

**Developing the Minnesota Cancer Plan
Step 2: Recommend Objectives and Strategies**

Workgroup: Treatment

Date: June 24, 2016

Objective: Increase participation in cancer treatment clinical trials

Desired Outcome:

At the end of five years, what would you like to accomplish? If you do not expect to achieve the objective by the end of five years, what would success look like? Cancer clinical trials are essential to improve the outcomes of Minnesotans who have been diagnosed with cancer. With adult participation in cancer clinical trials ~3 – 5 %, and minorities and women’ participation less, we propose a state sponsored initiative to educate the public, patients and providers about study opportunities within Minnesota and supply systematic mechanisms for patients and providers to connect with current study opportunities and resources.

Alignment:

Partners currently working on this objective and type of activity:

Organization	Activity (such as PSE change, education, programmatic)
These organizations are working on this objective however, for the most part, their work is not aligned – they are not working collectively to increase participation in clinical trials through the strategies recommended in this document: University of Minnesota, Mayo Clinic, Park Nicollet, HealthPartners/Regions, Minnesota Oncology, Fairview, Essentia Health, HCMC, Allina Health, CentraCare (Coborn), Minnesota Department of Health, National Cancer Institute, MetroMN Community Oncology Research Consortium, Sanford Health, Pharmaceutical companies, Biotech companies, ACS, LLS, PANCAN, MOCA, PAF, AARP, and other array of organizations representing patients and minorities. Could include IBM, which is involved with WATSON for clinical trial matching, ACS Clinical Trials Matching Service	

Stakeholders for this issue not currently working on it and potential role:

Organization	Potential role (PSE change, education, programmatic)

Strategies

<p>Strategy #1: Create statewide centralized clinical trial database that is accessible to health care providers and patients to locate current and accurate information.</p>
<p>Indicator to measure progress (such as increased number of engaged stakeholders, increased media events, increased number of local jurisdictions that pass policy): Statewide clinical trial database is created and maintained with resources for communicating clinical trial information to all persons including those with limited English proficiency.</p>
<p>Rationale: A centralized clinical trial database will increase access to information and thereby increase participation in clinical trials. See these examples: https://www.clinicaltrialsgps.com/georgia/ http://www.emergingmed.com/ https://www.breastcancertrials.org/bct_nation/home.seam American Cancer Society Clinical Trials Matching Service: http://www.cancer.org/treatment/treatmentsandsideeffects/clinicaltrials/app/clinical-trials-matching-service</p>
<p>This is an <u>X</u> evidence-based practice ___ promising practice ___ other. Please explain. Gaps in education regarding the importance of clinical trials and lack of awareness of clinical trial availability by both the provider and the patient contribute to low participation.</p>
<p>Does this strategy promote health equity by addressing a racial, economic, geographic or other barrier? If yes, explain. Yes, communities who experience cancer related disparities are under-represented in cancer clinical trials. This is in part due to a lack of trust but also due to lack of information and financial barriers (see strategy #2). This database can increase the information available to patients, which is likely a component of building trust.</p>

Rank this strategy for the greatest potential for traditional and non-traditional partners working together.

Rank ___ of ___ strategies

Strategy #2: Establish funding for a Cancer Care Equity Program (CCEP) to assist patients overcome financial barriers that prevent them from participating in clinical trials.

Indicator to measure progress (such as increased number of engaged stakeholders, increased media events, increased number of local jurisdictions that pass policy): A coalition of partners creates a business model and identifies potential funding sources for a CCEP in Minnesota.

Rationale: Multiple barriers contribute to poor accrual to adult cancer clinical trials. Gaps in education regarding the importance of clinical trials and lack of awareness of clinical trial availability by both the provider and the patient contribute to low participation. Economic barriers such as lack of insurance coverage, cost of transportation and unpaid time away from work, disproportionately affect individuals of lower socioeconomic status. Lack of access due to geographic distance to centers with clinical trial availability disproportionately affects underserved patients in rural areas. Cultural and literacy barriers also disproportionately affect patients of minority and underserved populations.

In a study of 1,256 cancer patients assessing barriers to cancer clinical trial participation, worries about health insurance coverage of clinical care costs represented one of the strongest barriers. A second study, which sought to evaluate why patients decline cancer clinical participation, demonstrated that distance from the cancer center and insurance denial were common reasons for refusal to participate. A third study of black patients found that economic stress played an important role in their willingness to participate in trials. Therefore, efforts to improve clinical trial participation must include interventions targeting the financial barriers that often influence patients' decisions to participate in trials. Ryan D. Nipp, et al. The Oncologist 2016;21: 467–474

This is an ___ evidence-based practice ___x_ promising practice ___ other. Please explain.

Massachusetts has a CCEP (limited to travel and lodging costs associated with cancer clinical trial participation)

Does this strategy promote health equity by addressing a racial, economic, geographic or other barrier? If yes, explain.

Yes, removing financial barriers will increase participation for members of communities that experience cancer related health disparities with the goal of evaluating the effectiveness of new treatments and improving outcomes.

Rank this strategy for the greatest potential for traditional and non-traditional partners working together.

Rank ___ of ___ strategies

Strategy #3: Implement a state-wide education and media campaign that is culturally and linguistically appropriate that increases public awareness of the benefits of participating in clinical trials.

Indicator to measure progress (such as increased number of engaged stakeholders, increased media events, increased number of local jurisdictions that pass policy): A coalition of partners develops and implements a state-wide education and media campaign that increases participation in clinical trials.

Rationale: Lack of information and lack of trust are barriers to participation in clinical trials: Barriers to CT participation have been studied extensively and include patients' limited awareness of CTs, misperceptions, distrust of doctors and researchers, and fear of CTs and general medical research. Healthcare providers may also contribute to low enrollment in trials because of limited awareness about CTs or lack of communication with patients about CTs. Furthermore, the technical language that physicians and/or researchers use and the difficulty level of CT education resources provided to patients can serve as barriers to recruitment and enrollment. Providers often overestimate their patients' health literacy skills and the clarity of their own communication. D.B. Friedman et al. / Contemporary Clinical Trials 38 (2014) 275–283

This is an ___ evidence-based practice ___x_ promising practice ___ other. Please explain.

Does this strategy promote health equity by addressing a racial, economic, geographic or other barrier? If yes, explain.

A state-wide education and media campaign could be targeted to populations with historically low participation in clinical trials.

Rank this strategy for the greatest potential for traditional and non-traditional partners working together.

Rank ___ of ___ strategies

Strategy #4: Join current legislative efforts to authorize the Department of Commerce to assure insurance companies comply with oral parity laws and add to that effort assurance that insurance companies provide coverage for clinical trials as required by the Affordable Care Act.

~~Work together with employers, plans, issuers, states, providers, and other stakeholders to help them come into compliance with the law and work with families and individuals to help them understand the coverage for clinical trials provision and benefit from it as intended.~~

- ~~Advocate for policy to encourage plans to adopt the current ACA guidance~~

Indicator to measure progress (such as increased number of engaged stakeholders, increased media events, increased number of local jurisdictions that pass policy):

Rationale: In general, PHS Act section 2709(a),⁸ as added by the Affordable Care Act, states that if a group health plan or health insurance issuer in the group and individual health insurance market provides coverage to a qualified individual (as defined under PHS Act section 2709(b)), then such plan or issuer: (1) may not deny the qualified individual participation in an approved clinical trial with respect to the treatment of cancer or another life-threatening disease or condition; (2) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in

the trial; and (3) may not discriminate against the individual on the basis of the individual's participation in the trial.

A qualified individual under PHS Act section 2709(b) is generally a participant or beneficiary who is eligible to participate in an approved clinical trial according to the trial protocol with respect to the treatment of cancer or another life-threatening disease or condition; and either: (1) the referring health care professional is a participating provider and has concluded that the individual's participation in such trial would be appropriate; or (2) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate.

This is an ___ evidence-based practice ___ promising practice ___ other. Please explain.

Does this strategy promote health equity by addressing a racial, economic, geographic or other barrier? If yes, explain.

Rank this strategy for the greatest potential for traditional and non-traditional partners working together.

Rank ___ of ___ strategies

