

1/7/2021

History of Changes for Study: NCT00509795

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Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related 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-by-Side format 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 selected.
- 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 | A | B | Submitted Date | Changes |
|---------|-----------------------|-----------------------|---------------------------------|---|
| 1 | <input type="radio"/> | <input type="radio"/> | July 31, 2007 | None (earliest Version on record) |
| 2 | <input type="radio"/> | <input type="radio"/> | August 17, 2007 | Recruitment Status, Study Status and Contacts/Locations |

<https://clinicaltrials.gov/ct2/history/NCT00509795?A=8&B=9&C=merged#StudyPageTop>

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| Version | A | B | Submitted Date | Changes |
|---------|----------------------------------|----------------------------------|------------------------------------|--|
| 3 | <input type="radio"/> | <input type="radio"/> | November 14, 2007 | Contacts/Locations and Study Status |
| 4 | <input type="radio"/> | <input type="radio"/> | December 4, 2007 | Study Status and Contacts/Locations |
| 5 | <input type="radio"/> | <input type="radio"/> | March 13, 2008 | Study Status and Eligibility |
| 6 | <input type="radio"/> | <input type="radio"/> | June 26, 2008 | Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Identification |
| 7 | <input type="radio"/> | <input type="radio"/> | January 22, 2009 | Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators |
| 8 | <input checked="" type="radio"/> | <input type="radio"/> | March 3, 2009 | Study Status and Contacts/Locations |
| 9 | <input type="radio"/> | <input checked="" type="radio"/> | April 28, 2009 | Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification |
| 10 | <input type="radio"/> | <input type="radio"/> | September 12, 2009 | Recruitment Status, Study Status and Contacts/Locations |
| 11 | <input type="radio"/> | <input type="radio"/> | December 1, 2009 | Study Status, Contacts/Locations and Sponsor/Collaborators |
| 12 | <input type="radio"/> | <input type="radio"/> | January 5, 2011 | Study Status |
| 13 | <input type="radio"/> | <input type="radio"/> | April 18, 2011 | Study Status and Study Design |
| 14 | <input type="radio"/> | <input type="radio"/> | May 4, 2011 | Study Status |
| 15 | <input type="radio"/> | <input type="radio"/> | December 1, 2011 | Recruitment Status, Study Status and Sponsor/Collaborators |
| 16 | <input type="radio"/> | <input type="radio"/> | April 13, 2012 | Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification |
| 17 | <input type="radio"/> | <input type="radio"/> | December 17, 2012 | Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow and Study Identification |
| 18 | <input type="radio"/> | <input type="radio"/> | December 20, 2012 | Outcome Measures, References and Study Status |

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Compare

Comparison Format: Merged
 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 Identifi](#)

Show only changed modules

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: ~~Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet Age-Related Macular Degeneration (AMD) (VIEW1)~~ *Vascular Endothelial Growth Factor(VEGF) Trap-Eye: Investigation of Efficacy and Safety in Subjects With Neovascular Age-Related Macular Degeneration (AMD) (VIEW1)*

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related 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

<https://clinicaltrials.gov/ct2/history/NCT00509795?A=8&B=9&C=merged#StudyPageTop>

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 safety of V...
Eye in patients with neovascular age-related macular degeneration. Approximately 1200 pa...
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

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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/NCT00509795?A=8&B=9&C=merged#StudyPageTop>

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