



The Role of the UK Stem Cell Bank in Stem Cell Research and Clinical Therapy

Background

The UKSCB was established in 2003 following a House of Lord's Select Committee Report into the science and ethics of hESC research:

- **Report recommended the setting up of a non-statutory UK Steering Committee to:**
 - monitor and approve the use of hESC lines within the UK including the import and export of stem cell lines
 - establish a Code of Practice for the use of human ESC
 - act as the oversight committee for the UK Stem Cell Bank
- **With the Bank's sponsors (the MRC and BBSRC) the UKSC oversaw the establishment of the Bank at NIBSC and the introduction of the Codes of Practice**
- **The Steering Committee chaired by Lord Patel continues to act as an ethical oversight committee monitoring and approving the activities of the Bank including the deposit of and access to the Bank's cell lines**

Role of the UK Stem Cell Bank

The Code of Practice specified a set of aims for the UK Stem Cell Bank:

- To work with the scientific and clinical communities, commercial organisations and regulatory agencies to assure the quality of human stem cell lines used in research and clinical therapy
- To develop and disseminate best practice in the culture, testing, characterisation and preservation of stem cell lines
- To establish, test and release well-characterised seed stocks of ethically-sourced **adult, foetal and embryonic** stem cell lines within a stringent quality framework
- To promote basic research in the UK and abroad through the provision of “Research Grade” cell banks
- To provide stringently tested, safe “Clinical Grade” cell banks under EU GMP conditions as starting material for therapeutic uses

Key Operational Principles

To further these aims the Bank developed a set of key operating principles:

Accountability

To the UKSCB Steering Committee and the Bank's sponsors (The MRC and BBSRC)

Transparency

Through open management processes and clear operational procedures

Interactivity

Through dialogue with :

- The user community both in the UK and abroad
- The regulatory agencies e.g. MHRA
- Sponsors and the Steering Committee
- The public and the media

Independence

No involvement in :

- Commercial product development
- Basic research on stem cell biology

Future Proofing

By anticipating future technical demands, regulatory developments and building the necessary expertise

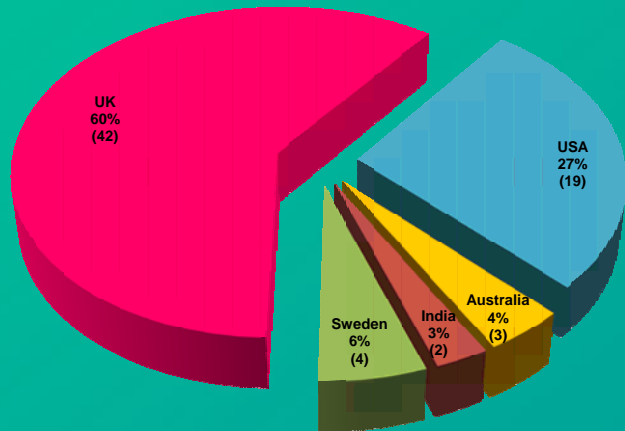
What the UK Stem Cell Bank Doesn't Do

The Code of Practice excludes the UK Stem Cell Bank from:

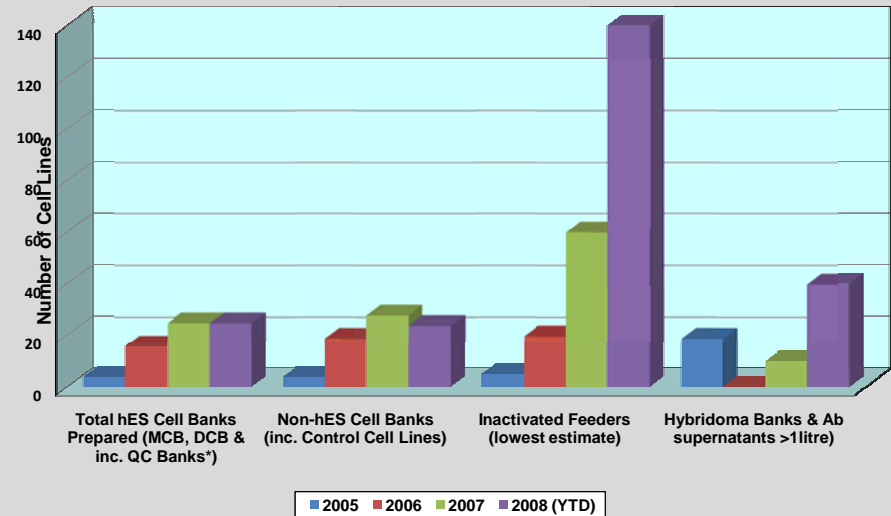
- Storing gametes or embryos
- Deriving embryonic stem cell lines
- Storing cord blood or bone marrow
- Undertaking research in the area of basic stem cell biology
- Undertaking research in the commercial arena (stem cell products or “near market” research)
- Providing large banks of stem cells for direct therapeutic application or clinical trial
- Charging for its stem cell lines (reviewed biannually)

Current Activity

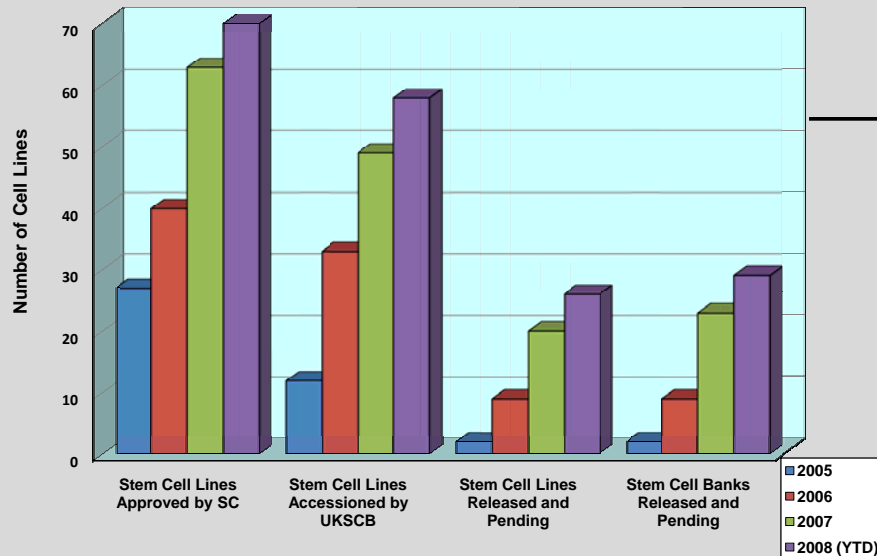
Cell Lines Approved (by Country)



All Banking Activity



hES Cell Banking Activity



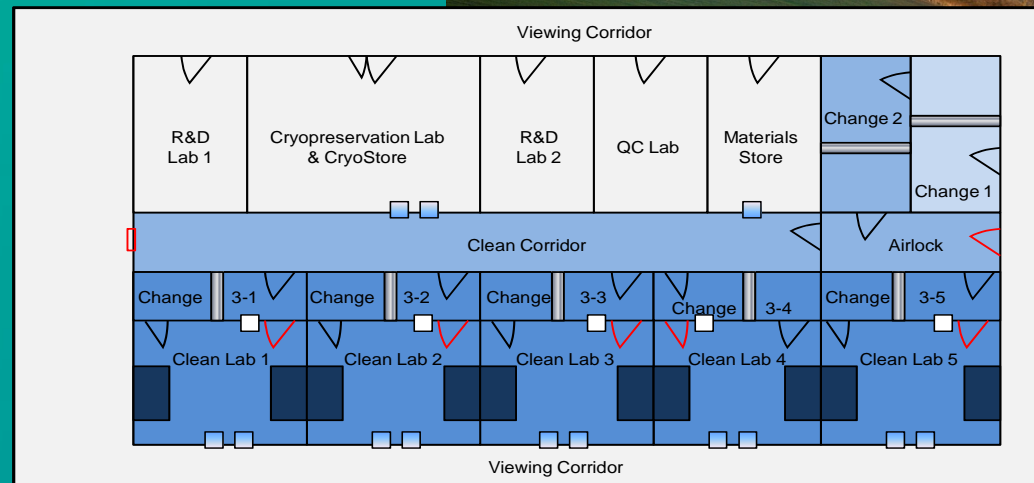
72 Cell lines approved by the SC
 65 Cell lines deposited in the UKSCB
 30 Cell lines Banked for distribution
 15 Cell lines released for use

The New UK Stem Cell Bank

- Contract awarded Nov '07
- Site works began Jan '08
- Building commenced Apr '08



- Five GMP laboratories
- QC laboratory
- Two R&D labs
- Cryostore
- Offices and meeting rooms for up to 17 staff



Beyond Pattison

- **Infrastructure**
 - New GMP facility with “hotel” cleanroom (HTA licensed)
 - MHRA Manufacturing Licence
- **Service Provision**
 - Scoping of characterisation and other tests under ISO 17025 for the provision of testing services
 - New products (DNA/RNA reference material, fixed cell suspensions,)
- **Training and Advice**
 - Technical and quality forum
 - New training course
- **Developing Best Practice Guidance**
 - ECVAM Good Cell Culture Practice (ATLA (2005)
 - ISCF International Stem Cell Banking Initiative Consensus Guidance on Best Practice(Stem Cell Res. Rev.)
- **Commercialisation Working Group**
 - Simplifying transfer agreements and Material Use License
 - Curation and banking policy (research banks of “clinic grade” cell lines)