DATA MIGRATION: OVERVIEW & BACKGROUND

Background Information

- Stakeholders
  - NCI: regulatory sponsor
  - Alliance: Lead Protocol Organization (LPO)
  - Roche/Genentech: industry partner (i.e., Company) that provides trial supplemental support for trial conduct
- Study Design
  - Planned for NDA-registration intent (NDA filing planned by Roche/Genentech)
    - Requires the site Principal Investigator to sign electronically as an attestation to the accuracy and completeness of the final data submitted on their behalf
  - Primary Endpoint: Disease Free Survival (DFS)
  - Trial Activation: September 2017
    - Entails (mostly) standard data collection
- *File-ability* Assessment
  - In 2021, Roche/Genentech cross-functional Working Group formed to assess the trial's NDA registration requirements

Summary of Company's Assessment

Significant Gaps Identified by the Company

- To mitigate the gaps, increased data collection required
  - Entails retrospective data (along with prospective) requiring a significant data migration in EDC
- Risk/benefits to overall goal of making treatment for patients available and accessible

Gaps Focused on:

1. Concomitant Medications
2. Post-Baseline Labs
3. Baseline Medical History
4. Primary Endpoint
   - Additional information regarding disease assessment modality, measurement, etc
5. Treatment Discontinuation
   - Additional information regarding adverse events leading to treatment d/c
6. Images/Scans for Storage

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Timeline of Events

- **September 2021**
  - Roche/Genentech presents initial findings
- **September 2021 – May 2022**
  - Negotiations b/w Alliance and Roche/Genentech pursue
- **June 2022**
  - CRP focus group developed for input on site impact
- **September 2022**
  - FDA responses to data mitigation proposal received
- **October 2022**
  - Data mitigation determinations finalized
- **December 2022**
  - Protocol amendment and Rave updates initiated

Today: Data migration roll out

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Data Mitigation Considerations

Overview of How Determinations were Made

- Since trial activation, Roche/Genentech have learned about updated FDA filing expectations
- Inquiries regarding the proposed data mitigation plan submitted to FDA
  - The added data collection was determined based on the FDA responses
  - Goal to minimize data collection as much as possible, that aligns with FDA responses

Risk/Benefit

- Delayed FDA approval – without the agreed upon increased data collection, anticipated that FDA will have substantial requests for this information during their review
- FDA denial – FDA may refuse to review a dataset that they would deem incomplete
- Focus high priority safety gaps
- Site impact
  - Minimizing site burden as much as possible
  - How to support sites for these efforts?
    - Providing material resources (e.g., webinar slides, newsletters, memo)
    - Increased per-case reimbursement
    - Will not impact site's IPEC reporting

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Data Mitigation
Final Determinations

1. Baseline Medical History: **NO**
2. Concomitant Medications
   - All Concomitant Medications: **NO**
   - Specified Category of Concomitant Medications: **YES**
     - Entails collection of immunosuppressants, corticosteroids, & hormone replacement therapies
3. Discontinuation of Treatment due to Adverse Events: **YES**
4. Images/Scans for Banking: **YES**
5. Disease Assessment Details: **YES**
   - E.g., modality, measurement
6. Lab Test Results (i.e., blood)
   - All Lab Test Results: **NO**
   - Subset of Lab Test Results: **YES**
     - Entails collection of lab data that are considered most pertinent,
     - Excludes some test results from routine orders such as from Comprehensive Metabolic Panel or Complete Blood Count

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Concomitant Medications

Added Data Collection

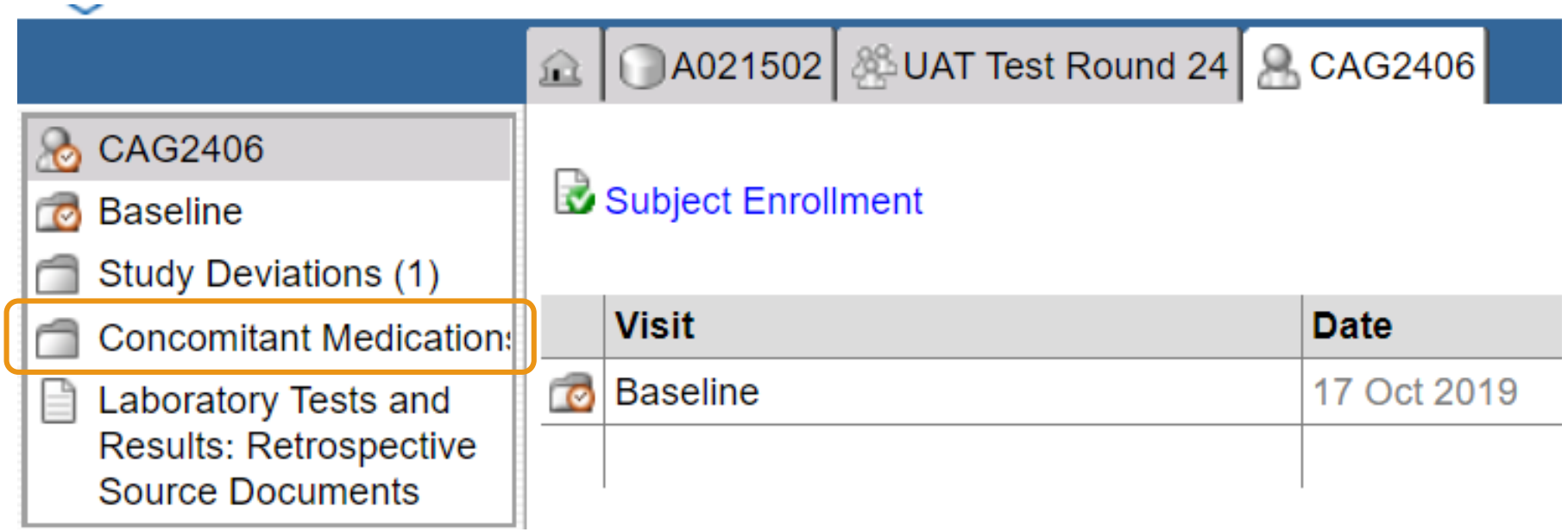
- Capture corticosteroid use (excluding standard antiemetics), immunosuppressants, and hormone replacement therapy
- Specifically: name, start/stop date, dose, route of administration

Justification

- Adequate characterization of safety profile is critical for filing.
- Shift tables for characterizing population-based safety events related to laboratory data and concomitant medications will provide critical data to identify the basis of such events.

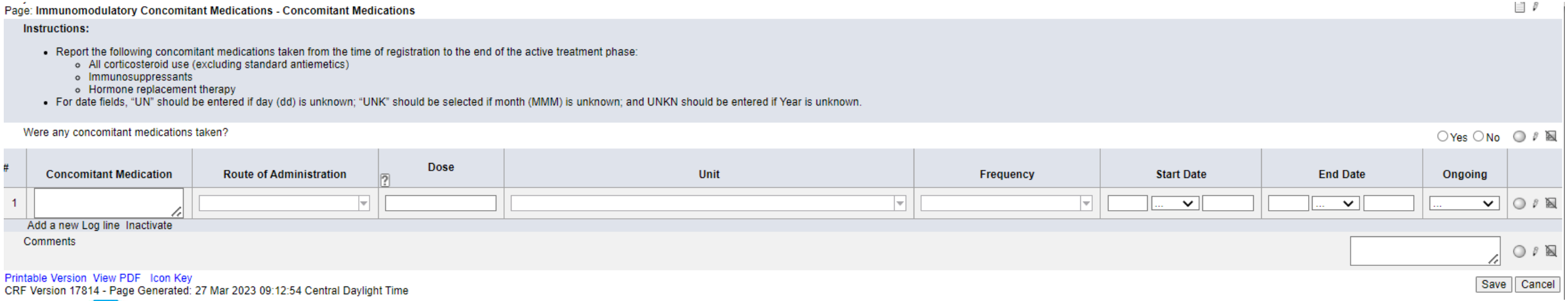
Concomitant Medications

- New folder added at the subject level.



Immunomodulatory Concomitant Medications

- New form added.
- If ‘Were any concomitant medications taken?’ is ‘Yes’, at least one log line must be completed.



Page: **Immunomodulatory Concomitant Medications - Concomitant Medications**

Instructions:

- Report the following concomitant medications taken from the time of registration to the end of the active treatment phase:
  - All corticosteroid use (excluding standard antiemetics)
  - Immunosuppressants
  - Hormone replacement therapy
- For date fields, “UN” should be entered if day (dd) is unknown; “UNK” should be selected if month (MMM) is unknown; and UNKN should be entered if Year is unknown.

Were any concomitant medications taken? ○ Yes ○ No

#	Concomitant Medication	Route of Administration	Dose	Unit	Frequency	Start Date	End Date	Ongoing
1								

Add a new Log line Inactivate

Comments

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Save Cancel

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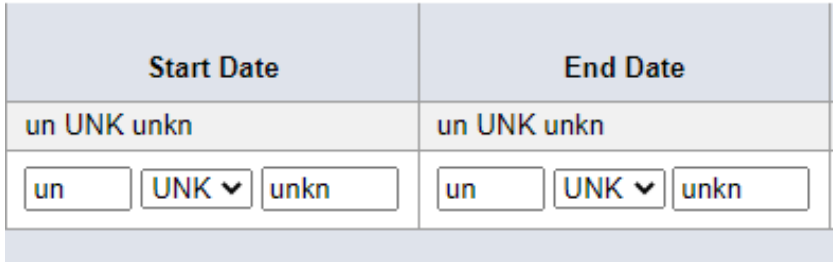
Immunomodulatory Concomitant Medications

- All patients will need to complete the Immunomodulatory Concomitant Medications CRF.
- Report all corticosteroid use (excluding standard antiemetics), immunosuppressants, and hormone replacement therapy per section 8.0 of the protocol.
  - Do NOT record any other concomitant medications
- Timeframe: registration to end of treatment.

Immunomodulatory Concomitant Medications

- Record one concomitant medication per log-line.
- Record unknown for any date fields if the full start or end date cannot be determined.
  - Day: un; Month UNK; Year: UNKN



- If no immunomodulatory concomitant medications were given, answer ‘Were any concomitant medications taken?’ as No.

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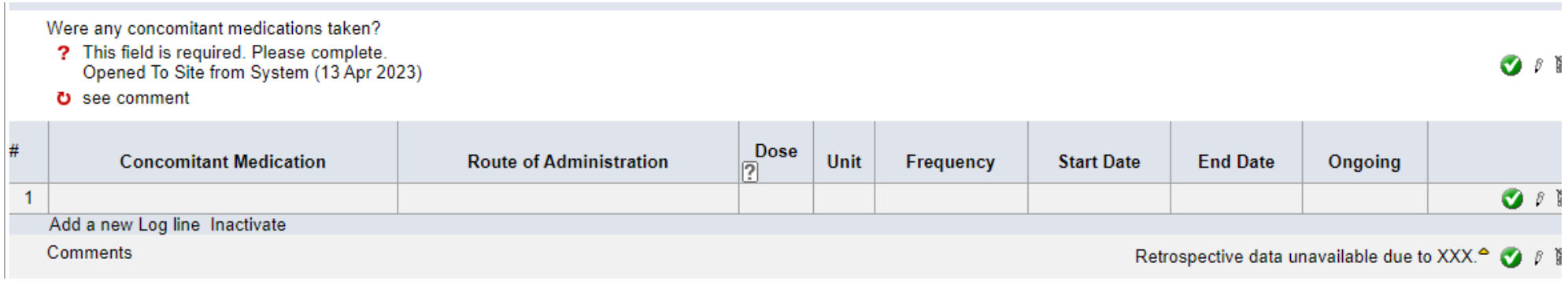
Immunomodulatory Concomitant Medications

- If information about specified concomitant medications is unavailable for retrospective data collection:
  - Enter “Were any concomitant medications taken?” as blank.
    - In query response box, enter “see comment”
  - Enter the comment field with why retrospective data is unavailable starting with: “Retrospective data unavailable.”


Were any concomitant medications taken?
? This field is required. Please complete.
Opened To Site from System (13 Apr 2023)
see comment

#	Concomitant Medication	Route of Administration	Dose	Unit	Frequency	Start Date	End Date	Ongoing	
1									

Add a new Log line Inactivate

Comments Retrospective data unavailable due to XXX.

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Post-Baseline Labs

Added Data Collection

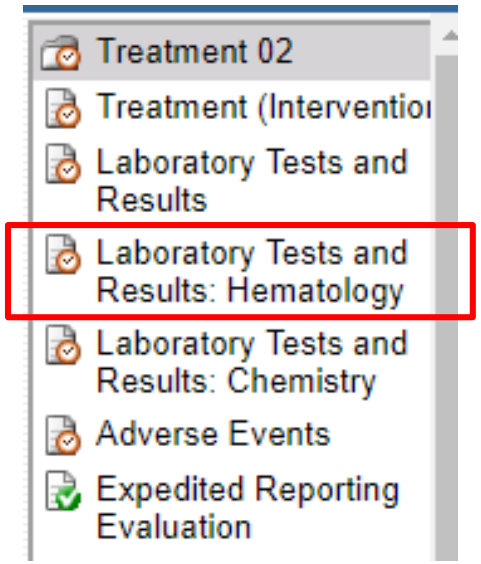
- Capture WBC, HgB, Platelet, Absolute Neutrophil Count, Lymphocytes, TSH, Alkaline Phosphatase, Total Bilirubin, Serum creatinine, Glucose, Potassium, SGOT (ALT), SPGT (AST) Sodium, Bicarbonate, and Calcium lab results.
- Specifically: (If assessed), collection date, lab value, lab test unit, and reference range upper and lower limits numeric values.

Justification

- Laboratory abnormalities worsening from baseline are required by FDA to be included in the US Prescribing Information.
- Comprehensive laboratory collection is required for the development of shift tables, a standard tool for safety assessment.

Laboratory Tests and Results: Hematology

This form will be added to every Treatment folder



Page: **Laboratory Tests and Results: Hematology - Treatment 01**

Cycle

INSTRUCTIONS: Tests should be entered in the treatment cycle they are drawn in.

Was White Blood Cell Count assessed? ○ Yes ○ No

(If yes),

Sample collection date

Lab value

Lab test units of measure
○ mm^(3)
○ 10^(9)/L
○ /µL
○ Other

(If Other), Specify unit

Reference range lower limit numeric value

Reference range upper limit numeric value

Was Hemoglobin (Hb or Hgb) Measurement assessed? ○ Yes ○ No

(If yes),

Sample collection date

Lab value

Lab test units of measure
○ mmol/l

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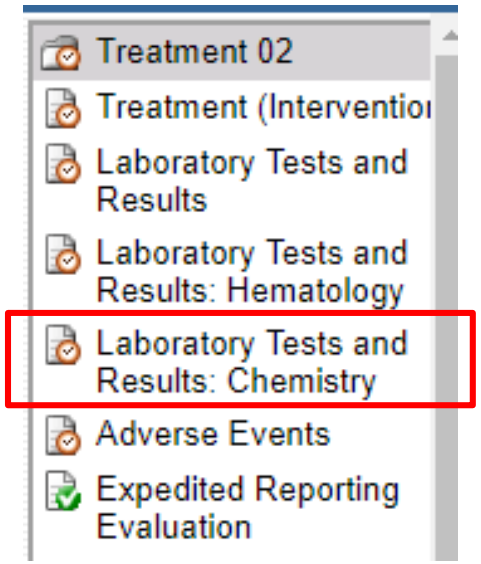
Laboratory Tests and Results: Chemistry

This form will be added to every Treatment folder



Page: **Laboratory Tests and Results: Chemistry - Treatment 01**

Cycle	
INSTRUCTIONS Tests should be entered in the treatment cycle thy are drawn in.	
Was Thyroid Stimulating Hormone (TSH) assessed?	○ Yes ○ No
(If yes),	
Sample collection date	
Lab value	
Lab test units of measure	○ µIU/mL ○ mIU/L ○ IE/L ○ Other
(If Other), Specify unit	
Reference range lower limit numeric value	
Reference range upper limit numeric value	
Was Alkaline Phosphatase (ALP) Measurement assessed?	○ Yes ○ No
(If yes),	
Sample collection date	
Lab value	

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Laboratory Tests and Results: Hematology/Chemistry

- All Lab Test results for applicable labs will need to be entered for every treatment cycle for all patients.

  New forms are present at baseline, treatment, and off treatment.
- Tests should be entered into the treatment cycle for which they were used to determine dosing. The lab set used to determine trial eligibility should be submitted in the baseline folder. The lab set which was drawn for end of treatment follow-up should be submitted in the Off-treatment folder.
- SDMC assistance will be available for data entry (described in upcoming slides)

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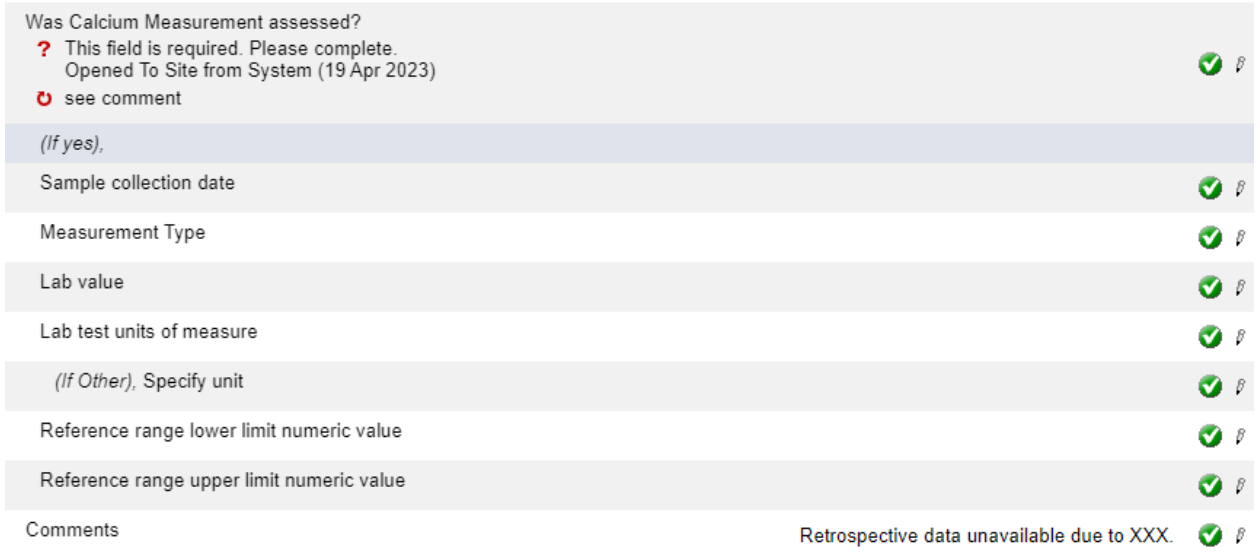
Laboratory Tests and Results: Hematology/Chemistry

- If a specific lab was not done, enter ‘Was [lab name] assessed?’ as No to the specific lab.
- If all lab tests were not performed, enter ‘Was [lab name] assessed?’ as No to for every lab result.

Laboratory Tests and Results: Hematology/Chemistry

- If lab test results are unavailable for retrospective data collection,
  - Enter “Was [lab name] assessed?’ as blank for every lab result.
    - In query response box, enter “see comment”
  - Enter the comment field with why retrospective data is unavailable starting with: “Retrospective data unavailable.”



Data Entry Assistance for Laboratory Tests and Results

- For NCTN sites, the Alliance SDMC can assist with **RETROSPECTIVE** data entry efforts.
  - Retrospective data is any lab results required for Rave folders rolled out up to 30 days after posting of Protocol Update #14.
- All **prospective** data entry (for patients who remain on protocol treatment) must be entered by the site.
  - Upload source documents per protocol.
- AIO Sites must enter all retrospective and prospective lab results.

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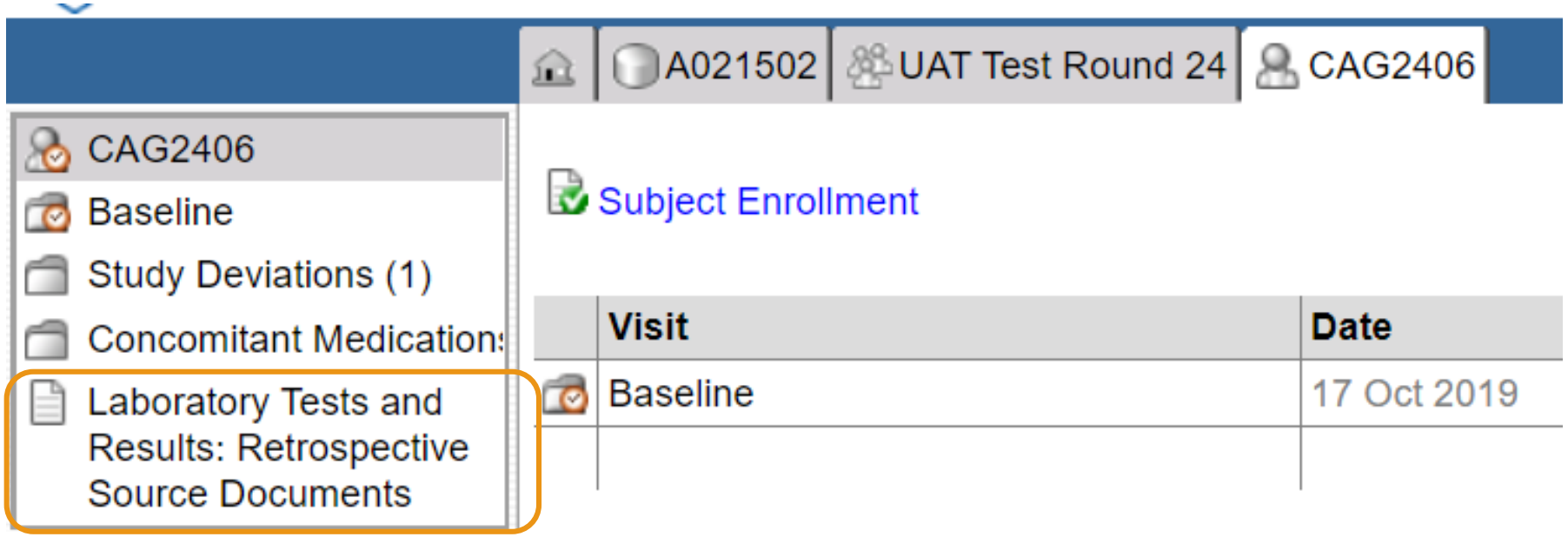
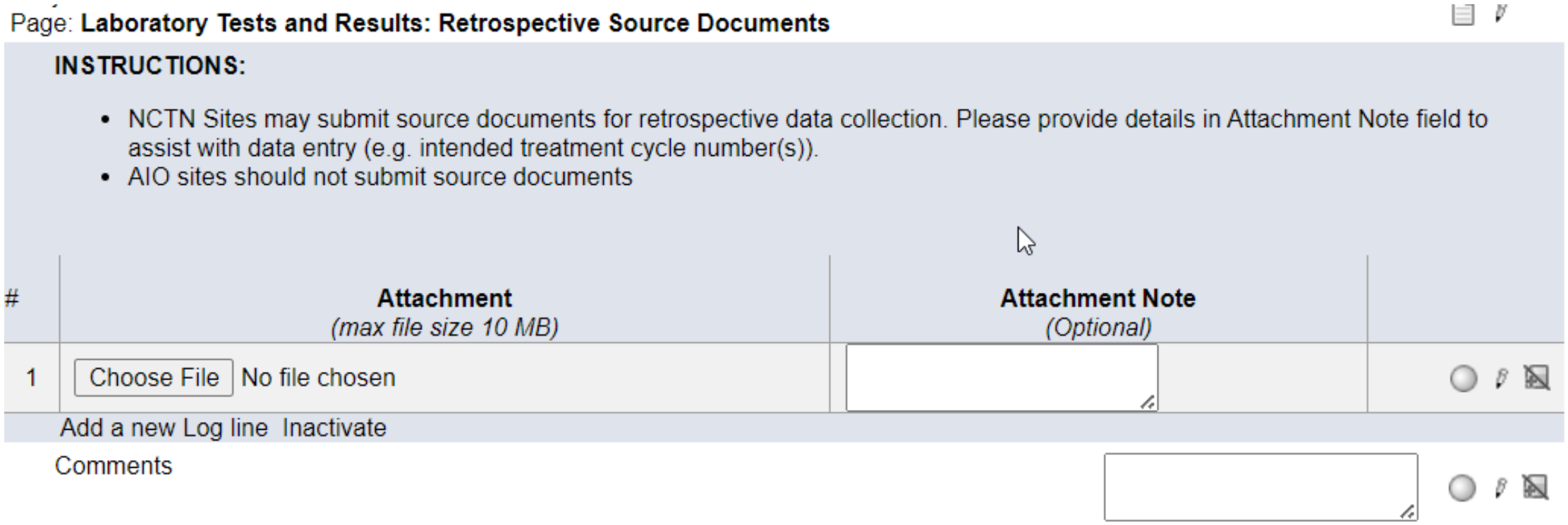
Data Entry Assistance Lab Test Results: New Form Added to Subject Level



This form will capture source documents the SDMC will use to assist NCTN sites with retrospective data entry.

Laboratory Tests and Results: Retrospective Source Documents

NCTN Sites Only



Page: **Laboratory Tests and Results: Retrospective Source Documents**

INSTRUCTIONS:

- NCTN Sites may submit source documents for retrospective data collection. Please provide details in Attachment Note field to assist with data entry (e.g. intended treatment cycle number(s)).
- AIO sites should not submit source documents

#	**Attachment** *(max file size 10 MB)*	**Attachment Note** *(Optional)*
1	Choose File No file chosen	

Add a new Log line Inactivate

Comments

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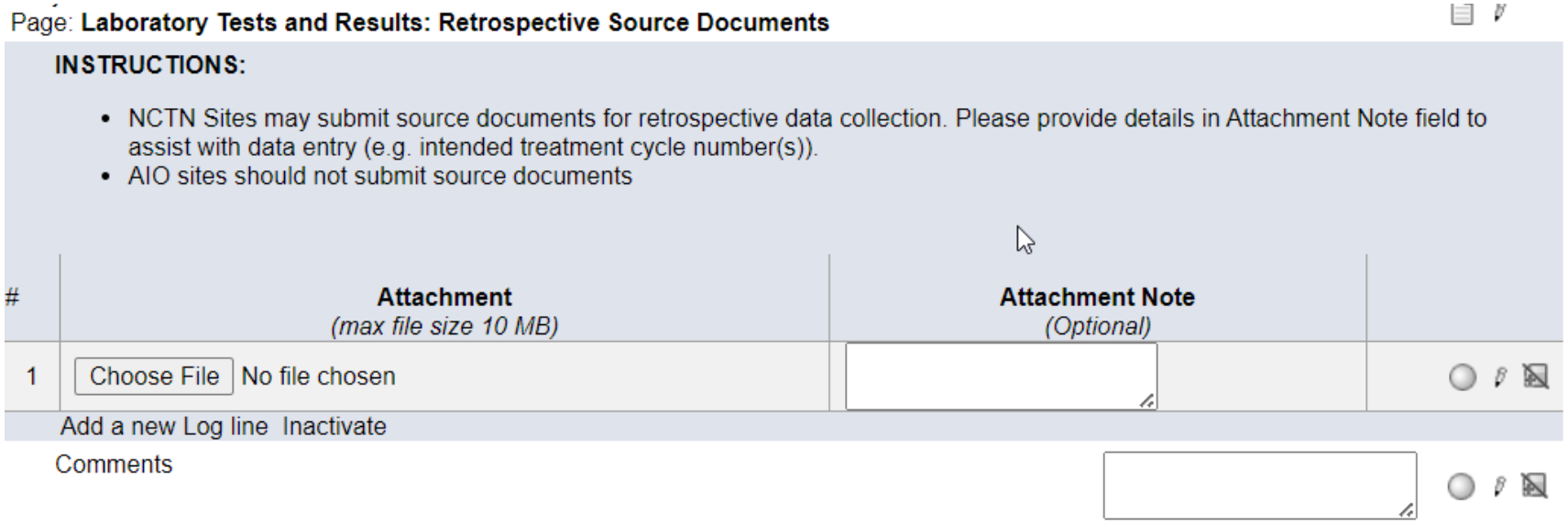
Data Entry Assistance Lab Test Results:
NCTN Sites Only

- Upload redacted source documents for hematology/chemistry lab test results.
- Provide details in attachment note field to assist with data entry, example (intended treatment cycle numbers).


Page: **Laboratory Tests and Results: Retrospective Source Documents**

INSTRUCTIONS:

- NCTN Sites may submit source documents for retrospective data collection. Please provide details in Attachment Note field to assist with data entry (e.g. intended treatment cycle number(s)).
- AIO sites should not submit source documents

#	**Attachment** *(max file size 10 MB)*	**Attachment Note** *(Optional)*
1	Choose File No file chosen	

Add a new Log line Inactivate

Comments

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Data Entry Assistance Lab Test Results:
NCTN Sites Only

- SDMC will enter lab results and attach applicable source documents to the appropriate cycle(s) in Rave.
- Data entry by SDMC will be available to view and edit by site staff in Rave.
- Sites will be responsible for any future queries for data entered by the SDMC.

Data Entry Assistance Lab Test Results:
NCTN Sites Only

- Recommendations:
  - One source document for all labs is acceptable, no need to separate out one source doc per cycle
  - Once all lab results have been uploaded for a patient/site, notify the DM.
    - This will be the SDMC trigger to begin data entry.

Additional details on discontinuation of treatment due to AE

Added Data Collection

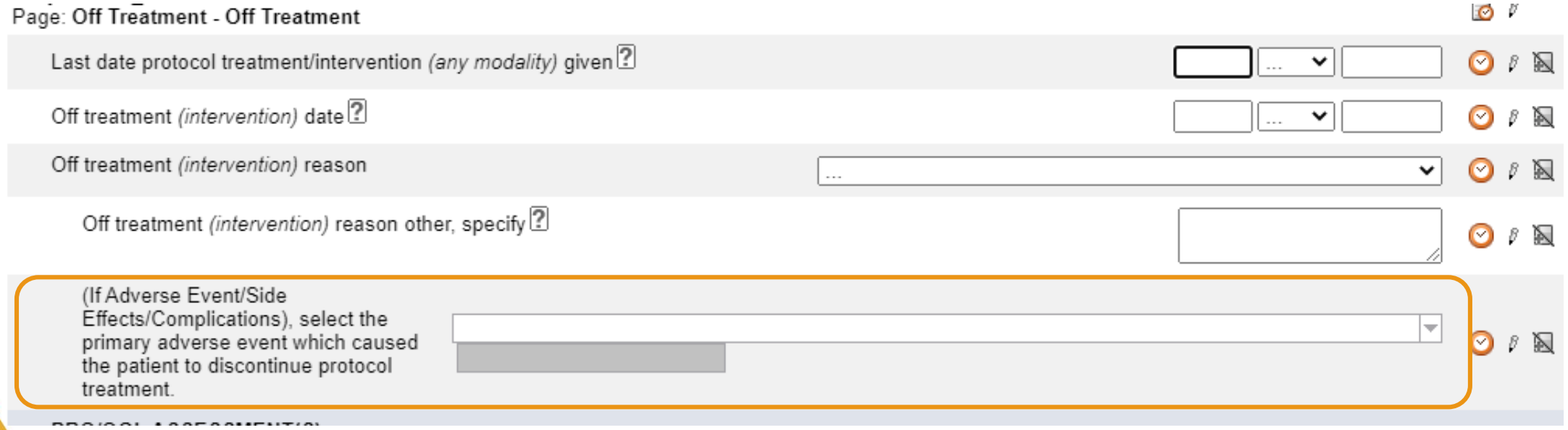
- Add single question to the Off Treatment form to be completed when a patient discontinues protocol treatment due to AE.

Justification

- Need to be able to categorize the specific AE that caused the patient to end protocol treatment for filing (table, narratives, etc).

Off Treatment

- Added new field to the Off Treatment form.
- Field is required when Off treatment reason = Adverse Event/Side Effects/Complications

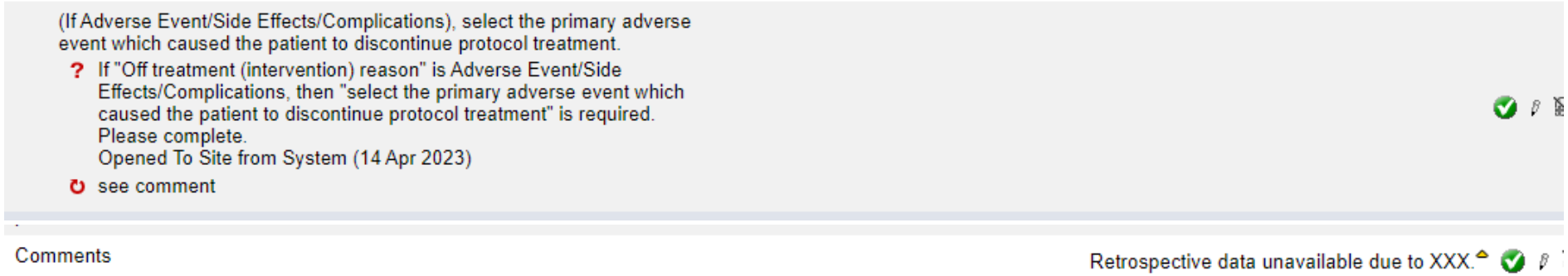


Off Treatment

- New field is required for patients who end protocol treatment due to Adverse Event/Side Effects/Complications.
  - Rave queries will be issued for retrospective data collection.
- Will be prompted to specify the primary adverse event, per CTCAE term, which caused the patient to discontinue protocol treatment.

Off Treatment

- If the primary AE causing the patient to discontinue protocol treatment is unavailable for retrospective data collection:
  - Enter field as blank.
    - In query response box, enter “see comment”
  - Enter the comment field with why retrospective data is unavailable starting with: “Retrospective data unavailable” …



Additional information on measurement, biopsy, etc to support the primary endpoint

Added Data Collection

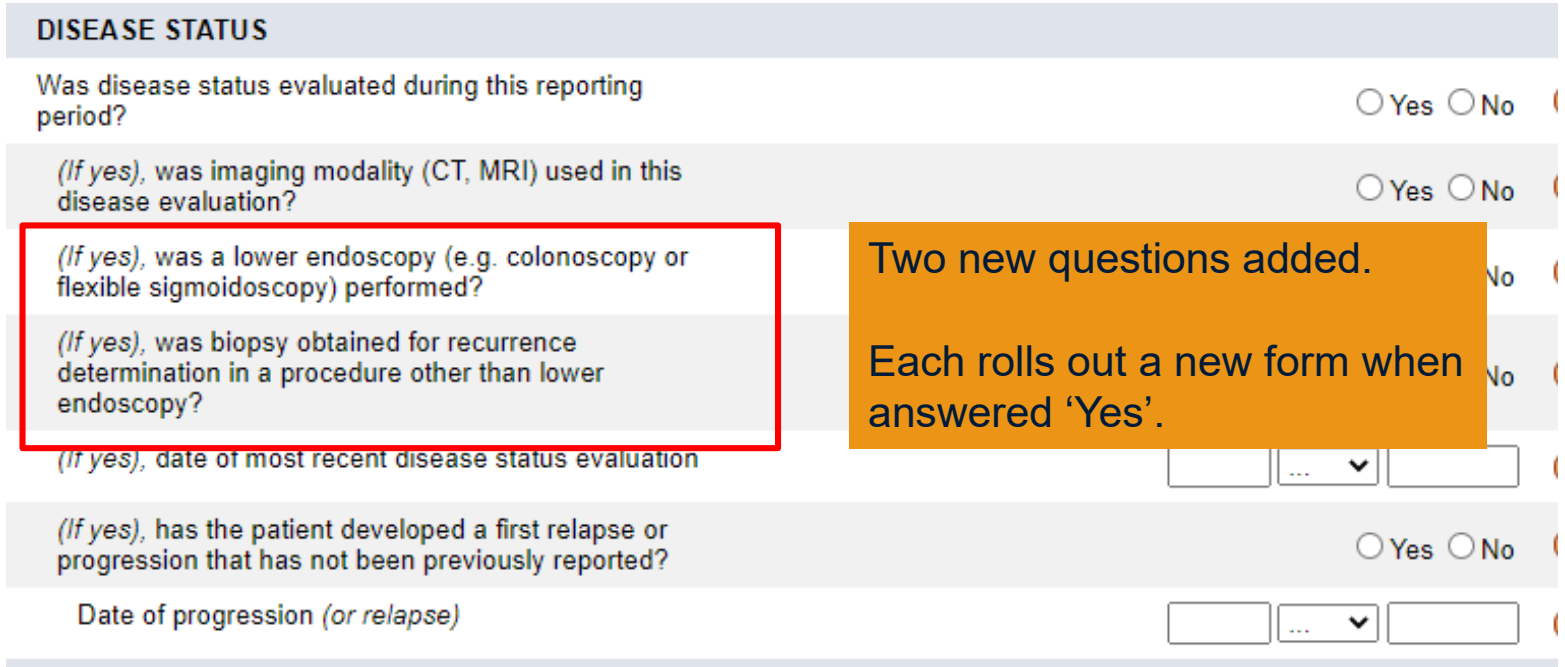
- Add CRFs to collect:
  - Lower Endoscopy details
  - Biopsy details
  - New field for tumor measurements at sites of recurrence.

Justification

- More information on radiographic confirmation and other clinically relevant information will enhance the data to ensure health authorities are conformable with endpoints.
- Requested information was outlined in the Protocol.

New Patient Status Questions for Form Roll-out

- Two questions were added to every Patient Status form.
- When a disease was evaluated, both questions will be required
  - Rave queries will be issued for retrospective data collection.



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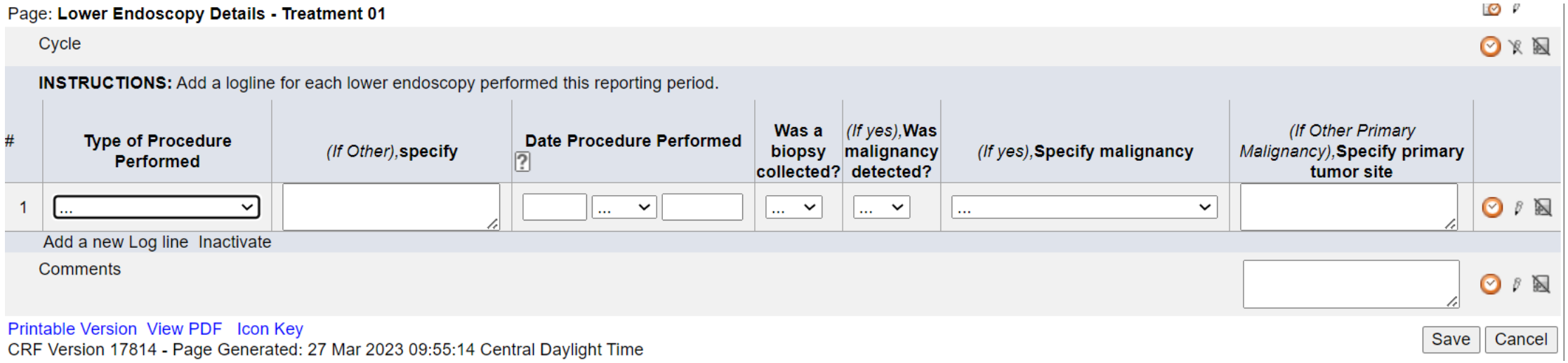
Lower Endoscopy Details

- New form available when ‘Was a lower endoscopy (e.g. colonoscopy or flexible sigmoidoscopy) performed?’ is answered ‘Yes’ on the Patient Status form.



Page: **Lower Endoscopy Details - Treatment 01**

Cycle

INSTRUCTIONS: Add a logline for each lower endoscopy performed this reporting period.

#	Type of Procedure Performed	*(If Other)*,specify	Date Procedure Performed	Was a biopsy collected?	*(If yes)*,Was malignancy detected?	*(If yes)*,Specify malignancy	*(If Other Primary Malignancy)*,Specify primary tumor site
1	...		...	...	...	...	

Add a new Log line Inactivate

Comments

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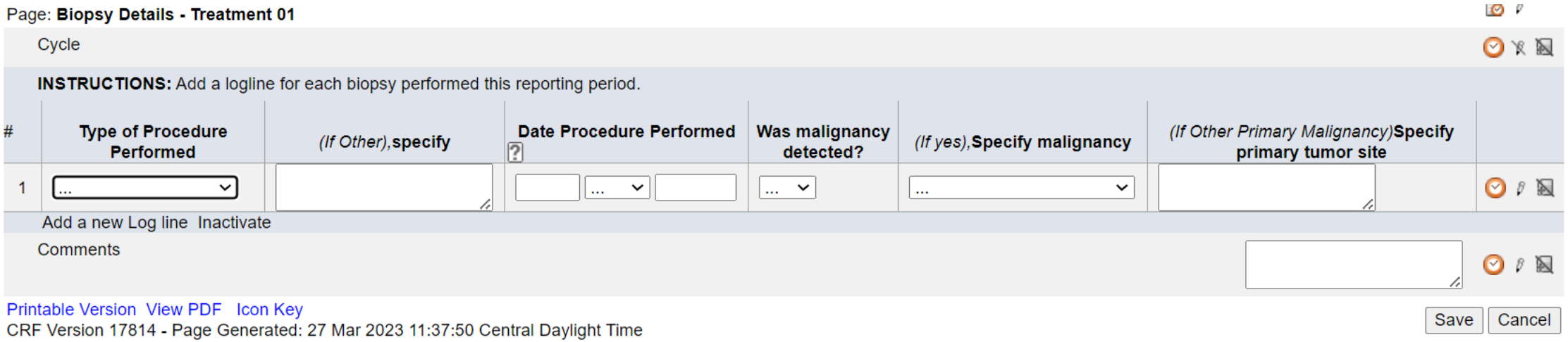
Lower Endoscopy Details

- Form will be required when a lower endoscopy (e.g., colonoscopy or flexible sigmoidoscopy) was done as part of a disease evaluation.

Biopsy Details

- New form available when ‘Was a biopsy obtained for recurrence determination in a procedure other than lower endoscopy?’ is answered ‘Yes’ on the Patient Status form.



Page: **Biopsy Details - Treatment 01**

Cycle

INSTRUCTIONS: Add a logline for each biopsy performed this reporting period.

#	Type of Procedure Performed	*(If Other),* specify	Date Procedure Performed	Was malignancy detected?	*(If yes),* Specify malignancy	*(If Other Primary Malignancy)* Specify primary tumor site
1	...		...	...	...	

Add a new Log line Inactivate

Comments

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Save Cancel

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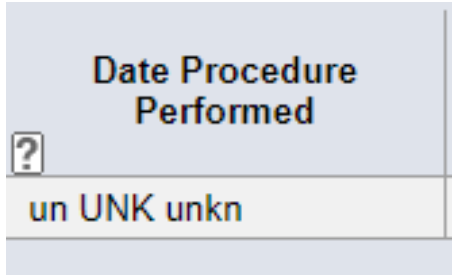
Biopsy Details

- Form will be required when a biopsy is obtained for recurrence determination (in a procedure other than lower endoscopy).

Lower Endoscopy & Biopsy Detail CRFs

- Forms must be completed at the end of the cycle prior to starting the next cycle.
- Add a log line for each procedure within a reporting period.
- Procedure dates may be unknown
  - Day: un; Month UNK; Year: UNKN



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Lower Endoscopy & Biopsy Detail CRFs

- If a lower endoscopy or biopsy was completed but the procedure results are unavailable for data entry:
  - Answer ‘Yes’ to the trigger question on the Patient Status CRFs to roll out the subsequent forms.
  - The fields on the applicable CRF will be left blank.
    - In query response box, enter “see comment”
  - Enter the comment field n applicable CRF (Lower Endoscopy Details or Biopsy Details) with why retrospective data is unavailable starting with: “Retrospective data unavailable” … (Example on next slide)

Lower Endoscopy & Biopsy Detail CRFs

#	Type of Procedure Performed	*(If Other),* specify	Date Procedure Performed	Was a biopsy collected?	*(If yes),* Was malignancy detected?	*(If yes),* Specify malignancy	*(If Other Primary Malignancy),* Specify primary tumor site	
1								

Was a biopsy collected?
? This field is required. Please complete.
Opened To Site from System (14 Apr 2023)
see comment

Date Procedure Performed
? This field is required. Please complete.
Opened To Site from System (14 Apr 2023)
see comment

Type of Procedure Performed
? This field is required. Please complete.
Opened To Site from System (14 Apr 2023)
see comment

Add a new Log line Inactivate

Comments — Retrospective data unavailable due to XXX.

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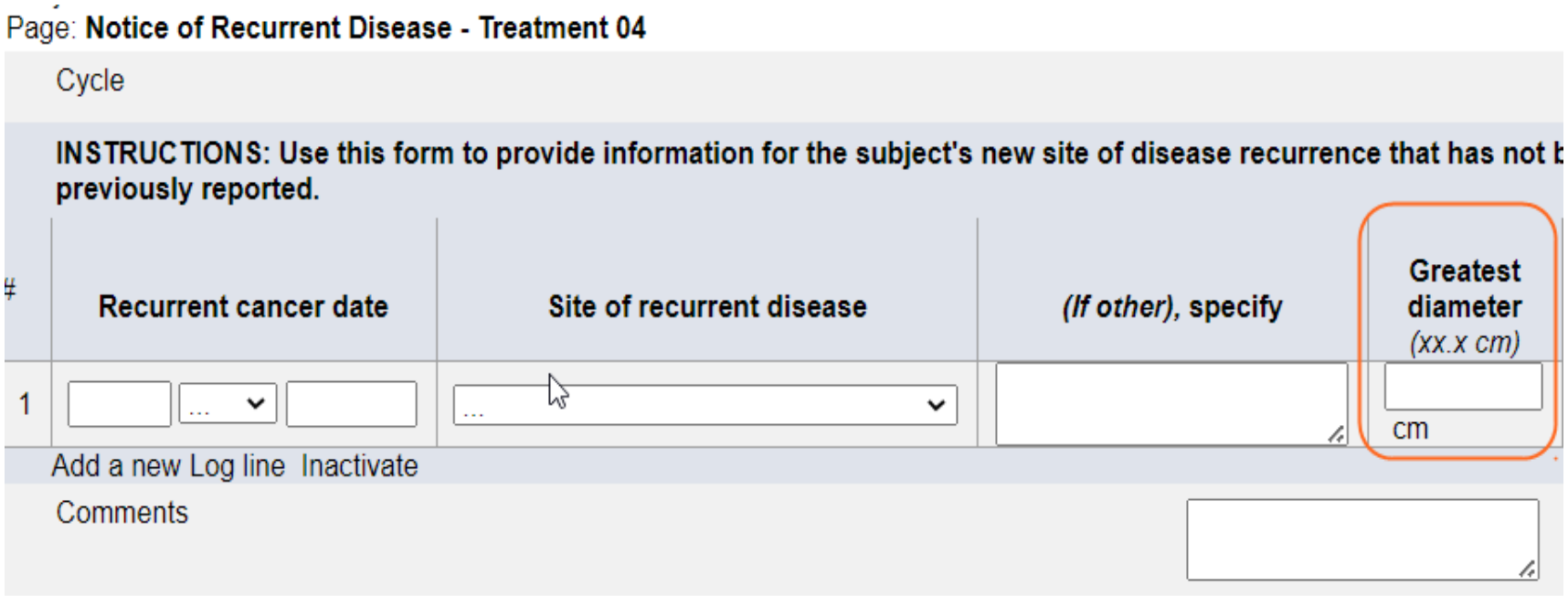
Notice of Recurrent Disease

- New field added to capture tumor measurement.


Page: **Notice of Recurrent Disease - Treatment 04**

Cycle

INSTRUCTIONS: Use this form to provide information for the subject's new site of disease recurrence that has not b previously reported.

#	Recurrent cancer date	Site of recurrent disease	*(If other)*, specify	Greatest diameter *(xx.x cm)*
1	...	...		cm

Add a new Log line Inactivate

Comments

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Notice of Recurrent Disease

- New field is required for patients who have recurred.
  - Rave queries will be issued for retrospective data collection.
- Will be prompted to enter the greatest diameter of the disease site.
  - Greatest diameter = Longest Diameter
  - Enter the ***longest diameter for the largest lesion per site*** of disease.
    - (i.e. - ***not*** the longest diameter for each lesion within the same site)
  - Enter diameter is **centimeters** (XX.X cm)

Notice of Recurrent Disease

- If the greatest diameter of the recurrent disease is unavailable for retrospective data collection:
  - Enter field as blank.
    - In query response box, enter “see comment”
  - Enter the comment field with why retrospective data is unavailable starting with: “Retrospective data unavailable” …

Images/Scans for Storage

Added Data Collection

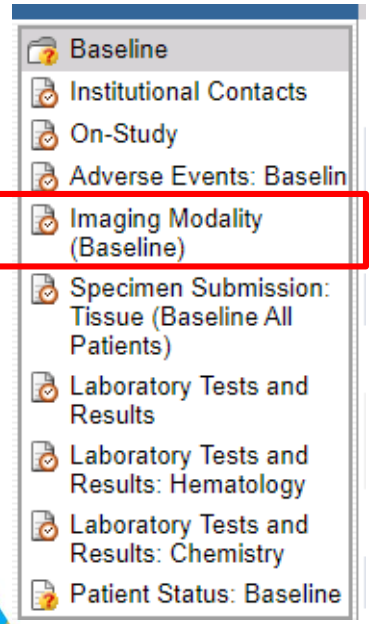
- Additional information on imaging modality
- Images/Scans submitted to TRIAD

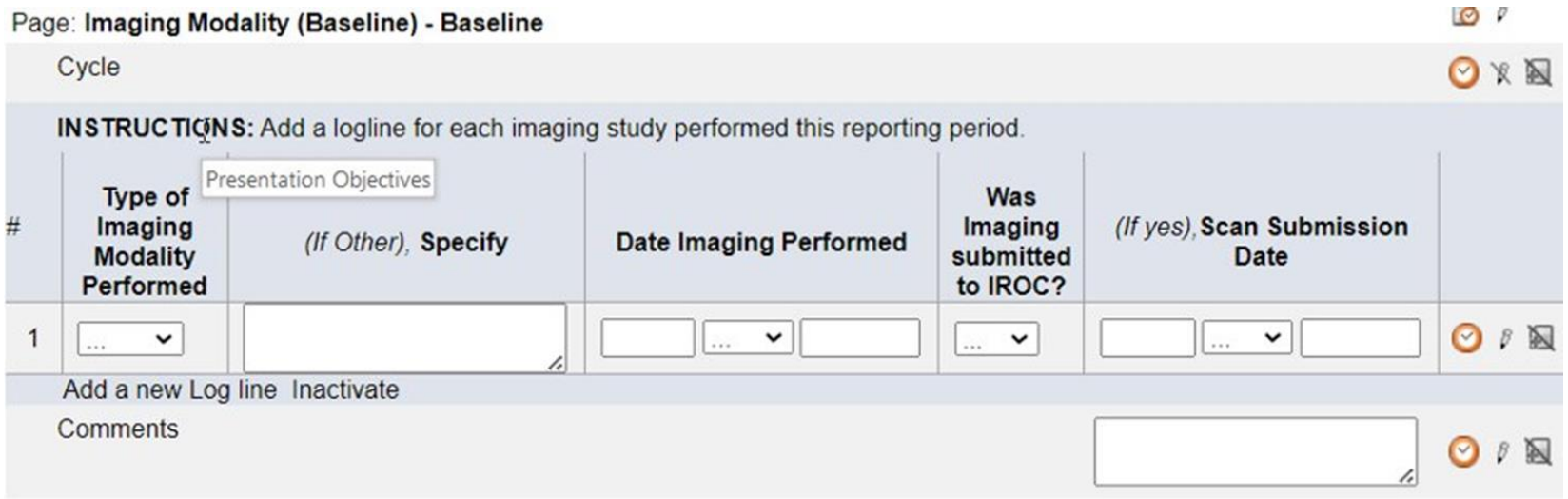
Justification

- Scans will be banked for future central, independent review of recurrences.
- FDA requests this information for filing.

Imaging Modality (Baseline)

This form will be added to every Baseline folder





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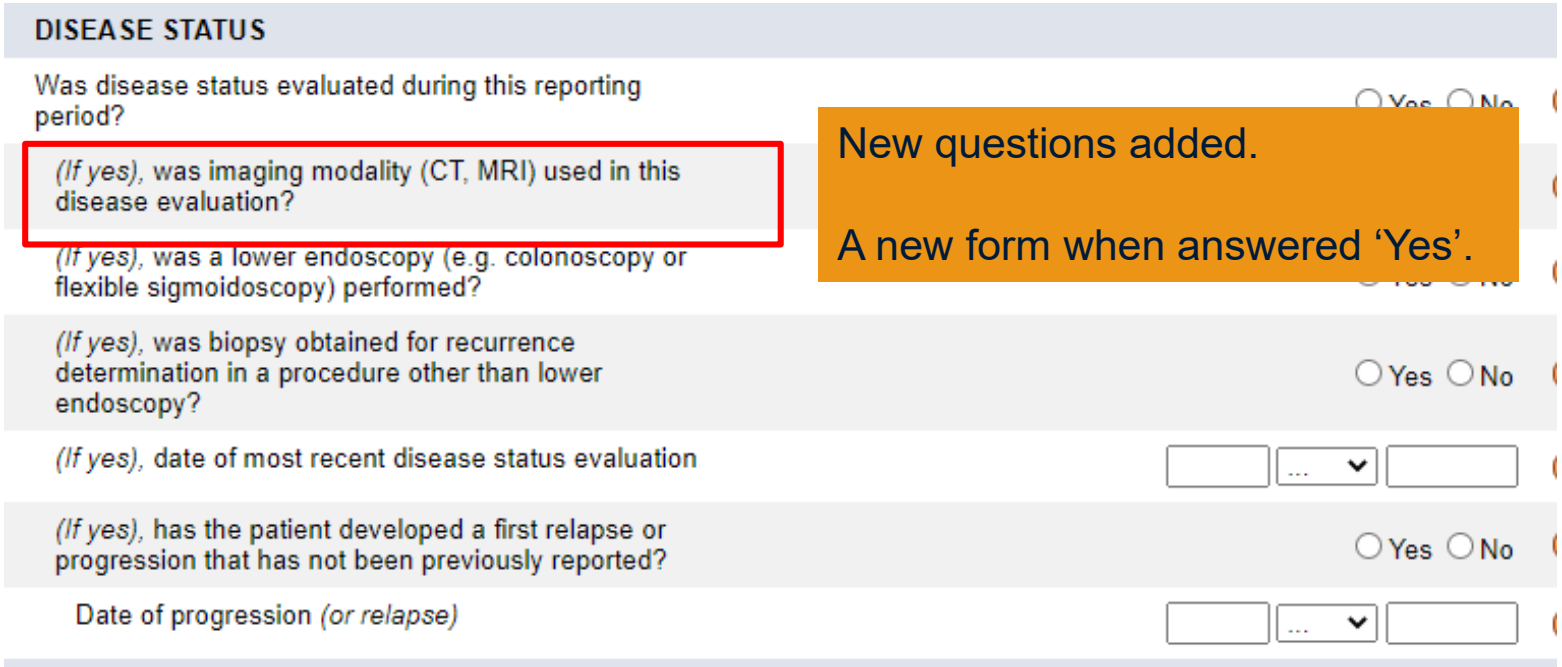
Imaging Modality (Baseline)

- All patients will need to complete the Imaging Modality: Baseline CRF.
  - Documents imaging performed and submission of scans to IROC

New Patient Status Questions for Form Roll-out

- A new question was added to every Patient Status form.
- When a disease was evaluated, this question will be required
  - Rave queries will be issued for retrospective data collection.



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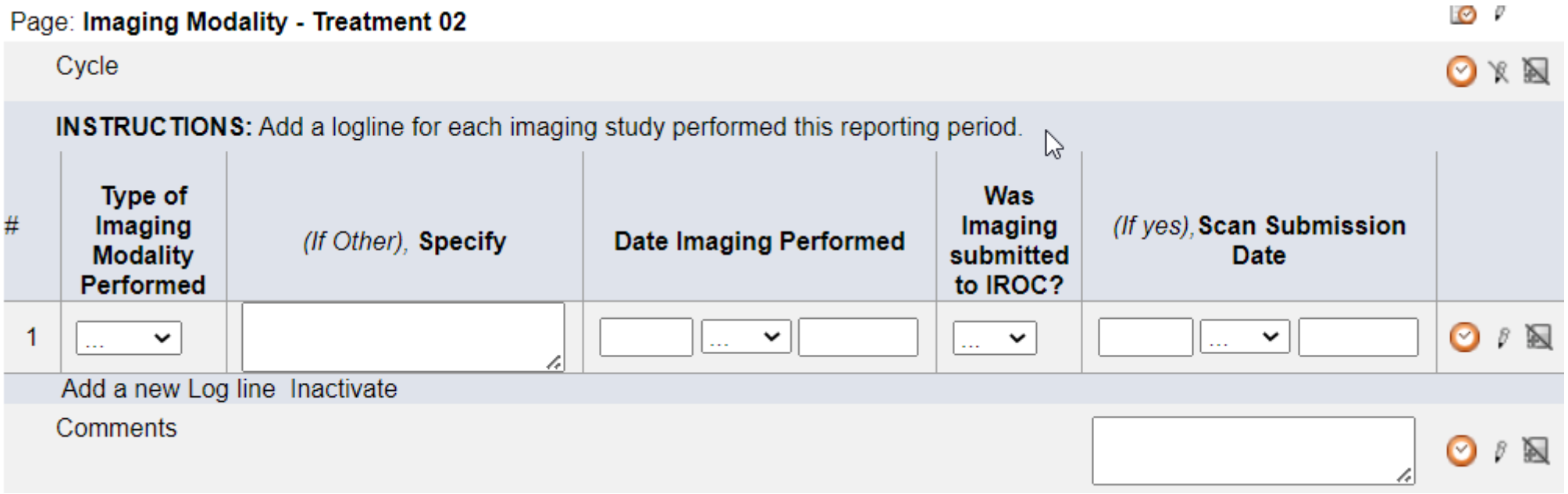
Imaging Modality

- New form will become available when ‘Was imaging modality (CT, MRI) used in this disease evaluation?’ is answered ‘Yes’ on the Patient Status form.
  - Baseline is used to capture any additional imagining done after registration but prior to treatment.



Page: **Imaging Modality - Treatment 02**

Cycle

INSTRUCTIONS: Add a logline for each imaging study performed this reporting period.

#	Type of Imaging Modality Performed	*(If Other),* Specify	Date Imaging Performed	Was Imaging submitted to IROC?	*(If yes),* Scan Submission Date
1	...			...	

Add a new Log line Inactivate

Comments

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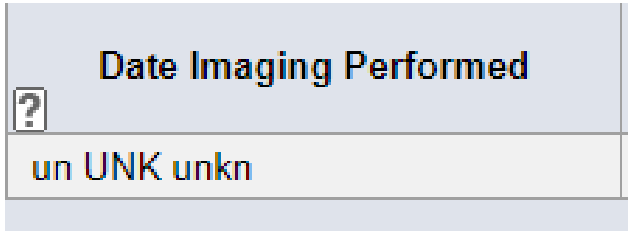
Imaging Modality

- Form will be required when imaging was done as part of a disease evaluation
  - Documents imaging performed and submission of scans to IROC

Imaging Modality

- Form must be completed at the end of the cycle prior to starting the next cycle.
- Add a log line for each imaging performed within a reporting period.
- Date Imaging Performed may be unknown
  - Day: un; Month UNK; Year: UNKN



- Scan Submission Date must be entered in full (no partial/unknown dates allowed).

Imaging Modality

- If imaging was done but information is unavailable for data entry:
  - Answer ‘Yes’ to the trigger question on the Patient Status CRFs to roll out the subsequent forms.
  - The fields on the applicable CRF will be left blank.
    - In query response box, enter “see comment”
  - Enter the comment field with why retrospective data is unavailable starting with: “Retrospective data unavailable”… (Example on next slide)

Imaging Modality

INSTRUCTIONS: Add a logline for each imaging study performed this reporting period.

#	Type of Imaging Modality Performed	*(If Other),* Specify	Date Imaging Performed	Was Imaging submitted to IROC?	*(If yes),* Scan Submission Date	
1						

Date Imaging Performed
? This field is required. Please complete.
Opened To Site from System (19 Apr 2023)
See comment

Was Imaging submitted to IROC?
? This field is required. Please complete.
Opened To Site from System (19 Apr 2023)
See comment

Type of Imaging Modality Performed
? This field is required. Please complete.
Opened To Site from System (19 Apr 2023)
See comment

Add a new Log line Inactivate

Comments — Retrospective data unavailable due to XXX.

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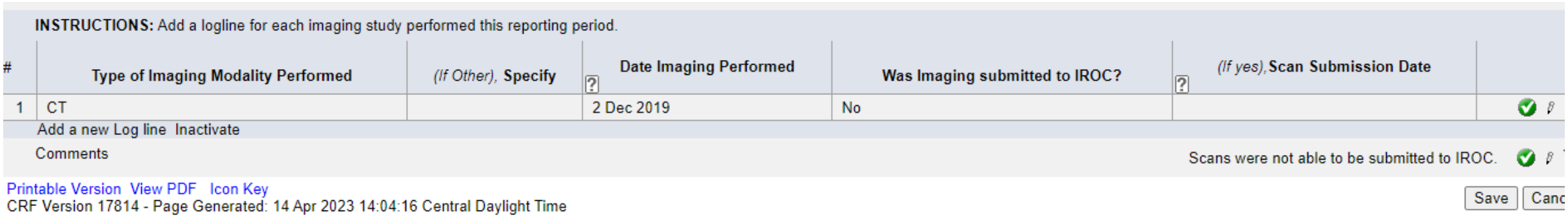
Imaging Modality

- If a scan is unable to be submitted to IROC:
  - Enter “Was imaging submitted to IROC?” as No
  - Enter the reason why in the comment field: “Scans were not able to be submitted to IROC.”



INSTRUCTIONS: Add a logline for each imaging study performed this reporting period.

#	Type of Imaging Modality Performed	*(If Other),* Specify	Date Imaging Performed	Was Imaging submitted to IROC?	*(If yes),* Scan Submission Date	
1	CT		2 Dec 2019	No		

Add a new Log line Inactivate

Comments: Scans were not able to be submitted to IROC.

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Timelines

Protocol Posting

- Data mitigation protocol update posted
- Rave Migration
- DTL Updated

+30 days

- DTL Approved by site
- Protocol Update approved by IRB
- Informational Webinar

+6 months

- Retrospective Data Collection

Ongoing post protocol update

- Prospective Data collection
- Data cleaning activities for all current and new data

Additional Per Case Reimbursements

- Additional funding will be provided to the sites who actively participate in obtaining retrospective data collection.
- Funding will be provided at the end of the retrospective data collection period.

Overdue Data/IPEC Impacts

- All retrospective forms will appear overdue within Rave (at time of migration or as data is entered) – some will be significantly overdue.
- The DQP will match Rave for overdue-ness.
- The current IPEC reports (for May 2023) ARE NOT impacted by any A021502 data mitigation activities. (Data was frozen before the Rave migration.)
- Special consideration will be taken by the IPEC committee for future reports for the retrospective data collection.

General information

- The Alliance will not contact sites for retrospective data collection or issue any queries if the site has an IRB status of “Withdrawn.”

- For patients that have transferred
  - The current site will be responsible for contacting the former site for the additional data/source documents needed.
  - The current site will be responsible for entry of data into Rave.
  - Budgeting/Payment will go to the current site for retrospective data collection/entry.

Resources

- Updated Data Completion Guidelines
- Recorded webinar
- Live webinar

Site Principal Investigator (PI)
CRF Sign Off

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Site PI Signature

- In accordance with FDA requirements[1] (Part III.B.1.a), the Principal Investigator (PI) must attest to the accuracy and completeness of the submitted data [to the FDA].

- A021502 DTL will be updated to add the “Rave Investigator” role to facilitate this regulatory requirement.

1: https://www.fda.gov/media/85183/download

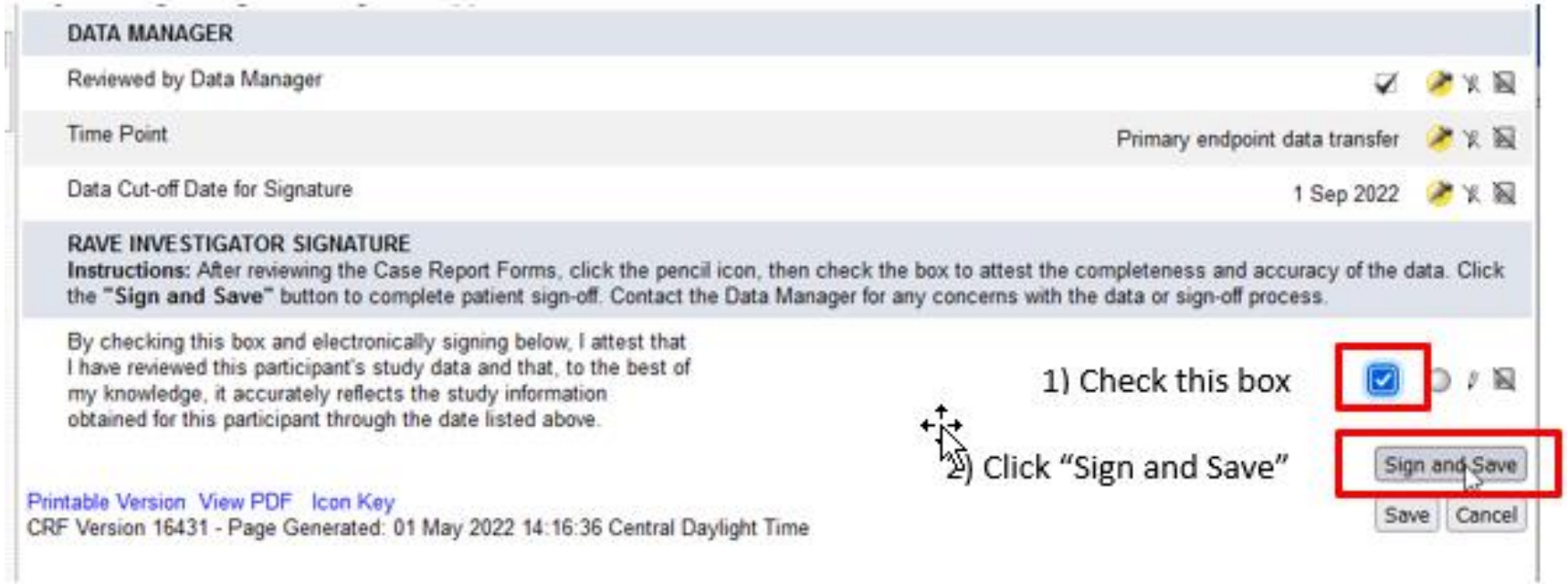
Site PI Signature – Rave Process

- At key milestones, the “Rave Investigator” will be prompted by the Alliance Data Manager to attest to the completeness and accuracy of the patient data via electronic signature within Medidata Rave.

- This will occur when all data is clean, complete, and locked prior to a key study milestone (e.g., primary endpoint analysis, database closure).

Site PI Signature – Rave Process

1. Log into Rave.
2. For each patient enrolled, review the data entered.
3. Complete sign-off within Rave.



3) When prompted, enter your iMedidata username and password to electronically sign.

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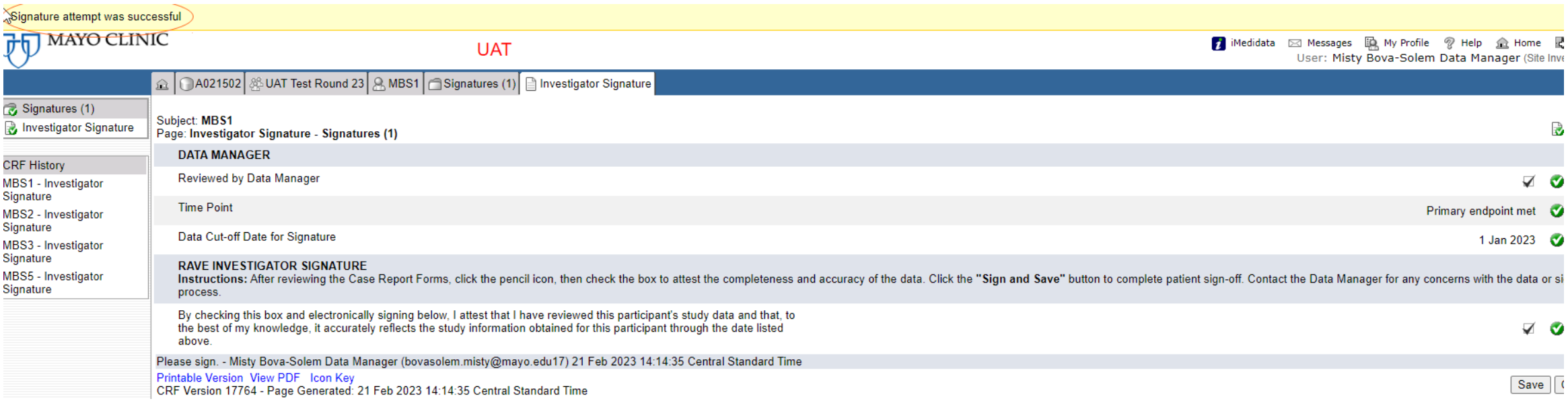

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Site PI Signature – General Comments

- Upon activation of the DTL, assigned “Rave Investigator” staff will receive an invitation to A021502.
  - To prepare for future work, the “Rave Investigator” should set-up their iMedidata account, complete the required training, and accept the invitation to the study.

- Do not complete the attestation for a patient until instructed to do so.
  - If any data is changed after the electronic signature is completed, the “Rave Investigator” will be required to complete the attestation and electronically sign again.

- The Data Manager will prompt the signature process at the proper time. This will include detailed instructions to assist site staff in completing the signature process.

Questions?

- Data management questions, please contact Hildebrandt.Stacey@mayo.edu