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## AFFIDAVIT OF DUNCAN HALL

1. I am a Records Request Processor at the Internet Archive, located in San Francisco, California. I make this declaration of my own personal knowledge.
2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.
3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to browse more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a display of available dates. The visitor may select one of those dates, and begin browsing an archived version of the Web. Links on archived files in the Wayback Machine point to other archived files (whether HTML pages or other file types), if any are found for the URL indicated by a given link. For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file containing the hyperlink.
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5. The Internet Archive assigns a URL on its site to the archived files in the format `http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL]` aka an "extended URL". Thus, the extended URL `http://web.archive.org/web/19970126045828/http://www.archive.org/` would be the URL for the record of the Internet Archive home page HTML file (`http://www.archive.org/`) archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28). A web browser may be set such that a printout from it will display the URL of a web page in the printout's footer. The date indicated by an extended URL applies to a preserved instance of a file for a given URL, but not necessarily to any other files linked therein. Thus, in the case of a page constituted by a primary HTML file and other separate files (e.g., files with images, audio, multimedia, design elements, or other embedded content) linked within that primary HTML file, the primary HTML file and the other files will each have their own respective extended URLs and may not have been archived on the same dates.



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7. I declare under penalty of perjury that the foregoing is true and correct.

DATE: 01/27/2021

*Duncan Hall*  
Duncan Hall

# EXHIBIT A

<https://web.archive.org/web/20090813064936/https://clinicaltrials.gov/ct2/show/NCT00637377>

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[No Study Results Posted](#)

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Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

This study is currently recruiting participants.

Verified by Bayer, July 2009

First Received: March 12, 2008 Last Updated: July 3, 2009 [History of Changes](#)

|                                       |             |
|---------------------------------------|-------------|
| <b>Sponsored by:</b>                  | Bayer       |
| <b>Information provided by:</b>       | Bayer       |
| <b>ClinicalTrials.gov Identifier:</b> | NCT00637377 |

► Purpose

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.

| <a href="#">Condition</a> | <a href="#">Intervention</a>             | <a href="#">Phase</a> |
|---------------------------|------------------------------------------|-----------------------|
| Macular Degeneration      | Drug: VEGF Trap-Eye<br>Drug: Ranibizumab | Phase III             |

Study Type: Interventional

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

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration (AMD).

Resource links provided by NLM:

[Genetics Home Reference](#) related topics: [X-linked juvenile retinoschisis](#)

[MedlinePlus](#) related topics: [Macular Degeneration](#)

[Drug Information](#) available for: [Ranibizumab](#) [Aflibercept](#)

[U.S. FDA Resources](#)

Further study details as provided by Bayer:

Primary Outcome Measures:

- The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss) [ Time Frame: week 52 ] [ Designated as safety issue: Yes ]

Secondary Outcome Measures:

- Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52 [ Time Frame: week 52 ] [ Designated as safety issue: Yes ]
- The proportion of subjects who gain at least 15 letters of vision at Week 52 [ Time Frame: week 52 ] [ Designated as safety issue: No ]
- Mean change from baseline in total NEI VFQ-25 score at Week 52 [ Time Frame: week 52 ] [ Designated as safety issue: No ]
- Mean change from baseline in CNV area at Week 52 [ Time Frame: week 52 ] [ Designated as safety issue: Yes ]

Estimated Enrollment: 1200

Study Start Date: April 2008

Estimated Study Completion Date: September 2011

Estimated Primary Completion Date: July 2011 (Final data collection date for primary outcome measure)

| <a href="#">Arms</a>   | <a href="#">Assigned Interventions</a>                                                                                                                                                                                                                           |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Arm 3:<br>Experimental | Drug: VEGF Trap-Eye<br>2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2.0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. |
| Arm 1:<br>Experimental | Drug: VEGF Trap-Eye<br>0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.                                                  |
| Arm 2:<br>Experimental | Drug: VEGF Trap-Eye<br>2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.                                                  |

|                          |                                                                                                                                                                                                 |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                          | less frequently than every 12 weeks.                                                                                                                                                            |
| Arm 4: Active Comparator | Drug: Ranibizumab<br>0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. |

## ► Eligibility

Ages Eligible for Study: 50 Years and older  
 Genders Eligible for Study: Both  
 Accepts Healthy Volunteers: No

## Criteria

### Inclusion Criteria:

- Signed informed consent.
- Men and women  $\geq$ 50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

### Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.
- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size  $>12$  disc areas (30.5 mm<sup>2</sup>; including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up  $>50\%$  of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

## ► Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00637377

### Contacts

Contact: Bayer Clinical Trials Contact [clinical-trials-contact@bayerhealthcare.com](mailto:clinical-trials-contact@bayerhealthcare.com)

 [Show 212 Study Locations](#)

### Sponsors and Collaborators

#### Bayer

### Investigators

Study Director: Bayer Study Director Bayer

## ► More Information

### Additional Information:

[Click here and search for drug information provided by the FDA](#) 

[Click here and search for information on any recalls, market or product safety alerts by the FDA which might have occurred with this product](#) 

[Click here to find results for studies related to marketed products](#) 

No publications provided

Responsible Party: Bayer Schering Pharma AG ( Therapeutic Area Head )  
 Study ID Numbers: 91689, EurdaCT No.: 2007-000583-25  
 Study First Received: March 12, 2008  
 Last Updated: July 3, 2009  
 ClinicalTrials.gov Identifier: [NCT00637377](#) [History of Changes](#)  
 Health Authority: Switzerland: Ethikkommission

Keywords provided by Bayer:

Eye diseases  
Vision Impairment and Blindness  
Eyes and Vision

Seniors  
Neovascular Age-Related Macular Degeneration (AMD)  
Retinal Disease

Study placed in the following topic categories:

Eye Diseases  
Mitogens  
Retinal Degeneration  
Macular Degeneration

Blindness  
Endothelial Growth Factors  
Retinal Diseases  
Vision, Low

Additional relevant MeSH terms:

Growth Substances  
Eye Diseases  
Physiological Effects of Drugs  
Retinal Degeneration

Macular Degeneration  
Endothelial Growth Factors  
Pharmacologic Actions  
Retinal Diseases

ClinicalTrials.gov processed this record on August 12, 2009

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[Links to all studies - primarily for crawlers](#)

<https://web.archive.org/web/20090911163626/https://clinicaltrials.gov/ct2/show/NCT00509795>

## Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW 1)

**This study is currently recruiting participants.**

Verified by Regeneron Pharmaceuticals, April 2009

First Received: July 31, 2007 Last Updated: April 28, 2009 [History of Changes](#)

|                                |                                    |
|--------------------------------|------------------------------------|
| Sponsors and Collaborators:    | Regeneron Pharmaceuticals<br>Bayer |
| Information provided by:       | Regeneron Pharmaceuticals          |
| ClinicalTrials.gov Identifier: | NCT00509795                        |

### Purpose

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.

| Condition            | Intervention                             | Phase     |
|----------------------|------------------------------------------|-----------|
| Macular Degeneration | Drug: VEGF Trap-Eye<br>Drug: Ranibizumab | Phase III |

Study Type: Interventional

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

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

### Resource links provided by NLM:

[Genetics Home Reference](#) related topics: [X-linked juvenile retinoschisis](#)

[MedlinePlus](#) related topics: [Macular Degeneration](#)

[Drug Information](#) available for: [Ranibizumab](#) [Aflibercept](#)

[U.S. FDA Resources](#)

### Further study details as provided by Regeneron Pharmaceuticals:

#### Primary Outcome Measures:

- The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (i.e. prevention of moderate vision loss) [ Time Frame: Week 52 ] [ Designated as safety issue: Yes ]

#### Secondary Outcome Measures:

- Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52 [ Time Frame: Week 52 ] [ Designated as safety issue: Yes ]
- The proportion of subjects who gain at least 15 letters of vision at Week 52 [ Time Frame: Week 52 ] [ Designated as safety issue: No ]
- Mean change from baseline in total NEI VFQ-25 score at Week 52 [ Time Frame: Week 52 ] [ Designated as safety issue: No ]
- Mean change from baseline in CNV area at Week 52 [ Time Frame: Week 52 ] [ Designated as safety issue: Yes ]

Estimated Enrollment: 1200  
Study Start Date: August 2007  
Estimated Study Completion Date: December 2011  
Estimated Primary Completion Date: December 2011 (Final data collection date for primary outcome measure)

| Arms                    | Assigned Interventions                                                                                                                                                                                                                                           |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1:<br>Experimental      | Drug: VEGF Trap-Eye<br>0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.                                                  |
| 2:<br>Experimental      | Drug: VEGF Trap-Eye<br>2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.                                                  |
| 3:<br>Experimental      | Drug: VEGF Trap-Eye<br>2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2.0 mg dose at week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. |
| 4: Active<br>Comparator | Drug: Ranibizumab<br>0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.                                                                  |

## Eligibility

Ages Eligible for Study: 50 Years and older  
Genders Eligible for Study: Both  
Accepts Healthy Volunteers: No

## Criteria

### Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women  $\geq$  50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

### Key Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size > 12 disc areas (30.5 mm<sup>2</sup>, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina, other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.
15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

## Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00509795

### Contacts

Contact: Regeneron 866-549-8439 [VIEW1study@rtp.ppd.com](mailto:VIEW1study@rtp.ppd.com)

### Show 191 Study Locations

### Sponsors and Collaborators

#### Regeneron Pharmaceuticals

Bayer

### Investigators

Study Director: Avner Ingerman, MD Regeneron Pharmaceuticals

## More Information

No publications provided

Responsible Party: Regeneron Pharmaceuticals ( Dr. Avner Ingerman )  
Study ID Numbers: VGFT-OD-0605  
Study First Received: July 31, 2007  
Last Updated: April 28, 2009  
ClinicalTrials.gov Identifier: [NCT00509795](#) [History of Changes](#)  
Health Authority: United States: Food and Drug Administration; Canada: Health Canada

Study placed in the following topic categories:

Eye Diseases  
Mitogens  
Retinal Degeneration

Macular Degeneration  
Endothelial Growth Factors  
Retinal Diseases

Additional relevant MeSH terms:

Growth Substances  
Eye Diseases  
Physiological Effects of Drugs  
Retinal Degeneration

Macular Degeneration  
Endothelial Growth Factors  
Pharmacologic Actions  
Retinal Diseases

ClinicalTrials.gov processed this record on September 11, 2009

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## JURAT

State/Commonwealth of FLORIDA

☐ City ☒ County of Broward )

On 01/27/2021, before me, Mikhail Clarke,  
*Date Notary Name*

the foregoing instrument was subscribed and sworn (or affirmed) before me by:

## Duncan Hall

*Name of Affiant(s)*

☐ Personally known to me -- OR --

☐ Proved to me on the basis of the oath of \_\_\_\_\_ -- OR --  
*Name of Credible Witness*

☒ Proved to me on the basis of satisfactory evidence: driver\_license  
Type of ID Presented



Notarized online using audio-video communication

WITNESS my hand and official seal.

Notary Public Signature: 

Notary Name: Mikhail Clarke

Notary Commission Number: HH7610

Notary Commission Expires: 06/08/2024

*Notarized online using audio-video communication*

### DESCRIPTION OF ATTACHED DOCUMENT

Title or Type of Document: Affidavit of Authenticity

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