

# IECRN



Inventory and Evaluation of  
Clinical Research Networks

## **IECRN National Leadership Forum Comments Report**

**July 28, 2006**



## A. Introduction

The National Leadership Forum presented the methods and findings of the IECRN Descriptive Survey and Best Practices Study with a focus on seven key domains of clinical research network (CRN) functioning. The Forum also provided attendees with the opportunity to discuss ways to improve clinical research networks and to make recommendations for increasing CRN effectiveness and efficiency.

During the first day of the National Leadership Forum (May 31, 2006) attendees used index cards to submit comments and questions pertaining to the plenary sessions, the breakout sessions, and the IECRN project more generally. Cards were color-coded to distinguish among breakout sessions. A total of 74 Comment Cards were collected, distributed by breakout session as shown below:

<b>Breakout Session</b>	<b>Number of Comment Cards</b>
Data Management (DM)	10
Financial Practices (FP)	2
Information Technology (IT)	8
Management and Governance (MG)	20
Network Operations (NT)	8
Recruitment and Retention (RC)	3
Training and Professional Development (TR)	23

The IECRN project team reviewed the feedback, which included general comments about the plenary and breakout sessions, comments and questions about the IECRN surveys and the Best Practices Study, and comments related to other issues of importance to the attendees. Multiple comments from the same participant are reported separately; similar comments by different individuals are only presented once to reduce redundancy. The session in which the comment was provided is noted in parentheses following each comment/question. Most comments are verbatim as written; a few required minor editing and/or elaboration for clarification.

The comments have been organized as follows, to encompass the range of feedback provided by attendees:

- 1. Comments about Forum sessions;*
- 2. Comments about the IECRN study;*
- 3. Further research questions that might be explored;*
- 4. Priorities/issues not addressed through the IECRN project; and*
- 5. Recommendations for the future.*

The comments and questions posed by Forum attendees are presented in the next section of this report (Section B). The report closes with a summary of comments and suggestions for possible next steps to further advance the clinical research enterprise (Section C).

## **B. Participant Comments and Questions**

### *1. Comments about Forum sessions*

The following comments provide feedback on attendees' impressions of how the IECRN findings were presented within each session and how the sessions were conducted.

- Lack of vision. (MG)
- Overprogrammed recommendations. (MG)
- Too much time spent reviewing survey. (DM)
- Data management must be differentiated from information technology; there is confusion on the part of some personnel on what constitutes data management. (DM)
- Session was well conducted by the moderator. (DM)
- Session could have done a better job showcasing best practices—the details of what data management centers are doing well. (DM)
- The session format restricted information and creativity. (DM)
- The session did not provide definition of best practices. (DM)
- Audience and presenters were unclear about definition of “network staff.” (TR)
- Overall unimpressed with content experts. (IT)
- Discussions were good, but session lacked focus; issues were raised but did not come to closure; interpretation of surveys was problematic because terms were ill-defined. (IT)
- Please provide list of attendees/registrants, and copy of all slides presented. (NT)

## ***2. Comments about the IECRN study***

Attendees also provided feedback about the methodology and findings of the IECRN study. Many of the comments were specific to the network domain being addressed within each session. Readers are referred to IECRN reports posted at <https://www.clinicalresearchnetworks.org> for more information about the purpose and scope of IECRN, the study methodology, terminology used, and results.

- Networks sampled are a select group—limits interpretation of best practices. (MG)
- Need to clarify how best practices were derived. (MG)
- Concerned about data quality and overall lack of definition of terms. (DM)
- Many survey questions were unclear. (DM)
- Results were difficult to interpret primarily due to undefined terms on the survey. (DM)
- Survey questions seemed high level and not granular enough to match the details of the process operations within a network. (DM)
- The quantitative assessment focused on professional development, not site training. (TR)
- Lack of clarity on use of terms “staff training” and “professional development,” leading to confusion about roles of research personnel and the training programs required. (TR)
- Survey questions appeared to be overly focused on NIH [National Institutes of Health] networks. (TR)
- Standardize research role definitions (e.g., PI [principal investigator], study coordinator), as well as “site staff” vs. “network staff.” (TR)
- Survey questions need to be reviewed to ensure the collection of accurate data, and to eliminate confusion between information technology and data management and possibly bioinformatics; more precise operational definitions need to be developed. (IT)
- Survey instruments lack detail—have they been validated? (IT)
- It would be helpful to have quantitative data regarding time for protocol development to compare to our own network. (NT)
- Need information on the characteristics of the CRNs studied.

## ***3. Further research questions that might be explored***

Some of the comments suggested additional research questions that could potentially be addressed through the IECRN or similar data collection efforts.

- Do most CRNs address a single disease (e.g., cystic fibrosis) or multiple diseases? (MG)
- Are the sites that participate in CRNs normally located in the same geographic region or dispersed nationally? (MG)
- As CRNs set their strategic plans do they have program-based evaluations, or do they rely on the scientific peer-review publication process and/or refunding of CRN as a mechanism to measure success for their CRN activities? (MG)

- Do CRNs mainly coordinate providing all services centrally (e.g. their own biostatistics team used for analysis) or might they more commonly “lease” outside services on demand? (MG)
- Now that interoperability between EHR [electronic health records] vendors is theoretically a non-issue, are there other technical barriers to sharing patient information across CRNs? Are there any non-technical barriers? (IT)
- Analyze data according to the following: size (e.g., funding/annual budgets, annual enrollment, FTEs [full-time employees]), characteristics (e.g., core infrastructure, operation center, data management center). (NT)

#### ***4. Priorities/issues not addressed through IECRN project***

Many of the comments pertain to issues that attendees believed had not been adequately addressed either by the findings of the IECRN studies or at the Forum. These comments can be helpful in setting the stage to address the ongoing needs of the clinical research community.

- Consider the challenge of engaging minority communities (elimination of health disparities). (RC)
- Need to learn more about improving efficiency and using efficiency metrics. (MG)
- May be helpful to identify the process of research and development through commercialization and then to describe efforts at each stage to show areas of redundant activity and gaps in the process; once this development cycle is defined, leadership and governance requirements may become more clear. (MG)
- Need mechanisms for quality improvements—supported by small awards. (MG)
- Need to determine standards before making policy decisions. (MG)
- Need standardization of training across institutions; identify and utilize core elements to decrease site burden when doing research in multiple CRNs. (TR)
- Need standardization of abbreviations and definitions. (TR)
- Need standardization of regulatory processes. (TR)
- Need standardization of review criteria. (TR)
- Improve compliance [with training] by clinical research practitioners if training were centralized and included a short site- or study-specific module. (TR)
- Study staff should be trained in the value of community input, roles, and responsibilities. (TR)
- Training should be standardized for basic training, for specific protocols, and for specific communities. (TR)
- NIH could offer annual PI, study coordinator, and research associate training; training should be evaluated. (TR)
- Sponsor needs to acknowledge the importance of training and professional development and provide funds accordingly. (TR)
- Need to evaluate training to ensure that it is adequate and effective. (TR)
- Need formal mentorship of junior but also mid-career researchers. (TR)

- Need mentorship program for smaller CRNs who are initiating programs (e.g., listserv). (NT)
- Need information on CRN policies/procedures/best practices for managing specimens for long term storage at repositories. (NT)
- Need information on how CRNs from academic centers have partnered with pharmaceutical companies. (NT)
- Need information on how smaller academic institution-based networks handle indemnification issues. (NT)

### ***5. Recommendations for the future***

Some of the comments included recommendations for approaches or practices that could be implemented to improve the effectiveness and efficiency of clinical research networks.

- Develop short training that stresses impact. (TR)
- Stress protocol development that addresses dissemination, sustainability, and spread. (TR)
- Include non-academic networks in next steps. (TR)
- Rather than just quantify “where we are” it would also be helpful to discuss where we want to go; NIH should fund the gap analysis. (TR)
- For professional development, incorporate funding for CRN training within network RFAs [Request for Applications]; move K type [Career Development] awards inside a specific network. (TR)
- Training modules standardized by NIH could be adopted by CRNs, universities, and sites. (TR)
- Standardize core competencies for different research roles and then have certification and funds for training and professional development. (TR)
- Create a long-term training curriculum with learning objectives; include focus on translation/implications of research results. (TR)
- Involve medical and other professional schools in the development of basic training curriculum. (TR)
- Don’t overburden CRNs with translational requirements as this requires behavioral research efforts that are independent of the CRN’s scientific question. (TR)
- Increase the link between generalists/family practitioners and clinical research networks and get them more involved. (TR)
- Base training curriculum on findings from needs assessments of what trainees think they need to know. (TR)
- Consider how CRNs could coordinate research-related experiences with NIH K-30 [Clinical Research Curriculum Award] and CTSA [Clinical and Translational Science Award] programs focused on training clinician-scientists. (TR)
- Consider what “succession planning requirements” should be put in place for long-term sustainability of CRNs. (TR)

- Grant selection for data coordinating centers should be separate from clinical centers to provide a fair evaluation of credentials. (IT)
- NIH should establish a clear requirement for data collection. (IT)
- NIH should provide a common structure for the RFA for a network. (NT)

### **C. Summary of Comments and Possible Next Steps**

Some of the comments reflect the researchers' and clinicians' frustrations in seeking and finding strategies ("best practices") to address their particular issues or problems. Although the Forum provided members of the clinical research community with a common venue for information exchange, attendees clearly expressed an interest in engaging in further discussion as well as gaining access to possible strategies and solutions for addressing common concerns. Below is a brief presentation of some possible avenues for the future as suggested by attendees:

#### ***Develop a clearinghouse or toolkit of resources***

Discussed during the sessions and included on the Comment Cards were suggestions for the collection and maintenance of reliable information and resources that can be shared by the clinical research community. Attendees were interested in having access to CRN-related resources referred to collectively as a "toolkit," "toolbox," and/or "clearinghouse." The comments gave attendee's views of the purpose and suggested contents of such a resource and also offered concerns and cautions about any such effort:

##### ***Purpose:***

- To provide resources (perhaps by domain); and
- To provide access to resources for new CRNs and PBRNs [practice-based research networks].

##### ***Suggested Sample Contents:***

- Policies and procedures;
- Templates;
- Approaches to CRN management;
- "Best practices";
- Mentoring/contact information;
- Case studies/success stories; and
- IT tools/systems and whether they can be shared by other CRNs.

##### ***Concerns:***

- Should not be directed by disease-specific research network;
- May be too idiosyncratic to particular network;
- There is likely not a "one-size-fits-all" solution, particularly for IT—solutions are more effective if customization is allowed to meet the needs of the CRN.

### ***Glossary of terms***

Several comments highlighted the need for standardization of the terminology used to describe the conduct and elements of clinical research practices to better facilitate communication among network members and the scientific community. One suggested solution was to develop a *glossary* with specialized terms and their definitions to serve as a resource and possibly be part of the “toolkit” or “clearinghouse” described above.

### ***Further identification of “best practices”***

Attendees were also interested in learning more about how CRNs with problems similar to theirs had identified workable strategies and solutions. While the IECRN provided a valuable foundation for the identification of “best practices,” Forum attendees’ comments indicate the desire for additional work in this area.