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

July 2018

CTIS INC.,



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

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DTL Review

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Institution Name Tier2:	Institution CTEP Code Tier2:
Audit Domain: COGC	Audit Type: COGC audit
Audit Date: 07/11/2017	Audit Category: Treatment

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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)



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Audit Domain: COGC	Audit Type: COGC audit
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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)



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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)



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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)



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Patient Case Review

E. Adverse Event

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Patient Case Review

D. Disease Outcome/Response

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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)