

# The EDICT Project: Policy Recommendations to Eliminate Disparities in Clinical Trials

## Article 1 of 4

### Objectives:

1. Identify populations that are underrepresented in clinical trials.
2. Identify participant barriers to clinical trials participation.
3. Identify three investigator/health professional barriers to participation of underrepresented populations.
4. Identify current major national and state regulations related to underrepresented population participation in clinical trials.
5. Describe the nine general policy areas that the Eliminating Disparities in Clinical Trials (EDICT) Project team has identified for policy change.

*Most of the information included in this article is adapted from the EDICT Project Policy Publication, "The EDICT Project: Policies to Eliminate Disparities in Clinical Trials," and the EDICT/Intercultural Cancer Council Fact Sheet, "Cancer Clinical Trials: Participation by Underrepresented Populations."*

### Background

It has been known for decades that members of certain populations are medically underserved due to many factors, such as age, gender, race, ethnicity, language, and geographic location. These populations also remain "underrepresented" in our nation's clinical trials, often resulting in clinical research that does not assess how treatments may affect members of specific populations differently.<sup>1</sup>

The Eliminating Disparities in Clinical Trials (EDICT) Project at Baylor College of Medicine in collaboration with the Intercultural Cancer Council was developed to propose thoughtful and viable policy solutions to the problem of underrepresentation of certain populations in clinical trials.<sup>2,3</sup> EDICT brought together over 300 national representative stakeholders from the public, private

and non-profit sectors for a two-year collaboration resulting in the development of thirty-three policy recommendations in nine categories. By utilizing a systems approach that comprehensively addresses disparities in clinical trials participation, these policy recommendations target both the root causes of disparities and the appropriate policy mechanism needed for change.

The policy recommendations have been the subject of an extensive revision process that began in earnest in September 2007. At that time, the EDICT team held a national Core Leadership Conference, to begin the first review of the policy recommendations. Subsequently, in October 2007-March 2008, the EDICT team conducted three "waves" of review with both internal EDICT members and targeted external stakeholders. The EDICT team then sought input from the public, as a reflection of both the inclusive deliberation process and the EDICT team's own research that revealed that more community involvement led to stronger recommendations.

The thirty-three policy recommendations have been

developed from the following nine categories identified as opportunities for policy change:

- Reinvigorating Regulation and Policy Related to Disparities in Clinical Trials
- Collaboration with the Pharmaceutical Industry
- Fostering Community Involvement in Clinical Trials
- Role of Biomedical Publications in Setting Standards for Inclusion in Clinical Trials
- Professional Education - Researchers, Healthcare Professionals and Members of Institutional Review Boards
- Reallocation of Research Funding to Avoid Duplication and Address Disparities
- Public Education About Clinical Trials
- Navigation of Individuals in Clinical Trials
- Assuring Healthcare Coverage in Clinical Trials

*A summary of the policies is included in the last section of this article.*

These policy recommendations, however, are not the culmination of the EDICT Project, as the EDICT team is committed to disseminating these recommendations throughout

the later part of 2008 and in 2009 in the hopes of achieving actual policy change.

### **Why Is It Important to Have Representation of All Populations in Clinical Trials?**

Clinical trials are a critical resource for the discovery of new life-saving drugs and for developing better prevention, diagnostic and treatment methods for disease. Many of today's most effective prevention and treatment modalities are based on previous clinical trials results.<sup>4</sup>

Certain populations, such as those that are low income, elderly, racial/ethnic minorities, women and those who live in rural areas represent the smallest percentage of clinical trial participants. Unfortunately, these same populations also bear a disproportionate burden of disease morbidity and mortality.<sup>5,6</sup>

Without adequate representation of these populations in clinical trials, researchers cannot learn about potential differences among groups and ensure the generalizability of results to the entire U.S. population.<sup>7,8</sup> For clinical trials to be useful to all populations, individuals from all backgrounds, ages and locations need to participate.

### **Who Is Underrepresented in Clinical Trials?**

The following populations are underrepresented in U.S. clinical trials:

**Elderly:** While nearly two-thirds of cancer patients are age 65 or older, this age group accounts for less than one-third of clinical trial enrollees.<sup>9</sup>

**Racial/Ethnic groups:** African Americans, Asian/Pacific Islanders, Hispanic/Latinos and Native Americans collectively represented less than 10% of participants in clinical trials testing cancer drugs in 1995-1999, according to an FDA review.<sup>10</sup>

**Women:** Eight of the ten drugs eliminated from the market in the last decade of the 20th century were removed because of unexpected side-effects that affected women more than men.<sup>11</sup>

**Children:** A study of thirty-one U.S. pediatric hospitals found that 79% of all patients were given at least one medication that had not been approved for children and was tested only on adults.<sup>12</sup>

**Adolescents:** Only 10% of 15-to-19 year old cancer patients enter into trials, while 60% under age 15 take part.<sup>13</sup>

**Low income:** Regardless of race or ethnicity, low socio-economic status has a negative impact on clinical research participation.<sup>6,14</sup>

**Those who live in rural areas:** Among patients enrolled in National Cancer Institute (NCI) sponsored trials, investigators found that suburban areas had the highest participation.<sup>15</sup>

**Others:** Additional populations who are underrepresented in clinical trials include those with special health needs (disabled, chronic illness, co-morbidities) and the uninsured.<sup>16</sup>

The Coalition of Cancer Cooperative Groups evaluated enrollment to NCI treatment trials from January 2003 through June 2005. The data presented below shows accrual rates by racial and ethnic status:

See Enrollment by race and ethnicity graphic (next page)

### **Participant Barriers to Clinical Trials Participation**

**Mistrust:** The historical mistreatment faced by groups such as African-Americans and Puerto Ricans has resulted in mistrust of research and the medical system, and ultimately, underrepresentation.<sup>17,18</sup>

**Lack of awareness:** A national survey of cancer patients found that 85%

of respondents were unaware that participating in a clinical trial was an option for them.<sup>19</sup>

**Cultural barriers:** Certain cultures non-western views of health and disease may make clinical trials a less desirable option.<sup>20</sup>

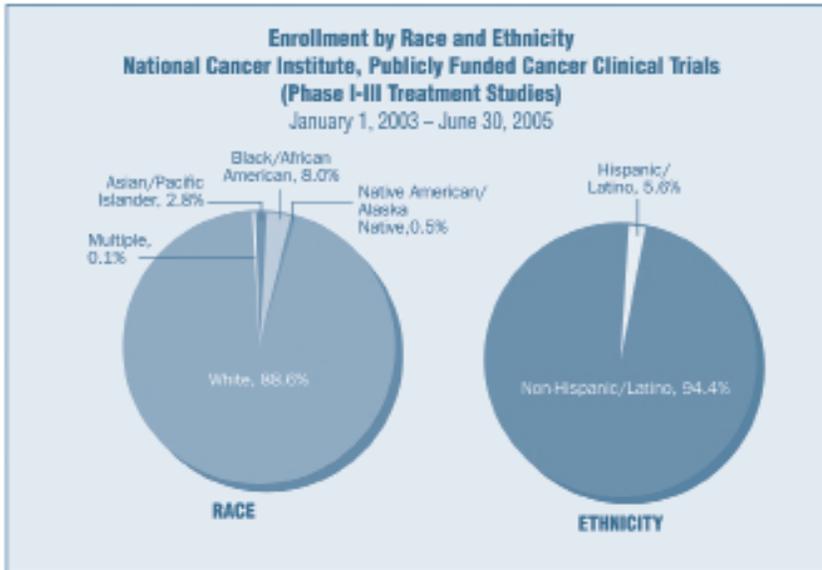
**Language/Linguistic differences:** Many U.S. clinical trials require English proficiency for potential participants, automatically excluding those who do not speak the language. Language factors also pose a serious barrier to provider-patient communications and attempts to recruit patients into clinical trials.<sup>21</sup>

**Low literacy:** The complexity of consent forms and other clinical trials materials may be a barrier to those patients with low literacy.<sup>22</sup>

**Socio-economic obstacles:** Underrepresented populations are more likely to encounter social and economic barriers to participating in clinical trials. Unreliable transportation and living in remote areas may prevent otherwise eligible patients from participating in clinical trials. Some low income groups have decreased participation due to competing issues such as unpaid work leave and lack of childcare.<sup>23</sup>

**Cost/Lack of insurance:** Costs associated with clinical trials are often a concern. A study of NCI-sponsored cancer treatment trials found that uninsured patients represented only 5.4% of all clinical trial participants. Even when participants have insurance coverage, many cannot participate due to high out of pocket expenses not covered by their benefit plan.<sup>24</sup>

**Study design eligibility criteria:** Traditional clinical trial eligibility criteria typically limits participation of those suffering from more than one health condition, which in turn



Source: Baseline Study of Patient Accrual Onto Publicly Sponsored Trials,” Coalition of Cancer Cooperative Groups for the Global Access Project, National Patient Advocate Foundation, April 2006.

often excludes the elderly, members of racial/ethnic groups, and patients with lower socio-economic status.<sup>25,26</sup>

**Physician/Investigator Barriers to Referring Patients to Cancer Trials**

**Lack of minority investigators:** 2004 data show that only 12% of all U.S. physicians are African American, Hispanic/Latino, Asian, or Native American. Yet, these minority groups make up more than 30% of the U.S. population.<sup>27</sup> Minority patients often choose physicians of their own background, but minority physicians are underrepresented as investigators for clinical trials in the United States. Physicians with access to minority patients could be an important source of racial and ethnic minority trial participants.<sup>28, 29</sup>

**Lack of physician referral:** Although physician referral is one of the most effective means of recruiting patients to cancer clinical trials, some physicians may be reluctant to refer because they perceive an excessive administrative or financial burden to their practice. Physicians may also hesitate to inform patients of trials based on their own attitudes and beliefs and their assumptions about

patient eligibility to enroll according to factors such as age, other existing conditions, cost, or ability to adhere to study protocol.<sup>30, 31</sup>

**Lack of physician awareness:**

Primary care and specialty physicians who are not affiliated with research institutions may be less aware of patient eligibility for clinical trials. Lack of awareness is one of the most common reasons physicians fail to refer patients to trials.<sup>32, 33</sup>

**Policy Efforts to Date that Address Clinical Trials Disparities**

It is important to acknowledge that there have been both national and state level initiatives in the past two decades designed to address disparities in clinical trial participation.

**National Initiatives:**

- **National Institutes of Health (NIH):** The NIH Revitalization Act of 1993 requires applicants for federal research funding to provide a strategy for inclusion of women and people of diverse racial and ethnic origin into clinical trials.<sup>34</sup> However, more than a decade later, women and minorities continue to be

underrepresented at varying levels in clinical trials.<sup>23, 35</sup> The Act does not address the appropriate representation of other identified underrepresented groups.

- **Food and Drug Administration (FDA):** The FDA Modernization Act of 1997 provides guidance on standardization of data collection of racial/ethnic groups in clinical trials, but does not address appropriate racial and ethnic inclusion.<sup>36</sup> Compliance with the guidelines of this Act has been reported to be optional and relatively low.<sup>28</sup> In addition, the Act does not provide guidance on other underrepresented groups.

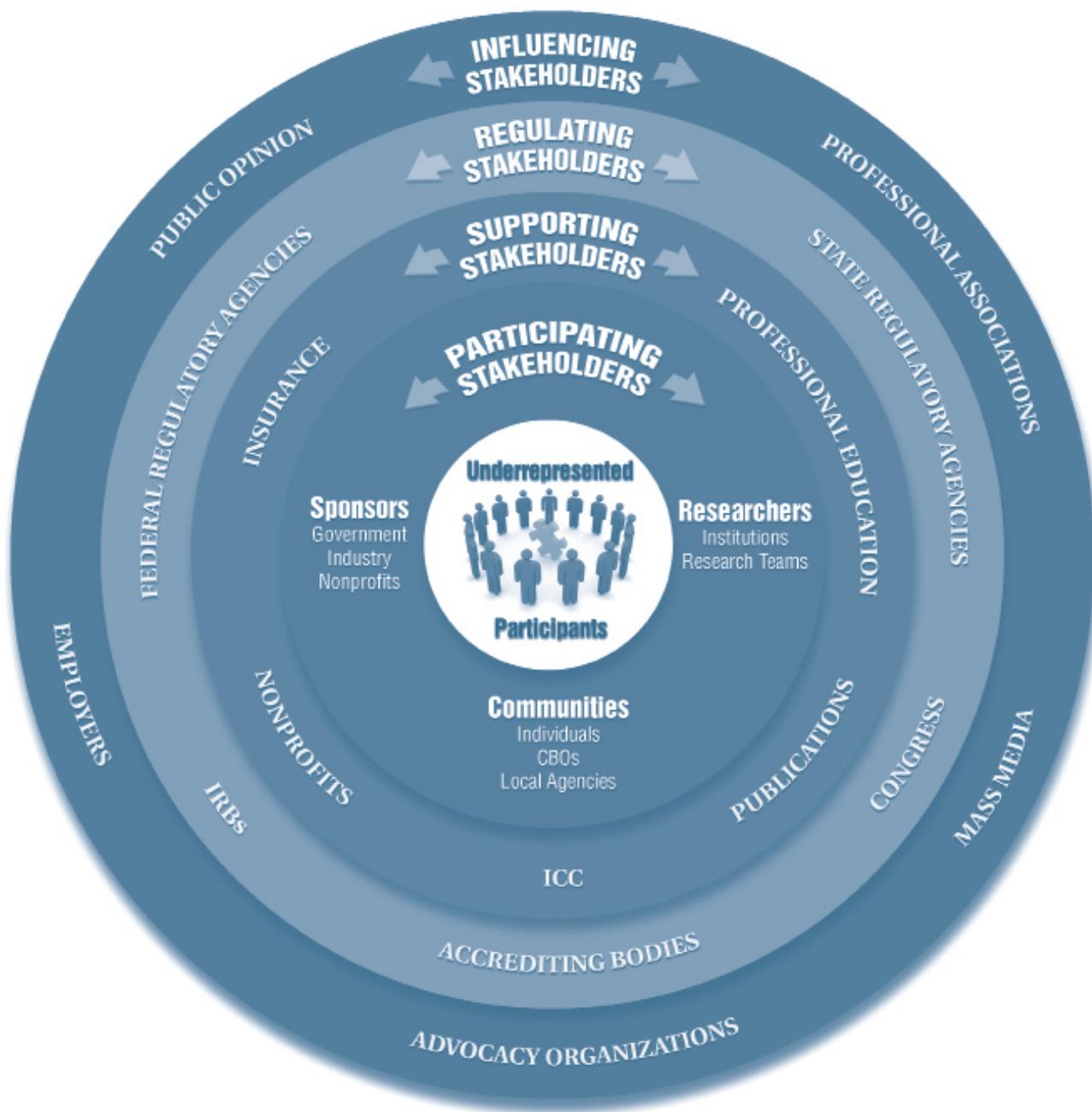
- **Centers for Medicare and Medicaid Services (CMS):** In 2000, CMS authorized payment of routine care costs for Medicare beneficiaries who are participants in clinical trials.<sup>37</sup> Yet, the elderly remain among the most under-represented populations in clinical trials today.<sup>38</sup>

**State Initiatives:**

- **States:** As of 2007, only 20 states in the U.S. required reimbursement of routine medical costs for clinical trial participants by legislative mandates or agreements with large health insurers.<sup>39</sup> Many private health insurers are exempt from these mandates.<sup>40</sup>

**EDICT Policy Development Process**

The EDICT collaborative endeavor involved a variety of national stakeholders, including medical researchers, healthcare professionals,



patient advocates, public health officials and pharmaceutical company representatives who worked together for two years to develop the EDICT policy recommendations.

The EDICT Policy Development Process evolved as a systematic approach to addressing the many challenges to clinical trials

participation by underrepresented populations and included:

- Assessing policy issues related to clinical trials disparities
- Identifying key experts, stakeholders, and partners
- Convening a National Policy Development Roundtable of stakeholders

- Creation of nine national specialized policy teams to develop policy proposals
- Successive internal/external review of proposed policies
- An open public comment period
- Dissemination of policy recommendations through education, communication, and stakeholder engagement

## **EDICT Policy Context Model of Stakeholders**

Based on its Policy Development Process, the EDICT Team created the EDICT Policy Context Model of Stakeholders, shown above. Given the complexity of policy context relating to disparities in clinical trials, this model was developed to capture the key features of the systems approach.

As the diagram indicates, assisting the underrepresented is at the core of the EDICT Project. Each concentric circle represents a level of stakeholders who must be engaged and involved to promote parity in clinical trials.

(See Policy Context Stakeholder Graphic)

## **Overview of EDICT Policy Recommendations**

The next section contains a brief summary of the **nine policy recommendations areas identified and developed by the EDICT team members**. More specific details related to individual policies within each area, including detailed rationale, background information and references, can be found at the EDICT website: [www.bcm.edu/edict](http://www.bcm.edu/edict)

### **1. Reinigorating Regulation and Policy Related to Disparities in Clinical Trials**

Although the NIH Revitalization Act of 1993 requires appropriate representation of women and minorities in federally-sponsored clinical trials, the government mandate has not translated into measurable improvements and does not address other underrepresented groups. Further complicating the problem, the policies of the Food and Drug Administration, are not aligned with the NIH law. The current FDA guidance, "Collection of Race and Ethnicity Data in Clinical Trials," mandates standardization of data collection of racial and ethnic groups without requiring appropriate

inclusion of racial and ethnic groups and other underrepresented groups.

To address this problem, the EDICT team recommends that NIH provide more direct instruction on appropriate inclusion plans for all underrepresented populations and substantial incentives for investigators to implement appropriate inclusion plans. The FDA should harmonize its policy with NIH policy to require appropriate inclusion of women and racial/ethnic groups as well as all other underrepresented populations in clinical trials. In addition, EDICT recommends the adoption of the Department of Health and Human Services (DHHS), Office of Minority Health (OMH) CLAS (Culturally and Linguistically Appropriate Services) standards in both federally funded and privately funded clinical trials.

### **2. Collaboration With the Pharmaceutical Industry**

Pharmaceutical industry sponsored trials are not subject to the NIH Revitalization Act that mandates inclusion of women and minorities in clinical trials. Investigators and sponsors conducting pharmaceutical industry sponsored trials have a general lack of incentives and have financial disincentives for including underrepresented populations. Current investigators also may lack the community relationships needed to recruit members of underrepresented groups.

Because nearly seventy-five percent of the funding for clinical trials comes from corporate sponsors, the EDICT team recommends that the pharmaceutical industry require investigators to have the subject population include members of underrepresented communities that appropriately correspond to the proportions such communities comprise in the targeted population. In addition, industry sponsors should select and develop investigators with

the capability of achieving appropriate inclusion based on the population served, and include in trial plans how affected communities will receive information and other benefits as a result of the trial.

### **3. Fostering Community Involvement in Clinical Trials**

Today, community organizations are usually left out of the clinical trials process, resulting in a lack of awareness and trust in the medical system that could possibly be rectified through increased community involvement in research - from planning to implementation.

Towards this end, the EDICT team recommends that investigators build a detailed plan for community engagement into the research protocol that includes demonstrated methods and measures for working with community organizations and institutions. It also recommends that community groups develop ongoing relationships with investigators and research institutes to promote meaningful dialogue that ensures community involvement.

### **4. Role of Biomedical Publications in Setting Standards on Inclusion in Clinical Trials**

Although peer-reviewed medical/science journals have addressed significant issues where increased attention by the scientific community is warranted, the discussion of diversity, inclusion and representation in clinical trials has been missing from published studies.

To change this situation, the EDICT team is calling on two chief editorial organizations for biomedical publications - the International Committee of Medical Journal Editors (ICJME) and the World Association of Medical Editors (WAME), as well as the Consolidated Standards for Reporting Clinical Trials (CONSORT) Group - to adopt standards that require

investigators to include in their manuscripts an analysis of how the subject population's demographics correspond to those of the population that bears the greatest disease burden.

### **5. Professional Education of Institutional Review Boards and All Health Care Professionals**

#### *Training for Institutional Review Boards (IRBs)*

Although the mission of institutional review boards is to safeguard the rights, safety, and well being of all trial subjects, IRB members often lack the training needed to recognize how disparities manifest themselves in research protocols. Thus, IRBs regularly approve research protocols that do not provide for inclusion of underrepresented populations.

The EDICT Team recommends that the Department of Health and Services (DHHS), Office of Human Research Protections (OHRP), which oversees the regulation of IRBs, and the Association for the Accreditation of Human Protections Programs (AAHRPP), to add specific requirements that IRBs receive training in healthcare disparities in general and disparities in participation in clinical trials.

#### *Training for Health Professionals and Researchers*

All levels of education and training and continuing professional education for physicians, nurses and other health professionals usually does not include sufficient information on clinical research in general, culturally and linguistically appropriate care, or the specific manifestations of disparities in clinical trials. Additionally, institutional clinical research training programs required of federally funded researchers, lack sufficient information regarding disparities in clinical trials. Accordingly, the EDICT Team recommends that all levels of professional education and continuing medical education for health professionals require education

addressing basic principles of clinical research and disparities in clinical trials. Institutions mandating clinical research training should address the existence of disparities and practical strategies for ameliorating them.

### **6. Reallocate Research Funding to Avoid Duplication and Address Disparities**

Because government, non-profit and industry sponsors often conduct medical studies on the same diseases, there is a duplication of research efforts in some disease categories and insufficient attention and resources for diseases, such as liver and kidney cancers, where significant disparities in outcomes and high case fatality rates exist.

Addressing this problem will require an impartial entity to access areas of duplicative research, which is why EDICT recommends that the Institute of Medicine conduct a new study that will recommend strategies for eliminating duplication and promoting coordination. Based on this assessment, Congress will be able to ensure that federal research funding complements private sector funding and gives priority to diseases with the greatest disparities and the highest case fatality rates.

### **7. Enhance Public Education About Clinical Trials**

Lack of awareness about clinical trials and fear or mistrust of medical research remain pervasive obstacles to participant accrual. Moreover, the complexity of consent forms and other clinical trials materials is often a barrier for those patients with low health literacy - the inability of an individual to access, understand and use health-related information and services to make appropriate health decisions.

Accordingly, EDICT team members recommend widespread development and implementation of culturally

appropriate recruitment and retention plans for clinical trials as well as community education provided in appropriate languages for non-English and limited-English speaking populations and appropriate reading levels for all populations.

### **8. Navigation and Support of Individuals in Clinical Trials**

Clinical Trials Navigation is a relatively new concept that helps patients navigate within today's complicated health system so that they can participate in clinical trials. Modeled after the "navigator" program created at Harlem Hospital, Clinical Trials Navigation provides personalized education and support to help patients keep their appointments and helps solve their non-medical problems, such as transportation to the trial.

Because of its potential to retain underrepresented patients in medical research studies, the EDICT team recommends that institutions and sponsors of clinical trials ensure that entities that conduct trials have the capacity to deliver Clinical Trials Navigation Services and encourage all research protocols to have specific Clinical Trials Navigation plans.

### **9. Assuring Insurance Coverage for Costs Associated with Clinical Trials**

The costs associated with participating in a clinical trial are a concern to all participants and have remained a major barrier to patient accrual. A study of NCI-sponsored treatment trials found that uninsured patients represented less than 6% of total participants. Even when participants do have insurance, some third-party payers do not cover the full costs associated with participating in clinical trials. Most employee insurance plans are exempted from state coverage mandates to cover clinical trials under federal benefits law.

Medicaid policies, implemented by the states, do not have universal standards for covering clinical trial participation. In 2000, the Centers for Medicare and Medicaid Services (CMS) authorized coverage of standard costs associated clinical trial participation for Medicare recipients, but did not require that covered protocols include underrepresented populations.

The EDICT team recognizes that addressing these issues and barriers will entail actions by both the business

community and federal and state policy makers to identify and close existing coverage gaps. Specifically, business groups and associations should request that their members provide coverage for clinical trials, and that employers ensure that the coverage is accessible and usable by employees. CMS should develop a reporting mechanism to gather information on Medicaid and SCHIP state coverage for clinical trials, encourage Medicaid and SCIP to adopt Medicare standards on clinical trials

coverage, and ensure that Medicare beneficiaries have education and information about their clinical trials benefits.

### Conclusion

For more information on the EDICT Project, its policy recommendations and dissemination activities, please visit the EDICT home page at [www.bcm.edu/edict](http://www.bcm.edu/edict).

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