



Stem Cell Institutions and Opportunities in Selected EU Markets

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Topic Introduction and Scope

- The focus of this GEN Market & Tech Analysis Report is to present some characteristics of selected Northern/Central EU markets vis-à-vis institutions, funding/opportunities in the broader stem cells field [and focusing as appropriate on stem cell banking, iPSCs, cord blood]. We present here data collected by our UK research team via primary market research from across Europe focusing on the following countries:
 - UK
 - Germany
 - The Netherlands
 - Belgium
 - Sweden
- Taken together, these data frame some of the characteristics, institutions as well as stem cell research opportunities in these countries
- In a future GENReport, we will provide an analysis of the regulatory landscape in selected EU countries

UK

■ UK Stem Cell Bank

- Located at the National Institute of Biological Standards and Control (NIBSC)
- Established in 2002
- Stores human embryonic, fetal and adult stem cell lines
- Contains more than 90 hESC lines – 22 Lines quality controlled lines available for research
- Operates under the guidance The Steering Committee for the UK Stem Cell Bank and the use of Stem Cell Lines
- Management committee: Dr Philip Minor, Dr Stephen Inglis, Dr Glyn Stacey, Dr Charles Hunt, Dr Marc Turner, Dr Austin Smith, Robin Buckle, Dr Colin Miles, Dr Suzanne Watt, Prof Peter Andrews, Dr Peter Braude, Mrs Shirley Nurock, Mrs Penny Carter, Mr Ben Sykes, Mrs Lesley Young, Dr Lyn Healy, Dr Iphigenie Charatsi, Mrs Amanda King, Dr Tim Allsopp, Dr Catriona Crombie, Dr Gareth Morgan
- All stem cell lines used are located on the UK Stem Cell Registry



hESC/iPSC Banks in the UK

▪ Roslin Cells

- Located in Edinburgh, Scotland
- Key Personnel - Aidan Courtney, Chief Executive Officer, Paul De Sousa, Chief Scientific Officer, Janet Downie, Chief Operating Officer, Kevin Bruce, Cell Therapy Partnering Manager
- Run a GMP 10,000 ft Cell therapy facility
- Licensed by the HTA, MHRA, HFEA
- Facilities:
 - Three HVAC systems
 - Flexibility of grade A against B, or grade A against C/D environments
 - State of the art MBSCs with in-built microscopes for open processing
 - Bioreactors/isolators and closed processing technology
 - O₂ and CO₂ controlled incubation
 - LN₂-free controlled rate freezing
 - LN₂-free cryostorage
 - LN₂ vapor phase cryostorage
 - Dedicated quality control laboratories including tissue culture and environmental monitoring
 - GMP-compliant Quality Management System
 - 10 research grade embryonic stem cell lines and 10 clinical grade cell lines
- Currently working on producing induced pluripotent cells in a GMP compliant manner for clinical use



Summary of Key UK ESC/iPS Banks

Name of Bank	Location Details
UK Stem Cell Bank	National Institute for Biological Standards and Control Blanche Lane, South Mimms Potters Bar, Hertfordshire EN6 3QG, UK Telephone: +44(0) 1707 641000
Roslin Cells, Ltd.	Scottish Centre for Regenerative Medicine, Edinburgh bioQuarter, 5 Little France Drive, Edinburgh, EH16 4UU, UK Telephone: +44 (0)131 651 9610



Sources of Funding for Stem Cell Research in the UK

▪ **Scottish Enterprise**

- Proof of Concept Program
- Projects that have reached patent level
- Supports the pre-commercialization of leading-edge technologies emerging from Scotland's universities, research institutes and NHS Boards.
- The program finances projects with strong commercialization potential
- Significant funding is available
- <http://www.scottish-enterprise.com/start-your-business/proof-of-concept-programme.aspx>

▪ **UK Technology Strategy Board**

- Knowledge Transfer Partnerships – Industry - academia partnerships
- Part government grant funding, usually around £20,000 per year
- <http://www.ktponline.org.uk/what-is-a-knowledge-transfer-partnership>

▪ **Biomedical Catalyst**

- £180 million
- Funding support for the best life science opportunities in the UK
- Divided into three categories of grant:
- Feasibility Award, Early Stage Award, Late Stage Award
- Support will be available for projects arising from any sector or discipline that are aimed at addressing healthcare challenges. Example solutions may include (but are not limited to): stratified healthcare (both therapy and diagnostic components), regenerative medicine, diagnostics, eHealth and mHealth solutions, enabling medical technologies and devices
- <http://www.innovateuk.org/content/competition/biomedical-catalyst.ashx>



Sources of Funding for Stem Cell Research in the UK

▪ **Smart Funding**

- Available for single companies in research & development
- Divided into three categories of grant:
 - Proof of market grant
 - Proof of concept grant
 - Development of prototype grant
- Pre start-ups, start-ups, and small and medium-sized businesses from all sectors across the UK may apply for the Smart program
- <http://www.innovateuk.org/content/competition/smart.ashx>

▪ **Eurekas Eurostars**

- Max Funding for UK SMEs is £300,000
- The first European funding and support programme to be specifically dedicated to SMEs.
- www.Eurostars-eureka.eu

▪ **Translational Stem Cell Research**

- Response Mode Funding Around £10 million/year
- Funding for translational stem cell research is available through a funding stream led by the MRC as part of the MRC/NIHR single health research strategy
- The Translational Stem Cell Research Committee (TSCRC) has been established to fund investigator-led research proposals that have clear translational goals, and will consider applications from across the UK
- The funding mechanism will also provide a platform for partnership funding which will be considered on a case-by-case basis
- <http://www.mrc.ac.uk/Fundingopportunities/Grants/TSCRC/index.htm>

- **UK Stem Cell Foundation**
 - Scottish Stem Cell Research Fund
 - £5 Million
 - Supported by Scottish Enterprise, the UKSCF is launching a new fund to support stem cell research in Scotland, with the aim of speeding the transition into practical treatments and therapies for patients
 - Available for universities, hospitals or recognised academic institutes in the UK
 - <http://www.ukscf.org/research/SSCRF.htm>

- **Anthony Nolan Trust**
 - Focusing on hematopoietic diseases

Germany

- All cord blood banking for clinical use is overseen by the Paul-Ehrlich-Institute, a body governed by the German Federal Ministry of Health
- Legislation was passed in 1999 governing the transplant and use of Stem Cell transplants from cord blood, overseen by the Paul-Ehrlich-Institute

- **ZKRD [German National Registry of Blood Stem Cell Donors; Zentrales Knochenmarkspender-Register für die Bundesrepublik Deutschland gemeinnützige GmbH]**
 - Main German registry
 - All donor-patient searches are conducted using this registry
- **DRST [The German Registry for Stem Cell Transplantation; Deutsches Register für Stammzelltransplantationen]**
 - Founded in 1998 by the German Working Group for Bone Marrow and Blood Stem Cell Transplantation (DAG-KBT) together with supporting organizations in Essen and Ulm
 - This registry documents autologous and allogeneic transplantation of hematopoietic stem cells taking place in Germany and contributes to quality assurance in this space



German Public Cord Blood Banks

■ DKMS Cord Blood Bank

- Not for Profit Organization
- Located at the University of Hospital of Dresden
- Key Personnel
 - Katharina Harf, CIO, DKMS Group
 - Dr Alexander Schmidt, President & CEO, Scientific Director of the DKMS Bone Marrow Centre in Tübingen
- Group founded in 1991
- Globally they have over 5,500 cord blood donations
- They work with a vast range of hospitals within Germany [>100]

■ Jose Carreras Cord Blood Bank

- Located in Düsseldorf, Germany, University Medical Center Düsseldorf
- Key Personnel
 - Gesine Koegler, PhD, Prof. Dr.
- Established in 1993 and accredited by NETCORD/FACT in 2003
- 21,848 Cord Blood Units in Storage



German Public Cord Blood Banks

▪ **University of Erlangen**

- Created and approved in 1999 for the storage of cord blood
- Approved by the Paul-Ehrlich Institute in 2004 to use stem cell products
- A public/private cord blood bank
- Currently stores 3,000 cord blood units with facilities that can store up to 15,000
- Patients have the opportunity to store their cord blood privately, as the bank has a private commercial partnership with Eticur
- The partnership with Eticur allows the University of Erlangen to use Eticur's distribution and collection network [>500 maternity hospitals]
- Key Personnel
 - Prof. Dr. Reinhold Eckstein - Head of Department, Transfusion and Hematology, University of Erlangen

▪ **Bayerische Stammzellbank GmbH**

- Located in Gauting, Munich
- Key Personnel
 - Hans Knaber



German Public Cord Blood Banks

- **NKR DNSB [North German Bone Marrow and Stem Cell Donor Registry & the German Blood Stem Cell Bank]**
 - Has been banking cord blood units for stem cell use since 2008
 - Located in Hannover
 - Key Personnel
 - Dr. Marlena Robin Winn, Managing GmbH NKR President NKR eV , CEO German Foundation for Life
 - Around 5000 cord blood units stored
 - Currently are not accepting cord blood donations after they cancelled their agreement with VITA 34
- **Mannheim**
 - Created in 1996
 - Located at the Institute of Transfusion Medicine and Immunology Mannheim
 - Key Personnel
 - Prof. Dr. Christian Seidl, Medical Director
 - Dr. Michael Müller-Steinhard, Medical Director – Cord Blood,
 - Harald Kluter
 - This bank has around 1,750 allogeneic cord blood units stored



German Private Cord Blood Banks

▪ VITA 34

- Key Personnel – Dr Holger Fodisch, Chairman, Alexander Strong, Chairman
- Founded in April 1997
- Located in Leipzig, Germany
- 117 employees
- ~ **89,000 Cord Blood samples stored**
- The only application proven cord blood bank in Germany
- Recently signed an agreement with the ZKRD allowing private donations that are banked with VITA 34 to be searched publically. The private owners of these samples are then given the choice as to whether to release their samples to those in need
- Work with roughly 850 maternity hospitals

▪ Eticur

- Key Personnel
 - Dr. med. Josef Frank, Director of Processing, Eticur
 - Professor Dr. med. Volker Weisbach, Head Doctor for the Placenta Blood Bank of the Friedrich-Alexander-University Erlangen,
 - Kathrin Floegel, Quality Director, Eticur



German Private Cord Blood Banks

■ Cryosave

- Formed in 2000, storage facilities all over the world, one of the main storage facilities exist in Germany
- Located in Aachen, Germany
- Key Personnel
 - Arnoud van Tulder, Executive Director, Chief Executive Officer
 - Marc Waeterschoot, Executive Director

The Netherlands



The Netherlands Cord Blood Landscape

- Main Donor Registry is the Europdonor Foundation registry, located at the Leiden University Medical Center
- Founded in 1988, it is now headed by Frans Claas, Chairman
- Runs the BMDW (Bone Marrow Donors Worldwide), a registry that documents both cord blood and bone marrow/stem cell donors around the world
- It also coordinates with the Transplant Centre Coordination Unit (TCCU) for all patients in need of Hematopoietic Stem Cell Transplantations in The Netherlands
- The Dutch units for stem cell transplantation are located in University Medical Centers in Amsterdam, Groningen, Leiden, Maastricht, Nijmegen, Rotterdam and Utrecht

- Leiden
- Sanquin Navelstrengbloedbank Leiden (Dutch Cord Blood Bank Leiden)
- Established in 1994
- Formed as Sanquin in 1998 after a merger between Dutch blood banks and the Central Laboratory of the Netherlands Red Cross Blood Transfusion Service (CLB)
- Sanguin is the Dutch blood supply institute, a not-for-profit organization supervised by the Ministry of Health

- Sanguin has 5 divisions, the Blood Bank division, the Plasma Products division, the Diagnostic Services division, the Reagents division and the Research division
- 3,098 Cord Blood Units are available for transplant
- Accredited by Netcord/FACT since 2009 and ISO 9000 certified
- Key Personnel: Willem E. Fibbe, MD, PhD, Director, Dr. Ir. T.J.F. Buunen (Chairman)



Private Stem Cell Bank in The Netherlands

- Cryosave
- Headquartered in the Netherlands within Amsterdam
- They do not have storage facilities within the Netherlands but offer collection services
- Samples are then banked in one of 5 other sites globally:
 - Belgium
 - Dubai
 - Germany
 - India
 - South Africa

Belgium



Belgium Public Cord Blood Banking: In Belgium, there are five cord blood banks storing samples of Allogeneic Cord Blood

- 1. Liège Cord Blood Bank**
 - Located at the University of Liège in Liège
 - Cord Blood Units stored - 2,669
 - Established in 1994
 - NETCORD/FACT Accredited
 - Key Personnel: Yves Beguin, MD, PhD, Director
- 2. Louvain Cord Blood Bank**
 - Located at the Catholic University of Louvain in Brussels
 - Cord Blood Units stored - 1,365
 - Established in 1994
- 3. Brussels Cord Blood Bank**
 - Located at the free University of Brussels
 - Cord Blood Units stored – 2,125
 - Established in 1994
 - Key Personnel: Dominique Bron, MD, PhD, Director
- 4. Leuven Cord Blood Bank**
 - Located at the Catholic University of Leuven
 - Cord Blood Units Stored - 7,447
 - Established in 1997
 - Key Personnel: Prof. Marc Boogaerts, MD, PhD, Director
- 5. Gent Cord Blood Bank**
 - Located at the University of Gent in Gent.
 - Cord Blood Units Stored - 2,055
 - Established in 2001
 - Key Personnel: Bart A. Vandekerckhove, MD, PhD, Director

- All the banks in Belgium are part of public university hospitals
- The top three banks are part of a network of cord blood banks with a common inventory under the hub of the Liège Cord Blood Bank
- All the banks in Belgium are affiliated both with the Belgian registry of marrow donors (the Marrow Donor Program – Belgium) and the NetCord international network of cord blood banks
- The Leuven cord blood bank is also affiliated with NetCord, while the Gent Cord Blood Bank is only participating in the Marrow Donor Program – Belgium.
- All cord blood banks in Belgium must obtain certification from the Ministry of Public Health after advice from the Upper Health Council on a yearly basis, with a full inspection once every 3 years.
- All public banks in Belgium store allogeneic related cord blood when a biological sibling has a disease treatable by allogeneic HSCT. None of these public banks offers storage of autologous cord blood units.



Private Cord Blood Bank in Belgium

- There doesn't seem to be a huge privatized biobanking community in Belgium, there are some agents working within these countries that take the samples and bank elsewhere

- **CryoSave**
 - Established in 2009
 - Located in Niel
 - Peripheral Blood, Cord Blood, and Adipose Tissue are processed and stored at the facility
 - Key Personnel – Sally Sennitt, Lab Director

Sweden

- Tobias Registry
 - Main cord blood registry in Sweden, records healthy donors of blood-forming stem cells
 - Created in 1992 and is currently administered by Stockholm Care AB, a section of Stockholm County Council
 - **Consists of approximately 40,000 donors**

- **Swedish National Cord Blood Bank (SWEDCORD)**
 - Established in 2006
 - Currently stores 2,424 cord blood units
 - 6 collection sites:
 - **Gothenburg**
 - **Linkoping**
 - **Lund**
 - **Stockholm**
 - **Umea**
 - **Uppsala**

- Swedish Cancer Society
- Swedish Research Council
- Swedish Foundation for Strategic Research
- Knut and Alice Wallenberg Foundation
- Funding is also available through two Strategic Research Centers, particularly a number of doctoral positions are funded through the StemTherapy Grants at the Stem Cell Research School at Lund University