Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Intravitreal Triamcinolone Acetonide Study

Enrollment Form

Obtain a Study ID

Patient Initials: ___ ___ ___ *(enter 'X' if no middle initial)*

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Date informed consent form signed for screening: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Name of Investigator _____ **DRCR ID#:** __ __ __ **-** __ __ __

Date of Birth: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy (age must be >= 18.0* yrs)

Which eye(s) is/are being evaluated for the study? ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

Date history elicited: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

A. DEMOGRAPHIC INFORMATION

1. **Date of Birth:** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy (age must be >= 18.0* yrs)

2. **Gender:** Male Female

3. **Ethnicity:** Hispanic or Latino Not Hispanic or Latino Unknown/not reported

4. **Race:** White
   Black/African-American
   Asian
   Native Hawaiian/Other Pacific Islander
   American Indian/Alaskan Native
   More than one race
   Unknown/not reported

If more than one race selected please specify: _____

B. DIABETES HISTORY

1. **Age at diagnosis of diabetes:** _____ yrs old *enter approx age if patient is not precise and records are not available*

2. **Type of Diabetes:** Type 1 Type 2 Uncertain

3. **Diabetes treatment**
   None
   Diet only
   Insulin
   Oral
   Insulin + Oral

4. **If using insulin:**

   a. ☐ **pump or** ☐ **injections**_____ **/day** *daily average, leave blank for pump users.*

   b. **age when insulin treatment started** ____ yrs old *enter approx age if patient is not precise and records are not available*

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

C. PATIENT HISTORY

(All boxes must be checked for patient eligibility)

Patient does NOT have:

- ☐ **1. A history of renal failure requiring dialysis or renal transplant.**
- ☐ **2. Any known allergies to any corticosteroid or any component of the delivery vehicle.**
- ☐ **3. A condition (medical, social) that would preclude participation in the study (e.g., unstable medical status including blood pressure and glycemic control).**

Patient is NOT:

- ☐ **4. Currently using topical, rectal, or inhaled corticosteroids more than 2 times per week.**
- ☐ **5. Expecting to move out of the area of the clinical center to an area not covered by another clinical center during the next 3 years.**

Patient has NOT:

- ☐ **6. Initiated intensive insulin treatment (a pump or multiple daily injections) within the past 4 months and does not plan to do so in the next 4 months.**
- ☐ **7. Been treated with systemic (e.g., oral, IV, IM, epidural, bursal) corticosteroids within past 4 months.**
- ☐ **8. Participated in an investigational trial within 30 days prior to study entry that involved treatment with any drug that has not received regulatory approval at time of study entry**.

D. OCULAR HISTORY

Complete this section if the Right Eye (OD) is being evaluated as a study eye.

(All boxes must be checked for eligibility)

Patient does NOT have a history of:

- ☐ **1. Prior intravitreal corticosteroids.**
- ☐ **2. Peribulbar steroid injection within past 6 months.**
- ☐ **3. Steroid-induced intraocular pressure elevation that required IOP-lowering treatment**
- ☐ **4. YAG laser capsulotomy within past 2 months.**
- ☐ **5. Previous herpetic ocular infection.**
- ☐ **6. Open-angle glaucoma (either primary open angle glaucoma or other cause of open angle glaucoma; note: angle-closure glaucoma is not an exclusion).**

7. Does patient have a history of ocular hypertension in his/her right (OD) eye? Yes No

If YES, what treatment is currently prescribed? None 1 topical med >1 topical med

(If treatment is prescribed complete the Concomitant Medication Form)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

Complete this section if the Right Eye (OD) is NOT being evaluated as a study eye.

(All boxes must be checked for eligibility)

Patient does NOT have a history of:

☐ **1. Prior intravitreal corticosteroids.**

☐ **2. Steroid-induced intraocular pressure elevation that required IOP-lowering treatment.**

☐ **3. Open-angle glaucoma (either primary open angle glaucoma or other cause of open angle glaucoma; note: angle-closure glaucoma is not an exclusion).**

4. Does patient have a history of ocular hypertension in his/her right (OD) eye? Yes No

If YES, what treatment is currently prescribed? None 1 topical med >1 topical med
(If treatment is prescribed complete the Concomitant Medication Form)

Complete this section if the Left Eye (OS) is being evaluated as a study eye.

(All boxes must be checked for eligibility)

Patient does NOT have a history of:

☐ **1. Prior intravitreal corticosteroids.**

☐ **2. Peribulbar steroid injection within past 6 months.**

☐ **3. Steroid-induced intraocular pressure elevation that required IOP-lowering treatment**

☐ **4. YAG laser capsulotomy within past 2 months.**

☐ **5. Previous herpetic ocular infection.**

☐ **6. Open-angle glaucoma (either primary open angle glaucoma or other cause of open angle glaucoma; note: angle-closure glaucoma is not an exclusion).**

7. Does patient have a history of ocular hypertension in his/her left (OS) eye? Yes No

If YES, what treatment is currently prescribed? None 1 topical med >1 topical med
(If treatment is prescribed complete the Concomitant Medication Form)

Complete this section if the Left Eye (OS) is NOT being evaluated as a study eye.

(All boxes must be checked for eligibility)

Patient does NOT have a history of:

☐ **1. Prior intravitreal corticosteroids.**

☐ **2. Steroid-induced intraocular pressure elevation that required IOP-lowering treatment.**

☐ **3. Open-angle glaucoma (either primary open angle glaucoma or other cause of open angle glaucoma; note: angle-closure glaucoma is not an exclusion).**

4. Does patient have a history of ocular hypertension in his/her left (OS) eye? Yes No

If YES, what treatment is currently prescribed? None 1 topical med >1 topical med
(If treatment is prescribed complete the Concomitant Medication Form)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

E. OCULAR PROCEDURE HISTORY

Complete this section for the Right Eye (OD).

Note: Criteria below each question related to eligibility are relevant only if the right eye is being evaluated as a study eye.

1. Previous focal/grid laser photocoagulation in the macula *Must be NO or ≥ 15 weeks (3.5 months) ago for study eye eligibility*	No Yes, < 15 weeks (3.5 months) ago Yes, ≥ 15 weeks (3.5 months) ago
1a. If Yes, how many prior focal laser treatment session have been performed on the right eye? (If exact number is not know, enter best estimate)	1 2 >=3
2. Previous panretinal scatter photocoagulation *Must be NO or all Rx ≥ 4 mos ago for study eye eligibility*	No Yes, < 4 mos ago Yes, all Rx ≥ 4 mos ago
3. Cataract Extraction *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
4. Vitrectomy *Must be No for study eye eligibility*	No Yes
5. Glaucoma filter/laser trabeculoplasty *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
6. Scleral buckle *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
7. Cornea transplant *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
8. Other ocular surgery *Must be ≥ 6 months ago for study eye eligibility* _____	Yes, < 6 mos ago Yes, ≥ 6 mos ago
9. Other ocular surgery *Must be ≥ 6 months ago for study eye eligibility* _____	Yes, < 6 mos ago Yes, ≥ 6 mos ago
10. Other ocular surgery *Must be ≥ 6 months ago for study eye eligibility* _____	Yes, < 6 mos ago Yes, ≥ 6 mos ago

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

Complete this section for the Left Eye (OS).

Note: Criteria below each question related to eligibility are relevant only if the left eye is being evaluated as a study eye.

1. Previous focal/grid laser photocoagulation in the macula *Must be NO or ≥ 15 weeks (3.5 months) ago for study eye eligibility*	No Yes, < 15 weeks (3.5 months) ago Yes, ≥ 15 weeks (3.5 months) ago
1a. If Yes, how many prior focal laser treatment session have been performed on the left eye? (If exact number is not know, enter best estimate)	1 2 >=3
2. Previous panretinal scatter photocoagulation *Must be NO or all Rx ≥ 4 mos ago for study eye eligibility*	No Yes, < 4 mos ago Yes, all Rx ≥ 4 mos ago
3. Cataract Extraction *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
4. Vitrectomy *Must be No for study eye eligibility*	No Yes
5. Glaucoma filter/laser trabeculoplasty *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
6. Scleral buckle *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
7. Cornea transplant *Must be NO or ≥ 6 months ago for study eye eligibility*	No Yes, < 6 mos ago Yes, ≥ 6 mos ago
8. Other ocular surgery *Must be ≥ 6 months ago for study eye eligibility* _____	Yes, < 6 mos ago Yes, ≥ 6 mos ago
9. Other ocular surgery *Must be ≥ 6 months ago for study eye eligibility* _____	Yes, < 6 mos ago Yes, ≥ 6 mos ago
10. Other ocular surgery *Must be ≥ 6 months ago for study eye eligibility* _____	Yes, < 6 mos ago Yes, ≥ 6 mos ago

F. MEDICATIONS

1. Is the patient currently using any medications or has the patient taken medications in the last 30 days?

☐ Yes ☐ No

(If Yes, record all medications on the Concomitant Medication Form.)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

G. Visual Acuity

Test visual acuity of each eye without cycloplegia or dilation using Electronic ETDRS protocol

ETDRS Charts cannot be used for visual acuity testing at patient enrollment.

Refraction and Visual Acuity Testing must be done on same day, and within 8 days prior to randomization

1. Visual Acuity testing date (includes refraction): __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*
(Must be within 8 days prior to randomization)

2. Is patient currently wearing corrective lenses? **Yes** **No**

2a. If Yes, record the correction: **OD** _____ _____ @ _____ ° **OS** _____ _____ @ _____ °
sph cyl axis sph cyl axis

3. Refraction: OD _____ _____ @ _____ ° **OS** _____ _____ @ _____ °
sph cyl axis sph cyl axis

4. Name of Refractionist: _____ **DRCR ID#:** __ __ __ - __ __ __

If any aspects of the EVA testing were not completed according to the protocol, please detail in COMMENTS.

5. EVA Instrument # *(from label):* _____

Calibration Checks
Verify the following:

☐ **6**. Testing distance = 3 meters (118 inches) from monitor screen to center of exam chair seat
☐ **7**. Brightness of screen within range on light meter
☐ **8**. Size of EVA calibration square: horizontal = 114 mm and vertical = 114 mm

9. E-ETDRS letter score: OD _____ OS _____
To qualify as a study eye, visual acuity score must be ≥ 24 letters (approximately 20/320 or better) and ≤ 68 letters (worse than approximately 20/40)
ETDRS Charts cannot be used for visual acuity testing at patient enrollment.
Fellow eye visual acuity score must be ≥ 19 letters (approximately 20/400 or better)

10. Name of VA Tester: _____ **DRCR ID#:** __ __ __ - __ __ __

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

H. Slit Lamp

Slit lamp exam is required on both eyes.

Slit Lamp exam date: ___ ___ **/** ___ ___ ___ **/**___ ___ ___ ___ ***dd/MMM/yyyy***
(Must be done within 21 days prior to randomization)

Complete this section for the Right Eye (OD).

1. Lids/ Conjunctiva: Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities _____

b. Estimated effect on visual acuity? ☐None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

2. Cornea: Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities _____

b. Estimated effect on visual acuity? ☐None ☐ 20/ 25- 20/40 ☐ 20/50 -20/100 ☐ > 20/100

3. Iris neovascularization: ☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization): Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities _____

b. Estimated effect on visual acuity? ☐None ☐20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

Complete this section for the Left Eye (OS)

1. Lids/ Conjunctiva: Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities _____

b. Estimated effect on visual acuity? ☐None ☐20/ 25- 20/40 ☐ 20/50 – 20/100 ☐ > 20/100

2. Cornea: Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities _____

b. Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

3. Iris neovascularization: ☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization): Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities _____

b. Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

I. IOP

IOP measurement is required on both eyes.

IOP measurement date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***
(Must be done within 21 days prior to randomization)

IOP Tester: _____

RIGHT EYE (OD)

1. Intraocular Pressure: _____ **mm Hg**
(Using Goldmann Tonometer)
(Must be <25 mm Hg for eligibility)

LEFT EYE (OS)

1. Intraocular Pressure: _____ **mm Hg**
(Using Goldmann Tonometer)
(Must be <25 mm Hg for eligibility)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

J. Lens Exam

Lens assessment is required on both eyes.

Lens exam date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
(Must be done within 21 days prior to randomization)

Complete this section for the Right Eye (OD)

1. Lens Status *(Study eye must be Phakic or Pseudophakic for eligibility)*	☐ Phakic	☐ Pseudophakic	☐ Aphakic	
If Phakic, complete the following:				
2. Nuclear sclerosis	☐ Absent	☐ Present, < standard	☐ Present, ≥ standard	
3. Posterior subcapsular cataract	☐ Absent	☐ Present, < standard	☐ Present, ≥ standard	
4. Cortical cataract	☐ Absent	☐ Present, < standard	☐ Present, ≥ standard	
5. If lens opacity(ies) present, estimated effect on visual acuity?	☐ None	☐ 20/ 25- 20/40	☐ 20/50 - 20/100	☐ > 20/100
If Pseudophakic or Aphakic, complete the following:				
6. Posterior capsular opacity?	☐ Yes	☐ No		
7. If Yes, estimated effect on visual acuity?	☐ None	☐ 20/ 25- 20/40	☐ 20/50 - 20/100	☐ > 20/100

Complete this section for the Left Eye (OS)

1. Lens Status *(Study eye must be Phakic or Pseudophakic for eligibility)*	Phakic	Pseudophakic	Aphakic	
If Phakic, complete the following:				
2. Nuclear sclerosis	☐ Absent	☐ Present, < standard	☐ Present, ≥ standard	
3. Posterior subcapsular cataract	☐ Absent	☐ Present, < standard	☐ Present, ≥ standard	
4. Cortical cataract	☐ Absent	☐ Present, < standard	☐ Present, ≥ standard	
5. If lens opacity(ies) present, estimated effect on visual acuity?	☐ None	☐ 20/ 25- 20/40	☐ 20/50 - 20/100	☐ > 20/100
If Pseudophakic or Aphakic, complete the following:				
6. Posterior capsular opacity?	☐ Yes	☐ No		
7. If Yes, estimated effect on visual acuity?	☐ None	☐ 20/ 25- 20/40	☐ 20/50 - 20/100	☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

K. Fundus Exam

Dilated Fundus exam is required on both eyes.

Dilated fundus exam date: ___ ___ **/** ___ ___ ___ **/**___ ___ ___ ___ ***dd/MMM/yyyy***
(Must be done within 21 days prior to randomization)

Complete this section for the Right Eye (OD)

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage): Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities_____

b. Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy: ☐ No ☐ Yes

If Yes complete a and b:

a. Describe any abnormalities_____

b. Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

4. Optic disc: Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities_____

b. Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine
(Must be present if right eye is being evaluated as a study eye)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

Complete this section for the Left Eye (OS)

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ . > 20/100

2. Vitreous (other than vitreous hemorrhage): Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities_____

b. Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ . > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy: ☐ No ☐ Yes

If Yes complete a and b:

a. Describe any abnormalities_____

b. Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ . > 20/100

4. Optic disc: Normal Abnormal

If abnormal complete a and b:

a. Describe any abnormalities_____

b. Estimated effect on visual acuity? ☐ None ☐ 20/ 25- 20/40 ☐ 20/50 - 20/100 ☐ . > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine
(Must be present if left eye is being evaluated as a study eye)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

L. Miscellaneous Eligibility Checks

Ocular exam date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
(Must be done within 21 days prior to randomization)

Complete this section if the Right Eye (OD) is being evaluated as a study eye.

(All boxes must be checked for eligibility)

The right eye is NOT expected to need:

☐ **1. Panretinal photocoagulation in the next 4 months.**

☐ **2. Major ocular surgery (including cataract extraction, scleral buckle, any intraocular surgery, etc.) within the next 6 months following randomization.**

The right eye does NOT have:

☐ **3. Evidence of an ocular condition such that, in the opinion of the investigator, visual acuity would not improve from resolution of macular edema (e.g. foveal atrophy, pigmentary changes, dense subfoveal hard exudates, nonretinal condition).**

☐ **4. Evidence of an ocular condition (other than diabetes) that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the study (e.g., vein occlusion, uveitis or other ocular inflammatory disease, neovascular glaucoma, Irvine-Gass Syndrome).**

☐ **5. A substantial cataract that, in the opinion of the investigator, is likely to be decreasing visual acuity by 3 lines or more (i.e., cataract would be reducing acuity to 20/40 or worse if eye was otherwise normal).**

☐ **6. Evidence of an external ocular infection (e.g. conjunctivitis, chalazion or significant blepharitis).**

☐ **7. Evidence of ocular toxoplasmosis.**

☐ **8. Pseudoexfoliation.**

The following are true:

☐ **9. The edema in the macula is most likely due to diabetes and NOT another condition such as cataract extraction or vitreoretinal interface disease (e.g. a taut posterior hyaloid or epriretinal membrane).**

☐ **10. (1) Media clarity, (2) pupillary dilation, and (3) patient cooperation were sufficient for adequate fundus photos.**

☐ **11. One of the following is true:**

(1) Eye does not have a history of ocular hypertension AND IOP is < 22 mm Hg

OR

(2) Eye has a history of ocular hypertension or IOP is 22 - < 25 AND all of the following are true: (i) IOP <25 mm Hg, (ii) most recent visual field performed within past 12 months is normal, (iii) patient is using 1 or no topical glaucoma medications, AND (iv) optic disc does NOT appear glaucomatous.

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

Complete this section if the Right Eye (OD) is NOT being evaluated as a study eye.

(All boxes must be checked for eligibility)

☐ **1. Pseudoexfoliation is not present.**

☐ **2. One of the following is true:**

(1) Eye does not have a history of ocular hypertension AND IOP is < 22 mm Hg

OR

(2) Eye has a history of ocular hypertension or IOP is 22 - < 25 AND all of the following are true: (i) IOP <25 mm Hg, (ii) most recent visual field performed within past 12 months is normal, (iii) patient is using 1 or no topical glaucoma medications, AND (iv) optic disc does NOT appear glaucomatous.

Complete this section if the Left Eye (OS) is being evaluated as a study eye.

(All boxes must be checked for eligibility)

The Left Eye is NOT expected to need:

☐ **1. Panretinal photocoagulation in the next 4 months.**

☐ **2. Major ocular surgery (including cataract extraction, scleral buckle, any intraocular surgery, etc.) within the next 6 months following randomization.**

The Left Eye does NOT have:

☐ **3. Evidence of an ocular condition such that, in the opinion of the investigator, visual acuity would not improve from resolution of macular edema (e.g. foveal atrophy, pigmentary changes, dense subfoveal hard exudates, nonretinal condition).**

☐ **4. Evidence of an ocular condition (other than diabetes) that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the study (e.g., vein occlusion, uveitis or other ocular inflammatory disease, neovascular glaucoma, Irvine-Gass Syndrome).**

☐ **5. A substantial cataract that, in the opinion of the investigator, is likely to be decreasing visual acuity by 3 lines or more (i.e., cataract would be reducing acuity to 20/40 or worse if eye was otherwise normal).**

☐ **6. Evidence of an external ocular infection (e.g. conjunctivitis, chalazion or significant blepharitis).**

☐ **7. Evidence of ocular toxoplasmosis.**

☐ **8. Pseudoexfoliation.**

The following are true:

☐ **9. The edema in the macula is most likely due to diabetes and NOT another condition such as cataract extraction or vitreoretinal interface disease (e.g. a taut posterior hyaloid or epriretinal membrane).**

☐ **10. (1) Media clarity, (2) pupillary dilation, and (3) patient cooperation were sufficient for adequate fundus photos.**

☐ **11. One of the following is true:**

(1) Eye does not have a history of ocular hypertension AND IOP is < 22 mm Hg

OR

(2) Eye has a history of ocular hypertension or IOP is 22 - < 25 AND all of the following are true: (i) IOP <25 mm Hg, (ii) most recent visual field performed within past 12 months is normal, (iii) patient is using 1 or no topical glaucoma medications, AND (iv) optic disc does NOT appear glaucomatous.

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

Complete this section if the Left Eye (OS) is NOT being evaluated as a study eye.

(All boxes must be checked for eligibility)

☐ **1. Pseudoexfoliation is not present.**

☐ **2. One of the following is true:**

(1) Eye does not have a history of ocular hypertension AND IOP is < 22 mm Hg

OR

(2) Eye has a history of ocular hypertension or IOP is 22 - < 25 AND all of the following are true: (i) IOP <25 mm Hg, (ii) most recent visual field performed within past 12 months is normal, (iii) patient is using 1 or no topical glaucoma medications, AND (iv) optic disc does NOT appear glaucomatous.

M. Blood Pressure

1. Blood Pressure exam date: ___ ___ **/** ___ ___ ___ **/**___ ___ ___ ___ *dd/MMM/yyyy*
(Must be done within 21 days prior to randomization)

2. Blood Pressure: _____/_____ mm Hg *(Measure in sitting position after patient has been sitting for at least 5 minutes)*
Must be performed within 21 days of randomization
Must be ≤ 180/110 to be eligible

O. OCT (First Measurement)

OCT measurement is required on both eyes.

1. OCT: Date Performed: Enter date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
Must be performed within 21 days of randomization

2. OCT: Time Performed: _____:_____ AM/ PM

3. OCT Technician ID: __ __ __ **-** __ __ __

4. OCT machine version: OCT1 OCT2 OCT3 (version < 4) OCT3 (version 4)
(If OCT3 version 4 was used, enter the signal strength for the scan below)

5. Eyes with OCT: ☐Right (OD) ☐Left (OS) ☐ Both (OU)

6. If not 'OU', please explain: _____
_____
_____

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

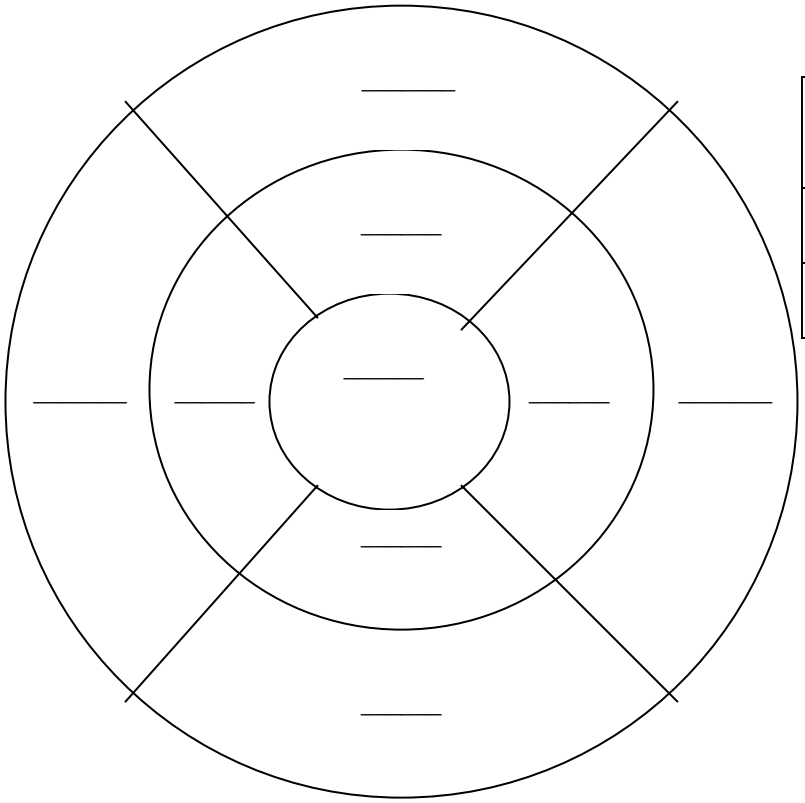
Note: Signal strength should be >= 6 AND standard deviation of center point thickness should be <= 10% for adequate scans.

COMPLETE THE FOLLOWING SECTION FOR THE RIGHT EYE

Enter the thickness for each of the subfields in the diagram shown below.

Mean of two OCT central subfield measurements must be >= 250 microns for study eye eligibility

Right Eye (OD)



Signal Strength	_____ *(If OCT3 Version 4 was used please enter signal strength.)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

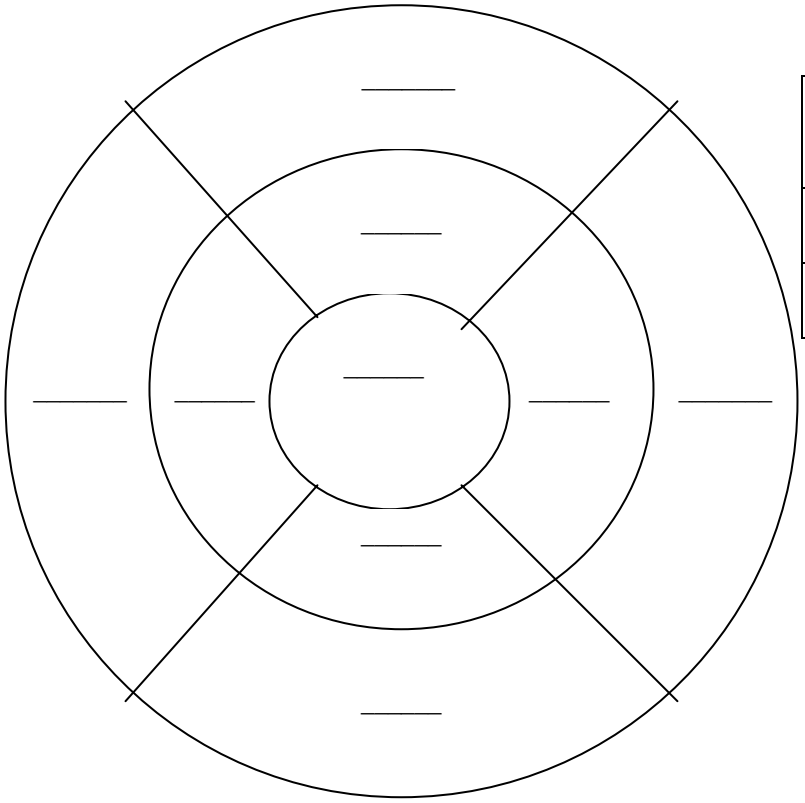
Baseline Visit Form

COMPLETE THE FOLLOWING SECTION FOR THE LEFT EYE

Enter the thickness for each of the subfields in the diagram shown below.

Mean of two OCT central subfield measurements must be >= 250 microns for study eye eligibility

Left Eye (OS)



Signal Strength	_____ *(If OCT3 Version 4 was used please enter signal strength.)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

P. OCT (Second Measurement)

OCT measurement is required on both eyes.

1. OCT: Date Performed: Enter date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
Must be performed within 21 days of randomization

2. OCT: Time Performed: _____:_____ AM/ PM

3. OCT Technician ID: __ __ __ - __ __ __

4. OCT machine version: OCT1 OCT2 OCT3 (version < 4) OCT3 (version 4)
(If OCT3 version 4 was used, enter the signal strength for the scan below)

5. Eyes with OCT: ☐Right (OD) ☐Left (OS) ☐ Both (OU)

6. If not 'OU', please explain: _____
_____
_____

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

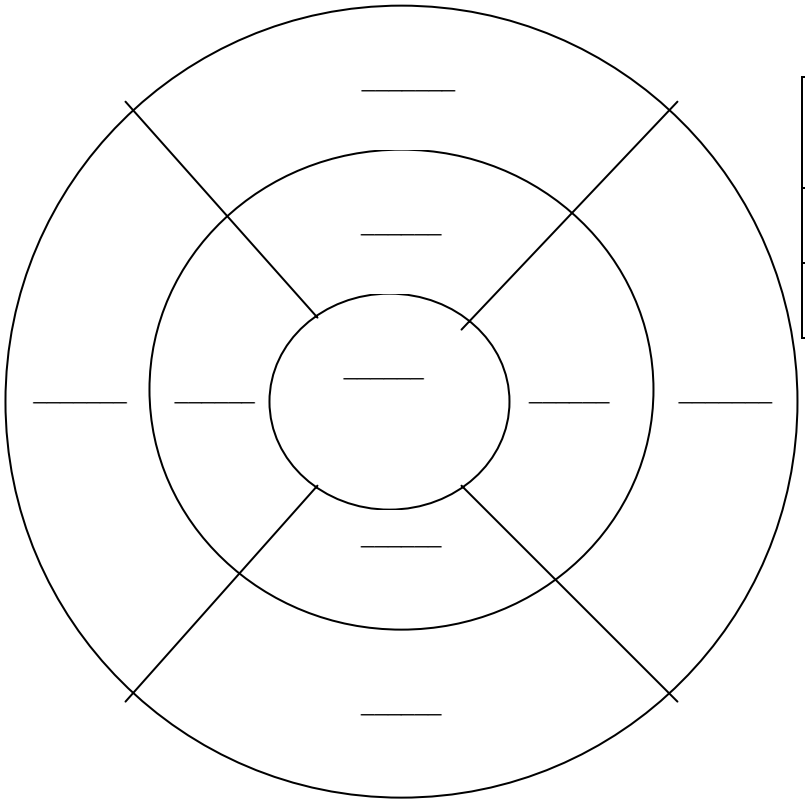
Note: Signal strength should be >= 6 AND standard deviation of center point thickness should be <= 10% for adequate scans.

COMPLETE THE FOLLOWING SECTION FOR THE RIGHT EYE

Enter the thickness for each of the subfields in the diagram shown below.

Mean of two OCT central subfield measurements must be >= 250 microns for study eye eligibility

Right Eye (OD)



Signal Strength	_____ *(If OCT3 Version 4 was used please enter signal strength.)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

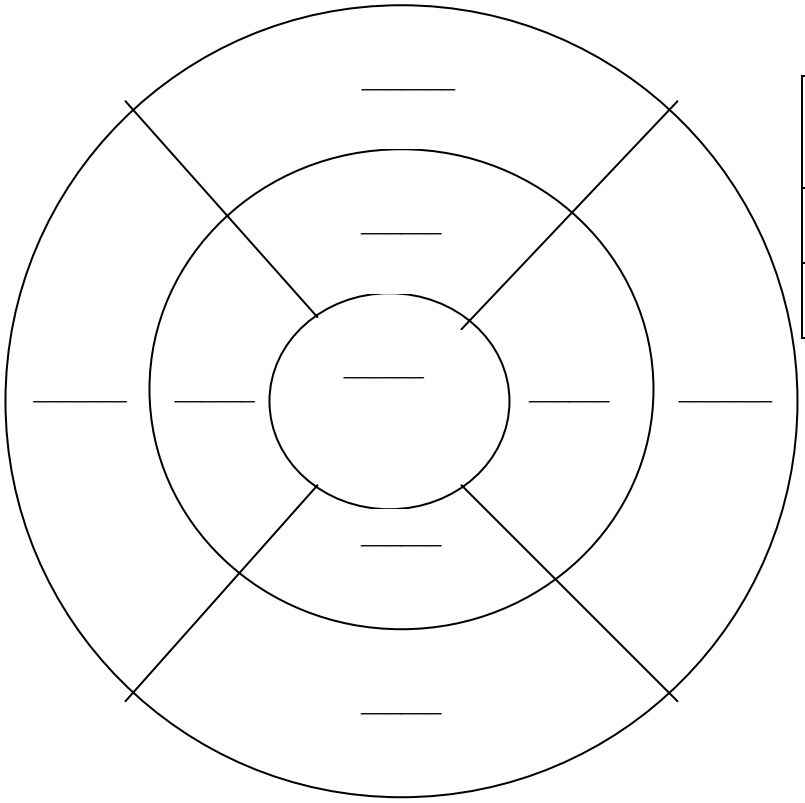
Baseline Visit Form

COMPLETE THE FOLLOWING SECTION FOR THE LEFT EYE

Enter the thickness for each of the subfields in the diagram shown below.

Mean of two OCT central subfield measurements must be >= 250 microns for study eye eligibility

Left Eye (OS)



Signal Strength	_____ *(If OCT3 Version 4 was used please enter signal strength.)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

Q. FUNDUS PHOTOGRAPHY

Fundus photos are required on both eyes.

1a. ETDRS Fundus Photos: Date Performed (7-fields and Fundus (Red) Reflex):
___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
Must be performed in both eyes within 21 days of randomization

1b. Photographer ID: __ __ __ **-** __ __ __

1c. Eyes with Photos: ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)

1d. If not 'OU', then explain: _____

1e. Camera Used: _____

2. Was a fluorescein angiogram performed? ☐ Yes ☐ No
(If Yes, please complete the fluorescein angiogram form)

R. FLUORESCEIN ANGIOGRAPHY

(Only perform fluorescein angiography if part of usual care)

1. Fluorescein Angiography: Date Performed: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
Must be performed within 21 days of randomization

1b. Fluorescein Angiographer ID: __ __ __ **-** __ __ __

1c. Eyes with Fluorescein Angiography: ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)

1d. Rapid Series Eye: ☐ Right (OD) ☐ Left (OS)

1e. Fluorescein Angiography Type: Film Digital

1f. Fluorescein Angiography done according to protocol? Yes No

S. LAB

Lab testing does not need to be repeated if HbA1c and lab normal values are available from within the prior 3 months. If not available at the time of randomization, test may be obtained within 3 weeks after randomization.

	Collection Date	Value	Lab Normal Range (Low Value to High Value)	Not completed but will be completed within 3 weeks.	Missed?*
HbA1c	___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*	_____	_____ to _____	☐	☐

***If missed provide reason in comments section**

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Eye being assessed for eligibility: _____

Intravitreal Triamcinolone Acetonide Study

Baseline Visit Form

T. Randomization

1. Date informed consent form sign ed for trial ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
2. Have all signatures and date fields been properly completed on the informed consent form? Yes No *must be YES for patient eligibility* *Fax Signature Page to the Jaeb Center* at **1-800-816-7601**
3. Has the Patient Contact Information Form been completed? Yes No *Must be YES before patient can be randomized* *Fax Form to the Jaeb Center* at **1-800-816-7601**
4. Were any of the data (other than visual acuity, refraction, and labs) recorded on this form transcribed DIRECTLY from another source (i.e., medical record, surgical notes, patient study worksheet) rather than being confirmed with the patient and directly entered on the website? Yes No *If yes, please fax the source documents to the Jaeb Center for review at 1-800-816-7601.*
5. Has a study investigator verified the patient's eligibility? Yes No *Must be YES for patient eligibility*
6. Is patient ready to have treatment (laser or intravitreal injection) today? Yes No *Must be YES for patient eligibility*
7. Name of Investigator _____ **DRCR ID#:** _____

U. COMMENTS

V. General Chart Comments (Optional)

This section is provided for convenience to record general chart information. This information is not considered study data, but can be printed for the site's file.

Intravitreal Triamcinolone Acetonide Study

Pre-Existing Condition Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Date History Elicited: Enter date: ___ ___ / ____ ____ ____ / ___ ___ dd/mmm/yy

1. Does the patient have any past or present medical conditions other than Diabetes Mellitus? YES NO

If Yes, check the appropriate disorders/systems, indicate if active and being treated and for the systems, describe the condition.

	Active?	**Currently Being Treated?**
☐ Hypertension	Yes No	Yes No
☐ Elevated Cholesterol	Yes No	Yes No
☐ Elevated Triglycerides	Yes No	Yes No

System **Note: Enter only one condition per system. If patient has more than one pre-existing condition for a given system, please enter the additional conditions at the bottom of the form where indicated**	**Description of Pre-Existing Condition**	**Active?**	**Currently Being Treated?**
☐ ENT		Yes No	Yes No
☐ Cardiovascular		Yes No	Yes No
☐ Respiratory		Yes No	Yes No
☐ Gastrointestinal		Yes No	Yes No
☐ Renal (kidney)		Yes No	Yes No
☐ Genitourinary		Yes No	Yes No
☐ Hepatic (Liver)		Yes No	Yes No

(Continued on next page)

Intravitreal Triamcinolone Acetonide Study

Pre-Existing Condition Form

System **Note: Enter only one condition per system. If patient has more than one pre-existing condition for a given system, please enter the additional conditions at the bottom of the form where indicated**	**Description of Pre-Existing Condition**	**Active?**	**Currently Being Treated?**
☐ Endocrine (other than Diabetes Mellitus)		Yes No	Yes No
☐ Neurological		Yes No	Yes No
☐ Musculoskeletal		Yes No	Yes No
☐ Skin		Yes No	Yes No
☐ Psychological		Yes No	Yes No
☐ Blood/Lymphatic		Yes No	Yes No
☐ Allergy		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No

(Continued on next page)

Intravitreal Triamcinolone Acetonide Study

Pre-Existing Condition Form

System **Note: Enter only one condition per system. If patient has more than one pre-existing condition for a given system, please enter the additional conditions at the bottom of the form where indicated**	**Description of Pre-Existing Condition**	**Active?**	**Currently Being Treated?**
☐ Additional Condition For System above or Other _____		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No
☐ Additional Condition For System above or Other _____		Yes No	Yes No

Intravitreal Triamcinolone Acetonide Study

Concomitant Medications Form

(One form Per Medication)

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___

1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

1. Medication Name: _____ **brand name/ generic name**

2. Dose per administration (include unit): _____ ☐ **Unknown**

3. Route: S.C.-subcutaneous
I.V.-intravenous
Gtt-drops
I.D.-intradermal
I.M.-intramuscular
P.O.-by mouth
P.R.-by rectum
Topical
Vaginal

4. Frequency: _____ (1-50) per _____ (day, week, month, year) ☐ **Unknown**

4a. Same dose consistent (e.g. same dose every day)? Yes No

If 'No', explain: _____

5. Indication: Treatment of diabetes
Pre-existing condition
Treatment for an Adverse Event
Other

Intravitreal Triamcinolone Acetonide Study

Concomitant Medications Form

(One form Per Medication)

5a. If 'Pre-existing condition', select system:

ENT
Cardiovascular
Respiratory
Gastrointestinal
Renal (Kidney)
Genitourinary
Hepatic (Liver)
Endocrine
Ophthalmic System
Neurological
Musculosketal
Skin
Psychological
Blood/Lymphatic
Allergy
Other _____

5b. If 'Treatment for Adverse Event', enter Adverse Event: _____

6. Start Date: If < 30 days, enter date: ___ ___/___ ___ ___/ ___ ___ dd/mmm/yy

If >30 days, select date range:

> 30 days ago to 3 months ago
> 3 months ago to 6 month ago
> 6 months ago to 1 year ago
> 1 year ago to 5 years ago
> 5 years ago to 10 years ago
> 10 years ago

7. Stop Date (or mark box if ongoing): ___ ___/___ ___ ___/ ___ ___ dd/mmm/yy ☐ **Ongoing**

COMMENTS

Complete after Enrollment Form on DRCR.net website *1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name*

A Randomized Trial Comparing Intravitreal Triamcinolone Acetonide and Laser Photocoagulation for Diabetic Macular Edema

Baseline Fluorescein Angiography Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

A. FLUORESCEIN ANGIOGRAPHY

1a. Fluorescein Angiography: Date Performed: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*
Must be performed within 21 days of randomization

1b. Fluorescein Angiographer ID: __ __ __ **-** __ __ __

1c. Eyes with Fluorescein Angiography: ☐ Right (OD) ☐ Left (OS) ☐ Both (OU)

1d. Rapid Series Eye: ☐ Right (OD) ☐ Left (OS)

1e. Fluorescein Angiography Type: Film Digital

B. COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Intravitreal Triamcinolone Acetonide Study

Laser Photocoagulation Treatment Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Laser photocoagulation should be given using the modified-ETDRS treatment technique.

Treatment Date: Enter date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Name of Investigator _____

A. Technique Performed

1. Eye Treated OD OS

2. Was 50 micron burn size used as per the protocol? Yes No

2a. If no, why not? _____

3. Average Power: _____ **mW**

4. Wave Length: Green Yellow

5. Number of Burns: _____

6. Was the treatment guided by Fluorescein Angiography? Yes No
Only Baseline fluorescein angiograms should be sent to the reading center

7. Did the patient experience any complications (e.g., heme, foveal burn, break in Bruch's membrane)? Yes No
If Yes, detail in the COMMENT section and complete an Adverse Event Form

8. Was the full treatment session completed in today's sitting? Yes No

B. COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Intravitreal Triamcinolone Acetonide Study

Intravitreal Injection Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Treatment Date: Enter date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Name of Investigator _____

Syringe number used for the injection. _____

Procedure- (See DRCRnet study procedures manual for injection procedure)

Medications recorded on the Intravitreal Triamcinolone Injection Form should NOT be recorded on the Concomitant Medication Form unless specified.

1. Eye Treated: OD OS

A. Antibiotics

Pre-op Topical Antibiotics Given in Office Today *(Please select one)*:

☐ Zymar (provided in the injection kit) administered at least 3 times over at least 15 minutes

☐ Zymar (provided in the injection kit), regimen deviated from protocol. Describe regimen _____

_____

☐ Other; describe antibiotic and regimen, and indicate reason for using "other" antibiotic: _____

_____

☐ None. Describe reason _____

_____

B. Anesthetic Used

(Check all that apply)

☐ Ophthetic (included in the injection kit) topical drop.

☐ Cotton-tipped applicator soaked in topical anesthetic over the injection site.

☐ Lidocaine gel over the injection site.

☐ Other topical; record name(s) and concentration(s) (e.g. Tetracaine) below

☐ Subconjunctival injection; record name(s) and concentration(s) below

☐ Retrobulbar injection; record name(s) and concentration(s) below

Intravitreal Triamcinolone Acetonide Study

Intravitreal Injection Form

Enter the name(s) and Concentration(s) of any 'other' topical medications, Subconjunctival injections, or Retrobulbar injections.

_____

_____

_____

C. Prep

(Check all that apply)

- ☐ 5% Povidone iodine (included in the injection kit) placed in lower fornix
- ☐ 5% povidone iodine cotton-tipped applicator (included in the injection kit) applied to upper and lower eyelids and eyelashes.
- ☐ 5% povidone iodine cotton-tipped applicator (included in the injection kit) applied to the conjunctiva over and surrounding the injection site
- ☐ 5% povidone-iodine flush using at least 10 cc of 5% povidone-iodine in the fornices and the caruncle.
- ☐ 10% povidone iodine Swabstick (included in the injection kit) applied to the conjunctiva over and surrounding the injection site
- ☐ Other; describe and indicate reason for using an "other" prep _____

_____

_____

Lid Speculum

Was an eyelid speculum used? Yes No

D. Injection

Location of injection: ☐ inferior-temporal ☐ inferior-nasal ☐ superior-temporal ☐ superior-nasal

Was the injection performed 3.0-4.0 mm posterior to the limbus, via the pars plana as per the injection procedure?
Yes No

If No, explain _____

_____

Intravitreal Triamcinolone Acetonide Study

Intravitreal Injection Form

E. Post Injection:

Was indirect ophthalmoscopy performed to confirm the perfusion of the central retinal artery? **Yes** **No**

Intraocular pressure (last recorded measurement): ___ mm Hg **OR** ☐ Not Measured

Did the patient receive treatment to lower the intraocular pressure? Yes No

If YES check all that apply, ☐ . **topical treatment(s); describe below**

☐ . **paracentesis**

☐ . **other; describe below**

_____

_____

Adverse Events:

Did the patient experience any complications from the intravitreal injection (other than an intraocular pressure rise requiring treatment)? Yes No

(If Yes, complete an Adverse Event Form)

F. Antibiotics Prescribed for Home Use:

Post injection antibiotics, check all that apply:

☐ . Zymar (provided in the injection kit) used QID for 3 days (inclusive of the day of injection)

☐ . Other; complete the Concomitant Medication Form

☐ . None, reason _____

_____

G. COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Injected Eye: _____

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___

1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Visit Date: Enter Date: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

Visit Type: 4 days post-injection **4 weeks post-injection**

Investigator: _____

A. Medical Update Section

Date Medical Update Elicited: Enter Date: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

1. **Did patient commence or change the usage of any medications since last visit?** ☐ Yes ☐ No
   (If Yes, complete the Concomitant Medication Form.)

2. **Did the patient experience any of the following?** ☐ Yes ☐ No
   If Yes, check all that apply and complete an Adverse Event Form for each.

☐ **Ocular or non-ocular surgery since last visit**

☐ **Hospitalization for any reason other than surgery since last visit?**

☐ **Any new non-ocular medical problems since last visit?**

☐ **A change in an existing non-ocular medical problem since last visit?**

☐ **Any new ocular medical problems since last visit?**

☐ **A change in an existing ocular medical problem since last visit?**

Complete the following if visit is the 4-day post-injection visit

Did the patient use the post injection antibiotics as prescribed? Yes No
(Do NOT enter on concomitant medication form)

If No, explain _____

_____

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Injected Eye: _____

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

A1. Study Eye Ocular Treatment Update

RIGHT EYE (OD)

Complete the following if the right eye is a study eye

1. Has the patient received any treatment for DME in the study eye (right eye) since the last visit (i.e. treatment was received at the study site or at a non-study site and therefore not recorded on a prior study case report form)? ☐ Yes ☐ No **If Yes, explain and provide dates:**

LEFT EYE (OS)

Complete the following if the left eye is a study eye

1. Has the patient received any treatment for DME in the study eye (right eye) since the last visit (i.e. treatment was received at the study site or at a non-study site and therefore not recorded on a prior study case report form)? Yes No **If Yes, explain and provide dates:**

B. Visual Acuity Section

Visual acuity should be measured in the injected eye without cycloplegia or dilation, using the Electronic Visual Acuity Tester.

Refraction is not required.

Visual acuity measurement is not required in the non-injected eye but may be recorded if performed.

Will visual acuity testing be performed on the RIGHT eye at this visit? Yes No

If No, reason: ☐ Not Required or Other _____

Will visual acuity testing be performed on the LEFT eye at this visit? Yes No

If No, reason: ☐ Not Required or Other _____

Visual Acuity testing date (includes refraction if performed): Enter Date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Injected Eye: _____

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

B1. Refraction (optional)

Was a refraction performed at this visit prior to VA testing? ☐ Yes ☐ No

If Yes, Refractionist: _____

If Yes, enter below and use for visual acuity testing.
If No, enter correction used for visual acuity testing.

Refraction/ Correction Used: OD _____ (sph) _____ (cyl) @ _____ (axis) o **OS** _____ (sph) _____ (cyl) @ _____ (axis) o

B2. Visual Acuity

EVA Instrument # *(from label):* _____

Calibration Checks
Verify the following:

☐ Testing distance = 3 meters (118 inches) from monitor screen to center of exam chair seat

☐ Brightness of screen within range on light meter

☐ Size of EVA calibration square: horizontal = 114 mm and vertical = 114 mm

ETDRS letter score: OD _____ (required if study eye)

OS _____ (required if study eye)

VA Tester: _____

☐ **Acuity testing completed but testing procedure deviated from protocol.**
Please detail: _____

_____

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

C. Repeat Visual Acuity Section (if needed)

Refraction and/or repeat visual acuity should be performed in the study eye(s) if there has been an unexplained 15-letter visual acuity loss since the previous refraction.

Was a refraction performed after the initial visual acuity testing in either eye?

No **Yes, OD (right eye)** **Yes, OS (left eye)** **Yes, OU (both eyes)**

If Yes, enter refraction and refractionist below:

Refractionist: _____

Refraction: **OD** _____ _____ @ _____ o **OS** _____ _____ @ _____ o
sph cyl axis sph cyl axis

Was visual acuity testing repeated in either eye?

No **Yes, OD (right eye)** **Yes, OS (left eye)** **Yes, OU (both eyes)**

If Yes, enter below:

EVA Instrument # *(from label):* _____

Calibration Checks
Verify the following:

☐ **Testing distance = 3 meters (118 inches) from monitor screen to center of exam chair seat**
☐ **Brightness of screen within range on light meter**
☐ **Size of EVA calibration square: horizontal = 114 mm and vertical = 114 mm**

ETDRS letter score: OD _____

OS _____

VA Tester: _____

☐ **Acuity testing completed but testing procedure deviated from protocol.**

Please detail: _____

_____

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

D. Slit Lamp Exam

Slit lamp exam is required in the injected eye.

Slit lamp is not required in a non-injected eye but may be recorded if performed.

Will a slit lamp exam be performed on the RIGHT eye at this visit? Yes No

If No, reason: ☐ Not Required or Other _____

Will a slit lamp exam be performed on the LEFT eye at this visit? Yes No

If No, reason: ☐ Not Required or Other _____

Slit lamp exam date: Enter Date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

RIGHT EYE (OD) – Required in right eye if right eye was injected

1. Lids/ Conjunctiva ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Cornea ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

3. Iris neovascularization
- ☐ Absent
- ☐ Present, pupillary margin only
- ☐ Present, beyond the margin, but not in the angle
- ☐ Present, In the angle

4. Anterior chamber (iris neovascularization) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____
_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

LEFT EYE (OS) – Required in left eye if left eye was injected

1. Lids/ Conjunctiva ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____
_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Cornea ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____
_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

3. Iris neovascularization

- ☐ Absent
- ☐ Present, pupillary margin only
- ☐ Present, beyond the margin, but not in the angle
- ☐ Present, In the angle

4. Anterior chamber (iris neovascularization) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____
_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

E. Intraocular Pressure Measurement

IOP measurement is required in the injected eye.

IOP measurement is not required in a non-injected eye but may be recorded if performed.

Will an intraocular pressure measurement be performed on the RIGHT eye at this visit? Yes No

If No, reason: ☐ **Not Required or Other** _____

Will an intraocular pressure measurement be performed on the LEFT eye at this visit? Yes No

If No, reason: ☐ **Not Required or Other** _____

IOP measurement date: **Enter Date:** ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

E1. IOP Treatment

Is patient currently on IOP lowering medication for the: *(If Yes, complete the Concomitant Medication Form)*

Right eye (OD)? Yes No

Left eye (OS)? Yes No

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Injected Eye: _____

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

E2. IOP Measurement

Right Eye (OD) – IOP is required in right eye if right eye was injected

Intraocular Pressure: _____ mm Hg
(Using Goldmann Tonometer)

Left Eye (OS) – IOP is required in right eye if right eye was injected

Intraocular Pressure: _____ mm Hg
(Using Goldmann Tonometer)

Protocol for Treatment of Elevated IOP
Treatment of elevated intraocular pressure will be instituted whenever the intraocular pressure is ≥ 30 mm Hg. The treatment to prescribe will be at investigator discretion and may include referral to another ophthalmologist. If the intraocular pressure is between 22 and 30 mm Hg, then the intraocular pressure should be remeasured within one month and treated if ≥30 mm Hg. Intraocular pressure >25 mm Hg at consecutive 4-month visits should be treated. If intraocular pressure is >25 mm Hg for 4 months, then a visual field should be performed to evaluate for glaucomatous damage.

F. Lens Assessment

(See procedure manual for lens assessment procedure)

Lens assessment is not required in either eye but may be recorded if performed

Will a lens assessment be performed on the RIGHT eye at this visit? Yes No

If No, reason: Not Required

Will a lens assessment be performed on the LEFT eye at this visit? Yes No

If No, reason: Not Required

Lens assessment date: Enter Date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Injected Eye: _____

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

Right Eye (OD) – (optional)

1. Lens Status	☐ Phakic ☐ Pseudophakic ☐ Aphakic
If Phakic, complete the following:	
2. Nuclear sclerosis *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
3. Posterior subcapsular cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
4. Cortical cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
5. If lens opacity(ies) present, estimated effect on visual acuity	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100
If Pseudophakic or Aphakic, complete the following:	
6. Posterior capsular opacity?	☐ Yes ☐ No
7. If Yes, estimated effect on visual acuity?	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Left Eye (OS) – (optional)

1. Lens Status	☐ Phakic ☐ Pseudophakic ☐ Aphakic
If Phakic, complete the following:	
2. Nuclear sclerosis *(see procedure manual for standard photos)*	☐ Absent ☐ Present,< standard ☐ Present, ≥ standard
3. Posterior subcapsular cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present,< standard ☐ Present, ≥ standard
4. Cortical cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present,< standard ☐ Present, ≥ standard
5. If lens opacity(ies) present, estimated effect on visual acuity	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

If Pseudophakic or Aphakic, complete the following:

6. **Posterior capsular opacity?** ☐ Yes ☐ No
7. **If Yes, estimated effect on visual acuity?** ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

G. Fundus Exam

Dilated fundus exam is required in the injected eye.

Dilated fundus exam is not required in a non-injected eye but may be recorded if performed.

Will a dilated fundus exam be performed on the RIGHT eye at this visit? Yes No

If No, reason: ☐ **Not Required or Other** _____

Will a dilated fundus exam be performed on the LEFT eye at this visit? Yes No

If No, reason: ☐ **Not Required or Other** _____

Dilated fundus exam date: **Enter Date:** ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Right Eye (OD) – Required on right eye if right eye was injected

1. **Vitreous hemorrhage** ☐ No ☐ Yes

   If Yes:

   Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. **Vitreous (other than vitreous hemorrhage)** ☐ Normal ☐ Abnormal

   a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Injected Eye: _____

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

3. Retina/choroid abnormality other than diabetic retinopathy ☐ No ☐ Yes

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If Yes complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

4. Optic disc ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

Left Eye (OS) – Required on left eye if left eye was injected

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

3. Retina/choroid abnormality other than diabetic retinopathy ☐ No ☐ Yes

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If Yes complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

4. Optic disc ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

H. OCT

OCT is not required in either eye but may be recorded if performed

Will OCT be performed on the RIGHT eye? Yes No

If No, reason: Not Required
Patient cooperation insufficient
Equipment failure
Other _____

Will OCT be performed on the LEFT eye? Yes No

If No, reason: Not Required
Patient cooperation insufficient
Equipment failure
Other _____

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Injected Eye: _____

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

1. Date OCT Performed: Enter date __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

2. Time OCT Performed: ____ : _____ am/ pm

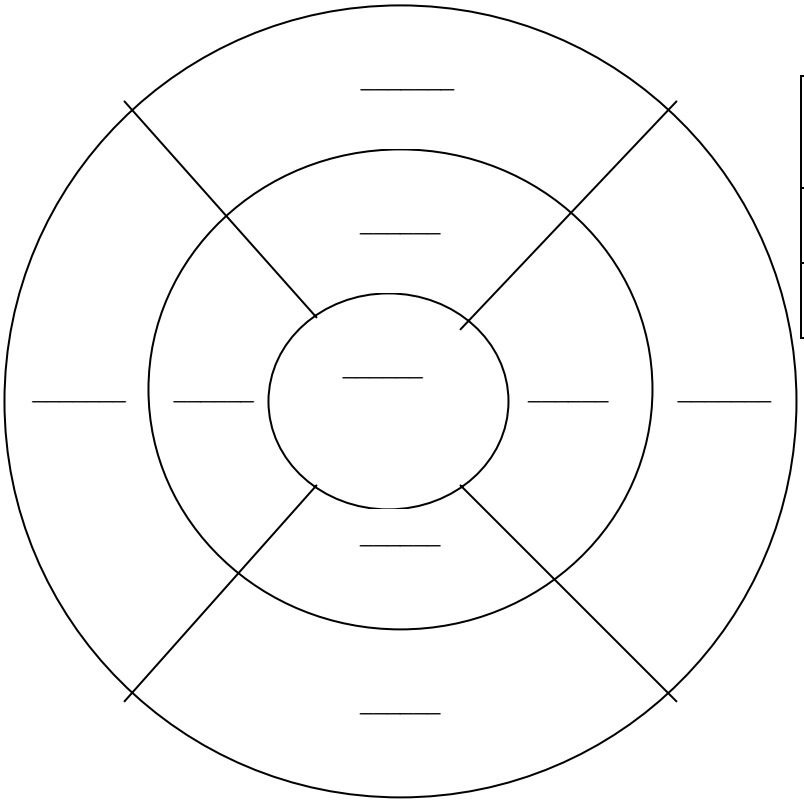
3. OCT Technician: _____

4. OCT machine version: OCT1 OCT2 OCT3 (version < 4) OCT3 (version 4)
(If OCT3 version 4 was used, enter the signal strength for the scan below)

Note: Signal strength should be >= 6 AND standard deviation of center point thickness should be <= 10% for adequate scans.

Right Eye (OD) – Optional

Enter the thickness for each of the subfields in the diagram shown below.



Signal Strength	_____ *(If OCT3 Version 4 was used please enter signal strength.)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

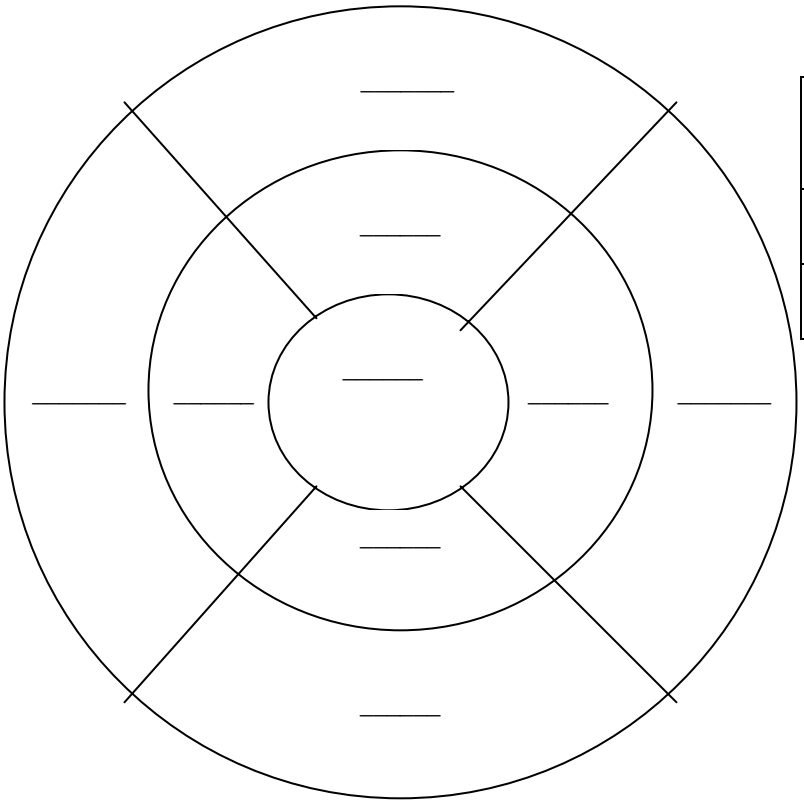
Injected Eye: _____

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

Left Eye (OS) - Optional

Enter the thickness for each of the subfields in the diagram shown below.



Signal Strength	_____ *(If OCT3 Version 4 was used please enter signal strength.)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Injected Eye: _____

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

I. General Chart Comments (Optional)

This section is provided for convenience to record general chart information. This information is not considered study data, but can be printed for the site's file.

J. COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Injected Eye: _____

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

Complete Only After all Other Follow-Up Sections Are Completed

1. For Eyes Randomized to Laser

A. Treatment of Study Eye

*(Ignore section if no eye is randomized to Laser **OR** if eye randomized to laser has received the study preparation of intravitreal triamcinolone.)*

1. Was the eye randomized to laser assessed for retreatment with laser at this visit? Yes No

Note: Eye should not be assessed for retreatment with laser unless at least 3.5 months have elapsed since the last laser treatment.

If NO, skip to question #4

If YES, complete the following:

2. Does the eye being assessed meet criteria for deferral of laser retreatment for DME? Yes No

a. If 'Yes', reason:

Max treatment already given
Success criteria met
Substantial improvement criteria met
Futility criteria met
Significant adverse effect of treatment
Other _____

b. If 'No', will retreatment with laser be performed: Yes No

If NO, reason: Patient Refuses
Equipment Failure
Other _____

3. Has the eye randomized to laser experienced a 15-letter decrease from baseline in best-corrected visual acuity (due to macular edema) that is present at two consecutive 4-month interval visits <u>AND</u> is the intent to treat this eye with the study intravitreal triamcinolone formulation? Yes No

If Yes, before continuing please contact the Jaeb Center at 1-866-372-7601 to confirm that the patient meets the criteria for a triamcinolone injection.

4. Is any treatment for DME in study eye other than laser photocoagulation or intravitreal triamcinolone injection to be prescribed/planned? Yes No

If Yes, Indicate any other treatment and why treatment is being given. _____

_____

5. If the eye is <u>not</u> being retreated, timing of next follow up visit for this eye _____ [wks/mos]

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

B. Treatment of Study Eye

(Complete section only if eye randomized to laser has previously received the study preparation of intravitreal triamcinolone.)

1. Will the patient receive treatment for diabetic macular edema in the eye randomized to laser at this visit?
Yes No

(Retreatment by the same method (laser or triamcinolone injection) should not be performed unless at least 3.5 months have elapsed since the previous treatment)

If Yes, mark all treatments that apply

- ☐ **Laser Photocoagulation**
- ☐ **Intravitreal Triamcinolone Acetonide (Study Formulation)**
- ☐ **Other _____**

2. If the eye is <u>not</u> being retreated, timing of next follow up visit for this eye _____ <u>[wks/mos]</u>

2. For Eyes Randomized to Triamcinolone

<u>A. Treatment of Study Eye</u>

*(Ignore section if no eye is randomized to Triamcinolone **OR** if eye randomized to triamcinolone has previously received laser photocoagulation during the study)*

1. Was the eye randomized to triamcinolone assessed for intravitreal triamcinolone retreatment at this visit?
Yes No

Note: Eye should not be assessed for reinjection with intravitreal triamcinolone unless at least 3.5 months have elapsed since the last injection.

If NO, skip to question #4

If YES, complete the following:

2. Does the eye randomized to triamcinolone meet criteria for deferral of triamcinolone retreatment for DME?
Yes No

a. If 'Yes', reason: Success Criteria Met
Treatment Toxicity
Futility Criteria Met
other _____

b. If 'No', will retreatment be performed: Yes No If NO, reason: _____

3. Has the eye randomized to triamcinolone experienced a 15-letter decrease from baseline in best-corrected visual acuity (due to macular edema) that is present at two consecutive 4-month interval visits <u>AND</u> is the intent to treat this eye with laser photocoagulation? Yes No

If Yes, please contact the Jaeb Center at 1-866-372-7601 to confirm that the patient meets the criteria for laser treatment before continuing.

Intravitreal Triamcinolone Acetonide Study

Post-Injection Visit Form

4. Is any treatment for DME in study eye other than intravitreal triamcinolone or laser treatment to be prescribed/planned? Yes No

If Yes, Indicate any other treatment and why treatment is being given. _____
_____

5. If the eye is not being retreated, timing of next follow up visit for this eye __ [wks/mos]

B. Treatment of Study Eye

(Complete section only if eye randomized to triamcinolone has previously received laser photocoagulation within the study.)

1. Will the patient receive treatment for diabetic macular edema in the eye randomized to laser at this visit?
Yes No

(Retreatment by the same method (laser or triamcinolone injection) should not be performed unless at least 3.5 months have elapsed since the previous treatment)

If Yes, mark all treatments that apply

- ☐ **Laser Photocoagulation**
- ☐ **Intravitreal Triamcinolone Acetonide (Study Formulation)**
- ☐ **Other _____**

2. If the eye is not being retreated, timing of next follow up visit for this eye _____ [wks/mos]

3. Treatment of Nonstudy Eye

Ignore section if both eyes are study eyes

Is DME present in the nonstudy eye that will be treated with the study intravitreal triamcinolone? Yes No
(If the other eye has received triamcinolone then the nonstudy eye may NOT be treated with triamcinolone)

If Yes, complete an Intravitreal Injection Form when the injection is given.
Note: This eye now becomes a study eye for adverse events and data collection at future visits.

D. COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Visit Date: Enter Date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Visit Type: 4 month 12 month 24 month 36 month

Investigator: _____

A. Medical Update Section

Date Medical Update Elicited: Enter Date: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

1. Did patient commence or change the usage of any medications since last visit? ☐ Yes ☐ No
(If Yes, complete the Concomitant Medication Form.)

2. Did the patient experience any of the following? ☐ Yes ☐ No
If Yes, check all that apply and complete an Adverse Event Form for each.

☐ **Ocular or non-ocular surgery since last visit**

☐ **Hospitalization for any reason other than surgery since last visit?**

☐ **Any new non-ocular medical problems since last visit?**

☐ **A change in an existing non-ocular medical problem since last visit?**

☐ **Any new ocular medical problems since last visit?**

☐ **A change in an existing ocular medical problem since last visit?**

A1. Study Eye Ocular Treatment Update
RIGHT EYE (OD)

Complete the following if the right eye is a study eye

1. Has the patient received any treatment for DME in the study eye (right eye) since the last visit (i.e. treatment was received at the study site or at a non-study site and therefore not recorded on a prior study case report form)? ☐ Yes ☐ No

If Yes, explain and provide dates:

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

LEFT EYE (OS)

Complete the following if the left eye is a study eye

1. Has the patient received any treatment for DME in the study eye (left eye) since the last visit (i.e. treatment was received at the study site or at a non-study site and therefore not recorded on a prior study case report form)?

☐ Yes ☐ No

If Yes, explain and provide dates:

B. Visual Acuity Section

Refraction is required in both eyes at this visit. Visual acuity measurement is required in both eyes after refraction, without cycloplegia or dilation, using the Electronic Visual Acuity Tester.

Will visual acuity testing be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will visual acuity testing be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Visual Acuity testing date (includes refraction if performed): Enter Date: __ __/__ __ __/__ __ __ __ ***dd/MMM/yyyy***

B1. Refraction – (Refraction is required in both eyes at this visit)

Was a refraction performed at this visit prior to VA testing? ☐ Yes ☐ No

If Yes, Refractionist: _____

If Yes, enter below and use for visual acuity testing.
If No, enter correction used for visual acuity testing.

Refraction/ Correction Used: OD _____ (sph) _____ (cyl) @ _____ (axis) o **OS** _____ (sph) _____ (cyl) @ _____ (axis) o

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

B2. Visual Acuity - Visual acuity measurement is required in both eyes at this visit.

EVA Instrument # *(from label):* _____

Calibration Checks

Verify the following:

☐ Testing distance = 3 meters (118 inches) from monitor screen to center of exam chair seat

☐ Brightness of screen within range on light meter

☐ Size of EVA calibration square: horizontal = 114 mm and vertical = 114 mm

ETDRS letter score: OD _____

OS _____

VA Tester: _____

Was the visual acuity tester masked to the patient's treatment group (intravitreal triamcinolone or laser)?

Yes No

☐ **Acuity testing completed but testing procedure deviated from protocol.**
Please detail: _____

_____

C. Repeat Visual Acuity Section (if needed)

Complete section if repeat visual acuity test or repeat refraction is needed

Was a refraction performed after the initial visual acuity testing in either eye?

No **Yes, OD (right eye)** **Yes, OS (left eye)** **Yes, OU (both eyes)**

If Yes, enter refraction and refractionist below:

Refractionist: _____

Refraction: **OD** _____ (sph) _____ (cyl) @ _____ o (axis) **OS** _____ (sph) _____ (cyl) @ _____ o (axis)

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

Was visual acuity testing repeated in either eye?

No Yes, OD (right eye) Yes, OS (left eye) Yes, OU (both eyes)

If Yes, enter below:

EVA Instrument # *(from label):* _____

Calibration Checks
Verify the following:

☐ **Testing distance = 3 meters (118 inches) from monitor screen to center of exam chair seat**

☐ **Brightness of screen within range on light meter**

☐ **Size of EVA calibration square: horizontal = 114 mm and vertical = 114 mm**

ETDRS letter score: OD _____

OS _____

VA Tester: _____

☐ **Acuity testing completed but testing procedure deviated from protocol.**

Please detail: _____

_____

D. Slit Lamp Exam

Slit lamp exam is required in both eyes.

Will a slit lamp exam be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will a slit lamp exam be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Slit lamp exam date: **Enter Date:** ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

RIGHT EYE (OD) – Slit lamp is required on the right eye

1. Lids/ Conjunctiva ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Cornea ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Iris neovascularization

☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

LEFT EYE (OS) - Slit lamp is required on the left eye

1. Lids/ Conjunctiva ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Cornea ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Iris neovascularization

☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovasculatization) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

E. Intraocular Pressure Measurement

IOP measurement is required in both eyes.

Will an intraocular pressure measurement be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will an intraocular pressure measurement be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

IOP measurement date: **Enter Date:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ *dd/MMM/yyyy*

E1. IOP Treatment

Is patient currently on IOP lowering medication for the: *(If Yes, complete the Concomitant Medication Form)*

Right eye (OD)? Yes No

Left eye (OS)? Yes No

E2. IOP Measurement

IOP Tester _____

Right Eye (OD) – IOP measurement is required on right eye

Intraocular Pressure: _____ **mm Hg**
(Using Goldmann Tonometer)

Left Eye (OS) – IOP measurement is required on left eye

Intraocular Pressure: _____ **mm Hg**
(Using Goldmann Tonometer)

Protocol for Treatment of Elevated IOP
Treatment of elevated intraocular pressure will be instituted whenever the intraocular pressure is ≥ 30 mm Hg. The treatment to prescribe will be at investigator discretion and may include referral to another ophthalmologist. If the intraocular pressure is between 22 and 30 mm Hg, then the intraocular pressure should be remeasured within one month and treated if ≥30 mm Hg. Intraocular pressure >25 mm Hg at consecutive 4-month visits should be treated. If intraocular pressure is >25 mm Hg for 4 months, then a visual field should be performed to evaluate for glaucomatous damage.

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

F. Lens Assessment

(See procedure manual for lens assessment procedure)

Lens assessment is required in both eyes.

Will a lens assessment be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will a lens assessment be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Lens assessment date: Enter Date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Right Eye (OD) – Lens assessment is required in the right eye

1. Lens Status ☐ Phakic ☐ Pseudophakic ☐ Aphakic

If Phakic, complete the following:

2. Nuclear sclerosis *(see procedure manual for standard photos)* ☐ Absent ☐ Present, < standard ☐ Present, ≥ standard

3. Posterior subcapsular cataract *(see procedure manual for standard photos)* ☐ Absent ☐ Present, < standard ☐ Present, ≥ standard

4. Cortical cataract *(see procedure manual for standard photos)* ☐ Absent ☐ Present, < standard ☐ Present, ≥ standard

5. If lens opacity(ies) present, estimated effect on visual acuity ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

If Pseudophakic or Aphakic, complete the following:

6. Posterior capsular opacity? ☐ Yes ☐ No

7. If Yes, estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

Left Eye (OS) – Lens assessment is required in the left eye

1. Lens Status	☐ Phakic ☐ Pseudophakic ☐ Aphakic
If Phakic, complete the following:	
2. Nuclear sclerosis *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
3. Posterior subcapsular cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
4. Cortical cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
5. If lens opacity(ies) present, estimated effect on visual acuity	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100
If Pseudophakic or Aphakic, complete the following:	
6. Posterior capsular opacity?	☐ Yes ☐ No
7. If Yes, estimated effect on visual acuity?	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

G. Fundus Exam

Dilated fundus exam is required in both eyes.

Will a dilated fundus exam be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will a dilated fundus exam be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Dilated fundus exam date: **Enter Date:** ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

Right Eye (OD) – Dilated fundus exam is required in the right eye

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy ☐ No ☐ Yes

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If Yes complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

4. Optic disc ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

Left Eye (OS) – Dilated fundus exam is required in the left eye

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy ☐ No ☐ Yes

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If Yes complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

4. Optic disc ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

H. BLOOD PRESSURE

Complete only at 12 month, 24 month, and 36 month visits.

1. Date blood pressure taken: Enter Date: __ __ / __ __ __ /__ __ __ __ ***dd/MMM/yyyy***

☐ **Blood pressure was not taken.**

Reason: _____

2. Blood pressure: _____/_____ mm Hg *(Measure in sitting position after patient has been sitting for at least 5 minutes)*

I. OCT

OCT is required in both eyes

Will OCT be performed on the RIGHT eye? Yes No

If No, reason:
Patient cooperation insufficient
Equipment failure
Other _____

Will OCT be performed on the LEFT eye? Yes No

If No, reason:
Patient cooperation insufficient
Equipment failure
Other _____

1. Date OCT Performed: Enter date __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

2. Time OCT Performed: ____ : _____ am/ pm

3. OCT Technician: _____

4. OCT machine version: OCT1 OCT2 OCT3 (version < 4) OCT3 (version 4)
(If OCT3 version 4 was used, enter the signal strength for the scan below)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

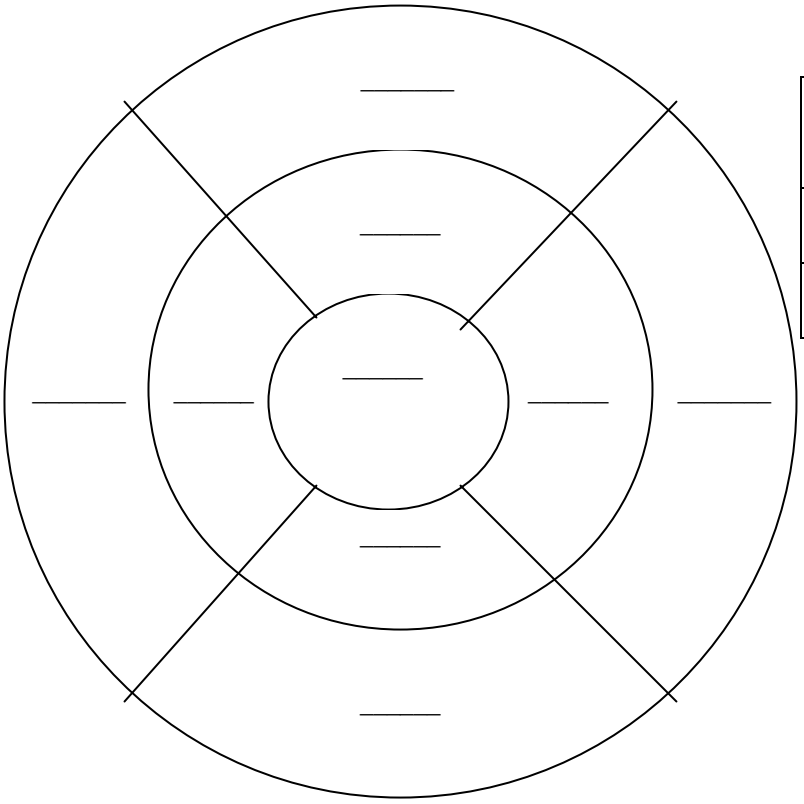
Note: Signal strength should be >= 6 AND standard deviation of center point thickness should be <= 10% for adequate scans.

Right Eye (OD) – Required on right eye

COMPLETE THE FOLLOWING SECTION FOR THE RIGHT EYE

Enter the thickness for each of the subfields in the diagram shown below.

Right Eye (OD)



Signal Strength	_____ *(If OCT3 Version 4 was used please enter signal strength.)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

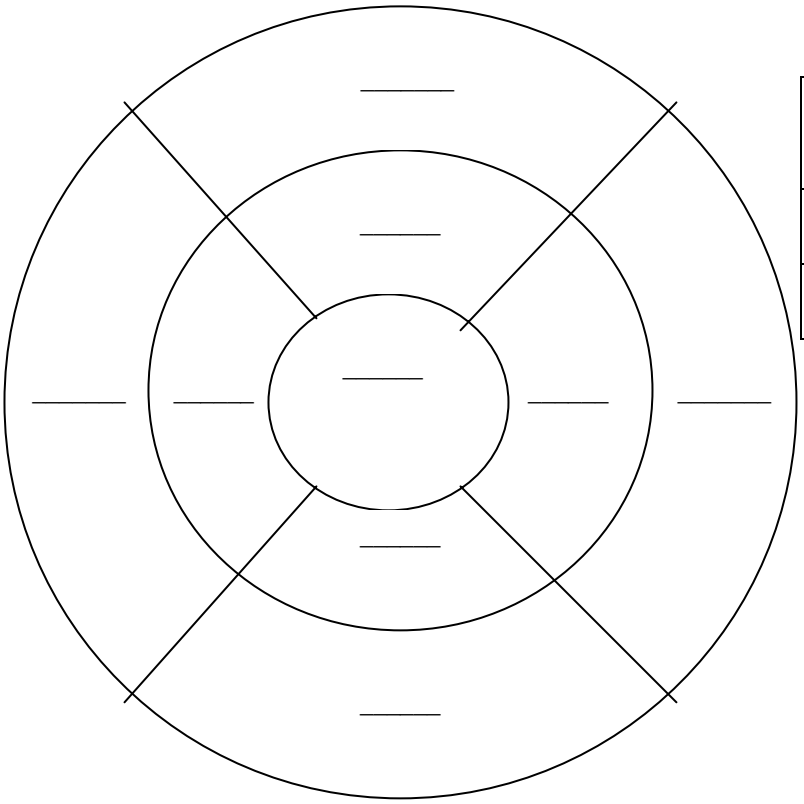
Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

Left Eye (OS) – Required on left eye

COMPLETE THE FOLLOWING SECTION FOR THE LEFT EYE

Enter the thickness for each of the subfields in the diagram shown below.

Left Eye (OS)



Signal Strength	_____ *(If OCT3 Version 4 was used please enter signal strength.)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

J. FUNDUS PHOTOGRAPHY

If 12 month, 24 month, or 36 month visit, 7-Field and Fundus (Red) Reflex fundus photos are required to be performed in both eyes.

If 4 month visit, 3-Field and Fundus (Red) Reflex fundus photos are required to be performed in both eyes.

Will fundus photos be taken on the RIGHT eye? Yes No

If No, reason: Media clarity insufficient
Pupillary dilation insufficient
Patient cooperation insufficient
Equipment failure
Film processing difficulties
Other_____

Will fundus photos be taken on the LEFT eye? Yes No

If No, reason: Media clarity insufficient
Pupillary dilation insufficient
Patient cooperation insufficient
Equipment failure
Film processing difficulties
Other_____

Date ETDRS Fundus Photos Performed: Enter Date: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

Note: If Media clarity or Pupillary dilation is insufficient for fundus photos, please obtain reflex photos. If only reflex photos are obtained, record this in the 'What photographs were completed?' portion of the form.

1. Photographer: _____

2. Camera Used: _____

3. What photographs were completed?

	OD	**OS**
	Required fields including fundus reflex	Required fields including red reflex
	Other; explain _____	Other; explain _____
	_____	_____
	_____	_____

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study
Outcome Assessment Visit
(4 Months, 12 Months, 24 Months, 36 Months)

K. Lab Form

Complete only at 4 month, 1 year, 2 year, and 3 year Outcome Assessment Visit.

	Collection Date	Value	Lab Normal Range (Low Value to High Value)	Not completed but will be completed within 3 weeks.	Missed ?*
HbA1c	__ __ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*	_____	_____ to _____	☐	☐

***If missed provide reason in comments section**

L. General Chart Comments (Optional)

This section is provided for convenience to record general chart information. This information is not considered study data, but can be printed for the site's file.

M. COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Follow-Up Impression Plan Section

Complete Only After all Other Follow-Up Forms Are Completed

1. For Eyes Randomized to Laser

A. Treatment of Study Eye

*(Ignore section if no eye is randomized to Laser **OR** if eye randomized to laser has received the study preparation of intravitreal triamcinolone.)*

1. Was the eye randomized to laser assessed for retreatment with laser at this visit? Yes No

Note: Eye should not be assessed for retreatment with laser unless at least 3.5 months have elapsed since the last laser treatment.

If NO, skip to question #4

If YES, complete the following:

2. Does the eye being assessed meet criteria for deferral of laser retreatment for DME? Yes No

a. If 'Yes', reason:

Max treatment already given
Success criteria met
Substantial improvement criteria met
Futility criteria met
Significant adverse effect of treatment
Other _____

b. If 'No', will retreatment with laser be performed: Yes No

If NO, reason: Patient Refuses
Equipment Failure
Other _____

3. Has the eye randomized to laser experienced a 15-letter decrease from baseline in best-corrected visual acuity (due to macular edema) that is present at two consecutive 4-month interval visits AND is the intent to treat this eye with the study intravitreal triamcinolone formulation? Yes No

If Yes, before continuing please contact the Jaeb Center at 1-866-372-7601 to confirm that the patient meets the criteria for a triamcinolone injection.

4. Is any treatment for DME in study eye other than laser photocoagulation or intravitreal triamcinolone injection to be prescribed/planned? Yes No

If Yes, Indicate any other treatment and why treatment is being given. _____

_____

_____

5. If the eye is not being retreated, timing of next follow up visit for this eye _____ [wks/mos]

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Follow-Up Impression Plan Section

Complete Only After all Other Follow-Up Forms Are Completed

B. Treatment of Study Eye

(Complete section only if eye randomized to laser has previously received the study preparation of intravitreal triamcinolone.)

1. Will the patient receive treatment for diabetic macular edema in the eye randomized to laser at this visit?
Yes No

(Retreatment by the same method (laser or triamcinolone injection) should not be performed unless at least 3.5 months have elapsed since the previous treatment)

If Yes, mark all treatments that apply

- ☐ **Laser Photocoagulation**
- ☐ **Intravitreal Triamcinolone Acetonide (Study Formulation)**
- ☐ **Other** _____

2. If the eye is <u>not</u> being retreated, timing of next follow up visit for this eye _____ <u>[wks/mos]</u>

2. For Eyes Randomized to Triamcinolone

<u>A. Treatment of Study Eye</u>

*(Ignore section if no eye is randomized to Triamcinolone **OR** if eye randomized to triamcinolone has previously received laser photocoagulation during study)*

1. Was the eye randomized to triamcinolone assessed for intravitreal triamcinolone retreatment at this visit?
Yes No

Note: Eye should not be assessed for reinjection with intravitreal triamcinolone unless at least 3.5 months have elapsed since the last injection.

If NO, skip to question #4

If YES, complete the following:

2. Does the eye randomized to triamcinolone meet criteria for deferral of triamcinolone retreatment for DME?
Yes No

a. If 'Yes', reason: Success Criteria Met
Treatment Toxicity
Futility Criteria Met
other _____

b. If 'No', will retreatment be performed: Yes No If NO, reason: _____

3. Has the eye randomized to triamcinolone experienced a 15-letter decrease from baseline in best-corrected visual acuity (due to macular edema) that is present at two consecutive 4-month interval visits <u>AND</u> is the intent to treat this eye with laser photocoagulation? Yes No

If Yes, please contact the Jaeb Center at 1-866-372-7601 to confirm that the patient meets the criteria for laser treatment before continuing.

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Follow-Up Impression Plan Section

Complete Only After all Other Follow-Up Forms Are Completed

4. Is any treatment for DME in study eye other than intravitreal triamcinolone or laser treatment to be prescribed/planned? Yes No

If Yes,

Indicate any other treatment and why treatment is being given. _____
_____

5. If the eye is not being retreated, timing of next follow up visit for this eye __ [wks/mos]

B. Treatment of Study Eye

(Complete section only if eye randomized to triamcinolone has previously received laser photocoagulation within the study.)

1. Will the patient receive treatment for diabetic macular edema in the eye randomized to laser at this visit?
Yes No

(Retreatment by the same method (laser or triamcinolone injection) should not be performed unless at least 3.5 months have elapsed since the previous treatment)

If Yes, mark all treatments that apply

- ☐ **Laser Photocoagulation**
- ☐ **Intravitreal Triamcinolone Acetonide (Study Formulation)**
- ☐ **Other** _____

2. If the eye is not being retreated, timing of next follow up visit for this eye _____ [wks/mos]

3. Treatment of Nonstudy Eye

Ignore section if both eyes are study eyes

Is DME present in the nonstudy eye that will be treated with the study intravitreal triamcinolone? Yes No
(If the other eye has received triamcinolone then the nonstudy eye may NOT be treated with triamcinolone)

If Yes, complete an Intravitreal Injection Form when the injection is given.
Note: This eye now becomes a study eye for adverse events and data collection at future visits.

D. COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Visit Date: Enter Date: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

Visit Type: 8 Month 16 Month 20 Month 28 Month 32 Month

Investigator: _____

A. Medical Update Section

Date Medical Update Elicited: Enter Date: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

1. **Did patient commence or change the usage of any medications since last visit?** ☐ Yes ☐ No
   (If Yes, complete the Concomitant Medication Form.)

2. **Did the patient experience any of the following?** ☐ Yes ☐ No
   If Yes, check all that apply and complete an Adverse Event Form for each.

☐ **Ocular or non-ocular surgery since last visit**

☐ **Hospitalization for any reason other than surgery since last visit?**

☐ **Any new non-ocular medical problems since last visit?**

☐ **A change in an existing non-ocular medical problem since last visit?**

☐ **Any new ocular medical problems since last visit?**

☐ **A change in an existing ocular medical problem since last visit?**

A1. Study Eye Ocular Treatment Update

RIGHT EYE (OD)

Complete the following if the right eye is a study eye

1. Has the patient received any treatment for DME in the study eye (right eye) since the last visit (i.e. treatment was received at the study site or at a non-study site and therefore not recorded on a prior study case report form)? ☐ Yes ☐ No

If Yes, explain and provide dates:

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

LEFT EYE (OS)

Complete the following if the left eye is a study eye

1. Has the patient received any treatment for DME in the study eye (left eye) since the last visit (i.e. treatment was received at the study site or at a non-study site and therefore not recorded on a prior study case report form)?

☐ Yes ☐ No

If Yes, explain and provide dates:

B. Visual Acuity Section

Visual acuity measurement is required in both eyes without cycloplegia or dilation, using the Electronic Visual Acuity Tester.

Refraction is not required.

Will visual acuity testing be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will visual acuity testing be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Visual Acuity testing date (includes refraction if performed): Enter Date: __ __ / __ __ __ / __ __ __ __ ***dd/MMM/yyyy***

B1. Refraction – (Optional)

Was a refraction performed at this visit prior to VA testing? ☐ Yes ☐ No

If Yes, Refractionist: _____

If Yes, enter below and use for visual acuity testing.
If No, enter correction used for visual acuity testing.

Refraction/ Correction Used: OD _____ (sph) _____ (cyl) @ _____ (axis) o **OS** _____ (sph) _____ (cyl) @ _____ (axis) o

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

B2. Visual Acuity - Visual acuity measurement is required in both eyes at this visit.

EVA Instrument # *(from label):* _____

Calibration Checks
Verify the following:

☐ Testing distance = 3 meters (118 inches) from monitor screen to center of exam chair seat

☐ Brightness of screen within range on light meter

☐ Size of EVA calibration square: horizontal = 114 mm and vertical = 114 mm

ETDRS letter score: OD _____

OS _____

VA Tester: _____

Was the visual acuity tester masked to the patient's treatment group? Yes No

☐ **Acuity testing completed but testing procedure deviated from protocol.**
Please detail: _____

_____

C. Repeat Visual Acuity Section (optional)

Refraction and/or repeat visual acuity should be performed in the study eye(s) if there has been an unexplained 15-letter visual acuity loss since the previous refraction.

Was a refraction performed after the initial visual acuity testing in either eye?

No **Yes, OD (right eye)** **Yes, OS (left eye)** **Yes, OU (both eyes)**

If Yes, enter refraction and refractionist below:

Refractionist: _____

Refraction: **OD** _____ _____ @ _____ o **OS** _____ _____ @ _____ o
sph cyl axis sph cyl axis

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

Was visual acuity testing repeated in either eye?

No Yes, OD (right eye) Yes, OS (left eye) Yes, OU (both eyes)

If Yes, enter below:

EVA Instrument # *(from label):* _____

Calibration Checks
Verify the following:

☐ **Testing distance = 3 meters (118 inches) from monitor screen to center of exam chair seat**

☐ **Brightness of screen within range on light meter**

☐ **Size of EVA calibration square: horizontal = 114 mm and vertical = 114 mm**

ETDRS letter score: OD _____

OS _____

VA Tester: _____

☐ **Acuity testing completed but testing procedure deviated from protocol.**

Please detail: _____

_____

D. Slit Lamp Exam

Slit lamp exam is required in both eyes.

Will a slit lamp exam be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will a slit lamp exam be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Slit lamp exam date: Enter Date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

RIGHT EYE (OD) – Slit lamp is required on the right eye

1. Lids/ Conjunctiva ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Cornea ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Iris neovascularization

☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

LEFT EYE (OS) - Slit lamp is required on the left eye

1. Lids/ Conjunctiva ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Cornea ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Iris neovascularization

☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

E. Intraocular Pressure Measurement

IOP measurement is required in both eyes.

Will an intraocular pressure measurement be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will an intraocular pressure measurement be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

IOP measurement date: **Enter Date:** ___ ___ **/** ___ ___ ___ **/**___ ___ ___ ___ *dd/MMM/yyyy*

E1. IOP Treatment

Is patient currently on IOP lowering medication for the: *(If Yes, complete the Concomitant Medication Form)*	**Right eye (OD)?**	Yes	No
	Left eye (OS)?	Yes	No

E2. IOP Measurement

IOP Tester _____

Right Eye (OD) – IOP measurement is required on right eye

Intraocular Pressure: _____ **mm Hg**
(Using Goldmann Tonometer)

Left Eye (OS) – IOP measurement is required on left eye

Intraocular Pressure: _____ **mm Hg**
(Using Goldmann Tonometer)

Protocol for Treatment of Elevated IOP
Treatment of elevated intraocular pressure will be instituted whenever the intraocular pressure is ≥ 30 mm Hg. The treatment to prescribe will be at investigator discretion and may include referral to another ophthalmologist. If the intraocular pressure is between 22 and 30 mm Hg, then the intraocular pressure should be remeasured within one month and treated if ≥30 mm Hg. Intraocular pressure >25 mm Hg at consecutive 4-month visits should be treated. If intraocular pressure is >25 mm Hg for 4 months, then a visual field should be performed to evaluate for glaucomatous damage.

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

F. Lens Assessment

(See procedure manual for lens assessment procedure)

Lens assessment is not required in either eye but may be recorded if performed

Will a lens assessment be performed on the RIGHT eye at this visit? **Yes** **No**

If No, reason: _____

Will a lens assessment be performed on the LEFT eye at this visit? **Yes** **No**

If No, reason: _____

Lens assessment date: **Enter Date:** ___ ___ **/** ___ ___ ___ **/**___ ___ ___ ___ *dd/MMM/yyyy*

Right Eye (OD) – (optional)

1. Lens Status ☐ Phakic ☐ Pseudophakic ☐ Aphakic

If Phakic, complete the following:

2. Nuclear sclerosis *(see procedure manual for standard photos)* ☐ Absent ☐ Present, < standard ☐ Present, ≥ standard

3. Posterior subcapsular cataract *(see procedure manual for standard photos)* ☐ Absent ☐ Present, < standard ☐ Present, ≥ standard

4. Cortical cataract *(see procedure manual for standard photos)* ☐ Absent ☐ Present, < standard ☐ Present, ≥ standard

5. If lens opacity(ies) present, estimated effect on visual acuity ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

If Pseudophakic or Aphakic, complete the following:

6. Posterior capsular opacity? ☐ Yes ☐ No

7. If Yes, estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

Left Eye (OS) – (optional)

1. Lens Status	☐ Phakic ☐ Pseudophakic ☐ Aphakic
If Phakic, complete the following:	
2. Nuclear sclerosis *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
3. Posterior subcapsular cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
4. Cortical cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
5. If lens opacity(ies) present, estimated effect on visual acuity	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100
If Pseudophakic or Aphakic, complete the following:	
6. Posterior capsular opacity?	☐ Yes ☐ No
7. If Yes, estimated effect on visual acuity?	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

G. Fundus Exam

Dilated fundus exam is required in both eyes.

Will a dilated fundus exam be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will a dilated fundus exam be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Dilated fundus exam date: **Enter Date:** ___ ___ **/** ___ ___ ___ **/**___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

Right Eye (OD) – Dilated fundus exam is required in the right eye

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy ☐ No ☐ Yes

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If Yes complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

4. Optic disc ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

Left Eye (OS) – Dilated fundus exam is required in the left eye

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy ☐ No ☐ Yes

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If Yes complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

4. Optic disc ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

H. OCT

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

OCT is required in both eyes

Will OCT be performed on the RIGHT eye? Yes No

If No, reason:

Patient cooperation insufficient
Equipment failure
Other _____

Will OCT be performed on the LEFT eye? Yes No

If No, reason:

Patient cooperation insufficient
Equipment failure
Other _____

1. Date OCT Performed: Enter date __ __ / __ __ __ / __ __ __ __ *dd/MMM/yyyy*

2. Time OCT Performed: ____ : _____ am/ pm

3. OCT Technician: _____

4. OCT machine version: OCT1 OCT2 OCT3 (version < 4) OCT3 (version 4)
(If OCT3 version 4 was used, enter the signal strength for the scan below)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

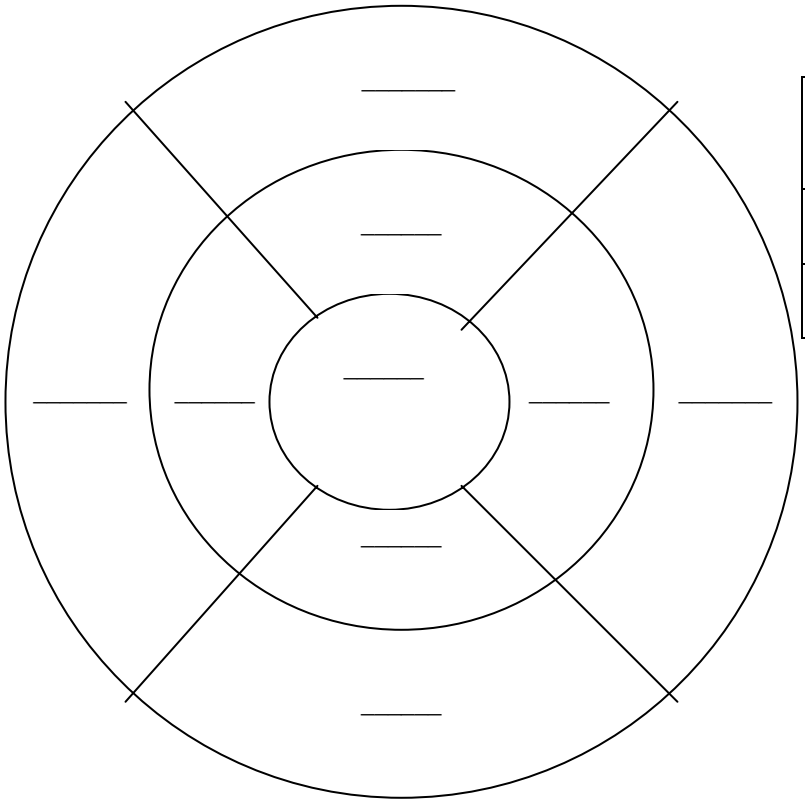
Note: Signal strength should be >= 6 AND standard deviation of center point thickness should be <= 10% for adequate scans.

Right Eye (OD) – Required on right eye

COMPLETE THE FOLLOWING SECTION FOR THE RIGHT EYE

Enter the thickness for each of the subfields in the diagram shown below.

Right Eye (OD)



Signal Strength	_____ *(If OCT3 Version 4 was used please enter signal strength.)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

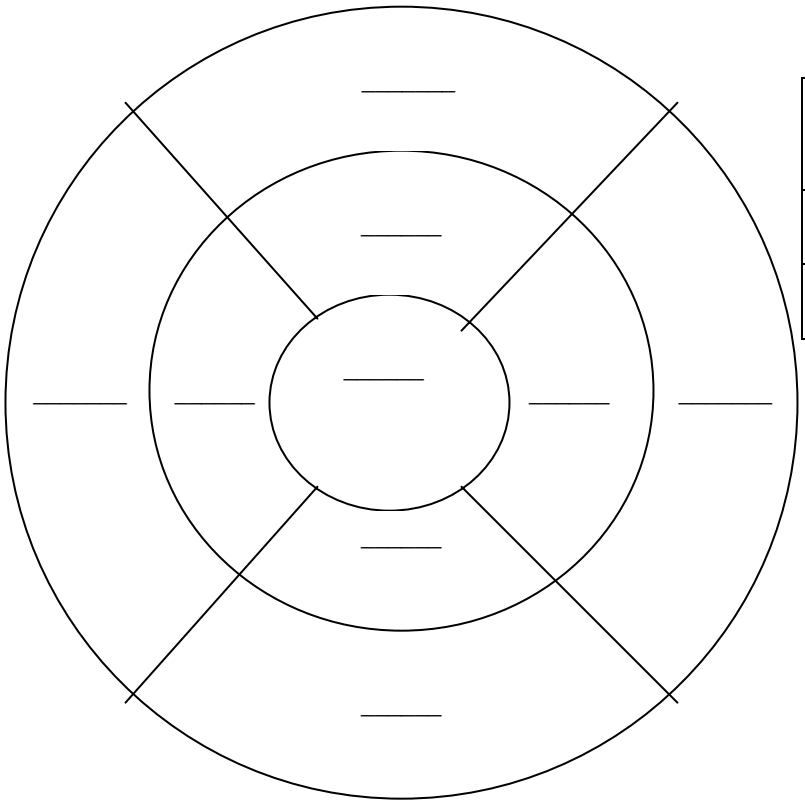
8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

Left Eye (OS) – Required on left eye

COMPLETE THE FOLLOWING SECTION FOR THE LEFT EYE

Enter the thickness for each of the subfields in the diagram shown below.

Left Eye (OS)



Signal Strength	_____ *(If OCT3 Version 4 was used please enter signal strength.)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

I. General Chart Comments (Optional)

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

This section is provided for convenience to record general chart information. This information is not considered study data, but can be printed for the site's file.

J. COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

Complete Only After all Other Follow-Up Sections Are Completed

1. For Eyes Randomized to Laser

A. Treatment of Study Eye

*(Ignore section if no eye is randomized to Laser **OR** if eye randomized to laser has received the study preparation of intravitreal triamcinolone.)*

1. Was the eye randomized to laser assessed for retreatment with laser at this visit? Yes No

Note: Eye should not be assessed for retreatment with laser unless at least 3.5 months have elapsed since the last laser treatment.

If NO, skip to question #4

If YES, complete the following:

2. Does the eye being assessed meet criteria for deferral of laser retreatment for DME? Yes No

a. If 'Yes', reason:

Max treatment already given
Success criteria met
Substantial improvement criteria met
Futility criteria met
Significant adverse effect of treatment
Other _____

b. If 'No', will retreatment with laser be performed: Yes No

If NO, reason: Patient Refuses
Equipment Failure
Other _____

3. Has the eye randomized to laser experienced a 15-letter decrease from baseline in best-corrected visual acuity (due to macular edema) that is present at two consecutive 4-month interval visits AND is the intent to treat this eye with the study intravitreal triamcinolone formulation? Yes No

If Yes, before continuing please contact the Jaeb Center at 1-866-372-7601 to confirm that the patient meets the criteria for a triamcinolone injection.

4. Is any treatment for DME in study eye other than laser photocoagulation or intravitreal triamcinolone injection to be prescribed/planned? Yes No

If Yes, Indicate any other treatment and why treatment is being given _____

_____

5. If the eye is not being retreated, timing of next follow up visit for this eye _____ [wks/mos]

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

B. Treatment of Study Eye

(Complete section only if eye randomized to laser has previously received the study preparation of intravitreal triamcinolone.)

1. Will the patient receive treatment for diabetic macular edema in the eye randomized to laser at this visit?
Yes No

(Retreatment by the same method (laser or triamcinolone injection) should not be performed unless at least 3.5 months have elapsed since the previous treatment)

If Yes, mark all treatments that apply

- ☐ **Laser Photocoagulation**
- ☐ **Intravitreal Triamcinolone Acetonide (Study Formulation)**
- ☐ **Other** _____

2. If the eye is <u>not</u> being retreated, timing of next follow up visit for this eye _____ [wks/mos]

2. For Eyes Randomized to Triamcinolone

A. Treatment of Study Eye

*(Ignore section if no eye is randomized to Triamcinolone **OR** if eye randomized to triamcinolone has previously received laser photocoagulation during study)*

1. Was the eye randomized to triamcinolone assessed for intravitreal triamcinolone retreatment at this visit?
Yes No

Note: Eye should not be assessed for reinjection with intravitreal triamcinolone unless at least 3.5 months have elapsed since the last injection.

If NO, skip to question #4

If YES, complete the following:

2. Does the eye randomized to triamcinolone meet criteria for deferral of triamcinolone retreatment for DME?
Yes No

a. If 'Yes', reason: Success Criteria Met
Treatment Toxicity
Futility Criteria Met
other _____

b. If 'No', will retreatment be performed: Yes No If NO, reason: _____

3. Has the eye randomized to triamcinolone experienced a 15-letter decrease from baseline in best-corrected visual acuity (due to macular edema) that is present at two consecutive 4-month interval visits AND is the intent to treat this eye with laser photocoagulation? Yes No

If Yes, please contact the Jaeb Center at 1-866-372-7601 to confirm that the patient meets the criteria for laser treatment before continuing.

4. Is any treatment for DME in study eye other than intravitreal triamcinolone or laser treatment to be prescribed/planned? Yes No

If Yes,

Indicate any other treatment and why treatment is being given. _____
_____

5. If the eye is not being retreated, timing of next follow up visit for this eye __ [wks/mos]

B. Treatment of Study Eye

(Complete section only if eye randomized to triamcinolone has previously received laser photocoagulation within the study.)

1. Will the patient receive treatment for diabetic macular edema in the eye randomized to laser at this visit?
Yes No

(Retreatment by the same method (laser or triamcinolone injection) should not be performed unless at least 3.5 months have elapsed since the previous treatment)

If Yes, mark all treatments that apply

- ☐ **Laser Photocoagulation**
- ☐ **Intravitreal Triamcinolone Acetonide (Study Formulation)**
- ☐ **Other** _____

2. If the eye is not being retreated, timing of next follow up visit for this eye _____ [wks/mos]

3. Treatment of Nonstudy Eye

Ignore section if both eyes are study eyes

Is DME present in the nonstudy eye that will be treated with the study intravitreal triamcinolone? Yes No
(If the other eye has received triamcinolone then the nonstudy eye may NOT be treated with triamcinolone)

If Yes, complete an Intravitreal Injection Form when the injection is given.
Note: This eye now becomes a study eye for adverse events and data collection at future visits.

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

8 Month, 16 Month, 20 Month, 28 Month, 32 Month Visit Form

COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Visit Date: Enter Date: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

Visit Type: Unspecified

Reasons for unspecified visit: Retreatment assessment
Adverse Event
Other _____

Investigator: _____

A. Medical Update Section

Date Medical Update Elicited: Enter Date: __ __ / __ __ __ /__ __ __ __ *dd/MMM/yyyy*

1. **Did patient commence or change the usage of any medications since last visit?** ☐ Yes ☐ No
   (If Yes, complete the Concomitant Medication Form.)

2. **Did the patient experience any of the following?** ☐ Yes ☐ No
   If Yes, check all that apply and complete an Adverse Event Form for each.

☐ **Ocular or non-ocular surgery since last visit**

☐ **Hospitalization for any reason other than surgery since last visit?**

☐ **Any new non-ocular medical problems since last visit?**

☐ **A change in an existing non-ocular medical problem since last visit?**

☐ **Any new ocular medical problems since last visit?**

☐ **A change in an existing ocular medical problem since last visit?**

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

A1. Study Eye Ocular Treatment Update

RIGHT EYE (OD)

Complete the following if the right eye is a study eye

1. Has the patient received any treatment for DME in the study eye (right eye) since the last visit (i.e. treatment was received at the study site or at a non-study site and therefore not recorded on a prior study case report form)? ☐ Yes ☐ No **If Yes, explain and provide dates:**

LEFT EYE (OS)

Complete the following if the left eye is a study eye

1. Has the patient received any treatment for DME in the study eye (left eye) since the last visit (i.e. treatment was received at the study site or at a non-study site and therefore not recorded on a prior study case report form)? ☐ Yes ☐ No **If Yes, explain and provide dates:**

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

B. Visual Acuity Section

Visual acuity should be measured in study eye(s) without cycloplegia or dilation, using the Electronic Visual Acuity Tester if:

- **Assessment for retreatment will be performed.**
- **Investigator determines acuity test is warranted.**

Refraction is not required. Visual acuity measurement is not required in the nonstudy eye but may be recorded if performed.

Will visual acuity testing be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will visual acuity testing be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Visual Acuity testing date (includes refraction if performed): Enter Date: __ __ / __ __ __ / __ __ __ __ ***dd/MMM/yyyy***

B1. Refraction – (Optional)

Was a refraction performed at this visit prior to VA testing? ☐ Yes ☐ No

If Yes, Refractionist: _____

If Yes, enter below and use for visual acuity testing.
If No, enter correction used for visual acuity testing.

Refraction/ Correction Used: OD _____ (sph) _____ (cyl) @ _____ (axis) o **OS** _____ (sph) _____ (cyl) @ _____ (axis) o

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

B2. Visual Acuity

EVA Instrument # *(from label):* _____

Calibration Checks
Verify the following:

☐ Testing distance = 3 meters (118 inches) from monitor screen to center of exam chair seat

☐ Brightness of screen within range on light meter

☐ Size of EVA calibration square: horizontal = 114 mm and vertical = 114 mm

ETDRS letter score: OD _____

OS _____

VA Tester: _____

☐ **Acuity testing completed but testing procedure deviated from protocol.**
Please detail: _____

_____

C. Repeat Visual Acuity Section (optional)

Refraction and/or repeat visual acuity should be performed in the study eye(s) if there has been an unexplained 15-letter visual acuity loss since the previous refraction.

Was a refraction performed after the initial visual acuity testing in either eye?

No **Yes, OD (right eye)** **Yes, OS (left eye)** **Yes, OU (both eyes)**

If Yes, enter refraction and refractionist below:

Refractionist: _____

Refraction: **OD** _____ _____ @ _____ o **OS** _____ _____ @ _____ o
sph cyl axis sph cyl axis

Was visual acuity testing repeated in either eye?

No **Yes, OD (right eye)** **Yes, OS (left eye)** **Yes, OU (both eyes)**

If Yes, enter below:

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

EVA Instrument # *(from label):* _____

Calibration Checks
Verify the following:

☐ **Testing distance = 3 meters (118 inches) from monitor screen to center of exam chair seat**

☐ **Brightness of screen within range on light meter**

☐ **Size of EVA calibration square: horizontal = 114 mm and vertical = 114 mm**

ETDRS letter score: OD _____

OS _____

VA Tester: _____

☐ **Acuity testing completed but testing procedure deviated from protocol.**

Please detail: _____

_____

D. Slit Lamp Exam

Slit lamp exam should be conducted in study eye(s) if:

- **Assessment for retreatment will be performed.**
- **Investigator determines exam is warranted.**

Slit lamp is not required in a nonstudy eye but may be recorded if performed.

Will a slit lamp exam be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will a slit lamp exam be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Slit lamp exam date: **Enter Date:** ___ ___ **/** ___ ___ ___ **/**___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

RIGHT EYE (OD)

1. Lids/ Conjunctiva ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Cornea ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Iris neovascularization

☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

LEFT EYE (OS)

1. Lids/ Conjunctiva ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Cornea ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Iris neovascularization

☐ Absent
☐ Present, pupillary margin only
☐ Present, beyond the margin, but not in the angle
☐ Present, In the angle

4. Anterior chamber (other than iris neovascularization) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

E. Intraocular Pressure Measurement

IOP measurement should be conducted in the study eye(s) if:

- **Assessment for retreatment will be performed.**
- **Investigator determines exam is warranted.**

IOP measurement is not required in a nonstudy eye but may be recorded if performed.

Will an intraocular pressure measurement be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will an intraocular pressure measurement be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

IOP measurement date: **Enter Date:** ___ ___ **/** ___ ___ ___ **/**___ ___ ___ ___ *dd/MMM/yyyy*

IOP Tester: _____

E1. IOP Treatment

Is patient currently on IOP lowering medication for the: *(If Yes, complete the Concomitant Medication Form)*	**Right eye (OD)?**	Yes	No
	Left eye (OS)?	Yes	No

E1. IOP Measurement

IOP Tester _____

Right Eye (OD)

Intraocular Pressure: _____ **mm Hg**
(Using Goldmann Tonometer)

Left Eye (OS)

Intraocular Pressure: _____ **mm Hg**
(Using Goldmann Tonometer)

Protocol for Treatment of Elevated IOP

Treatment of elevated intraocular pressure will be instituted whenever the intraocular pressure is $\geq$ 30 mm Hg. The treatment to prescribe will be at investigator discretion and may include referral to another ophthalmologist. If the intraocular pressure is between 22 and 30 mm Hg, then the intraocular pressure should be remeasured within one month and treated if $\geq$30 mm Hg. Intraocular pressure >25 mm Hg at consecutive 4-month visits should be treated. If intraocular pressure is >25 mm Hg for 4 months, then a visual field should be performed to evaluate for glaucomatous damage.

F. Lens Assessment

(See procedure manual for lens assessment procedure)

Lens assessment is not required in either eye but may be recorded if performed

Will a lens assessment be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will a lens assessment be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Lens assessment date: Enter Date: ___ ___ **/** ___ ___ ___ **/**___ ___ ___ ___ *dd/MMM/yyyy*

Right Eye (OD) – (optional)

1. Lens Status	☐ Phakic ☐ Pseudophakic ☐ Aphakic
If Phakic, complete the following:	
2. Nuclear sclerosis *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
3. Posterior subcapsular cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
4. Cortical cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
5. If lens opacity(ies) present, estimated effect on visual acuity	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100
If Pseudophakic or Aphakic, complete the following:	
6. Posterior capsular opacity?	☐ Yes ☐ No
7. If Yes, estimated effect on visual acuity?	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

Left Eye (OS) – (optional)

1. Lens Status	☐ Phakic ☐ Pseudophakic ☐ Aphakic
If Phakic, complete the following:	
2. Nuclear sclerosis *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
3. Posterior subcapsular cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
4. Cortical cataract *(see procedure manual for standard photos)*	☐ Absent ☐ Present, < standard ☐ Present, ≥ standard
5. If lens opacity(ies) present, estimated effect on visual acuity	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100
If Pseudophakic or Aphakic, complete the following:	
6. Posterior capsular opacity?	☐ Yes ☐ No
7. If Yes, estimated effect on visual acuity?	☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

G. Fundus Exam

Dilated fundus exam should be conducted in study eye(s) if:

- **Assessment for retreatment will be performed.**
- **Investigator determines exam is warranted.**

Dilated fundus exam is not required in a nonstudy eye but may be recorded if performed.

Will a dilated fundus exam be performed on the RIGHT eye at this visit? Yes No

If No, reason: _____

Will a dilated fundus exam be performed on the LEFT eye at this visit? Yes No

If No, reason: _____

Dilated fundus exam date: **Enter Date:** ___ ___ **/** ___ ___ ___ **/**___ ___ ___ ___ ***dd/MMM/yyyy***

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

Right Eye (OD)

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy ☐ No ☐ Yes

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If Yes complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

4. Optic disc ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

Left Eye (OS)

1. Vitreous hemorrhage ☐ No ☐ Yes

If Yes:

Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

2. Vitreous (other than vitreous hemorrhage) ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

3. Retina/choroid abnormality other than diabetic retinopathy ☐ No ☐ Yes

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If Yes complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

4. Optic disc ☐ Normal ☐ Abnormal

a. Is there a change compared to previous exam? ☐ No Change ☐ Improved ☐ Worsened

If abnormal complete sections b and c:

b. Describe any changes _____

_____

c. Estimated effect on visual acuity? ☐ None ☐ 20/25-20/40 ☐ 20/50-20/100 ☐ > 20/100

5. Center involvement of DME on clinical exam: Absent Borderline Present Cannot Determine

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

H. OCT

OCT is not required in either eye but may be recorded if performed

1. OCT: Date Performed: Enter date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

2. OCT: Time Performed: _____:_____ AM/ PM

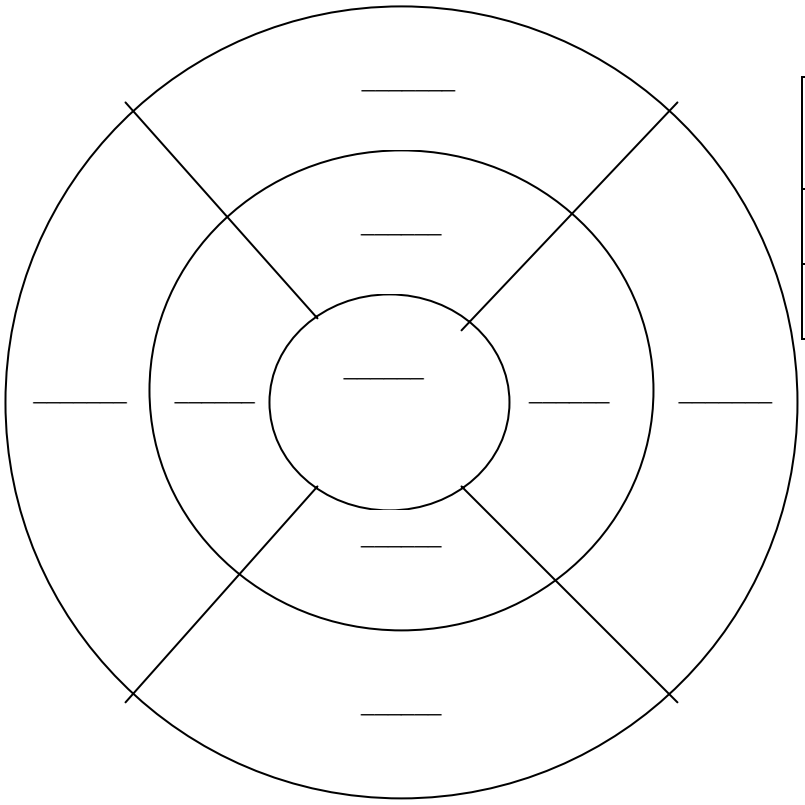
3. OCT Technician ID: __ __ __ - __ __ __

4. OCT machine version: OCT1 OCT2 OCT3 (version < 4) OCT3 (version 4)
(If OCT3 version 4 was used, enter the signal strength for the scan below)

Note: Signal strength should be >= 6 AND standard deviation of center point thickness should be <= 10% for adequate scans.

Right Eye (OD) - Optional

Enter the thickness for each of the subfields in the diagram shown below.



Signal Strength	_____ *(If OCT3 Version 4 was used please enter signal strength.)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

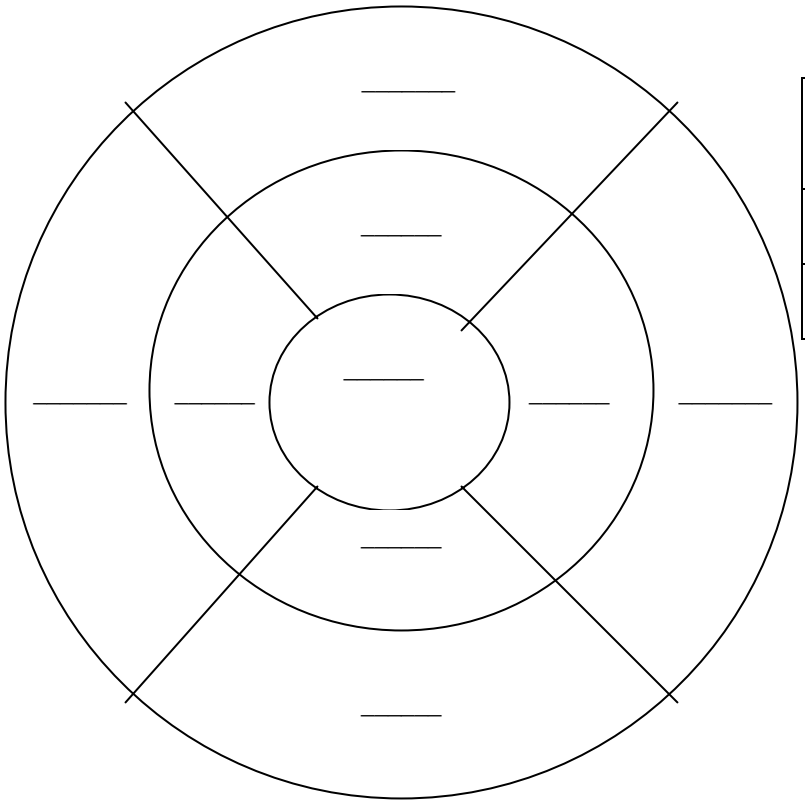
Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

Left Eye (OS) – Optional

Enter the thickness for each of the subfields in the diagram shown below.



Signal Strength	_____ *(If OCT3 Version 4 was used please enter signal strength.)*
Center	_____ ± _____ (microns)
Volume	_____ mm^3

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

I. General Chart Comments (Optional)

This section is provided for convenience to record general chart information. This information is not considered study data, but can be printed for the site's file.

J. COMMENTS

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

Complete Only After all Other Follow-Up Sections Are Completed

1. For Eyes Randomized to Laser

A. Treatment of Study Eye

*(Ignore section if no eye is randomized to Laser **OR** if eye randomized to laser has received the study preparation of intravitreal triamcinolone.)*

1. Was the eye randomized to laser assessed for retreatment with laser at this visit? Yes No

Note: Eye should not be assessed for retreatment with laser unless at least 3.5 months have elapsed since the last laser treatment.

If NO, skip to question #4

If YES, complete the following:

2. Does the eye being assessed meet criteria for deferral of laser retreatment for DME? Yes No

a. If 'Yes', reason:

Max treatment already given
Success criteria met
Substantial improvement criteria met
Futility criteria met
Significant adverse effect of treatment
Other _____

b. If 'No', will retreatment with laser be performed: Yes No

If NO, reason: Patient Refuses
Equipment Failure
Other _____

3. Has the eye randomized to laser experienced a 15-letter decrease from baseline in best-corrected visual acuity (due to macular edema) that is present at two consecutive 4-month interval visits AND is the intent to treat this eye with the study intravitreal triamcinolone formulation? Yes No

If Yes, before continuing please contact the Jaeb Center at 1-866-372-7601 to confirm that the patient meets the criteria for a triamcinolone injection.

4. Is any treatment for DME in study eye other than laser photocoagulation or intravitreal triamcinolone injection to be prescribed/planned? Yes No

If Yes, Indicate any other treatment and why treatment is being given _____

_____

5. If the eye is not being retreated, timing of next follow up visit for this eye _____ [wks/mos]

Pt. ID: ___ ___ ___ ___ -___ ___ ___ ___

Study Eye(s): _____

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

B. Treatment of Study Eye

(Complete section only if eye randomized to laser has previously received the study preparation of intravitreal triamcinolone.)

1. Will the patient receive treatment for diabetic macular edema in the eye randomized to laser at this visit?
Yes No

(Retreatment by the same method (laser or triamcinolone injection) should not be performed unless at least 3.5 months have elapsed since the previous treatment)

If Yes, mark all treatments that apply

- ☐ **Laser Photocoagulation**
- ☐ **Intravitreal Triamcinolone Acetonide (Study Formulation)**
- ☐ **Other** _____

2. If the eye is <u>not</u> being retreated, timing of next follow up visit for this eye _____ [wks/mos]

2. For Eyes Randomized to Triamcinolone

A. Treatment of Study Eye

*(Ignore section if no eye is randomized to Triamcinolone **OR** if eye randomized to triamcinolone has previously received laser photocoagulation during study)*

1. Was the eye randomized to triamcinolone assessed for intravitreal triamcinolone retreatment at this visit?
Yes No

Note: Eye should not be assessed for reinjection with intravitreal triamcinolone unless at least 3.5 months have elapsed since the last injection.

If NO, skip to question #4

If YES, complete the following:

2. Does the eye randomized to triamcinolone meet criteria for deferral of triamcinolone retreatment for DME?
Yes No

a. If 'Yes', reason: Success Criteria Met
Treatment Toxicity
Futility Criteria Met
other _____

b. If 'No', will retreatment be performed: Yes No If NO, reason: _____

3. Has the eye randomized to triamcinolone experienced a 15-letter decrease from baseline in best-corrected visual acuity (due to macular edema) that is present at two consecutive 4-month interval visits <u>AND</u> is the intent to treat this eye with laser photocoagulation? Yes No

If Yes, please contact the Jaeb Center at 1-866-372-7601 to confirm that the patient meets the criteria for laser treatment before continuing.

Intravitreal Triamcinolone Acetonide Study

Unspecified Visit Form

4. Is any treatment for DME in study eye other than intravitreal triamcinolone or laser treatment to be prescribed/planned? Yes No

If Yes,

Indicate any other treatment and why treatment is being given. _____
_____

5. If the eye is not being retreated, timing of next follow up visit for this eye __ [wks/mos]

B. Treatment of Study Eye

(Complete section only if eye randomized to triamcinolone has previously received laser photocoagulation within the study.)

1. Will the patient receive treatment for diabetic macular edema in the eye randomized to laser at this visit?
Yes No

(Retreatment by the same method (laser or triamcinolone injection) should not be performed unless at least 3.5 months have elapsed since the previous treatment)

If Yes, mark all treatments that apply

- ☐ **Laser Photocoagulation**
- ☐ **Intravitreal Triamcinolone Acetonide (Study Formulation)**
- ☐ **Other** _____

2. If the eye is not being retreated, timing of next follow up visit for this eye _____ [wks/mos]

3. Treatment of Nonstudy Eye

Ignore section if both eyes are study eyes

Is DME present in the nonstudy eye that will be treated with the study intravitreal triamcinolone? Yes No
(If the other eye has received triamcinolone then the nonstudy eye may NOT be treated with triamcinolone)

If Yes, complete an Intravitreal Injection Form when the injection is given.
Note: This eye now becomes a study eye for adverse events and data collection at future visits.

COMMENTS

Pt. ID: ___ ___ ___ ___ - ___ ___ ___ ___

Intravitreal Triamcinolone Acetonide Study

Adverse Event Form

PtID: ___ ___ ___ ___- ___ ___ ___ ___

Namecode: ___ ___ ___ ___ ___
1st 2 letters of first name, middle initial (X if none), 1st 2 letters of last name

Name of Investigator _____ **DRCR ID#:** _____

A. Description of Event

1. Type of Event: ☐ Systemic ☐ Right Eye (OD) ☐ Left Eye (OS)
(check one)

2. Adverse Event: _____
(Provide a brief description to categorize the event)

3. Date of Onset: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

4. Did this condition exist prior to enrollment? Yes No

5. Intensity (Severity) Mild Moderate Severe
(see definitions below)

6. Is there a reasonable possibility that the event was caused by the study treatment? Yes No
(see definitions below)

7. Does the event meet criteria for a serious adverse event Yes No
(see definitions below)

B. Treatment of Adverse Event

Did patient receive treatment for the Adverse Event? Yes No

If Yes, complete the following:

Surgery: Yes No

If yes, type of surgery _____

Date of surgery: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy*

Medication: Yes No

If yes, list medications here and add details on Concomitant Medication Form

_____

_____

Intravitreal Triamcinolone Acetonide Study

Adverse Event Form

Other: Yes No

If yes, detail _____

_____

C. Outcome

1. Outcome: Ongoing Complete Recovery Recovered with sequelae Fatal

2. Date of Resolution: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyyy* **OR** ☐ **Ongoing**

D. Additional Information for Serious Adverse Event

1. Weight: _____ **lbs / kgs** **OR** ☐ Not available

2. Outcomes Attributed to the Serious Adverse Event: *(check all that apply)*

☐ Death (date: ___ ___ / ___ ___ ___ /___ ___ ___ ___ *dd/MMM/yyy*)
☐ Congenital Anomaly
☐ Life Threatening
☐ Required Intervention to prevent permanent impairment/damage
☐ Hospitalization -- initial or prolonged
☐ Disability
☐ Other _____

3. Provide detailed description of the event
(see definitions below)

_____
_____
_____

4. Relevant Tests/Laboratory Data (including dates)? Yes No
(see definitions below)

If 'Yes', list: _____
_____
_____

Intravitreal Triamcinolone Acetonide Study

Adverse Event Form

5. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)**?** Yes No
(see definitions below)

If 'Yes', detail: _____

_____

_____

6. Concomitant medical products and therapy dates (exclude treatment of event)? Yes No
(see definitions below)

If 'Yes', please explain: _____

_____

_____

COMMENTS

Intensity (Question A.5)

Mild - Symptom(s) barely noticeable to subject or does not make subject uncomfortable; does not influence performance or functioning; prescription drug not ordinarily needed for relief of symptom(s).

Moderate - Symptom(s) of sufficient severity to make subject uncomfortable; performance of daily activity is influenced; subject is able to continue in study; treatment for symptom(s) may be needed.

Severe - Symptom(s) cause severe discomfort; severity may cause cessation of treatment with study medication; treatment for symptom(s) may be given and/or subject hospitalized.

Relationship to Study Treatment (Question A.6)

Reasonable possibility is not the same as “any possibility.” The following should be considered when evaluating the relationship:

- Timing of event
- Patient’s history
- Prevalence of finding in population at risk
- Other possible causes - diseases, exposures, therapies, etc
- Known pharmacology of study drug (and control)

Intravitreal Triamcinolone Acetonide Study

Adverse Event Form

Serious Adverse Event (Question A.7)

Any adverse event that meets one or more of the following criteria:

1 - Results in death
2 - Is life threatening
3 - Requires inpatient hospitalization or prolongation of existing hospitalization
4 - Results in persistent or significant disability/incapacity
5 - Is a congenital anomaly/birth defect.

Detailed description of the event (Question D.3)

Describe the event in detail using the reporter's own words, including a description of what happened and a summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If available and if relevant, include synopses of any office visit notes or the hospital discharge summary. To save time and space (and if permitted by the institution), fax copies of these records with any confidential information deleted to the Jaeb Center at 1-800-816-7601. DO NOT identify any patient, physician, or institution by name.

Relevant Tests/Laboratory Data (Question D.4)

Provide all appropriate information, including relevant *negative* test and laboratory findings, in order to most completely convey how the medical work-up/assessment led to strong consideration of medical-product-induced disease as etiology for clinical status, as other differential diagnostic considerations were being eliminated.

Include:

- Any relevant baseline laboratory data prior to the administration or use of the medical product/study procedure
- All laboratory data used in diagnosing the event
- Any available laboratory data/engineering analyses (for devices) that provide further information on the course of the event

If available, include:

- Any pre- and post-event medication levels and dates (if applicable)
- Synopses of any relevant autopsy, pathology, engineering, or lab reports

If preferred, copies of any reports may be submitted as attachments, with all confidential information deleted. DO NOT identify any patient, physician or institution by name.

Other relevant history, including preexisting medical conditions (Question D.5)

If available and applicable, provide information on:

- Other known conditions in patient, e.g., *Hypertension, Diabetes mellitus, Renal/hepatic dysfunction, etc.)*
- Significant history
  - *Race*
  - *Allergies*
  - *Pregnancy history*
  - *Smoking and alcohol use*
  - *Drug abuse, etc.*

Concomitant medical products and therapy dates (Question D.6)

List and provide therapy dates for any other medical products (drugs, biologics, medical devices, etc.) that a patient was using at the time of the event. DO NOT include products used to treat the event.