EDICT
Eliminating Disparities in Clinical Trials

Eliminating Disparities in Clinical Trials (EDICT) Project

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EDICT Project Goal:

- **Develop practical and implementable policy solutions to recruiting *and* retaining populations that are underrepresented in clinical trials…**

  through which change can occur at the public, private or non-profit sectors.

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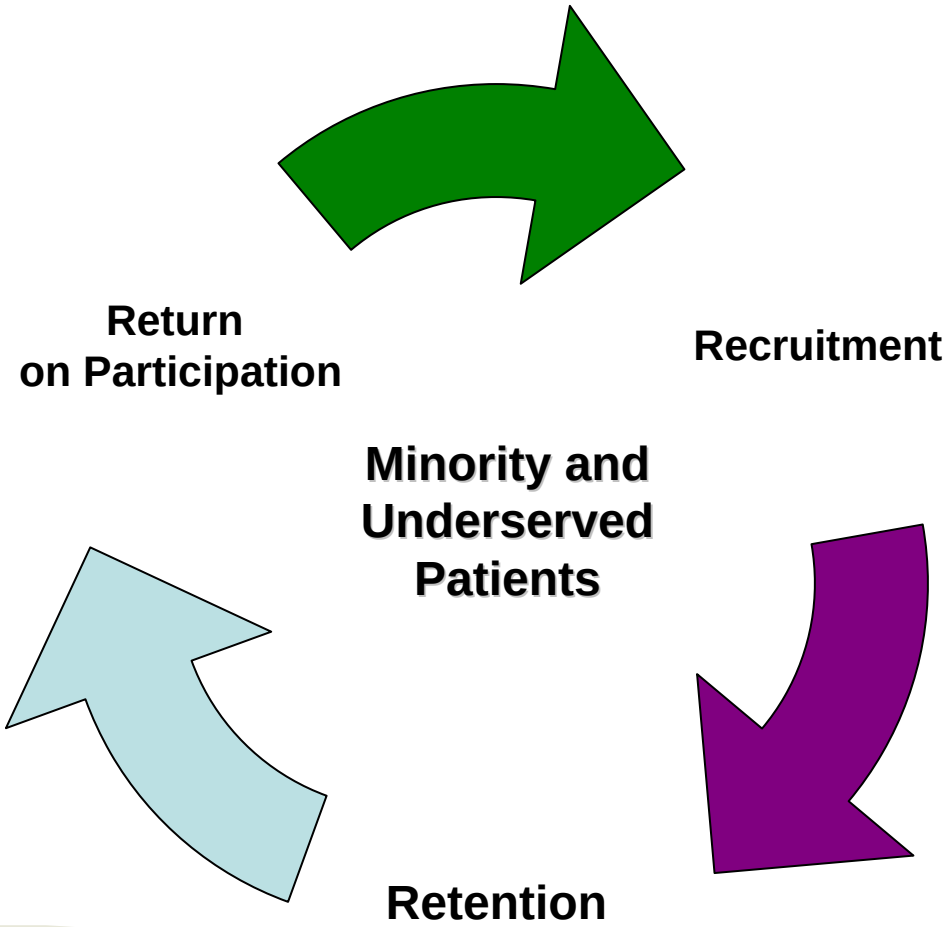
The Three R's + R



- **R**ecruitment - In addition to issues of active recruitment, this "R" also includes issues of access.
- **R**etention - Keeping participants satisfied and "on protocol."
- **R**eturn - Giving back to our participant populations.

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Who Is Underrepresented?

- Underserved, Poor
- Racial/Ethnic
- Children vs. Adolescents
- Women
- Rural
- Uninsured
- Elderly
- Special Health Needs, i.e., disabled, chronic illness, etc.

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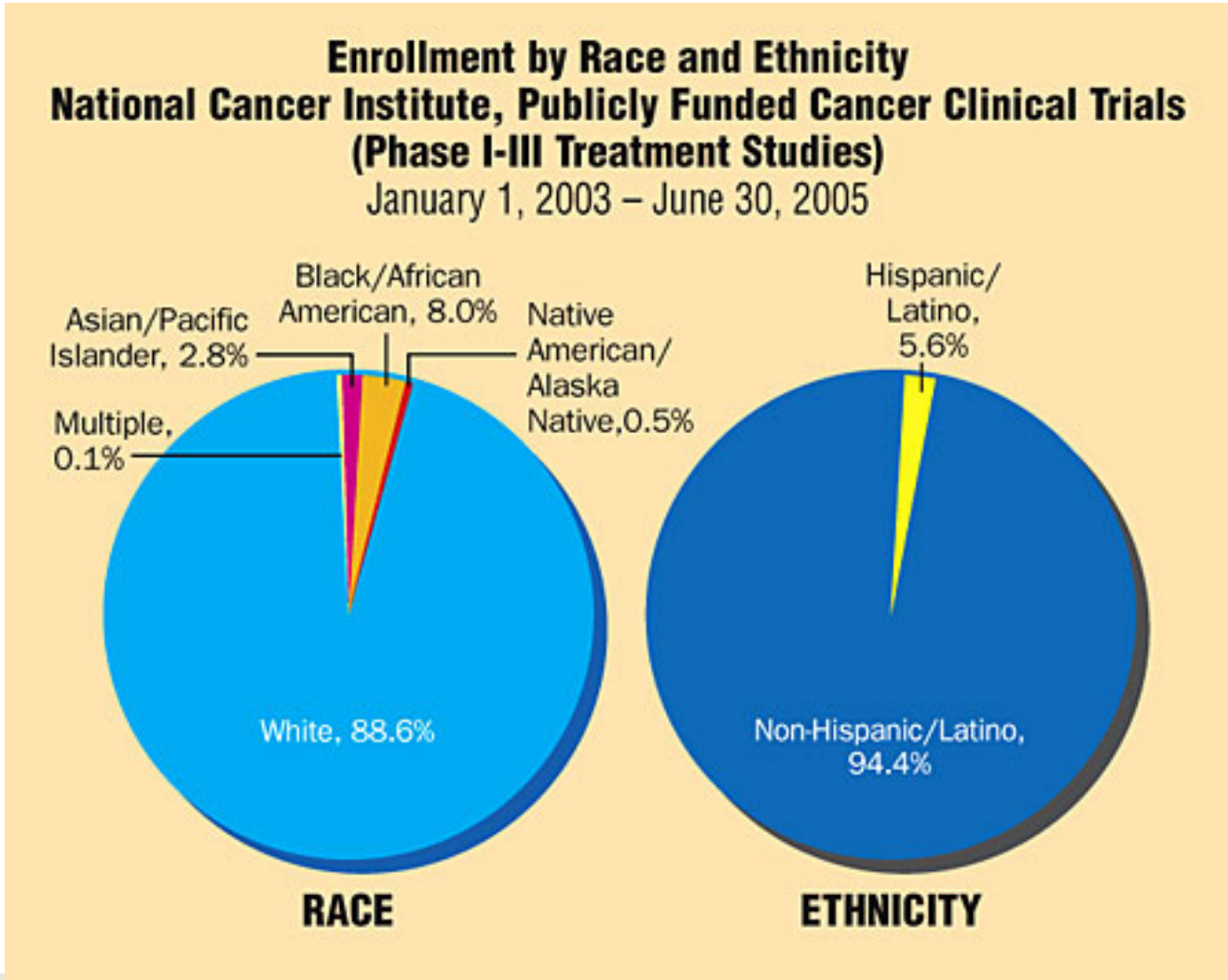
Examples of Underrepresented:

- **Racial/Ethnic Status**



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Examples of Underrepresented:

- **Elderly**
  - Because clinical trial participants are generally younger, the data obtained may not always extrapolate to the elderly
  - Diverse effects of aging, pharmacokinetic differences in metabolism and treatment efficacy and co-morbidities -- inclusion of elderly is critical
  - *Example:* While nearly 2/3 of cancer patients are age 65 and older, this groups accounts for less than 1/3 of clinical trial enrollees

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EDICT Policy Formulation Process - with Public, Private, Non-Profit Sectors

- Medical, policy, and legal literature
- Identification and interview of key experts, stakeholders, partners
- National Policy Roundtable – formulate policy areas through “Whole-Scale Change Process®”
- Teams of volunteers refine policy and implementation plans in facilitated meetings for 9 months

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Opportunity Teams

- ***OT1*** Allocation of Research Funding Proportionate to Case Fatality
- ***OT2*** **Assuring Healthcare Coverage in Clinical Trials**
- ***OT3*** Education and Training - Institutional and Professional
- ***OT4*** Education and Training - Public and Patients

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Opportunity Teams (continued)

- ***OT5*** Fostering Community Input and Involvement and Relationships
- ***OT6*** Patient/Participant Navigation
- ***OT7*** Pharmaceutical Partnerships
- ***OT8*** Publication-Related Policies
- ***OT9*** Regulatory Oversight and Enforcement

Team: "Assuring Healthcare Coverage in Clinical Trials"

Problem: ***Fears of insurance coverage and reimbursement are a well-known barrier to participation in clinical research***

- Study of NCI-sponsored trials - uninsured represent only 5.4% of participants
- 60% of participants surveyed - fear insurance denial as major reason for not participating
- Even when participants insured, some private party-third payers do not cover the full cost - may affect underserved populations more
- Cancer studies have shown that the cost of trial is not necessarily more than standard care

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Proposed Revision to CMS Medicare Clinical Trials Coverage

"The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies...

how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial.

If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary."

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Proposed Revision Has Produced Dialogue

- Opposition says changes not needed since NIH Revitalization Act requires and FDA guidelines recommend inclusion of underrepresented

- Concern that the self-certification process will increase burdens on institutions, potentially decreasing participation

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Federal Initiatives Have NOT Prevented Widespread Disparities in Clinical Trials

- NIH Revitalization Act applies only to federally funded
- 80% of trials are industry-funded
- Methodology NIH uses does not report retention
- Difficult to see how CMS can see a ROI if retention is unknown
- IRB spends most resources on initial reviews, not continuing reviews
- FDA guidelines not compulsory

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Little Reason to Believe the Proposed Changes Will Prove Impractical

- Little evidence how CMS's modest measures to address this problem will prove to be a burden

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In Summary, Why Is This Important?

- **Science Case** - enhance research quality
- **Business Case** - facilitate return on investment
- **Social Justice Case -** distribute the fruits of biomedical research justly

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More than a Decade After the Passage of the Revitalization Act…

- "Certain populations are still underrepresented in cancer-related trials, including minorities, older adults, adolescents, rural populations and individuals of low SES."

Shari Bolen, et al. "Defining Success in Recruitment of Underrepresented Populations to Cancer Clinical Trials: Moving toward a More Consistent Approach, 106 CANCER 1197, 1998 (2006)

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