D8480C00013 05-Mar-2006 AE

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

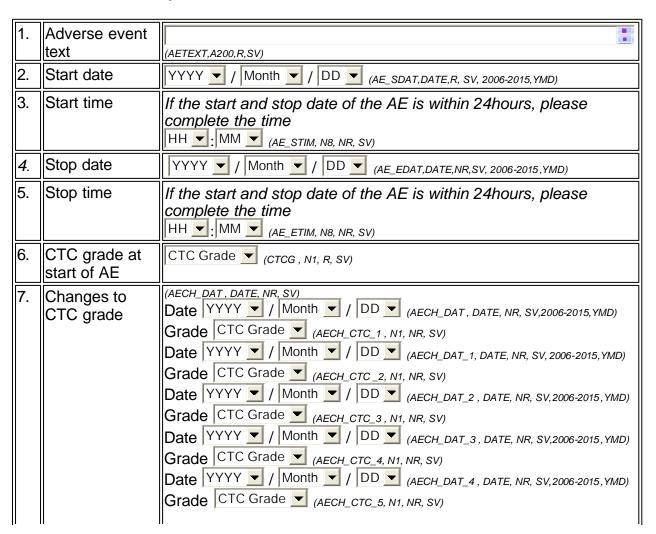
Adverse Events (section title)

 NEW

Adverse Events (section title)

			CTC grade	Action taken	subject receive	Did AE cause subject to discontinue study	AE causality
1							
2							
3							

Adverse Events Entry (section title)



		Date YYYY / Month / DD (AECH_DAT_5, DATE, NR, SV, 2006-2015, YMD) Grade CTC Grade (AECH_CTC_6, N1, NR, SV) Date YYYY / Month / DD (AECH_DAT_6, DATE, NR, SV, 2006-2015, YMD) Grade CTC Grade (AECH_CTC_7, N1, NR, SV) Date YYYY / Month / DD (AECH_DAT_7, DATE, NR, SV, 2006-2015, YMD) Grade CTC Grade (AECH_CTC_8, N1, NR, SV) Date YYYY / Month / DD (AECH_DAT_8, DATE, NR, SV, 2006-2015, YMD) Grade CTC Grade (AECH_CTC_9, N1, NR, SV) Date YYYY / Month / DD (AECH_DAT_9, DATE, NR, SV, 2006-2015, YMD) Grade CTC Grade (AECH_CTC_10, N1, NR, SV)
8.	Action taken	AZD2171 / Placebo (AEACTIP1, N1, R, SV) Action Taken AZD2171 ▼ Bevacizumab/Placebo (AEACTIP2, N1, R, SV) Action Taken Bevacizumab ▼
9.	Did patient receive treatment for AE?	o ○ No 1 ○ 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?	o No 1 Yes. If yes, please complete the DOSDISC and TERM form (AECAUDIS, N1, R, SV)
11.	Causality assessment	AE related to AZD2171 (AECAUS1, N1, R, SV) AE related to FOLFOX N1, R, SV) AE related to Bevacizumab N1, R, SV) AE related to study procedure(s) (AECAUSP, N1, R, SV) Study procedure(s) (S_AESP, A200, NR, SV)
12.	Outcome	o C Resolved (AEOUTC, N1, R, SV) 1 C Ongoing 2 C Death, Please ensure DEATH form has been filled out
13.	Adverse event serious	Date adverse event met criteria for serious AE: Month / DD (SAEDAT, DATE, R, SV) ((2006-2015, YMD)

		Date of hospitalisation YYYY \ /MM \ /DD \ (SAEHODAT, DATE, NR, SV) Date of discharge YYYY \ /MM \ /DD \ (SAEDIDAT, DATE, NR, SV) 3 \ Congenital abnormality/birth defect (SAECONG, N1, NR,SV) 4 \ Is immediately life threatening (SAELIFE, N1, NR,SV) 5 \ Results in persistent or significant disability or incapacity (SAEDISAB, N1, R, SV) 6 \ 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
		A200, R, SV) (SAESYMP,
		Diagnostic investigations of SAE
		A200, R, SV)
		Treatment of SAE
		✓ (SAETREAT,
		A200, R, SV)
		Other SAE comments
		Z (C_OTHSAE, A200, NR, SV)
14.	Initial review of SAE complete [Hidden Field]	☐ To be updated by PhV within 5 days of SAE notification

CTC Grade		
Value	<u>Label</u>	
1	Grade 1	

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

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

Action Taken, Bevacizumab/Placebo		
Value	<u>Label</u>	
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