

Research Advocacy Network

Advancing Patient-Focused Research

The Importance of Best Practices to Patients, Survivors, Advocates, and the General Public

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December 3, 2007

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

*It's All About the Patient: Putting
Biospecimen Research In Perspective*

Paula Kim , *TRAC- Translating Research Across Communities*
NCI Biospecimen Best Practices Forum
November 5 2007, Conference Center at Harvard Medical School
OBBR NCI – NIH, U.S. Department of Health and Human Services



Genomics

Proteomics

Pharmaco-genomics

HOPE

The Art of Translation...

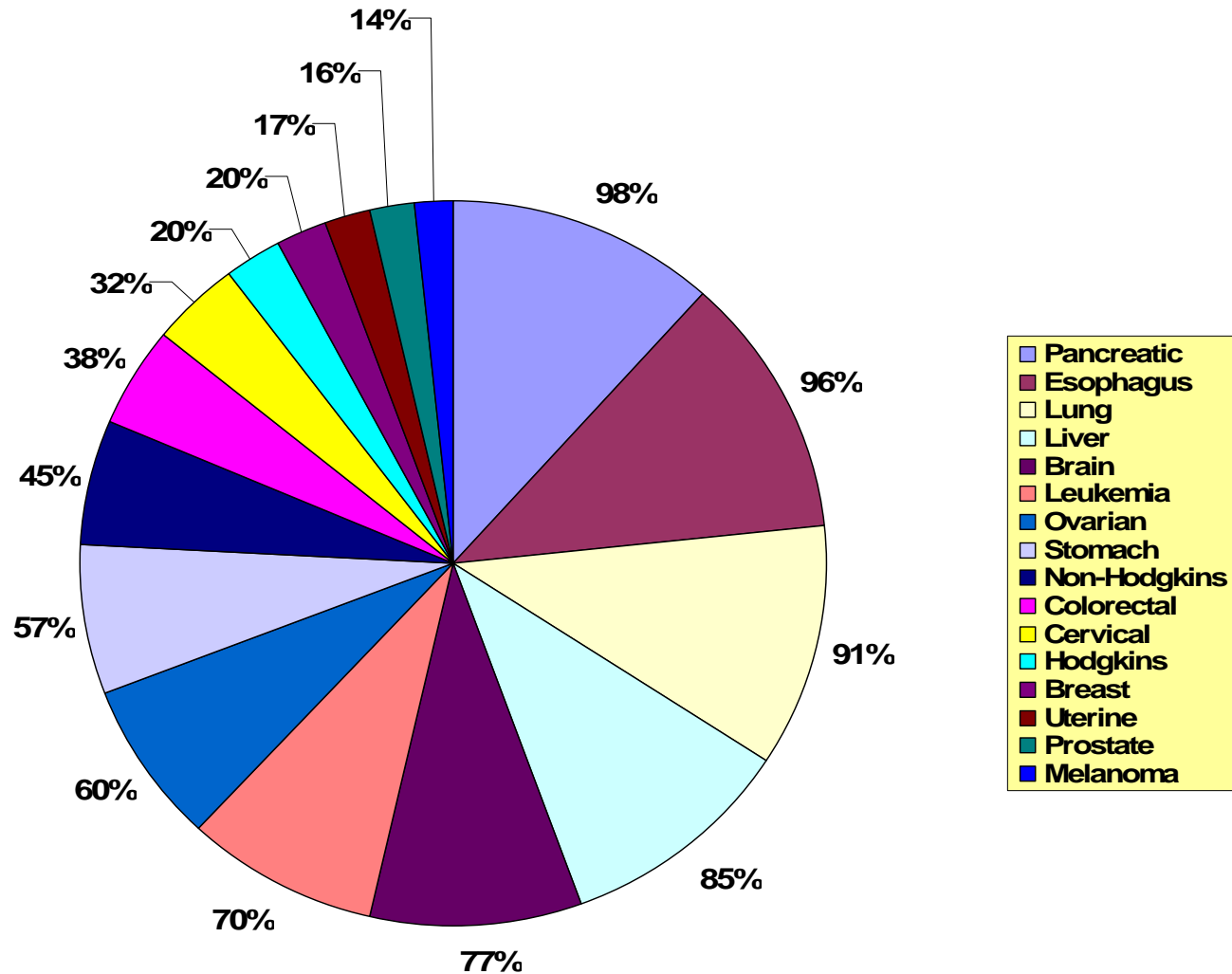
“ From the standpoint of medicine as an art for the preparation and cure of disease, the man who translates the hieroglyphics of science into the plain language of healing is certainly more useful.”

-William Osler, Physician

100 Years and Counting...

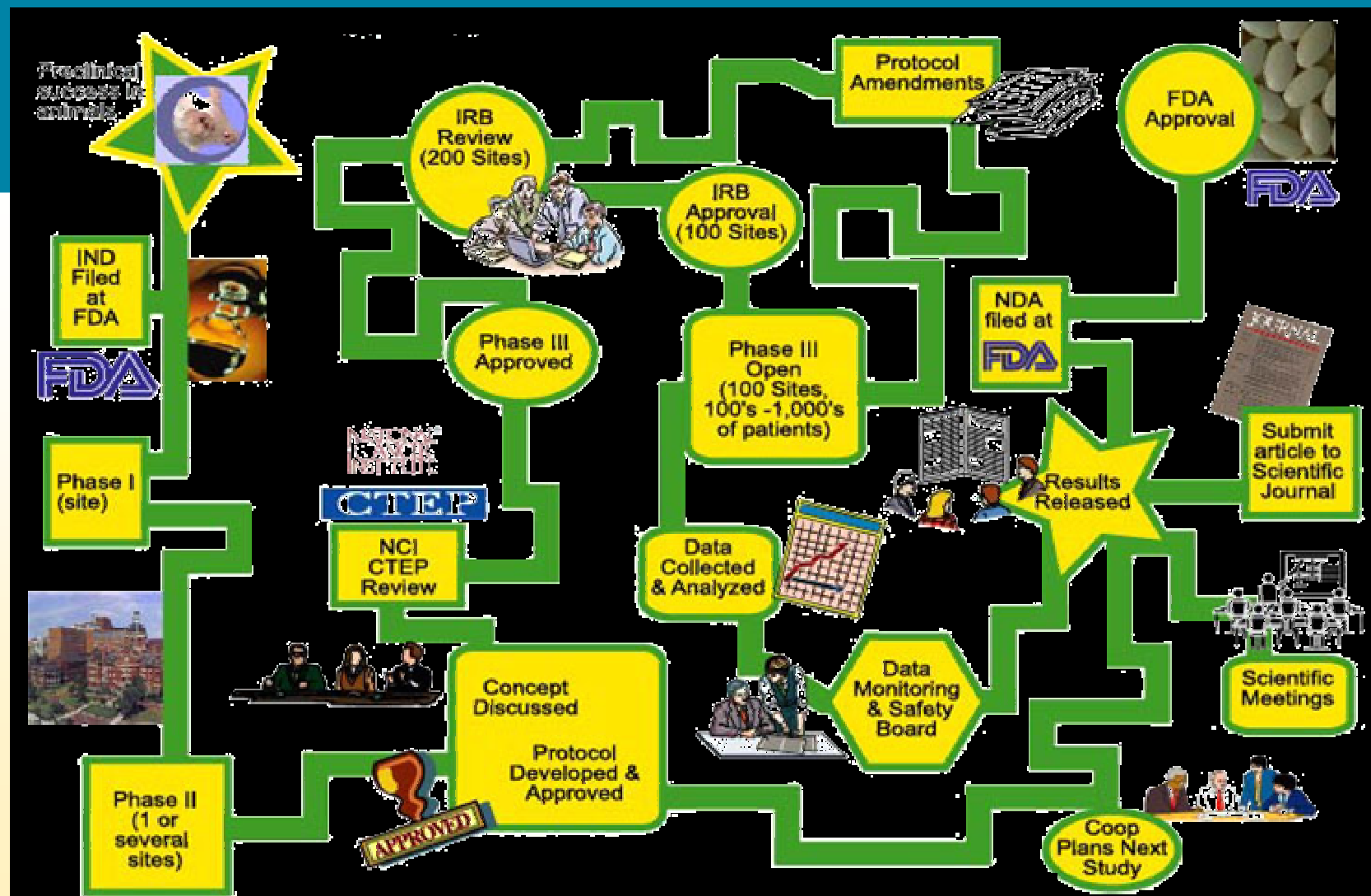
- Taken over a century, and now biospecimens, technology, and science for patient benefit is coming of age
- Biospecimens are precious human resources filled with unique genetic information
- The privilege of using biospecimens to advance research into clinical application brings great responsibility not to be taken lightly
- Biospecimens are part of resource toolkit

U.S. Cancer Mortality Rates



Source: NCI Facts Book, ACS Facts and Figures Raw data NCI Facts Book /
 Calculations are based on # of mortalities divided by # of Incidence

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?
How to pick treatment?
Do my kids need genetic testing?
Where is my tissue?
Eligible ? Insurance ?
Am I Going to Live?

Personalized medicine?

Biospecimen?

Biopsy? 2nd pass?

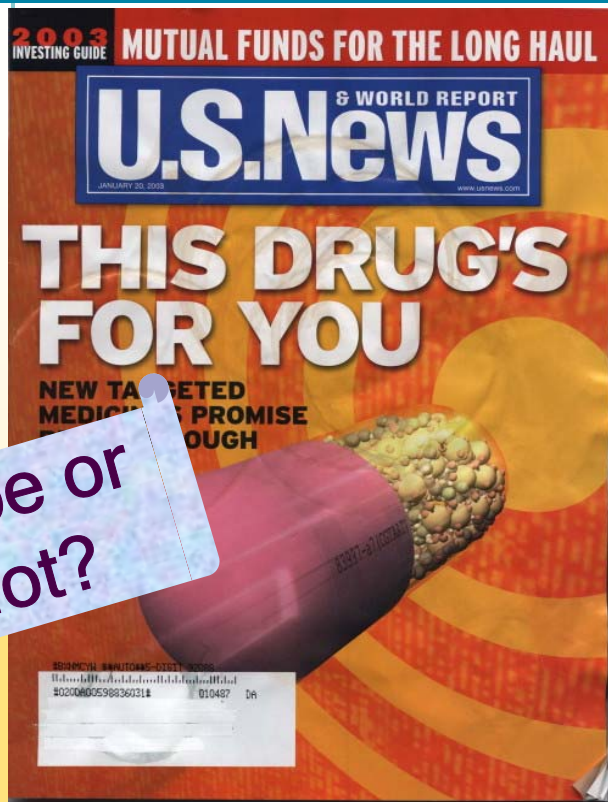
Targeted Therapies?

EGFR Inhibitor?

Proteomics?



The Promise



Hype or Not?

- Personal 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

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

- Trastuzumab-Herceptin®



HER 2

- Cetuximab-Erbitux®



EGFR

- Imatinib mesylate-Gleevec®



KIT

- Erlotinib-Tarceva®

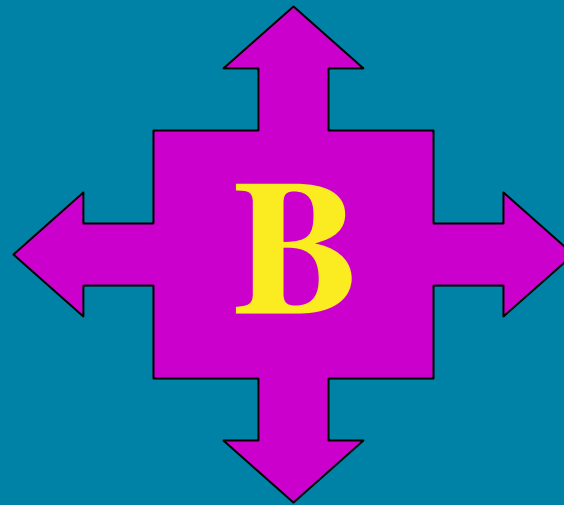


EGFR

Connect The Dots

Patients, Volunteers, Groups &
Public

Academic &
Community



Public Agencies
& Policy Makers

Industry & Private
Sector

B= Biospecimen

Why We Need To Keep Moving In the Right Direction

Information is not knowledge

- **Competing Priorities**
- **More Survivors**
- **Shrinking Budgets- Expanding Costs**
- **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

Consequences of Poor Practices-



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

Earn 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

- @ Partnering with the public and community
- @ Privacy and patient protection, cultural sensitivity
- @ Data Sharing and bioinformatics
- @ Handling of biospecimens
- @ SHARE, promote and provide research access
- @ Balancing Intellectual property

Practice, Process, Performance = Product

- 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 annotated biospecimens

The Potential Upside 

Data + specimen with integrity becomes Information into knowledge that puts real discovery into real life in real time for patient benefit

Examples of Novel Biospecimen Partners In Progress

- Friends for Life study
- Arizona Myeloma Network
- Research Advocacy Network patient and IRB education materials
- Genetic Alliance Biobank (e.g., IBCRF) – Broad Based, Rare diseases

Research Advocates: Partners In Progress

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

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“ We must harness the scientific, industrial, and social will to accelerate discoveries into accessible and meaningful clinical applications. Patients, families, friends, and loved ones 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 and Advocate Perspectives

Don't Leave Home Without Them

