

National CTSA Consortium Strategic Goal 4:
**To enhance the health of our communities
and the nation**

Strategic Goal 4B:
**To promote the translation of clinical and
translational research into practice and policy
via the CTSA Consortium's contributions to
comparative effectiveness research (CER)**

Institute of Medicine Report Definition of Comparative Effectiveness Research (CER)

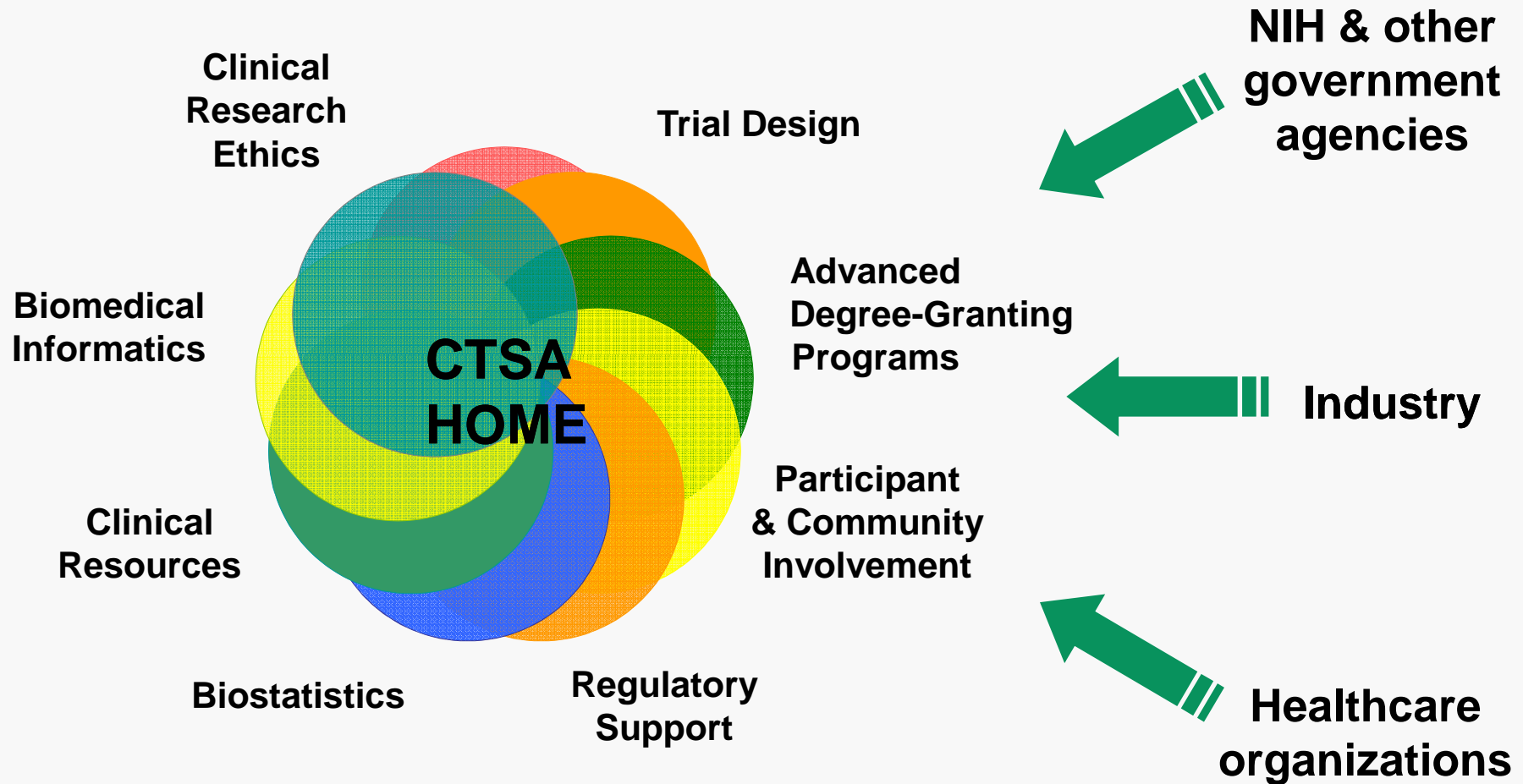
- “The generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist patients, clinicians, purchasers, policy makers, and the public to make informed decisions that will improve health care at both the individual and population levels.”

Federal Coordinating Council on CER Report

Definition of CER

- “CER is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in ‘real world’ settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances...”

Each CTSA Institution is a home for clinical and translational science



CTSA Consortium Resources and Functions That Could Advance CER

- Clinical research infrastructure in study design and methods expertise, statistics, epidemiology, and regulatory support.
- Formal programs in education, training, and career development, often including the domains central to CER.
- Programs in community engagement, both of the general public and of clinical practice communities.
- Informatics related to research and clinical practice
- Mandate to link different disciplines and to link and coordinate with other CTSA

Comparative Effectiveness Research Strategic Goal (4B) Deliverables

- Compile a capacity and needs assessment for CER and related resources across CTSA: *Done 7/09*
- Write White Paper on how CTSA Consortium can facilitate CER for NIH ICs, other federal agencies, outside stakeholders, and the healthcare system: *Done 9/09*
- Recommend CER methods development agenda to fulfill SG4B: *Draft report in progress, on timeline for 1/10*
- Facilitate links and networking among NIH ICs, other agencies, other entities, and individuals to conduct CER: *On timeline for meetings 12/10 and beyond and network*
- Frame CER workforce needs CTSA roles in CER training and career development programs in CER: *Draft report on timeline, on timeline for 12/09*

CTSA Consortium White Paper Recommendations for Comparative Effectiveness Research (1 of 6)

1. The CTSA Consortium should organize and support clinical trial infrastructure capacities to be responsive to the needs of CER, including especially the ability to link these capacities across institutions to support multi-site CER clinical trials. *This should result in more efficient generalizable comparative effectiveness trials, with shorter time required for trial preparation and execution, thereby generating results more rapidly.* If CER studies do not provide results in an acceptable time period, the value of the research will be severely compromised.

CTSA Consortium White Paper Recommendations for Comparative Effectiveness Research (2 of 6)

2. The CTSA Consortium should support education, training, and career development in CER by funding T, K, and other appropriate awards sufficiently to contribute substantially to the needed CER workforce. *This should help develop the workforce of scientists and disciplines of all types needed to conduct CER on the scale required for real support of healthcare improvement.*

CTSA Consortium White Paper Recommendations for Comparative Effectiveness Research (3 of 6)

3. The CTSA Consortium should develop capacities using CTSA Community Engagement components to incorporate input from the public and the clinical practice communities into generating, prioritizing, and developing CER questions and research protocols; interpreting CER results; and implementing CER results into practice. Also, this should include addressing disparities in health and healthcare in agenda-setting and conducting CER. *This should increase the relevance of CER to community health and healthcare needs and the implementation of these results for the benefit of the community and nation.*

CTSA Consortium White Paper Recommendations for Comparative Effectiveness Research (4 of 6)

4. The CTSA Consortium should develop the capacity to generate new research methods for evidence generation (studies and trials), evidence synthesis (systematic reviews and modeling studies), and evidence translation of CER to enhance current research and to provide approaches for the new opportunities and needs of CER. *This should result in higher quality data analyzed in a more sophisticated and useful manner to better inform clinical practice and policy decisions.*

CTSA Consortium White Paper Recommendations for Comparative Effectiveness Research (5 of 6)

5. The CTSA Consortium should participate in the implementation of electronic health records (EHR) and health information technology (HIT) to ensure the resulting data can be used for the conduct of CER and to study which types of EHR-based interventions are successful in changing practice and which are not. *The proper leveraging of EHRs and HIT will allow for efficient wide-scale conduct of CER and the embedding of information from CER to disseminate EHR-based clinical decision support to improve care.*

CTSA Consortium White Paper Recommendations for Comparative Effectiveness Research (6 of 6)

6. The CTSA Consortium should organize a CTSA Network for CER that links to agencies and entities outside CTSA. *This will provide direct access to the CTSA resources for CER among CTSA researchers nationally, and also to the other NIH ICs and key federal agencies such as AHRQ, CDC, FDA, other agencies, other entities, and stakeholders in the healthcare community and industry and the public.*

Mapping CTSA CER White Paper to IOM Report, FCC-CER Report, and CTSA Components (1 of 2)

Objectives	CTSA White Paper	IOM Report	FCC-CER Report	Related CTSA Components*
Develop priorities and conduct research	✓ (Rec. 3)	✓ (Rec. 5)	✓ (Rec. 1)	Community Engagement and Research
Clinical trial & data & informatics infrastructure	✓ (Rec. 1)	✓ (Rec. 8)	✓ (Rec. 3)	Design, Biostatistics and Clinical Research Ethics; Regulatory Knowledge and Support; Clinical Research Center
Workforce development by education and career development	✓ (Rec. 2)		✓ (Rec. 2)	Research Education, Training, and Career Development

Mapping CTSA CER White Paper to IOM Report, FCC-CER Report, and CTSA Components (2 of 2)

Objectives	White Paper	IOM Report	FCC-CER Report	Related CTSA Components*
Community engagement, including dissemination into practice	✓ (Rec. 3)	✓ (Rec. 6)	✓ (Rec. 4)	Community Engagement and Research; CER-specific components
Develop new innovative CER methods	✓ (Rec. 4)	✓ (Rec. 7)	✓ (Rec. 2)	Novel Methods; Research Education, Training, and Career Development; CER-specific components
Informatics and data systems to support CER	✓ (Rec. 5)	✓ (Rec. 8)	✓ (Rec. 3)	Biomedical Informatics; Design, Biostatistics, and Clinical Research Ethics
Linkages among CER stakeholders	✓ (Rec. 6)	✓ (Rec. 8)	✓ (Rec.4)	Governance; Entire CTSA; CER-specific components