ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 04/07/2016

ClinicalTrials.gov ID: NCT00422903

Study Identification

Unique Protocol ID:	EGF107692
Brief Title:	Letrozole In Combination With Lapatinib In Neoadjuvant Treatment Of Early Breast Cancer
Official Title:	Letrozole Versus Letrozole Plus Lapatinib (GW572016) in Hormone-sensitive, HER-2 Negative Operable Breast Cancer. A Double Blind Randomized Phase II Study With Biomarker Evaluation.
Secondary IDs:	

Study Status

Record Verification:	March 2016
Overall Status:	Completed
Study Start:	April 2007
Primary Completion:	April 2011 [Actual]
Study Completion:	April 2011 [Actual]

Sponsor/Collaborators

Sponsor:	GlaxoSmithKline
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes

	Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: Prot.4746/CE; Approv.152/05 Board Name: Comitato Etico Provinciale Board Affiliation: Azienda Ospedaliero-Universitaria di Modena,Azienda Unità Sanitaria Locale di Modena, Italy Phone: +39 059 422.2990 Email: comitatoetico@policlinico.mo.it
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Italy: Ministry of Health United States: Food and Drug Administration

Study Description

Brief Summary:	Evaluate the percentage of clinical objective responses (cOR) in patients with HER2 negative early breast cancer treated with pre operative (neoadjuvant)lapatinib and letrozole
Detailed Description:	

Conditions

Conditions:	Neoplasms, Breast
Keywords:	neo-adjuvant letrozole lapatinib primary breast cancer

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)

Allocation:	Randomized
Endpoint Classification:	Efficacy Study
Enrollment:	92 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Placebo Comparator: Letrozole plus placebo Letrozole 2.5 mg administered orally fro 6 mos. plus placebo 1500 mg administered orally throughout the study until definitive surgery	Drug: letrozole 2.5 mg administered orally daily placebo 1500 mg administered orally daily
Experimental: Letrozole plus lapatininb Letrozole 2.5 mg administered orally fro 6 mos. plus lapatinib 1500 mg administered orally throughout the study until definitive surgery	Drug: lapatinib 1500 mg administered orally daily Other Names: • lapatinib Drug: letrozole 2.5 mg administered orally daily

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	80 Years
Gender:	Female
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion criteria:

- Histologically confirmed infiltrating primary breast cancer of 2.0 cm or more in largest clinical diameter
- ER and/or PgR positive cancer (> 10% of positive cancer cell assessed by IHC)
- Postmenopausal status, defined by at least one of the following:

  ≥ 60 years of age < 60 years of age and amenorrheic for ≥ 12 months prior to day 1 < 60 years of age and amenorrheic for < 12 months prior to day, or without a uterus: luteinizing hormone (LH) and follicle stimulating hormone (FSH) values within postmenopausal range Prior bilateral oophorectomy Prior radiation castration with amenorrhea for at least 6 months
- HER2 negative tumors (IHC 0-2+, or FISH negative)
- Availability of tumor tissue suitable for biological and molecular examination before starting primary treatment

- Age over 18 years
- ECOG PS 0-1
- Normal organ and marrow function as defined below:

leukocytes > 3000/mL absolute neutrophil count > 1,500/mL platelets > 100,000/mL total bilirubin within normal institutional limits AST (SGOT)/ALT(SGPT)< 2.5 X institutional upper limit of normal Creatinine within normal institutional limits

- Cardiac ejection fraction within the institutional range of normal as measured by echocardiogram or MUGA scan.
- Eligibility of patients receiving medications or substances known to affect, or with the potential to affect the activity or pharmacokinetics of lapatinib will be determined following review of their use by the Principal Investigator.

A list of medications and substances known or with the potential to interact with CYP450 isoenzymes is provided

- Ability to understand and the willingness to sign a written informed consent document.
- Ability to swallow and retain oral medication.

Exclusion criteria:

- Stage IIIB, IIIC, and inflammatory breast cancer
- Stage IV breast cancer
- Contraindication to the treatment with letrozole
- Prior treatment with chemotherapy, endocrine therapy or radiotherapy. Prior treatment with EGFR targeting therapies
- Treatment with any other investigational agents, or with all herbal (alternative) medicines
- History of allergic reactions attributed to compounds of similar chemical or biologic composition to lapatinib
- Uncontrolled inter-current illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements
- HIV-positive patients receiving combination anti-retroviral therapy
- GI tract disease resulting in an inability to take oral medication, malabsorption syndrome, a requirement for IV alimentation, prior surgical procedures affecting absorption, uncontrolled inflammatory GI disease (e.g., Crohn's, ulcerative colitis)
- Concomitant requirement for medication classified as CYP3A4 inducers or inhibitors (See section 3.7.4.2 Other concomitant treatments)

Contacts/Locations

Study Officials: GSK Clinical Trials
Study Director
GlaxoSmithKline

Locations: Italy
GSK Investigational Site
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GSK Investigational Site
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GSK Investigational Site
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References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Letrozole + Placebo	Letrozole tablets in the dose of 2.5 milligrams (mg) plus matching placebo were administered orally once daily for 6 months prior to surgery.
Letrozole + Lapatinib	Letrozole tablets in the dose of 2.5 mg plus lapatinib ditosylate monohydrate tablets in the dose of 1500 mg were administered orally once daily for 6 months prior to surgery.

Overall Study

	Letrozole + Placebo	Letrozole + Lapatinib
Started	49	43
Completed	45	38
Not Completed	4	5
Disease Progression	3	1
Adverse Event	0	2
Informed Consent Withdrawn	1	2

Baseline Characteristics

Reporting Groups

	Description
Letrozole + Placebo	Letrozole tablets in the dose of 2.5 milligrams (mg) plus matching placebo were administered orally once daily for 6 months prior to surgery.
Letrozole + Lapatinib	Letrozole tablets in the dose of 2.5 mg plus lapatinib ditosylate monohydrate tablets in the dose of 1500 mg were administered orally once daily for 6 months prior to surgery

Baseline Measures

	Letrozole + Placebo	Letrozole + Lapatinib	Total
Number of Participants	49	43	92

	Letrozole + Placebo	Letrozole + Lapatinib	Total
Age, Continuous [units: Years] Median (Full Range)	70 (47 to 88)	70 (49 to 88)	70 (47 to 88)
Gender, Male/Female [units: Participants]			
Female	49	43	92
Male	0	0	0

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With Clinical Objective Response (cOR) in the Breast, Evaluated by an Independent Radiological Evaluation Monitoring Committee
Measure Description	cOR is defined as the documented evidence of complete response (CR) and partial response (PR) as assessed by ultrasound examination using Response Evaluation Criteria In Solid Tumors (RECIST). CR is defined as the disappearance of all target lesions (TLs) and non-TLs and the appearance of no new lesions (NLs). PR for TLs is defined as a >=30% decrease in the sum of the longest diameter (LD) of TLs, taking as a reference the Baseline sum LD. For non-TLs, it is defined as the persistence of >=1 non-TL and no new TLs or non-TLs.
Time Frame	From Baseline (Day 1) up to 6 months, evaluated every 12 weeks
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population: all participants who entered the study and received at least one dose of letrozole. Three participants withdrew consent and were not included in the efficacy analysis.

Reporting Groups

	Description
Letrozole + Placebo	Letrozole tablets in the dose of 2.5 milligrams (mg) plus matching placebo were administered orally once daily for 6 months prior to surgery.
Letrozole + Lapatinib	Letrozole tablets in the dose of 2.5 mg plus lapatinib ditosylate monohydrate tablets in the dose of 1500 mg were administered orally once daily for 6 months prior to surgery.

Measured Values

	Letrozole + Placebo	Letrozole + Lapatinib
Number of Participants Analyzed	48	41

	Letrozole + Placebo	Letrozole + Lapatinib
Percentage of Participants With Clinical Objective Response (cOR) in the Breast, Evaluated by an Independent Radiological Evaluation Monitoring Committee [units: percentage of participants]		
CR	2	12
PR	58	54

2. Primary Outcome Measure:

Measure Title	Percentage of Participants With Various Responses in the Breast, Evaluated Using Per Protocol Criteria
Measure Description	Complete clinical response=nodule not detectable; all ultrasound abnormalities detected at diagnosis have disappeared. Partial clinical response=the tumor's longest diameter (LD) is reduced by 50% or more; ultrasound characteristics of the tumor persist. Minimal response=the tumor's LD is reduced by 25%-49%. Stable disease=the tumor's LD is decreased by less than 25% and is increased by no more than 25% from the starting value. Progressive disease=the tumor's LD is increased by more than 25% from the starting value. Participants who were not evaluable did not have data available.
Time Frame	From Baseline (Day 1) up to 6 months, evaluated every 12 weeks
Safety Issue?	No

Analysis Population Description

ITT Population. Three participants withdrew consent and were not included in the efficacy analysis.

Reporting Groups

	Description
Letrozole + Placebo	Letrozole tablets in the dose of 2.5 milligrams (mg) plus matching placebo were administered orally once daily for 6 months prior to surgery.
Letrozole + Lapatinib	Letrozole tablets in the dose of 2.5 mg plus lapatinib ditosylate monohydrate tablets in the dose of 1500 mg were administered orally once daily for 6 months prior to surgery.

Measured Values

	Letrozole + Placebo	Letrozole + Lapatinib
Number of Participants Analyzed	48	41
Percentage of Participants With Various Responses in the Breast, Evaluated Using Per Protocol Criteria		

	Letrozole + Placebo	Letrozole + Lapatinib
[units: percentage of participants]		
Complete Response	2	12
Partial Response	27	34
Minimal Response	40	24
Stable Disease	33	20
Progressive Disease	6	2
Not Evaluable	2	7

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Pathological Complete Response (pCR) in the Breast and Axillary Nodes, Evaluated Using Miller and Payne Criteria
Measure Description	pCR is defined as the complete absence of infiltrating tumor cells (TCs) in the breast and lymph nodes. Miller and Payne criteria: Grade 1, no change/some alteration to individual malignant cells, but no reduction in overall cellularity; Grade 2, up to a 30% loss in TCs; Grade 3, between an estimated 30% and 90% reduction in TCs; Grade 4, more than a 90% reduction in TCs, only small cluster/dispersed cells remaining; Grade 5, no malignant identifiable cells; carcinoma in the milk ducts may be present. Grades 1 and 2 = No response; Grades 3 and 4= PR; Grade 5 = CR.
Time Frame	At the point of definitive surgery (up to 6 months after Baseline)
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Letrozole + Placebo	Letrozole tablets in the dose of 2.5 milligrams (mg) plus matching placebo were administered orally once daily for 6 months prior to surgery.
Letrozole + Lapatinib	Letrozole tablets in the dose of 2.5 mg plus lapatinib ditosylate monohydrate tablets in the dose of 1500 mg were administered orally once daily for 6 months prior to surgery.

Measured Values

	Letrozole + Placebo	Letrozole + Lapatinib
Number of Participants Analyzed	49	43

	Letrozole + Placebo	Letrozole + Lapatinib
Percentage of Participants With Pathological Complete Response (pCR) in the Breast and Axillary Nodes, Evaluated Using Miller and Payne Criteria [units: Percentage of participants] Number (95% Confidence Interval)	0 (0.0 to 7.3)	0 (0.0 to 8.2)

4. Secondary Outcome Measure:

Measure Title	Number of Participants With Breast Tumors Per Pathological Stage at Surgery
Measure Description	Tumors were categorized as follows: T0, no evidence of primary tumor, but carcinoma of the milk ducts, accumulation of abnormal cells in the breast lobules, or Paget disease (cancer condition that appears like a skin disease involving the breast nipple) with no associated tumor mass; T1, tumor was <=2 centimeters (cm) across; T2, tumor was >2 cm but <5 cm across; T3, tumor was >5 cm across; T4, tumor of any size growing into the chest wall or skin, including inflammatory breast cancer.
Time Frame	At the point of definitive surgery (up to 6 months after Baseline)
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants contributing data were analyzed.

Reporting Groups

	Description
Letrozole + Placebo	Letrozole tablets in the dose of 2.5 milligrams (mg) plus matching placebo were administered orally once daily for 6 months prior to surgery.
Letrozole + Lapatinib	Letrozole tablets in the dose of 2.5 mg plus lapatinib ditosylate monohydrate tablets in the dose of 1500 mg were administered orally once daily for 6 months prior to surgery.

Measured Values

	Letrozole + Placebo	Letrozole + Lapatinib
Number of Participants Analyzed	47	42
Number of Participants With Breast Tumors Per Pathological Stage at Surgery [units: participants]		
T0	1	0
T1	20	26

	Letrozole + Placebo	Letrozole + Lapatinib
T2	24	12
T3	2	2
T4	0	2

5. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Nodal Status at Surgery
Measure Description	The nodal status of cancer indicates the involvement of lymph nodes in the participant with cancer. N0 indicates no involvement of lymph nodes, and N+ indicates involvement of lymph nodes.
Time Frame	At the point of definitive surgery (up to 6 months after Baseline)
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants contributing data were analyzed.

Reporting Groups

	Description
Letrozole + Placebo	Letrozole tablets in the dose of 2.5 milligrams (mg) plus matching placebo were administered orally once daily for 6 months prior to surgery.
Letrozole + Lapatinib	Letrozole tablets in the dose of 2.5 mg plus lapatinib ditosylate monohydrate tablets in the dose of 1500 mg were administered orally once daily for 6 months prior to surgery.

Measured Values

	Letrozole + Placebo	Letrozole + Lapatinib
Number of Participants Analyzed	47	42
Number of Participants With the Indicated Nodal Status at Surgery [units: participants]		
N0	19	21
N+	28	21

6. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Type of Surgery
Measure Description	Mastectomy is the medical term for the surgical removal of one or both breasts. Breast-conserving surgery (BCS) involves removing only the affected part of the breast tissue during surgery, as opposed to removal of the entire breast.
Time Frame	At the point of definitive surgery (up to 6 months after Baseline 1)
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants contributing data were analyzed.

Reporting Groups

	Description
Letrozole + Placebo	Letrozole tablets in the dose of 2.5 milligrams (mg) plus matching placebo were administered orally once daily for 6 months prior to surgery.
Letrozole + Lapatinib	Letrozole tablets in the dose of 2.5 mg plus lapatinib ditosylate monohydrate tablets in the dose of 1500 mg were administered orally once daily for 6 months prior to surgery.

Measured Values

	Letrozole + Placebo	Letrozole + Lapatinib
Number of Participants Analyzed	49	43
Number of Participants With the Indicated Type of Surgery [units: participants]		
Mastectomy	13	15
BCS	34	27
Not done	2	1

7. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Conversion From Planned Mastectomy at Baseline to BCS at Surgery
Measure Description	The percentage of participants who were planned to undergo a mastectomy at baseline but later underwent BCS was measured.
Time Frame	At the point of definitive surgery (up to 6 months after Baseline)
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants contributing data were analyzed.

Reporting Groups

	Description
Letrozole + Placebo	Letrozole tablets in the dose of 2.5 milligrams (mg) plus matching placebo were administered orally once daily for 6 months prior to surgery.
Letrozole + Lapatinib	Letrozole tablets in the dose of 2.5 mg plus lapatinib ditosylate monohydrate tablets in the dose of 1500 mg were administered orally once daily for 6 months prior to surgery.

Measured Values

	Letrozole + Placebo	Letrozole + Lapatinib
Number of Participants Analyzed	49	43
Percentage of Participants With Conversion From Planned Mastectomy at Baseline to BCS at Surgery [units: percentage of participants]	56	46

8. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Adverse Events With a Classification of >=Grade 2
Measure Description	Toxicity was measured in grades (severity of the AE) as per National Cancer Institute Common Toxicity Criteria for Adverse Event (NCI CTCAE) version (v) 3.0. The CTCAE v3.0 displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline: Grade 1, mild; Grade 2, moderate; Grade 3, severe; Grade 4, life-threatening/disabling; Grade 5, death related to the AE. Mucositis is the painful inflammation and ulceration of the mucous membranes lining the digestive tract, and hypertension is high blood pressure.
Time Frame	From Baseline (Day 1) up to 6 months (until definitive surgery)
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants contributing data were analyzed.

Reporting Groups

	Description
Letrozole + Placebo	Letrozole tablets in the dose of 2.5 milligrams (mg) plus matching placebo were administered orally once daily for 6 months prior to surgery.

	Description
Letrozole + Lapatinib	Letrozole tablets in the dose of 2.5 mg plus lapatinib ditosylate monohydrate tablets in the dose of 1500 mg were administered orally once daily for 6 months prior to surgery.

Measured Values

	Letrozole + Placebo	Letrozole + Lapatinib
Number of Participants Analyzed	49	43
Number of Participants With the Indicated Adverse Events With a Classification of >=Grade 2 [units: participants]		
Musculoskeletal pain	4	2
Diarrhea	2	10
Mucositis	0	8
Liver toxicity	1	4
Skin disorders	1	18
Hypertension	1	2

9. Secondary Outcome Measure:

Measure Title	Mean Left Ventricular Ejection Fraction (LVEF)
Measure Description	Cardiac safety was evaluated as any signs or symptoms of deterioration in LVEF. LVEF is the measurement of how much blood is being pumped out of the left ventricle of the heart (the main pumping chamber) with each contraction. LVEF was evaluated using NCI CTCAE.
Time Frame	Baseline (Day 1), after 12 weeks, and after 24 weeks
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants contributing data were analyzed.

Reporting Groups

	Description
Letrozole + Placebo	Letrozole tablets in the dose of 2.5 milligrams (mg) plus matching placebo were administered orally once daily for 6 months prior to surgery.

	Description
Letrozole + Lapatinib	Letrozole tablets in the dose of 2.5 mg plus lapatinib ditosylate monohydrate tablets in the dose of 1500 mg were administered orally once daily for 6 months prior to surgery.

Measured Values

	Letrozole + Placebo	Letrozole + Lapatinib
Number of Participants Analyzed	49	43
Mean Left Ventricular Ejection Fraction (LVEF) [units: Percent volume] Mean (Full Range)		
Baseline	61 (50 to 78)	61 (54 to 76)
After 12 weeks	62 (50 to 76)	60 (52 to 75)
After 24 weeks	61 (50 to 84)	59 (50 to 75)

10. Secondary Outcome Measure:

Measure Title	Time to Treatment Failure From the Start of the Primary Therapy
Measure Description	Time to treatment failure is calculated as the interval between the date of randomization and the occurrence of local tumor progression (including ipsilateral [on the same side] and controlateral breast tumor progression), distant tumor progression, permanent treatment discontinuation (either for the experimental or conventional treatment arm), or death for any cause.
Time Frame	From Baseline (Day 1) up to study withdrawal (approx. 66 months)
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants contributing data were analyzed.

Reporting Groups

	Description
Letrozole + Placebo	Letrozole tablets in the dose of 2.5 milligrams (mg) plus matching placebo were administered orally once daily for 6 months prior to surgery.
Letrozole + Lapatinib	Letrozole tablets in the dose of 2.5 mg plus lapatinib ditosylate monohydrate tablets in the dose of 1500 mg were administered orally once daily for 6 months prior to surgery.

Measured Values

	Letrozole + Placebo	Letrozole + Lapatinib
Number of Participants Analyzed	13	6
Time to Treatment Failure From the Start of the Primary Therapy [units: Months] Median (95% Confidence Interval)	32.2 (6.3 to 38.5)	22.2 (NA to NA) [1]

[1] The confidence limits for the median value are not estimable because there are no time points that satisfy the condition using the method of Klein and Moeschberger (1997).

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
Letrozole + Placebo	Letrozole tablets in the dose of 2.5 milligrams (mg) plus matching placebo were administered orally once daily for 6 months prior to surgery.
Letrozole + Lapatinib	Letrozole tablets in the dose of 2.5 mg plus lapatinib ditosylate monohydrate tablets in the dose of 1500 mg were administered orally once daily for 6 months prior to surgery.

Serious Adverse Events

	Letrozole + Placebo	Letrozole + Lapatinib
	Affected/At Risk (%)	Affected/At Risk (%)
Total	1/49 (2.04%)	3/43 (6.98%)
Cardiac disorders		
Cardiac failure [A] †	0/49 (0%)	1/43 (2.33%)
Myocardial infarction [A] †	1/49 (2.04%)	0/43 (0%)
Hepatobiliary disorders		
Sphincter of Oddi dysfunction [A] †	0/49 (0%)	1/43 (2.33%)

	Letrozole + Placebo	Letrozole + Lapatinib
	Affected/At Risk (%)	Affected/At Risk (%)
Injury, poisoning and procedural complications		
Overdose [A] †	0/49 (0%)	1/43 (2.33%)
Nervous system disorders		
Spinal cord compression [A] †	0/49 (0%)	1/43 (2.33%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Letrozole + Placebo	Letrozole + Lapatinib
	Affected/At Risk (%)	Affected/At Risk (%)
Total	20/49 (40.82%)	36/43 (83.72%)
Gastrointestinal disorders		
Diarrhea [A] †	5/49 (10.2%)	26/43 (60.47%)
Dyspepsia [A] †	5/49 (10.2%)	5/43 (11.63%)
Nausea [A] †	6/49 (12.24%)	0/43 (0%)
General disorders		
Astenia/Fatigue [A] †	6/49 (12.24%)	7/43 (16.28%)
Injury, poisoning and procedural complications		
Mucositis [A] †	0/49 (0%)	7/43 (16.28%)
Investigations		
LFT transaminases [A] †	0/49 (0%)	8/43 (18.6%)
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain [A] †	9/49 (18.37%)	6/43 (13.95%)
Skin and subcutaneous tissue disorders		
Dermatology/Skin [A] †	0/49 (0%)	25/43 (58.14%)

	Letrozole + Placebo	Letrozole + Lapatinib
	Affected/At Risk (%)	Affected/At Risk (%)
Nail changes [A] †	0/49 (0%)	5/43 (11.63%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Official Title: GSK Response Center
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