

# CTEP-AERS vs AdEERS Training

# SAE Reporting Data Entry Systems

- **AdEERS (Adverse Event Expedited Reporting System)**
  - Current entry point for all expedited adverse event reporting for all CTEP, CIP and some DCP trials.
- **caAERS (Cancer Adverse Event Reporting System)**
  - Developed jointly by NCI and the community
- **CTEP-AERS (CTEP Adverse Event Reporting System)**
  - CTEP version of caAERS integrated into the CTEP Enterprise System
  - New entry point for all expedited adverse event reporting for non-Rave trials
    - This includes all non-Rave studies for the Groups/NCTN, ET-CTN, U01, N01s, etc.
- **caAERS-Rave**
  - New entry point within Rave for all adverse event reporting (expedited and routine) for new Rave trials (current Rave trials with complete study builds will transition to CTEP-AERS, cut-off date TBD).
  - Anticipated pilot spring 2014, full roll-out fall 2014.

# Why CTEP-AERS/caAERS-Rave?

- Compliant with the FDA Final Rule
- Anticipated to save time and reduce workload for the Community and CTEP
  - Highly specific rules engine allows the creation of protocol specific exception (PSE) rules for each protocol based directly on the actual protocol document
  - Immediate feedback prior to report completion/submission whether the adverse event meets Expedited Reporting Requirements as defined by the protocol
  - Anticipated to result in a reduction in adverse events incorrectly reported in an expedited fashion
- More user-friendly and incorporates the large body of community input received during the development of caAERS
- caAERS-Rave: uses the same rules engine and functionality of caAERS/CTEP-AERS but integrated into Rave for “one-stop shopping” for adverse event reporting

# CTEP-AERS Transition Timeline

- Training:
  - Began end of October 2013 and will continue as needed throughout 2014 and beyond
  - Standing trainings (3 per week) conducted beginning of December 2013
- Pilot:
  - October – December 2013
- CTEP-AERS open to full community for use in place of AdEERS for all relevant studies:
  - January 2014
- Required use of CTEP-AERS in place of AdEERS for all relevant studies:
  - March 2014
- Retirement of AdEERS front-end:
  - May 2014

# Transition Monitoring and Follow-up

- Continuous monitoring of usage statistics by CTEP Staff
- Beginning in February 2014, users will be contacted when they use AdEERS and reminded to use CTEP-AERS for their next SAE submission
  - Training offered with each contact
  - Will continue until AdEERS is retired

# CTEP-AERS Pilot

- Participating sites
  - Mayo Clinic Rochester
  - University Health Network-Princess Margaret Hospital
  - California Cancer Consortium
  - Tom Baker Cancer Centre
  - Highline Medical Center-Main Campus
- Start
  - October 25<sup>th</sup>, 2013
- Length
  - 2 months and/or ~20 SAE reports
- Feedback has been positive
  - Small bugs identified and fixed

# CTEP-AERS Training

- Training Webinars
  - Three standing timeslots available per week beginning December 2013 and continuing through the roll-out and beyond
- Online resources
  - Comprehensive Training Guide
  - Training Presentations
  - FAQ Document
  - Practice Application <https://betapps-ctep.nci.nih.gov/ctepaers/public/login>
- CTEP personnel available via email or phone
  - AEMD Help Desk (formerly known as the AdEERS MD Help Desk); [aemd@tech-res.com](mailto:aemd@tech-res.com), (301) 897-7497
  - Technical Help Desk for technical, application-related issues; [ncictephelp@ctep.nci.nih.gov](mailto:ncictephelp@ctep.nci.nih.gov), 1-888-283-7457
  - CTEP Staff as needed

# Protocol Amendments

- Will be treated as administrative amendments and may be done at any time prior to the retirement of AdEERS (May 2014)
- Language will be supplied in future correspondence to Lead Organizations via CTEP's Protocol & Information Office (PIO)

# What is not changing?

- AdEERS Reviewer, AdEERS Query Wizard (AQW)
  - These systems will remain in place at this time
  - All SAE reports will be accessible from these systems regardless of entry point (AdEERS, CTEP-AERS, caAERS-Rave)



NATIONAL<sup>®</sup>  
CANCER  
INSTITUTE

---