

Incorporating existing networks in multi-site studies

CTSI Research Career Development Seminar Multi-site Trial Development and Implementation Miniseries

Hosted by the Clinical Research Support Center (CRSC) and
CTSI's Research Education, Training, and Career Development core (CTSI-Ed)



CLINICAL AND TRANSLATIONAL
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Driven to DiscoverSM

International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)

- Structure established with colleagues in 1997 for a successful R01 application
- Funded as a network in 2006 to conduct HIV strategy trials (300+ sites in 37 countries)
- Expanded mission in 2009 to conduct trials on other infectious diseases
- Expanded infrastructure in 2020 to conduct COVID-19 trials
- Largely NIH funded (NIAID, Division of AIDS and Clinical Research)



INSIGHT Infrastructure

- **International Coordinating Centers (ICCs) and a Statistical and Data Management Center (SDMC) and Operations Center:**
 - MRC Clinical Trials Unit at UCL (London ICC)
 - Copenhagen HIV Program (Copenhagen ICC)
 - Kirby Institute (Sydney ICC)
 - Institute of Clinical Research Center (Washington ICC)
 - University of Minnesota (Minnesota SDMC, Operations Center, and Leadership Group)
 - Community Advisory Board; drug and specimen repositories
- **Expansion for COVID-19:**
 - Cardiothoracic Surgical Trials Network (CTSN ICC)
 - Prevention and Early Treatment of Acute Lung Injury Network (PETAL ICC)
 - U.S. Veterans Affairs Cooperative Studies Program (VA ICC)



Networks

- **PETAL Network (NHLBI funded; successor of ARDS Network)**
 - 12 clinical centers encompassing 44 hospitals; MGH Coordinating Center
- **IVY Network (CDC Epidemiology network for respiratory viruses)**
 - Vanderbilt Coordinating Center; 15 Clinical Centers (all academic)
- **PassItON (Convalescent Plasma Study) – NCATS Funded**
 - 40 Sites – academic and non-academic; Vanderbilt Coordinating Center
- **EMPACT Network (start-up funded by biotech start-up)**
 - 12 centers – academic – like-minded mission – personalized Rx (sepsis)
- **Pragmatic Critical Care Research Group**
 - 20 academic and non-academic clinical centers; Vanderbilt coord center



Minnesota Cancer Clinical Trials Network:

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February 2nd, 2022

Laurel Nightingale, MPH, MPP
Senior Project Manager, MNCCTN



3 Institutions, 5 Partners, many clinics

HUB: where *overall management* of the network happens

- Primarily located within the Masonic Cancer Center at UMN
- Staffed by project managers, project coordinators, regulatory, outreach and education, marketing

Research Partners: where *studies originate:*

- UMN, Mayo, Hormel

Clinical Partners: where the *studies are conducted*

- Essentia Health, MCHS, Sanford, M Health Fairview, and MMCORC

Mayo (MCHS)

- Mankato
- Albert Lea
- Austin

Essentia

- Deer River
- Hibbing
- Sandstone
- Virginia
- St Mary's Detroit Lakes
- Fosston
- Park Rapids
- St Joe's Brainerd
- Ely
- International Falls
- Duluth
- Fergus Falls
- Riverwood

Fairview

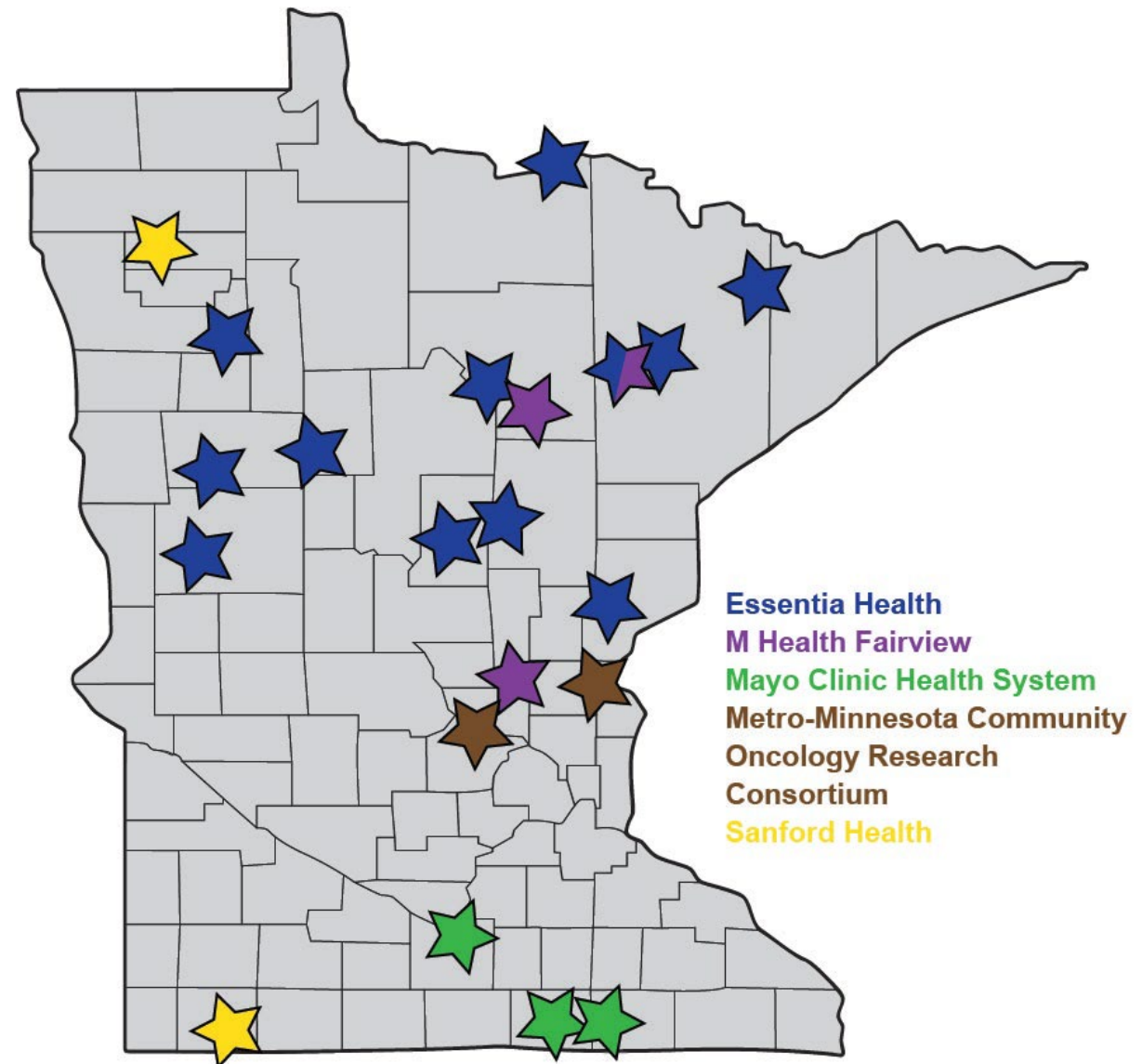
- Grand Itasca Clinic and Hospital
- Range
- Northland/Princeton

Sanford

- Thief River Falls
- Worthington

Metro-Minnesota Community Oncology Research Consortium (MMCORC)

- Monticello
- Hastings



Best-Fit Studies

- Studies that fit well with standard of care are easy for sites to incorporate into their daily operations
- Investigator-initiated trials, late phase 2 or phase 3
- Primarily interventional trials
 - Also acceptable:
 - Observational trial with planned subsequent interventional component
 - Data collection, survey collection, specimen collection
 - Smaller pilots

Benefits of Working with MNCCTN

- Access to semi-rural/rural communities, increased enrollment
- Project management, regulatory support, marketing and outreach for studies at network sites
- Infrastructure funds pay for:
 - Site staff time (investigators, coordinators, regulatory, pharmacist, etc)
 - Can pay for other costs if needed including shipping
 - Study expected to pay for most study-specific costs otherwise

Multi-site Challenges

- Longer start-up process
- Contracting
- IRB / Reliance

Grant Funding Program

- Second funding cycle just announced in January 2022
 - Five grant award categories available
 - 2 **Community Site Awards**, \$125,000 each (all partners—research and clinical)
 - **DEIJ** (Specifically addressing under-represented population), \$125,000
 - 2 **Discovery and Planning awards**, \$15,000 each (all partners—research and clinical)
 - **Single site pilot**, \$50,000 (clinical partners only)
 - 5 **Literature Review Scholarships**, (clinical partners only)
- LOI due February 25th
- More information can be found [here](#) or via this link:
z.umn.edu/MNCCTNGrantProgram

Questions? How to work with us?

- Email Director (Marie Rahne) or Senior Project Manager (Laurel Nightingale)
 - mrahne@umn.edu
 - nigh0021@umn.edu
- The earlier the better
 - Can start with just an idea or brief summary
 - Ensures MNCCTN sites are in grant application, budget, and protocol
 - Can help to sort out feasibility and community site procedures

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