



Innovative Medicines Initiative

IMI indicative Call topic

European induced pluripotent stem cell bank

All information regarding future IMI Call topics is indicative and subject to change. Final information about the IMI's future Calls will be communicated after approval by the IMI Governing Board.

Background

An induced pluripotent stem cell, or iPS cell, is a reprogrammed cell that has been produced from somatic cells from skin (fibroblasts & keratinocytes), hair, blood or other tissues. The introduction of reprogramming factors into these mature cell types leads to epigenetic changes to produce a stem cell-like state through the re-establishment of the cells' pluripotency. The iPS cells can then be differentiated into cells of interest including all three cell lineages required to form the body's organs, nervous system, skin, muscle and skeleton (Takahashi et al. 2007; Takahashi & Yamanaka, 2007; Phillips & Crook, 2010).

Rapid advances in stem cell research have opened up the potential for personalised medicine, with efficacy and toxicity testing of new therapies occurring in iPS cells differentiated from disease relevant populations. There is a high expectation that these scientific advancements will be exploited by generating, phenotyping and banking iPS cells and making them available for wider dissemination in the academic, biotech and pharma community.

The challenges of generating a cell bank that consistently provides quality assured biomaterial within a defined time frame are generally not understood or recognised at this point. The number of stem cell lines created worldwide is likely in the hundreds and is increasing rapidly; while the quality and consistency vary greatly (Loser et al, 2010); indeed many may not in fact be potentially pluripotent.

NEED FOR PUBLIC-PRIVATE COLLABORATIVE RESEARCH

There is a unique opportunity to expand on the scientific community's desire to generate well-characterised iPS cells and utilise the expertise, facilities and scientific experts to set-up a bespoke, not-for-profit specialist storage and distribution centre for iPS cells across Europe. The vision for the characterisation, storage and distribution centre is that it would be similar, in principle, to other established culture collections, but devoted entirely to consistent and high quality characterisation, banking, differentiation and distribution of iPS cell lines, whose processes are complex.

The unique attributes of the iPS centre will be the ability to provide patient-derived iPS cell cultures (and, with time, differentiated cells) at short notice and at appropriate scale and quality. Cells will be provided to academic researchers, private-public partnerships, biotechs & pharma for research, early drug discovery and safety assessment.

The aim of the iPS cell centre is, therefore, to respond to the current and rapidly increasing demand for efficacy and toxicity testing using iPS cells from disease relevant populations. The ability to link disease properties back to the physiology of defined cells (from phenotype differentiated cell types derived from patient specific iPS cells) and to explore the genetic linkage between patient and disease would be an enormous step forward for drug discovery. It will provide a centralised facility for academics, biotechs and pharma to store and retrieve their collections.

A number of EU research funders are now considering establishing large collections of iPS cells based on genetic disorders, drug response, and ethnic background, so now is a timely point to establish a central supply facility where collaboration and coordination will be developed with already existing banks, and existing lines transferred to the iPS centre in order to generate standardised processes, efficiency, consistency of biomaterial, scale, as well as standard operating procedures and practices that are globally agreed.

OVERALL OBJECTIVES

1. Consistent, high quality provision of iPS cells in a defined time frame to the bioscience sector.
2. A large, single European alternative to US initiatives to:
 - a. lead the world in processes and size of bank;
 - b. ease of supply, strengthen European Bioscience base.
3. Partner of choice for storing, characterisation, production & supply of iPS cells held by consortium members, academics, biotechs, and patient advocacy groups.
 - a. Opportunity to remove this burden from other publicly-funded iPS cell projects.
4. Clear and easily mined internet catalogue.
5. Broad range of therapeutic areas/patient diseases covered.
6. Partnership with key iPS banks around the world to create a consistent approach to banking.
7. A centralised repository for all existing European consortia providing iPS cells, such as IMI's future project on iPS cells funded under the 4th Call for proposals.
8. A recognised centre of scientific excellence for research techniques in cryopreservation, retrieval and characterisation of iPS cell lines, leading to reproducible and simple methodologies for generating iPS lines and/or differentiation protocols.
9. Provision of laboratory space and training facilities in stem cell culture.

SUGGESTED KEY DELIVERABLES

- Set-up of a not-for-profit specialist production, storage and distribution centre for iPS cells across Europe that will become self-funding within 5-7 years.
- Provide patient derived live iPS cells to a defined quality and within a defined time from placing an order:
 - iPS cell lines will be available to order within a year of the project initiation;
 - bio-banking facilities will be offered for upstream iPS cell intermediates including the raw clinical samples within the first few years;
 - the bank will offer an iPS differentiation service and supply of differentiated cells during the latter half of the project.
- Utilise the learning, expertise, facilities and subject matter experts of pharma, academia and other cell providers to develop a 'commercial standard' facility.
- Provide a searchable catalogue with standard nomenclature:
 - with ability to trace the lineage back to the source cell;
 - with the provision of phenotype (healthy, disease, drug treatment) and genotype (source tissue, pluripotency status, gene expression profiles) information.
- Provision of quality protocols and post-delivery support & training in iPS cell growth conditions.