NRG ONCOLOGY

Advancing Research. Improving Lives.™

Pre-Screening Instructions

for

NRG-GY008

(ClinicalTrials.gov NCT #02728258)

A PHASE II EVALUATION OF COPANLISIB (BAY 80-6946) (IND #130822), A SELECTIVE INHIBITOR OF PI3KCA, IN PATIENTS WITH PERSISTENT OR RECURRENT ENDOMETRIAL CARCINOMA HARBORING PIK3CA HOTSPOT MUTATIONS

Document provided by:

NRG Oncology Statistics and Data Management Center
One Sterling Plaza
201 North Craig Street, Suite 500
Pittsburgh, PA 15213
412-624-2666

Version: 1.0

Approval Date: 09-JAN-2017

Table of Contents

1.0 **DEFINITIONS** 3
2.0 **Q² SOLUTIONS SHIPMENT INFORMATION AND INFOSARIO ACCESS** 4
3.0 **KIT ORDERS** 5
4.0 **SPECIMEN PROCESSING** 7
5.0 **REPORTING LAB RESULTS TO NRG ONCOLOGY** 8

Confidential and Proprietary Property of NRG Oncology. May not be reproduced without permission.

NSABP-GY008
PRE-SCREENING INSTRUCTIONS

Use and Distribution of the Pre-Screening Instructions:

The NRG-GY008 Pre-Screening Instructions provide essential information to support the pre-screening requirements described in Section 4 and Section 8.2 of the NRG-GY008 protocol. ***Please refer to the Q² Solutions® Anatomic Pathology Laboratory Manual, provided in the initial shipment of lab kits, for detailed instructions regarding kits used for this study, sampling instructions, and storage and shipping requirements.*** The NRG-GY008 Pre-Screening Instructions should be distributed to staff involved with any aspect of pre-screening specimen collection and submission, including staff at affiliate institutions.

Special Note for the NRG-GY008 Study:

It is essential to consider each pathology department's policy regarding the release of slides, before screening a patient. A patient should not be offered participation in NRG-GY008 if a pathology department will not, by policy, release any type of specimens for research purposes.

1.0 DEFINITIONS

- **Infosario** – Q^2 Solutions web portal, used by sites to place resupply orders, retrieve lab results, and track specimens; https://infosario.quintiles.com
- **Infosario e-training** – Completed by site designees at the time of first access to the Infosario web portal. User names and passwords for this portal are provided via email by Q^2 Solutions following the submission of the Lab Kit Registration Form.
- **Initial Kit Order** – A predetermined quantity of supplies for NRG-GY008 pre-screening specimen collections.
- **Lab Kit Registration Form** – Online form found on the NRG-GY008 Documentation page of the NRG Oncology website; form must be submitted by each site at time of IRB submission; submitting this form will transfer site information and initial kit orders for NRG-GY008, to Q^2 Solutions.
- **Marken** – Courier used for shipment of samples to Q^2 Solutions.
- **NRG-GY008 Lab Report Upload Form** – Online form found on the NRG-GY008 Documentation page of the NRG Oncology website; this form enables sites to upload and submit pre-screening lab reports to NRG Oncology for confirmation of patient eligibility.
- **Q^2 Solutions Anatomic Pathology Laboratory Manual** – Q^2 Solutions document outlining kit supplies, collection requirements, and details for collection, processing, and shipment of specimens, also referred to as the Flow Chart.
- **Q^2 Solutions Laboratory Manual** – Q^2 Solutions document available on Infosario, containing general guidelines for specimen collection, completion of requisitions, courier information, and the Infosario portal. This document is emailed to sites upon submission of the Lab Kit Registration Form and is also available on the Infosario Portal.
- **Resupply orders** – Kit orders subsequent to the initial kit order that are placed through the Infosario web portal; e-training for the Infosario portal must be completed before site staff can place resupply orders through Infosario.
- **Step Zero** – the act of registering a patient in open, after the screening consent form is signed; patient ID will be assigned during this step.

Confidential and Proprietary Property of NRG Oncology. May not be reproduced without permission.

2.0 Q^2 SOLUTIONS SHIPMENT INFORMATION AND INFOSARIO ACCESS

2.1 Q^2 Solutions Shipment Information

Sites must submit Q^2 Solutions shipment information to the NRG Oncology Statistics and Data Management Center (SDMC) through the Lab Kit Registration Form. This form is accessible from the NRG Oncology website and requires an active CTEP Institution Code. A link to the form can be found on the NRG-GY008 page of the website.

On the Lab Kit Registration Form, the site may provide up to three names and e-mail addresses under "Infosario Information" of site staff who will require access to the Q^2 Solutions Infosario Portal to order additional bio specimen kits or to obtain lab reports for the NRG-GY008 study.

The information collected on this form will be sent by the NRG Oncology SDMC to Q^2 Solutions be loaded in the Q^2 Solutions database. **Completion of the online form is a requirement for site activation for participation in the NRG-GY008 study.** Allow up to **5 working days** for this information to be confirmed by Q^2 Solutions and for user accounts for the Infosario Portal to be made available.

At this time, Q^2 Solutions will request that Marken send an information pack, containing contact and shipping instructions and air way bills, to the site via FedEx.

Note: **Every time there is a site change that impacts the information submitted on the Lab Kit Registration Form, the form must be updated**. **Updating this form will insure that Q^2 Solutions and Marken have current site information for shipping kits and reports.**

Contact the Support Desk at support@nrgoncology.org for assistance with accessing the NRG Oncology website and for any questions or problems with the Lab Kit Registration Form.

2.2 Infosario Access

User names and passwords for Infosario access will be e-mailed to those individuals identified in the Infosario section of the Lab Kit Registration Form, and to the site coordinator.

Q^2 Solutions Infosario is used to:

- Order kits and track kit order status
- Respond to queries from Q^2 Solutions
- Track specimen receipt
- Access the Q^2 Solutions Laboratory Manual and the Anatomical Pathology Laboratory Manual, which address NRG-GY008 specimen requirements
- Complete and print requisitions online

In order for individuals to use Infosario for submitting resupply orders or retrieving lab reports, the Infosario eTraining modules must be completed. This online training can be started as soon as an Infosario user name and password are received from Q^2 Solutions, and will take approximately one hour to complete**.** More information on the Infosario portal and the required eTraining, can be found in the Q^2 Solutions Laboratory Manual.

Confidential and Proprietary Property of NRG Oncology. May not be reproduced without permission.

3.0 KIT ORDERS

At the time that the **Lab Kit Registration Form is submitted, the initial kit order for the site is implied.** Each institution will be identified by its CTEP Institution Code, which will be printed on all requisitions and labels. **Kits are site-specific, so they cannot be exchanged or shared between sites.**

3.1 Initial Kits

- At the time of submission of documents to the IRB, a site must complete the online Lab Kit Registration Form in order to receive an initial lab kit. The process for obtaining an initial kit order is as follows:
    1. Access the NRG Lab Kit Registration interface on the NRG Website
    2. Enter the site's CTEP Institution Code and select the NRG-GY008 protocol from the list of protocols.
    3. The Lab Kit Registration Form will open and be pre-populated with the CTEP Institution Code that was entered in Step 2, and any site information that was entered previously on this form.
    4. Complete the entire Lab Kit Registration Form. Any fields that are not completed appropriately, will be highlighted when the form is submitted. Problems with these highlighted fields must be corrected in order for the form to submit properly.
    5. Receive an online confirmation when the form is successfully submitted.
    6. The submission of the Lab Kit Registration Form will initiate the shipment of the initial kit order for the pre-screening genetic testing that is required by the NRG-GY008 protocol.
    7. Site staff should continue to revise the information on the Lab Kit Registration Form if and when it changes, throughout the life of the trial.
- **Please allow <u>10-15 business days</u> from the date the Lab Kit Registration Form is submitted, to receive initial kit orders from Q^2 Solutions.**
- Kits are labeled with a unique site-specific accession number, which is used on the kit box, requisition form, and all slides. **Kit supplies cannot be shared between sites.** Each site that will be enrolling patients to NRG-GY008, must complete an Lab Kit Registration Form in order to receive properly labeled kits.
- The following supplies will be included in the initial kit order:
    - Shippers
    - AWBs (airway bills)
    - FedEx Saturday Stickers
    - Specimen Shipping Bags (SSB)
    - Standard bulk supply (*this will include extra labels*)
    - Slide holders for 25 slides
    - Anatomic Pathology Laboratory Manual (*this will provide the site all the details needed for the pre-screening visit*)
- Check expiry date and do not used expired kits. Specimens collected using expired kit supplies will not be used. Kits typically expire in 6 months. **Do not mix kit contents between kits**. Expired kits can be discarded at the site.

Confidential and Proprietary Property of NRG Oncology. May not be reproduced without permission.

3.2 Resupply Orders

After the initial order for kits is placed through NRG Oncology SDMC, and the online e-training for Infosario is completed, sites may order subsequent kits online as needed, directly from Q^2 Solutions via Infosario.

To place a resupply order, the site should order via Q^2 Solutions Infosario or call Q^2 Solutions Laboratories Investigator Services Department at 1-800-676-8452. When contacting Q^2 Solutions, please reference protocol NRG-GY008 and use your site's CTEP Institution Code as your site number.

Please allow 7 to 10 business days for receipt of resupply orders.

3.3 Q^2 Solutions process for requisition form queries

If information on a requisition form is incomplete or incorrect, Q^2 Solutions will follow the process below:

- Q^2 Solutions will send the site a query via fax.
- If no reply is received, Q^2 Solutions will contact the site directly by telephone.
- If no reply is received, Q^2 Solutions will contact NRG Oncology for assistance in contacting the site to help with obtaining the required information.

Confidential and Proprietary Property of NRG Oncology. May not be reproduced without permission.

4.0 SPECIMEN PROCESSING

All screened patients will have specimens drawn for genetic mutation testing. The instructions for all specimen collection, labeling, and shipment can be found in the Anatomic Pathology Laboratory Manual for NRG-GY008, which is supplied by Q^2 Solutions in the initial kit order.

4.1 Specimen Labels

Labels for specimen collection are pre-printed with the protocol name and your site number. The patient number must be written on the label by the site. **Only the last five digits of the Patient ID (see sample in red below) should be recorded as the patient number on the labels.**

Sample Patient ID: **XX999 – NRG-GY008 – 99999**

Note: Failure to record the patient number in this way, could delay sample processing.

Additional instructions for specimen labeling can be found in the Q^2 Solutions Anatomic Pathology Laboratory Manual.

4.2 Shipping Specimens

An information pack from Marken, which contains contact information, and scheduling and shipping information, will be provided to sites when the initial kit supply is requested by the NRG Oncology SDMC. **Marken (1-800-627-5361 or 1-800-MARKEN-1) is the courier used for shipment of specimens to Q^2 Solutions.** The information packs will be delivered to the sites by FedEx and will include information on how to schedule a Marken shipment in addition to airway bills.

Specimens must be shipped at room temperature on the day of collection via Marken. If a specimen must be obtained on a Friday, verify with Marken that the specimen can be shipped that day.

4.3 Obtaining laboratory results

Investigators can view lab results via Infosario, a secure online web portal for electronic receipt of results. Infosario is the preferred method for obtaining results; however, investigators must opt-in to Infosario. If no action is taken in this regard, results will be provided via FedEx.

Note: It will take Q^2 Solutions 5 to 7 business days after receiving a specimen, for samples to be processed and results to be available on Infosario.

Results on Infosario are available as a .pdf document that can be viewed, saved, and/or printed.

4.4 Insufficient Specimens

If Q^2 Solutions receives a sample that is QNS (quantity not sufficient), this will be noted as a comment on the lab report next to the test.

Confidential and Proprietary Property of NRG Oncology. May not be reproduced without permission.

5.0 REPORTING LAB RESULTS TO NRG ONCOLOGY

All screened patients that have lab results that meet eligibility for NRG-GY008 must submit the confirmatory lab report to NRG Oncology for verification of eligibility. This submission must be made after the completion of Step Zero, and prior to patient randomization, in OPEN.

5.1 Confirming Patient Eligibility

Lab results that meet the eligibility criteria in Protocol Section 3.2.2 must be reported to NRG Oncology through the **NRG-GY008 Lab Report Upload Form**, which can be accessed through the NRG Oncology website on the NRG-GY008 Documentation page. The process for submitting patient lab results is as follows:

1. Click on the NRG-GY008 Lab Report Upload Form link on the NRG-GY008 page of the NRG Oncology website to open the form.
2. Select the appropriate Patient ID from the list of patients registered in Step Zero.
3. Click the 'Choose File' button to access the saved files on your computer.
4. Locate and select the lab report that was downloaded from Infosario for the patient. **Note: Paper lab reports, received via FedEx, must be scanned and saved in .pdf format prior to file upload.**
5. Verify that the file name displayed to the right of the 'Choose File' button is the correct file. If it is not, return to Step 3.
6. Click 'Upload File and Form' to submit the lab results to the NRG Oncology. A confirmation message will be displayed when results are successfully submitted.

There is no limit to the number of times that the NRG-GY008 Lab Report Upload Form may be submitted for a single patient.

After lab results are submitted to NRG Oncology, patient eligibility will be verified by the NRG-GY008 Data Manager. Once eligibility is verified, patient enrollment may then be completed through OPEN.

Note: Until a patient's eligibility if confirmed by the NRG Data Manager, *OPEN will not permit enrollment to continue for that patient.*

Contact the Support Desk at support@nrgoncology.org for assistance with accessing the NRG Oncology website or for help with the NRG-GY008 Lab Report Upload Form.

Confidential and Proprietary Property of NRG Oncology. May not be reproduced without permission.