1. What is the main focus of Good Clinical Practices (GCP)?
2. A. harmonized data collection
3. B. standard analysis practices
4. C. protection of subjects
5. D. standard monitoring practices

**Answer: C. protection of subjects**

1. Specify the role which focus on the observation (such as the name of a lab test) of a SDTM data set?
2. Identifier
3. Topic
4. Timing
5. Qualifier

**Answer: B. Topic**

1. Concomitant/Prior Medications (CM) is a component of which SDTM class?
2. Findings
3. Interventions
4. Events
5. Special Purpose

**Answer: B. Interventions**

1. What is the primary purpose of programming validation?
2. Ensure that the output from both the original program and the validation program match.
3. Efficiently ensure any logic errors are discovered early in the programming process.
4. Justify the means used to accomplish the outcome of a program and ensure its accurate representation of the original data.
5. Document all specifications pertaining to programmed output and ensure all were reviewed during the programming process.

**Answer: C. Justify the means used to accomplish the outcome of a program and ensure its accurate representation of the original data.**

1. Why is the Demographics (DM) domain required for all human clinical trials regulatory submissions?
2. It is a Findings domain that contains subject-related data not collected in other domains
3. It is the parent domain for all other observations for human clinical subjects.
4. It is a Findings domain that contains general subject characteristics about demography.
5. It contains the actual order of elements followed by the subject.

**Answer: B. It is the parent domain for all other observations for human clinical subjects.**

1. Which statement is correct regarding Intention-to-Treat Population?
2. Primary analysis should include all randomised subjects.
3. Primary analysis should include all randomised subjects and a subject should take a single study drug.
4. Primary analysis should include enrolled subjects.
5. Primary analysis should include subjects who have taken at least a single study drug.

**Answer: A. Primary analysis should include all randomised subjects.**

1. Exposure data pertaining to body temperature associated with a fever should reside in which SDTMIG domain?
2. Exposure (EX)
3. Clinical Events (CE)
4. Adverse Events (AE)
5. Vital Signs (VS)

**Answer: D. Vital Signs (VS)**

1. Topic variable for the Interventions and Events General Observation Class model is often stored as \_\_\_\_\_\_\_
2. Standardized Value (AEDECOD, MHDECOD)
3. Modified Value (CMMODIFY, PEMODIFY)
4. Verbatim Value (AETERM, CMTRT)
5. Original Value (AEORRES, MHORRES)

**Answer: C. Verbatim Value (AETERM, CMTRT)**

1. What is the maximum character limited allowed for ARMCD variable?
2. 8 characters
3. 20 characters
4. 40 characters
5. 200 characters

**Answer: B. 20 characters**

1. Which date/time determines the population of the EPOCH variable if included in a general observation class domain?
2. Start date/time of an observation or collection date/time
3. Reference time point date/time
4. Disease milestone instance date/time
5. Planned start or end of assessment interval, as appropriate

**Answer: A. Start date/time of an observation or collection date/time.**