**GUIDELINES FOR THE USE OF**

 **THE NCI, DIVISION OF CANCER PREVENTION**

**CASE REPORT FORM (CRF) TEMPLATES**

**Consortia 2012**

**Core CRF Templates**

**VERSION 10/15/2020**

TABLE OF CONTENTS

[INTRODUCTION 3](#_Toc35941988)

[GENERAL CONSIDERATIONS 4](#_Toc35941989)

[TREATMENT ASSIGNMENT CODE (TAC) AND TREATMENT ASSIGNMENT DESCRIPTOR (TAD) INFORMATION 5](#_Toc35941990)

[COMMON INSTRUCTIONS FOR CRF COMPLETION 6](#_Toc35941991)

[SCREENING 7](#_Toc35941992)

[DEMOGRAPHY 8](#_Toc35941993)

[REGISTRATION / RANDOMIZATION 10](#_Toc35941994)

[INFORMED CONSENT: SAMPLES AND INFORMATION FOR FUTURE HEALTH RESEARCH 11](#_Toc35941995)

[INTERVENTION ADMINISTRATION 12](#_Toc35941996)

[ADVERSE EVENTS (*2 templates*) 15](#_Toc35941997)

[OFF STUDY FORM 20](#_Toc35941998)

[ALCOHOL AND TOBACCO ASSESSMENT QUESTIONNAIRES 21](#_Toc35941999)

[Appendix A: SCHEDULE OF FORMS 22](#_Toc35942000)

[Appendix B: MDS CRF QUESTION CHECKLIST 23](#_Toc35942001)

## INTRODUCTION

The purpose of this document is to provide the Investigator, Site Coordinator and Data Management staff with instructions for using the Case Report Form (CRF) templates to create or revise a protocol-specific CRF set and to guide the completion of the template questions.

The DCP CRF templates referenced in this document are for use with DCP 2012 Consortia trials. The templates contain both mandatory and recommended content, and they can be used as the basis for developing the protocol-specific CRFs. The Guidelines’ instructions for completing these CRFs may also be modified by the CLO for consistency with the protocol-specific CRFs.

## GENERAL CONSIDERATIONS

* The Consortium Lead Organization (CLO) will submit the complete set of protocol-specific CRFs to the DCP Protocol Information Office (PIO) for review and approval.
* A number of questions in the CRF template set are identified as mandatory due to the requirements of the Minimum Data Set (MDS) and will need to be included when submitting the set of CRFs associated with a protocol (see Appendix B.) Please contact the DCP PIO or refer to the [MDS Instructions and Guidelines](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/MDS-Instructions-Guidelines.doc) for additional information regarding MDS reporting.
* It is strongly suggested that the protocol version and date, protocol title, form code with page numbers, and DCP CRF template version appear in the footer on every form. When changes are made to a form, all forms within the CRF set should be updated with the current revision’s version number and/or date.
* All questions included on the CRFs must use Common Data Elements (CDEs). DCP’s CDE Curator will work with each CLO to ensure all questions are CDE compliant.
* The protocol-specific CRF set should also include a Schedule of Forms submitted by the CLO with the CRF package. The Schedule of Forms describes which CRFs will be completed at each visit/event in a protocol-specific logical order (see Appendix A).
* Only the CLO can submit CRF revisions to DCP/PIO.
* The 2012 Consortia CLOs are not required to use the DCP 2012 Consortia CRF templates for their study CRFs. Institutional CRF templates or CRFs may be used as determined by the CLO.

## TREATMENT ASSIGNMENT CODE (TAC) AND TREATMENT ASSIGNMENT DESCRIPTOR (TAD) INFORMATION

* Each 2012 Consortia study will be issued a set of Treatment Assignment Codes (TACs.) TACs are codes representing a treatment assignment (i.e. unique study arm or dose level) used to uniformly group patients for treatment and analysis of the study.
* Each TAC will have a corresponding Treatment Assignment Descriptor (TAD), which defines the criteria for the TAC.
* A coding letter informing the sites of the TACs and TADs for each of the protocol-specific treatment assignments/interventions will be sent to the CLO/PI by the DCP PIO. The coding letter will be revised and redistributed as required to address any subsequent changes to the treatment assignment made during a protocol amendment.
* Each TAC will be associated with a set of dates that indicate when the TAC is assigned and when it is discontinued.

## COMMON INSTRUCTIONS FOR CRF COMPLETION

* CRFs should be completed according to the approved Master Data Management Plan (DMP) for each consortium.
* Please use a black or blue ink pen to record study information on the paper CRF.
* The information recorded on the CRF must be identical to the information found in the source documents (i.e., participant charts, laboratory result printouts).
* Do not place text where numbers are required unless there is an option to select Unknown, Not Applicable, etc.
* Numbers should be rounded to the nearest number of significant digits allotted for the data entry field.
* When checkboxes are provided on paper CRFs for responses, be sure to mark clearly the box with an X mark. Make sure the mark is not ambiguous.
* Corrections to the paper CRFs must be made in black or blue ink by crossing out the incorrect entry with a single horizontal line, placing the correct information next to the error and providing the initials of the person making the correction and date the correction was made next to the correction. Do not backdate. Do not use any type of correction fluid or tape, and do not erase any entries on the forms.
* Do not write in the margins of the paper CRFs.
* Avoid the use of abbreviations.
* Any participant who signs an informed consent, regardless of whether they received an intervention (which includes agent) or screening procedure, will be considered ON STUDY and must be reported in the MDS for that study. Refer to the [[DCP Consortia 2012: Baseline and Adverse Event (AE) Reporting Guidelines](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/DCP-C2012-Baseline-Adverse-Events-Guidelines.docx)](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/DCP-C2012-Baseline-Adverse-Events-Guidelines.docx?web=1) for additional information.

## SCREENING

* The purpose of this form is to gather screening information prior to registration and to track the screening status for each participant.

| **Question Group** | **Question** | **Instruction** |
| --- | --- | --- |
| **Screen 1** | **Screen 1 Date** | For studies that collect a Screen 1 Date: * When creating the study CRF template: specify the activities to be completed for Screen 1 on the SCREEN 1 line.
* When completing the study CRF for a participant: record the date the participant completed Screen 1 in the Screen 1 Date response field. If a given participant does not complete Screen 1, select the Not Applicable response option.

If the study is not collecting a Screen 1 Date:* Remove the entire question group from the study CRF.
 |
| **Screen 2** | **Screen 2 Date** | For studies that collect a Screen 2 Date: * When creating the study CRF template: specify the activities to be completed for Screen 2 on the SCREEN 2 line.
* When completing the study CRF for a participant: record the date the participant completed Screen 2 in the Screen 2 Date response field. If a given participant does not complete Screen 2, select the Not Applicable response option.

If the study is not collecting a Screen 2 Date:* Remove the entire question group from the study CRF.
 |
| **SCREENING OUTCOME** | **Does the participant meet all screening criteria?** | Check ‘Yes’ or ‘No’ to indicate whether the participant was a screen failure.If ’No‘, an Off Study form is required. If a SCREENING form is present in a study CRF set, this question must be included. |

## DEMOGRAPHY

* The purpose of this form is to gather demographic information at screening/baseline
* All questions on this form are mandatory.

| **Question** | **Instruction** |
| --- | --- |
| **Registering Consortium** | The designation of a consortium that will be officially recorded as the registering consortium for the study. For those studies not defined as interconsortia or INC, the field can be pre-populated with the name of the consortium conducting the study. If two or more consortia are jointly conducting the study, it is suggested that the question be implemented in check box format, listing each of the possible registering consortium, so the person completing the form can check the consortium to be credited with the registration of the participant.  |
| **Participant Method of Payment** | Text term for an entity, organization, government, corporation, health plan sponsor, or any other financial agent who pays a healthcare provider for the healthcare service rendered to a person or reimburses the cost of the healthcare service |
| **Gender** | Check ‘Male’, ‘Female’, ‘Unknown’ or ‘Unspecified’ as appropriate.Unknown = Not known, not observed, not recorded, or refusedUnspecified =Not stated explicitly or in detail |
| **Birth Date** | Record the participant’s date of birth. For MDS reporting, Birth Month and Birth Year must be collected. Collection of the Birth Day is optional. * Use either MM/YYYY date format or
* MM/DD/YYYY date format.
 |
| **Participant Zip Code** | The string of characters used to identify the five-digit zone improvement plan (ZIP) code and the four-digit extension code (if available) that represents the geographic segment that is a subunit of the ZIP code, assigned by the U.S. Postal Service to a geographic location to facilitate mail delivery; or the postal zone specific to the country, other than the U.S., where the mail is delivered |
| **Participant Country Code** | The three-digit code that represents the country where the addressee is located. Examples:* **CAN** (Canada)
* **CHN** (China)
* **ITA** (Italy)
* **MEX** (Mexico)
* **USA** (United States of America)
 |
| **Race** | Check one or more of the following standard NIH race categories: *(Note that there is no ’Other‘ category)***American Indian or Alaskan Native**: A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.**Asian**: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.**Black or African-American**: A person having origins in any of the black racial groups of Africa.**Native Hawaiian or Other Pacific Islander**: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.**Not Reported**: Race is not reported.**Unknown:**  Race is unknown.**White**: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa. |
| **Ethnicity** | Check one of the following standard NIH ethnicity categories:**Hispanic or Latino**: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.**Not Hispanic or Latino**: A person NOT meeting the definition for Hispanic or Latino.**Unknown**: Ethnicity is unknown.**Not Reported**: Ethnicity is not reported. |

## REGISTRATION / RANDOMIZATION

| **Question** | **Instruction** |
| --- | --- |
|  **Informed Consent Date** | Record the date the participant agreed to participation on the protocol by signing the informed consent document. Use MM/DD/YYYY date format.An Off Study form must be completed for all participants who signed an informed consent, including screen failures. |
| **Treatment Assignment Code (TAC)**  | The TAC (and TAD) information assigned to the Informed Consent should be defaulted to the value that is provided in the study’s coding letter. |
| **Treatment Assignment Descriptor (TAD)** |
| **Eligibility Status: Is the participant eligible for inclusion on this protocol?** | Check ‘Yes’ or ‘No’ to indicate whether the participant satisfies all of the eligibility criteria as stated in the protocol.If ’No‘, completion of an Off Study form is required.  |
| **Registration** | If the participant was not registered, check ‘Not Applicable’ and leave the Registration Date question blank. |
| **Registration Date** | Record the date when the participant was registered on the protocol. This date may be the same date that the informed consent was signed.  |
| **Randomization** | If this is not a randomized study, check ‘Not Applicable’ and leave the Date Participant Randomized and Randomization Number blank.  |
| **Date Participant Randomized** | If applicable, record the date a participant is assigned to a study intervention based on the protocol-specific randomization process.  |
| **Randomization Number** | If applicable, record the unique number assigned to a participant as a result of the randomization process.  |
| **Enrollment**  | If the participant was not enrolled, check ‘Not Applicable’ and leave the Enrollment Date question blank. |
| **Participant Enrollment Date** | The date the participant is accepted into the study. The study site may also be notified to the treatment arm and Study Participant Identifier on this date.  |

## INFORMED CONSENT: SAMPLES AND INFORMATION FOR FUTURE HEALTH RESEARCH

* The questions below must be completed for all participants who sign an informed consent including screen failures, and those participants who signed an informed consent prior to the implementation date of this data collection task.
* The CRF may be modified to include only those questions that are included in the protocol-specific informed consent. Additional questions in an accruing study site’s informed consent that pertain to the use of samples, specimens and/or information for future health research should be addedto this set of questions. This may include additional future specimen use questions required by the site’s local IRB.
* This CRF may be used when the participant responses to any or all of these questions are not collected on another CRF for the study.
* The participants’ responses to these questions must be submitted as part of the final clinical dataset for each study (Ref: [SOP 13 – Site Preparations for Study Closeout, Appendices A and B](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP13-Site-Prep-Closeout.docx).)

| **Question** | **Instruction** |
| --- | --- |
| **Informed Consent Version** | Record the version number of the informed consent signed by the participant  |
| **Informed Consent Version Date** | Record the version date of the informed consent signed by the participant. |
| **I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.** | Check ‘Yes’ or ‘No’ to indicate the participant’s response to the question. |
| **The information from my tobacco and alcohol use questionnaires may be used in future health research** |
| **My samples and related information may be kept in a Biobank for use in future health research.** |

## INTERVENTION ADMINISTRATION

* The purpose of this form is to gather information specific to the total intervention or treatment history of each participant. This includes information related to Washouts, Run-ins, and/or the planned Agent Administration. A separate question group, targeted to collect the information necessary for each intervention/history item, should be included on the form for each TAC and TAD that is assigned to the study.
* When using the template to create a study form please add additional rows or tables for each planned agent/placebo dosing step. Please see the example below for a study that has two agent intervention TACs, the second of which has two dosing steps:



| **Question Group** | **Question** | **Instruction** |
| --- | --- | --- |
| **Washout** | **Washout** | If the study has a protocol defined WASHOUT period, retain the WASHOUT question group on the study CRF. If it does not, remove the question group.When completing the form for a participant on a study that has a conditional Washout process, check NOT APPLICABLE if the washout is not required for the participant.  |
| **Treatment Assignment Code (TAC)**  | The TAC information assigned to the Washout period should be defaulted to the values provided in the study’s coding letter.When completing the CRF for a participant, record the date the participant was assigned to the Washout TAC (i.e. the TAC Start Date.) |
| **Treatment Assignment Descriptor (TAD)** |
| **TAC Start Date** |
| **Date Washout Started** | If applicable, record the date the participant started the washout period.  |
| **Date Washout Ended** | If applicable, record the date the participant completed the washout period.  |
| **Run-In** | **Run-In** | If the study has a protocol defined RUN-IN period, retain the RUN-IN question group on the study CRF. If it does not, remove the question group.When completing the form for a participant on a study that has a conditional RUN-IN process, check NOT APPLICABLE if the RUN-IN is not required for the participant.  |
| **Treatment Assignment Code (TAC)**  | The TAC information assigned to the Run-In period should be defaulted to the value that is provided in the study’s coding letter.When completing the CRF for a participant, record the date the participant was assigned to the Run-In TAC (i.e. the TAC Start Date.) |
| **Treatment Assignment Descriptor (TAD)** |
| **TAC Start Date** |
| **Date Run-In Started** | If applicable, record the date the participant started the Run-In period. |
| **Date Run-In Ended** | If applicable, record the date the participant completed the Run-In period.  |
| **Agent Administration** | **Agent Administration** | If Agent Administration is not required per the protocol, check ‘Not Applicable’. The table of additional TAC-specific questions should be left blank. |
| **Treatment Assignment Code (TAC)**  | Each of the TACs associated with Agent Administration should be defaulted to the values that are provided in the study’s coding letter. Each TAC should be listed above a separate instance of the dose questions. If the TAC is a compound TAC, multiple rows may be needed in the dose question table. Please refer to the “TREATMENT ASSIGNMENT CODE (TAC) AND TREATMENT ASSIGNMENT DESCRIPTOR (TAD) INFORMATION” section in this document for more information.When completing the CRF for a participant, record the date the participant was assigned to the given Agent Administration TAC (i.e. the TAC Start Date.) |
| **Treatment Assignment Descriptor (TAD)** |
| **TAC Start Date** |
| **Agent/Placebo** | Each of these agent dose questions should be defaulted to match the information captured in the agent intervention TADs. Please refer to the “TREATMENT ASSIGNMENT CODE (TAC) AND TREATMENT ASSIGNMENT DESCRIPTOR (TAD) INFORMATION” section in this document for more information. |
| **Dose** |
| **Dose Units** |
| **Route** |
| **Frequency** |
| **Date Agent Started** | Record the date the agent was started by the participant for the given TAC.  |
| **Date Agent Stopped** | Record the date the agent was stopped by the participant for the given TAC.  |

## ADVERSE EVENTS (*2 templates*)

* Two template AE forms are included in the CRF Core set. The first captures adverse event data in a tabular format allowing the capture of multiple adverse events on a single page. The second AE form only allows the capture of a single AE.
* All the questions on this form are mandatory for MDS reporting and must be included in the CRF set for every study.
* An adverse event is any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. An AE can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with participation in a study, whether or not related to that participation. This includes all deaths that occur while a participant is on a study. Use this form to document ALL adverse events experienced throughout the duration of the study including any run-in and follow-up periods, regardless of the relationship to study agent administration.
* For additional information regarding AE reporting, please refer to the *Consortia 2012 Adverse Event Reporting Guidelines*.
* If an adverse event is not reported during a visit, this should be documented in the source document but not an AE form.
* Record only one adverse event per line or per form. For example, nausea and vomiting must be recorded as separate adverse events.
* Record the appropriate codes for Severity, Attribution, Reported as SAE?, Action, and Outcome in the respective columns for each adverse event.
* Signs and symptoms that existed prior to the start of the study or that were reported during the baseline assessment are not considered adverse events. Baseline signs and symptoms that increase in grade or frequency while the participant is on study should be assessed for inclusion as adverse events. Refer to the “[DCP Consortia 2012: Baseline and Adverse Event (AE) Reporting Guidelines](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/DCP-C2012-Baseline-Adverse-Events-Guidelines.docx) for additional information.
* All clinically significant lab values documented after the baseline assessment must be reported as an adverse event.

| **Question** | **Instruction** |
| --- | --- |
| **At end of study only: check this box if participant experienced no adverse events** | At the end of the study, if the participant did not experience any adverse events throughout the study mark the ‘None’ box. All other fields on the form (except for the header information) should be blank. |
| **Adverse Event Reported Date** | Record the visit date at which the participant reported the adverse event.  |
| **Adverse Event Verbatim Term:** | Record the verbatim description of the adverse event as given by the participant in their own words such as “upset stomach”. |
| **MedDRA System Organ Class (SOC)** | The SOC is the highest level of the hierarchy in MedDRA and CTCAE (v4 and higher) and provides the broadest concept for grouping, retrieval, presentation and communication of AE data. It may represent disorders/manifestations in an anatomic or physiologic site/system (e.g., Gastrointestinal disorders), an etiology (e.g., Infections and infestations), a purpose/action (e.g., Surgical and medical procedures), or personal issues (e.g., Social circumstances). |
| **CTCAE (v 4.0)** | Record the CTCAE term (version 4.0 or as specified in the protocol) that most accurately reflects the verbatim term. In some cases, there is not a CTCAE term that accurately reflects the verbatim term. In those cases only, select the most appropriate SOC and then provide a comment in the general comment field to clarify any ambiguity in the verbatim term. |
| **Event Onset Date** | Record the complete date of the first observation of the adverse event.  |
| **Treatment Assignment Code (TAC)** | Record the TAC that was active at the time of the AE onset date. |
| **Event End Date** | Record the date that the event ended. If the complete end date is not known, at least the year must be provided. Report ‘UNK’ if the month and/or day is unknown.  |
| **AE Grade** | Each CTCAE term will have an associated grading scale for severity. Refer to the CTCAE Guideline and record the severity grade of the event by entering the appropriate grade for the coded CTCAE term. If a term is not coded, use the general CTCAE grading scale in the Guidelines.0 = Absent Adverse EventGrade 0 is universally defined as absence of Adverse Events or within normal limits or values1 = Mild Adverse EventAn adverse event that is asymptomatic; or involves mild or minor symptoms; or is of marginal clinical relevance; or consists of clinical or diagnostic observations alone; or for which intervention is not indicated; or for which only non-prescription intervention is indicated.2 = Moderate Adverse EventAn adverse event for which only minimal, local, or noninvasive intervention (e.g. packing, cautery) is indicated; or that limits instrumental activities of daily living (ADLs, e.g., shopping, laundry, transportation, or ability to conduct finances).3 = Severe Adverse EventAn adverse event that is medically significant but not life-threatening; or for which inpatient care or prolongation of hospitalization are indicated; or that is an important medical event that does not result in hospitalization, but may jeopardize the patient or may require intervention either to prevent hospitalization, to prevent the AE from becoming life-threatening or causing death; or that is disabling; or that results in persistent or significant disability, incapacity, or limitation of self-care activities of daily living (ADLs, e.g., getting in and out of bed, dressing, eating, getting around inside, bathing, or using the toilet).4 = Life-threatening Adverse EventAn adverse event that has life-threatening consequences; for which urgent intervention is indicated; that puts the patient at risk of death at the time of the event if immediate intervention is not undertaken; or that causes blindness or deafness.5 = Death Related to Adverse EventThe termination of life associated with an adverse event. |
| **AE Attribution** | Record the investigator’s assessment of the relationship between the event and the study agent by entering the appropriate code in the column as defined in the general guidelines. UnrelatedUnlikelyPossibleProbableDefinite |
| **Reported as SAE?** | Record whether the adverse event was reported as a serious adverse event (SAE) by entering the appropriate code in the column. Use the following list of values. 1 = Yes 2 = NoIf the event is an SAE, all relevant information must be reported to the appropriate DCP personnel and documented on the paper SAE report according to the guidelines outlined in the protocol. |
| **Action** | Record the action taken as a result of the adverse event by entering the appropriate code in the column. Use the following guidelines: |
| 1 = Agent Withdrawn | The agent was stopped for any reason |
| 2 = Agent Dose Reduced | The dose of the agent was lowered from the original dose or other dose reductions. |
| 3 = Agent Dose Increased | The dose of the agent was increased from a previous lower dose but not increased more  |
| 4 = Agent Dose Not Changed | The dose of the agent remains the same as originally allowed. |
| 5 = Unknown | Any change in the dose of the agent is unknown at the time of the event.  |
| 6 = Not Applicable | A change in the dose is not applicable. |
| If Action is recorded as ‘Agent Dose Reduced’ (2) or ‘Agent Dose Increased’ (3), relevant information must be captured within the source documents or participant chart to document additional details regarding the agent dose change. |
| **Outcome** | Record the outcome of each event by entering the appropriate code in the column. Use the following list of values:1. Recovered/Resolved 2. Recovering/Resolving3. Not Recovered/Not Resolved4. Recovered/Resolved with Sequelae5. Fatal6. Unknown |
| **Dropped due to** **AE?** | Record if the participant was taken off study (“dropped” from the study) due to the given AE. Note: The responses to this question (1 = Yes, 2 = No) will be compared against the REASON OFF STUDY on the Off Study form. If ’AE/SAE’ is selected for the reason the participant went off study, at least one AE must be identified as the reason why the participant dropped. |
| **Comments** | Record any data/comments related to the adverse event that are not captured in the other fields but are considered pertinent to the adverse event.For MDS reporting: The contents of the COMMENTS field should only be included in the MDS submission file for AEs that are coded to CTCAEv4 “Other, Specify” terms. Please contact the DCP PIO or refer to the MDS Instructions and Guidelines for additional information. |

## OFF STUDY FORM

* The purpose of this form is to document participant completion, removal from or dropout from the study.
* Follow-up is defined as the protocol-specific evaluation period between the end of the last dose of agent taken and off study. If the study has no defined follow-up period, the Date On Follow-up and Date Off Follow-up questions should be removed from the study CRF.
* This form must be completed for all participants who sign an informed consent, including screen failures.

| **Question** | **Instruction** |
| --- | --- |
| **Date On Follow-up** | Record the date the participant began follow-up. The follow-up period should be defined in the protocol. If the complete on follow-up date is not known, at least the year should be provided. Report ‘UNK’ if the month and/or day is unknown.  |
| **Date Off Follow-up** | Record the date the participant completed follow-up. The follow-up period should be defined in the protocol. If the complete off follow-up date is not known, at least the year should be provided. Report ‘UNK’ if the month and/or day is unknown. |
| **Date Off Study** | Record the date the participant completed the study or is no longer participating in the study for any reason. If there is a defined follow-up period included in the protocol, the Date Off Study must be the same as or after the Date Off Follow-up.  |
| **Date of Last Contact** | Record the last date when there was any form of communication with the participant. This may be the same as or before the Date Off Study.  |
| **Agent End Date** | Record the last date the participant took the study agent. If the complete date is not known, at least the year should be provided. Report ‘UNK’ if the month and/or day is unknown. |
| **Reason Off Study** | Mark only one reason why the participant went off study. If the reason is other than **Completed Study**, provide an explanation in the “Comments” field. The possible off study reasons are:Adverse EventDeath Disease ProgressionLost to follow-upOther, specifyParticipant WithdrawalParticipant Refused Follow-upPhysician DecisionProtocol Defined Follow-up CompletedProtocol ViolationStudy Complete Ineligible |
| **Comments** | The text that describes the reason the participant went off study |

##

## ALCOHOL AND TOBACCO ASSESSMENT QUESTIONNAIRES

Questionnaires assessing a participant’s tobacco and alcohol use will be administered at baseline and at the end of study to determine the potential impact of tobacco and alcohol use on 1) treatment toxicity and symptom burden, and 2) the efficacy of treatment intervention. These standardized assessments will aid in understanding the potential relationship between the use of these products and clinical endpoints or cancer prevention biomarkers.

CIRB/IRB review of these CRFs is required. All CRFs must be included in the final version of the protocol submitted for CIRB/IRB review. Additional materials may be required as part of this submission as specified in the protocol. See “Protocol Development” at <https://prevention.cancer.gov/clinical-trials/clinical-trials-management/protocol-information-office/pio-instructions-and-tools/2012-consortia>

These CRFs should be included in both the protocol and the CRF set or SVAR submitted for a study.

**General Instructions**

* Data collection will be required for all 2012 Consortia studies from cycles 8 and 9, and studies not yet “Active” as of March 22, 2017. These data may be collected on a voluntary basis for ongoing studies.
* Data will be collected at baseline and the end of every study.
	+ Data may also be collected at follow-up visits as determined by each protocol.
* CRFs may be modified to include additional data elements. However, all studies must collect the basic core elements included in these CRFs.
* Methods for completing questionnaires are dependent on the institutional preference and method of data collection
	+ The CRFs may be completed by either the Site Staff or the participant at the time of the designated visit.
* Instructions for completing the CRF questions are included within the CRFs
	+ Skip logic is noted when applicable
	+ Numbers should be entered as whole numbers, not as a range or fraction of a number
* Data will be submitted as part of the final clinical data set for the study as specified in [SOP 13: Site Preparations for Study Closeout, Appendix A](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP13-Site-Prep-Closeout.docx).

## Appendix A: SCHEDULE OF FORMS

* The purpose of the schedule of forms is to create an “at-a-glance” guide that identifies which forms are to be completed at various points within the protocol.
* The template should be modified to reflect the forms and time frames specific to an individual protocol.
* All forms should be listed in the left most column and all study visits (or events, if applicable) should be listed across the top of the table.

**EXAMPLE**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Pre-Intervention** | **Intervention** | **Follow-Up** |  |
| **Form/Visit** | **Screening****Visit** | **Randomization Visit** | **Month 1 Visit** | **Month 2 Visit** | **Follow-Up 1** | **Early Termination Visit** |
| Screening | X |  |  |  |  |  |
| Demography | X |  |  |  |  |  |
| Registration / Randomization | X |  |  |  |  |  |
| Randomization |  | X |  |  |  |  |
| Alcohol and Tobacco Assessment |  | X |  |  | X |  |
| Intervention Administration |  | X |  |  |  |  |
| Adverse Events |  | X | X | X | X | X |
| Off Study |  |  |  |  | X | X |

## Appendix B: MDS CRF QUESTION CHECKLIST

* The following questions are required for Minimum Data Set (MDS) reporting and are expected to be included in each study’s CRF set. If any question is not included in a CRF set, the CLO must provide the reason the question is not needed in the CRF set and/or note the source of the data.
* These are examples of valid reasons why a given MDS question would not be included in a study CRF set:
	+ ***Not Applicable:*** *Randomization Date is not needed as this is a non-randomized trial*
	+ ***Mapped Question****: A separate question to collect Participant Enrollment Date is not needed for our study as that date will always be the same as the Registration Date.*
	+ ***Derived Question:*** *The Eligibility Status question has not been included as the study’s CRFs have individual questions for each of the eligibility criteria. Our system will read in each eligibility response and then derive a response for Eligibility Status based on those separate responses.*
* This checklist should be submitted along with a CRF submission to guide reviewers in CRF review for consistency with the MDS reporting requirements.

| **MDS Collection Table** | **Question** | **Additional Information** | **Included?** | **If not included, provided explanation** |
| --- | --- | --- | --- | --- |
| Protocol | DCP Protocol Number  | Expected to be present on every study CRF | ☐ |  |
| Participant; Race; AE  | Participant Identifier | Expected to be present on every study CRF | ☐ |  |
| Participant | Participant Zip Code |  | ☐ |  |
| Participant | Participant Country Code |  | ☐ |  |
| Participant | Participant Birth Date |  | ☐ |  |
| Participant | Participant Gender |  | ☐ |  |
| Participant | Participant Ethnicity |  | ☐ |  |
| Participant | Informed Consent Date |  | ☐ |  |
| Participant | Screen 1 Date |  | ☐ |  |
| Participant | Screen 2 Date |  | ☐ |  |
| Participant | Registration Date |  | ☐ |  |
| Participant | Randomization Date | Not expected to be present in CRF set for non-randomized trials | ☐ |  |
| Participant | Eligibility Status |  | ☐ |  |
| Participant | Participant Enrollment Date |  | ☐ |  |
| Participant | Registering Consortium |  | ☐ |  |
| Participant | Registering Institution |  | ☐ |  |
| Participant | Participant Method of Payment |  | ☐ |  |
| Participant, AE | Treatment Assignment Code (TAC) |  | ☐ |  |
| Participant | Date Agent Started |  | ☐ |  |
| Participant | Agent End Date |  | ☐ |  |
| Participant  | Off Study Date |  | ☐ |  |
| Participant  | Off Study Reason |  | ☐ |  |
| Participant  | Reason Off Study Other, Specify |  | ☐ |  |
| Race | Participant Race |  | ☐ |  |
| AE | Adverse Event (AE) Verbatim Term |  | ☐ |  |
| AE | MedDRA System Organ Class (SOC) |  | ☐ |  |
| AE | CTCAE Term |  | ☐ |  |
| AE | AE Grade |  | ☐ |  |
| AE | AE Attribution |  | ☐ |  |
| AE | Reported as SAE? |  | ☐ |  |
| AE | Event Onset Date |  | ☐ |  |
| AE | Event End Date |  | ☐ |  |
| AE | Dropped due to AE? |  | ☐ |  |
| AE | Outcome |  | ☐ |  |
| AE | AE Comments |  | ☐ |  |