

The STATus Report

Seabreeze STAT COPD (CBP-201-207) Update

Volume 2 – Issue 1

January 2026 Topics:

- ❖ Monthly Message & Enrollment Update
- ❖ Seasonality of Exacerbations
- ❖ Case Report Form Corner
- ❖ Questions & Answers

Monthly Message

In the month of December, our sites and study team have demonstrated outstanding commitment, helping us reach key milestones:

- Our first sites were activated in Serbia, Australia, and the UK
- Sites who screened their first participants:
 - USA 1117 Dr. Syed
 - USA 1124 Dr. Denenberg
 - Georgia 1407 Dr. Tchkonina
 - Australia 1501 Dr. Srinivasan
 - Australia 1504 Dr. Brennan
- Argentina sites are currently undergoing site initiation visits; activation is targeted for January 2026
- Study flyers were approved for use in the US and UK, reach out to your CRA for more information

Want to try an experimental medication that may reduce COPD flare-ups?



Do you have COPD?

- Are you 40 – 80 years old?
- Diagnosed with COPD for at least 1 year?
- Experienced at least 1 COPD flare-up last year?
- Weigh 98 pounds or more with a BMI in range of 18 – 35?
- Current/former smoker (1+ pack/day for 10+ years?)

If you qualify and choose to participate, you may receive study-related care and study medication at no cost. You may also be compensated for your time and travel.

Other criteria apply – ask your doctor about the Seabreeze study.
Experimental medication has not been approved by US Food and Drug Administration.
ClinicalTrials.gov ID: NCT029840784

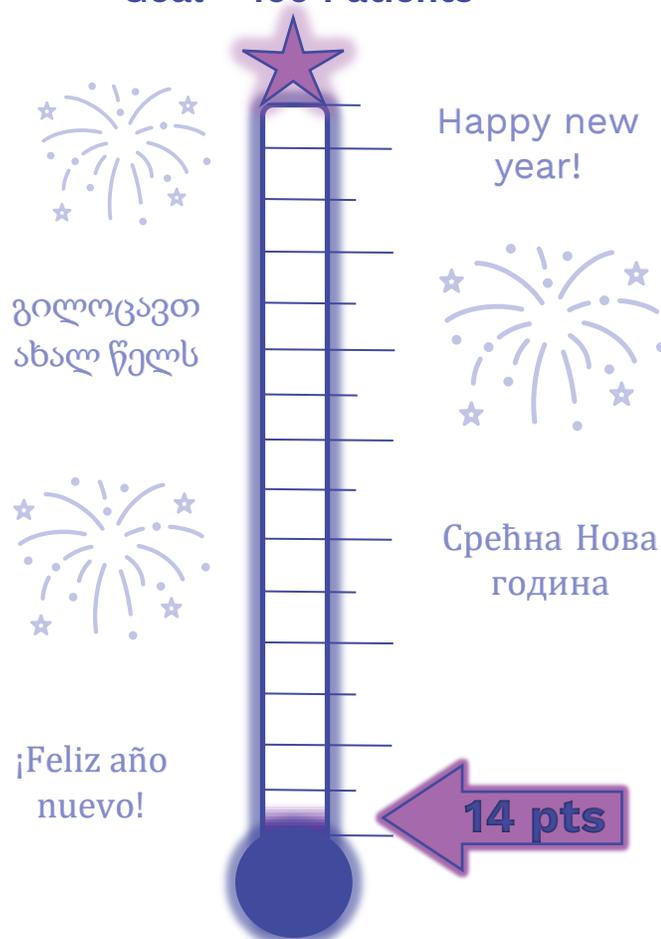
Seabreeze
STAT COPD

CLINICAL SITE NAME HERE
Contact Person Name Here
Contact Information Here

As we move into the new year, we look forward to building on this strong collaboration and continuing our shared success!

Enrollment Update

Goal = 160 Patients



Top Enrollers – December (as of 02 January 2026)

- ❖ 1402 Dr. Peikrishvili: 2 randomized
- ❖ 1406 Dr. Shvelidze: 2 randomized
- ❖ 1407 Dr. Tchkonina: 2 randomized

In Focus: Clinical Brief

Question & Answers

Q: Does exclusion #2 “regular use of immunosuppressive medication 12 weeks or 5 half-lives prior to randomization” apply if it was used for another indication other than COPD?

A: Yes it still applies, the participant should be excluded. This includes all systemic routes of administration (oral, SC, IM, IV) but not topical or nasal.

Q: Will regional holidays in January affect lab kit reordering and sample pickup?

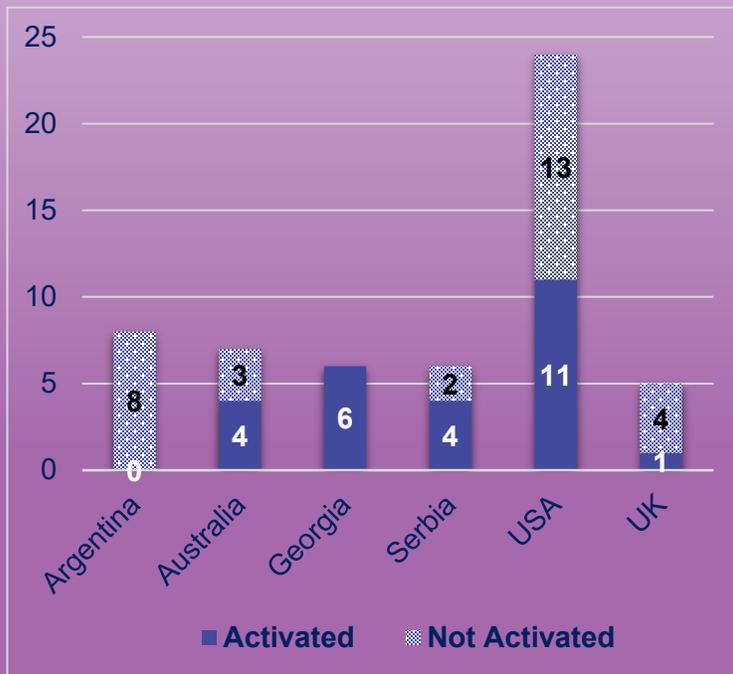
A: YES! Lab kit shipping may take longer than usual and couriers may be impacted. Please review your lab kit stock (including expiration date), place reorders, and communicate any potential schedule deviations to your CRA as soon as possible.

Q: What is meant by “predefined criteria” when evaluating time to ready-for-discharge in section 10.6.1 of the protocol?

A: For hospitalized participants only, investigators or their designees will assess participants daily during the initial hospitalization against the site’s standard discharge criteria based on clinical assessment (e.g., normalization of acidosis, symptoms returning to manageable levels, physical exam). The date and time the participant is ready for discharge based on clinical assessment and venous blood gas results should be recorded.

Site Activations

(as of 02 January 2026)



Case Report Form Corner

❖ Subject Creation:

Subjects can only be created in Suvoda IRT. The subject will automatically be transferred to EDC within 12 hours for data entry.

❖ IRT-EDC integration:

Specific fields within Suvoda IRT are transferred to EDC within 12 hours and cannot be edited in EDC. Examples include participant ID, randomization number, and hospitalized status. We are experiencing some issues with these transfers when the corresponding CRF is not open at the time of the data push. Please notify your CRA if you are experiencing missing read-only fields while we work to resolve this with data management.

Seabreeze STAT COPD Resources

Check out seabreezestatcopd.com for:

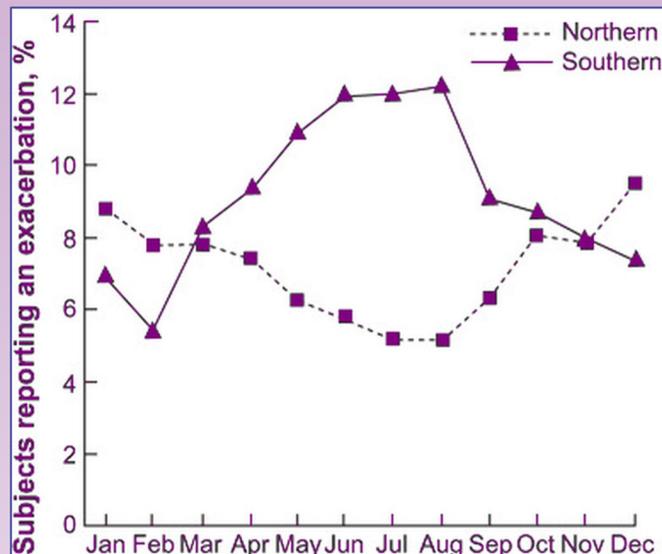
- ❖ Investigator Meeting recordings/slides with trivia questions
- ❖ Operational manuals (lab, pharmacy, CRF completion guidelines)
- ❖ Medical monitor contact information



Seasonality of COPD Exacerbations

COPD exacerbations often follow seasonal patterns, with colder months typically bringing higher risk:

- **Serbia & Georgia:** Winter's chill and increased respiratory infections contribute to elevated exacerbation rates.
- **United States & United Kingdom:** Seasonal peaks often occur during late fall and winter, aligning with influenza season.
- **Australia & Argentina:** Southern hemisphere countries experience similar patterns, but their peak seasons fall mid-year during their winter months.



The seasonal pattern of exacerbations in the northern hemisphere (n=4,849 patients) mirrored that in the southern hemisphere (n=622) in the 3-year TORCH study. Exacerbations occur year-round despite seasonality.

Source: Donaldson GC, Wedzicha JA. The causes and consequences of seasonal variation in COPD exacerbations. *Int J Chron Obstruct Pulmon Dis*. 2014;9:1101-1110. Published 2014 Oct 6. doi: [10.2147/COPD.S54475](https://doi.org/10.2147/COPD.S54475)

Exacerbation rates in COPD patients are usually reduced in summer compared with winter regardless of eosinophil level or exacerbation history. Nevertheless, during the summer, local environmental factors such as worsening of air quality driven by wildfires, coal-fired power stations (for home and industry cooling), or burning fields after harvest may lead to an increase in COPD exacerbations.

Understanding these seasonal dynamics helps us anticipate patient needs and optimize care strategies globally.