

History of Changes for Study: NCT00509795**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	A	B	Submitted Date	Changes
1	☐	☐	July 31, 2007	None (earliest Version on record)
2	☐	☐	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations

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

CompareComparison Format: ☒ Merged
☐ Side-by-Side[Scroll up to access the controls](#)**Changes (Merged) for Study: NCT00509795**

Compare v7 to v8

March 3, 2009 (v8) -- April 28, 2009 (v9)

Compare v9 to v10

Changes in: [Outcome Measures](#), [Arms and Interventions](#), [Study Status](#), [Eligibility](#), [Conditions](#) and [Study Identification](#)☐ 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 AMD (VIEW 4) (VIEW1)~~ *Vascular Endothelial Growth Factor(VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet 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 StatusRecord 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

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

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

Arms	Assigned Interventions
Experimental: 1	Drug: VEGF Trap-Eye <i>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.</i> Drug: VEGF Trap-Eye VGFT-OD-0605 is a double-masked, randomized, Phase III study. Subjects will be rand. assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) 2mg VEGF Trap-Eye adm. every 4 wks (2Q4), 2) 0.5mg VEGF Trap-Eye adm. every 4 wks (0.5Q4), 3) 2mg VEGF Trap-Eye adm. every 8 wks (2Q8), and 4) 0.5mg ranibizumab adm. every 4 wks (RQ4); subj. assigned to (2Q8) will receive the 2mg injection every 4 wks to wk 8 & then a sham inject at interim 4-wk visits (when study drug is not to be adm) during the first 52 wks of the study. VEGF Trap-Eye will be supplied in sealed 3mL single use vials each with a "withdrawable" vol. of approx. 0.5 mL at a concentration of 10mg/mL or 40 mg/mL. VEGF Trap-Eye will be withdrawn using aseptic technique through an 18 "gauge" needle attached to a 1 mL syringe. The syringe needle will then be removed and replaced with a 30 gauge needle to be used for the ITV inject. The inject. vol. will be 50µL (0.05 mL) for the 0.5mg & 2mg doses of VEGF Trap-Eye and 0.5 mg ranibizumab

Arms	Assigned Interventions
Experimental: 2	Drug: VEGF Trap-Eye 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. Drug: VEGF Trap-Eye VGFT-OD-0605 is a double-masked, randomized, Phase III study. Subjects will be rand. assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) 2mg VEGF Trap-Eye adm. every 4 wks (2Q4), 2) 0.5mg VEGF Trap-Eye adm. every 4 wks (0.5Q4), 3) 2mg VEGF Trap-Eye adm. every 8 wks (2Q8), and 4) 0.5mg ranibizumab adm. every 4 wks (RQ4); subj. assigned to (2Q8) will receive the 2mg injection every 4 wks to wk 8 & then a sham inject at interim 4-wk visits (when study drug is not to be adm) during the first 52 wks of the study. VEGF Trap-Eye will be supplied in sealed 3mL single use vials each with a "withdrawable" vol. of approx. 0.5 mL at a concentration of 10mg/mL or 40 mg/mL. VEGF Trap-Eye will be withdrawn using aseptic technique through an 18 "gauge" needle attached to a 1 mL syringe. The syringe needle will then be removed and replaced with a 30 gauge needle to be used for the ITV inject. The inject. vol. will be 50µL (0.05 mL) for the 0.5mg & 2mg doses of VEGF Trap-Eye and 0.5 mg ranibizumab

Arms	Assigned Interventions
Experimental: 3	Drug: VEGF Trap-Eye 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. Drug: VEGF Trap-Eye VGFT-OD-0605 is a double-masked, randomized, Phase III study. Subjects will be rand. assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens: 1) 2mg VEGF Trap-Eye adm. every 4 wks (2Q4); 2) 0.5mg VEGF Trap-Eye adm. every 4 wks (0.5Q4); 3) 2mg VEGF Trap-Eye adm. every 8 wks (2Q8); and 4) 0.5mg ranibizumab adm. every 4 wks (RQ4); subj. assigned to (2Q8) will receive the 2mg injection every 4 wks to wk 8 & then a sham inject at interim 4-wk visits (when study drug is not to be adm) during the first 52 wks of the study. VEGF Trap-Eye will be supplied in sealed 3mL single use vials each with a "withdrawable" vol. of approx. 0.5 mL at a concentration of 10mg/mL or 40 mg/mL. VEGF Trap-Eye will be withdrawn using aseptic technique through an 18 "gauge" needle attached to a 1 mL syringe. The syringe needle will then be removed and replaced with a 30 gauge needle to be used for the ITV inject. The inject. vol. will be 50µL (0.05 mL) for the 0.5mg & 2mg doses of VEGF Trap-Eye and 0.5 mg ranibizumab
Active Comparator: 4	Drug: Comparator Drug: ranibizumab 0.5 mg ranibizumab adm. every 4 wks (RQ4); 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.

Outcome Measures

Primary Outcome Measures:

1. ~~Primary measure will be visual acuity changes compared to baseline.~~ *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)*
~~Monthly~~ *Week 52*

Secondary Outcome Measures:

2. *Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52*
Week 52
3. *The proportion of subjects who gain at least 15 letters of vision at Week 52*
Week 52
4. *Mean change from baseline in total NEI VFQ-25 score at Week 52*
Week 52
5. ~~Secondary measures will be angiographic and anatomical changes compared to baseline.~~ *Mean change from baseline in CNV area at Week 52*
~~as dictated by protocol~~ *Week 52*

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: ~~Yes~~ *No*

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 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. ~~CNV must be at least 50% of total lesion size.~~

5. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
6. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
7. 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. ~~Prior treatment with anti-VEGF agents as follows:~~
 - ~~o Prior treatment with anti-VEGF therapy in the study eye is not allowed.~~
 - ~~o Prior treatment with anti-VEGF therapy in the fellow eye with an investigational agent (not FDA approved, e.g. bevacizumab) is allowed up to 3 months prior to first dose in the study, and such treatment will not be allowed during the study. Prior treatment with an FDA/Health Canada approved anti-VEGF therapy in the fellow eye is allowed.~~
 - ~~o Prior systemic anti-VEGF therapy, investigational or FDA/Health Canada approved, is only allowed up to 3 months prior to first dose, and will not be allowed during the study~~
5. Total lesion size > 12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
6. 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.)
7. Scar or fibrosis, making up > 50% of total lesion in the study eye.
8. Scar, fibrosis, or atrophy involving the center of the fovea.
9. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
10. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
11. ~~Presence of other causes of CNV, including pathologic myopia (spherical equivalent of -8 diopters or more negative, or axial length of 25 mm or more), ocular histoplasmosis syndrome,~~

~~angioid streaks, choroidal rupture, or multifocal choroiditis in the study eye.~~ *Presence of other causes of CNV in the study eye.*

12. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina, other than AMD, in either eye.
13. Prior vitrectomy in the study eye.
14. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
15. Any history of macular hole of stage 2 and above in the study eye.
16. 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/Locations

Central Contact: Regeneron

Telephone: 866-549-8439

Email: VIEW1study@rtp.ppdi.com

Study Officials: Avner Ingerman, MD

Study Director

Regeneron Pharmaceuticals

Locations: **United States, Alabama**

[Recruiting]

Birmingham, Alabama, United States, 35205

[Recruiting]

Birmingham, Alabama, United States, 35223

United States, Arizona

[Recruiting]

Phoenix, Arizona, United States, 85014

[Recruiting]

Phoenix, Arizona, United States, 85020

[Recruiting]

Tucson, Arizona, United States, 85704

[Recruiting]

Tucson, Arizona, United States, 85710

United States, California

[Recruiting]

Beverly Hills, California, United States, 90211

[Recruiting]

Campbell, California, United States, 95008

[Recruiting]

Fullerton, California, United States, 92835

[Terminated]

Glendale, California, United States, 91203

[Recruiting]

Irvine, California, United States, 92697

[Recruiting]

La Jolla, California, United States, 92037

[Recruiting]

Loma Linda, California, United States, 92354

[Withdrawn]

Los Angeles, California, United States, 90033

[Recruiting]

Los Angeles, California, United States, 90048

[Recruiting]

Menlo Park, California, United States, 94025

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Oakland, California, United States, 94609

[Recruiting]

Palm Springs, California, United States, 92262

[Recruiting]

Pasadena, California, United States, 91105

[Withdrawn]

Poway, California, United States, 92064

[Recruiting]

Sacramento, California, United States, 95819

[Active, not recruiting]

San Diego, California, United States, 92120

[Terminated]

San Francisco, California, United States, 94107

[Recruiting]

Santa Ana, California, United States, 92705

[Recruiting]

Torrance, California, United States, 90503

[Withdrawn]

Ventura, California, United States, 93003

[Recruiting]

Westlake Village, California, United States, 91361

[Recruiting]

Yorba Linda, California, United States, 92887

United States, Colorado

[Terminated]

Aurora, Colorado, United States, 80045

[Recruiting]

Denver, Colorado, United States, 80205

[Withdrawn]

Denver, Colorado, United States, 80205

[Withdrawn]

Denver, Colorado, United States, 80230

United States, Connecticut

[Recruiting]

Bridgeport, Connecticut, United States, 06606

[Withdrawn]

Hamden, Connecticut, United States, 06518

[Active, not recruiting]

New Haven, Connecticut, United States, 06510

[Recruiting]

New London, Connecticut, United States, 06320

United States, Florida

[Recruiting]

Altamonte Springs, Florida, United States, 32701

[Recruiting]

Boynton Beach, Florida, United States, 33426

[Recruiting]

Fort Myers, Florida, United States, 33907

[Withdrawn]

Ft. Lauderdale, Florida, United States, 33351

[Recruiting]

Ft. Myers, Florida, United States, 33912

[Withdrawn]

Gainesville, Florida, United States, 32610

[Recruiting]

Jacksonville, Florida, United States, 32224

[Withdrawn]

Miami, Florida, United States, 33136

[Recruiting]

Miami, Florida, United States, 33143

[Terminated]

Mount Dora, Florida, United States, 32757

[Recruiting]

Orlando, Florida, United States, 32803

[Recruiting]

Orlando, Florida, United States, 32806

[Recruiting]

Oscala, Florida, United States, 34472

[Recruiting]

Palm Beach Gardens, Florida, United States, 33410

[Recruiting]

Pensacola, Florida, United States, 32503

[Withdrawn]

Sarasota, Florida, United States

[Recruiting]

Stuart, Florida, United States, 34994

[Recruiting]

Tampa, Florida, United States, 33612

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Georgia

[Recruiting]

Augusta, Georgia, United States, 30909

United States, Hawaii

[Recruiting]

Aiea, Hawaii, United States, 96701

[Withdrawn]

Honolulu, Hawaii, United States, 96813

United States, Illinois

[Recruiting]

Oak Brook, Illinois, United States, 60523

United States, Indiana

[Recruiting]

Fort Wayne, Indiana, United States, 46804

[Recruiting]

Indianapolis, Indiana, United States, 46202

[Terminated]

Indianapolis, Indiana, United States, 46260

[Recruiting]

Indianapolis, Indiana, United States, 46280

[Recruiting]

New Albany, Indiana, United States, 47150

United States, Iowa

[Recruiting]

Iowa City, Iowa, United States, 52242-1091

United States, Kansas

[Recruiting]

Wichita, Kansas, United States, 67214

United States, Kentucky

[Recruiting]

Louisville, Kentucky, United States, 40202

[Recruiting]

Louisville, Kentucky, United States, 40207

[Terminated]

Paducah, Kentucky, United States, 42001

United States, Louisiana

[Recruiting]

New Orleans, Louisiana, United States, 70115

[Recruiting]

New Orleans, Louisiana, United States, 70121

[Terminated]

Shreveport, Louisiana, United States, 71105

United States, Maine

[Recruiting]

Bangor, Maine, United States, 04401

[Recruiting]

Portland, Maine, United States, 04102

United States, Maryland

[Recruiting]

Baltimore, Maryland, United States, 21209

[Recruiting]

Baltimore, Maryland, United States, 21287

[Recruiting]

Chevy Chase, Maryland, United States, 20815

[Recruiting]

Hagerstown, Maryland, United States, 21740

[Recruiting]

Towson, Maryland, United States, 21204

United States, Massachusetts

[Withdrawn]

Boston, Massachusetts, United States, 02111

[Recruiting]

Boston, Massachusetts, United States, 02114

[Recruiting]

Boston, Massachusetts, United States, 02215

[Withdrawn]

Boston, Massachusetts, United States

[Recruiting]

Peabody, Massachusetts, United States, 01960

United States, Michigan

[Recruiting]

Ann Arbor, Michigan, United States, 48105

[Recruiting]

Battle Creek, Michigan, United States, 49015

[Active, not recruiting]

Detroit, Michigan, United States, 48202

[Recruiting]

Grand Rapids, Michigan, United States, 49525

[Recruiting]

Jackson, Michigan, United States, 49201

[Recruiting]

Royal Oak, Michigan, United States, 48073

[Recruiting]

Southfield, Michigan, United States, 48034

[Withdrawn]

West Bloomfield, Michigan, United States, 48322

United States, Minnesota

[Withdrawn]

Edina, Minnesota, United States, 55435

[Recruiting]

Minneapolis, Minnesota, United States, 55404

[Recruiting]

Rochester, Minnesota, United States, 55905

United States, Missouri

[Recruiting]

Florissant, Missouri, United States, 63031

[Recruiting]

Kansas City, Missouri, United States, 64108

[Withdrawn]

Kansas City, Missouri, United States, 64111

[Recruiting]

Springfield, Missouri, United States, 65804

[Recruiting]

St. Louis, Missouri, United States, 63110

United States, Montana

[Recruiting]

Missoula, Montana, United States, 59801

United States, Nebraska

[Recruiting]

Lincoln, Nebraska, United States, 68506

[Withdrawn]

Omaha, Nebraska, United States, 68131

United States, Nevada

[Recruiting]

Las Vegas, Nevada, United States, 89144

United States, New Jersey

[Recruiting]

Lawrenceville, New Jersey, United States, 08648

[Terminated]

New Brunswick, New Jersey, United States, 08901

[Recruiting]

Northfield, New Jersey, United States, 08225

[Withdrawn]

Teaneck, New Jersey, United States, 07666

[Recruiting]

Toms River, New Jersey, United States, 08753

United States, New Mexico

[Recruiting]

Albuquerque, New Mexico, United States, 87106

United States, New York

[Recruiting]

Albany, New York, United States, 12206

[Recruiting]

Brooklyn, New York, United States, 11223

[Recruiting]

Lynbrook, New York, United States, 11563

[Recruiting]

New York, New York, United States, 10003

[Recruiting]

New York, New York, United States, 10021

[Recruiting]

New York, New York, United States, 10032

[Terminated]

Poughkeepsie, New York, United States, 12601

[Recruiting]

Rochester, New York, United States, 14620

[Recruiting]

Rochester, New York, United States, 14642

[Recruiting]

Slingerlands, New York, United States, 12159

[Recruiting]

Syracuse, New York, United States, 13224

United States, North Carolina

[Recruiting]

Asheville, North Carolina, United States, 28803

[Recruiting]

Charlotte, North Carolina, United States, 28210

[Recruiting]

Raleigh, North Carolina, United States, 27607

[Terminated]

Southern Pines, North Carolina, United States, 28387

[Recruiting]

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

[Withdrawn]

Cincinnati, Ohio, United States, 45202

[Recruiting]

Cincinnati, Ohio, United States, 45242

[Terminated]

Columbus, Ohio, United States, 43215

[Terminated]

Toledo, Ohio, United States, 43608

United States, Oklahoma

[Recruiting]

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

[Recruiting]

Ashland, Oregon, United States, 97520

[Recruiting]

Portland, Oregon, United States, 97210

[Recruiting]

Portland, Oregon, United States, 97227

[Recruiting]

Salem, Oregon, United States, 97302

United States, Pennsylvania

[Recruiting]

Kingston, Pennsylvania, United States, 18704

[Active, not recruiting]

Philadelphia, Pennsylvania, United States, 19104

[Recruiting]

Philadelphia, Pennsylvania, United States, 19107

[Recruiting]

Philadelphia, Pennsylvania, United States, 19124

[Recruiting]

Pittsberg, Pennsylvania, United States, 15231

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15212

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15213

[Recruiting]

West Mifflin, Pennsylvania, United States, 15122

[Withdrawn]

Wyomissing, Pennsylvania, United States, 19610

United States, Rhode Island

[Recruiting]

Providence, Rhode Island, United States, 02903-4928

United States, South Carolina

[Recruiting]

Charleston, South Carolina, United States, 29414

[Recruiting]

Columbia, South Carolina, United States, 29223

[Recruiting]

Greenville, South Carolina, United States, 29605

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, South Dakota

[Recruiting]

Rapid City, South Dakota, United States, 57701

United States, Tennessee

[Terminated]

Memphis, Tennessee, United States, 38119

[Terminated]

Memphis, Tennessee, United States, 38120

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Austin, Texas, United States, 78705

[Active, not recruiting]

Corpus Cristi, Texas, United States, 78413

[Recruiting]

Dallas, Texas, United States, 75390

[Terminated]

DeSoto, Texas, United States, 75115

[Recruiting]

Ft. Worth, Texas, United States, 76102

[Recruiting]

Ft. Worth, Texas, United States, 76104

[Withdrawn]

Galveston, Texas, United States, 77555

[Recruiting]

Houston, Texas, United States, 77030

[Withdrawn]

Houston, Texas, United States, 77030

[Terminated]

Houston, Texas, United States, 77030

[Recruiting]

McAllen, Texas, United States, 78503

[Recruiting]

Odessa, Texas, United States, 79761

[Recruiting]

San Antonio, Texas, United States, 78240

United States, Utah

[Recruiting]

Salt Lake City, Utah, United States, 84107

[Recruiting]

Salt Lake City, Utah, United States, 84132

United States, Vermont

[Recruiting]

Burlington, Vermont, United States, 05401

United States, Virginia

[Recruiting]

Charlottesville, Virginia, United States, 22908

[Recruiting]

Fairfax, Virginia, United States, 22031

[Recruiting]

Richmond, Virginia, United States, 23221

United States, Washington

[Recruiting]

Seattle, Washington, United States, 98104

[Recruiting]

Silverdale, Washington, United States, 98383

United States, Wisconsin

[Recruiting]

Madison, Wisconsin, United States, 53715

[Recruiting]

Madison, Wisconsin, United States, 58705

[Recruiting]

Milwaukee, Wisconsin, United States, 53226

Canada, Alberta

[Recruiting]

Calgary, Alberta, Canada, T3E 7MB

Canada, British Columbia

[Recruiting]

Vancouver, British Columbia, Canada, V5Z 3N9

[Recruiting]

Victoria, British Columbia, Canada, V8V 1B3

Canada, Nova Scotia

[Recruiting]

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

[Recruiting]

London, Ontario, Canada, N6A 4G5

[Recruiting]

Mississauga, Ontario, Canada, L4W 1W9

[Recruiting]

Ottawa, Ontario, Canada, K1H8L6

[Recruiting]

Toronto, Ontario, Canada, M4N3M5

[Active, not recruiting]

Toronto, Ontario, Canada, M5C 2T2

Canada, Quebec

[Recruiting]

Montreal, Quebec, Canada, H1T 2M4

[Recruiting]

Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

[Recruiting]

Regina, Saskatchewan, Canada, S4T 1A5

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

[Scroll up to access the controls](#)

[Scroll to the Study top](#)

[U.S. National Library of Medicine](#) | [U.S. National Institutes of Health](#) | [U.S. Department of Health & Human Services](#)