





### NCI Inaugural Symposium: International Harmonization of Biorepository Practices

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# Welcome to the Countries Represented Here Today



Why are We Here: To Realize a Future of Molecular Oncology/Molecular Medicine – Where No One Suffers and Dies from Cancer

> Advances in Molecular Research and Technologies (Depends on Quality Biospecimens – International Network) The Past Century 21st Century

Established system to treat established disease – a treatment/therapeutic focus (in cancer often too late)

Morphologic and pathologic diagnosis – drove treatment

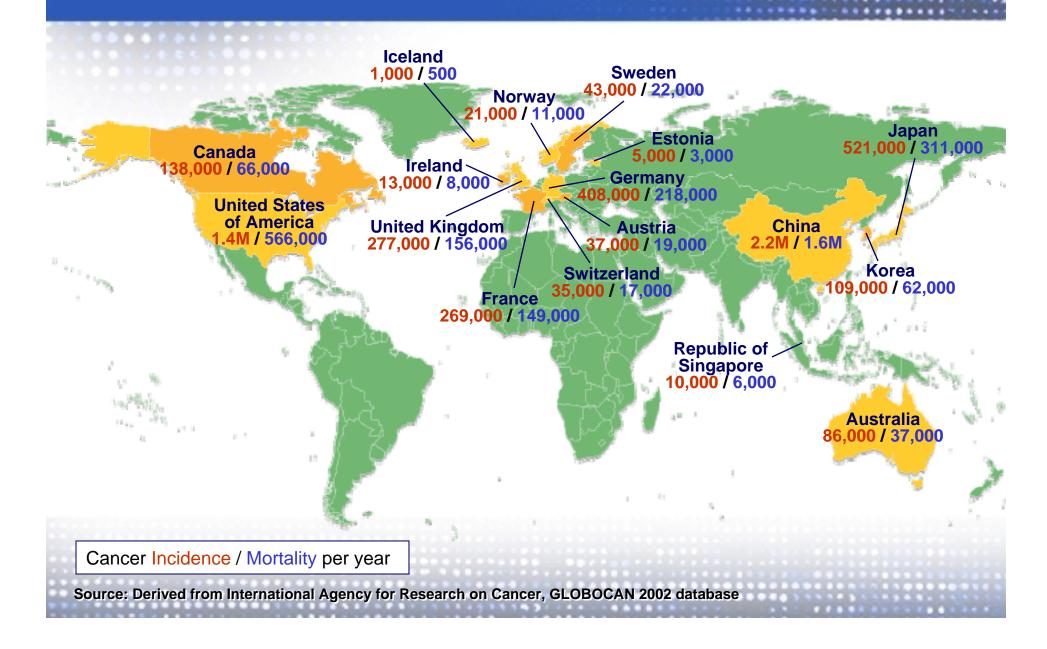
Expensive in all respects – not sustainable in 21<sup>st</sup> century

Healthy population not a focus as a major national advantage/asset Gradual shift to targeted Interventions for prevention and treatment – shift in focus to early detection and prevention

Driven by the molecular characterization of disease – mechanistic understanding of pathways and processes

Evidence based – preserves human and financial capital – sustainable – Health becomes major national asset

#### We Share a Profound Problem in Cancer Incidence and Mortality – and a Common Goal to Defeat this Common Enemy



#### The Future: Leveraging the Power of an International Network to "Harmonize" Biorepository and Bioinformatics Platforms to Defeat Cancer



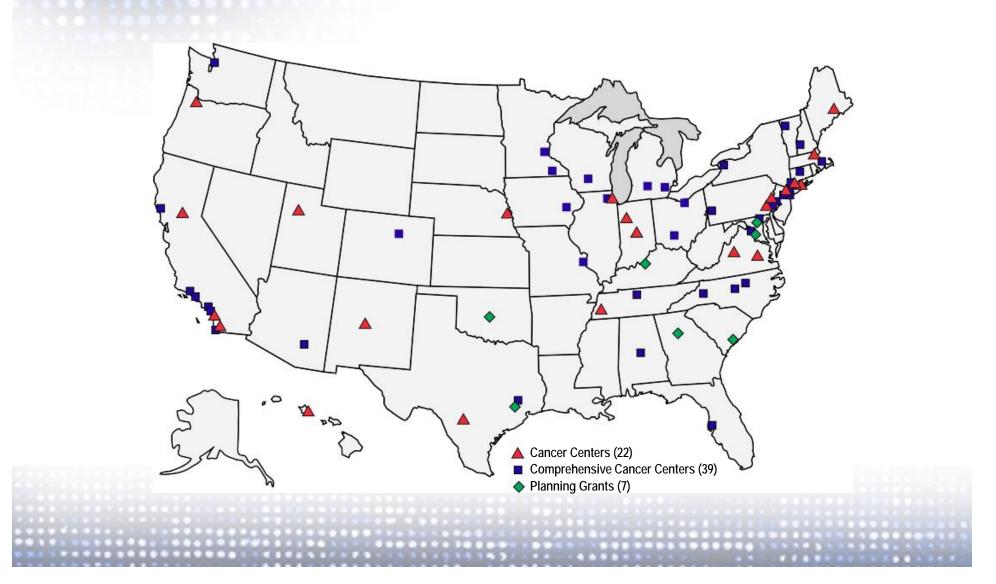
## **Creating an International Network of Biobanks for Cancer Research**

Our Hope: The U.S. NCI and the Nations that are leading in this critical area can serve as a catalyst ...

....for the formation of an integrated network of biobanks to facilitate and accelerate cancer research, development and delivery to cancer patients.

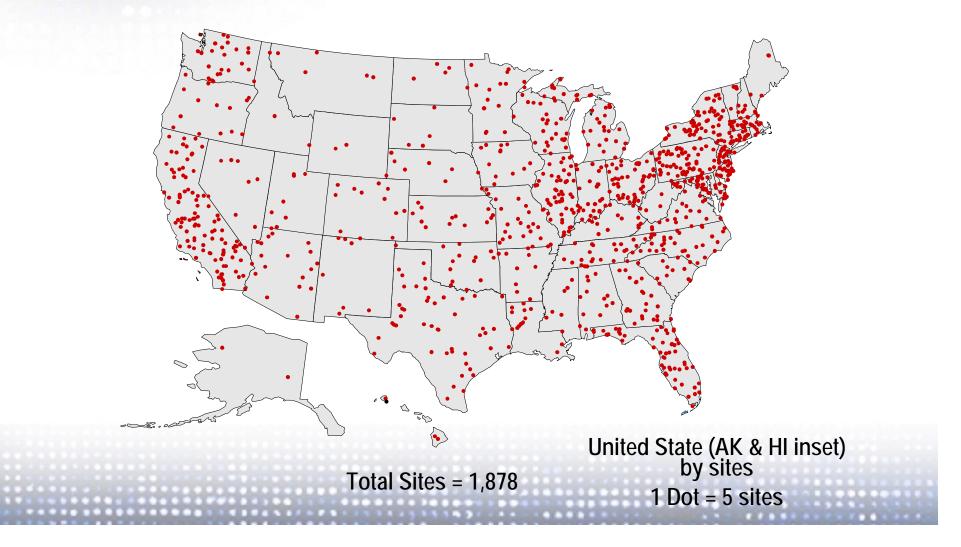


## Current and Emerging NCI Cancer Centers (Most are Biorepository Sites)



#### U.S. Cancer Clinical Trial Treatment Sites – as of Year 2004 (Potential Biorepository Sites)

(# of Sites by State that Currently have Patients Enrolled in an Open Trial)



## Following Several Years of Assessment of Biorepositories, Expert Input, and Planning

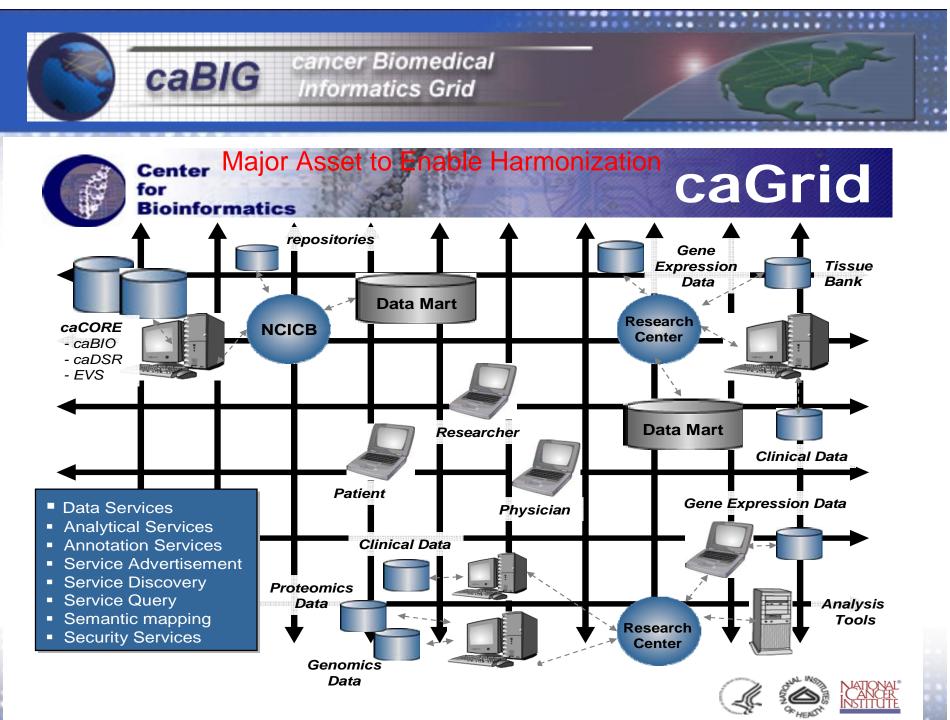
NCI is developing and will deploy U. S. cancer enterprise best practices/standards for biospecimens

- First-Generation Guidelines First Quarter 2006 (Compliance Encouraged)
- Longer-term Second-Generation Evidence-Based Guidelines (Compliance Expected)



## NCI's Path from First-Generation Guidelines to Evidence-Based Biospecimens/Biobanks



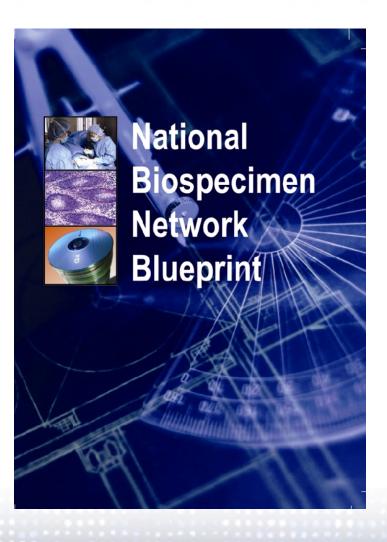


NCI is Providing Leadership for the Creation of a National Biospecimen Resource – Ultimately Needed for a Global Network

National Biospecimen Network Blueprint: "A Model for the Community – A Path for the Future of Personalized Medicine"

Currently Being Piloted through NCI's Prostate SPORES

www.ndoc.org/about\_ndc/reports/



## Areas of Common Concern/Opportunity for All Biorepositories

- Best Practices Standard Operating Procedures
- A Common Bioinformatics System
- Quality Assurance and Quality Control Standards
- Ethical, Legal, and Policy Issues
- Reporting Mechanisms
- Access
- Administration and Management



## **Charge and Goals for the Meeting**

- An International Working Group
- Piloting Best Practices
- A Demonstration Project
- A caBIG Compatible Bioinformatics Initiative to Establish this International Network

