

JDRFI Artificial Pancreas Project Key Advances: Year in Review



Thanks to your generosity and support, JDRFI's Artificial Pancreas Project continues to make momentous progress toward one of our most important goals: developing an artificial pancreas, a device that can reduce the risk of complications and help to ease the daily burdens of diabetes for our loved ones. By enabling people with type 1 diabetes to achieve tight blood glucose control, and therefore maintain or improve their overall health, the artificial pancreas would also give them the best possible chance to fully benefit from a biological cure when it is found.

During the last year, the project achieved several key milestones. On January 13, JDRFI announced an innovative partnership with Animas Corporation to develop an automated insulin delivery system – a first-generation artificial pancreas – that will help people with type 1 diabetes better control their disease; Animas is a Johnson & Johnson company and a leading pump manufacturer. A week later, on January 19, JDRFI announced a second partnership, this time with Becton, Dickinson and Company, a leading global medical technology company, aimed at improving the treatment of type 1 diabetes by developing novel insulin delivery products to enhance the use of insulin pumps. Advancements in pump technology will not only lead to improved glucose control but can potentially be incorporated into the earliest artificial pancreas prototypes, either those developed by Animas or by other companies committed to finding cures and treatments for type 1 diabetes.

A series of JDRFI-funded studies (the first in 2008, then three in 2009) showing the benefits of continuous glucose monitors (CGMs) set the stage for these announcements, and in many ways laid the foundation for their development. The four scientific studies have confirmed CGMs are more than simply devices of convenience for people with diabetes – they are

tools that can substantially improve blood sugar control in people of all ages when used regularly, without increasing the risk of dangerous low blood sugar. These benefits underscore the importance of continued research into a closed-loop artificial pancreas, a device that will incorporate a CGM as one of its three key components.

The CGM trials have already produced real, tangible results for people with type 1 diabetes – results made possible through the support of donors like you. First, and above all, are the benefits afforded by using the device, which include a substantial lowering of the risk of complications and a reduction in the daily burden of managing the disease, not to mention the peace of mind that both of these benefits can bring. Second, the CGM trials have led to greater clinical adoption and insurance coverage – ensuring the greatest number of people can benefit from CGMs and the collective burden of the disease is greatly reduced.

This success and promise has been poignantly captured by Gina Capone, a JDRFI advocate who has been documenting her efforts to acquire CGM insurance coverage on her blog. Shortly after the first CGM study was published, and after months of submissions and denials, she finally received good news from her insurance company: “I wanted to jump up and down. I called and texted every person I knew. It was a day that changed my life. It was a day that I felt I did it for me, and the entire diabetes community. I fought and won.”

JDRFI's partnership with Animas Corporation represents another giant step on the path to what could be among the most revolutionary advancements in treating type 1 diabetes: the development of an artificial pancreas, a fully automated system to dispense insulin to patients based on real-time changes in blood sugar levels. The objectives of the partnership, a major industry initiative within JDRFI's Artificial Pancreas Project, are to develop an automated system to manage diabetes, to conduct extensive clinical trials for safety and efficacy, and to submit the product to the U.S. Food and Drug Administration for approval.

“If successful, the development of this first-generation system would begin the process of automating how people with diabetes manage their blood sugar,” said Alan Lewis, Ph.D., President and Chief Executive Officer of JDRFI. “Ultimately, an artificial pancreas will deliver insulin as needed, minute-by-minute, throughout the day to maintain blood sugar levels within a target range. But even this early system, which will be partially automated, could bring dramatic changes in the quality of life for the three million people in the U.S. (300,000 in

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Canada) with type 1 diabetes, beginning to free kids and adults from testing, calculating, and treating themselves throughout the day.”

JDRFI will provide \$8 million (U.S.) in funding over the next three years, with a target of having a first-generation system ready for regulatory review within four or so years. DexCom, Inc., a leading manufacturer of CGM devices, will supply the CGM technology for the system being developed by JDRFI and Animas. JDRFI’s goal is to have multiple versions of an artificial pancreas available for people with diabetes, and so the organization will continue to explore partnerships with other industry leaders.

To enhance the effectiveness of insulin pumps, JDRFI will also support BD’s research and development of new products that deliver insulin from a pump to a patient in either an infusion set or patch-pump configuration, investing \$4.3 million (U.S.) in milestone-based financial support over the next few years. Research indicates there are significant opportunities to enhance pump therapy by improving convenience as well as minimizing pain, kinking, occlusions, and site infections. An additional goal of the program is improving the speed at which insulin works. These enhancements are intended to improve how people with diabetes control their insulin therapy and have a positive impact on their overall level of glycemic control.

While the eventual development of an artificial pancreas, its nuts and bolts construction, rests in the hands of our talented scientists and valued partners, it is our tremendous family of donors and volunteers that ultimately initiated this project and

will make it a reality – through generous support, advocacy, and personal commitment. Jeffrey Brewer, a JDRFI volunteer and international board member, is case in point of one individual making a difference for many in the type 1 diabetes community. In a video on JDRF’s APP website (www.artificialpancreasproject.com), Jeffrey shares the story behind his personal commitment to JDRFI, excerpts of which are below:

My son was diagnosed, and I had this interest in, “Can’t we automate this at this really opportune time,” when the technologies were beginning to develop to where it was actually possible to conceive of this thing called an artificial pancreas. Our family decided to support and further deepen JDRF’s commitment to looking at issues – how people can live with this disease in addition to focusing on curing it ... There’s no other organization focused on doing these things. I can quite confidently say that [the development of an artificial pancreas] would not be taking place otherwise; and without the support of donors, it would not be taking place very quickly. And so our support directly translates into an ability to speed these products to market, to help people to live with this disease.

In summary, the past year has seen important and exciting progress toward the development and delivery of a closed-loop artificial pancreas. JDRFI is proud of the role it has played – and continues to play – in advancing this new technology, and we are grateful for your partnership in helping to make it possible. ■