

SAMPLE
Good Clinical Practices
Individual Subject Data Accuracy Checklist

Protocol No.: MK-231 Brief Title: MK-231 vs Placebo in Lupus

Date Reviewed: 2/13/09

Subject No/Identifier.: 1004 Date of Birth: 12/22/51

Reviewer: Jean Johnson

Checklist: Entry Criteria	Yes	No	N/A	Comments
<i>Inclusion Criteria:</i>				Helpful Hints: The checklist is in a table format. Use the table dropdown box in the toolbar to add or delete rows as needed.
Subject ≥ 18 years of age	√			Helpful Hints: The inclusion/exclusion criteria can be cut and pasted from the protocol.
Males and females must practice effective measures of birth control	√			
Meets at least 4 of 11 ARC criteria for lupus	√			
Serum 25-OH vitamin D level ≤ 20ng/mL	√			
If on steroids, ≤ 20mg/day & stable for 4 weeks prior to screening	√			
If taking multivitamin, vitamin D dose ≤ 800IU daily and stable for last 3 months	√			
If on immunosuppressive meds, dose must be stable 3 month prior to screening	√			
<i>Exclusion Criteria:</i>				
Hx of receiving any supplement containing > 800IU of vitamin D 3 months prior to screen		√		
Serum Calcium > 10.4mg/dl at screen		√		
Urine calcium/creat ratio ≥ 0.8 at screen		√		
Hx of renal stones		√		
Hx of cancer		√		
Tx with rituximab within 12 mos. prior to screen		√		
Tx with digoxin		√		
Pregnancy or lactation		√		
Current Drug or ETOH abuse		√		
Consent obtained prior to study entry? Date Subject Signed <u>1/22/09</u>	√			Study blood sample drawn after subject signed consent
Were all required signatures and dates completed on the signature page?	√			
Most current consent form used CF # 2 Effective Period 11 /20/08 to 11/19/09	√			
<i>Subject identifier/cross index</i>	√			Using the subject identifier, can the subject's treatment, contact information and other study related test results be cross referenced?
<i>Eligibility maintained</i>				
[List tests, medications, etc.]				
Visit 2: Week 6 ± 7 days Did subject return for visit within ± 7 days? Physical and vitals checked? Concomitant meds checked? Drug compliance checked? Urine pregnancy test? Total selena-sledai score within range?	√ √ √ √ √ √			List any tests, evaluation scores, use of disallowed concomitant medications, etc., since the last visit that would disqualify subject's continued participation in the research.

