

**Time to Health-related Quality of Life score deterioration as a modality of longitudinal analysis for health-related quality of life studies in oncology: do we need RECIST for HRQoL to achieve standardization?**

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Additional descriptive results obtained on the breast cancer and pancreatic cancer studies

**Table A: Baseline characteristics of patients included in breast cancer study (study #1)**

	<b>N</b>	<b>%</b>
<b>Hospital</b>		
Dijon	271	71.2
Nancy	74	19.4
Reims	18	4.7
Strasbourg	18	4.7
<b>Marital status</b>		
married	281	73.8
not married	90	23.6
unknown	10	2.6
<b>Inclusion criteria</b>		
confirmed primitive breast cancer	242	63.5
suspicion of primitive breast cancer	138	36.2
unknown	1	0.3
<b>Cancer</b>		
confirmed	340	89.2
not confirmed	38	10.0
unknown	3	0.8
<b>Lymph node dissection(LND)</b>		
Axillary LND (ALND)	138	36.2
Sentinel lymph node biopsy (SLNB)	131	34.4
ALND+SLNB	32	8.4
No LND	75	19.7
unknown	5	1.3
<b>Surgery type</b>		
mastectomy	124	32.6
no mastectomy	241	63.3
unknown	16	4.1
<b>Chemotherapy</b>		
yes	155	40.7
no	218	57.2
unknown	8	2.1
<b>Radiotherapy</b>		
yes	254	66.7
no	119	31.2
unknown	8	2.1
<b>Hormone therapy</b>		
yes	170	44.6
no	203	53.3
unknown	8	2.1

**Table B : Baseline characteristics of patients included in the pancreatic cancer phase II study according to treatment arm (study #2)**

	Arm 1 FOLFIRI.3 + gemcitabine (N=49)		Arm 2 gemcitabine alone (N=49)		All patients (N=98)	
	N	%	N	%	N	%
<b>Sex</b>						
male	31	63.27	28	57.14	59	60.20
female	18	36.73	21	42.86	39	39.80
<b>WHO performance status</b>						
0	16	32.65	16	32.65	32	32.65
1	33	67.35	33	67.35	66	67.35
<b>Previous surgery</b>						
no	38	77.55	40	81.63	78	79.59
yes	11	22.45	9	18.37	20	20.41
<b>Surgery type</b>						
curative	5	10.20	4	8.16	9	9.18
palliative	5	10.20	5	10.20	10	10.20
not applicable	38	77.55	40	81.63	78	79.59
missing	1	2.04	0	0.00	1	1.02
<b>Number of metastatic sites</b>						
1	33	67.35	35	71.43	68	69.39
More than 1	16	32.65	14	28.57	30	30.61
<b>Previous chemotherapy</b>						
no	44	89.8	40	81.63	84	85.71
yes	2	4.08	3	6.12	5	5.10
missing	3	6.12	6	12.24	9	9.18
<b>Primary tumor location</b>						
head	18	36.70	29	59.20	47	48.00
body	17	34.70	11	22.50	28	28.60
tail	17	34.70	12	24.50	29	29.60
<b>Sites of metastasis</b>						
liver	39	79.60	35	71.40	74	75.50
lung	11	22.50	11	22.50	22	22.50
Lymph node	5	10.20	7	14.30	12	12.20
peritoneal	16	33.700	10	20.40	26	26.50
other	3	6.10	2	4.00	5	5.10

**Table C: Completion of HRQoL questionnaire at each measurement time by treatment arm for pancreatic cancer study (study #2).**

HRQoL assessment	Arm 2 gemcitabine alone N (%) <sup>1</sup>	Arm 1 FOLFIRI.3 + gemcitabine N (%)	All patients N (%)
<b>baseline</b>	30/49 (61.2)	34/49 (69.4)	64/98 (65.3)
<b>cycle 1</b>	9/21 (42.9)	17/43 (39.5)	33/83 (39.8)
<b>cycle 2</b>	2/12 (16.7)	14/32 (43.8)	23/53 (43.4)
<b>cycle 3</b>	1/4 (25.0)	9/25 (36.0)	10/37 (27.0)
<b>cycle 4</b>	1/4 (25.0)	4/16 (25.0)	5/20 (25.0)
<b>cycle 5</b>	0/2 (0.0)	3/12 (25.0)	4/15 (26.7)
<b>cycle 6</b>	0/2 (0.0)	2/11 (18.9)	2/9 (22.2)
<b>cycle 7</b>	0/1 (0.0)	1/10 (10.0)	1/7 (14.3)
<b>cycle 8</b>	0/1 (0.0)	1/10 (10.0)	1/6 (16.7)
<b>cycle 9</b>	0/1 (0.0)	1/9 (11.1)	1/6 (16.7)
<b>cycle 10</b>	0/0	1/9 (11.1)	1/4 (25.0)

<sup>1</sup> The percentage is given according to potentially responsive patients (excluding death and drop-out)