Run Date : 02/8/2012 6:18:18 AM

(Site Reported)

Adverse Event Expedited Report

Protocol Number :5876 **CTC Version :**CTCAE v4.0 **Principal Investigator :**

Title :

Institution : Johns Hopkins University **Report Type :** Original **Ticket #:**1193153 **Amendment #:** 0

Created Date :02/07/2012

Reporter Information

Reporter Name : Paul Baumgartner
Phone : 555-555-5555 **Fax :** 555-555-5555 **Email :** paul.baumgartner@semanticbits.com

Submitter Name : Paul Baumgartner
Phone : 555-555-5555 **Fax :** 555-555-5555 **Email :** paul.baumgartner@semanticbits.com

Physician Name : Site Physician
Phone : 555-555-5555 **Fax :** **Email :** site.physician@gmail.com

Patient Information

Patient ID :	9989	**Birth Date :**	10/ 1970	**Gender :**	Female
Race :	White	**Ethnicity :**	Not Hispanic or Latino		
Height(Centimeter) :	100.0	**Weight(Kilogram) :**	100.0	**Body Surface Area :**	1.4334

Baseline performance status at initiation of protocol - ECOG/Zubrod scale : 0
Disease Name : Ovarian epithelial cancer
Disease Name Not Listed :
Primary Site of Disease : Ovary
Date of Initial Diagnosis :

Course Information

Treatment Assignment Code : A
Description : (Cycle= 3 Weeks): Cisplatin 60 mg/m2 IV on day 1 Flavopiridol 100 mg/m2 CIV over 24 hours on day 1
Start date of first course : 01/02/2012
Start date of course associated with Expedited Report : 01/22/2012
Start date of primary AE : 01/04/2012
End date of primary AE :
Course Number on which event(s) occurred : 1
Total number of courses to date : 1
Was Investigational Agent(s) administered on this protocol?: Yes

Description of Event

Description and Treatment of Event : Nausea followed by severe vomiting. Hospitalization for 24hrs and TPN indicated.
Present Status : Recovered/Resolved without Sequelae **Date of Recovery or Death :** 01/10/2012
Retreated : No
Removed from Protocol Treatment (to date) : No **Date Removed from Protocol Treatment :**
Cause of Death :

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Death Date : **Autopsy Performed :**

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Prior Therapies

Therapy	Therapy Start Date	Therapy End Date	Comments	Chemotherapy Agents
Surgery				

Sites of Metastatic Disease

Lymphnode

Protocol Agents

Treatment Assignment Code : A

Agent	Total Dose Administered this Course	Last Administered Date	Comments	Agent Adjustment	Agent Delayed	Delay
Alvocidib (flavopiridol)	100mg	01/03/2012			No	

Adverse Events (CTCAE)

CTCAE CATEGORY	Adverse Event	Grade	Hospitalization/ Prolongation of Hospitalization	Start Date of AE	End Date of AE	Is Primary AE?	Comments
Gastrointestinal disorders	Vomiting	3	Yes	01/04/2012		Yes	threw up
Gastrointestinal disorders	Nausea	2	No	01/02/2012		No	sick to stomach

Attribution for Adverse Events

Attribute to **Gr.3 Vomiting: threw up**

Course	
Alvocidib (flavopiridol)	Possible
Disease	
Ovarian epithelial cancer	Unlikely

Attribute to **Gr.2 Nausea: sick to stomach**

Course	
Alvocidib (flavopiridol)	Probable
Disease	
Ovarian epithelial cancer	Unlikely