Consent Documentation Form (CDF)
Version B, July 2017

Subject ID Number: __________________

Visit Number: ___

Instructions: This form is completed by project staff after the initial Registry consent is signed, and again if the patient requests a modification to consent or to withdraw from the study.

1. Participant Consent Status
   o Initial study consent
   o Modification of consent

2. Type of Consent or Consent Modification
   o Full consent with contact
   o Partial consent, data collection, no contact
   o Partial withdrawal of consent, do not contact
   o Full withdrawal of consent, no data and no contact

3. Are there any restrictions in consent regarding specimens/images in repositories?
   o Yes
   o No
   o Not Applicable

4. Date of consent or modification (mm/dd/yyyy):

5. Interviewer’s / recorder’s initials:
Demographics Form (DEM)
Version B, July 2017

Subject ID Number: ___________________

Instructions: This form is to be completed for each patient (after initial informed consent is received) at baseline for data within the past 2 years. Information is obtained through patient interview or from patient chart or electronic medical record review.

1. Patient’s date of birth? (mm/dd/yyyy):

2. Patient’s gender?
   - Male
   - Female

3. Is the patient of Hispanic ethnicity (origin)?
   - Yes
   - No
   - Unknown
   - Refused

4. Which of the following best describes the patient’s race?
   - White
   - Black or African American
   - Asian
   - Native Hawaiian or Other Pacific Islander
   - American Indian or Alaska Native
   - Unknown
   - Refused
   - Other
   4a. Specify: ____________________________
   - Unknown

5. Patient’s country of origin (birth)?
   - US
   - Canada
   - Mexico
5a. Specify: __________________________

6. Which of the patient’s physical measurements (height and/or weight) are available (select all that apply)?
   - Height – Go to 6a
   - Weight – Go to 6c
   - Neither – Go to 7
   - Unknown – Go to 7

6a. Date of the patient’s most recent height measurement (mm/dd/yyyy):

6b. Patient’s height: _____
6b1. Specify unit:
   - Inches
   - Centimeters
   - Unknown

6c. Date of the patient’s most recent weight measurement (mm/dd/yyyy):

6d. Patient’s weight: _____
6d1. Specify unit:
   - lbs
   - kg
   - Unknown

7. What primary medical insurance does the patient currently have?
   - Commercial Insurance
   - Tricare (formerly CHAMPUS)
   - Medicaid or other state-promoted program
   - Medicare
   - No Insurance
o Declined
o Unknown
o Other

7a. Specify: __________________________  o Unknown

8. Visit date (mm/dd/yyyy):

9. Source of data:
   o Participant interview
   o Medical records review/abstraction

10. Form completion date (mm/dd/yyyy):

11. Interviewer’s/Recorder’s initials:
Medical History and Procedures Form (MHP)
Version A, July 2017

Subject ID Number: ___________________

Instructions: This form is to be completed for each patient (after initial informed consent is received) at baseline for data within the past 2 years (unless specified otherwise). Information is obtained through patient interview, or from patient chart or electronic medical record. Do not submit electronic Medical History and Procedures Form until all medical data (i.e. lab results, culture results, radiology reports) for baseline visit is available.

1. Has the patient had a spirometry measurement?
   o Yes
   o No - Go to 2
   o Unknown - Go to 2

1a. Was spirometry during exacerbation, stable conditions, or unknown (if more than one spirometry is available, use spirometry data from stable conditions)?
   o During exacerbation
   o During stable conditions
   o Unknown

1b. Spirometry date (mm/dd/yyyy):

1c. Pre-Bronchodilator?
   o Yes
   o No – Go to 1d
   o Unknown – Go to 1d

1c1. FVC (liters): ___________ o Unknown
1c2. FVC (% predicted): ___________ o Unknown

1c3. FEV1 (liters): ___________ o Unknown
1c4. FEV1 (% predicted): ___________ o Unknown
1d. Post-Bronchodilator?
   - Yes
   - No
   - Unknown

1d1. FVC (liters): ____________  o Unknown
1d2. FVC (% predicted): ____________  o Unknown

1d3. FEV1 (liters): ____________  o Unknown
1d4. FEV1 (% predicted): ____________  o Unknown

2. Has the patient had an Oxygen saturation measurement?
   - Yes
   - No – Go to 3
   - Unknown – Go to 3

2a. Was the measurement taken at rest or exercise (select all that apply)?
   - Rest
     2a1. What was the oxygen saturation level? _____ %
     2a2. Was the patient on room air or supplemental oxygen at the time of the measurement?
        - Room air
        - Supplemental oxygen
         2a2a. Amount of supplemental oxygen?
            - 1 liter per minute (lpm)
            - 2 liters per minute (lpm)
            - 3 liters per minute (lpm)
            - 4 liters per minute (lpm)
            - 5 liters per minute (lpm)
            - Greater than 5 liters per minute (lpm)
            - Unknown
   - Exercise
     2a3. What was the oxygen saturation level? _____ %
     2a4. Was the patient on room air or supplemental oxygen at the time of the measurement?
        - Room air
2a4a. Amount of supplemental oxygen?
   o 1 liter per minute (lpm)
   o 2 liters per minute (lpm)
   o 3 liters per minute (lpm)
   o 4 liters per minute (lpm)
   o 5 liters per minute (lpm)
   o Greater than 5 liters per minute (lpm)
   o Unknown
   o Unknown

3. Has patient completed a Six Minute Walk test?
   o Yes
   o No – Go to 4
   o Unknown – Go to 4

3a. Specify distance walked: _____  o Unknown
3a1. Specify unit:
   o Feet
   o Meters
   o Unknown

4. Has the patient ever been diagnosed with Bronchiectasis?
   o Yes
   o No – Go to 4b
   o Unknown – Go to 4b

4a. At what age was the diagnosis of bronchiectasis made?
   _____ years  o Unknown

4b. Please select any co-existing conditions/diseases that this patient has ever been diagnosed with:
   o Asthma
   o COPD
   o Alpha-1 antitrypsin deficiency (Alpha-1) – Complete 4c
   o Primary immunodeficiency (e.g. hypogammaglobulinemia) – Complete 4d
o Kartagener’s syndrome or Primary Ciliary Dyskinesia (PCD) – Complete 4e
o Cystic Fibrosis – Complete 4f
o Rheumatologic disease (e.g. Rheumatoid Arthritis [RA], Sjogren’s Syndrome) – Complete 4g
o Inflammatory Bowel Disease – Complete 4h
o Allergic Bronchopulmonary Aspergillosis (ABPA) – Complete 4i
o Gastroesophageal Reflux Disease (GERD) – Complete 4j
o Otitis and/or rhinosinusitis – Complete 4k
o Amyloid
o Congenital heart disease
o Foreign body obstruction
o Hematologic malignancy
o HIV
o Measles
o Mounier-Kuhn Syndrome
o Post-infectious – Pneumonia
o Post-infectious – Pertussis
o Post-infectious – Tuberculosis
o Relapsing polychondritis
o Sarcoidosis
o Smoke / toxin inhalation (e.g. environmental pollutants excluding cigarette smoke)
  o Systemic lupus erythematosus
  o Whooping cough
  o Williams-Campbell syndrome
  o Yellow nail syndrome
  o Young’s syndrome
  o None
  o Other
  o Unknown/Idiopathic

4c. Are the alpha-1 test results available?
  o Yes
  o No – Go to 4c4
  o Unknown – Go to 4c4
4c1. Alpha-1 test date (mm/dd/yyyy):

4c2. Level: __________ mg/dl   o Unknown   o Not Applicable

4c3. Phenotype:
   o MM   o SZ   o Null
   o MZ   o MS   o Unknown
   o ZZ   o SS

4c4. Specify end organ involvement of alpha-1 antitrypsin deficiency (select all that apply)?
   o Lung
   o Liver
   o None
   o Unknown

4c5. Has the patient started augmentation therapy related to Alpha-1?
   o Yes
   o No
   o Unknown

4d. Which primary immunodeficiency was the patient diagnosed with?
   o Common Variable Immunodeficiency (CVID)
   o Hypogammaglobulinemia
   o Other
   o Unknown

4d1. Has the patient had immunoglobulins measured?
   o Yes
   o No - Go to 4e
   o Unknown - Go to 4e

4d1a. Most recent date immunoglobulins measured (mm/dd/yyyy):

4d1b. IgG: ________ (mg/dL)   o Unknown
4d1c. IgM: ________ (mg/dL)   o Unknown
4d1d. IgA: ________ (mg/dL)   o Unknown
4d1e. IgE: _______  o Unknown
  4d1e1. Specify IgE units:
    o kU/L
    o mg/dL
    o Unknown

4e. Situs status (in relation to PCD/Kartagener’s Syndrome)?
  o Normal – Go to 4e2
  o Abnormal
  o Unknown – Go to 4e2
  o Other – Go to 4e2

4e1. Specify abnormal situs status (select all that apply):
  o Situs inversus totalis
  o Dextrocardia
  o Thoracic situs inversus
  o Abdominal situs inversus
  o Situs ambiguous (and/or other situs abnormalities)
  o Unknown

4e2. Has the patient had nasal nitric oxide measured?
  o Yes
  o No – Go to 4e3
  o Unknown – Go to 4e3

4e2a. Specify the following:
  o Reduced
  o Normal
  o Unknown

4e3. Has the patient had exhaled nitric oxide measured?
  o Yes
  o No – Go to 4e4
  o Unknown – Go to 4e4

4e3a. Specify the following:
  o Increased
Normal  
Unknown  

4e4. Has the patient had a mucosal biopsy (for cilia)?  
Yes  
No  
Unknown  

4f. Has the patient been tested for cystic fibrosis?  
Yes  
No  
Unknown  
Go to 4f2  

4f1. Test date (mm/dd/yyyy):  

4f1a. Sweat Cl: ________ (mmol/L)  
Unknown  

4f1b. Sweat Cl: ________ (mmol/L)  
Unknown  
Not Applicable  

4f1c. Genotype:  
Yes  
No  
Unknown  
Go to 4f2  

4f1d. Genotype test date (mm/dd/yyyy):  

4f1e. Lab:  
Ambry  
Genzyme  
Local  
Other commercial  
Unknown  

4f1f. Specify Mutation 1: ___________________  
Unknown  
None detected  

4f1g. Specify Mutation 2: ___________________  
Unknown  
None detected
4f2. Has the patient had a nasal potential difference measured?
   - Yes
   - No – Go to 4g or next applicable question
   - Unknown – Go to 4g or next applicable question

4f2a. Please specify result:
   - Normal
   - Abnormal
   - Unknown

4g. Which rheumatologic disease was the patient diagnosed with?
   - Rheumatoid arthritis
   - Sjogren’s syndrome
   - Other
   - Unknown

4g1. Has the patient had a rheumatoid factor performed?
   - Yes
   - No – Go to 4h
   - Unknown – Go to 4h

4g1a. Most recent date rheumatoid factor performed (mm/dd/yyyy)?

4g1b. Rheumatoid factor result:
   - Less than 15 IU/ml
   - Greater than or equal to 15 IU/ml
   - Unknown – Go to 4h

4h. Specify which inflammatory bowel disease the patient has been diagnosed with:
   - Ulcerative Colitis
   - Crohn’s Disease
   - Unknown

4i. Are ABPA test results available?
   - Yes
   - No – Go to 4j
4i1. Most recent date of ABPA (mm/dd/yyyy) test:

4i2. Total IgE: _____________ (IU/ml or kU/L)  o Unknown

4i3. White Blood Cell (WBC) count: ___________ (x 10 L)  o Unknown

4i4. % eosinophils: ___________ (%)  o Unknown

4i5. # eosinophils: ___________ (cells)  o Unknown

4j. Has the patient had Gastroesophageal Reflux Disease (GERD) testing?
   o Yes
   o No – Go to 4k or next applicable question
   o Unknown – Go to 4k or next applicable question

4j1. GERD testing included the following (select all that apply):
   o Esophagram
   o PH monitor – Go to 4j2
   o Endoscopy – Go to 4j3
   o Other – Go to 4j4
   o Unknown – Go to 4j4

4j2. Ambulatory pH monitoring date (mm/dd/yyyy):

4j2a. Reflux noted on pH monitoring?
   o Yes
   o No
   o Unknown

4j3. Date of most recent endoscopy (mm/dd/yyyy):

4j4. Was diagnosis made on Empiric treatment trial (i.e. without specific testing) (PPI or H2 blocker)?
   o Yes
4k. Specify otitis and/or rhinosinusitis diagnosis (select all that apply):
   o Otitis
   o Rhinosinusitis
   o Unknown

4k1. Specify otitis and/or rhinosinusitis onset:
   o adult onset
   o childhood onset
   o onset unknown

4k1a. Has the patient had sinus or ear surgery (including placement of ear tubes)?
   o Yes
   o No – Go to 5
   o Unknown – Go to 5

4k2. Has the patient had ear-tube placement?
   o Yes
   o No
   o Unknown

5. Has the patient ever (even if more than 2 years prior to enrollment) had a positive NTM culture from respiratory specimens (sputum, BAL, biopsy)?
   o Yes – Go to 5a
   o No
   o Unknown

5a. Has the patient ever (even if more than 2 years prior to enrollment) been diagnosed with NTM lung disease as recognized by the ATS/IDSA? Note: 2007 ATS/IDSA microbiologic criteria for NTM lung disease is considered meeting at least one of the following within the 12 months prior to diagnosis:
a) Positive culture results from at least two separate expectorated sputum samples or
b) positive culture results from at least one bronchial wash or lavage or
c) transbronchial or other lung biopsy with mycobacterial histopathologic features (granulomatous inflammation or AFB) and positive culture for NTM or biopsy showing mycobacterial histopathologic features (granulomatous inflammation or AFB) and one or more sputum or bronchial washings that are culture positive for NTM.
   o Yes
   o No – Go to 6
   o Unknown – Go to 6

5b. Please indicate when the NTM lung disease diagnosis/diagnoses was/were made. If diagnosed more than once, select timeframe for each episode (select all that apply):
   o Less than 2 years ago
   o 2 to 5 years ago
   o More than 5 years ago
   o Unknown

5c. Has the patient ever received treatment for NTM?
   o Yes
   o No – Go to 6
   o Unknown – Go to 6

5c1. Is the patient currently on active NTM therapy?
   o Yes
   o No – Go to 6
   o Unknown – Go to 6

6. Has the patient had an echocardiogram?
   o Yes
   o No - Go to 7
   o Unknown - Go to 7
6a. Date of most recent echocardiogram (mm/dd/yyyy):

6b. Was Right Ventricular Systolic Pressure (RVSP) estimated?
   o Yes
   o No – Go to 6c
   o Unknown – Go to 6c

6b1. RSVP (mmHg): ________________ o Unknown

6c. Was mitral valve prolapse noted?
   o Yes
   o No
   o Unknown

6d. Was aortic dilation noted?
   o Yes
   o No
   o Unknown

7. Has the patient had an EKG?
   o Yes
   o No – Go to 8
   o Unknown – Go to 8

7a. EKG date (mm/dd/yyyy):

7b. Specify QT interval: ___ milliseconds o Unknown

8. Chest wall deformity:
   o Normal – Go to 9
   o Abnormal
   o Unknown – Go to 9

8a. Specify abnormal chest wall deformity:
   o Pectus excavatum
   o Pectus carinatum
   o Unknown
9. Does the patient have scoliosis (if the patient has had lobectomy, pneumonectomy, or lung transplantation, this question should pertain to pre-lung surgery assessment)?
   - Yes
   - No
   - Unknown

10. Did the patient have respiratory distress at birth?
   - Yes
   - No
   - Unknown

11. Has the patient ever undergone chest surgery?
   - Yes
   - No
   - Unknown

12. Has the patient had a pneumonectomy?
   - Yes
   - No - Go to 13
   - Unknown - Go to 13

12a. Right or Left lung?
   - Right
   - Left
   - Unknown

12b. What was the pneumonectomy for (select all that apply)?
   - Bronchiectasis
   - NTM lung disease
   - Lung cancer
   - Hemoptysis
   - Other
   - Unknown
12c. Date of pneumonectomy (mm/dd/yyyy):

13. Has the patient had a lobectomy/wedge resection?
   - Yes
   - No - Go to 14
   - Unknown - Go to 14

13a. What was the lobectomy/wedge resection for?
   - Bronchiectasis
   - NTM lung disease
   - Both, bronchiectasis and NTM lung disease
   - Lung cancer
   - Hemoptysis
   - Other
   - Unknown

13b. Date of lobectomy/wedge resection (mm/dd/yyyy):

14. Has the patient had a lung transplant?
   - Yes
   - No - Go to 15
   - Unknown - Go to 15

14a. What was the lung transplant for (select all that apply)?
   - Bronchiectasis
   - NTM
   - Other
   - Unknown

14b. Single or bilateral lung transplant?
   - Single
   - Bilateral
   - Unknown

14c. Date of lung transplant (mm/dd/yyyy):

15. Has the patient ever had hemoptysis?
15a. Was it considered major [greater than 240 ml(cc) (one cup) over 24 hours] hemoptysis?
   o Yes
   o No
   o Unknown

15b. Did the hemoptysis require bronchial embolization, surgery, or transfusion?
   o Yes
   o No – Go to 16
   o Unknown – Go to 16

15b1. Indicate which (select all that apply):
   o Embolization
   o Surgery
   o Transfusion
   o Unknown

16. Does the patient have a history of cigarette smoking?
   o Yes, current smoker
   o Yes, previous smoker – Go to 16c
   o No - Go to 17
   o Unknown - Go to 17

Current Smoker
16a. # packs per day: ________________  o Unknown

16b. # of years: ________________  o Unknown

Previous Smoker
16c. Year Stopped (yyyy):

16d. # packs per day: ________________  o Unknown
16e. # of years: ___________________ o Unknown

17. Does the patient have a family history of Bronchiectasis?
   o Yes
   o No – Go to 18
   o Unknown – Go to 18

17a. Please indicate family members with history of Bronchiectasis (select all that apply):
   o Mother
   o Father
   o Sibling
   o Child(ren)

18. Does the patient have a family history of NTM?
   o Yes
   o No – Go to 19
   o Unknown – Go to 19

18a. Please indicate family members with history of NTM (select all that apply):
   o Mother
   o Father
   o Sibling
   o Child(ren)

19. Infertility is associated with Bronchiectasis. Has the patient ever had a problem with infertility?
   o Yes
   o No
   o Unknown

20. Has the patient been diagnosed as HIV positive?
   o Yes
   o No
   o Unknown
21. Has the patient had a hematologic or solid malignancy (excluding non-melanoma skin cancer)?
   - Yes
   - No – Go to 22
   - Unknown – Go to 22

21a. Specify malignancy (select all that apply):
   - Breast
     21a1. Specify treatment:
       - Radiation
       - Chemotherapy
       - Surgery
       - None
       - Unknown
   - Lung
     21a2. Specify treatment:
       - Radiation
       - Chemotherapy
       - Surgery
       - None
       - Unknown
   - Head/neck
     21a3. Specify treatment:
       - Radiation
       - Chemotherapy
       - Surgery
       - None
       - Unknown
   - Hematologic
     21a4. Specify treatment:
       - Radiation
       - Chemotherapy
       - None
       - Unknown
       - Other
       - Unknown
22. A bronchiectasis exacerbation is defined as:

A deterioration in **three or more** of the following key symptoms for at least 48 hours:
- Cough
- Sputum volume and / or consistency
- Sputum purulence
- Breathlessness and / or exercise tolerance
- Fatigue and / or malaise
- Hemoptysis

AND

When a clinician determines a change in bronchiectasis treatment is required (includes, but not limited to a course of antibiotics).

Has the patient experienced an exacerbation of bronchiectasis within the past 2 years?
- Yes
- No - Go to 23
- Unknown - Go to 23

22a. How many exacerbations of bronchiectasis has the patient experienced within the past 2 years?
- 1
- 2
- 3
- 4
- 5
- More than 5

22a1. Please specify number of exacerbations within the past 2 years: ___

23. How many times has the patient been hospitalized for pulmonary illness or exacerbation within the past 2 years?
23a. Please specify number of hospitalizations within the past 2 years: ____
  o Unknown

24. Has the patient participated in a treatment trial in the past 2 years?
  o Yes
  o No – Go to 25
  o Unknown – Go to 25

24a. Specify treatment trial (select all that apply):
  o Bronchiectasis treatment trial
  o NTM treatment trial
  o Other treatment trial – Go to 24a1
  o Unknown

24a1. Specify condition related to other treatment trial:
  o Alpha-1 Antitrypsin Deficiency
  o Asthma
  o Allergic bronchopulmonary aspergillosis (ABPA)
  o COPD
  o Cystic Fibrosis
  o Primary Ciliary Dyskinesia (PCD)
  o Other lung condition
  o Other condition (not lung-related)

24b. What kind of treatment was given to the patient during the treatment trial?
  o Placebo
  o Drug
  o Unknown
25. Visit date (mm/dd/yyyy):

26. Source of data:
   o Participant interview
   o Medical records review/abstraction

27. Form completion date (mm/dd/yyyy):

28. Interviewer’s / recorder’s initials:
Respiratory Symptoms Form (RSP)
Version B, July 2017

Subject ID Number: ________________

Visit Number: ____

Instructions: This form is to be completed for each patient (after initial informed consent is received) at baseline for data within the past 2 years, and at each annual follow-up visit using data made available during the visit window*. Information is obtained through patient interview, or from patient chart or electronic medical record. *Visit windows for each patient/visit can be found on the patient’s summary page on the DatStat portal. Please note that they differ for every patient and visit.

1. Has the patient experienced dyspnea during their stable state in this visit window*?
   o Yes
   o No - Go to 2
   o Unknown – Go to 2

1a. Specify dyspnea grade from this visit window*:
   o Grade 1: Not troubled by dyspnea (shortness of breath) except with strenuous activity.
   o Grade 2: Troubled by dyspnea (shortness of breath) when hurrying on the level or walking up a slight hill.
   o Grade 3: Walks slower than people of the same age on the level because dyspnea (shortness of breath) or has to stop for breath when walking at own pace on the level.
   o Grade 4: Stops for breath after walking about 100 yards (90 m) or after few minutes on the level.
   o Grade 5: Too breathless to leave the house, or breathless when dressing or undressing.
   o Unknown
2. Has the patient complained of fatigue during their stable state in this visit window*?  
   - Yes  
   - No  
   - Unknown

3. Has the patient experienced regular bouts of coughing during their stable state in this visit window*?  
   - Yes  
   - No - Go to 4  
   - Unknown - Go to 4

3a. Was the patient’s cough usually productive during this visit window*?  
   - Yes  
   - No – Go to 4  
   - Unknown – Go to 4

3a1. Specify color of sputum during this visit window*:  
   - White  
   - Mucoid Clear  
   - Mucopurulent (pale yellow/pale green)  
   - Purulent (dark yellow/dark green)  
   - Purulent (dark yellow/dark green with rusty spots/colors)  
   - Unknown

3a2. Specify amount of daily sputum in mL (1 tbsp = 15 ml) during this visit window*:  
   - <15 ml  
   - 15-45ml  
   - >45ml  
   - Unknown

4. Has the patient experienced hemoptysis (coughing of blood) during their stable state or during an exacerbation in this visit window*?  
   - Yes  
   - No – Go to 5
4a. When did the patient experience hemoptysis (select all that apply) during this visit window*?
   o During stable state
     4a1. Specify amount of blood coughed up during stable state in this visit window*:
       o Less than 300cc (sub-massive)
       o Greater than 300cc (massive)
       o Unknown
     o During exacerbation
     4a2. Specify amount of blood coughed up during exacerbation in this visit window*:
       o Less than 300cc (sub-massive)
       o Greater than 300cc (massive)
       o Unknown
       o Unknown – Go to 5

5. Has the patient had chest pain during their stable state or during an exacerbation in this visit window*?
   o Yes
   o No - Go to 6
   o Unknown - Go to 6

5a. Specify when the patient experienced chest pain (select all that apply) during this visit window*:
   o During stable state
   o During exacerbation
   o Unknown

5b. Was the chest pain experienced during this visit window* pleuritic in nature?
   o Yes
   o No
   o Unknown

6. Has the patient experienced wheezing during stable state or during
exacerbation in this visit window*?
  o Yes
  o No – Go to 7
  o Unknown – Go to 7

6a. Specify when the patient experienced wheezing (select all that apply) during this visit window*:
  o During stable state
  o During exacerbation
  o Unknown

7. Visit date (mm/dd/yyyy):

8. Source of data:
  o Participant interview
  o Medical records review/abstraction

9. Form completion date (mm/dd/yyyy):

10. Interviewer’s / recorder’s initials:
Imaging Form (IMG)
Version B, July 2017

Subject ID Number: __________________
Visit Number: ____

Instructions: This form is to be completed for each patient (after initial informed consent is received) at baseline for data within the past 2 years, and at each annual follow-up visit (as necessary) using data made available during the visit window*. Information is obtained through patient interview, or from patient chart or electronic medical record. Do not submit electronic Imaging Form until all imaging data (radiology reports) for the visit are available. *Visit windows for each patient/visit can be found on the patient’s summary page on the DatStat portal. Please note that they differ for every patient and visit.

1. Has the patient had a chest x-ray during this visit window*?
   o Yes
   o No – Go to 2
   o Unknown – Go to 2

1a. Chest X-ray date (mm/dd/yyyy). If more than one x-ray is available, use the one closest to the anniversary of consent:

1b. Was the chest x-ray during this visit window* abnormal?
   o Yes
   o No – Go to 2
   o Unknown – Go to 2

1c. Specify abnormalities in the chest x-ray from this visit window* (select all that apply):
   o Bronchiectasis
   o Cavities
   o Infiltrates
2. Has the patient had a Computed Tomography (CT) during this visit window*?
   o Yes
   o No - Go to 3
   o Unknown - Go to 3

2a. CT scan date (mm/dd/yyyy). If more than one CT is available, use the one closest to the anniversary of consent:

2b. Was the CT scan from this visit window* abnormal?
   o Yes
   o No – Go to 3
   o Unknown – Go to 3

2b1. Predominant abnormality in CT scan from this visit window* can be characterized by:
   o Bronchiectasis/nodular bronchiectasis
   o Fibrocavitary
   o Other
   o Unknown

2b2. Specify abnormalities in CT scan from this visit window* (select all that apply)?
   o Bronchiectasis/dilated airways
     2b2a. Specify location of bronchiectasis/dilated airways in the CT scan from this visit window* (select all that apply):
       o Left upper lobe
       o Lingula
       o Left lower lobe
       o Right upper lobe
       o Right middle lobe
       o Right lower lobe
2b2b. Specify location of tree-in-bud infiltrates in the CT scan from this visit window* (select all that apply):
   o Left upper lobe
   o Lingula
   o Left lower lobe
   o Right upper lobe
   o Right middle lobe
   o Right lower lobe
   o Unknown

2b2c. Specify location of cavities in the CT scan from this visit window* (select all that apply):
   o Left upper lobe
   o Lingula
   o Left lower lobe
   o Right upper lobe
   o Right middle lobe
   o Right lower lobe
   o Unknown

2c. Specify other abnormalities in the CT scan from this visit window* (select all that apply):
   o Infiltrates (other than tree-in-bud)
   o Scoliosis
   o Pectus
   o Other
   o Unknown

2d. Has the patient had additional CT scans during this visit window*?
   o Yes
   o No – Go to 3
   o Unknown – Go to 3

2d1. How many additional CT scans has the patient had during this
visit window*?
  o 1
  o 2
  o 3
  o More than 3
  o Unknown

3. Has the patient had sinus imaging during this visit window*?
  o Yes
  o No - Go to 4
  o Unknown - Go to 4

3a. Sinus imaging date (mm/dd/yyyy) If more than one is available, use the one closest to the anniversary of consent:

3b. Specify sinus imaging type from this visit window*:
  o X-ray
  o CT scan
  o Unknown

3c. Mucosal thickening and/or air fluid levels:
  o Yes
  o No
  o Unknown

4. Visit date (mm/dd/yyyy):

5. Source of Data:
  o Participant interview
  o Medical records review/abstraction

6. Form completion date (mm/dd/yyyy):

7. Interviewer’s / recorder’s initials:
Microbiology Form (MRB)
Version D, July 2017

Subject ID Number: ________________

Visit Number: ____

Instructions: This form is to be completed for each patient (after initial informed consent is received) at baseline for data prior to enrollment and at annual follow-up visit (as necessary) using data made available during the visit window*. The results for up to 9 lower respiratory cultures can be recorded; 3 per category. This form can be submitted more than once at baseline (to account for additional cultures from patient’s extended medical history). For Follow-up visit cultures, use the culture results closest (in date) to the anniversary of consent first.

For NTM cultures: If patient has had more than one episode of NTM lung disease, please include up to 3 most recent NTM culture(s) first, and then up to 3 NTM culture(s) from each of the NTM lung disease episodes (even if the episode didn’t meet the ATS/IDSA criteria). Reminder: This form can be submitted more than once at baseline (to account for additional cultures from patient’s extended medical history).

Do no submit electronic Microbiology Form until all data (culture results) for visit are available. *Visit windows for each patient/visit can be found on the patient’s summary page on the DatStat portal. Please note that they differ for every patient and visit.

1. Has the patient had a lower respiratory culture during this visit window*?
   o Yes
   o No – Go to 17
   o Unknown – Go to 17

I. BACTERIAL CULTURE
2. How many respiratory bacterial culture results (from this visit window*) are available?
   o 0 - Go to 7
   o 1 - Complete 3 and go to 6
   o 2 - Complete 3-4 and go to 6
   o 3 - Complete 3-5 and go to 6

3. Bacterial Culture Result #1

3a. Bacterial culture date (mm/dd/yyyy): ______________________
*If more than one culture is available, list in order by those closest to the anniversary of consent first:

3b. Culture Type:
   o Sputum
   o BAL/bronch wash
   o (T)BBX Biopsy
   o Other
   o Unknown

3c. Growth:
   o Yes
   o No - Go to next available culture (if applicable) or Question 6
   o Unknown - Go to next available culture (if applicable) or Question 6

3d. Specify growth (select all that apply):
   o Oropharyngeal flora/Normal flora/Usal flora/Mixed commensural flora
   o Pseudomonas aeruginosa
     3d1. Specify:
        o Mucoid
        o Nonmucoid
        o Both
        o Unknown
        o Haemophilus influenzae
        o Streptococcus pneumoniae
        o Staphylococcus aureus
     3d2. Specify:
Microbiology Form (MRB) – last updated 5/14/19

4. Bacterial Culture Result #2

4a. Bacterial culture date (mm/dd/yyyy): _____________________

*If more than one culture is available, list in order by those closest to the anniversary of consent first:*

4b. Culture Type:
   - Sputum
   - BAL/bronch wash
   - (T)BBX Biopsy
   - Other
   - Unknown

4c. Growth:
   - Yes
   - No - Go to next available culture (if applicable) or Question 6
   - Unknown - Go to next available culture (if applicable) or Question 6

4d. Specify growth (select all that apply):
   - Oropharyngeal flora/Normal flora/Usual flora/Mixed commensural flora
   - Pseudomonas aeruginosa
     4d1. Specify:
        - Mucoid
        - Nonmucoid
        - Both
        - Unknown
4d2. Specify:
- Methicillin Sensitive
- Methicillin Resistant
- Unknown
- Stenotrophomonas maltophilia
- Klebsiella pneumoniae
- Moraxella catarrhalis
- Nocardia
- Other bacteria
- Unknown

5. Bacterial Culture Result #3

5a. Bacterial culture date (mm/dd/yyyy): _____________________
*If more than one culture is available, list in order by those closest to the anniversary of consent first:*

5b. Culture Type:
- Sputum
- BAL/bronch wash
- (T)BBX Biopsy
- Other
- Unknown

5c. Growth:
- Yes
- No - Go to next available culture (if applicable) or Question 6
- Unknown - Go to next available culture (if applicable) or Question 6

5d. Specify growth (select all that apply):
- Oropharyngeal flora/Normal flora/Usual flora/Mixed commensural flora
- Pseudomonas aeruginosa

5d1. Specify:
Microbiology Form (MRB) – last updated 5/14/19

- Mucoid
- Nonmucoid
- Both
- Unknown
- Haemophilus influenzae
- Streptococcus pneumoniae
- Staphylococcus aureus

5d2. Specify:
- Methicillin Sensitive
- Methicillin Resistant
- Unknown
- Stenotrophomonas maltophilia
- Klebsiella pneumoniae
- Moraxella catarrhalis
- Nocardia
- Other bacteria
- Unknown

6. In the Investigator’s opinion, has the patient been chronically infected with bacteria?
- Yes
- No – Go to next available culture (if applicable) or Question 17
- Unknown – Go to next available culture (if applicable) or Question 17

6a. Which bacteria has the patient been chronically infected with (select all that apply)?
- Oropharyngeal flora/Normal flora/Usual flora/Mixed commensural flora
- Pseudomonas aeruginosa
- Haemophilus influenzae
- Streptococcus pneumoniae
- Staphylococcus aureus
- Stenotrophomonas maltophilia
- Klebsiella pneumoniae
- Moraxella catarrhalis
- Nocardia
- Other bacteria
II. MYCOBACTERIAL CULTURE

7. How many respiratory mycobacterial culture (from this visit window*) results are available?
   - 0 - Go to next available culture (if applicable) or Question 17
   - 1 - Complete 8 and go to 11
   - 2 - Complete 8-9 and go to 11
   - 3 - Complete 8-10 and go to 11

8. Mycobacterial Culture Result #1

8a. Mycobacterial culture date (mm/dd/yyyy): ______________________
   Please include up to 3 most recent NTM culture(s) first (in order by those closest to the anniversary of consent first), and then up to 3 NTM culture(s) from each of the NTM lung disease episodes.

8b. Culture Type:
   - Sputum
   - BAL/bronch wash
   - (T)BBX Biopsy
   - Other
   - Unknown

8c. AFB smear positive:
   - Yes
   - No
   - Unknown

8d. Growth:
   - Yes
   - No - Go to next available culture (if applicable) or Question 17
   - Unknown - Go to next available culture (if applicable) or Question 17

8e. Specify growth (select all that apply):
Microbiology Form (MRB) – last updated 5/14/19

- Mycobacterium avium complex
  - **8e1. Specify:**
    - M. avium
    - M. intracellulare
    - M. chimera
    - M. avium complex
    - Other

- **8e1a. Is macrolide resistance present?**
  - Yes
  - No
  - Unknown

- Mycobacterium abscessus complex (including subspecies)
  - **8e2. Presence of:**
    - M. Abscessus subspecies abscessus
    - M. Abscessus subspecies bolletii
    - M. Abscessus subspecies massiliense
    - M. Abscessus complex (not sub-speciated)
    - M. Abscessus
    - M. Abscessus chelonae

- **8e2a. Is the erm gene status known (molecular analysis and/or 14-day incubation with clarithromycin for inducible resistance)?**
  - Yes
  - No – Go to next available culture (if applicable) or Question 17
  - Unknown – Go to next available culture (if applicable) or Question 17

- **8e2a1. Status known by molecular analysis?**
  - Yes
  - No – Go to 8e2a2
  - Unknown – Go to 8e2a2

- **8e2a1a. Was abnormal mutational erm gene status detected (inducible resistance)?**
  - Yes
  - No
  - Unknown
8e2a2. Status known by 14-day incubation with clarithromycin?
   o Yes
   o No
   o Unknown

8e2a2a. Resistance present?
   o Yes
   o No
   o Unknown

   o Other mycobacteria

9. Mycobacterial Culture Result #2

9a. Mycobacterial culture date (mm/dd/yyyy): ____________________

Please include up to 3 most recent NTM culture(s) first (in order by those closest to the anniversary of consent first), and then up to 3 NTM culture(s) from each of the NTM lung disease episodes.

9b. Culture Type:
   o Sputum
   o BAL/bronch wash
   o (T)BBX Biopsy
   o Other
   o Unknown

9c. AFB smear positive:
   o Yes
   o No
   o Unknown

9d. Growth:
   o Yes
   o No - Go to next available culture (if applicable) or Question 17
   o Unknown - Go to next available culture (if applicable) or Question 17

9e. Specify growth (select all that apply):
o Mycobacterium avium complex
  9e1. Specify:
    o M. avium
    o M. intracellulare
    o M. chimera
    o M. avium complex
    o Other
  9e1a. Is macrolide resistance present?
    o Yes
    o No
    o Unknown

o Mycobacterium abscessus complex (including subspecies)?
  9e2. Presence of:
    o M. Abscessus subspecies abscessus
    o M. Abscessus subspecies bolletii
    o M. Abscessus subspecies massiliense
    o M. Abscessus complex (not sub-speciated)
    o M. Abscessus
    o M. Abscessus chelonae
  9e2a. Is the erm gene status known (molecular analysis and/or 14-day incubation with clarithromycin for inducible resistance)?
    o Yes
    o No - Go to next available culture (if applicable) or Question 17
    o Unknown – Go to next available culture (if applicable) or Question 17
  9e2a1. Status known by molecular analysis?
    o Yes
    o No – Go to 9e2a2
    o Unknown
  9e2a1a. Was abnormal mutational erm gene status detected (inducible resistance)?
    o Yes
    o No
    o Unknown
9e2a2. Status known by 14-day incubation with clarithromycin?
   o Yes
   o No
   o Unknown

9e2a2a. Resistance present?
   o Yes
   o No
   o Unknown

   o Other mycobacteria

10. Mycobacterial Culture Result #3

10a. Mycobacterial culture date (mm/dd/yyyy): ___________________

*Please include up to 3 most recent NTM culture(s) first (in order by those closest to the anniversary of consent first), and then up to 3 NTM culture(s) from each of the NTM lung disease episodes.*

10b. Culture Type:
   o Sputum
   o BAL/bronch wash
   o (T)BBX Biopsy
   o Other
   o Unknown

10c. AFB smear positive:
   o Yes
   o No
   o Unknown

10d. Growth:
   o Yes
   o No - Go to next available culture (if applicable) or Question 17
   o Unknown - Go to next available culture (if applicable) or Question 17

10e. Specify growth (select all that apply):
Microbiology Form (MRB) – last updated 5/14/19

- Mycobacterium avium complex
  10e1. Specify:
  - M. avium
  - M. intracellulare
  - M. chimera
  - M. avium complex
  - Other
  10e1a. Is macrolide resistance pattern present?
    - Yes
    - No
    - Unknown

- Mycobacterium abscessus complex (including subspecies)
  10e2. Presence of:
    - M. Abscessus subspecies abscessus
    - M. Abscessus subspecies bolletii
    - M. Abscessus subspecies massiliense
    - M. Abscessus complex (not sub-speciated)
    - M. Abscessus chelonae
  10e2a. Is the erm gene status known (molecular analysis and/or 14-day incubation with clarithromycin for inducible resistance)?
    - Yes
    - No – Go to next available culture (if applicable) or Question 17
    - Unknown – Go to next available culture (if applicable) or Question 17
  10e2a1. Status known by molecular analysis?
    - Yes
    - No – Go to 10e2a2
    - Unknown
  10e2a1a. Was abnormal mutational erm gene status detected (inducible resistance)?
    - Yes
    - No
    - Unknown
10e2a2. Status known by 14-day incubation with clarithromycin?
  o Yes
  o No
  o Unknown

10e2a2a. Resistance present?
  o Yes
  o No
  o Unknown
  o Other mycobacteria

11. In the Investigator's opinion, were ATS/IDSA NTM microbiologic criteria met? Note: 2007 ATS/IDSA microbiologic criteria for NTM lung disease is considered meeting at least one of the following within the past 12 months:
  a) Positive culture results from at least two separate expectorated sputum samples or
  b) positive culture results from at least one bronchial wash or lavage or
  c) transbronchial or other lung biopsy with mycobacterial histopathologic features (granulomatous inflammation or AFB) and positive culture for NTM or biopsy showing mycobacterial histopathologic features (granulomatous inflammation or AFB) and one or more sputum or bronchial washings that are culture positive for NTM.
  o Yes
  o No – Go to next available culture (if applicable) or Question 17
  o Unknown – Go to next available culture (if applicable) or Question 17

11a. Specify which mycobacteria (select all that apply):
  o Mycobacterium avium complex
  o Mycobacterium abscessus complex

11a1. Specify:
  o M. Abscessus
  o M. Abscessus cheloneae
  o M. Abscessus complex
  o M. Abscessus subspecies abscessus
  o M. Abscessus subspecies bolletii
III. FUNGAL CULTURE
12. How many respiratory fungal culture results (from this visit window*) are available?
   o 0 – Go to 17
   o 1 - Complete 13 and go to 16
   o 2 - Complete 13-14 and go to 16
   o 3- Complete 13-15 and go to 16

13. Fungal Culture Result #1

13a. Fungal Culture date (mm/dd/yyyy): ______________________
   *If more than one culture is available, list in order by those closest to the anniversary of consent first:

13b. Culture Type:
   o Sputum
   o BAL/bronch wash
   o (T)BBX Biopsy
   o Other
   o Unknown

13c. Growth:
   o Yes
   o No - Go to next available culture (if applicable) or Question 16
   o Unknown - Go to next available culture (if applicable) or Question 16

13d. Specify growth (select all that apply):
   o Aspergillus
13d1. Specify:
   o Fumigatus
   o Niger
   o Flavus
   o Versicolor
   o Other
   o Unknown
   o Scedosporum apiospermum/Pseudallesheria boydii
   o Unknown
   o Other fungi (i.e. crypto, cocci, histo., other)

14. Fungal Culture Result #2

14a. Fungal Culture date (mm/dd/yyyy): ______________________

*If more than one culture is available, list in order by those closest to the anniversary of consent first:*

14b. Culture Type:
   o Sputum
   o BAL
   o (T)BBX Biopsy/bronch wash
   o Other
   o Unknown

14c. Growth:
   o Yes
   o No – Go to next available culture (if applicable) or Question 16
   o Unknown – Go to next available culture (if applicable) or Question 16

14d. Specify growth (select all that apply):
   o Aspergillus
     14d1. Specify:
        o Fumigatus
        o Niger
        o Flavus
        o Versicolor
        o Other
15. Fungal Culture Result #3

15a. Fungal culture date (mm/dd/yyyy): ______________________

*If more than one culture is available, list in order by those closest to the anniversary of consent first:*

15b. Culture Type:
- Sputum
- BAL/bronch wash
- (T)BBX Biopsy
- Other
- Unknown

15c. Growth:
- Yes
- No - Go to next available culture (if applicable) or Question 16
- Unknown - Go to next available culture (if applicable) or Question 16

15d. Specify growth (select all that apply):
- Aspergillus
  15d1. Specify:
  - Fumigatus
  - Niger
  - Flavus
  - Versicolor
  - Other
  - Unknown
- Scedosporum apiospermum/Pseudallesheria boydii
- Unknown
- Other fungi (i.e. crypto, cocci, histo., other)

16. In the Investigator's opinion, has the patient been chronically
infected with fungi?
  o Yes
  o No – Go to 17
  o Unknown – Go to 17

16a. Which fungi has the patient been chronically infected with (select all that apply)?
  o Aspergillus
  o Scedosporum apiospermum/Pseudallesheria boydii
  o Unknown
  o Other fungi (i.e. crypto, cocci, histo.)

IV. MOLECULAR ANALYSIS/MICROBIOME/PCR ANALYSIS

17. Has the patient had a molecular analysis/microbiome/PCR analysis on respiratory secretions during this visit window*?
  o Yes
  o No – Go to 18
  o Unknown – Go to 18

17a. Please specify which sample this was performed on:
  o Oral swab
  o Sputum
  o BAL
  o nasal secretions
  o Other
  o Unknown

V. ADMINISTRATIVE INFORMATION

18. Visit date (mm/dd/yyyy):

19. Source of data:
  o Participant interview
  o Medical records review/abstraction
20. Form completion date (mm/dd/yyyy):

21. Interviewer’s / recorder’s initials:
Therapies and Treatment Form (TTF)
Version A, July 2017

Subject ID Number: ________________

Visit Number: ____

Instructions: This form is to be completed for each patient (after initial informed consent is received) at baseline for data within the past 2 years, and at each annual follow-up visit (as necessary) using data made available during the visit window*. Information is obtained through patient interview, or from patient chart or electronic medical record. *Visit windows for each patient/visit can be found on the patient’s summary page on the DatStat portal. Please note that they differ for every patient and visit.

1. Is the patient currently taking, or has the patient taken any antibiotics for lower respiratory tract indications (not related to the treatment of NTM) during this visit window*?
   o Yes
   o No – Go to 7
   o Unknown – Go to 7

2. During this visit window*, patient received antibiotics for (select all that apply):
   o Acute exacerbation of bronchiectasis (as defined by the Investigator) – Complete 2a and 3

2a. Did this exacerbation meet the criteria listed below?
A deterioration in three or more of the following key symptoms for at least 48 hours:
• Cough
• Sputum volume and / or consistency
• Sputum purulence
• Breathlessness and / or exercise tolerance
• Fatigue and / or malaise
• Hemoptysis

AND

A clinician determined that a change in bronchiectasis treatment was required (includes, but not limited to a course of antibiotics).
  o Yes
  o No
  o Unknown

  o Chronic suppression (antimicrobial purposes) – Complete 5
  o Immunomodulation (anti-inflammatory purposes including macrolides) – Complete 6
  o Unknown – Go to 7

3. Number of exacerbations of bronchiectasis treated with antibiotics during this visit window*:
   o 1
   o 2
   o 3
   o 4
   o 5
   o More than 5
   o Unknown

4. Route of administration of antibiotics for acute exacerbation (of bronchiectasis) during this visit window* (select all that apply):
   o Oral

   4a. Specify number of exacerbations of bronchiectasis specifically treated with course(s) of oral antibiotics during this visit window*:
      o 1
      o 2
      o 3
      o 4
      o 5
      o More than 5
4b. Specify number of exacerbations of bronchiectasis specifically treated with course(s) of IV antibiotics during this visit window*:
   - 1
   - 2
   - 3
   - 4
   - 5
   - More than 5
   - Unknown – Go to next antibiotic route of administration

4c. Specify number of exacerbations of bronchiectasis specifically treated with course(s) of inhaled antibiotics during this visit window*:
   - 1
   - 2
   - 3
   - 4
   - 5
   - More than 5
   - Unknown – Go to next antibiotic route of administration

5. Route of administration of antibiotics for chronic suppression (for antimicrobial purposes) during this visit window* (select all that apply):
   - Oral antibiotics
   - Inhaled antibiotics (reminder: other than as part of NTM regimen) – Go to 5b
   - Unknown – Go to 6
5a. Specify oral antibiotic for chronic suppression (other than as part of NTM regimen) during this visit window* (select all that apply):
   - Continuous (no periods off oral antibiotics)
   - Cyclic (periods of time off alternating with periods on oral antibiotics)
   - Unknown

5a1. Specify name(s) of oral antibiotics for chronic suppression (other than as part of NTM regimen) during this visit window* (select all that apply):
   - Amoxicillin
   - Amoxicillin/clavulanic acid
   - Azithromycin
   - Cephalosporin
   - Ciprofloxacin
   - Clarithromycin
   - Doxycycline/Tetracycline/Minocycline
   - Levofloxacin
   - Moxifloxacin
   - Trimethoprim sulfa
   - Unknown
   - Other; 5a2. Specify name: ____________________  o Unknown

5b. Specify inhaled antibiotics for chronic suppression (other than as part of NTM regimen) during this visit window* (select all that apply):
   - Continuous (no periods off inhaled antibiotics)
   - Cyclic (periods of time off alternating with periods on inhaled antibiotics)
   - Unknown

5b1. Specify name(s) of inhaled antibiotics for chronic suppression during this visit window* (select all that apply):
   - Amikacin
   - Aztreonam
   - Colistin
   - Gentamicin
   - Tobramycin
6. Route of administration of antibiotics for anti-inflammatory purposes (immunomodulation) during this visit window* (select all that apply):
   - Oral antibiotics (including macrolides)
   - Inhaled antibiotics
   - Unknown – Go to 7

6a. Specify name of antibiotic used for anti-inflammatory purposes (immunomodulation) (other than as part of NTM regimen) during this visit window* (select all that apply):
   - Azithromycin
   - Clarithromycin
   - Erythromycin
   - Unknown
   - Other; 6a1. Specify name: ________________________  o Unknown

7. Has the patient taken any non-antibiotic, non-steroid anti-inflammatory therapy (e.g.: neutrophil elastase inhibitor) during this visit window*?
   - Yes
   - No
   - Unknown

8. Is the patient currently taking, or has the patient recently taken (during this visit window*) any antibiotics, for the treatment of NTM disease?
   - Yes
   - No - Go to 13
   - Unknown - Go to 13

9. What type of mycobacterium is/was being treated during this visit window* (select all that apply)?
   - Mycobacterium avium complex
   - 9a. Please specify:
9a. Please specify:
- M. avium
- M. intracellulare
- M. chimera
- M. avium complex
- Other
- Unknown
- Mycobacterium abscessus complex

9b. Please specify:
- M. Abscessus
- M. Abscessus chelonae
- M. Abscessus complex
- M. Abscessus subspecies abscessus
- M. Abscessus subspecies bolletii
- M. Abscessus subspecies massiliense
- Other
- Unknown

9c. Specify: ____________________________  o Unknown
- Unknown

10. Specify NTM antibiotic type taken during this visit window* (select all that apply):
- Oral antibiotic

10a. Specify name(s) of oral antibiotic(s) taken during this visit window* (select all that apply):
- Azithromycin
  10a1. Date prescribed (mm/dd/yyyy):
  10a2. Still taking?
    - Yes
    - No – 10a2a. Specify date discontinued (mm/dd/yyyy):
      - Unknown
- Clarithromycin
  10a3. Date prescribed (mm/dd/yyyy):
  10a4. Still taking?
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- Yes
- No – 10a4a. Specify date discontinued (mm/dd/yyyy):
  - Unknown

- Rifabutin
  10a5. Date prescribed (mm/dd/yyyy):
  10a6. Still taking?
  - Yes
  - No – 10a6a. Specify date discontinued (mm/dd/yyyy):
    - Unknown

- Rifampin
  10a7. Date prescribed (mm/dd/yyyy):
  10a8. Still taking?
  - Yes
  - No – 10a8a. Specify date discontinued (mm/dd/yyyy):
    - Unknown

- Ethambutol
  10a9. Date prescribed (mm/dd/yyyy):
  10a10. Still taking?
  - Yes
  - No – 10a10a. Specify date discontinued (mm/dd/yyyy):
    - Unknown

- Ciprofloxacin
  10a11. Date prescribed (mm/dd/yyyy):
  10a12. Still taking?
  - Yes
  - No – 10a12a. Specify date discontinued (mm/dd/yyyy):
    - Unknown

- Levofloxacin
  10a13. Date prescribed (mm/dd/yyyy):
  10a14. Still taking?
  - Yes
  - No – 10a14a. Specify date discontinued
(mm/dd/yyyy):
  o Unknown

- Moxifloxacin
  10a15. Date prescribed (mm/dd/yyyy):
  10a16. Still taking?
    o Yes
    o No – 10a16a. Specify date discontinued (mm/dd/yyyy):
      o Unknown

- Doxycycline
  10a17. Date prescribed (mm/dd/yyyy):
  10a18. Still taking?
    o Yes
    o No – 10a18a. Specify date discontinued (mm/dd/yyyy):
      o Unknown

- Minocycline
  10a19. Date prescribed (mm/dd/yyyy):
  10a20. Still taking?
    o Yes
    o No – 10a20a. Specify date discontinued (mm/dd/yyyy):
      o Unknown

- Linezolid
  10a21. Date prescribed (mm/dd/yyyy):
  10a22. Still taking?
    o Yes
    o No – 10a22a. Specify date discontinued (mm/dd/yyyy):
      o Unknown

- Tidezolid
  10a23. Date prescribed (mm/dd/yyyy):
  10a23. Still taking?
    o Yes
    o No – 10a23a. Specify date discontinued (mm/dd/yyyy):
      o Unknown
o Clofazimine

10a24. Date prescribed (mm/dd/yyyy):
10a25. Still taking?
  o Yes
  o No – 10a25a. Specify date discontinued (mm/dd/yyyy):
    o Unknown

o Bedaquiline

10a26. Date prescribed (mm/dd/yyyy):
10a27. Still taking?
  o Yes
  o No – 10a27a. Specify date discontinued (mm/dd/yyyy):
    o Unknown

o Other oral antibiotic name

10a28. Specify other oral antibiotic name: __________________
  o Unknown

10a29. Date prescribed (mm/dd/yyyy):
10a30. Still taking?
  o Yes
  o No – 10a30a. Specify date discontinued (mm/dd/yyyy):
    o Unknown
  o Unknown oral antibiotic name – Go to next antibiotic type

o Inhaled medication/antibiotic

10b. Specify inhaled medication/antibiotic name(s) taken during this visit window* (select all that apply):
  o Amikacin (off the shelf)
    10b1. Date prescribed (mm/dd/yyyy):
    10b2. Still taking?
      o Yes
      o No – 10b2a. Specify date discontinued (mm/dd/yyyy):
        o Unknown
  o Amikacin Liposomal (ALIS aka Arikayce)
    10b3. Date prescribed (mm/dd/yyyy):
    10b4. Still taking?
o Yes
o No – 10b4a. Specify date discontinued (mm/dd/yyyy):
   o Unknown
o Other inhaled medication/antibiotic name
10b5. Specify other inhaled antibiotic name:

10b6. Date prescribed (mm/dd/yyyy):
10b7. Still taking?
o Yes
o No – 10b7a. Specify date discontinued (mm/dd/yyyy):
   o Unknown
   o Unknown inhaled antibiotic name – Go to next antibiotic type
o IV antibiotic
10c. Specify name(s) of IV antibiotics used during this visit window* (select all that apply):
o Amikacin
   10c1. Date prescribed (mm/dd/yyyy):
   10c2. Still taking?
o Yes
o No – 10c2a. Specify date discontinued (mm/dd/yyyy):
   o Unknown
o Cefoxitin
   10c3. Date prescribed (mm/dd/yyyy):
   10c4. Still taking?
o Yes
o No – 10c4a. Specify date discontinued (mm/dd/yyyy):
   o Unknown
o Imipenem
   10c5. Date prescribed (mm/dd/yyyy):
   10c6. Still taking?
o Yes
o No – 10c6a. Specify date discontinued (mm/dd/yyyy):
Meropenem

10c7. Date prescribed (mm/dd/yyyy):
10c8. Still taking?
   - Yes
   - No – 10c8a. Specify date discontinued (mm/dd/yyyy):
     - Unknown

Moxifloxacin

10c9. Date prescribed (mm/dd/yyyy):
10c10. Still taking?
   - Yes
   - No – 10c10a. Specify date discontinued (mm/dd/yyyy):
     - Unknown

Tigecycline

10c11. Date prescribed (mm/dd/yyyy):
10c12. Still taking?
   - Yes
   - No – 10c12a. Specify date discontinued (mm/dd/yyyy):
     - Unknown

Tobramycin

10c13. Date prescribed (mm/dd/yyyy):
10c14. Still taking?
   - Yes
   - No – 10c14a. Specify date discontinued (mm/dd/yyyy):
     - Unknown

Streptomycin

10c15. Date prescribed (mm/dd/yyyy):
10c16. Still taking?
   - Yes
   - No – 10c16a. Specify date discontinued (mm/dd/yyyy):
     - Unknown

Other IV antibiotic name
10c17. Specify other inhaled antibiotic name:

______________

10c18. Date prescribed (mm/dd/yyyy):

10c19. Still taking?
   o Yes
   o No – 10c19a. Specify date discontinued (mm/dd/yyyy):
     o Unknown
     o Unknown IV antibiotic name
     o Unknown antibiotic type – Go to 11

11. In the Investigator’s opinion were any of the antibiotic treatments from this visit window* part of the ATS/IDSA recommended NTM treatment?
   o Yes
   o No – Go to 12
   o Unknown – Go to 12

11a. Has the participant completed treatment for NTM during this visit window*?
   o Yes
   o No
   o Unknown

11b. Was the participant considered cured (remained culture negative for at least 12 months after treatment for NTM) during this visit window*?
   o Yes
   o No
   o Unknown

11c. Was the patient considered a treatment failure (remained culture positive for greater than or equal to 6 months during treatment) during this visit window*?
   o Yes
   o No
   o Unknown
12. Did the patient experience a recurrence of NTM disease (recovery of culture confirmed disease at least 6 months after being cured) during this visit window*?
   - Yes
   - No
   - Unknown

13. Is the patient currently taking, or has the patient recently taken, any antibiotics for the treatment of pulmonary fungal infection during this visit window*?
   - Yes
   - No – Go to 14
   - Unknown – Go to 14

13a. Please specify fungus being treated during this visit window*:
   - Aspergillus
   - Scedosporum apiospermum/Pseudallesheria boydii
   - Unknown
   - Other (crypto, cocci, histo.) fungi

13b. Specify anti-fungal being used for treatment during this visit window*:
   - Itraconazole
   - Voriconazole
   - Posaconazole
   - Caspofungin
   - Anidulafungin
   - Amphotericin
   - Other
   - Unknown

14. Has the patient used an inhaled bronchodilator during this visit window*?
   - Yes
   - No – Go to 15
   - Unknown – Go to 15
14a. Specify reason for inhaled bronchodilator use during this visit window* (select all that apply):
   - Bronchiectasis
   - NTM
   - Other (e.g. asthma, COPD, etc.)
   - Unknown

14b. Is the patient still/currently on an inhaled bronchodilator?
   - Yes
   - No
   - Unknown

14c. Identify which inhaled bronchodilator(s) is/was being used during this visit window* (select all that apply):
   - Albuterol/Proventil/Ventolin/ProAIR
   - Albuterol-Ipratropium/Duoneb/Combivent
   - AclidiniumArcapta
   - Ipratropium/Atrovent
   - Brovana/Arformoterol
   - Formoterol/Foradil/Perforomist
   - Indacaterol
   - Levalbuterol/Xopenex
   - Pirbuterol/Maxair
   - Olodaterol
   - Salmeterol/Serevent/Serevent Diskus
   - Striverdi
   - Tiotropium/Spiriva
   - TudorzaUnknown
   - Other
     14c1. Specify other inhaled bronchodilator: ____________________________
     - Unknown

15. Has the patient received inhaled or oral steroids during this visit window*?
   - Yes
Therapies and Treatment Form (TTF) – last updated 7/26/19

15a. Specify route of steroid administration during this visit window* (select all that apply):
   - Oral – Complete 15b – 15d
   - Inhaled (including inhaled steroid alone or inhaled steroid plus bronchodilator) – Complete 15e
   - Unknown – Go to 16

15b. Specify oral steroid taken during this visit window* (select all that apply):
   - Continuous
   - Intermittent
   - Unknown

15c. Specify reason for oral steroid use during this visit window* (select all that apply):
   - Pulmonary disease
   - Non-pulmonary disease
   - Unknown

15d. Is the patient still/currently on oral steroids?
   - Yes
   - No
   - Unknown

15e. During this visit window*, has the patient been (or continues to be) on inhaled corticosteroid alone or combination therapy?
   - Inhaled steroid
   - Combination steroid/bronchodilator
   - Unknown

16. Has the patient taken medication for gastric acid suppression during this visit window*?
   - Yes
   - No – Go to 17
16a. Specify medication for gastric acid suppression taken during this visit window* (select all that apply):
   o H2 Blocker
   o PPI
   o Antacid
   o Other
   o Unknown

16b. Is the patient still/currently on gastric acid suppression medication?
   o Yes
   o No
   o Unknown

17. Has the patient taken a mucous-active agent during this visit window*?
   o Yes
   o No – Go to 18
   o Unknown – Go to 18

17a. Specify mucous-active agent taken during this visit window* (select all that apply):
   o Hypertonic saline
   o Guaifenesin
   o Acetylcysteine
   o Dornase alpha
   o Mannitol
   o Other
   o Unknown

   17a1. Is the patient still/currently on a mucous active agent?
       o Yes
       o No – Go to 18
       o Unknown – Go to 18

   17a2. Specify which mucous active agent(s) the patient is still/currently on (select all that apply):
18. Has the patient used any measures to improve bronchial hygiene during this visit window*?
   - Yes
   - No – Go to 19
   - Unknown – Go to 19

18a. Specify which measures have been used to improve bronchial hygiene during this visit window* (select all that apply):

   - Positive Expiratory Pressure valve

   18a1. Specify (select all that apply):
      - Acapella valve
      - Aerobika valve
      - Flute valve
      - Flutter valve
      - Other
      - Unknown

   18a2. Is the patient still/currently using this measure?
      - Yes
      - No – Go to next bronchial hygiene measure used
      - Unknown – Go to next bronchial hygiene measure used

   18a3. Which valve(s) the patient still/currently using (select all that apply):
      - Acapella valve
      - Aerobika valve
      - Flute valve
      - Flutter valve
      - Other
      - Unknown

   - Chest percussion / postural drainage
18a4. Is the patient still/currently using this measure?
- Yes
- No – Go to next bronchial hygiene measure used
- Unknown – Go to next bronchial hygiene measure used
- Directed cough/active cycle of breathing

18a5. Is the patient still/currently using this measure?
- Yes
- No – Go to next bronchial hygiene measure used
- Unknown – Go to next bronchial hygiene measure used

18a6. Specify (select all that apply):
- AffloVest® (International Biophysics Corporation)
- InCourage® (RespirTech)
- SmartVest® (Electromed)
- The Vest® (Hill-Rom)
- Other
- Unknown

18a6a. Is the patient still/currently using this measure?
- Yes
- No – Go to next bronchial hygiene measure used
- Unknown – Go to next bronchial hygiene measure used

18a7. Is the patient still/currently using this measure?
- Yes
- No
- Unknown
- Unknown measure

19. Has the patient used oxygen supplementation during this visit window*?
- Yes
- No – Go to 20
- Unknown – Go to 20

19a. Specify oxygen supplementation used during this visit window* (select all that apply):
- Continuous
19b. Is the patient still/currently on oxygen supplementation?
   - Yes
   - No
   - Unknown

20. Has the patient participated in an outpatient pulmonary rehabilitation and/or maintenance rehab during this visit window*?
   - Yes
   - No – Go to 21
   - Unknown – Go to 21

20a. Is the patient still/currently participating in an outpatient pulmonary rehabilitation and/or maintenance rehabilitation?
   - Yes
   - No
   - Unknown

21. Visit date (mm/dd/yyyy):

22. Source of data:
   - Participant interview
   - Medical records review/abstraction

23. Form completion date (mm/dd/yyyy):

24. Interviewer’s / recorder’s initials:
Annual Follow-up Form (FUP)
Version B, July 2017

Subject ID Number: __________________

Visit Number: ____

Instructions: This form is to be completed annually corresponding to each Registry participants’ enrollment anniversary using data made available during this visit window as defined by DatStat (unless specified otherwise). Information is obtained through patient interview, or from patient chart or electronic medical record. *Visit windows for each patient/visit can be found on the patient’s summary page on the DatStat portal. Please note that they differ for every patient and visit.

I. FOLLOW-UP

1. Is clinical follow-up data available for this patient?
   o Yes
   o No - Go to 18

II. ANTHROPOMETRY

2. Has the patient had physical measurements (height and/or weight) during this visit window* (select all that apply)?
   o Height – Go to 2a
   o Weight – Go to 2c
   o Neither – Go to 3
   o Unknown – Go to 3

2a. Date of the patient’s height measurement (mm/dd/yyyy). If more than one measurement is available, use the one closest to the anniversary of consent:

2b. Patient’s height: _____
2b1. Specify unit:
   o Inches
   o Centimeters
   o Unknown

2c. Date of the patient’s weight measurement (mm/dd/yyyy). *If more than one measurement is available, use the one closest to the anniversary of consent:*

2d. Patient’s weight: _____
2d1. Specify unit:
   o lbs
   o kg
   o Unknown

III. PULMONARY FUNCTION

3. Has the patient had a spirometry during this visit window*?
   o Yes
   o No - Go to 4
   o Unknown - Go to 4

3a. Was spirometry during exacerbation, stable conditions, or unknown (if more than one spirometry is available, use spirometry data from stable conditions)?
   o During exacerbation
   o During stable conditions
   o Unknown

3b. Spirometry date (mm/dd/yyyy). *If more than one spirometry is available, use the one closest to the anniversary of consent:*

3c. Pre-Bronchodilator?
   o Yes
   o No – go to 3d
   o Unknown – Go to 3d
3c1. FVC (liters): ___________  o Unknown
3c2. FVC (% predicted): ___________  o Unknown

3c3. FEV1 (liters): ___________  o Unknown
3c4. FEV1 (% predicted): ___________  o Unknown

3d. Post-Bronchodilator?
  o Yes
  o No
  o Unknown

3d1. FVC (liters): ___________  o Unknown
3d2. FVC (% predicted): ___________  o Unknown

3d3. FEV1 (liters): ___________  o Unknown
3d4. FEV1 (% predicted): ___________  o Unknown

4. Has the patient had an oxygen saturation measurement during this visit window*?
  o Yes
  o No – Go to 5
  o Unknown – Go to 5

4a. Was the oxygen saturation measurement taken at rest or exercise (select all that apply)?
  o Rest
    4a1. What was the oxygen saturation level? _____ %
    4a2. Was the patient on room air or supplemental oxygen at the time of the measurement?
      o Room air
      o Supplemental oxygen
        4a2a. Amount of supplemental oxygen?
          o 1 liter per minute (lpm)
          o 2 liters per minute (lpm)
          o 3 liters per minute (lpm)
          o 4 liters per minute (lpm)
          o 5 liters per minute (lpm)
4a3. What was the oxygen saturation level? _____ %

4a4. Was the patient on room air or supplemental oxygen at the time of the measurement?
   - Room air
   - Supplemental oxygen
     - Amount of supplemental oxygen?
       - 1 liter per minute (lpm)
       - 2 liters per minute (lpm)
       - 3 liters per minute (lpm)
       - 4 liters per minute (lpm)
       - 5 liters per minute (lpm)
       - Greater than 5 liters per minute (lpm)
       - Unknown

5. Has patient completed a Six Minute Walk test during this visit window*?
   - Yes
   - No – Go to 6
   - Unknown – Go to 6

5a. Specify distance walked: _____
      o Unknown

5a1. Specify unit:
   - Feet
   - Meters
   - Unknown

IV. MEDICAL HISTORY

6. Has the patient been newly diagnosed with Bronchiectasis during this visit window*?
   - Yes
6a. At what age was the diagnosis of bronchiectasis made?

______ years  o Unknown

6b. Please select any co-existing conditions/diseases that this patient has ever been diagnosed with (regardless of if previously reported):

- Asthma
- COPD
- Alpha-1 antitrypsin deficiency (Alpha-1) – Complete 6c
- Primary immunodeficiency (e.g. hypogammaglobulinemia) – Complete 6d
- Kartagener’s syndrome or Primary Ciliary Dyskinesia (PCD) – Complete 6e
- Cystic Fibrosis – Complete 6f
- Rheumatologic disease (e.g. Rheumatoid Arthritis [RA], Sjogren’s Syndrome) – Complete 6g
- Inflammatory Bowel Disease – Complete 6h
- Allergic Bronchopulmonary Aspergillosis (ABPA) – Complete 6i
- Gastroesophageal Reflux Disease (GERD) – Complete 6j
- Otitis and/or rhinosinusitis – Complete 6k
- Amyloid
- Congenital heart disease
- Foreign body obstruction
- Hematologic malignancy
- HIV
- Measles
- Mounier-Kuhn Syndrome
- Post-infectious – Pneumonia
- Post-infectious – Pertussis
- Post-infectious – Tuberculosis
- Relapsing polychondritis
- Sarcoidosis
- Smoke / toxin inhalation (e.g. environmental pollutants excluding cigarette smoke)
- Systemic lupus erythematosus
<table>
<thead>
<tr>
<th>6c. Are the alpha-1 test results available? Note: If you have already reported Alpha-1 test results during a previous visit, you do not need to report them again (select ‘No’).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No – Go to 6c4</td>
</tr>
<tr>
<td>Unknown – Go to 6c4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6c1. Alpha-1 test date (mm/dd/yyyy):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>6c2. Level: __________ mg/dl</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Unknown</td>
</tr>
<tr>
<td>o Not Applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6c3. Phenotype:</th>
</tr>
</thead>
<tbody>
<tr>
<td>o MM</td>
</tr>
<tr>
<td>o MZ</td>
</tr>
<tr>
<td>o ZZ</td>
</tr>
<tr>
<td>o SZ</td>
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<tr>
<td>o MS</td>
</tr>
<tr>
<td>o SS</td>
</tr>
<tr>
<td>o Null</td>
</tr>
<tr>
<td>o Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6c4. Type of Alpha-1 antitrypsin deficiency (select all that apply)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Lung</td>
</tr>
<tr>
<td>o Liver</td>
</tr>
<tr>
<td>o Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6c5. Has the patient started augmentation therapy related to alpha-1 during this visit window*?</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Yes</td>
</tr>
<tr>
<td>o No</td>
</tr>
<tr>
<td>o Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6d. Which primary immunodeficiency was the patient diagnosed with?</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Common Variable Immunodeficiency (CVID)</td>
</tr>
</tbody>
</table>
6d1. Has the patient had immunoglobulins measured during this visit window*?
   o Yes
   o No - Go to 6e
   o Unknown - Go to 6e

6d1a. Date immunoglobulins measured (mm/dd/yyyy). If more than one measurement is available, use the one closest to the anniversary of consent:

6d1b. IgG: _______ (mg/dL)  o Unknown
6d1c. IgM: _______ (mg/dL)  o Unknown
6d1d. IgA: _______ (mg/dL)  o Unknown
6d1e. IgE: _______  o Unknown

   6d1e1. Specify IgE units:
   o kU/L
   o mg/dL
   o Unknown

6e. Situs status (in relation to PCD/Kartagener’s Syndrome)?
   o Normal – Go to 6e2
   o Abnormal
   o Unknown – Go to 6e2
   o Other – Go to 6e2

6e1. Specify abnormal situs status (select all that apply):
   o Situs inversus totalis
   o Dextrocardia
   o Thoracic situs inversus
   o Abdominal situs inversus
   o Unknown

6e2. Has the patient had nasal nitric oxide measured during this visit
window*?
  o Yes
  o No – Go to 6e3
  o Unknown – Go to 6e3

6e2a. Specify the following:
  o Reduced
  o Normal
  o Unknown

6e3. Has the patient had exhaled nitric oxide measured during this visit window*?
  o Yes
  o No – Go to 6e4
  o Unknown – Go to 6e4

6e3a. Specify the following:
  o Increased
  o Normal
  o Unknown

6e4. Has the patient had a mucosal biopsy (for cilia) during this visit window*?
  o Yes
  o No
  o Unknown

6f. Has the patient been tested for cystic fibrosis? Note: If you have already reported CF testing during a previous visit, you do not need to report it again (select ‘No’).
  o Yes
  o No - Go to 6f2
  o Unknown - Go to 6f2

6f1. Test date (mm/dd/yyyy). If more than one test is available, use the one closest to the anniversary of consent:
6f1a. Sweat Cl: ____________ (mmol/L)  o Unknown
6f1b. Sweat Cl: ____________ (mmol/L)  o Unknown  o Not Applicable

6f1c. Genotype:
   o Yes
   o No - Go to 6f2
   o Unknown - Go to 6f2

6f1d. Genotype test date (mm/dd/yyyy). *If more than one test is available, use the one closest to the anniversary of consent:*

6f1e. Lab:
   o Ambry
   o Genzyme
   o Local
   o Other commercial
   o Unknown

6f1f. Specify Mutation 1: ________________ o Unknown
   o None detected

6f1g. Specify Mutation 2: ________________ o Unknown
   o None detected

6f2. Has the patient had a nasal potential difference measured during this visit window*?
   o Yes
   o No – Go to 6g or next applicable question
   o Unknown – Go to 6g or next applicable question

6f2a. Please specify result:
   o Normal
   o Abnormal
   o Unknown

6g. Which rheumatologic disease was the patient diagnosed with?
   o Rheumatoid arthritis
- Sjogren’s syndrome
- Other
- Unknown

6g1. Has the patient had a rheumatoid factor performed during this visit window*?
  - Yes
  - No – Go to 7
  - Unknown – Go to 7

6g2. Date rheumatoid factor performed (mm/dd/yyyy). *If more than one is available, use the one closest to the anniversary of consent:

6g2a. Rheumatoid factor result:
  - Less than 15
  - Greater than or equal to 15
  - Unknown

6h. Specify which inflammatory bowel disease the patient has been diagnosed with:
  - Ulcerative Colitis
  - Crohn’s Disease
  - Unknown

6i. Are ABPA test results available from this visit window?
  - Yes
  - No – Go to 6j
  - Unknown – Go to 6j

6i1. Date of ABPA (mm/dd/yyyy) test. *If more than one test is available, use the one closest to the anniversary of consent:

6i2. Total IgE: ____________ (IU/ml or kU/L)  
  - Unknown

6i3. White Blood Cell (WBC) count: ____________ (x 10 L)  
  - Unknown

6i4. % eosinophils: ____________ (%)  
  - Unknown
6i5. # eosinophils: __________ (cells)  o Unknown

6j. Has the patient had Gastroesophageal Reflux Disease (GERD) testing during this visit window*?
   o Yes
   o No – Go to 7
   o Unknown – Go to 7

6j1. GERD testing included the following (select all that apply):
   o Esophagram
   o PH monitor – Go to 6j2
   o Endoscopy – Go to 6j3
   o Other – Go to 6j4
   o Unknown – Go to 6j4

6j2. Ambulatory pH monitoring date (mm/dd/yyyy). If more than one test is available, use the one closest to the anniversary of consent:

6j2a. Reflux noted on pH monitoring?
   o Yes
   o No
   o Unknown

6j3. Endoscopy date (mm/dd/yyyy). If more than one is available, use the one closest to the anniversary of consent:

6j4. Was diagnosis made on Empiric treatment trial (PPI or H2 blocker)?
   o Yes
   o No
   o Unknown

6k. Specify otitis and/or rhinosinusitis diagnosis (select all that apply):
   o Otitis
   o Rhinosinusitis
6k1. Specify otitis and/or rhinosinusitis onset:
- adult onset
- childhood onset
- onset unknown

6k1a. Has the patient had sinus or ear surgery (including placement of ear tubes) during this visit window*?
- Yes
- No – Go to 7
- Unknown – Go to 7

6k2. Has the patient had ear-tube placement during this visit window*?
- Yes
- No
- Unknown

7. Has the patient been diagnosed with NTM lung disease as recognized by the ATS/IDSA during this visit window*?
Note: 2007 ATS/IDSA microbiologic criteria for NTM lung disease is considered meeting at least one of the following within the 12 months prior to diagnosis:
- Positive culture results from at least two separate expectorated sputum samples or
- Positive culture results from at least one bronchial wash or lavage or
- Transbronchial or other lung biopsy with mycobacterial histopathologic features (granulomatous inflammation or AFB) and positive culture for NTM or biopsy showing mycobacterial histopathologic features (granulomatous inflammation or AFB) and one or more sputum or bronchial washings that are culture positive for NTM.
- Yes
- No
- Unknown

V. SURGICAL HISTORY
8. Has the patient had a lobectomy/wedge resection and/or pneumonectomy during this visit window*?
8a. What was the lobectomy/wedge resection and/or pneumonectomy for (select all that apply)?
   o Bronchiectasis
   o NTM lung disease
   o Lung cancer
   o Hemoptysis
   o Other
   o Unknown

8b. Specify procedure:
   o Lobectomy/wedge resection
   o Pneumonectomy
   o Unknown

8c. Specify date of procedure (mm/dd/yyyy):

9. Has the patient had a lung transplant during this visit window*?
   o Yes
   o No – Go to 10
   o Unknown – Go to 10

9a. Single or bilateral lung transplant?
   o Single
   o Bilateral
   o Unknown

9b. Date of lung transplant (mm/dd/yyyy):

10. Has the patient had hemoptysis during this visit window*?
   o Yes
   o No – Go to 11
   o Unknown – Go to 11
10a. Was it considered major [greater than 240 MLs/CCs (one cup) over 24 hours] hemoptysis?
   o Yes
   o No
   o Unknown

10b. Did the hemoptysis require bronchial embolization, surgery, or transfusion?
   o Yes
   o No – Go to 11
   o Unknown – Go to 11

10b1. Indicate which (select all that apply):
   o Embolization
   o Surgery
   o Transfusion
   o Unknown

VI. EXACERBATIONS

11. A bronchiectasis exacerbation is defined as:

A deterioration in three or more of the following key symptoms for at least 48 hours:
   • Cough
   • Sputum volume and / or consistency
   • Sputum purulence
   • Breathlessness and / or exercise tolerance
   • Fatigue and / or malaise
   • Hemoptysis

AND

When a clinician determines a change in bronchiectasis treatment is required (includes, but not limited to a course of antibiotics).
Has the patient experienced an exacerbation of bronchiectasis during
this visit window*?
  o Yes
  o No – Go to 12
  o Unknown – Go to 12

11a. How many exacerbations of bronchiectasis has the patient experienced during this visit window*?
  o 1
  o 2
  o 3
  o 4
  o 5
  o More than 5
    11a1. Please specify number of exacerbations experienced during this visit window: ___
    o Unknown

12. How many times has the patient been hospitalized for pulmonary illness or exacerbation during this visit window*?
  o 0 – Go to 13
  o 1
  o 2
  o 3
  o More than 3
    12a. Please specify number of hospitalizations experienced during this visit window: ___
    o Unknown – Go to 13

12a. How many days has the patient spent in the hospital during this visit window*?
  o 1
  o 2
  o 3
  o 4
  o 5
  o More than 5
  o Unknown
VII. MICROBIOLOGY

13. Are there any cultures (bacteria, mycobacteria, and/or fungi) available from this visit window*?
   - Yes – Complete the Microbiology form once this form has been completed
   - No
   - Unknown

VIII. THERAPIES & TREATMENTS

14. Has the patient taken any therapies or treatments for Bronchiectasis and/or NTM, or for an acute exacerbation of Bronchiectasis during this visit window*?
   - Yes – Complete the Therapies and Treatment form once this form has been completed
   - No
   - Unknown

IX. RADIOLOGY

15. Was a new chest x-ray obtained during this visit window*?
   - Yes – Complete Imaging form after this form is complete
   - No – Go to 16
   - Unknown – Go to 16

15a. Compared to prior chest x-ray, most recent chest x-ray was:
   - Same/unchanged
   - Improved
   - Worse
   - Unknown
   - Not applicable

16. Was a chest CT obtained during this visit window*?
   - Yes – Complete Imaging form after this form is complete
   - No – Go to 17
16a. Compared to prior chest CT, most recent chest CT was:
   - Same/Unchanged
   - Improved
   - Worse
   - Unknown
   - Not applicable

17. Has the patient participated in a treatment trial during this visit window*?
   - Yes
   - No – Go to 18
   - Unknown – Go to 18

17a. Specify treatment trial (select all that apply):
   - Bronchiectasis treatment trial
   - NTM treatment trial
   - Other treatment trial – Go to 17a1
   - Unknown

17a1. Specify condition related to other treatment trial:
   - Alpha-1 Antitrypsin Deficiency
   - Asthma
   - Allergic bronchopulmonary aspergillosis (ABPA)
   - COPD
   - Cystic Fibrosis
   - Primary Ciliary Dyskinesia (PCD)
   - Other lung condition
   - Other condition (not lung-related)

17b. What kind of treatment did the patient receive in the trial?
   - Drug
   - Placebo
   - Unknown

X. ADMINISTRATIVE INFORMATION
18. Visit date (mm/dd/yyyy):

19. Source of Data:
   - Participant interview
   - Medical records review/abstraction

20. Form completion date (mm/dd/yyyy):

21. Interviewer’s / recorder’s initials:
Study Termination Form (STF)  
Version A, July 2017

Subject ID Number: ________________

Visit Number: ____

Instructions: This form is completed at any annual follow-up visit when there is a change in participation status.

1. Current participant status?
   - Deceased
   - Lost to Follow-up – Go to 1d

1a. Is Bronchiectasis primary cause of death?
   - Yes
   - No
   - Unknown

1b. Is NTM primary cause of death?
   - Yes
   - No
   - Unknown

1c. Other primary cause of death?
   - Yes
   - No – Go to 1d
   - Unknown – Go to 1d

1c1. Specify other primary cause of death:
   - Heart disease
   - Malignant neoplasms
   - Chronic lower respiratory disease
   - Cerebrovascular disease
   - Alzheimer’s disease
   - Diabetes mellitus
- Influenza, pneumonia
- Accident (unintentional injuries)
- Nephritis, nephrotic syndrome, nephrosis
- Septicemia
- Essential hypertension, hypertensive renal disease
- Parkinson’s disease
- In situ neoplasms, benign neoplasms, neoplasms of uncertain or unknown behavior
- Chronic liver disease, cirrhosis
- Other
- Unknown

1d. Date lost (last date seen) or deceased (mm/dd/yyyy):

2. Interview/medical records date (mm/dd/yyyy):

3. Source of Data:
   - Participant interview
   - Medical records review/abstraction

4. Form Date (mm/dd/yyyy):

5. Interviewer’s / recorder’s initials: