

Memo

Study: **NSABP-B-55/OlympiA**
Date: **October 31, 2019**
Subject: **Data Cut Off (DCO) and Database Lock (DBL) Planning for Interim Analysis**



Dear NSABP-B-55/OlympiA Investigator,

First and foremost, **we would like to thank you for your hard work** and close collaboration with the NRG Oncology Statistics and Data Management Center (SDMC) over the last few months, while we have progressed with intense database cleaning activities.

As the NSABP-B-55 (OlympiA) study is approaching an integral phase, getting closer and closer to the required number of Invasive Disease-Free Survival (IDFS) events to conduct the interim analysis for efficacy review by the IDMC (Independent Data Monitoring Committee), we are writing to inform you of the estimated next study milestone dates. Please note that the dates are a prediction with a relatively wide confidence interval (note: the actual DCO will be set when exactly 165 Invasive Disease-Free Survival (IDFS) events are entered into the Rave database).

Even though the dates may be subject to change, **we believe that achieving these timings will help ensure any additional work will be minimal when the actual DCO is called:**

- No Rave queries and missing pages older than 30 days: 30th October 2019
- Predicted Data Cut Off (DCO): 13th November 2019
- Last data entered into Rave by: 27th November 2019

These steps above should be achieved regardless of whether the DCO falls on the predicted date or moves. **All patients' visits that have happened up to 13th Nov 2019 must be entered into Rave by the 27th November 2019.** If DCO is called on the 13th Nov, these are the tentative dates of the next milestones:

- Last query issued by NRG Oncology by: 09th December 2019
- Data Base Lock (DBL): 20th January 2020

The data from this study will represent the cumulation of over 6 years work and, if positive, could lead to an important new treatment option for these patients with a high unmet need. A study like NSABP-B-55/OlympiA is unlikely to ever be repeated. To this end, it is critical to ensure high quality data in order to answer the study objectives and enable a robust IDMC decision. Taking into consideration the amount of work still ahead of us, please can you ensure sufficient resources (i.e. site personnel, time) are in place to deliver the above study milestones.

We look forward to working together on upcoming major study milestones and we are certain we will be as successful as thus far.

Yours sincerely,

NRG Oncology

