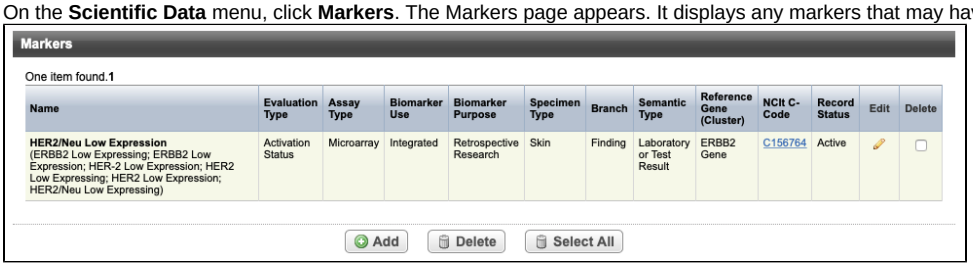
Adding Biomarkers - Include v4.5

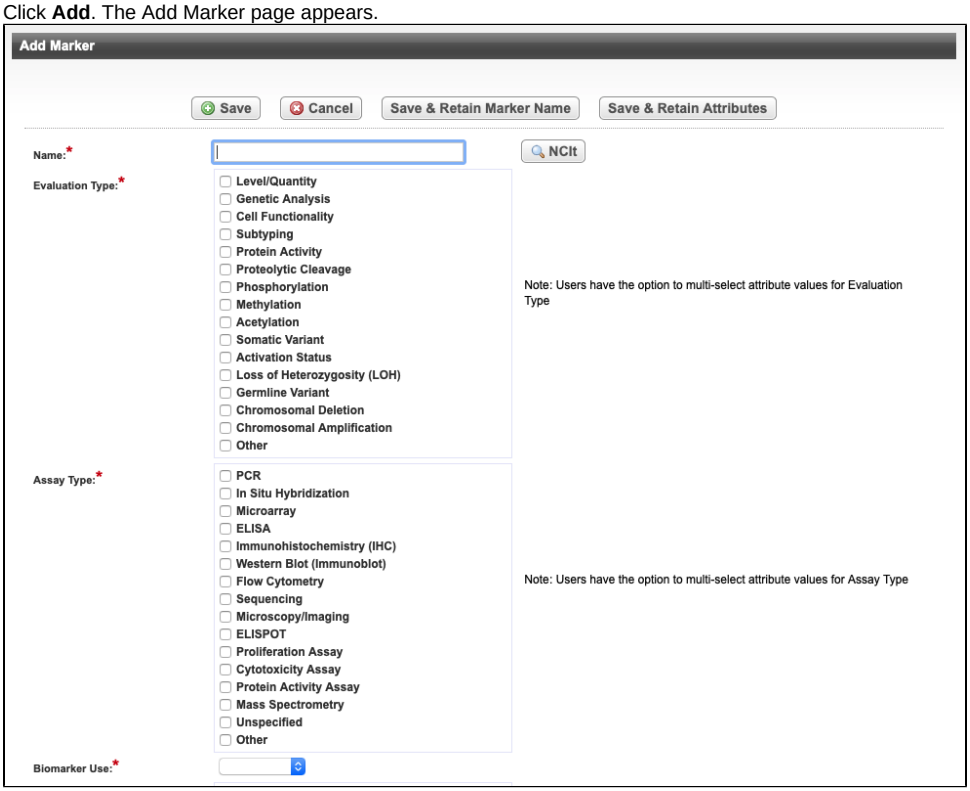
A trial can have multiple biomarker records. You can add them individually, or copy the marker records as you create them to enter variations of attributes (e.g., multiple assay types) for the same marker.

How to Abstract Markers

1. Search for the trial of interest. For instructions, refer to Searching for Trials in PA.
2. In the search results, click the NCI Trial Identifier link for that trial. The Trial Identification page appears.
3. On the **Trial Identification** page, check out the trial. For instructions, refer to Checking In and Checking Out Trials. (This checkout step is optional for Super Abstractors.)
4. On the **Scientific Data** menu, click **Markers**. The Markers page appears. It displays any markers that may have been recorded previously.



5. Click **Add**. The Add Marker page appears.



6. Search for and select the biomarker from NCIt by following the instructions in Searching for Biomarkers in NCIt.

> **You can enter a biomarker name directly**
>
> If you cannot find the biomarker indicated in the protocol document in NCIt, click **Cancel** to return to the **Markers** page, and enter the biomarker name directly in the **Name** field.

7. Select the appropriate attributes. The following table describes the fields. An asterisk (*) indicates a required field.

> You can select multiple attributes for **Evaluation Type, Assay Type**, **Biomarker Purpose**, and **Specimen Type**.
>
> If you select **Other** as an attribute for **Evaluation Type, Assay Type** or **Specimen Type**, you must enter text in the **Evaluation Type O ther Text** , **Assay Type Other Text** or **Specimen Other Text** fields respectively.

Trial Description	Instruction
Name*	Click **NCIt** and follow the instructions in Searching for Biomarkers in NCIt. If you cannot find the biomarker indicated in the protocol document in **NCIt**, enter the biomarker name directly in the **Name** field to create a placeholder value.
Evaluation Type*	Select the type of evaluation. Valid values include: • **Level/Quantity** • **Genetic Analysis** • **Cell Functionality** • **Subtyping** • **Protein Activity** • **Proteolytic Cleavage** • **Phosphorylation** • **Methylation** • **Acetylation** • **Activation Status** • **Loss of Heterozygosity (LOH)** • **Germline Variant** • **Somatic Variant** • **Chromosomal Amplification** • **Chromosomal Deletion** • **Other** • **Evaluation Type Other Text** (displayed and required if **Evaluation Type** = **Other**) ⚠ **Special instructions for "Other" text** If you select "**Other**," copy and paste the exact name of the evaluation (as written in the protocol) into the **Evaluation Type Other Text** box.
Assay Type* (CDE ID 64731)	Select the test type(s), the test name(s), or method(s) used to assess a specific marker. Valid values include: • **PCR** • **In Situ Hybridization** • **Microarray** • **ELISA** • **Immunohistochemistry** (IHC) • **Western Blot** (Immunoblot) • **Flow Cytometry** • **Sequencing** • **Microscopy/Imaging** • **ELISPOT** • **Proliferation Assay** • **Cytotoxicity Assay** • **Mass Spectrometry** • **TUNEL Assay** • **Real-Time RT-PCR (qRT-PCR)** • **HPLC** • **RT-PCR** • **Multiplex Immunoassay** • **Real-Time PCR (quantitative PCR)** • **Unspecified** - Details are not provided, and do not exist in the protocol document • **Other** - Other assay type ◦ **Assay Type Other Text** (displayed and required if **Assay Purpose** = **Other**) ⚠ **Special instructions for "Other" text** If you select "**Other**," copy and paste the exact name of the assay/method (as written in the protocol) into the **Assay Type Other Text** box.
Biomarker Use* (CDE ID 2939411)	Select the value that describes the assay use. Valid values include: • **Integral**. Tests that must be performed for the trial to proceed. Includes biomarkers evaluated for the purpose of eligibility/enrollment, stratification, and treatment assignment. • **Integrated**. Tests that are hypothesis-driven or measured to support objectives.

Biomarker Purpose* (CDE ID 2939397)	Select the value(s) that describes the reason or intention of the assay in the clinical study. Valid values include: • **Eligibility Criterion**. Biomarker measured to help determine if patients can participate in the research trial. • **Treatment Assignment.** Biomarker measured to help determine what treatment will be administered (or how much is given). • **Stratification Factor**. Biomarker measured to help classify patients into strata as part of the randomization process or for purposes of data analysis. • **Research**. Biomarker measured to support a hypothesis or trial objective which cannot be considered response assessment. • **Response Assessment**. Biomarker measured to help determine how well the treatment is working or to characterize the impact of treatment. • **Other (specify)**. • **Eligibility Criterion - Exclusion** • **Eligibility Criterion - Inclusion**
Specimen Type* (CDE ID 3111302)	Select the type(s) of sample. Valid values include: ○ **Serum**. Clear portion of the blood that remains after the removal of the blood cells and the clotting proteins. ○ **Plasma**. Fluid (noncellular) portion of the circulating blood, as distinguished from the serum that is the fluid portion of the blood obtained by removal of the fibrin clot and blood cells after coagulation. ○ **Blood** (includes Peripheral Blood Monocytic Cells [PBMCs]) ○ **Tissue** ○ **Urine** ○ **PBMCs** (Peripheral Blood Monocytic Cells) ○ **CSF** (Cerebrospinal Fluid) ○ **Bone Marrow** ○ **Saliva** ○ **Cryopreserved Cells** ○ **Buccal Mucosa** ○ **Feces** ○ **Unspecified** ○ **Other** ▪ **Specimen Type Other Text** (displayed and required if **Specimen Type** = **Other**). **Special instructions for "Other" text** If you select "**Other**," copy and paste the exact name of the specimen (as written in the protocol) into the **Assay Type Other Text** box.
Record Status	This field is populated by the PA system. When you save the biomarker information, the system sets the marker status to one of the following: • **Pending** - Indicates that a request for a new permissible value has been submitted [1] • **Active** - Indicates that the marker was listed in NCIt

a. The *Pending* status changes to *Accepted* once the Research Scientist enters corresponding NCIt C-Code in the Pending Markers Report. For information about updating the status of a marker, see Processing New Marker Requests.

8. Do one of the following to save the record:

- Scroll to the top or bottom of the page, and click **Save**.

- or -

- To create a new record for a different marker but with the same attribute selections, click **Save & Retain Attributes**. Then search for and select the biomarker from the NCIt, and save the record.

- or -

- To create a new record with the same marker name but with different attributes, click **Save & Retain Marker Name**. Then select the attributes for the next biomarker to be added, and save the record.

The Marker page displays the record(s) you created.