PhenX Toolkit

Data Collection Worksheet

Please Note: The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

Bronchodilator Responsiveness Testing

1. Pre-Bronchodilator Spirometry

After instructing the participant about the procedure for spirometry testing, proceed with the actual testing (Pre-bronchodilator) using a spirometer which meets American Thoracic Society/European Respiratory Society guidelines. A successful test session is defined as at least three acceptable maneuvers, with the two best forced expiratory volume in 1 second (FEV_1) values and the two best forced vital capacity (FVC) values from these maneuvers within 150 milliliters of each other.

2. Bronchodilator Administration

After at least 3 acceptable and 2 reproducible maneuvers (as defined above) are obtained, administer two puffs (180 mcg) of inhaled bronchodilator (albuterol), a short-acting beta-agonist, from a metered-dose inhaler to the participant using a spacer. A large-volume spacer, such as the Aerochamber®, should be used. A timer should be set up to sound 15 minutes after the last administered puff of bronchodilator.

3. Post-bronchodilator Maneuver

The post-bronchodilator (post-BD) maneuver can start any time after the 15-minute wait. The same criteria of at least 3 acceptable and 2 reproducible maneuvers should be followed. It is not critical that the post-BD maneuver be done immediately at 15 minutes, but rather that it is done at least 15 minutes but not more than 40 minutes after the last administered puff of bronchodilator.

Acceptable and Reproducible Maneuvers

For the purpose of spirometry testing, "acceptable" is defined as a maneuver that is free from error. "Reproducible" is defined as being without excessive variability between maneuvers. The following are some errors that can be seen or calculated

from a forced expiratory maneuver and that can affect acceptability: hesitation or false starts, cough, variable effort, glottis closure, early termination, and leaks.

Three acceptable maneuvers are needed to determine reproducibility. The two highest values for FVC and FEV_1 taken from acceptable forced expiratory maneuvers must show minimal variability (preferably within 150 milliliters of the second highest FVC or FEV_1). It is also important to inspect the volume-time curves to determine if the shapes of the curves are reproducible.

The American Thoracic Society defines FEV_1 and FVC as the best measurements from acceptable and reproducible maneuvers. It is not necessary that they all come from the same maneuver. The FEV_1/FVC and FEV_1/FEV_6 (forced expiratory volume in six seconds*)* ratios are computed as the ratio of the individual measurements. When errors occur, review common errors with the subject before proceeding with additional maneuvers.

Ask the participant to watch the technician perform the FVC maneuver again. The technician should demonstrate the correct placement of the mouthpiece, emphasize the maximum depth of inhalation, and then blast out the air. If the participant tries again and the reproducibility criteria are not met, the technician should continue administering the test as needed (up to a total of eight maneuvers), assuming that the subject is able to continue.

Some participants will never be able to provide three acceptable efforts, and having two reproducible maneuvers is okay. The goal is to meet the acceptability and reproducibility criteria, but these are not absolute requirements for data to be used. Previous studies have shown that inability to perform reproducible spirometry, even with good coaching, is an important risk factor in predicting future health.

Contraindications

Spirometry testing with bronchodilator responsiveness should not be done if the subject has or reports any of the following:

• chest or abdominal surgery in the past three months

• a heart attack in the last three months

• detached retina or eye surgery in the past three months

• hospitalization for any other heart problem in the past month

• a resting pulse rate more than 120 beats/minute (participant should be sitting for at least 5 minutes prior to pulse rate determination)

4. Calculation of bronchodilator responsiveness: There are several ways to

calculate bronchodilator responsiveness. The most commonly used methods include:

a) Percent of Baseline FEV_1:

(Post-BD FEV_1 Pre-BD FEV_1)*100/(Pre-BD FEV_1)

b) Percent of Predicted FEV_1:

(Post-BD FEV_1 Pre-BD FEV_1)*100/(Predicted FEV_1)

c) Absolute Volume:

(Post-BD FEV_1 Pre-BD FEV_1)

Aerochamber® is a registered trademark for Forest Pharmaceuticals, Inc.

Protocol source: https://www.phenxtoolkit.org/protocols/view/90301