BREAK OUT GROUP: IMAGE MANAGEMENT
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)
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
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.