BREAST CANCER INTERNATIONAL RESEARCH GROUP (BCIRG)

CONFIDENTIAL PATIENT DATA

INVESTIGATOR'S NAME : _____

RP 56976 - V-316

A MULTICENTER PHASE III RANDOMIZED TRIAL COMPARING DOCETAXEL IN COMBINATION WITH DOXORUBICIN AND CYCLOPHOSPHAMIDE (TAC) VERSUS 5-FLUOROURACIL IN COMBINATION WITH DOXORUBICIN AND CYCLOPHOSPHAMIDE (FAC) AS ADJUVANT TREATMENT OF OPERABLE BREAST CANCER PATIENTS WITH POSITIVE AXILLARY LYMPH NODES.

PATIENT INITIALS :
(First two letters of first name, first letter of surname)

PATIENT NUMBER :

☐ TAC ☐ FAC

BCIRG MONITORING COORDINATOR : [redacted]

BCIRG LOCAL MONITOR :

The case report form must be completed in black ball point pen or typewritten.
Any correction of the data must be initialed and dated, and must leave the initial entry readable

INTRODUCTION

CRF Sections :

- BASELINE
- CYCLE N° |____| X 6
- TEAR OFF LABELS
- END OF CHEMOTHERAPY
- ADJUVANT RADIOTHERAPY
- FOLLOW-UP N° |____|
- BREAST CANCER RELAPSE N° |____|
- ABBREVIATED FOLLOW-UP N° |____|
- DEATH REPORT FORM

- **Extra Forms : E.F.1 - E.F.10**
- **Extra Sections :**
  - **. Second Primary Malignancy**
  - **. Follow-Up N°** |____|
  - **. Breast Cancer Relapse N°** |____|
  - **. Abbreviated Follow-Up N°** |____|

If more forms are needed for examinations already described in cycles or for supplementary examinations, forms are available among the **Extra Forms** provided, separate from the CRF. They should be inserted into the Baseline, Cycle or Follow-up sections wherever needed.

STUDY RP 56976 - V-316
INSTRUCTIONS FOR COMPLETING THE CRF

This case report form is printed on No Carbon Required (NCR) paper. The **last** copy is for your files.

To ensure that all copies of this form are clear and legible, neatly print all entries with **black ball point pen**, using adequate pressure.

Write only **one** character in each box (number, letter or punctuation mark). Shaded areas should **not** be filled in.

All boxes must be filled. If a specific test is not done, not applicable, etc., this should be appropriately noted in the space provided (e.g., not done = ND, not applicable or not available = NA, unknown = UK specific explanations if required, i.e., sample tube broken, sample hemolized). If a choice is required, please complete the appropriate box with a check mark. **Shaded areas should not be filled in.**

Boxes have been provided for answers of maximum length. If the answer is a number, and the answer is only one digit, e.g. 5, it should be entered as | 0 | 5 |

Similarly, if the birthdate is March 10, 1970, it would be written as:

1	0	0	3	7	0
day		month		year	

An unknown date (e.g., exact day of specific item in **General Medical and Surgical History** module, etc.) should be appropriately indicated. An example is provided below:

		0	3	7	0
day		month		year	

Every error must be crossed out with a single line, initialed and dated. No correction fluid is allowed.

e.g.

X Y Z

~~A B C~~ *JPD 22/04/91*

Do not erase the original information entered into the boxes. The original entry must be legible.

If an entire page must be re-transcribed due to an error, photocopy an identical page and enter the required data. Attach the photocopied page to the original and indicate the reason for the correction on this page.

7. If comments / text are required, please write neatly (preferably in English) using CAPITAL BLOCK letters. Only acknowledged medical terminology should be used, especially in the description of adverse events.

8. If the patient is prematurely discontinued from the study treatment, the end of chemotherapy pages must be completed.

9. If a serious adverse experience occurs, both **BCIRG** Study Medical Coordinator and the Rhône-Poulenc Rorer affiliate Medical Director or Clinical Project Director must be immediately notified by telephone or FAX (within 24 hours working days). If necessary, the patient should be withdrawn from the study and the trial medication stopped.

   The **R-PR Adverse Event (s) Report Form** (appended to the study protocol) must be completed and forwarded to both **BCIRG** Study Medical Coordinator and Rhône-Poulenc Rorer affiliate Representative and Clinical Project Director within 3 days. The information entered on the **Clinical Adverse Experiences** form of the CRF must be consistent with the data recorded on the **R-PR Adverse Event (s) Report Form.**

10. Additional instructions for completing each section of the CRF are provided in the front of the CRF and in the CRF guidelines . If you have further questions, please do not hesitate to contact : **BCIRG** Monitor.

BASELINE

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316				0 0	BASELINE REGISTRATION FORM

INFORMED CONSENT

Date informed consent was obtained from patient : ☐☐ day ☐☐ month ☐☐ year

DATE OF BIRTH / SEX

Date of birth : ☐☐ day ☐☐ month ☐☐ year

Sex : ☐ 1 Male ☐ 2 Female

RACE

☐ 1 Caucasian

☐ 2 Black

☐ 3 Oriental

☐ 5 Hispanic

☐ 4 Other, specify : _____

CHILDBEARING POTENTIAL

Patient is of childbearing potential : ☐ 0 No ☐ 1 Yes

If **YES,** is adequate contraception being practiced ? ☐ 0 No* ☐ 1 Yes

** Patient is **NOT** eligible, adequate contraception should be implemented no hormonal contraception is allowed.*

PREGNANCY TEST (for females of childbearing potential)

To be performed within **2 days prior to registration.**

☐ 1 **Not Applicable**

Date of sample : ☐☐ day ☐☐ month ☐☐ year

Test	Results	
	Negative	Positive*
HCG (Check one only) ☐ Urine ☐ Serum	☐ 0	☐ 1

** Patient is **NOT** eligible*

BREAST CANCER SURGERY AND DIAGNOSIS

Primary tumor type	*BREAST* ☐ Left ☐ Right

SURGERY *(all that apply) specify dates*

	Date (day/month/year)	Most representative specimen used for diagnosis (check only one)
☐ 7 Lumpectomy	: :	☐
☐ 8 Quadrantectomy/Segmental	: :	☐
☐ 9 Mastectomy	: :	☐
☐ 6 Other, specify : _____	: :	☐

Paraffin block available to be sent to Central Operational Office ☐ No* ☐ Yes

HISTOPATHOLOGIC TYPE *(check one)*

☐ 10 Invasive ductal, NOS

☐ 11 Invasive lobular, classic or variants

☐ 12 Invasive special, (includes tubular, medullary, papillary, mucinous/colloid)

☐ 4 Other, specify : _____

HISTOPATHOLOGIC GRADE *(check one)*

☐ **GX :** Differentiation cannot be assessed

☐ **G1 :** Well differentiated

☐ **G2 :** Moderately differentiated

☐ **G3 :** Poorly differentiated / Undifferentiated

MARGINS IN THE DEFINITIVE SPECIMEN

Involved by the tumor

☐ 0 No

☐ 1 Yes, *Patient is NOT eligible.*

AXILLARY NODE DISSECTION

Date : : : (Day / Month / Year)

Number of resected axillary lymph nodes : *(minimum of 6)* ☐☐

Number of positive axillary lymph nodes : *(minimum of 1)* ☐☐

**Patient is NOT eligible.*

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316				0 0	BASELINE REGISTRATION FORM

STAGING AT FIRST DIAGNOSIS

AJCC edition 1992

Estrogen and Progesterone receptors performed on the primary tumor ☐ No* ☐ Yes

pT- Primary Tumor *(Post surgical)*

Size : pT = ☐☐.☐ cm

- ☐ *pTX Primary tumor cannot be assessed
- ☐ *pTO No evidence of primary tumor
- ☐ *pTIS Carcinoma in situ : intraductal carcinoma, or lobular carcinoma in situ, or Paget disease of the nipple with no tumor
- ☐ pT1 Tumor of 2cm or less in its greatest dimension
- ☐ pT2 Tumor more than 2cm but not more than 5cm in its greatest dimension
- ☐ pT3 Tumor more than 5cm in its greatest dimension
- ☐ *pT4 Tumor of any size with direct extension to chest wall or skin

pN- Regional Lymph nodes *(Post surgical)*

- ☐ *pNX Regional lymph nodes cannot be assessed
- ☐ *pNO No regional lymph nodes metastasis
- ☐ pN1 Metastasis to movable ipsilateral axillary node (s)
- ☐ *pN2 Metastasis to ipsilateral axillary lymph node (s) that are fixed to one another or to other structures
- ☐ *pN3 Metastasis to ipsilateral internal mammary lymph node (s)

M- Distant Metastases

- ☐ *MX Presence of distant metastasis cannot be assessed
- ☐ MO No distant metastasis
- ☐ *M1 Distant metastasis (including metastasis to ipsilateral supraclavicular lymph nodes)

Patient is NOT eligible.

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316				0 0	BASELINE REGISTRATION FORM

PATIENT WORKUP

All tests must have been performed within 3 months prior to registration.

Type of evaluation	Not Done	Date assessed (day/month/Year)	Tumor Involvement NO	Tumor Involvement YES
Chest X-Ray (PA and lateral) 10.	☐ 0		☐ 0	☐ 1
Chest CT-Scan 4.	☐ 0		☐ 0	☐ 1
Abdominal Ultrasound 13.	☐ 0		☐ 0	☐ 1
Abdominal CT Scan 5.	☐ 0		☐ 0	☐ 1
Bone Scan (ie. Scintigraphy)# 7.	☐ 0		☐ 0	☐ 1
Bone X-Ray 20.	☐ 0		☐ 0	☐ 1
Contralateral mammography ☐ 29 Left breast ☐ 30 Right breast ☐ 31 Not applicable due to prior mastectomy	☐ 0		☐ 0	☐ 1
Other, specify : _____	☐ 0		☐ 0	☐ 1
Other, specify : 3. _____	☐ 0		☐ 0	☐ 1

Positive Bone Scan should be confirmed by Bone X-Ray.

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316				0 0	BASELINE REGISTRATION FORM

HEMATOLOGY

To be performed **within 14 days prior to registration** and reviewed to evaluate patient eligibility.

Date of sample : day / month / year

Test	Units	Value
Hemoglobin	g/dl	
WBC	10^3/l	
Neutrophils (segs & bands)	10^9/l	
Platelets	10^9/l	

BLOOD CHEMISTRY

To be performed **within 14 days prior to registration** and reviewed to evaluate patient eligibility.

Date of sample : day / month / year

Laboratory Name : _____

Laboratory address : _____

_____

LAB ID N° :

Test	Units		Value	Upper normal range of the institution (same unit as value)
	Recommended	Actual (complete only if differs from recommended)		
Creatinine	µmol/l			
Alkaline Phosphatase	IU/l			
ASAT (SGOT)	IU/l			
ALAT (SGPT)	IU/l			
Total Bilirubin	µmol/l			

CREATININE CLEARANCE

To be completed only if Serum Creatinine > 175 µmol/l (2mg/dl).

☐ Not Applicable Date of sample : day / month / year

Test	Units	Value*
	Recommended	
☐ Calculated	ml/min	
☐ Corrected	ml/min	

**must be ≥ 60 ml/min otherwise patient is NOT eligible.*

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316				0 0	BASELINE REGISTRATION FORM

PERFORMANCE STATUS, WEIGHT, HEIGHT & BSA

To be performed within 7 days prior to registration.

Date of assessment : day / month / year

Performance Status (0 to 100, Karnofsky index) : %

Weight	Height	BSA
kg	cm	m^2

PHYSICAL EXAMINATION

To be performed within 7 days prior to registration.

☐ 0 Not Done Date of assessment : day / month / year

☐ 1 Normal ☐ 2 Abnormal, please specify in Existing Signs and Symptoms form, and fax B.10 for registration

ELECTROCARDIOGRAM

To be performed within 3 months prior to registration.

☐ 0 Not Done Date of assessment : day / month / year

☐ 1 Within normal limits ☐ 3 Non-significant abnormalities.

☐ 2 Significant abnormalities. If abnormalities are present, please specify in Existing Signs and Symptoms form, and fax B.10 for registration.

LEFT VENTRICULAR EJECTION FRACTION

To be performed within 3 months prior to registration.

Date of assessment : day / month / year

☐ 1 Radionuclide angiocardiography (MUGA scan) ☐ 2 Echocardiography

Test	Value	Unit	Lower limit of normal for the institution	Unit
LVEF, at rest ☐ 0 Not Done		%		%
Shortening fraction ☐ 0 Not Done		%		%

OTHER CRITERIA

	No	Yes
1. Prior systemic anticancer therapy for breast cancer (chemotherapy, hormonotherapy, immunotherapy etc.) .	☐ 0	☐ 1
2. Prior anthracycline therapy or taxoids (paclitaxel, docetaxel) for any malignancy.	☐ 0	☐ 1
3. Prior radiation therapy for breast cancer.	☐ 0	☐ 1
4. Bilateral invasive breast cancer.	☐ 0	☐ 1
5. Pre-existing motor or sensory neurotoxicity of a severity ≥ grade 2 by NCI criteria.	☐ 0	☐ 1
6. Other serious illness or medical condition :		
a) Congestive heart failure or unstable angina pectoris, previous history of myocardial infarction within 1 year from study entry, uncontrolled hypertension or high-risk uncontrolled arrhythmias.	☐ 0	☐ 1
b) History of significant neurologic or psychiatric disorders including psychotic disorders, dementia or seizures that would prohibit the understanding and giving of informed consent.	☐ 0	☐ 1
c) Active uncontrolled infection.	☐ 0	☐ 1
d) Active peptic ulcer, unstable diabetes mellitus or other contraindication for the use of corticosteroids.	☐ 0	☐ 1
7. Pregnant or lactating patient.	☐ 0	☐ 1
8. Patient will be accessible for treatment and follow-up at participating center.	☐ 0	☐ 1
9. Definite contraindications for the use of corticosteroids.	☐ 0	☐ 1
10. Treatment with ovarian hormonal replacement therapy at study registration.	☐ 0	☐ 1
11. Concurrent treatment with other experimental drugs, participation in another clinical trial with any investigational not marketed drug within 30 days prior to study entry.	☐ 0	☐ 1
12. Concurrent treatment with any other anticancer therapy.	☐ 0	☐ 1

13. Past or current history of neoplasm : ☐ 0 No ☐ 1 Yes* *(complete E.F.4)*

*Specify : *(Check all that apply)*

☐ 1 Curatively treated non-melanoma skin cancer.

☐ 2 In situ carcinoma of the cervix.

☐ 3 Other cancer curatively treated and with no evidence of disease for at least 10 years.

Previous ductal carcinoma in situ (DCIS) of the breast, specify: ☐ 4 Left breast ☐ 5 Right breast

☐ 6 Previous lobular carcinoma of the breast (LCIS).

☐ 7 Other, specify : _____

14. Chronic corticosteroid treatment : ☐ 0 No ☐ 1 Yes*

*Specify :

☐ 1 Initiated more than 6 months ago **AND** Dosage ≤ 20 mg methylprednisolone (or equivalent).

☐ 2 Other, specify : _____

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316				0 0	BASELINE

GENERAL MEDICAL/SURGICAL HISTORY AND CONCOMITANT CONDITIONS, OTHER THAN CANCER

☐ 0 Check if None

Please enter any significant and relevant medical/surgical history and concomitant medical conditions of the patient other than cancer.

Cardiac history (e.g.: Myocarditis, pericarditis,...) and risk factors (e.g.: obesity, high blood pressure,...) should be accurately documented.

Allergic history should be thoroughly documented (including allergy to polysorbate 80).

Any changes occurring during the study will be documented on the Clinical Adverse Experiences form.

Description	Date Ceased (day/month/year) or indicate if ongoing (Ong)
	☐ Ong 1
	☐ Ong 1
	☐ Ong 1
	☐ Ong 1
	☐ Ong 1
	☐ Ong 1
	☐ Ong 1
	☐ Ong 1
	☐ Ong 1
	☐ Ong 1

EMPLOYMENT STATUS

Check one primary category :

Employed :

☐ 1 Full time

☐ 2 Part time

Non-Employed :

☐ 3 Unemployed

☐ 4 Retired

☐ 5 Other, specify : _____

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316				0 0	BASELINE

MENOPAUSAL STATUS

Date of last menses : ___ ___ (month / year)

Bilateral ovariectomy : ☐ 0 No ☐ 1 Yes Date : ___ ___ ___ (day / month / year)

Hysterectomy : ☐ 0 No ☐ 1 Yes Date : ___ ___ ___ (day / month / year)

Hormonal treatment replacement : ☐ 0 No ☐ 1 Yes

Start date : ___ ___ ___ (day / month / year)

Stop date : ___ ___ ___ (day / month / year)

HORMONAL RECEPTOR STATUS

Test	Estrogen receptors	Progesterone receptors
Biochemical method **Date** (day/month/year) ___ ___ ___ ☐ 0 **Not Done**	☐ 1 Negative ☐ 3 Positive ☐ 4 Not assessable	☐ 1 Negative ☐ 3 Positive ☐ 4 Not assessable
Immunocytochemistry **Date** (day/month/year) ___ ___ ___ ☐ 0 Not Done	☐ 1 Negative ☐ 3 Positive ☐ 4 Not assessable	☐ 1 Negative ☐ 3 Positive ☐ 4 Not assessable

QUALITY OF LIFE QUESTIONNAIRE

To be administered **prior to randomization.**

Quality of life questionnaire collected prior to drug infusion.

QLQ-C 30 : ☐ 0 No ☐ 1 Yes

QLQ-BR 23 : ☐ 0 No ☐ 1 Yes ☐ NA*

*If QLQ-BR 23 is not available in patient's language check box **N.A**

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316				0 0	BASELINE

EXISTING SIGNS AND SYMPTOMS

☐ 0 Check if None

Please describe below any signs and symptoms reported at study entry whether related to previous or ongoing therapies or disease. Any relevant sign and symptom which occurred **in the past two weeks** should also be reported. During the study all ongoing signs and symptoms will be followed on the **Clinical Adverse Experiences** form at the appropriate cycle.

Signs and symptoms (Please report NCI term or the most appropriate medical term when NCI term is not available, i.e., pain, etc...).	**Grade#** (1-4)	**Indicate if Ongoing or Ceased**
Alopecia		☐ 1 Ongoing ☐ 2 Ceased
Nausea		☐ 1 Ongoing ☐ 2 Ceased
Vomiting		☐ 1 Ongoing ☐ 2 Ceased
Diarrhea		☐ 1 Ongoing ☐ 2 Ceased
Stomatitis		☐ 1 Ongoing ☐ 2 Ceased
Pulmonary		☐ 1 Ongoing ☐ 2 Ceased
Neuro-sensory		☐ 1 Ongoing ☐ 2 Ceased
Neuro-motor		☐ 1 Ongoing ☐ 2 Ceased
Cardiac dysrhythmias		☐ 1 Ongoing ☐ 2 Ceased
Cardiac function		☐ 1 Ongoing ☐ 2 Ceased
Cardiac ischemia		☐ 1 Ongoing ☐ 2 Ceased
Cardiac pericardial		☐ 1 Ongoing ☐ 2 Ceased
Skin		☐ 1 Ongoing ☐ 2 Ceased
Peripheral edema#		☐ 1 Ongoing ☐ 2 Ceased
Asthenia#		☐ 1 Ongoing ☐ 2 Ceased
Pain#		☐ 1 Ongoing ☐ 2 Ceased
Amenorrhea# irregular menses ☐ 1 ≥ 3 months ☐ 2		☐ 1 Ongoing ☐ 2 Ceased
		☐ 1 Ongoing ☐ 2 Ceased
		☐ 1 Ongoing ☐ 2 Ceased
		☐ 1 Ongoing ☐ 2 Ceased

If NCI grade is not applicable, code severity as : 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life threatening.

CYCLE N° ____

Section	Page n°
Study drug administration : TAC	C.1
Study drug administration : FAC	C.1
Febrile Neutropenia	C.2
Hematology	C.3
Blood chemistry	C.4
Clinical adverse experiences	C.5 - C.7
In-patient admission during cycle period	C.8
Out-patient care during cycle period	C.9
Performance status & weight Physical examination Employment status Quality of life questionnaire	C.10
Pre-medication, antibiotics, growth factors, transfusions and antimetics	C.11

Project No	Protocol No	Investigator No	Patient Initials	Patie	Visit No	Visit Title
RP 56976	V-316					CYCLE N°

STUDY DRUG ADMINISTRATION : TAC

Not applicable for Cycle 1

Setting ☐1 Out patient clinic ☐2 In patient clinic

Delay : ☐0 No ☐1 Yes

If YES, specify reason :

☐4 Non-Study drug related adverse experience(s).

☐ Study drug related adverse experience(s), specify below :

☐1 Hematological toxicity (including infection, or fever in absence of infection with neutropenia)

☐2 Non-Hematological toxicity.

☐3 Both.

☐5 Other *specify :* _____

Product name	Route	Intended dose (mg/m²)	Total dose given (mg)	Administration Date (day/month/year)	Reduced
☐2 **DOXORUBICIN***	IV				**Reduced :** ☐0 No ☐1 Yes **If YES, specify reason** ☐4 Non-Study drug related adverse experience(s) ☐ Study drug related adverse experience(s), specify below: ☐1 Hematological toxicity (including infection, or fever in absence of infection with neutropenia) ☐2 Non-Hematological toxicity. ☐3 Both. ☐5 Other *specify :* _____
☐3 **CYCLOPHOSPHAMIDE***	IV				**Reduced :** ☐0 No ☐1 Yes **If YES, specify reason** ☐4 Non-Study drug related adverse experience(s) ☐ Study drug related adverse experience(s), specify below: ☐1 Hematological toxicity (including infection, or fever in absence of infection with neutropenia) ☐2 Non-Hematological toxicity. ☐3 Both. ☐5 Other *specify :* _____
☐1 **DOCETAXEL*** (should be administered 1 hour after the end of doxorubucin infusion)	IV				**Reduced :** ☐0 No ☐1 Yes **If YES, specify reason** ☐4 Non-Study drug related adverse experience(s) ☐ Study drug related adverse experience(s), specify below: ☐1 Hematological toxicity (including infection, or fever in absence of infection with neutropenia) ☐2 Non-Hematological toxicity. ☐3 Both. ☐5 Other *specify :* _____

C.1

In case of interruption of drug administration complete (Extra Form, E.F.1)

Project No	Protocol No	Investigator No	Patient Initials	Patie	Visit No	Visit Title
RP 56976	V-316					CYCLE N°

STUDY DRUG ADMINISTRATION : FAC

Not applicable for Cycle 1

Setting ☐1 Out patient clinic ☐2 In patient clinic

Delay : ☐0No ☐1Yes

If YES, specify reason :

☐4 Non-Study drug related adverse experience(s).

☐ Study drug related adverse experience(s), specify below :

☐1 Hematological toxicity (including infection, or fever in absence of infection with neutropenia)

☐2 Non-Hematological toxicity.

☐3 Both.

☐5 Other *specify :* _____

Product name	Route	Intended dose (mg/m²)	Total dose given (mg)	Administration Date (day/month/year)
Reduced : ☐0No ☐1Yes **If YES, specify reason** ☐4 Non-Study drug related adverse experience(s) ☐ Study drug related adverse experience(s), specify below: ☐1 Hematological toxicity (including infection, or fever in absence of infection with neutropenia) ☐2 Non-Hematological toxicity. ☐3 Both. ☐5 Other *specify :* _____				
☐2 **DOXORUBICIN***	**IV**			
Reduced : ☐0No ☐1Yes **If YES, specify reason** ☐4 Non-Study drug related adverse experience(s) ☐ Study drug related adverse experience(s), specify below: ☐1 Hematological toxicity (including infection, or fever in absence of infection with neutropenia) ☐2 Non-Hematological toxicity. ☐3 Both. ☐5 Other *specify :* _____				
☐3 **CYCLOPHOSPHAMIDE***	**IV**			
Reduced : ☐0No ☐1Yes **If YES, specify reason** ☐4 Non-Study drug related adverse experience(s) ☐ Study drug related adverse experience(s), specify below: ☐1 Hematological toxicity (including infection, or fever in absence of infection with neutropenia) ☐2 Non-Hematological toxicity. ☐3 Both. ☐5 Other *specify :* _____				
☐7 **5-FLUOROURACIL***	**IV**			

In case of interruption of drug administration complete (Extra Form, E.F.1)

FEBRILE NEUTROPENIA

Did the patient experience fever **in absence of infection** concomitant with neutropenia? ☐ 0 No, Do not complete below.

☐ 1 Yes

If YES, DO NOT REPORT FEVER IN CLINICAL AE FORM, Report Blood Counts in HEMATOLOGY.

Was IV Antibiotics given ? ☐ 0 No ☐ 1 Yes **Report in pre-medication, growth factors, antibiotics and antiemetics**

Date patient became febrile : ☐☐ day ☐☐ month ☐☐ year Oral temperature : ☐☐.☐ °C

Duration of fever ≥ grade 2# : Start date : ☐☐ day ☐☐ month ☐☐ year Stop date : ☐☐ day ☐☐ month ☐☐ year

Maximum temperature experienced by the patient during the episode : ☐☐.☐ °C

Date patient became afebrile : ☐☐ day ☐☐ month ☐☐ year

Serious	Action Taken Study Medication	Significant Consequences	Relation to Study Medication
☐ 0 No	☐ 0 None	☐ 0 None	☐ 0 None
☐ 1 Yes*	☐ 1 Discontinued**	☐ 1 Hospitalized*	☐ 1 Remote
	☐ 3 Dose reduced	☐ 2 Death***	☐ 2 Possible
	☐ 4 Dose frequency changed		☐ 3 Probable
	☐ 5 Dose reduced and dose frequency changed		

#NCI grading system.
** Complete Serious Adverse Event Form.*
*** Complete End of Chemotherapy Section.*
**** Complete Death Report Form.*

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					CYCLE N°

HEMATOLOGY

Report all blood counts performed during the cycle.

Test	Units Recommended	Date of sample (day/month/year)		Date of sample (day/month/year)		Date of sample (day/month/year)	
		Actual units (complete only if differs from recommended)	Value	Actual units (complete only if differs from recommended)	Value	Actual units (complete only if differs from recommended)	Value
moglobin	g/dl						
WBC	$10^9/l$						
Neutrophils (segs & bands)	$10^9/l$						
Platelets	$10^9/l$						

Test	Units Recommended	Date of sample (day/month/year)		Date of sample (day/month/year)		Date of sample (day/month/year)	
		Actual units (complete only if differs from recommended)	Value	Actual units (complete only if differs from recommended)	Value	Actual units (complete only if differs from recommended)	Value
Hemoglobin	g/dl						
WBC	$10^9/l$						
eutrophils egs & bands)	$10^9/l$						
Platelets	$10^9/l$						

If repeat tests are performed, **Repeat Laboratory Tests, (Extra Form, E.F.5)** should be used. Actual units should be entered.

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					CYCLE N°

BLOOD CHEMISTRY

To be performed at the end of cycle.

☐ Check if Laboratory is the same as **Baseline**, otherwise complete Lab Name and address .

Date of sample : day / month / year

Laboratory Name : _____

Laboratory address : _____

LAB ID N° : _____

Test	Units		Value
	Recommended	Actual (complete only if differs from recommended)	
Creatinine	µmol/l		
Alkaline Phosphatase	IU/l		
ASAT (SGOT)	IU/l		
ALAT (SGPT)	IU/l		
Total Bilirubin	µmol/l		

☐ Check if Laboratory is the same as **Baseline**, otherwise complete Lab Name and address .

Date of sample : day / month / year

Laboratory Name : _____

Laboratory address : _____

LAB ID N° : _____

Test	Units		Value
	Recommended	Actual (complete only if differs from recommended)	
Creatinine	µmol/l		
Alkaline Phosphatase	IU/l		
ASAT (SGOT)	IU/l		
ALAT (SGPT)	IU/l		
Total Bilirubin	µmol/l		

*If repeat tests and/or creatinine clearance measured **Extra Form E.F.6** should be used.*

Project No	Protocol No	Investigator No	Patient Initials	Patie	Visit No	Visit Title
RP 56976	V-316					CYCLE N°

CLINICAL ADVERSE EXPERIENCES

☐ 0 Check if None

Clinical Adverse Experiences	Status of Adverse Experience 1 : Ongoing without any change. *(Do not complete)* New or any change to ongoing 2 : adverse events *(Complete all information)*	NCI Grade (1-4)	Serious 0 : No 1 : Yes *	Date Ceased (day/month/year) Ong = Ongoing Indicate if Ongoing or Ceased prior to next cycle	Action Taken Study Medication 0 : None 1 : Discontinued ** 2 : Interrupted 3 : Dose Reduced 4 : Dose Frequency Changed 5 : Dose Reduced and Dose Frequency changed	Significant Consequences 0 : None 1 : Hospitalized 2 : Death***	Relation to Study Medication 0 : None 1 : Remote 2 : Possible 3 : Probable
Alopecia	[1] [2]			☐ 1 Ongoing ☐ 2 Ceased			
Allergy	[1] [2]			☐ 1 Ongoing ☐ Ceased			
Local toxicity	[1] [2]			☐ 1 Ongoing ☐ 2 Ceased			
Nausea	[1] [2]			☐ 1 Ongoing ☐ 2 Ceased			
Vomiting	[1] [2]			☐ 1 Ongoing ☐ 2 Ceased			
Diarrhea	[1] [2]			☐ 1 Ongoing ☐ 2 Ceased			
Stomatitis	[1] [2]			☐ 1 Ongoing ☐ 2 Ceased			
Pulmonary	[1] [2]			☐ 1 Ongoing ☐ 2 Ceased			
Neuro-sensory	[1] [2]			☐ 1 Ongoing ☐ 2 Ceased			
Neuro-motor	[1] [2]			☐ 1 Ongoing ☐ 2 Ceased			
Cardiac dysrhythmias	[1] [2]			☐ 1 Ongoing ☐ 2 Ceased			
Cardiac function	[1] [2]			☐ 1 Ongoing ☐ 2 Ceased			

* All serious adverse experiences must be reported within 24 hours by phone or fax (cf. protocol) and in writing using the R-PR A.E. form within 3 days in addition to this Clinical Adverse Experience form. ** Complete End of Chemotherapy Section . ***Complete Death Report Form/End of Chemotherapy .

Project No	Protocol No	Investigator No	Patient Initials	Patie	Visit No	Visit Title
RP 56976	V-316					CYCLE N°

CLINICAL ADVERSE EXPERIENCES (continued)

Clinical Adverse Experiences	Status of Adverse Experience 1 : Ongoing without any change. *(Do not complete)* New or any change to ongoing 2 : adverse events *(Complete all information)*	Grade (1-4)	Serious 0 : No 1 : Yes *	Date Ceased (day/month/year) Ong = Ongoing Indicate if Ongoing or Ceased prior to next cycle	Action Taken Study Medication 0 : None 1 : Discontinued ** 2 : Interrupted 3 : Dose Reduced 4 : Dose Frequency Changed 5 : Dose Reduced and Dose Frequency changed	Significant Consequences 0 : None 1 : Hospitalized 2 : Death***	Relation to Study Medication 0 : None 1 : Remote 2 : Possible 3 : Probable
Cardiac ischemia	[1] [2]			[ ]1 Ongoing [ ]2 Ceased			
Cardiac pericardial	[1] [2]			[ ]1 Ongoing [ ] Ceased			
Skin	[1] [2]			[ ]1 Ongoing [ ]2 Ceased			
Nail disorders#	[1] [2]			[ ]1 Ongoing [ ]2 Ceased			
Weight gain#	[1] [2]			[ ]1 Ongoing [ ]2 Ceased			
Peripheral edema#	[1] [2]			[ ]1 Ongoing [ ]2 Ceased			
Asthenia#	[1] [2]			[ ]1 Ongoing [ ]2 Ceased			
Myalgia#	[1] [2]			[ ]1 Ongoing [ ]2 Ceased			
Arthralgia#	[1] [2]			[ ]1 Ongoing [ ]2 Ceased			
Pain#	[1] [2]			[ ]1 Ongoing [ ]2 Ceased			
Amenorrhea# irregular menses [ ]1 ≥ 3 months [ ]2	[1] [2]			[ ]1 Ongoing [ ]2 Ceased			
	[1] [2]			[ ]1 Ongoing [ ]2 Ceased			

If NCI grade is not applicable, code severity as : 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life threatening.

* All serious adverse experiences must be reported within 24 hours by phone or fax (cf. protocol) and in writing using the R-PR A.E. form within 3 days in addition to this Clinical Adverse Experience form. ** Complete End of Chemotherapy Section . ***Complete Death Report Form/End of Chemotherapy .

Project No	Protocol No	Investigator No	Patient Initials	Patie[illegible]	Visit No	Visit [illegible]
RP 56976	V-316					CYCLE N°

CLINICAL ADVERSE EXPERIENCES (continued)

Clinical Adverse Experiences	Status of Adverse Experience 1 : Ongoing without any change. *(Do not complete)* 2 : New or any change to ongoing adverse events *(Complete all information)*	NCI Grade# (1-4)	Serious 0 : No 1 : Yes *	Date of Onset (day/month/year) Ong = Ongoing	Date Ceased (day/month/year) Ong = Ongoing Indicate if Ongoing or Ceased prior to next cycle	Action Taken Study Medication 0 : None 1 : Discontinued ** 2 : Interrupted 3 : Dose Reduced 4 : Dose Frequency Changed 5 : Dose Reduced and Dose Frequency changed	Significant Consequences 0 : None 1 : Hospitalized 2 : Death***	Relation to Study Medication 0 : None 1 : Remote 2 : Possible 3 : Probable
Infection *(specify site)*	1 2			Ong	Ong			
Infection *(specify site)*	1 2			Ong	Ong			
	1 2				Ongoing Ceased			
	1 2				Ongoing Ceased			
	1 2				Ongoing Ceased			
	1 2				Ongoing Ceased			
	1 2				Ongoing Ceased			
	1 2				Ongoing Ceased			
	1 2				Ongoing Ceased			
	1 2				Ongoing Ceased			
	1 2				Ongoing Ceased			
	1 2				Ongoing Ceased			
	1 2				Ongoing Ceased			

If NCI grade is not applicable, code severity as : 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life threatening.

* All serious adverse experiences must be reported within 24 hours by phone or fax (cf. protocol) and in writing using the R-PR A.E. form within 3 days in addition to this Clinical Adverse Experience form. ** Complete End of Chemotherapy Section . ***Complete Death Report Form/End of Chemotherapy .

IN-PATIENT ADMISSION DURING CYCLE PERIOD

Since the last visit , has the patient been admitted for overnight stay to hospital? (excluding emergency room visit) *(see page C.9)* ☐ 0 No ☐ 1 Yes, Complete section below :

Admission/ Transfer Date or Ongoing (day/month/year)	Discharge/ Transfer Date or Ongoing (day/month/year)	Reason for admission	Unit (check one only)
☐ 1 Ongoing	☐ 1 Ongoing	☐ 2 Tumor related Adverse Event ☐ 3 Treatment related Adverse Event ☐ 4 Other specify :	☐ 2 Surgery ☐ 3 Internal medicine ☐ 4 ICU ☐ 6 Other specify:
☐ 1 Ongoing	☐ 1 Ongoing	☐ 2 Tumor related Adverse Event ☐ 3 Treatment related Adverse Event ☐ 4 Other specify :	☐ 2 Surgery ☐ 3 Internal medicine ☐ 4 ICU ☐ 6 Other specify:
☐ 1 Ongoing	☐ 1 Ongoing	☐ 2 Tumor related Adverse Event ☐ 3 Treatment related Adverse Event ☐ 4 Other specify :	☐ 2 Surgery ☐ 3 Internal medicine ☐ 4 ICU ☐ 6 Other specify:

During those hospitalizations, have any major procedures been performed ? ☐ 0 ***Check if None***

☐ 1 Surgery, specify in **Other Procedures form (E.F.7).**

☐ 2 Imaging (CT Scan, MRI), specify in **Other Procedures form (E.F.7).**

☐ 3 Other, specify in **Other Procedures form (E.F.7).**

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					CYCLE N°

OUT-PATIENT CARE DURING CYCLE PERIOD

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) ? ☐ 0 No ☐ 1 Yes, Complete section below :

1. Emergency room (patient was not admitted subsequently) indicate number of emergency room visits : ☐☐ ☐ 1 Not Applicable

2. Physician visits not mandated by study (indicate number of visits) : ☐ 1 Not Applicable

☐ 1 General practitionner : ☐☐

☐ 2 Oncologist/internist : ☐☐

☐ 3 Other : ☐☐ Specify : _____

3. Other health professional visits (indicate number of visits) : ☐ 1 Not Applicable

☐ 2 Nurse : ☐☐ (concomitant medication and care)

☐ 6 Rehabilitation : ☐☐

☐ 7 Physiotherapy : ☐☐

☐ 5 Other : ☐☐ (specify below):

_____

4. Procedures and tests not mandated by study (indicate number of) : ☐ 1 Not Applicable

☐ 1 Transfusions : ☐☐ units

☐ 3 Biopsy : ☐☐ procedures

☐ 2 Laboratory tests : ☐☐ tests

☐ 4 Other : ☐☐ procedures (specify below):

_____

EMPLOYMENT STATUS

Check one primary category :

Employed :

☐ 1 Full time

☐ 2 Part time

Non-Employed :

☐ 3 Unemployed

☐ 4 Retired

☐ 5 Other, specify : _____

TIME LOSSES

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

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

PERFORMANCE STATUS & WEIGHT

To be performed prior to the next cycle (Day 21).

☐₀ Not Done Date of assessment : ___ ___ ___ (day / month / year)

Performance Status (0 to 100, Karnofsky index) : ___ %

Weight : ___ . ___ kg

PHYSICAL EXAMINATION

To be performed prior to the next cycle (Day 21).

☐₀ Not Done Date of assessment : ___ ___ ___ (day / month / year)

Are there any change from previous examination ?

☐₀ No ☐₁ Yes, please specify in Clinical Adverse Experiences form.

QUALITY OF LIFE QUESTIONNAIRE

To be administered at the end of cycle 2, cycle 4 and at the end of last treatment cycle. ☐₁ NA

Quality of life questionnaire collected prior to drug infusion.

QLQ - C 30 : ☐₀ No ☐₁ Yes

QLQ - BR 23 : ☐₀ No ☐₁ Yes ☐ N.A*

*If QLQ-BR 23 is not available in patient's language check box N.A

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					CYCLE N°

PRE-MEDICATION , ANTIBIOTICS, GROWTH FACTORS, TRANSFUSIONS AND ANTIEMETICS

☐ Not Applicable

Product name (1 product per line) (use capital letters)	Route (IV, SC, PO, etc..)	Total daily dose specify units (mg, g, tab, etc..) Dose	Units	Start date (day/month/year) or indicate if ongoing (Ong)	Stop date (day/month/year) or indicate if ongoing (Ong)	Indication for use 11: Treatment of febrile neutropenia 7: Curative or symptomatic. 8: Antiemetic prophylaxis 9: Taxotere steroids prophylaxis 10: Other prophylaxis
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	
				☐ Ong	☐ Ong	

If more medications have to be recorded use (Extra Form E.F.3)

TEAR OFF LABELS

A photocopy of the labels forms must be left in the CRF remaining at the investigator site, the original pages will be brought back to the sponsor.

LABEL FORMS SECTION

(only for taxotere®)

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					CYCLE N°

Please affix below the tear off labels taken from the medication vials used during the cycle.

ATTACH LABEL HERE

ATTACH LABEL HERE

ATTACH LABEL HERE

END OF CHEMOTHERAPY REASON

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					END OF CHEMOTHERAPY

END OF CHEMOTHERAPY REASON

Specify primary reason for the patient's discontinuation from chemotherapy :

☐ 1 Received maximum number of cycles as per protocol

☐ 2 Breast cancer relapse **(Complete Breast Cancer Relapse Section)**

☐ 9 Second primary malignancy **(Insert Second Primary Malignancy Section)**

☐ 10 Adverse experience **(Complete Adverse Event Form)**

☐ 4 Consent withdrawn/refused further treatment, specify reason : _____

☐ 5 Death **(Complete Death Report Form)**

☐ 6 Patient required therapy/procedure not permitted

☐ 11 Other deviation from protocol, specify reason : _____

☐ 7 Lost to follow-up, date of last contact : |__|__| day |__|__| month |__|__|__|__| year

☐ 8 Other, specify : _____

_____

CASE REPORT FORM REVIEW

I have reviewed all data contained in this case report form and verified that the contents are consistent with observations and source records. They accurately reflect the condition of the patient before, during and at the completion of the study.

Investigator's signature : _____ Date : |__|__| day |__|__| month |__|__|__|__| year

ADJUVANT RADIOTHERAPY

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316				1	ADJUVANT RADIOTHERAPY

RADIATION THERAPY AS PER PROTOCOL

Did the patient **receive** radiation therapy ? ☐ 0 No ☐ 1 Yes, *complete below*.

Site (description)		Left / Right	Estimated total dose (specify units)		Start date (day/month/year)	Stop date (day/month/year)
			Dose	Units		
Breast	☐ No ☐ Yes	☐ Left ☐ Right		☐ 3 cGy ☐ 1 Gy ☐ 2 rads		
Boost	☐ No ☐ Yes	☐ Left ☐ Right		☐ 3 cGy ☐ 1 Gy ☐ 2 rads		
Axillary region	☐ No ☐ Yes	☐ Left ☐ Right		☐ 3 cGy ☐ 1 Gy ☐ 2 rads		
Supraclaviculary region	☐ No ☐ Yes	☐ Left ☐ Right		☐ 3 cGy ☐ 1 Gy ☐ 2 rads		
_____		☐ Left ☐ Right		☐ 3 cGy ☐ 1 Gy ☐ 2 rads		

EARLY DISCONTINUATION OF RADIATION THERAPY

☐ 1 Not Applicable

If patient did not complete radiation therapy as scheduled specify reason :

☐ 1 Toxicity (Specify in Follow-up Adverse Event Form E.F.10)

☐ 2 Other, specify : _____

FOLLOW-UP N° [____]

Please complete this form **until disease relapse every 6 months for the first 5 years and then once a year .**

Instructions :

- Concomitant therapy status
- Clinical adverse experiences status

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					FOLLOW-UP

PHYSICAL EXAMINATION AND PATIENT STATUS

Date of assessment : day / month / year

Performance Status (0 to 100, Karnofsky index) : %

Are there any change since previous assessment ? ☐ 0 No ☐ 1 Yes, *specify below*.

☐ 1 Breast cancer relapse (Complete Breast Cancer Relapse Section)

☐ 2 Second primary malignancy (Insert Second Primary Malignancy Section)

☐ 3 Significant cardiac disease (Specify in Follow-up Adverse Event Form)

☐ 4 Other relevant non cancer related abnormality (Specify in Follow-up Adverse Event Form)

☐ 5 Death (Complete Death Report Form)

☐ 6 Lost to follow-up, **Date of last contact :** day / month / year

☐ 7 Other, specify : _____

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					FOLLOW-UP

FOLLOW-UP PATIENT WORKUP

Type of evaluation	Not Done	Date assessed (day/month/Year)	Tumor Involvement NO	Tumor Involvement YES*
Chest X-Ray (PA and lateral)[a] 10.	☐0		☐0	☐1
Abdominal Ultrasound[b] 13.	☐0		☐0	☐1
Abdominal CT Scan[b] 5.	☐0		☐0	☐1
Bone Scan[b] (ie. Scintigraphy)#	☐0		☐0	☐1
Bone X-Ray[b] 20.	☐0		☐0	☐1
Left breast mammography[b] (not applicable if mastectomy) 29. ☐1 N.A	☐0		☐0	☐1
Right breast mammography[b] (not applicable if mastectomy) 30. ☐1 N.A	☐0		☐0	☐1
Other, specify : 3. _____	☐0		☐0	☐1
Other, specify : 3. _____	☐0		☐0	☐1
Other, specify : 3. _____	☐0		☐0	☐1

#Positive Bone Scan should be confirmed by Bone X-Ray.

**If tumor involvement complete* Breast Cancer Relapse Section or Second Primary Malignancy Section.
a : Every 6 months for the first 5 years and then once a year.
b : Once a year .

QUALITY OF LIFE QUESTIONNAIRE

To be administered **at 6,12 and 24 months follow-up visits, after the End of Chemotherapy.** ☐1 NA

QLQ - C 30 : ☐0 No ☐1 Yes

QLQ - BR 23 : ☐0 No ☐1 Yes ☐ N.A*

*If **QLQ-BR 23** is not available in patient's language check box **N.A**

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					FOLLOW-UP

HEMATOLOGY

To be performed every 6 months for the first 5 years and then once a year up to 10 years.

☐ 0 Not Done Date of sample : day / month / year

Test	Units		Value
	Recommended	Actual (complete only if differs from recommended)	
Hemoglobin	g/dl		
WBC	10^9/l		
Neutrophils (segs & bands)	10^9/l		
Platelets	10^9/l		

BLOOD CHEMISTRY

To be performed every 6 months for the first 5 years and then once a year up to 10 years.

☐ Check if Laboratory is the same as Baseline, otherwise complete Lab Name, address and Lab ID.

☐ 0 Not Done

Laboratory Name : _____

Laboratory address : _____

Date of sample : day / month / year

LAB ID N° :

Test	Units		Value
	Recommended	Actual (complete only if differs from recommended)	
Alkaline Phosphatase	IU/l		
ASAT (SGOT)	IU/l		
ALAT (SGPT)	IU/l		
Total Bilirubin	µmol/l		

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					FOLLOW-UP

HORMONOTHERAPY AS PER PROTOCOL

☐ 1 Not Applicable (Progesterone and Estrogen receptor negative).

Drug Name (1 product per line) (use capital letters)	Route	Total Daily Dose		Start date (day/month/year) or indicate if ongoing (Ong)	Stop date (day/month/year) or indicate if ongoing (Ong)
		Dose	Units		
TAMOXIFEN	PO			☐ 1 Ong	☐ 1 Ong
				☐ 1 Ong	☐ 1 Ong
				☐ 1 Ong	☐ 1 Ong

EARLY DISCONTINUATION OF TAMOXIFEN THERAPY

☐ 1 Not Applicable

If the patient did not complete 5 years tamoxifen as per protocol , specify reason :

☐ 1 Breast cancer relapse (Complete Breast Cancer Relapse Section)

☐ 2 Second Primary Malignancy (Insert Second Primary Malignancy Section)

☐ 3 Adverse Event(s) (Specify in Follow-up Adverse Event Form)

☐ 4 Other, specify : _____

CASE REPORT FORM REVIEW

I have reviewed all data contained in this Follow-Up Section and verified that the contents are consistent with observations and source records. They accurately reflect the condition of the patient during the follow-up.

Investigator's signature : _____ Date : ☐☐ day ☐☐ month ☐☐☐☐ year

FOLLOW-UP INSTRUCTIONS

CONCOMITANT THERAPY STATUS

To be completed only for those concomitant medications given for :

- Adverse Experiences related to study drug ongoing at the time of **End of Chemotherapy.**

Attach **Follow-up Concomitant Therapy Form E.F.9** if applicable.

CLINICAL ADVERSE EXPERIENCES STATUS

To be performed only for :

- Ongoing clinical adverse experiences at time of **End of Chemotherapy.**
- Relevant non cancer related signs and symptoms occurring after completion of chemotherapy (i.e. Congestive heart failure, toxicities related to tamoxifen and/or radiation therapy ...).

Attach **Follow-up Clinical Adverse Experiences Form E.F.10** if applicable.

BREAST CANCER RELAPSE SECTION N° |___|

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					BREAST CANCER RELAPSE SECTION

BREAST CANCER RELAPSE
(only before any chemotherapy and/or hormonotherapy for relapse)

Date of relapse : day / month / year

Check all that apply:

☐ Local relapse

- ☐ 1 Scar
- ☐ 2 Ipsilateral breast
- ☐ 3 Ipsilateral anterior chest wall
- ☐ 4 Skin or soft tissue within the local area

Histopathologic or cytological proof obtained : ☐ 0 No ☐ 1 Yes **Date :** day / month / year

☐ Regional relapse

- ☐ 1 Ipsilateral axillary lymph node
- ☐ 2 Ipsilateral internal mammary lymph node
- ☐ 3 Ipsilateral infraclavicular lymph node
- ☐ 4 Skin or soft tissue within the regional area

Histopathologic or cytological proof obtained : ☐ 0 No ☐ 1 Yes **Date :** day / month / year

☐ Distant relapse

- ☐ 1 Ipsilateral supraclavicular lymph node
- ☐ 2 Bone
- ☐ 3 Solitary liver nodule*
- ☐ 4 Multiple liver nodules
- ☐ 5 Solitary lung nodule*
- ☐ 6 Multiple lung nodules
- ☐ 7 Central Nervous System
- ☐ 8 Skin other than specified in local or regional relapse
- ☐ 9 Other distant nodes, specify : _____
- ☐ 10 Other, specify : _____

Histopathologic or cytological proof obtained : ☐ 0 No ☐ 1 Yes **Date :** day / month / year

*Histopathologic or cytological proof is required only for the first relapse .(specimen to be submitted to **CENTRAL OPERATIONAL OFFICE.***

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					BREAST CANCER RELAPSE SECTION

SYSTEMIC THERAPY FOR DISEASE RELAPSE
(first line of chemotherapy, and hormonotherapy)

☐ Check if None

Type of Therapy C : Chemotherapy H : Hormonal therapy I : Immunotherapy O : Other	Regimen/Drug	N° of Cycles for chemotherapy	Start Date and Stop Date (day/month/year)	Response 1 : CR 2 : PR 3 : NC/SD 4 : PD 5 : NE 6 : UK	Date of progression (day/month/year)
C H I O					
C H I O					
C H I O					
C H I O					

If 1st systemic
If 2nd systemic

ABBREVIATED FOLLOW-UP N° ____

After patient has received any chemotherapy and/or hormonotherapy for relapse and/or for occurrence of second primary malignancy.

Section	Page n°
Physical examination, and patient status Central nervous system tumor involvement	Abb.F.U. 1

Instructions :

- Concomitant therapy status
- Clinical adverse experiences status

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					ABBREVIATED FOLLOW-UP

This section should be completed ONLY if any systemic therapy (chemotherapy, hormonotherapy and immunotherapy) has been given (and documented) for breast cancer relapse or for occurrence of a second primary malignancy.

PHYSICAL EXAMINATION, AND PATIENT STATUS

Date of assessment : day / month / year

Are there any change since previous assessment ? ☐ 0 No ☐ 1 Yes, *specify below*.

☐ 1 Second primary malignancy (Insert Second Primary Malignancy Section)

☐ 2 Significant cardiac disease (Specify in Follow-up Adverse Event Form)

☐ 3 Death (Complete Death Report Form)

☐ 4 Lost to follow-up, **Date of last contact :** day / month / year

☐ 5 Other, specify : _____

CENTRAL NERVOUS SYSTEM TUMOR INVOLVEMENT

Did the patient progress in CNS: ☐ 0 No ☐ 1 Yes

If YES, Date of progression : day / month / year

FOLLOW-UP INSTRUCTIONS

CONCOMITANT THERAPY STATUS
To be completed only for those concomitant medications given for : - Adverse Experiences related to study drug ongoing at the time of **End of Chemotherapy.**
.ttach **Follow-up Concomitant Therapy Form E.F.9** if applicable.

CLINICAL ADVERSE EXPERIENCES STATUS
To be performed only for : - Ongoing clinical adverse experiences at time of **End of Chemotherapy.** - Relevant non cancer related signs and symptoms occurring after completion of chemotherapy (i.e. Congestive heart failure, toxicities related to tamoxifen and/or radiation therapy ...).
ttach **Follow-up Clinical Adverse Experiences Form E.F.10** if applicable.

DEATH REPORT FORM SECTION

DEATH REPORT FORM

Date of death : ___ ___ / ___ ___ / ___ ___ (day / month / year)

Was an autopsy performed ? ☐ 0 No ☐ 1 Yes, specify below and attach autopsy report. ☐ 2 Unknown

Site of disease at autopsy (check all that apply)

- ☐ 1 Lungs
- ☐ 2 Liver
- ☐ 3 GI tract
- ☐ 4 Kidney
- ☐ 5 CNS
- ☐ 6 Locoregional
- ☐ 7 Bone
- ☐ 8 No evidence of disease
- ☐ 0 Other, specify : _____

Cause of death (check the most probable cause) :

- ☐ Toxicity due to study chemotherapy (TAC or FAC).(please, specify in AE Form).
  - ☐ 1 Septic
  - ☐ 2 Non septic
- ☐ 3 Toxicity due to chemotherapy given after relapse .
- ☐ 4 Breast cancer
- ☐ 5 Malignant disease, other than breast cancer
- ☐ 6 Other, specify : _____

Investigator's signature : _____ Date : ___ ___ / ___ ___ / ___ ___ (day / month / year)

EXTRA FORMS

SECOND PRIMARY MALIGNANCY SECTION

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					SECOND PRIMARY MALIGNANCY SECTION

SECOND PRIMARY MALIGNANCY

Date of histopathology : ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

Diagnosis :

- ☐ 1 Contralateral breast cancer*
- ☐ 2 Ipsilateral breast cancer*
- ☐ 3 Endometrium cancer
- ☐ 4 Ovarian cancer
- ☐ 5 Leukemia
- ☐ 6 Other cancer, specify : _____

Histopathologic proof obtained : ☐ 0 No ☐ 1 Yes, specify type :

_____

_____

*Paraffin block and/or slides and pathological report from the Second Primary tumor to be submitted to **CENTRAL OPERATIONAL OFFICE.***

FURTHER ANTICANCER THERAPY

☐ 0 Check if None

In case of occurence of a second primary malignancy , if the patient has received any therapy which may affect the tumor, please specify below :

Type of Therapy (C : Chemotherapy, H : Hormonal, I : Immunotherapy, R : Radiotherapy, S : Surgery)	Regimen/Drug	Site/Procedure for radiotherapy, surgery and N° of Cycles for chemotherapy	Start Date and Stop Date (day/month/year)	Response (1 : CR, 2 : PR, 3 : NC/SD, 4 : PD, 5 : NE, 6 : UK)	Date of progression (day/month/year)
C H I R S					
C H I R S					
C H I R S					
C H I R S					

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316				0 0	BASELINE

PRIOR ANTI-TUMOR THERAPY

☐ Check if None If the patient has received any therapy which may affect the tumor, please specify below :

Type of Therapy C : Chemotherapy H : Hormonal I : Immunotherapy R : Radiotherapy S : Surgery	Regimen/Drug	Site/Procedure for radiotherapy and surgery	Start Date (day/month/year)	Stop Date (day/month/year)
C H I R S				
C H I R S				
C H I R S				
C H I R S				
C H I R S				
C H I R S				

SIGNIFICANT PRIOR THERAPY OTHER THAN ANTI-TUMOR

☐ Check if None

Please describe below any **significant** medication and/or therapies received by the patient within 30 days prior to the first study drug infusion.

Product name (1 product per line) (use capital letters)	Route (IV, SC, PO, etc..)	Start date (day/month/year)	Stop date (day/month/year)	Indication for use 5 : Prophylaxis. 7 : Curative or symptomatic.

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					EXTRA FORM

RE-ADMINISTRATION OF STUDY DRUG THERAPY : TAC

Setting ☐ 1 Out patient clinic ☐ 2 In patient clinic

Product name	Route	Total dose given (mg)	Date of Administration (day/month/year)
☐ 2 DOXORUBICIN ☐ 3 CYCLOPHOSPHAMIDE ☐ 1 DOCETAXEL	IV		

RE-ADMINISTRATION OF STUDY DRUG THERAPY : FAC

Setting ☐ 1 Out patient clinic ☐ 2 In patient clinic

Product name	Route	Total dose given (mg)	Date of Administration (day/month/year)
☐ 2 DOXORUBICIN ☐ 3 CYCLOPHOSPHAMIDE ☐ 7 5-FLUOROURACIL	IV		

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					EXTRA FORM CYCLE N°

ELECTROCARDIOGRAM

☐ 0 Not Done Date of assessment : ☐☐ day ☐☐ month ☐☐☐☐ year

☐ 1 Within normal limits ☐ 3 Non-significant abnormalities.

☐ 2 Significant abnormalities. If abnormalities are present, please specify in **Clinical Adverse Experiences** form .

LEFT VENTRICULAR EJECTION FRACTION

☐ 0 Not Done Date of assessment : ☐☐ day ☐☐ month ☐☐☐☐ year

☐ 1 Radionuclide angiocardiography (MUGA scan) ☐ 2 Echocardiography

Test	Value	Unit	Lower limit of normal for the institution	Unit
LVEF, at rest ☐ 0 Not Done		%		%
Shortening fraction ☐ 0 Not Done		%		%

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					EXTRA FORM CYCLE N°

PRE-MEDICATION , ANTIBIOTICS, GROWTH FACTORS, TRANSFUSIONS AND ANTIEMETICS

☐ 0 Check if None

Product name (1 product per line) (use capital letters)	Route (IV, SC, PO, etc..)	Total daily dose specify units (mg, g, tab, etc..) Dose	Units	Start date (day/month/year) or indicate if ongoing (Ong)	Stop date (day/month/year) or indicate if ongoing (Ong)	Indication for use 11: Treatment of febrile neutropenia 7 : Curative or symptomatic. 8 : Antiemetic prophylaxis 9 : Taxotere steroids prophylaxis 10: Other prophylaxis
				☐ 1 Ong	☐ 1 Ong	
				☐ 1 Ong	☐ 1 Ong	
				☐ 1 Ong	☐ 1 Ong	
				☐ 1 Ong	☐ 1 Ong	
				☐ 1 Ong	☐ 1 Ong	
				☐ 1 Ong	☐ 1 Ong	

OTHER CONCOMITANT THERAPY

☐ 0 Check if None

Product name (1 product per line) (use capital letters)	Indicate if Ongoing or Ceased prior to next cycle	Indication for use 5 : Prophylaxis. 7 : Curative or symptomatic.
	☐ 1 Ongoing ☐ 2 Ceased	
	☐ 1 Ongoing ☐ 2 Ceased	
	☐ 1 Ongoing ☐ 2 Ceased	
	☐ 1 Ongoing ☐ 2 Ceased	
	☐ 1 Ongoing ☐ 2 Ceased	
	☐ 1 Ongoing ☐ 2 Ceased	

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					EXTRA FORM

PAST HISTORY OF OTHER NEOPLASM

Diagnosis

Primary Tumor type	Anatomic site of primary cancer	Date of Diagnosis (day/month/year)

Surgery

☐0 Check if None

Date of Surgery (day/month/year)	Operative procedure

Therapy received

☐0 Check if None

Type of therapy C : Chemotherapy H : Hormonal I : Immunotherapy R : Radiotherapy	Regimen/Drug	Site for radiotherapy, and N° of Cycles for chemotherapy	Start Date and Stop Date (day/month/year)
☐ H I R			
C H I R			
C H I R			

Has there been any evidence of disease in the last 10 years ? ☐0 No ☐1 Yes*

**Patient is NOT eligible.*

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					EXTRA FORM

Repeat Laboratory Tests : HEMATOLOGY

Test	Units Recommended	Date of sample (day/month/year)		Date of sample (day/month/year)		Date of sample (day/month/year)	
		Units Actual (complete only if differs from recommended)	Value	Units Actual (complete only if differs from recommended)	Value	Units Actual (complete only if differs from recommended)	Value
Hemoglobin	g/dl						
WBC	10^9/l						
Neutrophils (segs & bands)	10^9/l						
Platelets	10^9/l						

Test	Units Recommended	Date of sample (day/month/year)		Date of sample (day/month/year)		Date of sample (day/month/year)	
		Units Actual (complete only if differs from recommended)	Value	Units Actual (complete only if differs from recommended)	Value	Units Actual (complete only if differs from recommended)	Value
Hemoglobin	g/dl						
WBC	10^9/l						
Neutrophils (segs & bands)	10^9/l						
Platelets	10^9/l						

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					EXTRA FORM

BLOOD CHEMISTRY

☐ Check if Laboratory is the same as **Baseline**, otherwise complete Lab Name and address .

Date of sample : day / month / year

Laboratory Name : _____

Laboratory address : _____

LAB ID N° : _____

Test	Units		Value
	Recommended	Actual (complete only if differs from recommended)	
Creatinine	µmol/l		
Alkaline Phosphatase	IU/l		
ASAT (SGOT)	IU/l		
ALAT (SGPT)	IU/l		
Total Bilirubin	µmol/l		

CREATININE CLEARANCE

To be completed only if Serum Creatinine > 175 µmol/l (2mg/dl).

☐ **Not Applicable** **Date of sample :** day / month / year

Test	Units	Value*
	Recommended	
☐ Calculated	ml/min	
☐ Corrected	ml/min	

**must be ≥ 60 ml/min before administration of study chemotherapy.*

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					EXTRA FORM

OTHER PROCEDURES

Please note any additional assessment whether related to tumor or not e.g. : radiological assessment, ECG, bacteriological examination, myelogram, etc.

Type of procedure	Date assessed (day/month/Year)	Comments * (if applicable)

* 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.

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					EXTRA FORM CYCLE N°

CLINICAL ADVERSE EXPERIENCES

Clinical Adverse Experiences	Status of Adverse Experience 1 : Ongoing without any change. *(Do not complete)* New or any change to ongoing 2 : adverse events *(Complete all information)*	NCI Grade (1 4)	Serious 0 : No 1 : Yes *	Date Ceased (day/month/year) Ong = Ongoing Indicate if Ongoing or Ceased prior to next cycle	Action Taken Study Medication 0 : None 1 : Discontinued ** 2 : Interrupted 3 : Dose Reduced 4 : Dose Frequency Changed 5 : Dose Reduced and Dose Frequency changed	Significant Consequences 0 : None 1 : Hospitalized 2 : Death***	Relation to Study Medication 0 : None 1 : Remote 2 : Possible 3 : Probable
	☐1 ☐2			☐1 Ongoing ☐2 Ceased			
	☐1 ☐2			☐1 Ongoing ☐ Ceased			
	☐1 ☐2			☐1 Ongoing ☐2 Ceased			
	☐1 ☐2			☐1 Ongoing ☐2 Ceased			
	☐1 ☐2			☐1 Ongoing ☐2 Ceased			
	☐1 ☐2			☐1 Ongoing ☐2 Ceased			
	☐1 ☐2			☐1 Ongoing ☐2 Ceased			
	☐1 ☐2			☐1 Ongoing ☐2 Ceased			
	☐1 ☐2			☐1 Ongoing ☐2 Ceased			
	☐1 ☐2			☐1 Ongoing ☐2 Ceased			
	☐1 ☐2			☐1 Ongoing ☐2 Ceased			
	☐1 ☐2			☐1 Ongoing ☐2 Ceased			

* All serious adverse experiences must be reported within 24 hours by phone or fax (cf. protocol) and in writing using the R-PR A.E. form within 3 days in addition to this Clinical Adverse Experience form. ** Complete End of Chemotherapy Section . ***Complete Death Report Form/End of Chemotherapy .

Rhône-Poulenc Rorer Research Development / Breast Cancer International Research Group

E.F.8

Project No	Protocol No	Investigator No	Patient Initials	Patient No	Visit No	Visit Title
RP 56976	V-316					EXTRA FORM FOLLOW-UP N°

CONCOMITANT THERAPY

If drug is PRN, the approximate **Total Daily Dose** must be recorded.

Product name (1 product per line) (use capital letters)	Route (IV, SC, PO, etc..)	Total daily dose specify units (mg, g, tab, etc..)		Start date (day/month/year) or indicate if ongoing (Ong)	Stop date (day/month/year) or indicate if ongoing (Ong)	Indication for use 5 : Prophylaxis. 7 : Curative or symptomatic.
		Dose	Units			
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	
				Ong	Ong	

Project No	Protocol No	Investigator N·	Patient Initials	Patient N·	Visit No	Visit Title	
RP 56976	V-316					☐ F.U ☐ Abb.F.U	EXTRA FORM

FOLLOW-UP CLINICAL ADVERSE EXPERIENCES

To be completed **only for** :

- Ongoing clinical Adverse events at time of end of chemotherapy.
- Relevant non cancer related signs and symptoms occurring after completion of chemotherapy (i.e. congestive heart failure toxicities related to tamoxifen and/or radiation therapy ...)

Clinical Adverse Experiences	Status of Adverse Experience 1 : Ongoing without any change. *(Do not complete)* 2 : New or any change to ongoing adverse events *(Complete all information)* 3 : No longer followed due to new chemotherapy regimen started	Grade (1-4)	Serious 0 : No 1 : Yes *	Date of Onset (day/month/year) Ong = Ongoing	Date Ceased (day/month/year) Ong = Ongoing	Significant Consequences 0 : None 1 : Hospitalized 2 : Death***	Most likely cause 1 : Study chemotherapy 2 : Tamoxifen as per protocol 3 : Radiotherapy as per protocol 4 : Tumor 5 : Other
	1 2 3			Ong	Ong		
	1 2 3			Ong	Ong		
	1 2 3			Ong	Ong		
	1 2 3			Ong	Ong		
	1 2 3			Ong	Ong		
	1 2 3			Ong	Ong		
	1 2 3			Ong	Ong		
	1 2 3			Ong	Ong		
	1 2 3			Ong	Ong		
	1 2 3			Ong	Ong		
	1 2 3			Ong	Ong		
	1 2 3			Ong	Ong		

* All serious adverse experiences occurring within 30 days of the last study drug infusion must be reported within 24 hours by phone or fax (cf. protocol) and in writing using the R-PR A.E. form within 3 days in addition to this Clinical Adverse Experience form. ***Complete Death Report Form.

E.F.10

Project No	Protocol No	Investigator Nc	Patient Initials	Patient N	Visit No	Visit Title
RP 56976	V-316					☐ F.U ☐ Abb.F.U EXTRA FORM

FOLLOW-UP CLINICAL ADVERSE EXPERIENCES (continued)

Clinical Adverse Experiences	Status of Adverse Experience 1 : Ongoing without any change. *(Do not complete)* 2 : New or any change to ongoing adverse events *(Complete all information)* 3 : No longer followed due to new chemotherapy regimen started	Grade (1-4)	Serious 0 : No 1 : Yes *	Date of Onset (day/month/year) Ong = Ongoing	Date Ceased (day/month/year) Ong = Ongoing	Significant Consequences 0 : None 1 : Hospitalized 2 : Death***	Most likely cause 1 : Study chemotherapy 2 : Tamoxifen as per protocol 3 : Radiotherapy as per protocol 4 : Tumor 5 : Other
Cardiac function	1 2 3			Ong	Ong		
Cardiac ischemia	1 2 3			Ong	Ong		
Cardiac pericardial	1 2 3			Ong	Ong		
Weight gain#	1 2 3			Ong	Ong		
Peripheral edema#	1 2 3			Ong	Ong		
Skin	1 2 3			Ong	Ong		
Nail disorders#	1 2 3			Ong	Ong		
Asthenia#	1 2 3			Ong	Ong		
Pain#	1 2 3			Ong	Ong		
Amenorrhea#	1 2 3			Ong	Ong		
	1 2 3			Ong	Ong		
	1 2 3			Ong	Ong		
	1 2 3			Ong	Ong		

If NCI grade is not applicable, code severity as : 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life threatening.

* All serious adverse experiences occurring within 30 days of the last study drug infusion must be reported within 24 hours by phone or fax (cf. protocol) and in writing using the R-PR A.E. form within 3 days in addition to this Clinical Adverse Experience form. ***Complete Death Report Form.

Project No	Protocol No	Investigator No	Patient Initials	Patient No.	Visit No	Visit Title
RP 56976	V-316					ABBREVIATED FOLLOW-UP EXTRA FORM

To be completed if patient develops CHF during follow-up period and inserted in the corresponding abbreviated follow-up section of the CRF.
All CHF have to be reported on a Serious Adverse Event Report Form.

CONGESTIVE HEART FAILURE / ADDITIONAL INFORMATION

Anthracycline/anthracenedione

Did the patient receive anthracycline or anthracenedione since the end of chemotherapy visit ?

☐ 0 **No** ☐ 1 **Yes,** *specify below the cumulative dose since the end of chemotherapy visit :*

Product Name	Cumulative dose mg/m²	Start date (day/month/year)	Stop date (day/month/year)
Doxorubicin			
Epirubicin			
Mitoxantrone			
Other, specify			
Other, specify			

Radiotherapy

Did the patient receive radiotherapy after relapse to the mediastinum and/or left chest wall since adjuvant radiotherapy (if any) ?

☐ 0 **No** ☐ 1 **Yes**

Project No	Protocol No	Investigator No	Patient Initials	Patient No.	Visit No	Visit Title
RP 56976	V-316					EXTRA FORM

CYCLE N° ___ Fu N° ___

ANTI-TUMOR THERAPY

Systemic anti cancer therapy : ___ o Check if None

REGIMEN	Type of Therapy G : Genetherapy H : Hormonal I : Immunotherapy C : Chemotherapy	Trade Name (one drug per line)	Start Date (day/month/year)
1	G H I C		
2	G H I C		

Non-systemic anti cancer therapy : ☐ o Check if None

Type of Therapy R : Radiotherapy S : Surgery	Site/Procedure for radiotherapy and surgery	Start Date (day/month/year)
R S		
R S		

BCIRG

Breast Cancer International Research Group

ALBERTA CANCER BOARD

- Information Request Form (IRF) -

From: ETIENNE DUQUET

To: DR GUASTALLA

Project name / Protocol No.: BP500078_V310

Patient / Subject No.: 13410 Patient / Subject initials: UUU

Investigator name: Guastalla

Investigator No.: FR000270

Date of Request: 21JUN00:16:10:37

Page: of

Page Name	Visit No.	Module(s)	Variable(s)	INFORMATION NEEDED Question	Old value	ANSWER Investigator Reply/Explanation	New value	DM correction required(Y/N)
00	BASELINE	MENOPAUSAL STATUS	FSH/LH	HAS LH AND FSH BEEN MEASURED?		[] YES [] NO		
				IF YES, DO THE VALUES CONFIRM THE POST-MENOPAUSAL STATUS?		[] YES [] NO		

CRA / Monitor signature: _____ Date (dd/mm/yyyy): _____ Investigator's signature: _____ Date (dd/mm/yyyy): _____

This form is not to be separated (except for Sender copy) until the investigator's signature has been obtained.
The form will be separated and distributed to the following:
(Original: BCIRG - CRF file) (Yellow: BCIRG Data Mgmt.) (Green: CRA) (Blue: Investigator CRF file) (Pink: Sender--outstanding request)

RHÔNE-POULENC RORER ADVERSE EVENT(S) REPORT FORM

1. REACTION INFORMATION

PATIENT INITIALS	STUDY CODE / PATIENT N°	COUNTRY	DATE OF BIRTH (DA.MO YR.)	AGE	SEX	REACTION ONSET (DA MO YR.)	CHECK ALL APPROPRIATE TO ADVERSE REACTION
							☐ PATIENT DIED ☐ INVOLVED OR PROLONGED IN PATIENT HOSPITALIZATION ☐ INVOLVED SEVERE OR PERMANENT DISABILITY ☐ LIFE THREATENING ☐ NONE OF THE ABOVE

DESCRIBE REACTION(S)
(Give signs or symptoms, diagnoses, course, underline the main event Include relevant lab data)

2. SUSPECT RPR DRUG INFORMATION

SUSPECT DRUG (Include all information available : Trade name, generic name, form and dosage, batch number. For double blind study, precise if code has been broken.)

DAILY DOSE (with unit)	ROUTE OF ADMINISTRATION
INDICATION FOR USE	
THERAPY DATES (DA.MO.YR.) from to	THERAPY DURATION

DID REACTION ABATE AFTER STOPPING DRUG ?
☐ Yes ☐ No ☐ NA*

DID REACTION REAPPEAR AFTER REINTRODUCTION ?
☐ Yes ☐ No ☐ NA*

*NA : Not Applicable e.g. only 1 dose or irreversible outcome

3. CONCOMITANT DRUG(S) AND HISTORY

CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (Generic names, exclude those used to treat reaction)

OTHER RELEVANT HISTORY (e.g. diagnoses, allergies, pregnancy with last month of period, etc.)

4. REPORTER OR INVESTIGATOR INFORMATION

NAME AND ADDRESS	REPORT SENT TO LOCAL AUTHORITY	CAUSALITY ASSESSMENT (CONCERNING RPR DRUG)	DATE : (DA.MO YR)
	☐ Yes ☐ No DATE (DA.MO YR)	☐ NOT RELATED ☐ REMOTE ☐ POSSIBLE ☐ PROBABLE	SIGNED

5. ADMINISTRATIVE INFORMATION (RESERVED FOR RPR STAFF)

DATE RECEIVED BY MANUFACTURER (DA.MO YR.) TRANSMITTED BY:	AFFILIATE CONTROL NUMBER	M.R.A./PHVIG CONTROL NUMBER	Y	N
		S	☐	☐
		NR	☐	☐
		U	☐	☐

RPR MANUFACTURER

LOCAL ASSESSMENT (if legally required)

DATE OF THE REPORT (DA.MO.YR.)	REPORT TYPE	REPORT SOURCE
	☐ INITIAL ☐ FOLLOW-UP	☐ STUDY ☐ HEALTH PROFES ☐ LITERATURE ☐ CONSUMER

Van Com 09 93