Request for PROPOSALS:

GLUCOSE RESPONSIVE GLUCOSE MODULATING THERAPIES

for the treatment of Insulin Dependent Diabetes Mellitus (IDDM)

JDRF and Eli Lilly

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Presentation Overview

- JDRF Mission
- JDRF Research Priority Programs
- Glucose Responsive Glucose Modulating Therapies – what are we looking for?
- Overview of Proposal Request
- Q+A opportunity

JDRF's Vision for the Future

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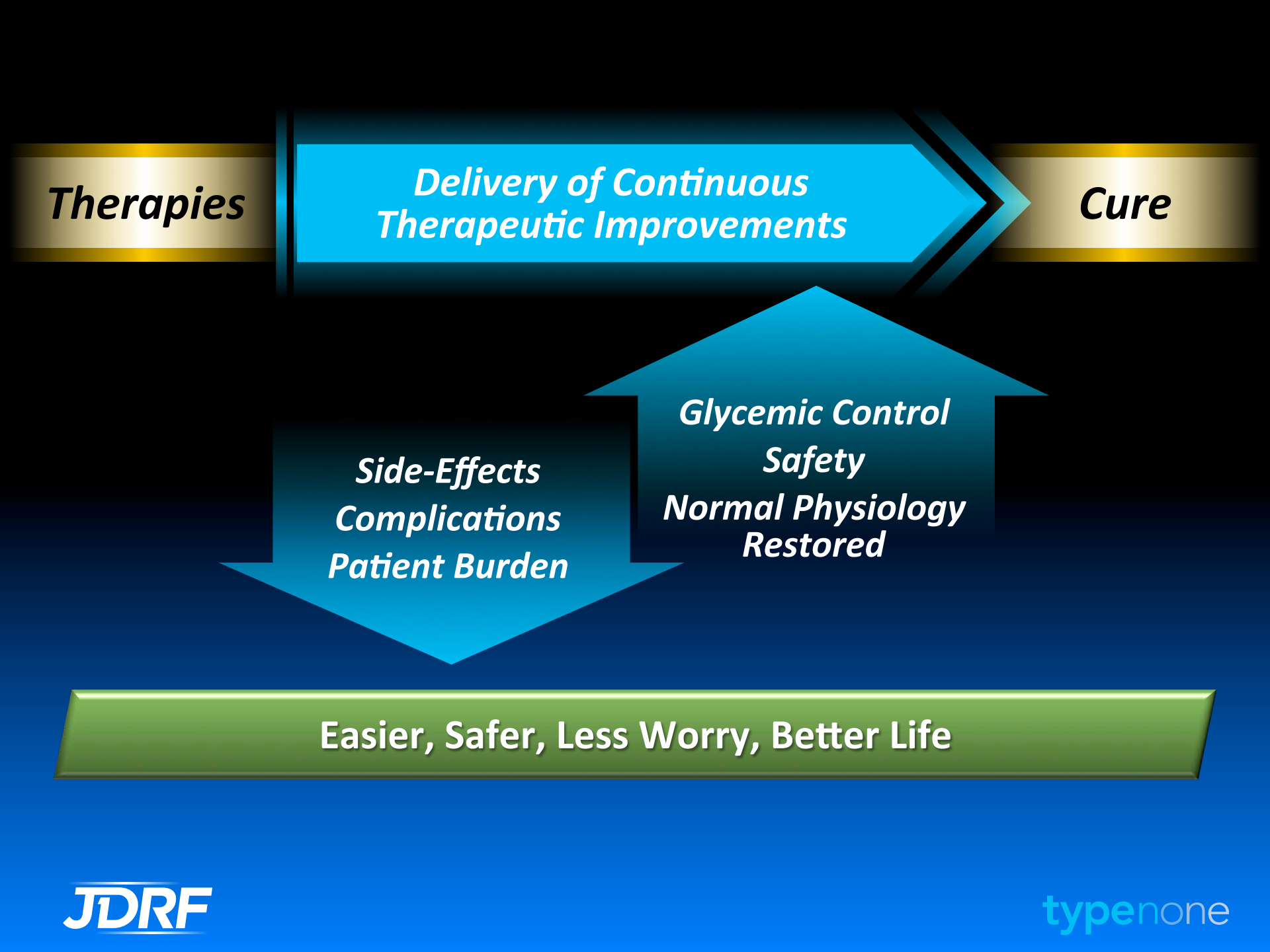
Therapies
Delivery of Continuous Therapeutic Improvements
Cure
Side-Effects
Complications
Patient Burden
Glycemic Control
Safety
Normal Physiology Restored
Easier, Safer, Less Worry, Better Life
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JDRF Research Priority Programs

Significant advances are improving how people live with the disease and bringing us closer to a biological cure and universal prevention.

ARTIFICIAL PANCREAS

COMPLICATIONS

BETA CELL REPLACEMENT

GLUCOSE CONTROL

RESTORATION

PREVENTION

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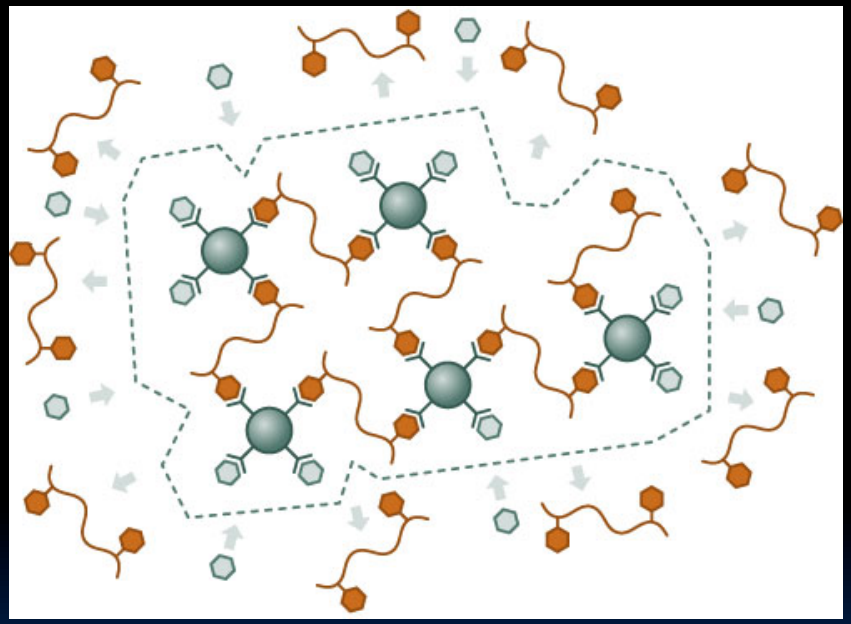
JDRF Supported SmartInsulin Program



Insulin Conjugate

Glucose

Glucose Binding Protein

2008:	Preclinical concept with preliminary in vitro results supported through IDDP to Smart Cells Inc. (2008)
2009:	Developed prototype insulin molecules and demonstrated proof-of-principle → Garnered additional support (JDRF, Angels, NIDDK-SDP, etc.)
2010:	Demonstrated proof-of-concept in animal models
2010:	Smart Cells Inc. acquired by Merck – SmartInsulin under development

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Glucose Responsive Glucose Modulation

Working Definition:

- Therapies that can modulate the activity and/or concentration of a freely-circulating insulin analog or other insulin receptor agonist as a function of changes in glucose concentration over the physiologically relevant range.

- Systems in which the activity and/or concentration of a freely-circulating glucagon, glucagon receptor agonist or insulin receptor antagonist are made dependent on changes in glucose concentration.

Projected Outcomes

Expected outcomes from project proposals would demonstrate but not be limited to:

- Modulation of activity/concentration of a glucose-concentration modulating agent in response to changes in solute concentration.
- Data indicating an understanding of the mechanism by which changes in glucose concentrations result in changes in activity and/or concentration.
- The establishment of analytical techniques to assess the underlying mechanism behind the changes in activity and/or concentration.
- Data supporting a path forward toward the utility of glucose as the trigger for changes in activity/concentration over the physiologically relevant concentration range.

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Mechanism: JDRF – Eli Lilly Co-funding

- Selected investigators and their institutions will be required to sign a modified JDRF "Program Award Agreement" which will stipulate conditions in addition to JDRF's standard Terms and Conditions. These may include:
  - Prior approval of publications/presentations
  - Protection of Intellectual Property
  - The grant to Eli Lilly of a non-exclusive research-use license and an option to negotiate an exclusive license to IP generated during the funding period.

RFA Timelines

- **Full Application Release:** Tuesday November 17, 2015
- **Application Submission Deadline:** Thursday January 14, 2016
  - Applicants should register and submit their completed full proposal application in RMS360 (http://jdrf.smartsimple.us).
- **Projected Application Review Period:** Late January – Late April
  - The review process will incorporate external experts who review as volunteers on our scientific review panel at the discretion of JDRF Scientific Staff and Eli Lilly. The reviewers will assess the scientific merit and validity of the submitted proposals. For all of the reviewed applications, JDRF Scientific Staff and Eli Lilly will make a joint final decision regarding a proposal's scientific merit.
- **Earliest Response to Applicants:** May 2016
- **Earliest Anticipated Start Date:** June 2016

Funding Mechanism

- Funding requests for Strategic Research Agreements (SRA) will be considered for a maximum of $200,000 USD per year, including a maximum of 10% indirect costs, for up to 2 years duration.

- Funding requests for Innovative Grants will be considered for a maximum of $110,000 USD per year, including a maximum of 10% indirect costs, for 1 year.
  - *Applications whose budget and/or timeline exceeds the above specified guidelines, must obtain JDRF staff approval prior to submitting the full proposal.

- Projects would be funded as
  - **Strategic Research Agreements (SRA)** (http://grantcenter.jdrf.org/grant-center/information-for-applicants/grant-mechanism-descriptions/strategic-research-agreements/
  - **Innovative Grants** (http://grantcenter.jdrf.org/grant-center/information-for-applicants/grant-mechanism-descriptions/innovative-grants/).

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Full Proposal Application

- Full proposal applications should be submitted via the RMS360 system (/jdrf.smartsimple.us) using the research plan template provided and including the following information:
  - Background /Rationale and Specific Aims of overall project
  - Overview of hypotheses, goals, deliverables and collaborative framework as applicable
  - Title, lead investigator and a description and specific aims of individual projects (if collaborative/network)
  - Expected deliverables and impact of the proposed study with potential next steps
  - Intellectual Property or commercial efforts associated with the current application
  - Total budget / budget by year by project
  - Biosketches for all Principal Investigators and Key Personnel

RMS360

- JDRF is using a grants management system to collect online application submissions called RMS360. The to RMS360 link is as follows: https://jdrf.smartsimple.us/s_Login.jsp.
  - Please note that if you are new to the system, you must register and log in details will be generated.
- Call details and deadlines can be found in the "Funding Opportunities" tab of RMS360.
- All materials and templates pertaining to the application can be found once you've initiated an application in RMS360.
- It is recommended to use Google Chrome or Firefox when using RMS360, as these browsers are most compatible with the system.

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Challenges → Opportunities

- Lack of technical/scientific prior art → Options wide open; staged approach
- Cross-functional expertise needed → Collaborative team of diverse backgrounds
- Unknown regulatory path → Insulin and non-insulin based therapies may provide guidance
- Acute and long term safety → Eli Lilly to offer scientific and technical expertise/know-how and other resources

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What is a Collaborative Team?

- A group of highly talented researchers from a spectrum of disciplines, perspectives, and research methods
- Willing to share knowledge, resources methods and data
- Individual projects should contribute to a common, well-defined research program goal
- Supported by appropriate data sharing and collaborative agreements
- Capable of developing and undertaking a decision-making structure to ensure good communication, smooth progress and collective approaches to overcome obstacles

Where should questions be directed?

- Questions on eligibility, suitability of proposals and network structure:
  - Sanjoy Dutta (sdutta@jdrf.org)
- Questions on logistics, deadlines or submission problems:
  - Jami Goodman (jgoodman@jdrf.org)
- For technical support, please contact SmartSimple Support Services via email support@smartsimple.com or phone (866) 239-0991. Support hours are Monday through Friday between 5:00am and 9:00pm US Eastern Standard Time.

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