CTEP-AERS Introductory Presentation

SAE Reporting Data Entry Systems

- **AdEERS (Adverse Event Expedited Reporting System)**
  - Retiring entry point for all expedited adverse event reporting for all CTEP, CIP and some DCP trials.

- **caAERS (Cancer/caBIG 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 expedited AE reporting for all trials**
    - This includes all open **Rave and non-Rave** studies for the Groups/NCTN, ET-CTN, U01, N01s, etc.

- **caAERS-Rave Integration**
  - Future entry point within Rave for all adverse event reporting (expedited and routine) for **new** (start date TBD) Rave trials
  - Anticipated pilot early summer 2014, full roll-out fall 2014.

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Why CTEP-AERS/caAERS-Rave?

- Compliant with the FDA Final Rule

- Anticipated to save time and reduce workload

  – **Rules engine** allows the creation of expedited reporting rules including protocol specific exceptions (PSEs) to expedited reporting for each protocol based 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 **reduce** adverse event reports **incorrectly reported** in an expedited fashion

- More user-friendly and incorporates the large body of community input received during the development of caAERS

CTEP-AERS Resources

- Home Page
  - http://ctep.cancer.gov/protocolDevelopment/electronic_applications/adverse_events.htm
- Training Webinars
- Online resources
  - Comprehensive Training Guide
  - Training Presentations
  - Recorded Training Demo
  - 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, (301) 897-7497
  - Technical Help Desk for technical, application-related issues; ncictephelp@ctep.nci.nih.gov, 1-888-283-7457
  - CTEP Staff as needed

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CTEP-AERS Transition Timeline

- Training:
  - WebEx trainings (4-7 per week) ongoing
  - Recorded training available on CTEP Website

- Pilot:
  - October – December 2013

- **CTEP-AERS opened to full community to begin transitioning:**
  - **January 1, 2014**

- Required use of CTEP-AERS in place of AdEERS:
  - 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

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Amendments to AdEERS Reports

- All AdEERS Reports submitted to NCI can (and should) use CTEP-AERS for amendments

- CTEP-AERS has been loaded with all AdEERS data for the last 5 years
  - Please contact the CTEP Help Desk if you need to amend any AdEERS reports created more than 5 years ago

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Protocol Amendments

- Protocols do **NOT** have to be amended prior to using CTEP-AERS
  - Due by May 2014
  - Will be treated as administrative amendments and may be done at any time prior to the retirement of AdEERS

- Language (replace AdEERS with CTEP-AERS) and instruction supplied to Lead Organizations via CTEP's Protocol & Information Office (PIO) (~mid-January 2014)

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)
    - Any current reports you normally receive will remain the same