

D8480C00013

05-Mar-2006

AE

**Adverse Events (AE)** (form title/tab name)**Adverse Events** (section title)

NEW

**Adverse Events** (section title)

	AE text	Start date	Start time	Stop date	Stop time	CTC grade	CTC grade changes	Action taken	Did subject receive treatment for AE	Did AE cause subject to discontinue study	AE causality
1											
2											
3											

**Adverse Events Entry** (section title)

1.	Adverse event text	<input type="text"/> (AETEXT, A200, R, SV)
2.	Start date	YYYY / Month / DD (AE_SDAT, DATE, R, SV, 2006-2015, YMD)
3.	Start time	If the start and stop date of the AE is within 24hours, please complete the time HH : MM (AE_STIM, N8, NR, SV)
4.	Stop date	YYYY / Month / DD (AE_EDAT, DATE, NR, SV, 2006-2015, YMD)
5.	Stop time	If the start and stop date of the AE is within 24hours, please complete the time HH : MM (AE_ETIM, N8, NR, SV)
6.	CTC grade at start of AE	CTC Grade (CTCG, N1, R, SV)
7.	Changes to CTC grade	(AECH_DAT, DATE, NR, SV) Date YYYY / Month / DD (AECH_DAT, DATE, NR, SV, 2006-2015, YMD) Grade CTC Grade (AECH_CTC_1, N1, NR, SV) Date YYYY / Month / DD (AECH_DAT_1, DATE, NR, SV, 2006-2015, YMD) Grade CTC Grade (AECH_CTC_2, N1, NR, SV) Date YYYY / Month / DD (AECH_DAT_2, DATE, NR, SV, 2006-2015, YMD) Grade CTC Grade (AECH_CTC_3, N1, NR, SV) Date YYYY / Month / DD (AECH_DAT_3, DATE, NR, SV, 2006-2015, YMD) Grade CTC Grade (AECH_CTC_4, N1, NR, SV) Date YYYY / Month / DD (AECH_DAT_4, DATE, NR, SV, 2006-2015, YMD) Grade CTC Grade (AECH_CTC_5, N1, NR, SV)

		Date <input type="text" value="YYYY"/> / <input type="text" value="Month"/> / <input type="text" value="DD"/> (AECH_DAT_5, DATE, NR, SV, 2006-2015, YMD) Grade <input type="text" value="CTC Grade"/> (AECH_CTC_6, N1, NR, SV) Date <input type="text" value="YYYY"/> / <input type="text" value="Month"/> / <input type="text" value="DD"/> (AECH_DAT_6, DATE, NR, SV, 2006-2015, YMD) Grade <input type="text" value="CTC Grade"/> (AECH_CTC_7, N1, NR, SV) Date <input type="text" value="YYYY"/> / <input type="text" value="Month"/> / <input type="text" value="DD"/> (AECH_DAT_7, DATE, NR, SV, 2006-2015, YMD) Grade <input type="text" value="CTC Grade"/> (AECH_CTC_8, N1, NR, SV) Date <input type="text" value="YYYY"/> / <input type="text" value="Month"/> / <input type="text" value="DD"/> (AECH_DAT_8, DATE, NR, SV, 2006-2015, YMD) Grade <input type="text" value="CTC Grade"/> (AECH_CTC_9, N1, NR, SV) Date <input type="text" value="YYYY"/> / <input type="text" value="Month"/> / <input type="text" value="DD"/> (AECH_DAT_9, DATE, NR, SV, 2006-2015, YMD) Grade <input type="text" value="CTC Grade"/> (AECH_CTC_10, N1, NR, SV)
8.	Action taken	AZD2171 / Placebo (AEACTIP1, N1, R, SV)      Bevacizumab/Placebo (AEACTIP2, N1, R, SV) Action Taken AZD2171 <input type="text"/> Action Taken Bevacizumab <input type="text"/>
9.	Did patient receive treatment for AE ?	0 <input type="radio"/> No 1 <input type="radio"/> Yes (AETREAT, N1, R, SV) If yes, please provide relevant details on the MED form (Please provide generic names where possible)
10.	Did AE cause patient to discontinue study ?	0 <input type="radio"/> No 1 <input type="radio"/> Yes. If yes, please complete the DOSDISC and TERM form (AECAUDIS, N1, R, SV)
11.	Causality assessment	AE related to AZD2171 0 <input type="radio"/> No 1 <input type="radio"/> Yes (AECAUS1, N1, R, SV) AE related to FOLFOX 0 <input type="radio"/> No 1 <input type="radio"/> Yes (AECAA1, N1, R, SV) AE related to Bevacizumab 0 <input type="radio"/> No 1 <input type="radio"/> Yes (AECAA2, N1, R, SV) AE related to study procedure(s) 0 <input type="radio"/> No 1 <input type="radio"/> Yes (AECAUSP, N1, R, SV) Study procedure(s) <input type="text"/> (S_AESP, A200, NR, SV)
12.	Outcome	0 <input type="radio"/> Resolved (AEOUTC, N1, R, SV) 1 <input type="radio"/> Ongoing 2 <input type="radio"/> Death, Please ensure DEATH form has been filled out
13.	Adverse event serious	0 <input type="radio"/> No 1 <input type="radio"/> Yes (AESER, N1, R, SV)  Date adverse event met criteria for serious AE : <input type="text" value="YYYY"/> / <input type="text" value="Month"/> / <input type="text" value="DD"/> (SAEDAT, DATE, R, SV) ((2006-2015, YMD)  Date investigator aware of serious AE <input type="text" value="YYYY"/> / <input type="text" value="MM"/> / <input type="text" value="DD"/> (SAEIADAT, DATE, R, SV) 2006-2015, YMD  AE is serious due to (please tick all that apply)  1 <input type="checkbox"/> Results in death (SAEDEATH, N1, NR, SV) If yes, please complete the DEATH form 2 <input type="checkbox"/> Requires inpatient hospitalisation or prolongation of existing hospitalisation (SAEHOSP, N1, NR, SV)

		Date of hospitalisation <input type="text" value="YYYY"/> <input type="text" value="MM"/> <input type="text" value="DD"/> (SAEHODAT, DATE, NR, SV)
		Date of discharge <input type="text" value="YYYY"/> <input type="text" value="MM"/> <input type="text" value="DD"/> (SAEDIDAT, DATE, NR, SV)
		3 <input type="checkbox"/> Congenital abnormality/birth defect (SAECONG, N1, NR, SV)
		4 <input type="checkbox"/> Is immediately life threatening (SAELIFE, N1, NR, SV)
		5 <input type="checkbox"/> Results in persistent or significant disability or incapacity (SAEDISAB, N1, R, SV)
		6 <input type="checkbox"/> Is an important medical event that may jeopardise the patient or may require medical intervention to prevent one of the outcomes listed above (SAEMEDEV, N1, R, SV)
		Event information
		Symptoms of SAE/clinical sequence of events <div style="border: 1px solid black; height: 60px; width: 100%;"></div> <div style="text-align: right;"> <input type="checkbox"/> (SAESYMP, A200, R, SV)         </div>
		Diagnostic investigations of SAE <div style="border: 1px solid black; height: 60px; width: 100%;"></div> <div style="text-align: right;"> <input type="checkbox"/> (SAEDIAG, A200, R, SV)         </div>
		Treatment of SAE <div style="border: 1px solid black; height: 60px; width: 100%;"></div> <div style="text-align: right;"> <input type="checkbox"/> (SAETREAT, A200, R, SV)         </div>
		Other SAE comments <div style="border: 1px solid black; height: 60px; width: 100%;"></div> <div style="text-align: right;"> <input type="checkbox"/> (C_OTHSAE, A200, NR, SV)         </div>
14.	Initial review of SAE complete [Hidden Field]	<input type="checkbox"/> To be updated by PhV within 5 days of SAE notification

CTC Grade	
Value	Label
1	Grade 1

2	Grade 2
3	Grade 3
4	Grade 4
5	Grade 5

Action Taken, AZD2171/Placebo	
Value	Label
0	None
1	Dose changed
2	Temporarily stopped
3	Permanently stopped

Action Taken, Bevacizumab/Placebo	
Value	Label
0	None
2	Temporarily stopped
3	Permanently stopped

Create an email rule: E-mail will be forwarded to PHV in Quintiles and relevant AZ Clintrace site in order for SAE Rec to take place.

Create e-mail rule so that when SAE reconciled box has been populated an e-mail goes to AZ