



# Perspectives on BsUFA III

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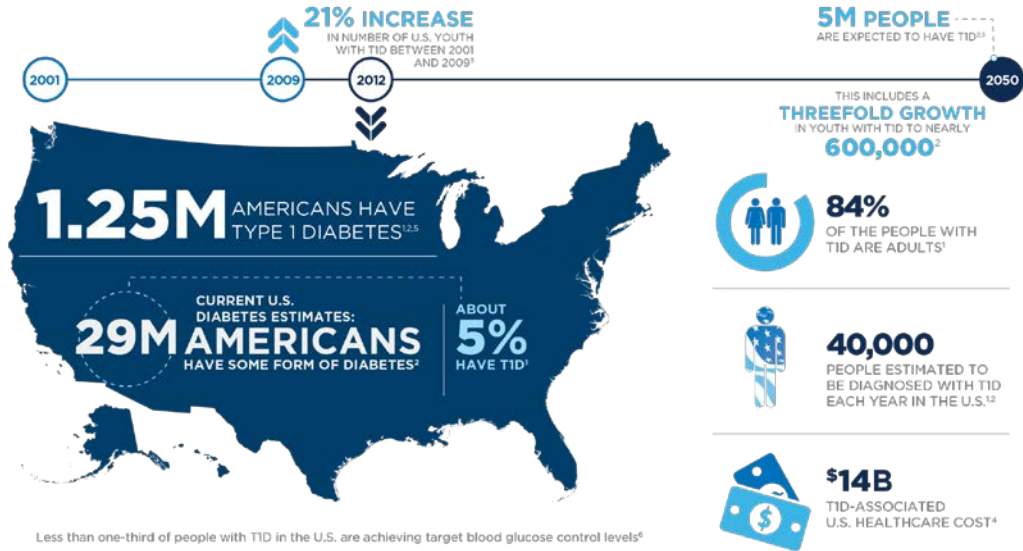
# Agenda

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1. About Type 1 Diabetes
2. About JDRF
3. Importance of Biosimilars in T1D
4. Thoughts for BsUFA III

# ABOUT TYPE 1 DIABETES

# About Type 1 Diabetes

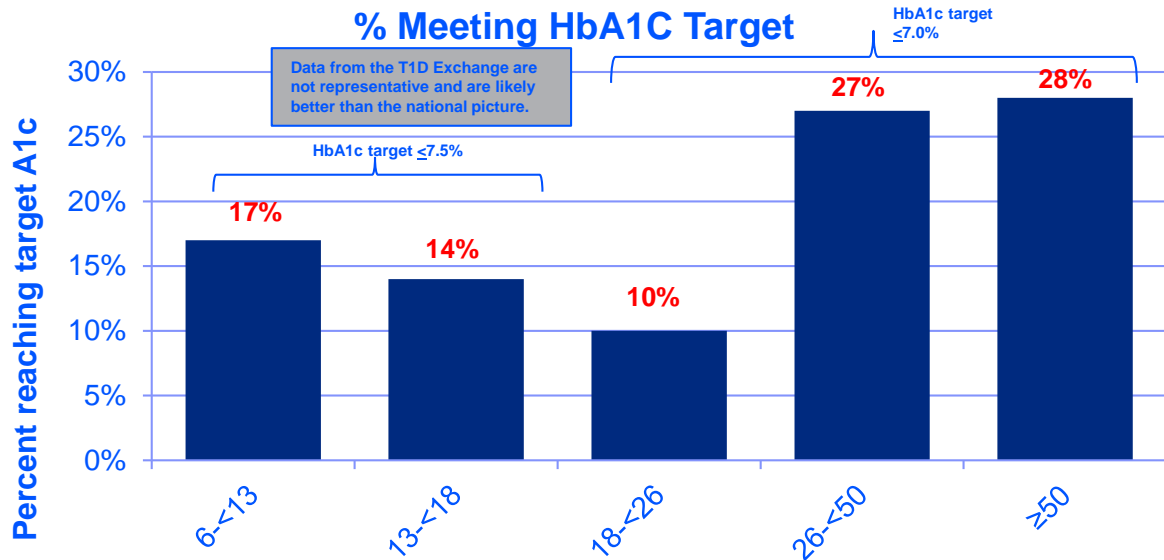


<sup>1</sup> CDC National Diabetes Statistics Report, 2014  
<sup>2</sup> Imperatore, et al. 2012. *Diab Care* 35: 2345-2352

<sup>3</sup> Dabelea, et al. 2014. *JAMA* 311: 1779-1786  
<sup>4</sup> Shapiro, Pharm 2013. Georgetown: 254273

<sup>5</sup> JDRF Estimations  
<sup>6</sup> T1D Exchange data

# Unmet Need in T1D



T1D Exchange registry data on file through July 2018 N=22,697 (>70 sites in USA) <https://t1dexchange.org/>

# Helping Those with T1D Live Full Lives

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## Those with T1D need:

- Advocacy for their needs to help drive advances to both cure the disease and help keep them healthy until cures are found
- Ongoing research for cures and treatments
- Educational information and support
- Access to good health care coverage, affordability and choice



# ABOUT JDRF

# Global Leader in T1D Research

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Committed Over

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**\$2.5B**

Cumulative  
Research Funding  
Since 1970



Awarded

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**400**

Active research  
grants around the  
world



Federal Funding

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**\$2.9B**

T1D research  
funding through  
the Special  
Diabetes Program



Currently  
Supporting

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**55+**  
Clinical  
Trials



# Getting Therapies to the T1D Community



# Importance of Biosimilars in T1D

# Insulin Transition and Biosimilar Pathway

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- Biosimilar Pathway for Insulin Transition Established

## Public Meetings/Input from JDRF

- December 2018 - Draft Guidance, “The “Deemed to be a License” Provision of the BPCI Act Questions and Answers Guidance for Industry”
- May 13, 2019 - The Future of Insulin Biosimilars: Increasing Access and Facilitating the Efficient Development of Biosimilar and Interchangeable Insulin Products
  - Patient perspective FDA should consider when evaluating a proposed biosimilar or interchangeable insulin product
  - Information needed to develop effective communications to improve understanding and promote awareness among patients, clinicians, pharmacists, and other stakeholders about biosimilar and interchangeable insulin products

# THOUGHTS FOR BsUFA III

# Thoughts for BsUFA III

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- Clearer understanding of biosimilars approval process
  - Continue to provide clarity on interchangeability requirements
  - FDA's position on the role the patient perspective as it relates to biosimilarity and interchangeability
- Clinician and Patient Education
  - Community alignment of key scientific points that will convey reliability of biosimilars
  - How can the patient community support educational efforts with providers and patients

# Thoughts for BsUFA III

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- Real World Evidence (RWE)
  - Any application of RWE in the post-marketing setting as it relates to biosimilars
- Continue efforts to improve hiring and retention of FDA review staff

# THANK YOU

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