

User Guide

Version 4.0

Using this site



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1 Find out about this site

The **About** section on the Home page describes the purpose of the site.



Welcome, User Video [\(Click here to Logout\)](#)

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About

This site	Next steps
<p>Access to clinical trial data provides opportunities to conduct further research that can help advance medical science or improve patient care. This helps ensure the data provided by research participants are used to maximum effect in the creation of knowledge and understanding.</p> <p>Researchers can use this site to request access to anonymised patient level data and/or supporting documents from clinical studies to conduct further research.</p>	<p>Study sponsors who have committed to use this site are Astellas, Bayer, Boehringer Ingelheim, Eisai, GSK, Lilly, Novartis, Roche, Sanofi, Takeda, UCB and Viiv Healthcare.</p> <p>Other clinical trial sponsors and funders are invited to join with the aim of transitioning to a fully independent system which allows access to data from clinical trials conducted by multiple companies and organisations. It is hoped that such a system will be put in place as soon as possible.</p> <p>If you are a study sponsor interested in listing studies on this site, contact information is provided here.</p>

The **How it works** section on the Home page summarises how requests can be submitted, how they are reviewed and how access to data is provided.

Within the **Submission** section on the Home page you will find a link to information on the Study sponsors. You will also be able to see information about the studies they list and other relevant information.

Within the **Access** section on the Home page there is a link to the requirements included in the Data Sharing Agreement.

Clicking on **Find out more >>** will provide you with more information.

How it works

Submission	Review
<p>Researchers can submit research proposals and request anonymised data from clinical studies listed on this site. Study sponsors will add more studies when the site is updated.</p> <p>Information on sponsor's criteria for listing studies and other relevant sponsor specific information is provided in the Study sponsors section of this site.</p> <p>Researchers can also submit enquiries to ask about access to study documents without patient level data. They can also submit enquiries to some study sponsors to ask about the availability of data from studies they have not listed on this site.</p> <p>Find out more >></p>	<p>Research proposals are reviewed by an Independent Review Panel. The study sponsors are not involved in the decisions made by the panel.</p> <p>Find out more >></p>
	Access
	<p>Following approval and after the relevant study sponsor or sponsors receive a signed Data Sharing Agreement, access to the data needed for the research is provided on a password protected website.</p> <p>Find out more >></p>



Clicking [Find out more >>](#) under Submission takes you to the **Submission of requests** page where you can download sample forms for research proposals and enquiries.

Click the **Next** button for more about how requests are reviewed.



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How it works

Submission of requests

How to submit a research proposal

After creating an account on this site, researchers can select studies needed for their research and complete an online form to submit their research proposal. A sample form (for reference only) [is provided here](#) so researchers can review the information that is required before submitting a research proposal.

After researchers submit a proposal it cannot be modified. If researchers need to modify their proposal (including adding or deleting studies) a new proposal needs to be submitted and the previous one withdrawn.

How to request data from studies that are not on this site

Some sponsors provide a facility where researchers can ask about access to data from studies that are not listed on this site. To enquire about the availability of data from these studies, after creating an account researchers complete an online form and provide information to enable the studies to be identified. Researchers can identify studies by searching study registers (e.g. [clinicaltrials.gov](#)) or literature databases.

The **Review of requests** page enables you to find out about how research proposals are reviewed and decisions that can be made by the panel. You can also see or download the panel's Charter and see a list of panel members.

Click the **Next** button for more about how access to data is provided.

How it works

Review of requests

wellcometrust

The Wellcome Trust has taken responsibility for managing the review of research proposals and the operation of the IRP. The Trust will also administer the IRP secretariat and appoint new panel members. [www.wellcome.ac.uk](#)

Review of research proposals

Research proposals are checked by the Wellcome Trust and the relevant sponsors to make sure the information is complete and that they meet the requirements of this initiative and the sponsor's requirements for informed consent. They are then sent to the [Independent Review Panel](#). The panel considers the following:

- The scientific rationale and relevance of the proposed research to medical science or patient care.
- The ability of the proposed research plan (design, methods and analysis) to meet the scientific objectives. This is a high-level review.
- The publication plan for the research.
- Real or potential conflicts of interest that may impact the planning, conduct or interpretation of the research and proposals to manage these conflicts of interest.
- The qualifications and experience of the research team to conduct the proposed research (a statistician with a degree in statistics or a related discipline should be part of the research team).

Before completing its review, the panel may ask for additional information from the researcher and may also seek the views of other non-study sponsor experts. Where views of other non-study sponsor experts are required, the researcher will be asked to provide names of three independent experts who could be consulted.

Decisions the Independent Review Panel can make

The Independent Review Panel will make one of the following decisions:

- Approval to provide access to the requested data.
- Approval to provide access to the requested data subject to conditions.
- Rejection with advice to re-submit the research proposal.
- Rejection of the research proposal.

The panel Chairman informs the IRP secretariat and relevant study sponsor or sponsors of the decision and provides any conditions of access and the rationale and reasons why a research proposal is not approved or why conditions are required. This rationale and reason is communicated to the researcher and any conditions are added to the [Data Sharing Agreement](#). There is no appeal process.

An overview of the number of research proposals submitted and the outcome of the Independent Review Panel's review is made available in the [Metrics](#) section of this site on a regular basis.



The **Access to data** page enables you to find out about how the data are accessed and details about the statistical software that is provided.

You can also find out about the public disclosure of the research that is conducted.

Click the **Back** button to go to your previous page.

How it works

Access to data

How data are provided on the website

Access to the data needed for the research is provided on a password-protected website (multi-sponsor analysis system). The website allows researchers to combine data from different studies, conduct research on the site and download their analyses. Access is provided for 12 months. Extensions may be given when justified up to a maximum of 24 months.

Researchers conduct their research in a private workspace. This workspace is not accessed by study sponsors or other third parties unless researchers provide permission so help can be provided. There are controls in place to prevent researchers downloading the patient level data provided to their computer. These controls further protect research participants' privacy and confidentiality, and also help ensure the data are used for the agreed research purpose.

Statistical software that is provided

Commonly used statistical software "R" and "SAS" are provided on the website so researchers can combine data from different clinical studies and conduct analyses. Please note that "R" is open source software and software support is not provided.

User guides and instructional videos are provided. [A video that provides an overview of the website can be viewed here.](#)

Research team use of the statistical software

Fees, including licenses, are paid by the study sponsors for research team members to access data on the website and use the statistical software. The number of licenses for each research proposal may be limited to a maximum of five.

Data and information provided for each study

The anonymised datasets and study documents available are described with each study on this site. The [Study sponsors section](#) of this site provides the anonymisation standards used by sponsors.

Support will be available to help researchers navigate the data.

Public disclosure of the research

After signed [Data Sharing Agreements](#) are received, the name and affiliation of the lead researcher, the title of the research, the requested studies, the lay summary, funding source and any potential conflicts of interest that were provided in the research proposal are posted in the [Metrics](#) section of this site. The publication citation and statistical analysis plan are also included after the research has been published.

The Data Sharing Agreement also includes requirements to post a summary of the analysis plan on a publicly available Internet register or website prior to conducting the research and a summary of results within one year of completing the analysis.



2 Find out about the study sponsors

Click the **Study sponsor** tab and logo to find out about the study sponsors, their criteria for listing studies on the site and other sponsor specific information.

Click the [Visit sponsor's website](#) link below the sponsor's logo to be taken to the sponsor's web site. Click the blue arrows to see more logos.

ClinicalStudy
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Study sponsors

This section of the site provides information on [study sponsor's](#) criteria for listing studies and other relevant sponsor specific information.

Select the sponsor's logo to view this information.



This information is provided on the next page.

Sponsor specific information

[Back](#)

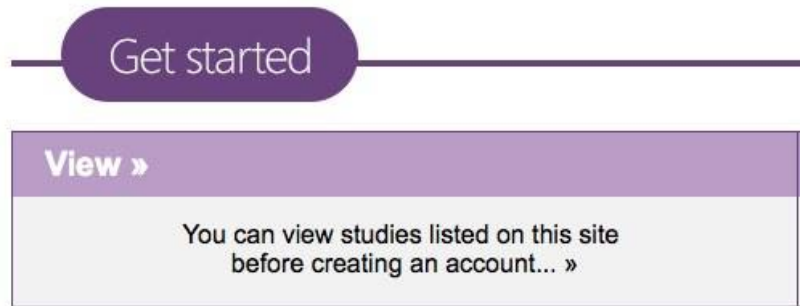
Study sponsor: GSK	
Studies listed	<p>Global interventional clinical studies that were ongoing or started after the formation of GSK (December 2000). This listing will complete in 2015.</p> <p>All interventional studies that are started in or after 2013.</p> <p>Other studies where data are provided to researchers.</p>
Exceptions	<p>Clinical studies where data labels and/or supporting documents are not in English.</p> <p>Clinical studies of rare diseases. This is because anonymisation of these data is more difficult to achieve. For these studies GSK will assess the feasibility of anonymisation as part of the review of enquiries.</p> <p>Clinical studies of GSK Consumer Healthcare products. This is because GSK anticipate more interest from researchers in accessing data from studies of pharmaceutical medicines and vaccines.</p>
When studies are listed	After the medicine studied has been approved by regulators (first approval) or terminated from development (all indications) and the study has been accepted for publication .
Additional conditions for data access	When patients agreed to take part in GSK clinical studies they gave permission (through informed consent) to use their data to study the medicine or disease GSK were researching. Further research must therefore study the medicine or disease that was researched in the original studies. For studies GSK conduct from 2013, patients will be asked to give permission for broader research so other research may be possible with data from these studies.
Datasets and documents provided	<p>Where available, the following anonymised patient level data and information is provided for each clinical study.</p> <p>Raw dataset. This is the dataset collected for each patient in the clinical study.</p> <p>Analysis-ready dataset. This is the dataset used for GSK's analysis and will be provided for studies that completed in or after 2007.</p> <p>Protocol with any amendments. This describes the objectives, design, methodology, statistical considerations, and organisation of a clinical study.</p> <p>Annotated case report form. This is a blank case report form with descriptions of the data collected and how they are described in the dataset.</p> <p>Reporting and analysis plan. This describes methods of analysis, procedures for data handling and data displays (figures and tables) GSK used for the study.</p> <p>Dataset specifications. This is the meta-data which describes the datasets e.g., variable labels, variable descriptions, code lists, formats.</p> <p>Clinical study report. This is the report of efficacy and safety data from the study. It forms the basis of submissions to regulatory authorities such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Appendices which include patient level data are not included as these data are provided in the datasets GSK provide. To protect research participants' privacy and confidentiality, case narratives are not routinely included. They may be provided where they are needed for a specific research proposal, provided research participants' privacy can be protected.</p>



3 View studies on this site

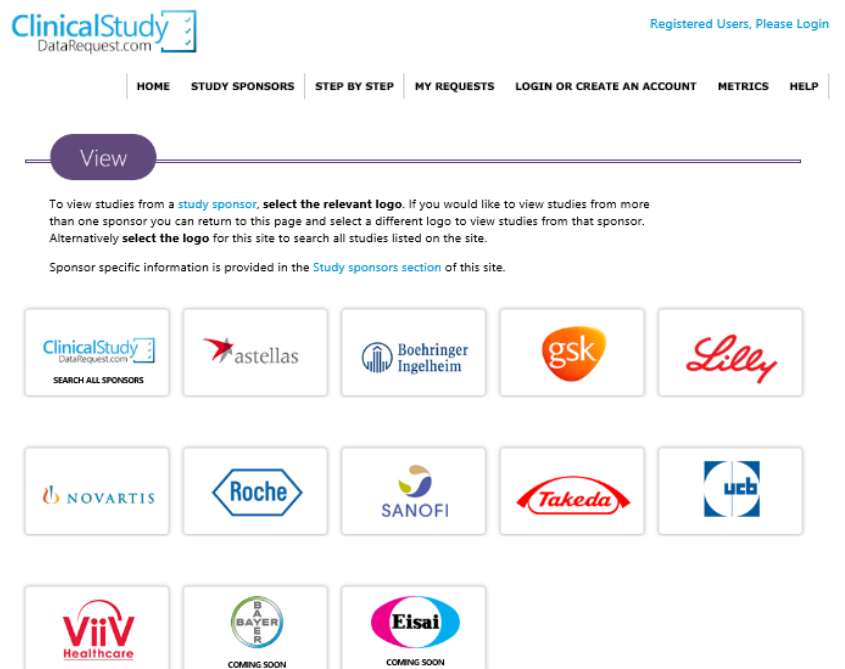
You can view studies listed on the site before creating an account.

Click the **View** box on the Home page.



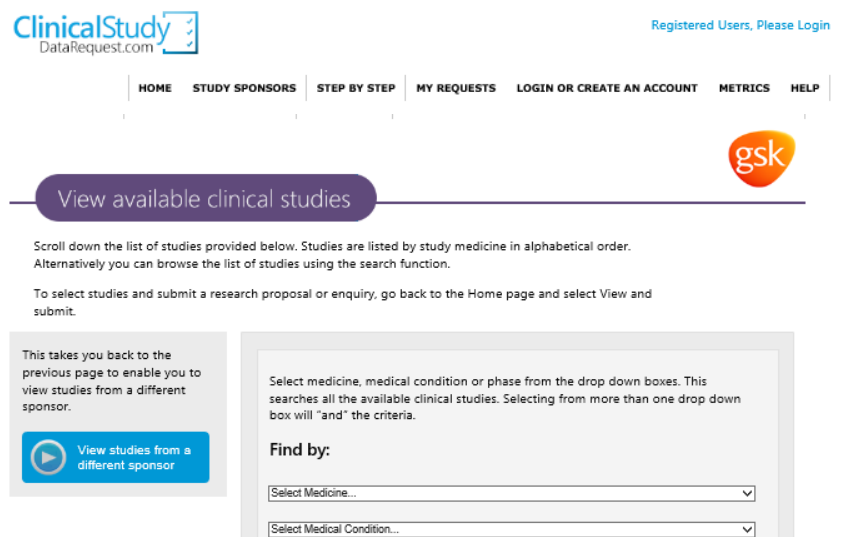
You are taken to the **View** page.

To view studies from a particular study sponsor, select the relevant logo or click the Clinical Study Data Request logo to search all sponsors. If you would like to view studies from more than one sponsor you can return to this page to select another sponsor.



After selecting a study sponsor's logo you are taken to the **View available clinical studies** page for that sponsor.

Click the **View studies from a different sponsor** button to be taken to the previous page.



To find studies for a particular medicine, select the medicine from the drop down box and click the **Search** button.

Similarly, to find studies for a particular medical condition, select the condition from the drop down box and click the **Search** button.

To find studies by phase, select the phase from the drop down box and click the **Search** button.

Select medicine, medical condition or phase from the drop down boxes. This searches all the available clinical studies. Selecting from more than one drop down box will "and" the criteria.

Find by:

Select Medicine...

Select Medical Condition...

Select Phase...

Alternatively search for studies using the GSK Clinical Study Identification Number or study title by entering full or partial information.

Enter Text Here

Selecting from more than one drop down box will combine the searches. For example, the search shown will find all phase 3 fluticasone propionate/salmeterol studies in asthma.

Select medicine, medical condition or phase from the drop down boxes. This searches all the available clinical studies. Selecting from more than one drop down box will "and" the criteria.

Find by:

fluticasone propionate/salmeterol

Asthma

Phase 3

Alternatively you can search available studies by entering text in this box. For example you can enter the sponsor's Clinical Study Identification Number or study title. Click the **Search** button to execute the search.

Alternatively search for studies using the GSK Clinical Study Identification Number or study title by entering full or partial information.

Enter Text Here

The search results are shown at the bottom of the page. Ten studies are shown on each page.

Click the study title to see additional information about the study. This additional information includes a link to clinicaltrials.gov for that study where it is available. Here you can find further details about the study.

You can also see the datasets and documents that are available for the study.

Study Sponsor: GSK

Study Title
A randomized, double-blind, parallel group study evaluating the safety of fluticasone propionate/salmeterol 100/50mcg HFA (2 inhalations of 50/25mcg) twice daily compared with fluticasone propionate 100mcg HFA (2 inhalations of 50mcg) twice daily in subjects 4-11 years of age with persistent asthma

Medicine or Vaccine (generic name)
fluticasone propionate/salmeterol

Sponsor Identification Number
SFA106484

ClinicalTrials.gov Identification Number
NCT00441441

Medical Condition
Asthma

Phase
Phase 3

Link to study details on the GSK Clinical Study Register
<http://www.gsk-clinicalstudyregister.com/quick-search-list.jsp?item=SFA106484&type=GSK+Study+ID&studyId=SFA106484>

Link to study details on ClinicalTrials.gov (if available)
<http://clinicaltrials.gov/show/NCT00441441>

Datasets and Documents Available for this Study
☒ Raw dataset
 ☒ Annotated case report form
 ☒ Dataset specifications
 ☒ Protocol with any amendments
☒ Analysis-ready dataset
☒ Reporting and analysis plan
☒ Clinical study report

Additional information about the data and documents available for this study

Date Added to this Site
May 2013



4 Create an account

To submit a research proposal or enquiry you need to create an account. Select the **Log-in or create an account** tab and select the [click here to create an account](#) link.



[Registered Users, Please Login](#)

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Log-in for registered users

Please log-in to create a new request or complete an unsubmitted request.

Username:
Password:

This system does not log you out automatically. Please log-out or lock your computer to protect your personal information.

Create an account

For new users, please [click here to create an account](#).

Please create an account to register on this site. Once you have created an account, you can log-in and create a new request.

Forgotten password

Username:

If you have forgotten your password (or if you have locked your account after multiple attempts) please provide your username and you will be sent a new password to the email account you provided previously.

Enter a username and password in the boxes provided and enter the code that is shown on the screen. Please note the requirements for a valid password.

Click the **Continue** button when you have finished.



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New account log-in information

Lead researchers for proposals can create a new account for this site by entering a username and password on this page. The lead researcher is the person responsible for the intellectual leadership and the overall management of the research. He/she is the main contact for the request and acts as guarantor for the accuracy of the information presented in the research proposal. There can only be one lead researcher for each request.

On the following pages you will be asked to provide contact and some biographical information about yourself and your employer, research institution or other affiliation. After the account is created you will be able to submit your research proposal or enquiry.

New account creation only needs to be done once. After you have created an account you can come back at anytime and simply log-in to access your information.

Username:

Password:

Repeat Password:

The password must be at least 6 characters long, contain at least one number, upper and lowercase letter and a special character. *Special characters include: ! @ # \$ % ^ & * () _ - + =*

You may use this username and password to log-in to the website at any time in the future to review or edit your submission and to check the status of your submission.



Enter the code shown:



Enter your contact information in the boxes provided. Click the **Continue** button when you have finished.

You will be taken to a page where you can enter details for your employer, company, research institution or other affiliation. This is optional.

When you have finished click the **Save** button.

Contact information

Please provide your contact information as requested below. You may return here at any time to update your information.

After the account is created you will be able to submit your research proposal or enquiry.

Contact information of lead researcher

Title:	<input type="text"/>
*First Name:	<input type="text"/>
Middle Name/Initial:	<input type="text"/>
*Last Name:	<input type="text"/>
*Post or Position	<input type="text"/>
*Email Address:	<input type="text"/>

Contact address

*Address Line 1:	<input type="text"/>
Address Line 2:	<input type="text"/>
Address Line 3:	<input type="text"/>
Address Line 4:	<input type="text"/>
*City:	<input type="text"/>
*Country:	United Kingdom <input type="button" value="v"/>
*Post Code/ZIP Code:	<input type="text"/>
*Phone Number:	<input type="text"/> ext. <input type="text"/>
Mobile Number:	<input type="text"/>
Fax Number:	<input type="text"/>

* indicates a mandatory field

Employer, company, research institution or other affiliation

This page allows you to add your employer, company, research institution or other affiliation.

Existing affiliations

You have no institution affiliations. To create one, follow the instructions below.

Enter your employer, company, research institution or other affiliation

Name:	<input type="text"/>
Type:	Academic Institution <input type="button" value="v"/>
City:	<input type="text"/>
Country:	United Kingdom <input type="button" value="v"/>



5 Delete your account

Before notifying us to delete your account you will need to log-in.

Click the **My account** tab. This will take you to a page with the information you provided previously. At the bottom of the page there is a section you can use to delete your account.

Type **"delete"** in the box provided.

When you have finished click the **Continue** button.

You will be taken to a page with the employer, company, research institution or other affiliation information you provided previously.

Click the **Save** button.

Contact information of lead researcher

Title: Dr

*First Name: John

Middle Name/Initial:

*Last Name: Smith

*Post or Position: Head of Department

*Email Address: JohnSmith@hotmail.com

Contact address

*Address Line 1: Number

Address Line 2:

Address Line 3:

Address Line 4:

*City: London

*Country: United Kingdom

*Post Code/ZIP Code: ABC 123

*Phone Number: 00000 ext.

Mobile Number:

Fax Number:

* indicates a mandatory field

Use the section below if you want to change your password

This function is only available after your account has been created.

Current Password:

(Required when changing password.)

New Password:

(Password will not change if left blank.)

Repeat New Password:

Use the section below if you want to delete your account

This function is only available after your account has been created.

Type "delete" into this box to notify us to delete your account: DELETE

Continue



6 Change your details

Before changing your details you will need to log-in.

Click the **My account** tab. This will take you to a page with the information you provided previously.

You can change information in the boxes by deleting or adding text.

When you have finished click the **Continue** button.

Contact information of lead researcher

Title:	Dr
*First Name:	John
Middle Name/Initial:	
*Last Name:	Smith
*Post or Position:	Head of Department
*Email Address:	JohnSmith@hotmail.com

Contact address

*Address Line 1:	Number
Address Line 2:	
Address Line 3:	
Address Line 4:	
*City:	London
*Country:	United Kingdom
*Post Code/ZIP Code:	ABC 123
*Phone Number:	00000 ext. <input type="text"/>
Mobile Number:	
Fax Number:	

* indicates a mandatory field

You will be taken to a page with the employer, company, research institution or other affiliation information you provided previously.

To delete an existing affiliation, click the **red X** button next to the relevant institution.

To add an employer, company, research institution or other affiliation enter information in the boxes provided.

When you have finished click the Save button.

Employer, company, research institution or other affiliation

This page allows you to add your employer, company, research institution or other affiliation.

Existing affiliations

Institution	Type	Address	Delete?
ideaPoint	Academic Institution	Quincy, GB	
Test Test	Biotechnology Company	Passau, DE	

Enter your employer, company, research institution or other affiliation

Name:	<input type="text"/>
Type:	Academic Institution
City:	<input type="text"/>
Country:	United Kingdom
<input type="button" value="Save"/>	



7 Reset your password

Before resetting your password you will need to log-in.

Click the **My account** tab. This will take you to a page with the information you provided previously.

You can change your password by entering information in the boxes near the bottom of the page.

When you have finished click the **Continue** button.

Use the section below if you want to change your password

This function is only available after your account has been created.

Current Password: (Required when changing password.)

New Password: (Password will not change if left blank.)

Repeat New Password:

You will be taken to a page with the employer, company, research institution or other affiliation information you provided previously.

If you do not want to change this information click the **Save** button.



Welcome, Test User IP
([Click here to Logout](#))

[HOME](#) [STUDY SPONSORS](#) [STEP BY STEP](#) [MY REQUESTS](#) [MY ACCOUNT](#) [METRICS](#) [HELP](#)

Employer, company, research institution or other affiliation

This page allows you to add your employer, company, research institution or other affiliation.

Existing affiliations

Institution	Type	Address	Delete?
ideaPoint	Academic Institution	Quincy, GB	
Test Test	Biotechnology Company	Passau, DE	

Enter your employer, company, research institution or other affiliation

Name:

Type:

City:

Country:



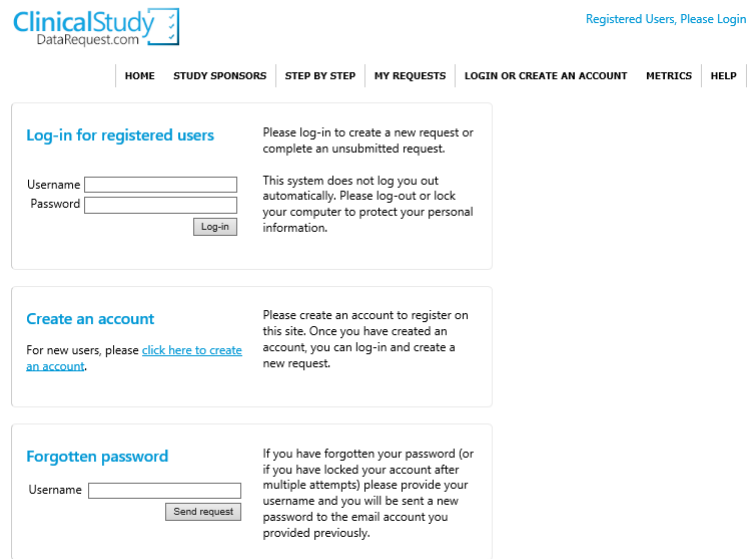
8 Forgotten password or username

Forgotten password

Click the **Log-in** or **create an account** tab.

Enter your username in the box at the bottom of the page and click the **Send request** button.

You will be sent a temporary password which you can use to log-in.



The screenshot shows the ClinicalStudy DataRequest.com website. The top navigation bar includes links for HOME, STUDY SPONSORS, STEP BY STEP, MY REQUESTS, LOGIN OR CREATE AN ACCOUNT, METRICS, and HELP. A link for 'Registered Users, Please Login' is also present. The main content area has three sections: 'Log-in for registered users' with fields for Username and Password and a Log-in button; 'Create an account' with a link to create an account; and 'Forgotten password' with a Username field and a Send request button. The 'Forgotten password' section also includes a note: 'If you have forgotten your password (or if you have locked your account after multiple attempts) please provide your username and you will be sent a new password to the email account you provided previously.'

You will be asked to update your password the next time you log-in.



The screenshot shows the ClinicalStudy DataRequest.com website with a yellow banner that says 'Please update your password.' Below the banner are three input fields: 'Current Password (if emailed to you):', 'New Password:', and 'Repeat New Password:'. A 'Change Password' button is located at the bottom left of the form. The top navigation bar and a 'Welcome, User Video (Click here to Logout)' link are also visible.

Forgotten username

If you have forgotten the Clinical Study Data Request site username, please email CSDR technical support staff at support@clinicalstudydatarequest.com and someone will respond to you within 2 business days.



9 Search and select studies needed for your research

Click the **View and submit** box on the Home page.

View and submit

After you create an account, you can select studies and submit a research proposal or enquiry... »

If you have not created an account and logged-in you will be taken to a page where you can either log-in or create an account.

ClinicalStudy
DataRequest.com

Registered Users, Please Login

HOME STUDY SPONSORS STEP BY STEP MY REQUESTS LOGIN OR CREATE AN ACCOUNT METRICS HELP

Log-in for registered users

Please log-in to create a new request or complete an unsubmitted request.

Username
Password

Log-in

This system does not log you out automatically. Please log-out or lock your computer to protect your personal information.

Create an account

For new users, please [click here to create an account](#).

Please create an account to register on this site. Once you have created an account, you can log-in and create a new request.

Forgotten password

Username

Send request

If you have forgotten your password (or if you have locked your account after multiple attempts) please provide your username and you will be sent a new password to the email account you provided previously.

If you have already logged-in, you are taken to the **View and submit** page.

To select studies from a particular study sponsor, select the relevant logo. If you would like to select studies from more than one sponsor you can return to this page to select those studies or click on the Clinical Study Data Request logo to search for studies across all sponsors.

ClinicalStudy
DataRequest.com

Welcome, User Video ([Click here to Logout](#))

HOME STUDY SPONSORS STEP BY STEP MY REQUESTS MY ACCOUNT METRICS HELP

View and submit

Please ensure you have read and understood the [How it works](#) section before you select studies.

To request studies from a [study sponsor](#), **select the relevant logo**. If you require studies from more than one sponsor you can return to this page and select a different logo to add studies from that sponsor. Alternatively **select the logo** for this site to search all studies listed on the site.

Please note that different studies and different study sponsors may have used different data standards and formats which may make it difficult to aggregate data across multiple studies.

If you can't find the studies you are looking for click the Enquiry button on the next page to see whether the relevant study sponsor provides a facility for you to ask about the availability of data from those studies. You can also ask questions about the studies you have selected before you submit a research proposal.

Sponsor specific information is provided in the [Study sponsors](#) section of this site.



After selecting a study sponsor's logo, you are taken to the **Available clinical studies** page for that sponsor.

To find studies for a particular medicine, select the medicine from the drop down box and click the **Search** button.

Similarly, to find studies for a particular medical condition, select the condition from the drop down box and click the **Search** button.

To find studies by phase, select the phase from the drop down box and click the **Search** button.

Selecting from more than one drop down box will combine the searches.

So for example, the search shown will find all phase 3 fluticasone propionate/salmeterol studies in asthma.

Alternatively you can search by entering text in this box.

For example, you can enter the sponsor's Clinical Study Identification Number or study title. Click the **Search** button to execute the search.



The search results are shown at the bottom of the page. Ten studies are shown on each page.

Click the study title to see additional information about the study. This additional information includes a link to clinicaltrials.gov for that study where it is available. Here you can find further details about the study.

You can also see the datasets and documents that are available for the study.

GSK1550188, A randomised, single-blind, placebo controlled, dose ascending, single dose study to evaluate the safety, tolerab...
Medicine: belimumab, Condition: Systemic Lupus Erythematosus, Phase: 1, GSK Clinical Study ID: BEL114243, Sponsor: GSK .

Study Sponsor: GSK

Study Title

A randomized, double-blind, parallel group study evaluating the safety of fluticasone propionate/salmeterol 100/50mcg HFA (2 inhalations of 50/25mcg) twice daily compared with fluticasone propionate 100mcg HFA (2 inhalations of 50mcg) twice daily in subjects 4-11 years of age with persistent asthma

Medicine or Vaccine (generic name)

fluticasone propionate/salmeterol

Sponsor Identification Number

SFA106484

ClinicalTrials.gov Identification Number

NCT00441441

Medical Condition

Asthma

Phase

Phase 3

Link to study details on the GSK Clinical Study Register

<http://www.gsk-clinicalstudyregister.com/quick-search-list.jsp?item=SFA106484&type=GSK+Study+ID&studyId=SFA106484>

Link to study details on ClinicalTrials.gov (if available)

<http://clinicaltrials.gov/show/NCT00441441>

Datasets and Documents Available for this Study

☒ Raw dataset ☒ Annotated case report form ☒ Dataset specifications ☒ Protocol with any amendments
☒ Analysis-ready dataset ☒ Reporting and analysis plan ☒ Clinical study report

Additional information about the data and documents available for this study

Date Added to this Site

May 2013

To select studies needed for your research, from the **Available clinical studies** page click the **Select study** button next to the required study.

When you have selected a study the Select study button is no longer available and the study is added to a box on the left hand side.

The number of studies you have selected is shown at the top of this box.

If you have selected a study by mistake you can remove it from the box by clicking the **X** button next to the study.

You can also clear all selected studies by clicking the Clear selected studies button at the bottom of the box.

2 studies selected

A randomized, double-blind, parallel group study evaluating the safety of fluticasone propionate/salmeterol 100/50mcg HFA (2 ...

X

A Stratified, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 12-Week Trial Evaluating the Safety and Efficacy ...

X

Clear selected studies

A randomized, double-blind, parallel group study evaluating the safety of fluticasone propionate/salmeterol 100/50mcg HFA (2 ...
Medicine: fluticasone propionate/salmeterol, Condition: Asthma, Phase: 3, GSK Clinical Study ID: SFA106484, Sponsor: GSK.

A Stratified, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 12-Week Trial Evaluating the Safety and Efficacy ...
Medicine: fluticasone propionate/salmeterol, Condition: Asthma, Phase: 3, GSK Clinical Study ID: SAS30021, Sponsor: GSK.

Select study

A 52-week multi-centre, open-labelled, non-comparative study assessing the safety of salmeterol xinafoate/fluticasone propion...
Medicine: fluticasone propionate/salmeterol, Condition: Asthma, Phase: 3, GSK Clinical Study ID: SAS30035, Sponsor: GSK.

Select study

A Double-Blind, Comparative Study to Compare Salmeterol/Fluticasone Propionate Combination Product (50/250mcg BID) with Conco...
Medicine: fluticasone propionate/salmeterol, Condition: Asthma, Phase: 3, GSK Clinical Study ID: SAS30036, Sponsor: GSK.



10 Ask study sponsors about studies not listed on the site

Some sponsors provide a facility where you can ask about the availability of data from studies that they have not listed on the site. To submit an enquiry you will need to create an account or log-in.

If you can't find the studies you are looking for on the sponsor's **Available clinical studies** page, click the **Enquiry** button.

If you have unsubmitted enquiries you can select a particular enquiry from a list to update it or you can create a new enquiry by clicking the **Submit new** button.

If you do not have unsubmitted research proposals or enquiries you are taken directly to the enquiry form.

For a new enquiry enter a Reference Name. Choose a name that will enable you to identify the enquiry.

Select the **Type of Enquiry** (option 2) for studies not listed on the site. The Study Sponsor drop down box provides the names of the sponsors who provide an opportunity here to enquire about studies not listed on the site.

For these sponsors, you can ask about the availability of data from studies that are not listed on the site by providing information to enable the study sponsor to identify the studies.

For example, you can enter the study sponsor's Clinical Study Information Number, study title or other reference information such as a clinicaltrials.gov identification number or publication reference. Please enter as much information as possible to help the sponsor identify the study.

When you have entered the information click the **Save & Complete Submission** button at the bottom of the page.



You are taken to a page where you can review your enquiry before it is submitted.

You can make changes by selecting the **Make a change** button. This will take you back to the enquiry form where you can make changes.

To submit your enquiry click the green **Submit** button at the bottom of the page.

You will receive an email acknowledgement. You will be contacted if further information is required before your enquiry is considered.



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[HOME](#) [STUDY SPONSORS](#) [STEP BY STEP](#) [MY REQUESTS](#) [MY ACCOUNT](#) [METRICS](#) [HELP](#)

Review your enquiry prior to submitting

Your submission has been SAVED, but NOT YET SUBMITTED.

Please review the submission information below and when you are ready, click "Submit" at the bottom of this page to send it to the relevant study sponsor or sponsors. If you want to make changes, just click on the "Make a change" button to go back and make changes. Alternatively, you can exit this page and your submission will be saved. You can come back to this website, log-in and update the request at a later date.

Enquiry Title:

Enquiry

Enquiry Form

Type of Enquiry:

Studies not listed on the site (you must select a sponsor below when using this option)

Study Sponsor	Study Id. No.	Study Title	Other Reference Information
GSK	GSK-1234	A study to...	

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[< Make a Change](#) [Save & Exit](#) [Submit](#)


Step 2 of 2



11 Ask questions about studies listed on the site before submitting a research proposal

Before submitting an enquiry to ask about studies listed on the site you will need to create an account or log-in and select the studies you want to ask about.

After you have selected studies you want to ask about from the **Available clinical studies** page, click the **Enquiry** button.



Available clinical studies

This takes you back to the previous page to enable you to add studies from a different sponsor.

[Select studies from a different sponsor](#)

This adds your selected studies to a research proposal and enables you to provide details of your research proposal.

[Research proposal](#)

Ask about clinical studies not listed on this site or ask other questions about your selected studies before submitting a research proposal.

[Enquiry](#)

Select medicine, medical condition or phase from the drop down boxes. This searches all the available clinical studies. Selecting from more than one drop down box will "and" the criteria.

Find by:

Select Medicine...

Select Medical Condition...

Select Phase...

Alternatively search for studies using the Roche Clinical Study Identification Number or study title by entering full or partial information.

Enter Text Here

Click the study title to find more information about the study.

If you have unsubmitted enquiries you can select a particular enquiry from a list to update it or you can create a new enquiry by clicking the **Submit new** button.

If you do not have unsubmitted research proposals or enquiries, you are taken directly to the enquiry form.

ClinicalStudy
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Unsubmitted requests

Click on the title to add selected studies to that request.

Title	Type	Created
Enquiry 99	Enquiry	17 Nov 2013
Proposal 1	Research Proposal	14 Nov 2013
Enquiry 1	Enquiry	14 Nov 2013
Enquiry 5	Enquiry	14 Nov 2013
First 1 Last		

[Submit new](#)

2 studies selected

A randomized, placebo-controlled study to evaluate the effect of tocilizumab on disease response in patients with active syst...

A randomized, open-label phase III Intergroup study: Effect of adding Bevacizumab to cross over fluoropyrimidine based chemot...



For a new enquiry enter a Reference Name. Choose a name that will enable you to identify the enquiry. This will be used to identify your enquiry on the site.

The studies you have selected are listed at the top of the page. You can remove studies by clicking the **X** button next to the study.

You can also add studies by clicking the **Add Another Study** button. This will take you back to the **View and Submit** page where you can select further studies.

After you have selected the relevant studies click the **Enquiry** button and select the name of the enquiry from the list of unsubmitted research proposals and enquiries.

Click on the **Type of Enquiry** (option 1) Studies listed on the site (you must select a listed study using this option). To ask questions about your selected studies enter them in the box provided.

When you have entered your question or questions click the **Save & Complete Submission** button at the bottom of the page.

Clinical studies selected

You are requesting data from the following clinical studies listed on this site.

GSK-107335

COPD prevalence estimation in Spanish population, Medicine, Condition: Pulmonary Disease, Chronic Obstructive, Phase: N/A, Clinical Study ID: 107335, Sponsor: GSK.

TAKEDA-SYR-322/CCT-001

A Phase 2, Double-blind, Randomized, Placebo-controlled, Parallel-group, Multicenter Study to Determine the Efficacy and Safety of SYR-322 in Subjects With Type 2 Diabetes in Japan, Medicine: alogliptin, Condition: Diabetes Mellitus, Type 2, Phase: 2, Clinical Study ID: SYR-322/CCT-001, Sponsor: Takeda.

ASTELLAS-178-CL-049

A Randomized, Double-Blind, Parallel Group, Active Controlled, Multi-center Long-term Study to Assess the Safety and Efficacy of the Beta-3 Agonist Mirabegron (YM178) 50 mg qd and 100 mg qd in Subjects with Symptoms of Overactive Bladder, Medicine: mirabegron, Condition: Urinary Bladder, Overactive, Phase: 3, Clinical Study ID: 178-CL-049, Sponsor: Astellas.

You can add further studies.

[Add Another Study](#) Before removing or adding another study, please save this enquiry by adding a Reference Name below.

***Reference Name:**

Enquiry

Please add a Reference Name before saving this enquiry [Save](#)

Enquiry Form

Enquiries are answered by the relevant study sponsor or sponsors.

Please complete this form in English.

When you are ready, click "Save and Complete Submission" at the bottom of this page.

Type of Enquiry:

☒ Studies listed on the site (you must select a listed study when using this option)

☒ Studies not listed on the site (you must select a sponsor below when using this option)

If you have questions about your selected studies please enter them below.

If you are seeking access to study documents please refer to sponsor specific pages for instructions.

When will these studies be available on the site?

The sponsors listed in the drop-down box below provide a facility where you can find out if data from their studies that are not listed on this site can be provided. Please search study registers (e.g. clinicaltrials.gov) or literature databases and provide the information below so the study sponsor can identify the study.

Where the study sponsor or sponsors are able to provide access, they will do so if the Independent Review Panel approves your submitted research proposal and the sponsor(s) receive a signed Data Sharing Agreement.

Study Sponsor	Study Id. No.	Study Title	Other Reference Information
Astellas			
Boehringer Ingelheim			
Else			
GSK			
Lilly			
Novartis			
Roche			
Takeda			
UCS			
VIV			

☐ Add Another Study (Unchecking this box will delete all study information below)

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[Save](#) [Save & Complete Submission](#) [Cancel](#)

Step 1 of 2

You are taken to a page where you can review your enquiry before it is submitted.

You can make changes by clicking the **Make a change** button. This will take you back to the enquiry form where you can make changes.

To submit your enquiry, click the green **Submit** button at the bottom of the page.

You will receive an email acknowledgement.

You will be contacted if further information is required before your enquiry is considered.

Review your enquiry prior to submitting

Your submission has been SAVED, but NOT YET SUBMITTED.

Please review the submission information below and when you are ready, click "Submit" at the bottom of this page to send it to the relevant study sponsor or sponsors. If you want to make changes, just click on the "Make a change" button to go back and make changes. Alternatively, you can exit this page and your submission will be saved. You can come back to this website, log-in and update the request at a later date.

Studies selected

GSK-107335

COPD prevalence estimation in Spanish population, Medicine, Condition: Pulmonary Disease, Chronic Obstructive, Phase: N/A, Clinical Study ID: 107335, Sponsor: GSK.

TAKEDA-SYR-322/CCT-001

A Phase 2, Double-blind, Randomized, Placebo-controlled, Parallel-group, Multicenter Study to Determine the Efficacy and Safety of SYR-322 in Subjects With Type 2 Diabetes in Japan, Medicine: alogliptin, Condition: Diabetes Mellitus, Type 2, Phase: 2, Clinical Study ID: SYR-322/CCT-001, Sponsor: Takeda.

ASTELLAS-178-CL-049

A Randomized, Double-Blind, Parallel Group, Active Controlled, Multi-center Long-term Study to Assess the Safety and Efficacy of the Beta-3 Agonist Mirabegron (YM178) 50 mg qd and 100 mg qd in Subjects with Symptoms of Overactive Bladder, Medicine: mirabegron, Condition: Urinary Bladder, Overactive, Phase: 3, Clinical Study ID: 178-CL-049, Sponsor: Astellas.

Enquiry Title:

Enquiry

Enquiry Form

Type of Enquiry:

Studies listed on the site (you must select a listed study when using this option), Studies not listed on the site (you must select a sponsor below when using this option)

If you have questions about your selected studies please enter them below. If you are seeking access to study documents without patient level data please state this below.

When will these studies be available on the site?

Study Sponsor	Study Id. No.	Study Title	Other Reference Information
GSK	GSK-1234	A study to	

[Make a Change](#) [Save & Exit](#) [Submit](#)

Step 2 of 2

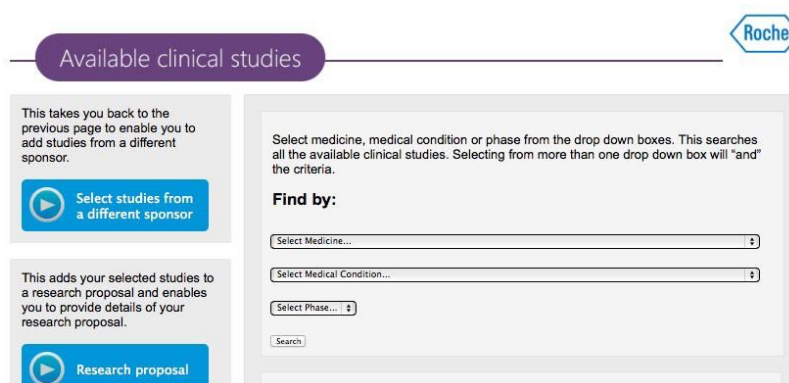


12 Submit a research proposal

Before submitting a research proposal you will need to create an account or log-in and select studies that are needed for your research.

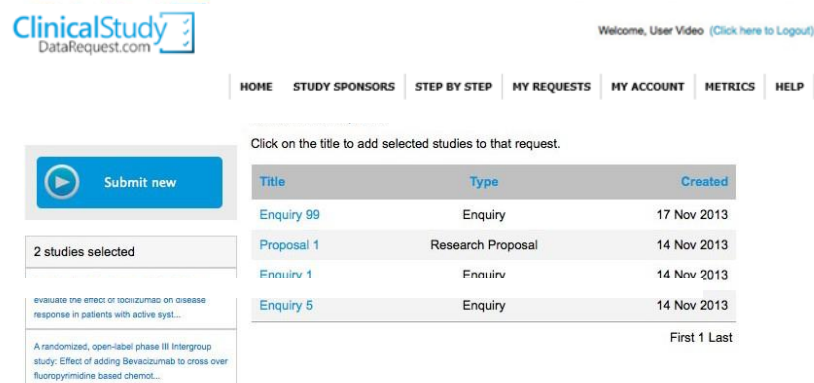
If you are enquiring about studies not listed on the site, please wait to complete the research proposal until after the enquiry is answered. This will allow you to select the studies, if available, so the studies are included in the research proposal.

After you have selected studies for your research from the **Available clinical studies** page (see section 9 of this User Guide), click the **Research proposal** button.



If you have unsubmitted research proposals you can select a particular research proposal from a list to update it or you can create a new research proposal by clicking the **Submit new** button.

If you do not have unsubmitted research proposals or enquiries you will be taken directly to the research proposal form.



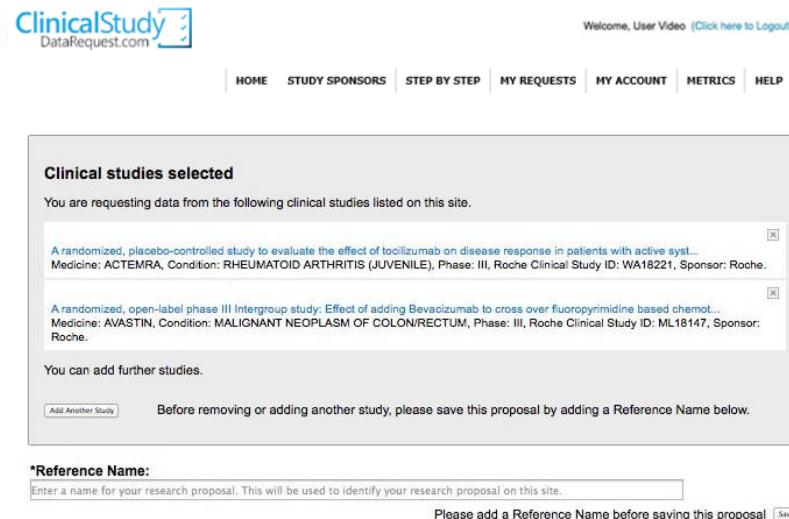
Title	Type	Created
Enquiry 99	Enquiry	17 Nov 2013
Proposal 1	Research Proposal	14 Nov 2013
Enquiry 1	Enquiry	14 Nov 2013
Enquiry 5	Enquiry	14 Nov 2013

For a new research proposal, enter a Reference Name. Choose a name that will enable you to identify the enquiry. This will be used to identify your research proposal on the site.

The studies you have selected are listed at the top of the page. You can remove studies by clicking the X button next to the study.

You can also add studies by clicking the **Add Another Study** button. This will take you back to the **View and Submit** page where you can select further studies.

After you have selected additional studies, click the **Research proposal** button and select the name of the research proposal from the list of unsubmitted research proposals and enquiries.



Clinical studies selected

You are requesting data from the following clinical studies listed on this site.

Title	Type	Created
Enquiry 99	Enquiry	17 Nov 2013
Proposal 1	Research Proposal	14 Nov 2013
Enquiry 1	Enquiry	14 Nov 2013
Enquiry 5	Enquiry	14 Nov 2013

***Reference Name:**

Enter a name for your research proposal. This will be used to identify your research proposal on this site.

Please add a Reference Name before saving this proposal **Save**



If you have received an answer to a previous enquiry related to your research proposal or if your research proposal is a re-submission of a previous research proposal that has been reviewed by the panel, enter the relevant Reference Name and number in the boxes provided.

*Have you received an answer to a previous enquiry related to this research proposal?

☒ Yes ☐ No

Please provide the enquiry Reference Name and Number

*Is this research proposal a re-submission of a previous research proposal that has been reviewed by the Independent Review Panel?

☒ Yes ☐ No

Please provide the previous research proposal Reference Name and Number

Follow the instructions provided to complete the research proposal form.

*A.3 Study Design

Limited to 2,500 characters.

Please provide a brief description of the study design. For example: case-control, cohort, cross-sectional, case-crossover, historical controlled, or hybrid designs, meta-analysis, pooled analysis. This field is required.

*A.4 Studies Selected and Study Populations

Limited to 2,500 characters.

Please provide the reasons why you have selected these studies for your proposed research. Please also provide a description of the study population or populations for the proposed research. For example: the study arms from the requested clinical studies; intent-to-treat or per-protocol populations; the inclusion and exclusion criteria for any cohort or subgroup analysis. This field is required.

*A.5 Primary and Secondary Endpoints for the Study

Limited to 2,500 characters.

Please describe the endpoints that will be analysed. For example, change in depression score from baseline to the last available follow-up, measured using the Beck Depression Inventory. Please note that to ensure the use of the data aligns with the informed consent provided by clinical study participants, research proposals must relate to the medicine or disease that was the subject of the original clinical studies. This field is required.

When you have finished click the **Save & Complete Submission** button.

Alternatively click the **Save** button and come back later to complete your research proposal.

SECTION E: OTHER INFORMATION

Please provide any additional information that should be considered when reviewing this proposal

Clicking the **Save & Complete Submission** button takes you to a page where you can review your research proposal before it is submitted.

You can make changes by clicking the **Make a change** button at the bottom of the page. This will take you back to the research proposal form where you can make changes.

NOTE: After you submit your proposal you will not be able to make any changes. If you need to modify your proposal (including adding or deleting studies) please submit a new proposal and withdraw your previous submission. To withdraw a proposal, please reference **page 26** of this guide for instructions on how to **Contact the administrator**.

To submit the research proposal click the green **Submit** button at the bottom of the page.

You will receive an email acknowledgement.

You will be contacted if further information is required before your research proposal is considered by the Independent Review Panel.

Review your proposal prior to submitting

Your submission has been SAVED, but NOT YET SUBMITTED.

Please review the submission information below and when you are ready, click "Submit" at the bottom of this page to send it to the relevant study sponsor or sponsors. If you want to make changes, just click on the "Make a change" button to go back and make changes. Alternatively, you can exit this page and your submission will be saved. You can come back to this website, log-in and update the request at a later date.

Studies selected
EISAI-1234-Eisai Test Study Eisai test study

Proposal Title:

EISAI-Training - TEST-Please IGNORE

Required fields are marked with an *

*I understand access to data will only be provided in the secure data access system. SAS and "R" statistical software are provided and there are controls to prevent the original study datasets from being downloaded.

Yes

*Have you received an answer to a previous enquiry related to this research proposal?

No

*Is this research proposal a re-submission of a previous research proposal that has been reviewed by the Independent Review Panel?

No

SECTION E: OTHER INFORMATION

Please provide any additional information that should be considered when reviewing this proposal

asdf

After you submit your proposal you will not be able to make any changes. If you need to modify your proposal (including adding or deleting studies) please submit a new proposal and withdraw your previous submission.

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13 Complete a saved but unsubmitted research proposal or enquiry

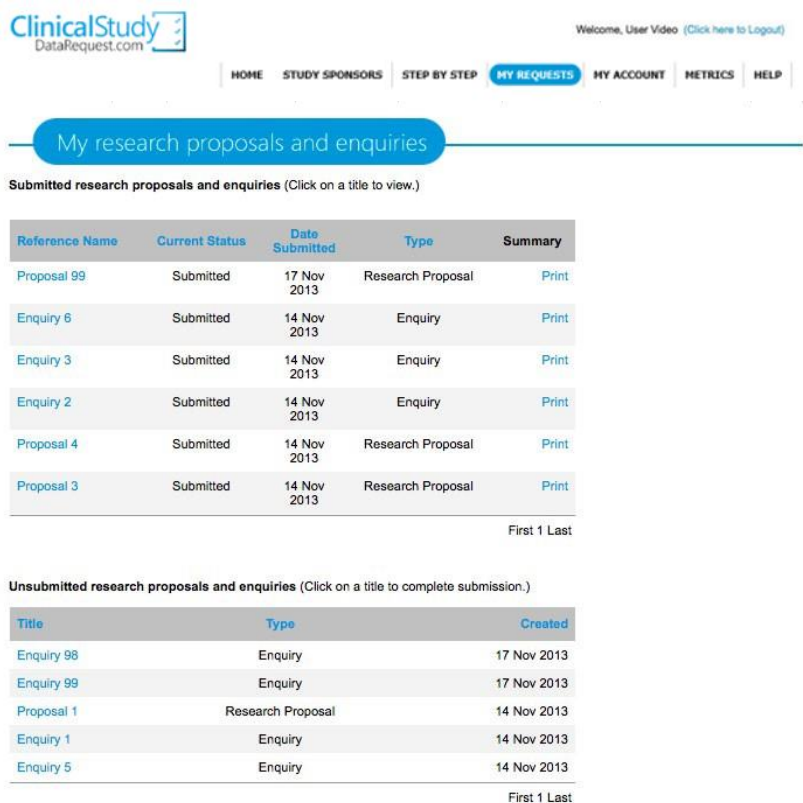
Before completing a saved but unsubmitted research proposal or enquiry you will need to log-in.

After you have logged-in click the **My requests** tab.

You will see a table of submitted research proposals and enquiries (if you have any) and a table of unsubmitted research proposals and enquiries.

Click the Reference Name for an unsubmitted research proposal or enquiry to complete the form.

Alternatively you may modify your request, save it and come back later to complete your submission.



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HOME STUDY SPONSORS STEP BY STEP **MY REQUESTS** MY ACCOUNT METRICS HELP

My research proposals and enquiries

Submitted research proposals and enquiries (Click on a title to view.)

Reference Name	Current Status	Date Submitted	Type	Summary
Proposal 99	Submitted	17 Nov 2013	Research Proposal	Print
Enquiry 6	Submitted	14 Nov 2013	Enquiry	Print
Enquiry 3	Submitted	14 Nov 2013	Enquiry	Print
Enquiry 2	Submitted	14 Nov 2013	Enquiry	Print
Proposal 4	Submitted	14 Nov 2013	Research Proposal	Print
Proposal 3	Submitted	14 Nov 2013	Research Proposal	Print

First 1 Last

Unsubmitted research proposals and enquiries (Click on a title to complete submission.)

Title	Type	Created
Enquiry 98	Enquiry	17 Nov 2013
Enquiry 99	Enquiry	17 Nov 2013
Proposal 1	Research Proposal	14 Nov 2013
Enquiry 1	Enquiry	14 Nov 2013
Enquiry 5	Enquiry	14 Nov 2013

First 1 Last



14 Review the status of your requests

Before reviewing the status of your requests, you will need to log-in.

After you have logged-in, click the **My requests** tab.

You will see a table of submitted research proposals and enquiries and a table of unsubmitted research proposals and enquiries (if you have any). This table provides the current status of your request.

Click the Reference Name for a submitted research proposal or enquiry to see that request.

ClinicalStudy
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HOME STUDY SPONSORS STEP BY STEP **MY REQUESTS** MY ACCOUNT METRICS HELP

My research proposals and enquiries

Submitted research proposals and enquiries (Click on a title to view.)

Reference Name	Current Status	Date Submitted	Type	Summary
Proposal 99	Submitted	17 Nov 2013	Research Proposal	Print
Enquiry 6	Submitted	14 Nov 2013	Enquiry	Print
Enquiry 3	Submitted	14 Nov 2013	Enquiry	Print
Enquiry 2	Submitted	14 Nov 2013	Enquiry	Print
Proposal 4	Submitted	14 Nov 2013	Research Proposal	Print
Proposal 3	Submitted	14 Nov 2013	Research Proposal	Print

First 1 Last

Unsubmitted research proposals and enquiries (Click on a title to complete submission.)

Title	Type	Created
Enquiry 98	Enquiry	17 Nov 2013
Enquiry 99	Enquiry	17 Nov 2013
Proposal 1	Research Proposal	14 Nov 2013
Enquiry 1	Enquiry	14 Nov 2013
Enquiry 5	Enquiry	14 Nov 2013

First 1 Last

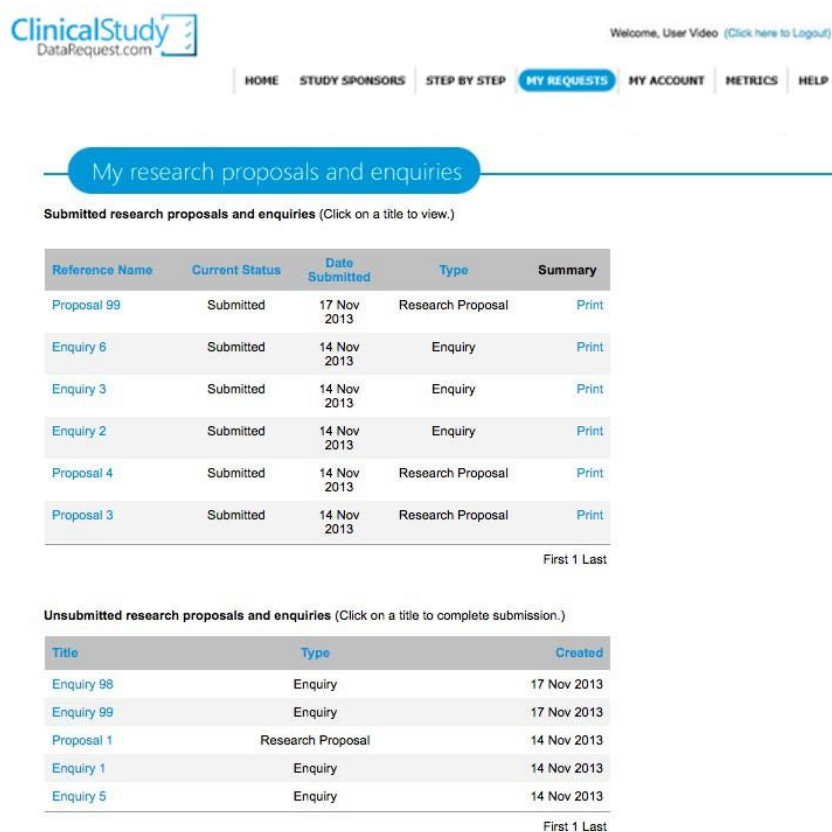


15 Provide additional information (Contact administrator)

You may be asked to provide further information. This information can be provided through the site. Before providing this information you will need to log-in.

After you have logged-in, click the **My requests** tab.

You will see a table of submitted research proposals and enquiries and a table of unsubmitted research proposals and enquiries (if you have any).



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HOME STUDY SPONSORS STEP BY STEP **MY REQUESTS** MY ACCOUNT METRICS HELP

My research proposals and enquiries

Submitted research proposals and enquiries (Click on a title to view.)

Reference Name	Current Status	Date Submitted	Type	Summary
Proposal 99	Submitted	17 Nov 2013	Research Proposal	Print
Enquiry 6	Submitted	14 Nov 2013	Enquiry	Print
Enquiry 3	Submitted	14 Nov 2013	Enquiry	Print
Enquiry 2	Submitted	14 Nov 2013	Enquiry	Print
Proposal 4	Submitted	14 Nov 2013	Research Proposal	Print
Proposal 3	Submitted	14 Nov 2013	Research Proposal	Print

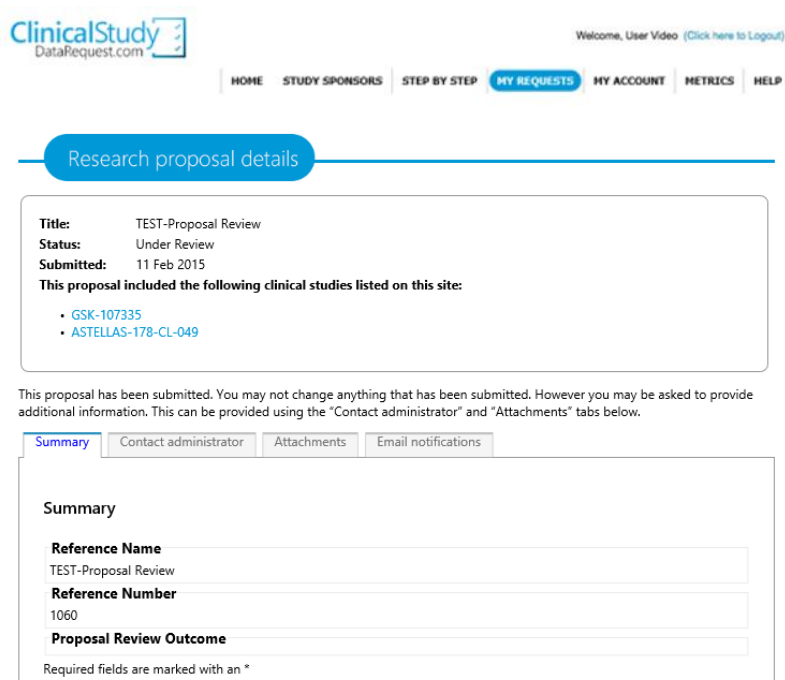
First 1 Last

Unsubmitted research proposals and enquiries (Click on a title to complete submission.)

Title	Type	Created
Enquiry 98	Enquiry	17 Nov 2013
Enquiry 99	Enquiry	17 Nov 2013
Proposal 1	Research Proposal	14 Nov 2013
Enquiry 1	Enquiry	14 Nov 2013
Enquiry 5	Enquiry	14 Nov 2013

First 1 Last

Click the Reference Name for the relevant submitted research proposal or enquiry. You will be taken to that submitted request.



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HOME STUDY SPONSORS STEP BY STEP **MY REQUESTS** MY ACCOUNT METRICS HELP

Research proposal details

Title: TEST-Proposal Review
Status: Under Review
Submitted: 11 Feb 2015

This proposal included the following clinical studies listed on this site:

- [GSK-107335](#)
- [ASTELLAS-178-CL-049](#)

This proposal has been submitted. You may not change anything that has been submitted. However you may be asked to provide additional information. This can be provided using the "Contact administrator" and "Attachments" tabs below.

Summary | Contact administrator | Attachments | Email notifications

Summary

Reference Name
TEST-Proposal Review

Reference Number
1060

Proposal Review Outcome

Required fields are marked with an *



Click the Email notifications tab to see information that has been sent to you.



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[HOME](#) [STUDY SPONSORS](#) [STEP BY STEP](#) [MY REQUESTS](#) [MY ACCOUNT](#) [METRICS](#) [HELP](#)

Research proposal details

Title: TEST-Proposal Review
Status: Under Review
Submitted: 11 Feb 2015
This proposal included the following clinical studies listed on this site:

- [GSK-107335](#)
- [ASTELLAS-178-CL-049](#)

This proposal has been submitted. You may not change anything that has been submitted. However you may be asked to provide additional information. This can be provided using the "Contact administrator" and "Attachments" tabs below.

[Summary](#) [Contact administrator](#) [Attachments](#) [Email notifications](#)

Email notifications

This area provides you with communications and notifications from the System.
 To respond to requests for additional information use the "Provide requested information" tab.

<input checked="" type="checkbox"/>	Type	Created	To/With	Subject
<input checked="" type="checkbox"/>	Email	11 Feb 2015	lmurphy@idea-point.com	DEMO - Research Proposal 1060 - TEST-Proposal Review

[First](#) [1](#) [Last](#)

Click the **Contact administrator** tab to provide the information you have been asked to provide. Or submit a request to **Withdraw** your proposal or enquiry.



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[HOME](#) [STUDY SPONSORS](#) [STEP BY STEP](#) [MY REQUESTS](#) [MY ACCOUNT](#) [METRICS](#) [HELP](#)

Research proposal details

Title: TEST-Proposal Review
Status: Under Review
Submitted: 11 Feb 2015
This proposal included the following clinical studies listed on this site:




- [GSK-107335](#)
- [ASTELLAS-178-CL-049](#)

This proposal has been submitted. You may not change anything that has been submitted. However you may be asked to provide additional information. This can be provided using the "Contact administrator" and "Attachments" tabs below.

[Summary](#) [Contact administrator](#) [Attachments](#) [Email notifications](#)

Contact administrator

This area allows you to respond to requests for additional information or to submit an unsolicited comment or question to the administrator if necessary.

To respond to a request for information from the administrator, please click the blue circle  in the 'Response' column beside the comment you are responding to. To send your response, click the 'Save' icon  or the green check box  that will be appear beside your response field. *Please note: You will not be able edit a comment or response if either party has responded, even though the pencil icon is visible. You will need to submit a new comment via the process described below.*

To generate a new comment/question to the administrator (unsolicited), please use the free text box at the bottom of the comment table.

Comment	Response	Created	Responded
---------	----------	---------	-----------

Unsolicited Comment/Question to the administrator

[Send](#)



Alternatively you can click the **Attachments** tab to upload documents to provide the additional information.



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Research proposal details

Title: TEST-Proposal Review

Status: Under Review

Submitted: 11 Feb 2015

This proposal included the following clinical studies listed on this site:

- [GSK-107335](#)
- [ASTELLAS-178-CL-049](#)

This proposal has been submitted. You may not change anything that has been submitted. However you may be asked to provide additional information. This can be provided using the "Contact administrator" and "Attachments" tabs below.

[Summary](#)

[Contact administrator](#)

[Attachments](#)

[Email notifications](#)

Attachments

This area allows you to upload files to provide information in response to requests for additional information associated with your research proposal or enquiry.

File types that are allowed to be uploaded include: **.doc, .docx, .xls, .xlsx, .ppt, .pptx, .txt, .rtf, .pdf.**

Uploading Instructions:

Click "Select Files" to open a window to browse to the document you wish to upload. Once the files have been selected, your files will be in a "Queued" status. Click the Red "X" mark if you wish to remove the file already in queue. When you're ready, click the "Upload" button and wait for the progress to turn into a Green "Check" mark to confirm your Upload.

Name	Status	Size	Progress

Total: 0

[Select Files](#) [Upload](#) [Clear](#)

[Refresh Attachments List](#)

No attachments exist for this proposal.



16 View metrics

Click the **Metrics** tab to see information about submitted research proposals and enquiries.



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Metrics

A summary of the number of research proposals and enquiries that have been submitted since **May 2013** is provided here. Metrics for research proposals are updated monthly and metrics for enquiries are updated every three months.

The table below provides metrics for different parts of the process following submission of a research proposal (Requirements check, Independent Review Panel (IRP) review, Data Sharing Agreement, Data preparation and conduct of the research project). The "In process" rows provide the number of research proposals in this part of the process. The other rows for each part of the process provide the total number of research proposals that have achieved that outcome.

Research proposals requesting access to patient level data (number of proposals)

Number of Research Proposals submitted up to 31 March 2015		119
Requirements check	In process	10
	Withdrawn by the requestor	9
	Did not meet requirements (further details)	10
	Potential conflict of interest or an actual or potential competitive risk	0
	Met requirements	90
IRP review	In process	1
	Withdrawn by the requestor	0
	Rejected or advised to re-submit	6
	Approved or approved with conditions	83
Data Sharing Agreement	In process	24
	Withdrawn by the requestor	2
	Not agreed (not signed)	0
	Agreed (signed) View details of these research proposals	57
Data preparation	In process	10
	Withdrawn by the requestor	0
	Complete (data available)	47
Research project	In process	47
	Withdrawn by the requestor	0
	Not published	0
	Published	0

* Multi-sponsor research proposals were possible starting 1 January 2014. Out of 97 proposals submitted since 1 January 2014, 12 were multi-sponsor proposals.

To see information about approved research proposals that have signed a Data Sharing Agreement click **Agreed (Signed)**.

Click the **Further Details** > link and you can view more details regarding the research proposal including a lay summary.



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Metrics

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The table below provides details of approved research proposals that have signed Data Sharing Agreements.

Proposal number	Study sponsor(s)	Title	Lead researcher	
611	GSK	Long-acting beta2-agonists for chronic obstructive pulmonary disease	Kayleigh Kew	Further Details
628	GSK	Predictive and Prognostic Value of Blood Cell Ratios in Patients with Metastatic Renal Cell Carcinoma Treated with Pazopanib	Arnoud J. Templeton, MD	Further Details
631	GSK	Predictors of BPH Progression	Stephen Freedland, MD	Further Details
637	GSK	Relationship of Activated Clotting Time and Bleeding Related Outcomes in the FUTURA OASIS-8 Trial	Sripal Bangalore, MD, MHA, FACC, FSCAI	Further Details



17 Help

For help using the site, click the **Help** tab to locate the specific section of the guide related to your issue.

Additional help links have been provided on this page for information not found in the User Guide.

For questions related to site functionality and/or site user account issues (forgot username, login issues etc.). Please contact: support@clinicalstudydatarequest.com

For questions related to the **SAS** data access site please contact: CTDTsupport@sas.com



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Help

The majority of help information can be located in the [User Guide](#) located under the "Step by Step" tab shown above.

To locate the specific section of the guide related to your issue, please view the information below. Additional help links have been provided on this page for information not found in the [User Guide](#).

What do you need help with?

Login, password or account issue

- Create or delete an account – Please reference section 4 and 5 of the [User Guide](#)
- Change your account details – Please reference section 6 of the [User Guide](#)
- Reset your password – Please reference section 7 and 8 of the [User Guide](#)

For issues not found in the user guide (example: Forgotten password)

- Please email the CSDR technical support staff at support@clinicalstudydatarequest.com. A technical support staff member will contact you.

Submitting an enquiry or proposal

- Submitting an enquiry – Please reference section 10 and 11 of the [User Guide](#)
- Submitting a proposal – Please reference section 12 or the [User Guide](#)

Question about a request you have already submitted

- Please reference section 15 of the [User Guide](#) and follow instructions how to "Contact administrator". This function can be used to submit a question.

Questions about specific studies

- Some sponsors provide an Enquiry facility where researchers can either ask for more information about studies already listed on the site or enquire about access to data from studies that are not listed on the site. If the sponsor you are interested in provides this facility (see the 'Study Sponsors' pages to check) then submit an Enquiry form with your questions or enquiry (see the directions in the [User Guide](#) sections 10 and 11.)

Submit a request to Technical Support

- The CSDR.com technical support staff is only equipped to assist in resolving technical issues related to the CSDR.com site.
- For functionality issues or issues not found on the step by step tab, please email CSDR technical support staff at support@clinicalstudydatarequest.com. Please provide your name, your email address, your phone number and a detailed description of the issue you are encountering. A technical support staff member will contact you.