

Juvenile Diabetes Research Foundation Artificial Pancreas Consortium Update

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History and Purpose

A mechanical means to restore euglycemia in diabetes has long been considered achievable, yet a portable and widely adopted artificial pancreas system has not been realized.^{1,2} The Artificial Pancreas Consortium was established in 2006 as part of the Juvenile Diabetes Research Foundation International (JDRF) Artificial Pancreas Project, a multimillion dollar, multiyear initiative with a mission to accelerate the development of systems for automated control of blood glucose in patients with diabetes. Consortium investigators seek to research and develop strategies, which can be commercialized, that will confer the long-term benefits of improved glycemic control by combining novel automated control algorithms and hormone therapies with continuous glucose monitors and pump devices.

Consortium Participants

Advancing the field of closed-loop artificial pancreas research requires expert diabetologists partnering with expert mathematicians and engineers. Consortium investigators include leading endocrinologists and control theorists at top research institutions in the United States and Europe (**Figure 1**). Many of the leading diabetes device manufacturers have also participated, providing pumps and sensors with enhanced capabilities that allow for closed-loop experiments to be performed. Consortium activities are coordinated by the Jaeb Center for Health Research, an organization with a strong track record of conducting high-impact, diabetes-related human clinical trials.³ Regulatory affairs are streamlined by an advisory group of experienced JDRF personnel and outside consultants, ensuring good coordination with the Food and Drug Administration (FDA) and other regulatory bodies. The JDRF and FDA have partnered to proactively address regulatory obstacles, and in March 2006 the FDA named the artificial pancreas one of its Critical Path initiatives (<http://www.fda.gov/oc/initiatives/criticalpath/>).

Progress to Date

Collaboration among consortium investigators and the coordinating center has produced a wealth of shared resources to accelerate consortium research, including:

- Design, optimization, and clinical testing of multiple algorithmic approaches to closed-loop control
- An *in silico* simulation platform, accepted by the FDA, for validating candidate closed-loop control algorithms in place of animal trials⁴

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Abbreviations: (FDA) Food and Drug Administration, (JDRF) Juvenile Diabetes Research Foundation International

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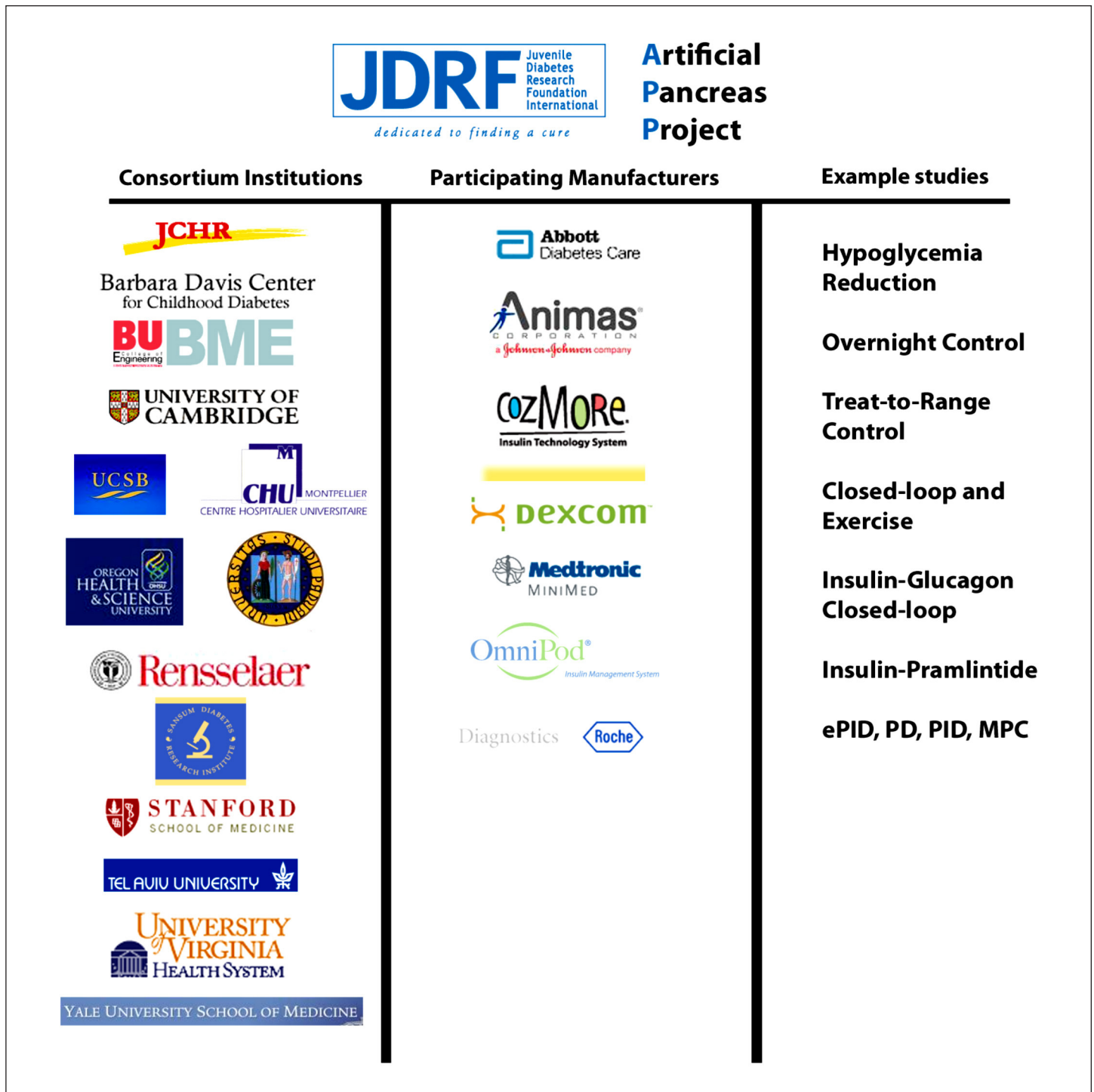


Figure 1. Consortium institutions, participating manufacturers, and example studies.

- Reusable templates for constructing the Investigational Device Exemption regulatory documents that must be approved by the FDA prior to any in-clinic, computer-assisted, closed-loop control research involving people
- A modular software platform—the Artificial Pancreas System—with a protocol-independent user interface and hooks to incorporate an arbitrary control algorithm and control various continuous glucose monitors and pump devices⁵
- A secure consortium Web site with a central repository for experimental data and interfaces to submit candidate control algorithms for centralized validation and to upload or download clinical data sets

Ongoing and recently completed in-clinic studies include fully automated closed-loop control investigations using model predictive control and proportional–integral–derivative/pharmacodynamics-based algorithms, semiautomated control investigations, and investigations into hypoglycemia prediction and avoidance. The consortium's public Web site (<http://consortium.jaeb-diabetes.net/>) offers (1) additional information about individual research protocols and (2) a list of the more than 70 publications and public presentations stemming from consortium-funded activities.

Future Activities

To be successful, the artificial pancreas must be realized and adopted. That is, the outstanding work and considerable efforts described here must be translated into commercially available products that provide clinically meaningful improvements in glycemic control and quality of life for people with diabetes. The next phase of the JDRF Artificial Pancreas Project aims, in close partnership with industry, to drive toward this goal. In the next 12 months, the JDRF consortium plans to perform groundbreaking research, including:

- the first outpatient studies of an overnight controller
- the first outpatient studies of a hypoglycemia minimization strategy
- the development and testing of a modular “treat-to-range” closed-loop approach
- multiple studies of dual hormone (insulin and glucagon) devices and a means to improve insulin kinetics

The prospects for an artificial pancreas are bright. The *National Institutes of Health* recently announced a major artificial pancreas initiative, and the majority of diabetes device companies are participating in the JDRF Artificial Pancreas Project effort and have stated publicly that “closing the loop” is a goal. The reward for this hard work will be people with diabetes living healthier and happier lives.

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