



Cancer Genome Characterization Centers (CGCCs) RFA Highlights

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Web Cast

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- URL: <http://videocast.nih.gov>
- To read presentation slides directly:
 - ▶ URL: <http://www.capconcorp.com/cgcc/web.asp>
- The e-mail address to which questions can be submitted:
 - ▶ cgccbid@yahoo.com

Agenda:

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Technical Details of the RFA, 35 min

Daniela S. Gerhard, Ph.D.

Questions and Answers

Biospecimen Issues, 15 min

Carolyn C. Compton, M.D., Ph.D.

caBIG and the Data Coordinating Center, 20 min

Kenneth H. Buetow, Ph.D.

Genome Sequencing Centers and TCGA, 15 min

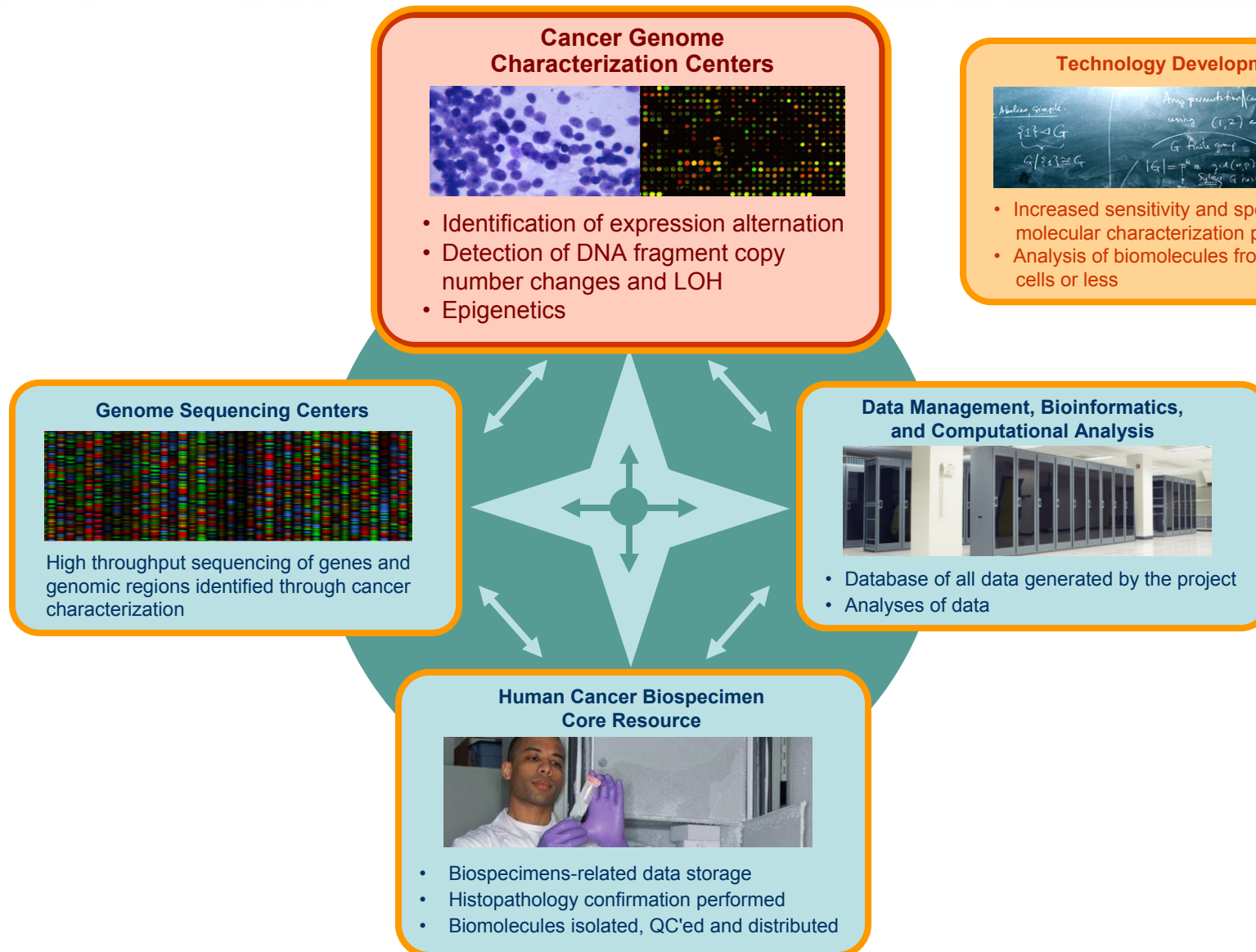
Jane L. Peterson, Ph.D.

The Peer Review Process, 15 min

Thomas M. Vollberg, Sr., Ph.D.

Questions and Answers

"How will it work"



Overall Goal of the CGCCs

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- Characterization of the molecular changes in cancer, as compared to control samples, through analysis of the genome, transcriptome or epigenome
- The biomolecules will be provided to the CGCCs by the Biospecimen Core Resource (BCR)

Genome Analysis: The Technology Platforms



- A technology platform is defined as a single method used to analyze either transcriptome, genome or epigenome. Examples of one vs. two platforms:
 - Expression profiling using a single technology from vendor A is **one** platform
 - Expression profiling and copy number DNA segment alternation detection from vendor A are **two** technology platforms
 - Expression profiling with vendor A and copy number DNA segment alternation detection with vendor B are **two** technology platforms

Critical CGCC Technology Platform Requirements

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- Technology platforms must be high-throughput and high quality
 - ▶ 1000 samples (500 cancer and 500 control) from single tumor type within the first year
 - ▶ Increased throughput expected in subsequent years
- Technology platforms utilized must be improved throughout the grant period

Requirement of Data Output Parameters of the CGCCs

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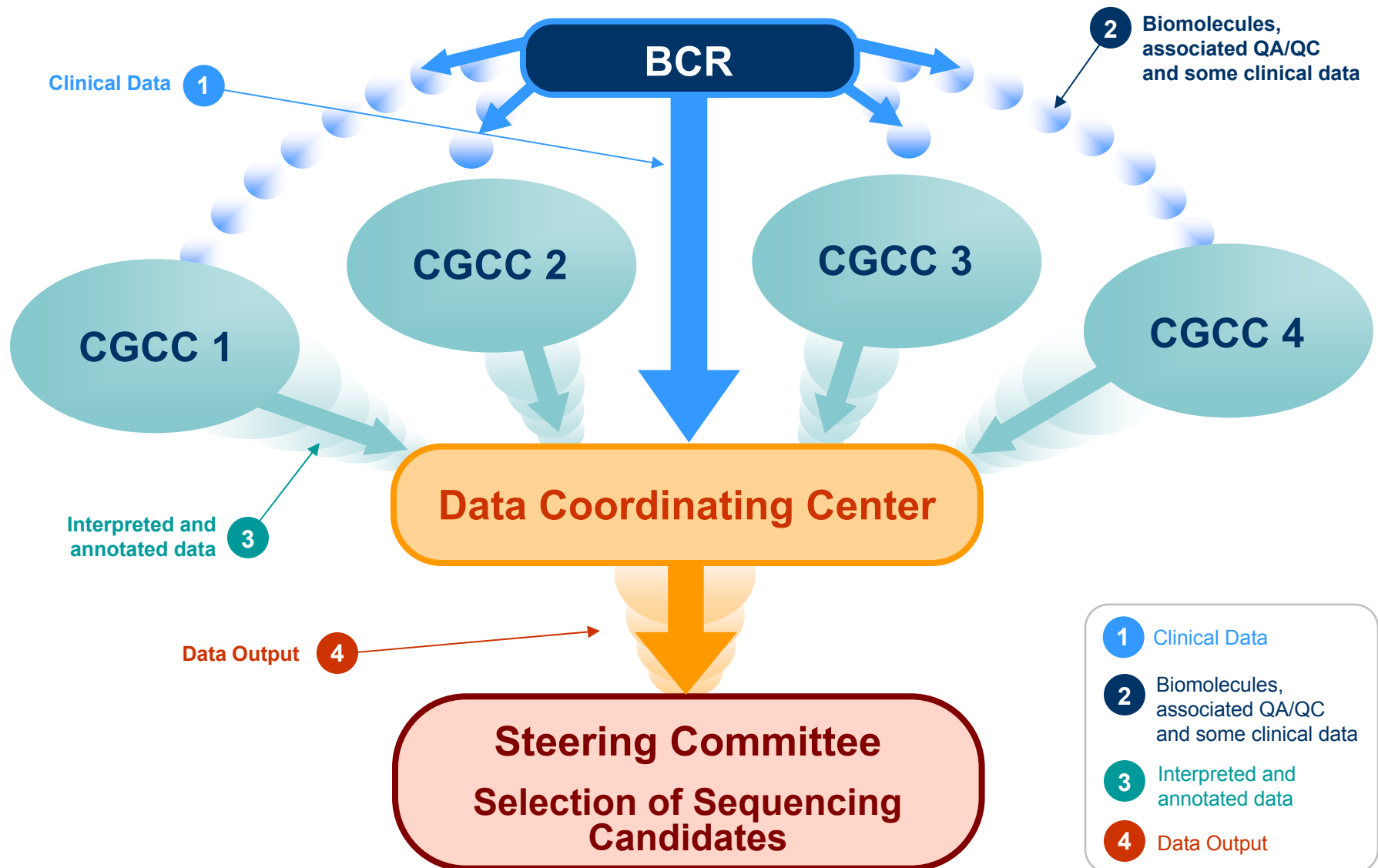
- Data generated must be optimized for:
 - ▶ Genome coverage, e.g.
 - All chromosome regions
 - Complete transcriptome
 - ▶ Specificity, e.g.
 - which splice form
 - amplified regions are defined at the best resolution achievable on a given platform
 - ▶ Sensitivity, e.g.
 - Levels of expression
 - Detection of small regions of hemizyosity



- Submit raw data to the Data Coordinating Center (DCC)
 - ▶ Register elements in caDSR
- Interpret data generated on the platform(s) selected
 - ▶ Provide QC and QA information
 - ▶ Annotate data
 - ▶ Submit all to DCC in a standard format to be agreed upon
- Prioritize candidates from genome characterization for sequencing
 - ▶ Submit to DCC in a format to be agreed upon

Transfer of materials and data

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Other CGCC Requirements



- The analysis cost per sample should be minimized without sacrificing the science
 - ▶ Continual cost improvements should be proposed all years
- Robust scientific communication between TCGA components will be essential
- TCGA Pilot Project Steering Committee Membership

Steering Committee Membership

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Voting members:

- Each Center's P.I.
- One Project Scientist each from NCI and NHGRI

Others:

- The members of TCGA management committee from the NCI and the NHGRI
- Principal Investigators from the Biospecimen Core Resource and the Data Coordinating Center

NIH Data Sharing Principles

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● Instantiated principles and practices to cover the needs of TCGA Pilot Project

▶ http://grants.nih.gov/grants/policy/nihgps_2003/index.htm

- “NIH believes that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. **investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single budget period are expected to include a plan for data sharing or state why data sharing is not possible.**”

Data and Resource Sharing



- TCGA Pilot Project is a “community resource project” intended to provide the foundation for future research
- Rapid release of validated data is essential to achieve the envisioned public health benefit
- A comprehensive strategy to rapidly share validated data, research resources and to manage intellectual property in a manner consistent with current NIH Guidelines and Best Practices is required
- Proposed strategy should demonstrate how it achieves the desired public health goals in the RFA
- The Technology Transfer or Sponsored Research Office at each institution can assist in preparing the required sharing plans

Data Sharing Plan Principles of TCGA

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- Agreement to rapidly release validated data according to TCGA Pilot Project Steering Committee guidelines; retention of data until publication is not acceptable
- Unreasonable delays in releasing data will be viewed as hindering TCGA
- Sharing algorithms, data mining software, etc. as open source consistent with caBIG is expected
- Accepted Data Sharing Plans will be incorporated into the Terms and Conditions of Award

Data Release Guidelines

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- Will be developed by TCGA Pilot Project Steering Committee
- Input will be sought from:
 - ▶ Medical personnel
 - ▶ Cancer biologists
 - ▶ Patients and their advocates
 - ▶ Ethicists
 - ▶ Lawyers
 - ▶ Genome scientists
 - ▶ Policy makers

Intellectual Property Principles

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- Consistent with Best Practices for the Licensing of Genomic Invention recommendations by NIH
http://www.ott.nih.gov/policy/genomic_invention.html
- NIH Research Tools policy
http://ott.od.nih.gov/policy/research_tool.html
- Each application must include Intellectual Property Management Plan consistent with the guidelines



- Intellectual property management practices that assure release of validated data consistent with the RFA
- Patenting and licensing of inventions should be consistent with NIH Guidelines and Best Practices
- Non-exclusive licensing is preferred
- Retention of rights by the investigator to share research tools and data is suggested
- Collaboration agreements should be consistent with the goals and terms of the RFA

Intellectual Property Plan - 2



- No “reach through” to future inventions of third-parties using research materials and data.
- Material Transfer Agreements (MTAs) are used with terms no more restrictive than the NIH Simple Letter of Agreement or the Uniform Biological MTA.
- IP Plans will be incorporated into the Terms and Conditions of Award
- Practices that block access to data or resources will be viewed as hindering TCGA Pilot Project



- Maximum of 2 different technology platforms (as defined) per application
- The proposal should advance the overall goals of TCGA Pilot Project
 - ▶ Technologies appropriate
 - ▶ Improvements
 - ▶ Interaction w/ other TCGA components indicated



- Scientific rationale well supported and explained
 - ▶ Analytical approach and QC appropriate
 - ▶ Throughput, cost, coverage and sensitivity well addressed
 - ▶ Improvements in technology platforms included and well defended
- Responsive Data Sharing Plan submitted
- Responsive IP Management Plan submitted
- Investigators and Environment

The CGCCs are Cooperative Agreements

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Each submission should provide
documented expertise in:

Molecular biology/genetics/oncology

Genomic analysis technologies

Clinical research

Bioinformatics

Biostatistics

TCGA Pilot Project Research Network

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- Biospecimen Core Resource
- Cancer Genome Characterization Centers, U24
- Genome Sequencing Centers, U54
- Data Coordinating Center
 - ▶ Future RFA for mining tool developments and other bioinformatics needs as data types become known and initial data generated

Steering Committee

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- The committee will be established once the awards are made
- The functions will evolve with the needs of the pilot project and will be defined throughout. Initially, they include:
 - ▶ Close interaction of the various components
 - ▶ Develop data release guidelines
 - ▶ Assessment of data
 - ▶ Evaluation of technologies and coordination of improvements

Key Dates

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Release Date:	March 10, 2006
Letters of Intent Receipt Date(s):	April 12, 2006
Application Receipt Dates(s):	May 12, 2006
Peer Review Date(s):	August 2006
Council Review Date(s):	September 2006
Earliest Start Date:	September 26, 2006



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