

Special Statutory Funding Program for Type 1 Diabetes Research (Special Diabetes Program [SDP])

Updated March 2023

Advancing development of artificial pancreas technologies:

- In 2015, no artificial pancreas devices were commercially available.
- Today, **three commercial artificial pancreas devices are on the market**¹, with other devices under FDA review.²
 - Note: The Tandem Control-IQ device is FDA approved for people with type 1 diabetes (T1D) ages 6 and older.³ Results from an SDP-supported trial published on March 15, 2023, showed that the device improved blood glucose control in young children between ages 2 and 5 with T1D, a particularly challenging population when it comes to glycemic control.⁴
- SDP-supported research contributed to the development or testing of all three commercial devices, as well as devices under FDA review.² It continues to play a critical role in advancing this field, such as by testing devices in populations understudied by industry.

Preventing T1D:

- In 2021, no approved therapies existed for slowing T1D progression.
- In 2022, **FDA approved the first ever drug (teplizumab) to delay onset of clinical T1D in people 8 years and older at high risk for developing the disease.**⁵
- Key research underlying the landmark approval stemmed from a clinical trial conducted by the SDP-supported Type 1 Diabetes TrialNet, which found that the immune-targeting drug teplizumab delayed T1D onset by at least 3 years.⁶
- The trial was made possible by decades of NIDDK- and SDP-supported research on teplizumab and other research to understand how T1D progresses and to identify novel therapeutic targets and agents.
- The FDA approval underscores the importance of TrialNet as a unique and critical network for testing novel T1D preventive therapies.

Economic impacts of inflation and sequester on the Special Diabetes Program:

- Using the Consumer Price Index for all Urban Consumers (CPI-U) or the GDP Price Index (GDPI) to account for inflation, **\$150 million in FY2023** (the final year of the current authorization) is the equivalent of approximately **\$99 million in FY2004**.

¹ MiniMed™ 770G (Medtronic), Control-IQ (Tandem), Omnipod® 5 (Insulet)

² Examples: (1) MiniMed 780G (Medtronic) (<https://www.niddk.nih.gov/news/archive/2021/testing-next-generation-artificial-pancreas-device-managing-type-1-diabetes>); and (2) Bionic Pancreas (Beta Bionics) (www.nih.gov/news-events/news-releases/bionic-pancreas-improves-type-1-diabetes-management-compared-standard-insulin-delivery-methods)

³ www.tandemdiabetes.com/products/t-slim-x2-insulin-pump/pediatric

⁴ www.nih.gov/news-events/news-releases/nih-supported-trial-shows-artificial-pancreas-improves-blood-glucose-control-young-children

⁵ www.fda.gov/news-events/press-announcements/fda-approves-first-drug-can-delay-onset-type-1-diabetes; People at high risk (stage 2 disease) have at least two blood markers of T1D (autoantibodies) and abnormal blood sugar levels, but do not yet need insulin.

⁶ <https://pubmed.ncbi.nlm.nih.gov/31180194/>; <https://pubmed.ncbi.nlm.nih.gov/33658358/>

- Using the Biomedical Research and Development Price Index (BRDPI) to adjust for the rate of inflation results in a greater loss of buying power: **\$150 million in FY2023** is equivalent to roughly **\$90 million in FY2004**.
- The effect of inflation has further been compounded by sequester, resulting in a lower actual funding level in FY2022 (\$141.5 million) than in FY2004 (\$150 million).⁷
- Despite these economic challenges, SDP-supported research has continued to make important advances with significant public health impacts (such as examples above). However, there have been scientific opportunities that could not be pursued and there are exciting research areas that hold great promise for advancing prevention, treatment, and cure of T1D and its complications.

⁷ In FY2023, SDP sequester cuts were restored in the FY2023 omnibus appropriations bill.