ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
FOLLOW-UP VISIT FORM - PART A

Form Completion Instructions:

This form should be completed at patient's follow-up visit by non-physician personnel. A physician, however, should review the medical history and medications sections of the form.

QUESTION #	ITEM	INSTRUCTIONS
10-18	Symptom History	These questions should be asked of the patient. Be careful to skip questions as indicated. If the patient is in doubt, check the "No" response. Refer to the ATS-DLD reference and/or instructions to Form #02A.
24-36	Medical History	For each general system, the initial questions should be asked first. If the answer is "No", the list of specific diseases should be skipped. If, however, the answer to the general question is "Yes", ask the patient to tell you what problems (s)he has had. Each of the individual diseases listed need not be asked except to help the patient, to prod his/her memory. Put a check in the space next to each of the diagnoses mentioned. If (s)he indicates being diagnosed with the problem, then ask whether (s)he has been hospitalized for it since the last visit. If a hospital chart is available and can be review prior to asking these questions, it should help you in interviewing the patient.
37	Medications	It may help to remind the patient to bring in his/her pills in order to complete this section of the form most accurately. This section refers to prescription drugs only.

ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
FOLLOW-UP VISIT FORM - PART A

Form Completion Instructions:

QUESTION #	ITEM	INSTRUCTIONS
37q	Supplemental Oxygen	These questions have been added and are mandatory
38a	Adverse Reaction	For each therapy given where an adverse reaction occurred, Form #11 should be completed. Refer to Form #10, Problem column to determine whether forms should be completed.
39a	Discontinued	If the patient was never on therapy (thus never stopped), enter "(0)No". If the patient was on therapy and has stopped, enter "(1)Yes". If the patient is presently on therapy enter "(0)No".
40a	Date Therapy Started	This is the date when the therapy regimen actually started.
40b	Most Recent	This is the date when most recent therapy given.

ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
Follow-Up Visit Form - Part A

This form should be completed for every follow-up visit.

1. Date form completed: F5AQØ1_fzd (fuzzed) ___ ___/ ___ ___/ ___ ___ (month / day / year)
2. Patient Registry ID: Newid (scrambled) ___ ___ ___ ___ ___
3. Patient name code: namecode (censored) ___ ___ ___ ___
4. Clinical Center code number: clinic (censored) ___ ___
5. Did you transfer from another Registry Clinical Center: F5AQØ5 ___(1)Yes ___(2)No

   If YES (name of Clinical Center): Never entered
6. Date of visit: F5AQØ6_fzd (fuzzed) ___ ___/ ___ ___/ ___ ___ (month / day / year)

   Visit number vsno
7. What is your marital status: F5AQØ7 ___(1)Never Married ___(4)Separated ___(2)Widowed ___(5)Divorced ___(3)Married ___(9)Unknown

OCCUPATIONAL HISTORY

8. a. What has been your employment status since your last visit? F5AQØ8A

   ___(1)Unemployed (Medical Reasons) ___(5)Retired (Medical)
   ___(2)Unemployed (Other Reasons) ___(6)Retired (Age)
   ___(3)Employed Part-Time ___(7)Full-Time Homemaker
   ___(4)Employed Full-Time ___(8)Other (specify): Never entered
   ___(9)Unknown

9. a. Have you ever worked for three or more months in a job where you were regularly exposed to dust or fumes? F5AQØ9A ___(1)Yes ___(2)No ___(9)Unknown

   b. If YES,

Specify Job	Number of Years Worked at Job	Last Year Employed at This Job
F5AQØ9B1	F5AQØ9B2	F5AQØ9B3
F5AQØ9C1	F5AQØ9C2	F5AQØ9C3
F5AQØ9D1	F5AQØ9D2	F5AQØ9D3

SYMPTOM HISTORY

White/Yellow: Clinical Coordinating Center, Pink: Clinical Center

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Patient Registry ID: ___ ___ ___ ___ ___
Date of Visit: ___ ___/ ___ ___/ ___ ___
month day year

These questions pertain mainly to your chest symptoms. Please answer YES or NO, if possible. If you are in doubt about an answer, check NO.

COUGH

10. a. Do you usually have a cough?.....F5AQ10A.....___(1)Yes ___(2)No

(Count a cough with first smoke or on first going out of doors. Exclude clearing throat.) (If NO, skip to 10c.)

b. Do you usually cough as much as 4 to 6 times a day, 4 or more days out of the week?.....F5AQ10B.....___(1)Yes ___(2)No

c. Do you usually cough at all on getting up, or first thing in the morning? .....F5AQ10C.....___(1)Yes ___(2)No

d. Do you usually cough at all during the rest of the day or night?.....F5AQ10D.....___(1)Yes ___(2)No

If YES to any of the above (10a - d), answer Questions 10e - f.
If NO to all, skip to Question 11a.

e. Do you usually cough like this on most days for 3 consecutive months or more during the year?...F5AQ10E.....___(1)Yes ___(2)No

f. For how many years have you had this cough?..F5AQ10F.....___ ___

PHLEGM

11. a. Do you usually bring up phlegm from your chest?..F5AQ11A.___(1)Yes ___(2)No

(Count phlegm with the first smoke or on first going out-of-doors. Exclude phlegm from the nose. Count swallowed phlegm.)
(If NO, skip to 11c.)

b. Do you usually bring up phlegm like this as much as twice a day, 4 or more days out of the week? .....F5AQ11B.....___(1)Yes ___(2)No

c. Do you usually bring up phlegm at all on getting up, or first thing in the morning? .....F5AQ11C.....___(1)Yes ___(2)No

d. Do you usually bring up phlegm at all during the rest of the day or night? .....F5AQ11D.....___(1)Yes ___(2)No

If YES to any of the above (11a - d), answer Questions 11e - f.
If NO to all, skip to Question 12a.

e. Do you usually bring up phlegm like this on most days for 3 consecutive months or more during the year? ..F5AQ11E___(1)Yes ___(2)No

f. For how many years have you had trouble with phlegm?...F5AQ11F.....___ ___

EPISODES OF COUGH AND PHLEGM

Patient Registry ID: ___ ___ ___ ___ ___
Date of Visit: ___ ___/ ___ ___/ ___ ___
month day year

12. a. Have you had periods or episodes of (increased*) cough and phlegm lasting for 3 weeks or more each year? F5AQ12A ___(1)Yes ___(2)No

*(For persons who usually have cough and/or phlegm)

If NO, skip to Question 13a.

If YES,
b. For how long have you had at least 1 such episode/year (years)? F5AQ12B ___ ___

WHEEZING

13. a. Does your chest ever sound wheezy or whistling:
1. When you have a cold: F5AQ13A1 ___(1)Yes ___(2)No
2. Occasionally apart from colds: F5AQ13A2 ___(1)Yes ___(2)No
3. Most days or night: F5AQ13A3 ___(1)Yes ___(2)No

If NO to all of the above, skip to Question 14a.
If YES to any of above in 13a,

b. How many years has this been present? F5AQ13B ___ ___

14. a. Have you ever had an attack of wheezing that has made you feel short of breath? F5AQ14A ___(1)Yes ___(2)No

If NO, skip to Question 15.
If YES,

b. How old were you when you had your first such attack? F5AQ14B ___ ___

c. Have you had 2 or more such episodes? F5AQ14C ___(1)Yes ___(2)No

d. Have you ever required medicine or treatment for the(se) attack(s)? F5AQ14D ___(1)Yes ___(2)No

BREATHLESSNESS

15. Are you disabled from walking by any condition other than heart or lung disease? F5AQ15 ___(1)Yes ___(2)No

If YES, specify condition(s): F5AQ15O

16. a. Are you troubled by shortness of breath when hurrying on the level or walking up a slight hill? F5AQ16A ___(1)Yes ___(2)No

If NO, skip to Question 17a.
If YES,

b. Do you have to walk slower than people of your age on the level because of breathlessness? F5AQ16B ___(1)Yes ___(2)No

c. Do you ever have to stop for breath when walking at

Patient Registry ID: ___ ___ ___ ___ ___
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your own pace on the level? .....F5AQ16C.....___(1)Yes ___(2)No

d. Do you ever have to stop for breath after walking about 100 yards (or after a few minutes) on the level? .....F5AQ16D___(1)Yes ___(2)No

e. Are you too breathless to leave the house or breathless on dressing or undressing?.....F5AQ16E.....___(1)Yes ___(2)No

f. For how many years have you been this short of breath? ....F5AQ16F.....___ ___

CHEST COLDS AND CHEST ILLNESSES

17. a. How often do you get colds? F5AQ17A
___(1) Never ___(3) Once a Year
___(2) 2-4 Times per Year ___(4) 5 or More Times per Year

b. If you get a cold, does it usually go to your chest? ("Usually" means more than 1/2 the time): F5AQ17B ___(1)Yes ___(2)No ___(3)I don't get colds

18. a. During the past 3 years, have you had any chest illnesses that have kept you off work, indoors at home, or in bed? F5AQ18A___(1)Yes ___(2)No

If NO to Question 18a, skip to Question 19.
If YES,

b. Did you produce phlegm with any of these chest illnesses?.....F5AQ18B.....___(1)Yes ___(2)No

c. In the last 3 years, how many such illnesses, with (*increased) phlegm, did you have which lasted a week or more (If none, enter 00)? .....F5AQ18C.....___ ___

*(For persons who usually have phlegm)

Symptom History Section Completed By: never entered
(Name)

ALCOHOL

19. Do you drink alcoholic beverages (beer, liquor or wine)? F5AQ19
___(1)Never ___(2)Ex-drinker ___(3)Currently

If NEVER, skip to Question 20. If Ex-drinker or Current drinker,

a. How many days per week, on the average, do/did you drink alcoholic beverages? .....F5AQ19A.....___.___

b. On days that you do/did drink alcohol, how many drinks do/did you have on the average? .....F5AQ19B.....___ ___

c. Are you a recovering alcoholic or ex-alcoholic?...F5AQ19C (censored)___(1)Yes ___(2)No
If NO, skip to Question 20.

If YES to Question 19c, complete the following:
d. How long has it been since you last had an alcoholic drink? F5AQ19D
___(1)More than 1 year ___(3)less than 6 months
___(2)6 months to one year

White/Yellow: Clinical Coordinating Center, Pink: Clinical Center

Patient Registry ID: ___ ___ ___ ___ ___
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month day year

SMOKING HISTORY

Tobacco Smoking:

20. a. Have you ever smoked **cigarettes**? .....F5AQ20A.....___(1)Yes ___(2)No

("No" means less than 20 packs of cigarettes or 12 oz. of tobacco in a lifetime or less than one cigarette a day for one year)

If YES to Question 20a.:

b. Do you now smoke cigarettes (as of 1 month ago)? F5AQ20B ___(1)Yes ___(2)No

c. How old were you when you first started regular cigarette smoking?.....F5AQ20C..... ___ ___ Age in years

d. If you have stopped smoking cigarettes completely, how old were you when you stopped? .....F5AQ20D.... ___ ___ Age in years

e. How many cigarettes do you smoke per day now?.....F5AQ20E..... ___ ___ ___cigarettes per day

f. On the average of the entire time you smoked, how many cigarettes did you smoke per day?.....F5AQ20F___ ___ ___cigarettes per day

g. Do or did you inhale the cigarette smoke?.....F5AQ20G.....___(1)Not at all
___(2)Slightly
___(3)Moderately
___(4)Deeply

21. a. Have you ever smoked a **pipe** regularly?....F5AQ21A.....___(1)Yes ___(2)No

("Yes" means more than 12 oz of tobacco in a lifetime)

If YES to Question 21a. (For persons who have ever smoked a pipe):

b. 1. How old were you when you started to smoke a pipe regularly? .....F5AQ21B1..... ___ ___ Age in years

b. 2. Are you still smoking a pipe?....F5AQ21B2.....___(1)Yes ___(2)No

b. 3. If you have stopped smoking a pipe completely, how old were you when you stopped? .....F5AQ21B3..... ___ ___ Age in years

c. On the average over the entire time you smoked a pipe, how much pipe tobacco did you smoke per week?....F5AQ21C.. ___ ___ oz per week

(A standard pouch of tobacco contains 1 1/2 oz)

d. How much pipe tobacco are you smoking now? .....F5AQ21D..... ___ ___ oz per week

e. Do or did you inhale the pipe smoke?.....F5AQ21E.....___(1)Not at all
___(2)Slightly
___(3)Moderately
___(4)Deeply

Patient Registry ID: ___ ___ ___ ___ ___
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Smoking History, continued:

22. a. Have you ever smoked **cigars** regularly? ....F5AQ22A.... ___(1)Yes ___(2)No

("Yes" means more than 1 cigar a week for a year)

If YES to Question 22a (For persons who have ever smoked cigars):

b. 1. How old were you when you started to smoke cigars regularly? ....F5AQ22B1.... ___ ___ Age in years

b. 2. Are you currently smoking cigars? ....F5AQ22B2.... ___(1)Yes ___(2)No

b. 3. If you have stopped smoking cigars completely, how old were you when you stopped? ....F5AQ22B3.... ___ ___ Age in years

c. On the average over the entire time you smoked cigars, how many cigars did you smoke per week? ....F5AQ22C.... ___ ___ cigars per week

d. How many cigars are you smoking now? ....F5AQ22D.... ___ ___ cigars per week

e. Do you or did you inhale the cigar smoke? ....F5AQ22E.... ___(1)Not at all
___(2)Slightly
___(3)Moderately
___(4)Deeply

23. Other **(non-tobacco) smoking:** F5AQ23
___(0)Never ___(2)Current
___(1)Ex-smoker ___(9)Unknown

(Specify, if available): never entered

MEDICAL HISTORY

24. Have you and/or any of your family members been diagnosed or hospitalized with a disease of the **lung** since your last visit? F5AQ24 ___(1)Yes ___(2)No

If YES, Check If:

For each letter there are 5 variables. Use the base letters and replace the "x" with the coorresponding number.

	Diagnosed By Doctor Since Your Last Visit	If You Have Been Hospitalized Since Your Last Visit	Any Family Members Diagnosed With Condition Since Your Last Visit F	M	O*
a. Emphysema: F5AQ24Ax	1	2	4	5	3
b. Pneumothorax: F5AQ24Bx	1	2	4	5	3
c. Bullous Lung Disease: F5AQ24Cx	1	2	4	5	3
d. Chronic Bronchitis: F5AQ24Dx	1	2	4	5	3
e. Asthma: F5AQ24Ex	1	2	4	5	3

*For Family History: F = Father, M = Mother, O = Other blood relative

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Date of Visit: ___ ___/ ___ ___/ ___ ___
month day year

Medical History, continued:

	Diagnosed By Doctor Since Your Last Visit	If You Have Been Hospitalized Since Your Last Visit	Any Family Members Diagnosed With Condition Since Your Last Visit F	M	O*
f. Infant Respiratory Distress Syndrome: F5AQ24Fx			4	5	3
g. COPD F5AQ24Gx	1	2	4	5	3
(Specify): never entered					
h. Bronchiectasis: F5AQ24Hx	1	2	4	5	3
i. Pulmonary Fibrosis: F5AQ24Ix	1	2	4	5	3
j. Lung Cancer: F5AQ24Jx	1	2	4	5	3
k. Pulmonary Embolism: F5AQ24Kx	1	2	4	5	3
l. Pneumonia: F5AQ24Lx	1	2	4	5	3
m. Pleural Disease: F5AQ24Mx	1	2	4	5	3
n. Tuberculosis: F5AQ24Nx	1	2	4	5	3
o. Primary Pulmonary Hypertension F5AQ24Ox	1	2	4	5	3
p. Allergies affecting Respiratory Tract (Hay Fever): F5AQ24Px	1	2	4	5	3
q. Other lung disease: F5AQ24Qx	1	2	4	5	3
(Specify): F5AQ24Q6					

25. Have you and/or any of your family members been diagnosed or hospitalized with a disease of the liver since your last visit? F5AQ25 ___(1)Yes ___(2)No
If YES, Check If:

For explanation on variable names, see Q.24 (REPLACE "x" with coorresponding number)

	Diagnosed By Doctor Since Your Last Visit	If You Have Been Hospitalized Since Your Last Visit	Any Family Members Diagnosed With Condition Since Your Last Visit F	M	O*
a. Hepatitis: F5AQ25Ax	1	2	4	5	3
b. Childhood Onset, Acute Hepatitis: F5AQ25Bx			4	5	3

*For Family History: F = Father, M = Mother, O = Other blood relative

White/Yellow: Clinical Coordinating Center, Pink: Clinical Center

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Patient Registry ID: ___ ___ ___ ___ ___
Date of Visit: ___ ___/ ___ ___/ ___ ___
month day year

Medical History, continued:

	Diagnosed By Doctor Since Your Last Visit	If You Have Been Hospitalized Since Your Last Visit	Any Family Members Diagnosed With Condition Since Your Last Visit F	M	O*
c. Childhood Onset, Chronic Hepatitis: F5AQ25Cx			4	5	3
d. Adult Onset, Hepatitis: F5AQ25Dx	1	2	4	5	3
e. Jaundice within 1st month of life: F5AQ25Ex			4	5	3
f. Cirrhosis: F5AQ25Fx	1	2	4	5	3
g. Liver Tumor: F5AQ25Gx	1	2	4	5	3
h. Other liver disease: F5AQ25Hx	1	2	4	5	3

(Specify): F5AQ25H6

***For Family History:** F = Father, M = Mother, O = Other blood relative

26. Have you been diagnosed or hospitalized with **heart** disease since your last visit? F5AQ26 ___(1)Yes ___(2)No
If YES, Check If:

For explanation on variable names, see Q.24. (REPLACE "x" with coorresponding number.)

	Diagnosed By Doctor Last Visit	If You Have Been HospitalizedSince You Last Visit
a. Coronary Artery Disease: F5AQ26Ax	1	2
b. Myocardial Infarction: F5AQ26Bx	1	2
c. Congestive Heart Failure: F5AQ26Cx	1	2
d. Chest Pain - Angina: F5AQ26Dx	1	2
e. Hypertension: F5AQ26Ex	1	2
f. Other heart disease: F5AQ26Fx	1	2

(Specify): F5AQ26F3

27. Have you ever been diagnosed or hospitalized with a disease of the **joints** or involving the **immune system** since your last visit? F5AQ27 ___(1)Yes ___(2)No

(Question 27 continued on next page)

Patient Registry ID: ___ ___ ___ ___ ___
Date of Visit: ___ ___/ ___ ___/ ___ ___
month day year

Medical History, continued:

If YES to question 27, Check If:

For explanation on variable names, see Q.24. (REPLACE "x" with coorresponding number.)

	Diagnosed By Doctor Since Your Last Visit	If You Have Been Hospitalized Since Your Last Visit
a. Adult Rheumatoid Arthritis: F5AQ27Ax	1	2
b. Juvenile Chronic Polyarthritis: F5AQ27Bx	1	2
c. Weber-Christian Disease (Necrotizing Panniculitis): F5AQ27Cx	1	2
d. Other joint/auto-immune disease: F5AQ27Dx	1	2

(Specify): F5AQ27D3

28. Have you been diagnosed with a disease of the **blood system** since your last visit? F5AQ28 ___(1)Yes ___(2)No

If YES, specify: never entered

29. Have you been diagnosed with a disease of the **kidney** since your last visit? F5AQ29 ___(1)Yes ___(2)No

If YES, specify: never entered

30. Have you been diagnosed with a disease of the **stomach, intestines,** or **pancreas** since your last visit? F5AQ30 ___(1)Yes ___(2)No

If YES, specify: never entered

31. Have you been diagnosed with any **neurologic** disease since your last visit? F5AQ31 ___(1)Yes ___(2)No

If YES, specify: never entered

32. Have you been diagnosed with a disease of the **glands or hormones** since your last visit? (e. g., suagr diabetes, thryoid disease, etc F5AQ32 (1)Yes ___(2)No

If YES, specify: never entered

33. Have you been diagnosed with any **other illnesses** not already mentioned? F5AQ33 ___(1)Yes ___(2)No

If YES, specify: F5AQ33A

Patient Registry ID: ___ ___ ___ ___ ___
Date of Visit: ___ ___/ ___ ___/ ___ ___
month day year

Medical History, continued:

34. Has anyone in your family been diagnosed with alpha 1-antitrypsin deficiency since your last visit?.....F5AQ34.....___(1)Yes ___(2)No

If NO, skip to Question 36. If YES, complete Question 35.

35. List blood relatives referred to in Question 34.

UNRELIABLE

a. Relationship: F5AQ35A1
Registry Pt ID: F5AQ35A2

b. Relationship: F5AQ35B1
Registry Pt ID: F5AQ35B2

c. Relationship: F5AQ35C1
Registry Pt ID: F5AQ35C2

UNRELIABLE

d. Relationship: F5AQ35D1
Registry Pt ID: F5AQ35D2

e. Relationship: F5AQ35E1
Registry Pt ID: F5AQ35E2

f. Relationship: F5AQ35F1
Registry Pt ID: F5AQ35F2

SURGICAL HISTORY

36. Have you had **surgery** since your last visit?.....F5AQ36.....___(1) Yes ___(2) No
If NO, skip to Question 37.

	Surgery Since Last Visit?	Date of Most Recent Surgery (mm/yy) (All dates are fuzzed)
a. Lung (Other than transplant): F5AQ36A1	___(1)Yes ___(2)No	F5AQ36A2-Fzd ___ ___/___ ___
(Specify type and site of surgery): F5AQ36A3		
1. Lung Transplant?.....F5A36A1	___(1)Yes ___(2)No	
2. Date of Lung Transplant: ....F5A36A2-Fzd (fuzzed)	___ ___/ ___ ___ month day year	
b. Chest (Other Than Lung): F5AQ36B1	___(1)Yes ___(2)No	F5AQ36B2-Fzd ___ ___/___ ___
(Specify type and site of surgery): F5AQ36B3		
c. Abdominal:.....F5AQ36C1	___(1)Yes ___(2)No	F5AQ36C2-Fzd ___ ___/___ ___
(Specify type and site of surgery): F5AQ36C3		
d. Liver (Other than transplant): F5AQ36D1	___(1)Yes ___(2)No	F5AQ36D2-Fzd ___ ___/___ ___
(Specify type and site of surgery): F5AQ36D3		

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Patient Registry ID: ___ ___ ___ ___ ___
Date of Visit: ___ ___/ ___ ___/ ___ ___
month day year

Surgical History, continued:

1. Liver Transplant?.....F5A36D1.....___(1)Yes ___(2)No

2. Date of Liver Transplant:.....F5A36D2_fzd (fuzzed) ___ ___/ ___ ___/ ___ ___
month day year

e. Other:.....F5AQ36E1.....___(1)Yes___(2)No F5AQ36E2_fzd ___ ___/___ ___

(Specify type and site of surgery): F5AQ36E3

Medical and Surgical History Sections Completed By:

never entered
(Name)

MEDICATIONS

37. In the past month, have you used any prescription drugs? F5AQ37 ___(1)Yes ___(2)No

If NO, skip to Question 38.
If YES, specify drugs taken. YES or NO must be indicated for each drug category.

a. Inhaled Bronchodilators: .....F5AQ37A.....___(1)Yes ___(2)No
(Specify): never entered

b. Oral Bronchodilators: .....F5AQ37B.....___(1)Yes ___(2)No
(Specify): never entered

c. Theophylline:.....F5AQ37C.....___(1)Yes ___(2)No
(Specify): never entered

d. Cromolyn: .....F5AQ37D.....___(1)Yes ___(2)No
(Specify): never entered

e. Systemic Corticosteroids:.....F5AQ37E.....___(1)Yes ___(2)No
(Specify): never entered

f. Inhaled Corticosteroids: .....F5AQ37F.....___(1)Yes ___(2)No
(Specify): never entered

g. Other Bronchodilators:....F5AQ37G.....___(1)Yes ___(2)No
(Specify): never entered

h. Beta-Blockers:.....F5AQ37H.....___(1)Yes ___(2)No
(Specify): never entered

Patient Registry ID: ___ ___ ___ ___ ___
Date of Visit: ___ ___/ ___ ___/ ___ ___
month day year

Medications, continued:

i. Insulin: F5AQ37I ___(1)Yes ___(2)No
(Specify): never entered

j. Nitroglycerin or Other Nitrates: F5AQ37J ___(1)Yes ___(2)No
(Specify): never entered

k. Digitalis: F5AQ37K ___(1)Yes ___(2)No
(Specify): never entered

l. Anticoagulants: F5AQ37L ___(1)Yes ___(2)No
(Specify): never entered

m. Antiarrhythmics F5AQ37M ___(1)Yes ___(2)No
(Specify): never entered

n. Oral Contraceptives: F5AQ37N ___(1)Yes ___(2)No
(Specify): never entered

o. Tranquilizers: F5AQ37O ___(1)Yes ___(2)No
(Specify): never entered

p. Other prescription drugs: F5AQ37P ___(1)Yes ___(2)No
(Specify): F5AQ37P3

q. Supplemental Oxygen Questions

1. Do you receive supplemental oxygen? F5AQ37Q1 ___(1)Yes ___(2)No

If YES, complete items 2-4 below.
If NO, skip to Question 38.

2. Type of oxygen delivery device: F5AQ37Q2
___(1) Nasal Cannula
___(2) Transtracheal Oxygen
___(3) Face mask, type: never entered
___(4) Other, specify: never entered

3. Oxygen Flow:

a. Liters/minute: F5A37Q3A ___ ___ . ___

b. FIO_2 (if Venturi mask) (%) F5A37Q3B ___ ___ ___

4. Number of hours/24 hour period of oxygen use F5AQ37Q4 ___ ___ . ___

Medication Section Completed By: never entered
(Name)

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Patient Registry ID: ___ ___ ___ ___ ___
Date of Visit: ___ ___/ ___ ___/ ___ ___
month day year

ALPHA 1-ANTITRYPSIN AUGMENTATION THERAPY

Be sure to get and review the patient's Augmentation Therapy Record (Form # 10) and submit it with the other visit forms. Give the patient a new Therapy Record to use until the next visit.

38. Have you ever been on alpha 1-antitrypsin augmentation therapy (Prolastin) since your last visit? .....F5AQ38..... ___(1)Yes ___(2)No

    a. If NO, identify reason why not (then skip to end of form): F5AQ38A1

    ___(1)Not recommended by physician

    ___(2)Financial reasons

    ___(3)Medical contra-indications (specify): F5AQ38A2

    ___(4)Other (specify): F5AQ38A3

    ___(9)Unknown

    If YES to question 38, continue.

    a. Have you experienced any problems related to the augmentation therapy since your last visit? ...F5AQ38A..... ___(1)Yes ___(2)No

    If YES, complete Form #11 - Adverse Reaction Form.

    b. Are you presently on augmentation therapy?:...F5AQ38B.... ___(1)Yes ___(2)No

39. a. Have you discontinued therapy permanently? ...F5AQ39A... ___(1)Yes ___(2)No
("Permanently" means no intention of continuing therapy)

    If NO, skip to Question 40a.

    b. If YES, for what reason(s) have you discontinued therapy: F5AQ39B

    ___(1)Financial ___(4)Other (Specify) F5AQ39B2

    ___(2)Adverse Reaction (specify on Form 11)

    ___(3)Medical F5AQ39B1 ___(9)Unknown/Unspecified

    c. If therapy has been stopped , date of last therapy received.....F5AQ39C_fzd...(fuzzed)..... ___ ___/ ___ ___/ ___ ___
    month day year

    If presently on augmentation therapy,

40. a. Date current therapy began: F5AQ40A_fzd.....(fuzzed) ___ ___/ ___ ___/ ___ ___
    month day year

Patient Registry ID: ___ ___ ___ ___ ___
Date of Visit: ___ ___/ ___ ___/ ___ ___
month day year

Augmentation Therapy, continued:

40. b. Date of most recent augmentation therapy F5AQ40B fzd (fuzzed) ___ ___/ ___ ___/ ___ ___
month day year

c. Dose (grams): F5AQ40C ___ ___.___

41. With what frequency are you given augmentation therapy? F5AQ41
___(1)Weekly ___(2)Monthly (in number of days) ___(3)Other (specify): never entered

Note: Coded by the CCC as the infusion interval (days). Code '98' is used to represent "occasional" or "intermittent" use.

42. Is therapy being given by a method other than infusion? F5AQ42
___(1)Yes (specify) never entered ___(2)No

Physician Signature: never entered

Patient Registry ID: ___ ___ ___ ___ ___
Date of Visit: ___ ___/ ___ ___/ ___ ___
month day year

This page should be completed for every follow-up visit.

ALPHA 1-ANTITRYPSIN AUGMENTATION THERAPY

Continued from Page 14 of Form 05A:

If YES to question 38a, continue:

38a. 1. When did the reaction(s) occur? F5A38A1

___(1)During the infusion
___(2)Immediately after the infusion but within 24 hours
___(3)Greater than 24 hours after the infusion
___(4)Other (Specify) F5A38A1S (never entered)
___(9)Unknown

38a. 2. With what frequency did the reaction(s) occur? F5A38A2

___(1)Single episode
___(2)"Two or three" times
___(3)Greater than three times
___(4)"After every infusion"
___(5)Other (Specify) F5A38A2S
___(9)Unknown

38a. 3. Was hospitalization or emergency room treatment required?: F5A38A3 ___(1)Yes ___(2)No

38a. 4. Did the reaction require medication and/or contact with your local physician?: F5A38A4 ___(1)Yes ___(2)No

If therapy was discontinued permanently, please complete the date therapy stopped in question 39c.

Comments: never entered

Form Completed By (Name): never entered

Physician Signature: never entered

Notes on Coding:

Questions 24a-q and 25a-f: Medical History

For each of the medical history questions 24a-q, and 25a-h, there are five variables in the database, each coded as "1" if yes and blank (missing) otherwise:

Question 24a. Emphysema

F2AQ24A1 - Patient Diagnosed by doctor
F2AQ24A2 - Hospitalized within the last year
F2AQ24A3 - Condition present in family member - Other blood relative
F2AQ24A4 - Condition present in family member - Father
F2AQ24A5 - Condition present in family member - Mother

Question 24b. Pneumothorax

F2AQ24B1 - Patient Diagnosed by doctor
F2AQ24B2 - Hospitalized within the last year
F2AQ24B3 - Condition present in family member - Other blood relative
F2AQ24B4 - Condition present in family member - Father
F2AQ24B5 - Condition present in family member - Mother

. . .

Question 24q. Other diseases of the lung

F2AQ24Q1 - Patient Diagnosed by doctor
F2AQ24Q2 - Hospitalized within the last year
F2AQ24Q3 - Condition present in family member - Other blood relative
F2AQ24Q4 - Condition present in family member - Father
F2AQ24Q5 - Condition present in family member - Mother

Question 25a. Hepatitis

F2AQ25A1 - Patient Diagnosed by doctor
F2AQ25A2 - Hospitalized within the last year
F2AQ25A3 - Condition present in family member - Other blood relative
F2AQ25A4 - Condition present in family member - Father
F2AQ25A5 - Condition present in family member - Mother

. . .

Question 25h. Other liver disease

F2AQ25H1 - Patient Diagnosed by doctor
F2AQ25H2 - Hospitalized within the last year
F2AQ25H3 - Condition present in family member - Other blood relative
F2AQ25H4 - Condition present in family member - Father
F2AQ25H5 - Condition present in family member - Mother