Patient Background Form (Form B) **B**

PROTCOL PATIENT ID	INSTITUTIONAL Pt. ID	TREATING PHYSICIAN	DATE FORM COMPLETED
D O X I L -			MM DD YYYY 2 0

◆ DISEASE INFORMATION

[1] Kind of Ovarian Cancer

1 ☐ Epithelial ovarian cancer 2 ☐ Primary fallopian tube cancer 3 ☐ Peritoneal cancer

[2] Time to Progression

1 ☐ < 6 months 2 ☐ ≧ 6 months

[3] Date of Diagnosis for Progression

m d 2 0 y

[4] Measurable or Non-Measurable lesion

1 ☐ Yes 2 ☐ No → Fill in [5] Criteria for Progressive Disease of CA-125.

[5] Criteria for Progressive Disease of CA-125*

1 ☐ A 2 ☐ B 3 ☐ C

* **Please refer 3.2 "Progression criteria of CA-125" on page 4 in the protocol.**

◆ CANCER THERAPY FOR OVARIAN CANCER

[1] Cytoreductive Surgery

1 ☐ No 2 ☐ Yes → Fill in SURGICAL REPORT on Form S.

[2] Prior Chemotherapy

	End date
1. _____	m d 2 0 y
2. _____	m d 2 0 y
3. _____	m d 2 0 y

[3] Others

1 ☐ No 2 ☐ Yes, treatment: _____ End date: m d 2 0 y

◆ NON-INVASIVE DIAGNOSTIC PROCEDURES -within 28 days before patient registration-

1	ECG	1 ☐ Not Done 2 ☐ Normal 88 ☐ Abnormal, specify: _____	Date of ECG m d 2 0 y
2	Chest X-Ray	1 ☐ Not Done 2 ☐ Normal 88 ☐ Abnormal, specify: _____	Date of Chest X-Ray m d 2 0 y
3	Other, specify: _____	2 ☐ Normal 88 ☐ Abnormal, specify: _____	Procedure Date m d 2 0 y

◆ MEDICAL HISTORY

[1] Previous or current diseases other than primary cancer	[2] Current disease?	[3] Treatment for current disease ?
1. _____	1 ☐ No 2 ☐ Yes →	1 ☐ No 2 ☐ Yes
2. _____	1 ☐ No 2 ☐ Yes →	1 ☐ No 2 ☐ Yes
3. _____	1 ☐ No 2 ☐ Yes →	1 ☐ No 2 ☐ Yes
4. _____	1 ☐ No 2 ☐ Yes →	1 ☐ No 2 ☐ Yes
5. _____	1 ☐ No 2 ☐ Yes →	1 ☐ No 2 ☐ Yes

Surgical Form (Form S) S

PROTCOL PATIENT ID	INSTITUTIONAL Pt. ID	TREATING PHYSICIAN	DATE FORM COMPLETED
D O X I L -			MM DD YYYY 2 0

◆ SURGICAL REPORT

・Please record the detail of cytoreductive surgery.

[1] Date of Surgery

m d y

[2] Kind of Surgery (select one)

1 ☐ Primary debulking surgery
2 ☐ Interval debulking surgery (IDS)

[3] Operative procedure Performed

1 ☐ Radical hysterectomy
2 ☐ Semiradical hysterectomy
3 ☐ Total hysterectomy
4 ☐ Partial hysterectomy
5 ☐ Bilateral Salpingo-Oophorectomy
6 ☐ Unilateral Salpingo-Oophorectomy
7 ☐ Pelvic node sampling/dissection
8 ☐ Para-aortic node sampling/dissection
9 ☐ Omentectomy
88 ☐ Other, specify below ↓ [ ]

[4] FIGO stage

1 ☐ 1A 2 ☐ 1B 3 ☐ 1C( )( ) 4 ☐ 2A 5 ☐ 2B 6 ☐ 2C( )( )
7 ☐ 3A 8 ☐ 3B 9 ☐ 3C 10 ☐ 4 11 ☐ Not applicable

[5] pTNM

T ( ) N ( ) M ( )

[6] Histologic type (select one)

Carcinomas

104 ☐ Clear cell carcinoma
105 ☐ Endmetrioid adenocarcinoma
106 ☐ Mixed epithelial carcinoma
107 ☐ Mucinous adenocarcinoma
108 ☐ Serous adenocaricinoma
112 ☐ Undifferentiated carcinoma
88 ☐ Other, specify: _____

[7] Residual Disease 1 ☐ < 1cm 2 ☐ ≧ 1cm

[8] Ascites 1 ☐ No 2 ☐ Yes

[9] Cytology of Ascitic Fluids 1 ☐ Negative 2 ☐ Suspicious 3 ☐ Positive 4 ☐ Not Done 5 ☐ Unavailable

◆ COMMENTS

Pre-Treatment Summary Form (Form P) P1

PROTCOL PATIENT ID	INSTITUTIONAL Pt. ID	TREATING PHYSICIAN	DATE FORM COMPLETED
DOXIL-			MM DD YYYY 20

◆ BASELINE FINDINGS

Please record the current abnormal physical findings before administration.

No.	[1] CTCAE Version 3.0	[2] Grade (0-4)	[3] Additional Information
1	WBC ↓	0 1 2 3 4	Date: / /20
2	ANC ↓	0 1 2 3 4	Date: / /20
3	Hemoglobin ↓	0 1 2 3 4	Date: / /20
4	Platelets ↓	0 1 2 3 4	Date: / /20
5	ALP ↑	0 1 2 3 4	Date: / /20
6	Albumin ↓	0 1 2 3 -	Date: / /20
7	Bilirubin ↑	0 1 2 3 4	Date: / /20
8	ALT/SGPT ↑	0 1 2 3 4	Date: / /20
9	AST/SGOT ↑	0 1 2 3 4	Date: / /20
10	Creatinine ↑	0 1 2 3 4	Date: / /20
11	Na ↑	0 1 2 3 4	Date: / /20
12	Na ↓	0 1 - 3 4	Date: / /20
13	K ↑	0 1 2 3 4	Date: / /20
14	K ↓	0 1 - 3 4	Date: / /20
15	Proteinurea	0 1 2 3 4	Date: / /20
16	Fever	0 1 2 3 4	
17	Anorexia	0 1 2 3 4	
18	Nausea	0 1 2 3 4	
19	Vomiting	0 1 2 3 4	
20	Diarrhea	0 1 2 3 4	
21	Stomatitis (clinical exam)	0 1 2 3 4	
22	Stomatitis (functional/symptomatic)	0 1 2 3 4	
23	*Stomatitis (Please select WHO Grade)*	※ WHO Grade 0 1 2 3 4	
24	Rash/Hand-foot skin reaction	0 1 2 3 -	
25	Fatigue	0 1 2 3 4	
26	Hair loss/alopecia	0 1 2 - -	
27	Cytokine release syndorome / acute infusion reaction		
28	other ( )	0 1 2 3 4	
29	other ( )	0 1 2 3 4	
30	other ( )	0 1 2 3 4	

※ Please record "other" colum if any abnormal physical findings before administration of Doxil

Pre-Treatment Summary Form (Form P) P2

PROTCOL PATIENT ID	INSTITUTIONAL Pt. ID	TREATING PHYSICIAN	DATE FORM COMPLETED
D O X I L -			MM DD YYYY 2 0

◆ TARGET LESION(S) EVALUATION -within 28 days before administration-

※ Please record this item only ◆DISEASE INFORMATION [4] Measurable or Non-Measurable lesion is "Yes" on B Form.

[1] Are there any target lesions? 1 ☐ No 2 ☐ Yes, specify below:

[2] Site of lesion	[3] Date of evaluation (m d y)	[4] Method** (If other, specify:__)	[5] Longest diameter
1.	2 0	:	mm
2.	2 0	:	mm
3.	2 0	:	mm
4.	2 0	:	mm
5.	2 0	:	mm
6.	2 0	:	mm
7.	2 0	:	mm
8.	2 0	:	mm
9.	2 0	:	mm
10.	2 0	:	mm

*** Method of evaluation:*
1 = Clinical examination 2 = Spiral CT scan 3 = CT scan 88 = Other
4 = Chest X-ray 5 = MRI 6 = Ultrasound (specify:__)

[6] Sum of longest diameters of all target lesions ____ mm

◆ NON-TARGET LESION(S) EVALUATION -within 28 days before administration-

※ Please record this item only ◆DISEASE INFORMATION [4] Measurable or Non-Measurable lesion is "Yes" on B Form.

[1] Are there any non-target lesions? 1 ☐ No 2 ☐ Yes, specify below:

[2] Site of lesion	[3] Date of evaluation (m d y)	[4] Method** (If other, specify:__)
1.	2 0	:
2.	2 0	:
3.	2 0	:
4.	2 0	:
5.	2 0	:

◆ BIOMARKERS

※ Please record this item only ◆DISEASE INFORMATION [4] Measurable or Non-Measurable lesion is "No" on B Form.

1	Before 1st surgery CA-125	U/mL	2 0 (m d y)	
2	Nadir of CA-125 during 1st treatment	U/mL	2 0 (m d y)	
3	Definition CA-125	U/mL	2 0 (m d y)	
4	Facility limit of normal CA-125	U/mL		

Drug Dose Form (Form D) D

PROTCOL PATIENT ID	INSTITUTIONAL Pt. ID	TREATING PHYSICIAN	DATE FORM COMPLETED
D O X I L -			MM DD YYYY 2 0

Cycle Number	0 1	

◆ PHYSICAL EXAMINATION -before administration-

[1] Performance Status (PS:ECOG)	[2] Weight
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	___.___kg

◆ BIOMARKERS

1	CA-125	U/mL	m d 2 0 y	

◆ DOSAGE ADMINISTRATION RECORD

[1]Date of administration of Doxil

Day1 m d 2 0 y

[2] Cycle delayed

1 ☐ Ontime
2 ☐ Delayed →

[3] Reason for delay (select from【REASON CODES】on CD Form)

___,___,___

If "88=other", specify : _____

[4] Drug name	[5] Dose level	[6] Total dose	[7] Dose level change	[8] Reason for Dose Level Change (select from【REASON CODES】on CD Form)	[9] Dosing Rate *Infusion reaction in cycle
DOXIL	1 ☐ 50 2 ☐ 40 _____ mg/m^2	_____ mg/body	1 ☐ Yes → 2 ☐ No	___,___,___ If "88=other", specify : _____	1 ☐ 90 minutes 2 ☐ 120 mimutes 3 ☐ 90→130 mimutes* 4 ☐ 120→180 mimutes* 88 ☐ other → _____ mimutes

◆ PREMEDICATION FOR RASH/HAND-FOOT SKIN REACTION

[1] Drug name	[2] Administration before Doxil
Dexamethasone	1 ☐ Yes 2 ☐ No

Drug Dose Form (Form D) D

PROTCOL PATIENT ID	INSTITUTIONAL Pt. ID	TREATING PHYSICIAN	DATE FORM COMPLETED
DOXIL-			MM DD YYYY 20

Cycle Number	02	

◆ PHYSICAL EXAMINATION -before administration-

[1] Performance Status (PS:ECOG)	[2] Weight
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	___.___kg

◆ BIOMARKERS

1	CA-125	U/mL	m d 20 y	

◆ INCEPTION CRITERIA

※ Please check Table4. "inception criteria" on page 12 in the protocol.

m d 20 y ※ Specify individual dates when assessment dates differ.

					【CTCAE Grade】	
1	ANC	/mm^3	3	Rash/Hand-foot skin reaction	1 ☐ ≦ 1 2 ☐ ≧ 2	
2	Platelets	×10^4/mm^3	4	Stomatitis (clinical exam and functional/symptomatic)	1 ☐ ≦ 1 2 ☐ ≧ 2	
			5	Other Non-hematologic toxicities	1 ☐ ≦ 1 2 ☐ ≧ 2	

◆ DOSAGE ADMINISTRATION RECORD

[1]Date of administration of Doxil

Day1 m d 20 y

[2] Cycle delayed

1 ☐ Ontime
2 ☐ Delayed →

[3] Reason for delay (select from【REASON CODES】on CD Form)

___,___,___

If "88=other", specify :_____

[4] Drug name	[5] Dose level	[6] Total dose	[7] Dose level change	[8] Reason for Dose Level Change (select from【REASON CODES】on CD Form)	[9] Dosing Rate *Infusion reaction in cycle
DOXIL	1 ☐ 50 2 ☐ 40 _____ mg/m^2	_____ mg/body	1 ☐ Yes → 2 ☐ No	___,___,___ If "88=other", specify :_____	1 ☐ 90 minutes 2 ☐ 120 mimutes 3 ☐ 90→130 mimutes* 4 ☐ 120→180 mimutes* 88 ☐ other → _____ mimutes

◆ PREMEDICATION FOR RASH/HAND-FOOT SKIN REACTION

[1] Drug name	[2] Administration before Doxil
Dexamethasone	1 ☐ Yes 2 ☐ No

Drug Dose Form (Form D) **D**

PROTCOL PATIENT ID	INSTITUTIONAL Pt. ID	TREATING PHYSICIAN	DATE FORM COMPLETED
D O X I L -			MM DD YYYY 2 0

Cycle Number	0 3	

◆ PHYSICAL EXAMINATION -before administration-

[1] Performance Status (PS:ECOG)	[2] Weight
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	___.___kg

◆ BIOMARKERS

1	CA-125	U/mL	m d 2 0 y	

◆ INCEPTION CRITERIA

※ Please check Table4. "inception criteria" on page 12 in the protocol.

m d 2 0 y ※ Specify individual dates when assessment dates differ.

					【CTCAE Grade】	
1	ANC	/mm^3	3	Rash/Hand-foot skin reaction	1 ☐ ≦ 1 2 ☐ ≧ 2	
2	Platelets	×10^4/mm^3	4	Stomatitis (clinical exam and functional/symptomatic)	1 ☐ ≦ 1 2 ☐ ≧ 2	
			5	Other Non-hematologic toxicities	1 ☐ ≦ 1 2 ☐ ≧ 2	

◆ NON-INVASIVE DIAGNOSTIC PROCEDURES

1	LVEF	1 ☐ Not Done 3 ☐ Done → _____ %	Date of LVEF m d 2 0 y
2	ECG	1 ☐ Not Done 2 ☐ Normal 88 ☐ Abnormal, specify: _____	Date of ECG m d 2 0 y

◆ DOSAGE ADMINISTRATION RECORD

[1]Date of administration of Doxil **Day1** m d 2 0 y

[2] Cycle delayed
1 ☐ Ontime
2 ☐ Delayed →

[3] Reason for delay (select from【REASON CODES】on CD Form) ___,___,___
If "88=other", specify : _____

[4] Drug name	[5] Dose level	[6] Total dose	[7] Dose level change	[8] Reason for Dose Level Change (select from【REASON CODES】on CD Form)	[9] Dosing Rate *Infusion reaction in cycle
DOXIL	1 ☐ 50 2 ☐ 40 _____ mg/m^2	_____ mg/body	1 ☐ Yes → 2 ☐ No	___,___,___ If "88=other", specify : _____	1 ☐ 90 minutes 2 ☐ 120 mimutes 3 ☐ 90→130 mimutes* 4 ☐ 120→180 mimutes* 88 ☐ other → _____ mimutes

◆ PREMEDICATION FOR RASH/HAND-FOOT SKIN REACTION

[1] Drug name	[2] Administration before Doxil
Dexamethasone	1 ☐ Yes 2 ☐ No

Drug Dose Form (Form D) D

PROTCOL PATIENT ID	INSTITUTIONAL Pt. ID	TREATING PHYSICIAN	DATE FORM COMPLETED
DOXIL-			MM DD YYYY 20

Cycle Number	04	

◆ PHYSICAL EXAMINATION -before administration-

[1] Performance Status (PS:ECOG)	[2] Weight
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4	___.___kg

◆ BIOMARKERS

1	CA-125	U/mL	m d 20 y	

◆ INCEPTION CRITERIA

※ Please check Table4. "inception criteria" on page 12 in the protocol.

m d 20 y ※ Specify individual dates when assessment dates differ.

					【CTCAE Grade】	
1	ANC	/mm^3	3	Rash/Hand-foot skin reaction	1 ☐ ≦ 1 2 ☐ ≧ 2	
2	Platelets	×10^4/mm^3	4	Stomatitis (clinical exam and functional/symptomatic)	1 ☐ ≦ 1 2 ☐ ≧ 2	
			5	Other Non-hematologic toxicities	1 ☐ ≦ 1 2 ☐ ≧ 2	

◆ DOSAGE ADMINISTRATION RECORD

[1]Date of administration of Doxil

Day1 m d 20 y

[2] Cycle delayed

1 ☐ Ontime
2 ☐ Delayed →

[3] Reason for delay (select from【REASON CODES】on CD Form)

___,___,___

If "88=other", specify :_____

[4] Drug name	[5] Dose level	[6] Total dose	[7] Dose level change	[8] Reason for Dose Level Change (select from【REASON CODES】on CD Form)	[9] Dosing Rate *Infusion reaction in cycle
DOXIL	1 ☐ 50 2 ☐ 40 _____ mg/m^2	_____ mg/body	1 ☐ Yes → 2 ☐ No	___,___,___ If "88=other", specify :_____	1 ☐ 90 minutes 2 ☐ 120 mimutes 3 ☐ 90→130 mimutes* 4 ☐ 120→180 mimutes* 88 ☐ other → _____ mimutes

◆ PREMEDICATION FOR RASH/HAND-FOOT SKIN REACTION

[1] Drug name	[2] Administration before Doxil
Dexamethasone	1 ☐ Yes 2 ☐ No

Toxicity Form (Form T) T

PROTCOL PATIENT ID	INSTITUTIONAL Pt. ID	TREATING PHYSICIAN	DATE FORM COMPLETED		
			MM	DD	YYYY
DOXIL-					20

Cycle Number		

◆ **ADVERSE EVENTS**

・Please record all Adverse Events occurred and highest Grade during the current cycle.

No.	[1] CTCAE Version 3.0	[2] Highest Grade	[3] Relationship to RX (Reasonable possibility)	[4] Additional Information (e.g. lab values, associated dates[mm/dd/yyyy])
1	WBC ↓	0 1 2 3 4	1 ☐ Yes 2 ☐ No	Nadir:[ ] /mm^3 Date: / / 20
2	ANC ↓	0 1 2 3 4	1 ☐ Yes 2 ☐ No	Nadir:[ ] /mm^3 Date: / / 20
3	Hemoglobin ↓	0 1 2 3 4	1 ☐ Yes 2 ☐ No	Nadir:[ ] g/dL Date: / / 20
4	Platelets ↓	0 1 2 3 4	1 ☐ Yes 2 ☐ No	Nadir:[ ] /mm^3 Date: / / 20
5	ALP ↑	0 1 2 3 4	1 ☐ Yes 2 ☐ No	Nadir:[ ] IU/L Date: / / 20
6	Albumin ↓	0 1 2 3 -	1 ☐ Yes 2 ☐ No	Nadir:[ ] g/dL Date: / / 20
7	Bilirubin ↑	0 1 2 3 4	1 ☐ Yes 2 ☐ No	Nadir:[ ] mg/dL Date: / / 20
8	ALT/SGPT ↑	0 1 2 3 4	1 ☐ Yes 2 ☐ No	Nadir:[ ] IU/L Date: / / 20
9	AST/SGOT ↑	0 1 2 3 4	1 ☐ Yes 2 ☐ No	Nadir:[ ] IU/L Date: / / 20
10	Creatinine ↑	0 1 2 3 4	1 ☐ Yes 2 ☐ No	Nadir:[ ] mg/dL Date: / / 20
11	Na ↑	0 1 2 3 4	1 ☐ Yes 2 ☐ No	Nadir:[ ] mEq/L Date: / / 20
12	Na ↓	0 1 - 3 4	1 ☐ Yes 2 ☐ No	Nadir:[ ] mEq/L Date: / / 20
13	K ↑	0 1 2 3 4	1 ☐ Yes 2 ☐ No	Nadir:[ ] mEq/L Date: / / 20
14	K ↓	0 1 - 3 4	1 ☐ Yes 2 ☐ No	Nadir:[ ] mEq/L Date: / / 20
15	Proteinurea	0 1 2 3 4	1 ☐ Yes 2 ☐ No	Date: / / 20
16	Fever	0 1 2 3 4	1 ☐ Yes 2 ☐ No	
17	Anorexia	0 1 2 3 4	1 ☐ Yes 2 ☐ No	
18	Nausea	0 1 2 3 4	1 ☐ Yes 2 ☐ No	
19	Vomiting	0 1 2 3 4	1 ☐ Yes 2 ☐ No	
20	Diarrhea	0 1 2 3 4	1 ☐ Yes 2 ☐ No	
21	Stomatitis (clinical exam)	0 1 2 3 4	1 ☐ Yes 2 ☐ No	
22	Stomatitis (functional/symptomatic)	0 1 2 3 4	1 ☐ Yes 2 ☐ No	
23	*Stomatitis (Please select WHO Grade)*	※ WHO Grade 0 1 2 3 4	1 ☐ Yes 2 ☐ No	
24	Rash/Hand-foot skin reaction	0 1 2 3 -	1 ☐ Yes 2 ☐ No	
25	Fatigue	0 1 2 3 4	1 ☐ Yes 2 ☐ No	
26	Hair loss/alopecia	0 1 2 - -	1 ☐ Yes 2 ☐ No	
27	Cytokine release syndorome / acute infusion reaction	0 1 2 3 4	1 ☐ Yes 2 ☐ No	
28	other ( )	0 1 2 3 4	1 ☐ Yes 2 ☐ No	
29	other ( )	0 1 2 3 4	1 ☐ Yes 2 ☐ No	
30	other ( )	0 1 2 3 4	1 ☐ Yes 2 ☐ No	

[5] Did infusion reaction occure during the current cycle ? 1 ☐ No 2 ☐ Yes, specify below ↓

[6] Symptom of infusion reaction

_____ , _____ , _____ , _____ , _____ , _____

[7] Treatment for infusion reaction (select from【TREATMENT CODES】on CD Form)

If "88=other", specify

						: _____
	,		,		,	

DOXIL 【 REASON CODES 】

・Reason for Delay

[Recovered within 2 weeks after the scheduled Day1 of next cycle]

10 *=ANC ＜1,500/mm3 (≧Grade2)*
11 *=PLT ＜75,000/mm3(≧Grade2)*
12 *=Non-hematologic toxicities ≧Grade2*
(except for Fatigue, Nausea, Vomiting, Anorexia)

[Recovered within 4 weeks after the scheduled Day1 of next cycle]

13 *=Rash/Hand-foot skin reaction ≧Grade2*
14 *=Stomatitis ≧Grade2*

[Other]

88 *=Other (specify: __)*

・Reason for Dose Level Change

20= *Rash/Hand-foot skin reaction ＝Grade3*
21 *=Stomatitis (CTCAE : clinical exam or functional/symptomatic) ≧Grade3*
22 *=ANC or WBC Grade4 persisting ≧7 days*
23 *=ANC ≧ Grade3 and Fever(axilla) ≧38.0 ℃*
24= *PLT ≧Grade3*
25 *=Total Bilirubin 1.5mg/dL ≦and ＜3mg/dL*
26 *=Adverse drug reaction ＝Grade3*
(except for Fatigue, Nausea, Vomiting, Anorexia, Hypokalemia, Hyponatremia)
88 *=Other (specify: __)*

DOXIL 【 TREATMENT CODES 】

・Treatment for Infusion Reaction

30 *=Administration of anti-allergic drug*
31 *=Administration of steroid drug*
32 *=Administration of vasopressor*
33 *=Oxygen inhalation*
34 *=Continuation of Doxil (Dosing Rate = 1mg/minute)*
35 *=Discontinuation and change dosing rate of Doxil*
88 *=Other (specify: __)*

Supportive Care Form (Form SC) SC

PROTCOL PATIENT ID	INSTITUTIONAL Pt. ID	TREATING PHYSICIAN	DATE FORM COMPLETED
D O X I L -			MM DD YYYY 2 0

Cycle Number	

◆ SUPPORTIVE CARE FOR RASH/HAND-FOOT SKIN REACTION

[1] Cooling of limb during administration of Doxil

1 ☐ Yes → 【Location】
- 1 ☐ wrist and ankle
- 2 ☐ wrist only
- 3 ☐ ankle only

2 ☐ No → 【Reason for No cooling】
- 1 ☐ Forgot
- 2 ☐ Too cold
- 88 ☐ other → _____

[2] Drug name	[3] Administration	[4] Start Date	[5] Total Dose (During this cycle)
Oral Vitamine B6	1 ☐ Yes → 2 ☐ No	m d 2 0 y or 1 ☐ Continue from previous cycle	1 ☐ 100 mg/day × _____days 2 ☐ ____mg/day × _____days

[6] Drug name	[7] Administration	[8] Start Date	[9] Total Dose (During this cycle)
Dexamethasone	1 ☐ Yes → 2 ☐ No	m d 2 0 y	【Day 1～4】 1 ☐ 8 mg × 2 times/day × _____days 2 ☐ ___mg × ___ times/day × _____days 3 ☐ Not Administration; _____days 【Day 5】 1 ☐ 4 mg × 2 times/day 2 ☐ ___mg × ___ times/day 3 ☐ Not Administration 【Day 6】 1 ☐ 4 mg/day 2 ☐ ___mg/day 3 ☐ Not Administration

◆ SUPPORTIVE CARE FOR STOMATITIS

[1] Drug name	[2] Adhibition	[3] Frequency of gargle (During this cycle)
Aznol gargle liquid	1 ☐ Yes → 2 ☐ No	1 ☐ Always (75%≦ Frequency ≦100%) 2 ☐ Sometimes (25%≦ Frequency ＜75%) 3 ☐ Rarely (Frequency ＜ 25%)

[4] Drug name	[5] Adhibition	[6] Start Date	[7] Frequency of gargle (During this cycle)
Xylocaine Aznol gargle liquid	1 ☐ Yes → 2 ☐ No	m d 2 0 y	1 ☐ Always (75%≦ Frequency ≦100%) 2 ☐ Sometimes (25%≦ Frequency ＜75%) 3 ☐ Rarely (Frequency ＜ 25%)

◆ POINTS TO REMEMBER OF DAILY LIFE

[1] Did patient follow the "POINTS TO REMEMBER OF DAILY LIFE"?

Rash/Hand-Foot skin reaction →
- 1 ☐ Always (75%≦ Frequency ≦100%)
- 2 ☐ Sometimes (25%≦ Frequency ＜75%)
- 3 ☐ Rarely (Frequency ＜ 25%)

/ **Stomatitis** →
- 1 ☐ Always (75%≦ Frequency ≦100%)
- 2 ☐ Sometimes (25%≦ Frequency ＜75%)
- 3 ☐ Rarely (Frequency ＜ 25%)

Solid Tumor Evaluation Form (Form E) E

PROTCOL PATIENT ID	INSTITUTIONAL Pt. ID	TREATING PHYSICIAN	DATE FORM COMPLETED		
			MM	DD	YYYY
DOXIL-					20

◆ TIME OF EVALUATION

1 ☐ Follow up: Current Cycle No._____ 2 ☐ Study off

◆ TARGET LESION(S) EVALUATION

[1] Are there any target lesions? 1 ☐ No 2 ☐ Yes, specify below:

[2] Site of lesion	[3] Date of evaluation (m d y)	[4] Method** (If other, specify:__)	[5] Longest diameter
1.	20	:	mm
2.	20	:	mm
3.	20	:	mm
4.	20	:	mm
5.	20	:	mm
6.	20	:	mm
7.	20	:	mm
8.	20	:	mm
9.	20	:	mm
10.	20	:	mm

*** Method of evaluation:*
1 = Clinical examination 2 = Spiral CT scan 3 = CT scan 88 = Other
4 = Chest X-ray 5 = MRI 6 = Ultrasound (specify:__)

[6] Sum of longest diameters of all target lesions _____ mm

◆ NON-TARGET LESION(S) EVALUATION

[1] Are there any non-target lesions? 1 ☐ No 2 ☐ Yes, specify below:

[2] Site of lesion	[3] Date of evaluation (m d y)	[4] Method** (If other, specify:__)	[5] Follow-up status
1.	20	:	1 ☐CR 2 ☐IR/SD 3 ☐PD
2.	20	:	1 ☐CR 2 ☐IR/SD 3 ☐PD
3.	20	:	1 ☐CR 2 ☐IR/SD 3 ☐PD
4.	20	:	1 ☐CR 2 ☐IR/SD 3 ☐PD
5.	20	:	1 ☐CR 2 ☐IR/SD 3 ☐PD

◆ NEW LESION(S)

[1] New lesions since the baseline evaluation? 1 ☐ No 2 ☐ Yes, specify below:

[2] Site of lesion	[3] Date of evaluation (m d y)	[4] Method** (If other, specify:__)
1.	20	:

◆ TUMOR RESPONSE

[1] Evaluation of TARGET lesion 1 ☐ CR 2 ☐ PR 3 ☐ SD 4 ☐ PD 88 ☐ inevaluable for response

[2] Evaluation of NON-TARGET lesion 1 ☐ CR 2 ☐ IR/SD 3 ☐ PD 88 ☐ inevaluable for response

[3] Overall response
1 ☐ CR 2 ☐ PR 3 ☐ SD 4 ☐ PD 88 ☐ inevaluable for respons
(Report reason in COMMENTS box)

◆ COMMENTS

Treatment Completion Form (Form C) C

PROTCOL PATIENT ID	INSTITUTIONAL Pt. ID	TREATING PHYSICIAN	DATE FORM COMPLETED
D O X I L -			MM DD YYYY 2 0

◆ END OF STUDY

[1] Did the patient complete the protocol defined 4 cycles treatment?

1 ☐ Yes

2 ☐ No → Specify below ([2] Reason of study off)

[2] Reason of study off

[2-1] Primary reason for study off (select one)

1 ☐ Disease progression or appear new lesion during active treatment

2 ☐ Adverse events (Please select any relevant reasons ↓)

21 ☐ Over 2-week delay (Please select any relevant events)
⇒ 10☐ANC 11☐PLT 12☐Non-hematologic toxicities (except for Fatigue, Nasea, Vomiting, Anorexia)

22 ☐ Over 4-week delay (Please select any relevant events)
⇒ 20☐Rash/Hand-foot skin reaction 21☐Stomatitis

23 ☐ Over more than 2 times dose reduction
⇒
- 30☐Rash/Hand-foot skin reaction
- 31☐Stomatitis
- 32☐ANC or WBC Grade4 persisting ≧7 days
- 33☐ANC ≧ Grade3 and Fever(axilla) ≧38.0℃
- 34☐PLT
- 35☐Total Bilirubin
- 36☐Adverse drug reaction (except for Fatigue, Nausea, Vomiting, Anorexia, Hypokalemia, Hyponatremia)
- 88☐Other

24 ☐ Grade4 non-hematologic toxicities

25 ☐ Total Bilirubin ≧3mg/dL

26 ☐ LVEF ≦50% after administration of Doxil

27 ☐ LVEF (before registration) ≧20% reduction

88 ☐ Other, specify below [2-2]

3 ☐ Patient withdrawal or refusal for toxicity reason → specify below [2-2]

4 ☐ Patient withdrawal or refusal for reason other than toxicity → specify below [2-2]

5 ☐ Death → specify below [2-2] (Death date, Primary cause of death)

88 ☐ Other, specify below [2-2]

[2-2] Specify the reason : _____

◆ BEST TUMOR RESPONSE

[1] Best tumor response

1 ☐ CR (→CA125:_____U/mL) 2 ☐ PR 3 ☐ SD 4 ☐ PD 88 ☐ inevaluable for response

◆ COMMENTS

Follow-Up Form (Form Q) Q

PROTCOL PATIENT ID	INSTITUTIONAL Pt. ID	TREATING PHYSICIAN	DATE FORM COMPLETED
DOXIL-			MM DD YYYY 20

◆ ADVERSE EVENTS

Any protocol treatment-related toxicities(≧Grade2) present at 8 weeks after the end of study or before a non-protocol therapy start?

1 ☐ No 2 ☐ Yes, specify below ↓

No.	[1] CTCAE Version 3.0	[2] Highest Grade	[3] Additional Information (e.g. lab values, associated dates[mm/dd/yyyy])
1		2・3・4	
2		2・3・4	
3		2・3・4	
4		2・3・4	
5		2・3・4	
6		2・3・4	
7		2・3・4	
8		2・3・4	
9		2・3・4	
10		2・3・4	