



CASE REPORT FORM

XRP9881B/3001

A randomized, open-label, phase III study of RPR109881 IV every 3 weeks versus capecitabine (Xeloda®) tablets twice daily for 2 weeks in 3-week cycles in patients with metastatic breast cancer progressing after taxanes and anthracycline therapy

Investigator's name			
Site number	<input type="text"/>		
Subject number	<input type="text"/>		
Subject initials	<input type="text"/>	<input type="text"/>	<input type="text"/>
	first name	middle name	last name

CASE REPORT FORM

XRP9881B/3001

Initials

Site number

Subject's number

INSTRUCTIONS FOR COMPLETION OF CRF

- Please use a black ball point pen and answer all the questions
- Subject must sign an informed consent prior to beginning the study. A copy of this signed informed consent must be available for review by the sponsor's representative along with original medical records for each subject.
- In case of error, please do not use correcting fluid (Liquid paper); cross out the error, write the correction beside, date and initial. DO NOT WRITE OVER AN ENTRY IN AN ATTEMPT TO MAKE A CORRECTION.
- When the answer is a number : use one digit per box and respect the position of the decimal point :
Ex: 0.10 mg 0 . 1 0 mg
- Dates should be written as follows : DAY/MONTH/YEAR
Ex: 12 June 2001 1 2 /|J|U|N/| 2 0 0 1
- In case of unknown day or month for a date, please indicate UK
Ex: October 97 U K /|O|C|T/| 1 9 9 7
- In case of evaluation not done concerning a complete module:
tick not done in the header of the module
- In case of evaluation not done concerning a single item:
Please indicate ND Ex: Weight N D
- For any text entries, please write in CAPITAL LETTERS on the line provided.
Do not write comments in the margins of the CRF pages.
- An additional loose cardboard page is provided with each case report from. Please place this underneath the page being completed to protect the remaining pages.
- Upon completion, the CRF must be signed and dated by the principal investigator listed in the 1572 form or the investigator agreement letter.

Screening



- Verification of Inclusion / Exclusion Criteria
- Informed Consent/Demography / Informed Consent / Randomization
- Female Fertility and Contraception / Pregnancy Test
- Cancer Diagnosis / Hormonal Receptor Status
- Surgery for Cancer (Excluding Biopsy)
- Prior Anti-Cancer Chemotherapy
- Prior Anti-Tumor Therapy
- Prior Radiotherapy for Cancer
- Physical Examination / Vital Signs / ECOG Performance Status / Height and Weight / Neurological Examination
- ECG / Relevant Medical / Surgical History – Excluding Breast Cancer
- Laboratory Findings:
 - Hematology / Coagulation
 - Biochemistry
 - Urinalysis
- Existing Signs and Symptoms
- Previous Concomitant Treatments
- Patient Workup
- Tumor Assessment – Target Lesions
- Tumor Assessment – Non-Target Lesions
- Out-Patient Care / Employment Status / Time Losses
- In-Patient Admission
- Quality of Life
- CRF Tracking Pages
- EQ-5D Questionnaire

DIVIDER_SCREEN - 24-NOV-2003

INCLUSION CRITERIA

Patient must present with ALL of the following criteria to be ELIGIBLE for the study.

- [I 1] Histologically or cytologically proven diagnosis of breast adenocarcinoma that is now metastatic ($T_xN_xM_1$) or locally recurrent and inoperable with curative intent;
- [I 2] All patients must have received an anthracycline and a taxane prior to entry in the protocol. These drugs may have been given in the adjuvant or in the metastatic setting, may have been given concurrently or sequentially, and may have been given in combination with other drugs. Patients must have received a standard dose of anthracycline and of taxane expected to have potentially resulted in a response.
 - For taxanes
 - a. Patients must have progressed while receiving paclitaxel or docetaxel therapy or within 12 months following the last dose of paclitaxel or docetaxel.
 - b. The taxane-based treatment must have been the last chemotherapy the patient received.
 - For anthracyclines
 - a) Progressed while on anthracycline treatment, with or without an initial response,
- OR
 - b) Patients must have received an adequate course of anthracyclines defined as follows:
 - In the adjuvant setting, patients must have received a regimen considered standard for adjuvant therapy, which would usually result in a cumulative dose of doxorubicin of 240-300 mg/m² or doxorubicin equivalent.
 - In the metastatic setting patients must have received a regimen considered standard for therapy for metastatic disease, which would usually result in a cumulative dose of doxorubicin of at least 300 mg/m² or doxorubicin equivalent.
- [I 3] Completion of all prior chemotherapy, immunotherapy (including trastuzumab [Herceptin®]), targeted non-cytotoxic therapy, and radiotherapy ≥ 3 weeks prior to randomization. Prior treatment with radiotherapy, chemoembolization therapy, or cryotherapy is allowed if these therapies are not directed to the areas of measurable disease being used for the purposes of this protocol. Patients on bisphosphonate therapy may continue such therapy;
- [I 4] Evidence of measurable disease as defined by Response Evaluation Criteria in Solid Tumors (RECIST). Measurable lesions are lesions that can be accurately measured in at least one dimension with longest diameter ≥ 20 mm. With spiral CT scan, lesion must be ≥ 10 mm in at least one dimension.
- [I 5] Male or female patients at least 18 years old;
- [I 6] ECOG (Eastern Cooperative Oncology Group) performance status of 0, 1, or 2;
- [I 7] Patients must have resolution of all clinically significant toxic effects (excluding alopecia) of any prior surgery, radiotherapy, cryotherapy, chemoembolization therapy, hormone therapy, immunotherapy, targeted non-cytotoxic therapy, or chemotherapy to grade ≤ 1 by National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 3.0, or to within the limits listed in the specific inclusion/exclusion criteria;

INCLUSIA - 21-NOV-2003

INCLUSION CRITERIA (CONTINUED)

Patient must present with ALL of the following criteria to be ELIGIBLE for the study.

[I 8] Adequate organ function as defined by:

- Absolute neutrophil count (ANC) $\geq 1,500/\mu\text{L}$
- Platelets $\geq 100,000/\mu\text{L}$
- Hemoglobin $\geq 9.0 \text{ g/dL}$ (no RBC transfusion support ≤ 2 weeks prior to the first treatment dose on study).
- Prothrombin time/International normalized ratio (PT/INR) and Partial thromboplastin time (PTT), $\leq 1.5 \times$ upper limit of normal (ULN)
- Creatinine, $\leq 1.5 \times$ ULN, or calculated creatinine clearance (CrCl) $> 60 \text{ mL/min}$
- Total bilirubin, Within normal limits (WNL)
- Serum aspartate aminotransferase AST, serum glutamate-oxalate transferase [SGOT] and serum alanine aminotransferase (ALT; serum glutamate-pyruvate transferase) [SGPT] If AP is $\leq 2.5 \times$ ULN, then ALT/AST must be $\leq 2.5 \times$ ULN.
If AP is $> 2.5 - \leq 5.0 \times$ ULN, then ALT/AST must be $\leq 1.5 \times$ ULN
- Alkaline phosphatase (AP) $\leq 5.0 \times$ ULN

[I 9] Patients must be post-menopausal, surgically sterile, or using effective contraception (the definition of effective contraception will be based on the judgment of the investigator). All female patients of childbearing potential must have a negative pregnancy test (serum or urine) within the 7 days prior to randomization;

[I 10] Patients (or legally acceptable representative) must agree to, sign, and date an EC/IRB-approved patient informed consent form(Ethics Committee / Institutional Review Board);

[I 11] Patients must be willing and able to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures.

INCLUS1 - 10/APR/2003

EXCLUSION CRITERIA

Patients presenting with ANY of the following criteria are **not ELIGIBLE** for the study;

- [E 1]History of any second malignancy with the exception of adequately treated basal cell or squamous cell skin cancer, or *in situ* carcinoma of the cervix uteri. Inclusion of any other *in situ* cancer must be discussed with the sponsor. Patients wth a history of contralateal breast cancer who have been disease-free for more than 5 years prior to randomization are permitted.
- [E 2]History of hypersensitivity grade ≥ 3 to taxanes, Polysorbate-80, or to compounds with similar chemical structures. Patients with known intolerance to fluoropyrimidines or patients with dihydropyrimidine dehydrogenase (DPD) deficiency;
- [E 3]The following breast cancer treatments:
 - Patients receiving >1 adjuvant regimen. However, patients who have received neoadjuvant therapy immediately followed by surgery and immediately followed by adjuvant therapy without intervening progression are considered to have received one adjuvant regimen and are allowed in the trial. Patients who receive chemotherapy after having had metastatic disease, including cutaneous metastases, even if currently without evidence of disease, should not be considered to have received adjuvant treatment since recurrence is a near certainty and not only a risk;
 - Patients receiving >1 chemotherapy regimen for metastatic or locally recurrent and inoperable breast cancer. A chemotherapy regimen is defined as a single or a combination of chemotherapy agents given until documented disease progression or relapse. For example, patients who received sequential doxorubicin and docetaxel in the metastatic setting without intervening progression are allowed in the trial;
- [E 4]Prior treatment with capecitabine or any taxane-analogs except for paclitaxel or docetaxel (eg, epothilones are not permitted, novel preparations of paclitaxel are not permitted, generic paclitaxel is permitted);
- [E 5]Concurrent treatment with potent inhibitors of cytochrome P450 3A4, such as ketoconazole, itraconazole, erythromycin, or patients planning to receive these treatments. For patients who were receiving treatment with such agents, a one-week washout period is required prior to randomization.
- [E 6]Concurrent treatment on another clinical trial or with any other cancer therapy including chemotherapy, immunotherapy (including trastuzumab [Herceptin®]), hormonal therapy, radiotherapy, chemoembolization therapy, cryotherapy, targeted non-cytotoxic therapies or patients planning to receive these treatments during the study;
- [E 7]Her-2 positive patients may participate in this trial. Concurrent treatment with trastuzumab [Herceptin®] is not permitted.
- [E 8]Known brain or leptomeningeal disease (CT or MRI scan of the brain required only in case of clinical suspicion of central nervous system involvement);
- [E 9]Any of the following within the 6 months prior to randomization: myocardial infarction, severe/unstable angina, coronary/peripheral artery bypass graft surgery, clinically significant or cardiac arrhythmias (grade 3-4);
- [E 10]History of inflammatory bowel disease or chronic diarrhea;
- [E 11]Peripheral neuropathy grade ≥ 2 ;
- [E 12]Other severe acute or chronic medical or psychiatric condition, or significant laboratory abnormality requiring further investigation that may cause undue risk for the patient's safety, inhibit protocol participation, or interfere with interpretation of study results, and in the judgement of the investigator would make the patient inappropriate for entry into this study;
- [E 13]Known human immunodeficiency virus (HIV) infection requiring treatment or acquired immunodeficiency-syndrome (AIDS)-related illness;
- [E 14]Patients who are pregnant or breastfeeding;
- [E 15]Patient is the investigator or any sub-investigator, research assistant, pharmacist, study coordinator, other staff or relative thereof directly involved in the conduct of the protocol.

EXCLUS1 - 10/APR/2003

Site Number [REDACTED]

Subject Number [REDACTED]

**VISIT DATE**

Visit Date	[REDACTED] / [REDACTED] / [REDACTED]	
(day)	(month)	(year)

VSDT1 - 10/APR/2003

INCLUSION / EXCLUSION CRITERIA

Does the subject satisfy all inclusion and exclusion criteria? No Yes

If NO, please specify below (one deviation per line).

Criterion Number
(example I3, E12) Specify the Deviation

- [1] [REDACTED] _____
- [2] [REDACTED] _____
- [3] [REDACTED] _____
- [4] [REDACTED] _____

Any waiver of these inclusion and exclusion criteria must be approved by the sponsor on a case-by-case basis prior to subject inclusion. This must be documented by both the sponsor and the Investigator.

INCEXC1 - 25-FEB-2004

DEMOGRAPHY

Subject's Initials [REDACTED] [REDACTED] [REDACTED] (first) (middle) (last)	Birth Date [REDACTED] / [REDACTED] / [REDACTED] (day) (month) (year)	Sex <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Race 1 <input type="checkbox"/> White 2 <input type="checkbox"/> Black 3 <input type="checkbox"/> Asian/Oriental 4 <input type="checkbox"/> Multiracial 999 <input type="checkbox"/> Other
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DEMO1 - 10/APR/2003

INFORMED CONSENT

Date Consent Obtained [REDACTED] / [REDACTED] / [REDACTED] (day) (month) (year)

INFCON3 - 10/APR/2003

RANDOMIZATION

Randomization Date [REDACTED] / [REDACTED] / [REDACTED] (day) (month) (year)
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RANDOMA - 02-JAN-2004

Site Number _____

Subject Number _____

**FERTILITY AND CONTRACEPTION** Tick if not done

Is the subject a fertile male or a female of child-bearing potential?

 No Yes

If NO, specify reason:

 Post-menopause

Last Menses:

_____ / _____
 (month) (year)

 Surgical Sterilization (Bilateral Tubal

Ligation or Vasectomy), please specify:

_____ / _____ / _____
 (day) (month) (year)

 Other, please specify:

Method of Contraception

997 None1 IUD2 Condom / Diaphragm3 Oral Contraceptive*4 Hormonal Implant5 Depot Injectable6 Condom plus Contraceptive Sponge7 Condom plus Spermicide8 Diaphragm plus Spermicide999 Other, please specify:

FERCCPA - 22-DEC-2003

PREGNANCY TEST Tick if not done

Specimen Collection Date*

_____ / _____ / _____
 (day) (month) (year)

Test Type

Urine
 Serum

Result

Negative
 Positive

*Please perform within 7 days of study drug administration

PREGA - 14-JUL-2003

TNM STAGING SYSTEM

Primary Tumor (T)

TX: Primary tumor cannot be assessed

T0: No evidence of primary tumor

Tis Carcinoma in situ

- Tis (DCIS) Cuctal carcinoma in situ
- Tis (LCIS) Lobular carcinoma in situ
- Tis (Paget) Paget's disease of the nipple with no tumor

Note: Paget's disease associated with a tumor is classified according to the size of the tumor.

T1: Tumor ≤ 2 cm in greatest dimension

T1mic: Microinvasion ≤ 0.1 cm in greatest dimension

T1a: Tumor > 0.1 cm but not > 0.5 cm in greatest dimension

T1b: Tumor >0.5 cm but not > 1 cm in greatest dimension.

T1c: Tumor > 1.0 cm but not > 2 cm in greatest dimension

T2: Tumor > 2 cm but not > 5 cm in greatest dimension

T3: Tumor > 5 cm in greatest dimension

T4: Tumor of any size with direct extension to

- (a) chest wall or
- (b) skin, only as described below.

- T4a: Extension to chest wall, not including pectoralis muscle
- T4b: Edema (including peau d'orange) or ulceration of the skin of the breast, or satellite skin nodules confined to the same breast
- T4c: Both T4a and T4b
- T4d: Inflammatory carcinoma.

STAGING3A - 24-NOV-2003

TNM STAGING SYSTEM

Regional Lymph Nodes(N)

NX: Regional lymph nodes cannot be assessed (e.g., previously removed)

N0: No regional lymph node metastasis

N1: Metastasis to movable ipsilateral axillary lymph node(s)

N2: Metastasis to ipsilateral axillary lymph node(s) fixed or matted, or in clinically apparent ipsilateral internal mammary nodes in the absence of clinically evident lymph node metastasis

- N2a: Metastasis in ipsilateral axillary lymph nodes fixed to one another (matted) or to other structures.
- N2b: Metastasis only in clinically apparent* ipsilateral internal mammary nodes and in the absence of clinically evident axillary lymph node metastasis

N3: Metastasis in ipsilateral infraclavicular lymph node(s), or in clinically apparent* ipsilateral internal mammary lymph node(s) and in the presence of clinically evident axillary lymph node metastasis; or metastasis in ipsilateral supraclavicular lymph node(s) with or without axillary or internal mammary lymph node involvement

- N3a: Metastasis in ipsilateral infraclavicular lymph node(s) and axillary lymph node(s)
- N3b: Metastasis in ipsilateral internal mammary lymph node(s) and axillary lymph node(s)
- N3c: Metastasis in ipsilateral supraclavicular lymph node(s)

STAGING3B - 24-NOV-2003

TNM STAGING SYSTEM

Regional lymph nodes (pN)

pNX Regional lymph nodes cannot be assessed (eg, previously removed or not removed for pathologic study);

pN0 No regional lymph node metastasis histologically, no additional examination for isolated tumor cells;

pN0(i-) No regional lymph node metastasis histologically, negative IHC;

pN0(i+) No regional lymph node metastasis histologically, positive IHC, no IHC cluster > 0.2 mm;

pN0(mol-) No regional lymph node metastasis histologically, negative molecular findings (RT-PCR);

pN0(mol+) No regional lymph node metastasis histologically, positive molecular findings (RT-PCR);

pN1mi Micrometastasis (>0.2 mm, none >2.0 mm);

pN1 Metastasis in one to three axillary lymph nodes and/or in internal mammary nodes with microscopic disease detected by sentinel lymph node dissection but not clinically apparent;

pN1a Metastasis in one to three axillary lymph nodes;

pN1b Metastasis in internal mammary nodes with microscopic disease detected by sentinel lymph node dissection but not clinically apparent;

pN1c Metastasis in one to three axillary lymph nodes and in internal mammary lymph nodes with microscopic disease detected by sentinel lymph node dissection but not clinically apparent

pN2 Metastasis in four to nine axillary lymph nodes, or in clinically apparent* internal mammary lymph nodes in the absence of axillary lymph node metastasis

pN2a Metastasis in four to nine axillary lymph nodes (at least one tumor deposit >2.0 mm)

pN2b Metastasis in clinically apparent* internal mammary lymph nodes in the absence of axillary lymph node metastasis

pN3 Metastasis in 10 or more axillary lymph nodes, or in infraclavicular lymph nodes, or in clinically apparent* ipsilateral internal mammary lymph nodes in the presence of one or more positive axillary lymph nodes; or in more than three axillary lymph nodes with clinically negative microscopic metastasis in internal mammary lymph nodes; or in ipsilateral supraclavicular lymph nodes;

pN3a Metastasis in 10 or more axillary lymph nodes (at least one tumor deposit > 2.0 mm), or metastasis to the infraclavicular lymph nodes

pN3b Metastasis in clinically apparent* ipsilateral internal mammary lymph nodes in the presence of one or more positive axillary lymph nodes; or in more than three axillary lymph nodes and in internal mammary lymph nodes with microscopic disease detected by sentinel lymph node dissection but not clinically apparent

pN3c Metastasis in ipsilateral supraclavicular lymph nodes

Distant metastasis (M)

MX Distant metastasis cannot be assessed

M0 No distant metastasis

M1 Distant metastasis.

STAGING3C - 24-NOV-2003

Site Number _____

Subject Number _____

**CANCER DIAGNOSIS**Primary Tumor Site 4 1 BreastPrimary Tumor Subsite (*please give description*)
_____Histological Type (*tick one only*)

- | | | |
|---|---|--|
| <input type="checkbox"/> Ductal Carcinoma in situ | <input type="checkbox"/> Infiltrating Lobular Carcinoma | <input type="checkbox"/> Medullary Carcinoma |
| <input type="checkbox"/> Lobular Carcinoma in situ | <input type="checkbox"/> Infiltrating Mixed Carcinoma (ductal + other type) | <input type="checkbox"/> Mucinous Carcinoma |
| <input type="checkbox"/> Infiltrating Ductal Carcinoma | <input type="checkbox"/> Infiltrating Carcinoma Unspecified | <input type="checkbox"/> Tubular Carcinoma |
| 999 <input type="checkbox"/> Other, <i>please specify</i> _____ | | |

First Histo-pathological Diagnosis of the Current Cancer Date
_____(day) / _____(month) / _____(year)Staging at first Diagnosis (AJCC Edition 2003) (*If not assessable, please specify TX, NX, MX, Stage X*)TNM/Stage T N M Stage Extent at Study Entry (*tick one only*)

- Metastatic Loco-regional Recurrence

If the patient has only loco-regional Recurrence, is the disease operable with curative intent?

- No Yes 996 Not Applicable

First Relapse/Progression after first diagnosis Date
_____(day) / _____(month) / _____(year)

CADIAGA - 11-DEC-2003

HORMONE AND HER-2 RECEPTOR STATUS Tick if evaluation not done

Date Performed

(day) (month) (year)

Estrogen Receptors	<input type="checkbox"/> Negative	<input type="checkbox"/> Positive	995 <input type="checkbox"/> Not done	_____(day) / _____(month) / _____(year)
Progesterone Receptors	<input type="checkbox"/> Negative	<input type="checkbox"/> Positive	995 <input type="checkbox"/> Not done	_____(day) / _____(month) / _____(year)
FISH	<input type="checkbox"/> Negative	<input type="checkbox"/> Positive	995 <input type="checkbox"/> Not done	_____(day) / _____(month) / _____(year)
Herceptest	<input type="checkbox"/> 1+	<input type="checkbox"/> 2+	<input type="checkbox"/> 3+	995 <input type="checkbox"/> Not done

HORMREC2 - 15-JAN-2004

Site Number [_____]

Subject Number [_____]



SURGERY FOR CANCER EXCLUDING BIOPSY

997 <input type="checkbox"/> None	Operative Procedure	Surgery Date (day/month/year)
		[____]/[____]/[____]
[1] Right Partial Mastectomy (<i>include tumorectomy, lumpectomy, quadrantectomy</i>)		995 <input type="checkbox"/> Not Done
[2] Left Partial Mastectomy (<i>include tumorectomy, lumpectomy, quadrantectomy</i>)		[____]/[____]/[____]
[3] Right Total Mastectomy (<i>include radical, modified, extended</i>)		995 <input type="checkbox"/> Not Done
[4] Left Total Mastectomy (<i>include radical, modified, extended</i>)		[____]/[____]/[____]
[5] Lymph Node Excision		995 <input type="checkbox"/> Not Done
[6] Other, specify _____		[____]/[____]/[____]
[7] Other, specify _____		[____]/[____]/[____]
[8] Other, specify _____		[____]/[____]/[____]

CASURG3 - 19/JUN/2002

Site Number

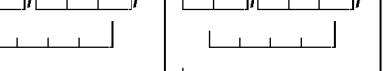
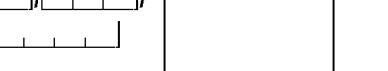
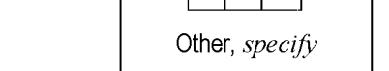
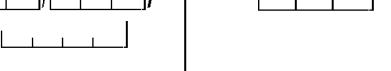
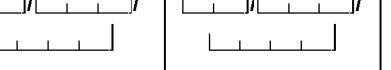
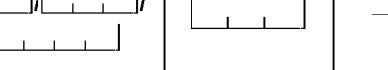
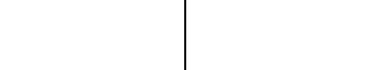
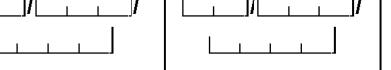
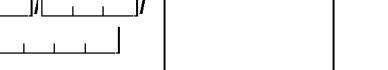
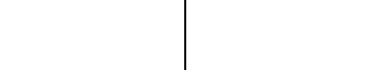
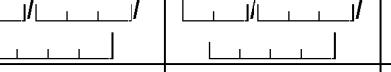
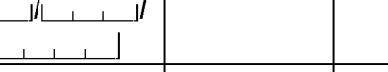
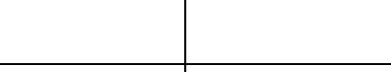
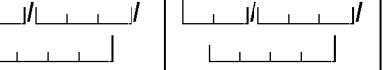
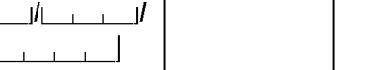
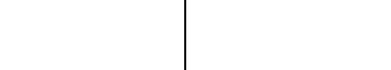
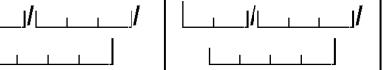
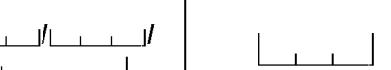
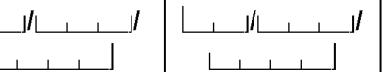
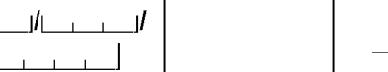
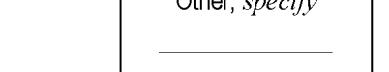
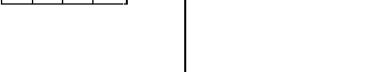
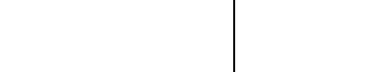
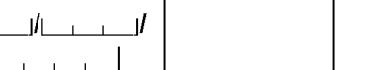
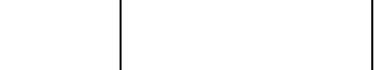
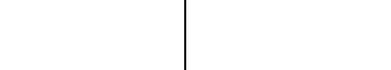
Subject Number

Screening



PRIOR ANTI-CANCER CHEMOTHERAPY

997 None

Treatment History								
997	<input type="checkbox"/> None							
Regimen No.	Drug per Regimen (Brand or Generic Name)	Total Cumulative Dose (mg)	Start Date (day/month/year)	End Date (day/month/year)	Intent	Reason For Discontinuation	Relapse/Progression Date (day/month/year)	Best Response per Regimen
								3:Adjuvant 4:Neo Adjuvant 6:Metastatic 999:Other
1	[1] _____	_____						
	[2] _____	_____						
	[3] _____	_____						
	[4] _____	_____						
2	[1] _____	_____						
	[2] _____	_____						
	[3] _____	_____						
	[4] _____	_____						

CHEM06 - 24-NOV-2003

Site Number []

Subject Number []

Screening**PRIOR ANTI-TUMOR THERAPY**

997 <input type="checkbox"/> None								
Regimen No.	Type 2: Gene Therapy 3: Immunotherapy 4: Hormonotherapy 7: Targeted Therapy 999: Other	Regimen/Drug	Site/Procedure	Start Date (day/month /year)	End Date (day/month /year)	Intent 3:Adjuvant 4:Neo Adjuvant 6:Metastatic	Reason For Discontinuation 1:Adverse Event 2:Lack of Efficacy 8:Progressive Disease: 999:Other	Best Response per Regimen 1 :Complete Response 2 :Partial Response 3 :Stable Disease 4 :Progressive Disease 5 :Not Evaluable 996 :Not Applicable 998 :Unknown
1	[]	[] []	[] []	[] / [] / [] [] / [] / []	[] / [] / [] [] / [] / []	[]	[] Other, specify _____	[]
2	[]	[] []	[] []	[] / [] / [] [] / [] / []	[] / [] / [] [] / [] / []	[]	[] Other, specify _____	[]
3	[]	[] []	[] []	[] / [] / [] [] / [] / []	[] / [] / [] [] / [] / []	[]	[] Other, specify _____	[]
4	[]	[] []	[] []	[] / [] / [] [] / [] / []	[] / [] / [] [] / [] / []	[]	[] Other, specify _____	[]

TUMTHERA - 15-DEC-2003

ORGAN CODES FOR PRIMARY TUMOR SITE

Adrenal glands	33	Eye	3	Ovary	36	Uterus	37
Anus	15	Gallbladder / biliary tract	18	Pancreas	17	Vaginal	39
Ascites	21	Heart	29	Pericardium	30	Vulvovaginal region	40
Bladder	31	Hypo pharynx	8	Pleura	27	Vessels	46
Blood	47	Kidneys	32	Pleural effusion	28		
Bone	43	Laboratory test	49	Prostate	34	Other central nervous system	90
Bone Marrow	44	Larynx	23	Rectum	14	Other head and neck	91
Brain	1	Liver	16	Retroperitoneum	20	Other visceral	92
Breast	41	Lung	26	Skin	42	Other soft tissue	93
Cervix	38	Lymph node	45	Small intestine	12	Other urinary tract	94
Clinical progression	48	Meninges	2	Stomach	10	Other male genital organ	95
Colon	13	Naso pharynx	7	Testis	35	Other female genital organ	96
Diaphragm	22	Omentum / peritoneum	19	Tongue	5	Other	999
Duodenum	11	Oral cavity	4	Trachea	24		
Esophagus	9	Oro pharynx	6	Thyroid	25		

Organ_codes.doc - 28/02/02

Site Number []

Subject Number []



PRIOR RADIOTHERAPY FOR CANCER

Sequence No.	Site Code	Sub-site Specify	Cumulative Dose	Units	Intent		
						Start Date (day/month/year)	End Date (day/month/year)
997	<input type="checkbox"/> None				1 Curative 2 Palliative 3 Adjuvant 4 Neo Adjuvant 998 Unknown		
1	[]	[]	[]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[]	[]	[]
2	[]	[]	[]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[]	[]	[]
3	[]	[]	[]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[]	[]	[]
4	[]	[]	[]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[]	[]	[]
5	[]	[]	[]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[]	[]	[]
6	[]	[]	[]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[]	[]	[]
7	[]	[]	[]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[]	[]	[]
8	[]	[]	[]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[]	[]	[]
9	[]	[]	[]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[]	[]	[]
10	[]	[]	[]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[]	[]	[]
11	[]	[]	[]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[]	[]	[]
12	[]	[]	[]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[]	[]	[]

CARADIO3 - 09/APR/2003

ECOG PERFORMANCE STATUS

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light and sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

PERINST12.doc - 31/MAY/2002

Site Number []

Subject Number []

**ELECTROCARDIOGRAM** Tick if not doneECG Date [] / [] / []
(day) (month) (year)Interpretation Normal Abnormal, Not Clinically Significant Abnormal, Clinically Significant (*record description on the EXISTING SIGNS AND SYMPTOMS form*)

ECGB - 31-OCT-2003

RELEVANT MEDICAL / SURGICAL HISTORY EXCLUDING BREAST CANCER Tick if not done997 No Relevant Medical/Surgical History

Medical History	Start Date (month)	Ongoing? (study entry)	If not Ongoing: End Date (month)	
			(year)	(year)
[1]	[] / []	<input type="checkbox"/> 4	[] / []	[] / []
[2]	[] / []	<input type="checkbox"/> 4	[] / []	[] / []
[3]	[] / []	<input type="checkbox"/> 4	[] / []	[] / []
[4]	[] / []	<input type="checkbox"/> 4	[] / []	[] / []
[5]	[] / []	<input type="checkbox"/> 4	[] / []	[] / []
[6]	[] / []	<input type="checkbox"/> 4	[] / []	[] / []
[7]	[] / []	<input type="checkbox"/> 4	[] / []	[] / []
[8]	[] / []	<input type="checkbox"/> 4	[] / []	[] / []
[9]	[] / []	<input type="checkbox"/> 4	[] / []	[] / []
Surgical History			Surgery Date (month) (year)	
[10]	[] / []		[] / []	[] / []
[11]	[] / []		[] / []	[] / []
[12]	[] / []		[] / []	[] / []

MEDHIST2 - 10/APR/2003

Site Number

Subject Number



SCREENING

LABORATORY FINDINGS - HEMATOLOGY

Tick if not done

To be performed within 14 days prior to randomization.

Sample Date | / | / | (day) (month) | / | (year)

| 9 | 9 | 9 | 9 | 9 | 9 |

Lab ID (For Aventis use)

Please enter the lab result as it appears on the lab report. Do not enter leading or trailing zeros.

	Value				Units									
[1] Hemoglobin	<input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	30	<input type="text"/>	g/dl	32	<input type="text"/>	g/l	66	<input type="text"/>	mmol/l				
[2] Hematocrit	<input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	161	<input type="text"/>	L/L	1	<input type="text"/>	%							
[3] White Blood Cell	<input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	138	<input type="text"/>	$10^9/l$	133	<input type="text"/>	$10^3/\mu L$	7	<input type="text"/>	$/mm^3$	98	<input type="text"/>	$10^3/mm^3$	
[4] Neutrophil	<input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	138	<input type="text"/>	$10^9/l$	133	<input type="text"/>	$10^3/\mu L$	7	<input type="text"/>	$/mm^3$	1	<input type="text"/>	%	
[5] Lymphocyte	<input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	138	<input type="text"/>	$10^9/l$	133	<input type="text"/>	$10^3/\mu L$	7	<input type="text"/>	$/mm^3$	1	<input type="text"/>	%	
[6] Monocyte	<input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	138	<input type="text"/>	$10^9/l$	133	<input type="text"/>	$10^3/\mu L$	7	<input type="text"/>	$/mm^3$	1	<input type="text"/>	%	
[7] Eosinophil	<input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	138	<input type="text"/>	$10^9/l$	133	<input type="text"/>	$10^3/\mu L$	7	<input type="text"/>	$/mm^3$	1	<input type="text"/>	%	
[8] Basophil	<input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	138	<input type="text"/>	$10^9/l$	133	<input type="text"/>	$10^3/\mu L$	7	<input type="text"/>	$/mm^3$	1	<input type="text"/>	%	
[9] Platelet	<input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	138	<input type="text"/>	$10^9/l$	133	<input type="text"/>	$10^3/\mu L$	7	<input type="text"/>	$/mm^3$	98	<input type="text"/>	$10^3/mm^3$	

LABS2 - 02-MAR-2005

Site Number

Subject Number



SCREENING

LABORATORY FINDINGS - COAGULATION

Tick if not done

To be performed within 14 days prior to randomization.

Sample Date 

| 9 | 9 | 9 | 9 | 9 | 9 |

Lab ID (For Aventis use)

Please enter the lab result as it appears on the lab report. Do not enter leading or trailing zeros.

Value

Units

[1] PTT

83 Seconds

[2] PT

—
—
—

83 Seconds

[3] INR

LABS4 - 02-MAR-2005

Site Number

Subject Number [, , ,]



SCREENING

LABORATORY FINDINGS - BIOCHEMISTRY

Tick if not done

To be performed within 14 days prior to randomization.

Sample Date | / | / |
(day) (month) (year)

| 9 | 9 | 9 | 9 | 9 | 9 |

Lab ID (For Aventis use)

Please enter the lab result as it appears on the lab report. Do not enter leading or trailing zeros.

	Value				Units
[1] Sodium	[.]	42	meq/l	66	mmol/l
[2] Potassium	[.]	42	meq/l	66	mmol/l
[3] Calcium	[.]	12	meq/l	66	mmol/l
[4] Phosphate	[.]	48	mg/dL	66	mmol/l
[5] BUN	[.]	48	mg/dL	66	mmol/l
[6] Creatinine	[.]	48	mg/dl	95	umol/L
[7] Albumin	[.]	30	g/dl	32	g/L
[8] Total Protein	[.]	30	g/dl	32	g/L
[9] SGOT (AST)	[.]	102	IU/L	48	mg/dL
[10] SGPT (ALT)	[.]	102	IU/L		
[11] Total Bilirubin	[.]	48	mg/dL	51	mg/L
[12] Alkaline Phosphatase	[.]	22	U/L	102	IU/L
[13] Glucose	[.]	48	mg/dL	66	mmol/l
				32	g/L

LABS1 - 07-MAR-2005

CREATININE CLEARANCE

996 Not applicable

Do not enter leading or trailing zeros.

Value

Calculated ml/min

LABS5 - 02-MAR-2005

Site Number

Subject Number



SCREENING

URINALYSIS

Tick if not done

Sample Date	[] / [] / []	[9] [9] [9] [9] [9] [9]
	(day) (month) (year)	Lab ID (For Aventis use)

Dipstick:

[1] pH [] . []

Tick one:

[2] Protein Negative Positive Trace specify: _____

[3] Glucose Negative Positive Trace specify: _____

LABS3 - 07-MAR-2005

Site Number []

Subject Number []

Screening**EXISTING SIGNS AND SYMPTOMS (ESS)**997 No Existing Signs and Symptoms

Please record ESS Term and NCI Short Name for syndrome, sign and symptom which occurred within 7 days of Study Drug Administration

ESS Term / NCI Short Name	Onset Date (day/month/year)	Grade (1-4)	Outcome 1:Recovered without sequelae 2:Recovered with sequelae 3:Ongoing 998:Unknown	End Date
				only if outcome is recovery (day/month/year)
1 ESS Term: _____ NCI Short Name: _____ Select: _____	<input type="text"/> / <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/> / <input type="checkbox"/>	<input type="text"/> / <input type="text"/> / <input type="text"/> / <input type="text"/>
2 ESS Term: _____ NCI Short Name: _____ Select: _____	<input type="text"/> / <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/> / <input type="checkbox"/>	<input type="text"/> / <input type="text"/> / <input type="text"/> / <input type="text"/>
3 ESS Term: _____ NCI Short Name: _____ Select: _____	<input type="text"/> / <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/> / <input type="checkbox"/>	<input type="text"/> / <input type="text"/> / <input type="text"/> / <input type="text"/>

AEB - 21-NOV-2003

DOSE UNIT

MG	Milligram	MCG	Microgram
ML	milliliter	MCG/KG	Microgram per kilogram
IU	International Units	OZ	Ounce
MG/KG	Milligram per kilogram	TBSP	Tablespoon
GM	Gram	TSP	Teaspoon
MEQ	Milli-equivalent	ML/MIN	Milliliter per minute
CC	Cubic centimeter		

ABBREV1 - 21/APR/2003

ROUTE OF ADMINISTRATION

PO	Oral	SL	Sublingual
IM	Intra-muscular	VAG	Vaginal
TOP	Local, topical	SC	Subcutaneous
PR	Rectal	IV	Intravenous
INH	Inhalation	OPH	Ophthalmic
IN	Intranasal		

ABBREV2 - 21/APR/2003

FREQUENCY

PRN	As needed	2XW =	Twice a week	QD	Every day
AC	Before meals	3XW =	Three times a week	Q2D	Every 2 days
PC	After meals	ONCE	Once	BID	Twice a day
HS	Every bedtime	TWICE	Twice	TID	3 times a day
QH	Every hour	QW	Every week	QID	4 times a day
Q2H	Every 2 hours	Q2W	Every 2 weeks	Q4 & 6H	Every 4 to 6 hours

ABBREV3 - 21/APR/2003

Site Number []

Subject Number []

Screening**PREVIOUS / CONCOMITANT BISPHOSPHONATES**997 No Previous/Concomitant Bisphosphonates

Record all Bisphosphonates that were taken in the last 120 days prior to first study administration.

Drug/Therapy (Brand or Generic Name)	Reason 2: Adverse Event/ Existing Condition 3: Prophylaxis 5: Tumor Related Pain 6: Tumor Related Excluding Pain 999: Other	Dose	Unit	Freq.	Route	Start Date	End Date <i>Or tick if ongoing</i>
						(day/month/year)	(day/month/year)
[1]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
[2]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
[3]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
[4]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
[5]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
[6]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
[7]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CONMEDSA - 14/JUL/2003

Site Number []

Subject Number []

Screening**PREVIOUS / CONCOMITANT TREATMENTS**997 No Previous/Concomitant Treatments

Record all treatments that the subject has taken during the past 7 days prior to study drug administration.

Drug/Therapy (Brand or Generic Name) Other	Reason 2: Adverse Event/ Existing Condition 3: Prophylaxis 5: Tumor Related Pain 6: Tumor Related Excluding Pain 999: Other	Start Date (day/month/year)	End Date
			<i>Or tick if ongoing</i>
[1] _____	_____	_____	_____ 4 <input type="checkbox"/> Ongoing
[2] _____	_____	_____	_____ 4 <input type="checkbox"/> Ongoing
[3] _____	_____	_____	_____ 4 <input type="checkbox"/> Ongoing
[4] _____	_____	_____	_____ 4 <input type="checkbox"/> Ongoing
[5] _____	_____	_____	_____ 4 <input type="checkbox"/> Ongoing
[6] _____	_____	_____	_____ 4 <input type="checkbox"/> Ongoing
[7] _____	_____	_____	_____ 4 <input type="checkbox"/> Ongoing

CONMEDSB- 24-NOV-2003

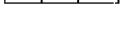
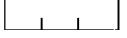
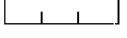
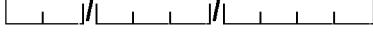
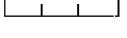
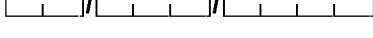
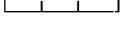
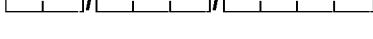
CONTINUED

Site Number _____

Subject Number _____

**PATIENT WORKUP**0 Tick if not done

To be performed within 21 days prior to randomization.

Method of Evaluation	Site Assessed	Assessment Date (day/month/year)
1: Physical Exam 2:X-ray 4:Conventional CT Scan 5:MRI 6:Ultrasound 7:Radionucleide 9:Spiral CT Scan 999:Other, Specify  	Example: Chest Bone Abdomen Brain	
	CHEST	 995 <input type="checkbox"/> Not Done
	ABDOMEN	 995 <input type="checkbox"/> Not Done
	PELVIS	 995 <input type="checkbox"/> Not Done
	BONE	 995 <input type="checkbox"/> Not Done
		
		
		
		
		

PATWORKA - 09-DEC-2003

ORGAN CODES FOR PRIMARY TUMOR SITE

Adrenal glands	33	Eye	3	Ovary	36	Uterus	37
Anus	15	Gallbladder / biliary tract	18	Pancreas	17	Vaginal	39
Ascites	21	Heart	29	Pericardium	30	Vulvovaginal region	40
Bladder	31	Hypo pharynx	8	Pleura	27	Vessels	46
Blood	47	Kidneys	32	Pleural effusion	28		
Bone	43	Laboratory test	49	Prostate	34	Other central nervous system	90
Bone Marrow	44	Larynx	23	Rectum	14	Other head and neck	91
Brain	1	Liver	16	Retroperitoneum	20	Other visceral	92
Breast	41	Lung	26	Skin	42	Other soft tissue	93
Cervix	38	Lymph node	45	Small intestine	12	Other urinary tract	94
Clinical progression	48	Meninges	2	Stomach	10	Other male genital organ	95
Colon	13	Naso pharynx	7	Testis	35	Other female genital organ	96
Diaphragm	22	Omentum / peritoneum	19	Tongue	5	Other	999
Duodenum	11	Oral cavity	4	Trachea	24		
Esophagus	9	Oro pharynx	6	Thyroid	25		

Organ_codes.doc - 28/02/02

Site Number []

Subject Number []

**TUMOR ASSESSMENT – TARGET LESIONS** Tick if not done

Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions throughout the study and repeat the same methods of measurement throughout the study.

Lesion Number	Location (site) Use organ code from list attached	Description (subsite)	Assessment Date (day/month/year)	Method of Assessment	Measurement of Target Lesions (RECIST criteria longest diameter) (mm)
1	[]		[]	1: Physical Exam 2: X-Ray 4: Conventional CT Scan 5: MRI (NMR) 6: Ultrasound 7: Radionuclide 8: Lumbar Puncture 9: Spiral CT Scan 999: Other, specify	[]
2	[]		[]		[]
3	[]		[]		[]
4	[]		[]		[]
5	[]		[]		[]
6	[]		[]		[]
7	[]		[]		[]
8	[]		[]		[]
9	[]		[]		[]
10	[]		[]		[]

TUMASSEA - 03-NOV-2003

Site Number _____

Subject Number _____

**TUMOR ASSESSMENT – NON TARGET LESIONS** Tick if not done

Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions throughout the study and repeat the same methods of measurement throughout the study.

Lesion Number	Location (site) Use organ code from list attached	Description (subsite)	Assessment Date (day/month/year)	Method of Assessment 1: Physical Exam 2: X-Ray 4: Conventional CT Scan 5: MRI (NMR) 6: Ultrasound 7: Radionuclide 8: Lumbar Puncture 9: Spiral CT Scan 999: Other, specify _____
11	[]		[] / [] / [] []	[]
12	[]		[] / [] / [] []	[]
13	[]		[] / [] / [] []	[]
14	[]		[] / [] / [] []	[]
15	[]		[] / [] / [] []	[]
16	[]		[] / [] / [] []	[]
17	[]		[] / [] / [] []	[]
18	[]		[] / [] / [] []	[]
19	[]		[] / [] / [] []	[]
20	[]		[] / [] / [] []	[]

Insert Extra Page to Report more Lesions

TUMASSES-B - 03-NOV-2003

Site Number _____

Subject Number _____

**IN-PATIENT ADMISSION DURING CYCLE PERIOD** Tick if not done

Since the last visit, has the patient been admitted for overnight stay to hospital? (excluding emergency room visit)

0 No 1 Yes, Complete Section Below, and complete an SAE form, if applicable.

During those hospitalizations, have any major procedures been performed?

0 No 1 Yes, Please fill-in *Other Procedure Form* 996 Not Applicable

Admission/Transfer* Date or Ongoing (day/month/year)	Discharge/Transfer* Date or Ongoing (day/month/year)	Reason for Admission	Unit (check one only)
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____

*When a patient is transferred from unit to another one (e.g. from surgery to internal medicine).

INPAT1 - 12/SEP/2002

Site Number []

Subject Number []



QUALITY OF LIFE

Was the EORTC QLQ-30 and QLQ BR23 completed? No Yes

If NO, please indicate the **Primary Reason** (tick one only)

2 Patient refused due to physical condition (too ill, depressed, unable to concentrate)

3 Patient refused due to other reason

6 Patient not given form by staff

999 Other Reason Please specify _____

Comments: _____

QLC MPI - 17-MAY-2004

Site Number []

Subject Number []



TRACKING PAGES

CRF PAGE TRACKING FORM - SCREENING

Repeated Pages – Enter the last page number used for each repeating page. Only fill out for the **last transmission** of CRFs for this subject.

Page Name	Last Page Used
[1] Prior Anti-Cancer Chemotherapy	Page No. 5 []
[2] Prior Anti-Tumor Therapy	Page No. 6 []
[3] Lab Findings – Hematology	Page No. 10 []
[4] Lab Findings - Coagulation	Page No. 11 []
[5] Lab Findings – Biochemistry/Creatinine Clearance	Page No. 12 []
[6] Urinalysis	Page No. 13 []
[7] Existing Signs and Symptoms	Page No. 14 []
[8] Previous / Concomitant Treatments	Page No. 16 []
[9] Tumor Assessment – Non-Target Lesions	Page No. 19 []
Responsible Person (Site Representative)	
Name:	Signature:
	Date
	/ /
	(day) (month) (year)

DO NOT FILL OUT ANY ADDITIONAL REPEATING PAGES AFTER COMPLETING THIS FORM. If additional information concerning this case needs to be provided, contact the monitor of the study to get information on how to proceed.

TRACKCRF1 - 26-JAN-2004

Site Number

Subject Number



EQ-5D QUESTIONNAIRE

To Be Completed by Investigator/Designee ONLY

Was the EQ5D questionnaire completed? No Yes

Questionnaire Date / /

Response to subject health state question from EQ-5D Questionnaire

If EQ-5D Questionnaire not completed, please indicate the **Primary Reason** (tick one only)

- Patient refused due to physical condition (too ill, depressed, unable to concentrate)

- 3 Patient refused due to other reason

- 6 Patient not given form by staff

- 999 Other Reason *Please specify*

Comments: _____

EQ5D2 - 26-AUG-2004

CYCLE 1

CYCLE

- Visit Date / Physical Exam / Vital Signs / ECOG Performance Status / Weight / Neurological Exam
- Quality of Life
- RPR109881 Pre-medication
- Study Medication Administration – RPR109881
- Study Medication Administration – Capecitabine
- Study Drug Administration Numbers
- Lab Findings: Hematology (Day 1, Day 8 & Day 15)
- Lab Findings: Biochemistry – Day 1
- Lab Findings: Biochemistry – Day 15
- Adverse Events
- Outpatient Care / Employment Status / Time Losses
- In-patient Admission
- Previous / Concomitant Treatments
- Patient Workup
- Tumor Assessment – Target Lesions
- Tumor Assessment – Non-Target Lesions
- Overall Response

DIVIDER2.doc - 31/MAY/2002

CYCLE 1



ECOG PERFORMANCE STATUS

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light and sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

PERINST12.doc - 31/MAY/2002

Site Number _____

Subject Number _____



CYCLE 1

VISIT DATE (DATE OF FIRST DRUG ADMINISTRATION)

Visit Date | | / | | / | |
 (day) (month) (year)

VSDT1 - 10/APR/2003

PHYSICAL EXAMINATION Tick if not done

Physical Exam Date | | / | | / | |
 (day) (month) (year)

Report significant abnormal findings on the EXISTING SIGNS AND SYMPTOMS form.

PEA - 15-JUL-2003

VITAL SIGNS Tick if not done

Tick if same as Visit Date or Examination Date | | / | | / | |
 (day) (month) (year)

Body Temperature

Blood Pressure (mmHg)

Heart Rate

(systolic/diastolic)

(beats/min)

| | . | |
 1 °C 2 °F

| | . | |

| | . | |

VITALA - 18/MAR/2002

ECOG PERFORMANCE STATUS Tick if not done

Tick if same as Visit Date or Date | | / | | / | |
 (day) (month) (year)

ECOG Performance Status 0 1 2 3 4

PERFSTAT3 - 09/SEP/2002

WEIGHT Tick if not done

Tick if same as Visit Date or Evaluation Date | | / | | / | |
 (day) (month) (year)

Weight | | . | | 1 kg 2 lb Body Surface Area | | . | | m²

HTWTB - 02-JAN-2004

NEUROLOGICAL EXAMINATION Tick if not done

Tick if same as Visit Date or Examination Date | | / | | / | |
 (day) (month) (year)

Result

1 Abnormal, please report abnormalities on the Existing Signs and Symptoms form.2 Normal

NEUROEXM1 - 03/APR/2002

Site Number [REDACTED]

Subject Number [REDACTED]



CYCLE 1

QUALITY OF LIFE

Was the EORTC QLQ-30 and QLQ BR23 completed? No Yes

If NO, please indicate the **Primary Reason** (tick one only)

2 Patient refused due to physical condition (too ill, depressed, unable to concentrate)

3 Patient refused due to other reason

6 Patient not given form by staff

999 Other Reason Please specify _____

Comments: _____

QLC MPI - 17-MAY-2004

Site Number []

Subject Number []

CYCLE 1**RPR109881 PRE-MEDICATION**997 No RPR109881 Pre-Medication

Drug/Therapy (Brand or Generic Name)	Reason 3: Prophylaxis	Dose	Unit	Freq.	Route	Start Date (day/month/year)	End Date <i>Or tick if ongoing</i> (day/month/year)
[1] _____	_____					_____	_____
[2] _____	_____					_____	_____
[3] _____	_____					_____	_____
[4] _____	_____					_____	_____
[5] _____	_____					_____	_____
[6] _____	_____					_____	_____
[7] _____	_____					_____	_____

CONMEDSA - 14/JUL/2003

Site Number _____

Subject Number _____

**STUDY MEDICATION ADMINISTRATION RPR109881** Tick if not done

Administration Start Date _____/_____/_____ (day) (month) (year)	Infusion Start Time ____:_____ (24-hour clock)	Administration End Date _____/_____/_____ (day) (month) (year)	Infusion End Time ____:_____ (24-hour clock)
Intended Dose (mg/m ²) _____.____	Total Dose Given (mg) _____.____		

ONCADMIN7 - 05/MAY/2003

STUDY MEDICATION ADMINISTRATION CAPECITABINE Tick if not done

Administration Start Date _____/_____/_____ (day) (month) (year)	Administration End Date _____/_____/_____ (day) (month) (year)	Intended Dose (mg/m ² /day) _____.____
Number of Tablets taken per Cycle _____.____		(150 mg) (500 mg)

ONCADMINA - 31-OCT-2003

ADMINISTRATION Tick if not done

Was the dose 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 996 <input type="checkbox"/> Not Applicable Delayed?	Was the dose 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 996 <input type="checkbox"/> Not Applicable Interrupted?
<i>If Yes, Specify the Main Reason</i>	
1 <input type="checkbox"/> Non Study Drug-related Adverse Event(s)	1 <input type="checkbox"/> Non Study Drug-related Adverse Event(s)
2 <input type="checkbox"/> Study Drug-related Hematological Toxicity (Including Infection with Neutropenia or Fever in Absence of Infection with Neutropenia)	2 <input type="checkbox"/> Study Drug-related Hematological Toxicity (Including Infection with Neutropenia or Fever in Absence of Infection with Neutropenia)
3 <input type="checkbox"/> Study Drug-related Non-hematological Toxicity	3 <input type="checkbox"/> Study Drug-related Non-hematological Toxicity
4 <input type="checkbox"/> Study Drug-related Hematological and Non-hematological Toxicity	4 <input type="checkbox"/> Study Drug-related Hematological and Non-hematological Toxicity
999 <input type="checkbox"/> Other _____	999 <input type="checkbox"/> Other _____

ONCADMIN3 - 22-SEP-2004

ADMINISTRATION Tick if not done

Was the Dose 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 996 <input type="checkbox"/> Not Applicable Reduced?	
<i>If yes, specify the main reason</i>	
1 <input type="checkbox"/> Non Study Drug-related Adverse Event(s)	
2 <input type="checkbox"/> Study Drug-related Hematological Toxicity (Including Infection with Neutropenia or Fever in Absence of Infection with Neutropenia)	
3 <input type="checkbox"/> Study Drug-related Non-hematological Toxicity	
4 <input type="checkbox"/> Study Drug-related Hematological and Non-hematological Toxicity	
999 <input type="checkbox"/> Other _____	

ONCADMIN6 - 22-SEP-2004

Site Number | _____ |

Subject Number | _____ |



CYCLE 1

STUDY DRUG ADMINISTRATION NUMBERS

Tick if not done

RPR109881 Kit Numbers _____
 |
 |
 |
 |

Solvent PR Numbers _____
 |
 |
 |
 |

Capecitabine Kit Numbers _____
 |
 |
 |
 |

BATCHNUM1 - 03/APR/2002

Site Number _____

Subject Number _____

**LABORATORY FINDINGS - HEMATOLOGY** Tick if not done

To be performed at Day 1, Day 8 and Day 15 and as clinically indicated.

Please enter the lab result as it appears on the lab report. Do not enter leading or trailing zeros.

[1] Sample Date

--	--	--	--	--	--

 (day) | (month) | (year)| **9,9,9,9,9,9** |

Lab ID (For Aventis use)

	Value	Units		
[1] Hemoglobin		30	g/dl	32 g/l 66 mmol/l
[2] Hematocrit		161	L/L	1 %
[3] White Blood Cell		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 98 $10^3/mm^3$
[4] Neutrophil		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[5] Lymphocyte		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[6] Monocyte		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[7] Eosinophil		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[8] Basophil		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[9] Platelet		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 98 $10^3/mm^3$

LABS6 - 29-MAR-2005

LABORATORY FINDINGS - HEMATOLOGY Tick if not done[2] Sample Date

--	--	--	--	--	--

 (day) | (month) | (year)| **9,9,9,9,9,9** |

Lab ID (For Aventis use)

	Value	Units		
[1] Hemoglobin		30	g/dl	32 g/l 66 mmol/l
[2] Hematocrit		161	L/L	1 %
[3] White Blood Cell		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 98 $10^3/mm^3$
[4] Neutrophil		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[5] Lymphocyte		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[6] Monocyte		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[7] Eosinophil		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[8] Basophil		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[9] Platelet		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 98 $10^3/mm^3$

LABS6 - 29-MAR-2005

LABORATORY FINDINGS - HEMATOLOGY Tick if not done[3] Sample Date

--	--	--	--	--	--

 (day) | (month) | (year)| **9,9,9,9,9,9** |

Lab ID (For Aventis use)

	Value	Units		
[1] Hemoglobin		30	g/dl	32 g/l 66 mmol/l
[2] Hematocrit		161	L/L	1 %
[3] White Blood Cell		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 98 $10^3/mm^3$
[4] Neutrophil		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[5] Lymphocyte		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[6] Monocyte		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[7] Eosinophil		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[8] Basophil		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 1 %
[9] Platelet		138	$10^9/l$	133 $10^3/\mu L$ 7 $/mm^3$ 98 $10^3/mm^3$

LABS6 - 29-MAR-2005

Site Number _____

Subject Number _____

**LABORATORY FINDINGS – BIOCHEMISTRY – DAY 1** Tick if not done*To be performed at Day 1 and Day 15 and as clinically indicated*Sample Date | / | / | / |
(day) (month) (year)

| 9, 9, 9, 9, 9, 9 |

Lab ID (For Aventis use)

Please enter the lab result as it appears on the lab report. Do not enter leading or trailing zeros.

	Value			Units	
[1] Sodium	_____ . _____	42	<input type="checkbox"/>	meq/l	66 <input type="checkbox"/> mmol/l _____
[2] Potassium	_____ . _____	42	<input type="checkbox"/>	meq/l	66 <input type="checkbox"/> mmol/l _____
[3] Calcium	_____ . _____	12	<input type="checkbox"/>	meq/l	66 <input type="checkbox"/> mmol/l 48 <input type="checkbox"/> mg/dL 51 <input type="checkbox"/> mg/L _____
[4] Phosphate	_____ . _____	48	<input type="checkbox"/>	mg/dL	66 <input type="checkbox"/> mmol/l 51 <input type="checkbox"/> mg/L _____
[5] BUN	_____ . _____	48	<input type="checkbox"/>	mg/dL	66 <input type="checkbox"/> mmol/l 32 <input type="checkbox"/> g/L _____
[6] Creatinine	_____ . _____	48	<input type="checkbox"/>	mg/dl	95 <input type="checkbox"/> umol/L 66 <input type="checkbox"/> mmol/l 51 <input type="checkbox"/> mg/L _____
[7] Albumin	_____ . _____	30	<input type="checkbox"/>	g/dl	32 <input type="checkbox"/> g/L _____
[8] Total Protein	_____ . _____	30	<input type="checkbox"/>	g/dl	32 <input type="checkbox"/> g/L 48 <input type="checkbox"/> mg/dL _____
[9] SGOT (AST)	_____ . _____	102	<input type="checkbox"/>	IU/L	_____
[10] SGPT (ALT)	_____ . _____	102	<input type="checkbox"/>	IU/L	_____
[11] Total Bilirubin	_____ . _____	48	<input type="checkbox"/>	mg/dL	51 <input type="checkbox"/> mg/L 95 <input type="checkbox"/> umol/L _____
[12] Alkaline Phosphatase	_____ . _____	22	<input type="checkbox"/>	U/L	102 <input type="checkbox"/> IU/L 91 <input type="checkbox"/> ukat/l _____
[13] Glucose	_____ . _____	48	<input type="checkbox"/>	mg/dL	66 <input type="checkbox"/> mmol/l 32 <input type="checkbox"/> g/L _____

LABS1 - 07-MAR-2005

CREATININE CLEARANCE Not applicable*Do not enter leading or trailing zeros.*

Value

Calculated | | | | ml/min

LABS5 - 02-MAR-2005

Site Number _____

Subject Number _____

**LABORATORY FINDINGS – BIOCHEMISTRY – DAY 15** Tick if not done*To be performed at Day 1 and Day 15 and as clinically indicated*Sample Date | / | / | / |
(day) (month) (year)

| 9, 9, 9, 9, 9, 9 |

Lab ID (For Aventis use)

Please enter the lab result as it appears on the lab report. Do not enter leading or trailing zeros.

	Value			Units	
[1] Sodium	_____ . _____	42	<input type="checkbox"/>	meq/l	66 <input type="checkbox"/> mmol/l _____
[2] Potassium	_____ . _____	42	<input type="checkbox"/>	meq/l	66 <input type="checkbox"/> mmol/l _____
[3] Calcium	_____ . _____	12	<input type="checkbox"/>	meq/l	66 <input type="checkbox"/> mmol/l 48 <input type="checkbox"/> mg/dL 51 <input type="checkbox"/> mg/L _____
[4] Phosphate	_____ . _____	48	<input type="checkbox"/>	mg/dL	66 <input type="checkbox"/> mmol/l 51 <input type="checkbox"/> mg/L _____
[5] BUN	_____ . _____	48	<input type="checkbox"/>	mg/dL	66 <input type="checkbox"/> mmol/l 32 <input type="checkbox"/> g/L _____
[6] Creatinine	_____ . _____	48	<input type="checkbox"/>	mg/dl	95 <input type="checkbox"/> umol/L 66 <input type="checkbox"/> mmol/l 51 <input type="checkbox"/> mg/L _____
[7] Albumin	_____ . _____	30	<input type="checkbox"/>	g/dl	32 <input type="checkbox"/> g/L _____
[8] Total Protein	_____ . _____	30	<input type="checkbox"/>	g/dl	32 <input type="checkbox"/> g/L 48 <input type="checkbox"/> mg/dL _____
[9] SGOT (AST)	_____ . _____	102	<input type="checkbox"/>	IU/L	_____
[10] SGPT (ALT)	_____ . _____	102	<input type="checkbox"/>	IU/L	_____
[11] Total Bilirubin	_____ . _____	48	<input type="checkbox"/>	mg/dL	51 <input type="checkbox"/> mg/L 95 <input type="checkbox"/> umol/L _____
[12] Alkaline Phosphatase	_____ . _____	22	<input type="checkbox"/>	U/L	102 <input type="checkbox"/> IU/L 91 <input type="checkbox"/> ukat/l _____
[13] Glucose	_____ . _____	48	<input type="checkbox"/>	mg/dL	66 <input type="checkbox"/> mmol/l 32 <input type="checkbox"/> g/L _____

LABS1 - 07-MAR-2005

CREATININE CLEARANCE Not applicable*Do not enter leading or trailing zeros.*

Value

Calculated | | | | ml/min

LABS5 - 02-MAR-2005

Site Number []

Subject Number []

CYCLE 1

**ADVERSE EVENTS**997 No Adverse Event Occurred in this Reporting Period

If any Adverse Event Occurred, Record One per Line Below

1=Ongoing without change *do not complete remainder of row.*
 2=New AE *complete remainder of row.*
 3=Change to ongoing AE *complete remainder of row.*

Action Taken Codes

- 2= Dose Decreased
- 3= Permanently Discontinued
- 4= Temporarily Interrupted
- 5= Frequency Change
- 6= Dose Decrease and Frequency Change
- 996= Not Applicable
- 997= None

Outcome Codes

- 1= Recovered without Sequelae
- 2= Recovered with Sequelae
- 3= Ongoing
- 4= Died
- 5= Worsen in Intensity
- 998= Unknown

SAE Criteria Codes

- 1= Resulted in Death
- 2= Was Life-threatening
- 3= Was Persistently or Significantly Disabling / Incapacitating
- 4= Required or Prolonged Hospitalization
- 5= Is a Congenital Anomaly or Birth Defect
- 6= Is Medically Important

AE Description	Status of AE	Relationship	Action Taken		Start Date	Grade	Outcome (select one only)	End Date	Seriousness	If SAE, tick all criteria that apply
			Study Treatment (select one only)	Additional Treatment Given						
[1] Description: <hr/> NCI Short Name: <hr/> NCI Select: <hr/>	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes
[2] Description: <hr/> NCI Short Name: <hr/> NCI Select: <hr/>	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes

* Serious Adverse Event (SAE) Report must be completed and supplied to the sponsor within 24 hours, or at the latest on the following working day.

AE5.DOC - 21-OCT-2003

Project: XRP9881B

Study: 3001

FINAL - 19/JAN/2004

Page 109.00

White, yellow = AVENTIS copies

Bottom copy = investigator copy

Site Number _____

Subject Number _____

**CYCLE 1****IN-PATIENT ADMISSION DURING CYCLE PERIOD** Tick if not done

Since the last visit, has the patient been admitted for overnight stay to hospital? (excluding emergency room visit)

0 No 1 Yes, Complete Section Below, and complete an SAE form, if applicable.

During those hospitalizations, have any major procedures been performed?

0 No 1 Yes, Please fill-in *Other Procedure Form* 996 Not Applicable

Admission/Transfer* Date or Ongoing (day/month/year)	Discharge/Transfer* Date or Ongoing (day/month/year)	Reason for Admission	Unit (check one only)
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____

*When a patient is transferred from unit to another one (e.g. from surgery to internal medicine).

INPAT1 - 12/SEP/2002

Site Number []

Subject Number []

CYCLE 1



PREVIOUS / CONCOMITANT TREATMENTS

997 No Previous/Concomitant Treatments

Record all treatments that the subject has taken during this cycle

Drug/Therapy (Brand or Generic Name) Other	Status 1:Ongoing without change from previous report <i>(do not complete remainder of row)</i>	Reason 2: Adverse Event/ Existing Condition 3: Prophylaxis 5: Tumor Related Pain 6: Tumor Related Excluding Pain 999: Other	Start Date <i>Or tick if previously reported</i> (day/month/year)		End Date <i>Or tick if ongoing</i> (day/month/year)
[1] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	5 <input type="checkbox"/> Previous	4 <input type="checkbox"/> Ongoing
[2] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	5 <input type="checkbox"/> Previous	4 <input type="checkbox"/> Ongoing
[3] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	5 <input type="checkbox"/> Previous	4 <input type="checkbox"/> Ongoing
[4] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	5 <input type="checkbox"/> Previous	4 <input type="checkbox"/> Ongoing
[5] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	5 <input type="checkbox"/> Previous	4 <input type="checkbox"/> Ongoing
[6] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	5 <input type="checkbox"/> Previous	4 <input type="checkbox"/> Ongoing
[7] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	5 <input type="checkbox"/> Previous	4 <input type="checkbox"/> Ongoing

CONMEDSC-24-NOV-2003

Site Number _____

Subject Number _____

**CYCLE 1****PATIENT WORKUP**0 Tick if not done

To be performed days 15-21 of all even numbered cycles.

Method of Evaluation	Site Assessed	Assessment Date (day/month/year)
1: Physical Exam 2:X-ray 4:Conventional CT Scan 5:MRI 6:Ultrasound 7:Radionucleide 9:Spiral CT Scan 999:Other, Specify _____	Example: Chest Bone Abdomen Brain	
_____	CHEST	_____ 995 <input type="checkbox"/> Not Done
_____	ABDOMEN	_____ 995 <input type="checkbox"/> Not Done
_____	PELVIS	_____ 995 <input type="checkbox"/> Not Done
_____	BONE	_____ 995 <input type="checkbox"/> Not Done
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

PATWORKA - 09-DEC-2003

CYCLE 1



ORGAN CODES FOR PRIMARY TUMOR SITE

Adrenal glands	33	Eye	3	Ovary	36	Uterus	37
Anus	15	Gallbladder / biliary tract	18	Pancreas	17	Vaginal	39
Ascites	21	Heart	29	Pericardium	30	Vulvovaginal region	40
Bladder	31	Hypo pharynx	8	Pleura	27	Vessels	46
Blood	47	Kidneys	32	Pleural effusion	28		
Bone	43	Laboratory test	49	Prostate	34	Other central nervous system	90
Bone Marrow	44	Larynx	23	Rectum	14	Other head and neck	91
Brain	1	Liver	16	Retroperitoneum	20	Other visceral	92
Breast	41	Lung	26	Skin	42	Other soft tissue	93
Cervix	38	Lymph node	45	Small intestine	12	Other urinary tract	94
Clinical progression	48	Meninges	2	Stomach	10	Other male genital organ	95
Colon	13	Naso pharynx	7	Testis	35	Other female genital organ	96
Diaphragm	22	Omentum / peritoneum	19	Tongue	5	Other	999
Duodenum	11	Oral cavity	4	Trachea	24		
Esophagus	9	Oro pharynx	6	Thyroid	25		

Organ_codes.doc - 28/02/02

Site Number _____

Subject Number _____

**CYCLE 1****TUMOR ASSESSMENT – TARGET LESIONS** Tick if not done

Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions throughout the study and repeat the same methods of measurement throughout the study.

Lesion Number	Location (site) Use organ code from list attached	Description (subsite)	Assessment Date (day/month/year)	Method of Assessment	Measurement of Target Lesions (RECIST criteria longest diameter) (mm)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

TUMASSEA - 03-NOV-2003

Site Number _____

Subject Number _____

**CYCLE 1****TUMOR ASSESSMENT – NON TARGET LESIONS** Tick if not done

Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions throughout the study and repeat the same methods of measurement throughout the study.

Lesion Number	Location (site) Use organ code from list attached	Description (subsite)	Assessment Date (day/month/year)	Method of Assessment 1: Physical Exam 2: X-Ray 4: Conventional CT Scan 5: MRI (NMR) 6: Ultrasound 7: Radionuclide 8: Lumbar Puncture 9: Spiral CT Scan 999: Other, specify	Response 1: Complete Response 4: Progressive Disease 5: Not Evaluable 6: New Lesion 7: Incomplete Response/SD
11	[]		[] / [] / []	[]	[]
12	[]		[] / [] / []	[]	[]
13	[]		[] / [] / []	[]	[]
14	[]		[] / [] / []	[]	[]
15	[]		[] / [] / []	[]	[]
16	[]		[] / [] / []	[]	[]
17	[]		[] / [] / []	[]	[]
18	[]		[] / [] / []	[]	[]
19	[]		[] / [] / []	[]	[]
20	[]		[] / [] / []	[]	[]

TUMASSES\$ - 11-DEC-2003

EVALUATION OF TARGET LESIONS

Complete Response (CR)	Disappearance of all target lesions.
Partial Response (PR)	A ≥ 30% decrease in the sum of the longest dimensions of the target lesions, taking as reference the baseline sum longest dimensions.
Progression (PD)	A ≥ 20% increase in the sum of longest dimensions of the target lesions, taking as reference the smallest sum of the longest dimensions recorded since the treatment started, or the appearance of one or more new lesions.
Stable Disease (SD)	Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease, taking as reference the smallest sum longest dimensions since the treatment started.

Evtar1.doc - 19/MAR/2002

EVALUATION OF NON-TARGET LESIONS

Complete Response (CR):	Disappearance of all non-target lesions and normalization of tumor marker levels to ≤ ULN.
Non-Complete Response (non-CR)	Persistence of ≥ 1 non-target lesions and/or maintenance of tumor marker levels > ULN.
Non-Progression (non-PD)	
Progression (PD)	Unequivocal progression of existing non-target lesions, or the appearance of ≥ 1 new lesions.
<i>The cytological confirmation of the neoplastic origin of any effusion that appears or worsens during treatment when the measurable tumor has met criteria for response or stable disease is mandatory to differentiate between response or stable disease and progressive disease.</i>	

EVTARL2.doc - 19/03/02

OVERALL RESPONSE

Target Lesions ¹	Non-Target Lesions ²	New Lesions ³	Overall Response
CR	CR	No	CR
CR	Non-CR/Non-PD	No	PR
PR	Non-PD	No	PR
SD	Non-PD	No	SD
PD	Any response	Yes or No	PD
Any response	PD	Yes or No	PD
Any response	Any response	Yes	PD

OVRESP1 - 19-MAR-2002

¹ Measurable lesions only

² May include measurable lesions not followed as target lesions or non-measurable lesions

³ Measurable or non-measurable lesions

Site Number | _____ |

Subject Number | _____ |



CYCLE 1

OVERALL RESPONSE

Tick if not done

Overall Response Achieved at the end of this cycle, According to RECIST Criteria

1 CR (Complete Response)

2 PR (Partial Response)

3 SD (Stable Disease)

4 PD (Progressive Disease)

5 Not Evaluable, *please specify* _____

OVRSP1 - 03/APR/2002

If biopsy was performed as part of evaluation process, please complete an Other Procedures form.

Site Number []

Subject Number []



TRACKING PAGES

CRF PAGE TRACKING FORM – CYCLE 1

Repeated Pages – Enter the last page number used for each repeating page. Only fill out for the **last transmission** of CRFs for this subject.

Page Name	Last Page Used
[1] Lab Findings – Hematology	Page No. 106 []
[2] Lab Findings – Biochemistry – Day 1 (Cycle 1)	Page No. 107 []
[3] Lab Findings – Biochemistry – Day 15 (Cycle 1)	Page No. 108 []
[4] Adverse Events – Cycle 1	Page No. 109 []
[5] Previous/Concomitant Treatments – Cycle 1	Page No. 112 []
[6] Tumor Assessment – Non-Target Lesions – Cycle 1	Page No. 115 []

Responsible Person (Site Representative)

Name: _____ Signature: _____ Date: _____ / _____ / _____
(day) (month) (year)

DO NOT FILL OUT ANY ADDITIONAL REPEATING PAGES AFTER COMPLETING THIS FORM. If additional information concerning this case needs to be provided, contact the monitor of the study to get information on how to proceed.

TRACKCRF1 - 26-JAN-2004

CYCLE

- Visit Date / Physical Exam / Vital Signs / ECOG Performance Status / Weight / Neurological Exam
- Quality of Life
- RPR109881 Pre-medication
- Study Medication Administration – RPR109881
- Study Medication Administration – Capecitabine
- Study Drug Administration Numbers
- Lab Findings: Hematology (Day 1, Day 8 & Day 15)
- Lab Findings: Biochemistry – Day 1
- Lab Findings: Biochemistry – Day 15
- Adverse Events
- Outpatient Care / Employment Status / Time Losses
- In-patient Admission
- Previous / Concomitant Treatments
- Patient Workup
- Tumor Assessment – Target Lesions
- Tumor Assessment – Non-Target Lesions
- Overall Response

DIVIDER2.doc - 31/MAY/2002

ECOG PERFORMANCE STATUS

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light and sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

PERHNS12.doc - 31/MAY/2002

Site Number _____

Subject Number _____



CYCLE 2

VISIT DATE (DATE OF FIRST DRUG ADMINISTRATION)

Visit Date | | | / | | | / | | |
 (day) (month) (year)

VSDT1 - 10/APR/2003

PHYSICAL EXAMINATION Tick if not done

Physical Exam Date | | | / | | | / | | |
 (day) (month) (year)

Report significant abnormal findings on the ADVERSE EVENTS form.

PEA - 15-JUL-2003

VITAL SIGNS Tick if not done

Tick if same as Visit Date or Examination Date | | | / | | | / | | |
 (day) (month) (year)

Body Temperature . <input type="checkbox"/> °C <input type="checkbox"/> °F	Blood Pressure (mmHg) (systolic/diastolic) /	Heart Rate (beats/min)
--	--	-----------------------------------

VITALA - 18/MAR/2002

ECOG PERFORMANCE STATUS Tick if not done

Tick if same as Visit Date or Date | | | / | | | / | | |
 (day) (month) (year)

ECOG Performance Status 0 1 2 3 4

PERFSTAT3 - 09/SEP/2002

WEIGHT Tick if not done

Tick if same as Visit Date or Evaluation Date | | | / | | | / | | |
 (day) (month) (year)

Weight | | | . | | | kg lb Body Surface Area | | | . | | | m²

HTWTB - 02-JAN-2004

NEUROLOGICAL EXAMINATION Tick if not done

Tick if same as Visit Date or Examination Date | | | / | | | / | | |
 (day) (month) (year)

Result

 Abnormal, please report abnormalities on the Adverse Events module. Normal

NEUROEXM1 - 03/APR/2002

Site Number | _____ |

Subject Number | _____ |



QUALITY OF LIFE

Was the EORTC QLQ-30 and QLQ BR23 completed? No Yes

If NO, please indicate the **Primary Reason** (tick one only)

2 Patient refused due to physical condition (too ill, depressed, unable to concentrate)

3 Patient refused due to other reason

6 Patient not given form by staff

999 Other Reason Please specify _____

Comments: _____

QLC MPI - 17-MAY-2004

Site Number []

Subject Number []

CYCLE 2**RPR109881 PRE-MEDICATION**997 No RPR109881 Pre-Medication

Drug/Therapy (Brand or Generic Name)	Reason 3: Prophylaxis	Dose	Unit	Freq.	Route	Start Date (day/month/year)	End Date <i>Or tick if ongoing</i> (day/month/year)
[1] _____	_____					_____	_____
[2] _____	_____					_____	_____
[3] _____	_____					_____	_____
[4] _____	_____					_____	_____
[5] _____	_____					_____	_____
[6] _____	_____					_____	_____
[7] _____	_____					_____	_____

CONMEDSA - 14/JUL/2003

Site Number _____

Subject Number _____

**STUDY MEDICATION ADMINISTRATION RPR109881** Tick if not done

Administration Start Date _____/_____/_____ (day) (month) (year)	Infusion Start Time ____:_____ (24-hour clock)	Administration End Date _____/_____/_____ (day) (month) (year)	Infusion End Time ____:_____ (24-hour clock)
Intended Dose (mg/m ²) _____	Total Dose Given (mg) _____		

ONCADMIN7 - 05/MAY/2003

STUDY MEDICATION ADMINISTRATION CAPECITABINE Tick if not done

Administration Start Date _____/_____/_____ (day) (month) (year)	Administration End Date _____/_____/_____ (day) (month) (year)	Intended Dose (mg/m ² /day) _____._____._____
Number of Tablets taken per Cycle _____._____._____		(150 mg) (500 mg)

ONCADMINA - 31-OCT-2003

ADMINISTRATION Tick if not done

Was the dose Delayed? <i>If Yes, Specify the Main Reason</i> 1 <input type="checkbox"/> Non Study Drug-related Adverse Event(s) 2 <input type="checkbox"/> Study Drug-related Hematological Toxicity (Including Infection with Neutropenia or Fever in Absence of Infection with Neutropenia) 3 <input type="checkbox"/> Study Drug-related Non-hematological Toxicity 4 <input type="checkbox"/> Study Drug-related Hematological and Non-hematological Toxicity 999 <input type="checkbox"/> Other _____	Was the dose Interrupted? <i>If Yes, Specify the Main Reason</i> 1 <input type="checkbox"/> Non Study Drug-related Adverse Event(s) 2 <input type="checkbox"/> Study Drug-related Hematological Toxicity (Including Infection with Neutropenia or Fever in Absence of Infection with Neutropenia) 3 <input type="checkbox"/> Study Drug-related Non-hematological Toxicity 4 <input type="checkbox"/> Study Drug-related Hematological and Non-hematological Toxicity 999 <input type="checkbox"/> Other _____
---	---

ONCADMIN3 - 22-SEP-2004

ADMINISTRATION Tick if not done

Was the Dose Reduced? <i>If yes, specify the main reason</i> 1 <input type="checkbox"/> Non Study Drug-related Adverse Event(s) 2 <input type="checkbox"/> Study Drug-related Hematological Toxicity (Including Infection with Neutropenia or Fever in Absence of Infection with Neutropenia) 3 <input type="checkbox"/> Study Drug-related Non-hematological Toxicity 4 <input type="checkbox"/> Study Drug-related Hematological and Non-hematological Toxicity 999 <input type="checkbox"/> Other _____

ONCADMIN6 - 22-SEP-2004

Site Number []

Subject Number []



CYCLE 2

STUDY DRUG ADMINISTRATION NUMBERS

Tick if not done

RPR109881 Kit Numbers

Solvent PR Numbers

Capecitabine Kit Numbers

BATCHNUM1 - 03/APR/2002

Site Number _____

Subject Number _____

**LABORATORY FINDINGS - HEMATOLOGY** Tick if not done

To be performed at Day 1, Day 8 and Day 15 and as clinically indicated.

Please enter the lab result as it appears on the lab report. Do not enter leading or trailing zeros.

[1] Sample Date

--	--	--	--	--	--

 (day) | (month) | (year)| **9,9,9,9,9,9** |

Lab ID (For Aventis use)

	Value	Units		
[1] Hemoglobin		30	□ g/dl	32 □ g/l 66 □ mmol/l
[2] Hematocrit		161	□ L/L	1 □ %
[3] White Blood Cell		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 98 □ 10 ³ /mm ³
[4] Neutrophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[5] Lymphocyte		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[6] Monocyte		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[7] Eosinophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[8] Basophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[9] Platelet		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 98 □ 10 ³ /mm ³

LABS6 - 29-MAR-2005

LABORATORY FINDINGS - HEMATOLOGY Tick if not done[2] Sample Date

--	--	--	--	--	--

 (day) | (month) | (year)| **9,9,9,9,9,9** |

Lab ID (For Aventis use)

	Value	Units		
[1] Hemoglobin		30	□ g/dl	32 □ g/l 66 □ mmol/l
[2] Hematocrit		161	□ L/L	1 □ %
[3] White Blood Cell		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 98 □ 10 ³ /mm ³
[4] Neutrophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[5] Lymphocyte		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[6] Monocyte		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[7] Eosinophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[8] Basophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[9] Platelet		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 98 □ 10 ³ /mm ³

LABS6 - 29-MAR-2005

LABORATORY FINDINGS - HEMATOLOGY Tick if not done[3] Sample Date

--	--	--	--	--	--

 (day) | (month) | (year)| **9,9,9,9,9,9** |

Lab ID (For Aventis use)

	Value	Units		
[1] Hemoglobin		30	□ g/dl	32 □ g/l 66 □ mmol/l
[2] Hematocrit		161	□ L/L	1 □ %
[3] White Blood Cell		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 98 □ 10 ³ /mm ³
[4] Neutrophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[5] Lymphocyte		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[6] Monocyte		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[7] Eosinophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[8] Basophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[9] Platelet		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 98 □ 10 ³ /mm ³

LABS6 - 29-MAR-2005

Site Number _____

Subject Number _____

**LABORATORY FINDINGS – BIOCHEMISTRY – DAY 1** Tick if not done*To be performed at Day 1 and Day 15 and as clinically indicated*Sample Date | / | / | / |
(day) (month) (year)

| 9, 9, 9, 9, 9, 9 |

Lab ID (For Aventis use)

Please enter the lab result as it appears on the lab report. Do not enter leading or trailing zeros.

	Value			Units	
[1] Sodium	_____ . _____	42	<input type="checkbox"/>	meq/l	66 <input type="checkbox"/> mmol/l _____
[2] Potassium	_____ . _____	42	<input type="checkbox"/>	meq/l	66 <input type="checkbox"/> mmol/l _____
[3] Calcium	_____ . _____	12	<input type="checkbox"/>	meq/l	66 <input type="checkbox"/> mmol/l 48 <input type="checkbox"/> mg/dL 51 <input type="checkbox"/> mg/L _____
[4] Phosphate	_____ . _____	48	<input type="checkbox"/>	mg/dL	66 <input type="checkbox"/> mmol/l 51 <input type="checkbox"/> mg/L _____
[5] BUN	_____ . _____	48	<input type="checkbox"/>	mg/dL	66 <input type="checkbox"/> mmol/l 32 <input type="checkbox"/> g/L _____
[6] Creatinine	_____ . _____	48	<input type="checkbox"/>	mg/dl	95 <input type="checkbox"/> umol/L 66 <input type="checkbox"/> mmol/l 51 <input type="checkbox"/> mg/L _____
[7] Albumin	_____ . _____	30	<input type="checkbox"/>	g/dl	32 <input type="checkbox"/> g/L _____
[8] Total Protein	_____ . _____	30	<input type="checkbox"/>	g/dl	32 <input type="checkbox"/> g/L 48 <input type="checkbox"/> mg/dL _____
[9] SGOT (AST)	_____ . _____	102	<input type="checkbox"/>	IU/L	_____
[10] SGPT (ALT)	_____ . _____	102	<input type="checkbox"/>	IU/L	_____
[11] Total Bilirubin	_____ . _____	48	<input type="checkbox"/>	mg/dL	51 <input type="checkbox"/> mg/L 95 <input type="checkbox"/> umol/L _____
[12] Alkaline Phosphatase	_____ . _____	22	<input type="checkbox"/>	U/L	102 <input type="checkbox"/> IU/L 91 <input type="checkbox"/> ukat/l _____
[13] Glucose	_____ . _____	48	<input type="checkbox"/>	mg/dL	66 <input type="checkbox"/> mmol/l 32 <input type="checkbox"/> g/L _____

LABS1 - 07-MAR-2005

CREATININE CLEARANCE Not applicable*Do not enter leading or trailing zeros.*

Value

Calculated | | | | ml/min

LABS5 - 02-MAR-2005

Site Number _____

Subject Number _____

**LABORATORY FINDINGS – BIOCHEMISTRY – DAY 15** Tick if not done*To be performed at Day 1 and Day 15 and as clinically indicated*Sample Date | / | / | / |
(day) (month) (year)

| 9, 9, 9, 9, 9, 9 |

Lab ID (For Aventis use)

Please enter the lab result as it appears on the lab report. Do not enter leading or trailing zeros.

	Value			Units	
[1] Sodium	_____	.	_____	42 <input type="checkbox"/> meq/l	66 <input type="checkbox"/> mmol/l
[2] Potassium	_____	.	_____	42 <input type="checkbox"/> meq/l	66 <input type="checkbox"/> mmol/l
[3] Calcium	_____	.	_____	12 <input type="checkbox"/> meq/l	66 <input type="checkbox"/> mmol/l 48 <input type="checkbox"/> mg/dL 51 <input type="checkbox"/> mg/L
[4] Phosphate	_____	.	_____	48 <input type="checkbox"/> mg/dL	66 <input type="checkbox"/> mmol/l 51 <input type="checkbox"/> mg/L
[5] BUN	_____	.	_____	48 <input type="checkbox"/> mg/dL	66 <input type="checkbox"/> mmol/l 32 <input type="checkbox"/> g/L
[6] Creatinine	_____	.	_____	48 <input type="checkbox"/> mg/dl	95 <input type="checkbox"/> umol/L 66 <input type="checkbox"/> mmol/l 51 <input type="checkbox"/> mg/L
[7] Albumin	_____	.	_____	30 <input type="checkbox"/> g/dl	32 <input type="checkbox"/> g/L
[8] Total Protein	_____	.	_____	30 <input type="checkbox"/> g/dl	32 <input type="checkbox"/> g/L 48 <input type="checkbox"/> mg/dL
[9] SGOT (AST)	_____	.	_____	102 <input type="checkbox"/> IU/L	
[10] SGPT (ALT)	_____	.	_____	102 <input type="checkbox"/> IU/L	
[11] Total Bilirubin	_____	.	_____	48 <input type="checkbox"/> mg/dL	51 <input type="checkbox"/> mg/L 95 <input type="checkbox"/> umol/L
[12] Alkaline Phosphatase	_____	.	_____	22 <input type="checkbox"/> U/L	102 <input type="checkbox"/> IU/L 91 <input type="checkbox"/> ukat/l/L
[13] Glucose	_____	.	_____	48 <input type="checkbox"/> mg/dL	66 <input type="checkbox"/> mmol/l 32 <input type="checkbox"/> g/L

LABS1 - 07-MAR-2005

CREATININE CLEARANCE Not applicable*Do not enter leading or trailing zeros.*

Value

Calculated | / | / | ml/min

LABS5 - 02-MAR-2005

Site Number []

Subject Number []

CYCLE 2**ADVERSE EVENTS**997 No Adverse Event Occurred in this Reporting Period

If any Adverse Event Occurred, Record One per Line Below

1=Ongoing without change *do not complete remainder of row.*
 2=New AE *complete remainder of row.*
 3=Change to ongoing AE *complete remainder of row.*

Action Taken Codes

- 2= Dose Decreased
- 3= Permanently Discontinued
- 4= Temporarily Interrupted
- 5= Frequency Change
- 6= Dose Decrease and Frequency Change
- 996= Not Applicable
- 997= None

Outcome Codes

- 1= Recovered without Sequelae
- 2= Recovered with Sequelae
- 3= Ongoing
- 4= Died
- 5= Worsen in Intensity
- 998= Unknown

SAE Criteria Codes

- 1= Resulted in Death
- 2= Was Life-threatening
- 3= Was Persistently or Significantly Disabling / Incapacitating
- 4= Required or Prolonged Hospitalization
- 5= Is a Congenital Anomaly or Birth Defect
- 6= Is Medically Important

AE Description	Status of AE	Relationship	Action Taken		Start Date	Grade	Outcome (select one only)	End Date	Seriousness	If SAE, tick all criteria that apply
			Study Treatment (select one only)	Additional Treatment Given						
1 Description: <hr/> NCI Short Name: <hr/> NCI Select: <hr/>	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes
2 Description: <hr/> NCI Short Name: <hr/> NCI Select: <hr/>	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes

* Serious Adverse Event (SAE) Report must be completed and supplied to the sponsor within 24 hours, or at the latest on the following working day.

AE5.DOC - 21-OCT-2003

Project: XRP9881B

Study: 3001

FINAL - 19/JAN/2004

Page 209.00

White, yellow = AVENTIS copies

Bottom copy = investigator copy

Site Number _____

Subject Number _____

**CYCLE 2****IN-PATIENT ADMISSION DURING CYCLE PERIOD** Tick if not done

Since the last visit, has the patient been admitted for overnight stay to hospital? (excluding emergency room visit)

0 No 1 Yes, Complete Section Below, and complete an SAE form, if applicable.

During those hospitalizations, have any major procedures been performed?

0 No 1 Yes, Please fill-in *Other Procedure Form* 996 Not Applicable

Admission/Transfer* Date or Ongoing (day/month/year)	Discharge/Transfer* Date or Ongoing (day/month/year)	Reason for Admission	Unit (check one only)
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____

*When a patient is transferred from unit to another one (e.g. from surgery to internal medicine).

INPAT1 - 12/SEP/2002

Site Number

Subject Number

CYCLE 2



PREVIOUS / CONCOMITANT TREATMENTS

997 No Previous/Concomitant Treatments

Record all treatments that the subject has taken during this cycle

Record all treatments that the subject has taken during this cycle				
Drug/Therapy (Brand or Generic Name) Other	Status 1:Ongoing without change from previous report <i>(do not complete remainder of row)</i> 2:New or change to ongoing treatment <i>(complete remainder of row)</i>	Reason 2: Adverse Event/ Existing Condition 3: Prophylaxis 5: Tumor Related Pain 6: Tumor Related Excluding Pain 999: Other	Start Date <i>Or tick if previously reported</i> (day/month/year)	End Date <i>Or tick if ongoing</i> (day/month/year)
[1] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____ / / _____ 5 <input type="checkbox"/> Previous	_____ / / _____ 4 <input type="checkbox"/> Ongoing
[2] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____ / / _____ 5 <input type="checkbox"/> Previous	_____ / / _____ 4 <input type="checkbox"/> Ongoing
[3] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____ / / _____ 5 <input type="checkbox"/> Previous	_____ / / _____ 4 <input type="checkbox"/> Ongoing
[4] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____ / / _____ 5 <input type="checkbox"/> Previous	_____ / / _____ 4 <input type="checkbox"/> Ongoing
[5] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____ / / _____ 5 <input type="checkbox"/> Previous	_____ / / _____ 4 <input type="checkbox"/> Ongoing
[6] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____ / / _____ 5 <input type="checkbox"/> Previous	_____ / / _____ 4 <input type="checkbox"/> Ongoing
[7] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____ / / _____ 5 <input type="checkbox"/> Previous	_____ / / _____ 4 <input type="checkbox"/> Ongoing

CONMEDSC- 24-NOV-2003

Site Number _____

Subject Number _____

**CYCLE 2****PATIENT WORKUP**0 Tick if not done

To be performed days 15-21 of all even numbered cycles.

Method of Evaluation	Site Assessed	Assessment Date (day/month/year)
1: Physical Exam 2:X-ray 4:Conventional CT Scan 5:MRI 6:Ultrasound 7:Radionucleide 9:Spiral CT Scan 999:Other, Specify <input type="checkbox"/> <input type="checkbox"/>	Example: Chest Bone Abdomen Brain	
	CHEST	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	ABDOMEN	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	PELVIS	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	BONE	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

PATWORKA - 09-DEC-2003

CYCLE 2



ORGAN CODES FOR PRIMARY TUMOR SITE

Adrenal glands	33	Eye	3	Ovary	36	Uterus	37
Anus	15	Gallbladder / biliary tract	18	Pancreas	17	Vaginal	39
Ascites	21	Heart	29	Pericardium	30	Vulvovaginal region	40
Bladder	31	Hypo pharynx	8	Pleura	27	Vessels	46
Blood	47	Kidneys	32	Pleural effusion	28		
Bone	43	Laboratory test	49	Prostate	34	Other central nervous system	90
Bone Marrow	44	Larynx	23	Rectum	14	Other head and neck	91
Brain	1	Liver	16	Retroperitoneum	20	Other visceral	92
Breast	41	Lung	26	Skin	42	Other soft tissue	93
Cervix	38	Lymph node	45	Small intestine	12	Other urinary tract	94
Clinical progression	48	Meninges	2	Stomach	10	Other male genital organ	95
Colon	13	Naso pharynx	7	Testis	35	Other female genital organ	96
Diaphragm	22	Omentum / peritoneum	19	Tongue	5	Other	999
Duodenum	11	Oral cavity	4	Trachea	24		
Esophagus	9	Oro pharynx	6	Thyroid	25		

Organ_codes.doc - 28/02/02

Site Number _____

Subject Number _____

**CYCLE 2****TUMOR ASSESSMENT – TARGET LESIONS** Tick if not done

Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions throughout the study and repeat the same methods of measurement throughout the study.

Lesion Number	Location (site) Use organ code from list attached	Description (subsite)	Assessment Date (day/month/year)	Method of Assessment 1: Physical Exam 2: X-Ray 4: Conventional CT Scan 5: MRI (NMR) 6: Ultrasound 7: Radionuclide 8: Lumbar Puncture 9: Spiral CT Scan 999: Other, specify	Measurement of Target Lesions (RECIST criteria longest diameter) (mm)
1	. .		. /
2	. .		. /
3	. .		. /
4	. .		. /
5	. .		. /
6	. .		. /
7	. .		. /
8	. .		. /
9	. .		. /
10	. .		. /

TUMASSEA - 03-NOV-2003

Site Number []

Subject Number []



CYCLE 2

TUMOR ASSESSMENT – NON TARGET LESIONS

 Tick if not done

Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions throughout the study and repeat the same methods of measurement throughout the study.					
Lesion Number	Location (site) Use organ code from list attached	Description (subsite)	Assessment Date (day/month/year)	Method of Assessment	Response
11	[]		[] / [] / []	1: Physical Exam 2: X-Ray 4: Conventional CT Scan 5: MRI (NMR) 6: Ultrasound 7: Radionuclide 8: Lumbar Puncture 9: Spiral CT Scan 999: Other, specify _____	1: Complete Response 4: Progressive Disease 5: Not Evaluable 6: New Lesion 7: Incomplete Response/SD
12	[]		[] / [] / []	[]	[]
13	[]		[] / [] / []	[]	[]
14	[]		[] / [] / []	[]	[]
15	[]		[] / [] / []	[]	[]
16	[]		[] / [] / []	[]	[]
17	[]		[] / [] / []	[]	[]
18	[]		[] / [] / []	[]	[]
19	[]		[] / [] / []	[]	[]
20	[]		[] / [] / []	[]	[]

TUMASSES\$ - 11-DEC-2003

EVALUATION OF TARGET LESIONS

Complete Response (CR)	Disappearance of all target lesions.
Partial Response (PR)	A $\geq 30\%$ decrease in the sum of the longest dimensions of the target lesions, taking as reference the baseline sum longest dimensions.
Progression (PD)	A $\geq 20\%$ increase in the sum of longest dimensions of the target lesions, taking as reference the smallest sum of the longest dimensions recorded since the treatment started, or the appearance of one or more new lesions.
Stable Disease (SD)	Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease, taking as reference the smallest sum longest dimensions since the treatment started.

Evtar1.doc - 19/MAR/2002

EVALUATION OF NON-TARGET LESIONS

Complete Response (CR):	Disappearance of all non-target lesions and normalization of tumor marker levels to \leq ULN.
Non-Complete Response (non-CR)	Persistence of ≥ 1 non-target lesions and/or maintenance of tumor marker levels $>$ ULN.
Non-Progression (non-PD)	
Progression (PD)	Unequivocal progression of existing non-target lesions, or the appearance of ≥ 1 new lesions.
<i>The cytological confirmation of the neoplastic origin of any effusion that appears or worsens during treatment when the measurable tumor has met criteria for response or stable disease is mandatory to differentiate between response or stable disease and progressive disease.</i>	

EVTARL2.doc - 19/03/02

OVERALL RESPONSE

Target Lesions ¹	Non-Target Lesions ²	New Lesions ³	Overall Response
CR	CR	No	CR
CR	Non-CR/Non-PD	No	PR
PR	Non-PD	No	PR
SD	Non-PD	No	SD
PD	Any response	Yes or No	PD
Any response	PD	Yes or No	PD
Any response	Any response	Yes	PD

OVRESP1 - 19-MAR-2002

¹ Measurable lesions only

² May include measurable lesions not followed as target lesions or non-measurable lesions

³ Measurable or non-measurable lesions

Site Number | _____ |

Subject Number | _____ |



CYCLE 2

OVERALL RESPONSE

Tick if not done

Overall Response Achieved at the end of this cycle, According to RECIST Criteria

1 CR (Complete Response)

2 PR (Partial Response)

3 SD (Stable Disease)

4 PD (Progressive Disease)

5 Not Evaluable, *please specify* _____

OVRSP1 - 03/APR/2002

If biopsy was performed as part of evaluation process, please complete an Other Procedures form.

Site Number []

Subject Number []



TRACKING PAGES

CRF PAGE TRACKING FORM – CYCLE 2

Repeated Pages – Enter the last page number used for each repeating page. Only fill out for the **last transmission** of CRFs for this subject.

Page Name	Last Page Used
[1] Lab Findings – Hematology – Cycle 2	Page No. 206 []
[2] Lab Findings – Biochemistry – Day 1 (Cycle 2)	Page No. 207 []
[3] Lab Findings – Biochemistry – Day 15 (Cycle 2)	Page No. 208 []
[4] Adverse Events – Cycle 2	Page No. 209 []
[5] Previous/Concomitant Treatments – Cycle 2	Page No. 212 []
[6] Tumor Assessment – Non-Target Lesions – Cycle 2	Page No. 215 []

Responsible Person (Site Representative)

Name: _____ Signature: _____ Date: _____ / _____ / _____
(day) (month) (year)

DO NOT FILL OUT ANY ADDITIONAL REPEATING PAGES AFTER COMPLETING THIS FORM. If additional information concerning this case needs to be provided, contact the monitor of the study to get information on how to proceed.

TRACKCRF1 - 26-JAN-2004

CYCLE

- Visit Date / Physical Exam / Vital Signs / ECOG Performance Status / Weight / Neurological Exam
- Quality of Life
- RPR109881 Pre-medication
- Study Medication Administration – RPR109881
- Study Medication Administration – Capecitabine
- Study Drug Administration Numbers
- Lab Findings: Hematology (Day 1, Day 8 & Day 15)
- Lab Findings: Biochemistry – Day 1
- Lab Findings: Biochemistry – Day 15
- Adverse Events
- Outpatient Care / Employment Status / Time Losses
- In-patient Admission
- Previous / Concomitant Treatments
- Patient Workup
- Tumor Assessment – Target Lesions
- Tumor Assessment – Non-Target Lesions
- Overall Response
- CRF Tracking pages
- EQ-5D Questionnaire

DIVIDER2.doc - 31/MAY/2002

ECOG PERFORMANCE STATUS

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light and sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

PERHNS12.doc - 31/MAY/2002

Site Number |_____|

Subject Number |_____|



CYCLE |__|__|

VISIT DATE (DATE OF FIRST DRUG ADMINISTRATION)

Visit Date	/ / /	
(day)	(month)	(year)

VSDT1 - 10/APR/2003

PHYSICAL EXAMINATION Tick if not done

Physical Exam Date	/ / /	
(day)	(month)	(year)

Report significant abnormal findings on the ADVERSE EVENTS form.

PEA - 15-JUL-2003

VITAL SIGNS Tick if not done

<input type="checkbox"/> Tick if same as Visit Date or Examination Date	/ / /		
(day)	(month)	(year)	
Body Temperature		Blood Pressure (mmHg) (systolic/diastolic)	Heart Rate (beats/min)
. /
<input type="checkbox"/> °C <input type="checkbox"/> °F			

VITALA - 18/MAR/2002

ECOG PERFORMANCE STATUS Tick if not done

<input type="checkbox"/> Tick if same as Visit Date or Date	/ / /	
(day)	(month)	(year)
ECOG Performance Status		<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4

PERFSTAT3 - 09/SEP/2002

WEIGHT Tick if not done

<input type="checkbox"/> Tick if same as Visit Date or Evaluation Date	/ / /			
(day)	(month)	(year)		
Weight	. . .	<input type="checkbox"/> kg <input type="checkbox"/> lb	Body Surface Area	. . . m ²

HTWTB - 02-JAN-2004

NEUROLOGICAL EXAMINATION Tick if not done

<input type="checkbox"/> Tick if same as Visit Date or Examination Date	/ / /		
(day)	(month)	(year)	
Result			
<input type="checkbox"/> Abnormal, please report abnormalities on the Adverse Events module.			
<input type="checkbox"/> Normal			

NEUROEXM1 - 03/APR/2002

Site Number |_____|

Subject Number |_____|



CYCLE |__|__|

QUALITY OF LIFE

Was the EORTC QLQ-30 and QLQ BR23 completed? No Yes

If NO, please indicate the **Primary Reason** (tick one only)

2 Patient refused due to physical condition (too ill, depressed, unable to concentrate)

3 Patient refused due to other reason

6 Patient not given form by staff

999 Other Reason Please specify _____

Comments: _____

QLCMP1 - 17-MAY-2004

Site Number |_____|

Subject Number |_____|

CYCLE |__|__|

**RPR109881 PRE-MEDICATION**997 No RPR109881 Pre-Medication

Drug/Therapy (Brand or Generic Name)	Reason 3: Prophylaxis	Dose	Unit	Freq.	Route	Start Date (day/month/year)	End Date <i>Or tick if ongoing</i> (day/month/year)
[1] _____	_____					_____	_____
[2] _____	_____					_____	_____
[3] _____	_____					_____	_____
[4] _____	_____					_____	_____
[5] _____	_____					_____	_____
[6] _____	_____					_____	_____
[7] _____	_____					_____	_____

CONMEDSA - 14/JUL/2003

Site Number _____

Subject Number _____



CYCLE |__|__|

STUDY MEDICATION ADMINISTRATION RPR1098810 Tick if not done

Administration Start Date _____/_____/_____ (day) (month) (year)	Infusion Start Time ____:_____ (24-hour clock)	Administration End Date _____/_____/_____ (day) (month) (year)	Infusion End Time ____:_____ (24-hour clock)
Intended Dose (mg/m ²) _____.____	Total Dose Given (mg) _____.____		

ONCADMIN7 - 05/MAY/2003

STUDY MEDICATION ADMINISTRATION CAPECITABINE0 Tick if not done

Administration Start Date _____/_____/_____ (day) (month) (year)	Administration End Date _____/_____/_____ (day) (month) (year)	Intended Dose (mg/m ² /day) _____.____
Number of Tablets taken per Cycle _____.____		(150 mg) (500 mg)

ONCADMINA - 31-OCT-2003

ADMINISTRATION0 Tick if not done

Was the dose 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 996 <input type="checkbox"/> Not Applicable Delayed?	Was the dose 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 996 <input type="checkbox"/> Not Applicable Interrupted?
<i>If Yes, Specify the Main Reason</i>	
1 <input type="checkbox"/> Non Study Drug-related Adverse Event(s)	1 <input type="checkbox"/> Non Study Drug-related Adverse Event(s)
2 <input type="checkbox"/> Study Drug-related Hematological Toxicity (Including Infection with Neutropenia or Fever in Absence of Infection with Neutropenia)	2 <input type="checkbox"/> Study Drug-related Hematological Toxicity (Including Infection with Neutropenia or Fever in Absence of Infection with Neutropenia)
3 <input type="checkbox"/> Study Drug-related Non-hematological Toxicity	3 <input type="checkbox"/> Study Drug-related Non-hematological Toxicity
4 <input type="checkbox"/> Study Drug-related Hematological and Non-hematological Toxicity	4 <input type="checkbox"/> Study Drug-related Hematological and Non-hematological Toxicity
999 <input type="checkbox"/> Other _____	999 <input type="checkbox"/> Other _____

ONCADMIN3 - 22-SEP-2004

ADMINISTRATION0 Tick if not done

Was the Dose 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes 996 <input type="checkbox"/> Not Applicable Reduced?	
<i>If yes, specify the main reason</i>	
1 <input type="checkbox"/> Non Study Drug-related Adverse Event(s)	
2 <input type="checkbox"/> Study Drug-related Hematological Toxicity (Including Infection with Neutropenia or Fever in Absence of Infection with Neutropenia)	
3 <input type="checkbox"/> Study Drug-related Non-hematological Toxicity	
4 <input type="checkbox"/> Study Drug-related Hematological and Non-hematological Toxicity	
999 <input type="checkbox"/> Other _____	

ONCADMIN6 - 22-SEP-2004

Site Number |_____|

Subject Number |_____|



CYCLE |__|__|

STUDY DRUG ADMINISTRATION NUMBERS

Tick if not done

RPR109881 Kit Numbers _____

Solvent PR Numbers _____

Capecitabine Kit Numbers _____

BATCHNUM1 - 03/APR/2002

Site Number _____

Subject Number _____



CYCLE | | |

LABORATORY FINDINGS - HEMATOLOGY Tick if not done

To be performed at Day 1, Day 8 and Day 15 and as clinically indicated.

Please enter the lab result as it appears on the lab report. Do not enter leading or trailing zeros.

[1] Sample Date

--	--	--	--	--	--

 (day) | (month) | (year)

| 9,9,9,9,9,9 |

Lab ID (For Aventis use)

	Value	Units		
[1] Hemoglobin		30	□ g/dl	32 □ g/l 66 □ mmol/l
[2] Hematocrit		161	□ L/L	1 □ %
[3] White Blood Cell		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 98 □ 10 ³ /mm ³
[4] Neutrophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[5] Lymphocyte		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[6] Monocyte		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[7] Eosinophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[8] Basophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[9] Platelet		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 98 □ 10 ³ /mm ³

LABS6 - 29-MAR-2005

LABORATORY FINDINGS - HEMATOLOGY Tick if not done[2] Sample Date

--	--	--	--	--	--

 (day) | (month) | (year)

| 9,9,9,9,9,9 |

Lab ID (For Aventis use)

	Value	Units		
[1] Hemoglobin		30	□ g/dl	32 □ g/l 66 □ mmol/l
[2] Hematocrit		161	□ L/L	1 □ %
[3] White Blood Cell		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 98 □ 10 ³ /mm ³
[4] Neutrophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[5] Lymphocyte		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[6] Monocyte		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[7] Eosinophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[8] Basophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[9] Platelet		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 98 □ 10 ³ /mm ³

LABS6 - 29-MAR-2005

LABORATORY FINDINGS - HEMATOLOGY Tick if not done[3] Sample Date

--	--	--	--	--	--

 (day) | (month) | (year)

| 9,9,9,9,9,9 |

Lab ID (For Aventis use)

	Value	Units		
[1] Hemoglobin		30	□ g/dl	32 □ g/l 66 □ mmol/l
[2] Hematocrit		161	□ L/L	1 □ %
[3] White Blood Cell		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 98 □ 10 ³ /mm ³
[4] Neutrophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[5] Lymphocyte		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[6] Monocyte		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[7] Eosinophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[8] Basophil		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 1 □ %
[9] Platelet		138	□ 10 ⁹ /l	133 □ 10 ³ /μL 7 □ /mm ³ 98 □ 10 ³ /mm ³

LABS6 - 29-MAR-2005

Site Number _____

Subject Number _____



CYCLE |__|__|

LABORATORY FINDINGS – BIOCHEMISTRY – DAY 1 Tick if not done*To be performed at Day 1 and Day 15 and as clinically indicated*Sample Date | / | / | / |
(day) (month) (year)

| 9, 9, 9, 9, 9, 9 |

Lab ID (For Aventis use)

Please enter the lab result as it appears on the lab report. Do not enter leading or trailing zeros.

	Value			Units	
[1] Sodium	_____ . _____	42	<input type="checkbox"/>	meq/l	66 <input type="checkbox"/> mmol/l _____
[2] Potassium	_____ . _____	42	<input type="checkbox"/>	meq/l	66 <input type="checkbox"/> mmol/l _____
[3] Calcium	_____ . _____	12	<input type="checkbox"/>	meq/l	66 <input type="checkbox"/> mmol/l 48 <input type="checkbox"/> mg/dL 51 <input type="checkbox"/> mg/L _____
[4] Phosphate	_____ . _____	48	<input type="checkbox"/>	mg/dL	66 <input type="checkbox"/> mmol/l 51 <input type="checkbox"/> mg/L _____
[5] BUN	_____ . _____	48	<input type="checkbox"/>	mg/dL	66 <input type="checkbox"/> mmol/l 32 <input type="checkbox"/> g/L _____
[6] Creatinine	_____ . _____	48	<input type="checkbox"/>	mg/dl	95 <input type="checkbox"/> umol/L 66 <input type="checkbox"/> mmol/l 51 <input type="checkbox"/> mg/L _____
[7] Albumin	_____ . _____	30	<input type="checkbox"/>	g/dl	32 <input type="checkbox"/> g/L _____
[8] Total Protein	_____ . _____	30	<input type="checkbox"/>	g/dl	32 <input type="checkbox"/> g/L 48 <input type="checkbox"/> mg/dL _____
[9] SGOT (AST)	_____ . _____	102	<input type="checkbox"/>	IU/L	_____
[10] SGPT (ALT)	_____ . _____	102	<input type="checkbox"/>	IU/L	_____
[11] Total Bilirubin	_____ . _____	48	<input type="checkbox"/>	mg/dL	51 <input type="checkbox"/> mg/L 95 <input type="checkbox"/> umol/L _____
[12] Alkaline Phosphatase	_____ . _____	22	<input type="checkbox"/>	U/L	102 <input type="checkbox"/> IU/L 91 <input type="checkbox"/> ukat/l _____
[13] Glucose	_____ . _____	48	<input type="checkbox"/>	mg/dL	66 <input type="checkbox"/> mmol/l 32 <input type="checkbox"/> g/L _____

LABS1 - 07-MAR-2005

CREATININE CLEARANCE Not applicable*Do not enter leading or trailing zeros.*

Value

Calculated | | | | ml/min

LABS5 - 02-MAR-2005

Site Number _____

Subject Number _____



CYCLE |__|__|

LABORATORY FINDINGS – BIOCHEMISTRY – DAY 150 Tick if not done*To be performed at Day 1 and Day 15 and as clinically indicated*Sample Date | / | / | / |
(day) (month) (year)

| 9, 9, 9, 9, 9, 9 |

Lab ID (For Aventis use)

Please enter the lab result as it appears on the lab report. Do not enter leading or trailing zeros.

	Value			Units
[1] Sodium	_____ . _____	42	<input type="checkbox"/>	meq/l mmol/l
[2] Potassium	_____ . _____	42	<input type="checkbox"/>	meq/l mmol/l
[3] Calcium	_____ . _____	12	<input type="checkbox"/>	mmol/l mg/dL mg/L
[4] Phosphate	_____ . _____	48	<input type="checkbox"/>	mg/dL mmol/l mg/L
[5] BUN	_____ . _____	48	<input type="checkbox"/>	mg/dL mmol/l g/L
[6] Creatinine	_____ . _____	48	<input type="checkbox"/>	umol/L mmol/L mg/L
[7] Albumin	_____ . _____	30	<input type="checkbox"/>	g/dl g/L
[8] Total Protein	_____ . _____	30	<input type="checkbox"/>	g/dl g/L mg/dL
[9] SGOT (AST)	_____ . _____	102	<input type="checkbox"/>	IU/L
[10] SGPT (ALT)	_____ . _____	102	<input type="checkbox"/>	IU/L
[11] Total Bilirubin	_____ . _____	48	<input type="checkbox"/>	mg/dL mg/L umol/L
[12] Alkaline Phosphatase	_____ . _____	22	<input type="checkbox"/>	U/L IU/L ukat/L
[13] Glucose	_____ . _____	48	<input type="checkbox"/>	mg/dL mmol/l g/L

LABS1 - 07-MAR-2005

CREATININE CLEARANCE996 Not applicable*Do not enter leading or trailing zeros.*

Value

Calculated | / | / | ml/min

LABS5 - 02-MAR-2005

Site Number _____

Subject Number _____

CYCLE |__|__|

**ADVERSE EVENTS**997 No Adverse Event Occurred in this Reporting Period

If any Adverse Event Occurred, Record One per Line Below

1=Ongoing without change *do not complete remainder of row.*
 2=New AE *complete remainder of row.*
 3=Change to ongoing AE *row.*

Action Taken Codes

- 2= Dose Decreased
- 3= Permanently Discontinued
- 4= Temporarily Interrupted
- 5= Frequency Change
- 6= Dose Decrease and Frequency Change
- 996= Not Applicable
- 997= None

Outcome Codes

- 1= Recovered without Sequelae
- 2= Recovered with Sequelae
- 3= Ongoing
- 4= Died
- 5= Worsen in Intensity
- 998= Unknown

SAE Criteria Codes

- 1= Resulted in Death
- 2= Was Life-threatening
- 3= Was Persistently or Significantly Disabling / Incapacitating
- 4= Required or Prolonged Hospitalization
- 5= Is a Congenital Anomaly or Birth Defect
- 6= Is Medically Important

AE Description	Status of AE	Relationship	Action Taken		Start Date	Grade	Outcome (select one only)	End Date	Seriousness	If SAE, tick all criteria that apply	
			Study Treatment (select one only)	Additional Treatment Given							
1 Description: <hr/> NCI Short Name: <hr/> NCI Select: <hr/>	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	Reasonable Possibility that AE is Associated with Study Treatment?	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes
2 Description: <hr/> NCI Short Name: <hr/> NCI Select: <hr/>	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	Reasonable Possibility that AE is Associated with Study Treatment?	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes	<input type="checkbox"/> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes

* Serious Adverse Event (SAE) Report must be completed and supplied to the sponsor within 24 hours, or at the latest on the following working day.

AE5.DOC - 21-OCT-2003

Project: XRP9881B

Study: 3001

FINAL - 19/JAN/2004

Page 309.00

White, yellow = AVENTIS copies

Bottom copy = investigator copy

Site Number _____

Subject Number _____



CYCLE |__|__|

IN-PATIENT ADMISSION DURING CYCLE PERIOD

 Tick if not done

Since the last visit, has the patient been admitted for overnight stay to hospital? (excluding emergency room visit)

0 No 1 Yes, Complete Section Below, and complete an SAE form, if applicable.

During those hospitalizations, have any major procedures been performed?

0 No 1 Yes, Please fill-in *Other Procedure Form* 996 Not Applicable

Admission/Transfer* Date or Ongoing (day/month/year)	Discharge/Transfer* Date or Ongoing (day/month/year)	Reason for Admission	Unit (check one only)
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	<input type="checkbox"/> Chemotherapy Administration <input type="checkbox"/> Tumor Related Adverse Event <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	<input type="checkbox"/> Surgery <input type="checkbox"/> Internal Medicine <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	<input type="checkbox"/> Chemotherapy Administration <input type="checkbox"/> Tumor Related Adverse Event <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	<input type="checkbox"/> Surgery <input type="checkbox"/> Internal Medicine <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	<input type="checkbox"/> Chemotherapy Administration <input type="checkbox"/> Tumor Related Adverse Event <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	<input type="checkbox"/> Surgery <input type="checkbox"/> Internal Medicine <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	<input type="checkbox"/> Chemotherapy Administration <input type="checkbox"/> Tumor Related Adverse Event <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	<input type="checkbox"/> Surgery <input type="checkbox"/> Internal Medicine <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____

*When a patient is transferred from unit to another one (e.g. from surgery to internal medicine).

INPAT1 - 12/SEP/2002

PREVIOUS / CONCOMITANT TREATMENTS

997 No Previous/Concomitant Treatments

Record all treatments that the subject has taken during this cycle

Drug/Therapy (Brand or Generic Name) Other	Status 1:Ongoing without change from previous report <i>(do not complete remainder of row)</i>	Reason 2: Adverse Event/ Existing Condition 3: Prophylaxis 5: Tumor Related Pain 6: Tumor Related Excluding Pain 999: Other	Start Date <i>Or tick if previously reported</i> (day/month/year)		End Date <i>Or tick if ongoing</i> (day/month/year)
[1] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	5 <input type="checkbox"/> Previous	_____
[2] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	5 <input type="checkbox"/> Previous	_____
[3] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	5 <input type="checkbox"/> Previous	_____
[4] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	5 <input type="checkbox"/> Previous	_____
[5] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	5 <input type="checkbox"/> Previous	_____
[6] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	5 <input type="checkbox"/> Previous	_____
[7] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	5 <input type="checkbox"/> Previous	_____

CONMEDSC-24-NOV-2003

Site Number _____

Subject Number _____



CYCLE |__|__|

PATIENT WORKUP0 Tick if not done

To be performed days 15-21 of all even numbered cycles.

Method of Evaluation	Site Assessed	Assessment Date (day/month/year)
1: Physical Exam 2:X-ray 4:Conventional CT Scan 5:MRI 6:Ultrasound 7:Radionucleide 9:Spiral CT Scan 999:Other, Specify _____	Example: Chest Bone Abdomen Brain	
_____	CHEST	_____ 995 <input type="checkbox"/> Not Done
_____	ABDOMEN	_____ 995 <input type="checkbox"/> Not Done
_____	PELVIS	_____ 995 <input type="checkbox"/> Not Done
_____	BONE	_____ 995 <input type="checkbox"/> Not Done
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

PATWORKA - 09-DEC-2003

ORGAN CODES FOR PRIMARY TUMOR SITE

Adrenal glands	33	Eye	3	Ovary	36	Uterus	37
Anus	15	Gallbladder / biliary tract	18	Pancreas	17	Vaginal	39
Ascites	21	Heart	29	Pericardium	30	Vulvovaginal region	40
Bladder	31	Hypo pharynx	8	Pleura	27	Vessels	46
Blood	47	Kidneys	32	Pleural effusion	28		
Bone	43	Laboratory test	49	Prostate	34	Other central nervous system	90
Bone Marrow	44	Larynx	23	Rectum	14	Other head and neck	91
Brain	1	Liver	16	Retroperitoneum	20	Other visceral	92
Breast	41	Lung	26	Skin	42	Other soft tissue	93
Cervix	38	Lymph node	45	Small intestine	12	Other urinary tract	94
Clinical progression	48	Meninges	2	Stomach	10	Other male genital organ	95
Colon	13	Naso pharynx	7	Testis	35	Other female genital organ	96
Diaphragm	22	Omentum / peritoneum	19	Tongue	5	Other	999
Duodenum	11	Oral cavity	4	Trachea	24		
Esophagus	9	Oro pharynx	6	Thyroid	25		

Organ_codes.doc - 28/02/02

Site Number | _____ |

Subject Number | _____ |



CYCLE |__|__|

TUMOR ASSESSMENT – TARGET LESIONS Tick if not done

Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions throughout the study and repeat the same methods of measurement throughout the study.

Lesion Number	Location (site) Use organ code from list attached	Description (subsite)	Assessment Date (day/month/year)	Method of Assessment	Measurement of Target Lesions (RECIST criteria longest diameter) (mm)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

TUMASSEA - 03-NOV-2003

Site Number |_____|

Subject Number |_____|



CYCLE |__|__|

TUMOR ASSESSMENT – NON TARGET LESIONS Tick if not done

Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions throughout the study and repeat the same methods of measurement throughout the study.

Lesion Number	Location (site) Use organ code from list attached	Description (subsite)	Assessment Date (day/month/year)	Method of Assessment 1: Physical Exam 2: X-Ray 4: Conventional CT Scan 5: MRI (NMR) 6: Ultrasound 7: Radionuclide 8: Lumbar Puncture 9: Spiral CT Scan 999: Other, specify	Response 1: Complete Response 4: Progressive Disease 5: Not Evaluable 6: New Lesion 7: Incomplete Response/SD
11	_____		_____ / _____ _____ / _____	_____	_____
12	_____		_____ / _____ / _____ _____ / _____	_____	_____
13	_____		_____ / _____ / _____ _____ / _____	_____	_____
14	_____		_____ / _____ / _____ _____ / _____	_____	_ _
15	_____		_____ / _____ / _____ _____ / _____	_____	_ _
16	_____		_____ / _____ / _____ _____ / _____	_____	_ _
17	_____		_____ / _____ / _____ _____ / _____	_____	_ _
18	_____		_____ / _____ / _____ _____ / _____	_____	_ _
19	_____		_____ / _____ / _____ _____ / _____	_____	_ _
20	_____		_____ / _____ / _____ _____ / _____	_____	_ _

TUMASSES\$ - 11-DEC-2003

EVALUATION OF TARGET LESIONS

Complete Response (CR)	Disappearance of all target lesions.
Partial Response (PR)	A $\geq 30\%$ decrease in the sum of the longest dimensions of the target lesions, taking as reference the baseline sum longest dimensions.
Progression (PD)	A $\geq 20\%$ increase in the sum of longest dimensions of the target lesions, taking as reference the smallest sum of the longest dimensions recorded since the treatment started, or the appearance of one or more new lesions.
Stable Disease (SD)	Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease, taking as reference the smallest sum longest dimensions since the treatment started.

Evtar1.doc - 19/MAR/2002

EVALUATION OF NON-TARGET LESIONS

Complete Response (CR):	Disappearance of all non-target lesions and normalization of tumor marker levels to \leq ULN.
Non-Complete Response (non-CR)	Persistence of ≥ 1 non-target lesions and/or maintenance of tumor marker levels $>$ ULN.
Non-Progression (non-PD)	
Progression (PD)	Unequivocal progression of existing non-target lesions, or the appearance of ≥ 1 new lesions.
<i>The cytological confirmation of the neoplastic origin of any effusion that appears or worsens during treatment when the measurable tumor has met criteria for response or stable disease is mandatory to differentiate between response or stable disease and progressive disease.</i>	

EVTARL2.doc - 19/03/02

OVERALL RESPONSE

Target Lesions ¹	Non-Target Lesions ²	New Lesions ³	Overall Response
CR	CR	No	CR
CR	Non-CR/Non-PD	No	PR
PR	Non-PD	No	PR
SD	Non-PD	No	SD
PD	Any response	Yes or No	PD
Any response	PD	Yes or No	PD
Any response	Any response	Yes	PD

OVRESP1 - 19-MAR-2002

¹ Measurable lesions only

² May include measurable lesions not followed as target lesions or non-measurable lesions

³ Measurable or non-measurable lesions

Site Number |_____|

Subject Number |_____|



CYCLE |__|__|

OVERALL RESPONSE

Tick if not done

Overall Response Achieved at the end of this cycle, According to RECIST Criteria

1 CR (Complete Response)

2 PR (Partial Response)

3 SD (Stable Disease)

4 PD (Progressive Disease)

5 Not Evaluable, *please specify* _____

OVRSP1 - 03/APR/2002

If biopsy was performed as part of evaluation process, please complete an Other Procedures form.

Site Number []

Subject Number []



TRACKING PAGES

CRF PAGE TRACKING FORM – CYCLE []

Repeated Pages – Enter the last page number used for each repeating page. Only fill out for the **last transmission** of CRFs for this subject.

Page Name	Last Page Used
[1] Lab Findings – Hematology – Cycle _____	Page No. 306 []
[2] Lab Findings – Biochemistry – Day 1 – Cycle _____	Page No. 307 []
[3] Lab Findings – Biochemistry – Day 15 – Cycle _____	Page No. 308 []
[4] Adverse Events – Cycle _____	Page No. 309 []
[5] Previous/Concomitant Treatments – Cycle _____	Page No. 312 []
[6] Tumor Assessment – Non-Target Lesions – Cycle _____	Page No. 315 []

Responsible Person (Site Representative)

Name: _____ Signature: _____ Date: _____ / _____ / _____
(day) (month) (year)

DO NOT FILL OUT ANY ADDITIONAL REPEATING PAGES AFTER COMPLETING THIS FORM. If additional information concerning this case needs to be provided, contact the monitor of the study to get information on how to proceed.

TRACKCRF1 - 26-JAN-2004

Site Number [_____]

Subject Number [_____]



CYCLE |__|__|

EQ-5D QUESTIONNAIRE

To Be Completed by Investigator/Designee ONLY

Was the EQ5D questionnaire completed? No Yes

Questionnaire Date [_____] / [_____] / [_____] (day) (month) (year)

Response to subject health state question from EQ-5D Questionnaire [_____]

If EQ-5D Questionnaire not completed, please indicate the Primary Reason (tick one only)

2 Patient refused due to physical condition (too ill, depressed, unable to concentrate)

3 Patient refused due to other reason

6 Patient not given form by staff

999 Other Reason Please specify _____

Comments: _____

EQ5D2 - 26-AUG-2004

DAY 120

DAY 120 VISIT

- Visit Date / Patient Workup
- Tumor Assessment – Target Lesions
- Tumor Assessment – Non-Target Lesions
- Overall Response
- Out-patient care / Employment Status / Time Losses
- In-Patient Admission during Cycle Period
- Quality of Life

DIVIDER_120 - 12-DEC-2003

ORGAN CODES FOR PRIMARY TUMOR SITE

Adrenal glands	33	Eye	3	Ovary	36	Uterus	37
Anus	15	Gallbladder / biliary tract	18	Pancreas	17	Vaginal	39
Ascites	21	Heart	29	Pericardium	30	Vulvovaginal region	40
Bladder	31	Hypo pharynx	8	Pleura	27	Vessels	46
Blood	47	Kidneys	32	Pleural effusion	28		
Bone	43	Laboratory test	49	Prostate	34	Other central nervous system	90
Bone Marrow	44	Larynx	23	Rectum	14	Other head and neck	91
Brain	1	Liver	16	Retroperitoneum	20	Other visceral	92
Breast	41	Lung	26	Skin	42	Other soft tissue	93
Cervix	38	Lymph node	45	Small intestine	12	Other urinary tract	94
Clinical progression	48	Meninges	2	Stomach	10	Other male genital organ	95
Colon	13	Naso pharynx	7	Testis	35	Other female genital organ	96
Diaphragm	22	Omentum / peritoneum	19	Tongue	5	Other	999
Duodenum	11	Oral cavity	4	Trachea	24		
Esophagus	9	Oro pharynx	6	Thyroid	25		

Organ_codes.doc - 28/02/02

Site Number []

Subject Number []



DAY 120

VISIT DATE

Visit Date [] / [] / []
 (day) (month) (year)

VSDT1 - 10/APR/2003

PATIENT WORKUP

Tick if not done

Method of Evaluation	Site Assessed	Assessment Date (day/month/year)
1: Physical Exam 2:X-ray 4:Conventional CT Scan 5:MRI 6:Ultrasound 7:Radionucleide 9:Spiral CT Scan 999:Other, Specify _____	Example: Chest Bone Abdomen Brain	
[] _____	CHEST	[] / [] / [] 995 <input type="checkbox"/> Not Done
[] _____	ABDOMEN	[] / [] / [] 995 <input type="checkbox"/> Not Done
[] _____	PELVIS	[] / [] / [] 995 <input type="checkbox"/> Not Done
[] _____	BONE	[] / [] / [] 995 <input type="checkbox"/> Not Done
[] _____	_____	[] / [] / []
[] _____	_____	[] / [] / []
[] _____	_____	[] / [] / []
[] _____	_____	[] / [] / []
[] _____	_____	[] / [] / []

PATWORKA - 09-DEC-2003

Site Number []

Subject Number []



DAY 120

TUMOR ASSESSMENT – TARGET LESIONS

 Tick if not done

Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions throughout the study and repeat the same methods of measurement throughout the study.

Lesion Number	Location (site) Use organ code from list attached	Description (subsite)	Assessment Date (day/month/year)	Method of Assessment 1: Physical Exam 2: X-Ray 4: Conventional CT Scan 5: MRI (NMR) 6: Ultrasound 7: Radionuclide 8: Lumbar Puncture 9: Spiral CT Scan 999: Other, specify	Measurement of Target Lesions (RECIST criteria longest diameter) (mm)
1	[]		[]		[]
2	[]		[]		[]
3	[]		[]		[]
4	[]		[]		[]
5	[]		[]		[]
6	[]		[]		[]
7	[]		[]		[]
8	[]		[]		[]
9	[]		[]		[]
10	[]		[]		[]

TUMASSEA - 03-NOV-2003

Site Number []

Subject Number []



DAY 120

TUMOR ASSESSMENT – NON TARGET LESIONS

 Tick if not done

Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions throughout the study and repeat the same methods of measurement throughout the study.					
Lesion Number	Location (site) Use organ code from list attached	Description (subsite)	Assessment Date (day/month/year)	Method of Assessment 1: Physical Exam 2: X-Ray 3: Conventional CT Scan 4: MRI (NMR) 5: Ultrasound 6: Radionuclide 7: Lumbar Puncture 8: Spiral CT Scan 999: Other, specify	Response 1: Complete Response 4: Progressive Disease 5: Not Evaluable 6: New Lesion 7: Incomplete Response/SD
11	[]		[] / [] / []	[] / [] / []	[] / []
12	[]		[] / [] / []	[] / [] / []	[] / []
13	[]		[] / [] / []	[] / [] / []	[] / []
14	[]		[] / [] / []	[] / [] / []	[]
15	[]		[] / [] / []	[] / [] / []	[]
16	[]		[] / [] / []	[] / [] / []	[]
17	[]		[] / [] / []	[] / [] / []	[]
18	[]		[] / [] / []	[] / [] / []	[]
19	[]		[] / [] / []	[] / [] / []	[]
20	[]		[] / [] / []	[] / [] / []	[]

TUMASSES\$ - 11-DEC-2003

EVALUATION OF TARGET LESIONS

Complete Response (CR)	Disappearance of all target lesions.
Partial Response (PR)	A $\geq 30\%$ decrease in the sum of the longest dimensions of the target lesions, taking as reference the baseline sum longest dimensions.
Progression (PD)	A $\geq 20\%$ increase in the sum of longest dimensions of the target lesions, taking as reference the smallest sum of the longest dimensions recorded since the treatment started, or the appearance of one or more new lesions.
Stable Disease (SD)	Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease, taking as reference the smallest sum longest dimensions since the treatment started.

Evtar1.doc - 19/MAR/2002

EVALUATION OF NON-TARGET LESIONS

Complete Response (CR):	Disappearance of all non-target lesions and normalization of tumor marker levels to \leq ULN.
Non-Complete Response (non-CR)	Persistence of ≥ 1 non-target lesions and/or maintenance of tumor marker levels $>$ ULN.
Non-Progression (non-PD)	
Progression (PD)	Unequivocal progression of existing non-target lesions, or the appearance of ≥ 1 new lesions.
<i>The cytological confirmation of the neoplastic origin of any effusion that appears or worsens during treatment when the measurable tumor has met criteria for response or stable disease is mandatory to differentiate between response or stable disease and progressive disease.</i>	

EVTARL2.doc - 19/03/02

OVERALL RESPONSE

Target Lesions ¹	Non-Target Lesions ²	New Lesions ³	Overall Response
CR	CR	No	CR
CR	Non-CR/Non-PD	No	PR
PR	Non-PD	No	PR
SD	Non-PD	No	SD
PD	Any response	Yes or No	PD
Any response	PD	Yes or No	PD
Any response	Any response	Yes	PD

OVRESP1 - 19-MAR-2002

¹ Measurable lesions only

² May include measurable lesions not followed as target lesions or non-measurable lesions

³ Measurable or non-measurable lesions

Site Number []

Subject Number []



DAY 120

OVERALL RESPONSE

Tick if not done

Overall Response Achieved at the end of this cycle, According to RECIST Criteria

1 CR (Complete Response)

2 PR (Partial Response)

3 SD (Stable Disease)

4 PD (Progressive Disease)

5 Not Evaluable, *please specify* _____

OVRSP1 - 03/APR/2002

If biopsy was performed as part of evaluation process, please complete an Other Procedures form.

Site Number [_____]

Subject Number [_____]



TRACKING PAGES

CRF PAGE TRACKING FORM – DAY 120

Repeated Pages – Enter the last page number used for each repeating page. Only fill out for the **last transmission** of CRFs for this subject.

Page Name	Last Page Used
[1] Tumor Assessment – Non-Target Lesions – Day 120	Page No. 402 [_____]
Responsible Person (Site Representative)	
Name:	Signature:
<hr/>	
Date [_____] / [_____] / [_____] (day) (month) (year)	

DO NOT FILLOUT ANY ADDITIONAL REPEATING PAGES AFTER COMPLETING THIS FORM. If additional information concerning this case needs to be provided, contact the monitor of the study to get information on how to proceed.

TRACKCRF1 - 26-JAN-2004

DIVIDER - END OF TREATMENT



END OF TREATMENT

- Visit Date / Physical Exam / Vital Signs / ECOG Performance Status / Height and Weight / Neurological Exam
- Hematology
- Biochemistry
- Adverse Events
- Out-patient Care / Employment Status / Time Losses
- In-patient Care
- Quality of Life
- Previous Concomitant Treatments
- Patient Workup
- Tumor Assessment - Target Lesions
- Tumor Assessment – Non-Target Lesions
- Overall Response

DIVIDER_EOT - 12-DEC-2003

ECOG PERFORMANCE STATUS

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light and sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

PERHNS12.doc - 31/MAY/2002

Site Number _____

Subject Number _____

**END OF TREATMENT****VISIT DATE**

Visit Date				
(day)	(month)	(year)		

VSDT1 - 10/APR/2003

PHYSICAL EXAMINATION Tick if not done

Physical Exam Date				
(day)	(month)	(year)		

Report significant abnormal findings on the ADVERSE EVENTS form.

PEA - 15-JUL-2003

VITAL SIGNS Tick if not done

<input type="checkbox"/> Tick if same as Visit Date or	Examination Date				
(day)	(month)	(year)			
Body Temperature		Blood Pressure (mmHg) (systolic/diastolic)		Heart Rate (beats/min)	
.		.		.	
<input type="checkbox"/> °C	<input type="checkbox"/> °F				

VITALA - 18/MAR/2002

ECOG PERFORMANCE STATUS Tick if not done

<input type="checkbox"/> Tick if same as Visit Date or	Date			
(day)	(month)	(year)		
ECOG Performance Status <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4				

PERFSTAT3 - 09/SEP/2002

WEIGHT Tick if not done

<input type="checkbox"/> Tick if same as Visit Date or	Evaluation Date				
(day)	(month)	(year)			
Weight	.	<input type="checkbox"/> kg	<input type="checkbox"/> lb	Body Surface Area . m ²	

HTWTB - 02-JAN-2004

NEUROLOGICAL EXAMINATION Tick if not done

<input type="checkbox"/> Tick if same as Visit Date or	Examination Date				
(day)	(month)	(year)			
Result					
<input type="checkbox"/> Abnormal, please report abnormalities on the Adverse Events module.					
<input type="checkbox"/> Normal					

NEUROEXM1 - 03/APR/2002

Site Number _____

Subject Number _____

**END OF TREATMENT****LABORATORY FINDINGS - HEMATOLOGY** Tick if not done

[1] Sample Date | / | / | / | (day) (month) (year)

| 9, 9, 9, 9, 9, 9 |

Lab ID (For Aventis use)

	Value	Units	
[1] Hemoglobin	30	g/dl	32
[2] Hematocrit	161	L/L	g/l
[3] White Blood Cell	138	$10^9/l$	133
[4] Neutrophil	138	$10^9/l$	$10^3/\mu L$
[5] Lymphocyte	138	$10^9/l$	7
[6] Monocyte	138	$10^9/l$	$/mm^3$
[7] Eosinophil	138	$10^9/l$	1
[8] Basophil	138	$10^9/l$	%
[9] Platelet	138	$10^9/l$	98
			$10^3/mm^3$

LABS6 - 29-MAR-2005

LABORATORY FINDINGS - HEMATOLOGY Tick if not done

[2] Sample Date | / | / | / | (day) (month) (year)

| 9, 9, 9, 9, 9, 9 |

Lab ID (For Aventis use)

	Value	Units	
[1] Hemoglobin	30	g/dl	32
[2] Hematocrit	161	L/L	g/l
[3] White Blood Cell	138	$10^9/l$	133
[4] Neutrophil	138	$10^9/l$	$10^3/\mu L$
[5] Lymphocyte	138	$10^9/l$	7
[6] Monocyte	138	$10^9/l$	$/mm^3$
[7] Eosinophil	138	$10^9/l$	1
[8] Basophil	138	$10^9/l$	%
[9] Platelet	138	$10^9/l$	98
			$10^3/mm^3$

LAD66 - 29-MAR-2005

LABORATORY FINDINGS - HEMATOLOGY Tick if not done

[3] Sample Date | / | / | / | (day) (month) (year)

| 9, 9, 9, 9, 9, 9 |

Lab ID (For Aventis use)

	Value	Units	
[1] Hemoglobin	30	g/dl	32
[2] Hematocrit	161	L/L	g/l
[3] White Blood Cell	138	$10^9/l$	133
[4] Neutrophil	138	$10^9/l$	$10^3/\mu L$
[5] Lymphocyte	138	$10^9/l$	7
[6] Monocyte	138	$10^9/l$	$/mm^3$
[7] Eosinophil	138	$10^9/l$	1
[8] Basophil	138	$10^9/l$	%
[9] Platelet	138	$10^9/l$	98
			$10^3/mm^3$

LABS6 - 29-MAR-2005

Site Number _____

Subject Number _____

**END OF TREATMENT****LABORATORY FINDINGS - BIOCHEMISTRY**

Tick if not done
0

Sample Date	_____ / _____ / _____	9,9,9,9,9,9	Lab ID (For Aventis use)																																										
(day)	(month)	(year)																																											
<p>Please enter the lab result as it appears on the lab report. Do not enter leading or trailing zeros.</p> <table border="1"> <thead> <tr> <th></th> <th>Value</th> <th>Units</th> </tr> </thead> <tbody> <tr> <td>[1] Sodium</td> <td>_____ . _____</td> <td>42 <input type="checkbox"/> meq/l 66 <input type="checkbox"/> mmol/l</td> </tr> <tr> <td>[2] Potassium</td> <td>_____ . _____</td> <td>42 <input type="checkbox"/> meq/l 66 <input type="checkbox"/> mmol/l</td> </tr> <tr> <td>[3] Calcium</td> <td>_____ . _____</td> <td>42 <input type="checkbox"/> meq/l 66 <input type="checkbox"/> mmol/l 48 <input type="checkbox"/> mg/dL 51 <input type="checkbox"/> mg/L</td> </tr> <tr> <td>[4] Phosphate</td> <td>_____ . _____</td> <td>48 <input type="checkbox"/> mg/dL 66 <input type="checkbox"/> mmol/l 51 <input type="checkbox"/> mg/L</td> </tr> <tr> <td>[5] BUN</td> <td>_____ . _____</td> <td>48 <input type="checkbox"/> mg/dL 66 <input type="checkbox"/> mmol/l 32 <input type="checkbox"/> g/L</td> </tr> <tr> <td>[6] Creatinine</td> <td>_____ . _____</td> <td>48 <input type="checkbox"/> mg/dl 95 <input type="checkbox"/> umol/L 66 <input type="checkbox"/> mmol/l 51 <input type="checkbox"/> mg/L</td> </tr> <tr> <td>[7] Albumin</td> <td>_____ . _____</td> <td>30 <input type="checkbox"/> g/dl 32 <input type="checkbox"/> g/L</td> </tr> <tr> <td>[8] Total Protein</td> <td>_____ . _____</td> <td>30 <input type="checkbox"/> g/dl 32 <input type="checkbox"/> g/L 48 <input type="checkbox"/> mg/dL</td> </tr> <tr> <td>[9] SGOT (AST)</td> <td>_____ . _____</td> <td>102 <input type="checkbox"/> IU/L</td> </tr> <tr> <td>[10] SGPT (ALT)</td> <td>_____ . _____</td> <td>102 <input type="checkbox"/> IU/L</td> </tr> <tr> <td>[11] Total Bilirubin</td> <td>_____ . _____</td> <td>48 <input type="checkbox"/> mg/dL 51 <input type="checkbox"/> mg/L 95 <input type="checkbox"/> umol/L</td> </tr> <tr> <td>[12] Alkaline Phosphatase</td> <td>_____ . _____</td> <td>22 <input type="checkbox"/> U/L 102 <input type="checkbox"/> IU/L 91 <input type="checkbox"/> ukat/L</td> </tr> <tr> <td>[13] Glucose</td> <td>_____ . _____</td> <td>48 <input type="checkbox"/> mg/dL 66 <input type="checkbox"/> mmol/l 32 <input type="checkbox"/> g/L</td> </tr> </tbody> </table>					Value	Units	[1] Sodium	_____ . _____	42 <input type="checkbox"/> meq/l 66 <input type="checkbox"/> mmol/l	[2] Potassium	_____ . _____	42 <input type="checkbox"/> meq/l 66 <input type="checkbox"/> mmol/l	[3] Calcium	_____ . _____	42 <input type="checkbox"/> meq/l 66 <input type="checkbox"/> mmol/l 48 <input type="checkbox"/> mg/dL 51 <input type="checkbox"/> mg/L	[4] Phosphate	_____ . _____	48 <input type="checkbox"/> mg/dL 66 <input type="checkbox"/> mmol/l 51 <input type="checkbox"/> mg/L	[5] BUN	_____ . _____	48 <input type="checkbox"/> mg/dL 66 <input type="checkbox"/> mmol/l 32 <input type="checkbox"/> g/L	[6] Creatinine	_____ . _____	48 <input type="checkbox"/> mg/dl 95 <input type="checkbox"/> umol/L 66 <input type="checkbox"/> mmol/l 51 <input type="checkbox"/> mg/L	[7] Albumin	_____ . _____	30 <input type="checkbox"/> g/dl 32 <input type="checkbox"/> g/L	[8] Total Protein	_____ . _____	30 <input type="checkbox"/> g/dl 32 <input type="checkbox"/> g/L 48 <input type="checkbox"/> mg/dL	[9] SGOT (AST)	_____ . _____	102 <input type="checkbox"/> IU/L	[10] SGPT (ALT)	_____ . _____	102 <input type="checkbox"/> IU/L	[11] Total Bilirubin	_____ . _____	48 <input type="checkbox"/> mg/dL 51 <input type="checkbox"/> mg/L 95 <input type="checkbox"/> umol/L	[12] Alkaline Phosphatase	_____ . _____	22 <input type="checkbox"/> U/L 102 <input type="checkbox"/> IU/L 91 <input type="checkbox"/> ukat/L	[13] Glucose	_____ . _____	48 <input type="checkbox"/> mg/dL 66 <input type="checkbox"/> mmol/l 32 <input type="checkbox"/> g/L
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LABS1 - 07-MAR-2005

CREATININE CLEARANCE996 Not applicable*Do not enter leading or trailing zeros.*

Value

Calculated

_____ ml/min

LABS5 - 02-MAR-2005

Site Number | _____

Subject Number

END OF TREATMENT



ADVERSE EVENTS

997 No Adverse Event Occurred in this Reporting Period

If any Adverse Event Occurred, Record One per Line Below

1=Ongoing without change *do not complete remainder of row.*
2=New AE *complete remainder of*
3=Change to ongoing AE *row.*

Action Taken Codes

2= Dose Decreased
3= Permanently Discontinued
4= Temporarily Interrupted
5= Frequency Change
6= Dose Decrease and Frequency Change
996= Not Applicable
997= None

Outcome Codes

1= Recovered without Sequelae
2= Recovered with Sequelae
3= Ongoing
4= Died
5=Worsen in Intensity
998= Unknown

SAE Criteria Codes

- 1= Resulted in Death
- 2= Was Life-threatening
- 3= Was Persistently or Significantly Disabling / Incapacitating
- 4= Required or Prolonged Hospitalization
- 5= Is a Congenital Anomaly or Birth Defect
- 6= Is Medically Important

AE Description	Status of AE	Relationship	Action Taken			Start Date	Grade	Outcome (select one only)	End Date	Seriousness	
			Study Treatment (select one only)	Additional Treatment Given	Other Significant Intervention					If SAE, tick all criteria that apply	
1 Description: <hr/> NCI Short Name: <hr/> NCI Select: <hr/>	<input type="checkbox"/>	Reasonable Possibility that AE is Associated with Study Treatment?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> (day) / <input type="checkbox"/> (month) / <input type="checkbox"/> (year)	<input type="checkbox"/>	<input type="checkbox"/> (day) / <input type="checkbox"/> (month) / <input type="checkbox"/> (year)	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	1) <input type="checkbox"/> 4) <input type="checkbox"/> 2) <input type="checkbox"/> 5) <input type="checkbox"/> 3) <input type="checkbox"/> 6) <input type="checkbox"/>	
2 Description: <hr/> NCI Short Name: <hr/> NCI Select: <hr/>	<input type="checkbox"/>	Reasonable Possibility that AE is Associated with Study Treatment?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> (day) / <input type="checkbox"/> (month) / <input type="checkbox"/> (year)	<input type="checkbox"/>	<input type="checkbox"/> (day) / <input type="checkbox"/> (month) / <input type="checkbox"/> (year)	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	1) <input type="checkbox"/> 4) <input type="checkbox"/> 2) <input type="checkbox"/> 5) <input type="checkbox"/> 3) <input type="checkbox"/> 6) <input type="checkbox"/>	

**Serious Adverse Event (SAE) Report must be completed and supplied to the sponsor within 24 hours, or at the latest on the following working day.*

AE5.DOC - 21-OCT-2003

Site Number _____

Subject Number _____

**END OF TREATMENT****OUT-PATIENT CARE** Tick if not done

Since the last visit, has the patient seen a physician or another healthcare professional or had any investigations as an out-patient (including emergency room visits)? No Yes, please answer the following questions:

Emergency room (patient was not admitted subsequently) indicate 996 Not Applicable
number of emergency room visits:

Physician visits not mandated by study (indicate number of visits): 996 Not Applicable

General Practitioner/Internist: No Yes Number of Visits:

Oncologist: No Yes Number of Visits:

Other Physician: No Yes Number of Visits:

Specify Other: _____

Other health professional visits (indicate number of visits): 996 Not Applicable

Nurse (Concomitant Medication and Care): No Yes Number of Visits:

Rehabilitation: No Yes Number of Visits:

Physiotherapy: No Yes Number of Visits:

Other Health Professional: No Yes Number of Visits:

Specify Other: _____

During this cycle period, have any major procedures or tests been performed?

No Yes, fill-in form *Other Procedures*.

OUTPTC1 - 13/AUG/2002

EMPLOYMENT STATUS Tick if not done

Check One Primary Category:

Employed:

Full Time Employed

Non-Employed:

Unemployed

Part Time Employed

Retired

999 Other, specify _____

EMPLSTAT2 - 21-NOV-2003

TIME LOSSES Tick if not done

1. How many days since last visit during this cycle did the patient miss from work due to his/her disease or treatment? days

996 Not Applicable

2. How many days did the patient approximately miss from his/her usual activities other than work due to his/her disease or treatment? days

TIMLOS1 - 13/AUG/2002

Site Number _____

Subject Number _____

**END OF TREATMENT****IN-PATIENT ADMISSION DURING CYCLE PERIOD** Tick if not done

Since the last visit, has the patient been admitted for overnight stay to hospital? (excluding emergency room visit)

0 No 1 Yes, Complete Section Below, and complete an SAE form, if applicable.

During those hospitalizations, have any major procedures been performed?

0 No 1 Yes, Please fill-in *Other Procedure Form* 996 Not Applicable

Admission/Transfer* Date or Ongoing (day/month/year)	Discharge/Transfer* Date or Ongoing (day/month/year)	Reason for Admission	Unit (check one only)
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
____/____/____ 4 <input type="checkbox"/> Ongoing	____/____/____ 4 <input type="checkbox"/> Ongoing	1 <input type="checkbox"/> Chemotherapy Administration 2 <input type="checkbox"/> Tumor Related Adverse Event 3 <input type="checkbox"/> Treatment Related Adverse Event 999 <input type="checkbox"/> Other, specify: _____	1 <input type="checkbox"/> Surgery 2 <input type="checkbox"/> Internal Medicine 3 <input type="checkbox"/> ICU 999 <input type="checkbox"/> Other, specify: _____
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*When a patient is transferred from unit to another one (e.g. from surgery to internal medicine).

INPAT1 - 12/SEP/2002

Site Number | _____ |

Subject Number | _____ |



END OF TREATMENT

QUALITY OF LIFE

Was the EORTC QLQ-30 and QLQ BR23 completed? No Yes

If NO, please indicate the **Primary Reason** (tick one only)

2 Patient refused due to physical condition (too ill, depressed, unable to concentrate)

3 Patient refused due to other reason

6 Patient not given form by staff

999 Other Reason Please specify _____

Comments: _____

QLCMP1 - 17-MAY-2004

Site Number []

Subject Number []

END OF TREATMENT**PREVIOUS / CONCOMITANT TREATMENTS**997 No Previous/Concomitant Treatments

Drug/Therapy (Brand or Generic Name) Other	Status 1:Ongoing without change from previous report <i>(do not complete remainder of row)</i> 2:New or change to ongoing treatment <i>(complete remainder of row)</i>	Reason 2: Adverse Event/ Existing Condition 3: Prophylaxis 5: Tumor Related Pain 6: Tumor Related Excluding Pain 999: Other	Start Date <i>Or tick if previously reported</i> (day/month/year)	End Date <i>Or tick if ongoing</i> (day/month/year)
[1] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	_____ 5 <input type="checkbox"/> Previous 4 <input type="checkbox"/> Ongoing
[2] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	_____ 5 <input type="checkbox"/> Previous 4 <input type="checkbox"/> Ongoing
[3] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	_____ 5 <input type="checkbox"/> Previous 4 <input type="checkbox"/> Ongoing
[4] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	_____ 5 <input type="checkbox"/> Previous 4 <input type="checkbox"/> Ongoing
[5] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	_____ 5 <input type="checkbox"/> Previous 4 <input type="checkbox"/> Ongoing
[6] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	_____ 5 <input type="checkbox"/> Previous 4 <input type="checkbox"/> Ongoing
[7] _____	1 <input type="checkbox"/> 2 <input type="checkbox"/>	_____	_____	_____ 5 <input type="checkbox"/> Previous 4 <input type="checkbox"/> Ongoing

CONMEDSC-24-NOV-2003

Site Number _____

Subject Number _____

**END OF TREATMENT****PATIENT WORKUP**0 Tick if not done

Method of Evaluation	Site Assessed	Assessment Date (day/month/year)
1: Physical Exam 2:X ray 4:Conventional CT Scan 5:MRI 6:Ultrasound 7.Radionucleide 9:Spiral CT Scan 999:Other, Specify _____	Example: Chest Bone Abdomen Brain	
_____	CHEST	_____ 995 <input type="checkbox"/> Not Done
_____	ABDOMEN	_____ 995 <input type="checkbox"/> Not Done
_____	PELVIS	_____ 995 <input type="checkbox"/> Not Done
_____	BONE	_____ 995 <input type="checkbox"/> Not Done
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

PATWORKA - 09-DEC-2003

ORGAN CODES FOR PRIMARY TUMOR SITE

Adrenal glands	33	Eye	3	Ovary	36	Uterus	37
Anus	15	Gallbladder / biliary tract	18	Pancreas	17	Vaginal	39
Ascites	21	Heart	29	Pericardium	30	Vulvovaginal region	40
Bladder	31	Hypo pharynx	8	Pleura	27	Vessels	46
Blood	47	Kidneys	32	Pleural effusion	28		
Bone	43	Laboratory test	49	Prostate	34	Other central nervous system	90
Bone Marrow	44	Larynx	23	Rectum	14	Other head and neck	91
Brain	1	Liver	16	Retroperitoneum	20	Other visceral	92
Breast	41	Lung	26	Skin	42	Other soft tissue	93
Cervix	38	Lymph node	45	Small intestine	12	Other urinary tract	94
Clinical progression	48	Meninges	2	Stomach	10	Other male genital organ	95
Colon	13	Naso pharynx	7	Testis	35	Other female genital organ	96
Diaphragm	22	Omentum / peritoneum	19	Tongue	5	Other	999
Duodenum	11	Oral cavity	4	Trachea	24		
Esophagus	9	Oro pharynx	6	Thyroid	25		

Organ_codes.doc - 28/02/02

Site Number []

Subject Number []

**END OF TREATMENT****TUMOR ASSESSMENT – TARGET LESIONS**
 Tick if not done

Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions throughout the study and repeat the same methods of measurement throughout the study.

Lesion Number	Location (site) Use organ code from list attached	Description (subsite)	Assessment Date (day/month/year)	Method of Assessment	Measurement of Target Lesions (RECIST criteria longest diameter) (mm)
1	[]		[]	[]	[]
2	[]		[]	[]	[]
3	[]		[]	[]	[]
4	[]		[]	[]	[]
5	[]		[]	[]	[]
6	[]		[]	[]	[]
7	[]		[]	[]	[]
8	[]		[]	[]	[]
9	[]		[]	[]	[]
10	[]		[]	[]	[]

TUMASSEA - 03-NOV-2003

Site Number []

Subject Number []

**END OF TREATMENT****TUMOR ASSESSMENT – NON TARGET LESIONS**
 Tick if not done

Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions throughout the study and repeat the same methods of measurement throughout the study.

Lesion Number	Location (site) Use organ code from list attached	Description (subsite)	Assessment Date (day/month/year)	Method of Assessment 1: Physical Exam 2: X-Ray 4: Conventional CT Scan 5: MRI (NMR) 6: Ultrasound 7: Radionuclide 8: Lumbar Puncture 9: Spiral CT Scan 999: Other, specify	Response 1: Complete Response 4: Progressive Disease 5: Not Evaluable 6: New Lesion 7: Incomplete Response/SD
11	[]		[] / [] / []	[] / [] / []	[] / []
12	[]		[] / [] / []	[] / [] / []	[] / []
13	[]		[] / [] / []	[] / [] / []	[] / []
14	[]		[] / [] / []	[] / [] / []	[]
15	[]		[] / [] / []	[] / [] / []	[]
16	[]		[] / [] / []	[] / [] / []	[]
17	[]		[] / [] / []	[] / [] / []	[]
18	[]		[] / [] / []	[] / [] / []	[]
19	[]		[] / [] / []	[] / [] / []	[]
20	[]		[] / [] / []	[] / [] / []	[]

TUMASSES - 11-DEC-2003

EVALUATION OF TARGET LESIONS

Complete Response (CR)	Disappearance of all target lesions.
Partial Response (PR)	A $\geq 30\%$ decrease in the sum of the longest dimensions of the target lesions, taking as reference the baseline sum longest dimensions.
Progression (PD)	A $\geq 20\%$ increase in the sum of longest dimensions of the target lesions, taking as reference the smallest sum of the longest dimensions recorded since the treatment started, or the appearance of one or more new lesions.
Stable Disease (SD)	Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease, taking as reference the smallest sum longest dimensions since the treatment started.

Evtar1.doc - 19/MAR/2002

EVALUATION OF NON-TARGET LESIONS

Complete Response (CR):	Disappearance of all non-target lesions and normalization of tumor marker levels to \leq ULN.
Non-Complete Response (non-CR) Non-Progression (non-PD)	Persistence of ≥ 1 non-target lesions and/or maintenance of tumor marker levels $>$ ULN.
Progression (PD)	Unequivocal progression of existing non-target lesions, or the appearance of ≥ 1 new lesions.
<i>The cytological confirmation of the neoplastic origin of any effusion that appears or worsens during treatment when the measurable tumor has met criteria for response or stable disease is mandatory to differentiate between response or stable disease and progressive disease.</i>	

EVTARL2.doc - 19/03/02

OVERALL RESPONSE

Target Lesions ¹	Non-Target Lesions ²	New Lesions ³	Overall Response
CR	CR	No	CR
CR	Non-CR/Non-PD	No	PR
PR	Non-PD	No	PR
SD	Non-PD	No	SD
PD	Any response	Yes or No	PD
Any response	PD	Yes or No	PD
Any response	Any response	Yes	PD

OVRESP1 - 19-MAR-2002

¹ Measurable lesions only

² May include measurable lesions not followed as target lesions or non-measurable lesions

³ Measurable or non-measurable lesions

Site Number | _____ |

Subject Number | _____ |



END OF TREATMENT

OVERALL RESPONSE

Tick if not done

Overall Response Achieved at the end of this cycle, According to RECIST Criteria

1 CR (Complete Response)

2 PR (Partial Response)

3 SD (Stable Disease)

4 PD (Progressive Disease)

5 Not Evaluable, *please specify* _____

OVRSP1 - 03/APR/2002

If biopsy was performed as part of evaluation process, please complete an Other Procedures form.

WITHDRAWAL FROM STUDY TREATMENT



WITHDRAWAL FROM STUDY TREATMENT

- Completion of Study Treatment
- Investigator Signature

DIVIDER_COMPTRT - 11-DEC-2003

Site Number [REDACTED]

Subject Number [REDACTED]



WITHDRAWAL FROM STUDY TREATMENT

WITHDRAWAL FROM STUDY TREATMENT

Last Dose Date [REDACTED]
(day) / (month) / (year)

Please provide the PRIMARY REASON the subject discontinued study treatment (tick one only)

- 1 Adverse Event *Please complete an ADVERSE EVENT form as appropriate.*
- 3 No Longer Requires Study Treatment
- 4 Protocol Violation
- 6 Lost to Follow-up
- 7 Death *Please fax a SERIOUS ADVERSE EVENT REPORT form and complete IN CASE OF DEATH form if appropriate.*
- 8 Progressive Disease
- 9 Subject did not Wish to Continue
- 999 Other Reason *Please specify* _____

Comments: _____

SMWV1 - 10/APR/2003

INVESTIGATOR SIGNATURE

I have reviewed the studybook for this subject. To the best of my knowledge, the entries are complete and accurate.

Investigator's Name (block letters) _____

Investigator's Signature _____

Date [REDACTED]
(day) / (month) / (year)

INVSIG1 - 10/APR/2003

Site Number []

Subject Number []



TRACKING PAGES

CRF PAGE TRACKING FORM – END OF TREATMENT

Repeated Pages – Enter the last page number used for each repeating page. Only fill out for the **last transmission** of CRFs for this subject.

Page Name	Last Page Used
[1] Adverse Event – End of Treatment	Page No. 503 []
[2] Previous/Concomitant Treatment – End of Treatment	Page No. 507 []
[3] Tumor Assessment – Non-Target Lesions – End of Treatment	Page No. 510 []

Responsible Person (Site Representative)

Name:	Signature:	Date
_____	_____	_____ _____ _____ _____ (day) (month) (year)

DO NOT FILL OUT ANY ADDITIONAL REPEATING PAGES AFTER COMPLETING THIS FORM. If additional information concerning this case needs to be provided, contact the monitor of the study to get information on how to proceed.

TRACKCRF1 - 26-JAN-2004



RESPONSE

- Best Overall Response / General Comments
- Date of First Response
- Date of Disease Progression

DIVIDER_RESPONSE - 09-JUN-2004

Site Number | _____ |

Subject Number | _____ |



BEST OVERALL RESPONSE

Tick if not done

Best Overall Response of this study according to RECIST

1 CR (Complete Response)

2 PR (Partial Response)

3 SD (Stable Disease)

4 PD (Progressive Disease)

5 Not Evaluable, *please specify* _____

OVRSP1 - 03/APR/2002

GENERAL COMMENTS

Tick if not done

GENCOM1 - 27-MAY-2004

Site Number

Subject Number



DATE OF FIRST RESPONSE

First Response Date Not Applicable
RESDT1 - 09-JUN-2004

RESDT1 - 09-JUN-2004

Site Number | _____ |

Subject Number | _____ |



DATE OF DISEASE PROGRESSION

Disease Progression Date					996	<input type="checkbox"/>	Not Applicable
	(day)	(month)	(year)				

DISDT1 - 09-JUN-2004



FOLLOW-UP |__|__|

FOLLOW-UP |__|

- Visit Date/ Patient Follow-up Status
- Quality of Life
- Further Anti-Cancer Chemotherapy
- Further Anti-Tumor Therapy
- Adverse Events

DIVIDER5 - 31-OCT-2003

Site Number |_____|

Subject Number |_____|



FOLLOW-UP |__|__|

VISIT DATE (DATE OF CONTACT)

Visit Date |_____|/|_____|/|_____|
(day) (month) (year)

VSDT1 - 10/APR/2003

PATIENT FOLLOW-UP STATUS

Date of Last Contact |_____|/|_____|/|_____| (latest date the patient was known to be alive)
(Follow-up date) (day) (month) (year)

Patient's status as of end of Follow-up (tick one only)

- 1 Alive
- 2 Dead (*complete section "In Case of Death"*)
- 3 Lost to Follow-up

Source of Information

- 4 Physician Contact
- 5 Family Contact
- 23 Subject Contact
- 999 Other, specify: _____

PAFUSTAT2 - 09/APR/2003

Site Number |_____|

Subject Number |_____|



FOLLOW-UP |__|__|

QUALITY OF LIFE

Was the EORTC QLQ-30 and QLQ BR23 completed? No Yes

If NO, please indicate the **Primary Reason** (tick one only)

2 Patient refused due to physical condition (too ill, depressed, unable to concentrate)

3 Patient refused due to other reason

6 Patient not given form by staff

999 Other Reason Please specify _____

Comments: _____

QLCMP1 - 17-MAY-2004

Site Number _____

Subject Number _____

FOLLOW-UP | | |**FURTHER ANTI-CANCER CHEMOTHERAPY**997 None

Drug per Regimen (Brand or Generic Name)		Start Date (day/month/year) <i>Or tick if previously reported</i>	End Date (day/month/year) <i>or tick if ongoing</i>	Reason For Discontinuation 1:Adverse Event 2:Lack of Efficacy 8:Progressive Disease 999:Other	Relapse/Progression Date (day/month/year)	Best Response per Regimen 1 :Complete Response 2 :Partial Response 3 :Stable Disease 4 :Progressive Disease 5 :No: Evaluable 996 :No: Applicable 998 :Unknown
1	[1] _____	_____ / _____ / _____	_____ / _____ / _____	_____ / _____ / _____	_____ / _____ / _____	_____ / _____ / _____
	[2] _____	_____ / _____ / _____				
	[3] _____	_____ / _____ / _____				
	[4] _____	_____ / _____ / _____				
		5 <input type="checkbox"/> Previous	4 <input type="checkbox"/> Ongoing			
2	[1] _____	_____ / _____ / _____	_____ / _____ / _____	_____ / _____ / _____	_____ / _____ / _____	_____ / _____ / _____
	[2] _____	_____ / _____ / _____				
	[3] _____	_____ / _____ / _____				
	[4] _____	_____ / _____ / _____				
		5 <input type="checkbox"/> Previous				
3	[1] _____	_____ / _____ / _____	_____ / _____ / _____	_____ / _____ / _____	_____ / _____ / _____	_____ / _____ / _____
	[2] _____	_____ / _____ / _____				
	[3] _____	_____ / _____ / _____				
	[4] _____	_____ / _____ / _____				
		5 <input type="checkbox"/> Previous				

CHEM07 - 1-DEC-2003

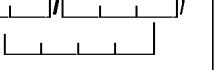
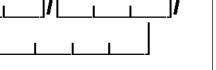
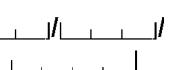
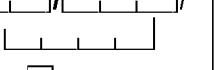
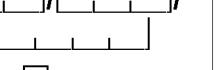
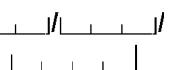
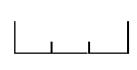
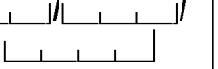
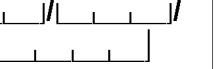
Site Number

Subject Number

FOLLOW-UP | _ | _



FURTHER ANTI-TUMOR THERAPY

Regimen No.	Regimen/Drug	Site/Procedure	Start Date (day/month /year) <i>Or tick if previously reported</i>	End Date (day/month /year) <i>or tick if ongoing</i>	Reason For Discontinuation 1:Adverse Event 2:Lack of Efficacy 8:Progressive Disease 999: Other ⋮	Relapse/Progression Date (day/month/ year)	Best Response per Regimen 1 :Complete Response 2 :Partial Response 3 :Stable Disease 4 :Progressive Disease 5 :Not Evaluable 996 :Not Applicable 998 :Unknown
1			 5 <input type="checkbox"/> Previous	 4 <input type="checkbox"/> Ongoing			
2			 5 <input type="checkbox"/> Previous	 4 <input type="checkbox"/> Ongoing			
3			 5 <input type="checkbox"/> Previous	 4 <input type="checkbox"/> Ongoing			

TUMTHER6 - 11-DEC-2003

Site Number

Subject Number

FOLLOW-UP | _ | _



ADVERSE EVENTS

997 No Adverse Event Occurred in this Reporting Period

Action Taken Codes

Outcome Codes

SAE Criteria Codes

If any Adverse Event Occurred, Record One per Line Below

1=Ongoing without change do *not* complete remainder of row.
2>New AE complete remainder of
3=Change to ongoing AE row.

Outcome Codes

1= Recovered without Sequelae
2= Recovered with Sequelae
3= Ongoing
4= Died
5=Worsen in Intensity
998= Unknown

SAE Criteria Codes

- 1= Resulted in Death
- 2= Was Life-threatening
- 3= Was Persistently or Significantly Disabling / Incapacitating
- 4= Required or Prolonged Hospitalization
- 5= Is a Congenital Anomaly or Birth Defect
- 6= Is Medically Important

***Serious Adverse Event (SAE) Report must be completed and supplied to the sponsor within 24 hours, or at the latest on the following working day.**

AE5.DOC - 21-OCT-2003

Site Number []

Subject Number []



TRACKING PAGES

CRF PAGE TRACKING FORM – FOLLOW-UP

Repeated Pages – Enter the last page number used for each repeating page. Only fill out for the **last transmission** of CRFs for this subject.

Page Name	Last Page Used
[1] Further Anti-Cancer Chemotherapy – Follow-up _____	Page No. 6603 []
[2] Adverse Events – Follow-up _____	Page No. 6605 []
[3] Tumor Assessment – Non-Target Lesions – Follow-up _____	Page No. 9807 []

Responsible Person (Site Representative)

Name: _____	Signature: _____	Date [] / [] / [] (day) (month) (year)
-------------	------------------	---

DO NOT FILL OUT ANY ADDITIONAL REPEATING PAGES AFTER COMPLETING THIS FORM. If additional information concerning this case needs to be provided, contact the monitor of the study to get information on how to proceed.

TRACKCRF1 - 26-JAN-2004



COMPLETION OF STUDY

COMPLETION OF STUDY

- Completion of Study
- Investigator Signature

DIVIDER_COMP - 06-NOV-2003

Site Number

Subject Number



COMPLETION OF STUDY

COMPLETION OF STUDY

Please provide the **Primary Reason** the subject discontinued study (tick one only)

- Lost to Follow-up
 Death *Please fax a SERIOUS ADVERSE EVENT REPORT form and complete IN CASE OF DEATH form if appropriate.*
 Subject did not Wish to Continue
 Other Reason *Please specify*

Date Subject Completed/Discontinued from the Study _____ / _____ / _____
(day) (month) (year)

Comments: _____

DISPOSITA - 06-NOV-2003

INVESTIGATOR SIGNATURE

I have reviewed the studybook for this subject. To the best of my knowledge, the entries are complete and accurate.

Investigator's Name (block letters) _____

Investigator's Signature _____ Date _____
(day) (month) (year)

INVSIG1 - 10/APR/2003

DEATH



IN CASE OF DEATH

- Death Form
- Source of Information

DIVIDER_DEATH - 21-NOV-2003

Site Number []

Subject Number []



IN CASE OF DEATH

DEATH

996 Not Applicable

Death Date [] / [] / []
(day) (month) (year)

Cause of Death, indicate *MOST probable cause* (tick one only)

1 Malignant Disease

4 Septic toxicity related to study drug [with at least one related AE at the last cycle, i.e., infection, sepsis or fever in absence of infection (with outcome: Died)]

5 Non-Septic toxicity related to study drug [with at least one related AE except the one listed for septic, (with outcome: Died)]

3 Adverse Event unrelated to Study Drug

999 Other, specify _____

ONCDEATH1 - 03/APR/2003

SOURCE OF INFORMATION

Source of Information (*tick all that apply*)

1 Death Certificate

2 Autopsy

3 Hospital Chart Notes and/or Other Medical Report

4 Physician Contact

5 Family Contact

999 Other, specify _____

SOURCE1 - 08-JAN-2004

ADDITIONAL FORMS

- EQ-5D Questionnaire
- Radiotherapy for Cancer
- Other Procedures - Unscheduled
- ECG
- Pregnancy Test
- Patient Work-up
- Tumor Assessment – Target Lesions
- Tumor Assessment – Non-Target Lesions
- Overall Response

DIVIDER_OTH - 11-DEC-2003

Site Number []

Subject Number []



Follow-up | | |

EQ-5D QUESTIONNAIRE

To Be Completed by Investigator/Designee ONLY

Was the EQ5D questionnaire completed? 0 No 1 Yes

Questionnaire Date [] / [] / []
(day) (month) (year)

Response to subject health state question from EQ-5D Questionnaire []

If EQ-5D Questionnaire not completed, please indicate the **Primary Reason** (tick one only)

2 Patient refused due to physical condition (too ill, depressed, unable to concentrate)

3 Patient refused due to other reason

6 Patient not given form by staff

999 Other Reason Please specify _____

Comments: _____

EQ5D2 - 26-AUG-2004

Site Number | _____ |

Subject Number | _____ |



Cycle |__|__|

RADIOTHERAPY FOR CANCER

Sequence No.	Site Code	Sub-site Specify	Cumulative Dose	Units	Intent		
						Start Date (day/month/ year)	End Date (day/month/ year)
997	<input type="checkbox"/> None				1 Curative 2 Palliative 3 Adjuvant 4 Neo Adjuvant 998 Unknown		
1	[_____]	[_____]	[_____]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[_____]	[_____]	[_____]
2	[_____]	[_____]	[_____]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[_____]	[_____]	[_____]
3	[_____]	[_____]	[_____]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[_____]	[_____]	[_____]
4	[_____]	[_____]	[_____]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[_____]	[_____]	[_____]
5	[_____]	[_____]	[_____]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[_____]	[_____]	[_____]
6	[_____]	[_____]	[_____]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[_____]	[_____]	[_____]
7	[_____]	[_____]	[_____]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[_____]	[_____]	[_____]
8	[_____]	[_____]	[_____]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[_____]	[_____]	[_____]
9	[_____]	[_____]	[_____]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[_____]	[_____]	[_____]
10	[_____]	[_____]	[_____]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[_____]	[_____]	[_____]
11	[_____]	[_____]	[_____]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[_____]	[_____]	[_____]
12	[_____]	[_____]	[_____]	12 <input type="checkbox"/> Gy 176 <input type="checkbox"/> Rad	[_____]	[_____]	[_____]

CARADIO3 - 09/APR/2003

Site Number |_____|

Subject Number |_____|

**SCREENING_Cycle |__|__|/Follow-up |__|__|****OTHER PROCEDURES – UNSCHEDULED**
 Tick if not done

Please note any additional assessment, whether related to tumor or not, e.g. Radiological Assessment, Bacteriological Examination, Myelogram, etc.

Type of Procedure 1:Cultures 2:Imaging 3:Puncture/drainage 4:Biopsy 5:Test 6:Surgery 14:Bone marrow aspiration 999:Other, specify	Description	Assessed Date (day/month/year)	Comments*, if applicable
1.	_____	_____	_____
2.	_____	_____	_____
3.	_____	_____	_____
4.	_____	_____	_____
5.	_____	_____	_____
6.	_____	_____	_____
7.	_____	_____	_____
8.	_____	_____	_____
9.	_____	_____	_____
10.	_____	_____	_____

*If the Procedure was repeated several times a day, please note how many times it was performed. When relevant, please note the result of the procedure.

OTHPROC1 – 03/APR/2002

Site Number | _____|

Subject Number



Cycle |__|__| / **Follow-up** |__|__|

ELECTROCARDIOGRAM

Tick if not done

ECG Date | / | / |
(day) (month) (year)

Interpretation 2 Normal

Abnormal, Not Clinically Significant

Abnormal, Clinically Significant (record description on the ADVERSE EVENTS form)

ECGA – 13/SEP/2002

Site Number |_____|

Subject Number |_____|



Cycle |__|__|

PREGNANCY TEST

Tick if not done

Specimen Collection Date	Test Type	Result														
<table><tr><td>_____</td><td>/</td><td>_____</td><td>/</td><td>_____</td></tr><tr><td>(day)</td><td>(month)</td><td colspan="3">(year)</td></tr></table>	_____	/	_____	/	_____	(day)	(month)	(year)			<table><tr><td>1 <input type="checkbox"/> Urine</td><td>1 <input type="checkbox"/> Negative</td></tr><tr><td>2 <input type="checkbox"/> Serum</td><td>2 <input type="checkbox"/> Positive</td></tr></table>	1 <input type="checkbox"/> Urine	1 <input type="checkbox"/> Negative	2 <input type="checkbox"/> Serum	2 <input type="checkbox"/> Positive	
_____	/	_____	/	_____												
(day)	(month)	(year)														
1 <input type="checkbox"/> Urine	1 <input type="checkbox"/> Negative															
2 <input type="checkbox"/> Serum	2 <input type="checkbox"/> Positive															

PREGA - 14-JUL-2003

Site Number |_____|

Subject Number |_____|



Follow-up |__|__|

PATIENT WORKUP0 Tick if not done

Method of Evaluation	Site Assessed	Assessment Date (day/month/year)
1: Physical Exam 2:X ray 4:Conventional CT Scan 5:MRI 6:Ultrasound 7.Radionucleide 9.Spiral CT Scan 999:Other, Specify _____	Example: Chest Bone Abdomen Brain	
<input type="checkbox"/>	CHEST	<input type="checkbox"/> 995 <input type="checkbox"/> Not Done
<input type="checkbox"/>	ABDOMEN	<input type="checkbox"/> 995 <input type="checkbox"/> Not Done
<input type="checkbox"/>	PELVIS	<input type="checkbox"/> 995 <input type="checkbox"/> Not Done
<input type="checkbox"/>	BONE	<input type="checkbox"/> 995 <input type="checkbox"/> Not Done
<input type="checkbox"/>	_____	<input type="checkbox"/>
<input type="checkbox"/>	_____	<input type="checkbox"/>
<input type="checkbox"/>	_____	<input type="checkbox"/>
<input type="checkbox"/>	_____	<input type="checkbox"/>
<input type="checkbox"/>	_____	<input type="checkbox"/>

PATWORKA - 09-DEC-2003

Site Number | _____ |

Subject Number | _____ |



Follow-up |__|__|

TUMOR ASSESSMENT – TARGET LESIONS Tick if not done

Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions throughout the study and repeat the same methods of measurement throughout the study.

Lesion Number	Location (site) Use organ code from list attached	Description (subsite)	Assessment Date (day/month/year)	Method of Assessment	Measurement of Target Lesions (RECIST criteria longest diameter) (mm)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

TUMASSEA - 03-NOV-2003

Site Number |_____|

Subject Number |_____|



Follow-up |__|__|

TUMOR ASSESSMENT – NON TARGET LESIONS Tick if not done

Please complete the form using ALL DISEASE SITES. Maintain the same numbering of lesions throughout the study and repeat the same methods of measurement throughout the study.

Lesion Number	Location (site) Use organ code from list attached	Description (subsite)	Assessment Date (day/month/year)	Method of Assessment 1: Physical Exam 2: X-Ray 4: Conventional CT Scan 5: MRI (NMR) 6: Ultrasound 7: Radionuclide 8: Lumbar Puncture 9: Spiral CT Scan 999: Other, specify	Response 1: Complete Response 4: Progressive Disease 5: Not Evaluable 6: New Lesion 7: Incomplete Response/SD

TUMASSES\$ - 11-DEC-2003

Site Number |_____|

Subject Number |_____|



Follow-up |__|__|

OVERALL RESPONSE

Tick if not done

Overall Response Achieved at the end of this cycle, According to RECIST Criteria

1 CR (Complete Response)

2 PR (Partial Response)

3 SD (Stable Disease)

4 PD (Progressive Disease)

5 Not Evaluable, *please specify* _____

OVRSP1 - 03/APR/2002

If biopsy was performed as part of evaluation process, please complete an Other Procedures form.

Documentation of Screen Failure



DOCUMENTATION OF SCREEN FAILURE

- Documentation of Screen Failure
- Investigator Signature

DIVIDER7 - 31-OCT-2003

Site Number _____

Subject Number _____



Documentation of Screen Failure

VISIT DATE

Visit Date	_____/_____/_____			
	(day)	(month)	(year)	

VSDT1 - 10/APR/2003

DEMOGRAPHY

Subject's Initials	Birth Date	Sex	Race
<input type="text"/> <input type="text"/> <input type="text"/> (first) (middle) (last)	<input type="text"/> <input type="text"/> <input type="text"/> (day) (month) (year)	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> White 2 <input type="checkbox"/> Black 3 <input type="checkbox"/> Asian/Oriental 4 <input type="checkbox"/> Multiracial 999 <input type="checkbox"/> Other

DEMO1 - 10/APR/2003

INFORMED CONSENT

Date Consent Obtained	_____/_____/_____			
	(day)	(month)	(year)	

INFCON3 - 10/APR/2003

INCLUSION / EXCLUSION CRITERIA

Does the subject satisfy all inclusion and exclusion criteria? 0 No 1 Yes

If NO, please specify below (one deviation per line).

Criterion Number (example I3, E12)	Specify the Deviation
[1] <input type="text"/>	_____
[2] <input type="text"/>	_____
[3] <input type="text"/>	_____
[4] <input type="text"/>	_____

Any waiver of these inclusion and exclusion criteria must be approved by the sponsor on a case-by-case basis prior to subject inclusion. This must be documented by both the sponsor and the Investigator.

INCEXC1 - 25-FEB-2004

Site Number | _____|

Subject Number



Documentation of Screen Failure

DOCUMENTATION OF SCREEN FAILURE

Please provide the **Primary Reason** the subject failed screening (tick one only)

- 6 Lost to Follow-up

7 Death *Please fax a SERIOUS ADVERSE EVENT REPORT form and complete IN CASE OF DEATH form if appropriate.*

9 Subject did not Wish to Continue

12 Fail to Meet Entrance Criteria

oo Other Reason *Please specify*

Date Subject Failed Screening

Comments:

DISPOSITA - 18/MAR/2002

INVESTIGATOR SIGNATURE

I have reviewed the studybook for this subject. To the best of my knowledge, the entries are complete and accurate.

Investigator's Name (block letters) _____

Investigator's Signature

The diagram illustrates the scale of time across three levels: day, month, and year. It features a horizontal axis with vertical tick marks. The first two tick marks are grouped together under the label '(day)'. The next two groups of tick marks are grouped together under the label '(month)'. The final two groups of tick marks are grouped together under the label '(year)'. This visual representation emphasizes the hierarchical nature of time measurement.

INVSIG1 - 10/APR/2003

QUALITY OF LIFE QUESTIONNAIRES



QUALITY OF LIFE QUESTIONNAIRES

- EORTC QLQ-30 – Page 1 of 2
- EORTC QLQ-30 – Page 2 of 2
- EORTC QLQ-BR23 – Page 1 of 2
- EORTC QLQ- BR23 – Page 2 of 2

DIVIDER_DEATH - 21-NOV-2003

Site Number | _____|

Subject Number



SCREENING_Cycle |__|__|/Follow-up |__|__|

EORTC QLQ-30 QUESTIONNAIRE

Tick if not done

Questionnaire Date / / (day) / (month) / (year)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

		Not at all	A Little	Quite a Bit	Very Much
[1]	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
[2]	Do you have any trouble taking a <u>long</u> walk?	1	2	3	4
[3]	Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
[4]	Do you need to stay in bed or a chair during the day?	1	2	3	4
[5]	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

DURING THE PAST WEEK

		Not at all	A Little	Quite a Bit	Very Much
[6]	Were you limited in doing either your work or other daily activities?	1	2	3	4
[7]	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
[8]	Were you short of breath?	1	2	3	4
[9]	Have you had pain?	1	2	3	4
[10]	Did you need to rest?	1	2	3	4
[11]	Have you had trouble sleeping?	1	2	3	4
[12]	Have you felt weak?	1	2	3	4
[13]	Have you lacked appetite?	1	2	3	4
[14]	Have you felt nauseated?	1	2	3	4
[15]	Have you vomited?	1	2	3	4
[16]	Have you been constipated?	1	2	3	4

Please go on to the next page

QLQ30A - 14-APR-2004

Site Number | _____|

Subject Number



SCREENING_Cycle |__|__|/Follow-up |__|__|

EORTC QLQ-30 QUESTIONNAIRE (CONTINUED)

Tick if not done

Questionnaire Date / / (day) / (month) / (year)

DURING THE PAST WEEK

		Not at all	A Little	Quite a Bit	Very Much
[17]	Have you had diarrhea?	1	2	3	4
[18]	Were you tired?	1	2	3	4
[19]	Did pain interfere with your daily activities?	1	2	3	4
[20]	Have you had difficulty in concentrating on things, like reading a newspaper?	1	2	3	4
[21]	Did you feel tense?	1	2	3	4
[22]	Did you worry?	1	2	3	4
[23]	Did you feel irritable?	1	2	3	4
[24]	Did you feel depressed?	1	2	3	4
[25]	Have you had difficulty remembering things?	1	2	3	4
[26]	Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
[27]	Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
[28]	Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

- [29] How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very Poor			Excellent			

- [30] How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very Poor			Excellent			

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QLQ30B - 14-APR-2004

Site Number [_____]

Subject Number [_____]

**SCREENING_Cycle |__|__|/Follow-up |__|__|****EORTC QLQBR23 QUESTIONNAIRE**
 Tick if not done

Questionnaire Date [_____] / [_____] / [_____] (day) (month) (year)

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week:

DURING THE PAST WEEK

	Not at all	A Little	Quite a Bit	Very Much
[31] Did you have a dry mouth?	1	2	3	4
[32] Did food and drink taste different than usual?	1	2	3	4
[33] Were your eyes painful, irritated or watery?	1	2	3	4
[34] Have you lost any hair?	1	2	3	4
[35] Answer this question only if you had any hair loss: Were you upset by the loss of hair?	1	2	3	4
[36] Did you feel ill or unwell?	1	2	3	4
[37] Did you have hot flushes?	1	2	3	4
[38] Did you have headaches?	1	2	3	4
[39] Have you felt physically less attractive as a result of your disease or treatment?	1	2	3	4
[40] Have you been feeling less feminine as a result of your disease or treatment?	1	2	3	4
[41] Did you find it difficult to look at yourself naked?	1	2	3	4
[42] Have you been dissatisfied with your body?	1	2	3	4
[43] Were you worried about your health in the future?	1	2	3	4

DURING THE PAST FOUR WEEKS

	Not at all	A Little	Quite a Bit	Very Much
[44] To what extent were you interested in sex?	1	2	3	4
[45] To what extent were you sexually active? (with or without intercourse)	1	2	3	4
[46] Answer this question only if you have been sexually active. To what extent was sex enjoyable for you?	1	2	3	4

Please go on to the next page

Site Number | _____|

Subject Number



SCREENING_Cycle |__|__|/Follow-up |__|__|

EORTC QLQ-BR23 QUESTIONNAIRE (CONTINUED)

Tick if not done

Questionnaire Date / / (day) / (month) / (year)

DURING THE PAST WEEK

	Not at all	A Little	Quite a Bit	Very Much
[47] Did you have any pain in your arm or shoulder?	1	2	3	4
[48] Did you have a swollen arm or hand?	1	2	3	4
[49] Was it difficult to raise your arm or to move it sideways?	1	2	3	4
[50] Have you had any pain in the area of your affected breast?	1	2	3	4
[51] Was the area of your affected breast swollen?	1	2	3	4
[52] Was the area of your affected breast oversensitive?	1	2	3	4
[53] Have you had skin problems on or in the area of your affected breast (e.g. itchy, dry, flaky)?	1	2	3	4

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QLQBR23B - 14-APR-2004

Site Number _____

Subject Number _____



Site-Based Data Clarification Form (sDCF)

#	Page No. (1)	Visit No.	Line No. (If Applicable)	Item Description	Old Value	New Value	Reason for Change
A.							<input type="checkbox"/> New Information <input type="checkbox"/> Data Previously Recorded Incorrectly
B.							<input type="checkbox"/> New Information <input type="checkbox"/> Data Previously Recorded Incorrectly
C.							<input type="checkbox"/> New Information <input type="checkbox"/> Data Previously Recorded Incorrectly
D.							<input type="checkbox"/> New Information <input type="checkbox"/> Data Previously Recorded Incorrectly
E.							<input type="checkbox"/> New Information <input type="checkbox"/> Data Previously Recorded Incorrectly
F.							<input type="checkbox"/> New Information <input type="checkbox"/> Data Previously Recorded Incorrectly
G.							<input type="checkbox"/> New Information <input type="checkbox"/> Data Previously Recorded Incorrectly
H.							<input type="checkbox"/> New Information <input type="checkbox"/> Data Previously Recorded Incorrectly
I.							<input type="checkbox"/> New Information <input type="checkbox"/> Data Previously Recorded Incorrectly

(1): for composite page number, e.g. 26.1, please report the complete number

Investigator / Authorized Designee (Initials):	Date: <u> </u> / <u> </u> / <u> </u> (day) (month) (year)
Database Updated by:	Date: <u> </u> / <u> </u> / <u> </u> (day) (month) (year)

Site Number | _____|

Subject Number



Request for Waiver

REQUEST FOR WAIVER

Request Date | / | (month) | / | (year)

Please specify below (one deviation per line).

Criterion Number
(example I3, E12)

Specify the Deviation

- [1]  _____
 - [2]  _____
 - [3]  _____
 - [4]  _____

Specify the reason for requesting the waiver:

Will the granting of the waiver negatively impact the benefit/risk ratio for this patient? No Yes

Will the granting of this waiver interfere with the analysis of safety and efficacy endpoints? No Yes

Does your IRB / Ethics committee require that this waiver be submitted? No Yes

WAIVER1 -DRAFT 17-FEB-2004

WAIVER SIGNATURES

Investigator's Name (block letters) _____

Investigator's Signature _____ Date _____
(day) / (month) / (year)

Was the waiver granted? No Yes

Comments: _____

Responsible Medical Expert Name (block letters) _____

Responsible Medical Expert's Signature _____ Date _____
(day) / (month) / (year)

WAIWSIG1 - 24-FEB-2004

Site Number _____

Subject Number _____



SCREENING_Cycle |__|__| /Follow-up |__|__|

EuroQol EQ-5D Questionnaire English

Tick if not done

Questionnaire Date | / | / | / |
 (day) (month) (year)

By placing a checkmark in one box in each group below, please indicate which statement best describes your own health state today.

Mobility

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

Self-care

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain/Discomfort

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

Anxiety/Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

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EQ5DA_ENGLISH - 16-APR-2004

Site Number _____

Subject Number _____



SCREENING_Cycle |__|__| /Follow-up |__|__|

EQ5D QUESTIONNAIRE (CONTINUED) ENGLISH

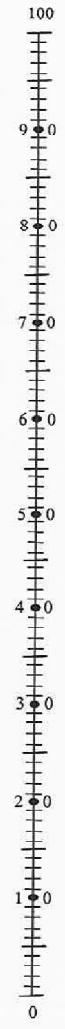
Tick if not done

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own
health state
today

Best
imaginable
health state



Worst
imaginable
health state