

**21<sup>st</sup> Century Cures Act**  
**Selected Provisions applicable to**  
**the Regulation of Vaccines**

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# Selected Provisions

- Subtitle C - Modern Trial Design and Evidence Development
  - Section 3021. Novel clinical trial designs
  - Section 3022. Real world evidence
  - Section 3023. Protection of human research subjects
  - Section 3024. Informed consent waiver or alteration for clinical investigations

# Section 3021. Novel Clinical Trial Designs

- Section 3021 requires FDA to conduct a public meeting and issue guidance addressing use of complex adaptive and other novel trial designs
  - Use of such designs and how they satisfy the requirement for “substantial evidence of effectiveness”
  - How sponsors can get feedback related to technical issues
  - What quantitative and qualitative information should be submitted to FDA
  - What are recommended methodologies and analysis

# Section 3022. Real world evidence

- Requires FDA to establish a program to evaluate the potential use of RWE to support approval of new indications for an approved drug and to fulfill post approval commitments
- Real world evidence (RWE): “...data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials.”
  - Could potentially include ongoing safety surveillance, observational studies, registries, claims data and patient centered outcomes
- Purpose of then program is to develop a framework to define sources of real world evidence, gaps in data collection activities, methodologies for collection of data and analyses
- FDA to issue draft guidance within 5 years regarding when sponsors of drugs may rely on RWE

## **Section 3023. Protection of human research subjects.**

- Seeks to harmonize differences between HHS and FDA regulations and update these regulations to the extent practicable
  - Reducing regulatory duplication and modernization of regulations
  - Directs HHS and FDA to allow researchers to use joint or shared IRB review

## **Section 3024. Informed consent waiver or alteration for clinical investigations.**

- Amends the FD&C Act to add an exemption from informed consent requirements for clinical trials that pose no more than minimal risk and where appropriate safeguards protecting the rights, safety, and welfare of subjects are in place.