

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 #0925-0753). Do not return the completed form to this address.

The screenshot shows a web application interface for sending a final report cover letter. The interface is divided into several sections:

- Header:** Contains audit details such as 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), and Membership Type (Main Member).
- Sidebar:** Lists navigation options including Audit Scheduling Information, Auditor Information, Final Reports (Send Final Report, Send Follow-up, Acknowledgment Email), Final Report Information, FR Template Maintenance, Follow-up Information, Roster Maintenance, Document Management, Reports, Templates & Worksheets, and Guides.
- Main Content Area:** Titled "Send Final Report Cover Letter", it features a "Cover Letter Template" dropdown menu set to "Pediatric Oncology Branch". Below this are fields for "Email To\*", "CC", and "Attachment" (with a dropdown for "Pediatric Branch Report"). The main body of the email contains the text: "Dear Caryn, Please see the attached NCI Pediatric Branch Data Audit. Sincerely, Theresa". At the bottom of the form are buttons for "Save", "Send", "Clear", and "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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**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:
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Audit Date: 07/11/2017	Audit Category: Treatment

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