

MRI Site Training for *Anika Therapeutics Inc.*

FastTRACK

(Hyalofast Trial for Repair of Articular Cartilage in the
Knee)

PROJ-040-0003-TRAINING MRI





Emailing Qmetrics

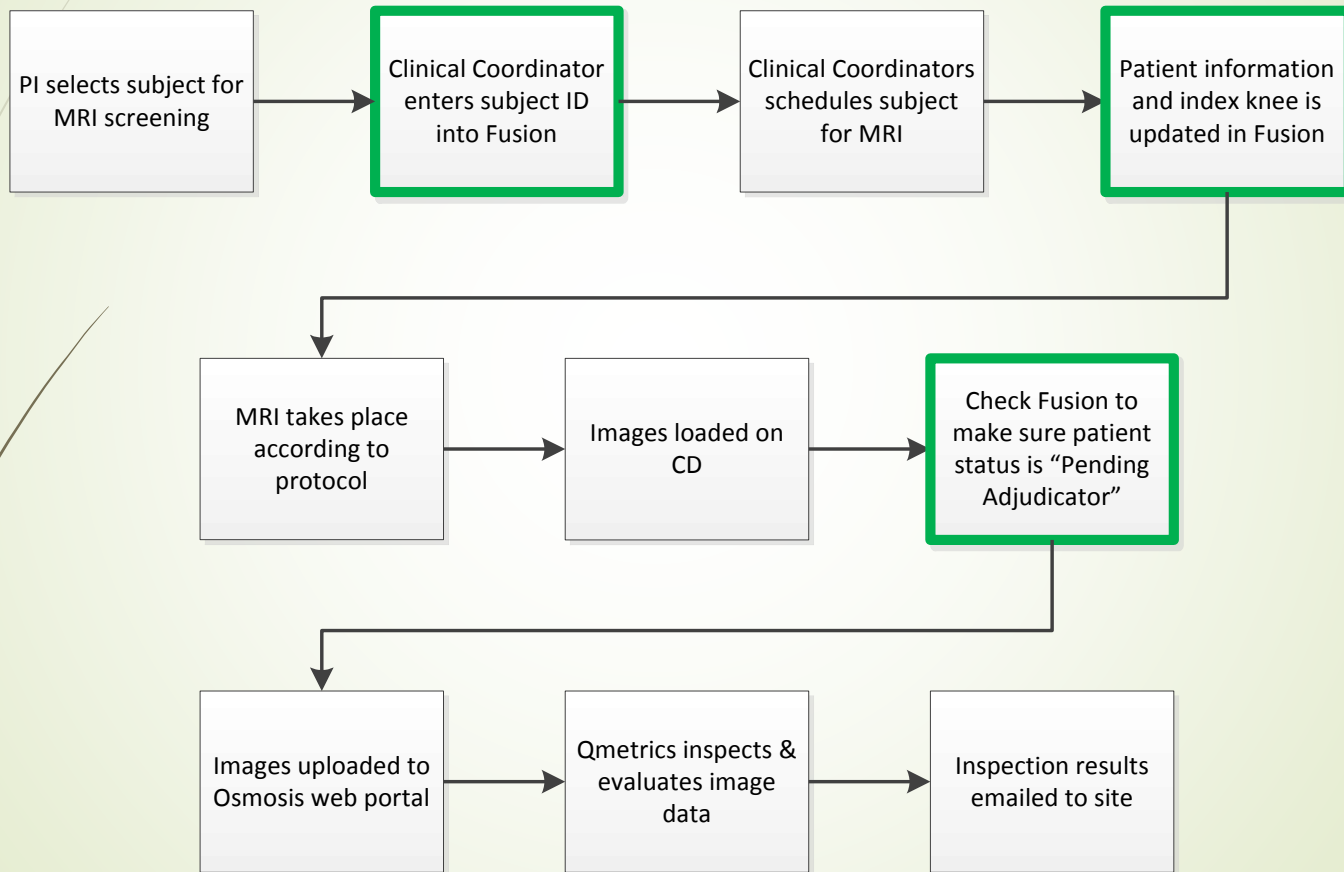
- Email amber.carr@qmetricstech.com
- Subject line should include:
 - Hyalofast
 - 428
 - MRI
- When replying to emails, please select
REPLY ALL



Qmetrics Technologies' Role:

- ▶ Qualifying MRI sites
- ▶ Training the MRI sites on imaging protocol
- ▶ Quality inspection of all MR images
- ▶ Screening all subjects for eligibility
- ▶ Analyzing images for treatment effect at 1mo, 12 mo, 24 mo, and 36 mo

Imaging Workflow



* Fusion is maintained through Axiom, a separate vendor. If you have questions about the Fusion database, email anika@axiommetrics.com

Qmetrics Provides to Site:

- ▶ T2 Phantom Belt
 - With 5 small tubes/phantoms
 - Must be used for every subject at every time point
 - Standardizes subject scans



Qmetrics Provides to Site:

- ▶ Foot Rest
 - Standardizes knee position, improves comfort

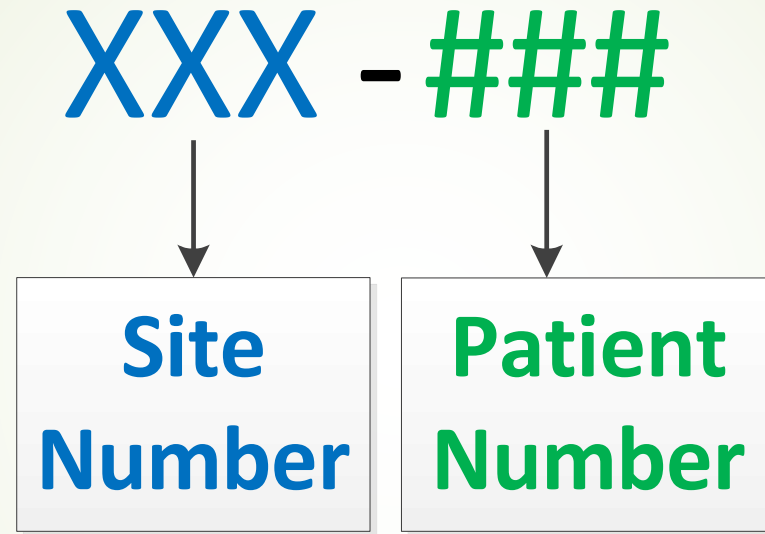




Qmetrics Provides to Site:

- PDF of site-specific MRI protocol
- PDF of these training slides
- MR Imaging Site Operations Guide
- Osmosis username and password

Naming Convention & Subject ID



Your Site Number: **428**

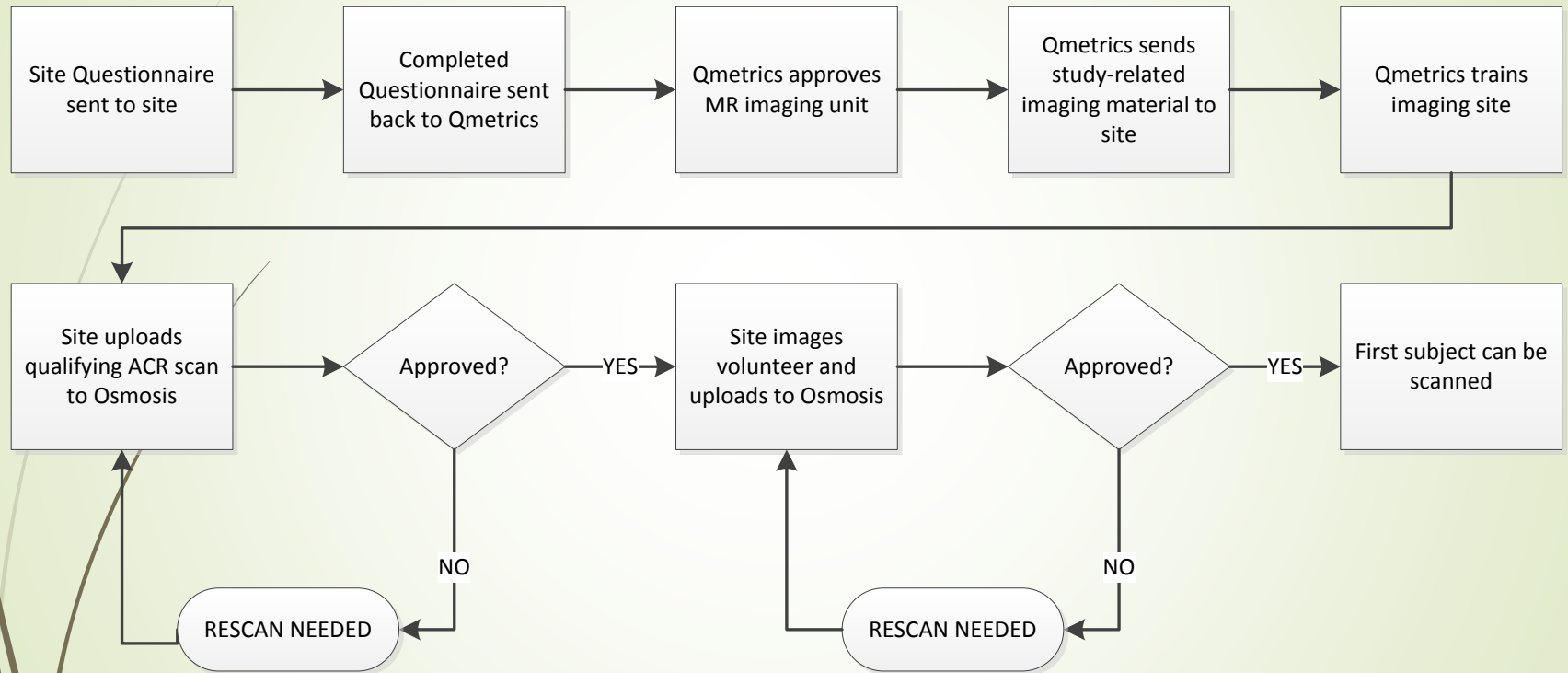
IMPORTANT: Subject ID must match the ID that is entered into the Axiom database called Fusion

Site Qualification Process



Anika – FastTRACK Hyalofast

Image Site Qualification Process



Site Qualification- ACR Scan

The ACR scan demonstrates the geometric linearity of the MRI B0 field and ensure that significant geometric distortions are not present in the acquired image data.

These scans will be performed:

- During the site qualification process
- Once a year throughout the study.
- After every scanner update



Site Qualification– ACR Quality Scan

- American College of Radiology program
- Used for 10 different imaging modalities in 38,000 facilities across US
- Site must submit a phantom scan to ACR for approval
- Site uploads the ACR image to the Qmetrics web portal
- Qmetrics reviews in order to assess the magnet capabilities for this study
- Naming convention: 428-ACR

ACR Phantom & Scan Entry

- **Patient ID** = subject's study ID
 - 428-ACR
- **Patient Name** = subject's study ID
 - 428-ACR
- **Study Description** = 2018





Volunteer Scan

- Demonstrates understanding and compliance with study protocol and procedures
- Volunteer can be a staff member
- Volunteer has to be scanned **with the study imaging protocol**
- Helps Qmetrics assess that image quality is suitable for study requirements
- Once completed and approved, the site is ready for first subject
- Naming convention: 428-VOL

MRI Imaging Subjects



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SAGITTAL 3D WE MEDIC

- ▶ Plane: Sagittal, straight, not oblique, not along ACL
- ▶ WE Option: On
- ▶ TR: 30ms
- ▶ TE: 18
- ▶ Flip angle: 8
- ▶ Matrix: 320x320
- ▶ Slice thickness: 1mm
- ▶ Spacing between slices: no overlapping slices
- ▶ FOV: 150mm
- ▶ Center cranially to the knee joint space
- ▶ Cover from medial to lateral edge of femur



DUAL ECHO FAST FAT SAT SPIN ECHO

- ▶ Plane: Sagittal, straight, same as that of structural
- ▶ Fat Sat Option: On
- ▶ TR: 6000ms
- ▶ TE: 20ms, 60ms
- ▶ ETL: 20-12
- ▶ Slice thickness: 1mm
- ▶ Spacing between slices: no skip no gap
- ▶ Matrix: 256x256
- ▶ FOV: 150mm
- ▶ No Wrap
- ▶ Center at the same location as for structural
- ▶ Cover from medial to lateral edge of femur



MRI Protocol Adherence

- Every parameter of the MRI protocol must be used every time, for every study subject without deviation
- The study protocol must be programmed into the scanner to maintain consistency and to avoid mistakes
- MRI imaging protocols will be site-specific



MR Imaging Time Points

- Screening
- 1 month post-op (1mo)
- 12 months post-op (12mo)
- 24 months post-op (24mo)
- 36 months post-op (36mo)

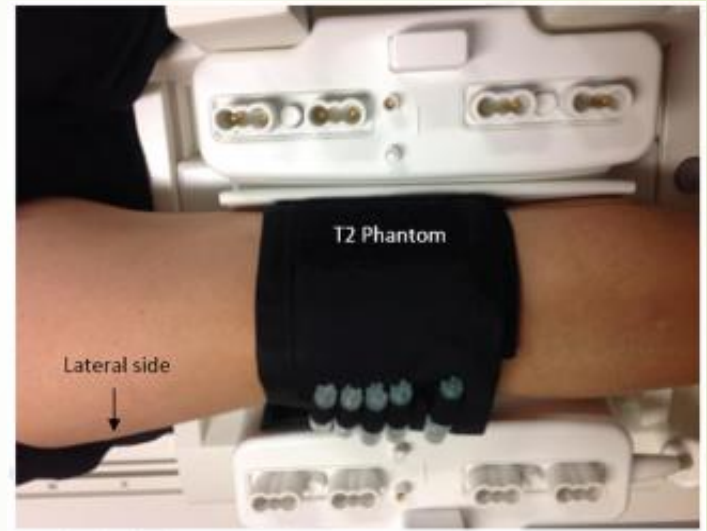


MR Imaging Subject Information at Scanner

- **Patient ID** = subject's study ID
 - 428-001
- **Patient Name** = subject's study ID
 - 428-001
- **Study Description** = index knee (Left or Right)
- *Do not fill in subject's height, weight, address or any other personal health information*

Subject Positioning- T2 Phantom Belt

- Position the knee coil on the gantry to accommodate feet first position of the subject and the side of the index knee
- Strap the T2 phantom belt around the knee so that the T2 phantoms are laterally just distal to patella. Secure the strap using the Velcro



Subject Positioning- Footrest

- Knee pad under the knee
- Foot rest at the end of the table
- Tape foot to the footrest so that the subject's index knee is at the center mark of the coil at the caudal end of patella

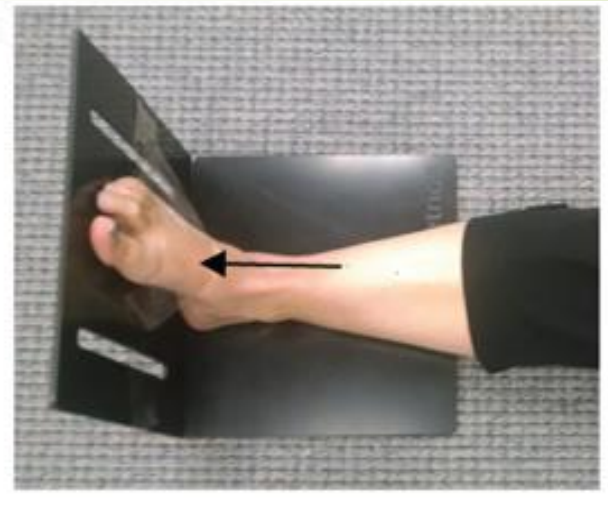
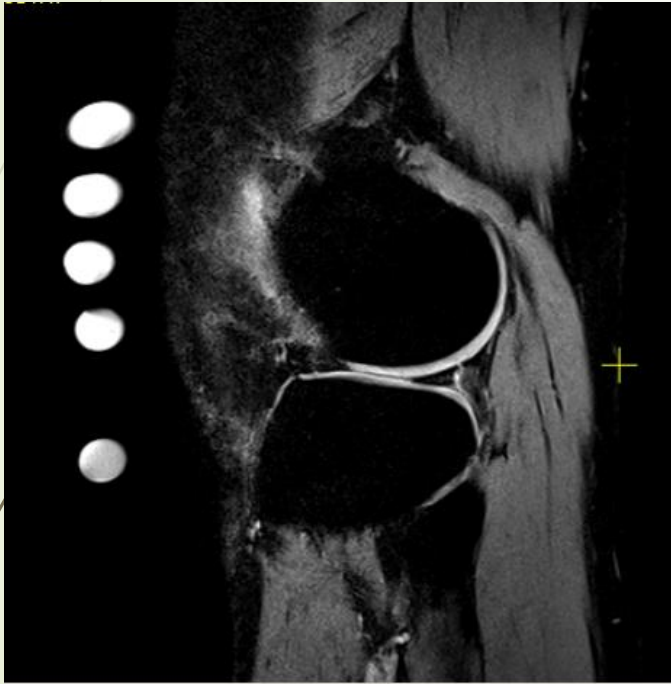


Image Quality

- ▶ Check the quality of the images before the patient leaves the table
 - ▶ No wrap
 - ▶ No motion
 - ▶ Homogenous fat suppression
 - ▶ No zipping or overlapping slices
- ▶ The FOV of all images must cover the **bony components** of the entire knee
- ▶ T2 phantoms must be visible in at least 3 consecutive slices
- ▶ Tell us your imaging time

Image Quality – Acceptable



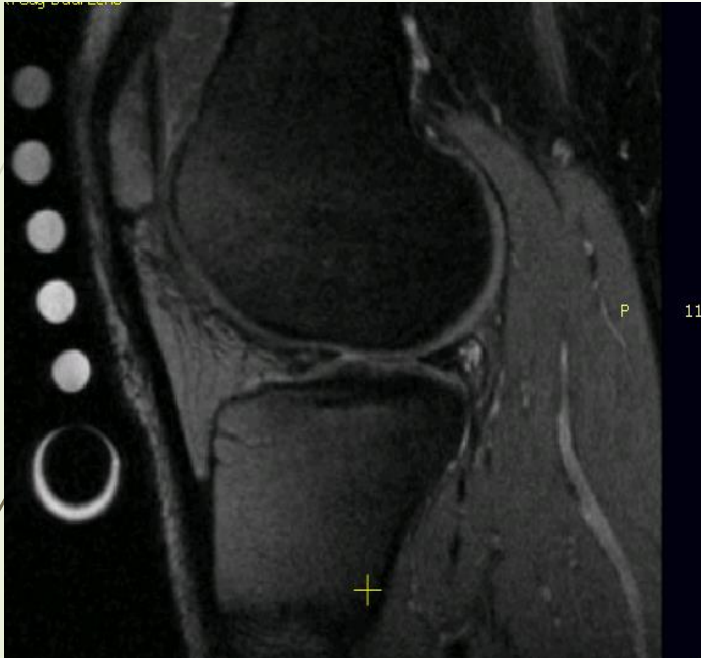
- Example of **high quality** image
- High quality 3D sequence showing good fat suppression, no patient motion and all T2 phantoms in the phantom belt.

Image Quality – Unacceptable



- Example of **low quality** image
- First echo of dual echo series shows considerable subject motion

Image Quality – Unacceptable



- Example of **low quality** image
- Shows no fat suppression, leading to water suppression in the anterior knee.



Due Dates

- Osmosis practice upload: due **Monday, May 13th**
- UAL/ACR scan: due **Wednesday, May 15th**
- Volunteer scan: due **Wednesday, May 22nd**



End of Presentation

Are there any questions?

Next: Osmosis Training