

Virginia Commonwealth University/ American College of Radiology Imaging Network

ACRIN 6688 Phase II Study of Fluorine-18 3'-deoxy-3'-fluorothymidine (F-18-FLT) in invasive breast cancer

AMENDMENT 9 Summary of Changes

Schema: Below the schema under Sample Size, the term “evaluable was added to the language and defined: *“The trial will continue to accrue until the target of 54 eligible and evaluable participants has been met. “Evaluable” is defined as: all required image series have been completed; local site has determined that all images are adequate and have been submitted to ACR Imaging Core Lab; and submitted images have passed quality control review by the ACR Imaging Core Lab. Ineligible and inevaluable cases will be replaced.”*

Section 5 Study Overview: “.....eligible women with evaluable images” was added to the paragraph.

Section 6 Participant selection/Eligibility Criteria Under the table, additional language was added : *“** Total of fifty-four (54) eligible and evaluable patients with locally advanced breast cancer is required for this study. It is anticipated that the accrual will be completed in 18 months with minimum of 36 patients enrolled in a year. The trial will continue to accrue until the target of 54 eligible and evaluable participants has been met. “Evaluable” is defined as: all required image series have been completed; local site has determined that all images are adequate and have been submitted to ACR Imaging Core Lab; and submitted images have passed quality control review by the ACR Imaging Core Lab. Ineligible and inevaluable cases will be replaced.”*

6.1.9 Language was changed for pregnancy test from serum to institutional SOC

Section 17.2 Sample Size/Accrual Rate

In this section, the term “evaluable was added to the language and defined: *“The trial will continue to accrue until the target of 54 eligible and evaluable participants has been met. “Evaluable” is defined as: all required image series have been completed; local site has determined that all images are adequate and have been submitted to ACR Imaging Core Lab; and submitted images have passed quality control review by the ACR Imaging Core Lab. Ineligible and inevaluable cases will be replaced.”*

Informed consent

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

This section was modified to *“54 participants will take part in this study who are eligible and images are evaluable”*.

WHAT ARE THE RISKS

Technical language in ‘Note’s were removed from this section and remains in Section 11.4