NIH U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- · A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- · Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in red.
- Study additions are displayed in green.

Study Record Versions

Version	Α	В	Submitted Date	Changes
1	•		March 17, 2008	None (earliest Version on record)
2	0	0	<u>April 24, 2008</u>	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	0	0	<u>June 19, 2008</u>	Contacts/Locations and Study Status

https://clinicaltrials.gov/ct2/history/NCT00637377?A=1&B=1&C=merged#StudyPageTop

1/20

Version	Α	В	Submitted Date	Changes
4	\circ	\circ	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	0	0	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	\circ	\circ	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	\circ	0	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	\circ	0	<u>December 1, 2008</u>	Study Status and Contacts/Locations
9	0	0	<u>January 5, 2009</u>	Contacts/Locations and Study Status
10	0	0	<u>February 5, 2009</u>	Contacts/Locations and Study Status
11	\circ	\circ	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	\circ	\circ	<u>April 2, 2009</u>	Contacts/Locations, Study Status and Eligibility
13	\circ	0	May 4, 2009	Study Status
14	0	0	<u>June 4, 2009</u>	Contacts/Locations, Study Status and Eligibility
15	\circ	\circ	<u>July 3, 2009</u>	Contacts/Locations, Study Status and Eligibility
16	\circ	\circ	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	0	0	<u>September 23, 2009</u>	Recruitment Status, Contacts/Locations and Study Status
18	0	0	November 19, 2009	Study Status
19	0	0	<u>February 19, 2010</u>	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	0	0	<u>July 9, 2010</u>	Contacts/Locations and Study Status
21	\circ	0	October 6, 2010	Study Status

https://clinicaltrials.gov/ct2/history/NCT00637377?A=1&B=1&C=merged#StudyPageTop

Version	Α	В	Submitted Date	Changes
22	\circ	\circ	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	\circ	0	February 21, 2011	Study Status
24	\circ	\circ	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	0	0	<u>June 6, 2011</u>	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	0	0	<u>December 16, 2011</u>	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	\circ	0	<u>February 27, 2012</u>	Study Status
28	\circ	0	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status and References
29	0	0	<u>April 25, 2014</u>	Sponsor/Collaborators, Study Status, Baseline Characteristics and References
30	0	0	November 28, 2014	Study Status and References
Comp	are		Comparison Form	at: Merged Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: March 17, 2008 (v1)

Study Identification

Unique Protocol ID: 91689

Brief Title: VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and

https://clinicaltrials.gov/ct2/history/NCT00637377?A=1&B=1&C=merged#StudyPageTop

3/20

Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related

Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

311523 VIEW 2

Study Status

Record Verification: March 2008

Overall Status: Not yet recruiting

Study Start: March 2008

Primary Completion:

Study Completion: September 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that March 17, 2008

Met QC Criteria:

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that March 17, 2008

Met QC Criteria:

Last Update Posted: March 18, 2008 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators: Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

https://clinicaltrials.gov/ct2/history/NCT00637377? A=1&B=1&C=merged #StudyPageTop

4/20

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-

Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will

be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases

Vision Impairment and Blindness

Eyes and Vision

Seniors

Neovascular Age-Related Macular Degeneration (AMD)

Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms Assigned Interventions

https://clinicaltrials.gov/ct2/history/NCT00637377? A=1&B=1&C=merged #Study Page Top

DOCKET A L A R M

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

