JOHNS HOPKINS inhealth

PRECISION MEDICINE:

FAQs & Quick Links for Researchers (and Centers of Excellence)

Date: September, 2020

Category 1: Before Becoming a PMCOE

Q1: What is inHealth?
A1: inHealth is a strategic initiative to advance precision medicine at Johns Hopkins. By leveraging university-wide assets from the disciplines of medicine, engineering, nursing, public health, and our Applied Physics Laboratory, our team is developing patient-level insights that will improve health care.

The inHealth program is a part of the Johns Hopkins Medicine Strategic Plan to use data and technology in innovative ways to guide decision making in every corner of the Johns Hopkins organization.

Q2: What is a PMCOE and how is it different than what we're doing today?
A2: A PMCOE, or Precision Medicine Center of Excellence, helps researchers translate insights into clinical applications. inHealth is building new tools and resources to make it easier for Johns Hopkins clinicians to conduct big-data research and bring the results to their patients. The PMCOE designation, a 2-year program, includes resources such as:

- Data collection in Epic
- Data collection in REDCap
- Navigating the IRB approval process
- Extracting data for research use as part of a no-cost PMAP subscription
- Engineering support from the Johns Hopkins Applied Physics Lab (APL) and more
- Health economics and support to define value
- Marketing your research and commercial value

Q3: What's the difference between the CAMP program and becoming a PMCOE?
A3: In previous years, the Center of Excellence Analytics in Medicine Program (CAMP) trained research teams on the Precision Medicine Analytics Platform (PMAP). Participants exited the program with a concrete data projection that included a draft proposal for IRB and a data management plan. CAMP participants tackle 4 big issues:

- What is your research question?
- What data is available to help you answer those questions?

- Who do you need on your science team?
- How can you leverage precision medicine to attain NIH grant funding?

PMCOE applicants have answers to these questions. Clinical research teams can articulate not only their research aims, but also the metrics that would be used to show improved patient outcomes and financial benefit to the health system. Learn more about CAMP here.

In 2020, instead of CAMP, Dr. Paul Nagy will be teaching a series of classes, beginning with "Introduction to Precision Medicine Data Analytics" course (Fall, 2020): This course will introduce students to the rapidly evolving field of precision medicine and the role of big data analytics in improving patient care, clinical decision making, and population health management. Students will be provided access to the Johns Hopkins Precision Medicine Analytics Platform (PMAP) and learn how the infrastructure is built to support clinical research…

Learn more about ME 600.721 through link above.

Q4: Isn't Precision Medicine focused just on genome sequencing?
A4: Precision Medicine at Johns Hopkins, also known as inHealth, is more than genome sequencing- we like to call it whole-person Precision Medicine. inHealth starts with an understanding of patient subgroups at the most granular level, drawing from genetic insights, patient health history, environmental factors, and disease-specific expertise.
Leveraging best-in-class data infrastructure and analytics, Johns Hopkins endeavors to increase the precision and customization of patient care, to design custom research and trials more precisely, and to develop new solutions to unmet healthcare needs. Learn more here.

Q5: What is the PMCOE application and selection process and how long does it take?
A5: We've created a click-through PMCOE journey roadmap to walk you through the incremental steps to apply for PMCOE designation and evaluation for selection. View our Journey Roadmap for more details here.

Note: application to become a PMCOE is not a guarantee of admission into the program.

The length of this process is highly dependent on the level of preparation your team has completed prior to applying to be a PMCOE. The inHealth program selects one cohort a year and formal launch is dependent upon many variables.

Q6: If our team is chosen as part of the "call for applications," what funding support do we receive?
A6: You DO NOT receive any monetary support in the application phase of the PMCOE process.

You DO receive the investment of subject matter experts' time to help you evaluate and measure your research objective(s).

Q7: What should a prospective PMCOE have in place before applying for the program?
A7: Research teams interested in becoming a PMCOE should be in the planning phase as the inHealth team works to frame your pilot research project and prepare you for launch. This planning includes the **submission and approval of an umbrella IRB for your center** and the **identification of your team**. (See Question 11 "What does a PMCOE team look like?")

Concurrently, the inHealth team will make use of the data you already have, with the understanding that you'll collect higher quality data in the future. The goal is to bring your existing data into the Precision Medicine Analytics Platform (PMAP) and move to the analytic space more rapidly, while also continuing to invest in your ability to collect data effectively. PMCOE applicants may receive a deferred acceptance if they lack enough data to meet these requirements.

Q8: Who are the existing PMCOEs?
A8:

Year	Center of Excellence
2018	Multiple Sclerosis Prostate Cancer
2019	Myositis Scleroderma Arrhythmic Right Ventricular Cardiomyopathy (ARVC) Neurofibromatosis (NF) Pancreatic Cancer Bladder Cancer
2020	Chronic Obstructive Pulmonary Disease (COPD) Alzheimer's Disease (AD) Precision Rehab

Year	Center of Excellence
2020	Kidney (AKI/CKD) Neuro Critical Care Unit (NCC) Lung Cancer Pediatric Genetic Syndromes COVID- CROWN Registry

Q9: What does a recommended PMCOE team look like?

A9: To start the PMCOE application process, research teams should have a dedicated Primary Investigator (PI), one junior faculty member, and one full- or part-time staff member supporting IRB and administrative work. A dedicated data research manager is highly recommended but not required. Additional roles that will optimize your success include project manager, data scientist, software engineer, and finance analyst. These roles may be filled post-PMCOE designation with support from the inHealth team.

The PMCOE process uses a value-driven framework and a successful PMCOE rigorously demonstrates at least one of these value categories.

- Lowering the cost of care
- Better patient outcomes
- Commercial translation potential

Q10: What does the PMCOE lifecycle look like?

A10: You can check the PMCOE product cycle here.

Q11: What are the benefits of being a PMCOE?

A11: A PMCOE leverages the Precision Medicine Analytics Platform (PMAP) to apply rigorous value-driven methods to data that will be used in clinics within and outside of the Johns Hopkins ecosystem. The goal is to derive value — lower cost of care, better patient outcomes, commercial potential, prestigious research — and push it out into the world. The responsibility is on the PMCOE to drive their science forward. inHealth frames the research in a way that benefits you and a broader audience.

Q12: Can we do this ourselves?
A12: Absolutely. All steps in the PMCOE lifecycle or journey map can be followed independently. PMAP and other inHealth resources are available at a cost.

Q13: How do you test the value of PMCOE research aims to demonstrate change?
A13: In order to demonstrate value, prospective PMCOEs must specify:

- If the clinical validity of the proposed intervention/ tool will be tested. (Does it identify affected patients; or does it lead to a change in management and/or change in outcomes?)
- What metrics will be used to demonstrate value.
- A detailed description of the proposed pilot study.

Try out the inHealth Value Tool.

Q14: What have other PMCOEs had to say about their experience?
A14: "One of the major things that attracted me to PMAP and the PMCOE program is the access we'll have to Epic data. And, also the fact that there is already a support infrastructure - people we can access for expertise. I see being a PMCOE as a way to participate with the overall activity in PM across the institution. Perhaps our data could be helpful to other people. 'Look, this is how we solved this problem. Maybe you'd like to consider that.' We're open to sharing our data. Yes, we're collecting the data and yes, we're making the investment, but we see this as a way to collaborate with everybody else…"

Q15: If we aren't capturing the right structured data in Epic, who can help us with that before we go down this route?
A15: As a designated PMCOE, you are awarded $60K/ year over 2 years to support the build out of your data collection resources through Smart forms or other data capture tools.

Category 2: After Becoming a PMCOE

Q16: As clinical researchers, how do we up our data science game?

A16: Don't be intimidated when it comes to data science tooling. A great way to grow your data science skills is to learn from others. inHealth is expanding its team and resources in order to support researchers.

- The Precision Medicine website was set up as a portal for all your clinical research needs in PMAP.
- The PMAP Cookbooks provide step-by-step details on big data computing within crunchr using Jupyter Notebooks.
- Events such as Crunch Time and the annual Johns Hopkins Precision Medicine Symposium serve as networking opportunities.
- Courses on Precision Medicine offered by Paul Nagy (search offerings through the Department of Health Sciences Informatics) provide hands-on learning opportunities.

Q17: How is clinical data on consented patients ingested into PMAP?

A17: The eformR will list each of the study protocols (e-form S). Study protocols will define the process of consenting. Consent information is generally a part of the Clinical Research Management System (CRMS) that your clinical team will update.

Q18: What if we want to use eConsent as part of our IRB study submission?

A18: A pilot is underway to establish an institution-wide eConsent process. If successful, this process will be implemented and available to all clinical research protocols approved by JH IRB (anticipated Q1 2021).

Category 3: PM Tools

Q19: What is PMAP?

A19: The Precision Medicine Analytics Platform (PMAP) is a system that lets you obtain comprehensive clinical research data sets. The platform ingests disparate clinical and research data sources and provides machine learning tools to draw insights. In PMAP, the data collected for your studies is protected.

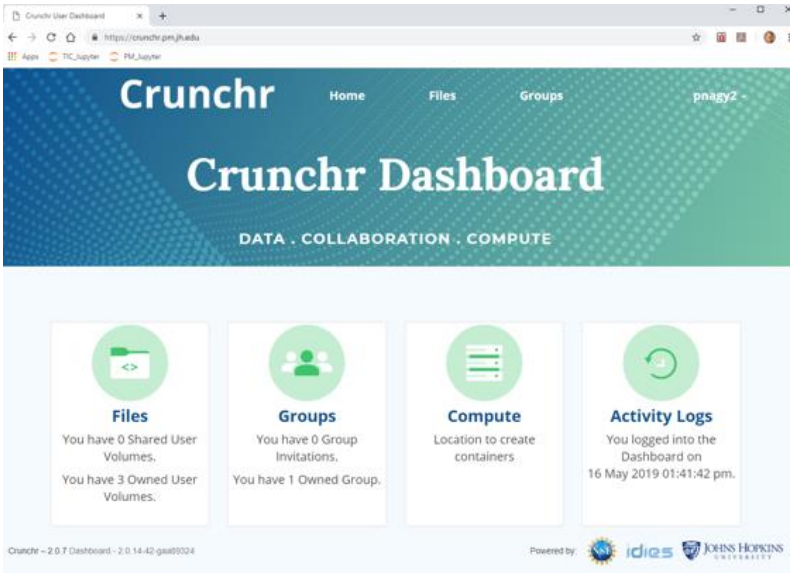
Q20: What tools are available to researchers for conducting analysis?

A20: In the analysis layer of precision medicine at Johns Hopkins, several different environments are available:

- SAFE Desktop: A secure virtual desktop that emulates a traditional desktop experience while providing access to various desktop analytical tools such as SAS, Stata, RStudio, Anaconda, PowerBI, and NVivo.
  Learn more about SAFE Desktop: https://bit.ly/JHMsafe

- crunchr: A collaborative data science platform based on the leading data science platform, Jupyter. This environment comes packed with support for Python and R within JupyterLab and RStudio. For security purposes, Crunchr platform (crunchr.pm.edu) can only be reached from the Safe Desktop.

  To request a SAFE desktop for your study team or to request access to an existing SAFE folder, please submit the request using the SAFE Desktop Request Form.



Go to Johns Hopkins Precision Medicine Analytics Platform (PMAP) Cookbook for detailed instructions on how to get to the crunchr website.

- Phoenix: A Linux-based HPCC(High Performance Compute Cluster) that can fit your most demanding analytical and processing needs.

Q21: What learning resources are available for the analytic tools on PMAP?

A21: There are several learning resources available while getting started on PMAP.

The Johns Hopkins PMAP Cookbook has links to many important FAQs and How To's including:

- Before you start cooking
- Intro to crunchr and Jupyter Notebooks
- Accessing your data
- Working with EMR data
- Conducting NLP projects
- Working with medical images
- Programming resources

Access the various analytic environments here:

- Python
- R
- Stata

Access the Data Catalog User Guide here OR view the Data Catalog video tutorial

Access crunchr Support through SAFE Desktop here.

Q22: How do I access the Data Catalog to see what data sources are available in PMAP?
A22: Data Catalog uses tags to assist with catalog searching, so that users do not need to know exact table and field names in order to find entries of interest. Example tags include: Demographics. Labs, Medication, Vital, Biospecimen.

Q23: Why wouldn't we just use REDCap for our research?
A23: With the Precision Medicine Analytics Platform (PMAP), you can combine data from multiple sources, including REDCap. Researchers can bring in data from a REDCap database, and enrich it with data from Epic, or from other systems such as imaging or genomics.

When projects use SAFE Desktop or PMAP as intended, they're considered Tier 1 Risk (lowest risk) by the Johns Hopkins Data Trust. This low-risk tier waives the need for a review by the Data Trust, unless data is being shared outside the institution. For this reason, most researchers don't need separate approval from the Data Trust when they get IRB approval, skipping a step that sometimes takes months.

Q24: Once I have access to SAFE, how can I access my PMAP data projection database?
A24: If you would like access to an existing research project in PMAP, you MUST request access through the PI.*. The PI needs to fill out this form and submit for access request here.
**The PI has a legal requirement to control access to study data for his/her research team*

If you are a researcher or a member of a study team and would like additional information, please visit the Support Resources on the PM Portal.

Q25: Is there sample data available for PMAP training?
A25: A de-identified dataset of asthma patient records are available for PMAP training. Submit this request form for access to the Training Dataset.

Q26: How can I get involved with the Johns Hopkins inHealth initiative and drive research efforts in precision medicine?
A26: There are multiple ways to get involved with the inHealth Precision Medicine initiative at Johns Hopkins:

1. Precision Medicine Analytics Platform (PMAP)

- Review the details here and how PMAP works.
- Sign up and explore PMAP for Free. Review pricing for the Precision Medicine Analytics platform.
- Members of the PMAP team will follow-up to with you to document your data requirements.

2. Become a Precision Medicine Center of Excellence (PMCOE)

- Are you ready to articulate your research aims? Have you considered the metrics you will use to show improved patient outcomes? What is the financial benefit to the health system (lowering the cost of care, better patient outcomes and/or commercial translation potential)?
- To learn more about the formal process of applying to become a PMCOE, **Contact us** here.

Category 4: Financial

Q27: What's my investment of time and trade-off to working in PMAP?
A27: Johns Hopkins is seeing improvements in research and clinical care delivery through precision medicine. PMAP allows insights to be made more efficient- faster and with less trial and error.

Research is accelerated in PMAP by combining Epic data with research databases and other data collection tools (radiology, wearables, monitors, etc.) into one place.

PMAP cross-links this data to create a super record for our patients. The data is stored in the PMAP Data Lake and a slice of that data can be cut for projections and researcher use.

Q28: If we include an additional data feed after we set up our PMAP Data Projection, what's the incremental cost for incorporating that data?

A28: We determine this on a case-by-case basis. Please find the different levels of PM access at the conclusion of your PMCOE tenure and/or Contact us to learn more.

Q29: What resources and expertise will be allocated to us, and for how long?
A29: For the duration of the 2-year PMCOE program, the following resources will be allocated from inHealth:

- Assigned project manager – 25% FTE
- IRB submission support
- Support to build data collection and data management
- Data science resources & expertise
    - Prototype PMAP clinical decision support application, in preparation for your pilot intervention study.

A30: How do we fund our PMCOE work at the conclusion of the program?
Q30: One key aim for PMCOE is getting additional funding and grants. Many still do clinical research like Swiss watches – one of a kind, non-standardized, non-machinable way. PMAP is an opportunity to turn research into an industrial, seamless, scalable process. A good first step is taking a new path to collect data with goal of being able to do discovery with data. We can help you collect data in a granular fashion up front in a way that's not adding burden to physicians to collect notes.

Category 5: Technical

Q31: Is there a reference tool that explains what it means to conduct precision medicine research?
A31: The PMAP Cookbook is a textbook of computational notebooks to help investigators at Johns Hopkins conduct clinical research.

The Cookbook provides examples of how to work with clinical data within PMAP using a combination of R and Python programming languages and modern data science libraries.

Q32: Who gets to see my data?
A32: Data from each PMCOE is ingested into PMAP and stored in the same location with all other Johns Hopkins data. PMAP is secure and HIPAA-compliant. Access controls (based on JHED IDs) limit clinicians and researchers to the data defined by their IRB approval.

Q33: I don't have data skills but I'm interested in precision medicine research. What do I do?
A33: You'll need to fill the skill set of two key roles:

- Data management know-how to maintain data integrity and serve selected data to researchers.
- A biostatistician or data scientist to conduct data analysis.

Options include finding expertise in your team or department, or working with partners in CCDA, School of Public Health, APL, or others.

Q34: If the data we're interested in is not in PMAP, what are the steps to have a new data source added?
A34: inHealth is continuously ingesting new data sources into PMAP. Review the Data Catalog. If your data source is not listed, there is a process in place to present your case for inclusion. You can work with your PMCOE project manager or someone on the Precision Medicine team to submit a request for consideration. We formally evaluate, rank and weigh new data sources according to the following criteria:

- Strategic Priority
- Research Efficiency
- Data Quality
- Generalizability
- Work Effort Required

Q35: Is there a helpful glossary to decipher PM-specific common terms and abbreviations?
A35: Yes, find this glossary of common terms here.

Q36: What sources feed into PMAP?
A36: The PMAP Data Catalog contains information about the data that are available in the PMAP. The research community can browse and search the contents of the Data Catalog that includes sources such as Epic, REDCap, open specimen data set, imaging data set, etc.

The Data Catalog does not show the actual patient data. Rather, it provides information about the available data to guide subsequent requests for that data. It is THE place to look for the most up-to-date information on PMAP data.

- For further information about using the Data Catalog, refer to the video tutorial here.
- For access to the Data Catalog click here.

Category 6: Process

Q37: What are the steps to access data in PMAP?
A37: To gain access to data in PMAP, there are concrete steps with documented artifacts at each stage for auditing and reporting purposes. These steps include:

- IRB approval for research proposal
- Cohort discovery to find patient sample size
- Data selection
- Data preparation
- Data validation

Q38: What is the IRB approval process for establishing a PMAP registry (eformR)?
A38: Before beginning the IRB Approval Process, the following steps must be completed:

- Meet with inHealth leadership
- Determine human and financial resources
- Develop strategy and fix initial priorities
- Meet with the Institute for Clinical and Translational Research (ICTR) team designees
- Identify research resources (who will have access to your PMAP registry data?)
- Explore the PMAP Data Catalog

- Draft registry data specifications

You can find the new IRB application flow here.

Q39: How do we access our data and what research tools are available?
A39: See "PM Tools" section for a full list. Your data will be made available to your study team directly from the SAFE Desktop. The SAFE desktop provides a secure environment to store and analyze data with a premium suite of analytical and clinical tools.

Q40: How can I learn more about the precision medicine initiative and stay up to date on new developments?
A40: There are several ways to follow what's going on with precision medicine at Johns Hopkins:

- Join the Technology Innovation Center mailing list for updates on PMAP from here: bit.ly/ticsubscribe
- Follow inHealth on Twitter for inHealth and precision medicine industry news.
- Contact us directly with a targeted question from here: bit.ly/PMAPhelp

Q41: Can you provide an example of a data projection?
A41: Yes, we recommend requesting access to a de-identified dataset of asthma patient records. The dataset encompasses 60k patients with over 110M data elements encompassing encounters, medications, labs, procedures, symptoms, and vital measurements. To compile relevant Jupyter notebook tutorials you will need to be granted access to the PMAP database with this data and complete an attestation. The form request can be found here.