MEDICAL IMAGING SERVICES

Pfizer

A3921120

Phase III, randomized, double-blind, placebo-controlled, study of the efficacy and safety of tofacitinib in subjects with active ankylosing spondylitis (AS).
Image Acquisition Guideline

Pfizer – 239961 Image Acquisition Guideline

Project:	**239961**
Document File Name:	**239961 Image Acquisition Guideline**
Document Revision:	**2.0**
Version Date:	**18-May-2018**
Author:	**Rick Nelson/Owen Hendry/David Bennett**

Copyright Page

Document Approvals

Document Title: 239961 Image Acquisition Guideline
Document Version: 2.0
Project: 239961

PAREXEL internal signatures will be captured electronically through the PMED system.

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

Rick Nelson, CAPM
Project Manager
PAREXEL Informatics

30-MAY-2018

David Bennett, PhD
Associate Director, Scientific and Medical Services
PAREXEL Informatics

30-May-2018

Owen Hendry, MS
Scientist, Scientific and Medical Services
PAREXEL Informatics

Owen Hendry 30-may-2018

Nicole Eyland

Digitally signed by Nicole Eyland
DN: cn=Nicole Eyland, o, ou=Development Operations, email=Nicole.eyland@pfizer.com, c=US
Date: 2018.05.18 15:06:38 -04'00'

18-May-2018

Nicole Eyland
Study Manager
Sponsor Name

Date

Document Revision History

Version	Date	Author	Description
1.0	14-My-2018	Rick Nelson/Owen Hendry/David Bennett	Initial release of the document
2.0	18-May-2018	Rick Nelson	Updated language in the *Imaging Schedule* section

Introduction

PAREXEL Informatics has developed the following acquisition guidelines for standardization of the study imaging components across radiology centers participating in the Pfizer A3921120 clinical trial. Provided here are image acquisition guidelines for the following imaging modalities:

IMAGING SCHEDULE

X-ray of sacroiliac joints (AP pelvis)	Screening	Acquired during the screening visit or historical[1]

[1]Previous radiographs (up to 2 years old) of the SI joints (ideally AP view of the pelvis) documenting the diagnosis of AS will be acceptable and should be used in lieu of performing screening radiographs if they can be obtained and sent to the central reader for confirmation. If the results are considered unevaluable during the image QC process or by the central reader, the x-ray must be repeated. If a historical radiograph cannot be obtained, x-ray of the AP pelvis view at the screening visit must be obtained to visualize the SI joints.

**** Patient safety in relation to image acquisition is the responsibility of the Investigator sites. ****

Important Notes

- Regularly scheduled imaging for this study should be acquired in strict adherence to these guidelines.
- PAREXEL recommends having only one primary experienced and trained technician scanning all trial subjects. Sites should have a trained back-up technician for each modality.
- All data must be archived at the site as required by regulatory agencies. PAREXEL may request re-transmittal of the archived images.
- Images sent to PAREXEL shall be clear of any marks, writings, measurements or annotations.
- Keep imaging data (including raw/original data) digitally archived until PAREXEL has provided feedback on the quality of the images.
- All confidential site and patient information must be de-identified prior to sending the data to PAREXEL.
- Image data is sent to PAREXEL within 48 hours of acquisition

IMPORTANT: Imaging modality, anatomical coverage and acquisition parameters should remain consistent between study subjects.

For inquiries regarding these guidelines, contact:
Tel: 1-978-435-64-64
Fax: 1-844-377-8209
Email: 239961-Imaging@PAREXEL.com

ADDITIONAL NOTES

SENDING IMAGING TO PAREXEL

Electronic Transfer preferred

- Images shall be in uncompressed DICOM format
- eTransfer will automatically blind patient and site info in the image header. Additional information and instructions for eTransfer can be found in the Site Operations Manual

Hardcopy Film: least preferred method

Original X-Rays should be provided to PAREXEL. Please complete and apply subject labels provided by PAREXEL. Use PAREXEL provided shipping supplies for courier shipment to PAREXEL. Original X-rays should be marked as such and will be returned to the site as soon as possible following acceptance at PAREXEL if requested. All copied originals will require approval by PAREXEL to ensure image quality is not lost in copying.

Thank you for your participation and cooperation in this clinical study.

IMAGE ACQUISITION GUIDELINES

X-RAY

Appropriate shielding of the eyes, thyroid, breast region and gonads should be performed without obscuring the anatomy of interest.

AP PELVIS X-RAY

OBJECTIVE: Clear view of sacroiliac joints for assessment of sacroiliitis

PATIENT POSITIONING (see diagram next page)**:**

1. Place the subject on the table in the supine position.
2. Center the mid-sagittal plane of the body to the midline of the grid, and adjust it in a true supine position.
3. Flex the elbows and rest the hands on the upper chest.
4. The heels should be placed 20-25 cm (8 – 10 inches) apart.
5. Medially rotate both feet and lower limbs the same degrees.
6. Immobilize the legs with a sandbag across the ankles, if needed.
7. Check the distance from the anterior superior iliac spine to the table and make sure the pelvis is not rotated.
8. Center the cassette/receptor midway between anterior superior iliac spine and the pubic symphysis. The cassette/receptor will be about 2 inches (5 cm) inferior to the pubic symphysis in average-sized subjects.
9. If the pelvis is deep, palpate for the crest of the ilium and adjust the position of the cassette so that its upper border will project 1 to 1½ inches (2.5 to 3.8 cm) above the crest of the ilium.

Required Parameters (Please comply with these for all study subjects):

Anatomical Coverage	Pelvis including clear view of both Sacroiliac joints in one view
Markers	Metal or digital marker in the upper or lower right or left hand corner of the image should be “R” or “Right” or “L” or “Left” and “AP”
Central Ray Direction	Caudo-cranial 10 to 20 degrees (see diagram next page)

Suggested Parameters (use clinical standard for optimal imaging on your instrument):

Breathing Instructions	Suspended breathing
Imaging System	Bucky screen technique
Film/Focus distance	**40 inches (100 cm)** *see film/focus distance as shown on the diagram (next page)*
Imaging kVp	65-85 kVp, may vary based on body size
Exposure Time	**Manual** < 1.0 second exposure **Automated** Central photocell
Central Ray	Perpendicular to the midpoint of the cassette/receptor
Film Size	14x17 inches (35x43 cm)

AP PELVIS X-RAY - POSITIONING