



# 21<sup>st</sup> Century Cures Act

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# Introduction

- ▶ The 996-page bill includes major tweaks to the way in which the US Food and Drug Administration (FDA) regulates drugs, devices and biologics
- ▶ Boosts funding for medical research
- ▶ Eases some regulatory requirements to speed innovation
- ▶ The bill provides for \$4.8 billion in new funding for the National Institutes of Health. \$1.8 billion is reserved for the “cancer moonshot” launched by Vice President Biden.

# Provisions Overview

- ▶ Addressing Mental Health and Substance Abuse Disorders
- ▶ Health Information Technology (HIT) and Digital Health Initiatives
- ▶ Exploration of Telehealth Solutions
- ▶ Multiple Medicare Payment related changes
- ▶ Research Provisions, Funding and Priorities

# Research Provisions I

- ▶ Medical Innovation
  - ▶ Precision Medicine Initiative
  - ▶ Cancer Moonshot Initiative
  - ▶ Brain Initiative
  - ▶ Regenerative Medicine Initiative

# Research Provisions II

- ▶ Reducing Administrative Burdens and Enhancing Collaboration
  - ▶ Revise NIH requirements historically associated with significant administrative burdens
  - ▶ Collaborative Efforts
  - ▶ Develop a NIH Strategic Plan

# Research Provisions III

- ▶ Streamline FDA and Human Subject Research (HSR) Requirements
- ▶ Streamline Research Use of Health Data
- ▶ Certificates of Confidentiality
- ▶ FDA Research Process Changes

# For the Researcher

- ▶ Consider the tone and tempo of the Legislation
- ▶ Plan with an eye to the future
- ▶ Consult Colleagues



# Questions?

Thank you for your time and  
attention.