

PROTOCOL DEVIATIONS AT DATABASE LOCK (29/04/2019)

Centre	Pt. ID	Category of deviation	Deviation short name
Site 01	01-002	G – Visit Schedule/Interval	Interval between infusions not respected
Site 01	01-006	D – Study Procedures	On study frequency of QLQ not respected
Site 01	01-013	G – Visit Schedule/Interval	Interval between infusions not respected
Site 01	01-014	F – Study Treatment Dosing	Dose re-escalated after reduction
Site 01	01-014	H - Other	Use of study labelled medication on non-study patient
Site 01	01-016	F – Study Treatment Dosing	Protocol dosing schedule not respected (75% at start instead of 100%)
Site 01	01-016	G – Visit Schedule/Interval	Interval between infusions not respected
Site 01	01-016	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 01	01-017	F – Study Treatment Dosing	Dose adjustment not as per protocol
Site 01	01-018	D – Study Procedures	On study frequency of QLQ not respected
Site 01	01-018	G – Visit Schedule/Interval	Interval between lab tests not respected
Site 01	01-020	D – Study Procedures	EoT visit not done within protocol timelines
Site 01	01-020	D – Study Procedures	On study frequency of QLQ not respected
Site 01	01-020	F – Study Treatment Dosing	Dose adjustment not as per protocol
Site 01	01-021	G – Visit Schedule/Interval	Interval between infusions not respected
Site 01	01-022	D – Study Procedures	EoT visit not done within protocol timelines; pt continued after DP
Site 01	01-023	F – Study Treatment Dosing	Dose adjustment not as per protocol
Site 01	01-027	D – Study Procedures	On study frequency of QLQ not respected
Site 01	01-032	D – Study Procedures	C1D1 vital signs not done prior to infusion
Site 01	01-035	D – Study Procedures	On study frequency of QLQ not respected
Site 01	01-035	D – Study Procedures	On study frequency of QLQ not respected
Site 01	01-037	D – Study Procedures	On study frequency of QLQ not respected
Site 01	01-037	D – Study Procedures	On study frequency of QLQ not respected
Site 02	02-001	D – Study Procedures	Baseline CEA not done
Site 02	02-003	E – Serious Adverse Event Reporting	SAE not reported within requested timelines
Site 02	02-004	D – Study Procedures	On study frequency of QLQ not respected
Site 02	02-004	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 02	02-005	D – Study Procedures	On study frequency of QLQ not respected
Site 02	02-005	G – Visit Schedule/Interval	Interval between infusions not respected
Site 02	02-007	D – Study Procedures	Baseline CEA not done
Site 02	02-007	E – Serious Adverse Event Reporting	SAE not reported within requested timelines

Randomized crossover trial to assess the effects and quality of life in patients with locally advanced or metastatic pancreatic cancer treated with gemcitabine in combination with nab-paclitaxel. QOLINPAC

EudraCT # 2013-004101-75, NCT02106884

Site 02	02-007	F – Study Treatment Dosing	Dose re-escalated after reduction
Site 02	02-007	G – Visit Schedule/Interval	Interval between infusions not respected
Site 02	02-007	G – Visit Schedule/Interval	Interval between lab tests not respected
Site 02	02-007	F – Study Treatment Dosing	Dose adjustment not as per protocol
Site 02	02-007	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 02	02-010	B – Inclusion/Exclusion Criteria	No QLQ completed. Patient not eligible for main endpoint analysis.
Site 02	02-011	D – Study Procedures	On study frequency of QLQ not respected
Site 02	02-011	G – Visit Schedule/Interval	Interval between infusions not respected
Site 02	02-011	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 02	02-013	D – Study Procedures	On study frequency of QLQ not respected
Site 02	02-013	F – Study Treatment Dosing	Dose re-escalated after reduction
Site 02	02-013	F – Study Treatment Dosing	Dose re-escalated after reduction
Site 02	02-013	F – Study Treatment Dosing	Dose adjustment not as per protocol
Site 02	02-013	F – Study Treatment Dosing	Dose adjustment not as per protocol
Site 02	02-015	D – Study Procedures	On study frequency of QLQ not respected
Site 02	02-015	D – Study Procedures	On study frequency of QLQ not respected
Site 02	02-015	G – Visit Schedule/Interval	Interval between infusions not respected
Site 02	General	D – Study Procedures	On study frequency of QLQ not respected
Site 03	03-002	D – Study Procedures	Baseline vital signs not done
Site 03	03-002	D – Study Procedures	On study frequency of QLQ not respected
Site 03	03-002	E – Serious Adverse Event Reporting	SAE not reported within requested timelines
Site 03	03-003	D – Study Procedures	Lab C1D1 not done
Site 03	03-003	E – Serious Adverse Event Reporting	SAE not reported within requested timelines
Site 03	03-004	G – Visit Schedule/Interval	Interval between infusions not respected
Site 04	04-003	G – Visit Schedule/Interval	Interval between lab tests not respected
Site 04	04-004	G – Visit Schedule/Interval	Interval between infusions not respected
Site 04	04-007	G – Visit Schedule/Interval	Interval between lab tests not respected
Site 05	05-001	A – Consent Procedures	ICF page for optional biopsy was not signed. Biopsy not taken.
Site 05	05-001	B – Inclusion/Exclusion Criteria / D – Study Procedures	Baseline coagulation not done
Site 05	05-002	D – Study Procedures	On study frequency of QLQ not respected
Site 05	05-003	A – Consent Procedures	ICF page for optional biopsy was not signed. Biopsy not taken.
Site 05	05-004	G – Visit Schedule/Interval	Interval between infusions not respected
Site 05	05-005	E – Serious Adverse Event Reporting	SAE not reported within requested timelines
Site 06	06-001	G – Visit Schedule/Interval	Interval between lab tests not respected

Site 06	06-002	E – Serious Adverse Event Reporting	SAE original source doc not available, copy available
Site 06	06-002	F – Study Treatment Dosing	Dose reduction and re-escalated after reduction
Site 06	06-002	G – Visit Schedule/Interval	Interval between lab tests not respected
Site 06	06-003	A – Consent Procedures	Copy of original signed ICF not given to patient
Site 06	06-003	E – Serious Adverse Event Reporting	SAE original source doc not available, copy available
Site 06	06-003	F – Study Treatment Dosing	Dose adjustment not as per protocol
Site 07	07-001	F – Study Treatment Dosing	Dose adjustment not as per protocol
Site 07	07-002	F – Study Treatment Dosing	Dose re-escalated after reduction
Site 07	07-004	F – Study Treatment Dosing	Per protocol dose not respected
Site 07	07-008	G – Visit Schedule/Interval	EoT visit not done within protocol timelines
Site 08	08-001	G – Visit Schedule/Interval	Interval between infusions not respected
Site 08	08-001	G – Visit Schedule/Interval	Interval between infusions not respected
Site 08	08-001	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 09	09-002	A – Consent Procedures	Original signed version of the ICF V3.0 lost, only scan available. ICF was resigned upon discovery.
Site 09	09-002	B – Inclusion/Exclusion Criteria / D – Study Procedures	Baseline urine dipstick not done
Site 09	09-002	D – Study Procedures	Baseline heart rate not done
Site 09	09-002	D – Study Procedures	On study frequency of QLQ not respected
Site 09	09-002	F – Study Treatment Dosing	Dose reduction not per protocol
Site 09	09-002	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 09	09-002	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 09	09-002	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 10	10-001	B – Inclusion/Exclusion Criteria / D – Study Procedures	Baseline urine dipstick not done
Site 10	10-001	D – Study Procedures	Baseline neutrophils not done (WBC done). WBC and neutrophils done C1D1
Site 10	10-001	D – Study Procedures	Progression TR sample not done
Site 10	10-001	E – Serious Adverse Event Reporting	SAE not reported within requested timelines
Site 10	10-003	A – Consent Procedures	ICF V3.0 not presented to patient (still on study when V3.0 was released)
Site 10	10-004	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 10	10-006	A – Consent Procedures	ICF V3.0 not presented to patient (still on study when V3.0 was released)
Site 10	10-006	G – Visit Schedule/Interval	Interval between infusions not respected
Site 10	10-007	D – Study Procedures	Progression TR sample not done

Site 11	11-004	E – Serious Adverse Event Reporting	SAE not reported within requested timelines
Site 11	11-004	F – Study Treatment Dosing	Dose adjustment not as per protocol
Site 11	11-004	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 11	11-007	E – Serious Adverse Event Reporting	SAE not reported within requested timelines
Site 11	11-007	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 11	11-008	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 11	11-009	G – Visit Schedule/Interval	Interval between infusions not respected
Site 11	11-009	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 11	11-010	F – Study Treatment Dosing	Dose adjustment not as per protocol
Site 11	11-013	D – Study Procedures	On study frequency of QLQ not respected
Site 11	11-013	D – Study Procedures	On study frequency of QLQ not respected
Site 11	11-013	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 11	11-016	G – Visit Schedule/Interval	Interval between infusions not respected
Site 11	11-019	G – Visit Schedule/Interval	Interval between infusions not respected
Site 11	11-019	G – Visit Schedule/Interval	Interval between infusions not respected
Site 11	11-020	G – Visit Schedule/Interval	Interval between infusions not respected
Site 11	11-023	G – Visit Schedule/Interval	Interval between lab tests not respected
Site 11	11-024	D – Study Procedures	On study frequency of QLQ not respected
Site 11	11-024	G – Visit Schedule/Interval	Interval between infusions not respected
Site 11	11-024	D – Study Procedures	Pt not discontinued as per protocol for patient best interest
Site 11	11-024	D – Study Procedures	EoT visit not done within protocol timelines; pt continued after DP
Site 11	11-024	G – Visit Schedule/Interval	Interval between lab tests not respected
Site 12	12-003	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 12	12-006	F – Study Treatment Dosing	Dose adjustment not as per protocol
Site 12	12-006	F – Study Treatment Dosing	Dose adjustment not as per protocol
Site 12	12-011	F – Study Treatment Dosing	Dose adjustment not as per protocol
Site 12	12-011	D – Study Procedures	On study frequency of QLQ not respected
Site 12	12-011	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 13	13-001	G – Visit Schedule/Interval	Interval between lab tests not respected

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Site 13	13-001	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 13	13-003	B – Inclusion/Exclusion Criteria	Change of diagnosis to neuroendocrine tumour after treatment start. Patient not eligible.
Site 14	14-001	H - Other	Drug misuse
Site 14	14-002	B – Inclusion/Exclusion Criteria / D – Study Procedures	Baseline coagulation not done
Site 14	14-002	D – Study Procedures	C1D1 lab not done prior to infusion; Baseline lab available
Site 14	14-002	F – Study Treatment Dosing	Dose adjustment not as per protocol
Site 16	16-001	F – Study Treatment Dosing	Dose reduction not per protocol
Site 16	16-001	G – Visit Schedule/Interval	Interval between infusions not respected
Site 16	16-001	G – Visit Schedule/Interval	Interval between infusions not respected
Site 16	16-002	D – Study Procedures	Baseline vital signs not done
Site 16	16-003	D – Study Procedures	On study frequency of QLQ not respected
Site 16	16-004	E – Serious Adverse Event Reporting	SAE not reported within requested timelines
Site 16	16-005	E – Serious Adverse Event Reporting	SAE not reported within requested timelines
Site 17	17-001	F – Study Treatment Dosing	Dose re-escalated after reduction
Site 17	17-001	G – Visit Schedule/Interval	Interval between tumour evaluations by imaging not respected (longer than 10 weeks). Intervals shorter than 6 weeks were not considered as deviations.
Site 18	18-001	E – Serious Adverse Event Reporting	SAE not reported within requested timelines
Site 18	18-002	E – Serious Adverse Event Reporting	SAE not reported within requested timelines