

**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.

<u>QUESTION #</u>	<u>ITEM</u>	<u>INSTRUCTIONS</u>
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	<p>For each general system, the initial questions should be asked first. If the answer is "No", the list of specific diseases should be skipped.</p> <p>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.</p> <p>If a hospital chart is available and can be review prior to asking these questions, it should help you in interviewing the patient.</p>
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:

<u>QUESTION #</u>	<u>ITEM</u>	<u>INSTRUCTIONS</u>
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: F5A001Fzd (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: F5A005 ___(1)Yes ___(2)No
 If YES (name of Clinical Center): Never entered
6. Date of visit: F5A006fzd (fuzzed) ___/___/___
month day year
Visit number vsno
7. What is your marital status: F5A007 ___(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? F5A008A
 ___(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? F5A009A ___(1)Yes ___(2)No
 ___(9)Unknown

b. If YES,

Specify Job	Number of Years Worked at Job	Last Year Employed at This Job
<u>F5A009B1</u>	<u>F5A009B2</u>	<u>F5A009B3</u>
<u>F5A009C1</u>	<u>F5A009C2</u>	<u>F5A009C3</u>
<u>F5A009D1</u>	<u>F5A009D2</u>	<u>F5A009D3</u>

SYMPTOM HISTORY

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

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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

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

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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
 - ___(2) 2-4 Times per Year
 - ___(3) Once a 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
 - ___(2)6 months to one year
 - ___(3)less than 6 months

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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

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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 corresponding 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: <u>F5AQ24Ax 1</u>	<u>2</u>	<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
b. Pneumothorax: <u>F5AQ24Bx 1</u>	<u>2</u>	<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
c. Bullous Lung Disease: <u>F5AQ24Cx 1</u>	<u>2</u>	<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
d. Chronic Bronchitis: <u>F5AQ24Dx 1</u>	<u>2</u>	<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
e. Asthma: <u>F5AQ24Ex 1</u>	<u>2</u>	<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>

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

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

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 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: <u>F5A024Fx</u>			<u>4</u>	<u>5</u>	<u>3</u>
g. COPD: <u>F5A024Gx</u> <u>1</u>		<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
(Specify): <u>never entered</u>					
h. Bronchiectasis: <u>F5A024Hx</u> <u>1</u>		<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
i. Pulmonary Fibrosis: <u>F5A024Ix</u> <u>1</u>		<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
j. Lung Cancer: <u>F5A024Jx</u> <u>1</u>		<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
k. Pulmonary Embolism: <u>F5A024Kx</u> <u>1</u>		<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
l. Pneumonia: <u>F5A024Lx</u> <u>1</u>		<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
m. Pleural Disease: <u>F5A024Mx</u> <u>1</u>		<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
n. Tuberculosis: <u>F5A024Nx</u> <u>1</u>		<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
o. Primary Pulmonary Hypertension: <u>F5A024Ox</u> <u>1</u>		<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
p. Allergies affecting Respiratory Tract (Hay Fever): <u>F5A024Px</u> <u>1</u>		<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
q. Other lung disease: <u>F5A024Qx</u> <u>1</u>		<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
(Specify): <u>F5A024Q6</u>					

25. Have you and/or any of your family members been diagnosed or hospitalized with a disease of the liver since your last visit? F5A025 (1) Yes _____ (2) No _____
 If YES, Check If:

For explanation on variable names, see Q. 24 (REPLACE "x" with corresponding 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: <u>F5A025Ax</u> <u>1</u>		<u>2</u>	<u>4</u>	<u>5</u>	<u>3</u>
b. Childhood Onset, Acute Hepatitis: <u>F5A025Bx</u> <u>1</u>			<u>4</u>	<u>5</u>	<u>3</u>

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

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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	1	2	4	5	3
e. Jaundice within 1st month of life: F5AQ25Ex			4	5	3
f. Cirrhosis: F5AQ25Fx 1	1	2	4	5	3
g. Liver Tumor: F5AQ25Gx 1	1	2	4	5	3
h. Other liver disease: F5AQ25Hx 1	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 corresponding number.)

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

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Medical History, continued:

If YES to question 27, Check If:

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

	Diagnosed By Doctor Since Your Last Visit	If You Have Been Hospitalized Since Your Last Visit
a. Adult Rheumatoid Arthritis:..... F5AQ27Ax..... 1		<u>2</u>
b. Juvenile Chronic Polyarthritis:..... F5AQ27Bx..... 1		<u>2</u>
c. Weber-Christian Disease (Necrotizing Panniculitis):..... F5AQ27Cx..... 1		<u>2</u>
d. Other joint/auto-immune disease:..... F5AQ27Dx..... 1		<u>2</u>
(Specify): <u>F5AQ27D3</u>		

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

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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.

<p>a. Relationship: <u>F5AQ35A1</u> Registry Pt ID: <u>F5AQ35A2</u></p> <p>b. Relationship: <u>F5AQ35B1</u> Registry Pt ID: <u>F5AQ35B2</u></p> <p>c. Relationship: <u>F5AQ35C1</u> Registry Pt ID: <u>F5AQ35C2</u></p>	<p>d. Relationship: <u>F5AQ35D1</u> Registry Pt ID: <u>F5AQ35D2</u></p> <p>e. Relationship: <u>F5AQ35E1</u> Registry Pt ID: <u>F5AQ35E2</u></p> <p>f. Relationship: <u>F5AQ35F1</u> Registry Pt ID: <u>F5AQ35F2</u></p>
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UNRELIABLE

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)
a. Lung (Other than transplant):	<u>F5AQ36A1</u> (1)Yes ___ (2)No	<u>F5AQ36A2</u> - f2d
(Specify type and site of surgery):	<u>F5AQ36A3</u>	
1. Lung Transplant?	<u>F5AQ36A1</u> (1)Yes ___ (2)No	
2. Date of Lung Transplant:	<u>F5AQ36A2</u> - f2d (fuzzed)	____/____/____ <small>month day year</small>
b. Chest (Other Than Lung):	<u>F5AQ36B1</u> (1)Yes ___ (2)No	<u>F5AQ36B2</u> - f2d
(Specify type and site of surgery):	<u>F5AQ36B3</u>	
c. Abdominal:	<u>F5AQ36C1</u> (1)Yes ___ (2)No	<u>F5AQ36C2</u> - f2d
(Specify type and site of surgery):	<u>F5AQ36C3</u>	
d. Liver (Other than transplant):	<u>F5AQ36D1</u> (1)Yes ___ (2)No	<u>F5AQ36D2</u> - f2d
(Specify type and site of surgery):	<u>F5AQ36D3</u>	

(All dates are fuzzed)

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Surgical History, continued:

1. Liver Transplant?.....F5A36D1.....(1)Yes ___(2)No
2. Date of Liver Transplant:.....F5A36D2-fzd (fuzzed)...../_____/_____
 month day year
e. Other:.....F5A036E1.....(1)Yes ___(2)No F5A036E2-fzd
(Specify type and site of surgery): F5A036E3

Medical and Surgical History Sections Completed By:

never entered
(Name)

MEDICATIONS

37. In the past month, have you used any prescription drugs? F5A037 ___(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:.....F5A037A.....(1)Yes ___(2)No
(Specify): never entered
- b. Oral Bronchodilators:.....F5A037B.....(1)Yes ___(2)No
(Specify): never entered
- c. Theophylline:.....F5A037C.....(1)Yes ___(2)No
(Specify): never entered
- d. Cromolyn:.....F5A037D.....(1)Yes ___(2)No
(Specify): never entered
- e. Systemic Corticosteroids:.....F5A037E.....(1)Yes ___(2)No
(Specify): never entered
- f. Inhaled Corticosteroids:.....F5A037F.....(1)Yes ___(2)No
(Specify): never entered
- g. Other Bronchodilators:.....F5A037G.....(1)Yes ___(2)No
(Specify): never entered
- h. Beta-Blockers:.....F5A037H.....(1)Yes ___(2)No
(Specify): never entered

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 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. FIO₂ (if Venturi mask) (%)..... F5A37Q3B
 - 4. Number of hours/24 hour period of oxygen use..... F5AQ37Q4
- Medication Section Completed By: never entered
(Name)

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

- | | |
|--|---|
| <input type="checkbox"/> (1) During the infusion | <input type="checkbox"/> (4) Other (Specify) <u>F5A38A1S</u>
(never entered) |
| <input type="checkbox"/> (2) Immediately after the infusion
but within 24 hours | <input type="checkbox"/> (9) Unknown |
| <input type="checkbox"/> (3) Greater than 24 hours after the infusion | |

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

- | | |
|---|--|
| <input type="checkbox"/> (1) Single episode | <input type="checkbox"/> (4) "After every infusion" |
| <input type="checkbox"/> (2) "Two or three" times | <input type="checkbox"/> (5) Other (Specify) <u>F5A38A2S</u> |
| <input type="checkbox"/> (3) Greater than three times | <input type="checkbox"/> (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