STATE OF THE CURE FOR TYPE 1 DIABETES

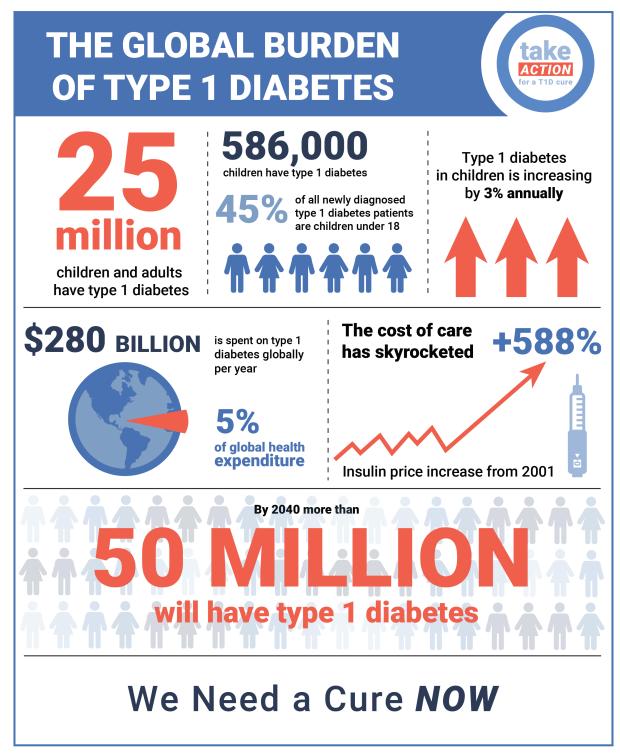


State of the Cure

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Sources: IDF, CDC, JDRF, + ADA Published Information

Introduction

The 2018 State of the Cure for type 1 diabetes is the seventh annual edition of this report. Like all prior State of the Cure reports, it summarizes progress made during 2018 toward a Practical Cure (PC) for type 1 diabetes.

Any review of progress to a Practical Cure must begin with the difficult fact that we are not there yet, and the past twelve months have yielded only moderate progress. While there are some areas of notable development in 2018, the overall key finding is largely the same as prior years— there is still a long road ahead. The year ends with only ten potential Practical Cure projects in human trials, none of which have published conclusive results.

As noted in the infographic on the left, more than 25 million people throughout the world have type 1 diabetes. The lifetime cost of care for a single person living with T1D amounts to \$11 million, which equates to \$14 billion in healthcare expenditures in the U.S. per year, and \$280 billion globally. Furthermore, the cost of care for T1D is rising dramatically, with the price of a 10-millimeter vial of insulin shooting up from \$40 in 2001 to more than \$275 today, a 588 percent increase.

At the same time, research grant spending by the two largest diabetes fundraising organizations, the American Diabetes Association (ADA) and Juvenile Diabetes Research Foundation (JDRF), has remained at significantly lower levels versus the previous decade. For the 2017 fiscal year, JDRF spent only 38 percent of its income on research, down from 67 percent in 2008. *Of that, only seven percent was used to specifically fund cure research*. Meanwhile, the ADA spent only four percent of its annual revenue specifically on T1D research, a remarkably small amount.

This year 205,000 people signed *the Juvenile Diabetes Cure Alliance (JDCA) 4th Annual More for a T1D Cure Petition* asking the ADA, JDRF and other notable T1D research organizations to significantly increase levels of cure research spending. The petition results are consistent with JDCA T1D community surveys conducted over the past six years. Survey findings have shown unambiguously the number one reason the majority of T1D donors participate in fundraising events is to support T1D cure research.

Furthermore, nine out of every ten donors state that they would donate to Practical Cure research if that option was made easily available to them. Yet, to date, no T1D organization has implemented Practical Cure research as a main objective. Adoption of a focused Practical Cure research program is the only way to ensure promising projects move through the research pipeline to completion as fast as possible and in time to affect those currently living with the disease. The time for change is now.

HOW DO T1D DONORS WANT THEIR MONEY USED?

25 MILLION PEOPLE have a family member

or a close relative with T1D

Together they donate \$450 MILLION DOLLARS per year to TYPE 1 DIABETES



Source: JDCA Survey of Donor Sentiment, November 2018

Donor Priorities: Survey Results

The vast majority of the donations that fuel the major type 1 diabetes charities come from those most directly connected to T1D: people living with type 1 as well as family and friends. The JDCA conducts annual surveys to gauge attitudes and intentions of T1D financial donors. Over the last six years, we have heard from over 5,000 donors in 16 different surveys. This section summarizes the key takeaways.

One main finding has been consistent over six years— the overwhelming majority of donors want their money to be used for research that seeks a cure for T1D. Other 2018 donor survey findings include:

- **98%** of donors believe cure research should be the number one priority for charities. This point is consistent with survey findings from prior years. See **Chart 2a.**
- 78% said 100 percent of the money raised at fundraising walks should be used for cure research. Said differently, four out of five walkers want ALL of the walk proceeds to be used for cure research.
- 94% of donors would donate to support Practical Cure research if that option were made easily available to them. See Chart 2b.
- 88% said the ADA and JDRF should seek direct donor input when making research funding decisions. Yet, donors are not represented in any meaningful way in budget spending decisions at either organization.
- 54% of respondents said "I will stop participating" or "I am less likely to participate" in future fundraising walks after learning how much of the ADA and JDRF income was actually used for research, indicating a potential risk for both organizations. See Chart 2c.

Chart 2a:

"Is cure research the primary reason you make a donation to a diabetes charity and/ or participate in a fundraising activity?" Answer is percent who agree.



Source: JDCA Survey of Donor Sentiment, November 2018

Chart 2b:

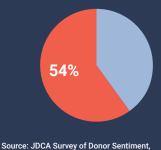
"Would you donate to Practical Cure research projects if that option was made easily available to you?" Answer is percent who agree.



Source: JDCA Survey of Donor Sentiment, November 2018

Chart 2c:

Answer is percent who will stop/ are less likely to participate in future JDRF fundraising walks after learning JDRF spent only 38% of its annual income on T1D research.

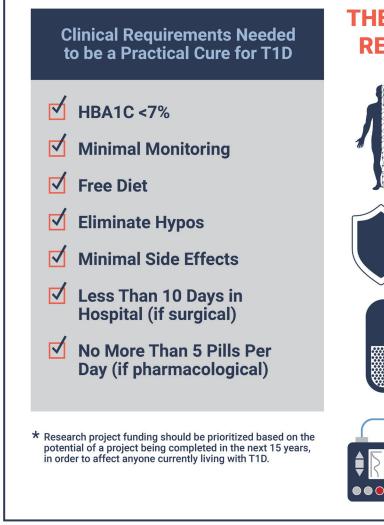


Source: JDCA Survey of Donor Sentiment November 2018

A PRACTICAL CURE FOR T1D

DEFINITION: Any solution which delivers a near-normal lifestyle for people living with established type 1 diabetes.

TIMING: Available in the next 15 years.*



THE HIGHEST POTENTIAL **RESEARCH PATHWAYS:**



Cell Transplantation

Implanting islet cells, stem cells, or precursor cells to achieve insulin independence. Cells are protected by an encapsulation device or immune system modification.



Immune System Modification

Therapy to stop the immune system from destroying beta cells, including modifying, blocking and re-training.



Glucose-Responsive Insulin

"Smart Insulin" can be delivered through a pill, patch, gel or injection and chemically activates in response to changes in blood sugar.



Advanced Artificial Pancreas

A device that mimics the pancreas by monitoring changes in blood sugar and independently administers insulin without the patient's input.

Practical Cure Definition

The definition of a Practical Cure was developed based on the wishes and desires of people who are currently living with type 1 diabetes. It is defined as any solution which minimizes the disruptive aspects of T1D and delivers a near-normal quality of life. A PC may also be referred to as a "functional cure" by the scientific research community.

A Practical Cure is different from a perfect or idealized cure in that it does not represent a reversal or complete elimination of the disease. This distinction is important. Scientists have been pursuing an idealized cure for almost 100 years without success. Alternatively, there are several projects in human trials that have the potential to become a Practical Cure, and there could be many more if resources and funding are allocated toward it. A point of view to prioritize the pursuit of a Practical Cure above all other types of research has been voiced by the T1D community over the past six years.

A PRACTICAL CURE IS OUTCOME FOCUSED

The infographic on the previous page shows the various outcome criteria that a Practical Cure must meet, including no dietary restrictions, minimal monitoring, insignificant side effects, elimination of hypos and HbA1C readings under seven percent with sustainability over time. There are also guidelines for the invasiveness of the type of solution, whether it be pharmacological or surgical. Any research approach, pathway or philosophy that can deliver these outcome objectives is valued, desired and merits pursuit.

A PRACTICAL CURE IS TIME-BOUND

Any Practical Cure solution must have a reasonable chance of being available within the next 15 years— in time to transform the lives of people who are currently living with the disease. Considering that, on average, it requires 10-15 years from the beginning of human trials to receive FDA pre-market approval, research projects that are currently in human clinical trials have the best chance of meeting the timetable.

There are two essential benefits to having a time goal. The most important benefit is that a time goal puts the emphasis on helping people who are currently living with T1D as opposed to focusing on a cure for future generations. The second important benefit of a time goal is that it provides a structure for prioritizing projects. Projects that have already advanced into human trials should be given priority, fully funded and wholly resourced so they can move through human trials to conclusive results as quickly as possible. A defined time objective prioritizes projects that have a chance of being in market within the next 15 years— in time to transform the lives of people who are currently living with the disease.

Practical Cure Pathways

There are four broad research pathways that have the potential to result in a Practical Cure within the next 15 years. Certain solutions may require a combination of the pathways while others may stand on their own. The four pathways are shown in the infographic on page five and discussed below.

CELL TRANSPLANTION

Cell transplantation involves implanting islet cells, stem cells or precursor cells into a person with type 1 diabetes to achieve insulin independence. There are two main issues with cell transplantation which still need to be resolved: cell supply and cell survival. To date, the only proven source of cell supply is islet cells taken from cadavers, which have very limited availability. Research into deriving a sustainable cell supply from human stem cells has seen promising advances over the past decade and is currently being tested in humans. The remaining hurdle of increasing cell survival involves the development of an encapsulation device or sustainable long-term immune system modification to protect the cells from the body's immune response. There are currently three active trials in human testing.

IMMUNE SYSTEM MODIFICATION/ IMMUNOMODULATION

Immune system modification/ immunomodulation utilizes drugs or stem cell therapy to stop the body's immune system from attacking insulin-producing beta cells. Currently, immune system modification is being tested with the hope of regenerating existing beta cells still remaining in the body. If regeneration proves ineffective, immune system modification would need to be combined with cell transplantation. There are currently seven active trials in human testing.

GLUCOSE-RESPONSIVE INSULIN (GRI)

Glucose-responsive insulin, also known as "smart insulin," is chemically activated in response to changes in blood glucose. Smart insulin remains inactive until blood glucose rises above normal levels. At that point, the chemical component activates the insulin. Once blood glucose returns to normal, the insulin action ceases, avoiding low blood sugar. To qualify as a Practical Cure, smart insulin would have to last long enough to eliminate the need for multiple daily injections. To date, Merck is the only company that has tested GRI in humans, and that trial failed. There are currently no GRI trials in human testing.

ADVANCED ARTIFICIAL PANCREAS (AP)

An advanced artificial pancreas is a device that mimics the glucose-regulating functions of a healthy pancreas, automatically controlling blood glucose levels and delivering insulin. In a recently completed survey of the T1D community, 88 percent of respondents said an AP device would qualify as a Practical Cure if "it is small enough that you could generally forget that you are wearing it." To date, no current devices are small enough.



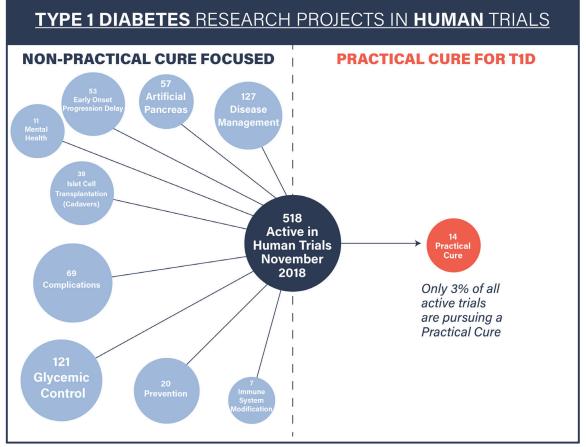




Practical Cure Projects in Human Trials

As of November 2018, there were 518 active T1D research trials in FDA-approved human trials. These trials are researching a wide range of topics related to type 1 diabetes with the largest concentration working to improve glycemic control and disease management. As noted in the introduction and detailed on the following page, there are only ten Practical Cure projects currently in development. Those ten projects are being tested in 14 clinical trials (some projects are being tested in more than one trial). See **Chart 5a**.

Chart 5a:



Source: clinicaltrials.gov

Each Practical Cure project is summarized in the charts on the following pages and organized by project pathway. Please note that the JDCA presents these projects without any indication of preference or ranking. To qualify as a PC, all trials must target an increase in C-peptide production as a primary or secondary endpoint measure. The trial must also be testing patients with fully established T1D (C-peptide \leq .5 ng/mL + one year past original diagnosis based on ADA diagnosis criteria— the point when the body is no longer able to produce its own insulin).

Since last year, three projects have been removed from the Practical Cure list. BCG was removed because the current trial is not using C-peptide as a primary or secondary endpoint measure— a significant change from the phase I BCG trial. Caladrius has been removed because it no longer meets JDCA standards for testing in fully established T1D. Monolayer Cellular Device at Cliniques Universitaires Saint-Luc-UCL has been removed because it has been concluded without results for more than three years. All three projects have the potential to return to the PC list should they initiate additional human trials.

Active Practical Cure Projects

by Pathway

BetaO₂ BAir Bio-Artificial

Pancreas

Tel Aviv, Israel

Islet cells are encapsulated in

puck, which is implanted in the

device the size of a hockey

abdomen. Requires daily

oxygen injections.

Beta-O2 Technologies Ltd.

Phase I/II

March 2018 Description

Active, Not Recruiting

Estimated Completion:

CELL TRANSPLANT



for T1D Stem Cells Arabia Amman, Jordan

Phase I/II Recruiting Estimated Completion: January 2019

Description

Autologous stem cells are removed, purified, and returned with expectation that they will evolve into beta cells. White blood cells are removed and treated with mesenchymal stem cells and returned to the patient to stop the autoimmure attack.

ψ νιαςγτ:	E
PEC-Encap	
Viacyte	
San Diego, CA	

Phase I/II Paused Estimated Completion: December 2020

Description Precursor cells, derived from an embryonic stem cell line, mature into functional beta cells when implanted under the skin. Cells are protected by an encapsulation device.

Jewish General Hospital

Ustekinumab

lewish General Hospital

Montreal, Canada

Completed: Results not yet

INGAP-P to induce beta cell

regeneration combined with

Ustekinumab for autoimmune

IMMUNE SYSTEM MODIFICATION / IMMUNOMODULATION

Phase I

posted.

Description

modulation.

Drug combination.

UF FLORIDA

Reversing Established Type 1 Diabetes University of Florida Gainesville, FL

Phase I/II Active, Not Recruiting Estimated Completion: September 2018

Description ATG is aimed at stopping the autoimmune attack and GCSF is intended to stimulate beta cell regrowth. Drug combination.

The Second Xiangya Hospital of Central South Univ

Umbilical Cord Blood Regulatory T Cells Plus Liraglutide Second Xiangya Hospital of Central University

Hunan, China Phase I/II Recruiting Estimated Completion: November 2019

Description

Infusion of regulatory T cells grown from umbilical cord blood to control immune response. Liraglutide to stimulate beta cell growth.



Stem Cell Educator Tianhe Stem Cell Biotech Hackensack, NJ

Phase I/II Recruiting Estimated Completion:

June 2019 Description A patient's blood is passedthrough a machine which, through exposure to cord blood stem cells, re-trains the regular blood cells to cease the autoimmune attack.

University of California

T1D Immunotherapy University of California San Francisco, CA

Phase I Active, Not Recruiting Estimated Completion: March 2017

Description The study aims to assess the

The study aims to assess the effect of Tregs on beta cell function as well as on other measures of diabetes severity and the underlying autoimmune response.



Monotherapy with Rapamycin Fondazione Italiana Diabete Onius, Italy

Phase II Recruiting Estimated Completion: March 2019

Description Rapamycin to modulate immune system by reducing IL2. Vildagliptin to promote beta cell regeneration.

Drug combination.



OMEGA-3 and Vitamin D in High Dose DRI/University of Miami Miami, FL

Phase I/II Not Yet Recruiting Estimated Completion: December 2022

Description Combination of Omega-3 and Vitamin D is designed to halt immune system response and preserve residual B-cell function. Two oral drugs.

There are currently no active glucose-responsive insulin or advanced artificial pancreas PC projects in human trials.

Cure Research Spending

The four organizations that fund the majority of type 1 diabetes research conducted in the United States are Juvenile Diabetes Research Foundation (JDRF), the American Diabetes Association (ADA), the National Institutes of Health (NIH) and the Leona M. and Harry B. Helmsley Charitable Trust. JDRF, the ADA and Helmsley Charitable Trust are all non-profit organizations unaffiliated with the government, while the NIH is a US government agency.

Juvenile Diabetes Research Foundation

Founded in 1970 with a mission of finding a cure for T1D, JDRF has grown to become one of the largest and most influential type 1 diabetes organizations in existence. With chapters throughout the world and strong relationships with all the principle investigative research centers, JDRF is uniquely positioned to bring about a major breakthrough.

■ Until 2008, expenditures were consistent with the organization's mission and roughly 70 percent of all income was used to fund research grants. That percentage has steadily declined to 38 percent in 2017. See Chart 6a.

JDRF research spending declined from 67% in 2008 to 38% in 2017.

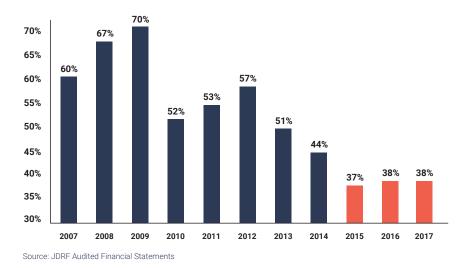


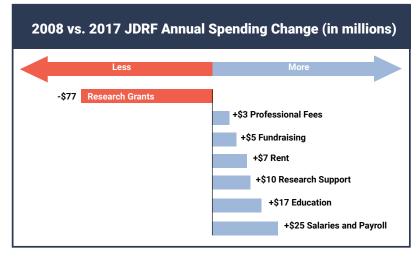
Chart 6a: JDRF Research Grants as a Percent of Annual Income

Internal costs associated with giving research grants, such as salaries, overhead, fundraising and public education also reached a record high, rising dramatically from the early 2000s. In 2007, costs associated with administering research grants were six cents per grant dollar. As of 2017, it rose to 26 cents per research grant dollar.

■ As research spending has dropped to a record low, all other categories have increased, with salaries and payroll rising the most. See **Chart 6b**.

Chart 6b:

2008 vs. 2017 JDRF Annual Spending Change (in millions)

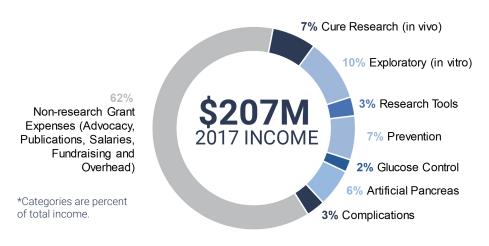


Source: JDRF Audited Financial Statements

During 2017, JDRF posted an annual income of \$207 million. The 38 percent attributed to research addressed a range of topics including cure research, prevention and complications. See Chart 6c.

Chart 6c:

JDRF Utilization of 2017 Annual Income Highlighting Research Grant Categories



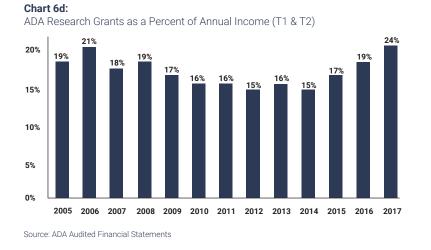
Source: JDRF Audited Financial Statements and JDRF Grant Center

- JDRF funded 494 individual research projects in 2017, a 13 percent decrease from the prior year (571 in 2016).
- The five largest JDRF grant recipients in 2017 collected 19 percent of total grant funding (\$15.2 million). The top five are (in millions): (1) JDRF Canadian Clinical Trial Network (\$3.7); (2) University of Florida (\$3.1); (3) The University of Adelaide (\$2.9); (4) Benaroya Research Institute at Virginia Mason (\$2.8); and (5) The Jaeb Center for Health Research (\$2.7).

American Diabetes Association

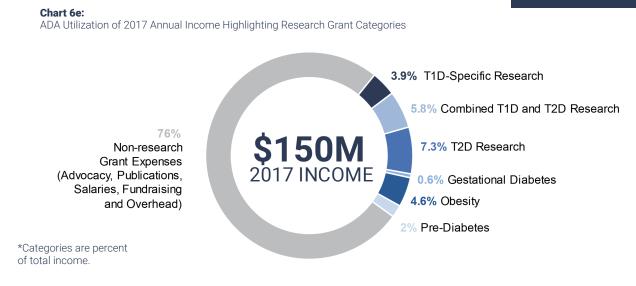
The ADA was founded in 1940 with the mission of finding a cure for all types of diabetes. It has evolved over time to become one of the largest diabetes organizations in the world.

During the 13 years that the JDCA has been tracking the ADA, research spending is down compared to the early 2000s but is relatively constant in terms of the proportion of income. See Chart 6d.



In 2017, the ADA posted revenue of \$150 million, raised primarily from donations and fundraising event proceeds. Only four percent of that income was allocated specifically to T1D research. See Chart 6e.

The ADA spent only 4% of their annual income on T1D research.



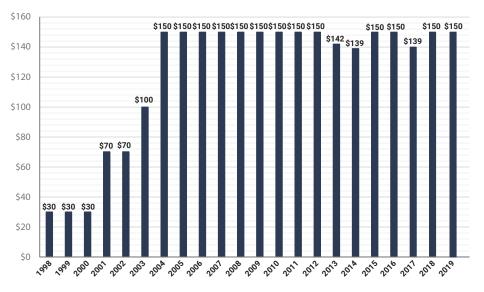
Source: ADA Audited Financial Statements

If the ADA were to commit to a substantial investment and increase their focus on type 1 diabetes, the impact would be monumental. The organization has an outstanding fundraising infrastructure, strong ties on Capitol Hill and access to researchers throughout the world.

National Institutes of Health

The NIH, funded by tax dollars, is the single largest source of funds for T1D research and provides funding for over 250 organizations. The NIH allocated funds to T1D totaled \$383 million in 2016, the most recent year this data was available. Of the \$383 million in total NIH funding, the top five research centers received a total of \$96 million, as shown in the sidebar on the right.

Chart 6f:



NIH Special Diabetes Program Funding: (in millions)

Since 1998, in addition to previously established research fundraising programs, the US government has set aside a special budget for type 1 diabetes research called the NIH Special Funding Program for Type 1 Diabetes. Throughout the past decade, almost 1/2 of the NIH budget for T1D funding has come from funding for the Special Diabetes Program, which has been set at roughly \$150 million annually. See **Chart 6f.** The program was renewed through 2019 and predominately funds large multi-center projects, studies and networks.

It is important to note that very little of this investment has been used to advance a Practical Cure and there are no active Practical Cure trials funded by the NIH.

THE TOP FIVE T1D RESEARCH CENTERS

University of South Florida

- Total T1D budget \$28m
- \$24m of USF's budget comes from the TEDDY Study which is examining child diets, illnesses, allergies and other life experiences with the goal of determining the causes of T1D.

The University of Virginia

- Total T1D budget of \$21m
- The majority of UVA's budget was driven by AP-focused research.

University of Pennsylvania

- Total T1D budget of \$17m
- Awarded for a wide range of research projects, including beta cell health, insulin effectiveness and environmental studies.

Boston University

- Total T1D budget of \$16m
- \$12m was used for a single grant for a pivotal trial for the bionic pancreas.

Joslin Diabetes Center

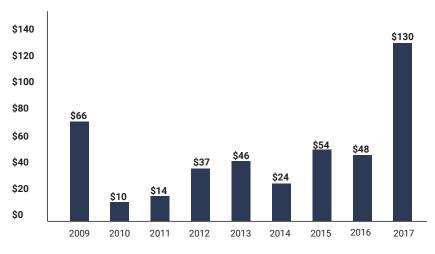
- Total T1D budget of \$14m
- Research project focus includes metabolic research, T1D pathogenesis and immunology research.

Source: NIH Report of Special Diabetes Program Funding, 2018

The Leona M. and Harry B. Helmsley Charitable Trust

The Helmsley Trust was established in 1999 by Leona Helmsley, a real estate billionaire, who upon her death left most of her estate to the Trust. The Trust does not raise money or accept donations.

Helmsley also launched its T1D program in 1999, the same year the Trust was established, and has made significant contributions each year since. See **Chart 6g.** In the nine years since opening, the Trust has spent an average of \$48 million dollars per year on T1D research grants, making it one of the largest supporters of T1D in the world. The continued choice to make T1D a top priority is a huge benefit to the T1D community.





Helmsley specifies two broad objectives for T1D research: "Improve Outcomes for People with T1D" and "Prevent and Delay the Disease." Since the fund began, roughly 53 percent of spending has been attributed to the former, while 47 percent has been spent on the latter.

Helmsley confines its grantmaking to projects that adhere to their objectives, and as a result, does not actively fund Practical Cure research initiatives. If Helmsley adopted Practical Cure as an area of focus, they could have a profound impact on PC progress. PC research is very much in line with Helmsley's guiding principles: "Helmsley supports innovative projects that are high-risk, h igh-reward and have a long-term vision. We encourage bold thinking and new approaches, supporting projects that others cannot fund but have a clear impact on the lives of people with T1D."

Source: The Leona M. and Harry B. Helmsley Charitable Trust

Fundraising for T1D

The ADA and JDRF are the two largest fundraisers for diabetes in the world. Each organization has built an extremely effective fundraising apparatus which combines professional staff with highly passionate volunteers. Both utilize campaigns that are directed nationally but executed on a local chapter level in cities throughout the United States.

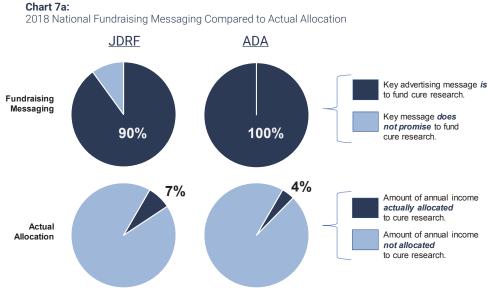
Combined, the two organizations hosted 282 national fundraising events in 2017, including walks, rides and galas, which generated over \$350 million in donations. These events are a prime source of funding for both organizations and deliver 3/4 of JDRF's annual income and 1/2 of the ADA's annual income.

Most of these nationally-directed events either explicitly or implicitly communicate that the proceeds will be used for cure research. Many familiar event names feature a cure message, including JDRF One Walk for a World Without Type 1 Diabetes, Ride to Cure Diabetes, Team JDRF to Cure Diabetes, Tour de Cure and the Step Out Walk to Stop Diabetes.

In 2018, 90 percent of all JDRF national fundraising events featured a cure message, a number consistent with prior years. Yet, only seven percent of JDRF's annual income was utilized for cure research. The ADA featured a cure message in 100 percent of its 2018 events, but only an estimated four percent of annual income was used specifically for T1D research. See **Chart 7a**.

In summary, the fundraising promise remains unaligned with the way proceeds are used. As illustrated in the *Donor Priorities* section of this report, T1D donors clearly prioritize cure research, but only a small portion of donations are actually used to fund cure research.

90% of all JDRF national fundraising events featured a cure message. Only 7% of JDRF's annual income was utilized for cure research.



Source: JDRF and ADA websites and promotional materials. 282 national events reviewed individually.

Donating with Impact

When making an individual donation, the 4S's of Good Giving provides a powerful, straightforward and easy-to-implement approach that will help to ensure your generosity is used the way it is intended. See **Chart 8a**.



Strategy:

Within the T1D community, we know from ongoing market research that nine out of ten people want their gifts to be used to fund cure research. In this case, the objective is to give a gift that is actually used for cure research—any other application would be off strategy.

Select:

There are many fantastic organizations within the T1D community. These can be broken down into three basic groups: (1) major charities such as the ADA and JDRF; (2) medical research centers (either with a national presence or in your local area); (3) specific research projects.

Specify:

When giving to a charity, the only way to ensure your money is used the way you want it to be used is to specify in writing.

Write a letter along with your gift specifically stating how the donation should be used. For example: "*This donation in the amount of \$XX is to be fully used to fund cure research grants.*" If the recipient is not willing or able to use the money to fund cure research they are obligated to return the money. The JDCA also provides cutout donation cards on the next page that you can use to specify that your gift should be used for T1D cure research.

Substantiate:

Every donor has the right to ask how a previous donation was used. This information can help you determine whether you want to continue or adjust your giving strategy. Asking how your gift is used also keeps the recipients on their toes and reminds them they are accountable and dependent upon you, the donor.

Instructions:

- 1. Fill out the card.
- 2. Include the card with your next donation or use it to stipulate a past donation.

HIS DONATION IS FOR A CURE

I require and specify that this donation is to be used *exclusively* for type 1 diabetes cure research.

Recipient Organization Name Donation Dollar Amount Date of Donation Name (Print) Name (Sign) Instructions for the recipient of this card: The donor whose name is indicated on this card requires that the gift in the amount noted above must be fully and wholly used to fund research grants. The gift is not authorized to be used for any other purpose. If the recipient can not fulfill this explicit requirement of the donor, the recipient must return the gift to the donor. **S DONATION IS FOR A CURE** I require and specify that this donation is to be used exclusively for type 1 diabetes cure research **Recipient Organization Name** Donation Dollar Amount Date of Donation Name (Print) DONAT Name (Sign) Instructions for the recipient of this card: The donor whose name is indicated on this card requires that the gift in the amount noted above must be fully and wholly used to fund research grants. The gift is not authorized to be used for any other purpose. If the recipient can not fulfill this explicit requirement of the donor, the recipient must return the gift to the donor. HIS DONATION IS FOR A CURE I require and specify that this donation is to be used exclusively for type 1 diabetes cure research **Recipient Organization Name** Donation Dollar Amount Date of Donation Name (Print) Name (Sign) Instructions for the recipient of this card: The donor whose name is indicated on this card requires that the gift in the amount noted above must be fully and wholly used to fund research grants. The gift is not authorized to be used for any other purpose. If the recipient

can not fulfill this explicit requirement of the donor, the recipient must return the gift to the donor.

