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THE EUROPEAN BANK FOR INDUCED PLURIPOTENT STEM CELLS (EBISC): OPPORTUNITIES & CHALLENGES THROUGH PUBLIC-PRIVATE COLLABORATION[1]

INTRODUCTION

In June 2016, I was invited by the University of Warsaw to speak to the topic of "collaborative public and private research: opportunities for biobanks" at the conference it was to host that month on "Biobanking: a challenge in times of big data". More specifically, I was asked to present the experience of the public-private project for establishment of the *European Bank for induced Pluripotent Stem Cells* (EBiSC, or the Bank)[2], and this paper arises from that presentation. Here, I demonstrate the opportunities open to EBiSC to promote induced pluripotent stem cell (iPSC) research, and how they have been pursued through the joint undertaking of the *Innovative Medicines Initiative* (IMI) of the European Commission and members of the *European Federation of Pharmaceutical Institutes and Associations* (EFPIA), in collaboration with a consortium of experts from across academia, government and business.

Among IMI-funded projects, EBiSC is unusual in creating a perpetual rather than a finite resource, with capacity to support multiplicity and diversity in research and the generation of valuable data. Among large-scale international iPSC collections, policies including the neutrality of its custodian, minimisation of barriers to accessibility across public and private sector research, access to clinical and genetic data, and optimal pricing make EBiSC an attractive non-profit alternative to cell banks that hold intellectual property rights, are government owned, or tailored to a specific project or disease area[3]. Now, three years

[1] This paper touches on matters regarding EBiSC governance frameworks that are being developed with colleagues on the EBiSC project, for publication elsewhere.

[2] See http://www.ebisc.

[3] R. McKernan, F. Watt, *What is the point of large-scale collections of human induced pluripotent stem cells?*, "Nature Biotechnology" 2013, Vol. 31, issue 10, pp. 875–877.

into the project, as EBiSC is fully operational, it is timely to evaluate some of the prospects and challenges encountered by this collaborative exercise in resource-building.

OPPORTUNITIES

The promise of research involving induced pluripotent stem cells (iPSC), and the opportunities (and challenges) for EBiSC, are rooted in iPSC technologies emerging from the pioneering work of Shinya Yamanaka, which in 2006 demonstrated the use of genetic factors to "induce" pluripotent stem cells from adult cells[4]. Unlike primary tissue, iPS cells are not only capable of differentiation into most bodily tissues but can also be cultivated indefinitely, making them ideal for long term research and scalable industrial uses. Separate developments in cryopreservation, cell characterisation and quality control enable advanced cell banking practices, and the combination of iPSC technology and gene sequencing enables generation of cell line-specific data, and disease- and person-specific research. If rapid advances in genome sequencing have provided access to the genetic code of disease development, iPSC technology is the blueprint by which this code can be functionally translated into new treatments on a patient by patient basis[5]. By accessing quality-assured iPSC lines derived from diagnosed patients, the linking of gene code to the cell line phenotype reflective of the disease enables researchers to refine original clinical diagnosis into one based on disease stratification and thereby design more precise experiments to discover novel pathogenic pathways, drug targets and new medicines[6].

In addition to iPSC technology and genome sequencing, new techniques in gene editing and tissue type differentiation enable the generation of groups of related cell lines, genome-specific controls and novel tools that continue to expand the potential for drug discovery, new therapeutics, and precision medicine. Digital technologies and informatics augment the scientific value of these materials by facilitating accumulation, storage and secure access to vast amounts of cell line-specific genetic data, information and research results. The association of a diverse set of "immortal" cell lines and tools with accessible genotypic and phenotypic data is the foundation of a resource with lasting utility for the iPSC research community.

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[4] K. Takahashi, S. Yamanaka, *Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors*, "Cell" 2006, Vol. 126, issue 4, pp. 663–676.

[5] IMI European Bank for induced pluripotent Stem Cells, *Description of Work*: No 115582-4, 8.

[6] *Ibidem*.

Opportunities for EBiSC lie in the facilitation of iPS cell banking, exchange of resources and collaborative research because, although the promise of iPS technology is not contested[7], there is still ambiguity about how this potential is to be realised. In Europe, the IMI, in its 2012 6th Call for Proposals, observed that: "there is a high expectation that [these] scientific advancements will only come to fruition if the generation, genotyping, phenotyping and banking of iPS cells is available without constraint for use in the academic, biotech and pharma communities"[8]. The problem is that despite growth in the number of iPSC lines and stem cell banks being generated in Europe and elsewhere, iPS cell research is limited by inconsistency in cell quality, and inadequate provision of banking services[9]. IPS cell line generation and banking are spread across a broad spectrum of institutions in Europe, and lack sufficient scale to support the current and anticipated demand for the use of this valuable tool in academic and industrial research. Many iPS cell lines do not exhibit pluripotency, and others are not accompanied by a complement of clinical data or supporting genotypic or phenotypic data[10]. Banking standards across projects vary dramatically. Banking services are routinely proposed by EU-funded research consortia, but are generally a minor component of larger iPSC projects focused on the function of stem cells in human disease, and the quantity of iPS cells generated by the research may exceed their capacity for long term cell banking[11]. Further, although both public and private stem cell banks exist, the international availability of materials and data from them is limited. This is particularly true of iPSC lines derived from patients with genetic mutations: the development of collections has not been systematic and they are accessible only from those institutes carrying out the derivation, or their closely associated collaborators[12].

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[7] T. Eschenhagen, C. Mummery, B. C. Knollmann, *Modeling sarcomeric cardiomyopathies in the dish – from human heart samples to iPSC cardiomyocytes*, „Cardiovascular Research" 2015, Vol. 105, issue 4, pp. 424–438; Y. Z. Xie, R. X. Zhang, *Neurodegenerative diseases in a dish: the promise of iPSC technology in disease modeling and therapeutic discovery*, "Neurological Sciences" 2015, Vol. 36, issue 1, pp. 21–27; R. D. Dolmetsch, D. H. Geschwind, *The Human Brain in a Dish: The Promise of iPSC-Derived Neurons*, "Cell" 2011, Vol. 145, issue 6, pp. 831–834; M. C. Marchetto, K. J. Brennand, L. F. Boyer, F. H. Gage, *Induced pluripotent stem cells (iPSCs) and neurological disease modeling: progress and promises*, "Human Molecular Genetics" 2011, Vol. 20, issue 2, p. 2; S. Nishikawa, R. A. Goldstein, C. R. Nierras, *The promise of human induced pluripotent stem cells for research and therapy*, "Nature Reviews: Molecular Cell Biology" 2008, Vol. 9, issue 9, pp. 725–729.

[8] IMI 6th Call for Proposals, 2012.

[9] *Ibidem*.

[10] *Ibidem*.

[11] *Ibidem*.

[12] *Ibidem*.

The IMI concluded that present iPSC circumstances provide "a unique opportunity to create an industrial scale, not-for-profit, storage and distribution Centre for iPS cells across Europe, which will be of lasting value within the EU"[13]. Recognising that research and cell banking require different skill sets, EBiSC was conceived by the IMI as a dedicated banking facility, directed to meeting researcher needs: quality control, genetic diversity, bespoke services, information and data, transparency of ethical provenance, minimisation of legal barriers to use, reasonable cost and defined time frame. As a collaborative project involving voluntary contribution of resources and expertise, EBiSC would avoid duplication in the generation of iPS cell lines, reduce research costs and result in greater efficiency in conduct of research overall.

The EBiSC objective is apparently straightforward: to establish a centralised EU-based repository that will increase the accessibility of high quality iPS cells and associated data, for long-term use by all qualified researchers worldwide. The IMI vision was that the project should, through harmonised ethical and legal frameworks and technical standards, overcome inconsistencies in cell quality and fragmentation of banking services observed across Europe and in the US[14]. EBiSC would as far as possible free up access to a genetically diverse collection of iPS cell lines and associated data at minimal cost to all qualified researchers, acting as a hub of scientific excellence and knowledge[15]. Creation of an accessible "one stop shop" for materials, data and services would increase their use and reuse[16], facilitate a cumulative body of results, and promote harmonisation of standards and policies in the global iPSC environment.

Specific advantages for a range of actors in the field are expected to emerge from the project. The standardisation of procedures to derive the cells and minimise performance variability enables *academic users* for the first time to address how individual genotypes are manifested in the properties of mature cellular phenotypes such as liver, heart cells or dopaminergic neurons[17]. By filling gaps in the comprehensive data sets (eg genome sequencing, expression profiling, cell pathology), EBiSC makes it possible for *clinical researchers* to build a more rational explanation for the aetiology of complex, common diseases[18]. The development of global, harmonised standards in iPSC culture and expansion, enables research intensive *biotech users* to focus more intently on resolution of the next generation of manufacturing challenges (ie reducing the cost of goods, increasing reliability

[13] *Ibidem*.

[14] *Ibidem*.

[15] S. Stern, *Biological Resource Centres: Knowledge Hubs for the Life Sciences*, Brookings Institution Press, Washington, D.C., 2004.

[16] *Ibidem*.

[17] IMI EBiSC *Description of Work*: No 115582-4, 8.

[18] *Ibidem*.

of raw materials)[19]. Access to a diverse range of disease-related iPSC lines enables the *pharmaceutical industry*, with one reagent, to adopt phenotype screens for more efficient and affordable stratification and development of new medicines, as well as perform pre-clinical drug testing[20]. By contributing anonymised biological samples under ethically and morally robust procedures, *patients* will assist in, and benefit from, the realisation of the potential of iPSC technology for the long term benefit of society[21].

COLLABORATION

The opportunity for EBiSC to facilitate these technical advances has come in the form of public and private investment: €22M of IMI funding, in-kind contributions from members of the *European Federation of Pharmaceutical Institutes and Associations* (EFPIA), and voluntary expertise and facilities from members of the multi-disciplinary iPS cell community. Unlike other large-scale international iPSC collections, many of which are either reliant on public funding or operate entirely on commercial principles[22], EBiSC has been established on the premise that it will ultimately be independent of public funding, and financially self-sustainable, on a non-profit basis, once the initial IMI grant for start-up has been depleted.

The strength of the EBiSC project is its consortium, an inclusive and dynamic partnership, which represents every relevant category of stakeholder and provides the capacity and expertise to fulfil the objectives of the project. Under the coordinatorship of Pfizer Ltd, and management of Roslin Cells Ltd (now Roslin Cell Sciences Limited), the consortium brings together international experts from academia, global pharma, biotech business, government and industry, and draws on a wide range of resources from the public, private and non-profit sectors. The original 26 members represent 10 European states, and a range of economic sectors, as well as research and industrial demand for iPSC materials and data across the full spectrum of genetic and disease cohorts. Participation comes from SMEs, research institutions, national government bodies and EFPIA partners, active iPSC production centres, and international experts in biobanking, iPSC generation, bioengineering, and cell distribution. With these resources, EBiSC is

[19] *Ibidem*.
[20] *Ibidem*.
[21] *Ibidem*.
[22] R. McKernan, F. Watt, *What is the point*…, pp. 875–877.

well-equipped to fulfil the vision of a centralised, EU stem cell repository for efficient delivery of high quality cell lines in support of iPSC research worldwide.

FRAMEWORKS & POLICIES

The EBiSC response to these opportunities is evident in the set of governance frameworks, which reflect the ethical, legal and practical policies agreed among consortium partners to give shape to the Bank and define its relationships with depositors, users and stakeholders. These frameworks comprise an EBiSC Materials Deposit Agreement (EMDA), an EBiSC Access & Use Agreement (EAUA) for standard use, and a Participant Access & Use Agreement (P-AUA) affirming the perpetual rights of access granted to participants, under the EBiSC Project Agreement, in the cell lines contributed to the Bank during the term of the project. In addition, the consortium has developed a specific form of Consent and a Donor Information Leaflet appropriate to the IMI principles and purposes of the Bank.

DEPOSITION & ACCESS

The Bank is built on the principle of *voluntary uncompensated deposition* of cell lines and data that are as far as possible unencumbered by limitations on research use. "Depositors" who contribute samples of their cell lines are generally academic or private iPSC derivation centres and likely to be customers or "users" of the Bank. Rather than relinquishing all legal rights, the depositor retains notional *ownership* of the contributed materials, and remains free to share the retained portion of the cell line with affiliates and external collaborators.

The Bank is a neutral *custodian*, which receives no financial benefit from cell line dissemination beyond a modest fee per cell line from the customer to cover its operations. Although it does not offer depositors any direct commercial advantage in return for their cell lines, it does provide technical cell banking and quality control services, access to a number of vials of backup cells, and an infrastructure for dissemination not generally available to project based or industrial researchers. The depositor and EBiSC are to be acknowledged by the user in the publication of any research involving banked cell lines.

The resources of the Bank are *accessible on a non-exclusive* basis to every eligible user, subject to a light touch application process. Project participants and

their affiliates benefit from perpetual and irrevocable access rights to lines deposited during the project, and a preferential pricing policy that reimburses bare costs of cell line expansion and shipping; non-EBiSC external parties pay a still reasonable fee to cover EBiSC operations on a non-profit basis.

Transparency is facilitated by an information management system (IMS), public website, and customer interface. A cell line specific information pack (CLIP) provides the potential user with characterisation data, directions for routine access to clinical data and links to managed access databases. It also informs the user of any unavoidable *third party obligations* (TPOs) of the depositor, such as flow-through patent rights held by the owner of iPSC reprogramming technology, or limitations on use imposed by donor consent, that will pass with the iPSC line and data and affect researcher freedom to operate. The dissemination of banked cell lines is handled by the *European Cell and Culture Collection* (ECACC).

The "user" or customer of the Bank benefits from a genetically diverse collection of materials at minimal cost and effort, each cell line being increasingly augmented by clinical information and genotypic data, as well as related cell lines such as family clusters and gene-edited controls. The scope of permissible "research use" encompasses academic and industry-conducted research, including pre-competitive activities aimed at discovery and development of drugs and commercial products, but excluding direct exploitation of banked material. *Users* take ownership of any derivatives or new intellectual property generated through their research use of the EBiSC lines, but commercial activity involving substantially unaltered material obtained from the Bank, or other research activities conducted on a fee for service basis, requires a separate arrangement with the depositor/owner of the line.

CONSENT & DATA

The EBiSC consortium, acutely aware of the ethical implications of its work, and the importance of public trust for successful research, is grounded in clear policies regarding consent and data management. Eligibility for cell line deposit requires the support of informed consent in favour of iPSC generation, and express consent to the collection and analysis of genetic information for future unspecified research. Unlike specific health research studies, EBiSC offers donors no expectation (without ruling out the possibility) of return of research results or incidental findings, nor any direct financial or other benefit. The donor cannot entirely "withdraw" from EBiSC resource-building; he or she can control what is left of original samples and data, and may halt access to clinical data, but may

not require destruction of iPS cell lines derived from donated tissue, nor data generated from them during downstream use. At present, the EBiSC form of consent permits ongoing access to medical records, but it also assures the donor of genetic privacy through a "managed access" data storage system[23] to address the very minor risk that openly accessible genotypic data might result in donor re-identification.

SOME CHALLENGES

Despite seemingly simple objectives, the EBiSC opportunities come with corresponding challenges. The continuity of the Bank depends on its ability to attract both academia and industry, become financially independent, address all relevant stakeholder needs and gain the support of multiple "publics", including tissue donors, clinicians, ethics committees, and research funders. The cost of generating iPS cells, and the personal data they contain, make the economics of sharing difficult, meaning that the business plan can be neither purely "open" nor completely commercial. The non-profit EBiSC strategy must meet the needs of a diverse set of actors, and secure vital private investment through fulfilment of industry expectations of utility and novelty.

The regulatory environment is also complex, characterised by multiple legal jurisdictions, plurality of ethical opinion and limited apparatus for structuring change. Despite EU standards of cell quality and safety, and data protection across the Member States, national discretion permits variation in cell banking practices across Europe. Spanish authorities, for example, maintain control over all transfers of Spanish-derived iPS cell lines, whether situated in or out of the country, to third parties. Outside of Europe, foreign rules and EBiSC policy may diverge, raising questions about the extent to which the Bank should monitor access to banked cells, and the criteria that ought to apply.

Change further complexifies the landscape, and requires an adaptable governance model. New technologies, such as gene editing, that were unknown at the start of the project, now feature in plans for an enhanced EBiSC cell line catalogue, and the consortium has already evolved, with the addition of new corporate members and a change of coordinatorship. The potential implications of the untimely "Brexit" decision are also on the horizon.

[23] Genetic data will be stored with the European Bioinformatics Institute http://www.ebi.ac.uk, and accessed by application to a data access committee (DAC) under specialised data access agreement (DAA).

"VALUE CHAIN"

Many of the challenges confronted by EBiSC during implementation of its policy frameworks have to do with the complex "value chain" of interactivity associated with iPS cell banking, research and development in a regulatory environment that protects data privacy and is ambivalent about the status of property in human material[24]. At one end of the chain, the EBiSC resource depends on the altruism of human donors who contribute blood or skin cells for iPSC reprogramming, without expectation of financial compensation or other benefit. Given that full property rights are rarely attributed to human tissue, that consent and contract are looked to as alternative sources of rights and solutions, and that EBiSC has no direct contact with tissue donors, the Bank is reliant on the clinical community (intermediary clinicians, clinical researchers, research centres or patient groups) to procure iPSC originating tissue and administer consent. Complexities arising from this include that clinical contacts for rare disease patients and special family groups may lack motivation to obtain tissue samples where travel and other costs are incurred, and may also feel a need to protect their patients from disclosing medical records or personal information. Practitioners have also expressed the desire for ongoing communication links with researchers, or to be a named author in future research publications involving cells generated from their patients. The absence of legal relationship between EBiSC and clinicians means that there is no obvious arena in which to address these needs.

Beyond tissue donation, the question as to depositor "ownership" of banked iPS cell lines is problematic, because although it is accepted that property in the cell lines can accrue to an iPSC centre by the reprogramming of donated material, more than one actor may be involved in the creation or manipulation of an EBiSC cell line. Depositors tend to query which iPSC derivation centre or researcher is entitled to own and deposit the line, and the legal and commercial implications of ownership of cells placed in EBiSC custody, despite that the EBiSC model of voluntary contribution does not intend the depositor to benefit. Ultimately, the question as to who owns the physical artefact is minimised by an emphasis on the value of cell lines as a source of novel data rather than biological material. EBiSC offers all users, including the depositor, the same non-exclusive right to use the banked material, so that no one is prevented the opportunity of accessing valuable research data from the cell line. It remains an open question whether exploration

[24] G. T. Laurie, S. Harmon, G. Porter, *Mason & McCall Smith's Law and Medical Ethics*, Oxford 2016, p. 490.

of a property-based approach, to facilitate easier transfer of iPS cells and avoid the limitations of consent[25], might better serve the public interest in future.

ACCESSIBILITY

Easy access to cells and data, unencumbered by restrictions on research use, is also difficult to achieve. Instant "freedom to operate" is elusive, as most banked iPS cell lines are likely to be subject to flow-through intellectual property rights (IPRs) held by patent holders of reprogramming and other technologies. Transparency through disclosure is only effective if EBiSC is able to obtain accurate information from the depositor, which is an onerous administrative task. Although obliged to disclose, depositors are not required to take positive steps to conduct new IPR searches, nor warrant that use of the material will not infringe IPRs. They frequently supply anecdotal or incomplete documentation related to existing IPRs, probably because the individuals involved are researchers who are not aware of, or have no access to, relevant licenses held elsewhere in their organisation, or have obtained lines from other sources without accompanying information. EBiSC is working to provide depositors with clear guidance on the importance of this information, and to facilitate access to it by other means, but the user is still ultimately responsible for establishing its freedom to operate with the cells.

CELL LINE PROVENANCE

In spite of having agreed on the pillars of consent necessary to support iPSC research, it has been a challenge for EBiSC to ensure that every cell line in the catalogue is accompanied by either the standard EBiSC consent template, or other appropriate form of consent. The tracing of ethical provenance and assessment of suitability of consent in relation to each cell line was a cause of significant delay to the "hot start" process which attempted the rapid establishment of a collection by gathering existing lines, or generating them from previously procured tissue. Problems included the location of consent forms, which may be held by physicians or clinics rather than the iPSC centres, their translation into English, and evaluation of language and context as a basis of determination of eligibility. In the

[25] G. T. Laurie, E. Postan, *Rhetoric or Reality: What is the Legal Status of the Consent Form in Health-Related Research?*, "Medical Law Review" 2013, Vol. 21, issue 3, pp. 371–414.

absence of legal rules of interpretation, a cautious approach to consent was taken, which increased selectivity and the possibility of rejection or restrictive use of scientifically important cell lines.

Even new cell line commissioning does not guarantee standardisation of EBiSC consent, because they may be created for multiple research uses, by an iPSC derivation centre that wishes to procure the originating tissue under its own form of consent. Centres have asked EBiSC for permission to amalgamate their materials with pieces of "essential" text from EBiSC which, although such practice would streamline administration for the convenience of patient and researcher, raises questions about the level of informedness of the donor. A solution to this may lie in closer engagement with collaborating iPSC centres regarding their commitment to EBiSC and the preparation of mutually acceptable consent materials.

DATA & PRIVACY

The "managed access" approach to handling of genetic data poses a significant barrier to access and constraint on iPSC research, particularly as most data pertaining to iPS cell lines will have a genetic component requiring the application and specialised data access agreement mechanism. A solution for future consideration is to adapt the present EBiSC policy to encourage storage of de-identified genetic data in open access databases, with appropriate consent. Explicit consent to publication of genotypic data in open access databases would be sought, on the basis that "the goal of open science and the principle of transparency argue in favour of maintaining open access databases, even when faced with scenarios of possible – yet extremely unlikely – identification of donors"[26].

CONCLUSION

The outcomes at the end of the third year of the project indicate that the EBiSC collaboration has been successful in achieving the primary goal of establishing a useful and legitimate long-term resource for iPSC research. A robust

[26] B. Knoppers, R. Isasi, N. Benvenisty (*et al.*), *Publishing SNP Genotypes of Human Embryonic Stem Cell Lines: Policy Statement of the International Stem Cell Forum Ethics Working Party*, "Stem Cell Reviews and Reports" 2011, Vol. 7, issue 3, p. 484.

set of constitutive governance frameworks, reflecting deliberate ethical and legal policy-making, supports and facilitates the Bank. Operations are now fully functional and the Bank is increasingly able to supply the needs of researchers with materials and data of particular relevance. The online catalogue has begun to reach anticipated scale, and public and market awareness of EBiSC will enable it to move toward self-sustainability. At this juncture, the EBiSC resource is a platform ready for exploitation, which could take a number of different directions, including expansion of the catalogue to include a wider array of novel cell lines, value added services and accessible clinical and genetic data. To conclude, despite development yet to come, EBiSC is the type of public-private collaboration, capable of increasing access to novel materials and data, and harmonising quality and standards across the iPSC community, to which iPS cell research may expect to be increasingly indebted.

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http://www.ebisc

THE EUROPEAN BANK FOR INDUCED PLURIPOTENT STEM CELLS (EBISC): OPPORTUNITIES & CHALLENGES THROUGH PUBLIC-PRIVATE COLLABORATION

Summary

The *European Bank for induced Pluripotent Stem Cells* is a global iPSC research resource designed to overcome inadequacies in iPSC research and banking services in order to make a diverse collection of quality-controlled iPS cell lines and genetic data easily accessible to researchers in Europe and worldwide. Opened to the public in 2016, EBiSC is a joint undertaking of the *Innovative Medicines initiative* of the European Commission, and the *European Federation of Pharmaceutical Institutes and Associations* (EFPIA), in collaboration with a consortium of international experts from the iPSC community in academia, government and business. The paper identifies opportunities for this large-scale resource through collaboration across the public and private sectors, and highlights challenges encountered during its establishment with regard to cell line provenance, a multiplicity of actors and interests, intellectual property rights restrictions, ownership of banked material, and management of access to genetic data.

KEYWORDS

private sector, collaboration across the public and private sectors, biobank, pluripotent stem cells

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sektor prywatny, partnerstwo publiczno-prywatne, biobank, pluripotencjalne komórki macierzyste