Fall 2020 SWOG ONCOLOGY RESEARCH PROFESSIONALS OPEN FORUM A Meeting – Virtual

SUMMARY

Date: Thursday, September 24, 2020
Time: 2:15 – 3:15 pm CT

Agenda:

Welcome

QA Audit and CAPA Presentation with Q&A

AE & SAE Presentation with Q&A

Conclusion and Evaluation Poll

Welcome
0:00:00
Deb Bergevin welcomed the group.

Noted any Chat questions they cannot get to will be answered and posted on the SWOG website, along with the presentation slides and handouts.

QA Audit and CAPA Presentation with Q&A

0:00:28

Bergevin introduced Elaine Armstrong, QA manager, SWOG Operations Office, to present on quality assurance (QA) audits, regulatory review, and corrective and preventative actions (CAPAs).

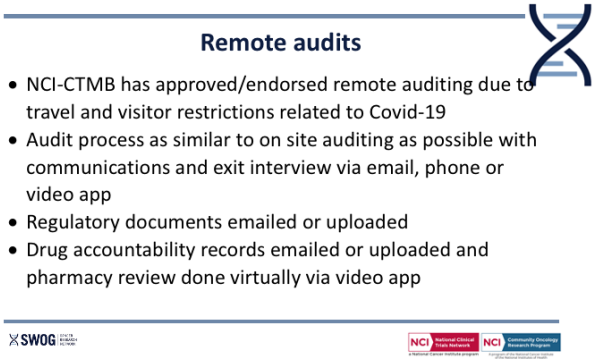
- Bergevin noted Armstrong is the go-to person for QA questions

Also introduced Heather Hillman, senior nurse auditor, SWOG Operations Office, for insights on proper CAPAs.

0:01:01

Armstrong said most in the group know SWOG has moved to remote audits.

- NCI Clinical Trials Monitoring Branch approved these, given travel restrictions
- Said NCI working on SOPs on this that will go out soon
- Armstrong noted the remote procedure is pretty similar to the onsite
  - But all communications through technology
- Regulatory docs emailed or uploaded
  - Not typically privacy concerns with these
- Drug accountability records also emailed or uploaded
- Been doing pharma reviews with videoconferencing



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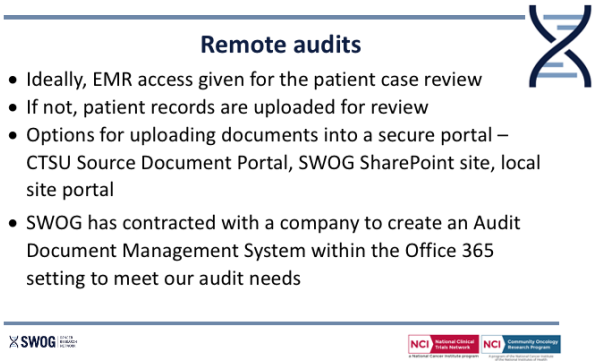
- Armstrong said giving her office access to the site's EMR system is most efficient
  - 1 year earlier most sites would have been unwilling to do this
  - Now about 50%
  - SWOG signs a privacy agreement
- If site doesn't want this approach, needs to upload the records
  - More work for site (and SWOG), but SWOG is flexible
  - Upload options:
    - CTSU Source Document Portal
    - SWOG SharePoint site



        - Been having glitches
        - Meeting next week to build dedicated audit system in SharePoint
    - Local site portal
- Largest remote audit thus far 25–30 cases
    - Armstrong said she would be reluctant to do remote audit for really large site with 75 or 100 cases
        - None this size on schedule until after first of year

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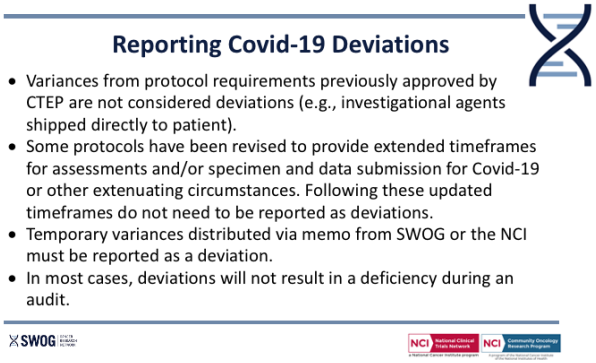
0:04:23
COVID-19 deviations

- Paper form provided months ago for sites to record deviations
- Now must be reported in Rave
- Get lots of questions about whether these deviations are major or minor

Armstrong provided guidelines

- Variances for protocol requirements that have been officially approved by CTEP are not deviations
    - E.g., shipping investigational agents direct to patients
- If protocol has been revised to extend timeframes (e.g., assessments or submission of data or specimens), those are not deviations and don't need to be reported
- Temporary variances via SWOG memos DO need to be reported
    - Not official protocol changes
- Armstrong reminded group that in almost all cases, deviations won't result in audit deficiency
    - Primarily a way for SWOG to collect important information



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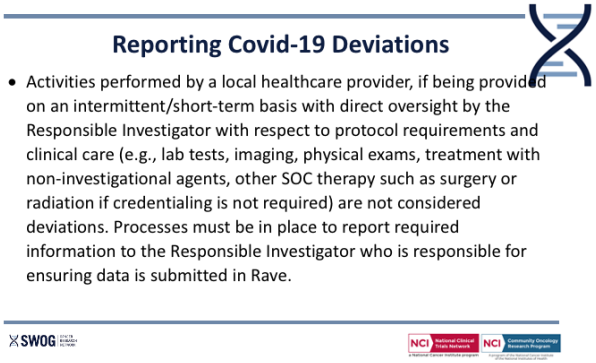
Armstrong provided guidance on specifics:

- Activities performed by a local healthcare provider
  - E.g., patient lives 4 hours away: okay for their labs to be done locally?
  - Not something new; just done infrequently in past
  - Not encouraged, but NCI says okay during COVID
    - Site investigator must still provide direct oversight
  - Examples of things that could be done by a local provider:
    - Labs
    - Imaging
    - Physical exams
    - Treatment with non-investigational agents
    - SoC therapy such as surgery or radiation
      - If no extra credentialing is required
  - These are not deviations
  - But site must have process to submit required information to research site so it can submit data
  - If a local provider is not cooperating after numerous requests, site should cease work with provider



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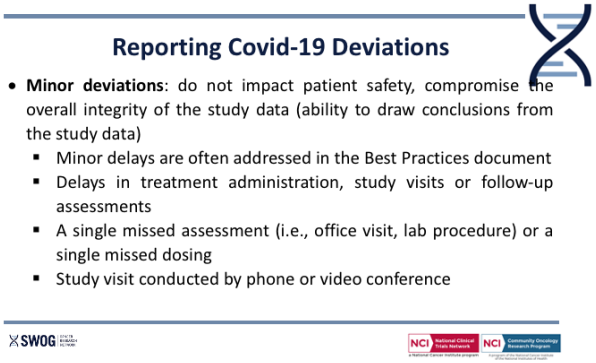
Minor deviations:

- Don't impact patient safety or compromise study data integrity
- SWOG has best practices document that includes windows for labs, treatments, etc.
  - If delay falls within best practices window, not a deviation
- Minor delays in treatment administration, study visits, or follow-up assessments will be lesser deviations
  - E.g., single missed lab or office assessment, or single day of treatment
- Study visits conducted by phone or videoconference are minor deviations



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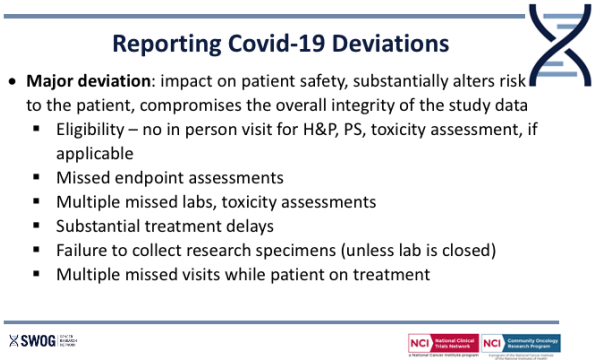
Major deviations:

- Those that could impact patient safety, increase risk, or affect overall data integrity
- NCI has issued guidance:
    - Visits for H&P, performance status, toxicity assessment that are needed to determine eligibility *must* be done in person
    - Failure to follow all eligibility criteria is a major deviation
    - Missed endpoint assessment is a major deviation
    - *Multiple* missed labs or toxicity assessments add up to major deviation
        - Becomes unsafe to keep patient on treatment if site misses assessments for many visits in a row
    - Failure to collect research specimens is a major deviation
        - Unless lab is shut down (some shut down temporarily)
    - Multiple missed visits while patient is on treatment is major deviation
        - More flexibility if patient is already in follow-up



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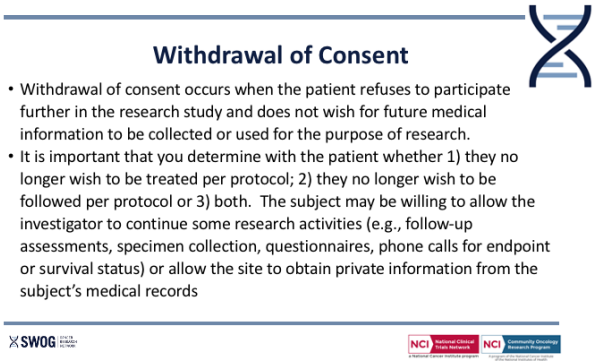
Armstrong discussed withdrawal of consent.

- Several issues have arisen over past couple of months
- Withdrawal of consent:
    - Patient refuses to participate further in the research and does not wish to have their future medical information collected for research
- If patient says they want to withdraw from study, important to have conversation with them to determine what exactly they want to withdraw from
    - Sometimes patients quit study treatment but are willing to be followed
    - May want to stop treatment but still be willing to come in for follow-up visits
    - May be willing to let their medical data be reported from their chart
    - May be okay with a once-a-year phone call
        - Survival is often an endpoint, so having basic follow-up data is important



- Very important to determine exactly what patient agrees to
- Also very important to document this in research record
    - Sometimes in audit they see one sentence saying patient withdrew consent with no other information
    - Not then sure whether process occurred as it should have

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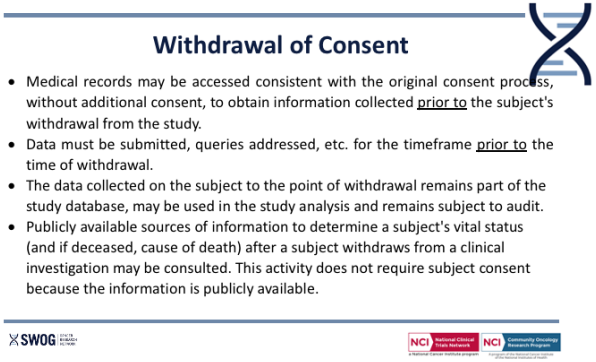
0:12:38

- If patient withdraws consent, medical records may be accessed consistent with original consent process without additional consent *to obtain information collected prior to subject's withdrawal*
    - If there's a query for site to submit information from time before the patient's consent withdrawal, site can collect and submit that data
    - All information up to withdrawal remains part of study database and can be used in study analysis
    - SWOG has had requests to remove a patient's data from the database:
        - Not allowed to do that
        - FDA states it's acceptable to keep data from before withdrawal
    - *Can* report patient data even after consent withdrawal date if obtained from *publicly available* data source
        - E.g., social security death index
    - Sites sometimes have local guidance on this topic
        - FDA and OHRP say this is okay
    - Have had situations in which site did not want to provide audit data for patient who had withdrawn consent
        - But data up to time of withdrawal stays part of study and is subject to audit
        - Can be very important information in final study analysis
            - E.g.., especially for registration study



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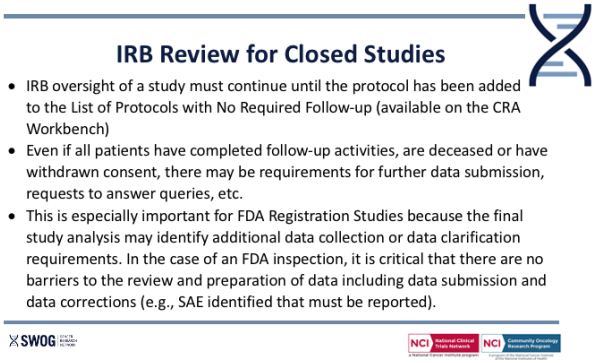
IRB review of closed studies

- Often sites ask to close out study with IRB because site is no longer following patients
    - Patients have completed follow-up or have withdrawn consent
- SWOG policy is that sites should maintain IRB oversight of a study until it is added to "List of Protocols with No Required Follow-up"
    - List is on CRA Workbench
- Important because even though a site is no longer following patients, may be need for clarification or need for additional information
    - If site has closed out study with IRB, it may not be able to submit requested data
- This is particularly important for FDA Registration Studies
    - Submission to the FDA often requires additional analysis with additional data or clarification
    - Site won't be able to submit that data if it has closed study with IRB
    - Example:
        - FDA does inspection and there is an SAE identified that had not been previously reported
        - Site needs to be able to submit this data



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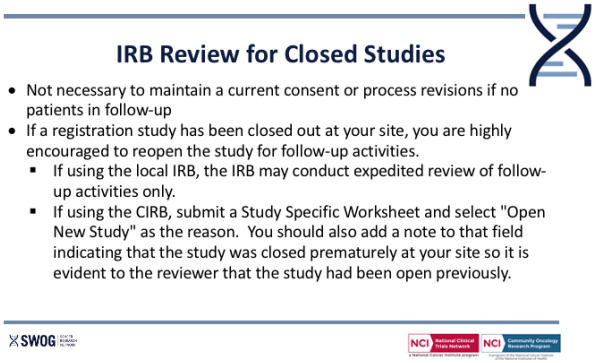
- Armstrong recognized it can be lot of work to submit for IRB review
    - But if not following patients, nothing to do except keep study open
        - With CIRB, really nothing to do
        - With local IRB, need only continuing review
            - Usually can be done by rolling study over to S9808
            - No need to maintain current consents or process revisions if no patients being followed
    - Exception happened few years ago:
        - Study revised to extend follow-up time
        - Patients had to be reconsented



- Especially for registration studies, if site has already closed study, highly encouraged to reopen the study for follow-up activities
    - For local IRB, site only needs to do expedited review for follow-up activity
    - For CIRB, submit Study Specific Worksheet and select “Open New Study” as reason
        - Then add note indicating that site closed study prematurely so CIRB is aware site had study open previously
        - Getting to final analysis on S1605 and have word that several sites have closed it
            - They had had it open with CIRB
            - Since little to no work to be done at site level, if using CIRB, SWOG doesn’t consider it a burden to site to keep study open

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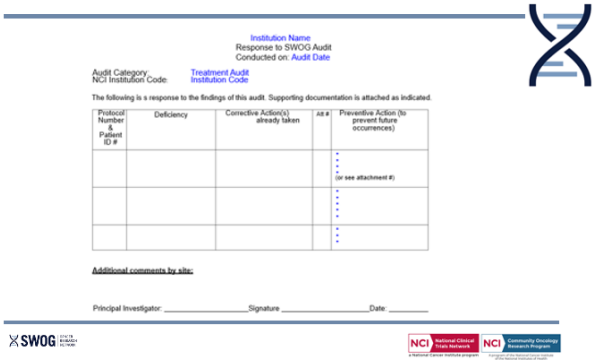
0:18:39
Armstrong introduced Heather Hillman to present on CAPA responses.

- An area often in need of NCORP guidance

0:18:57

Hillman said many CAPAs come to them: sometimes happy with them, sometimes not.

- Wanted to review what makes auditors happy and what does not
- Slide displays template sites will receive if they have to respond to audit deficiency
- Said there are multiple versions of this template
    - This is a plain one
    - Site needs to complete areas in blue
- Okay to cut and paste into template
    - With care


Institution Name
Response to SWOG Audit
Conducted on: Audit Date

Audit Category: Treatment Audit
NCI Institution Code: Institution Code

The following is a response to the findings of this audit. Supporting documentation is attached as indicated.

Protocol Number & Patient ID #	Deficiency	Corrective Action(s) already taken	Att #	Preventive Action (to prevent future occurrences)
				(or see attachment #)

Additional comments by site:

Principal Investigator: _____ Signature _____ Date: _____

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0:20:01

Hillman said SWOG wants sites to respond to *major* deficiencies only.

- Said she gets calls from sites that cannot tell from a report what it is SWOG wants them to address
    - Example, a major specimen deficiency
        - Located under data quality
    - But several other things also under data quality that are not things SWOG wants them to address


SAVE TIME AND EFFORT –

ADDRESS
MAJOR DEFICIENCIES ONLY

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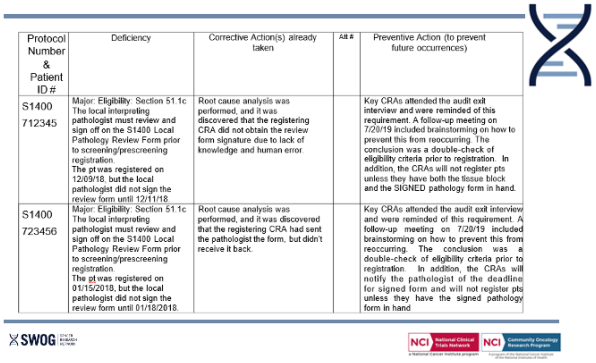
0:20:58

- Hillman said sites should look at report to identify major deficiencies to address
- Said she would send them email identifying pages to address
- Said example of CAPA on slide was well done
    - First page has two major eligibilities
    - Approximately same thing
        - Local pathologist signing off on S1400 local pathology review form
    - Under Corrective Actions, even though similar deficiencies, site has identified causes for each



Protocol Number & Patient ID #	Deficiency	Corrective Action(s) already taken	Att #	Preventive Action (to prevent future occurrences)
S1400 712345	Major: Eligibility: Section 51.1c The local interpreting pathologist must review and sign off on the S1400 Local Pathology Review Form prior to screening/prescreening registration. The pt was registered on 12/09/18, but the local pathologist did not sign the review form until 12/11/18.	Root cause analysis was performed, and it was discovered that the registering CRA did not obtain the review form signature due to lack of knowledge and human error.		Key CRAs attended the audit exit interview and were reminded of this requirement. A follow-up meeting on 7/20/19 included brainstorming on how to prevent this from reoccurring. The conclusion was a double-check of eligibility criteria prior to registration. In addition, the CRAs will not register pts unless they have both the tissue block and the SIGNED pathology form in hand.
S1400 723456	Major: Eligibility: Section 51.1c The local interpreting pathologist must review and sign off on the S1400 Local Pathology Review Form prior to screening/prescreening registration. The pt was registered on 01/15/2018, but the local pathologist did not sign the review form until 01/18/2018.	Root cause analysis was performed, and it was discovered that the registering CRA had sent the pathologist the form, but didn't receive it back.		Key CRAs attended the audit exit interview and were reminded of this requirement. A follow-up meeting on 7/20/19 included brainstorming on how to prevent this from reoccurring. The conclusion was a double-check of eligibility criteria prior to registration. In addition, the CRAs will notify the pathologist of the deadline for signed form and will not register pts unless they have the signed pathology form in hand.

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        - Identified what the problem was
    - Under Preventive Actions
        - If site says it will have a meeting to discuss, auditor wants to see a specific date for that meeting
        - If site says data will be reviewed, they want to know timeline
            - E.g., each patient quarterly, 10% of cases
            - Site should be specific about what it will do

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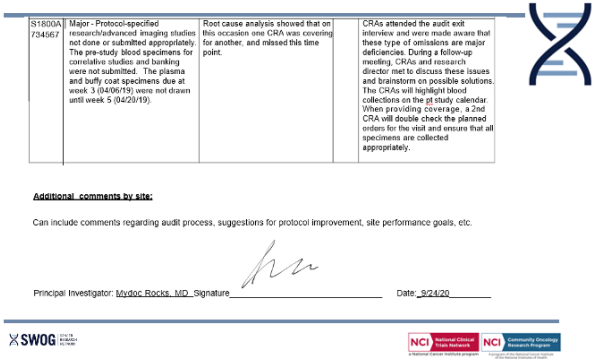
- Rest of the CAPA from previous page
- Includes PI signature and date
- Something auditors will review and say “perfect”

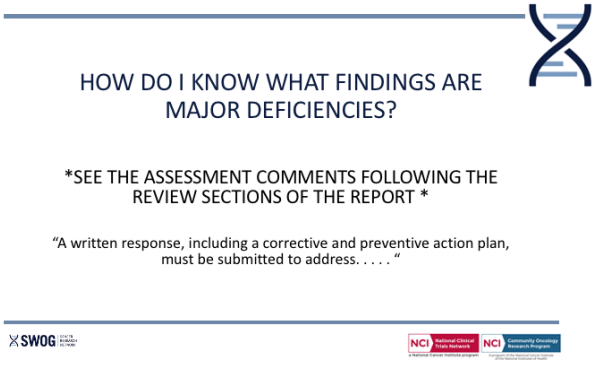


S1800A 734567	Major - Protocol-specified research/advanced imaging studies not done or submitted appropriately. The pre-study blood specimens for correlative studies and banking were not submitted. The plasma and buffy coat specimens due at week 3 (04/06/19) were not drawn until week 5 (04/20/19).	Root cause analysis showed that on this occasion one CRA was covering for another, and missed this time point.	CRAs attended the audit exit interview and were made aware that these type of omissions are major deficiencies. During a follow-up meeting, CRAs and research director met to discuss these issues and brainstorm on possible solutions. The CRAs will highlight blood collections on the pt study calendar. When providing coverage, a 2nd CRA will double check the planned orders for the visit and ensure that all specimens are collected appropriately.

0:22:59

Which findings are major deficiencies?

- See the assessment of this in review section after all deficiencies are listed
- There is a separate page with the assessment
    - Will usually say “A written response, including a corrective and preventive action plan, must be submitted to address …”
    - Will then tell you exactly what problem was with deficiency
    - Look for that phrase



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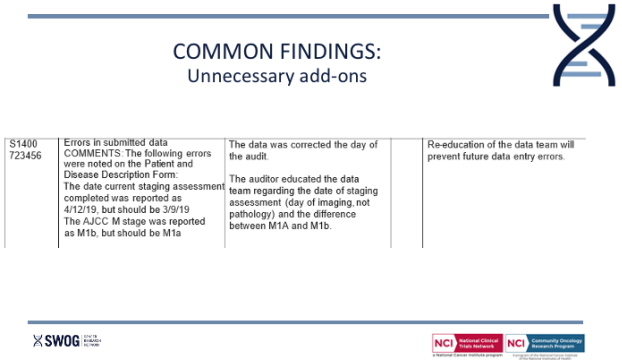
Common findings: Unnecessary add-ons

- Some common findings auditors don't like to see
- "Errors in submitted data"
- Sometimes there are so many errors that auditors will ask you to address these
- Most times auditor does not want site to address these unless it's specifically requested
- In this example, site addressed things that auditors included in report mostly for educational purposes
    - This happened, and we would like to see it corrected
- In example, site mentioned "re-education of data team"
    - Auditors need dates, who will attend, what content



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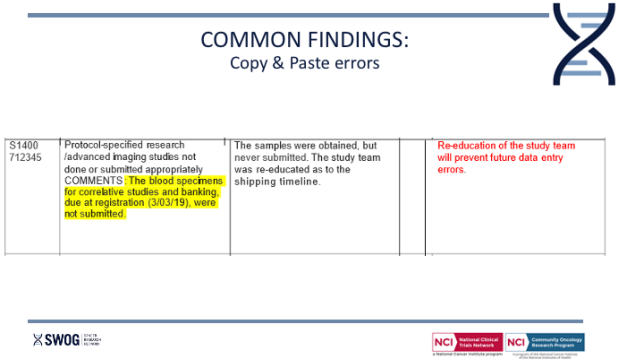
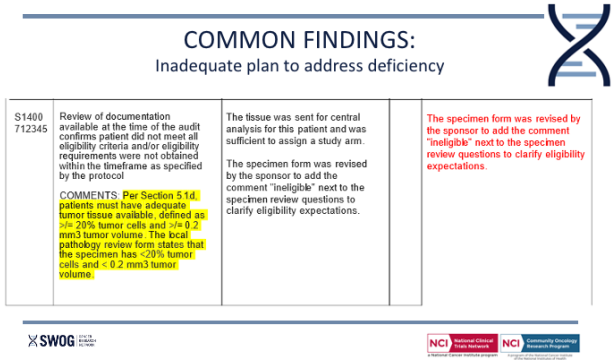
Common findings: Copy and paste errors

- Example in which site's major deficiency was blood specimens not submitted
- Site addressed major deficiency but also minor deficiency
    - But as they copied and pasted, put same response under preventive action
    - Does not address deficiency
- This report went back to writers for revision



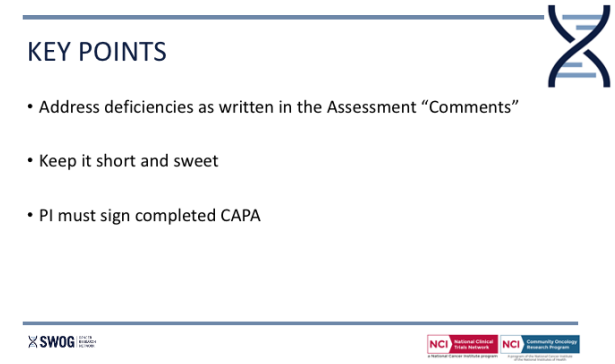
0:25:44
Common findings: Inadequate plan to address deficiency

- Example was major deficiency about local pathology review form not being signed
- Site said specimen form was revised (see slide)
    - Refers to change made in protocol
    - But this was not preventive action plan on site's part
    - Auditors want to know what *site* did
    - Protocols sometimes unclear, but still up to site to fulfill eligibility requirements



0:27:02
Key points

- Address deficiencies
    - Find in comments section of assessment
    - Written action plan is requested
- Keep it short and sweet
    - So auditors don't get things they don't want
    - Saves sites time
- PI must sign completed CAPA



0:27:49
Bergevin said there was time for questions.

For Armstrong: How are charts to be color-coded if uploaded?

- Armstrong replied that she had not yet had to work on patient chart that was uploaded
- Asked colleagues if there was way to color code them like paper charts
- Hillman [? 0:28:28] said closest thing they have is first document portal where they have categories
    - Audit folders: treatment, eligibility, inequality

    - Not sufficient right now, but do have color-coded tabs
- Armstrong said when docs are uploaded to SWOG SharePoint, SWOG creates a single folder
    - If NCORP, separate folder for each site
    - Perhaps SWOG should provide more tiered set of folders that say, e.g., eligibility, treatment, labs, …
    - Might help if SWOG had categories so sites could provide docs by category
- Hillman noted sites make their own breakdown when sending documents
    - Depends on how they have their charts organized
    - If sites label things, auditors can usually figure it out

Bergevin said that was all the time available for questions

- Would post answers to questions not addressed in session

AE & SAE Presentation with Q&A

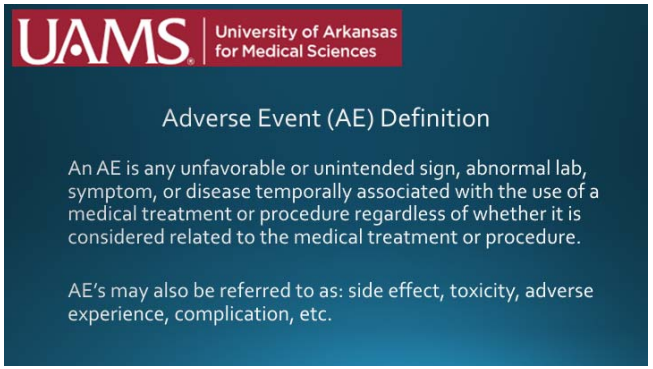
0:30:23

Bergevin introduced Kacie Simpson, assistant director of clinical research operations with U Arkansas for Medical Sciences, and Kari Williams, SWOG's SAE program manager, to present on adverse event (AE) and serious adverse event (SAE) reporting.

0:30:43
Simpson presented on AEs.

0:30:56
Simpson said an AE is any unfavorable or unintended sign, abnormal lab, symptom, or disease temporarily associated with the use of medical treatment or procedure, regardless of whether it's considered related to the medical treatment or procedure.

AEs may also be called side effects, toxicities, adverse experiences, or complications.



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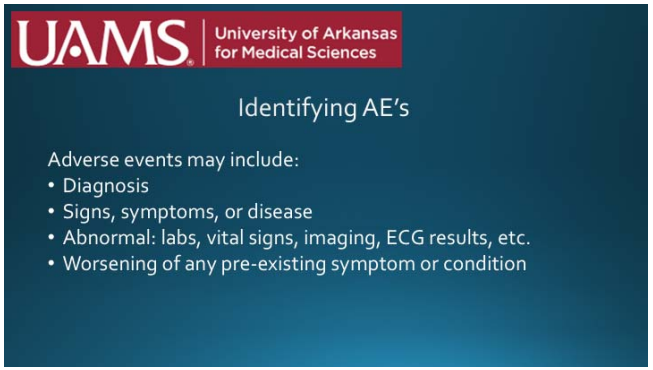
Simpson said an AE may be

- Diagnosis
- Sign or symptom
- Disease
- Abnormal lab, vital sign, testing results, or imaging
- Worsening of any pre-existing condition



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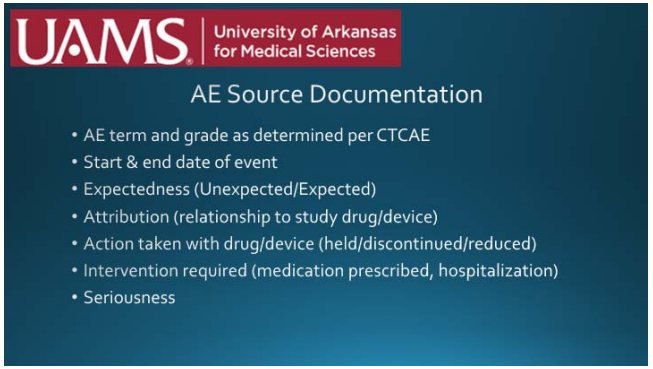
AE source documentation

- Items on slide are common data points for AE collection and case report forms
- Protocols that use CTCAE expect AE to be documented using most relevant CTCAE term
    - Start and end date of AE
    - Whether AE was expected per protocol
    - Whether AE was related to study
    - Any action taken due to AE
    - Intervention required
    - Whether AE was serious



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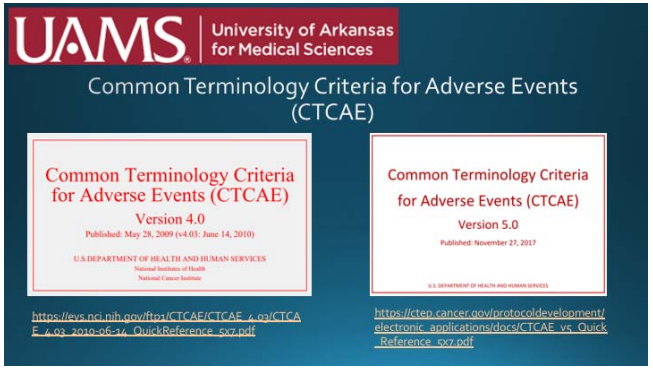
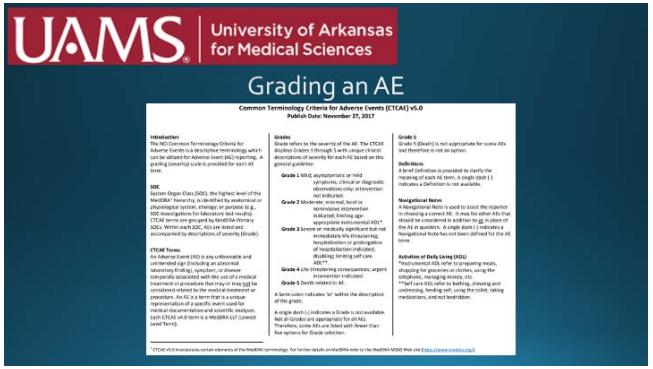
Common Terminology Criteria for Adverse Events (CTCAE)

- Used for coding AEs
- Version 5 is current version
    - Some older protocols still require AEs under previous version 4.0.03
    - Refer to protocol to determine version required
- Simpson highly recommended downloading the PDF of CTCAE
    - Will allow searching to find correct CTCAE term
- Saw on CTSU website recently that NCI is preparing for new version of CTCAE
    - Version 6 coming fall 2022
    - NCI asking for our input on changes
    - Check CTSU website for info



0:33:42
Grading an AE

- Second page of CTCAE provides overview on selecting an AE term and grading
- Simpson suggested that if list does not provide term that accurately describes an AE, user can refer to appropriate body system
    - Then select “other” and define AE term
- Lab AEs tend to have result ranges
- Non-lab AEs graded on clinical assessment

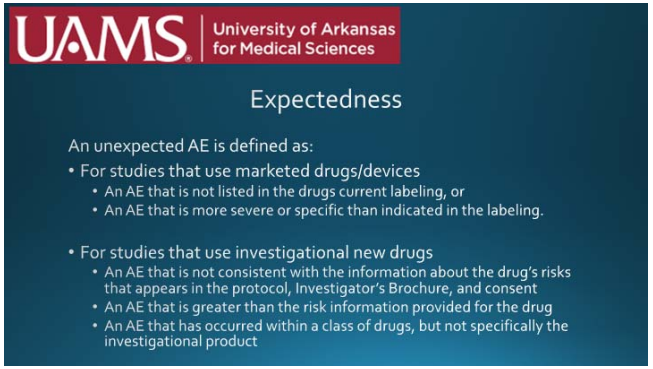


0:34:22
Event dates

- Need to document start date of event
- If subject is unsure, ask them for best guess
    - Ask if they know month or year AE began
- If event remains ongoing, should be continually assessed for improvement, worsening, or resolution
- If AE is resolved, resolution date should be documented
- AEs are followed until
    - Resolution
    - Return to baseline
    - Death
    - End of study per protocol

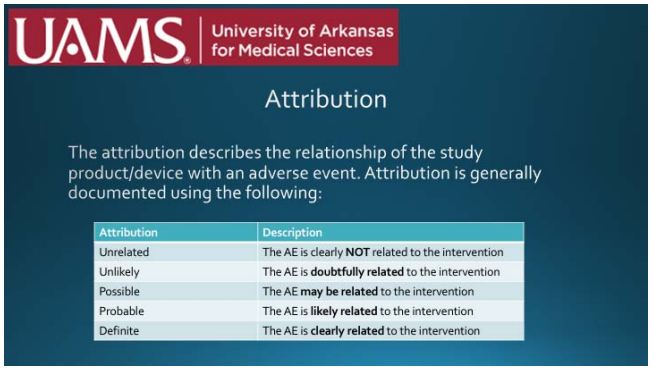
0:35:13
Expectedness

- Unexpected AEs are
  - Those not listed in marketed drug labeling
  - Those more severe than indicated in labeling
  - Those not consistent with information in protocol, investigator's brochure, or consent form
  - Those that occurred within class of drugs but not specifically the investigational product



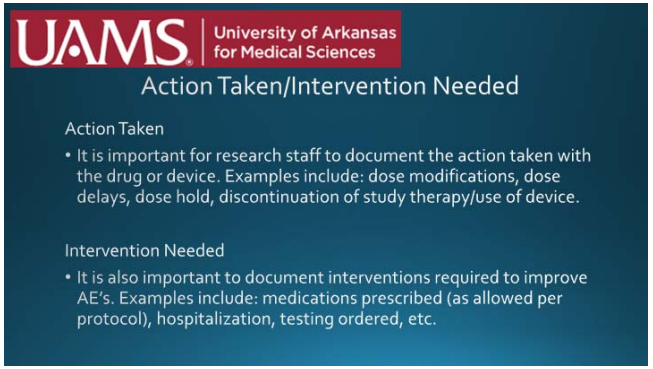
0:35:41
Attribution

- AE attribution describes relationship of study intervention to AE
- Attribution typically documents relation to intervention as
  - Unrelated
  - Unlikely
  - Possible
  - Probable
  - Definite



0:36:03
Action taken

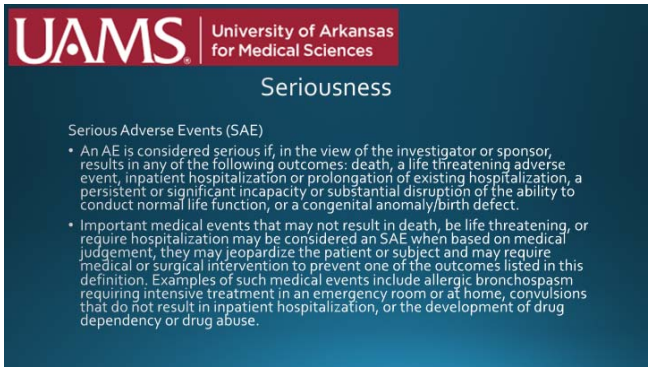
- Important to document action taken with study intervention or if intervention was needed
- Actions include
  - Dose delays
  - Holds
  - Modifications
  - Discontinuations
- … of study intervention
  - Medication prescribed



- Test ordered
- Hospitalization required

0:36:30
Seriousness

- Very important to document seriousness of AE
- AE considered an SAE if
  - If it is life threatening, requires hospitalization, or prolongs hospitalization
  - If it persistently or significantly disrupts the ability to conduct normal life functions
  - If it results in a congenital anomaly or birth defect
  - Or if it results in death
- AEs that may require medical or surgical intervention to prevent one of the indications above may also be considered SAEs
- Examples of SAEs include
  - Allergic reactions
  - Convulsions
  - Development of drug dependency and abuse

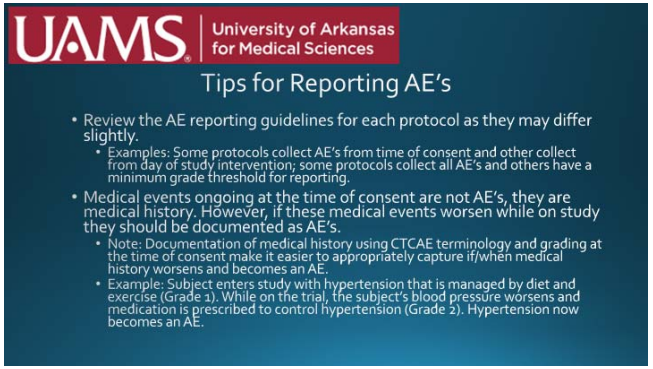


Simpson noted presenter Kari Williams would discuss SAEs in more detail.

0:37:32

Tips for reported AEs

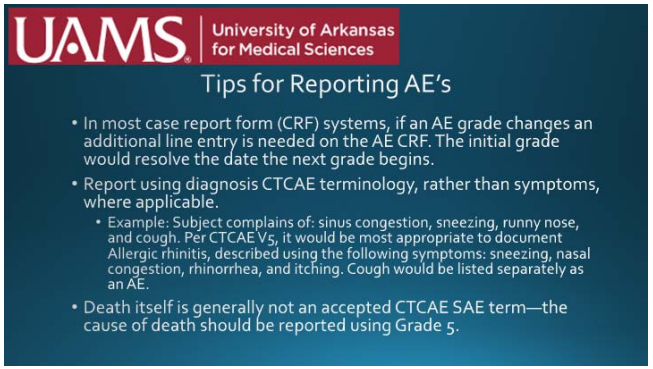
- Review AE reporting requirements for all protocols, as they may differ by protocol
    - Some protocols collect from the time of consent
    - Others collect from the start of intervention
- Determine whether all AEs are collected or just those of a certain grade or relationship to intervention
- Is an event medical history or an AE?
    - Events ongoing at time of consent are medical history
    - However, if event worsens while patient is on study, that becomes an AE
    - Simpson noted her site documents medical history using CTCAE terminology and grading at time of consent
        - Makes it much easier to document if event worsens
    - Example: Patient enters study with grade 1 hypertension managed by diet and exercise
        - While on study, patient's hypertension worsens and medication is prescribed to control it
        - This increases the grade to grade 2
        - Grade 2 hypertension becomes an AE



0:39:06

More tips

- Most case report form (CRF) systems require an additional entry when an AE grade changes
    - To record this, must first resolve initial AE
    - Then use date next grade begins as resolution date for initial AE
- Best to report using a diagnosis CTCAE terms rather than listing all of the symptoms, if possible
    - Example:
        - Subject complains of sinus congestion, sneezing, runny nose, and cough



        - Per CTCAE version 5, would be documented as allergic rhinitis, which is described using all of those terms
        - However, the cough is not part of that description for allergic rhinitis
            - Thus, that would be listed as a separate AE term
- Death is generally not an accepted CTCAE term
    - Cause of death should be reported, using grade 5 where applicable

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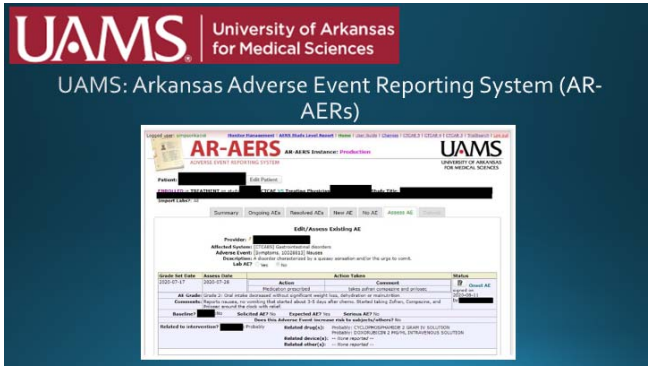
0:40:23
Screenshot of UAMS AE reporting tool: Arkansas Adverse Event Reporting System (AR-AERs)



- System allows documenting all components of AEs and SAEs discussed above
- Is 21CFR-11 compliant
- Has audit trail
- Investigators can review, edit, enter, and sign off here
- Able to give view-only access to monitors and auditors so they can review AEs
- Using this system to collect all elements of AEs has drastically reduced paper usage in office
- Also reduced number of queries
    - Simpson said in previous system they collected basic information in EMR and would have to find physician to get additional AE information
    - Current system allows all to be captured in one location

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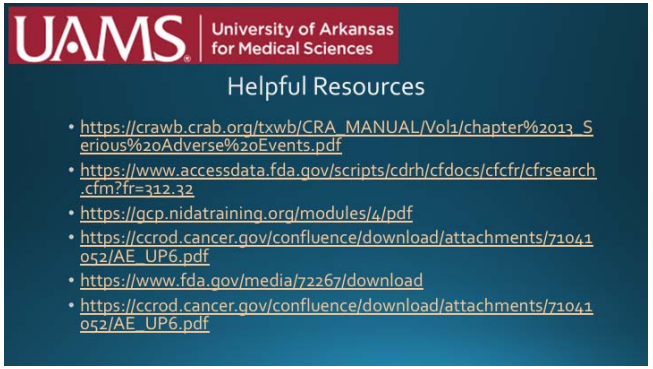
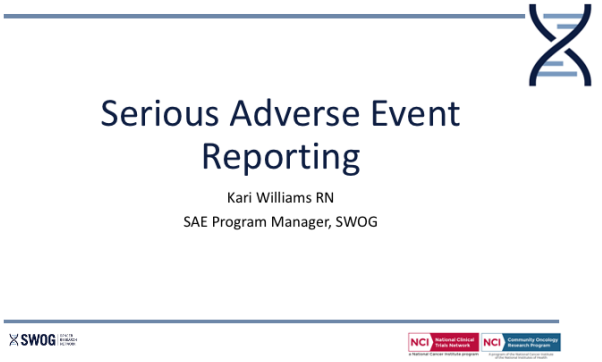
0:41:37
Resources

- Simpson said the slide contained helpful links she found in preparing presentation
- Believed these would be provided in a handout

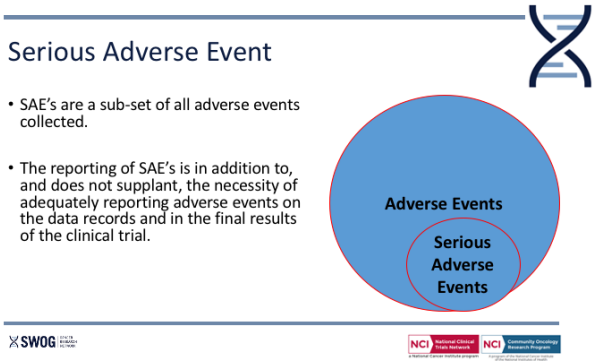


0:41:57
Kari Williams presented on SAE reporting.



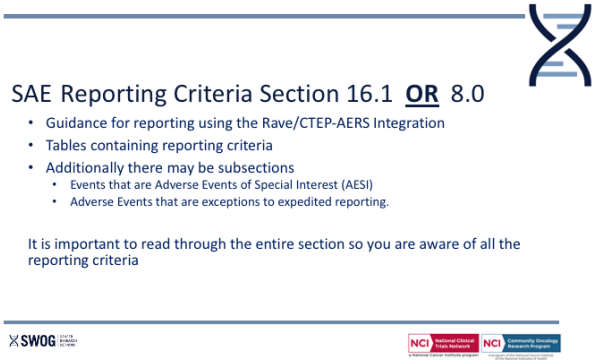
0:42:05
Williams said that when collecting AEs, sites always want to be reviewing to identify those that are also SAEs.

- SAEs are subset of AEs



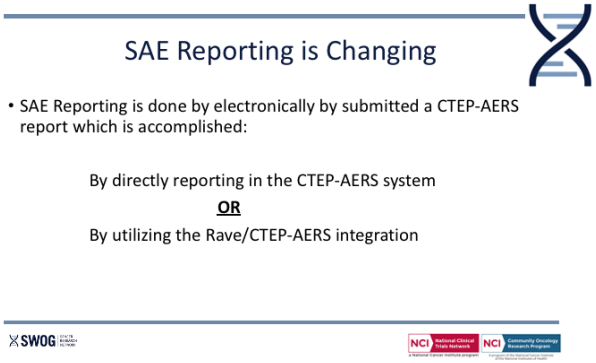
0:42:30
SAE reporting criteria

- Protocol section 16.1 or section 8 will have SAE recording criteria
- Move of these criteria to section 8 is recent
    - So for now will have protocols with both
- Will find guidance there for using Rave/CTEP-AERS Integration to record SAEs, if it applies to protocol
    - Does for most new protocols
- Will include tables for general reporting criteria
- Williams said users would also want to carefully review it for additional subsections that list exceptions
    - Sometimes for things that don't need to be reported through expedited reporting
- Will also list AEs of special interest
    - Often regardless of grade or attribution these are to be reported on expedited reporting form



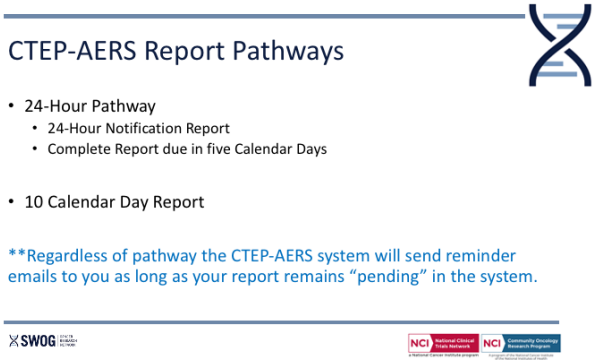
0:43:43
Changes

- Reporting is changing
- Older protocols allow going just to CTEP/AERS to report
- Newer protocols use integrated system
    - Start in Rave
    - Complete appropriate AE form for appropriate treatment cycle
        - It then moves all that information to CTEP/AERS system to finish report



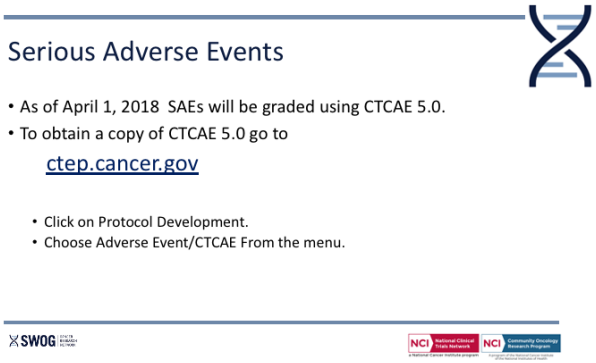
0:44:21
Pathways

- Williams reminded group of 2 reporting pathways
  - 24-hour pathway
    - Creates 2 reports
    - First is 24-hour notification
      - When submitted, creates copy of report due in 5 calendar days
      - Allows you to report information rapidly and complete details as they are available
      - If you don't complete both reports, it will drop out of system as unsubmitted and will take everything with it
  - Regular 10-day calendar report
- For both pathways, system sends emails reminding you of reports pending
  - Once a report times out of system, it can't be retrieved
  - Would have to start over



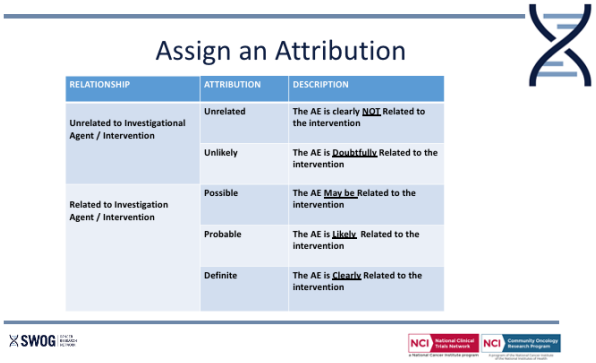
0:45:43
SAEs are reported using version 5 of CTCAE

- Version loaded in CTEP/AERS system
- No need to choose it
- In some older protocols, may have AEs in older version
- But all SAEs reported in version 5



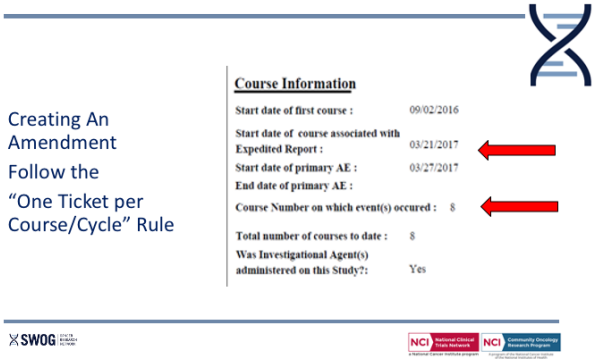
0:46:16
Attribution

- Table reiterates assignment of attribution
- PI will be doing this with all information you provide



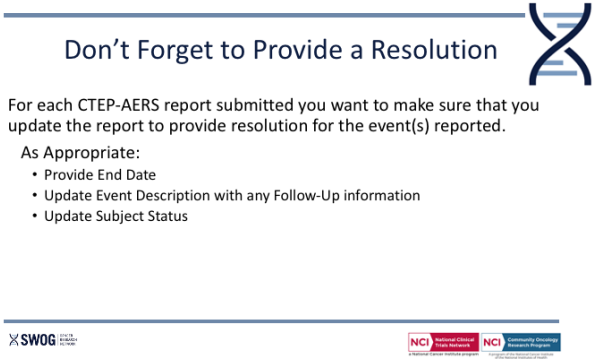
0:46:29
When to create amendment vs a new report

- Follow NCI guidance: One ticket per course or cycle of treatment
  - If you submitted a report and patient has another SAE but you know you've already submitted a report, always refer back
  - Want to look at the start date of the course you associated last report with
  - If same course or cycle of treatment, simply amend that report
  - True even if it is another admission for something completely different
  - Will all be consolidated in one ticket



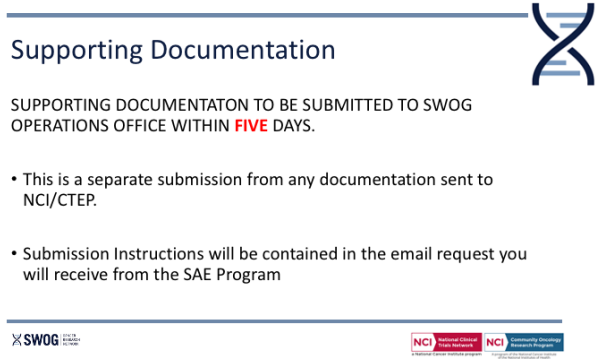
0:47:31
Don't forget resolution

- Should provide resolution on SAE report whenever possible
- Always make sure to circle back and update
- Provide end dates for events, if you can
  - Sometimes there is not an end
- Give any follow-up information
- Update subject status
  - Good practice and will save you work
  - Updating it years down the road can be difficult



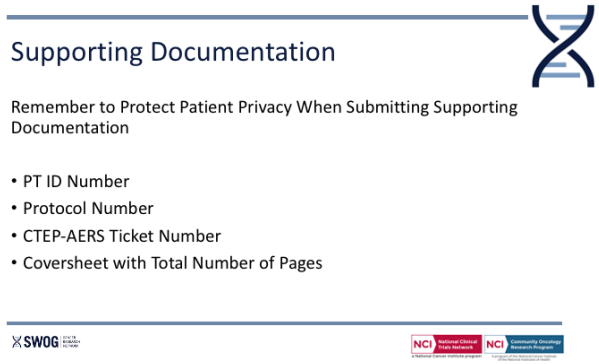
0:48:17
Documentation

- For protocols requiring documentation for review, you will get email from either Williams or Patti Felts
    - After they review your report and complete submission they will send email requesting supporting documentation
- They try to tailor it to make clear what they're asking for
- But it is any clinical information you have that supports the report you submitted
- They supply you with contact information to send it to



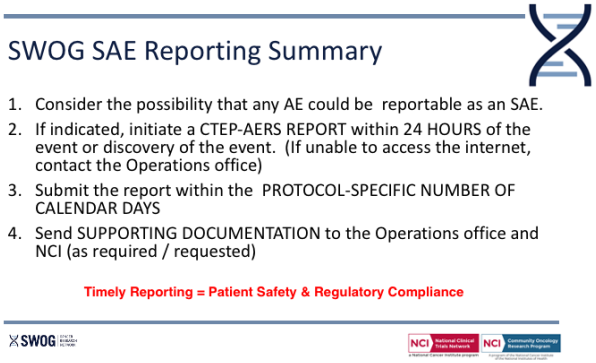
0:48:58

- Remember to put patient ID, protocol number, ticket number, cover sheet (to indicate number of pages)
    - Include first page of report so they can be sure to associate documentation with right report



0:49:30
Summary of SAE reporting

- As you collect AEs, consider SAEs
- Consult protocol
- Report as indicated
    - 24-hour or 10 calendar day
    - Good idea to report within 24 hours of learning of SAE
    - They understand that sometimes you don't know right away
    - They look at date you were first aware
    - But you want to start report within 24 hours
    - Get submitted ASAP
- Send supporting documentation as quickly as possible so report can be reviewed



0:50:33
Questions

Bergevin relayed questions.
For Simpson:
Are concomitant medications considered "intervention"? If so, should the intervention box be checked on the CTEP-AERS CRF if already entered as a concomitant medication?

- Simpson said her gut response was yes, as it would tie AE to con-med prescribed for that specific event

Is the AE program something UAMS created or is it based through a tech company?

- Simpson replied it's a UAMS program

Will all slides be available after webinar?

- Bergevin said yes, would be posted to SWOG website

Bergevin said these were all the AE/SAE questions, so she wanted to return to remaining questions on audits and CAPAs.

Are uploaded documents still de-identified since they wouldn't be if the audit was on site?

- Armstrong said CTSU audit source document portal asks sites to de-identify data
- CTSU system will do it for you, but she's not sure how well that works
- Said technically they don't have be de-identified, if they're in secure portal, because SWOG auditors have permission to have access to that data
- However, most sites have policies requiring it
- If site doesn't require it, SWOG doesn't

Has SWOG been presented with the EPIC CareLink contract by any sites? Is this something SWOG is willing to sign?

- Armstrong did not know answer, but thought there was a good chance they have
- Said most remote audits are for registration studies
    - Most nurse auditors working alone on those audits
    - They are the ones that have signed most contracts
- Armstrong has been involved in only 2 remote audits
- But they have access to Epic for many cases
- Simpson noted that her site uses Epic CareLink
    - Believed her Lung-MAP studies have used it for auditing
- Armstrong said this makes her suspect they have signed it

Are temporary allowances that impact eligibility criteria major or minor deviations?

- Armstrong replied this was in reference to memos
- Those spelled out in those memos as temporary allowances would be minor
- Versus blatantly not meeting criteria

Bergevin read out a submitted question about patients lost to follow-up:
How many times should we contact a patient (without successfully contacting them) before we consider them as lost to follow-up?

- Armstrong said response to this is posted on CRA Workbench
- She believed it is 4 times, but not certain
- CRA Workbench has "lost to follow-up" link

Any suggestions for methods of trying to contact patients?

- Armstrong suggested questioner ask that of someone at another site who would have more experience with that

For CAPA, can reeducation alone be preventive action plan?

- Armstrong said it depends
    - For audits that go well in which there's only one major deficiency, this might be an appropriate response
    - But for something that had occurred multiple times, this would not be sufficient

Bergevin read some comments from the Chat.

(Re: upload of redacted information to SWOG website for remote audit:)
Tiered folders would save sites time for creating their own. Most sites don't have electronic patient charts and would be starting from scratch.

- Armstrong said was good to know
- Would have call tomorrow on updating auditing SharePoint site and would bring up this point

Bergevin read out a tip:
There are some good apps for CTCAE grading in searchable mobile format.

Bergevin thanked presenters, attendees, and IMS techs.

- Reminded attendees to check SWOG website for slides, handouts, and answers to Chat questions

Conclusion and Evaluation Poll
0:58:51

Bergevin asked attendees to complete the evaluation poll (shown below).

Open Forum Poll Questions for Session A:

• *Overall, the QA Audit and CAPA topics are applicable to my current work.*
1 = strongly agree 2 = somewhat agree 3 = somewhat disagree 4 = strongly disagree

• *The presenters were effective and knowledgeable about the topics.*
1 = strongly agree 2 = somewhat agree 3 = somewhat disagree 4 = strongly disagree

• *Overall, the AE and SAE Reporting topic is applicable to my current work.*
1 = strongly agree 2 = somewhat agree 3 = somewhat disagree 4 = strongly disagree

• *The presenters were effective and knowledgeable about the topics.*
1 = strongly agree 2 = somewhat agree 3 = somewhat disagree 4 = strongly disagree

• *What topics would you like to see at future Open Forums? (Open text field)*

• *Additional Comments: (Open text field)*

0:59:10
Meeting adjourned.