

## **PROPOSAL TITLE: Recommendations from the Systems Liaison Working Group**

### **INTRODUCTION**

According to recently completed HMORN research on cardiologists' attitudes and experiences regarding clinical trials, many cardiologists affiliated with HMORN member plans report a strong interest in participating in multiple types of cardiovascular clinical trials. Cardiologists' clinical research interests span the spectrum from diagnostic tools to preventive strategies to acute and chronic management with new pharmacological agents or devices. However, HMORN-affiliated cardiologists face considerable barriers to greater research participation, and they would welcome support to increase their involvement in cardiovascular clinical trials.

An overarching goal of the HMORN is to be the "research partner of choice for those seeking to shape health and health care delivery." Toward that end, the HMORN is actively working through the Coordinated Clinical Studies Network (CCSN), Cancer Research Network, CERT collaboratives, and the Cardiovascular Research Network to create and maintain infrastructure that can improve the research participation of its affiliated primary care and specialty physicians. Greater efforts are needed to enhance front-line clinician involvement within participating HMORN health plans to help in generating the evidence that demonstrates the efficacy, or inefficacy, of novel therapies or management strategies, as well as in facilitating more rapid translation of such research into clinical practice.

### **A VISION FOR 2012**

*By 2012, our vision is that a larger proportion of health plan-affiliated community physicians at all HMORN member plans will enroll greater numbers of patients into clinical trials.*

### **DESIRED END-PRODUCTS**

Documents or other products we hope could be available within the next 5 years:

#### 1. Strategies to Facilitate Network Collaborations

- Effective and productive HMO Research Network collaborations such as the CRN and the CVRN to serve as vehicles to identify research interests of specialists and primary care providers and to coordinate development of attractive and fundable clinical studies in cancer and CVD.
- Closer ties between research departments and clinicians within HMORN member plans. The CRN3 plan to establish Organizational Advisory Committees at each of the participating sites is one potential model for a bi-directional bridge between the research interests between each research center and its health plan. This committee is comprised of primary and specialty clinicians, IT personnel and high-level managers, and intends to facilitate research translation activities at the sites. If successful, it could be emulated or expanded to include other disease areas.
- A network of experienced researchers and clinicians who would be available for consultations to offer their expertise in addressing barriers to clinical studies and to provide better clinical context to proposed studies.

#### 2. Tools to Enhance Study Implementation

- Methodology to leverage the Virtual Data Warehouse (VDW) and Electronic Medical Records (EMRs) to identify potentially eligible patients for at least one phase III

cardiovascular clinical trial at multiple HMORN member plans. This effort will complement similar work currently being done through the CRN.

- Robust disease/patient registries and data tools such as disease counters and an effective VDW, coupled with online medical records in most sites, that are configured for simplified access for community physicians, in such support areas as preparatory-to-research work and identification of potential enrollees.
- A “Toolbox” of manuals and streamlined IRB & business processes to assist clinician conduct of research.
- Two guides developed by the CCSN that may be of use: one pertaining to recruitment and data collection in the context of multi-site studies, and a second general guide with strategic advice for conducting multi-site studies.

### 3. Tools to Support Research-related Training

- NIH, FDA, pharma, and health plan enhancements (such as scholarships for CME and other training and/or underwriting development of materials) to support acquisition of research skills and knowledge by community physicians, in such areas as requirements for Good Clinical Practices; HIPAA and IRB compliance; and clinical study methodology, recruitment/enrollment, and management.

### 4. Improved Strategies for Finding Trial-related Information

- NIH enhancements to <http://clinicaltrials.gov> and industry equivalents, e.g., searchable databases of trials still open to recruitment by community physicians, and links to expedite application as investigator, etc.

## **RECOMMENDATIONS**

- The HMO Research Network is an appropriate home to oversee continuing focus on this deliverable. A standing HMORN committee, perhaps through the Asset Stewardship Committee, that will be the repository of knowledge about fielding multi-site clinical trials in the HMORN should be identified. This committee will be aware of local coordination efforts and strategies and will serve as a facilitator for multi-site studies.
- The HMO Research Network’s newest collaborative, the CVRN, offers an opportunity to host this area of infrastructure development and model possible strategies in the cardiovascular arena.
- Federal and industry funders of clinical trials should consider a small shift in priorities towards trials that target community practices for conducting “real world” studies, sometimes called “practical clinical trials,” across the full spectrum of topics.
- Our CCSN research found research nurses to be one of the best sources of support for cardiologists interested in conducting clinical trials. Investigating strategies to help groups hire such staff or have access to a cadre of research-trained nurses would be useful.
- The CCSN has shown it is possible to streamline IRB functions for multi-site research. In-roads have also been made with respect to other post-award administrative steps such as subcontract development. HMORN Administrators have been collaborating fruitfully since 2005, and this work may result in further streamlining of business processes as well, in such important areas as proposal management, budgeting and budget reconciliation, grants administration, and staffing.
- Funding should be found for more systematic and streamlined training for community physicians in areas that enhance their capabilities to participate in research.
- CTSA Partnerships, in which many of the HMO Research Network sites are participants or part of CTSA proposals, provide an opportunity for streamlined evaluation of

promising new therapies. We recommend that each HMORN site foster and sustain these partnerships with their local CTSA and across CTSA to the extent possible.

### **CONCLUDING THOUGHTS AND KNOWN BARRIERS**

Community-based healthcare systems provide a largely untapped resource for conducting cardiovascular trials and health services research. The HMORN presents considerable opportunities for conducting research in community settings, which offer a large pool of diverse patients, investigators, and clinical data. Given the current and growing challenges of recruiting patients into cardiovascular trials, innovative efforts are needed to address key barriers within community-based health systems that will leverage their unique strengths and capabilities and facilitate greater participation in clinical trials. Our recommendations are based on research that showed that the two main barriers to fuller participation among HMORN cardiologists are lack of time and insufficient infrastructure to support trials. Besides working internally with HMORN constituent organizations to reduce the barriers to greater participation among cardiologists in clinical studies, it is our hope that outside agencies will see the value in increasing HMORN cardiologists' participation in clinical studies and find ways to support this effort.

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## **ADDITIONAL BACKGROUND AND CONTEXTUAL INFORMATION**

### ***ANTECEDENT ACTIVITIES THAT INFORMED THESE RECOMMENDATIONS***

The recommendations in this proposal are based on the findings from the research presented in our manuscript, "Cardiology Clinical Trial Participation in Community-Based Healthcare Systems: Obstacles and Opportunities," which has been submitted for publication and is attached.