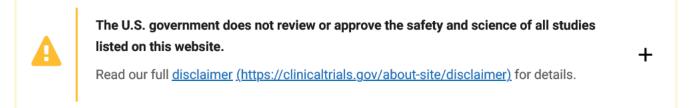
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A Study of Ranibizumab Injection in Subjects With Clinically Significant Macular Edema (ME) With Center Involvement Secondary to Diabetes Mellitus (RISE) (RISE)

ClinicalTrials.gov ID 

NCT00473330

Sponsor 🕕 Genentech, Inc.

Information provided by () Genentech, Inc. (Responsible Party)

Last Update Posted 1 2017-04-17

# **Record History Tab**

### **Study Record Versions**

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- This table shows the list of all the versions of this study record arranged in order by date.
- The first column shows the date the study record was updated, and the second column shows the elements in the study record that were changed.
  - To view a version of a study record, click the version date.
  - To compare versions, select two versions using the check boxes and click the "Compare" button at the bottom of the list.

	<u>2007-05-13</u>	None (earliest version on record)	Feedback	
	<u>2007-07-12</u>	Recruitment Status	Fee	
Compare				

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		Study Status
		Contacts/Locations
I	<u>2007-08-06</u>	Study Status Contacts/Locations
	<u>2007-09-12</u>	Study Status Contacts/Locations
	<u>2007-10-15</u>	Study Status Conditions Arms and Interventions Outcome Measures Eligibility Contacts/Locations Study Identification Study Description
	<u>2008-09-24</u>	Study Status Contacts/Locations Study Identification Conditions Study Design Arms and Interventions Sponsor/Collaborators Outcome Measures Eligibility
	<u>2009-02-02</u>	Recruitment Status Study Status
	<u>2009-11-02</u>	Study Status Contacts/Locations Outcome Measures
	<u>2010-11-11</u>	Study Status

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	(		<u>2012-12-10</u>	Study StatusStudy IdentificationSponsor/CollaboratorsStudy DescriptionConditionsStudy DesignArms and InterventionsOutcome MeasuresEligibilityParticipant FlowBaseline CharacteristicsAdverse EventsMore Information
	(		<u>2013-07-31</u>	Recruitment Status Study Status
	(		<u>2014-08-25</u>	Study Status Study Description Arms and Interventions Outcome Measures Participant Flow Baseline Characteristics Adverse Events More Information
			Date	Changes
			Date	Version 9: 2010-11-11 Changes
<b>DOCKET</b> A L A R M Find authenticated court documents without watermarks at <u>docketalarm.com</u> .				

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#### **Study Identification**

#### **Unique Protocol ID**

FVF4170g

#### **Brief Title**

A Study of Ranibizumab Injection in Subjects With Clinically Significant Macular Edema With Center Involvement Secondary to Diabetes Mellitus (RISE)

#### **Official Title**

A Phase III, Double-Masked, Multicenter, Randomized, Sham Injection-Controlled Study of the Efficacy and Safety of Ranibizumab Injection in Subjects With Clinically Significant Macular Edema With Center Involvement Secondary to Diabetes Mellitus

Secondary IDs

	Study Status
	Record Verification
	2010-11
	Overall Status
	Active, not recruiting
	Study Start
	2007-07
	Primary Completion
	2012-10 [Estimated]
	Study Completion
Date Cha	inges
	2007-05-13

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Record History | ver. 9: 2010-11-11 | NCT00473330 | ClinicalTrials.gov

#### First Submitted that Met QC Criteria

2007-05-13

**First Posted** 

2007-05-15

Last Update Submitted that Met QC Criteria

2010-11-11

#### Last Update Posted

2010-11-15 [Estimated]

## Sponsor/Collaborator

Sponsor

Genentech, Inc.

**Responsible Party** 

Collaborators

## Oversight

**U.S. FDA-regulated Drug** 

**U.S. FDA-regulated Device** 

**Data Monitoring** 

**Study Description** 

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