

CORE AND DESCRIPTIVE SURVEY SUMMARY

1 Overview

The Inventory and Evaluation of Clinical Research Networks (IECRN) is a project funded by the National Institutes of Health (NIH) to (1) to develop an inventory and database of clinical research networks; (2) to describe organizational and operational characteristics of a sample of networks in several key practice domains; (3) to identify and examine network best practices that lead to successful achievement of specified outcomes; and (4) to conduct a National Leadership Forum to discuss the study findings, highlight selected best practices, and disseminate this information to the research community.

IECRN is part of the NIH Roadmap Initiative, charting new directions for accelerating medical discoveries to improve health and to speed translation of these discoveries into practice. In particular, IECRN is related to the Roadmap's Reengineering the Clinical Research Enterprise component that seeks to enhance the efficiency and productivity of clinical research by promoting clinical research networks that can rapidly conduct high quality studies capable of addressing multiple research questions.

This report summarizes the findings from two key components of the IECRN Project: the Core and Descriptive Surveys.

1.1 Core Survey

The Core Survey served as a screening tool to determine whether a network satisfied the project's definition of a clinical research network and collected descriptive and contact information about the network to be posted on the IECRN Web Inventory at <https://www.clinicalresearchnetworks.org/>.

Public domain sources were searched for potential clinical research networks. The project's operational definition (see Exhibit 1-1) of a clinical research network was applied to nearly 700 groups and programs that were potentially clinical research networks. Those networks that appeared to meet the definition of a clinical research network received the Core Survey beginning in August 2005, with ongoing supplemental mailings sent to additional potential networks.

1.2 Descriptive Surveys

The Descriptive Surveys sought to examine the practices, policies, and procedures associated with the major areas of network functioning, including management and governance, financial practices, network operations, recruitment and retention, training and professional development, data management, and information technology (IT) on a smaller sample of networks. Data collection was constructed around these themes as seven separate instruments.

Six of the seven Descriptive Surveys (the exception being the Financial Practice module) also included a set of questions administered through a telephone interview. This quantitative component of the Descriptive Surveys addressed barriers and facilitators that may influence the networks' practices within each functional area.

The Descriptive Survey instruments are presented in Appendixes B to H.

1.3 Instrument Pretest

The IECRN Evaluation Team conducted pretests on each survey instrument to identify any question wording or ordering that was unclear to respondents, to determine if any critical measures had been omitted from the survey instrument, and to provide an estimate of respondent burden.

1.4 Confidentiality

The information requested for the IECRN Core Survey contained network identifiable information. Networks were asked permission to include their details compiled through the Core Survey on the IECRN web site. Networks participating in the Descriptive Surveys were assured confidentiality, as responses would either be reported in aggregate or without respondent or network identifying information.



1.5 Data Collection Process

Survey procedures were designed to maximize response rates (i.e., when required, a phone call was made to the network contact listed in the public domain database to confirm the appropriate clinical research network representative to communicate with regarding the survey) and reduce respondent burden. The multimode administration (paper and web-based) of the quantitative surveys was implemented to provide convenient response options for the clinical research network.

1.6 Data Analysis

Quantitative data were analyzed in aggregate using SAS according to analysis plans developed for each survey module. Means as well as frequencies and their associated percentages were calculated for both individual variables as well as for variables that were derived from combinations of other variables. Statistical significance was analyzed using chi-square tests for comparison of proportions. In cases where comparisons with smaller samples were analyzed, a two-tailed Fisher's exact test was used. T-tests were used to test for statistically significant differences between means. All data were further analyzed according to three key strata: network age (≥ 5 years vs. < 5 years); primary study type (clinical trials vs. non-clinical trials); and primary funding source (NIH vs. non-NIH).

Qualitative data obtained through in-depth telephone interviews, was initially coded from verbatim transcripts using NVivo software by analysts. This produced comprehensive coding schemes that could then be used for additional, more thorough re-reading and recoding of the transcripts. Further analysis and synthesis revealed recurrent themes related to the contextual, structural, and operational characteristics, as well as barriers and facilitators that may affect a network's successful implementation of these activities within each of the above functional areas.

2. Survey Response Rate

2.1 Core Survey

Of the 292 networks receiving the Core Survey through March 1, 2006, 31 were deemed ineligible, 7 networks chose not to participate, 3 networks did not respond, and 4 network's responses

were incomplete for a response rate of 96%. The Core Survey Database was frozen for reporting purposes on March 1, 2006, with responses from 244 eligible networks.

2.2 Descriptive Surveys

The overall response rate for all the quantitative Descriptive Survey modules was 73%, with a range of 67% for the Financial Practices module to 87% for Management and Governance module. Not all networks selected for the Descriptive Survey received the Descriptive Survey modules. Table 1 shows the response rate distribution for the seven Descriptive Surveys.

Table 1. Quantitative Descriptive Survey response rate by module

Survey instrument	Sent	Received	Nonresponse	Refused	Response rate (%)
Data Management	101	74	26	1	73
Financial Practices	100	67	30	3	67
Information Technology	101	74	26	1	73
Management and Governance	103	90	5	8	87
Network Operations	102	69	32	2	68
Recruitment and Retention	101	72	29	1	71
Training and Professional Development	102	71	31	1	70

The number of cases analyzed for each module of the qualitative component of the Descriptive Surveys ranged from 34 to 79.

Table 2. Qualitative Descriptive Survey interviews by module

Survey instrument	Interviews
Data Management	35
Information Technology	38
Management and Governance	79
Network Operations	34
Recruitment and Retention	39
Training and Professional Development	38



3. Key Network Characteristics

Of the research networks surveyed, 95 completed one or more of the different quantitative Descriptive Survey instruments. The following is a summary of the networks by age, funding source, geographical coverage, type of studies, and special study population.

The age of the networks was a mean 9.6 years (range: 0.5 – 50 years), with most stating that their primary funding source was the U.S. government (74%) rather than foreign governments (3%), academia (9%), nonprofit (6%) or for-profit (5%) organizations. Two networks did not have a primary funding source. Of surveyed networks, 54% had an exclusive U.S. geographic coverage, and 6% had foreign geographical coverage, while the remainder reported implementing activities on U.S. and foreign soil.

With respect to the type of study, 41% of networks reported primarily conducting phase I-IV clinical trials, with networks that conduct phase III clinical trials most prominent; and an additional 4% of networks stated focusing on clinical trials. Other types of studies that networks concentrated on were observational epidemiological studies (15%), other intervention including behavioral studies (7%), other observational studies (6%), outcomes research (5%), and field or community intervention trials (3%); 15% of surveyed networks did not focus on any particular type of study.

When assessing the networks as to whether they were targeting a special study population, 33% indicated concentrating on children under the age of 18, and 15% stated focusing on people aged 65 years and older. Moreover, 15%, 20%, and 33% directed their research activities toward males, females or minority populations, respectively. Half of the networks said they focused their research activities on underserved or rural populations (26%) or other special populations (26%); 20% of networks did not specify a population focus.

4. Quantitative Survey Results

4.1 Core Survey

Of 261 eligible clinical research networks, 244 (96%) responded to the Core Survey and have been included in the network inventory on the IECRN web site. Network age ranged from 6 months to 50 years. The mean and median network age was 9.6 and 6 years, respectively. Over 60% of networks received most of their funding from the U.S. Federal Government. Thirty-nine percent of all networks received funding from only one sponsor. Fifty-five percent of NIH-funded networks had only one funding source.

Networks reported conducting from 0 to 10 different study types in the past 5 years. Older networks conducted more of every type of study than newer networks in the past 5 years, with the exception of best practices modelling. NIH-funded networks conducted more clinical trials studies than non-NIH funded networks, while intervention studies, observational studies, outcomes research, and best practice modelling were conducted more often by non-NIH funded networks. Clinical trial studies were conducted most frequently overall, followed by observational studies (39% and 28%, respectively).

Thirty-five percent of networks reported studying children under the age of 18 while 23% studied people aged 65 or over. Minority and underserved/rural populations were studied by 30% and 26% of networks, respectively.

4.2 Management and Governance Descriptive Survey

Responses from 90 networks were included in the Management and Governance analysis. According to the three major comparator variables, 46 had been in existence at least 5 years (older) and 44 were established less than 5 years ago (newer); 51 performed primarily clinical trials (clinical trials networks) while 39 performed primarily other types of studies (non-clinical trials networks); and 55 received their primary funding from the NIH (NIH-funded), while 35 had primary funding from an organization other than NIH or had no current funding (non-NIH-funded).

Overall, 57% of networks were amenable to new members joining the network, with a greater proportion of non-NIH-funded networks stating so than their NIH-funded counterparts. Sixty-two



percent of the networks reported that their primary funder encouraged collaboration with other research networks. A significantly greater proportion of NIH-funded networks compared to their non-NIH-funded counterparts reported such encouragement. Over one-fourth (27%) of all surveyed networks indicated having no present connection with other research networks, and 28% reported failed collaboration attempts. Forty-five percent of newer networks compared to only 9% of older networks had no connections with other networks, and a statistically significantly greater proportion of older networks reported failed attempts of collaboration with other research networks. Forty-six percent stated they were pursuing activities to establish connections with other networks.

Approximately one-fourth to one-third of surveyed networks reported making a contribution to national practice guidelines (28%), national recommendations (24%), new standards of care (32%), or assessment tools for measuring research quality (23%).

Most networks possessed written or formulated network management materials including strategic plans, mission statements, by-laws, and network policy guidelines. Compared to non-NIH-funded networks, a significantly greater proportion of NIH-funded networks reported having executive publications and presentations, IT and data management, recruitment and retention, and laboratory committees. Older networks were significantly more likely to have a science, community and outreach, unit performance, or laboratory committee. Clinical trials networks were significantly more likely than non-clinical trials networks to have a budget/finance, policies and procedures, or laboratory committee.

Compared to non-clinical trials networks, clinical trials networks reported a significantly greater proportion of other health professionals and IT staff involved in conducting network activities. Non-clinical trials networks had a significantly greater proportion of community-based physicians and research assistants involved in the networks' implementation of activities. Compared to non-NIH-funded networks, NIH-funded networks had significantly greater proportions of project statisticians/methodologists, IT staff and data management staff involved in network activities.

Two-thirds of surveyed networks (69%) reported that the primary funder was either highly or somewhat involved in overseeing network governance. Eighty percent stated that their network leadership group participated in setting their scientific agenda. Compared to newer networks, older networks were significantly more likely to have specific committees/representatives and community groups involved in this process. Sixty-nine percent of NIH-funded networks acknowledged their sponsor was involved in setting the network's agenda, while only 37% of non-NIH-funded networks noted their



involvement. A scientific planning committee existed in 55% of all networks. Almost all networks (94%) stated scientific concepts were evaluated prior to development of scientific protocols, and 48% also stated that network funds were available to develop new concepts.

Almost all (86%) networks reported some information sharing between network partners, including funding opportunities (70%) and opportunities for presentations and publications (83%). Overall, one-quarter of surveyed networks (26%) also reported some information sharing with other research networks. Compared to non-NIH-funded networks, NIH-funded networks possessed written information sharing policies and guidelines. Compared to non-NIH-funded networks, a significantly larger proportion of NIH-funded networks had policies and guidelines on sharing of research data within a network, selection of study abstracts for presentation and publication, submission of proposals for presentations, making presentations, submissions for publications, and authorship of publications. Of all surveyed networks, 53% had procedures for disseminating study findings to the public. A significantly greater proportion of NIH-funded networks had such procedures than their non-NIH-funded counterparts.

4.3 Financial Practices Descriptive Survey

Responses from 67 networks were included in the Financial Practices analysis. According to the three major comparator variables, 42 had been in existence at least 5 years (older) and 25 were established less than 5 years ago (newer); 37 performed primarily clinical trials (clinical trials networks) while 30 performed primarily other types of studies (non-clinical trials networks); and 38 received their primary funding from the NIH (NIH-funded), while 29 had primary funding from an organization other than NIH or had no current funding (non-NIH-funded).

Fifty-two networks (52%) reported the U.S. Federal Government as primary funding source, with most of these networks (69%) receiving their funding from NIH. Network funding was provided through grants, contracts, or cooperative agreements in approximately equal proportions. The mean duration of funding from networks' primary funding source was 5.3 years. NIH-funded research networks reported significantly longer periods of funding from their primary funding source than non-NIH-funded networks.

Forty-six networks (69%) reported secondary sources of funding. A higher percentage of older research networks noted a secondary funding source (60% vs. 81%) than newer networks. In



particular, older research networks received significantly more secondary funding from foundations than newer networks. More than 85% of all research networks stated that their primary funding sources covered administrative costs as well as salaries for their research and support staff. A significantly higher proportion of clinical trials networks covered research staff salary, laboratory and diagnostic, pharmaceutical and patient care costs than non-clinical trials networks. Also, a significantly higher proportion of NIH-funded networks reported assuming research staff salary, laboratory and diagnostic, pharmaceutical and patient care costs. Only six (9%) of surveyed research networks did not cover costs for site-specific activities – these networks were all non-NIH-funded networks. Most networks allocated funds to network management and/or leadership entities (85%) as well as to statistical and data management (83%) entities.

Most networks responded to funding announcements (86%) rather than conducting targeted marketing, private fundraising, or other fundraising activities. The mean number of funding applications submitted by research networks per year ranged between 2.0 for newer networks and 3.8 for non-NIH-funded networks. All network groups reported the funding of more than 50% of all applications submitted. Forty-three percent of networks said that they were funded on a study-to-study basis, with funding sufficient to cover study costs for 54% of these networks. In those networks that were not funded on a study-to-study basis, 77% stated that they combined funding sources for a specific study.

Thirty-nine percent of networks reported experiencing cost overruns sometimes, all or almost all of the time with only 37% of all networks never experiencing cost overruns. Almost one-third of surveyed networks (29%) said that they experienced cost overruns because of an increase in the scope of study rather than because they had underestimated the original budget (26%). Seventy-six percent of networks managed cost overruns by absorbing them internally rather than by seeking additional funding, reducing study sample or staff sizes, or limiting the number of outputs. Of all nonfinancial incentives offered by the networks to ensure network performance during funding shortfalls, appeal to altruism was most often reported (49%). One-fifth of all networks also said that they billed third party payers for routine clinical care or experimental treatment costs. Further, 43% of NIH-funded networks billed third-party payers as compared to none billed by non-NIH-funded networks.

4.4 Network Operations Descriptive Survey

Results are based on the 69 networks that responded to the Network Operations Survey. According to the three major comparator variables, 43 had been in existence at least 5 years (older) and 26 were established less than 5 years ago (newer); 37 performed primarily clinical trials (clinical trials networks) while 32 performed primarily other types of studies (non-clinical trials networks); and 41 received their primary funding from the NIH (NIH-funded) while 28 had primary funding from an organization other than NIH or had no current funding (non-NIH-funded).

Sixty-three percent of the networks have a documented procedure for identifying and recruiting sites. Competition was used by a significantly greater proportion of NIH-funded networks compared to others. Availability of facilities was a key criterion used to evaluate a site's qualifications for participation in the network. A greater proportion of clinical trials networks and NIH-funded networks compared to their counterparts reported investigator qualifications, staff qualifications, past experience with studies, and accessibility to an institutional review board (IRB) as the criteria used. Nearly half of all surveyed networks conducted site visits (39%), carried out internal reviews (42%), and obtained consulting recommendations (42%) to evaluate site qualifications. Several factors, including inadequate infrastructure, inadequate patient accrual plan, lack of investigator qualifications or experience, and past performance on studies, were indicated as site exclusion criteria by more than half of all networks. Forty-five percent of all networks operated satellite sites in conjunction with their research sites. Networks with satellite sites indicated that geographic proximity to participant population (77%) and previous working relationship with main site (77%) were the two primary reasons satellite sites were chosen.

The majority of surveyed networks indicated they used investigator-initiated protocol proposals (94%). The majority of surveyed networks provided the following types of operational support for the development of protocols or study plans: procedures manuals/standard operating procedures (SOPs) (84%); data collection forms (94%); survey instruments (75%); informed consent forms/procedures (91%); participant education materials (75%); laboratory documents/forms (64%); and laboratory specimen tracking systems (65%).

Eighty-seven percent of all networks maintained a database with administrative information about network operations. Three-quarters of networks with an administrative database regularly provided their network leadership with reports generated from the database. The types of reports typically included



status of protocol development and implementation (80%), site performance (71%), and status of participant recruitment (89%).

For most networks, the local site was involved in the review of protocols for compliance with Human Subject Protection (HSP) requirements (81%), followed by an organizational/institutional IRB (74%). Approximately one-quarter of all networks indicated central network IRB involvement (26%). Most studies in the majority of networks surveyed were conducted under two regulations: Good Clinical Practices (GCP; 70%) and 45 CFR 46 (Common Rule; 72%).

More than three-quarters of all networks were required to report safety data (78%); with clinical trials networks and NIH-funded networks compared to others significantly more likely to be involved in this activity. A greater proportion of clinical trials networks and NIH-funded networks reported that Data Safety Monitory Boards (DSMB) were responsible for monitoring safety data. Whether external sites were monitored was related to the network's funding source, with a greater proportion of NIH-funded networks compared to others reporting that they conducted external site monitoring.

4.5 Recruitment and Retention Descriptive Survey

Results are based on the 72 networks that responded to the Recruitment and Retention Survey. According to the three major comparator variables, 43 had been in existence at least 5 years (older) and 29 were established less than 5 years ago (newer); 38 performed primarily clinical trials (clinical trials networks) while 34 performed primarily other types of studies (non-clinical trials networks); and 43 received their primary funding from the NIH (NIH-funded) while 29 had primary funding from an organization other than NIH or had no current funding (non-NIH-funded).

Only 42% of respondents indicated their network had a recruitment committee. Networks consistently reported that setting recruitment goals (88%), developing plans (92%), and monitoring recruitment/retention (96%) were the main functions of their recruitment and retention committees. Almost all networks considered recruitment and retention issues when designing protocols and study plans (96%). Two-thirds of networks reported that study duration was very important in their approach to planning their recruitment and retention strategies. About one-third of networks reported that research sites were required to conduct disease-burden or similar analyses when patient accrual plans were submitted. The results of these analyses most often resulted in a change in recruitment and retention

strategies or the addition of research sites (both 83%) or a change in the inclusion/exclusion criteria used in protocols and study designs (61%).

Networks used a variety of methods to inform the development of their recruitment strategies, most commonly gathering expert opinions (47%) and holding recruitment training sessions for sites (49%). Only 22% of networks reported using institutional review board (IRB)-approved qualitative research methods such as focus groups to identify retention issues or patient compliance issues. Eighty-four percent of clinical trials networks responded that sites develop their own recruitment materials, compared to 39% of non-clinical trials networks. Similarly, 85% of NIH-funded networks indicated that all or some of their sites developed their own materials versus only 31% of non-NIH-funded networks. Non-NIH-funded networks were significantly more likely than NIH-funded networks to have a central IRB review their recruitment and retention materials. In general, central IRBs required less time to review new or revised materials submissions than local IRBs. Half of all central IRB reviews were completed within 1 month while only 14% of local IRB reviews were within the same timeframe.

Recruitment funds were provided to research sites by 44% of surveyed networks. Community-based physicians played a role in recruitment at the majority (62%) of networks. NIH-funded networks were more likely than non-NIH-funded networks to establish a web site portal for potential participants. Nearly one-quarter (24%) of established networks indicated that other recruitment strategies were used, including radio and television public service announcements, recruiting during clinic visits, and community education. Videotapes demonstrating procedures and issues surrounding informed consent were used by 24% of clinical trials networks but none of the non-clinical trials networks utilized videotapes.

Providing retention materials and incentives (57%), conducting retention and compliance staff trainings (49%), and providing patient compliance tools (49%) were the most commonly used retention strategies. Approximately half of the networks indicated their research sites used tracing procedures to locate inactive participants (47%).

The majority of networks used a recruitment plan to guide and monitor how recruitment practices are implemented (60%). The most common network response to slow recruitment was an extension of a study's recruitment timeframe, reported by 77% of networks. A significantly higher percentage of NIH-funded networks changed the protocol and/or study plan.



4.6 Training and Professional Development Descriptive Survey

Responses from 71 networks were included in the Training and Professional Development analysis. According to the three major comparator variables, 44 had been in existence for at least 5 years (older) and 27 were established less than 5 years ago (newer); 39 performed primarily clinical trials (clinical trials networks) while 32 performed primarily other types of studies (non-clinical trials networks); and 44 received their primary funding from the NIH (NIH-funded) while 27 had primary funding from an organization other than NIH or had no current funding (non-NIH-funded).

Overall, half of the respondents had written policies or procedures regarding staff training. Networks that primarily focused on the conduct of clinical trials were significantly more likely than networks that conduct other types of research to have written training policies or procedures. Similarly, NIH-funded networks were significantly more likely to have written policies or procedures than non-NIH-funded networks. Approximately one-third (34%) of the respondents had written training goals for network-level staff. Close to half of the networks (43%) had written training goals for site staff, with NIH-funded networks significantly more likely to have written training goals for site staff than non-NIH-funded networks.

The majority of networks (67%) did not include a committee that addresses training issues. Only 15% of respondents had a standing committee dedicated solely to training issues. Overall, over half (53%) of networks had a network level staff person who coordinated staff training activities. In terms of the types of training practices offered for network level staff, training on research procedures (86%) and human subject protections (86%) were provided the most frequently, followed by training on data management activities (80%) and study coordination management (76%).

Over three-fourths (79%) of the total networks developed training materials for site staff. Overall, networks were most likely to provide training for study coordinators (90%), followed by principal investigators (PIs)/co-PIs (84%), data management staff (84%), other investigators (73%), and research assistants (69%).

Close to half (43%) of the respondents had network policies that provide support of professional development activities for network staff. Overall, the most prevalent type of network staff support reported by respondents was paid travel to professional conferences (90%), followed by direct

financial reimbursement of tuition (57%), and flexible schedules (53%). Less than one-third (28%) of the respondents had network policies that provide support of professional development activities for site staff. The most prevalent type of site staff support was paid travel to professional conferences (63%), followed by direct financial reimbursement of tuition (58%). Overall, 19% of networks had a staff person who coordinated professional activities.

Respondents were most likely to provide professional development opportunities for PIs/co-PIs (48%), study coordinators (39%), and new investigators (38%). The most frequent type of program participated in by network researchers was new investigator awards or training programs (32%). Less than 5% of respondents reported participation in senior research fellowships (4%), Initiative for Minority Student Development (2%), and Research for Scientific Enhancement (0%) programs, respectively.

4.7 Information Technology Descriptive Survey

Responses from 74 networks were included in the IT analysis. According to the three major comparator variables, 43 had been in existence at least 5 years (older) and 31 were established less than 5 years ago (newer); 41 performed primarily clinical trials while 33 performed primarily other types of studies; and 43 received their primary funding from NIH (NIH-funded), while 31 had primary funding from an organization other than NIH or had no current funding (non-NIH-funded).

Nearly 70% of responding networks had IT dispersed over six or more locations, and only 14% had it primarily or completely centralized at one locale. Overall, 67% of responding networks had centralized management of IT, while only 10% had decentralized management. Only 50% of networks had a dedicated IT director or manager. Clinical trials networks were significantly more likely to have such a position than non-clinical trials networks. Seventy percent of responding networks did not have a standing committee of any kind that deals with IT issues, and only 26% had a dedicated IT committee.

Overall, 72% of responding networks said that they had some written policies or procedures related to IT. Clinical trials networks were much more likely to have these than non-clinical trials networks, as were NIH-funded networks compared to non-NIH-funded funded networks. The most frequently available policies/procedures overall were data backup (87%), system security/privacy (83%), and incident reporting and problem handling (81%).



Overall, responding networks had an average of 3.9 (SD = 5.8) full-time equivalent IT staff. NIH-funded networks had a significantly greater number of IT staff than non-NIH-funded networks. Because of the large standard deviation for this measure and some uncertainty about how respondents interpreted this question, these results should be interpreted with caution.

The most prevalent IT functions supported were online training (66%), participant randomization (62%), and clinical trials data management (62%). Clinical trials networks and NIH-funded networks were much more likely to support a wide variety of functions with IT than were their counterparts. Only 24% of responding networks used software for knowledge discovery. This was significantly more likely in NIH-funded networks than non-NIH-funded funded (35% vs. 10%).

Among all responding networks, the predominant IT infrastructure was some type of web-based architecture (63%). Thirty-three percent of clinical trials networks and 32% of NIH-funded networks employed n-tier web technology, the most sophisticated architecture. The most prevalent type of computer linkage connection was shared Internet access (64%). Clinical trials networks were more likely than non-clinical trials networks to use shared Internet access, as were NIH-funded networks compared to non-NIH-funded networks.

Nearly all responding networks (93%) had web sites. One hundred percent of NIH-funded networks had a web site. Of those networks with web sites, 94% had a public portion, but only 84% had a restricted portion for network members to access network-sensitive information.

Sixty-two percent of all networks used no data interchange standards. Only 15% of responding networks used Health Level 7 (HL7), and only 11% use Clinical Data Interchange Standards Consortium (CDISC) standards. Only 38% of responding networks used XML for data transfer and storage. Clinical trials networks were more likely than non-clinical trials networks to use XML, and NIH-funded networks were more likely than non-NIH-funded networks.

Overall, 69% of responding networks used some standard vocabulary. NIH-funded networks were much more likely than non-NIH-funded networks to use at least one standard vocabulary. The most commonly used vocabularies were MedDRA (34%) and common data elements (31%). Only 5% of networks reported using Logical Observation Identifiers Names and Codes (LOINC). Only 34% of responding networks indicated the use any messaging strategy to integrate software. Clinical trials networks were more likely than non-clinical trials networks to use a messaging strategy, as were NIH-



funded networks compared to non-NIH-funded networks. The most frequent messaging strategies were custom programming (22%) and XML (22%).

4.8 Data Management Descriptive Survey

Responses from 74 networks were included in the Data Management analysis. According to the three major comparator variables, 41 had been in existence at least 5 years (older) and 33 were established less than 5 years ago (newer); 40 performed primarily clinical trials while 34 performed primarily other types of studies; and 43 received their primary funding from NIH (NIH-funded) while 31 had primary funding from an organization other than NIH or had no current funding (non-NIH).

Overall, 69% of responding networks had data management performed primarily in data management centers, and only 7% had it performed primarily at the research sites. NIH-funded networks were much more likely to have data management performed centrally, and there was a significant trend toward centralization in NIH-funded networks. Clinical trials networks were much more likely than non-clinical trials networks to use private contractors or other organizations than academic centers for data management, as were NIH-funded networks compared to non-NIH-funded networks. Academic centers were the predominant data management organizations for both non-clinical trials networks (68%) and non-NIH networks (71%).

Sixty-two percent of networks had a dedicated data management director or manager. Clinical trials networks were more likely to have such a position than non-clinical trials networks, as were NIH-funded networks compared non-NIH-funded networks. Fifty percent of responding networks had a standing committee of some kind that deals with data management issues, but only 34% had a dedicated data management committee.

Overall, 78% of responding networks said that they had some written policies or procedures related to data management. Clinical trials networks were much more likely to have these than non-clinical trials networks, as were NIH-funded networks compared to non-NIH-funded networks. Overall, 88% of responding networks had SOPs for one or more SOPs for the 13 data management tasks included in the survey. NIH-funded networks were more likely than non-NIH networks to have SOPs for all but one of the data management tasks queried.



Responding networks reported having an average of 7.9 (SD = 13.8) full-time equivalent data management staff. NIH-funded networks had a significantly greater number of data management staff than non-NIH-funded networks, as did older networks compared to newer networks. The mean was highly influenced by a few networks that reported large data management staff. Because of the large standard deviation for this measure and some uncertainty about how respondents interpreted this question, these results should be interpreted with caution.

The most common data transfer methods were delivery of hard copy (58%), electronic transmission (54%), and direct data entry (47%). NIH-funded networks were more likely than non-NIH networks to use electronic transmission and direct data entry, while less likely to use hard-copy delivery. Hard-copy delivery was the predominant method of data transfer for 42% of responding networks, followed by direct data entry (31%). The most common file types used for clinical data storage were relational databases (80%) followed by spreadsheets (32%). NIH-funded networks were more likely than non-NIH-funded networks to use relational databases and much less likely to use spreadsheets. Clinical trials networks were also more likely than non-clinical trials networks to use relational databases.

Only 19% of responding networks reported using a model such as CDISC. Overall, 62% of responding networks indicated they have developed some kind of common data standards. NIH-funded networks were much more likely than non-NIH-funded networks to have developed such standards. While 62% of responding networks have developed some kind of common standards, overall 73% routinely used such standards. Again, NIH-funded networks were much more likely than non-NIH-funded networks to routinely use such standards.

5. Qualitative Descriptive Survey Key Results

5.1 Management and Governance

Barriers discussed by the respondents included lack of funding, time, and staff; lack of availability of the study participant pool; bureaucracy and competition; insufficient or poor communication; and issues surrounding mistrust of and problems with network leadership. With regard to barriers to development of a scientific focus, respondents most frequently discussed the perceived lack of scientific flexibility and difficulties in scientific focus on which all stakeholders agreed. The role of the sponsor was a prominent factor, particularly in discussions of cross-network collaboration, whereas issues



such as practitioner versus academic focus and lack of an internal infrastructure to support research were raised more often in the context of internal scientific activity.

Facilitators of the key components of management and governance were often the converse of the barriers. These included the presence of dedicated, adequate, and/or stable funding; strong sponsor support; a “community of scientists” with the appropriate mix of scientific, clinical and methodological expertise; collegiality; investigator commitment to collaboration;” open, two-way communication; willingness to meet face-to-face, discuss issues, and compromise; focused but flexible leadership; and willingness and ability to develop a scientific agenda that reflects the common research needs and goals of the network’s investigators or those investigators seeking to collaborate across network boundaries.

5.2 Network Operations

As facilitators of overall network functioning, respondents emphasized the importance of collegial communication and thorough review of protocols to guarantee a sound study plan and high quality scientific outcomes, despite the challenges involved with the lengthy review process and the volume of paperwork and regulations. Resource, time, and distance limitations were identified as critical barriers experienced by the network leadership and key staff as they attempt to manage regulatory requirements and communicate efficiently and effectively among themselves. In response to these challenges, respondents often developed a standard procedure or process for managing the operational side of network functioning, and emphasized the importance of keeping and training qualified staff to enact these approaches.

5.3 Recruitment and Retention

Many of the network respondents noted that recruitment and retention of study participants is truly the *sine qua non* of clinical research - without the subjects, there can be no research findings. The discussions on barriers and facilitators to success in this key area of network functioning suggest that attracting and retaining research subjects requires the synergy of efforts undertaken by a wide range of network participants. Critical aspects of these efforts include planning, attention to detail, good training of recruiters/study coordinators, solid communication, and ongoing evaluation and monitoring of recruitment and retention efforts. In particular, monitoring was found to be the key factor in gauging the



success or failure of recruitment and retention efforts. When all of these elements work effectively together, networks report success in conducting clinical research. Lessons learned on overcoming barriers to recruitment and retention may be useful to newly established networks preparing to recruit for their first studies.

5.4 Training and Professional Development

It was found that more established networks tend to have more robust, formal training programs than less established networks. Being affiliated with a university was identified as a structural factor supporting both training and professional development activities. Networks that are affiliated with universities appeared to receive support for more formal activities, such as those related to professional development, the development of needs assessment and evaluation tools, and the development of training materials.

Lack of time, insufficient funds, and not enough dedicated staff, as well as changing regulatory requirements, were perceived by network respondents as interfering with efficient and effective training. In contrast, having access to more experienced staff, investing the time needed to provide training, and using technical/electronic training to supplement face-to-face interactions were factors linked to successful and efficient training efforts. An important element of success, the interviews suggested, is the ability of networks to build on and tailor existing training programs over time. Programs put in place to “meet the need” when the network is first established can be improved as training staff becomes more experienced and specific training needs, and ways to address them, become more evident.

While typically not supported directly through network funds, most networks considered professional development valuable and worthwhile, and some offer access to conference attendance or provide opportunities for junior investigators to conduct studies and publish papers. University affiliation and alternate sources of funding tend to be facilitators while a lack of sufficient funding was cited as a significant barrier. A few networks seek alternate sources of funding to compensate for support gaps.



5.5 Information Technology

Barriers and facilitators to information technology were found to reflect variations on three basic themes: creating a “whole” out of the network parts; deciding what technologies – if any – are the best way to unify the network; and figuring out how to support both the technology and the technical staff. Processes associated with creating or sustaining a network presents several problems for informatics. System architecture barriers can be enormous, and after a network has addressed the hardware and software integration challenges, respondents noted that the end-users themselves come with different skill levels and aptitudes. Respondents also indicated that the need to train end-users is almost continuous, since technologies are changing rapidly and turnover at many sites is high, requiring basic training for new hires.

A significant barrier to meeting these challenges, the networks indicated, is having the necessary fiscal resources. Infrastructure development, as well as qualified technical staff, is often more expensive than a small network can afford. Thus, the underlying barriers associated with information technology were fairly clear: How do we get everyone in the network “on the same page?” And whatever solution – whether high- or low-tech – is decided upon, how do we find and pay for the staff to put a unified system in place? Finally, how do we do all this in the most cost-effective manner? The interviews also suggest that many of these challenges are confronted at the site level. Even networks that manage their own informatics seemed to struggle around issues of integration across participating sites. If the information technology for the network is provided by another organization, however, such as a university center or CRO, the problems appear to be less profound or pervasive.

5.6 Data Management

Typical barriers to effective and efficient data management included not having enough funds, people, or time. Interviewees suggested that funding was the critical link, as networks operating on a grant cycle can typically employ data entry staff only for the duration of the grant, and studies with insufficient funds allocated for data management staff often encounter backlogs both in data entry and analysis. In contrast, facilitators of efficient data management within networks were finding cost-effective ways of conducting business, such as using a web-based or other electronic form of data capture and transfer; having experienced and knowledgeable staff and enough of them to manage the workload (with



fewer needed if data are collected and transferred electronically); and having standard operating procedures for data collection/entry, quality control checks, and data transfer.

6. Navigating the Report

More in-depth findings are presented separately in the following chapters of this report. Chapter 3 provides the results of the Core Survey, and each of the seven quantitative Descriptive Surveys is presented in Chapters 4 through 10. A report on the qualitative analysis of barriers and facilitators appears in Chapter 11.

