

eRA Support and Reporting of NIH Sponsored Research

Tuesday, September 9, 2003



Topics

- ➔ Co-investigator
- ➔ Key personnel
- ➔ Enterprise reporting of scientific spending
- ➔ E-Grants (eRA & Grants.gov)

Co-Investigator Tracking

Why do we need to track Co-Investigators?

- Change in science from single projects to teams across disciplines
- Need to be able to recognize the contributions of co-investigators* on team/multi-disciplinary projects by tenure committees, publishers, and funders of research

*Other specific definitions to clarify the contributions may be needed

Co-Investigator Tracking

What needs to be done to make these changes?

➤ Does policy need to be changed?

➤ Yes

- ❖ If authority is given to a co-investigator that is currently vested in the PI
- ❖ If the definition is changed from what currently is defined in policy:
 - An individual involved with the principal investigator in the scientific development or execution of a project. The co-investigator may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered “key personnel.” The designation of a co-investigator, if applicable, does not affect the principal investigator’s roles and responsibilities as specified in this policy statement.

➤ The database will need to allow this (and other) designation with percent effort and records

➤ Include co-investigator listing on Notice of Grant Award

Key Personnel Specification

What do you want to accomplish?

- Recognize other scientists on a project
- Analyze key personnel at the time of grant submission and changes made over the life of the grant
- Conduct aggregate analysis of the scientific expertise across disciplines working across NIH
- Track changes in the research expertise and determine how that affects given research disciplines
- Gather information on salary and percent effort and conduct analysis on them across disciplines
- Provide better information for management of portfolios for NIH staff
- Reduce reporting complications involved with edits/changes to “key personnel” in system

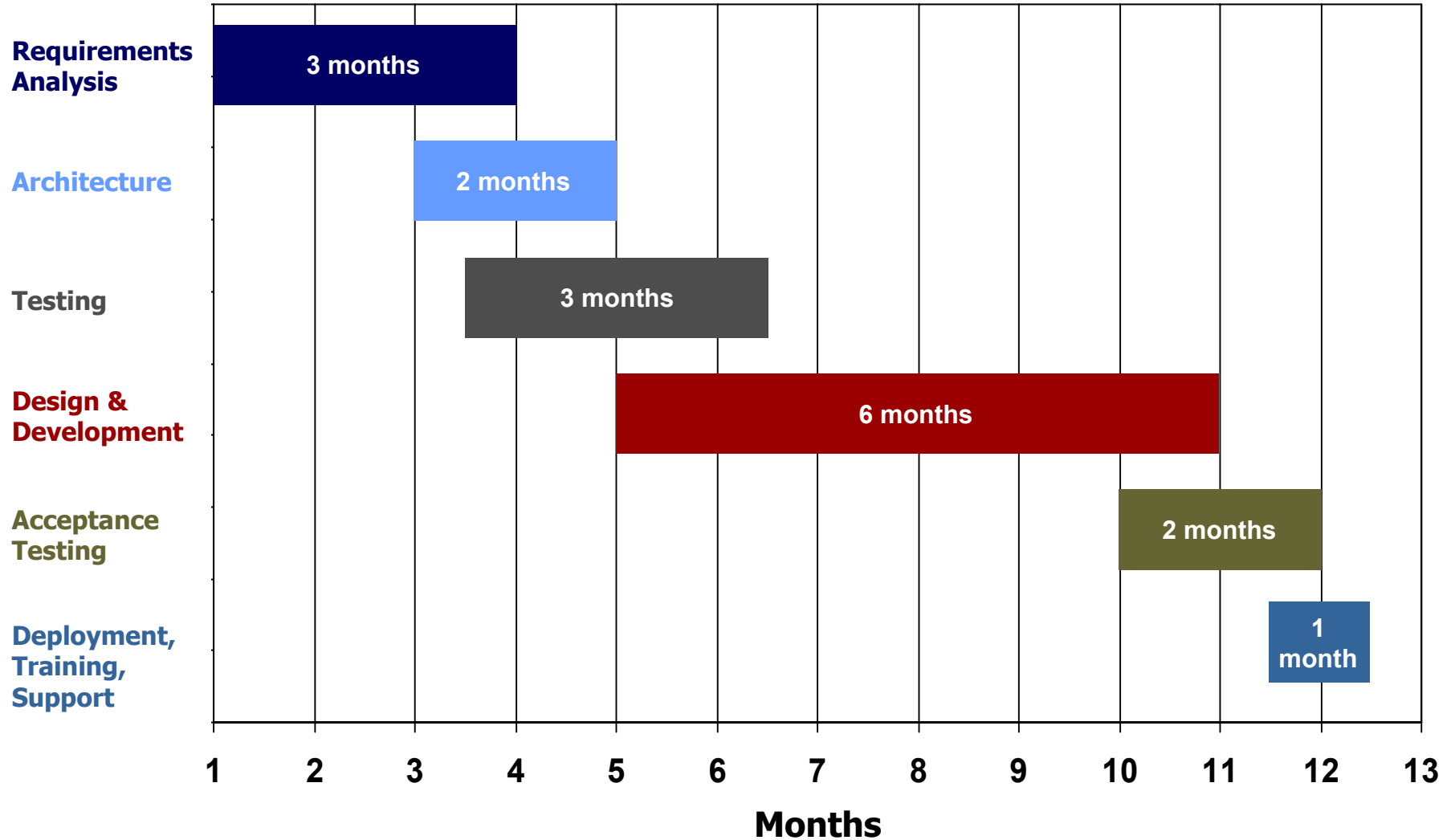
Key Personnel Specification

What needs to be done to make these changes?

- Refine policy definition for “key personnel”:
 - **“Individuals who contribute in a substantive way to the scientific development or execution of a project, whether or not they receive compensation from the grant supporting that project. The principal investigator and collaborators are included in this category.”**
- Define “roles” for key personnel or adopt roles identified by Grants.gov (PD/PI, Co-PD/PI, Key Person, Post Doctoral Associate, Other Professional, Graduate Student, Undergraduate Student, Technician, Consultant, Other)
- Generate a list of key personnel roles in the system, add to data schema, and modify all current applications

Key Personnel / Co-Investigator

Approximately one year to implement changes



Key Personnel / Co-Investigator

Approximately one year to implement changes

Requirements
Analysis

Budget estimated at **\$1,000,000**

(64 months of work hours at \$100/hour)

Architecture

- Requirements Analysis = 2 people x 3 months

Testing

- Architecture = 2 people x 2 months

Design &
Development

- Testing = 2 people x 3 months

- Design & Development = 6 people x 6 months*

Acceptance
Testing

- Acceptance Testing = 2 people x 2 months

Deployment,
Training,
Support

- Deployment, Training, Support = 3 people x 1 month

* Without adding full business processing, we can drop 4 developers from the Design & Development stage; this will reduce costs but not time.

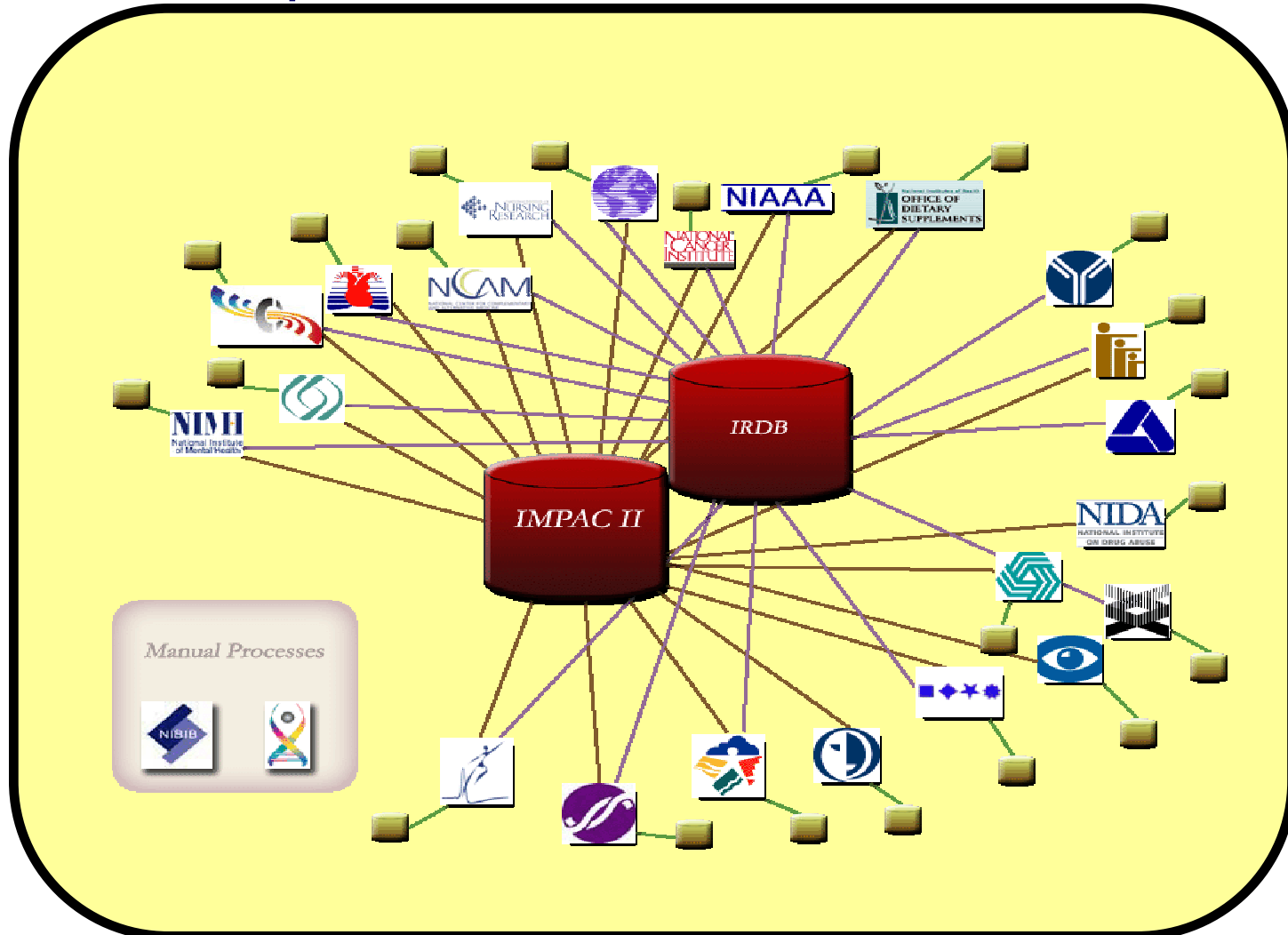
Key Personnel / Co-Investigator

Why does it take a year and cost \$1 million?

- The new Rational Unified Process (RUP) used by eRA for enterprise systems ensures a quality product
- RUP requires analysis of:
 - **8 stove-piped IMPAC II modules**
 - **4 J2EE modules**
 - **Common database reporting module**

Enterprise Reporting of Scientific Spending

- Is this possible?
- What's the problem?



Rapid Reporting of Scientific Spending

Current Status:

- **>20 databases:** Used to index (map) scientific projects
- **Poor reporting:** NIH-wide reports not available
- **Overlapping:** Different business processes solving similar business problems
- **Inefficiency:** Duplication of resources (human & machine)
- **Load:** Unnecessary load on eRA databases
- **Lack of a common understanding:** Scientific definitions to index (map) to dollars

Rapid Reporting of Scientific Spending

What do we need to do to make these changes?

- Agree to a strategy that allows flexibility within the ICs and capitalizes on existing solutions and front-end technology.

Rapid Reporting of Scientific Spending

What do we need to do to make these changes? (cont.)

- Strawman for discussion:
 - Let ICs have their own front-end and definitions
 - Redesign the eRA reporting repositories
 - Establish a common data model to be used by all
 - Capitalize on cost savings generated to encourage ICs to use one of the following:
 - ❖ Adaptation of the “STARS” system used by 10 ICs
 - ❖ eRA/nVision collaborations – QVR and CRISP headings
 - Develop a meta-layer and map IC definitions to an enterprise role up view to be shared with all ICs and the OD
- Establish, within the Office of the Director, a group that is responsible for defining the terms in the meta-layer and how they map to IC definitions

Estimated Projected Budget for FY03

Project Management	\$4.2 million
Support & Operations	\$4.0 million
Communications & Outreach	\$3.5 million
Architecture	\$1.7 million
Quality Assurance & Configuration Management	\$6.5 million
Technology Infrastructure	\$8.6 million
Analysis, Design, & Application Development	\$12.5 million
Total	\$41 million

Impact on the Project

- Additional requests will have significant impact on activities planned for 2003 and 2004
- Costs to implement would absorb 50% of the budget for analysis, design, and development of new software

Current eRA FY2004 Priorities

- Grants.gov and CGAP integration
 - Expand pilot of electronic receipt of applications
 - Integrate workflow of electronic application in current business process applications, including Receipt and Referral, Peer Review, IC Operations and Grants Management
- HHS OPDIV coordination
 - Analysis and migration of all OPDIV legacy data into eRA database
 - Analysis and development of any changes needed for OPDIV use of eRA systems as the HHS Enterprise system for all research grants
 - Coordination of data-mart with CIT and ACF GATES system for unified reporting system of research and non-research funding across HHS

Current eRA FY2004 Priorities (cont.) ...

- Continue ongoing three-year effort to convert all current and shared modules developed in legacy Oracle forms to Web-based J2EE-developed systems
- X-Train 2.0: Complete design and development for both internal NIH and external institutional use for training grant administration
- RFA/PA: Complete design and development for use by NIH and OPDIVs as creation and total workflow process
- Council Module: Analysis, design and development of workflow for grants to be used by Program and Budget to track, report and support business flows more efficiently
- Analysis and initial design of an electronic workflow process for entire lifecycle of a grant, including all e-notifications (email notifications to relevant actors of changes to grant status or process) and e-requests (external and internal requests made to NIH for changes in status or process on the grant)
- Additional details provided on slides **37-43** as background material

eRA Update

DHHS Consolidation of Grants Systems

- DHHS will begin to collapse from 11 to 2 systems in 2004 :
 - **eRA system (IMPAC II) chosen as the system for all research grants within DHHS**
 - **ACF chosen as the system for all other grants**
- eRA CRISP on the Web will be the public reporting system for all DHHS grants

What Are the Numbers so Far?

Agency	# of Users
AHCPR	186
CDC	62
FDA	1
NSF	15

Impact on the eRA Project

- Each OPDIV is welcomed and treated as another IC
- In the past, a school tax system used on a per volume basis = to the NIH IC tap
 - **This needs to be reexamined with regards to reporting systems, legacy data, data marts, UFMS tie in, requirements to add new features and other migration issues**
- Each OPDIV is welcome to participate with representatives on the project team and each functional area
- DHHS likely to have a core team of architects and project managers working across the Department to help the migration

Competing Grant Application Process

- CGAP: NIH's implementation of the electronic 398 and other NIH applications
 - **Not specifically a part of NIH eRA Commons**
- Grants.gov: Government-wide storefront for all grant applications

How: eRA Exchange

- **Computer-to-computer** information exchange;
no front-end
 - **In-coming applications and requests**
 - **Out-going messages and status updates**
- XML as the technology for structured data
- PDF for text and graphics

Target Timetable

➤ Phase 1: January 2003

- **Standard XML documentation, technology and application receipt flow**
- *Inception, tech architecture and analysis*

➤ Phase 2: February—June 2003

- **Application receipt and validation**
- *Build and test the receipt of XML data stream*

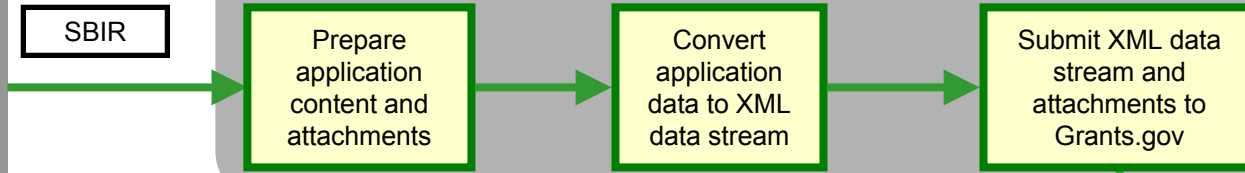
➤ Phase 3: July—August 2003

- **Business-to-Government flow and interchange infrastructure**
- *Complete design and build business-to-government exchange*
- *Pilot*

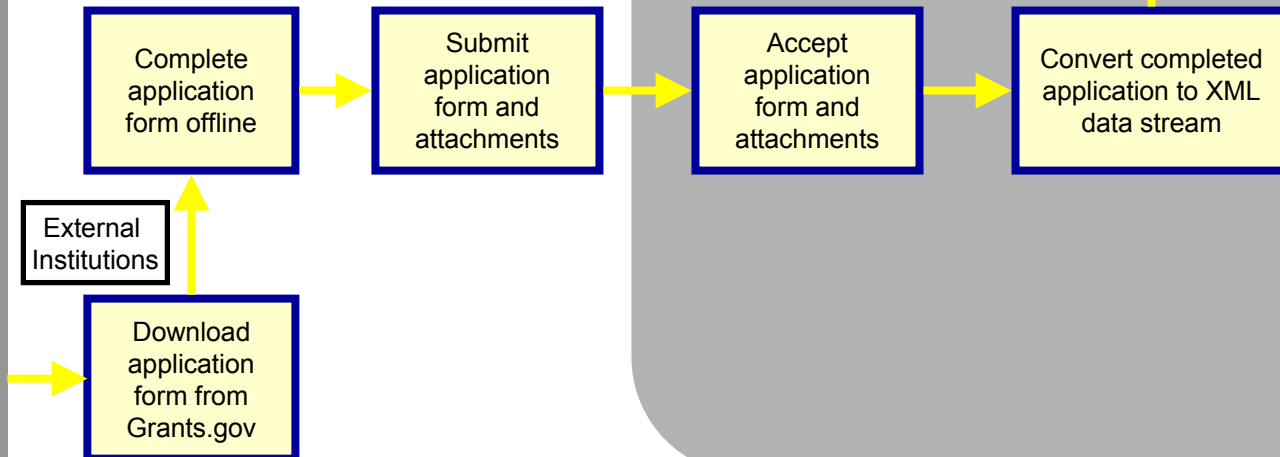
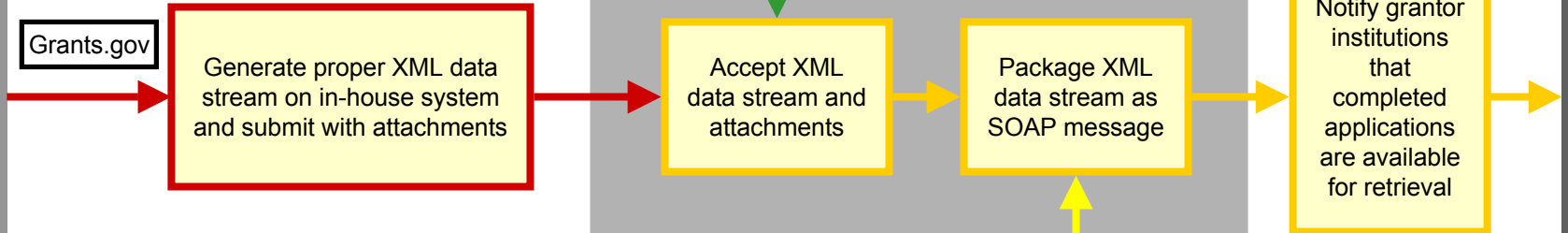
➤ Phase 4: August—November 2003

- **Integration with bi-directional communications on IPF, PPF, FSR and potentially other requests**
- *Build out the integrated system for e-Applications : test and gradual introduction*

Commercial Service Providers



Grants.gov *A trusted broker*



Registered Grantees

Grantor Institutions

Coordination with Grants.gov

- Grants.gov hired development contractor (Northrop Grumman, AT&T, Ekagra)
- Monthly coordination meetings with Grants.gov and NIHD (Dr. McGowan, Jim Cain, Charlie Havekost)
- eRA staff participates in the Grants.gov team



Many Applications Released

➤ Unrestricted Interfaces

- NIH and OER Web Sites - <http://www.nih.gov/grants>
- CRISP on the Web - Awards Database - <http://crisp.cit.nih.gov>

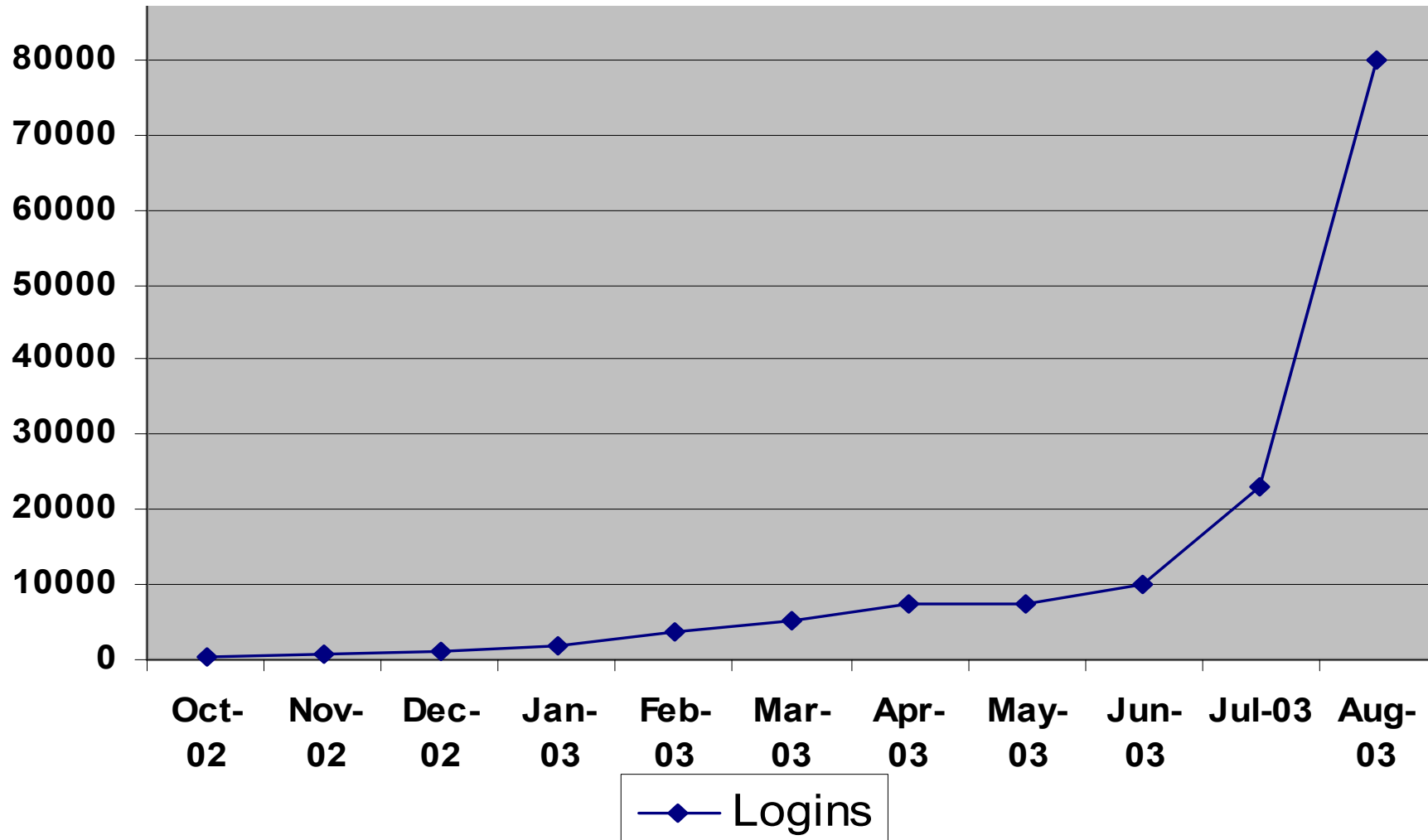
➤ Restricted Interfaces – <http://commons.era.nih.gov>

- Commons Registration – Initial set-up for organizations
- Accounts Administration – User account maintenance
- Application/Award Status – Monitor grant applications & awards
- Institutional & Professional Profiles (IPF & PPF)– Maintain repetitive
- Information about institutions and investigators
- Competitive Application(CGAP)– Competing Grant Application
- Trainee Appointments (X-Train) – Trainee Appointment maintenance
- Submission of non-competing progress reports (e-SNAP)
- Financial Status Report (FSR)
- Internet Assisted Review (IAR)
- Interagency Edison (iEdison) – Invention Reporting

Current Status of NIH eRA Commons

- **Registration/User Information**
 - **More than 80,000 total log-ins**
 - **More than 500 organizations**
 - **More than 4,700 user accounts**
 - **More than 2,600 PIs**

Hits Per Month



August Release Highlights

- **electronic Simplified Non-competing Application Process (eSNAP)**
 - Users can submit Population Tracking Inclusion Enrollment reports.
 - Users can enter a Signing Official (SO) as the Administrative Official (AO) on the face page of the eSNAP without having to create an AO role for the SO.
 - Users can indicate that an individual page has been completed; the status of the page will be shown on the Manage eSNAP screen.
 - eRA Commons.
 - A new tool is available for NIH validation of the historical data associated with an IAR/PI Commons account request .
 - The PI can include additional NIH support to an account that is attached to another profile.
- **Grants Closeout Module (GCM)**
 - Module tuned for improved system performance.
 - Closeout specialist and central IC email address (where summary statements are sent) are copied on all emails . “Closeout” is included in the email subject to enable staff to create Outlook forwarding rules.
 - Users can search for an individual grant by serial number and mark it as pending or unfunded.
 - Council meeting date added to the Check Pending List.
 - Users can sort on any column of the Pending List, My Closeout, Show All, and FRC Report.
 - Three new data elements added: destroyed date, whether or not the Program Official received the final progress report, and whether the report is acceptable.

August Release Highlights (cont.)

➤ **Grants Management (GM)**

- Notices of Grant Awards include Budget and Project Period Start and End dates for Fellowships after activation .
- The wording of edit check result messages are modified per the recommendations of a user working group.
- Users can access the Subproject Maintenance Screen from GM.
- The document number for Type 9 grants is in the new format with the last character always equal to 'A'. The business rule that validates the award document number is modified to validate this new format.
- IC Search Track Order Report (ICSTORE).
- Users can query for and display Loan Repayment Program (LRP) applications.
- Subprojects added to "Add Additional Grants" functionality.
- Institute and Center Operations (ICO).
- Users can "advance" the council date for an application from the October round to the preceding August or May round.
- Loan Repayment Program (LRP) applications are included in the GUM hit list.
- ICs can require population tracking of any application with a human subjects exemption of E4 by setting the tracking exception code to "00."

August Release Highlights (cont.)

➤ **Internet Assisted Review (IAR)**

- IAR into production - all SRAs and GTAs with an IMPAC II account can use IAR.
- A calendar on the Edit Dates screen enables the user to choose a date from the calendar instead of typing it in.
- A meeting-wide option for including reviewer names in the preliminary summary statement body is available. Users can choose to include or omit reviewer names.
- The grant application number is a hyperlink for viewing the grant image.
- If users submit or delete a critique for an application and then click back to the list of applications, they will return to the same application instead of the top of the list .
- Ability to zip all preliminary summary statements into one zip file.
- Ability to view a critique on the Submit Successful screen.
- The option to view all meeting critiques (in Adobe PDF format) sorted by PI name.

➤ **Peer Review**

- Four reports available for output in MS Excel format: Assignments – Master Copy (landscape), Administrative Data, Composite Score, and Voter Matrix .
- RFA/PA added to the IRG/SRG Reassignment hit list report.
- SRA remarks added to the Assign Reviewers and IRG/SRG Reassignment screens.
- Line 5 removed from addresses; the city, state, and zip code fields will be used to build the last line of the address.

August Release Highlights (cont.)

➤ **Population Tracking (Pop Tracking)**

- Pop Tracking integrated with the eRA Commons eSNAP module.
- Phase 3 Checklist available through the Application Program Interface (API) .

➤ **Program Class Code (PCC) Application Program Interface (API)**

- Wildcard capability in the PCC validation table to replace pattern-matching logic that was embedded in the business rules.
- ICO's PCC Definition screen reminds users of the wildcard options (relevant help text screen also added).
- PCC validation table values replaced with equivalent wildcard patterns.

➤ **Program Module (PGM)**

- Portfolio pages separated for Pending Type 5's and Post Award/ Active grants.
- Ability to include/exclude grants not assigned to a PO for tracking/interest purposes.
- Enhanced filtering of a portfolio list by FY, Council, PCC, and Subprojects.
- Attention Flag column in each portfolio page shows concerns on a grant .
- Ability to override the system-defined sort with user's sort preference on each portfolio page.
- Integrated with new shared eRA modules: eRA Program Checklists and eRA Web QT.
- Ability to view historical PO notes on each grant in a PO's portfolio.
- Signed/Unsigned column to indicate whether PO approval is complete.
- New portfolio page for withdrawn grants.
- Ability to expand/collapse sections of the eRA Grant Snapshot for printing.

August Release Highlights (cont.)

➤ Receipt and Referral Maintenance

- Ability to select the column on which to sort on the View Application Status screen.
- Changes to correspond to degree and address restructuring.
- Corrected processing for setting Program Class Codes, for including Award Document Numbers, and for displaying review-meeting associations for reinstated applications.
- Modified mailer processing to suppress change mailers when only the group extension code has changed.

➤ Subprojects

- Reconciled subproject API business rules with those enforced on the Subproject screen.
- Rollover occurs sooner when the subproject information is drawn from a noncompeting continuation award
- Subproject "total cost" business rules revised to account for supplemental award amounts.
- Subproject API extended to allow upload of IC-assigned project terms.
- Consistency of human-subject coding enforced among subprojects and parent applications. A subproject cannot be flagged with human subjects if no human subject involvement is indicated on the parent award. Conversely, users receive a warning if the parent award indicates human subject involvement but *none* of the subprojects carries this indication.
- Consistency of animal subject coding enforced among subprojects and parent applications. A subproject cannot be indicated with animal subjects if no animal subject involvement is indicated on the parent award.
- Overnight CRISP rollover processing retired. Rollover driven by system events.
- Fixed bug that allowed users without ICO_GRANT_UPDATE_ROLE to maintain subprojects via the Subproject screen.
- Leaving the human-subject checkbox unchecked results in human subject code "10" (instead of NULL).
- Subproject screen allows population tracking subprojects to be marked "awarded" and "IC approved."
- Subproject screen invokes newer version of the Edit Check module, with results for entire set of subprojects presented in one consolidated display.
- Application Affiliation records created in the database to track the relationship between subprojects and their parent applications.

Priority Setting for eRA

- Wish list from everyone
- Vetted through functional groups: user groups, project team, EPMC, Project Team Retreat, Steering Committee
- Top 10–15 priorities long term
 - **New – biggest impact**
 - **Migration out of legacy system**
 - **Required**
 - **Maintenance**
- Details left to the Project Team for releases:
 - **Group Advocate**
 - ❖ Wish list to Project Team
 - ❖ Budget and architectural review
 - ❖ Feedback for what is possible

*Thank you for your time
and your comments*

Additional Background Material

eRA Fall Release FY04 Highlights

These are enhancements & new development in addition to normal maintenance & mods to support new Password Policy

CGAP Pilot

- Test exchange of information and submission mechanism for small number of live e-applications from SBIRs and Grants.gov
 - Type 1 in Oct. against test/staging DB; Type 2 in Nov.
 - Institutions have DUNS and are registered in CCR and Grants.gov
 - Modular budgets, R01s, appendices mailed
- **Fall functionality:**
 - Receive the ticket or application
 - Retrieve applications
 - Load applications into database
 - Provide error messages at all stages
 - Process requests for status of the e-application
 - Transmit status info to requester
 - Reference implementation (sample code)
 - Tech doc. and guide on how to format msg.
 - Paperless business process in R&R

CGAP Receipt & Referral

- Develop First Contact Module including new screens: Receipt Workload Hitlist. First Contact Detail Screen; ARA Detail, and Duplicate Submission Detail
- New Breakout Module (currently Breakout is manual)
- Changes to existing C/S Screens to process e-applications and add new workflow
- R&R maintenance

eRA Fall Release FY04 Highlights

These are enhancements & new development in addition to normal maintenance & mods to support new Password Policy

GM

- Document current NGA system
- Minimum changes to NGA for OPDIVs
- On Admin screen display status of GM/PO checklists and provide access to checklists and sign-off comments
- Checklist items on GM worksheet
- Various maintenance fixes

Web QT

- Respond to pilot user high priority requests
- Maintain Queries – save, add, edit, run, and delete queries
- Page level HELP
- Expand pilot

eSNAP

- Option to change form if No Target in eSNAP Inclusion
- e-Notification for type 5 (push)
- eSNAP rollforward... Copy Performance Sites/Key Personnel to Next Grant Year on eSNAPS
- Remove data validation from SAVE so user can save incomplete data
- File upload for Other Support.

Committee Mgmt.

- High priority enhancements requested by J2EE CM Web pilot users
- Document specs to move from updating ROLES to updating Profiles

eRA Fall Release FY04 Highlights

These are enhancements & new development in addition to normal maintenance & PW policy implem.

Program

- Program Approvals page
- Read access to any POs portfolio
- Add PCC as parameter on search page
- Restructure so users see default portfolio after clicking My Portfolio
- Default search criteria to perform PI searches w/o wildcards and default user's IC; default override
- PCC sort on all portfolio pages
- Provide usage statistics
- Add additional sort options
- Add additional hitlist data to portfolios
- Change logic on specific portfolios
- Permit Program Assistants to login to PGM

Peer Review

- Add indicator to identify CGAP applications
- Change Percentile rules to allow one IC to update another's data
- General maintenance and bug fixes

Internet Asst.Rev (IAR)

- Improve performance on List of Applications screen
- Additional values for Active Account
- Implement IAR demo facility
- Fix to search and display on IAR entered fields (IAR email)
- Add Profile Name to Create Account

eRA Fall Release FY04 Highlights

These are enhancements & new development in addition to normal maintenance & PW policy implem.

J2EE Grant Folder

- Replace client/server grant folder with J2ee grant folder in all client/server applications
- Add Reports section at bottom of J2EE Folder UI to serve as J2EE Reports menu
- Grant folder documents customizable by business area
- Reports section customizable by business area
- Add to Reports section: PI History, PI Brief, Grant Snapshot for all applications
- Add additional reports to Reports section as requested by business areas
- Add hyperlink to grant number to invoke new Grant Snapshot report

iEdison

- Put hold on new functionality; verify requirements with current functionality; stabilize system functionally
- Modify Officer Upload Process
- Addition of locking for update in J2EE web client
- Verification of document handling functionality (timeouts) - web client
- Several maintenance fixes

X-Train/TA/Payback

- Full requirements for X-Train and Training Activities
- Various fixes and maintenance

eRA Fall Release FY04 Highlights

These are enhancements & new development in addition to normal maintenance & PW policy implem.

GM Closeout

- Include specialist info on Institution report
- Allow user to set default IC
- Several modifications to logic and edits

Subprojects & CRISP+

- Modify subproject screen and CRISP+ to implement subproject policy in FY04 (all subprojects entered by ICs)
- Special Population Tracking Provisions
- Fix bugs and maintenance

J2EE Base System; Status

- No Cost Extensions
- Just-in-Time for IRB, IACUC, Other Support and Checklist
- CGAP Status in Status and verification by PI and SO of submitted application
- Don't Show Award dollars if not Awarded
- Modify 'Show NIH Support' to filter out Training Grants for other institutions
- Consolidate Status/eSNAP into Status allowing launch of eSNAP from status
- Fix bugs; minor enhancements

eRA Fall Release FY04 Highlights

These are enhancements & new development in addition to normal maintenance & PW policy implem.

Security

- Implement eRA Password Policy in all eRA applications. Include: reset PW ability, expiration at 180 days, lockout after 5 unsuccessful attempts to login, etc.
- Changes in all applications to support above

FSR

- Special FSR submission rules for Foreign grants to allow annual submission of SNAP grants to foreign institutions
- Handling of new AWD_DOC_NUM format

Pop Tracking

- FY Definition for Final Year entry
- Roll Forward Restriction of Enrollment Comments

Person

- Document design and level of effort for enforcing policy in CM and TA that normal user updates profile only; the role becomes a subset of the profile

OPDIV Integration

- Various modifications to support OPDIV integration in IMPAC II

Documentation

- End-of-project documentation related to end of development contract