



Clinical Research Seminar

Using the Internet to Conduct Research and Recruit Subjects

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Types of Studies that Work Best

- ❑ Cohort Studies
 - Loss to follow up may be a problem
- ❑ Health Education
- ❑ Surveys
 - difficulty determining denominator and low response rate issues raise issues about generalizability
- ❑ Traditional Clinical Trials
 - Randomization
 - Data entry
 - Study management/communications
- ❑ Online Clinical Trials
 - “Nutriceuticals” or non-invasive interventions



Benefits of Internet in Research

- ❑ Capture data in real time
- ❑ Data collection for clinical research
 - Paperless
- ❑ Communications and management for multi-site trials
- ❑ Subject recruitment
 - Reach greater target population



Risks

- No direct contact with subjects
 - Unable to intervene if subjects become distressed or experience other adverse events
- Breach of confidentiality
 - Most common risk
 - Via insecure transfer of data
 - Via environment in which subject is accessing Internet (e.g., Internet café, public library)

Validity

- ❑ Non-representative populations (i.e., tend to be of higher SE and educational status)
- ❑ Falsification of data
- ❑ Multiple submissions by same subject
 - “Subject naught”
- ❑ Invalid results places subjects unnecessarily at risk

Consent

□ Waiver of consent

- [45 CFR 56.116(d)]: (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration;

-AND-

- (4) Subjects will be provided with additional information/results after participation

Consent

- Waiver of documentation of consent
 - [45 CFR 56.117(c)] : (1) Only record linking subject to research would be the consent document and this is the primary risk of harm (i.e., in the event of breach of confidentiality) **-OR-**
 - (2) Research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research context
 - Can still create a consent page that subjects must read and electronically accept before proceeding
- Subjects may also print/sign consent form from Internet and fax/mail to investigator to receive password for website



Privacy

- Identifiable vs. Anonymous
 - Screen names/handles/e-mail addresses commonly used online
 - Though subject names may not appear with these, often can be “readily ascertained” via search engines
 - Online identity may be as important to a subject as real identity

Privacy

□ Public vs. Private

- Most online activity is publicly accessible
- Federal regulations base definition of private information on the “reasonable expectation” of privacy
 - e.g., chat rooms, chatters expect privacy and not to have their chat studied

Minors as Subjects

- ❑ If research qualifies for waiver of parental permissions, no additional safeguards required
- ❑ Otherwise parental consent must be obtained unless criteria for Waiver of Informed Consent or Waiver of Documentation of Informed Consent are met
- ❑ Online services can help but none are 100% foolproof
 - AdultCheck
 - NetNanny

Confidentiality

- Breaches
 - Inadvertent disclosure (e.g., stolen laptops/computers with subject data)
 - Deliberate attempts to gain access (i.e., hackers, no documented evidence of this occurring in a research setting)
- E-mail is considered “individually identifiable information” by IRB
- Information or data transmitted by e-mail is not secure unless additional steps are taken (e.g., encryption)



Web Systems Security

- ❑ Website on secure server behind firewall
- ❑ Server housed in locked room with restricted access
- ❑ Data are encrypted (Secure Socket Layering (SSL) technology)
- ❑ Login restricted by username and password
- ❑ Automatic timeout
- ❑ Daily backup of web-server and database

Subject Compensation

- ❑ Several Different Approaches May Be Used
 - Mailed check/cash
 - E-money (e.g., PayPal)
 - Electronic gift cards (e.g., giftcertificates.com)
 - Charitable donation
- ❑ Be careful with raffles!
 - Closely scrutinized by IRB
 - Must be conducted in a way that is equitable to all subjects



Study Advertisement/Recruitment Sites

- ❑ Online search engines
 - Google
 - Yahoo
- ❑ Links on other sites
 - Gout.com
- ❑ Trial listing services
 - Centerwatch
 - Study response project
- ❑ Banner Ads
 - Gay.com
- ❑ NIH
 - ClinicalTrials.gov

Example of a Recruitment/Study Registration Site

Address  <http://studyresponse.syr.edu/studyresponse/index.htm>   Go  Links 

The StudyResponse Project

An Online Social Science Research Resource



Welcome to StudyResponse!

The StudyResponse project facilitates online research for behavioral, social, and organizational science researchers by distributing email participation requests to adult research participants. The StudyResponse project accumulates the characteristics and outcomes across research studies in order to explore the features of studies that encourage quality responding. The StudyResponse project is hosted by the School of Information Studies at Syracuse University and has received institutional review board approval (#02165).

We need you to participate in online research!

Every StudyResponse research project offers incentives for voluntary participation in social science research. Many of the projects are questionnaires about topics that people find interesting. By [registering](#) with us as a research volunteer, you may be able to:

-  Obtain incentives while participating in social science research
-  Learn about current social science research topics
-  Contribute to the development of social research and its applications in the family, the workplace, and society

Home

Information for Participants

Participant Registration

Participant Update

Information for Researchers

Researcher Registration

FAQ

Meet the founders

Centerwatch Clinical Trial Site

 **CenterWatchSM**
Clinical Trials Listing ServiceTM

The Global Destination for
Clinical Trials Information

 CenterWatch
Bookstore

 Tell A Friend
About CW

 [Advanced Search](#) | [Site Map](#) | [About CW](#) | [Contact Us](#) | [Your Privacy](#)

This section provides background info. about the clinical trials industry. Find answers to FAQs about participating in clinical research studies and a glossary of terms. Also *en Español*

Patient and General Resources

 Trial Listings

 About Clinical Research

 Notification Services

 Health Associations

 Drug Directories

 Patient Education

Additional Resources for Patients

Industry Professional Resources

 Site Identification Services

 Clinical Trial Results

 Product & Service Providers

 Drugs in Clinical Trials

 Jobs In Clinical Research

 Professional Bookstore

Additional Resources for Professionals

Welcome to the CenterWatch Clinical Trials Listing Service!



Institutional Research Subject Recruitment



MASSACHUSETTS
GENERAL HOSPITAL

CLINICAL RESEARCH PROGRAM

185 Cambridge Street
Boston, MA 02114
617.726.5500

[Home](#)

[MGH's Clinical
Research Day 2008
Award Winners](#)

[Clinical Innovation
Award - Letter of Intent
due July 11](#)



- ▶ [For Patients & Study Volunteers](#)
- ▶ [For MGH Faculty & Staff](#)
- ▶ [For Research Sponsors](#)
- ▶ [About the CRP](#)
- ▶ [Contact Us](#)

RSVP for Health
Partner with us as a study volunteer! **Enroll Now!**

View/Post Clinical Trials



**For Medical
Professionals
Outside of MGH**

[Disclaimer](#)

Disease Specific

BU ALZHEIMER'S DISEASE CENTER

[Donate](#)[Contact](#)[ABOUT US](#)[CLINICAL CARE](#)[OUR RESEARCH](#)[OUR TEAM](#)[JOBS & CAREERS](#)

RESEARCH PARTICIPATION

Why Participate in Research?

Your participation in research provides important information regarding possible effective treatments and preventions for Alzheimer's disease. Only through community participation in research will progress be made in the fight against Alzheimer's disease.

Types of Research Studies and Their Purpose

We have several different types of ongoing studies at the ADC. Each study has its own goals. Our [memory and aging](#) studies help us to learn about the changes that occur in people's memory as they age. [Clinical trials](#) (or treatment trials) and prevention trials help to determine if new or currently used medications can prevent Alzheimer's disease or slow its progression. Our family and [genetic studies](#) look at the link between Alzheimer's disease and genetics; these studies help us to understand genetic risk factors associated with Alzheimer's disease.

[Caregiving studies](#) specifically focus on issues related to activities in daily life, such as driving, coping emotionally with caregiver activities, and support strategies for caregivers. Our [imaging studies](#) help us learn how brain images can provide more information about diagnosing and detecting Alzheimer's disease. If we can identify changes that are occurring in the brain throughout the disease process, we can help to diagnose and treat people with Alzheimer's disease as early as possible in the disease

ABOUT

- [Mission](#)
- [Center Cores](#)
- [ADCRP](#)
- [Ethnicity and AD](#)
- [How Can I Help?](#)
 - [Monetary Donations](#)
 - [Research Participation](#)



(Click on image to play video)



Craig's List

For local research studies. However, note there are many restrictions on posts:

- ❑ Cannot post continuously
- ❑ Cannot post same ad repeatedly
- ❑ Cannot post same ad in more than one city at a time
- ❑ Restrictions vary by city
 - Designated cities restrict posts to 3 days (Boston, San Francisco, New York)
 - Other cities allow posts for up to 45 days

craigslist

boston ^w gbs nwb bmw nos sob

post to classifieds

my account

help, faq, abuse, legal

search craigslist

for sale ▼ >

event calendar

S	M	T	W	T	F	S
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	1	2	3	4	5

avoid scams & fraud

personal safety tips

craigslist blog

craigslist feedback

community

activities lost+found
 artists musicians
 childcare local news
 general politics
 groups rideshare
 pets **volunteers**
 events classes

personals

strictly platonic
 women seek women
 women seeking men
 men seeking women
 men seeking men
 misc romance
 casual encounters
 missed connections
 rants and raves

discussion forums

1099 gifts pets
 apple haiku philos
 arts health politic
 atheist **help** psych

housing

apts / housing
 rooms / shared
 sublets / temporary
 housing wanted
 housing swap
 vacation rentals
 parking / storage
 office / commercial
 real estate for sale

for sale

barter arts+crafts
 bikes auto parts
 boats baby+kids
 books cars+trucks
 business cds/dvd/vhs
 computer clothes+acc
 free collectibles
 furniture electronics
 general farm+garden
 jewelry games+toys
 material garage sale
 rvs household
 sporting motorcycles

jobs

accounting+finance
 admin / office
 arch / engineering
 art / media / design
 biotech / science
 business / mgmt
 customer service
 education
 food / bev / hosp
 general labor
 government
 human resources
 internet engineers
 legal / paralegal
 manufacturing
 marketing / pr / ad
 medical / health
 nonprofit sector
 real estate
 retail / wholesale
 sales / biz dev
 salon / spa / fitness
 security
 skilled trade / craft

us cities

atlanta
 austin
 boston
 chicago
 dallas
 denver
 houston
 las vegas
 los angeles
 miami
 minneapolis
 new york
 orange co
 philadelphia
 phoenix
 portland
 raleigh
 sacramento
 san diego
 seattle
 sf bayarea
 wash dc
 more ...

canada

calgary
 edmonton
 halifax
 montreal
 ottawa
 toronto
 vancouver
 victoria

us states

alabama
 alaska
 arizona
 arkansas
 california
 colorado
 connecticut
 dc
 delaware
 florida
 georgia
 guam
 hawaii
 idaho
 illinois
 indiana
 iowa
 kansas
 kentucky
 louisiana
 maine
 maryland
 mass
 michigan
 minnesota
 mississippi
 missouri
 montana
 n carolina
 n hampshire
 nebraska
 nevada
 new jersey

countries

argentina
 australia
 austria
 bangladesh
 belgium
 brazil
 canada
 caribbean
 chile
 china
 colombia
 costa rica
 czech repub
 denmark
 egypt
 finland
 france
 germany
 great britain
 greece
 hungary
 india
 indonesia
 ireland
 israel
 italy
 japan
 korea
 lebanon
 malaysia
 mexico
 micronesia
 netherlands

Craig's List "Volunteers"

[Would you like to change a life in one hour a week? -](#)

[Eco Designs -](#)

[Dedicated Volunteers Needed -](#)

→ [Healthy Women Volunteers Needed 45-64 years old - \(BWH\)](#)

→ [Brain Imaging Research Study of the Social Brain in Autism - \(Boston University School of Medicine\)](#)

[Volunteers to help with hospital equipment going to poor countries - \(North Andover, MA\)](#)

[Fun people needed!!! - \(Beverly\)](#)

→ [Psychology study on emotional pain and self-injury - \(Harvard University\)](#)

→ [Do you have Asthma and allergy to cats or dust mites? - \(BOSTON-MGH\)](#)

→ [Participants needed for non-invasive vision studies - \(Cambridge/Central Square/MIT\)](#)

→ [Couples Needed for Study of Veteran Relationships - \(Jamaica Plain\)](#)

[Has somebody suggested you cut back or quit drinking? - pic](#)

[Spend time with a needy person - \(Reading\)](#)

Website for NIH Funded Research

Address  http://clinicaltrials.gov/



Go

Links »

Google



ls.gov



Set

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

[Home](#) [Search](#) [Study Topics](#) [Contact Us](#)

ClinicalTrials.gov is a registry of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details. This information should be used in conjunction with advice from health care professionals.

[Read more...](#)

► [Search for Clinical Trials](#)

Find trials for a specific medical condition or other criteria in the ClinicalTrials.gov registry. ClinicalTrials.gov currently has **57,460 trials** with locations in **156 countries**.

► [Investigator Instructions](#)

Get instructions for clinical trial investigators/sponsors about how to register trials in ClinicalTrials.gov.

► [Background Information](#)

Learn about clinical trials and how to use ClinicalTrials.gov, or access other consumer health information from the US National Institutes of Health.

Resources:

[Understanding Clinical Trials](#)

[What's New](#)

[Glossary](#)

Study Topics:

[List by Condition](#)

[List by Drug Intervention](#)

[List by Sponsor](#)

[List by Location](#)

Disease Specific Sites: Link on TAP's Gout.com

GOUT.com
Your resource for gout information

Site Map

SEARCH

What Is Gout?

The Root Causes of Gout


How Can You Cope With Attacks?

What About Diet and Gout?


How Do Others Deal With Gout?

For Family and Friends

Information for Healthcare Professionals



You've come
to the **RIGHT PLACE**

 Enlarge Text

ONLINE GOUT STUDY

By sharing information about your gout, you can help researchers identify factors that cause repeated gout attacks. Conducted by a collaborative team at the Boston University School of Medicine, this study is funded by the National

GOUT: GET THE FACTS

Do you want new information about gout over time? [Then sign up for the Gout.com Information Program today!](#)

QUICK POLL

Does your gout affect your work?

- ☐ Yes, I sometimes can't work
- ☐ No, I get through it somehow
- ☐ No, I'm retired



Case Study: The Non-Gay Identifying Men Who Have Sex with Men Studies (US and India)

□ Compensation

■ US: giftcertificates.com

- Eligible **AND** ineligible subjects randomly selected for online gift code
- Code was displayed in a separate window with text warning respondent to print or carefully write down code (i.e., **NOT** e-mailed)

■ India: Used similar method with an online vendor in India



Case Study: The Non-Gay Identifying Men Who Have Sex with Men Studies (US and India)

□ Recruitment

- US: Google AdWords, gay.com, manhunt.com, African-American and gay community newspapers (Boston, NYC, Washington DC)
- India: Banner advertising in gay chat room on indiatimes.com website

US Internet Study

Google ad displayed: 698,172

Google ad clicked: 2,203

Screened: 1,457

Eligible: 1,029

Created Login: 769

Reached
Mid-point: 192

Completed:
517

Indian Internet Study

India Times ad displayed: 352,982

India Times ad clicked: 840

Screened: 457

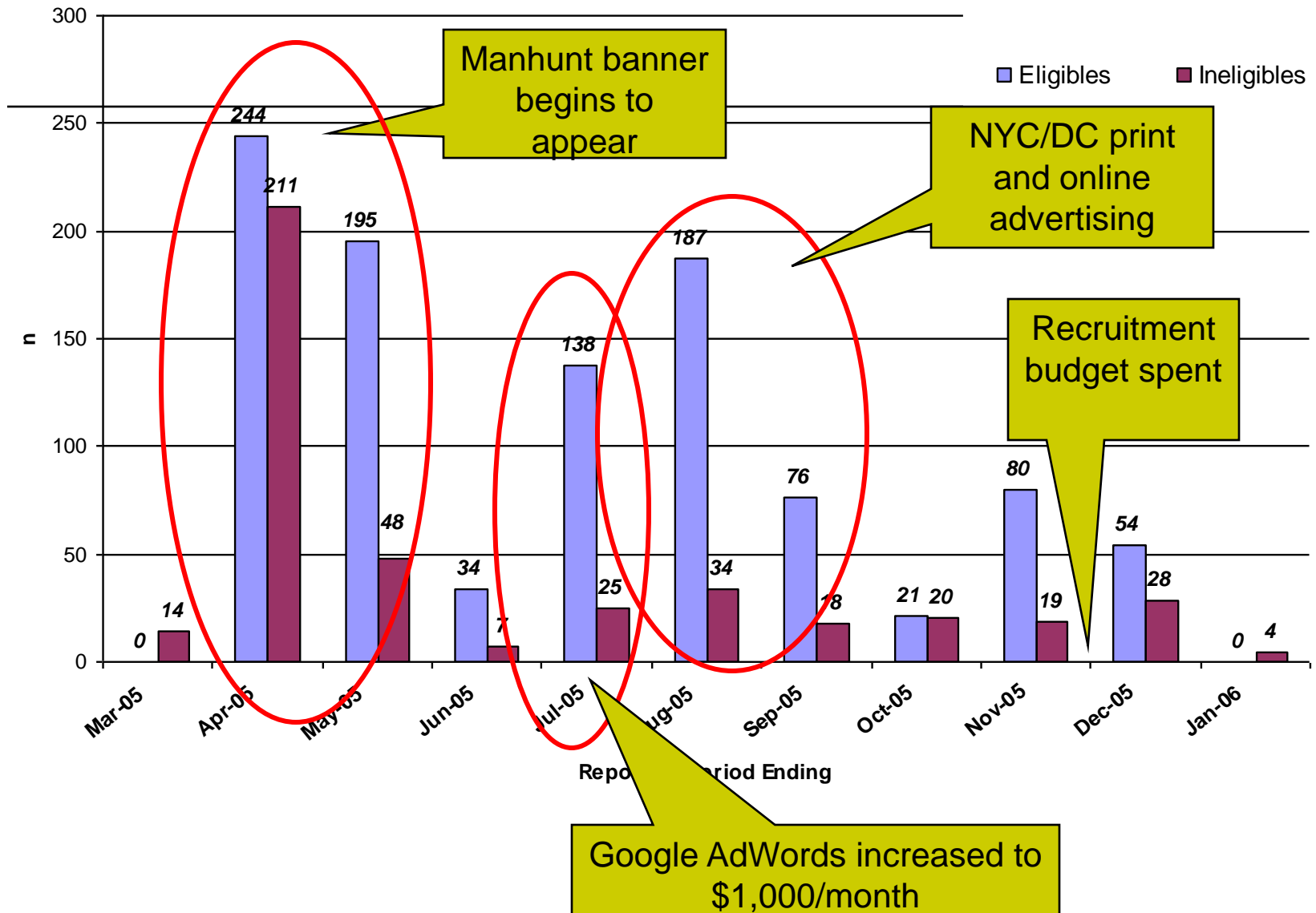
Eligible: 302

Created Login: 225

Reached
Mid-point: 64

Completed:
114

Accrual of Eligibles and Ineligibles: March 29, 2005-January 3, 2006





Internet in Clinical Trials

- ❑ Study management and communications
- ❑ Randomization
- ❑ Data collection
- ❑ Real-time SAE reporting
- ❑ Data querying
- ❑ Real-time reporting
- ❑ Form dissemination
- ❑ FAQ
- ❑ Etc.

Great for International Trials



Welcome to the DIFLUNISAL TRIAL

Participating Sites:



Boston University, USA



University Hospital San Matteo, Pavia, Italy



Mayo Clinic, USA



Hospital Santo Antonio, Portugal



Kumamoto University, Japan



Umea University, Sweden



Shinshu University, Japan

Investigator Login: ☒ Investigators ☐ Boston

Data Entry, Screening, Randomization, Tracking



Brigham and Womens Hospital



Mayo Clinic Rochester



Cleveland Clinic



Vanderbilt Medical Center



Hospital for Special Surgery



Data Coordinating Center

Username:

Password:

Submit

If you forgot your password or you are a new user, then please [click here](#).

Stratified Randomization



Randomization

Screening ID

Re-enter Screening ID

Study ID

Re-enter Study ID

Last Name, First Name

Birth Date (mmddyyyy)

Gender

Race

Hispanic

Dependence and Recent Use

Check Entries

[Home](#)

Confirm Eligibility and Randomize



[Home](#) [Assign group](#) [Subject](#)

	Screening ID:	5243
	Subject ID:	1032
	Subject Initials:	MMR

Eligibility check list

The subject has been Randomized into the intervention group. The Subject ID is 1032.

✓	HIV diagnosis confirmed
✓	Between 18 and 70
✓	Subject has a telephone
✓	Subject lives within 150 miles
✓	Subject is not trying to become pregnant
✓	Subject can provide 2 contacts
✓	Subject does not have legal charges pending
✓	Subject meets the drinking requirements

[illegible]

Enrollment Report

Export PDF File

	Male	Female	TOTAL
Screened	78	29	107
Eligible	55	23	78
Consented	50	23	73
Randomized	50	23	73

	A	B	TOTAL
Randomized	38	35	73
Gender: Male	26	24	50
Gender: Female	12	11	23
IVD: Yes	19	17	36
IVD: No	19	18	37
Site: 1	38	35	73
Site: 2	0	0	0

Electronic Data Capture “Cleaner”

Interviewer Read:

Now I’m going to ask you about some symptoms or problems.

Interviewer Instruction:

If the answer to Part A is YES, ask when they had the symptoms. Note: PAST = you had the symptom or problem in the past (more than three months ago) but no longer have it. If the answer to Part A is NO, skip to the next question.

	Symptom	A Have you ever had it?			B When did you have it?		
		Yes	No	DK	Now	Past	DK
2.1	Trouble hearing	1 <input checked="" type="radio"/>	2 <input type="radio"/>	8 <input type="radio"/>	1 <input checked="" type="radio"/>	2 <input type="radio"/>	8 <input type="radio"/>
2.2	Ringing in ears	1 <input type="radio"/>	2 <input checked="" type="radio"/>	8 <input type="radio"/>			
2.3	Wear a hearing aid	1 <input checked="" type="radio"/>	2 <input type="radio"/>	8 <input type="radio"/>	1 <input type="radio"/>	2 <input type="radio"/>	8 <input type="radio"/>
2.4	Trouble swallowing	1 <input type="radio"/>	2 <input type="radio"/>	8 <input checked="" type="radio"/>			

Secure, Web-based Data Querying (no faxes)

ECHO

Evaluation Center for HIV & Oral Health



[Home](#) | [Data Entry](#) | [Reports](#) | [Search](#) | [Log Out](#)

Data Problems

☐ Include Corrected Problems?

Please click on a reason to open a particular problem and resolve it.

Site	Client	Visit Date	Reason	Corrected Value	Original Value	Created	Problem Corrected	Resolved
2	demo3	01/08/2008	Birthdate is greater than HIV date			01/10/2008		
2	Peter0808	08/08/2007	Q28 Must select an option chosen in Q27			09/27/2007		
2	SusieQ123	08/08/2007	Q28 Must select an option chosen in Q27			09/27/2007		
2	test3	01/05/2008	Birthdate is greater than HIV date			01/09/2008		

Web-based Problem Resolution

Navigation

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[Activity Report](#)

[Report Archive](#)

Lists

[Problem List](#)

[Flagged List](#)

[Query List](#)

☐ Include Resolved Problems?

Please click on a reason to open a particular problem and resolve it.

Counselor	Interviewed	BMC MRN	First	Last	DOB	Reason	Corrected Value	Comment	Created
7	09/10/2007	3034858	A	M		6 Alcohol AND drug use in the last 30 days > 0 but either 30 day alcohol is blank or zero OR all of the 30 day drug questions are blank or zero.			10/01/2007
3	09/25/2007	3516464				9 Duplicate last name, first name, dob, and MRN with a different SSN			10/03/2007
3	08/22/2007	3516464				9 Duplicate last name, first name, dob, and MRN with a different SSN			10/03/2007
7	09/21/2007	2130225				9 Duplicate MRN with same Interview Date and Counselor ID			10/10/2007
7	09/21/2007	2130225				9 Duplicate MRN with same Interview Date and Counselor ID			10/10/2007
5	09/19/2007	2765425				9 HQ is complete and substance abuse reported (pg.1) , but 'Alcohol in past 3 months' (pg. 1) not answered.			10/10/2007
1	09/20/2007	3340951				4 Alcohol AND drug use in the last 30 days > 0 but either 30 day alcohol is blank or zero OR all of the 30 day drug questions are blank or zero.			10/10/2007
1	10/03/2007	3514439				1 Substance abuse NOT reported (Pg.1), but BI was indicated (pg.11)			10/22/2007
4	10/09/2007	2785668				8 Substance abuse NOT reported (Pg.1), but BI was indicated (pg.11)			10/22/2007
3	05/22/2007	3544831				8 Duplicate last name, first name and dob with a different MRN			10/22/2007
3	09/19/2007	3544818				8 Duplicate last name, first name and dob with a different MRN			10/22/2007

Click-through to Correct Data

MaSBIRT Web Site

Navigation

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Data Problem Correction Page

Counselor 4

Interview 8/23/2007

Date

BMC

MRN

First

Last

Reason Substance abuse was reported in prescreen and the questionnaire was completed but no substance abuse was reported for any of the substance categories.

Please enter a corrected value, if possible. If the correction can not be expressed as a single value, please enter a comment.

Corrected Value

Comment Substance abuse reported for marijuana

Created 11/7/2007 11:34:00 AM

Submit

Online Clinical Trials: Nutraceuticals



Center for Internet-Based Epidemiologic Research

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New England Medical Center

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750 Washington St
Tufts-NEMC #406
Boston, MA 02111

866.832.1936

PROGRESSION OF KNEE OSTEOARTHRITIS: A DOUBLE-BLIND, PLACEBO-CONTROLLED ONCE WEEKLY DOSING REGIMEN

VITAMIN D FOR KOA

Symptomatic knee OA has an incidence of 240/100,000 person/years and is one of the most frequent cause of dependency in lower limb tasks, especially in the elderly. It causes 68 million work loss days per year and more than 5% of the annual retirement rate¹⁻³. It is the most frequent reason for joint replacement at a cost to the community of billions of dollars per year. No effective medical remedies for OA currently exist. However, the pharmaceutical industry is attempting to develop drugs that retard progression of OA. If efficacious, these proprietary medications will be expensive to employ in a population in which OA is endemic. Furthermore, there is evidence that vitamin D supplementation, a simple non-proprietary intervention, could slow progression of OA. Even if only modestly effective, it could have considerable impact by reducing the societal burden of OA.

This is a randomized clinical trial using Internet-based randomization, electronic data capture, coordination and monitoring. The Tufts-New England Medical Center Department of Rheumatology will be enrolling participants with knee pain to participate in this trial. Vitamin D 14,000 IU will be compared to placebo in a randomized placebo-controlled clinical trial testing the efficacy of vitamin D, 14,000 IU versus placebo taken orally once per week, as a disease-modifying agent among individuals with symptomatic knee osteoarthritis (OA). Tolerability and safety will be assessed by adverse effects (AE) reporting, physical examination, vital signs, and clinical laboratory tests. The primary clinical outcome will be assessed by changes in the WOMAC questionnaire. The primary pathological process measure will be change in knee cartilage volume as measured by magnetic resonance imaging (MRI).

This study is being conducted at Tufts-New England Medical Center.



Example: Paperless Trial System

- ❑ MGH / Roche Diagnostics collaboration
- ❑ Web-based electronic data capture
- ❑ Double entry of paper forms
- ❑ Data cleaning (queries)
- ❑ Monitoring
- ❑ Reporting
- ❑ Data exporting
- ❑ Electronic Signature (21 CFR, part 11)

Reports	Forms (data entry)	Queues
Visit Status Summary	Inclusion/Exclusion	Awaiting Double Entry
Baseline Demographics	Minnesota Questionnaire	Awaiting Data Checking
Interim Medical History Endpoints	Baseline Demographics	Awaiting Problem Resolution
Decompensated CHF and NYHA Classes	Interim Medical History	Awaiting Monitoring
Data Problems	Concomitant Medications	Awaiting Signing
Protocol Deviations	Living Condition/PE/EKG	Signed
View Forms By Subject ID	Treatment Decision	
	Adverse Events	
	Echocardiogram	
Excel Files	Lab Data	
Monitor Initiated Data Problems	End Lab Data	
Enrollment Date	Discontinuation	



Possibilities

“We now have the potential to conduct a cohort study of users of the World Wide Web” ...

“...[the Internet] can have people recruit themselves, enter their own data into our computers, and provide for fast, convenient electronic follow-up.”

Rothman KJ, Cann CI, Walker AM. Epidemiology and the internet. Epidemiology 1997; 8:123-5.

Example of Cohort Study

Internet-based study of time to pregnancy

- ❑ Elizabeth Hatch, Kenneth Rothman Laura Wise, BUSPH co-investigators
- ❑ Study taking place in Denmark where centralized medical records are available
- ❑ Subjects consent online and provide Central Population Registration # and consent to view record



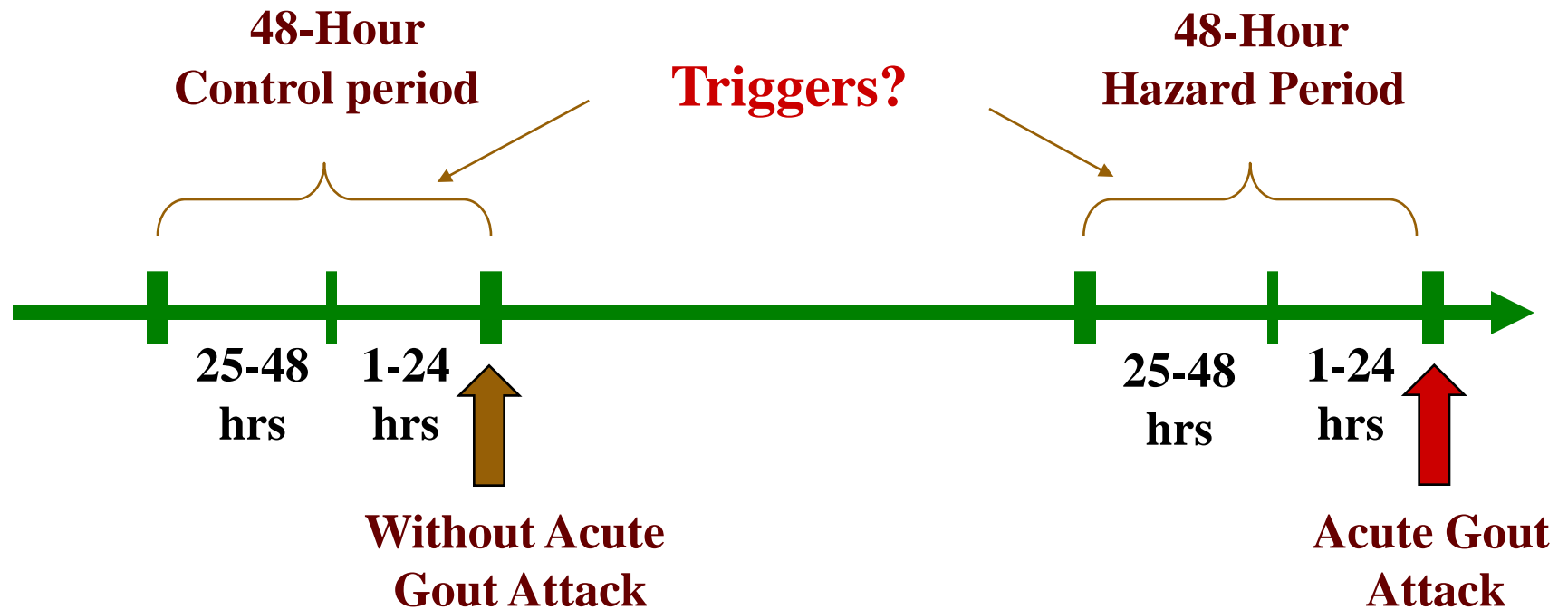
Internet-based Study of Time to Pregnancy

- ❑ Over 7,000 women screened to date
- ❑ 3,700 eligible and have consented to take part
- ❑ Subjects followed bi-monthly or until pregnant
- ❑ 85% of subjects had 4 month follow up
- ❑ Self reported medical history validated against medical record

Online Gout Study, Yuqing Zhang, PI Study

- ❑ Subjects recruited online
- ❑ Each subject serves as own control
 - control period= no symptoms
 - hazard period = acute attack
- ❑ Online consent with waiver of documentation
- ❑ All study questionnaires completed online
- ❑ Disease status and symptoms confirmed with medical records

Case-crossover Study of Triggers for Gout



Recruitment Plan

- | | | |
|---|--|---|
| 1 | Referral through former rheumatology fellows | <i>Only 1 subject enrolled</i> |
| 2 | Banners/ads and links to other sites | <i>Costly or difficult to get permission</i> |
| 3 | Search engines (link to search terms) | <i>Google</i> |
| 4 | Prevention magazine | <i>Lag time for publication</i> |
| 5 | e-Zines | <i>Not up to our standards</i> |
| 6 | Set up a chat room | <i>Too time intensive/ Concern re Medical questions</i> |
| 7 | Traditional print media | <i>Expensive, too many markets</i> |

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Web

Results 1 - 10 of about 580,000 for [gout research](#). (0.23 s)

[Gout Cure - Gout Research - Clinical Trials for Gout ...](#)

Gout research and clinical trials lead to better understanding of **gout**, hyperuricemia, and pseudogout. Researchers focus on finding the causes of **gout** and ...

[arthritis.about.com/od/goutrese/Gout_Research_Gout_Clinical_Trials.htm](#) - 23k -

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[Gout - Information - Causes - Diagnosis - Symptoms - Treatment](#)

Learn more about **gout** basics, history, cause, diagnosis, treatment options, prevention, **gout** diet, **gout** medications, and **gout research**. ...

[arthritis.about.com/od/gout/Gout_Gout_](#)

[Information_Cause_Symptoms_Medication_Treatment.htm](#) - 30k - [Cached](#) - [Similar pages](#)

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[Gout : by Ray Sahelian, M.D., Gout research, diet and supplement ...](#)

Gout Research Update In middle-aged men, high blood levels of uric acid are a strong predictor of death, from both cardiovascular disease and all causes. ...

[www.raysahelian.com/gout.html](#) - 24k - [Cached](#) - [Similar pages](#)

[Gout - researchDiet & Lifestyle](#)

Health Problems **Gout Research** Diet & Lifestyle ... Dr Blau's **research** led to many other people suffering from **gout** who reported being helped by cherries. ...

[www.internethelibrary.com/Health_problems/Gout%20-%20researchDiet&Lifestyle.htm](#)

Sponsored Links

[Gout Information](#)

Get Information On **Gout**, Plus Treatment & Prevention at AOL® Body.
[Body.AOL.com](#)

[Crossroads Research, Inc.](#)

Conducting Quality Clinical Trials
Independent **Research** Site- Maryland
[www.CrossroadsResearch.net](#)

[Do you have Gout? Help](#)

with an online **research** study
Boston University Medical Center
[bumc.bu.edu/goutstudy](#)

[Gout Arthritis Info](#)

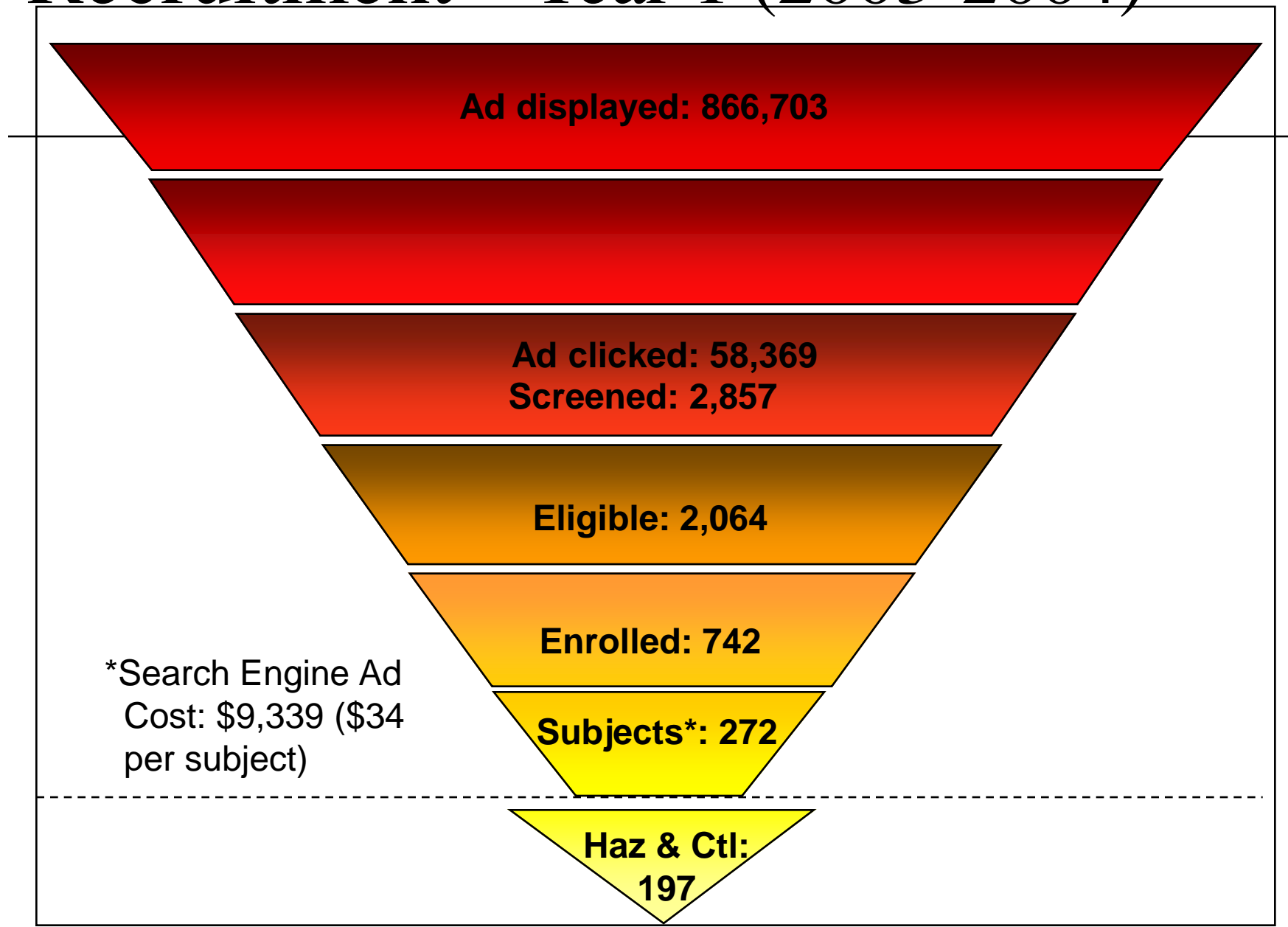
Learn About the Condition, **Gout**.
Find Answers to Your Questions
[RevolutionHealth.com/Arthritis](#)



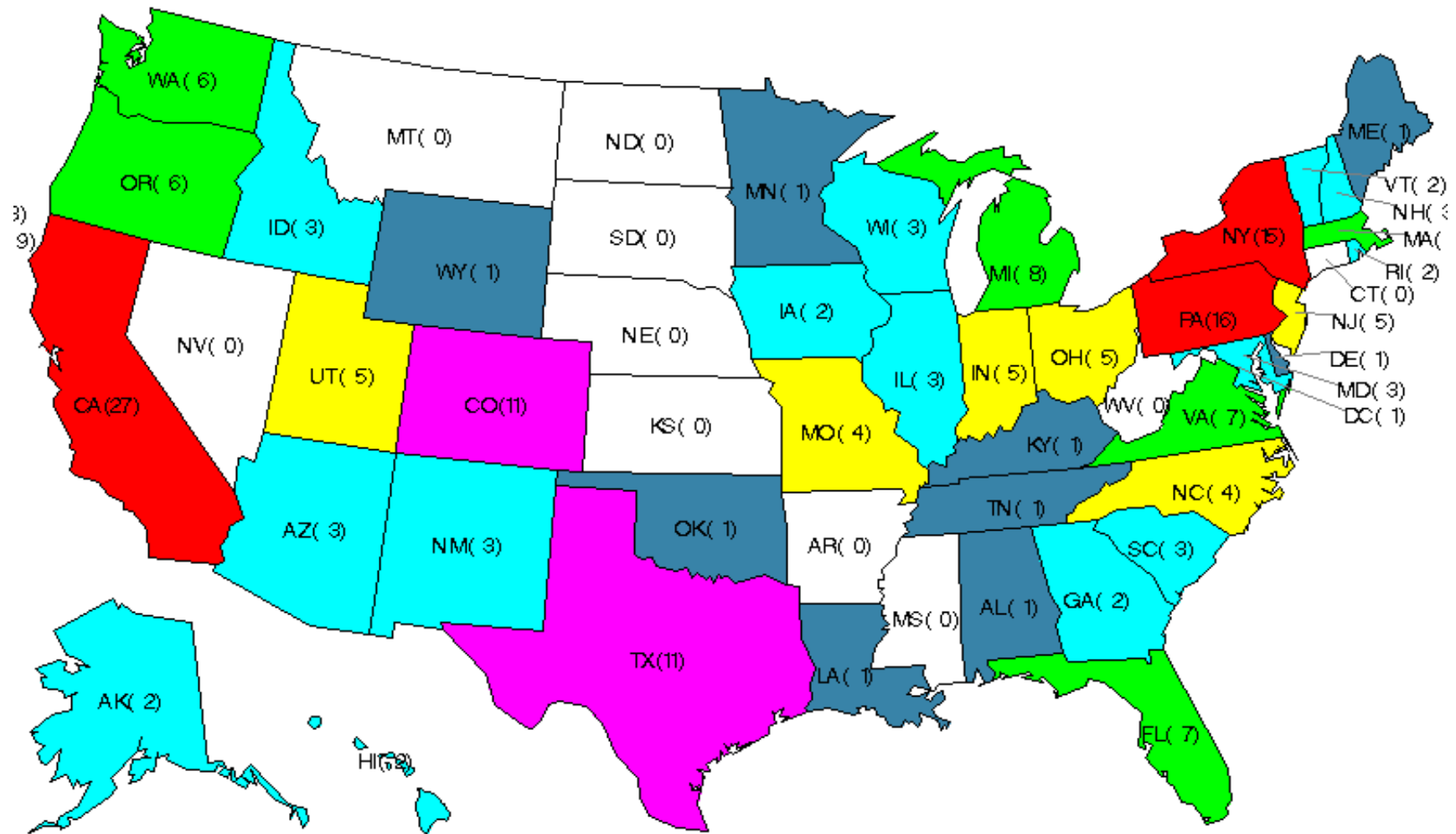
Incentives

- ❑ 5 Points accumulated for each questionnaire with \$1/point cash pay-out at end of study
- ❑ ‘Gout Study’ pens mailed with Medical Record Release forms as incentive to sign and return forms

Recruitment – Year 1 (2003-2004)



GOUT SUBJECTS BY STATE



Frequency Count

0

1

2-3

4-5

6-9

10-14

15+

N= 197 Subjects with Hazard and Control Visits



Study Continues: Gout II

- Original Gout Study: 02/03 - 05/05
- New Gout Study: 11/05 –
 - Recruitment strategy to use Google based on results of Gout I

But Things Change...

In the meantime, Google went public and prices went up -- dramatically

- ❑ Ad placement went from first or second ad to third or fourth
- ❑ Cost/click rose from \$0.16 to > \$0.40
- ❑ Click-through rate dropped from 6.9% to 2.4%

RECRUITMENT: G1 VS G2

Ad displayed: 866,703
NEW 2,084,013

Ad clicked: 58,369
NEW 50,668

Screened: 2,857
NEW 2,110

Eligible: 2,064
NEW 1,578

Enrolled: 742
NEW 469

Subjects*: 272
NEW 185

Haz & Ct: 197
NEW 90

*Search Engine
Ad Cost: \$9,339
(\$34/subject)
NEW \$87



Chat
Files
Photos
Links
Database
Polls
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Promote

! Groups Tips

Did you know...

You can [promote your group](#) from your own Web site?

! 360°

Keep connected to your friends and family through blogs, photos and more.
[Create your own 360° page now.](#)

[Up Thread](#) | [Message Index](#) | [View Source](#) |
[Unwrap Lines](#)

Message 5251 of 5408 < [Previous Message](#) | [Next Message](#) >

Reply

Forward

Delete

From: "Online Gout Study" <goutstudy@yahoo.com>

[goutstudy](#)

Date: Tue Nov 29, 2005 6:14 pm

Offline

Subject: Online Gout Study

[Send Email](#)

Hi All,

Boston University is conducting an online study to determine possible triggers for acute gout flares. If you have had an acute gout attack within the past year, reside in the US and would like to participate, we could use your help. All questionnaires are completed entirely online and all information is strictly confidential.

For more information please visit our website:

<https://dcc2.bumc.bu.edu/goutstudy/>

If you have questions or concerns about this study, please contact us at goutinfo@....

Thanks,
Online Gout Study

Typical Chat Room Postings

Why yes, I do have a few questions or concerns about this study.

- (1) Why is the listed website close to, but not actually, a BUMC website? Why is the root site "under construction?"
- (2) Why is the author or organizer of the study remaining anonymous - "Online Gout study," forsooth.
- (3) What level of statistical control could you possibly expect by polling a group?

Beware that gout study. They insist on sending emails to you as attachments instead of as text and they will send annoying 'thank you' messages and 'birthday greeting' messages.

> another pleb trying to milk the gout group of hard earned cash no doubt. "I"
> miss the gout police arnold and walter they would have sussed out this dodgy
> character



Current Strategies

- ❑ Google advertisements
- ❑ Link on Gout.com
- ❑ Postings under volunteer section of Craig's list (selected cities)
- ❑ Link on Centerwatch



Hits to Online Gout Study Website in Last Year

- Google Ads : 36,488
- Craigslist: 596
- TAP website, gout.com: 182
- CenterWatch : 1



The online case-crossover study is a novel approach to study triggers for recurrent disease flares

Yuqing Zhang^{a,*}, Christine E. Chaisson^b, Timothy McAlindon^c, Ryan Woods^b,
David J. Hunter^a, Jingbo Niu^a, Tuhina Neogi^a, David T. Felson^a

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Accepted 17 April 2006

Conclusions

- ❑ Several types of study designs lend themselves to Internet implementation
- ❑ The Internet poses unique challenges in risk to human subjects, validity of study data, obtaining informed consent, privacy, confidentiality, and recruitment
- ❑ Important to begin with a well-defined target population to determine the feasibility of Internet recruitment and retention
- ❑ Things change quickly so be prepared to revise your strategies