



Protocol # 16-OBE2109-008

A double-blind, placebo-controlled study investigating the efficacy and safety of daily oral administration of OBE2109 alone and in combination with add-back therapy for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women

Imaging Training Webinar

 **CANFIELD Scientific, Inc.**

4 Wood Hollow Road | Parsippany | New Jersey 07054 | 1-800-815-4375 | 1-973-887-1249 | www.CanfieldSci.com

CANFIELD Scientific, Inc.



- Worldwide imaging company – Parsippany, NJ, USA
- Established in 1986, 200+ employees, 8 PhD's
- Imaging and Photographic documentation for clinical research
 - ✓ Over 2400 clinical studies
- Imaging solutions for clinical practices, medspas
 - ✓ Over 10,000 customers in Plastics, Derm, Other

Medical Imaging Background



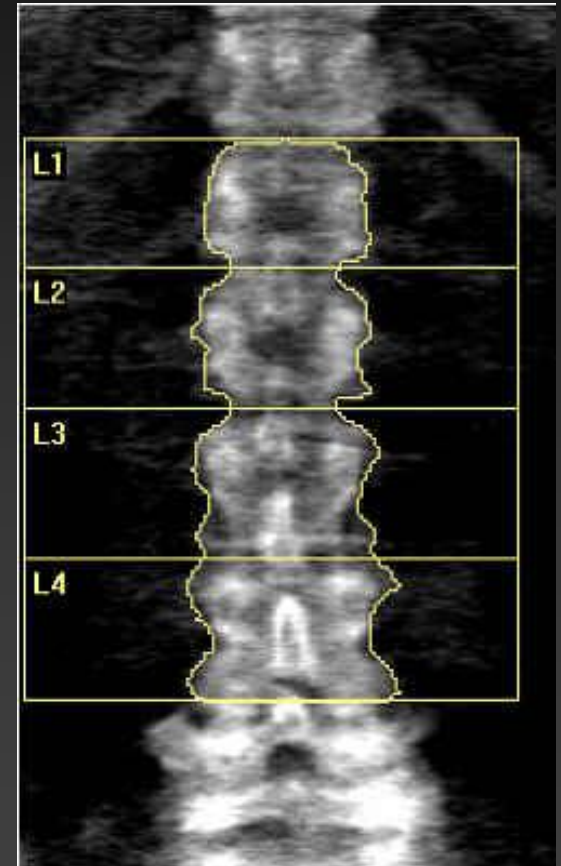
Medical Imaging provides human anatomic and/or physiologic information of variable clinical meaningfulness for the following potential uses:

- Support for Efficacy Endpoints
- Support for Clinical Endpoints
- Support for Safety Endpoints
- Research for unexpected results

Medical Imaging

Standardized Medical Imaging Acquisition Guidelines (IAG) have been developed for this study to:

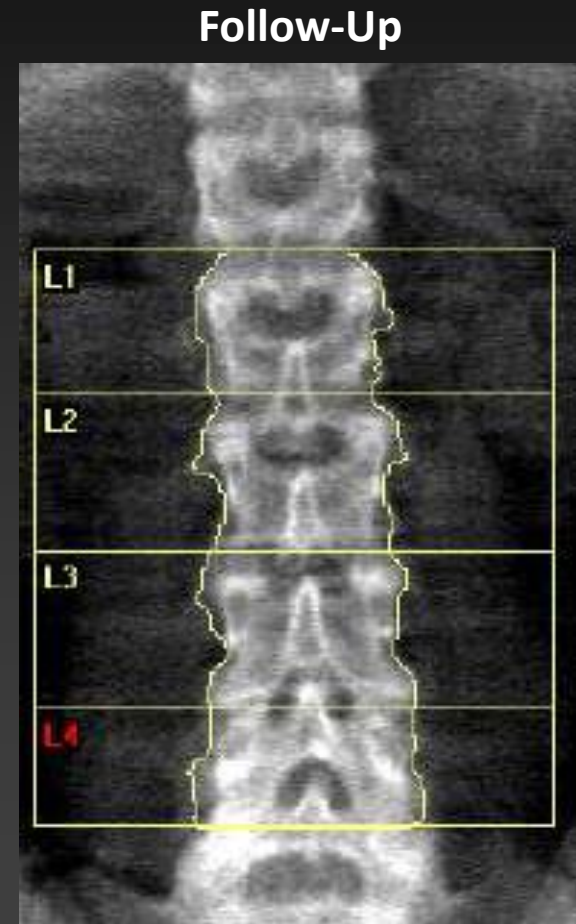
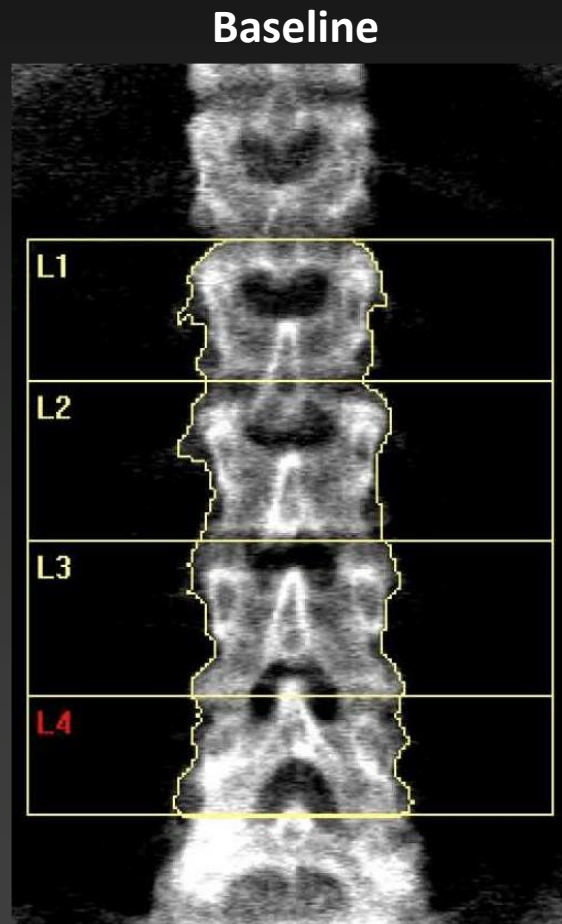
- Maintain a verifiable and reproducible record of how imaging data is obtained for future clinical trial research
- Ensure image data is captured in compliance with the study protocol
- Minimize imaging variability by ensuring image data is of optimal quality within a clinical site and across multiple clinical sites
- Maximize impact of imaging data to support study endpoints and hypotheses



Serial Medical Imaging

Good serial medical imaging can be achieved by adhering to the provided study-specific IAG. The following must be kept consistent:

- Imaging Facility and DXA Scanner
- Scan Parameters
- Subject Positioning
- DXA Scan Analysis Region of Interest



Canfield

Imaging Acquisition Guidelines (IAG)

Canfield will mail the Imaging Acquisition Guidelines (IAG) to each Imaging Facility. The contents of the IAG will include:

- Canfield Clinical Services Project Management Team Contact Information
- Image Acquisition and Submission Schedule
- Pre-Qualification Phantom Scan Acquisition & Submission Guidelines
- Monthly QC Phantom Logs Acquisition & Submission Guidelines
- Cross-Calibration Scan Acquisition & Submission Guidelines
 - Cross-Calibration Phantom Shipment Notification Form
- Treatment Visit Scan Acquisition Guidelines
 - Hologic
 - GE/Lunar
 - Scan Examples QRG
- Treatment Withdrawal Criteria
- Clinical Services Website (CSW) Image Upload and View Instructions
- Digital Media Labels
- Supply Request Form
- Web Service Authorization Form

Canfield

Imaging Reference Manual (IRM)

Canfield will mail the Imaging Reference Manual (IRM) to each Treating Investigative Site. The contents of the IRM will include:

- Canfield Clinical Services Project Management Team Contact Information
- Image Acquisition and Submission Schedule
- Treatment Visit Scan Central Review Outline
 - Subject Biography Form
- Treatment Withdrawal Criteria
- Clinical Services Website (CSW) Image Viewing Instructions
- Web Services Authorization Form

Electronic Study Resources

The screenshot shows the Canfield Clinical Services website interface. At the top, there's a header with the Canfield logo, 'Help', and 'Log Out' links. Below the header, there's a navigation bar with 'Protocol: Sponsor' and 'Center: All Centers' sections, each with a 'Change' button. The 'Study Resources' link is highlighted in the navigation bar. Below the navigation bar, there's a 'Study Resources' section with a 'Documents' table. The table has columns for 'TYPE', 'NAME', 'SIZE', and 'DESCRIPTION'. It lists four PDF documents:

| TYPE | NAME | SIZE | DESCRIPTION |
|------|--|---------------|--|
| PDF | ClinicalServicesTeamContact-CanfieldUserManual.pdf | 26,505 bytes | Clinical Services Study Team Contact Information |
| PDF | Supply Request Form-CanfieldUserManual.pdf | 126,277 bytes | Supply Request Form |
| PDF | PhotographyTimepoints-CanfieldUserManual.pdf | 103,361 bytes | Photographic Visit Schedule |
| PDF | WebServicesAuthorizationForm.pdf | 35,516 bytes | Web Services Authorization Form |

Electronic Documents are available on the Canfield Clinical Services Website. Refer to the “Study Resources” hyperlink.

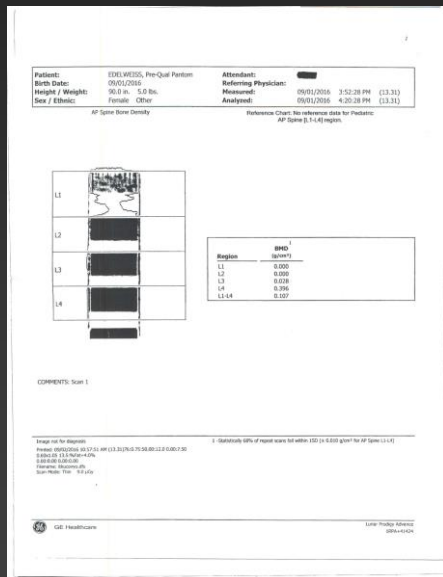
Quality Control Requirements

| Scan Requirement | Phantom Scan Type | Frequency | Documentation |
|----------------------------------|--------------------------------|--|--|
| Pre-Qualification Phantom | Site-Owned Spine Phantom | 1 time (beginning of study) | Pre-Qualification Phantom Scan Certificate of Approval |
| Monthly Phantom QC Log | QA Phantom | Monthly (30 days +/- 5 days) beginning after Pre-Qualification | Email Confirmation from Canfield |
| Cross-Calibration Phantom | Canfield Shipped Spine Phantom | 1 time (during the study) | Cross-Calibration Phantom Scan Certificate of Completion |

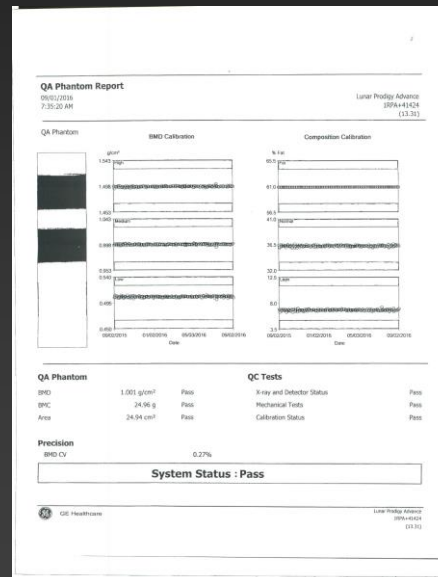


Phantom Scans

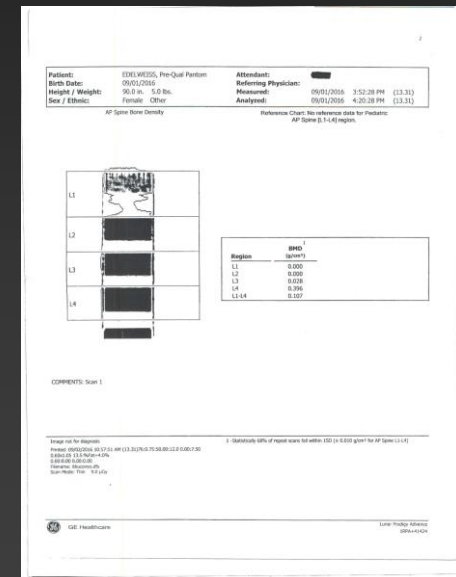
- A complete Phantom Scan includes:
 - Pre-Qualification: 10 (1 x each scan) Phantom DXA Scan Analysis Report
 - Monthly Phantom QC Log: 1 (for the month) Phantom DXA Scan Log
 - Cross-Calibration: 10 (1 x each scan) Phantom DXA Scan Analysis Report



Pre-Qual



Monthly QC



Cross-Calib

GE/Lunar Sample Reports for demo only

Cross-Calibration Phantom Scan Shipment

- Canfield will ship a Bona Fide Phantom to your site one time during the course of the study.
- The phantom scans should be completed within 5 business days of receipt.
- Canfield will review the scans and provide confirmation of completion by sending a certificate of completions.
- Once the certificate is received, Canfield will provide pre-printed Airway Bills (AWBs) for your site to ship the Bona Fide Phantom.
- Please ship the Bona Fide Phantom as soon as possible and complete the *Cross-Calibration Phantom Shipment Notification Form* and provide to Canfield to avoid queries.

| | | | |
|---|-------------------|---|----------------------|
| Canfield Scientific, Inc. – Quality Management System (QMS) CANFIELD IMAGING ACQUISITION GUIDELINES | | CANFIELD Scientific, Inc. Document Version 1.0 – Effective: DD-MMM-YYYY | |
| Obseva / 16-0812109-008 | | | |
| OBSEVA obstetrics & beyond Shipment Notification Form | | | |
| To: | CSPMT | CSI Code: | |
| Fax: | +001-973-887-1249 | Site Number: | |
| Phone: | 1-800-815-4375 | Investigator: | |
| International: | +1-800-4050-8091 | | |
| SHIPMENT DATE | | COURIER | TRACKING INFORMATION |
| | | | |
| Date: _____ | | Signature: _____ | |
| Date: DD-MMM-YYYY | | | |
| Print Name and Title: _____ | | | |
| <small>NOTE: PLEASE FAX (see above) OR EMAIL THE CSPMT (listed in the contact section) THE REQUEST AS SOON AS YOU HAVE THE INFORMATION AVAILABLE. THIS FORM MUST BE COMPLETE AND ACCURATE IN ITS ENTIRETY FOR SHIPMENT TRACKING PURPOSES.</small> | | | |
| Template Version: 3.1 – 25-Apr-2016 Canfield Confidential and Proprietary Information | | Page 1 of 1 Printed copies of unsigned documents are considered uncontrolled | |


Treatment Visit Schedule

| Scan Type | Frequency | Documentation |
|-----------------------------|---|---|
| Treatment Visits | <ul style="list-style-type: none">• Day 1• Week 24• Week 52• Week 76• If subject terminates early, please refer to protocol for visit procedures and labeling | Email Hyperlink to BMD Central Review Result Report (within 5 business days of upload receipt) |
| Repeat Scan Requests | In the event the BMD Central Reviewer deems scan should be repeated for Image Quality or due to % change in bone loss | Email Hyperlink to BMD Central Review Result Report (within 5 business days of upload receipt) |

Tx Investigative Site: Subject Baseline/Day 1 Visit

- Complete the Subject Biography Form for each subject. Ensure all information is written in the correct format indicated as well as complete and accurate in its entirety for data reconciliation purposes.
- A copy of this form should be provided to the subject, or emailed or faxed to the Imaging Facility. This form will assist the Imaging Facility with entering the subject information to create the Subject biography on the DXA Scanner.
- A copy of this form should be uploaded, emailed or faxed to Canfield. This form will allow Canfield to reconcile against Subject Biography information included on the scan analysis reports.
- Chiltern has also provided subject scan cards to provide the subject or Imaging Facility for easy reference.

| | | | |
|--|--|---|--|
| Canfield Scientific, Inc. – Quality Management System (QMS) CANFIELD IMAGING REFERENCE MANUAL | | CANFIELD Scientific, Inc. | |
| ObsEva / 16-0BE2109-008 | | Document Version 1.0 – Effective: DD-MMM-YYYY | |



OBSEVA
obstetrics & beyond

Subject Biography Form

| | | | |
|-----------|-------------------|---------------|--|
| CSI Code: | 2278 | Site Number: | |
| To: | CSPMT | Investigator: | |
| Fax: | +001-973-887-1249 | | |

| DESCRIPTOR | IDENTIFIER | FORMAT | SUBJECT INFORMATION |
|-----------------------------|-----------------------------------|--|--|
| Patient Identification (ID) | Patient ID Number | NNNNN (where N = 1 digit country code + 2 digit site ID + 2 digit subject number) | _____ |
| Date of Birth (or Born On) | Subject year of birth only | 01/JUL/YYYY (where Y = subject actual year of birth) | 01Jul _____ |
| Sex | F | F | F |
| Weight (at Baseline/Day 1) | Subject Weight | NN.N | _____ * _____ CHECK ONE: <input type="checkbox"/> lbs <input type="checkbox"/> kg |
| Height (at Baseline/Day 1) | Subject Height | NN.N | _____ * _____ CHECK ONE: <input type="checkbox"/> in <input type="checkbox"/> cm |
| Comment | List non-removable artifacts | Only use field if applicable, Review example list of non-removable artifacts | |

Date: _____ Signature: _____

dd/MM/yy

Print Name and Title: _____

NOTE: PLEASE FAX (see above) OR EMAIL THE CSPMT (listed in the contact section) A COPY OF THIS FORM FOR THE DAY 1 VISIT AND ANY VISITS WHERE WEIGHT AND HEIGHT CHANGES OCCUR. THIS FORM MUST BE COMPLETE AND ACCURATE IN ITS ENTIRETY FOR RECONCILIATION PURPOSES.

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Imaging Facility:

Subject Baseline/Day 1 Visit

- Use the Subject Biography Form to create a subject biography on the DXA Scanner.
 - It is extremely important that all information is entered as outlined.
 - Date of Birth must be masked using the convention provided (01JULYYY, where YYYY is the subject actual year of birth)
 - No additional information should be provided especially patient name as this is a violation of Protected Health Information (PHI).
 - Should Canfield receive PHI, a repeat scan may be requested.
- At **Follow-up** visits, locate the subject and capture under the previously entered subject biography. Updates to height and weight should be made as needed.

| Treatment Visit Scan Subject Biography QRG | | |
|--|--|---|
| Descriptor | Identifier | Format |
| Acquisition Date | Date of Scan | DD/MMMM/YYYY |
| Patient Identification (ID) | ID Number | NNNNN (where N = 5 digit number, 1 digit country code + 2 digit site ID + 2 digit subject number) |
| Date of Birth (or Born On) | Subject year of birth <u>only</u> | 01/JUL/YYYY (where Y = subject actual year of birth) |
| Sex | F | F |
| Weight (update as needed) | Subject Weight in kg | NNN.N |
| Height (update as needed) | Subject Height in cm | NN. N |
| Exam Type | Exam Type | Example: AP Lumbar Spine or Total Left Hip |
| Comment | Identify non-removable artifacts, if any | Example: Pacemaker leads, bone fractures, previous surgeries, radioactive seeds, bone implants, surgical staples, foreign bodies, heavy metal poisoning, kidney stones, etc.) |
| Scan Code (or Attendant) | DXA Technologist's Name | (Last Name, First Name) |

Imaging Facility: Subject Treatment Visit

- Ensure the same machine and scan modes are adhered to at all **follow-up visits**. Refer to the Subject Scan Card.
 - Subject Scan Cards will be specific to the subject as well as specific to the DXA machine.
- Ensure that the subject has removed all objects from their pockets and is not wearing clothing with metal such as jewelry, belts, snaps, underwire bras, zippers, etc.
 - Inability or refusal to remove jewelry is not an exclusion for DXA, however subjects should be encouraged to remove all metal objects if possible.
- Ensure the subject is explained the exam procedures and instructions for positioning.
- Required Scan Acquisition Sites:
 - AP Lumbar Spine (From L1 to L4)
 - Left Hip (Including Femoral Neck)
- Scanning instructions for image acquisition will be followed and the IAG will outline additional points for emphasis.

This scan is for Primrose Clinical Study 16-OBE2109-008
Please follow Canfield's DXA image acquisition guideline for GE-
Healthcare (Lunar)

- Obtain scan of Lumbar Spine and Left Hip
 - If contraindicated due to prosthetic or inability to position correctly, then the right hip should be scanned. Be sure to scan the same hip for all visits within a subject during the trial.
- Use the Standard or Thick mode (based on patient's body habitus).
- Uncheck the Onescan mode before scanning study subjects.
- Please be certain scan mode is consistent throughout all imaging time points.
- Please follow instructions for entering Scanner Biography as outlined in IAG.
- Copy all the scans onto the labeled media **BEFORE** analyzing or archiving the data.
- Scans will be acquired at Study Day1, Week 24, Week 52 and Week 76

Subject Number: _____

For any questions regarding study parameters please contact:

Requesting Physician: _____ OR

Study Coordinator: _____

This scan is for Primrose Clinical Study 16-OBE2109-008

Please follow Canfield's DXA image acquisition guideline for Hologic

- Obtain scan of Lumbar Spine and Left Hip
 - If contraindicated due to prosthetic or inability to position correctly, then the right hip should be scanned. Be sure to scan the same hip for all visits within a subject during the trial.
- Please use the ARRAY scan mode (Explorer machines use "e" mode)
 - **Fast scan modes** (i.e., Fast Array, Turbo, "X", Quick Mode, etc.) **are not acceptable, and will require a repeat scan** in Array or Performance
- Please be certain the scan mode is consistent throughout all imaging time points
- Please follow instructions for entering Subject Biography as outlined in IAG
- Copy all the scans onto the labeled media **BEFORE** analyzing or archiving the data
- Scans will be acquired at Study Day1, Week 24, week 52 and Week 76

Subject Number: _____

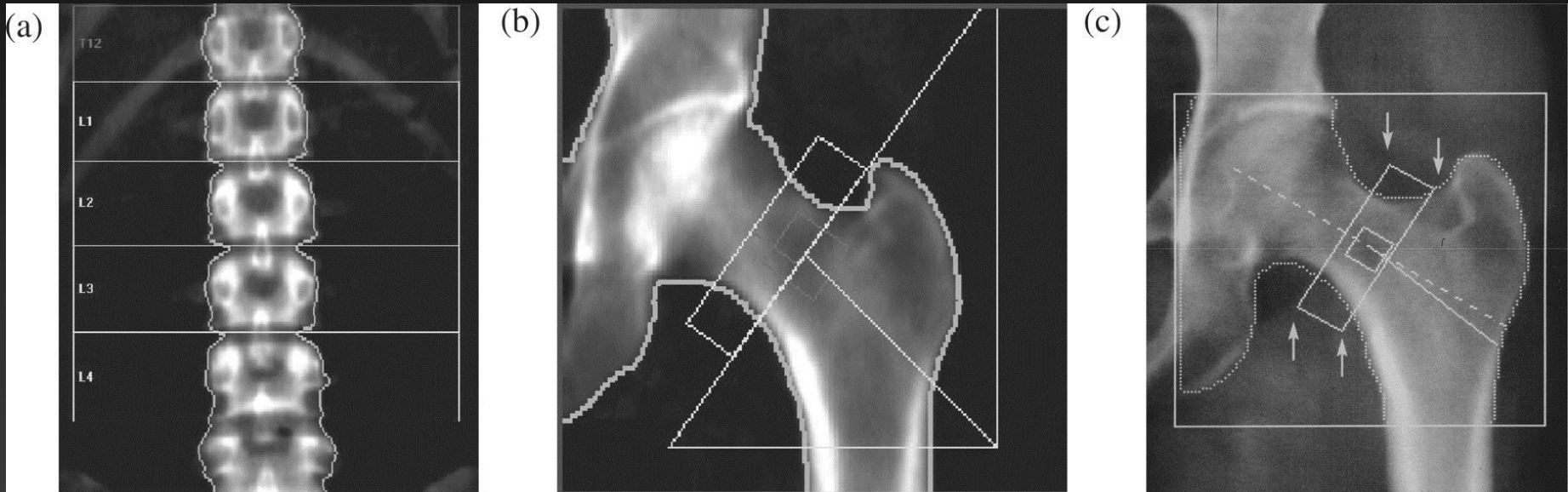
For any questions regarding study parameters please contact:

Requesting Physician: _____ OR

Study Coordinator: _____

16-OBE2109-008_Scan Card Hologic_V1_02Feb2017

Required Scans

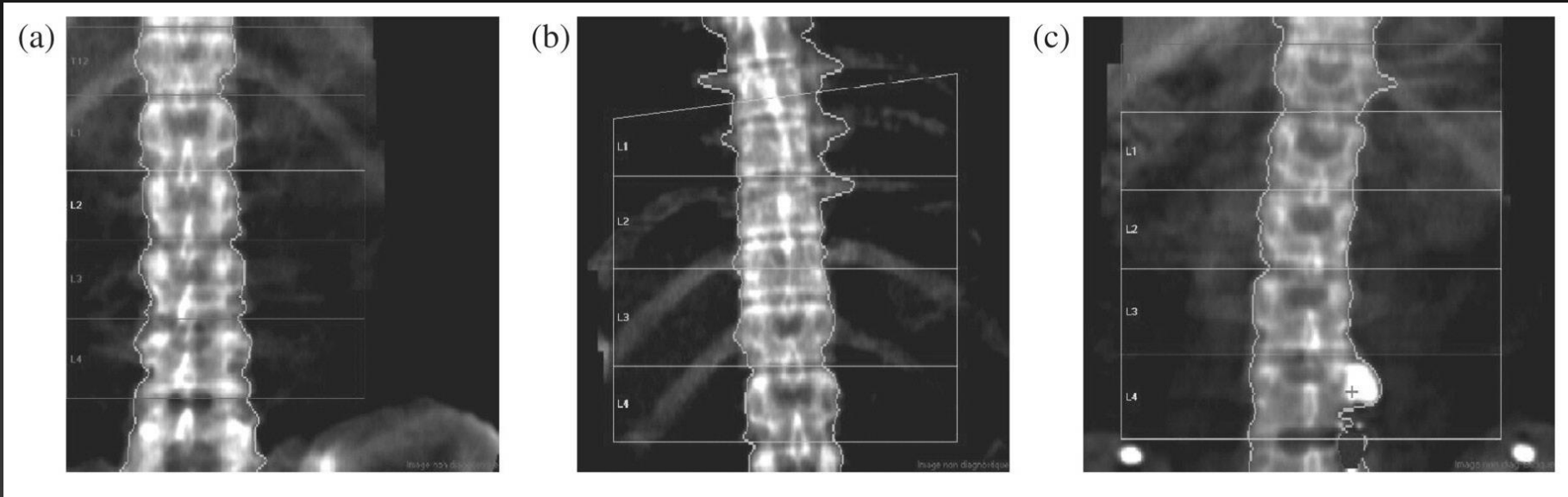


A) Lumbar Spine Scan – Correct Positioning and analysis of the L1-L4 spine

B) Total Hip Scan (Lunar) – Correct Positioning and Analysis

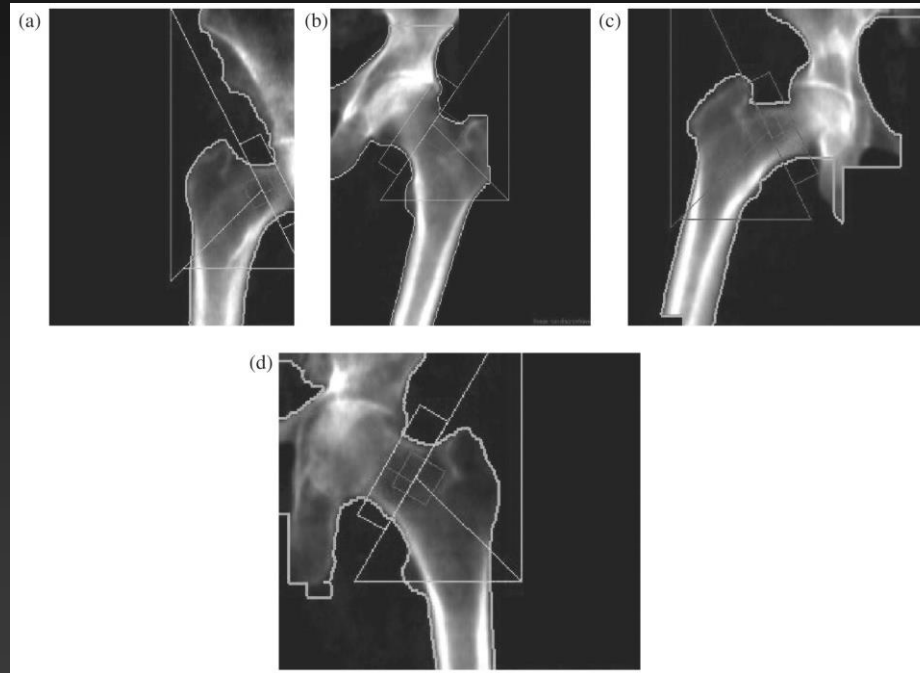
C) Total Hip Scan (Hologic) – Correct Positioning and Analysis

Spine Scan Issues



- A) Lumbar Spine Scan – Incorrect Positioning: Too close to the right side of the image
- B) Lumbar Spine Scan – Incorrect Analysis: Vertebral levels are misidentified
- C) Lumbar Spine Scan – Artifact: Metal Button over L4

Hip Scan Issues



- A) Total Hip Scan – Incorrect Positioning: Did not go far enough laterally and part of the femoral head is missing
- B) Total Hip Scan – Incorrect Positioning: Femur is adducted
- C) Total Hip Scan – Incorrect Positioning: Femur is abducted
- D) Total Hip Scan – Incorrect Positioning: Suboptimal internal rotation (too much of lesser trochanter showing)

Canfield Clinical Services Website

Web Services Authorization Form

- Top portion to be completed by the Investigative Site Staff and Radiology Site Staff
- Group e-mail accounts are not allowed
- Access authorized by Study Sponsor
- Username/Password sent via email

Web View Access: Allows access to view images, the BMD Central Review Result Report, and address Data Clarification Forms (DCFs).

✓ Applicable to Treating Investigative Site

Web Transfer Access: Allows upload of images to Canfield

✓ Applicable to Imaging Facility

| Canfield Scientific, Inc. – Quality Management System (QMS) | | CANFIELD Scientific, Inc. | |
|--|---|--|---------------------------------|
| CLINICAL SERVICES WEB AUTHORIZATION | | APPLICATION FORM | |
| <p>Users must complete Sections A and B and fax this form to Canfield Scientific, Inc. (CSI) at 1-973-887-1249 or email to webauth@canfieldsci.com. Upon sponsor approval, CSI will setup a user account and permissions to the clinical study noted in Section B. When an account has been established, a notification will be sent to the e-mail address provided in Section A, Line 5.</p> | | | |
| A. USER INFORMATION (all information must be provided) | | | |
| <p>Are you currently, or have you ever been, an authorized user of Canfield Scientific, Inc. (CSI) web services (have you ever had an active account)? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Current Username: _____</p> | | Investigator Name | Site Number |
| 1 | Last Name | First Name | Middle Initial |
| 2 | Company | Study Role (i.e. Investigator, Coordinator, CRA) | |
| 3 | Company Street Address | City | |
| 4 | State | Zip Code | Country |
| 5 | Telephone Number | E-mail address | |
| 6 | <p>By signing my name, I agree not to disclose any information about this study or these web services outside of that required to perform my responsibilities as they pertain to the clinical protocol/project stated in Section B, herein. I agree that when using these services, the username and password I supply will be considered my "electronic signature", and that this electronic manifestation constitutes the same legal obligation as my written signature, as required by regulation.</p> <p>_____</p> <p style="text-align: right;">Please sign full name</p> <p>_____</p> <p style="text-align: right;">Date (dd/mm/yyyy)</p> | | |
| B. STUDY INFORMATION | | | |
| 7 | Sponsor Name | ObsEva | Protocol/Project 16-OBE2109-008 |
| <p>Please check the services to authorize: <input type="checkbox"/> Web View <input type="checkbox"/> Web Transfer <input type="checkbox"/> Web Analysis</p> <p style="text-align: center;">DO NOT WRITE BELOW THIS LINE</p> | | | |
| SPONSOR AUTHORIZATION (to be completed by Sponsor ONLY) | | | |
| Print Name | | Signature | Date (dd/mm/yyyy) |
| CANFIELD AUTHORIZATION | | | |
| Account Setup Confirmation: | | Quality Control (QC Check) | |
| Initials | Date (dd/mm/yyyy) | Initials | Date (dd/mm/yyyy) |

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Image Transfer

<https://clinicalservices.canfieldsci.com>

All subject images should be uploaded to
Canfield Clinical Services Website within 24 hours


Image Upload Quick Reference Guide

**IMAGE UPLOAD**

INITIAL SETUP

1 Login at <https://clinicalservices.canfieldsci.com> using your supplied username and password.

You will be prompted to change your password upon your initial login.



2 Select the appropriate study protocol.





IMAGE UPLOAD


1 Select the Upload tab.

Then, select New or Existing Subject.

Enter subject information.




2 Click Choose Files.



3 Browse to the locations of the scan on your media or local computer.


Highlight images and click Open.

4 Click Upload Files to transmit images to Canfield.



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16-OR02109-008 User Manual
Page 1 of 2

5 As the images are uploading, the progress of each image will be displayed on the bottom of the screen.




6 Click on View Uploaded Images to open the Upload Report Page.

Please review thumbnails to confirm all subject images have been uploaded.



7 Print the Upload Report Page for your records.



✓ Upload Reports can be accessed at any time by opening the Upload Report tab.




IMAGE ARCHIVAL

1 Ensure all scans are properly saved to media or digital archival. If scans are saved to media, ensure media is properly labeled with Canfield supplied media labels. All scans and/or media should be retained until the end of the study.

✓ If you experience any issues, please contact the Canfield Clinical Services Project Team at 1-800-815-4375.

If transfers cannot be completed online, please place the media in protective case. Place case into protective padding in shipment envelope. Use the supplied pre-printed airbills for this study. Pick-up can be arranged by contacting your local courier.

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Image Transfer

Acceptable File Types

- The following file types are able to be uploaded to Canfield:
 - .pdf (**Preferred)
 - .jpg, .jpeg
 - .tif, .tiff
 - .dcm, .dicom
 - .bmp
 - .nts, .dfs
- For all other file types, they will have to be saved to disc or USB and mailed to Canfield.
- Canfield can supply disks or USB drives as needed as well as pre-printed AWBs. Please contact the Canfield Project Team for assistance.

Image Transfer Upload Procedures

CANFIELD Clinical Services

Login

New Users [Sign up here](#)

Username

required

Password

case sensitive

[Forgot password?](#)

Login

1.800.815.4330 + 1.973.276.0300



Warning: The use of this system is restricted to approved clinical users who have been granted appropriate permissions.

Help & Technical Support: 1.800.815.4330 or +1.973.276.0300
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The information on this website along with any downloaded document is confidential. Copying, disclosure, or allowing others to use this information is prohibited and in violation of the Health Insurance Portability and Accountability Act.

PROTOCOL: **Sponsor** [Change](#) CENTER: **All Centers** [Change](#) [Study Resources](#) [+ create a new dcf](#)

Overview DCFs Visit Overview View Images Upload Report **Upload** Analysis Report Analysis

Overview

Visit Summary

| Visit Type | Count |
|------------|-------|
| Baseline | 3 |
| Follow Up | 2 |

| EARLIEST IMAGES IN | LATEST IMAGES IN | EARLIEST IMAGES OUT | LATEST IMAGES OUT | DROPPED SUBJECTS |
|---------------------------------|------------------------------------|----------------------------------|------------------------------------|------------------|
| 19-Jun-2012 001 : ABC | 30-Sep-2012 XY1352 : ABC | 25-Sep-2012 0001 : ABC | 01-Oct-2012 XY1352 : ABC | - |

Image Transfer Upload Procedures

The screenshot displays the Canfield Image Transfer web application interface. At the top, the 'PROTOCOL: Sponsor' and 'CENTER: 001' are visible. The navigation bar includes 'Overview', 'DCFs', 'Visit Overview', 'View Images', 'Upload Report', 'Upload', 'Analysis Report', and 'Analysis'. The 'Upload' tab is active, showing the 'Upload Visit' section. In this section, the 'Existing Subject' button is circled in red. Below it, there are input fields for 'Subject ID', 'Secondary ID', 'Visit', and 'Image Date'. The 'Choose Files' button is also circled in red. A 'File Upload' dialog box is open, showing the 'Computer' tab with 'OS (C:)' and 'CANON_DC (H:)' drives. The 'Existing Subject' button is circled in red. The 'Choose Files' button is also circled in red. The 'File Upload' dialog box shows the 'Computer' tab with 'OS (C:)' and 'CANON_DC (H:)' drives. The 'Existing Subject' button is circled in red. The 'Choose Files' button is also circled in red. The 'File Upload' dialog box shows the 'Computer' tab with 'OS (C:)' and 'CANON_DC (H:)' drives. The 'Existing Subject' button is circled in red. The 'Choose Files' button is also circled in red.

PROTOCOL: **Sponsor** Change CENTER: **001** Change Study Resources create a new dcf

Overview DCFs Visit Overview View Images Upload Report Upload Analysis Report Analysis

Upload Visit

Existing Subject **New Subject**

Subject ID Secondary ID Visit Image Date

05-Mar-2013

File Name

Please select all of a single subject. Drag files here or press the Choose Files button.

Choose Files Clear List

PROTOCOL: **Sponsor** Change CENTER: **001** Change Study Resources create a new dcf

Overview DCFs File Upload

Upload Visit

Existing Subject New Subject

Subject Visit

File Name

Please select all of a single subject. Drag files here or press the Choose Files button.

Choose Files Clear List

File Upload

Computer

Organize

Hard Disk Drives (1)

OS (C:) 357 GB free of 463 GB

Devices with Removable Storage (4)

DVD RW Drive (D:)

Removable Disk (E:)

Removable Disk (F:)

CANON_DC (H:)

Select a file to preview.

File name: All Files (*.*)

Open Cancel

Allowed file extensions: .jpg .jpeg .tif .tiff .dcm .nif .cr2 .t2k .xml .log

The size of each file must be 50MB or less.

By my having logged on to this site, I certify and acknowledge my name will be associated with data submitted within this transmission. These images and data are original and unedited. I understand the content of these related transmissions has the potential to be utilized within a regulatory review.

Upload Files

Image Transfer Upload Procedures

The screenshot displays the CANFIELD Image Transfer Upload Procedures interface. On the left, a sidebar lists uploaded images: 0072.JPG, 0074.JPG, 0080.JPG, 0083.JPG, and 0084.JPG. The central panel shows details for a specific image, including a 'Print' button, a 'CARD ID' (597366198231364815140), and a list of uploaded images with their names, sizes, and MD5 hashes. The right sidebar contains a disclaimer about data security and a 'Help' link.

| Image Name | Size | MD5 |
|--------------|-----------------|----------------------------------|
| DSC_0072.JPG | 5,024,720 bytes | 01767a576174c14315a441060807f126 |
| DSC_0074.JPG | 4,604,908 bytes | 24bada55983aaebfbf73af2425036b79 |
| DSC_0080.JPG | 4,303,876 bytes | 27e0bd3cc6b006df67e547833da74848 |

- Review the Upload Confirmation Report to ensure that all of the required images have been successfully submitted.
- If an image does not submit successfully, please repeat the upload procedures for that image.
- The Upload Confirmation Report must be reviewed at time of upload and can be referenced on the website for the entirety of the study.

Data Clarification Forms

PROTOCOL: **Sponsor** [Change](#) CENTER: **001** [Change](#) [Study Resources](#) [+ create a new dcf](#)

[Overview](#) [DCFs](#) [Visit Overview](#) [View Images](#) [Upload Report](#) [Upload](#) [Analysis Report](#) [Analysis](#)

DCFs

Open to Canfield [Open to Center](#) [Overdue](#) [All Open](#) [All](#)

| DCF # | Item To Clarify | Status | Open To |
|-----------------------|-----------------|--------|---------|
| 37549 | Subject ID | Opened | Center |

DCF 37549

SPONSOR
Sponsor

PROTOCOL
Sponsor

CENTER
001

SCREENING ID
001

SUBJECT ID
*

SECONDARY ID
ABC

VISIT
Baseline

IMAGE DATE
05-Mar-2013

OPENED ON
05-Mar-2013 @ 7:41 am

OPENED BY
DeAnna Vander Ploeg

STATUS
Opened

OPEN TO
Center

ITEM TO CLARIFY
Subject ID

DeAnna Vander Ploeg
05-Mar-2013 @ 7:41 am

Subject randomization number not provided on the Baseline visit ID Card for Screen ID 001. Please confirm the four digit subject randomization number for initials ABC.

Your Comment

[Respond](#) [Close DCF](#) [Void DCF](#)

Data Clarification Queries (DCFs) should be responded to within 3 business days

An OPEN DCF may result in a delay in the completion of the BMD Central Review

BMD Central Review



BMD Central Review Result Report Form

- All site submissions will be archived into the Canfield Database.
- The DXA Scan Analysis Report will be provided to a Central Reader for evaluation. The Central Reader may request repeat scans as needed.
- Once the Central Read is complete, the Treating Investigative Site and Imaging Facility will receive a notification with a hyperlink to the subject BMD Central Review Result Report with 5 days of upload receipt.
- The Treating Investigative Site is responsible for reviewing and printing forms.

| | | | |
|---|--|----------------------------------|--|
| Canfield Scientific, Inc. – Quality Management System (QMS) | | CANFIELD Scientific, Inc. | |
| ObsEva / 16-OBE2109-008 [PRIMOSE] | | BMD CENTRAL REVIEW RESULT REPORT | |

| | | |
|-------|-------------|-----------------------------|
| Site: | Subject ID: | Secondary ID (Subject YOB): |
| 01 | 01010 | 1980 |

| Bone Mineral Density (BMD) Reporting | | | | | |
|--------------------------------------|--------------------------|--------------------------|-------------------|--------------------------|---|
| Anatomical Area: | Visit: Baseline/Day 1 | Visit Date: 26Feb2016 | Visit: Week 12 | Visit Date: 27May2016 | Change in % BMD from Baseline/Day 1: |
| Lumbar Spine | 1.408 | g/cm ² | 1.386 | g/cm ² | -1.5 |
| Total Left Hip | 1.118 | g/cm ² | 1.091 | g/cm ² | -2.4 |
| Left Femoral Neck | 1.205 | g/cm ² | 1.181 | g/cm ² | -2.0 |

Action Required:

☐ None

☐ Repeat Scan Reason:

☐ Treatment Withdrawal Criteria Met Note: If selected, refer to manual for further instruction.

Central Reader Comments:

Report Generated:
07Aug2016

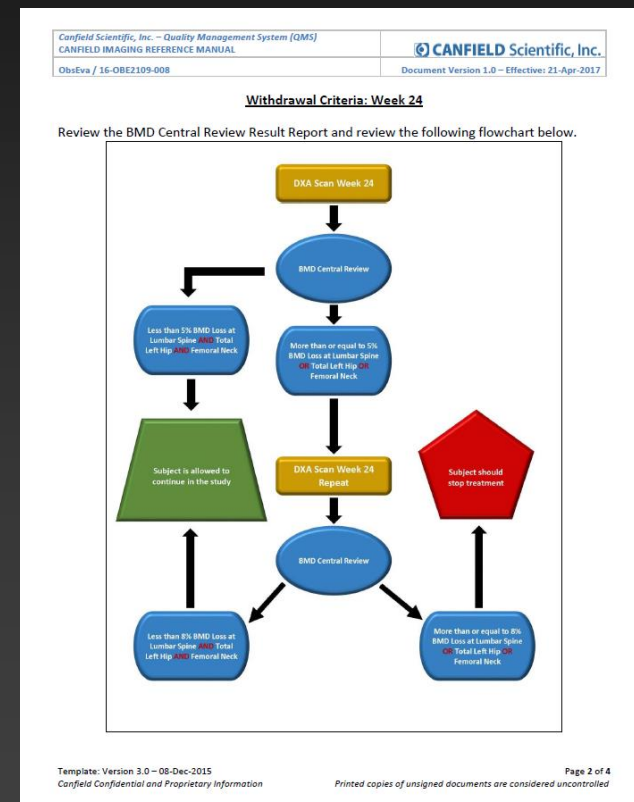
Template Effective date: 15-Jun-2016
Canfield Confidential and Proprietary Information

Page 1 of 1
Printed copies of unsigned documents are considered uncontrolled

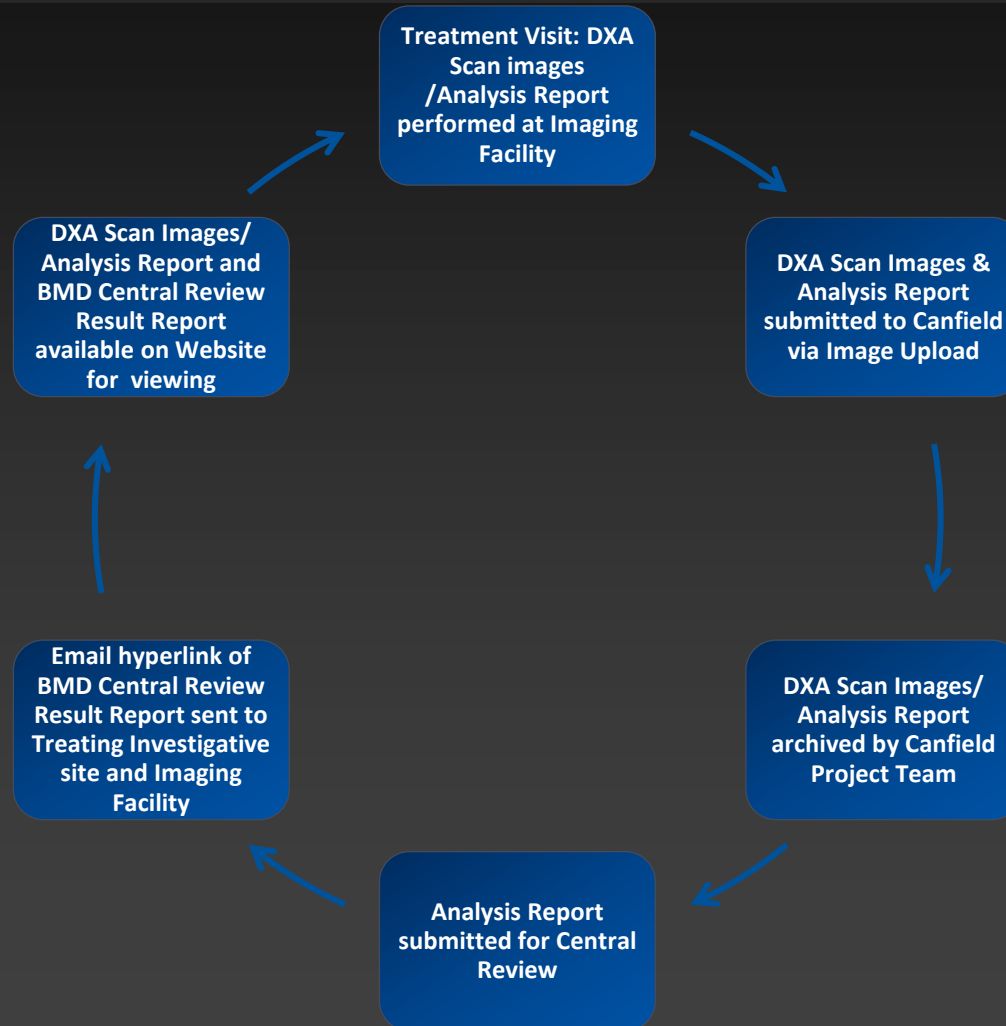
BMD Withdrawal Criteria

- Review the BMD Central Review Result Report as it will indicate whether a subject has met the withdrawal criteria for change in % BMD.
- If Treatment Withdrawal criteria has been met, please refer to the Treatment Withdrawal Criteria section within the IRM and follow the algorithm provided for subject withdrawal procedures.
 - NOTE: There are separate charts for Week 24, 52, and 76.
- Each BMD Central Review Result Report should be printed and filed in subject's chart.

Week 24 Example



Imaging Cycle



Canfield Project Team

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If the assigned study staff is unavailable,
please ask for any available Project Manager.

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