Guidelines for Completing the ITPR Excel Workbook

After the ITPR data is submitted to DCP, it goes through several data quality checks. The following guidelines must be adhered to when completing the ITPR Excel worksheets in order to avoid data discrepancies that will prohibit the data from being loaded into the database. The list below represents the guidelines for each worksheet that is to be completed within the Excel workbook.

Guideline Number	Worksheet	Guideline Instruction
1	On all worksheets	NCI Protocol Number must be valid. It cannot be blank for any row that contains data and it must exactly match the value in DCP's database. Please copy the value Westat provides in the first row to all subsequent rows on the template. (TLC #1)
2	On all worksheets	Reporting Period Start Date must be a valid reporting period as stated in the contract. It cannot be blank for any row that contains data and it must exactly match the value in DCP's database. Please copy the value Westat provides in the first row to all subsequent rows on the template. (TLC #2.1)
3	On all worksheets	Reporting Period Start Date cannot have already been submitted and processed. (i.e. each quarter has unique period dates) (TLC #2.2)
4	On all worksheets	Reporting Period End Date must be a valid reporting period as stated in the contract. It cannot be blank for any row that contains data and it must exactly match the value in DCP's database. Please copy the value Westat provides in the first row to all subsequent rows on the template. (i.e. each quarter has unique period dates) (TLC #3.1)
5	On all worksheets	Reporting Period End Date cannot have already been submitted and processed (TLC #3.2)
6	Progress Comments	If a Comment Type is selected, a value must be present in the Comment field of that data row. (TLC #4.1)
7	Progress Comments	Comment Type must be chosen from the drop-down list. The values available are: Accrual, Agent Supply, Staffing, Other, and Correction (TLC #4.2)
8	Progress Comments	If a value is present in the Comments field, there must be a Comment Type must be given for that data row. (TLC #5)
9	Cumulative Participant Accrual and AEs	Registration Number and Randomization Number must be less than 10 characters long, and they must not consist of patient specific values (i.e. Data of Birth, Initials, etc.) (TLC #10)
10	Cumulative Participant Accrual	If the study was approved before 01/01/2002, it must use the "Old" system Gender/Minority Reporting. The Old System does not use a separate Ethnicity term; therefore the ITPR Ethnicity field must remain blank. (TLC #7)
11	Cumulative Participant Accrual	If the study was approved after 01/01/2002, it must use the "New" system Gender/Minority Reporting. The New System uses a separate Ethnicity term; therefore the ITPR Ethnicity field must be given a value from its drop-down list. (TLC #8)

Guideline Number	Worksheet	Guideline Instruction
12	Cumulative Participant Accrual	The following fields are mandatory on the Cumulative Accrual Worksheet: Reporting Period Start Date, Reporting Period End Date, NCI Protocol Number, Registration Number, Registration Date, Birth Year, Gender, Race, Randomization Number (TLC #9)
13	Cumulative Participant Accrual	The Reporting Period End Date must be greater than or equal to all other dates in the report (TLC #11)
14	Cumulative Participant Accrual	A patient's Registration Date must be earlier than (or the same as) all other dates associated with the patient. (i.e. Randomization Date, Begin Run-In Date, Start Agent Date, etc.) (TLC #12)
15	Cumulative Participant Accrual	If an End Run-In Date is given for a patient's record, a Begin Run-In Date must also be given. (TLC #13)
16	Cumulative Participant Accrual	A Begin Run-In Date must be earlier than (or the same as) the End Run-In Date (TLC #14)
17	Cumulative Participant Accrual	If an End Study Agent Date is given for a patient's record, a Start Study Agent Date must also be given. (TLC #15)
18	Cumulative Participant Accrual	Start Study Agent Date must be earlier than (or the same as) End Study Agent Date (TLC #16)
19	Cumulative Participant Accrual	If an End Follow-Up Date is given for a patient's record, a Begin Follow-up Date must also be given. (TLC #17)
20	Cumulative Participant Accrual	Begin Follow-Up Date must be earlier than (or the same as) End Follow-Up Date (TLC #18)
21	Cumulative Participant Accrual	End Run-In Date must be earlier than (or the same as) the Start Agent Date (TLC #19)
22	Cumulative Participant Accrual	End Study Agent Date must be earlier than (or the same as) the Begin Follow-Up Agent Date (TLC #20)
23	Cumulative Participant Accrual	Birth Year must be after 1910 (TLC #21)
24	Cumulative Participant Accrual	The following fields must contain a value selected from their drop-down list: Gender (Male, Female, or Unknown) Race (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12) (TLC #22)
25	Cumulative Participant Accrual	The following fields can only contain values selected from their drop-down list: Off Agent Reason Off Study Reason Ethnicity (TLC #23)

Guideline Number	Worksheet	Guideline Instruction
26	Cumulative Participant Accrual	If the study does not assign a Randomization Number (i.e. the patient record contains "NA" or "N/A" in the Randomization Number field) then Randomization Date field must be blank (TLC #24)
27	Cumulative Participant Accrual	If the End Study Agent Date is entered then the Off Agent Reason must also be entered (TLC #25)
28	Cumulative Participant Accrual	If End Study Agent Date is blank then Off Agent Reason and Off Agent Comment must also be blank (TLC #26)
29	Cumulative Participant Accrual	If Off Study Date is entered then Off Study Reason must also be entered (TLC #27)
30	Cumulative Participant Accrual	If Off Study Date is blank then Off Study Reason and Off Study Comment must also be blank (TLC #28)
31	Cumulative Participant Accrual	If a valid Randomization Number is present in a patient's record, Start Study Agent Date is expected. If this value is not yet available, a comment must be added (preferable in the general comments field, column W) to document the reason why it is not available. (TLC #29)
32	Cumulative Participant Accrual	If Off Study Date and Begin Run-In Date are entered then End Run-In Date must also be entered (TLC #30)
33	Cumulative Participant Accrual	If Off Study Date and Start Agent Date are entered then End Agent Date must also be entered (TLC #31)
34	Cumulative Participant Accrual	If Off Study Date and Begin Follow-Up Date are entered then End Follow-Up Date must also be entered (TLC #32)
35	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) all rows belonging to that patient must have the same Registration Date. (TLC #43)
36	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) all rows belonging to that patient must have the same Randomization Date (TLC #44)
37	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) all rows belonging to that patient must have the same Randomization Number for all those patient's rows must be the same (TLC #45)
38	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) all rows belonging to that patient must have the same Birth Year (TLC #46)

Guideline Number	Worksheet	Guideline Instruction
39	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) all rows belonging to that patient must have the same Gender (TLC #47)
40	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) all rows belonging to that patient must have the same Ethnicity (TLC #48)
41	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) all rows belonging to that patient must have the same Race (TLC #49)
42	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) the Start Study Agent Date must be entered for all those patient's rows (TLC #50)
43	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) the Start Study Agent Date on each row should define a unique dosing period. (TLC #51)
44	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) the End Study Agent Date on each row should define a unique dosing period. (TLC #52)
45	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) the Off Study information must be identical on all rows, or must only be present on the last row. (TLC #53)
46	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) all rows belonging to that patient must have the same Begin Run-In Date (TLC #54)
47	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) all rows belonging to that patient must have the same End Run-In Date (TLC #55)
48	Cumulative Participant Accrual	If a patient has more than one row the Start Study Agent Date on the row that defines the earliest dosing period, must be earlier than the Start Study Agent Date, End Study Agent Date, Begin Follow-up Agent Date, End Follow-Up Agent Date and Off Study Date for all subsequent rows for that patient (TLC #56)
49	Cumulative Participant Accrual	If a patient has more than one row the End Study Agent Date on the row that defines the earliest dosing period, must be earlier than the Start Study Agent Date, End Study Agent Date, Begin Follow-up Agent Date, End Follow-Up Agent Date and Off Study Date for all subsequent rows for that patient (TLC #57)

Guideline Number	Worksheet	Guideline Instruction
50	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) all rows (except one) must Off Agent Reason must be given on all rows except for the last row for that patient (TLC #58)
51	Cumulative Participant Accrual	All Cumulative Participant Accrual Records for a single study must be in accordance with one of the two Gender/Minority reporting systems. (TLC #59)
52	Cumulative Participant Accrual	A warning message will be generated if a patient has been registered but no Run-in information, Agent information, or Off-Study information has been provided within a three month time period. (TLC #60)
53	Cumulative Participant Accrual	A warning message will be generated if a patient has been randomized but no Run-in information, Agent information, or Off-Study information has been provided within a three month time period. (TLC #61)
54	Cumulative Participant Accrual	A warning message will be generated if a patient has ended the run-in phase but no Agent information, or Off-Study information has been provided within a three month time period. (TLC #62)
55	Cumulative Participant Accrual	A warning message will be generated if a patient has ended the agent phase but no Follow-up or Off-Study information has been provided within a three month time period. (TLC #63)
56	Cumulative Participant Accrual	A warning message will be generated if a patient has ended the Follow-Up phase but no Off-Study information has been provided within a three month time period. (TLC #64)
57	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) the Begin Follow-Up Date must be identical on all rows, or must only be present on the last row. (TLC #65)
58	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) the End Follow-Up Date must be identical on all rows, or must only be present on the last row. (TLC #66)
59	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) the Begin Run-In Date must be identical on all rows, or must only be present on the first row. (TLC #67)
60	Cumulative Participant Accrual	If a patient has gone on and off agent (i.e. the patient has multiple rows of data on the Accrual Worksheet) the End Run-In Date must be identical on all rows, or must only be present on the first row. (TLC #68)
61	Cumulative Participant Accrual	All patients that appeared on the previous ITPR must also appear on the current ITPR (TLC #70)
62	Cumulative Participant Accrual	All data should be presented in accordance with HIPAA guidelines. (TLC #71)

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63	Cumulative Participant Accrual	If "Other" is chosen as the Off Agent Reason then Off Agent Comment must be entered (TLC #74)
64	Cumulative Participant Accrual	If "Other" is chosen as the Off Study Reason then Off Study Comment must be entered (TLC #75)
65	Cumulative Participant Accrual	If Randomization Number is not NA or N/A, a Randomization Date must be given (TLC #78)
66	Cumulative Participant Accrual	If a Randomization Date is entered, it must be earlier than (or the same as) the Begin Run-In Date, Start Agent Date, Begin Follow-up, Off Study Date (TLC #80)
67	Cumulative Adverse Events and Cumulative Participant Accrual	All Adverse Event Records must match to an Accrual Record. Therefore, Adverse Event Rows must have a Registration Number and a Randomization number that are identical to one or more records on the Cumulative Participant Accrual Worksheet. (TLC #33)
68	Cumulative Adverse Events and Cumulative Participant Accrual	If Off Study Date is entered then Event Status must also be entered (TLC #34)
69	Cumulative Adverse Events and Cumulative Participant Accrual	All AE Onset Date's must be greater than (or be equal to) the patient's Registration Date (TLC #69)
70	Cumulative Adverse Events and Cumulative Participant Accrual	If "AE/SAE" is chosen as the Off Agent Reason, there must be a corresponding AE for that patient in the Cumulative Adverse Events Worksheet (TLC #72)
71	Cumulative Adverse Events and Cumulative Participant Accrual	If an AE on the Cumulative Adverse Events Worksheet indicates that a patient has been dropped due to the event, the patient must have an Off Study Reason of "AE/SAE" chosen on the Cumulative Participant Accrual Worksheet (TLC #73)
72	Cumulative Adverse Events and Cumulative Participant Accrual	A warning message will be generated if an AE onset date is greater than the patient's off study date. (TLC #79)

Guideline Number	Worksheet	Guideline Instruction
73	Cumulative Adverse Events	If the patient has an Event Ended Date then the Recovery Status must be "Resolved" (TLC #76.1)
74	Cumulative Adverse Events	If the Recovery Status is "Resolved" the patient must have an Event Ended Date (TLC #76.2)
75	Cumulative Adverse Events	If the Event Grade for an AE is 5 then Reported As SAE value should be "Yes" (TLC #77)
76	Cumulative Adverse Events	If the value "Blinded" is selected in the Agent Type column, all of these fields (Agent Dose at AE, Dose Units, AND Agent Frequency) must be left blank. (TLC #81)
77	Cumulative Adverse Events	The following fields are mandatory on the Cumulative Adverse Event Worksheet: Reporting Period Start Date Reporting Period End Date NCI Protocol Number Registration Number Randomization Number Adverse Event Description Event Grade Event Onset Date Reported as SAE Blind Broken Due (TLC #35)
78	Cumulative Adverse Events	The following fields must contain a value selected from their drop-down lists: Event Grade Reported as SAE Blind Broken Due to this AE (TLC #36)
79	Cumulative Adverse Events	The following fields can only contain values selected from their drop-down lists: Agent Type Dose Units Agent Frequency CTC Term Event Status Dropped due to this AE (TLC #37)
80	Cumulative Adverse Events	The Reporting Period End Date must be greater than or equal to all other dates in the report (TLC #38)
81	Cumulative Adverse Events	Event Onset Date must be less than or equal to the Event Ended Date (TLC #39)
82	Cumulative Adverse Events	If the CTC Term contains "Other Specify' then the "CTC Other Specify" comment field must be entered (TLC #40)

Guideline Number	Worksheet	Guideline Instruction
83	Cumulative Adverse Events	If there is a value in the "CTC Other Specify" field, CTC Term must be one of the "Other Specify" values. (TLC #41)
84	Cumulative Adverse Events	If a CTC Term is given, the AE Grade value must corresponding to the list of valid CTC grades described in the CTC Dictionary v2.0 (TLC #42)