**Did the participant/subject take any dietary supplements before or during the study**?

Yes **(# of days**):

No (**Leave rest of form blank)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Dietary Supplement Generic Name** | **Brand/formulation** | **Indication** | **Dose** | **Frequency** | **Route** |
|  |  |  |  |  |  |
| **Multivitamin or Multivitamin/Mineral Supplements (list)** |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| **Individual Nutrients (Vitamins)** |  |  |  |  |  |
| biotin |  |  |  |  |  |
| folic acid |  |  |  |  |  |
| folinic acid |  |  |  |  |  |
| Vitamin B1 (thiamin) |  |  |  |  |  |
| Vitamin B2 (riboflavin) |  |  |  |  |  |
| Vitamin B3 (niacin) |  |  |  |  |  |
| Vitamin B6 (pyridoxine) |  |  |  |  |  |
| Vitamin B12 (cobalamin) |  |  |  |  |  |
| Vitamin C (ascorbic acid) |  |  |  |  |  |
| Vitamin D2 (ergocalciferol) |  |  |  |  |  |
| Vitamin D3 (cholecalciferol) |  |  |  |  |  |
| Vitamin E (tocopherol) |  |  |  |  |  |
| Vitamin K (phylloquinone) |  |  |  |  |  |
|  |  |  |  |  |  |
| **Individual Nutrients (Minerals)** |  |  |  |  |  |
| Calcium |  |  |  |  |  |
| Magnesium |  |  |  |  |  |
| Phosphorus |  |  |  |  |  |
| Selenium |  |  |  |  |  |
|  |  |  |  |  |  |
| **Other Supplements** |  |  |  |  |  |
| Arginine |  |  |  |  |  |
| Carnitine |  |  |  |  |  |
| Citrate |  |  |  |  |  |
| Citrulline |  |  |  |  |  |
| Coenzyme Q10 |  |  |  |  |  |
| Creatine |  |  |  |  |  |
| Lipoic acid (thioctic acid) |  |  |  |  |  |
| N-acetyl cysteine |  |  |  |  |  |
| Succinate |  |  |  |  |  |
| Uridne |  |  |  |  |  |
|  |  |  |  |  |  |
| **Other** |  |  |  |  |  |
| **Individual dietary supplements not listed above** |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| **Specially Compounded** **Formulations** (list ingredients) |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Select from the following for dietary supplement route of administration: Buccal, Inhaled, Intramuscular, Intravenous/Parenteral, Nasal, By Mouth, Enteral (via tube) Subcutaneous, Sublingual, Transdermal, Unknown, Other specify

## General Instructions[[1]](#endnote-1)

Collecting dietary supplements taken prior to the study in a defined time window (e.g., 30 days) is important when there may be potential interactions with the study intervention. Thus, a potential participant/subject may need to stop a dietary supplement prior to starting the study intervention (washout period). Furthermore, the study exclusion criteria may identify dietary supplements that cannot be taken during the study and so prior dietary supplements are identified to determine whether an individual may be eligible for the study.

Collecting concomitant dietary supplements taken during a study is also important for safety reasons. Some dietary supplements may interact with the study intervention and must not be taken during the study. Additionally, there may be some dietary supplements that are not known to interact with the study intervention and may be identified through an adverse event. It may be helpful to ask study participants/subjects or their caregivers to bring dietary supplements in their original containers to follow-up visits so that they can be more easily and accurately recorded on the CRF. Alternatively, the Dietary Supplement Label Data Base (<http://www.dsld.nlm.nih.gov/dsld/>) may be used with study participants/subjects to identify specific products purchased commercially. (Note: Because there are over 55,000 dietary supplement products on the market and new products continually appear, the data base may not contain the specific product you are seeking.)

In addition to this Dietary Supplements form, the Prior and Concomitant Medications form should be filled out at the baseline visit and every study visit/time point thereafter.

Important note: None of the data elements included on this CRF are considered Core (i.e., strongly recommended for all studies to collect). These data elements are supplemental and should be collected for clinical trials if the research team considers them appropriate for their study.

## Specific Instructions

*Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.*

* **Any Dietary Supplements?** – Choose one. If this question is answered YES then at least one prior/concomitant dietary supplement record needs to be recorded. Do NOT record study dietary supplements taken (if study has a dietary supplement intervention) on this form.
* **Dietary Supplement Generic Name** – Record the verbatim name (generic or trade name) of the dietary supplement(s) the participant/subject reports taking. Dietary supplements may be taken as a commercial multivitamin or multivitamin/mineral preparation (e.g. a children’s chewable multivitamin), individual nutrients (e.g., individual vitamins or minerals), or specially compounded formulations (e.g., a mitochondrial specific formulation which may be referred to as a “mitochondrial cocktail”).
* **Brand/formulation-**record the brand name and chemical form. For example, for calcium, indicate if it is calcium carbonate, calcium citrate, etc. For coenzyme Q10, note if it is ubiquinol, ubiquinone, idebenone, MitoQ, etc.
* **Indication** – Record the reason the participant/subject gives for taking the dietary supplement.
* **Dose** – Record the strength and units of the dietary supplement the participant/subject is taking.
* **Frequency** - Record how often the medication is being taken. .
* **Route** – Record the route of administration. Acceptable responses for Route are shown below the table.

1. This form includes elements from the NAMDC Dietary Supplements Patient Survey (Amel Karaa, MD; Sumit Parikh, MD). [↑](#endnote-ref-1)