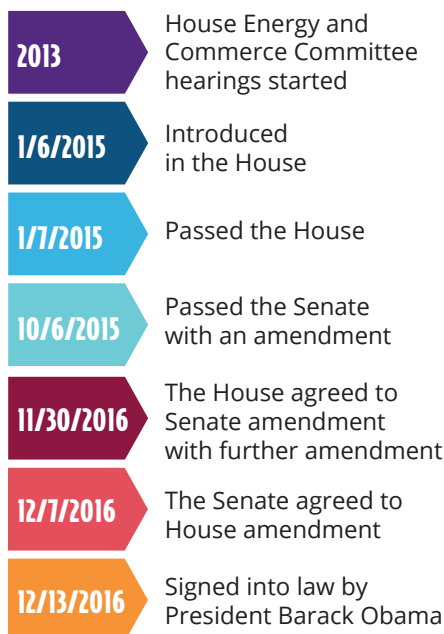


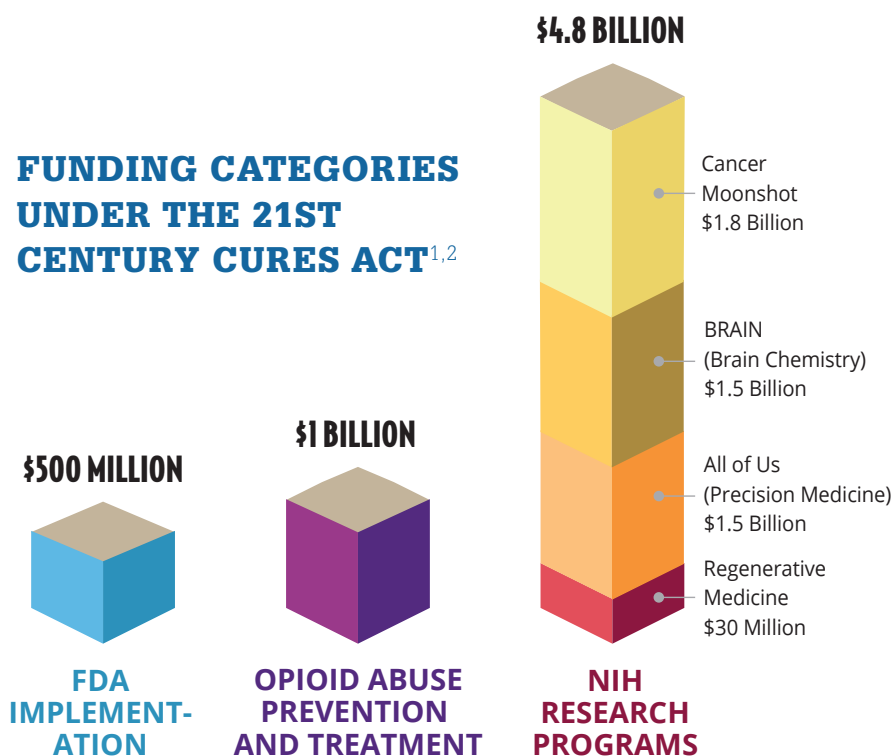
By the Numbers: Policy Changes from the 21st Century Cures Act

Section Editor: The ISPOR Student Network

TIMELINE FOR THE 21ST CENTURY CURES ACT³



FUNDING CATEGORIES UNDER THE 21ST CENTURY CURES ACT^{1,2}



FDA GUIDANCE MILESTONES⁵

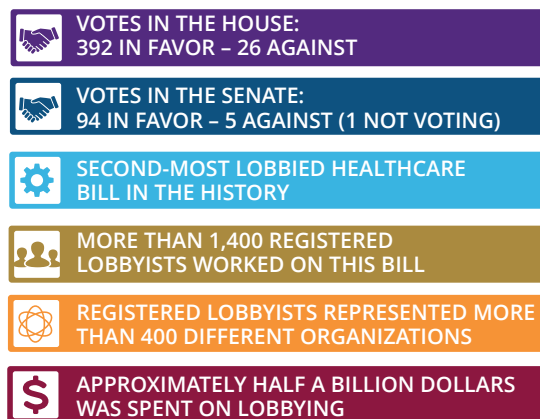
DRAFT GUIDANCE ISSUED

- **12 Jun 2018:** Patient-Focused Drug Development: Collecting Comprehensive and Representative Input - Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders
- **13 Jun 2018:** Limited Population Pathway for Antibacterial and Antifungal Drugs - Guidance for Industry
- **13 Jun 2018:** Humanitarian Device Exemption (HDE) Program - Draft Guidance for Industry and Food and Drug Administration Staff

GUIDANCE TO BE RELEASED

- **13 Dec 2019:** Protection of human research subjects
- **13 Dec 2019:** Qualification of drug development tools
- **Date to be announced:** Novel clinical trial designs
- **Date to be announced:** Real world evidence

SOME NUMBERS ON THE 21ST CENTURY CARES ACT⁴



Contributors: Christy Choi, University of Minnesota; Jayesh Patel; Nazneen Shaikh; Shannon Vaffis, University of Arizona; Aakash Gandhi, University of Maryland; Koen Degeling, University of Twente

¹ Barlas S. 21st Century Cures Bill May Lead To Faster Drug/Device Approvals: But Moving Away from Clinical Trials Worries Some. *Pharmacy and Therapeutics*. 2017;42(2):76-77.

² 21st Century Cures Act: Actions Overview, Available from: <https://www.congress.gov/bill/114th-congress/house-bill/34/actions>

³ National Institutes of Health, Implementation of Funding Plan for the NIH Innovation Projects Under the 21st Century Cures Act, Available from: <https://www.nih.gov/research-training/medical-research-initiatives/cures>

⁴ Sydney Lupkin, A Frenzy Of Lobbying On 21st Century Cures, *Kaiser Health News*; 2016. Available from: <https://khn.org/news/a-frenzy-of-lobbying-on-21st-century-cures/>

⁵ FDA.gov, US Food and Drug Administration - 21st Century Cures Act Deliverables, Available from: <https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCA/21stCenturyCuresAct/ucm562475.htm>