Informatics-guided workflow for procuring biospecimens from cancer patients

3rd Annual Biospecimen Research Network (BRN) Symposium: Advancing Cancer Research Through Biospecimen Science

OBBR, NCI

Bethesda, MD 2010

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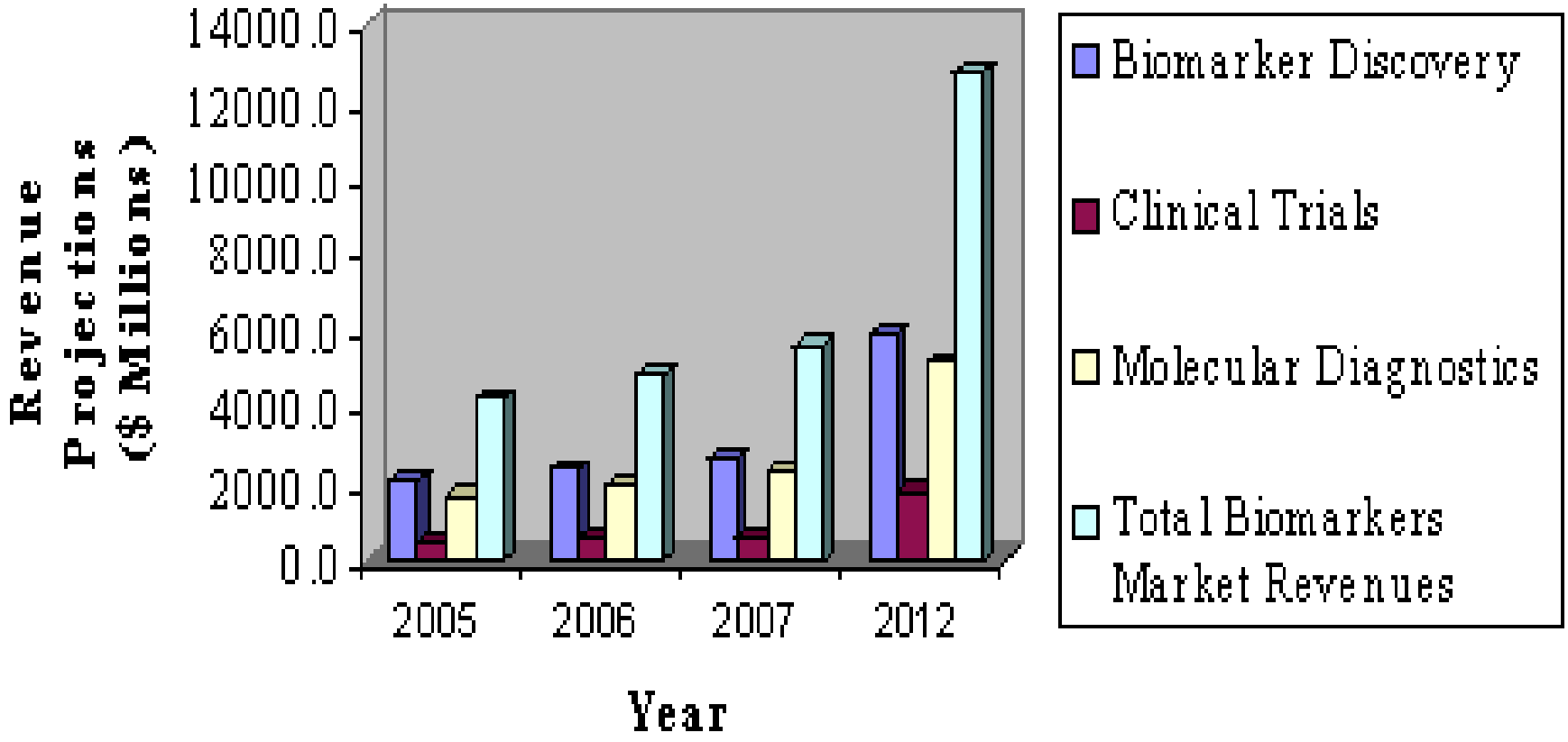
Tissue Bank and Cancer Research Program

Cancer Center

Hackensack University Medical Center

Demands for basic, translational and clinical science related to biomarkers will dramatically increase in the future

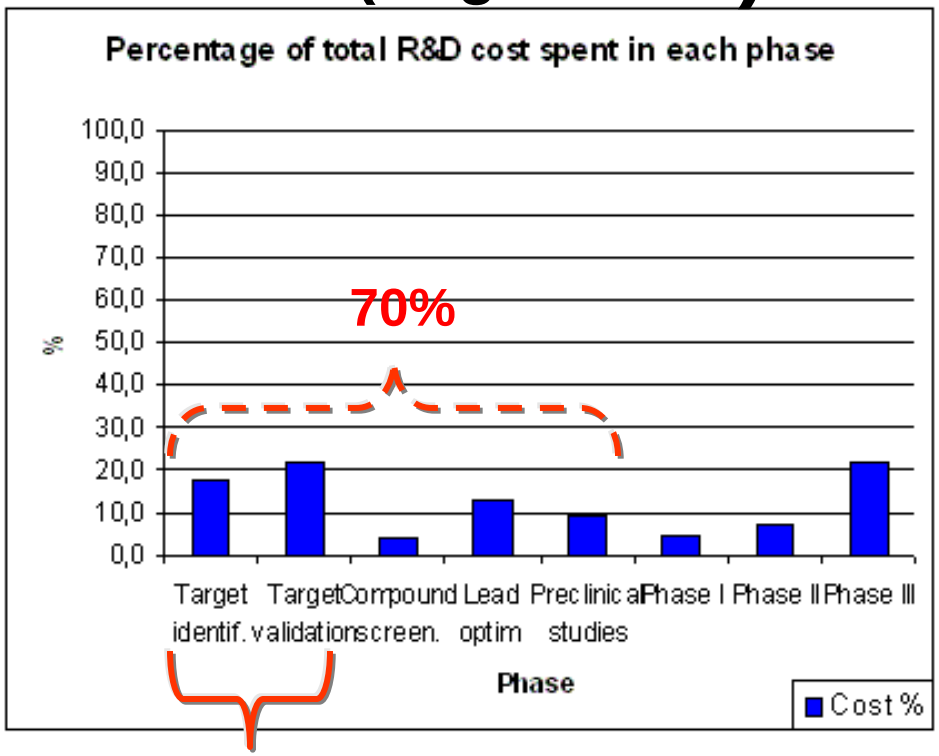


Source: BCC Research, 2007

Biomarkers: The Expanding Global Market (BIO61A)

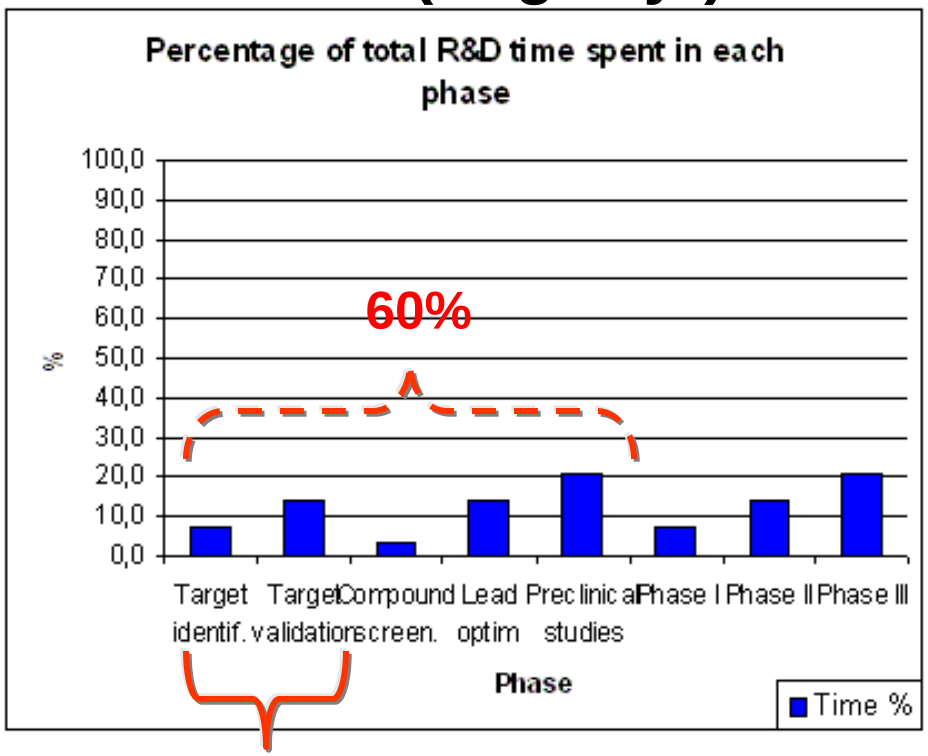
Biomarker discovery (target identification and validation) is associated with high cost and time

Cost (Avg 1billion)



40%

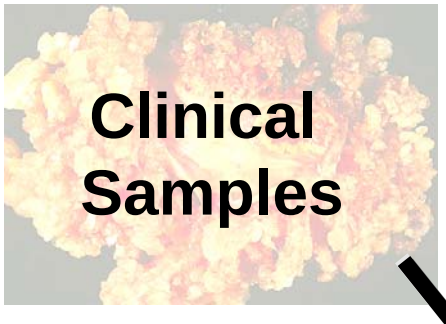
Time (Avg 12yr)



20%

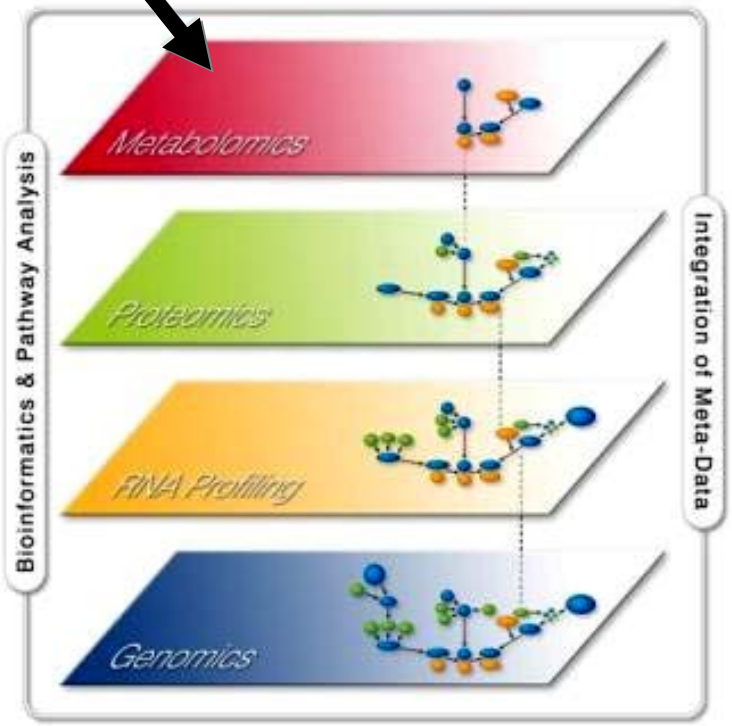
Source: Life Science Insights, Ernst & Young, Tufts CSDD and Boston Consulting Group, July 2004.

Much of biomarker discovery efforts were focused on lab benches for the past 15 years



Samples land on lab bench

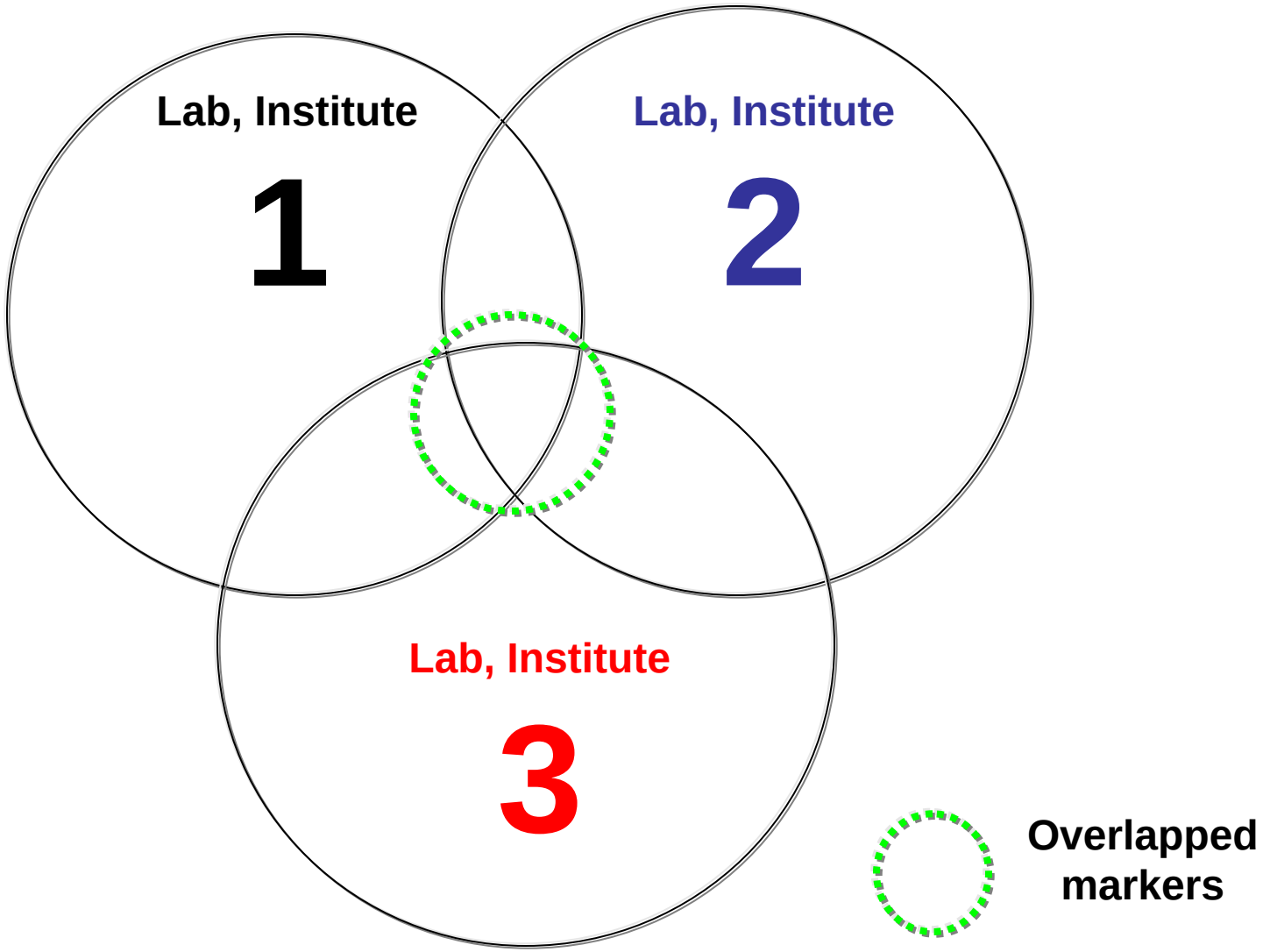
Sample "Procurement" neglected



Biomarker (molecular target)

40% Cost of R&D

A small number of tumor biomarkers overlap between laboratories and institutes



1. **Too much capital, time and efforts spent on lab benches with bad samples.**

Mixture of samples

100 (perfect) X 0 (junk) = 0 (product)

(Score) (Score) (getting close to)

2. **Biomarker discoveries begin with procurement of <u>high quality clinical biospecimens</u>.**

Hackensack University Medical Center (120 yrs old)

1. **Voted best in NJ and top 50 hospitals in US**
    a. **900 bed (Main campus) + 300 bed (North campus)**
    b. **Ranks 4th in US for patient volume**
    c. **Larger than most NCI-designated cancer centers**
    d. **Approximately 150 clinical trials active**
    e. **Ranks 5th in US for cancer patient volume (>60,000/yr)**
        (i) Out of >35,000/yr surgical procedures, about ½ is cancer related
        (ii) Currently, the Tissue Bank procures <2% of blood and <0.5% of tissues

Multiple departments are involved in the Tumor Bank tissue procurement workflow

DEPARTMENTS

A. In- and Out-patient Clinic
B. Laboratories/ Phlebotomy
C. Couriers
D. Surgical Procedure Rooms
E. Pathology Department
F. IT and Telecommunication department
G. Tissue Repository

PEOPLE

- Research, Education and Charge Nurses
- Schedule, Research and Data Coordinators
- Receptionist and Assistants ..etc

Challenges and Solutions in Tissue Procurement Workflow

PROBLEMS

1. **Sample loss (-$500) due to lack of communication & information**

2. **Quality of biomaterials compromised due to lack of coordination**

3. **Disruption of routine workflows in Operating Rooms, Special Procedures and Pathology due to unexpected arrival of patients or samples without consent forms**

4. **IT- and Tele-communication not frequently accessible due to high patient volume and short staff**

Solution

Informatics-guided workflow, automate communications and a designated coordinators are used to help the procurement workflow

SOLUTIONS

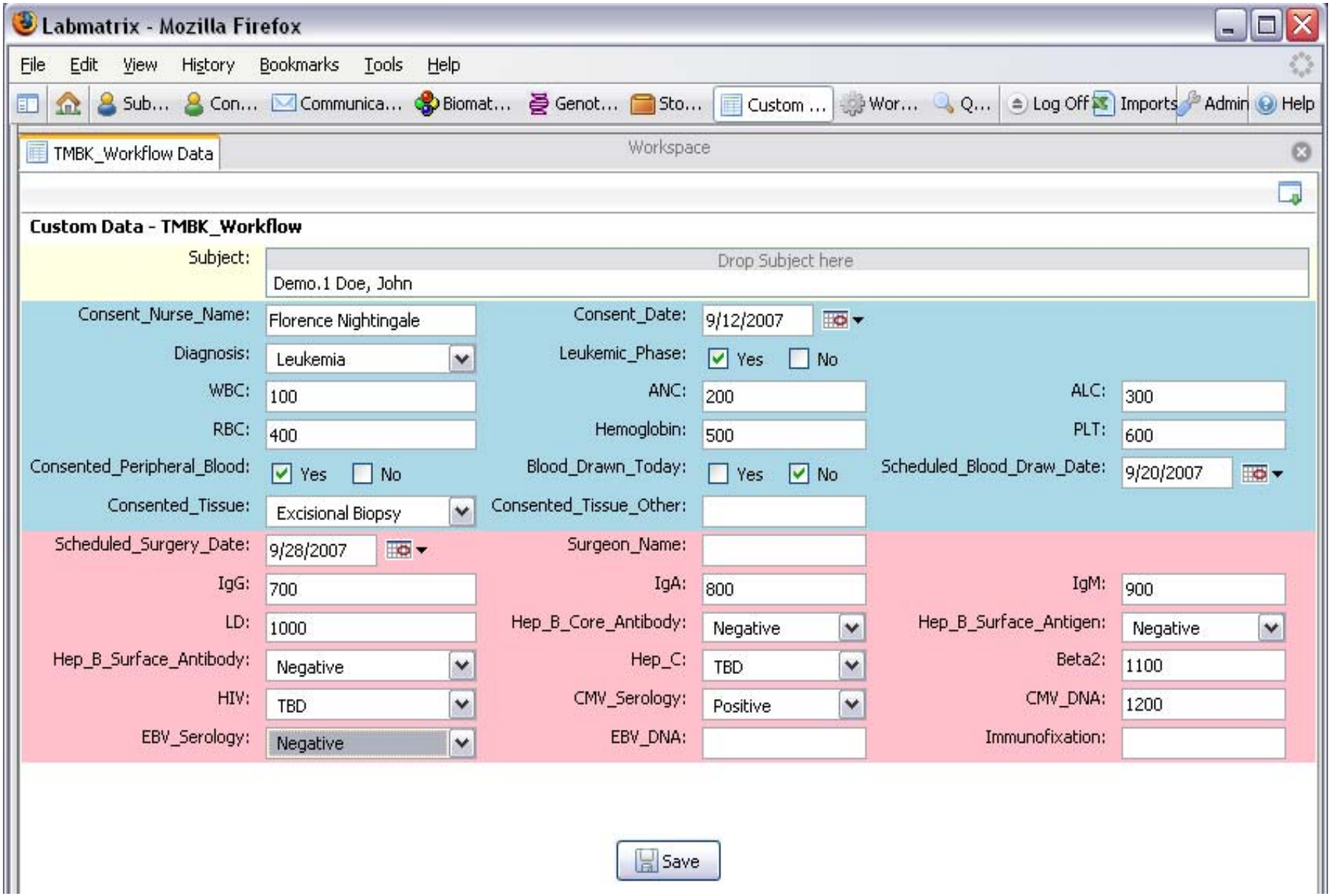
1. **Communication and information are facilitated by informatic software (LabMatrix) and IT automation in real time.**

2. **Key events are electronically tracked by web-based software in real time through a centralized data management.**

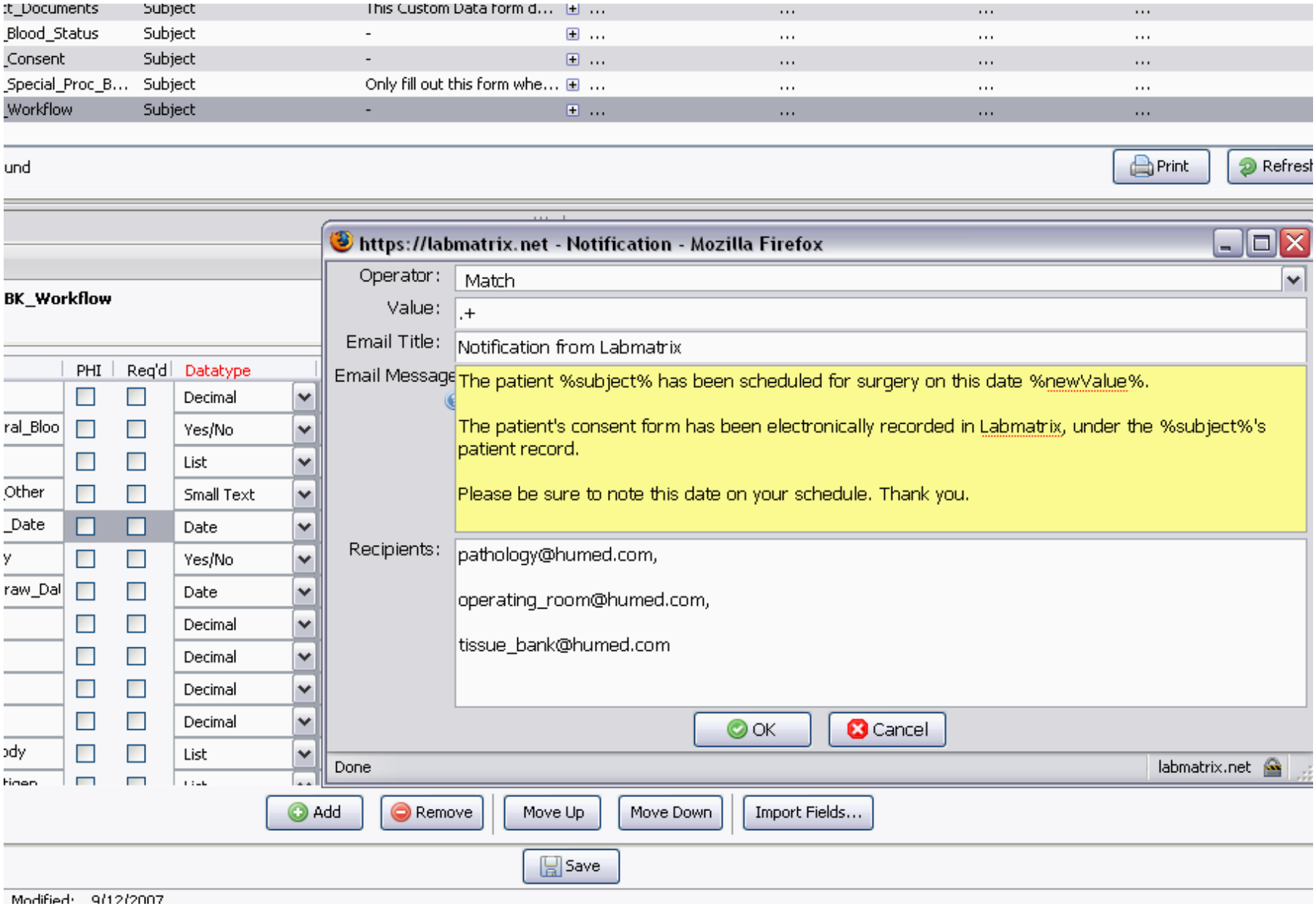
3. **Digitized informed consents and relevant legal documents are always accessible by RASi in real time via hospital network.**

4. **Designated clinical data coordinators follows through the whole workflow point-by-point.**

Research nurses and coordinators initiate bioinformatics-guided tissue procurement process (*Lymphoma Division)

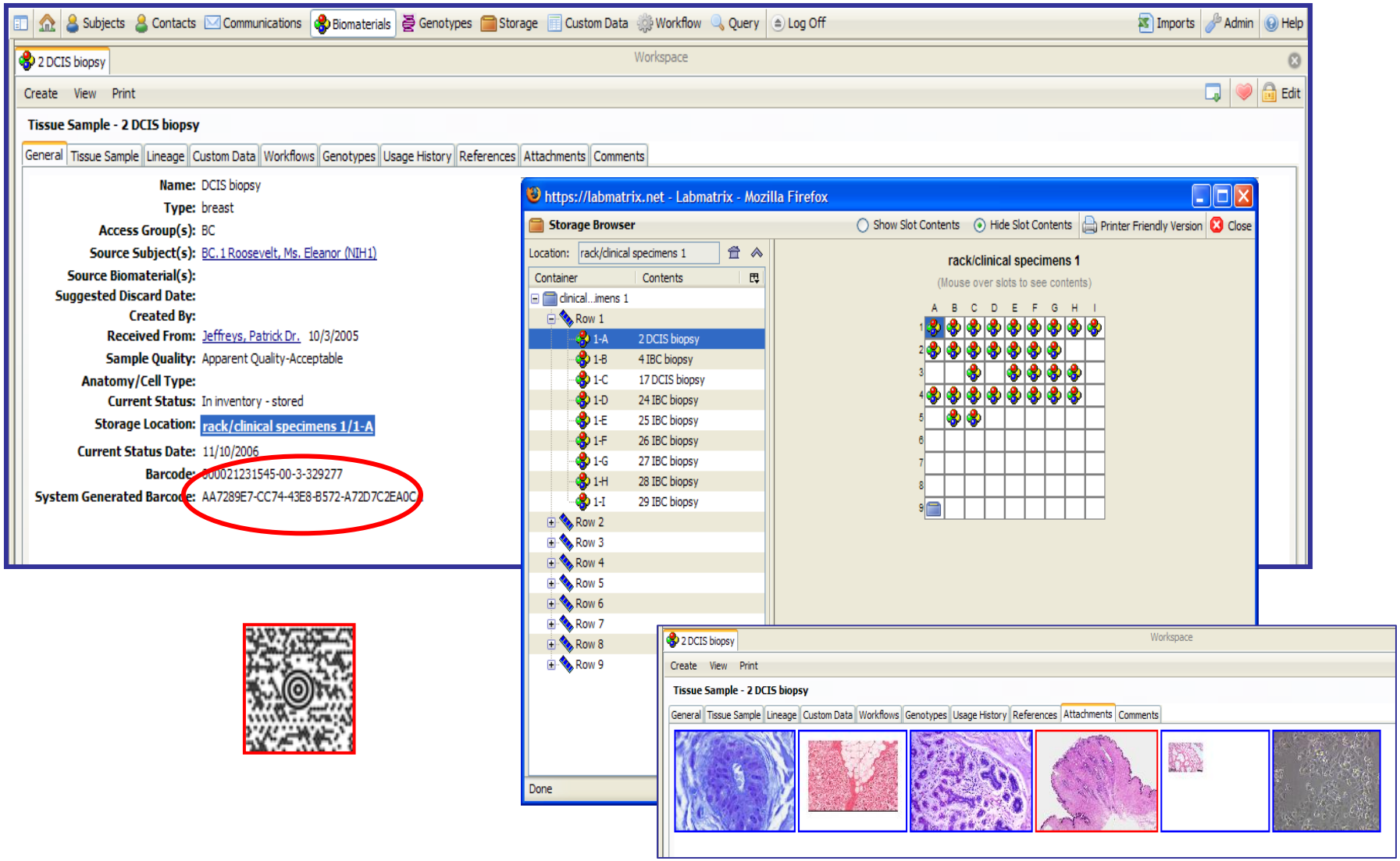


Automated emails and paging procedures alert members of the tissue procurement “TEAM” in real-time

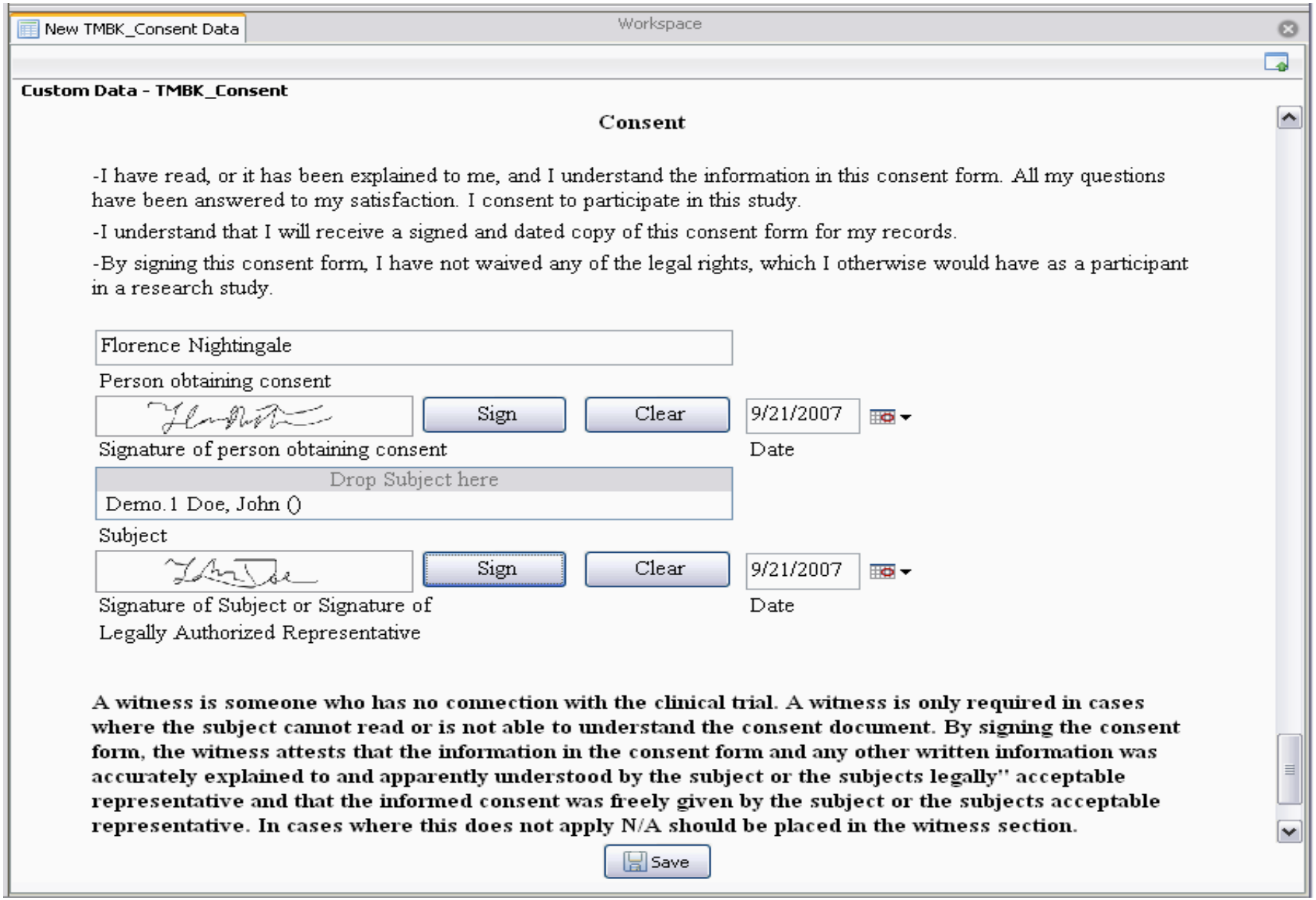


All digitized data associated with clinical samples are stored and documented

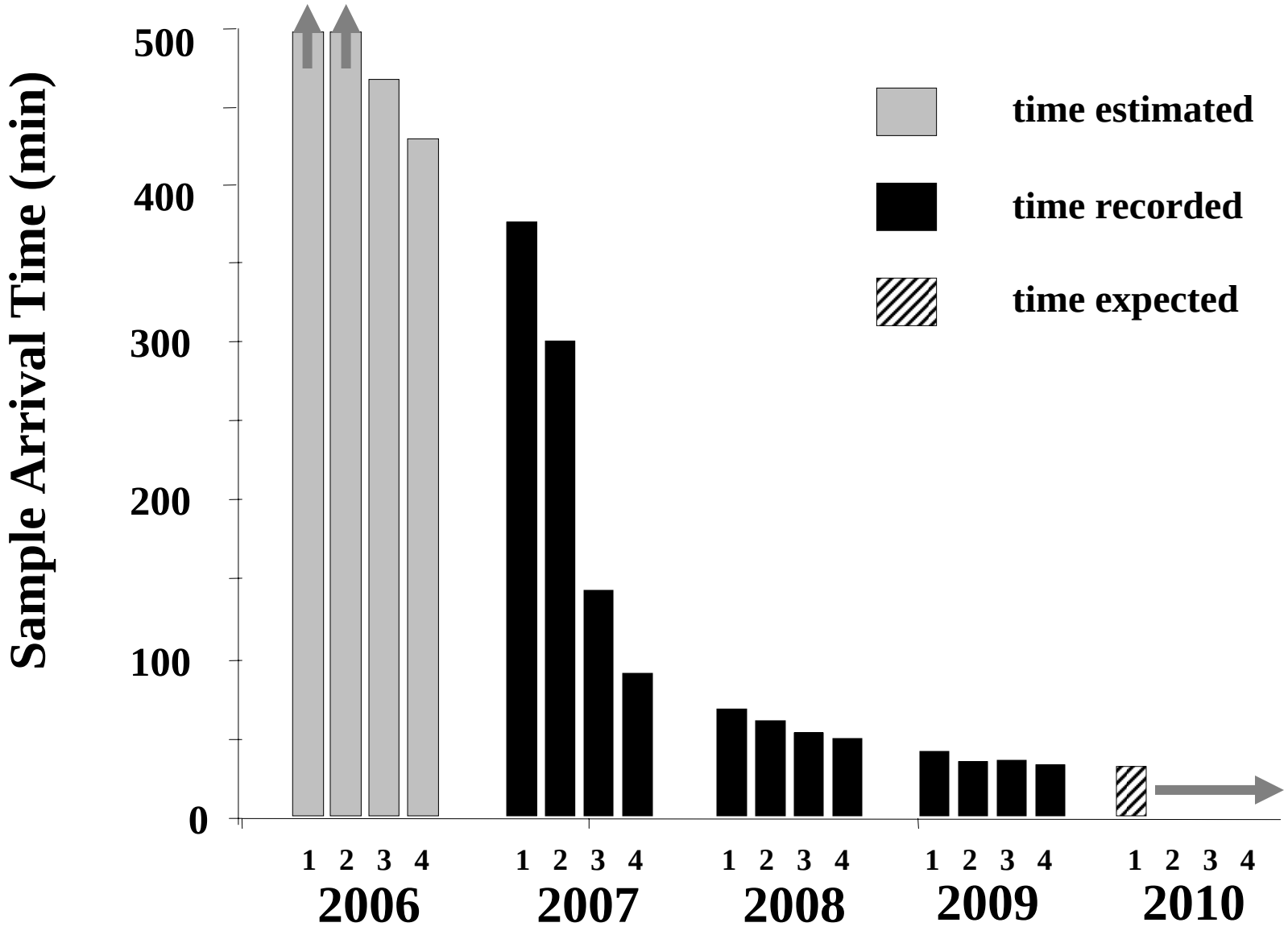
(Biospecimen management and tracking)



A combination of patient education and consent procedures are accomplished in digitized formats



Improved workflow: Blood samples arrive within 40min



From >60,000 cancer patients/yr, the Tissue Bank procures <2% of blood and <0.5% of tissues

Biggest Challenge: Increase the Number of Consents

The Problem = Misconceptions

a. **Don't want to be the guinea pig**
b. **Don't want surgeons to take out extra tissue**
c. **Afraid of not getting the best treatment when not agreeing to consent, so patients sign consent forms but donating only blood and not tissue**
d. **Afraid that pathologist will not have enough tissue to diagnose**
e. **Don't want personal identification/information released to public**
f. **Afraid that insurance companies will request research information**

Entry Point of Informed Consent: Success Rate

- **10%: Nurse or coordinator calls patient and consent for the first time – no prior knowledge of tissue banking**
- **50%: Nurse or coordinator calls patient after educating the patient about Tissue Banking during hospital visit and consent at later date**
- **80%: Educating and consenting patients in pre-admit setting as patient is already signing important documents (15min)**
- **85%: Nurse or coordinator educate and consent within the outpatient clinic (15min)**
- **75%: Patient is educated and consented by physicians at initial office consultation (5min)**
- **90%: Patient is educated and consented by nurse or coordinator pre-surgery (>20min).**

Challenges of Obtaining Informed Consent at HUMC

- **Physicians, nurses and staff are too busy to consent due to workload**
- **Physicians do not want disruptions in everyday workflow**
- **Physicians in various clinical settings do not have research nurses who can consent – lack of manpower**

Conclusion: Unlikely to get help from the clinical side

Solution: Educate patients and general public

- **Need user friendly information brochures and interactive medium**
- **Need to educate IRB from non-academic medical centers**

Regional medical center like HUMC needs help from OBBR and biospecimen research network

Summary

- **Informatics and automation are used to guide the procurement workflow to maximize communications between interdepartmental personnel.**
- **In real time and web-based software are used to increase efficiency of the data management during the procurement process.**
- **Patient/general public, clinicians and IRB must be educated to significantly improve tissue banking**
- **User friendly (7-8 grade reading level) tissue banking brochures and interactive medium in multiple languages are required for an effective informed consent process**

Acknowledgment

1. **Andrew Pecora (Chairman, Director of the Cancer Center)**
2. **Andre Goy (Chief of Lymphoma, Deputy Director of the Cancer Center)**
3. **Liz Koller (Admin Director, Cancer Center)**
4. **Jonathan Walland (Director, Clinical Research)**
5. **<u>Tissue Bank Staff</u>**

   <u>Clinical</u>: Russ Haystrand, Tania Zielonka, Peggy Ford

   <u>Scientific</u>: Yvonne Remache, Ushma Jag, Jordan Lu, Angelica Castro, Raj Gharbaran, Sang Park, Hiren Patel, Cooper Walland
6. **>8 Couriers**
7. **>20 Phlebotomists**
8. **>6 schedulers in OR procedures**
9. **>10 OR nurses, educators, charge nurses**
10. **>10 Radiation Oncology staff (Core and FNA biopsies)**
11. **>5 Surgeons currently actively participating (Dr. Dan Smith)**
12. **>20 Research nurses**
13. **>40 Research Data and Clinical Data Coordinators**
14. **>4 Preadmission staff**