# EXPONENTIAL IMPACT

ANNUAL REPORT 2017

HSCI | HARVARD STEM CELL INSTITUTE

1000 scientists. One goal. Discovering cures.

# Contents

# Message from the directors

SCIENTIFIC AND MEDICAL BREAKTHROUGHS do not follow straight lines or predictable paths. Rather, they emerge from exciting collisions of collaboration and insight from researchers, clinicians, and entrepreneurs across disciplines and expertise.

That insight has been the foundation of the Harvard Stem Cell Institute (HSCI) for over 13 years. We were inspired to create a truly unique and powerful innovative engine to empower more than 1,000 researchers, clinical specialists, bioengineers, and other experts affiliated with Harvard University and its world-class hospitals, as well as with the biotechnology companies in Boston and Cambridge, to change the future of medicine together.

As a result, today HSCI has an exponential impact on regenerative medicine. In the following pages, we share how our scientists are discovering transformative treatments and bringing them to the clinic, developing new research approaches to advance scientific discovery across disease areas, and training the next generation of pioneers in the field.

Highlights from 2017 include:

- Through the **Boston Autologous Islet Replacement Therapy program**, we have made exciting advances in the past year to develop a treatment for diabetes. Since Doug Melton's initial innovation of converting patient stem cells into insulin-producing pancreatic beta cells, we have been collaborating with area hospitals to further develop the technology. In the last quarter of 2017, Semma Therapeutics—our partner in the biotechnology industry—raised $114 million in their series B round of funding.

- As early pioneers of *in vitro* cell models, HSCI researchers have brought that work to the next level in the past year with advances in **three-dimensional organoids**. These are human cell cultures that model the complexity of tissues and organs. We have developed multiple types—brain, lung, kidney, and intestine, among others—in order to investigate basic science questions as well as develop new treatments at a level of detail and fidelity previously unattainable.

- We are proud to train the **next generation of scientists**, on whom so much depends. In the summer of 2017, we welcomed the latest cohort of undergraduate students to participate in the HSCI Internship Program. Students from around the world came to work on research projects in HSCI laboratories and develop connections that will have a lasting impact as they continue their scientific careers.

And we are just getting started. Your support enabled many remarkable developments in 2017 that keep us on the trajectory of exponential impact. Stem cell science has changed the way we understand ourselves and disease, and we hope you will join HSCI as we continue to find ways to harness the power of stem cells in transforming patients' lives.

With thanks,

Doug Melton, PhD, *Founding Co-Director*

David Scadden, MD, *Founding Co-Director*

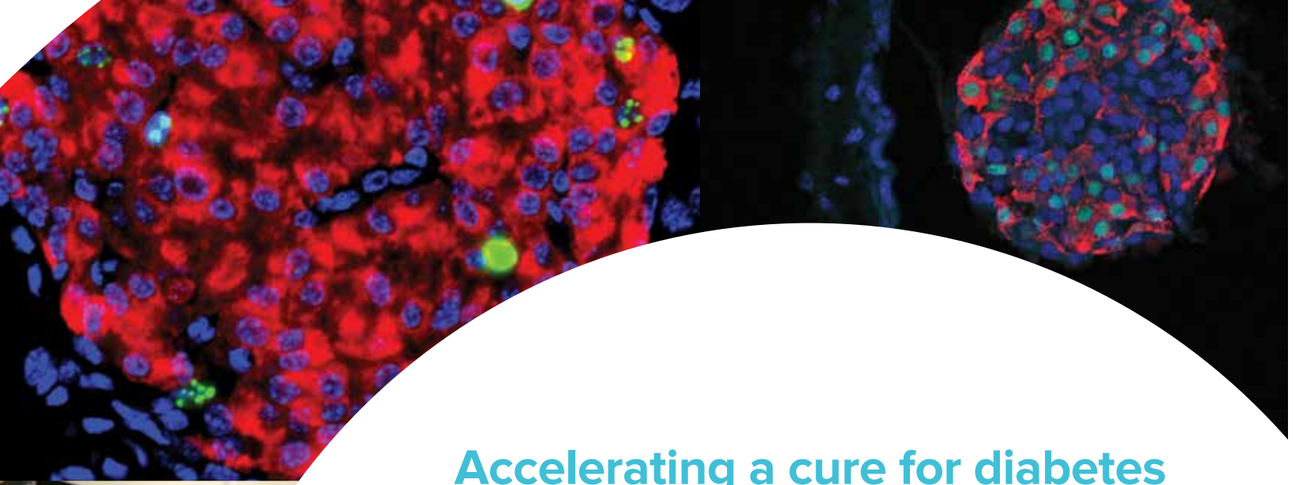
Brock Reeve, MPhil, MBA, *Executive Director*

# The Harvard Stem Cell Institute engine

AT THE HARVARD STEM CELL INSTITUTE (HSCI), collaboration continually lights the spark of discovery, fueling our quest for meaningful advances in science and medicine.

At the core of our work is HSCI's innovation engine—fueled by a network of academic laboratories, hospitals, and members of the biotechnology industry across domains and disciplines. Connected across the HSCI community, everyone works together to harness stem cell science to transform human health.

Powered by this engine, HSCI has an exponential impact that exceeds the sum of its parts, enabling progress in regenerative medicine that would have been unimaginable a decade ago.



# Accelerating a cure for diabetes

## FROM LABORATORY TO CLINIC

MANAGING A CHRONIC DISEASE LIKE DIABETES can be exhausting. Patients with diabetes must alter their diet and exercise regularly; prick their fingers multiple times a day to test their blood sugar level; and, when that level is high, inject themselves with insulin. Without this constant management, diabetes can lead to serious or even fatal medical complications.

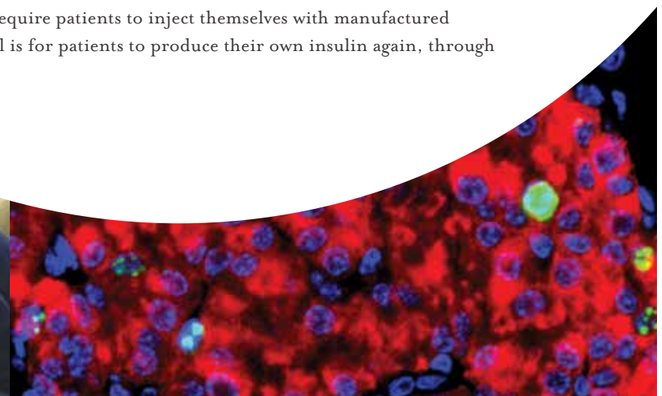
At the Harvard Stem Cell Institute (HSCI), Doug Melton, PhD is changing this paradigm. He is developing a stem cell-based treatment that could allow patients with diabetes to go about their lives as if they did not have the disease—as if they were, effectively, cured.

Melton announced in 2014 that his laboratory was able to produce fully functional human beta cells, the cells in the pancreas that produce insulin, by directing the development of embryonic stem cells. Since that milestone, Melton has leveraged HSCI's network of hospital and industry collaborators to accelerate the transfer of this technology from the laboratory to the clinic.

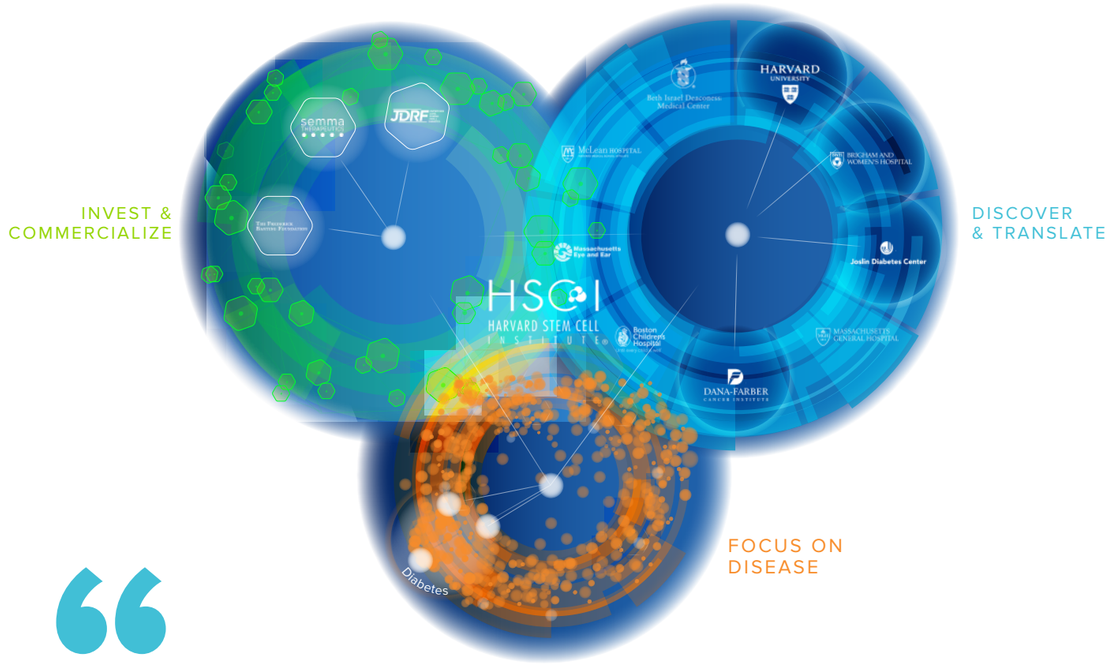
### BETA CELL TRANSPLANTS

In healthy individuals, beta cells respond to rising blood sugar levels by releasing a precise amount of insulin, which triggers body cells to take up sugars from the bloodstream to use for energy. In patients with type 1 diabetes, an autoimmune response destroys beta cells before they can produce insulin. In patients with type 2 diabetes, beta cells do not produce enough insulin. Furthermore, their bodies may not respond properly to insulin.

Current treatments require patients to inject themselves with manufactured insulin—Melton's goal is for patients to produce their own insulin again, through a beta cell transplant.








> Our goal is to change the course of diabetes."
>
> — DOUG MELTON, PHD

It took Melton's team more than a decade to understand how the body makes pancreatic beta cells. They researched hundreds of signals, molecules, and environmental conditions to determine the combination that would cause a stem cell to become a pancreatic precursor cell, then a pancreatic cell, and finally a beta cell.

One challenge the group overcame was to make cells that both looked like beta cells and worked like them, increasing the amount of insulin released in response to rising blood sugar. Melton's beta cells were the first laboratory-created pancreatic cells to be fully functional when transplanted into animal models. "Making the cells functional was the key advance," Melton says.

### MOBILIZING THE HSCI NETWORK

Reaching out to collaborators who were already connected through the HSCI network, Melton has rapidly mobilized clinical and industry resources as part of the Boston Autologous Islet Replacement Therapy (BAIRT) program.

In 2017, the BAIRT program made substantial progress toward securing approval from the Food and Drug Administration for a clinical trial that tests a new approach: giving patients a supply of their own insulin-producing beta cells.

With their clinical expertise in diabetes and transplants, BAIRT collaborators at Brigham and Women's Hospital and Joslin Diabetes Center are working directly with patients. For this initial trial, they are working with patients who develop diabetes following surgical removal of the pancreas.

Starting with patient blood samples, the research team will first derive induced pluripotent stem cells, and then use them to generate hundreds of millions of beta cells. HSCI researchers will contribute their knowledge of stem cell biology and derivation techniques. The cells will be produced at the Dana-Farber Cancer Institute's clinical-grade cell manufacturing facility.

The research team is currently investigating the best site in the body to transplant the beta cells, and how to adapt this therapeutic approach for patients with type 1 or type 2 diabetes.

Semma Therapeutics, a biotechnology company co-founded by Melton in 2015, is also a collaborator in the BAIRT program. Semma is bringing together industry experts to drive preclinical and regulatory strategies for this emerging treatment. In 2017, the company announced that it had raised $114 million in a series B round of funding.

### MOVING FORWARD TOGETHER

Because HSCI collaborators span the university, hospital, and biotechnology industry settings, the BAIRT program has been able to assemble the necessary resources quickly to advance this therapeutic approach.

"Our goal is to change the course of diabetes," Melton says. "It takes a whole community to do this, and I'm excited to see everyone come together to push forward."

# Modeling human organs

## DISCOVERIES DRIVEN BY ORGANOIDS

WHAT WILL BE THE BIGGEST MEDICAL BREAKTHROUGH 10 years from now? How about in 20 years, or 50?

There could be any number of answers to these questions, and although we cannot predict exactly what will happen, we can be certain of this: the breakthroughs of the future depend on laying the right scientific groundwork today.

Researchers at the Harvard Stem Cell Institute (HSCI) are doing just that by pioneering better ways to study human health and disease. Nowhere is this more apparent than in our work with organoids: small, three-dimensional tissue cultures that model the complexity of organs.

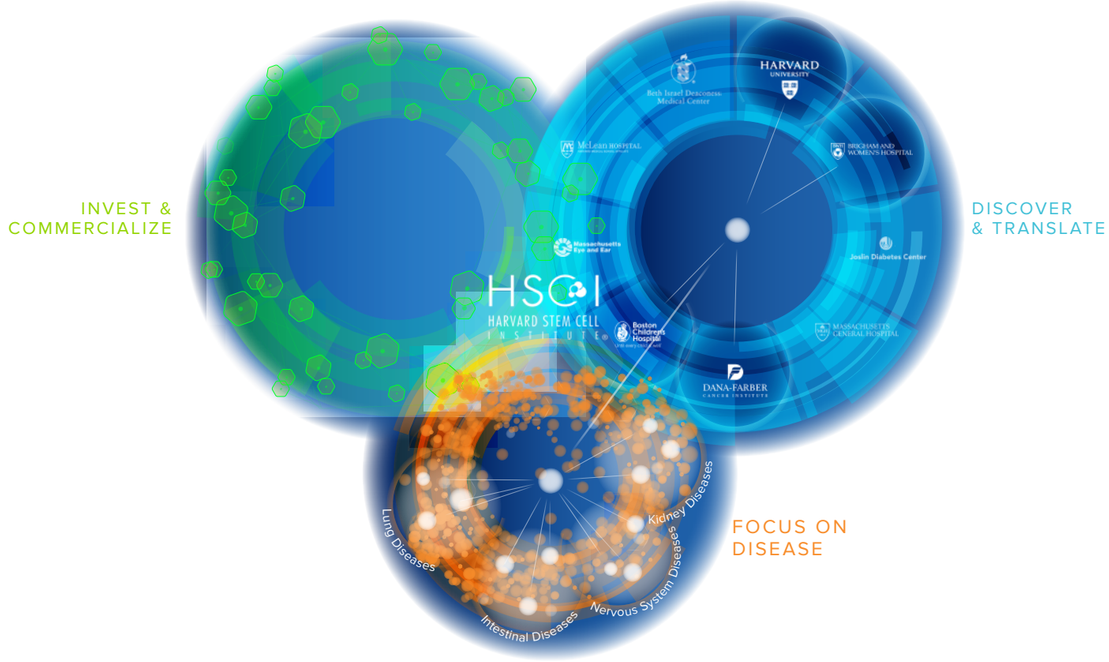
HSCI researchers have determined the precise growth conditions in the laboratory that coax stem cells to self-organize, forming structures that resemble miniature organs composed of different cell types. Organoids can range in size, from less than the width of a hair up to five millimeters across.

> "The primary goal right now is to use the organoids as disease models, but along the way I predict we are going to learn a lot about how the brain is formed."
>
> — PAOLA ARLOTTA, PHD

There are potentially as many types of organoids as there are different tissues and organs in the body. HSCI researchers have been able to produce organoids that resemble the brain, kidney, lung, and intestine, and many more are on the way.

This approach of modeling organs is giving scientists an improved understanding how organs form and grow, setting the stage for new insights on human development and disease. In 2017, HSCI scientists pushed organoid research forward in many areas, perhaps most notably in nervous system and and lung diseases.






### NERVOUS SYSTEM DISEASES

Most of what we know about embryonic brain development has been learned by making observations in mice and other animal models, then extrapolating them to human biology. Now, brain organoids grown from human cells are opening a window to understanding some of the most elusive aspects of human development and disease.

Brain organoids are a particularly powerful model for studying complex, intrinsically human characteristics or diseases. "Some of the most prominent neuropsychiatric or neurodevelopmental diseases of our time, such as schizophrenia or autism spectrum disorder, are uniquely human diseases," says Paola Arlotta, PhD.

Arlotta's laboratory has developed methods to grow brain organoids for long periods of time. That way, the cultures can achieve a greater complexity and maturity than what was possible before. These organoids contain thousands of cells and multiple types of brain cells that interact with each other in sophisticated ways, making them good models for studying how diseases affect communication among brain cells.

Brain organoids are also enabling insights into how the brain is formed during early embryonic development, a subject that has been studied for more than a century yet still puzzles scientists today. "The primary goal right now is to use the organoids as disease models, but along the way I predict we are going to learn a lot about how the brain is formed," Arlotta says.

### LUNG DISEASES

Stem cells hold great promise as therapeutic tools due to their unlimited capacity to divide and regenerate tissue, but some diseases might be caused by anomalies in stem cells themselves.

"For a long time, it's been thought that lung diseases like emphysema could be caused by stem cell defects, but it has not been possible to test this idea," says Carla Kim, PhD. "Now, we can create organoids from patient cells and conduct experiments to find out which specific cell types cause lung disease. If we are able to understand what goes wrong at the stem cell level, there could be a whole new cell type that could be targeted for therapeutic intervention."

Kim and her group were the first researchers to grow lung organoids that model two distinct parts of the lung: the airways and the alveolar sacs where blood undergoes gas exchange. They developed a special culture setup that puts cells in contact with both air and liquid, mimicking the lung environment in humans.

In addition to studying the causes of disease, organoids can also be used more directly to identify and test new drugs. For example, in cystic fibrosis, ciliated cells that normally remove mucus from the lung do not function properly.

"We are able to make organoids with ciliated cells derived from patient stem cells, and then test for drugs that might make the ciliated cells work better," Kim says. "This is a very exciting time for studying the lung."

# Training the next generation

## FUTURE PIONEERS OF STEM CELL SCIENCE

AS COLLEGE STUDENTS LEARN ABOUT cutting-edge biology topics in their courses, they often look beyond the classroom to find ways to explore actively and contribute to the field. However, opportunities to participate in laboratory research may be limited at small liberal arts colleges or even in large international universities.

Every summer since 2005, the Harvard Stem Cell Institute (HSCI) has welcomed undergraduate students from around the globe to conduct research in the world-class stem cell science laboratories of Cambridge and Boston.

HSCI inspires students to pursue careers in stem cell science by training them in the technical skills they will need and connecting them with a diverse network of scientists.

### HANDS-ON LEARNING, MENTORSHIP, AND COMMUNICATION

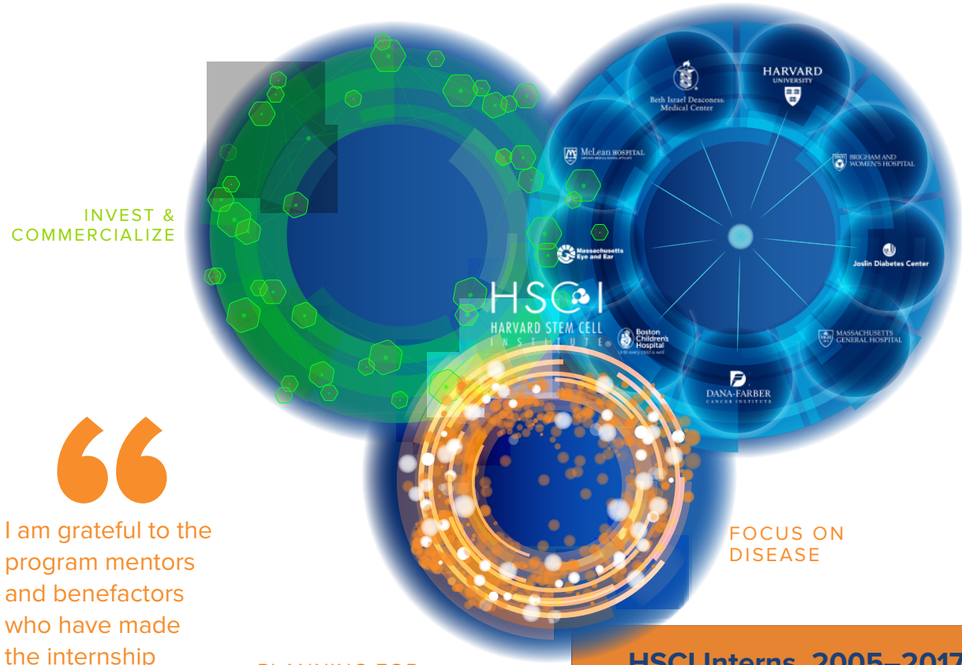
During the ten-week internship, students take on laboratory research projects under the mentorship of HSCI faculty members. Additionally, students complete a course on the principles of stem cell biology, attend research seminars that highlight the breadth of HSCI research topics, and participate in a professional development session to learn about scientific career options.

The internship culminates in a symposium where students share their project findings with the research community, developing the communication skills that are key to scientific collaboration. Many students go on to publish their results in scientific journals, further broadening the impact of their work.










> "I am grateful to the program mentors and benefactors who have made the internship program possible and sparked my career as a stem cell biologist."
>
> — ARUN SHARMA, PHD

### PLANNING FOR COLLABORATION

HSCI's internship program plants the seeds for future collaborations. Because interns come from diverse academic and cultural backgrounds around the world, each of them contributes a unique perspective that benefits both the program and the broader HSCI community. Students build relationships with HSCI researchers—and, more importantly, with each other—enriching and growing our network of future scientific leaders.

### LASTING IMPACT

The internship program has a lasting impact on alumni as they continue their careers. "It is thanks to my wonderful HSCI experience that I decided to pursue a PhD in Stem Cell Biology and Regenerative Medicine at Stanford University," says Arun Sharma, PhD. As an undergraduate student from Duke University, Sharma completed his 2011 internship in the Beth Israel Deaconess laboratory of Anthony Rosenzweig, MD.

Sharma is currently a postdoctoral fellow in the Harvard Medical School laboratory of Christine Seidman, MD, an HSCI Affiliate Faculty member. He studies heart muscle cells that are derived from human stem cells—the same research area of focus for his original HSCI internship project.

"I am grateful to the program mentors and benefactors who have made the internship program possible and sparked my career as a stem cell biologist."

## HSCI Interns, 2005–2017

**490**
TOTAL INTERNS

**33**
INTERNATIONAL COLLEGES AND UNIVERSITIES REPRESENTED

**20**
COUNTRIES REPRESENTED

**111**
U.S. COLLEGES AND UNIVERSITIES REPRESENTED

**76%**
ALUMNI HAVE PURSUED ADVANCED DEGREES*

**90%**
ALUMNI REPORTED CONTINUED INTEREST IN STEM CELL RESEARCH*

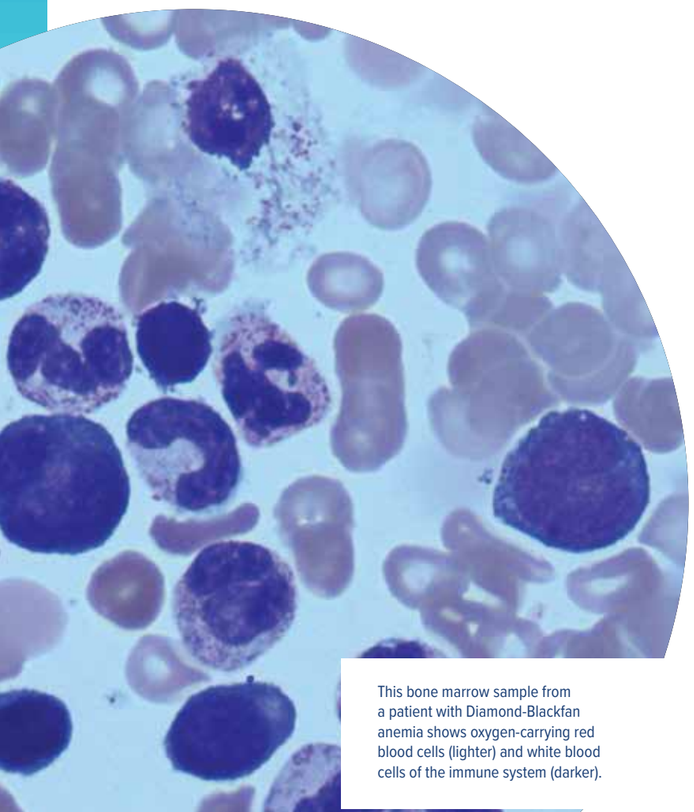
**27%**
ALUMNI HAVE BEEN AN AUTHOR ON A PUBLISHED PAPER FROM THEIR INTERNSHIP*

*Data collected in 2016*

# Research highlights from 2017

THE HARVARD STEM CELL INSTITUTE (HSCI) encompasses a diverse range of research, from investigating the basic principles of human biology to developing new therapies for patients. HSCI researchers focus both on specific disease areas—including cardiovascular diseases, kidney diseases, skin diseases, and cancer—and on processes that affect multiple disease areas, such as aging and fibrosis.

Here we highlight a few of the many exciting research advances made by HSCI scientists in 2017.



This bone marrow sample from a patient with Diamond-Blackfan anemia shows oxygen-carrying red blood cells (lighter) and white blood cells of the immune system (darker).

## USING PATIENT STEM CELLS TO FIND BLOOD DISORDER DRUGS

A collaboration between **George Daley, MD, PhD** and **Leonard Zon, MD** led to the identification of a potential drug to treat Diamond-Blackfan anemia: a rare, severe blood disorder where the bone marrow does not make enough red blood cells to carry oxygen around the body.

Daley and Zon collected patient skin cells and converted them into stem cells. Then, they transformed the stem cells into a type of cell that would normally produce red blood cells. Using these cells as a model for Diamond-Blackfan anemia, they tested over a thousand chemical compounds to see if any would rescue the cells' ability to produce red blood cells.

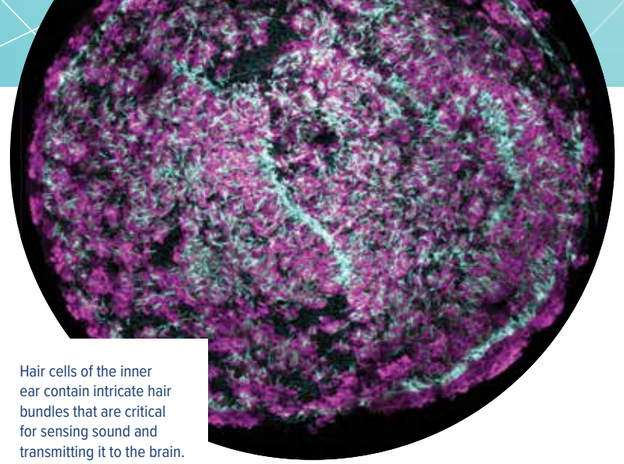
One compound they tested had a particularly strong effect, and successfully reversed anemia in mice.

## BONE MARROW TRANSPLANTS: IMPROVING THE STEM CELL DONATION PROCESS

Because human bone marrow contains blood system stem cells, doctors use transplants of healthy bone marrow to treat patients with blood cancers or disorders. Alternatively, donors undergo drug injections over many days in order to mobilize stem cells from the bone marrow to the peripheral blood for collection.

To improve the donation process, **Jonathan Hoggatt, PhD** and **David Scadden, MD** searched for a novel drug combination that would mobilize stem cells more quickly. The combination they identified and tested in mice mobilized stem cells within 15 minutes in a single injection.

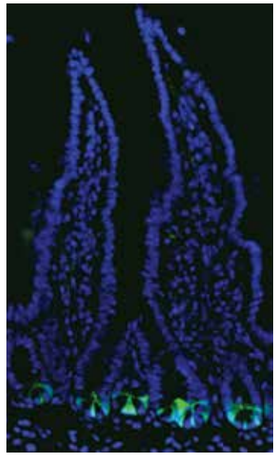
**Magenta Therapeutics**, a biotechnology company co-founded by Scadden, is continuing the clinical development of this new therapeutic strategy.



Hair cells of the inner ear contain intricate hair bundles that are critical for sensing sound and transmitting it to the brain.

## UNDERSTANDING HOW THE INTESTINE REGENERATES

The intestine is highly regenerative by nature, as it has to withstand constant wear and tear from breaking down food, absorbing nutrients, and eliminating waste. As part of his fundamental research on the digestive tract, **Ramesh Shivdasani, MD, PhD** identified a previously unknown mechanism by which stem cells regenerate the inner intestinal lining.



The inner lining of the intestine forms millions of finger-like projections. Stem cells—shown here in green—reside at the bottom and replicate daily, generating new cells to maintain the tissue.

Until now, scientists thought that when the population of stem cells in the intestinal lining is depleted, a second population of dormant stem cells becomes active.

Instead, Shivdasani showed that when stem cells were damaged in the mouse intestinal lining, a type of mature intestinal cell reverted back to a stem cell state.

## GROWING SMALL INTESTINE GRAFTS FROM STEM CELLS

Severe gastrointestinal diseases can require the removal of the small intestine, which in turn leads to complications because nutrients are not absorbed into the blood. Transplants can help restore small intestine function but are currently limited by a shortage of donor organs.

To solve the problem, **Harald Ott, MD** took a bioengineering approach to create small intestine grafts. First, he removed the original cells from small segments of rat intestine tissue. Next, he repopulated the resulting structural scaffolds with two types of human cells: intestinal cells made from stem cells, and cells that line blood vessels.

When implanted in rats, the grafts were able to circulate blood and absorb nutrients.

## REPLACING HAIR CELLS IN THE EAR TO TREAT HEARING LOSS

Sounds are picked up by hair cells in the inner ear, which translate them into signals for the brain to interpret. Because these hair cells do not regenerate, any damage to them results in hearing loss.

To tackle this problem, **Jeffrey Karp, PhD** and **Albert Edge, PhD** collaborated on a method to replace hair cells in both mouse and human ear tissue. First, they identified a drug combination that increased a certain population of stem cells in the ear. Then, they converted the stem cells into hair cells.

This therapeutic approach is under further development by **Frequency Therapeutics**, a biotechnology company co-founded by Karp.

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# Donor stories

DONORS WHO SUPPORT the Harvard Stem Cell Institute do so for a multitude of reasons. Honoring loved ones who are affected by disease and making a meaningful impact on society by advancing human health are just two examples.

We extend our thanks to all our donors for making our work possible—and to these donors for sharing their stories about why they support stem cell research at Harvard.

**"I support the Harvard Stem Cell Institute, and in particular, its muscular disease research. I want to see children and young adults who are afflicted with any one of the many forms of muscular dystrophy enjoy the same freedoms and pleasures of mobility that so many of us so easily take for granted."**

— NEIL BREWER, EDUCATOR AT INDIANA UNIVERSITY SOUTHEAST

The collaborative mindset of scientists at the Harvard Stem Cell Institute produces groundbreaking results. Research into Barth syndrome—a rare, often fatal, disorder that severely weakens the heart and immune system—was launched into the realm of clinical trials in part due to work by HSCI's Dr. Bill Pu. He created the first heart disease-on-a-chip, in collaboration with Harvard University's excellent hospital system and groups like the Wyss Institute.

HSCI researchers are making extraordinary advances in practical, clinically oriented medical solutions for some of the world's most challenging disorders, extending both the length and quality of life for people affected by disorders such as Barth syndrome. There is simply no other place like it in the world."

— STEPHEN B. MCCURDY, FOUNDING CHAIRMAN OF THE BARTH SYNDROME FOUNDATION

**"Back in 2005, my husband John and I read about Doug Melton and the Harvard Stem Cell Institute in *The Boston Globe*. Our son's wife had diabetes and the idea of donating directly to promising research made sense. We began donating what we could each month. We never stopped. Last year John passed away. I honor John as he wished by supporting HSCI in furthering knowledge and health, our best hope for understanding and overcoming so many diseases."**

— SUSAN E. TAVELA

"The Harvard Stem Cell Institute is at a point of what I call 'increasing returns to scale.' Because of the accumulated knowledge, because of the human capital that's involved, because of the discoveries and the development of tools that can be used to cross different disease categories, the potential return on investment has never been higher. My personal commitment is to make sure that these scientists and these teams have the capital that they need to run experiments that will ultimately transform human health."

— WILLIAM SAHLMAN, BAKER FOUNDATION PROFESSOR OF BUSINESS ADMINISTRATION AT HARVARD BUSINESS SCHOOL

# 2017 Donors

**We gratefully acknowledge all the donors who have supported the Harvard Stem Cell Institute, including those listed below who made gifts during the 2017 calendar year. Each of these individuals and organizations have provided crucial support to stem cell science at Harvard University. Their contributions have made a real, lasting impact on biomedical research.**

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Beryl and Harold Wells
Gregory E. Wilde
William K. Bowes, Jr. Foundation
Tawanwong Woraharn
Marilyn and Stuart Zerner

†Deceased.

## MEMORIAL GIFTS

**We extend our thanks to those supporters who chose to remember a loved one through a memorial gift. Those who were memorialized with gifts to the Harvard Stem Cell Institute during the 2017 calendar year are listed below.**

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Julian I. Edison
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Alison M. Urzan

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**We thank those supporters who chose to recognize a loved one through a gift. Those who had a gift made in their honor to the Harvard Stem Cell Institute during the 2017 calendar year are listed below.**

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