

The Importance of Best Practices to Patients, Advocates & The Public

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TRAC- Translating Research Across Communities

NCI Biospecimen Best Practices Forum

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Office of Biorepositories and Biospecimen Research

National Cancer Institute - National Institutes of Health

U.S. Department of Health and Human Services

Across The Scientific Spectrum



Physical
Behavioral
Social
Cultural
Economic
Political
Spiritual
Technological

HOPE

The Art of Translation...

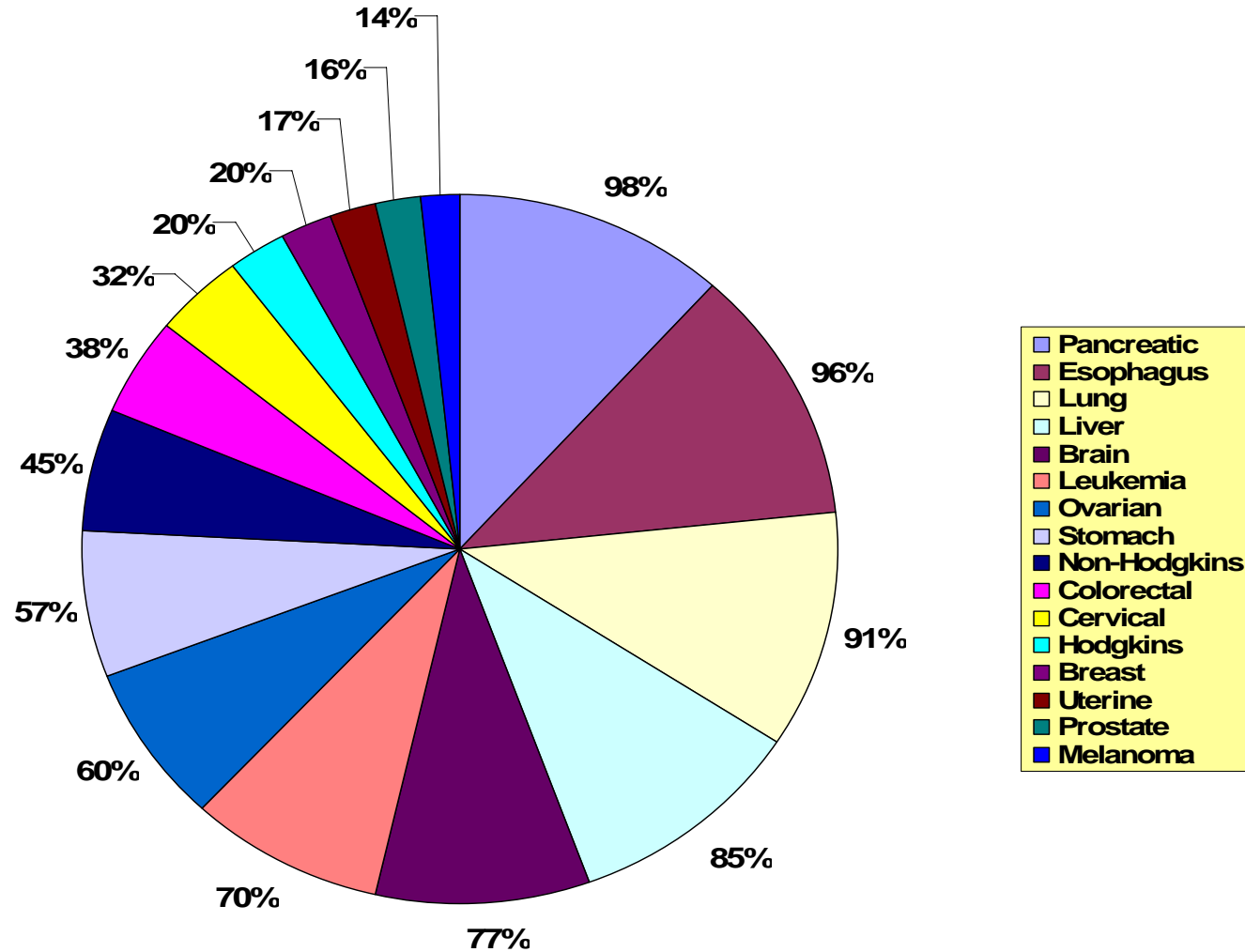
“ From the standpoint of medicine as an art for the preparation and cure of disease, the man who translates the hieroglyphics of science into the plain language of healing is certainly more useful.”

-William Osler, Physician

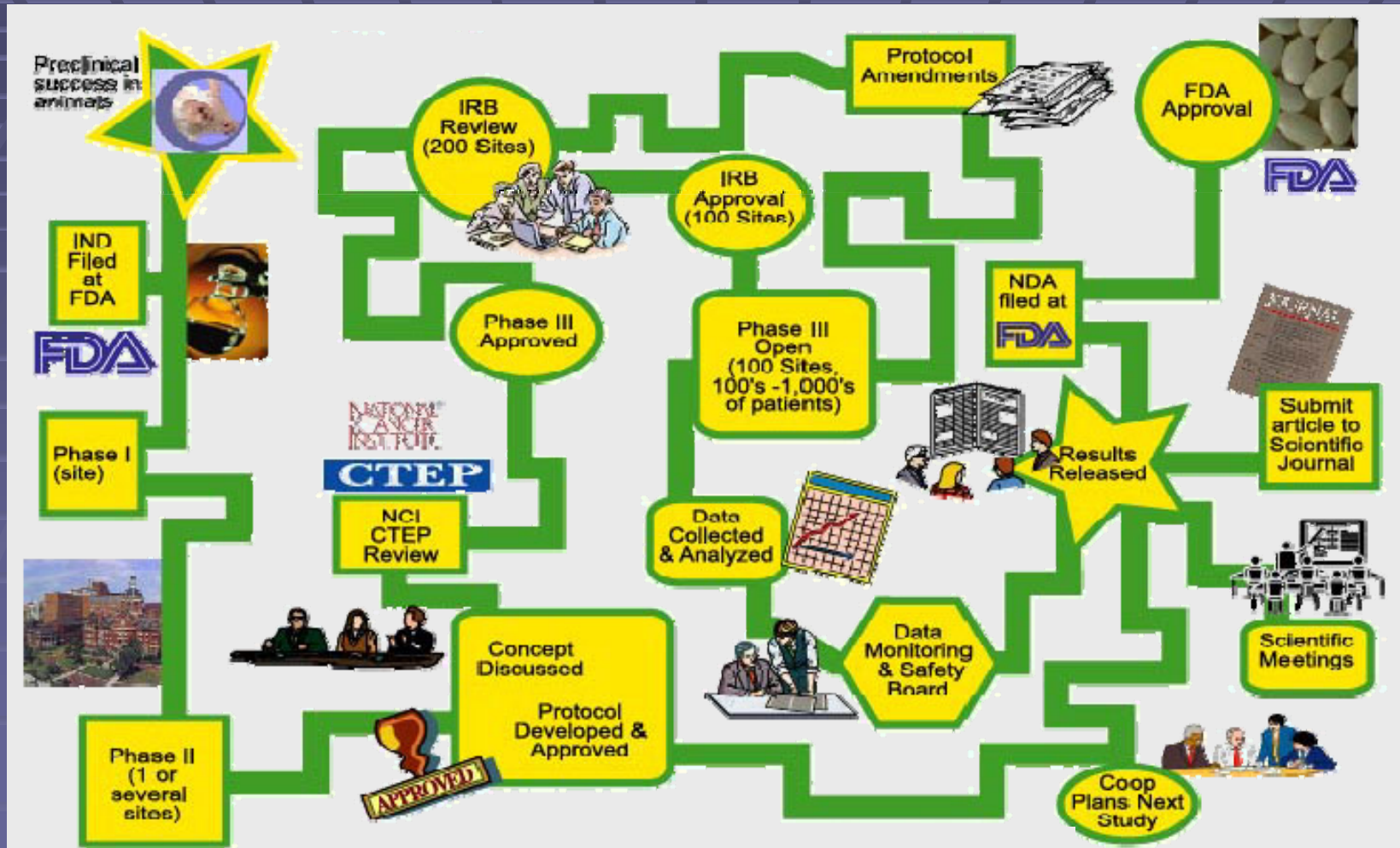
100 Years and Counting...

- It has taken more than a century, but the marrying of biospecimens, technology, and science for patient benefit is coming of age
- Biospecimens are precious human resources filled with unique genetic information
- The privilege of using these resources to advance and translate research into clinical application for patient progress brings great responsibility not to be taken lightly
- Biospecimens are part of resource toolkit

U.S. Cancer Mortality Rates



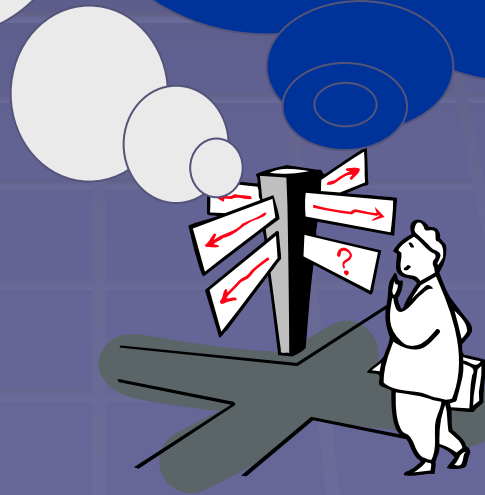
Getting a New Product Through This Process Is Not Easy... Many Years and Lots of \$\$\$



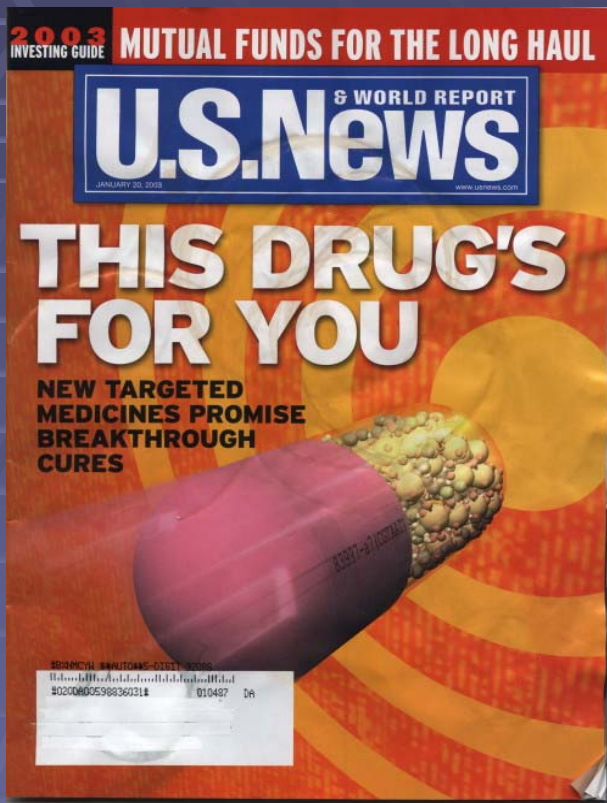
Patient Dilemma with Words and Decisions...

Invasive ? Non-invasive?
Academic Center ? Local ?
Informed Consent?
Do my kids need genetic
testing?
Where is my tissue?
Eligible ? Insurance ?
Am I Going to Live?

Personalized medicine?
Biospecimen?
Targeted Therapies?
EGFR Inhibitor? Biopsy?
Proteomics?



The Promise



- Targeted Therapies
- Seek and Control instead of Search and Destroy
- Genetic Testing
- Reduced Toxicities
- Predictive/Preventive Capability
- Reduced drug failure rates
- A CURE

All Drugs Are Targeted Therapies

- The problem is the numbers of compounds AND targets known to work together well are few and far between...here are a few examples of working ones

■ Trastuzumab-Herceptin®  HER 2

■ Cetuximab-Erbitux®  EGFR

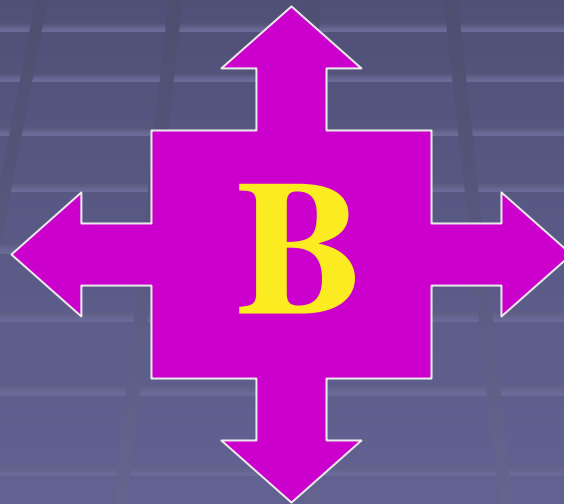
■ Imatinib mesylate-Gleevec®  KIT

■ Erlotinib-Tarceva®  EGFR

Connect The Dots

Research: Patients,
Volunteers, Groups & Public

Research:
Academic &
Community



Research: Public
Agencies & Policy
Makers

Research: Industry &
Private Sector

Why We Need To Keep Moving In the Right Direction

- Information is not knowledge
- Competing Funding Priorities
- More Survivors; Still Feared
- Shrinking Budgets
- Increased Regulations
- Fast Moving Science
- Requirements and Expectations



RISK



BENEFIT

ADVANCE PUBLIC HEALTH

- Ⓢ Federal Law
- Ⓢ HIPAA; IRB;
- Ⓢ Black Letter Law
- Ⓢ Benefit
- Ⓢ Simplification
- Ⓢ Misuse
- Ⓢ No patient uptake
- Ⓢ No biospecimens
- Ⓢ No progress
- Ⓢ No cures

- Ⓢ State Law
- Ⓢ Common Rule
- Ⓢ Common Sense
- Ⓢ Risk
- Ⓢ Complication
- Ⓢ Appropriate
- Ⓢ No participation
- Ⓢ No research
- Ⓢ No answers
- Ⓢ No hope

Earning Public Trust & Confidence

Confidence in you and your team

Confidence in the reason

Confidence in the test

Confidence in the system

Confidence in the procedure

Confidence in the test results

Confidence in the diagnosis

Confidence in the recommendation

Confidence in the outcome

Confidence...period

Biospecimen Best Practices Are More Than Just Freezer Temperature and Hold Time

- ③ Partnering with the public
- ③ Privacy and patient protection
- ③ Data Sharing and bioinformatics
- ③ Handling of biospecimens
- ③ Promoting access for research
- ③ Intellectual property
- ③ Future patient access to sample
- ③ Intellectual Property

Consequences of Poor Practices-

- **False + and False -**
- **Inaccuracy; non-reproducibility**
- **Erodes public confidence**
- **Wastes time & money**
- **Impedes clinical benefit**
- **Takes another 100 Years**

Practice, Process, Performance = Product

- Joist
- Fascia
- 200 psi
- 4 in 12
- 20/30 finish
- Romex
- Title 24
- Combi
- TJI
- Is the footing designed to carry a live load of 100 lbs PSF?
- Do you nail drywall at 6" o.c. or 12" o.c.?
- Does the concrete cure for 28 or 40 days?
- Imagine making choices and decisions that affect our lives...without access to guidance, information, and resources ?
- Imagine trying to build your dream house without well designed plans and standards or a qualified architect or builder ..
- **BEST PRACTICES, STANDARDS AND BLUEPRINTS ARE CRUCIAL WHETHER IT'S A HOUSE OR A BIOSPECIMEN !**

Benefits for All

Commitment for:

Infrastructure + resources + best practices
can yield high-quality biospecimens

The Potential Upside 

data with integrity that becomes information
transformed into *knowledge* that puts real
discovery into real life in real time for
patient benefit

Research Advocates: Partners In Progress

- ② Scientific committees
- ② Clinical trial design
- ② IRB; Data Safety Monitoring Board
- ② Grant Review
- ② Biospecimens
- ② Bring The Patient Perspective

Why We Must Get This Right...

“ We must harness the scientific, industrial, and social will to accelerate discoveries into accessible and meaningful clinical applications. Patients, families, friends, and loved one are counting on us...Because in the end, it’s not about you, or me, or the science, it’s about the patient.”

Paula Kim - Research & Patient Advocate

Patient & Advocate Perspectives

Don't Leave Home Without Them

