

ATHN 2010 ANNUAL REPORT

Securing Data. Advancing Knowledge. Transforming Care.



The American Thrombosis and Hemostasis Network (ATHN) is a non-profit organization committed to advancing and improving care for individuals affected by bleeding and thrombotic disorders.

A Nationwide Resource.

Our mission is to provide stewardship of a secure national database, adherent to all privacy guidelines, which will be used to support clinical outcomes analysis, research, advocacy and public health reporting in the hemostasis and thrombosis community.

Committed to Shared Values.

- » Improving clinical outcomes and continuity of care
- » Facilitating research
- » Fostering collaboration
- » Maintaining confidentiality
- » Conserving resources through a standards-based data infrastructure

Dear Friends and Colleagues,

This report marks the start of our fifth year of operations. During this period, our organization has assumed the stewardship role of a secure national database and is working to advance knowledge of bleeding and thrombotic disorders. Knowledge derived from the database combined with the expanding network of ATHN Affiliated specialty care centers will help transform care for the individuals we serve.

ATHN's strength lies in its founding vision and its follow-through on commitments made to the hemostasis and thrombosis community. The development of WebTracker™ and the ATHNdataset; funding to increase data capacity at treatment centers through ATHNdata.quality.counts; ATHNready, which leverages the database to support patient and treatment center emergency preparedness; pilot research projects and an annual Data Summit provide tangible evidence of accomplishment. The diverse and dedicated volunteer Board of Directors of ATHN; its professional leadership and growing staff; the expanding network of ATHN Affiliates as well as its collaborations with a wide range of patient, government and industry partners have earned increasing respect and cooperation of the community.

ATHN has been blessed with significant long-term funding from Novo Nordisk that provides a solid foundation for our work. We have been awarded a number of project-specific grants, including the recently completed cooperative agreement from the Centers for Disease Control and Prevention (CDC) through which we developed and tested ATHNready technology tools for emergency preparedness. Baxter's donation of Advoy®—the nation's first electronic, web-based patient bleed and infusion diary—to ATHN further recognizes the community's efforts toward a national data source and ATHN's role as trusted steward.

By maintaining a clear sense of our priorities and strategic direction, we will enter a new phase of growth from which we will build on this foundation for outcomes improvement and research in hemostasis, and later, thrombosis. As we move forward, it will be critical that we keep focused on our strategic plan while we remain open to new opportunities, diversify our funding sources ensuring long-term sustainability and cultivate the relationships we worked so hard to create. In 2010 and beyond, we must further our resolve to deliver on these new promises to those we continue to serve.

Thomas Abshire, MD
ATHN Chair, Board of Directors

Diane Aschman, MS
ATHN President and CEO

STRATEGIC DIRECTION AND KEY MILESTONES



ATHN's strategy comprises five key strategic directions, with organizational sustainability as the underpinning.

Technology

ATHN will maintain and grow a stable, reliable information infrastructure expandable to other disorders, service providers and uses, including research.

Milestones Achieved:

- The ATHN infrastructure is successfully hosted and secured at a commercial site.
- Beta testing of the web-based platform is coming to a close, with centers scheduled for migration to a production environment prior to the 2010 Data Summit.
- In consideration of the community's desire for one national database, Baxter has donated Advoy to ATHN. Renamed ATHNadvoy and managed under the stewardship of ATHN, patient data will be stored and managed side-by-side with other data under the stewardship of ATHN. Treatment center and patient consent were received prior to the transfer of historical data.

Data Management

ATHN will amass an accurate, quality-validated limited data set (the ATHNdataset) that is enriched to address key mission-driven projects, securely stored and backed-up.

Milestones Achieved:

- Data Use and Business Associate Agreements (DUBAAs) have been executed by 69 centers. Other centers are in active negotiation.
- Treatment centers have begun seeking patient authorization for participating in the ATHNdataset. Patient response has been very positive.
- In 2008, ATHN launched ATHNdata.quality.counts. The program funds data management at ATHN Affiliate treatment centers to build and strengthen capacity at the local level. ATHN is in its second round of funding. The third round will be announced in Fall 2010. To date, \$1.25 M was awarded to 43 centers. Interim and annual reports of awardees provide insight into best practices and barriers to data management.
- ATHN was awarded funding from the Hemophilia Alliance for computer equipment on behalf of treatment centers to improve operational excellence in data capture.
- A data access policy is under development by ATHN's Privacy, Data Access and Security Committee, a group with significant consumer representation.

Public Health and Safety

ATHN will be a valuable resource to CDC, the Maternal and Child Health Bureau (MCHB), the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) in the support of public health and safety.

Milestones Achieved:

- ATHN participated in the development of the Healthy People 2020 goals for the nation.
- ATHN encouraged and continues to support the adoption of the national information infrastructure powered by WebTracker as an accurate and efficient means of creating and submitting surveillance reports for CDC's Universal Data Collection (UDC), the Hemophilia Data Set to MCHB, Healthy People 2020 outcomes and adverse event reports to the FDA.
- In support of public health education, four papers have been submitted to American Journal of Preventive Medicine, Special Supplement; ATHN also presented findings and lessons learned at the National Conference on Blood Disorders in Public Health, Genetic Alliance Conference, the American Public Health Association meeting, the National Hemophilia Foundation annual meeting, state chapter meetings and at a Hemophilia Federation of America sponsored webinar.
- We have been exploring options for capturing population-based data, including expansion of the ATHN Affiliate membership.



- The use of WebTracker to support outcomes assessment and performance measurement is a key subject at this year's Data Summit.

Research

ATHN aims to be the most convenient, accessible and sought-after network and database to facilitate research in bleeding disorders (and at some future time, thrombotic disorders).

Milestones Achieved:

- ATHN completed two pilot projects for which it designed, developed and hosted electronic case report forms. These "proof of concept" projects, such as the Plasminogen-deficiency Registry, provided benefit to their sponsors while enabling ATHN to gain experience applicable to other studies.
- At the urging of the 2009 ATHN Research Think Tank, ATHN initiated a Safety Management Working Group. The Group's charge is to develop and maintain ATHN's safety management plan consistent with FDA regulations for adverse events, including any prospective monitoring systems or projects.
- Participants in the Research Think Tank as well as the Industry Liaison Group repeatedly underlined the importance of consistent and accurate data in the ATHNdataset. Toward that end, in 2010 ATHN established a Data Quality Working Group. The Group has developed a self-audit of data and pilot tested the audit with more than 12 ATHNdata.quality.counts grantees.

Care Continuity and Outcomes Improvement

ATHN will use measurements based on the ATHNdataset to drive quality, service-oriented and patient-centered care for patients with bleeding and thrombotic disorders.

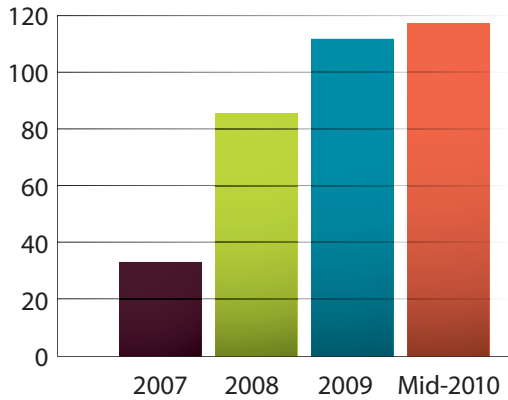
Milestones Achieved:

- The ATHNready program to support emergency preparedness at HTC's was completed under cooperative agreement with CDC. Tools developed and tested with patients, emergency personnel and providers included: the Care Continuity Plan, complete with electronic templates to be used by treatment centers in developing their emergency plan; Personal Health Report, a portable USB flash drive with patient-specific information produced using the WebTracker infrastructure and HTC Finder, an interactive web-based tool to assist patients in identifying a treatment center in an emergency. We continue to urge adoption of these tools.

ATHN'S STRATEGIC DIRECTION 2010-12



ATHN AFFILIATE GROWTH AMONG FEDERALLY-FUNDED TREATMENT CENTERS



Supporting Specialty Clinics. Advancing Specialty Care.

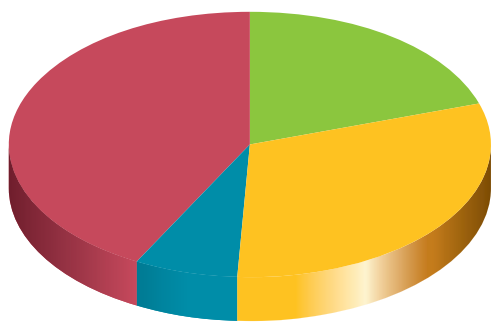
By partnering with ATHN Affiliate treatment centers to establish a safe and secure national database of patient health information, ATHN will enable clinicians to gain a better understanding of bleeding and blood clotting disorders.

Today, 118 treatment centers are ATHN Affiliates. These Affiliates represent a cross section of the community, including academic research centers, large centers and smaller ones, Lab Tracker users and non-users, those with 340B pharmacy program affiliations and those without.

Treatment centers across the country are experiencing tangible financial benefits of the ATHN Affiliate program. Since 2008, ATHN has awarded more \$1.25M in ATHNdata.quality.counts funding to increase capacity of treatment centers to maintain secure and accurate data.

The graph at left illustrates ATHN affiliate growth since 2007.

AFFILIATE WEBTRACKER ROLLOUT STATUS



- Beta testing and mapping, 20%
- Readiness assessments completed or in process, 31%
- IRB pending or site on hold, 7%
- DUBAA pending, 42%

Affiliate WebTracker Rollout Status

The national WebTracker rollout is successfully underway. WebTracker is a powerful data management tool designed to enable treatment centers to record data once and reuse it over and over again for care, clinic management, research and reporting to federal/state agencies. The new software also allows for patients who choose to participate in the ATHNdataset to share a limited amount of non-identifiable data related to their care with ATHN. The ATHNdataset will facilitate research to help improve care and support advocacy efforts on behalf of patients with bleeding and clotting disorders. Data can also be easily exported to fulfill UDC surveillance and MCHB reporting requirements.

The graph at left illustrates the progress of the WebTracker rollout to date.

FINANCES

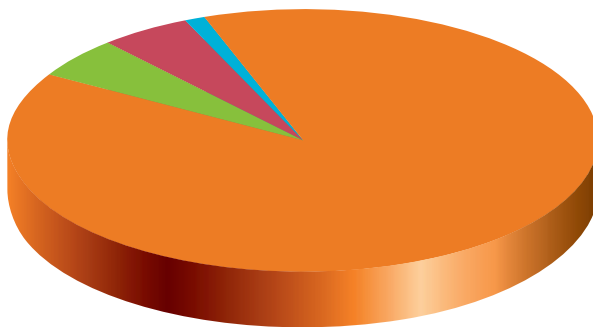
ATHN is recognized as a 501(c)3 organization. Sources of income during 2009 included corporate and government grants, investment income and service contracts with treatment centers. Most significant are the long-term grant from Novo Nordisk, Inc. and the cooperative agreement (U27DD000319) funded by CDC.

Distribution of those funds benefit the treatment centers dedicated to bleeding and thrombotic disorders, the patients they serve, and the public health agencies who support greater access to care and population health. More specifically, during 2009, 25% of expenditures supported data management at the local level through the ATHNdata.quality.counts program. Ten percent (10%) of funds were dedicated to ATHNready suite of tools for emergency preparedness, as funded by CDC. And, an

additional 58% supported other key programs. Such programs include the development and testing of the new web-based infrastructure powered by WebTracker; community relations; and ATHN sponsored events (e.g., the Research Think Tank and the annual Data Summit attended by more than 200 individuals). Only 7% of funds were used for general management and fundraising.

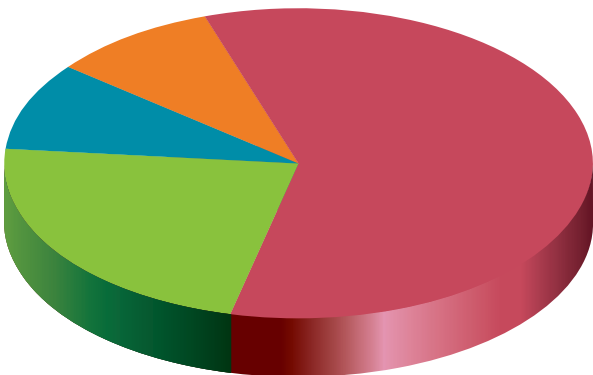
The graphs below depict our sources of income and use of funds to support our not-for-profit mission. Our financials were audited by an independent accounting firm.

2009 INCOME



- Corporate Grants, 89%
- Government Grants, 6%
- Investments, 4.5%
- Other, 0.5%

2009 EXPENDITURES



- Grants to HTC's: ATHNdata.quality.counts, 25%
- ATHN Programs (other), 58%
- Emergency Preparedness, 10%
- General Management & Fundraising, 7%

ATHN BOARD OF DIRECTORS

**We owe a debt of gratitude to our esteemed board members
for their continued professional guidance.**

Thomas Abshire, MD

Chair, ATHN Board of Directors

Senior Vice President, Medical Services,
The Medical Sciences Institute
Chief Medical Officer, Blood Center of Wisconsin

Susan Cutter, MSW, MPA

Regional Coordinator
Penn Comprehensive Hemophilia and Thrombosis Program
Hospital of the University of Pennsylvania

Patricia Dominic

Chief Executive Officer
Hemophilia of Georgia, Inc.

Ann Forsberg, MA, MPH

Regional Administrator,
Hemophilia Treatment Center Program
New England Hemophilia Center
UMASS Memorial Hospital

Wanda Foster, RN, MS, FACHE

Vice President Nursing / Chief Nursing Officer
McDonough District Hospital

Robert W. Fox

Treasurer, ATHN

President and Chief Executive Officer
Mary M. Gooley Hemophilia Center

David Green, MD, PhD

Professor, Emeritus, Division of Hematology/Oncology
Northwestern University School of Medicine
Northwestern Center for Bleeding Disorders

Chris Guelcher, APRN, BC, PNP, CPON

Pediatric Nurse Practitioner
Department of Hematology/Oncology
Children's National Medical Center

Steven Humes, MM, MPH, Secretary

Regional Coordinator, Region IV, North Hemophilia
Treatment Center Network
University of North Carolina at Chapel Hill
Hemophilia Diagnostic and Treatment Center

Janna Journeycake, MD

Assistant Professor, CCBD
North Texas Hemophilia and Thrombosis
Program-Pediatric Program
Center for Cancer and Blood Disorders;
Hematology/Oncology, Children's Medical Center

Barbara A. Konkle, MD

Chair-Elect, ATHN Board of Directors

Director, Translational Research/Medical Director,
Hemostasis Reference Laboratory, Puget Sound Blood Center
Professor of Medicine, University of Washington

Roshni Kulkarni, MD

Professor, Pediatric and Adolescent Hematology/Oncology,
Dept of Pediatrics and Human Development,
Michigan State University

Ellis J. Neufeld, MD

Associate Professor of Pediatrics/
Associate Chief of Hematology & Oncology,
Children's Hospital Boston

Tom Ortel, MD, PhD

Associate Professor of Medicine & Pathology
Hemostasis & Thrombosis Center
Duke University Health System

Michael Recht, MD, PhD

Adjunct Associate Professor, Pediatrics
Oregon Health and Science University School of Medicine
Regional Director, Oregon Hemophilia Treatment Center

Amy Shapiro, MD

Immediate Past Chair, ATHN Board of Directors

Medical Director
Indiana Hemophilia and Thrombosis Center

Diane J. Aschman, MS

President and CEO

American Thrombosis and Hemostasis Network

Jeanne Lusher, MD

Ex Officio ATHN Board Member (non-voting)

Hemostasis and Thrombosis Center
Co-Director, Hematology / Oncology
Children's Hospital of Michigan
Distinguished Professor of Pediatrics, Wayne State University

W. Keith Hoots, MD

NHLBI Liaison (non-voting)

Division Director
National Health Lung and Blood Institute
US Department of Health and Human Services

Vanessa Byams, MPH

CDC Liaison (non-voting)

Health Scientist, Division of Blood Disorders
National Center on Birth Defects and Developmental
Disabilities, Centers for Disease Control and Prevention

COMMITTEE MEMBERS

ATHN benefits greatly from the guidance of its standing committees, working groups and liaisons under the areas of Operations; Research; Clinical; Administration; and Liaison with Community and Industry partners. We are proud of our volunteer support and most appreciative of the one hundred individuals who donate their time and energy to help us achieve our objectives.



Operational Committees

2010 Community Relations and Communications Committee

Focus: Ensure that an accurate and compelling communication strategy cultivates collaborative relationships between ATHN and the bleeding and thrombosis community, including but not limited to ATHN Affiliates, government and industry partners, community-based patient advocacy organizations and the patients they serve.

Membership

- Wanda Foster, Co-chair
- Judith Baker
- Theresa Bruner
- Mary Lou Damiano
- Christine Guelcher, Co-chair
- Steven Humes
- Lew Parker
- Diane Aschman
- Karen Droze
- Kathleen Van Gorden
- Sarah Reymer
- Leslie McGeady

2010 Privacy, Security and Data Access Committee

Focus: Provide guidance to the Board and oversight of ATHN's operations to ensure privacy of patient data, security of the ATHN dataset, as well as open and transparent processes for data access and sharing consistent with ATHN's core values.

Membership

- Tami Wood-Lively, Chair
- Paul Brayshaw, Consumer
- Pam Bryant
- Randall Curtis
- Steve Faust - NHF
- James Huang
- Jeanne Lusher
- Derek Robertson
- Chris Roberson
- Mary Ann Schall
- Mark Skinner - WFH
- Chad Stevens - HFA
- Crystal Watson
- Eric Werner
- Mike Souci, CDC Liaison

2010 Technology Committee

(*WebTracker Subcommittee; **ATHNdata.quality.counts Grant Review)

Focus: Propose and oversee maintenance and growth of a secure, stable and flexible web-based information infrastructure that would create a secure, stable and flexible infrastructure with standardized content as the solid foundation for ATHN's future.

Membership

- Ann Forsberg, Chair**
- Geoffrey Allen
- Diane Aschman**
- Pam Bryant*
- Sue Cutter
- John Drake**
- Karmin Enge*
- Rebecca Golden
- Rebecca Hauke*
- Mike O'Connor
- Lew Parker*
- Steven Pipe**
- Angie Riedel*
- Brenda Riske*
- Cindy (Ying) Su*, CDC liaison
- Raymond Stanhope - NHF
- Julie Thomas
- Leonard Valentino
- Crystal Watson*

2010 ATHNadvoy Working Group

(Joint Community Relations and Technology)

Focus: Support the transition and integration of ATHNadvoy following the donation from Baxter.

Membership

- Tami Wood-Lively, Chair
- Jane Dinnen
- Natalie Duncan
- Karmin Enge
- Dave Rushlow
- Angie Riedel
- Susan Wischman

2010 ATHNready Working Group

(Joint Community Relations and Technology)

Focus: Keep the ATHNready materials up-to-date by reviewing the Emergency Guide for Professionals to be included on the ATHNready flash drives; and to publish, with input from the Technology Committee, an addendum to the Care Continuity Plan related to restoring access to WebTracker following a disaster.

Membership

- Wanda Foster, Co-chair
- Chris Guelcher, Co-chair
- Judith Baker
- Mary Lou Damiano
- Karen Droze
- Steve Humes
- Sarah Reymmer
- Julie Thomas

Research Committees

2010 Research Committee

Focus: Provide guidance to the Board regarding ATHN's research agenda, site credentialing and the core capabilities to be developed in order to facilitate research across study sites.

Membership

- Ellis Neufeld, Chair
- Diane Aschman
- Tom Abshire
- Barbara Konkle

2010 Safety Management Working Group

Focus: Develop and maintain ATHN's safety management plan consistent with FDA regulations for adverse events, including any prospective monitoring systems or projects.

Membership

- Peter Kouides, Chair
- Pam Bryant
- Erin Cockrell
- David Cooper
- Anjali Sharathkumar
- Vilmarie Rodriguez
- Eric Werner
- Mike Makris, Advisor
- Robert Wise, FDA liaison

2010 Data Quality Working Group

Focus: Develop and pilot test a methodology to validate and help ensure quality data for the ATHNdataset and other studies.

Membership

- Anne Neff, Chair
- Ann Forsberg
- Jeffrey Hord
- Pat Mancini
- Betsy Wilson

2010 Project Review Panel

Focus: Implement an open and transparent screening process for reviewing project ideas generated by ATHN committees, ATHN Affiliates or other entities.

Membership

- Jeanne Lusher, Co-chair
- Judith Andersen, Co-chair
- Diane Aschman
- Jorge Di Paola
- Gita Massey
- Laurel McKernan
- Madhvi Rajpurkar
- Margaret Ragni
- James P. Riddel, Jr.
- Harold Roberts
- Kimo Stine
- Suvandar Majumdar

Clinical Committees

2010 Rare Coagulation Disorders Committee

(By Working Group)

Focus: Guide the development of rare bleeding disorders templates for WebTracker and a related research portal, recommend collaborative studies to the ATHN Board and ensure the scientific integrity of projects and publications related to rare disorders.

Membership

PAI-1, plasminogen, HHT

- Amy Shapiro, Chair
- Mike Chesnutt
- Becky Dudley
- Anne Neff

Anticoagulation Proteins and Fibrinogen WG

- Suchitra Acharya, Co-chair
- Marilyn Manco-Johnson, Co-chair
- Roshni Kulkarni
- Amy Shapiro
- Julie Thomas
- Shannon Carpenter
- Michael Paidas

FXIII, platelet disorders WG

- Diane Nugent, Chair
- Nigel Key
- Debra Honig
- Regina Butler
- Julie Thomas
- Shannon Carpenter

Vitamin K proteins, FV, FV-VIII, FXI

- Marion Koerper, Chair
- Donna DiMichele, Advisor
- Anne Neff
- Skye Peltier

2010 Thrombosis Committee

Focus: Establish priorities in the development of a thrombosis module for WebTracker, recommend collaborative studies to the ATHN Board and ensure the scientific integrity of projects and publications related to thrombosis.

Membership

- Tom Ortel, Chair
- Gita Massey
- Maura Malone
- Jim Munn
- Rick Shearer
- Donald Yee
- Guy Young

Administrative Committees

2010 Budget and Finance Committee

*(*investment subcommittee)*

Focus: Review financial policies, requirements and practices of the organization, recommend and monitor the annual budget, oversee the annual audit and the investment subcommittee and provide guidance to the Board related to the fiscal well being of ATHN.

Membership

- Robert Fox, Chair*
- Diane Aschman*
- Trish Dominic*
- Robi Ingram-Rich
- Amy Shapiro
- Pam Betz

2010 Development Committee

Focus: Secure adequate funding through contracts, grants and other contributions for research, operations and capital endowment providing ATHN the long-term and stable support needed to carry out its mission.

Membership

- Ellis Neufeld, Chair
- Diane Aschman
- David Green
- Trish Dominic
- Steve Humes
- Tami Wood-Lively

2010 ATHN Nominating Committee

Focus: Develop general criteria regarding qualifications and selection of Board members, recommend candidates for election to the Board of Directors and otherwise support the Board in succession planning and efficient transition consistent with ATHN by-laws, policies and procedures.

Membership

- Tom Abshire, Chair
- Diane Aschman
- Susan Cutter
- Ann Forsberg
- David Green
- Michael Recht

2010 Bylaws Committee

Focus: Maintain ATHN by-laws as an evolving reflection of the organization.

Membership

- Robi Ingram-Rich, Chair
- Keith Hoots
- Tami Wood-Lively

2010 CEO Evaluation and Compensation Committee

Focus: Determine various elements of executive compensation and executive succession planning, conduct evaluation of the CEO as well as to provide guidance to the Board related to management's proposals regarding certain employee benefit plans and incentive programs.

Membership

- Bob Fox, Chair
- Trish Dominic
- Ann Forsberg
- Wanda Foster
- Amy Shapiro
- Tom Abshire

Liaison Groups

ATHN Community Liaison Group

Focus: Enable two-way communication between the ATHN Board of Directors and numerous community stakeholders on project direction, status, progress, issues and challenges; and facilitate alignment with broader community needs and resources.

Membership

- Centers for Disease Control and Prevention (CDC), Division of Blood Disorders
- Committee of Ten Thousand (COTT)
- Hemophilia and Thrombosis Research Society (HTRS)
- Hemophilia Federation of America (HFA)
- HRSA Maternal and Child Health Bureau (MCHB)
- National Alliance for Thrombosis and Thrombophilia (NATT)
- National Hemophilia Foundation (NHF)
- World Federation of Hemophilia (WFH)

ATHN Industry Liaison Group

Focus: Bring together an advisory group of the supplier community in support of this community-wide resource and provide input on the needs of the industry regarding data types, data access, analysis, clinical studies and post-marketing surveillance.

Membership

- Bayer HealthCare Pharmaceuticals, Inc.
- Baxter Bioscience
- CSL Behring
- Grifols Biologicals
- Food and Drug Administration (FDA)
- Novo Nordisk, Inc.
- Octapharma, USA, Inc.
- Wyeth Pharmaceuticals

FINANCIAL CONTRIBUTORS (to date)

Founding and Sustaining

Novo Nordisk, Inc.

Project Support

Baxter Bioscience
Centers for Disease Control and Prevention
Hemophilia Alliance
Hemophilia of Georgia
Indiana Hemophilia and Thrombosis Center
Partners Healthcare System