
This prediction tool is intended to help physicians estimate the risk of serious drug-related toxicity (SDRT) in the first cycle for cancer patients who are treated on phase I trials.

The main goal of phase I trials is to determine the highest dose of a drug or combination of drugs that can be safely taken. Although great care is already taken to maximize safety in clinical trials by eliminating certain patients — such as those who do not have normal organ function — some patients are still at high risk for SDRT during phase I trials.

This tool is intended to identify patients at risk for early (cycle 1) SDRT so that patients and clinicians can assess the baseline risk of SDRT before a decision is made about participation in a phase I trial. It was developed using information from more than 3,100 patients enrolled in 127 phase 1 trials. Refer to the publication cited below for more details, including the definition of SDRT.

Who Can Use this Tool?

This tool should be used only for patients who do not have leukemia or lymphoma and who are entering trials where they will be treated with cytotoxic or molecularly-targeted agents, alone or in combination. The tool should not be used for patients entering clinical trials testing vaccines, radiation therapy, or loco-regional therapy (therapy that affects only a specific area rather than being systemic) or on dedicated organ dysfunction trials.

In addition, patients must:

- Be 18 years old or more

Have solid tumors

Have an absolute neutrophil count of at least 1 x 109/L

Have a hemoglobin level of at least 8 g/dl

Have a platelet count of at least 75 x 109/L

Have aspartate aminotransferase (AST) equal to or less than 5 x upper limit of normal (ULN), alanine aminotransferase (ALT) equal to or less than 5 x ULN, and total bilirubin equal to or less than 2 x ULN.

If you are a patient, we recommend that you use this tool ONLY in consultation with your healthcare provider.

What Information Will You Need?

To use the tool, you need to input the following information. In order for this nomogram to accurately assess a patient's risk for cycle 1 SDRT, you need to include accurate values for all of the information below. If any of the patient's values fall outside of the ranges specified below, this nomogram cannot accurately predict the risk of SDRT and should not be used.

ECOG Performance Status: This number is used by the physician to assess how the disease is progressing. (The range is 0 - 3)

White Blood Cell (WBC) count: White blood cell count (Range is 2.1 - 38.2 billion cells/L)

Creatinine clearance: (Lower limit is 13 mL/min)

Albumin level: (Range is 1.8 to 5 g/dL)

Aspartate aminotransferase (AST) level: (Range is 7 to 176 units/L)

Number of drugs being tested in the trial : (Range is 1 to 3)

Are any of the drugs that are being tested biological drugs? (Answer is "Yes" or "No". Biologic drugs are drugs requiring recombinant DNA technology to manufacture.)

If you are a patient, we recommend that you use this tool only in consultation with your healthcare provider.

Contact Us

If you have questions or comments about this prediction tool, please contact us at nomograms@mskcc.org.

Use This Tool

Use our phase I clinical trial drug-related toxicity prediction tool .

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