BREAK OUT GROUP: IMAGE MANAGEMENT

THE SCOPE…

- The scope of this guidance
  - "in vivo imaging"
  - "imaging used to assess therapy effects"
- More or less, this is radiology imaging and cardiology imaging. Could also include visible light (dermatology photos, endoscopy)

IMAGING SHOULD BE INCLUDED EARLY

- Help select the imaging metric
- Full QC cycle needs to be planned and followed
- Training should include
  - software (e.g. how to measure the lesion)
  - hardware (e.g. select acceptable monitor)
  - set up environment (e.g. lighting, ergonomics)
- Encourage test & retest of readers/method

Same Right Answer > Same Wrong Answer >

DATA IDENTIFICATION

- Encourage de-identification as a separate step after clinical acquisition
- De-identification should be done at local site. But don’t assume that it is done properly (re-de-identify)
- There should be a full audit trail from point where de-identification is done

IMAGES SHOULD BE…

- Digital (exceptions: mammo, some CR?)
  - Digitizing is not a substitute
- DICOM
- Annotations in a standard form (AIM, DICOM SR)
- If using a new/novel imaging method, raw data should be saved until QC accepted
- Not lossy compressed unless lack of effect on measurement shown (burden shifted)

CLINICAL FINDINGS

- The performing site should have images interpreted by a licensed professional if the images have accepted clinical value
- If this is in place, there is not responsibility for researchers to address clinical findings in images

WHEN IMAGING IS USED FOR ENROLLMENT…

- Images should be saved and have mechanism in order to ‘attach’ to final subject identifier.
- May introduce a bias since site sends images for patients it feels does qualify (some of which might be rejected) but not for those they feel do not qualify.