

The 21st Century Cures Act Turns One

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National Institutes of Health
Office of Research on Women's Health

21st Century Cures Act – Signed into Law December 13, 2016



Public Law No: 114-255 (12/13/2016)



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Image from: <https://upton.house.gov/news/documentsingle.aspx?DocumentID=398723>

The 21st Century Cures Act – Goals of the Legislation

GOALS OF THE LEGISLATION

RESEARCH



Remove barriers to research collaboration



Invest in STEM education



Provide new incentives for the development of rare disease drugs

GETTING TREATMENTS TO PATIENTS MORE QUICKLY



Foster coordination to find cures more quickly



Modernize clinical trials to increase access to drugs and treatments



Incorporate patient feedback in drug development and review process

KEEPING JOBS HERE AT HOME



Ensure U.S. remains a global leader in medical innovation, protecting and creating jobs at home



Encourage development of new medical apps to save lives and create jobs

#CURESatOne



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<https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf>

Image from: <https://energycommerce.house.gov/cures/>

21st Century Cures Act – The NIH Innovation Fund

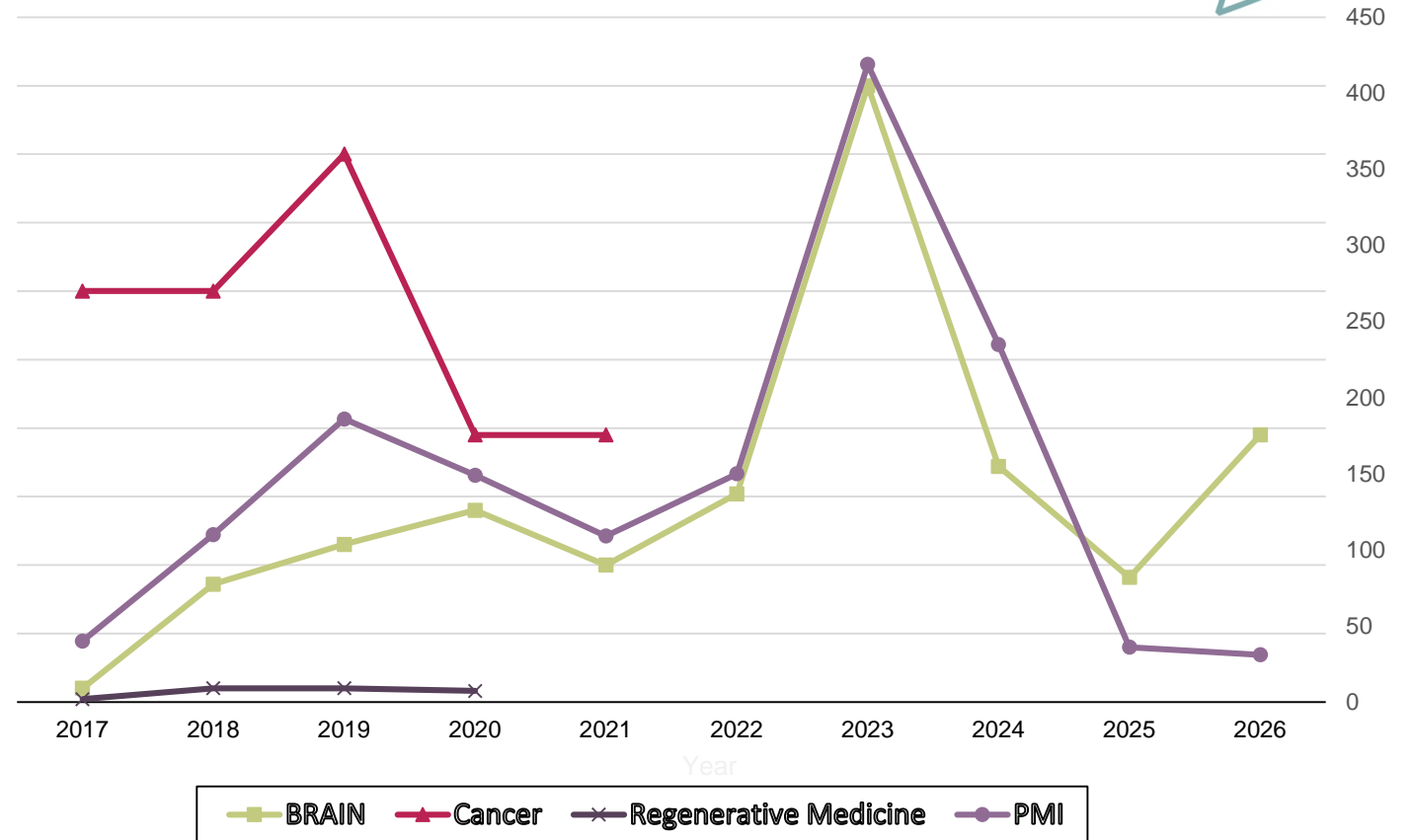
PMI = \$1.45 B

BRAIN = \$1.5 B

Moonshot = \$1.8 B

Regenerative med = \$30 M

\$4.8B over 10 years



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21st Century Cures Act – Reaffirms Commitment to Inclusion

• Inclusion

- Ensure women, children, and racial/ethnic minorities are appropriately represented in clinical research
- Improve research related to sexual and gender minority populations
- Assemble data on study populations in clinical research on women, minorities, age categories
- Encourage collaboration to utilize diverse study populations

• Workforce

- Raises NIH's Loan Repayment caps to \$50,000
- Creates 5 year renewable terms for IC Directors
- Expands Senior Biomedical Research Service authority



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21st Century Cures Act – NIH, ORWH, and Women’s Health

- Modified Reporting Requirements
- Inclusion Across the Lifespan
- NIH Institute, Centers, and Offices Strategic Plans and Women’s Health Research
- Coordinating Committee for Research on Women’s Health Membership

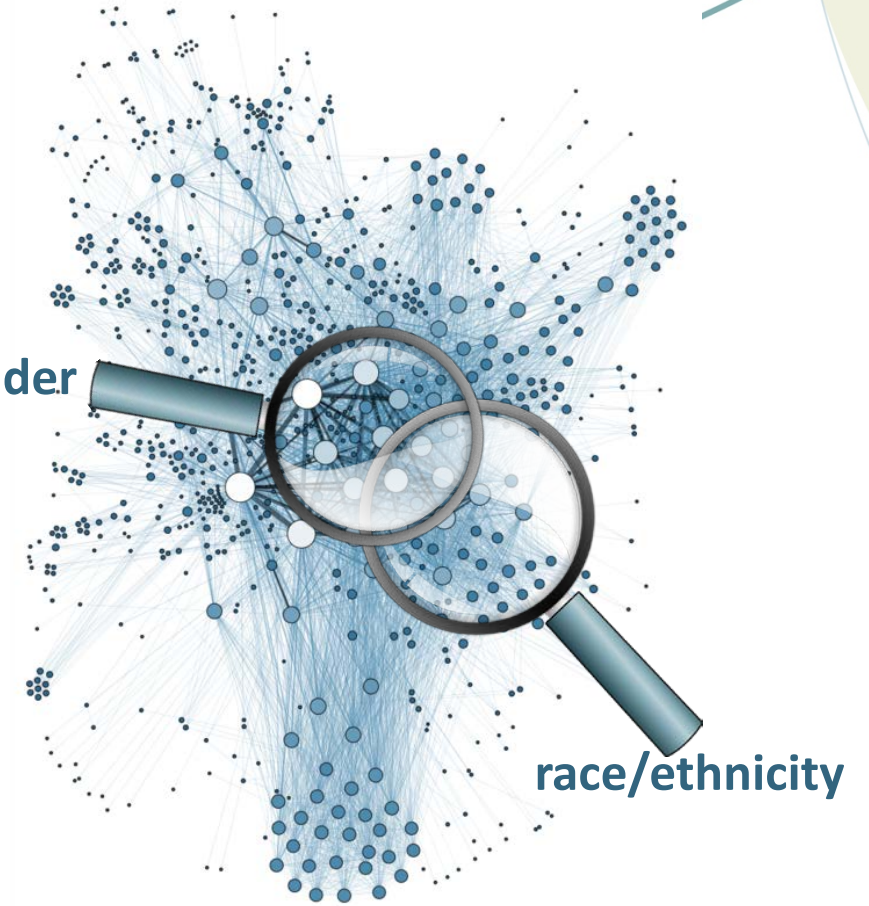


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21st Century Cures Act – Valid Analysis and ClinicalTrials.gov

- Requires reporting of “valid analyses” on sex/gender & race/ethnicity inclusion data to **ClinicalTrials.gov** after completion of applicable NIH-defined Phase III clinical trials
 - **Valid Analyses:** stratified analyses exploring how well intervention works among sex/gender & racial/ethnic groups
 - **Applicable Clinical Trials:** in general, trials investigating FDA-regulated therapeutics, biologics & devices

sex/gender



race/ethnicity

NOT-OD-18-014

Public Law No: 114-255, Section 2053



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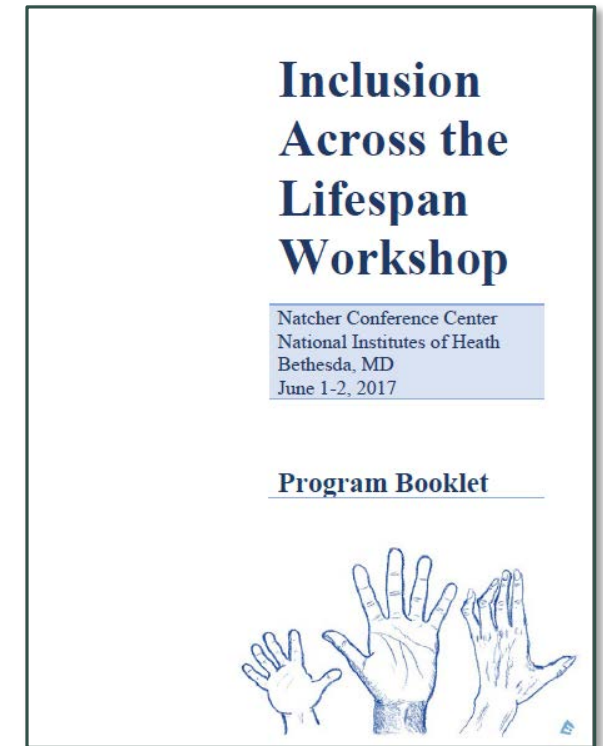
(Images: Martin Grandjean, 2014, CC BY-SA 3.0; Max Pixel, CC0)

21st Century Cures Act – Inclusion Across the Lifespan

Inclusion Across the Lifespan Policy:

- ✓ Expands “Inclusion of Children as Participants in Clinical Research” Policy to include all ages
- ✓ Clarifies justifications for age-based exclusion
- ✓ Requires participant age at enrollment to be provided in progress reports

NOT-OD-18-116



<https://grants.nih.gov/grants/funding/lifespan/lifespan.htm>



21st Century Cures Act – NIH, ORWH, and Women’s Health

- The CCRWH shall be composed of the Directors of the national research institutes (or the **senior-level staff designees** of the Directors).
- IC Directors **shall consult at least once annually** with the Director of ORWH regarding objectives of the ICs to ensure that future activities by such ICs take into account women and are focused on reducing health disparities.
- Any strategic plans issued by an IC shall include details on the aforementioned objectives [**accounting for women and reducing health disparities for women**].



(Kevin McCoy, 2004; CC BY-SA 2.0)

Public Law No: 114-255, Sections 2031(c) and 2038(c)



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Thank you!



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