

STATE OF THE **CURE** FOR TYPE 1 DIABETES

2020

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1: Introduction

Welcome to the 9th annual edition of *The State of the Cure for Type 1 Diabetes*. Like all prior State of the Cures, it summarizes progress made in the past year towards a Practical Cure (PC) for type 1 diabetes (T1D).

Any review of progress toward a Practical Cure must begin with the sobering fact that there is still a long road ahead. This report will identify key structural problems in the research ecosystem and offer solutions. Last year, the JDCA identified two roadblocks to efficient PC development: the decline of T1D research funding to historic lows at major T1D nonprofits, and the scarcity of active PC research in human trials. One year later, these issues have only been exacerbated by COVID-19, putting the entire T1D cure research ecosystem in a vulnerable state.

The four largest government or philanthropic funders of T1D research in the United States are JDRF, the American Diabetes Association (ADA), the National Institutes of Health (NIH), and the Leona M. and Harry B. Helmsley Charitable Trust. JDRF and the ADA are facing a large drop in fundraising as the in-person events that drive the organizations' incomes were compromised by COVID-19. Although the NIH remains the largest not-for-profit funder of T1D research grants in the United States, only 16% of its total diabetes budget was spent on T1D research in 2019, with the other 84% going to type 2 research. Only Helmsley, an independent trust whose level of focus on T1D is determined by trustees, is in a position to maintain or even strengthen its T1D research program going into 2021. The financial data in this report does not reflect the COVID economy, as the latest publicly available information is from Fiscal Year 2019. However, examining 2019 financials shows the priorities of the major T1D research-funding organizations heading into a year of unprecedented fiscal challenges.

The need for a Practical Cure has only intensified for people with T1D in 2020. Managing T1D is a 24-hour a day reality and the financial, emotional, and physical burdens the T1D community experience are only made worse by the global pandemic. A Practical Cure is the only kind of solution that would alleviate these stresses and allow people with T1D to live a normal life.

Now more than ever, the community of donors, researchers and funders should come together with the singular purpose of pursuing a T1D Practical Cure. In doing so, the organizations which fund T1D research will emerge from this moment of widespread change more mission-oriented and aligned with the T1D donor base.

THE GLOBAL BURDEN OF TYPE 1 DIABETES



45 million

children and adults have type 1 diabetes

1,100,000

children have type 1 diabetes

45% of all newly diagnosed type 1 diabetes patients are children under 18



Type 1 diabetes in children is increasing by **3% annually**



\$76 BILLION

is spent on type 1 diabetes globally per year (3.5x more than 2008)

The cost of care has skyrocketed **+686%**



By 2045 more than

70 MILLION
will have type 1 diabetes

We Need a Cure NOW

Source: IDF Diabetes Atlas, 2019 and AJMC, 2019

2: Donor Priorities Survey Results

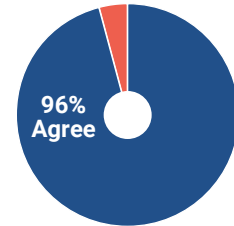
The vast majority of the donations that fuel the major type 1 diabetes charities come from those most affected by T1D: people living with T1D, as well as, their family and friends. This section will summarize key findings from biannual surveys of T1D donors and fundraising event participants. The purpose of these surveys is to understand what motivates T1D donors to give their time and/or money to support various diabetes charities.

COVID-19 directly impacted the grassroots fundraising events that drive the majority of T1D nonprofit revenues. Starting in March 2020, JDRF and the ADA moved their grassroots fundraising events to virtual platforms to comply with social distancing. Nevertheless, the key finding of this year's survey is the same as all prior years: participants took part because they wanted to raise money to fund T1D cure research. Additional key findings are summarized below.

- **96%** of donors believe cure research should be the number one priority for charities. **See Chart 2a.** This result is consistent with survey findings from prior years.
- **84%** of donors believe 100% of the money raised at fundraising events should be used for cure research. Said differently, four out of five participants want ALL of the event proceeds to be used for cure research.
- **91%** of donors would donate to support Practical Cure research if that option were made easily available to them. This trend has remained consistent for the past seven years. **See Chart 2b.**
- **90%** of donors 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.
- **65%** 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:

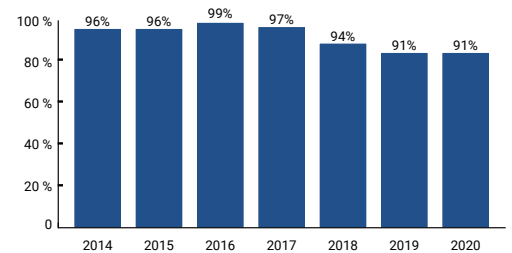
"Is cure research the primary reason you make a donation to a diabetes charity and/or participate in a fundraising activity?" Answer is percent who agree.



Source: JDCA Survey of Donor Sentiment, March 2020

Chart 2b:

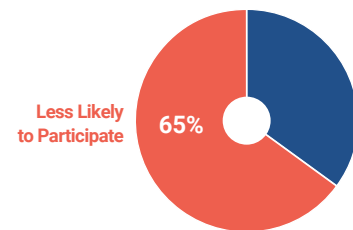
"Would you donate to Practical Cure research projects if that option was made easily available to you?" Answer is percent who agree.



Source: JDCA Annual Surveys of Donor Sentiment, 2014-2020

Chart 2c:

Percent of donors who are **less likely to participate** in future ADA/JDRF fundraising walks after learning what the organizations spend on research.



Source: JDCA Survey of Donor Sentiment, March 2020

HOW DO **T1D** DONORS WANT THEIR **MONEY** USED?

25 MILLION PEOPLE

have a family member or close relative
with T1D

Together they donate

\$450 MILLION DOLLARS

per year to TYPE 1 DIABETES

96%

**Say they want their money to be
used for cure research**

Source: JDCA Survey of Donor Sentiment and JDCA Estimate of Annual Donations from the ADA, JDRF, and Other Research Institutions

3: 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 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 but have made little progress since the discovery of insulin. Alternatively, there are a few 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 towards it. **Over the past seven years, the T1D community has expressed their preference to prioritize the pursuit of a Practical Cure over all other types of research.**

A PRACTICAL CURE IS OUTCOME FOCUSED

The clinical requirements infographic on the right shows the various outcome criteria that a Practical Cure must meet. The requirements are based on direct feedback from the T1D community and represent the outcomes that patients want. Any research approach, pathway, or philosophy that can deliver these outcome objectives should be pursued.

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. On average, it requires 10-15 years from the beginning of human trials to receive FDA pre-market approval. As a result, 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 first and most important benefit is that a time goal puts an emphasis on helping people who are currently living with the disease. The second important benefit of a time goal is that it provides a structure for prioritizing projects. Clinical trials 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.

Clinical Requirements Needed to be a Practical Cure for T1D

- HBA1C <7% and/or >75% Time in Range (70-180 mg/dl)
- Minimal Monitoring
- Free Diet
- Eliminate Hypos
- Only Mild and Temporary Side Effects (no long-term side effects)
- Less than 5 Days in Hospital (if surgical)

4: Practical Cure Pathways

There are seven research pathways that can 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 pathways are discussed below.

Immune System Modification utilizes drugs or stem cell therapy to stop the body's immune system from attacking insulin-producing beta cells. To date, the only way to achieve this is by taking full-body immune-suppressing medication, which reduces the body's overall disease fighting capability. But, if the side effects related to immune suppression are reduced, the risks of immune suppression may become less than the risks of complications associated with type 1 diabetes. Alternatively, targeted immune system modification therapies, which do not carry the same risks as full-body immune suppression, have seen promising advances over the last ten years.



Encapsulation involves the development of a device to protect cells from the body's immune response. There are two types of encapsulation: microencapsulation, in which each cell or islet is housed in its own micro-capsule, and macroencapsulation, in which many cells and islets are contained within a single device. Essential to a successful encapsulation approach is the identification of a biomaterial which is accepted by the immune system and capable of supporting vein and tissue growth so the encapsulated insulin-producing cells are able to release insulin into the blood.



Cell Regeneration involves regenerating residual beta cell mass that persists in the body even after many years of living with T1D. Currently, a number of projects and therapies are being tested in people with fully established T1D in hopes that once the autoimmune attack is curtailed, beta cells will be able to freely regenerate.



Gene Editing Cell Therapy involves editing cells using gene therapy so that they are not recognized by the T1D autoimmune attack. Although promising, this pathway is relatively new and therefore still in the very early stages of testing.



Cell Transplantation involves implanting islet cells, stem cells, or precursor cells into a person with type 1 diabetes to achieve insulin independence. 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.



Glucose-Responsive Insulin (GRI), also known as "smart insulin," is chemically activated in response to changes in blood glucose. GRI 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. A number of companies are currently developing GRIs, almost all of which are still in preclinical development.



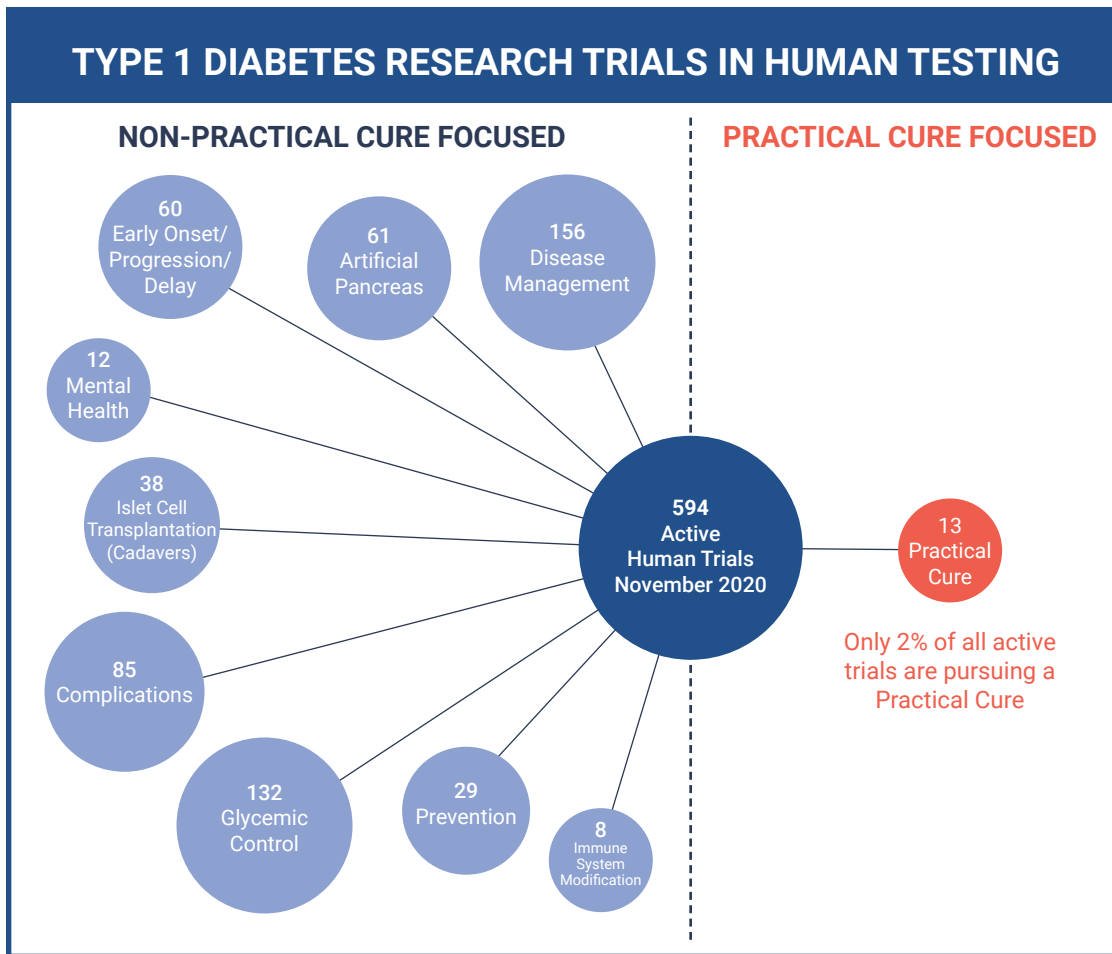
The Advanced Artificial Pancreas is a device that mimics the glucose-regulating functions of a healthy pancreas, automatically controlling blood glucose levels and delivering insulin. In a recently completed survey of the T1D community, 88% of respondents said an AP device would qualify as a Practical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



5: Practical Cure Projects in Human Trials

As of November 2020, there were 594 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. In addition, there are only seven Practical Cure projects currently in development. Those seven projects are being tested in 13 clinical trials (some projects are being tested in more than one trial). **See Chart 5a.**

Chart 5a:




Source: Clinicaltrials.gov

To be included as a Practical Cure, trials must target an increase in C-peptide production as a primary or secondary endpoint measure, with the exception of Glucose-Responsive Insulin and Artificial Pancreas trials. 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). Please note that the JDCA presents these projects without any indication of preference or ranking.

Since our last Practical Cure update in June 2020, one new project has been added, PIpepToIDC at City of Hope. Two projects have been removed, Beta-02 and Monotherapy, both of which completed with unsuccessful results. Full details for each of the seven active Practical Cure projects are detailed on the following page.

Active Practical Cure Projects



Stem Cell Educator
Tianhe Stem Cell Biotech, Hackensack, NJ and Beijing, China (5 Trials)

Research Pathways

- Immune System Modification
- Cell Regeneration

Phase: II/III
Paused Due to COVID-19

Timeline
Estimated Completion: December 2021

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



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

Research Pathways

- Immune System Modification
- Cell Regeneration

Phase: I/II
Recruiting

Timeline
Estimated Completion: December 2023

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



TOL-3021
Tolerion, Portola Valley, CA


Research Pathways

- Immune System Modification
- Cell Regeneration

Phase: II
Not Yet Recruiting

Timeline
Estimated Completion: December 2023

Description
Vaccine designed to selectively repress T cells inappropriately activated in type 1 diabetes.



Umbilical Cord Blood Regulatory T Cells Plus Liraglutide
Second Xiangya Hospital, Hunan, China


Research Pathways

- Immune System Modification
- Cell Regeneration

Phase: I/II
Recruiting

Timeline
Estimated Completion: December 2020

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



Liraglutide or Golimumab
Benaroya Research Institute, Seattle, Washington


Research Pathways

- Immune System Modification
- Cell Regeneration

Phase: I
Early Phase 1
Paused Due to COVID-19

Timeline
Estimated Completion: June 2020

Description
Liraglutide works to increase insulin release from the pancreas and decrease excessive glucagon release. Golimumab decreases inflammation caused by autoimmune attacks.



PipepToIDC
City of Hope Medical Center, Duarte, CA

Research Pathways

- Immune System Modification
- Cell Regeneration

Phase: I/II
Recruiting

Timeline
Estimated Completion: October 2022

Description
Immunotherapy vaccine composed of the patient's cultured immune cells, a beta cell protein, and vitamin D3 teaches the immune system to stop attacking beta cells and reduces inflammation.



PEC-Encap
Viacyte, San Diego, CA (3 Trials)

Research Pathways

- Cell Transplant
- Encapsulation

Phase: I/II
Recruiting

Timeline
Estimated Completion: January 2021

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.

6: Cure Research Spending

The four organizations that fund most of the type 1 diabetes research conducted in the United States are JDRF, the American Diabetes Association (ADA), the Leona M. and Harry B. Helmsley Charitable Trust, and the National Institutes of Health (NIH). JDRF, Helmsley, and the ADA are all nonprofit organizations, while the NIH is a US government agency. This section summarizes spending at these organizations in 2019, the most recent year financial data is available. The main takeaway is that research spending, specifically T1D cure research spending, has declined dramatically over the last decade and is now at record lows.

In 2020, COVID-19 dramatically reduced the fundraising capacity of the major diabetes nonprofits. In early August, JDRF announced that since the COVID-19 pandemic hit the US in March, fundraising had declined by 40% compared to the prior year. Although the ADA has not specifically stated the amount of fundraising lost to date, we expect to see similar declines. Because the responsibility for funding T1D cure research has largely fallen to these four entities, any interruption to their ability to raise money could be detrimental to the T1D cure research ecosystem and will further exacerbate already low research spending levels. It is imperative that these organizations protect their current research budgets and cover the decline in fundraising by reducing other programs.

JDRF

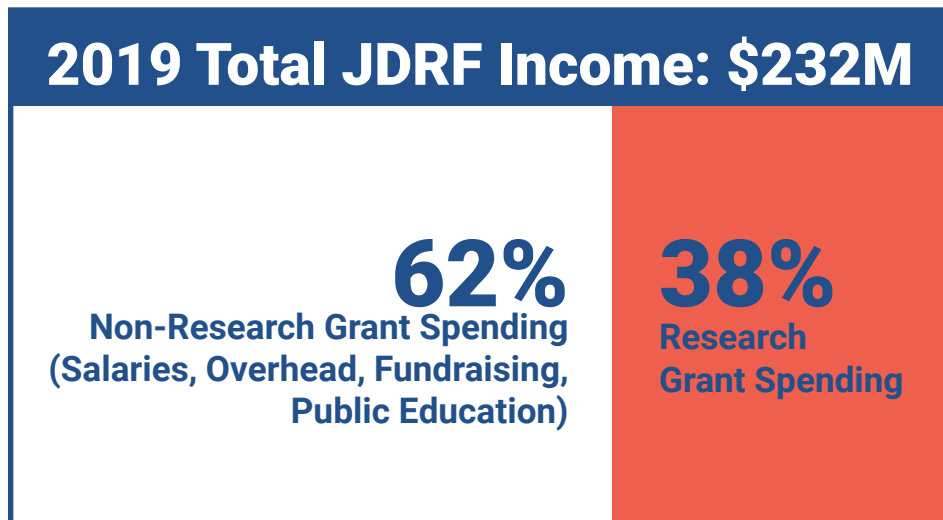
Founded in 1970 with a mission of finding a cure for T1D, JDRF has grown to become one of the largest and most influential type 1 diabetes organizations in existence. With chapters throughout the world and strong relationships with all the principal investigative research centers, JDRF is uniquely positioned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

JDRF's total annual revenue for 2019 tied a 15-year record-high at \$232m*. The previous \$232m record was reported in 2008 when research grant spending as a percent of total revenue was 67%. Comparatively, in 2019, it was only 38%. This remains a significant concern for all in the T1D community interested in T1D research funding. The other 62% went to non-research grant expenses such as salaries, overhead, fundraising, administration, and public education. **See Chart 6a.**

**Note: \$15m of JDRF's annual income came from the JDRF T1D Fund, a "disregarded tax entity" of JDRF. All T1D Fund revenue is consolidated in JDRF's total revenue.*

Chart 6a:

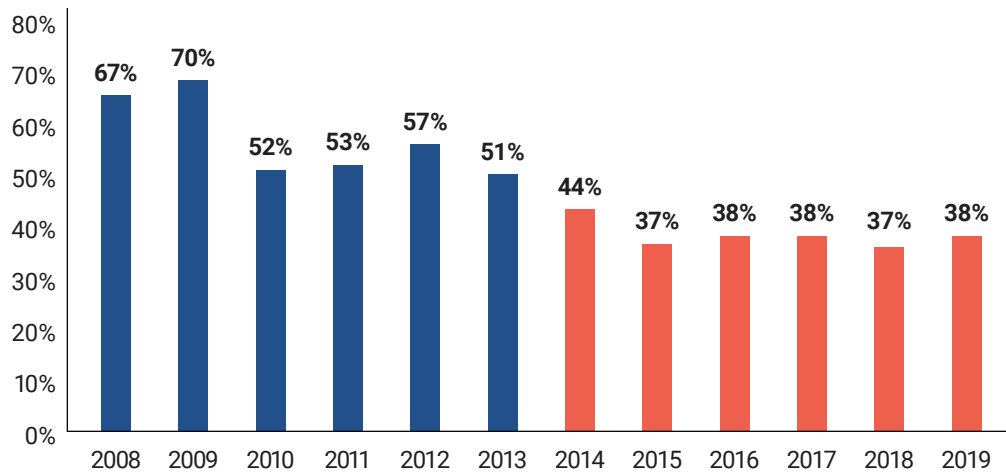
JDRF Research Grant Spending Vs. Non-Research Grant Spending



JDRF Research Spending and Administration Costs

Research expenditures were consistent with JDRF’s mission of funding T1D research until 2008, when 67% of organizational income was used to fund research grants. That percentage has steadily declined to 38% in 2019. Said differently, JDRF research grant spending decreased from \$156m in 2008 to \$85m in 2019. **See Chart 6b.**

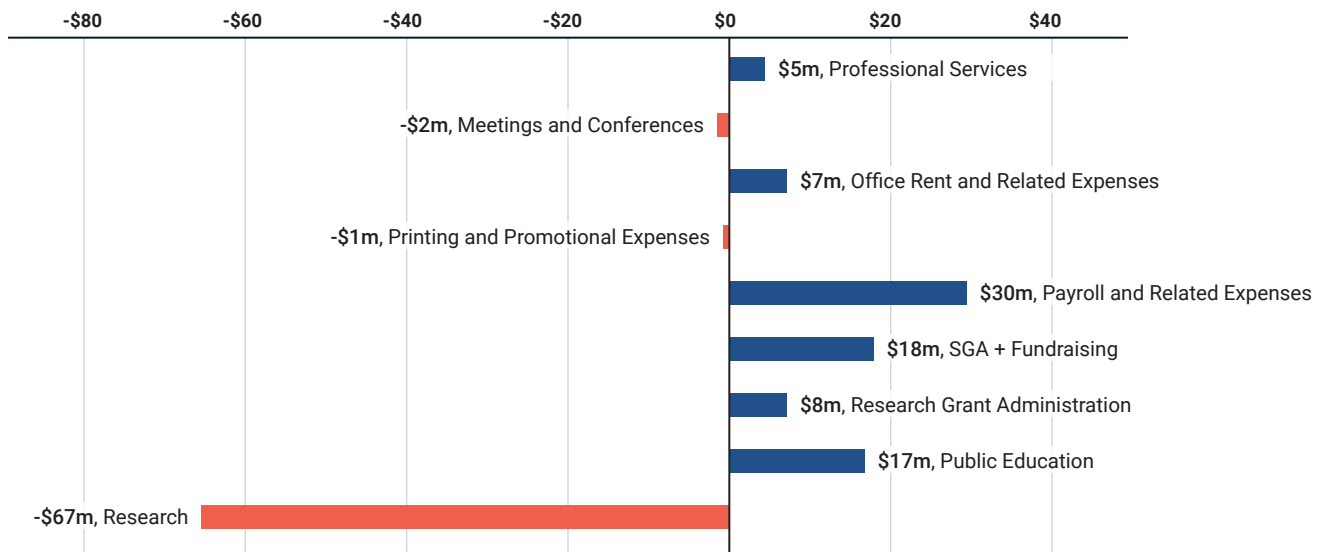
Chart 6b:
JDRF Research Grants as a Percent of Annual Income



Source: JDRF Audited Financial Statements

As research spending dropped to record lows, all other expenditure categories have increased, most notably salaries and payroll. Over the past ten years JDRF payroll expenses more than doubled while research grant spending, the most important and strategic job of JDRF, declined by \$67 million. See Chart 6c.

Chart 6c:
2008 vs. 2019 JDRF Annual Spending Change (in millions)

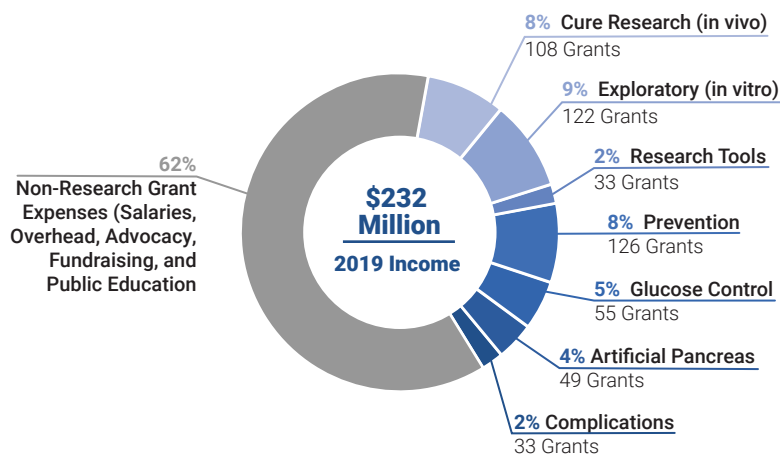


Source: JDRF Audited Financial Statements, 2008 vs. 2019

JDRF Cure Research Spending

The JDCA individually reviewed each of the 529 projects JDRF funded in 2019. Only 8% of JDRF's total income (\$19m) was attributed to cure research in humans or animals. **See Chart 6d.**

Chart 6d:
JDRF 2019 Research Grant as Percent of Total Income by Category



Source: JDRF Audited Financial Statement, 2019 and JDRF Grant Center

During the past five years, the JDRF research funding strategy appears to have become less focused. JDRF spread \$89m over 529 grants in 2019, compared to \$100m over 387 grants in 2014. In addition, cure research spending is down 33% from \$27m in 2014 to \$18m in 2019, while the amount of money JDRF allocated to prevention research more than doubled. **See Chart 6e.** JDRF's choice to prioritize prevention research spending over cure funding is a major concern for people living with established T1D, as it highlights a clear JDRF strategy shift away from cure research.

Chart 6e:
JDRF Grants as Percent of Total Income Category

Research Categories	2014	2015	2016	2017	2018	2019
Cure Research (in vivo)	12%	7%	7%	7%	7%	8%
Basic and Exploratory (in silico/in vitro)	5%	10%	13%	10%	8%	9%
Research Tools	6%	3%	4%	3%	3%	2%
Prevention	4%	2%	6%	7%	9%	8%
Glucose Control	4%	2%	1%	2%	2%	4%
Artificial Pancreas	7%	7%	4%	6%	6%	5%
Complications	5%	4%	3%	3%	2%	2%
Psychosocial	n.a.	n.a.	n.a.	n.a.	n.a.	<1%
Total	45%	37%	38%	38%	37%	38%

Source: JDRF Audited Financial Statements and JDRF Grant Center

COVID-19 Drives Change at JDRF

During 2020, JDRF implemented a series of major structural changes in response to its decline in fundraising. In-person events, the bread-and-butter of JDRF fundraising, were put on hold to comply with public health measures. Although many events were converted to virtual, JDRF expects that overall fundraising in 2020 will be significantly less than prior years.

This crisis in cash flow provided the spark for management to make major changes in operations. Several of the changes follow recommendations made by the JDCA over the years and have the potential to make JDRF leaner and more focused. However, other potential changes pose a challenge to the organization's mission. The main changes are identified below:

A Leaner Organization

JDRF reduced the size of its organization considerably during 2020. The number of JDRF employees was cut from 700 to 400, and the number of regional chapter offices decreased from 63 to 29. JDRF also reduced the size of its Board of Directors from 35 to 15, a reduction that the JDCA has advocated in discussions with a number of past JDRF CEOs and Board Chairs. A smaller board— one similar in size to high performing for-profit and non-profit organizations— will allow for a more focused discussion on strategic direction and performance achievement.

Additional Cuts to Research Spending

JDRF has indicated that the decrease in fundraising will cause research funding to decrease proportionally. A JDRF spokesperson said, "going forward with a smaller budget during the global pandemic, we plan to continue to spend about the same share of resources on mission as in years past." A 40% decrease in research grant funding would decrease the grant budget from \$89m to \$53m, a \$36m drop.

Rather than decreasing the research budget proportionally with the other expense categories, this time of upheaval could be used to return JDRF to its primary mission of funding research to cure T1D. JDRF leadership, including the Board and CEO, have a duty to protect the community's investment in T1D research now and into the future.

Looking Outside of the T1D Community for Financial Support

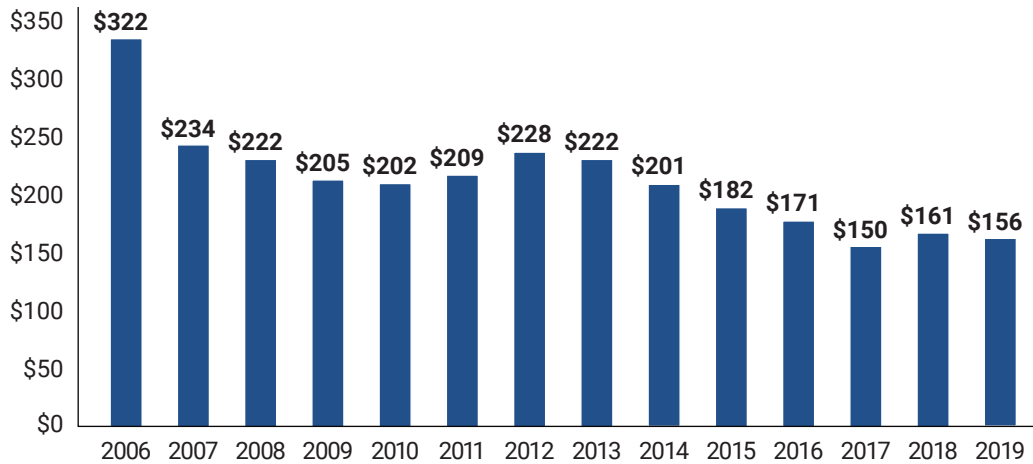
JDRF has begun actively pursuing communities outside of T1D. According to a JDRF press release, "moving forward, JDRF will also engage people outside areas where we have chapters and staff and look outside the T1D community for support from people with type 2 diabetes and other autoimmune disorders." The spirit of this move is to raise money from previously untapped sources. However, there are added costs required to solicit these communities and once donations are received there will be an expectation of reciprocity and an inherent pressure for JDRF to deliver value to these non-T1D groups. Over time, this may put the mission of the JDRF at risk.

The JDCA surveyed the T1D community to gauge support for the move outside of T1D. The move is strongly opposed by JDRF donors, 81% of whom believe the plan to expand into T2D and other autoimmune disorders is "unaligned/completely off-track with JDRF's mission."

The American Diabetes Association

The American Diabetes Association (ADA) was founded in 1940 with the mission of finding a cure for all types of diabetes. Although it remains one of the largest and most powerful diabetes non-profits in the world, the organization has experienced a 50% decline in revenue over the past 15 years. **See Chart 6f.**

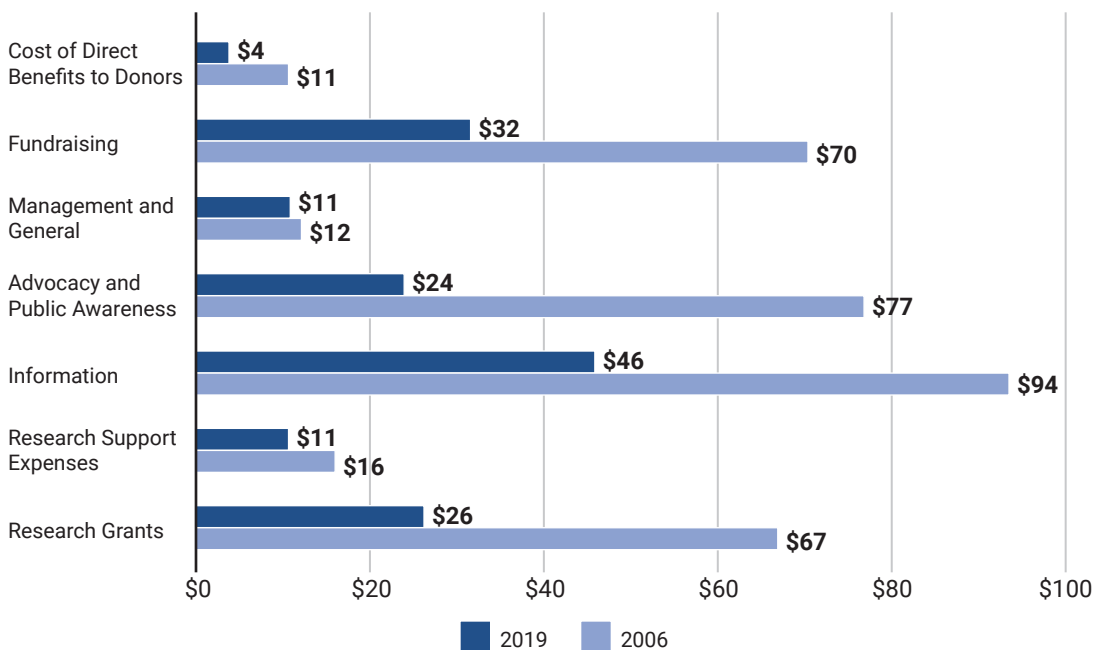
Chart 6f:
ADA Revenue by Year (in millions)



Source: ADA Audited Financial Statements, 2006-2019

74% of the loss in ADA revenue from 2006 can be attributed to the decline of two sources: fundraising events and direct donations, which collectively dropped from \$200m in 2006 to \$78m in 2019. An additional 23% of the loss in revenue came from the deterioration of two paid services: subscriptions and sales of materials. In 2006, the ADA earned \$52 million by selling publications about diabetes and related products. By 2019, the amount earned from these services dropped to \$14m, presumably due to the rise of digital information sources.

Chart 6g:
ADA Major Expense Categories by Year (in millions): 2019 vs. 2006



Source: ADA Audited Financial Statements, 2006 vs. 2019

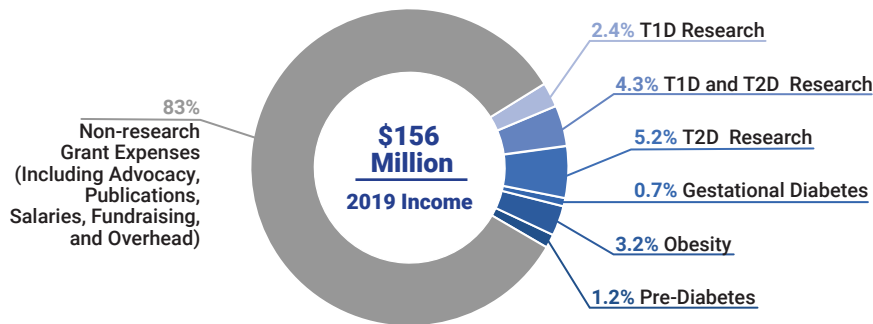
With less revenue, the ADA was forced to cut its programmatic and operational spending significantly. Consequently, almost all major ADA programs and services have been rolled back. **See Chart 6g.**

Advocacy and public awareness declined more than any category, down 69% (-\$53m) from 2006. Research grant spending, the number one priority of T1D donors, is down 61% (-\$41m) from \$67 million in 2006 to only \$26 million in 2019.

The vast majority of the \$26m that the ADA spent on research grants in 2019 went to T2D-related research. **See Chart 6h.** Only \$4m (2.4% of ADA's total income) went to T1D-specific research. For every dollar given to the ADA, only two cents were used for T1D research. This sustained low percentage has remained consistent over the past eight years.

ADA Research Grant Spending

Chart 6h:
ADA Research Grants as Percent of Total Income by Category in 2019



Source: ADA Audited Financial Statement, 2019 and ADA Grant Center

The T1D community is an extremely active fundraising enterprise that has previously shown strong support for the ADA. However, in recent years it appears the T1D community has increasingly rallied behind JDRF in lieu of the ADA, who only spent 2% of its total income on T1D-specific research. Although JDRF research grant spending has also decreased over the last decade (67% to 38% of total revenue), it remains the preferred charity for those interested in supporting T1D.

The decrease in donor engagement at the ADA, as illustrated by a dramatic decline in donor-driven revenue sources, should serve as a cautionary tale for all major T1D nonprofits. Major diabetes organizations have a practical, as well as moral, imperative to spend their income in-line with the priorities of donors. These donors are essential to the continued financial survival of the organizations, and, in turn, the organizations are essential to driving progress towards a Practical Cure. When they became unaligned with donors, fundraising declines over time.

The National Institutes of Health

In Fiscal Year 2019, the National Institutes of Health (NIH) was the largest not-for-profit funder of T1D research grants in the United States. Out of a \$1.1 billion budget for diabetes, the organization directed \$173 million to T1D research. Key summary points below:

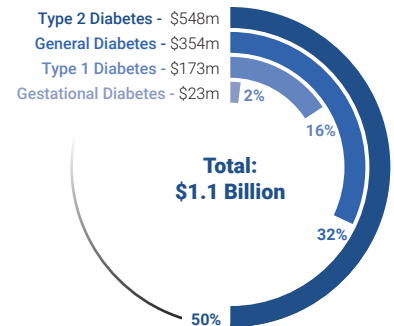
- **\$1.1 billion** was the NIH annual budget for diabetes research in 2019.
- **\$173 million** was the amount allocated by the NIH to fund T1D research grants, 16% of the total diabetes budget. **See Chart 6i.**
- **\$902 million** was the amount allocated by the NIH to fund T2D and general diabetes research, 82% of the total budget.
- The NIH funded **zero** Practical Cure projects in 2019.
- **\$25 million** million was awarded to T1D research projects in animal or human testing that could have a potential PC application in the future. **See Chart 6j.**
- The University of South Florida was the top recipient of T1D funding, receiving **\$33 million** to administer the TEDDY study, a long-term multi-center research project studying the genetic causes of T1D.

Special Diabetes Program Status

T1D research funding at the NIH is primarily secured by the Special Statutory Funding Program for Type 1 Diabetes Research, also known as the Special Diabetes Program (SDP). Congress established the SDP in 1998 as a dedicated funding stream for research grants to prevent, cure, manage, and reduce complications of T1D. The SDP, and the NIH in general, are funded by taxpayers and should be representative of their best interests and priorities.

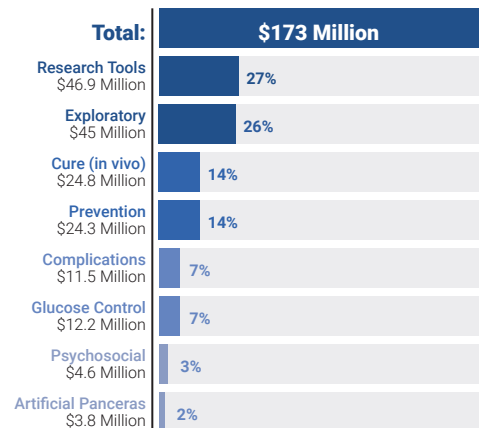
Funding for the SDP was patched together from various sources in 2020. In March 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act granted \$75 million to fund the program through November 30, 2020. In October 2020, an additional resolution was passed to carry SDP funding through December. On December 21, Congress approved a bill that will fund the program at \$150 million per year through Fiscal Year 2023. With a long-term funding source finally in place, NIH-funded T1D researchers should be able to continue their work advancing the understanding of the disease uninterrupted.

Chart 6i:
NIH Diabetes Spending



Source: NIH Grant Database

Chart 6j:
NIH T1D Spending by Research Type



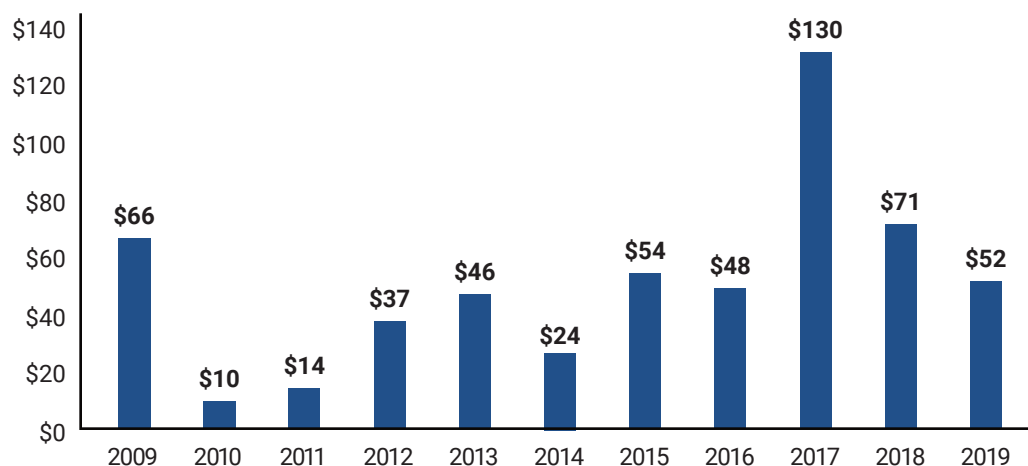
Source: NIH Grant Database

The Leona M. and Harry B. Helmsley Charitable Trust

The Helmsley Trust is a private foundation established in 1999 by Leona Helmsley, a real estate mogul who left a significant portion of her estate to the Trust upon her death. In 2019, the assets of the Helmsley Trust surpassed \$6 billion.

The Trust has freedom to support any cause chosen by its Trustees. Over the past 11 years, the program has made T1D one of its top priorities, allocating an average of \$50 million to T1D grants per year. In 2019, the Trust allocated \$52m in grants to T1D. **See Chart 6k.** The T1D community is fortunate to have a large private Trust fighting for our cause.

Chart 6k:
Helmsley T1D Spending by Year (Millions)



Source: Helmsley Charitable Trust Website

T1D Program Objectives

The two main objectives of Helmsley's T1D program are to "Improve Outcomes for People with T1D" and to "Prevent and Delay T1D." The former program aims to ease the burden of diabetes management and improve quality of life through funding grants in glucose control, broadening access to care, and community education/support. The latter focuses on near-term clinical therapies, funding grants that strengthen research infrastructure and develop impactful research tools to prevent and delay T1D.

A Practicle Cure Program for T1D?

Helmsley does not currently have a program that is focusing specifically on finding a cure for T1D. However, the organization could make a powerful impact on cure progress should it branch out in that direction. The JDCA believes that a Practical Cure program would fit with Helmsley's objective of making near-term impact by delivering a truly life-changing solution to the T1D community.

7: Fundraising for T1D

The ADA and JDRF have built extremely effective fundraising apparatuses that combine professional staff with highly passionate volunteers. Combined, the two organizations hosted 218 (mostly virtual) fundraising events in 2020.

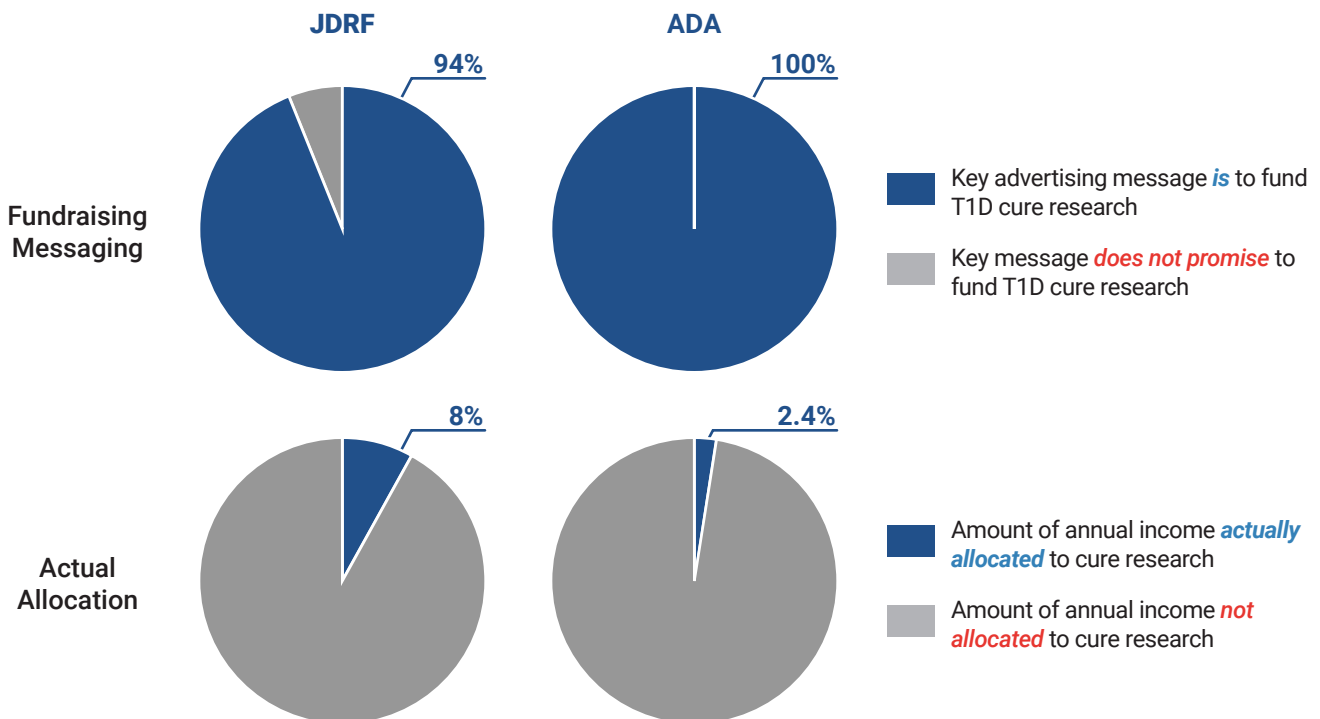
COVID-19 directly impacted these events. Starting in March, walks, galas, and bike rides were either moved to a virtual platform, rescheduled, or canceled. As a result, these events were not able to raise the same amount of revenue as the in-person events of prior years. However, they utilize the same marketing message.

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

In 2020, 94% of all JDRF national fundraising events featured a cure message, a number consistent with prior years. Yet, only 8% of JDRF's annual income was utilized for cure research. The ADA featured a cure message in 100% of its 2020 events, but only an estimated 2% of annual income was used specifically for T1D research. **See Chart 7a.**

Consequently, JDRF and the ADA's fundraising promise remains largely misaligned with the way they allocate revenue.

Chart 7a:
2019 National Fundraising Messaging Compared to Actual Allocation



Source: JDRF and ADA 2019 Websites and Promotional Materials. 218 National Events Reviewed Individually.

8: 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**.

Chart 8a:
The 4S's of Good Giving



Strategy:

The first and most important step is to clearly state what impact you want your gift to deliver. If you are one of the 97% who want their gifts used to fund cure research, your 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) national or local medical research centers (either with a national presence or in your local area); (3) specific research projects. Choose the one that is most capable of delivering your strategy.

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.

THIS 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.



THIS DONATION IS FOR A CURE

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Juvenile Diabetes
Cure Alliance
The Voice of the Donor For a Cure