PLEASE RETURN FORMS TO:
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DATA MANAGER: Cristina MORININI, Elena PORRO - E-MAIL ielsg@ticino.com - FAX ++41 91 811 91 82 - PHONE ++41 91 811 90 40 - 811 90 60 - 811 90 41

REGISTRATION FORM

IDENTIFICATION DATA

INSTITUTION ..... PT CODE ..... COUNTRY .....

SEX ☐ F ☐ M DATE OF BIRTH (dd/mm/yyyy) ..... INVESTIGATOR .....

☐ **INFORMED CONSENT SIGNED ON (dd/mm/yyyy) .....**

ELEGIBILITY CRITERIA

☐ Previously untreated primary mediastinal diffuse large B-cell lymphoma, CD20 positive. Patients must have histological confirmation of the diagnosis (it is recommended that the immunohistochemical panel includes: CD45, CD20, CD30, CD15, CD10, BCL6, BCL2, MUM-1), and in addition have a *dominant mass* within the anterior mediastinum.

☐ No evidence of extranodal disease outside the chest including spleen and bone marrow.

☐ Age at least 18 years.

☐ Fit to receive chemotherapy and radiotherapy with curative intent.

☐ Planned Rituximab treatment combined with any anthracycline-containing chemotherapy regimen without consolidation with autologous stem cell.

Planned chemotherapy regimen: ☐ R-CHOP/CHOP like ☐ R-DA-EPOCH ☐ R-V/MACOP-B ☐ R-ACVBP ☐ other ……

☐ At least 6 courses of Rituximab should be administered

☐ Able and willing to give informed consent, and to undergo staging including PET scanning

☐ Willingness to comply with an appropriate contraceptive method in women of childbearing potential or men.

☐ Histological diagnostic material available for review.

☐ No history of malignancy other than squamous cell carcinoma, basal cell carcinoma of the skin or carcinoma in situ of the cervix within the last 5 years.

☐ No evidence of clinically significant cardiac disease at diagnosis, as defined by history of symptomatic ventricular arrhythmias, congestive heart failure or myocardial infarction within 12 months before study entry. Cardiac impairment due to local extension of lymphoma will not be an exclusion criterion in the absence of other cardiac disease.

☐ No known HIV-positive serology.

☐ No pregnant or lactating women.

☐ No psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule.

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ON STUDY BASELINE FORM

IDENTIFICATION AND BASELINE DATA

INSTITUTION ..... INVESTIGATOR ..... PT REGISTRATION NUMBER ……

DIAGNOSIS AND PATHOLOGY

DIAGNOSIS' DATE (dd/mm/yyyy) .....

HISTOLOGY NUMBER ..... PATH. INSTITUTE .....

BONE MARROW INVOLVEMENT ☐ YES ☐ NO

MEDICAL HISTORY

DID THE SUBJECT HAVE ANY SIGNIFICANT MEDICAL CONDITION ☐ YES ☐ NO if yes specify below

..... ☐ ACTIVE ☐ NOT ACTIVE

..... ☐ ACTIVE ☐ NOT ACTIVE

..... ☐ ACTIVE ☐ NOT ACTIVE

CLINICAL PARAMETERS

ECOG PS SCALE ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
(0 asymptomatic; 1 symptomatic, fully ambulatory; 2 symptomatic, in bed less than 50% of day; 3 symptomatic, in bed more than 50% of day but not bedridden; 4 bedridden)

B- SYMPTOMS ☐ YES ☐ NO if yes:
☐ NIGHT SWEATS ☐ UNEXPL. FEVER ☐ UNEXPL. WEIGHT LOSS (≥10% body weight)

OTHER SYMPTOMS ☐ YES ☐ NO if yes specify .....

EXTRANODAL INVOLV. ☐ YES ☐ NO if yes specify .....

DISEASE STAGING

(Carbone, PP et al. Cancer Res 1971; 31:1860-1861)

ANN ARBOR STAGE ☐ **I** ☐ **II** ☐ **III** ☐ **IV**

PHYSICAL EXAMINATION

DATE OF EXAM (dd/mm/yyyy) ..... WEIGHT (kg)..... HEIGHT (cm) .....

NOTE: NO LYMPHOMA ASSESSMENT TO BE RECORDED ON THIS PART

BODY SYSTEM	NOT DONE	NORMAL	ABNORMAL*	DESCRIPTION OF ABNORMALITIES
HEENT**	☐	☐	☐ CS ☐ NCS	.....
CARDIOVASCULAR	☐	☐	☐ CS ☐ NCS	.....
RESPIRATORY	☐	☐	☐ CS ☐ NCS	.....
ABDOMINAL / GI	☐	☐	☐ CS ☐ NCS	.....
EXTREMITIES	☐	☐	☐ CS ☐ NCS	.....
SKIN	☐	☐	☐ CS ☐ NCS	.....
UROGENITAL	☐	☐	☐ CS ☐ NCS	.....
NEUROLOGIC	☐	☐	☐ CS ☐ NCS	.....
LYMPHNODES	☐	☐	☐ CS ☐ NCS	.....

* CS Clinically Significant, record event on medical history – NCS Not Clinically Significant
** Head Eye Ear Nose Throat

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ON STUDY BASELINE FORM

LABORATORY VALUES

LAB TEXT		NOT DONE	NORMAL	ABNORMAL*	
HEMOGLOBIN	……. g/dl	☐	☐	☐ CS ☐ NCS	.....
PLATELET COUNT	……. 109/L	☐	☐	☐ CS ☐ NCS	.....
WBC COUNT	……. 109/L	☐	☐	☐ CS ☐ NCS	.....
NEUTROPHILS	……. %	☐	☐	☐ CS ☐ NCS	.....
LYMPHOCYTES	……. %	☐	☐	☐ CS ☐ NCS	.....
MONOCYTES	……. %	☐	☐	☐ CS ☐ NCS	.....
EOSINOPHILES	……. %	☐	☐	☐ CS ☐ NCS	.....
BASOPHILES	……. %	☐	☐	☐ CS ☐ NCS	.....
CREATININE	……. μmol/L	☐	☐	☐ CS ☐ NCS	.....
LDH	……. U/L	☐	☐	☐ CS ☐ NCS	.....
BETA-2 MICROGLOB.	……. mg/L	☐	☐	☐ CS ☐ NCS	.....
ALKALINE PHOSPHAT	……. U/L	☐	☐	☐ CS ☐ NCS	.....
ALAT	……. U/L	☐	☐	☐ CS ☐ NCS	.....
ALBUMIN	……. g/L	☐	☐	☐ CS ☐ NCS	.....
IgM	……. g/L	☐	☐	☐ CS ☐ NCS	.....
IgG	……. g/L	☐	☐	☐ CS ☐ NCS	.....
IgA	……. g/L	☐	☐	☐ CS ☐ NCS	.....
TSH	……. mUl/L	☐	☐	☐ CS ☐ NCS	.....
PROTEIN ELECTROPHORESIS		☐	☐	☐ CS ☐ NCS	.....

* CS Clinically Significant, record event on medical history – NCS Not Clinically Significant

TUMOR ASSESSMENT - MEASURABLE LESIONS

SPECIFY LOCATION WITHIN ORGAN	LONGEST DIAMETER	METHOD OF ASSESSMENT*	DATE OF ASSESSMENT (dd/mm/yyyy)
.....	……..... (mm)	.....	.....
.....	……..... (mm)	.....	.....
.....	……..... (mm)	.....	.....
.....	……..... (mm)	.....	.....
.....	……..... (mm)	.....	.....

*(1 CT scan; 2 PET/CT; 3 other, specify)

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ON STUDY BASELINE FORM

CARDIAC FUNCTION

ECG DATE (dd/mm/yyyy) .....

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify:

.....

ECHOCARDIOGRAM DATE (dd/mm/yyyy) ..... EF% .....

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify:

.....

CHEST X-RAY (PA + lateral) DATE (dd/mm/yyyy) .....

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify:

.....

CT SCAN (chest, abdomen, pelvis) DATE (dd/mm/yyyy) .....

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify:

.....

FDG-PET/CT SCAN (baseline local results) DATE (dd/mm/yyyy) .....

☐ POSITIVE ☐ NEGATIVE

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RANDOMIZATION FORM

IDENTIFICATION AND BASELINE DATA

INSTITUTION ..... INVESTIGATOR ..... PT REGISTRATION NUMBER ……

TREATMENT RECEIVED

☐ R-CHOP/CHOP like ☐ R-V/MACOP-B

☐ R-DA-EPOCH ☐ R-ACVBP or other

POST CHEMOTHERAPY PET/CT LOCAL REVIEW SCORE

☐ NO UPTAKE (negative) ☐ RESIDUAL UPTAKE <MBP (positive)

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RADIOTHERAPY FORM

TO BE FILLED 4 MONTHS AFTER RANDOMIZATION IF RT WAS PERFORMED

IDENTIFICATION AND BASELINE DATA

INSTITUTION ..... INVESTIGATOR ..... PT REGISTRATION NUMBER ……

RADIOTHERAPY

START DATE (dd/mm/yyyy) ..... END DATE (dd/mm/yyyy) .....

TYPE OF RT (describe method, volume and fields).....

TOTAL DOSE RT ……. Gy FRACTION DOSE ……. Gy

RADIOTHERAPY DISCONTINUATION

DATE OF RT DISCONTINUATION(dd/mm/yyyy) .....

CAUSE OF RT DISCONTINUATION ☐ PD ☐ UNACCEPTABLE TOXICITY ☐ DEATH ☐ PATIENT'S REFUSAL

☐ OTHER .....

PLEASE RETURN FORMS TO:
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FOLLOW-UP FORM MONTH 3

IDENTIFICATION AND BASELINE DATA

INSTITUTION ..... INVESTIGATOR ..... PT REGISTRATION NUMBER .....

DATE OF FOLLOW-UP VISIT (dd/mm/yyyy) **.....**

OUTCOME

IS THE PATIENT ALIVE ☐ YES ☐ NO ☐ UNKNOWN (LOST)

if dead specify DATE OF DEATH ..... CAUSE OF DEATH .....

CURRENT STATUS ☐ CR ☐ PR ☐ SD ☐ PD ☐ NA

If PD please specify site and extent: .....

FURTHER THERAPY .....

START DATE (dd/mm/yyyy) ..... END DATE ..... RESPONSE.....

PHISICAL EXAMINATION

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify .....

LABORATORY VALUES

LAB TEXT		NOT DONE	NORMAL	ABNORMAL*	
HEMOGLOBIN	..... g/dl	☐	☐	☐ CS ☐ NCS	.....
PLATELET COUNT	..... 109/L	☐	☐	☐ CS ☐ NCS	.....
WBC COUNT	..... 109/L	☐	☐	☐ CS ☐ NCS	.....
NEUTROPHILS	..... %	☐	☐	☐ CS ☐ NCS	.....
LYMPHOCYTES	..... %	☐	☐	☐ CS ☐ NCS	.....
LDH	..... U/L	☐	☐	☐ CS ☐ NCS	.....

* CS Clinically Significant, record event on medical history – NCS Not Clinically Significant

ADVERSE EVENTS (FOR ANY ADVERSE EVENT PLEASE SPECIFY)

TYPE	RELATED	NCI/CTC GRADE	DATE	DURATION DAYS	RESOLVED
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO

SERIOUS ADVERSE EVENT

DID THE SUBJECT HAVE ANY SERIOUS ADVERSE EVENT ☐ YES ☐ NO if yes fill the SAE REPORT FORM

CHEST X-RAY (PA + lateral) DATE (dd/mm/yyyy) .....

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify .....

OTHER EXAMS .....

REMARKS .....

PLEASE RETURN FORMS TO:
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FOLLOW-UP FORM MONTH 6

IDENTIFICATION AND BASELINE DATA

INSTITUTION ..... INVESTIGATOR ..... PT REGISTRATION NUMBER .....

DATE OF FOLLOW-UP VISIT (dd/mm/yyyy) **.....**

OUTCOME

IS THE PATIENT ALIVE ☐ YES ☐ NO ☐ UNKNOWN (LOST)
if dead specify DATE OF DEATH ..... CAUSE OF DEATH .....
CURRENT STATUS ☐ CR ☐ PR ☐ SD ☐ PD ☐ NA
If PD please specify site and extent: .....
FURTHER THERAPY .....
START DATE (dd/mm/yyyy) ..... END DATE ..... RESPONSE.....

PHISICAL EXAMINATION

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify .....

LABORATORY VALUES

LAB TEXT		NOT DONE	NORMAL	ABNORMAL*	
HEMOGLOBIN	……. g/dl	☐	☐	☐ CS ☐ NCS	.....
PLATELET COUNT	……. 109/L	☐	☐	☐ CS ☐ NCS	.....
WBC COUNT	……. 109/L	☐	☐	☐ CS ☐ NCS	.....
NEUTROPHILS	……. %	☐	☐	☐ CS ☐ NCS	.....
LYMPHOCYTES	……. %	☐	☐	☐ CS ☐ NCS	.....
LDH	……. U/L	☐	☐	☐ CS ☐ NCS	.....

* CS Clinically Significant, record event on medical history – NCS Not Clinically Significant

ADVERSE EVENTS (FOR ANY ADVERSE EVENT PLEASE SPECIFY)

TYPE	RELATED	NCI/CTC GRADE	DATE	DURATION DAYS	RESOLVED
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO

SERIOUS ADVERSE EVENT

DID THE SUBJECT HAVE ANY SERIOUS ADVERSE EVENT ☐ YES ☐ NO if yes fill the SAE REPORT FORM

CT SCAN (chest, abdomen, pelvis) DATE (dd/mm/yyyy) .....

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify .....

OTHER EXAMS .....

REMARKS .....

PLEASE RETURN FORMS TO:
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FOLLOW-UP FORM MONTH 9

IDENTIFICATION AND BASELINE DATA

INSTITUTION ..... INVESTIGATOR ..... PT REGISTRATION NUMBER .....

DATE OF FOLLOW-UP VISIT (dd/mm/yyyy) **.....**

OUTCOME

IS THE PATIENT ALIVE ☐ YES ☐ NO ☐ UNKNOWN (LOST)

if dead specify DATE OF DEATH ..... CAUSE OF DEATH .....

CURRENT STATUS ☐ CR ☐ PR ☐ SD ☐ PD ☐ NA

If PD please specify site and extent: .....

FURTHER THERAPY .....

START DATE (dd/mm/yyyy) ..... END DATE ..... RESPONSE.....

PHISICAL EXAMINATION

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify .....

LABORATORY VALUES

LAB TEXT		NOT DONE	NORMAL	ABNORMAL*	
HEMOGLOBIN	……. g/dl	☐	☐	☐ CS ☐ NCS	.....
PLATELET COUNT	……. 109/L	☐	☐	☐ CS ☐ NCS	.....
WBC COUNT	……. 109/L	☐	☐	☐ CS ☐ NCS	.....
NEUTROPHILS	……. %	☐	☐	☐ CS ☐ NCS	.....
LYMPHOCYTES	……. %	☐	☐	☐ CS ☐ NCS	.....
LDH	……. U/L	☐	☐	☐ CS ☐ NCS	.....

* CS Clinically Significant, record event on medical history – NCS Not Clinically Significant

ADVERSE EVENTS (FOR ANY ADVERSE EVENT PLEASE SPECIFY)

TYPE	RELATED	NCI/CTC GRADE	DATE	DURATION DAYS	RESOLVED
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO

CHEST X-RAY (PA + lateral) DATE (dd/mm/yyyy) .....

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify .....

OTHER EXAMS .....

REMARKS .....

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FOLLOW-UP FORM MONTH 12

IDENTIFICATION AND BASELINE DATA

INSTITUTION ..... INVESTIGATOR ..... PT REGISTRATION NUMBER .....

DATE OF FOLLOW-UP VISIT (dd/mm/yyyy) **.....**

OUTCOME

IS THE PATIENT ALIVE ☐ YES ☐ NO ☐ UNKNOWN (LOST)

if dead specify DATE OF DEATH ..... CAUSE OF DEATH .....

CURRENT STATUS ☐ CR ☐ PR ☐ SD ☐ PD ☐ NA

If PD please specify site and extent: .....

FURTHER THERAPY .....

START DATE (dd/mm/yyyy) ..... END DATE ..... RESPONSE.....

PHISICAL EXAMINATION

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify .....

LABORATORY VALUES

LAB TEXT		NOT DONE	NORMAL	ABNORMAL*	
HEMOGLOBIN	……. g/dl	☐	☐	☐ CS ☐ NCS	.....
PLATELET COUNT	……. 109/L	☐	☐	☐ CS ☐ NCS	.....
WBC COUNT	……. 109/L	☐	☐	☐ CS ☐ NCS	.....
NEUTROPHILS	……. %	☐	☐	☐ CS ☐ NCS	.....
LYMPHOCYTES	……. %	☐	☐	☐ CS ☐ NCS	.....
LDH	……. U/L	☐	☐	☐ CS ☐ NCS	.....
TSH	……. mUI/L	☐	☐	☐ CS ☐ NCS	.....

* CS Clinically Significant, record event on medical history – NCS Not Clinically Significant

ADVERSE EVENTS (FOR ANY ADVERSE EVENT PLEASE SPECIFY)

TYPE	RELATED	NCI/CTC GRADE	DATE	DURATION DAYS	RESOLVED
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO

CT SCAN (chest, abdomen, pelvis) DATE (dd/mm/yyyy) .....

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify .....

ECHOCARDIOGRAM DATE (dd/mm/yyyy) ..... EF% .....

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify:.....

OTHER EXAMS .....

REMARKS .....

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FOLLOW-UP FORM MONTH 18

IDENTIFICATION AND BASELINE DATA

INSTITUTION ..... INVESTIGATOR ..... PT REGISTRATION NUMBER .....

DATE OF FOLLOW-UP VISIT (dd/mm/yyyy) **.....**

OUTCOME

IS THE PATIENT ALIVE ☐ YES ☐ NO ☐ UNKNOWN (LOST)

if dead specify DATE OF DEATH ..... CAUSE OF DEATH .....

CURRENT STATUS ☐ CR ☐ PR ☐ SD ☐ PD ☐ NA

If PD please specify site and extent: .....

FURTHER THERAPY .....

START DATE (dd/mm/yyyy) ..... END DATE ..... RESPONSE.....

PHISICAL EXAMINATION

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify .....

LABORATORY VALUES

LAB TEXT		NOT DONE	NORMAL	ABNORMAL*	
HEMOGLOBIN	……. g/dl	☐	☐	☐ CS ☐ NCS	.....
PLATELET COUNT	……. 109/L	☐	☐	☐ CS ☐ NCS	.....
WBC COUNT	……. 109/L	☐	☐	☐ CS ☐ NCS	.....
NEUTROPHILS	……. %	☐	☐	☐ CS ☐ NCS	.....
LYMPHOCYTES	……. %	☐	☐	☐ CS ☐ NCS	.....
LDH	……. U/L	☐	☐	☐ CS ☐ NCS	.....

* CS Clinically Significant, record event on medical history – NCS Not Clinically Significant

ADVERSE EVENTS (FOR ANY ADVERSE EVENT PLEASE SPECIFY)

TYPE	RELATED	NCI/CTC GRADE	DATE	DURATION DAYS	RESOLVED
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO

CHEST X-RAY (PA + lateral) DATE (dd/mm/yyyy) .....

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify .....

OTHER EXAMS .....

REMARKS .....

PLEASE RETURN FORMS TO:
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FOLLOW-UP FORM MONTH 24

IDENTIFICATION AND BASELINE DATA

INSTITUTION ..... INVESTIGATOR ..... PT REGISTRATION NUMBER .....

DATE OF FOLLOW-UP VISIT (dd/mm/yyyy) **.....**

OUTCOME

IS THE PATIENT ALIVE ☐ YES ☐ NO ☐ UNKNOWN (LOST)

if dead specify DATE OF DEATH ..... CAUSE OF DEATH .....

CURRENT STATUS ☐ CR ☐ PR ☐ SD ☐ PD ☐ NA

If PD please specify site and extent: .....

FURTHER THERAPY .....

START DATE (dd/mm/yyyy) ..... END DATE ..... RESPONSE.....

PHISICAL EXAMINATION

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify .....

LABORATORY VALUES

LAB TEXT		NOT DONE	NORMAL	ABNORMAL*	
HEMOGLOBIN	……. g/dl	☐	☐	☐ CS ☐ NCS	.....
PLATELET COUNT	……. 109/L	☐	☐	☐ CS ☐ NCS	.....
WBC COUNT	……. 109/L	☐	☐	☐ CS ☐ NCS	.....
NEUTROPHILS	……. %	☐	☐	☐ CS ☐ NCS	.....
LYMPHOCYTES	……. %	☐	☐	☐ CS ☐ NCS	.....
LDH	……. U/L	☐	☐	☐ CS ☐ NCS	.....
TSH	……. mUl/L	☐	☐	☐ CS ☐ NCS	.....

* CS Clinically Significant, record event on medical history – NCS Not Clinically Significant

ADVERSE EVENTS (FOR ANY ADVERSE EVENT PLEASE SPECIFY)

TYPE	RELATED	NCI/CTC GRADE	DATE	DURATION DAYS	RESOLVED
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO

CT SCAN (chest, abdomen, pelvis) DATE (dd/mm/yyyy) .....

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify .....

ECHOCARDIOGRAM DATE (dd/mm/yyyy) ..... EF% .....

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify:.....

OTHER EXAMS .....

REMARKS .....

PLEASE RETURN FORMS TO:
IELSG STUDIES COORDINATION - ONCOLOGY INSTITUTE OF SOUTHERN SWITZERLAND - OSPEDALE SAN GIOVANNI - CH-6500 BELLINZONA - SWITZERLAND
DATA MANAGER: Cristina MORININI, Elena PORRO - E-MAIL ielsg@ticino.com - FAX ++41 91 811 91 82 - PHONE ++41 91 811 90 40 - 811 90 60 - 811 90 41

FOLLOW-UP FORMS — MONTH 30-36-42-48-54-60

IDENTIFICATION AND BASELINE DATA

INSTITUTION ..... INVESTIGATOR ..... PT REGISTRATION NUMBER .....

DATE OF FOLLOW-UP VISIT (dd/mm/yyyy) **.....**

OUTCOME

IS THE PATIENT ALIVE ☐ YES ☐ NO ☐ UNKNOWN (LOST)

if dead specify DATE OF DEATH ..... CAUSE OF DEATH .....

CURRENT STATUS ☐ CR ☐ PR ☐ SD ☐ PD ☐ NA

If PD please specify site and extent: .....

FURTHER THERAPY .....

START DATE (dd/mm/yyyy) ..... END DATE ..... RESPONSE.....

PHISICAL EXAMINATION

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify .....

LABORATORY VALUES

LAB TEXT		NOT DONE	NORMAL	ABNORMAL*	
HEMOGLOBIN	……. g/dl	☐	☐	☐ CS ☐ NCS	.....
PLATELET COUNT	……. 109/L	☐	☐	☐ CS ☐ NCS	.....
WBC COUNT	……. 109/L	☐	☐	☐ CS ☐ NCS	.....
NEUTROPHILS	……. %	☐	☐	☐ CS ☐ NCS	.....
LYMPHOCYTES	……. %	☐	☐	☐ CS ☐ NCS	.....
LDH	……. U/L	☐	☐	☐ CS ☐ NCS	.....

* CS Clinically Significant, record event on medical history – NCS Not Clinically Significant

ADVERSE EVENTS (FOR ANY ADVERSE EVENT PLEASE SPECIFY)

TYPE	RELATED	NCI/CTC GRADE	DATE	DURATION DAYS	RESOLVED
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO
.....	☐ YES ☐ NO ☐ POSSIBLY	.....	.....	.....	☐ YES ☐ NO

ECHOCARDIOGRAM*

DATE (dd/mm/yyyy) ..... EF% .....

☐ NOT DONE ☐ NORMAL ☐ ABNORMAL if abnormal specify:.....

*yearly (months 36-48-60)

OTHER EXAMS .....

REMARKS .....

PLEASE RETURN FORMS TO:
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SERIOUS ADVERSE EVENT (SAE) REPORT FORM (occurring during radiotherapy)

SAE MUST BE COLLECTED **ONLY IN THE RANDOMIZATION POPULATION** FROM THE TIME OF RANDOMIZATION AND UP TO 4 MONTHS

IDENTIFICATION AND BASELINE DATA

INSTITUTION ..... INVESTIGATOR ..... PT REGISTRATION NUMBER ……

DATE OF ONSET (dd/mm/yyyy) .....

SERIOUS ADVERSE EVENT (SAE) DEFINITION:

.....

(This field must contain ONE serious clinical condition. If a series of signs, symptoms occur in the same patient at the same time and a unique diagnosis that explains all of them cannot be found, report each sign and symptom in separate SAE pages)

SAE DESCRIPTION (CLINICAL HISTORY AND EVOLUTION OF THE RELEVANT SAE), CONCOMITANT DISEASES AND/OR RELEVANT MEDICAL CONDITION:

.....

.....

.....

.....

REASON OF SERIOUSNESS

☐ FATAL
☐ LIFE-THREATETING
☐ DISABLING
☐ REQUIRES IMPATIENT/PROLONGED HOSPITALIZATION
☐ OTHER: PLEASE SPECIFY ……..

ACTION TAKEN REGARDING PROTOCOL TREATMENT

☐ NONE ☐ TEMPORARY DISCONTINUATION ☐ DELAY
☐ DOSE REDUCTION ☐ PERMANENT DISCONTINUATION ☐ OTHER .....

.....

CASUALITY ASSESSMENT REGARDING RADIOTHERAPY

☐ SUSPECTED ☐ UNSUSPECTED

PLEASE RETURN FORMS TO:
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SERIOUS ADVERSE EVENT (SAE) FOLLOW-UP FORM

IDENTIFICATION AND BASELINE DATA

INSTITUTION ..... INVESTIGATOR ..... PT REGISTRATION NUMBER .....

DATE OF ONSET (dd/mm/yyyy) .....

OUTCOME

- ☐ ONGOING
- ☐ LOST TO FOLLOW-UP
- ☐ WORSENING
- ☐ RECOVERY DATE .....
- ☐ RECOVERY WITH SEQUELAE DATE .....
- ☐ DEATH DATE .....

CAUSE OF DEATH

.....

.....

.....

REMARKS .....

.....

.....

.....

PLEASE RETURN FORMS TO:
IELSG STUDIES COORDINATION - ONCOLOGY INSTITUTE OF SOUTHERN SWITZERLAND - OSPEDALE SAN GIOVANNI - CH-6500 BELLINZONA - SWITZERLAND
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WITHDRAWAL FORM

IDENTIFICATION AND BASELINE DATA

INSTITUTION ..... INVESTIGATOR ..... PT REGISTRATION NUMBER ……

DATE OF WITHDRAWAL .....

CAUSE OF WITHDRAWAL

☐ RT DISCONTINUATION specify: ☐ TOXICITY ☐ PT DECISION

☐ PD

☐ DEATH

☐ PROTOCOL VIOLATION

☐ OTHER .....

.....

.....

REMARKS .....

.....

PLEASE RETURN FORMS TO:
IELSG STUDIES COORDINATION - ONCOLOGY INSTITUTE OF SOUTHERN SWITZERLAND - OSPEDALE SAN GIOVANNI - CH-6500 BELLINZONA - SWITZERLAND
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FOLLOW-UP FORMS FOR NON RANDOMIZED OR WITHDRAWN PATIENTS
MONTH 12-24-36-48-60

IDENTIFICATION AND BASELINE DATA

INSTITUTION ..... INVESTIGATOR ..... PT REGISTRATION NUMBER ……

DATE OF FOLLOW-UP VISIT (dd/mm/yyyy) **.....**

OUTCOME

IS THE PATIENT ALIVE ☐ YES ☐ NO ☐ UNKNOWN (LOST)
if dead specify DATE OF DEATH ..... CAUSE OF DEATH .....
CURRENT STATUS ☐ CR ☐ PR ☐ SD ☐ PD ☐ NA
If PD please specify site and extent: .....
FURTHER THERAPY .....
START DATE (dd/mm/yyyy) ..... END DATE ..... RESPONSE.....

REMARKS .....

PLEASE RETURN FORMS TO:
IELSG STUDIES COORDINATION - ONCOLOGY INSTITUTE OF SOUTHERN SWITZERLAND - OSPEDALE SAN GIOVANNI - CH-6500 BELLINZONA - SWITZERLAND
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CRFs SUMMARY

CRFs have to be completed on line connecting to the following address: www.ielsg.org/edc.html

REGISTRATION FORM - Before starting R-chemotherapy

ON STUDY BASELINE FORM - After registration, before randomization

UPLOADING OF BASELINE PET-CT AND POST R-CHEMOTHERAPY PET-CT FOR RESPONSE EVALUATION (dedicated website *www.ielsg.org/edc.html*) Mandatory for patient randomization

RANDOMIZATION FORM - Only PET-negative patients

RANDOMIZED PATIENTS

RADIOTHERAPY FORM - 4 months after randomization if applicable

FOLLOW-UP - MONTH 3 - 6 - 9 - 12 - 18 - 24 - 30 - 36 - 42 - 48 - 54 - 60

SAE REPORT FORM (within 24 hours from the onset)

SAE FOLLOW-UP FORM (within 2 weeks after definitive assessement)

WITHDRAWAL FORM - In case of withdrawal for any reason

NON RANDOMIZED / WITHDRAWN PATIENTS

FOLLOW-UP MONTHS 12-24-36-48-60