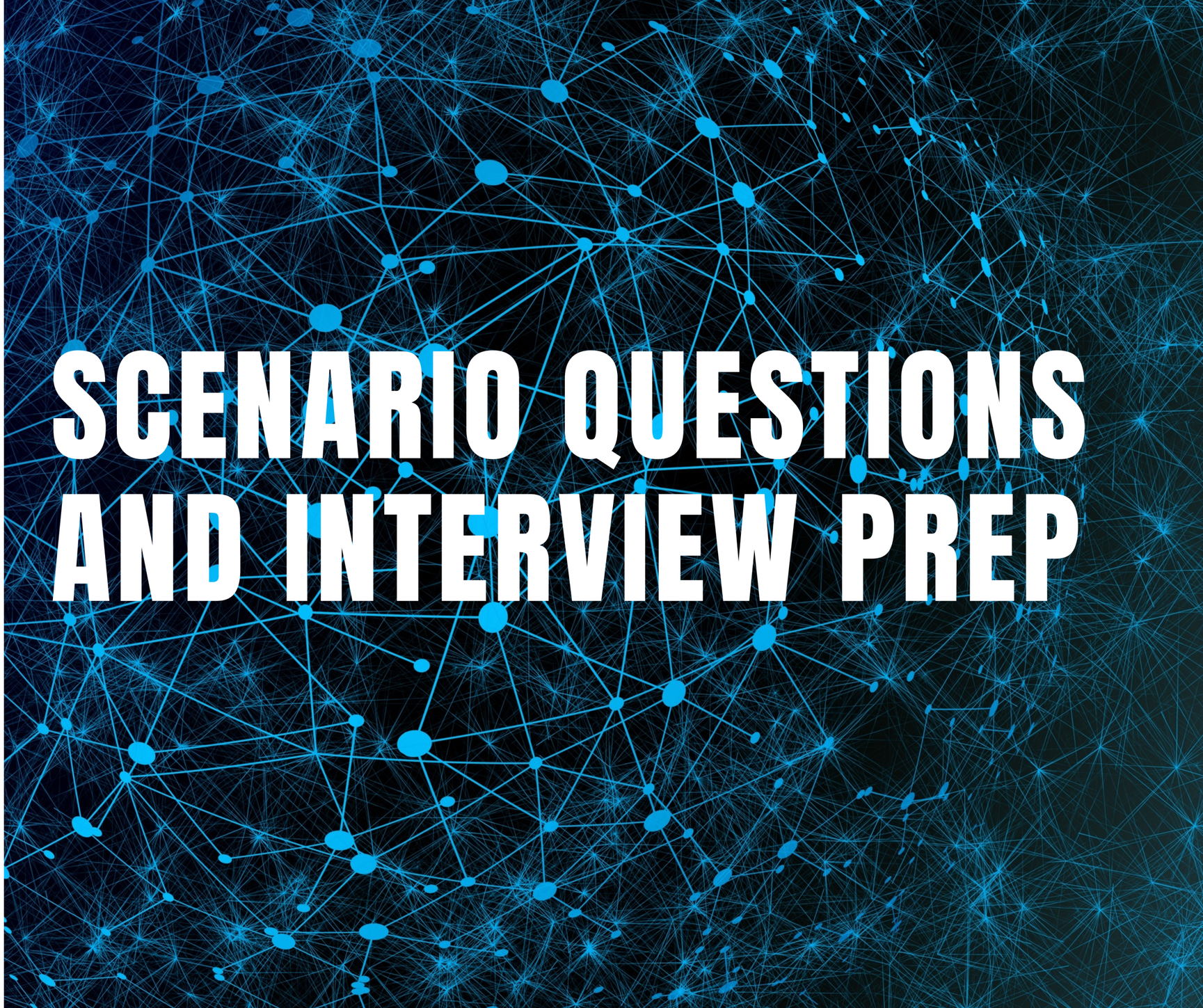
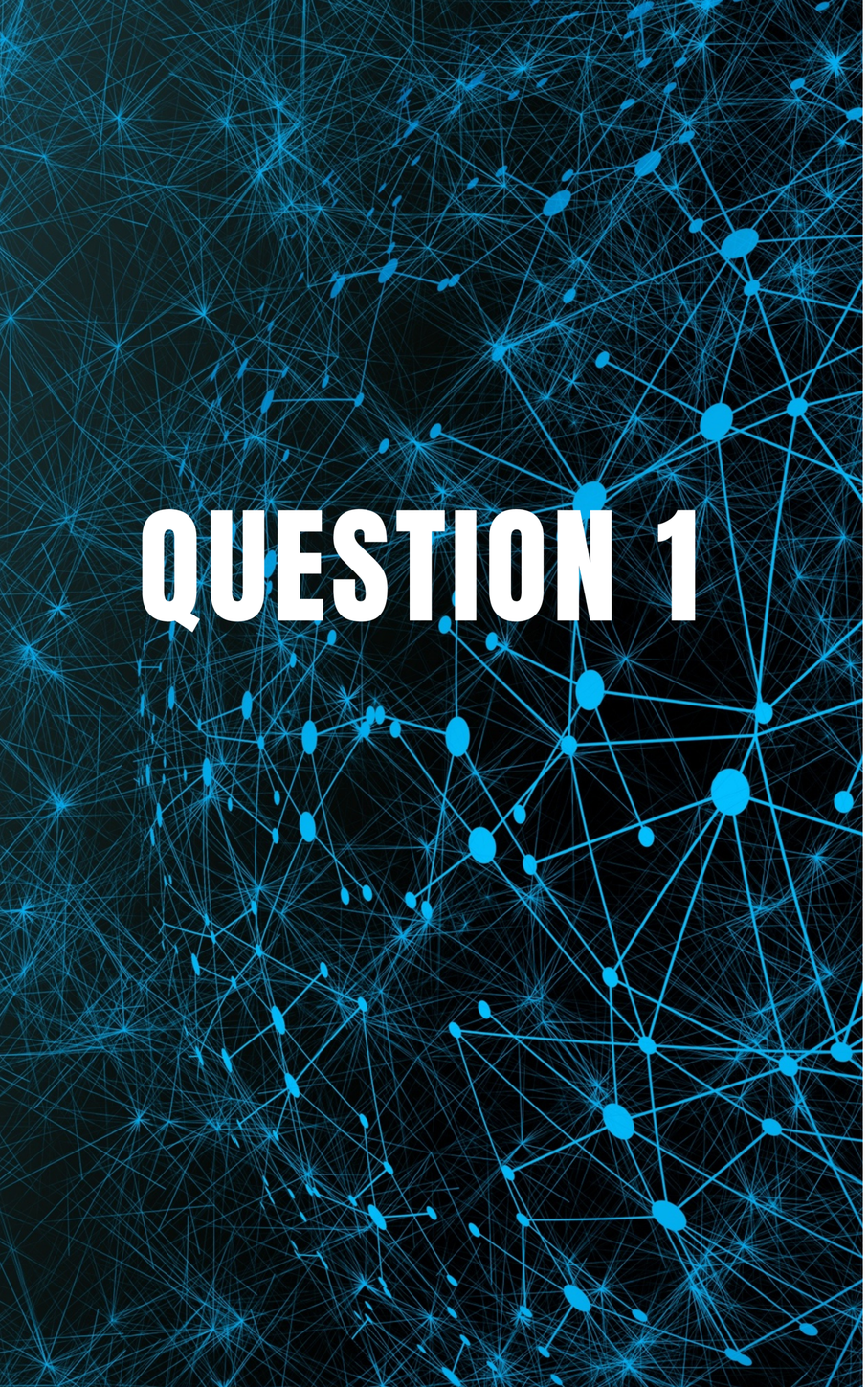
CLASS NINE

SCENARIO QUESTIONS AND INTERVIEW PREP



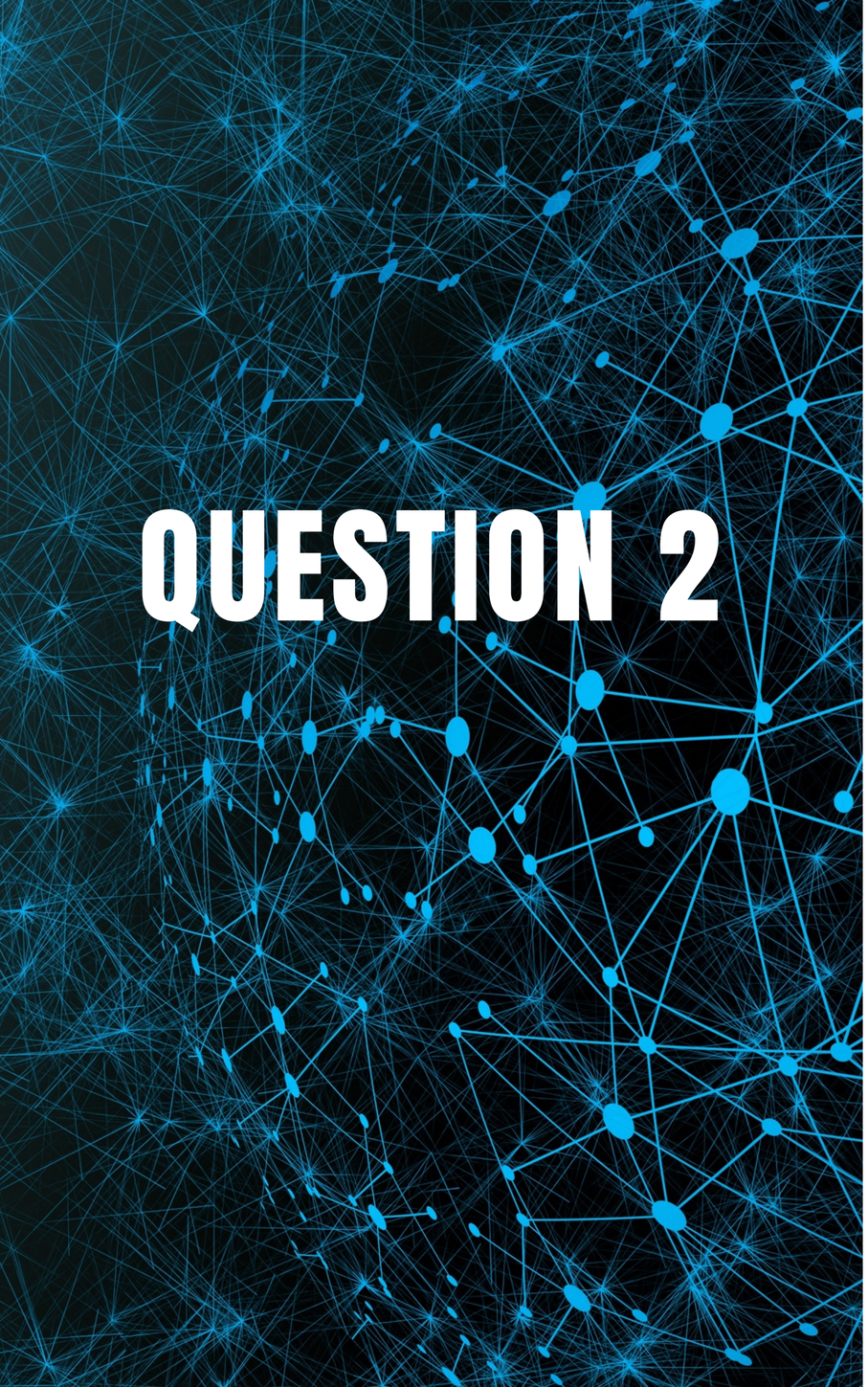


A Study XTC is in the middle of Phase 3 trial (the second year anniversary). The efficacy endpoint is set at 35% improvement compared to Azacitadine

1) What events/activities should the Safety specialist have carried out at this stage of the Clinical Trial? (Briefly explain the activities and time points in the product lifecycle.)

2) Prepare a CCRP for this study

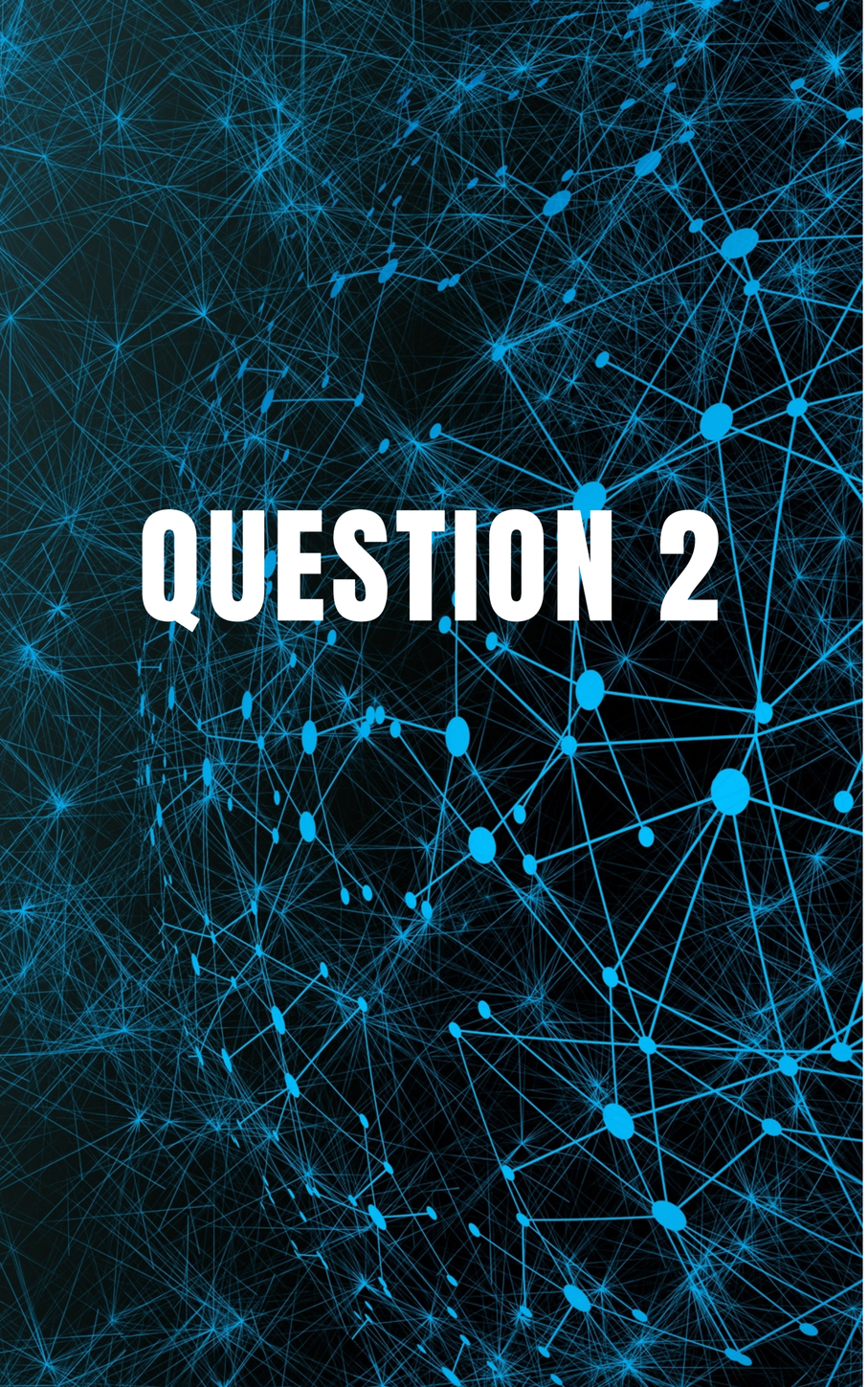
3) What documents will the CCRP impact in CT, briefly describe the importance of this document.



B) Incidence rate of Pancytopenia increased by 55% following signal detection

1) Discuss all scenarios with the steps you will take as a safety specialist to bring this to closure.

. Clinical trial/unlisted
. Clinical trial/listed
. PM/Unlabelled
. PM/Labelled
. PM + CT/Unlabelled



2. On further surveillance, Pancytopenia was linked to Medication Dosing Errors. Please discuss your process of risk management in the context of HCPs and Patient/Caregivers