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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 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	0	0	<u>July 31, 2007</u>	None (earliest Version on record)
2	0	\bigcirc	<u>August 17, 2007</u>	Recruitment Status, Study Status and Contacts/Locations

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Version	Α	В	Submitted Date	Changes
3	\bigcirc	\bigcirc	November 14, 2007	Contacts/Locations and Study Status
4	\bigcirc	0	December 4, 2007	Study Status and Contacts/Locations
5	\bigcirc	\bigcirc	<u>March 13, 2008</u>	Study Status and Eligibility
6	\bigcirc	\bigcirc	<u>June 26, 2008</u>	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	\bigcirc	0	<u>January 22, 2009</u>	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	۲	0	<u>March 3, 2009</u>	Study Status and Contacts/Locations
9	\bigcirc	۲	<u>April 28, 2009</u>	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	\bigcirc	0	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	\bigcirc	\bigcirc	<u>December 1, 2009</u>	Study Status, Contacts/Locations and Sponsor/Collaborators
12	\bigcirc	0	<u>January 5, 2011</u>	Study Status
13	\bigcirc	\bigcirc	<u>April 18, 2011</u>	Study Status and Study Design
14	\bigcirc	0	<u>May 4, 2011</u>	Study Status
15	\bigcirc	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 Adverse Events Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	\bigcirc	0	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow and Study St
18	0	0	December 20, 2012	Outcome Measures, References and Study Status

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021		History of Changes for Study: NCT00509795						
Compare Co	omparison Format:	ison Format: O Side-by-Side						
Scroll up to access the controls								
Compare v7 to v8	С	Changes (Merged) for Study: NCT00509795 March 3, 2009 (v8) April 28, 2009 (v9)	Compare v9 to v10					
Changes in: <u>Outco</u>	<u>me Measures, Arms</u>	and Interventions, Study Status, Eligibility, Conditions and Stu	<u>Idy Identification</u>					
	□ Show only changed modules							
Study Identification								
Unique Proto	col ID: VGFT-OD-06	305						
Brie	<mark>1) (VIEW1)</mark> V	 Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1) (VIEW1) Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1) 						
Officia		ed, Double Masked, Active Controlled Phase III Study of the Efficacy f Repeated Doses of Intravitreal VEGF Trap in Subjects With Neova eneration	-					
Seconda	ry IDs:							
Study Status								
Record Verifi	cation: March 2009	April 2009						
Overall	Status: Recruiting	Recruiting						
Study	y Start: August 2007	August 2007						
Primary Com	oletion: October 2010	December 2011 [Anticipated]						
Study Com	oletion: January 2012	2- December 2011 [Anticipated]						
First Sub	mitted: July 31, 2007	7						

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

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