

## **CTSUS Webinar: NCTN Colorectal Cancer Trials Webinar**

**Webinar Date: Thursday, December 14<sup>th</sup> at 3pm – 4pm EST**

### **Summary of Site Questions and Answers**

#### **A021502 Q&A:**

- 1. Question: Can cycle 1 FOLFOX be given at local oncologists or at the center in which the trial is being conducted?**

Answer: All chemotherapy and immunotherapy must be administered at the registering institution.

- 2. Question: Any funding provided/reimbursed for dMMR testing?**

Answer: No, as this is not part of the protocol but is considered standard of care.

- 3. Question: In version 7/13/17, the schema states an additional six months of Atezolizumab alone. However, you presented that it is an additional 13 months in Arm 1. Can you kindly clarify?**

Answer: For the atezolizumab study arm, patients receive 12 cycles then an additional 13 cycles for a total of 25 cycles. This represents one year of treatment with atezolizumab on the experimental arm.

- 4. Question: Are you accruing at anticipated rate?**

Answer: The study has only recently opened but multiple sites have activated the protocol and the study is actively accruing patients.

#### **NRG-GI004 Q&A:**

- 1. Question: Is there a competing trial to Keynote 177?**

Answer: The study population for Keynote 177 is patients with metastatic MSI-H CRC. The ATOMIC trial is limited to stage III MSI-H or dMMR colon cancers.

- 2. Question: Is this study currently accruing?**

Answer: Yes.

**3. Question: Do we need to wait for central confirmation of dMMR prior to starting treatment?**

Answer: No. Patients can be enrolled if found to be dMMR on a local IHC test or one set to a reference laboratory.

**4. Question: Any information on the manual for BioClinica for image submission?**

Answer: The study protocol does not require electronic image submission.

**S1613 Q&A:**

**1. Question: Is HER2 amplification a prerequisite testing prior to antiEGFR therapy?**

Answer: HER2 amplification is a negative predictive marker for efficacy of antiEGFR therapy. We therefore strongly encourage physicians to obtain this test prior to exposure to antiEGFR therapy, especially due to availability of S1613. The study allows you to get this test done as part of the screening step, even at diagnosis. Please note that the study is not available for patients who have had prior antiEGFR therapy.