ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY

CLINICAL CENTER INSTRUCTIONS FOR THE AUGMENTATION THERAPY RECORD

Form Completion Instructions:

Clinical Center personnel should review this form with the patient at the patient's initial Registry visit. This form and patient instructions will be given to the patient at the time and it should be returned by the patient at the next follow-up visit. The top portion of the form with ID, namecode and dates should be completed for the patient at this time.

When the form is returned, the Clinical Center personnel should review the form with the patient present. Is it completed correctly? Are the dates that were previously filled in still correct? After review with the patient, if there are any comments previously not noted which should be, filled them in. Keep careful notes regarding any problems that may have occurred in response to the therapy so that after the patient has left the clinic, Form #11, the Adverse Reaction Form may be completed properly.

All attempts to make the form as complete as possible should be made.

ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY

PATIENT INSTRUCTIONS FOR THE AUGMENTATION THERAPY RECORD

Form Completion Instructions:

You should have received a blank Augmentation Therapy Form at your clinic visit. If not, call or write the Registry Clinical Center and ask for one.

Each time you are given augmentation therapy, one row of this form should be completed.

If you are scheduled to receive augmentation therapy and miss it, indicate that by including a row with the scheduled date and note in the "comment" area that the therapy was missed and write why it was missed. For example, vacation, rescheduled, discontinued, etc.

If you have any questions about the dose column, either the Clinical Center or your physician may be able to help you. It is probably a good idea to bring this form with you to your augmentation therapy appointment and complete it at that time.

Use as many of the rows as you need until your next visit. If you miss the next visit, just continue to use this form until you do go to the Registry Clinical Center. If you run out of rows on the form and need another form either continue on a new blank sheet of paper documenting the same items from the form, or call or write you Clinical Center to ask for additional forms.

Most importantly, be as thorough as possible and, **DON'T FORGET TO BRING THIS FORM WITH YOU TO OUR NEXT VISIT TO THE CLINICAL CENTER**. Thank you for your cooperation and if you have any questions at all, contact the Registry Clinical Center.

REGISTRY OF PATIENTS WITH DEFICIENCY OF ALPHA 1-ANTITRYPSIN
PATIENT AUGMENTATION THERAPY RECORD

Instructions to the Patient: You should complete an entry on this record each time you receive alpha 1-antitrypsin augmentation therapy. You should turn in this record at your next visit to the Clinical Center and receive a new record.

Period Covering: Never Entered __ __/ __ __/ __ __ (month day year) to Never Entered __ __/ __ __/ __ __ (month day year)

Patient Registry ID: NewID (scrambled)

Date of Visit (when form returned): Datevst_fzd (fuzzed) __ __/ __ __/ __ __ (month day year)

Name Code: namecode (censored)

clinical center code number - clinic - censored

Weight (kg): weight (not research related)

Augmentation Therapy date (month/day/year)	Dosage (grams)	Where Therapy Given 1=Local M.D. 2=Clinical Ctr 3=Other	Prolastin Lot Number (Patients can have up to 5 Prolastin Lot numbers)	How Therapy Given 1=Infusion 2=Other	Problems ? (Circle One)	Comments
Augdate_fzd (fuzzed)	Dosage	wheregvn	PROL1-PROL5	HowGvn	Problems	Never Entered
__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	
__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	
__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	
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__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	
__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	
__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	

REGISTRY OF PATIENTS WITH DEFICIENCY OF ALPHA 1-ANTITRYPSIN
PATIENT AUGMENTATION THERAPY RECORD

Augmentation Therapy date (month/day/year)	Dosage (grams)	Where Therapy Given 1=Local M.D. 2=Clinical Ctr 3=Other	Prolastin Lot Number	How Therapy Given 1=Infusion 2=Other	Problems ? (Circle One)	Comments
__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	_____
__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	_____
__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	_____
__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	_____
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__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	_____
__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	_____
__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	_____
__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	_____
__ __/ __ __/ __ __	__ __ __ . __	__	__ __ __ __ __ __	__	No Yes	_____

Notes on Coding:

Each Augmentation therapy date is entered as a separate record. Variables entered on each record include:

ID	
AUGDATE -	Augmentation therapy date
CLINIC -	Clinical center where patient is seen
DATEVST -	Date of visit
DOSAGE -	Dosage (grams)
HOWGVN -	See form for coding instructions
PROBLEMS -	See form (1=yes, 2=no)
PROL1-PROL5 -	Up to 5 Prolastin lot numbers (May use multiple lots at a single infusion)
WEIGHT -	Weight in kg
WHERGVN -	Where given - see form