

- **Question: Will the polling Q&A be posted with the slide set?**  
-Answer: We will include polling questions and answers via a Q&A document which we will provide.

**Poll Questions:**

1. **A patient no showed their C3D15 visit, a required timepoint per protocol. Is this a protocol deviation?**

Correct Answer: Yes, the C3D15 visit was a required timepoint, and it did not occur; therefore, the protocol was not followed as written.

2. **A patient experienced an adverse event while on protocol treatment. Is this a protocol deviation?**

Correct Answer: No, patients experience adverse events routinely on SWOG protocols.

3. **A patient missed their appointment due to a snowstorm. Is this an audit deficiency?**

Correct Answer: No, we understand that you cannot control the weather or patient compliance.

4. **A patient missed their appointment due to a snowstorm. Is this a protocol deviation?**

Correct Answer: Yes, it is a deviation since the protocol was not followed as written.

5. **A patient demanded to reschedule their treatment due to an upcoming vacation. Is this a protocol deviation, audit deficiency, neither, or both?**

Correct Answer: Protocol deviation since the protocol was not followed as written. No audit deficiency since the patient decided to delay treatment.

6. **Informed consent was not signed by the patient until two hours after registration. Is this a protocol deviation, audit deficiency, neither, or both?**

Correct Answer: Both. The protocol was not followed, and the patient's consent was not documented prior to registration.

7. **Patient has received prior anti-cancer treatment that is specifically excluded in eligibility criteria. Is this a protocol deviation, audit deficiency, neither, or both?**

Correct Answer: Both. The protocol was not followed, and the patient may be at greater risk if they continued protocol treatment.

8. **During a lab draw, a patient stated "Nope. You won't get another tube from me today." Is this a protocol deviation, audit deficiency, neither, or both?**

Correct Answer: Protocol deviation since the protocol was not followed. This is not an audit deficiency since the patient refused.

9. **Patient experienced Grade 3 colitis following C1D15 treatment, but C2D1 treatment was not held/reduced per protocol. Is this a protocol deviation, audit deficiency, neither, or both?**

Correct Answer: Both. The protocol was not followed, and the patient was put at risk by not modifying the dose per protocol.

10. **Baseline data was entered into Rave 124 days after registration. Is this a protocol deviation, audit deficiency, neither, or both?**

Correct Answer: Both. SWOG protocols do list timeframes for data submission. 124 days is outside of that window. Baseline data entered into Rave > 3 months after registration is also considered a major deficiency at audit.