

IECRN



Inventory and Evaluation of
Clinical Research Networks

IECRN National Leadership Forum Breakout Sessions Report

July 28, 2006



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IECRN NATIONAL LEADERSHIP FORUM

BREAKOUT SESSION REPORT

The Inventory and Evaluation of Clinical Research Networks (IECRN) National Leadership Forum was held on May 31 – June 1, 2006. On the afternoon of May 31, 2006, seven different breakout sessions were held. These sessions were organized around the seven practice domains used for the IECRN study: Management and Governance, Network Operations, Data Management, Recruitment and Retention, Training and Professional Development, Financial Practices, and Information Technology. The breakout sessions were led by one facilitator and two content experts each. Summaries of the breakout sessions were presented by the content experts and facilitators for discussion by all attendees on June 1, 2006. The following report summarizes the information gathered from the each of the seven breakout and summary sessions.

1. MANAGEMENT AND GOVERNANCE SUMMARY REPORT

1.1 Management and Governance Session Purpose

The primary purpose of the breakout session was to examine findings from the IECRN Management and Governance Descriptive Survey and the Best Practices Study as well as to explore issues suggested by the findings. Session leaders were charged with introducing key findings, identifying unexpected or surprising results from either or both study components, and facilitating discussion about whether and how the results compared with the attendees' knowledge of and experiences with clinical research networks.

1.2 Management and Governance Session Process

Content experts for this session were **Dr. Ira Shoulson**, Louis C. Lasagna Professor of Experimental Therapeutics and Professor of Neurology, Pharmacology and Medicine at the School of Medicine, University of Rochester, and **Dr. Andrew Nierenberg**, Associate Director of the Depression

Clinical and Research Program, Massachusetts General Hospital and Associate Professor of Psychiatry, School of Medicine, Harvard University. The session moderator was **Dr. Patricia Dolan Mullen**, Professor of Behavioral Sciences and Health Education and Training Director at the Center for Health Promotion Research and Development, School of Public Health, University of Texas-Houston Health Sciences Center. The session leaders chose to use the electronic audience response system.

Two IECRN project staff members, both of whom had served as interviewers for this survey module, took notes during the session. These notes, together with materials put together by the Content Experts and Moderator in preparation for and after the session, formed the basis for the plenary report-out on the second day of the Forum. These same materials have also been synthesized for this report.

1.3 Selected Characteristics of Management and Governance Session Participants

Based on information collected from 64 participants of the Management and Governance breakout session,¹ 36 percent (23) reported a **primary affiliation** with an academic center, 23 percent (15) with a government agency, 16 percent (10) with a clinical research network (CRN), 11 percent (7) with a contract research organization, and 5 percent (3) with a research foundation. The remaining 10 percent (6) fell into the “other category” (5) or reported an affiliation (1) with “a company.”

With respect to the **position held in the clinical research network**, 20 percent (13) of those present said they were not currently associated with a clinical research network. Thirty percent (19) of the 64 respondents indicated holding an administrative position within the network, while 27 percent (17) reported serving as network leaders. The remaining participants indicated holding positions as site investigators (8%/5), statisticians (3%/2), research associates (3%/2) study coordinators (2%/1), or some other unspecified position (8%/5).

1.4 Management and Governance Session Content—Presentations

The session began with a presentation/slideshow by the content experts stimulated by, but not directly derived from, the IECRN findings.

¹ Some session attendees (including IECRN staff members) did not participate in the electronic response system.

1.4.1 Leadership

Content experts began by emphasizing the special challenges of leading clinical research networks, which tend to be composed of “very smart people” who may have strong views on a variety of subjects. It was also pointed out that, while highly experienced in their respective clinical content areas, network leaders typically receive no training specifically in how to manage and lead CRNs.

Pursuing the theme of leadership, a typology was introduced from J. R. Hackman’s recent book entitled *Leading Teams*. The four-fold typology presents the expected outcomes for team functioning when leaders utilize different combinations of specification of means and ends. For example, specifying both means and ends results in wasted human resources, while specifying neither leads to anarchy. The table suggests that the most effective leadership strategy, resulting in self-managed, goal-directed work, is to specify the ends (what needs to be accomplished) but not the means (how to accomplish that goal).

1.4.2 Role of Networks

Presenters defined the role of networks as follows:

Providing the milieu, leadership, infrastructure, resources, training and research participants to carry out (conceive, plan, conduct, analyze, report) multi-center, scientifically based clinical research studies that address unmet needs of those affected by or at risk for a specific condition or disease.

1.4.3 Structural Tensions Within Networks

The presenters subsequently introduced a series of polarities thought to represent competing tensions with which clinical research networks must contend. These were offered as foils to discussion.

Individual Versus Group Motivation: Personal Needs and Interests, Individual Recognition, Authorship, and Personal Competition were counterposed to Common Identification and Mission, Branding, Group Ownership, and Distributed Compensation. The individual versus group distinction was extended to encompass conflicts of interest, in which considerations of individual privacy, autonomy, and

participation were contrasted with public interests of disclosure and the need to recuse oneself from certain decisions or areas of decisionmaking.

Academic Versus Business Approaches to Network Management: A more democratic, less hierarchical, more collaborative “bottom up” approach stressing independence, training, and a horizontal “consortium” was contrasted with a more top-down, hierarchical, structured, and “micro-managed” approach as represented by a business model. The academic side was seen as allied with a nonprofit orientation, the business side with a “for profit” mentality.

Research Versus Development: As a subset of the Academic versus Business distinction, a research orientation characterized as: hypothesis-driven, and motivated primarily by “pure science” (scientific curiosity, methodologically based, amenable to replication, peer review, and open communication) was contrasted with a more purposeful, applied, strategic, development approach based on an engineering model of “what works.”

1.4.4 IECRN Study Findings

Major themes: Content experts then presented some of the major themes from the IECRN Descriptive Survey and Best Practices Study findings, as follows:

- Collaboration, collegiality, common good;
- Freshness and diversity of cultural milieu;
- Investigators’ mutual respect and trust;
- Informed scientific agenda (expertise);
- Finding common scientific ground (equipoise);
- Practice-based versus academic-based orientation;
- Theory versus reality (academic versus business); and
- Government versus corporate sponsors.

Barriers and Facilitators: Presenters also highlighted selected barriers to and facilitators of effective and efficient network functioning from the IECRN results as follows:

- Money—finances, funding;
- Time commitment;
- Availability (pool) of research participants;
- Leadership (motivation, style, ego); and
- Sponsor agenda.

Participating session attendees used the electronic response system to rank facilitators of and barriers to CRN Management and Governance.

The order of perceived facilitators (from most to least selected) was scientific agenda, funding, communication, collegiality, sponsor direction, community support, protected time, and diversity.

The order of perceived barriers was funding, communication, collegiality, sponsor direction, protected time, scientific agenda, community support, and diversity.

1.4.5 Toolkit

The idea of creating a toolkit on CRN management and governance was first raised during the presentation and then discussed at greater length by the whole group (see below).

The basic idea behind the toolkit as presented is to develop a way of sharing information and knowledge about CRN management and governance across a variety of audiences, including network leaders as well as sponsors within NIH Institutes and other agencies (CDC, FDA, AHRQ). This would be a publicly accessible repository of documents and other tools (e.g., bylaws, organizational structures, publication policies, performance standards, policies, and training requirements) that could provide models for other networks to use in developing or refining their own governance practices and structures.

Session attendees used the electronic response system to indicate which toolkit elements they would find most useful. The results were as follows (in order of most to least useful):

- Resources on committee functions and organization;
- Common NIH resources;
- Constitutions and bylaws;
- Publication policies;
- Conflicts of interest policies;
- Websites; and
- Network publications.

1.5 Session Content—Discussion

Part of the session was occupied with “from the floor” discussion of issues raised by the presentation.

1.5.1 *Issue: Reconciling Individual Versus Group (Network) Interests with Regard to Career Paths and Goals, Publication Credits, etc.*

The consensus was that this is a thorny issue for networks, and there is a need to strike a balance between supporting legitimate personal goals of network investigators and promoting the common goals and “common good” of the network. Authorship issues, in particular, can be contentious. It is important to resolve questions of who gets to be an author, as well as to consider how this process can be developed fairly within the network context. Failure to resolve these issues may cause resentment that others are getting credit for “your work,” there needs to be a sense of “we-ness,” or common collective identity, among network investigators.

One attendee offered the view that it is important that the network leader be a full professor with no tenure issues to resolve. Attendees suggested various approaches to addressing this problem.

- The “product” should reside with the network while still allowing for citation of individual authors. (However, others pointed out that group authorship is often not recognized for promotion and tenure purposes in academia.)
- Have those who developed the study design and conducted the analysis cited by name on the masthead but also show the network as their affiliation.
- Acknowledge the participating sites and individuals from those sites in a footnote to the article’s masthead.
- Keep a running log of network-associated activities for junior faculty which can be used for promotion and tenure purposes.
- Develop an explicit publication policy in which they retain as first author the individual who had the largest role in developing the protocol, and put the network name at the end of the masthead. (The membership of this network voted against group authorship.)
- Encourage junior investigators to conduct and publish results of secondary analyses as a way of broadening opportunities for authorship. In addition, every study is required to develop an explicit publication plan that is made available in the public database.

1.5.2 Issue: Coping with the Tensions Between an Academic Versus a Business Orientation

While agreeing that these tensions may pose problems for networks, some session attendees thought the polarity (as presented) was exaggerated. They expressed the view that it would be best to have a model combining elements of both the business and the academic orientations. The following points were raised:

- There should be some kind of strategic plan (if not a business plan per se) that networks use to focus ideas and move them forward in the pipeline. One network reported that they use strategic planning grants that assess studies in terms of cost, potential impact on the field, publications, and the degree to which the study responds to a need. A small group within the network gets to “bid” on publications.
- Networks should look at research and development (R&D)/Industrial Engineering efforts, as we are now entering into the fourth generation of R&D “co-development.”

- The purpose of a project (to cure a disease or to further one’s career through publication) is what defines the difference between the business and academic orientations; one should manage projects according to their purpose.
- In considering the issue of “research versus development,” a lot can be learned from business, especially as principal investigators (PIs) increasingly become like CEOs.
- The question for networks is how to lead and manage for quality control rather than just monitoring.
- Issues of sponsorship (government versus commercial) are important here.
- Commercial networks are most interested in bringing products to market. It is important to strategize and to blend funding from different sources.
- Within one network there is a constant “push and pull” that requires flexibility in dealing with the sometimes conflicting demands of governmental and commercial funding sources.

1.5.3 Issue: Need for and Possible Content of a Toolkit

Attendees discussed issues related to the toolkit idea presented earlier, including whether this would be a worthwhile effort for the National Institutes of Health (NIH) to sponsor and, if so, what it should contain. According to the attendees, a toolkit

- Would help new networks get established;
- Could contain draft policies and procedures;
- Might include materials related to training on regulatory issues;
- Should include any guidance for NIH Project Officers;
- Should contain any common body of material from NIH relative to network governance (possibly including recent NIH Recommendations with respect to coordinating center functions, which were presented as slides at the session and can be found at (http://www.nimh.nih.gov/council/interventions_research.cfm); and
- Any such effort by NIH should provide guidelines and not be prescriptive.

1.5.4 *Issue: Evaluation*

Finally, attendees discussed whether and how they evaluate their own efforts.

- One network engages in ongoing evaluation and feedback to sites because NIH requires these data. They have a group responsible for evaluating each site's performance relative to established standards. Site funding is linked to the results. This network also looks at the metrics they use to evaluate sites and refines or revises those that do not seem to make sense.
- Another network has developed an objective site assessment tool/report card that includes several measures divided into categories such as recruitment, protocol adherence, etc. Site averages across categories help NIH see how sites are doing; sites were required to attach their assessments to their re-applications for the second round of funding. This has proven to be a useful tool for evaluation.
- A third network indicated they had dealt with these issues by putting as many requirements as possible “up front” in the Request for Applications (RFAs) and developing bylaws early on. In the beginning, network committees got progress reports on different trials/studies. However, peers were reluctant to decide not to fund certain sites, so the sponsor has now assumed this role. This network representative also pointed out that (from a sponsor's perspective), funding infrastructure is not easy—considerable upfront planning is required. This is an area of tension and tools are needed to help confront these issues.
- Another network (not funded by NIH) reported that they set aside money for site incentives and seek positive ways of encouraging site performance.
- One network indicated that they had carried out an evaluation because their sponsor required it. However, they ended up publishing the results, which provided a boost to the network.

1.6 **Conclusions**

Some tentative conclusions about network management and governance emerged from the session.

1.6.1 Managing Networks

For managing networks:

- Committee structure is important, as are face-to-face meetings.
- A toolkit might be useful.
- Structurally, it may be best to have a small leadership group (5-6 people) rather than a large committee making key decisions and guiding the group.
- The leaders' roles should be to set overall direction and goals for the network.

1.6.2 Contributions of a Business Model to Network Management and Governance

Contributions of a business model to network management and governance include:

- Strategic planning;
- Processes from industrial engineering;
- An ends-driven mission;
- Performance metrics for evaluating site and group performance; and
- Linking future funding to performance.

1.6.3 Overall

- We need a better understanding of the sociology of clinical research networks.
 - CRNs need to borrow from business models.
 - More sharing should occur between and among CRNs and sponsors.
- CRNs suffer from a lack of leadership training.
- Research, development, and practice should be closely linked to one another.

The ultimate question to ask about network research is whether it will address unmet needs and/or improve patient outcomes.

2. NETWORK OPERATIONS SUMMARY REPORT

2.1 Network Operations Session Purpose

The purpose of the breakout session was to examine the findings from the IECRN Network Operations Descriptive Survey. Session leaders were charged with introducing key findings and identifying results that were unexpected or surprising, and with facilitating discussion about session participants' experiences and how and whether they related to the findings of the study.

2.2 Network Operations Session Process

Content experts for this session were **Kevin Peterson**, Associate Professor, Department of Family Practice and Community Health, University of Minnesota, and **David Schoenfeld**, Professor, Department of Biostatistics, Harvard School of Public Health. The session did not have a moderator. The leaders of this session opted to use the electronic audience response system that was available.

An IECRN project staff member took notes during the session, which served to provide the information needed to formulate the Network Operations Breakout Session report to all attendees on the second day of the Forum. Following the conference, content experts were asked to synthesize the results and provide this final Network Operations Summary report.

2.3 Demographics of Network Operations Session Participants

The breakout session consisted of approximately 125 people. Eighty-five (85) percent of the participants were involved with a clinical research network (CRN) and 78 percent participated in the descriptive survey. When asked for self-assessment of level of research experience, 21 percent indicated that they were "intermediate," 45 percent said they were "advanced," and 28 percent said they were "expert" (6% reported that the question did not apply to them). Most of those present (60%) were involved primarily with NIH-funded trials, 15 percent with pharmaceutical trials, 7 percent with intervention/translation trials, and 15 percent with observational studies.

2.4 IECRN Survey, Barriers and Facilitators, and Best Practice Findings

The IECRN Descriptive Survey considered six different areas of network operations, the findings of which were presented and discussed in the breakout session:

- Site identification;
- Recruitment policies;
- Protocol development;
- Infrastructure support;
- Regulatory procedures; and
- Site monitoring.

2.4.1 Site Identification and Recruitment

The Network Operations report cited that **staff and investigator qualifications** were used by several of the CRNs in identifying productive clinical network sites. The importance of this was confirmed by the session participants.

In addition, the Network Operations report cited that some surveyed networks used **competition** in identifying sites for clinical trial, while others used **recommendations** concerning which sites to use. The session participants also divided into these two categories. Some attendees confirmed that they use site selection, and added that additional performance based criteria were important. In particular, performance on previous trials in terms of both recruitment and data quality were important in the likelihood that the CRN would ask the site to participate in another trial.

Other CRNs, however, did not use selection. Instead of “recommendations,” however, this subset took the approach that inexperienced sites could be accepted if they were willing to be trained. Through the discussion it appeared that the CRNs that emphasized the role of training were much more likely to involve new or inexperienced practices. The other CRNs emphasized the role of performance, particularly in previous studies. Apparently the “trainings” were operating in an environment where many clinics had little previous experience in research. (As an expert, Kevin Peterson thinks the difference

between these two types of approaches is that some are in emerging fields (primary care, pediatrics) where the others are in fields with existing research capacity.)

Additional issues pertaining to site selection were raised by the participants:

- Size of patient base;
- Flexibility to follow patient if insurance changes;
- The need to examine community centers for their participation, since these patients seem more locked in to the clinics; and
- Infrastructure support that exists at the clinic.

2.4.2 Protocol Development

The same theme emerged during much of the discussion of protocol development. Participant comments suggested that experienced networks continually urge investigators to standardize, simplify, replicate, and “trim the fat” from proposals. Additional issues that were recognized by the group included the following:

- Protocol selection—only the appropriate proposals can be done successfully.
- Poll the membership—see if the members are interested in a particular question.
- Trim the data collection—a typical problem that arises among less experienced researchers. In particular, the following issues were identified as important in trimming data collection:
 - Balance cost and value;
 - Make part of the governance system;
 - Create a mechanism to report problems;
 - Have two-part review composed of scientific peer review and community affiliate review;
 - Focus on the end points, specific objectives;
 - Involve study coordinators in review of protocols;
 - Involve monitors whose job it is to trim data collection;



- Involve patient users' groups to identify essential elements; and
- Involve practitioners.

2.4.3 Infrastructure Support

A range of issues pertaining to infrastructure support were also raised. For example:

- Staff training is an important issue. At some networks this included the following:
 - Training programs for all new sites;
 - Training in good clinical practice (GCP); and
 - One class a year offered at national forum.
- PEAs (practice enhancement assistants) were recognized by several networks as a good way to provide additional support to clinics while maintaining quality and integrity of data and centralized training.

2.4.4 Regulatory Procedures

A variety of regulatory issues were brought up. These focused on the difficulties of multiple institutional review board (IRB) reviews, which are found to be cumbersome, costly, and lacking uniformity.

The session participants discussed how the current regulatory system is confusing and difficult to navigate. People mentioned many different IRBs that could be used, including regional IRBs, commercially organized IRBs, and university IRBs. Each of these boards seemed, according to the participants, to review the same protocol differently and to have different issues with consent forms. It was unclear, overall, whether such a system is necessary to protect patient safety. It was felt that IRB reform would be major advance, however difficult it might be to accomplish.

2.4.5 Site Monitoring

The topic of site monitoring was mentioned and the findings of the report confirmed by session participants. In addition, the discussion emphasized that a local relationship with the site was essential. In order to promote research, incentives had to be correctly aligned (win-win). It was also mentioned that existing models should be adopted. Some networks do a site review of all data after the first 10 enrollees at a site. Data quality is seen as a potential problem with multiple site entry and must be monitored. In addition, mentoring was thought to be of some value for networks. In particular, the ACTG-international program partnered new sites with old sites. This helped to develop relationships and to promote good models. Site interests were kept in a database, and these could be matched to studies and other sites.

The group also addressed the three questions that were previously identified by the IECRN regarding surprising findings, insightful comments, and potential enhancements. These additional comments were made:

- Surprising findings:
 - Recommendations are not clearly defined. How does a CRN walk away from this with a better understanding of what to do with their network?
 - Unclear under which conditions the findings best apply. That is, it seemed that some participants were applying “best practice” recommendations to CRN that are unlike their own. This was reflected in a further comment that said that the IECRN had basically given a description of “what is, not what is best.”
- Some additional insightful comments included these:
 - It would be valuable to see more drilldown of the issues, and more detail. This might include a better understanding of how the infrastructure for the participating networks was funded, what kind of sites the networks involved, characteristics of the successful sites, and the purposes of the networks participating in the IECRN Best Practices Study.
- Enhancements:
 - One participant mentioned that the purpose of his network was not how it functioned per se, but how it was able to improve the delivery of health care. The measure that he wanted to see was a metric for health improvement in the community.

- Another valuable enhancement would be to list the “Best Practices Networks” and contacts so that the people could be contacted as a resource for less experienced networks.

2.5 Best Practices, Other Than Those From the IECRN Best Practices Study

The participants in the breakout session discussed a number of successful or best practices that they utilize in their networks that relate to protocol development, protocol implementation, and communication.

2.5.1 Protocol Development

Several comments pertained specifically to the process and practices associated with protocol development:

- **Funded grant proposals are not protocols!** One of the participants reported that her network was funded for individual studies. The investigators often thought that the grant proposals could be used as the protocol. She reiterated that a protocol has to be much more detailed than a grant proposal and should have a different format.
- **Use protocol and consent form templates.** An important suggestion was to have investigators use a protocol template to develop protocols. These templates have been developed and used with success by her network. Consent form templates were also useful.
- **The time to develop protocols is time well spent.** Everyone agreed that protocol development should not be rushed.

2.5.2 Protocol Implementation

Participants also had useful suggestions about protocol implementation:

- **Perform a patient recruitment survey.** One site would have each site do a survey of its enrollment for a week. The patients identified were tested for eligibility in the clinical trial. This gives a good estimate of the site’s ability to enroll in the study.

- **Maintain a database of all past and concurrent studies.** Another site maintains a database of all past and present studies conducted in their network institutions. They use this for projecting enrollment and seeing whether there are competing studies.

2.5.3 Communication

Communication is a key element of effective networks and participants in the breakout session offered several relevant comments:

- **The coordinating center may need two shifts in national studies.** One center actually had two staffing shifts to facilitate communication with their sites on the West Coast.
- **Half of the sites have regular meetings.** Half the participants were able to schedule meetings well in advance. The other sites had more of an ad hoc meeting schedule.
- **A central web site can be an information hub.** Many of the participants were experimenting with using a web site as a central information hub. The hope is that it would eventually replace email that tends to get voluminous.

2.6 Conclusions

Toward the end of the session, the electronic audience response system was used to address a series of questions regarding network operational priorities; the questions and results are reported below:

Which of the following is most important?

Resources and mentoring	40%
IRB and regulatory reform	33%
Protocol development issues	14%
Site characteristics	10%
Community involvement	2%



Which of the following is most likely to be adopted by your network?

Resources and mentoring	33%
Protocol development issues	26%
IRB and regulatory reform	20%
Community involvement	17%
Site characteristics	4%

If you could do one thing, which one would you do?

IRB and regulatory reform	40%
Resources and mentoring	40%
Community involvement	12%
Protocol development issues	7%
Site characteristics	0%

2.7 Future Recommendations

Several recommendations emerged from the Network Operations breakout session discussion.

2.7.1 Regarding the IECRN Report/Project

- Clearer definitions of terms and recommendations are needed.
- Drill further into issues such as funding, characteristics of successful sites.
- Include metrics concerning health improvement in the community, not simply how networks function.



2.7.2 Regarding Network Operations

- Standardize, simplify, replicate, and trim the fat from proposal and protocol development/implementation.
- Reform the regulatory and IRB systems.
- Utilize information technology to improve communication and maintain databases of network activities, past and present.
- Increase community involvement with networks.



3. DATA MANAGEMENT SUMMARY REPORT

3.1 Data Management Session Purpose

The purpose of the breakout session was to examine the findings from the IECRN Data Management Descriptive Survey (quantitative and qualitative), as well as explore relevant findings from the Best Practices Study. Session leaders were charged with introducing key findings and identifying results that were unexpected or surprising, and with facilitating discussion about session participants' experiences and how and whether they related to the findings of the study.

3.2 Data Management Session Process

Content experts for this session were **Elsa Villarino**, Chief, TB Trials Consortium Team, Clinical and Health Systems Research Branch, Centers for Disease Control and Prevention, and **Meredith Nahm**, Director of Clinical Data Integration, Duke Clinical Research Institute. The session was moderated by **Therese Brown Gibson**, Program Director, Health Communications, Aspen Systems/Lockheed Martin.

The session participants were asked to use the electronic audience-response system to respond to questions. The format used was that the survey results were presented for each of the topic areas. Session participants were asked whether or not the practice indicated by the descriptive survey result was a best practice. Additionally, respondents were asked whether or not, in the absence of barriers such as funding, politics, existing structure, they would implement the practice for their network. An average of 52 persons responded to the polling questions asked in the breakout session with an overall range of 41-72 respondents. Thus, quantitative information from the audience response system used in the session is only reported for items having over a two-thirds response rate.

An IECRN project staff member took notes during the session, which served to provide the information needed to formulate the Data Management Breakout Session report to all attendees on the second day of the Forum. Following the conference, content experts were asked to synthesize the results and provide this final Data Management Summary report.

3.3 Demographics of Data Management Session Participants

Approximately 90 people attended the breakout session. Seventy-three (73) percent of the respondents indicated that they were associated with a clinical research network (CRN). Fifty-two (52) percent of the attendees responded that their network responded to the descriptive survey for Data Management.

3.4 IECRN Survey, Barriers and Facilitators, and Best Practices Findings

It was not possible to cover all of the results of the descriptive survey in the hour-and-a-half long session. Therefore, the content experts chose several topics from the survey to highlight in the breakout session. These topics were the following:

- Data center placement, management, and oversight of the data center;
- Policies and procedures;
- Methods used to transfer data; and
- Data standards.

3.4.1 Defining Survey Terms

There were several overarching observations that arose from the breakout session discussion. The first was that the descriptive survey for data management used undefined terminology that could be construed differently by respondents. The absence of clear definitions limited the value of the survey and the session. Examples of such terms are the following;

- “Direct data entry,”
- “Electronic transmission,” and
- “Data management activities” (as used in the descriptive survey question: Are data management activities carried out at the sites, a central data center, or shared?)

The second observation was that participants were concerned that the findings of the survey would be utilized to mandate requirements for future National Institutes of Health (NIH) Requests for

Applications (RFAs) and Requests for Proposals (RFPs). The session participants felt that no evidence base exists for data management operations. In lieu of quantitative evidence, things should not be labeled “best practice.”

3.4.2 Centralizing Data Management

The descriptive survey report indicated a trend toward centralization of the data management activities with the use of a central data center. Eighty-three (83) percent of the respondents indicated that they saw centralization as a best practice. Eighty-eight (88) percent said they would implement a central data center for their networks. In the discussion, the session attendees listed several factors that may impact a centralization decision. One of these was whether or not the trial was international. Sixty-seven (67) percent of the session attendees responded that they thought using a central data center was a best practice for global and international trials.

Other points made were that centralization improves data quality through consistency and fidelity of data processing as well as uniform training for sites on measurement and data recording procedures. One participant noted a difference that he had observed with industry sponsors: industry sponsors tend toward processing all of the data either by the sponsor’s personnel or the sponsor’s contractor and do not permit sites to process or maintain data ownership. Another session participant commented that some activities are better done at sites, such as curating the data, while temporary storage could be done at an intermediary location (perhaps a regional hub), and that integration and analysis should be done centrally.

3.4.3 Management and Oversight

Ninety-five (95) percent responded that it was a best practice to have a director of data management. In the discussion, it was clarified that the best practice was to have an individual responsible for data management and that naming a specific position, director, manager, etc. was, in fact, not helpful. The staffing level of such an individual should depend on what is needed from data management to support the scientific aims of the study. If the data management staff is large in number, then a director may be necessary; if the staff are few in number, a manager may be quite appropriate. If the studies or

technology and processes are complex, a data management specialist, an informaticist, or a higher-level individual may be what is needed.

The session participants were apprehensive of RFAs and RFPs mandating a specific position or a percentage of time allotted to this function. A mandate would take away room to creatively distinguish themselves as grantees. Another point made was that a data manager without a data center is no good, and that, if you have a data center, you generally have a data manager. One hundred (100) percent indicated that they would implement having an individual responsible for data management.

A second question was asked about having a data management standing committee. Fifty-nine (59) percent of the respondents indicated that having a committee dedicated to data management was a best practice. Seventy-one (71) percent indicated that they would implement. Individuals commented that if you have a competent data center, you don't need a standing committee. There was general discussion that having a committee dedicated to data management provides a forum for the multiple stakeholders to come to discuss, understand, and come to agreement on data management aspects and assures that goals for multiple stakeholders are met.

3.4.4 Policies and Procedures

Eighty-nine (89) percent of the respondents indicated that documenting policies and procedures is necessary for data quality. Points raised during the discussion were that documenting is highly desirable, but the drawback is that it adds burden in the form of additional work. The group was asked which was most likely to produce high quality standard operating procedures (SOPs)—having them written by the network, written by the organization managing the data, or just having SOPs that are specific to the studies conducted by the network. The feeling of the session was that the most important thing was having procedures that were specific for the studies conducted. It is not important whether an organization called them SOPs, guidelines, policies, or work instructions. In fact, it was brought up during the session report (Forum day 2) that different organizations use these terms differently, and that referring to the procedures as SOPs, guidelines, or work instructions was not helpful. It may be best to refer to them as “procedures specific to the conduct and operations of the study.” The discussion also resulted in agreement that implementers of procedures have to have input into the development of such procedures. All session respondents indicated that they would implement the practice of having procedures specific to the conduct of the study.

3.4.5 Methods Used to Transfer Data

In the descriptive survey, the most used method of data transfer among the respondents was delivery of hard copy, i.e., paper records. In the breakout session, we asked several questions in an attempt to learn why electronic data capture (EDC) was not the most common practice. We did not have two-thirds of the session attendees respond to the question “Is EDC a best practice?” However, 88 percent of the respondents indicated that they would use EDC in the absence of barriers such as funding, politics, current structure, and so forth. Sixty-nine (69) percent of the respondents indicated that there were studies for which EDC is not appropriate. The respondents were split at near 50 percent (26 vs. 28) as to whether EDC increases or decreases the cost of trials conducted by their network. Five respondents indicated that EDC increased the time from final protocol to data lock on their network. Forty-three respondents indicated that EDC decreases the time from final protocol to database lock. One of the respondents indicated that his network conducted a study of an EDC procedure and the draft results indicated that it accelerated the research process by 6 months and had a net savings. He further emphasized the need for studies on the costs and savings of these implementations. Others indicated the need for studies on the impact of EDC on data quality. The discussion highlighted the paucity of an evidence base for data management operations and the need for evaluating new methods and technology with scientific rigor.

We asked what method sites would rather use for entry of data on their network—EDC, paper forms mailed to the data center, or paper forms faxed to the data center. Twenty-eight people indicated that sites on their network would rather use EDC. Eight indicated paper forms mailed, and seven indicated paper forms faxed. Likewise, we asked for query (discrepancy identification and resolution) on whether sites on your network prefer EDC (queries identified and resolved during data entry when possible), paper queries mailed between sites and the data center, paper queries faxed between the sites and the data center, or paper queries [scanned] and emailed between the sites and the data center. Forty-two respondents indicated EDC queries, one indicated paper queries mailed, and three indicated a preference for paper queries faxed.

3.5 Best Practices, Other Than Those From the IECRN Best Practices Study

3.5.1 Data Quality

The issue of data quality came up at several points in the discussion. Data quality was not covered in the descriptive survey. However, the session participants noted that data quality was the end result of the research and should be the goal of all intermediary processes. One participant gave the example that if you integrate poor quality data at a central center, it is still poor quality and cannot benefit from any “best-practice” centralization. The group seemed to agree that data quality begins at the clinical investigational site where data are measured and recorded. One participant noted that traditional data management does not address the highest potential source of error — the source, or medical record. Further, to really address data quality, the accuracy of the data at its source must increase.

One session participant posited that, based on his experience, if clinicians received something usable back from the data that they record, as in decision support, then the quality of the initial data increases. We took an ad-hoc poll. Seventy-three (73) percent of the respondents indicated that they thought capturing data at the point of care and using it for decision support was a best practice.

3.6 Conclusions

The main conclusions developed during this breakout session are as follows:

- The absence of clear definition of terms limited the value of the IECRN report and the breakout session.
- Centralization of data management is generally desirable.
- Most participants believe that having an individual overseeing data management is a best practice, while a smaller majority feels there is a value in having a data management standing committee.
- Written documentation regarding policies and procedures is generally desired but is thought to be more useful if developed on an individual study basis.
- While paper records appear to be the most common method for data transfer at the current time, the majority of participants express support for electronic data capture (when funding, politics, and structures are not barriers). Future research is needed into the cost and time-effectiveness of EDC technology.

3.7 Future Recommendations

Recommendations for the future include the following:

- Define terms more clearly.
- Obtain quantitative evidence to determine “best practices.”
- Conduct studies to determine the cost-effectiveness and other benefits of EDC, as well as the impact on data quality, in different types of study environments.
- Evaluate all new data management methods and technologies with scientific rigor.



4. RECRUITMENT AND RETENTION SUMMARY REPORT

4.1 Recruitment and Retention Session Purpose

The purpose of the breakout session was to examine the findings from the IECRN Recruitment and Retention Descriptive Survey (quantitative and qualitative), as well as explore relevant findings from the Best Practices Study. Session leaders were charged with introducing key findings and identifying results that were unexpected or surprising, and with facilitating discussion about session participants' experiences and how and whether they related to the findings of the study.

4.2 Recruitment and Retention Session Process

Content experts for this session were **Ken Getz**, Chairman of CISCRP and Senior Research Fellow at the Tufts Center for the Study of Drug Development, and **Jennifer Backhouse**, Mid Anglia Cancer Research Network Manager. The session was moderated by **Frances Heilig**, Director of Health Communications, Aspen Systems/Lockheed Martin. The leaders of this session opted not to use the electronic audience response system that was available.

An IECRN project staff member took notes during the session, which served to provide the information needed to formulate the Recruitment and Retention Breakout Session report to all attendees on the second day of the Forum. Following the conference, content experts were asked to synthesize the results and provide this final Recruitment and Retention Summary report.

4.3 Demographics of Recruitment and Retention Session Participants

4.3.1 Area in Which Research Was Conducted

About 45 participants attended the Recruitment and Retention breakout session. Based on the introductions of individuals who had questions or comments, most seemed to be actively involved in or responsible for recruitment and retention, either as study coordinators, recruitment coordinators, principal investigators, National Institutes of Health (NIH) scientific advisors, or program officers. The

group represented a self-reported range of broadly described research areas, including substance abuse, cardiovascular disease, cystic fibrosis, mental health, and neurology, serving a range of populations, including older adults, African Americans, inner city substance abusers, and women.

4.3.2 Member of Clinical Research Network (CRN)

A few participants acknowledged their network’s sponsor, including the National Heart, Lung and Blood Institute (NHLBI), the National Institute of Mental Health (NIMH), and the National Institute on Drug Abuse (NIDA), but not the network with which they were affiliated.

4.3.3 Position Held in CRNs

As noted, participants indicated that they held various positions within the academic setting or as government network sponsors.

4.4 IECRN Survey, Barriers and Facilitators, and Best Practices Findings

4.4.1 Descriptive Survey (Quantitative)

The IECRN descriptive survey of 62 networks yielded the following findings:

- Sixty-two (62) percent of networks report recruitment relationships with community-based physicians.
- Eighty-five (85) percent of network sites create their own recruitment communications materials rather than obtaining them through the network.
- Ninety-two (92) percent of network sites communicate regularly with other sites about recruitment/retention successes and challenges.
- The most common response to slow recruitment is extension of study’s recruitment timeframe.
- The most common response to low retention is contacting inactive participants.
- Age of network did not have significant impact on extent of activities.

- NIH-funded and clinical trials networks employ a wider variety of activities than non-NIH-funded and CRNs that do not primarily conduct clinical trials.

4.4.2 Descriptive Survey (Qualitative)

The qualitative survey of about 30 networks revealed key barriers and facilitators for effective recruitment and retention as follows:

4.4.2.1 Recruitment Barriers

Major barriers to successful recruitment include the following:

- Poor planning and preparation;
- Poor principal investigator (PI) and site selection;
- Slow institutional review board (IRB) review and approval;
- Unanticipated and disruptive protocol amendments;
- Insufficient and poor allocation of time and resources; and
- Competition between studies.

4.4.2.2 Recruitment Facilitators

The qualitative analysis identified the following:

- Comprehensive and detail-oriented planning and preparation;
- Adequate training;
- Realistic protocol design based on input from stakeholders;
- Carefully selected and “well-supported” PIs and sites;
- Multidimensional recruitment communication and promotion; and
- Extensive community outreach.



4.4.2.3 Retention Barriers

The barriers that pertain to retention are presented below:

- Poor communication with participants;
- Study staff turnover;
- Lack of sufficient participant commitment; and
- Lack of sufficient incentives.

4.4.2.4 Retention Facilitators

The analyses suggest that the following facilitate successful retention:

- Accountability of PI and study staff;
- Strong, trusting, and open relationships with study personnel;
- Well-established and actively managed relationships with participants; and
- Demonstrated appreciation and perceived value of participants and study staff.

4.4.3 Best Practices Study

Seven networks in the **Best Practices Study** revealed these common techniques for ensuring participant enrollment and retention:

- Establish a partnership with the affected community as described by the Huntington’s Study Group (HSG);
- Ensure that research offers a win-win scenario, which was described by the Research Units for Pediatric Psychopharmacology-Autism Network (RUPP-AN);
- Work with local experts to develop recruiting strategies, as noted by the Clinical Directors Network (CDN);

- Adapt the recruitment strategy to the local context, which was described by the Emergency Medicine Network (EmNET); and
- Take advantage of economies of scale, which was a practice explained by the United Kingdom’s National Cancer Research Network (NCRN).

4.5 Best Practices, Other Than Those From the IECRN Best Practices Study

The breakout session attendees did not specifically identify additional best practices but did call for more in-depth study of evidence-based findings related to recruitment and retention successes.

4.6 Conclusions

The session participants concluded that the IECRN surveys revealed few surprises in the recruitment and retention arena and were broad and general in nature, but were a good start in examining the practices of networks.

Key themes discussed during the session were the following:

- The importance of careful upfront planning;
- The consistency of challenges faced within and across networks;
- The importance of tailoring recruitment strategies to communities served by the network, including strategies for reaching families and special communities; and
- Building and sustaining strong relationships with stakeholders is essential, including broad stakeholder groups for recruitment and study volunteers for retention.

The group noted that the IECRN effort to survey networks and review commonalities and best practices emphasizes the need for the following:

- Quantitative metrics on strategies and approaches utilized and their effectiveness;
- Guidelines and standardized, proven strategies and approaches to export within and across networks; and
- More opportunities to share successful strategies and practices;

4.7 Future Recommendations

During the session, participants discussed numerous suggestions and recommendations for next steps, including the following:

- Establish a working group or ongoing forum to share successful practices and valuable resources across networks.
- Spend time reviewing IECRN’s online profiles of networks and their practices and identify ways to expand the profiles.
- Learn lessons from private sector networks and investigative sites.
- Develop a clearinghouse for resources and templates that can be repurposed.
- Create “out-of-the-box” incentives to attract volunteers such as convenience enhancers like drive-through sample dropoffs and tax credits.

5. TRAINING AND PROFESSIONAL DEVELOPMENT SUMMARY REPORT

5.1 Training and Professional Development Session Purpose

The purpose of the breakout session was to examine the findings from the IECRN Training and Professional Development Descriptive Survey (quantitative and qualitative), as well as explore relevant findings from the Best Practices Study. Session leaders were charged with introducing key findings and identifying results that were unexpected or surprising, and with facilitating discussion about session participants' experiences and how and whether they related to the findings of the study.

5.2 Training and Professional Development Session Process

Content experts for this session were **John Hickner**, Professor of Family Medicine at the University of Chicago and Founding Director of the AAFP National Research Network, and **James Mold**, Director, Oklahoma University Health Sciences Center. The session was moderated by **Michael Davis**, Westat consultant. The leaders of this session opted not to use the electronic audience response system that was available.

An IECRN project staff member took notes during the session, which served to provide the information needed to formulate the Training and Professional Development Breakout Session report to all attendees on the second day of the Forum. Following the conference, content experts were asked to synthesize the results and provide this final Training and Professional Development Summary report.

During the discussion of IECRN findings, participants were encouraged to focus on issues of most importance to their networks. Selected study findings were presented by the content experts and discussed. The specific questions used to guide the discussion were the following:

- Conceptualization:
 - Have all important concepts been captured?
 - What else is missing?

- Validation
 - Do the findings seem right to you?
 - Which are surprising?
 - Which need further elucidation?
- Implications
 - What are the implications of these findings?
 - Which findings could have the largest impact?
 - Which ones would be easiest to disseminate and implement?

5.3 Demographics of Training and Professional Development Session Participants

Information on the demographics of session participants was not collected at the breakout session.

5.4 IECRN Survey, Barriers and Facilitators, and Best Practices Findings

The group discussion focused on several themes related to the IECRN project findings.

5.4.1 Definitional Issues and Challenges Associated with the Heterogeneity of Networks

Primarily because of the heterogeneity of the networks involved in the study, the definitions of “training, professional development, network staff, and site staff” may have been interpreted differently by different respondents. Therefore, the quantitative results in these areas should be interpreted with considerable caution. The survey questions seemed to be written from the perspective of National Institutes of Health (NIH)-affiliated networks and the group felt that questions may have been harder for non-NIH sponsored networks to interpret. This may have led to a lower response rate for some of the items.

Important differences between networks included their structure (e.g., practice-based research networks [PBRNs] versus others), funding (NIH versus Foundation versus mixed), focus and purpose (efficacy versus effectiveness versus implementation/translation), and affiliation (academic medical center versus foundation versus industry versus private nonprofit). To some degree, these differences were taken into account in the subgroup analyses, but more subgroup analyses might be illuminating. Within the category of academic medical center affiliations, there may be subgroups of importance to training and professional development, though these were not well defined by the group. For example, medical centers with general clinical research center funding and/or clinical research fellowship programs may have responded quite differently to some of the survey items compared to medical centers without these programs.

5.4.2 Research Team Members Left Out of the Survey

Several types of investigators were left out of the survey including non-network-affiliated principal investigators (PIs), data managers, statisticians, economists, community clinicians, and community educators.

5.4.3 Timing and Relevance of Training

Though not addressed by the survey, participants in the breakout session strongly emphasized the importance of the timing and relevance of training programs to trainees. These issues were also addressed by the exemplars that were interviewed in the Best Practices Study. Several participants mentioned the importance of conducting pretraining needs assessments to guide training.

Questions were raised regarding whether generic (e.g., human subjects protection, Health Insurance Portability and Accountability Act [HIPAA], good clinical practices, etc.) training could be effective when delivered at times remote from a study with generic examples rather than study-specific ones, or whether all training should be study-specific to some degree and delivered “just in time” (just prior to the study). Opinions were expressed in support of both views; the majority seemed to feel that some of each was necessary.

5.4.4 Training Across Distance

Many networks must train site staff located far from the network headquarters. Examples were provided about how that can be done more efficiently. Information technologies ought to be very useful for remote training, though “low-tech” solutions are also effective (e.g., the PROS network’s “garbage pail” training materials and phone calls).

5.4.5 Scope of Training and Professional Development

The survey reports seemed to suggest that only “network staff” were involved in professional development activities, and there was no professional development for site staff. It wasn’t clear whether that was a reflection of the data, an oversight on the part of those who developed the report, or a misunderstanding of the respondents. Again, there were differences between networks with regard to which staff were considered “network staff” and which were considered “site staff.” A participant suggested that there should be professional development opportunities for PIs who specifically want to learn research principles and methods used in clinical research networks.

Significant time was spent on the subject of “training” as a vehicle for translating research into practice. Examples included training site staff in the particular medical conditions being studied, training the control group clinicians and staff in effective intervention group methods at the conclusion of studies, and teaching site clinicians and staff the results and implications of completed studies.

5.4.6 Succession Planning

It was noted by one participant that older networks were reportedly less likely to provide professional development. This led to a discussion of the importance of “succession planning” (i.e., preparing new network leadership to take over the roles of the original leaders).

5.5 Best Practices, Other Than Those From the IECRN Best Practices Study

The discussion did not focus on the identification of additional “best practices.”

5.6 Conclusions

It became clear during this session and the review of the report results that training and professional development mean different things to different people and different networks. Many participants expressed concern that the IECRN survey missed out on many of these differences, which include who the appropriate targets of training and professional development are, as well as the appropriate content of such offerings. Better definition of terms was recommended to improve the value of endeavors like the IECRN by helping to provide more accurate, valid data. Additionally, delving deeper into the data (i.e., via further subgroup analyses) might make the end results more useful to a broader variety of networks, since the current results seem to be lacking in this regard.

The “who’s” and “what’s” for training and professional development might also be better addressed by ensuring some standardization, whether it is of roles or of content. (This is discussed further in the section below.)

5.7 Future Recommendations

The discussion that addressed the implications of the findings and possible next steps is presented in this section.

5.7.1 Standardization of Research Roles and Basic Training Requirements

A great deal of time was spent in the breakout session discussing standardization. The group seemed to agree that this should begin with standardization of the various roles of members of the research team (e.g., research assistants, research coordinators, project coordinators, project directors) and standardization of the kinds of basic knowledge and skills required by each. Once roles are defined more precisely, certification could be established, leading to specific training requirements and programs for



the different team members (i.e., a training matrix). This could also lead to more appropriate and relevant subsequent training requirements relating to human subjects protection, HIPAA, etc.

5.7.2 Standardization of Good Clinical Practice, Human Subjects Protection, and HIPAA Training Requirements

There was a great deal of animated discussion about the problems faced by networks that have to deal with multiple institutional- and funder-specific training requirements in the areas of good clinical practices, human subjects protection, and HIPAA. There was a strong plea from the group for standardization of these requirements. The standards should, however, allow investigators to substitute or add project-specific examples when appropriate.

Several of the PBRN representatives also expressed concern that some of the training requirements seemed more geared to clinical trials than to the kinds of work that they were doing most of the time, and that their community clinicians and staff would be better served by training programs more appropriate to the kinds of lower risk work they typically do (e.g., passing out questionnaires or completing simple screening procedures).

Nonacademic team members (e.g., community clinicians and staff) should receive appropriate continuing professional education credits and, in some cases, financial reimbursement for participation in training.

5.7.3 Training Methods

Many examples of successful training programs were mentioned, though there was insufficient time to capture all of the details. The suggestion was made that someone should develop a toolkit for CRNs about training and professional development that would include concepts as well as specific examples of successful approaches. Hopefully the IECRN web site will also be a place to share such examples.

5.7.4 Evaluation of the Impact of Training Methods Within and Across Networks

There was general agreement that there is little information available about the impact of training programs in CRNs and that there is an urgent need for evaluation, both within and across networks.

5.7.5 New Mechanisms for Professional Development Focused on CRN Research

Some participants believed that there is a need for training and professional development programs specific to clinical research conducted in networks. An example mentioned was the R25 award recently received by Case Western Reserve University to train PBRN researchers. A question was raised about whether the K30 mechanism could be another way to provide such training, perhaps through distance learning methods.

5.7.6 Training as a Way to Link Research, Practice, and Community Health

A spectrum of opinions was expressed regarding whether the concepts of training and professional development should always include concepts of dissemination and implementation (translation of research into practice). Clearly there are CRNs that focus entirely on efficacy trials, depending upon other networks to extend their findings to practices, communities, and patients. However, many networks are in a good position to translate research findings into practice and should be encouraged (and paid—see below) to do so. For those who do work directly with practice communities to improve care, there was a suggestion that, just as generic and study-specific training should be standardized, community-specific training should similarly be standardized as much as possible.

The concept of CRNs as transdisciplinary “learning communities” was also discussed briefly.

5.7.7 Funding for Training

There appeared to be universal agreement among attendees at this breakout session that more funding within grants and contracts was needed to cover the costs of training and evaluation of the impact of training. Along with this support, the funding agencies could emphasize the importance of training and provide guidance regarding the types of training and evaluations expected.

5.7.8 Miscellaneous Suggestions

Pleas were made that research skills training be made a part of all professional education programs and that community clinicians be strongly encouraged to join CRNs.

One participant suggested that certain “nontraditional” areas of training might be particularly important for CRN directors and possible members. An example is “negotiation and conflict resolution.” A suggestion was made that there is a need for mentorship of younger networks by more experienced networks and a way is needed to organize and coordinate this.

The suggestion was made that there be more standardized training for institutional review board members, particularly related to the unique aspects of CRN research.

6. FINANCIAL PRACTICES SUMMARY REPORT

6.1 Financial Practices Session Purpose

The purpose of the breakout session was to examine the findings from the IECRN Financial Practices Descriptive Survey. Session leaders were charged with introducing key findings and identifying results that were unexpected or surprising, and with facilitating discussion about session participants' experiences and how and whether they related to the findings of the study. In addition, participants were asked to identify promising strategies for preventing and managing cost overruns and securing funding, and to suggest specific tools, types of information, or approaches that would be helpful to networks in managing their finances.

6.2 Financial Practices Session Process

Content experts for this session were **Deborah Roth**, Chief Operating Officer, Duke Clinical Research Institute, and **Donna Marinucci**, Vice President, Operations, Coalition of Cancer Cooperative Groups. The session was moderated by **Sadie Bennett**, Project Manager, Lockheed Martin/Aspen Systems. The electronic audience response system was not used for this session.

An IECRN project staff member took notes during the session, which provided the information needed to formulate the Financial Practices Breakout Session report presented during the plenary session on the second day of the Forum. Following the conference, content experts synthesized the results of the breakout session and prepared this final Financial Practices Summary report.

6.3 Demographics of Financial Practices Session Participants

Information on the demographics of session participants was not collected during the Financial Practices breakout session.

6.4 IECRN Survey, Barriers and Facilitators, and Best Practices Findings

The breakout session included a brief presentation to provide the participants with an overview of the Financial Practices survey results. The Financial Practices component of the IECRN project included a descriptive survey but did not include a qualitative component for barriers, facilitators, or best practices.

6.4.1 Survey Results

The session began with a review of the survey topics related to Financial Practices, which included the following:

- Network funding sources;
- Duration of funding;
- Budgeting and allocation of funds;
- Financial development activities; and
- Financial management and monitoring procedures.

Fifty-nine (59) networks responded to the Financial Practices survey. The breakdown by major survey variables was as follows: 63 percent (37) of the clinical research networks (CRNs) have been in existence longer than 5 years; 56 percent (33) were primarily focused on conducting clinical trials; and 58 percent (34) were involved in conducting trials funded primarily by the National Institutes of Health (NIH).

With regard to primary funding source, the U.S. Federal Government is by far the primary funding source for the respondent networks, representing 46 of the 59 respondent networks, or 78 percent. Of these, 70 percent received their funding from NIH. Other primary funding sources included academic institutions (4), foundations/nonprofit organizations (4), and for-profit/commercial entities (3). There were no networks that reported that their primary funding source was a state or local government, endowment, or professional association. Primary funding for networks was reported to be in the form of grants, contracts, and cooperative agreements in roughly equal proportions.

Forty-three (43) of the respondent networks (or 73%) reported that they also received funding from secondary sources. This raises significant issues regarding the importance of successful strategies for integrating funding from various sources.

The mean duration of funding from the networks' primary funding source was 5.2 years with NIH-funded networks reporting longer periods of funding (5.9 years) compared with non-NIH-funded networks (4.4 years).

With regard to budgeting and allocation of network funds, 45 percent of the networks well funded on a study-by-study basis. Of these, only 56 percent reported that funding was sufficient to cover study costs. Of the remainder, 70 percent combined funding from different sources for a specific study.

The most significant finding with regard to financial management was that 40 percent of networks experience cost overruns either all or almost all of the time. An additional 27 percent reported that they experience cost overruns sometimes. Only 7 percent of networks reported that they never experience cost overruns. The two most frequently mentioned reasons for cost overruns were increases in the scope of the studies conducted and underestimates of the original budget.

6.5 Best Practices, Other Than Those From the IECRN Best Practices Study

A key survey finding that was reinforced by the session participants relates to the adequacy and stability of network funding.

6.5.1 Adequacy of Funding

With regard to the adequacy of funding, the participants expressed a high level of concern regarding future limitations on the availability of network funding, particularly given the high level of dependence of the respondent networks on Federal funding. Accordingly, there was a strong consensus regarding the need for networks to aggressively seek secondary funding in order to ensure their viability and success. In addition to the diversity of the actual sources of secondary funding, it was also noted that there are a variety of approaches to incorporating secondary funding into a network's overall funding structure. A number of examples were cited. These included the use of secondary funds from an industry

sponsor to supplement an individual clinical research project, such as the use of industry funds to pay the investigative sites in combination with the use of primary funding for the operations of the central clinical operations and data/statistical coordinating center. Another example was the use of industry funds to conduct mechanistic and correlative substudies in concert with a clinical trial. This provides a vehicle for the sites to leverage their efforts and efficiency by collecting additional samples or data for subjects who are already participating in the study. A final example is the use of industry funding for secondary analyses and manuscripts using the database from a completed clinical research project.

6.5.2 Stability of Funding

The ongoing stability of funding for CRNs is a significant concern and has the potential to severely limit the effectiveness of networks as a critical component of the nation’s clinical research enterprise. A key survey finding was that 45 percent of networks are funded on a study-by-study basis and that only 56 percent of these indicated that their funding was sufficient. Specific areas that are often underfunded include protected time for investigators, support for secondary analyses, and professional development of investigators and research staff. The participants discussed the critical need for funding for core infrastructure and recommended that efforts be made to identify the most appropriate model of network funding in order to ensure this support.

Another key finding from the survey discussed in the breakout session was the frequency of cost overruns and the extent to which these expenses are internally absorbed by networks. Participants shared practices currently in use in their networks to reduce the risk of budget underestimation. One such practice featured the use of a feasibility and budget committee including both scientific and operational representatives who perform a detailed review after a protocol concept has been approved for scientific merit. The importance of conducting an early feasibility assessment (i.e., prior to full protocol development) was highlighted. It was also noted that studies are getting increasingly complicated to conduct (particularly with regard to the volume of data collected) and, accordingly, that network leadership must play a strong role in prioritization to ensure that approved protocols are both operationally and financially feasible and that decisions regarding the activities to be conducted are made in the context of funding availability. There was a strong consensus about the need for a standard set of financial management tools to assist networks in understanding the true costs of a clinical trial in order to make better decisions regarding future trials.

The participants noted that many networks are focused on a specific disease or patient population and the question was raised as to whether this focus was a potential barrier to sharing infrastructure across networks. Specific opportunities cited for collaboration across networks included the centralization of data management activities. There was an interest in understanding better whether shared centralized infrastructure is more efficient.

6.6 Conclusions

A number of key conclusions emerged from the discussion and included the following:

- Funding for core infrastructure is vital. Current network funding models do not generally include funding for core infrastructure, and funding on a study-by-study basis is very challenging.
- Availability of secondary funding is critical to network success. CRNs do not aggressively seek new sources of funding and need to do so in the future.
- Cost overruns are frequent and efforts are needed to better estimate and manage network expenses, including controlling the scope of studies.
- Given current and future funding constraints, cost mitigation is essential and strategies for collaboration and sharing of administrative and infrastructure functions should be further explored.

6.7 Future Recommendations

Below are several recommendations that emerged from the discussion.

6.7.1 Identify the Optimal Model for Network Funding

Further explore existing network models (e.g., networks that have core infrastructure funding, networks that are funded on a study-by-study basis) in order to develop an optimal model for network funding. This may include the development of models for public/private partnerships in order to optimally leverage Federal funding for the ongoing funding of core network infrastructure and industry funding for the conduct of specific studies.

6.7.2 Secondary Funding

Further explore the specific strategies and approaches used by those networks that have been successful in securing secondary funding in order to establish and share best practices. A potential target for such investigation may be older networks (i.e., those in existence longer than 5 years) given that these networks devote more effort to securing secondary funding and have a higher proportion of secondary funding. Also identify and disseminate best practices for combining funding sources for a specific study as well as identifying those activities that should ideally be funded through a secondary source.

6.7.3 Sharing of Infrastructure Across Networks

Determine which components of network infrastructure and operations are transportable across different disease areas and patient populations. Determine what efficiencies and economies of scale can be achieved through the creation and utilization of centralized infrastructure and operational capabilities that are available to multiple networks (such as the Cancer Trials Support Unit which provides services to the NCI-funded Cancer Clinical Trial Cooperative Groups).

6.7.4 Improve Network Financial Management Including Budget Estimation, Financial Monitoring, and Decisionmaking

Develop and disseminate a standard set of financial management tools and resources for CRNs. This should include the development of costing models to distinguish between fixed vs. variable costs and estimate the cost of conducting an individual protocol (both at the level of the coordinating center and at individual investigative sites). Tools are also needed to assist networks in tracking the actual costs of individual studies separately from the costs of maintaining the network infrastructure in order to provide a more accurate basis for estimating future budgets. These tools will be critical in enabling network leadership to make decisions about the initiation of new protocols in the context of the funds required for the completion of ongoing protocols as well as funds needed for the maintenance of the network infrastructure over the funding period.

6.7.5 Foster the Role of Network Leadership in Decisionmaking Regarding Network Activities from a Financial Perspective

Develop and disseminate best practices regarding the processes and mechanisms to be used by network leadership in assessing, prioritizing, and making decisions regarding the initiation of new protocols and in controlling the scope of existing protocols based on the operational and financial implications, in addition to scientific merit.



7. INFORMATION TECHNOLOGY SUMMARY REPORT

7.1 Information Technology Session Purpose

The purpose of the breakout session was to examine the findings from the IECRN Information Technology Descriptive Survey (quantitative and qualitative), as well as explore relevant findings from the Best Practices Study. Session leaders were charged with introducing key findings and identifying results that were unexpected or surprising, and with facilitating discussion about session participants' experiences and how and whether they related to the findings of the study.

7.2 Information Technology Session Process

Content experts for this session were **Charles Jaffe**, Senior Global Strategies for the Digital Health Group at Intel Corporation, and **Rebecca Kush**, President of CDISC. The session was moderated by **Wayne Kubick**, Senior Vice President with Lincoln Technologies. The leaders of this session opted not to use the electronic audience response system that was available.

An IECRN project staff member took notes during the session, which served to provide the information needed to formulate the Information Technology (IT) Breakout Session report to all attendees on the second day of the Forum. Following the conference, content experts were asked to synthesize the results and provide this final Information Technology Summary report.

7.3 Demographics of Information Technology Session Participants

The composition of the breakout session was similar to that of the Data Management breakout session held earlier. Based on a show of hands, the attendees were distributed into the following disciplines:

- Twenty-seven (27) percent (30 of approximately 110) considered themselves involved in IT (some were more properly considered to be in informatics);
- Five people were primarily “clinical;”

- Ten were involved with data management; and
- Ten were statisticians.

7.4 IECRN Survey, Barriers and Facilitators, and Best Practices Findings

There were several concerns about the descriptive survey instruments. Comments raised included questions of whether instruments were validated, whether terminology and questions were sufficiently defined, and whether participants confused data management with information technology in some areas. As a result, participants expressed concern that readers may draw inappropriate general conclusions and that the survey did not provide sufficient detail to draw specific conclusions.

Presentation of both the descriptive qualitative study results and the Best Practice IT results led to a discussion about outsourcing. Although concerns were expressed about the ability of an external IT source “knowing” the business of clinical research, some session participants said they would welcome the ability to offload their IT management to an external vendor. At least one respondent said that he found the management of IT in his network a “headache” and would greatly welcome a caBIG-type initiative, whereby he could obtain his IT support from an external source. One of the content experts noted that enormous resources are poured into networks duplicating their efforts, and that perhaps it would be more cost effective if networks could tap into a centralized resource provided by the National Institutes of Health (NIH). Others noted, however, that it should be optional and those networks with an effective IT should not be required to outsource. Aside from outsourcing, in general, the prospect of an IT toolkit offered by NIH would be welcomed by many networks.

There was general agreement, in responding to the Best Practices findings, that a major obstacle is bridging the communications gap between IT personnel and clinical staff, especially when there’s a lack of computer savvy at sites. Many sites have limited or no IT support. Moreover, in the practice-based research networks (PBRNs), clinicians are focused more on providing care than on staying up to date with computer technology. Informatics professionals and business analysts are often the best to broker the communications, but are in short supply and not available to many networks. A one-size-fits-all solution is not realistic. The most successful technology is very carefully tailored to meet the networks’ particular requirements.

Internationally relevant data standards would be particularly beneficial to establish a common baseline level of interoperability; they are minimally used at present, and many networks haven't gotten to the stage of maturity where they can apply them. Here again, NIH could be helpful by establishing a standards-based set of minimum requirements.

7.5 Best Practices, Other Than Those from the IECRN Best Practices Study

Representatives from Best Practices Study nominees were asked to give a short summary of their experiences to be shared with the group. The following groups contributed and their reports are summarized in the presentation slides (day 2 of the Forum):

- ARDSNet—use of IT for quality control and decision support;
- NHLBI/NERI—ADEPT data management system, to improve efficiency;
- CARENet—pairing patient-reported and investigator-reported data into a central repository;
- MFMU—use of personal digital assistants (PDAs) for nurses to support routine operational tasks and automate reporting;
- UMinn—use of IT to recruit networks and participants and collect data; and
- SWOG – creation of a custom study operations portal web site as easy to use as Amazon.com.

One comment expressed regret that details of best practices were not further described in the report or the session so they could be evaluated and possibly applied by other networks. When asked, only about five people indicated that they had read any of the study results, including the Best Practices report that had been posted on the IECRN web site.

7.6 Conclusions

The following conclusions were drawn from the overall discussion:

- Individual site/investigator/patient needs must first be taken into account prior to implementing any IT solution; improving communications between IT and clinical personnel and understanding of the business process is a prerequisite.
- Networks have the most to gain by learning from each other. Establishing a baseline of standards and an infrastructure for collaboration should be an NCI priority.
- Industry trends toward IT advances, interoperability, and the electronic health record (EHR) should influence NIH to prepare a toolkit of standards, procedures, products, and capabilities that can be applied by sites to establish a more effective IT infrastructure.

7.7 Future Recommendations

- NIH should consider establishing an IT toolkit that would be made available to clinical research sites.
- NIH should define a set of baseline data standards that are internationally relevant to support increased interoperability of research data among networks.
- Additional details of best practice lessons learned should be shared among research sites.

