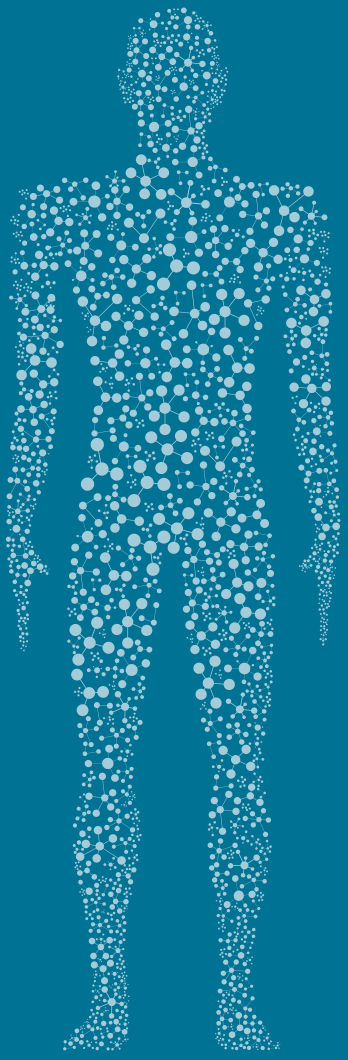
Duchossois Family Institute Impact Report

THE UNIVERSITY OF CHICAGO

March 2026

DFI CREDO

The DFI will optimize wellness and thriving longevity through groundbreaking science on the human immune system, genetics, the microbiome, and their shared systems.



By developing new knowledge about the optimal relationships between the human body and the microbiome, the DFI will identify, develop, and disseminate practices and treatment methods that break new ground in improving health around the world.

Written by Molly Huber | Designed by Chloe Noble, Alyssa Cieslak, and Jaimie Lake

Essential steps to optimizing health and thriving longevity:

Demonstrate impact of the microbiome in causing disease

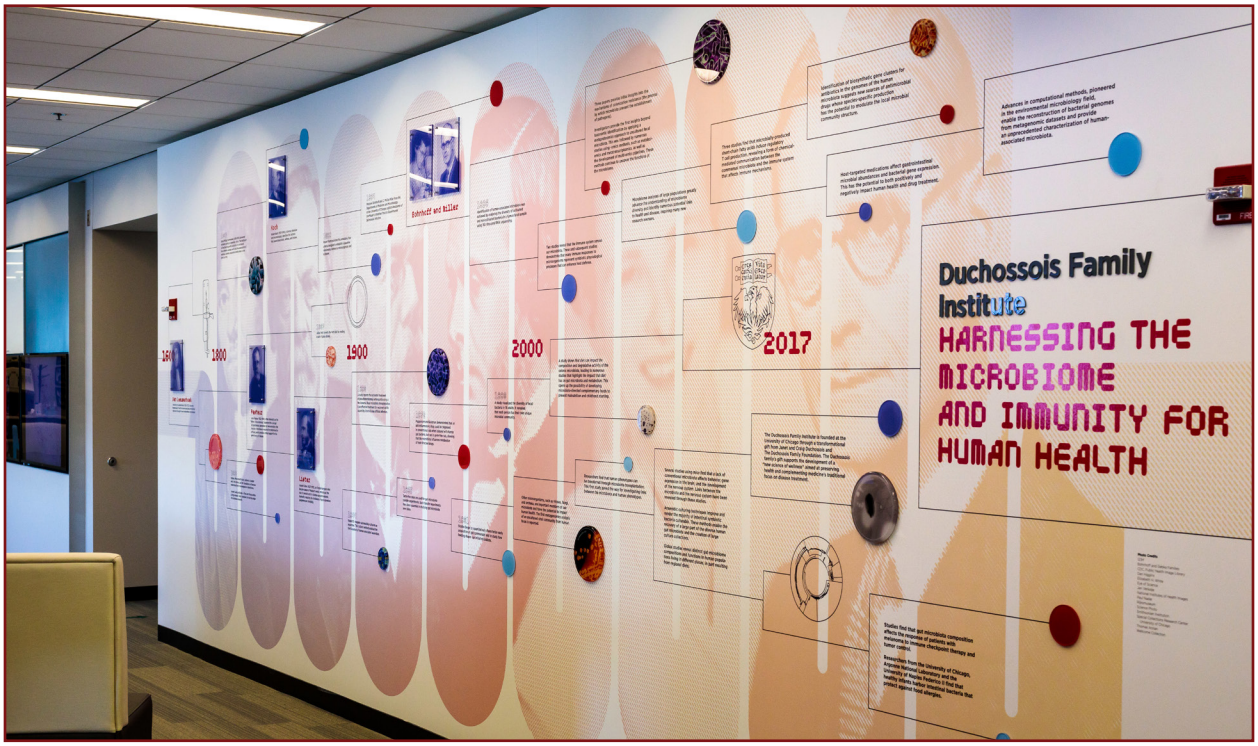
Engage clinicians who will commit time to study specific patient populations

Show how changes in the microbiome and metabolome are associated with disease states

Correct microbiome and metabolome defects associated with adverse outcomes

The Duchossois Family Institute:
Harnessing the Microbiome and Immunity for Human Health

The Duchossois Family Institute launched in 2017 through a transformational gift to support microbiome science, motivated by a vision to create a new science of wellness that optimizes human health and makes a tangible impact on human life. Now, less than a decade later, the DFI is delivering microbiome therapeutics to patients in a clinical trial—a therapy that was conceived, designed, and manufactured right here on campus.



The DFI is an environment of firsts, bests, and onlys:

- The first of its kind current Good Manufacturing Practices facility (cGMP) dedicated to the microbiome at an academic medical center
- A first-in-human clinical trial of a live biotherapeutic in liver disease patients
- The only place capable of producing a single therapeutic capsule that contains multiple beneficial bacterial strains
- The first and only rapid metabolomic test of microbiome composition
- The only clinical study to evaluate microbiome dysbiosis in hospitalized patients across disease types
- The best, most promising research to identify a blood biomarker for microbiome composition
- The best training opportunities for the next generation of basic science investigators and clinicians

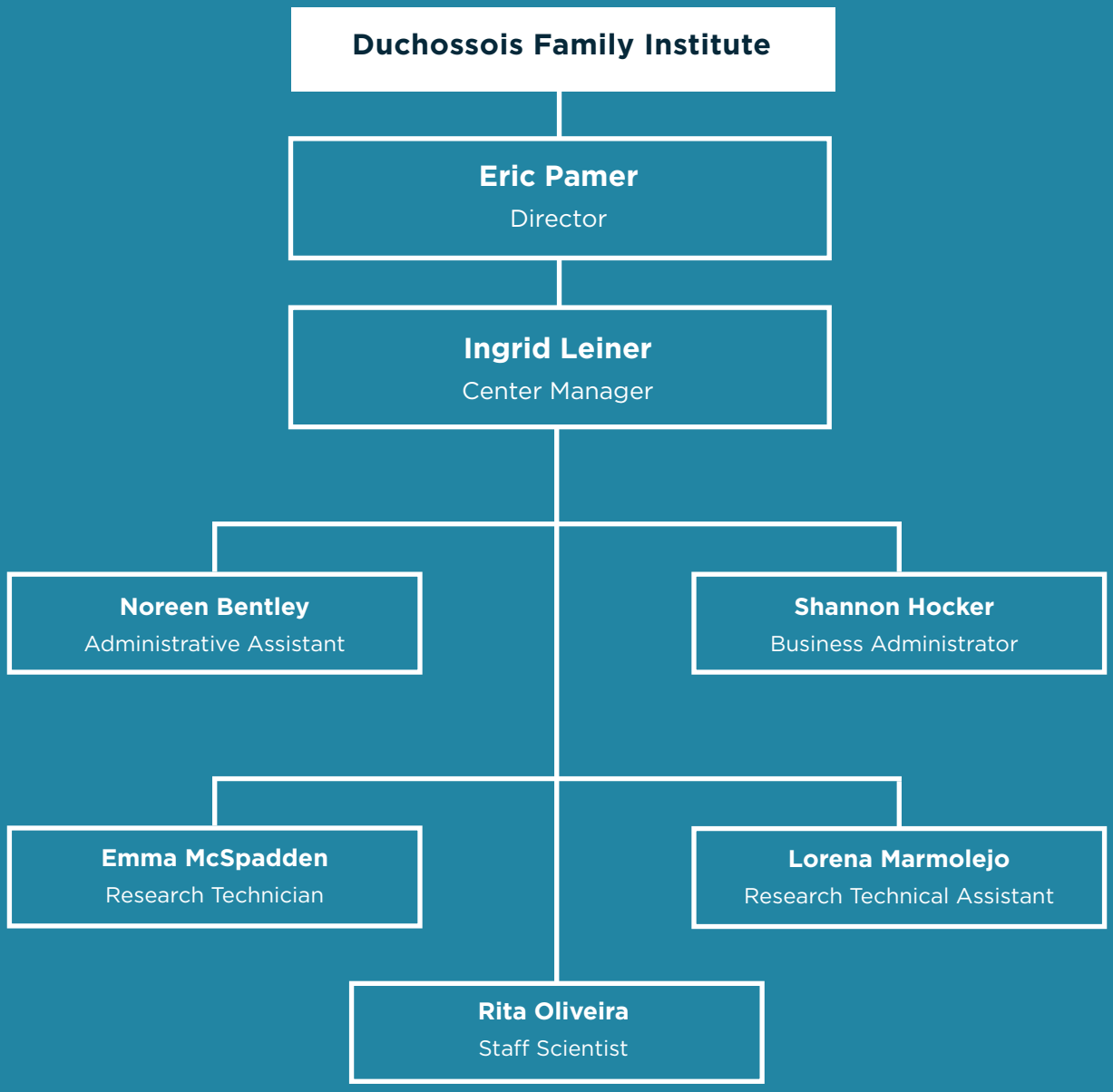
Speak to any DFI researcher or collaborator, and they will tell you the same: The field looks to the DFI to lead the way forward.

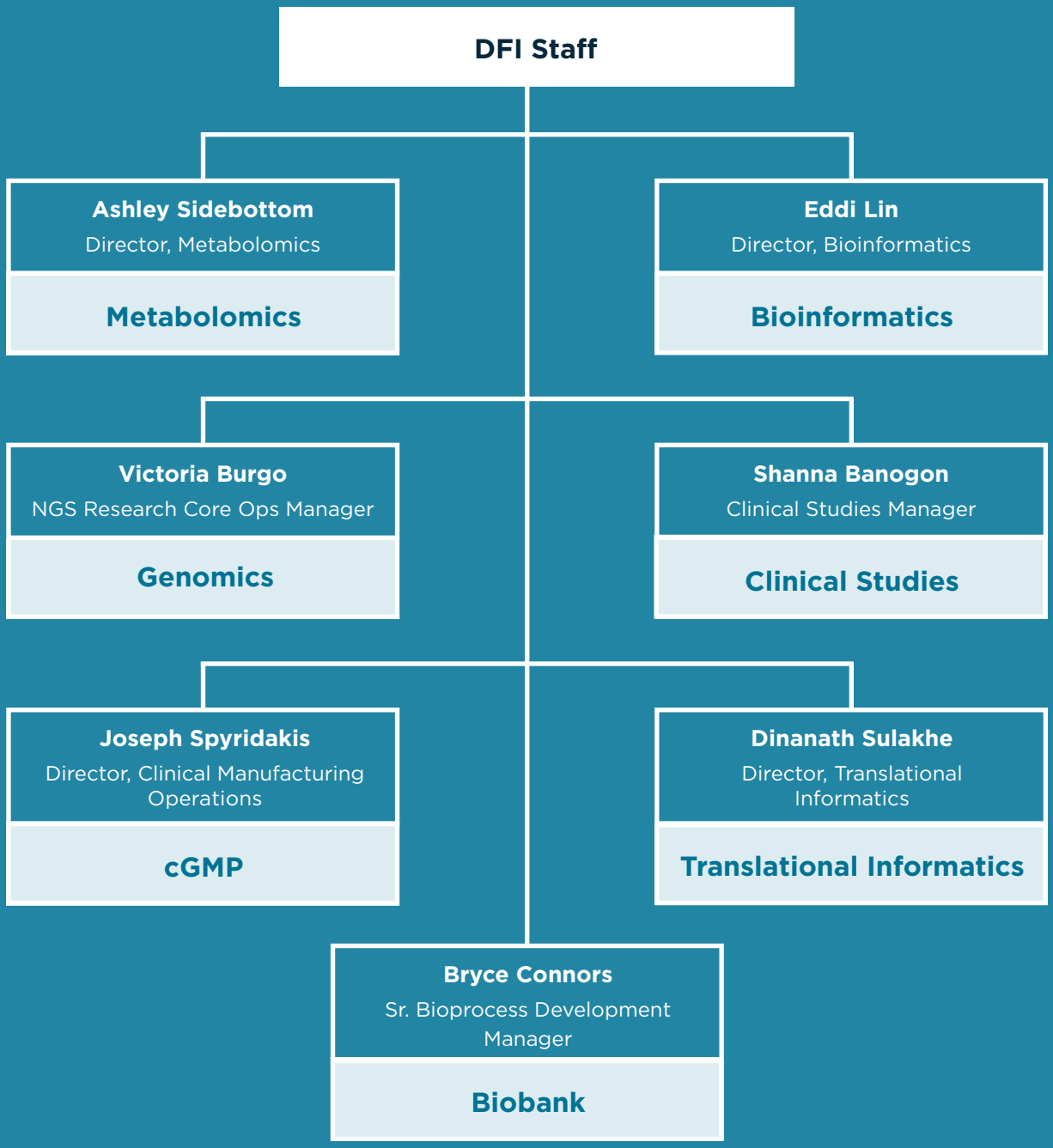
"The activity happening here distinguishes the DFI from anything going on anywhere else," said Eric Pamer, MD, director of the DFI. "We have been moving forward on many fronts over a number of years—we have foundational research as well clinically-focused research and resources that have enabled us to make substantial advances in understanding and augmenting the microbiome."

The DFI has also built a robust culture of interdisciplinary collaboration and scholarship—one that amplifies opportunities to ask big questions and explore novel lines of inquiry about how we can modulate the microbiome to improve health. As this culture grows, so too grows the reputation of the DFI as a global leader in the microbiome and the potential for impact that sustains into the future.

"The DFI is a really special place to work. Everyone I can think of comes to work excited about what they're doing," said **Matthew Odenwald, MD'17, PhD'15,** DFI researcher, hepatologist, and assistant professor of medicine. "You have clinicians like myself, immunologists, bacterial strain manufacturing experts, people studying DNA and metabolites, researchers in different disease areas, people doing statistical modeling…so many people with different ideas come here to work toward a similar end-goal. It's pretty remarkable and a testament to the University of Chicago's prescience."

DFI Organization Chart




DFI Staff
Ashley Sidebottom
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Metabolomics
Eddi Lin
Director, Bioinformatics
Bioinformatics
Victoria Burgo
NGS Research Core Ops Manager
Genomics
Shanna Banogon
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Dinanath Sulakhe
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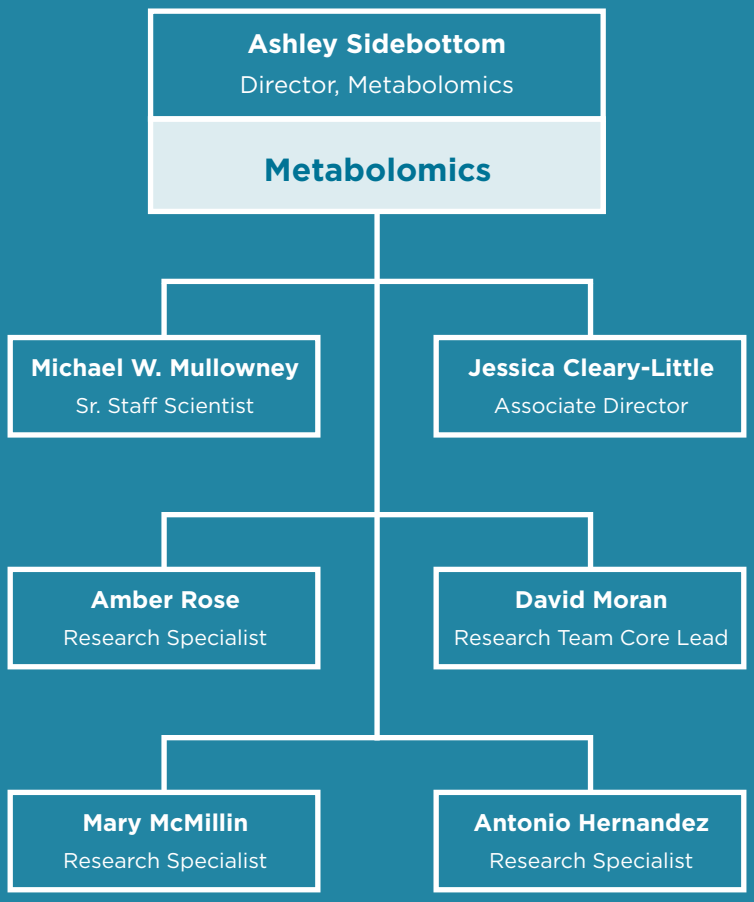
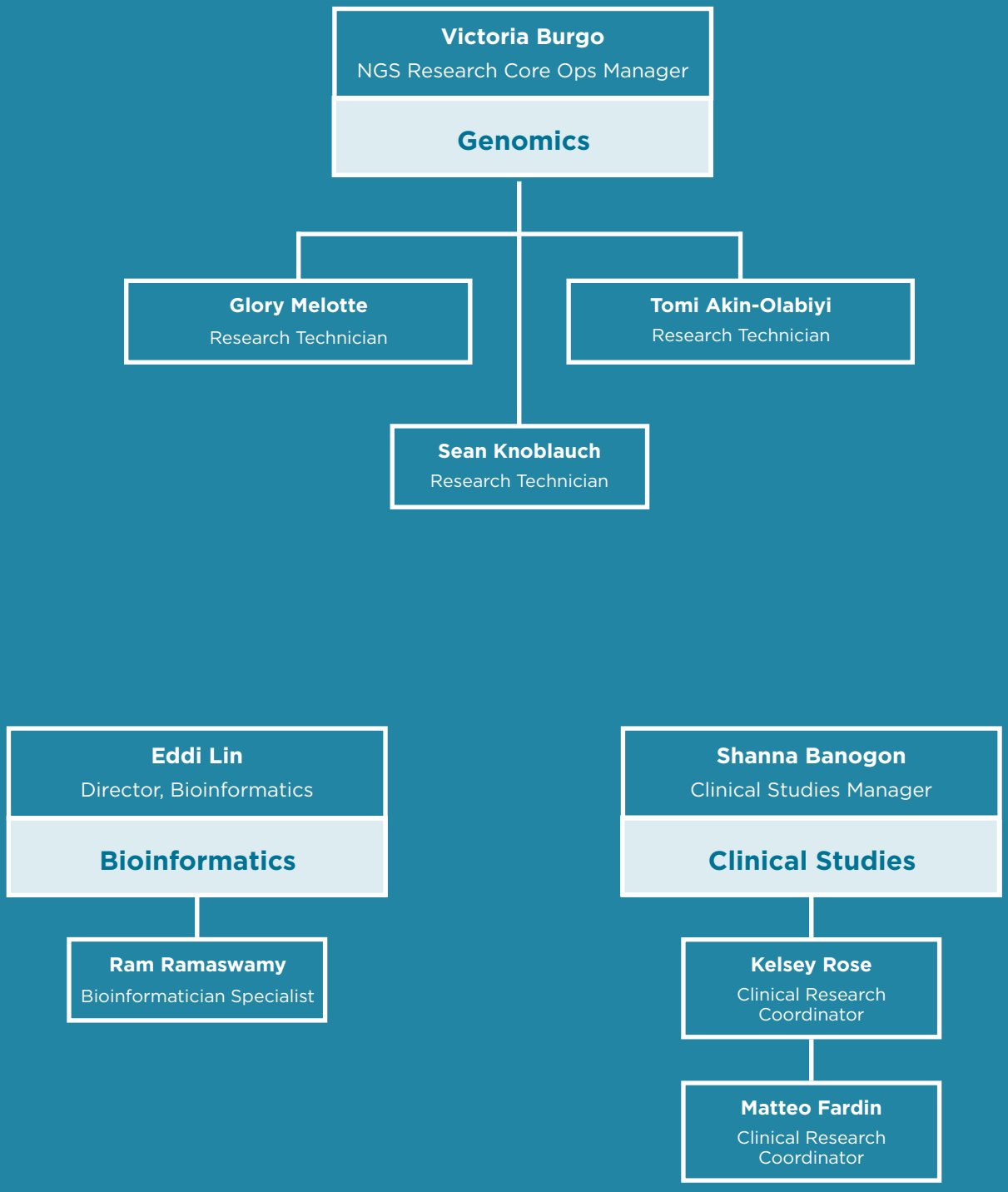
DFI Organization Chart, continued




Victoria Burgo
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Kelsey Rose
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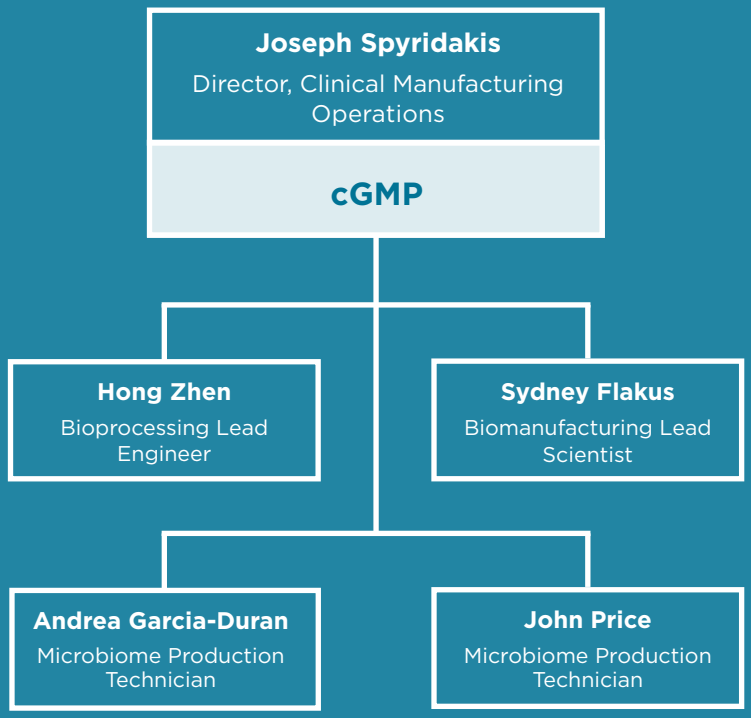
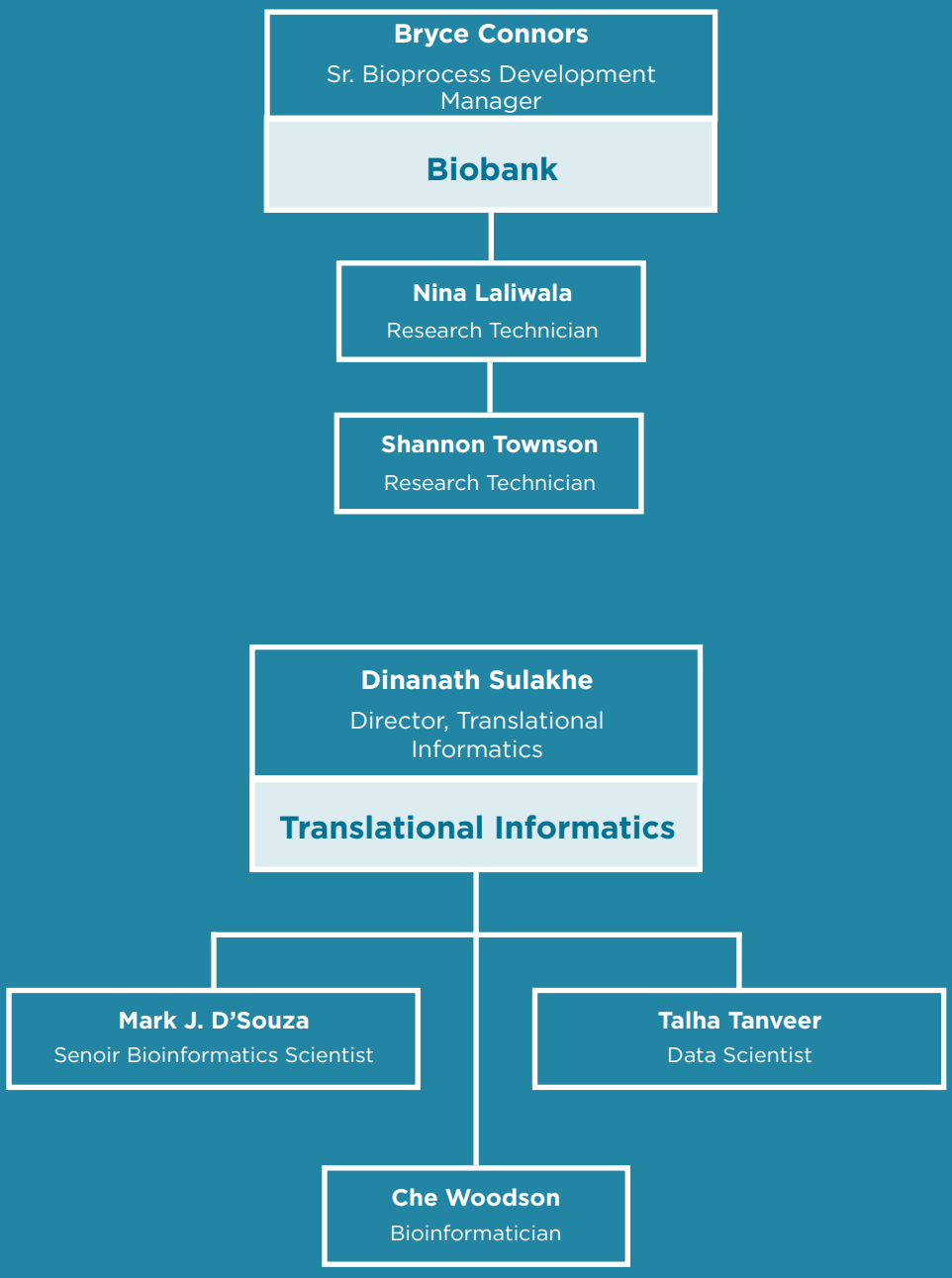
Matteo Fardin
Clinical Research Coordinator

DFI Organization Chart, continued

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Dinanath Sulakhe
Director, Translational Informatics
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Talha Tanveer
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Che Woodson
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First in Humans

After years of research, planning, infrastructure development, and regulatory navigation, the MARCO trial is underway. This phase I, first-in-human trial is designed to test a novel microbial treatment for patients hospitalized with liver disease whose microbiomes are damaged by broad-spectrum antibiotics.

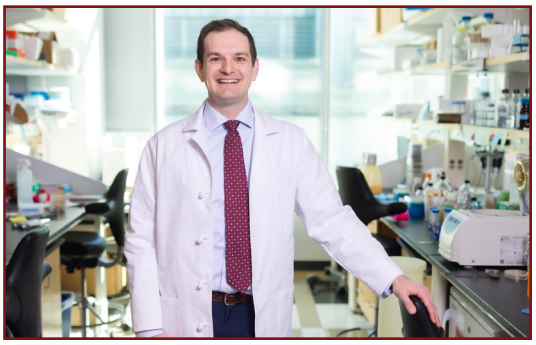
While these antibiotics play an invaluable role in killing the harmful bacteria that cause infections, they also wipe out the beneficial, health-promoting bacteria in the gut, putting patients at increased risk for subsequent poor outcomes. The disruptive impact of antibiotics also provides an opportunity for drug-resistant bacteria to take hold and spread. "The gut ecosystem is like a rainforest, incredibly diverse, and delivering antibiotics is like clear-cutting the rainforest," said **Chris Lehmann, MD**, a DFI infectious disease expert who helped develop the clinical trial. "What comes back is dangerous—something that could kill you or your neighbor."

The novel intervention being tested in the MARCO trial aims to help these patients by reconstituting their microbiome with naturally occurring, healthy bacteria that respond to treatment better, resist infections effectively, and prevent complications of disease.

This clinical trial of a live biotherapeutic product is the flagship project of the DFI: the idea was conceived here; the live biotherapeutic was researched, manufactured, and tested here; the Investigational New Drug (IND) protocols were formulated here. **The trial administered the live biotherapeutic to its first patient in November 2025—a significant milestone for both the DFI and for the translation of microbiome research into improved patient treatments.**

"Microbiome research has gotten a bad rap—investigators have been able to find interesting correlations between microbes and patient outcomes, but most studies do not go further to test causation in clinical trials," said Dr. Odenwald.

The microbiome-based patient interventions that *do* exist—particularly fecal microbiome transplants (FMT)—can be imprecise, difficult to scale, and potentially risky. FMT involves the transfer of fecal matter from a healthy donor into a patient's gastrointestinal tract to restore a healthy microbial community. While this approach has been successful in treating recurrent *Clostridioides difficile* infection, a condition that commonly infects people who have recently taken antibiotics, it also carries the risk of transmitting drug-resistant infections from the donor into an already-compromised patient. And, since the treatment relies on stool donations from healthy subjects—which are much less common and harder to secure than blood donations—FMT access is tenuous.



The live biotherapeutic manufactured by the DFI circumvents many of the issues that plague traditional FMT treatment.

"We know the bugs we're giving, and at what dose. We're not giving patients bugs that are pathogenic. Plus, we can scale the production of this therapeutic through our GMP facility. Our approach relies on bacteria that we can preserve, grow up over time, and make the same therapy, and in large quantities, over and over again," said Dr. Odenwald. "What we've built at the DFI helps us get around a lot of issues."

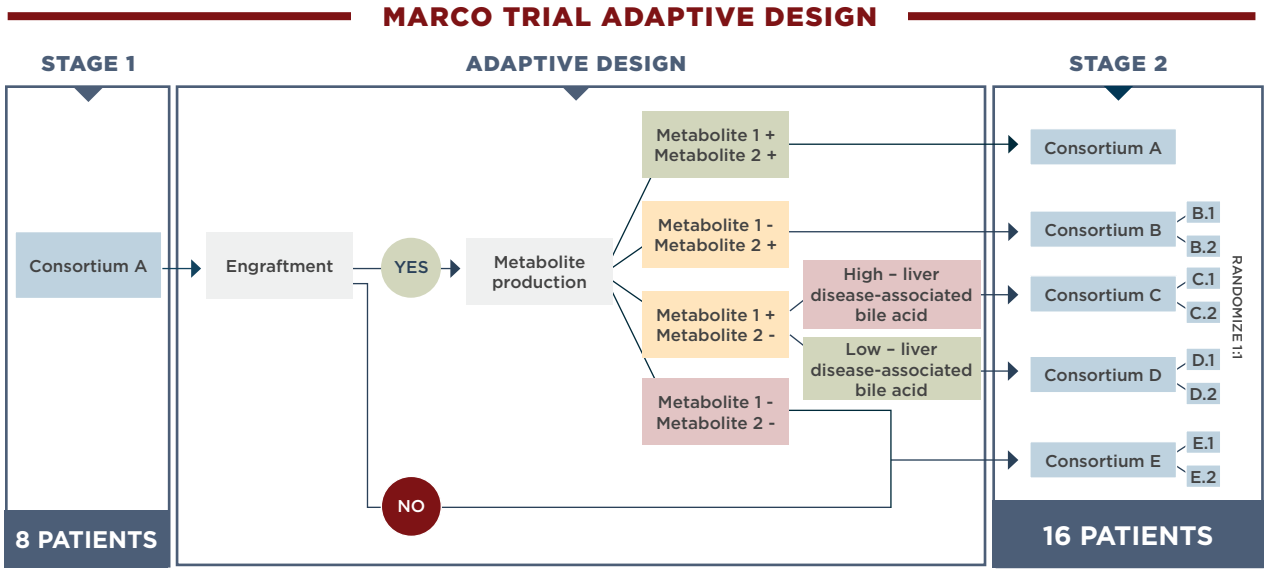
Novel Trial, Adaptive Design

The stage is set, the bacteria are manufactured and ready for delivery, and now Dr. Odenwald and his clinical colleagues are screening and enrolling UChicago patients with liver disease in the MARCO trial.

The trial design begins with eight patients. Every day for seven days, each patient enrolled in the trial will receive a "consortium" of seven capsules, each containing a specific bacterial strain that has been researched, tested, and correlated with restoring microbiome health. All eight initial patients will get the same doses each day, supported by a clinical team who will monitor their symptoms. After a week of treatment, DFI researchers will conduct analyses of patients' stool to measure their responses: Did the bugs engraft in the gut? Did they produce the health-promoting metabolites that we expected them to? Were the biotherapeutics safe and well-tolerated?

In addition to stool sample collection and analysis immediately following the seven-day treatment protocol, stool samples from the initial eight-patient cohort will be collected and analyzed at four different time points over the next year to evaluate the longer-term efficacy of the treatment. Based on the results, the next 16 patients enrolled in the clinical trial will either receive the original consortium of bugs or they will be randomly assigned to receive a different consortium of bacteria that are also known to have health-promoting properties. Bacteria that didn't engraft or have the expected impact in the first patient cohort will be swapped out for different strains in the next patient group.

"The adaptive design of MARCO, which allows us change the consortia of bugs to improve the clinical trial, breaks the mold," said Dr. Lehmann. "At a drug company, they care about getting from point A to point B as quickly as possible. We can think adaptively, creatively, and develop a clinical study that is more likely to be successful."



The adaptive design of the MARCO trial will enable the clinical trial team to test different strains of bacteria that promote gut health, swapping out strains that didn't perform the expected function in the initial stage of the clinical trial.

Dr. Odenwald, who started working in the DFI during his clinical fellowship and spearheaded the clinical trial protocol process with the Food and Drug Administration, marveled at the speed at which the goal of producing and delivering a microbiome patient therapy has come to fruition. When he met Dr. Pamer, the DFI space in the Knapp Center for Biomedical Discovery (KCBD) was still under construction. The DFI GMP facility—now a state-of-the-art facility and a model for other academic medical centers—was a defunct intensive care unit.

"Being able to do this clinical trial, it's pretty amazing," said Dr. Odenwald. "A lot of people work their entire careers and don't get to do something like this. We are fortunate to have this opportunity to conduct clinical research that we anticipate will reduce the development of diseases and improve responses to a wide array of medical treatments. The DFI is making these opportunities available to trainees, laboratory investigators, and clinicians."

The Next Step

The MARCO trial is designed with broad impact in mind. If the phase I trial works, and the bacterial consortia are safe and tolerable in liver disease patients, the trial protocol can be easily translated for impact across a range of conditions, helping to restore the gut microbiome in hospitalized patients that receive broad-spectrum antibiotics.

"The DFI was not formed to treat only patients with liver disease," said Dr. Odenwald. "The goal is to improve and advance human health. I think we all keep that in mind in our work."

In addition to the potential for improved patient outcomes, the MARCO trial will also yield foundational insights that will push forward the field of microbiome science.

"Even if the trial works like we want it to, there are still going to be things we can learn from and improve upon," said Dr. Odenwald. "We can take the consortia [from MARCO] and learn more about it in the lab—what materials do these bacteria make in combination? What could we feed them to make them function differently? There will still be so much to learn, and we have outstanding basic scientists in the DFI that can help teach us."

A Game-Changing Diagnostic

Underpinning the MARCO trial is the DFI's development of an entirely new diagnostic test that enables clinicians to assess the health of a patient's microbiome and, within a matter of hours, determine their eligibility to participate in the clinical trial.

"This was a big push," said Dr. Pamer. "We wanted to come up with a one-day test with parameters that show whether a patient has a sick or healthy microbiome. We didn't want to waste our clinical trial by giving capsules to patients to fix a microbiome that doesn't need to be fixed."

Designing and executing this test was no small feat. Usually, to understand what is going on in the gut microbiome, the genomics team evaluates a fecal sample to understand which bugs exist there. Then the DFI metabolomics team runs tests to understand what the bugs are saying to each other and to their host. The teams' tests are sophisticated, but they take some time and require a few different measurement instruments.

Michael Mullowney, PhD, the senior staff scientist in the Host-Microbe Metabolomics Facility who helped develop the test, explained that the facility is set up to run a series of established panels that measure specific types of molecules that occur in the gut microbiome. The facility runs these tests for academic labs and to support clinicians' research. The metabolomics facility also coordinates across the University on custom analyses: researchers will come to the facility with an observation about the gut, and the metabolomics team investigates which molecules may be driving that trend.

"DFI clinical investigators came to us to see if we could figure out a way to do our analyses faster, and on a single instrument," said Dr. Mullowney. "This was driven by the goal to establish the MARCO trial: we needed a way to measure gut microbiome health, then administer a therapy rapidly, because the gut microbiome changes so quickly."

	TRADITIONAL STANDARD		NEW DFI DIAGNOSTIC
TIMELINE	UP TO ONE WEEK	→	6 HOURS
EQUIPMENT	MULTIPLE ANALYSIS INSTRUMENTS	→	ONE INSTRUMENT
APPLICATION	RESEARCH ONLY	→	PATIENT SCREENING IN THE CLINIC

"No one else is even doing this. This rapid diagnostic doesn't exist anywhere else. We are it."

ERIC PAMER, DFI DIRECTOR

While the analytic technology existed at the time, it didn't exist in the right combination for the envisioned diagnostic to support the MARCO trial.

"We didn't want to reinvent the wheel," said **Ashley Sidebottom, PhD,** director of the DFI Host-Microbe Metabolomics Facility. "We knew that pieces of this puzzle were out there, but no one had put them all together—this was our job."

Through an iterative process over almost three years, Dr. Sidebottom and her metabolomics team, including Dr. Mullowney, figured out a way to measure gut health based on approximately 20 common microbiome metabolites that are well studied and correlated with health and disease, two of which are the focus of the MARCO trial. Their method for measuring these metabolites on one instrument, versus relying on a series of instruments and resources, significantly cuts down the time from sample collection to result—from multiple days to just six hours.

"If a sample comes in at 10 a.m., we'll know the result by 4 p.m. that same afternoon," said Dr. Pamer. "This is entirely new and does not exist anywhere else."

The next major hurdle was getting this hard-won accomplishment translated for clinical application. Developing a test to use in patient samples is highly regulated—it requires a completely different facility from the research cores of the DFI.

"We now had this diagnostic test to use in a research setting, but there's not much you can do with it in a clinical setting," said **Angelica Moran, MD, PhD**, assistant professor of pathology. "And no other clinical labs run it—not Labcorp, not Mayo Clinic, no one. So, we had to develop and validate it ourselves."

This DIY approach required a CLIA-certified lab—a clinical laboratory that meets federal quality standards set by the Clinical Laboratory Improvement Amendments (CLIA), ensuring the accuracy, reliability, and quality of patient test results. The clinical metabolomics CLIA lab that Dr. Moran established is able to meet stringent federal standards and to run tests with a high degree of accuracy. Without this critical resource, the DFI's field-leading research would not be able to directly benefit patients.

"Angelica is my counterpart on the clinical side, making sure everything passes inspection," said Metabolomics Director Dr. Sidebottom. "The test was developed in a DFI lab, and the MARCO clinical trial can now use it to test patient samples every day."

The clinical test screened fecal samples of approximately 30 liver disease patients before the MARCO trial enrolled its first patient in November. Dr. Odenwald recruits the patients he thinks could benefit from the trial, the test co-developed by metabolomics experts and a clinical pathologist demonstrates whether a patient's microbiome needs support, and the next day, eligible patients start taking capsules manufactured by the DFI's cGMP facility.

Dr. Moran's goal is to develop more diagnostic tests for use in diseases correlated with the microbiome, and to design new blood-based tests of microbiome health.

"If you asked five years ago, I think many microbiology and pathology faculty would have said that this is a pipe dream," said Dr. Moran. "But our research is getting out there—we're giving talks, publishing papers, we're getting interest from people who want to learn more. People are buying into this now, and they're seeing how this can become a reality."

Manufacturing New Therapeutics

The DFI's remarkable success to date and its burgeoning potential for patient impact owe much to the DFI's current Good Manufacturing Practices (cGMP) facility, the first facility of its kind at an academic medical center with the capacity to manufacture clinical-grade microbiome therapeutics.

"Because of the facilities at the DFI, we're not doing science only for the sake of science," said Dr. Moran. "The DFI clinical team really wants to advance patient care, to run clinical trials and to design these microbiome-based therapeutics. We're able to do research to identify the bacteria that are missing, then go to the cGMP facility and make the pills to help."

The facility has manufactured and completed all the capsules for the MARCO trial over the past year under the leadership of new DFI cGMP Facility Director **Joseph Spyridakis**. Spyridakis joined the DFI in July 2024 from Nelson Labs, a global provider of laboratory testing and advisory services for medical technology and pharmaceutical companies, where his responsibilities included operations site expansion, implementation of new test methods, and cGMP compliance.

One of the biggest challenges—and opportunities—for Spyridakis is developing live biotherapeutics at the same time that the FDA is figuring out how best to regulate them. Much of the FDA guidance and testing requirements apply to things like pharmaceutical powders and medical devices, but not living bacteria. This lack of applicable guidance has presented some frustrations in developing the appropriate quality controls for MARCO, but it has also empowered Spyridakis to think creatively.

"First and foremost, I consider myself a scientist. So, in the absence of other guidelines, we've been able to think more freely and focus on the science behind our products," said Spyridakis. "We've been able to go back and forth with the FDA to determine what we feel is most appropriate based on the science, and we aren't focused solely on established regulatory requirements. In the end, science will lead you to the right solution."

In addition to ensuring that live biotherapeutics for MARCO are manufactured to FDA standards, Spyridakis is also responsible for showcasing the cGMP facility to other institutions that want to learn from the DFI model. In recent months, representatives from the University of Utah, City of Hope, and the University of Calgary have visited the DFI's cGMP facility with hopes of replicating the facility at their own institutions.

"It's a challenge to have a cGMP facility in an academic setting. The maintenance, the documentation requirements, the material requirements—it's a lot you have to keep in line," said Spyridakis. "But everyone who visits is very impressed with the facility, the state-of-the-art technologies, how it's built, and how we maintain it. We're pretty open with what we share so that others can build their own facilities."

Dr. Pamer recognized years ago that this facility and its experts, like Spyridakis, would be seminal for microbiome research and patient care.

"There is significant know-how that makes this work possible. It's not just about having our cGMP facility—in fact, UChicago has a few other cGMP facilities—but it's the capacity to grow these very difficult-to-grow bacteria and then maintain their stability over time. This is what sets us apart. Our work on this over 3-4 years has enabled us to grow, at this point, 17 different bacterial species that we can use to make products for clinical trials."

The Next Evolution in Biotherapeutics

The DFI cGMP facility is also supporting a groundbreaking development in biotherapeutic manufacturing: growing multiple bacterial strains together for use in a single therapeutic capsule.

In current therapeutics and therapeutic trials—including our MARCO trial—patients receive one bug per capsule to restore their microbiome. In MARCO, patients have to swallow seven capsules per day to test the therapeutic impact of the consortium of bugs. This can be problematic on both a practical and a scientific level: seriously ill patients may have trouble swallowing multiple capsules, and we are limited to choosing only a handful of strains to restore a gut ecology with hundreds or thousands of bacteria that impact health outcomes.

The DFI took a giant step toward addressing this issue with the appointment of **Bryce Connors, PhD**, as the cGMP facility's senior bioprocess development manager in spring 2025. Dr. Connors, a recent chemical and biological engineering graduate of University of Wisconsin—Madison, has conducted novel, never-before-undertaken research on how to grow different bacteria together for use in live biotherapeutics.

"Individually, these bugs are really difficult to grow in the lab," said Dr. Connors. "I was interested in the problem of how to grow them together and understand the multispecies ecology that's happening. It's an intersection of engineering and biology that requires a foot in both worlds."

Dr. Connors explained that, while a single-strain bacterial therapeutic can certainly be challenging to work with, you can usually predict how it will behave, the byproducts it will produce, and when it should be harvested for manufacture. When you assemble two or three bacteria, the degree of difficulty scales up exponentially: each strain has unique growth properties and patterns, they may have different harvest times, they may produce byproducts that are harmful to the other strains. Dr. Connors has developed a method that accounts for and overcomes these challenges.

"This is a new type of microbiome therapeutics," said Dr. Connors. "We're now doing 3-4 bugs per fermentation. My end goal would be to design a lab-based culture that would include up to around a hundred carefully selected bacteria to restore the microbiome."

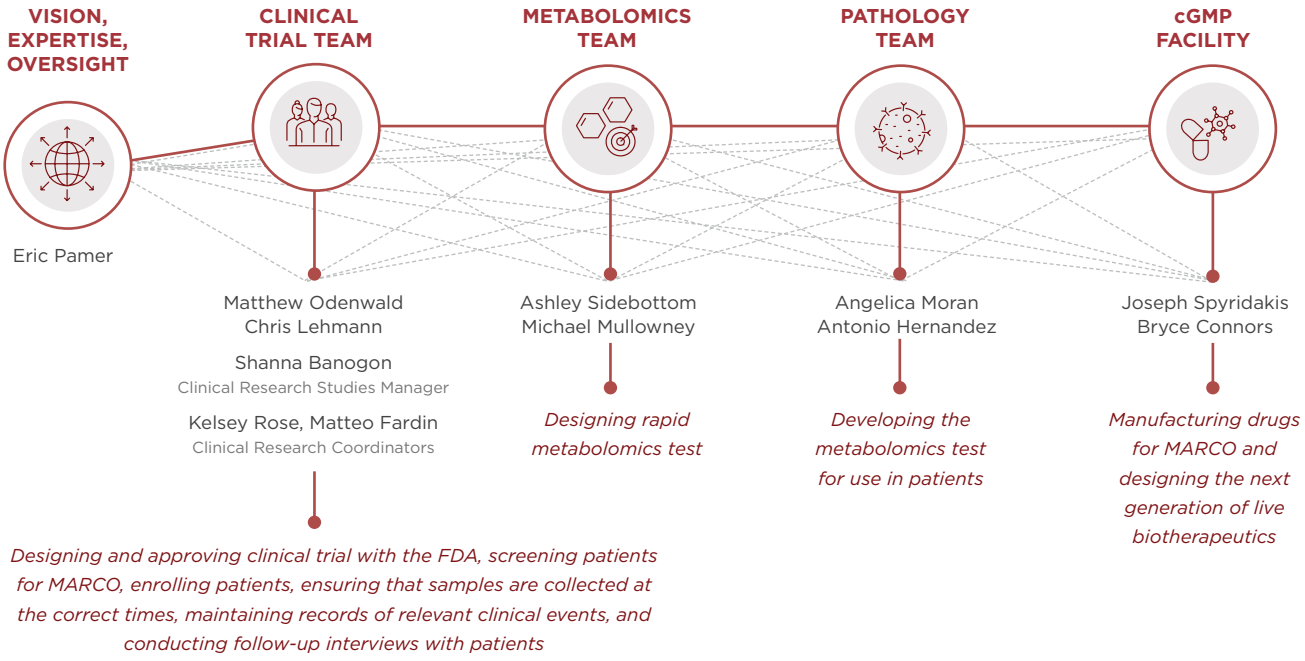
Dr. Connors's expertise has significantly increased the manufacturing capacity of the cGMP facility, supporting the development of single-strain capsules for the MARCO trial and developing three-strain capsules for future phases.

> **"When we added Bryce [Connors], it was like moving from a bicycle to a Harley-Davidson motorcycle. He was able to get the manufacturing team humming, and it's been a pleasure to see how the team has moved along since."**
>
> CHRIS LEHMANN, MD

Dr. Connors's inquisitiveness and determination to push the limits of what's possible is a perfect fit for the cGMP facility team and for the DFI.

"There's always an eagerness to keep advancing with the team and the cGMP facility," said Spyridakis. "We're thinking about the next phase, the next evolution. The fact that we're constantly striving for advancement is really exciting."

Team Contributions to MARCO Trial



Cross-campus Impact

The DFI continues to make an impact across the entire University. Researchers seek out the DFI to help them advance investigations in a range of conditions where the microbiome may play a critical role in improving patient outcomes.

Lymphoma

The DFI is collaborating with UChicago Medicine's lymphoma team to set up a clinical trial to augment the microbiomes of patients undergoing CAR T-cell therapy. When lymphoma patients receive this therapy—an immunotherapy that uses the body's own immune system to fight cancer—they often experience fevers, which are treated with antibiotics that wipe out the microbiome and may decrease the efficacy of the CAR T treatment. Hematology and Oncology Fellow **Reid Shaw, MD**, and Lymphoma Program Director **Justin Kline, MD**, aim to test whether microbiome restoration will help improve patient responses to this immunotherapy. The team is currently establishing a phase I clinical protocol with the help of Dr. Odenwald, who spearheaded the development of the DFI's MARCO trial. They will use biotherapeutics manufactured at the DFI in the trial.

Justin Kline, MD

Reid Shaw, MD

Matthew Odenwald, MD, PhD

"We can help [the lymphoma team] with bacterial consortium design, live biotherapeutic dosing, and monitoring microbiome responses to treatment. We can also help complete preclinical work the FDA may want to see and can use our experience and our approved Investigational New Drug (IND) application to benefit them and others at the University of Chicago," said Dr. Odenwald.

The team expects the FDA to review the study application in early 2026.

Leukemia

The DFI has also worked with the director of UChicago Medicine's Leukemia Program, **Olatoyosi Odenike, MD**, to design and execute a clinical study to evaluate the microbiomes of patients with acute leukemia. As in several other disease areas, the health of the microbiome is correlated with cancer outcomes. The innovative study collected daily stool and blood samples from leukemia patients that had been treated with antibiotics and found wild day-to-day shifts in patient microbiome composition. The sickest patients experienced the most dynamic changes in their gut, while less-sick patients had less pronounced swings and were able to endure the antibiotic-induced microbiome changes with limited effects.

This observation has led Dr. Odenike and her DFI collaborator Dr. Lehmann to begin investigating the resistome—a natural collection of antimicrobial-resistant genes in the gut. The current understanding is that the resistome presents a threat to individual and public health: these genes can be disseminated into pathogenic bacteria, resulting in the development and spread of antibiotic-resistant infections. In their clinical study of leukemia patients, Drs. Odenike and Lehmann observed that antimicrobial resistance was strong in patients that had the least pronounced day-to-day variation in their microbiome composition—in other words, a stronger resistome was correlated with a less chaotic microbiome. This suggests that the resistome, contrary to its reputation as a collection of "bad guys" in the gut, may actually confer beneficial protection to patients being treated with antibiotics. DFI investigators will build on this finding to identify other patterns and behavior of the resistome and its impact on health.

Hunting a blood biomarker for microbiome health

The hundreds of stool and blood samples collected in this study have also enabled DFI investigators to pursue a "white whale" in microbiome research: a blood biomarker for microbiome composition. To date, researchers have evaluated the health of the microbiome through stool samples, which are difficult to collect, especially from seriously ill patients. Assessing the gut microbiome through a blood draw—just as clinicians do for diabetes, heart health, liver health, anemia, and infections during routine check-ups—would pave the way for innovative, noninvasive diagnostic tests for diseases correlated with microbiome composition.

DFI Bioinformatics Specialist Ramanujam (Ram) Ramaswamy has leveraged the rich data gleaned from blood and stool samples in the leukemia study to create a machine learning model that can predict the composition of a microbiome accurately based on a marker in blood. He has isolated a panel of chemicals in the blood that seem to only be produced by an intact, healthy microbiome—these chemicals cannot be produced anywhere else in the body. Ramaswamy and his DFI collaborators need to validate this finding in another set of blood and stool samples, but are excited by the potential.

"We're generating a wealth of data each year that [DFI researchers] and other research groups can use to make discoveries," said Dr. Lehmann. "There are so many things being studied here, at this time, in this place—discoveries are always ongoing. The leukemia study dataset will undoubtedly generate more of this work."

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CHRIS LEHMANN, MD

Investigating The Breadth Of Microbiome Dysbiosis

Dr. Lehmann, an infectious diseases doctor who also trained in pediatrics and internal medicine, is concerned about burgeoning microbiome dysbiosis—an imbalance of microbial communities in the gut—across many disease types as a result of widespread antibiotics use.

While antibiotics stand as one of the greatest achievements in modern medicine, the havoc they wreak on the gut is significant and, as DFI researchers and others have shown, a ravaged microbiome is associated with poorer health outcomes for many conditions. An imbalanced microbiome also increases the chances that antimicrobial-resistant bacteria will bloom in the gut, making infections harder to treat and creating conditions for diseases to spread.

One year ago, Dr. Lehmann launched an observational study in UChicago Medicine's Mitchell Hospital—which treats a diversity of patients, including transplant, critical care, and obstetrics and gynecology—with the goal of determining just how widespread and severe microbiome dysbiosis is. The study has enrolled just over 100 patients, with a goal of enrolling up to 500, and assessing whether each patient has a healthy or imbalanced microbiome.

"Studies have already shown that microbiome dysbiosis is happening in newborns, in nursing homes, in liver disease patients," said Dr. Lehmann. "But what if it's happening everywhere, in every kind of patient? Then we are looking at a public health emergency."

Over 33 million people were admitted to hospitals in the United States in 2024. So far, approximately 28 percent of the Mitchell Hospital patients enrolled in Dr. Lehmann's study have a reasonable degree of microbiome dysbiosis. If this statistic is similar in the general population of hospitalized patients in the US, over 9 million people have imbalanced microbiomes that are vulnerable to developing and spreading antibiotic-resistant infections.

On the other side of the coin, over 9 million people are eligible for the microbiome-restoring therapeutics that the DFI has begun to produce and test in the MARCO trial.

"When I was making my decision to pursue an infectious diseases fellowship, I had seen the writing on the wall: we are going to figure out the microbiome's role in disease during my career, and at the same time, antimicrobial-resistant pathogens are going to get worse," said Dr. Lehmann. "I knew that I wanted to understand how the microbiome could have an impact on this growing problem of antimicrobial resistance. I wanted to build my career on this. I came to UChicago because I knew I could work alongside others who were building their careers on the same questions."

One of Dr. Lehmann's fellows—second-year infectious diseases fellow Chad Hinkle—recently presented this study at the 2025 IDWeek Conference, the joint annual meeting of the Infectious Diseases Society of America, the Society for Healthcare Epidemiology of America, the HIV Medicine Association, the Pediatric Infectious Diseases Society, and the Society of Infectious Diseases Pharmacists. His presentation garnered significant interest from researchers at the CDC, Emory, and Rush University, to name a few.

> **"All of these people are looking to us to lead the field. We're not only leading now, but we're creating a chain of mentorship and enthusiasm, filling the field with experts that 'grew up' in the DFI. This is one of the greatest benefits: the exponential growth of mentorship and knowledge."**
>
> CHRIS LEHMANN, MD

Dr. Lehmann plans to publish the results of the Mitchell Hospital observational study, lending critical data and attention to the issue of microbiome dysbiosis.

Intensive Care Unit

Bhakti Patel, MD, and **Krysta Wolfe, MD**, associate professors in the Section of Pulmonary and Critical Care Medicine, are investigating the microbiome to improve outcomes in patients admitted to the intensive care unit (ICU).

Over 5 million patients require intensive care annually and up to three-quarters of the survivors will have new disability one year later, characterized by a constellation of physical, psychological, and cognitive impairments known as post-intensive care syndrome. There is often no treatment for these impairments; while some patients survive the ICU, they routinely fail to thrive.

"For us, it's not a win when they survive if they now have to live with these conditions with no treatments," said Dr. Wolfe.

Care for these patients is further complicated by patient diversity in the ICU. Unlike patients being treated for cancer or diabetes, patients in the ICU are hospitalized for a variety of reasons—there is no condition that unites them apart from the severity of their illness, keeping precision treatments out of reach.

Drs. Patel and Wolfe are investigating the microbiome to turn the tide of prevention and treatment in the ICU. They aim to better understand how a patient's microbiome impacts their biology and which microbiome functions help a patient recover after hospitalization. As MARCO seeks to improve survival and outcomes for patients with liver disease, Drs. Patel and Wolfe want to identify a pharmacological approach to prevent disability, improve outcomes, and encourage patients to thrive after an ICU stay.

The two clinicians are currently leading UChicago Medicine's participation in a 22-site consortium, called the APS Consortium, to support the development of deeper mechanistic understanding of Acute Respiratory Distress Syndrome (ARDS), pneumonia, and sepsis—critical illness syndromes that inflict significant morbidity and mortality. The consortium will conduct a "deep dive" on patients with these illnesses—their background, biological samples, lab results, imaging, overall health while hospitalized, etc.

UChicago Medicine is the microbiome partner in this effort: the DFI will characterize gut microbiome function by measuring metabolites in stool samples. Drs. Patel and Wolfe expect to find new connections that link microbiome features to long-term outcomes and help phenotype common critical care syndromes based on microbiome function.

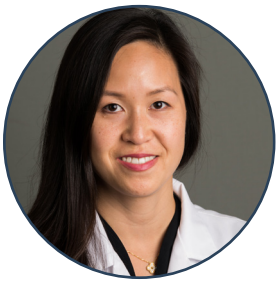
“We were chosen for this clinical consortium because of all of the resources available at the University of Chicago and at the DFI,” said Dr. Patel. “We have significant clinical trials and patient data, and with the DFI, we have a one-of-a-kind resource to conduct fecal metabolomics in a high-throughput way.”

This capacity will be invaluable, given the scale of the APS effort. The clinical study aims to enroll up to 4,000 patients and collect fecal samples or rectal swabs from 1,000 to 2,000 of them—creating “the largest cohort of patient stool samples known to man,” said Dr. Patel.

“If through this effort we’re able to link microbiome function to biology and outcomes in critically ill patients, we can then leverage the work that the DFI has already done with the MARCO trial,” said Dr. Patel. “We can evaluate a patient’s microbiome within a day, develop interventions in the cGMP facility, then do precision medicine in the ICU.”

Both clinicians emphasized a theme that is common to efforts made possible by the DFI: the potential for life-changing patient impact.

“Can you imagine if we could phenotype a patient for sepsis the moment they are admitted to the ICU?” said Dr. Wolfe. “We could then treat them based on their precise needs, informed by their biology. We could improve their resilience after the ICU. It would be revolutionary.”



Heart Transplant

Ann Nguyen, MD, medical director of UChicago Medicine's heart transplant program, recently completed enrollment of a 200-patient study to investigate the correlations between the gut microbiome and heart transplant patients. Like clinicians leading the MARCO trial and the ICU research, Dr. Nguyen aims to establish a link that will open doors to precision treatments and ultimately improve patient outcomes.

Now that patient enrollment is complete and patient stool samples and clinical data are input into a centralized platform for analysis, Dr. Nguyen has begun to evaluate the study's outcomes. The first outcome she's focused on is infection—a common complication for heart transplant patients.

"An early, unique finding from this study is that a fecal sample can alert us that an infection is coming," said Dr. Nguyen. "We have found that in fecal samples obtained 2-3 weeks prior to an infection, there is a decrease in microbiome diversity. This is all very new, and we'll have to sift through the data to understand it better, but this could be a correlation that leads to a next step."

The study is also enabling Dr. Nguyen to look at other correlations that could signal poor patient outcomes following heart transplant. She is evaluating samples from transplant patients with elevated cell-free DNA in their blood—a biomarker that a patient may reject the donor heart—against the health of their microbiome. She has found that patients with the blood biomarker for adverse transplant outcomes also have low microbiome diversity, which itself is associated with poor patient outcomes across disease types. With further research, this finding could lead to new, improved diagnostics for post-transplant outcomes without an invasive heart biopsy.

"It's taken years to collect all this information, and now we're finally able to look at the data," said Dr. Nguyen. "We're still in the discovery phase and there is still a lot to sift through, but I am hoping we can find something to push us forward, maybe to some sort of intervention trial, like MARCO."

Dr. Nguyen is certain, though, that she will continue to pursue research related to the microbiome.

"This study invigorated my passion for microbiome work and I want to continue," she said. "I want to use the information we've gathered to keep going and to make real findings that we can use for patients."

What is the ultimate goal of your work? By the time you retire, what do you hope to have accomplished in the microbiome space?

"By the end of my career, I would like the science to be making a difference in people's lives. Every time someone is given an antibiotic that will damage their microbiome, they will immediately receive a "chaser" that will restore their microbiome. We will have discovered a therapy that restores the microbiome the moment it needs to be restored."

CHRIS LEHMANN, MD

"When microbiome testing becomes routine, this is when microbiome therapeutics will have 'made it.' You'll go to a primary care doctor and their mindset will be, 'let's test your microbiome and see how it's doing,' just like testing your blood sugar or cholesterol—and when this gets to the point where this is commonplace and normal and accessible to everyone. I think it will happen in our lifetimes, I really do."

ANGELICA MORAN, MD, PHD

"The day I need to find a new research direction is the day we find exactly the bacteria required to restore the microbiome based on mechanistic knowledge of individual and ecological function, and we can fit 100 bacteria into a pill."

BRYCE CONNORS, PHD

Microbiome Metabolism

Sam Light, PhD, faculty director of the DFI's Host-Microbe Metabolomics Facility and assistant professor of microbiology, takes a molecular approach to understanding the role of gut microbes in human health and disease.

His lab studies the different types of metabolisms that gut bacteria use to produce energy, such as fermentation and respiration, and how the resulting metabolites—the small molecules like amino acids, sugars, and fatty acids that are found in foods or are the byproducts of cellular activities—influence health and disease.

"One of the ways the microbiome impacts health is through the production of metabolites. These small molecules are like drugs, and they enter our blood and impact our biology in a similar fashion to drugs," said Dr. Light. "Our goal is to define the strategies gut microbes use to survive in the gut and establish how this relates to production of these drug-like molecules in health and disease."

During a recent research project, published in *Cell Host & Microbe*, Light and his team screened gut microbiome samples from human donors to identify microbes specialized for the metabolism of a variety of compounds, including steroid hormones—a wide variety of molecules that play crucial roles in the body, from inflammation regulation to reproductive function.

As Dr. Light's team studied how gut microbes responded to the presence of different metabolites, they discovered a new bacterial species that was particularly adept at inactivating the steroid hormone cortisol. They further identified the genes the bacteria were using to break down steroids and found these same genes in other prominent gut bacteria.

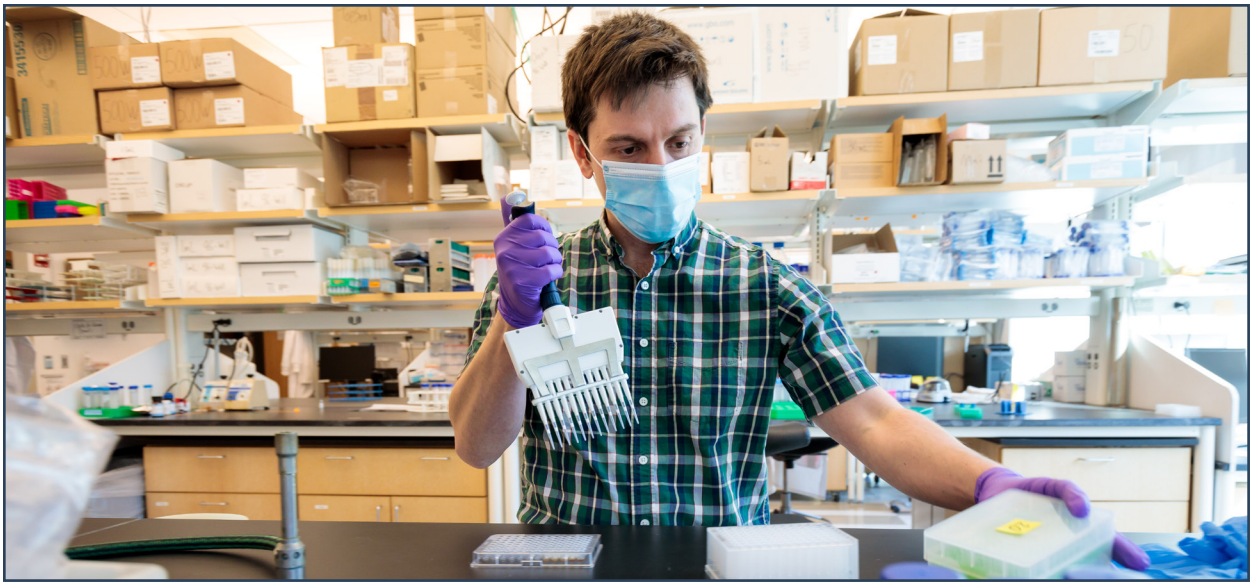
Since cortisol and related steroids play an important role in managing and treating inflammation in the gut, Dr. Light's team investigated samples from patients with Crohn's disease, a condition that causes chronic inflammation in the digestive tract. His team saw higher levels of steroid-inactivating genes in these patients, suggesting that in patients suffering from a flare up of Crohn's disease, the bacteria were actively breaking down steroids that could help keep inflammation in check.

"If you're trying to treat Crohn's or ulcerative colitis, having too many of these particular microbes around could make the treatment less effective and promote inflammatory flares," Dr. Light said. His team is using mice models to further explore this finding and hopes to analyze more patient samples to better understand how microbes behave to contribute to or protect against inflammatory disease.

Dr. Light's team is currently taking a molecular-level look at the gut microbiome's role in type 2 diabetes. In collaboration with Raghu Mirmira, MD, PhD, director of UChicago's Diabetes Research and Training Center, the team discovered in mouse models that dietary monosodium glutamate—commonly known as MSG, a flavor-enhancer used throughout the restaurant industry and added to many packaged foods—boosts the production of a metabolite called imidazole propionate (ImP) that impairs glucose tolerance, leading to more severe complications of type 2 diabetes.

"We knew that ImP existed and was associated with diabetes, but we didn't previously understand how diet interacts with the gut metabolism in this specific way to influence disease outcomes," said Dr. Light. "You can imagine that this could lead to updated dietary guidance for people with diabetes and other therapeutic angles, as well."

Dr. Light aims to publish this finding in early 2026. He is enthusiastic about the potential of studies like this one to elucidate the connections between the microbiome, diet, and overall health.



"One of the things that's exciting about these studies is that it really clarifies how the microbiome and diet interact to affect health more broadly," he said. "While we know diet and microbiome interact, we still don't have a great understanding of the underlying mechanisms."

Dr. Light credits the DFI for these exciting new research directions. Like his DFI colleagues, he believes that the study of the microbiome has the potential to advance our understanding of health and disease and to open new avenues for treatment and prevention.

"Being at the DFI transformed my research program," Dr. Light said. "Having the community, the infrastructure, the sequencing, the mouse models: all of the resources within the DFI are helping us to understand, at a molecular level, the many associations and functions in the microbiome. Developing this fundamental understanding is really the next stage for translating microbiome discoveries."

The Science of Resilience

Laurie Comstock, PhD, is a bacterial geneticist in the DFI who is driving forward our fundamental understanding of bacterial behavior in the gut: how they survive and thrive, how they collaborate and compete, and importantly, how their activity promotes human health.

Over the past year, Dr. Comstock's lab has advanced two projects to answer these foundational questions—the answers to which may inform future interventions to improve patient outcomes.

The first project centers on inflammatory bowel diseases (IBD), conditions like Crohn's disease (CD) and ulcerative colitis (UC) that present complex challenges to patients, doctors, researchers, and communities.

They affect nearly every aspect of a patient's life: they cause pain and discomfort, damage organs, interrupt meals and social situations, obstruct sleep, interfere with mental health, increase risk for cancer, and reduce average lifespan. Their incidence has grown steadily—nearly one percent of Americans are now affected—and globally, with levels rising nearly everywhere it is measured.

The gut microbiota of IBD patients is drastically different from patients without these conditions: their guts produce fewer metabolites that confer health benefits to their host. Fecal microbiome transplant—mentioned above as a successful treatment for *Clostridioides difficile* infection—has had very limited therapeutic success in IBD, as the donor bacterial strains often do not engraft long-term in the recipient's inflamed intestine.

Researchers know little about the factors that allow gut bacteria to survive in an inflamed gut and produce metabolites that are beneficial to overall health. To begin to address this question, Dr. Comstock's lab analyzed the factors that allow one of the most predominant and ubiquitous gut bacteria, *Phocaeicola vulgatus*, to colonize the inflamed gut.

The lab started by creating a barcoded mutant bank of *P. vulgatus.* A mutant bank is where each gene of the organism is mutated. Changing just one gene in each organism in the bank allows researchers to run tests in mouse models to identify genes that confer the properties they seek to identify—in this case, the ability to survive in an inflamed gut.

"Researchers can expose a bank of mutant organisms to any conditions. It's an extremely useful tool," said Dr. Comstock. "To date, no one has used it for IBD, so these will be the first such analyses."

Through this effort, Dr. Comstock's lab identified more than 250 genes that contribute to the ability of beneficial bacteria to colonize the inflamed gut. Her team is now studying the genes that have the most significant impact on colonization and determining exactly how they allow the bacteria to persist during inflammation.

"These data will be informative as we select strains and modify bacteria to be more resilient to withstand the harsh inflammatory environment [in IBD] and to genetically modify bacteria to be more resilient," said Dr. Comstock. "The future of the field is to genetically modify organisms so they can provide health-promoting metabolites and functions in patients."

The lab's second major effort this year focuses on the competition among bacterial communities in the human gut—how bacteria wage war against one another to gain territory and the defenses they can engage to protect themselves from attack.

Dr. Comstock's lab has previously demonstrated that some bacteria—Bacteroidales, in particular—make tiny, pointed, toxin-filled tubes that they deploy against other bacteria to defend their territory. These weapons, which essentially act as poison-tipped spears, are called type 6 secretion systems and while they are undoubtedly hostile, they are also tightly regulated. Researchers have demonstrated that the weapons don't fire at random—antagonistic bacteria seem to spring to action only when they perceive a threat. However, scientists have yet to understand exactly how and when bacteria push the "big red button" to deploy their weapons.

Leveraging resources at the DFI, Dr. Comstock's team is closer to understanding how this bacterial weapons system works. They have identified a small molecule that appears to be responsible for turning on the weapons system when the bacteria sense danger. The bacteria secrete the small molecule and when the molecules reach a critical density, the weapons system begins firing. The DFI metabolomics group is helping Dr. Comstock's team elucidate the molecule's structure to better understand its role as a trigger.

> **"Before, we didn't have any idea how the system was regulated, but now we have identified a chemical signal that trigger bacteria to become antagonistic and is also sensed by other bacteria to turn on their defenses to ward off attacks. I could envision using this system to turn genes on and off in the gut and to sense microbe density for therapeutic interventions."**
>
> LAURIE COMSTOCK, PHD

Dr. Comstock's lab is also studying whether these signaling systems can "crosstalk" with pathogenic bacteria, thereby inducing pathogenic bacteria to turn off the factors that allow them to cause disease.

By advancing our knowledge of the most basic mechanisms that promote health and combat disease, DFI researchers bolster the potential to create new and more effective patient therapies.

Emerging Knowledge

Over the past year, DFI researcher and assistant professor of pathology **Arjun Raman, SB'08, MD, PhD**, has sustained ambitious and impactful investigations at a variety of scales: from the microbes of the gut to the to the rules that govern all biological organization.

At the gut microbiome level, Dr. Raman has made significant progress in a study to understand the potential impact of the microbiome in reversing stress-induced pregnancy complications. When the mother is exposed to stressors such as malnourishment, the uterus and fetus are negatively impacted, creating long-term complications for the child. Dr. Raman's group is in the process of determining whether microbiome interventions can reverse these negative impacts and restore health to the uterus.

"We're very much at a stage where we can say this can work, that there is an interaction between the gut microbiome and the uterus," said Dr. Raman.

While this work received recent funding from the Gates Foundation, Dr. Raman emphasized that the resources available at the DFI, and the critical basic science it facilitates, supported his team to this point.

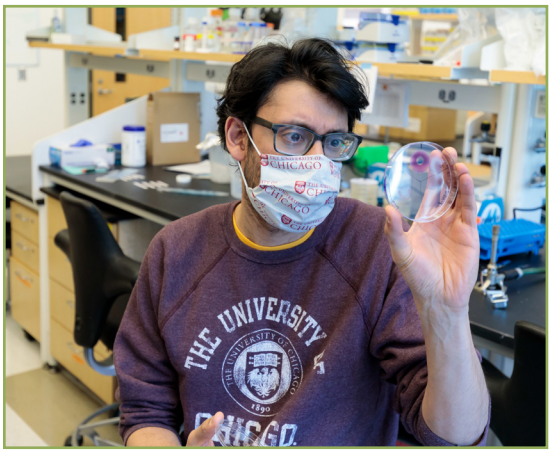
"The Duchossois investment is really what enabled us to get this data and to get this work off the ground," said Dr. Raman. "If we didn't have the DFI infrastructure, we wouldn't be able to demonstrate the connection. Especially at a time when almost no one is investing in women's health, support for fundamental research like this is of the utmost importance."

Dr. Raman also continues to pursue work that, at first blush, may not fit neatly into the category of microbiome research—but its potential impacts are far-reaching. He is working toward a generative framework for emergent systems—that is, understanding systems that cannot currently be understood by the sum of their parts.

"Unlike in an airplane, for example, there is no wiring diagram that we can write down right now that can tell us how to put amino acids together to create folded and functional proteins, or how to put genes together to create functional cells, or how to put microbes or species together to create collective ecosystems that do something like foraging or schooling or, in the case of your gut, controlling the metabolism and physiology of humans."

Dr. Raman explains that we have no insight into the constructive process of these systems—given a list of parts, we don't know how to create a functional whole, because the interactions between parts gives rise to properties that are unpredictable.

A central premise of Dr. Raman's research is that there *is* a way to infer the "instruction manual" of emergent biological systems, using a new model of statistical physics that his lab created. The model reduces the instructions down to its key components—an approach which is in direct contrast to the generative AI models widely in use today.



"Today, generative AI is created by pattern-matching. To 'learn' addition, it takes a snapshot of a third-grader's addition worksheet, for example, and stores it, so when you ask, 'What's 2+2?' it can give you the answer," explained Dr. Raman. "But if you ask it, 'What is addition?', it can't give you a clear answer. It doesn't learn the fundamental rules of the information it stores."

By contrast, Dr. Raman's model *relies* on these fundamental rules: the model learns, statistically, what the plus-sign means, rather than memorizing an entire addition table to generate the outcome of 2+2. And when the model learns the simple rules, it can make predictions for a variety of emergent systems—not only the variables in the specific "worksheets" it has been trained on.

"This framework is general, not just for microbiome design," said Dr. Raman. "It can be used for baseball statistics, predicting sales at Walmart, designing new proteins. This is a different way of doing AI, with a fraction of the data required by current generative AI frameworks."

With partnership from the Polsky Center for Entrepreneurship and Innovation, Dr. Raman has built a company around this model called Boltzmann Labs, built with scientists in mind and named for the mathematician and theoretical physicist who developed statistical mechanics, one of the pillars of modern physics.

"If you treat every problem as its own thing, in a silo, then everything becomes infinitely difficult to understand," said Dr. Raman. "But if you have a theoretical understanding of how to predict and engineer emergence—where it comes from, what it will do tomorrow, and how to mathematically describe it—then you can traverse scales and systems."

For Dr. Raman, this isn't a "pie in the sky" vision, but one that's well within reach. "I believe we will have this theory in 10-15 years. This is my big bet."

Dissemination & Commercialization

Dr. Raman's computational framework developed into a new company, **Boltzmann Labs,** with support from the Polsky Center. Ongoing collaboration with Ken Onishi, AM'17, PhD'21, the Polsky Center's manager for business development and licensing in the microbiome space, as well as Dr. Raman's friendship with Polsky Center Managing Director Samir Mayekar, have helped him get his startup off the ground and secure valuable connections early on.

"The special thing about Polsky is that they have a bird's eye view of faculty activity and can connect BSD [Biological Sciences Division] researchers to non-BSD researchers," said Dr. Raman.

This is how Dr. Raman came to be connected to Mike Franklin, PhD, Morton D. Hull Distinguished Service Professor for the Department of Computer Science and the faculty director of UChicago's Data Science Institute. Dr. Franklin—an expert in big data, databases, and the design and analysis of computing systems—is also an entrepreneur: he founded and served as chief technology officer of Truviso, a data analytics company acquired by Cisco Systems, and serves as a technical advisor to various data-driven technology companies and organizations.

"I never would have talked to Mike if Samir hadn't introduced us," said Dr. Raman. "He's now my co-mentor and we have a collaboration with [the Department of] Computer Science that has been really important for Boltzmann. Polsky helped all of this happen."

The Polsky Center recognizes the immense potential of Dr. Raman's company, especially given the wild popularity of artificial intelligence and the differentiating factors that distinguish Dr. Raman's model in the burgeoning AI market.

The first key differentiator is that Dr. Raman's model uses significantly less computing power than most models. Because it "learns" simple, fundamental rules instead of storing heaps of data from which it derives answers, his framework uses up to 75 percent less computing power than popular models. As concerns grow about AI's energy footprint—with massive data centers driving up emissions and requiring significant amounts of electricity to run and large amounts of water to cool—more energy-efficient AI architecture is ripe for development and potential investment.

The interpretability of Dr. Raman's model also distinguishes it in the market. Most AI models, like ChatGPT, are "black box models": you know the query that you put into the model and you know the answer it spits out, but you have no idea how the model arrived at its answer. The workings of most AI neural networks are a mystery. Dr. Raman's model, by contrast, is fully interpretable—it can demonstrate exactly how it arrived at a conclusion. This interpretability and transparency is especially important for the scientific research for which Dr. Raman's model was initially designed.

In the spring, the Polsky Center organized a private pitch competition in San Francisco with other universities, and Dr. Raman had the opportunity to pitch to seven venture capital companies.

"We cleaned up in terms of interest," Dr. Raman recalled. "Everyone talked to us. Everyone was interested in how we're different than OpenAI and Perplexity, and why we think we're doing this the right way. We explained how this is a brand-new, totally different way of thinking about AI."

Since then, Dr. Raman and his three team members at Boltzmann Labs have been focused on acquiring paying customers for the technology. They've produced successful results for a water engineering firm that wanted to improve the water quality in municipal lakes and rivers, and they've recently been speaking with a Major League Baseball team to optimize their player roster and a personal wellbeing company to evaluate customer profiles.

"We told these companies that the things that they're trying to optimize for are just like the gut microbiome," said Dr. Raman. "Once you have the rules in place, all the variables—from microbes to a full network—can be plugged right in. There are so many directions this technology can take."

Duchossois Family Institute Fellowship

The DFI Fellowship offers exceptional opportunities for young scientists to work at the forefront of microbiome research and train with the field's leading minds.

Sambhawa Priya, PhD

This year, the DFI fellowship continues to support **Sambhawa Priya, PhD,** in her work to integrate rich electronic health record (EHR) data with microbiome data, with the goal of uncovering insights to predict and diagnose disease.

"We don't yet know which specific microbes, microbial genes, or metabolites are associated with patient health outcomes," said Dr. Priya. "This is mainly because studies often have access to gut microbiome data without comprehensive, patient-level clinical data, or detailed clinical data without corresponding microbiome data. What's unique about the DFI is that it enables us to bring together this rich clinical and biological information to learn and discover new biomarkers for health outcomes."

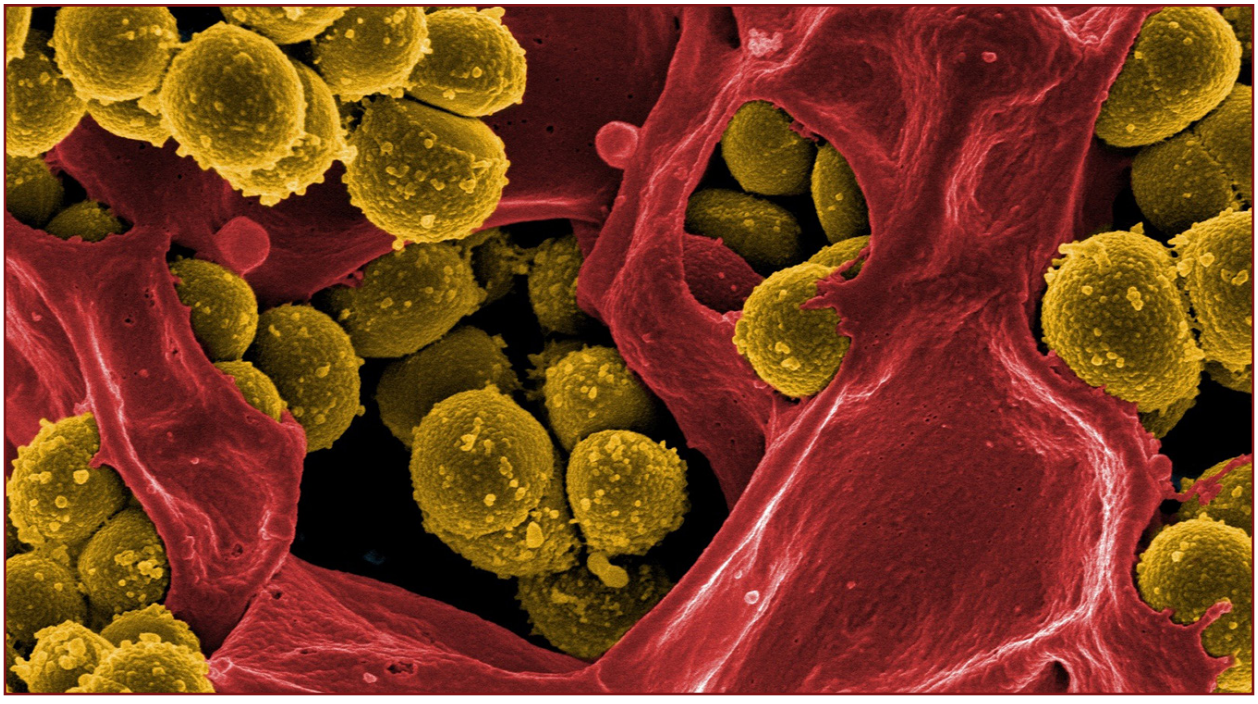
Dr. Priya has a wealth of information to work with: over 3,000 microbial samples from over 1,000 unique patients with liver disease, liver and heart transplants, and from the medical intensive care unit, as well as samples from healthy donors.

By digging into this data with machine learning, she hopes to find patterns across datasets that relate to health outcomes. One particular question she wants to investigate is what paired microbiome and clinical data can tell us about infection. For example, if we know that a patient experienced an infection after transplant in the hospital, can we go back and examine their microbiome samples collected in the days to weeks leading up to the infection to identify early biomarkers that we can use to predict and prevent infections for future patients? Building machine learning models using these datasets could also help researchers predict outcomes like mortality, hospital readmission, and other adverse events.

"There is little prior work that's integrating microbiome and electronic health record data at scale to understand what new insights this integration can unlock," said Dr. Priya. "This will be the first study of its kind."

Dr. Priya's work as a DFI Fellow directly supported two major grant submissions to the National Institutes of Health this year, and she hopes that her data integration efforts will lay the groundwork to create "digital twins" for patients, especially those that are critically ill. A digital twin—a virtual model of a patient's health, informed by their clinical and biological data—would help clinicians predict how a patient will respond to healthcare interventions, anticipate and prevent adverse events, and deliver precision medicine based on an individual's specific needs.

> **"This fellowship gives me unprecedented access to rich datasets and allows me to work at the cutting edge. I'm really deeply appreciative of the support."**
>
> SAMBHAWA PRIYA, PHD



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