NIH eRA Commons Working Group (CWG)

Date/Time: Wednesday, January 8, 2003, 1–5:45 p.m.
Location: Marriott Residence Inn–Irvine Airport, Irvine, Calif.
Chair: George Stone
Next Meeting: Wednesday, April 30, 2003, 1–5 p.m., Washington, D.C.

Action Items

1. (Steve Dowdy, Ken Forstmeier) Write a statement concerning the development of data standards for transmitting data electronically about human subject protocols and the benefits the NIH and FDA would derive from working with the extramural community.
2. (JJ McGowan) Choose an NIH representative to be involved with the human subject data standard initiative.
3. (Tim Twomey) Distribute a high-level bug list for eSNAP to the CWG.
4. (Tim Twomey) Send email request to CWG members asking them to process from one to three SNAPs.
5. (CWG) Send list of SNAPs they intend to process and the specific dates for this action to Tim Twomey (check Status for grant list).
6. (Tim Twomey) Provide follow-through and targeted support for each CWG member as they process their eSNAPs.
7. (Dan Hall) Prepare and distribute a list of the functionality and enhancements scheduled for the March deployment to the CWG.
8. (David Wright) Send out an action list from this meeting as soon as possible.
9. (Dan Hall) Investigate the use of the e-Notification system for administrative change notice dissemination.
10. (Dan Hall) Investigate how roles are defined, including the AA role. Reevaluate the restrictions on the AA role and its interoperability with other roles.
11. (Sandy Seppala) Post the SBIR Partnership Meeting minutes on the eRA Web site.

Documents

The following documents were discussed in the meeting:

- Agenda and NIH eRA Commons update: http://era.nih.gov/Docs/Agenda_eRA_Update_1-8-03.pdf
- eRA Update (JJ McGowan's presentation): http://era.nih.gov/Docs/eRA_Project_System_Update_01-08-03.pdf

- CWG Reviewer Meeting Discussion Topics: http://era.nih.gov/Docs/CWG_Reviewer_questions_final.pdf
- NIH Action Items for NIH Competitive Application Reengineering: http://era.nih.gov/Docs/NIH_Action_Items_CWG_01-08-03.pdf

Introduction

George Stone welcomed the group, mentioning that it was the eighth meeting of the Commons Working Group. The purpose of the group is to share views and gather the requirements necessary for partner institutions to communicate with NIH through the NIH eRA Commons system.

He welcomed Pamela A. Webb, now the Senior Director, Sponsored Research, Office of Research Administration at Stanford University, to her new position. George noted that Pamela's representation of Stanford on the CWG is a result of Stanford, through Mr. Geoff Grant, offering an institutional commitment to the NIH eRA project.

eRA Update

John (JJ) McGowan

Presentation: eRA Project System Update (http://era.nih.gov/Docs/eRA_Project_System_Update_01-08-03.pdf)

Dr. McGowan, who addressed the CWG through a conference call and a PowerPoint presentation, provided an overview of the status of the eRA project at the NIH. Some of the points most relevant to the CWG are included here.

Dr. McGowan noted that the project is in good health but is under some stress, which, however, can be a keen motivator for moving the project forward. Some of the key stress factors are:

- Rolling out applications and functionality in a timely way.
- Recognition that usability must be improved.
- Need to migrate NIH internal systems quickly.
- Re-engineering of business practices.
- Demands for increase in scope and responsibilities based on expanded user access.
- Response to scaled-back functionality implemented last May to match existing resources.
- Current resources have not matched need for the project for it to remain healthy (but help may be on the way).

He noted that this year is a ramp-up year for the NIH eRA Commons where usage of the different applications will start to increase and that full market penetration for eSNAP (electronic Progress Reports) should happen sometime next year.

As we bid farewell to the IMPAC I system, which served the NIH well for the last 30 years, we recognized that we would have to take a technological leap to J2EE architecture. This migration would have to be very fast to be successful and to minimize the exorbitant costs required for the maintenance of the old system based on Oracle Forms. Currently, the model shows two databases, IMPAC II and NIH eRA Commons, based on client-server architecture and Oracle Forms. The future model shows simply the

eRA database, combining the IMPAC II and NIH eRA Commons databases into one system based on J2EE architecture.

Overall, users are actively engaged in the use of eRA systems and user feedback indicates a common agreement that things are better today compared to two years ago.

There has been a "budget revolution" regarding the eRA project. In FY 1999, $15 million per year was allocated to eRA. In FY 2000, an initial 5-year financial plan was established and a business case increased funding to $34 million per year. The financial plan, because of the J2EE migration, now is being revised to reflect the new reality of the project. In FY 2001, the initial cost model was developed and the project began its first, baseline year of the 5-year plan. Funding was received in May 2001 and project funding was based on priorities on a May-to-May cycle.

In FY 2002, an eRA Planning and Tracking Cost tool was developed that tightly coupled requirements with cost. This led to the development of a more realistic budget based on actual baseline business projections. This process clearly showed that there were not enough resources to develop requested requirements AND keep the project on schedule. Therefore, the project was down-scoped in May 2002 by eliminating requirements. However, many of these eliminated requirements had to be added back into the schedule because a successful deployment was dependent upon them. There was also a significant increase in resources necessary for NIH eRA Commons support.

Budget recommendations above and beyond the base for the next two years include:

FY 2003

- Request a $10 million contingency fund allotment
  - $4.9 million in requested budget base increase to be used for further software development and maintenance
  - $1.5 million for Loan Repayment Program (this will be built into the internal process but will be separate from other IMPAC II applications)
  - $0.6K for QVR (IMPAC II reporting tool) support
  - $3.0 million in contingency fund money

FY 2004

- Request a $4.9 million increase to budget base
- Request a 10 percent contingency fund allotment, ~$5 million

The FY2003 software-development priorities can be divided into three areas: external facing (e.g., CGAP, eSNAP, FSR data stream), internal facing (e.g., CGAP processing, Committee Management, Program interface), and common components (e.g., data architecture, Person module, e-Notifications).

From these categories, the priorities for FY 2003 are—

- Data Quality
- E-Grants
- Program Portfolio Management Interface

- IC Staff Roles and Management Interface
- Enhancing reports and query tools
- Partial integration of loan repayment applications
- iEdison
- X-Train (version 2)
- Pilots: Knowledge Management (Review, Program) and Wireless

The NIH eRA Commons modules will be deployed through FY 2004 as follows.

In Production now:

- Computer Retrieval of Information on Scientific Projects (CRISP)
- Interagency Edison (iEdison)
- Institutional Profile
- Professional Profile
- Accounts Administration
- Application/Award Status
- X-Train
- FSR

Target January 2003 for production:

- Institutional Registration
- eSNAP: Progress Reports
- Internet Assisted Review (IAR)

Target FY 2004 for production:

- Competing Grant Applications

By the end of 2003, two years of grant application images will be available electronically. In conjunction with this, eRA staff is working with ICs to eliminate paper mailings.

SBIR Initiative Status

There are six companies who are SBIR grantees, each developing products that can be marketed to NIH grantee organizations:

- Cayuse, Inc.
- Clinical Tools, Inc.
- ERA Software Systems, Inc.
- Formatta Corp.
- InfoEd International

- Research and Management Systems, Inc. (RAMS)

An initial meeting with all awardees to establish milestones took place at the NIH on Nov. 13, 2002.

Action: (Sandy Seppala) Post the SBIR Partnership Meeting minutes on the eRA Web site.

The meeting allowed for the awardees to introduce themselves and for a discussion of the timeline. Of particular importance was the need the awardees have for the NIH to issue a set of XML standards. JJ Maurer was introduced as the lead analyst for the NIH on this effort. He put forward an aggressive timeline for the development of standards and the proof of concept of receipt of an XML data stream to support the simple R01 competitive application.

As SBIR awardees contemplate Phase II in the development of value-added solutions to eRA for the grantee community, the source of additional funding must be considered. JJ acknowledged this fact, indicating that he would be looking for future funding for Phase II. The magnitude of support remains to be determined, but could be as high as $18 million overall for Phase II of the development process.

JJ noted that NIH partners are not limited to these six funded SBIRs. The NIH is actively seeking agencies, foundations, profit and not-for-profit organizations to partner with.

The program contact for the SBIR awards is Dr. Amy Swain, NCRR, and she can be contacted at swaina@ncrr.nih.gov.

Impact of DHHS E-Grants

The NIH has a working relationship with DHHS staff, and, as the CWG likely know, Paul Markovitz has been on detail to the E-Grants project. With the eRA SBIR project plus the agreement of a data-stream standard that is compatible with the direction of E-Grants, there is a very strong possibility that the SBIR vendors' products will act as models for E-Grants. At the same time, with the model for E-Grants showing a "trusted broker" scenario, the NIH SBIR model integrates well.

The long-term vision of the E-Grants project, besides the "trusted broker," shows an "electronic storefront" scenario. When this is finally implemented, all grant applications for the U.S. government will come through one "storefront" and then be transmitted to the applicable agency for processing. This long-term model also works well with the direction of the eRA project.

The key points for the NIH eRA strategy are:

- SBIRs are an integral part of our strategy to—
  - Develop business-to-government software and procedures
  - Fully penetrate the market to conduct e-grants within three years
  - Build, enhance and customize components for research organizations
- We need the SBIR and other partners to be successful

We will provide opportunities for the private sector to—

- Use the data stream for research and to develop products (core and non-core data)
- Use an Adobe-linked 398 (core and non-core)
- Market to others with the support of the NIH (XML or Adobe take the core plus features of the 194-specific to market for each agency and research organization)

Dr. Elias Zerhouni, the new director of the NIH, has enough technical background to know that the NIH today does not have the technology implemented to handle the complexity of research and data of the future. He is exploring, through several committees, how to establish the NIH in the best position to achieve its goals for this century. One advisory committee has prepared a "Vision for Medical Discovery in the 21st Century" report, which includes three sections:

- A Foundation for Achievement
- A Roadmap to Meet New Challenges
- An Investment in Future Health

Dr. Zerhouni has identified some major roadblocks to solving these key questions:

- How can we address the challenge of biological systems complexity?
- Are we entering an era of "big" science?

Dr. Zerhouni's committees are moving very quickly to determine what needs to change and how best to change them to meet these future challenges.

For the NIH, there are four themes in its future roadmap:

- Revolutionary methods of research
- New pathways to discovery
- Multi-disciplinary research teams of the future
- Re-engineering the clinical research enterprise

These themes lead us to ask the questions: Should the eRA be—

- A business processing and reporting tool?
- A business intelligence tool?
- A knowledge discovery tool?
- A clinical research tool?

With these visions and challenges in mind, the NIH is pondering the efficacy of having all its data in one database so that knowledge can be mined more efficiently. There are many roadblocks for this to be a reality, e.g., data dictionaries, but the overall vision seems sound. Should the eRA be involved in this effort? Neither the NIH nor its grantee institutions have a universal data protocol. Would it make sense for the NIH to invest in establishing one?

JJ asked that the CWG provide input in sorting out these issues over the next weeks/months.

In response to JJ's presentation, several questions and comments were posed.

Will the DHHS use the NIH eRA system? DHHS is interested but we have taken a low-profile position while we get our business processes and systems in place so that they work efficiently. DHHS is looking at how applicable it might be for the entire agency to use a single eRA system. JJ emphasized that the eRA systems, as they are configured, cannot be applied to other agencies like a commercial off-the-shelf (COTS) product. However, the database business rules could be released and adapted to other agencies. JJ sees three possibilities for agencies in adopting the eRA system model:

- Follow the NIH business rules and come on at no cost
- Customize the components for their own use at some cost
- Build upon the lessons learned of the eRA project, but build an architecturally independent system

DHHS is not as technologically advanced as the NIH and should provide money to the NIH for its technology if it would like to take advantage of it. JJ is working with the DHHS to show them that the NIH is developing a very complex product, not just buying a COTS product and modifying it.

Reengineering Clinical Research

Dr. Zerhouni is addressing the importance of clinical research reporting as part of the roadmap he has described. For the NIH, this means having a common functionality to support IRB and clinical research for all the NIH ICs. A key issue here is defining a standardized dataset. It is in this arena that the CWG has previously registered interest. AT the most recent CWG meeting, Steve Dowdy suggested that this topic be raised: that the CWG might want to weigh in on the importance of this topic and work closely with the NIH to recognize a standard dataset that would meet both the NIH's and the FDA's requirements for IRB and clinical research reporting. JJ indicated that, while the NIH sees the overall vision as very complex, there are some "low-hanging fruit" that can be plucked now. While the agency still is exploring the limits of protocol management, one area that bears early consideration is adverse event reporting, since several of the NIH ICs already have defined data dictionaries to support this type of reporting.

Steve Dowdy indicated that, in fact, many institutions are working together on this issue. A consortium of ten institutions is working with Steve to develop a standard data dictionary for IRB functionality in the COEUS system. Pharmaceuticals are working on a second version of a common data stream. Dartmouth is putting together a system for multiple institution communication for their clinical component. Yet another group is trying to define common terminology (e.g., "deferred," "referred," "tabled").

The CWG agreed that their institutions would prefer that the NIH be involved in defining the data standards for protocol management. George Stone pointed out the fact that the CWG is a great nucleus for addressing data standards for these critical business processes.

JJ indicated that there is no forum as yet at the NIH to which institutions can look to for guidance and answers to questions. Dr. Zerhouni has convened a clinical research informatics working group. However, the group has just formed and is still not far along in their work. JJ strongly suggested that if there are issues that the CWG want addressed, that they be directed to him and he would funnel them to the appropriate group or person.

JJ noted that the FDA is very interested in electronic processing of IRB-related information. JJ and others are looking at the requirements and possibilities that would not impose a regulatory burden on the agency. One excellent model would be for the eRA to refine Reporting vehicles as an example of what its system and business rules are capable. This would be an excellent public relations tool for this program, as well as the means by which the FDA and the NIH could come together toward a common dataset.

George Stone reminded the group that Steve Dowdy would be moderating a panel covering this topic at the FDP meeting the following day. It was agreed that the FDP would be an excellent vehicle for the FDA to become involved in the formulation of a common dataset. The group agreed that it is important to get the FDA involved in the project in the first phase, and Steve indicated he would be sure that such a recommendation came out of the panel.

The importance of this topic to the CWG membership resulted in Steve Dowdy and Ken Forstmeier suggesting that the CWG craft a statement to encourage the NIH to work with the extramural community in the furtherance of IRB and clinical research reporting data standards.

Action: (Steve Dowdy, Ken Forstmeier) Write a statement concerning the development of data standards for transmitting data electronically about human subject protocols and the benefits the NIH and FDA would derive from working with the extramural community.

Action: (JJ McGowan) Choose an NIH representative to be involved with the human-subject, data-standard initiative.

NIH eRA Commons Deployment

Tim Twomey

Tim Twomey provided an overview (http://era.nih.gov/Docs/Agenda_eRA_Update_1-8-03.pdf) of the latest NIH eRA Commons functionality, including newly released modules. The NIH eRA Commons functionality includes:

- New graphical user interface (GUI) interface
- New Institution Registration
- Accounts administration: creation and maintenance
- Institutional Profile (IPF)
- Person Profile (PPF)
- Grant Status
- Demonstration facility
- FSR
- eSNAP
- IAR

He reviewed the deployment schedule for NIH eRA Commons 2 from the first release on Oct. 11, 2002, through the July 12, 2003, planned deployment. Version 2.2.1.0, the most recent deployment, takes place this week on Jan. 10 and includes the following:

- Open registration
- Basic screen/user interface enhancements
- Bug fixes/minor enhancements to eSNAP/FSR/IAR
- FSR open to all registered organizations
- IAR release to two study sections to pilot
- eSNAP pilot to CWG

He noted that registration is now open but that it was not widely advertised. This allows new users to register gradually and for analysts to address bugs and issues before there is a huge influx of new registrants.

As of January 7, 72 institutions and 700 users were registered on the NIH eRA Commons. Tim defined users as registrants who have browsed the site in their role or have used a module.

X-Train. X-Train 1.5 is deployed and 23 grantee organizations are using it with 289 trainee appointments processed since Oct. 1, 2001. Deployment of version 2.0 is planned for mid-FY2003.

Training and Outreach. There are several places for users to obtain information and help for the NIH eRA Commons, including:

- On-line/content-sensitive help
- User Guides (PDF format)
- "Cheat sheets"
- FAQs and other resources
- Enhanced demo/training site
- NIH eRA Commons Support page (http://era.nih.gov/commons)
- Seminars and workshops at national and regional meetings
- Helpdesk

eSNAP. Tim said that more work was needed on the interface before it is released to a wider audience. However, major functionality is in this week's release. One issue is the few number of eSNAPs processed so far. Without more test eSNAPs, it is difficult to ascertain what problems must be addressed. Toward this end, Tim requested that each CWG member agree to submit at least one eSNAP for the March deadline.

After some discussion, it was agreed that each CWG member institution would work closely with Tim Twomey and his staff to process from one to three eSNAPs in a relatively short timeframe. Tim said that when an institution requests it, he enables their ability to process eSNAPs on the NIH eRA Commons.

Action: (Tim Twomey) Send email request to CWG members asking them to process from one to three eSNAPs.

Action: (CWG) Send list of eSNAPs they intend to process and the specific dates for this action to Tim Twomey (check Status for grant list).

Action: (Tim Twomey) Provide follow-through and targeted support for each CWG member as they process their eSNAPs.

The group also would like to be attuned to the functionality of each deployment.

Action: (Dan Hall) Prepare and distribute a list of the functionality and enhancements scheduled for the March deployment to the CWG.

The group asked that an action list from this meeting be sent out as soon as possible, prior to the distribution of the minutes.

Action: (David Wright) Send out an action list from this meeting as soon as possible.

The issue of eSNAP elicited several suggestions and comments. The group asked that the high-level "bug" list be distributed so that they could better prepare input and not duplicate already reported problems.

Action: (Tim Twomey) Distribute a high-level bug list for eSNAP to the CWG.

FSR

The Financial Status Reports (FSR) module is open to all registered organizations. To date, 300+ FSRs have been processed of which approximately 100 are from the extramural community. However, not all of the data from the old system has been uploaded to the new system yet and the old system is still in place.

It was noted that the old FSR system is on a different server and in a different department than the NIH eRA Commons. Consequently, there are some extra roadblocks to transferring the old data into the new system.

Roles

The group discussed at length user role permissions and their shortcomings. Some of the issues cited included the following:

Notification to Admin. The administrator currently is not notified should one of their group encounter a registration problem. Consequently, the follow-through that would be expected from the administrator doesn't take place until the user mentions it to the administrator. It was suggested that an automatic email be delivered to the administrator at the same time the user is notified of a problem.

SO Access. The Signing Official (SO) has access to all accounts and can make changes to them. However, the changes they make affect other people, who are not notified of the changes. There needs to be a way for appropriate people to be notified of any changes an SO makes to an account.

It was noted that it is not possible to design a program that includes all roles and rights for every institution. The system must have a built-in flexibility so that it can be more universally applied.

Action: (Dan Hall) Investigate the use of the e-Notification system for *administrative* change notice dissemination.

Face Pages and Roles. Currently, all roles can see the Type 5 Face Pages except the AA role. The group suggested that either the AA should not be restricted or a new role should be created that has permission to view and administer Face Pages. This new role could be assigned to appropriate staff at the institution level.

Action: (Dan Hall) Investigate how roles are defined, including the AA role. Reevaluate the restrictions on the AA role and its interoperability with other roles.

Validation. There was some concern that the validation of new registrants was taking longer than anticipated. Tim Twomey and Dan Hall indicated that as of now, the NIH is committed to processing account requests (i.e., completing validation) within 48 hours of receiving the account request.

Future Deployments

The March deployment will include the following:

- Enhanced demo and training facility
- Improved account affiliation management
- More user-interface enhancements for eSNAP

- Expanded IAR pilot
- Other fixes and enhancements

There will be a deployment in July, which will include the following:

- X-Train Version 2, Phase 1
- Organizational hierarchy and grant assignment
- Human subject reporting screens in eSNAP
- eNotification for T5 progress reports
- Other fixes and enhancements
- IAR full production

Internet Assisted Review (IAR)

Dan Hall

The IAR module—

- Allows reviewers to submit preliminary critiques and scores prior to review meeting
- Facilitates meeting discussion and speeds up review process
- Integrates with NIH eRA Commons accounts

Dan emphasized that, while the IAR allows reviewers to preliminarily score and critique applications, nothing gets finalized before the actual review meeting.

A major hurdle for the IAR system to overcome was to allow users who are not affiliated with registered research institutions to log in to the same system as users who are affiliated with registered research institutions. The system is able to support both types of accounts (more than 80 percent of reviewers are PIs affiliated with registered research institutions).

The initiation of the IAR process falls outside the purview of the institution. The NIH Scientific Review Administrator (SRA) initiates an invitation to a meeting. If the selected reviewer is already registered in the NIH eRA Commons, the reviewer receives an automatic invitation to the meeting. If the reviewer isn't registered, the reviewer is sent an email containing an account registration URL and asked to register. The reviewer must have the email URL to enter the registration page. The reviewer's email address and phone number is then matched to that of the original email and corresponding data for final validation. Once validated, the reviewer can enter the IAR module.

The IAR module uses the same interface as the NIH eRA Commons. If a reviewer has an IAR role, it is so noted in the upper right corner of the screen.

Dan noted the difference between an affiliated reviewer (has been listed by institution as affiliated with it in the NIH eRA Commons) and an unaffiliated reviewer (does not have a listing with an institution). If a reviewer account is unaffiliated and they should be affiliated with a particular institution, there is a mechanism for the institutional administrator to do this. This functionality will be made easier to use in the March release. The institutional administrator can also remove a reviewer from its institutional affiliation through the "delete account" screen. However, the reviewer is not deleted from the system but rather reverts to "unaffiliated" status.

Currently, only PIs can have a role in the IAR.

In coming enhancements to the IAR module, there will be a new column in Status that will show pending PIs and unaffiliated PIs.

CGAP Data Stream Approach and Models

JJ Maurer

JJ Maurer has been named the lead analyst for CGAP design, development and deployment. He has taken action first in the area of design of the way in which the CGAP data stream might be received by the NIH. His presentation focused on this aspect of the CGAP process. He plans to divide the overall task into four phases:

- **Phase 1:** Standard XML documentation, technology and application receipt flow
- **Phase 2**: Application receipt and validation
- **Phase 3:** Business-to-government flow and interchange infrastructure
- **Phase 4:** Integration with bi-directional communications on IPF, PPF, FSR and other possible requests

Phase 1: Applications Only

During the first phase, the data standards for applications will be defined. The technical architecture for receiving and storing the applications will be defined as well as the NIH internal business flow to process the electronic applications.

Phase 2: Receipt of e-Applications

During Phase 2, the transaction receipt and format validation will be determined, and the prototype and test of the receipt function with external partners will be conducted.

Phase 3: Applications and B2B

During the third phase, exchanging transaction-related messages (not email) with outside institutions and businesses will be defined. A pilot, with a limited set of live applications, will be conducted.

Phase 4: PPF, IPF Integration

This entire phase—defining and implementing PPF, IPF bi-directional transactions and defining a receipt stream for FSR and e-SNAP—will be purposely delayed until the end of the task. This is being done in recognition of the complexity of this part of the transaction. In essence, this phase will address the issue of how to consolidate or exchange data on Profiles.

Target Timetable

JJ emphasized that the timetable for this project need not conform to the release schedule of the NIH eRA Commons. Tentatively, the 2003 schedule is as follows:

Phase 1: Now to the end of January

Phase 2: February–April

Phase 3: May–July

Phase 4: August–November

Short-Term Actions

The following has been accomplished so far:

- Developing more detailed plan
- Activated a focus group for e-Receipt and Referral
- Activated the SBIR listserv and communicated approach
- Started developing the technical solution for packaging, transporting and storing XML and documents
- Assigned resources
- Procured and received test hardware. Must be configured.

Receipt and Exchange Models

Towards a definition of how the CGAP data stream will be transmitted, JJ presented a proposal to address the system load that will have to be anticipated to support the three major annual receipt dates. The basis for the model takes into account the current way in which applications are submitted, as well as how submission practices will change for CGAP.

By October 2003, if all goes well, institutions will be able to submit grant data to the NIH through a service provider (SBIR application or service), Federal E-Grants broker, or 398 kit (the forms, which will be resident on the user's computer, will be submitted to the NIH at which time relevant data will be extracted, parsed and transferred to the database). In the future, if current federal plans come to fruition, all grants will be submitted to the NIH through a Federal E-Grants broker. However, in that plan, the Service Provider and 398 kit will still be in place but between the institution and the Broker instead of between the institution and the NIH.

One problem that JJ is seeking to overcome is the rush to submit grant applications at a deadline. This is the phenomenon where most of the proposals to be submitted for a particular review cycle are submitted within 24 hours of the deadline. In his proposed scenario, when the institution is ready to submit, it communicates that to the NIH and is given an "e-ticket." This "e-ticket" assigns an accession number and a place in the submission queue. Later, the NIH signals for the institution download of its submission data. This process accommodates the mass submissions at a deadline by not receiving the entire application, but only a request to submit. This, in turn, greatly reduces the burden on the computing environment and creates a more orderly, less intensive electronic submission process.

JJ conceded that there are many details to be worked out, e.g., many institutions do not operate on a 24x7 basis so could not download on a weekend or late at night. Also, there must be assurance from the Service Provider that nothing will be changed in the grant once the submission ticket is issued. The group suggested that the download timeframe be defined on the submission ticket.

JJ's objective in presenting this new ticket submission process was to get consensus on the concept. The CWG agreed that the concept was a good one.

There was a question regarding system downtime possibly penalizing on-time grant submissions. NIH representatives at the meeting said that certainly the NIH would make accommodation for system downtime.

A suggestion was made to investigate Microsoft's program, Background Intelligent Transfer Service (BITS). It provides, according to the description on the Microsoft Web site, "the documentation and samples necessary to write client applications that transfer files (downloads or uploads) between a client and server, and monitors jobs within the transfer queue. Use BITS for applications that need to asynchronously transfer files in the foreground or background, throttle the transfer to preserve the responsiveness of other network applications, and automatically resume file transfers after network disconnects and machine reboots." It uses the Simple Object Access Protocol (SOAP) to pass information to partners across platforms and through firewalls.

Messages—Web Services

JJ reviewed the types of transaction-related messages that will need to be built into the computer-to-computer exchange for CGAP:

- A message acknowledging that an XML file has been sent and/or received by a computer
- Message acknowledging that the transaction has attachments
- Each message type has its own XML schema and workflow paths

Message types include the following examples:

- Form 398 with PDF project plan and CV attachments
- Appendices to a Form 398
- Request for submission of 398
- Queue ticket
- Notification of receipt of XML file
- Notification of acceptance of application by NIH
- Notification of IRG and IC assignment
- FSR, eSNAP, Profile submission
- Protocols (e.g., clinical trial protocols)

JJ noted that we also have to address several issues as we move forward with communications for the NIH eRA Commons and related projects:

- This approach is not validated with E-Grants. In fact, there is no one hired as yet in the E-Grants office to address communications issues.
- Each service provider must have a listener to acknowledge inquiry and begin the transaction process.
- Each service provider must write the interfaces to their own systems and NIH exchange.
- Standards may change.
- Protocol and technology are not defined.

eSNAP Issues

Following JJ Maurer's presentation, comments were raised regarding the extent to which the eSNAP software incorporates the streamlining of the SNAP business process that was recommended by the CWG. The position taken by one member of the CWG was that they questioned whether the new eSNAP incorporated any of the streamlining to which NIH had supposedly agreed. One particular example was cited, the Personnel Report, as an instance where the NIH agreed to remove this information as part of streamlining.

George Stone strongly defended the fact that the new version includes all agreed-upon streamlining benefits. He reminded the CWG of discussions involving the former OPERA Director, Ms. Carol Tippery, regarding the Personnel Report. He recalled Carol's recounting of the numerous times over her 29-year history with the NIH where she worked unsuccessfully for the removal of the Personnel Report. As part of the eSNAP streamlining, she had again made this effort and was again rebuffed, this time at the DHHS. Marcia Hahn, the NIH staff who played a key role in vetting the CWG suggested eSNAP improvements to various NIH committees, corroborated George's recollection of the need for the NIH to retain the Personnel Report.

George explained that, as a compromise of sorts, the content of the Personnel Report will be auto-populated once key personnel data is entered during the competitive cycle, or as part of the first time the eSNAP is submitted. In all subsequent years, unless key personnel changes, there will be no further need to take any action to complete this Report.

In an effort to allay concerns regarding other aspects of eSNAP, George and other NIH staff quickly enumerated the other changes that have now been implemented in the new eSNAP process.

Streamlining the Competitive Grant Application Process (CGAP)

George Stone and David Wright

George Stone and David Wright reviewed each area of change suggestions made previously by the CWG and provided an explanation regarding the results of their investigation. They reiterated the fact that this continues to be a work in progress. Consistent with that statement, George and David presented slides and discussed progress on the approximately 30 action items that had been identified as an outcome of several previous CWG meetings. Also, they spoke of a meeting that was held with NIH reviewers/applicants that was held immediately prior to the CWG meeting.

Based on suggestions from Suzanne Fisher, Brent Stanfield and Richard Panniers of CSR, several NIH staff met with scientists from UC Irvine, UC Riverside and UCLA. As a means to capture their perspective on at least some of the major issues around the reengineering of the CGAP, they were asked to provide answers to several questions. The survey is included as an attachment to the minutes (http://era.nih.gov/Docs/CWG_Reviewer_questions_final.pdf). The expressed points of view will be included as we proceed with reaching a consensus on the items being considered for reengineering.

As a means to facilitate discussion, David identified the extensive list of action items within categories, as follows. In the matrix below, the analysis of each item is included.

Item	Results
IPF, EIN, Congressional District	
IPF/DUNS	Critical for identification of submitting institution and must be available for validation process.
EIN	Required for award financials and is associated with the IPF.
Congressional District	Used by the NIH for reporting to Congress and validated by the NIH according to ZIP code. However, this submission requirement is not necessary so it probably could be eliminated.
Abstract: ASCII vs. Rich Text	
ASCII vs. Rich Text	Rich text to facilitate referral process. ASCII-only to facilitate manual indexing for CRISP. Current auto-index pilot software requires ASCII.
ASCII	Doesn't show Greek characters and mathematical computation. The audience should determine the necessity of these characters.
Rich Text	Can show Greek characters.
Addresses and Signatures	
Box 9: Applicant Organization	Requirement of IPF. No need for repeated submission.
Box 12: Administrative official	Required. GMOs use as a first point of contact for negotiations and awards.
Box 14: PI Signature	Required. Legally binds PIs. Precedent exists for electronic delegation.
Percent Effort	
Required to determine if effort is reflective of scope (42CFR, 52h)	Can be provided in the budget justification narrative.
Required to support administrative regulations and cost principles (45 CFR, 74.25)	Provided through the budget page.
Maintain narrative for determination of scope	No comment.
Submission as JIT for administrative regulations and cost principles	No comment.

Item	Results
Budget and Other Support	
Itemized Budget Information	Used by GMOs to assess liability of cost and reasonableness of scope of work. Used by reviewers to assess reasonableness of scope of work.
Other Support	Used to assess experience and expertise. Used by reviewer, program, and grants management to identify possible scientific, commitment, and budgetary overlap.
Consider overall simplification consistent with modular applications	No comment.
Text-based Information	
PDF will be standard file format for application materials	Issues include: image and print quality, file conversion and PDF versioning. Suggestion: Standardize font type and font size.
Research Plan: Formatting the Submission	
Research Plan	Sections A–D must be in a separate file to allow validation of formatting. Other sections to be submitted as one or more separate files.
Formatting validation rules to be determined and in place prior to submission	Validation of page limits and fonts. Adherence to data requirements and business rules.
Leniency with formatting violations	NIH to provide warning with time for correction.
Appendices	
Streamlining of receipt via JIT submission directly to the SRA	No comment.
CSR to support receipt of paper-based appendix material directly to SRA after application assignment	No comment.
Streamlining via submission of electronic documents	PDF documents (converted from MS Word, WordPerfect, text) once conversion service in place. Upload document through NIH eRA Commons Status module. Preference for submission of single, multi-component file.

Item	Results
Process must ensure receipt of "documents" by all relevant NIH staff	Reviewer, IC GMO, IC Program.
Potential for "push" notification to PI	Notification of application assignment, SRA contact information, due date of materials.
Biosketch and Citations	
Content and Format of Biosketch	Support for standard content and format for ease of analysis by reviewers/GMO. Support for optional content and format to accommodate PIs to excerpt from CV.
Questions posed to reviewers/applicants with assistance from CSR	No comment.
Citation Options	Utility in PPF to select citations and download in PDF to embed in the stream. Just in Time (JIT) upload via the eRA Status interface when assignment has been made (similar to electronic appendix materials). JIT association (via institutional or third-party software) via the eRA Status interface when assignment has been made. Consider using number of citations rather than page length to standardize length.

Administrative Items

Travel Reimbursement—George reminded the group that eRA would reimburse expenses for this meeting. Send requests for lodging reimbursements to George Stone.

***SBIR Questions*—**Chris Harker of Cayuse, Inc., inquired whether it was appropriate for him to contact members of the CWG with questions pertaining to his product. George made the distinction that Chris was welcome to contact the CWG so long as the contact involved requirements gathering or question pertaining to scope of the SBIR grant that Cayuse received. Contact of the CWG for exclusive general marketing purposes would not be acceptable. David followed up with the suggestion that if Chris or any other vendor was not sure if it was appropriate, they should contact us for clarification.

***Next Meeting*—**The next meeting will be held on Wednesday, April 30, 2003, 1:00–5:00 p.m., in Washington, D.C., in conjunction with the FDP meeting.

Attendees

CWG Members

Lynette Arias (Oregon Health Sciences Univ.)

Ellen Beck (UCLA)

Denise Clark (Cornell Univ.)

Steve Dowdy (MIT)

Jane Fant, (Univ. of Medicine and Dentistry of N.J.)

Ken Forstmeier (Penn State Univ.)

Jill Keezer (Cal Poly State Univ.)

Graydon Kirk (Emory Univ.)

Tolliver McKinney (St. Jude Children's Hospital)

Jim Randolph (Univ. of Mich.)

Sandi Robins (Univ. of Wisc.)

Susan Ross (Northwestern Univ.)

Mark Sweet (Univ. of Wisc.)

Pamela A. Webb (Stanford Univ.)

Tom Wilson (Baylor College of Medicine)

Nancy Wray (Dartmouth Coll.)

Others Institutional Representatives

Bob Beattie (Univ. of Mich.)

Michael Benedict (City of Hope)

Sac Carreathers (City of Hope)

Tammy Custer (Cornell Univ.)

Dan Dwyer (Cornell Univ.)

Phil Martin (Dartmouth)

David Mayo (Caltech)

Melody Page (Univ. of Texas, M.D. Anderson Cancer Center)

Holly Sommers (Emory Univ.)

Richard Valenzuela (UCLA)

Vendors

Chris Harker (Cayuse Software)

NIH Staff

Suzanne Fisher (CSR)

Marcia Hahn (OPERA)

Richard Panniers (CSR)

George Stone (OPERA)

Tim Twomey (eRA)

Regina White (OD)

David Wright (OPERA)

NIH Contractors

Dan Hall (Z-Tech)

JJ Maurer (Ekagra)

Sandy Seppala (LTS)