Current Status

<table>
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<th>Group</th>
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<th>Pts randomised</th>
</tr>
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<tr>
<td>TOTAL</td>
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</tr>
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</table>

Message from the Study Chair

Dear all,

Thankyou for your ongoing great efforts on recruiting to the OUTBACK study.

Recently we have got to a landmark of 200 patients recruited and seen the first patient randomised from Saudi Arabia. We continue to investigate other options for high quality sites in countries that see a lot of cervix cancer.

I am aware that some of you continue to struggle with whether or not to call nodes on PET positive or not, and would like to provide the following additional guidance on the basis of discussions with our lead PET physician as well as the GOG and RTOG Principal Investigators.

1. Only nodes that are reported as clearly positive on PET/CT should be used for the purposes of stratification

2. It is recommended that nodes which are reported as equivocal, particularly if they are in a location which would change patient management be biopsied

3. It is not possible to assign a specific SUV cut-off for whether or not to call a node positive. In general, a node that has uptake that is more intense than the liver is positive irrespective of size. For small nodes (that is nodes of a centimetre or less) partial volume effects become relevant. These should be considered PET positive if the intensity of uptake is visually greater than blood pool activity, best assessed in the abdomen from the aorta. The pattern of nodal uptake is also important and it is very helpful to review results in the multi-disciplinary meeting and/or discuss with the reporting PET physician if there is uncertainty or conflicting results between imaging modalities

Best wishes, Linda Mileshkin
A Phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone: THE OUTBACK TRIAL (ANZGOG 0902, GOG 0274, RTOG 1174)

Trial Newsletter—July 2013

Recruitment Graph: Accrual per month (April 2011—July 2013)

InForm system - RECIST (follow-up)

You may have noticed that for some of your patients a follow-up RECIST visit dated 1 Jan 2009 shows in the InForm system. This is a dummy RECIST visit that had to be entered by the OUTBACK team as part of the database update back in February. The dummy visit is locked and cannot be edited by sites. This only concerns a small number of patients at certain sites. If you encounter this dummy RECIST visit for a patient, don’t worry. There is an easy work-around.

To enter a real RECIST visit just click on the ‘New’ button at the bottom left on the Date Tab of the RECIST form.
A Phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone: THE OUTBACK TRIAL (ANZGOG 0902, GOG 0274, RTOG 1174)

**Study Aids**

There are several study aids available for this trial to assist with the collection of data required to be entered into the InForm system.

The study aids can be downloaded from the ANZGOG, GOG and RTOG websites.

The following study aids are available:
- Nodal assessment: PET
- Radiotherapy: EBRT, Boosts, Brachytherapy, Total Doses
- Toxicity: Treatment, Follow-up

**Frequently Asked Questions (FAQ)**

**Q: Where do I find the SAE form in the InForm database?**

A: The cisplatin and adjuvant chemo visits have an SAE tab. If you answer ‘Yes’ to the SAE question, the ‘SAE details tab’ will trigger. On the ‘SAE details’ tab you need to click ‘New’ to enter the SAE.

**Q: When does the patient need to be reviewed prior to receiving chemotherapy?**

A: The patient needs to be reviewed within 72 hours of administration of chemo. Please refer to Sections 8.1.1.1 and 8.1.2.2 in the protocol.

**Q: How is the follow-up schedule for patients calculated?**

A: All follow-up time points are calculated from the date of randomisation. Please refer to Schedule 10 in the protocol.

For example, the 9 month follow-up visit needs to be scheduled 9 months after the patient was randomised.

**Q: Do all patients need to have a PET/CT as well as a separate CT chest/abdo/pelvis at baseline?**

A: Under the amended protocol (Version 4.0) we have specified that if sites are able to access both a MRI pelvis and PET/CT at baseline then a separate CT chest/abdo/pelvis is not required. Hopefully this change will reduce the number of scans needed for many women.