

The STATus Report

Seabreeze STAT COPD (CBP-201-207) Update

Volume 1 – Issue 2

December 2025 Topics:

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

Monthly Message

November was a month of momentum and meaningful impact! As we observed **COPD Awareness Month**—a global initiative to raise understanding of chronic obstructive pulmonary disease and the importance of early detection—we turned awareness into action.

This month, our Seabreeze STAT COPD study reached several major milestones:

- Three sites screened their very first participants:
 - 1111 – Dr. Joshua
 - 1121 – Dr. Kable
 - 1401 – Dr. Toidze
- Site leading the way in November:
 - 1103 – Dr. Llerena, with the highest number of screenings and randomizations!

On the activation front, we've made significant progress across regions:

- *Georgia: All 6 sites activated*
- *United States: 10 sites activated*
- *Australia: 3 sites activated*

We look forward to activating our first sites in Argentina, United Kingdom, and Serbia in the coming weeks. These achievements reflect the dedication and collaboration of every team member involved.

Happy Holidays in every language of our study regions:

- English: Happy Holidays!
- Serbian: Srećni praznici!
- Georgian: გილოცავთ დღესასწაულებს!
- Spanish: ¡Felices fiestas!

Enrollment Update

Goal = 160 Patients



Top Enrollers – November (as of 26 November 2025)

- ❖ 1103 Dr. Llerena: 2 randomized
- ❖ 1402 Dr. Peikrishvili: 2 randomized

In Focus: Clinical Brief

Question & Answers

Q: What should I do if a participant is unable to perform spirometry due to an exacerbation?

A: Per footnote *t* and section 10.3, post-BD spirometry should be performed *if the participant's condition allows*. Make every effort to obtain spirometry; however, it is not a protocol deviation if the participant cannot complete the assessment.

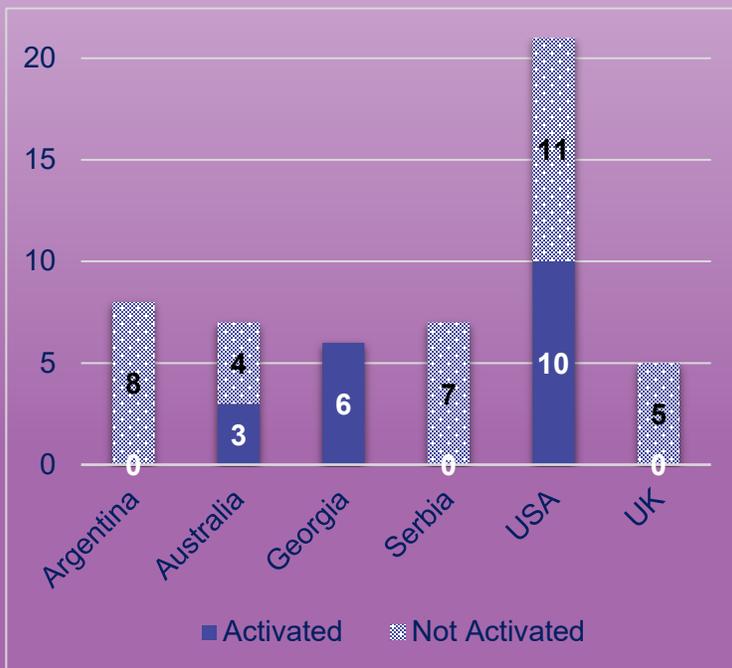
Q: What if my local lab does not offer the exact test(s) specified in the protocol for screening?

A: We understand there are regional differences, and it may not always be possible to use the exact test. At this time, using a comparable test would be considered a protocol deviation; however, we are working on an amendment to allow more flexibility in the future.

Q: Is spirometry confirming airflow obstruction required for eligibility for all participants?

A: Only participants who enroll while in stable condition (channel 1) must have current or historical evidence of airflow obstruction. Participants who enroll through channel 2 are not required to meet this criterion. Please note this criterion was moved from Inclusion #4 to Inclusion #6 with protocol amendment 2.0 to clarify this distinction.

Site Activations (as of 24 November 2025)



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.

❖ Data Corrections:

EDC previously did not allow data corrections after monitoring. The issue was fixed on 19 November—thank you for your patience.

❖ CRF Update:

Consider updating your source documents to reflect the latest CRF update released 19 November.

❖ Reminder:

Please complete data entry in EDC within 5 days of each participant visit.

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



Seabreeze STAT Medical Monitors



Peter Polos, MD, New Jersey, USA
EST (Nov) / EDT (Mar)

Cristian Rodriguez, MD, Florida, USA
EST (Nov) / EDT (Mar)

Georgi Yanev, MD
Sofia, Bulgaria
EET (Oct) / EEST (Mar)

Cristian Rodriguez, MD
Santiago, Chile
CLT (Sept) / CLST (Apr)

Michael Rasmussen, MD
Sydney, Australia NSW
AEST (Oct) / AEDT (Mar)

Cristian Rodriguez, MD

Seabreeze STAT Asthma (CBP-201-206)

- Lead Medical Monitor
- US Regional Medical Monitor

Seabreeze STAT COPD (CBP-201-207)

- Argentina Regional Medical Monitor
- Back-up to European Regional Medical Monitor

T - US: +1 858 255 7546; T: +1 609 285 7235

T - Chile: +56 9 23807688

crodriguez@connectpharm.com

Peter Polos, MD

Seabreeze STAT COPD (CBP-201-207)

- Lead Medical Monitor
- US Regional Medical Monitor
- Back-up to European Regional Medical Monitor

T: +1 908 963 7783

ppolos@connectpharm.com

Georgi Yanev, MD

Seabreeze STAT Asthma & COPD

(CBP-201-206 & CBP-201-207)

- European Regional Medical Monitor
- Back-up to Australian Regional Medical Monitor

T: +359 887 426 036

georgi.yanev@propharmagroup.com

Michael Rasmussen, MD

Seabreeze STAT Asthma & COPD

(CBP-201-206 & CBP-201-207)

- Australian Regional Medical Monitor

T: +61 0407 553 836

michael.rasmussen@propharmagroup.com