



National Cancer Institute

CTEP Cancer Therapy
Evaluation Program



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

*Presented by
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(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

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