



DRI's POSEIDON Trial Aims to Stop Diabetes Progression in Children and Adults

“My impetus for starting this study is to determine if modulating inflammation and immunity could halt, or at least delay, the progression of type 1 diabetes.”

David Baidal, M.D., Rodolfo Alejandro, M.D., Janine Sanchez, M.D., Ana M. Alvarez Gil, A.R.N.P., Camillo Ricordi, M.D., and Khemraj Hirani, Ph.D., discuss the POSEIDON Study at a recent planning session.

There is a great need to identify safe and effective therapies that can impact the progression of autoimmune disorders, like type 1 diabetes (T1D), especially in children. Several scientific reports have suggested that the use of high-dose omega-3 fatty acids and vitamin D, both of which have known anti-inflammatory properties, may be beneficial. Encouragingly, data from recent case studies and emerging research publications have shown that this may be possible.

The Diabetes Research Institute (DRI) will formally test this approach in the newly launched POSEIDON clinical trial (Pilot Study of Omega-3 and Vitamin D High Doses in T1D). According to DRI Director Dr. **Camillo Ricordi**, inflammation may be one of the triggers for autoimmunity and may lead to disease onset, among other effects.

“My impetus for starting this study is to determine if modulating inflammation and immunity could halt, or at least delay, the progression of type 1 diabetes. Inflammation may be one of the triggers for autoimmunity that leads to the onset of the disease, but also affects insulin resistance and, therefore, islet dysfunction,” said Dr. Ricordi. “Results from our recent case studies examining the

role of omega-3/vitamin D in preserving beta cell function in three pediatric subjects with type 1 diabetes warrant further investigation of this potential therapeutic strategy.”

The DRI plans to enroll 56 children and adults, ages 6 – 65, who are newly diagnosed and who have had diabetes for up to 10 years.

“If combination omega-3 and vitamin D therapy is able to delay progression or halt autoimmunity in type 1 diabetes, this is expected to result in retention of insulin secretion, minimal use of exogenous insulin, and improved metabolic control thus minimizing the risks associated with unstable blood glucose levels,” Dr. Ricordi continued.

“Reversing autoimmunity could be beneficial well beyond subjects with type 1 diabetes. In fact, similar strategies should be tested in other autoimmune diseases like Crohn’s, rheumatoid arthritis and lupus erythematosus,” said Dr. Ricordi.

For more information on this patient study or to download an application form, visit www.DiabetesResearch.org/POSEIDON

IT'S A GREAT TIME TO CONSIDER A CHARITABLE GIFT ANNUITY!

Through a charitable gift annuity, you can make a meaningful gift to the Diabetes Research Institute Foundation and receive a fixed annual income for life. **As of July 1, 2018, charitable gift annuity rates increased, which means the annual payment to you will be higher.** There has not been a rate increase since 2012.

AGE	RATE OF RETURN SINGLE LIFE ANNUITY*
65	5.1
70	5.6
75	6.2
80	7.3
85	8.3
90+	9.5

Some benefits of a charitable gift annuity include:

- Fixed income stream for the remainder of your life, a portion of which will be tax-free
- A partial tax deduction
- Ability to donate different assets including cash or securities
- Reduction or elimination of capital gains tax liability
- Support for your favorite organization, such as the Diabetes Research Institute Foundation, beyond your lifetime

If you are interested in exploring the possibility of a charitable gift annuity, please contact **Jill Shapiro Miller** at (954) 964-4040.

**A charitable gift annuity can benefit up to two people. Rates are based upon the age of the income recipient(s) when the gift is made.*



IRA Rollover

If you're planning to make a withdrawal from your IRA, please consider making a gift to the Diabetes Research Institute Foundation! In addition to making an impact in the search for a cure for diabetes, benefits include:

- It's an easy and convenient way to make a gift from one of your major assets.
- It's counted toward your required minimum distribution.
- The withdrawal will not be counted as taxable income.

For your gift to qualify:

- You must be over 70 1/2 years of age.
- The transfer must go directly from your IRA to the DRI Foundation.
- Your total gift cannot exceed \$100,000.
- Your gift must be outright.

For more information or to learn additional planning pointers, contact Jill Shapiro Miller at 800-321-3437.



First a Cure Shirts

Some folks like their coffee first, but at the DRI, finding a cure is at the top of our list. Do you feel the same way? Show your support by wearing this eye-catching statement shirt! Featuring the words "Ok, But First a Cure" on the front, the black and white shirts come in unisex baseball tees and ladies' drapey-fit crop tops. Adult and child sizes are available while supplies last. Order online: DiabetesResearch.org/ok



Donate Your Car

Getting a new car for the holidays? Think about donating the old one to the Diabetes Research Institute Foundation via Vehicles for Charity. Regardless of condition, automobiles, trucks, vans, recreational vehicles, motorcycles, dirt bikes, tractors, boats and trailers will be accepted and towed free of charge within two to four days of the request. Vehicles will be sold at auction or to a salvage company with 100 percent of the net proceeds donated to the DRIF, and it's tax deductible. Call 1.833.430.DRIF or visit: VehiclesforCharity.org/Donate/DRIF.html

THE SIMKINS FAMILY: Committed to a Cure

With deep South Florida roots that span decades, the Simkins family is well known in the community for their philanthropic endeavors and more. Without doubt, their name is synonymous with Love and Hope and the Diabetes Research Institute.

Over the course of 40 years, Kathy Simkins and the late Leon J. Simkins were extremely instrumental in ensuring the forward momentum of the DRI's cure-focused work. Leon made a series of transformative donations in the millions of dollars, and to honor his extraordinary generosity, the Institute's research tower bears his name. Kathy, who lost her brother at an early age to diabetes complications, is National Chairman of Love and Hope and also served on the DRI Foundation's National Board of Directors.

In the earliest days, they graciously hosted the annual Love and Hope Underwriting Party (later called the Preview Party) in their gorgeous Miami Beach home. And the intimate affairs are still remembered fondly today.

"It was such a special evening, but it wasn't just one night. The ladies of the Love and Hope Committee would come to our house for a week before the event to wrap napkins and chairs with beautiful decorations," recalled Michelle Rubell, the daughter of Kathy and Leon. "My mom would cook for the group, and it was all very personal. Experiencing that as a child was so valuable to me and to all of us."

"Finding a cure for diabetes always was and continues to be very important to me," Kathy explained. "We've been working at this for so many years, and I am so proud that my family is continuing the legacy that we started."

The children literally grew up with Love and Hope, and as they got older, they joined Kathy, Leon, and his wife, Serena, by getting actively involved in the mission to cure diabetes. Michelle is on the Love and Hope Executive Committee, as well as the Young Society of

TEAM DRI

On September 23, organizers **Keith Adwar** and **David Newman** (pictured center), along with two dozen cyclists, participated as Team DRI at the Massapequa Park Bicycle Club Tour of the Hamptons. The duo has been raising money and awareness for the Diabetes Research Institute in multiple ways for several years. David was a cyclist who encouraged Keith to take up riding after he was diagnosed with type 2



diabetes. Later, David's son was diagnosed with type 1 diabetes, and they knew they wanted to support diabetes research. This year's Ride for the DRI event helped raise \$40,000.

"Thinking about the years of their lives that they dedicated to this and the substantial amount of money they raised for the DRI—it was an incredible thing for us to witness. We all wanted to emulate that."



Serena Simkins, Michelle and Jason Rubell, Michael and Nikki Simkins, Ron and Amira Simkins, Kathy Simkins and Stephen Alger

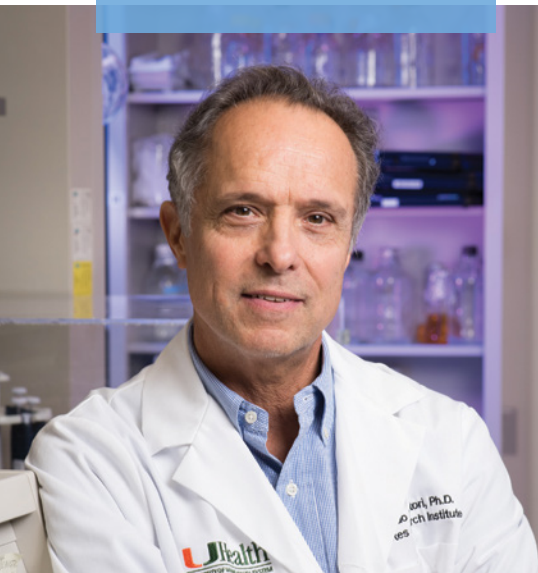
Love and Hope Committee, along with her husband, Jason Rubell, Nikki and Michael, David, Ron and Amira, and Albert Simkins.

"We were inspired by the example they set," Michelle continued. "Thinking about the years of their lives that they dedicated to this and the substantial amount of money they raised for the DRI—it was an incredible thing for us to witness. We all wanted to emulate that."

Today, Michelle and Jason are doing just that. Earlier this year, they hosted a beautiful dinner for the Love and Hope sponsors in their home, and they plan to do much more moving ahead. "We are extremely committed to helping the DRI find a cure for diabetes."

According to Kathy, "We look forward to the day when we can all celebrate the cure!"

The Diabetes Research Institute and Foundation wish to thank the entire Simkins family for their ongoing and tireless commitment.



UNDER THE MICROSCOPE

WITH RICARDO PASTORI, PH.D.

One of the key challenges to developing a biological cure is to identify an unlimited source of insulin-producing cells, which are destroyed by the immune system in those with type 1 diabetes (T1D). Replacing these cells in patients through islet transplantation requires a steady supply that falls far short of the potential need due to the scarcity of donor pancreases from which these cells come.

Dr. **Ricardo Pastori**, director of molecular biology and research professor of medicine, immunology, and microbiology, is focused on finding alternative sources of islets to address this shortage. One potential cell source is human pluripotent stem cells (hPSc), as they are capable of becoming any type of cell in the body. However, the use of hPSc cells poses some safety risks for patients, such as the formation of tumors. Working together, Dr. Pastori and Dr. **Juan Dominguez-Bendala**, director of stem cell development for translational research, are at the forefront of engineering innovative “safeguard” approaches to eliminate these risks.

The researchers are also looking beyond transplantation to regenerating a patient’s own insulin-producing cells. They previously reported first-ever results using a single molecule that is already approved by the Food and Drug Administration for use in patients. Dr. Pastori tells us more about these groundbreaking initiatives underway.

Q. What is your area of research at the DRI?

A. My research focuses on the development of molecular strategies to advance treatments, and ultimately a cure, for type 1 diabetes. Currently, Dr. Dominguez-Bendala and I have joined efforts to develop regenerative approaches for pancreatic islets and beta cells, among other projects.

Q. How did the collaboration between the two of you come about?

A. My main background is in molecular biology, which is the study of the composition, structure and interactions of molecules that make up the body’s cells and carry out their functions. I also interface with DRI colleagues from other disciplines, which is critical for our mission to discover a cure. The pancreatic progenitor cell/islet regeneration project is the result of having explored these disciplines. Many aspects of this project are of molecular biology in nature. That has led to Dr. Dominguez-Bendala and I working together in a holistic way and bringing our respective expertise to these projects.

Q. The team recently published some exciting findings. Can you explain more about this research and next steps?

A. We first reported that a natural protein called bone morphogenetic protein 7 (BMP-7) was able to convert the exocrine cells of the human pancreas (the cells in charge of secreting digestive juices) into functional endocrine cells when cultured in the lab. We later found that this process actually activates progenitor cells (stem cells) in the pancreas, which we confirmed by conducting a series of tests. This discovery opens the door to the possibility of reawakening these cells in patients, sidestepping the need for transplantation. We will soon be reporting more exciting findings related to this project.

Additionally, Dr. Dominguez-Bendala and I are Principal Investigators on a grant that was awarded by the National Institutes of Health’s (NIH) Human Islet Research Network (HIRN). The grant support will allow us to further investigate these progenitor cells to better understand how they regenerate. We will use an array of state-of-the-art technologies, including a method to examine human pancreas sections in a special dish invented at the DRI that offers us a unique window through which to monitor live beta cell regeneration in real time.

Q. We’ve been reading a lot in the news about a new technology called CRISPR, which you are also using in your research. Can you explain more about this project?

A. CRISPR is a powerful gene editing tool that can be used to investigate and treat human diseases. Dr. Dominguez-Bendala and I are collaborating on a project to improve the safety of stem cells for the treatment of diabetes. The approach will overcome the relatively high incidence of tumors (teratomas) and enrich the numbers of insulin-producing cells we can “grow,” which are hurdles that stand in the way of the routine transplantation of these cells. In order to address these problems, we set out to engineer stem cells with “suicide genes” that will be activated in (a) any cell that is not a beta cell; and/or (b) any cell that may form a tumor. Our research team has just wrapped up the first phase of this project and a comprehensive report of these findings was recently submitted for publication. A second phase of this research will take steps to further improve the safety of generating human stem cell lines using CRISPR gene editing techniques.

Dr. Diego Correa Honored at UM’s Inaugural Award Program

The University of Miami Miller School of Medicine’s Faculty Council held its first-ever awards program earlier this year to recognize faculty members who contribute above and beyond the norm in research and medical education. Among the two awardees at this inaugural event was **Diego Correa**, M.D., M.Sc., Ph.D., research assistant professor at the Diabetes Research Institute and the Department of Orthopaedics. Dr. Correa was presented with the Faculty Council Research Award by **Edward Abraham**, M.D., dean and chief academic officer of the Miller School.

“I feel truly honored,” said Dr. Correa. “As a young investigator trying to establish a solid research agenda, this award certainly gives me extra motivation to work hard with my team to contribute scientifically and medically to the community on and off campus.”



Giacomo Lanzoni, Ph.D., Named to DRI Faculty

One of the DRI’s bright, young investigators, Dr. **Giacomo Lanzoni**, assistant professor of research, recently joined the ranks of the Institute’s esteemed faculty. Dr. Lanzoni’s research is focused on developing stem cell-based approaches to replace the insulin-producing cells that are destroyed in type 1 diabetes. Dr. Lanzoni, who came to the DRI in 2010, has been involved in a number of innovative projects and earned numerous awards and honors, including the Marc S. Goodman Prize to an Outstanding Young Scientist. “I don’t just imagine that a stem cell therapy could impact the life of patients with diabetes: I am sure it will, and I put my passion into making it a reality,” he says.



Can a Mechanism of Pregnancy Improve Islet Transplantation?

Almost immediately following conception, the viable embryo begins to secrete a natural compound called preimplantation factor, or PIF, and does so throughout the entire pregnancy. PIF plays a critical role in the mother’s ability to recognize and accept the embryo. Without the presence of PIF, the mother’s immune system would reject it.

Since PIF has demonstrated important immunological effects, it has been tested in a wide array of immune disorders and transplant models, as well as in several clinical trials, with encouraging results. DRI researchers, too, are investigating the possibility that PIF may help eliminate the need for anti-rejection drugs in islet transplantation. Recently, Dr. **Norma Sue Kenyon**, DRI Deputy Director and Martin Kleiman Professor, was awarded a JDRF Innovative Grant to further explore this novel research avenue.



THE 411 ON THE 504 PLAN

Creating a 504 Plan for your child can be a daunting task, according to parents at one of our recent PEP Squad meetings. Even with plans already submitted to the school, many questions remained. So, we turned to the experts at the DRI to provide the answers you need. Check out these quick tips and watch the complete educational video series at: DiabetesResearch.org/504.

PLAN AHEAD

Get the paperwork before the school year ends and work on it with your doctor over the summer so you’re ready for next year.



CUSTOMIZE THE PLAN

A generic plan will only create frustration. It must be customized to match your child’s unique needs (i.e. younger children will need more oversight than older kids).



BEYOND THE MEDICAL

Think about other accommodations for your child, like plans for substitute teachers, allowances for timed tests, safety on field trips, emergency preparedness and more.



504 PLAN



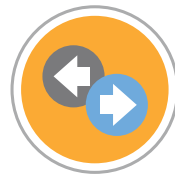
DAILY COMMUNICATION

Develop a partnership with teachers and school administration. An open line of communication is key!



REGULAR REVIEW

Don’t set it and forget it! Has your child’s insulin-to-carb ratio changed? Has s/he started a new CGM or pump? Then, you have to update the 504 Plan. Everything must be documented.



AVOIDING CONFLICT

Meet with the teacher to prevent possible classroom disruptions. If additional oversight is needed, it’s helpful to know your school board policy. It might allow for additional services, like a nurse aide.

“The DRI is the best hope for a cure, and I want to help get it there.”



BOARD SPOTLIGHT John Carrion

John Carrion, who has served as a DRIF board member since 2004, was recently appointed to the position of Northeast Region Board Chairman. He is a Portfolio Manager for Millennium Capital Partners and, prior to that, was Managing Director at Deutsche Bank and

Director at JPMorgan Chase in New York City. He and his wife, **Debra Carrion**, have identical twin boys, **Jake** and **Michael**, who are now 20 years old. At the age of 4, Jake was diagnosed with type 1 diabetes, and John was overcome with a feeling of helplessness.

“Just sitting there as my son was getting pricked and prodded was a feeling that I have never felt before, and one I do not want to experience again,” he explained. “In order to feel productive, I started my research on diabetes and what was being done to find a cure.”

That’s when he discovered the Diabetes Research Institute. After flying to Miami to tour the facility, the Long Island resident felt he had

found the place he was looking for. “I knew the horse I was going to back in this race for a cure,” he said.

John and Debra organized a group of friends, and together, in their living room, they dreamed up the idea for the first Kids Party for a Cure fundraiser. They continued to chair the Long Island event for years to come and helped raise more than \$1.3 million. They have participated in or sponsored a number of Foundation events and are actively involved in Buy In for a Cure, slated for 2019.

When John was approached to take on the role of Board Chair, he reached out to the DRI’s Dr. **Jay Skyler**, who described the overall plan for achieving the goal of a cure.

Fired up by their discussion, John stated, “The DRI is the best hope for a cure, and I want to help get it there.” John aims to use whatever resources he can to “bring in more people, with new contacts, fresh ideas, and renewed vigor” so that the Foundation can provide the necessary funding to the DRI to get this job done.



Another Successful Year of Fundraising for NABTU

Nearly 35 years ago, North America’s Building Trades Unions (NABTU) made a historic pledge to support the Diabetes Research Institute’s mission to find a cure for diabetes, and that unwavering commitment holds strong today. While several events for the D.A.D.’s Day (Dollars Against Diabetes) campaign are held throughout the year, some take place over its namesake Father’s Day weekend, including a very successful bucket collection near One World Trade Center and other high-traffic locations in New York City. Special thanks are extended to SMART Local 28 for donating their personal time for this important fundraising and awareness effort!



The annual Labor of Love & Softball Slam was also held in June and featured a weekend of fun events, plus the new Bowling and Texas Hold’em Poker Tournament. It was generously hosted by the Philadelphia Building & Construction Trades Council in their “City of Brotherly Love.”

The Diabetes Research Institute and Foundation offer deepest gratitude to all union members for their hard work and support!



EVENTS

1. Several of South Florida's best chefs cooked multi-course gourmet meals tableside while diners helped raise more than \$315,000 at Out of the Kitchen. Pictured: **George, Michael, Peter and Helen Politis.**
2. Nearly 300 guests tested their luck at the Love and Hope High Rollers casino event at the Faena Forum, raising \$320,000. Pictured: **Linda Gibb, Barbara Shapiro, Barry Gibb and Sandra Levy.**
3. **Delia DeRiggs-Whitton, Susan Herbst, Rebecca Castronovo and Stacy McKenna**, along with 120 other guests, enjoyed culinary delights prepared by **Chef Jeanine** at the 15th Annual Cooking for a Cure.
4. Dinner, dancing and Broadway star performances were the highlight of DREAMS in the City, which brought in more than \$500,000. Pictured: Dr. **Camillo Ricordi**, Honoree **Jennifer Ross, Stephen Ross**, and **Lindsey Inserra-Hughes.**
5. Miami Dolphins players, NFL alum, and produce industry professionals helped raise nearly \$120,000 at the 35th Annual Don Strock Diabetes Golf Classic. Pictured: **Don Strock, Dan Marino and Bruce Fishbein.**
6. Exotic cars were on display at the 10th Annual Gold Coast Concours/Bimmerstock event in Glen Cove, Long Island. Pictured: **Delia DeRiggs-Whitton** (at mic) and **Joe LaPadula** (right) with others on stage.
7. The 8th Annual Donaldson Organization Golf Outing, held at the Winged Foot Golf Club in New York, raised more than \$730,000. Pictured: **Doug Donaldson and Bob Donaldson**, with **Ty and Matthew Donaldson**
8. Dressed in their best hats, more than 275 guests helped raise \$130,000 at the 7th Annual Haute Tea luncheon. Pictured: CBS4's **Lisa Petrillo**, honorees **Robin Gale, Linda Finkelstein, Pamela Bernstein and Barbara Amoils**, with Dr. **Camillo Ricordi.**

There are additional photos and event recaps on our website. Please visit DiabetesResearch.org/Events

address service requested

CALENDAR

For information on the events or to make reservations, visit DiabetesResearch.org or call one of the DRI Foundation offices listed below.

2018

DECEMBER 12

Empire Ball
NEW YORK

2019

FEBRUARY 12

A Gift of Love... A Gift of Hope Luncheon
FLORIDA

MARCH 3

Carnival for a Cure
NEW YORK

MARCH 9

Love & Hope's High Rollers
FLORIDA

APRIL

Out of the Kitchen
FLORIDA

MAY 2

DREAMS in the City
NEW YORK

MAY 8

Don Strock Diabetes Golf Classic
FLORIDA

JUNE 6

Buy In for a Cure
LONG ISLAND

For more info visit: DiabetesResearch.org/Events

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