

PAREXEL International
Imaging Investigator Site Operations Manual



INVESTIGATOR SITE OPERATIONS MANUAL

UCB/ PAREXEL PA0011

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Abbreviations and Acronyms

| | |
|--------------------|--|
| CIL | Core Imaging Laboratory |
| CSM | Clinical Site Manager |
| DICOM | Digital Imaging and Communications in Medicine |
| IAG | Image Acquisition Guidelines |
| PAREXEL CRS | PAREXEL Clinical Research Services |
| QC | Quality Check |

1 Introduction

1.1 Study Background

UCB PA0011 is a multicentre, Phase 3, randomised, double-blind, placebo-controlled study evaluating the efficacy and safety of bimekizumab in the treatment of subjects with active psoriatic arthritis. 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 UCB & PAREXEL CRS PA0011 study. This document is specifically related to the management of imaging data acquisition, including shipment, tracking, and quality control.

The study consent must be signed before getting images for the study. All imaging scans will be acquired in a standardized manner, following pre-established Image Acquisition Guidelines (IAG) developed by PAREXEL Informatics and approved by UCB & PAREXEL CRS. Images will be submitted to PAREXEL Informatics Medical Imaging for processing and independent analysis. Imaging data for all subjects will be acquired according to the imaging schedule outlined in the protocol, as well as listed in the table below:

Please refer to the [Image Acquisition Guidelines for the imaging schedule](#).

The preferred modality of imaging in this study is X-RAY.

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

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

Images received at PAREXEL **MUST NOT CONTAIN** any markings, assessments or confidential subject information.

Subject's name, investigator site name/number and any other information that can be used to identify the subject or investigator site must be removed from the images before sending.

Cases will be prepared for independent review upon notification of study completion and receipt of complete imaging data.

Independent Reviewer findings are independent assessments and will not be communicated to the sites. All subject care decisions are made at the site by the Primary Investigator(s) including whether the subject should continue on the study.

Independent Reviewer(s) will remain blinded to the assessments made at the Investigator Sites.

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 Medical Imaging will provide the Investigator Site with the necessary materials listed below to perform the functions associated with this Investigator Site Operations Manual.

- The **Image Acquisition Guidelines (IAG)** are generated by PAREXEL Informatics Medical Imaging in an effort to standardize all imaging associated with the clinical trial across multiple Investigator Sites, subjects 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 located in the site-study binder.
- The **Media Labels** are completed with subject/visit information and placed on each individual film or media (CD, DVD), making sure not to obscure anatomy, being sent to PAREXEL Informatics Medical Imaging. Please place the label on the actual media and not the media case.
- The **Image Acceptance Notification** is sent from PAREXEL Informatics Medical Imaging to the Investigator Site when acceptable imaging data is received.
- The **Query Notification** is sent from PAREXEL Informatics Medical Imaging to the Investigator Site upon receipt of unacceptable imaging data at PAREXEL Informatics Medical Imaging. 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 Informatics Medical Imaging 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, if performed.
- **Additional Site Supplies:** digital media (CD, DVD, bubble mailers, masking pencils, and airbills).

1.4 Responsibilities

The **Core Imaging Laboratory (CIL)** is the centralized facility at PAREXEL Informatics Medical Imaging, for all processes associated with image data collection and review by Independent Reviewers. PAREXEL Informatics Medical Imaging 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 UCB & PAREXEL CRS (or designee) at a specified time.

The **Investigator Sites** are responsible for enrolling subjects 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 Informatics Medical Imaging in a timely manner so that access to applicable applications/ portals (e.g. e transfer portal, FTP accounts) is removed.

Investigator sites are to provide a test X-ray prior to first subject imaging to PAREXEL Informatics Medical Imaging. The test image is to be of a phantom object- NOT of a human subject.

1.5 PAREXEL Informatics Medical Imaging Contact Information

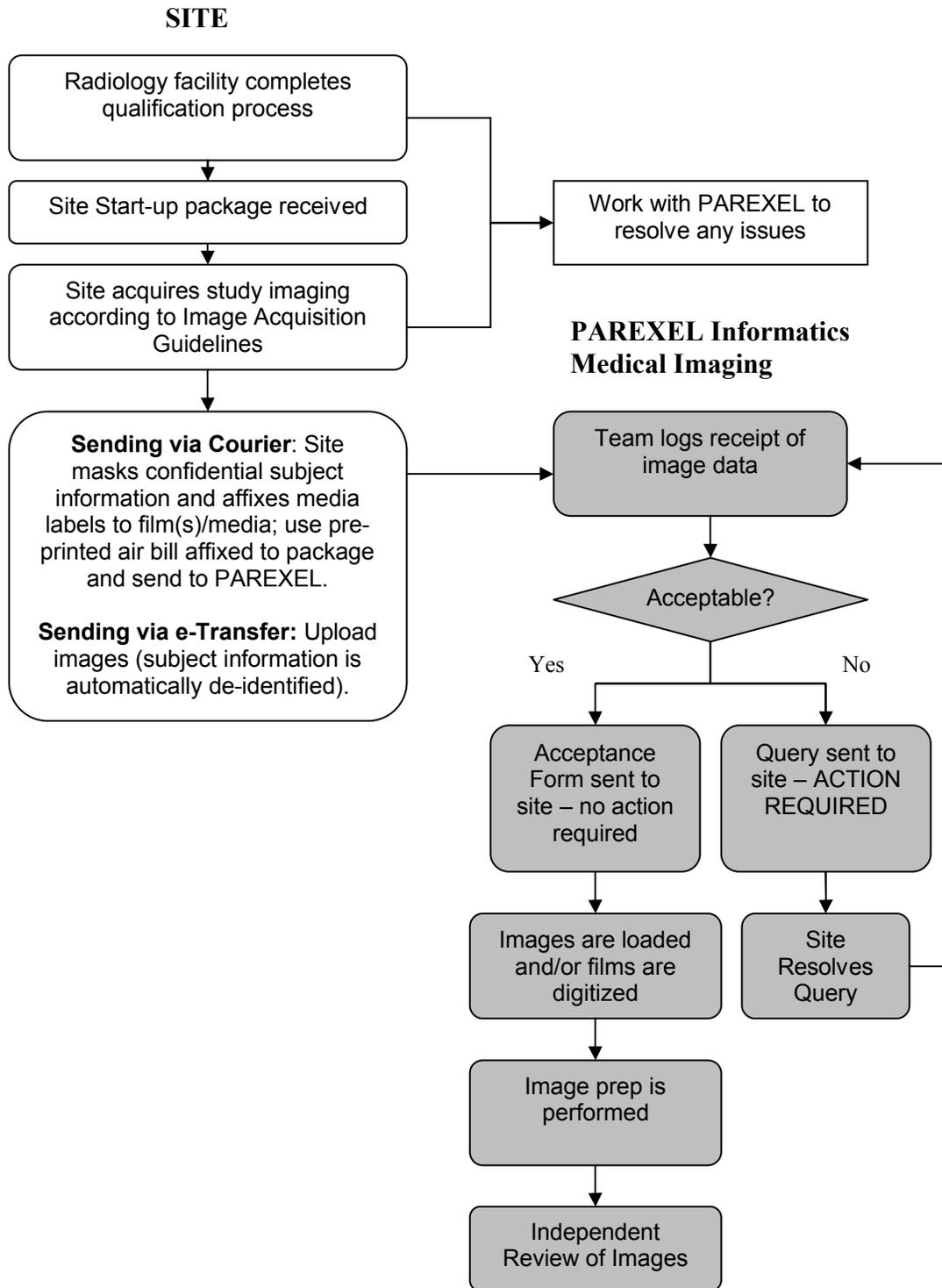
Project Team 235076
235076-Imaging@PAREXEL.com
Fax: +44 8002790095

Note: Contacts may change during the study. PAREXEL Informatics Medical Imaging 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 study. Please notify the radiology staff in advance of a study subject 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 Informatics Medical Imaging with the necessary subject and visit information. Please refer to the Image Acquisition Guidelines (IAG) 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 radiology technician will save uncompressed, DICOM format images to the site preferred media (CD, film, DVD) and maintain a copy of the exam at the facility. If eTransfer is not being used the technician must de-identify subject name and investigator site name and any other information that can be used to identify the subject or investigator site contained in the DICOM Header.

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.

2. The study coordinator must verify the names of the subject and investigator site and any other information that can be used to identify the subject or investigator site has been completely masked.
3. Confidential subject 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
4. 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 Informatics Medical Imaging.

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 Informatics Medical Imaging. 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 lesion markers or measurements are present
 - Confidential subject information is de-identified.
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 subject information is not permitted.

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6. The Study Coordinator is responsible for maintaining subject confidentiality by ensuring the imaging technicians de-identify confidential subject information on all exams being submitted on digital media.
7. Hardcopy films may be masked using the specialized masking pencils. Please contact PAREXEL Informatics Medical Imaging to request masking pencils.

2.3 Image Transfer via Courier

Performed by: Study Coordinator
References: Airbill
Scope: This procedure describes the steps used to send images from the Investigator Site to PAREXEL Informatics Medical Imaging.

1. The Study Coordinator will use the pre-printed airbills that are provided by PAREXEL Informatics Medical Imaging for this study.

Note: Additional airbills must be requested directly from PAREXEL Informatics Medical Imaging

2. The Study Coordinator will place the hard copy films or digital media in the package for shipment.
3. If hardcopy films are being sent, these will be placed in the padded envelopes that can be provided by PAREXEL Informatics Medical Imaging. 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.
4. The date of shipment and airbill tracking number should be maintained for future reference.

Note: Please ship imaging data to PAREXEL Informatics Medical Imaging within 48 hours of acquisition (do not wait for a subject to be randomized or wait to collect multiple timepoints).

2.4 Image Data Transfer via Perceptive eTransfer

Performed by: Study Coordinator or designee
Scope: This procedure describes the steps used to send images from the Investigator Site to PAREXEL Informatics Medical Imaging via eTransfer

This web-based electronic transfer solution allows investigator sites to transfer de-identified study images to PAREXEL Informatics Medical Imaging 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.

User Access

1. The PAREXEL Informatics Medical Imaging 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 Informatics Medical Imaging team at 235076-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.dicomgrid.com/>

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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 spolocnosti 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

Sign In

5. If login is not successful please check the credentials again and/or contact the PAREXEL Informatics Medical Imaging 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)

Choose File No file chosen

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 7 of 26

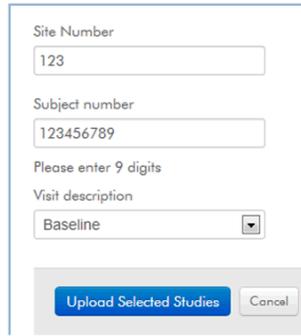
Scanning may take up to a few minutes to complete. Your screen may appear to be frozen. Please be patient.

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

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- 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:

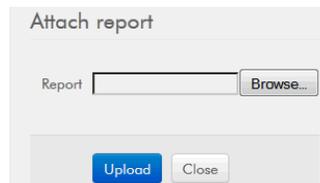
Congratulations, your image files were uploaded

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

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

Uploading Reports and/or Documents

- A user can upload specific reports or documents associated with an image exam. The user will navigate to the timepoints list and select the report button for the subject/timepoint after the necessary images have finished uploading.
- The window below will appear, the user will select the document, and click upload.



Viewing Images in the Image Viewer

- Once uploaded, images can be viewed through the browser using the “View study in viewer” button:  NOTE: the viewer is only available is using Google Chrome or Mozilla Firefox.
- 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

Please notify PAREXEL Informatics Medical Imaging of staff changes so that access can be granted/removed in a timely manner.

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 Informatics Medical Imaging in a timely manner upon receipt of acceptable image data.

- PAREXEL Informatics Medical Imaging will perform a quality assurance check on the imaging data received.

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2. An Acceptance Notification is sent from PAREXEL Informatics Medical Imaging 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.

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 Informatics Medical Imaging. A query will be sent from PAREXEL Informatics Medical Imaging 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 Informatics Medical Imaging 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).
2. The study coordinator is required to **respond within 5 business** days of query receipt.
3. If a written response on the query notification is being sent to PAREXEL Informatics Medical Imaging, the study coordinator is required to maintain a copy of the query response in the study file.
4. Do not include any confidential subject 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 Informatics Medical Imaging **within the 5 business** day timeframe. This notification must include a definitive date for query resolution.
6. If the site is unable to successfully resolve the query, PAREXEL Informatics Medical Imaging may request the assistance of the PAREXEL CSMs and notify UCB & PAREXEL CRS 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 Informatics Medical Imaging 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 Informatics Medical Imaging study team and request an account for MyTrials. To Access the Imaging and MyQueries section of the portal please contact PAREXEL Informatics Medical Imaging.
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**

Access Request

To gain access to a new trial or application, or modify existing access rights, enter the key you received via email below, and click the Register button.

Key Activation :

[Register](#) [Clear](#)

[Help ?](#)

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

MY TRIALS

Select one or 'All Sponsors' from the list provided:

Filter By: [All Sponsors](#) Search for a Trial: [?] [Reset](#)

| Sponsor | Program | Trial | Alias | Description |
|----------------------|-----------|-------------------------|---------|----------------|
| Ajax Pharmaceuticals | Program A | Trial A | Trial A | 208923-Trial A |

1 items in 1 page(s)

[Help ?](#)

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

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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 Informatics Medical Imaging. 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 Informatics Medical Imaging (only PAREXEL Informatics Medical Imaging 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 Informatics Medical Imaging 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.

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.

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- **Query History** - Click "Show" to see the query history. All communications between PAREXEL Informatics Medical Imaging and site / CSM 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 Informatics Medical Imaging. 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 Informatics Medical Imaging to the Investigator Site upon receipt of acceptable imaging data at PAREXEL Informatics Medical Imaging.



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

3.2 Query Notification

This notification is sent from PAREXEL Informatics Medical Imaging to the Investigator Site when unacceptable imaging data is submitted to PAREXEL Informatics Medical Imaging. The notification will describe the issue of concern, such as, missing data, or deviations from the Image Acquisition Guidelines (IAG). 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:
|

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Signature Approval Page

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

Joelle Hibert
Project Leader (*Study Manager or Designee*)
PAREXEL

Date

Alexander Marten
Medical Director (*Clinical Scientist or Designee*)
PAREXEL

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.

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Meaning: Document contents approved.

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