1/7/2021



# ClinicalTrials.gov archive

### History of Changes for Study: NCT00509795

# Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Macular Degeneration(AMD) (VIEW1)

Latest version (submitted December 20, 2012) 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-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 versions
- 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	0	0	<u>July 31, 2007</u>	None (earliest Version on record)
2	0	0	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations



### 1/7/2021

Version	Α	В	Submitted Date	Changes
3	0	0	November 14, 2007	Contacts/Locations and Study Status
4	$\circ$	$\circ$	<u>December 4, 2007</u>	Study Status and Contacts/Locations
5	0	0	March 13, 2008	Study Status and Eligibility
6	0	$\circ$	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Mea Identification
7	0	0	<u>January 22, 2009</u>	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility Sponsor/Collaborators
8	•	0	March 3, 2009	Study Status and Contacts/Locations
9	0	<u></u>	<u>April 28, 2009</u>	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Stu
10	0	0	<u>September 12, 2009</u>	Recruitment Status, Study Status and Contacts/Locations
11	$\circ$	$\circ$	<u>December 1, 2009</u>	Study Status, Contacts/Locations and Sponsor/Collaborators
12	$\circ$	$\circ$	<u>January 5, 2011</u>	Study Status
13	0	0	<u>April 18, 2011</u>	Study Status and Study Design
14	0	0	<u>May 4, 2011</u>	Study Status
15	0	0	<u>December 1, 2011</u>	Recruitment Status, Study Status and Sponsor/Collaborators
16	0	0	<u>April 13, 2012</u>	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported & Baseline Characteristics, Participant Flow, Elig bility, Study Description and Study Identifi
17	0	0	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flo
18	0	0	<u>December 20, 2012</u>	Outcome Measures, References and Study Status

https://clinical trials.gov/ct2/history/NCT00509795? A=8&B=9&C=merged #Study Page Topton Annual Control of the Control of th



History of Changes for Study: NCT00509795

1/7/2021



Comparison Format:



O Side-by-Side

Scroll up to access the controls

Compare v7 to v8

Changes (Merged) for Study: NCT00509795 March 3, 2009 (v8) -- April 28, 2009 (v9)

Changes in: Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study

□ Show only changed modules

### Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Double Masked Study of Efficacy and Safety of IVT VECF Trap Eye in Subjects W

1) (VIEW1) Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of E

Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, S

Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovasci

Macular Degeneration

Secondary IDs:

### **Study Status**

Record Verification: March 2009 April 2009

Overall Status: Recruiting

Study Start: August 2007

Primary Completion: October 2010 December 2011 [Anticipated]

Study Completion: January 2012 December 2011 [Anticipated]

First Submitted: July 31, 2007



History of Changes for Study: NCT00509795

1/7/2021

First Submitted that July 31, 2007

Met QC Criteria:

First Posted: August 1, 2007 [Estimate]

Last Update Submitted that March 3, 2009 April 28, 2009

Met QC Criteria:

Last Update Posted: March 5 April 29, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Regeneron Pharmaceuticals

Responsible Party:

Collaborators: Bayer

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

**Study Description** 

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

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

be randomized in the US and Canada.

**Detailed Description:** 

**Conditions** 

Conditions: Neovascular Age Related Macular Degeneration

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment



History of Changes for Study: NCT00509795

1/7/2021

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
------	------------------------



# DOCKET

# 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.

