

# Artificial Pancreas Project

## Background

'Perfecting a closed loop artificial pancreas' is one of JDRF's six therapeutic goals, and this year JDRF is launching a new initiative to help accelerate the availability of an artificial pancreas to people with type 1 diabetes.

Research shows that the majority of people with diabetes are not reaching recommended glycemic control levels, resulting in complications from hyperglycemia such as blindness, kidney failure, heart attacks, and amputations; bouts of hypoglycemia which can cause hospitalizations, car accidents, and other problems; and obstacles for other therapies such as islet transplantation.

Ultimately, a true artificial pancreas will enable a person with diabetes to maintain normal glucose levels by providing the right amount of insulin at the right time, just as the pancreas does in non-diabetic individuals. In the near term, we expect artificial pancreases to be external devices comprised of three components: 1) insulin pumps, already widely available; 2) continuous glucose monitors (CGMs), which are coming on the market now; and 3) an algorithm to communicate between the two.

Even before such a 'closed loop' artificial pancreas is available, we expect continuous glucose monitors to help people with diabetes better manage glucose levels. CGMs will provide continuous readings, including data on whether glucose levels are rising or falling, which will enable people with diabetes to intervene (e.g. eat carbohydrates or take insulin) to ward off hyper- or hypoglycemia.

## Project Activities

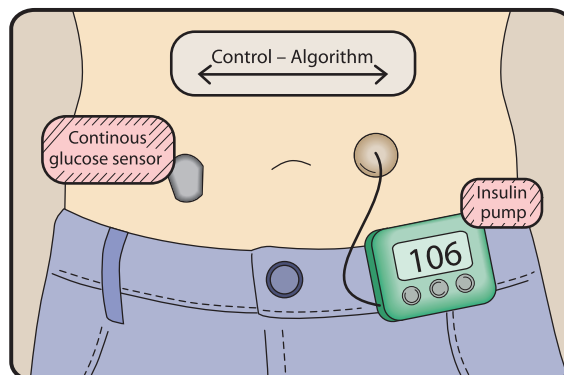
The overall goal of the project is to ensure that within five years patients have access to artificial pancreas technologies that will improve glycemic control, and that in the long term there is broad patient access and a thriving competitive market for these technologies.

To achieve these goals, JDRF is launching an aggressive, multi-year campaign to speed regulatory approval and obtain health insurance coverage of artificial pancreas technologies. As part of this campaign, we plan to seek approval and coverage for the continuous glucose monitor first, while laying the groundwork for the artificial pancreas.

As part of this campaign, JDRF will:

- Commission research to show cost-effectiveness and improved outcomes of patients using these technologies.
- Engage in an active dialogue with the Food and Drug Administration (FDA), HHS, and the Congress to help speed the adoption of patient outcome oriented standards.
- Advocate for Medicare coverage of these technologies to the Centers for Medicare and Medicaid Services (CMS), HHS, and the Congress.
- Advocate for private health plan coverage of these technologies.
- Seek Federal Employees Health Benefit Plan coverage of these technologies.
- Encourage clinician use of these technologies.

## How an Artificial Pancreas Would Work



# Questions and Answers on:

## Revolutionizing Diabetes Care through the Development and Availability of an Artificial Pancreas

### What is an artificial pancreas?

An artificial pancreas is a “closed-loop” device that would regulate glucose levels in the body of someone with diabetes by continuously measuring the level of glucose and dispensing doses of insulin based on those measurements. An artificial pancreas would enable a person with diabetes to maintain “normal” glucose levels by providing the right amount of insulin at the right time, just as a pancreas does in people without the disease.

Currently, no artificial pancreas is available for people with diabetes, but in the near future we believe one could be created by linking an insulin pump to a continuous glucose monitor. Thus, an important next step toward an artificial pancreas will be ensuring the widespread availability of continuous glucose monitors.

### Why is an artificial pancreas needed?

An artificial pancreas could potentially revolutionize diabetes care and management, significantly improving the ability of people with diabetes to maintain strict blood glucose control, and – as a direct result – helping reduce kidney disease, heart attacks and stroke, amputations, blindness, and death from severe hypoglycemia.

Extensive research shows that glucose control is the primary factor in avoiding the devastating complications of diabetes. Often blood sugar levels are too high (hyperglycemia), which leads to complications such as blindness, kidney failure, heart attacks, and amputations. Blood sugar levels that are too low (hypoglycemia) can lead to hospitalization, car accidents, and other serious problems.

But clinical research shows that most people with diabetes are not controlling blood glucose levels nearly well enough. A 2005 study showed that even vigilant patients who check blood glucose frequently spent less than 30 percent of the day in the normal glucose range. The risk of complications – and the economic burden placed on our health care system

– could be significantly lowered with devices that improve blood glucose control. And good glucose control will probably enhance the effectiveness of promising new cure therapies such as beta cell regeneration and islet transplantation.

### What is a Continuous Glucose Monitor (CGM)?

Continuous glucose monitors are devices that provide continuous “real-time” readings and data about trends in glucose levels. This can allow people with diabetes to understand the level of their glucose and whether it is rising or falling, and to intervene by eating food or taking insulin to prevent it from going too high or too low. Currently, two CGM devices have been approved by the FDA, and at least one CGM is still under review by the FDA.

### Why are CGMs important?

Even before a ‘closed loop’ artificial pancreas is available, we expect continuous glucose monitors to help people with diabetes better manage glucose levels. In fact, clinical studies have shown that patients using CGMs spend much more time in the normal glucose range compared with patients using conventional “finger-stick” blood glucose methods. With tighter control – as measured by long-term hemoglobin, or A1c, testing – their risk of complications should drop dramatically.

### What are the barriers to the widespread use of a continuous glucose monitor?

There are both scientific and regulatory barriers. At least one CGM is still under review by the FDA. Those CGM devices approved by the FDA are approved for use in addition to using finger sticks. The companies must seek approval from the FDA in the future for the devices to be used instead of finger sticks. Their use in clinical care needs to be documented as advantageous over current methods of treating diabetes in order for the medical community to recommend them. In addition, patients must find them convenient and affordable,

## **JDRF Questions & Answers on:**

### **Revolutionizing Diabetes Care through the Development and Availability of an Artificial Pancreas**

*something that will only come about with a robust market for the devices (with several to choose from) and adequate reimbursement from government and private insurance programs.*

#### What is still needed to close the loop?

*Once the CGM technology has been approved by the FDA, closing the loop will require linking the CGM with an insulin pump. This link will require the refinement of sophisticated computer algorithms to calculate how much insulin the patient will need at any given time. These closed loop systems will need to be tested outside the lab, in real world settings, reviewed by the FDA for safety and effectiveness, reimbursed by insurers, and recommended by doctors.*

#### Why is JDRF getting involved in promoting the artificial pancreas?

*As an independent entity, not aligned with any commercial enterprise or device manufacturer, JDRF is in a unique position to address many of the scientific and regulatory issues that currently exist and to create an environment that facilitates the delivery of an artificial pancreas. We think we have the potential to accelerate introduction by several years and pave the way for widespread patient access.*

#### What can JDRF do to speed development and availability of CGMs and Artificial Pancreases?

*JDRF's role will consist primarily of 1) funding independent research to evaluate the outcomes of patients using these technologies; 2) engaging in an active dialogue with the FDA to help speed the adoption of patient-outcome-oriented standards; 3) advocating for Medicare and private health plan coverage of these technologies to enable widespread usage; and 4) working with the medical community to ensure clinical acceptance of these technologies.*

#### Will an Artificial Pancreas also benefit people with type 2 diabetes?

*Yes. Patients with type 2 diabetes often suffer from poor glucose control and the diabetic complications that come with it. Given the large (and increasing) number of people with type 2 diabetes who are insulin dependent, an artificial pancreas may be just as appropriate as for a type 1 diabetes patient, providing tremendous clinical benefits for a large (and growing) number of people in the U.S. and resulting in dramatically reduced health care costs.*