



## **Research Committee Report to the Board AHCDC AGM / 15 April 2008**

### **Members of the Research Committee:**

J. St-Louis (chair), V. Blanchette, M. Carcao, A. Chan, C. Demers, D. Lillicrap, B. Ritchie and JKM. Wu

### **Mandate of the Research Committee**

1. Facilitate collaborative research in Canada
2. Maintain a compilation of ongoing research activities and surveys involving the AHCDC
3. Maintain a list of the publications and presentations arising from AHCDC associated research;
4. Assist the Executive and Board in the oversight of funds allocated in support of national research in the AHCDC budget (Inhibitor Lab, Genotype Lab, salary of T. Soll)
5. Continue negotiations with Baxter regarding their offer of research funds

### **Activities in 2008**

Activities of the committee were carried out through email exchange in 2007-2008.

Regarding item 1 of the mandate: the chair answered various queries and correspondence relating to opportunities for collaborative research. Work was done during the year on a plan for a new research grant program to begin in 2009 (see B-CHERP under item 5 below).

Regarding item 2 and 3 of the mandate: Trevor Soll kept a compilation of publications up to date on the AHCDC web site. Annie Kaplan reminded the members on a regular basis to send to Trevor appropriate new references. The list of active research endeavours and surveys as it appears on the web site was not updated in the last year however the list of open competitions and grants was kept current.

Regarding item 4 of the mandate: the Chair was asked to join in on the teleconferences of the executive committee on a regular basis through the past year.

Regarding item 5 of the mandate: negotiations with Baxter were again the main thrust of the activity of the committee in this past year. After discussions at the committee level regarding possible options, a proposal with 2 components was put to Baxter to establish the parameters of the ongoing partnership for research between AHCDC and Baxter. This

multi-year agreement was negotiated after consultation with the executive and the board of AHCDC in December 2007. The new program is named B-CHERP and its 2 components are the creation of a position of data analyst for CHARMS and the launch of a new epidemiological and clinical grant program for research in hereditary bleeding disorders in Canada. Please refer to the document in Annex 1 for more details.

Other activities in 2007-2008 have included the Chair sitting in on the jury of CHS Research Grant Program and the jury of CHS/Wyeth Care-until-Cure competition as well as on the panel adjudicating the AHCDC grants for fellowship training in hemophilia.

### **Outstanding Issues**

The membership of the AHCDC and the Board will have to name the members who will be sitting on the management committee of B-CHERP (standing members of the renewed Research Committee?)

Within the framework of AHCDC Renewal, the terms of reference of and composition of the new Research Committee will need to be agreed upon.

Jean St-Louis, MD, FRCPC  
April 15, 2008

## **ANNEX 1**



### **Baxter AHCDC Collaboration for Hemophilia Research**

#### **THE BAXTER CANADIAN HEMOPHILIA EPIDEMIOLOGICAL RESEARCH PROGRAM Proposal for a New Partnership December 14, 2007**

#### **INTRODUCTION**

Since 2005 Baxter Bioscience and the Association of Hemophilia Clinic Directors of Canada (AHCDC) have entered into a partnership to advance hemophilia research in Canada through support of AHCDC and some of its key infrastructures that enable large population-based research of global relevance. The following is a proposal to establish the platform through which these efforts will continue to materialize and flourish in the coming years.

#### **THE BAXTER CANADIAN HEMOPHILIA EPIDEMIOLOGICAL RESEARCH PROGRAM (B-CHERP)**

##### **1. - GOALS:**

The Baxter Canadian Hemophilia Epidemiological Research Program (B-CHERP) will provide Canadian investigators and hemophilia clinic directors new resources to conduct quality population-based clinical research in hereditary bleeding disorders in Canada. A particular emphasis of the program will be to capitalize on the existing network and assets of hemophilia clinics throughout Canada. In particular, of the core infrastructures established in Canada, the Canadian Hemophilia Assessment and Resource Management System (CHARMS) will be targeted for enhanced utilization as a research tool.

##### **2. - FIELD OF STUDY:**

The program will support and fund clinical, descriptive and epidemiological studies of hereditary bleeding disorders initiated by Canadian investigators. While inquiries of

correlations between clinical and biological or genetic determinants are expected, the program will not support strictly fundamental research. For the purpose of this program, hereditary bleeding disorders include hemophilia A and B including inhibitor patients, Von Willebrand disease, and other rare inherited bleeding disorders.

### 3. – ORGANIZATIONAL STRUCTURE AND ALLOCATION OF FUNDS:

The B-CHERP will comprise two related components. The funding secured for this program will serve to establish these 2 components: 1) the creation of a position of data analyst for CHARMS and 2) the creation of a fund to provide peer-reviewed research grants for projects compatible with the objectives of the program. While this initiative will be firmly grounded in the existing AHCDC framework, a new oversight committee will ensure that the program is well managed and reaches its stated goals.

#### 3.1. – CHARMS Data Analyst.

CHARMS is a critical source of information which remains underused. This blood product tracking and clinical database is installed at all 24 comprehensive care hemophilia clinics in Canada. While data collection has been ongoing for several years, the promises of CHARMS remain partly unfulfilled because resources have not been sufficiently applied to analysis of and reporting on the data. The new position will fill this essential need.

The CHARMS Data Analyst will oversee the type and the quality of the data gathered in CHARMS; conduct on behalf of AHCDC regular analysis of and reporting on the data; and assist directors and investigators in using CHARMS to obtain answers to research questions. The person selected will have a suitable training (PhD or equivalent) in epidemiology or public health and in research. Hired by AHCDC in a supportive role, the person will not have an appointment as a professor or independent investigator.

Although the mandate of the analyst will be national, the person will tentatively be integrated within the McMaster Transfusion Research Program and receive direct day-to-day supervision by the directors of the Hamilton hemophilia clinic. The person will provide quarterly reports to the Management Committee of the B-CHERP, the CHARMS committee and the executive committee of the AHCDC.

#### 3.2. – Grant Program.

A yearly open competition for research grants will be established to cover operating costs other than the salary of the analyst (e.g. costs of ERB approval, research nurse and other clinic reimbursements, costs of investigational laboratory testing, etc.). Grant applications will be peer-reviewed and scored. One to 3 projects will be

funded every year, each with a maximum grant of \$75 000 annually. If adequate progress is demonstrated, funding can be renewed up to a maximum of 3 years in total.

### 3.3. – Management Committee and Accountability.

A Management Committee will be constituted with a membership that comprises four members of AHCDC, an experienced research administrator or investigator from outside the AHCDC and a medical representative from Baxter Bioscience. The representative from Baxter will play a consultative role and will not vote. The Management Committee will meet at 3-monthly intervals and will be assigned the responsibility of reviewing the overall and specific objectives of the research program and ensuring that appropriate milestones are achieved. The Management Committee will not itself review the grant applications but will convene an expert panel each year for the purpose of peer-reviewing and scoring the applications. Finally, the activities of the B-CHERP will be highlighted each year in an update to the full membership of the AHCDC at their Annual General Meeting.

## 4. - PRELIMINARY RESEARCH PROGRAM:

Previously identified high-level areas of inquiry remain the research priorities of AHCDC. More specifically, it is planned that the research program will continue to center on the issues of optimization of care and outcomes at the transition phase of late adolescence and early adulthood in patients with severe hemophilia. Two complementary areas of investigation are encompassed in this broad topic: 1) A formal evaluation of preference and patterns of treatment in adolescents and young adults with severe hemophilia; 2) An evaluation of the influence of various biological variables on the status of patients in that age group and on the benefits for them of optimized hemophilia care.

These are not exclusive foci of investigations as competing proposals may be brought forward given the expected open process for grant approval detailed here.

## 5. – MILESTONES:

In order to reach its stated goals the following milestones are proposed for the B-CHERP.

### 5.1. – CHARMS Data Analyst.

5.1.1. – Full description of position, mandate and qualifications completed by 2008-03-01.

5.1.2. - Agreement between AHCDC and host institution signed by 2008-05-01.

5.1.3. - Selection and hiring by 2008-10-01.

- 5.1.4. - Quality and performance standards of database defined by 2008-12-01.
- 5.1.5. - First report on status of database and initial plan of action submitted by 2009-02-01.
- 5.1.6. - Subsequent progress report on effects of corrective measures by 2009-06-01.
- 5.1.7. - Validation that quality standards have been reached by 2009-09-01.

5.2. – Grant Program.

- 5.2.1 - Draft document of the new grant program developed by 2008-06-01.
- 5.2.2. - Final approval by AHCDC and Baxter signed by 2008-07-01.
- 5.2.3. - Creation of an administrative center for secretarial and related tasks by 2008-10-01
- 5.2.4. - Production of materials for publicity and applications by 2008-12-01.
- 5.2.5. Launch of first competition by 2009-02-01.
- 5.2.6. - Announcement of results of first competition by 2009-07-01.

5.3. – Management Committee.

- 5.3.1 - Initial working group of AHCDC members named by 2008-02-01.
- 5.3.2. - Final committee with outside parties constituted by 2008-04-01.
- 5.3.3. - First official meeting by 2008-05-01.
- 5.3.4. - Detailed progress report to AHCDC Board and AGM by 2008-06-01
- 5.3.5. - Formation of peer-review panel for grant evaluation by 2009-01-01

Beyond these specific targets, general conditions specified in the letters of understanding of December 2006 still apply. In particular, sums disbursed by Baxter after January 1<sup>st</sup> 2007 would only serve to meet expenses directly engaged in conducting the program as described above. It will be expected that at least one research abstract will be accepted annually at a conference hosted by either the American Society of Hematology, the International Society for Thrombosis and Haemostasis or the World Federation of Hemophilia by the end of 2009, with publication accepted in a peer-reviewed journal by the end of 2010.

6. – BUDGET:

For the position of CHARMS analyst and in order to be able to attract qualified candidates, funding is sought to secure a 3 year term with a 4 month probation period and annual performance reviews. Extension beyond 3 years will depend entirely on obtaining new funding. The proposed budget for this component of the program is \$125,000 per year for 3 years including salary, benefits, travel, equipment and other costs.

Funds requested for the grant program amount to \$250,000 per year for direct grants to the investigators and \$25,000 per year for administrative and publicity costs. Again a 3-year horizon should be a minimum to justify the efforts of establishing the program.

## **CONCLUSION**

Canada is well placed to contribute to further advances in hemophilia care through its highly organized and collaborative national network of hemophilia clinics and through access to national data available through CHARMS. This newly proposed Baxter Canadian Hemophilia Epidemiological Research Program will capitalize on these resources and on the investments made in 2005 and 2006 to guarantee the ongoing development of CHARMS and of the NHML. The members and leadership of AHCDC recognize and are grateful for the commitment and vision demonstrated by Baxter in this creative and unique partnership.