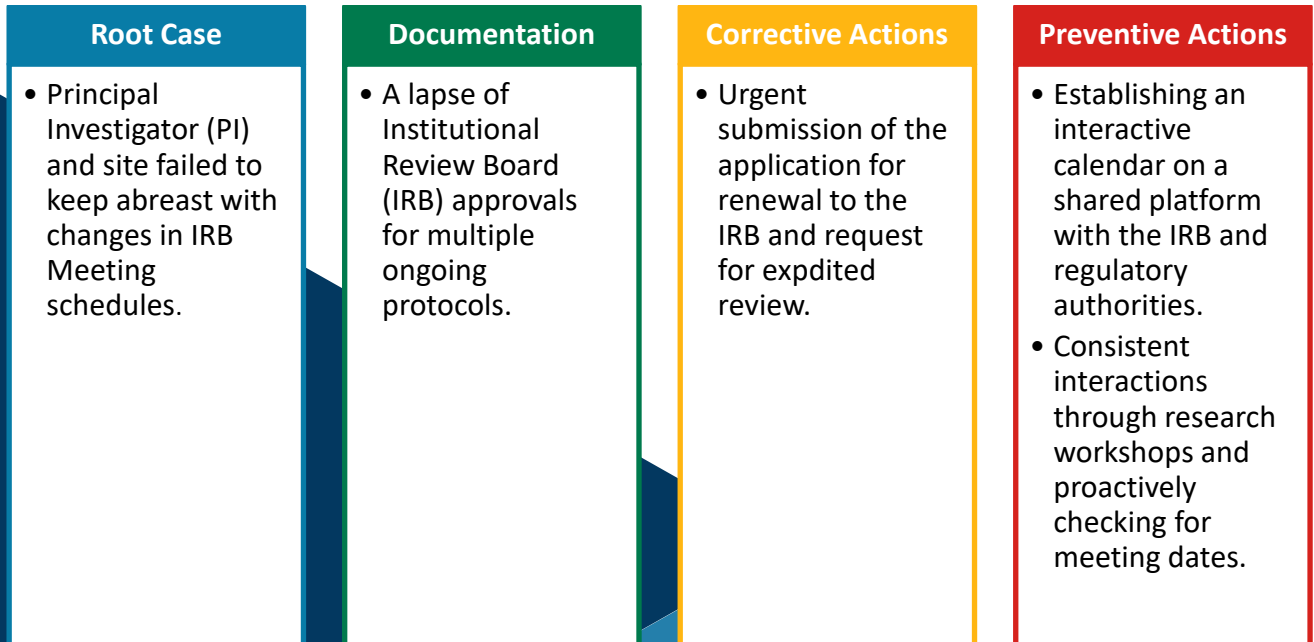


# Investigator Responsibilities Activity: Video 1 IRB Submission Answer Key

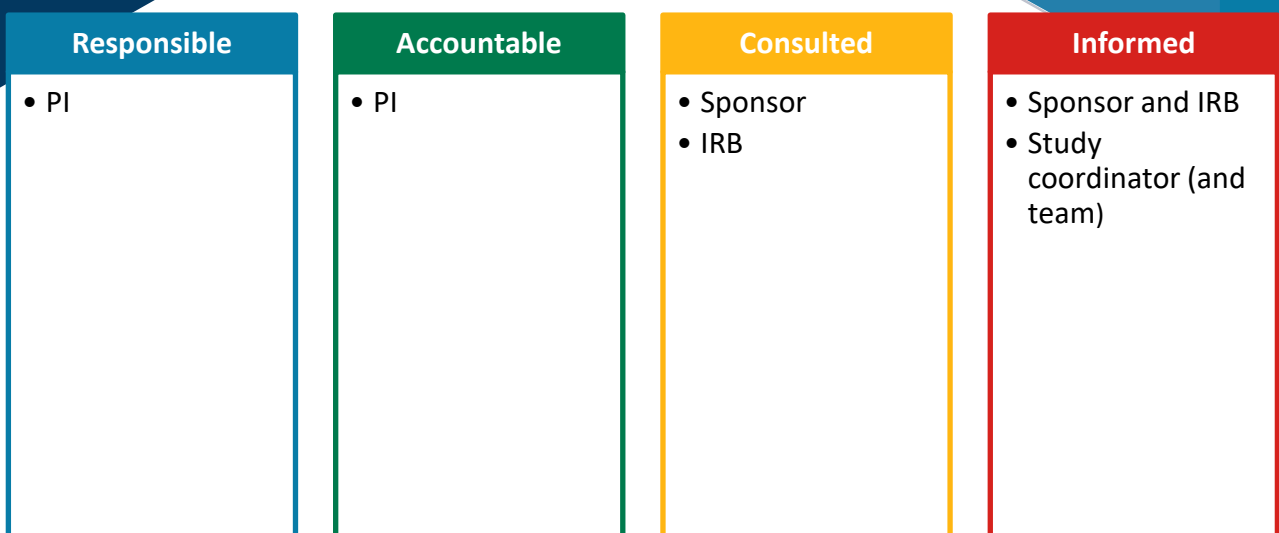
## Quality Improvement Instructions:

Watch the video scenario, complete the following chart to determine what happened and how to improve site operations as well as documentation considerations.



## RACI Matrix Instructions:

Change is only implemented effectively when responsibility and communication pathways are defined. Determine what role at the site should be included in the responsibility and communication to improve site operations.



# Investigator Responsibilities Activity:

## Video 2 Protocol Adherence Answer Key

### Quality Improvement Instructions:

Watch the video scenario, complete the following chart to determine what happened and how to improve site operations as well as documentation considerations.

Root Case	Documentation	Corrective Actions	Preventive Actions
<ul style="list-style-type: none"> <li>Enrolling ineligible participants.</li> </ul>	<ul style="list-style-type: none"> <li>Enrollment violation CRFs and scans uploaded in the File Exchange System</li> </ul>	<ul style="list-style-type: none"> <li>Completion of enrollment violation incident reports and submitting to the IoR.</li> <li>Submitting the detailed incident (for each participant) reports to the CMC.</li> <li>Clinical management of the participants as guided by the CMC.</li> <li>Reporting all the events to the IRB and the regulatory authorities (if applicable)</li> <li>Pause enrollments until the IoR gets instructions from the protocol team to resume.</li> </ul>	<ul style="list-style-type: none"> <li>Sub-Investigator training, and hiring an oncologist experienced in managing AIDS-KS to assist with screening.</li> <li>Drafting a clarification memo on eligibility criteria</li> </ul>

### RACI Matrix Instructions:

Change is only implemented effectively when responsibility and communication pathways are defined. Determine what role at the site should be included in the responsibility and communication to improve site operations.

Responsible	Accountable	Consulted	Informed
<ul style="list-style-type: none"> <li>PI</li> </ul>	<ul style="list-style-type: none"> <li>PI</li> </ul>	<ul style="list-style-type: none"> <li>Protocol team</li> <li>Sponsor</li> </ul>	<ul style="list-style-type: none"> <li>Sponsor, IRBs and regulatory authorities</li> <li>All key study personnel</li> </ul>

# Investigator Responsibilities Activity: Video 3 Drug Inventory Answer Key

## Quality Improvement Instructions:

Watch the video scenario, complete the following chart to determine what happened and how to improve site operations as well as documentation considerations.

Root Case	Documentation	Corrective Actions	Preventive Actions
<ul style="list-style-type: none"><li>Poor communication between clinic and pharmacy.</li></ul>	<ul style="list-style-type: none"><li>Study product accountability records restricted to pharmacy personnel and the blinded email thread between the PI and the PoR.</li></ul>	<ul style="list-style-type: none"><li>Ordering study products.</li><li>Revising the clinic-pharmacy communication SOP or equivalent.</li></ul>	<ul style="list-style-type: none"><li>Training clinic staff on involvement of pharmacy personnel in scheduling all participant visits.</li><li>Weekly site meetings to discuss all key components of study progress.</li></ul>

## RACI Matrix Instructions:

Change is only implemented effectively when responsibility and communication pathways are defined. Determine what role at the site should be included in the responsibility and communication to improve site operations.

Responsible	Accountable	Consulted	Informed
<ul style="list-style-type: none"><li>PI</li></ul>	<ul style="list-style-type: none"><li>PI</li></ul>	<ul style="list-style-type: none"><li>Pharmacist of Record</li><li>Sponsor</li></ul>	<ul style="list-style-type: none"><li>Protocol team and sponsor</li></ul>

# Investigator Responsibilities Activity: Video 4 Safety Oversight Answer key

## Quality Improvement Instructions:

Watch the video scenario, complete the following chart to determine what happened and how to improve site operations as well as documentation considerations.

Root Case	Documentation	Corrective Actions	Preventive Actions
<ul style="list-style-type: none"> <li>Treatment failure</li> </ul>	<ul style="list-style-type: none"> <li>Laboratory charts and participant CRFs</li> </ul>	<ul style="list-style-type: none"> <li>Switching to an alternative recommended treatment combination.</li> <li>Continue with close monitoring of the viral load and immunologic markers.</li> <li>Reaching out to the protocol team for guidance.</li> </ul>	<ul style="list-style-type: none"> <li>Use of novel adherence (to treatment) monitoring strategies.</li> <li>Switching to long-acting injectable combinations if available.</li> </ul>

## RACI Matrix Instructions:

Change is only implemented effectively when responsibility and communication pathways are defined. Determine what role at the site should be included in the responsibility and communication to improve site operations.

Responsible	Accountable	Consulted	Informed
<ul style="list-style-type: none"> <li>PI</li> </ul>	<ul style="list-style-type: none"> <li>PI</li> </ul>	<ul style="list-style-type: none"> <li>Protocol Team</li> <li>Sponsor</li> </ul>	<ul style="list-style-type: none"> <li>Protocol team and sponsor</li> <li>IRBs and regulatory authorities</li> </ul>