

Steps in FDG-PET/CT Process:

Presumptions:

Primary FDG-PET analysis with semiquantitative (SUV) measurements
CT portion of PET/CT used as attenuation correction map only

Subject Preparation

Imaging Procedure

Image Post-Processing

(Media Transfer/Receipt)

Image Analysis and Interpretation – as outlined below

[Image quality assessment to confirm correctness and completeness of image submission]

Image set loaded to Reader (Physician performing Image Analysis) worklist

Reader selects worklist task

Digital image datasets within assigned timepoint opened for display

(Timepoint exams defined by charter re: exam types and dates of inclusion)

Reader performs review of imaging exams within defined timepoint

For standard oncology trial, Baseline only timepoint is reviewed first

Reader iterates with software application to identify lesions and ***perform lesion analysis***

Target lesion identification and analysis

Non-target lesion identification +/- analysis (or comments)

Lesion analysis performed by providing measurement object as separate file

Label lesion

Capture metadata generated from measurement object

Repeat Target +/- Non-target lesion identification/analysis as defined by imaging charter

Close subtask

@Open next timepoint for given subject

Review next 'on-study' timepoint with prior timepoints

Perform lesion analysis on current timepoint to correspond to lesions identified before

Identify presence/absence of New lesions

Derive change metrics for lesions +/- lesion group (e.g. target lesions)

Determine response assessment as defined by imaging charter

(Evaluate covariates and other possible sources of technical variation for assessment of affect likelihood upon response assessment)*

Close subtask

Continue same workflow (from @) until all timepoints reviewed for given subject

*This represents several separate QC checks which may be performed at different 'steps'