eRA Support and Reporting of NIH Sponsored Research

Thursday, October 16, 2003

Target Timetable

- **Phase 1: January 2003**
  - Standard XML documentation, technology a~
  - *Inception, tech architecture and analysis*

- **Phase 2: February—**
  - Application receipt and va~
  - *Build and test the rec~*

- **Phase 3:** J~
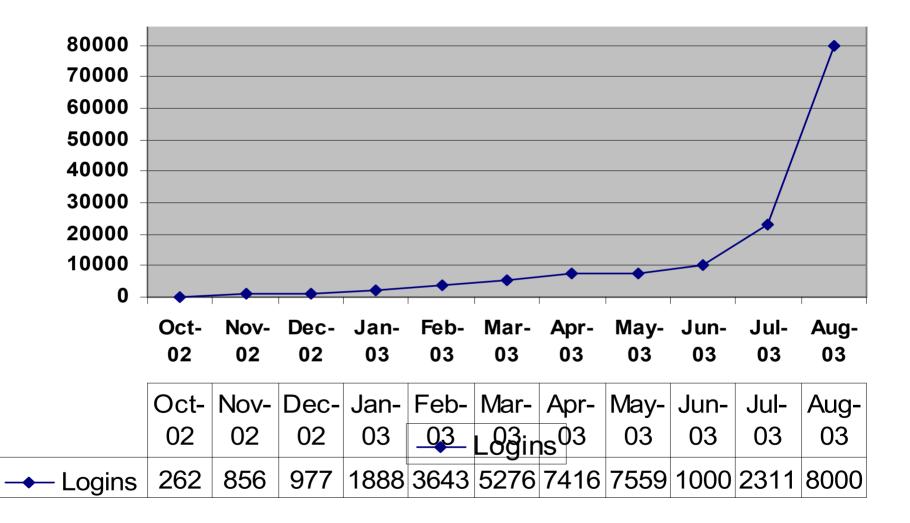 - Busine~ ~frastructure
  - *C~ ~ment exchange*
  - ~

- ~ ~November 2003
  - ~ional communications on IPF, PPF, FSR and potentially other
  - *~grated system for e-Applications : test and gradual introduction*

We have received our first 14 experimental e-grants currently processing

Registered Grantees

Grantor Institutions

Commercial Service Providers

SBIR

Prepare application content and attachments

Convert application data to XML data stream

Submit XML data stream and attachments to Grants.gov

Grants.gov
A trusted broker

Grants.gov

Generate proper XML data stream on in-house system and submit with attachments

Accept XML data stream and attachments

Package XML data stream as SOAP message

Notify grantor institutions that completed applications are available for retrieval

Complete application form offline

Submit application form and attachments

Accept application form and attachments

Convert completed application to XML data stream

External Institutions

Download application form from Grants.gov

We Opened it Up in July

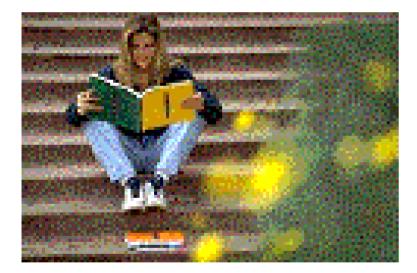|	Oct-02	Nov-02	Dec-02	Jan-03	Feb-03	Mar-03	Apr-03	May-03	Jun-03	Jul-03	Aug-03
◆ Logins	262	856	977	1888	3643	5276	7416	7559	1000	2311	8000

External eRA Interface (Commons)

- Registration/User information
  - **More than 105,659 total log-ins (10/**
  - **More than 566 (a doubling since April)**
  - **More than 5,519 user accounts**
- Creating 1,500 accounts per month. 3,000 projected for September.
- Internet Assisted Review accounts are now 10% of the total (up from 3% in April)

Setting Expectations

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

An Enterprise View of the Research Portfolio

NIH Roadmap ACCELERATING MEDICAL DISCOVERY TO IMPROVE HEALTH

Identify-Plan-Develop-Implement-Fund-Evaluate Outcomes and Research Opportunities

Points to Consider

- eRA is funded to provide a core transaction system for grants and the base system to analyze all funded research projects funded by grants, contracts, and by the intramural program.

- The current eRA vision is not an integrated enterprise solution for NIH or the Department.

- OPDIVs and NIH need to examine the return on investment and the potential of making eRA an integrated solution

How Research Initiatives Move Forward (a patchwork view)

- Initiative planning and development
  - **ICs systems**

- Implement
  - **eRA is the transaction system for receipt, review, award, and administer grants**
  - **ICs – pay lists, workflow, routing, documenting intermediate steps not currently in eRA**

- Evaluate
  - **eRA multiple tools to evaluate data for all funded research projects grants, contracts and intramural programs at NIH**
  - **IC specific systems use eRA data (downloads or shared tables) for scientific coding and other analysis**

Launching a Research Effort

IC's & OPDIVs

- Initiate concepts and initiative development:
  - **Recommend and approve:**
    - ❖ Extramural Community, Branch, Division, IC, Council
  - **Integration with future year budget planning**
  - **Implementation**
    - ❖ Tie budget changes from formulation
    - ❖ PA, RFA, RFC document generation
  - **Evaluation**

Launching a Research Effort

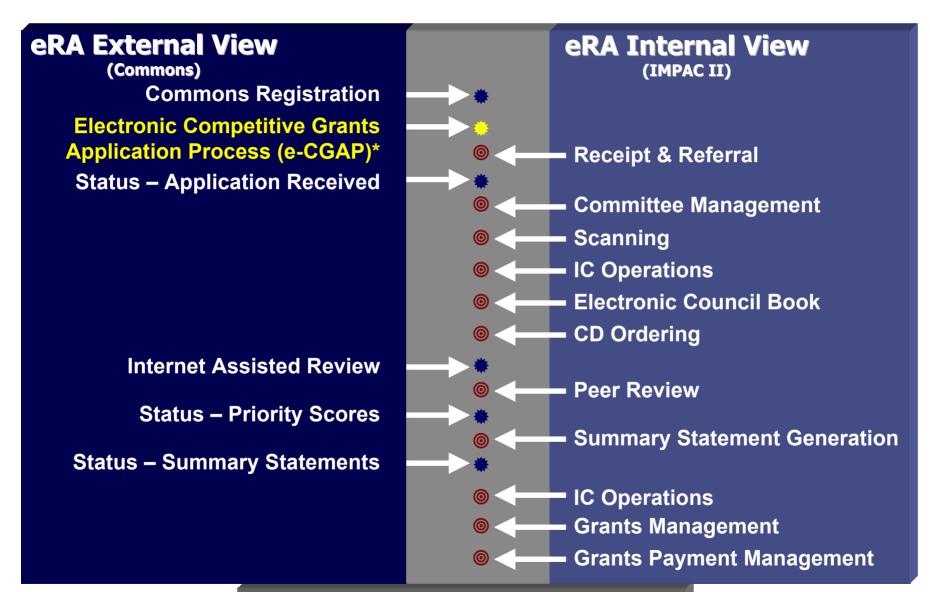|	
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OER	- Announce **Early Notification System (ENS) within OER** **Publication in the NIH Guide/FedBiz OPPs**

Launching a Research Effort

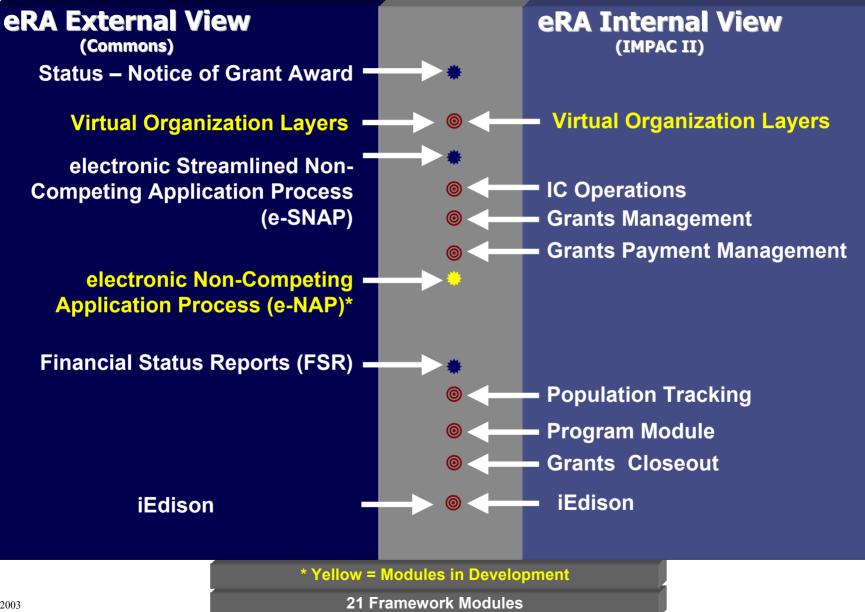|	
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OER	- Announce **Early Notification System (ENS) within OER** **Publication in the NIH Guide/FedBiz OPPs**
eRA	**Implement, analyze, and monitor the projects received, reviewed and funded for the initiative**

The eRA Core *(Receipt Through Award Transaction Modules)*

eRA External View
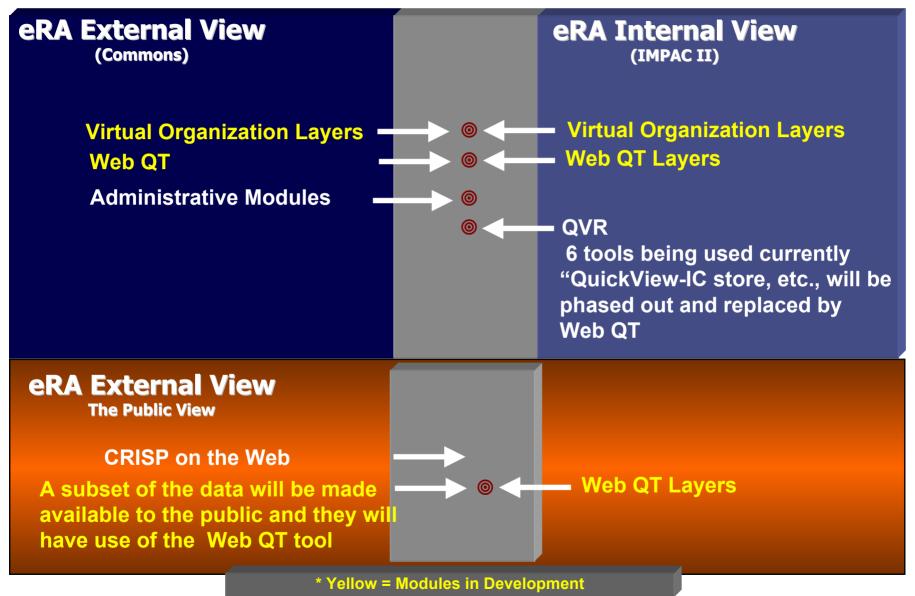### (Commons)

Commons Registration →

Electronic Competitive Grants Application Process (e-CGAP)* →

Status – Application Received →

Internet Assisted Review →

Status – Priority Scores →

Status – Summary Statements →

eRA Internal View
(IMPAC II)

← Receipt & Referral

← Committee Management

← Scanning

← IC Operations

← Electronic Council Book

← CD Ordering

← Peer Review

← Summary Statement Generation

← IC Operations

← Grants Management

← Grants Payment Management

* Yellow = Modules in Development

21 Framework Modules

The eRA Core *(Post Award Transaction Modules)*

eRA External View
(Commons)

eRA Internal View
(IMPAC II)

Status – Notice of Grant Award →

Virtual Organization Layers → ← **Virtual Organization Layers**

electronic Streamlined Non-Competing Application Process (e-SNAP) →

← IC Operations

← Grants Management

← Grants Payment Management

electronic Non-Competing Application Process (e-NAP)* →

Financial Status Reports (FSR) →

← Population Tracking

← Program Module

← Grants Closeout

iEdison → ← iEdison

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* Yellow = Modules in Development

21 Framework Modules

The eRA Core *(Aggregate Processing, Reporting Tools)*

eRA External View
(Commons)

eRA Internal View
(IMPAC II)

Virtual Organization Layers → ◎ ← **Virtual Organization Layers**

Web QT → ◎ ← **Web QT Layers**

Administrative Modules → ◎

◎ ← **QVR**

6 tools being used currently "QuickView-IC store, etc., will be phased out and replaced by Web QT

eRA External View
The Public View

CRISP on the Web →

A subset of the data will be made available to the public and they will have use of the Web QT tool → ◎ ← **Web QT Layers**

* Yellow = Modules in Development

eRA Modules

IMPAC II

- Committee Management
- CRISP Plus
  - Scientific Reporting Module
- IC Operations
  - Program Management Interface
- Electronic Council Book
- Grants Payment Management
- Grants Management
- Grants Closeout System
- Paperless Business Practices (Scanning)
- Population Tracking
- Receipt & Referral
- Reporting Databases & Tools
  - Quick View
  - Grants Payment Reporting Module
  - QVR
  - J2EE Query Tool
- Peer Review
  - Summary Statement Generation
  - Internet Assisted Review
- CD Ordering
- SITS
- Trainee Activities
- User Administration Module
- X-Train
- Electronic 901s
  - Workflow Architecture

NIH eRA Commons

- Commons Base System
  - Accounts Administration
  - Profiles (IPF and PPF)
- X-Train and Status (Commons v.1 modules)
- Status System
- e-SNAP
- c-GAP
- FSR System
- IEdison
- CRISP on the Web

Background Modules

- ICE – IC Extensions. APIs.
- Common Mailers (will be merged into e-Notification)
- Batch Assignment Module for POs, PCCs, GMOs, GSs
- J2EE Base System (formerly the "framework modules")
- Status Code Computation Module
- Type 5 Processing
- Type 4, 6, 7 Processing

Shared Modules

- Person Data
- Grant Folder
- Grant Update Module (GUM)
- Subproject Maintenance Module
- ICSTORe
- Edit Checker
- eRA Notifications and Mailers
- Customizable Checklists

= Still in Development

Points to Consider

- We are missing critical opportunities to:
  - **Leverage the DHHS consolidation to add other transaction process or information needed by multiple OPDIVs**
    - A contract management system that uses the same receipt, review, and committee management modules already in place
    - Adverse event reporting, OLAW, protocol management, state dept clearances etc
    - Adopting key personnel and co-pi standard terms for use across intramural and extramural
  - **Integrate business intelligence/knowledge discovery tools to:**
    - Improve, quality, efficiency, decision support
    - Analyze all research projects for gaps, redundancies, and emerging

Future Vision:
To Plan, Transact, Monitor, Evaluate Research

Knowledge Man & Discovery

- Initiate concepts
- Engage community
- Plan future years
- Submit budget
- Track
- Workflow

- eRA current scope & budget

- New priorities
- OPDIVs
- Scientific coding
- Adverse event reporting
- Clinical management tools
- R & D Contracts

Are We Prepared for the Future?

- The amount of biological data generated by new technologies has completely overwhelmed our ability to understand it.

  - Genomics has provided us with a massive "parts catalog"; proteomics seeks to define these individual "parts" and the structures they form. But there is as yet no "user's guide" describing how these parts are put together to allow those interactions that sustain life or cause disease.

  - Successful intervention depends on knowing how a protein behaves in context, as it interacts with the rest of the relevant cellular machinery to generate

- Function at a higher level.

Modeling the Heart--from Genes to Cells to the Whole Organ

Denis Noble Science 295:1678, 2002

Additional Background Material

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
  - Submission of non-competing progress reports (e-SNAP)
  - Financial Status Report (FSR)
  - Internet Assisted Review (IAR)
  - Interagency Edison (iEdison) – Invention Reporting

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
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Thank you for your time and your comments