





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

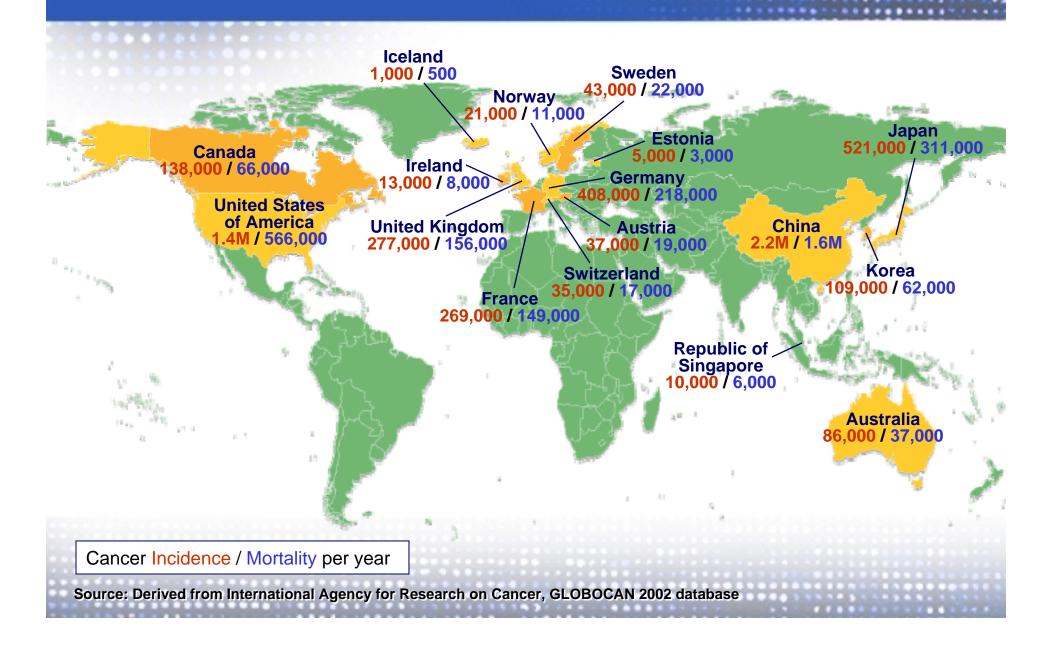
Expensive in all respects – not sustainable in 21st century

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



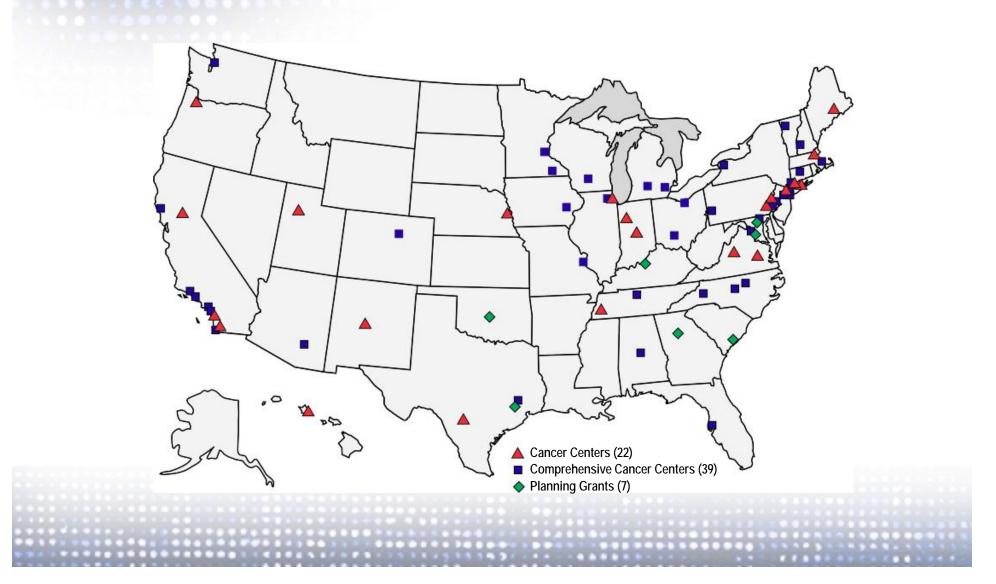
Creating an International Network of Biobanks for Cancer Research

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.

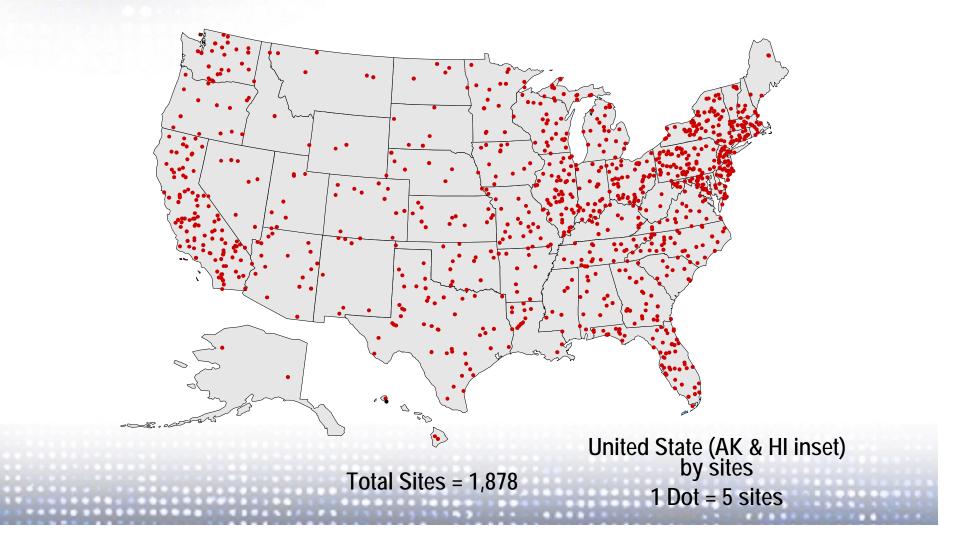


Current and Emerging NCI Cancer Centers (Most are Biorepository Sites)



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

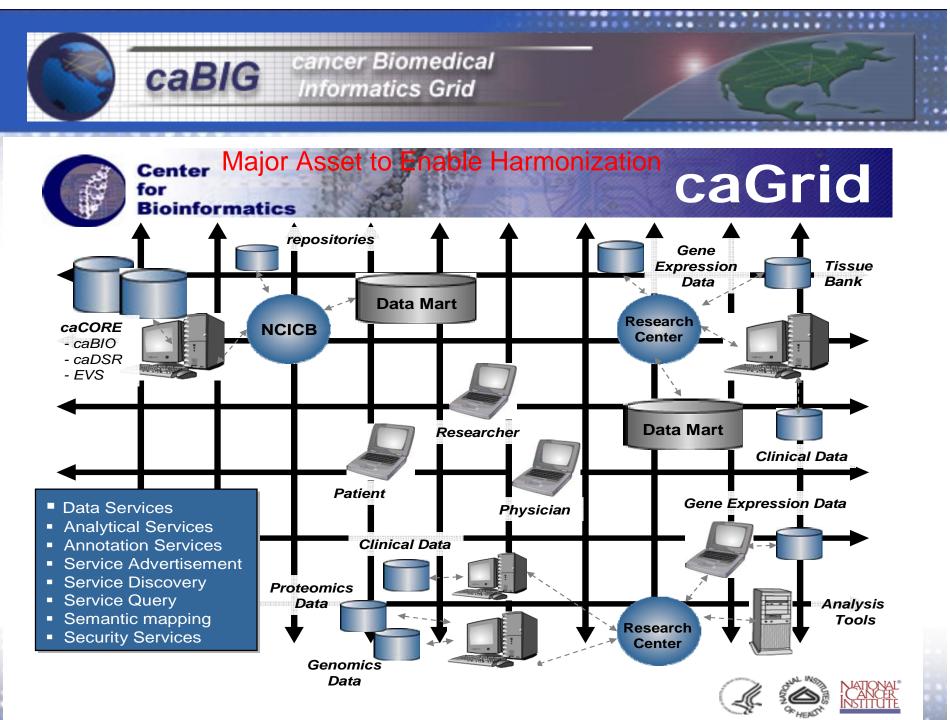
NCI is developing and will deploy U. S. cancer enterprise best practices/standards for biospecimens

- 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



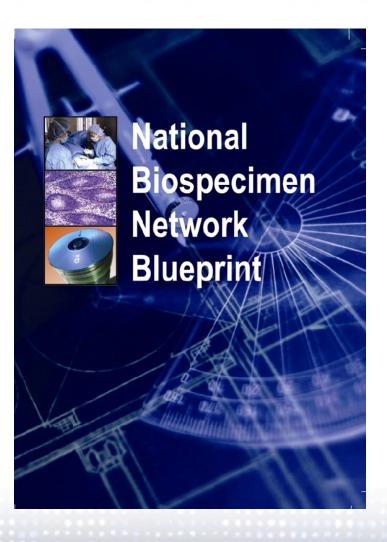


NCI is Providing Leadership for the Creation of a National Biospecimen Resource – Ultimately Needed for a Global Network

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

