Prior to NCI approval of a NCI Formulary protocol, the institution is required to set-up the protocol to enable key data elements to be submitted to the clinical data reporting system and enable viewing of the submitted data via Theradex Web Reporting by the institution Clinical Investigator, NCI and the NCI Pharmaceutical Collaborator.

This process is in addition to the Institution/Clinical Investigator responsibilities for reporting all IND required documentation to the FDA in accordance with Sponsor responsibilities per 21 CFR Part 312.

Theradex staff is available for training and technical support throughout the set-up process. Theradex can be contacted via e-mail at ***Theradex Support******.*** Webex conference calls will be provided when needed.

Set-up of a study for data submission and viewing via Web Reporting requires the following:

* 1. Institution must contact ***Theradex Support*** at least 2 weeks prior to protocol approval to notify them of the upcoming NCI Formulary Protocol. Provide a contact person with detailed familiarity with the institutional case report forms (CRF). Theradex will work with the identified individual to work through the data mapping and data transfer process.
	2. Institution will provide a file defining the Identifier and Label for all CRFs and Fields, and specify the Dictionary for select fields and the associated list of values. The file will be XML and in a structure Theradex defines. If a Cancer Center does not use an Electronic Data Capture system and does not have CRFs, Theradex we will provide 6 standard CRF definitions to use.
	3. Institution will use the Theradex Data Mapping Utility to indicate which of their CRFs and Fields corresponds to each of the required data items, and to map Dictionary lists of values to Theradex standard dictionary values. No custom data derivations or mappings not already provided by the Data Mapping Utility will be provided.

* 1. Submission of study subject data will be performed weekly, with a full replacement of data, via FTP as a series of CSV files, one per CRF. The CSV columns are Study ID, Patient ID, and a column for each field on the CRF.
	2. Testing to ensure that Web Reporting is correctly representing study data and no errors in data mapping occurred.

**Data Fields and Mappings Required for Web Reporting:**

|  |
| --- |
| **A. PROTOCOL INFORMATION** |
| Protocol ID |
| Protocol Title |
| Investigational Agent Names |
| Treatment Assignment Codes and Descriptions |

|  |  |
| --- | --- |
| **B. ENROLLMENT DATA ITEMS** | **Dictionary Required?** |
| Patient ID |  |
| Treatment Assignment Code |  |
| Date of Intervention/Treatment Assignment |  |
| Registration Date |  |
| Birthdate |  |
| Gender | Yes |
| Race | Yes |
| Ethnicity | Yes |
| Performance Status | Yes |
| Disease Code |  |
| Registering Institution Code |  |
| Submitting Institution Code |  |
| Participant Subgroup Code (optional) |  |

|  |  |
| --- | --- |
| **C. DRUG ADMINISTRATION DATA ITEMS** | **Dictionary Required?** |
| Start Date |  |
| Course Number |  |
| Drug Name | Yes, if list of values |
| Dose |  |

|  |  |
| --- | --- |
| **D. ADVERSE EVENTS DATA ITEMS** | **Dictionary Required?** |
| Adverse Event Code |  |
| Adverse Event Term |  |
| Adverse Event Grade |  |
| Related | Yes |
| Serious (optional) |  |
| Date of Onset |  |
| Date Resolved (optional) |  |
| Ongoing (optional) |  |

|  |  |
| --- | --- |
| **E. OFF TREATMENT DATA ITEMS** | **Dictionary Required?** |
| Off Treatment Question (optional) | If field used |
| Date Off Treatment |  |
| Off Treatment Reason | Yes |
| Off Treatment Other Reason (optional) |  |

|  |  |
| --- | --- |
| **F. OFF STUDY DATA ITEMS** | **Dictionary Required?** |
| Date Off Study |  |
| Date of Death |  |
| Off Study Reason | Yes |
| Off Study Other Reason (optional) |  |

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| --- |
| **G. EFFICACY DATA ITEMS** |