

DREAM | AWARD

AN HTRS AND ATHN MENTORED
RESEARCH AWARD

Turn a DREAM into reality.

Contents

- Overview
- DREAM Award Past Recipients
- The ATHNdataset: What's in it?
- Application Process and Timeline

Overview

- The goal of the DREAM Award is to advance the care of patients with bleeding and clotting disorders by funding research in the field of hemostasis.
 - Research to use the national ATHNdataset
 - Young investigators to be mentored:
 - ATHN-affiliated HTC
 - Database research and statistics
 - Multi-center collaboration is encouraged
 - 2019 DREAM Award supported by an educational grant from Shire

Overview

- Two grants of \$50,000 over 12 months or one grant of \$100,000 over 24 months
- Primary mentor must be an established clinician, epidemiologist, or related researcher working in hemostasis at a U.S.-based, ATHN-affiliated HTC
- Second mentor should be experienced in dataset research/statistical analysis

DREAM Award Winners

2015	Baxalta Funded	
1 yr.	Tyler W. Buckner, MD, MSc University of Colorado	Regional and Center-Level Variation in Utilization of Orthopedic Surgical Interventions in Persons with Hemophilia
1 yr.	Ming Y. Lim, MB, BChir, MA Medical University of SC	Inhibitors in Non-Severe Hemophilia A Patients

DREAM Award Winners

2016 Hemophilia of Georgia Funded		
2 yr.	Lynn Malec, M.D. Children's Hospital of Pittsburgh	Is Prophylaxis Putting Hemophilic Joints in the PINK: An ATHN-LINKED Observational Study
2 yr.	Stacy Croteau, M.D. Boston Children's Hospital	Evolving Real-World Use of Standard and EHL Products in Moderate and Severe Hemophilia Patients: A Practical Application of the ATHNdataset
1 yr.	Bobby Tran, M.D. Emory University	Characteristics Associated with Prescribed Prophylaxis of Factor Replacement

DREAM Award Winners

2017	Baxalta Funded	
2 yr.	Kristina Haley, DO Oregon Health & Science University	ATHENA1: Characterizing the Impact and Treatment of Reproductive Tract Bleeding on Women with Bleeding Disorders.

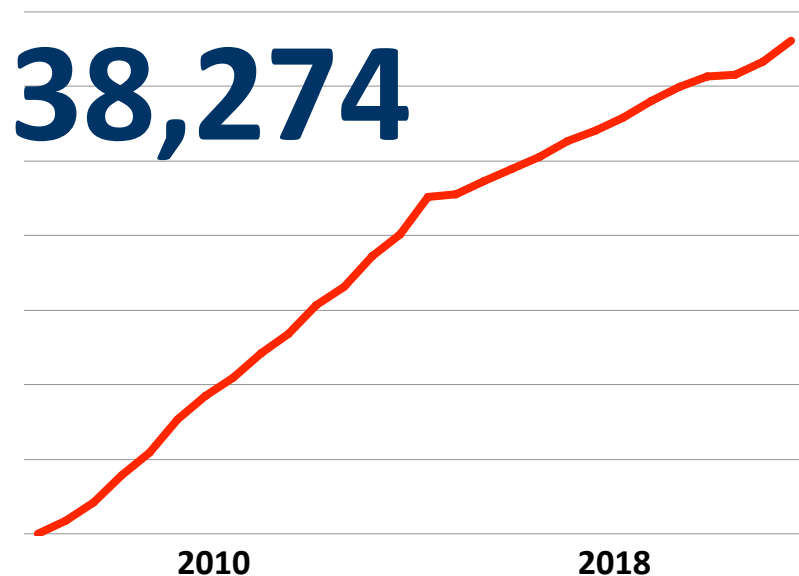
DREAM Award Winners

2018	Shire Funded	
2 yr.	Jennifer G. Davila, MD Children's Hospital at Montefiore/ HTC at Montefiore Medical Center	Characterizing the Real-World Use of Direct Oral Anticoagulants in Pediatric Thrombosis Patients Using ATHN: a VENUS Subcommittee Study
2018	Hemophilia of Georgia Funded	
1 yr.	Beverly A. Schaefer, MD University of Buffalo/Hemophilia Center of Western New York	Impact of Obesity on Laboratory Profiles, Treatment, and Outcomes of Individuals with Type 1 VWD and Low VWF

The ATHNdataset

Available through ATHN

ATHNdataset



- Patients who opted in to the ATHNdataset since Sept. 2010
- Demographic and clinical data
- Quarterly reports available to ATHN-affiliated HTC's

Patients by Primary Diagnosis

(38,274 Authorized Patients as of Sept. 30, 2018)

ATHNdataset	PATIENT AUTHORIZATIONS BY PRIMARY DIAGNOSIS TOTAL U.S. (AS OF SEPT. 30, 2018)	
PRIMARY BLEEDING OR CLOTTING DISORDER	TOTAL U.S. ATHNdataset CASES	% ATHNdataset
Factor VIII Deficiency	12,660	33.08%
Factor IX Deficiency	3,743	9.78%
Von Willebrand Disease	9,225	24.10%
Rare Disorders	2,084	5.44%
Platelet Disorders	2,584	6.75%
Thrombophilias	1,436	3.75%
Venus Thrombosis	3,487	9.11%
Other/Unknown	3,055	7.98%
TOTAL	38,274	100%

ATHNdataset: Sample Core Data Elements

Voluntarily Submitted by HTC

DEMOGRAPHICS	CLINICAL INFO	OUTCOMES
Date of Birth	Primary Diagnosis	Bleed Events
Gender	Date of Diagnosis	Location of Bleeds
Race	Disease Severity	
Ethnicity	Inhibitor Status	
Education	HIV/HCV Co-morbidities	Date of Death
Employment Status	Coagulation Meds	Cause of Death
Zip code	Reason for Medication	
Payer	Immunizations	

A complete list of core data elements is included in the DREAM Award RFP available on athn.org.

Note: As a HIPAA compliant limited data set, 16 PHI elements are excluded.

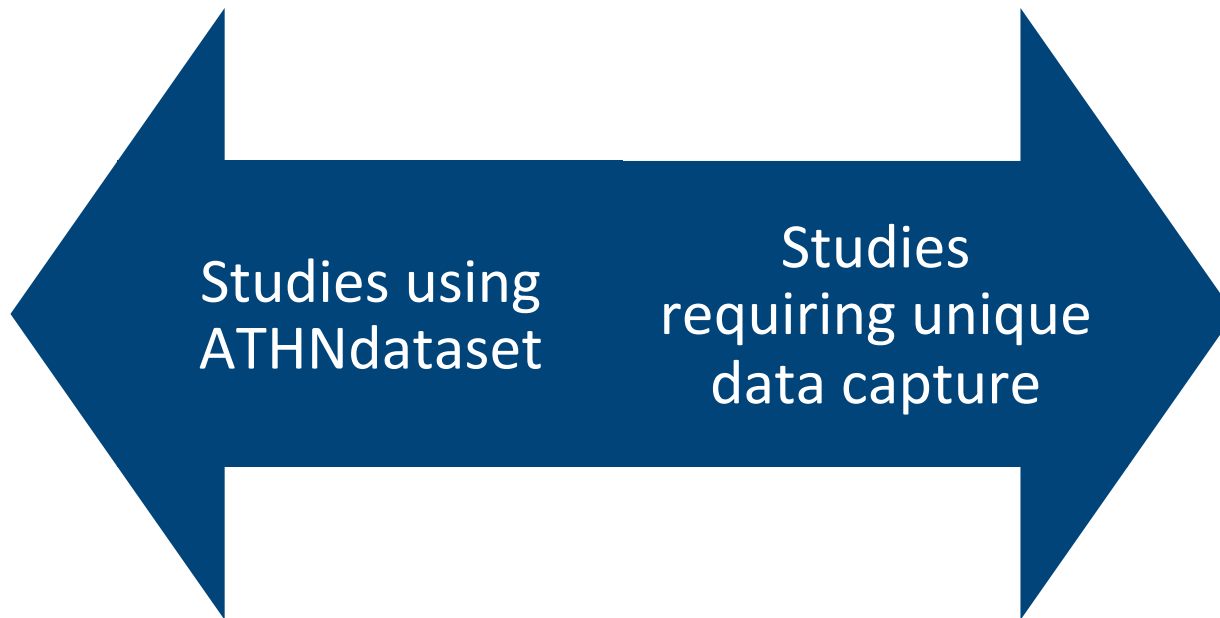
What's NOT Included?

ATHNdataset is a HIPAA-compliant limited data set

- Name
- Postal address, other than city and ZIP code
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers, serial and license numbers
- Device identifiers/serial numbers
- Web URLs
- IP address numbers
- Biometric identifiers, including fingerprints and voiceprints
- Full-face photographic images/comparable images

Considerations

Determining your data set, sample, and resource needs:



Considerations

Can your research question be reliably answered by querying the existing data set?

- Your analysis plan will determine subsets, queries, and analyses to be performed
- Patient authorization/IRB approval is not required

Considerations

Does your study require
“enriched” data to
answer the research
question?

*“Enriched” data such as validation
of data or additional chart
abstraction*

- If multi-center, other centers have to agree to participate to gather and insert enriched data for the targeted population (may require funding by project)
- Data must be extracted from the medical record and entered into Clinical Manager to be covered under the ATHN dataset patient authorization

Data Sharing and Use Agreement

Execute prior to start to confirm access and limitations on use

**American Thrombosis and Hemostasis Network (ATHN)
Data Sharing and Use Agreement
ATHNdataset**

Requestor Name	<Insert organization> on behalf of <insert PI Name> "Principal Investigator" collectively known as "Requestor."
Affiliation	
Mailing Address	
Telephone Number	
EMAIL Address	
Method of Data Transfer (ATHN to researcher)	

The American Thrombosis and Hemostasis Network (ATHN) is committed to providing ATHN Affiliates, academic, and other investigators an opportunity to use data collected as part of the ATHNdataset for purposes that are consistent with ATHN's mission and patients' authorization for data use. In allowing investigators and entities to use the data, ATHN is bound by its responsibility to guard the confidentiality of patient participants and ensure that data are used for a legitimate purpose. Toward that end, ATHN is required to obtain assurances from Requestor that Requestor will only use or disclose data as permitted herein. The provisions of this Agreement are intended to meet the Data Use Agreement requirements of HIPAA.

- Prior to receiving data or analyses requested, researchers must execute a simple agreement:
 - Usage must be for approved project
 - Usage must be consistent with the patient authorization commitments and HIPAA requirements
 - Researcher must acknowledge ATHN Affiliate contributions to the dataset

Study Implementation Support

Avenues for Information & Support



- ATHN Core Data Elements – Available in the DREAM Award RFP at athn.org
- Clinical Manager – To see the range of data elements as they are captured in Clinical Manager, ask your ATHN Administrator or HTC Data Manager for a demo
- eWeb Reports – To look at, or extract, sample data in your HTC's database, have the HTC Data Manager run a report for you
- Submit questions to ATHN by emailing ATHN Support – support@athn.org

DREAM Award Application & Review Timeline

Pre-Proposal

Full Details Outlined in RFP

- Pre-proposals are a required first step in the DREAM Award submission process
- Applicants are required to follow all formatting instructions and submit their application as one pdf document to htrs@bcw.edu
- Submissions should be received on or before **Friday, February 15, 2019 by 11:59 p.m. ET**
- Pre-proposals will be reviewed by members of a peer review committee comprised of HTRS and ATHN members
- All details of the required components of a pre-proposal are included in the RFP

Full Proposal

- Applicants are invited to submit full proposals as a result of successful pre-proposal submission and review
- HTRS/ATHN will make every effort to notify successful pre-proposal applicants as quickly as possible to allow applicants the maximum amount of time to prepare full proposals
- Invited applicants are required to follow all formatting instructions and submit their application as one pdf document to htrs@bcw.edu on or before **Friday, May 31, 2019 at 11:59 p.m. ET**
- All details of the required components of a full proposal are included in the RFP

Applicant Timeline

- Pre-proposals due February 15, 2019, 11:59 p.m. ET to htrs@bcw.edu
- Invited full proposals due May 31, 2019, 11:59 p.m. ET
- Announcement of recipient(s) – August 2019
- Project period: 12-month projects running from October 1, 2019 through September 30, 2020 or 24-month projects running from October 1, 2019 through September 30, 2021
- Award funds will be disbursed within 30 days of the date of execution of the legal Grant Agreement contract between HTRS/ATHN and the recipient HTC/institution

DREAM | AWARD

AN HTRS AND ATHN MENTORED
RESEARCH AWARD

Turn a DREAM into reality.