

Category	Item	2022 (£)	Description	Total (£)
Current assets	Current assets	33,385	Funds held in bank	35,090
	Corporation tax	1,705	Recoverable	
Current liabilities	Accruals	-1,213	Accountancy fees	-5,455
	Director salary	-4,257	Glyn Stacey	
	Corporation tax	15	Refund due for 2021-0022	
			Net current assets	29,635

Approved by the Board of Directors on 27/04/2023 and signed on its behalf by Glyn Stacey