

OnCore Communication Memo

Memo #: 25 – Foundation Trials Sponsor Designation

To: All Research Managers, SRC Coordinator, CTO-AD

From: System Administrator

Effective Date: July 14, 2016

Purpose: In order to distinguish between National Group sponsored studies and Industry sponsored studies, National Group Foundation sponsors have been added to OnCore. National Group Foundation studies need to be reported as Industry studies rather than National Group, which is the reason for this change.

Notes: The following Sponsors have been added, with the sponsor type of Industry, to capture these trials:

- GOG Foundation, Inc.
- RTOG Foundation, Inc.
- Children’s Oncology Group Foundation, Inc.
- ALLIANCE Foundation Trials, LLC (AFT)
- NSABP Foundation, Inc.

The Foundation studies that are currently in OnCore that required updating have been updated prior to this memo release. The list of current Foundation studies are as follows, indicating the previous and current sponsors (if updated):

Protocol No.	Previous Sponsor	Current Updated Principal Sponsor	Sponsor Type
GOG-3001	GOG	Amgen	Industry
GOG-3003	GOG	GOG Foundation, Inc.	Industry
GOG-3004	GOG	AstraZeneca	Industry
GOG3005-M13-694	AbbVie Inc.	GOG Foundation, Inc.	Industry
GOG3011-0403	Not Indicated	GOG Foundation, Inc.	Industry
GOG3012-TESARO	Not indicated	GOG Foundation, Inc.	Industry
GOG-3013-PFIZER	Pfizer Inc.	Pfizer Inc.	Industry
RTOG-3501	RTOG	RTOG Foundation, Inc.	Industry
NOVOCURE-RTOG-3503	RTOG	RTOG Foundation, Inc.	Industry
RTOG-3508/ABBVIE-M13-813	AbbVie Inc.	RTOG Foundation, Inc.	Industry
AFT-05-PALLAS	ALLIANCE Foundation Trials, LLC (AFT)	ALLIANCE Foundation Trials, LLC (AFT)	Industry

Protocol No.	Previous Sponsor	Current Updated Principal Sponsor	Sponsor Type
COG-AAML1321	COG-Children's Oncology Group	Children's Oncology Group Foundation, Inc.	Industry
COG-ADVL1111	COG-Children's Oncology Group	National Cancer Institute	Externally Peer Reviewed
COG-AAML1522	Celgene Corporation	Celgene Corporation	Industry
COG-ADVL1322	GlaxoSmithKline	Children's Oncology Group Foundation, Inc.	Industry
COG-ADVL1621	Merck & Co., Inc.	Merck & Co., Inc.	Industry
COG-ACCL1333	COG-Children's Oncology Group	Bristol Meyers Squib	Industry
COG-AALL1521	Incyte Corporation	Children's Oncology Group Foundation, Inc.	Industry

Instructions: There are different ways of determining whether a study is a Foundation trial, a National Group trial or an Industry trial. Some protocols may have the indication in the protocol title – this protocol would use RTOG Foundation, Inc. as the sponsor:

RTOG FOUNDATION STUDY 3501

TRYHARD: A PHASE II, RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED STUDY OF LAPATINIB (TYKERB®) FOR NON-HPV LOCALLY ADVANCED HEAD AND NECK CANCER WITH CONCURRENT CHEMORADIATION

Limited Participation Study

Other protocols are more confusing and require utilizing clinicaltrials.gov to determine the Sponsor – this protocol would use GOG Foundation, Inc. as the sponsor even though the Sponsor technically is AbbVie, it was done in collaboration with GOG. (GOG-3005)

This study is currently recruiting participants. (see Cont:

Verified June 2016 by AbbVie

Sponsor:

AbbVie

Collaborators:

Gynecologic Oncology Group

Australia New Zealand Gynaecological Oncology Group

Information provided by (Responsible Party):

AbbVie

This protocol would use Pfizer, Inc. as the sponsor, even though it might be opened through a National Group (GOG-3013):

This study is currently recruiting participants.

Verified July 2016 by Pfizer

Sponsor:

Pfizer

Information provided by (Responsible Party):

Pfizer

This protocol would use NRG as the sponsor (NRG-BR001):

This study is currently recruiting participants. (see

Verified June 2016 by NRG Oncology

Sponsor:

NRG Oncology

Collaborators:

National Cancer Institute (NCI)

Radiation Therapy Oncology Group

Information provided by (Responsible Party):

NRG Oncology

Further Instructions: The actual pharmaceutical company may be added as a secondary sponsor in OnCore, for example if you need to track the sponsor separately, or for eventual financial console usage, but where applicable the Foundation should be the primary sponsor so they fall under the correct sponsor type.