

Pearls of Wisdom: Patient Case Review

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Patient Case Review: Common Problems

- Incomplete or expired consent document signed by patient.
- Eligibility criteria are not met.
- Treatment is not given per protocol instructions.
- Cannot verify treatment adherence with oral medications.
- Failure to evaluate response according to the protocol.
- Failure to assess & report adverse events according to protocol.
- General data quality issues (timeliness, complete, correct).

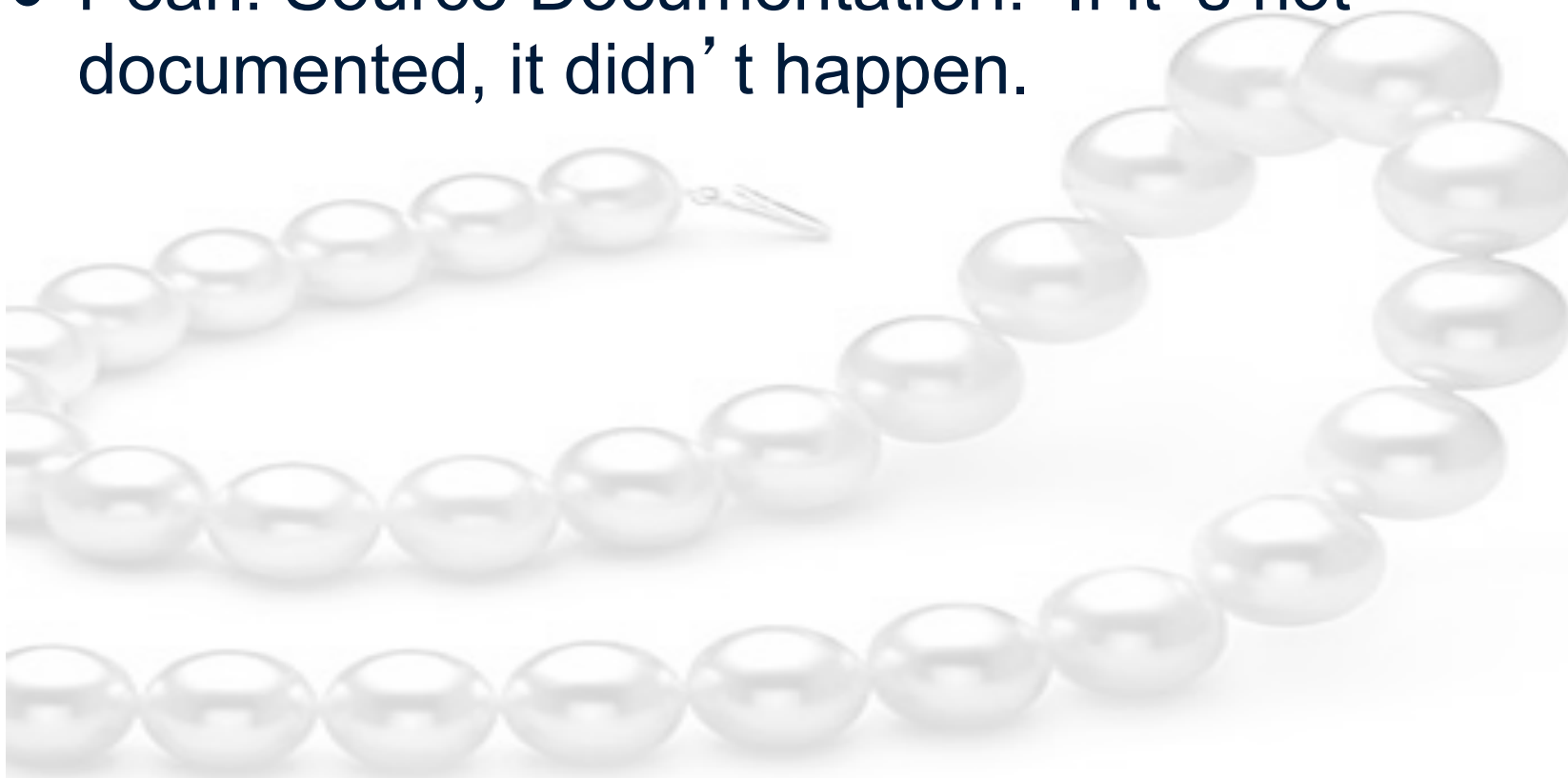
Incomplete or expired consent document signed by patient

- Pearl: Complete and Verify



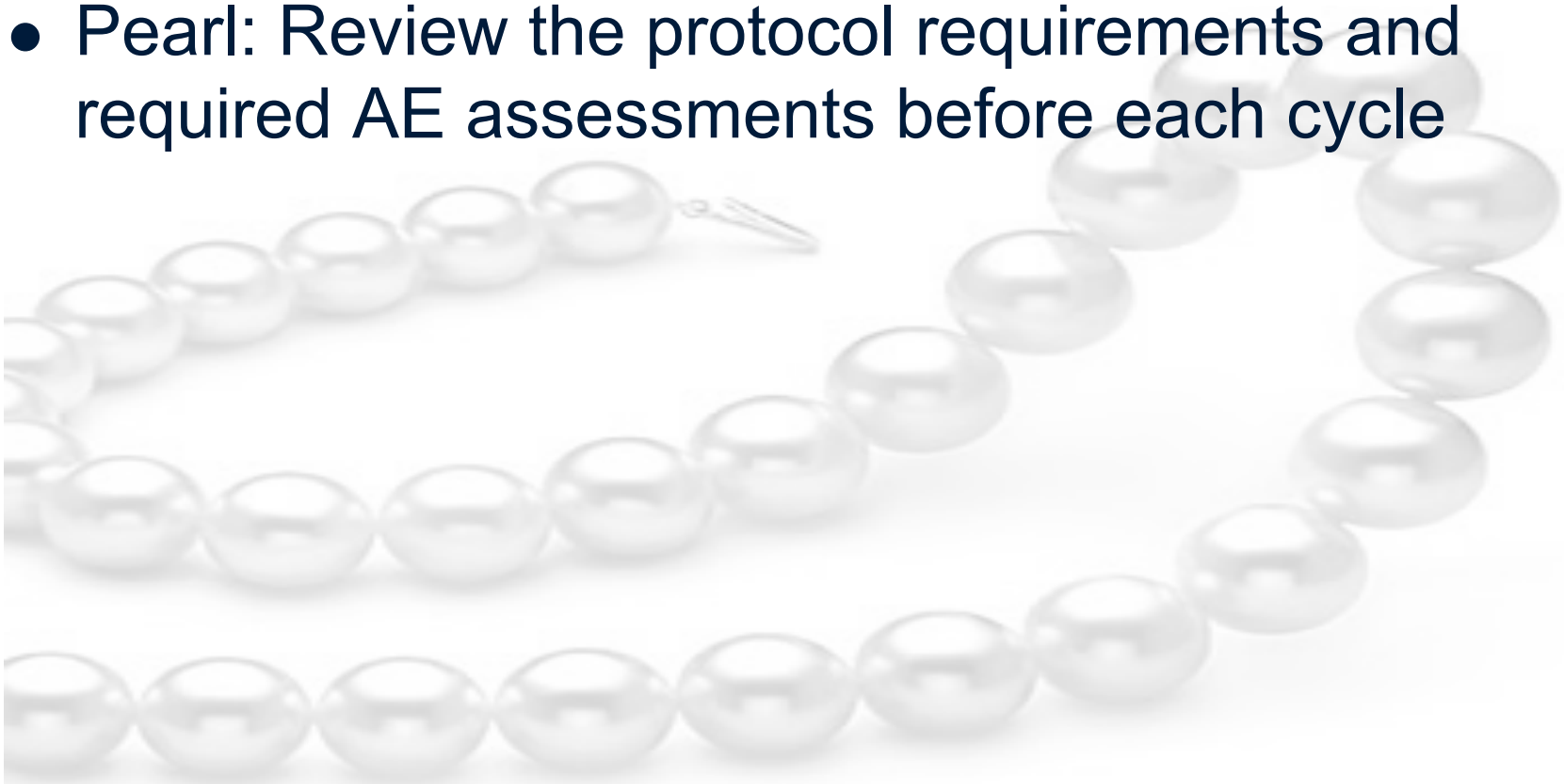
Eligibility criteria are not met

- Pearl: Source Documentation! If it's not documented, it didn't happen.



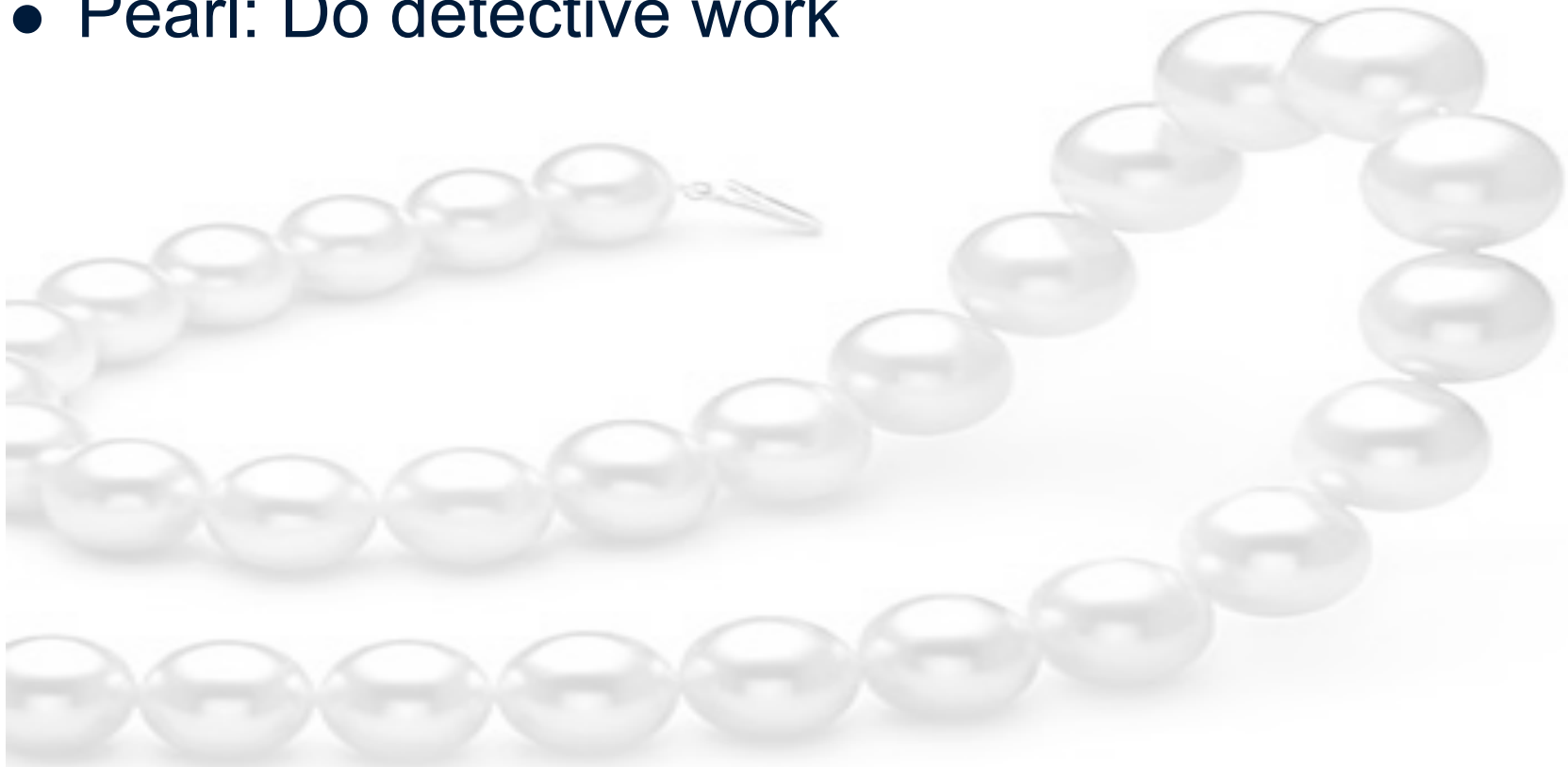
Treatment is not given per protocol instructions

- Pearl: Review the protocol requirements and required AE assessments before each cycle



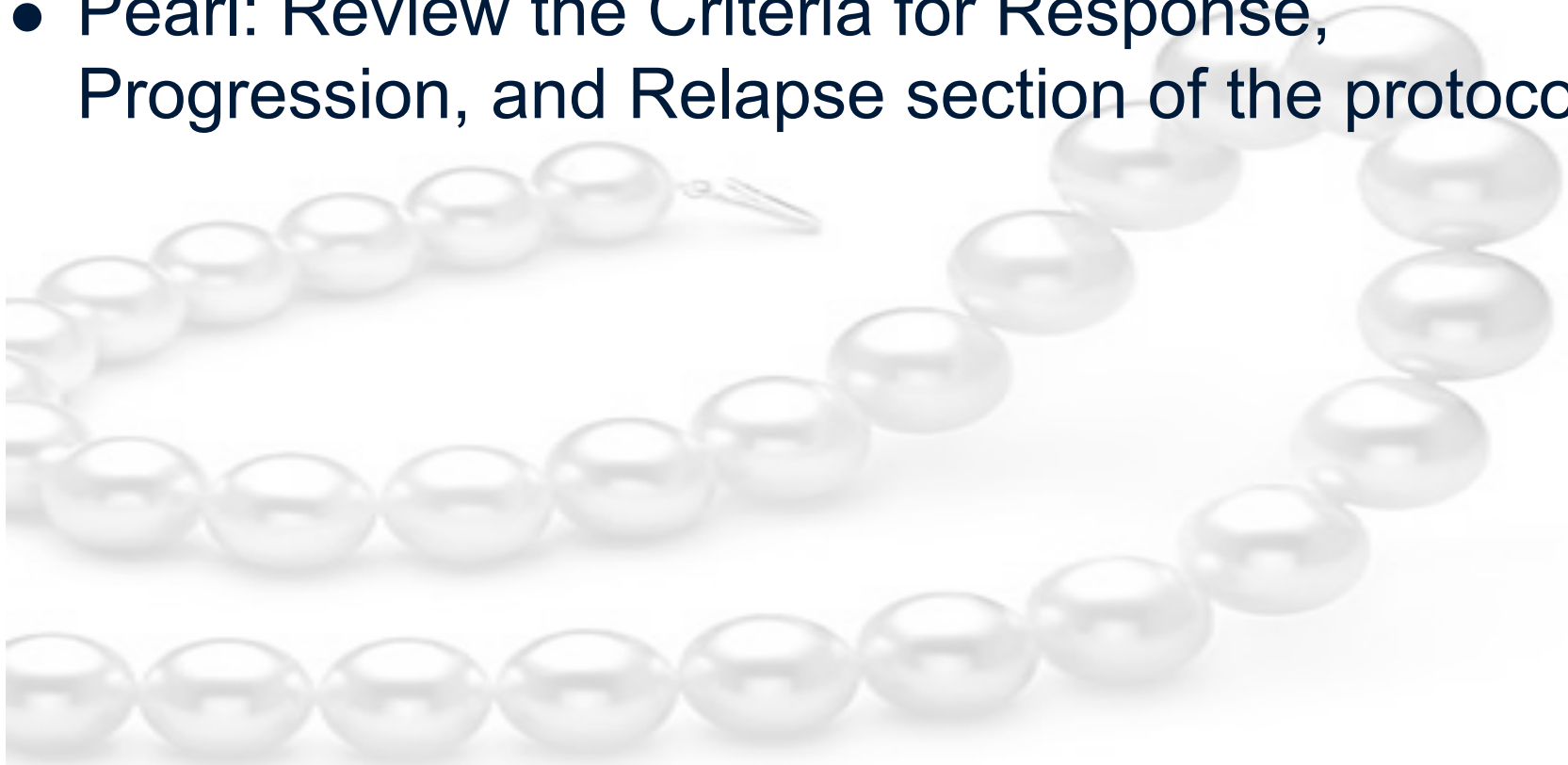
Cannot verify treatment adherence with oral medications

- Pearl: Do detective work



Failure to evaluate response according to the protocol

- Pearl: Review the Criteria for Response, Progression, and Relapse section of the protocol



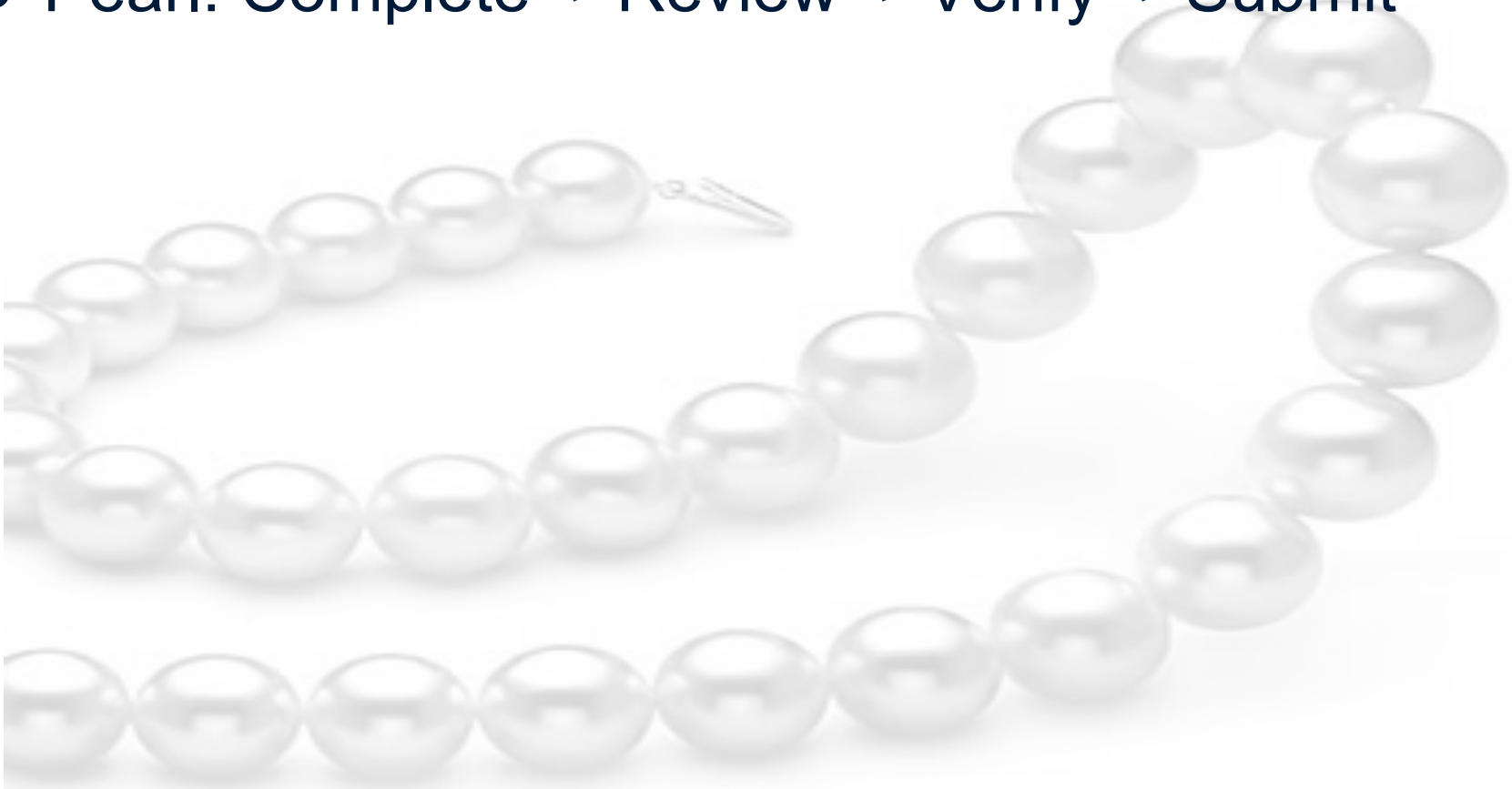
Failure to assess and report adverse events according to protocol

- Pearl: Clarify, never guess!



General Data Quality Issues

- Pearl: Complete → Review → Verify → Submit



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**Please save questions for the panel at
the end of the presentations.**