

The STATus Report

Seabreeze STAT COPD (CBP-201-207) Update

Volume 2 – Issue 7

July 2026 Topics:

- ❖ Monthly Message
- ❖ Enrollment Update
- ❖ Questions & Answers
- ❖ Study Reminders

Monthly Message

ANNOUNCEMENTS

The DMC met 05 June and reported no safety concerns and that the study can continue as planned.

We're excited to share that the study has officially completed its enrollment at 159 patients! We closed enrollment as of 02 July at 5 pm PT and were 1 participant short of target (one participant in screening did not exacerbate).

The IRT is closed for screening and randomization. Please thank all patients currently in screening for their participation and inform them the study has completed enrollment.

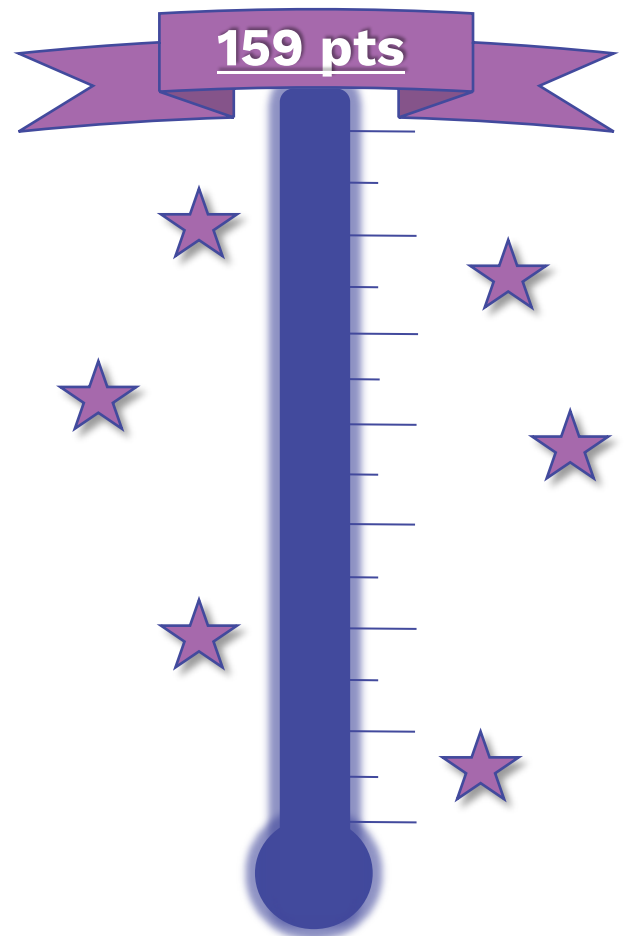
STUDY REMINDERS

- ❖ 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 and at EOT.
- ❖ Refer to updated CCGs while completing eCRFs.
- ❖ Entering calculated BUN values is not a protocol deviation following approval of protocol version 3.

SCREENING HIGHLIGHTS

Congratulations to Dr. Cochrane's site and Dr. Ramakrishnan's site for screening **and** randomizing their first patient this past month!

Enrollment Update



Top Sites to Randomize

(as of 02 Jul 2026)

- ❖ 1406 Shvelidze 7 patients
- ❖ 1309 Jovanović 4 patients
- ❖ 1303 Mojsilović 3 patients

In Focus: Clinical Brief

Question & Answers

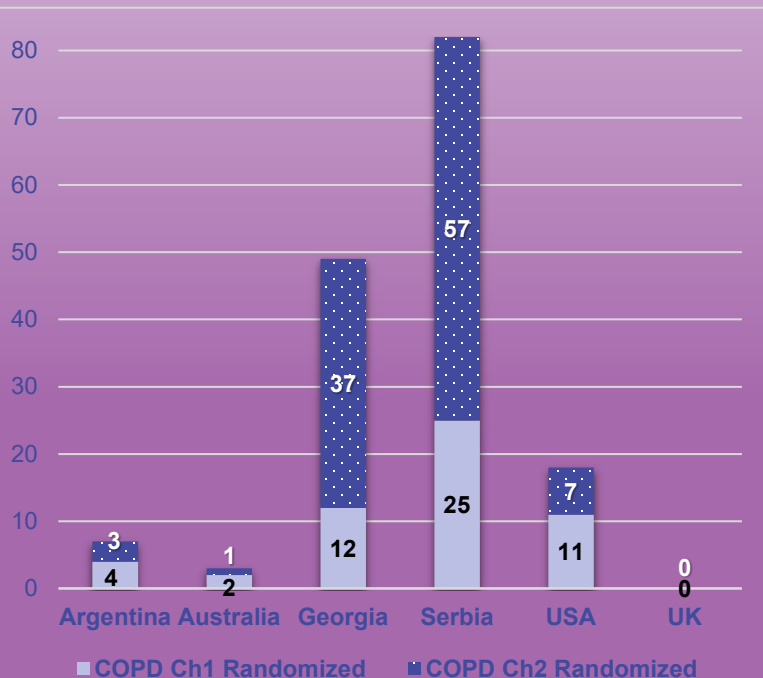
Q: What happens if laboratory tests show as cancelled?

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 02 Jul 2026)



Study Demographics (as of 02 Jul 2026)

Sex Pivot Count		
Sex	Count	% of Randomized
Female	62	39.0%
Male	97	61.0%
Grand Total	159	100.0%

Acute COPD Pivot Count		
Acute COPD	Count	% of Randomized
No	107	67.3%
Yes	52	32.7%
Grand Total	159	100.0%

Baseline Smoking Status Pivot Count		
Smoking Status	Count	% of Randomized
Current	73	45.9%
Former	86	54.1%
Grand Total	159	100.0%

Average Age: 65 Oldest: 80 Youngest: 40

Seabreeze STAT COPD Resources

Check out seabreezestatcopd.com for:

- ❖ Study Materials: Laboratory Manual, Pharmacy Manual, 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-201-207 database was updated 05 June 2026. Updates include:

- ❖ Index COPD Exacerbation Follow-Up
 - Skip logic updates to disable fields that are not required for entry.
 - Additional CRF instructional labels
- ❖ 12-Lead ECG, Adverse Events, Serious Adverse Events
 - Length of free text fields increased
- ❖ Chemistry (Local Lab), Hematology (Local Lab)
 - Field label [If abnormal, clinically significant?] updated to [Clinically Significant:]
- ❖ Laboratory Tests
 - CRF name updated to “Central Laboratory Tests” to differentiate from the local lab CRFs

WE WANT TO HEAR FROM YOU!!

What would be helpful for your site to read about in future newsletters?
Please email us at Clinical207@connectpharm.com.