



Run by: PANATHULAG

Date: 10/14/2009 05:07 PM

PROTOCOL - COMPLETE SHEET (Abbreviated)

Page 1 of 3

P GOG-0076EE

ADMINISTRATIVE INFORMATION**Document Type :** P**NCI Document # :** GOG-0076EE**Local Document # :** GOG-0076EE**Clinical Rating :****Correlative Rating :****Treatment :** Yes**CTC Version :**

4.0

Title : A Limited Access Phase II Trial of Weekly Topotecan (NSC # 609699), Paclitaxel (NSC # 673089), and Cisplatin (NSC # 119875) in the Treatment of Advanced, Persistent, or Recurrent Carcinoma of the Cervix**NIH Admin. Code :** CTEP**Participant Type :** Group**Monitoring Method :** CDUS - Abbreviated**Phase :** II**PI Opt Flag :****Potential IND Study :** N/A**Inpatient Therapy :** No**Current Status :** Approved**Current Status Date :** 10/14/2005**On-Hold :** No**Review Type :** Development/Strategy Review**Office File Location :** PIO**Lead Organization :** Gynecologic Oncology Group (GOG)**Principal Investigator :** Long, Harry J.**Office phone :** (507)284-4320**Office fax :** (507) 284-1803**Email :** long.harry@mayo.edu**CTEP Mail To :** DiSaia, Philip J., M.D.**Organization :** Gynecologic Oncology Group

GOG Admin Off, Four Penn Ctr

1600 John F. Kennedy Blvd., Suite 1020
Philadelphia

PA - 19103

USA

Email : pjdisaia@uci.edu**Office phone :** 215-854-0770**Office fax :** 215-854-0716**REVIEW INFORMATION**

Change Type	Change Number	Local Change Number	Receipt Date	Review Meeting Type	Review Date	CTEP Coordinator	Document Result	Informed Consent Result
Amendment	1	REVISIO N 1	11/16/2006	ROUTING	11/16/2006	Trimble, Edward Lloyd	Approved	Approved
Original	0	0	09/13/2005	CTEP	10/06/2005	Trimble, Edward Lloyd	Approved	Approved
				CTEP	09/29/2005	Trimble, Edward Lloyd	Deferred	N/A

STUDY THERAPIES**Therapy Name**

Drug and/or Immunotherapy

STUDY AGENT INFORMATION

Agent	Lead Agent	NSC #	IND #	Monitor	Commercial /Investigational	PMB Dist.
Topotecan	Yes	609699		Wright	Commercial	No
CISplatin	No	119875			Commercial	No
Paclitaxel (Taxol)	No	673089		Colevas	Commercial	No

STUDY DISEASE INFORMATION

Disease	Lead Disease	Reporting MedDRA	Monitor
Squamous cervical cancer	Yes	10041848	
Adenocarcinoma of the cervix	No	10008224	
Cervical cancer, NOS	No	10008238	



Run by: PANATHULAG

Date: 10/14/2009 05:07 PM

PROTOCOL - COMPLETE SHEET (Abbreviated)

Page 2 of 3

P GOG-0076EE Contd ...

FUNDING INFORMATION

Funding PI/Investigator	Role	Institution	Reporting Grant	Activity Code	IC	Serial #	Funding Status / Date
DiSaia, Philip J.	Grant PI	Gynecologic Oncology Group (GOG)	Yes	U10	CA	27469	Active 09/14/2005

Funding Comment:**STUDY SUBGROUPS**

Subgroup Code	Description	Category	Disease Name	Therapy Name
SG1	All patients			

ACCRUAL INFORMATION**PROJECTED ACCRUAL**

Projected Start Date	Projected End Date	Projected Min.	Projected Max.	Actual Total	Projected PTS/Month	Actual PTS/Month
02/01/2006	07/01/2007	25	66	0	4	

ACTUAL ACCRUAL

Collection Date	Total Accrual	PTS/Month	Accrual Source
03/31/2008	0		CDUS
12/31/2007	0		CDUS
09/30/2007	0		CDUS
06/30/2007	0		CDUS
03/31/2007	0		CDUS
12/31/2006	0		CDUS
09/30/2006	0		CDUS
06/30/2006	0		CDUS
03/31/2006	0		CDUS
12/31/2005	0		CDUS

DOCUMENT COMMENTS

Comment Date	Comment
09/18/2009	CTCAE version change: 3.0 to 4.0 by CTIS
11/16/2006	Activation Amendment

DOCUMENT HISTORY

Document Type	Change#	History	History Date	Comment
Protocol	0	Document Received	09/13/2005	
Protocol	0	Out for QC	09/14/2005	
Protocol	0	IRB Received	09/14/2005	Org_trial_status set to Active
Protocol	0	PRC Review	09/29/2005	
Protocol	0	PRC Review	10/06/2005	Deferred from review date 09/29/2005 .
Protocol	0	CTEP Coordinator Signed	10/07/2005	Dr. Mooneys signed for T. Trimble



Run by: PANATHULAG

Date: 10/14/2009 05:07 PM

PROTOCOL - COMPLETE SHEET (Abbreviated)

Page 3 of 3

P GOG-0076EE Contd ...

DOCUMENT HISTORY

Document Type	Change#	History	History Date	Comment
Protocol	0	Out for QC	10/07/2005	
Protocol	0	Out for Signature	10/07/2005	Approval packet
Protocol	0	Sent to PMB	10/13/2005	
Protocol	0	Approval Letter Sent to Investigator	10/14/2005	
Protocol	0	Approved	10/14/2005	
Protocol	0	Distribution of Approved Document: EMMES	10/14/2005	
Protocol	0	Distribution of Approved Document: PDQ	10/14/2005	
Protocol	0	PMB Approval Received	10/14/2005	
Protocol	0	Projected Activation	02/01/2006	
Amendment	1	Document Received	11/16/2006	
Amendment	1	Routing Review	11/16/2006	
Amendment	1	Out for Signature	11/20/2006	
Amendment	1	Approval Letter Sent to Investigator	11/21/2006	
Amendment	1	CTEP Coordinator Signed	11/21/2006	
Amendment	1	Distribution of Approved Document: EMMES	11/21/2006	
Amendment	1	Distribution of Approved Document: PDQ	11/21/2006	

STUDY STATUS HISTORY

Status	Status Date
Approved	10/14/2005
In Review	09/13/2005

CURRENT PROTOCOL SPECIALIST : DeCelle, Mary