Happy Fall!

It has been one year since we enrolled our first patient and the STELLAR study is well underway! To date, we have enrolled 59 patients and are now active in six countries: the U.S., Canada, Italy, Germany, Belgium and the Netherlands.

Thank you for your hard work and active engagement in this important clinical trial. We look forward to our continued collaboration in the STELLAR study.

Protocol Amendment 4

The long awaited Protocol Amendment 4 has been released!

Based on the IDMC’s recommendation, we have reduced the starting dose for lomustine on Arm A from 110g/m^2 to 90g/m^2.

In addition, we have adjusted the dose modifications for Arm A. The new protocol also allows for windows for select randomization procedures, including audiometry, PFT and ECG.

We will be holding a WebEx in the near future to go over Protocol Amendment 4 in detail.

Study Reminders

- Please remember to send in your prescreening logs on a weekly basis.
- Pathology samples should be sent to University of Toronto following randomization. These should be identified by the patient randomization number, not the screening number.
- Be on the lookout for the updated Pathology Manual, Pathology Transmittal Form and Pharmacy Manual.
- The eflorenithine dosing chart outlining the corresponding mL per dose and number of bottles to be dispensed per the patient’s BSA can be found in the STELLAR booklet. Let your CRA know if you need a copy.

SAE/AE Reporting

Progression of AA disease that is unrelated to study drug should NOT be reported as AEs or SAEs. This includes Progression of Disease (POD), the signs/symptoms of POD, and death due to POD. POD should be captured as Outcome in EDC.

If there are any questions about whether an event meets SAE reporting criteria, please contact CHOSafety@PRAhs.com.
Study Coordinator Meetings

Nikki, Kat, Marietta and Kartik have been on the road holding regional study coordinator meetings in the past months in Chicago, Illinois and Denver, Colorado. Our next meeting will be held on November 3rd in San Diego, California. Thank you to those of you who came out to attend! We loved meeting you and hope you found the discussions valuable.

From left to right: Nikki Nepomuceno (CRA), Kathleen Villamejor (Director, Clinical Operations), Marietta Franco (Head, Clinical Operations), Kartik Aysola (Medical Science Liaison).

Data Entry

Audiometry, PFT and urinalyses are performed every 3 months post-randomization. These can be performed at the visit closest to the 3-month mark. A query will fire in EDC if not performed exactly at 3 months, but you may respond saying that these tests were conducted at the visit closest to the 3-month mark.

Lomustine Weekly Hematology

Labs that lead to a dose delay, reduction or discontinuation must be captured in EDC on a weekly basis beginning from the lab that lead to the delay/reduction/discontinuation until resolution.

Only the following must be captured in EDC: white blood cells, neutrophils, platelets and hemoglobin.

Site Spotlight

Dr. Karen Fink and Dr. Vanessa Nestor, Nurse Practitioner, along with the research team at Baylor Scott & White Research Institute and the Charles A. Sammons Cancer Center strongly believe that clinical trials are an integral part of caring for brain tumor patients. They are proud to offer multidisciplinary care for patients in the North Texas region, and are excited to have a trial for patients with progressing anaplastic astrocytomas, since most clinical trials for brain tumor patients exclude these lower grade tumors. Dr. Fink's research team is honored to be participating in the STELLAR trial and look forward to improved outcomes for brain tumor patients.

From left to right: Chevelle Smith MA, Lauren Zablosky, Helena Goodrich MA, Brendan Paulman, Karen Fink M.D., Ph.D. (PI), LaMetria West, Jacqueline Asea RN, MSN, CCRP (Research Supervisor). Not pictured: Vanessa Nestor APRN, DNP, FNP-c (Sub-I), Laura Schnurr-Breen RN (Research Manager), Silviya Meletath M.D.