

The Harvard SHRINE Network

This guide is specific to the Harvard Medical School implementation of SHRINE. Those outside Harvard may also find it useful as a reference for their own institutions' networks.

1 - Requirements for Using SHRINE

1.1 - Eligibility

You are eligible to use SHRINE if you meet both the following two criteria:

1. Employed by one of the participating hospitals:

- Beth Israel Deaconess Medical Center (BIDMC)
- Brigham and Women's Hospital (BWH) / Partners HealthCare (PHS)
- Boston Children's Hospital (BCH)
- Dana-Farber Cancer Institute (DFCI)
- Massachusetts General Hospital (MGH) / Partners HealthCare (PHS)

and

2. Appointed at Harvard Medical School as Instructor or above or as Fellow

- Instructor or above

If you are a faculty member appointed at or above the level of Instructor, you may both initiate Query Topics and perform queries (see 2.1 below for more info). You may also invite an eligible fellow employed at your hospital to participate in any approved topic (see 2.2 below).

- Fellow

If you are a Fellow, you may perform queries under the sponsorship of an eligible faculty member (Instructor or above) based at the same hospital. Sponsorship means the faculty member sends you a Query Topic Invitation after having initiated and received approval for that topic. When you respond to the faculty sponsor's invitation and confirm your own eligibility, you may then perform queries associated only with that topic. See 2.2 below for more info.

If you are not employed by a participating hospital, you may access SHRINE data indirectly if you meet all three of the following conditions:

- Employed by Harvard University (e.g., HMS, HSPH, HBS, FAS, SEAS) and
- Appointed as Instructor or above and
- Collaborate with a hospital-based SHRINE user in the medical specialty of your interest, who must initiate and receive approval for a Query Topic and perform queries on your behalf.

1.2 - User Registration

Your first step is to register at your hospital, where your employment and appointment will be verified. Links to the participating institutions' registration pages are below.

- [BIDMC](#)
- [BWH](#) (Partners HealthCare System/PHS)
- [BCH](#)

- o [MGH](#) (Partners HealthCare System/PHS)
- o [DFCI](#)

Complete the registration process as identified by your institution. This process might take a few minutes or a few days, depending on the specific verification process. After you are registered, you will access SHRINE using the account credentials provided in that process.

Note: You must be behind your hospital's firewall to access SHRINE.

1.3 - Query Topic Approval

Before you can query any data, you must use the Data Steward application (see next section) to describe how you intend to use the SHRINE system to support your research. For example, you might use SHRINE to develop preliminary data for a grant proposal.

While approval from the Data Steward administrator is required, IRB approval is not. The IRB at each participating institution has declared by an expedited review that aggregate data counts are not "human research" and as such are exempt from the IRB review process.

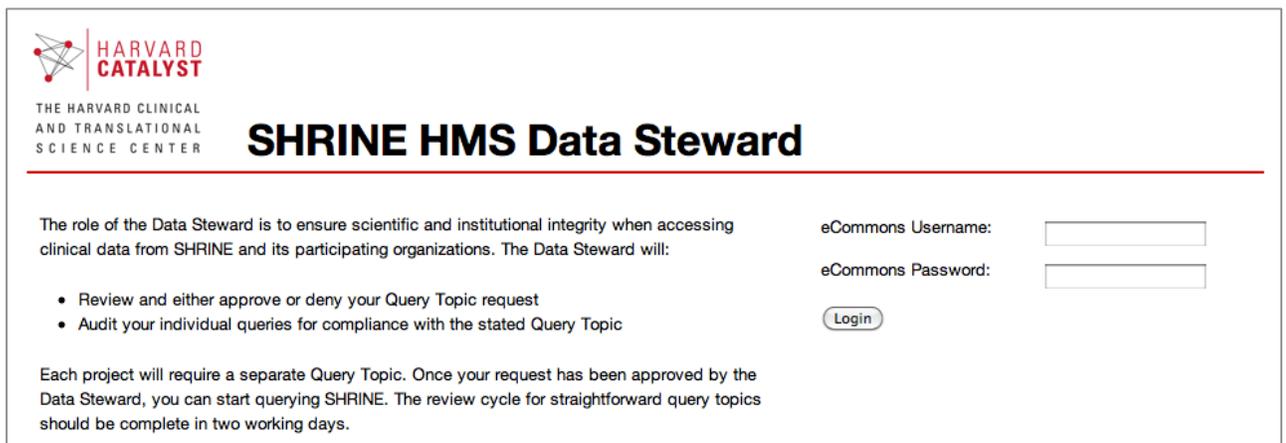
2 - Data Steward Application

Before SHRINE data can be accessed, the Data Steward administrator must review and approve Query Topic requests made by Instructors and above, and verify the status of invited Fellows. All individual queries are then subject to review for compliance with approved topics. Query histories are logged and audited on a regular basis to ensure that there are no violations of the Terms-of-Access Agreement that you must accept when you log in to SHRINE. Any use of the Query Tool to investigate patient data inappropriately will result in immediate suspension of your account, and notification will be sent to your institution regarding possible misconduct.

The Data Steward application can be reached via [this link](#). You can also access it from within the SHRINE Query Tool by clicking Request New Topic in the tool view.

2.1 - Query Topic Approval: Instructor or Above

Log in to the Data Steward application with your eCommons ID.



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SHRINE HMS Data Steward

The role of the Data Steward is to ensure scientific and institutional integrity when accessing clinical data from SHRINE and its participating organizations. The Data Steward will:

- Review and either approve or deny your Query Topic request
- Audit your individual queries for compliance with the stated Query Topic

Each project will require a separate Query Topic. Once your request has been approved by the Data Steward, you can start querying SHRINE. The review cycle for straightforward query topics should be complete in two working days.

eCommons Username:

eCommons Password:

On the next screen, click "Create a new Query Topic." Enter a name for your new Query Topic, select a general reason from the dropdown menu, and provide a short description of the types of queries you would like to perform on that topic (query intent); click Create.

Create Query Topic

Please enter a descriptive query topic name

Reason for query topic

If Other, explain

Are you collaborating with a non-SHRINE associate?

If Yes, explain

Please describe your Query's Intent

I want to conduct a clinical trial evaluating a new therapeutic treatment for patients whose asthma is triggered by a latex allergy. I need to find more eligible patients than exist at my own hospital.

Your new Query Topic will be displayed with the option to edit it.


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Hello Jane Smith [Logout](#)

Your query topic has been created

Id	1
Name	Asthma incidence
PI	Jane Smith
Approval Status	PENDING
Approved Date	
Reason	COHORT_IDENTIFICATION
Reason Other	
Collaborating	False
Collaborating Explanation	
Date Created	2012-02-14 14:18:29 EST
Last Updated	2012-02-14 14:18:29 EST
Query Intent	I want to conduct a clinical trial evaluating a new therapeutic treatment for patients whose asthma is triggered by a latex allergy. I need to find more eligible patients than exist at my own hospital.

[Edit](#) [Back to topics list](#)

When you have finished entering/editing your new query request, click "Back to topics list." Your new query request will appear in the "Owned Query Topics" tab (the default view). The Data Steward administrator will review it and contact you if more information is needed. When your Query Topic is approved, you will receive an email notification.



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Query Topics

[+ Create a new Query Topic](#)

Owned Query Topics | Member Query Topics

Id	Name	Approval Status	Approval Date	Date Created	Last Updated
 1	Asthma incidence	PENDING		2/14/12 2:18 PM	2/14/12 2:18 PM

If you would like to invite a fellow(s) to collaborate in your Query Topic after it is approved, click the magnifying glass next to the Query Topic ID number. Its Topic Description tab will appear. Click the Members tab and then the Invite new member(s) link. Enter the email address(es) of the fellow(s) into the form and click Invite. Fellows' subsequent steps in the process are described below.



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Topic Description | Members | Query History

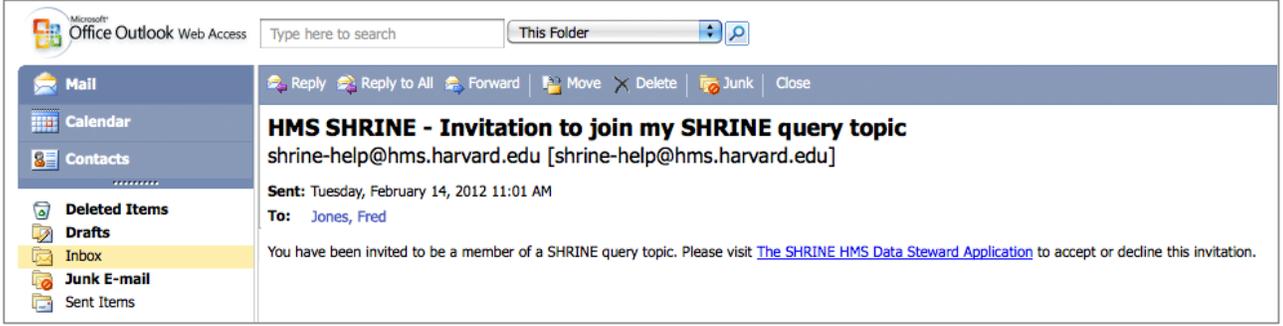
[+ Invite new member\(s\)](#)

Username _____ Email _____

[Back to topics list](#)

2.2 - Query Topic Invitation: Fellows

When your faculty sponsor invites you to query an approved topic, you will receive an email from the Data Steward application with a custom link to the login page. When you click this link and log in with your eCommons ID and password, the application first verifies that you are the person invited to participate in the query; then it checks Harvard Catalyst Profiles to verify your employment at the same hospital as your sponsor and appointment as a fellow.



Microsoft Office Outlook Web Access

Type here to search | This Folder

Mail | Calendar | Contacts

Deleted Items | Drafts | **Inbox** | Junk E-mail | Sent Items

Reply | Reply to All | Forward | Move | Delete | Junk | Close

HMS SHRINE - Invitation to join my SHRINE query topic
 shrine-help@hms.harvard.edu [shrine-help@hms.harvard.edu]

Sent: Tuesday, February 14, 2012 11:01 AM
 To: Jones, Fred

You have been invited to be a member of a SHRINE query topic. Please visit [The SHRINE HMS Data Steward Application](#) to accept or decline this invitation.

Assuming successful login and employment/appointment verification, the Data Steward screen will then present information about the Query Topic and ask you to accept or decline the invitation.



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SHRINE HMS Data Steward

Hello Fred Jones [Logout](#)

Query Name	Asthma incidence
PI	Jane Smith
Approval Status	APPROVED
Approved Date	2012-02-15 15:27:42 EST
Reason	COHORT_IDENTIFICATION
Reason Other	
Collaborating	False
Collaborating Explanation	
Date Created	2012-02-14 14:18:29 EST
Last Updated	2012-02-14 14:18:29 EST
Query Topic Text	I want to conduct a clinical trial evaluating a new therapeutic treatment for patients whose asthma is triggered by a latex allergy. I need to find more eligible patients than exist at my own hospital.

Accept Invitation
Decline

Once you accept, the Data Steward application will add you as an authorized user on that Query Topic. You may now visit your hospital's SHRINE home page to log in and perform queries on the approved topic.



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SHRINE HMS Data Steward

Hello Fred Jones [Logout](#)

i
You are now approved to use query topic Asthma incidence

Id	1
Name	Asthma incidence
PI	Jane Smith
Approval Status	APPROVED
Approved Date	2012-02-15 15:27:42 EST
Reason	COHORT_IDENTIFICATION
Reason Other	
Collaborating	False
Collaborating Explanation	
Date Created	2012-02-14 14:18:29 EST
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[Back to topics list](#)

3 - Data Availability

The data available to be searched in SHRINE are demographics, diagnoses, medications, and a sample of laboratory results. The date range covered by the data is 1/1/2001 – 12/31/2013.

The ability to search across multiple institutions' disparate data sets is made possible by the SHRINE Core Ontology, a collection of terms that describe the data and can be used to construct queries. The terms are arranged into a hierarchy for easy navigation; the ontology can be searched for a particular term as well.

Established terminology standards were selected where possible to represent each type of data (see table below), following recommendations of relevant government and private sector bodies, and modified as necessary to fit the requirements of SHRINE. As these underlying standards change (for example, regular updates of ICD-9-CM and RxNorm), the Core Ontology will follow after a reasonable delay to accommodate the effort of introducing the changes, resolving issues and completing quality assurance processes.

Data Type	Standard
Demographics	<u>HITSP C32</u>
Demographic Attribute	Vocabulary
Age	N/A
Gender	HL7 <u>Administrative Gender</u>
Marital Status	HL7 Marital Status
Race	CDC <u>Race & Ethnicity Code Sets</u>
Ethnicity	N/A
Language	<u>ISO 639-1</u>
Diagnoses	<u>ICD-9-CM</u> , Clinical Classification Software (<u>CCS</u>) hierarchy
Medications	RxNorm (Ingredient), National Drug File Reference Terminology (<u>NDF-RT</u>) hierarchy
Labs	<u>LOINC</u> codes

3.1 - Local Data Mapping

Each participating institution's data is loaded with native coding schemes used by local information technology solutions. To understand SHRINE queries issued using terms from the Core Ontology, a mapping is created and maintained for each institution that enables a translation from SHRINE Core Ontology term to a corresponding local term, which in turn enables the system to perform a query at that institution.

Mapping of local institutional standards to the SHRINE Core Ontology is identified in the table below, followed by more detailed explanations where indicated for BWH/MGH and DFCI.

Vocabulary	BIDMC	BWH & MGH (PHS)	BCH	DFCI
Demographics	Local	Local	Local	Local
Diagnoses	ICD-9-CM	ICD-9-CM derived from TSI or IDX LMR problems COSTAR derived from OnCall problems 3.1.1 ↓	ICD-9-CM derived from Epic billing system	ICD-9-CM derived from IDX Outpatient billing system 3.1.2 ↓
Medications	Inpatient: Provider Order Entry (POE) Outpatient: Online Medical Record (OMR) (More Info on BIDMC.org)	TSI / LMR / COSTAR 3.1.3 ↓	Inpatient and clinic: Provider Order Entry (POE)	NDC and Outpatient Pharmacy internal codes 3.1.4 ↓
Labs	Local	LOINC / Local	Local	Adult Outpatient: Sunquest Laboratory Information System codes Pediatric: not yet available

3.1.1 - BWH and MGH (PHS) Diagnoses

Diagnoses are organized into 22 major categories generally by body system, such as Digestive System, or by disease type, such as Infectious and Parasitic Diseases.

LMR and OnCall codes and descriptions are developed locally. A number of analytic processes are performed to make the data as consistent and reliable as possible. If a provider described a diagnostic condition in several different ways, the analytic processes attempt to collapse all of the synonyms under one consistent code and description. For example, if the LMR code for the common ailment of Upper Respiratory Infection is LPA1960, but it is described as Upper Respiratory Infection 79% of the time, as URI 19% of the time, and as Cold 2% of the time, these are manually reviewed, determined to be synonymous, and altered to a single description of Upper Respiratory Infection.

In general, diagnostic ICD-9-CM coding for inpatient encounters is more accurate than for outpatient encounters due to the strict requirements involved in DRG billing for both diagnoses and procedures associated with an inpatient stay. In addition, discharge diagnoses or principal diagnoses often are better defined by the time patients' records are reviewed for billing. In contrast, outpatient billing tends to be less accurate on diagnostic codes. In addition, illness visits often are coded for signs and symptoms rather than a well-defined diagnosis, especially in the early stage of an episode of care.

These groups in the diagnoses Terms view are of special interest:

- Sign or Symptoms - These codes, comprising 780.xx through 789.xx., include presenting conditions as being febrile, or having abdominal tenderness or edema.
- E-Codes - Required for public reporting of accident or traumatic situations or adverse events from medical care.
- V-Codes - A special category for patient or family history of illness.

3.1.2 - DFCI Diagnoses

Diagnosis data at DFCI are ICD-9-CM codes derived from the IDX patient billing system for outpatient visits.

Illness visits often are coded for signs and symptoms rather than a well-defined cancer diagnosis, especially in the early stage of an episode of care. In addition, VCodes, which indicate a history of cancer, are often used for patients receiving follow-up care. Other patient diagnoses and problems that are recorded for adults in PHS LMR, children in BCH EMR, and DFCI Cancer Registry are not yet available in SHRINE.

3.1.3 - BWH and MGH (PHS) Medications

Medications at PHS institutions BWH and MGH are derived from TSI, the [Longitudinal Medical Record](#) (LMR), and OnCall systems.

Medications from TSI are associated with hospital encounters only. These comprise mainly inpatient status patients, but also include emergency department, surgical day care (SDC), or observation status patients. Hospital-based patient medications for BWH include inpatients, emergency room, observation stays, and newborns. For MGH, medications include inpatients, dialysis, observation stays, surgical day care, newborns and some research patients.

Medications from the LMR are associated with outpatient encounters, while the codes are defined locally. A number of analytic processes are performed to make the data as consistent and reliable as possible. If a provider describes a medication in several different ways, the analytic processes applied attempt to collapse all of the synonyms under one consistent code and description. For example, if the LMR code for the common medication of aspirin is 3644, but it is described as Aspirin 79% of the time, as ASA 19% of the time, and as Bayer 3% of the time, these are reviewed manually, determined to be synonymous, and altered to a single description—Aspirin.

Medications from the OnCall system are associated with outpatient encounters within MGH. The codes are in the [COSTAR](#) coding system.

Code System	Partners Institution	Encounter Type
TSI Charge Codes	BWH, MGH	Hospital encounters (inpatient, emergency, observation, dialysis, newborns, research patients)
LMR	BWH, MGH	Outpatient encounters
COSTAR	MGH	Outpatient encounters

3.1.4 - DFCI Medications

Only medications dispensed in DFCI's outpatient infusion areas are collected in the DFCI outpatient pharmacy system. Most of the medications dispensed are to treat cancer and symptoms related to cancer. Other patient medications that are recorded for adults in PHS LMR and Children in BCH EMR are not yet available in SHRINE.

4 - Query Results

Information provided in the results of your query include:

- Query name
- Elapsed execution time
- Aggregated query results from participating hospitals

The results are time and date stamped.

When you log out of SHRINE, your query results are saved for future reference. You can also use the saved query to perform it again automatically in future sessions.

4.1 - Patient Privacy

To protect patient privacy, data are de-identified before incorporation into the Core Ontology. In addition, we blur the aggregate patient counts returned as query results so that they are an estimate of the actual number. For information about the technology used to implement this additional obfuscation, refer to the following paper:

[Murphy SN, Chueh HC. A Security Architecture for Query Tools used to Access Large Biomedical Databases. Proceedings of the 2002 AMIA Annual Symposium. 2002 Nov 9-13, San Antonio, TX p. 552-6.](#)

If you run the same query more than once, you receive slightly different results each time. SHRINE is designed to lock out users who run the same query approximately seven times within a 30-day period.

When you log out of SHRINE, your results are saved and may be viewed again in future sessions.

4.2 - Further Study

To follow up with a potential cohort of interest, you must identify a collaborator at the institution where you located patients. Your collaborator then must work with the institution's IRB to seek approval of the proposed study. If you currently do not collaborate with an investigator at that institution and do not know who might be doing similar research, visit the Harvard Catalyst website to explore options and make connections. For example, visit the [Harvard Catalyst Profiles](#) research social networking system to conduct keyword searches for collaborators at Harvard-affiliated institutions. You can also search Profiles using the Search box in the top-right corner of every page on the [Harvard Catalyst](#) website.

5 - Terms of Data Access Agreement

This Terms-of-Data-Access Agreement is designed to permit approved users access to the SHRINE federated query tool for the purpose of requesting aggregate clinical data from participating Harvard Catalyst Clinical and Translational Science Center organizations who are members of the SHRINE network ("Participating SHRINE Organization"). The currently participating SHRINE Organizations are: Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Children's Hospital Boston, Dana-Farber Cancer Institute and Massachusetts General Hospital. Each Participating SHRINE Organization individually contributes and allows access to aggregate clinical data for research purposes only. Your signature certifies that you understand and agree to all applicable terms contained herein.

1. I assert that I am a member of the Harvard Medical School Faculty and am employed by a Participating SHRINE Organization (or that organization's Physician's Organization);
 - a. appointed at or above the Instructor level ("Qualified Faculty Member"); or
 - b. appointed as a Fellow and am supervised by an approved SHRINE Qualified Faculty Member at my institution.
2. I understand that access to SHRINE is currently limited to Qualified Faculty Members of Participating SHRINE Organizations (as defined above) and their supervised Fellows.
3. The following provision applies only to supervised Fellows:
 - a. I understand that I may only submit queries and obtain SHRINE data directly associated with the validated Query Topic specifically delegated to me by my supervising Qualified Faculty Member.
4. I understand that the term "Qualified Faculty Member" does not include Fellows.
5. I understand that as a Qualified Faculty Member I may collaborate with investigators who are not Qualified Faculty Members under the following conditions:
 - a. My collaborator is appointed at or above the Instructor level at Harvard University and is employed at Harvard University;
 - b. Our collaboration must be in my area of scientific expertise;
 - c. I am the only individual who will be authorized to conduct actual queries.
 - d. I assume full responsibility for adherence by my collaborator with the SHRINE Business Rules and will obtain and retain a signed copy of this Terms-of-Access Agreement to certify my collaborator's compliance with the SHRINE Business Rules.
6. I understand that collaboration and/or sharing of primary data with other individuals or parties, including but not limited to other academic health centers and industry, is prohibited.
7. I understand that my Participating SHRINE Organization has agreed to comply with the Business Rules under which access to clinical data is allowed and that I will be held accountable by my employing institution.
8. I understand that only aggregate numbers of patients satisfying an approved data query will be provided at this time.
9. I further acknowledge the additional level of ethical sensitivity inherent in accessing data from institutions and patients other than my employing institution and agree to exercise exemplary ethical conduct when so doing. This includes but is not limited to the following specific issues:
 - a. I agree to restrict requested query topics and associated individual queries to bona fide research issues;
 - b. I agree to restrict all queries to the query topic approved by the Data Steward.
 - c. I will not formulate queries that could be used for competitive institutional or individual advantage;
 - d. I understand that all proposed query topics will be reviewed and approved or rejected by a Data Steward and that subsequent individual query requests will be audited for adherence to the initial approval.
 - e. I agree not to attempt to identify any individual or set of patients contained in the aggregate data.
10. I understand that the use of each approved query topic will be limited to a six month period following approval of the query request.
11. I understand that if I wish to identify any of the Participating SHRINE Organizations by name in a publication, permission to use that name must be solicited from the named Institution (Link to designated Institutional Official).
12. I understand that disposition of any intellectual property deriving from SHRINE data acquisition and analysis is governed by a separate agreement requiring that I initiate the resolution process by reporting potential "discoveries" to my institution's technology transfer or intellectual property office.
13. I agree to adhere to my home institution's policy regarding retention and destruction of data.
14. This Terms-of-Data-Access Agreement will end upon termination of my appointment at Harvard Medical School or termination of my employment by a Participating SHRINE Organization.
15. I understand that any violation of this agreement will subject me to disciplinary action by my institution in consultation with the appropriate office at Harvard Medical School/Harvard University.