Jeopardy

RECIST	AE'S	PROTOCOL	CONSENT	MISC
$100	$100	$100	$100	$100
$200	$200	$200	$200	$200
$300	$300	$300	$300	$300
$400	$400	$400	$400	$400
$500	$500	$500	$500	$500

RECIST- $100

- Question: All measurable lesions up to maximum of 2 lesions per organ and 5 lesions total are considered what?

- Target Lesions

RECIST- $200

- Question: A 20% increase in the sum of target lesions when compared to the smallest sum reported AND a greater than or equal to 5mm increase over that sum and/or presence of new lesions are considered what?
- Progressive Disease

RECIST- $300

- Question: Small lesions (longest diameter <10mm or lymph nodes ≥ 10 to < 15mm short axis) and all other lesions, including bone lesions and pleural effusions are considered what?

- Non-measurable disease/lesions

RECIST- $400

- Question: Lesions that can be measured in at least 1 dimension as ≥ 10mm by CT scan are considered what?

- Measurable disease/lesions

RECIST- $500

- Question: A 30% decrease in the Sum of Target Lesions when compared to the baseline sum AND a response of non-PD in non-target lesions are considered what?

- Partial Response

AE's- $100

- Question: Who is the person responsible for attributions of adverse events?

- Treating Investigator

AE's- $200

- Question: What are adverse events that are considered "expected" and their presence/absence should be provided and graded for each cycle of treatment?

- Solicited

AE's- $300

- Question: What new guidelines went into effect April 1, 2018 but, should not be used until specified by the study protocol?

- CTCAE Version 5.0

Daily Double: What does CTCAE stand for?

Answer: Common Terminology Criteria for Adverse Events

AE's- $400

- Question: How many days do you have to submit a CTEP-AERs Report?

- Protocol specific-depends on grade and hospitalization (24 hour 5 calendar days to 10 calendar days)

AE's- $500

- Question: What is the section of the protocol that gives protocol specific exceptions to expedited reporting?

- SPEER portion of the CAEPR

Protocol- $100

- Question: Name 2 places to find the type of allowed imaging and when the imaging is required.

- Test Schedule and Imaging section of the protocol

Protocol- $200

- Question: Where would you find contact information for protocol specific questions?

- First several pages of the protocol, (e.g title page) and the protocol page on the Alliance website

Protocol- $300

- Question: Name two places where can you find lab clarification within a protocol?

- Test schedule footnotes and specimen submission section of the protocol.

Protocol- $400

- Question: Who is ultimately responsible for determining if a patient is eligible for a trial?

- Treating Investigator

Protocol- $500

- Question: Where can you find pill diaries, Performance Status Scale, and other study specific forms?

- Within the Appendix of the protocol and the protocol page on the Alliance website

Consent- $100

- Question: The document that allows researchers and research staff to use and disclose a patient's health information is called what?

- HIPAA (Health Insurance Portability and Accountability Act)

Consent- $200

- Question: Name two places where the "signed" consent form should be?

- Original in Patient Chart (EMR and/or Research folder)
- Copy with patient

Consent- $300

- Question: Name 5 sections within a consent.

Usual approach
Other choices
Why is this study being done
What are the study groups
How long will I be in the study
Possible risks
Signature block

More information
Injury
Rights
Costs
Possible benefits
Questions
Optional research

Consent- $400

- Question: Name 3 key components to a consent dictation (not including sections of the consent form).

- Name of study (with no acronyms)
- Adequate time
- Reviewed and signed before sedation
- Reviewed and signed prior to study procedures
- Copy given to patient

Consent- $500

- Question: Name 3 things that need to happen before you are granted permission to consent a patient to a clinical trial.

- CITI training completed
- Listed on the Delegation of Authority
- Rostered on the NCORPSYS
- Listed in the RCR
- Trained properly to consent patients

Misc.- $100

- Question: The proper way to correct an error on a study document is how?

- Single strikethrough, initial and date

Daily Double:

What shouldn’t you do when correcting an error?

Never use white-out and/or never write over.

Misc.- $200

- Question: Name 2 places you can look to see if a specimen should be sent on dry ice or ambient.

- Specimen collection and submission section of the protocol
- Lab manual (if provided)

Misc. - $300

- Question: Name 2 places where you can find out if the study drug is provided.

- Drug information section of the protocol
- Protocol title page
- CTSU website study agent tab
- Consent

Misc.- $400

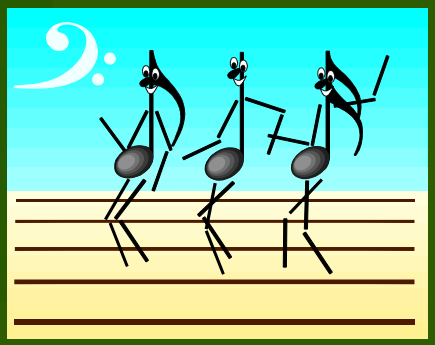
- Question: List 3 types of identifiers that are required to be removed in order to be considered "de-identified".

- Name
- Date of birth, admissions, discharge, or death
- All geographic subdivisions smaller than a state
- All ages over 89
- Numbers: telephone, fax, SSN, and email
- Medical record number, accounts, license number, vehicle identification number
- Device identification
- Internet protocol IP addresses

Misc.- $500

- Question: What are the names of the two presenters for today's presentation?

- Kristin Honer and Tammie Mlodozyniec



Questions?