

Arm 1: 12 months treatment

**SSG XVIII
Screening at baseline Form 2**

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ _ _

Rand. number [] [] [] []

Age at diagnosis: [] [] yrs

Main presenting symptoms or signs of GIST (other concomitant diseases are not to be reported)

1.

2.

3.

Surgery

Date of surgery Day Month Year [] [] [] [] [] [] [] [] [] []

Type of open surgery:

Completeness of surgery:
 Complete, clear margins (R0) Microscopically infiltrated margins or suspected, or tumor rupture (R1)

Tumor spillage at surgery:
 No Yes

Intra-abdominal bleeding/tumor spillage prior to surgery:
 No Yes

Tumor site

Site of primary tumor – *NB! Only one alternative may be ticked*
 stomach small intestine colon rectum esophagus
 mesentery retroperitoneum other, specify

Size of primary tumor [] [] [] [] mm (the largest diameter)

Morphology

Number of mitoses/50 high power fields [] [] []

Immunohistochemical stainings performed:
 KIT/CD117 CD34 Ki-67 S-100 SMA
 Vimentin Desmin Other

Arm 1: 12 months treatment

**SSG XVIII
Screening at baseline**

Form 3A

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials

Rand. number

Weight kg

Height cm

- ECOG PS:** 0 Fully active, able to carry on all pre-disease performance without restriction
 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
 2 Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours

Chest X-ray or CT, date

Day Month Year

Abdominal CT/MRI, date

Research serum/blood sample, date

Tissue available for Central Pathology Review/Mutation analysis: No Yes

Laboratory data

Test	Result	Unit	Normal reference range (including unit)
B-Hb -
B-leuk -
B-neutr -
B-lymph -
B-eos -
B-monocytes -
B-baso -
B-platelets -
Creatinine -
AST -
ALT -
LDH -
Alk Phos -
Bilirubin -
Albumin -
Protein -

Arm 1: 12 months treatment

SSG XVIII
Screening at baseline

Form 3B

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ _ _

Rand. number

Concomitant medications

Trade name	Indication
Drug 1
Drug 2
Drug 3
Drug 4
Drug 5
Drug 6
Drug 7
Drug 8
Drug 9
Drug 10

Arm 1: 12 months treatment

SSG XVIII Adverse Event Follow-up. Month 1, week 4	Form 4 B
Send this form to: SSG secretariat Regional Tumor Registry Lund University Hospital SE-221 85 LUND, Sweden	Patient Initials <input style="width: 50px;" type="text"/> <input style="width: 50px;" type="text"/> <input style="width: 50px;" type="text"/> Rand. number <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>

NCI/NIH Common Toxicity Criteria (*circle* the correct alternative)

	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Oedema, periorbital	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Oedema, leg	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Oedema, other	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Weight gain	< 5%	5 – <10%	10 – <20%	20%	–
Muscle cramps	None	Mild	Moderate	Severe	–
Vomiting	None	1 episode in 24 hours over pretreatment	2–5 episodes in 24 hours over pretreatment	6 episodes in 24 hours over pretreatment; or need for IV fluids	Requiring parenteral nutrition; or physiologic consequences requiring intensive care; hemodynamic collapse
Nausea	None	Able to eat	Oral intake significantly decreased	No significant intake, requiring IV fluids	–
Diarrhea	None	Increase of < 4 stools/day over pre-treatment	Increase of 4–6 stools/day, or nocturnal stools	Increase of 7 stools/day or incontinence; or need for parenteral support for dehydration	Physiologic consequences requiring intensive care; or hemodynamic collapse
Constipation	None	Requiring stool softener or dietary modification	Requiring laxatives	Obstipation requiring manual evacuation or enema	Obstruction or toxic megacolon
Flatulence	None	Mild	Moderate	Severe	-
Dyspepsia/Heartburn	None	Mild	Moderate	Severe	-
Loose stools	None	Mild	Moderate	Severe	-
Abdominal distension	None	Mild	Moderate	Severe	-
Dysphagia	None	Mild dysphagia, but can eat regular diet	Dysphagia, requiring predominantly pureed, soft, or liquid diet	Dysphagia, requiring IV hydration	Requiring enteral or parenteral nutritional support or complete obstruction (cannot swallow saliva) or perforation
Headache	None	Mild pain not interfering with function	Moderate: pain or analgesics interfering with function, but not with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Dermatitis or rash	None	Macular or papular eruption or erythema without associated symptoms	Macular or papular eruption or erythema with pruritus or other associated symptoms covering <50% of body surface or localized desquamation or other lesions covering <50% of body surface area	Symptomatic generalized erythroderma or macular, papular or vesicular eruption or desquamation covering > 50% of body surface area	Generalized exfoliative dermatitis or ulcerative dermatitis
Pruritus	None	Mild or localized, relieved spontaneously or by local measures	Intense or widespread, relieved spontaneously or by systemic measures	Intense or widespread and poorly controlled despite treatment	–
Hemorrhage Specify site:	None	Mild without transfusion	–	Requiring transfusion	Catastrophic bleeding, requiring major non-elective intervention

Arm 1: 12 months treatment

**SSG XVIII
Adverse Event Form 4 B cont'd
Follow-up. Month 1, week 4**

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials

Rand. number

NCI/NIH Common Toxicity Criteria (circle the correct alternative)

	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Fever (no neutropenia, granulocyte count > 1.0 x 10 ⁹ /L)	None	38.0–39.0°C (100.4–102.2°F)	39.1–40.0°C (102.3–104.0°F)	> 40.0°C (>104.0°F) for < 24 hrs	> 40.0°C (>104.0°F) for > 24 hrs
Infection (no neutropenia)	None	Mild, no active treatment	Moderate, localized infection, requiring local or oral treatment	Severe, systemic infection, requiring IV antibiotic or antifungal treatment, or hospitalization	Life-threatening sepsis (e.g., septic shock)
Febrile neutropenia (neutrophil count < 1.0, fever 38.5°C or higher)	None	–	–	Present	Life-threatening sepsis (e.g., septic shock)
Dyspnea (shortness of breath)	None	–	Dyspnea on exertion	Dyspnea at normal level of activity	Dyspnea at rest or requiring ventilator support
Palpitation	None	Present	–	–	–
Myalgia (muscle pain)	None	Mild pain not interfering with function	Moderate: pain or analgesics interfering with function, but not with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Arthralgia (joint pain)	None	Mild pain not interfering with function	Moderate pain: pain or analgesics interfering with function, but not interfering with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Pain, other	None	Mild	Moderate	Severe	Disabling
Fatigue (includes lethargy, asthenia)	None	Increased fatigue over baseline, but not altering normal activities	Moderate (e.g., decrease in performance status by 1 ECOG level or 20% Karnofsky or Lansky) or causing difficulty performing some activities	Severe (e.g., decrease in performance status by 2 ECOG levels or 40% Karnofsky or Lansky) or loss of ability to perform some activities	Bedridden or disabling
Paresthesia	Normal	Loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	Objective sensory loss or paresthesia (including tingling), interfering with function, but not with activities of daily living	Sensory loss or paresthesia interfering with activities of daily living	Permanent sensory loss that interferes with function
Blurred vision	None	–	Symptomatic and interfering with function, but not interfering with activities of daily living	Symptomatic and interfering with activities of daily living	–
Taste disturbance	Normal	Slightly altered	Markedly altered	–	–
Increased lacrimation	Normal	Slightly altered	Markedly altered	–	–
Photosensitivity	None	Painless erythema	Painful erythema	Erythema with desquamation	–
Other:					
Other:					
Other:					
Hemoglobin	Normal	< normal – 100 g/L	80 – < 100 g/L	65 – 80 g/L	< 65 g/L
Leukocyte count	Normal	< normal – 3.0 x 10 ⁹ /L	2.0 – < 3.0 x 10 ⁹ /L	1.0 – < 2.0 x 10 ⁹ /L	< 1.0 x 10 ⁹ /L
Neutrophil count	Normal	1.5 – < 2.0 x 10 ⁹ /L	1.0 – < 1.5 x 10 ⁹ /L	0.5 – < 1.0 x 10 ⁹ /L	< 0.5 x 10 ⁹ /L
Platelets	Normal	< normal – < 75.0 x 10 ⁹ /L	50.0 – < 75.0 x 10 ⁹ /L	10.0 – < 50.0 x 10 ⁹ /L	< 10.0 x 10 ⁹ /L
Bilirubin	Normal	> normal – 1.5 x N	> 1.5 – 3.0 x N	> 3.0 – 10.0 x N	> 10.0 x N
AST	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
ALT	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
Alk Phos	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
LDH	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x
Hypoalbuminemia	Normal	<normal – 3 g/dl	≥2 – <3 g/dl	< 2 g/dl	–
Hypoproteinemia	None	Mild	Moderate	Severe	Life-threatening
Creatinine	Normal	> normal – 1.5 x N	> 1.5 – 3.0 x N	> 3.0 – 6.0 x N	> 6.0 x N

Arm 1: 12 months treatment

**SSG XVIII
Adverse Event
Follow-up. Month 3, week 12**

Form 5 B

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials

Rand. number

NCI/NIH Common Toxicity Criteria (*circle* the correct alternative)

	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Oedema, periorbital	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Oedema, leg	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Oedema, other	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Weight gain	< 5%	5 – <10%	10 – <20%	20%	–
Muscle cramps	None	Mild	Moderate	Severe	–
Vomiting	None	1 episode in 24 hours over pretreatment	2–5 episodes in 24 hours over pretreatment	6 episodes in 24 hours over pretreatment; or need for IV fluids	Requiring parenteral nutrition; or physiologic consequences requiring intensive care; hemodynamic collapse
Nausea	None	Able to eat	Oral intake significantly decreased	No significant intake, requiring IV fluids	–
Diarrhea	None	Increase of < 4 stools/day over pre-treatment	Increase of 4–6 stools/day, or nocturnal stools	Increase of 7 stools/day or incontinence; or need for parenteral support for dehydration	Physiologic consequences requiring intensive care; or hemodynamic collapse
Constipation	None	Requiring stool softener or dietary modification	Requiring laxatives	Obstipation requiring manual evacuation or enema	Obstruction or toxic megacolon
Fiatulence	None	Mild	Moderate	Severe	-
Dyspepsia/Heartburn	None	Mild	Moderate	Severe	-
Loose stools	None	Mild	Moderate	Severe	-
Abdominal distension	None	Mild	Moderate	Severe	-
Dysphagia	None	Mild dysphagia, but can eat regular diet	Dysphagia, requiring predominantly pureed, soft, or liquid diet	Dysphagia, requiring IV hydration	Requiring enteral or parenteral nutritional support or complete obstruction (cannot swallow saliva) or perforation
Headache	None	Mild pain not interfering with function	Moderate: pain or analgesics interfering with function, but not with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Dermatitis or rash	None	Macular or papular eruption or erythema without associated symptoms	Macular or papular eruption or erythema with pruritus or other associated symptoms covering <50% of body surface or localized desquamation or other lesions covering <50% of body surface area	Symptomatic generalized erythroderma or macular, papular or vesicular eruption or desquamation covering > 50% of body surface area	Generalized exfoliative dermatitis or ulcerative dermatitis
Pruritus	None	Mild or localized, relieved spontaneously or by local measures	Intense or widespread, relieved spontaneously or by systemic measures	Intense or widespread and poorly controlled despite treatment	–
Hemorrhage Specify site:	None	Mild without transfusion	–	Requiring transfusion	Catastrophic bleeding, requiring major non-elective intervention

Arm 1: 12 months treatment

**SSG XVIII
Adverse Event Form 5 B cont'd
Follow-up. Month 3, week 12**

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials

Rand. number

NCI/NIH Common Toxicity Criteria (circle the correct alternative)

	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Fever (no neutropenia, granulocyte count > 1.0 x 10 ⁹ /L)	None	38.0–39.0°C (100.4–102.2°F)	39.1–40.0°C (102.3–104.0°F)	> 40.0°C (>104.0°F) for < 24 hrs	> 40.0°C (>104.0°F) for > 24 hrs
Infection (no neutropenia)	None	Mild, no active treatment	Moderate, localized infection, requiring local or oral treatment	Severe, systemic infection, requiring IV antibiotic or antifungal treatment, or hospitalization	Life-threatening sepsis (e.g., septic shock)
Febrile neutropenia (neutrophil count < 1.0, fever 38.5°C or higher)	None	–	–	Present	Life-threatening sepsis (e.g., septic shock)
Dyspnea (shortness of breath)	None	–	Dyspnea on exertion	Dyspnea at normal level of activity	Dyspnea at rest or requiring ventilator support
Palpitation	None	Present	–	–	–
Myalgia (muscle pain)	None	Mild pain not interfering with function	Moderate: pain or analgesics interfering with function, but not with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Arthralgia (joint pain)	None	Mild pain not interfering with function	Moderate pain: pain or analgesics interfering with function, but not interfering with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Pain, other	None	Mild	Moderate	Severe	Disabling
Fatigue (includes lethargy, asthenia)	None	Increased fatigue over baseline, but not altering normal activities	Moderate (e.g., decrease in performance status by 1 ECOG level or 20% Karnofsky or Lansky) or causing difficulty performing some activities	Severe (e.g., decrease in performance status by 2 ECOG levels or 40% Karnofsky or Lansky) or loss of ability to perform some activities	Bedridden or disabling
Paresthesia	Normal	Loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	Objective sensory loss or paresthesia (including tingling), interfering with function, but not with activities of daily living	Sensory loss or paresthesia interfering with activities of daily living	Permanent sensory loss that interferes with function
Blurred vision	None	–	Symptomatic and interfering with function, but not interfering with activities of daily living	Symptomatic and interfering with activities of daily living	–
Taste disturbance	Normal	Slightly altered	Markedly altered	–	–
Increased lacrimation	Normal	Slightly altered	Markedly altered	–	–
Photosensitivity	None	Painless erythema	Painful erythema	Erythema with desquamation	–
Other:					
Other:					
Other:					
Hemoglobin	Normal	< normal – 100 g/L	80 – < 100 g/L	65 – 80 g/L	< 65 g/L
Leukocyte count	Normal	< normal – 3.0 x 10 ⁹ /L	2.0 – < 3.0 x 10 ⁹ /L	1.0 – < 2.0 x 10 ⁹ /L	< 1.0 x 10 ⁹ /L
Neutrophil count	Normal	1.5 – < 2.0 x 10 ⁹ /L	1.0 – < 1.5 x 10 ⁹ /L	0.5 – < 1.0 x 10 ⁹ /L	< 0.5 x 10 ⁹ /L
Platelets	Normal	< normal – < 75.0 x 10 ⁹ /L	50.0 – < 75.0 x 10 ⁹ /L	10.0 – < 50.0 x 10 ⁹ /L	< 10.0 x 10 ⁹ /L
Bilirubin	Normal	> normal – 1.5 x N	> 1.5 – 3.0 x N	> 3.0 – 10.0 x N	> 10.0 x N
AST	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
ALT	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
Alk Phos	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
LDH	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x
Hypoalbuminemia	Normal	<normal – 3 g/dl	≥2 – <3 g/dl	< 2 g/dl	–
Hypoproteinemia	None	Mild	Moderate	Severe	Life-threatening
Creatinine	Normal	> normal – 1.5 x N	> 1.5 – 3.0 x N	> 3.0 – 6.0 x N	> 6.0 x N

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 6, week 24 **Form 6 A**

Send this form to:
 SSG secretariat
 Regional Tumor Registry
 Lund University Hospital
 SE-221 85 LUND, Sweden

Patient Initials

Rand. number

Visit date Day Month Year

Current status

Alive, no recurrence

Alive, GIST recurred – **complete the GIST recurrence form**

Dead – **complete the End of study form**

Exams

Weight kg

ECOG PS: 0 1 2 3 4 5

CT/MRI No Yes

Research serum/blood No Yes

Study medication - only to be completed if patient was treated with imatinib within the study since last visit

Current dose of imatinib within the study mg/day

Therapy interruption(s) of imatinib within the study since last visit: From Day Month Year to Day Month Year

From Day Month Year to Day Month Year

Reason for therapy interruption(s): Adverse effect, specify.....
 Other reason, specify

Date(s) when dose of imatinib within the study was reduced since last visit: From Day Month Year to Day Month Year

From Day Month Year to Day Month Year

Reason for dose reduction: Adverse effect, specify.....
 Other reason, specify

Please fill in the End of treatment form if the patient discontinued the imatinib treatment assigned according to the protocol.

Please fill in the Complication log if patient was diagnosed with a heart disease or a second cancer since the study treatment was initiated.

NOTE! Please fill in the adverse event form.

Arm 1: 12 months treatment

SSG XVIII Adverse Event Follow-up. Month 6, week 24	Form 6 B
Send this form to: SSG secretariat Regional Tumor Registry Lund University Hospital SE-221 85 LUND, Sweden	Patient Initials <input style="width: 40px;" type="text"/> <input style="width: 40px;" type="text"/> <input style="width: 40px;" type="text"/> Rand. number <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>

NCI/NIH Common Toxicity Criteria (*circle* the correct alternative)

	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Oedema, periorbital	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Oedema, leg	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Oedema, other	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Weight gain	< 5%	5 – <10%	10 – <20%	20%	–
Muscle cramps	None	Mild	Moderate	Severe	–
Vomiting	None	1 episode in 24 hours over pretreatment	2–5 episodes in 24 hours over pretreatment	6 episodes in 24 hours over pretreatment; or need for IV fluids	Requiring parenteral nutrition; or physiologic consequences requiring intensive care; hemodynamic collapse
Nausea	None	Able to eat	Oral intake significantly decreased	No significant intake, requiring IV fluids	–
Diarrhea	None	Increase of < 4 stools/day over pre-treatment	Increase of 4–6 stools/day, or nocturnal stools	Increase of 7 stools/day or incontinence; or need for parenteral support for dehydration	Physiologic consequences requiring intensive care; or hemodynamic collapse
Constipation	None	Requiring stool softener or dietary modification	Requiring laxatives	Obstipation requiring manual evacuation or enema	Obstruction or toxic megacolon
Flatulence	None	Mild	Moderate	Severe	-
Dyspepsia/Heartburn	None	Mild	Moderate	Severe	-
Loose stools	None	Mild	Moderate	Severe	-
Abdominal distension	None	Mild	Moderate	Severe	-
Dysphagia	None	Mild dysphagia, but can eat regular diet	Dysphagia, requiring predominantly pureed, soft, or liquid diet	Dysphagia, requiring IV hydration	Requiring enteral or parenteral nutritional support or complete obstruction (cannot swallow saliva) or perforation
Headache	None	Mild pain not interfering with function	Moderate: pain or analgesics interfering with function, but not with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Dermatitis or rash	None	Macular or papular eruption or erythema without associated symptoms	Macular or papular eruption or erythema with pruritus or other associated symptoms covering <50% of body surface or localized desquamation or other lesions covering <50% of body surface area	Symptomatic generalized erythroderma or macular, papular or vesicular eruption or desquamation covering > 50% of body surface area	Generalized exfoliative dermatitis or ulcerative dermatitis
Pruritus	None	Mild or localized, relieved spontaneously or by local measures	Intense or widespread, relieved spontaneously or by systemic measures	Intense or widespread and poorly controlled despite treatment	–
Hemorrhage Specify site:	None	Mild without transfusion	–	Requiring transfusion	Catastrophic bleeding, requiring major non-elective intervention

Arm 1: 12 months treatment

**SSG XVIII
Adverse Event Form 6 B cont'd
Follow-up. Month 6, week 24**

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials

Rand. number

NCI/NIH Common Toxicity Criteria (circle the correct alternative)

	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Fever (no neutropenia, granulocyte count > 1.0 x 10 ⁹ /L)	None	38.0–39.0°C (100.4–102.2°F)	39.1–40.0°C (102.3–104.0°F)	> 40.0°C (>104.0°F) for < 24 hrs	> 40.0°C (>104.0°F) for > 24 hrs
Infection (no neutropenia)	None	Mild, no active treatment	Moderate, localized infection, requiring local or oral treatment	Severe, systemic infection, requiring IV antibiotic or antifungal treatment, or hospitalization	Life-threatening sepsis (e.g., septic shock)
Febrile neutropenia (neutrophil count < 1.0, fever 38.5°C or higher)	None	–	–	Present	Life-threatening sepsis (e.g., septic shock)
Dyspnea (shortness of breath)	None	–	Dyspnea on exertion	Dyspnea at normal level of activity	Dyspnea at rest or requiring ventilator support
Palpitation	None	Present	–	–	–
Myalgia (muscle pain)	None	Mild pain not interfering with function	Moderate: pain or analgesics interfering with function, but not with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Arthralgia (joint pain)	None	Mild pain not interfering with function	Moderate pain: pain or analgesics interfering with function, but not interfering with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Pain, other	None	Mild	Moderate	Severe	Disabling
Fatigue (includes lethargy, asthenia)	None	Increased fatigue over baseline, but not altering normal activities	Moderate (e.g., decrease in performance status by 1 ECOG level or 20% Karnofsky or Lansky) or causing difficulty performing some activities	Severe (e.g., decrease in performance status by 2 ECOG levels or 40% Karnofsky or Lansky) or loss of ability to perform some activities	Bedridden or disabling
Paresthesia	Normal	Loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	Objective sensory loss or paresthesia (including tingling), interfering with function, but not with activities of daily living	Sensory loss or paresthesia interfering with activities of daily living	Permanent sensory loss that interferes with function
Blurred vision	None	–	Symptomatic and interfering with function, but not interfering with activities of daily living	Symptomatic and interfering with activities of daily living	–
Taste disturbance	Normal	Slightly altered	Markedly altered	–	–
Increased lacrimation	Normal	Slightly altered	Markedly altered	–	–
Photosensitivity	None	Painless erythema	Painful erythema	Erythema with desquamation	–
Other:					
Other:					
Other:					
Hemoglobin	Normal	< normal – 100 g/L	80 – < 100 g/L	65 – 80 g/L	< 65 g/L
Leukocyte count	Normal	< normal – 3.0 x 10 ⁹ /L	2.0 – < 3.0 x 10 ⁹ /L	1.0 – < 2.0 x 10 ⁹ /L	< 1.0 x 10 ⁹ /L
Neutrophil count	Normal	1.5 – < 2.0 x 10 ⁹ /L	1.0 – < 1.5 x 10 ⁹ /L	0.5 – < 1.0 x 10 ⁹ /L	< 0.5 x 10 ⁹ /L
Platelets	Normal	< normal – < 75.0 x 10 ⁹ /L	50.0 – < 75.0 x 10 ⁹ /L	10.0 – < 50.0 x 10 ⁹ /L	< 10.0 x 10 ⁹ /L
Bilirubin	Normal	> normal – 1.5 x N	> 1.5 – 3.0 x N	> 3.0 – 10.0 x N	> 10.0 x N
AST	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
ALT	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
Alk Phos	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
LDH	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x
Hypoalbuminemia	Normal	<normal – 3 g/dl	≥2 – <3 g/dl	< 2 g/dl	–
Hypoproteinemia	None	Mild	Moderate	Severe	Life-threatening
Creatinine	Normal	> normal – 1.5 x N	> 1.5 – 3.0 x N	> 3.0 – 6.0 x N	> 6.0 x N

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 9, week 36 **Form 7 A**

Send this form to:
 SSG secretariat
 Regional Tumor Registry
 Lund University Hospital
 SE-221 85 LUND, Sweden

Patient Initials

Rand. number

Visit date Day Month Year

Current status

Alive, no recurrence

Alive, GIST recurred – **complete the GIST recurrence form**

Dead – **complete the End of study form**

Exams

Weight kg

ECOG PS: 0 1 2 3 4 5

Study medication - only to be completed if patient was treated with imatinib within the study since last visit

Current dose of imatinib within the study mg/day

Therapy interruption(s) of imatinib within the study since last visit: From to

From to

Reason for therapy interruption(s): Adverse effect, specify.....
 Other reason, specify

Date(s) when dose of imatinib within the study was reduced since last visit: From to

From to

Reason for dose reduction: Adverse effect, specify.....
 Other reason, specify

Please fill in the End of treatment form if the patient discontinued the imatinib treatment assigned according to the protocol.

Please fill in the Complication log if patient was diagnosed with a heart disease or a second cancer since the study treatment was initiated.

NOTE! Please fill in the adverse event form.

Arm 1: 12 months treatment

**SSG XVIII
Adverse Event
Follow-up. Month 9, week 36**

Form 7 B

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials

Rand. number

NCI/NIH Common Toxicity Criteria (circle the correct alternative)

	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Oedema, periorbital	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Oedema, leg	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Oedema, other	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Weight gain	< 5%	5 – <10%	10 – <20%	20%	–
Muscle cramps	None	Mild	Moderate	Severe	–
Vomiting	None	1 episode in 24 hours over pretreatment	2–5 episodes in 24 hours over pretreatment	6 episodes in 24 hours over pretreatment; or need for IV fluids	Requiring parenteral nutrition; or physiologic consequences requiring intensive care; hemodynamic collapse
Nausea	None	Able to eat	Oral intake significantly decreased	No significant intake, requiring IV fluids	–
Diarrhea	None	Increase of < 4 stools/day over pre-treatment	Increase of 4–6 stools/day, or nocturnal stools	Increase of 7 stools/day or incontinence; or need for parenteral support for dehydration	Physiologic consequences requiring intensive care; or hemodynamic collapse
Constipation	None	Requiring stool softener or dietary modification	Requiring laxatives	Obstipation requiring manual evacuation or enema	Obstruction or toxic megacolon
Fiatulence	None	Mild	Moderate	Severe	-
Dyspepsia/Heartburn	None	Mild	Moderate	Severe	-
Loose stools	None	Mild	Moderate	Severe	-
Abdominal distension	None	Mild	Moderate	Severe	-
Dysphagia	None	Mild dysphagia, but can eat regular diet	Dysphagia, requiring predominantly pureed, soft, or liquid diet	Dysphagia, requiring IV hydration	Requiring enteral or parenteral nutritional support or complete obstruction (cannot swallow saliva) or perforation
Headache	None	Mild pain not interfering with function	Moderate: pain or analgesics interfering with function, but not with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Dermatitis or rash	None	Macular or papular eruption or erythema without associated symptoms	Macular or papular eruption or erythema with pruritus or other associated symptoms covering <50% of body surface or localized desquamation or other lesions covering <50% of body surface area	Symptomatic generalized erythroderma or macular, papular or vesicular eruption or desquamation covering > 50% of body surface area	Generalized exfoliative dermatitis or ulcerative dermatitis
Pruritus	None	Mild or localized, relieved spontaneously or by local measures	Intense or widespread, relieved spontaneously or by systemic measures	Intense or widespread and poorly controlled despite treatment	–
Hemorrhage Specify site:	None	Mild without transfusion	–	Requiring transfusion	Catastrophic bleeding, requiring major non-elective intervention

Arm 1: 12 months treatment

SSG XVIII
Adverse Event **Form 7 B cont'd**
Follow-up. Month 9, week 36

Send this form to:
 SSG secretariat
 Regional Tumor Registry
 Lund University Hospital
 SE-221 85 LUND, Sweden

Patient Initials

Rand. number

NCI/NIH Common Toxicity Criteria (circle the correct alternative)

	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Fever (no neutropenia, granulocyte count > 1.0 x 10 ⁹ /L)	None	38.0–39.0°C (100.4–102.2°F)	39.1–40.0°C (102.3–104.0°F)	> 40.0°C (>104.0°F) for < 24 hrs	> 40.0°C (>104.0°F) for > 24 hrs
Infection (no neutropenia)	None	Mild, no active treatment	Moderate, localized infection, requiring local or oral treatment	Severe, systemic infection, requiring IV antibiotic or antifungal treatment, or hospitalization	Life-threatening sepsis (e.g., septic shock)
Febrile neutropenia (neutrophil count < 1.0, fever 38.5°C or higher)	None	–	–	Present	Life-threatening sepsis (e.g., septic shock)
Dyspnea (shortness of breath)	None	–	Dyspnea on exertion	Dyspnea at normal level of activity	Dyspnea at rest or requiring ventilator support
Palpitation	None	Present	–	–	–
Myalgia (muscle pain)	None	Mild pain not interfering with function	Moderate: pain or analgesics interfering with function, but not with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Arthralgia (joint pain)	None	Mild pain not interfering with function	Moderate pain: pain or analgesics interfering with function, but not interfering with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Pain, other	None	Mild	Moderate	Severe	Disabling
Fatigue (includes lethargy, asthenia)	None	Increased fatigue over baseline, but not altering normal activities	Moderate (e.g., decrease in performance status by 1 ECOG level or 20% Karnofsky or Lansky) or causing difficulty performing some activities	Severe (e.g., decrease in performance status by 2 ECOG levels or 40% Karnofsky or Lansky) or loss of ability to perform some activities	Bedridden or disabling
Paresthesia	Normal	Loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	Objective sensory loss or paresthesia (including tingling), interfering with function, but not with activities of daily living	Sensory loss or paresthesia interfering with activities of daily living	Permanent sensory loss that interferes with function
Blurred vision	None	–	Symptomatic and interfering with function, but not interfering with activities of daily living	Symptomatic and interfering with activities of daily living	–
Taste disturbance	Normal	Slightly altered	Markedly altered	–	–
Increased lacrimation	Normal	Slightly altered	Markedly altered	–	–
Photosensitivity	None	Painless erythema	Painful erythema	Erythema with desquamation	–
Other:					
Other:					
Other:					
Hemoglobin	Normal	< normal – 100 g/L	80 – < 100 g/L	65 – 80 g/L	< 65 g/L
Leukocyte count	Normal	< normal – 3.0 x 10 ⁹ /L	2.0 – < 3.0 x 10 ⁹ /L	1.0 – < 2.0 x 10 ⁹ /L	< 1.0 x 10 ⁹ /L
Neutrophil count	Normal	1.5 – < 2.0 x 10 ⁹ /L	1.0 – < 1.5 x 10 ⁹ /L	0.5 – < 1.0 x 10 ⁹ /L	< 0.5 x 10 ⁹ /L
Platelets	Normal	< normal – < 75.0 x 10 ⁹ /L	50.0 – < 75.0 x 10 ⁹ /L	10.0 – < 50.0 x 10 ⁹ /L	< 10.0 x 10 ⁹ /L
Bilirubin	Normal	> normal – 1.5 x N	> 1.5 – 3.0 x N	> 3.0 – 10.0 x N	> 10.0 x N
AST	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
ALT	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
Alk Phos	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
LDH	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x
Hypoalbuminemia	Normal	<normal – 3 g/dl	≥2 – <3 g/dl	< 2 g/dl	–
Hypoproteinemia	None	Mild	Moderate	Severe	Life-threatening
Creatinine	Normal	> normal – 1.5 x N	> 1.5 – 3.0 x N	> 3.0 – 6.0 x N	> 6.0 x N

Arm 1: 12 months treatment

SSG XVIII
Adverse Event
Form 8 B
Follow-up. Month 12, week 52

Send this form to:
 SSG secretariat
 Regional Tumor Registry
 Lund University Hospital
 SE-221 85 LUND, Sweden

Patient Initials

Rand. number

NCI/NIH Common Toxicity Criteria (circle the correct alternative)

	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Oedema, periorbital	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Oedema, leg	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Oedema, other	None	Asymptomatic, not requiring therapy	Symptomatic, requiring therapy	Symptomatic edema limiting function and unresponsive to therapy or requiring drug discontinuation	Anasarca (severe generalized edema)
Weight gain	< 5%	5 – <10%	10 – <20%	20%	–
Muscle cramps	None	Mild	Moderate	Severe	–
Vomiting	None	1 episode in 24 hours over pretreatment	2–5 episodes in 24 hours over pretreatment	6 episodes in 24 hours over pretreatment; or need for IV fluids	Requiring parenteral nutrition; or physiologic consequences requiring intensive care; hemodynamic collapse
Nausea	None	Able to eat	Oral intake significantly decreased	No significant intake, requiring IV fluids	–
Diarrhea	None	Increase of < 4 stools/day over pre-treatment	Increase of 4–6 stools/day, or nocturnal stools	Increase of 7 stools/day or incontinence; or need for parenteral support for dehydration	Physiologic consequences requiring intensive care; or hemodynamic collapse
Constipation	None	Requiring stool softener or dietary modification	Requiring laxatives	Obstipation requiring manual evacuation or enema	Obstruction or toxic megacolon
Fiatulence	None	Mild	Moderate	Severe	-
Dyspepsia/Heartburn	None	Mild	Moderate	Severe	-
Loose stools	None	Mild	Moderate	Severe	-
Abdominal distension	None	Mild	Moderate	Severe	-
Dysphagia	None	Mild dysphagia, but can eat regular diet	Dysphagia, requiring predominantly pureed, soft, or liquid diet	Dysphagia, requiring IV hydration	Requiring enteral or parenteral nutritional support or complete obstruction (cannot swallow saliva) or perforation
Headache	None	Mild pain not interfering with function	Moderate: pain or analgesics interfering with function, but not with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Dermatitis or rash	None	Macular or papular eruption or erythema without associated symptoms	Macular or papular eruption or erythema with pruritus or other associated symptoms covering <50% of body surface or localized desquamation or other lesions covering <50% of body surface area	Symptomatic generalized erythroderma or macular, papular or vesicular eruption or desquamation covering > 50% of body surface area	Generalized exfoliative dermatitis or ulcerative dermatitis
Pruritus	None	Mild or localized, relieved spontaneously or by local measures	Intense or widespread, relieved spontaneously or by systemic measures	Intense or widespread and poorly controlled despite treatment	–
Hemorrhage Specify site:	None	Mild without transfusion	–	Requiring transfusion	Catastrophic bleeding, requiring major non-elective intervention

Arm 1: 12 months treatment

SSG XVIII Adverse Event Follow-up. Month 12, week 52	Form 8 B cont´d Patient Initials <input style="width: 50px;" type="text"/> <input style="width: 50px;" type="text"/> <input style="width: 50px;" type="text"/> Rand. number <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>
Send this form to: SSG secretariat Regional Tumor Registry Lund University Hospital SE-221 85 LUND, Sweden	

NCI/NIH Common Toxicity Criteria (*circle* the correct alternative)

	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Fever (no neutropenia, granulocyte count > 1.0 x 10 ⁹ /L)	None	38.0–39.0°C (100.4–102.2°F)	39.1–40.0°C (102.3–104.0°F)	> 40.0°C (>104.0°F) for < 24 hrs	> 40.0°C (>104.0°F) for > 24 hrs
Infection (no neutropenia)	None	Mild, no active treatment	Moderate, localized infection, requiring local or oral treatment	Severe, systemic infection, requiring IV antibiotic or antifungal treatment, or hospitalization	Life-threatening sepsis (e.g., septic shock)
Febrile neutropenia (neutrophil count < 1.0, fever 38,5°C or higher)	None	–	–	Present	Life-threatening sepsis (e.g., septic shock)
Dyspnea (shortness of breath)	None	–	Dyspnea on exertion	Dyspnea at normal level of activity	Dyspnea at rest or requiring ventilator support
Palpitation	None	Present	–	–	–
Myalgia (muscle pain)	None	Mild pain not interfering with function	Moderate: pain or analgesics interfering with function, but not with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Arthralgia (joint pain)	None	Mild pain not interfering with function	Moderate pain: pain or analgesics interfering with function, but not interfering with activities of daily living	Severe pain: pain or analgesics severely interfering with activities of daily living	Disabling
Pain, other	None	Mild	Moderate	Severe	Disabling
Fatigue (includes lethargy, asthenia)	None	Increased fatigue over baseline, but not altering normal activities	Moderate (e.g., decrease in performance status by 1 ECOG level <u>or</u> 20% Karnofsky <u>or Lansky</u>) <u>or</u> causing difficulty performing some activities	Severe (e.g., decrease in performance status by 2 ECOG levels <u>or</u> 40% Karnofsky <u>or Lansky</u>) <u>or</u> loss of ability to perform some activities	Bedridden or disabling
Paresthesia	Normal	Loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	Objective sensory loss or paresthesia (including tingling), interfering with function, but not with activities of daily living	Sensory loss or paresthesia interfering with activities of daily living	Permanent sensory loss that interferes with function
Blurred vision	None	–	Symptomatic and interfering with function, but not interfering with activities of daily living	Symptomatic and interfering with activities of daily living	–
Taste disturbance	Normal	Slightly altered	Markedly altered	–	–
Increased lacrimation	Normal	Slightly altered	Markedly altered	–	–
Photosensitivity	None	Painless erythema	Painful erythema	Erythema with desquamation	–
Other:					
Other:					
Other:					
Hemoglobin	Normal	< normal – 100 g/L	80 – < 100 g/L	65 – 80 g/L	< 65 g/L
Leukocyte count	Normal	< normal – 3.0 x 10 ⁹ /L	2.0 – < 3.0 x 10 ⁹ /L	1.0 – < 2.0 x 10 ⁹ /L	< 1.0 x 10 ⁹ /L
Neutrophil count	Normal	1.5 – < 2.0 x 10 ⁹ /L	1.0 – < 1.5 x 10 ⁹ /L	0.5 – < 1.0 x 10 ⁹ /L	< 0.5 x 10 ⁹ /L
Platelets	Normal	< normal – < 75.0 x 10 ⁹ /L	50.0 – < 75.0 x 10 ⁹ /L	10.0 – < 50.0 x 10 ⁹ /L	< 10.0 x 10 ⁹ /L
Bilirubin	Normal	> normal – 1.5 x N	> 1.5 – 3.0 x N	> 3.0 – 10.0 x N	> 10.0 x N
AST	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
ALT	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
Alk Phos	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x N
LDH	Normal	> normal – 2.5 x N	> 2.5 – 5.0 x N	> 5.0 – 20.0 x N	> 20.0 x
Hypoalbuminemia	Normal	<normal – 3 g/dl	≥2 – <3 g/dl	< 2 g/dl	–
Hypoproteinemia	None	Mild	Moderate	Severe	Life-threatening
Creatinine	Normal	> normal – 1.5 x N	> 1.5 – 3.0 x N	> 3.0 – 6.0 x N	> 6.0 x N

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 15 Form 9

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ ___ ___

Rand. number [][][][]

Visit date Day Month Year
[][] [][] [][][]

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight [][][] kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII

Follow-up. Month 18

Form 10

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ _ _

Rand. number [][][][]

Visit date Day Month Year
[][] [][] [][][]

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight [][][][] kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
CT/MRI <input type="checkbox"/> No <input type="checkbox"/> Yes
Research serum/blood <input type="checkbox"/> No <input type="checkbox"/> Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 21

Form 11

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ _ _

Rand. number [][][][]

Visit date Day Month Year
[][] [][] [][][]

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight [][][] kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 24

Form 12

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ ___ ___

Rand. number [][][][][]

Visit date Day Month Year
[][][][][][][][][]

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight [][][][] kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
CT/MRI <input type="checkbox"/> No <input type="checkbox"/> Yes
Research serum/blood <input type="checkbox"/> No <input type="checkbox"/> Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 27

Form 13

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ _ _

Rand. number [][][][]

Visit date Day Month Year
[][] [][] [][][]

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight [][][] kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII

Follow-up. Month 30

Form 14

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ ___ ___

Rand. number [][][][]

Visit date Day Month Year
[][] [][] [][][]

Current status

Alive, no recurrence

Alive, GIST recurred – **complete the GIST recurrence form**

Dead – **complete the End of study form**

Exams

Weight [][][][] kg

ECOG PS: 0 1 2 3 4 5

CT/MRI No Yes

Research serum/blood No Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII

Follow-up. Month 33

Form 15

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ ___ ___

Rand. number [][][][]

Visit date Day Month Year
[][] [][] [][][]

Current status

Alive, no recurrence

Alive, GIST recurred – **complete the GIST recurrence form**

Dead – **complete the End of study form**

Exams

Weight [][][][] kg

ECOG PS: 0 1 2 3 4 5

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 36

Form 16

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ _ _

Rand. number [][][][]

Visit date Day Month Year
[][] [][] [][][]

Current status

Alive, no recurrence

Alive, GIST recurred – **complete the GIST recurrence form**

Dead – **complete the End of study form**

Exams

Weight [][][][] kg

ECOG PS: 0 1 2 3 4 5

CT/MRI No Yes

Research serum/blood No Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

SSG XVIII
Follow-up. Month 42

Form 17

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ _ _

Rand. number [][][][]

Visit date Day Month Year
[][] [][] [][][]

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight [][][] kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
CT/MRI <input type="checkbox"/> No <input type="checkbox"/> Yes
Research serum/blood <input type="checkbox"/> No <input type="checkbox"/> Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

SSG XVIII
Follow-up. Month 48 **Form 18**

Send this form to:
 SSG secretariat
 Regional Tumor Registry
 Lund University Hospital
 SE-221 85 LUND, Sweden

Patient Initials

Rand. number

Visit date Day Month Year

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
CT/MRI <input type="checkbox"/> No <input type="checkbox"/> Yes
Research serum/blood <input type="checkbox"/> No <input type="checkbox"/> Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

SSG XVIII
Follow-up. Month 54 **Form 19**

Send this form to:
 SSG secretariat
 Regional Tumor Registry
 Lund University Hospital
 SE-221 85 LUND, Sweden

Patient Initials

Rand. number

Visit date Day Month Year

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight <input type="text"/> <input type="text"/> <input type="text"/> kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
CT/MRI <input type="checkbox"/> No <input type="checkbox"/> Yes
Research serum/blood <input type="checkbox"/> No <input type="checkbox"/> Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 60 **Form 20**

Send this form to:
 SSG secretariat
 Regional Tumor Registry
 Lund University Hospital
 SE-221 85 LUND, Sweden

Patient Initials

Rand. number

Visit date Day Month Year

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight <input type="text"/> <input type="text"/> <input type="text"/> kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
CT/MRI <input type="checkbox"/> No <input type="checkbox"/> Yes
Research serum/blood <input type="checkbox"/> No <input type="checkbox"/> Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 66

Form 21

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ _ _

Rand. number [][][][]

Visit date Day Month Year
[][] [][] [][][]

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight [][][][] kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
CT/MRI <input type="checkbox"/> No <input type="checkbox"/> Yes
Research serum/blood <input type="checkbox"/> No <input type="checkbox"/> Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII

Follow-up. Month 72

Form 22

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ _ _

Rand. number

Visit date Day Month Year

Current status

Alive, no recurrence

Alive, GIST recurred – **complete the GIST recurrence form**

Dead – **complete the End of study form**

Exams

Weight kg

ECOG PS: 0 1 2 3 4 5

CT/MRI No Yes

Research serum/blood No Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 78

Form 23

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ ___ ___

Rand. number [][][][]

Visit date Day Month Year
[][] [][] [][][]

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight [][][] kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
CT/MRI <input type="checkbox"/> No <input type="checkbox"/> Yes
Research serum/blood <input type="checkbox"/> No <input type="checkbox"/> Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 84 Form 24

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials

Rand. number

Visit date Day Month Year

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight <input type="text"/> <input type="text"/> <input type="text"/> kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
CT/MRI <input type="checkbox"/> No <input type="checkbox"/> Yes
Research serum/blood <input type="checkbox"/> No <input type="checkbox"/> Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 96 Form 25

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials

Rand. number

Visit date Day Month Year

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight <input type="text"/> <input type="text"/> <input type="text"/> kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
CT/MRI <input type="checkbox"/> No <input type="checkbox"/> Yes
Research serum/blood <input type="checkbox"/> No <input type="checkbox"/> Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 108 **Form 26**

Send this form to:
 SSG secretariat
 Regional Tumor Registry
 Lund University Hospital
 SE-221 85 LUND, Sweden

Patient Initials

Rand. number

Visit date Day Month Year

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight <u> </u> <u> </u> <u> </u> kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
CT/MRI <input type="checkbox"/> No <input type="checkbox"/> Yes
Research serum/blood <input type="checkbox"/> No <input type="checkbox"/> Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 120 Form 27

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials

Rand. number

Visit date Day Month Year

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight <input type="text"/> <input type="text"/> <input type="text"/> kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
CT/MRI <input type="checkbox"/> No <input type="checkbox"/> Yes
Research serum/blood <input type="checkbox"/> No <input type="checkbox"/> Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII
Follow-up. Month 132 Form 28

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials ___ ___ ___

Rand. number [][][][]

Visit date Day Month Year
[][] [][] [][][][]

Current status

<input type="checkbox"/> Alive, no recurrence
<input type="checkbox"/> Alive, GIST recurred – complete the GIST recurrence form
<input type="checkbox"/> Dead – complete the End of study form

Exams

Weight [][][] kg
ECOG PS: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
CT/MRI <input type="checkbox"/> No <input type="checkbox"/> Yes
Research serum/blood <input type="checkbox"/> No <input type="checkbox"/> Yes

Please fill in the Complication log if patient was diagnosed with a new heart disease or a second cancer since the last follow-up visit.

Arm 1: 12 months treatment

SSG XVIII
End of treatment

Form 29

Send this form to:
 SSG secretariat
 Regional Tumor Registry
 Lund University Hospital
 SE-221 85 LUND, Sweden

Patient Initials

Rand. number

Complete this form after discontinuation of assigned imatinib treatment according to the protocol

	Day	Month	Year
Date for discontinuation of assigned imatinib treatment according to the protocol	<input type="text"/>	<input type="text"/>	<input type="text"/>
Reason for discontinuation of assigned imatinib treatment according to the protocol:			
<input type="checkbox"/> Completed assigned therapy			
<input type="checkbox"/> GIST recurrence			
<input type="checkbox"/> Adverse effects/lab values, specify.....			
<input type="checkbox"/> Patient wished to discontinue adjuvant imatinib			
<input type="checkbox"/> Patient withdrew consent			
<input type="checkbox"/> Death			
<input type="checkbox"/> Other, specify.....			

Treated with imatinib after discontinuation of assigned imatinib treatment according to the protocol			<input type="checkbox"/> No	<input type="checkbox"/> Yes
If Yes, specify reason for treatment with imatinib after discontinuation of assigned imatinib treatment according to the protocol:				
	Day	Month	Year	
<input type="checkbox"/> Adjuvant treatment*: Start date	<input type="text"/>	<input type="text"/>	<input type="text"/>	
	Discontinuation date	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Reason for discontinuation:		
<input type="checkbox"/> GIST recurrence – complete the GIST recurrence form				

*Adjuvant imatinib **must not** be continued after the assigned time period (either 12 or 36 months). The subjects who were rendered free from overt metastases by surgery are an exception and may continue adjuvant imatinib beyond 12/36 months. This alternative concerns these patients only.

Arm 1: 12 months treatment

**SSG XVIII
Complication log** **Form 30**

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials

Rand. number

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Complete this form continuously and send it to the SSG secretariat at the end of study (or earlier upon request)

Cardiac event (report one cardiac event per row)	Date of diagnosis				
	Day Month Year				
1. <input type="checkbox"/> Myocardial infarction <input type="checkbox"/> Cardiac failure <input type="checkbox"/> Coronary artery disease <input type="checkbox"/> Other cardiac disease, specify	<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>				
2. <input type="checkbox"/> Myocardial infarction <input type="checkbox"/> Cardiac failure <input type="checkbox"/> Coronary artery disease <input type="checkbox"/> Other cardiac disease, specify	<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>				
3. <input type="checkbox"/> Myocardial infarction <input type="checkbox"/> Cardiac failure <input type="checkbox"/> Coronary artery disease <input type="checkbox"/> Other cardiac disease, specify	<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>				
4. <input type="checkbox"/> Myocardial infarction <input type="checkbox"/> Cardiac failure <input type="checkbox"/> Coronary artery disease <input type="checkbox"/> Other cardiac disease, specify	<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>				
5. <input type="checkbox"/> Myocardial infarction <input type="checkbox"/> Cardiac failure <input type="checkbox"/> Coronary artery disease <input type="checkbox"/> Other cardiac disease, specify	<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>				

Later cancer diseases (other than GIST)	Date of diagnosis				
	Day Month Year				
1. Specification of cancer.....	<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>				
2. Specification of cancer.....	<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>				
3. Specification of cancer.....	<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>				

Please fill in below before the form is sent to the SSG secretariat:

<p>First time: No complications (tick if no complications are registered in the log) <input type="checkbox"/> Day Month Year</p> <p>Latest contact with patient: <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table></p> <p>Patient reached end of study <input type="checkbox"/> No <input type="checkbox"/> Yes – fill in the End of study form</p> <p>Second time (only to be completed if patient reached the end of study after the form was sent the first time): No complications after the form was sent the first time (tick if no new complications are registered in the log) <input type="checkbox"/> Day Month Year</p> <p>Latest contact with patient: <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table></p>								

Arm 1: 12 months treatment

**SSG XVIII
End of study**

Form 31

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials _____

Rand. number

Complete this form at end of study, i.e. after last follow-up contact with the patient

	Day	Month	Year
Date for last follow-up contact	<input type="text"/>	<input type="text"/>	<input type="text"/>

Treated with imatinib after discontinuation of assigned imatinib treatment according to the protocol No Yes
 If Yes, specify reason for treatment with imatinib after discontinuation of assigned imatinib treatment according to the protocol:

	Day	Month	Year
<input type="checkbox"/> Adjuvant treatment*: Start date	<input type="text"/>	<input type="text"/>	<input type="text"/>
Discontinuation date	<input type="text"/>	<input type="text"/>	<input type="text"/>
Reason for discontinuation:		

GIST recurrence – **complete the GIST recurrence form**

*Adjuvant imatinib **must not** be continued after the assigned time period (either 12 or 36 months). The subjects who were rendered free from overt metastases by surgery are an exception and may continue adjuvant imatinib beyond 12/36 months. This alternative concerns these patients only.

Status at End of Study, i.e. last follow-up contact with the patient (fill in one or more items):

Alive, no GIST recurrence

Alive, GIST recurrence – **complete the GIST recurrence form**

Alive with cancer other than GIST – **complete the Complication log**

Lost to follow-up

Patient withdrew consent

	Day	Month	Year
<input type="checkbox"/> Dead; Date of death	<input type="text"/>	<input type="text"/>	<input type="text"/>

Cause of death GIST Other cause of death, specify.....

Autopsy performed No Yes

Don't forget to fill in the Complication log and the Investigator confirmation form.

Arm 1: 12 months treatment

**SSG XVIII
GIST Recurrence**

Form 32

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials _____

Rand. number [][][][][][]

This form should only be completed in case of GIST recurrence

Date of GIST recurrence: [][][][][][][][][]
Day Month Year

Recurrence site(s):
 Liver Abdominal cavity Lung Bone Other, specify.....

Serum sample taken at tumor recurrence No Yes

Tumor tissue sample taken from recurrent GIST No Yes

First-line systemic therapy for recurrent GIST

Type of systemic therapy given for recurrence None Imatinib Other, specify.....

Date of initiation of systemic therapy given for first GIST recurrence: [][][][][][][][][]
Day Month Year

Starting dose of systemic therapy given for first GIST recurrence: _____/day
Unit

Best response to systemic therapy given for recurrence:
 CR PR SD PD Not evaluable Unknown

Highest dose of systemic therapy given for recurrent GIST before disease progression: _____/day
Unit

Date of progression after first-line systemic therapy given for recurrent GIST: [][][][][][][][][]
Day Month Year

Date of discontinuation of first-line systemic therapy given for recurrent GIST: [][][][][][][][][]
Day Month Year

Systemic therapy dose escalated at disease progression No Yes, specify _____/day
Unit

Date of dose escalation of first-line systemic therapy given for recurrent GIST: [][][][][][][][][]
Day Month Year

Second-line systemic therapy for recurrent GIST None

Specification of second-line systemic therapy given for recurrent GIST

Date of initiation of second-line systemic therapy given for recurrent GIST: [][][][][][][][][]
Day Month Year

Date of discontinuation of second-line systemic therapy given for recurrent GIST: [][][][][][][][][]
Day Month Year

Third-line systemic therapy for recurrent GIST None

Specification of third-line systemic therapy given for recurrent GIST

Date of initiation of third-line systemic therapy given for recurrent GIST: [][][][][][][][][]
Day Month Year

Date of discontinuation of third-line systemic therapy given for recurrent GIST: [][][][][][][][][]
Day Month Year

Fourth-line systemic therapy for recurrent GIST None

Specification of fourth-line systemic therapy given for recurrent GIST

Date of initiation of fourth-line systemic therapy given for recurrent GIST: [][][][][][][][][]
Day Month Year

Date of discontinuation of fourth-line systemic therapy given for recurrent GIST: [][][][][][][][][]
Day Month Year

Later-line systemic therapy for recurrent GIST

Later-line systemic therapy given for recurrent GIST No Yes

Other treatment for recurrent GIST

Surgery for GIST recurrence No Yes, specify type of surgery

Radiotherapy for GIST recurrence No Yes

Arm 1: 12 months treatment

SSG XVIII
Investigator confirmation Form 33

Send this form to:
SSG secretariat
Regional Tumor Registry
Lund University Hospital
SE-221 85 LUND, Sweden

Patient Initials

Rand. number

I hereby confirm that the data registered on CRF number 1 to CRF number are correct and completely filled in

except from CRF number to CRF number and CRF number to CRF number (only to be completed if not all CRFs in the interval are filled in)

Investigator signature: Date

Day	Month	Year
<input type="text"/>	<input type="text"/>	<input type="text"/>

Name in block letters:

I hereby confirm that the data registered on CRF number to CRF number are correct and completely filled in

except from CRF number to CRF number and CRF number to CRF number (only to be completed if not all CRFs in the interval are filled in)

Investigator signature: Date

Day	Month	Year
<input type="text"/>	<input type="text"/>	<input type="text"/>

Name in block letters:

I hereby confirm that the data registered on CRF number to CRF number are correct and completely filled in

except from CRF number to CRF number and CRF number to CRF number (only to be completed if not all CRFs in the interval are filled in)

Investigator signature: Date

Day	Month	Year
<input type="text"/>	<input type="text"/>	<input type="text"/>

Name in block letters:

I hereby confirm that the data registered on CRF number to CRF number are correct and completely filled in

except from CRF number to CRF number and CRF number to CRF number (only to be completed if not all CRFs in the interval are filled in)

Investigator signature: Date

Day	Month	Year
<input type="text"/>	<input type="text"/>	<input type="text"/>

Name in block letters: