**Did the participant 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)** | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| **Individual Nutrients (Vitamins)** | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank |
| Biotin | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Folic acid | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Methylfolate | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Folinic acid | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Omega-3 fatty acids | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Pyrroloquinoline quinone (PQQ) | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Vitamin B1 (thiamine) | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Vitamin B2 (riboflavin) | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Vitamin B3 (niacin) | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Vitamin B6 (pyridoxine) | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Vitamin B12 (cobalamin) | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Vitamin C (ascorbic acid) | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Vitamin D2 (ergocalciferol)  | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Vitamin D3 (cholecalciferol) | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Vitamin E (tocopherol) | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Vitamin K (phylloquinone) | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| **Individual Nutrients (Minerals)** | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank |
| Calcium | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Magnesium | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Phosphorus | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Selenium | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Zinc | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| **Other Supplements** | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank |
| Arginine | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Bicarbonate | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| L-Carnitine  | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Citrate | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Citrulline | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Coenzyme Q10 as ubiquinol | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Coenzyme Q10 as ubiquinone | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Creatine | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Alpha-Lipoic acid (thioctic acid) | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| N-acetyl cysteine | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Succinate | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Uridine | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Nicotinamide riboside | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Idebenone | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Dichloroacetate | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Polyphenols | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Beta carotene | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Brewer’s yeast | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Choline | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Chromium | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Cod liver oil | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| DHEA | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Echinacea | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Evening primrose | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Fiber | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Flaxseed | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Flax seed oil | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Ginkgo | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Ginseng | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Glucosamine/Chondroitin | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Lecithin | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Lycopene | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Melatonin | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Saw palmetto | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| St. John's wort | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Turmeric | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Wheat germ | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Soy protein powder | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Soy supplements | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Weight loss supplements | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| **Other** | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| **Individual dietary supplements not listed above**  | cell intentionally left blank | cell intentionally left blank | cell intentionally left blank | cell intentionally left blank | cell intentionally left blank |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| **Specially Compounded** **Formulations** (list ingredients) | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank | Cell intentionally left blank |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |
| Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site | Data to be filled in by site |

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:

Recorder Signature: Date:

## General Instructions[[1]](#footnote-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 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 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 Database (<https://ods.od.nih.gov/Research/Dietary_Supplement_Label_Database.aspx>) may be used with study participants 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 database may not contain the specific product the participant is 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 Module are classified as Core (i.e., strongly recommended for all Mitochondrial disease clinical studies to collect). All of the data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study.

Please see the Data Dictionary for element classifications.

## Specific Instructions

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

* **Visit date**: Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html); YYYY-MM-DD T:hh:mm:ss.
* **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 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 gives for taking the dietary supplement.
* **Dose** – Record the strength and units of the dietary supplement the participant is taking.
* **Frequency** – Record how often the dietary supplement is being taken.
* **Route** – Record the route of administration. Acceptable responses for Route are shown below the table.

## References

# NIH Office of Dietary Supplements. Dietary Supplements for Primary Mitochondrial Disorders. Bethesda, MD: National Institutes of Health Available from: <https://ods.od.nih.gov/factsheets/PrimaryMitochondrialDisorders-HealthProfessional/#coQ>

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