

ClinicalTrials.gov: Trial Registration and Results Reporting

The ORDR Collaborative Patient registry for
Rare Diseases will be linked to
ClinicalTrials.gov to assist clinicians,
investigators and the patients



ClinicalTrials.gov: Trial Registration and Results Reporting

Rebecca J. Williams, PharmD, MPH
National Library of Medicine, NIH
February 3, 2009



Agenda

- Background
- Registration requirements in the U.S.
- Results reporting requirements in the U.S.
- International Issues

Background

Reasons to Register Clinical Trials and Report Results

- Human Subject Protections
 - Allows potential participants to find studies
 - Assists ethical review boards and others to determine appropriateness of studies being reviewed (e.g., harms, benefits, redundancy)
 - Promote fulfillment of ethical responsibility to human volunteers – research contributes to medical knowledge
- Research Integrity
 - Facilitates tracking of protocol changes
 - Increases transparency of research enterprise
- Evidence Based Medicine
 - Facilitates tracking of studies and outcome measures
 - Allows for more complete identification of relevant studies
- Allocation of Resources
 - Promotes more efficient allocation of resources

Background: What's All The Fuss About?

- Human subjects participate in trials but the resulting data are not always made available to the medical community
- Ethical and scientific concerns

The Washington Post

A Silenced Drug Study Creates An Uproar

By Shankar Vedantam
Washington Post Staff Writer
Wednesday, March 18, 2009; A01

The study would come to be

It was a long-term trial of the
circles was that newer drugs
otherwise.

- “The results of Study 15 were never published or shared with doctors, even as less rigorous studies that came up with positive results for Seroquel were published and used in marketing campaigns aimed at physicians and in television ads aimed at consumers.”
- “The results of Study 15 were provided only to the Food and Drug Administration -- and the agency has strenuously maintained that it does not have the authority to place such studies in the public domain.”

As a result, newly unearthed documents show, Study 15 suffered the same fate as many industry-sponsored trials that yield data drugmakers don't like: It got buried. It took eight years before a taxpayer-funded study rediscovered what Study 15 had found -- and raised serious concerns about an entire new class of expensive drugs.

Study 15 was silenced in 1997, the same year Seroquel was approved by the Food and Drug Administration to treat schizophrenia. The drug went on to be prescribed to hundreds of thousands of patients around the world and has earned billions for London-based AstraZeneca International -- including nearly \$12 billion in the past three years.

SPECIAL ARTICLE

Outcome Reporting in Industry-Sponsored Trials of Gabapentin for Off-Label Use

S. Swaroop Vedula, M.D., M.P.H., Lisa Bero, Ph.D., Roberta W. Scherer, Ph.D.,
and Kay Dickersin, Ph.D.

ABSTRACT

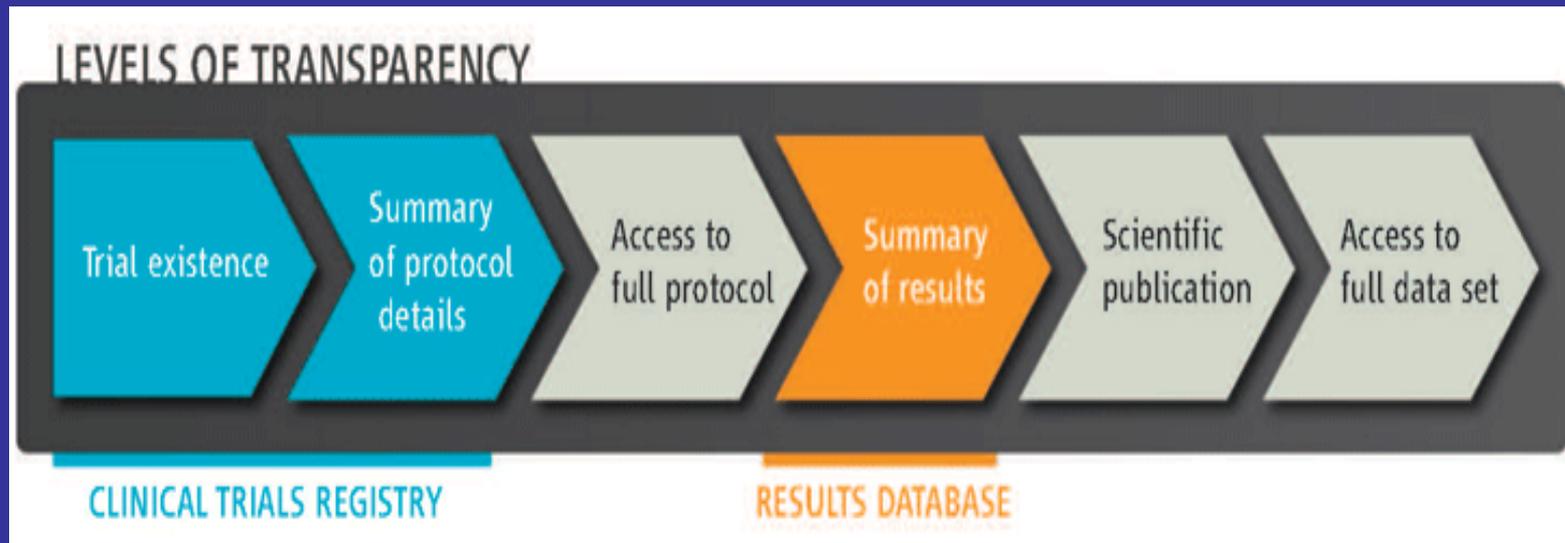
BACKGROUND

There is good evidence of selective outcome reporting in published reports of randomized trials.

METHODS

We examined reporting practices for trials of gabapentin funded by Pfizer and Warner-Lambert's subsidiary, Parke-Davis (hereafter referred to as Pfizer and Parke-Davis) for off-label indications (prophylaxis against migraine and treatment of bipolar disorders, neuropathic pain, and nociceptive pain), comparing internal company documents with published reports.

Levels of “Transparency”



Registration Requirements in the U.S.

FDAAA

Sec. 801 Expanded Clinical Trial Registry

- Enacted on September 27, 2007
- Requires Trial Registration (Dec 2007)
 - Phase II-IV drug and device trials for all diseases
 - Data elements: ClinicalTrials.gov + ~ WHO/ICMJE
- Requires Results Reporting (Sept 2008)
 - Trials of FDA-approved or cleared drugs and devices
 - “Basic” Results: Baseline Characteristics, Primary & Secondary Outcomes, Statistical Analyses
 - Adverse Events (Sept 2009)
 - “Expansion” of results by rulemaking (Sept 2010)
- Added enforcement provisions

Potential Enforcement Provisions

- Notices of non-compliance
- Civil monetary penalties (up to \$10,000/day)
- Withholding of NIH grant funds

Registration Requirements

- FDAAA: “Applicable Clinical Trials” must be registered within 21 days of enrollment
 - Drugs, devices, biologics only
 - Not phase 1
- ICMJE: Interventional studies must be registered prior to enrollment
 - All intervention types
 - Includes phase 1

Rate of New Registrations

- After FDAMA: 25-30 per week
- After ICMJE: 250 per week
- After FDAAA: 350 per week

ClinicalTrials.gov Statistics

(as of 01/04/2010)

	<u>Number</u>	<u>Percent</u>
Total	83,540	100%
Type of Trial*		
Observational	13,717	16%
Interventional	69,471	83%
– Drug & Biologic	50,460	
– Surgical Procedure	8,886	
– Behavioral, Gene Transfer, Other	13,579	
– Device**	4,995	
International Sites (171 countries)		
US only	38,797	46%
Non-US only	30,161	36%
US & Non-US mixed	5,865	7%
Missing	8,717	10%

*91 Expanded Access records; 261 missing Study Type

**261 applicable device clinical trials – “delayed posting”

ClinicalTrials.gov Statistics (cont.)

(as of 01/04/2010)

	<u>Number</u>	<u>Percent</u>
Trials by Data Provider		
US Federal (including NIH)	19,258	23%
Industry	26,257	31%
University, Other	38,025	46%
Total	83,540	

User Statistics

Page Views per month	50 Million
Unique Visitors per day	65,000

Full Text View

Tabular View

Study Results

Related Studies

A Study of Adalimumab for the Induction of Clinical Remission in Japanese Subjects With Crohn's Disease

This study has been completed.

First Received: March 7, 2007 Last Updated: October 13, 2009 [History of Changes](#)

Sponsor:	Abbott
Collaborators:	Abbott Japan Co.,Ltd Eisai Limited
Information provided by:	Abbott
ClinicalTrials.gov Identifier:	NCT00445939

Purpose

The purpose of this study is to demonstrate the efficacy and safety of adalimumab for the induction of clinical remission in Japanese subjects with Crohn's disease.

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Crohn's Disease	Biological: adalimumab Biological: placebo	Phase II Phase III

Study Type: Interventional
Study Design: Treatment, Randomized, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Placebo Control, Parallel Assignment, Safety/Efficacy Study

Official Title: A Multi-Center, Randomized, Double-blind, Placebo-controlled Study of Adalimumab for the Induction of Clinical Remission in Japanese Subjects With Crohn's Disease

Resource links provided by NLM:

[Genetics Home Reference](#) related topics: [Crohn disease](#)

[MedlinePlus](#) related topics: [Crohn's Disease](#)

[Drug Information](#) available for: [Adalimumab](#)

[U.S. FDA Resources](#)

Further study details as provided by Abbott:

Primary Outcome Measures:

- The Number of Subjects With a Clinical Remission (Crohn's Disease Activity Index [CDAI] < 150) at Week 4 [Time Frame: 4 Weeks] [Designated as safety issue: No]

Secondary Outcome Measures:

- Clinical Remission (CDAI < 150) at Week 2 [Time Frame: Week 2] [Designated as safety issue: No]
- Clinical Response (CR-70 and CR-100) in Period A [Time Frame: Weeks 2 and Week 4] [Designated as safety issue: No]
- Clinical Response (CR-70 and CR-100) in Period B [Time Frame: Week 6 and Week 8] [Designated as safety issue: No]
- Clinical Remission (CDAI <150) at Week 6 and Week 8 [Time Frame: Week 6 and Week 8] [Designated as safety issue: No]

Enrollment: 90

Study Start Date: February 2007

Primary Completion Date: December 2007 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Adalimumab 160 mg/80 mg: Experimental	Biological: adalimumab 160 mg at Week 0, 80 mg at Week 2
Adalimumab 80 mg/40 mg: Experimental	Biological: adalimumab 80 mg at Week 0, 40 mg at Week 2
Placebo: Placebo Comparator	Biological: placebo Placebo at Week 0 and Week 2

▶ Eligibility

Ages Eligible for Study: 15 Years to 75 Years

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Crohn's Disease Activity Index (CDAI) score of ≥ 220 and ≤ 450
- If subjects have previously been administered infliximab, subjects who discontinued use due to a loss of response or intolerance to infliximab therapy

Exclusion Criteria:

- Ulcerative colitis or indeterminate colitis
- History of cancer, lymphoma, leukemia or lymphoproliferative disease, active tuberculosis (TB), or Human immunodeficiency virus (HIV)
- Body weight is below 30 kg
- Surgical bowel resections within the past 6 months
- Females who are pregnant or breast-feeding or considering becoming pregnant during the study

▶ Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00445939

Locations

Japan

Hokkaido, Japan

Miyagi, Japan

Chiba, Japan

Tokyo, Japan

Kanagawa, Japan

Shizuoka, Japan

Aichi, Japan

Shiga, Japan

Kyoto, Japan

Okinawa, Japan

Hyogo, Japan

Okayama, Japan

Sponsors and Collaborators

Abbott
Abbott Japan Co.,Ltd
Eisai Limited

Investigators

Study Director: Morio Ozawa Abbott Japan Co.,Ltd

▶ More Information

Additional Information:

[You can access information on these products by clicking on the product name.](#) 

No publications provided

Responsible Party: Abbott (Eiichi Makino)
Study ID Numbers: M04-729
Study First Received: March 7, 2007
Results First Received: December 23, 2008
Last Updated: October 13, 2009
ClinicalTrials.gov Identifier: [NCT00445939](#) [History of Changes](#)
Health Authority: Japan: Ministry of Health, Labor and Welfare

Additional relevant MeSH terms:

Anti-Inflammatory Agents
Digestive System Diseases
Gastrointestinal Diseases
Therapeutic Uses
Crohn Disease
Inflammatory Bowel Diseases

Antirheumatic Agents
Adalimumab
Intestinal Diseases
Gastroenteritis
Pharmacologic Actions

ClinicalTrials.gov processed this record on December 29, 2009

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[U.S. National Institutes of Health](#), [U.S. Department of Health & Human Services](#),
[USA.gov](#), [Copyright](#), [Privacy](#), [Accessibility](#), [Freedom of Information Act](#)

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[Related Studies](#)

A Study of Adalimumab for the Induction of Clinical Remission in Japanese Subjects With Crohn's Disease

This study has been completed.

Study NCT00445939 Information provided by Abbott

First Received: March 7, 2007 Last Updated: October 13, 2009 [History of Changes](#)

Tracking Information

First Received Date
ICMJE

March 7, 2007

Last Updated Date

October 13, 2009

Start Date ICMJE

February 2007

Primary Completion Date

December 2007 (final data collection date for primary outcome measure)

Current Primary Outcome Measures
ICMJE

The Number of Subjects With a Clinical Remission (Crohn's Disease Activity Index [CDAI] < 150) at Week 4 [Time Frame: 4 Weeks]
[Designated as safety issue: No]

(submitted: March 20, 2009)

Original Primary Outcome Measures
ICMJE

Crohn's Disease Activity Index (CDAI)

(submitted: March 7, 2007)

Change History

[Complete list of historical versions of study NCT00445939 on ClinicalTrials.gov Archive Site](#)

Current Secondary Outcome Measures
ICMJE

- Clinical Remission (CDAI < 150) at Week 2 [Time Frame: Week 2] [Designated as safety issue: No]
- Clinical Response (CR-70 and CR-100) in Period A [Time Frame: Weeks 2 and Week 4] [Designated as safety issue: No]
- Clinical Response (CR-70 and CR-100) in Period B [Time Frame: Week 6 and Week 8] [Designated as safety issue: No]

(submitted: March 20, 2009)

← History of this study ↑ Current version of this study

- Hide unchanged portions (except top/bottom lines)
- Hide non-essential portions (contact info, locations, etc.)

Changes to NCT00445939 on 2008_06_22

Type of info changed: Protocol, Recruitment status, Recruitment, Location/Contact, Misc.

	← Before (Updated 2008_01_10)	After (Updated 2008_06_22) →
1	<clinical_study>	<clinical_study>
2	<name_title> Michael Snyder	<name_title> Eiichi Makino
3	</name_title>	</name_title>
4	<status> Active, not recruiting	<status> Completed
5	</status>	</status>
6	<date> 2008-01	<date> 2008-04
7	</date>	</date>
8	<design> Double Blind (Subject, Investigator)	<design> Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
9	</design>	</design>
10	<primary_name> Human anti-TNF monoclonal antibody / adalimumab high-dose	<primary_name> adalimumab
11	</primary_name>	</primary_name>
12	</arm_group_label>	</arm_group_label>
		<div style="background-color: #e0ffe0; padding: 5px;"> <other_name> ABT-D2E7 </other_name> </div> <div style="background-color: #e0ffe0; padding: 5px;"> <other_name> adalimumab </div>

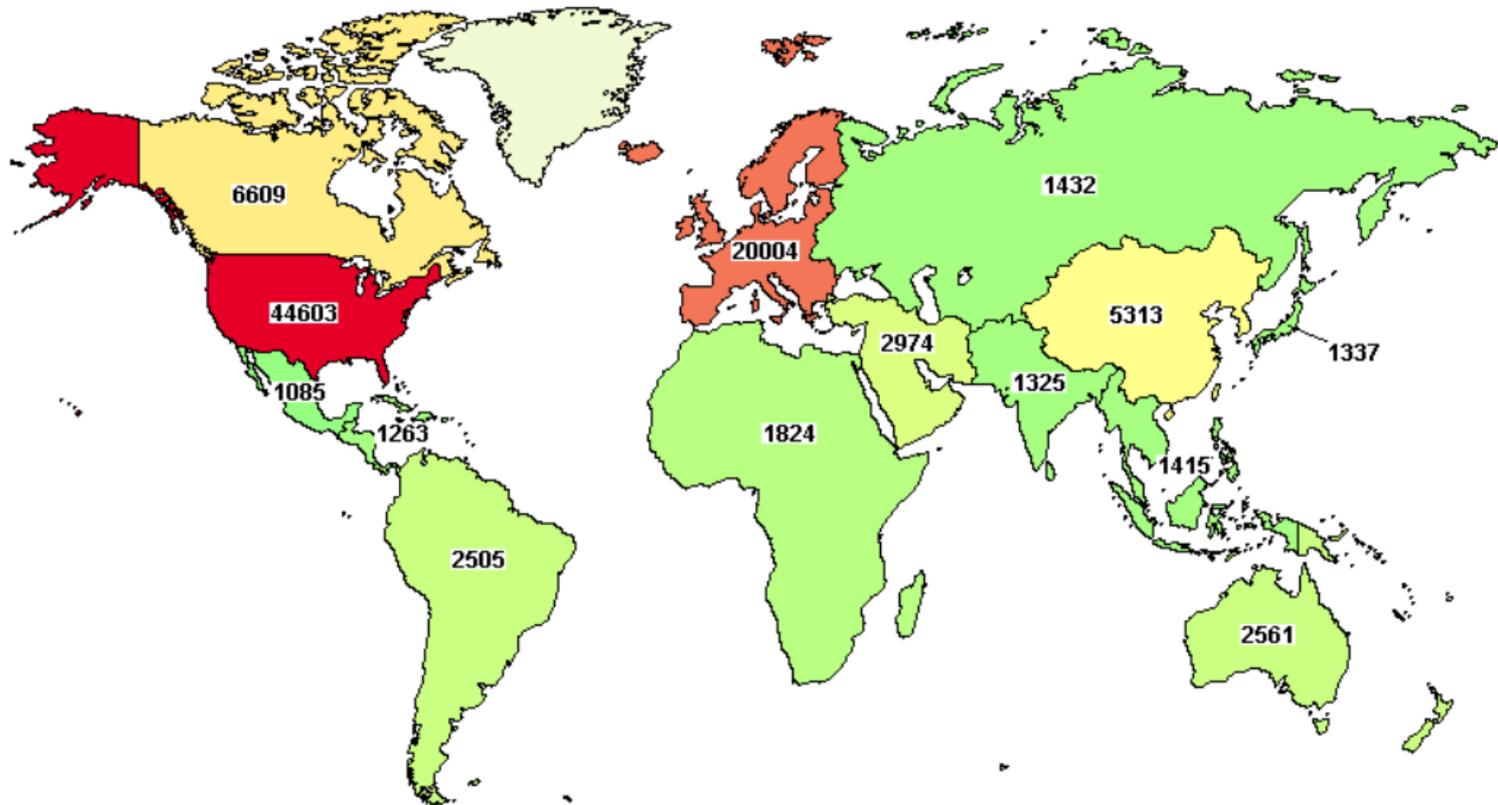
Key	
	Before After
1	Unchanged. Unchanged.
2	Deleted. Deleted.
3	Changed from this... ...to this.
4	Added. Added.
...

ClinicalTrials.gov

International Distribution

Map of all 83427 studies found by search of: ALL

Click on the map below to show a more detailed map (when available) or search for studies (when map not available).



Colors indicate number of studies with locations in that region

Least  Most

Labels give exact study count

Interventional Studies by Location

(N = 69,391 as of 12/28/2009)

- 32,221 (46%) US Only
- 25,207 (36%) Non-US Only
- 5,472 (8%) US & Non-US
- 6,491 (9%) Missing

Browse by Rare Disease

[Basic Search](#)

[Advanced Search](#)

Studies by Topic

[Studies on Map](#)

Categorize All Studies in ClinicalTrials.gov

[Main Category:](#) Rare Diseases, Alphabetic (A-Z)

[Rare Disease First Letter:](#) All Rare Diseases

Search for Rare Disease

Click on a link to search for the Rare Disease. Use the back button to return to this page to try another Rare Disease.

[Aase Syndrome](#) 21 studies
[Abdominal Aortic Aneurysm](#) 63 studies
[Abdominal Obesity Metabolic Syndrome](#) 110 studies
[Abetalipoproteinemia](#) 2 studies
[Absent T Lymphocytes](#) 1 study
[Acanthocheilonemiasis](#) 3 studies
[Acanthocytosis](#) 2 studies
[Acanthosis Nigricans](#) 2 studies
[Achalasia](#) 11 studies
[Achondroplasia](#) 1 study
[Acoustic Neuroma](#) 5 studies
[Acquired Fructose Intolerance](#) 3 studies
[Acquired Hemophilia](#) 3 studies
[Acromegaly](#) 73 studies
[ACTH Deficiency](#) 1 study

ORD Genetic and Rare Disease (GARD) Information Center

National Institutes of Health
Office of Rare Diseases Research
 About ORDR | User Tips | ORDR Search Text Size: A A A

Your portal to rare disease information and research

Genetic and Rare Diseases Information Center (GARD)

- GARD Home
- About GARD
- Contact GARD
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- ORDR Home
- NHGRI Health Information Page

Acoustic neuroma
 Please note that the lists contained on the search results page may take you to other parts of the NIH. See [Disclaimer](#) and/or [Privacy](#) for details.

These Web pages are updated as the Genetic and Rare Diseases Information Center receives questions and as new information becomes available. If you don't see many information resources on this page, it may be because the Information Center hasn't yet received a question about this condition.

If you have a question, please [contact us](#) — we will answer your question and update this page with new resources and information.

Questions & Answers
 If you would like to submit a question, [Contact GARD](#)

[Show All Resources](#)

For more information about Acoustic neuroma click on the boxes below:

[More Detailed Information](#) [NLM Gateway](#) [Support Groups](#) [Clinical Trials & Research](#)

Clinical Trials & Research (Found 1 resource)
 Resources where you may find research studies and clinical trials

- [ClinicalTrials.gov](#) lists trials that are studying or have studied Acoustic neuroma. Click on the link to go to ClinicalTrials.gov to read descriptions of these studies.

Home | Contact ORDR | Contact GARD | Site Map | Site Policies



Note: If you need help accessing information in different file formats such as PDF, MP3, see [Views, Players, and Plug-ins](#).

ClinicalTrials.gov
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Home Search Study Topics Glossary Search

List Results Refine Search Results by Topic Results on Map Search Details

Found 5 studies with search of: "Acoustic neuroma"

[Hide studies that are not seeking new volunteers.](#) [Display Options](#)

Rank	Status	Study
1	Recruiting	Concentration and Activity of Lapatinib in Vestibular Schwannomas Conditions: Vestibular Schwannoma; NF2; Neurofibromatosis 2; Acoustic Neuroma; Auditory Tumor Intervention: Drug: lapatinib
2	Recruiting	Lapatinib Study for Children and Adults With Neurofibromatosis Type 2 (NF2) and NF2-Related Tumors Conditions: Neurofibromatosis 2; Vestibular Schwannoma Intervention: Drug: Lapatinib
3	Recruiting	Natural History Study of Patients With Neurofibromatosis Type 2 Conditions: Spinal Cord Disease; Intracranial Central Nervous System Disorder; Neurologic Disorders; Brain Neoplasms Intervention:
4	Recruiting	Corticosteroids in Prevention of Facial Palsy After Cranial Base Surgery Condition: Facial Palsy Intervention: Drug: methylprednisolone
5	Completed	Phase II Study of the Multichannel Auditory Brain Stem Implant for Deafness Following Surgery for Neurofibromatosis 2 Condition: Neurofibromatosis 2 Intervention: Device: Multichannel Auditory Brain Stem Implant

Results Reporting Requirements in the U.S.

Basic Results Reporting Requirements

- Results of FDA-*approved/cleared* products
- Generally, submission within 12 months of the *earlier* of estimated/actual primary completion date
- Delayed Submission of Results
 - Seeking initial approval
 - Seeking approval of a new use
 - Extensions for “good cause”

Things to Note: Results Database

- Entries are independent of publication status (currently most are lacking publications)
- Structured data
- Enables tracking of outcome measures
- First government run results database
- EMEA is harmonizing their requirements

Current Status – “Basic Results”

(as of 12/02/09)

- Launched in September 2008
- 1,934 Results Records submitted
 - Industry: 1,441 records from 182 data providers (~8 records/provider)
 - Other: 494 records from 280 data providers (~2 records/provider)
- Rate of submission continues to increase
 - 90 records per week now
 - Anticipate about 150 per week

Sample Posted Results

[Full Text View](#)

[Tabular View](#)

Study Results

[Related Studies](#)

A Study of Adalimumab for the Induction of Clinical Remission in Japanese Subjects With Crohn's Disease

This study has been completed.

Study NCT00445939 Information provided by Abbott

First Received: March 7, 2007 Last Updated: October 13, 2009 [History of Changes](#)

Study Type:	Interventional
Study Design:	Randomized, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Placebo Control, Parallel Assignment
Condition:	Crohn's Disease
Interventions:	Biological: adalimumab Biological: placebo

▶ Participant Flow

 [Hide Participant Flow](#)

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

Subjects with moderate to severe Crohn's Disease (Crohn's Disease Activity Index [CDAI] ≥ 220 and ≤ 450) were enrolled into study. The period from the first dose of study drug to the evaluation at Week 4 is Period A. The period from the study drug injection at Week 4 to the evaluation at Week 8 is Period B.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

All subjects were evaluated at Week 4. If responders (CDAI decrease ≥ 70 points compared to Baseline), rolled over to a maintenance study. If non-responders (CDAI decrease of < 70 points compared to Baseline), continued in study and received: adalimumab 160/80 mg + 40/40 mg, or adalimumab 80/40 mg + 40/40 mg or placebo + adalimumab 160/80 mg.

Participant Flow

“A table ..., including the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any.”

[Sec. 282(j)(3)(C)(i)]

Arms

Participant Flow: Overall Study

	Arm 1: VAQTA™	Arm 2: VAQTA™ +ProQuad™
STARTED	1453	347
Vaccination 1 + Safety Follow-up	1453	347
Postvaccination 1 Post-Safety Follow-up	1393	325
Vaccination 2 + Safety Follow-up	1301	292
Postvaccination 2 Post-Safety Follow-up	1265	271
COMPLETED	1253	264
NOT COMPLETED	200	83
Lost to Follow-up	104	56
Protocol Violation	6	3
Withdrawal by Subject	35	7
Subject Moved	1	4
Unspecified	47	13
Adverse Event	1	0

Milestone

Reasons Not Completed

Reporting Groups

	Description
Adalimumab 160 mg/80 mg	Adalimumab 160 mg at Week 0, 80 mg at Week 2
Adalimumab 80 mg/40 mg	Adalimumab 80 mg at Week 0, 40 mg at Week 2
Placebo	Placebo at Week 0, placebo at Week 2
Adalimumab 40mg /40 mg	Non-responders continued after 4 weeks, Adalimumab 160 at Week 0, 80 mg at Week 2, 40 mg at Week 4, 40 mg at Week 6; Adalimumab 80 mg at Week 0, 40 mg at Week 2, 40 mg at Week 4, 40 mg at Week 6.

Participant Flow for 2 periods

Period: Period A - Week 0 - Week 4

	Adalimumab 160 mg/80 mg	Adalimumab 80 mg/40 mg	Placebo	Adalimumab 40mg /40 mg
STARTED	33	34	23	0
COMPLETED	32 ^[1]	32 ^[2]	23 ^[3]	0
NOT COMPLETED	1	2	0	0
Adverse Event	1	2	0	0

^[1] 23 rated as responders and 9 rated as non-responders in evaluation on Week 4.

^[2] 20 rated as responders and 12 rated as non-responders in evaluation on Week 4.

^[3] 7 rated as responders and 16 rated as non-responders in evaluation on Week 4.

Period: Period B - Week 4 - Week 8

	Adalimumab 160 mg/80 mg	Adalimumab 80 mg/40 mg	Placebo	Adalimumab 40mg /40 mg
STARTED	16 ^[1]	0 ^[2]	0 ^[3]	21 ^[4]
COMPLETED	14	0	0	20
NOT COMPLETED	2	0	0	1
Adverse Event	2	0	0	1

^[1] Non-responders continued after 4 weeks, previous 16 placebo subjects allocated to 160/80 mg group.

^[2] Non-responders continued after 4 weeks, previous 80/40 mg subjects allocated to 40/40 mg group.

^[3] Non-responders continued after 4 weeks, previous placebo subjects allocated to 160/80 mg group.

^[4] Non-responders continued after 4 weeks, previous 160/80 and 80/40 subjects allocated to 40/40 group.

Baseline Measures

“A table of the demographic and baseline data collected overall and for each arm of the clinical trial...”

[Sec. 282(j)(3)(C)(i)]

▶ Baseline Characteristics

Reporting Groups

	Description
Vytorin	Ezetimibe 10mg/Simvastatin 20mg
Atorvastatin	Atorvastatin 10mg

Baseline Measures

	Vytorin	Atorvastatin	Total
Number of Participants [units: participants]	108	95	203
Age [units: years] Mean ± Standard Deviation	58.4 ± 10.7	58.7 ± 8.7	58.5 ± 9.8
Gender [units: participants]			
Female	57	56	113
Male	51	39	90
Baseline LDL-C strata [units: Participants]			
<130 mg/dl	2	3	5
>=130 to <160 mg/dl	77
>=160 to <190 mg/dl	84
>=190 mg/dl	20	17	37
Body Mass Index [units: kg/m ²] Mean ± Standard Deviation	25.3 ± 2.9	25 ± 2.8	25.2 ± 2.8

“Default” Required Measures

User-Specified Measure

Categories

Baseline Characteristics

[Hide Baseline Characteristics](#)

Reporting Groups

	Description
Adalimumab 160 mg/80 mg	Adalimumab 160 mg at Week 0, 80 mg at Week 2
Adalimumab 80 mg/40 mg	Adalimumab 80 mg at Week 0, 40 mg at Week 2
Placebo	Placebo at Week 0, placebo Week 2

Baseline Measures

	Adalimumab 160 mg/80 mg	Adalimumab 80 mg/40 mg	Placebo	Total
Number of Participants [units: participants]	33	34	23	90
Age [units: years] Mean \pm Standard Deviation	32.0 \pm 9.60	30.6 \pm 9.26	30.4 \pm 6.93	31.1 \pm 8.80
Gender^[1] [units: participants]				
Female	13	18	7	38
Male	20	16	16	52
Region of Enrollment [units: participants]				
Japan	33	34	23	90

[1] Gender, Male/Female who received first dose of study drug

Outcome Measure

“...a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial...”

[Sec. 282(j)(3)(C)(ii)]

1. Primary Outcome Measure: Primary Endpoint: In-Segment Late Loss (LL)

Measure Type	Primary
Measure Name	Primary Endpoint: In-Segment Late Loss (LL)
Measure Description	In-segment minimal lumen diameter (MLD) post-procedure minus (-) in segment MLD at 240 day follow-up and 5 mm proximal and 5mm distal to the stent equals Late Loss. MLD defined: The average of two orthogonal views (when possible) of the narrowest point within the area of assessment.
Time Frame	240 days
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Only a certain number of patients were required to have angiographic follow-up to provide this endpoint information.

Reporting Groups

	Description
Xience V™ EECSS	XIENCE V™ Everolimus Eluting Coronary Stent System
TAXUS® EXPRESS2™ ECSS	TAXUS® EXPRESS2™ Paclitaxel Eluting Coronary Stent System. 1 patient randomized never signed consent, therefore no data collected. Taxus analysis group = 332.

Measured Values

	Xience V™ EECSS	TAXUS® EXPRESS2™ ECSS
Number of Participants Analyzed [units: participants]	301	134
Primary Endpoint: In-Segment Late Loss (LL) [units: millimeters] Mean ± Standard Deviation	0.14 ± 0.41	0.28 ± 0.48

4. Secondary Outcome Measure: Maternal Satisfaction With Perineal Pain Management

Measure Type	Secondary
Measure Name	Maternal Satisfaction With Perineal Pain Management
Measure Description	5 point Likert scale asking for agreement with the statement "I was satisfied with my pain relief for the pain in my bottom during the first day after delivery". Scale ranged from strongly disagree to strongly agree.
Time Frame	at 24 hours postpartum
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Epidural Morphine	2.5 mg dose of epidural morphine given within one hour following vaginal delivery
Placebo	5 ml of epidural preservative-free saline given within one hour following vaginal delivery

Measured Values

	Epidural Morphine	Placebo
Number of Participants Analyzed [units: participants]	113	115
Maternal Satisfaction With Perineal Pain Management [units: participants]		
Strongly Disagree	1	3
Disagree	9	11
Not sure	6	8
Agree	43	38
Strongly Agree	45	45
Missing information	9	10

Categories

1. Primary: The Number of Subjects With a Clinical Remission (Crohn's Disease Activity Index [CDAI] < 150) at Week 4 [Time Frame: 4 Weeks]

 [Hide Outcome Measure 1](#)

Measure Type	Primary
Measure Title	The Number of Subjects With a Clinical Remission (Crohn's Disease Activity Index [CDAI] < 150) at Week 4
Measure Description	CDAI is used to quantify the symptoms of patients with Crohn's Disease. A score below 150 indicates remission and a score above 450 indicates severe disease. Comparison of the number of subjects with a clinical remission (CDAI < 150) in the adalimumab 160 mg (Week 0)/ 80 mg (Week 2) and adalimumab 80 mg (Week 0)/ 40 mg (Week 2) groups at Week 4.
Time Frame	4 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The primary analysis will be performed on the full analysis set (randomized subjects who received at least one dose of study drug) using the non-responder imputation for missing remission observations.

Reporting Groups

	Description
Adalimumab 160 mg/80 mg	Adalimumab 160 mg at Week 0, 80 mg at Week 2
Adalimumab 80 mg/40 mg	Adalimumab 80 mg at Week 0, 40 mg at Week 2
Placebo	Placebo at Week 0, placebo at Week 2

Measured Values

	Adalimumab 160 mg/80 mg	Adalimumab 80 mg/40 mg	Placebo
Number of Participants Analyzed [units: participants]	33	34	23
The Number of Subjects With a Clinical Remission (Crohn's Disease Activity Index [CDAI] < 150) at Week 4 [units: Participants]	11	6	3

No statistical analysis provided for The Number of Subjects With a Clinical Remission (Crohn's Disease Activity Index [CDAI] < 150) at Week 4

Statistical Analysis

“...including the results of scientifically appropriate tests of the statistical significance of such outcome measures.”

[Sec. 282(j)(3)(C)(ii)]

Measured Values

	Open Label Baseline	Open Label Week 12
Number of Participants Analyzed [units: participants]	514	514
Mean Number of Micturition Episodes Per 24 Hours [units: episodes] Mean \pm Standard Deviation		
Number of micturition episodes per 24 hours	12.7 \pm 3.9	9.7 \pm 3.4

Statistical Analysis 1 for Mean Number of Micturition Episodes Per 24 Hours

Groups ^[1]	All groups
Method ^[2]	2-sided paired t-test
P Value ^[3]	<0.0001
Mean Difference (Net) ^[4]	-3.0
Standard Deviation	\pm 3.1
95% Confidence Interval	(-3.2 to -2.7)

} **Statistical Analysis**

[1] Additional details about the analysis, such as null hypothesis and power calculation:

Open-label study with statistical comparison between baseline and Week 12. Null hypothesis: The mean change from baseline in number of micturition episodes per 24 hours at Week 12 is equal to 0. The sample size was based on a statistical power for each of the three individual diary endpoints of .95 which would yield an overall power of 85%.

[2] Other relevant information, such as adjustments or degrees of freedom:

paired t-test comparing baseline with post-baseline values

[3] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

All paired t-tests were performed with a two-sided test at significance level of 5%. Efficacy was claimed only when all 3 primary diary endpoints demonstrated statistical significance in change from baseline to Week 12.

[4] Other relevant estimation information:

No text entered.

Reporting Groups

	Description
Treatment A	ER niacin 2 g/laropiprant 40 mg daily for 7 days
Treatment B	ER niacin 2 g daily for 7 days
Treatment C	laropiprant 40 mg once daily for 7 days
Treatment D	placebo daily for 7 days

Measured Values

	Treatment A	Treatment B	Treatment C	Treatment D
Number of Participants Analyzed [units: participants]	18	18	19	20
Urinary 11-Dehydrothromboxane B2 (11-dTxB2) [units: pg/mg creatinine] Least Squares Mean (95% Confidence Interval)	414.6 (316.8 to 542.6)	371.6 (283.8 to 486.5)	407.3 (312.2 to 531.4)	466.1 (358.4 to 606.3)

Statistical Analysis 1 for Urinary 11-Dehydrothromboxane B2 (11-dTxB2)

Groups ^[1]	reatment A vs. Treatment B
Non-Inferiority/Equivalence Test ^[2]	Yes
Geometric least-squares mean ratio ^[3]	1.12
90% Confidence Interval	(0.9 to 1.38)

Statistical Analysis

[1] Additional details about the analysis, such as null hypothesis and power calculation:

The endpoint is the urine levels of 11-dTxB2 on Day 7 following a 7 day course of daily dosing in the overall 24 hour collection interval. The point estimate and 90% confidence intervals (CIs) were calculated for the geometric mean ratio (GMR) [Treatment A/B] of the urine levels of 11-dTxB2 on Day 7.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

Two treatments are comparable if the geometric mean ratio is contained within the interval [0.50-2.00].

[3] Other relevant estimation information:

No text entered.

Serious Adverse Events

“A table of anticipated and unanticipated serious adverse events grouped by organ system, with number and frequency of such event in each arm of the clinical trial.”

[Sec. 282(j)(3)(I)(iii)(I)]

Frequent Adverse Events

“A table of anticipated and unanticipated adverse events that are not included in the [Serious Adverse Events] table ... that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency of such event in each arm of the clinical trial.”

[Sec. 282(j)(3)(I)(iii)(II)]

Table 3. Adverse Events (Safety Population).*

Event	Placebo (N=929)	Simvastatin plus Ezetimibe (N=943)	P
	no./total no. (%)		
Clinical			
Any event	852 (91.7)	854 (90.6)	
Any serious event‡	463 (49.8)	468 (49.6)	
Incident cancer§	70 (7.5)	105 (11.1)	
Recurrent cancer	5 (0.5)	3 (0.3)	
New cancer	65 (7.0)	102 (10.8)¶	
New cancer after ezetimibe	65 (7.0)	101 (10.7)	
Event attributed to study treatment			
Any	110 (11.8)	134 (14.2)	
Serious	3 (0.3)	5 (0.5)	
Event resulting in permanent discontinuation of study treatment			
Any	122 (13.1)	144 (15.3)	
Attributed to treatment	29 (3.1)	46 (4.9)	
Serious event resulting in permanent discontinuation of study treatment			
Any	79 (8.5)	77 (8.2)	
Attributed to treatment	1 (0.1)	2 (0.2)	
Musculoskeletal condition	181 (19.5)	165 (17.5)	
Hepatitis	6 (0.6)	5 (0.5)	
Gastrointestinal condition	281 (30.2)	308 (32.7)	
Gallbladder-related condition	11 (1.2)	10 (1.1)	
Allergic reaction or rash	102 (11.0)	104 (11.0)	
Laboratory findings			
Creatine kinase			
>10 times ULN without muscle-related symptoms	2/915 (0.2)	2/925 (0.2)	
>10 times ULN with muscle-related symptoms	0	0	
>10 times ULN with muscle-related symptoms and drug relationship	0	0	
Liver enzymes			
Alanine aminotransferase or aspartate aminotransferase ≥3 times ULN (consecutive)**	5/915 (0.5)	16/925 (1.7)	

Serious Adverse Events

	EZ/Simva 10/40 mg	Placebo
Total, serious adverse events		
# participants affected	471	465
Blood and lymphatic system disorders		
Anaemia ‡		
# participants affected / at risk	12/943 (1.27%)	8/929 (0.86%)
Haemolytic anaemia ‡		
# participants affected / at risk	1/943 (0.11%)	0/929 (0.00%)
Iron deficiency anaemia ‡		
# participants affected / at risk	1/943 (0.11%)	2/929 (0.22%)
Pernicious anaemia ‡		
# participants affected / at risk	0/943 (0.00%)	1/929 (0.11%)
Cardiac disorders		
AV dissociation ‡		
# participants affected / at risk	0/943 (0.00%)	1/929 (0.11%)
Acute coronary syndrome ‡		
# participants affected / at risk	0/943 (0.00%)	2/929 (0.22%)
Acute myocardial infarction ‡		
# participants affected / at risk	2/943 (0.21%)	0/929 (0.00%)
Angina pectoris ‡		
# participants affected / at risk	3/943 (0.32%)	8/929 (0.86%)
Aortic valve disease mixed ‡		
# participants affected / at risk	0/943 (0.00%)	1/929 (0.11%)
Aortic valve incompetence ‡		
# participants affected / at risk	1/943 (0.11%)	1/929 (0.11%)
Aortic valve stenosis ‡		
# participants affected / at risk	69/943 (7.32%)	60/929 (6.46%)
Arrhythmia ‡		
# participants affected / at risk	2/943 (0.21%)	2/929 (0.22%)
Arteriosclerosis coronary artery ‡		
# participants affected / at risk	0/943 (0.00%)	1/929 (0.11%)
Atrial fibrillation ‡		
# participants affected / at risk	45/943 (4.77%)	27/929 (2.91%)
Atrial flutter ‡		
# participants affected / at risk	8/943 (0.85%)	1/929 (0.11%)

Certain Agreements

“Whether there exists an agreement (other than an agreement solely to comply with applicable provisions of law protecting the privacy of participants) between the sponsor or its agent and the principal investigator (unless the sponsor is an employer of the principal investigator) that restricts in any manner the ability of the principal investigator, after the completion date of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial.”

[Sec. 282(j)(3)(C)(iv)]

More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

- The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.
- The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

- Restriction Description:** Pfizer has the right to review disclosures, requesting a delay of <60 days. Investigator will postpone single center publications until after disclosure of pooled data (all sites), <12 mo from study completion/termination at all participating sites. Investigator may not disclose previously undisclosed confidential info other than study results.

Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

How Are Results Reported?

- Tables are “constructed” by the data provider
 - Columns are pre-set as study arms, but can be changed by the data provider
 - Rows are measures—some are pre-set, others are customized for each study
 - Type of measure determines specific design of “cells”
- Attempt to balance fixed structure with flexibility

<u>Outcome Measure Type</u>*	Primary
<u>Outcome Measure Reporting Status</u>*	Indicate whether posting results data for this outcome measure. At least one outcome in each record must be "Posted". Posted
<u>Anticipated Posting Date</u>	If the Reporting Status is "Not Posted", please enter a month and 4 digit year for the anticipated posting date. Month: -- Please Select -- Year: <input type="text"/>
<u>Outcome Measure Title</u>*	<input type="text" value="change in diastolic blood pressure"/>
<u>Outcome Measure Time Frame</u>*	<input type="text" value="3 months"/>
<u>Outcome Measure Description</u>*	<input type="text" value="-- Please Select -- minus value at baseline."/>
<u>Safety Issue</u> (FDAAA)	<input type="text" value="-- Please Select -- are assessing a safety issue?"/>
<u>Measure Type</u>*	Mean
<u>Measure of Dispersion</u>*	Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types. 95% Confidence Interval
<u>Unit of Measure</u>*	-- Please Select -- Not Applicable Standard Deviation Inter-Quartile Range Full Range Standard Error 95% Confidence Interval

P-Value: (e.g. <math><0.01</math>)

If desired, provide additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance.

**Statistical
Test of
Hypothesis:**

Method:

- Please Select --
- ANCOVA
- ANOVA
- Chi-squared
- Chi-squared, Corrected
- Cochran-Mantel-Haenszel
- Fisher Exact
- Kruskal-Wallis
- Log Rank
- Mantel Haenszel
- McNemar
- Mixed Models Analysis
- Regression, Cox
- Regression, Linear
- Regression, Logistic
- Sign test
- t-test, 1 sided
- t-test, 2 sided
- Wilcoxon (Mann-Whitney)
- Other**

If other, please specify:

nt information, such as adjustments or degrees of freedom.



Issues in Reporting Results

ICJME

“...will not consider results posted in the same primary clinical trials register in which the initial registration resides as previous publication if the results are presented in the form of a brief, structured (<500 words) abstract or table.”

Who is the Audience?



PI and Clinical Research Team

Other Medical Researchers in same field

Other Medical Researchers in other fields

Other Readers of the medical literature

Science Writers

Lay Public (readers of consumer health literature)

What Does QA Address?

- Tables should convey study design, conduct and analysis
- Data must make sense
 - Measure name, units, and data must match
 - Use words precisely (e.g., incidence, rate)
 - No invalid entries
 - E.g., 823 hours/day; “time to survival”
 - No missing parameters or data
- Results record must be logical and internally consistent

International Issues

Found 1573 studies with search of **Korea, Democratic People's Republic of | Korea, Republic of**

[Hide studies that are not seeking new volunteers.](#)

[+ Display Options](#)

Rank	Status	Study
1	Completed	<p>Evaluation of GW406381 in Treating Adults With Osteoarthritis Of The Knee</p> <p>Condition: Osteoarthritis, Knee Intervention: Drug: GW406381</p>
2	Completed	<p>A Study of Solifenacin Succinate Compared to Tolterodine in Patients With Overactive Bladder</p> <p>Condition: Overactive Bladder Intervention: Drug: Solifenacin succinate</p>
3	Completed	<p>Randomized Evaluation of Long Term Anticoagulant Therapy (RE-LY) With Dabigatran Etexilate</p> <p>Conditions: Atrial Fibrillation; Cerebrovascular Accident Interventions: Drug: Dabigatran etex; Drug: Warfarin</p>
4	Terminated	<p>Safety and Efficacy Study of Retreated Clevudine in Chronic HBV Patients Who Received Clevudine in L-FMAU-201</p> <p>Condition: Hepatitis B Intervention: Drug: Clevudine</p>
5	Active, not recruiting	<p>A Type 2 Diabetes Study of the Longer-Term Glycemic Effect of AVANDAMET vs. Metformin</p> <p>Conditions: Non-Insulin-Dependent Diabetes Mellitus; Type 2 Diabetes Mellitus Intervention: Drug: Rosiglitazone maleate/metformin hydrochloride (AVANDAMET)</p>
6	Completed Has Results	<p>A Clinical Trial To Assess Fesoterodine On Treatment Satisfaction And Symptom Improvement In Overactive Bladder Patients</p> <p>Condition: Overactive Bladder Intervention: Drug: fesoterodine fumarate</p>
7	Completed Has Results	<p>Novel Epopilone Plus Capecitabine Versus Capecitabine Alone in Patients With Advanced Breast Cancer</p> <p>Conditions: Breast Cancer; Metastases Interventions: Drug: Ixabepilone + Capecitabine; Drug: Capecitabine</p>
8	Recruiting	<p>LOGiC - Lapatinib Optimization Study in ErbB2 (HER2) Positive Gastric Cancer: A Phase III Global, Blinded Study Designed to Evaluate Clinical Endpoints and Safety of Chemotherapy Plus Lapatinib</p> <p>Conditions: ErbB2 (HER2) Amplified Gastric; Esophageal; or Gastro-esophageal Junction Adenocarcinoma That is Unresectable Due to Locally Advanced Metastatic, or Locally Recurrent Disease. Intervention: Drug: Lapatinib</p>

International Collaborations

- ICMJE
- WHO
- EMEA
- HealthCanada
- Israel

World Health Organization

(ICTRP - International Clinical Trials Registry Platform)

- Search portal for identifying clinical trials
- Includes trials from ClinicalTrials.gov as well as 10 “Primary Registries”
 - 97,017 trials in ICTRP
 - Includes 84,540 trials from ClinicalTrials.gov

EMEA

- Scope:
 - Trials of medicinal products (drugs)
 - Conducted in EU (or regulated by EMEA or NCAs)
- Registration dataset will be made public (EudraCT)
- Results database being developed (regulation is pending)
- Ongoing work to harmonize with ClinicalTrials.gov

International Issues: Need for Collaboration

International Registries

(as of 12/23/09)

Region	National Registry	ClinicalTrials.gov
ClinicalTrials.gov	83,425	---
Australia & New Zealand	3,635	2,544
China	628	1,423
India	688	1,140
Germany	155	5,577
Iran	201	216
UK (ISRCTN)	4,824	4,212
Japan (UMIN)	2,803	1,335
Netherlands	2,020	2,701
Africa	13	1,825
Sri Lanka	43	12

Number of Interventional Studies with Sites in Multiple Countries in ClinicalTrials.gov (N = 69,442 as of 12/30/2009)

Number of Countries with Study Sites*	Number of Studies
1	54,283 (78%)
2	3,227 (5%)
3-6	2,822 (4%)
7-20	2,263 (3%)
21-53	359 (<1%)

*6,488 registered interventional studies do not include study site information⁶⁶

International Registration Policies

(Source: John C. McKenney, President, SEC Associates)

Mandatory transparency requirements are in place (or will soon be) for the following entities. Most have (or will have) their own registry:

- Argentina
- Brazil
- Croatia
- Czech Republic
- European Union
- France
- India
- Iran
- Israel
- Italy
- Maine, US
- Malaysia
- Netherlands
- Norway
- Peru
- South Africa
- Spain
- Taiwan
- United States
- Turkey

International Registration Policies*

(Source: John C. McKenney, President, SEC Associates)

Mandatory for Trialist ¹ to Post (In Effect)	Mandatory for Government to Post (In Effect)	Mandatory for Trialist ¹ to Post (Implementation Pending)	Mandatory for Government to Post (Implementation Pending)	Legislation / Regulations (Active Debate)	Voluntary Registration (In Effect)	Voluntary Registration (Implementation Pending)
Brazil ² India ³ Iran ⁴ Israel Italy Maine, US South Africa Taiwan US	Czech Rep. France Malaysia ⁵ Peru	Argentina Brazil ²	Croatia EU Netherlands ⁷ Norway Spain Turkey	Canada Chile Switzerland Turkey	Australia China Cuba Germany ⁸ Hong Kong Japan Latin America New Zealand Sri Lanka Taiwan PMS ⁸ UK	Africa Germany ⁸ LA & C ⁹

¹Trialst = Sponsor or Investigator

²Law in effect; registry in development

³Mandatory from 15 June 2009

⁴Recent changes from “voluntary” in this table

⁵Linked registry for MOH-related trials

⁶Prototype registry exists; “real” version in 2009

⁷Two registries in effect

⁸Post-marketing studies

⁹Latin America & Caribbean

Technical Capabilities of Registries

Registry	Data Provider				Public		
	Interactive Web-based Data Entry	Accepts XML	Recruitment Status Update	Other Protocol Info Update	Free Text Search	Fielded Search	Uses Synonymy
ClinicalTrials.gov	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Australia/New Zealand (ANZCTR)	Yes	No	Yes	Yes	Yes	Yes	No
China (ChiCTR)	Yes	No	?	?	Yes	No	No
India (CTRI)	Yes	No	?	?	Yes	Yes	No
Germany (DRKS)	Yes	No	?	?	Yes	No	No
Iran (IRCT)	Yes	No	Yes	Yes	No	Yes	No
ISRCTN.org	Yes	No	Yes	Yes	Yes	No	No
Japan (UMIN)	Yes	No	Yes	Yes	Yes	Yes	No
Japan (JapicCTI)	?	No	Yes	Yes	Yes	Yes	No
Japan (JMACCT)	?	No	?	?	No	Yes	?
Netherlands (NTR)	Yes	No	?	?	No	Yes	No
Africa (PACTR)	Yes	No	Yes	Yes	Yes	No	No
Sri Lanka (SLCTR)	Yes	No	Yes	Yes	No	Yes	No

Potential Ongoing Overlap: Number of ClinicalTrials.gov Organizational Accounts for Key Regions

Region	Total Number of Existing Accounts	Accounts Opened Since 8/13/2009
Australia/New Zealand	152	5
China	214	17
India	140	5
Germany	301	15
Iran	48	3
UK	264	12
Japan	200	7
Netherlands	120	3
Africa	89	7
Sri Lanka	2	0

Case Study —The GAS Study

- Registered in (at least) three registries
 - ISRCTN, ClinicalTrials.gov, ANZCTR
- Three different PIs (US, UK, Aus); three different “sponsors.”
- ANZCTR and ClinicalTrials.gov records have same title; ISRCTN lists ANZCTR as secondary ID
- WHO portal lists two records, but does not recognize them as duplicates; does not have the ISRCTN record

On WHO Site: Search for “Neurodevelopmental Outcome” in Title Field

 World Health Organization

INTERNATIONAL CLINICAL TRIALS REGISTRY PLATFORM
SEARCH PORTAL

Home Advanced Search Search Tips UTN ICTRP website Contact us

Back to Search Sort by 10 records for 7 trials found! [\(What is this?\)](#)

2 GAS Study Records
(Not identified as duplicates)

Show records per page

Recruitment status	Main ID	Public Title	Date of Registration
Recruiting	NCT00809055	Magnetic Resonance Imaging (MRI) and Neurodevelopmental Outcomes in Preterm Infants Following Administration of High-Dose Caffeine	15/12/2008
Recruiting	NCT00756600	A Multi-Site Randomized Controlled Trial Comparing Regional and General Anesthesia for Effects of Neurodevelopmental Outcome and Apnea in Infants	18/09/2008
Recruiting	NCT00713635	Prenatal Effects of Congenital Heart Disease (CHD) on Neurodevelopmental Outcome	09/07/2008
Recruiting	NCT00464100	Near-Infrared Spectroscopy (NIRS) Neurodevelopmental Outcomes	18/04/2007
Recruiting	ACTRN12606000441516	A multi-site randomised controlled trial comparing regional and general anaesthesia for effects on neurodevelopmental outcome and apnoea in infants	16/10/2006
Recruiting	NTR364	Effect of early fatty acid status on neurodevelopmental outcome at 9 years.	12/09/2005
Recruiting	NTR306	The effect of treatment of neonatal electrographic seizures, detected with the continuous cerebral function monitoring, with respect to occurrence of postneonatal epilepsy and neurodevelopmental outcome.	09/09/2005

Reasons for Concern

- Duplicate records
 - Make it impossible to determine how many trials and how many participants are being studied for a given intervention
 - Undermine the ability to identify or prevent publication/outcome reporting bias
- Increases burden on data providers (e.g., consistency and updating)
- Registries may lack sophisticated search capacity (e.g., use of synonymy)

Synonyms for “ramipril”

- acovil
- altace
- carasel
- delix
- hoe 498
- ramace
- triatec
- tritace
- vesdil
- zabien

Imagine trying to identify the ramipril trials around the world by using all of the existing registries with all of these names.

Alternative Model

- Register first in ClinicalTrials.gov
- Carry NCT# to any additional registries
- Additional regional requirements could then be added by:
 - Working with ClinicalTrials.gov
 - Importing data to regional registry which contains additional modules
 - Having region-specific requirements

In Sum

- Broad acceptance of need for trial registration
- Drug trials receive more attention than other human studies
- Results reporting in public database
 - Technical success
 - National (international) experiment
 - Harmonization with EMEA is promising
- Lack of international collaboration could undermine fundamental public health objectives

Additional Information

- Email LISTSERV and other FDAAA information:
 - <http://prsinfo.clinicaltrials.gov/fdaaa.html>
- Other general information:
 - <http://prsinfo.clinicaltrials.gov>
- Questions?
 - register@clinicaltrials.gov