Data Submission Schedule for A021502:
Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair

This schedule reflects case report form expectations and requirements based on parameters defined in the A021502 protocol document. Additional case report forms may become available and therefore required, based on responses to trigger questions within individual forms as described in the footnotes below.

Folder Name in the Data Entry System		**Baseline**	**Treatment**	**Off Treatment**	**Follow-Up**		**Study Deviations**	**Early Termination of Follow-Up**	**Early Termination of Follow-Up**
		On Study	Each cycle	End of treatment	Clinical Follow-Up	Survival and Disease Status Follow-Up	Any time	Consent Withdrawal	Lost to Follow-Up
Form Name and Time of Form Submission	On-Study	X							
	Specimen Submission: Blood (Baseline for A021502-ST1/A021502-PP1) [1]	X							
	Specimen Submission: Stool (Baseline for A021502-ST1) [2]	X							
	Specimen Submission: Tissue (Baseline)	X							
	Adverse Events: Baseline	X							
	Specimen Submission: Tissue (Baseline All Patients)	X							
	Laboratory Tests and Results	X	X		X				
	Supporting Documentation: Baseline[3]	X							
	Patient Status: Baseline	X							
	NCI PRO-CTCAE[4]	X	X	X					
	NCI PRO-CTCAE Booklet Compliance Form[5]	X	X	X					
	PRO/QOL: Registration Fatigue/Uniscale Assessment[6]	X							
	PRO/QOL: Registration Fatigue/Uniscale Assessment Compliance[7]	X							
	PRO/QOL: FACT-C FACT/GOG-NTX, EQ-5D-5L[8],	X	X	X	X	X			

[1] Specimen Submission: Blood (Baseline for A021502-ST1/A021502-PP1) form will become available and be required in the current folder if the On-Study form indicates patient gave consent to the stool for Correlative Science Companion Study A021502-ST1 ('Did the patient consent to the blood for Correlative Science Companion Study, (A021502-ST1 and A021502-PP1)?' is answered 'Yes').
[2] The Specimen Submission: Stool form will become available and be required in the current folder if the On-Study form indicates patient gave consent to the stool for Correlative Science Companion Study A021502-ST1 ('Did the patient consent to the stool for Correlative Science Companion Study A021502-ST1?' is answered 'Yes').
[3] The Supporting Documentation: Baseline form will become available and be required in the current folder if the Patient Status: Baseline folder indicates supporting documents were submitted this cycle. ('Were supporting documents submitted this cycle? is yes" The following documentation is required at Baseline: H&P, colonoscopy report*, imaging report, pathology report from colonoscopy and surgery, operative report, result of MSI/dMMR testing. Please refer to section 6 of the protocol for complete details.
[4] The Patient Status: NCI PRO-CTCAE form will become available and be required in the current folder if the Patient Status form (Baseline/Treatment/Off Treatment) indicates the patient completed the PRO-CTCAE assessment(s) ('Did the participant complete the PRO-CTCAE assessment(s)?' is answered 'Yes').
[5] The Patient Status: NCI PRO-CTCAE Booklet Compliance form will become available and be required in the current folder if the Patient Status form (Baseline/Treatment/Off Treatment) form indicates the patient did not complete the PRO-CTCAE assessment(s) ('Did the participant complete the PRO-CTCAE assessment(s)?' is answered 'No').
[6] The PRO/QOL: Registration Fatigue/Uniscale Assessment will become available and be required in the current folder if the Patient Status: Baseline form indicates that the PRO/QOL was completed ('Did the participant complete the Registration Fatigue/Uniscale Assessment?' is answered 'Yes').
[7] The PRO/QOL: Registration Fatigue/Uniscale Assessment Compliance form will become available and be required in the current folder if the Patient Status: Baseline form indicates that the PRO/QOL was not completed ('Did the participant complete the Registration Fatigue/Uniscale Assessment?' is answered 'No').
[8] The PRO/QOL forms (FACT-C, FACT/GOG-NTX, and The EQ-5D-5L) will become available and be required in the current folder if the Patient Status form (Baseline/Treatment/Off Treatment/Clinical Follow-up/Survival Follow-up) indicates that the PRO/QOL was completed ('Did the participant complete the PRO/QOL *(A021502-HO1)* assessment(s)?' is answered 'Yes').

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Folder Name in the Data Entry System		Baseline	Treatment	Off Treatment	Follow-Up		Study Deviations	Early Termination of Follow-Up	Early Termination of Follow-Up
		On Study	Each cycle	End of treatment	Clinical Follow-Up	Survival and Disease Status Follow-Up	Any time	Consent Withdrawal	Lost to Follow-Up
	PRO/QOL Booklet Compliance Form[9]	X	X	X	X	X			
	Puberty Development Assessment (Baseline)[10]	X							
	Treatment (Intervention)		X						
	Treatment: Dose Modifications[11]		X						
	Adverse Events		X						
	Expedited Reporting Evaluation		X						
	Supporting Documentation[12]		X		X	X			
	Laboratory Tests and Results		X		X				
	Patient Status: Treatment (Intervention)		X						
	Notice of New Primary[13]		X		X	X			
	Notice of Recurrent Disease[14]		X		X	X			
	Puberty Development Assessment[15]		X	X	X	X			
	Specimen Submission: Blood[16]		X		X	X			
	Specimen Submission: Tissue[17]		X		X	X			
	Specimen Submission: Stool[18]		X		X	X			
	Late Adverse Events[19]				X	X			
	Late AE Reporting[20]				X	X			

[9] The PRO/QOL Booklet Compliance Form will become available and be required in the current folder if the Patient Status form (Treatment/Baseline/Treatment/Off Treatment/Clinical Follow-up/Survival Follow-up) form indicates that the PRO/QOL was not completed ('Did the participant complete the PRO/QOL *(A021502-HO-1)* assessment(s)?' is 'No'). Note: If the patient did not consent to the PRO/QOL *(A021502 HO-1)* sub-study, the form is answered, 'Not applicable'.

[10] The Puberty Development Assessment (Baseline) form will become available and be required in the current folder if the Patient Status: (Baseline) form indicates that puberty developmental status was assessed ('Was puberty development (Tanner Stage/Menarche) assessed this reporting period?' is answered 'Yes').

[11] The Treatment: Dose Modifications form will become available and be required in the current folder any time a modification is indicated on the Treatment form ('Was protocol treatment modified?' is answered 'Yes').

[12] See the monitoring table (on page 4) for detailed information on required source/supporting documentation. The Supporting Documentation form become available and be required in the current folder if the Patient Status form (Treatment/Clinical Follow-up/Survival Follow-up) indicates that there are supporting documents to upload ('Do you have supporting documentation to upload (see Protocol section 6 for required reports?') is answered 'Yes')

[13] Notice of New Primary will become available and be required in the current folder if the Patient Status form (Treatment/Baseline/Clinical Follow-up) form indicates that the a new primary cancer was reported ('Has a new primary cancer been diagnosed that has not been previously reported?' is answered 'Yes').

[14] Notice of Recurrent Disease form will become available and be required in the current folder Patient Status form (Treatment/Baseline/Clinical Follow-up) form indicates that the a disease recurrence was reported ('Has the patient developed a first relapse or progression that has not been previously reported?' is answered 'Yes').

[15]The Puberty Development Assessment form will become available and be required in the current folder if the Patient Status: (Treatment), Patient Status: (Clinical Follow-Up), Patient Status (Survival Follow-Up), or Off Treatment form indicates that puberty developmental status was assessed ('Was puberty development (Tanner Stage/Menarche) assessed this reporting period?' is answered 'Yes').

[16] Specimen Submission: Blood form will become available and be required in the current folder if the blood specimens submitted on the Patient Status: Treatment form ('Were blood specimens submitted?' is answered 'Yes').

[17] Specimen Submission: Tissue form will become available and be required in the current folder if the participant added tissue specimens submitted on the Patient Status: Treatment form ('Were tissue specimens submitted?' is answered 'Yes').

[18] Specimen Submission: Stool form will become available and be required in the current folder if the participant added stool specimens submitted on the Patient Status: Treatment form ('Were stool specimens submitted?' is answered 'Yes').

[19] The Late Adverse Events form will become available and be required in the current folder if Patient Status Form (Clinical Follow-up/Survival Follow-up) indicates that late adverse events occurred ('Has the patient had a grade 3+ adverse event that has not been previously reported?' is answered 'Yes')

[20] The Late AE Reporting form will become available and be required in the current folder if Patient Status Form (Clinical Follow-up/Survival Follow-up) indicates that late adverse events occurred ('Has the patient had a grade 3+ adverse event that has not been previously reported?' is answered 'Yes')

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Folder Name in the Data Entry System		Baseline	Treatment	Off Treatment	Follow-Up		Study Deviations	Early Termination of Follow-Up	Early Termination of Follow-Up
		On Study	Each cycle	End of treatment	Clinical Follow-Up	Survival and Disease Status Follow-Up	Any time	Consent Withdrawal	Lost to Follow-Up
	Deviations[21]						X		
	Off Treatment[22]			X					
	Lost to Follow-Up[23]								X
	Consent Withdrawal[24]							X	
	Consent Withdrawal QOL (HO1) Only[25]							X	
	Consent Withdrawal Tissue Specimen Only[26]							X	
	Consent Withdrawal Blood Specimen Only[27]							X	
	Consent Withdrawal Stool Specimen Only[28]							X	
	Consent Withdrawal Clinical Follow-Up Only[29]							X	
	Consent Withdrawal All Follow-Up[30]							X	

[21] The Study Deviations folder and form are always present. Please report study deviations as they occur in accordance with the A021502 Deviation Guidance Document.
[22] The Off Treatment forms will become available and required in the Off Treatment folder if the Patient Status: Baseline form indicates that the patient will not receive treatment ('Will the patient proceed to the first (on-study) cycle of protocol treatment?' is answered 'No') or the Patient Status: Treatment form indicates that the patient will not continue treatment ('Will the patient continue protocol treatment (intervention) in the subsequent cycle? ' is answered 'No.')
[23] Patients are eligible to be confirmed lost to follow-up after two years of unsuccessful contact with the patient. Once a patient is eligible to be confirmed lost to follow-up, the Lost to Follow-up form will become available in the Early Termination of Follow-up folder.
[24] The Consent Withdrawal Form is added by the CRA as an 'Add Event.'
[25] The Consent Withdrawal QOL (HO1) Only form will become available and will be required in the Early Termination of Follow-Up folder if the Consent Withdrawal Form indicates that the patient has withdrawn consent for the HO1.
[26] The Consent Withdrawal Tissue Specimen Only form will become available and will be required in the Early Termination of Follow-Up folder if the Consent Withdrawal Form indicates that the patient has withdrawn consent for the tissue specimen only.
[27] The Consent Withdrawal Blood Specimen Only form will become available and will be required in the Early Termination of Follow-Up folder if the Consent Withdrawal Form indicates that the patient has withdrawn consent for the blood specimen only.
[28] The Consent Withdrawal Stool Specimen Only form will become available and will be required in the Early Termination of Follow-Up folder if the Consent Withdrawal Form indicates that the patient has withdrawn consent for the stool specimen only.
[29] The Consent Withdrawal Clinical Follow-Up Only form will become available and will be required in the Early Termination of Follow-Up folder if the Consent Withdrawal Form indicates that the patient has withdrawn consent for the Clinical Follow-up Only.
[30] The Consent Withdrawal All Follow-Up form will become available and will be required in the Early Termination of Follow-Up folder if the Consent Withdrawal Form indicates that the patient has withdrawn consent for the All Follow-up.

Data Submission Schedule for A021502:
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SOURCE DOCUMENTATION REQUIREMNTS FOR MONITORING

The following data and documents will be reviewed through central/on-site data monitoring and source data verification (SDV) activities.

Category	Case Report Form	Data Fields	Additional Instructions	Acceptable Source Document
Informed Consent	Review Forms: Informed Consent	Date of signature[1, 3] Signature page[1, 3] Correlative Study indications[1] Entire document[2]	Central Monitoring: De-identified Informed Consent Document (ICD): Last page of signed and dated ICD (including page/s with options indicated by patient for additional studies). Patient's full signature should be redacted but date should be retained.	Informed Consent Document
Eligibility[4]	Baseline: On-Study: Description of Primary Disease	Histologic Grade[1] Location of Primary Tumor[1] Pathological T stage[1] Clinical M Stage[1]	*Tumor characteristics*, aside from *pathologic T stage* and *clinical M stage*, are not source verified	Path report IHC report Operative report Radiology report Colonoscopy report Lab report (for registration eligibility) Clinic note Other relevant report Informed Consent Document
	Baseline: On-Study: Mismatch Repair Testing	Test used[1]	IHC Test, Test date, and IHC Results are source verified; *Does patient have Lynch Syndrome?* is not source verified	
	Baseline: On-Study: Patient History	Patient History[1]	*Prior cancer diagnosis date* and *NSAID Use* fields are not source verified	
	Baseline: On-Study: Patient Characteristics	ECOG Performance Status[1] Karnofsky Performance Status[1] Lansky-Play performance Status[1]	Only *Performance Status* source verified; only one *Performance Status* is required to be completed per protocol	
	Baseline: On-Study: Correlative Studies	All fields[1]		
Disease Assessment	Baseline: Patient Status: Baseline	Protocol Treatment[1] Survival Status[1] Disease Status[1]	Verification of claimed assessment *PRO/QOL Assessment(s)* not source verified	Radiology report Lab report Colonoscopy report Relevant medical records (e.g., clinic note, other)
Treatment/IP Administration (cycle 1 – 3[1]; all cycles[2])	Treatment (Intervention) ___	Agent name Not required per protocol Dose level (day 1) Units of measure Dose (total) Units of measure Was protocol treatment modified? Was protocol treatment omitted? Was protocol treatment delayed? Start date	Review treatment administration documentation	Relevant medical record (e.g., clinic note, other)

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Category	Case Report Form	Data Fields	Additional Instructions	Acceptable Source Document
		Stop date		
Treatment/IP Administration (cycle 1 – 3[1]; all cycles[2])	Treatment ___: Treatment (Intervention): Dose Modifications, Omissions and Delays	Dose modification reason Dose omission reason Dose delay reason	Review treatment modification documentation	Relevant medical records (e.g., clinic note, other)
Adverse Events	Treatment ___: Adverse Events Clinical Follow-up ___: Patient Status: Clinical Follow-Up/Observation: Late Adverse Events Survival Follow-up ___: Patient Status: Survival and Disease Status Follow-up/Event Monitoring: Late Adverse Events	All fields[2]		Relevant medical records (e.g., clinic note, other)
Disease Assessment	Treatment ___: Patient Status: Treatment (Intervention)	Survival Status[1] Disease Status[1] New Primary[1]		Radiology report (conventional CT and MRI or chest x-ray) Lab report Colonoscopy report Relevant medical records (e.g., clinic note, other)
Off Treatment (all cycles[2])	Off Treatment	All fields		Relevant medical records (e.g., clinic note, other)
Disease Assessment	Clinical Follow-up ___: Patient Status: Clinical Follow-Up/Observation	Survival Status[1] Disease Status[1] New Primary[1]		Radiology report (conventional CT and MRI or chest x-ray) Lab report Colonoscopy report Relevant medical records (e.g., clinic note, other)
Disease Assessment	Survival Follow-up ___: Patient Status: Survival and Disease Status Follow-up/Event Monitoring	Survival Status[1] Disease Status[1] New Primary[1]		Radiology report (conventional CT and MRI or chest x-ray) Lab report Colonoscopy report Relevant medical records (e.g., clinic note, other)
Disease Recurrence	Notice of Recurrent Disease	All fields[1]		Radiology report (conventional CT and MRI or chest x-ray) Lab report Colonoscopy report
New Primary	Notice of New Primary	All fields[1]		Radiology report (conventional CT and MRI or chest x-ray) Lab report Colonoscopy report
Consent Withdrawal	Consent Withdrawal (all types)	All fields[2]		Relevant medical record (e.g., clinic note, other)
Lost to Follow-up	Lost to Follow-up	All fields[2]		Relevant medical record (e.g., clinic note, other)

[1] Central and on-site monitoring
[2] On-site monitoring only
[3] For Central Monitoring: De-identified Informed Consent Document (ICD): Last page of signed and dated ICD (including page/pages with options indicated for additional studies). Patient's full signature should be redacted but date should be retained
[4] On-site monitoring of inclusion criteria: age ≥ 18 years old; absolute neutrophil count; platelet count (in relation to prior FOLFOX6 treatment); Is the patient's TSH within normal limits?; If no, does the patient have a normal Free T4 and is clinically euthyroid?; TSH lower limit of normal; TSH upper limit of normal; Does patient have documented Gilbert's syndrome?; total bilirubin; total bilirubin upper limit of normal; SGOT (AST); SGOT upper limit of normal; SGPT (ALT); SGPT upper limit of normal; Is this patient's Creatinine > 1.5 x institutional upper limit of normal? *or* Is this patient's Creatinine Clearance ≥ 45 mL/min?; Creatinine upper limit of normal; Is this a woman of childbearing potential?; If yes, negative pregnancy test date (≤ 7 days prior to registration)

FOLDER	Folder Target Dates (date due) *Found on Subject Home Page*	Overdue Days
BASELINE	14 Days after Registration/Randomization Date.	15 additional days from Target Date
TREATMENT 01	14 Days (Treatment cycle length) after Registration/Randomization.	15 additional days from Target Date
TREATMENT 02+	14 days after "Date of most recent contact" on the last Patient Status: Treatment form.	15 additional days from Target Date
OFF TREATMENT	7 days after "Date of most recent contact" on the last Patient Status: Treatment form or 7 days from Registration date (no treatment).	7 additional days from Target Date
CLINICAL FOLLOW-UP	180 days (6 months, +/- 30 days) after "Date of most recent contact" on any Patient Status form. CF Cycle Length = 180 days for 5 years after registration, or until evidence of relapse/recurrence (1824 days) from registration (whichever comes first). If unable to obtain any patient information, the target date will be 180 days from the target date of the previous folder.	30 additional days from Target Date
Survival and Disease Status Follow-up	180 days (6 months, +/- 30 days) after "Date of most recent contact". If unable to obtain any patient information, the target date will be 180 days from the target date of the previous folder. SFU cycle length = 180 days until death or 8 years after registration whichever comes first.	30 additional days from Target Date