

# The STATus Report

Seabreeze STAT COPD (CBP-201-207) Update

Volume 2 – Issue 2

February 2026 Topics:

- ❖ Monthly Message & Enrollment Update
- ❖ Upcoming Protocol Amendment
- ❖ Case Report Form Corner
- ❖ Questions & Answers

## Monthly Message

As we step into February, a month dedicated to both Heart Health Awareness and the celebration of Valentine's Day, it's a meaningful reminder of the vital role research plays in improving the well-being of patients living with chronic conditions like COPD.

Cardiovascular health and respiratory health are deeply interconnected as patients with COPD have a higher chance of developing heart disease, stroke, and there is a higher risk of cardiovascular events following an acute exacerbation. This highlights how the Seabreeze STAT COPD may contribute to a broader understanding of patient outcomes and long-term wellness.

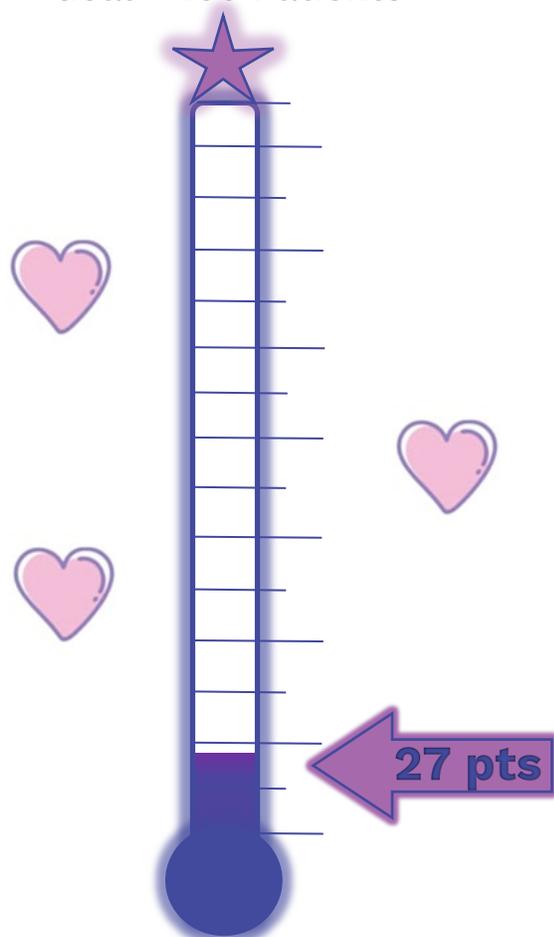
With this momentum in mind, we're excited to share the significant progress made in January:

- The number of participants randomized almost doubled from last month (14 to 27)!!!
- Major congratulations to our newly activated sites in Serbia with a total of 21 participants screened this month:
  - 1301 Dr. Čekerevac (6)
  - 1303 Dr. Mojsilovic (4)
  - 1304 Dr. Djuric (6)
  - 1305 Dr. Radojevic (4)
  - 1309 Dr. Jovanovic (1)

Serbia delivered an impressive surge in screenings this month, setting off some healthy competition—who's ready to catch up?

## Enrollment Update

Goal = 160 Patients



## Top Enrollers – January (as of 29 January 2026)

- ❖ 1301 Dr. Čekerevac: 4 randomized
- ❖ 1303 Dr. Mojsilovic: 2 randomized
- ❖ 1304 Dr. Djuric: 2 randomized

# In Focus: Clinical Brief

## Question & Answers

**Q: Should COPD exacerbations be reported as adverse events?**

**A:** Acute COPD exacerbations are an efficacy endpoint in the study. All participants must have had at least a moderate COPD exacerbation (*i.e.*, requiring systemic steroids) to enter the trial. Section 11.3.1 of the protocol states the expected progression, signs, or symptoms of the disease or disorder being studied should not be recorded as an AE unless they become more severe or occur with a greater frequency than expected for the participant's condition. Therefore, all COPD exacerbations should not be listed as an adverse event. A severe COPD exacerbation would generally qualify as a Serious Adverse Event since they are defined per protocol Section 10.2 to have “resulted in hospitalization or observation for over 24 hours in an ED or urgent healthcare facility”.

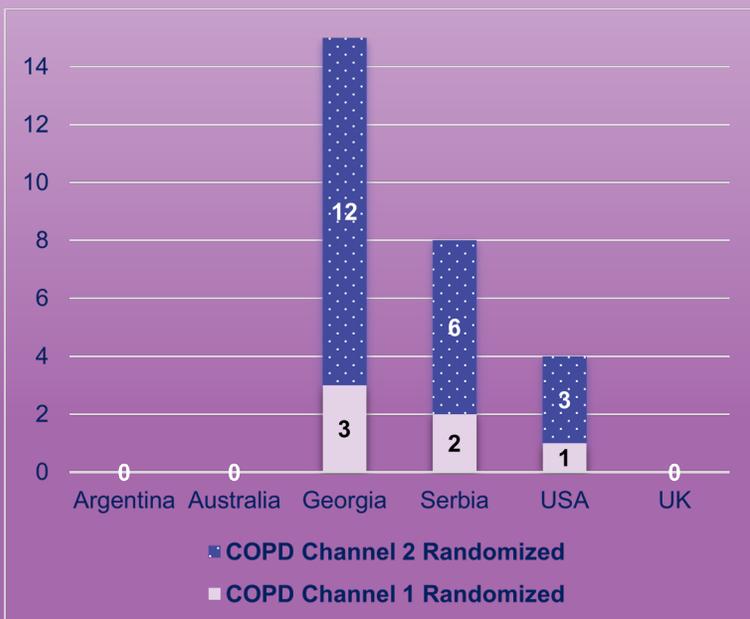
**Q: Can ipratropium bromide or other short-acting muscarinic antagonists (SAMAs) be used during a COPD exacerbation?**

**A:** It is not recommended to use SAMAs as rescue medication during the trial period but may be used in exceptional circumstances such as for managing a COPD exacerbation event at the discretion of the Investigator. See Section 8.2.1 of the protocol.

**Q: For channel 1 (stable condition) participants, can visit 1a labs be used for the eosinophil count of  $\geq 250$  cells/ $\mu$ L inclusion criteria?**

**A:** Yes. This will be clarified in the recently published protocol amendment version 3.0.

## Randomizations per Region (as of 29 January 2026)



## Case Report Form Corner

- ❖ **Data Entry for Data Monitoring Committee meeting (DMC):**  
Connect is preparing for a DMC meeting in mid-March. Please complete data entry in EDC within 5 days of each participant visit.
- ❖ **Medical History**  
Reminder that COPD should not be listed on Medical History form.
- ❖ **Spirometry**  
One row on the spirometry page should be completed for each required pre-BD and post-BD assessment according to the protocol.

## Seabreeze STAT COPD Resources

Check out [seabreezestatcopd.com](http://seabreezestatcopd.com) for:

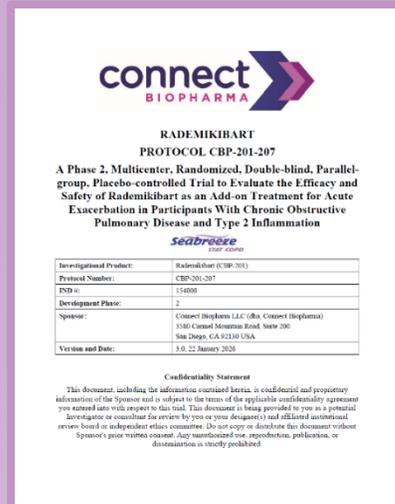
- ❖ Operational manuals (lab, pharmacy, CRF completion guidelines)
- ❖ Medical monitor contact information



# Upcoming Protocol Amendment

Protocol amendment version 3.0 was recently published by Connect Biopharma on 22 January 2026.

This protocol amendment reflects the valuable input received from sites to simplify enrollment and reduce operational friction. It also includes many clarifications based on questions received from study sites. All protocol amendments are driven by our commitment to supporting your success.



CHANGE	RATIONALE
Added 1 day window for Visit 5	To assist with weekend scheduling
Reduced the number of required local laboratory tests at V1b	Minimized to essential tests only to assess participant eligibility for operational efficiency
Added flexibility in timing of prior exacerbation to “approximately” 12 months prior to screening	To capture historical exacerbations that occur very shortly before 12 months prior
For channel 1 participants (stable condition): added “approximately” to the screening period duration	To capture index exacerbations that occur very shortly after 26 weeks
Participants who had previously used SAMAs (e.g., ipratropium) for rescue treatment prior to trial entry permitted to continue at the discretion of the Investigator	Regional differences in SAMA prescribing
Included multiple minor clarifications	To address frequently asked questions

## 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](mailto:Clinical207@connectpharm.com).



### Mystery Package Alert

We’ve been cooking up a little thank-you—a small dose of sweetness to celebrate a team that makes a big impact. Consider this your first clue... and our way of saying: *thank you for your dedication to the Seabreeze STAT Program and for helping bring hope to patients. We appreciate you!*