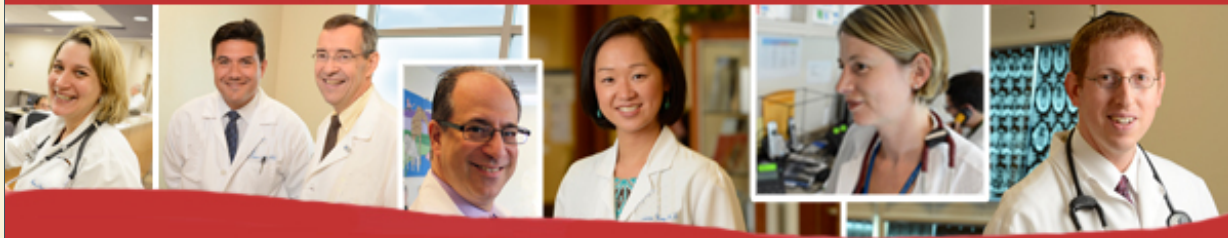


## Rutgers Cancer Institute of New Jersey





# Clinical Trials Connection

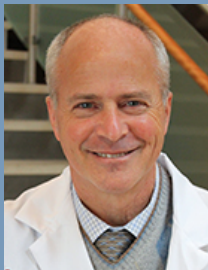
*A Cancer Resource for Healthcare Professionals*

May 2016

### Resources for Physicians

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## Hematologic Oncology Clinical Trials

[View printable version](#)

A Phase I, Open-label, Adaptive Dose-escalation, Multicenter Study to Evaluate the Tolerability, Safety, Pharmacokinetics, and Anti-tumor Activity of ADCT-402 in Patients with Relapsed or Refractory B-lineage Acute Lymphoblastic Leukemia (B-ALL)

The study aims to:

- Evaluate the safety and tolerability and determine the maximum tolerated dose (MTD) of ADCT-402 in patients with relapsed or refractory B-ALL in Part 1.
- Determine the recommended dose of ADCT-402 for Part 2 (expansion).
- Evaluate the safety and tolerability of ADCT-402 in Part 2 (expansion) at the dose level recommended in Part 1.
- (NOTE: This trial is open to eligible patients 12 and older.)

[Learn more about this trial](#)

## Phase IA/1B Study of CC-122 for Subjects with Advanced Solid Tumors, NHL and MM

The study aims to:

- Determine the safety and tolerability of CC-122 given orally and to define the non-tolerable dose, MDT and the recommended phase 2 dose.

## Clinical Trial Spotlight

### Phase I Trial of MSB0010718C in Patients with Metastatic or Locally Advanced Solid Tumors

The purpose of this study is to determine the safety and effectiveness of an investigational agent known as MSB0010718C, which belongs to a family of molecules called anti-PD-L1 antibodies. PD-L1 is a cell surface protein considered to be able to inhibit an anti-tumor response of the immune system. MSB0010718C is found to interfere with the activity of PD-L1 and is thought to potentially have an effect on the immune system in order to induce an anti-tumor attack. Those with metastatic or locally advanced solid tumors, including melanoma and non-small cell lung cancer, are eligible to participate although other criteria must also be met.

[Learn more](#)

- Determine the PK and extent of urinary excretion of CC-122.
- Preliminarily assess anti-tumor activity of CC-122.
- Determine the CNS penetration of CC-122.
- Evaluate the PD effects of CC-122 on gene expression, cytoskeletal structure and cell surface organization in peripheral blood cell components.

[Learn more about this trial](#)

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## Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE)

The study aims to:

- Compare the overall survival between two strategies of lenalidomide maintenance following induction with a proteasome inhibitor IMiD combination: limited duration of maintenance (24 months) versus indefinite maintenance therapy until disease progression.
- Compare the progression-free survival between two strategies of lenalidomide maintenance following induction with a proteasome inhibitor IMiD combination: limited duration of maintenance (24 months) or indefinite maintenance therapy until disease progression.
- Compare the progression-free survival between VRd and CRd induction followed by lenalidomide maintenance in patients with newly diagnosed symptomatic multiple myeloma.

[Learn more about this trial](#)

## Other Available Trials

[Breast](#)

[Gastrointestinal/  
Hepatobiliary](#)

[Gynecologic](#)

[Melanoma](#)

[Pediatric](#)

[Phase I](#)

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## An Open-label, Multi-center Phase I Study to Investigate the Safety and Tolerability of REGN1979, an Anti-CD20 x Anti-CD3 Bispecific Monoclonal Antibody, in Patients with CD20+ B-cell Malignancies

The study aims to:

[Prostate](#)

[Thoracic](#)

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Cancer Center

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National Cancer Institute

- Assess the safety, tolerability, and dose-limiting toxicities (DLTs) of REGN1979 administered intravenously (IV).
- Characterize the pharmacokinetic (PK) profile of REGN1979.
- Assess the immunogenicity of REGN1979.
- Study the preliminary antitumor activity of REGN1979 administered to patients with CD20+ B-cell malignancies (non-Hodgkin's lymphoma [NHL] and chronic lymphocytic leukemia [CLL]) previously treated with anti-CD20 antibody therapy.

[Learn more about this trial](#)

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## An Open Label, Phase II Study to Evaluate Efficacy and Safety of Daratumumab in Relapsed or Refractory Mantle Cell Lymphoma, Diffuse Large B-Cell Lymphoma, and Follicular Lymphoma

The study aims to:

- Evaluate daratumumab separately in three relapsed or refractory NHL subtypes that are CD38 positive: mantle cell lymphoma (MCL), diffuse large B cell lymphoma (DLBCL), and follicular lymphoma (FL). There are two main objectives.
- Assess overall response rate (ORR, including complete response (CR) and partial response (PR)) of daratumumab in subjects with CD38+ disease in each NHL subtype.
- Evaluate association between ORR and CD38 expression level in order to determine a threshold for CD38 expression level in each NHL subtype, above which daratumumab activity is enhanced.

[Learn more about this trial](#)

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## Blinatumomab in First Relapse of Childhood B-Lymphoblastic Leukemia

The study aims to:

- Compare disease free survival (DFS) of HR and IR relapse B-ALL patients who are randomized following Induction Block 1 chemotherapy to receive either two intensive chemotherapy blocks or two 5-week blocks of blinatumomab (HR/IR Randomization).

- Compare DFS of LR relapse B-ALL patients who are randomized following Block 1 chemotherapy to receive either chemotherapy alone or chemotherapy plus blinatumomab (LR Randomization).
- Compare overall survival (OS) of HR and IR relapse B-ALL patients who are randomized following Induction Block 1 chemotherapy to receive either two intensive chemotherapy blocks or two 5-week blocks of blinatumomab (HR/IR Randomization).

[Learn more about this trial](#)



As New Jersey's only National Cancer Institute-designated Comprehensive Cancer Center, Rutgers Cancer Institute of New Jersey offers patients access to treatment options not available at other institutions within the state. The Cancer Institute currently enrolls approximately 17 percent of all new adult cancer patients and approximately 70 percent of all pediatric cancer patients onto a clinical trial. Enrollment in these studies nationwide is fewer than five percent of all adult cancer patients.

[Learn more](#)

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