

Medicine at a Crossroads: Informatics Driving Discovery and Improving Human Health

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Society of Neurological Surgeons June 9, 2013

























> No longer is data generation the major bottleneck, rather



Computational challenges around

Data analysis



Data integration



An Inflection Point

"Biomedical research and the practice of medicine, separately and together are reaching an inflection point: the capacity for description and for collecting data, is expanding dramatically, but the efficiency of compiling, organizing manipulating these data – and extracting true understanding of fundamental biological processes, and insights into human health and disease, from them – has not kept pace."

Toward Precision Medicine: Building a knowledge network of biomedical research and a new taxonomy of disease. National Research Council, 2011





Toward Precision Medicine National Research Council, 2011



Precision Medicine





Precision Medicine







Toward Precision Medicine National Research Council, 2011





National Research Council, 2011



A New Taxonomy of Disease

"Could it be that something as fundamental as our current system for classifying diseases is actually inhibiting progress?"



Toward Precision Medicine. National Research Council, 2011:10



Heterogeneous Data Types





(BIG) Data Sources



Public Databases



Social Networking Sites





Terminologies for Curating Biomedical Datasets





2015 2012 the use of SNOMED C access to information

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<u>UMLS</u> (Unified Medical Language System)

<u>Informatics in Action</u>

> Integrates > 100 existing biomedical terminologies





<u>ClinicalTrials.gov</u>

1997: Congress Passes Law (FDAMA) Requiring Trial Registration

The first U.S. Federal law to require trial registration was the Food and Drug Administration Modernization Act of 1997 (FDAMA) (PDF).

Section 113 of FDAMA required that the National Institutes of Health (NIH) create a public information resource on certain clinical trials regulated by the Food and Drug Administration (FDA). Specifically, FDAMA 113 required that the registry include information about federally or privately funded clinical trials conducted under investigational new drug applications (INDs) to test the effectiveness of experimental drugs for patients with serious or life-threatening diseases or conditions.

The information in the registry was intended for a wide audience, including individuals with serious or life-threatening diseases or conditions, members of the public, health care providers, and researchers.



1997 FDMA



2004 ICMJE

About ICM JE Uniform Requirements for Manuscripts (URM) Journals Following URM U

Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Publishing and Editorial Issues Related to Publication in Biomedical Journals: Obligation to Register Clinical Trials

http://www.icmje.org/publishing_10register.html

2007: Congress Passes Law (FDAAA) Expanding ClinicalTrials.gov Submission Requirements

In 2007 the requirements for submission to ClinicalTrials.gov were expanded after Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA) (PDF) Section 801 of FDAAA (FDAAA 801) requires more types of trials to be registered; additional trial registration information; and the submission of summary results, including adverse events, for certain trials. The law also included penalties for noncompliance, such as the withholding of NiH grant funding and civil monetary penalties of up to \$10,000 a day.

- ClinicalTrials.gov: See the FDAAA 801 Requirements page
- NIH Office of Extramural Research: Frequently Asked Questions: FDAAA Further Resources for NIH Grantees

2007 FDAAA





International Scope

Types of Studies

- Interventional Trials
 - Drug or Biologic
 - Behavioral
 - Surgical Procedures
 - Devices
- Observational Studies
- Device Trials



ClinicalTrials.gov

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

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more <u>about</u> clinical studies and about this site, including relevant history, policies, and laws.





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Several hundred Neurosurgery Studies



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UMLS-driven Search

ClinicalTrials.gov A service of the U.S. National Institutes of Health	Example: "Heart attack" AND "Los Angeles" Search for studies: Search Advanced Search Help Studies by Topic Glossary
Find Studies About Clinical Studies	Submit Studies Resources About This Site
Home > Find Studies > Search Results	Text Size 💌
17 studies for	nd for: neurosurgery AND deep brain stimulation Open Studies Modify this search How to Use Search Results
List By Topic On a Map Sea	rch Details
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1 Recruiting <u>Neurotransmitter N</u> (WINCS) During Der Condi Interver	easurements Using Wireless Instantaneous Neurotransmitter Concentration System p Brain Stimulation Neurosurgery ions: Essential Tremor; Parkinson's Disease; Dystonia ntion: Device: WINCS (Wireless Instantaneous Neurochemical Concentration Sensing System)
2 Recruiting <u>Deep Brain Stimula</u> Cond Interven	tion and Capsulotomy for the Treatment of Refractory Anorexia Nervosa ition: Anorexia ions: Procedure: Deep Brain Stimulation(DBS); Procedure: Capsulotomy
3 Recruiting <u>Sub-thalamic Nucle</u> Cond Interven	us Stimulation in Parkinson Disease ition: Parkinson's Disease ions: Procedure: New targeting procedure without electrophysiology; Procedure: Classical neurosurgical procedure
4 Recruiting <u>SubGenual CG25 D</u> Cond Interver	eep Brain Stimulation in Severe Resistant Depression Ition: Depression Ition:
5 Recruiting Effectiveness of Dr Compulsive Disord	eep Brain Stimulation for Treating People With Treatment Resistant Obsessive- er ition: Obsessive-Compulsive Disorder
Interve	tion: Device: Deep brain stimulation (DBS)
6 Recruiting Deep Brain Stimula	tion for the Treatment of Refractory Anorexia Nervosa
Cond	ition: Anorexia Nervosa
Interve	tion: Procedure: Deep Brain Stimulation

17 recruiting studies involving deep brain stimulation



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Trial Record - Purpose - Study Type

- Study Design
- Official Title



Resource links provided by NLM:

Genetics Home Reference related topics: dopa-responsive dystonia early-onset primary dystonia essential tremor Parkinson disease Perry syndrome

MedlinePlus related topics: Dystonia Parkinson's Disease Tremor

U.S. FDA Resources

Further study details as provided by Mayo Clinic:

Primary Outcome Measures:

adenosine release in brain as measured by WINCS (Wireless Instantaneous Neurochemical Concentration Sensing System)recording device
 [Time Frame: 30 minutes] [Designated as safety issue: Yes]

Pre, during, post DBS (deep brain stimulation)

Secondary Outcome Measures:

dopamine release in brain as measured by WINCS (Wireless Instantaneous Neurochemical Concentration Sensing System)recording device
 [Time Frame: 30 minutes] [Designated as safety issue: Yes]

Pre, during, post DBS (deep brain stimulation)

Estimated Enrollment:	45
Study Start Date:	January 2010
Estimated Study Completion Date:	January 2014
Estimated Primary Completion Date:	January 2014 (Final data collection date for primary outcome measure)

Experimental: WINCS WINCS (Wireless Instantaneous Neurochemical Concentration Sensing System), which is capable of wireless control and data transmission; and in addition is capable of detecting by fast scan cyclic voltametry (FSCV).	ss Instantaneous Neurochemical Concentration icol will involve, after implantation of the DBS will have a single electrochemical recording ited along the same trajectory path as the the DBS electrode

Eligibility

Ages Eligible for Study:	18 Years to 90 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:



Trial Record (cont.)

- Resources
- Primary Outcomes
- Secondary Outcomes
- Estimated Enrollment
- Study Dates
- Eligibility

Exclusion Criteria:

- pregnant patients,
- prisoners,
- · children (age less than 18), and
- · any patients identified as unsuitable for these protocol by the Mayo DBS committee.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01705301

Locations

United States, Minnesota

Recruiting Mayo Clinic Rochester, Minnesota, United States, 55901 Contact: Debra Gorman, RN 507-266-3044 gorman.deborah@mayo.edu Principal Investigator: Kendall H Lee, MD, PhD Principal Investigator: Su-youne Chang, PhD

Sponsors and Collaborators

Mayo Clinic

More Information

No publications provided

Responsible Party: Su-Youne Chang, PI, Mayo Clinic ClinicalTrials.gov Identifier: NCT01705301 History of Changes Other Study ID Numbers: 09-007441 Study First Received: Last Updated: April 26, 2013 Health Authority:

October 9, 2012 United States: Institutional Review Board

Additional relevant MeSH terms:

Brain Diseases Dystonia Dystonic Disorders Parkinson Disease Tremor Essential Tremor Dyskinesias Neurologic Manifestations Nervous System Diseases Signs and Symptoms

Movement Disorders Central Nervous System Diseases Parkinsonian Disorders Basal Ganglia Diseases Neurodegenerative Diseases Neurotransmitter Agents Molecular Mechanisms of Pharmacological Action Pharmacologic Actions Physiological Effects of Drugs

ClinicalTrials.gov processed this record on June 06, 2013

Trial Record (cont.)

- Contacts
- Locations
- Sponsors
- More Information



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Results

- Participant Flow

- Recruitment Details
- Pre-Assignment Details
- Reporting Groups





Results (cont.)

- Baseline Characteristics
- Outcome Measures
- Adverse Events
- More Information



Serious Adverse E	Events							
Hide Serious Adverse	Events							
Time Frame	Index procedure through the 30 day follow-up v	visit.						
Additional Description	No text entered.							
Reporting Groups								
	Description							
MO.MA Roll-In Cases	All subjects who were enrolled prior to the piv eligibility criteria and were screened and enro MO.MA proximal flow blockage cerebral prote	All subjects who were enrolled prior to the pivotal phase of the trial at each US site. All subjects who fulfilled t eligibility criteria and were screened and enrolled to undergo carotid stenting with cerebral protection with the MO.MA proximal flow blockage cerebral protection device						
MO.MA Pivotal Subjects	All subjects who fulfilled the eligibility criteria a cerebral protection with the MO.MA proximal to	and were screened and en flow blockage cerebral pro	rolled to undergo carotid stenti tection device	ng with				
Serious Adverse Event	s							
		MO.MA Roll-In Cases	MO.MA Pivotal Subjects					
Total, serious adverse e	vents							
# participants affected	d / at risk	11/37 (29.73%)	37/225 (16.44%)					
Blood and lymphatic sys	stem disorders							
Anaemia * 1								
# participants affe	ected / at risk	0/0 (0.00%)	4/225 (1.78%)					
# events		0	4					
Coagulopathy * 1								
# participants affe	ected / at risk	0/0 (0.00%)	1/225 (0.44%)					
# events		0	1					
Cardiac disorders								
Bradycardia * 1								
# participants affe	ected / at risk	1/37 (2.70%)	2/225 (0.89%)					
# events		1	2					
Cardiac failure conge	estive ^{* 1}							
# participants affe	ected / at risk	0/0 (0.00%)	1/225 (0.44%)					
# events		0	1					
Cardio-respiratory arr	rest ^{*1}							
# participants affe	ected / at risk	0/0 (0.00%)	1/225 (0.44%)					
# events		0	1					
Coronary artery disea	ase ^{* 1}							
# participants affe	ected / at risk	0/0 (0.00%)	1/225 (0.44%)					
# events		0	1					

Results (cont.)

- Adverse Events



eMerge Consortium

Informatics in Action



Large-scale genomic data integrated with clinical workflow through EHR systems

http://www.genome.gov/27540473#al-2





SHRINE (Shared Health Research Information Network)

- Query across multiple institutions for research purposes
- > Objectives
 - > Increase data set size for analysis and detection of patterns
 - > Share routine clinical data not disease specific
 - > Increase pool of individuals for clinical studies
 - > Demonstrate cooperation across traditionally competing institutions

http://catalyst.harvard.edu/services/shrine/



SHRINE Query Interface



Query: What is the distribution of individuals with pervasive developmental disorders across 5 collaborating hospitals?



<u>Electronic Health Data</u> <u>for Predicting Risk</u>





Reis et al. BMJ 2009; Sep;339:b3677



Medicine at a Crossroads

- Petabytes of data are being collected
- Data need to be shared
- The data need to be stored, processed, filtered, visualized, integrated, and interpreted
- Social, legal, ethical, and economic issues need to be resolved







