National Cancer Institute
Division of Cancer Prevention

Requirements for PROGRESS REPORTS: Phase I & II Clinical Trials of Chemoprevention Agents *Instructions & Templates*

The following document presents the information needed for completing the quarterly and annual progress reports. The information is presented in the order in which the progress report should be compiled (i.e., cover page, summary, tables). In some cases the information is provided on a template form which can be downloaded and used for the submission. In other areas the required information is presented in a narrative format which details each section of the progress report and the content required in that section. Ensure that all pages use a running footer indicating NCI contract number and date of submission.

Format for Progress Report Document:

Section 1: Cover page

Section 2: Summary of Progress

Section 3: Accrual Summary (table)

Section 4: Cumulative Subject Accrual Data (table)

Section 5: Subject Demographic Information (table)

Section 6: Cumulative Adverse Event Data (table)

Note: Sample Progress Report format and table templates begin on the next page.

DCP Internet Supplemental Information
Appendix I

Section 1:
PROGRESS REPORT COVER PAGE

Title	The title of the study or protocol as it appears in contract
Date of Report	The date the report was submitted to the Project Officer
Reporting Period	The time period (*i.e., 4/1/98 – 4/30/98)* presented in the report
Principal Investigator	The full name and title of the Principal Investigator.
Principal Co-Investigator (s)	The full name(s) and title of the Co-Investigator(s).
NCI Protocol Number	The number assigned to the protocol by NCI (*e.g.*N01-CN-85008)
Local Protocol Number	The institution protocol number for the referenced study.
IRB Protocol Number	This may be the same as the institution's protocol number for some sites.
Study Initiation Date	Date study was initiated at site
Protocol Amendments and Dates	Begin with the most recent amendment number and date.
IND Number and Holder	The IND number assigned by the FDA and the Sponsor of the IND under which the protocol is submitted.
Institutions	All institutions at which subjects may be or have been enrolled.
Prepared for	Name and address of Project Officer at NCI. (See below)
Prepared by	Individual responsible for preparing this report, including title, address, and telephone number.

Mailing Instructions: DCP Project Officer named in contract
Attn: Protocol Information Office
Division of Cancer Prevention
National Cancer Institute

Regular Mail: Executive Plaza North, Suite 300E, MSC 7340
Bethesda, MD 20892-7340

Express Mail: 6130 Executive Blvd., Suite 300E
Rockville, MD 20852

Section 2
SUMMARY OF PROGRESS

INSTRUCTIONS: Use this format to describe activities for the defined reporting period. Summary page shall accompany each progress report.

Title of the Study	The title of the study or protocol as it appears in contract or grant description.
Study Purpose	A one-sentence description of the study.
Study Population	Brief description of subject population under study.
Treatment Groups	A brief description of all treatment groups and the duration of study agent (active and/or placebo) exposure.
Number of subjects planned/accrued	Discuss actual accrual verses planned accrual
Study Status	Status may be (as applicable): screening – reviewing subjects for inclusion in study; ongoing – subjects are receiving the study agent(s) or in a run-in period; completed – last subject has completed treatment and all data have been collected by the site; and follow-up – subjects on follow-up.
Study Results to Date	A summary of study results or interim results (when available) for the reporting period.
Problem Areas	This section should address any problems encountered since the previous reporting period. Describe actions used to resolve the problems and the results of these actions.
Action, Dose-Response, or Agent Bioavailability Data	A summary of data regarding the actions, dose-response, or bioavailability of agent(s) (when available, *i.e.*, non-blinded studies) for the reporting period, if available.
Protocol Amendments	List the following information for each protocol revision, consent revision, and protocol amendment: • Description and date (i.e. Amendment #2, dated 6/15/99) • Date approved by NCI, DCP • IRB submission date • IRB approval date • Date of amendment activation
Exceptions/Deviations	Document rationale for action, status, and NCI response.

Section 3
ACCRUAL SUMMARY TABLE

The Accrual Summary Table will be completed for each reporting period and for the annual report. Each table will reflect data from the current reporting period as well as cumulative data which represents data from study initiation through completion of the current quarter. The number reported for the current quarterly reporting period should represent the accrual activity as of the last day of the quarter.

Definition of terms:

Number Screened Number of subjects evaluated for potential admission to the protocol. If an invasive protocol procedure (*i.e.*, blood draw) is performed to determine eligibility, an informed consent describing the procedure must first be signed by the subject.

Number Enrolled Number of subjects who meet eligibility criteria and have given consent to participate in the study.

Number On Study This number is the sum of the enrollment sub-categories listed below.

Number on Run-In (if applicable) – Number of subjects in the run-in period, when placebo only is administered on the treatment schedule in order to determine if subjects will be compliant with the dosing regimen.

Number Currently Receiving Treatment – Number of subjects receiving the study agent(s) as of the end of the report period.

Number on Follow-up (if applicable) – This category applies only to those protocols which require a defined 'follow-up' period after completion of the prescribed agent for observing safety and continuation of effect. Further classify each subject into one of the following categories:

Completed Treatment – the number of subjects who completed receiving the study agent(s) by the end of the current reporting period (normal completion).

Stopped Treatment Early – indicate the number of subjects who stopped the treatment before the intervention phase was completed, but continued on to the 'follow-up' phase of the protocol.

Other – Identify the number of subjects whose treatment may be temporarily held/suspended (toxicity) with the aim of restarting the agent.

Number Off Study Represents the total of the Off Study categories listed below:

Number Completed Study – Number of subjects who finished the intervention as described by protocol and if applicable, also completed the protocol-defined follow-up period.

Number Dropped Out (Includes Death) – Number of subjects who terminated the study early based on the protocol completion criteria. For example, subjects who met eligibility criteria, signed the informed consent, were not considered screen failures, were given patient identification numbers or randomized, were given treatment but did not complete follow-up and terminated the study early, are considered "dropped from the study."

Number of Deaths – Total number of subjects who died during the study period, including follow-up. The total number of deaths is further broken down into the following categories:

Definitely related to agent

Possibly related to agent

Unrelated to agent

The Accrual Summary Table is located on the following page

Section 3:
ACCRUAL SUMMARY TABLE

Protocol Title:
NCI Protocol Number:
Dates of Reporting Period:

	Last Day of Report Period		Cumulative Period	
Enrollment Category	**Subtotal**	**Total**	**Subtotal**	**Total**
Number Screened				
Number Enrolled				
Total Number On Study:		(sum A,B,C)		
A. Number On Run-in (if applicable)				
B. Number Currently Receiving Treatment				
C. Number on Follow-up (if applicable)	(sum C.1, C.2,C.3)			
C.1 Number Completed Treatment				
C.2 Number Stopped Treatment Early				
C.3 Other				
Number Off Study:		(sum D,E,F)		
D. Number Completed Study				
E. Number Dropped Out				
F. Number of Deaths:	(sum F.1, F.2,F.3)			
F.1 Definitely Related to agent				
F.2 Possibly Related to Agent				
F.3 Unrelated to Agent				

Section 4
Instructions for Completing
CUMULATIVE SUBJECT ACCRUAL TABLE

General Instructions: This table will be completed at the intervals specified by the contract (monthly, quarterly, etc.) and will be submitted in both hard copy and disc format. Additional categories may be added to this table as relevant to the study. The following list defines the data to be entered into each field of the Cumulative Subject Accrual Table:

Subject ID:	The unique numeric study identification number for the subject (not their hospital record number, Social Security number, or randomization number).
Initials	Subject's initials
Date of Birth	Use consistent format (*e.g.*, month/day/year)
Gender	Either M for male or F for female
Race or Ethnic Background	Code as follows: 1=American Indian or Alaskan Native 2=Asian or Pacific Islander 3=Black, not of Hispanic Origin 4=Hispanic 5=White, not of Hispanic Origin 6=Other or Unknown
BSA	Body surface area, if applicable. Define any calculations used to obtain m^2.
Run-In Start	Date that pre-randomization placebo trial period (run-in) began
Run-In End	Date that placebo trial period (run-in) ended.
Study Agent Dose	Include dosage, units and frequency (*e.g.*, 200 mg bid).
Date Enrolled	Date (month/day/year) the subject signed the Informed Consent.
Start Study Agent	Date (month/day/year) subject received first dose of the agent/placebo while on study. This category includes any placebo run-in period.

End Study Agent — Date (month/day/year) subject received last dose of the agent/placebo.

Date on Follow-up — Date (month/day/year) that the post-treatment, protocol-specific observation period began.

Date off Follow-up — End (month/day/year) of post-treatment, protocol-specific observation period.

Date Off Study — Date subject completed the study (treatment or treatment with follow-up) or the last date of contact.

Reason Off Study — If subject is off study, specify as:
1=Completed
2=Adverse Event
3=Lost to Follow-up
4=Death
5=Other (specify)

The Cumulative Subject Accrual Table is located on the next page.

Section 4

CUMULATIVE SUBJECT ACCRUAL TABLE

Title of Protocol

Reporting Period

Subject ID	Initials	Date of Birth	Gender	Race[1]	BSA (m^2)	Date Run-in Started	Date Run-in Ended	Study Agent Dose (units & frequency	Date Enrolled	Date Study Agent Started	Date Study Agent Ended	Date on Follow-up

Race Codes: 1 - American Indian or Alaskan Native

[2] Reason Off Study: 1 - Completed

2 - Asian or Pacific Islander

2 - Dropout

due an AE

3 - Black, not of Hispanic Origin

3 - Lost to follow-up

4 - Hispanic

4- Death

5 - White, not of Hispanic Origin

5- Other

(specify)

6 –Other

Section 5

DEMOGRAPHIC INFORMATION TABLE

Title of Protocol
Reporting Period

Instructions: Indicate the actual accrual numbers for the cumulative period (current reporting period plus all previous reporting periods) of males and females in each of the categories.

Gender and Race: Cumulative Accrual

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female							
Male							
Total							

Age Distribution Table: Cumulative Accrual

	Age #10	Age 11–20	Age 21–30	Age 31–40	Age 41–50	Age 51–60	Age 61–70	Age 71–80	Age $81	Total
Female										
Male										
Total										

Section 6
Instructions for Completing
CUMULATIVE ADVERSE EVENT TABLE

GENERAL	Update this table at the intervals specified in the contract. If information is unavailable, please use NA (not available) for that box.
	The following items represent the minimum data requirements to be reported. Present information in a table format. This report represents cumulative data, so new subject entries should be added to the existing list for each reporting period.
Subject ID	The unique subject identification number assigned for this protocol. (not medical record number, Social Security number, or randomization number).
Initials	The subject's initials (First,Last)
Agent Dose at AE	The dose of study agent the subject was receiving at the time of the event. The unit (*e.g.*, mg) and frequency (*e.g.*, bid) may be specified within the parentheses in the column header or within the table.
Duration of Agent prior to event	The number of days the subject received the study agent before experiencing the event. Calculated as the event start date minus the agent start date, plus 1 (one) day.
Event	The event (*e.g.*, nausea, headache, pain in hands, *etc.*) as described verbatim by the subject, and collected/reported by the site personnel. Do not combine several events in one record or entry. List each event separately. Note: *Progression of Cancer*: Progression of an existing cancer or occurrence of a new cancer in the target organ is not considered an adverse event. Please refer to definitions in protocol document. *Procedure/diagnostic exam*: An invasive procedure (*e.g.* diagnostic exam, surgery) is not an Adverse Event. However, adverse events occurring in the process of performing a procedure, or AE(s) that require a procedure for follow-up, are reportable (*e.g.*, rectal bleeding resulting from colonoscopy).

Event Grade	Refer to NCI Common Toxicity Criteria Version 2.0 for grading of toxicities (http://ctep.info.nih.gov/CTC3/default.htm)
Event Start Date	Specify date (mm/dd/yy) that event started. The minimum data requirement in this field is month and year.
Event Stop Date	Specify date (mm/dd/yy) that event ended. The minimum data requirement in this field is month and year.
Event Recovery Status	Indicate whether the adverse event is Resolved (R) or Not Resolved.(NR) at the time of this report.
Relation to Agent	Principal Investigator's assessment of relationship between event and study agent. The following terms should be used: Not related Unlikely Possible Probable Definite
Drop Out Due to AE?	Specify whether subject dropped out of the study due to an adverse event. Yes=Y; No=N
SAE (Y or N)?	Indicate if the adverse event qualifies as a Serious Adverse Event (SAE). ICH Guideline E2A defines an SAE as an adverse experience, occurring at any dose, that includes any of the following: • results in death • is life threatening • requires inpatient hospitalization or prolongation of existing hospitalization • results in persistent or significant disability/incapacity • is a congenital anomaly/birth defect. Refer to NCI guidelines for reporting these events.

Section 6

CUMULATIVE ADVERSE EVENT (AE) TABLE

Title of Protocol
Reporting Period

Subject ID	Initials	Agent Dose at AE (Units/ frequency)	Duration of Agent prior to Event (days)	Event	Event Grade[1]	Event Start Date	Event Stop Date	Event Recovery Status	Relation to Agent	Drop Due to AE? (Y/N)	SAE (Y/N)

[1] Refer to NCI guidelines for grade assessment.