Dear Reader,

Novo Nordisk Haemophilia Foundation (NNHF) has pleasure in presenting its work in 2008 and the first quarter of 2009 in this, its third Annual Report.

This period has been very successful for NNHF and its partners. We now have 27 projects and five fellowships in 24 countries to improve haemophilia care in the developing world. Seven projects and one fellowship were successfully concluded, and at the time of writing, all other projects are in progress.

NNHF thanks its partners and their teams for their enthusiasm and engagement in executing the projects and fellowships. NNHF would also like to thank the Ministers of Health, their staff and other authorities for their support and cooperation.

Finally, we would like to thank our Council Members for their constructive oversight.

Best regards,

Your NNHF Management

NOVO NORDISK
HAEMOPHILIA
FOUNDATION

REPORT 2008/2009

NOVO NORDISK Haemophilia Foundation
Andreasstrasse 15
CH-8050 Zurich
Switzerland

Phone +41 43 222 43 00
Fax +41 43 222 43 43

www.nnhf.org
info@nnhf.org

FACTS ON HAEMOPHILIA

Haemophilia is a congenital bleeding disorder that affects males. Approximately 1 in 5,000 males is born with haemophilia. With a world population of more than 6 billion, it is estimated that about 600,000 males have haemophilia A or B.

Patients with haemophilia A have either decreased, defective or absent production of the blood clotting protein, Factor VIII (FVIII). Those with haemophilia B have similar deficiencies with clotting Factor IX (FIX).

Haemophilia is characterised as “severe” when the activity of the affected clotting factor is less than 1% of normal. Severe haemophilia A is associated with spontaneous bleeding, i.e. bleeding not caused by injury.

Haemophilia is termed “moderate” when clotting factor activity is between 1% and 5% of normal, and “mild” when the relevant clotting factor activity is greater than 5% but less than normal. Approximately 20% of haemophilia patients have severe disease and they are at risk of bleeding several times per month.

Severe haemophilia usually becomes apparent in the first years of life—when the child starts to move about independently—haemorrhages often occur in the joints, particularly knees and ankles. Other mild, moderate or even life-threatening bleeds can occur in the muscles, soft tissues, gastrointestinal tract or even the brain. In addition, trauma, major surgery, tooth extractions or other minor surgical interventions require medical intervention to manage the associated bleeding.

Treatment of haemophilia A and B patients is normally based on replacement therapy, i.e. substitution of the missing clotting factor by intravenous injection. This may be carried out “on demand” when bleeding occurs or prophylactically.

The replacement clotting factors have been typically obtained from human plasma or, more recently, from recombinant genetic engineering technology.
THE NNHF COUNCIL

Kåre Schultz (President)
Leif Fenger (Vice President)
Lars Rebien Sørensen
Jean-Paul Digy
Charlotte Eldevik
Ulla Hedner
Thomas Højberg*
Sylvia Hous
Jean Price*
Marko Oikainen

The Council Members of NNHF exercise their duty without remuneration except for the reimbursement of their expenses.

THE NNHF MANAGEMENT

General Manager
Susanne Brandl (as of 1 April 2009)
Stephen Robinson (until 31 March 2009)
Project Manager
Susanne Brunner
Communications Manager
Nuriye Uluçan
Team Assistant
Michelle Lagoa Hegg

Trainees
Denise Ineichen
Stephanie Smith

Elected 26 March 2009
Resigned

REPORT 2008/2009

Contributors

Photos
Jesper Wiborg

All data is based on publicly available or locally provided information. Although NNHF does its best to ensure the reliability of any data, NNHF assumes no responsibility for it.
“OUR OBJECTIVE IS TO IMPROVE THE CARE AND TREATMENT OF HAEMOPHILIA PATIENTS, WHEREVER THEY LIVE”

Kåre Schultz
President of the Novo Nordisk Haemophilia Foundation
BENEFITING HAEMOPHILIA CARE IN THE DEVELOPING WORLD

With its partners, the Novo Nordisk Haemophilia Foundation (NNHF) delivers development programmes according to need for changing haemophilia care infrastructure.
“TO ACCELERATE PROGRESS IN HAEMOPHILIA CARE, THE KEY SUCCESS FACTOR LIES IN THE COLLABORATION OF PARTIES ENGAGED IN IMPROVING HAEMOPHILIA ON A LOCAL AS WELL AS GLOBAL LEVEL. THEREFORE, WE ARE AIMING TO JOIN FORCES IN OUR GLOBAL PARTNER NETWORK AND EXECUTE DEVELOPMENT PROGRAMMES TO THE BENEFIT OF THE PATIENTS.”

Susanne Brandl
General Manager
Novo Nordisk Haemophilia Foundation

Novo Nordisk Haemophilia Foundation (NNHF) was created in 2005, in Zurich, Switzerland, as an independent, non-profit entity to address the significant need for improving haemophilia care in the developing world. An estimated 75% of the global haemophilia population resides in countries where haemophilia is not a healthcare priority and many people with haemophilia go undiagnosed or are inadequately treated.

As haemophilia is treatable and patients can lead almost normal lives with proper care according to modern standards, NNHF is aiming to bridge the gap between the developed and the developing worlds.

Corporate social responsibility
The creation of NNHF highlights Novo Nordisk’s strong tradition of corporate social responsibility in establishing foundations as a means for furthering medical and social aims. Addressing the ambitious challenge of moving haemophilia higher on the global agenda and providing patient access to care are key elements of an integrated approach to changing the face of haemophilia.

Development programmes
NNHF funds development programmes to deliver capacity building, patient education, diagnosis and registries in the developing world.

Developing world
The geographical scope of NNHF covers countries defined in the OECD Development Assistance Committee (OECD DAC) list. For sustainability reasons, preferred countries belong to the low, lower-middle and upper-middle income categories. In addition to these, NNHF is also active in so-called transition countries, i.e. those which have recently joined the European Union or are intending to.

Partners
NNHF partners bring strong motivation to the programmes and come from all parts of the haemophilia community. They include healthcare professionals and patient organisations. Health ministries play an especially important role due to their endorsement and continued support.

Results-based project management
Development programmes supported by NNHF are carried out as locally managed projects lasting for periods of one to three years, with approximate financial values of between CHF 30,000 and CHF 500,000.

To ensure a successful execution of the projects, NNHF supports the local project partner to establish a project management plan including quarterly follow-ups and serves as a sparring partner. NNHF programmes follow results-based project management, a principle adapted by modern foundations, favoring sustainability of project achievements.

NNHF portfolio
In the first four years of its existence, significant milestones on the long road to improving access to care have been achieved by the foundation and its partners.

As of April 2009, NNHF has a portfolio of 27 projects and five fellowships in 24 countries worldwide, with a total value of CHF 5.3 million.

The regional distribution of NNHF projects is Central & South America and the Caribbean (6), Central and Eastern Europe (5), Africa (2), Near East (5), Middle East (6) and Far East (3). In addition, the foundation has awarded five fellowships, each with a value of CHF 25,000, to further education of physicians from China (2), Iraq, Sri Lanka and Thailand in an internationally recognised comprehensive haemophilia care centre.

At the end of 2008, one fellowship and seven projects had already been successfully completed in Uzbekistan, Venezuela, Poland, Bulgaria, China, Jordan and Pakistan.

So far, about 6,000 patients and their families as well as 3,000 haemophilia experts have been educated through dedicated training activities within NNHF programmes. A lot more members of the haemophilia community and the general public were also reached with awareness campaigns via various media, supported by educational material developed in most of the project countries.

Critical to the success of the projects and sustainability of what is achieved are motivated partners and a plan fitting a profound understanding of local requirements. Early involvement of partners and other stakeholders builds confidence and is essential to achieve smooth project execution, ensure endorsement and continued support and create a strong local haemophilia network.

Outlook
The outlook for increased access to care in the developing world is very encouraging for 2009. Based on its progress in 2008, NNHF received a 50% increase in funding from CHF 2.2 million to 3.3 million for 2009. This authorized a modest increase in project and communication personnel allowing NNHF to take on more programmes and fellowships and promote better practice exchange through global collaboration.

An additional programme to be launched in the near future is the NNHF Award for an outstanding individual achievement for the haemophilia community.

Together with our global partner network, the first essential steps have been taken to improve care standards in the project countries. The results are encouraging and a reference for future programmes to improve haemophilia care and treatment in the developing world.
THE NOVO NORDISK HAEMOPHILIA FOUNDATION IS AIMING TO BRIDGE THE GAP BETWEEN THE DEVELOPED AND THE DEVELOPING WORLDS
NNHF PORTFOLIO
27 projects and 5 fellowships in 24 countries

FELLOWSHIPS
- CHINA I
- CHINA II
- IRAQ
- THAILAND
- SRI LANKA

CENTRAL AND EASTERN EUROPE
- POLAND
- ROMANIA
- BULGARIA I
- BULGARIA II
- MACEDONIA

Status
- Approved 2005, completed
- Approved 2006, ongoing
- Approved 2006, completed
- Approved 2009
- Approved 2006, ongoing

MIDDLE EAST
- LEBANON
- PALESTINE
- JORDAN I
- JORDAN II
- IRAQ

Status
- Approved 2006, ongoing
- Approved 2008, ongoing
- Approved 2006, completed
- Approved 2009
- Approved 2006, ongoing

NEAR EAST
- LEVANT
- IRAQ

Status
- Approved 2006, ongoing
- Approved 2008
- Approved 2009
- Approved 2008
- Approved 2008

MIDDLE EAST
- UZBEKISTAN I
- UZBEKISTAN II
- IRAQ

Status
- Approved 2006, completed
- Approved 2006, completed
- Approved 2006, ongoing

AFRICA
- ALGERIA
- SOUTH AFRICA

Status
- Approved 2005, ongoing
- Approved 2008, ongoing

FAR EAST
- CHINA
- VIETNAM
- MALAYSIA

Status
- Approved 2006, completed
- Approved 2007, ongoing
- Approved 2008, ongoing

CUBA
- VENEZUELA
- PANAMA
- BRAZIL
- URUGUAY
- CHILE

Status
- Approved 2007, ongoing
- Approved 2005, completed
- Approved 2005, completed
- Approved 2007, ongoing
- Approved 2007, ongoing

CENTRAL AND SOUTH AMERICA, CARIBBEAN
- CUBA
- VENEZUELA
- PANAMA
- BRAZIL
- URUGUAY
- CHILE

Status
- Approved 2007, ongoing
- Approved 2005, completed
- Approved 2006, ongoing
- Approved 2007, ongoing
- Approved 2007, ongoing

*NNHF Report, 2007/2008, see www.nnhf.org

27 projects and 5 fellowships in 24 countries
BENEFITS IN FIVE COUNTRIES

There are many countries where haemophilia care needs improvement and many long roads to achieve this. NNHF now reports that another five of its programmes have successfully reached completion and made significant impact.

CHINA

In this vast country with a population of 1.3 billion, only about 5% of the expected number of people with haemophilia are known. Thus, the improvement of haemophilia care and treatment and the level of awareness throughout the towns and cities in the countryside is an enormous challenge.

This NNHF project in China focused on education, screening and registration within the already existing structures. Compromising six main centres in Shanghai (lead), Beijing, Tianjin, Hefei, Guangzhou and Jinan and the recently created patient association “Hemophilia Home of China”.

To improve haemophilia diagnosis, six lab technicians from three centres were sent to the Royal Free Hospital Laboratory in London for training with Dr Angus McCraw and his team. Several months later, follow up training was held in China with the same participants to consolidate the initial skills learned within their own premises and develop quality assurance policies.

"SINCE WE HAVE BEEN PROFITING FROM LABORATORY TRAINING WE HAVE BEEN ABLE TO IMPLEMENT QUALITY ASSURANCE POLICIES AND USE THE ACQUIRED KNOWLEDGE TO THE BENEFIT OF OUR PATIENTS. SETTING UP A NATIONAL REGISTRY HELPS US TO GAIN STATISTICS ON THE DISEASE PREVALENCE AND ALSO SIMPLIFIES PATIENT MANAGEMENT."

Professor Hongli Wang
Shanghai Ruijin Hospital

In total, 1,616 people with haemophilia were tested or retested to unequivocally confirm their diagnosis and status for bleeding disorder type, virology and complications such as inhibitors, where indicated. The patient data was entered into the newly created, national, web-based bleeding disorders registry which has now been installed in 21 centres. Overall, this registry now contains data for 2,844 people with haemophilia.

The group of six haemophilia centres collaborated very closely together. They established links to most of the 22 Chinese provinces, each taking responsibility for about two to three main cities in other provinces.

With a comprehensive training programme for healthcare professionals and patients with their families, the project team reached out to 330 physicians, 89 nurses and 65 lab technicians in the course of six medical staff training sessions. A total of 464 patients and 275 family members were educated in eleven patient education workshops over a two-year period. Six educational brochures for doctors and patients, two DVDs, a first haemophilia monograph, national diagnosis and treatment guidelines and a nursing manual were developed and published. More than 34,000 copies for physicians as well as patients were printed.

"RECENT GOVERNMENT INTENTIONS TO IMPROVE HEALTHCARE IN CHINA WILL ULTIMATELY PERCOLATE THROUGH TO GREATLY BENEFIT HAEMOPHILIA CARE, WITH THE HELP OF THIRD PARTIES SUCH AS NNHF, THESE CHANGES CAN BE ACCELERATED. SO, THE OUTLOOK IS VERY OPTIMISTIC."

Professor Yongqiang Zhao
Beijing Union Medical College Hospital

The Chinese patient association strongly supported the project execution by many contributions in kind. A major advance was the construction of an attractive and interactive website with regular newsletters, updates on educational materials, chat rooms, competitions, online physician consultations and web-casted surgeries and clinical case studies and other content. A strong media programme went hand in hand with these project activities. Professors from Shanghai and Beijing appeared on national television to talk about “Haemophilia inheritance” and “Haemophilia treatment”. This was supported by the distribution of the print material in national meetings, and publication in medical journals and magazines.

The results achieved are indeed impressive and encouraging to extend the activities to more centres and ensure outreach throughout China. A subsequent project will greatly accelerate diagnosis and clinical management to the benefit of the many patients who are still undetected and lack access to care.
**BULGARIA**

At the end of 2008, the first Bulgarian project was completed. Bulgaria is a very recent European Union entry country with a population of about 7.2 million.

While basic haemophilia and other bleeding disorders diagnosis and treatment is given in six haematology departments of the medical universities in Plovdiv, Varna, Pleven, Stara Zagora and Sofia, and in the Haematological Hospital “Joan Pavel” in Sofia, which work as Haemophilia Treatment Centres, there are large differences in the quality of treatment delivery across the country.

Starting with Sofia and the western Bulgarian region, the aim of the NNHF project was to build up a Comprehensive Haemophilia Treatment Centre in Sofia using a multidisciplinary approach, to complete an exhaustive patient status analysis including genetic consultation and initiate education for healthcare professionals and patients.

A total of 146 people with haemophilia and other congenital coagulation disorders were examined by the multidisciplinary team of specialists composed of two haematologists, a coagulation specialist, an orthopaedic surgeon, a hepatologist, a paediatrician, a rheumatologist and a physiotherapist.

Of the 146, 127 were haemophilia A and nine were haemophilia B patients. Ten patients were diagnosed with other congenital coagulation disorders. The number of samples screened additionally for inhibitors was 299. In three training courses, 26 physicians and eight nurses were educated and five educational sessions were held for 136 patients and 25 family members. Eight educational brochures were developed for healthcare professionals and patients and more than 5,000 copies distributed nationally with the help of the Bulgarian Haemophilia Society.

The national registry of congenital coagulation disorders was updated with all newly available data and epidemiological information and now includes 811 patients, representing an increase of about 21% due to the project. The results were shared with the Ministry of Health and the National Health Insurance System. The national prophylaxis and treatment guidelines for bleeding disorders developed in 1999 were updated and newly approved as a part of the National Standard of Clinical Haematology by the Ministry of Health.

Overall, this regional project significantly raised standards in the care and treatment of bleeding disorders in western Bulgaria and will be followed by a similar project on a national level.

---

**POLAND**

After Uzbekistan and Venezuela, the third NNHF project to be completed was in Poland, a European transition country of about 39 million people, where at that time, the economy was rapidly improving although the health system lagged behind.

At the start of the project in 2007, haemophilia care had been anchored in the adult and paediatric centres in the capital city of Warsaw, which resulted in centralised and limited distribution of coagulation factors and lack of broad disease awareness and education elsewhere.

The NNHF project was designed to ensure nationwide access to diagnosis, care and education through outreach. Two years were taken to decentralise haemophilia care to another 16 regional blood centres. Heading a national physician and patient education programme, which included training sessions for home treatment as well as a comprehensive diagnostic campaign, was a newly established group of haemophilia experts. The task of this expert group was also to develop national treatment guidelines accepted by the Ministry of Health.

“HAEMOPHILIA CARE IN POLAND NEEDED TO BE EXTENDED CONSISTENTLY TO ALL TREATMENT CENTRES AND PATIENTS AROUND THE COUNTRY. BY SETTING UP A NATIONAL REFERENCE LABORATORY, MAKING DIAGNOSIS AND HAEMOPHILIA EXPERTISE AVAILABLE, ESTABLISHING A NATIONAL DATABASE AND CREATING NATIONAL HAEMOPHILIA GUIDELINES, WE ACHIEVED OUR OBJECTIVES AND CREATED A COUNTRYWIDE HAEMOPHILIA NETWORK.”

Dr Anna Klukowska

Haematologist, Assistant Professor, Medical University Warsaw, Paediatric Department Haematology/Oncology

The education programme reached 350 doctors, 96 nurses and 26 laboratory technicians, and via 20 workshops, 760 patients and their families. Educational material was developed and distributed including 2,500 copies of the first comprehensive and original book about haemophilia for patients. A screening programme was foreseen for about 850 patients and, in the end, 1,006 patients were included. Their clinical data were registered in a newly introduced electronic national registry system.

This concerted effort on all fronts to improve haemophilia care in Poland led to the first national programme for prophylaxis in children introduced by the Ministry of Health.
JORDAN

Jordan is a Middle Eastern country with a good service-based economy, relative political stability and a modern health system. It is centrally located and has good connections to its neighbours. It has a population of about six million inhabitants and about 300 people with haemophilia are diagnosed and treated in established haemophilia centres and hospitals.

For these reasons, a two-year project was approved for Jordan consisting of a genetic study of haemophilia A and B patients and pre-implantation genetic diagnosis for haemophilia A combined with genetic counselling. The purpose of this advanced study was to equip a molecular genetics laboratory and establish the technological capability for Jordan to serve as a reference centre for the region. In addition to the genetic study, haemophilia patients were diagnosed or re-diagnosed to confirm their status prior to entry into a national registry. In total, 232 patients were studied, while 181 were found to have haemophilia A and 51 to have haemophilia B. The patients were further tested for infectious diseases including hepatitis B, hepatitis C and HIV. A prevalence of 0% was found for hepatitis B, approximately 30% for hepatitis C and less than 1% for HIV. Complications such as inhibitors were also tested and found to be present in 11% of 165 haemophilia A patients, but were completely absent in the 51 haemophilia B patients.

The genetic study was approved by the Ethics Committee of Jordan University Hospital and informed consent was obtained from all participants according to the Declaration of Helsinki. A total of 17% haemophilia A patients from 42 unrelated families and 51 haemophilia B patients from twelve families participated in this study. All haemophilia A patients were screened for intron 22 inversion and those negative were tested for intron 1 inversion. For those negative for intron 22 and 1 inversions the entire FVIII gene DNA was sequenced. Intron 22 inversions were found in 66 patients belonging to 22 families and intron 1 inversion in one patient (from one family). Missense mutations were found in 108 patients (from 19 families). Of these, five families (42 patients) were identified with novel mutations (four missense and one frameshift mutation). All haemophilia B patients were sequenced directly for the entire FIX gene. Five novel mutations were identified which include one missense, three frameshift mutations and one insertion mutation.

Pre-implantation Genetic Diagnosis (PGD) for haemophilia A patients, an important alternative to standard prenatal diagnosis, was studied with the aim of optimising a simple, efficient and reliable procedure which is applicable to a wider range of individuals at risk of transmitting haemophilia A to their offspring. Two protocols were optimised which could be applicable to clinical studies.

A haemophilia education centre was established at the Faculty of Medicine of the Jordan University. In cooperation with the Jordanian and Canadian haemophilia associations, several patient education sessions took place in the new education centre on haemophilia management and reached, in total, 70 patients, 180 family members and six physicians.

This project led by Professor Abdalla S.S. Awidi of Jordan University Hospital has laid the foundation for further genetic studies of haemophilia in the Middle East. A follow-up project has been approved to establish a national registry of hereditary bleeding disorders and to continue genetic testing and counselling, carrier detection, prenatal diagnosis and comprehensive education.

PAKISTAN

For the first time, a one-year national patient education project was launched in Pakistan. Synchronised with an already running clinical haemophilia diagnosis and management project in Karachi, it was possible to share the workload and to make use of synergies.

The educational component was carried out by Dr Tahira Zafar, consultant haematologist and director of the Haemophilia Centre at the Pakistan Institute of Medical Sciences (PIMS) in Islamabad, in close collaboration with the Pakistan Haemophilia Patients Welfare Society (PHPWS).

The key elements of this project were to provide and to publish educational material in Urdu, perform training workshops for patients and their families, improve disease awareness through media coverage, and attract representatives of public healthcare services. NNHF contributed to the development and printing costs of communication material, purchased office and communication equipment and conducted six workshops.

This well-executed project involved the main stakeholders in the haemophilia community and at authority level. Six workshops with 735 participants including government officials and media representatives were realised with the focus on the following: Haemophilia – the disease, health lifestyle in haemophilia, physiotherapy, dental awareness, women with bleeding disorders, psychosocial issues, joints and muscles. Based on the workshop content, educational booklets were produced in Urdu and distributed to workshop participants as well as to the chapters of the PHPWS in all provinces. The workshops were further covered by local newspapers. In total, 150 patients and family members, 24 physicians, ten nurses, twelve government officials and 16 media representatives were trained in different aspects of haemophilia – depending on their needs and area of activity. Most of them attended several workshops.

The knowledge gained from this project experience was shared as a better practice by Dr Tahira Zafar with the NNHF global project partner network and will serve as a basis for a newly approved project grant, extending the education programme to a national level.
**ALGERIA**

**Partner**
Société Algérienne d’Hématologie et de Transfusion Sanguine (SAHTS), Algiers

**Represented by**
Prof. Mariem Belhani

**GDP per capita**
USD 7,100

**Known patients**
1,145

**Expected patients**
3,420

**Population**
7.2 million

**Planned duration**
Two years

**Impact**
- Increased disease awareness
- Better information of haemophilia patients and their families
- Improved specialist knowledge amongst 160 healthcare providers
- Increased disease awareness on authority level

**Objectives**
- Creation of comprehensive haemophilia treatment centre
- Improve diagnosis of haemophilia patients:
  - Update skills of healthcare providers
  - Provide patient information
- Establish national haemophilia registry
- Establish specialist care by reinforcing the national reference centre and opening two regional treatment centres
- Support and update national haemophilia registry
- Regularly examine and perform laboratory tests
- Create awareness programme in Sofi a
- Update current haemophilia guidelines for prevention and treatment of bleeding
- Standardise screening and testing methods
- Perform broad multidisciplinary educational programme to upgrade existing level of treatment standards
- Assess clinical, psychological and social patient status
- Establish two national laboratories and train laboratory technicians
- Establish specialist care by reinforcing the national reference centre and opening two regional treatment centres
- Form Comprehensive Haemophilia Treatment Centre in Sofi a
- Support and update national haemophilia registry
- Regularly examine and perform laboratory tests
- Support and update national haemophilia registry
- Increase disease awareness
- Improve diagnosis of haemophilia patients:
  - Update skills of healthcare providers
  - Provide patient information
- Establish national haemophilia registry
- Establish specialist care by reinforcing the national reference centre and opening two regional treatment centres
- Support and update national haemophilia registry
- Regularly examine and perform laboratory tests
- Create awareness programme in Sofi a
- Update current haemophilia guidelines for prevention and treatment of bleeding
- Standardise screening and testing methods
- Perform broad multidisciplinary educational programme to upgrade existing level of treatment standards
- Assess clinical, psychological and social patient status
- Establish two national laboratories and train laboratory technicians

**BULGARIA I**

**Partner**
National Center of Haematology and Transfusion Sanguine (NCHT), Sofia

**Represented by**
Prof. Toshko Jelev Lissitchkov

**GDP per capita**
USD 13,200

**Known patients**
581

**Expected patients**
1,600

**Population**
16.6 million

**Planned duration**
Two years

**Impact**
- More than 100 patients and families received genetic consultation
- 150–200 patients in regular rehabilitation
- About twelve haematologists and seven nurses trained
- 1,500 of 4,500 registered patients (re-)screened
- 500 patients educated, 2,000 patients received newsletter, patient website established
- 1,500 of 4,500 registered patients (re-)screened
- Three equipped haemophilia testing laboratories
- Doctors, nurses and lab technicians in six major centres trained
- Standardise screening and testing methods
- Perform regular examinations and consultations of patients with congenital bleeding disorders
- Establish comprehensive national haemophilia education programme in existing haematology services as well as in the countryside
- Update current haemophilia guidelines for prevention and treatment of bleeding
- Standardise screening and testing methods
- Three equipped haemophilia testing laboratories
- Educate doctors, nurses, lab technicians and patients – train-the-trainer concepts
- Improve national patient registry
- Assess clinical, psychological and social patient status
- Improve national patient registry
- Perform broad multidisciplinary educational programme to upgrade existing level of treatment standards
- Assess clinical, psychological and social patient status
- Perform broad multidisciplinary educational programme to upgrade existing level of treatment standards
- Assess clinical, psychological and social patient status
- Improve national patient registry
- Assess clinical, psychological and social patient status
- Improve national patient registry
**Establishment of haemophilia comprehensive care**

**CUBA**

**Partner:** Instituto de Hematología e Immunología (IHI), La Habana

**Represented by:** Prof. José M. Ballester Santosveiva

**Planned duration:** Two years

**Population:** 11.5 million

**Expected patients:** 1,150

**Known patients:** 559

**GDP per capita:** USD 4,500

**Objectives:**
- Improve IHI to be established as national reference centre
- Set up two regional comprehensive care centres in Pinar del Rio and Víla Clara

**Impact:**
- Comprehensive haemophilia care introduced
- About 70 patients educated, their diagnoses confirmed and educational material provided
- Twelve haemophilia specialists trained
- Laboratory equipped and four laboratory technicians trained
- Workshops held for about 60 healthcare specialists

**INDIA new**

**Partner:** Sir Ganga Ram Hospital, New Delhi

**Represented by:** Dr Anupam Sachdeva

**Planned duration:** Three years

**Population:** 1.2 billion

**Expected patients:** 120,000

**Known patients:** 10,000

**GDP per capita:** USD 2,900

**Objectives:**
- Develop training modules to improve the knowledge of diagnosis, treatment and preventive measures in haemophilia care
- Perform regional workshops for paediatricians – train-the-trainer concept
- Develop national haemophilia treatment guidelines

**Impact:**
- Multi-centre cooperation and national haemophilia network of paediatricians and health workers established
- Around 750–900 paediatricians trained
- Disease awareness within haemophilia community increased
- Standard set of manuals and guidelines provided to healthcare professionals

**IRAQ**

**Partner:** Medical City Hospital, Baghdad

**Represented by:** Dr Nazar Al-Anbaki

**Planned duration:** Two years

**Population:** 28.9 million

**Expected patients:** 2,890

**Known patients:** 1,000

**GDP per capita:** USD 4,500

**Objectives:**
- Improve diagnosis and introduce a comprehensive screening programme
- Establish a national haemophilia registry
- Create national haemophilia treatment guidelines
- Increase disease awareness also at authority level

**Impact:**
- 15 haematologists, seven lab technicians, six nurses trained
- IT specialists trained for implementation of registry
- Patients educated
- Guidelines published
- Authorities involved in improvement process

**JORDAN I completed**

**Partner:** Jordan University Hospital, Amman

**Represented by:** Prof. Abdalla S.S. Awidi

**Planned duration:** Two years

**Population:** 6.3 million

**Expected patients:** 630

**Known patients:** 290

**GDP per capita:** USD 5,000

**Objectives:**
- Develop national haemophilia treatment guidelines
- Perform regional workshops for paediatricians – train-the-trainer concept
- Develop training modules to improve the knowledge of diagnosis, treatment and preventive measures

**Impact:**
- Extend basic programme to four regions
- Design and implement a broad educational haemophilia programme
- Strengthen the haemophilia treatment centre in Beirut by implementing multidisciplinary approach
- Results of genetic diagnosis published

**JORDAN II new**

**Partner:** Jordan University Hospital, Amman

**Represented by:** Prof. Abdalla S.S. Awidi

**Planned duration:** One and a half years

**Population:** 6.3 million

**Expected patients:** 630

**Known patients:** 290

**GDP per capita:** USD 5,000

**Objectives:**
- Establish a national registry of hereditary bleeding disorders based on international standards
- Continue and expand genetic testing and counselling, carrier detection as well as prenatal diagnosis
- Establish a national registry of hereditary bleeding disorders

**Impact:**
- National registry of hereditary bleeding disorders established
- 650 patients tested and educated
- 180 healthcare professionals trained
- Results of genetic diagnosis published

**LEBANON**

**Partner:** Association Libanaise de l’Hémosthile, Beirut

**Represented by:** Dr Claudia Djambas Khayat

**Planned duration:** Two years

**Population:** 4 million

**Expected patients:** 400

**Known patients:** 139

**GDP per capita:** USD 11,100

**Objectives:**
- Strengthen the haemophilia treatment centre in Beirut by implementing multidisciplinary approach
- Design and implement a broad educational haemophilia programme for healthcare professionals and patients with their families
- Extend basic programme to four regions

**Impact:**
- 200 new patient diagnoses expected
- Overall 400 patients educated
- Haemophilia capacity of first-line doctors and nurses improved, haematologists trained
- Regular medical consultation services established
- Disease awareness at authority level improved
**PAKISTAN I completed**

**Objective:** Education of persons with haemophilia and their families at a national level

**Partner:** Pakistan Haemophilia Patients Welfare Society (PHPWS), Islamabad

**Represented by:** Dr Tahira Zafar

**Planned duration:** One year

**Population:** 176.2 million

**Expected patients:** 17,620

**Known patients:** 1,250

**GDP per capita:** USD 2,600

**Impact:**
- 500 patients and 300 parents educated
- 200 healthcare professionals and 100 PHPWS representatives trained
- Educational material developed and distributed to more than 600 partner institutions
- Awareness increased amongst patients, family members and government representatives

**Objectives:**
- Develop educational resource material in local language (Urdu)
- Establish inter-provincial collaboration of haemophilia stakeholders
- Perform comprehensive education for patients and their families
- Create awareness amongst government representatives

---

**PAKISTAN II completed**

**Objective:** Capacity building for haemophilia care programme – a pilot study

**Partner:** National Institute of Blood Disease and Bone Marrow Transplantation (NIBD), Karachi

**Represented by:** Dr Tahir S. Shamsi

**Planned duration:** Two years

**Population:** 176.2 million

**Expected patients:** 17,620

**Known patients:** 1,250

**GDP per capita:** USD 2,600

**Impact:**
- 650 patients educated and screened
- Four medical professionals trained as master trainers
- Haemophilia database created
- Disease awareness within haemophilia community increased

**Objectives:**
- Update knowledge and skill level of doctors, nurses and laboratory technicians in a regional pilot project in Karachi and environs
- Establish effective and adaptable model of diagnosis
- Increase awareness and knowledge in the haemophilia community, including authorities and institutions

---

**PAKISTAN III new**

**Objective:** Extension of education programme to a national level

**Partner:** Pakistan Haemophilia Patients Welfare Society (PHPWS), Islamabad

**Represented by:** Dr Tahira Zafar

**Planned duration:** Two years

**Population:** 176.2 million

**Expected patients:** 17,620

**Known patients:** 1,250

**GDP per capita:** USD 2,600

**Impact:**
- Increased awareness at authority level
- Healthcare providers trained
- Increased awareness at authority level

**Objectives:**
- Develop educational training modules, material and publications in local language (Urdu)
- Establish inter-provincial collaboration of haemophilia stakeholders
- Perform comprehensive education for patients and their families
- Create awareness amongst government representatives

---

**PAKISTAN**

**Objective:** Capacity building for haemophilia care

**Partner:** University Children's Hospital, Medical Faculty, Univ. "St Cyril and Methodius", Skopje

**Represented by:** Prof. Sofijska Glamocanin

**Planned duration:** One year

**Population:** 2.1 million

**Expected patients:** 210

**Known patients:** 313

**GDP per capita:** USD 2,600

**Impact:**
- 286 patients assessed and educated
- Three regional workshops held – 75 doctors, 50 nurses from 20 regional centres trained
- Haemophilia treatment prioritising in National Health Strategy

**Objectives:**
- Assess haemophilia patients' health and clinical status
- Perform regional workshops for healthcare professionals
- Perform advanced haemophilia diagnosis
- Upgrade national haemophilia registry
- Create disease awareness at authority level

---

**MALAYSIA**

**Objective:** Educational programme for haemophilia and vWD patients & parents

**Partner:** The National Blood Centre, Kuala Lumpur

**Represented by:** Dr Faraizah Abdul Karim

**Planned duration:** Three years

**Population:** 25.7 million

**Expected patients:** 2,570

**Known patients:** 1,713

**GDP per capita:** USD 15,700

**Impact:**
- Diagnosis results included in national registry
- 150 patients, 50 parents educated
- 45 healthcare providers trained

**Objectives:**
- Develop training modules
- Create national platform for patients to meet and share their experiences
- Educate patients, parents and healthcare providers (including on psychological aspects)

---

**PALESTINE**

**Objective:** Train-the-trainer – education, screening and registry

**Partner:** Palestinian Authorities, Ministry of Health, Ramallah

**Represented by:** Mrs Diana Massad

**Planned duration:** Two years

**Population:** 4 million

**Expected patients:** 400

**Known patients:** 186

**GDP per capita:** USD 1,036

**Impact:**
- 240 patients educated and (re-)screened
- About 120 healthcare professionals trained
- National haemophilia registry implemented
- Disease awareness increased in general public and at authority level

**Objectives:**
- Provide means for diagnosis
- Ensure capacity building by implementing train-the-trainer concept
- Establish regular treatment follow up and monitoring
- Educate patients
- Implement a national haemophilia registry

---

**Macedonia**

**Objective:** Capacity building in haemophilia care

**Partner:** University Children's Hospital, Medical Faculty, Univ. "St Cyril and Methodius", Skopje

**Represented by:** Prof. Sofijska Glamocanin

**Planned duration:** One year

**Population:** 2.1 million

**Expected patients:** 210

**Known patients:** 313

**GDP per capita:** USD 2,600

**Impact:**
- 286 patients assessed and educated
- Three regional workshops held – 75 doctors, 50 nurses from 20 regional centres trained
- Haemophilia treatment prioritising in National Health Strategy

**Objectives:**
- Assess haemophilia patients' health and clinical status
- Perform regional workshops for healthcare professionals
- Perform advanced haemophilia diagnosis
- Upgrade national haemophilia registry
- Create disease awareness at authority level

---

**Impact**

- Increase awareness and knowledge in the haemophilia community,
- Implement a haemophilia database
- Establish effective and adaptable model of diagnosis
- Provide means for diagnosis
- Ensure capacity building by implementing train-the-trainer concept
- Establish regular treatment follow up and monitoring
- Educate patients
- Implement a national haemophilia registry

**Objectives**

- Develop educational resource material in local language (Urdu)
- Establish inter-provincial collaboration of haemophilia stakeholders
- Perform comprehensive education for patients and their families
- Create awareness amongst government representatives
- Provide means for diagnosis
- Ensure capacity building by implementing train-the-trainer concept
- Establish regular treatment follow up and monitoring
- Educate patients
- Implement a national haemophilia registry

---

**Impact**

- 300 patients and 300 parents educated
- Healthcare providers trained
- Increased awareness at authority level

**Objectives**

- Develop educational training modules, material and publications in local language (Urdu)
- Establish inter-provincial collaboration of haemophilia stakeholders
- Perform comprehensive education for patients and their families
- Create awareness amongst government representatives
- Provide means for diagnosis
- Ensure capacity building by implementing train-the-trainer concept
- Establish regular treatment follow up and monitoring
- Educate patients
- Implement a national haemophilia registry

---

**Impact**

- 286 patients assessed and educated
- Three regional workshops held – 75 doctors, 50 nurses from 20 regional centres trained
- Haemophilia treatment prioritising in National Health Strategy

**Objectives**

- Develop training modules
- Create national platform for patients to meet and share their experiences
- Educate patients, parents and healthcare providers (including on psychological aspects)

---

**Impact**

- Diagnosis results included in national registry
- 150 patients, 50 parents educated
- 45 healthcare providers trained

**Objectives**

- Develop training modules
- Create national platform for patients to meet and share their experiences
- Educate patients, parents and healthcare providers (including on psychological aspects)
### PANAMA

**Latin American haemophilia network – pilot project in Panama**

**Partner**
- Panamanian Haemophilia Association, Panama City

**Represented by**
- Dr Belgica Moreno

**Planned duration**
- One year

**Population**
- 1.4 million

**Expected patients**
- 340

**Known patients**
- 250

**GDP per capita**
- USD 17,800

**Objectives**
- Develop generic needs assessment tool for haemophilia in developing countries
- Implement assessment tool in pilot country to determine development project scope
- Develop a national haemophilia registry

**Impact**
- Needs of the haemophilia community identified and prioritised
- Doctors, nurses and laboratory staff trained
- Patients and families educated
- Haemophilia platform created and treatment improved
- Increased awareness and data at authority level
- Computerised haemophilia patient registry established

**Partner**
- Paediatric Clinic, Warsaw

**Represented by**
- Dr Anna Klukowska

**Planned duration**
- Two years

**Population**
- 10.5 million

**Expected patients**
- 2,260

**Known patients**
- 202

**GDP per capita**
- USD 17,800

**Objectives**
- Establish multi-centre collaboration between haemophilia doctors, nurses and laboratory technicians
- Train healthcare professionals and update treatment guidelines
- Educate patients and their families
- Screen about 850 severe haemophilia patients
- Update the national haemophilia registry

**Impact**
- About 850 severe haemophilia patients screened and diagnosis confirmed
- Approximately 170 doctors, 50 nurses and 850 patients trained
- Treatment guidelines updated (70 healthcare professionals involved)
- National haemophilia registry implemented

**Partner**
- Haematology Department, University of Medicine, Durban

**Represented by**
- Prof. Dr Margit Serban

**Planned duration**
- One year

**Population**
- 22.2 million

**Expected patients**
- 2,220

**Known patients**
- 1,210

**GDP per capita**
- USD 12,500

**Objectives**
- Create four haemophilia centres in the main regions based on existing infrastructure
- Improve laboratory status and train laboratory technicians
- Standardise diagnosis and train doctors and nurses
- Educate patients
- Improve existing national haemophilia registry
- Create a specialised group of haemophilia carers

**Impact**
- Regional access to haemophilia care and treatment created
- About 15 doctors, ten lab technicians trained
- More than 1,000 patients educated and screened

### SOUTH AFRICA

**Comprehensive haemophilia care in KwaZulu Natal (KZN)**

**Partner**
- Nelson R. Mandela School of Medicine, Durban

**Represented by**
- Dr Rajendra Thajjal

**Planned duration**
- Two years

**Population**
- 10.0 million (KZN)

**Expected patients**
- 1,000 (KZN)

**Known patients**
- 532 (KZN)

**GDP per capita**
- USD 1,500 (KZN)

**Objectives**
- Consolidate the KwaZulu Natal HCCC by offering multidisciplinary care
- Develop satellite haemophilia care – set up two satellite haemophilia treatment centres and perform outreach activities
- Run regional screening programme

**Impact**
- Two satellite haemophilia treatment centres established
- Haemophilia capacity of healthcare providers improved
- Around 500 patients assessed and educated
- Regional haemophilia registry created

**Partner**
- Centro Hospitalario Pereira Rossello, Panama

**Represented by**
- Dr Ismael Rodriguez Greco

**Planned duration**
- One year

**Population**
- 3.5 million

**Expected patients**
- 250

**Known patients**
- 202

**GDP per capita**
- USD 12,300

**Objectives**
- Create awareness in haemophilia community
- Design and implement comprehensive training programme for doctors, nurses, laboratory technicians, patients and their families
- Develop diagnostic, treatment and rehabilitation protocols
- Improve personal care and preventive measures

**Impact**
- Two annual plenary haemophilia community workshops held
- About ten haematologists, 25 laboratory technicians and specialised representatives of 18 departmental health centres trained
- Diagnostic, treatment and rehabilitation protocols developed
- Educational material for patients and healthcare professionals developed and distributed
- Interactive workshops for 60 patients, their families and healthcare professionals held in cooperation with patient organisation

### URUGUAY

**Improvement of haemophilia care by awareness creation**

**Partner**
- Centro Hospitalario Pereira Rossello, Montevideo

**Represented by**
- Dr Ismael Rodriguez Greco

**Planned duration**
- One year

**Population**
- 3.5 million

**Expected patients**
- 250

**Known patients**
- 202

**GDP per capita**
- USD 12,300

**Objectives**
- Create awareness in haemophilia community
- Design and implement comprehensive training programme for doctors, nurses, laboratory technicians, patients and their families
- Develop diagnostic, treatment and rehabilitation protocols
- Improve personal care and preventive measures

**Impact**
- Two annual plenary haemophilia community workshops held
- About ten haematologists, 25 laboratory technicians and specialised representatives of 18 departmental health centres trained
- Diagnostic, treatment and rehabilitation protocols developed
- Educational material for patients and healthcare professionals developed and distributed
- Interactive workshops for 60 patients, their families and healthcare professionals held in cooperation with patient organisation

### ROMANIA

**Improvement of haemophilia care through outreach**

**Partner**
- Emergency Clinical Hospital “Louis Turcanu” Haemophilia Centre, Timisoara

**Represented by**
- Prof. Dr Margit Serban

**Planned duration**
- Two years

**Population**
- 11.3 million

**Expected patients**
- 2,220

**Known patients**
- 1,210

**GDP per capita**
- USD 12,500

**Objectives**
- Create four haemophilia centres in the main regions based on existing infrastructure
- Improve laboratory status and train laboratory technicians
- Standardise diagnosis and train doctors and nurses
- Educate patients
- Improve existing national haemophilia registry
- Create a specialised group of haemophilia carers

**Impact**
- Regional access to haemophilia care and treatment created
- About 15 doctors, ten lab technicians trained
- More than 1,000 patients educated and screened

**Partner**
- Emergency Clinical Hospital “Louis Turcanu” Haemophilia Centre, Timisoara

**Represented by**
- Prof. Dr Margit Serban

**Planned duration**
- Two years

**Population**
- 11.3 million

**Expected patients**
- 2,220

**Known patients**
- 1,210

**GDP per capita**
- USD 12,500

**Objectives**
- Create four haemophilia centres in the main regions based on existing infrastructure
- Improve laboratory status and train laboratory technicians
- Standardise diagnosis and train doctors and nurses
- Educate patients
- Improve existing national haemophilia registry
- Create a specialised group of haemophilia carers

**Impact**
- Regional access to haemophilia care and treatment created
- About 15 doctors, ten lab technicians trained
- More than 1,000 patients educated and screened

### UZBEKISTAN II

**School for children at the national haemophilia centre**

**Partner**
- Centre of Haemophilia and Depression of Haematopoiesis, Tashkent

**Represented by**
- Dr Asiaz Dj. Makhmudova

**Planned duration**
- One year

**Population**
- 27.6 million

**Expected patients**
- 2,760

**Known patients**
- 1,138

**GDP per capita**
- USD 2,700

**Objectives**
- Create a school including a playroom, library and computer facilities for patients admitted for several months
- Provide professional psychological support for patients and their families
- Establish a hotline for patients, family and healthcare professionals

**Impact**
- Social integration ensured by improving quality of life of children with haemophilia
- Educate patients, family and healthcare professionals (100 patients/year plus family members)
Vietnam

**Latin American haemophilia network – pilot project in Panama**

**Partner**  
National Pediatrics Hospital, Hanoi

**Represented by**  
Dr Duong Ba Truc

**Planned duration**  
Two years

**Population**  
87 million

**Expected patients**  
8,700

**Known patients**  
754

**GDP per capita**  
USD 2,900

**Objectives**
- Develop guidelines for diagnosis and care of people with hereditary bleeding disorder
- Carry out a screening programme
- Set up a registry
- Enhance patient support network

**Impact**
- Around 500 persons diagnosed or carrier status determined
- 20 physicians and 30 nurses plus 20 technicians trained in specialised care
- Diagnosis, treatment and care guidelines established
- Diagnosis results included in national registry established
- Patient support network established

---

China I completed

**Fellow**  
Dr Baolai Hua, Peking Union Medical College Hospital (PUMCH), Department of Hematology, Beijing

**Host country**  
United Kingdom

**Host institute**  
The Royal Free Hospital, London

**Objectives**
- Improve capability in assessment of patients’ haemostatic status
- Focus on training in the field of thrombelastography and thrombin generation tests (TGT)

**With a view to**
- Establishing a testing centre for thrombelastography and TGT in the lab of PUMCH
- Improving diagnosis and treatment monitoring of haemophilia and other bleeding disorders at PUMCH

---

Iraq

**Fellow**  
Dr Osama Naji

**Host country**  
United Kingdom

**Host institute**  
The Royal Free Hospital, London

**Objectives**
- Improve capabilities in prenatal diagnosis for haemophilia

**With a view to**
- Gaining enough experience and training to confidently manage pregnancy in women with inherited bleeding disorders, including any complications that may arise as a result of their defective coagulation

---

China II new

**Fellow**  
Dr Jing Dai

**Host country**  
United Kingdom

**Host institute**  
The Royal Free Hospital, London, WHO Standards Laboratory for Coagulation with the NIBSC, North London

**Objectives**
- Improve knowledge in diagnosis including new detection techniques
- Learn how to assure the quality of lab testing and set up of standards of performance

**With a view to**
- Implementing international standards by establishing a quality control system at Ruijin Hospital and consequently setting up a national reference laboratory
- Dispersing knowledge about diagnosis and quality assurance to ensure consistency throughout the region

---

Sri Lanka new

**Fellow**  
Dr R.D.H. Ramanayake

**Host country**  
United States of America

**Host institute**  
The University of North Carolina, Chapel Hill

**Objectives**
- Acquire knowledge in diagnosis and management of patients with bleeding disorders
- Learn how to prepare and provide special types of blood products, e.g. cryoprecipitate

**With a view to**
- Dispersing knowledge in the diagnosis and management of bleeding disorders
- Creating diagnosis and treatment guidelines for bleeding disorders
- Conducting research and studies related to bleeding disorders

---

Thailand new

**Fellow**  
Dr Noppacharn Uaprasert

**Host country**  
United States of America

**Host institute**  
The University of North Carolina, Chapel Hill

**Objectives**
- Improve research skills in molecular pathogenesis of coagulation disorders with emphasis on haemophilia

**With a view to**
- Establishing a haemostasis and thrombosis research and education centre at the Faculty of Medicine, Chulalongkorn University in Bangkok
Haemophilia is a hereditary disorder of blood coagulation resulting in the deficiency of clotting Factor VIII in haemophilia A and clotting Factor IX in haemophilia B. Both these disorders have the same inheritance pattern and result from an abnormal gene on the X chromosome.

In its severe form, if left untreated, it results in chronic incapacity and handicap in early life and even death; however, it is not uncommon for moderate and mild forms as well as haemophilia carriers to result in chronic bleeding problems if undiagnosed. It is essential therefore that these disorders can be differentiated in the laboratory so that appropriate treatment with clotting agents when available can be administered.

The developing world, according to the WHO, is mostly made up of countries in Asia, South America and Africa. Four-fifths of the population of the world lives in these countries and the vast majority of haemophiliacs in those regions are undetected and untreated. One of the main reasons for this is through poor diagnosis. There is a lack of knowledge of diagnosis of bleeding disorders amongst primary-care physicians and as a result of this, a profound lack of support and resource for pathology laboratories.

The purpose of medical laboratories is to provide a high-quality service through precise, relevant and comprehensive data that can be applied to patient management. The laboratory has a vital role in the diagnosis of patients with inherited disorders, as any misdiagnosis will result in serious implications to their treatment. For example, Factor VIII deficiency can easily be misdiagnosed as a Factor IX deficiency. In order to combat this problem the laboratory must follow quality rules that can be described as Good Laboratory Practice (GLP), or in a more encompassing way using the term Good Medical Laboratory Services (GMLS), thus including clinical requirements in addition to laboratory ones.

The pathology laboratories in the developed world have had to encompass this concept, which has now been introduced in standards required by Clinical Laboratory Accreditation and incorporate the ISO 15189 standard. This approach highlights a new concept in medical laboratories where clinical pathologists are advised to review their thinking and management style and are encouraged to work as a team aiming for the same goal, thus improving the quality of results. Now is the ideal time for the developing world to follow suit so that laboratory services in these countries can be uplifted.

In many countries now, laboratory accreditation inspections ensure laboratories comply with quality standards. A key part to these standards includes Quality Assurance (QA).

QA is an overall term used to describe all measures taken to ensure the reliability of laboratory testing and reporting and covers all aspects of the process from sample taking, separation and analysis, External Quality Control (IQC), through to result reporting. QA is fundamental to laboratory technology and synonymous with accurate diagnosis. It has taken many years for QA to be fully appreciated and it’s essential that it becomes an integral part of the educational curriculum. Implementing QA, however, does not come without a price and should be built in to the laboratory budget.

This additional expense may be difficult for a laboratory to justify to hospital managers when they can barely afford to test the patient, but it needs addressing. IQC, which is used to establish whether or not a series of techniques and procedures are performing consistently on a day-to-day basis, and External Quality Assessment (EQA) is a major part of this and essential to a successful quality laboratory and a reliable result.

Participation in an EQA scheme is strongly advised as continued participation in EQA schemes has been clearly linked to improved laboratory performance. The ultimate objective is the improvement of healthcare through improved laboratory performance by proficiency testing of an individual laboratory. It helps build confidence between laboratory and users of their service. In addition, such schemes can also provide information concerning the relative performance
of analytical procedures, including the method principle, reagents and instruments through its data collection. Currently there are a number of schemes worldwide. Australia has a scheme covering the South Pacific region and UK NEQAS offer a national scheme as well as an international one, which has, in collaboration with the World Federation of Hemophilia (WFH), been designed to help improve diagnosis of bleeding disorders in developing countries.

Recently, the Christian Medical College in Vellore has successfully set up a national scheme for coagulation testing in India. The Philippines are now using this scheme as the cost in participating in other available schemes became prohibitive, and this allows them to gain the expertise to enable them to set up their own national scheme.

The use of reference materials is another necessity for standardisation of the tests and assay procedures, without which, accurate results cannot be guaranteed and quality assurance improved. Most tests in the laboratory should use a reference material traceable to a WHO standard. These are available through the National Institute for Biological Standards and Control, but at a cost, which may be beyond the resources of laboratories in the developing countries. However, reference plasmas are also available through diagnostic companies manufacturing reagents for coagulation testing which are in themselves traceable to international standards.

In the investigation of bleeding disorders the results of clotting tests can be affected by the collection and processing of blood samples, and by the selection, design, quality control and interpretation of screening tests and specific assays. These effects have important diagnostic and therapeutic implications. The quality of the sample is paramount for coagulation testing. The aim in collecting and handling blood specimens is to preserve the components to be analysed in a state as close as possible to that in vivo.

Therefore in order to achieve reliable, accurate and reproducible results, laboratories must pay particular attention to the standardisation of specimen collection and handling procedures. As soon as blood is removed from circulation changes occur, tissue thromboplastin is released, platelets, clotting factors and natural anticoagulants are activated, and active enzymes appear transiently in the circulation and enzyme-inhibitor complexes form. The basic essential is that sampling procedures are standardised, and phlebotomists, clinicians performing venepunctures, know the relevant standards and understand the rationale behind them. As soon as the specimen has been withdrawn from the patient’s vein it begins to deteriorate. It must therefore be transported as quickly as possible to the laboratory. During transport, specimens should be held upright and handled gently to minimise trauma, which may cause haemolysis and activation of coagulation. It should be noted that due to its labile nature, specimens for factor VIII assay should be analysed within two hours of collection, especially in tropical countries and in non-air-conditioned environments. If not tested immediately then they should be stored in a freezer between –40 to –80 °C.

Equipment and reagents are the “tools of the trade” of any laboratory. It is important to have continuity of supply of reagents with attention being paid to batches and to their shelf life and stability. Equipment requires maintenance in order to be kept in good working order.

**QUALITY ASSURANCE**

- Employ both normal and abnormal control levels of Internal Quality Control (IQC) materials
- Record interventions when IQC is out of range
- Follow Standard Operating Procedures carefully
- Use reference materials in laboratory assay testing which are traceable to International Standards
- When performing clotting factor assays, ensure that deficient plasmas used in factor assay determination, even when produced by a manufacturer, are truly deficient by checking the level before introducing into the assay system
- Participate in an External Quality Assessment scheme as local and affordable to you as possible

“IN MANY COUNTRIES NOW, LABORATORY ACCREDITATION INSPECTIONS ENSURE LABORATORIES COMPLY WITH QUALITY STANDARDS. A KEY PART TO THESE STANDARDS INCLUDES QUALITY ASSURANCE.”

Dr Angus McCraw
Report of the statutory auditors to the Board of Foundation of Novo Nordisk Haemophilia Foundation Zurich

As statutory auditors, we have examined the financial statements of Novo Nordisk Haemophilia Foundation, which comprise the balance sheet, income statement and notes, for the year ended 31 December 2008.

These financial statements are the responsibility of the Board. Our responsibility is to perform a limited statutory examination on these financial statements. We confirm that we meet the licensing and independence requirements as stipulated by Swiss law.

We conducted our examination in accordance with the Swiss Standard on Limited Statutory Examination. This standard requires that we plan and perform a limited statutory examination to identify material misstatements in the financial statements. A limited statutory examination consists primarily of inquiries of foundation personnel and analytical procedures as well as detailed tests of foundation documents as considered appropriate in the circumstances. However, the testing of the operational processes and the internal control system, as well as inquiries and further testing procedures to detect fraud or other legal violations, are not within the scope of this examination.

Based on our limited statutory examination, nothing has come to our attention that causes us to believe that the financial statements do not comply with Swiss law and the foundation's deed and internal regulations.

PricewaterhouseCoopers AG
Patrick Balkanyi Audit expert
Thomas Illi Auditor in charge
Zurich, 24 February 2009

Enclosure:
Financial statements (balance sheet, income statement and notes)

### ANNUAL ACCOUNTS 2008
NOVO NORDISK HAEMOPHILIA FOUNDATION, ZURICH

#### Balance sheet as of December 31st (in Swiss Francs)

<table>
<thead>
<tr>
<th>Assets</th>
<th>2008</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and Equivalents</td>
<td>2,178,057</td>
<td>2,364,825</td>
</tr>
<tr>
<td>Other Receivables to third parties</td>
<td>5,180</td>
<td>2,691</td>
</tr>
<tr>
<td>to related parties</td>
<td>24,170</td>
<td>1,194</td>
</tr>
<tr>
<td>Prepaid expenses</td>
<td>124</td>
<td>556</td>
</tr>
<tr>
<td><strong>Total Assets</strong></td>
<td><strong>2,207,931</strong></td>
<td><strong>2,369,266</strong></td>
</tr>
</tbody>
</table>

#### Equity and Liabilities

<table>
<thead>
<tr>
<th>Liabilities</th>
<th>2008</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade accounts payable to third parties</td>
<td>14,416</td>
<td>2,309</td>
</tr>
<tr>
<td>to related parties</td>
<td>10,440</td>
<td>36,198</td>
</tr>
<tr>
<td><strong>Deferred Income</strong></td>
<td><strong>1,592,562</strong></td>
<td><strong>1,942,304</strong></td>
</tr>
</tbody>
</table>

#### Income statement for the business year (in Swiss Francs)

<table>
<thead>
<tr>
<th>2008</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income donation income</td>
<td>2,143,686</td>
</tr>
<tr>
<td>exhibition and conferences</td>
<td>(15,473)</td>
</tr>
<tr>
<td>personnel costs</td>
<td>(845,661)</td>
</tr>
<tr>
<td>travel and communications costs</td>
<td>(167,701)</td>
</tr>
<tr>
<td>project grants</td>
<td>(1,789,042)</td>
</tr>
<tr>
<td><strong>Gross income</strong></td>
<td><strong>(1,789,042)</strong></td>
</tr>
<tr>
<td>rent costs</td>
<td>(85,211)</td>
</tr>
<tr>
<td>service fees</td>
<td>(23,000)</td>
</tr>
<tr>
<td>administration costs</td>
<td>(52,608)</td>
</tr>
<tr>
<td><strong>Administrative costs</strong></td>
<td><strong>(190,821)</strong></td>
</tr>
<tr>
<td><strong>Operating profit (loss)</strong></td>
<td><strong>183,825</strong></td>
</tr>
<tr>
<td>interest income</td>
<td>1,476</td>
</tr>
<tr>
<td>bank fees</td>
<td>(1,386)</td>
</tr>
<tr>
<td>currency gains (losses)</td>
<td>(1,518)</td>
</tr>
<tr>
<td><strong>Financial income (expense)</strong></td>
<td><strong>(1,410)</strong></td>
</tr>
<tr>
<td><strong>Gain (Loss)</strong></td>
<td><strong>182,415</strong></td>
</tr>
</tbody>
</table>

#### Notes to the annual financial statements

1. **Disclosures according to Art. 663b OR (in Swiss Francs)***
   - Liabilities towards pension funds. | 2008 | 2007 |
   | 31,000 | 62,000 |

2. **Risk assessment**

   The Novo Nordisk Haemophilia Foundation Council makes an adequate risk assessment annually and has initiated appropriate measures in consequence, in order to ensure that the risk of a significant error in the Foundation accounts can be regarded as small.

   There are no further facts requiring disclosures according to Art. 663b OR.