PROTOCOL DEVIATIONS AT DATABASE LOCK (09/07/2018)

Patient ID	PV code	Visit	Protocol variation: description	Additional description	Type
100-01-001	CETTRT4	Infusion visit 2	Cetuximab dose reduction for reason other than Toxicity/AE: (BY MISTAKE! BSA MISCALCULATED!)	Reduction by 30%	Minor
100-01-002	GCP		The SAE 201300057 is not reported within 2 days from the onset of the event (interval = 855 days).		MAJOR_GCP
100-01-002	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - PI decision)	Monitor observation: The lesion was not accessible	Minor
100-01-002	CETTRT3	Infusion visit 12	Period between two successive Cetuximab administrations (Infusion visit 9 - Infusion visit 12) is more than 21 days [27]	Due to Toxicity (AE)	Minor
100-01-003	GCP		The SAE 201100007 is not reported within 2 days from the onset of the event (interval = 4 days).		MAJOR_GCP
100-01-003	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - reason not documented)		Minor
100-01-003	EFFA2	Screening visit	Tumour assessment (14/07/2011) not done within 21 days before first cetuximab administration (08/08/2011). (Difference = 25 days)		None
100-01-003	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Patient best interest [General deterioration and anorexia] ; Date of assessment: 12/01/2012; Date of last cetuximab administration = 05/01/2012).		None
100-01-004	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening: 635 U/L; Baseline: 718 U/L (ULN: 240)	Minor
100-01-004	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Complete Response] ; Date of assessment: 20/12/2012; Date of last cetuximab administration = 05/12/2012).		None
100-01-004	EFFA1	End of treatment visit	Tumour assessment (20/12/2012) not done within 12 weeks of the previous tumor assessment (14/06/2012). (Difference = 27.0 weeks, first cetuximab administration = 04/10/2011)		Minor
100-01-004	CETTRT3	Infusion visit 33	Period between two successive Cetuximab administrations (Infusion visit 32 - Infusion visit 33) is more than 21 days [127]	Due to surgery (surgical closure of colostomy on 21/06/2012) - Period more than 12 weeks (18 weeks)	Minor
100-02-001	GCP		The SAE 201100001 is not reported within 2 days from the onset of the event (interval = 7 days).		MAJOR_GCP
100-02-001	EFFA2	Screening visit	Tumour assessment (12/01/2011) not done within 21 days before first cetuximab administration (08/02/2011). (Difference = 27 days)		None
100-02-001	CETTRT5	Infusion visit 1	Study medication given instead of commercial medication		MAJOR_GCP
100-02-001	CETTRT5	Infusion visit 2	Study medication given instead of commercial medication		MAJOR_GCP
100-02-001	CETTRT5	Infusion visit 3	Study medication given instead of commercial medication		MAJOR_GCP
100-02-002	EFFA2	Screening visit	Tumour assessment (13/01/2011) not done within 21 days before first cetuximab administration (09/02/2011). (Difference = 27 days)		None
100-02-002	CETTRT5	Infusion visit 1	Study medication given instead of commercial medication		MAJOR_GCP
100-02-002	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: 09/10/2012; Date of last cetuximab administration = 10/07/2012).		None
100-02-002	CETTRT5	Infusion visit 2	Study medication given instead of commercial medication		MAJOR_GCP
100-02-002	CETTRT3	Infusion visit 55	Period between two successive Cetuximab administrations (Infusion visit 52 - Infusion visit 55) is more than 21 days [28]	Due to Toxicity (AE) and holiday	Minor
100-04-001	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Patient best interest [Successful Surgery liver] ; Date of assessment: 07/08/2012; Date of last cetuximab administration = 06/08/2012).		None
100-04-001	CETTRT3	Infusion visit 17	Period between two successive Cetuximab administrations (Infusion visit 16 - Infusion visit 17) is more than 21 days [81]	Due to surgery (sigmoidectomy + lymph nodes excision on 20/03/2012)	None
100-04-001	EFFA1	Infusion visit 24	Tumour assessment (05/06/2012) not done within 12 weeks of the previous tumor assessment (08/02/2012). (Difference = 16.9 weeks, first cetuximab administration = 24/10/2011)		Minor
100-04-002	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Patient best interest [Decision to change treatment to try to get a better tumor response]; Date of assessment: 23/05/2014; Date of last cetuximab administration = 22/05/2014).		None

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100-04-003	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Withdrawal of consent [Date of withdrawal=05/02/2014])		Minor
100-04-003	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Withdrawal of consent or patient request; Date of assessment: 30/06/2014; Date of last cetuximab administration = 23/06/2014).		None
100-04-003	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (06/06/2014) done within 1 month prior the End of treatment visit (30/06/2014)	None
100-05-001	GCP		The SAE 201300044 is not reported within 2 days from the onset of the event (interval = 4 days).		MAJOR_GCP
100-05-001	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening: not done; Baseline: 642 U/L (ULN: 105)	Minor
100-05-001	CETTRT5	Infusion visit 8	Commercial medication given instead of study medication	comment DRC (patient was treated with 4 vials of commercial and 4 vials of study medication)	MAJOR_GCP
100-06-001	GCP		The SAE 201200030 is not reported within 2 days from the onset of the event (interval = 9 days).		MAJOR_GCP
100-06-001	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - decision of investigator because of ethical reason)		Minor
100-06-001	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (18/06/2012) is older than 4 weeks from the End of treatment visit (01/08/2012)	Minor
100-08-001	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (08/08/2013) done within 1 month prior the End of treatment visit (14/08/2013)	None
100-08-001	EFFA1	Infusion visit 32	Tumour assessment (11/06/2013) not done within 12 weeks of the previous tumor assessment (17/04/2013). (Difference = 7.9 weeks, first cetuximab administration = 24/10/2012)		Minor
100-08-001	EFFA1	Infusion visit 40	Tumour assessment (08/08/2013) not done within 12 weeks of the previous tumor assessment (11/06/2013). (Difference = 8.3 weeks, first cetuximab administration = 24/10/2012)		Minor
100-08-002	GCP		The SAE 201300055 is not reported within 2 days from the onset of the event (interval = 7 days).		MAJOR_GCP
100-08-002	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Patient died unexpectedly because of pleural infection, no tumor evaluation was performed	None
100-08-002	EFFA1	Infusion visit 32	Tumour assessment (15/07/2013) not done within 12 weeks of the previous tumor assessment (15/05/2013). (Difference = 8.7 weeks, first cetuximab administration = 28/11/2012)		Minor
100-08-002	EFFA1	Infusion visit 40	Tumour assessment (11/09/2013) not done within 12 weeks of the previous tumor assessment (15/07/2013). (Difference = 8.3 weeks, first cetuximab administration = 28/11/2012)		Minor
100-08-003	GCP		The SAE 201500072 is not reported within 2 days from the onset of the event (interval = 327 days).		MAJOR_GCP
100-08-003	EFFA1	Infusion visit 32	Tumour assessment (29/10/2013) not done within 12 weeks of the previous tumor assessment (04/09/2013). (Difference = 7.9 weeks, first cetuximab administration = 27/03/2013)		Minor
100-08-003	EFFA1	Infusion visit 40	Tumour assessment (24/12/2013) not done within 12 weeks of the previous tumor assessment (29/10/2013). (Difference = 8.0 weeks, first cetuximab administration = 27/03/2013)		Minor
100-08-003	EFFA1	Infusion visit 56	Tumour assessment (30/04/2014) not done within 12 weeks of the previous tumor assessment (05/03/2014). (Difference = 8.0 weeks, first cetuximab administration = 27/03/2013)		Minor
100-08-003	OTH1	Infusion visit 56	Based on the results on 30/04/2014 (IV56) the sponsor considered that the progressive disease was shown. The investigator did not agree and assessed the disease as stable disease. The patient should have been taken off study according to the sponsor, but the treatment was continued for 8 more weeks until 25/06/2014 (IV60). The patient was discontinued on 02/07/2014 due to a Disease progression evaluated on 01/07/2014.		Minor
100-08-004	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (20/01/2015) done within 1 month prior the End of treatment visit (11/02/2015)	None

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100-08-004	EFFA1	Infusion visit 32	Tumour assessment (26/03/2014) not done within 12 weeks of the previous tumor assessment (29/01/2014). (Difference = 8.0 weeks, first cetuximab administration = 21/08/2013)		Minor
100-08-004	EFFA1	Infusion visit 48	Tumour assessment (16/07/2014) not done within 12 weeks of the previous tumor assessment (26/03/2014). (Difference = 16.0 weeks, first cetuximab administration = 21/08/2013)		Minor
100-08-004	EFFA1	Infusion visit 56	Tumour assessment (29/10/2014) not done within 12 weeks of the previous tumor assessment (16/07/2014). (Difference = 15.0 weeks, first cetuximab administration = 21/08/2013)		Minor
100-09-001	EFFA1	Infusion visit 8	Tumour assessment (17/01/2012) not done within 8 weeks of first Cetuximab treatment (09/12/2011). (Difference = 5.6 weeks)		Minor
100-09-002	EFFA2	Screening visit	Tumour assessment (09/07/2012) not done within 21 days before first cetuximab administration (01/08/2012). (Difference = 23 days)		None
100-09-002	CETTRT5	Infusion visit 10	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: 10/01/2013; Date of last cetuximab administration = 12/12/2012).		None
100-09-002	CETTRT5	Infusion visit 11	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	CETTRT5	Infusion visit 12	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	CETTRT5	Infusion visit 13	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	CETTRT5	Infusion visit 14	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	CETTRT5	Infusion visit 15	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	CETTRT5	Infusion visit 16	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	EFFA1	Infusion visit 16	Tumour assessment (23/10/2012) not done within 8 weeks of the previous tumor assessment (13/09/2012). (Difference = 5.7 weeks, first cetuximab administration = 01/08/2012)		Minor
100-09-002	CETTRT5	Infusion visit 17	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	CETTRT5	Infusion visit 18	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	CETTRT5	Infusion visit 19	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	CETTRT5	Infusion visit 20	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	CETTRT5	Infusion visit 4	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	CETTRT5	Infusion visit 5	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	CETTRT5	Infusion visit 6	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	CETTRT5	Infusion visit 7	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	CETTRT5	Infusion visit 8	Commercial medication given instead of study medication		MAJOR_GCP
100-09-002	CETTRT5	Infusion visit 9	Commercial medication given instead of study medication		MAJOR_GCP
100-09-003	EFFA1	End of treatment visit	Tumour assessment (15/01/2013) not done within 8 weeks of the previous tumor assessment (20/09/2012). (Difference = 16.7 weeks, first cetuximab administration = 14/08/2012)		Minor
100-09-003	EFFA1	Infusion visit 8	Tumour assessment (20/09/2012) not done within 8 weeks of first Cetuximab treatment (14/08/2012). (Difference = 5.3 weeks)		Minor
100-09-004	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Withdrawal of consent or patient request; Date of assessment: 02/07/2014; Date of last cetuximab administration = 21/05/2014).		None
100-09-004	EFFA1	Infusion visit 16	Tumour assessment (02/09/2013) not done within 8 weeks of the previous tumor assessment (23/07/2013). (Difference = 5.9 weeks, first cetuximab administration = 12/06/2013)		Minor
100-09-004	EFFA1	Infusion visit 40	Tumour assessment (03/02/2014) not done within 12 weeks of the previous tumor assessment (06/12/2013). (Difference = 8.4 weeks, first cetuximab administration = 12/06/2013)		Minor
100-09-004	EFFA1	Infusion visit 48	Tumour assessment (28/03/2014) not done within 12 weeks of the previous tumor assessment (03/02/2014). (Difference = 7.6 weeks, first cetuximab administration = 12/06/2013)		Minor
100-09-004	EFFA1	Infusion visit 8	Tumour assessment (23/07/2013) not done within 8 weeks of first Cetuximab treatment (12/06/2013). (Difference = 5.9 weeks)		Minor
100-11-001	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: 12/12/2011; Date of last cetuximab administration = 17/11/2011).		None

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100-11-001	CETTRT3	Infusion visit 13	Period between two successive Cetuximab administrations (Infusion visit 12 - Infusion visit 13) is more than 21 days [22]	Due to Toxicity (AE)	Minor
100-11-001	CETTRT2	Infusion visit 4	The patient was escalated however the patient had a mild rash acneiform on the face (chin) that lasted for 5 days during the first 3 weeks.		Minor
100-11-002	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - Clinically not possible)		Minor
100-13-001	GCP		The SAE 201200018 is not reported within 2 days from the onset of the event (interval = 133 days).		MAJOR_GCP
100-13-001	EFFA1	End of treatment visit	Tumour assessment (31/10/2011) not done within 8 weeks of the previous tumor assessment (16/08/2011). (Difference = 10.9 weeks, first cetuximab administration = 04/07/2011)		Minor
100-14-001	GCP		The SAE 201100008 is not reported within 2 days from the onset of the event (interval = 3 days).		MAJOR_GCP
100-14-001	GCP		The SAE 201100014 is not reported within 2 days from the onset of the event (interval = 4 days).		MAJOR_GCP
100-14-001	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Withdrawal of consent [Date of withdrawal=23/08/2011])		Minor
100-14-001	CETTRT5	Infusion visit 1	Study medication given instead of commercial medication		MAJOR_GCP
100-14-001	CETTRT5	Infusion visit 10	Study medication given instead of commercial medication		MAJOR_GCP
100-14-001	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (11/05/2012) done within 1 month prior the End of treatment visit (21/05/2012)	None
100-14-001	CETTRT3	Infusion visit 11	Period between two successive Cetuximab administrations (Infusion visit 10 - Infusion visit 11) is more than 21 days [42]	Due to Toxicity (AE)	Minor
100-14-001	CETTRT5	Infusion visit 11	Study medication given instead of commercial medication		MAJOR_GCP
100-14-001	CETTRT5	Infusion visit 12	Study medication given instead of commercial medication		MAJOR_GCP
100-14-001	CETTRT5	Infusion visit 13	Study medication given instead of commercial medication		MAJOR_GCP
100-14-001	EFFA1	Infusion visit 16	Tumour assessment (03/02/2012) not done within 8 weeks of the previous tumor assessment (30/09/2011). (Difference = 18.0 weeks, first cetuximab administration = 23/08/2011)		Minor
100-14-001	CETTRT5	Infusion visit 2	Study medication given instead of commercial medication		MAJOR_GCP
100-14-001	CETTRT3	Infusion visit 21	Period between two successive Cetuximab administrations (Infusion visit 20 - Infusion visit 21) is more than 21 days [42]	Due to surgery (omentectomy+hysterectomy+TME on 27/02/2012)	None
100-14-001	CETTRT5	Infusion visit 3	Study medication given instead of commercial medication		MAJOR_GCP
100-14-001	CETTRT5	Infusion visit 4	Study medication given instead of commercial medication		MAJOR_GCP
100-14-001	CETTRT5	Infusion visit 5	Study medication given instead of commercial medication		MAJOR_GCP
100-14-001	CETTRT5	Infusion visit 6	Study medication given instead of commercial medication		MAJOR_GCP
100-14-001	CETTRT5	Infusion visit 7	Study medication given instead of commercial medication		MAJOR_GCP
100-14-001	CETTRT5	Infusion visit 8	Study medication given instead of commercial medication		MAJOR_GCP
100-14-001	EFFA1	Infusion visit 8	Tumour assessment (30/09/2011) not done within 8 weeks of first Cetuximab treatment (23/08/2011). (Difference = 5.4 weeks)		Minor
100-14-001	CETTRT5	Infusion visit 9	Study medication given instead of commercial medication		MAJOR_GCP
100-14-002	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - baseline biopsy was not performed because the liver metastasis was not accessible for biopsy)		Minor
200-01-001	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - not reasonable for the patient)		Minor
200-01-001	EFFA2	Screening visit	Tumour assessment (07/12/2011) not done within 21 days before first cetuximab administration (09/01/2012). (Difference = 33 days)		Minor
200-01-002	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - not reasonable for the patient)		Minor
200-01-002	EC1	Screening visit	Exclusion criterion 1 violated: Adjuvant therapy (Xelox) was given till 5.6 months prior to enrolment / 5.7 month prior to C1D1.		Minor
200-01-002	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Withdrawal of consent or patient request ; Date of assessment: 26/06/2012; Date of last cetuximab administration = 23/05/2012).		None
200-03-001	GCP		The SAE 201200023 is not reported within 2 days from the onset of the event (interval = 3 days).		MAJOR_GCP

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200-03-001	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - no rebiopsy due to biopsy (27.03.2012) was performed)		Minor
200-06-001	GCP		The SAE 201200032 is not reported within 2 days from the onset of the event (interval = 5 days).		MAJOR_GCP
200-06-001	IC11	Screening visit	Inclusion criteria 11 violated (ASAT = < 2.5 x ULN, up to = < 5 x ULN in case of liver metastases).	Screening: 265 U/L; Baseline: not done (ULN: 50 U/L); waiver granted	Minor
200-06-001	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening: 531 U/L; Baseline: not done (ULN: 122 U/L); waiver granted	Minor
200-06-001	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (27/12/2012) done within 1 month prior the End of treatment visit (02/01/2013)	None
300-01-001	EFFA2	Screening visit	Tumour assessment (06/03/2012) not done within 21 days before first cetuximab administration (12/04/2012). (Difference = 37 days)		Minor
300-01-001	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening= Baseline: 481 U/L (ULN: 126)	Minor
300-01-001	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Patient best interest [resection of primary tumor then treatment by hepatic intra-arterial chemotherapy with oxaliplatine and by intravenous injection of cetuximab. Date] ; Date of assessment: 24/10/2012; Date of last cetuximab administration = 17/10/2012).		None
300-01-001	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (12/10/2012) done within 1 month prior the End of treatment visit (24/10/2012)	None
300-01-001	EFFA1	Infusion visit 24	Tumour assessment (12/10/2012) not done within 12 weeks of the previous tumor assessment (06/08/2012). (Difference = 9.6 weeks, first cetuximab administration = 12/04/2012)		Minor
300-01-002	CETTRT1		Patient discontinued before arm allocation (Reason = Disease progression ; Date of assessment: 06/07/2012); Date of first cetuximab administration = 08/06/2012; Date of last cetuximab administration = 15/06/2012.		None_ARM
300-01-002	GCP		The SAE 201200027 is not reported within 2 days from the onset of the event (interval = 6 days).		MAJOR_GCP
300-01-002	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - metastasis not reachable)		Minor
300-01-002	EFFA2	Screening visit	Tumour assessment (13/05/2012) not done within 21 days before first cetuximab administration (08/06/2012). (Difference = 26 days)		None
300-01-002	OTH1	End of treatment	The patient was discontinued on 06/07/2012 due to Clinical Progression and not Radiographic progression. No more CT scan was done after the End of Treatment visit as the patient died on 05/11/2012.		None
300-01-003	CETTRT1		Patient discontinued before arm allocation (Reason = Disease progression ; Date of assessment: 19/07/2012); Date of first cetuximab administration = 05/07/2012; Date of last cetuximab administration = 12/07/2012.		None_ARM
300-01-003	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - metastasis not reachable)		Minor
300-01-003	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Brain metastasis finding at End of treatment visit (19/07/2012)	None
300-07-001	GCP		The SAE 201200017 is not reported within 2 days from the onset of the event (interval = 10 days).		MAJOR_GCP
300-07-001	GCP		The SAE 201200026 is not reported within 2 days from the onset of the event (interval = 8 days).		MAJOR_GCP
300-07-001	GCP		The SAE 201200036 is not reported within 2 days from the onset of the event (interval = 123 days).		MAJOR_GCP
300-07-001	GCP		The SAE 201300042 is not reported within 2 days from the onset of the event (interval = 223 days).		MAJOR_GCP
300-07-001	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - Metastasis not accessible)		Minor
300-07-001	CETTRT3	Infusion visit 20	Period between two successive Cetuximab administrations (Infusion visit 16 - Infusion visit 20) is more than 21 days [28]	Due to Toxicity (AE)	Minor
300-07-001	EFFA1	Infusion visit 24	Tumour assessment (05/07/2012) not done within 8 weeks of the previous tumor assessment (31/05/2012). (Difference = 5.0 weeks, first cetuximab administration = 09/02/2012)		Minor
300-07-001	CETTRT2	Infusion visit 4	The patient was not escalated however at Infusion visit 4 (date = 01/03/2012), no skin reaction grade 1 or higher		None_SI

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300-07-003	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - METASTASIS NOT ACCESSIBLE)		Minor
300-07-004	GCP		The SAE 201300051 is not reported within 2 days from the onset of the event (interval = 6 days).		MAJOR_GCP
300-07-004	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - Investigator refused to do it.)		Minor
300-07-004	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: 21/10/2013; Date of last cetuximab administration = 12/09/2013).		None
300-07-004	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (12/09/2013) is older than 4 weeks from the end of treatment visit (21/10/2013).	Minor
300-07-005	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - Investigator refuse to do it.)		Minor
300-07-005	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: ND/ND/ND; Date of last cetuximab administration = 23/10/2013).		None
300-07-005	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (02/10/2013)	Minor
400-02-001	EFFA2	Screening visit	Tumour assessment (14/01/2012) not done within 21 days before first cetuximab administration (09/02/2012). (Difference = 26 days)		None
400-02-001	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (21/03/2013) done within 1 month prior the End of treatment visit (10/04/2013)	None
400-02-001	EFFA1	Infusion visit 32	Tumour assessment (13/09/2012) not done within 12 weeks of the previous tumor assessment (19/07/2012). (Difference = 8.0 weeks, first cetuximab administration = 09/02/2012)		Minor
400-02-001	CETTRT3	Infusion visit 36	Period between two successive Cetuximab administrations (Infusion visit 35 - Infusion visit 36) is more than 21 days [105]	Due to surgery (liver metastasis resection on 13/12/2012) - Period more than 12 weeks	Minor
400-02-001	EFFA1	Infusion visit 40	Tumour assessment (21/03/2013) not done within 12 weeks of the previous tumor assessment (13/09/2012). (Difference = 27.0 weeks, first cetuximab administration = 09/02/2012)		Minor
400-02-001	CETTRT3	Infusion visit 42	Period between two successive Cetuximab administrations (Infusion visit 38 - Infusion visit 42) is more than 21 days [28]	Due to Toxicity (AE)	Minor
400-02-002	CETTRT1		Patient discontinued before arm allocation (Reason = Adverse event ; Date of assessment: 11/03/2012); Date of first cetuximab administration = 29/02/2012; Date of last cetuximab administration = 07/03/2012.		None_ARM
400-02-002	GCP		The SAE 201200020 is not reported within 2 days from the onset of the event (interval = 7 days).		MAJOR_GCP
400-02-002	GCP		The SAE 201200021 is not reported within 2 days from the onset of the event (interval = 5 days).		MAJOR_GCP
400-02-002	EFFA2	Screening visit	Tumour assessment (01/02/2012) not done within 21 days before first cetuximab administration (29/02/2012). (Difference = 28 days)		None
400-02-002	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Patient died unexpectedly because of adverse event, no tumor evaluation was performed	None
400-02-003	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Patient best interest [Physician's decision] ; Date of assessment: 18/09/2013; Date of last cetuximab administration = 11/09/2013).		None
400-02-003	CETTRT3	Infusion visit 27	Period between two successive Cetuximab administrations (Infusion visit 26 - Infusion visit 27) is more than 21 days [62]	Due to surgery (liver metastasis resection on 08/11/2012)	None
400-02-003	EFFA1	Infusion visit 32	Tumour assessment (29/01/2013) not done within 12 weeks of the previous tumor assessment (14/09/2012). (Difference = 19.6 weeks, first cetuximab administration = 05/04/2012)		Minor
400-02-003	EFFA1	Infusion visit 40	Tumour assessment (27/03/2013) not done within 12 weeks of the previous tumor assessment (29/01/2013). (Difference = 8.1 weeks, first cetuximab administration = 05/04/2012)		Minor
400-02-003	EFFA1	Infusion visit 48	Tumour assessment (22/05/2013) not done within 12 weeks of the previous tumor assessment (27/03/2013). (Difference = 8.0 weeks, first cetuximab administration = 05/04/2012)		Minor
400-02-003	EFFA1	Infusion visit 56	Tumour assessment (17/07/2013) not done within 12 weeks of the previous tumor assessment (22/05/2013). (Difference = 8.0 weeks, first cetuximab administration = 05/04/2012)		Minor

Patient ID	PV code	Visit	Protocol variation: description	Additional description	Type
400-02-004	CETTRT3	Infusion visit 32	Period between two successive Cetuximab administrations (Infusion visit 31 - Infusion visit 32) is more than 21 days [84]	Due to surgery (liver metastasis, rectosigmoideal resection on 15/01/2013)	None
400-02-004	EFFA1	Infusion visit 32	Tumour assessment (27/12/2012) not done within 12 weeks of the previous tumor assessment (31/10/2012). (Difference = 8.1 weeks, first cetuximab administration = 14/05/2012)		Minor
400-02-004	EFFA1	Infusion visit 40	Tumour assessment (24/04/2013) not done within 12 weeks of the previous tumor assessment (27/12/2012). (Difference = 16.9 weeks, first cetuximab administration = 14/05/2012)		Minor
400-02-004	EFFA1	Infusion visit 48	Tumour assessment (18/06/2013) not done within 12 weeks of the previous tumor assessment (24/04/2013). (Difference = 7.9 weeks, first cetuximab administration = 14/05/2012)		Minor
400-02-004	EFFA1	Infusion visit 56	Tumour assessment (14/08/2013) not done within 12 weeks of the previous tumor assessment (18/06/2013). (Difference = 8.1 weeks, first cetuximab administration = 14/05/2012)		Minor
400-02-004	EFFA1	Infusion visit 64	Tumour assessment (26/09/2013) not done within 12 weeks of the previous tumor assessment (14/08/2013). (Difference = 6.1 weeks, first cetuximab administration = 14/05/2012)		Minor
400-02-005	IC11	Screening visit	Inclusion criteria 11 violated (Hemoglobin > = 10.0 g/dL).	Screening: 9.7 g/dL; Baseline: 9.5 g/dL	Minor
400-02-005	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: 26/09/2012; Date of last cetuximab administration = 19/09/2012).		None
400-02-005	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (15/08/2012) is older than 4 weeks from the End of treatment visit (26/09/2012)	Minor
400-02-006	OTH2		Node target lesions are measured in smallest diameter in all target lesions evaluations.		Minor
400-02-007	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: 19/11/2013; Date of last cetuximab administration = 30/10/2013).		None
400-02-007	CETTRT3	Infusion visit 18	Period between two successive Cetuximab administrations (Infusion visit 17 - Infusion visit 18) is more than 21 days [62]	Due to surgery (right hepatolobectomy on 11/04/2013)	None
400-02-007	EFFA1	Infusion visit 24	Tumour assessment (28/06/2013) not done within 12 weeks of the previous tumor assessment (28/02/2013). (Difference = 17.1 weeks, first cetuximab administration = 13/11/2012)		Minor
400-02-007	EFFA1	Infusion visit 32	Tumour assessment (28/08/2013) not done within 12 weeks of the previous tumor assessment (28/06/2013). (Difference = 8.7 weeks, first cetuximab administration = 13/11/2012)		Minor
400-02-008	EFFA1	End of treatment visit	Tumour assessment (07/01/2014) not done within 12 weeks of the previous tumor assessment (30/08/2013). (Difference = 18.6 weeks, first cetuximab administration = 17/01/2013)		Minor
400-02-008	EFFA1	Infusion visit 32	Tumour assessment (30/08/2013) not done within 12 weeks of the previous tumor assessment (05/07/2013). (Difference = 8.0 weeks, first cetuximab administration = 17/01/2013)		Minor
400-02-008	CETTRT3	Infusion visit 39	Period between two successive Cetuximab administrations (Infusion visit 38 - Infusion visit 39) is more than 21 days [70]	Due to surgery (liver metastasis resection on 14/11/2013)	None
400-02-009	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: 09/04/2014; Date of last cetuximab administration = 19/03/2014).		None
400-02-009	CETTRT3	Infusion visit 23	Period between two successive Cetuximab administrations (Infusion visit 22 - Infusion visit 23) is more than 21 days [84]	Due to surgery (liver metastasis resection on 15/08/2013)	None
400-02-009	EFFA1	Infusion visit 32	Tumour assessment (26/11/2013) not done within 12 weeks of the previous tumor assessment (17/07/2013). (Difference = 18.9 weeks, first cetuximab administration = 06/02/2013)		Minor
400-02-009	EFFA1	Infusion visit 40	Tumour assessment (29/01/2014) not done within 12 weeks of the previous tumor assessment (26/11/2013). (Difference = 9.1 weeks, first cetuximab administration = 06/02/2013)		Minor
400-02-009	EFFA1	Infusion visit 48	Tumour assessment (26/03/2014) not done within 12 weeks of the previous tumor assessment (29/01/2014). (Difference = 8.0 weeks, first cetuximab administration = 06/02/2013)		Minor
400-02-010	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Patient died unexpectedly because of adverse event, no tumor evaluation was performed	None
400-02-011	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Patient withdrawn her consent from the CT scan AND last tumor evaluation	None

Patient ID	PV code	Visit	Protocol variation: description	Additional description	Type
				(13/11/2014) done within 1 month prior the End of treatment (05/12/2014)	
400-02-011	EFFA1	Infusion visit 24	Tumour assessment (10/05/2014) not done within 12 weeks of the previous tumor assessment (04/03/2014). (Difference = 9.6 weeks, first cetuximab administration = 05/11/2013)		Minor
400-02-011	EFFA1	Infusion visit 32	Tumour assessment (11/07/2014) not done within 12 weeks of the previous tumor assessment (10/05/2014). (Difference = 8.9 weeks, first cetuximab administration = 05/11/2013)		Minor
400-02-011	EFFA1	Infusion visit 40	Tumour assessment (11/09/2014) not done within 12 weeks of the previous tumor assessment (11/07/2014). (Difference = 8.9 weeks, first cetuximab administration = 05/11/2013)		Minor
400-02-011	EFFA1	Infusion visit 48	Tumour assessment (13/11/2014) not done within 12 weeks of the previous tumor assessment (11/09/2014). (Difference = 9.0 weeks, first cetuximab administration = 05/11/2013)		Minor
400-02-012	EFFA1	End of treatment visit	Tumour assessment (10/09/2014) not done within 12 weeks of the previous tumor assessment (15/05/2014). (Difference = 16.9 weeks, first cetuximab administration = 05/12/2013)		Minor
400-02-013	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (13/03/2015) done within 1 month prior the End of treatment visit (27/03/2015)	None
400-02-013	CETTRT3	Infusion visit 32	Period between two successive Cetuximab administrations (Infusion visit 31 - Infusion visit 32) is more than 21 days [35]	Due to surgery (laporectomy on 12/08/2014)	None
400-02-013	EFFA1	Infusion visit 32	Tumour assessment (05/08/2014) not done within 12 weeks of the previous tumor assessment (04/06/2014). (Difference = 8.9 weeks, first cetuximab administration = 17/12/2013)		Minor
400-02-013	EFFA1	Infusion visit 40	Tumour assessment (10/10/2014) not done within 12 weeks of the previous tumor assessment (05/08/2014). (Difference = 9.4 weeks, first cetuximab administration = 17/12/2013)		Minor
400-02-013	CETTRT3	Infusion visit 48	Period between two successive Cetuximab administrations (Infusion visit 47 - Infusion visit 48) is more than 21 days [56]	Due to surgery (liver metastasis resection on 08/01/2015)	None
400-02-013	EFFA1	Infusion visit 48	Tumour assessment (13/03/2015) not done within 12 weeks of the previous tumor assessment (10/10/2014). (Difference = 22.0 weeks, first cetuximab administration = 17/12/2013)		Minor
400-02-014	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening: 1119 U/L; Baseline: 1286 U/L (ULN: 290)	None
400-02-014	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (24/03/2014) is older than 4 weeks from the End of treatment visit (09/05/2014) but patient had fatigue grade 2 on 09/05/2014	Minor
400-02-015	GCP		The SAE 201400064 is not reported within 2 days from the onset of the event (interval = 6 days).		MAJOR_GCP
400-02-015	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [EOT visit was not done. Amputation is indicated. After the patient didn't come to the hospital and we lost to follow up. So the protocol therapy stopped suddenly and the EOT was not done. Last contact on 28/08/2014.] ; Date of assessment: NA/N; Date of last cetuximab administration = 28/08/2014).		None
400-02-015	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (11/08/2014) done within 1 month prior the End of treatment visit (Lost to follow-up and 28/08/2014 = date of last contact)	None
400-06-001	GCP		The SAE 201300050 is not reported within 2 days from the onset of the event (interval = 8 days).		MAJOR_GCP
400-06-001	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	The CT confirming the progression for the patient at the end of treatment is not available at the site - as it was done abroad	None
400-06-001	EFFA1	Infusion visit 32	Tumour assessment (04/12/2012) not done within 12 weeks of the previous tumor assessment (16/10/2012). (Difference = 7.0 weeks, first cetuximab administration = 10/05/2012)		Minor
400-06-001	EFFA1	Infusion visit 40	Tumour assessment (28/01/2013) not done within 12 weeks of the previous tumor assessment (04/12/2012). (Difference = 7.9 weeks, first cetuximab administration = 10/05/2012)		Minor

Patient ID	PV code	Visit	Protocol variation: description	Additional description	Type
400-06-001	EFFA1	Infusion visit 48	Tumour assessment (25/03/2013) not done within 12 weeks of the previous tumor assessment (28/01/2013). (Difference = 8.0 weeks, first cetuximab administration = 10/05/2012)		Minor
400-06-001	EFFA1	Infusion visit 56	Tumour assessment (23/05/2013) not done within 12 weeks of the previous tumor assessment (25/03/2013). (Difference = 8.4 weeks, first cetuximab administration = 10/05/2012)		Minor
400-06-002	EFFA1	Infusion visit 32	Tumour assessment (20/12/2012) not done within 12 weeks of the previous tumor assessment (30/10/2012). (Difference = 7.3 weeks, first cetuximab administration = 24/05/2012)		Minor
400-06-002	EFFA1	Infusion visit 40	Tumour assessment (08/02/2013) not done within 12 weeks of the previous tumor assessment (20/12/2012). (Difference = 7.1 weeks, first cetuximab administration = 24/05/2012)		Minor
400-06-002	EFFA1	Infusion visit 48	Tumour assessment (05/04/2013) not done within 12 weeks of the previous tumor assessment (08/02/2013). (Difference = 8.0 weeks, first cetuximab administration = 24/05/2012)		Minor
400-06-002	EFFA1	Infusion visit 56	Tumour assessment (04/06/2013) not done within 12 weeks of the previous tumor assessment (05/04/2013). (Difference = 8.6 weeks, first cetuximab administration = 24/05/2012)		Minor
400-06-003	EFFA1	End of treatment visit	Tumour assessment (20/08/2013) not done within 12 weeks of the previous tumor assessment (11/03/2013). (Difference = 23.1 weeks, first cetuximab administration = 14/06/2012)		Minor
400-06-003	EFFA1	Infusion visit 32	Tumour assessment (14/01/2013) not done within 12 weeks of the previous tumor assessment (19/11/2012). (Difference = 8.0 weeks, first cetuximab administration = 14/06/2012)		Minor
400-06-003	EFFA1	Infusion visit 40	Tumour assessment (11/03/2013) not done within 12 weeks of the previous tumor assessment (14/01/2013). (Difference = 8.0 weeks, first cetuximab administration = 14/06/2012)		Minor
400-06-004	EFFA1	End of treatment visit	Tumour assessment (18/12/2014) not done within 12 weeks of the previous tumor assessment (25/08/2014). (Difference = 16.4 weeks, first cetuximab administration = 03/08/2012)		Minor
400-06-004	EFFA1	Infusion visit 32	Tumour assessment (04/03/2013) not done within 12 weeks of the previous tumor assessment (09/01/2013). (Difference = 7.7 weeks, first cetuximab administration = 03/08/2012)		Minor
400-06-004	EFFA1	Infusion visit 40	Tumour assessment (02/05/2013) not done within 12 weeks of the previous tumor assessment (04/03/2013). (Difference = 8.4 weeks, first cetuximab administration = 03/08/2012)		Minor
400-06-004	EFFA1	Infusion visit 48	Tumour assessment (26/06/2013) not done within 12 weeks of the previous tumor assessment (02/05/2013). (Difference = 7.9 weeks, first cetuximab administration = 03/08/2012)		Minor
400-06-004	CETTRT3	Infusion visit 95	Period between two successive Cetuximab administrations (Infusion visit 93 - Infusion visit 95) is more than 21 days [22]	Due to Toxicity (AE)	Minor
400-06-005	EFFA1	Infusion visit 32	Tumour assessment (03/04/2013) not done within 12 weeks of the previous tumor assessment (11/02/2013). (Difference = 7.3 weeks, first cetuximab administration = 06/09/2012)		Minor
400-06-005	EFFA1	Infusion visit 40	Tumour assessment (27/05/2013) not done within 12 weeks of the previous tumor assessment (03/04/2013). (Difference = 7.7 weeks, first cetuximab administration = 06/09/2012)		Minor
400-06-007	CETTRT1		Patient discontinued before arm allocation (Reason = Death [Other events not related to study medication or progression of disease:] ; Date of death: 01/12/2012); Date of first cetuximab administration = 31/10/2012; Date of last cetuximab administration = 08/11/2012.		None_ARM
400-06-007	GCP		The SAE 201200041 is not reported within 2 days from the onset of the event (interval = 5 days).		MAJOR_GCP
400-06-007	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening: 821 U/L; Baseline: 842 U/L (ULN: 306)	Minor
400-06-007	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Patient died unexpectedly because of adverse event, no tumor evaluation was performed	None
600-01-001	GCP		The SAE 201100011 is not reported within 2 days from the onset of the event (interval = 15 days).		MAJOR_GCP
600-01-001	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening: 296 U/L; Baseline: not done (ULN: 90); Waiver granted	Minor
600-01-001	EFFA1	Infusion visit 32	Tumour assessment (05/01/2012) not done within 12 weeks of the previous tumor assessment (14/11/2011). (Difference = 7.4 weeks, first cetuximab administration = 07/06/2011)		Minor
600-01-002	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: 12/09/2011; Date of last cetuximab administration = 31/08/2011).		None
600-01-003	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - non-biopsiable lesion)		Minor

Patient ID	PV code	Visit	Protocol variation: description	Additional description	Type
600-01-003	CETTRT5	Infusion visit 8	Commercial medication given instead of study medication		MAJOR_GCP
600-01-004	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - non biopsiable tumor)		Minor
600-01-004	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Patient best interest [Treatment stopped due to stability of the retroperineal lesions observed in the control CT scan, the patient did not have surgery. There is residual] ; Date of assessment: 16/04/2012; Date of last cetuximab administration = 28/03/2012).		None
600-01-004	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (01/03/2012) is older than 4 weeks from the End of treatment visit (16/04/2012)	Minor
600-01-005	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - non biopsiable)		Minor
600-01-005	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Patient best interest [Surgery] ; Date of assessment: 21/03/2012; Date of last cetuximab administration = 14/03/2012).		None
600-01-006	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - Non biopsiable)		Minor
600-01-006	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: 23/05/2012; Date of last cetuximab administration = 25/04/2012).		None
600-01-007	CETTRT1		Patient discontinued before arm allocation (Reason = Adverse event ; Date of assessment: 20/02/2012); Date of first cetuximab administration = 30/01/2012; Date of last cetuximab administration = 06/02/2012.		None_ARM
600-01-007	GCP		The SAE 201200016 is not reported within 2 days from the onset of the event (interval = 3 days).		MAJOR_GCP
600-01-007	BIOP1	Screening visit	Biopsy tumour sample not taken at baseline: (Reason = Other - The patient did not consent)		Minor
600-01-007	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	The patient refuses to continue with the study treatment due to the toxicity.	None
600-01-008	IC11	Screening visit	Inclusion criteria 11 violated (ASAT = < 2.5 x ULN, up to = < 5 x ULN in case of liver metastases).	Screening= Baseline: 158 U/L (UPL: 40 U/L)	Minor
600-01-008	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening= Baseline: 572 U/L (UPL: 110 U/L)	Minor
600-01-009	EFFA2	Screening visit	Tumour assessment (05/01/2012) not done within 21 days before first cetuximab administration (13/02/2012). (Difference = 39 days)		Minor
600-01-009	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (02/04/2012) done within 1 month prior End of treatment visit (25/04/2012)	None
600-01-010	EFFA2	Screening visit	Tumour assessment (06/02/2012) not done within 21 days before first cetuximab administration (15/03/2012). (Difference = 38 days)		Minor
600-01-010	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening: 230 U/L; Baseline: not done (ULN: 90)	Minor
600-01-010	EFFA1	Infusion visit 8	Tumour assessment (04/04/2012) not done within 8 weeks of first Cetuximab treatment (15/03/2012). (Difference = 2.9 weeks)		Minor
600-01-011	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening: 654 U/L; Baseline: not done (ULN: 110)	Minor
600-01-012	GCP		The SAE 201200022 is not reported within 2 days from the onset of the event (interval = 5 days).		MAJOR_GCP
600-01-012	EFFA2	Screening visit	Tumour assessment (01/02/2012) not done within 21 days before first cetuximab administration (21/03/2012). (Difference = 49 days)		Minor
600-01-013	GCP		The SAE 201200029 is not reported within 2 days from the onset of the event (interval = 9 days).		MAJOR_GCP
600-01-013	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: 19/12/2012; Date of last cetuximab administration = 21/11/2012).		None
600-01-013	CETTRT3	Infusion visit 9	Period between two successive Cetuximab administrations (Infusion visit 8 - Infusion visit 9) is more than 21 days [28]	Due to Toxicity (AE)	Minor
600-01-014	EFFA1	Infusion visit 24	Tumour assessment (25/01/2013) not done within 12 weeks of the previous tumor assessment (15/10/2012). (Difference = 14.6 weeks, first cetuximab administration = 02/07/2012)		Minor

Patient ID	PV code	Visit	Protocol variation: description	Additional description	Type
600-01-015	EFFA2	Screening visit	Tumour assessment (07/06/2012) not done within 21 days before first cetuximab administration (09/07/2012). (Difference = 32 days)		Minor
600-01-015	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: 27/09/2012; Date of last cetuximab administration = 28/08/2012).		None
600-01-015	EFFA1	End of treatment visit	Tumour assessment (27/09/2012) not done within 8 weeks of the previous tumor assessment (09/07/2012). (Difference = 11.4 weeks, first cetuximab administration = 09/07/2012)		Minor
600-01-015	CETTRT3	Infusion visit 4	Period between two successive Cetuximab administrations (Infusion visit 2 - Infusion visit 4) is more than 21 days [22]	Due to Toxicity (AE)	Minor
600-01-016	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: 05/12/2012; Date of last cetuximab administration = 28/11/2012).		None
600-01-016	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (31/10/2012) is older than 4 weeks from the End of treatment visit (05/12/2012)	Minor
600-01-016	CETTRT3	Infusion visit 4	Period between two successive Cetuximab administrations (Infusion visit 2 - Infusion visit 4) is more than 21 days [22]	Due to Toxicity (AE)	Minor
600-01-017	CETTRT1		Patient discontinued before arm allocation (Reason = Withdrawal of consent or patient request ; Date of assessment: 14/08/2012); Date of first cetuximab administration = 24/07/2012; Date of last cetuximab administration = 31/07/2012.		None_ARM
600-01-017	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Withdrawal of consent or patient request ; Date of assessment: 14/08/2012; Date of last cetuximab administration = 31/07/2012).		None
600-01-017	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	The patient withdraw consent	None
600-01-018	GCP		The SAE 201200040 is not reported within 2 days from the onset of the event (interval = 3 days).		MAJOR_GCP
600-01-018	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Patient died unexpectedly because of adverse event, no tumor evaluation was performed	None
600-01-020	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: ND/ND/ND; Date of last cetuximab administration = 13/05/2013).		None
600-01-020	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (29/04/2013) , last Cetuximab infusion given on 13/05/2013 and End of treatment visit not done due to Surgery (Segmentectomy VI-VII + Cholecystectomy) performed on 30/05/2013	None
600-01-021	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Patient best interest [Treatment delay] ; Date of assessment: 22/10/2014; Date of last cetuximab administration = 08/10/2014).		None
600-01-021	EFFA1	End of treatment visit	Tumour assessment (22/10/2014) not done within 12 weeks of the previous tumor assessment (02/07/2014). (Difference = 16.0 weeks, first cetuximab administration = 19/03/2013)		Minor
600-01-021	EFFA1	Infusion visit 32	Tumour assessment (28/10/2013) not done within 12 weeks of the previous tumor assessment (28/08/2013). (Difference = 8.7 weeks, first cetuximab administration = 19/03/2013)		Minor
600-01-021	EFFA1	Infusion visit 40	Tumour assessment (30/12/2013) not done within 12 weeks of the previous tumor assessment (28/10/2013). (Difference = 9.0 weeks, first cetuximab administration = 19/03/2013)		Minor
600-01-021	EFFA1	Infusion visit 48	Tumour assessment (12/02/2014) not done within 12 weeks of the previous tumor assessment (30/12/2013). (Difference = 6.3 weeks, first cetuximab administration = 19/03/2013)		Minor
600-01-021	EFFA1	Infusion visit 64	Tumour assessment (02/07/2014) not done within 12 weeks of the previous tumor assessment (19/05/2014). (Difference = 6.3 weeks, first cetuximab administration = 19/03/2013)		Minor
600-01-021	CETTRT3	Infusion visit 70	Period between two successive Cetuximab administrations (Infusion visit 67 - Infusion visit 70) is more than 21 days [28]	Due to Toxicity (AE)	Minor

Patient ID	PV code	Visit	Protocol variation: description	Additional description	Type
600-01-022	EFFA2	Screening visit	Tumour assessment (07/03/2013) not done within 21 days before first cetuximab administration (09/04/2013). (Difference = 33 days)		Minor
600-01-022	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Withdrawal of consent or patient request ; Date of assessment: 31/07/2013; Date of last cetuximab administration = 24/07/2013).		None
600-01-022	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (24/07/2013) done within 1 month prior End of treatment visit (31/07/2013)	None
600-01-023	EFFA2	Screening visit	Tumour assessment (26/02/2013) not done within 21 days before first cetuximab administration (05/04/2013). (Difference = 38 days)		Minor
600-01-023	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening: 317 U/L; Baseline: not done (ULN: 90)	Minor
600-01-023	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (27/05/2013) done within 1 month prior End of treatment visit (21/06/2013)	None
600-01-023	OTH1	Infusion visit 7	Based on the occurence of new lesion and results on 27/05/2013 (IV7) that showed a progressive disease, the patient should have been taken off study but the treatment was continued for 2 more weeks until 11/06/2013 (IV9). The patient was discontinued on 17/06/2013 due to this Disease progression.		Minor
600-01-024	EFFA1	Infusion visit 16	Tumour assessment (30/10/2013) not done within 8 weeks of the previous tumor assessment (15/07/2013). (Difference = 15.3 weeks, first cetuximab administration = 28/05/2013)		Minor
600-01-024	CETTRT3	Infusion visit 21	Period between two successive Cetuximab administrations (Infusion visit 19 - Infusion visit 21) is more than 21 days [43]	Due to Toxicity (AE)	Minor
600-01-024	EFFA1	Infusion visit 24	Tumour assessment (27/12/2013) not done within 12 weeks of the previous tumor assessment (30/10/2013). (Difference = 8.3 weeks, first cetuximab administration = 28/05/2013)		Minor
600-01-024	CETTRT3	Infusion visit 7	Period between two successive Cetuximab administrations (Infusion visit 6 - Infusion visit 7) is more than 21 days [49]	Due to surgery (sigmoidectomy + terminal colostomy on 23/07/2013)	None
600-01-025	EFFA1	End of treatment visit	Tumour assessment (30/07/2014) not done within 12 weeks of the previous tumor assessment (17/04/2014). (Difference = 14.9 weeks, first cetuximab administration = 30/05/2013)		Minor
600-01-025	EFFA1	Infusion visit 32	Tumour assessment (30/12/2013) not done within 12 weeks of the previous tumor assessment (11/11/2013). (Difference = 7.0 weeks, first cetuximab administration = 30/05/2013)		Minor
600-01-025	EFFA1	Infusion visit 40	Tumour assessment (17/04/2014) not done within 12 weeks of the previous tumor assessment (30/12/2013). (Difference = 15.4 weeks, first cetuximab administration = 30/05/2013)		Minor
600-01-025	CETTRT3	Infusion visit 53	Period between two successive Cetuximab administrations (Infusion visit 50 - Infusion visit 53) is more than 21 days [22]	Due to Toxicity (AE)	Minor
600-01-026	CETTRT3	Infusion visit 30	Period between two successive Cetuximab administrations (Infusion visit 27 - Infusion visit 30) is more than 21 days [49]	Due to Toxicity (AE)	Minor
600-01-026	EFFA1	Infusion visit 32	Tumour assessment (10/02/2014) not done within 12 weeks of the previous tumor assessment (23/12/2013). (Difference = 7.0 weeks, first cetuximab administration = 09/07/2013)		Minor
600-01-026	EFFA1	Infusion visit 40	Tumour assessment (02/06/2014) not done within 12 weeks of the previous tumor assessment (10/02/2014). (Difference = 16.0 weeks, first cetuximab administration = 09/07/2013)		Minor
600-01-027	EFFA1	End of treatment visit	Tumour assessment (03/09/2015) not done within 12 weeks of the previous tumor assessment (22/05/2015). (Difference = 14.9 weeks, first cetuximab administration = 16/07/2013)		Minor
600-01-027	CETTRT3	Infusion visit 18	Period between two successive Cetuximab administrations (Infusion visit 16 - Infusion visit 18) is more than 21 days [30]	Due to Toxicity (AE)	Minor
600-01-027	CETTRT3	Infusion visit 40	Period between two successive Cetuximab administrations (Infusion visit 38 - Infusion visit 40) is more than 21 days [28]	Due to Toxicity (AE)	Minor
600-01-027	CETTRT4	Infusion visit 40	Cetuximab dose reduction for reason other than Toxicity/AE: (Due to investigator's decision)	Reduction by 30% after a delay by 1 week due to Toxicity(AE). Dose	Minor

Patient ID	PV code	Visit	Protocol variation: description	Additional description	Type
				remained reduced till last infucion (IV103)	
600-01-027	EFFA1	Infusion visit 64	Tumour assessment (19/11/2014) not done within 12 weeks of the previous tumor assessment (17/09/2014). (Difference = 9.0 weeks, first cetuximab administration = 16/07/2013)		Minor
600-01-028	CETTRT1		Patient discontinued before arm allocation (Reason = Death [Other events not related to study medication or progression of disease:] ; Date of death: 20/10/2013); Date of first cetuximab administration = 04/09/2013; Date of last cetuximab administration = 04/09/2013.		None_ARM
600-01-028	GCP		The SAE 201300053 is not reported within 2 days from the onset of the event (interval = 60 days).		MAJOR_GCP
600-01-028	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Patient died unexpectedly because of adverse event, no tumor evaluation was performed	None
600-01-029	GCP		The SAE 201400063 is not reported within 2 days from the onset of the event (interval = 3 days).		MAJOR_GCP
600-01-029	GCP		The SAE 201400067 is not reported within 2 days from the onset of the event (interval = 4 days).		MAJOR_GCP
600-01-029	EFFA2	Screening visit	Tumour assessment (25/07/2013) not done within 21 days before first cetuximab administration (28/08/2013). (Difference = 34 days)		Minor
600-01-029	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: 13/01/2016; Date of last cetuximab administration = 16/12/2015).		None
600-01-029	EFFA1	Infusion visit 16	Tumour assessment (21/01/2014) not done within 8 weeks of the previous tumor assessment (06/11/2013). (Difference = 10.9 weeks, first cetuximab administration = 28/08/2013)		Minor
600-01-029	EFFA1	Infusion visit 24	Tumour assessment (26/02/2014) not done within 8 weeks of the previous tumor assessment (21/01/2014). (Difference = 5.1 weeks, first cetuximab administration = 28/08/2013)		Minor
600-01-029	CETTRT3	Infusion visit 32	Period between two successive Cetuximab administrations (Infusion visit 30 - Infusion visit 32) is more than 21 days [30]	Due to Toxicity (AE)	Minor
600-01-029	EFFA1	Infusion visit 40	Tumour assessment (16/07/2014) not done within 12 weeks of the previous tumor assessment (21/05/2014). (Difference = 8.0 weeks, first cetuximab administration = 28/08/2013)		Minor
600-01-029	CETTRT3	Infusion visit 64	Period between two successive Cetuximab administrations (Infusion visit 63 - Infusion visit 64) is more than 21 days [29]	Due to Toxicity (AE)	Minor
600-01-029	EFFA1	Infusion visit 80	Tumour assessment (03/07/2015) not done within 12 weeks of the previous tumor assessment (25/03/2015). (Difference = 14.3 weeks, first cetuximab administration = 28/08/2013)		Minor
600-01-029	EFFA1	Infusion visit 88	Tumour assessment (07/09/2015) not done within 12 weeks of the previous tumor assessment (03/07/2015). (Difference = 9.4 weeks, first cetuximab administration = 28/08/2013)		Minor
600-01-029	EFFA1	Infusion visit 96	Tumour assessment (12/11/2015) not done within 12 weeks of the previous tumor assessment (07/09/2015). (Difference = 9.4 weeks, first cetuximab administration = 28/08/2013)		Minor
600-01-030	GCP		The SAE 201400066 is not reported within 2 days from the onset of the event (interval = 5 days).		MAJOR_GCP
600-01-030	GCP		The SAE 201500071 is not reported within 2 days from the onset of the event (interval = 16 days).		MAJOR_GCP
600-01-030	GCP		The SAE 201600076 is not reported within 2 days from the onset of the event (interval = 823 days).		MAJOR_GCP
600-01-030	CETTRT3	Infusion visit 25	Period between two successive Cetuximab administrations (Infusion visit 24 - Infusion visit 25) is more than 21 days [22]		Minor
600-01-030	CETTRT3	Infusion visit 40	Period between two successive Cetuximab administrations (Infusion visit 39 - Infusion visit 40) is more than 21 days [29]	Due to holiday	Minor
600-01-030	CETTRT3	Infusion visit 46	Period between two successive Cetuximab administrations (Infusion visit 44 - Infusion visit 46) is more than 21 days [22]	Due to Toxicity (AE)	Minor
600-01-030	CETTRT3	Infusion visit 50	Period between two successive Cetuximab administrations (Infusion visit 49 - Infusion visit 50) is more than 21 days [23]	Due to the CT scan results were pending	Minor
600-01-031	CETTRT3	Infusion visit 10	Period between two successive Cetuximab administrations (Infusion visit 9 - Infusion visit 10) is more than 21 days [141]	Due to surgeries (central hepatectomy + metastasectomy SVI; cholecystectomy on 13/02/2014 and total colectomy on 10/04/2014) - Period more than 12 weeks	Minor

Patient ID	PV code	Visit	Protocol variation: description	Additional description	Type
600-01-031	OTH1	End of treatment visit	Based on the occurrence of new lesion on 06/05/2014 (between IV 9 and IV10) that showed a progressive disease, the patient should have been taken off study but the treatment was continued for 35 more weeks until 05/01/2015 (IV39). The patient was discontinued on 28/01/2015 due to a Disease progression evaluated on 29/12/2014.		Minor
600-01-031	EFFA1	Infusion visit 16	Tumour assessment (06/05/2014) not done within 8 weeks of the previous tumor assessment (22/01/2014). (Difference = 14.9 weeks, first cetuximab administration = 25/11/2013)		Minor
600-01-031	EFFA1	Infusion visit 32	Tumour assessment (15/10/2014) not done within 12 weeks of the previous tumor assessment (07/08/2014). (Difference = 9.9 weeks, first cetuximab administration = 25/11/2013)		Minor
600-01-032	EC1	Screening visit	Exclusion criterion 1 violated: FOLFOX was given till 1.3 months prior to enrolment / 1.7 month prior to C1D1.		MAJOR_EFF
600-01-032	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Patient best interest [Investigator's decision]; Date of assessment: 26/11/2014; Date of last cetuximab administration = 26/11/2014).		None
600-01-032	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Patient is out of study due to not be eligible, no tumor evaluation was performed	None
600-01-033	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [Surgery] ; Date of assessment: 30/01/2014; Date of last cetuximab administration = 27/01/2014).		None
600-01-034	GCP		The SAE 201400060 is not reported within 2 days from the onset of the event (interval = 5 days).		MAJOR_GCP
600-01-034	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (27/05/2014) is older than 4 weeks from the End of treatment visit (02/07/2014)	Minor
600-01-035	GCP		The SAE 201500075 is not reported within 2 days from the onset of the event (interval = 13 days).		MAJOR_GCP
600-01-035	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening: 628 U/L; Baseline: not done (ULN: 110)	None
600-01-035	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Study closure; Date of assessment: 25/07/2016; Date of last cetuximab administration = 27/06/2016).		None
600-01-035	EFFA1	Infusion visit 48	Tumour assessment (07/01/2015) not done within 12 weeks of the previous tumor assessment (29/09/2014). (Difference = 14.3 weeks, first cetuximab administration = 23/01/2014)		Minor
600-01-035	CETTRT3	Infusion visit 56	Period between two successive Cetuximab administrations (Infusion visit 55 - Infusion visit 56) is more than 21 days [26]	Due to Toxicity (AE)	Minor
600-01-035	EFFA1	Infusion visit 56	Tumour assessment (11/03/2015) not done within 12 weeks of the previous tumor assessment (07/01/2015). (Difference = 9.0 weeks, first cetuximab administration = 23/01/2014)		Minor
600-01-035	CETTRT3	Infusion visit 91	Period between two successive Cetuximab administrations (Infusion visit 90 - Infusion visit 91) is more than 21 days [28]	Due to Toxicity (AE)	Minor
600-01-035	EFFA1	Infusion visit 96	Tumour assessment (22/02/2016) not done within 12 weeks of the previous tumor assessment (11/11/2015). (Difference = 14.7 weeks, first cetuximab administration = 23/01/2014)		Minor
600-01-036	BIOP2		Patient didn't give optional biopsy ICF at progression but Yes was selected by error, no biopsy taken on End of treatment visit	eCRF comment: Error in completing the information on IC in the eCRF	None
600-01-036	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Other [complete response]; Date of assessment: 30/03/2016; Date of last cetuximab administration = 22/02/2016).		None
600-01-036	EFFA1	End of treatment visit	Tumour assessment (19/03/2016) not done within 12 weeks of the previous tumor assessment (24/11/2015). (Difference = 16.6 weeks, first cetuximab administration = 12/02/2014)		Minor
600-01-036	CETTRT3	Infusion visit 102	Period between two successive Cetuximab administrations (Infusion visit 101 - Infusion visit 102) is more than 21 days [28]	Due to Toxicity (AE)	Minor
600-01-038	GCP		The SAE 201400058 is not reported within 2 days from the onset of the event (interval = 6 days).		MAJOR_GCP
600-01-038	GCP		The SAE 201600077 is not reported within 2 days from the onset of the event (interval = 5 days).		MAJOR_GCP
600-01-038	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening: 333 U/L; Baseline: not done (ULN: 110)	None

Patient ID	PV code	Visit	Protocol variation: description	Additional description	Type
600-01-038	EFFA1	Infusion visit 16	Tumour assessment (10/06/2014) not done within 8 weeks of the previous tumor assessment (27/03/2014). (Difference = 10.7 weeks, first cetuximab administration = 05/02/2014)		Minor
600-01-038	EFFA1	Infusion visit 32	Tumour assessment (29/09/2014) not done within 12 weeks of the previous tumor assessment (22/07/2014). (Difference = 9.9 weeks, first cetuximab administration = 05/02/2014)		Minor
600-01-038	EFFA1	Infusion visit 72	Tumour assessment (29/06/2015) not done within 12 weeks of the previous tumor assessment (18/03/2015). (Difference = 14.7 weeks, first cetuximab administration = 05/02/2014)		Minor
600-01-038	EFFA1	Infusion visit 48	Tumour assessment (07/01/2015) not done within 12 weeks of the previous tumor assessment (29/09/2014). (Difference = 14.3 weeks, first cetuximab administration = 05/02/2014)		Minor
600-01-038	CETTRT3	Infusion visit 96	Period between two successive Cetuximab administrations (Infusion visit 95 - Infusion visit 96) is more than 21 days [24]	Investigator's decision	Minor
600-01-040	GCP		The SAE 201500073 is not reported within 2 days from the onset of the event (interval = 3 days).		MAJOR_GCP
600-01-040	EFFA2	Screening visit	Tumour assessment (28/02/2014) not done within 21 days before first cetuximab administration (31/03/2014). (Difference = 31 days)		Minor
600-01-040	EFFA1	End of treatment visit	Tumour assessment (17/12/2015) not done within 12 weeks of the previous tumor assessment (03/09/2015). (Difference = 15.0 weeks, first cetuximab administration = 31/03/2014)		Minor
600-01-040	CETTRT3	Infusion visit 13	Period between two successive Cetuximab administrations (Infusion visit 12 - Infusion visit 13) is more than 21 days [22]	Due to Toxicity (AE)	Minor
600-01-040	EFFA1	Infusion visit 56	Tumour assessment (08/06/2015) not done within 12 weeks of the previous tumor assessment (23/02/2015). (Difference = 15.0 weeks, first cetuximab administration = 31/03/2014)		Minor
600-01-040	CETTRT3	Infusion visit 66	Period between two successive Cetuximab administrations (Infusion visit 65 - Infusion visit 66) is more than 21 days [22]	Due to holiday	Minor
600-01-040	EFFA1	Infusion visit 8	Tumour assessment (16/06/2014) not done within 8 weeks of first Cetuximab treatment (31/03/2014). (Difference = 11.0 weeks)		Minor
600-02-001	GCP		The SAE 201100010 is not reported within 2 days from the onset of the event (interval = 3 days).		MAJOR_GCP
600-02-001	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening: 788 U/L; Baseline: not done (ULN: 300)	Minor
600-02-001	CETTRT5	Infusion visit 1	Study medication given instead of commercial medication		MAJOR_GCP
600-02-002	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (23/07/2014) done within 1 month prior the End of treatment visit (07/08/2014)	None
600-02-002	EFFA1	Infusion visit 32	Tumour assessment (28/05/2014) not done within 12 weeks of the previous tumor assessment (02/04/2014). (Difference = 8.0 weeks, first cetuximab administration = 17/10/2013)		Minor
600-02-002	EFFA1	Infusion visit 40	Tumour assessment (23/07/2014) not done within 12 weeks of the previous tumor assessment (28/05/2014). (Difference = 8.0 weeks, first cetuximab administration = 17/10/2013)		Minor
600-04-001	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening: 311 U/L; Baseline: not done (ULN: 90); Waiver granted	Minor
600-04-001	OTH1	Infusion visit 25	Based on the occurrence of new lesion on 13/12/2011 (IV25) that showed a progressive disease, the patient should have been taken off study but the treatment was given on 13/12/2011 because the Principal investigator hadn't the CT scan report available on this visit. The patient was discontinued on 15/02/2012 due to this Disease progression.		Minor
600-04-002	EFFA1	End of treatment visit	Tumour assessment (11/06/2013) not done within 12 weeks of the previous tumor assessment (27/02/2013). (Difference = 14.9 weeks, first cetuximab administration = 30/01/2012)		Minor
600-04-002	EFFA1	Infusion visit 32	Tumour assessment (15/09/2012) not done within 12 weeks of the previous tumor assessment (21/07/2012). (Difference = 8.0 weeks, first cetuximab administration = 30/01/2012)		Minor
600-04-003	GCP		The SAE 201200038 is not reported within 2 days from the onset of the event (interval = 10 days).		MAJOR_GCP
600-04-003	GCP		The SAE 201200039 is not reported within 2 days from the onset of the event (interval = 18 days).		MAJOR_GCP
600-04-003	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening= Baseline: 443.11 U/L (ULN: 90)	Minor

Patient ID	PV code	Visit	Protocol variation: description	Additional description	Type
600-04-003	BIOP2	Infusion Visit 4	Patient didn't give optional biopsy ICF on treatment and at progression but Yes was selected by error, and biopsy taken on Infusion visit 4	eCRF comment: Error in completing the information on IC in the eCRF; Biopsy sample has been destroyed	MAJOR_GCP
600-04-004	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Withdrawal of consent or patient request; Date of assessment: 10/06/2013; Date of last cetuximab administration = 03/06/2013).		None
600-04-005	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Withdrawal of consent or patient request; Date of assessment: 25/03/2014; Date of last cetuximab administration = 18/03/2014).		None
600-04-005	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (20/03/2014) done within 1 month prior the End of treatment visit (25/03/2014)	None
600-04-005	EFFA1	Infusion visit 24	Tumour assessment (16/08/2013) not done within 8 weeks of the previous tumor assessment (12/07/2013). (Difference = 5.0 weeks, first cetuximab administration = 07/03/2013)		Minor
600-04-005	EFFA1	Infusion visit 32	Tumour assessment (08/10/2013) not done within 12 weeks of the previous tumor assessment (16/08/2013). (Difference = 7.6 weeks, first cetuximab administration = 07/03/2013)		Minor
600-04-007	DISC	End of treatment visit	Premature study treatment discontinuation (Reason = Withdrawal of consent or patient request; Date of assessment: 31/12/2014; Date of last cetuximab administration = 24/12/2014).		None
600-04-007	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (08/10/2014) is older than 4 weeks from the End of treatment visit (31/12/2014)	Minor
600-04-007	EFFA1	Infusion visit 16	Tumour assessment (30/08/2013) not done within 8 weeks of the previous tumor assessment (15/06/2013). (Difference = 10.9 weeks, first cetuximab administration = 25/04/2013)		Minor
600-04-007	EFFA1	Infusion visit 56	Tumour assessment (08/05/2014) not done within 12 weeks of the previous tumor assessment (25/01/2014). (Difference = 14.7 weeks, first cetuximab administration = 25/04/2013)		Minor
600-04-007	EFFA1	Infusion visit 80	Tumour assessment (08/10/2014) not done within 12 weeks of the previous tumor assessment (31/07/2014). (Difference = 9.9 weeks, first cetuximab administration = 25/04/2013)		Minor
600-04-008	GCP		The SAE 201400062 is not reported within 2 days from the onset of the event (interval = 5 days).		MAJOR_GCP
600-04-008	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (21/10/2014) done within 1 month prior the End of treatment visit (11/11/2014)	None
600-05-001	GCP		The SAE 201100013 is not reported within 2 days from the onset of the event (interval = 5 days).		MAJOR_GCP
600-05-001	IC11	Screening visit	Inclusion criteria 11 violated (Hemoglobin > = 10.0 g/dL).	Screening: 9.2 g/dL; Baseline: 9.7 g/dL	Minor
600-05-001	IC11	Screening visit	Inclusion criteria 11 violated (Alkaline phosphatase = < 2.5 x ULN).	Screening: 373 U/L; Baseline: not done (ULN: 129)	Minor
600-05-001	EFFA3	End of treatment visit	Tumour assessment not done at End of Treatment Visit.	Last tumor evaluation (26/03/2012) done within 1 month prior the End of treatment visit (03/04/2012)	None

Legend:

PV code	PV code: Description
ICXX	Inclusion criteria not met according to check boxes at Screening visit (any inclusion criterion different from 'Yes' without taking waiver into account)
ECXX	Exclusion criteria not met according to check boxes at Screening visit (any exclusion criterion different from 'No' without taking waiver into account)
CETTRT1	No arm allocation (patient withdrawn before Infusion visit 4)
CETTRT2	1) Patients who were escalated but should not have been as per protocol 2) Patients who were not escalated but should have been as per protocol
CETTRT3	Period between two successive Cetuximab administrations is more than 21 days
CETTRT4	Cetuximab dose reduction with reason for deviation = other
CETTRT5	1) For patients in following centers: 400-02, 400-06, 600-01 and 600-03: Commercial medication given instead of study medication (as all infusions doses should be study medication) 2) For patients in other centers: Cycle 1 to 3: Study medication given instead of commercial medication Cycle 4 and further: - If arm A: Commercial medication given instead of study medication - If arm B: Study medication given instead of commercial medication
BIOP1	Biopsy at baseline not taken and reason
BIOP2	No consent given for additional biopsies but additional biopsies taken
EFFA1	Tumor evaluation not performed every 8 weeks +/- 2 weeks between successive assessment for the period from first administration of cetuximab until 6 months after first administration of cetuximab. The first tumor evaluation is compared to the first administration of cetuximab. Tumor evaluation not performed every 12 weeks +/- 2 weeks between successive assessment for the period from 6 months after first administration of cetuximab until last infusion visit.
EFFA2	Tumor assessment of target lesions at screening not performed within 21 days before first cetuximab administration. If the tumor assessment at screening is performed on different dates, the minimum date is taken.
EFFA3	Tumor evaluation not performed at End of Treatment visit
DISC	Premature study treatment discontinuation and reason other than Progression of disease, Adverse Event or Death
GCP	SAE reporting not within 2 days from onset of the event
OTH1	Protocol variations not belonging to one of the previous code categories
OTH2	Protocol variations not belonging to one of the previous code categories