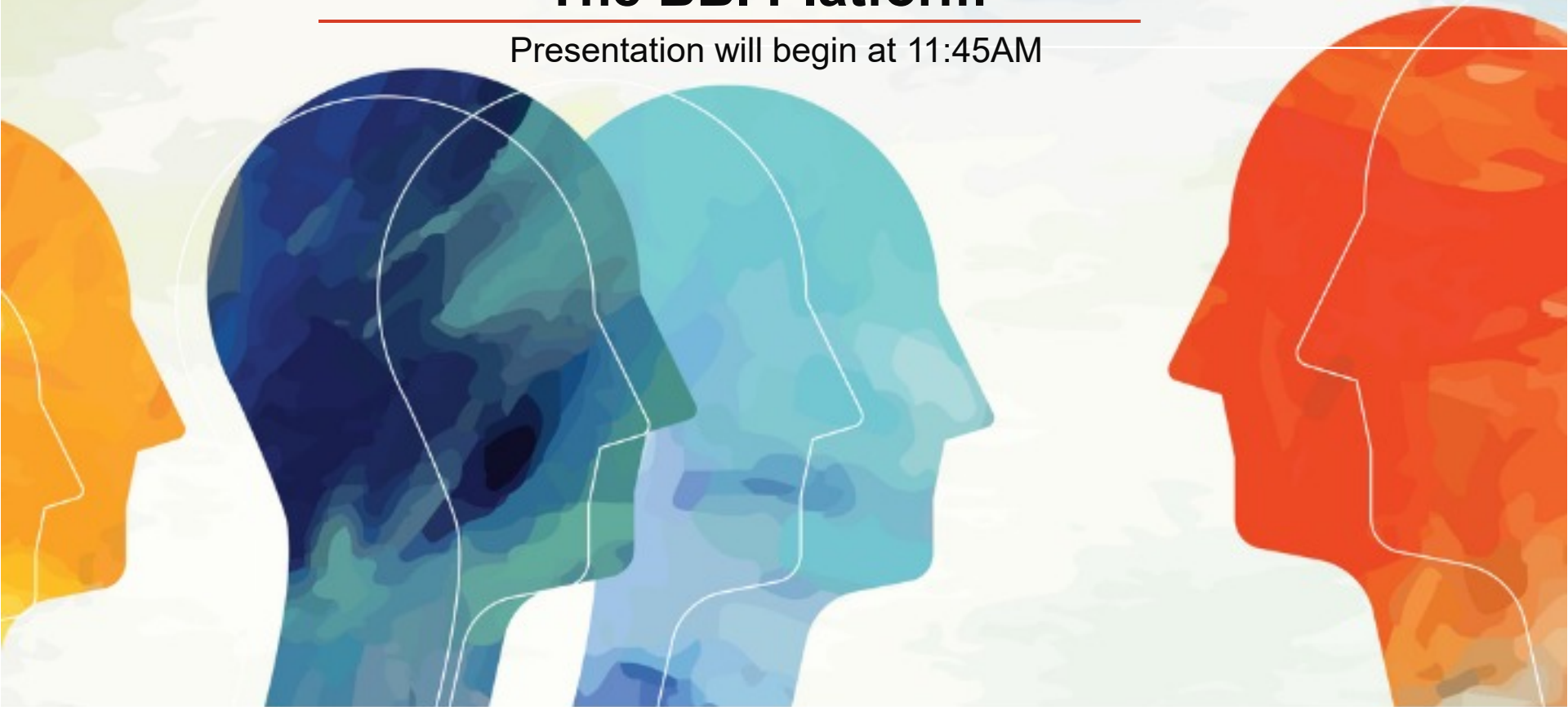


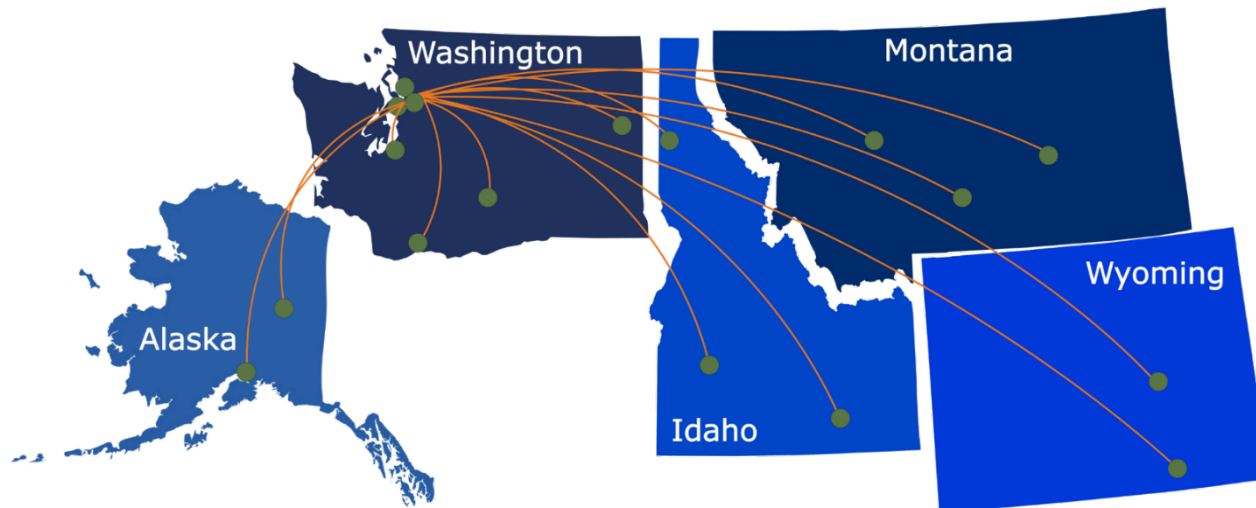
Translating Diagnostics into Clinical Care: The BBI Platform

Presentation will begin at 11:45AM



ITHS

Institute of **Translational** Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.



What We Offer:

- 1 Research Support Services:** Members gain access the different research services, resources, and tools offered by ITHS, including the ITHS Research Navigator.
- 2 Community Engagement:** Members can connect with regional and community based practice networks
- 3 Education & Training:** Members can access a variety of workforce development and mentoring programs and apply for formal training programs.
- 4 Funding:** Members can apply for local and national pilot grants and other funding opportunities. ITHS also offers letters of support for grant submissions.

Contact our **Research Navigator**



- **Project Consultation**
- **Strategic Direction**
- **Resources and Networking**

Melissa D. Vaught, Ph.D.
ithsnav@uw.edu
206.616.3875

Feedback

At the end of the seminar, a link to the feedback survey will be sent to the email address you used to register.

Translating Diagnostics into Clinical Care: The BBI Platform

Presented by Dr. Brian Shirts, MD
Email: shirtsb@uw.edu



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Learning Objectives

- 1 Identify two major barriers to translate ideas into clinical diagnostic tests
- 2 Develop two strategies for overcoming barriers to translating diagnostics to clinical care
- 3 Determine two optimal sources for assistance with different clinical diagnostics development situations



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The Brotman Baty Institute for
Precision Medicine
&
Diagnostic Test Translation



Disclosures

All speakers have no relevant conflicts of interest to disclose.

Overview

- What is the BBI
 - BBI membership
 - Programs and Working Groups
- Focus on Precision Diagnostics Platform
- So you want to translate a diagnostics test from bench to bedside
 - Case study brainstorming examples
 - Clinical Applications of Research in Emerging Technologies (CARET) program

What is the BBI?

- **A partnership** between UW Medicine, the Fred Hutch, and Seattle Children's
- Made possible by a \$50M gift, over 5 years, by Jeff and Susan Brotman and Pam and Dan Baty



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Seattle Children's
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What is the BBI?

- Accelerate development & application of precision approaches in a **clinical setting**
- Foster **basic science** with strong relevance to precision medicine
- Leverage complementary strengths of clinicians & researchers across **three founding institutions**



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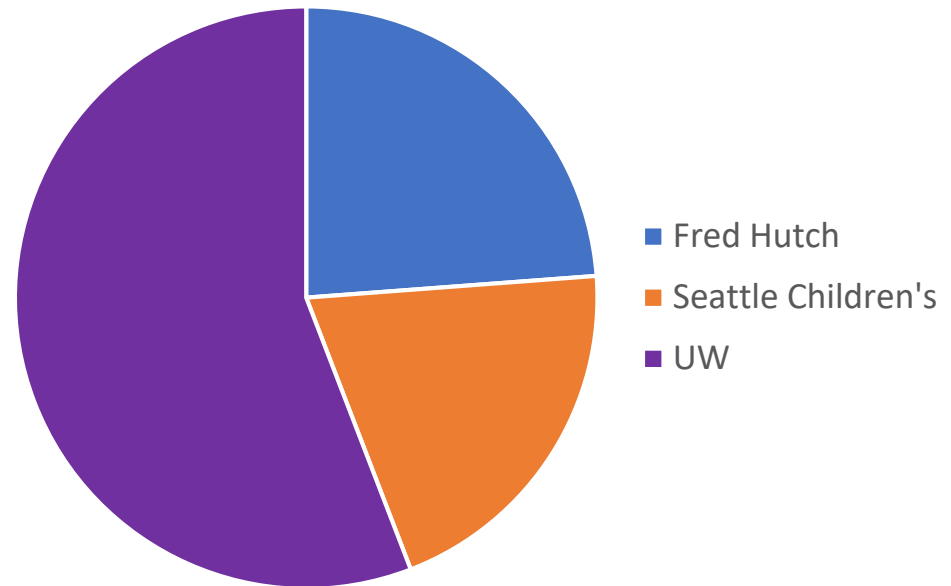
Seattle Children's
HOSPITAL · RESEARCH · FOUNDATION

BBI Membership

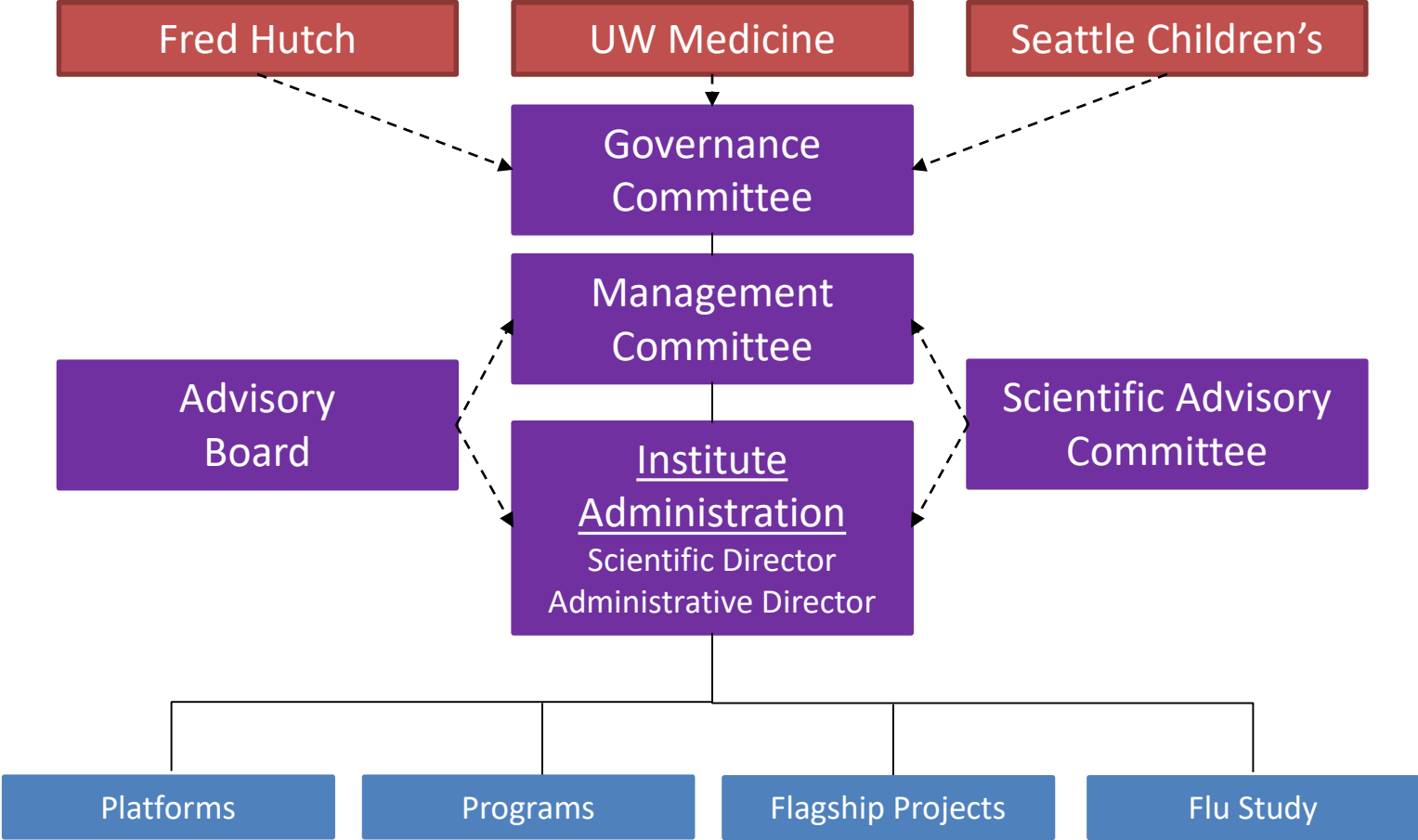
BBI Members by Institution

231 Official Members

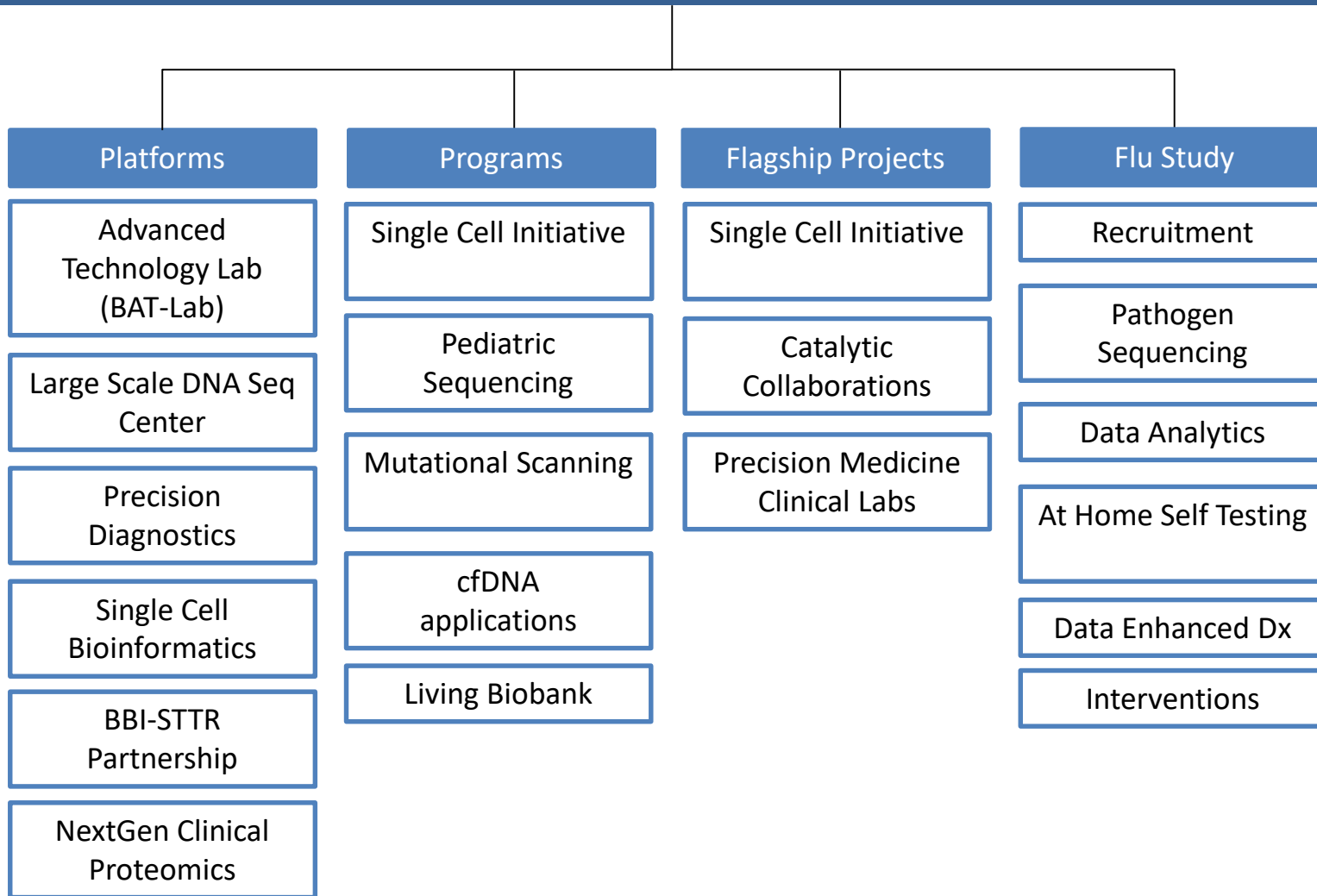
Goal of 150



BBI Structure



What is the BBI?



Programs / Working Groups

Working Group	Leaders	Ongoing work
Single cell molecular atlas of disease	Cole Trapnell (UW) David Beier (SCRI) Pete Nelson (FHCRC)	Generating data for 30 projects from 2018 RFA
Pediatric genomic sequencing	Mike Bamshad (UW) Ghayda Mirzaa (SCRI) Heather Mefford (UW)	Epilepsy Peds cancer germline risk Neurodevelopmental disease
Cell-free DNA diagnostics	Tina Lockwood (UW) Steve Henikoff (FHCRC) Sarah Leary (SCRI)	16 projects from recent RFA in progress
Mutational scanning	Doug Fowler (UW) Lea Starita (UW) Alice Berger (FHCRC) Rick James (SCRI)	White paper in progress
Living biobank	Kelly Smith (UW) David Byrd (UW) Eric Holland (FHCRC) Bonnie Cole (SCH)	Evaluating proposals from recent RFA
Genetics risk scores	In planning stages	

Precision Diagnostics Platform

- Member labs
- Clinical lab pilot awards
- Multidisciplinary variant review teams
- Molecular tumor boards
- Assay support for BBI working groups
- Clinical Applications of Research in Emerging Technology (CARET) Unit



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Clinical Lab Pilot Awards

- Pilots in clinical labs for validation/implementation.
- RFAs for faculty and trainee pilot awards
- 3-4 faculty pilot grants per year, \$50,000 each, and 5 trainee pilot awards, \$10,000 each.
- Support for implementing new technologies in BBI-affiliated clinical diagnostic labs, and to foster trainee education in this area

Multidisciplinary Consensus Variant Review Teams



Cancer Predisposition



Cancer Therapy



Pediatric Syndromes

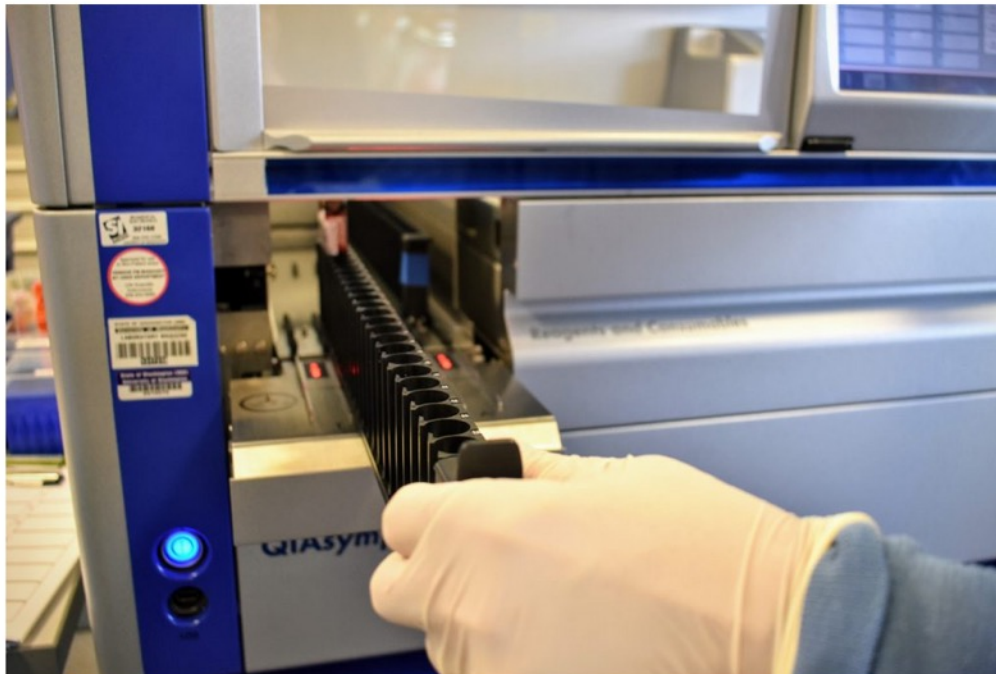


Marrow Failure

Test Catalog

- Interfaced with Online Test Guide (Hoffman)
- Tests in OLTG can be tagged for BBI

BBI Precision Diagnostics Platform

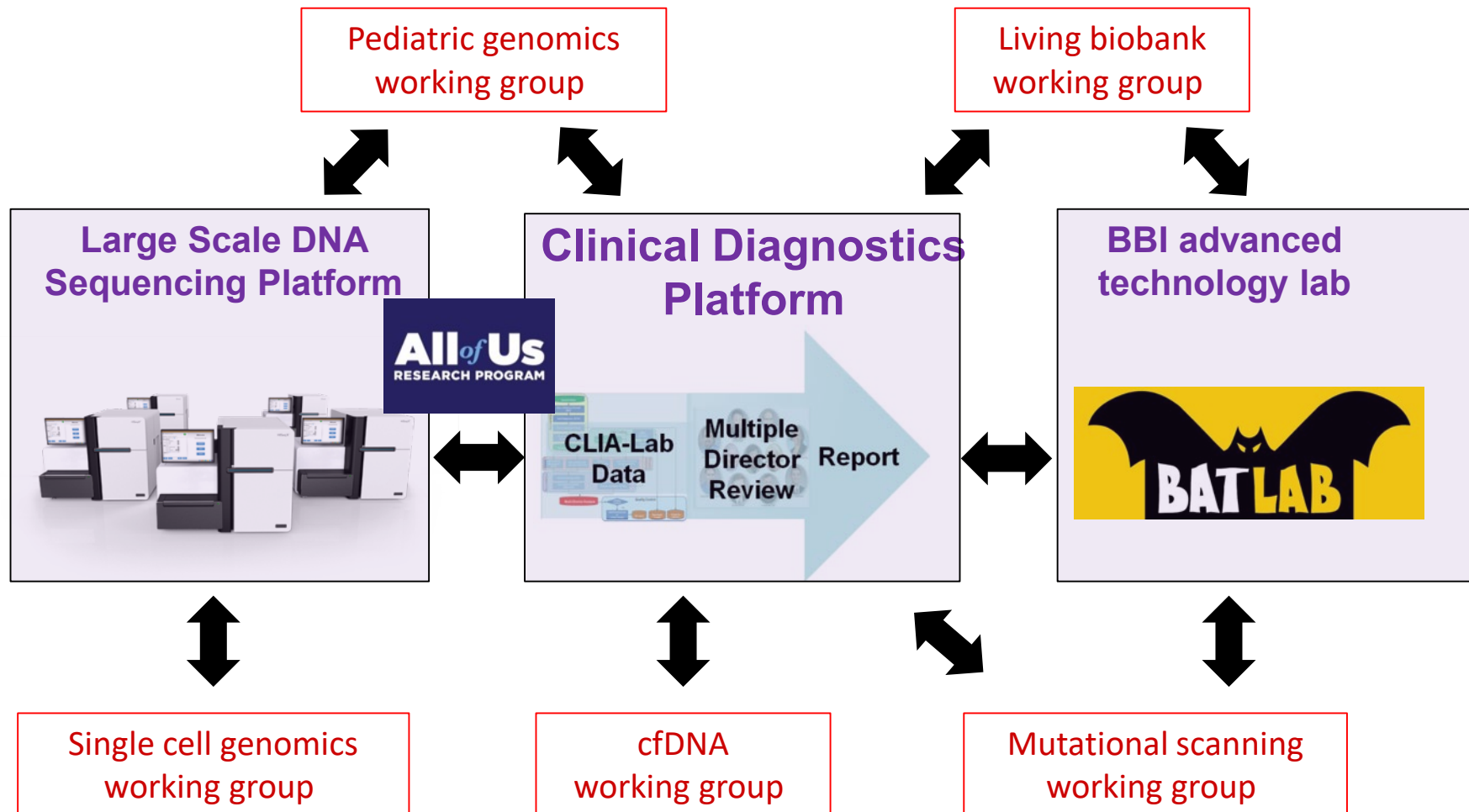


ALK Mutations
BRAF Mutations
BROCA Cancer Risk Panel
CellFree DNA Prenatal Screen
ColoSeq - Lynch and Polyposis Panel
ColoSeq _ Polyposis
ColoSeq Tumor Panel
EGFR Mutations
Epileptic Encephalopathy Panel
Heme Amplicon Panel by NGS
Heme Single Gene by NGS
Huntington Disease DNA Screen
IDH Mutations
Immunoplex Panel
KRAS Mutations (DNA)
Megalencephaly Panel
Microsatellite Instability
NRAS Mutations
Spinocerebellar Ataxia Panel
UW OncoPlex Cancer Gene Panel
UW-OncoPlex Single Gene

Molecular Tumor Boards

- **Current**
 - **GU** Precision Tumor Board (Pritchard, True, Reder)
 - **Pediatric** Precision Tumor Board (Lockwood, Cole, Leary)
 - **GI** Precision Tumor Board (Konnick, Cohen)
- **Planned**
 - Outreach to community; currently piloting at SCCA with GU Precision Tumor Board
 - Mendelian Molecular Board

Interfaces with Precision Diagnostics Platform



Precision Diagnostics Platform

- Member labs
- Clinical lab pilot awards
- Multidisciplinary variant review teams
- Molecular tumor boards
- Assay support for BBI working groups
- **Clinical Applications of Research in Emerging Technology (CARET) Unit**



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So...

you want to make a clinical diagnostic test

Case 1

- In your laboratory you develop a new technique for analyzing RNA which you think may be 20% more sensitive for identifying the cause of viral pneumonia than current testing.
- You think it would be great if all patients with suspected viral pneumonia could get this test.
- What can you do to make this happen?

Case 1

- Discuss



PRECLINICAL CONSULTING

ITHS > Investigators > ITHS Research Services > Preclinical Consulting

Preclinical Consulting

With Preclinical Research Development, we help investigators gain access to the expertise and tools needed to prepare innovative ideas for human testing. We support and sustain novel technologies and methodologies through the early phases of development, when funding and expertise are most needed.

The overall goal of the Preclinical Research Development program is to accelerate new medical product development in the academic setting and to enhance the opportunities for their commercialization. In order to compete effectively for translational research dollars and position inventions for future investment, academic investigators must now be able to clearly articulate viable commercialization, clinical, and regulatory strategies for their products. In addition the investigator must assemble a nonclinical data package (e.g., pharmacology, pharmacokinetics, and product characterization), that will support the regulatory requirements for initiation of clinical trials.

+	Services
+	Who can use the ITHS Preclinical Research Development program?
+	Programs
+	Partnerships
+	Contact Us
+	Request Services

Investigators

Research Navigator

ITHS Research Services

Preclinical Consulting

Drug and Device Advisory Committee (DDAC)

Preclinical Researcher Toolkit

Investigational Device Development

Investigational New Drug Development

Clinical Trials Consulting

Bioethics Consultation Service

Biomedical Informatics

Biostatistics

Research Coordination Support Services

Recruitment Support Service

Trial Innovation Network

Data and Safety Monitoring

Regulatory Monitoring

Post a Research Study

Resource Directory

ITHS Research Units

Funding Opportunities

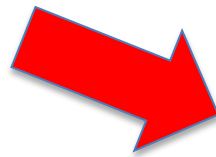
Case 2

- In your research you find out that customizing a few parameters in the way that tandem mass spectroscopy is performed can help distinguish the different forms of vitamin D.
- You think that this may help determine who is at risk of complications of vitamin D deficiency.
- How can you find if your technique will be useful for clinical diagnostics?

Case 2

- Discuss

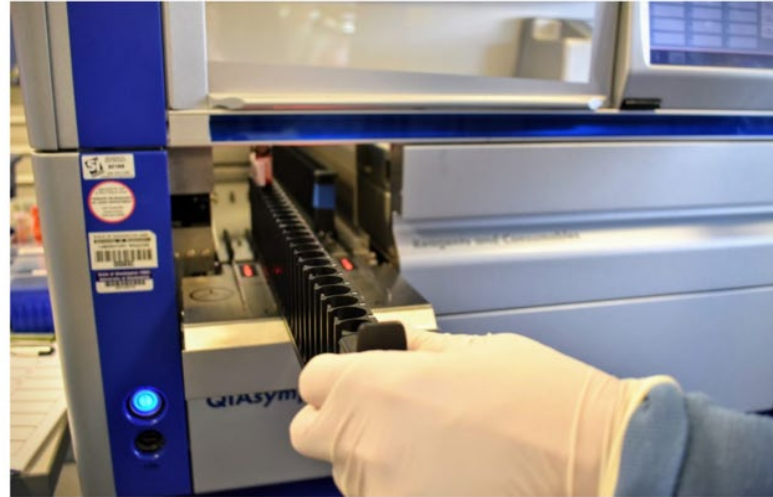
THE BBI CARET PROGRAM CAN HELP



BBI Precision Diagnostics Platform

Platform Contact

1959 NE Pacific St, RR120
Seattle, WA 98195
(206) 598-6429



This BBI Precision Diagnostics Platform serves as an umbrella for BBI-affiliated clinical labs and molecular tumor boards at UW Medicine, Fred Hutchinson, Seattle Children's and the Seattle Cancer Care Alliance. It provides test branding, marketing, and other services that are not core capabilities of the individual labs, formal consultative services for the development of clinical diagnostics, and is operating a Pilot Granting Program for clinical lab test development.

The Precision Diagnostics Platform is overseen by Dr. Colin Pritchard, MD, PhD, Associate Professor of Laboratory Medicine at the University of Washington.

[Precision Diagnostics Platform Test Menu](#)

[CARET – Consultative Services for Clinical Diagnostics Development](#)

CARET - Rationale

- Many researchers and clinicians have great ideas about diagnostic advances, but no idea how to translate these to clinical production
- Need - System to pair these researchers with Laboratory Medicine faculty
- Need- Resources to lower barriers for diagnostics implementation

CARET - Purpose

- Help translation of new tests into clinical care in partnership with BBI affiliated laboratories
 - Evaluation and consultation services on the potential of new diagnostic approaches for use in clinical testing.
 - Support pilot studies for test validation in human samples.

CARET - Resources

- Guidebook and framework for consultants
- Assistance with internal memorandums of understanding
- Assistance with external consulting agreements
- Connections with ITHS, Tech Transfer offices (UW Co-Motion)

Clinical Applications of Research in Emerging Technology

CARET - Consultants

- Consultants
 - Genetics, Genomics, Sequencing: Brian Shirts
 - Proteomics, Metabolomics, Mass Spec: Andy Hoofnagle
 - Pathology, Microscopy, Digital Imaging: Nick Reader
 - Immunology: Mark Wener
 - Seattle Children's: Jane Dickerson, Wayne Chandler, Mike Astion
 - Many more

BBI and YOU

[SEATTLE FLU STUDY](#)[ABOUT](#)[BBI DATA & TOOLS](#)[NEWS & RESULTS](#)[PLATFORMS](#)[CALENDAR](#)[CONTACT](#)[LOGIN](#)

A Powerful Collaboration For Precision Medicine

Precision medicine, genomics and data science have the potential to transform health care.

UW Medicine, The Fred Hutchinson Cancer Research Center, and Seattle Children's have co-founded The Brotman Baty Institute to accelerate both the basic sciences of precision medicine and the delivery of benefits to patients.

The Institute is made possible by the generosity of Jeff and Susan Brotman, and Dan and Pam Baty.

brotmanbaty.org

<https://brotmanbaty.org/caret/>



Upcoming Program Meetings

2020 Mutational Scanning Symposium & Workshop

In 2020, the Brotman Baty Institute & the Center for the Multiplex Assessment of Phenotype are co-sponsoring a two-day event: a Mutational Scanning Symposium on Monday, January 13 and a workshop on Tuesday, January 14. Abstract submissions will open in September.

Guest speakers are Cailin, Plesa, PhD | University of Oregon, Nadav Ahituv, PhD | UCSF, Jesse Bloom, PhD | FHCRC, and Stephanie Zimmerman, PhD | UW – Genome Sciences.

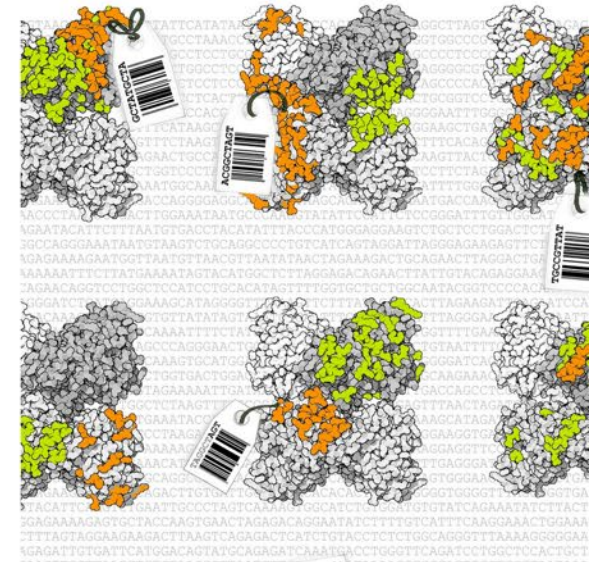
[Register to attend](#)

Location

HUB (Husky Union Building) Ballroom – 2nd Floor

Date & Time

Jan 13, 2020
10:00 am -



Upcoming Grant Deadlines



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Resize font:
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[Returning?](#)

The 2019 Brotman Baty Institute Granting Program

The Brotman Baty Institute (BBI) aims to create a community of investigators across the three founding institutions (UW, FHCRC, Seattle Children's) to advance basic science and translational research with clear relevance to precision medicine.

IMPORTANT INFORMATION

All PIs listed on a BBI grant application must be BBI Members. In addition, any funding requested under a BBI grant must go to a BBI member lab or budget number. If you would like to check to see if your collaborator is a BBI member, or if you would like to request that they are invited to BBI, please contact Nola Klemfuss at klemfuss@uw.edu.

IMPORTANT DATES

Application Deadline: November 1, 2019

Applicant Notified of Award: January 1, 2020

Progress Report Deadline: August 1, 2020

Below are the 2 RFAs that are available. Please select the grant(s) below to gain access to the RFA application and the opportunity to submit your application.

Catalytic Collaborations: The BBI Catalytic Collaborations Pilot Grant program invests in innovative, collaborative projects that address basic science or translational research questions related to precision medicine, with special consideration for proposals from junior investigators and those that highlight new or ongoing collaborations involving investigators from at least two of the co-founding institutions.

Precision Medicine Clinical Labs: This grant funds innovative and collaborative diagnostic technology development and validation proposals with clear aims and outcomes to propel the field in the near term, and to foster development of trainees interested in careers in clinical diagnostics for precision medicine in the long term. Focus is on support for clinical implementation of new diagnostic technologies within member labs. Favorable scoring will be given to faculty pilot projects that are collaborative and articulate a clear plan to develop, validate, and implement a diagnostic technology in clinical practice within 2 years. Favorable scoring will be given to trainee pilot awards that have a well-defined training and mentoring plan and career goals. Applications may include funds for conference travel, publication costs, and educational programs.

For further information, please contact Nola Klemfuss at klemfuss@uw.edu



Q & A

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Thank You

Open for Questions

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Feedback Survey

A link to the feedback survey has been sent to the email address you used to register.

Please get out your device, find that email, and spend a few moments completing that survey before you leave today.

Tip: If on a mobile device, shift view to landscape view (sideways) for better user experience.

Career Development Series 2019



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