

A Survivor's Perspective on Personalized Medicine

How International Collaboration and
Technical Support Can Change the
Future for Cancer Patients

Diane B. Paul, Patient Advocate

Background—Professional and
Cancer

Involvement With caBig®

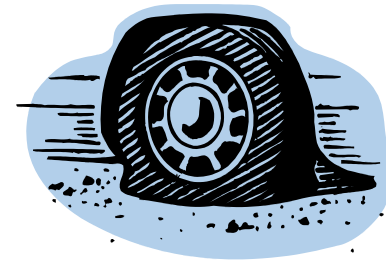
Barriers to Collaboration

Advantages of International
Collaboration

1963 SEMANTIC INTEROPERABILITY



NOT



Semantic Interoperability

LIFT

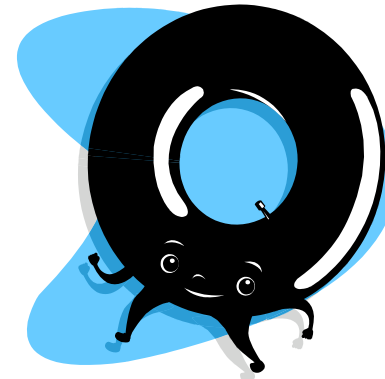
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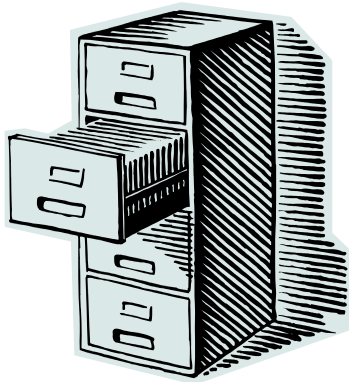
Semantic Interoperability



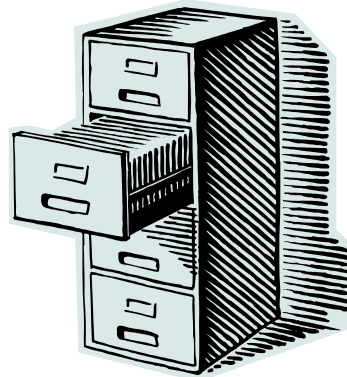
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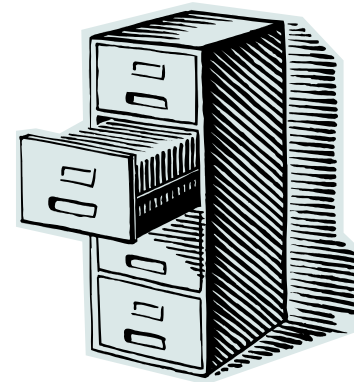
1979 Silos of information



Admissions

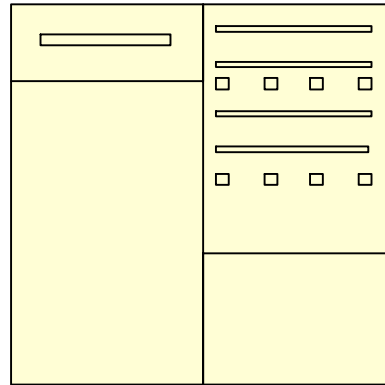


Financial Aid



Registration

Database



Diane B. Paul, Patient Advocate

ISSUES IN CONVERSION

- PRIVACY
- SECURITY
- OWNERSHIP
- CULTURE

Cancer

- Diagnosed 8/2/1993
- Ovarian Cancer Stage IIIC
- Last treatment 1/24/1994
- No recurrences

Advocacy Activities

- SHARE
- OVARIAN CANCER NATIONAL ALLIANCE
- NCI CARRA PROGRAM
- ACOR LIST

1996 Semantic Interoperability

Doxil™ |

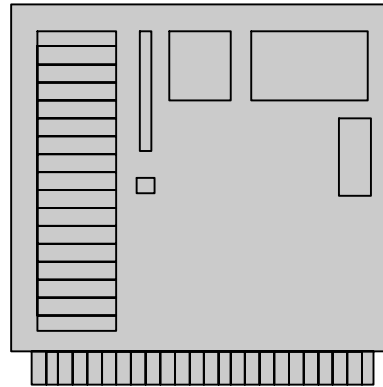


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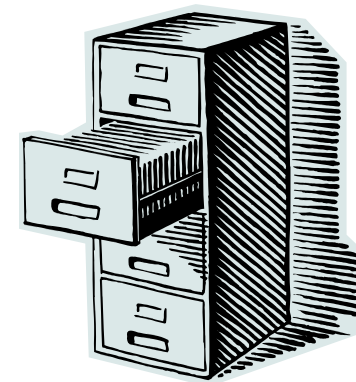
2004 Silos of information



researchers



NCI



FDA

caBIG®

- Architecture
- CTMS
- CTMS Steering Committee

Barrier to Collaboration

- Proprietary Issues
- Grant System (in US)
- Governmental Regulatory Systems

Advantages of International Collaboration

- Larger Pool of Patients, particularly important in rare cancers
- Cut Drug Development Costs
 - Consecutive testing adds time and money to development
 - Repetitive governmental reviews adds time and money to development

Advantages of International Collaboration

- **Deliver Treatments
more rapidly to
patients**

Some Good News

The U.S. Food and Drug Administration and the European Medicines Agency (EMA) today announced an agreement to launch a bilateral Good Clinical Practices (GCP) Initiative, designed to ensure that clinical trials submitted in drug marketing applications in the United States and Europe are conducted uniformly, appropriately and ethically. The initiative will begin with an 18-month pilot phase on September 1, 2009 and will focus on collaborative efforts to inspect clinical trial sites and studies. Products regulated by the FDA's Center for Drug Evaluation and Research in the United States, and by the EMA for the European Union will be the focus of the initiative.

[FDA, European Medicines Agency Launch Good Clinical Practices Initiative](#)

Mon, 03 Aug 2009 09:14:00 -0500

US LIFETIME CANCER RISKS

ONE IN TWO MEN

ONE IN THREE WOMEN

WILL DEVELOP CANCER IN THEIR
LIFETIME

Diane B. Paul, Patient Advocate

PERSONALIZED MEDICINE

- OVERALL HEALTH
- STATISTICAL INFORMATION ABOUT DIAGNOSIS AND TREATMENT
- PATIENT'S DESIRES

PERSONALIZED MEDICINE

- BIOMARKERS
- TREATMENT OUTCOMES
- SIDE EFFECTS

BENEFITS

- NO TREATMENTS WHICH DON'T PROVIDE BENEFIT
- ABILITY TO MAKE REASONABLE PLANS FOR FUTURE
- TIME IN TREATMENT WILL BE MEANINGFUL

RARE CANCERS

“Last Monday, I met with a new coalition of advocacy organizations concerned with a group of cancers - brain, esophagus, liver, lung, myeloma, pancreas, ovarian, and stomach - each with a survival rate of less than 50 percent. Representing 20 different organizations, the group presented data showing that 276,040 deaths (49.1 percent of the cancer deaths predicted in 2009) will come from those eight forms of cancer. The advocates are concerned that those same cancers only account for approximately 18 percent of the [NCI funded research portfolio](#), and they seek a greater emphasis on these cancers...

There will always be tensions around decisions to allocate our precious research resources. NCI must continually attempt to balance research between those cancers that affect the most people and those that take the highest number of lives.”

<http://www.cancer.gov:80/directorsnotes/060409>