Corrective and Preventive Action System (CAPAS) Audit Follow-up Process
Alliance CRP Information Session
November 1, 2018

Presented by
Barbara Barrett
(Slides developed by CTEP)
On-Line CAPA Submission Process

...coming as a program near you

Q4 FY2019
Corrective and Preventive Action System (CAPAS)

- NCI (National Cancer Institutes) is working on initiative to develop a web interface for sites to provide the corrective and preventive action for the deficiencies captured in the audit finding report.

- The interface will allow the site point of contact (identified by Group) to securely login to the system, review the follow-up items resulting from an audit, select the deficiency(ies) and provide the Corrective and Preventive Action (CAPA) at the protocol/patient/deficiency level.

- The interface will allow sites to upload documents to support CAPA response.

- The interface will allow sites to submit the responses to the auditing groups for review.

- The groups can request modification to the responses (if needed) in order to accept the responses.

- Groups will continue to submit the accepted responses to NCI.
Corrective and Preventive Action System (CAPAS) - Benefits

- Standardize the collection of CAPA response from sites across the groups
- Collect the CAPA responses and supporting documented in secured manner
- Allows sites the ability to provide a Corrective and Preventive Action (CAPA) at the protocol/patient/deficiency level
- System generated email notifications to track the progress
- NCI can perform trend analysis at various level of the follow-up request to monitor the deviations being identified
CAPA Process- Requirements

- Two site Point of Contacts should be identified for each audit
- Site Point of Contact will require a CTEP-IAM account and has to be on the Person Roster for the site
- Each site will be provided 15 business days to respond to the follow-up request from the time the final auditing findings report is submitted to NCI
- Sites will continue to receive the Final Audit Reports from auditing groups
- CAPA responses for all the follow-up items are to be submitted to groups at the same time
- Site Principal Investigator (PI) must acknowledge that the CAPA responses were reviewed and approved by him/her before submitting it to the group
High level Plan

- NCI IT Contractor is working closely with CTMB and Groups to finalize the requirements and develop the system
- The system will be piloted to the selected groups/site tentatively in Q3 FY2019
- The feedback from pilot groups/sites will be collected to prioritize with NCI
- The system will be live tentatively in Q4 FY2019
Stay Tuned for the rest of the story…….
THANK YOU

CTIS
One Research Ct., Suite 200
Rockville, MD 20850

Tel: 1-888-CTEPHELP
Email: nxictephelp@ctep.nci.nih.gov