

# JUVENILE DIABETES CURE ALLIANCE

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January 19, 2012

## Organizations Mentioned:

- American Diabetes Association (ADA)
- Diabetes Research Institute Foundation (DRIF)
- JDRF
- Joslin Diabetes Center (Joslin)

## **Type 1 Diabetes Charitable Foundations**

### Update Report:

## **Type 1 Human Clinical Trial Landscape**

### Conclusions:

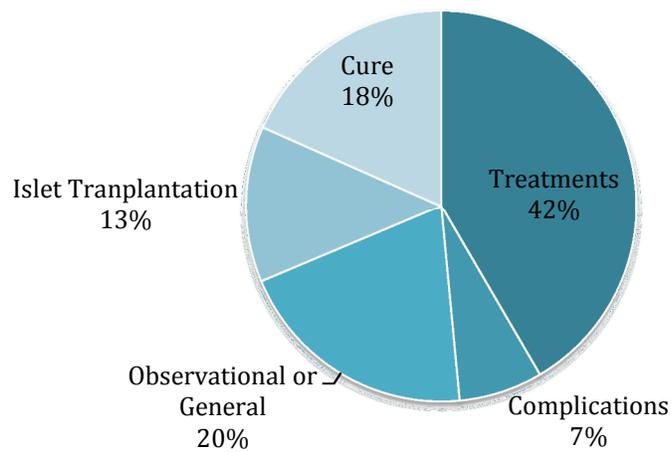
- There are over 330 type 1 diabetes human clinical trials that are underway or are about to begin that investigate a broad range of aspects related to type 1
- The majority of these trials investigate treatments to better manage the disease, are observational/general studies or target complications that are associated with type 1 and by themselves do not have the potential to cure type 1
- Cure oriented clinical trials are under-represented in this universe and account for just 18% of the total, implying that there is an unequivocal need to fund more Practical Cure research in order to drive these projects into the clinical trial stage of development

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This is the last in a series of three reports that examines the type 1 diabetes (type 1) clinical trial landscape. In this report, we broadly analyze the type 1 trial universe, the focus of research attention and the implications for the development of a type 1 Practical Cure.

The JDCA reviewed over 330 type 1 human clinical trials that are registered with the U.S. National Institutes of Health.<sup>1</sup> This group captures both domestic and non-U.S. studies. A breakdown of these trials by category is depicted in the following chart:

### Breakdown of Type 1 Clinical Trials



**As can be seen in the chart, most studies target non-cure objectives.** The largest trial category (Treatments) includes products or techniques to improve the management of type 1 and may involve new devices or new insulin. Observational or general studies designed to improve the understanding of type 1 plus projects that address complications associated with type 1 represent approximately one quarter of the total. Even if all of these management, observational or complications studies prove successful, people living with established type 1 will not be cured.

Trials relating to the transplantation of human insulin-producing islets into individuals with type 1 are 13% of the total. Islet transplantation procedures involve the use of harsh immunosuppressive drugs to prevent rejection of the newly implanted islets. Due to the toxic nature of the anti-rejection drugs, the JDCA does not categorize these trials as cure related.

**The remaining cure oriented trials comprise only a small percentage (18%) of the total.** However, many of these projects are prevention oriented and even a successful trial outcome would not cure an individual with fully established type 1. As stated in our last report, the JDCA believes that only five treatments in clinical trials, or just 1% of the total number of type 1 trials, have the potential to deliver a Practical Cure.<sup>2</sup>

**Relatively few cure oriented clinical trials are currently funded by the four major type 1 charities that we cover.** The JDCA estimates that these four organizations, in the aggregate,

provide funding to approximately one-fourth of the cure oriented clinical trials. The clear inference is that a very small percentage of total donor contributions that are made to these four charities actually fund cure oriented clinical trials.

### **Summary and Conclusion**

There are over 300 human clinical trials underway that explore many aspects of type 1. Unfortunately for donors who seek a cure, the number of cure oriented trials is only a fraction of the total. The 18% of clinical trials that the JDCA has identified as cure oriented is in stark contrast to the 90% of donors who contribute for the reason of a cure.<sup>3</sup> An even more striking statistic is that only five treatments, or just 1% of the total number of type 1 clinical trials, have the potential to deliver a Practical Cure by 2025, in our view.

A powerful disconnect exists between the results that donors most desire (a cure) and the type of research that is in clinical trials. Correcting this dilemma requires a prioritization of Practical Cure research by the four major type 1 charities with a focus on driving more projects into the clinical trial stage of development. Donors who seek a cure for those now living with fully established type 1 and contribute for this reason may wish to consider placing stipulations on their donations to specifically fund Practical Cure research.

<sup>1</sup> The U.S. National Institutes of Health website [www.clinicaltrials.gov](http://www.clinicaltrials.gov) as of November 22, 2011

<sup>2</sup> JDCA *Type 1 Clinical Trials That Target a Practical Cure* report dated January 11, 2012

<sup>3</sup> JDCA *Why Donors Give* report dated September 19, 2011

### **Analyst Certification**

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