

NCI CDISC Harmonization Working Group

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Agenda

- COVID-19
- Migration of COVID-19 to studies
- TRIAD Forms
- CDISC Oncology Review
- SME Webinar

COVID-19 Updates

- Forms have been posted on the CDSIC Wiki
 - Theradex Approach
 - Opted for multiple migrations to keep sites in a singular environment and avoid additional training.

THERADEX ONCOLOGY DEV

10002 National Cancer Institute Developmental Th... NCIDTC-0001 COVID-19 (1) COVID-19 Testing

Subject: NCIDTC-0001
Page: COVID-19 Testing - COVID-19 (1)

CDASHIG 2.0
INSTRUCTIONS: Record results of all COVID-19 testing.

Was the participant tested for COVID-19? Yes No

#	Sample Collection Date	Assay Date	Result	Name of COVID-19 Assay (if available)	(If positive) Outcome	(If positive) Therapy
1	<input type="text"/>	<input type="text"/>	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Indeterminate <input type="radio"/> Unknown	<input type="text"/>	<input type="radio"/> Recovered or Resolved <input type="radio"/> Recovered or Resolved with Sequelae <input type="radio"/> Fatal <input type="radio"/> Unknown	<input type="text"/>

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COVID-19 Updates



DEV

10002 National Cancer Institute Developmental Th... NCIDTC-0001 COVID-19 (1) COVID-19 Related Study Interruptions

Subject: NCIDTC-0001
Page: COVID-19 Related Study Interruptions - COVID-19 (1)

CDASHIG 2.0

Did the participant have any delayed or missed protocol visits, labs, or assessments for any reason related to COVID-19 (diagnosis, travel restrictions, participant or physician decision, etc)? Yes No

#	Date of interruption or delay	Type	Brief summary/justification of deviation	Was CIRB notified?	If yes, Date	Was the local IRB notified?	If yes, Date	Comment (e.g. location of specimens, etc)
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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Save Cancel

10002 National Cancer Institute Developmental Th... NCIDTC-0001

Subject: NCIDTC-0001
Page: COVID-19 Related Study Interruptions - COVID-19 (1)

CDASHIG 2.0

Did the participant have any delayed or missed protocol visits, labs, or assessments (diagnosis, travel restrictions, participant or physician decision, etc)?

#	Date of interruption or delay	Type
1	<input type="text"/>	<input type="text"/>

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- Missed Study Visit
- Phone or Virtual Visit
- Late or Missed Study Lab
- Late or Missed Correlative Lab
- Cycle Treatment Given Early or Late
- Late or Missed Imaging Study Procedure
- Late or Missed Other Study Procedure
- Late, Missed, or Unable to Ship Study Specimen
- Late or Missed QOL/PRO
- Other, specify

TRIAD Forms

- Reviewing set of forms with ACR
 - Majority of content may be administrative
 - Priority item for the NCI
 - Meeting with ACR to review forms