

The STATus Report

Seabreeze STAT Asthma (CBP-201-206) Update

Volume 2 – Issue 5

May 2026 Topics:

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

Monthly Message

May 5th, 2026, was World Asthma Day.

The Global Initiative for Asthma (GINA) theme for World Asthma Day 2026 is: “Access to anti-inflammatory inhalers for everyone with asthma – still an urgent need”.

The Seabreeze STAT study requires that participants receive treatment with low, medium, to high dose inhaled corticosteroids.

What is new in GINA 2026?

On World Asthma Day, ERS and ATS held a webcast to provide an update on the changes in GINA 2026.

- Four new acute asthma flowcharts for primary care and ED settings with criteria for mild to life-threatening presentations
- New decision tree for biologic selection in severe asthma with type 2 inflammation
- Defined risk markers for fatal asthma: prior intubation, recent hospitalization/ED visits, current or recently stopped OCS. Warning on SABA toxicity mimicking worsening asthma.

Congratulations to all sites that screened their first patient!

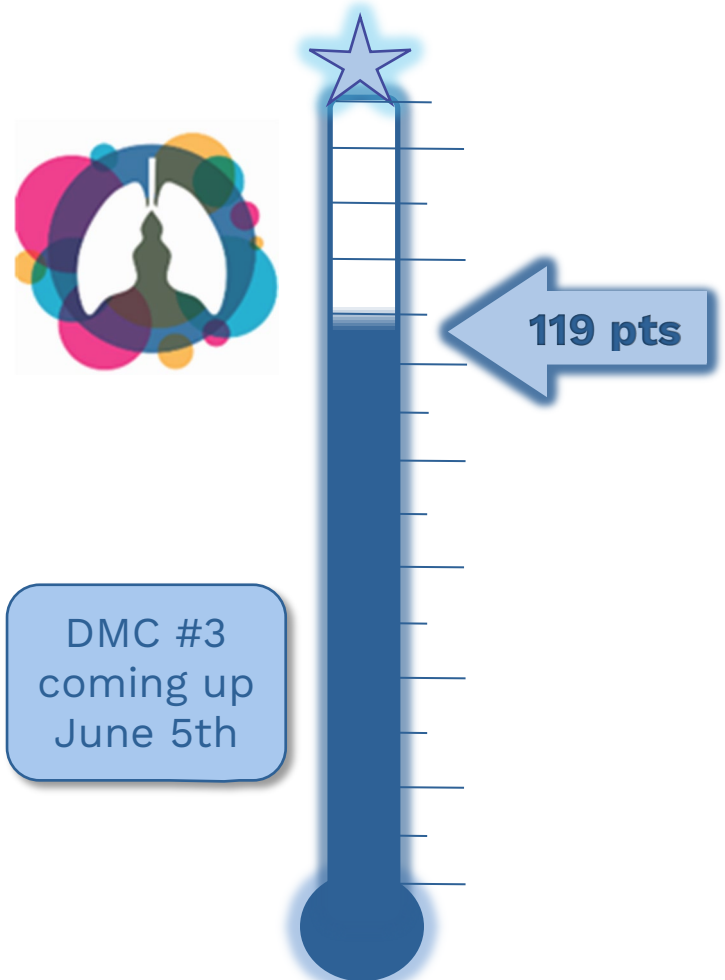
1602 Dr. Bordon

1302 Dr. Lazovic-Popovic

1202 Dr. Singh

Enrollment Update

Goal = 160 Patients



First Time Randomizations

(15 April – 15 May)

- ❖ AUSTRALIA 1504 Dr. Brennan
- ❖ ARGENTINA 1603 Dr. Rojas
- ❖ SERBIA 1302 Lazovic-Popovic

In Focus: Clinical Brief

Questions & Answers

Q. If a patient had asthma in childhood that later resolved, does a subsequent adult asthma diagnosis restart the clock on asthma duration for eligibility purposes?

A: No. The ≥ 12 -month asthma history requirement is based on the initial physician diagnosis of asthma, as supported by medical records or patient report. A prior diagnosis in childhood satisfies this requirement even if symptoms resolved and asthma was later re-diagnosed in adulthood. All other inclusion criteria must also be met.

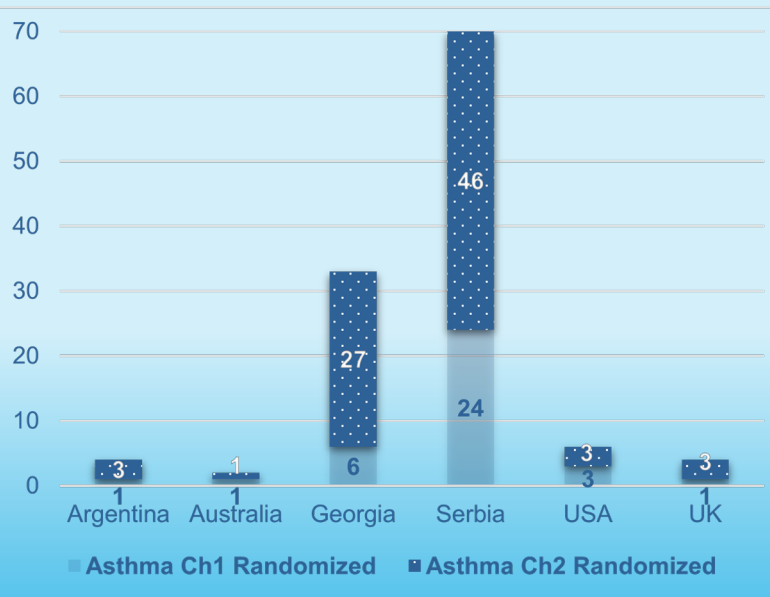
Q. If local lab provides only serum urea, can sites calculate BUN values for eligibility?

A: Yes, however this is a protocol deviation since BUN is required. The calculated BUN should be entered in EDC.

Q. Is an urgent healthcare visit required for eligibility at Visit 1b?

A: Yes. Per protocol, a participant is eligible at Visit 1b only if the index asthma exacerbation required an urgent healthcare visit for treatment. This refers to the level of care needed, not a specific facility. For the purposes of this trial, an urgent healthcare setting may include an ED, a hospital inpatient ward, an urgent healthcare facility, or an outpatient clinic equipped to provide the protocol-specified level of care. If the participant's index exacerbation required a visit in any of these settings, the answer should be "Yes."

Randomizations per Region (as of 15 May 2026)



Reminders/Updates

- ❖ **Thank you** for your cooperation in continued data entry for data cleaning.
- ❖ **Reminder:** Asthma should not be listed on the Medical History form. Instead, it should be listed on the Asthma History and Exacerbation History form.
- ❖ **Reminder:** Treatment Failure Log Forms should be completed on a rolling basis and at EOT. Please consult updated CCGs while completing these forms.
- ❖ **Reminder:** Submit pre-screening log forms to your CRA on a weekly basis.

Seabreeze STAT Asthma Resources

Check out seabreezestatasthma.com for:

- ❖ Operational manuals (Lab, Pharmacy, CRF Completion Guidelines)
- ❖ Now added Questions and Answers from all newsletters
- ❖ Password: seabreeze2025



LabConnect Memo

All studies are migrating to ConnectOne for enhanced functionality.

A brief instructional video for accessing and navigating within ConnectOne can be reached through the following link:

<https://www.labconnect.com/connect-one.html>

Access the ConnectOne system using the following link:

<https://connectone.labconnect.com/>

LABCONNECT 

2304 Silverdale Drive, Suite
100 Johnson City, TN 37601

April 6, 2026

As part of our commitment to excellence, we have launched our ConnectOne portal enhancements, which have gone live today.

As part of this enhancement, all studies currently housed in SponsorREACH are moving to the ConnectOne portal by the end of April. This will be completed with minimal disruption to you. Communications will be shared in the portal as it relates to migration status. As a courtesy we will also send a direct email to each study as its migration has been complete.

As such it remains important that all users who currently interface with SponsorReach migrate their login credentials to the ConnectOne portal.

As a reminder, log on instructions are outlined below for your convenience.

A brief instructional video for accessing and navigating within ConnectOne can be reached through this link:

<https://www.labconnect.com/connect-one.html>

Access to ConnectOne:

- Access the ConnectOne system using the following link: <https://connectone.labconnect.com/>
- Click **Client Log In** in the upper right corner of the screen.
- Enter your email address as your username, and your existing SponsorREACH portal password to log into ConnectOne. If the "password expired" notification pops up, click the "forgot password" link to update it.
- Complete the electronic user agreement that opens directly in the ConnectOne portal.

Note: All historic laboratory reports are available on the ConnectONE portal, ensuring seamless access to your data.

What to Expect:

- **Enhanced Functionality:** ConnectOne offers improved performance, designed to streamline your clinical trial processes. In addition to current functionality, future PowerBI capabilities will be available in 2026.
- **Support:** Our team will be available to assist you with any questions or concerns during this period.

We understand the importance of continuity and reliability in your clinical trials. Rest assured; we have taken extensive measures to ensure a smooth transition for your operations. Our legacy SponsorREACH portal will remain active during your transition to ConnectOne.

If you have any questions or need further information, please do not hesitate to contact us.

Thank you for your continued trust and partnership.

We are your answer to advance.

 **ATS 2026**
Orlando, May 15-20

Come for the **Science.**
Stay for the **Community.**

ORLANDO



Our team will be at the **ATS 2026** in Orlando. Feel free to meet them and talk about the study or just ask questions you have for them!

Email us to arrange a meeting:
clinical206@connectpharm.com

We look forward to seeing you there!

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.