

The STATus Report

Seabreeze STAT Asthma (CBP-201-206) Update

ACTION NEEDED

See Last Page

Volume 2 – Issue 3

March 2026 Topics:

- ❖ Study Updates and Reminders
- ❖ Enrollment Updates
- ❖ Questions & Answers

Monthly Message

Ah, March. Spring is near and so is International Women's Day, celebrated on March 8th! For the recent International Women's Day, we acknowledge the historical and present-day biases that led to delayed advances in women's health.

Like many other diseases, asthma phenotype and response to treatment can vary between the sexes. While boys are more likely to have asthma in childhood, after puberty this statistic shifts, and it's women and girls who bear the brunt of the disease¹. In addition to higher prevalence, women are also more likely to develop severe asthma than men². Interestingly, a study out of Yale that looked at differentially expressed genes in men and women with asthma found that genes involved in eosinophil release were enriched in men³. To date in our study, 66% of all screened participants are women!

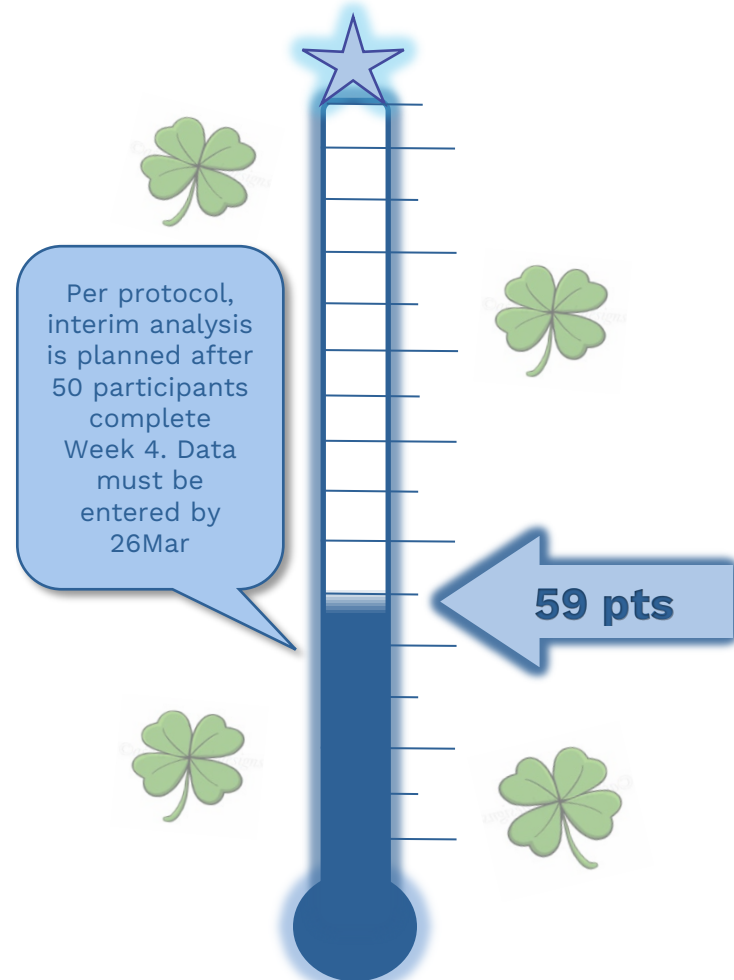
These realities underscore why this work matters, and why progress can't wait. With that in mind, here's a look at the study milestones achieved since our last newsletter:

- Randomizations increased from 42 to 59
- Welcome (Bienvenidos!) to our first activated sites in Argentina:
 - 1603 – Dr. Rojas
 - 1606 – Dr. Yanez
 - 1609 – Dr. Wehbe
 - 1611 – Dr. Manarinno
- Congratulations to our sites that screened their first participant this month:
 - 1204 – Dr. Manoharan
 - 1504 – Dr. Brennan
- And to our site that randomized their first participant this month:
 - 1501 – Dr. Srinivasan

Congratulations to 1402 Dr. Peikrishvili for randomizing participant #50!

Enrollment Update

Goal = 160 Patients



Top Enrollers

(14Feb – 13Mar)

- ❖ 1305 Dr. Radojevic: 4 randomized
- ❖ 1309 Dr. Jovanovic: 4 randomized
- ❖ 1301 Dr. Čekerevac: 3 randomized

In Focus: Clinical Brief

Question & Answers

Q: Are Visits 3 and 4 (days 1 and 2) mandatory?

A: Visit 3 and Visit 4 are required for participants who are hospitalized. For participants who are not hospitalized, these visits are highly encouraged but not mandatory.

Q: Should a patient be excluded due to a viral or bacterial upper respiratory infection?

A: Fever recorded as $>38^{\circ}\text{C}$ and/or a suspected *pulmonary* infection are excluded, however there is no specific exclusion for upper respiratory infections in the absence of fever. Eligibility for patients with an upper respiratory infection without fever should be determined at the investigator's discretion, based on the severity of symptoms and the patient's underlying clinical status.

Q: Why is fever $>38^{\circ}\text{C}$ excluded?

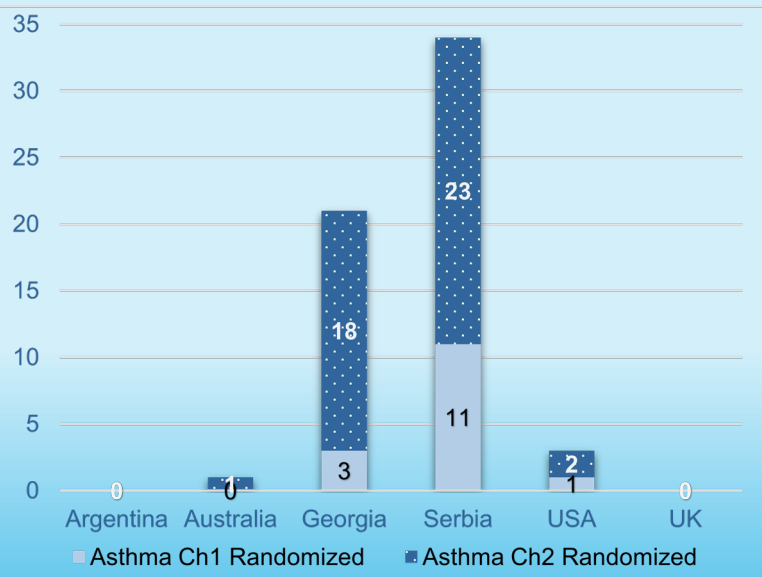
A: 1 - Fever and infection-related symptoms can mimic or overlap with adverse events (e.g., systemic responses).

2 - Fever often indicates an active infection (viral or bacterial), and biologics like rademikibart, which modulate the immune system by blocking IL-4 α —a key component in type 2 inflammatory pathways—may alter immune response. It has not been investigated whether dosing during an active infection could impair immune defense or worsen the infection.

3 - Dosing a febrile patient could increase medical risk.

Q&A from past newsletters can now be found on the study website!
seabreezestat asthma.com

Randomizations per Region (as of 13 March 2026)



Reminders/Updates

❖ **Upcoming interim analysis:**

Now that 50 participants have been randomized, Connect is preparing for the interim analysis in April. It is important that all data is entered by 26 March. Please respond to queries and enter data within three (3) days.

❖ **Medical History**

Reminder that asthma should not be listed on Medical History form. Instead, it should be on the Asthma History and Exacerbation History form.

Seabreeze STAT Asthma Resources

Check out seabreezestat asthma.com for:

- ❖ Protocol/Amendments and Operational Manuals (Lab, Pharmacy, CCGs)
- ❖ Safety Reporting Forms and Study Team contact information
- ❖ Recruitment Materials (coming soon!)



ACTION NEEDED

Treatment Failure Log Form in EDC

Important EDC Update – Action Required From Sites

During routine data review in preparation for the upcoming interim analysis, we identified that the current EDC setup does not fully support accurate derivation of the primary endpoint, treatment failure. To address this, we have added a new EDC page specifically designed to capture the information needed to calculate this endpoint correctly and consistently.

What this means for sites:

- A new EDC log form was added 27 Feb for randomized participants: “Treatment Failure”
- This page is necessary to ensure the primary endpoint is captured accurately for analysis
- Completion of this page is required for the interim analysis

Timing is critical.

All required data must be entered no later than 26 March, in advance of the scheduled interim analysis data cut.

Please plan accordingly to allow sufficient time for data entry and query resolution. Detailed instructions can be found in the updated CRF Completion Guidelines, version 3.0, published on 06 March. We appreciate your continued attention to data quality and your support in completing this important update within the required timeline!

Complete the form by answering the questions:

1. Did treatment failure occur after randomization or study drug administration, and prior to End of Trial? Treatment failure is defined according to Section 10.1 of the of the protocol: “death due to any cause, (re)admission to a hospital for asthma, ED (re)visit or unscheduled medical visit for worsening of asthma symptoms, or the necessity to intensify pharmacologic treatment.” Do not include any admissions, visits, or treatment that occurred at Visit 2 for the index (qualifying) exacerbation.
2. If treatment failure did occur, enter the corresponding earliest date after Visit 2 and follow the relevant instructions for additional data entry.

The screenshot shows a web interface with a 'Log Forms' dropdown menu. The menu items are: Concomitant Medications, Concomitant Procedures, Any Adverse Events?, and Treatment Failure (highlighted with a red circle). Below the menu is a preview of the 'Treatment Failure' form, which contains detailed instructions for data entry, including definitions of treatment failure and instructions on how to enter dates and events.

WE WANT TO HEAR FROM YOU!!

What would be helpful for your site to read about in future newsletters?
Please email us at Clinical206@connectpharm.com.

REFERENCES

1. <https://publications.ersnet.org/content/errev/30/162/210067#C6> (Chowdhury, 2021).
2. [https://journal.chestnet.org/article/S0012-3692\(19\)34295-3/fulltext](https://journal.chestnet.org/article/S0012-3692(19)34295-3/fulltext) (Wang, 2020).
3. <https://www.atsjournals.org/doi/10.1165/rcmb.2024-0565OC> (Kay, 2024).