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Trini Ajazi, MM
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MEMORANDUM

To: Alliance Members

From: Trini Ajazi, Alliance Chief Administrative Officer

Date: February 14, 2014

Re: NCI National Clinical Trials Network (NCTN) Transition Update

As of March 1, 2014, the cooperative group system will transition to the NCTN. The following is our understanding of what this transition entails.

Transition Weekend

The NCI, Cancer Trials Support Unit (CTSU) and Alliance information systems will be transitioned to support the NCTN between **February 28 and March 3**. During this time the rosters for the cooperative group will be transitioned to the NCTN rosters that include roster packages for Lead Academic Participating Sites (LAPS) from CTEP and Community Clinical Oncology Program (CCOP) from DCP. **Institutions will experience service interruptions for multiple CTSU applications during the transition weekend.** Medidata Rave is expected to be available. **Alliance information systems, including the Alliance member website and patient registration/randomization will not be available during the transition period.**

- **The Oncology Patient Enrollment Network (OPEN) will not be available for patient registration starting at 3:00 PM ET on February 28. OPEN is expected to be available at 9:00 AM ET on March 3.** Please plan accordingly for patient registrations.
- Please note the following regarding patient registrations for CALGB 10701 and CALGB 140503.
 - CALGB 10701: To allow for the urgent treatment of patients with acute lymphocytic leukemia, patients may begin treatment on CALGB 10701 prior to study enrollment. If treatment begins during the OPEN system service interruption, registration to CALGB 10701 **MUST** occur on the next scheduled business day (03/03/2014).
 - CALGB 140503: Protocol section 5.7 outlines emergency randomization procedures for randomization after business hours. Please follow CALGB 140503 section 5.7 instructions. Note: patients must have been pre-registered prior to the OPEN system service interruption.
- Alliance BioMS may experience service interruptions. If BioMS is not available, please follow the downtime procedures for BioMS. Users may contact bioms@alliancencntr.org or 1(855)-55-BIOMS for assistance.

Membership Roster

- The legacy (ACOSOG, CALGB, NCCTG) rosters will be frozen in the Regulatory Support System (RSS) and in the legacy Alliance systems on February 24, 2014. **Any changes to legacy rosters must be made before February 24, 2014.** Any institutional personnel that need to be authorized to register patients must be on the legacy group roster. No changes can be made between Monday, February 24 and Monday, March 3.
- In order to participate in adult NCTN trials as of March 3, 2014, a site must be a member of at least one of the adult NCTN Groups (Alliance, ECOG-ACRIN, NRG or SWOG). The Alliance will accept the LAPS and CCOP network rosters loaded by NCI. These rosters must be the same across all NCTN groups. Any legacy ACOSOG, CALGB, NCCTG main member or affiliate (LAPS-aligned or non-LAPS affiliate) that did not receive approval as an Alliance member will not be rostered, as an Alliance member on March 1. Legacy members that do not continue their membership and are still following/treating patients on Alliance studies will be placed in a follow-up status in RSS, in order to allow them continued access to systems for data submission.
- Following the transition, institutional roster changes will be handled through the CCOP system for CCOP institutions and the RSS for non-CCOP institutions. The Alliance will manage their roster through the RSS. However, we are allowing sites to manage most institutional role changes with the exception of Principal Investigator (PI), Co-PI, and Lead and Secondary Clinical Research Professionals (CRPs). For instructions on how to manage your institutional role changes, log into www.ctsu.org and click on the icon for "Training Video" located under Site Roles in the Regulatory tab. Roster request changes that are not handled through the CTSU Roster Update Management System may be emailed to roster@alliancencn.org.

Alliance Information Systems

Following the transition weekend, access to the Alliance member website, Medidata Rave and BioMS will continue in the current manner. Users must use their CTEP-IAMS credentials to access these systems. Any person who is not on the Alliance roster will not be able to access these systems. To obtain CTEP-IAMS credentials, visit <https://eapps-ctep.nci.nih.gov/iam>.

It is expected that access to the NCCTG and CALGB member websites will also continue in the current manner. Users may log in with their NCCTG and CALGB credentials, although there may be issues with the CALGB reporting system. Members will be notified if there is a change. The Alliance is moving protocol content from the legacy websites to the Alliance website. Eventually, these legacy websites will be retired.

For information systems help, email AllianceServiceCenter@allianceNCTN.org.

Patient Registration and Crediting

As of March 3, all patient registrations to NCTN trials must occur through OPEN. All new accruals to NCTN trials will be credited to the new NCTN Network Groups even if the studies are still identified under the Cooperative Group nomenclature (e.g. CALGB 140503). Accruals credited to the Alliance are subject to an audit by the Alliance.

Phase 2 and 3 studies that are currently available to cross-group participation will remain available for network participation; in the new NCTN any Participating Organization can be credited with enrollments.

Funding

Payments credit for treatment/intervention registrations will be made based on patient enrollment through OPEN. Under the NCTN, upfront follow-up payments will be included in the base intervention payments for treatment trials.

Payment for some ancillary specimen submissions, QoL and other supplemental funds will require institutions to log into OPEN to document fulfillment. For non-Federal reimbursement of Alliance ancillary study requirements, receipt of specimens using BIOMS will be used to trigger payment. Funding has changed for some ancillary specimen submissions. Updated funding sheets will be available.

NCI per case management payments for intervention, screening, QOL and bio-specimen collection, if applicable, will be made by the Network Group credited with the accrual OR the equivalent will be paid via the NCTN LAPS grant or CCOP grant directly. Per case management funding information for all NCTN trials will be listed on the CTSU with the protocol specific information. For trials that have additional funding from industry or other sources, payments will be distributed by the Network Group credited with the accrual to its sites. Questions regarding payments should be directed to the Network Group(s) in which a site has membership.

https://www.ctsu.org/readfile.aspx?fname=whatsnew/CTSU_Navigating_NCTN_FINAL_020414.pdf

Protocol Amendments

During the course of 2014, active legacy trials will be amended to designate Alliance as the lead NCTN Group on the protocol title page.

NCI CIRB

The NCI CIRB requirement will be phased in, expected later this year. A waiver process is being developed. No sites will be excluded from participation in the NCTN until this process has been fully developed and all Group members, CCOPs/MB-CCOPs, and LAPs have an opportunity to apply for CIRB membership and/or submit a waiver application.

All U.S. institutions/sites participating in NCTN trials as member of 1 or more Network Groups are required to use the NCI's CIRB as the IRB of record unless a waiver has been granted by the NCI. All NCI sponsored phase 3 and select early phase clinical trials that are reviewed by CIRB must be CIRB approved prior to site activation.

https://www.ctsu.org/readfile.aspx?fname=whatsnew/CTSU_Navigating_NCTN_FINAL_020414.pdf

Audit

Following the transition, all audits will be conducted as Alliance audits. These audits will be scheduled based on the earliest required audit date for the legacy ACOSOG, CALGB or NCCTG.

The Alliance will provide additional information as it becomes available. Please also check the CTSU Member website under Transition News. <https://www.ctsu.org>.