Announcement:

Call for Applications from
Entities Seeking to Participate in the
caBIG® Support Service Provider Program
Date of Issuance: 01 July, 2009
Updated: 15 January, 2010

Key Dates

Inquiries and responses to this Announcement must be received by the dates described in the below schedule. Responses to inquiries will be posted at https://cabig.nci.nih.gov/esn/ssp. Information from Rounds 1-5 are also posted there.

Round 5
Questions Due: 2/15/2010
Proposals Due: 3/1/2010 no later than 5:00 PM (Eastern)
Application Decision By: 4/1/2010

Round 6
Questions Due: 5/15/2010
Proposals Due: 6/1/2010 no later than 5:00 PM (Eastern)
Application Decision By: 7/1/2010

Dates for Round 7 and beyond will be posted to https://cabig.nci.nih.gov/esn/ssp by March 31, 2010

Issued By

National Cancer Institute for the cancer Biomedical Informatics Grid® (caBIG®) Program.

Eligibility

All applications conforming to the requirements for applications described in this Announcement will be eligible for evaluation in connection with the caBIG® Support Service Providers Program. Existing caBIG licensed Support Service Providers do not need to reapply to retain their participation.

Inquiries and Responses

Inquiries and Responses to this Announcement should be sent to caBIG_SSP@mail.nih.gov on or before the due date provided above in the "Key Dates" section for this application round.

Proposals must be delivered electronically to caBIG_SSP@mail.nih.gov and will be time-stamped with the time sent. Please be advised that emailed responses must be electronically time stamped <u>no later than</u> 5:00 P.M. (Eastern Standard Time) on or before the due date provided above in the "Key Dates" section for this application round.

Contents

Background

The National Cancer Institute's (NCI) cancer Biomedical Informatics Grid®, or caBIG®, is an open source, open access information network that connects the cancer research community and enables the sharing of tools and data through a common, standards-based electronic infrastructure. caBIG® allows investigators to answer research questions more rapidly and efficiently, thereby promising to accelerate progress in all aspects of cancer research– from etiologic research to prevention, early detection and treatment. Because caBIG® will provide a common unifying force that facilitates progress in cancer research, the most important beneficiaries will be cancer patients and the public at large.

The NCI Center for Biomedical Informatics and Information Technology (NCI CBIIT) conducted the caBIG® initiative first as a pilot during 2004-2006 and then launched the enterprise phase of caBIG® in early 2007 with an emphasis on widespread institutional adoption of the program and tools. This emphasis on widespread adoption is expected to generate an expanding community with diverse needs for support, which NCI anticipates will be met largely through the resources available through the caBIG® Enterprise Support Network (ESN).

A functioning ESN will enable further progress toward achieving the caBIG® program goal of establishing and extending interoperability as an integral component of broader biomedical research and clinical care. The ESN will support the needs of both individuals and institutions of the current caBIG® community, the broader cancer research enterprise, and, potentially, the biomedical research community as a whole that wish to adopt caBIG® standards, applications, and infrastructure, including IT administrators, end users, and administrators and senior decision makers. For more information, see https://cabig.nci.nih.gov/esn.

The ESN is intended to augment the existing capacity of the caBIG® Workspaces, which are the primary organizational units through which the research community has been involved in the caBIG® Program. The Workspaces will remain the thematic areas or virtual environments where caBIG® activities are grouped and prioritized. Specific software products and solutions will continue to be developed by the Developers based on needs identified by the caBIG® Workspaces and then tested, validated, and applied by the Adopters. The final products or solutions will be shared among the caBIG® community and are openly available to all interested users. Additional information about the ESN components can be found at Getting Support on the caBIG website.

In the Enterprise Phase of the caBIG® initiative, caBIG® technology is being adopted by an increasing number of sites, including NCI-funded institutions and others not directly funded by NCI. The expanding community of caBIG® technology adopters will need broad end user and technical support services to realize successful implementation of caBIG® tools and products. To meet this need, NCI CBIIT launched the caBIG® Support Service Providers Program as an integral component of the ESN. The structure of the program described below was developed with community input pursuant to a Request for Information (RFI) using web-based caBIG® communication channels that was issued in September 2006 by the NCI Program Management Contractor, Booz-Allen-Hamilton and an informational meeting in August 2007 of invitees

drawn from all respondents to the RFI and additional respondents who responded to a public posting of the meeting on the caBIG® announce list. The first Call for Applications was released in late April of 2008.

Information about the caBIG® initiative can be found at https://cabig.nci.nih.gov/. A description of the caBIG® Bundles (Life Sciences Distribution, Clinical Trials Compatibility Framework, and Data Sharing and Security Framework) being deployed by adopting institutions can be found at https://cabig.nci.nih.gov/tools/toolsuite_view. Relevant caBIG® technologies include:

- caCORE Infrastructure: http://ncicb.nci.nih.gov/NCICB/infrastructure
- Enterprise Vocabulary Services (EVS): http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/vocabulary
- Cancer Data Standards Repository (caDSR):
- http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/cadsr
- caCORE Software Development Kit (caCORE SDK): http://ncicb.nci.nih.gov/NCICB/infrastructure/cacoresdk
- caGrid Introduce Toolkit: http://www.cagrid.org/wiki/Introduce
- Common Security Module (CSM): http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/csm
- caAdapter: http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/caadapter
- caGrid: https://cabig.nci.nih.gov/workspaces/Architecture/caGrid/
- caGrid Introduce Toolkit: http://www.cagrid.org/wiki/Introduce
- caBIG® Compatibility Guidelines: https://cabig.nci.nih.gov/guidelines_documentation/
- Model Driven Architecture (MDA): http://www.omg.org/mda/
- Unified Modeling Language (UML): http://www.uml.org/
- Web Services Resource Framework- (WSRF-) compliant grid services: http://www.globus.org/wsrf/
- Data Sharing and Security Framework https://cabig-kc.nci.nih.gov/DSIC/KC/index.php/Main_Page

caBIG® Support Service Providers Program Description

This purpose of this Announcement is to describe the caBIG® Support Service Provider Program and to notify prospective applicants of the procedures and requirements for participation in the program. The NCI CBIIT will consider applications from qualified applicants that would like to become caBIG® Support Service Providers for 5 service areas as described below. The new fifth category of services in this announcement is: Data Sharing and Security Framework Implementation Support Services. Successful applicants will be invited to enter into negotiations to be granted a limited license to NCI's caBIG® program trademarks adequate to identify the applicant as a caBIG® Support Service Provider and market the caBIG® Support Service Provider's support services. Specifically, once licensed, they will be granted the right to label themselves as "Licensed caBIG® Support Service Providers" and may use that

label in marketing and other communications in connection with the caBIG® program. There is a Support Service Provider web page on the caBIG® community website and caBIG® participants seeking Support Service Providers will be directed to this page. Licensed Support Service Providers will also have special designations at caBIG® meetings, to include the caBIG® Annual Meeting.

NCI intends to exercise full stewardship over the caBIG® trademarks by selecting the caBIG® Support Service Providers, designating licensees, approving renewals for licenses and managing the program. In managing the program, NCI will review initial applications, provide access to caBIG® Support Service Providers through the caBIG® community website, and review performance for continued use of the caBIG® trademark. Renewal criteria will be based on demonstrated adherence to the terms and conditions of the license and continued maintenance of high quality services, assessed in part through feedback from customers of caBIG® Support Service Providers. NCI will select a limited number of the best qualified applicants for each designated service category.

caBIG® Support Service Providers will be sought for the following five service categories:

- Help Desk Support
- Adaptation and Enhancement of caBIG®-Compatible Software Applications
- Deployment Support for caBIG® Software Applications
- Documentation and Training Materials and Services
- Data Sharing and Security Framework Implementation Support Services.

    Applicants interested in Documentation and Training Materials and Services can apply for documentation only, training only, or both.

Applicants for each service category will be evaluated against the following criteria, which are described in more detail below:

- Technical capabilities
- Staffing and scalability
- Geographic coverage (when applicable)
- Domain expertise in biomedicine

Applicants will be evaluated against these criteria, which were developed with community input received in response to the September 2006 RFI and the August 2007 meeting of interested respondents. They will then be ranked against other applicants in the service categories to determine the field of initially qualified applicants.

This Announcement is not a procurement, and no funds will be awarded to successful applicants. caBIG® Support Service Providers will be independent entities (from commercial, academic or non-profit organizations) that are approved by NCI as meeting specific criteria for performance. Actual services will be rendered by caBIG® Support Service Providers to their clients under separate business arrangements organized by and between those parties only. Such contractual arrangements will be independent of the NCI and the caBIG® program. Designation of the

applicant as a Provider will not constitute an endorsement of the Provider's business by NCI. Rather, the designation will serve merely as an indication that the Provider has successfully complied with the evaluation criteria described in this Announcement.

Contents and Organization of Applications

Applicants are required to submit <u>separate</u> applications for each service category in which they seek to serve as caBIG® Support Service Providers. Applicants should clearly identify the service categories for which they are applying and respond to the evaluation criteria for each service category.

Applicants are requested to limit their applications to no more than 3 pages of background and general material, and 10 pages of response per service category (13 pages total) for which they seek to serve as an caBIG® Support Service Provider. **Note:** Applicants responding to both documentation and training may increase the page limit by 3 additional pages. NCI will not review any documents submitted beyond this page limitation. That is, if you are responding to documentation and training, you have 3 pages for background and general material, and 13 pages to respond to the documentation and training service category for a total of 16 pages. If you are applying for documentation only, or training only, you have 3 pages for background and general material, and 10 pages of response, for a total of 13 pages.

Applicants should include proposals for assessing customer satisfaction, i.e., receiving feedback from the clients they serve. Proposals for evaluating customer satisfaction should be included within the page limitation of the response (13 or 16 pages as described above). The proposals may be discussed during negotiations with initially qualified applicants. This feedback will be considered at the time of license renewal.

Service Categories and Evaluation Criteria

The grid below lists the service categories (across the top) against the evaluation criteria categories (vertically) that will be used to assess applicants for each service category. Both the individual service categories and the corresponding evaluation criteria are described in more detail below.

Service Categories					
Evaluation Criteria	**Help Desk Support**	**Adaptation and Enhancement of caBIG®-Compatible Software Applications**	**Deployment Support for caBIG® Software Applications**	**Documentation and Training Materials and Services**	**Data Sharing and Security Framework Implementation Support Services**
Technical Capabilities	X	X	X	X	X
Staffing and Scalability	X	X	X	X	X
Geographic Coverage	X			X	X
Domain Expertise in Biomedicine	X	X	X	X	X

Service Categories

Following is a brief description of the five service categories announced in this call for applications:

1. Help Desk Support

This service category includes support for the end users and local IT administrators in institutions using the caBIG® applications and tools contained within the two caBIG® Bundles Analytical tools bundles (Life Sciences Distribution, Clinical Trials Compatibility Framework, , as well as those wishing to adapt tools or connect their tools to the grid. Forms of support will include phone-based help desk, triage, trouble ticket tracking and escalation as necessary.

2. Adaptation and Enhancement of caBIG®-Compatible Software Applications

This service category supports caBIG®-compatible software development and includes adaptation of existing systems for caBIG® compatibility, custom enhancements to existing caBIG® tools that satisfy specific user-driven requirements while maintaining caBIG® compatibility, and *de novo* development of caBIG®-compatible applications and tools.

3. Deployment Support for caBIG® Software Applications

Deployment support includes onsite or offsite procurement and provisioning of hardware, operating systems and other software, such as application servers and databases, along with installation and configuration of caBIG® software, legacy data transformation and migration. Deployment support also includes integration of multiple caBIG® tools and caBIG®-compatible applications through open application programming interfaces (APIs). Possible services include data management, security services, hosting, performance tuning, network connectivity, grid enablement and maintenance of web server/database and application-specific administrative IT tasks. Deployment service activities may need to occur in laboratory or clinical environments that would involve integration into existing processes and procedures, some of which may be dictated by either technical requirements at the host site, requirements of current FDA Good Clinical, Manufacturing or Laboratory Practice (cGXP requirements) or regulatory requirements imposed by Federal, state or local governments.

4. Documentation and Training Materials and Services

This service category includes development of documentation and training materials and the provision of training services for caBIG® software applications, caBIG® compatibility for existing systems, and use of caCORE infrastructure.

Documentation can include both technical and end user manuals and should be complementary to any existing documentation and adhere to appropriate caBIG® guidelines. Training materials can include instructional content in best practices for software development methodologies, caBIG® software application use. Training services include training in semantic and syntactic interoperability as defined in the caBIG® Compatibility Guidelines and caCORE infrastructure supporting the development of caBIG®-compatible applications. This category also includes technical mentoring as a form of training service Technical mentoring refers to providing guidance and support to customers developing technologies and methods in compliance with caBIG® standards and practices in order to meet requirements for compatibility and/or certification. Applicants are encouraged to respond to documentation only, training only, or both. If responding to both, applicants must establish their capabilities for each subcategory in separate sections of the same application. **Note**: Applicants responding to both documentation and training can increase the page limit by 3 additional pages, for a total of 16 pages.

5. Data Sharing and Security Framework Implementation Support Services

This service category includes individualized support to end users in organizations that wish to use the caBIG Data Sharing and Security Framework (DSSF) to facilitate data sharing via the caBIG infrastructure. The DSSF is designed to contribute to an understanding of the nature of any mandatory legal restrictions on data sharing and agreements, if any, necessary to facilitate proposed exchanges of information. Individuals and organizations can use the DSSF to analyze distinct issue areas in order to assess the sensitivity of a given data set for sharing/exchange. The analyses are conducted locally to ensure institutional compliance with state law and institutional policy. The DSSF implementing tools include policies and

procedures, model documents, best practices and other tools that can be used to assist individuals and organizations in overcoming barriers to data sharing that may exist. The DSSF and current implementing DSSF tools may be found on the Data Sharing and Intellectual Capital (DSIC) [Knowledge Center wiki](#). Providers in this service category will support end users who want to use the existing DSSF tools, as well as those wishing to adapt these tools to fit institutional policies and requirements. This service category also includes support for end users who may wish to develop new DSSF support tools or to formulate individualized strategies utilizing the capabilities and areas of expertise described below that will enable them to share data via the caBIG infrastructure in compliance with their unique institutional requirements. The support service category also includes customized support for end users who need to navigate potential barriers stemming from local, state or international requirements.

As noted above, the caBIG Enterprise Support Network (ESN) is intended to augment the existing capacity of the caBIG® Workspaces, which will remain the thematic areas or virtual environments where caBIG® activities are grouped and prioritized. Two ESN components are envisioned for the DSIC domain area. In addition to caBIG Support Service Providers that are the subject of this Announcement, there is an existing component, the Data Sharing and Intellectual Capital (DSIC) Knowledge Center, which was established through subcontract to the NCI in September 2008. While both components are intended to serve the overarching goal of reducing nontechnical barriers to data sharing via the caBIG infrastructure, they serve different functions.

The DSIC Knowledge Center provides a centralized, authoritative repository of caBIG processes, model agreements, and other related general resources for implementation of the caBIG DSSF to encourage and facilitate data sharing to advance scientific discovery, consistent with applicable legal, regulatory, ethical, proprietary, contractual and socio-cultural requirements. The tools and guidance provided by the DSIC Knowledge Center are intended to assist the caBIG® community in facilitating data sharing activities but do not constitute legal advice and cannot be used by individuals or organizations to assure compliance with applicable federal, state and laws and institutional policies. In contrast, the services of a caBIG Support Service Provider in the category of caBIG DSSF Implementation Support will be defined by client-specific needs for customized policies, procedures, agreements and contracts, educational and training materials and informal guidance and opinions based on legal and policy research. The key difference is that clients of caBIG Support Service Providers in the category of DSSF Implementation Support will be able to rely on the independent, professional advice of such service providers in overcoming barriers to data sharing via the caBIG infrastructure.

Evaluation Criteria for Service Categories

1. *Evaluation Criteria for Help Desk Support*

Technical capabilities

The applicant must:

a. provide a multi-tier user support plan that includes setting up and delivering help desk/telephone-based user support services for users within diverse, decentralized, non-standard IT environments (*i.e.,* non-standardized desktop operating Systems (OS), hardware, networking, and software);

b. include an escalation plan that provides sufficient technical expertise at the higher tiers to address problems with the caBIG® technology stack;

c. have sufficient technical expertise on staff such that the majority of issues can be handled directly but provide a plan to interface with technical staff outside the applicant's organization and other components of the caBIG® Enterprise Support Network, e.g., application developers and Knowledge Center staff, when interface is appropriate and desired;

d. demonstrate experience with using infrastructure software, such as Customer Relationship Management (CRM), knowledge base tools, ticket/incident tracking tools, call centers (on-shore and off-shore) and closure and client satisfaction tracking and reporting systems; and

e. provide a template service contract that contains:
    i. explicit descriptions of the services to be delivered;
    ii. industry-standard performance metrics, tracking, and reporting;
    iii. mechanisms for managing problems; and
    iv. industry-standard client responsibilities.

The template service contract should be attached to the proposal and will not be included in the page count. The template should include the level of detail similar to that found in an executed service contract, including the specific components listed under each Service Category.

Staffing and scalability

The applicant must:

a. document that it has sufficient personnel currently on staff with the ability to spot issues across the domains covered by the caBIG® bundles or provide a detailed staffing and training plan; and

b. provide a staffing plan that will scale as the caBIG® program grows while maintaining service for its existing caBIG® clients.   The staffing plan is to be included within the 10 page response limit. This plan should address the organization's ability to apply the appropriate the number of staff with the necessary skills and experience, as well as address the scalability necessary for the long-term success of the program.

Geographic coverage

The applicant must demonstrate the ability to provide:

a. complete US coverage across time zones within the U.S., specifically, US Eastern, US Central, US Mountain, and US Pacific, at a minimum of 8 hours per work day for each time zone; and

b. complete US coverage for potential deployment of on-site personnel at a client's location in at least two tiers of time- and urgency-related responsiveness.

Domain expertise

The applicant must demonstrate:

a. user support capability suitable for the diverse abilities and backgrounds of staff in an academic-based biomedical research setting;

b. an understanding of the academic-based biomedical research environment, specifically, the distribution (or lack) of organizational authority as related to IT standards, systems, hardware, and software (as opposed to a more centralized IT support environment); and

c. biomedical research domain knowledge relevant to the applications and tools within the caBIG® Bundles. Applicants should list the caBIG® applications and/or technologies that they are able to support. It is not expected that every successful applicant will be able to support all caBIG®-compatible applications and/or technologies.

2. *Evaluation Criteria for Adaptation and Enhancement of caBIG®-Compatible Software Applications*

   Technical capabilities

   The applicant must:

   a. document experience with the caBIG® technology stack, specifically:
      i. caCore (EVS, caDSR, caCore SDK, CSM, caAdaptor) ;
      ii. MDA and UML;
      iii. caGrid- and Web Services Resource Framework (WSRF)-compliant grid services;
      iv. caGrid Introduce Toolkit; and
      v. caBIG® Compatibility Guidelines;

   b. employ an industry-standard software development methodology;

   c. provide evidence of the use of industry standard practices for project management, code versioning, and document management;

   d. demonstrate expertise in the fields of semantic mapping, harmonization of data sets, syntactic standards, controlled terminologies and self-describing data elements, structures and models;

   e. demonstrate the ability to ensure that the tools adapted or enhanced are caBIG®-compatible;

   f. demonstrate the ability to contribute enhancements to the current codebase of caBIG®-compatible applications that the applicant intends to support; and

   g. provide a template service contract that maximizes the level of understanding of caBIG® clients regarding deliverables and services, in terms of:

      i. approach for capturing scope of work and delivery schedules;
      ii. plan for ensuring applications are caBIG®-compatible;
      iii. dispute resolution; and
      iv. warranties and other representations regarding ongoing support.

   The template service contract should be attached to the proposal and will not be included in the page count. The template should include the level of detail similar to that found in an executed service contract, including the specific components listed under each Service Category.

Staffing and scalability

The applicant must:

a. document that it has sufficient personnel currently on staff with experience in the caBIG® technology stack or provide a detailed staffing and training plan;

b. provide a staffing plan that will scale as the caBIG® program grows while maintaining service for its existing caBIG® clients;(The staffing plan is to be included within the 10 page response limit. This plan should address the organization's ability to apply the appropriate the number of staff with the necessary skills and experience, as well as address the scalability necessary for the long-term success of the program. There is no minimum size for staffing, but staffing should be sufficient to meet the support criteria.), and

c. submit the names of the staff, their resumes, and a description of their experience with each component of the caBIG® technology stack, specifically:
  - caCore (EVS, caDSR, caCore SDK, CSM, caAdaptor) ;
  - MDA and UML;
  - caGrid- and Web Services Resource Framework (WSRF)-compliant grid services;
  - caGrid Introduce Toolkit; and caBIG® Compatibility Guidelines.

Resumes should be attached to the proposal; they are not included in the page count.

Geographic coverage

Geographic coverage is not an evaluation criterion for this service category.

Domain expertise

The applicant must:

a. demonstrate the ability to successfully develop software that will be used in a biomedical research or health care delivery environment, e.g., software that supports clinical trials, clinical care, molecular bioinformatics, laboratory operations, or biospecimen management;

b. demonstrate the ability to successfully develop software that is subject to the following regulations or best practices:

  i.   FDA regulations for electronic records and signatures (21 CFR Part 11);

  ii. Standards for Privacy of Individually Identifiable Health Information and the Security Standards for the Protection of Electronic Protected Health Information, 45 C.F.R. Part 160 and 45 C.F.R. Part 164 (the Privacy and

Security Rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA));

 iii. Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. Part 46 (the "Common Rule") and FDA Regulations concerning the Informed Consent of Human Subjects, 21 C.F.R. Part 50; and

 iv. Current FDA Good Laboratory/Clinical/Manufacturing Practices (cGXP requirements); and

c. demonstrate knowledge or participation in relevant standards development organizations such as MGED, CDISC, HL7, SNOMED.

3. *Evaluation Criteria for Deployment Support for caBIG® Software Applications*

Technical capabilities

The applicant must:

a. demonstrate ability to support implementation of enterprise class software applications in administratively decentralized academic-based biomedical research medical center environments (both remote and onsite);

b. provide evidence of ability to design, build, and staff (or hand over) "server" rooms in academic-based biomedical research centers;

c. demonstrate ability to provide IT systems as an application service provider (ASP), (it is not expected that a Support Service Provider will offer ASP services before the market requires support of this offering);

d. demonstrate ability to repackage application stacks as distributions with "turnkey" installation requirements;

e. demonstrate ability to replace/upgrade data-rich legacy software systems, including the ability to conduct data migration;

f. provide validation strategies for transformed and transferred data;

g. demonstrate capability to integrate multiple applications or tools through open APIs;

h. demonstrate ability and commitment to integrating packaged software through open APIs rather than writing new software code, in order to discourage forking or new versions of the code; and

i. provide a template service contract that covers:
 i. an approach for capturing scope of work and delivery schedules;

ii. dispute resolution; and

iii. warranties and other representations regarding ongoing support.

The template service contract should be attached to the proposal and will not be included in the page count. The template should include the level of detail similar to that found in an executed service contract, including the specific components listed under each Service Category.

Staffing and scalability

The applicant must:

a. document that it has sufficient personnel currently on staff to provide deployment services or provide a detailed staffing and training plan; and

b. provide a staffing plan that will scale as the caBIG® program grows while maintaining service for its existing caBIG® clients.

The staffing plan is to be included within the 10 page response limit. This plan should address the organization's ability to apply the appropriate the number of staff with the necessary skills and experience, as well as address the scalability necessary for the long-term success of the program. There is no minimum size for staffing, but staffing should be sufficient to meet the support criteria.

c. submit the names of the staff and their resumes. Resumes should be attached to the proposal; they are not included in the page count.

Geographic coverage

Geographic coverage is not an evaluation criterion for this service category.

Domain expertise

The applicant must:

a. demonstrate the ability to deploy and/or support IT operations in regulated biomedical environments, which include management of clinical trials data subject to 21 CFR Part 11, the Clinical Laboratory Improvements Act (CLIA), cGXP requirements, etc.; and

b. demonstrate the ability to deploy and/or support IT operations in highly unstructured academic settings.

4. *Evaluation Criteria for Documentation and Training Materials and Services*

Technical capabilities

The applicant must:

a. demonstrate expertise in the processes of documentation development;

b. establish ability to interact and communicate with subject matter experts and other technical and administrative personnel in order to author appropriate software documentation;

c. demonstrate experience with documentation development and authoring tools;

d. show examples of having developed software documentation according to technical communication best practices;

e. document experience developing documentation and training materials and/or delivering training services to relevant audiences;

f. provide evidence of training facilities relevant to the domain areas to use as locations for training;

g. demonstrate experience with and access to a sufficient suite of distance learning technology tools;

h. demonstrate experience with and access to relevant software tools for the development and distribution of online documentation and training materials;

i. document development of software development curricula encompassing development technologies and methods utilized by the caBIG® community; and

j. demonstrate experience in providing training through a number of training approaches.

Applicants will be encouraged to respond to one or both of these categories (documentation and/or training). If responding to both categories, they will be required to establish their capabilities for each subcategory in separate sections of the same application. **Note**: Applicants responding to both categories (documentation and training) can increase the page limit by 3 additional pages.

Staffing and scalability

The applicant must:

a. document that it has sufficient personnel currently on staff to develop documentation and training materials and/or provide training services, or provide a detailed staffing and training plan;

b. establish that personnel are skilled in training and educating, not merely acting as technical experts;

c. provide a plan for having personnel become proficient in the caBIG® tools, standards and infrastructure for which they will be creating documentation and training materials; and

d. provide a staffing plan that will scale as the caBIG® program grows while maintaining service for its existing caBIG® clients.

The staffing plan is to be included within the 10 page response limit. (If applying to both documentation and training, there is a 13 page response limit.) This plan should address the organization's ability to apply the appropriate the number of staff with the necessary skills and experience, as well as address the scalability necessary for the long-term success of the program. There is no minimum size for staffing, but staffing should be sufficient to meet the support criteria.

e. submit the names of the staff and their resumes. Resumes should be attached to the proposal; they are not included in the page count.

Geographic coverage

The applicant must:

a. demonstrate the ability to host training sessions or conferences on large scale, *e.g.,* greater than 50 attendees;

b. demonstrate the ability to deliver training remotely (at client sites); and

c. demonstrate the ability to deliver documentation and training materials electronically.

Domain expertise

The applicant must:

a. demonstrate the ability to develop user training and documentation materials for highly educated users with biomedical backgrounds but varied informatics abilities;

b. provide information concerning prior development of self-paced user training tools; and

c. demonstrate an appreciation for the target audience in determining the appropriate training approach.

5. Evaluation Criteria for Data Sharing and Security Framework Implementation Support Services

Technical (functional) capabilities

The applicant entity must address its capabilities in some or all of these functional areas of expertise for which it applies to become a caBIG licensed provider of services:

a. Demonstrate ability to analyze laws, regulations, directives or governmental policies and guidance governing or affecting the development, implementation, or use of caBIG® tools; may include informal or formal professional opinions if requested by clients

b. Demonstrate ability to develop or modify institutional policies and procedures to facilitate the use of caBIG® tools, consistent with applicable laws, regulations, directives, and governmental policies and guidance, and with other institutional policies and objectives; may take the form of customizing current DSSF tools or developing new tools that address the needs of individual client/end users.

c. Demonstrate ability to develop or modify proposed study or research protocols, preparation of consent documents, and other materials necessary to secure IRB/other internal organizational approvals and obtain participant consent or authorization as appropriate, all with the objective of facilitating appropriate data sharing or information exchange via the caBIG infrastructure

d. Demonstrate ability to draft and negotiate contractual documents relating to development and deployment of caBIG-compatible tools, including the conduct of studies or use or disclosure of information collected during studies that make use of such tools (e.g., software license agreements, clinical trial agreements, material transfer agreements, patent license agreements, data access/use agreements, collaboration agreements, data sharing plans for grant applications and contract proposals, and other sponsored funding, technology transfer or resource sharing agreements), all with the objective of facilitating appropriate data sharing or information exchange via the caBIG infrastructure

e. Demonstrate ability to prepare or modify relevant regulatory compliance and technology transfer training materials; though not required, consideration will be given to documented experience in providing training on these topics to relevant audiences

f. Establish ability to identify and route technical issues to appropriate technical experts, and to interface with technical experts while maintaining support to clients in legal, human subjects research ethics, regulatory and policy matters when such interface is appropriate and desired

g. Demonstrate experience in interacting and communicating effectively with various institutional stakeholders involved in decisions that affect data sharing, including researchers and their study teams as well as the institutional subject matter experts such as privacy officers, compliance officers, chief information officers, legal counsel, human research protection program directors, IRB staff, IRB chairs, technology transfer office, research associate deans, and sponsored program offices.

h. Demonstrate an understanding of the boundaries between the responsibilities of the DSIC Knowledge Center and a Support Service Provider for caBIG® DSSF Implementation Support.

i. In addition, the applicant must provide a template service contract or engagement agreement compliant with applicable laws and standards of practice that contains:

      i. explicit descriptions of the services to be delivered;
      ii.   industry-standard performance metrics, tracking and reporting;
      iii. mechanisms for managing problems; and,
      iv. industry-standard client responsibilitiesand client rights including addressing client rights to arbitration and/or alternative dispute resolution.

The template service contract should be attached to the application and will not be included in the page count. The template agreement should include the level of detail similar to that found in an executed service contract.

Staffing

The applicant must:

a. document that it has sufficient State Bar licensed attorneys, policy analysts or other qualified personnel currently on staff or available through contractual or other affiliation arrangement with the documented experience, professional expertise and organizational ability to address issues in DSSF domain areas for which it intends to provide support service(s).

b. provide a staffing plan so that the majority of issues and areas applied for can be handled responsively with near immediate support. The staffing plan is to be included within the 10 page response limit. There is no minimum size for staffing, but staffing should be sufficient to meet the full range of the domain support areas for which the applicant proposes to provide services.

c. submit the names of the staff and their brief resumes. Resumes should be attached to the proposal; they are not included in the 10 page limit. Each resume should not exceed 3 pages in length.

Geographic coverage

Geographic coverage is not an evaluation criterion for this service category. However, applicants should explain any limitations to nationwide coverage. It is understood that, for example, an applicant entity or its staff may be licensed to practice law in only one or certain few jurisdictions. This does not limit the entity's ability to perform as a SSP for purposes of this program for "out of state" institutions that may require support that does not rise to the "practice of law" as defined by the state in which the institution does business or to the extent that applicants affiliate with local counsel as may be required. Applicants should list the states in which they have staff available who are licensed to practice as well as indicate the range of services they propose to provide to institutions that are not within their licensure(s), if such distinctions for licensed versus unlicensed services exist within the list of capabilities they propose to support.

Domain (substantive) expertise

The applicant must demonstrate substantive expertise in some or all of the domain areas of the DSSF used to assess the sensitivity of data prior to sharing. Demonstrated expertise in the following areas is an indicator of an applicant's ability to support the deployment of the DSSF to assist individual and institutional end users in sharing data and/or engaging in collaborative activities through the use of caBIG tools and infrastructure:

a. U.S. Federal and state laws, regulations, and policies governing human research, including the conduct of clinical trials and observational studies

b. U.S. Federal and state laws, regulations and policies concerning health privacy

c. U.S. Federal and state laws, regulations, and policies governing the management of and access to biospecimen resources and associated data,

d. U.S. Federal and state laws, regulations, and policies governing intellectual property protection of biomedical innovations and associated technology transfer issues

e. Corporate structures, business affiliations, and sponsorship, venture funding or other financing strategies employed in the biomedical community that affect an entity's decisions regarding data sharing

f. Contracting for IT support services that relate to the deployment of caBIG® tools in an institution, including the preparation of service level agreements to identify institutional responsibilities and specify institutional expectations for ongoing service from the contractor

g. U.S. Federal and state laws, regulations, and policies governing public-private partnership and contracting arrangements for matters described above

h. International laws, directives and policies concerning human research, biospecimen resource and data management and health privacy regulation

Process for Selection of caBIG® Support Service Providers; License to Use caBIG® Trademarks

NCI CBIIT will make an initial determination of qualified applicants that may then seek to enter into negotiations with NCI to become licensed to use the caBIG® trademarks in specifically designated fields of use. The initial determination of qualification does not guarantee that an applicant will be designated a Licensed caBIG® Support Service Provider since, as a prerequisite for the designation, a trademark license acceptable to NCI at its discretion must first be negotiated with the qualified applicant. NCI in its sole, reasonable discretion reserves the right to limit the number of caBIG® Support Service Providers to ensure it can provide effective stewardship of the caBIG® trademarks within the available resources of the caBIG® program. Licenses to use the caBIG® Trademarks are issued for this program for the sole purpose of use in connection with advertising support services within the specified field of use; the licenses are NOT to be used in connections with claims of caBIG® compatibility for a product. caBIG® compatibility for software products is conferred via the procedures defined at the caBIG® community website at https://cabig.nci.nih.gov .

License to Use caBIG® Trademarks

Successful applicants will be eligible to negotiate a license with NCI to use the caBIG® trademarks in their advertising for support services within a specified field(s) of use. Licensed caBIG® Support Service Providers may use this designation in marketing documents, websites, sales tools, and other communications only as described and limited by the license to highlight the fact that they have been granted licenses in a merit-based, competitive process. Licenses will be issued with "field of use" restrictions, granting the licensees the rights to use the caBIG® trademarks in some or all of the specific service categories for which they have qualified and been selected. Licenses may be granted in a subset of the categories for which applied.

No pre-set limits on numbers of providers for each category have been determined. The NCI reserves the right to (a) limit the number of licenses issued in any category and (b) not issue any licenses in a particular category. It is therefore possible that an applicant may minimally meet all of the criteria in a particular category and but still not receive a license because of license limitations imposed to contain the size of the license holder cadre for NCI management purposes and the relative merit of the proposal versus other proposals in that category.

Licenses may be subject to annual review and renewal by the NCI. Renewal criteria may be presented to prospective licensees during negotiations on the terms and conditions for the license agreement. If issued, renewal criteria will be based on demonstrated adherence to the terms and conditions of the license and continued maintenance of high quality services, assessed in part through feedback from customers of caBIG® Support Service Providers.