DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410)779-5455 Fax:(410)779-5707	10/24/2016-11/15/2016* FEI NUMBER 3012722972

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jan M. Casadei, PhD , Chief, Regulatory Affairs Branch

FIRM NAME	STREET ADDRESS
National Cancer Institute (NCI)	9609 Medical Center Drive, Rm 5-W520,, MSC 9740
CITY, STATE, ZIP CODE, COUNTRY Rockville, MD 20850	TYPE ESTABLISHMENT INSPECTED Sponsor

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Failure to ensure proper monitoring of the study and ensure the study is conducted in accordance with the protocol and/or investigational plan.

Specifically,

A. Protocol 14-C-0157-9577 (DA-TEDDI-R) requires any Grade 3 to 5 serious adverse events (SAE) to be reported to the sponsor, via CTEP-AERS within 24 hours of learning of the AE, followed by a complete expedited report within 5 calendar days of the initial 24-hour report. In addition, Grade 1 and Grade 2 SAEs resulting in more than a 24 hour hospitalization must be reported within 10 calendar days of learning of the AE.

Section 12.1.1 of Protocol 14-C-0157-9577 states "this study will be monitored by Clinical Trials Monitoring Service (CTMS)," managed by Theradex. Both National Cancer Institute (NCI) Guidelines for Auditing Clinical Trials and Theradex SOPs requires one site visit and two data audits each year for protocols monitored under CTMS. Theradex CTMS performed an initial site visit on October 14, 2014, followed by other audits on February 17, 2015, June 14, 2016 and June 28, 2016. Between February 17, 2015 and June 14, 2016, there was over a one year lapse in monitoring.

During this lapse in monitoring, the following SAEs were not reported to the sponsor within the timeframes required by the protocol:

AE number	Patient Number	AE start date	Date CI became aware	CTEP report date	Event

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
John Dan, Investigator
Quynh-Van Tran, FDA Center Employee or Employee of Other Federal Agencies
David L Chon, Investigator

Unverified
X John Dan
John Dan
Investigator
Signed by: John Dan -5

DATE ISSUED
11/15/2016

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Rockville, MD 20850	Sponsor

2602271	1010005	4/2/15	4/22/15	6/30/16	Grade 3 Lung infection
2830601	1010009	5/4/15	5/16/15	8/5/15	Death 5/16/15,
2209732	1010011	11/4/15	12/7/15	5/25/16	Grade 3 Lung Infection
2708728	1010014	1/19/16	5/9/16	5/31/16	Grade 3 lung infection
-	1010014	2/23/16	3/1/16	Not reported	Grade 4 Febrile neutropenia with hospitalization
2393882	1010015	2/24/16	3/2/16	5/25/16	Grade 3 lung infection
2985143	1010015	3/28/16	4/7/16	10/6/16	Grade 4 anemia; Grade 4 platelet count decreased
2369360	1010015	5/20/16	5/25/16	10/6/16	Grade 3 Gastric Hemorrhage

***DATES OF INSPECTION**

10/24/2016(Mon),10/25/2016(Tue),10/26/2016(Wed),10/27/2016(Thu),10/31/2016(Mon),11/02/2016(Wed),11/09/2016(Wed),11/15/2016(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	John Dan, Investigator Quynh-Van Tran, FDA Center Employee or Employee of Other Federal Agencies David L Chon, Investigator Unverified X John Dan John Dan Investigator Signed by: John Dan -S	11/15/2016