

Public reporting burden for this collection of information is estimated to average 1,800 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (OMB#xxxx-xxxx). Do not return the completed form to this address.

Audit Domain CTMSP1P2	Institution Name University Health Network-Princess Margaret Hospital	Audit Date 03/08/2017	Audit Type Data Audit
Membership Study Type Treatment		Institution CTEP Code 11030	Membership Type Main Member
Audit Category Treatment			

Send Final Report Cover Letter	
*Audit Level: Protocol Level	
Sent History	Cover Letter Template
	Pediatric Oncology Branch
Email To*	
CC	
Attachment	
Subject	Pediatric Branch Report
Dear Caryn,	
Please see the attached NCI Pediatric Branch Data Audit.	
Sincerely,	
Theresa	
Save Send Clear	
Back To Search Results	



Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Rockville, Maryland 20850

Follow-up/Corrective And Preventive Action Plan

Institution Name Tier1: Children's Hospital of Alabama	Institution CTEP Code Tier1: AL013
Institution Name Tier2:	Institution CTEP Code Tier2:
Audit Domain: COGC	Audit Type: COGC audit
Audit Date: 07/11/2017	Audit Category: Treatment

In order to improve the efficiency the following corrective action plan was developed. You must use this plan to respond to all the follow-up requested. You can include additional documentation as PDF along with this plan and send it to <email address>. If supporting documentation is more than X number of pages, please send them via US Mail or Fax <Fax number>

IRB Review

Protocol Number: ADVL1211
Follow-up Request Comments: https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getAssessmentScreens.action#

Corrective and Preventive Action Plan: (enter comments below)



Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Rockville, Maryland 20850

Follow-up/Corrective And Preventive Action Plan

Institution Name Tier1: Children's Hospital of Alabama	Institution CTEP Code Tier1: AL013
Institution Name Tier2:	Institution CTEP Code Tier2:
Audit Domain: COGC	Audit Type: COGC audit
Audit Date: 07/11/2017	Audit Category: Treatment

In order to improve the efficiency the following corrective action plan was developed. You must use this plan to respond to all the follow-up requested. You can include additional documentation as PDF along with this plan and send it to <email address>. If supporting documentation is more than X number of pages, please send them via US Mail or Fax <Fax number>

ICC Review

Protocol Number: ADVL1211
Follow-up Request Comments:
<https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getAssessmentScreens.action#>

Corrective and Preventive Action Plan: (enter comments below)



Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Rockville, Maryland 20850

Follow-up/Corrective And Preventive Action Plan

Institution Name Tier1: Children's Hospital of Alabama	Institution CTEP Code Tier1: AL013
Institution Name Tier2:	Institution CTEP Code Tier2:
Audit Domain: COGC	Audit Type: COGC audit
Audit Date: 07/11/2017	Audit Category: Treatment

In order to improve the efficiency the following corrective action plan was developed. You must use this plan to respond to all the follow-up requested. You can include additional documentation as PDF along with this plan and send it to <email address>. If supporting documentation is more than X number of pages, please send them via US Mail or Fax <Fax number>

DTL Review

Protocol Number: ADVL1211
Follow-up Request Comments:
<https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getAssessmentScreens.action#>

Corrective and Preventive Action Plan: (enter comments below)



Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Rockville, Maryland 20850

Follow-up/Corrective And Preventive Action Plan

Institution Name Tier1: Children's Hospital of Alabama	Institution CTEP Code Tier1: AL013
Institution Name Tier2:	Institution CTEP Code Tier2:
Audit Domain: COGC	Audit Type: COGC audit
Audit Date: 07/11/2017	Audit Category: Treatment

In order to improve the efficiency the following corrective action plan was developed. You must use this plan to respond to all the follow-up requested. You can include additional documentation as PDF along with this plan and send it to <email address>. If supporting documentation is more than X number of pages, please send them via US Mail or Fax <Fax number>

Pharmacy Review

Protocol Number: ADVL1211
Follow-up Request Comments: https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getPharmacyAssessmentScreen.action#

Corrective and Preventive Action Plan: (enter comments below)



Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Rockville, Maryland 20850

Follow-up/Corrective And Preventive Action Plan

Institution Name Tier1: Children's Hospital of Alabama	Institution CTEP Code Tier1: AL013
Institution Name Tier2:	Institution CTEP Code Tier2:
Audit Domain: COGC	Audit Type: COGC audit
Audit Date: 07/11/2017	Audit Category: Treatment

In order to improve the efficiency the following corrective action plan was developed. You must use this plan to respond to all the follow-up requested. You can include additional documentation as PDF along with this plan and send it to <email address>. If supporting documentation is more than X number of pages, please send them via US Mail or Fax <Fax number>

Patient Case Review

A. Informed Consent

Protocol Number	Patient Number
ADVL1211	830653
Follow-up Request Comments: https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getPatientCaseAssessmentScreen.action#	

Corrective and Preventive Action Plan: (enter comments below)



Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Rockville, Maryland 20850

Follow-up/Corrective And Preventive Action Plan

Institution Name Tier1: Children's Hospital of Alabama	Institution CTEP Code Tier1: AL013
Institution Name Tier2:	Institution CTEP Code Tier2:
Audit Domain: COGC	Audit Type: COGC audit
Audit Date: 07/11/2017	Audit Category: Treatment

In order to improve the efficiency the following corrective action plan was developed. You must use this plan to respond to all the follow-up requested. You can include additional documentation as PDF along with this plan and send it to <email address>. If supporting documentation is more than X number of pages, please send them via US Mail or Fax <Fax number>.

Patient Case Review

B. Eligibility

Protocol Number	Patient Number
ADV1211	830653

Follow-up Request Comments:
<https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getPatientCaseAssessmentScreen.action#>

Corrective and Preventive Action Plan: (enter comments below)



Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Rockville, Maryland 20850

Follow-up/Corrective And Preventive Action Plan

Institution Name Tier1: Rhode Island Hospital	Institution CTEP Code Tier1: RI005
Institution Name Tier2:	Institution CTEP Code Tier2:
Audit Domain: CTMSP1P2	Audit Type: Data Audit
Audit Date: 01/11/2017	Audit Category: Treatment

In order to improve the efficiency the following corrective action plan was developed. You must use this template to respond to all the follow-up items requested. You can include additional documentation as PDF along with the corrective and preventive action plan and send it to tgarriga@CTIS1theradex.com. If supporting documentation is more than 20 pages, please send them via US Mail or Fax them to 609-799-9391.

Patient Case Review

C. Treatment

Protocol Number	Patient Number
9882	RI005-006

Follow-up Request Comments: Please provide a corrective and preventative action plan to ensure that discrepancies between records documenting accountability of investigational agents are reconciled. In addition, provide a plan and ensure that patients return any unused drug and patient diaries.

Corrective and Preventive Action Plan: (enter comments below)



Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Rockville, Maryland 20850

Follow-up/Corrective And Preventive Action Plan

Institution Name Tier1: Children's Hospital of Alabama	Institution CTEP Code Tier1: AL013
Institution Name Tier2:	Institution CTEP Code Tier2:
Audit Domain: COGC	Audit Type: COGC audit
Audit Date: 07/11/2017	Audit Category: Treatment

In order to improve the efficiency the following corrective action plan was developed. You must use this plan to respond to all the follow-up requested. You can include additional documentation as PDF along with this plan and send it to <email address>. If supporting documentation is more than X number of pages, please send them via US Mail or Fax <Fax number>

Patient Case Review

E. Adverse Event

Protocol Number	Patient Number
ADVL1211	830653
Follow-up Request Comments: https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getPatientCaseAssessmentScreen.action#	

Corrective and Preventive Action Plan: (enter comments below)



Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Rockville, Maryland 20850

Follow-up/Corrective And Preventive Action Plan

Institution Name Tier1: Children's Hospital of Alabama	Institution CTEP Code Tier1: AL013
Institution Name Tier2:	Institution CTEP Code Tier2:
Audit Domain: COGC	Audit Type: COGC audit
Audit Date: 07/11/2017	Audit Category: Treatment

In order to improve the efficiency the following corrective action plan was developed. You must use this plan to respond to all the follow-up requested. You can include additional documentation as PDF along with this plan and send it to <email address>. If supporting documentation is more than X number of pages, please send them via US Mail or Fax <Fax number>

Patient Case Review

D. Disease Outcome/Response

Protocol Number	Patient Number
ADVL1211	830653
Follow-up Request Comments: https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getPatientCaseAssessmentScreen.action#	

Corrective and Preventive Action Plan: (enter comments below)



Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Rockville, Maryland 20850

Follow-up/Corrective And Preventive Action Plan

Institution Name Tier1: Children's Hospital of Alabama	Institution CTEP Code Tier1: AL013
Institution Name Tier2:	Institution CTEP Code Tier2:
Audit Domain: COGC	Audit Type: COGC audit
Audit Date: 07/11/2017	Audit Category: Treatment

In order to improve the efficiency the following corrective action plan was developed. You must use this plan to respond to all the follow-up requested. You can include additional documentation as PDF along with this plan and send it to <email address>. If supporting documentation is more than X number of pages, please send them via US Mail or Fax <Fax number>

Patient Case Review

F. General Data Management Quality

Protocol Number	Patient Number
ADVL1211	830653
Follow-up Request Comments: https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getPatientCaseAssessmentScreen.action#	

Corrective and Preventive Action Plan: (enter comments below)