What Happens March 1st?

March 1, 2014 is the day our legacy groups, NSABP, RTOG, and GOG, cease to exist as NCI-funded cooperative groups and NRG Oncology takes its place as one of the five NCI-funded Lead Protocol Organizations (LPOs). March 1 is also the official start of the NCI’s National Clinical Trials Network (NCTN) which is replacing the 50-year old Clinical Cooperative Group Program. Much work has taken place behind the scenes to bring these new organizations into existence. Detailed below is important information about these changes.

Please note: The foundations that have supported our groups (NSABP Foundation, Inc., RTOG Foundation, Inc., and the Gynecologic Oncology Group) will continue in their research missions and will continue to be a vital resource to NRG Oncology.

Transition Weekend

The NCI, Cancer Trials Support Unit (CTSU), NRG Oncology, and NRG Oncology legacy groups will update their information systems to support the NCTN between February 28 and March 3. During this time, the rosters from the legacy groups will be “frozen,” and the new NRG Oncology group roster will be uploaded into the NCI Regulatory Support System (RSS) and into the legacy group systems. Service interruptions for multiple CTSU applications are expected during this time. Most importantly, **OPEN will not be available for patient enrollment from 3 PM ET on February 28 until 9 AM ET on March 3; therefore, no patients can be enrolled on NRG Oncology or legacy group studies during that time.** Please plan accordingly for patient enrollments.

We recommend that you do not plan for enrollments on Monday March 3 if at all possible. Medidata Rave is expected to be available during this time for data entry as are the GOG and RTOG legacy data entry portals. The NSABP Coordinator Online will be unavailable from 3 PM ET on March 1 until noon on March 3. Please note that there is the possibility of unforeseen interruptions in the days following the transition.

Please alert all staff likely to be effected by these changes. For additional information on the NCTN and NRG Oncology’s transition into the NCTN visit the **Transition News** page on the NRG Oncology website (www.nrgoncology.org) under News.

All Patient Registrations will be through OPEN

As of March 1 enrollment for all NCTN trials, including NRG Oncology trials, will be through the Oncology Patient Enrollment Network (OPEN), NCI’s web-based registration system. Some, but not all, of the DCP CCOP trials are also in OPEN. The OPEN system is integrated with CTSU’s Enterprise system, which maintains protocol regulatory and roster data. All site investigators who treat patients or provide study drug, and all research personnel who enroll patients, submit study data or need access to protocol documents, forms, and educational materials, must have a CTEP-Identity and Access Management (IAM) account to access OPEN. Most investigators and research staff already have a CTEP-IAM username and password as this system has been used to access trials in Medidata Rave as well as for enrollment via OPEN.

Note: Annual reregistration is required to maintain your CTEP-IAM account. Reregistration is a separate process from updating your password every 60 days. Prior to account expiration, investigators and associates receive an e-mail notification. Follow the instructions in the e-mail notification or go to https://eapps-ctep.nci.nih.gov/iam/, for instructions on how to reregister. For more information, please see the CTEP-IAM Fact Sheet.
Data Submission & Protocol Information

Data submission and protocol information for trials opened under the legacy groups will continue to be accessed via the legacy group websites for the near future. In the coming months we will transition access for these legacy portals to the NRG Oncology website. We will keep you updated on the timeline for these changes.

NRG Oncology & Legacy Rosters

As of February 26 the NCI legacy group membership rosters (institutions, personnel, and roles) were frozen in the NCI databases (CTSU, RSS, CTMB). Patient enrollment will be disabled at 3 PM ET on February 28 and NCI will upload new roster information for all NCTN groups, including NRG Oncology, into all of its databases over the weekend. When patient enrollments begin again at 9 AM ET on March 3 the new membership structure will be in place and sites will be able to credit NRG Oncology for their patient enrollments. NRG Oncology has worked with our legacy member sites and NCI to develop our new roster to reflect the relationships preferred by our sites and the requirements of the NCI. We have over 200 Main Member sites and more than 1,400 total sites. Forms to add, change, or discontinue member sites or roster personnel will be available on the NRG Oncology website beginning March 3. We will also begin to take applications for new members of all membership types at that time. Visit the NRG Oncology Membership home page to access these materials. Questions concerning institution and person rosters should be sent to: Roster@nrgoncology.org. Questions about membership applications should be sent to: Membership@nrgoncology.org.

Group-specific legacy rosters will be maintained by NSABP, RTOG, and GOG so that we can process reimbursements for study activities prior to March 1, 2014 and for current and future non-federal (e.g. pharmaceutical) studies, but will be maintained by the legacy groups, not within the NCI databases. The legacy groups will inform you of the extent of maintenance and intended use of the legacy rosters.

Membership Structure

With the start of the NCTN, NCI has instituted a new three tier membership structure and NRG Oncology legacy group members have been aligned with this new structure. NRG Oncology member sites have been organized as follows:

**Lead Academic Participating Sites (LAPS), Main Members, and CCOPS** *(NCI Tier 1)* – Sites with these designations are considered Main Members in NRG Oncology in accordance with the NRG Oncology Group Bylaws. To maintain NRG Oncology membership, these sites must credit NRG with 15 cases per year. Accrual from their Affiliate/Aligned Affiliate, Sub-Affiliate/Sub-Aligned Affiliate, Component and Sub-Component sites counts toward their accrual requirement. Main Member sites enter into contractual agreements with NRG Oncology and are responsible for the conduct of their Affiliate/Aligned Affiliate, Sub-Affiliate/Sub-aligned Affiliate, Component and Sub-Component sites. Any payments due from NRG Oncology for clinical trial activities will be sent to the Main Member site. Main Member sites can be Voting Main Members if they meet the requirement of 40 NRG Oncology credited cases per year.

**Affiliate/Aligned Affiliate, Integrated Components, and CCOP Components** *(NCI Tier 2)* – Sites with these designations are considered Affiliates or Components in NRG Oncology. Reimbursement (federal and/or non-federal support) for their clinical trial activities is sent to their Main Member site for distribution to the Affiliate/Aligned Affiliate or Component. These sites are expected to credit NRG Oncology with three cases per year.

**Sub-Affiliates and Sub-Components** *(NCI Tier 3)* – These sites function as a third tier under a LAPS, Main Member, Affiliate, or CCOP Component. They are intended to be a healthcare practice location of their parent that consents and/or enrolls patients and/or receives investigational drug. Reimbursement for their clinical trial activities is sent to their Main Member site for distribution as appropriate.

Purchased Service (Member) Agreements

March 1 marks the beginning of a new grant cycle and NRG Oncology must enter into a purchased service agreement (PSA) with each of its LAPS, Main and CCOP Members for their member network participation in NRG Oncology clinical trials including studies originally opened by our legacy groups. PSAs have been sent to the Contact Principal Investigator and fiscal contact at each of our Main and CCOP Member sites. Affiliate and CCOP Component members as part of their parent member network, will fall under the parent's PSA and thus will not enter into a separate PSA with NRG Oncology. We are allowing institutions to continue to enroll patients while their PSA is being executed but we will not process payments for activities that occurred
after March 1 until the new PSA is fully executed. Questions concerning PSAs should be sent to: NRGPSA@gog.org.

**Per Case Reimbursements**

Institutions that enrolled patients in NRG Oncology legacy group trials before March 1, 2014 will continue to receive payments for study activities that occurred prior to March 1 (service dates prior to March 1) according to the terms of their legacy group member agreement(s). Payments for study activities after March 1 (service dates starting March 1) will be paid according to the terms of the NRG Oncology PSA. Payments for study activities with a service date of after March 1 or later will be processed only after the NRG Oncology PSA is fully executed. Questions about payment issues should be sent to: Payments@nrgoncology.org.

**New Protocol Numbering System**

One of the most obvious signs of our transformation into NRG Oncology is the protocol numbering system that will be used for all new NRG Oncology protocols. Protocol numbers will have two components—“NRG” and a disease site/program abbreviation separated by a hyphen, followed by a number assigned in the order of the research concept’s approval by the NCI. *For example, NRG-GI001 is the first NRG Oncology gastrointestinal protocol* to obtain CTEP approval for a research concept, and NRG-BR001 is the number assigned to the first CTEP-approved breast cancer protocol. Below is the list of disease site/program identifiers.

<table>
<thead>
<tr>
<th>Disease Site/Program</th>
<th>Identifier</th>
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<tbody>
<tr>
<td>Brain</td>
<td>BN</td>
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<tr>
<td>Breast</td>
<td>BR</td>
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<tr>
<td>Gastrointestinal</td>
<td>GI</td>
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<td>Genitourinary</td>
<td>GU</td>
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<td>Gynecologic</td>
<td>GY</td>
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<td>Head &amp; Neck</td>
<td>HN</td>
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<tr>
<td>Lung</td>
<td>LU</td>
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<tr>
<td>Cancer Control</td>
<td>CC</td>
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*Includes CCOP and Symptom Management trials*

Protocols opened in the legacy groups will retain their original numbers even though the sponsoring group will now be NRG Oncology. For example, the Radiation Therapy Oncology Group’s protocol RTOG 1308 is now NRG Oncology RTOG 1308 and the protocol face sheet has been updated to reflect this change. Protocol face sheets will be updated as each protocol is amended.

**NRG Oncology Quality Assurance Audits**

The NRG Oncology Quality Assurance Audit program retains the expertise and experience that typified the programs of the three legacy groups. While the Clinical Trials Monitoring Branch (CTMB) Audit Guidelines have been recently revised the changes will have minimal effect on member institutions. However, some changes will be noted in the logistics of audit conduct.

First, for those member institutions that were previously a member of multiple legacy groups, the due date for the next audit will be based on the earliest due date resulting from the prior individual audits. For example, if NSABP had a due date of 8/15/2014, RTOG had a due date of 02/25/15, and GOG had a due date of 9/16/15, the initial NRG audit would be due on or before 8/15/14. Case lists will be chosen commensurate with accrual. After the first three-year cycle, all member institutions will have a due date based on a prior NRG audit. During the first year, there are many audits to be harmonized. Consequently, there will be little flexibility in audit scheduling.

Second, the majority of affiliate audits will be conducted simultaneously with the Main Member audit. Moreover, these affiliate audits will be conducted at the Main Member location. Main Member research team members will not be permitted to *independently* conduct audits of their affiliates, but may be asked to participate with the external audit team.

Third, for participants who have undergone a transformation in membership type (change in affiliation, change from Affiliate to CCOP, change from Affiliate/Component to Main Member, change from Affiliate to Component, etc.), case selection will encompass the period since the prior audit.
The NRG Oncology Statistics and Data Management Center

Just as the NSABP, RTOG and GOG Operations Centers are coming together to form the NRG Oncology Operations Center, the three legacy statistics centers are transitioning to form the NRG Oncology Statistics and Data Management Center (SDMC). The three principal investigators of the SDMC are: Joseph Costantino, Group Statistician; James Dignam, Deputy Group Statistician for Biostatistics; and John Blessing, Deputy Group Statistician for Operations. The three offices with shared responsibilities and personnel will still be located in Pittsburgh, Philadelphia, and Buffalo. During the early days of the transition, you will continue to work with the same staff on the same issues that you have in the past until we potentially move toward each location being more specialty-focused.

Substantial harmonization of activities has been occurring in such areas as IT structure and processes, database creation, protocol development, data management processes, data analyses, data monitoring, data reporting, QC, QA, e-mail addresses, and auditing and we will be establishing a combined instance of Rave for the submission of data to NRG Oncology. As these activities begin to affect your interactions with us, we will notify you. We look forward to working with all of you as we move forward. We have been working to create a harmonized, cohesive and unified SDMC which builds on the strengths of our three legacy groups, and we want to hear if we are or are not achieving that aim.

Contact Us!

Protocol-specific questions should be addressed to the appropriate NRG Oncology Research Center personnel that initiated the trial. For example, questions concerning data management or regulatory issues on NSABP B-51 will be addressed to the NRG Oncology NSABP legacy group staff in Pittsburgh and questions concerning RTOG 1005 will be addressed to NRG Oncology RTOG legacy group staff in Philadelphia. Contact information is available on the legacy group websites.

Non-protocol specific questions concerning NRG Oncology issues should be directed as follows:

- Purchased Service Agreements: NRGPSA@gog.org
- Roster Information: Roster@nrgoncology.org
- Membership Applications: Membership@nrgoncology.org
- Per Case Reimbursement: Payments@nrgoncology.org