

INSTRUCTIONS: This form must be completed for all consenting subjects at the time of entry into the Marfan Trial.

Section A: KEY IDENTIFYING INFORMATION

A1. Study Identification Number _____ - _____ - _____ - _____

A2. Study visit BASELINE (0)

a. What number screening is this? _____

A3. Date of form completion
____ / ____ / ____
M M D D Y Y Y Y

A4. Name of person completing form

PRINT FULL NAME INITIALS

A5. Date of visit
____ / ____ / ____
M M D D Y Y Y Y

For column 2 (age), please indicate the subject's age at initial diagnosis. Round the subject's age to the nearest full year; Round up to the nearest year if ≥ 6 months; Round down for < 6 months. If age is unknown, enter -8 in the space for Years.

Section B: PAST MEDICAL HISTORY AND REVIEW OF SYMPTOMS

B1. Cardiovascular

- a. Arrhythmia requiring medication
- b. Hypertension requiring medication
- c. Hypotension requiring medication
- d. Exercise intolerance
- e. CHF requiring medication
- f. Syncope

1. Has the subject ever had the following?		2. Age (Round age to the nearest full year).	3. Is this still active?	
YES	NO	AGE	YES	NO
1	2 (B1b)	____ ____ Years	1	2
1	2 (B1c)	____ ____ Years	1	2
1	2 (B1d)	____ ____ Years	1	2
1	2 (B1e)	____ ____ Years	1	2
1	2 (B1f)	____ ____ Years	1	2
1	2 (B1g)	____ ____ Years	1	2

- g. How many other items to report? ____

If "0", skip to B2a, otherwise report other items in the table to the right. Photocopy and attach this page to document more than 3 "other" items.

1. Other Item Name	2. Age (Round age to the nearest full year).	3. Is this still active?	
		YES	NO
_____	____ ____ Years	1	2
_____	____ ____ Years	1	2
_____	____ ____ Years	1	2

B2. Endocrine

- a. Use of hormones to limit growth

1. Has the subject ever had the following?		2. Age (Round age to the nearest full year).	3. Is this still active?	
YES	NO	AGE	YES	NO
1	2 (B2b)	____ ____ Years	1	2

- b. How many other items to report? ____

If "0", skip to B3a, otherwise report other items in the table to the right. Photocopy and attach this page to document more than 3 "other" items.

1. Other Item Name	2. Age (Round age to the nearest full year).	3. Is this still active?	
		YES	NO
_____	____ ____ Years	1	2
_____	____ ____ Years	1	2
_____	____ ____ Years	1	2

B3. Neurodevelopmental

- a. Attention deficit requiring medication
- b. Hyperactivity requiring medication
- c. Developmental delay requiring special therapy
- d. Learning differences, requiring special education or special services

1. Has the subject ever had the following?		2. Age (Round age to the nearest full year).	3. Is this still active?	
YES	NO	AGE	YES	NO
1	2 (B3b)	____ ____ Years	1	2
1	2 (B3c)	____ ____ Years	1	2
1	2 (B3d)	____ ____ Years	1	2
1	2 (B3e)	____ ____ Years	1	2

- e. How many other items to report? ____

If “0”, skip to B4a, otherwise report other items in the table to the right. Photocopy and attach this page to document more than 3 “other” items.

1. Other Item Name	2. Age (Round age to the nearest full year).	3. Is this still active?	
		YES	NO
_____	____ ____ Years	1	2
_____	____ ____ Years	1	2
_____	____ ____ Years	1	2

B4. Psychiatric

- a. Depression requiring therapy

1. Has the subject ever had the following?		2. Age (Round age to the nearest full year).	3. Is this still active?	
YES	NO	AGE	YES	NO
1	2 (B4b)	____ ____ Years	1	2

- b. How many other items to report? ____

If “0”, skip to C1a, otherwise report other items in the table to the right. Photocopy and attach this page to document more than 3 “other” items.

1. Other Item Name	2. Age (Round age to the nearest full year).	3. Is this still active?	
		YES	NO
_____	____ ____ Years	1	2
_____	____ ____ Years	1	2
_____	____ ____ Years	1	2

Section C: SURGICAL HISTORY

C1. Cardiac Surgery

a. Atrioventricular (AV) valve surgery

1. Has the subject had the following cardiac surgery?		2. Age (Round age to the nearest full year).
YES	NO	AGE AT THE TIME OF SURGERY
1	2 (C1b)	____ ____ Years

b. How many other items to report? ____

If "0", skip to D1, otherwise report other items in the table to the right. Photocopy and attach this page to document more than 3 "other" items.

1. Other Item Name	2. Age at the time of surgery (Round age to the nearest full year).
_____	____ ____ Years
_____	____ ____ Years
_____	____ ____ Years

Section D: MEDICATIONS

For the medications D1-D4, please indicate the ages the subject took the medications. Round the subject's age to the nearest full year; Round up to the nearest year if ≥ 6 months; Round down for < 6 months. If age is unknown, enter -8 in the space for Years. If the subject is currently taking a medication enter, "-1" for question D. Age STOPPED.

If a subject took the same drug multiple times (e.g., took a BB from ages 1-3 yrs, then again from 8-12 yrs.), each time should be recorded on a separate line.

D1. How many times has the subject ever been prescribed (or, ever taken) a beta blocker? ____

If "0", skip to D2, otherwise report each time below. Photocopy and attach this page to document > 4 times.

A. Medication Code Codelist D	B. Dose (mg/day) Record -8 if dose unknown	C. Age STARTED	D. Age STOPPED	E. Medication Name Worksheet (Only data entered if "other")
1. ____ . ____	____ . ____	____ ____ Years	____ ____ Years	
2. ____ . ____	____ . ____	____ ____ Years	____ ____ Years	
3. ____ . ____	____ . ____	____ ____ Years	____ ____ Years	
4. ____ . ____	____ . ____	____ ____ Years	____ ____ Years	

D2. How many times has the subject ever been prescribed (or, ever taken) an ACE inhibitor? ____

If "0", skip to D3, otherwise report each time below. Photocopy and attach this page to document > 4 times.

A. Medication Code Codelist D	B. Dose (mg/day) Record -8 if dose unknown	C. Age STARTED	D. Age STOPPED	E. Medication Name Worksheet (Only data entered if "other")
1. ____ . ____	____ . ____	____ Years	____ Years	
2. ____ . ____	____ . ____	____ Years	____ Years	
3. ____ . ____	____ . ____	____ Years	____ Years	
4. ____ . ____	____ . ____	____ Years	____ Years	

D3. How many times has the subject ever been prescribed (or, ever taken) a calcium channel blocker? ____

If "0", skip to D4, otherwise report each time below. Photocopy and attach this page to document > 4 times.

A. Medication Code Codelist D	B. Dose (mg/day) Record -8 if dose unknown	C. Age STARTED	D. Age STOPPED	E. Medication Name Worksheet (Only data entered if "other")
1. ____ . ____	____ . ____	____ Years	____ Years	
2. ____ . ____	____ . ____	____ Years	____ Years	
3. ____ . ____	____ . ____	____ Years	____ Years	
4. ____ . ____	____ . ____	____ Years	____ Years	

D4. How many times has the subject ever been prescribed (or, ever taken) other anti-hypertensive medication? ____

If "0", skip to D5, otherwise report each time below. Photocopy and attach this page to document > 4 times.

A. Medication Code Codelist D	B. Dose (mg/day) Record -8 if dose unknown	C. Age STARTED	D. Age STOPPED	E. Medication Name Worksheet (Only data entered if "other")
1. ____ . ____	____ . ____	____ Years	____ Years	
2. ____ . ____	____ . ____	____ Years	____ Years	
3. ____ . ____	____ . ____	____ Years	____ Years	
4. ____ . ____	____ . ____	____ Years	____ Years	

D5. How many other current daily medications (other than those listed above) is the subject currently taking? ____

If "0", skip to D6, otherwise report medications below. Photocopy and attach this page to document > 4 medications.

ENTER '-1' into question D. Age STOPPED

A. Medication Code Codelist D	B. Dose (mg/day) Record -8 if dose unknown	C. Age STARTED	D. Age STOPPED	D. Medication Name Worksheet (Only data entered if "other")
1. ____ . ____	____ . ____	____ Years	____ Years	
2. ____ . ____	____ . ____	____ Years	____ Years	
3. ____ . ____	____ . ____	____ Years	____ Years	
4. ____ . ____	____ . ____	____ Years	____ Years	

D6. How many medications is the subject allergic to? ____

If “0”, skip to D7, otherwise report medications below. Photocopy and attach this page to document > 4 medications.

A. Medication Code Codelist D	B. Medication Name Worksheet (Only data entered if “other”)	C. Reaction Code (key at right)	D. Reaction Code, Specify (Only if “other”)
1. ____ . ____	_____	____	_____
2. ____ . ____	_____	____	_____
3. ____ . ____	_____	____	_____
4. ____ . ____	_____	____	_____

Code	Reaction
1	Anaphylaxis
2	Breathing problems
3	Skin reaction (includes hives, rash, etc.)
4	GI reaction
5	Swelling
99	Other reaction (specify)

D7. How many known intolerances to any cardiac medications does the subject have? ____

If “0”, skip to Z1, otherwise report medications below. Photocopy and attach this page to document > 4 medications.

A. Medication Code Codelist D	B. Medication Name Worksheet (Only data entered if “other”)	C. Reaction Code (key at right)	D. Reaction Code, Specify (Only if “other”)
1. ____ . ____	_____	____	_____
2. ____ . ____	_____	____	_____
3. ____ . ____	_____	____	_____
4. ____ . ____	_____	____	_____

Code	Reaction
1	Fatigue
2	Respiratory problems (includes cough, congestion, worsened asthma)
3	Learning problems
4	Gastrointestinal upset (includes vomiting, diarrhea, etc.)
5	Behavioral changes (includes irritability, hyperactivity, etc.)
6	Depression
7	Sleep problems (includes insomnia, nightmares, etc.)
99	Other reaction (specify)

Affix Marfan Trial Subject ID: __ __ - __ __ __ __ __ __ - __

Section Z: TIME TO COMPLETE FORM

Z1. How long did it take to complete this form? __ __ __ minutes

END OF FORM