

The STATus Report

Seabreeze STAT COPD (CBP-201-207)

Volume 2 – Issue 8
August 2026 Topics:

- ❖ Study Reminders
- ❖ Data Cleaning

STUDY REMINDERS

- ❖ Treatment Failure Log Forms should be completed on a rolling basis and at EOT.
- ❖ Refer to updated CCGs while completing eCRFs.

Follow-Up of Adverse Events: Protocol Section 11.8

- ❖ Nonserious AEs will be followed until after the last scheduled trial visit and until the event resolves, the condition stabilizes, or until the event is explained/judged to be no longer clinically significant.
- ❖ SAEs will be followed until the event resolves (when the event no longer meets any of the seriousness criteria), the condition stabilizes, or until the event is explained/judged to be no longer clinically significant.

Database Lock Timelines

- ❖ Last participant last visit (LPLV) is **24 August 2026**.
- ❖ Continue to enter study data within 5 days (or less) of a visit and answer queries promptly. Help us lock our database sooner!
- ❖ We will be locking our database in batches over the next several weeks:
 - Batch 1: Completed 30 July
 - Batch 2: 28 August
 - Batch 3: 09 September
 - **Batch 4: 14 September (Final Batch)**
 - Sites in Batch 4 **must have PI sign off completed in 1 day**
 - **Final database lock: 16 September**

DATA CLEANING



Fun Fact

Over the life of the study, more than **23,000 queries** have been issued. That means **97% of all issued queries are closed!**

Check out seabreezestatcopd.com for:

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



DATABASE LOCK BINGO

We see all the hard work happening across sites.

How many of these have you completed during the final push to Database Lock?

B	I	N	G	O
 Closed a query	 Entered visit data within 5 days	 Answered a sponsor email	 Updated source documentation	 Completed a participant visit
 Found a missing document	 Performed AE follow-up	 Reviewed CCG guidance	 Helped a teammate	 Resolved an open issue
 Responded to a monitor request	 Reviewed eCRFs		 Submitted study documentation	 Cleared a query backlog
 Tracked down a data discrepancy	 Logged into the Seabreeze portal	 Completed study paperwork	 Worked through a long to-do list	 Double-checked data quality
 Closed out an action item	 Helped move the study forward	 Met a deadline	 Supported a participant	 Made progress toward database lock



BONUS CHALLENGE

How many squares can your site check?

-  1 Row = Data Quality Hero
-  2 Rows = Query Closure Champion
-  3 Rows = Database Lock Leader
-  Full Card = Seabreeze Super Site

Thank you! 

More than 23,000 queries have been issued during the study, and approximately 97% have already been closed. Your commitment, responsiveness, and attention to detail are helping drive us toward final database lock.

We appreciate YOU!

WE'RE ALMOST THERE!



KEEP UP THE AMAZING WORK! 