Why Enhancing Diversity in Clinical Trials is Good Policy

EDICT v2.0
CREDO

• All individuals will have the opportunity and necessary support to participate voluntarily in clinical trials for which they are eligible.

• Participants and researchers will understand and promote the benefits of diversity in clinical trials.

• Results from clinical research will benefit the participants’ communities and society at large.
The Four R’s

- **Recruitment** - In addition to issues of active recruitment, this “R” also includes issues of access.
- **Retention** - Keeping participants satisfied and “on protocol.”
- **Return** - Giving back to our participant populations.
- **Resources**

**Underrepresented Patients**

**Recruitment**

**Retention**

**Return on Participation**

**Resources**
Opportunity Teams

OT1 Allocation of Research Funding Proportionate to Case Fatality

OT2 Insurance - Assuring Healthcare Coverage in Clinical Trials

OT3 Professional Education and Training

OT4 Public and Patient Education and Training

OT5 Community Input, Involvement & Relationships

OT6 Clinical Trials Navigation

OT7 Pharmaceutical/Industry Partnerships

OT8 Publication-Related Policies

OT9 Regulatory Oversight and Enforcement
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
“EDICT’s

Eight Community Dialogue Meetings”

New York City, Cincinnati, Charleston WV, Tampa, Cayey/San Juan, Tucson/Phoenix, Honolulu and San Francisco
So Why Enhancing Diversity in Clinical Trials is Good Policy?

**Economics**

**Diversity**

**Investigation**

**Collaboration**

**Transparency**
Economics

- Current clinical trials may favor the selection of therapies that may not meet the needs of a diverse population
- Individual - fewer adverse events, burden of less effective therapies
- Insurers - reimbursement for ineffective medications, higher patient costs
- Industry - medicine ineffective for some populations, lost time, sunk costs
- Government - improved allocation of research resources, also insurers, misplaced policies
Diversity

- Current therapies may not meet needs of diverse populations
- Socio-cultural factors that influence outcome of therapies (SDH is at play)
- Need more diverse or minority investigators
- Not just racial and ethnic minorities, gender, age, co-morbidities to name a few
- Inclusion in research a means of ensuring that the products and evidence generated are relevant and reliable for different populations of patients
Investigation/Investigators

- Attention to diversity up front may change protocol development (design not human subjects protection)
- Partner with communities for effective education and conduct of research (navigators?)
- The science case may go beyond your science!
- Burden of disease
- Investigators need to be educated not just convenience samples
- Need for diversity among investigators, staff and reviewers
Collaborations

• Core of EDICT – the participant is a collaborator!
• Needed among and across public, private, non-profit
• Need industry to get involved
• Government - at least focus on federal partners: CMS, FDA, NIH, and others
• Must have community engagement
Transparency/Translation

- Position statements inadequate – “dissemination by design”
- Cost should not and is not the problem
- What can be done without being required to (e.g., push policy forward i.e. FDA)
- Needed for collaborative projects with CMS - support data analysis projects using CMS data that benefits all, not proprietary
- Systems approach illustrates where and why
- Enhances trust among those participating
"policy is not self-executing"

policies not enforced or taken to logical conclusion....

• Government agencies need the authority and the ability to enforce
• Need industry to step-up and get involved in enforcing diversity in clinical trials...par exemplar, Genentech
• Non-profits can effect change as well
“Do not let what you CANNOT do... interfere with what YOU CAN DO "

http://www.bcm.edu/edict