RTOG
RADIATION THERAPY ONCOLOGY GROUP

Getting Started on RTOG 1174

Sites can get started on RTOG 1174 (ANZGOG 0902/GOG-0274), "A Phase III Trial of Adjuvant Chemotherapy as Primary Treatment for Locally Advanced Cervical Cancer Compared to Chemoradiation Alone: The OUTBACK Trial" by following directions included in the RTOG broadcast emails sent on 2/22/2012 and 3/16/2012. The broadcast emails have been included below in this document but can also be accessed by clicking "Broadcasts" from the left menu of the RTOG 1174 Protocol Information page.

RTOG BROADCAST 3/16/2012

Attention sites interested in enrolling to RTOG 1174 (ANZGOG 0902/GOG-0274), "A Phase III Trial of Adjuvant Chemotherapy as Primary Treatment for Locally Advanced Cervical Cancer Compared to Chemoradiation Alone: The OUTBACK Trial"

Listed below are the required steps for registering patients to this trial. Sites should allow adequate processing time (7-10 days) before trying to register the first patient.

- Submit IRB approval to CTSU.
- Request access to InForm training via ANZGOG, receive password, and get trained (or submit proof of prior InForm training to ANZGOG).
- Complete Site Approval Form Cover Sheet (http://www.rtog.org/LinkClick.aspx?fileticket=_VqkMtATXHo%3d&tabid=290) and top part of Site Approval Form (http://www.rtog.org/LinkClick.aspx?fileticket=Lgeri1l66VQ%3d&tabid=290) and FAX to RTOG at 267-940-9406.
- Receive notification from RTOG that your site is approved for enrollment.

RTOG BROADCAST 2/22/2012

Activated
RTOG 1174 (ANZGOG 0902/GOG-0274), "A Phase III Trial of Adjuvant Chemotherapy as Primary Treatment for Locally Advanced Cervical Cancer Compared to Chemoradiation Alone: The OUTBACK Trial"

Institutions can download a copy of the protocol for IRB review at http://www.rtog.org/ClinicalTrials/ProtocolTable/StudyDetails.aspx?action=openFile&FileID=8941.

Notes:
RTOG is very excited to announce activation for participation in this ANZGOG-led trial. As this trial is being led by a Group outside of the US NCI system, there are some procedural differences.
Please be sure to read the Group-Specific Study Handbook posted on the RTOG website at http://www.rtog.org/LinkClick.aspx?fileticket=MI6h0alB0AY%3d&tabid=290.

Please also note the following:
- Site RA(s) and Physician(s) participating in this trial must go to outback@ctc.usyd.edu.au and request access to InForm training. If previously trained on InForm, submit proof of prior training to NHMRC Clinical Trials Centre (ANZGOG) at outback@ctc.usyd.edu.au
- Once training is completed, the site will be set up in the ANZGOG/InForm "Live" system.

- The site must fill in Site Name, City, and County info along with the Date of Ethical (IRB) Approval on the Site Approval Form and submit the form to RTOG via fax at 267-940-9406.
- RTOG will fill in the GCIG representative information and notify ANZGOG that all regulatory documents are complete. Once ANZGOG has received this completed form and the site has completed InForm training, the site and RTOG will be notified that recruitment can commence at the site.
- ANZGOG will provide "Live" log on and passwords to the RA(s) and Physician(s) at the site for patient registration and data submission; please note these are different from the log on and password you will use for InForm training.
- All patients must be entered onto the trial via the ANZGOG InForm System.
- For cases credited to RTOG, the site must re-register the patient via the RTOG website (RTOG 1174), patient registration portal, **AFTER** registering the patient via the ANZGOG InForm System. This is necessary to collect NCI-mandated data not being captured by ANZGOG.
- In the Group-Specific Study Handbook, the street address for the RTOG Biospecimen Resource in Section 6.13.4 is outdated. An official modification will be processed in the near future; in the interim, please make note of the correct address as follows:

  U. S. Postal Service Mailing Address: For Non-frozen Specimens Only
  RTOG Biospecimen Resource
  University of California San Francisco
  Campus Box 1800
  2340 Sutter St, Room S341
  San Francisco, CA 94143-1800

  Courier Address (FedEx, UPS, etc.): For Frozen Specimens
  RTOG Biospecimen Resource
  University of California San Francisco
  2340 Sutter St, Room S341
  San Francisco, CA 94115