

Patient ID: \_\_\_\_\_

Date form completed: \_\_\_\_\_  
mm/dd/yyyy

**Instructions:** Complete this form at the time of awareness of any occurrence which are protocol variations.

**Protocol Deviations:**

1. ☐ **Screening**, date: \_\_\_\_\_ (mm/dd/yyyy)

1.1 Initial screening was more than 30 days prior to Baseline

☐ Partial Re-screen was not done (31-42 days elapsed between Screening and Baseline)

☐ Complete Re-screen was not done (more than 42 days elapsed between Screening and Baseline)

Reason: \_\_\_\_\_ ( refer to Reasons of OP deviation codebook )

Specify if other reason: \_\_\_\_\_

2. ☐ **Randomization**, date: \_\_\_\_\_ (mm/dd/yyyy)

2.1 ☐ Patient randomized before approval of Exemption Petition

Reason: \_\_\_\_\_ ( refer to Reasons of OP deviation codebook )

Specify if other reason: \_\_\_\_\_

2.2 ☐ Ineligible patient randomized

Reason: \_\_\_\_\_ ( refer to Reasons of OP deviation codebook )

Specify if other reason: \_\_\_\_\_

2.3 ☐ Patient randomized under an incorrect ID: \_\_\_\_\_

2.4 ☐ Patient randomized according to wrong stratum, specify correct stratum: \_\_\_\_ (1=Used silymarin; 2=Never used silymarin)

2.5 ☐ Patient did not begin taking study drug on the date of randomization

Reason: \_\_\_\_\_ ( refer to Reasons of OP deviation codebook )

Specify if other reason: \_\_\_\_\_

3. ☐ **Visit**, time point: \_\_\_\_\_ (Screen,0,2,4,6,8,12,16,20,24,F-04,F-12,DC) date: \_\_\_\_\_ (mm/dd/yyyy)

3.1 ☐ Entire in-person visit or phone call missed

Reason: \_\_\_\_\_ ( refer to Reasons of OP deviation codebook )

Specify if other reason: \_\_\_\_\_

3.2 ☐ Incomplete visit:

a. Self Assessments ☐ missed or ☐ completed at wrong visit,  
specify at which visit self assessment were completed: \_\_\_\_\_  
(0,2,4,8,12,20,24,F-04,F-12,DC)

Reason: \_\_\_\_\_ ( refer to Reasons of OP deviation codebook )

Specify if other reason: \_\_\_\_\_

b. Laboratory Evaluation ☐ missed or ☐ partially complete, specify which samples were not drawn:

☐ Safety Labs ☐ Biomarkers  
☐ PK ☐ Genetics

Reason: \_\_\_\_\_ ( refer to Reasons of OP deviation codebook )

Specify if other reason: \_\_\_\_\_

**Patient ID:** \_\_\_\_\_

**Date form completed:** \_\_\_\_\_  
*mm/dd/yyyy*

4. ☐ Other Protocol Deviation, date: \_\_\_\_\_ (mm/dd/yyyy)

4.1 Specify deviation: \_\_\_\_\_

*Reason for deviation:* \_\_\_\_\_