

# The INCLUDE Project at the National Institutes of Health (NIH): A Call for Broad Research Participation to Advance Quality-of-Life Goals for People with Down Syndrome

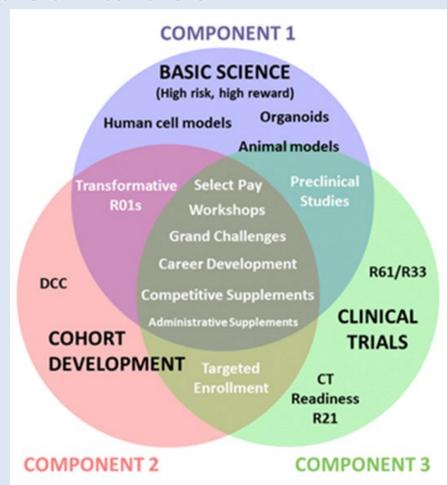
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## BACKGROUND

A Congressional directive in fiscal year (FY) 2018 called for an NIH-wide research initiative on critical health and quality-of-life needs for individuals with Down syndrome (DS). The NIH launched a new DS research initiative known as **INCLUDE** (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE; <https://www.nih.gov/include-project>). INCLUDE is exploring conditions that affect individuals with DS and the general population, such as Alzheimer's disease (AD), autism, cataracts, celiac disease, congenital heart disease (CHD), and diabetes. The **DS-Connect® registry** (<https://dsconnect.nih.gov/>) is enhancing research participation and data sharing through the INCLUDE DCC.

## INCLUDE Project Objectives

1. Conduct targeted, high-risk, high-reward basic science studies on chromosome 21.
2. Assemble a study population of individuals with DS across the lifespan.
3. Include individuals with DS in existing and future clinical trials.

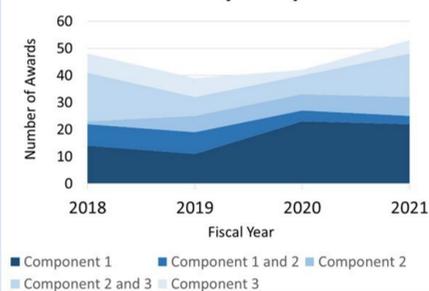


## FY2021 Funded Projects

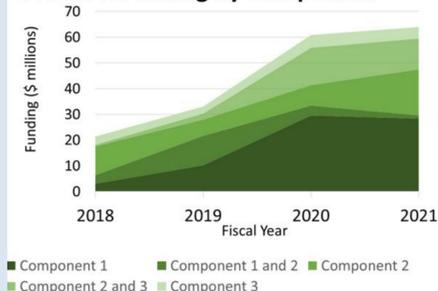
The NIH has invested \$183 million in the past 4 years on INCLUDE on 202 new projects. **The FY 2021 INCLUDE investment was \$65 million for total NIH funding of ~\$109 million. Sample research projects:**

- Investigate the **impact of COVID-19** on individuals with DS.
- Study the molecular epidemiology of **acute lymphoblastic leukemia** in children with Down syndrome
- Develop and validate **cognitive measures** in the NIH Toolbox for children with DS.
- Study the effects of **hypoglossal nerve stimulation** on language and cognition
- Study a cohort of adults with DS to identify **biomarkers of neurodegeneration** and risk and resilience factors for AD

INCLUDE Awards by Component



INCLUDE Funding by Component



INCLUDE DCC: <https://includedcc.org/>

- Enabling discovery through **collaborative resources, data integration and open science.**
- The INCLUDE DCC is creating a **cloud-based, digital platform** to easily access and share Down syndrome resources to maximize and accelerate research.
- The DCC has engaged in workshops and other outreach to the DS community to increase its representation.
- **The INCLUDE Data Hub launched March 21, 2022**

## DS-Connect®

### DS-Connect®: The Down Syndrome Registry

A secure, confidential, online survey tool to collect basic health information about people with DS and connect them with research opportunities.



### In the past 7 years:

- 80+ studies have requested recruitment support\*
  - Over 90% were approved by the RRC
  - 12 INCLUDE projects have received recruitment support, including 5 clinical trials
- \*Requires submission of a summary of protocol, purpose and IRB Status and review by the Research Review Committee (RRC) for approval

## Current Funding Opportunities

The following FOAs are available in FY22:

Four RFAs published in FY21 or FY22:

- Digital Technology and Mobile Health (mHealth) to Improve Diagnosis, Assessments, Interventions, Management and Outcomes (**NOT-OD-21-092**)
- INCLUDE Exploratory/Developmental Research Grant Award (R21) (**RFA-OD-21-007**) and Clinical Trial Readiness (R21) (**RFA-OD-22-007**)
- Small Research Grants for Analysis, Curation, and/or Sharing of DS Research Data (R03) (**RFA-OD-22-008**)
- Transformative Research Award for the INCLUDE Project (R01) (**RFA-OD-22-009**)
- Clinical Trials Development for Co-Occurring Conditions in DS (R61/R33) (**RFA-OD-22-010**)
- Administrative and competitive supplements to existing awards and CSA Program (**NOT-OD-21-001**)

Plan to reissue many FOAs that expire in FY21/FY22

See: <https://www.nih.gov/include-project/funding>

## Down Syndrome Research Plan

NIH has updated the DS research plan to reflect broad stakeholder input into its revised goals and objectives, garnered via two Requests for Information. The bibliography includes nearly 600 articles resulting from NIH investments and published between 2014-2020, representing a 74% increase over those published in the prior 7-year period. Goals include diversifying the investigator community and research participants. The NIH INCLUDE Down Syndrome Research Plan is scheduled to be released in summer 2022.

## CONCLUSIONS

- The NIH-wide INCLUDE initiative is making major investments in DS research, in basic science, cohort development, and clinical trials domains
- The INCLUDE Data Coordinating Center will accelerate discovery in DS research by creating a collaborative, integrated data ecosystem for DS research; the INCLUDE Data Hub launched March 21, 2022
- DS-Connect® is an online registry for families that is also available to investigators to help them recruit for DS research studies
- Engagement with the DS community is essential to encourage broad, diverse representation in research and to improve quality-of-life for those with DS

## Down Syndrome Consortium

