SPIROMICS
SubPopulations and InteRmediate Outcome Measures In COPD Study

ADVERSE EVENTS

ID NUMBER:									

FORM CODE: **AES**
VERSION: **1.0 02/26/2025**

Event: _____

0a) Date of Collection: ☐☐ / ☐☐ / ☐☐☐☐ 0b) Staff Code: ☐☐☐

Instructions: *This form should be completed if a participant has an adverse event.*
An adverse event is defined as an unexpected or unintentional medical occurrence that happens to a participant ***during a research procedure****. Adverse events can include physical or psychological harm or putting the participant at risk. Serious adverse events (SAEs) include events that result in death, are life-threatening, require hospitalization, or cause a significant disability.*
If an unanticipated problem occurs that indicates a greater risk of harm to the participants, the Adverse Events (AES) form should be entered in addition to the Incident, Deviation, and Violation Tracking (PDF) form.

1) With which study visit is this Adverse Event associated?

☐ In-person Clinic Visit (E1)1
☐ Other6

1a) If Other, please describe: _____

2) Adverse Event: _____

2a) Start Date: ☐☐ / ☐☐ / ☐☐☐☐

2b) Stop Date: ☐☐ / ☐☐ / ☐☐☐☐

2c) Severity:

☐ Mild1

Event results in mild or transient discomfort, not requiring intervention or treatment; does not limit or interfere with daily activities (e.g., insomnia, mild headache).

☐ Moderate2

Event is sufficiently discomforting so as to limit or interfere with daily activities; may require interventional treatment (e.g., fever requiring antipyretic medication).

☐ Severe3

Event results in significant symptom(s) that prevent(s) normal daily activities; may require hospitalization or invasive intervention (e.g., anemia resulting in blood transfusion).

2d) Outcome of Adverse Event:

- ☐ Resolved, No Sequelae$_1$
- ☐ Still present - no treatment$_2$
- ☐ Still present - being treated$_3$
- ☐ Residual effects present - not treated$_4$
- ☐ Residual effects present - treated$_5$
- ☐ Death$_6$
- ☐ Unknown$_7$

2e) Was the Adverse Event expected?

- ☐ No$_0$
- ☐ Yes$_1$

2f) Was the Adverse Event serious?

- ☐ No$_0$
- ☐ Yes$_1$

2g) Please provide a detailed narrative description of the event:

_____

_____

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END OF FORM