Response in AHOD1331 will be based only on FDG-PET and not decrease in size of lesions.

The only size determinations of concern to the primary institution is measurement of bulk disease at baseline and measurement to assess for progressive disease.
Measurement of Bulk Disease

• Maximum transverse diameter of mediastinum on PA upright chest radiograph >1/3 the diameter of the thorax at the level of the diaphragm

• Maximum diameter of non-mediastinal nodal mass = or > 6 cm. in axial or craniocaudal plane. This is new from prior protocols
Mediastinal Bulk
Mass > 1/3 diameter of thorax at level of diaphragm
Non-mediastinal nodal bulk > 6cm.
Non-mediastinal bulk not > 6 cm. in axial plane but > 6 cm. cranio-caudally

Axial 4.8 cm.

Cranial-caudal 7.0 cm.
Cluster many small nodes = NOT BULK
Deauville Criteria – System of FDG-PET response based on 5 levels of decrease in avidity; found to be of good prognostic accuracy in adult trials
Deauville Criteria

1. No uptake above surrounding background
2. \(<\text{ or }\leq\text{ mediastinal blood pool}\)
3. \(>\text{ mediastinal blood pool but }<\text{ or }\leq\text{ liver}\)
4. Moderate increase compared to liver
5. Marked increase compared to liver
Interim post Cycle 2 PET Response

- FDG-PET positive is defined as Deauville scores 4 or 5 (SRL)
- FDG-PET negative is defined as Deauville scores 1, 2, or 3 (RRL)

SRL – Slowly Responding Lesion
RRL – Rapidly Responding Lesion
End chemotherapy PET(PET 5) Response

• FDG-PET positive is defined as Deauville scores 3, 4, or 5 (IMR)
• FDG-PET negative is defined as Deauville scores 1 or 2 (CMR)

IMR – Incomplete Metabolic Response
CMR – Complete Metabolic Response
All PET avid areas now < liver

Pre-study

Post chemotherapy

Deauville 2
One node at or < Blood Pool

Aorta

SVC

Right paratracheal mass < or = blood pool

Deauville 1
Mediastinum = Liver post therapy

Pre-study

Post therapy

Deauville 3
Mediastinum > liver post therapy

Pre-study

Post therapy

Deauville 4 or 5
Spleen – Complete Response

Prior Protocols

• No residual contrast CT abnormality
• No residual PET avidity

AHOD1331

• Residual contrast CT abnormality decreased by >50% or is <1cm. in diameter
• No residual PET avidity
Spleen

Pre-Study

Post therapy Negative