



STATE OF THE CURE FOR TYPE 1 DIABETES

A comprehensive look at the year's progress
towards a T1D Practical Cure.



2021

Table Of Contents

Chapter 1: <i>Introduction</i>	Page 1
Chapter 2: <i>Noteworthy Practical Cure News</i>	Page 2
Chapter 3: <i>Donor Priorities</i>	Page 3
Chapter 4: <i>Practical Cure Definition</i>	Page 5
Chapter 5: <i>Practical Cure Pathways</i>	Page 6
Chapter 6: <i>Practical Cure Projects in Human Trials</i>	Page 7
Chapter 7: <i>Cure Research Funding</i>	Page 9
Chapter 8: <i>Fundraising for T1D</i>	Page 16
Chapter 9: <i>What It Will Take To Achieve a Practical Cure</i>	Page 17

Chapter 1: Introduction

Welcome to the 10th edition of *The State of the Cure for Type 1 Diabetes*. This annual report provides a review of the progress made during the past year towards a Practical Cure for T1D. While 2021 did have some bright spots, the year was largely defined by the impacts of the COVID pandemic.

As with every other sphere of life, COVID-19 challenged the T1D research landscape. The research conferences where scientists meet, mingle, and share results were conducted via virtual platforms. COVID restrictions slowed or delayed recruitment and participation in critical human trials. Established researchers continued their work but only one new Practical Cure clinical trial began recruiting patients. Lastly, non-profit revenues suffered when in-person fundraising events were canceled or transitioned to a virtual platform.

Unfortunately, COVID exacerbated a long-term trend of declining T1D cure research spending. When fundraising revenue among the major diabetes non-profits took a big hit, research grant funding was the first cut that T1D nonprofits made to balance their books. As a result, JDRF and the American Diabetes Association (ADA) spent less on T1D research grants than they have in the past twenty years.

T1D projects in human trials also stalled during 2021. Only 10 human trials – out of 590 T1D trials in the FDA pipeline – are pursuing a T1D Practical Cure. Just one new Practical Cure project started recruiting in 2021, and one project dropped out without publishing results.

Despite these setbacks, 2021 also had a few bright spots. Research into stem-cell-derived beta cells made notable progress, advancing towards the goal of providing an infinite supply of functioning beta cells for transplant into people with T1D. The JDRF T1D Fund, a venture philanthropy fund that is an independent subsidiary of the JDRF, continued to attract new money to T1D commercial enterprises. The National Institutes of Health (NIH) committed to maintaining its Special Diabetes Program, ensuring crucial funding for T1D research through 2023. The Helmsley Charitable Trust, a private endowment foundation, continued to prioritize T1D as one of its main research platforms.

As we reflect on both the good and the challenging aspects of 2021, we arrive at one fundamental question: *What will it take to achieve a Practical Cure for T1D within the next 15 years?*

Achieving a Practical Cure within our lifetime requires a paradigm shift driven by donors and adopted across the T1D research ecosystem. We cannot maintain the status quo and expect better results. Now is the time for the unified voice of the T1D donor community to bring this dream to life by pushing research institutions to prioritize a Practical Cure.

Chapter 2: Noteworthy Practical Cure News

January 14, 2021



CITY OF HOPE BEGINS RECRUITING FOR A PRACTICAL CURE TRIAL

City of Hope, a Southern California cancer research center, began recruiting patients for a phase 1/2 safety trial testing a 'reverse vaccine' meant to train the immune system not to attack the pancreas.

March 10, 2021



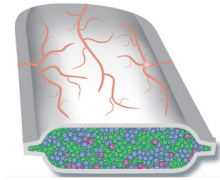
VERTEX STEM CELLS FAST-TRACKED BY FDA

Vertex officially started its first human trial of VX-880, a line of insulin-producing pancreatic cells derived from stem cells.

February 2, 2021

VIACYTE BEGINS RECRUITING PATIENTS FOR BETA CELL REPLACEMENT TRIAL

ViaCyte started a human trial testing a new device, developed in collaboration with the company that produces Gore-Tex, that is designed to replace cells' ability to produce insulin in patients with T1D.



May 20, 2021

STEM CELL COMPETITORS SHARE THE STAGE

For the first time, ViaCyte, Vertex, and Sigilon – three well-known competitors developing stem cell solutions for T1D—shared a public stage to discuss their progress.



July 15, 2021



ELI LILLY MAKES BET ON GLUCOSE-RESPONSIVE INSULIN COMPANY

Eli Lilly acquired a small biotech which is developing a glucose responsive 'smart' insulin currently in preclinical production.

August 30, 2021

ADA CEO ANNOUNCES RESIGNATION

The American Diabetes Association (ADA) announced that Chief Executive Officer Tracey D. Brown stepped down after a 2 year term. The ADA has not yet named a long-term successor, but the CEO search provides an opportunity to appoint a leader who will make T1D cure research a priority once again.



November 17, 2021



CANADIAN HEALTH AGENCY GREEN LIGHTS FIRST T1D GENE EDITING TRIAL

The Canadian health regulatory agency approved partners ViaCyte and CRISPR Therapeutics to begin the first ever T1D human trial that utilizes CRISPR-Cas9 gene editing. The companies first partnered in 2018 to develop insulin-producing cells that are hidden from immune rejection via gene editing.

Chapter 3: Donor Priorities

The T1D community is a fundraising powerhouse, driving hundreds of millions of dollars in donations to T1D organizations every year. Annual surveys seek to understand what motivates T1D donors and event participants to give. These surveys address two essential questions: *What are the top priorities of the people who donate to or participate in fundraising events for type 1 diabetes? When we give, how do we hope our money is used?*

COVID-19 continues to directly impact the grassroots fundraising events that drive T1D nonprofit revenues. Starting in March 2020, JDRF and the ADA moved their grassroots fundraising events to virtual platforms to comply with social distancing. While some in-person events occurred in 2021, the vast majority of events continue to occur on a virtual platform.

Regardless of this change, the key finding of this year's survey is the same as the years before COVID: People donate to and participate in fundraising events for T1D because they want to fund cure research.

Key Survey Findings:

97% Believe cure research should be the number one priority for T1D organizations. **See Chart 3a.** This result is consistent with survey findings from prior years.

83% Believe ALL of the money raised at fundraising events should be used for cure research.

95% Would donate to Practical Cure research if that option were made easily available to them. This trend has remained consistent for the past seven years. **See Chart 3b.**

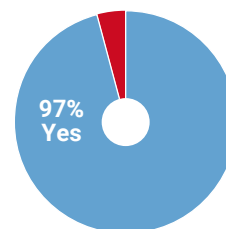
96% Believe the ADA and JDRF should seek direct donor input when making research funding decisions. Yet, donors are not represented in any meaningful way in budget spending decisions at either organization.

79% Said that compared to last year, they are "less optimistic that there will be a cure for T1D in the near future."

3/4 Said "I will stop participating" or "I am less likely to participate" in future fundraising walks after learning how much revenue was actually used for research. **See Chart 3c.**

Chart 3a:

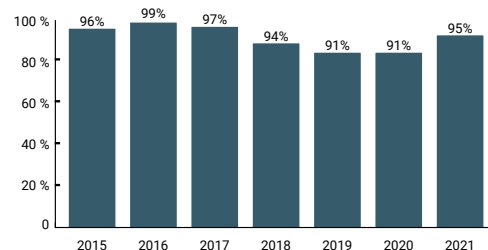
"Do you believe cure research should be the number one priority for diabetes charities?"



Source: JDCA Survey of Donor Sentiment, March 2021

Chart 3b:

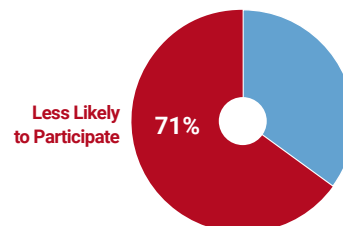
"Would you donate to Practical Cure research projects if that option was made easily available to you?" Answer is percent who agree.



Source: JDCA Annual Surveys of Donor Sentiment, 2015-2021

Chart 3c:

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 2021

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

25 MILLION PEOPLE
have a family member or close relative
with T1D

Together they donate
\$350 MILLION DOLLARS
per year to TYPE 1 DIABETES

97%

want their money to be used for
cure research

Source: JDCA Survey of Donor Sentiment, 2021 and JDCA Estimate of Annual Donations from the ADA, JDRF, and Other Research Institutions

Chapter 4: Practical Cure Definition

A Practical Cure is any solution which minimizes the disruptive aspects of T1D and delivers a near-normal quality of life. A Practical Cure (sometimes referred to as a 'functional cure') differs from an idealized cure (or 'perfect' cure) in that it does not have to result in a reversal or complete elimination of the disease.

Scientists have pursued a 'perfect' cure for nearly 100 years. While that research has led to a better understanding of the disease, we are still far from a clear path to the 'perfect' cure. A Practical Cure may not eradicate T1D from the body, but it will eliminate the daily challenges and long-term complications of the disease.

The definition of a Practical Cure was established by people who are currently living with T1D and encompasses their vision of a life where the daily disruptiveness of the disease is eliminated. One great benefit of the Practical Cure – in contrast to a perfect cure – is that it has the real potential to be available in our lifetime.

A PRACTICAL CURE IS OUTCOME FOCUSED

There are six outcome criteria that people with T1D say would eliminate the burden of the disease. See Chart 4a. Any research approach, pathway, or philosophy that can deliver these outcome objectives merits pursuit.

A PRACTICAL CURE IS TIME-BOUND

A 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. Research projects that are currently in human clinical trials have the best chance of delivering this goal.

There are two essential benefits to having a time goal. First, it puts an emphasis on helping people who are currently living with the disease. Second, 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 to conclusive results as quickly as possible.

Chart 4a:

Clinical Requirements Needed to be a Practical Cure for T1D	
<input checked="" type="checkbox"/>	HBA1C <7% and/or >75% Time in Range (70-180 mg/dl)
<input checked="" type="checkbox"/>	Minimal Monitoring
<input checked="" type="checkbox"/>	Free Diet
<input checked="" type="checkbox"/>	Eliminate Hypos
<input checked="" type="checkbox"/>	Only Mild and Temporary Side Effects (No Long-term Side Effects)
<input checked="" type="checkbox"/>	Less than 5 Days in Hospital (If Surgical)

Projects that have already advanced into human trials should be given priority, fully funded, and wholly resourced so they can move to conclusive results as quickly as possible.

Chapter 5: Practical Cure Pathways

CELL SUPPLY SOLUTIONS



Cell Transplantation involves putting insulin-producing cells into a person with type 1 diabetes to achieve insulin independence. Today, the only proven source of insulin-producing cells is from recently deceased cadavers, an approach that cannot be widely adopted. However, research into alternative sources of cell supply is progressing rapidly. Stem-cell sources, which offer nearly unlimited supply, are now in human trials.



Cell Regeneration involves 'reawakening' residual beta cell mass that persists in the body even after many years of living with T1D. Several 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 regenerate.

CELL PROTECTION SOLUTIONS



Immune System Modification involves stopping the body's immune system from attacking insulin-producing beta cells. To date, the only clinically approved way to achieve this is by taking full-body immune-suppressing medication, which reduces the body's overall disease fighting capability. Some modest advances have been made over the past ten years in the development of targeted immune system modification therapies.



Encapsulation involves protecting insulin-producing cells from immune rejection with a physical barrier. 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. A substantial amount of research has been conducted over the past twenty years on this pathway. Scientists hope to achieve the right balance of durability and glucose sensitivity.

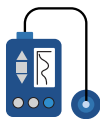


Gene Editing involves editing insulin-producing cells using gene modifying technology, so that they do not trigger a T1D autoimmune attack. While the potential scope of this pathway is vast, it is relatively new and in early stages of testing. In November 2021, the Canadian health regulatory agency gave the green light to the first ever T1D human trial that utilizes gene editing.

ADVANCED INSULIN DELIVERY SOLUTIONS



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 GRI, all of which are still in preclinical development.



Advanced Artificial Pancreas is a device that mimics the glucose-regulating functions of a healthy pancreas, automatically controlling blood glucose levels and delivering insulin. When surveyed, 88% of people with T1D 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 devices are small enough.

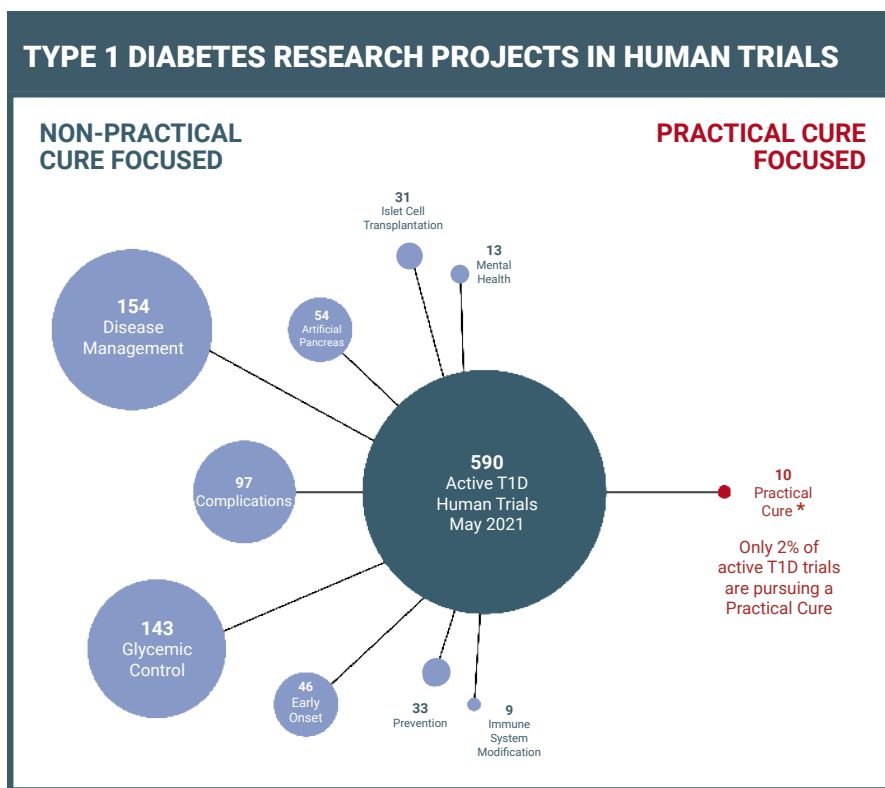
Chapter 6: Practical Cure Projects in Human Trials

As of September 2021, there are 590 T1D research projects registered in the United States that are actively being tested in humans.

These projects are noteworthy because they have advanced beyond scientific theory and animal testing to a stage where they are being tested in humans. Every new drug or device sold in the US must show safety and efficacy in human trials before it is approved by the FDA. Therefore, the products being tested in human trials today are the ones that are most likely to be on a pathway to market availability in the next 15 years.

Overall, the T1D projects in development today predominantly aim to improve glycemic control and diabetes management. See Chart 6a. There are only six Practical Cure projects being tested in ten human trials (some projects have multiple trials running concurrently). In total, just 2% of all active T1D trials are targeting a Practical Cure.


Chart 6a: 2021 T1D Research Projects in Human Trials



Source: clinicaltrials.gov

In 2021, one new Practical Cure trial began and one was withdrawn without publishing results. In January, City of Hope began recruiting patients with T1D for a clinical trial of PIpepToIDC, a "reverse vaccine" aimed at stopping the T1D autoimmune attack. The trial that was withdrawn this year was testing TOL-3021, a local immune therapy. Details for each of the six active Practical Cure projects are found on the following page. Please note that the JDCA presents these projects without any indication of preference or ranking.

* To qualify as a Practical Cure, Cell Supply and Cell Protection projects must target an increase in C-peptide production as a primary or secondary endpoint measure. Advanced Insulin Delivery Solutions qualify only if they substantially eliminate the burden of the disease. In addition, Practical Cure trials must test patients whose T1D has progressed to the point where their body is no longer able to produce insulin.



Stem Cell Educator
Throne Biotechnologies,
Paramus, NJ

Research Pathways

- Immune System Modification
- Cell Regeneration

Phase: II/III
Not Yet Recruiting

Timeline
Estimated Completion: December 2022

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
Diabetes Research Institute,
Miami, FL


Research Pathways

- Immune System Modification
- Cell Regeneration

Phase: I/II
Recruiting

Timeline
Estimated Completion: December 2023

Description
A combination of omega-3 and vitamin D designed to halt immune system response and preserve residual B-cell function.



Umbilical Cord Blood Regulatory T Cells Plus Liraglutide
Second Xiangya Hospital of Central South University,
Hunan, China


Research Pathways

- Immune System Modification
- Cell Regeneration

Phase: I/II
Recruiting

Timeline
Estimated Completion: December 2021

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, WA


Research Pathways

- Immune System Modification
- Cell Regeneration

Phase: I
Recruiting

Timeline
Estimated Completion: December 2021

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



P1pepToIDC
City of Hope Medical Center,
Duarte, CA

Research Pathways

- Immune System Modification
- Cell Regeneration

Phase: I
Recruiting

Timeline
Estimated Completion: October 2023

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.



Stem-Derived Insulin Producing Cells
ViaCyte, San Diego, CA

Research Pathways

- Cell Transplantation

Phase: I/II
Recruiting

Timeline
Estimated Completion: April 2023

Description
Stem cells mature into functional beta cells when implanted under the skin. ViaCyte is actively testing cell encapsulation and gene editing as cell protection techniques.

Chapter 7: Cure Research Funding

The five not-for-profit organizations that fund the majority of the type 1 diabetes research conducted in the United States are JDRF, the JDRF T1D Fund, the American Diabetes Association (ADA), the Leona M. and Harry B. Helmsley Charitable Trust, and the National Institutes of Health (NIH). This section summarizes spending at these organizations in Fiscal Year (FY) 2020, the most recent year financial data is available.

JDRF

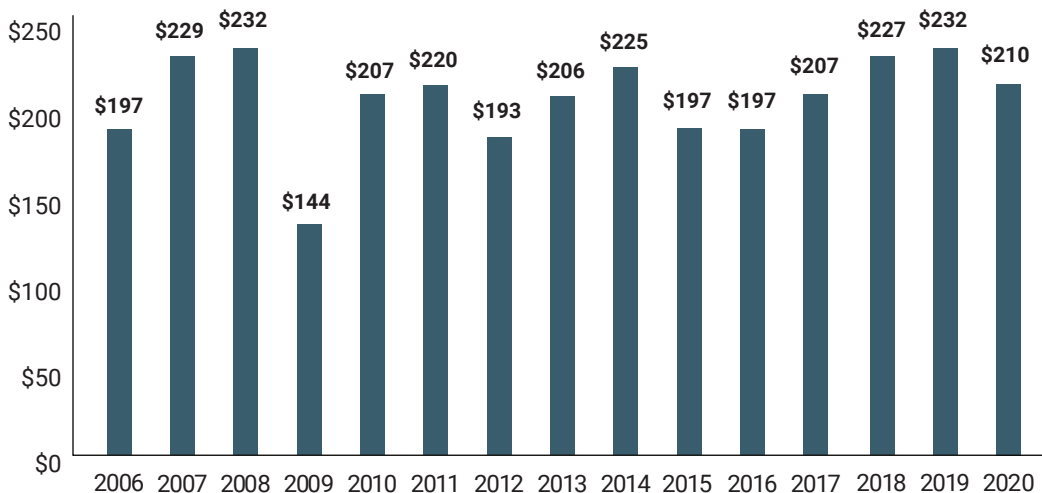
Founded in 1970 with a mission of finding a cure for T1D, JDRF has grown to become one of the largest and most influential type 1 diabetes organizations in the world. With a global chapter presence and strong relationships with research centers, JDRF is uniquely positioned to bring about a T1D research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

JDRF Revenue: Less of a COVID Impact than Expected

JDRF's 2020 Fiscal Year spanned July 1, 2019 - June 30 2020, which includes the impact of the first three months of COVID – the spring fundraising season.

JDRF posted a revenue of \$210 million in FY 2020, a **-\$22 million** drop from the prior year. See Chart 7a.

*** Chart 7a: JDRF Revenue Trend by Fiscal Year (Millions)**



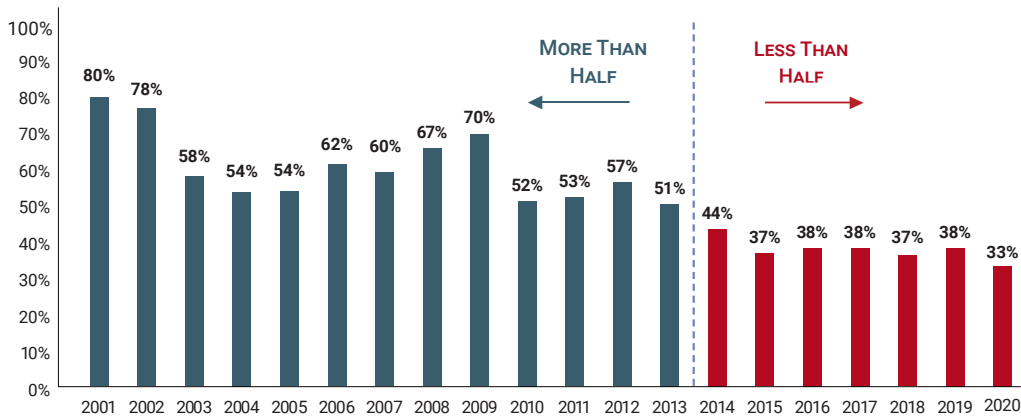
* Charts 7a, 7b, 7c, and 7d are sourced from JDRF's publicly available Audited Financial Statements.

JDRF Expenses: Research Grants Cut by \$20 Million

The **-\$22 million** revenue decrease at JDRF was met with a commensurate \$20 million cut in research grant spending. In FY 2020, JDRF spent \$69 million on research grants, a **-\$20 million** drop from \$89 million in FY 2019.

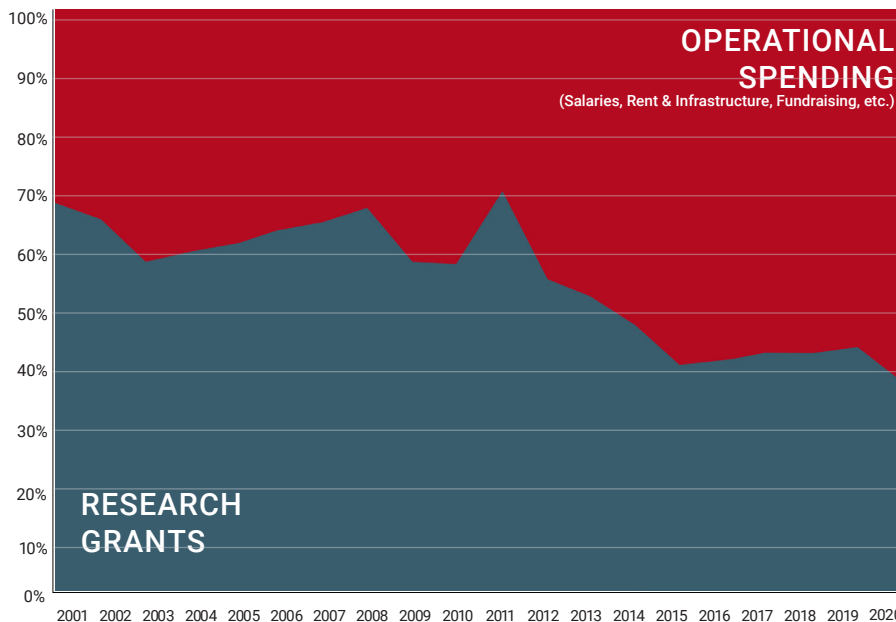
Research grant spending has been steadily declining in importance at JDRF over the past 20 years. In 2001, 80% of organizational income was used to fund research grants. That percentage dropped to a record low of 33% in 2020. **See Chart 7b.**

*** Chart 7b: JDRF Research Grant Spending as % of Total Revenue by Fiscal Year**



While research grant spending dropped to a 20-year low in both absolute dollars and percent of revenue, all other expenditure categories have increased in that time period. **See Chart 7c.** In particular, payroll has more than doubled. In FY 2020, 37 cents of every dollar JDRF raised was spent on salaries, making it JDRF's largest expense category.

*** Chart 7c: JDRF Research Grant vs. Operational Spending (as % of Total Expenses) by Fiscal Year**

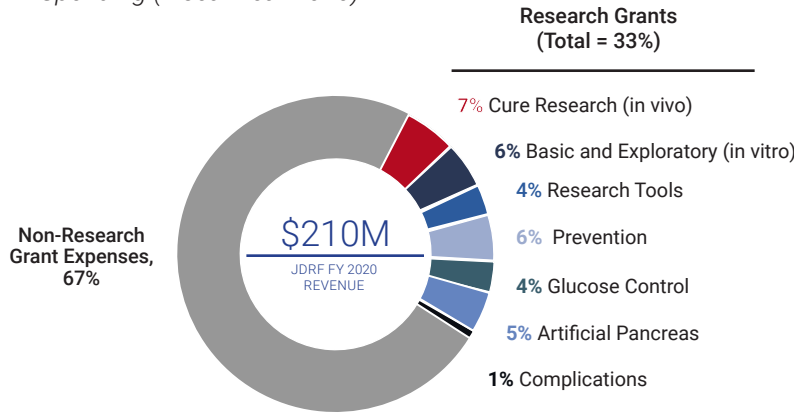


JDRF Cure Research Spending

In 2020, JDRF funded \$69 million of T1D research grants. The JDCA individually reviewed and categorized each of the 450 grants. See Chart 7d.

Cure research in human and/or animal testing (known as “in vivo” research) was cut by -28% between FY 2019 and FY 2020 and -52% between FY 2014 and FY 2020. No research area has declined as much in absolute dollars over the past 5 years.

* Chart 7d: JDRF Spending (Fiscal Year 2020)



During the past five years, JDRF’s research funding strategy has become less focused. JDRF spread \$69m over 450 grants in 2020, compared to \$100m over 387 grants in 2014. In addition, cure research spending is down -52% from \$27m in 2014 to \$13m in 2020, while the amount of money JDRF allocated to prevention research increased by 44%. See Chart 7e. 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 strategy shift away from curing the disease.

Chart 7e: Research Grant Spending Five-Year Trend by Category (Millions)

Research Categories	2014	2019	2020	2019-2020 % Change	2014-2020 % Change
Cure Research (in vivo)	\$27	\$18	\$13	-28%	-52%
Basic and Exploratory (in vitro)	\$11	\$20	\$14	-35%	18%
Research Tools	\$14	\$5	\$8	60%	-43%
Prevention	\$9	\$18	\$13	-28%	44%
Glucose Control	\$9	\$11	\$7	-36%	-22%
Artificial Pancreas	\$16	\$13	\$11	-15%	-31%
Complications	\$11	\$5	\$3	-40%	-73%
Total	\$99	\$90	\$69	-22%	-30%

Source: JDRF Grant Database

JDRF T1D FUND

The JDRF T1D Fund (“the Fund”) is a relative newcomer to the T1D ecosystem. The Fund is a wholly owned subsidiary of JDRF and was founded with JDRF donor money in 2016. Its mission is to accelerate the development of drugs, diagnostics, devices, and vaccines to treat, prevent, and cure T1D. Unlike JDRF, who mainly gives grants to academic researchers, the Fund uses donor capital to invest in early-stage companies with T1D commercial potential.

Since inception, the Fund has invested \$79 million in various funding rounds of 28 private companies. Unlike a for-profit venture capital fund, donors to the T1D Fund forgo any right to share in the Fund profits or reclaim their initial capital. As a venture philanthropy fund, it has a fiduciary and moral obligation to ensure that all its investments are aligned with the mission.

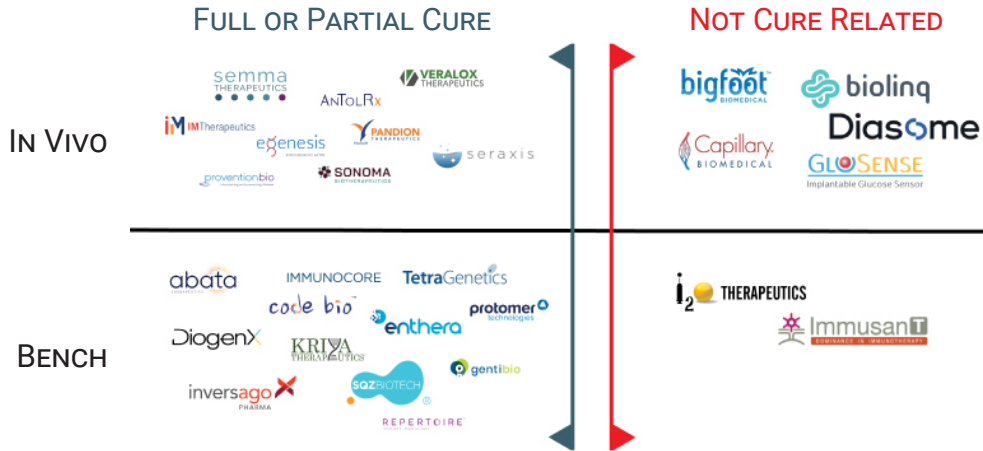
The Fund has been successful at raising money to date, and is investing an increasing amount each year. We estimate that the Fund has made roughly \$15 million of investments per year on average; in comparison, JDRF averages \$80 million in yearly research grant expenditure.

While the Fund’s initial investments were typically in small companies that were narrowly focused on T1D, it appears it is shifting focus to larger companies with potential to apply their technology outside of T1D. Furthermore, only two of its investments to date support projects which could deliver a T1D Practical Cure.

Highlights of the Fund:

- 28** Total investments since 2016
- 21** Investments addressing some aspect of a cure
- 8** Investments with a T1D project in human trials
- 2** Investments with a project that meets the criteria of a Practical Cure solution (Semma/Vertex and Seraxis)
- 1** Investment has received FDA market approval – Bigfoot Biomedical. This is a glycemic control device and distinctly not a Practical Cure.

Chart 7f: T1D Fund Investment Cure Focus to Date



Source: The JDCA, “A Special Look at the JDRF T1D Fund.” October 28, 2021.

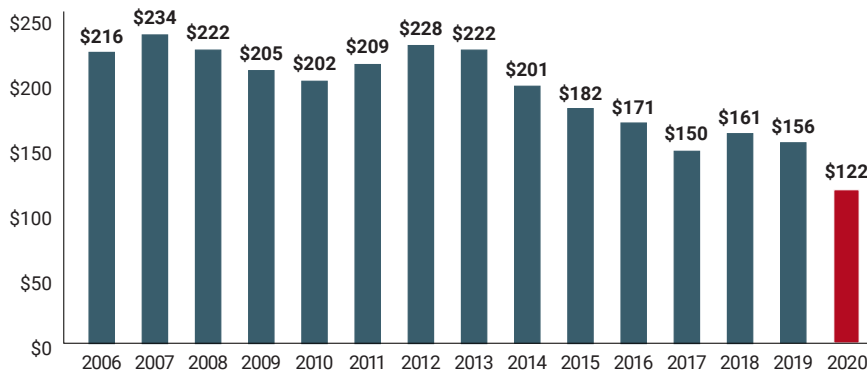
THE AMERICAN DIABETES ASSOCIATION

The 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 ADA has experienced a massive decline in revenue over the past 15 years. See chart 7g.

ADA Revenue: Sustained 15-Year Losses

In FY 2020, the ADA’s revenue was \$122 million, its lowest in 15 years. The ADA’s revenue has dropped -44% since 2006, the first year that the organization’s financial records were posted online.

Chart 7g: ADA Revenue by Fiscal Year (Millions)



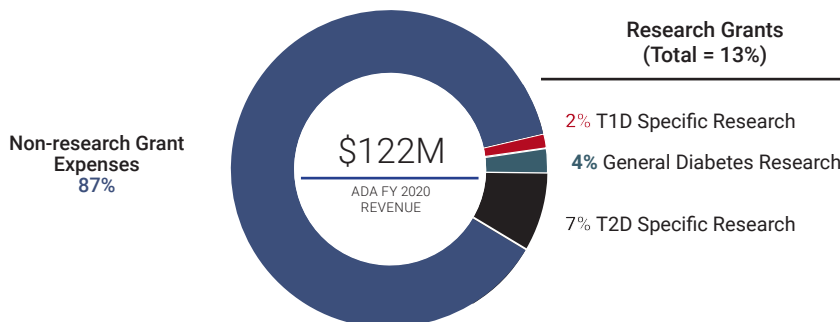
Over the past 15 years, the ADA’s business model has been fundamentally challenged. The organization, which used to rely on paid subscriptions to its diabetes journals for revenue and relevance, has struggled to transition into the information age. At the same time, it has not found a way to provide ongoing value to the community of donors, who contributed almost -\$70 million less to the organization in 2020 as compared to 2006.

The ADA only dedicated \$1.8 million to T1D research in FY 2020.

ADA Expenses: T1D Research Not the Focus

Most of the ADA’s resources are directed to non-research expenses such as publishing, advocacy, fundraising, salaries, and overhead. Much of this activity, as well as most of its research grant funding, is focused on type 2 diabetes. See Chart 7h.

Chart 7h: ADA Spending (Fiscal Year 2020)



Source: ADA FY 2020 IRS Form 990

THE NATIONAL INSTITUTES OF HEALTH

The NIH is the largest nonprofit funder of T1D research in the United States. Run by the U.S. Department of Health and Human Services and funded by taxpayer dollars, the agency supports a broad scope of medical research. In FY 2020, the NIH funded \$205 million in T1D research. See chart 7i.

Highlights of NIH Spending:

\$42B Total NIH Budget for FY 2020

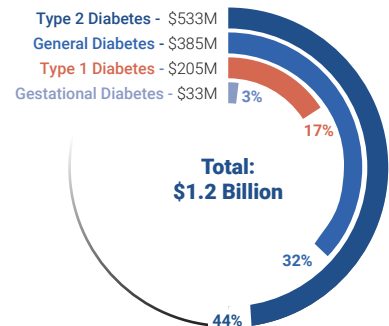
\$1.2B NIH budget for diabetes research in 2020

\$950M Amount allocated by the NIH to fund T2D, general diabetes, and gestational diabetes research, 79% of the total budget

\$205M Amount allocated by the NIH to fund T1D research grants, 17% of the total diabetes budget

0 Number of Practical Cure projects the NIH funded in 2020

Chart 7i: NIH Diabetes Spending
(Fiscal Year 2020) (Millions)



Source: NIH Grant Database

T1D Special Diabetes Program

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 program allocates \$150 million annually to T1D research, comprising the majority of NIH funding for T1D. Congress has approved funding for this program through 2023.

The Special Diabetes Program does not currently support any Practical Cure projects and typically funds large multi-center observational studies of people with T1D and early-stage scientific research. However, this funding source is crucial to the T1D research ecosystem. Many advances in the scientific understanding of T1D over the past two decades have been funded by SDP money.

THE LEONA M. AND HARRY B. HELMSLEY CHARITABLE TRUST

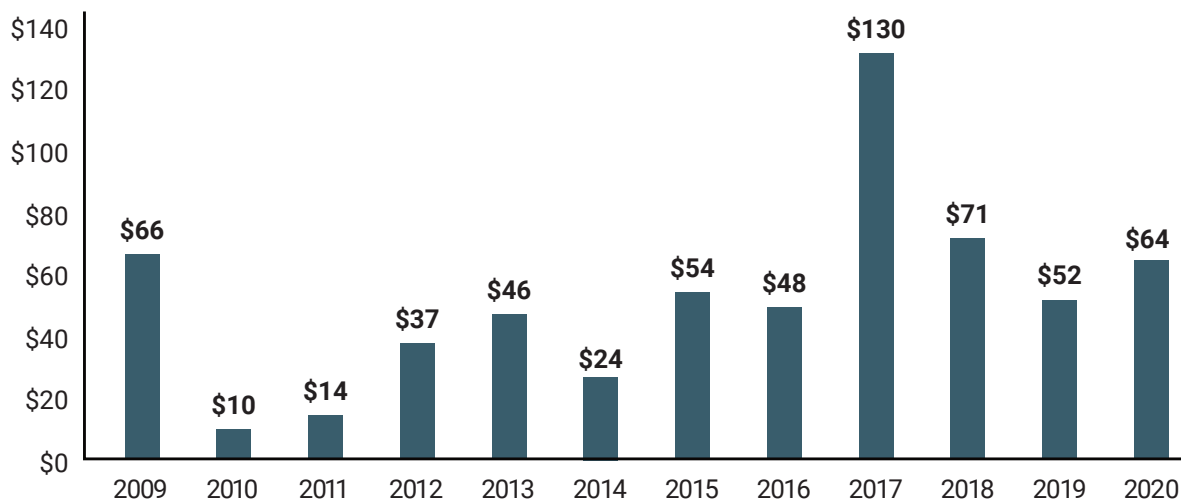
The Helmsley Trust was established by real estate mogul Leona Helmsley in 1999. In FY 2020, the assets of the Helmsley Trust totaled over \$6 billion, and it distributed over \$300m in grants across six program areas – one of which is T1D. Over the past 12 years, the program has made T1D a priority, allocating an average of \$51 million to T1D grants per year. In 2020, the Trust allocated \$64m to T1D grants. **See chart 7j.**

As a private foundation that does not accept donations, the Trust has freedom to support any philanthropic cause chosen by its Trustees. Establishing T1D as a focus area has driven over \$600 million to T1D grants over the last decade. The T1D community is fortunate that the trustees have chosen to make this disease a funding priority.

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 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 research tools to prevent and delay T1D.

Helmsley does not currently have a program that is focusing specifically on finding a cure for T1D.

Chart 7j: Helmsley T1D Grants by Year (Millions)



Source: Helmsley Grant Database

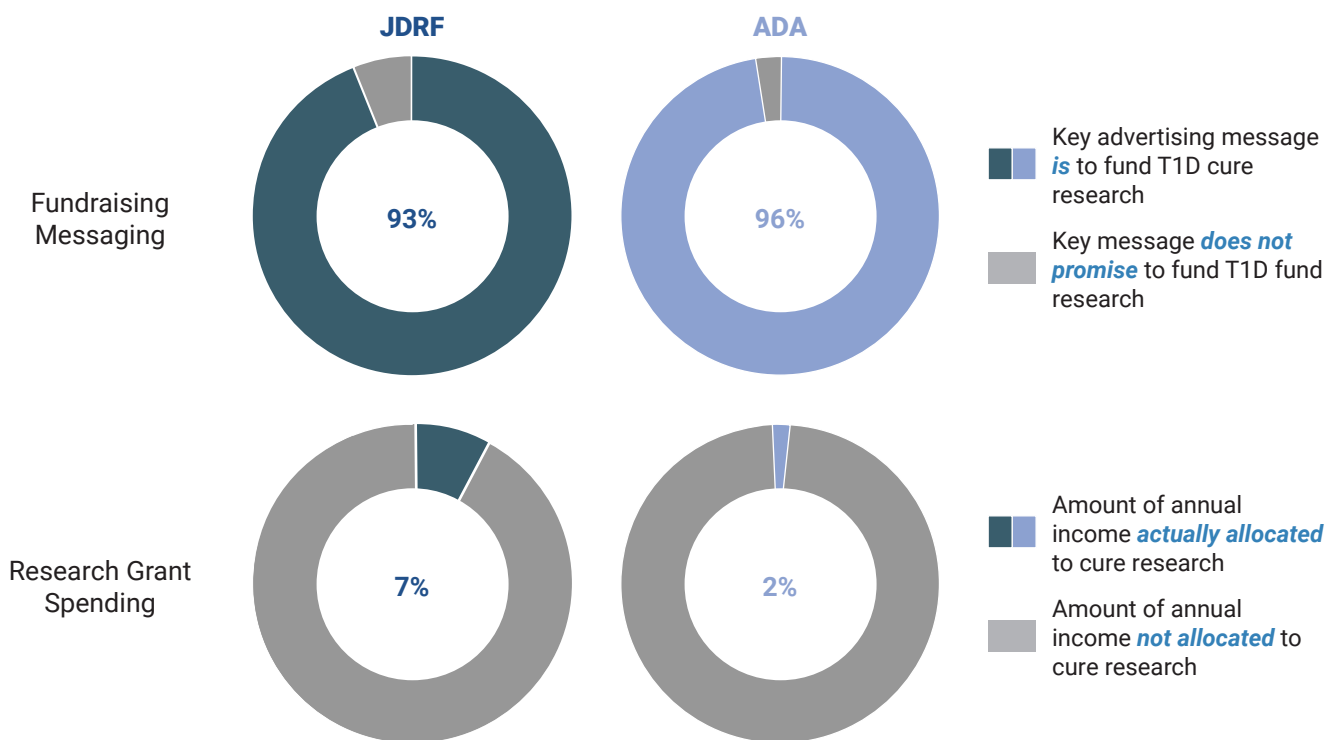
Chapter 8: Fundraising for T1D

Each year, the T1D community participates in fundraising events that drive hundreds of millions of dollars in revenue to T1D non-profits. Walks, rides, and galas are not only a important revenue source for nonprofits, but an opportunity to connect the T1D community.

In 2021, JDRF and the ADA advertised for 170 national walks, rides, and galas, most of them virtual due to COVID safety protocols. While the physical nature of fundraising events underwent a radical shift, one constant remained: JDRF and the ADA used the cure promise in almost all event advertising.

Nearly all JDRF and ADA national fundraising messaging either explicitly or implicitly communicate that the proceeds will be used for cure research. Many familiar event names feature a cure message, including Ride to Cure Diabetes, Tour de Cure and the Step Out Walk to Stop Diabetes. In 2021, 93% of all JDRF national fundraising events featured a cure message, a number consistent with prior years. Yet, only 7% of JDRF's annual income was utilized for cure research. The ADA featured a cure message in 96% of its 2021 events, but only an estimated 2% of annual income was used specifically for T1D research. See chart 8a.

Chart 8a: Fundraising Messaging vs. Research Spending



Source: JDCA review of JDRF/ADA national advertising

Chapter 9: *What It Will Take to Achieve a Practical Cure*

Is there really a chance to see a Practical Cure in the next 15 years? If so, what will it take to achieve it?

The quick answer is that there IS a chance to see a Practical Cure in the next 15 years. However, it will require a paradigm shift in how the major players in T1D research allocate resources.

The following four recommendations below are a blueprint for researchers, fundraisers, and donors to push us towards a Practical Cure for T1D:

1. Make the T1D Practical Cure a Priority Objective

Establishing a T1D Practical Cure/functional cure as one of the primary goals of the research community will ensure that it receives the right amount of funding and focus. To date, neither the scientific community nor the major diabetes not-for-profit organizations have adopted pursuit of a Practical Cure as a top priority. This must change.

2. Provide Motivating Incentive

Compensation and bonus incentives should be structured to inspire nonprofit leaders and research investigators to vigorously pursue a Practical Cure. Such incentives will align CEOs, principal investigators, and staff toward finding a Practical Cure as soon as possible.

3. Restore Cure Funding

The historic decline in T1D grant funding that was detailed in Chapter Seven of this report must be reversed. In 2020, T1D research grant funding by the two main diabetes not-for-profit organizations dropped to 20 year lows. Reversing this decline and restoring cure funding will align donors with the not-for-profit organizations and accelerate a cure.

4. Donors Must Speak Up

As the primary source of income for the main diabetes charities, donors play a key role in ensuring that a Practical Cure research platform is a top priority. Ongoing pressure from donors like you to adopt, institutionalize, fund, and fully resource Practical Cure research is critical to the development of a Practical Cure in the next 15 years. Make your voice heard.





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

