Arm 2: 36 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

Day Month Year
Date of surgery |_|_|_|_|_|_|

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 2: 36 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

	Day	Month	Year
Chest X-ray or CT, date			
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	.....	.....	..... – .....

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 2: 36 months treatment

SSG XVIII
Follow-up. Month 1, week 4 **Form 4 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

Current dose of imatinib within the study |_|_|_| mg/day

Therapy interruption(s) of imatinib within the study since last visit:
Day Month Year Day Month Year
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:
Day Month Year Day Month Year
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 2: 36 months treatment

SSG XVIII

Adverse Event **Form 4 B**

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
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 2: 36 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 38,5ºC 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 2: 36 months treatment

SSG XVIII

Follow-up. Month 3, week 12 **Form 5 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 Day Month Year ___ to Day Month Year ___

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 Day Month Year ___ to Day Month Year ___

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 2: 36 months treatment

SSG XVIII

Adverse Event **Form 5 B**

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**
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 2: 36 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 38,5ºC 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 2: 36 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:
Day Month Year — Day Month Year
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:
Day Month Year — Day Month Year
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 2: 36 months treatment

SSG XVIII

Adverse Event **Form 6 B**

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
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 2: 36 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 38,5ºC 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 2: 36 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 Day Month Year |_|_|_|_|_|_| to Day Month Year |_|_|_|_|_|_|

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 Day Month Year |_|_|_|_|_|_| to Day Month Year |_|_|_|_|_|_|

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 2: 36 months treatment

SSG XVIII

Adverse Event **Form 7 B**

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**
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 2: 36 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 38,5ºC 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 2: 36 months treatment

SSG XVIII

Follow-up. Month 12, week 52 Form 8 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:
Day Month Year Day Month Year
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:
Day Month Year Day Month Year
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 2: 36 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
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 2: 36 months treatment

SSG XVIII

Adverse Event **Form 8 B cont´d**

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**
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 38,5ºC 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 2: 36 months treatment

SSG XVIII
Follow-up. Month 15 **Form 9 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 Day Month Year to Day Month Year

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 Day Month Year to Day Month Year

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 2: 36 months treatment

SSG XVIII
Adverse Event **Form 9 B**
Follow-up. Month 15

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
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 2: 36 months treatment

SSG XVIII
Adverse Event **Form 9 B cont´d**
Follow-up. Month 15

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 38,5ºC 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 2: 36 months treatment

SSG XVIII
Follow-up. Month 18 **Form 10 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 ___ ___ ___ 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 Day Month Year ___ ___ ___ to Day Month Year ___ ___ ___

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 2: 36 months treatment

SSG XVIII
Adverse Event **Form 10 B**
Follow-up. Month 18

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
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 2: 36 months treatment

SSG XVIII

Adverse Event **Form 10 B cont´d**

Follow-up. Month 18

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 38,5ºC 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 2: 36 months treatment

SSG XVIII
Follow-up. Month 21 **Form 11 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 Day Month Year ___ ___ ___ to Day Month Year ___ ___ ___

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 Day Month Year ___ ___ ___ to Day Month Year ___ ___ ___

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 2: 36 months treatment

SSG XVIII
Adverse Event **Form 11 B**
Follow-up. Month 21

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
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 2: 36 months treatment

SSG XVIII
Adverse Event **Form 11 B cont´d**
Follow-up. Month 21

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 38,5ºC 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 2: 36 months treatment

SSG XVIII
Follow-up. Month 24 **Form 12 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 ___ 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 Day Month Year to Day Month Year

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 2: 36 months treatment

SSG XVIII
Adverse Event **Form 12 B**
Follow-up. Month 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**
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 2: 36 months treatment

SSG XVIII
Adverse Event **Form 12 B cont´d**
Follow-up. Month 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 38,5ºC 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 2: 36 months treatment

SSG XVIII
Follow-up. Month 27 **Form 13 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 Day Month Year ___ to Day Month Year ___

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 Day Month Year ___ to Day Month Year ___

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 2: 36 months treatment

SSG XVIII
Adverse Event **Form 13 B**
Follow-up. Month 27

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
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 2: 36 months treatment

SSG XVIII
Adverse Event **Form 13 B cont´d**
Follow-up. Month 27

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 38,5ºC 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 2: 36 months treatment

SSG XVIII
Follow-up. Month 30 **Form 14 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 ☐☐ ☐☐ ☐☐☐☐ 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 Day Month Year ☐☐ ☐☐ ☐☐☐☐ to Day Month Year ☐☐ ☐☐ ☐☐☐☐
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 2: 36 months treatment

SSG XVIII
Adverse Event **Form 14 B**
Follow-up. Month 30

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
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 2: 36 months treatment

SSG XVIII
Adverse Event **Form 14 B cont´d**
Follow-up. Month 30

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 38,5ºC 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 2: 36 months treatment

SSG XVIII
Follow-up. Month 33 **Form 15 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 Day Month Year ___ ___ ___ to Day Month Year ___ ___ ___

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 Day Month Year ___ ___ ___ to Day Month Year ___ ___ ___

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 2: 36 months treatment

SSG XVIII
Adverse Event **Form 15 B**
Follow-up. Month 33

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
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 2: 36 months treatment

SSG XVIII

Adverse Event **Form 15 B cont´d**

Follow-up. Month 33

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 38,5ºC 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 2: 36 months treatment

SSG XVIII
Follow-up. Month 36 **Form 16 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 ___ ___ ___ 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 Day Month Year ___ ___ ___ to Day Month Year ___ ___ ___

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.

March 2008/MM

NOTE! Please fill in the adverse event form.

Arm 2: 36 months treatment

SSG XVIII
Adverse Event **Form 16 B**
Follow-up. Month 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**
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 2: 36 months treatment

SSG XVIII

Adverse Event **Form 16 B cont´d**

Follow-up. Month 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 38,5ºC 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 2: 36 months treatment

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

☐ 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 2: 36 months treatment

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

☐ 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 2: 36 months treatment

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

☐ 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 2: 36 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

☐ 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 2: 36 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

☐ 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 2: 36 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 2: 36 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

☐ 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 2: 36 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

☐ 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 2: 36 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

☐ 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 2: 36 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

☐ 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 2: 36 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

☐ 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 2: 36 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

☐ 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 2: 36 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

Date for discontinuation of assigned imatinib treatment according to the protocol |__|__| Day |__|__| Month |__|__|__|__| Year

Reason for discontinuation of assigned imatinib treatment according to the protocol:

- ☐ Completed assigned therapy
- ☐ GIST recurrence
- ☐ Adverse effects/lab values, specify…….....…….....….....
- ☐ Patient wished to discontinue adjuvant imatinib
- ☐ Patient withdrew consent
- ☐ Death
- ☐ Other, specify……..…….....

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:

☐ Adjuvant treatment*: Start date |__|__| Day |__|__| Month |__|__|__|__| Year

Discontinuation date |__|__| Day |__|__| Month |__|__|__|__| Year

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.

Arm 2: 36 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 |_|_|_|

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.	☐ Myocardial infarction	☐ Cardiac failure	☐ Coronary artery disease	
	☐ Other cardiac disease, specify			
2.	☐ Myocardial infarction	☐ Cardiac failure	☐ Coronary artery disease	
	☐ Other cardiac disease, specify			
3.	☐ Myocardial infarction	☐ Cardiac failure	☐ Coronary artery disease	
	☐ Other cardiac disease, specify			
4.	☐ Myocardial infarction	☐ Cardiac failure	☐ Coronary artery disease	
	☐ Other cardiac disease, specify			
5.	☐ Myocardial infarction	☐ Cardiac failure	☐ Coronary artery disease	
	☐ Other cardiac disease, specify			

Later cancer diseases (other than GIST)	**Date of diagnosis** Day Month Year
1. Specification of cancer.....	
2. Specification of cancer.....	
3. Specification of cancer.....	

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

First time:
No complications (tick if no complications are registered in the log) ☐

Day Month Year
Latest contact with patient: |_|_|_|

Patient reached end of study ☐ **No** ☐ **Yes** – fill in the End of study form

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) ☐

Day Month Year
Latest contact with patient: |_|_|_|

Arm 2: 36 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

Date for last follow-up contact (Day Month Year) |_|_| |_|_| |_|_|

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:

☐ Adjuvant treatment*: Start date (Day Month Year) |_|_| |_|_| |_|_|

Discontinuation date |_|_| |_|_| |_|_|

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

☐ Dead; Date of death (Day Month Year) |_|_| |_|_| |_|_|

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 2: 36 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 2: 36 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)

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)

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)

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)

Name in block letters: ....