

The STATus Report

Seabreeze STAT Asthma (CBP-201-206) Update

Volume 1 – Issue 2

December 2025 Topics:

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

Monthly Message

In November, our Seabreeze STAT Asthma study reached several major milestones:

Six sites screened their very first participants!

- 1102 – Dr. Matz
- 1104 – Dr. Bosch
- 1107 – Dr. Castro
- 1109- Dr. Dudley
- 1403- Dr. Gonjilashvili
- 1407- Dr. Tchkonია

The site leading the way in screenings and randomizations:

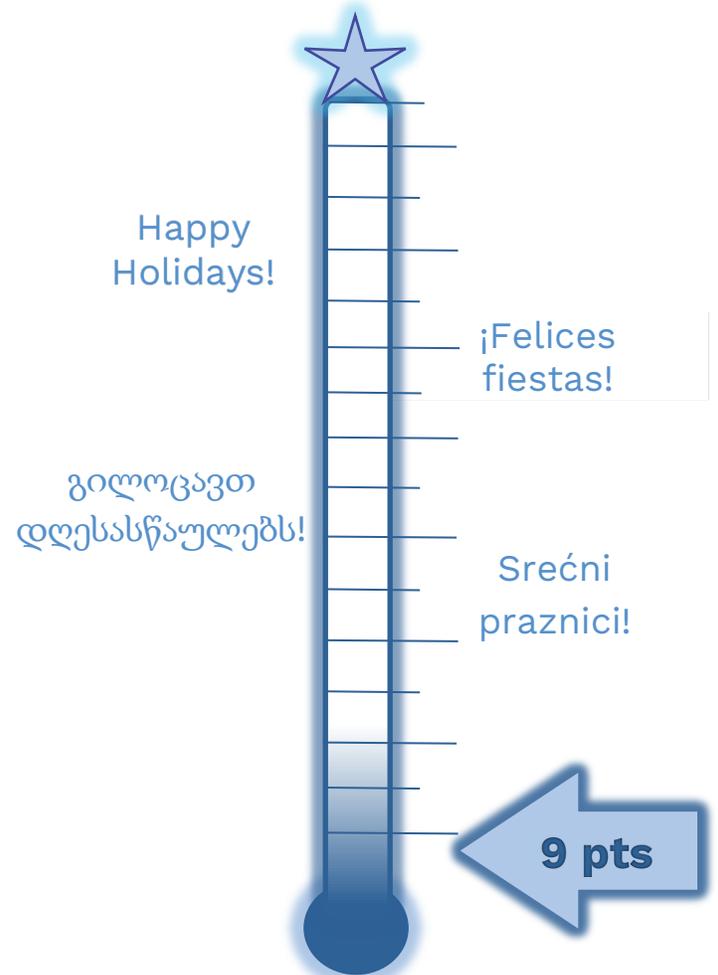
- Site 1406 – Dr. Shvelidze, with 3 randomizations!
- Site 1103 – Dr. Llerena, with 13 screenings!

On the activation front, we have made significant progress across regions with sites activated in Georgia, United States, Australia and United Kingdom. We look forward to activating our first sites in Argentina and Serbia in the coming weeks.

These achievements reflect the dedication and collaboration of every team member involved.

Enrollment Update

Goal = 160 Patients



New Sites to Randomize

(as of 11 December 2025)

- ❖ Site 1403-Dr. Gonjilashvili
- ❖ Site 1103-Dr. Llerena

In Focus: Clinical Brief

Question & Answers

Q: What should I do if a participant is unable to perform spirometry due to an exacerbation?

A: Per footnote *t* and section 10.3, post-BD spirometry should be performed *if the participant's condition allows*. Make every effort to obtain spirometry; however, it is not a protocol deviation if the participant cannot complete the assessment.

Q: What if my local lab does not offer the exact test(s) specified in the protocol for screening?

A: We understand there are regional differences, and it may not always be possible to use the exact test. Currently, using a comparable test would be considered a protocol deviation; however, we are working on an amendment to allow more flexibility in the future.

Q: Can participants repeat V1a Pulmonary Function Tests due to not meeting ATS standards?

A: Yes, up to 3 spirometry repeats are allowed at Visit 1a if a participant fails due to not meeting ATS standards. The investigator should be mindful of the participant's tolerance to withholding inhaler pre-test, as indicated in the protocol, and verify that the washout period has been met before repeat testing (Section 10.3).

Site Activations (as of 12 December 2025)



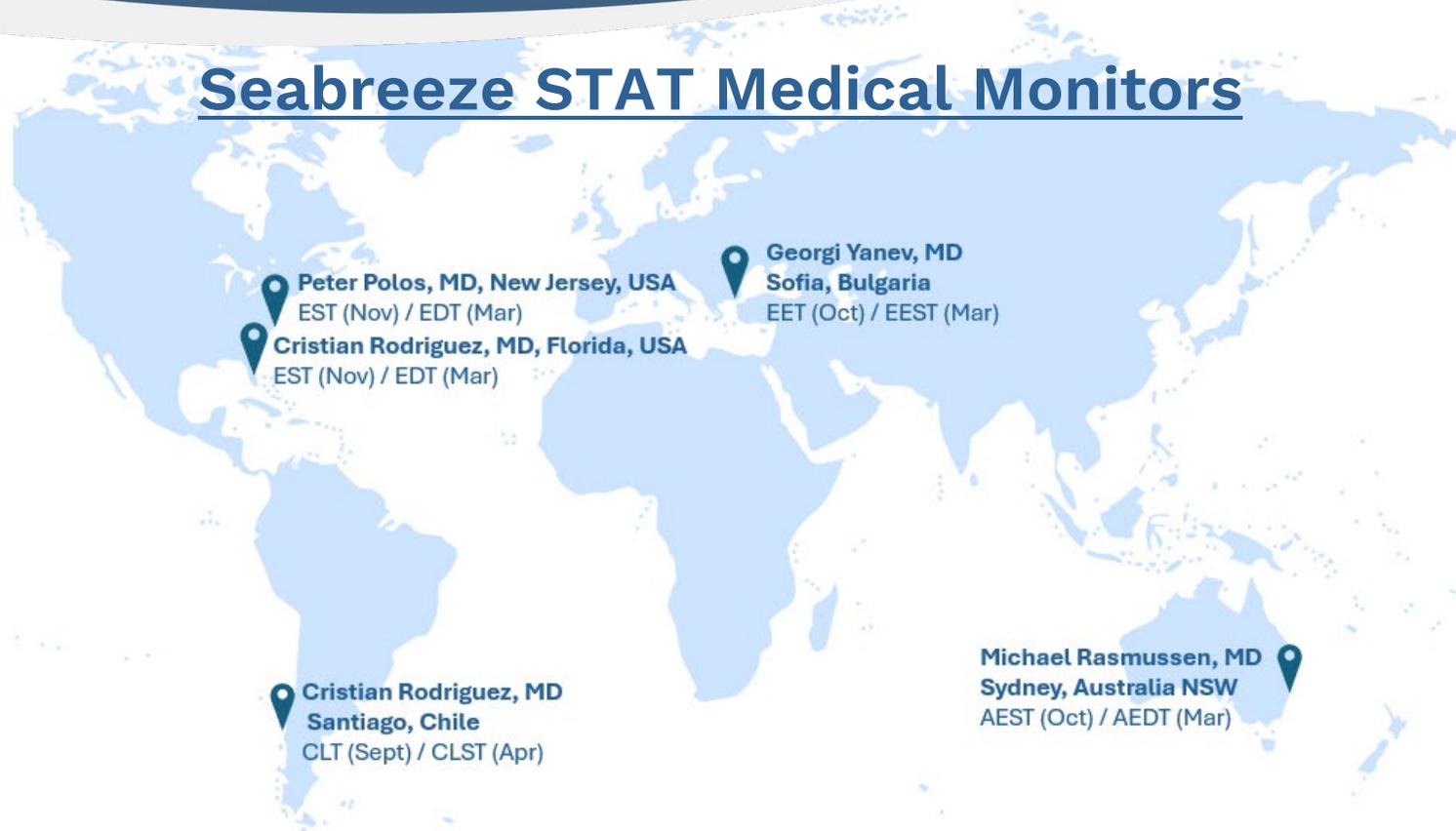
Reminders/Updates

- ❖ **Study Advertisements:** Flyers have been developed to aid in participant recruitment. Advarra IRB has approved the flyers, and US sites can print them from the Advarra website. Study monitors can provide you the flyers for submission to local IRB/IEC. Flyers will be available soon in the UK and Australia.
- ❖ **Subject Creation:** Subjects can only be created in Suvoda IRT. The subject will automatically be transferred to EDC within 12 hours for data entry.
- ❖ **Data Corrections:** EDC previously did not allow data corrections after monitoring. This issue has been corrected. We appreciate your patience.
- ❖ **CRF Update:** Due to the latest CRF update, review and update your source documents, if necessary.
- ❖ **Reminder:** Please complete data entry in EDC within 5 days of each participant visit.
- ❖ **Note:** Connect offices in the United States will be closed from 25 December- 04 January. We will return to the office 05 January 2025.

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.

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Seabreeze STAT Asthma Resources

Check out seabreezestatasthma.com for:

- ❖ Investigator Meeting recordings/slides with interactive trivia questions
- ❖ Protocol/Amendments and Operational Manuals (Lab, Pharmacy, CCGs,)
- ❖ Safety Reporting Forms and Study Team contact information

