

Severe Chronic Neutropenia International Registry United States Office at the University of Washington	SCNIR 600 Stewart Street, Suite #1503 Seattle, WA 98101	Phone: 206-543-9749 800-726-4463 Fax: 206-543-3668

INSTRUCTIONS FOR COMPLETING REGISTRATION FORM

NOTE: In this document, if you are completing this form for yourself or your dependent then the use of the terms “you/your” refers to either you or your dependent.

If you are a medical professional and you are completing this form for your patient then the use of the terms “you/your” refers to your patient.

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Physician Contact Information: Include the contact information for your primary physician. It is common for an individual to see multiple physicians such as a Hematologist, Oncologist, or Primary Care Provider. Select the physician by whom you are seen most often within a calendar year.

Patient Contact Information: Include your contact information. Also include the name, relationship, phone number, and email for the “Parent/Legal Guardian” if you are completing this form for an individual who is less than 18 years of age or incapable of completing the form on their own. If you are completing this form for yourself then leave the “Parent/Legal Guardian” section blank.

Date of Birth: Indicate the Month, Day, and Year in which you were born.

Sex: Check either, “Male” or “Female.”

Race: Check the racial classification with which you identify most. Select only one option.

Date of Onset*: The date of onset is the date that neutropenic symptoms were first recognized. This may be noted in your medical records. Or you may rely on memory to estimate a date.

Date of Diagnosis*: The date of diagnosis is the date that your physician clinically diagnosed your condition as neutropenia. This should be noted in your medical records.

Diagnosis*: Indicate the type of neutropenia with which you have been diagnosed. If you select, “Other”, specify the type of neutropenia with which you were diagnosed.

If your patient has a sub-diagnosis of Barth Syndrome, Shwachman-Diamond Syndrome (SDS), Glycogen Storage Disease (Type 1b), or Myelokathexis please submit the corresponding lab evaluations that support the sub-diagnosis (e.g., Gene Dx, laboratory reports, SDS report from the SickKids Molecular Genetics Laboratory in Toronto, Canada).

*You may need to consult with your physician to complete this section.

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NOTE: The evaluations requested on the top of page 2 may have been done before or after your initial exposure to Cytokine (Filgrastim).

As a patient you have the right to your medical records. To obtain a copy of the specified evaluations please contact the physician who did the evaluation(s) for you. Request the evaluation(s) by name. For example, Anti-neutrophil antibodies report, bone marrow evaluation, etc. Your physician’s office will explain to you what paperwork must be completed before your medical records can be released.

Keep a copy of your medicals records for your file. You may be asked to resubmit copies of certain documents if they are obscured and/or missing from your registration.

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Anti-neutrophil antibodies report: Indicate whether anti-neutrophil antibodies were detected. If you were tested, submit a copy of the corresponding lab report.

Bone Marrow Evaluation: Indicate whether a bone marrow evaluation was done. If yes, submit ALL corresponding pathology reports.

Cytogenetic Evaluation: Indicate whether a cytogenetic evaluation was done. If yes, submit ALL corresponding hematology reports.

Bone Density Report: Indicate whether a bone density evaluation was done. If yes, submit ALL corresponding radiology reports.

Bone Marrow Slides: Indicate whether bone marrow slides have been prepared. If yes, submit one stained and one unstained slide for the Registry to keep.

CBC's: Indicate whether CBC's (complete blood counts) with differentials have been done. If yes, submit ALL corresponding lab reports to date. You must provide at least three (3) CBCs with ANC less than 500 prior to your initial dose of cytokine (G-CSF/Neupogen®). A valid CBC generally contains at least the following information (see below for a sample CBC):

Complete Blood Count (CBC) with differential			
Test Results	Result	Units	Reference Interval
White Blood Count	1.5 L	x 10 ³ /mm ³	5.0-10.0
Red Blood Count	3.50 L	x 10 ⁶ /mm ³	4.1-5.3
Hemoglobin	10.8 L	g/dL	12.0-18.0
Hematocrit	31.1 L	%	37.0-52.0
MCV	84.9 L	fL	85.0-115.0
Platelets	302	x 10 ³ /mm ³	150-400
Polys (neutrophils)	23 L	%	45-76
Lymphs	68 H	%	17-44
Monocytes	7	%	3-10
Eos	2	%	0-4
Basos	0.6	%	0.2
Polys (absolute)	.34 L	x 10 ³ /mm ³	1.8-7.8
Lymphs (absolute)	1.0	x 10 ³ /mm ³	0.7-4.5
Monocytes (absolute)	0.1	x 10 ³ /mm ³	0.1-1.0
Eos (absolute)	0.1	x 10 ³ /mm ³	0.0-0.4
Basos (absolute)	0.0	x 10 ³ /mm ³	0.0-0.2

If you have been diagnosed with cyclic neutropenia then provide documentation of regular cycling in the form of CBCs done 3 times per week for 6 weeks prior to your initial exposure to cytokine (G-CSF/ Neupogen®).

Bone Marrow Transplant: Indicate whether a bone marrow transplant was done. If yes, provide the date of the transplant.

Treatment History

NOTE: Complete this section if you have ever taken cytokine (G-CSF/Neupogen®, GM-CSF, EPO). Otherwise, check the box that states, "Check here if cytokine (G-CSF/Neupogen®) has never been taken. Skip to the section entitled, "Other Medications for Neutropenia."

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G-CSF/Neupogen®:

Start Date*: indicate the date when you first began taking cytokine (G-CSF/Neupogen®). Typically, this information can be found in your medical records.

End Date*: indicate the date when you stopped taking cytokine (G-CSF/Neupogen®). If you have not stopped taking cytokine (G-CSF/Neupogen®) then leave this date field blank. Typically, this information can be found in your medical records.

**It is common to start and stop taking cytokine (G-CSF/Neupogen®) on several occasions before enrolling in the Registry. Indicate each occurrence of taking cytokine (G-CSF/Neupogen®). An occurrence has a discrete beginning and an end. If you need more space to complete this section then attach a separate sheet of paper and include it with the registration form.*

Quantity: indicate how much cytokine (G-CSF/Neupogen®) you are/were taking between the Start and End dates specified. If you are unsure of the quantity, then consult with the physician who prescribed you the medication or the pharmacy that filled your prescription for this information.

mcg/ml/cc: indicate the units in which your dose is measured in either micrograms (mcg), milliliters (ml), or cubic centimeters (cc). If you are unsure of the units, then consult with the physician who prescribed you the medication or the pharmacy that filled your prescription for this information.

Frequency: indicate how often you take cytokine (G-CSF/Neupogen®). If you are unsure of the frequency, then consult with the physician who prescribed you the medication or the pharmacy that filled your prescription for this information. See below for a list of frequency codes.

Code:		Code:	
qd	= once a day	qtd	= every 3 rd day
bid	= twice a day	qwk	= once a week
tid	= 3 times a day	biw	= twice a week
qid	= 4 times a day	tiw	= 3 times a week
qod	= every other day	prn	= as needed

Discontinue reason: if you have ever stopped taking cytokine (G-CSF/Neupogen®), then indicate the reason for discontinuing use in the space provided.

Other Cytokine (for neutropenia such as GM-CSF, EPO, etc.):

Start Date: complete this section as you would for G-CSF/Neupogen®.
End Date: complete this section as you would for G-CSF/Neupogen®.
Quantity: complete this section as you would for G-CSF/Neupogen®.
mcg/ml/cc: complete this section as you would for G-CSF/Neupogen®.
Frequency: complete this section as you would for G-CSF/Neupogen®.
Discontinue Reason: complete this section as you would for G-CSF/Neupogen®.

Other medications for neutropenia: indicate whether you have taken any of the following medications to treat neutropenia. If you are asked to specify the medication then include the name of the medication in the space provided.

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Significant clinical history of infections

NOTE: History of Infections must be BEFORE the initial dose of cytokine (G-CSF/Neupogen®)/Cytokine.

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For each infection that is listed indicate the frequency of occurrences prior to your initial dose of cytokine (G-CSF/Neupogen®)/Cytokine. Estimate the number of occurrences for the year before beginning cytokines.

An episode is a discrete occurrence with a beginning and an end. For example, you may have had an earache that lasted for four (4) weeks. This would count as one (1) episode and you would check the box under, "1-3 per Year." If you were to develop an earache that lasted for one (1) week out of each month for six (6) months then each earache would count as a separate episode. In this scenario the total number of earaches is six (6) and you would check the box under, "4-12 per Year."

Select a frequency for EACH infection. Do NOT leave any infection unaccounted for. If the frequency is unknown then check "None."

Growth and Development/Physical Assessment

NOTE: these assessments must be BEFORE the initial dose of cytokine (G-CSF/Neupogen®)/Cytokine.

You will need a physical exam from your physician that lists a height, weight, spleen and liver assessment to complete this section.

Date of assessment: indicate the date that height, weight, spleen and liver were assessed.

Height: indicate your height in centimeters or feet and inches.

Weight: indicate your weight in kilograms or pounds and ounces.

Spleen: indicate whether your spleen was palpable, not palpable, or not assessed. If palpable, specify measurement in centimeters. Typically, this information is found in your medical records. If you need help interpreting your medical record or completing this section contact the Registry at 1-800-726-4463 or consult with your physician.

Liver: indicate whether your liver was palpable, not palpable, or not assessed. Typically, this information is found in your medical records. If you need help interpreting your medical record or completing this section contact the Registry at 1-800-726-4463 or consult with your physician.

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Reproductive Assessment

Number of live births: indicate how many babies you have given birth to. Otherwise write, "0".

Number of still births: indicate how many stillborn babies you have given birth to. Otherwise write, "0".

Number of miscarriages/terminations: indicate how many miscarriages or terminations you have had. Otherwise write, "0".

Significant clinical history of non-infectious events

Is this a problem NOW?: indicate whether any of the listed clinical events are a problem for you at this time. Typically, this information is found in your medical records. If you need help interpreting your medical record or completing this section contact the Registry at 1-800-726-4463 or consult with your physician.

Was this a problem BEFORE the initial dose of cytokine (G-CSF/Neupogen®)?*: indicate whether any of the listed clinical events were a problem for you before you started taking cytokine (G-CSF/Neupogen®)/ Cytokine. Typically, this information is found in your medical records. If you need help interpreting your medical record or completing this section contact the Registry at 1-800-726-4463 or consult with your physician

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**Answer this question only if you have ever taken cytokine (G-CSF/Neupogen®)/Cytokine. Otherwise, check "No" for each clinical event listed below the question.*

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Family History

Indicate whether your parents are related to each other by blood. If yes, then specify the relationship.

Mother: For this form, Mother is defined as biological mother. If you do not know your biological mother's medical history, then write N/A in the space next to "Mother". Otherwise, indicate whether your mother is living, deceased, enrolled in registry, neutropenia, or leukemia by checking the appropriate box. If your mother has been diagnosed with another blood disorder then specify this blood disorder in the space provided.

Father: For this form, Father is defined as biological father. If you do not know your biological father's medical history, then write N/A in the space next to "Father". Otherwise, indicate whether your father is living, deceased, enrolled in registry, neutropenia, or leukemia by checking the appropriate box. If your father has been diagnosed with another blood disorder then specify this blood disorder in the space provided.

Brothers: For this form, Brother is defined as biological brother or half brother. If you do not know your brother's medical history or do not have a biological or half brother, then write N/A on line 1. Otherwise, for each brother indicate his initials on the lines provided. Also, indicate whether your brother(s) is living, deceased, enrolled in registry, neutropenia, or leukemia by checking the appropriate box. If your brother(s) has been diagnosed with another blood disorder then specify this blood disorder in the space provided.

Sisters: For this form, Sister is defined as biological sister or half sister. If you do not know your sister's medical history or do not have a biological or half sister, then write N/A on line 1. Otherwise, for each brother indicate his initials on the lines provided. Also, indicate whether your sister(s) is living, deceased, enrolled in registry, neutropenia, or leukemia by checking the appropriate box. If your sister(s) has been diagnosed with another blood disorder then specify this blood disorder in the space provided.

Other affected family member: If you do not have any other affected family members then write N/A in the space below, "Specify Relationship". If you do have an affected family member, then specify your relationship to this family member (e.g. 1st cousin, aunt, grandmother, etc.). Indicate whether this family member is living, deceased, enrolled in registry, neutropenia, or leukemia by checking the appropriate box. If this family member has been diagnosed with another blood disorder then specify this blood disorder in the space provided.

NOTE: if your family history is unknown then check, "Check here if Family History is Unknown. Do NOT fill out the remainder of the page and submit form.