Protocol No Investig	ator No. Patient Patie	Site No.	tient No.	Visit Title ABBREVATED				
	ompleted ONLY if any system	nic therapy (chemotherapy	, hormonother	FOLLOW-UP L				
	s been given and documented							
	PATIE	NT STATUS						
Date of assessment :	day month y	L L L						
Are there any changes s	since previous assessment ?		Yes, specify	below /				
☐ ₁ Breast cancer i	☐ ₁ Breast cancer relapse (Complete Forms B.C.R.1 and B.C.R.2)							
1	y malignancy (Complete form	•						
	liac disease (Specify in form I	E.F.9) or if CHF then comp	lete below CH	F section				
	te Death Report Form)		1 1					
\square_6 Lost to follow-u \square_7 Other, specify:	p, Date of last contact: L	day month yea		Mark 4-14-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-				
	CONGESTIV	E HEART FAILUR						
•	ience congestive heart failure] 1 Yes, fill-in SAE form and							
Anthracycline / A	nthracenedione							
	ve anthracycline or anthracenous of the cut	edione since the end of che imulative dose since the er						
Product Name	Cumulative dose mg/m²	Start date		Stop date				
Doxorubicin		day morth year	day	month year				
		day month year	day	month year				
☐ ₃ Mitoxantrone		day month year	day	month year				
Other specify:		day month year	day	month year				
Radiotherapy								
•	Did the patient receive radiotherapy after relapse to the mediastinum and/or left chest wall since the end of							
	chemotherapy visit other than the adjuvant radiotherapy (if any)? □₀ No □₁ Yes							

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Protocol No BCIRG 005	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title
TAX GMA 301					ADJUVANT RADIOTHERAPY

ADJUVANT RADIOTHERAPY								
Did the patient receive radiation therapy?				d	Please specify the main reason why the patient received radiation therapy: (Select only one.) As per protocol (Breast Conserving Surgery) Institutional Guidelines (Post Mastectomy Radiotherapy) Investigator Decision 4 Patient Request 5 Other, specify If patient received radiation therapy, please complete below.		:t	
Site (description)	Left/I	Right	tot	timated al dose ecify uni Ur	е	Start Date	Stop Date	Stop Reason 1. As planned 2. Toxicity* 3. Other
Breast / Chest Wall	□1 □2	Left Right		□ ₃ □ ₁ □ ₂	cGy Gy rads	day month year	day month year	
Boost _{2.} Breast		Left Right		$ \begin{array}{c} $	cGy Gy rads	day month year	day month year	
Boost Axillary _{3.} Lymph node		Left Right		\square_3 \square_1 \square_2	cGy Gy rads	day month year	day month year	
Axillary region		Left Right		$ \begin{array}{c} \square_3 \\ \square_1 \\ \square_2 \end{array} $	cGy Gy rads	day month year	day month year	
Supraclavicula r region s		Left Right		□3 □1 □2	cGy Gy rads	day month year	day month year	
Internal mammary chain [©]		Left Right		$ \begin{array}{c} \square_3 \\ \square_1 \\ \square_2 \end{array} $	cGy Gy rads	day month year	day month year	
Other, specify:		Left Right		□ ₃ □ ₁ □ ₂	cGy Gy rads	day month year	day month year	
*If toxicity, report on E.F.9 ORIGINAL - BCIRG YELLOW - BCIRG PINK - CRA CARDBOARD - For your records Breast Cancer International Research Group								

BASELINE

DAOLLINL	
	Page No.
PATIENT REGISTRATION FORM AND BASELINE ASSESSMENT PATIENT DATE OF BIRTH / SEX/ INFORMED CONSENT TUMOR SAMPLE SHIPMENT FOR HER2NEU CHILD BEARING POTENTIAL PREGNANCY TEST PERFORMANCE STATUS	B/R.1
BREAST CANCER SURGERY AND DIAGNOSIS	B/R.2
HEMATOLOGY BLOOD CHEMISTRY HORMONAL RECEPTOR STATUS	B/R.3
PATIENT WORKUP	B/R.4
LEFT VENTRICULAR EJECTION FRACTION ELECTROCARDIOGRAM	B/R.5
OTHER CRITERIA	B/R.6
PHYSICAL EXAMINATION WEIGHT, HEIGHT & BSA QUALITY OF LIFE QUESTIONNAIRE MENOPAUSAL STATUS	B.7

CONFIDENTIAL PATIENT DATA

INVESTIGATOR'S NAME:
INVESTIGATOR'S NO.:
BCIRG 005 (TAX GMA 301) A MULTICENTER PHASE III RANDOMIZED TRIAL COMPARING DOCETAXEL IN COMBINATION WITH DOXORUBICIN AND CYCLOPHOSPHAMIDE (TAC) VERSUS DOXORUBICIN AND CYCLOPHOSPHAMIDE FOLLOWED BY DOCETAXEL (AC T) AS ADJUVANT TREATMENT OF OPERABLE BREAST CANCER HER2NEU NEGATIVE PATIENTS WITH POSITIVE AXILLARY LYMPH NODES.
PATIENT INITIALS: First Mid Last
PATIENT NUMBER:
CRA BUSINESS CARD:
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of the proprietor.

It should not be disclosed to any third party, by any means, even in parts, without the previous written agreement

Protocol No BCIRG 005 TAX GMA 301	Investigator No	Patient Initials	Site No.	Patient No.	BASELINE
					REGISTRATION

PLEASE COMPLETE REGISTRATION FORM (Pages B/R.1 to B/R.6) AND FAX TO BCIRG AS PER "SECTION 5.8 - STUDY ENTRY REGISTRATION" SECTION OF THE PROTOCOL

BCIRG 003/ PATIENT REGISTRATION FORW AND BASELINE ASSESSMENT						
Site Information: Principal Investigator's Name / Institution (country):						
Fax Number: country code area code fax number						
Phone Number: country code area code phone number						
Startup date of treatment planned: day month year						
PATIENT DATE OF BIRTH /SEX/ INFORMED CONSENT						
Patient Date of birth:						
Date informed consent was obtained from patient:						
TUMOR SAMPLE SHIPMENT FOR HER2NEU						
HER2Neu sample was sent to Central Lab?						
☐ ₀ No ☐ ₁ Yes If Yes, date specimen was sent: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐						
Date specimen was collected:						
Please specify sample number from originating site lab: No.:						
CHILDBEARING POTENTIAL						
Patient is of childbearing potential:						
If YES, is adequate contraception being practiced?						
If YES, specify contraception method:						
** Patient is NOT eligible if adequate contraception not implemented. Only non hormonal contraception is allowed. Hormonal contraception must be stopped before study entry and report on page E.F.3						
PREGNANCY TEST (For patient of childbearing potential only)						
Not Applicable To be performed within 7 days prior to registration.						
Date of sample: Results: Positive* Negative						
PERFORMANCE STATUS						
To be performed within 14 days prior to registration.						
10 be performed within 14 days prior to registration.						
Date of assessment: Performance Status (0 to 100, Karnofsky index): % day month year						
* Patient is NOT eligible.						
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STAGING AT FIRST DIAGNOSIS AJCC Cancer Staging Manual, 5th Edition 1997 pT- Primary Tumor (Post surgical) *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 2 cm or less in its greatest dimension pT2 Tumor more than 2 cm but not more than 5 cm in its greatest dimension pT3 Tumor more than 5 cm 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 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.

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	BASELINE REGISTRATION
	BREAST CANC	ER SURGI	ERY AND DIA	AGNOSIS	
Primary tum	or type BREAST [] ₁ Left		₂ Right	
SURGERY (check all that apply and specify	dates)			
	antectomy/ Segmental			Date Onth year onth year onth year	
☐ ₃ Masted	etomy		day m	onth year	_
	specify:		day m	onth year	
Other,	specify:		day m	onth year	_
HISTOPATHOLOGIC TYPE (check one)					
	ing Ductal Carcinoma ing Lobular Carcinoma	☐ ₃ Otl	her, specify:		
NUCLEAR	GRADE		(Refer to AJCC Ca	ancer Staging Manual, 5t	h Edition, 1997)
G1: Well	e cannot be assessed Differentiated rately Differentiated		G3: Poorly G4: Undiffe	Differentiated erentiated	
MARGINS I	N THE DEFINITIVE SPECIMEN				
Involved by the	ne tumor or DCIS:		D 1	Yes *	
AXILLARY	LYMPH NODE DISSECTION				
	e Dissection**		mber of positive ax nimum of 1):	illary nodes	
STAGING A	AT FIRST DIAGNOSIS Refe	er to the back of	B/R.1 for a full des	scription of each staging	g category.
pT	pN M	Size:	pT =	cm	
* Patient is NOT e	igible. days allowed from node dissection to re	gistration.			

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Protocol No BCIRG 005 TAX GMA 301	Investiga	ator No.	Patient Initials 	Site	No.	Patient No	BASELINE REGISTRATION	
1700 01111 001			HEMATO	LOGY				
		To be perform	ned within 14 o			tion.		
Date of Sa]				
	day	month	year	Ur	nits			
	Test		Recommended (Comple		Actual te ONLY if differs ecommended)	Value		
Hemoglobin			g/dl					
WBC			10 ⁹ /	I				
Neutrophi	ils (segs & band	ds)	10 ⁹ /	1				
Platelets			10 ⁹ /	l				
BLOOD CHEMISTRY								
		To be perforr	ned within 14 o	days prior t	o registra	tion.		
Date of sample:	Date of sample: Laboratory Name: Laboratory Address:							
			Units				Upper normal limit for the institution (same unit as value)	
Test Recomi		Recommende	Actual (Complete ONLY if differs from recommended)			Value		
Creatinine	9*	μmol/l						
Alkaline F	Phosphatase	IU/I						
ASAT (SC	GOT)	IU/I						
ALAT (SC	SPT)	IU/I						
Total Bilir		μmol/l						
*Complete Creatin	nine Clearance on p	page E.F.6 if the Seru						
		HORMO	DNAL RECE	· · · · · · · · · · · · · · · · · · ·	SIAIUS			
ļ	Test		Estrogen re			Progesterone receptors		
Biochemical me			Positive			☐ ₁ F	Positive	
	Date		Negativ	е			Negative	
day month year Not Done		Not ass	essable/Not l	Done	☐ ₅	Not assessable/Not Done		
Immunohistoch	emistry		Positive				Positive	
	Date	, ,	D 2 Negativ	е			Negative	
day mont Not Done	th year		Not ass	essable/Not	Done	_ 5 1	Not assessable/Not Done	
					1			

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	BASELINE
					REGISTRATION

PATIENT WORKUP							
All tests must have bee	n performed	within 3 months prior to registration.					
Type of Evaluation	Not Done	Date Assessed	Tumor Involvement				
.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			No	Yes*			
Chest X-Ray (PA and lateral)**		day month year	□.	□ ₁			
2. Chest CT-Scan**	□.	day month year	□.	□ ₁			
3. Chest MRI**	□.	day month year	□。	□₁			
4. Abdominal Ultrasound***	□₀	day month year	□。	□₁			
5. Abdominal CT Scan***		day month year	□.	□₁			
6. Abdominal MRI***	口。	day month year	□.				
7. Bone Scan (i.e. Scintingraphy)#	□₀	day month year	□.				
8. Bone X-Ray#		day month year	□。	□ 1			
Contralateral Breast Imaging##	□.	day month year	□.				
Ultrasound □ ₁₅ Left □ ₁₆ Right	□.	day month year	□ 0				
12. Other, specify:	□ o	day month year					
12. Other, specify:	٥	day month year	□ 0	□1			

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^{*} Patient is NOT eligible.

** Chest X-Ray or CT-Scan or MRI is MANDATORY.

*** Abdominal Ultrasound or MRI or CT Scan is MANDATORY.

Bone Scan is MANDATORY. Positive Bone Scan should be confirmed by Bone X-Ray or CT-Scan or MRI to rule out metastatic hot spots on Bone Scan.

Contralateral Breast Imaging is MANDATORY.

Protocol No BCIRG 005	Investigator No.	Patient Initials	Site No.	Patient No.	BASELINE
TAX GMA 301					REGISTRATION

LEFT VENTRICULAR EJECTION FRACTION									
To be	To be performed within 3 months prior to registration.								
Date of assessment: day month year									
LVEF at rest	Value	Unit	Lower normal limit for the institution	Unit					
☐ 1 Radionuclide angiocardiography (MUGA scan)		%		%					
☐ ₂ Echocardiography									

ELECTROCARDIOGRAM
To be performed within 3 months prior to registration.
Date of assessment: day month year
☐ ₁ Within normal Limits
□₃ Non-significant abnormalities
□₂ Significant abnormalities (If present, specify in B9)

BCIR	col No G 005 MA 301		Inv	estigato	or No.			Patient Initials	- 1		Site	No.			Patie	ent No.		1	ELINE TRATION
OTHER CRITERIA																			
Pleas	Please check the appropriate box for each question: No Yes												Yes						
1.	1. Patients will be accessible for treatment and follow-up. Patients registered for this trial must be treated and followed at participating centers which will include principal or co-investigator's sites.																		
2.	2. Prior or current systemic anticancer therapy for breast cancer (immunotherapy, genetherapy, hormonotherapy, chemotherapy).																		
3.	Prior an	thrac	ycline	therap	y, taxo	oids (pac	lita	axel, doce	etax	œl	.) for	any ma	ligr	nancy				\square $_{\circ}$	
4.	Prior rad	diatior	n thera	apy for	breast	cancer.												\Box_{\circ}	
5.	Other so	Con	gestiv		t Failu			able angin	a pe	ecto	ris, pr	evious	hist	ory of	f				□₁
	b)	dem						r psychiat prohibit the									rs,	□ o	□ 1
	c)	activ	ve und	controll	ed infe	ction												\Box 。	□₁
	d)	activ	ve pe	otic ulc	er, uns	table dia	abe	etes melli	tus									$\square_{\mathfrak{o}}$	□₁
6.								uch as ra her for os										□₀	□ 1
7.	 Chronic treatment with corticosteroids unless initiated > 6 months prior to study entry and at low dose (≤ 20 mg methylprednisolone or equivalent). 								□₀	□ 1									
8.	Concurr stopped					n hormo	na	al replace	mer	nt th	erapy	. Treatn	nen	t mus	st be			\Box_{\circ}	
9.	Definite	contr	aindic	ations	for the	use of	coi	rticosteroi	ids.									\square_{\circ}	□₁
10.		ation i	in and	ther cli				ancer ther y investig								30 days			□ ₁
11.	Patient criteria.	has p	re-exi	sting m	otor o	r sensor	y r	neurotoxio	city	of a	seve	rity <u>></u> gr	ade	e 2 by	NCI			□₀	
12.	Patient	is lact	tating															\Box 。	□₁
13.	Past or	curre	nt his	tory of	other n	eoplasn	n:											$\square_{\mathfrak{o}}$	□₁
	If "Yes"	, spec	ify be	low (ch	ieck al	l that ap	ply	y) and co	mpl	ete	form l	E.F.4							
				Curat	ively tr	eated n	on.	-melanom	na s	kin (cance	er.							
				In site	u carci	noma of	th	e cervix.											
				Cano	er cura	atively tre	eat	ted and w	vith i	no e	viden	ice of di	sea	se fo	r at le	east 10	year	S.	
				Ipsila	teral d	uctal cai	cii	noma in s	situ	(DC	IS) of	the bre	ast						
				Lobu	lar card	cinoma d	of t	the breast	t (LC	CIS)	(lpsil	ateral o	C	ontral	atera	l)			
				Othe	r, spec	ify: _													
ORIGINA	L - BCIRG			YEL	LOW - B	CIRG				F	INK - (CRA			CAI	RDBOAF	RD - Fo	or your rec	ords

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PHYSICAL EXAMINATION To be performed within 14 days prior to registration. Date of assessment:	Protocol No BCIRG 005 TAX GMA 301	Investigator No.		Patient Initials	Site No.	Patient No.	BASELINE				
Date of assessment:	PHYSICAL EXAMINATION										
Normal 2 Abnormal, please specify in form B.9		To be	erform	ed within 14 day	s prior to registra	ation.					
Weight Height BSA Record the assessment closest to the first infusion. Date of assessment:	Date of assessme			•	☐ Ahnormal	nlease specify in form	RQ				
Record the assessment closest to the first infusion. Date of assessment:			WFIC			, please speeiny in form	D.0				
Weight Height BSA						usion.					
QUALITY OF LIFE QUESTIONNAIRE QUALITY OF LIFE QUESTIONNAIRE	Date of assessme			year			de de desde con de conse				
QUALITY OF LIFE QUESTIONNAIRE QUALITY OF LIFE QUESTIONNAIRE To be completed within 14 days prior to registration. Date of completion:	We	eight		Height		BSA					
QUALITY OF LIFE QUESTIONNAIRE						L. L.	m²				
Date of completion:	□ 1 ID		ITV (AIDE					
Date of completion:				·-		- (*** d. 14 544 . 74 . 4 . 4 . 4 . 4 . 4 . 4 . 4 . 4					
EORTC QLQ-C30 (version 3.0)	│	To be	complet	ted within 14 day	s prior to registra	ation.					
EURO QOL-5D	Date of completion	dav month									
MENOPAUSAL STATUS (To be completed within 3 months prior to treatment) Date of last menses:	EORTC QLQ-C30	(version 3.0)	₀ No	,	_						
MENOPAUSAL STATUS (To be completed within 3 months prior to treatment) Date of last menses:	EORTC QLQ-BR2	,	•	□ ₁ Ye	s \square_2 N	lot available in patient's la	anguage				
Date of last menses:					 						
Hormonal treatment replacement: □₀ No □₁ Yes Stop Date: □₀ No □₁ Yes Stop Date: □₀ No □₁ Yes Date: □৹ No □₁	ME	ENOPAUSAL S	TAT	US (To be con	npleted within 3 r	months prior to treatmen	t)				
If yes, report hormonal treatment on E.F.3 Bilateral ovariectomy: □₀ No □₁ Yes Date: □₀ Mo □₁ Yes Date: □৹	Date of last mense	es: day month		Vest							
If yes, report hormonal treatment on E.F.3 Bilateral ovariectomy: □₀ No □₁ Yes Date: □□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□	Hormonal treatmer	nt replacement:	₀ No	☐ ₁ Yes	Stop Date:						
Hysterectomy: O No	If yes, report horm					day month	year				
In case of hysterectomy without bilateral ovariectomy in patients ≤ 55 years old, FSH and LH values must be collected, within 3 months prior to registration, in order to determine menopausal status. FSH/LH	Bilateral ovariector	my:	₀ No	☐ ₁ Yes	Date:	day month	year				
within 3 months prior to registration, in order to determine menopausal status. FSH/LH Date of sample: Date of sample:	Hysterectomy:		₀ No	□ ₁ Yes	Date:						
Date of sample: Date of sample:						I and LH values must be c	ollected,				
Test Complete ONLY if differs from recommended Units Units Value Complete ONLY if differs from recommended Units Units Units Value Complete ONLY if differs from recommended Units Un	FSH/LH	☐ ₁ Not Applicable			Laboratory Nam	ne:					
Test Recommended Actual (Complete ONLY if differs from recommended) Value (same as reported units) FSH IU/I Lower Upper LH IU/I IU/I CARDBOARD - For your records	Date of sample:	day month	yea	r I	Laboratory Add	lress:					
Test Recommended (Complete ONLY if differs from recommended) Value FSH IU/I Lower Upper LH IU/I Value Complete ONLY if differs from recommended) Lower Upper LH IU/I Value Complete ONLY if differs from recommended) PINK - CRA CARDBOARD - For your records		U	nits			Postmenopausal In	stitution Limits				
Neconimerated differs from recommended) Lower Upper	Test				Value	(same as repo	rted units)				
FSH IU/I IU/I LH IU/I IU/I ORIGINAL - BCIRG YELLOW - BCIRG PINK - CRA CARDBOARD - For your records		Recommended	differs from			Lower	Upper				
ORIGINAL - BCIRG YELLOW - BCIRG PINK - CRA CARDBOARD - For your records	FSH	IU/I		recommended)							
	LH	IU/I	<u> </u>								
	ORIGINAL - BCIRG					 	r your records				

Protocol No	Investigator No.	Patient	Cito No.		
BCIRG 005		Initials	Site No.	Patient No.	BASELINE
TAX GMA 301					

GENERAL MEDICAL/ SURGICAL HISTORY AND CONCOMITANT CONDITIONS, OTHER THAN CANCER	_
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 cardiac risk factors (eg: obesity, high blood pressure) should be accurately documented.	
All and the first and the first and the first and the first all and the first and the	

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 or indicate if ongoing (Ong)
	day month year 1 Ong
	day month year
	day month year 🔲 1 Ong
	day month year 1 Ong
	day month year
	day month year 1 Ong
	day month year
	day month year

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Protocol No BCIRG 005 TAX GMA 301	I Investigator No I	atient nitials	Site No. Pa	tient No.	BASELINE					
EXISTING SIGNS AND SYMPTOMS										
□ ₀ Check if n	one			· · · · · · · · · · · · · · · · · · ·						
Please describe below any signs and symptoms reported at study entry whether related to previous or ongoing therapies or diseases. 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. Report all Relevant Medications on E.F.3										
	Signs and symptoms (Please report NCI term or the most appropriate medical term when NCI term is not available.) Grade # (1-4) Indicate if Ongoing or Ceased (or specify dates of infection)									
Cardiac Ischemi	a / Infarction				₂ Ceased					
Cardiac Left Ver	ntricular Function				₂ Ceased					
Cardiovascular// (specify:	Arrhythmia - Other)				₂ Ceased					
Dry Skin					₂ Ceased					
Dyspnea			☐ ₁ Ongoing		₂ Ceased					
Fatigue					₂ Ceased					
Irregular Menses	S		☐₁ Ongoing		₂ Ceased					
Lymphatics					₂ Ceased					
Neuropathy-mot	or				₂ Ceased					
Neuropathy-sens	sory				₂ Ceased					
Pericardial Effus	sion / Pericarditis				₂ Ceased					
Peripheral Edem	na#				₂ Ceased					
Pleural Effusion					₂ Ceased					
Infection without	neutropenia (specify site)		day month year	day mon	h year 1 Ongoing					
					₂ Ceased					
					2 Ceased					
					₂ Ceased					
					₂ Ceased					
					2 Ceased					
					2 Ceased					
				······································	2 Ceased					
# If NCI version 2 ORIGINAL - BCIRG	2.0 grade is not applicable, code severit			e, 4= Life threat						

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Protocol No	Investigator No.	Patient Initials	Site No.	Patient	No.	Visit Tit	le
BCIRG 005 TAX GMA 301		i ilidais				BREAST CANCER RELAPSE SECTION	
	D.D.	EASTCA	NCER RELA	ADSE		<u> </u>	
	<u> </u>	EASI CA	NOEN NEL	AFSL			
Date of relapse :	day month	year					
Check all that apply	<i>/</i> :						
Local rela	· <u> </u>						
	Scar						
	psilateral breast	about wall					
	☐ ₃ Ipsilateral anterio		!				
Mandaton, historiat	Skin or soft tissue \Box_4 Skin or soft tissue hologic or cytological pro			Date:			
					day	month	year
☐ Regional	relapse ☐ 1 Ipsilateral axillary	lymph node					
	☐₂ Ipsilateral interna		mph pode				
	-						
Mandatory histopat	\square_4 Skin or soft tissue hologic or cytological pro			Date:	111		1 1
☐ Distant re				day	mont	th year	
	☐₁ lpsilateral suprac	avicular lympl	h node				
	☐ ₂ Contralateral brea	ast cancer*					
	☐ ₃ Solitary Bone Le	sion					
	☐ ₄ Multiple Bone Le	sions					
	☐ 5 Solitary Liver Les	sion*					:
	☐ 6 Multiple Liver Les	ions					
	☐ ₇ Solitary Lung Les	ion*					
	☐ 8 Multiple Lung Les	ions					
	☐ ₉ Central Nervous S	System					
	☐ ₁₀ Skin, other than	specific in loc	al or regional relar	pse			
	☐ ₁₁ Other distant not	les, specify:				<u></u>	
	☐ ₁₂ Other, specify:						
Histopathologic o	r cytological proof obtai	ned: □₀N	o □₁ Yes	Date :	day r	month	year
* Histopathological	or cytological proof is pro	eferred. Spec	cimen to be submit	tted to BCIR	G as per p	orotocol.	
ORIGINAL - BCIRG	YELLOW - BCIR	G	PINK - CR/	Α	CARDBO	OARD - For your re	cords
	Breast	Cancer Inte	rnational Resear	ch Group			

Protocol No	Investigator No.	Patient	Site No.	Patient No.	Visit Title
BCIRG 005		Initials	Oile IVO.		BREAST CANCER
TAX GMA 301					RELAPSE SECTION

ANTI-TUM	OR THERAPY FOR BREA	AST CANCER REI	_APSE
□₀ Check if None	Systemic anti-cancer	therapy:	
Type of Therapy G: Gene therapy H: Hormonal I: Immunotherapy C: Chemotherapy O: Other	Trade Name (one drug per line)	Start Date	Stop Date
G H I C		day month year	day month year
□		day month year	day month year
□。 Check if None	Non-systemic anti-can	cer therapy :	
Type of Therapy R : Radiotherapy S : Surgery	Site/Procedure for radiotherapy and surgery	Start Date	Stop Date
R		day month year	day month year
R S		day month year	day month year

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	Breast Cancer In	ternational Research Grou	р

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		· · · · · ·		1					_								.,						_			
Visit Title CYCLE No		C.10	taxel*	Veer					70], Yes, specify reason :	experience(s),	icity (including utropenia)	al toxicity		d adverse experience(s)									CARDBOARD - For your records		
Patient No.	C → T ARMS	☐ ₂ In patient clinic, fill in page C.10	□ Docetaxel*	day	, Y.1				Docetaxel Dose Reduced	□, No	Study drug related adverse experience(s), specify below:	☐ 1 Hematological toxicity (including infection or febrile neutropenia)	2 Non-Hematological toxicity	☐ ₃ Both	1 Non-Study drug related adverse experience(s)	☐ ₅ Other, Specify:		orile neutropenia)						CARDBOAF		
Site No.	DMINISTRATION FOR TAC AND AC		ohamide*		i.v.			For Cycle 1 DO NOT COMPLETE BELOW.	se Reduced	☐1 Yes, specify reason :	se experience(s),	oxicity (including neutropenia)	gical toxicity		4 Non-Study drug related adverse experience(s)		drug related adverse experience(s), specify below:	Hematological toxicity (including infection or febrile neutropenia)	l toxicity		adverse experience(s)			PINK - CRA	ional Research Group	
Patient Initials	ADMINISTRATIO	S	Cyclophosphamide*	month yes				For Cycle 1 DO NOT	Cyclophosphamide Dose Reduced	N₀	Study drug related adverse experience(s), specify below:	☐ 1 Hematological toxicity (including infection or febrile neutropenia)	Non-Hematological toxicity	□ Both	Uon-Study drug rela	☐ 5 Other, Specify:	Study drug related adverse ex	1 Hematological toxid	☐ 2 Non-Hematological toxicity	☐ 3 Both	₄ Non-Study drug related adverse experience(s)	5 Other, Specify:	form E.F.1		Breast Cancer International Research Group	
Investigator No	STUDY DRUG A	☐ , Out patient clinic	Doxorubicin*	/kep	i.v.				ced	\Box_1 Yes, specify reason :	experience(s),	iicity (including sutropenia)	al toxicity		d adverse experience(s)		Str		y reason :				ug administration, complete	YELLOW - BCIRG		
Protocol No BCIRG 005 TAX GMA 301		Setting	Product name (check appropriate box(es))	Date of Administration	Route	Intended dose (mg/m²)	Total dose given (mg)		Doxorubicin Dose Reduced	0 No	Study drug related adverse experience(s), specify below:	☐ 1 Hematological toxicity (including infection or febrile neutropenia)	D ₂ Non-Hematological toxicity	□ □ Both	4 Non-Study drug related adverse experience(s)	☐ ₅ Other, Specify:		Delay: ∏ ₀ No	☐1 Yes, specify reason :				* In case of interruption of drug administration, complete form E.F.1	ORIGINAL - BCIRG		7000 07 17 0 000

Protocol No BCIRG 005 TAX GMA 301	Investig	ator No.	Patient Initials	Site No	. Patie	ent No.	Visit Title			
			LEMATO	LOCY						
□ Not Done		a tha avala (in al-	HEMATO		Ab		-1.04 (00)-			
Report all blood counts pe after the last infusion of ch			uding day - i or day i	before chemo	therapy infusion of the	e next cycle) and	at 21 to 28 days			
		Date	e of Sample	Date	of Sample	Date of	Sample			
		L L	nonth year	J day m	nonth year	day month	year			
Test	Units Recommende	Actual un	nits Value	Actual un (Complete onl differs from recommende	nits Value	Actual units (Complete only if differs from recommended)	Value			
Hemoglobin	g/di									
WBC	10 ⁹ /l									
Neutrophils (seg & bands)	10 ⁹ /l									
Platelets	10 ⁹ /l									
		Date	e of Sample	Date	of Sample	Date of	Sample			
		L day L n	nonth year	day	nonth year	day month	year			
Test	Units Recommende	Astrolum	nits Value	Actual un (Complete onl differs from recommender	nits Value	Actual units (Complete only if differs from recommended)	Value			
Hemoglobin	g/dl									
WBC	10 ⁹ /I									
Neutrophils (seg & bands)	10 ⁹ /I									
Platelets	10 ⁹ /I									
If repeated tests are perfo	ormed, form E	F.5 should be us	sed.							
□ o Not Done		Е	SLOOD CHE	EMISTR	TRY					
To be performed at the end chemotherapy.	d of cycle wit					fter the last infusi	on of			
Date of sample:	day mor	th year		Laboratory N						
			Units			11				
Test		Recommend	Actual (Complete ONLY in from recommend	fdiffers	Value	Upper norm the inst (same unit	titution			
Creatinine		μ mol/l								
Alkaline Phosphatas	е	IU/I								
ASAT (SGOT)		IU/I								
ALAT (SGPT)		IU/I								
Total Bilirubin		μ mol/l								
If repeated tests and/or cre			ed, form E.F.6 shoul							
ORIGINAL - BCIRG	YE	LLOW - BCIRG Breast C	ancer Internatio	PINK - CRA		RDBOARD - For yo	our records			

Protocol No BCIRG 005 TAX GMA 301	Investigator No	tor No.		Patient Site No.	Patient No		Visit Title CYCLE No
☐ ₀ Check if none		CLIN	IICAL AI	NICAL ADVERSE EXPERIENCES	ICES		
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)	arse anny nny plete) ge to vvents mation)	Serious # 0: No 1: Yes*	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 Study Medication 0: None 1: Remote 2: Possible 3: Probable
Allergic Reaction / Hypersensitivity	10 2			☐ 1 Ongoing ☐2 Ceased			
Alopecia	1 2			☐ , Ongoing ☐ ₂ Ceased			
Arthralgia	1 2			☐ , Ongoing ☐, Ceased			
Cardiac Ischemia / Infarction	1 2			U , Ongoing U , Ceased			
Cardiac Left Ventricular Function	1 2			Ongoing \$\int_2\$ Ceased			
Cardiovascular / Arrhythmia - other specify	1 2			☐ , Ongoing ☐2 Ceased			
Diarrhea	1 2			☐ , Ongoing ☐ ₂ Ceased			
Dyspnea	10 2			☐ , Ongoing ☐ ₂ Ceased			
Fatigue	1 2			☐ 1 Ongoing ☐2 Ceased			
Injection Site Reaction	1 2			☐ 1 Ongoing ☐2 Ceased			
Irregular Menses	1 2			☐ 1 Ongoing ☐2 Ceased			
* All serious adverse experiences must be reported within 24 hours by phone or fax. ** Complete End of Chemotherapy Section. *** Complete Death Report Form/ End of Chemotherapy and SAE form.	es must be reported w y Section. End of Chemotherapy	ਹੁ:₩	phone or fax. NCI version?	r phone or fax. If NCI version 2.0 grade is not applicable, code severity as: 1=Mild, 2=Moderate, 3=Severe,4=Life Threatening. Adverse Experiences not listed should be reported on C.5 or E.F.8	severity as: 1=Mild, 2=Moc ed should be reported on	derate, 3=Severe,4= C.5 or E.F.8	=Life Threatening.

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Protocol No BCIRG 005 TAX GMA 301	호 - -	Investigator No.	_	Patient Initials	ent Site No. 	o. Patient No.		Visit Title CYCLE No
☐ ₀ Check if none		•	SIS	SAL AD	NICAL ADVERSE EXPERIENCES	ENCES		
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	Status of Adverse Experience Ongoing without any nange (Do not complete) New or any change to ongoing adverse events (Complete all information)	Grade# (1-4)	Serious 0: No 1: Yes*	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
Myalgia	<u>_</u>	2			☐ 1 Ongoing ☐2 Ceased	pe		
Nail Changes		2□			☐ 1 Ongoing □2 Ceased	pe		
Nausea		2			☐ 1 Ongoing ☐2 Ceased	pə		
Neuropathy-Motor	<u></u>	2			☐ 1 Ongoing ☐2 Ceased	pə		
Neuropathy-Sensory		2			☐ 1 Ongoing ☐2 Ceased	pa		
Pericardial Effusion / Pericarditis	1	2			☐ 1 Ongoing ☐2 Ceased	pa		
Peripheral Edema	1	2			☐ 1 Ongoing ☐2 Ceased	pa		
Pleural Effusion	_ _	2			☐ 1 Ongoing ☐2 Ceased	pa		
Rash/ Desquamation		2			\square , Ongoing \square_2 Ceased	pe		
Stomatitis / Pharyngitis		2			☐ 1 Ongoing ☐ ₂ Ceased	ра		
Vomiting		2			☐ 1 Ongoing ☐ ₂ Ceased	pa		
* All serious adverse experiences must be reported within 24 hours by phone or fax. ** Complete End of Chemotherapy Section. *** Complete Death Report Form/ End of Chemotherapy and SAE form.	ses must be rep py Section. / End of Chemot	oorted within 24 b	# <u>P</u>	one or fax. Cl version 2	.0 grade is not applicable, o	phone or fax. If NCI version 2.0 grade is not applicable, code severity as: 1=Mild, 2=Moderate, 3=Severe,4=Life Threatening. Adverse Experiences not listed should be reported on C.5 or E.F.8	derate, 3=Severe,4= C.5 or E.F.8	=Life Threatening.

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	1 [Т					,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,									
Visit Title CYCLE No			Relation to Study Medication 0: None 1: Remote 2: Possible 3: Probable												=Life Threatening.	
			Significant Consequences 0: None 1: Hospitalized* 2: Death***												lerate, 3=Severe,4: C.5 or E.F.8	
Patient No) LEG	CES	Action Taken Study Medication 0: None 1: Discontinued** 2: Interrupted 3: Dose Reduced 4: Dose Frequency Changed 5: Dose Reduced and Dose Frequency Changed												severity as: 1=Mild, 2=Moc	
Site No.	NICAL ADVEDSE EXBEDIENCES		Indicate if Ongoing or Ceased prior to next cycle	ongoing 02 Ceased	ongoing	ongoing	1 Ongoing []2 Ceased	1 Ongoing 1 Ceased	1 Ongoing \square_2 Ceased	ongoing	1 Ongoing 7 Ceased	ongoing	ongoing \square_2 Ceased	ongoing	riphone or fax. If NCI version 2.0 grade is not applicable, code severity as: 1=Mild, 2=Moderate, 3=Severe,4=Life Threatening. Adverse Experiences not listed should be reported on C.5 or E.F.8	
Patient Initials	NUV IV.	אַר אַנ אַר אַנ	Serious II 0: No 1: Yes*												phone or fax. f NCI version 2.0 g Adv	
			Grade# (1-4)												# و	,
Investigator No.			Status of Adverse Experience 1: Ongoing without any change (Do not complete) 2: New or any change to ongoing adverse events (Complete all information)	2	2	2	2	2	2	2	2	2	2	2	oorted within 24 therapy and SAE	
			Status c Expe Expe 1: Ongoing v change (Do 2: New or an ongoing a (Complete	Ē	<u> </u>	Ĺ	Ţ		1	1					ces must be rep py Section. End of Chemo	
Protocol No BCIRG 005 TAX GMA 301	Chack if none	- 1	Clinical Adverse Experiences	Weight Gain	Weight Loss										* All serious adverse experiences must be reported within 24 hours by ** Complete End of Chemotherapy Section. # I *** Complete Death Report Form/ End of Chemotherapy and SAE form.	

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Visit Title CYCLE No		Significant Study Consequences Medication O: None I: Remote I: Remote I: Remote I: Remote I: Remote I: Remote I: Pospitalized* 2: Death***										Threatening.
Patient No.	(pen	Medication None Signature O: None Signature O: None Signature Sig										3=Severe,4=Life Threatening.
Site No.	EXPERIENCES (continued)	Indicate if Ongoing or Ceased (provide date when applicable)	☐, Ongoing ☐, Ceased	day month year	Asymptotic Month of the control of t		day month year	day month year ongoing day month year ongoing	day month year day month year	day month year day month year day month year day month year day month year day month year day month year day month year		
ratient Initials	ADVERSE EXP	Date of Onset (for infection and fever)		day month year	day month year		day month year					
©.	CLINICAL /	Serious * 0: No 1: Yes*									is not appl	is not appl
Investigator No	CLIF	Grade (1-4)#							3 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		2.0 grade in 24 hours	3
Inve		Status of Adverse Experience 1: Ongoing without any change (Do not complete) 2: New or any change to ongoing adverse events (Complete all information)] 2 [] 2] 2		2 2 2	2 2 2	2 2	2 2
		Statu: Ex Ex Cy 1: Ongoir change (l 2: New or ongoing a	_		, 						1	1
Protocol No BCIRG 005 TAX GMA 301	☐ Check if None	Clinical Adverse Experiences	Febrile Neutropenia (where Neutropenia is defined as AGC/ANC <1.0 x 109/L)	Fever≥ 38.5 °C	Fever in the absence of neutropenia (where Neutropenia is defined as AGC/ANC <1.0 x 10 /L)	Catheter-related Infection	appenty such	Infection with unknown ANC (specify site)	Infection with unknown ANC (specify site) Infection without neutropenia (where Neutropenia is defined as AGC/ANC <1.0 x 10 %L) specify site)	Infection with unknown ANC (specify site) Infection without autropenia (where Neutropenia (where Neutropenia is defined as AGC/ANC <1.0 x 10 ⁹ /L) specify site) Infection (documented clinically or microbiologically) with grade 3 or 4 neutropenia (specify site)	Infection with unknown ANC (specify site) Infection with unknown ANC (specify site) Infection without eeutropenia (where all the contropenia (where all the complete End of Chemotherapy and SAE form. * All serious adverse experiences must be reported within 24 hours by phone or fax.** ** Complete End of Chemotherapy Section.**	Infection with unknown ANC (specify site) Infection without where veutropenia (where veutropenia is defined as AGC/ANC <1.0 x 10 ⁹ /L) specify site) Infection (documented clinically or microbiologically) with grade 3 or 4 neutropenia (specify site) * All serious adverse experi* Complete End of Chemoth* Complete Death Report For ARIGINAL - BCIRG

······································							
Protocol No	Investigator N	o.	Patient Initials	Site	No.	Patient No.	Visit Title
BCIRG 005 TAX GMA 301					- 1		CYCLE №
		 	······································				
□ ₀ Not done	e PEF	RFORMAN	ICE ST	ATUS 8	& WE	IGHT	
To be performed price chemotherapy.	or to the next cycle (day -1 o	r day 1 before che	emotherapy i	nfusion of the	next cycle	e) and at 21 to 28 days after	er the last infusion of
	Date of assess	sment:	lay mo	onth	year		
Performance S	tatus (0 to 100, Karnofsł	(y index):	9	%			
		Weight:		_	□₁	lb □ ₂ kg	
O Not done	!	PHYSIC	AL EX	AMINA	TION		
To be performed prior	or to the next cycle (day -1 o	or day 1 of the nex	kt cycle) and	at 21 to 28 da	ys after th	e last infusion of chemothe	erapy.
If there are any	y changes since the las opriate.		assessmei these char	da		month year Adverse Experiences	form
7.00	QU	ALITY OF	LIFE	QUESTI	ONNA	AIRE	
To be completed	d: Day -1 to Day 1 for C Day -1 to Day 1 for C End of Chemotherap	ycle 4 ycle 7 of the AC		And the second of the second o		1 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
☐ ₁ Not Applic	able Date o	f completion:	day	month	<u> Ј</u>	year	
Quality of life qu	uestionnaire completed	I.					
EORTC QLQ-C	30 (version 3.0)	□ ₀ No	\square_1	Yes	\square_2	Not available in patie	nt's language
EORTC QLQ-BI	R23 (version 1.0)	□ ₀ No	\square_1	Yes	\square_2	Not available in patie	nt's language
EURO QOL-5D		□ ₀ No	□₁	Yes	\square_2	Not available in patie	nt's language
· · · · · · · · · · · · · · · · · · ·	The state of the s						

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Protocol No BCIRG 005 TAX GMA 301	Investigate	or No.		Patient Initials	Site No		Patient No.	Visit Title
	CANT CONC E-MEDICATION, A							
□₀ Check if None	If drug	is PRN, t	he appr	oximate Tota	l Daily Dose n	nust be re	ecorded.	
Product Name (1 product per line) (use capital letters) (Trade Name)	Route (I.V., SC, PO, etc)	Total and daily specify (mg, getco	dose / units g, tab,		t date e if ongoing	or in	Stop date dicate if ongoing	Indication for use 1: Treatment of febrile neutropenia 2: Curative or symptomatic 3: Antiemetic prophylaxis 4: Taxotere steroid prophylaxis 5: Prophylaxis 6: Other
				day month	year ngoing	day	month year Ongoing	j
				day month	year ngoing	day	month year	
				day month	year ngoing	day	month year Ongoing	
				day month	year	day	month year Ongoing	J
				day month	year ngoing	day	month year Ongoing	
				day month	year ngoing	day	month year Ongoing	
				day month	year ngoing	day	month year Ongoing	
				day month	year Ingoing	day	month year Ongoing	
				day month	year	day	month year Ongoing	
If required, use form E.F.3 Record use of Bisphosphonal agents is NOT PERMITTED as ORIGINAL - BCIRG			otective a	gents such as C			in this module, howev	
			ancer li		Research Gr		,	

Protocol No	· Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title
BCIRG 005		I I I		1 1 1 1 1	0,015,10
TAX GMA 301		<u> </u>] []		CYCLE Nº[]

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)? Out-patient (including emergency room visits) O
Emergency room (patient was not admitted subsequently). Indicate number of emergency room visits:
2. Physician visits not mandated by study (indicate number of visits): ☐₁ Not Applicable
☐ 1 General practitioner:
Oncologist/ Internist:
☐ ₃ Other: Specify:
3. Other health professional visits (indicate number of visits): □₁ Not Applicable
☐ ₁ Nurse: ☐ ₃ Rehabilitation: ☐ (concomitant medication and care)
Physiotherapy:
4. During this cycle period, have any major procedures or tests been performed?
□ ₀ No
Yes, please complete form E.F.7 or E.F.2 if applicable.

Protocol No BCIRG 005	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title
TAX GMA 301					CYCLE №

IN-PATIENT ADMISSION DURING CYCLE PERIOD								
Since the last visit, has the patient been admitted for overnight stay to hospital (excluding emergency room visit)?								
□ 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)					
☐ Ongoing	Ongoing	Chemotherapy treatment Tumor related Adverse Event** Treatment related Adverse Event** Other, specify**:	Surgery 1 Internal Medicine 3 ICU 4 Other, specify:					
☐ Ongoing	Ongoing	Chemotherapy treatment Tumor related Adverse Event** Treatment related Adverse Event** Other, specify**:	Surgery					
☐ ₁ Ongoing	Ongoing	Chemotherapy treatment Tumor related Adverse Event** Treatment related Adverse Event** Other, specify**:	Surgery 1 2 Internal Medicine 3 ICU 4 Other, specify:					
During those hospitalization	ns, have any major procedure	s been performed?						
	□ ₀ No							
Table 1 Yes, please fill-in form E.F.7or E.F.2 if applicable.								
*When a patient is transferred from one unit to another one (e.g. from surgery to internal medicine). **Complete an SAE form and fax it to the BCIRG Safety Manager.								
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Protocol No BCIRG 005	Investigator No.				Patient Initials		Site No.			Patient No.			Visit Title			
TAX GMA 301						L			L							DEATH REPORT FORM

DEATH REPORT FORM
Date of death : day month year
Was an autopsy performed? □ 0 No □ 1 Yes, specify below and attach autopsy report
Site of disease at autopsy (check all that apply):
□ ₁ Lungs
□ ₂ Liver
□ ₃ Gl tract
□ ₄ Kidney
□ ₅ CNS
□ ₆ Local regional
□ ₇ Bone
☐ 8 No evidence of disease
Other, specify:
Cause of death (check the most probable cause):
Toxicity due to study treatment. (Please specify in AE form).
□ ₁ Septic
☐ ₂ Non septic
\prod_3 Toxicity due to anti-cancer treatment given after relapse or second primary malignancy.
☐ ₄ Breast cancer
☐ ₅ Malignant disease, other than breast cancer
Other, specify:
Investigator's signature : Date : Date :

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Protocol No BCIRG 005	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title
TAX GMA 301					CYCLE

Please enter the appropriate information from the medication (Taxotere, Cyclophosphamide, Doxorubicin and Solvents - Chemotherapy only) vials used during the cycle.

Medication Name	# of Vials	Cycle Number	Lot or Batch Number	Expiry Date
				day month year
				day month year
				day month year
				day month year
				day month year
				day month year
				day month year
		,		day month year
	:			day month year
				day month year
				day month year
				day month year
				day month year
				day month year
				day month year

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title END OF CHEMOTHERAPY
		1			

	END OF CHEMOTHERAPY REASON							
Specify	y primary reason for the patient's discontinuation from chemotherapy:							
1	Received maximum number of cycles as per protocol*							
2	Breast cancer relapse (Complete forms B.C.R.1 and B.C.R.2)							
3	Second primary malignancy (Complete form S.P.M.F.1)							
4	Adverse experience (Complete forms C.3, C.4, C.5 and C.6)							
5	Consent withdrawn / refused further treatment, specify reason:							
6	Death (Complete Death Report Form)							
7	Patient required therapy and / or procedure not permitted							
8	Other deviation from protocol, specify reason:							
9	Lost to follow-up, date of last contact: day month year							
10	Other, specify:							
· · · · · ·								

CASE REPORT FORM REVIEW								
I have reviewed all data contained in this case report form and verified the observations and source records. They accurately reflect the condition of at the end of chemotherapy.								
Investigator's signature:	Date: day month year							

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^{*}TAC arm: 6 cycles of TAC. AC \rightarrow T arm: 4 cycles of AC followed by 4 cycles of T

Protocol No BCIRG 005 TAX GMA 301	Investigat	or No. Patient Initials	ite No.	Patient N	No.	Visit Title EXTRA FORM			
BASELINE CYCLE No. F.U. No.									
		ANTI-TUMOR	THE	ERAPY					
☐ o Check if No	ne	Systemic anti-ca	ncer tl	nerapy :					
Type of The G: Gene therap H: Hormonal I: Immunothera C: Chemotheral O: Other	у	Trade Name (one drug per line)	Start	Date	Stop Date				
ППП С Н П О	c			day month	year	day	month year		
G H I	c				year	day	month year		
□ Check if No	one	Non-systemic and	ti-cand	cer therapy	' :				
Type of The R : Radiotherapy S : Surgery		Site/Procedure for radiotherap surgery	Start	Date	Stop Date				
R 🗌	s 🗌			day month	year	day	month year		
R 🗌	s 🗌			day month	year	day	month year		

ORIGINAL - BCIRG	YELLOW - BCIRG	PINK - CRA	CARDBOARD - For your records
	Breast Cancer In	ternational Research Grou	up

Protocol No BCIRG 005	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title EXTRA FORM
TAX GMA 301					CYCLE No.

RE-ADMINISTRATI	ON OF S	TUDY DRUG THE	RAPY: TAC AND AC → T
Setting	☐ ₁ Out p	patient clinic] In patient clinic, complete page C.10
Product name	Route	Total dose given (mg) after Interruption	Date of Administration
Doxorubicin	IV		day month year
☐ ₃ Cyclophosphamide	iV		day month year
☐ ₁ Docetaxel	IV		day month year

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	Breast Cancer Int	ernational Research Group	

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials Site	No.	Patient No.	Visit Title EXTRA FOR							
BASELINE	CYCLE No.	F.U. No.		ABB. FU No.								
□ ₀ Not Do	one ELE	CTROCARDIOGI	RAM									
Date of assessment: day month year												
□₁ W	fithin normal limits □3	Non-Significant abnorm	alities									
□₂ Si	gnificant abnormalities. If abnorm	alities are present, please	e specify in f	orm B.9, C.4, C.5 or	E.F.9.							
□ ₀ Not Do	one LEFT VENTRI	CULAR EJECTION	ON FRA	CTION								
	Date of asse	essment:	month	Vear								
LVEF at rest Value Unit Lower normal limit for the institution Unit												
(MUG	nuclide angiocardiography A scan) rdiography		%		%							
	Date of asse		month	year								
	LVEF at rest	Value	Unit	Lower normal lim for the institution	I IInit							
(MUG	nuclide angiocardiography A scan) irdiography	L.L.	%	L.L.								
	Date of asse		month	year								
	LVEF at rest	Value	Unit	Lower normal lim for the institution	i iinit							
(MUG	(MUGA scan)											
ORIGINAL - BCIRO	☐ 2 Echocardiography											

Version 3: July 16, 2001

Protocol No					Patient		I		
BCIRG 005 TAX GMA 301		nvestigat	tor No.		Initials	Site No.		Patient No.	Visit Title EXTRA FORM
BASELINE		CYCL	E No.		F.U. N	o. [,	ABB. FU No.	
SIGNIFIC	CANT	CONC	COMIT	TANT	THERAF	Y OTHE	R TH	AN ANTI-TUN	/IOR
	lf :	drug is F	RN, the	approxii	mate Total Da	ily Dose must	be rec	orded.	
Product Name (1 product per line (use capital letters (Trade Name)	oer line) I letters) Jame) (I.V., SC, PO, etc) specify units (mg, g, tab, etc)		dose y units g, tab,		t date	or ii	Stop date	Indication for use 1: Treatment of febrile neutropenia 2: Curative or symptomatic 3: Antiemetic prophylaxis 4: Taxotere steroid prophylaxis 5: Prophylaxis 6: Other	
					day month	ngoing	day	month year Ongoing	
					day month	year ngoing	day	nonth year Ongoing	
					day month	year ngoing	day	month year Ongoing	
					day month	year ngoing	day	nonth year] 1 Ongoing	
					day month	year ngoing	day	month year]	
					day month	year ngoing	day [] Ongoing	
					day month	year			
					oay month 1 Or		day	nonth year Ongoing	
					day month 1 Or	ngoing	day	ongoing year	
					day month	year ngoing	day	month year Ongoing	
ORIGINAL - BCIRG	YELL	OW - BCIF	*******		PINK - C	······································		L RDBOARD - For your reco	ords
		B	reast Ca	ıncer In	ternational F	Research Gro	gue		1

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Protocol No BCIRG 005 TAX GMA 301	stigator No.	Patient Initials	iite No.	Patient N	۱o.	Visit Title EXTRA FORM BASELINE					
	AST OR	CURRENT HIS	STOR	Y OF NE	OPLASM						
Diagnosis											
Anatomic site of primary	tumor type	Histologi	cal type	Э	Dat	te of Dia	jnosis				
			,		day	month	year				
					day	month	year				
Has there been any evid	ence of diseas	e in the last 10 years	? 🔲 。	No □₁ Ye	es* 🔲 ₂ N.A.	(Diagnos	is within 10 years)				
* Patient is not eligible.					d Advantage to the second of t		<u></u>				
	ANTI-TU	MOR THERA	PY F	OR NEO	PLASM						
□₀ Check if None		Systemic anti-ca	ncer ti	herapy :							
Type of Therapy G: Gene therapy H: Hormonal I: Immunotherapy C: Chemotherapy O: Other		Trade Name (one drug per line)			t Date	ξ	itop Date				
G H I C				day month	year	day	month year				
G H I C	l			day month	year	day	month year				
□₀ Check if None		Non-systemic an	ti-can	cer therapy	/ :						
Type of Therapy R: Radiotherapy S: Surgery	Site/Pro	cedure for radiothera surgery	py and	Star	t Date	S	itop Date				
R S				day month	year	day	month year				
R S				day month	year	day	month year				
ORIGINAL - BCIRG YELLOW - BCIRG PINK - CRA CARDBOARD - For your records Breast Cancer International Research Group											

	Protocol No BCIRG 005 TAX GMA 301	 Inve	estiga 	ator I	No.			Pati Initi	 	Sit	e No	o. 			Pa	atien	t No.	1		Visit Title EXTRA FORM
***************************************	BASELINE		CYC	LEN	—— ۷o.								F.U.	No	. <u>L</u>] ,	ABB.	F.l	U. No

	····	F	IEMATOL	.OGY			P INC. VIVI
		Date of	Sample	Date of	Sample	Date of	Sample
		day month	year	day month	year	day month	year
Test	Units Recommended	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 /I						
Neutrophils (seg & bands)	10 ⁹ /l						
Platelets	10 ⁹ /l						
		Date of	Sample	Date of	Sample	Date of	Sample
Test	Units Recommended	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						
Neutrophils (seg & bands)	10 ⁹ /l						
Platelets	10 ⁹ /I						
		Date of	Sample	Date of	Sample	Date of	Sample
		day month	year	day month	year	day month	year
Test	Units Recommended	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						
Neutrophils (seg & bands)	10 ⁹ /l						***************************************
Platelets	10 ⁹ /l						

ORIGINAL - BCIRG	YELLOW - BCIRG	PINK - CRA	CARDBOARD - For your records
	Breast Cancer Int	ternational Research Group	

Protocol No BCIRG 005 TAX GMA 301	Investigat	or No.			Patient Initials		Site	No.		Patie	nt No.	Visit Title EXTRA FORM
						-						
BASELINE	☐ CYCL	E No.							. No.		ABB.F	.U. No.
□ ₀ Not Do	ne		В	LC	OD CH	IEM	ST	RY				
Date of sam	ole: day mor	th y	ear	J				ory Name: ory Addres	s:			
				Un	its		T					
To	Recom	mend	ed	Actual (Complete ONL) from recomm	Y if differs		Value			the i	ormal limit for nstitution unit as value)	
Creatinine		μ m	ol/l									
Alkaline Phos	ohatase	11	J/I									
ASAT (SGOT)		IL	J/I									
ALAT (SGPT)		R	JA									
Total Bilirubin		μ m	ol/l									
Date of sample: Laboratory Name: Laboratory Address:												
				Un	its						Unner no	ormal limit for
Te	est	Recom	ommended		Actual (Complete ONLY if differs from recommended)			Valı	ue		the i	nstitution unit as value)
Creatinine		μm	ol/l									
Alkaline Phosp	ohatase	11	JA									
ASAT (SGOT)		IL	J/I									
ALAT (SGPT)		IL	J/I									
Total Bilirubin		μm	ol/l									
□ ₀ Not Do	one	(CRE	AT	ININE (CLE	AR	ANCE		***	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
	To be	e complet	ed on	ly if S	Serum Crea	atinine	is >	140 μm	iol/l (1.6mg/	dl).	
Date of sam	ple: day	month		year								
	Test Units Recommended Value											
Using Cod	ıla)			ml/m	iin							
		ml/min										
ORIGINAL - BCIRO	S YI	ELLOW - BO					VK - (CAF	RDBOARD - F	or your records
		Brea	ast Ca	ance	r Internati	onal F	Rese	earch Gr	oup			

Protocol No BCIRG 005 TAX GMA 301	Patient Initials	Site No.	Patient No. Visit Tit		
BASELINE CYCLE No.		F.U.	No. ABB.F	.U. No	
	OTHER PRO	CEDURES	***************************************		
Please note any additional as	sessment whether re	elated to tumor or no	ot e.g.: imaging, cultures	s, etc.	
a: Procedure (enter the appropriate number)					
1= Cultures 2= Imaging 3= Puncture/ Drainage 4= Biopsy 5= Surgery 6= Test 7= Other, specify procedure b: Description	Date as	ssessed	Comme (if applica		
a					
ba	day month	year			
b	day month	year			
a b	day month	J J year			
a		1 1 1 1 1			
b	day month	year	**************************************		
ab	day month	year			
ab	day month	J L J year			
a		yea			
b	day month	year			
a [] b	day month	J J year			
a		t 1 1 t 1 1	4.		
b	day month	year			
a		,, , , , ,			
<u>b</u>	day month	year year			
ab	day month	year			
ab	day month	year			
a	Gay Month	ува	***************************************		
b	day month	year			
ORIGINAL - BCIRG YELLOW - B	DIRG	PINK - CRA	CARDBOARD - Fo	or your records	

Visit Title Patient No. EXTRA FORM CYCLE № C	(5:3)	Medication O: None T: Discontinued** Significant Study Consequences O: None T: Discontinued** Significant Study Study O: None O: None T: Prostile T: Prost	rcyChanged 2: Death*** Reduced and Dose cy Changed											1=Mild, 2=Moderate, 3=Severe,4=Life Threatening.	CARDBOARD - For your records	
Site No.	EXPERIENCES (CYCLES	Date Ceased (for infection only) 1: Indicate if Ongoing 3: Or Ceased 4		day month year	day month year Ongoing	day month year Ongoing	day monh year Ongoing	day month Ongoing	☐1 Ongoing ☐2 Ceased	☐1 Ongoing ☐2 Ceased	☐, Ongoing ☐, Ceased	☐, Ongoing ☐, Ceased	Ongoing D Ceased	İ	PINK - CRA	Research Group
Patient Initials	ADVERSE EXPER	Date of Onset (for infection and fever)		day month year Ongoing	day month year Ongoing	day month year Ongoing	day month year Ongoing	day month Ongoing						by phone or fax. # If NCI version 2.0 grade is not applicable, code severity as:	C	st Cancer International Research Group
	CLINICAL AL	Serious* 0: No 1: Yes*	3													Breast
Investigator No.	SIS	Grade# (1-4)				Ω 8 4								in 24 hour 1 SAE form 9 / L	- BCIRG	
Inve		Status of Adverse Experience 1: Ongoing without any change (Do not complete) 2: New or any change to	ongoing adverse events (Complete all information)	2 🗌	2	2	2	2	2	2	2	2	2	ie reported with iemotherapy and ANC < 1.0 X 10	YELLOW - BCIRG	
		Status of Advers Experience 1: Ongoing without any change (Do not comple	ongoing adverse events (Complete all informatio	1	Ō	_	<u>_</u>	_	1	_t	<u>_</u>	1		ences must the ready Section m/ End of Change as AGC//		
Protocol No BCIRG 005 TAX GMA 301		Clinical Adverse Experiences		Fever (in the absence of neutropenia, where neutropenia is defined as AGC< 1.0X10 ⁹ L)	Catheter-related Infection (specify site)	Infection with unknown ANC (specify site)	Infection without neutropenia**** (specify site)	Infection (documented clinically or microbiologically) with grade 3 or 4 neutropenia (specify site)						* All serious adverse experiences must be reported within 24 hours by phone or fax. ** Complete End of Chemotherapy Section. *** Complete Death Report Form' End of Chemotherapy and SAE form. ***Where Neutropenia is defined as AGC/ANC < 1.0 X 10 ⁹ / L	ORIGINAL - BCIRG	

Protocol No BCIRG 005 TAX GMA 301	Investigator No.		Patient Initials	s Site No.	Patient No.	Visit Title EXTRA FORM F.U. No.	KM J. No.
	TO CT	INICAL	ADVERSE	EXPERIENCES	(FOLLOW-UP)		
To be completed only for:			or probabi ymptoms o related to	Ongoing clinical Adverse events possibly or probably related to study drug 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).	f chemotherapy. apy.		
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.	Se Grade# (1-4) 0: 1	Serious 0: No 1: Yes*	Date of Onset (day/monthyear) Ong=Ongoing	Date Ceased (day/month/year) Ong=Ongoing	Significant 1: Consequences 2 0: None 3 1: Hospitalized* 3 2: Death** 4 5: 5:	Most Likely Cause 1: Study chemotherapy 2: Tamoxilen as per profocol 3: Radiotherapy as per profocol 4: Umor 5: Other
	1 2 3 3			day month year	day monh year		
	1 2 3			day month year	day month year		
	1 2 3			day month year	day month year		
	1 2 3			day month year	day month year		
	1 2 3			day month year	day month year		
	1 0 2 0 3 0			day month year	day month year 0ng		
	1 2 3			day month year 0ng	day month year Ong		
	1 2 3			day month year ong	day month year 0ng		
	1 2 3			asy month year ong	day month ong		
	1 2 3 3			day month year	day month year Ong		
	1 2 3			day month year	day month year		-
* All serious adverse expe	# If NCI version 2.0 grade is not applicable, cc. * All serious adverse experiences must be reported within 24 hours by phone or fax. ** Complete Death Report Form and SAE form.	ade is not ap nin 24 hours by	plicable, phone or fa	ode severity as: 1=Mild, *** Report Deta	2=Moderate, 3=Severe, 4=Life Threatening lis in E.F.10	atening.	
ORIGINAL - BCIRG	YELLC	YELLOW - BCIRG		PINK - CRA		CARDBOARD - For your records	scords
		ш	3reast Ca	Breast Cancer International Research Group	Group		
Version 3: July 16, 2001				E.F.9			

Protocol No	Invest	igator No.	Patient	1	Site No.	De	itient No.	Visit T	1
BCIRG 005	, , ,		Initials	٠, ١,	Sile No.		ilient No.		
TAX GMA 301								F.U. No.	لللا
		nt develops CHF at	any time a	after the E	nd of Chemot	herapy vis	it and inserted		
into the corresp									
All CHF must b	e reported on	a Serious Adverse	Event Re	port Form	•	-			
		CONG	ESTIVE	HEA	RT FAILU	RE			
Anthra	cycline / A	nthracenedion	ie						
Did the	patient receiv	e anthracycline or	anthracene	edione sin	ce the end of	chemothe	erapy visit ?		
□ ₀ N	o [] ₁ Yes, specify be	elow the cu	ımulative	dose since the	end of c	hemotherapy v	isit:	
Product	Name	Cumulative of	dose		Start date		Sto	p date	
1 Todaci	IVANIC	mg/m²					0.0	,p date	· · · · · · · · · · · · · · · · · · ·
☐ ₁ Doxor	ubicin		· · ·	day	month	year	day mont	n ye	ear
☐ ₂ Epirub	icin		·····	day	month	year	day mont	n ye	ear
☐ ₃ Mitoxa	ntrone			day	month	year	day mont	n ye	ear
Other	specify:			day	month	year	day mont	h ye	ваг
Other	specify:			day	month	year	day mont	h ye	ear
Radiot	herapy								
Did the pa	tient receive r	adiotherapy to the	mediastinu	m and/or	left chest wall	since the	end of chemot	herapy	
		ant radiotherapy (if							
□ ₀ No	\square_1	Yes							
			,,,,,,						

Protocol No BCIRG 005 TAX GMA 301		Investigator No.	Patient Initials	Site No.	Patient No.		t Title A FORM
BASELINE		CYCLE No.		F.U.	No.		
			PATIENT	MAGING			
		Refer to pa	ages B/R.4 or F.U.3	3 for appropriate term	minology.	т	
		Type of evaluation		Date	Assessed		mor ement
	*************************************					No	Yes*
				day month	year	□。	□₁
				day month	year year	□°	
				day month	year	□。	
				day month	year	□₀	
				day month	year	По	
				day month	year year	□°	
				day month	year	По	
				day month	year	□₀	
				day month	year	Оο	
				day month	year	По	□₁
				day month	n year	Пο	□₁
				day mont/	n year	□₀	□₁
1 3 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1						**************************************	

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	Breast Cancer Inte	ernational Research Group	

Protocol No BCIRG 005 TAX GMA 301	Investigato	r No. Patient Initials	Site No.	Patio	ent No.	Visit Title SECOND PRIMARY MALIGNANCY SECTION				
		SECOND PRIM	ARY MAL	IGNANC	Υ					
Histopatholoç	Date of occurrence: Diagnosis: Primary breast cancer * Left 2 Right A Ovarian cancer Leukemia Other cancer, specify: 7 Non-melanoma skin cancer Right Carcinoma in situ of the cervix Histopathologic proof obtained: Date of histopathology: Date of histopathology: Send Block to BCIRG.									
Send Block to BCIRG.										
* If Ipsilateral to the primary tumor and same histology, please fill in only the breast cancer relapse form.										
ANTI-TUMOR THERAPY FOR SECOND PRIMARY MALIGNANCY										
□₀ Crieck	General Check if None Systemic anti-cancer therapy:									
Type of Therapy G: Gene therapy H: Hormonal I: Immunotherapy C: Chemotherapy O: Other		Trade Name (one drug per line)	Start Da	ate	Stop Date				
G H				day month	year	day month year				
□ □ [G H				day month	year	day month year				
□。 Check	k if None	Non-systemic	c anti-cance	er therapy :						
Type of Therapy R: Radiotherapy S: Surgery Site/Procedure for radiotherapy and surgery				Start Date		Stop Date				
R 🗌	s 🗌			day month	уваг	day month year				
R 🗌	s 🗌			day month	year	day month year				
ORIGINAL - BCIF	RG Y	ELLOW - BCIRG Breast Cancer Intel		(- CRA		DBOARD - For your records				

Protocol No BCIRG 005	Investigator No.	Patient Initials	Site No.	Patient No.	FOLLOW-UP SUMMARY					
TAX GMA 301										
	PHYSICAL EXAMINATION AND PATIENT STATUS									
To be performed as per protocol follow-up flowchart (see CRF guidelines). To be completed yearly and sent to CIRG Edmonton Office suite 1100, 9925-109th Street Edmonton, Alberta, CANADA T5K 2J8										
Date of follow	day month	year	☐ Not Done	Follow-up numbe	er					
	/ changes since previous asses ast cancer relapse (Complete f			es, specify below:						
□₂ Sed	cond primary malignancy (Comp	olete form S.P.N	/l.F.1)							
	☐ 5 Death (Complete death report form)									
☐ 6 Los	st to follow-up. Date of last co	ontact:								
	er, specify:		mortus	year						
Date of follow	dav month	vear	☐ Not Done	Follow-up numb	er					
	y changes since previous asset			es, specify below:						
	ast cancer relapse (Complete fo		•							
	ond primary malignancy (Comp		<i>I</i> I.F.1)							
	th (Complete death report form			1 1 1						
	t to follow-up. Date of last co	ontact: day	month	year						
□ ₇ Oth	er, specify:									
Date of follow Are there an	<i>y</i> -up visit: dav month y changes since previous asses	vear	□ Not Done	Follow-up num	ber					
•	ast cancer relapse (Complete fo		· · · · · · · · · · · · · · · · · · ·	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,						
	ond primary malignancy (Comp		•							
	th (Complete death report form		•							
	t to follow-up. Date of last co									
	er, specify:	day	month	year						
Date of follow	/-up visit:		☐ Not Done	Follow-up num	ber					
Are there an	y changes since previous asses	ssment?		es, specify below:						
	ast cancer relapse (Complete fo		-	co, opean, polon.						
	ond primary malignancy (Comp		•							
	th (Complete death report form		,							
	t to follow-up. Date of last co									
	er, specify:	day	month	year						
Ongoing Adverse	events possibly or probably related	to study drug, to	dicities related to hormo	onotherapy or radiotherapy	y have to be					
ORIGINAL - BCIR		CARDBO	ARD - For your records							
	Breast Ca	ancer Internati	onal Research Gro	oup						

Protocol No BCIRG 005 TAX GMA 301	r No.	Patient Initials	Site No.	Pati	ent No.		LOW-UP MBER
НО	RMONOTI	HERAPY	AS PER PRO	TOCOL			
Not Done (at the investigated Not Applicable (Progester	tor's discretion	or if patient h	as previously stopp				
Product Name (1 product per line) (use capital letters)	Start or indicate		going	Early Disc Hormon	ontinuati notherap		
TAMOXIFEN	day month	year	dey month Ongoing	1 BCR 3 AE 4 other	2 S	SPM	
	day month	•	day month Ongoing	year	☐ 1 BCR ☐ 3 AE ☐ 4 other_	₂ S	SPM
* BCR = Breast Cancer Relapse (Complete AE = Adverse Events (specify in form El	te forms BCR1 and F9)	BCR2), SPM = :	Second Primary Maligna	ancy (comple	ete form SPMF1),	
□₀ Not Done		V-UP PAT	IENT IMAGIN	G			
Town of a subsetion			_			1	mor
Type of evaluation		Not Done	Date	Assessed	l	No	/ement Yes*
Left Breast Imaging ^c	1	□0	day month		rear	o	,
Right Breast Imaging ^c		<u> </u>	dey month	y	ear	□ 0	ı
12. Other, specify:		3 0	day month		year	□₀	□₁
12. Other, specify:		3 0	day month		year	□₀	□₁
12. Other, specify:		13 0	day month		year	По	
c: Once a year for 10 years.							·
* If tumor involvement com	plete Breast Cance	r Relapse Sectio	n or Second Primary Ma	ilignancy Se	ection.		
	CASE RI	EPORT F	ORM REVIEV	٧		· · · · · · · · · · · · · · · · · · ·	
I have reviewed all data cont with observations and source follow-up. Investigator's signature:	ained in this foll e records. They	llow-up section accurately re	n and verified that to	he conten	its are consis ient during	tent	
mireaugator a algitature.				day	month	yea	
ORIGINAL - BCIRG YELLO	OW - BCIRG	CARDB	OARD - For your record	ls			
	Breast Cano	cer Internation	nal Research Groun	`			