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**Audit Domain:** CTMSP1P2  
**Institution Name:** University Health Network-Princess Margaret Hospital  
**Membership Study Type:** Treatment

**Audit Date:** 03/08/2017  
**Institution CTEP Code:** 11030  
**Audit Category:** Treatment

**Audit Type:** Data Audit  
**Membership Type:** Main Member

### 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**

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

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

**Corrective and Preventive Action Plan:** (enter comments below)



Department of Health & Human Services

Public Health Service  
National Institutes of Health  
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Rockville, Maryland 20850

**Follow-up/Corrective And Preventive Action Plan**

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**ICC Review**

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**DTL Review**

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<b>Audit Domain:</b> COGC	<b>Audit Type:</b> COGC audit
<b>Audit Date:</b> 07/11/2017	<b>Audit Category:</b> Treatment

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**Pharmacy Review**

<b>Protocol Number:</b> ADVL1211
<b>Follow-up Request Comments:</b> <a href="https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getPharmacyAssessmentScreen.action#">https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getPharmacyAssessmentScreen.action#</a>

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Rockville, Maryland 20850

**Follow-up/Corrective And Preventive Action Plan**

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

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**Patient Case Review**

**A. Informed Consent**

<b>Protocol Number</b>	<b>Patient Number</b>
ADVL1211	830653
<b>Follow-up Request Comments:</b> <a href="https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getPatientCaseAssessmentScreen.action#">https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getPatientCaseAssessmentScreen.action#</a>	

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<b>Audit Date:</b> 07/11/2017	<b>Audit Category:</b> Treatment

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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**

<b>Institution Name Tier1:</b> Rhode Island Hospital	<b>Institution CTEP Code Tier1:</b> RI005
<b>Institution Name Tier2:</b>	<b>Institution CTEP Code Tier2:</b>
<b>Audit Domain:</b> CTMSP1P2	<b>Audit Type:</b> Data Audit
<b>Audit Date:</b> 01/11/2017	<b>Audit Category:</b> 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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Institution Name Tier2:	Institution CTEP Code Tier2:
Audit Domain: COGC	Audit Type: COGC audit
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**Patient Case Review**

**E. Adverse Event**

Protocol Number	Patient Number
ADVL1211	830653
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**Patient Case Review**

**D. Disease Outcome/Response**

Protocol Number	Patient Number
ADVL1211	830653
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**Patient Case Review**

**F. General Data Management Quality**

Protocol Number	Patient Number
ADVL1211	830653
<b>Follow-up Request Comments:</b> <a href="https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getPatientCaseAssessmentScreen.action#">https://coreappstest.ctisinc.com/CTMBWeb/finalreport/getPatientCaseAssessmentScreen.action#</a>	

**Corrective and Preventive Action Plan: (enter comments below)**