# Baseline Evaluation

Patient ID __ __ - __ **ID** __ - __ __ __
Date of Evaluation: **DOEDATE**

## SECTION I: ADVERSE EFFECTS

1. Does the patient currently have any of the following:

| | | Yes | No | | | Yes | No |
|---|---|---|---|---|---|---|---|
| a. | Fatigue **FATIG** | ☐ | ☐ | l. | Joint aches **JOINT** | ☐ | ☐ |
| b. | Trouble sleeping **TSLP** | ☐ | ☐ | m. | Diarrhea **DIARR** | ☐ | ☐ |
| c. | Headache **HEADACH** | ☐ | ☐ | n. | Vomiting **VOMIT** | ☐ | ☐ |
| d. | Dizziness **DIZZ** | ☐ | ☐ | o. | Upset stomach **USTOM** | ☐ | ☐ |
| e. | Depression **DEPRESS** | ☐ | ☐ | p. | Muscle pain **MUSPN** | ☐ | ☐ |
| f. | Weight loss (unintentional) **WGTLOSS** | ☐ | ☐ | q. | Rash **RASH** | ☐ | ☐ |
| g. | Decreased appetite **DAPP** | ☐ | ☐ | r. | Skin irritation **SKIN** | ☐ | ☐ |
| h. | Vision problems **VISION** | ☐ | ☐ | s. | Cold/Flu-like symptoms **FLU** | ☐ | ☐ |
| i. | Nausea **NAUS** | ☐ | ☐ | t. | Hair loss **HAIR** | ☐ | ☐ |
| j. | Upper abdominal pain **ADPAIN** | ☐ | ☐ | u. | Other **SYMOTH** | ☐ | ☐ |
| k. | Breathing problems **BREATH** | ☐ | ☐ | | If yes, specify: **SYMOTHS** | | |

2. Has the patient experienced any adverse events (reportable at the level of detail of an adverse event), since the last protocol visit? **AE**
   ☐ Yes *(Complete an Adverse Events form, if SAE complete the MedWatch form too)*
   ☐ No

## SECTION II: CONCOMITANT MEDICATIONS

1. Has there been any change (start or stop) in prescription medications since the last protocol visit? **CONMED**
   ☐ Yes ☐ No If Yes, update the Concomitant Medication Log
2. Is the patient currently taking any herbs, "natural" or herbal medications? **MEDHERB** ☐ Yes ☐ No☐ Unknown
3. Is the patient currently taking vitamins or minerals? ☐ Yes ☐ No ☐ Unknown **MEDVIT**
   If Yes, *(check all that apply)*
   ☐ Multi-vitamin **VITMULT** ☐ Vitamin D **VITD** ☐ Vitamin E **VITE** ☐ Folate **VITFOL** ☐ Iron **VITFE** ☐ Calcium **VITCA** ☐ Other **VITOTH**

## SECTION III: STUDY MEDICATION

Confirm acceptable method of contraception, when applicable

1. Was counseling on adherence provided during visit? **MATI**☐ Yes ☐ No
2. Was study drug dispensed according to randomization? ☐ Yes ☐ No **DRGDSP** If Yes, complete the Study Drug Log If No, complete the Off Protocol form

## SECTION IV: PHYSICAL ASSESSMENT

1. Height: **HGT** 1 ☐ inches 2 ☐ cm **HINCM** ☐ Not done (pre-treatment height is required)
2. Weight: **WGT** 1 ☐ lbs 2 ☐ kg **WLBKG** ☐ Not done
3. Blood pressure: **BPS** / **BPD** mmHg ☐ Not done

## SECTION V: BONE MINERAL DENSITY

1. Was a bone densitometry test performed prior to initiating therapy? ☐ Yes ☐ No **BONET**
   If Yes,
   a. Date of test *(mm/dd/yy)*: **BONEM** / **BONED** / **BONEY** ☐ Unknown
   b. Any evidence of osteopenia? ☐ Yes ☐ No ☐ Unknown **OSTPEN**
   c. Any evidence of osteoporosis? ☐ Yes ☐ No ☐ Unknown **OSTPOR**

## SECTION VI: BIOSPECIMENS **BIOSPEC**

1. Were samples obtained at this visit? ☐ Yes ☐ No **CLAB** **GEN** **IMM**
   If Yes, *(check all that apply):* ☐ NIDDK repository **NIDDKR** ☐ Central lab ☐ Genetics ☐ Immunology study

Data collector initials: **DCID** Date data collection completed *(mm/dd/yy)*: **DCM**/**DCD**/**DCY**