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*Duncan D Hall*  
Duncan Hall

# EXHIBIT A

<https://web.archive.org/web/20110408231012/http://clinicaltrials.gov/ct2/show/NCT0101297>

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## Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO) (GALILEO)

**This study is ongoing, but not recruiting participants.**

First Received on October 30, 2009. Last Updated on January 25, 2011 [History of Changes](#)

|                                |                           |
|--------------------------------|---------------------------|
| Sponsor:                       | Bayer                     |
| Collaborator:                  | Regeneron Pharmaceuticals |
| Information provided by:       | Bayer                     |
| ClinicalTrials.gov Identifier: | NCT01012973               |

### Purpose

To determine the efficacy of vascular endothelial growth factor (VEGF) Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion

| Condition              | Intervention                                              | Phase     |
|------------------------|-----------------------------------------------------------|-----------|
| Retinal Vein Occlusion | Drug: VEGF Trap-Eye (BAY86-5321)<br>Other: Sham treatment | Phase III |

Study Type: Interventional  
Study Design: Allocation: Randomized  
Endpoint Classification: Safety/Efficacy Study  
Intervention Model: Parallel Assignment  
Masking: Double Blind (Subject, Investigator, Outcomes Assessor)  
Primary Purpose: Treatment

Official Title: A Randomized, Double-masked, Sham-controlled Phase 3 Study of the Efficacy, Safety and Tolerability of Repeated Intravitreal Administration of VEGF Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion (CRVO)

### Resource links provided by NLM:

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

[MedlinePlus](#) related topics: [Edema](#)

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

[U.S. FDA Resources](#)

### Further study details as provided by Bayer:

#### Primary Outcome Measures:

- The proportion of subjects who gain at least 15 letters in BCVA on the EDTRS chart compared with baseline at the Week 24 endpoint [ Time Frame: Week 24 ] [ Designated as safety issue: No ]

#### Secondary Outcome Measures:

- Change from baseline in BCVA score [ Time Frame: week 24 ] [ Designated as safety issue: No ]
- Absolute change from baseline in central retinal thickness, assessed by OCT [ Time Frame: Week 24 ] [ Designated as safety issue: No ]
- Proportion of subjects progressing to anterior segment neovascularization, neovascularization of the optic disc (NVD), or neovascularization of the retina elsewhere (NVE) requiring pan-retinal photocoagulation [ Time Frame: Week 24 ] [ Designated as safety issue: No ]
- Change in the NEI-VFQ-25 total score from baseline [ Time Frame: Week 24 ] [ Designated as safety issue: No ]
- Change in the EQ-5D score from baseline [ Time Frame: Week 24 ] [ Designated as safety issue: No ]

Estimated Enrollment: 165  
Study Start Date: October 2009  
Estimated Study Completion Date: March 2012  
Estimated Primary Completion Date: February 2011 (Final data collection date for primary outcome measure)

| Arms                                                                               | Assigned Interventions                                                                                                                                                                                                                                                                                                                                                     |
|------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Arm 1: Experimental<br>Intervention:<br>Drug: VEGF<br>Trap-Eye<br>(BAY86-<br>5321) | Drug: VEGF Trap-Eye (BAY86-5321)<br>Intravitreal injection. Weeks 0 to 20 injection of VEGF Trap-Eye every 4 weeks; weeks 24 to 52 every 4 weeks plus additional on week 60 and 68 re-assessment and either (PRN) injection of VEGF Trap-Eye or sham injection; last visit (no treatment) at week 76.                                                                      |
| Arm 2: Sham<br>Comparator<br>Intervention:<br>Other: Sham<br>treatment             | Other: Sham treatment<br>Sham treatment. Weeks 0 to 20 sham treatment every 4 weeks; weeks 24 to 48 every 4 weeks re-assessment and sham injection; week 52 VEGF Trap-Eye injection (unless investigator declines for medical reasons), weeks 60 and 68 re-assessment and either (PRN) injection of VEGF Trap-Eye or sham injection; last visit (no treatment) at week 76. |

## ► Eligibility

Ages Eligible for Study: 18 Years and older  
Genders Eligible for Study: Both  
Accepts Healthy Volunteers: No

### Criteria

#### Inclusion Criteria:

- Center-involved macular edema secondary to central retinal vein occlusion (CRVO) for no longer than 9 months with mean central subfield thickness  $\geq 250 \mu\text{m}$  on optical coherence tomography (OCT)
- Adults  $\geq 18$  years
- early treatment diabetic retinopathy study (ETDRS) best corrected visual acuity (BCVA) of 20/40 to 20/320 (73 to 24 letters) in the study eye

#### Exclusion Criteria:

- Any prior treatment with anti-VEGF agents in the study eye (Pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc.) or previous administration of systemic anti-angiogenic medications
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration  $> 9$  months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

## ► Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01012973

[+ Show 73 Study Locations](#)

### Sponsors and Collaborators

Bayer  
Regeneron Pharmaceuticals

### Investigators

Study Director: Bayer Study Director Bayer

## ► More Information

#### Additional Information:

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

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

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

No publications provided

Responsible Party: Bayer HealthCare AG ( Therapeutic Area Head )

ClinicalTrials.gov Identifier: [NCT01012973](#) [History of Changes](#)

Other Study ID Numbers: 14130, EudraCT: 2009-010973-19

Study First Received: October 30, 2009

Last Updated: January 25, 2011

Health Authority: Germany: Federal Institute for Drugs and Medical Devices; Australia: Department of Health and Ageing Therapeutic Goods Administration; Austria: Agency for Health and Food Safety; France: Afssaps - French Health Products Safety Agency; Hungary: National Institute of Pharmacy; Italy: Ministry of Health; Latvia: State Agency of Medicines; Japan: Pharmaceuticals and Medical Devices Agency; Singapore: Health Sciences Authority; South Korea: Korea Food and Drug Administration (KFDA)

#### Keywords provided by Bayer:

Macular Edema  
Central Retinal Vein Occlusion  
CRVO  
VEGF Trap-Eye  
best-corrected visual acuity

#### Additional relevant MeSH terms:

Macular Edema  
Retinal Vein Occlusion  
Macular Degeneration  
Retinal Degeneration  
Retinal Diseases  
Eye Diseases  
Venous Thrombosis  
Thrombosis

Embolism and Thrombosis  
Vascular Diseases  
Cardiovascular Diseases  
Endothelial Growth Factors  
Growth Substances  
Physiological Effects of Drugs  
Pharmacologic Actions

ClinicalTrials.gov processed this record on April 07, 2011

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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](#)

|                                |             |
|--------------------------------|-------------|
| Sponsored by:                  | Bayer       |
| Information provided by:       | Bayer       |
| ClinicalTrials.gov Identifier: | 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.

| 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 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)

| Arms                        | Assigned Interventions                                                                                                                                                                                                                                           |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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.                                                  |
| Arm 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

##### 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 periorcular 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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# 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: 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: 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: 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 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 periorbital 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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 )  
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On 01/20/2021, before me, William Scott,  
*Date* *Notary Name*

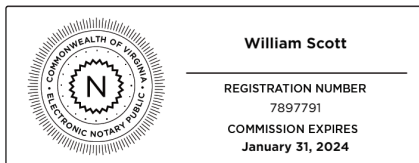
the foregoing instrument was subscribed and sworn (or affirmed) before me by:

Duncan D 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*



WITNESS my hand and official seal.

Notary Public Signature: William Scott

Notary Name: William Scott

Notary Commission Number: 7897791

Notary Commission Expires: 01/31/2024

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