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)
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 2^{nd}, 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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