

The STATus Report

Seabreeze STAT Asthma (CBP-201-206) Update

Volume 2 – Issue 7

July 2026 Topics:

- ❖ Monthly Message
- ❖ Data Cleaning Update
- ❖ Questions & Answers
- ❖ Study Reminders/Updates

Monthly Message

ANNOUNCEMENTS

We're excited to share that the study reached its randomization target of 160 patients on 15 June! Please ensure you enter screen failures in accordance with the instructions on page 3.

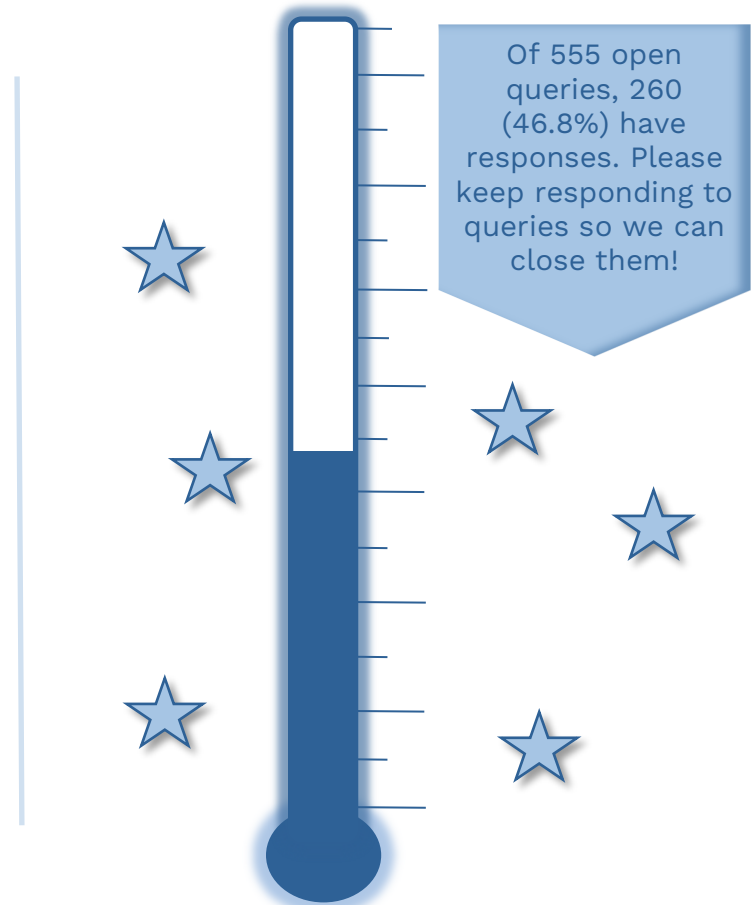
Study Reminders

- ❖ Last participant last visit is 07Aug.
- ❖ Continue to enter study data within 5 days (or less) of a visit and answer queries promptly. Help us lock our database sooner!
- ❖ Treatment Failure Log Forms should be completed on a rolling basis through EOT.
- ❖ Refer to updated CCGs while completing eCRFs.

Screening Highlights

Congratulations to Dr. Joshua's site for randomizing the study's final participant!

Data Cleaning



Fun Fact

Over the life of the study, more than 25,000 queries have been issued. That means 97.8% of all issued queries are closed!

In Focus: Clinical Brief

Question & Answers

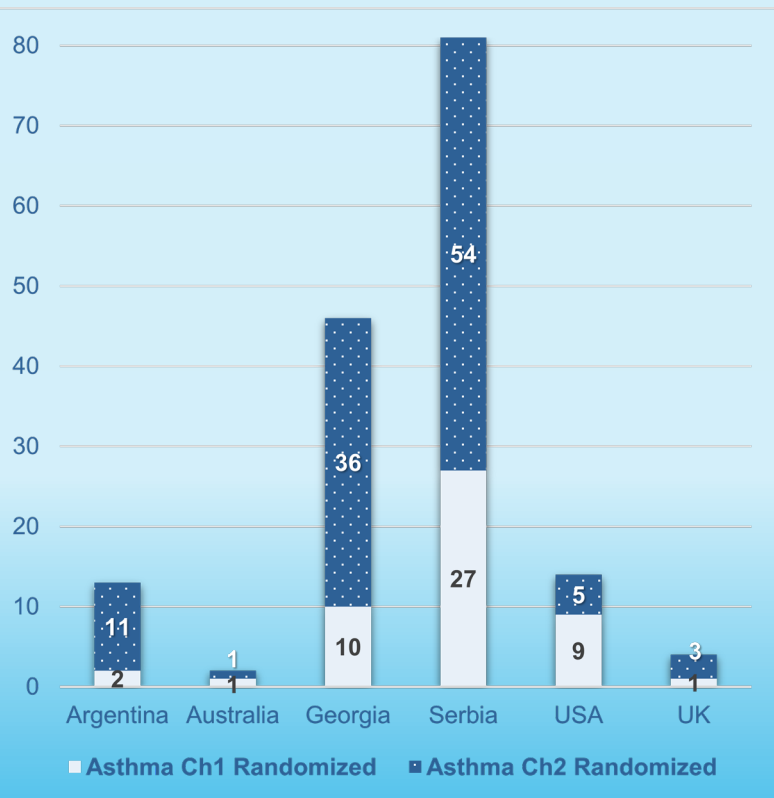
Q: What happens if laboratory tests show as cancelled?

A: LabConnect “cancelled” laboratory tests refer to samples received out of stability or unusable for testing (example: hemolyzed). Please attempt to ship samples as soon as possible after collection and request pickup ahead of time. Refer to your courier starter pack for proper shipping instructions. If the patient is willing to return, samples can be re-drawn at an unscheduled visit.

Q: When should sites schedule a courier pick-up for central laboratory samples?

A: Please request lab sample pickup ~48 hours in advance if possible. Refer to your site-specific “courier starter-pack” for minimum advance notice requirements.

Randomization Disposition (as of 16 July 2026)



Study Demographics

Sex Pivot Count		
Sex	Count	% of Randomized
Female	98	61.3%
Male	62	38.8%
Grand Total	160	100.0%

Baseline Smoking Status Pivot Count		
Smoking Status	Count	% of Randomized
Current smoker	4	2.5%
Former smoker or non-smoker	156	97.5%
Grand Total	160	100.0%

Average Age:	55
Oldest	74
Youngest	13

Seabreeze STAT Asthma Resources

Check out seabreezestatasthma.com for:

- ❖ Operational manuals:
 - Lab, Pharmacy, CCGs, Study Forms, MM Maps, Protocol Amendments
- ❖ Questions and Answers from all newsletters
- ❖ Password: seabreeze2025



Screen Failing Patients in IRT and EDC

As the study has completed enrollment, patients who screened, but did not randomize should be now be marked as screen failures in IRT and EDC.

- ❖ On the V1a eligibility page, update “Did participant meet all eligibility criteria?” from ‘Yes’ to ‘No’ (this is necessary to activate the 2 fields that follow this question).
- ❖ “If No, Criterion Not Met” — **Leave this field blank.**
- ❖ “Supplemental Screen Failure Reason” — Select ‘Participant did not experience an exacerbation’.

Database Updates

The CBP-201-206 database was updated 10 July. Updates include:

- ❖ 12-Lead ECG, Adverse Events, Injection Day Vital Signs, and Vital Signs CRFs
 - Range edit checks added
- ❖ Smoking History CRF
 - Edit checks added and modified
- ❖ Index Asthma Exacerbation Follow-Up
 - Skip logic updates to disable fields that are not required for entry.
 - Additional CRF instructional labels
- ❖ Laboratory Tests
 - CRF name updated to “Central Laboratory Tests” to differentiate from the local lab CRFs
- ❖ Chemistry (Local Lab), Hematology (Local Lab)
 - Field label [If abnormal, clinically significant?] updated to [Clinically Significant:]

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.