

GCRC Progress Reports

Status and Plan

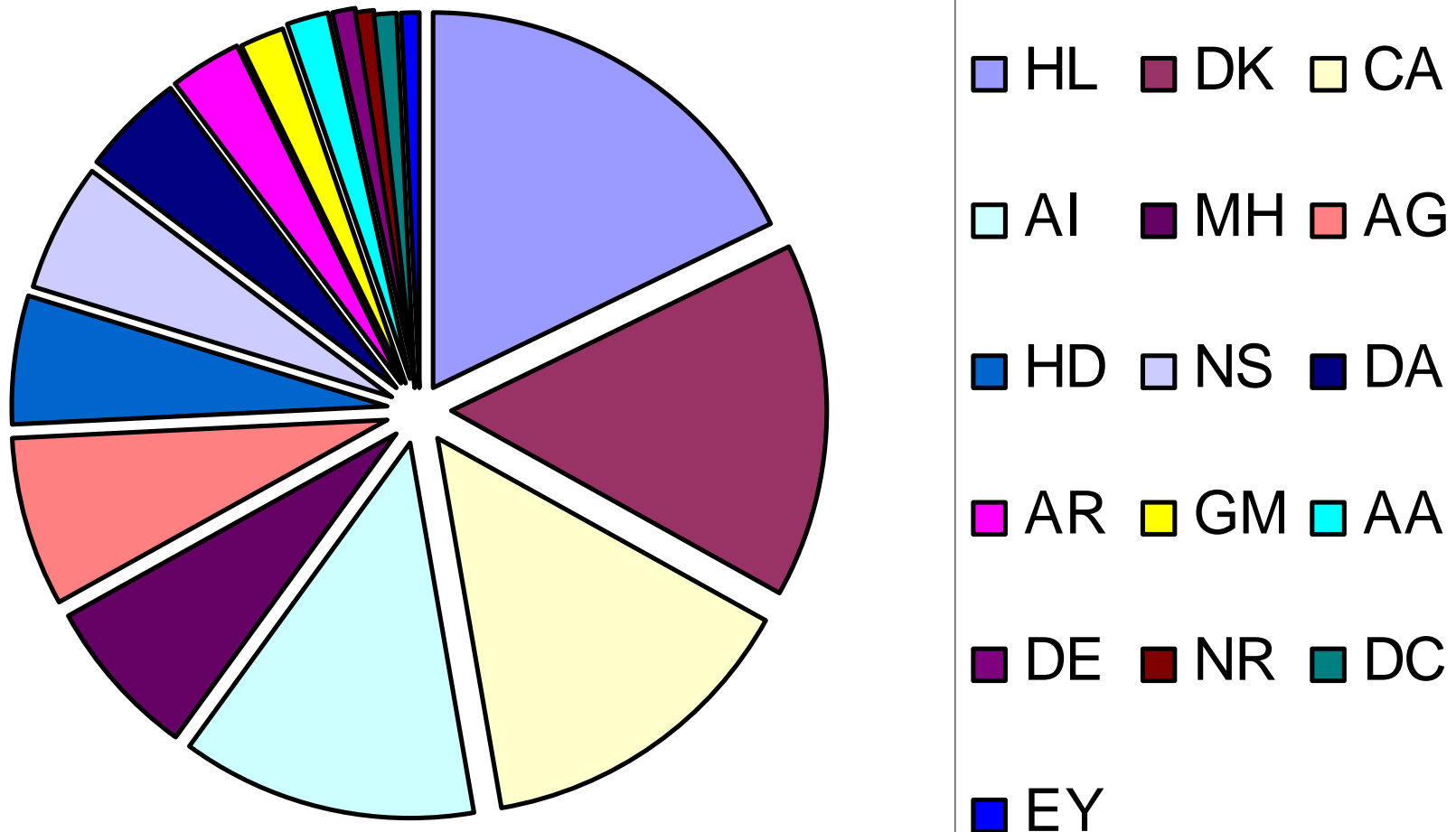
National Center for Research Resources
National Institutes of Health

September 22, 2004

General Clinical Research Centers

- ✓ NIH Program for over 40 years
- ✓ Circa \$280M in FY2004
- ✓ Around 80 GCRCs, distributed across U.S.
- ✓ Every GCRC attached to a large institution
- ✓ A GCRC is a clinical research resource provider (beds, nurses, labs, IT, ...)
- ✓ GCRC reports are large & complex (M01)

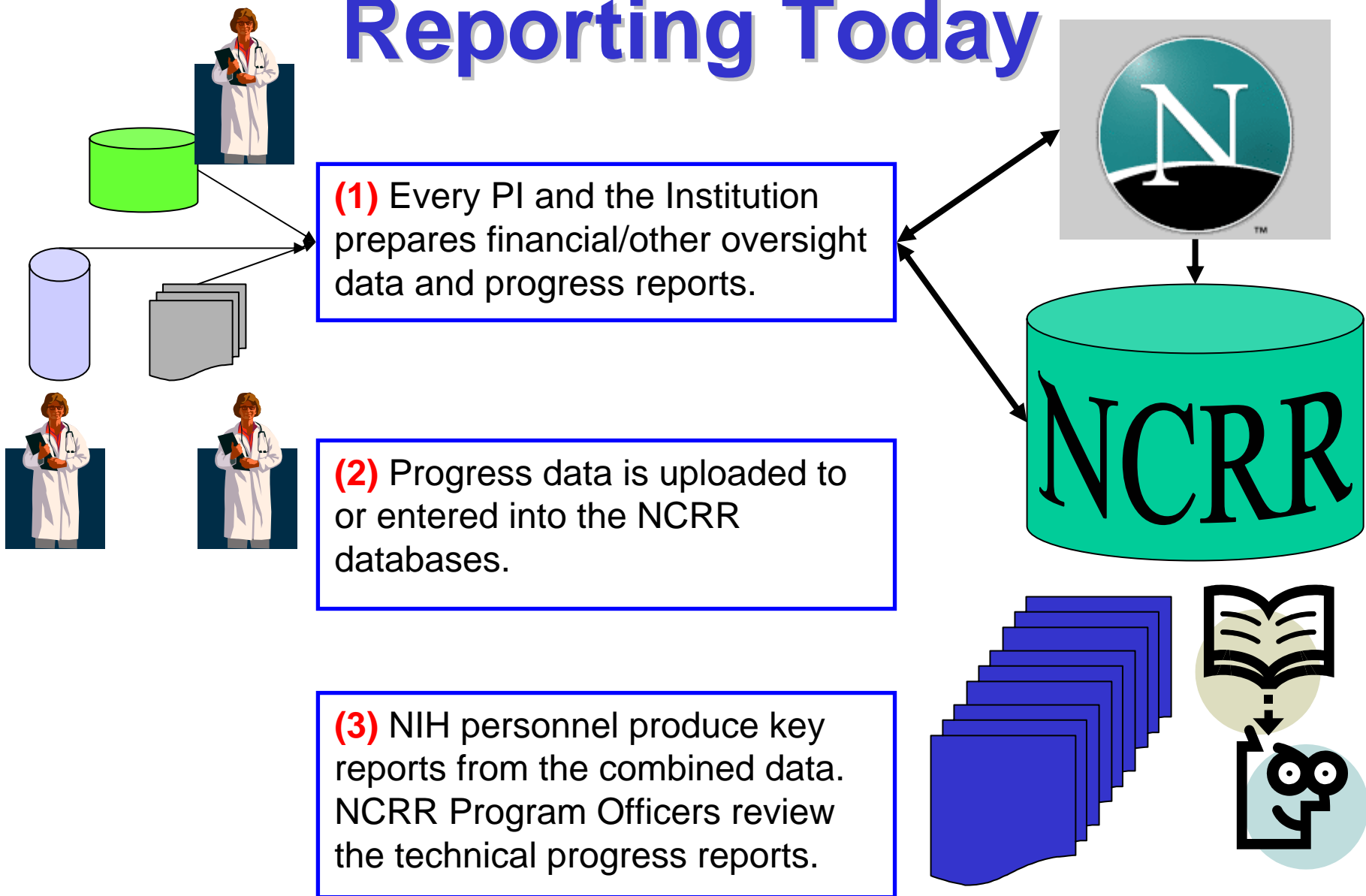
Trans-NIH Pls in GCRCs



Purpose Of GCRC Annual Progress Reports

- ✓ Stewardship and accountability of federal funds
- ✓ Monitor number & areas of disease-related studies
- ✓ Track GCRC utilization and their common and unique resources
- ✓ Collect GCRC scientific accomplishments, publications, and advances for evaluation
- ✓ Provide information for modifications in overall program and to identify new resources

Reporting Today



System-to-System Benefits

- ✓ Reduce administrative load on GCRC administrators, staff, nurses & researchers.
- ✓ Prepare secure informatics groundwork to make multi-site collaborative work routine.
- ✓ Harmonize informatics choices with the larger federal government & NIH directions.

Part Of The Corporate NIH Charge In Information Reporting

- ✓ Will offer eRA eXchange for FY05 GCRC Annual Reports
- ✓ Plan to use NIH SERCH for rapid in-depth review and workflow
- ✓ Use CIT shared servers and support.



NIH SERCH
Office of the Director

Near Term Actions (1)

1. *NCRR continues pilot for PI reporting using XML. (**Not** for GCRCs.) 3Q04 pilot*
2. GCRCs & NIH define XML-based plan for system-to-system reporting. 3Q04
3. NCRR ready to receive system-to-system reports from GCRCs for test. 4Q04
4. GCRCs have option to file annual reports, system-to-system in FY05. Potential for grant renewal submissions to NIH by FY06.

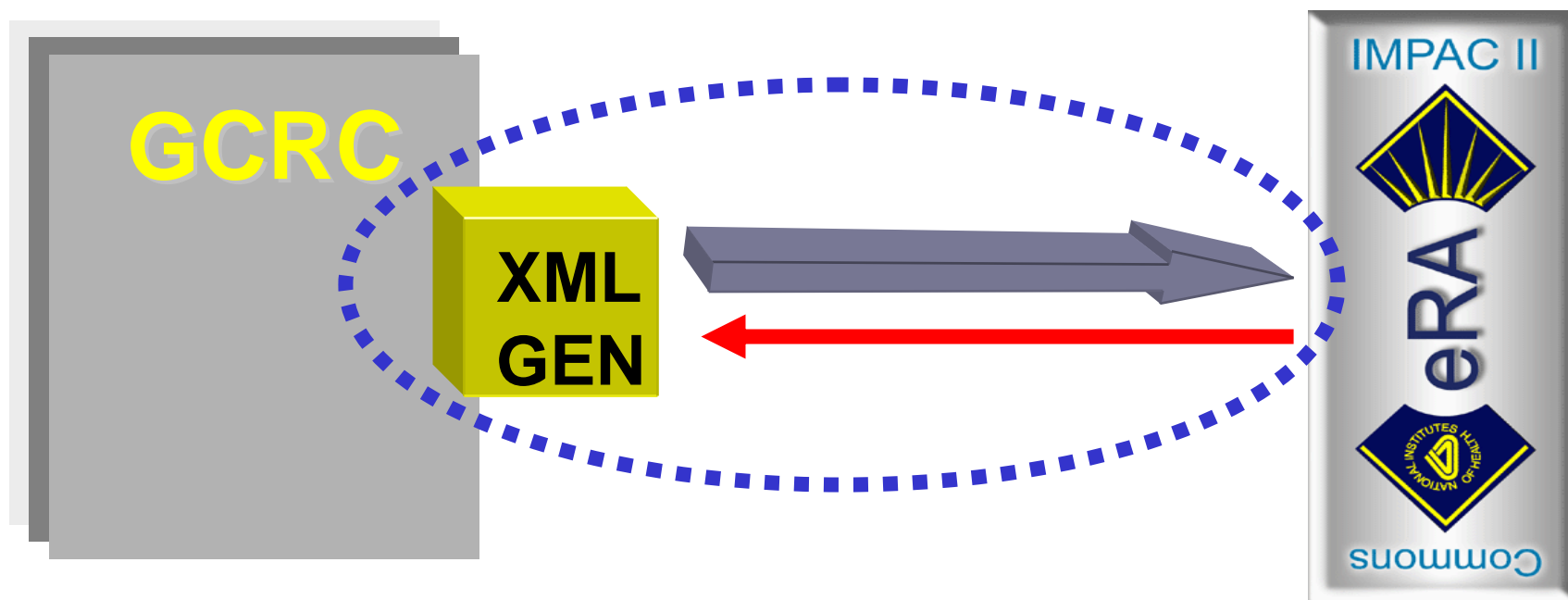
Near Term Actions (2)

NCRR solicits discussion and inputs for informatics resources to reduce burdens on GCRC staff and for investigators that use GCRCs. NCRR completes an inventory and requirement analysis simultaneously.

- ✓ Administrative and financial management
- ✓ Streamline IRB, GAC, NIH, FDA, IBC submissions
- ✓ Adverse event reporting
- ✓ Protocol authoring & tracking
- ✓ Automation of nurse, data, and lab result entry
- ✓ Participant recruitment and scheduling
- ✓ Tools to support analysis, reporting, publishing
- ✓ Secure remote controlled access to databases.
- ✓ ...

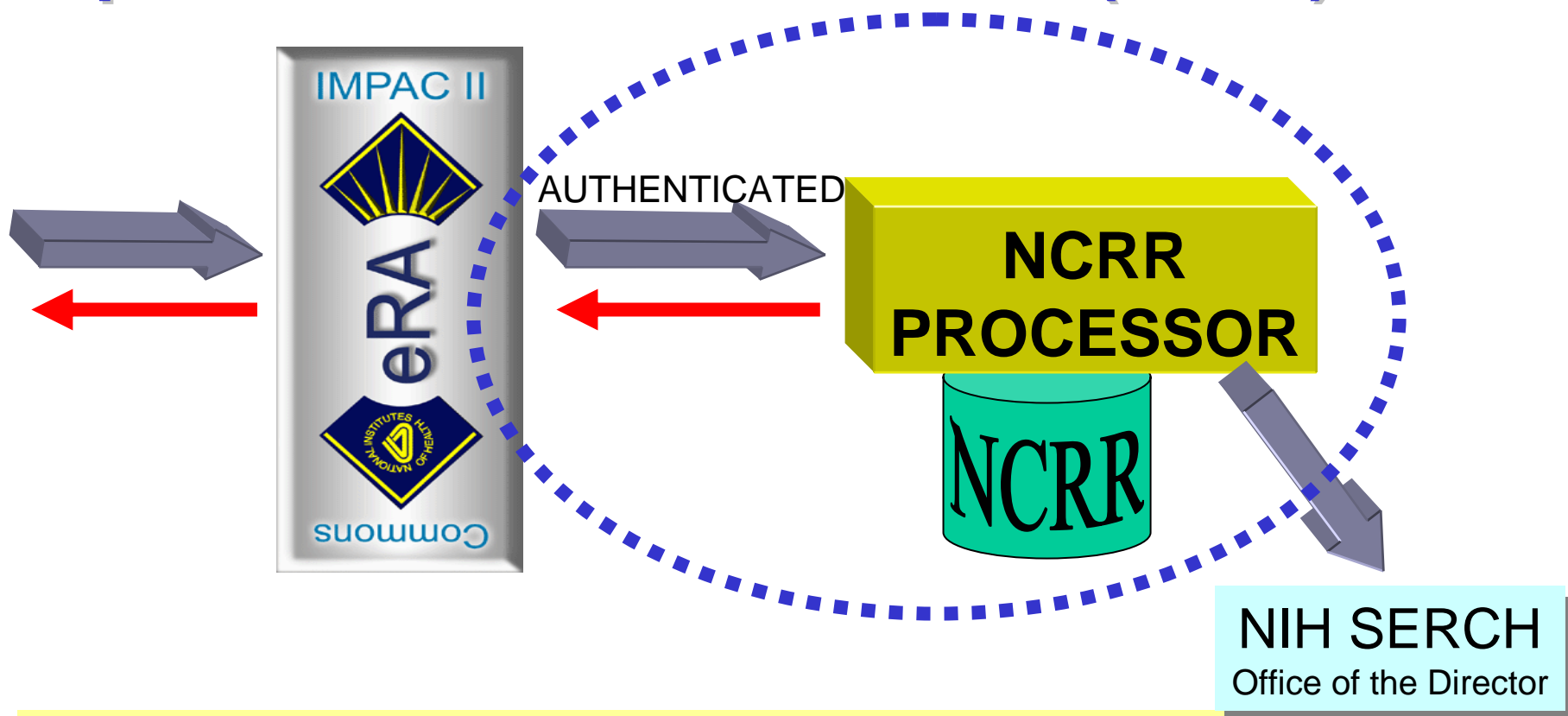
Plan to use 3rd party requirements analysis company to work with all stakeholders in 2004-2005.

GCRCs & NIH define XML-based plan for system-to-system reporting (3Q04)



Minimal process & system changes in a GCRC

NCCR ready to receive system-to-system reports from GCRCs for test (4Q04)



Single interface for NCCR and eRA eXchange

Snapshot

- ✓ Project team in place
- Overall plan not yet complete, prioritizing requirements, identifying risks and status of relevant technologies. *Inward-facing interface in need of eRA eXchange details.*
- XML-based plan for GCRC interface on track for end of September. First version of XMLGEN looks good. *Need eRA data.*
- ✓ GCRC Informatics leads engaged & excited.

Needs – Outward Facing

- Details of eRA mechanisms for identification, authentication, encryption and authorization.
- eRA participation in schema and architecture reviews. *Starting to happen.*
- Reference implementation (CGAP SBIRs?).
- Test on operational system (Commons Demo?)
- eRA timetable
- eRA XML repository and configuration management processes.

Known Risks and Plans B

- Failure to complete detailed requirements analysis and planning, thence implementation in timetable. *Still possible. Maximizing outreach and discovery. Backup: Schedule slip.*
- ✓ Cannot build XML/PDF package in GCRCs. *No longer considered a likely risk.*
- Cannot interface GCRCs cleanly with eRA eXchange. *Still possible. Size of payload and non-proposal XML to be tested shortly by eRA. Backup: secure FTP bypassing eRA eXchange.*
- Business rule processing and feedback path not workable with eRA implementation. *Not considered likely but is possible. Backup: secure bypass and engage eRA on architecture.*

Summary

- ✓ The NCRR implementation team is cautiously optimistic that we will meet the goals we have given our customers.
- ✓ Working with the eRA team is great; an open and productive relationship.

People

✓ eRA

Izja Lederhendler, Jennifer Flach, David Wright,
Mike Goodman, JJ Maurer, ...

✓ NCRR

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