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National Specimen Banks to Support NCI Clinical Trial Networks

Request for Application (RFA)
U24 Cooperative Agreement

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

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Importance of Specimen Banking in NCI Clinical Trials

- **Identification of subgroups of patients with defined molecular abnormalities in tumors**
- **Development of robust molecular technologies for FFPE and fresh frozen specimens**
- **Development of more effective diagnostic assays to guide treatment for cancer patients**
- **Evaluation of patients and collection of specimens in real time for assessment of integral markers**
- **Validation of markers of prognosis, diagnosis and response to therapy**

➢ **Access to specimens from patients uniformly treated in large, multi-site, randomized clinical trials (NCI phase III and II) with high-quality clinical data**

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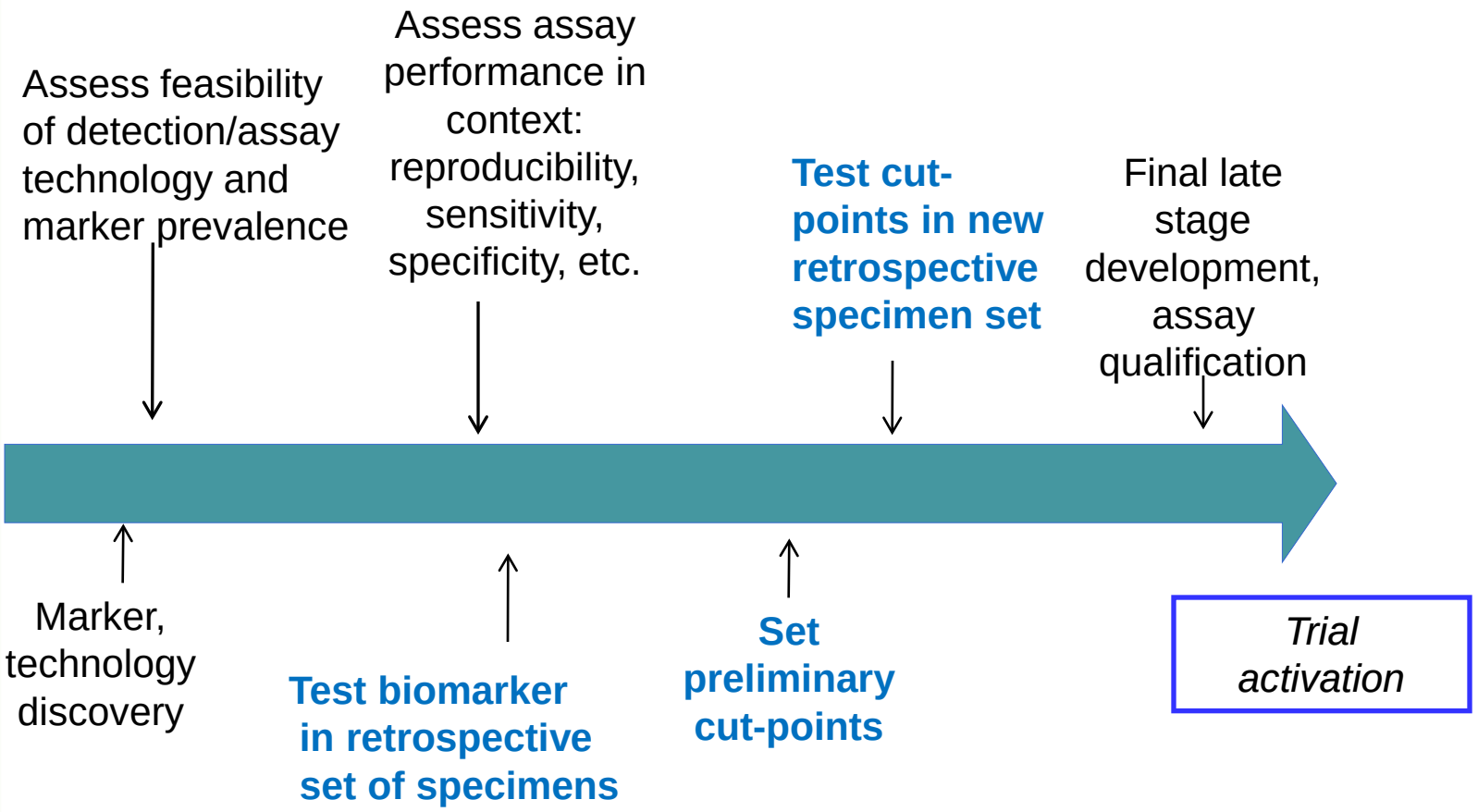
Clinical Assay Development



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2010 Institute of Medicine Report

- **Support collection of biospecimens from patients treated in the Cooperative Group trials**
- **Submit annotated biospecimens into the high-quality, standardized central biorepositories**
- **Establish national inventory of samples held in central biorepositories**
- **Define process for specimen access by researchers**

Response:

- **Reorganization and consolidation of the Specimen Banks to support of NCI Clinical Trial Networks**

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Cooperative Group Bank (CGB) History

- 9 Cooperative Group Banks: ACOSOG, CALGB, COG, GOG, ECOG, NCCTG, NSABP, RTOG, SWOG
- Collect, store and provide researchers with well-annotated specimens and clinical data from phase III and large phase II NCI Cooperative Group Clinical trials
- Individual banks had no dedicated funding until 9/2005
- NCI Cooperative Group Banking RFA:
  Nine U24 Cooperative Agreement Grants (9/2005-3/31/2010)
- Currently on NCI U24 grant supplements
  (4/1/10-3/31/11 and 4/1/11-3/31/12)
- Insufficient funds for harmonization of IT systems, centralized database, connection to STAT centers and easy access for the research community

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Tumor/Organ Site of Specimens Collected in 9 CGBs

	ACOSOG	CALGB	COG	ECOG	GOG	NCCTG	NSABP	RTOG	SWOG
Brain			X	X		X		X	
Breast	X	X		X		X	X	X	X
GI	X	X	X	X		X	X	X	X
GU		X	X	X				X	X
GYN					X			X	
Head/Neck			X	X				X	X
Lymphoma		X		X					X
Melanoma				X					X
Myeloma				X					X
Periph. Neuro.		X	X	X		X			
Liver			X						
Leukemia		X	X	X					X
Lung	X	X				X		X	X
Sarcoma			X					X	
Serum	X	X	X	X	X	X	X	X	X
Thyroid			X						

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Specimen Activities in 9 Cooperative Group Banks (2000-2007)

Solid Tumor Specimens Collected	**807,767**
Solid Tumor Specimens Distributed	**720,172**
Serum Specimens Collected	**143,047**
Serum Specimens Distributed	**38,663**
Intra/Inter Group Investigators Supported	**1,257**
External Investigators Supported	**283**
Leukemia Specimens Collected	**49,491**
Leukemia Specimens Distributed	**28,728**
Bone Marrow, Blood Collected	**45,068**
Bone Marrow, Blood Distributed	**18,914**
Intra/Inter Group Investigators Supported	**370**
External Investigators Supported	**30**

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Scientific Impact (2000-2008)

- **OncotypeDx™ test on FFPE breast cancer tissue *(Paik S et al., NEJM 2004)*→ TAILORx breast cancer trial**
- ***K-ras* mutation status in advanced colorectal cancer Tx with cetuximab *(Karapetis CS et al., NEJM 2008)***
- **MicroRNA signature and event-free survival in AML *(Marcucci et al., NEJM 2008)***
- **HER2 over-expression in tissues (IHC, FISH) with response to paclitaxel in node-positive breast cancer *(Hayes et al., NEJM 2007)***
- **Prediction of disease severity in early stage multiple myeloma (*Barlogie et al., Blood 2008*)**

➢ **Overall > 1,350 RESEARCH PUBLICATIONS and 36 PATENTS BY BANK SPECIMEN USERS**

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Reorganization of the National Specimen Banks

- **Exploration of optimal structure to address the IOM report**
  - Cooperative Group Chairs
  - Cooperative Group Banking Consortium
  - GBC IT group
  - NCI IT group
  - CaHUB
  - CTEP, CDP

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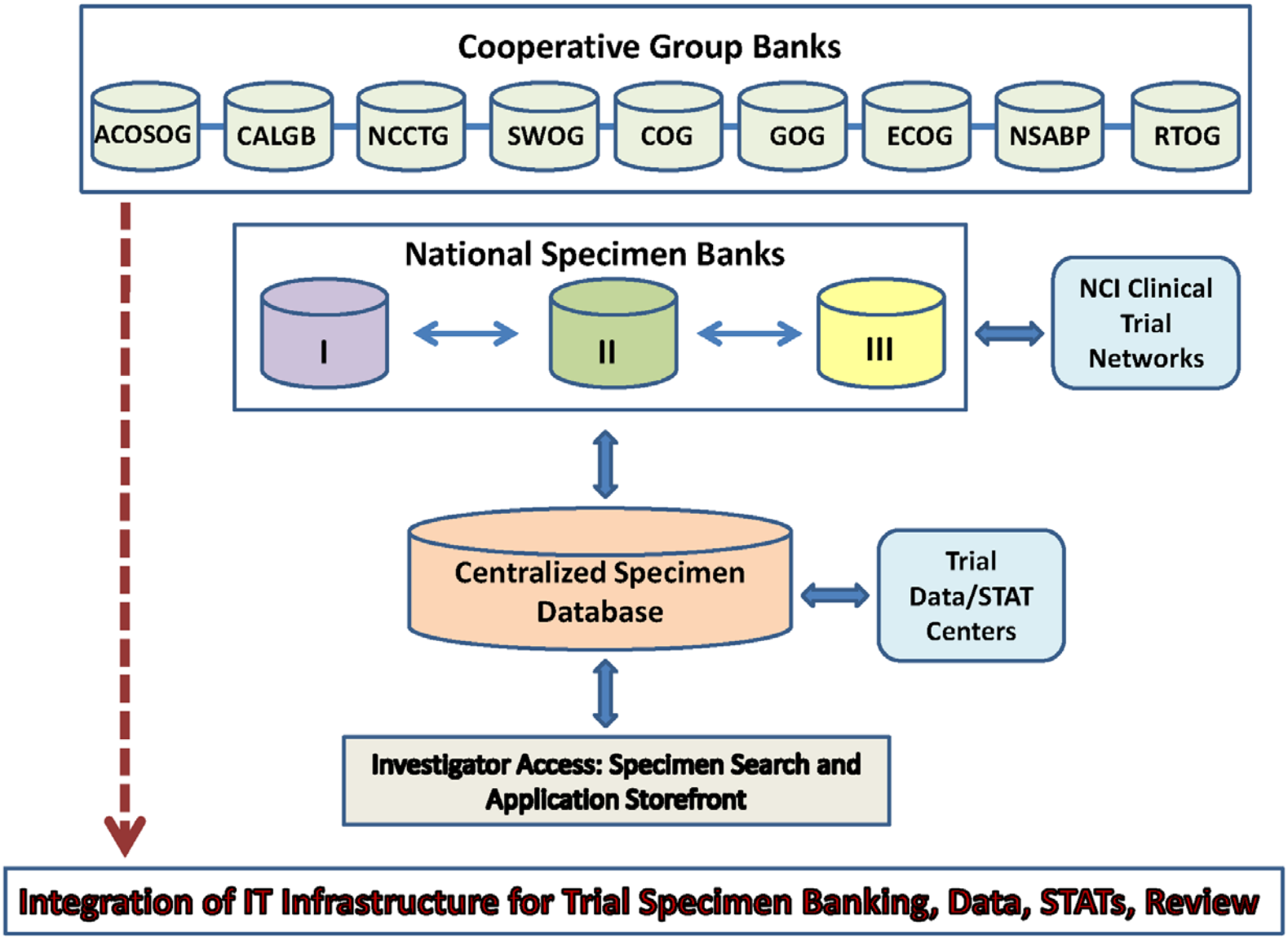
Proposed Reorganization of the National Specimen Banks



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IOM Recommendations:

- **Support collection of biospecimens from patients treated in Cooperative Group trials**
  - Prospective collection and storage of specimens on ongoing and future NCI clinical trials
  - Collection of frozen specimens
- **Submit annotated biospecimens into high-quality, standardized central biorepositories**
  - Standard Operating Procedures across all banks
  - Common data elements for annotation
  - OBBR Best Practices

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IOM Recommendation

- **Establish national inventory of samples held in central biorepositories**
  - IT tracking system connecting all banks
  - IT connections between banks, STAT centers and NCI clinical trial system to retrieve de-identified specimen-associated data
  - Central inventory database of specimens available for research

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IOM Recommendation

- **Define process for specimen access by researcher**
  - Central inventory database of specimens available for research
  - Centralized application and review processes; search engine for specimen retrieval
  - Review by Cooperative Group scientists (technical and disease experts), statisticians, outside experts

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U24 RFA Budget

- **3 awards to support 3 National Specimen Banks**
- **Total cost for 3 banks: $12.5M per year**
  - **$8.7M for prospective collection, storage and distribution of specimens on ongoing and new NCI Cooperative Group trials**
  - **$830K for integration of other NCI trial network collections into the banking operation**
  - **$2.97M for development of harmonized IT infrastructure for integrated national banking resource**
- **Total cost for 3 banks over 5 years: $62.5M**