RCE Program Evaluation: Report on the First Five Years of the Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCE) Program

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Office of Biodefense Research Affairs,
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by

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Executive Summary

This report describes the conduct and results of an interim, descriptive evaluation of NIAID's Regional Centers of Excellence (RCE) for Biodefense and Emerging Infectious Diseases Research Program (NIAID, See http://www3.niaid.nih.gov/Biodefense/Research/rce.htm). The evaluation plan resulted from a comprehensive process that engaged a wide range of stakeholders in identifying the elements of success of the Program, co-authoring an evaluation framework, and defining the major elements of the interim evaluation.

Overview

NIAID has funded ten Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (eight in 2003; two in 2005). This nationwide network of multidisciplinary academic centers is intended to conduct wide-ranging research on infectious diseases that could be used in bioterrorism; develop diagnostics, therapeutics, and vaccines needed for biodefense; serve as a training ground for biodefense researchers; and partner with state and local public health agencies to help ensure a strong, coordinated response in a time of crisis. (Fauci, See http://www3.niaid.nih.gov/Biodefense/About/directors_statement.htm)."

This evaluation addressed those major goals, as well as the extent of collaboration and communication within and across Centers; innovation and flexibility afforded by the Program; and progress toward product development. The interim evaluation relied on existing data, including the RCE Program database and the NIAID IMPAC II database, annual Center reports, Pub Med and the Web of Science; and an Information Request that asked RCE Administrators to provide specific information they would already have on hand. Due to timeline and resource constraints, and the relative lack of maturity of the RCE program, DMID excluded peer evaluation processes, financial analyses, substantial new data collection activities, and any activities that would require OMB clearance, such as formal interviewing or surveys of researchers.

This was an interim evaluation of the program *as a whole*. It was not intended to be a Center-by-Center evaluation. In general, reporting is done in the aggregate, across Centers. In selected instances, data are reported by Center, anonymously, to illustrate consistency or variability of given practices or outcomes.

Since few examples of evaluating large scale research initiatives such as center grant research exist, the interim descriptive evaluation should be considered a pilot study. A separate report will reflect on the lessons learned through this process and the implications for future evaluations.

Summary of Findings

Given the short time the Centers have been in existence, substantial impact on some of the longer term outcomes are not expected, although progress toward those end points is anticipated. The findings shows evidence that each of the major goals addressed in this interim, descriptive evaluation are being addressed:

- ***Collaboration and Communication:*** The RCE Program has had a wide reach, with over 290 participating institutions and 488 principal investigators involved. Many other investigators have had the opportunity to apply for funds or use core facilities. Investigators collaborate and communicate regularly within Centers for a variety of purposes. About 40% of RCE project teams have members from more than one institution and this collaboration appears to carry on into subsequent, non RCE grant projects. Cross institutional co-authorship is found on 51% of RCE publications. Cross-RCE interactions are less frequent than within RCE interactions, as would be expected.

- ***Research Conducted on Category A, B and C Agents:*** The RCE Program has research projects focused on 51 different agents, out of a possible 59 of NIAID's Category A, B and C priority pathogens. Thus the program is addressing its intended mission. Of the 563 funded projects, 58% address Category A agents, 21% Category B and 6% Category C. Just over half of the research projects are considered basic research. Vaccine research (16%), therapeutics research (14%) and diagnostics research (9%) comprise smaller percentages of the portfolio. Each Center has established a niche within the overall portfolio, in accordance with an expectation that Centers will specialize. The majority of Centers are researching between 14 and 16 different agents, suggesting that the Centers have found a balance between specialization and breadth and transfer across agents. A few outliers to this general trend warrant further investigation.

- ***Scientific Knowledge on Category A, B and C Agents:*** There is strong evidence that the research being produced is contributing substantially to scientific knowledge. The RCE Program has published more than 477 articles to date, with the number of publications increasing each year. RCE publications are well regarded, as indicated by higher than expected citation rates. RCE articles have been published in frequently cited, highly ranked journals. Citation of RCE publications is significantly higher than for other papers in the same journal and the same field.

- ***Innovative and Flexible Responses:*** The RCE Program has a number of unique features that promote flexibility, innovation and responsiveness at the Center level. For instance, Centers are able to restructure projects or cores, redirect carryover funds, reallocate funds from less successful projects to promising projects and designate funds for special purposes that support a strategic priority. These features have supported almost all of the goals of the RCE Program, including enabling the Centers and the Program to respond rapidly to emerging priorities, emergencies and threats, allow new investigators to enter the field and enable preliminary data to be developed using nontraditional approaches. The RCE Program appears to be making the largest proportional contribution (by percent of projects, relative to NIAID overall) in small, emerging scientific areas such as Francisella tularensis, Ebola, Noroviruses and Burkholderia. Most, though not all, Centers have successfully attracted large applicant pools in response to their solicitations for projects and investigators, making the application process competitive for all types of funding. Less than a third of all applications are funded.

New projects and investigators new to the RCE Program have been added steadily each year.

- ***Leverage Other Sources of Support:*** RCE investigators are successfully building on their RCE research to earn additional, follow on grants. RCE investigators have received 105 additional grants that stem directly from their RCE Research. The majority of these follow-on grants are funded by NIAID. Data on the dollar amounts of follow on grants were not collected.

- ***Expanded Cadre of Investigators:*** As of 2006, the RCE Program had brought more than 296 investigators who were new to biodefense, into this field. As noted above, investigators who are new to the RCE Program are added each year. The majority of funded investigators are new to biodefense.

- ***Readiness to Respond in an Emergency:*** Centers are expected to build relationships and provide resources that would support first responders in the event of an infectious disease-related emergency. Centers have been varied in their approach to this aspect of their mission. All Centers have compiled a list of resources that can be used in an emergency, and responded to a NIAID request to itemize resources available to support responses to Hurricane Katrina. In addition, the Centers provided support for nine other public health related situations. However, there are several core activities that were expected of all Centers that some Centers have not reported doing.

- ***Translate and Apply Science to Practice:*** The RCE program expects activities that can lead to the development of products or clinical interventions in the long term. An early indicator of progress is the establishment of novel support mechanisms that facilitate product development. Each Center reported at least one product development resource. These include infrastructure such as core facilities, laboratories and instrumentation; guidance on product development through dedicated staff members, committees or training; funding sources such as industry collaborations and dedicated funding sources for product development; and biological materials and processes that support ongoing research toward product development. The RCE Program has also developed a Product Development Working Group to periodically review and advise on concepts with product development potential. The group has reviewed 12 concepts. There have been 68 patent applications based on RCE research. Nearly half of these are related to vaccine development. Nearly a third are therapeutics-related.

The RCE Program's unique funding mechanisms are a critical input to the RCE Program, supporting and enabling the achievement of many of its goals. The Program is still in its early years, particularly as some Centers were not funded until 2005. Growth trends were observable on most measures over time, although a leveling off might be anticipated on many measures as the program reaches and maintains full capacity. This study provides baseline information that will be useful as a point of comparison in future evaluations.

In sum, the RCE Program is supporting collaboration, innovation, substantial research contributions and bringing new investigators into the field of biodefense. Research is leading to patent applications, concepts with product development potential and providing the foundation for successful applications for other sources of funding. While Centers have been called upon in a number of emergency situations, this aspect of their mission may warrant further attention. This interim evaluation has established baseline information against which future data can be compared. This inquiry has also suggested some areas for further discussion and clarification that may enhance the Program.

Acknowledgments

This descriptive, interim evaluation was funded by NIAID and the NIH Office of the Director by contract number H-2007-01. The primary authors were Kathleen M. Quinlan and Gruschenka Mojica of Concept Systems, Inc. Concept Systems, Inc. wishes to thank the many people who contributed to this effort. As described in the body of this report, the effort was collaborative. The evaluation framework was developed through a participatory process, involving many stakeholders. An Evaluation Measurement Task Force developed the evaluation questions and measures and determined the scope of the interim evaluation. The RCE administrators and investigators provided information that is analyzed and presented here. DMID staff extracted data from the RCE program database, IMPAC II and PubMed. Concept Systems, Inc. aggregated and analyzed the data and wrote this report. The Evaluation Measurement Task Force (EMTF) will review the results reported here to determine implications for Program enhancement. Concept Systems, Inc. provided some observations for Task Force discussion in a separate document entitled “Areas for Further Consideration”.

This evaluation should be cited as follows:

Concept Systems, Inc. RCE Program Interim Evaluation: Report on the First Five Years of the Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCE) Program. Bethesda (MD): National Institute for Allergy and Infectious Diseases, Division of Microbial and Infectious Diseases; 2008 Feb.

I. Introduction

This report describes the conduct and results of an interim, descriptive evaluation of NIAID's Regional Centers of Excellence (RCE) for Biodefense and Emerging Infectious Diseases Research Program. This interim evaluation addresses the first five years of the RCE Program (2003-2007) and is based on an evaluation plan that is the result of a comprehensive process that engaged a wide range of stakeholders in co-authoring an evaluation framework and defining the major elements of the plan for the interim evaluation. Further details of how the evaluation plan was constructed are available in the "Plan for an Interim Evaluation of the RCE Program" prepared in March 2007 by Concept Systems, Inc. for the Office of Biodefense Affairs (OBRA), Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID).

We use the term descriptive to indicate primary reliance on descriptive, rather than inferential, statistics and to indicate that the study is not intended to be correlational or experimental in nature. The study was conducted (facilitation of planning, data aggregation, analysis and report writing) by an external contractor, and, as such, can be viewed as an external evaluation. However, the plan was developed and its implementation conducted in close collaboration with the RCE Program, giving it characteristics of an internal evaluation. The RCE Program and the Centers made final decisions on the elements to be included in the evaluation plan and completed the data collection. The respective roles of the contractor and the program are detailed in the acknowledgments section and in the methods section below.

This evaluation should be cited as:

Concept Systems, Inc. RCE Program Interim Evaluation: Report on the First Five Years of the Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCE) Program. Bethesda (MD): National Institute for Allergy and Infectious Diseases, Division of Microbial and Infectious Diseases; 2008 Feb.

We begin with a brief explanation of the context and background to this project and the project goals. Section IV provides a short summary of the methods. The reader is referred to appendices for additional details. Section V reports results, organized according to the components on the logic model and the questions derived from that framework. Section VI provides a discussion of those results. Section VII summarizes observations and recommendations. This project also served as a tool for piloting measures for possible use in future evaluations. A separate report will provide recommendations for system changes that would support future evaluations.

II. Background: Our Understanding

A. Context

Since 2001, NIAID has greatly accelerated its biodefense research programs, launching several new initiatives. As part of this effort, NIAID has funded ten Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research. This nationwide network of multidisciplinary academic centers was established to conduct wide-ranging research on infectious diseases that could be used in bioterrorism, and develop diagnostics, therapeutics, and vaccines needed for biodefense. These Centers were designed to serve as a training ground for biodefense researchers. The Centers were also expected to partner with state and local public health agencies to help ensure a strong, coordinated response in a time of crisis. (Fauci, See http://www3.niaid.nih.gov/Biodefense/About/directors_statement.htm).

Eight Centers (NIAID, See http://www3.niaid.nih.gov/Biodefense/Research/rce.htm) were established in 2003, with two more added in 2005. Each Center consists of several well-defined components including research projects, developmental research projects, career development projects, scientific cores, and emergency response plans.

Bioterrorism has been identified as one of the most pressing emergent public health threats of our time. To support the critical emphasis placed on bioterrorism, recent allocations to biodefense constitute the largest amount of new funding ever given at one time to NIH. The heightened need to demonstrate the value of the funding for biodefense investment coincides with several trends in health research funding policy emphasizing the need for systematic evaluation of large scale research initiatives such as the RCE Program. The RCE Program is among those that are setting the standard for such systematic evaluation.

In late 2006, NIAID began working with Concept Systems, Inc. to develop a collaboratively-authored evaluation framework for the RCE program; and a plan for an interim evaluation of the RCEs to be conducted in 2007, in preparation for the second five year cycle of the program. The planning phase of work engaged a wide variety stakeholders representing the Centers, NIAID and other government agencies. Input resulted in a conceptual framework (see Figure 1), logic model (see Figure 2) and plan for the interim evaluation. It also led to recommendations for other potential uses of the framework.

B. Broad Goals of this Interim Evaluation

Broadly, this project involves the conduct of this descriptive interim evaluation and focused reflection on the process to inform future, definitive evaluations of the RCE Program. The interim evaluation was designed to:

- Be specifically relevant to the RCE program, its operations, Centers and management;
- Make use of existing data, tools and channels as much as possible;
- Be easy to communicate to stakeholders, and enable implementation without unnecessary burden to operations and programs;
- Provide evidence to assess the success and enhance the effectiveness of the program as a whole;
- Provide an opportunity to pilot test measures and data collection and analysis protocols that will inform future, definitive evaluations of the RCEs and, potentially, other Center grant evaluations in NIAID;

- Enhance the evaluation capacity of the RCE Program.

This interim evaluation was not intended to provide an evaluation of individual Centers. Rather, the purpose was to descriptively document the activities, outputs and selected short term outcomes of the RCE Program as a whole. In general, the report presents findings in the aggregate. However, it is instructive to examine differences across Centers as a way of assessing consistency in program implementation. Thus, de-identified Center data are presented for many measures. To assure anonymity of the Centers, blind codes have been assigned. Different codes are assigned to the same Center in different sections of the results.

C. Purposes of and Audiences for the Interim Evaluation

As an interim evaluation, the primary audience for the results is within NIAID. NIAID leadership will use the information to assess the results of the investment in the RCE Program to date. They are particularly interested in value-added and unique contributions achieved through a center grant approach, as compared to the traditional R01 mechanism. While a direct comparison between grant mechanisms is not feasible, the interim evaluation focuses on those elements that are unique to the mission and function of the RCE program. The interim evaluation results will be used to support decision-making about how to proceed with the RCE program in the future. Those closest to the program, including RCE program officers, will use the results to improve the program.

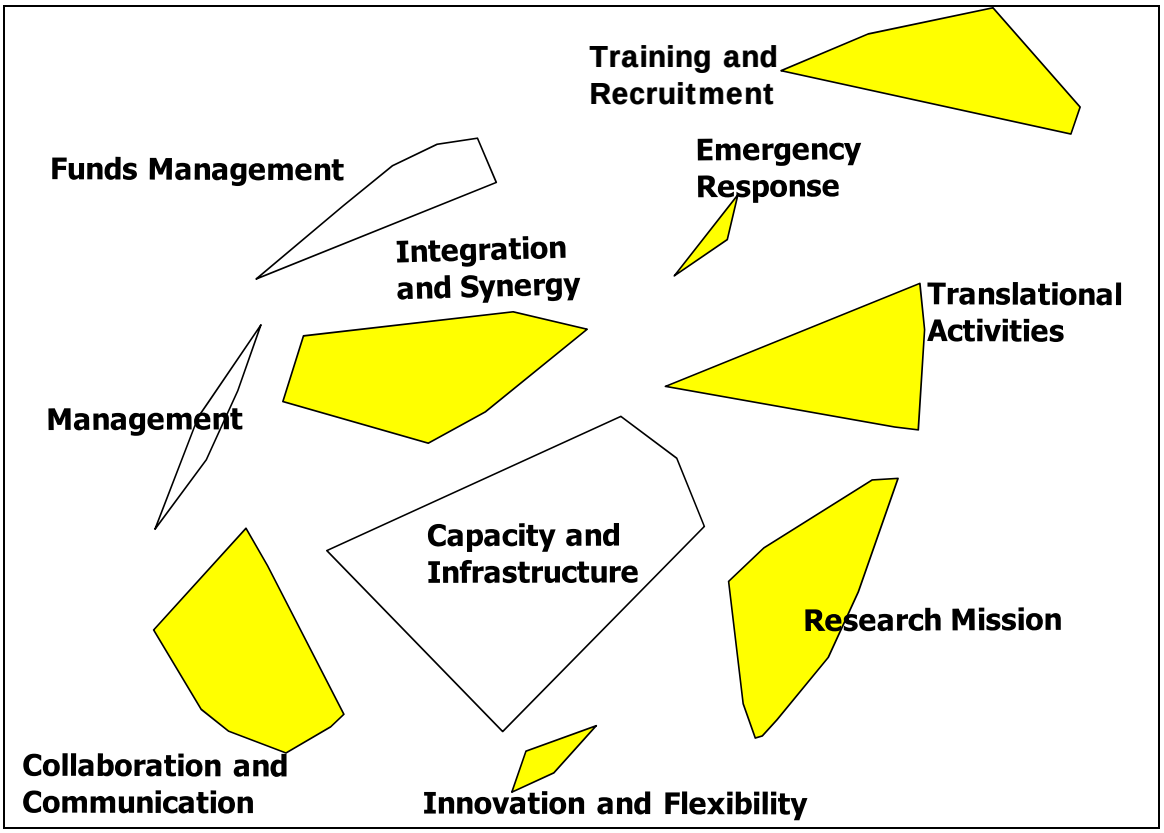
Center leaders are a secondary audience for the evaluation. They may use the results to better understand the impact of the program as a whole, clarify the mission and expectations of their centers, develop metrics they can use internally and across centers, learn about what other centers are doing, and identify opportunities for improvement. Center leaders may also wish to share results with their constituents to give them a better understanding of their role in the centers and how their role contributes to the overall impact of the program.

Other members of the scientific and evaluation communities, as well as other constituencies, also have an interest in the RCE program, but are not the primary audiences for this evaluation.

III. Conceptual Framework and Major Evaluation Areas and Questions

Through an iterative process of stakeholder input, a map of success elements was constructed for the RCE Program. This map identified 10 major success factors, each of which had specific ideas associated with it that defined the factor. The map of success factors is presented in Figure 1. Appendix 1 shows further details of the contents of each of those 10 major clusters of ideas.

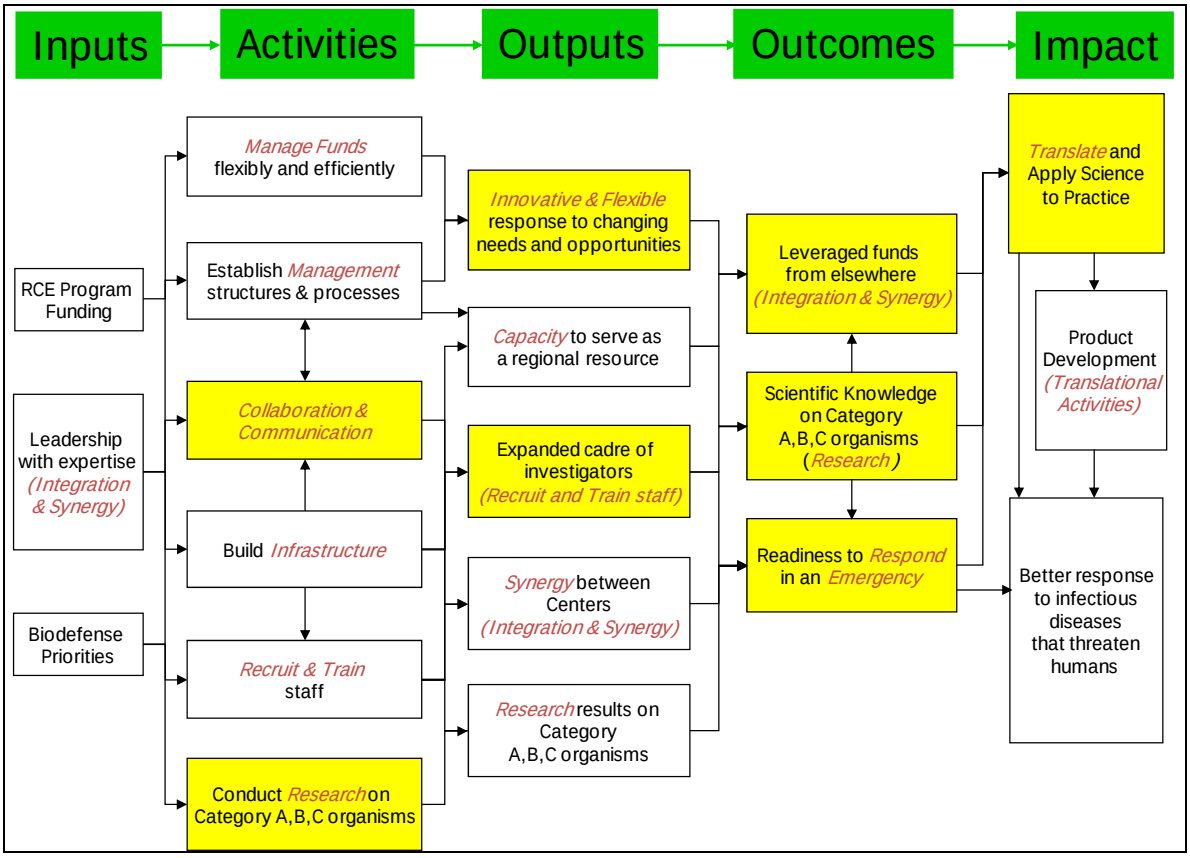
Figure 1. Concept Map of RCE Success Factors, with Interim Evaluation Focus Highlighted.



The concept map became the foundation for the program logic model, shown in figure 2. In the logic model, the original 10 success factors (clusters of ideas on the concept map) are referenced via italicized text. Note that some of the factors appear more than once on the logic model, reflecting the fact that the concept spans activities to outputs to outcomes and, in some cases, impact.

Given time and resource constraints, the interim evaluation focused on a subset of the map, and consequently, the logic model. Highlighted items in the map and logic model were included in the interim evaluation. Components were selected based upon clarity of the construct, feasibility, importance, expected progress and utility and placement in the logic model. Thus, eight major components on the logic model were selected as the focus of the interim evaluation. Table 1 summarizes each of these eight areas and the evaluation questions that corresponded to each component. Taken together, these eight priority areas constitute the scope of the interim evaluation.

Figure 2. Logic Model for DMID's RCE Program, with Interim Evaluation Components Highlighted.



While the questions and measures are organized in Table 1 below by logic model component, the evaluation should be considered as a whole. Measures may provide evidence that sheds light on more than one question. Notable examples are highlighted in the text, but no attempt has been made to log comprehensively all possible overlaps.

Table 1: Logic Model Components and Associated Evaluation Questions.

Logic Model Component	Evaluation Questions
Collaboration and Communication: This area is considered an important goal of the RCE program that distinguishes it from traditional grants. The emphasis is on collaboration among researchers. Collaboration with local public health agencies is addressed under support for emergency response below.	*How well are RCEs fostering communication among their constituents?* *How well are RCEs fostering collaboration across institutions?*
Conduct Research on Category A, B, C organism: Research is central to the mission of the centers. As one interviewee put it, "If our expectations in this area are not met, then nothing else matters." The original "research mission" cluster was divided into multiple components on the logic model. This component provides a critical assessment of the scope of the research.	*Are the RCEs conducting research that is appropriate to the mission (i.e. the "right" subject matter/kinds of scientific problems)?*
Scientific Knowledge on Category A, B, C organisms: The "Research Mission" cluster on the concept map was divided into multiple logic model components. This cluster is farther "downstream" on the logic model than the one above, looking at the research outcomes.	*Is RCE research leading to significant scientific advances on Category A, B and C agents and emerging infectious diseases?*
	Have there been scientific advances that would have been particularly difficult using traditional grant mechanisms (or that were facilitated significantly by the RCE mechanism)?
Innovative and flexible response to changing needs and opportunities: The unique structure of the RCE grant program offers several mechanisms designed to enable faster, more flexible funding for promising projects. Innovation is difficult to operationalize and even harder to measure without some form of peer review. Given the constraints of the interim evaluation, the measures proposed in relation to measuring the impact of the research (see "Scientific Knowledge on Category A, B, C organisms above) provide a proxy for the degree of innovation of the work undertaken by the Centers.	*How flexibly do the RCEs respond to changing scientific needs?*
	Are Centers adding new projects and investigators as appropriate?

Logic Model Component	Evaluation Questions
Leveraged funds from elsewhere: The concept map cluster called Integration and Synergy addresses a variety of ideas. One idea that stands out as its own component on the logic model is "leverage funds from elsewhere." The RCE grants are expected to seed research, making it viable for other funding.	*Are the RCEs leveraging other support?*
Expanded cadre of investigators: A 2006 study was conducted that examined the biosketches of RCE investigators to determine the number and percent of RCE investigators who were new to biodefense and emerging infectious disease research. This analysis has already been conducted and responds to a key component on the RCE logic model. Therefore, the interim evaluation includes the results of that 2006 study. We also examine the number of investigators who are added to the RCEs over time, in connection with the "Innovative and flexible response to changing needs and opportunities" area.	*Are the RCEs recruiting and training new investigators in the area of biodefense and emerging infectious disease research (expanding the cadre of researchers in these areas)?*
Readiness to respond in an Emergency: The RCEs are not intended to be first responders in an emergency. Rather, they are intended to provide research support and expertise in support of the primary responders, which is the focus of the measures described here.	*How well prepared are the RCEs to help responders in the event of a biodefense or emerging infectious disease emergency?*
Translate and apply science to practice: The RCE program and the statements in this cluster refer specifically to activities that can lead to the development of products or clinical interventions. Translational activities itself is a broad term and includes the translation and application of knowledge to real world problems, as seen on the RCE logic model. The case examples developed under emergency response in the next section will also provide evidence for the application of knowledge in response to real world emerging infectious disease threats.	*Is the RCE program (individual RCEs, trans-Center activities or NIAID program) developing novel support mechanisms to facilitate product development?*
	Is there evidence of progress toward product development (patent filings)?

IV. Methods

An Evaluation Measurement Task Force, comprised of RCE program officers, two Principal Investigators and other invited DMID and NIAID leadership, recommended measures to address each of the priority questions.

A. Data Sources and Measures

Due to time and resource constraints, the interim evaluation focused on analysis of existing data, rather than initiating new data collection.

Six major data sources were used:

- The RCE Program database. This is a database of all RCE funded activities that includes various types of information required to track each project. For the purposes of the interim evaluation, the following information was extracted for each funded activity: the grant number, project title, principal investigator, Center affiliation, Institution, primary research category, primary organism and start dates. Research projects were separated from administrative, core and other miscellaneous funded activities. Program officers supplied information about the end dates of the projects from paper files, coded them according to additional research categories, and indicated whether a project involved a multi-institutional team or not. Based on start and end dates, CSI staff coded each project by fiscal years in which it was active. The evaluation covered the time frame 2003 - July 2007. Thus, any data reported for 2007 or fiscal year 2007 are partial.

- IMPAC II database. This database is maintained by NIH and contains information on all NIAID projects. It was determined that the RCE program database provides a more accurate depiction of the projects within the RCE program, so IMPAC II was not used for RCE project information. However, in some cases, comparisons were made between the number of RCE projects on particular topics and NIAID projects on those topics. IMPAC II was used to gather data on other NIAID projects on those topics. Data from the IMPAC II database are available only for the period 2003-2006. 2007 data are not available.

- PHS 2590 Forms, also called Progress Reports. Progress Reports were used to extract information about emergency response activities. Instructions in the Progress Report explicitly requested this type of information be provided in a specially designated section of the Progress Report each year. Data from the Progress Reports are available from 2003-2006 only. 2007 Progress Reports had not been filed at the time of this evaluation. In addition, we report the findings of a 2006 study of the biosketches of principal investigators which NIAID staff had completed prior to this interim evaluation. Biosketches are also provided in the Progress Report.

- Pub Med and Web of Science. Information about publications was drawn from Pub Med (http://www.ncbi.nlm.nih.gov/sites/entrez) by searching on the relevant NIAID grant numbers. The Web of Science database (http://scientific.thomson.com/products/wos/ was used for all bibliometric analyses. This database encompasses the Science Citation Index-Expanded, the Social Science Citation Index and the Arts & Humanities Citation Index. The Web of Science is the standard leading data source for bibliometric citation analysis. In the year ending 2006, over 33 million citations were processed for inclusion in the Web of Science database, drawn from over 1.65 million titles. The majority of these citations (66%) are from ISI-indexed

documents, including over 8800 journals which are the top tier scholarly journals in over 200 fields.

- Information Request to RCE Administrators: A detailed request was sent to RCE administrators in late August 2007, asking for specific information about: case examples of when emergency assistance was provided; meetings held; solicitations for projects and investigators; case examples of flexibility; resources to support product development; participating institutions; steering committee members; patents; recognitions and awards; additional funding received by RCE PI's based upon RCE project work. Initially, it was believed that some of this information could be gathered from the Progress Reports. Indeed, RCE administrators relied, in some cases, on their Progress Reports, to complete the Information Requests. However, the information was not consistently reported across Progress Reports, necessitating this outreach to administrators in each Center. Administrators also relied on paper files, internal databases, the institutional memory of RCE leaders and staff and polling of investigators. Copies of the information request instructions and templates are available upon request.

- Product Development Working Group Notes: The RCE Program coordinates a Product Development Working group to review product development concepts from the RCEs. The minutes were content analyzed to identify product development concepts.

Questions and measures were identified for each of the focal components on the logic model. Table 2 below shows the measures associated with each of the priority questions and the corresponding data sources used to collect the information.

Table 2: Table of Questions, Measures and Data Sources, Organized by Logic Model Component.

Proposed measures	Data source
Communication and Collaboration: *How well are RCEs fostering collaboration across institutions?*	
1) Number of scientific meetings, seminars, workshops and science management, etc. meetings that have been held.	Information Request to RCEs
Communication and Collaboration: *How well are RCEs fostering communication among their constituents?*	
3) Cross-institutional co-authored papers (e.g. % of published papers with cross-institutional co-authorship).	Pub Med and Web of Science
5) Cross-institutional project teams on funded projects (e.g. % of funded projects that involve cross-institutional collaboration).	RCE program database; Program Officer Review
6) Cross-institutional project teams on new funded applications (e.g. number of new proposed projects for other NIH funding from RCE investigators that involve cross-institutional collaboration)	Information Request to RCEs
29) Number and list of participating institutions and steering committee members	Information Request to RCEs
Conduct Research on Category A, B and C Agents: *Are the RCEs conducting research that is appropriate to the mission (i.e. the "right" subject matter/kinds of scientific problems)?*	
11) Amount of possible Category A-C scope of work that is actually addressed in the RCE portfolio of projects	RCE program database

Proposed measures	Data source
12) Number and % of projects that fit various subtypes of research, such as vaccine discovery, therapeutics, animal models, etc.	RCE program database; IMPAC II database
10) Number of projects for each organism, by Center, by year and comparison to non-RCE work in same fields (selected)	RCE program database; IMPAC II database
Scientific Knowledge on Category A, B, C Agents: *Is RCE research leading to significant scientific advances on Category A, B and C agents and emerging infectious diseases?*	
7) Bibliometric analyses of the RCE publications (e.g. number of publications per year, journal impact factor, journal performance indicator, field performance indicator, number of citing journals, number of citing categories; number of cited journals; citing journal multidisciplinarity index; cited journal disciplinarity index)	Pub Med Web of Science
8) Number of publications over time for Category A agents	Pub Med
9) Awards or recognition gained for research	Information Request to RCEs
Scientific Knowledge on Category A, B, C Agents: *Have there been scientific advances that would have been particularly difficult using traditional grant mechanisms (or that were facilitated significantly by the RCE mechanism)?*	
13) Case examples describing specific ways in which the features of this funding mechanism enabled work that would have been difficult under other grant mechanisms	Information Request to RCEs
Innovative and Flexible Response: *How flexibly do RCEs respond to changing scientific needs?*	
20) Case examples of flexibility and innovation	Information Request to RCEs
21) Number of funded projects over time in selected topic areas where the RCE charge changed to respond to emergent issues (e.g. SARS or norovirus). Compare RCE vs. Non-RCE research on selected topics.	RCE program database; IMPAC II database
Innovative and Flexible Response: *Are Centers adding new projects and investigators as appropriate?*	
22) Number of solicitations from RCEs for projects or investigators.	Information Request to RCEs
23) Number of applications in response to solicitations.	Information Request to RCEs
24) Increases in projects and/or investigators over time.	RCE Program Database
Leverage other Sources of Support: *Are the RCEs leveraging other support?*	
25) Number of U01 funded grants that stem from RCE research (there may be about 5-10, based on estimates from the EMTF knowledge)	Information Request to RCEs
26) Number of R01 grants that stem from RCE research	Information Request to RCEs
27) Other sources of support (e.g. industry funding) stemming from RCE research	Information Request to RCEs

Proposed measures	Data source
Expanded Cadre of Investigators: *Are the RCEs recruiting and training new investigators in the area of biodefense and emerging infectious disease research (expanding the cadre of researchers in these areas)?*	
28) Number and % of RCE investigators who are new to biodefense or emerging infectious disease research	Previous study of biosketches of RCE investigators
Readiness to Respond in an Emergency: *How well prepared are the RCEs to help responders in the event of a biodefense or emerging infectious disease emergency?*	
18) Checklist of activities by centers that illustrates that the RCEs have taken certain steps required to support an emergency response: e.g. contacts/meetings with local emergency responders; participation in simulations or table top exercises; designated contact person; list of experts compiled; list of resources compiled; public outreach conducted; membership on state or local committee; protocols for emergency response established.	PHS 2590 (Progress Report)
19) Case examples of situations in which the RCEs have been called upon to assist an emergency response and have done so	Information Request to RCEs
Translate and Apply Science to Practice: *Is the RCE program (individual RCEs, trans-Center activities or NIAID program) developing novel support mechanisms to facilitate product development?*	
17) List of resources in place to support product development, including special characteristics of each Core (e.g. animal models, sequencing, drug screening).	Information Request to RCEs
Translate and Apply Science to Practice: *Is there evidence of progress toward product development (patent filings, etc.)?*	
14) Number of patent applications	Information Request to RCEs
15) List of concepts reviewed by the RCE Product Development Working Group	Product Development Working Group Notes

B. Procedures

CSI provided detailed guidance and templates for data extraction, based on extensive conversations with RCE Program Officers. NIAID staff with greatest familiarity with the data sources extracted information and put it into templates developed for each purpose. RCE administrators extracted specific information from databases, files, people and other resources at their Centers. Instructions and templates were very specific. Every effort was made to define terms in a way that would ensure the greatest consistency, accuracy and relevance. Copies of the guidance documents and templates prepared for each data source are available upon request.

All data were extracted between July 1, 2007 and September 30, 2007. Thus, this report documents the program from its inception (2003) until late summer 2007. Note that eight Centers were funded in 2003, while two Centers did not begin operations until 2005. This fact should be taken into account when reviewing any data presented by year. Furthermore, any data reported for 2007 or

fiscal year 2007 are partial. Comparisons between 2007 and previous years can be estimated by extrapolating out from the partial year 2007.

Data provided through the RCE program database were verified by program officers. There is reason to believe that data reporting is consistent and accurate for funded projects, as the definition of a project is clear and shared. Given that accounting trails follow projects, funded project data should be acceptably accurate.

Data provided by RCE administrators were reviewed for relevance by CSI staff and, when necessary, program officers.

Publications data extracted from Pub Med were not verified against the publications reported on Progress Reports. There may be considerable variability in the criteria used by different individual researchers and different RCEs about whether a publication arises from RCE work. In the absence of a clearly agreed upon definition, some objective, defensible criteria must be established. A reasonable criterion is whether an RCE grant is cited as a source of support in the acknowledgments section of the publication. While this may lead to a conservative estimate of publications (because authors may have forgotten to include the necessary citations to the grant or cited it by name rather than by grant number) it will help establish this practice as a normative henceforth and improve the quality of subsequent evaluations.

C. Analysis

Analyses consist primarily of simple descriptive statistics. Qualitative data were content analyzed for major themes and illustrative examples of these themes were included. In most cases, there are no benchmarks against which to compare the results. The prominent exception to this rule is the bibliometric analyses. Bibliometric analyses rely on comparisons to the field at large and other articles in the same journals, thus justifying significance testing and other inferential statistics.

D. Interpretation

Preliminary results were presented to the program officers on November 2, 2007. Program officer input helped identify the strengths, weaknesses and value of particular measures and analyses, which will help inform future, more definitive evaluations. Several measures selected here were experimental. Thus, it is important to reflect on their value in light of program goals and results. A January 2008 meeting of the Evaluation Measurement Task Force, a broader group of stakeholders, will also provide an opportunity to discuss the findings and their implications for program enhancement, determine how to disseminate findings most effectively, and gather feedback on the evaluation results and process. Individual Centers may wish to compare their own performance against the norms reported here to identify their own strengths and areas for improvement.

V. Results

The results are reported by component on the logic model. The sequence of presentation is, approximately, from left to right on the logic model, so inputs and activities are presented first and outputs and outcomes are presented later in the discussion. The exception is that "Scientific Knowledge of Category A, B and C agents" (an outcome) follows directly and logically from "Research Conducted on Category A, B and C" agents (an activity), as both of these are derived from the original concept map cluster called "Research Mission". Most of these major concepts have more than one evaluation question. Results are presented by question within each component on the logic model. Center level data are presented with blind codes, which have been randomly assigned. The same Center will have a different code assigned in each of the results sections to assure anonymity. The purpose of reporting Center level data is to assess consistency of implementation across the program, not to evaluate individual Centers.

A. Collaboration and Communication

More than 290 institutions across 47 states and Puerto Rico participate in or are funded by the RCE program. Only Maine, South Carolina, and Alaska are not touched by the RCE Program. Each of the Centers has a steering committee of anywhere from 6 to 55 members (mean=19) that provides leadership to that Center. Appendix 2 lists the institutions represented by steering committee members, by Center. Appendix 3 lists participating institutions, by Center. Participating institutions may be defined differently by different Centers and may include those with whom a formal memorandum of understanding exists as a "member" or "affiliate"; institutions that use core facilities; institutions that provide a steering committee member; or that receive RCE funding. Appendix 4 lists funded institutions alphabetically. To view an interactive map of the extent of involvement in the RCE Program, see http://www.conceptsystemsglobal.com/niaid/

We looked at several different measures for collaboration and communication. First we look at communication by examining patterns of meetings held by the Centers. Then we examine collaboration by counting instances at cross-institutional collaboration.

How well are RCEs fostering communication across investigators and institutions?

Centers host a variety of meetings which provide opportunities for investigators to communicate about their work and build collaborations. Centers reported on each meeting they've held, categorizing them by meeting type, frequency, estimated number of participants, whether the meetings were trans-RCE (involving participants from more than 1 center) or cross-institutional (involving participants from more than 1 institution). Table 3 provides a high level summary of how common various types of meetings are. All Centers hold a major meeting or conference of more than 50 people at least annually. All Centers also hold leadership/management meetings. Most of these occur annually. All Centers also engage in scientific agenda setting meetings, whose primary purpose is to determine topics or projects on which to issue solicitations, or assess whether to recommend funding a project. In most cases (80% of the Centers), scientific agenda setting meetings occur at least annually. The Centers also provide a variety of professional development opportunities. Half of the Centers report holding seminars (defined as a discussion on a particular topic or projects). The majority (70%) run training courses (defined as having a primary purpose of training investigators on a topic or method). All of them have held workshops (a working session in which participants interact or have hands-on experience on a particular topic).

Table 3. Meeting Types Used by Centers.

Meeting Types	Percent of RCEs that Reported each Type of Meeting	# RCEs
Annual Meeting or Conference of more than 50 attendees	100%	10
Leadership/Management Meeting	100%	10
Leadership/Management Meeting (at least annually)	80%	8
Scientific Agenda Setting	100%	10
Scientific Agenda Setting (at least annually)	80%	8
Seminar	50%	5
Training course	70%	7
Workshop	100%	10

A series of graphs in Appendix 5 provides further detail about the frequency and estimated attendance at different types of meetings. From those graphs, we see that conferences, defined as multiple sessions included as part of a single event, are common and tend to be either one-time or annual events. Conferences tend to be large; half of all conferences involve more than 100 people. Thirty-four (34) conferences were noted. Given that 18 of them are annual events, there may have be as many as 58 conferences hosted within the RCE Program.

Seminars tend to be held more regularly and typically involve 51-100 people (50% of entries) or 26-50 people (43%). Workshops are primarily one-time events and involve groups similar in size to seminars. At least 27 training courses have been developed and offered. These training courses meet on a variety of periodicities, ranging from one-time events to bi-weekly sessions. Most training courses (67%) enroll 25 or fewer participants. Another 22% enroll between 26 and 50 people.

Leadership/management meetings tend to be small. Half of these meetings involve less than 10 people and another 41% involve 11-25. Only 9% involve 26-50 people. There is considerable variability in the frequency of these meetings, ranging from bi-weekly to one-time events.

Scientific agenda setting meetings also exhibit considerable variability in meeting frequency. Determining topics or projects on which to issue solicitations or assessing whether to recommend funding a project seems to be the purview of a relatively small leadership group. Forty-eight percent (48%) of these meetings involve 11-25 people, another 40% involve fewer than 10 people. Ten percent (10%) are reported to involve more than 50 people, however. This meeting type has the largest number of entries (50), relative to the other meeting types. Conferences (34) and leadership/management meetings (32) are the second and third most frequently reported types of meetings.

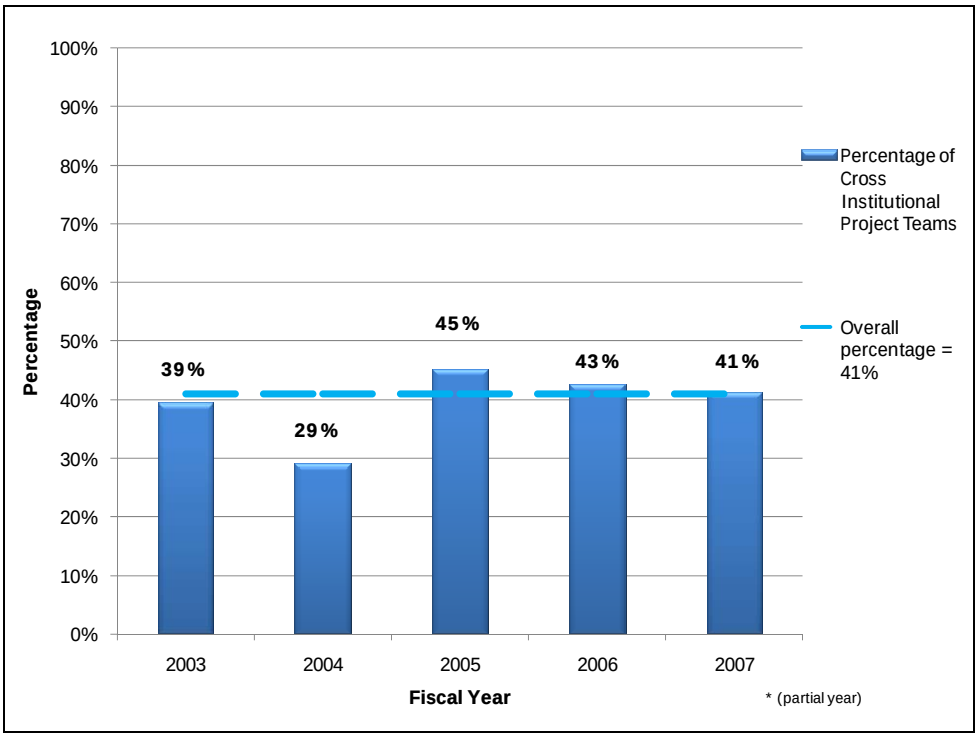
The majority of meetings (90%, 150/167 entries) involve participants from more than one institution. On the other hand, only 22% (36/167) are trans-RCE, involving participants from more than one Center.

How well are RCEs fostering collaboration among their constituents?

For this question, we examined cross institutional collaboration on RCE project teams, additional grants that stem directly from RCE research, and publications.

First, each RCE project was coded by the program officers for whether it involved cross-institutional collaboration. As shown in figure 3, 41% of all funded projects involved investigators from more than one institution. There are no apparent trends over time; the maximum percentage of newly added projects, by year, that are cross institutional is 45% (2005) and the minimum percent is 29% (2004).

Figure 3. Percentage of New RCE Funded Projects involving Cross Institutional Project Teams by Fiscal Year.



It was hypothesized that researchers' interactions through RCE research projects would lead to ongoing collaborations that would be evident on follow on (non-RCE) projects that stem from RCE research. RCE administrators and their investigators coded whether a project team was cross-institutional or not when submitting data about follow on grants and contracts. Forty-four (44%) percent of follow-on projects involve cross institutional teams, with a range, by year, from 31% (2004) to 59% (2005). Again, there is no apparent trend over time.

Cross-institutional collaboration was slightly higher as measured by cross-institutional co-authorship on published papers. Overall, 51% of published papers which cited one RCE grant numbers had authors from more than one institution. In addition, overall, 52% of published papers had cross-

departmental authorship. The rates were very consistent over time, as show in figure 4. Of interest, there is more variability when the data are disaggregated by Center. The percent of cross institutional coauthorship per Center ranged from 25% to 67%, as show in figure 5.

Figure 4. Percentage of RCE Program Publications with Cross-institutional and Cross-Departmental Co-Authored Papers by Year.

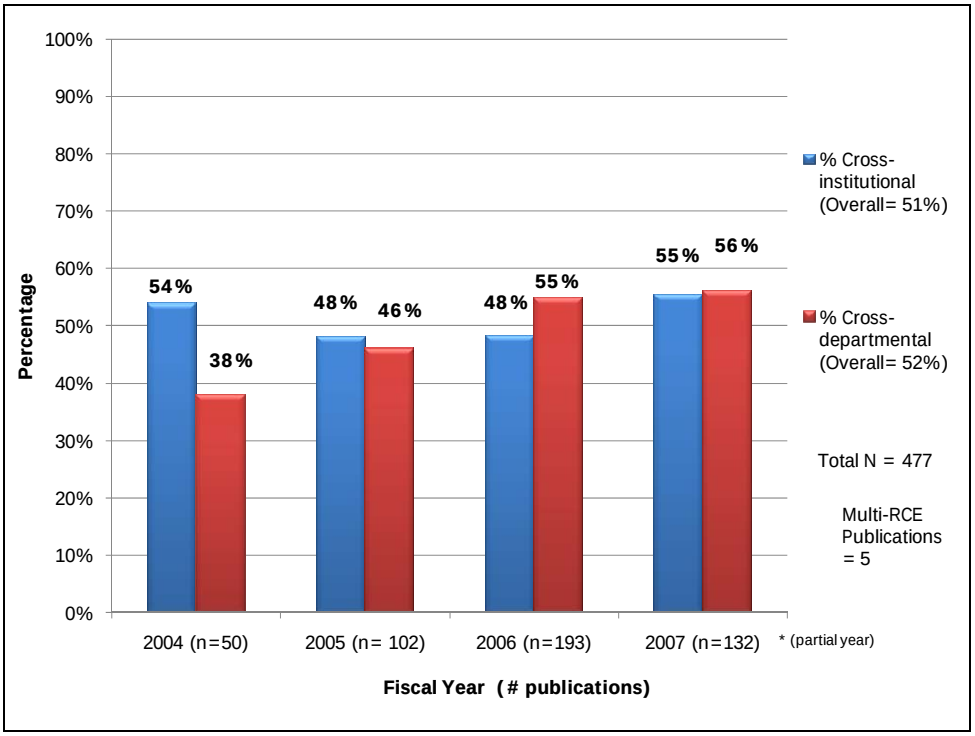
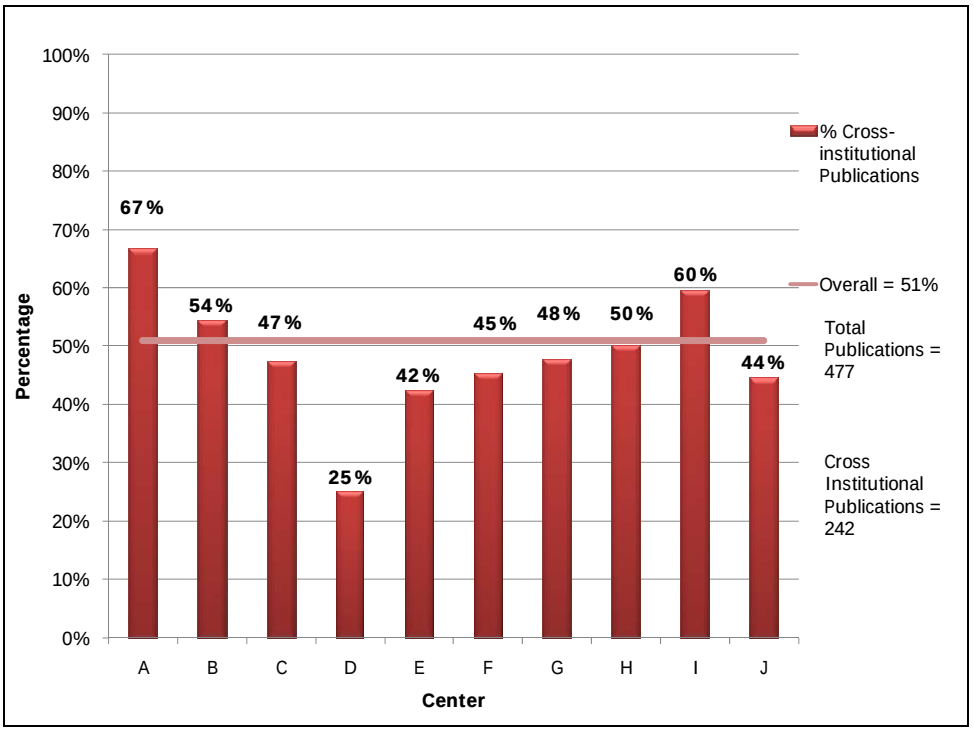


Figure 5. Cross institutional publications by Center, 2004-2007.



B. Conduct Research on Category A, B and C Agents

The research mission of the RCEs appears at several points in the logic model. The primary activity of the RCE Program is to fund and conduct research, which leads to research results and increased scientific knowledge on Category A, B and C agents. The first evaluation question examines the research portfolio, to see that it addresses the range of topics within the RCE mission.

Are the RCEs conducting research that is appropriate to the mission (i.e. the "right" subject matter/kinds of scientific problems)?

The RCE Program has funded a cumulative total of 563 projects. The number of active projects has increased during the life of the project, in part because two Centers were not established until 2005. Figure 6 shows the distribution of projects in the RCE Portfolio by the NIAID Category A, B, and C Priority Pathogens[1] list. The majority of projects (58%) focus on Category A agents, while 21% focus on Category B agents and 6% focus on Category C agents. The remainder of projects are not classifiable by a single agent. Figures 7 through 9 break down each of the three categories of agent in further detail. In total, 42 agents are addressed in the portfolio. Note that some projects may have activities that involve more than one agent. Agents receiving the most attention, by number of projects, are Bacillus anthracis (69 projects), Francisella tularensis (60), poxviruses (56) and Yersinia pestis (53). Within Category B agents, West Nile Virus has 24 projects dedicated to it.

[1] http://www3.niaid.nih.gov/biodefense/PDF/cat.pdf

Figure 6. Distribution of Projects in RCE Portfolio by Category, Fiscal Years 2003-2007.

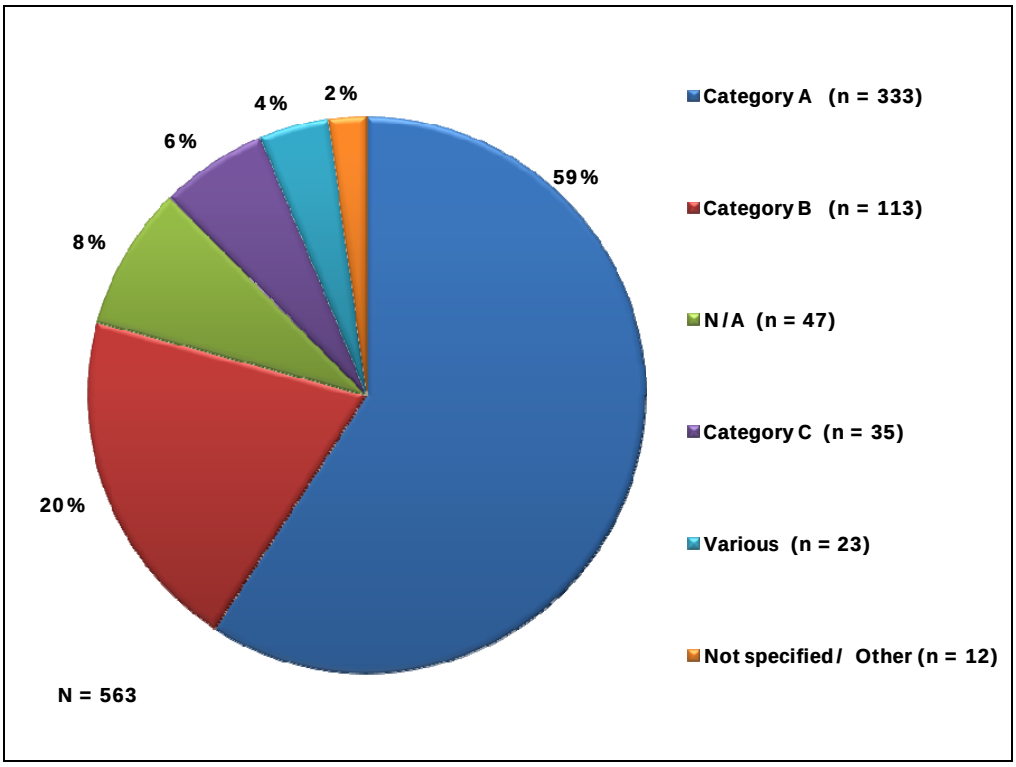


Figure 7. Number of RCE Projects Addressing Category A Agents in RCE Portfolio, Fiscal Years 2003-2007.

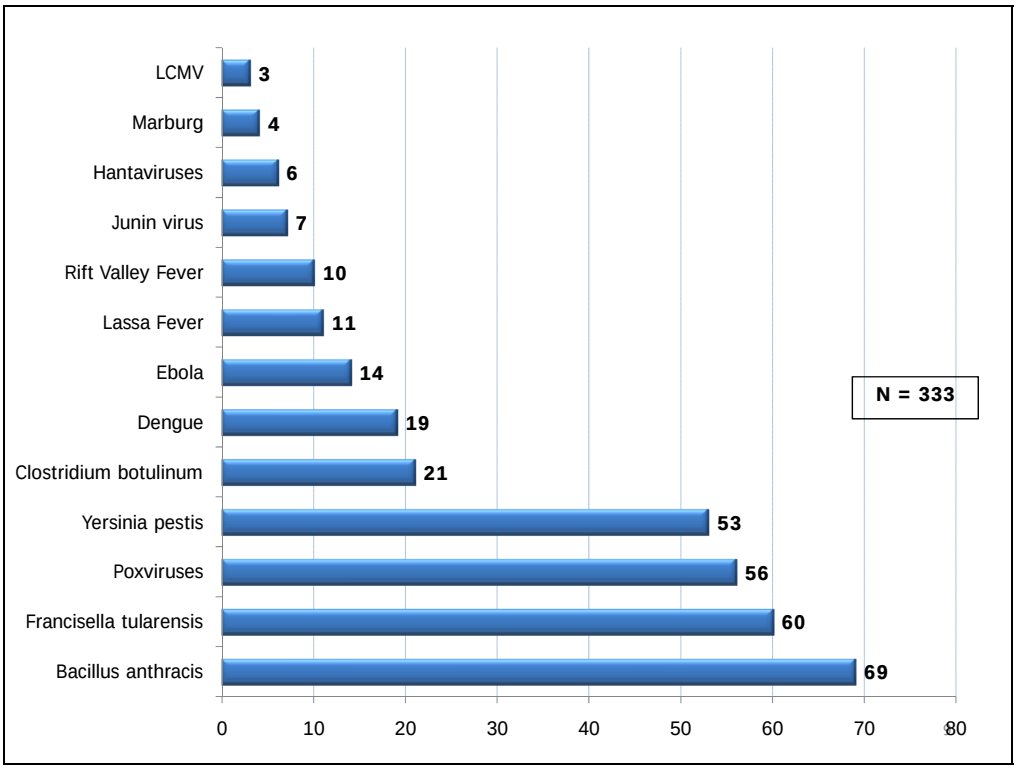


Figure 8. Number of RCE Projects Addressing Category B Agents in RCE Portfolio, Fiscal Years 2003-2007.

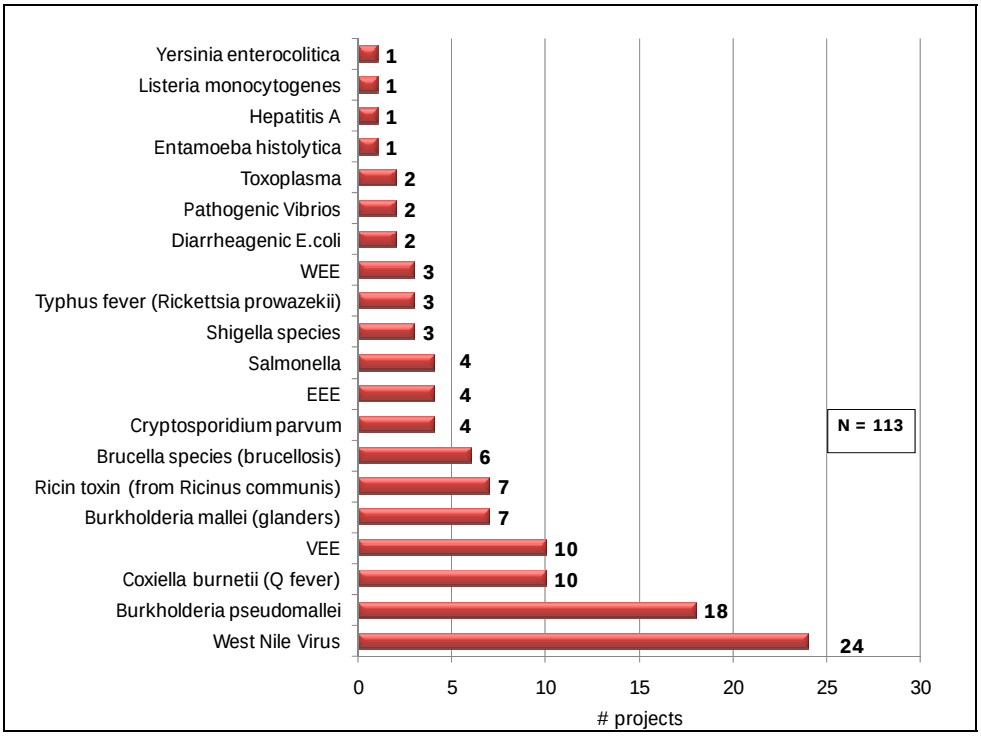
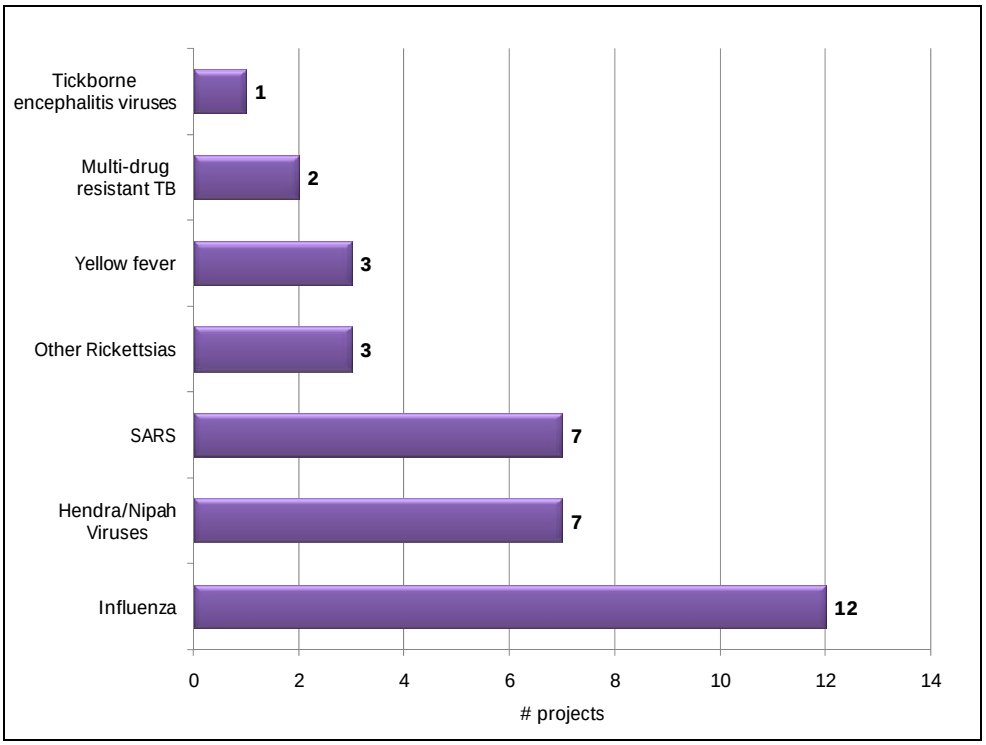
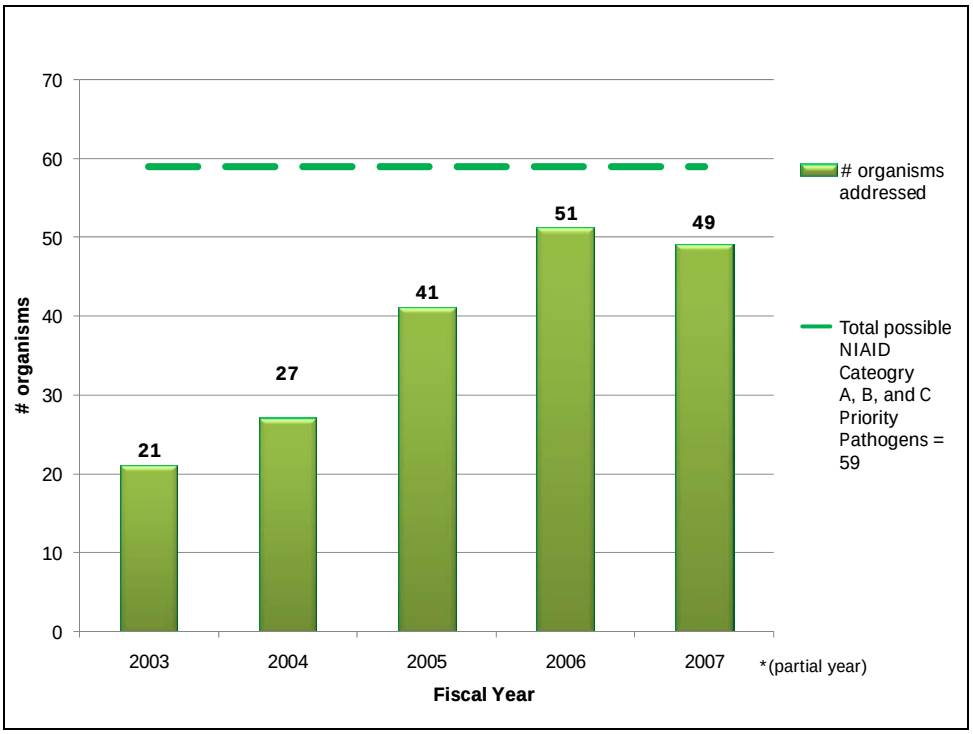


Figure 9. Number of RCE Projects Addressing Category C Agents in RCE Portfolio, Fiscal Years 2003-2007.



As can be seen in figure 10, the RCE's research portfolio has broadened over time as projects were started up and all Centers became funded. Note that two Centers were not funded until 2005. The portfolio seems to be leveling off at approximately 50 agents. The NIAID Category A, B, and C Priority Pathogens[2] list currently contains 59 agents, meaning that 85% of all of the RCE's possible scope is being addressed.

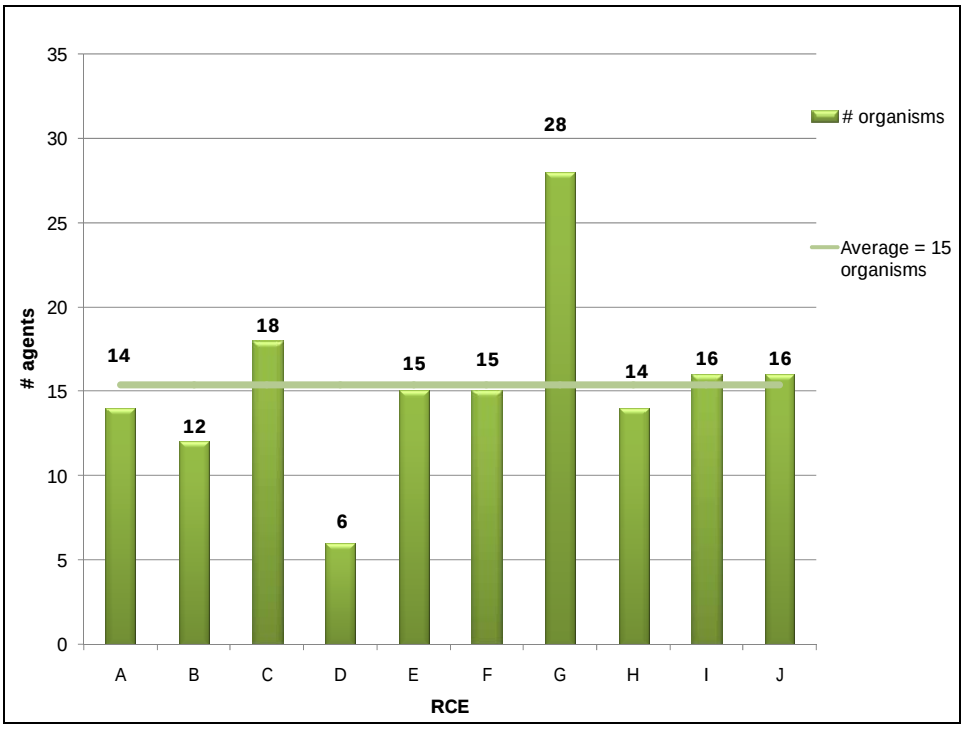
Figure 10. Number of Organisms Addressed by the RCE Program by Fiscal Year.



Centers have been expected to develop specialties. As can be seen in Figure 11, each Center is addressing approximately 15 different agents. Spreading themselves across a large variety of organisms, then, may be a weakness. One Center, in particular, has chosen to define itself in an even more focused way.

[2] http://www3.niaid.nih.gov/biodefense/PDF/cat.pdf

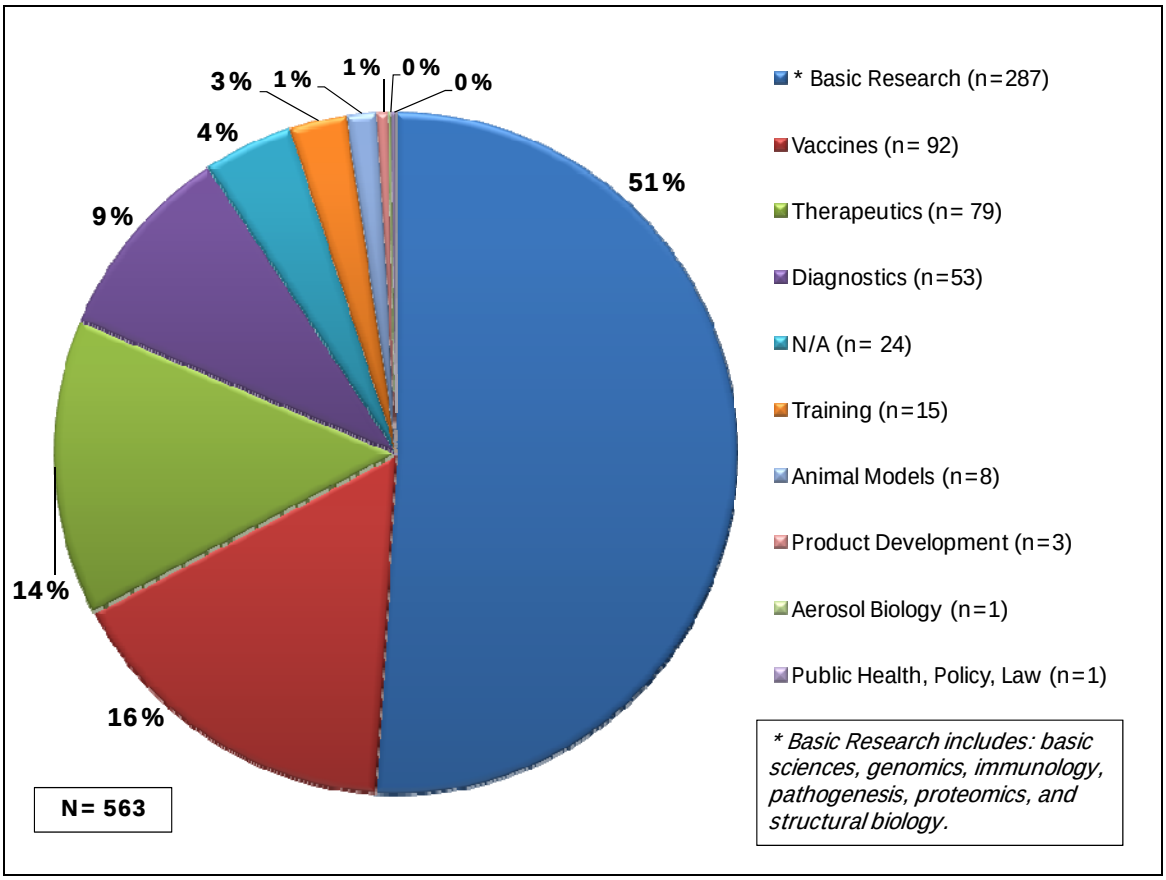
Figure 11. Number of Organisms Addressed by Center, Fiscal Years 2003-2007.



For each of the Category A agents, the number of RCE projects was compared to the number of NIAID projects (from the IMPAC II database) to derive a percent of the overall NIAID portfolio contributed by the RCE Program. The percent is based on number of projects only. These data are illustrated in a set of time series (2003-2006) graphs in Appendix 6. Across most of the agents (Botulinum toxin, Yersinia pestis, poxviruses, Francisella tularensis, Ebola and Category A Viral Hemorrhagic Fevers) the number of active projects in both the NIAID and the RCE Program has increased over the time period 2003-2006. For Anthrax, the number of NIAID projects decreased slightly in 2006 (from 250 in 2005 to 226 in 2006). In 2006, the RCE Program constituted 23% (52/226) of NIAID's Bacillus anthracis projects, 24% (12/49) of Botulinum toxin projects, 28% (41/148) of Yersinia pestis projects, 25% (44/178) of poxviruses projects, 32% (48/151) of Francisella tularensis projects, 33% (12/36) of Ebola projects, and 34% (57/169) of Viral Hemorrhagic Fever projects. These figures must be interpreted cautiously because projects vary considerably in size and scope. No financial data were gathered that could allow a determination of portfolio percentage based on budget.

Figure 12 characterizes the RCE Portfolio by type of research. More than half (51%) of the funded projects are basic research, which includes the basic sciences, genomics, immunology, pathogenesis, proteomics and structural biology. A substantial percent (16%) of projects focus on vaccine research, 14% focus on therapeutics research and 9% are diagnostics.

Figure 12. Number of RCE Program Projects by Research Type, Fiscal Years 2003-2007.



For each type of research, the number of RCE projects was compared to the number of NIAID projects to derive a percent of the overall NIAID portfolio contributed by the RCE Program. These are illustrated in a set of time series (2003-2006) graphs in Appendix 7. Across all types of research investigated (basic research, vaccines, therapeutics, diagnostics) the number of active projects in both NIAID overall and the RCE Program has increased over the time period 2003-2006. As the RCE Program became fully funded and active, its contribution (by percent) to the NIAID portfolio has tended to increase across all types of research. By 2006, the RCE Program constituted 16% (225/1,381) of NIAID's basic research projects, 14% (75/539) of vaccine projects, 10% (59/584) of the therapeutics projects and 22% (46/210) of the diagnostics projects. The RCE Program is making a larger contribution (by percent) in the smaller areas of research, such as diagnostics, which had only 210 projects overall. As noted above, these figures must be interpreted cautiously because projects vary considerably in size and scope.

C. Scientific Knowledge on Category A, B, and C Agents (Research)

Having established the nature of the research conducted by the RCE, we can look at the outcome of that research activity by examining research publications.

Is RCE research leading to significant scientific advances on Category A, B and C agents and emerging infectious diseases?

Extensive bibliometric analyses were completed and are described in detail in Appendix 8. Here we summarize some of the key findings.

Table 4 shows the number (n) of publications by year, totaling 477 publications. As would be expected, the number of publications per year has increased as the RCE Program has matured. It is important to note that the 2007 total includes only the first half of that year (January to mid-July). Notably, there are a large number of publications (132 publications) for 2007, even though the data for that year are partial. As a point of comparison, there were 193 publications in 2006, suggesting that the RCEs are on track to publish more papers in 2007 than 2006.

There have been a total of 2,524 citations of RCE papers by other papers (1,929, when adjusted for self citations, any time one of the paper's authors subsequently cites the paper). On average, each publication had 5.29 citations (4.04 citations when self-citations are removed). Citation rates for more recent papers are understandably lower because citations increase over time. In fact, many (145) publications have not yet been cited. Of those not cited, though, the majority (99) were published in 2007. However, this means that in the first 4 years of the RCE initiative, nearly 70% of the publications have been cited at least one time by other publications.

For all years, the observed citation rates exceeded the expected citations. Expected citation rates are based on the number of citations of a certain article type (abstract, article, review, note, etc.) published in a specific journal cumulatively through the most recent completed year. (See Appendix 8, figure 1 for an illustration of this calculation).

Table 4. Observed and Expected Citations for all RCE Program Publications by Year, 2004-2007.

Publication Year	All Publications	Observed Citations		Expected Citations	
		Mean	sd	Mean	sd
2004	50	15.2	12.84	10.05	7.95
2005	102	10.34	13.71	5.21	4.3
2006	193	3.38	4.42	0.75	0.65
2007* (partial year)	132	0.43	1.05	0	0
Total	477	5.29	9.43	2.47	4.6

RCE publications have an average journal impact factor of 5.79, with no discernable trends over time. The Journal Impact Factor (JIF) reflects the current impact of the journal. Journals that are more frequently cited have a higher JIF. It is meaningful to look at the average JIF of a set of

publications to estimate the current impact of journals in which program researchers are publishing. As a point of comparison, Table 5 shows the journal impact factor for 2006 for selected journals (those for which there were at least 5 RCE papers published), as well as the number of articles of RCE publications in these journals. The Journal Impact Factor (JIF) data show that RCE publications have been consistently published in highly ranked journals throughout the life of the RCE.

Table 5. Selected Journals, their Journal Impact Factor and Number of RCE Publications in those Journals.

Journal Name	Journal Impact Factor	Number of RCE Publications
Science	30.03	7
Journal of Experimental Medicine	14.48	7
Proceedings of the National Academy of Sciences of the United States of America	9.64	28
Journal of Immunology	6.29	13
Journal of Biological Chemistry	5.81	12
Journal of Infectious Diseases	5.36	10
Journal of Virology	5.34	64
Emerging Infectious Diseases	5.09	8
Cellular Microbiology	5.07	9
Bioinformatics	4.89	7
Antimicrobial Agents and Chemotherapy	4.15	6
Infection and Immunity	4.00	48
Journal of Bacteriology	3.99	13
Biochemistry	3.63	6
Applied and Environmental Microbiology	3.53	10
Virology	3.53	26
Journal of Clinical Microbiology	3.44	5
Vaccine	3.16	7
American Journal of Tropical Medicine and Hygiene	2.55	7

There are two other key bibliometric indicators presented in Table 6, by year, which can be compared to the RCE observed citations. The Journal Performance Indicator is similar to the expected citations (as shown in Table 4 above), but the JPI is based on citations of all articles of a specific journal published in a particular year, while the expected citations are based on each specific type of article (abstract, article, review, note, etc.) for a journal. The average Journal Performance Indicator (JPI) for RCE publications is 2.53. While the JPI allows us to compare RCE citation rates to those for other publications *in the same journal*, one can also compare RCE citation rates to other papers *in the same field*, using the field performance indicator. The field performance indicator (FPI) is based on the number of citations to all articles in a particular field. As with citations and expected citations, the JPI and FPI will be higher for older publications because more time has passed to allow citation of the publications. That trend is illustrated in the RCE publications data.

Table 6. Observed Citation Rates, Compared to Journal Performance Indicator and Field Performance Indicator, by Year.

Year	Publications	Observed Citations		Journal Performance Indicator (JPI)		Field Performance Indicator (FPI)	
		Mean	sd	Mean	sd	Mean	sd
2004	50	15.2	12.84	10.41	7.87	7.68	3.13
2005	102	10.34	13.71	5.22	4.35	3.73	1.38
2006	193	3.38	4.42	0.79	0.69	0.55	0.22
2007 * (partial year)	132	0.43	1.05	0	0	0	0
Total	477	5.29	9.43	2.53	4.65	1.82	2.72

Observed citation rates in all cases significantly exceeded ($p<.001$) the expected citation rate and the rates typically obtained for the journal (JPI) and field (FPI). T-tests were conducted to examine whether these differences are statistically significant. The summary statistics for these tests are shown for all publications in Table 7.

Table 7. Citation t-test Summary Statistics for all Publications.

Paired Samples Statistics		Mean	N	Std. Deviation	Std. Error Mean	t-value
Pair 1	Citations	5.2914	477	9.42713	0.43164	9.025 ($p < .001$)
	Expected Citations	2.4738	477	4.59778	0.21052	
Pair 2	Citations	5.2914	477	9.42713	0.43164	8.888 ($p < .001$)
	Journal Performance Indicator (JPI)	2.5285	477	4.65381	0.21308	
Pair 3	Citations	5.2914	477	9.42713	0.43164	9.255 ($p < .001$)
	Field Performance Indicator (FPI)	1.8243	477	2.72078	0.12458	

In sum, RCE publication productivity is increasing over time, RCE publications are well regarded, as indicated by citations from other publications. Citation of RCE publications is significantly higher than for other articles in the same journals and fields.

Table 8 compares the number of RCE publications to NIAID publications on Category A agents, which represent the majority of the RCE portfolio. A series of graphs in Appendix 9 illustrates publications for each agent, by year. The RCE program made the biggest contribution (by percent of publications) to the research literature on Francisella tularensis (40/112 = 36%) and Ebola (15/49 =31%). Both of those fields are the smallest and newest research fields. It was not feasible to run full bibliometric analyses on RCE vs. non-RCE publications directly or to make comparisons on specific agents.

Table 8: Comparison of RCE and NIAID Publications on Category A Agents.

Category A Agent	RCE Publications	NIAID Publications	Percentage of NIAID Publications by RCE Program
Bacillus anthracis	54	474	11%
Botulinum toxin	28	151	19%
Yersinia pestis	32	200	16%
Variola major	61	2,951	2%
Francisella tularensis	40	112	36%
Ebola	15	49	31%
Totals	215	3,937	5%

A final measure examined Center reports on awards or special recognition received for RCE research. Investigators in the RCE Program received 16 awards or specially designated recognition since the program's inception. Half of the RCEs reported one or more awards or recognitions.

Have there been scientific advances that would have been particularly difficult using traditional grant mechanisms (or that were facilitated significantly by the RCE mechanism)?

This research question overlaps with the first question in the following section, in that both questions draw on case examples from the RCEs of how the RCE grant mechanism enabled flexibility, innovation and unique scientific advances.

D. Innovative and Flexible Response

Innovation and flexibility was one of the areas deemed most important during the evaluation planning stage. The RCE Program was intended to create an environment in which researchers could do innovative research and respond flexibly and rapidly to changing scientific needs and

priorities. Several approaches have been taken to examining the extent to which the program accomplished these goals.

How flexibly do the RCEs respond to changing scientific needs?

This research question, like the last one related to the research mission above, is based on an analysis of specific examples provided by the RCEs. Centers described how the features of the RCE Program have enabled the RCEs greater flexibility, more rapid response, or the opportunity to pursue particularly innovative work. The emphasis was on capturing ways in which the grant's features enabled work that would have been difficult under other grant mechanisms. RCE administrators were instructed to provide no more than 4 examples of up to 150 to 200 words. They were asked to be "as specific as possible, indicating the particular project, problem or opportunity you were able to address and the mechanism or feature of the mechanism that facilitated the example (e.g. timely turnaround, ability to override traditional grant scores, opportunity to discontinue an unproductive developmental project)."

More than 50 case examples were submitted. Each of the 10 RCE's submitted at least 1 example. Some examples emphasized the mechanisms and structure that enabled flexibility and innovation, including: restructuring projects and cores; redirecting carryover funds; reallocation of funds from less successful projects to promising projects; and designation of special purposes for New Opportunities grants or Development Research grants. Examples were selected that illustrate each of these key themes and are provided below each theme in italics in Table 10. Centers and institutions have been de-identified to the extent possible.

Table 9. Selected Case Examples Illustrating Mechanisms and Structures that Enable Flexibility and Innovation.

Theme	**Illustrative Example**
Restructuring projects or cores	*Strategic project's 7, 8 and 9 restructured into a single project (RP11). This change was prompted to simplify the structure and the relationships of the individual projects which faced delays in obtaining regulatory approval for the initiation of vaccine related clinical studies.*
	….The addition of a major research focus to an existing project…. is an example of flexibility possible under the RCE mechanism. This capacity for shifting/blending projects allows the RCE to expand promising areas of research outside of the grant application mechanism. This allows for a more timely response to fruitful research accomplishment.
	…..a complement to the ability to expand successful research programs is the ability to terminate unsuccessful projects/cores and either redistribute the resources, reshape the project/core, or both. …..an example is….when a combination of inadequate performance and an increased need in another direction led to the reestablishment of the Training & Education core from a Public Health Educator network function to a Public Health and Emergency Response function, with entirely new staffing.

Theme	Illustrative Example
Redirection of carryover funds	*Redirection of money from carryover funds towards projects studying Category A bacterial pathogens and toxins. Rapid addition of instrumentation -- the Cooperative Agreement funding mechanism has allowed the reapportionment of resources, or the capitalization of unexpended funds, for this purpose …*
Reallocation of funds from less successful projects to promising projects	*The RCE's ability to terminate projects that are floundering has enabled us to fund new projects that have flourished. In 2005, … [our RCE's management committee] evaluated each research project and identified several that were not meeting milestones. The projects were either given notice of their termination, or given the opportunity to put effort into meeting their milestones and were reevaluated at a later date. The funds freed up by the terminated projects were offered as New Research Projects.*
	Override traditional grant scores to fund a valuable and innovative project
	Mid-point review of RP6 resulting in reduced funding; reallocated funds to new project
Designation of special purposes for New Opportunities or Developmental Research funding mechanisms	*…In order to promote collaboration between investigators from different institutions and broader participation in [our RCE program], [our] leadership chose to establish a Collaborative Pilot Projects Program supported through the New Opportunities funding mechanism. This program provided $100,000 in direct funds to two collaborating investigators based at two different institutions.*
	Because the Developmental Research Projects funds within the RCE can be allocated on a programmatic basis, and may be targeted to develop synergy, the RCE funded three Developmental Projects that also involve Burkholderia. These projects expand the scope of the Burkholderia research within [our RCE] and have catalyzed formation of an active Burkholderia group that shares information, interacts to facilitate research and create synergy…

Some case examples emphasized the types of achievements that resulted from this flexibility. Based on these examples, the unique structure of the funding mechanisms and policies have contributed to most of the goals of the RCE program. This finding suggests the importance of these funding policies as a critical input to the RCE program. Table 11 outlines the accomplishments thematically and illustrates each with one or more case examples, in italics, selected to represent the theme succinctly.

Table 10. Selected Case Examples of Achievements that Resulted from Flexible Mechanisms and Structures.

Theme	**Illustrative Example**
Collaborate	*The funding of RP1.8 (Biochip Diagnostic Tool for BT-induced Diseases) and DP7 (Portable Rapid Diagnostics System for Category B Toxins) allowed [this RCE]] to bring together a company and a university researcher for portable and rapid BT instrument development. Although it is certainly possible that the two groups may have eventually found each other on their own, the flexibility that allowed [our RCE] to fund their two different but complementary projects, and to bring them together, directly facilitated their now active and synergistic collaboration on innovative BT detection instrumentation.*
	The use of released funds from completed projects or unused cores has also enabled funding….collaborative studies between Drs. A and B of University X and Dr. C at University Y….This reallocation of funds also had the result of bringing another university and another RBL into [this RCE's] network, since prior to this award University X had no relation with [this RCE].
	The original application….included a diagnostics project, based on nano-devices. The investigators are bioengineers. While they are experts in the technologies needed to develop highly sensitive, small scale devices to detect biological agents or their components, they had little real world experience with specific pathogens. Separately, the RCE had a project on the structure and function of botulinum toxins. The two projects originally did not have any interactions. Because of the flexible structure and rebudgeting ability of the RCE, the RCE steering committee was able to allocate a relatively small amount of additional funding to allow the two groups to interact and pursue a common goal of developing a new, ultra-sensitive detection system for botulinum toxins. Recent results suggest that an assay that is faster, cheaper, and more sensitive than the current "gold standard" assay will be possible. Prototype devices will be ready for testing this year.
Expand training	*Biosafety training course began as a lecture series and was modified to include hands-on laboratory training; funding was available through reallocation.*
	Expansion of the Veterinary Fellowship program from University A to University B to increase outreach in the regions veterinary medicine schools.
Expand access to Core Facilities	*Core Laboratories Enable Broad Based Participation in Biodefense and Emerging Infectious Diseases Research: it was decided that the core laboratories should be funded sufficiently so that visiting investigators could make use of the resource without a core facility charge. It was anticipated that investigators would access these facilities and the expertise of the core PI and staff and obtain sufficient data for their research program to compete successfully for other sources of funding…Core laboratories that can function without usage charges is rare and only possible with a flexible funding format such as that found with the RCE program. In our opinion, [our] core laboratories have been very well received by the scientific community and have enabled [our RCE] to support the work of over 140 investigators from nearly 70 institutions across the country.*

Theme	Illustrative Example
Address critical investigator needs	*The New Opportunities program has allowed [our RCE] to rapidly address a critical need (NO2: Translational Critical Path Initiative)…Funding of NO2 gave [our RCE] a rapid mechanism to provide critically-needed guidance and assistance on product development to….investigators in [the region].*
Act quickly to take advantage of emerging opportunities	*The NIH RCE Program Office notified us that they had an unexpected largesse of Cynomolgus monkeys that could be made available free, on a competitive basis, to various projects in the RCEs. One proviso was that NIH needed a VERY RAPID response. Within 24 hours, [our RCE] submitted a request for 45 monkeys for 3 defined projects… The monkeys were awarded to [us], which can be attributed in part to the rapid response and coordination between the Admin Core, the Investigators, and the NIAID.*
Respond rapidly to emerging priorities	*Drs. X and Y each were funded as pilot studies of dengue virus infections using funds released by discontinued or decreased {our] Cores in an effort we termed "New Directions" grants. This enabled [our RCE] to begin a program on dengue viruses, aiming to discover novel therapies as well as vaccines. Dengue has emerged as a real world problem during the lifetime of the RCE program, and was recently placed on the select agent list as a category A agents. Flexibility in how this RCE is able to allocate funding, always with NIH oversight and approval, has been crucial in enabling [us]to respond to a novel threat in a rapid manner.*
	Having support in place for a monoclonal antibody core enabled work to begin rapidly on the development of monoclonal antibodies to the emerging H5N1 strain of avian influenza and to the highly virulent reconstructed 1918 influenza viruses. These monoclonal antibodies are potential therapeutic agents should an outbreak occur. Having to seek funding through traditional routes would have significantly delayed their development.
Respond rapidly to emergencies and threats	*Support for the development of diagnostic technology enabled…investigators…to rapidly apply their technology and aid the international community in the diagnosis of a Marburg outbreak in Angola.*
	…. the ability to respond to this [e-coli] outbreak with sequencing resources was only possible given the research flexibility of the RCE mechanism. Thus, it was possible to redirect both funding resources as well as personnel effort to a temporarily, highly prioritized area. This would not have been possible under a traditional R01 mechanism where this fast diversion to a new area of focus would be difficult to justify and/or execute.

Theme	Illustrative Example
Develop preliminary data using nontraditional methods	*Traditional mechanisms of funding (e.g., NIH, NSF) typically encourage and fund hypothesis-driven proposals. However, the advent of high-throughput genomics and proteomics have led to the development of technologies that enable whole genome, proteome, and transcriptome profiling where straightforward, hypothesis-driven questions are not always easy to ask initially. In these systems biology approaches, broader questions usually apply, for example: What genes are turned on when X happens? What proteins are recognized by the host immune response following infection by Y? And, specifically, with respect to my project, What mutations in the entire Francisella genome attenuates the Live Vaccine Strain? The RCE funding mechanism, being primarily product-driven and encouraging new and innovative technologies to be employed toward the development of these products, fosters systems biology approaches which, in addition to product development, generate the preliminary data that can lead to hypotheses for proposals that may be submitted to more traditional funding mechanisms.*
Make significant scientific breakthroughs	*The original application….included a Major Project proposal for vaccine development for Rift Valley fever virus (RVFV). This particular project did not receive a favorable review, and we were instructed to delete it from our portfolio. [The RCE PI] recognized this project as both scientifically relevant and an important contribution to public health and vaccine development for a tropical disease that occurs mainly in sub-Saharan Africa. Due to the flexibility of the RCE program, the project was split into two smaller Developmental Projects which were funded for the first two years of the parent grant…..these projects have led to a patent application for the reverse genetics system for RVFV that was developed, and have provided the opportunity for [the investigators] to obtain a DHS award and an NIH Challenge grant involving vaccine development for RVFV (both human and animal)…[and an RCE] Major Project to develop a new live RVFV vaccine using two attenuated strains.*
	a postdoctoral fellow….awarded a Career Development fellowship… discovered that cathepsins, a family of cellular proteases, play an essential role in the infection of human cells by Ebola virus (Science, 2005; 308 (5728):1643)….also discovered that currently available non-therapeutic chemical inhibitors of cathepsins blocked infection by the virus. Because there are no therapeutic treatments for Ebola virus infection, this discovery and the potential to identify and develop a cathepsin inhibitor became a very high priority for [this RCE]….The Scientific Steering Committee chose to fund [continued research by the investigators]… .

Theme	Illustrative Example
Leverage RCE Funds	*An example….leveraging RCE funds for advancement of a biodefense product is an inter-regional collaboration to generate pilot efficacy data of a novel Ebola vaccine. Investigators from RCE X requested assistance from RCE Y's small animal core and BSL-4 core in efficacy studies involving a baculovirus VLP/DNA vaccine against Ebola. The scientist had in vitro data in the form of antibody neutralization generated in an Ebola-pseudo type assay, but lacked the funds and resources to perform a challenge experiment. Mice were vaccinated at RCE X using a variety of vaccine regimens then shipped to [RCE Y]. Mice were challenged with a lethal dose of mouse adapted Ebola Zaire. Mice vaccinated with the baculovirus-expressed VLP mixture survived until the project end and showed no clinical signs of disease. These data were incorporated into an R01 application which resulted in a priority score of 138 and the potential of funding a more comprehensive program*
	…..the Steering Committee recommended that several of the [original] multi-component projects begin to focus on the most promising approach. The enabled the program to solicit and select additional research proposals from the broader [regional] community….these projects [included]… a vaccine technology platform that has already resulted in a patent application and has attracted venture capital funding…..

In addition to examining case studies of flexibility and innovation, we also looked at the number of funded projects over time in selected topic areas where the RCE charge changed to respond to emergent issues. The number of RCE projects was compared to the number of NIAID projects, as shown in Table 12. As shown with publications above, the RCE Program is making the largest contribution, by percent, in the smaller, emerging areas of research, and the contribution has been growing during the life of the RCEs. For instance, in Noroviruses, the RCE role has grown from 19% (3/16) in 2003 to 38% (8/21) of the active NIAID projects in 2006. Similar trends are seen with Burkholderia at 0% (0/9) in 2003 to 43% (6/14) in 2006. The RCE program has contributed a smaller percentage in SARS research, accounting for 9% (7/81) of NIAID's active projects in 2006.

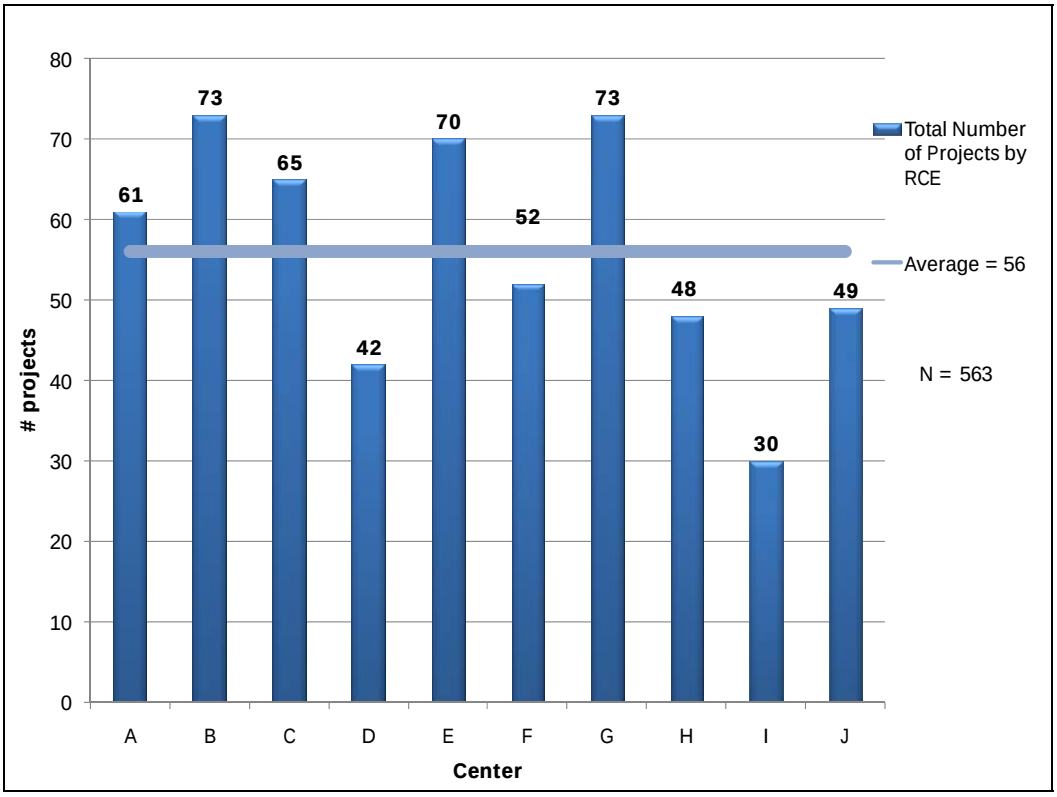
Table 11. Number of Active RCE and NIAID Projects Addressing Selected Topic Areas, by Fiscal Year .

	Antibiotic Resistance		Burkholderia mallei		Multi-drug resistant TB		Norovirus		SARS	
Fiscal Year	RCE Program	NIAID	RCE Program	NIAID	RCE Program *	NIAID	RCE Program	NIAID	RCE Program	NIAID
2003	2	321	0	9	0	55	0	9	0	57
2004	4	319	0	10	0	47	3	16	5	84
2005	6	336	5	17	0	43	6	20	6	91
2006	7	336	6	14	0	58	8	21	7	81
* Two projects began in 2007.										

Are Centers adding new projects as appropriate?

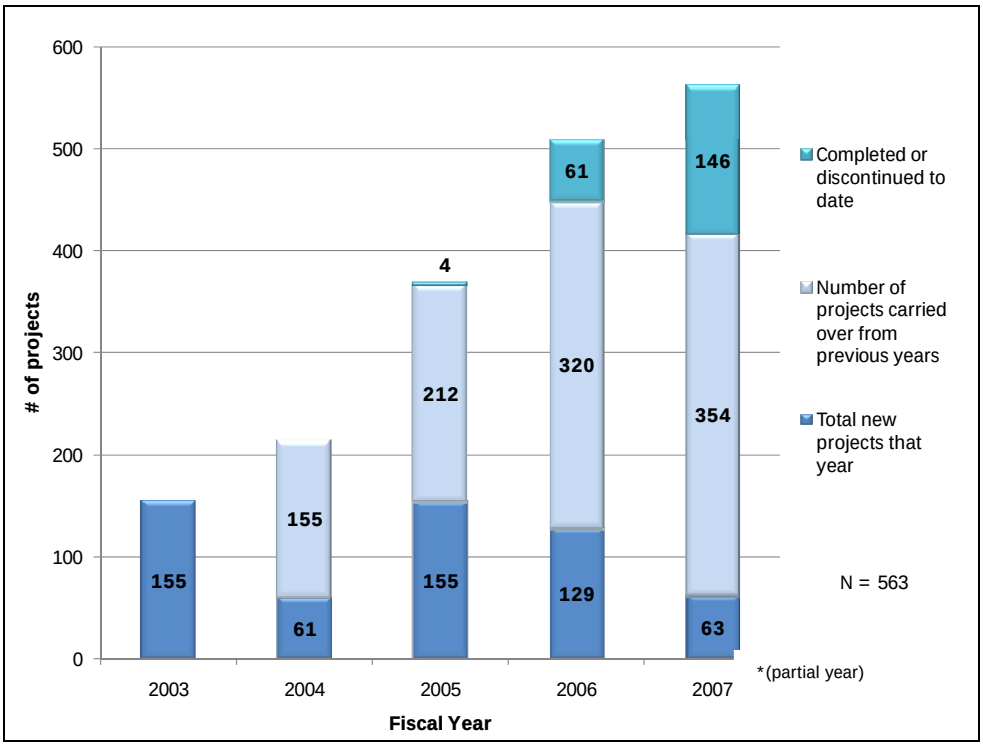
Cumulatively, the RCE Program has funded 563 projects. The average number of projects per Center is 56, ranging from 30 to 73, as illustrated in Figure 13.

Figure 13. Total Number of Projects by Center, Fiscal Years 2003-2007.



As shown in Figure 14, projects have been added in each year of the program, with surges in new projects in 2003 and 2005, years in which new Centers were added to the program. The average project duration is 2.8 years. By 2005, projects began to drop from the program, either due to completion or discontinuation.

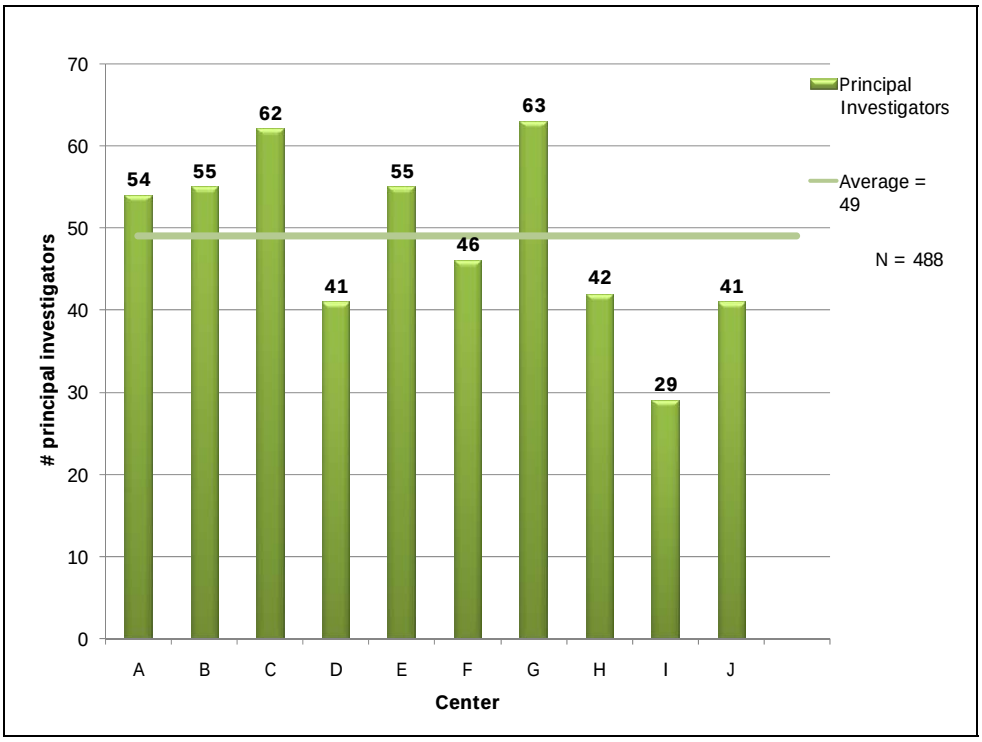
Figure 14. Active RCE Program Projects by Fiscal Year.



Are Centers adding new investigators as appropriate?

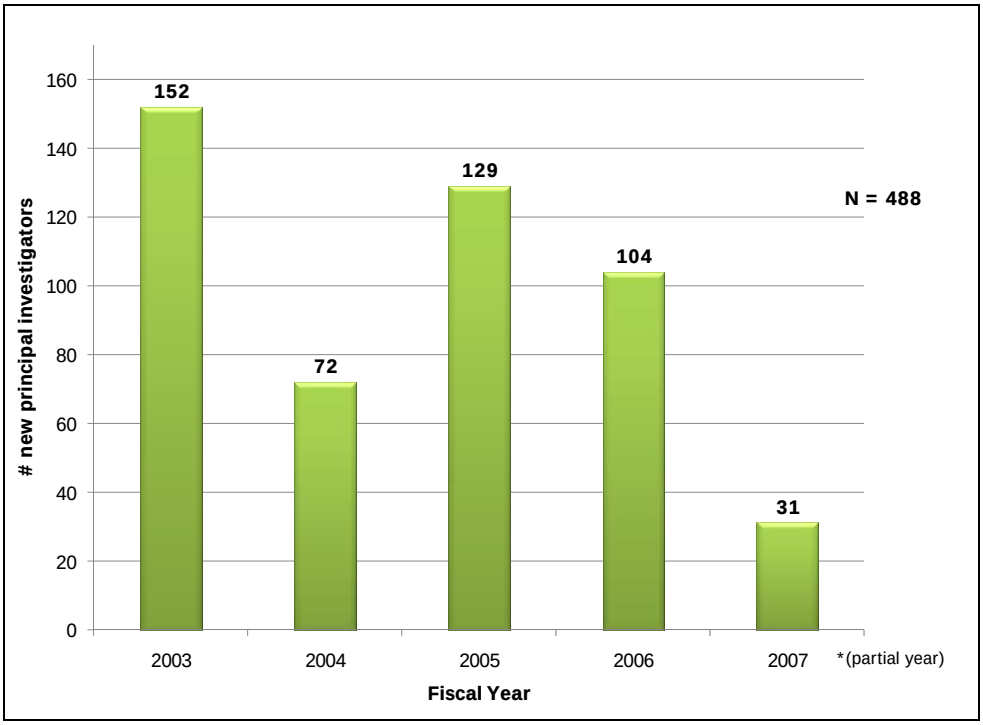
The RCE Program has involved 488 principal investigators. The average number of principal investigators per Center is 49, ranging from 29 to 63, as shown in Figure 15.

Figure 15. Principal Investigators by Center, Fiscal Years 2003-2007.



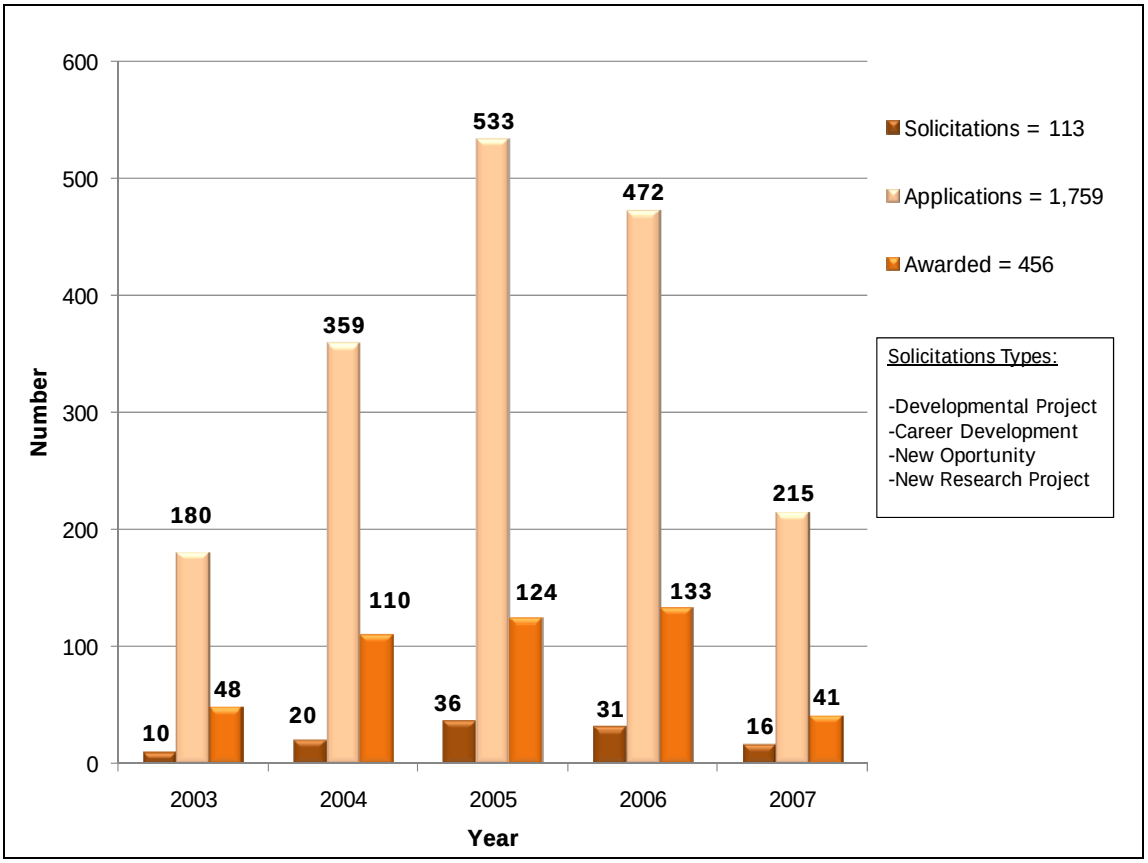
As the program has grown and new projects have been added, investigators who are new to the RCE Program have also been added, as shown in Figure 16. The overall ratio of projects to principal investigators is 1.16 (564/488). While some principal investigators have more than 1 project, in general, the same individuals are not being tapped repeatedly to serve as principal investigators on many projects. Instead, the Program is expanding its cadre of investigators over time.

Figure 16. Principal Investigators New to the RCE Program by Fiscal Year.



A key feature of the RCE Program is that Centers issue solicitations and review applications for projects and investigators for four main types of projects: developmental projects, career development projects, new opportunities projects and new research projects. See Appendix 10 for a full description of each of these project types. In this section, we examine the number of solicitations issued by RCEs, the number of applications in response to those solicitations and the number of awards made, as reported by Center administrators. In total, across the Centers, 113 solicitations were issued, 2,058 applications were received and 531 awards were made. The overall acceptance rate (531/2,058) has been 26%, with the acceptance rate remaining relatively steady over time. Figure 17 summarizes these data by year. Note that 2007 is a partial year. Two Centers were added in 2005.

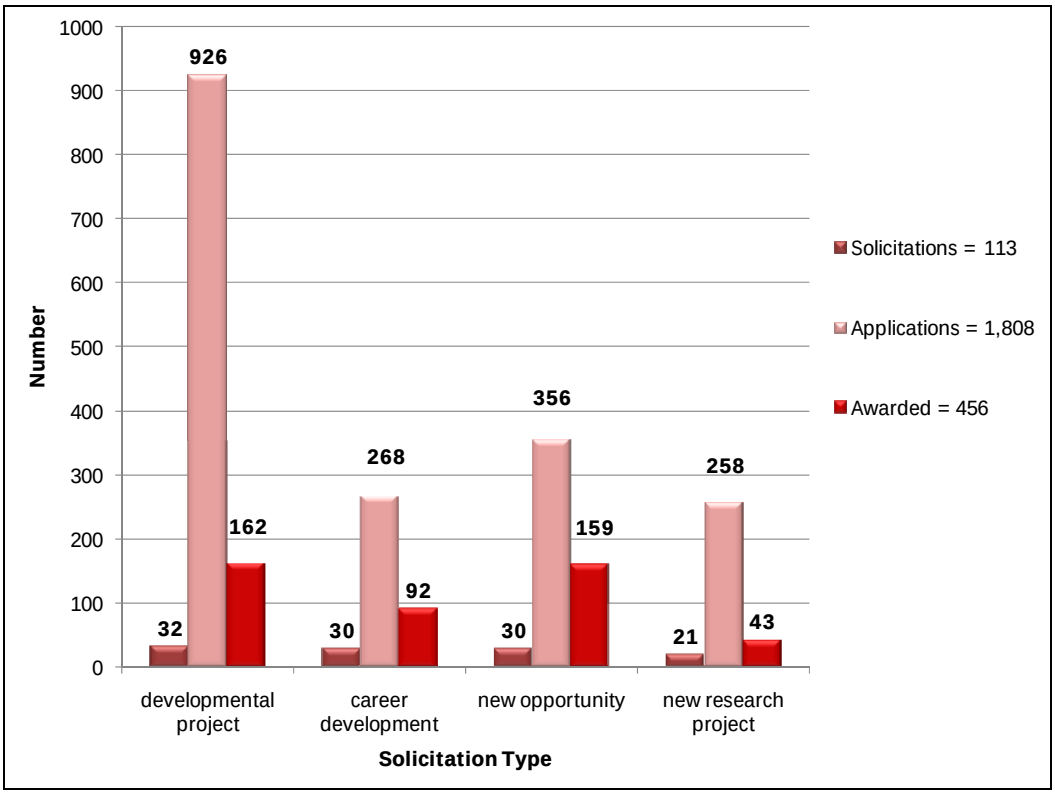
Figure 17. Applications and Awards in Response to RCE Program Solicitations by Year.



The 113 solicitations were relatively evenly distributed across the four project types, with 28% (n=32) developmental projects; 27% (n=30) career development; 27% (n=30) new opportunities; and 19% (n=21) new research projects. Appendix 11 shows graphs that break down the number of solicitations by year and type. The number of solicitations per year grew for all project types from 2003 to 2005, as Centers became fully operational. A slight decline is anticipated for 2007 for three of the four projects types, extrapolating out from the partial year figures. New research projects show a different pattern, as they are on course to exceed 2006 figures. This might be expected because as ideas are tested and people become trained through other types of projects, there is more capacity as time passes for exploratory projects to yield results that are ready for full scale research project funding.

Figure 18 breaks out solicitations, applications and awards for each type of project.

Figure 18. Applications and Awards in Response to Categories of RCE Program Solicitations, 2003-2007.



The acceptance rates for each type are summarized in Figure 19. Note that in some cases, data reports were partial. A Center may have reported an award made, but not reported the number of applications. This missing data affect the outcome when the data are disaggregated by project type. Therefore, acceptance rates by type have been corrected for missing data, so they will not match perfectly with computations based on the numbers shown in figure 18 above. Developmental projects attract the most applications and are the most competitive, with an adjusted acceptance rate of 17%. New opportunities grants are the least competitive, with an adjusted acceptance rate of 45%.

Figure 19. RCE Program Solicitation Adjusted Acceptance Rates by Solicitation Category, 2003-2007.

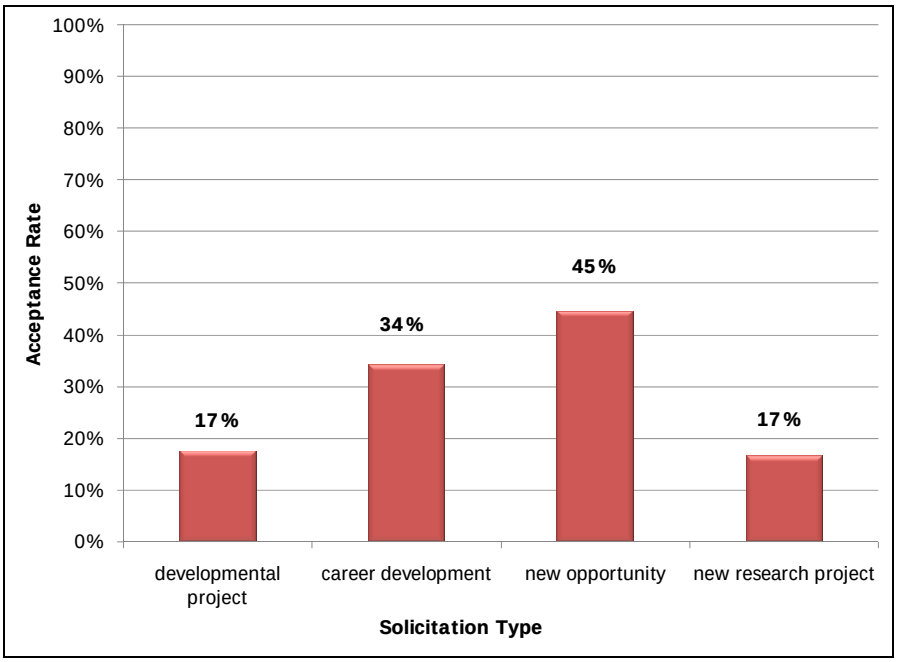


Figure 20 breaks out the number of solicitations, applications and awards by Center.

Figure 20. Applications and Awards in Response to RCE Program Solicitations by Center, 2003-2007.

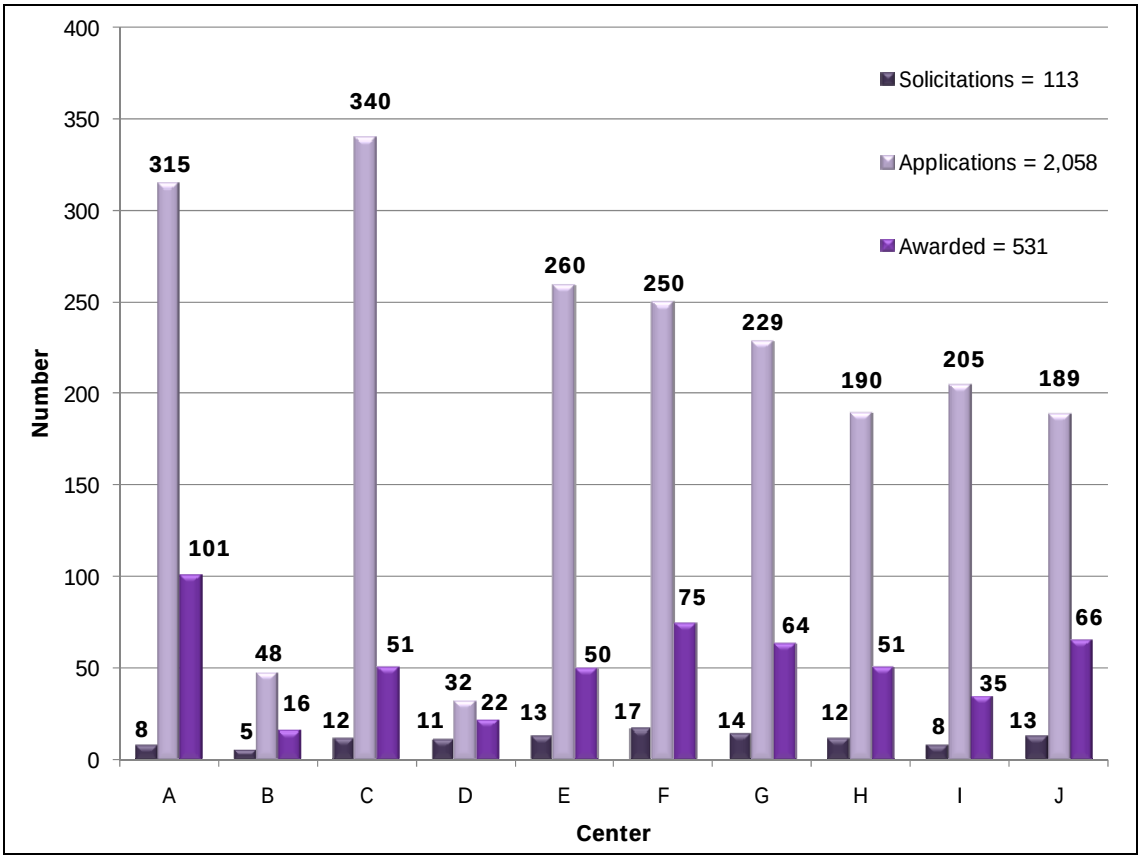
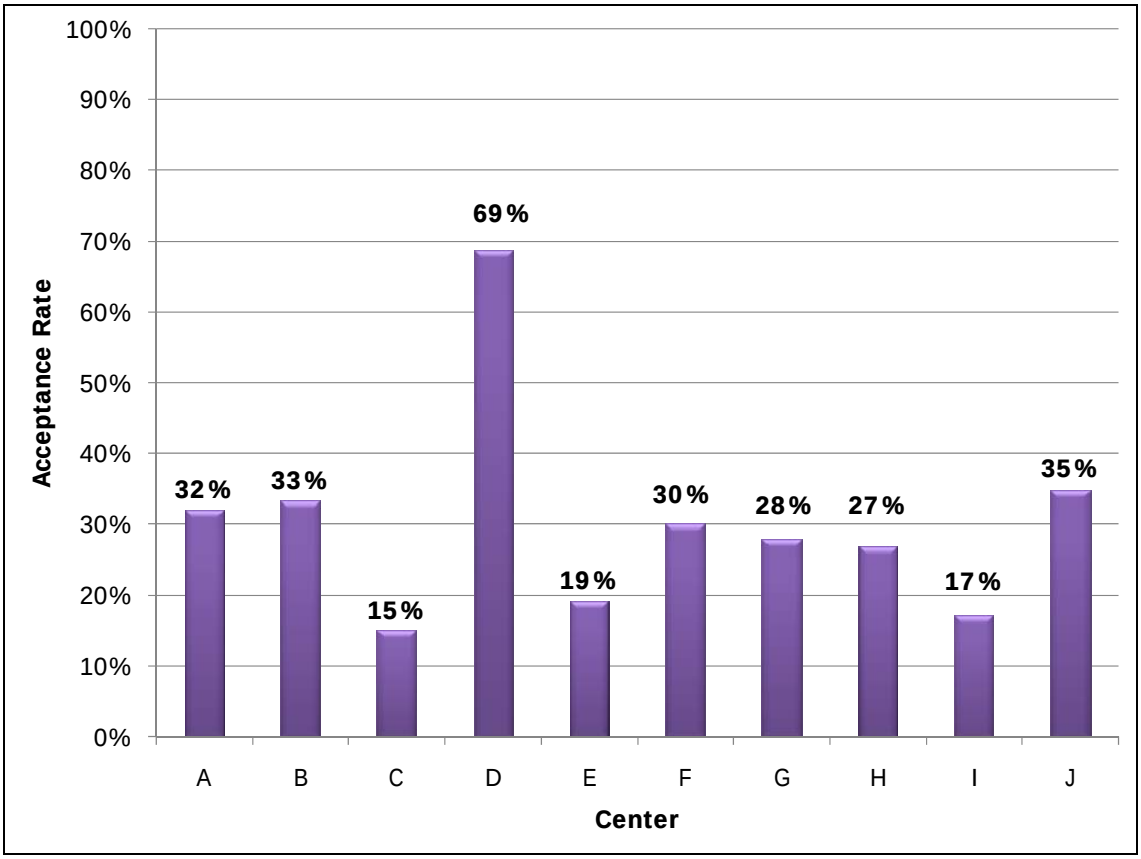


Figure 21 shows the adjusted acceptance rates by Center. These graphs illustrate the variability across Centers. While 6 Centers are near the overall average, falling within the 27%-35% range, three Centers are notably more competitive, with adjusted acceptance rates of 15% to 19%. One Center stands out for having a particularly small number of applications and high acceptance rate (69%).

Figure 21. RCE Program Solicitation Adjusted Acceptance Rates by Center, 2003-2007.



E. Leverage Other Sources of Support

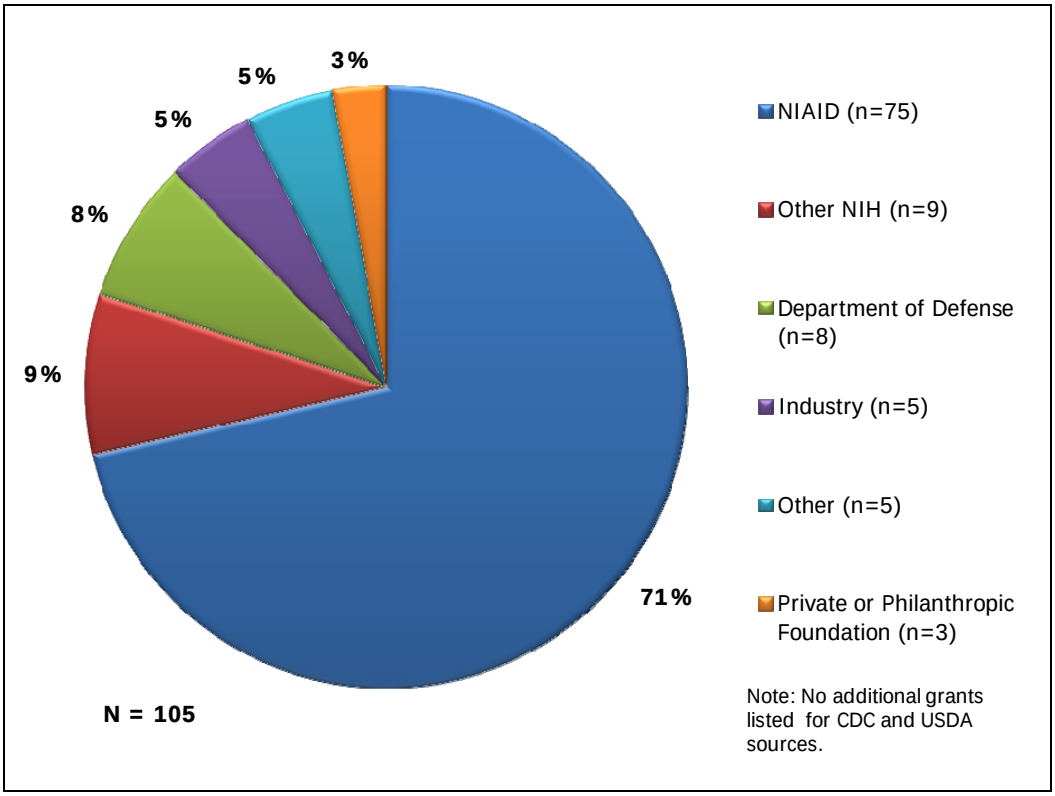
One of the goals of the RCE is to build the capacity to enable projects to successfully compete for traditional sources of funding. The section examines how extensively the RCEs are leveraging funds from elsewhere.

Are the RCEs leveraging other support?

As can be seen in Figure 22, RCE researchers have won 105 non-RCE grants or contracts that stem directly from their RCE research. The majority (71%) of these additional grants are funded by NIAID. Other NIH grants account for an additional 9% of the total, the Department of Defense funded 8% of the follow on projects. The Centers for Disease Control and Prevention and the USDA were not cited as the source of any additional funding. Additional funded projects from sources

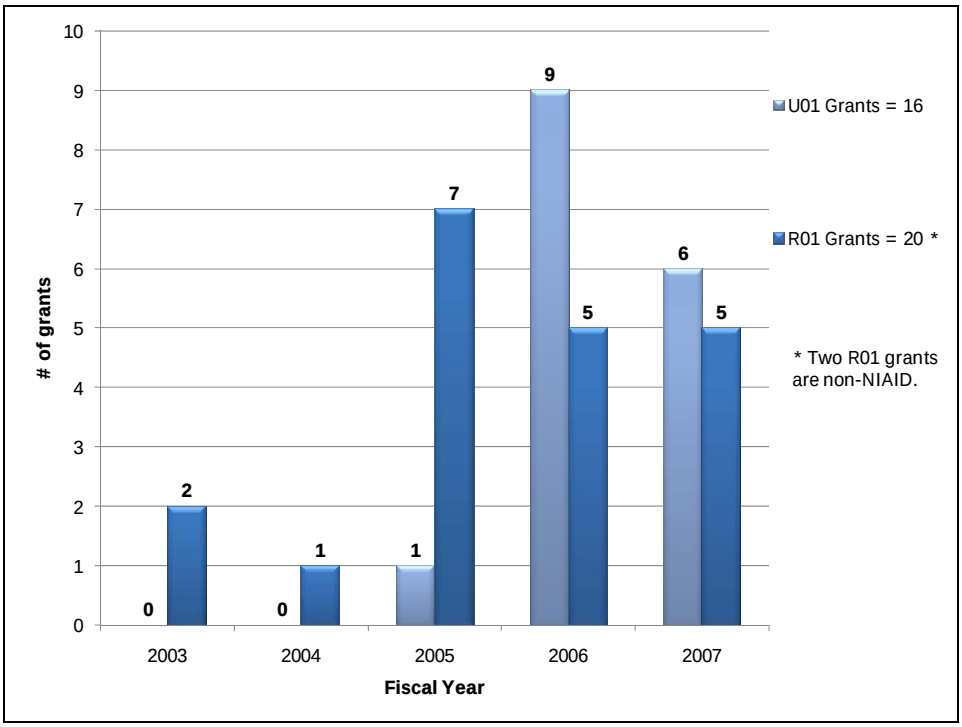
other than the US federal government comprise just under 13% of the total number of additional projects funded. No financial data were collected, thus this report relies only on the number of projects, regardless of size or economic value. A complete list of the additional grants, by title, is provided in Appendix 12.

Figure 22. Funding Sources of Additional Projects Stemming from RCE Research 2003-2007.



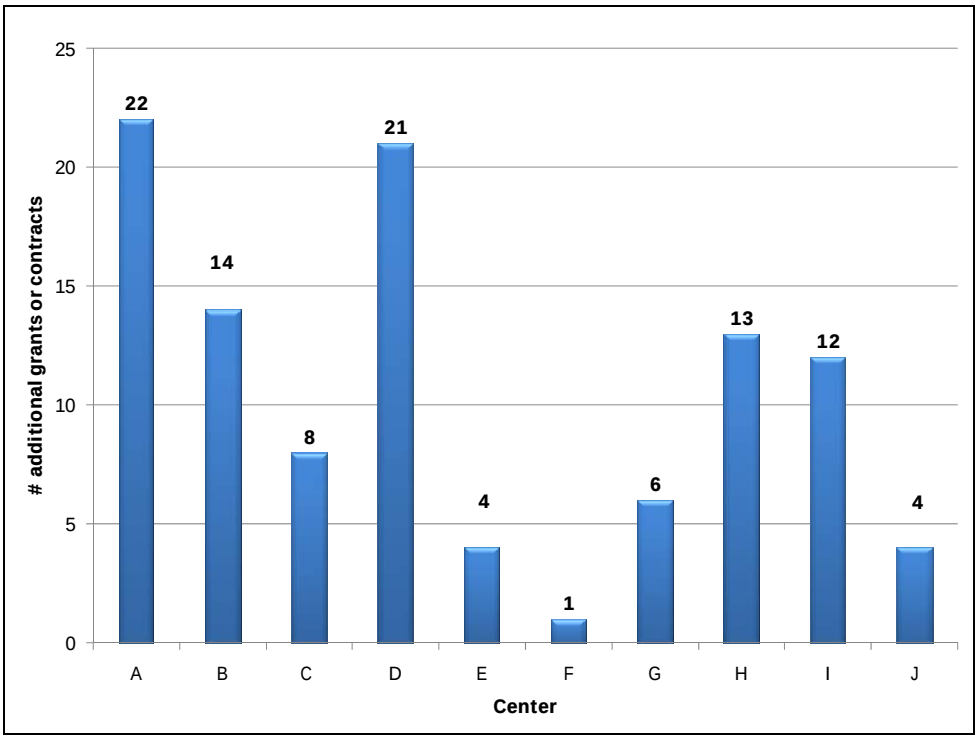
Selected measures focused specifically on tracking the number of NIAID RO1 and UO1 grants that stem from RCE Research. As illustrated in Figure 23, the number of these grants has increased over time, as would be expected of a capacity-building program. Data for 2007 are partial, but the figures suggest the program is on course to meet or exceed 2006 figures. The relatively large number of follow on UO1 grants are of particular note because they fund projects with product development potential, a goal of the RCE Program.

Figure 23. Number of R01 and U01 NIAID Grants Stemming from RCE Research by Year.



There is considerable variability across Centers on this measure, shown in Figure 24. While the average number of additional sources of funding across Centers is 11, this number ranges from 1 to 22.

Figure 24. Additional Non-RCE Funded Projects Stemming from RCE Research, by Center.



F. Expanded Cadre of Investigators

This component was not selected as a priority for focus in the interim evaluation. Nonetheless, data gathered elsewhere in this effort provide some information about issues related to training and recruitment. For example, based upon data collected about meetings held, the RCE Program has developed more than 27 training courses. In addition, more than 16 workshops (defined as "a working session in which participants interact or have hands-on experience), have been offered at least once. Seminars (discussions focused on a particular topic or project) and conferences (multiple sessions as part of a single event) also contribute to professional development and are hosted regularly by the Centers.

Are the RCEs recruiting and training new investigators in the area of biodefense and emerging infectious disease research (expanding the cadre of researchers in these areas)?

Centers have funded 488 investigators, as reported above, and added principal investigators who are new to the RCE Program each year. A study conducted by the RCE Program in 2006 examined the biosketches of each investigator (as provided in the Progress Reports) to determine how many investigators are new to the field of biodefense and emerging infectious disease research. No attempt was made in this evaluation to verify or update this study. That study found that, as of 2006, the RCE Program had brought into the biodefense field:

- 107 new researchers through funded *research projects*. (70% of all research project PIs)
- 121 new researchers through *funded developmental* projects. (83% of all developmental project PIs)
- 68 new researchers through funded *career development* projects.
  - 9 career development projects are involved in training researchers, physicians, veterinarians, and emergency response personnel.

Thus, the majority of researchers entering the RCE program through the research projects and development projects are new to the field.

G. Readiness to Respond in an Emergency

One of the goals of the RCE Program is to provide scientific support to first responders during infectious-disease related emergencies. This study looked at activities that would suggest that the Centers were prepared to help should a situation arise. It also examined instances in which the Centers have participated in an infectious disease emergency.

How well prepared are the RCEs to help responders in the event of a biodefense or emerging infectious disease emergency?

There are a variety of activities Centers might engage in that would enable them to help responders in the event of an emergency. Table 12 shows the percent of RCEs that reported engaging in each activity (n=10). All Centers were expected to complete a basic set of activities, as noted by

asterisks in the table. However, as many as 4 of the 10 Centers (40%) did not engage in the required activities. Some Centers went beyond these basic activities in support of this aspect of their mission. For instance, 60% of the Centers have participated in table top exercises at least once.

Table 12. Percent of Centers Participating in Selected Emergency Preparedness Activities.

Activity:	% RCEs that engaged in this activity
Activation: participation in a public health emergency.	**100%**
Participation in simulations (in the field).	**20%**
Participation in table top exercises (around a table).	**60%**
RCE membership on state committees tasked with emergency response.	**50%**
RCE membership on local committees tasked with emergency response.	**40%**
Identified designated RCE contact person for each locality. *	**60%**
Identified official designated ER contact person(s) within the region. *	**60%**
Communication between RCE and locality contact person. *	**70%**
Compiled list of experts who can help in an emergency. *	**80%**
Compiled list of resources that can be used in an emergenc.y *	**100%**
Conducted public outreach.	**80%**
Other contacts/mtgs with local emergency responders, not covered above.	**60%**

Appendix 13 provides a more detailed breakdown of each Center's activities by year.

A second measure for this topic focused on examples of situations in which the RCEs responded to infectious disease emergencies. All of the Centers provided indirect support in the Hurricane Katrina emergency by responding to a request for lists of experts and services that might be available. In addition to that level of support, 4 Centers reported providing additional support, as noted in Table 13 below. In addition to Katrina, there were a total of 10 additional responses by the RCEs to infectious disease-related incidents in the period 2003-2007. Table 14 organizes abstracts from the case examples by event. The services rendered are in boldface type.

Table 13. Case Examples of Emergency Response.

Event	Case Example
Hurricane Katrina (2005) – Deployed resources	*Following Hurricane Katrina, evacuees from New Orleans were temporarily housed in the **Houston Astrodome**…. [our RCE] staff was called to Houston to **assist with infectious disease surveillance and the rapid assessment of health needs of nearly 200,000 displaced persons**… Essential health staff from other states affiliated with [our RCE] were incorporated into this effort, which ultimately comprised a workforce of nearly 300 health providers and volunteers who labored for nearly three weeks.*
	*Influx of Gulf Coast evacuees displaced by Hurricane Katrina. [Dr. X] spearheaded the **creation of an infectious diseases triage and management plan for use by medical volunteers at** … **a rapidly deployed temporary shelter in St. Louis** with capacity to house 2000 evacuees in September 2005. Using the existing 24/7 emergency pager program, he also served as the on-call infectious diseases consultant for the [local] County DOH as they received displaced evacuees in September 2005.*
	*members of our RCE participated in Operation Assist, a program of the National Center for Disaster Preparedness in the Mailman School of Public Health of Columbia University that **deployed several equipped, manned mobile medical units to affected areas.***
	*….a request was made for [our] **participation in the Medical Coordination and Referral for Physicians Hotline Program**. These clinicians would receive inquiries from the hurricane-afflicted areas and act as consultants in their areas of expertise.*
SARS outbreak (2003)	*Dr. X of [our RCE] travelled to China to **"assist in coordinating diagnostic and research efforts. Dr. X was instrumental in the establishment of 3 infectious disease centers within China**…."*
	*Dr. X of [our RCE] travelled to Taipei and "**advised the government** on matters of transmissibility, quarantine, epidemiology, control, etc. related to public health measures to be used to control SARS, how to relate events to WHO, and how to control public panic."*
Spinach Related E-coli outbreak (Multiple states, 2006	*….we offered rapid, in-depth **whole genome sequencing of a prototypical outbreak strain.** An isolate of the spinach-associated outbreak of E. coli 0157::H7 was obtained from …. the National Food Safety & Toxicology Center at Michigan State University. [Our RCE's] analysis complemented the sequence analysis performed at MSU by providing greater genetic detail in areas of ambiguity.*
Electrical Blackout across multiple States (2003)	*[our] investigators with refrigerators, freezers or incubators on reliable emergency power offered space to any RCE member in need. BSL2 and BSL3 **facilities were available**. New York City Department of Health used the facilities available at [ABC University].*
Event	**Case Example**
Indian Ocean Tsunami (2004-2005)	*[Our RCE] emergency response staff have responded to the Indian Ocean Tsunami (2004-2005) in Sumatra. These events have included concern for*

	infectious disease and the establishment of companion surveillance activities. The outcome of this technical assistance was ***public health programs to control the spread of infectious disease*** *and* ***setting the stage for further collaborative research.***
Suspected Tularemia (St. Louis, 2006) –	*activated [our RCE's] Emergency Management Group phone tree and* ***disseminated information*** *to [a local] School of Medicine and our hospitals. [Dr. X] also assisted local health departments with the* ***development of an appropriate case definition*** *to enhance surveillance.*
Expert Consultation provided on 4 other matters:	*Outbreak of rash illness in children and adolescents following a large-scale mud wrestling event in the [X metropolitan region](identified as Enterobacter folliculitis) (2006)*….[*Dr. X] responded to a call from the [local] County Department of Health on the 24/7 emergency pager and provided timely clinical assistance that was used by the health department to advise the public via press conference the same day.*
	Teleconferences with CDC on potential influenza pandemic (2003-2004).
	Increased numbers of tularemia, ehrlichia and Rocky Mountain spotted fever were noted during the early summer of 2007 in the state of Missouri… A Health Alert was written by the Missouri Department of Health and Senior Services and edited by Dr. X regarding the recognition and early treatment of tick-borne infections.
	A patient at a local…hospital presented with rash and fever after minimal contact with a recent vaccinia vaccinee. (2007). Situation not yet resolved at time of reporting.

H. Translate and Apply Science to Practice

Product development is a long-term desired outcome of RCE research. A marker of progress in the early stages of the RCEs is the establishment of resources that support product development. The first question documents the extent and type of these resources. The second question focuses on product development concepts and patents filed, expected outcomes of the Program investment.

Is the RCE program (individual RCEs, trans-Center activities or NIAID program) developing novel support mechanisms to facilitate product development?

More than 35 product development resources were reported by the Centers. Each Center reported at least 1. The resources were content analyzed to identify 4 major categories of product development resources, which appear as headers in Table 15 below. Subcategories are noted in the left hand column and examples of each subtheme are provided in the right hand column.

Table 14. Selected Examples of Key Categories of Product Development Resources.

Subcategory	Illustrative Example
Infrastructure	
Core Facilities and Laboratories	*"Small Animal Core facilities provide BSL2 and BSL3 facilities for animal studies. This core provides investigators with facilities to test therapeutics and vaccines in vivo. In vivo data is essential for the development of any potential product."*
	National Screening Laboratory for the Regional Centers of Excellence in Biodefense and Emerging Infectious Diseases (NSRB). This core laboratory provides the ability to conduct high throughput small molecule screens to identify inhibitors of microbiological pathogens and the pathologies caused by these pathogens. The medicinal chemistry capability of the lab enables investigators to synthesize new chemical comounds with improved biologic and/or pharmaceutical properties. Investigators affiliated with any RCE can make use of the facility.
	"RNAi Screening Laboratory. This resource enables investigators to identify cellular targets critical for biological function and disease pathogenesis. These targets can be further studied and inhibitors identified through small molecule based screening. Inhibitory RNAs can also be used directly as a therapeutic agent."
Instrumentation	*"Drug screening suite -- A dedicated set of instrumentation is being put in place this year to add to capacity to screen compounds…. and to also screen libraries not routinely or easily available in the biodefense network or elsewhere."*
Guidance on Product Development	
Dedicated Staff Assistance	*"An Associate Director for Product Development was appointed in 2006 at 20% effort. [The Associate Director]… has over 30 years' experience in product development, FDA regulatory requirements, and in manufacturing of medical products. He met with faculty at different locations… reviewed their projects, and made recommendations to help in the product development cycle. He has presented training…. Met with three major companies and is discussing retaining them as advisors to faculty."*
Dedicated Committees	*"Translational Development Subcommittee. Charged with developing information and policies to ensure that research scientists with promising products and technologies are linked with Center Cores and outside resources to enhance product development."*
	"Our External Scientific Advisory Board meets annually to help guide Center product development activities. The ESAB includes four senior executives from the pharmaceutical industry (both "big pharma" and biotechnology companies), one representative of the FDA, and two experts on civilian biodefense who previously held high level posts in the federal government."
Training	*"Product Development Seminars. A concerted effort is made to include product development related topics as part of the Center's seminar series and the annual Center retreat program."*

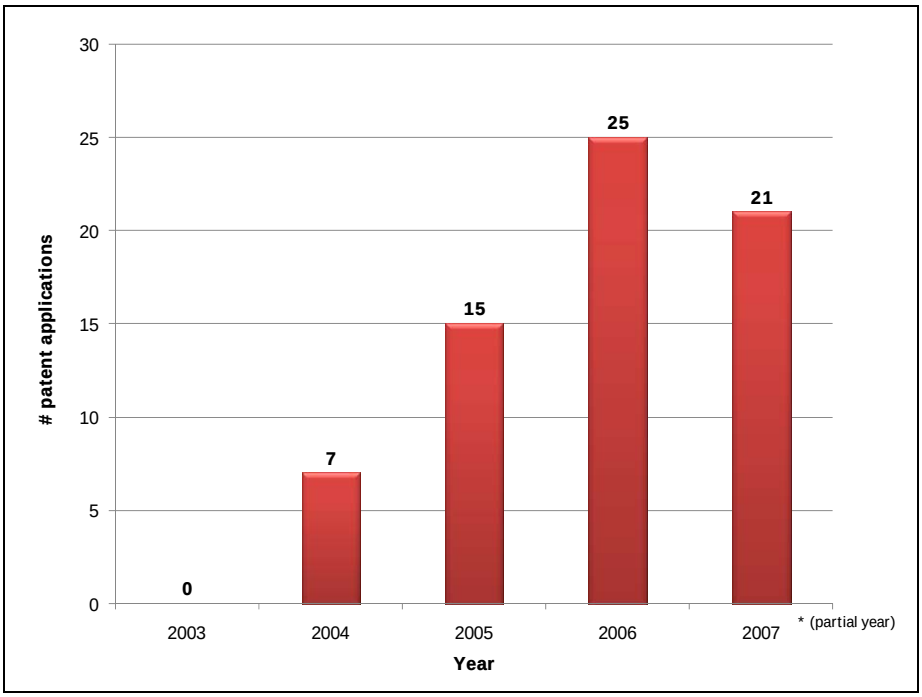
Subcategory	Illustrative Example
Funding Sources	
Dedicated Funding Source within Center	*"New Opportunities: focus on Product Development. One of the objectives of this funding source is to support projects that have reached the stage of early product development. In order to be considered for support through New Opportunities, Investigators must have identified a specific vaccine or therapeutic formulation for testing in animal models."*
Industry Collaboration	*Members of Center leadership team met with various industry organizations in order to establish future collaborations.*
Biological Materials and Processes	
Assays	*"Established efficient and simple high-throughput and medium-throughput assays for the screening of anti-viral compounds against flaviviruses."*
Compounds	*Collaboration with medicinal chemists for the development and production of lead compounds to drugs has been established.*

Is there evidence of progress toward product development (product development concepts and patent filings)?

Twelve (12) product development concepts have been reviewed by the Program's Product Development Working Group. A list of these concepts is provided in Appendix 14.

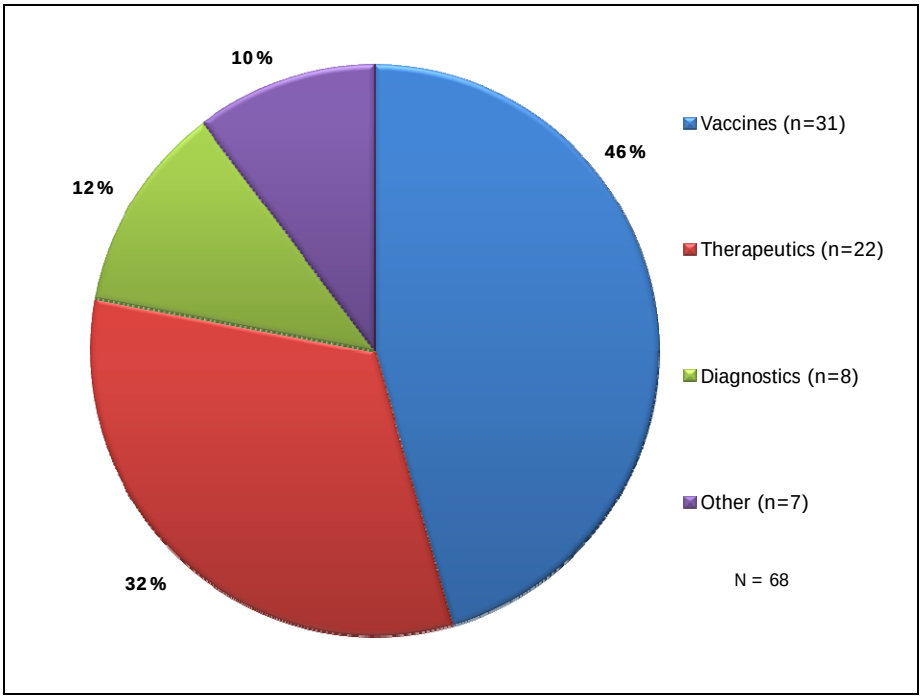
A total of 68 patent applications based on RCE research have been filed. As shown in Figure 25, the number of patent applications has increased over time, as would be expected as research projects mature. Data for the year 2007 are partial, yet the Program is on track to meet or exceed the 2006 figures.

Figure 25. Number of Patent Applications for RCE Program, 2003-2007.



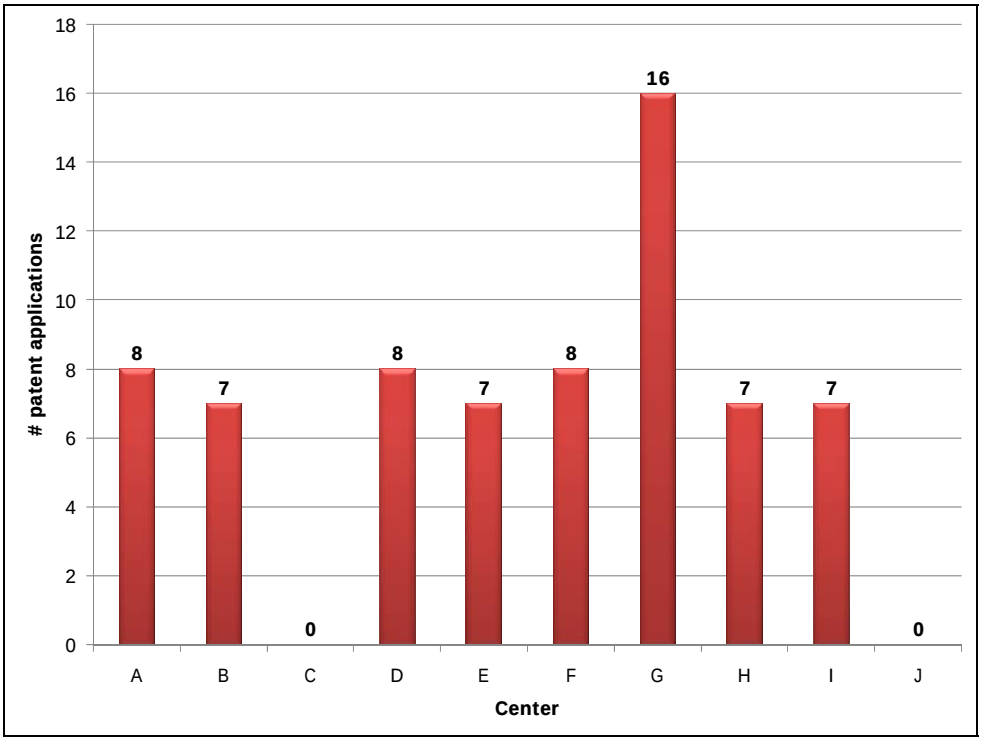
As shown in Figure 26, the largest percent of patents are for vaccines (46%). The second largest percent are for therapeutics (32%). These findings are consistent with the number of RCE projects in these areas. Recall that the largest percent of non-basic science research projects were vaccine projects, followed closely by therapeutics.

Figure 26. Patent Applications by Type for RCE Program 2003-2007.



The median number of patents applied for by a Center is 7. Seven (7) of the Centers reported between 7 and 9 patents, as illustrated in Figure 27. Three outliers existed. Once Center reported 16 patent applications and 2 Centers reported none.

Figure 27. Number of Patent Applications by Center, 2003-2007.



VI. Discussion and Summary

Given the short time the Centers have been in existence, impact on some of the longer term outcomes would not be expected to be substantial, although progress toward those end points should be evident. This report shows evidence that each of the major goals addressed in this interim, descriptive evaluation are being addressed:

A. **Collaboration and Communication:** The RCE Program has had a wide reach, with over 290 participating institutions and 488 principal investigators. Many other investigators have had the opportunity to apply for funds or use core facilities. Investigators collaborate and communicate regularly within Centers in support of the leadership/management of the Centers, to set scientific agendas (by determining topics or projects on which to issue solicitations, or assess projects), to discuss topics and projects and to train investigators. About 40% of RCE project teams have members from more than one institution and 44% of follow on (non-RCE) project teams have cross-institutional membership. Cross institutional co-authorship runs a bit higher at 51% of RCE publications. Cross-RCE interactions are less frequent than within RCE interactions, as would be expected. The majority of meetings are within RCE (not trans-RCE). Nonetheless, a number of conferences, workshops, seminars and training courses have been trans-RCE. Only 4 out of 477 publications have been jointly funded by two RCEs.

B. **Research Conducted on Category A, B and C Agents:** The RCE Program has research projects focused on 51 different agents, out of a possible 59 Category A-C agents. Thus the program is addressing its intended mission. Of the 563 funded projects, 58% address Category A agents, 21% Category B and 6% Category C. Thus the distribution of resources matches the priority level of the category. Just over half of the research projects are considered basic research. Vaccine research (16%) and therapeutics research (14%) and diagnostics (9%) comprise smaller percentages of the portfolio. Given that little is known about many of the agents under study, it is expected that basic research would precede application-oriented studies. Each Center has established a niche within the overall portfolio, in accordance with an expectation that Centers will specialize. It is remarkable that the majority of Centers are researching between 14 and 16 different agents, suggesting that the Centers have found a balance between specialization and breadth and transfer across agents. A few outliers to this general trend warrant further investigation.

C. **Scientific Knowledge on Category A-C Agents):** There is strong evidence that the research being produced is contributing substantially to scientific knowledge. The RCE Program has published more than 477 articles to date, with the number of publications increasing each year. RCE publications are well regarded, as indicated by higher than expected citation rates. RCE articles have been published in frequently cited, highly ranked journals. Citation of RCE publications is significantly higher than for other papers in the same journal and the same field.

D. **Innovative and Flexible Response:** The RCE Program has been designed with a number of unique features that promote flexibility and responsiveness at the Center level. Increased flexibility – particularly related to funding – allows Centers to support innovative research. For instance, Centers are able to restructure projects or cores, redirect carryover funds, reallocate funds from less successful projects to promising projects and designate funds for special purposes that support a strategic priority. These features have supported almost all

of the goals of the RCE Program, particularly enabling the Centers and the Program to respond rapidly to emerging priorities, emergencies and threats. Of interest, the nature of the grant program allows new investigators to enter the field and enables preliminary data to be developed using nontraditional approaches. The fact that projects are substantially assessed periodically means that unproductive projects are discontinued earlier than they might be with traditional grant mechanisms. Given these mechanisms, it is not surprising that the RCE Program is making the largest proportional contribution (by percent, relative to NIAID overall) in small, emerging scientific areas such as Francisella tularensis and Ebola, Noroviruses and Burkholderia. Most, though not all, Centers have successfully attracted large applicant pools in response to their solicitations for projects and investigators, making the application process competitive for all types of funding. Less than a third of all applications are funded. New projects and investigators new to the RCE Program have been added steadily each year.

E. Leverage Other Sources of Support: RCE investigators are successfully building on their RCE research to earn additional, follow on grants. RCE investigators have received 105 additional grants that stem directly from their RCE Research. The majority of these follow-on grants are funded by NIAID. Data on the dollar amounts of follow on grants were not collected, but would be worth considering for inclusion in the future to provide a truer picture of the leveraging of RCE dollars.

F. Expanded Cadre of Investigators: As of 2006, the RCE Program had brought more than 296 investigators who were new to biodefense, into this field. As noted above, investigators who are new to the RCE Program are added each year. The majority of funded investigators are new to biodefense.

G. Readiness to Respond in an Emergency: Centers are expected to build relationships and provide resources that would support first responders in the event of an infectious disease related emergency. Centers have been varied in their approach to this aspect of their mission. All Centers have compiled a list of resources that can be used in an emergency and responded to a NIAID request to itemize resources available to support responses to Hurricane Katrina. In addition to Hurricane Katrina, the Centers provided support during nine other public health related situations. However, there are several core activities that were expected of all Centers that some Centers have not reported doing.

H. Translate and Apply Science to Practice: The RCE program expects activities that can lead to the development of products or clinical interventions in the long term. As it is not possible in such an early phase of the program to expect substantial applications to practice, one must examine whether there is progress along the pathway toward this goal. An early indicator of progress is the establishment of novel support mechanisms that facilitate product development. Indeed, each Center reported at least one product development resource. These include infrastructure such as core facilities, laboratories and instrumentation; guidance on product development through dedicated staff members, committees or training; funding sources such as industry collaborations and dedicated funding sources for product development; and biological materials and processes that support ongoing research toward product development. The RCE Program has also developed a Product Development Working Group to periodically review and advise on concepts with product development potential. The group has reviewed 12 concepts. There have been 68 patent applications based on RCE research. Nearly half of these are related to vaccine development. Nearly a third are therapeutics-related. Centers generally report seven or eight patent applications,

although one Center has twice that number and two Centers reported none. Institutions generally have internal review processes and there are expenses associated with filings. Given these constraints, the substantial number of filings is notable.

The RCE Program's unique funding mechanisms are a critical input to the RCE Program, supporting and enabling the achievement of many of its goals. The Program is still in its early years, particularly as some Centers were not funded until 2005. Growth trends were observable on most measures over time, although a leveling off might be anticipated on many measures as the program reaches and maintains full capacity. This study provides baseline information that will be useful as a point of comparison in future evaluations.

This was an interim evaluation of the program *as a whole*. It was not intended to be a Center-by-Center evaluation. In general, reporting is done in the aggregate, across Centers. In selected instances, data are reported by Center, anonymously, to illustrate the variability of given activities or practices.

Since few examples of evaluating large scale research initiatives such as center grant research exist, the interim descriptive evaluation should be considered a pilot study. A separate report will reflect on the lessons learned through this process and the implications for future evaluations.

Relatedly, it is generally recommended that a definitive evaluation of a large research initiative include some form of peer evaluation (Jefferson & Godlee, 1999; Kostoff, 1994a, 1994b; 1995). It is also typical to include input from the researchers within the Centers. The timeline and resource constraints, and the relative maturity of the RCE program, required DMID to exclude these components at this time:

- Any activities that would require OMB clearance, such as formal interviewing or surveys of researchers;
- Substantial new data collection activities;
- Peer evaluation processes.

In sum, the RCE Program is supporting collaboration, innovation, substantial research contributions and bringing new investigators in the field of biodefense and emerging infectious diseases. RCE research is leading to patent applications, concepts with product development potential and additional sources of funding. While Centers have provided assistance during a number of emergency situations, this aspect of their mission may warrant further attention. This interim evaluation has established baseline information against which future data can be compared. This inquiry has also suggested some areas for further discussion and clarification that may enhance the Program.

VII. References

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VIII. Appendices

1. Concept Map Contents, by Cluster

Cluster A: Training and Recruitment

45 develop an expanded cadre of new researchers, clinicians, and technical personnel who can help lead the national biodefense mission.

80 bring new people into the area of biodefense and emerging infectious disease research.

7 promote and encourage opportunities for mentoring junior faculty/researchers in the field of biodefense and emerging infectious disease research.

10 recruit qualified students, trainees, women and minorities.

8 encourage the participation of post-docs, students, and other non-PI scientists at each RCE's regional meeting.

21 create training that is relevant to and integrated with the goals of the strategic plans.

76 develop policies, criteria and processes for selecting career development candidates, including special efforts to recruit qualified women and minorities.

16 help new investigators obtain funding.

26 develop more standardized training programs across RCEs by looking at successful programs at each RCE and developing some best practices.

55 supplement RCE activities by applying for direct training supports through T, K and F awards.

68 establish training programs with pharmaceutical company partners to allow training of scientists in drug discovery and non-clinical development.

Cluster B: Emergency Response

70 be ready and available to help the public health systems in the event of a biodefense or emerging infectious disease emergency.

64 increase the interaction between the RCE research community and the public health sector to aid in possible emergency situations.

71 provide technical experts to interact with the mass media and calm the public during an emergency.

Cluster C: Translational Activities

46 develop support mechanisms for translational activities that are not available in the traditional academic research setting.

62 develop trans-RCE resources for product development activities to assist researchers with moving ahead in product development.

35 think creatively about mechanisms to fund sites to do Phase 1 and 2 clinical trials of vaccines and therapeutics for emerging diseases in disease endemic countries.

30 address the fact that the academic reward structure is largely incompatible with product development.

72 define who the stakeholders are once product development moves into the pipeline.

48 file patent applications in a timely manner.

40 be able to provide financial support to foreign institutes for resources and/or services linked to domestic projects.

Cluster D: Research Mission

13 engage the best scientists with relevant knowledge and skills from throughout the region.

3 develop critical, new knowledge about biodefense and emerging infectious diseases.

39 expand basic research opportunities on microbial physiology, ecology, molecular pathogenesis and animal model development for Category A, B, C organisms.

11 maintain balance between basic research and translational / product development efforts.

52 translate research on emerging infectious diseases into useful interventions and diagnostic tools for an effective bioterrorism response.

6 focus on relevant emerging infections as opposed to a strict focus on select agent pathogens.

60 make scientific advances that would not be possible with traditional funding mechanisms.

18 focus on microorganisms that cause human disease or toxins derived from them.

54 expand the understanding of and ability to modify the innate and adaptive immune response to Category A, B, C organisms.

20 make the next generation of therapeutics, vaccines and diagnostics against Category A-C agents.

12 emphasize rigorous hypothesis-driven research on the epidemiologic and ecological aspects of biodefense and emerging infections

94 allow studies on emerging diseases outside of the United States.

47 focus on selected agents that are recognized as having bioterrorism potential.

24 demonstrate broad research coverage of the range of organisms listed on the Category A-C list.

23 provide clinical research capacity.

59 take special note of populations within our communities that have compromised immunity or increased risk because of occupational exposure.

Cluster E: Innovation and Flexibility

4 value and reward original ideas and innovative technologies.

56 have the capacity to rapidly move into areas of growing importance.

51 respond to changing scientific needs and opportunities by supporting novel, high-risk projects.

19 demonstrate its flexibility in addressing emerging infectious disease research needs.

Cluster F: Collaboration and Communication

61 promote interdisciplinary coordination and collaboration.

44 bring together researchers working on a given agent or platform to discuss their work.

27 hold an annual meeting of investigators from all funded RCEs to share progress and research insights.

32 make its research progress transparent to the public through the internet or other means.

14 create platforms for easy discussion and sharing of data among the researchers.

17 facilitate regular communication and dialogue across the centers.

50 have rapid and effective communication among the participants of each Center.

88 coordinate the activities of all centers to promote collaborative activities and efficient

use of resources.

49 demonstrate a high level of integration and collaboration between investigators within an RCE.

31 promote coordination between the RCEs and the Regional Biodefense Laboratories (RBLs).

75 encourage collaborations with non-RCE programs.

38 demonstrate complementarity with other NIAID and government-sponsored biodefense and emerging infectious disease research efforts.

25 develop collaboration between different RCEs.

37 avoid duplication of functions that are provided by other government programs or the private sector.

65 collaborate with other agencies and organizations on research related to other forms of bioterrorism.

Cluster G: Management

41 create a competitive and impartial process for selection and phasing in and out of projects, including reviewing and managing developmental projects.

91 periodically measure progress towards achievement of its long term and short term goals.

86 present and publish results in a timely way.

93 have transparent communication between NIH and the RCE's.

85 promote timely and effective communication between NIAID grants management and RCE grant administrators.

9 have clear and appropriate organizational structures and lines of authority.

2 analyze and identify best practices for the management of RCEs.

74 foster the exchange of ideas between Center administrators on how each RCE manages its consortium.

77 establish overall policies and procedures for management of cores and Center resources.

84 create an RCE-wide nondisclosure agreement to protect intellectual property.

81 be centrally coordinated and monitored by a Management and Oversight Committee.

Cluster H: Funds Management

89 promote flexibility in internal allocation of funds to innovative new projects and investigators.

53 facilitate releasing of funding to get monies to investigators in a timely manner.

83 transition successful developmental projects into new NIAID grants.

82 provide a mechanism so that well-performing developmental projects or career development projects can continue to receive RCE funding at the end of their one- or two-year funding period.

42 Improve the transparency of how funds are distributed within an RCE.

33 distribute funding among regions based on achievement of program goals.

78 facilitate the acquisition of equipment for the containment laboratories.

Cluster I: Integration and Synergy

15 be in compliance with U.S. laws and regulations and Department of Health and Human Services (DHHS) and NIH policies.

87 have leadership with expertise in biodefense and emerging infectious diseases research.

1 be flexible enough to add new investigators/initiatives from other institutions within

the region not currently participating in the RCE.

92 make sure appropriate systems are in place to provide for biosafety and security of materials, data and facilities.

90 demonstrate synergy between and within centers.

5 leverage additional non NIH scientific and technical resources to increase the impact of NIAID funds.

36 have linkages to federal, state and local agencies.

73 become more integrated with other NIAID programs to truly leverage our funds in the most effective and efficient manner.

66 compare itself with other similar government programs (such as other NIH Centers of Excellence) to look for features and best practices it could adopt.

Cluster J: Capacity and Infrastructure

43 have adequate access to BSL 3/4 biocontainment facilities.

63 develop and maintain comprehensive core facilities to support the research and training activities of the RCE.

34 develop an infrastructure for research on emerging infectious diseases.

22 have a set of clearly defined long term and short terms goals.

29 make core facilities available to qualified users in the region.

69 Share resources across Centers where appropriate

58 serve as a regional resource for their regions.

67 develop relationships between academia and industry.

28 promote the development of specialized areas of expertise for each of the Centers.

79 add chemistry resources to support screening activities and, ultimately, small molecule optimization programs.

57 encourage collaborations with foreign countries in the field of emerging infections.

2. Institutional Affiliation of Past and/or Current Steering Committee Members by RCE

RCE	*Institution*
GLRCE	Loyola University of Chicago
GLRCE	University of Michigan
GLRCE	The University of Chicago
GLRCE	University of Illinois
GLRCE	Illinois State University
GLRCE	IIT Research Institute
GLRCE	Battelle Memorial Institute
GLRCE	University of Cincinnati
GLRCE	Wright State University
GLRCE	Michigan State University
GLRCE	The Mayo Clinic
GLRCE	University of Michigan
GLRCE	University of Illinois
GLRCE	Battelle Memorial Institute
GLRCE	University of Notre Dame
GLRCE	Battelle Memorial Institute
GLRCE	Loyola Medical Center
GLRCE	The Ohio State University
GLRCE	Argonne National Laboratory
GLRCE	The University of Chicago
GLRCE	University of Minnesota, Minneapolis
GLRCE	Medical College of Wisconsin
GLRCE	Purdue University
GLRCE	Northwestern University
GLRCE	Northwestern University
GLRCE	University of Wisconsin Madison
MARCE	Center for Vaccine Development, University of Maryland Baltimore
MARCE	Dept of Microbiology and Immunology, Uniformed Services University of the Health Sciences
MARCE	Virginia Tech, Bioinformatics Facility 1
MARCE	Uniformed Services University of the Health Sciences

RCE	*Institution*
MARCE	Graduate School of Public Health, University of Pittsburgh
MARCE	University of Virginia
MARCE	Center for Vaccine Development, University of Maryland Baltimore
MARCE	Department of Microbiology and Immunology, University of Maryland, Baltimore
MARCE	Center for Vaccine Development, University of Maryland Baltimore
MARCE	Department of Comparative Medicine, University of Maryland Baltimore
MARCE	University of Pittsburgh
MARCE	Center for Vaccine Development, University of Maryland, Baltimore
MARCE	Dept. Microbiology and Tropical Medicine The George Washington University
MARCE	University of Virginia
MARCE	The Johns Hopkins Medical Institution
MARCE	Department of Microbiology and Immunology, University of Pennsylvania
MARCE	University of Pennsylvania
MRCE	Washington University
MRCE	Midwest Research Institute
MRCE	University of Western Ontario
MRCE	Washington University
MRCE	Case Western Reserve University
MRCE	Midwest Research Institute
MRCE	Case Western Reserve University
MRCE	Washington University
MRCE	University of Iowa

RCE	*Institution*
MRCE	University of Missouri - Columbia
MRCE	University of Iowa
MRCE	St. Louis University
MRCE	Midwest Research Institute
MRCE	Washington University
MRCE	Washington University
MRCE	Washington University
MRCE	University of Iowa
MRCE	St. Louis University
NBC	Mount Sinai School of Medicine
NBC	Albert Einstein College of Medicine
NBC	Rockefeller University
NBC	UMDNJ, New Jersey Medical School
NBC	New York University, School of Medicine
NBC	Yale University/Keck Laboratory
NBC	Wadsworth Center, New York State Dept. of Health
NBC	University at Buffalo, Department of Microbiology
NBC	Wadsworth Center, New York State Dept. of Health
NBC	Stony Brook University
NBC	Yale University School of Medicine
NBC	Yale University/Keck Laboratory
NBC	Wadsworth Center, New York State Dept. of Health
NBC	New York University, School of Medicine
NBC	Mount Sinai School of Medicine

RCE	*Institution*
NBC	UMDNJ, New Jersey Medical School
NBC	AMDeC Foundation, Inc.
NBC	Mount Sinai School of Medicine
NBC	Columbia University Medical Center
NBC	Rockefeller University
NBC	Columbia University, Mailman School of Public Health
NBC	Columbia University, Mailman School of Public Health
NBC	Formerly of Columbia University
NERCE	Brown University, Memorial Hospital of Rhode Island
NERCE	Tufts University
NERCE	Brown University, The Miriam Hospital
NERCE	Harvard Medical School, Brigham and Women's Hospital
NERCE	Brown University, lRhode Island Hospital
NERCE	Yale School of Medicinel
NERCE	Harvard Medical School
NERCE	Boston University
NERCE	University of Massachusetts Medical Center
NERCE	Yale Medical School
NERCE	Boston University
NERCE	Massachusetts Institute of Technology
NERCE	Harvard Medical School
NERCE	Massachusetts General Hospital
NERCE	Dartmouth Medical School
NWRCE	University of Washington

RCE	*Institution*
NWRCE	University of Washington
NWRCE	University of Washington
NWRCE	University of Washington
NWRCE	University of Washington
NWRCE	University of Washington
NWRCE	University of Washington
NWRCE	University of Washington
NWRCE	University of Washington
NWRCE	University of Washington
NWRCE	University of Washington
PSRCE	University of California, Irvine
PSRCE	University of California, Irvine
PSRCE	University of California, Los Angeles
PSRCE	University of California, Irvine
PSRCE	Lawrence Livermore
PSRCE	Scripps Research Institute
PSRCE	Northern Arizona University
PSRCE	Scripps Research Institute

RCE	*Institution*
PSRCE	
RMRCE	Self-employed consultant
RMRCE	University of Texas Medical Branch
RMRCE	University of Texas Medical Branch
RMRCE	University of North Carolina
RMRCE	National Cancer Institute
RMRCE	Infectious Disease Research Institute
SERCEB	Duke University
SERCEB	Emory University
SERCEB	University of North Carolina Chapel Hill
SERCEB	Vanderbilt University
SERCEB	Duke University
SERCEB	University of Michigan
SERCEB	University of Florida
SERCEB	University of Alabama Birmingham
WRCE	Tulane University Health Sciences Center
WRCE	University of Texas at Austin
WRCE	University of Texas Medical Branch
WRCE	University of Arkansas for Medical Sciences
WRCE	University of Houston
WRCE	Texas Southern University
WRCE	University of Texas Health Center at Tyler
WRCE	The University of Texas at Tyler
WRCE	Texas Tech University

RCE	*Institution*
WRCE	Lovelace Respiratory Research Institute
WRCE	University of Arkansas for Medical Sciences
WRCE	The University of Texas at Dallas
WRCE	University of Texas Medical Branch
WRCE	Louisiana State University Health Sciences Center
WRCE	University of Texas Medical Branch
WRCE	Oklahoma State University
WRCE	Louisiana State University Health Sciences Center
WRCE	Rice University
WRCE	University of Texas at Brownsville and the Texas Southmost College
WRCE	University of Texas at Brownsville and the Texas Southmost College
WRCE	San Antonio Metropolitan Health District
WRCE	Los Alamos National Laboratory
WRCE	University of Texas Medical Branch
WRCE	Sandia National Laboratories
WRCE	The Methodist Hospital Research Institute
WRCE	New Mexico State University
WRCE	Oklahoma State University

RCE	*Institution*
WRCE	University of Texas Health Science Center - San Antonio
WRCE	University of Texas Medical Branch
WRCE	Texas A & M University
WRCE	University of Texas Medical Branch
WRCE	University of Texas Medical Branch
WRCE	Research Institute for Children, Children's Hospital
WRCE	University of Incarnate Word
WRCE	University of Oklahoma Health Sciences Center
WRCE	University of Texas Southwestern Medical Center
WRCE	Los Alamos National Laboratory
WRCE	University of Texas at El Paso
WRCE	Baylor College of Medicine
WRCE	University of New Mexico
WRCE	University of Texas at El Paso
WRCE	Southwest Foundation for Biomedical Research
WRCE	University of Texas at San Antonio
WRCE	The University of Texas Southwestern Medical Center
WRCE	Lovelace Respiratory Research Institute
WRCE	University of Texas Health Science Center-Houston

RCE	*Institution*
WRCE	University of Texas Health Science Center - Houston
WRCE	University of Texas Medical Branch
WRCE	Arizona State University
WRCE	University of Texas Health Center at Tyler
WRCE	University of Oklahoma
WRCE	Louisiana State University
WRCE	Texas Tech University
WRCE	Texas Tech University
WRCE	University of Texas Medical Branch

3. Participating Institutions by RCE

RCE	*Participating Institution*	*State*
GLRCE	Argonne National Laboratory	IL
GLRCE	Batelle Memorial Institute	VA
GLRCE	Illinois Institute of Technology	IL
GLRCE	Illinois Institute of Technology Research Institute	IL
GLRCE	Illinois State University	IL
GLRCE	Loyola University of Chicago	IL
GLRCE	Mayo Clinic	MN
GLRCE	Medical College of Wisconsin	WI
GLRCE	Michigan State University	MI
GLRCE	National Wildlife Health Center	WI
GLRCE	Northwestern University	IL
GLRCE	Purdue University	IN
GLRCE	The Ohio State University	OH
GLRCE	The University of Chicago	IL
GLRCE	University of Cincinnati	OH
GLRCE	University of Illinois at Chicago	IL
GLRCE	University of Illinois at Urbana-Champaign	IL
GLRCE	University of Indiana at Bloomington	IN
GLRCE	University of Michigan	MI
GLRCE	University of Minnesota at Duluth	MN
GLRCE	University of Minnesota at Minneapolis	MN
GLRCE	University of Notre Dame	IN
GLRCE	University of Toledo	OH
GLRCE	University of Wisconsin at Madison	WI
GLRCE	University of Wisconsin at Milwaukee	WI
GLRCE	Wayne State University	MI
GLRCE	Wright State University	OH
MARCE	Blood Systems Research Institute	CA
MARCE	Drexel University	PA
MARCE	Food and Drug Administration, Center for Biologics Evaluation and Research	MD
MARCE	George Washington University	DC
MARCE	Georgetown University	DC
MARCE	Johns Hopkins Applied Physics Laboratory	MD

RCE	*Participating Institution*	*State*
MARCE	Johns Hopkins University	MD
MARCE	Uniformed Services University of the Health Sciences	MD
MARCE	University of Georgia	GA
MARCE	University of Maryland Biotechnical Institute	MD
MARCE	University of Maryland, Baltimore	MD
MARCE	University of Missouri	MO
MARCE	University of Pennsylvania	PA
MARCE	University of Pittsburgh	PA
MARCE	University of Vermont	VT
MARCE	University of Virginia	VA
MARCE	Virginia Bioinformatics Institute	VA
MARCE	Virginia Biotechnology Institution, College of Veterinary Medicine	VA
MARCE	Virginia Commonwealth University	VA
MARCE	West Virginia University	WV
MRCE	Apath, LLC	MO
MRCE	Case Western Reserve University	OH
MRCE	Cleveland Clinic Lerner College of Medicine	OH
MRCE	Iowa State	IA
MRCE	Kansas State University	KS
MRCE	Midwest Research Institute	MO
MRCE	St. Louis University	MO
MRCE	Stowers Institute	MO
MRCE	University of Iowa	IA
MRCE	University of Kansas	KS
MRCE	University of Kansas Center for Research, Inc.	KS
MRCE	University of Missouri - Columbia	MO
MRCE	University of Missouri - Kansas City	MO
MRCE	University of Nebraska - Lincoln	NE
MRCE	Washington University	MO
MRCE	Wichita State University	KS
NBC	Albany Medical College	NY
NBC	Albert Einstein College Of Medicine of Yeshiva University	NY
NBC	AMDeC Foundation Inc.	NY
NBC	Columbia University Genome Center, Joint Centers for Systems Biology, Irving Cancer Research Center	NY

RCE	*Participating Institution*	*State*
NBC	Columbia University, Mailman School Of Public Health	NY
NBC	Cornell University, College of Veterinary Medicine	NY
NBC	Cornell University, Weill Medical Center	NY
NBC	Mt. Sinai School of Medicine	NY
NBC	New York Medical College	NY
NBC	New York Structural Biology Center	NY
NBC	New York University, School of Medicine	NY
NBC	Ordway Research Institute	NY
NBC	Rensselaer Polytechnic Institute	NY
NBC	Rockefeller University	NY
NBC	Rutgers, The State University of New Jersey	NJ
NBC	Sandia National Laboratories	NM
NBC	Sloan Kettering Institute for Cancer Research	NY
NBC	Stony Brook University, Health Sciences Center	NY
NBC	Trudeau Institute, Inc.	NY
NBC	University at Albany, College of Arts and Sciences, School of Public Health	NY
NBC	University of Buffalo, School of Medicine and Biomedical Science	NY
NBC	University of Medicine and Dentistry of New Jersey, Department of Medicine	NJ
NBC	University of Puerto Rico, Medical Sciences Campus	PR
NBC	University of Rochester, School of Medicine & Dentistry	NY
NBC	Wadsworth Center	NY
NBC	Yale University, School of Medicine	CT
NERCE	Aerodyne Research, Inc.	MA
NERCE	Albert Einstein College of Medicine	NY
NERCE	Argonne National Laboratory	IL
NERCE	Baylor College of Medicine	TX
NERCE	Beth Israel Deaconess Medical Center	MA
NERCE	Boston Biomedical Research Institute	MA
NERCE	Boston University Medical Center	MA
NERCE	Brandeis University	MA
NERCE	Brigham and Women's Hospital	MA
NERCE	Brown University	RI
NERCE	Case Western Reserve University	OH
NERCE	CBR Institute for Biomedical Research	MA

RCE	*Participating Institution*	*State*
NERCE	Cellicon Biotechnologies, Inc.,	MA
NERCE	Children's Hospital Boston	MA
NERCE	Clemsen University	SC
NERCE	Cleveland Clinic	OH
NERCE	Colorado State University	CO
NERCE	Columbia University	NY
NERCE	Dana-Farber Cancer Institute	MA
NERCE	Dartmouth Medical School	NH
NERCE	Epivax, Inc	RI
NERCE	Genomic Profiling Systems	MA
NERCE	Georgetown University	DC
NERCE	Harvard Medical School	MA
NERCE	Harvard School of Public Health	MA
NERCE	Integral Molecular	PA
NERCE	L2Diagnostics	CT
NERCE	Massachusetts General Hospical	MA
NERCE	Massachusetts Institute of Technology	MA
NERCE	Medical College of Wisconsin	WI
NERCE	Memorial Hospital of RI	RI
NERCE	Meso Scale Diagnostics	MD
NERCE	Microbiotix, Inc	MA
NERCE	Mount Sinai School of Medicine	NY
NERCE	Nanopharma Corporation	MA
NERCE	New York Medical College	NY
NERCE	Northeastern University	MA
NERCE	Northwestern University	IL
NERCE	NovoBiotic Pharmaceuticals, LLC	MA
NERCE	NYS Department of Health, Wadsworth Institute	NY
NERCE	Oregan Health & Science University	OR
NERCE	RiboNovix	MA
NERCE	Sopherion Therapeutics	NJ
NERCE	State University of New York Stony Brook	NY
NERCE	Tufts University	MA
NERCE	Tufts University School of Medicine	MA
NERCE	Tufts University School of Veterinary Medicine	MA
NERCE	University of Alabama, Birmingham	AL
NERCE	University of Chicago	IL

RCE	*Participating Institution*	*State*
NERCE	University of Colorado at Denver, Health Sciences Center	CO
NERCE	University of Illinois, Urbana-Champaign	IL
NERCE	University of Massachusetts Dartmouth	MA
NERCE	University of Massachusetts Medical School	MA
NERCE	University of Medicine & Dentistry of New Jersey	NJ
NERCE	University of Miami School of Medicine	FL
NERCE	University of Nevada, Las Vegas	NV
NERCE	University of New Mexico School of Medicine	NM
NERCE	University of Northern Colorado	CO
NERCE	University of Pennsylvania School of Medicine	PA
NERCE	University of Tennessee	TN
NERCE	University of Texas Medical Branch	TX
NERCE	University of Vermont	VT
NERCE	University of Washington	WA
NERCE	University of Wisconsin, Madison	WI
NERCE	Utah State University	UT
NERCE	Vanderbilt University	TN
NERCE	Washington University School of Medicine	MO
NERCE	Yale University School of Medicine	CT
NWRCE	Emory University	GA
NWRCE	Fred Hutchinson Cancer Research Center	WA
NWRCE	Harborview Medical Center	WA
NWRCE	Institute for Systems Biology	WA
NWRCE	Montana State University	MT
NWRCE	NIAID Rocky Mountain Laboratories	MT
NWRCE	Oregon Health Sciences University	OR
NWRCE	Oregon State University	OR
NWRCE	Seattle & King County Public Health	WA
NWRCE	University of Alaska Fairbanks	AL
NWRCE	University of California Irvine	CA
NWRCE	University of California San Francisco	CA
NWRCE	University of Idaho	ID
NWRCE	University of Michigan Medical School	MI
NWRCE	VA Medical Center Boise	ID
NWRCE	VA Puget Sound Health Care System	WA
PSRCE	California Department of Public Health	CA

RCE	*Participating Institution*	*State*
PSRCE	California Institute of Technology	CA
PSRCE	Children's Hospital Los Angeles/University of Southern California	CA
PSRCE	City of Hope National Medical Center	CA
PSRCE	La Jolla Institute for Allergy and Immunology	CA
PSRCE	Lawrence Livermore National Laboratory	CA
PSRCE	Nesher Technologies	CA
PSRCE	Northern Arizona University	AZ
PSRCE	Northern University	IL
PSRCE	Stanford University	CA
PSRCE	Texas A&M	TX
PSRCE	The Scripps Research Institute	CA
PSRCE	University of Arizona	AZ
PSRCE	University of California, Berkeley	CA
PSRCE	University of California, Davis	CA
PSRCE	University of California, Irvine	CA
PSRCE	University of California, Los Angeles	CA
PSRCE	University of California, San Diego	CA
PSRCE	University of California, San Francisco	CA
PSRCE	University of California, Santa Barbara	CA
PSRCE	University of Hawaii at Manoa	HI
PSRCE	University of Nevada, Reno	NV
PSRCE	University of New Mexico	NM
PSRCE	University of Wisconsin, Madison	WI
PSRCE	Whitehead Institute for Biomedical Research	MA
RMRCE	Accuthera, Inc.	CO
RMRCE	ADA Technologies	CO
RMRCE	Alexion Antibody Techology	CT
RMRCE	Amgen, Inc.	CO
RMRCE	Center for Biocatalysis and Bioprocessing, University of Iowa	IA
RMRCE	Center for Pharmaceutical Science & Technology, University of Kentucky	KY
RMRCE	Centers for Disease Control and Prevention	CO
RMRCE	Colorado School of Mines	CO
RMRCE	Colorado State University	CO
RMRCE	Colorado Veterinary Medical Foundation	CO

RCE	*Participating Institution*	*State*
RMRCE	DeltaNu, LLC	WY
RMRCE	Denver Health and Hospital Authority	CO
RMRCE	Don Hill & Associates, Inc	MD
RMRCE	Etubics	WA
RMRCE	HAL Allergy Group	The Netherlands
RMRCE	Infectious Disease Research Institute	WA
RMRCE	Integrative Technologies, LLC	
RMRCE	InViragen	CO
RMRCE	Kansas State Univeristy	KS
RMRCE	LigoCyte Pharmaceuticals, Inc	MT
RMRCE	MaxThera, Inc.	MA
RMRCE	Migenix, Inc.	BC
RMRCE	Migenix, Inc.	BC
RMRCE	Montana State University	MT
RMRCE	National Cancer Institute	MD
RMRCE	National Jewish Medical and Research Center	CO
RMRCE	Precision Photonics	CO
RMRCE	Protein Sciences Corporation	CT
RMRCE	Rocky Mountain Biosystems, Inc.	CO
RMRCE	RxKinetics, Inc	CO
RMRCE	Sanofi Pasteur, Inc	PA
RMRCE	Sirius Medicine LLC	CO
RMRCE	SomaLogic, Inc	CO
RMRCE	South Dakota State University	SD
RMRCE	Stony Brook University	NY
RMRCE	Tetralogic Pharmaceuticals	PA
RMRCE	The Children's Hospital	CO
RMRCE	United States Department of Agriculture/Arthropod-Borne Animal Diseases Research Laboratory	WY
RMRCE	University of California, Irvine	CA
RMRCE	University of California, Los Angeles	CA
RMRCE	University of California, San Diego	CA
RMRCE	University of Colorado at Denver and Health Sciences Center	CO
RMRCE	University of Montana	MT
RMRCE	University of North Carolina	NC

RCE	*Participating Institution*	*State*
RMRCE	University of North Dakota	ND
RMRCE	University of Northern Colorado	CO
RMRCE	University of Texas Medical Branch	TX
RMRCE	University of Utah	UT
RMRCE	University of Virginia Health System	VA
RMRCE	University of Washington	WA
RMRCE	University of Wyoming	WY
RMRCE	Utah State University	UT
SERCEB	Beth Israel Deaconess Medical Center	MA
SERCEB	Duke University	NC
SERCEB	East Carolina University	NC
SERCEB	Emory University	GA
SERCEB	Georgia Institute of Technology	GA
SERCEB	Georgia State University	GA
SERCEB	Southern Research Institute	AL
SERCEB	Tulane Primate Center	LA
SERCEB	University of Alabama Birmingham	AL
SERCEB	University of Florida	FL
SERCEB	University of Kentucky	KY
SERCEB	University of Michigan	MI
SERCEB	University of New Mexico	NM
SERCEB	University of North Carolina Chapel Hill	NC
SERCEB	University of Southern Alabama	AL
SERCEB	University of Tennesee Health Science Center	TN
SERCEB	University of Texas Southwestern	TX
SERCEB	Vanderbilt University	TN
SERCEB	Wake Forest University	NC
WRCE	Arizona State University	AZ
WRCE	Baylor College of Medicine	TX
WRCE	Children's Hospital	LA
WRCE	Louisiana State University Health Sciences Center at New Orleans	LA
WRCE	Louisiana State University Health Sciences Center at Shreveport	LA
WRCE	Lovelace Respiratory Research Institute	NM
WRCE	Molecular Sciences Institute	CA
WRCE	Oklahoma State University	OK

RCE	*Participating Institution*	*State*
WRCE	Rice University	TX
WRCE	San Antonio Metro Health District	TX
WRCE	Sandia National Laboratories	NM
WRCE	Southwest Foundation for Biomedical Research	TX
WRCE	St. Jude Children's Research Hospital	TN
WRCE	Texas A&M University	TX
WRCE	Texas A&M University Health Science Center at Houston	TX
WRCE	Texas A&M University Health Science Center at College Station	TX
WRCE	Texas Southern University	TX
WRCE	Texas Tech University	TX
WRCE	Tulane University Health Sciences Center/Tulane National Primate Research Center	LA
WRCE	University of Arkansas for Medical Sciences	AR
WRCE	University of California at Davis	CA
WRCE	University of Houston	TX
WRCE	University of Illinois	IL
WRCE	University of New Mexico Health Sciences Center	NM
WRCE	University of North Texas Health Science Center	TX
WRCE	University of Oklahoma	OK
WRCE	University of Oklahoma Health Science Center	OK
WRCE	University of Texas at Austin	TX
WRCE	University of Texas at Brownsville/Texas Southmost College	TX
WRCE	University of Texas at Dallas	TX
WRCE	University of Texas at El Paso	TX
WRCE	University of Texas at San Antonio	TX
WRCE	University of Texas at Tyler	TX
WRCE	University of Texas Health Center at Tyler	TX
WRCE	University of Texas Health Science Center at Houston	TX
WRCE	University of Texas Health Science Center at San Antonio	TX
WRCE	University of Texas Medical Branch at Galveston	TX
WRCE	University of Texas Southwestern Medical Center	TX

4. Funded Institutions (Alphabetical)

Institution
Albany Medical College
Albert Einstein College of Medicine
Apath, LLC
Argonne National Laboratory
Arizona State University (WRCE)
Baylor College of Medicine
Beckman Research Inst. of the City of Hope
Beth Israel Deaconess Medical Center
Boston Medical Center
Brigham and Women's Hospital
Brown University
California Department of Health Services
California Institute of Technology
Case Western Reserve University
CC Technology, Inc.
Celldex Therapeutics, Inc.
Center for Biologics Evaluation and Research, FDA
Center for Vaccine Development University of Maryland, Baltimore
Children's Hospital Los Angeles
Colorado State University
Columbia University in the City of New York
Dartmouth College
Denver Health Medical Center
Drexel University
Duke University Medical Center
East Carolina University
Emory University
Fred Hutchinson Cancer Research Center
George Washington University
Georgetown University
Georgia Tech Research Corporation
Harvard Medical School
Harvard School of Public Health
Health Research, Inc./New York State Dept. of Health
Henry M. Jackson Foundation for the Advancement of Military Medicine
Institute for Systems Biology
Institute of Human Virology (Baltimore)
Inviragen, LLC
Joan & Sanford I. Weill Medical College of Cornell University

Institution
Johns Hopkins Bloomberg School of Public Health
Johns Hopkins University Homewood Research Administration
Kansas State University
La Jolla Institute for Allergy and Immunology
Lawrence Livermore National Laboratory
Louisiana State University Health Sciences Center
Lovelace Respiratory Research Institute
Massachusetts General Hospital
Massachusetts Institute of Technology
Mayo Clinic Rochester
Medical College of Wisconsin
Memorial Hospital of Rhode Island
Michigan State University
Molecular Sciences Institute
Montana State University
Mount Sinai School of Medicine
National Jewish Medical & Research Center
Nesher Technologies, Inc.
New York State Department of Health
New York University School of Medicine
NIAID, NIH, Laboratory of Human Bacterial Pathogenesis
Northern Arizona University
Northwestern University
Ohio State University (WRCE)
Ohio State University Research Foundation (GLRCE)
Oregon Health & Science University
Oregon State University
Precision Photonics Corporation
Public Health Foundation Enterprises, Inc.
Purdue University
Research Foundation of the State University of New York
Research Institute for Children
Rockefeller University
RxKinetix, Inc.
Saint Louis University
Sandia National Laboratories
Scripps Research Institute
SomaLogic, Inc.
Southern Research Institute
Southwest Foundation for Biomedical Research
St. Jude Children's Research Hospital
Stanford University
State University of New Jersey, Rutgers

Institution
Stony Brook University School of Medicine
Texas A&M University System Health Sciences Center
Texas Agricultural Experiment Station
The Center for Blood Research
The Children's Hospital
The TAMUS Health Science Center Research Foundation
Trudeau Institute, Inc.
Tufts University
University Hospitals of Cleveland
University of Alabama at Birmingham
University of Alaska, Fairbanks
University of California, Berkeley
University of California, Davis
University of California, Los Angeles
University of California, San Diego
University of California, San Francisco
University of California, Santa Barbara
University of Chicago
University of Cincinnati (GLRCE)
University of Colorado Health Sciences Center
University of Florida
University of Hawaii at Manoa
University of Houston
University of Idaho
University of Illinois
University of Illinois Urbana-Champaign
University of Iowa (MRCE)
University of Kansas Center for Research
University of Kentucky Research Foundation
University of Maryland, Baltimore
University of Massachusetts Dartmouth
University of Massachusetts Medical School
University of Medicine and Dentistry of New Jersey
University of Michigan
University of Michigan (SERCEB)
University of Missouri
University of Montana
University of Nebraska-Lincoln
University of Nevada, Reno
University of New Mexico Health Science Center
University of North Carolina at Chapel Hill
University of North Dakota
University of Oklahoma
University of Oregon

Institution
University of Pennsylvania
University of Pittsburgh
University of Puerto Rico
University of South Alabama
University of Tennessee
University of Texas at Austin
University of Texas at El Paso
University of Texas Health Science Center at Houston
University of Texas Health Science Center at San Antonio
University of Texas Medical Branch
University of Texas San Antonio
University of Texas Southwestern Medical Center at Dallas
University of Utah
University of Vermont
University of Virginia
University of Washington
University of Wisconsin
University of Wyoming
Utah State University
Vanderbilt University Medical Center
Virginia Commonwealth University
Virginia Polytechnic Institute & State University
Wake Forest University Health Sciences
Washington University
West Virginia University Research Corporation
Wichita State University
William Marsh Rice University
Yale University

5. Additional Graphs on Frequency and Numbers of Participants for Various Meeting Types Held by Centers

Figure 1. Leadership/Management: Meeting Frequency.

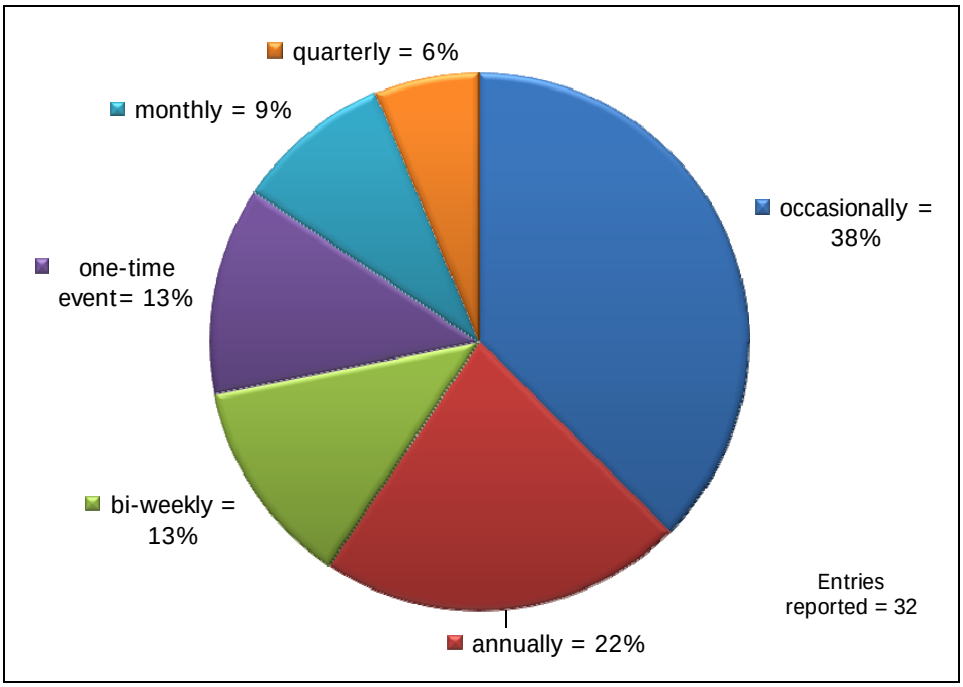


Figure 2. Leadership/Management: Estimated Number of Attendees.

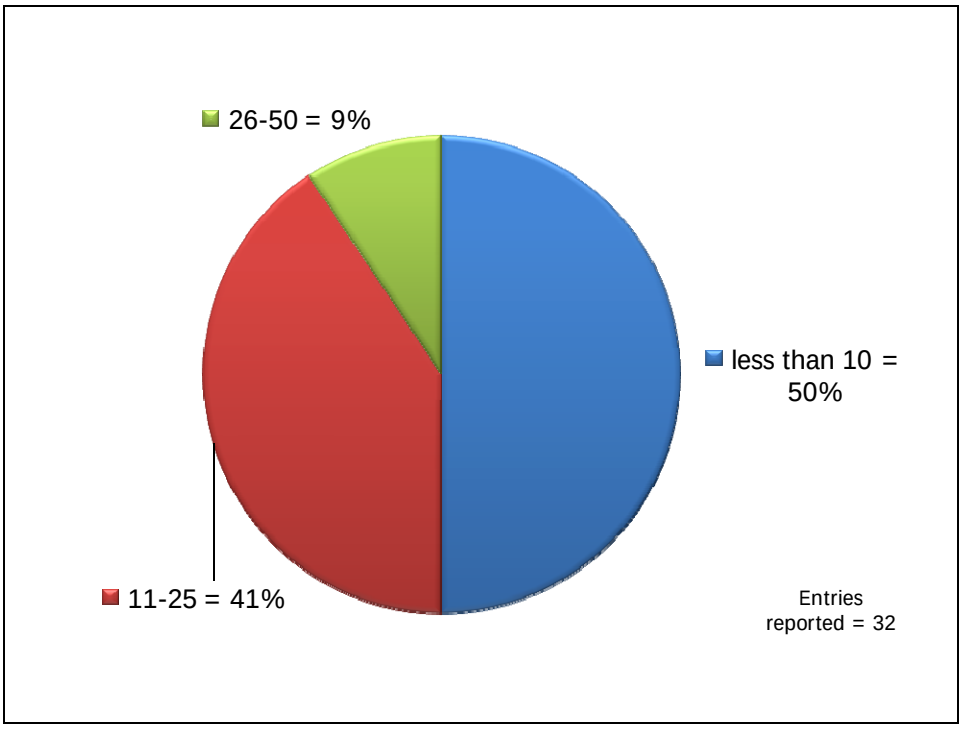


Figure 3. Scientific Agenda Setting: Meeting Frequency.

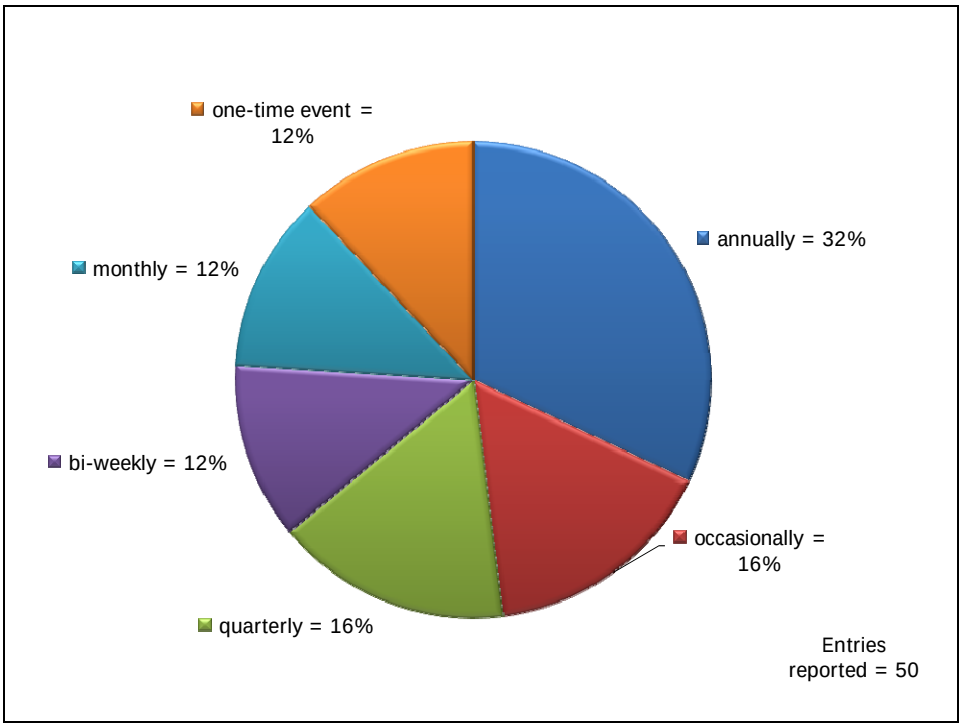


Figure 4. Scientific Agenda Setting: Estimated Number of Attendees.

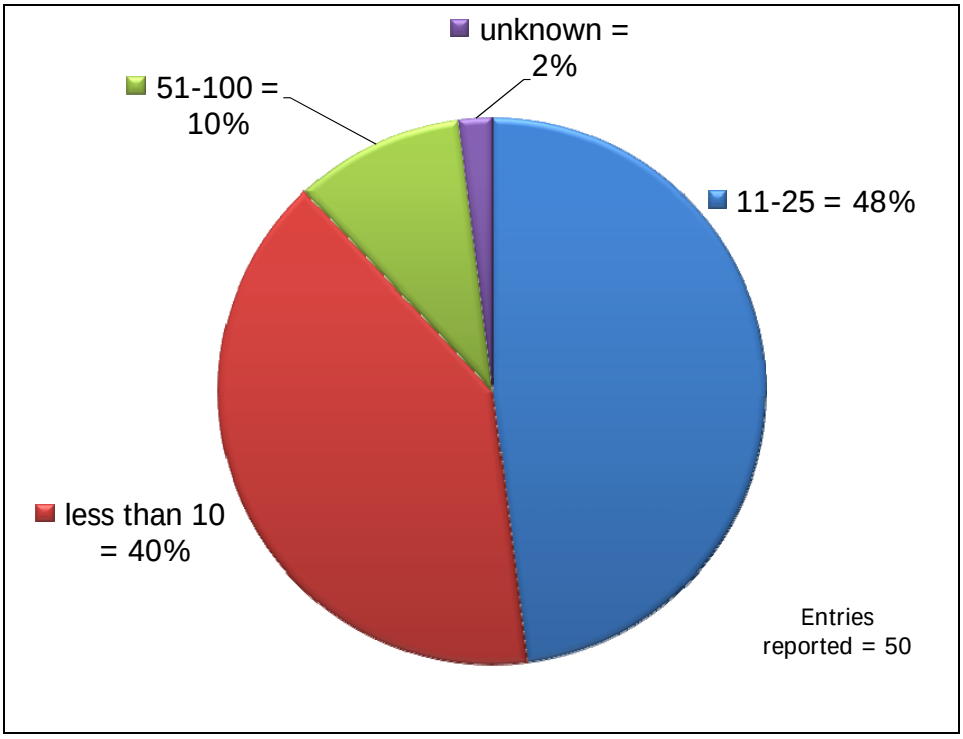


Figure 5. Workshop: Meeting Frequency.

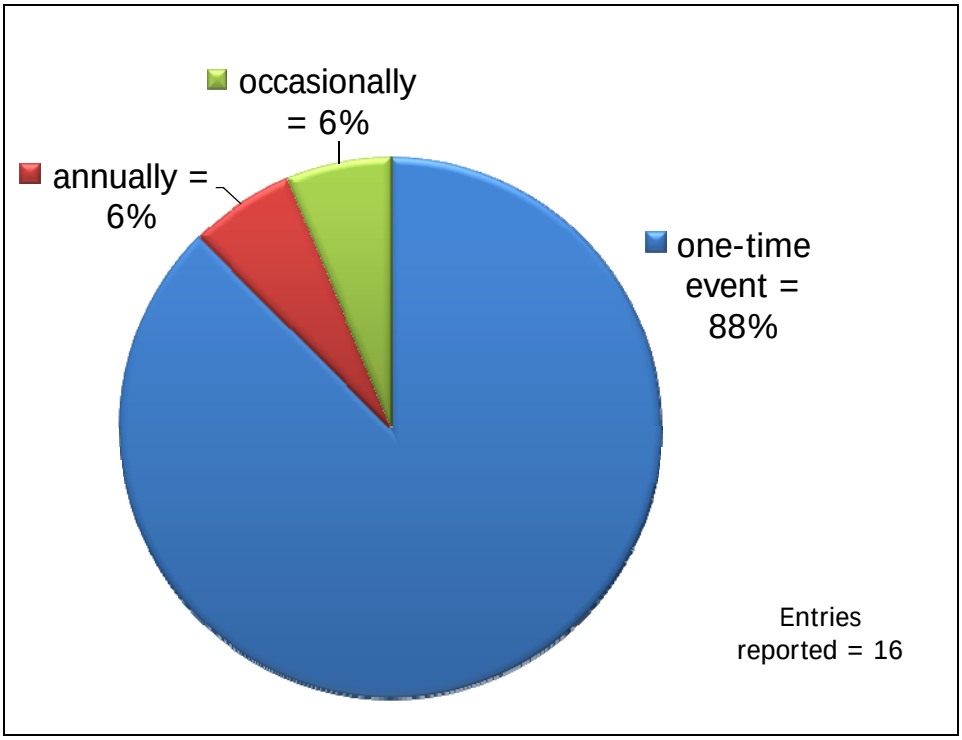


Figure 6. Workshop: Estimated Number of Attendees.

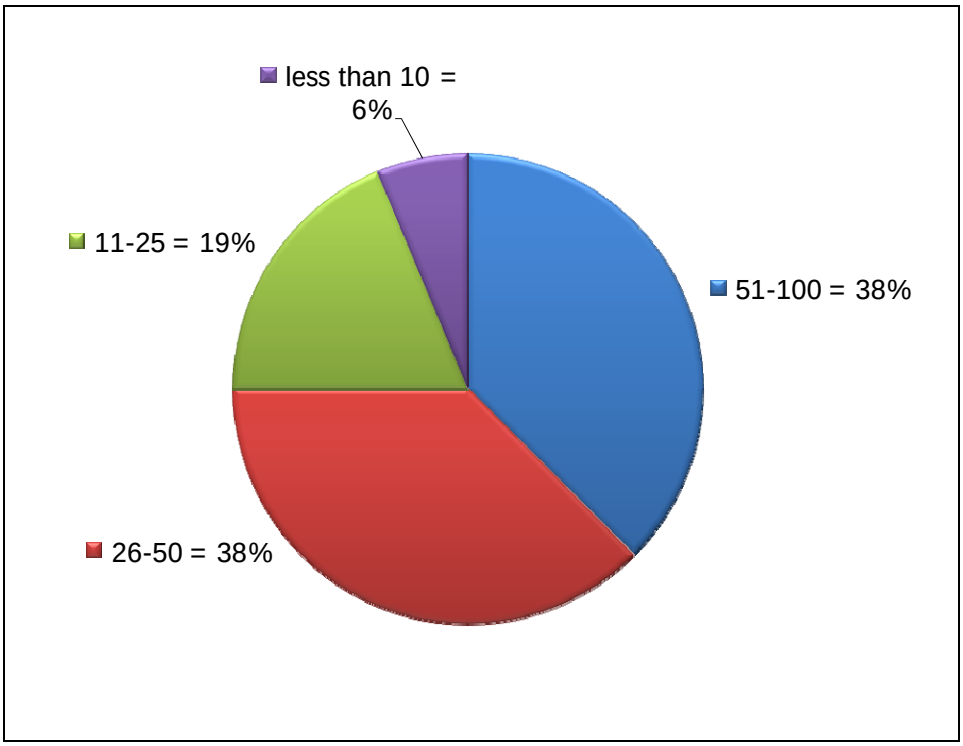


Figure 7. Seminar: Meeting Frequency.

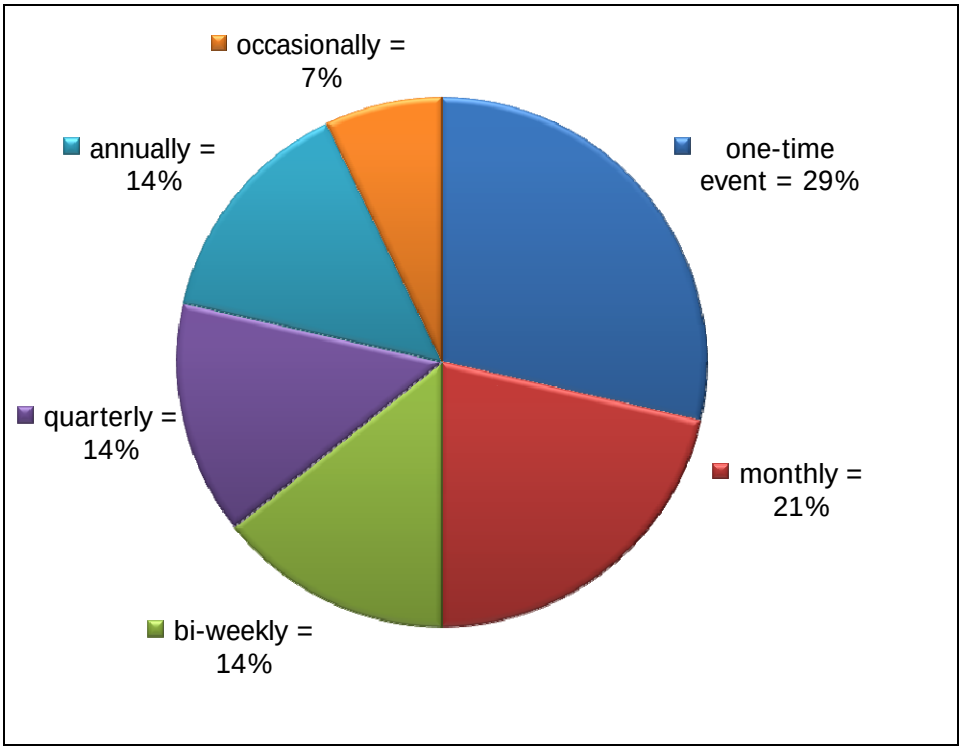


Figure 8. Seminar: Estimated Number of Attendees.

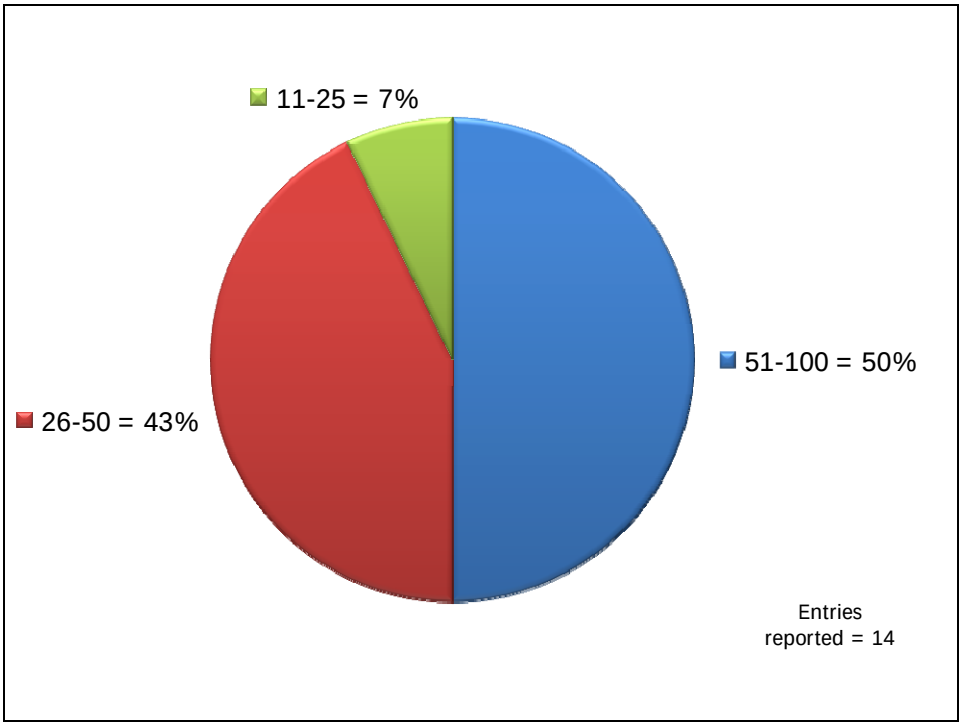


Figure 9. Conference: Meeting Frequency.

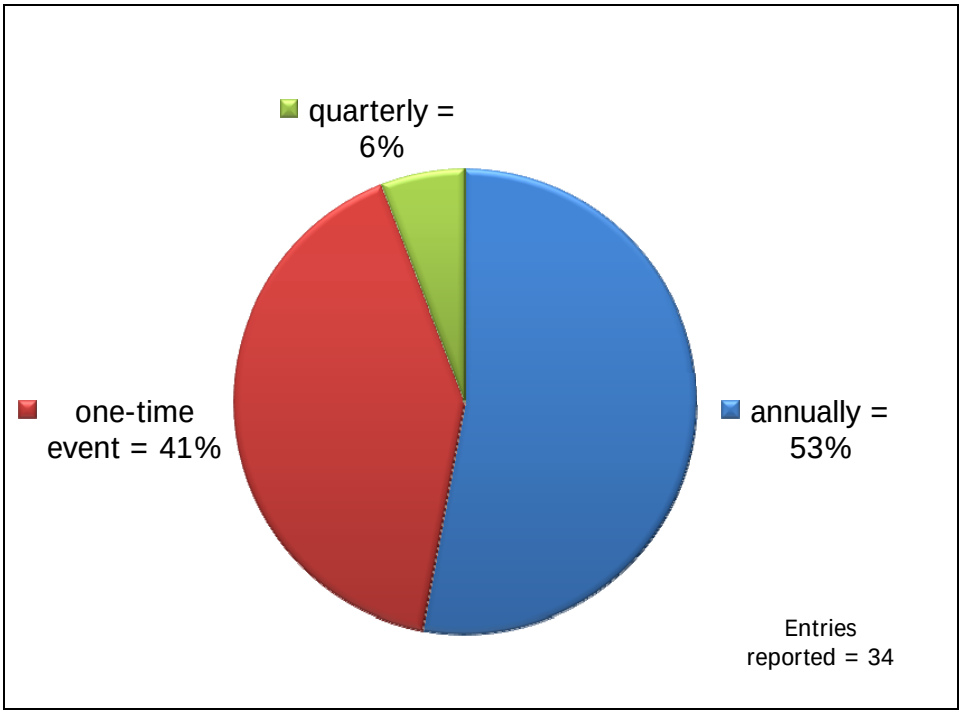


Figure 10. Conference: Estimated Number of Attendees.

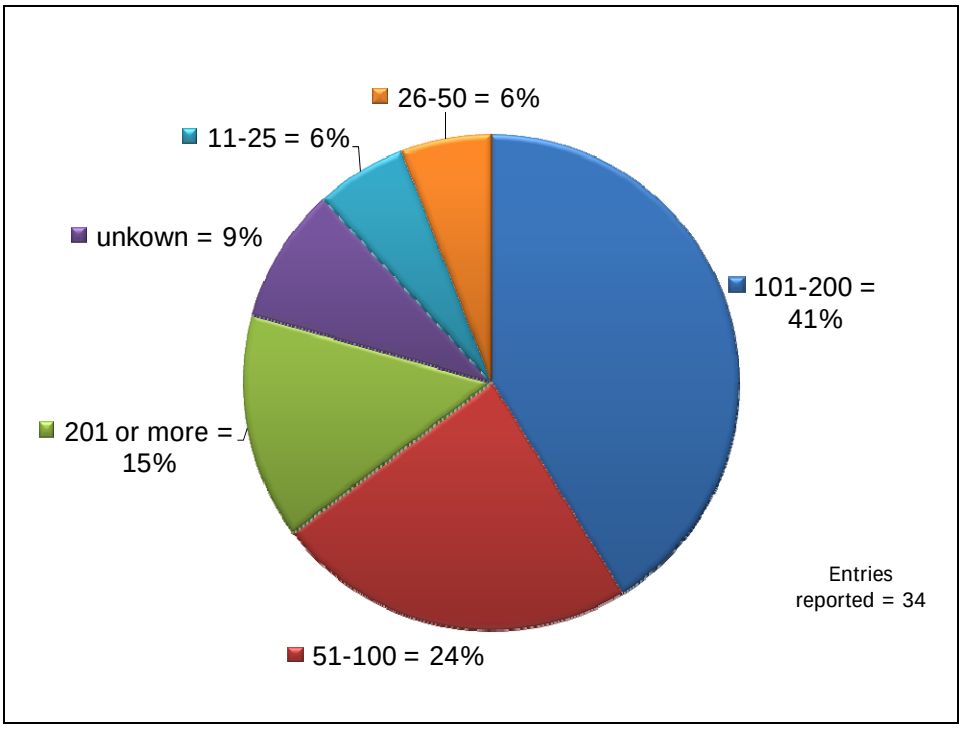


Figure 11. Training Course: Meeting Frequency.

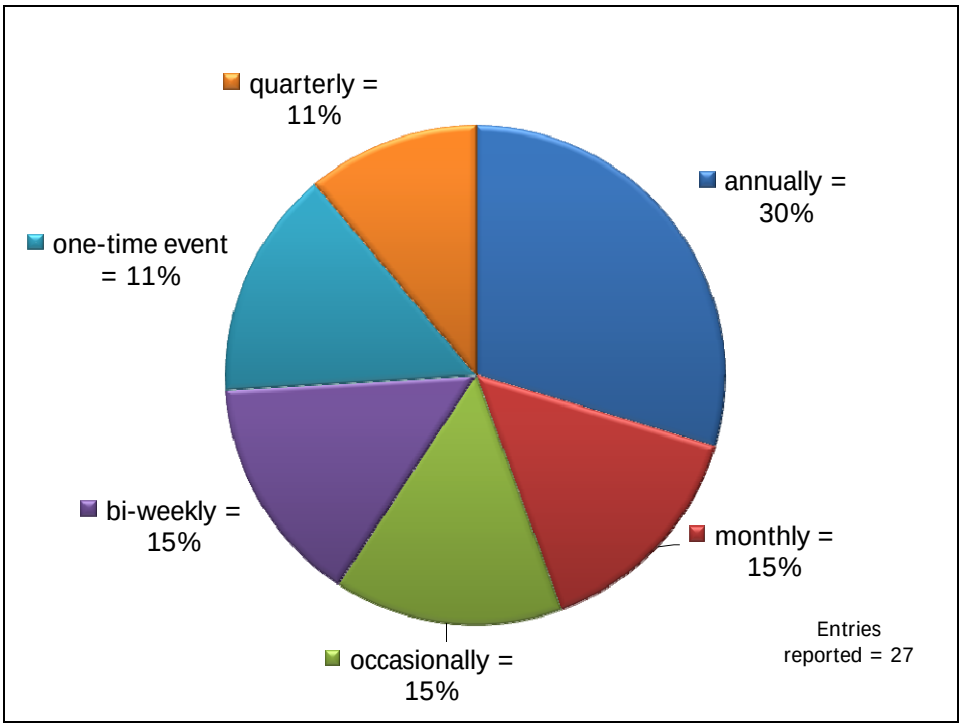
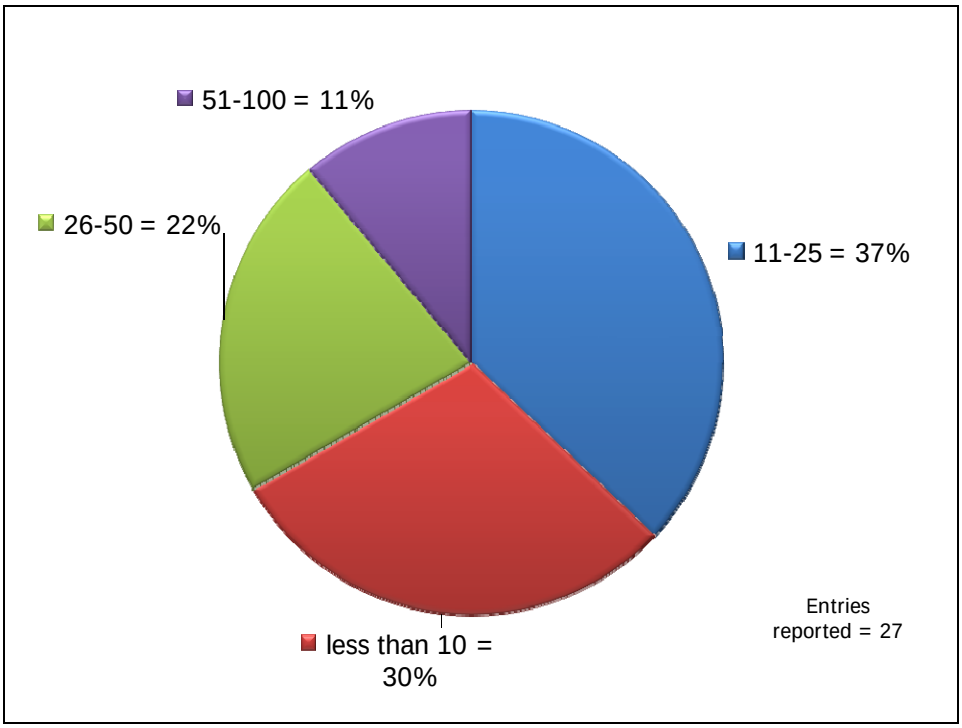


Figure 12. Training Course: Estimated Number of Attendees.



6. Additional Graphs Illustrating the RCE Portfolio Relative to the NIAID Portfolio, by Agent

Figure 1. RCE and NIAID Projects Addressing Yersinia pestis by Fiscal Year.

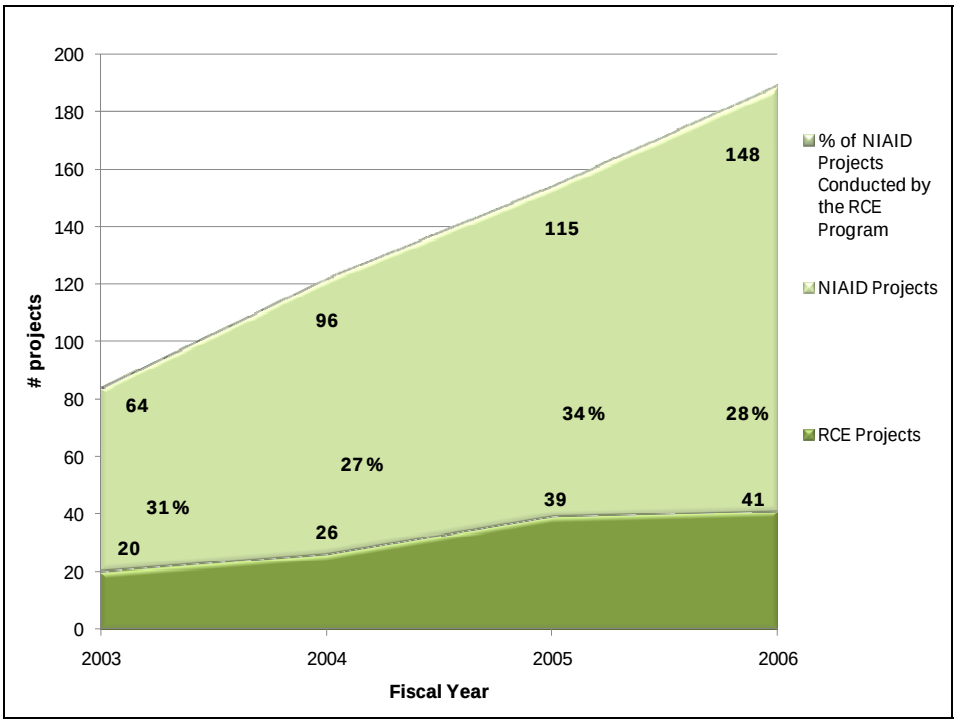


Figure 2. RCE and NIAID Projects Addressing Botulinum toxin by Fiscal Year.

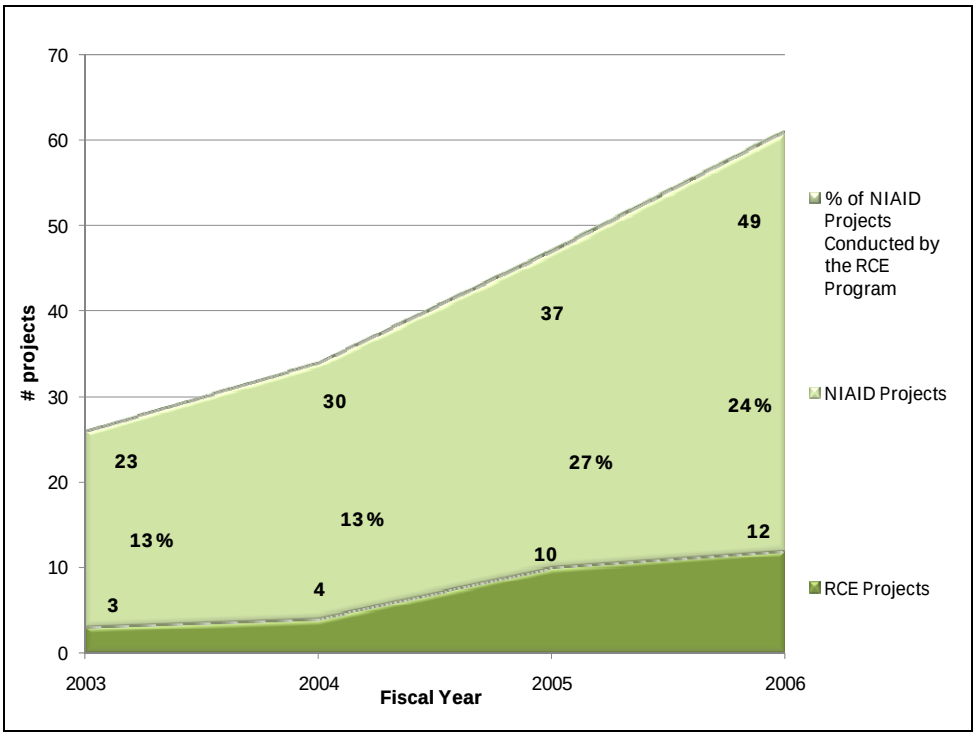


Figure 3. RCE and NIAID Projects Addressing Anthrax by Fiscal Year.

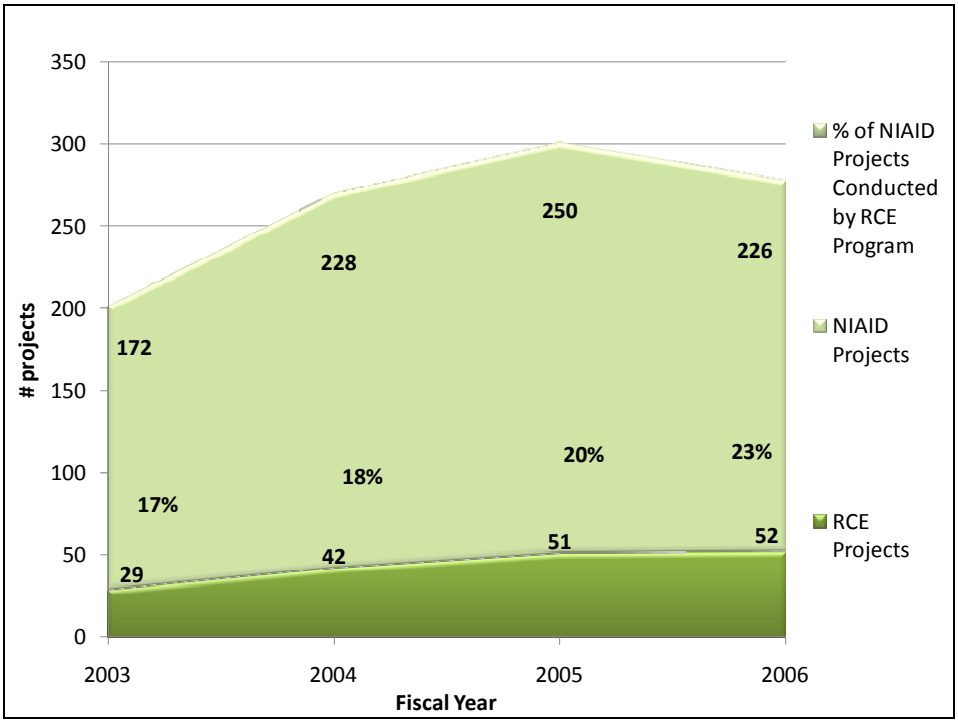


Figure 4. RCE and NIAID Projects Addressing Poxviruses by Fiscal Year.

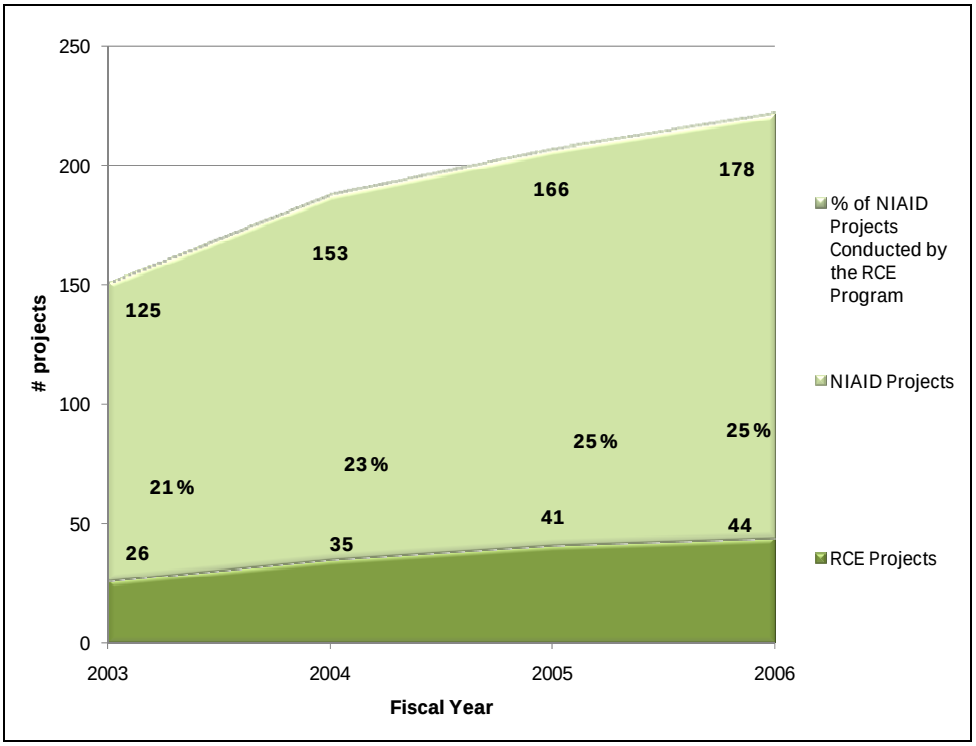


Figure 5. RCE and NIAID Projects Addressing Francisella tularensis by Fiscal Year.

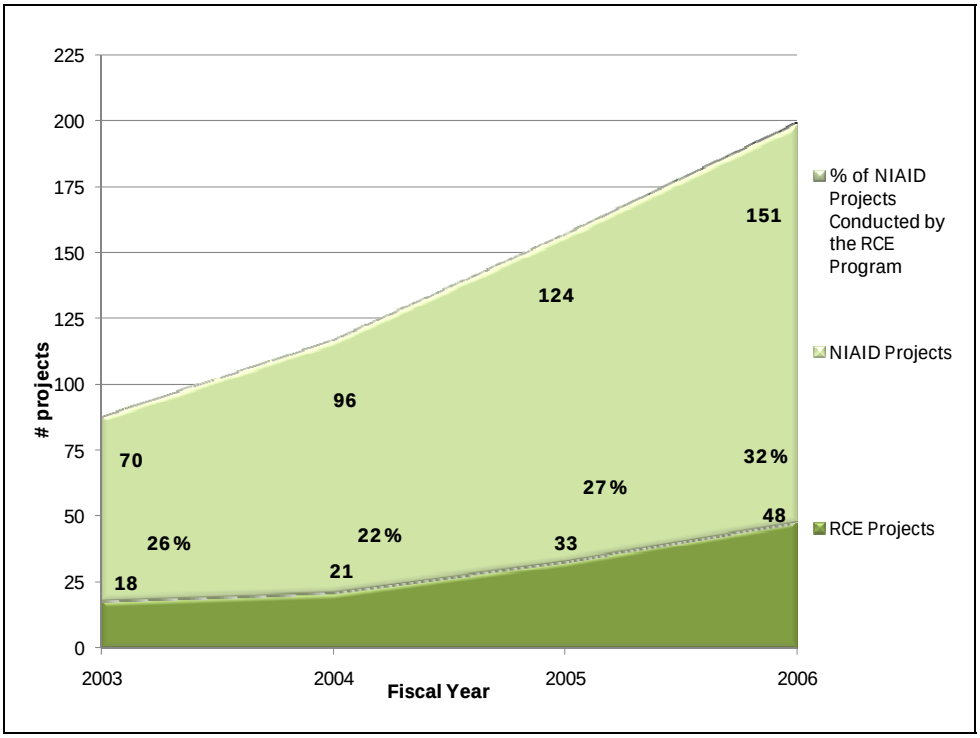


Figure 6. RCE and NIAID Projects Addressing Ebola by Fiscal Year.

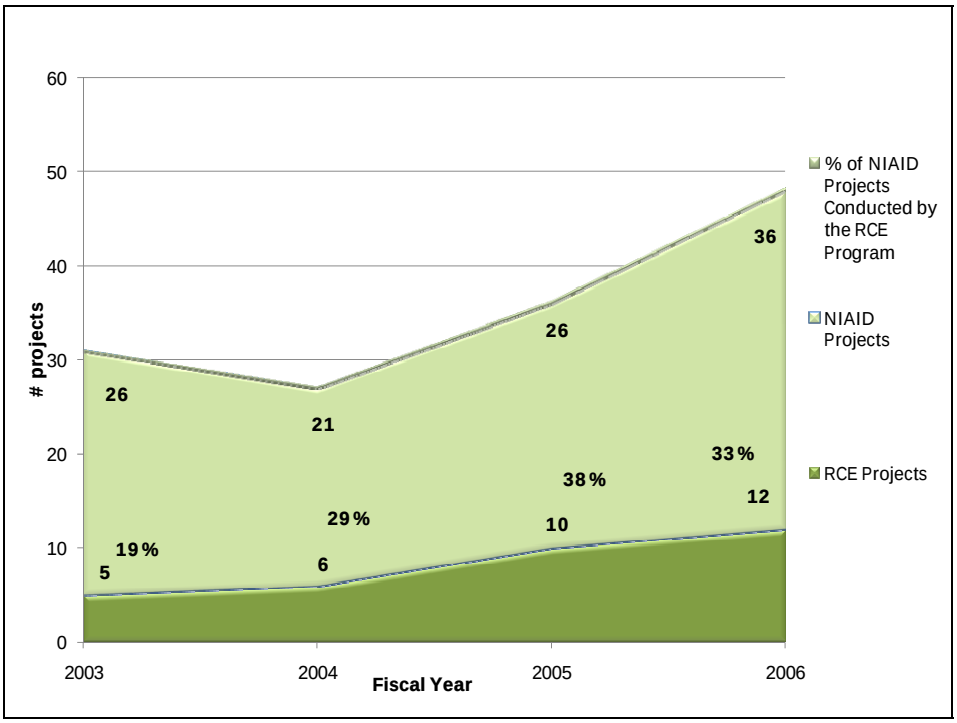
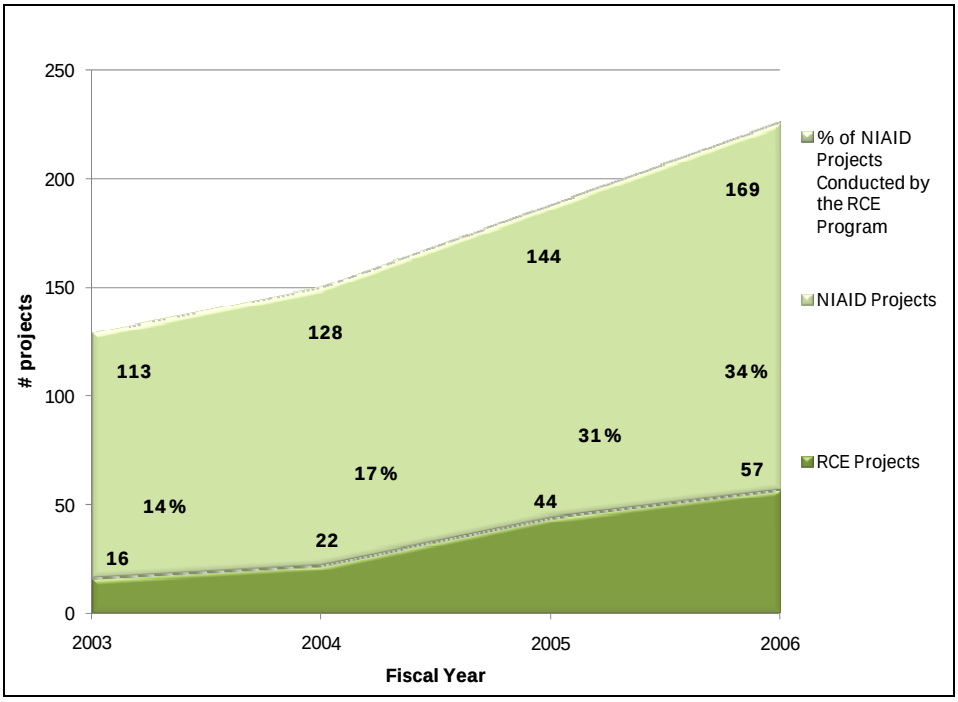


Figure 6. RCE and NIAID Projects Addressing Category A Viral Hemorrhagic Fevers by Fiscal Year



7. Additional Graphs Illustrating the RCE Portfolio Relative the NIAID Portfolio, by Type of Research

Figure 1. RCE and NIAID Basic Research Projects by Fiscal Year.

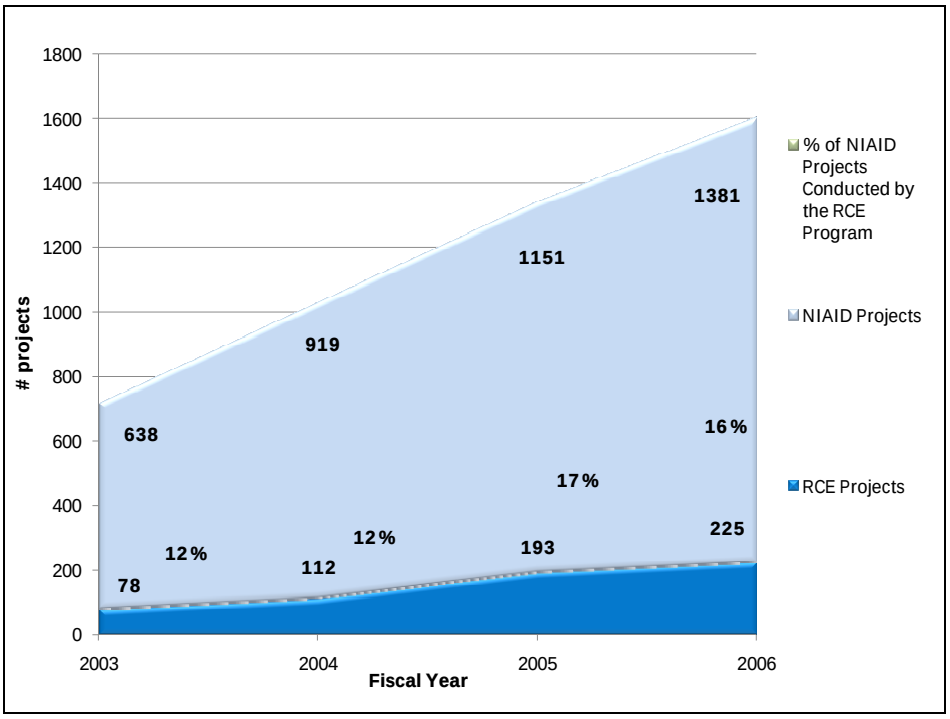


Figure 2. RCE and NIAID Diagnostics Projects by Fiscal Year.

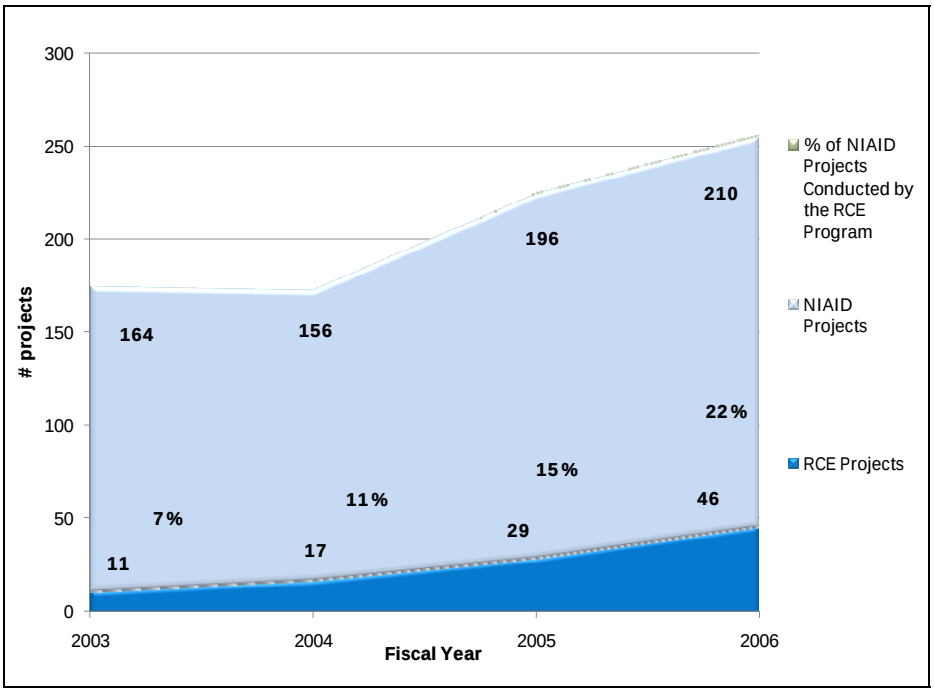


Figure 3. RCE and NIAID Vaccines Projects by Fiscal Year.

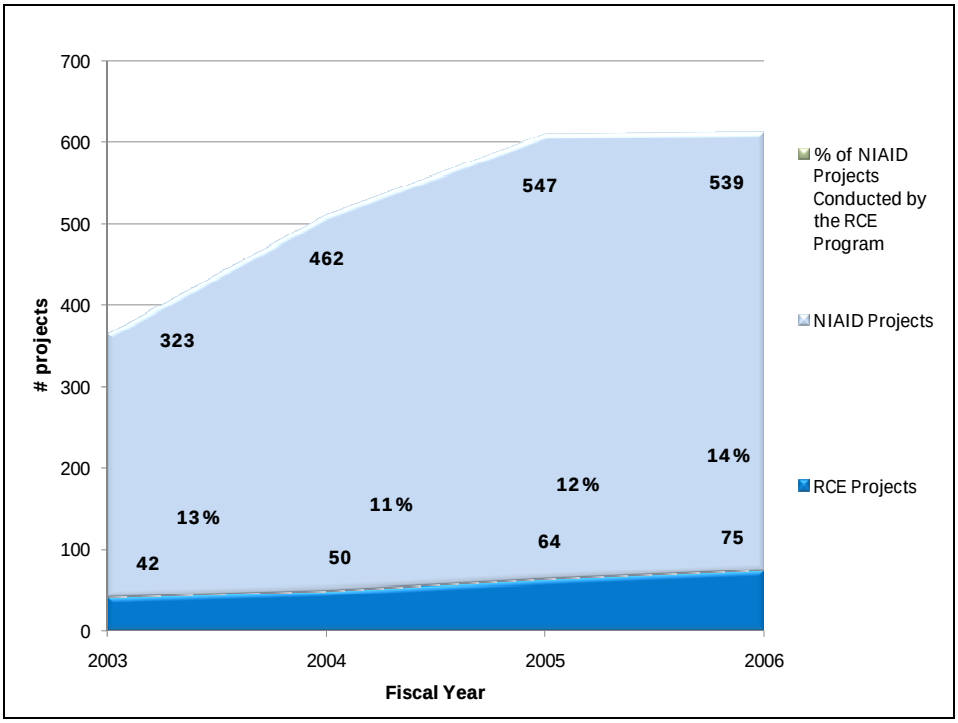
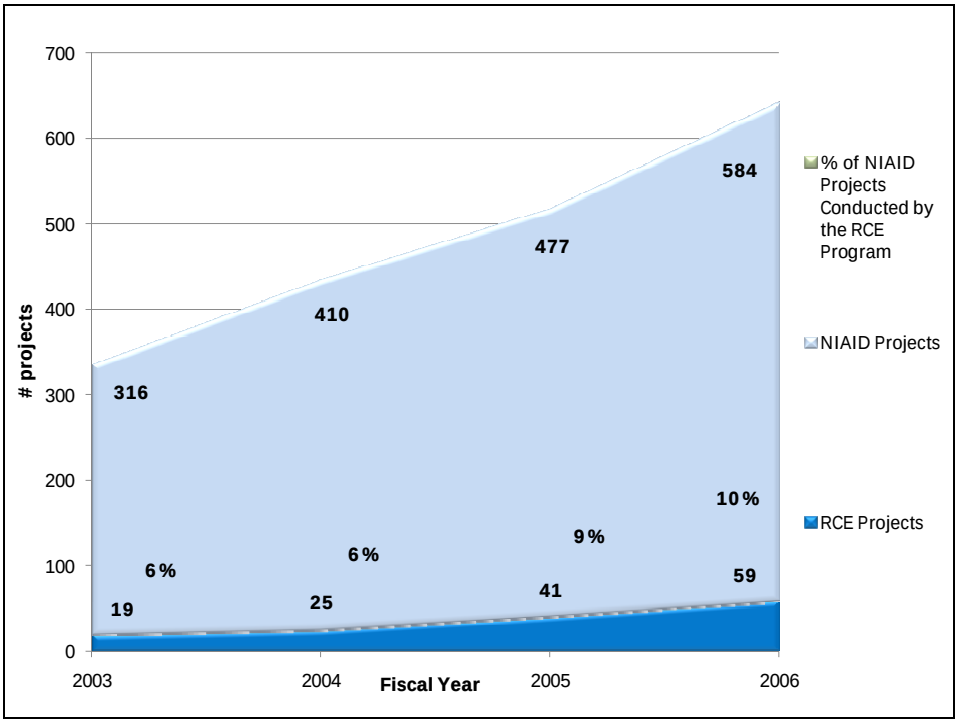


Figure 4. RCE and NIAID Therapeutics Projects by Fiscal Year.



8. Bibliometric Analyses of RCE Program Publications: Further Details

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I. Background

Bibliometric analysis involves the quantitative assessment of scientific publications, the works they cite, and the citations of them. Citations are made in published scientific work to acknowledge the prior relevant work of other scientists. When one document (A) mentions or refers to another document (B) the latter has been cited by the former as a source of information, as support for a point of view, as authority for a statement of fact, etc. The term *citation* is used to indicate that document B has been cited in a reference of document A. Articles that refer to another are termed *citing* articles. Articles that an article refers to are called *cited* articles. If article A has a reference to article B, we would say that B has a citation from A, A is a citing article of B and that B is a cited article of A.

Bibliometric analysis is a critically important source of objective information about the outputs of scientific work. It can be used to estimate the influence and impact of a single publication, or the recognition of the entire published opus of a researcher, a research journal, or even a field of research. As in any statistical endeavor, bibliometric analysis has the potential to generate misleading and biased results. It can only be applied to the published literature in journals that are indexed with respect to citations – it does not cover unpublished works, works in un-indexed journals, and non-journal printed works such as books, dissertations, reports, or government documents. It treats citations as equal, regardless of whether a work is being cited for its positive contribution to a field or being criticized as for its negative impact or poor quality. Different authors employ differing levels of care in compiling references. Some authors cite liberally, others sparingly. Some fields and disciplines have traditions that cite more broadly, others more narrowly.

Even given these potential sources of error, bibliometric analysis has emerged in the past few decades as a serious and growing endeavor that can help illuminate scientific influence and impact. The social system of scientific peer review helps to restrain and moderate the use of unjustifiable citations, and helps assure that publications that appear in the literature meet basic standards of scientific quality. And, while citations of any specific publication may be misleading, analyses of hundreds or thousands of articles and citations is likely to help mitigate specific error and provide some framework for comparative analysis that has stronger credibility and validity.

Bibliometric analysis is used in the RCE evaluation as one source of input about scientific productivity and impact, not as a sole determiner. When coupled with other sources of evidence it can help provide a pattern of evidence about research contributions.

II. Sample

All publications that directly arise from the ten RCE centers for the first five years of the initiative were eligible for inclusion in this bibliometric analysis. However, it is important to recognize that, because it takes time for accepted publications to actually be published, for the published articles to be indexed, and for the articles to be cited and their citations indexed, this analysis will underestimate real productivity (especially more recent).

There may be considerable variability in the criteria used by different individual researchers and different RCEs about whether a publication arises from RCE work. In the absence of a clearly agreed upon definition, some objective, defensible criteria must be established. A reasonable criterion is whether an RCE grant is cited as a source of support in the acknowledgments section of the publication. While this may lead to a conservative estimate of publications (because authors may

have forgotten to include the necessary citations to the grant) it will help establish this practice as a normative henceforth and improve the quality of subsequent evaluations.

Thus, RCE publications were identified through a PubMed search for each of the 10 RCE grant numbers up until July 11, 2007. Researchers are expected to – and have been explicitly instructed – to reference the grant number on any publications that are supported by an RCE grant. Articles were not reviewed for relevance to RCE work or compared to Progress Report data in which the RCEs report their publications for the year. Thus, any publication that referenced an RCE grant number was included in the analysis. Through this search, 501 publications were identified.

Each publication (in this case, each journal article published by RCE authors) has a unique code that identifies the article in the bibliometric database. The Web of Science database (http://scientific.thomson.com/products/wos/ was used for all bibliometric analysis. This database encompasses the Science Citation Index-Expanded, the Social Science Citation Index and the Arts & Humanities Citation Index. The Web of Science is the standard leading data source for bibliometric citation analysis. This database is used by the National Science Foundation in their science and engineering indicators and by other international indicator publications.

In the year ending 2006, over 33 million citations were processed for inclusion in the Web of Science database, drawn from over 1.65 million titles. The majority of these citations (66%) are from ISI-indexed documents, including over 8800 journals which are the top tier scholarly journals in over 200 fields. A complete list of the ISI-indexed journals is available at http://scientific.thomson.com/mjl/. ISI also captures all materials that appear in the bibliographies of indexed articles. Thus, the remaining approximately 34% of the citations are from non-ISI indexed cited references such as cited books, technical reports, government material, as well as individually cited book chapters.

When ISI indexes publications, they categorize the article by type into general categories like editorials, letters, reports, correction notes, reviews, etc. In this report, we examine all publications and conduct separate analyses by the "research" type which is the only type of category subgroup with sufficient numbers to warrant analysis.

Twenty four (24) articles from the original PubMed database were not included in the analysis because data was not available about them on the Web of Science, either because the publication is not indexed on ISI or that particular issue of the journal had not been processed.

III. Measures

The following variables were extracted for each RCE publication:

Type of Publication: Indicates whether the publication is a research article, review, editorial material, a proceedings paper, etc.

Publication Year: The official year publication was published.

Citations: Represents the number of publications that have cited the article.

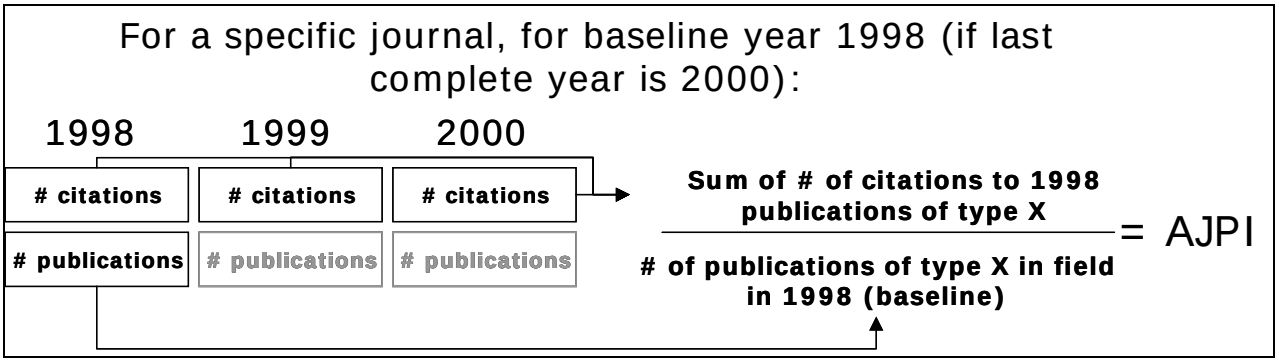
Self-Citations: A measure used to identify citing papers that have one or more authors in common with the authors of the source paper. A self-citation is counted if any citing author is

identical to any cited author. Since many articles have multiple authors, and not all authors will be RCE researchers, a self-citation may involve a citation of an article by a non-RCE co-author.

Adjusted Citations: This represents the number of total citations minus the number of self-citations. This correction mitigates the possibility that an author can inflate their own citation rates by frequently citing their own work.

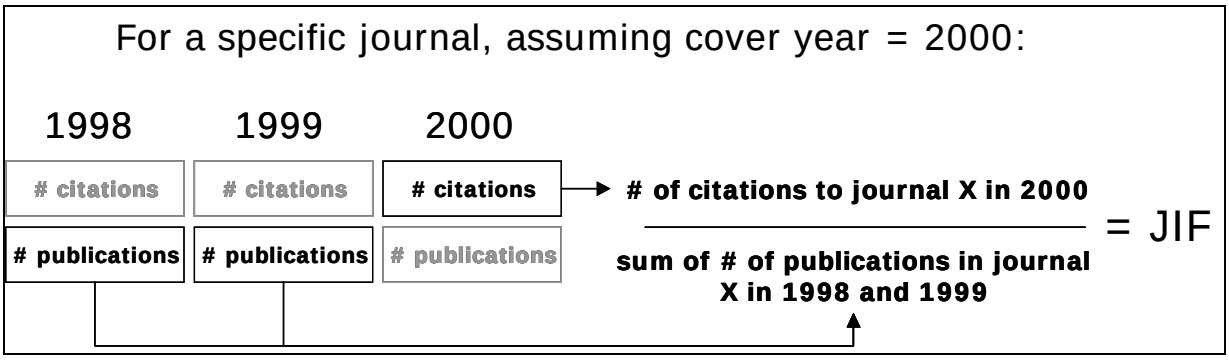
Expected Citations (Adjusted Journal Performance Indicator, AJPI): The average total number of citations of a certain article type (abstract, article, review, note, etc.) published in a specific journal cumulatively by the most recent completed year (Figure 1). This variable is also sometimes referred to as the Adjusted Journal Performance Indicator (AJPI). It is identical to the Journal Performance Indicator (JPI) (see below), except that it is specific to the article type (article, editorial, review, etc.). Consequently it is a more rigorous and exacting criterion for comparison than the JPI. As an example, an expected citation value of 1.98 for a specific publication in 1998 in Journal X means that for every article of that type (e.g., research article) published in Journal X in 1998, there has cumulatively been an average of 1.98 citations thus far. If a single publication has been cited two or more times, it is being cited at a higher than average rate for comparable types of articles from the same journal published in the same year.

Figure 1. Computation of the Expected Citations or Adjusted Journal Performance Indicator (AJPI).



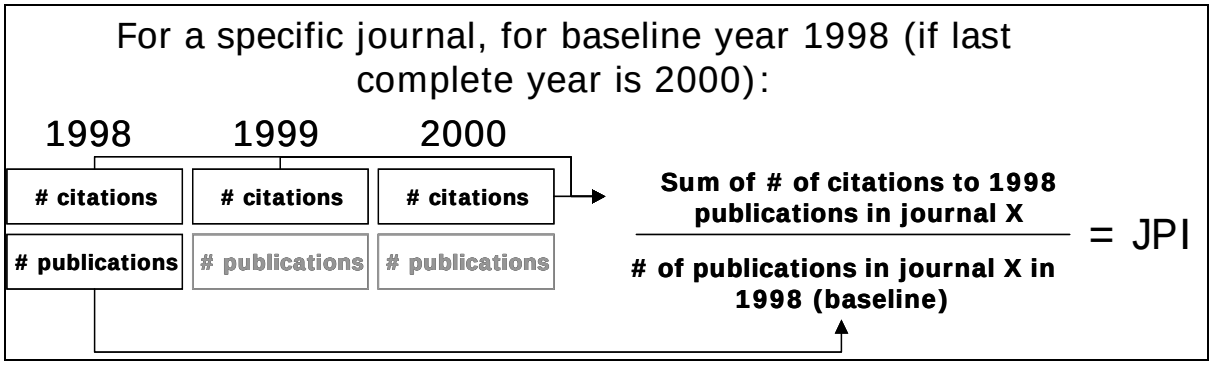
Journal Impact Factor (JIF): The average number of citations during the current (or "cover") year of all articles published in the previous two year for that journal (see Figure 2). For example, a Journal Impact Factor (JIF) of 4.9 for the cover year of 2000 means that in the year 2000 there was an average of 4.9 citations for each article published in the prior two years (1998-99). This variable is useful for comparing journal impacts, but not for estimating expected impact for a specific publication. It reflects the current impact of the journal but does not reflect as well what would have been expected for articles published in that journal in a specific prior year. It is meaningful, however, to look at the average JIF of a set of publications to estimate the current impact of journals published.

Figure 2. Computation of the Journal Impact Factor (JIF).



Journal Performance Indicator (JPI): This represents the average number of citations for all articles of a specific journal that were published in a particular year (called the "baseline" year). For example, a JPI of 2.15 for baseline year 1998 for journal X denotes that for every article published in journal X in 1998, there has cumulatively been an average of 2.15 citations since that time. The computation is shown graphically in Figure 3. The difference between the JPI and the AJPI, or Expected Citations (see above), is that the JPI is computed for the entire journal and includes all types of articles in the journal; the AJPI is computed for each specific type of article for a journal. Consequently, while not as narrow as the AJPI, the JPI is a useful general index of journal performance.

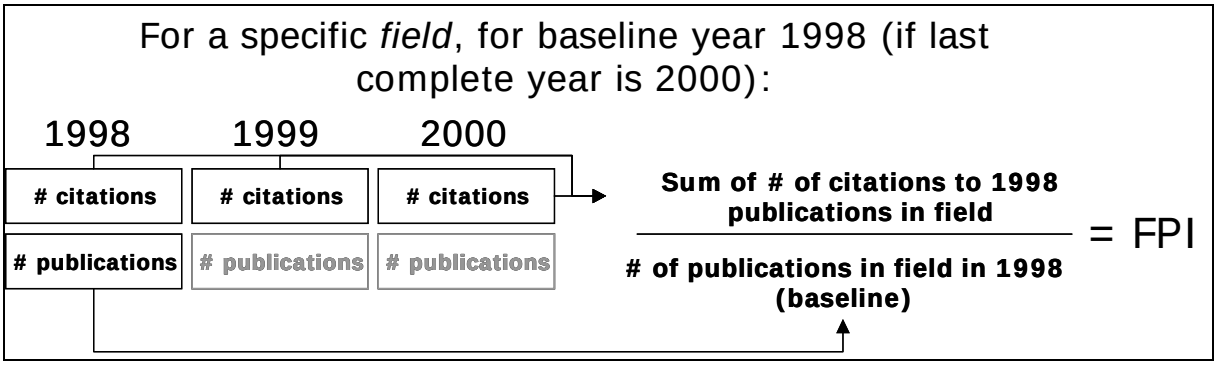
Figure 3. Computation of the Journal Performance Indicator (JPI).



Field Performance Indicator (FPI): The FPI is identical to the JPI except that it is calculated across all journals in a specific field rather than for one journal (Figure 4). The ISI Current Contents (CC) field definitions are used to determine a field. The Current Contents database classifies each journal into one or more of approximately 200 fields or disciplines. The FPI is the average number of citations for all articles that were published in a particular year (called the "baseline" year) in all journals in a CC field. For example, if the FPI is 2.62 for baseline year 2000 for Field X, this means

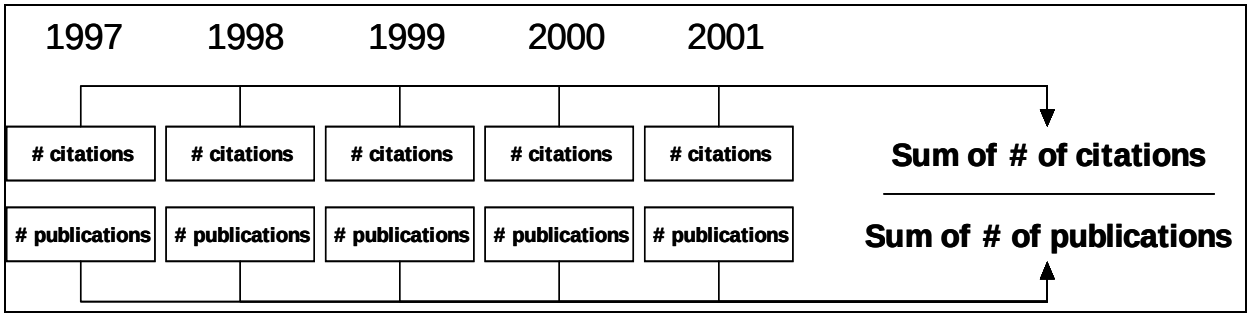
that for all articles published in all journals in Field X in 2000 there has cumulatively been an average of 2.62 citations.

Figure 4. Computation of the Field Performance Indicator (FPI).



5-Year Journal Impact Factor (JIF5). The average number of citations received by the journal over a 5-year period (based on the years 1997-2001). For example, a 5-year impact of 2.75 means that there is an average of 2.75 cites per publication for all publications for the period 1997-2001 for that journal. The computation is depicted graphically in Figure 5. You will note that while the 5-year factor variables cover all publications over the five-year period, the JIF covers only the publications in the "cover" year.

Figure 5. Computation of a 5-year impact indicator.



5-Year Field Impact Factor (FIF5): This indicator is essentially the JIF5 computed across all journals in a CC field. This is also sometimes referred to as the "baseline" 5-year impact. The computation is shown graphically in Figure 5. Note that the 5-year factor variables cover all publications over the five-year period, whereas the JIF covers only the publications in the "cover" year.

Number of Citing Journals: Refers to the number of unique journals that cite a publication.

Number of Citing Categories: The number of unique CC fields for all citing journals for a publication.

Citing 5-Year Journal Impact Factor: This is the JIF5 for all journals of the citations of a publication.

Citing 5-Year Field Impact Factor: This is the FIF5 for all fields of the citations of a publication.

Number of Cited Journals: Refers to the number of unique journals that are cited by a publication.

Number of Cited Categories: The number of unique CC fields for all journals cited by a publication.

Cited 5-Year Journal Impact Factor: This is the JIF5 for all journals that are cited by a publication.

Citing 5-Year Field Impact Factor: This is the FIF5 for all fields of the journals that are cited by a publication.

Citing Journal Disciplinarity Index (JDI): The ratio of the Number of Citing Categories divided by the Number of Citing Journals. This can be considered an index of multi-disciplinarity in that it describes the number of fields per citing article. For example, if there are 3 citing journals in a total of 4 citing fields, the Citing JDI would be 4/3 = 1.33 or 1.33 fields on average per citing journal. Higher values would indicate that the article is being cited by journals that "reach" a broader number of fields. If each citation journal represents a single unique field, the index would be 1. However, if multiple citations all address the same field, the index would be less than 1 (to the lower limit of 1/N where N is the number of citing journals), suggesting that the disciplinary reach is not as great.

Cited Journal Disciplinarity Index (JDI): The ratio of the Number of Cited Categories divided by the Number of Cited Journals. Like its counterpart for citations, this can be considered an index of multi-disciplinarity in that it describes the number of fields per *cited* article. For example, if there are 10 references in a publication and they encompass 15 unique fields, this index would be 15/10 = 1.5. Higher values would indicate that the article is citing journals that "reach" a broader number of fields. Since references in articles occur when the article is published, while citations to the article necessarily occur subsequently, this Disciplinarity Index is likely to be an earlier indicator of multi-disciplinarity than the Citing JDI.

IV. Analysis

Unit of analysis: One of the major sources of analytic confusion stems from the structure of the RCE centers and how it relates to reporting. For this evaluation, 477 unique publications have been identified that meet the criteria for a RCE-related publication and have full bibliometric data available. However, several of these publications were worked on collaboratively by researchers from different RCEs and both grant numbers were reported. The situation is depicted in Table 1. Of the 477 unique publications, most (473) were listed by only one Center. However, 4 publications were jointly listed by 2 Centers.

Table 1. Unique and listed publications by RCE.

# of Centers Listing each Publication	# of Unique Publications	# of Listed Publications
1	473	473
2	4	8
Total	477	481

The issue is essentially a unit of analysis problem, and is critical for bibliometric analysis. When analyzing data across centers or for the RCE initiative as a whole, unique publications should be used as the unit of analysis. For example, when summarizing the number of publications per year across all RCEs, each publication should only be counted once. However, for any analyses done at the Center level, publication listing should be used as the unit of analysis. For instance, if we want to compute the average number of publications per Center, we should use listed publications, in effect counting multiple listed publications separately for each of the Centers that claimed it. Following that logic, any Center-level bibliometric statistics (JIF, JPI) should be computed for listed publications. In this report, since no Center-level results are provided, all results are for unique publications only.

Partial Data: Another major analytic challenge is related to the timing of the data collection. Publications occurring throughout any given year are cited on an ongoing basis, and the indexing of this information occurs continuously. Consequently, there is always a lag of several months between a publication or citation and its incorporation into the bibliometric databases. For the RCE evaluation, we have followed convention in organizing publications by publication year (calendar year 2004 – 2007). However, because the data collection (PubMed search) for the RCE interim evaluation took place in July 2007, the most recent reports only partially cover publications for the year 2007.

The citation database was constructed in late summer, 2007. According to ISI, most of the 2006 publication data should have already been indexed by the time the database was compiled, but it is possible that some were not. Perhaps more critically, data for the current RCE year are necessarily incomplete because: a) the search was conducted is several months before the RCE year is complete; and, b) indexing for the current year is in progress. As a result, *some data such as numbers of publications and citations will certainly be underestimated*. However, data from the current year is included because it enables us to estimate publication-specific bibliometric statistics. For instance, we can still meaningfully compare the average Journal Impact Factor (JIF) for the available 2007 publications with those of previous years to see whether any trends are apparent.

V. Results

A. Number of Publications By Year

Table 2 and Figure 6 show the number of RCE publications by year. It is important to note that the 2007 total includes only the first half of that year (January to mid-July). Notably, there are a large number of publications (132 publications) for 2007, even though it is incomplete. As a point of comparison, there were 193 publications in 2006, suggesting that the RCEs are on track to publish more papers in 2007 than 2006.

Table 2. Number of publications by year.

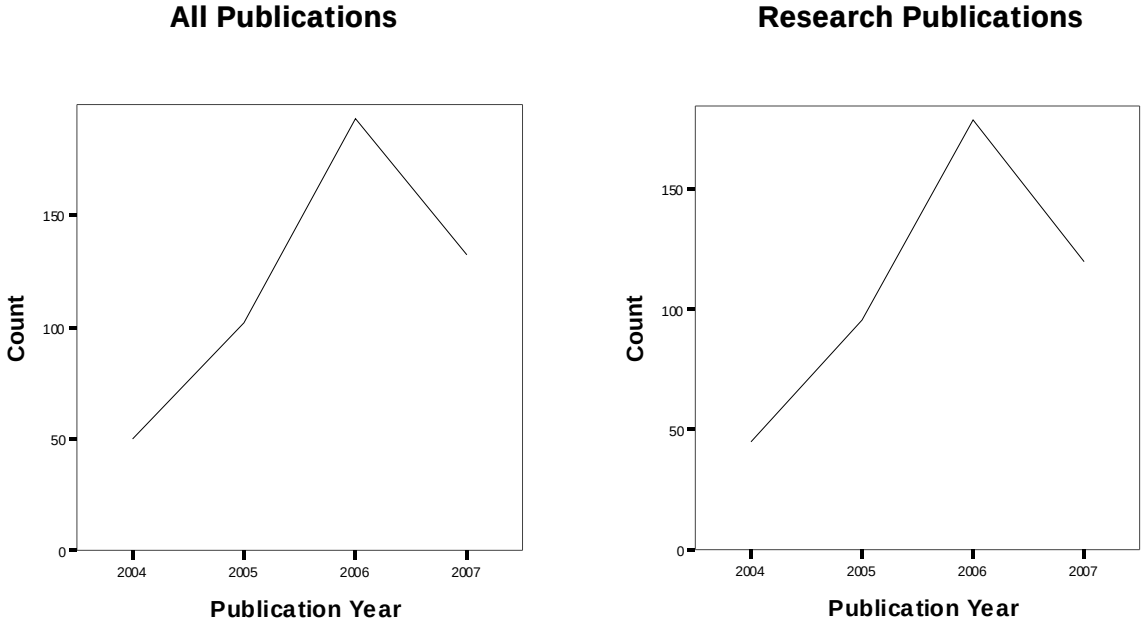
All Publications

Valid	Frequency	Percent	Valid Percent	Cumulative Percent
2004	50	10.5	10.5	10.5
2005	102	21.4	21.4	31.9
2006	193	40.5	40.5	72.3
2007	132	27.7	27.7	100.0
Total	477	100.0	100.0	

Research Publications

Valid	Frequency	Percent	Valid Percent	Cumulative Percent
2004	45	10.2	10.2	10.2
2005	96	21.8	21.8	32.0
2006	179	40.7	40.7	72.7
2007	120	27.3	27.3	100.0
Total	440	100.0	100.0	

Figure 6. Number of publications by year.



B. Summary Statistics

Descriptive statistics for all publications are shown in Table 3. On average, each publication had 5.29 citations and 4.04 citations when self-citations are removed. RCE publications appear to be located in well-cited journals. On average, over the previous two years, articles in the journals of RCE publications were cited 5.8 times (JIF). Citing journal statistics are provided only for publications that had any citations.

Table 3. Descriptive statistics for all RCE publications and only research publications.

All Publications

	N	Mean	Std. Deviation
Citations	477	5.2914	9.42713
Self Citations	477	1.2474	2.05840
Adjusted Citations	477	4.0440	8.02335
Expected Citations	477	2.4738	4.59778
Journal Impact Factor (JIF)	463	5.7899	4.83728
Journal Performance Indicator (JPI)	477	2.5285	4.65381
Journal Impact Factor 5 year (JIF5)	477	10.7120	9.06556
Field Impact Factor 5 year (FIF5)	477	7.3426	2.28484
# of Citing Journals	477	3.8910	6.24741
# of Citing Fields	477	4.2075	5.87697
Citing Journal Impact Factor- 5 year (JIF5)	476	6.7826	9.31746
Citing Field Impact Factor- 5 year (FIF5)	477	4.2731	3.70755
# of Cited Journals	477	20.1803	9.14961
# of Cited Fields	477	16.8532	6.87275
Cited Journal Impact Factor- 5 year (FIF5)	477	17.7233	8.16642
Cited Field Impact Factor- 5 year (FIF5)	477	7.9782	1.50923
Citing Journal Disciplinarity Index (JDI)	332	1.2034	.86794
Cited Journal Disciplinarity Index (JDI)	475	.8950	.32804
Difference (Citations-Expected Citations)	477	2.8176	6.81846
Valid N (listwise)	326		

Research Publications

	N	Mean	Std. Deviation
Citations	440	5.3295	9.54849
Self Citations	440	1.2523	2.07436
Adjusted Citations	440	4.0773	8.15250
Expected Citations	440	2.4651	4.59645
Journal Impact Factor (JIF)	430	5.4724	4.22893
Journal Performance Indicator (JPI)	440	2.5222	4.66223
Journal Impact Factor 5 year (JIF5)	440	10.3448	8.17539
Field Impact Factor 5 year (FIF5)	440	7.3262	2.23119
# of Citing Journals	440	3.9250	6.36593
# of Citing Fields	440	4.2091	5.86732
Citing Journal Impact Factor- 5 year (JIF5)	439	6.7491	9.30214
Citing Field Impact Factor- 5 year (FIF5)	440	4.2732	3.69563
# of Cited Journals	440	19.6568	7.84200
# of Cited Fields	440	16.5841	6.28026
Cited Journal Impact Factor- 5 year (FIF5)	440	17.5916	7.80057
Cited Field Impact Factor- 5 year (FIF5)	440	8.0267	1.38318
Citing Journal Disciplinarity Index (JDI)	309	1.2004	.87879
Cited Journal Disciplinarity Index (JDI)	440	.8948	.31175
Difference (Citations-Expected Citations)	440	2.8645	6.76562
Valid N (listwise)	305		

C. Frequency Distributions

The frequency distributions for citations are shown in Table 4 for citations, Table 5 for self-citations and Table 6 for adjusted citations (citations minus self-citations). As expected for publications as recent as these, many (145) publications have not yet been cited. Of those not cited, the majority (99) were published in 2007. However, this means that in the first 4 years of the RCE initiative, nearly 70% of the publications have been cited at least one time by other publications.

Table 4. Frequency distribution of the number of citations (coded by frequency ranges) per publication.

All Publications

Valid	Frequency	Percent	Valid Percent	Cumulative Percent
0	145	30.4	30.4	30.4
1 to 5	198	41.5	41.5	71.9
6 to 10	66	13.8	13.8	85.7
11 to 15	26	5.5	5.5	91.2
16 to 20	15	3.1	3.1	94.3
21 to 50	25	5.2	5.2	99.6
> 50	2	.4	.4	100.0
Total	477	100.0	100.0	

Research Publications

Valid	Frequency	Percent	Valid Percent	Cumulative Percent
0	131	29.8	29.8	29.8
1 to 5	187	42.5	42.5	72.3
6 to 10	58	13.2	13.2	85.5
11 to 15	24	5.5	5.5	90.9
16 to 20	15	3.4	3.4	94.3
21 to 50	23	5.2	5.2	99.5
> 50	2	.5	.5	100.0
Total	440	100.0	100.0	

Table 5. Frequency distribution of the number of self-citations per publication.

All Publications

Valid	Frequency	Percent	Valid Percent	Cumulative Percent
.00	253	53.0	53.0	53.0
1.00	85	17.8	17.8	70.9
2.00	55	11.5	11.5	82.4
3.00	35	7.3	7.3	89.7
4.00	15	3.1	3.1	92.9
5.00	12	2.5	2.5	95.4
6.00	6	1.3	1.3	96.6
7.00	9	1.9	1.9	98.5
8.00	4	.8	.8	99.4
10.00	1	.2	.2	99.6
15.00	1	.2	.2	99.8
19.00	1	.2	.2	100.0
Total	477	100.0	100.0	

Research Publications

Valid	Frequency	Percent	Valid Percent	Cumulative Percent
.00	230	52.3	52.3	52.3
1.00	83	18.9	18.9	71.1
2.00	51	11.6	11.6	82.7
3.00	31	7.0	7.0	89.8
4.00	14	3.2	3.2	93.0
5.00	11	2.5	2.5	95.5
6.00	5	1.1	1.1	96.6
7.00	8	1.8	1.8	98.4
8.00	4	.9	.9	99.3
10.00	1	.2	.2	99.5
15.00	1	.2	.2	99.8
19.00	1	.2	.2	100.0
Total	440	100.0	100.0	

Table 6. Frequency distribution of the number of adjusted citations (citations minus self-citations) per publication.

All Publications

Valid	Frequency	Percent	Valid Percent	Cumulative Percent
0	184	38.6	38.6	38.6
1 to 5	195	40.9	40.9	79.5
6 to 10	49	10.3	10.3	89.7
11 to 15	19	4.0	4.0	93.7
16 to 20	8	1.7	1.7	95.4
21 to 50	20	4.2	4.2	99.6
> 50	2	.4	.4	100
Total	477	100	100	

Research Publications

Valid	Frequency	Percent	Valid Percent	Cumulative Percent
0	169	38.4	38.4	38.4
1 to 5	181	41.1	41.1	79.5
6 to 10	44	10.0	10.0	89.5
11 to 15	18	4.1	4.1	93.6
16 to 20	7	1.6	1.6	95.2
21 to 50	19	4.3	4.3	99.5
> 50	2	.5	.5	100.0
Total	440	100.0	100.0	

D. Frequencies by Year

The citations, self-citations and adjusted citations are shown by year in Table 7 through 9, respectively. Only 3 of 50 papers published in 2004 had no citations by the middle of 2007, and only 2 research publications had been cited at least once. Citation rates for more recent papers are understandably lower because insufficient time has elapsed.

Table 7. Frequency distribution of the number of citations per year.

All Publications

Citations	Count	Publication Year				Total
		2004	2005	2006	2007	2004
0	Count	3	7	36	99	145
	% within Publication Year	6.0%	6.9%	18.7%	75.0%	30.4%
1 to 5	Count	4	36	126	32	198
	% within Publication Year	8.0%	35.3%	65.3%	24.2%	41.5%
6 to 10	Count	14	29	22	1	66
	% within Publication Year	28.0%	28.4%	11.4%	0.8%	13.8%
11 to 15	Count	12	10	4	0	26
	% within Publication Year	24.0%	9.8%	2.1%	0.0%	5.5%
16 to 20	Count	6	6	3	0	15
	% within Publication Year	12.0%	5.9%	1.6%	0.0%	3.1%
21 to 50	Count	10	13	2	0	25
	% within Publication Year	20.0%	12.7%	1.0%	0.0%	5.2%
> 50	Count	1	1	0	0	2
	% within Publication Year	2.0%	1.0%	0.0%	0.0%	0.4%
Total	Count	50	102	193	132	477
	% within Publication Year	100.0%	100.0%	100.0%	100.0%	100.0%

Research publications

Citations		Publication Year				Total
		2004	2005	2006	2007	2004
0	Count	2	6	34	89	131
	% within Publication Year	4.4%	6.3%	19.0%	74.2%	29.8%
1 to 5	Count	3	34	120	30	187
	% within Publication Year	6.7%	35.4%	67.0%	25.0%	42.5%
6 to 10	Count	12	27	18	1	58
	% within Publication Year	26.7%	28.1%	10.1%	.8%	13.2%
11 to 15	Count	11	9	4	0	24
	% within Publication Year	24.4%	9.4%	2.2%	.0%	5.5%
16 to 20	Count	6	6	3	0	15
	% within Publication Year	13.3%	6.3%	1.7%	.0%	3.4%
21 to 50	Count	10	13	0	0	23
	% within Publication Year	22.2%	13.5%	.0%	.0%	5.2%
> 50	Count	1	1	0	0	2
	% within Publication Year	2.2%	1.0%	.0%	.0%	.5%
Total	Count	45	96	179	120	440
	% within Publication Year	100.0%	100.0%	100.0%	100.0%	100.0%

Table 8. Frequency distribution of the number of self-citations per year.

All Publications

Self-Citations		Publication Year				Total
		2004	2005	2006	2007	2004
0	Count	7	26	105	115	253
	% within Publication Year	14.0%	25.5%	54.4%	87.1%	53.0%
1 to 5	Count	34	66	85	17	202
	% within Publication Year	68.0%	64.7%	44.0%	12.9%	42.3%
6 to 10	Count	9	8	3	0	20
	% within Publication Year	18.0%	7.8%	1.6%	.0%	4.2%
11 to 15	Count	0	1	0	0	1
	% within Publication Year	.0%	1.0%	.0%	.0%	.2%
16 to 20	Count	0	1	0	0	1
	% within Publication Year	.0%	1.0%	.0%	.0%	.2%
Total	Count	50	102	193	132	477
	% within Publication Year	100.0%	100.0%	100.0%	100.0%	100.0%

Research Publications

Self-Citations		Publication Year				Total
		2004	2005	2006	2007	2004
0	Count	5	23	98	104	230
	% within Publication Year	11.1%	24.0%	54.7%	86.7%	52.3%
1 to 5	Count	31	63	80	16	190
	% within Publication Year	68.9%	65.6%	44.7%	13.3%	43.2%
6 to 10	Count	9	8	1	0	18
	% within Publication Year	20.0%	8.3%	.6%	.0%	4.1%
11 to 15	Count	0	1	0	0	1
	% within Publication Year	.0%	1.0%	.0%	.0%	.2%
16 to 20	Count	0	1	0	0	1
	% within Publication Year	.0%	1.0%	.0%	.0%	.2%
Total	Count	45	96	179	120	440
	% within Publication Year	100.0%	100.0%	100.0%	100.0%	100.0%

Table 9. Frequency distribution of the number of adjusted citations (citations minus self-citations) per year for all publications.

All Publications

Adjusted Citations		Publication Year				Total
		2004	2005	2006	2007	2004
	Count	3	12	58	111	184
	% within Publication Year	6.0%	11.8%	30.1%	84.1%	38.6%
1 to 5	Count	13	48	113	21	195
	% within Publication Year	26.0%	47.1%	58.5%	15.9%	40.9%
6 to 10	Count	16	19	14	0	49
	% within Publication Year	32.0%	18.6%	7.3%	.0%	10.3%
11 to 15	Count	5	8	6	0	19
	% within Publication Year	10.0%	7.8%	3.1%	.0%	4.0%
16 to 20	Count	3	4	1	0	8
	% within Publication Year	6.0%	3.9%	.5%	.0%	1.7%
21 to 50	Count	9	10	1	0	20
	% within Publication Year	18.0%	9.8%	.5%	.0%	4.2%
> 50	Count	1	1	0	0	2
	% within Publication Year	2.0%	1.0%	.0%	.0%	.4%
Total	Count	50	102	193	132	477
	% within Publication Year	100.0%	100.0%	100.0%	100.0%	100.0%

Research Publications

Adjusted Citations		Publication Year				Total
		2004	2005	2006	2007	2004
0	Count	2	11	55	101	169
	% within Publication Year	4.4%	11.5%	30.7%	84.2%	38.4%
1 to 5	Count	11	45	106	19	181
	% within Publication Year	24.4%	46.9%	59.2%	15.8%	41.1%
6 to 10	Count	14	18	12	0	44
	% within Publication Year	31.1%	18.8%	6.7%	.0%	10.0%
11 to 15	Count	5	7	6	0	18
	% within Publication Year	11.1%	7.3%	3.4%	.0%	4.1%
16 to 20	Count	3	4	0	0	7
	% within Publication Year	6.7%	4.2%	.0%	.0%	1.6%
21 to 50	Count	9	10	0	0	19
	% within Publication Year	20.0%	10.4%	.0%	.0%	4.3%
> 50	Count	1	1	0	0	2
	% within Publication Year	2.2%	1.0%	.0%	.0%	.5%
Total	Count	45	96	179	120	440
	% within Publication Year	100.0%	100.0%	100.0%	100.0%	100.0%

E. Summary Statistics by Year

The summary statistics by year are shown in Table 10 through Table 29. As would be expected, average citations increase as publications age. The expected citations (AJPI), Journal Performance Indicator (JPI) and Field Performance Indicator (FPI) rely on a baseline year and also tend to increase as publications age. The Journal Impact Factor (JIF) data show that RCE publications have been consistently published in highly ranked journals throughout the life of the RCE. As a point of comparison, the 5-year Impact Factor indices are in effect moving averages and would reflect overall changes in the journal or field but not the age of the publication itself. The number of citing journals, number of citing fields, citing JIF5 and citing FIF5 all tend to increase with the age of the publications. There are no discernable trends over time in cited publications.

*Table 10. Citations by year***.**

All Publications

Publication Year	Citations		
	Mean	N	sd
2004	15.20	50	12.84
2005	10.34	102	13.71
2006	3.38	193	4.42
2007	0.43	132	1.05
Total	5.29	477	9.43

Research Publications

Publication Year	Citations		
	Mean	N	sd
2004	16.16	45	13.07
2005	10.60	96	14.04
2006	3.05	179	3.28
2007	0.45	120	1.08
Total	5.33	440	9.55

Table 11. Self-citations by year.

All Publications

Publication Year	Self Citations		
	Mean	N	sd
2004	3.08	50	2.53
2005	2.45	102	2.92
2006	0.88	193	1.28
2007	0.17	132	0.48
Total	1.25	477	2.06

Research Publications

Publication Year	Self Citations		
	Mean	N	sd
2004	3.18	45	2.56
2005	2.52	96	2.98
2006	0.81	179	1.15
2007	0.18	120	0.50
Total	1.25	440	2.07

Table 12. Adjusted Citations by Year.

All Publications

Publication Year	Adjusted Citations		
	Mean	N	sd
2004	12.12	50	11.49
2005	7.89	102	11.88
2006	2.50	193	3.76
2007	0.27	132	0.79
Total	4.04	477	8.02

Research Publications

Publication Year	Adjusted Citations		
	Mean	N	sd
2004	12.98	45	11.74
2005	8.08	96	12.18
2006	2.24	179	2.90
2007	0.28	120	0.82
Total	4.08	440	8.15

Table 13. Expected Citations by Year.

All Publications

Publication Year	Expected Citations		
	Mean	N	sd
2004	10.05	50	7.95
2005	5.21	102	4.30
2006	0.75	193	0.65
2007	0.00	132	0.00
Total	2.47	477	4.60

Research Publication

Publication Year	Expected Citations		
	Mean	N	sd
2004	10.04	45	7.95
2005	5.25	96	4.40
2006	0.72	179	0.55
2007	0.00	120	0.00
Total	2.47	440	4.60

Table 14. Journal Impact Factor by Year.

All Publications

Publication Year	Journal Impact Factor (JIF)		
	Mean	N	sd
2004	5.80	50	4.24
2005	5.79	102	5.17
2006	5.74	193	4.47
2007	5.85	132	5.33
Total	5.79	477	4.84

Research Publications

Publication Year	Journal Impact Factor (JIF)		
	Mean	N	sd
2004	5.74	45	4.38
2005	5.86	96	5.30
2006	5.28	179	3.32
2007	5.34	120	4.43
Total	5.47	440	4.23

Table 15. Journal Performance Indicator by Year.

All Publications

Publication Year	Journal Performance Indicator (JPI)		
	Mean	N	sd
2004	10.41	50	7.87
2005	5.22	102	4.35
2006	0.79	193	0.69
2007	0.00	132	0.00
Total	2.53	477	4.65

Research Publications

Publication Year	Journal Performance Indicator (JPI)		
	Mean	N	sd
2004	10.30	45	7.97
2005	5.35	96	4.44
2006	0.74	179	0.58
2007	0.00	120	0.00
Total	2.52	440	4.66

Table 16. Five Year Journal Impact Factor by Year.

All Publications

Publication Year	Journal Impact Factor 5 year (JIF5)		
	Mean	N	sd
2004	11.43	45	8.61
2005	11.22	96	9.92
2006	9.69	179	6.94
2007	10.21	120	8.17
Total	10.34	440	8.18

Research Publications

Publication Year	Journal Impact Factor 5 year (JIF5)		
	Mean	N	sd
2004	11.35	50	8.24
2005	10.96	102	9.72
2006	10.33	193	8.53
2007	10.84	132	9.65
Total	10.71	477	9.07

Table 17. Field Performance Indicator by Year.

All Publications

Publication Year	Field Impact Factor		
	Mean	N	sd
2004	7.68	50	3.13
2005	3.73	102	1.38
2006	0.55	193	0.22
2007	0.00	132	0.00
Total	1.82	477	2.72

Research Publications

Publication Year	Field Impact Factor		
	Mean	N	sd
2004	7.74	45	3.26
2005	3.77	96	1.36
2006	0.54	179	0.20
2007	0.00	120	0.00
Total	1.84	440	2.73

Table 18. Five Year Field Impact Factor (5-year) by Year.

All Publications

Publication Year	Field Impact Factor 5 year (FIF5)		
	Mean	N	sd
2004	7.73	50	1.94
2005	7.27	102	1.90
2006	7.03	193	1.87
2007	7.70	132	3.06
Total	7.34	477	2.28

Research Publications

Publication Year	Field Impact Factor 5 year (FIF5)		
	Mean	N	sd
2004	7.68	45	1.95
2005	7.26	96	1.93
2006	7.08	179	1.83
2007	7.61	120	2.96
Total	7.33	440	2.23

Table 19. Number of Citing Journals by Year.

All Publications

Publication Year	# of Citing Journals		
	Mean	N	sd
2004	11.38	45	8.53
2005	7.43	96	9.14
2006	2.53	179	2.43
2007	0.42	120	0.95
Total	3.93	440	6.37

Research Publications

Publication Year	# of Citing Journals		
	Mean	N	sd
2004	10.82	50	8.38
2005	7.28	102	8.93
2006	2.69	193	2.81
2007	0.40	132	0.92
Total	3.89	477	6.25

Table 20. Number of Citing Fields by Year.

All Publications

Publication Year	# of Citing Fields		
	Mean	N	sd
2004	10.89	45	6.79
2005	8.09	96	7.69
2006	2.90	179	3.13
2007	0.55	120	1.71
Total	4.21	440	5.87

Research Publications

Publication Year	# of Citing Fields		
	Mean	N	sd
2004	10.56	50	6.85
2005	7.98	102	7.57
2006	3.08	193	3.61
2007	0.53	132	1.65
Total	4.21	477	5.88

Table 21. Citing Journal Impact Factor (5-year) by Year.

All Publications

Publication Year	Citing Journal Impact Factor- 5 year (JIF5)		
	Mean	N	sd
2004	9.56	50	5.82
2005	9.15	102	7.96
2006	7.92	193	10.35
2007	2.21	132	8.16
Total	6.78	477	9.32

Research Publications

Publication Year	Citing Journal Impact Factor- 5 year (JIF5)		
	Mean	N	sd
2004	10.09	45	5.72
2005	8.98	96	7.22
2006	7.66	179	10.47
2007	2.31	120	8.51
Total	6.75	440	9.30

Table 22. Citing Field Impact Factor (5-year) by Year.

All Publications

Publication Year	Citing Field Impact Factor- 5 year (FIF5)		
	Mean	N	sd
2004	6.77	50	2.09
2005	6.07	102	2.90
2006	4.95	193	3.59
2007	.95	132	2.49
Total	4.27	477	3.71

Research Publications

Publication Year	Citing Field Impact Factor- 5 year (FIF5)		
	Mean	N	sd
2004	6.87	45	1.94
2005	6.09	96	2.79
2006	4.89	179	3.62
2007	.93	120	2.47
Total	4.27	440	3.70

Table 23. Number of Cited Journals by Year.

All Publications

Publication Year	# of Cited Journals		
	Mean	N	sd
2004	18.74	50	9.01
2005	19.69	102	9.17
2006	20.65	193	8.92
2007	20.42	132	9.54
Total	20.18	477	9.15

Research Publications

Publication Year	# of Cited Journals		
	Mean	N	sd
2004	18.49	45	8.55
2005	18.73	96	7.43
2006	20.06	179	7.63
2007	20.24	120	8.18
Total	19.66	440	7.84

Table 24. Number of Cited Fields by Year.

All Publications

Publication Year	# of Cited Fields		
	Mean	N	sd
2004	15.02	50	6.74
2005	16.85	102	7.10
2006	17.58	193	6.42
2007	16.48	132	7.29
Total	16.85	477	6.87

Research Publications

Publication Year	# of Cited Fields		
	Mean	N	sd
2004	14.82	45	6.45
2005	16.36	96	6.30
2006	17.41	179	6.06
2007	16.19	120	6.41
Total	16.58	440	6.28

Table 25. Cited Journal Impact Factor (5-year) by Year.

All Publications

Publication Year	Cited Journal Impact Factor- 5 year (FIF5)		
	Mean	N	sd
2004	18.41	50	9.03
2005	18.08	102	8.32
2006	17.73	193	7.83
2007	17.18	132	8.24
Total	17.72	477	8.17

Research Publications

Publication Year	Cited Journal Impact Factor- 5 year (FIF5)		
	Mean	N	sd
2004	18.58	45	8.84
2005	17.71	96	8.04
2006	17.59	179	7.37
2007	17.13	120	7.88
Total	17.59	440	7.80

Table 26. Cited Field Impact Factor (5 year) by Year.

All Publications

Publication Year	Cited Field Impact Factor- 5 year (FIF5)		
	Mean	N	sd
2004	7.89	50	1.82
2005	8.05	102	1.51
2006	7.95	193	1.37
2007	8.00	132	1.58
Total	7.98	477	1.51

Research Publications

Publication Year	Cited Field Impact Factor- 5 year (FIF5)		
	Mean	N	sd
2004	8.05	45	1.49
2005	8.02	96	1.52
2006	7.97	179	1.28
2007	8.10	120	1.40
Total	8.03	440	1.38

Table 27. Citing Journal Disciplinarity Index by Year.

All Publications

Publication Year	Citing Journal Disciplinarity Index (JDI)		
	Mean	N	sd
2004	1.11	50	0.48
2005	1.22	102	0.71
2006	1.22	193	0.93
2007	1.21	132	1.32
Total	1.20	477	0.87

Research Publications

Publication Year	Citing Journal Disciplinarity Index (JDI)		
	Mean	N	sd
2004	1.07	45	0.46
2005	1.23	96	0.71
2006	1.22	179	.94
2007	1.20	120	1.35
Total	1.20	440	0.88

Table 28. Cited Journal Disciplinarity Index by Year.

All Publications

Publication Year	Cited Journal Disciplinarity Index (JDI)		
	Mean	N	sd
2004	0.85	50	0.26
2005	0.91	102	0.29
2006	0.92	193	0.35
2007	0.86	132	0.34
Total	0.89	477	0.33

Research Publications

Publication Year	Cited Journal Disciplinarity Index (JDI)		
	Mean	N	sd
2004	0.86	45	0.27
2005	0.92	96	0.29
2006	0.93	179	0.35
2007	0.84	120	0.27
Total	0.89	440	0.31

Table 29. Difference between Observed and Expected Citations by Year.

All Publications

Publication Year	Difference (Citations-Expected Citations)		
	Mean	N	sd
2004	5.15	50	9.44
2005	5.13	102	11.31
2006	2.62	193	4.03
2007	0.43	132	1.05
Total	2.82	477	6.82

Research Publications

Publication Year	Difference (Citations-Expected Citations)		
	Mean	N	sd
2004	6.11	45	9.17
2005	5.36	96	11.60
2006	2.33	179	3.04
2007	.45	120	1.08
Total	2.86	440	6.77

F. Citation t-tests

Observed citation rates in all cases exceeded the expected citation rate and the rates typically obtained for the journal (JPI) and field (FPI). T-tests were conducted to examine whether these differences are statistically significant. The summary statistics for these tests are shown for all publications in Table 30.

Table 30. Citation t-test summary statistics for all publications.

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Citations	5.2914	477	9.42713	0.43164
	Expected Citations	2.4738	477	4.59778	0.21052
Pair 2	Citations	5.2914	477	9.42713	0.43164
	Journal Performance Indicator (JPI)	2.5285	477	4.65381	0.21308
Pair 3	Citations	5.2914	477	9.42713	0.43164
	Field Performance Indicator (FPI)	1.8243	477	2.72078	0.12458

The results of the significance tests are presented in table 31. Observed citation rates are significantly higher that expected rates (AJPI) (for a one-tailed test, df = 476, critical t-value = 1.65). Observed citation rates are significantly higher than both the Journal Performance Index (JPI) and Field Performance Index (FPI) (for a one-tailed test, df = 476, critical t-value = 1.65).

Table 31. T-tests for citations for all publications. A Paired Samples Test.

		Paired Differences					t	dt	Dig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95 % Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Citations-Expected Citations	2.8163	6.81846	0.3122	2.20418	3.43108	9.025	476	.000
Pair 2	Citations-Journal Performance Indicator (JPI)	2.76289	6.78897	0.31085	2.15209	3.37369	8.888	476	.000
Pair 3	Citations-Field Performance Indicator (FPI)	3.46714	8.18174	0.37462	2.73104	4.20325	9.255	476	.000

For research publications, the summary statistics are shown in Table 32. The t-tests are provided in Table 33. The results for all three tests are in the hypothesized direction, with observed publications higher than the expected, journal, and field indicators; the results are statistically significant (for a one-tailed test, df = 439, critical t-value = 1.65).

Table 32. Citations t-tests summary statistics for research publications.

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Citations	5.3295	440	9.54849	0.45521
	Expected Citations	2.4651	440	4.59645	0.21913
Pair 2	Citations	5.3295	440	9.54849	0.45521
	Journal Performance Indicator (JPI)	2.5222	440	4.66223	0.22226
Pair 3	Citations	5.3295	440	9.54849	0.45521
	Field Performance Indicator (FPI)	1.8350	440	2.73416	0.13035

Table 33. T-tests for citations for research publications. A Paired Samples Test.

		Paired Differences					t	dt	Dig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95 % Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Citations-Expected Citations	2.86445	6.76562	.32254	2.23054	3.49837	8.881	439	.000
Pair 2	Citations-Journal Performance Indicator (JPI)	2.80732	6.68821	.31885	2.18066	3.43398	8.805	439	.000
Pair 3	Citations-Field Performance Indicator (FPI)	3.49454	8.22569	.39214	2.72383	4.26526	8.911	439	.000

G. Citation Trends

Although it is early to establish trends over time for RCE publication citations, it is instructive to examine whether there are differences between 2005 and 2006 citation rates (the only two years for which complete data are available, given that two Centers were not established until 2005). To accomplish this, a difference score was first obtained by subtracting expected citations from observed citations. This score was then analyzed using a one-way Analysis of Variance (ANOVA). Descriptive statistics for this analysis for all publications are shown in Table 34, and ANOVA results are in Table 35. The results show that for both 2005 and 2006, the difference score was positive, indicating that observed citations were higher than expected ones. The ANOVA results are statistically significant (p=.006).

Table 34. Descriptive statistics for citation trend analysis for all publications.

Difference (Citations-Expected Citations)								
Year	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
2005	102	5.1285	11.31174	1.12003	2.9067	7.3504	-7.67	90.81
2006	193	2.6237	4.02911	.29002	2.0517	3.1958	-1.55	34.00
Total	295	3.4898	7.48219	.43563	2.6324	4.3471	-7.67	90.81

Table 35. Analysis of Variance (ANOVA) for citation trend analysis for all publications.

Difference (Citations-Expected Citations)					
	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	418.679	1	418.679	7.648	.006
Within Groups	16040.382	293	54.745		
Total	16459.061	294			

The same pattern observed for all publications, holds for research publications. Descriptive statistics are given in Table 36, and ANOVA results are in Table 37.

Table 36. Descriptive statistics for citation trend analysis for research publications.

Difference (Citations-Expected Citations)								
Year	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
2005	96	5.3558	11.60005	1.18393	3.0054	7.7062	-7.67	90.81
2006	179	2.3306	3.04336	.22747	1.8817	2.7794	-1.55	16.15
Total	275	3.3867	7.39991	.44623	2.5082	4.2651	-7.67	90.81

Table 37. Analysis of Variance (ANOVA) for citation trend analysis for research publications.

Difference (Citations-Expected Citations)					
	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	571.901	1	571.901	10.818	.001
Within Groups	14431.959	273	52.864		
Total	15003.861	274			

VI. Conclusions

Several tentative general conclusions can be reached on the basis of the bibliometric analysis:

- RCE publication productivity is increasing over time
    - Publications have increased each year. Although 2007 data are incomplete, extrapolating out from publications to date, the RCEs are on track to publish more than they did in 2006.
- RCE publications are well regarded, as indicated by citations from other publications.

    - Nearly 70% of the publications have been cited at least once by other publications. This is noteworthy because citations accumulate over time and RCE publications are still relatively new. If we eliminate 2007 publications, for which there has been little time to accumulate citations, 87% of RCE publications have been cited.
    - On average, each publication had 5.29 citations and 4.04 citations when self-citations are removed.
- Over time, it appears that RCE articles have been published consistently in frequently cited journals.
    - The Journal Impact Factor (JIF) has been steady over the four years (total of 5.79), as has the five year JIF (10.34). As a point of comparison, the current impact factor for *Science* is 30.028 (7 RCE papers published here); the *Journal of Experimental Medicine* is 14.48 (8 RCE papers published); the *Journal of Immunology* is 6.293 (13 RCE papers); the *Journal of Virology* is 5.341 (64 RCE papers published) and *Journal of Virological Methods* is 2.097 (6 RCE papers published).
- Citation of RCE publications is significantly higher than for journal and field comparisons
    - RCE publications are cited more frequently than the average publication in their journals.
    - RCE publications are cited more frequently than the average publication in their field.

9. Additional Graphs of RCE and NIAID Publications by Category A Agent

Figure 1. RCE and NIAID Publications Addressing Anthrax by Year.

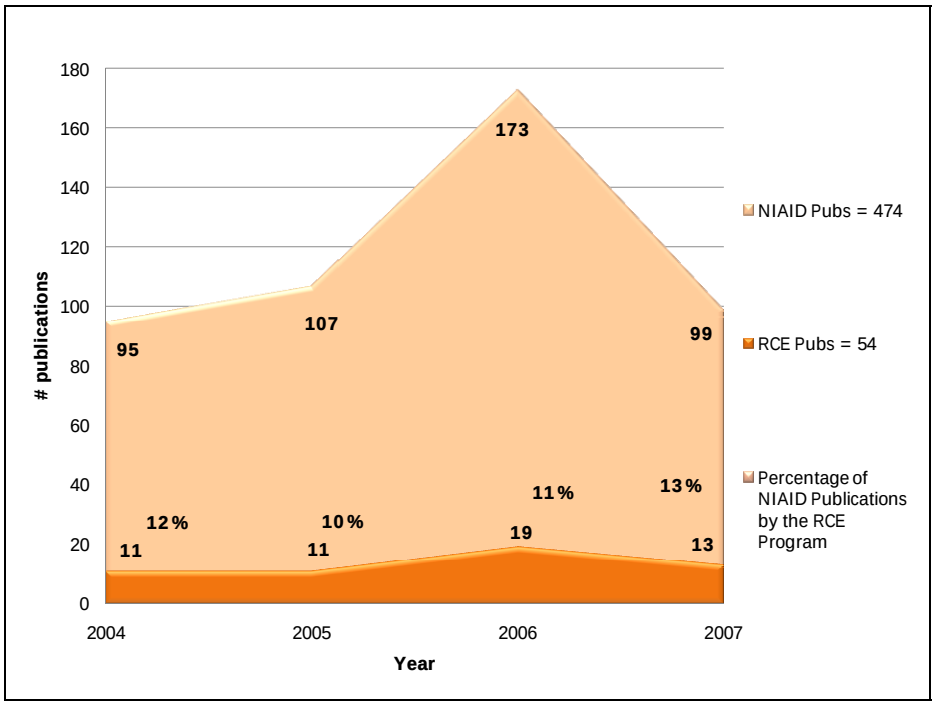


Figure 2. RCE and NIAID Publications Addressing Botulism by Year.

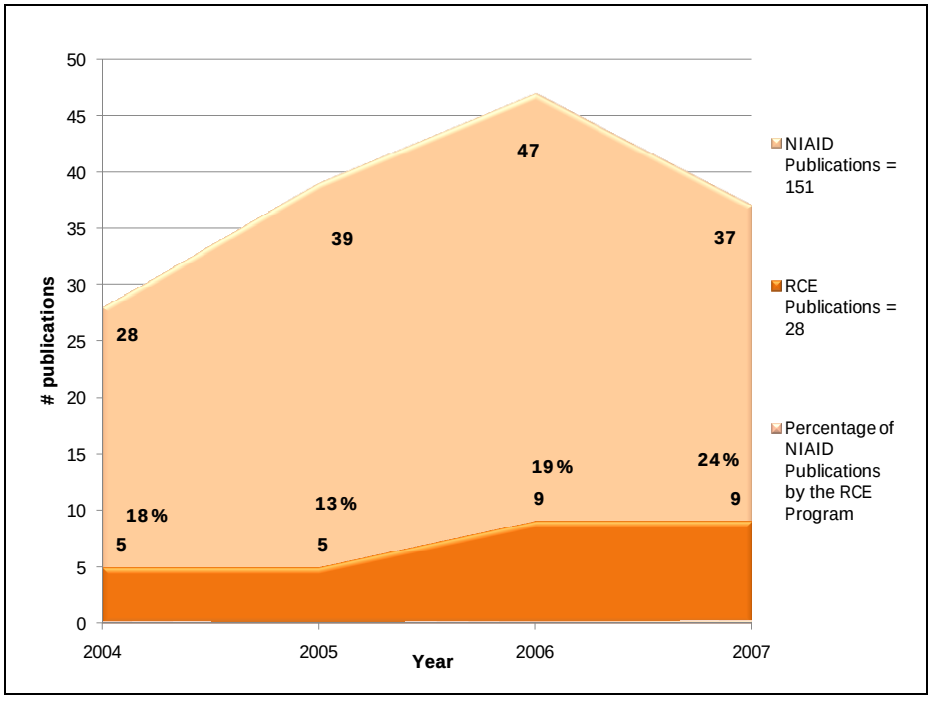


Figure 3. RCE and NIAID Publications Addressing Yersinia pestis by Year.

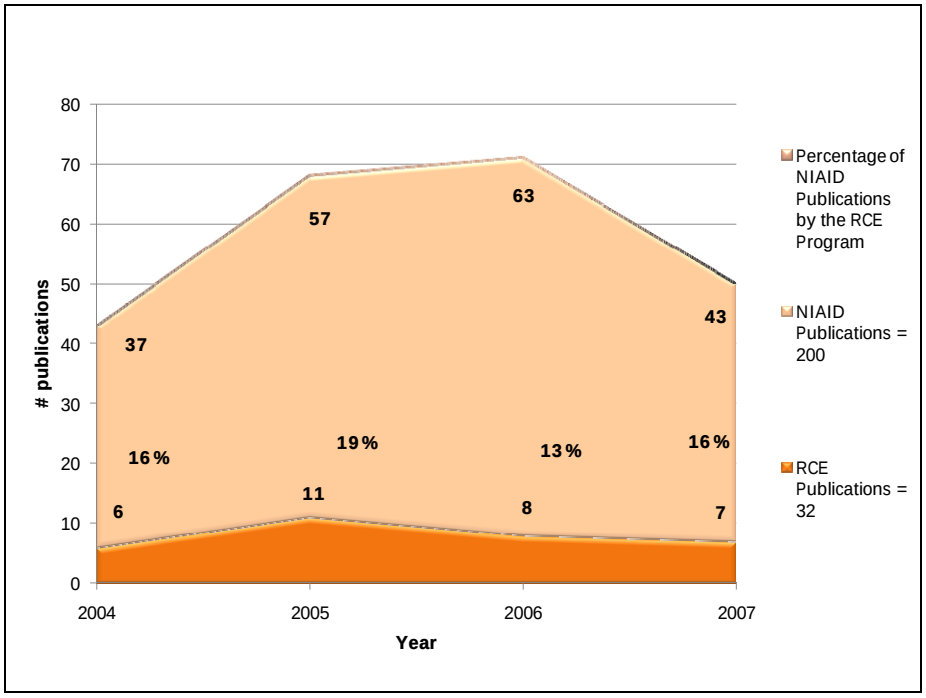


Figure 4. RCE and NIAID Publications Addressing Smallpox by Year.

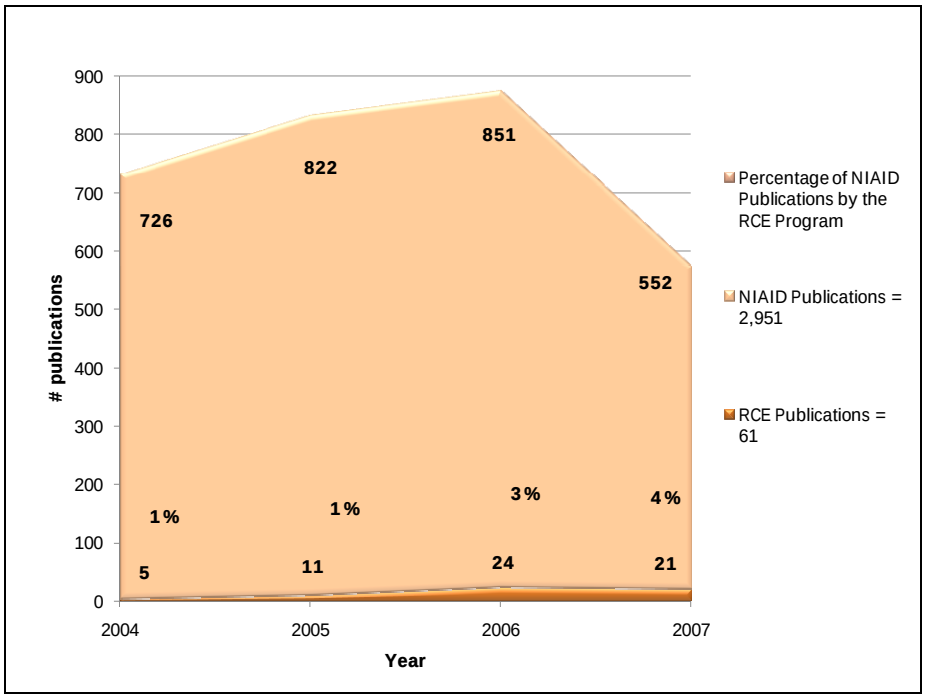


Figure 5. RCE and NIAID Publications Addressing Francisella tularensis by Year.

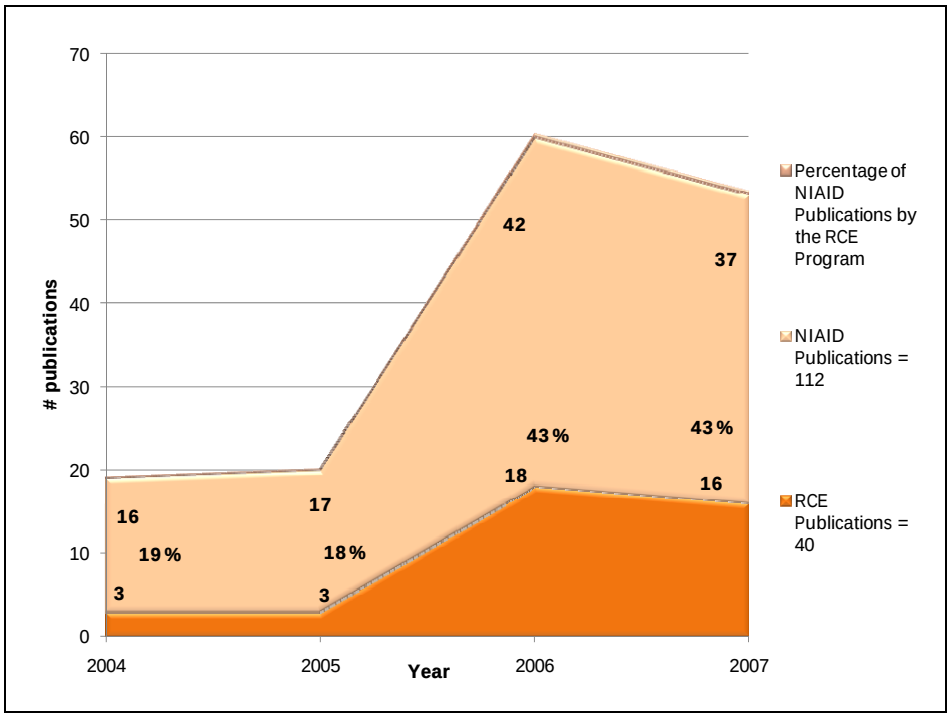
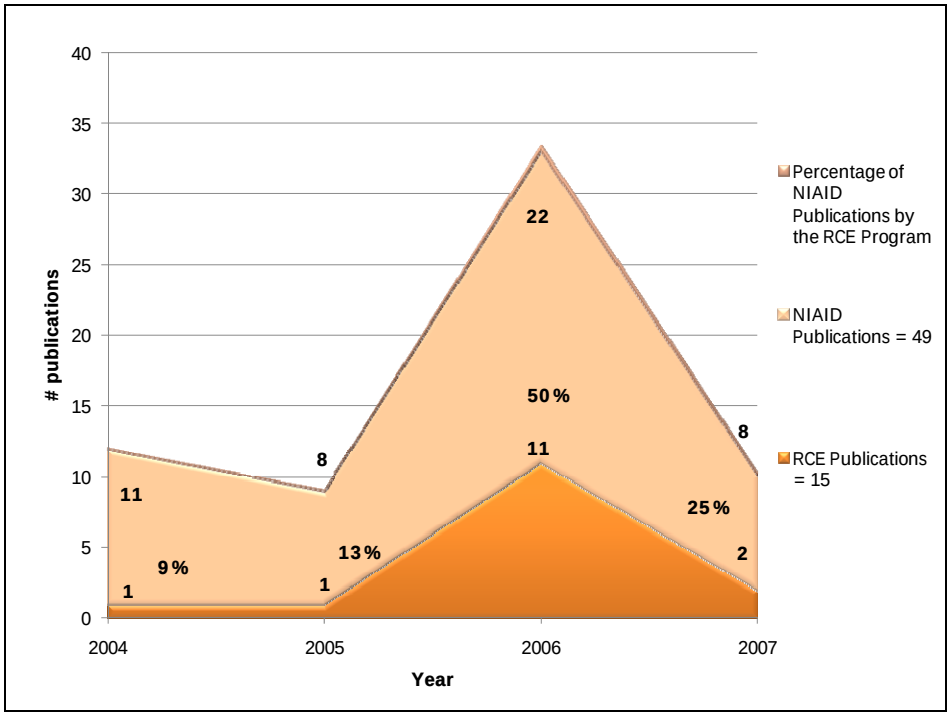


Figure 6. RCE and NIAID Publications Addressing Ebola by Year.



10. Description of Project Types[3]

Developmental Projects

Every RCE must identify and support Developmental Research Projects ("pilot" projects) that take advantage of emergent technology and new research opportunities. These projects may involve scientists within the RCE or extend to appropriate regional scientists outside the Center. Key purposes of this RCE activity are expanding the scope and range of research, investigators, and institutions involved in biodefense and emerging infectious diseases research and allowing for testing of novel ideas (with
little preliminary data) and new technologies.

Career Development

The RCE must include a consistent and significant commitment to career development and training, with the goal of increasing the availability of qualified researchers and other personnel for biodefense and furthering their career development. The training must be an integral part of the strategic plan, and complement the research activities. The RCE budget should support the salary and research costs of candidates with outstanding potential, as well as other reasonable costs for career development and training activities. Career Development Projects for individuals may focus on advanced postdoctoral candidates, junior faculty, or established investigators who wish to develop or refocus their careers on biodefense and emerging infectious diseases research, as well as technical support staff. This may include mentored research experiences for current health professionals and faculty/staff interested in starting and pursuing research in the areas of biodefense and emerging infectious diseases. Each candidate must have a mentor and devote at least 80% of his/her effort to biodefense/emerging
infectious diseases research. The description of these plans should include the policies, criteria, and processes for selecting candidates and monitoring their progress, including special efforts to recruit qualified women and minorities. Career Development Projects are not intended for pre-doctoral candidates.

Other career development activities may be directed to groups of individuals; for example, there may be training programs for graduate students, technicians and others to learn specific skills, such as how to work in Biosafety Level (BSL) 3/4 areas or develop clinical research protocols. Other creative types of training are encouraged. If short-term training courses or similar activities are proposed, the application should describe the target audience, the curriculum, the faculty, and how participants will be recruited.

Because Career Development Projects will generally be for less than two years in duration, studies which involve interventional clinical trials are not viewed as appropriate for the scope of this activity unless clearly associated with an on-going Research Project. Both types of career development projects should include plans for evaluating success and for following the impact of the training on the careers of the participating trainees.

[3] http://www.niaid.nih.gov/. RFA: AI-02-050.

Research Projects

Research Projects, which together will enable the RCE to contribute significantly to the NIAID biodefense and emerging infectious diseases mission. The range of research topics that may be proposed is outlined above. A project may be similar in scope and design to a Research Project Grant (R01), or it may be more extensive and resemble a Program Project Grant (P01) and include more than one related research project with more than one investigator. Collectively, the projects should support the strategic plan
and emphasize synergy and integration of overall themes. Centers are expected to focus on and incorporate into the research projects state-of-the art technology and approaches. Each research project must include measurable milestones, with timelines, and criteria for assessing success/productivity at periodic intervals. Applicants are encouraged to carefully consider the scope and range of research proposed and develop a Research Program that is coherent overall and consistent with available resources and personnel.

New Opportunities

"New Opportunities" funds are not part of the Center's original operational budget, but are intended for use by NIAID to fund new components and activities of the Centers. These funds will be applied to objectives such as: enhancing the capabilities of the Centers and the Biodefense Network, encouraging inter-Center activities, and providing additional research, product development, and training opportunities. It is important to remember that one of the goals for the RCEs is to develop vaccines, therapeutics, and diagnostics that are targeted to the Category A-C agents, and projects directly related to achieving this goal will be given high priority. Projects exhibiting real novelty and genuine innovation will also be given extra consideration. There should be full and open solicitations for projects to be submitted for this money: the opportunity for submission of concepts should be published on each Center's website.

11. Solicitations by Year: Further Details.

Figure 1. Developmental Projects Solicitations by Year.

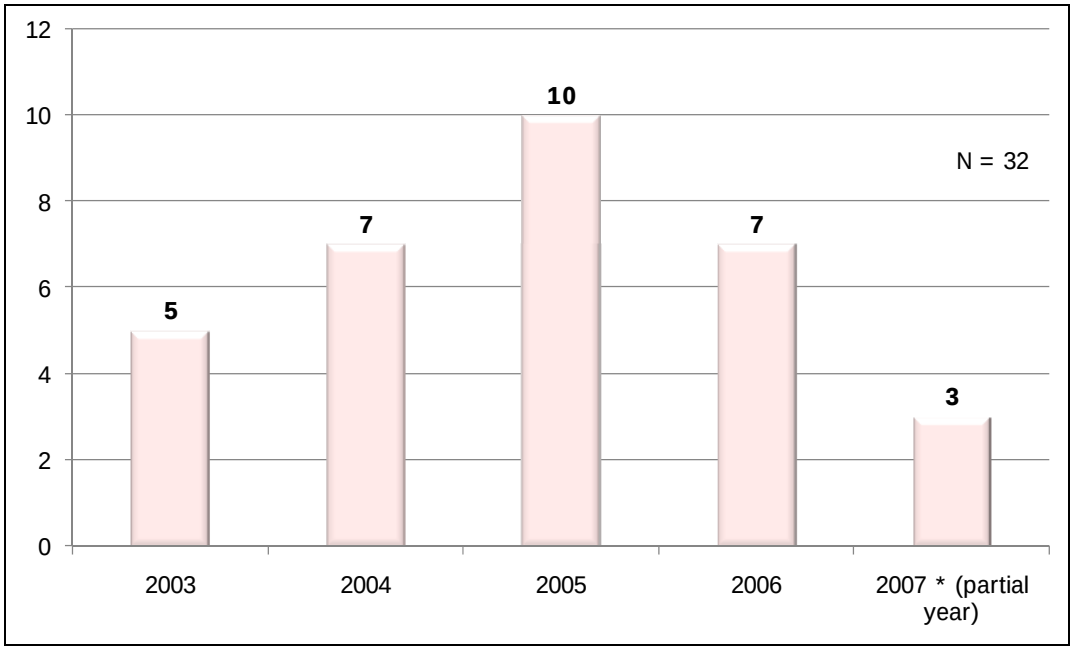


Figure 2: Career Development Solicitations by Year.

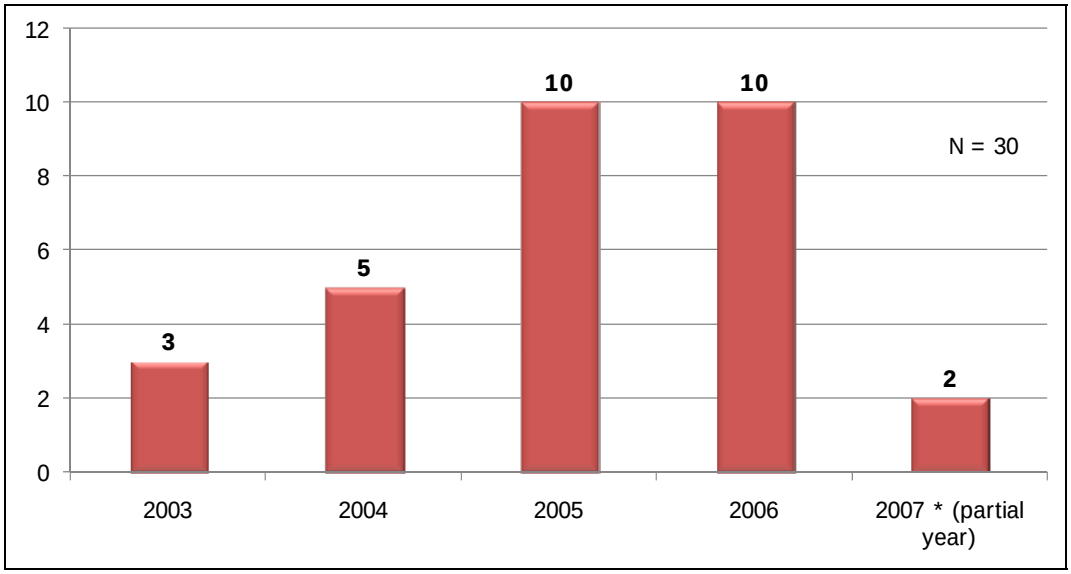


Figure 3. New Opportunity Solicitations by Year.

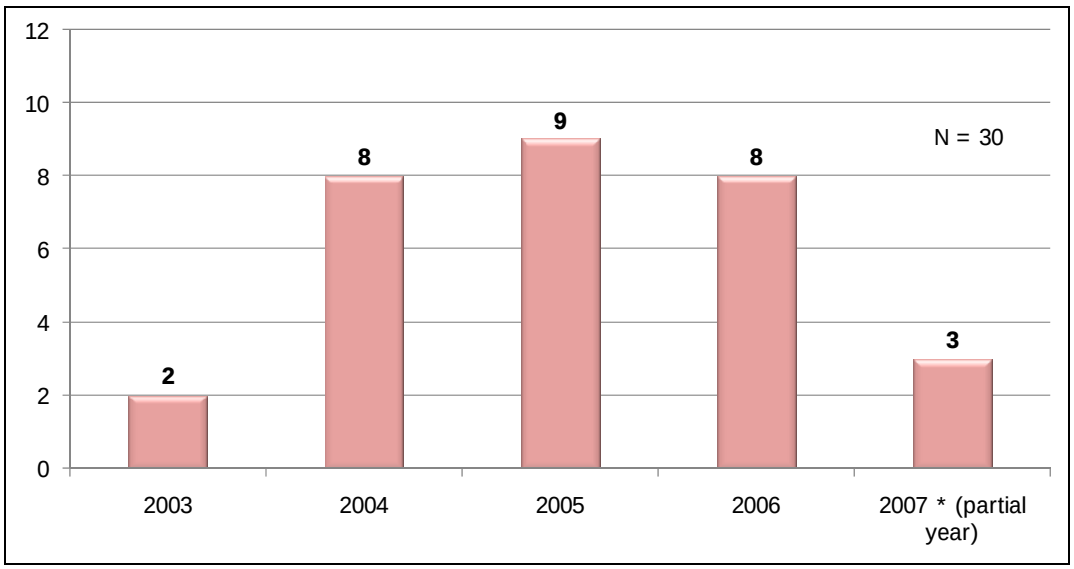
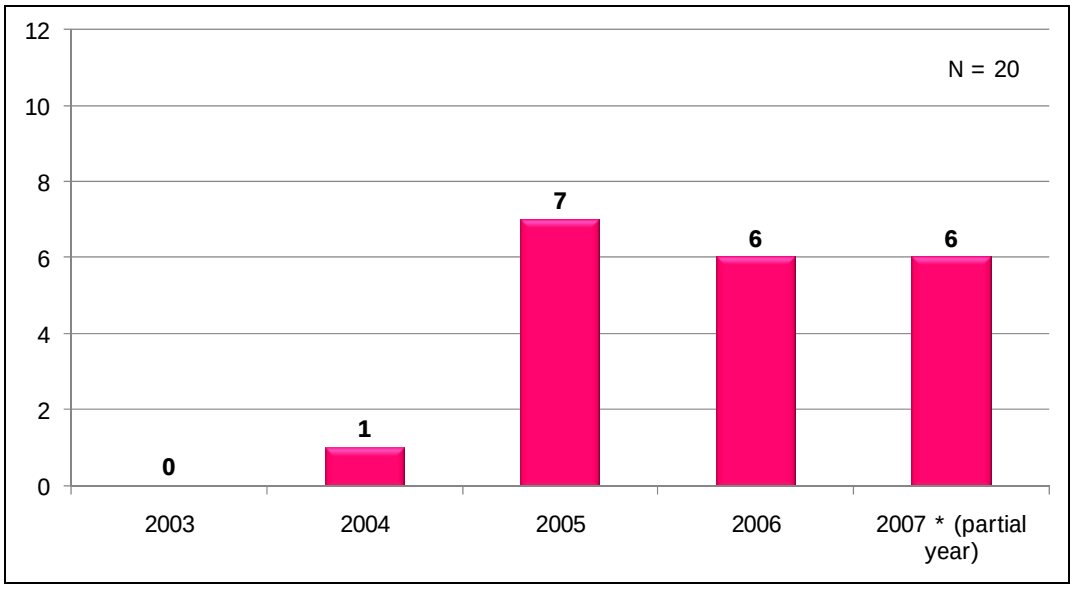


Figure 4. New Research Project Solicitations by Year.



12. Additional Grants Stemming from RCE Research

New Project Title	*Source*	*Year Awarded*
Anti-Y. pestis Vaccination and Passive Protection	NIAID	2003
A Staged Strategy for Virus Identification and Discovery	NIAID	2003
Modulation of Dendritic Cell Function by Ebola virus	NIAID	2004
Intracellular Survival Determinants of Yersinia pestis	NIAID	2004
Study of Monkeypox Virus in Rodents	NIAID	2004
Molecular and biological characterization of Spanish flu	NIAID	2004
Diversity, replication, pathogenicity and cell biology of Crimean Congo hemorrhagic fever virus	Department of Defense	2004
Large Scale Antibody and T Cell Epitope Discovery Program (Co-Investigator)	Other NIH	2004
Mass Tag PCR Detection of Respiratory Pathogens	NIAID	2004
Cellular Determinants of Hantavirus Pathogenesis	NIAID	2004

New Project Title	*Source*	*Year Awarded*
Rift Valley Fever Virus Studies	Other	2004
Dengue and West Nile virus Protease Inhibitors	NIAID	2004
Inhibition of host innate immune response in Nipah virus	NIAID	2004
Rift Valley Fever Virus MP-12 Vaccine Completion	NIAID	2004
Cell-mediated protection against pneumonic plague	NIAID	2004
Ebola VP35 Interferon-Antagonist: Mechanism and Significance	NIAID	2005
Development of post-Exposure Vaccine for Smallpox	NIAID	2005
Assay:Molecules that Inhibit Anthrax Intoxication(RMI)	Other NIH	2005
Alphavirus-based Vaccine for Prevention of MPV	NIAID	2005
Monoclonal Antibody Therapy for West Nile Virus Infection	NIAID	2005
The Basis of Anthrax-Induced Vascular Damage	NIAID	2005
Dynamics of Clathrin Coat Formation in Cells	NIAID	2005
Vaccinia Virus Antibody Kinetics and Residual Immunity	NIAID	2005

New Project Title	*Source*	*Year Awarded*
Tularemia Vaccine Development Team	NIAID	2005
Genetic Tools for analyzing B. pseudomallei virulence	NIAID	2005
Developing vaccine candidates for the SARS Coronavirus	NIAID	2005
Identification of T-cell Antigens for Q Fever Vaccination	NIAID	2005
Multiscale Integrative Immunology for Adjuvant Development	NIAID	2005
Mechanisms of Age Induced Thymic Atrophy	Other NIH	2005
Poxvirus regulation of NF-kappaB:Mechanisms for Virulence	NIAID	2005
Efficacy of ST-246 Against Monkeypox Virus	Industry	2005
Immune Function and Biodefense in Children, Elderly and Immunocompromised Populations: TLRs in Innate Immunity and the Induction of Adaptive Immunity in the Neonate and Infant	NIAID	2005
Therapeutics targeting cathepsin-activated viral entry	NIAID	2006
Antiviral Drugs for Lassa Fever Virus	NIAID	2006

New Project Title	***Source***	***Year Awarded***
Novel Compounds to Boost Short-Term Human Defense Response Against Human Pathogens	Department of Defense	2006
Mechanism of Action Studies for Valortim	Industry	2006
Receptor Trafficking in Entry of Murine Leukemia Viruses	NIAID	2006
Microencapsulated Vaccines Against Select Agents	Department of Defense	2006
Regulation of Gene Expression in Francisella	NIAID	2006
Live attenuated vaccines for epidemic and pandemic flu	NIAID	2006
Development of a novel Lassa fever vaccine	NIAID	2006
A Novel Systemic and Mucosal Adjuvant for Biodefense (Co-Investigator)	Other NIH	2006
LcrV Plague Vaccines with Altered Immune Modulatory Properties	NIAID	2006
Progression of Primary Pneumonic Plague	NIAID	2006
Viral Arrays for Biodefense	NIAID	2006
Adenosine Receptor Agonists as an Immunotherapy for Biodefense	NIAID	2006
Small Animal Model Development and Proof-of-concept Testing of Therapeutics and Vaccines in Small Animal Models of *Burkholderia* and Rickettsial Diseases	NIAID	2006
Identification and Analysis of Flavivirus Protease and RNA Helicase Inhibitors	NIAID	2006

New Project Title	*Source*	*Year Awarded*
Immunotherapeutics Against Ebola Sudan: Development, Structural and Functional Analysis	NIAID	2006
Modulation of Host Cell Functions by Coxiella burnetii	NIAID	2006
Innate Immune Evasion and/or Antagonism by Eastern Equine Encephalitis Virus	NIAID	2006
LcrV Plague Vaccine with Altered Immune Modulatory Properties	NIAID	2006
New approach to study West Nile virus fusion into cells	NIAID	2006
Microarray analysis of *Brucella melitensis* pathogenesis.	Private or Philanthropic Foundation	2006
Bacterial cell killing topoisomerase I--DNA lesion	NIAID	2006
Norovirus Infection of Dendritic Cells and Macrophages	NIAID	2006
A Diagnostic Microarray for hemorrhagic fever encephalitis viruses	NIAID	2006
Western, Eastern and Venezuelan Equine Encephalomyelitis	Industry	2006
Investigating post-translational regulation of innate immunity in C. elegans	NIAID	2007
Development of Novel Genetic Tools for Metabolic Selection in Y. Pestis	NIAID	2007
Characterization of inflammasome activation in anthrax lethal toxin-mediated cytotoxicity	NIAID	2007

New Project Title	*Source*	*Year Awarded*
Development of New Protein-based Therapies for Pre- and Post-exposure to *B. mallei*, the Causative Agent of Glanders	Private or Philanthropic Foundation	2007
Transformational Medical Technologies Initiative	Department of Defense	2007
Screens to identify small molecule inhibitors of Ebola virus entry into cells	Other	2007
The Yersinia insecticidal toxin complex	NIAID	2007
Mechanism of Action Studies for Valortim II	Industry	2007
An Accelerated Path to Safe and Effective Therapeutics (APSET) for Bioterrorism Agents	Department of Defense	2007
Genetics of Host Resistance to Franciscella tularensis in Mice	NIAID	2007
Interferon antagonism as a common virulence factor of hemorrhagic fever viruses	Department of Defense	2007
An Alternative Approach to a New Smallpox Vaccine: MVA and Inflammatory Stimuli	NIAID	2007
Study of the transmission of microorganisms in a hospital environment	Private or Philanthropic Foundation	2007

New Project Title	*Source*	*Year Awarded*
Prevention of Immune Pathology during Avian Influenza Infection	NIAID	2007
A Screen for Small Molecule Compounds that Inhibit Bacterial Toxins	Other NIH	2007
Development of IMPDH-Targeted Drugs against Crytosporidium	NIAID	2007
Comparison of Anthrax Toxins from Different Sources	NIAID	2007
Novel genetic tools for Burkholderia mallei and other bacterial select agents	NIAID	2007
Systems biology approach to understanding host-pathogen interactions (Co-Investigator)	Other NIH	2007
Burkholderia: International Collaboration to Development of Novel Diagnostics	NIAID	2007
Center for the Study of Preparedness and Catastrophic Event Response (PACER)	Other	2007
Development of a novel nanoparticle vaccine adjuvant	Other	2007
Northeast Biodefense Center Capital Completion Project	NIAID	2007
Recombinant Yellow Fever 17D-Lassa Vaccine	NIAID	2007
Alternatives to antibiotic resistance selective markers for Francisella	NIAID	2007
Human Mab cocktails to Prevent and Treat H5N1 Avian Influenza	NIAID	2007
Dendritic Cell Targeting Enhances Flavivirus Vaccine Efficacy	NIAID	2007

New Project Title	*Source*	*Year Awarded*
Commercial Development of Protien Capsular Matrix Vaccines	Industry	2007
Poxvirus Proteins Involved in Virion Binding, Membrance Fusion and Entry Into Cells	NIAID	2007
New Therapeutics for Shiga toxin-E.coli disease	NIAID	2007
Recombinant Yellow Fever 17D-Lassa Vaccine	NIAID	2007
Development of a Recombinant Subunit Ebola Vaccine	NIAID	2007
Microneedle-based immunization against pandemic influenza	Other NIH	2007
Self-administered microneedle patches for influenza vaccines	NIAID	2007
Small molecule inhibitors of ricin and shiga toxins	NIAID	2007
Assay for Inhibitors of Angiogenesis and Anthrax Toxin Receptor 1	Other NIH	2007
Clinical Trial for Community Acquired Methicilin Resistant Staphylococcus Aureus (CA_MRSA) Infections	NIAID	2007
Interaction of microvesicles and bacterial toxins with immune cells	NIAID	2007
Microencapsulation and Vaccine Delivery Research	Department of Defense	2007

New Project Title	*Source*	*Year Awarded*
Surface Proteins and Sortases of Bacillus anthracis”	NIAID	2007
Inhibiting the Inhibitor: Small Molecule Screening with Small Pox N1L	NIAID	2007
Siderophore biosynthesis inhibitors as new antibiotics for biodefense	NIAID	2007
Center forNano-Biosensors	Other	2007
Development of rapid biodetection methods using bacteriophage amplification	Department of Defense	2007
Targeting Vaccine Vectors and Antigens to Dendritic Cells Using Protein L	Other NIH	2007
Molecular Mechanism of Poxvirus Host Range Genes	NIAID	2007

13.Checklist of Emergency Response Activities

Activity:	I				A				B				H				C				D				G				E				J				F			
Fiscal Year	04	05	06	07	04	05	06	07	04	05	06	07	04	05	06	07	04	05	06	07	04	05	06	07	04	05	06	07	04	05	06	07	04	05	06	07	04	05	06	07
Activation: participation in a public health emergency.		x				x				x				x				x				x				x				x				x				x		
Participation in simulations (in the field).			x	x			x							x																								x	x	x
Participation in table top exercises (around a table).							x									x			x	x							x	x									x		x	x	x
RCE membership on state committees tasked with emergency response.			x	x			x	x							x	x						x	x	x													x	x	x
RCE membership on local committees tasked with emergency response.			x	x											x	x					x	x	x	x								x								
Identified designated RCE contact person for each locality.		x	x	x						x	x	x		x					x	x											x	x					x	x	x
Identified official designated ER contact person(s) within the region.		x	x	x											x	x			x	x			x	x							x	x					x	x	x
Communication between RCE and locality contact person.		x	x	x															x	x				x		x					x	x			x	x	x	x	x
Compiled list of experts who can help in an emergency.		x	x	x		x				x	x	x		x	x	x		x	x	x	x	x	x	x							x	x					x	x	x
Compiled list of resources that can be used in an emergency.		x	x	x		x	x	x		x	x	x		x	x	x		x	x	x			x			x	x	x			x	x			x	x	x	x	x
Conducted public outreach.		x	x	x		x	x	x							x	x			x	x							x	x			x	x			x	x	x	x	x
Other contacts/mtgs with local emergency responders, not covered above.		x	x	x			x	x																	x	x	x	x			x	x			x	x	x	x	x

14.Product Development Concepts

Concept	***Category***	***Disease/Agent***
Assay for Rapid Universal Bacterial Detection	diagnostics	Multi- agent
GreeneChips: A Sensitive, High Throughput Multiplex Diagnostic System	diagnostics	Multi- agent
Quartz Crystal Microbalance Immunosensor for Virus Diagnostics	diagnostics	Multi- agent
Lipid A Mimetics for Protection Against Pulmonary Plague	therapeutics	Plague
Serine Elastase Inhibitor for Treatment of ARDS and Sepsis	therapeutics	Multi- agent
Subunit Vaccine Against Botulism	vaccines	Botulism
Development of LcrV Plague Vaccines with Altered Immune Modulatory Properties	vaccines	Plague
A Rationally Attenuated *F. tularensis* Vaccine	vaccines	Tularemia
Yersinia pestis vaccine: Adenovirus Vectored Vaccine for V Antigen	vaccines	Plague
Vaccine for the Protection AgainstTularemia	vaccines	Tularemia
Development and Evaluation of Human Brucellosis Vaccine Candidates	vaccines	Brucellosis
RepliVAX: A Platform for Vaccines to Prevent Flavivirus Infections	vaccines	Viral Hemorrhagic Fevers