Updates on the New Cooperative Group Structure

ECOG-ACRIN
cancer research group
Reshaping the future of patient care

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IOM Recommendations

Goal I. Improve speed and efficiency

- Consolidate ops, improve processes, streamline gov't oversight

Goal II. Incorporate innovative science

- Biorepositories, novel designs, standards for new technologies

Goal III. Improve prioritization, selection, support, and completion of trials

- Rethink role of NCI, increase accrual volume, diversity, and speed, increase funding

Goal IV. Incentivize participation

- Support clinical investigators, cover cost of patient care in clinical trials

Key Excerpt from the IOM Report

"The committee concluded that a robust, standing cancer clinical trials network is essential to effectively translate discoveries into clinical benefits for patients."

"…it is imperative to preserve and strengthen the unique capabilities of the Cooperative Group Program as a vital component in NCI's translational continuum."

Characteristics of Success

- Loyalty and commitment of cancer center, academic and community physicians to enter their patients
- Commitment and involvement of patients
- Strong participation of clinical and laboratory scientists
- Willingness to work as a team
- Commitment to the “public good”
- Key interface with industry
- Ability to leverage NCI dollars

Group Chair Guiding Principles for Successful Reconfiguration

1. Patients best served by strong scientific programs
2. Groups an integrated hub for Ph IIIs, large Ph IIs
3. Flexibility required to maximize potential
4. Strong membership culture worth preserving
5. Review process should incentivize scientific innovation
6. Viability of Groups linked to resource reqs
7. Multi-sector involvement generates science that would not otherwise happen

Reconfigured Groups

1. Alliance
   - CALGB, NCCTG, ACOSOG
2. Children's Oncology Group
3. ECOG–ACRIN Cancer Research Group
4. NRG Group
   - NSABP, RTOG, GOG
5. SWOG

National Cancer Institute

Tentative Timeline for Potential Implementation

BSA Concept Review	Nov 2011
NCI DEA & NIH Review FOA/Guidelines	Nov 2011 – July 2012
New FOA Released/Published	July 2012
Receipt Competing Applications	Winter 2012 [Nov 2012- Feb 2013]
Review Competing Applications	Summer 2013 [May 2013 - Aug 2013]
NCAB Review	Dec 2013
Rollout of Awards in FY2014	March 2014

National Cancer Institute

5-Year Annual Funding Request for NCI Clinical Trials Network

Category for Base Division Set-Aside for Network Program	Annual Total Cost for FY14 to FY18 Based on 20% Reduction in Accrual Compared to Average Accrual Over Last 6 Years (Approx. 20,000 Treatment Trial Enrollments)
Funding Based on FY2011 Levels:	
Group Operations & Statistical Centers (includes Capitation), Lead Academic Participating Sites, and Core Services	$ 152,644,335
Funding Request Based on New Funding Model & BIQSFP:	
Increase Capitation to "High-Performance" DCTD-funded Sites	$ 11,520,000
Increase Capitation to "High-Performance" DCP-funded CCOPs & MB-CCOPs	$ 10,080,000
Increase Funding for Integral and Integrated Markers (BIQSPF)	$ 4,000,000
Subtotal:	$ 25,600,000
Grand Total:	$ 178,244,335 *

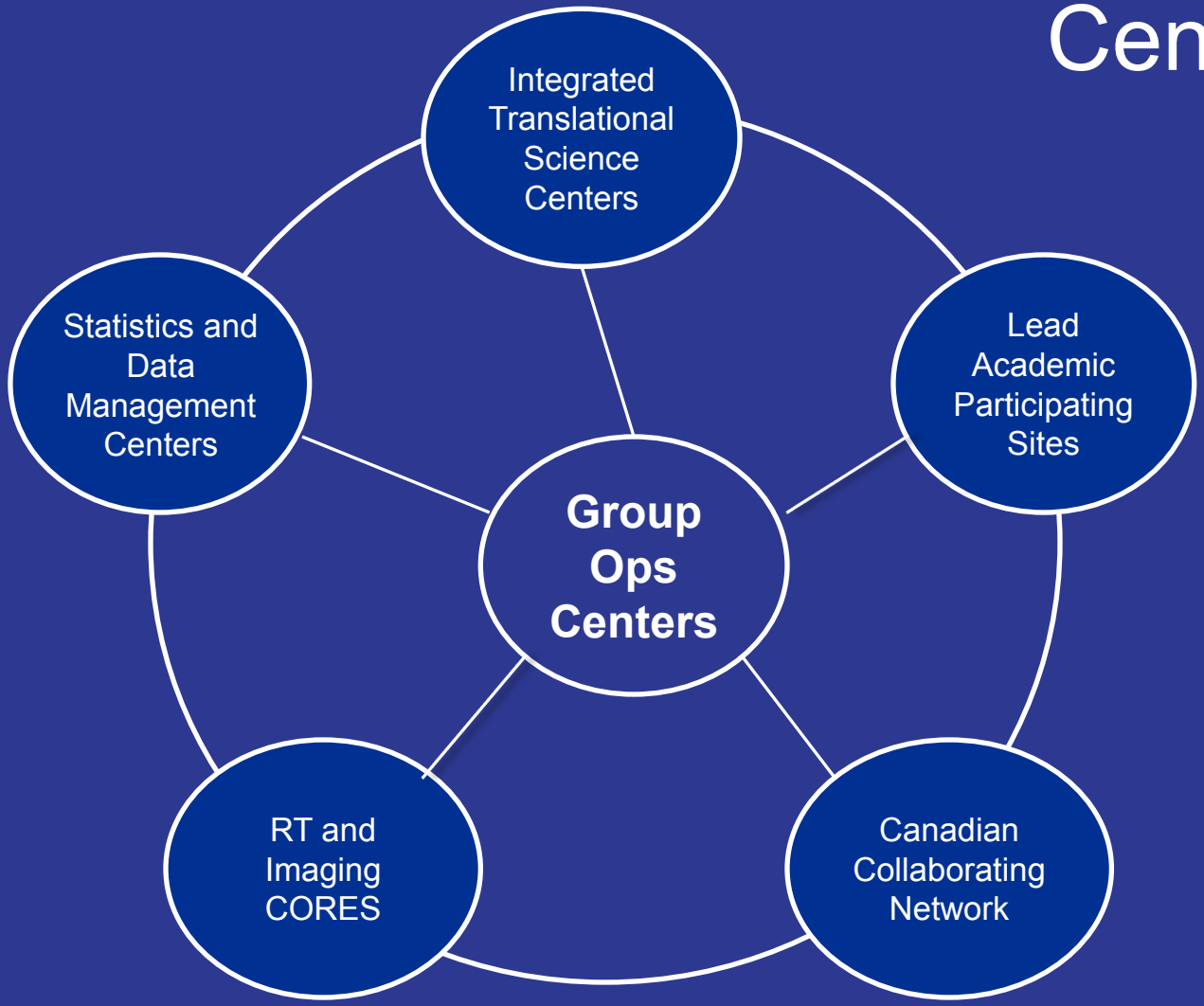
* The 5-Year Total Cost Funding Request for FY2014 to FY2018 for the NCTN is $891,221,675

National Cancer Institute

Overview of RFA: Cooperative Agreement FOAs and Estimated # Grants

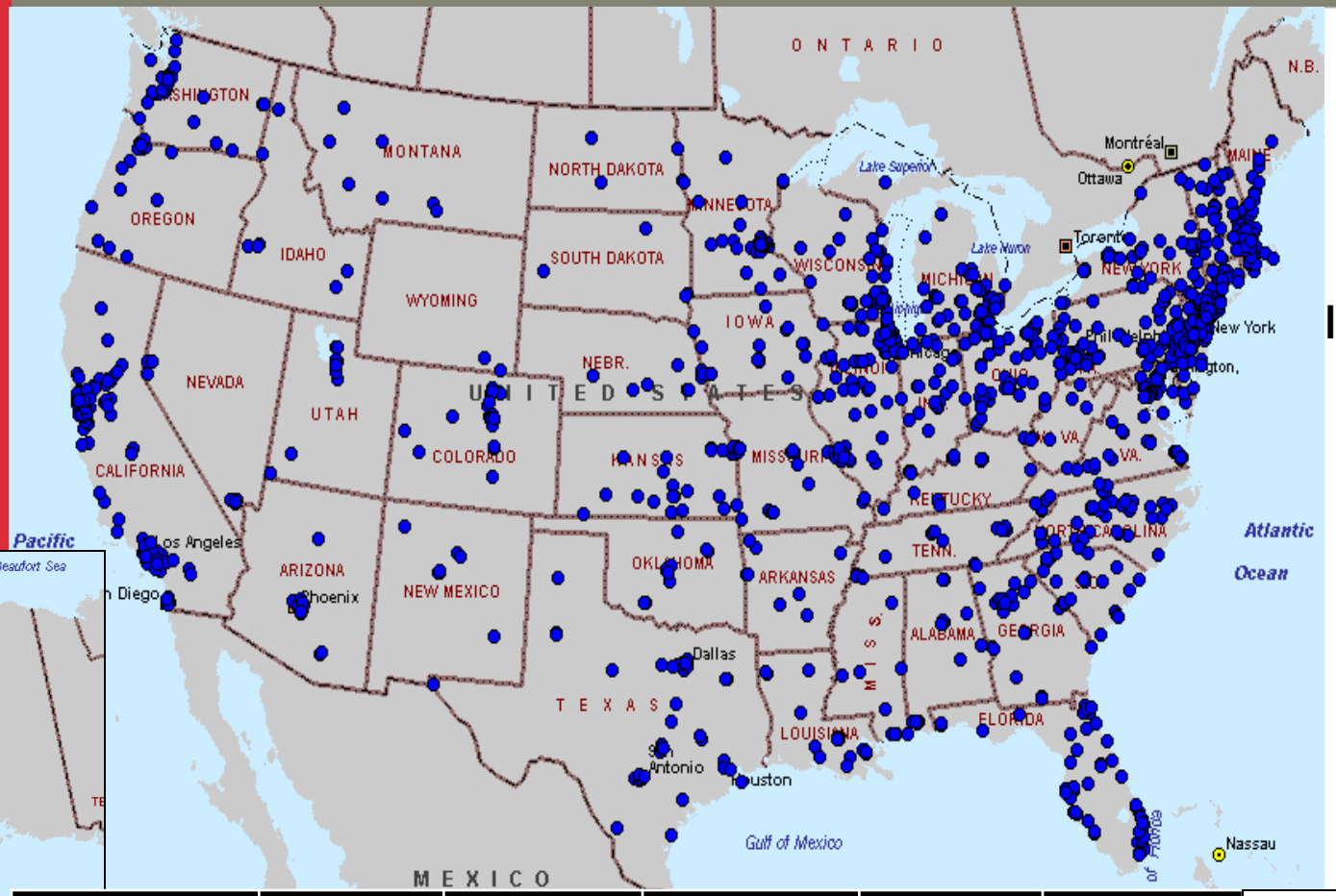
Network Component	Mechanism (Duration)	Est. Max. # Grants	Frequency New Application Accepted?	Multiple PI Option?
Group Operations Centers	U10 (5 Yrs)	5	Every 5 Years	Yes
Group Statistical & Data Mgt Centers	U10 (5 Yrs)	5	Every 5 Years	Yes
Canadian Collaborating Network	U10 (5 Yrs)	1	Every 5 Years	Yes
Integrated Translational Science Awards	U10 (5 Yrs)	1 to 5	Every 5 Years	Yes
RT and Imaging Core Services	U24 (5 Yrs)	1 to 2	Every 5 Years	Yes
Lead Academic Participating Sites	U10 (5 Yrs)	30 to 40	Any Year	Yes

NCTN Group Operations Center Hubs



National Cancer Institute

Overview of the Current Program



3,100 Institutions

14,000 Investigators

About 25,000 pts enrolled on tx trials annually

Trials	FY2006	FY2007	FY2008	FY2009	FY2010
All Phases: Treatment Trials	27,667	24,715	25,784	29,285	23,468

Accrual Distribution:

Phase 3: 83.4%

Phase 2: 15.1%

Phase 1/Pilot: 1.5%

Patient Accrual To Therapeutic Clinical Trials

Coop Group Trials by Phase	Patients
Ph I	426
Ph II	4,440
Ph III	14,486
Other / Pilot	110
Total Patients on CG Trials	19,462

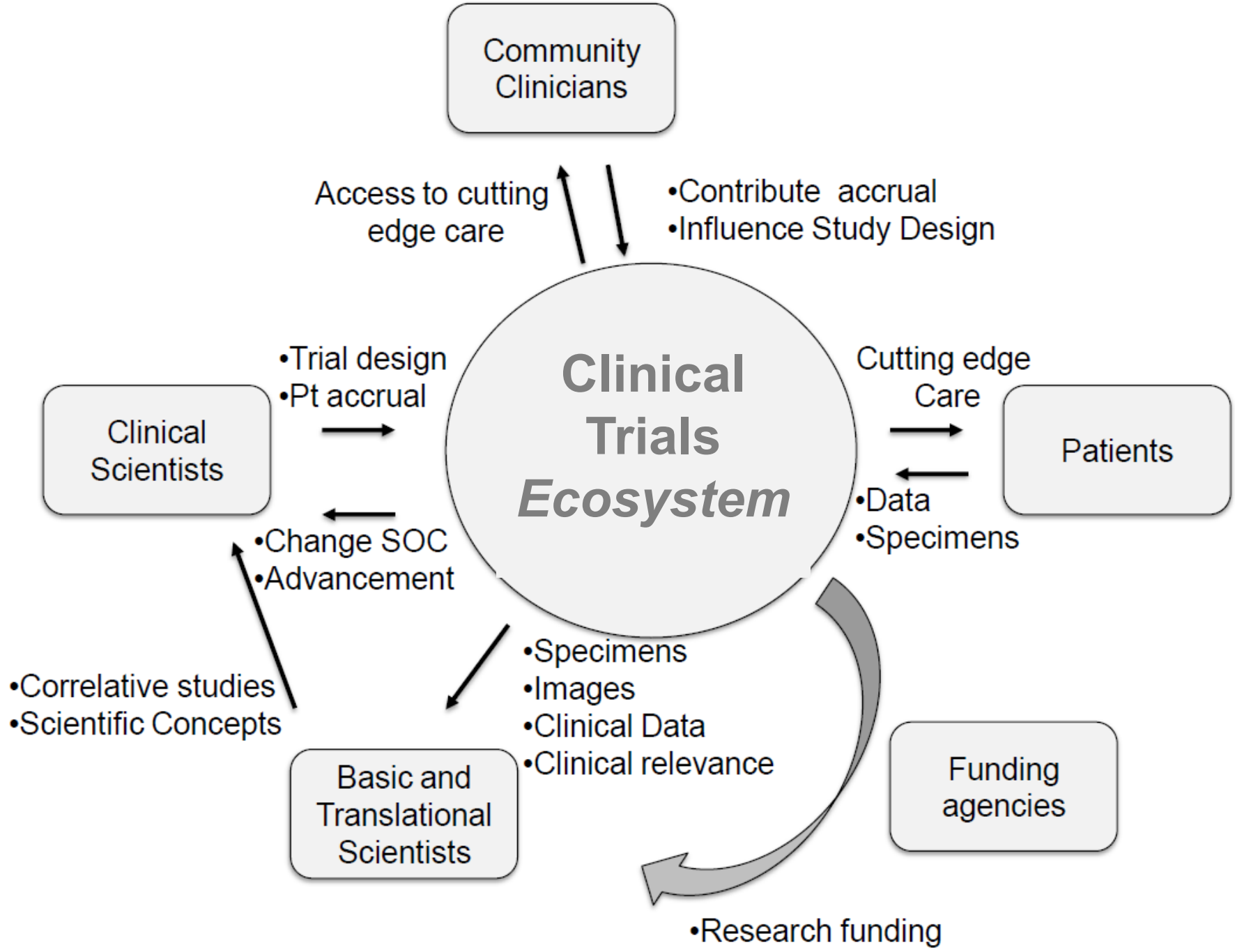
Concepts/Approvals by the NCI Steering Committees

Fiscal Year	Evaluated	Approved
2007	15	9
2008	28	15
2009	37	22
2010	47	24
2011	75	33
2012 (thru 1/31)	21	11
Total Concepts	223	114

- 7 approved concepts withdrawn by respective CG prior to protocol development
- 69 approved concepts developed into protocols have opened

NCTN Clinical Trials Portfolio

- More Process Driven Phase IIs
  - Community involvement required
  - CIRB
  - CTSU
- Fewer Large Phase IIIs
  - Still required
    - adjuvant, targeted combinations
  - Major issues with biomarker screening
  - Opportunity to integrate screening and TCGA-like processes
    - ALCHEMIST in NSCLC


Community Clinicians
Access to cutting edge care
•Contribute accrual
•Influence Study Design
Clinical Trials Ecosystem
•Trial design
•Pt accrual
Clinical Scientists
•Change SOC
•Advancement
Cutting edge Care
Patients
•Data
•Specimens
•Correlative studies
•Scientific Concepts
•Specimens
•Images
•Clinical Data
•Clinical relevance
Basic and Translational Scientists
Funding agencies
•Research funding

Group-wide RDE Initiative

1. Medidata Rave® -- NCI Cancer Therapy and Evaluation Program purchased licensing rights from Medidata Solutions to use and distribute

2. Rave is a web-based remote data entry (RDE) system for capturing, managing and reporting clinical research data

3. Designed to facilitate the conduct of NCI-supported clinical research

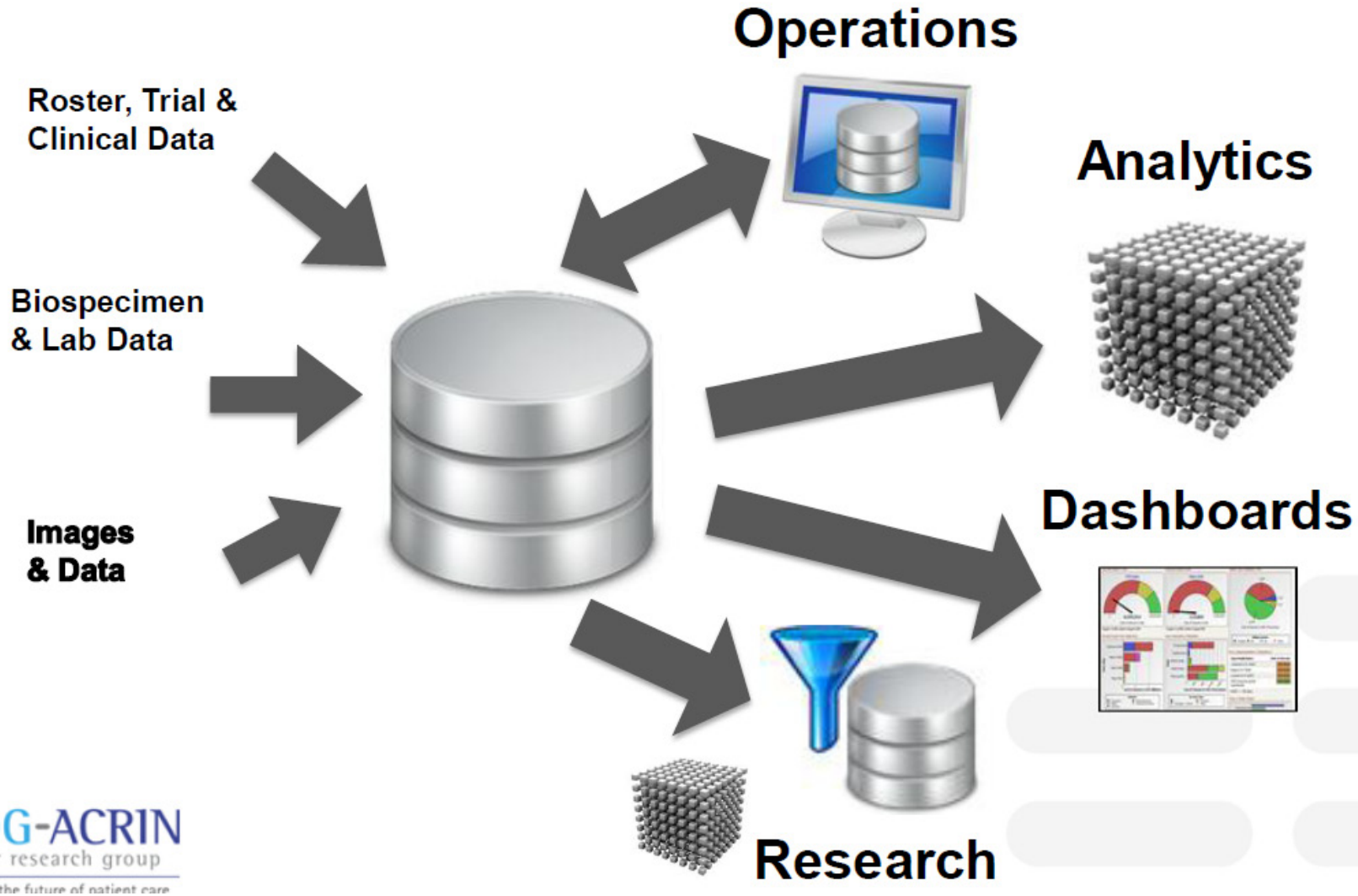
4. Enables the user to record patient information using forms customized per study (visit, lab and adverse event data)

5. Program officially initiated April 1, 2011

ECOG-ACRIN IT Vision

- Integrated Data Warehouse
  - CRF data
  - Imaging data
  - Tissue/Specimen repository inventory
  - Digital pathology
  - “Omics”

Warehouse Uses



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Lead Academic Participating Sites

- Cancer center guidelines changed
- Better visibility/coordination across centers
- Better engagement of cancer centers, SPORES, U01s
- Better reimbursement for high accrual

Leveraging Public and Non-profit Support

- ECOG and ACRIN 2007-2012:
  - Peer Review Grants 83
  - NIH (R01, R21, other) 65
  - Foundation (Komen, ASCO, etc.) 18

ECOG Core Support 2007-2012

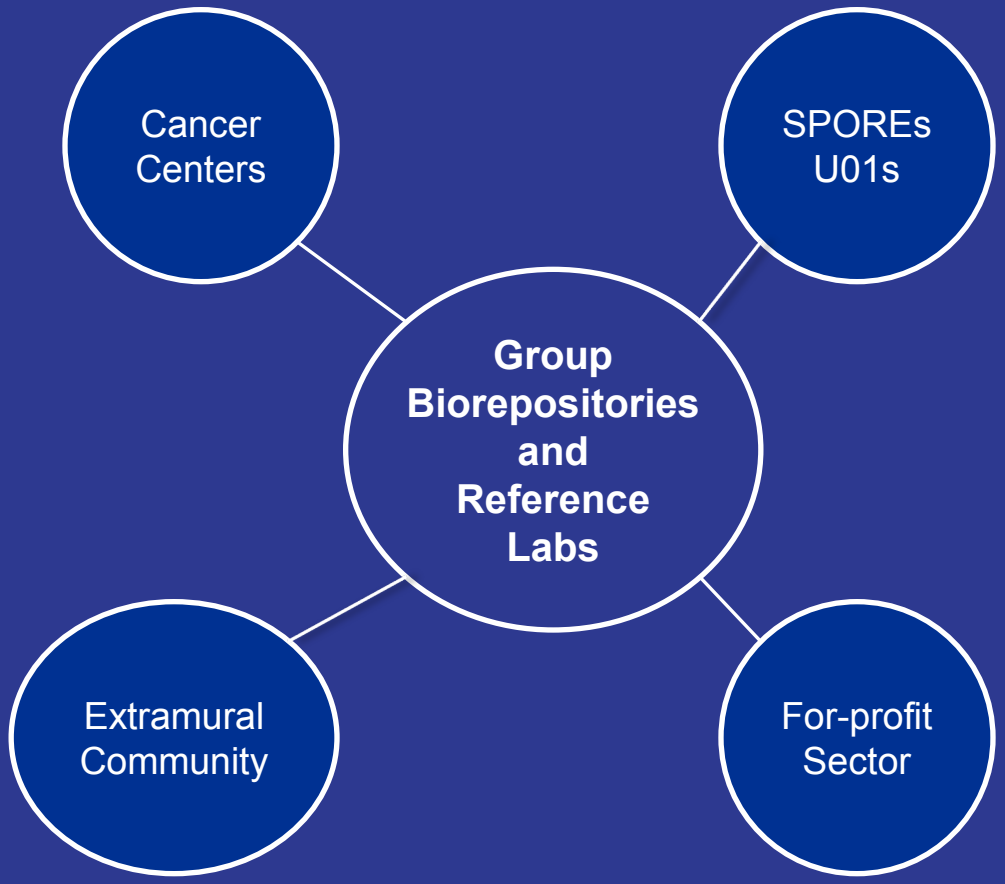
	Totals	Personnel	Biorepositories	Case Reimbursements
Amts ($M)	100.3	36.5	17.2	46.6
Federal	55.8 (55%)	19.8 (54%)	8.9 (52%)	27.1 (58%)
Non-Federal *	44.5 (45%)	16.7 (46%)	8.3 (48%)	19.5 (42%)

* $38M=industry; $6.5M=nonprofit

Integrated Translational Science Centers

- All groups involved
- Integrated next-gen sequencing, advanced imaging, immunobiology
  - Cancer centers/SPORES
  - Academic partners
  - For-profit partners
- Excellent cross-group/cancer center interaction
- Platform for sustained scientific effort

Biorepositories and Reference Labs the Hub for Science



Group-related Biorepositories

- Precious Resource
  - Excellent clinical annotation
  - Large scale trials
  - Linked to Group biostatistics
- Technology now available for FFPE next-gen sequencing
- Processes in place for review and distribution

Group-related Biorepositories

- Chairs committed to national distribution
- Key linkages
  - Biostatistics – outcomes data
  - Group management infrastructure
  - Continued financial and in kind support
  - Shared governance
- # of awards should = # of Groups

In Summary: Benefits of Consolidation

- Restructuring a work in progress to which Groups and NCI are committed in good faith
- Process itself has led to better understanding of strength, weakness and opportunities
- New structure being overlaid on system-wide adjustments (OEWG, Medidata Rave, etc.)
- Restructured Groups may share platform/ innovation
- Better potential for system-wide interactions

In Summary: Challenges of Group Consolidation

- Reversion to the mean with homogeneity
- Accrual opportunities decreasing
- Lack of infrastructure support → fractionation
- Need comprehensive strategy for next-gen sequencing
- Must maintain high level community participation
- Major restructuring at a time of financial constriction for NCI, Centers, Groups