

PAREXEL International
Imaging Investigator Site Operations Manual



INVESTIGATOR SITE OPERATIONS MANUAL

AbbVie, Inc. M16-011

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REVISION HISTORY

Date	Author	Version	Description of Revision
02-Nov-2018	Sherri levers	1.0	Initial Release of Document
03-Jan-2019	Sherri levers	2.0	Removed eligibility confirmation form from 1.3 and added detail on the form to 3.1 and 3.6. 2.1 Added contains no marking or measurements verbiage. 2.3 added data protection and media label detail. 2.4 added statement that eTransfer is preferred. 2.5 added "imaging eligibility" to the confirmation form named in this section
29-Jan-2019	Sherri levers	3.0	2.1 Step 5: Added "(The original film sent to PAREXEL will not be returned.)" 2.2 Step 4: Removed "If films need to be returned to the site, please note this on the label"

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Abbreviations and Acronyms

CIL	Core Imaging Laboratory
DICOM	Digital Imaging and Communications in Medicine
IAG	Image Acquisition Guidelines
PsA	Psoriatic Arthritis
SJC	Swollen Joint Count
TJC	Tender Joint Count
QC	Quality Check

1 Introduction

1.1 Study Background

A Phase 3, Randomized, Double-Blind, Study Comparing Risankizumab to Placebo in Subjects with Active Psoriatic Arthritis (PsA) Who Have a History of Inadequate Response to or Intolerance to at Least One Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy

Objectives:

Primary

Period 1 Double-Blind

To compare the efficacy of risankizumab versus placebo for the treatment of signs and symptoms of PsA in the study population.

Secondary

Period 1 Double-Blind

1. To compare the efficacy of risankizumab versus placebo for the inhibition of progression of structural damage as assessed by radiographs in the study population.
2. To compare the safety and tolerability of risankizumab versus placebo in the study population.

Period 2 Open-Label

To evaluate the long-term safety, tolerability and efficacy of risankizumab in subjects with PsA who have completed Period 1.

For specific study inquiries relating to study design or study objectives, please reference the Study Protocol.

This Investigator Site Operations Manual provides instructions for the imaging component of the AbbVie, Inc. Study M16-011. This document is specifically related to the management of imaging data acquisition, including shipment, tracking, and quality control.

An institutional review board (IRB)/ethics committee (EC)-approved informed consent must be signed prior to acquiring images of healthy volunteers and study subjects.

All imaging scans will be acquired in a standardized manner, following pre-established Image Acquisition Guidelines (IAG) developed by PAREXEL Informatics and approved by AbbVie, Inc.. Images will be submitted to PAREXEL for processing and independent analysis. Imaging data for all patients will be acquired according to the imaging schedule outlined in the protocol, as well as listed in the table below:

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IMAGING ANATOMY	IMAGED ANATOMY	IMAGING SCHEDULE*
Radiograph (X-RAY)	Bilateral Hands (PA view) Bilateral Feet (AP View)	Screening/Baseline Week 16** Week 24 Week 52 Week 100 Premature discontinuation***

*Radiographs of hands and feet will be performed for all subjects at Screening, Week 24, Week 52, and Week 100.

**All subjects who fail to attain at least a 20% improvement in either or both tender joint count (TJC) and swollen joint count (SJC) at Week 12 and Week 16 compared to Baseline will have an additional radiographic examination at Week 16.

*** All subjects will receive radiographs of hands and feet if they discontinue from the study or from study drug at or after Week 12 and if it has been at least 12 weeks from when radiographs were last obtained during Period 1 or at least 24 weeks during Period 2. In such subjects, radiographs should be obtained as close as possible to the date of study drug discontinuation.

- Radiographs of hands and feet must be performed during the screening process in compliance with the imaging acquisition guidelines (IAG) and image quality acceptability must be confirmed via central quality control (QC) by PAREXEL.
- Screening radiographs of hands and feet will serve as baseline radiographs for central Van der Heijde's modified Sharp scoring for PsA.

The required modality of imaging in this study is radiograph.

Note: Modalities selected at baseline should remain consistent throughout the study.

All images will be submitted to PAREXEL within 48 hours of acquisition (2 business days).

Images received at PAREXEL **MAY NOT CONTAIN** any markings, assessments or confidential patient information.

You must remove from the images the names of the patient and investigator site and any other information that can be used to identify the patient or investigator site.

Radiographs will undergo Independent Review.

Independent Reviewer findings are independent assessments and will be communicated by PAREXEL to the investigator sites for assessment of eligibility based on presence or absence of erosions on Screening radiographs. All patient care decisions are made at the site by the Primary Investigator(s) including whether the patient should continue on the study.

Independent Reviewer(s) will remain blinded to the assessments made at the investigator sites. Data pertaining to local read results are not being collected.

1.2 Purpose of this Manual

The purpose of this manual is to provide:

- Contact information for additional assistance
- Description of operating procedures for Investigator sites
- Sample forms

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1.3 Start Up Package Components

PAREXEL Informatics will provide the investigator site with the necessary materials listed below to perform the functions associated with this Investigator Site Operations Manual. All documents will be supplied electronically.

- The **Image Acquisition Guidelines (IAG)** are generated by PAREXEL in an effort to standardize all imaging associated with the clinical trial across multiple investigator sites, patients and timepoints. The standardized guidelines are distributed to each investigator site participating in this study. Please note that there are separate guidelines for acquiring each involved region, varying scanner types and modalities. The IAGs are provided by email.
- The **Media Labels** are completed with patient/visit information and placed on each individual film or media (CD, DVD), making sure not to obscure anatomy, being sent to PAREXEL. Please place the label on the actual media and not the media case.
- The **Study Imaging Tracking Log** is used at the investigator site to document the shipment status of all images related to the clinical trial. The log is updated with information regarding image acquisition and shipment dates and corresponding shipment tracking numbers. It is optional.
- **Additional Site Supplies:**
 - Positioning templates
 - Dactylometer
 - Induration card
 - Film and cassettes for Conventional Radiography sites upon request
 - Digital media (CD, DVD) upon request
 - Shipping and other supplies (bubble mailers, masking pencils, and airbills) upon request
- The **Site Supply Request** form can be sent to the PAREXEL team via fax or e-mail to request additional site supplies. Use of this form is optional; additional supplies may also be requested via email 236765-imaging@parexel.com.
- The **Image Acceptance Notification** is sent from PAREXEL to the investigator site when acceptable imaging data is received.
- The **Query Notification** is sent from PAREXEL to the investigator site upon receipt of unacceptable imaging data at PAREXEL. The notification will describe the query and indicate the action(s) required to be taken towards submission of acceptable imaging data.
- The **Site Acceptance Form** is sent from PAREXEL to the investigator site when all qualification requirements have been met. This notification informs the site that they have been approved for the imaging portion of the study. The form may also contain recommendations and/or feedback regarding any test transfer data.

1.4 Responsibilities

The **Core Imaging Laboratory (CIL)** is the centralized facility at PAREXEL Informatics, for all processes associated with image data collection and review by Independent Reviewers. PAREXEL is responsible for the receipt, tracking, processing, quality control (QC), archiving of the image data. Data generated by the reviewer are maintained at the CIL and will be transferred to AbbVie, Inc. (or designee) at a specified time.

The **Investigator Sites** are responsible for enrolling patients and obtaining imaging per Image Acquisition Guidelines and study protocol. The Investigator Site is also responsible for managing image scheduling and for preparing and forwarding image data to the CIL within 48 hours of acquisition. Any changes in staff must be communicated to PAREXEL in a timely manner so that access to applicable applications/ portals (e.g. e transfer portal, FTP accounts) is removed.

An IRB approved informed consent must be signed prior to acquiring images of healthy volunteers and study subjects.

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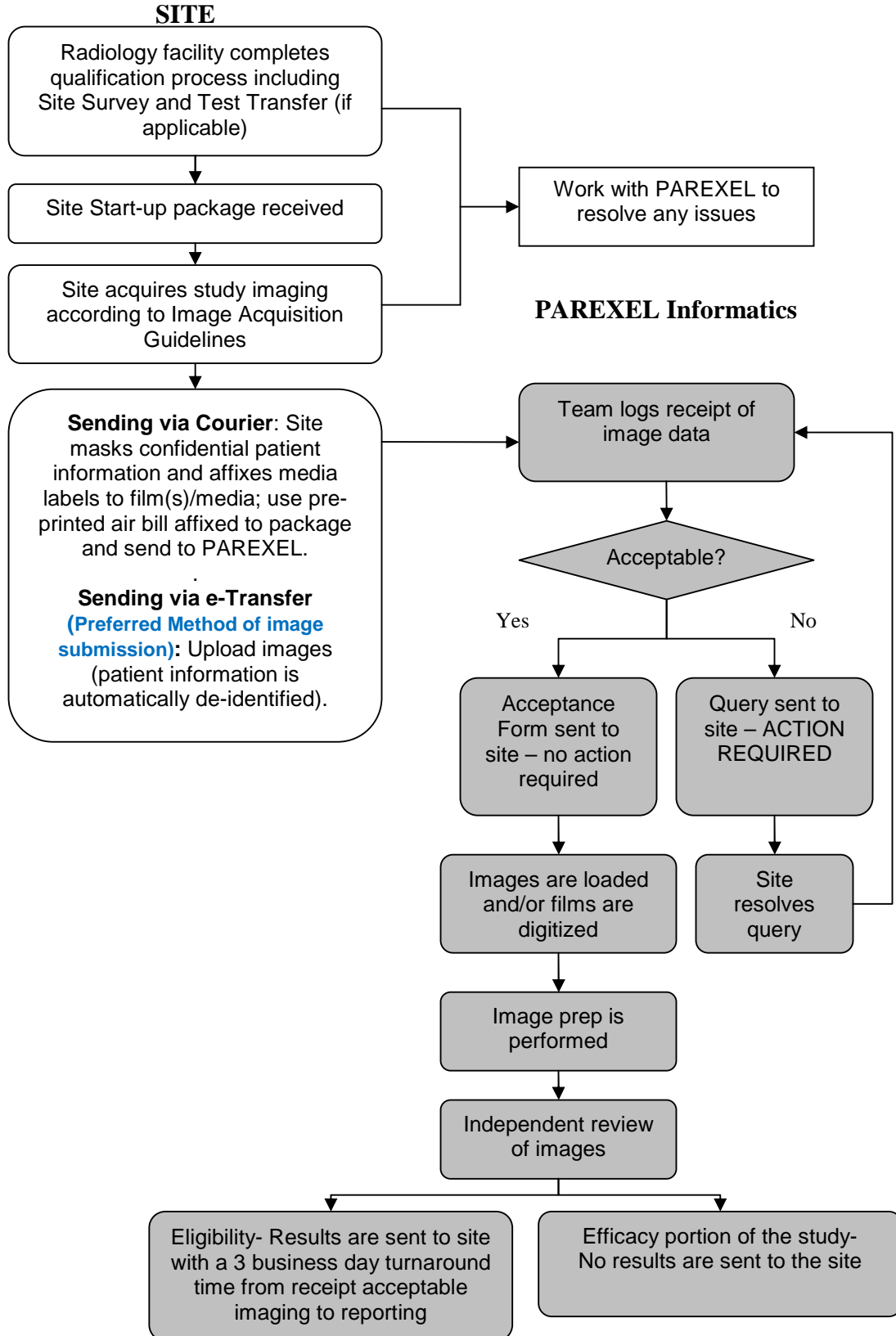
1.5 **PAREXEL Contact Information**

Team 236765
236765-Imaging@parexel.com
Fax # +1 978 222-8466
2 Federal Street
Billerica, MA 01821 USA

Note: Contacts will change during the study. PAREXEL will send along updated spreadsheets periodically to keep sites informed of new contact information. Please place these updates in the study binder to keep current with communication needs

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1.6 Study Flowchart



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2 Image Processing Procedures

This section details the image acquisition, collection and data transfer procedures for the investigator sites participating in this clinical trial. Please notify the radiology staff in advance of a study patient and include the Image Acquisition Guidelines with the image requisition.

2.1 Image Acquisition

Performed by: Study Coordinator, Radiology Technician
Scope: This procedure describes the steps necessary to acquire study images and to provide PAREXEL with the necessary patient and visit information. Please refer to the Image Acquisition Guidelines for the specific parameters to be used for image acquisition.

1. The radiology or respective technician will acquire the images according to the IAG. The technician will upload uncompressed, DICOM format images without markings or measurements to the Perceptive eTransfer portal.
2. If eTransfer is not being used the technician must de-identify patient name and investigator site name and any other information that can be used to identify the patient or investigator site contained in the DICOM Header. Imaging data that has been masked and contains no marking or measurements are placed on the media (CD, film, DVD). A copy of the exam is maintained at the facility.

Note: If you need to de-identify electronic data, and your IT department is unable to help, you may wish to consider whether DicomEditor is appropriate. For more information about this free software, please visit: <http://mirwiki.rsna.org/index.php?title=DicomEditor>. DicomEditor is not a PAREXEL product. We do not endorse it, do not make any representations about its performance, and do not supply any training or support for the software. If you haven't done so already, we suggest you try DicomEditor prior to using it for study images so that you are sure there are no issues with it.

3. The study coordinator must verify the names of the patient and investigator site and any other information that can be used to identify the patient or investigator site has been completely masked.
4. Confidential patient information is defined as individually identifiable information including but not limited to:
 - name (full name or first name and last initial or first initial and last name)
 - full date of birth
 - social security number
 - home address
 - phone number
 - medical record number
5. If the images are being saved to hardcopy films, please print two original copies, one remains at the site and the other is sent to PAREXEL. (The original film sent to PAREXEL will not be returned.)
6. Hard copy film may be masked using the specialized masking pencils. Please contact PAREXEL to request masking pencils.

2.2 Preparation and Tracking of Images

Performed by: Study Coordinator or Designee
Scope: This procedure describes the methods used to prepare and track images for transfer from the investigator site to PAREXEL. Study shipments are to be sent within 48 hours of acquisition.

1. The study coordinator receives the imaging data from the Radiology Department and verifies:
 - Images stored on digital media are in **uncompressed DICOM format**
 - No markers or measurements are present other than the Right and Left markers
 - Confidential patient information is de-identified.

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2. The Study Coordinator will contact the site's Radiology Department if any problems are noted.
3. The Study Coordinator will complete and affix media labels directly onto the media, CD / DVD.
4. If hard copy films are sent, each film must have a media label attached in a manner that does not obstruct anatomy.
5. Submitting imaging data containing confidential patient information is not permitted.
6. The study coordinator is responsible for maintaining patient confidentiality by ensuring the imaging technicians de-identify confidential patient information on all exams being submitted on digital media.
7. Hardcopy films may be masked using the specialized masking pencils. Please contact PAREXEL to request masking pencils if these are needed.

2.3 Image Transfer via Courier

Performed by:	Study Coordinator
References:	Airbill, Imaging Study Tracking Log
Scope:	This procedure describes the steps used to send images from the investigator site to PAREXEL.

Due to strict data protection laws the preferred method of data transfer is eTransfer. Data that is submitted through eTransfer is automatically anonymized with a visible chain of custody. However if eTransfer is not possible data may be submitted via courier if the following requirements are met:

- Only use pre-printed media labels supplied by PAREXEL. These are completed and placed on all media shipped to PAREXEL.
 - Only one exam per subject is placed on each CD that is submitted to PAREXEL. Please do not batch exams.
1. The study coordinator will complete the media labels to include all required information (site number, subject number, visit description, exam date and modality. Media labels are affixed directly onto the media, CD / DVD.
 2. The study coordinator will use the pre-printed airbills that are provided by PAREXEL for this study.
Note: Additional airbills must be requested directly from PAREXEL
 3. The Study Coordinator will place the hard copy films or digital media in the package for shipment.
 4. If hardcopy films are being sent, these will be placed in the padded envelopes that can be provided by PAREXEL if needed. Taping around the edges of the envelope will help to secure the images. Shipping boxes can also be obtained free of charge from the appropriate courier.
 5. The date of shipment and airbill tracking number should be maintained for future reference.
Note: Please ship imaging data to PAREXEL within 48 hours of acquisition (do not wait for a patient to be randomized or wait to collect multiple timepoints).

2.4 Image Data Transfer via Perceptive eTransfer – Preferred Method of Image Submission

Performed by:	Study Coordinator or designee
Scope:	This procedure describes the steps used to send images from the investigator site to PAREXEL via eTransfer

This web-based electronic transfer solution allows investigator sites to transfer de-identified study images to PAREXEL Informatics through an internet browser. The eTransfer website is HIPAA and 21CFR Part 11 compliant.

There are only two requirements to use eTransfer:

1. A computer with internet access
2. JAVA plug-in (already installed on most computers)

Recommended internet browser: Google Chrome (no JAVA plug-in required).

Other compatible internet browsers: Internet Explorer (7, 8, 9 or 10), Safari, or Firefox (all require JAVA for upload)

If JAVA is not installed, the Perceptive eTransfer system will guide the user through the JAVA installation process. If installing the JAVA plug-in is blocked the user will contact the Information Technology Administrator at the site.

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User Access

1. The PAREXEL study team will create an account using the email address provided by the sponsor as the user log in ID. The site user will then receive an email notification containing the account credentials and login instructions.
2. Additional user accounts can be requested by emailing the PAREXEL team at 236765-Imaging@parexel.com.
3. Navigate to the system log in page and select the training link to view a 10 minute training clip.
4. Log into the system and the home page appears:

<https://parexel.ambrahealth.com/index.html>

Image Sharing

Sign In

Login

Password

[Forgot your password?](#)

Training Video (English)

1. English - Introduction to Perceptive eTransfer
2. Spanish (Spain) - Introduccion a la transferencia electronica de Perceptive
3. French - Presentation du systeme Perceptive eTransfer
4. German - Einfuhrung in Perceptive eTransfer
5. Italian - Introduzione al sistema Perceptive eTransfer
6. Korean - Introduction to Perceptive eTransfer
7. Czech - Uvod do systemu eTransferu spolcnosti Perceptive
8. Portuguese (Brazil) - Introducao ao eTransfer da Perceptive
9. Simplified Chinese - Introduction to Perceptive eTransfer
10. Spanish (Argentina) - Introduccion a la transferencia electronica de Perceptive

5. If login is not successful please check the credentials again and/or contact the PAREXEL team.

User Settings

1. The user's name appears in the top right menu of the homepage. Select this to edit:
 - First and/or last name
 - Reset the password
 - Set email notifications

Settings [Defaults](#) [Notifications](#) [Request access to an organization](#)

2. To edit notification preferences, the user will select the "Notifications" tab. To receive email notifications. Select "On Upload".

Uploading Images

1. Select the trial/site from the dropdown list. Returning users will see the list of all previously transmitted images for the trial.
2. To upload images, the user will select the trial and site from the "Studies" dropdown list then select "Upload Studies".

Upload Studies

Choose files to be scanned and verified

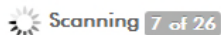
Select files for DICOM wrapping (Ctrl+click to select multiple)

No file chosen

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NOTE: If uploading a non-DICOM file (i.e. JPEG, AVI, DXA/IQC files) the user must check the “Select files for DICOM wrapping”

3. Select “choose file” and a browsing window will appear. The user will select the folder where the study images are stored and select “open”.
4. The “scanning” symbol will appear when a folder has been selected.



Scanning may take up to a few minutes to complete. Your screen may appear to be frozen. Please be patient.

5. The user will complete the trial/subject required information.

Site Number

Subject number

Please enter 9 digits

Visit description

6. The user will select “Upload Selected Studies”. As the images upload, a status bar will appear. Do not navigate away from the webpage while the upload is in progress. Open another eTransfer webpage to upload another scan concurrently. Upon successful upload the following message will be displayed:

Congratulations, your image files were uploaded

Description	Images	Patient Name	Modality	Study Date
<input checked="" type="checkbox"/> ANONYMIZED Uploaded	26	ANON1633	CT	05-29-2012

7. If the image upload notification feature is on, the user will receive an email within minutes of a successful upload from Perceptive eTransfer.

Viewing Images in the Image Viewer

1. Once uploaded, images can be viewed through the browser using the “View study in viewer” button:
2. The user can use the scroll on the bottom of the viewer to go through all images.

For technical support contact the DicomGrid support team by phone at 1-888-315-0790 (available 24/7) or by email at support@dicomgrid.com

2.5 Acceptance Process

Performed by: Study Coordinator or Designee
Scope: This procedure outlines the actions required of the Study Coordinator upon receipt of an Acceptance Notification. The notification will be sent from PAREXEL in a timely manner upon receipt of acceptable image data.

1. PAREXEL will perform a quality assurance check on the imaging data received.

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2. An Acceptance Notification is sent from PAREXEL to the investigator site upon receipt of image data informing the site that the imaging for the timepoint is complete and of acceptable quality.
3. This notification may also contain feedback or recommendations for follow up visits.
4. The Acceptance Notification also serves as documented resolution to a Query.
5. File the Acceptance Notification in the study file. No further action is required.
 - a. Note that for Eligibility, a separate **Imaging Eligibility Confirmation** communication will be sent to the investigator site regarding the result of the central review.

2.6 Query Process

Performed by: Study Coordinator or Designee
Scope: This procedure outlines the actions required by the Study Coordinator upon receipt of a Query from PAREXEL. A query will be sent from PAREXEL in a timely manner. The study coordinator may complete and return a query notification, respond via email/phone or login to the MyQueries portal to resolve the query.

1. A query is sent from PAREXEL to the investigator site upon receipt of unacceptable image data. The query will describe the issue and indicate the action(s) required to resolve the issue(s). Outstanding queries may impact the central review timeline.
2. The study coordinator is required to respond within 10 business days of query receipt but within 48 hours if Screening Timepoint (due to eligibility expedited processes).
3. If a written response on the query notification is being sent to PAREXEL, the study coordinator is required to maintain a copy of the query response in the study file.
4. Do not include any confidential patient information in the query response. Only the subject number should be used to identify a subject.
5. If resolution of the query cannot be completed, the site is required to notify PAREXEL within the 10 business day timeframe but within 48 hours if Screening Timepoint (due to eligibility expedited processes). This notification must include a definitive date for query resolution.
6. If the site is unable to successfully resolve the query, PAREXEL may request the assistance of the contracted CRO monitors and notify AbbVie, Inc. of the issue.

2.7 MyQueries Portal

Performed by: Study Coordinator or Designee
Scope: This procedure describes the process for responding to queries sent from PAREXEL via MyQueries

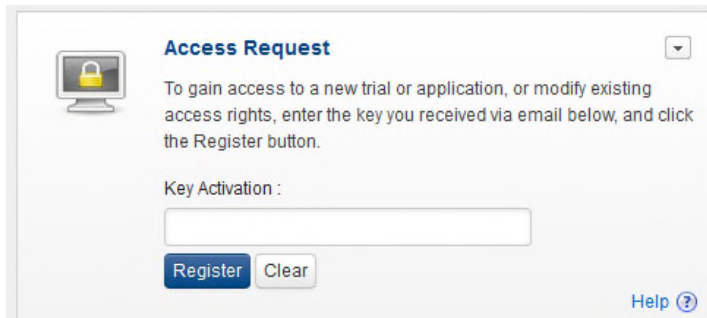
MyQueries is a web-based service for investigator sites, to receive, view, track, and respond to queries from any computer with web access.

1. Contact the PAREXEL team and request an account for MyTrials.
2. An email will be sent from Perceptive Customer Care with the following email address: do-not-reply@perceptive.com, with an activation code.
3. Login to MyTrials @ WWW.MYTRIALS.COM.
 - If you already have an account log on with your User Name and Password.
 - If you are using MyTrials for the first time, select “register new account” in the “Join MyTrials” box.

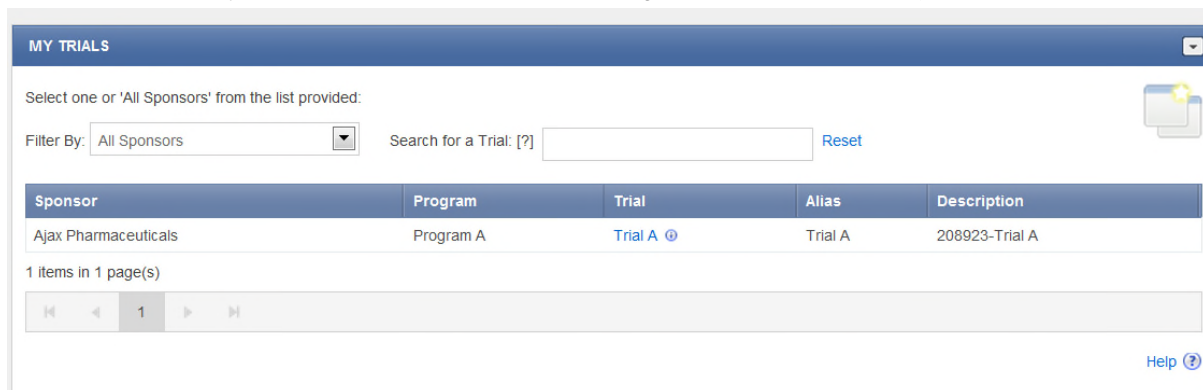
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4. After logging in to the system or creating a new account; enter the activation key(s) that you have received via email. ****Please note you may receive more than one key****



5. All trials that you have access to will appear upon login. Select the desired project.



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6. Listed under the MyQueries tab are the new and outstanding queries for the project.

MYQUERIES

You have 4 new queries.

You have 12 outstanding queries.

Search

[View closed queries](#)

7. Click the links to view queries.

MYQUERIES

Query List

Query Summary

Filter By: Outstanding Search Clear

Query ID	Site ID	Subject ID	Visit ID	Last Sent Date	Closed Date	Age	Status
7985	0008			27-May-2014	N/A	72 days	Outstanding
7988	0008			27-May-2014	N/A	72 days	Outstanding
7991	0008			27-May-2014	N/A	72 days	Outstanding

Query List (Queries can be filtered by any column header)

- **Subject ID** - If the query is regarding a site issue, this field may be blank.
- **Query ID** - A query with a number after the query ID (e.g.1234-3) represents the number of times the query was resent
- **Site ID** - If the query is regarding a site issue, the subject field may be blank.
- **Visit ID** -The visit description. If a query is not associated to a visit, this field may be blank.
- **Last Sent Date** -The date the query was sent, or resent from the PAREXEL. The Last Sent Date is updated with every response from the team, but may not be the latest date in the query history.
- **Age** -The number of days since the query was created.

Status

- **New** - Queries that have not been opened/viewed by the site user. Queries can be new to one user and outstanding to another.
- **Outstanding** - Queries that have not been closed by PAREXEL (only PAREXEL can change the status to 'closed'). Outstanding queries may be filtered by "overdue" and "responded".
 - **Overdue** – A query that has not been responded to within 10 business days. The status remains "outstanding" and will be displayed in red text.
 - **Responded** – A query that a site responded to (the status remains "outstanding").
- **Closed** - Queries that have been closed by the PAREXEL team.

Search for Queries

- A user can search for queries, including specific text from the query comments section.
- All fields in the query record are included in the search. The search text must be in English.

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View Query Details


Select a query from the Query List to view details or to respond. The following information is displayed:

- **Query Comments** - The most recent communication is displayed in this section.
- **Query History** - Click "Show" to see the query history. All communications between PAREXEL and site / monitor users are included.
- **Query Response** - If the selected query is outstanding and the user has the appropriate permissions, the user will be able to send a query response to PAREXEL. The response must be in English. Enter the response into the query response field and select "send".
- To navigate between queries in the list, click Next or Previous at the bottom of the Query Detail Page.

3 Forms

3.1 Acceptance Notification

This notification is sent from PAREXEL to the investigator site upon receipt of acceptable imaging data at PAREXEL.



Acceptance Notification

Attention: Study Coordinator
CC: Clinical Research Associate
From: Parexel Medical Imaging Team
Date: April 15, 2015

Info:
Project: 12345
Investigator: Dr. Jones
Site: 23466- Boston Radiology
Subject: 00001 Initials: ABC
Image Data: CT Exam Date: April 10, 2015

CIL Comments:
The images for subject 00001 have been accepted. No further action is required

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3.2 Query Notification

This notification is sent from PAREXEL to the investigator site when unacceptable imaging data is submitted to PAREXEL. The notification will describe the issue of concern, such as, missing data, or deviations from the Image Acquisition Guidelines. The notification will indicate the action required.


Query Communication
Attention: Study Coordinator CC: Clinical Research Associate From: Parexel Medical Imaging Team Date: December 15, 2015 Query ID: 122345
Info: Project: 12345 Investigator: Dr. Jones Site: 23466- Boston Radiology Subject: 00001 Initials: ABC Query: Missing exams CIL Comments:
Please submit the baseline exam for subject 00001.
Site Response:

3.3 Media Labels


The media labels are completed with applicable patient and visit information. The label is placed on each individual film or media (CD, DVD, film) being sent to PAREXEL. When affixed, the label must not obstruct any anatomy on the films.

PAREXEL STUDY #236765 Protocol M16-011 Site # _____ Subject # _____ Visit: Screening, W16, W24, W52, W100, Premature Discontinuation, Unscheduled (circle one) Scan date ___/___/___ (dd/mon/yy)

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3.4 **Site Supply Request**

This template can be sent to the PAREXEL team via fax or e-mail to request additional site supplies. *Use of this form is optional*; additional supplies may also be requested via email 236765-imaging@parexel.com

	
Protocol M16-011	Site Supply Request
Attention: 236765-Imaging Team FAX: 1-978-222-8466 EMAIL: 236765-Imaging@parexel.com	
FROM:	
EMAIL or PHONE #:	
4 DIGIT SITE #:	
INVESTIGATOR NAME:	
DATE:	_ / _ / _
	D D M M M Y Y Y Y
<u>Supplies (Please include Quantity, where indicated) :</u>	
<input type="checkbox"/> Pre-printed airbills	_____ Each
<input type="checkbox"/> Padded envelopes for shipping	_____ Each
<input type="checkbox"/> Digital Media	_____ Each
<i>Specify Type:</i> _____	
<input type="checkbox"/> Film (Box of 100)	
<input type="checkbox"/> Dactylometer	
<input type="checkbox"/> Induration card	
<input type="checkbox"/> Other (specify): _____	_____ Each

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3.5 Study Imaging Tracking Log

This is used at the investigator site to document the shipment status of all images related to the clinical trial. The log is updated with information regarding image acquisition and shipment dates and corresponding shipment tracking numbers. *It is optional.*

Study Imaging Tracking Log AbbVie, Inc. Protocol M16-011					
Investigator Name: _____			Site number: _____		
Subject Number	Exam Date DD/MM/YYYY	Visit Name	Transfer Method (eTransfer, courier)	Date Sent to PAREXEL	Airbill Number (if applicable)

3.6 Imaging Eligibility Confirmation Form

This Notification is sent electronically to the investigator site for every subject's Screening timepoint to inform them if a certain subject has met the eligibility criterion of the presence of ≥1 erosion on radiograph for Study M16-011. Please see screen shot below for an example.

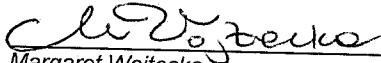
AbbVie M16-011 (236765) Imaging Eligibility Confirmation Form	
<p>PAREXEL Informatics has completed an independent assessment for your subject's screening imaging for the AbbVie M16-011 clinical trial.</p> <p>Please find the results below and file with the subject's source documents. Please do not hesitate to contact your study monitor with any questions or concerns.</p>	
Site ID	
Investigator	
Subject ID	
Timepoint	Screening
X-Ray Date of Exam (dd/mmm/yyyy)	
The subject has at least one erosion on radiograph (X-ray)?	Yes
	No
	Not Evaluable
Date of Assessment (dd/mmm/yyyy)	
<p>PAREXEL'S ASSESSMENT IS BASED ONLY ON THE AVAILABLE IMAGING DATA, DOES NOT CONSTITUTE MEDICAL ADVICE, AND MAY NOT BE USED FOR PATIENT CARE. INVESTIGATORS WILL HAVE SOLE RESPONSIBILITY FOR PATIENT CARE THROUGHOUT THE LIFE OF THE STUDY.</p>	

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Signature Approval Page

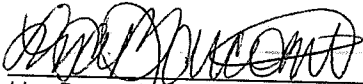
This document has completed a review and is understood and accepted by the following:



Margaret Wojtecka
Study Project Manager I, Immunology
AbbVie, Inc.

29 JAN 2019

Date



Lisa Barcomb
Scientific Director, Immunology
AbbVie, Inc.

29 January 2019

Date

Signatures of the appropriate PAREXEL team members are captured electronically and appended to the last page of this document.

PAREXEL International Electronic Signature Page

This page is the manifestation of the electronic signature(s) used in compliance with PAREXEL International's electronic signature policies and procedures and in compliance with applicable regulations.

UserName: Ievers, Sherri (ieverss)

Title: Project Manager, Medical Imaging, MEDICAL IMAGING

Date: Tuesday, 29 January 2019, 08:55 PM GMT Standard Time

Meaning: Document contents approved.

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