



This list of clinical research protocols for the elderly and for myelodysplastic syndromes is compiled for your convenience.

For more information on these protocols, call PDQ, a service of the National Cancer Institute, at 1-800-4-CANCER.

A searchable PDQ Web site is available at <http://cancernet.nci.nih.gov/trialsrch.shtml>. The National Institutes of Health also offers a searchable Web site for clinical trials at <http://clinicaltrials.gov>.

CLINICAL RESEARCH PROTOCOLS FOR THE ELDERLY AND FOR MYELODYSPLASTIC SYNDROMES

Acute Myeloid Leukemia

EORTC-06993-AML-15 Phase II Pilot Study of Gemtuzumab Ozogamicin With or Without Mitoxantrone, Etoposide, Cytarabine, and Idarubicin in Elderly Patients With Acute Myeloid Leukemia

Chairperson: Sergio Amadori. Telephone: 39-06-5914745. Lead organization: EORTC Lung Cancer Group. Age range: 61 and over.

EORTC-06954 Phase III Randomized Study of Acute Myeloid Leukemia in Elderly Patients (AML-13): MICE (DHAD/ARA-C/VP-16) With vs Without G-CSF Followed by Oral vs Intravenous Mini-ICE (IDA/ARA-C/VP-16) Followed in Selected Patients by BAVC (BCNU/AMSA/VP-16/ARA-C) With PBSC Support

Chairperson: Theo De Witte. Telephone: 024-361-47-62. Lead organization: EORTC Leukemia Group. Age range: 61 to 80.

Brain Tumors

CWRU-3399, NCI-G00-1853 Phase II Study of Stereotactic Radiosurgery in Elderly Patients or Patients With Poor Performance Status Who Have Brain Metastases

Chairperson: Huong Pharm. Telephone: 216-844-2515. Lead organization: Ireland Cancer Center. Age range: Over 18.

NCCTG-967351 Phase II Study of Radiation Therapy and High Dose Corticosteroids for Elderly Patients With Primary Central Nervous System Non-Hodgkin's Lymphoma

Chairperson: Brian Patrick

O'Neill. Telephone: 507-284-8431. Lead organization: North Central Cancer Treatment Group. Age range: 70 and over.

Breast Cancer

SWS-SAKK-25/99, EU-99007 Phase I/II Study of Capecitabine and Vinorelbine in Elderly Women With Metastatic Breast Cancer With or Without Bone Involvement

Chairperson: D. Hess. Telephone: 071-494-11-11. Lead organization: Swiss Institute for Applied Cancer Research. Age range: 65 and over.

IBCSG-10-93, NCI-F93-0008, EU-93013 Phase III Randomized Study of Surgery With or Without Axillary Node Clearance Followed by Adjuvant Tamoxifen in Elderly Women With Breast Cancer

Chairperson: Diana Crivellari. Telephone: 39-434-659206. Lead organization: International Breast Cancer Study Group. Age range: 60 and over.

Colon Cancer

E-1299 Phase II Study of Fluorouracil-Uracil and Leucovorin Calcium in Elderly Patients With Metastatic Colorectal Cancer

Chairperson: Howard Hochster. Telephone: 212-263-6485. Lead organization: Eastern Cooperative Oncology Group. Age range: 75 and over.

Hematologic Malignancies

CWRU-4496, NCI-G97-1350, AMC-1C-93 Phase II Study of Oral Combination Chemotherapy and

Granulocyte Colony-Stimulating Factor in Elderly Patients With Intermediate and High Grade Non-Hodgkin's Lymphoma)

Chairperson: Scot C. Remick. Telephone: 216-844-1196. Lead organization: Ireland Cancer Center. Age range: 60 and over.

CRC-TU-NH3003, EU-93028

Phase III Randomized Study of CHOP (CTX/DOX/VCR/PRDL) vs MCOP (DHAD/CTX/VCR/PRDL) in Patients Aged 65 Years and Over With Intermediate- or High-Grade Non-Hodgkin's Lymphoma

Chairperson: Eric Michael Bessell. Telephone: 115-969-11-69. Lead organization: Cancer Research Campaign Clinical Trials Unit-Birmingham (CRCTU). Age range: 65 and over.

Lung Cancer

NCCTG-N9921 Phase II Study of Carboplatin and Paclitaxel in Elderly Patients With Metastatic or Recurrent Unresectable Non-Small Cell Lung Cancer

Chairperson: Aminah Jatoi. Telephone: 507-284-2511. Lead organization: North Central Cancer Treatment Group. Age range: 65 and over.

ITA-MILES, EU-98019, ITA-GOCSI-MILES Phase III Randomized Study of Vinorelbine, Gemcitabine, or Both in Elderly Patients With Stage IIIB or Stage IV Non-Small Cell Lung Cancer

Chairperson: Cesare Gridelli. Telephone: 39-81-590-32-69. Lead organization: Istituto Nazionale per lo Studio e la Cura dei Tumori. Age range: 70 and over.

Multiple Myeloma

MRC-LEUK-MYEL-VIII, EU-94031 Phase III Randomized Study of ABCM (DOX/BCNU/CTX/L-PAM) vs ABCM Followed by Oral CTX/PRED for Induction of First Plateau Phase in Elderly Patients With Multiple Myeloma

Chairperson: Ian C. M. MacLennan. Telephone: 44-21-414-4069. Lead organization: Medical Research Council's Working Party on Leukemia in Adults and Children. Age range: under 75.

Myelodysplastic Syndromes

MSKCC-98037, NCI-G99-1542 Phase I Pilot Study of Ras Peptide Cancer Vaccine in Patients With Myelodysplastic Syndrome

Chairperson: Stephen D. Nimer. Telephone: 212-639-7871. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: over 17.

MDA-ID-99060, NCI-T99-0043 Phase I Study of 6-Hydroxymethylacylfulvene in Patients With Refractory Myelodysplastic Syndrome, Acute Myeloid Leukemia, Acute Lymphocytic Leukemia, or Blastic Phase Chronic Myelogenous Leukemia

Chairperson: Francis J. Giles. Telephone: 713-792-7305. Lead organization: University of Texas - MD Anderson Cancer Center. Age range: 18 and over.

JHOC-99072307, NCI-T99-0092 Phase I Study of Azacitidine in Combination With Phenylbutyrate in Patients With Recurrent, Refractory, or Untreated Acute Myeloid

Leukemia or Myelodysplastic Syndrome

Chairperson: Carole Miller. Telephone: 410-955-8603. Lead organization: Johns Hopkins Oncology Center. Age range: 18 and over.

MDA-DM-99290, NCI-450

Phase I Study of BMS-214662 in Patients With Acute Leukemia, Myelodysplastic Syndrome, or Chronic Myeloid Leukemia in Blast Phase

Chairperson: Jorge Cortes. Telephone: 713-794-5783. Lead organization: University of Texas - MD Anderson Cancer Center. Age range: 15 and over.

MDA-DM-98187, NCI-T98-0001 Phase I Study of Dolastatin 10 in Patients With Refractory or Relapsed Acute Leukemia, Myelodysplastic Syndrome, or Chronic Myelogenous Leukemia in Blast Phase

Chairperson: Jorge Cortes. Telephone: 713-794-5783. Lead organization: University of Texas - MD Anderson Cancer Center. Age range: not specified.

CWRU-1998, NCI-G00-1732, CWRU-059812 Phase I Study of Fludarabine, Carboplatin, and Topotecan in Patients With Relapsed or Refractory Acute Leukemia or Advanced Myelodysplastic Syndrome

Chairperson: Brenda W. Cooper. Telephone: 216-844-3213. Lead organization: Ireland Cancer Center. Age range: 12 and over.

JHOC-J9966, NCI-G00-1816, JHOC-99110501 Phase I Study of

Nonmyeloablative Cyclophosphamide Plus Haploidentical Allogeneic Bone Marrow Transplantation in Patients With Hematologic Malignancies

Chairperson: Paul V. O'Donnell. Telephone: 410-614-0205. Lead organization: Johns Hopkins Oncology Center. Age range: 0.5 to 70.

MDA-DM-99245, NCI-94

Phase I Study of PS-341 in Patients With Refractory or Relapsed Acute Myeloid Leukemia, Acute Lymphoblastic Leukemia, Myelodysplastic Syndrome, or Chronic Myeloid Leukemia in Blast Phase

Chairperson: Jorge Cortes. Telephone: 713-794-5783. Lead organization: University of Texas - MD Anderson Cancer Center. Age range: 18 and over.

MDA-DM-99169, NCI-T99-0101 Phase I Study of R115777 in Patients With Myelodysplastic Syndrome

Chairperson: Razelle Kurzrock. Telephone: 713-794-1226. Lead organization: University of Texas - MD Anderson Cancer Center. Age range: 18 and over.

MSKCC-99057, NCI-G99-1661

Phase I Study of Sodium Salicylate in Patients With Advanced Myelodysplastic Syndrome or Refractory or Relapsed Acute Myelogenous Leukemia

Chairperson: Stephen D. Nimer. Telephone: 212-639-7871. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: over 18.

MSKCC-99126, NCI-G00-1815 Phase I Study of Yttrium Y 90

Humanized Monoclonal Antibody M195 and Etoposide Followed by Autologous Peripheral Blood Stem Cell Transplantation in Patients With Advanced Myelodysplastic Syndrome or Refractory Leukemia

Chairperson: Peter Maslak. Telephone: 212-639-5518. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: 18 and over.

UW-26-245-B, NCI-V96-0848

Phase I Trial of Subcutaneous Outpatient Interleukin-2 for Patients With Myelodysplastic Syndrome

Chairperson: John A. Thompson. Telephone: 206-598-2514. Lead organization: University of Washington Medical Center. Age range: 15 and over.

MDA-DM-97325, NCI-T98-

0017 Phase I/II Randomized Study of PR1 Leukemia Peptide Vaccine and Montanide ISA-51 in Patients With Chronic Myeloid Leukemia, Acute Myeloid Leukemia, or Myelodysplastic Syndrome

Chairperson: Jeffrey J. Mollrem. Telephone: 713-792-2933. Lead organization: University of Texas - MD Anderson Cancer Center. Age range: over 18.

MDA-ID-99341, NCI-673

Phase I/II Study of Daunorubicin Liposomal and SU5416 in Patients With Acute Myeloid Leukemia, Refractory Anemia With Excess Blasts (RAEB), RAEB in Transformation, or Chronic Myelomonocytic Leukemia Refractory to Induction Chemotherapy

Chairperson: Francis J. Giles. Telephone: 713-792-7305. Lead organization: University of Texas -

MD Anderson Cancer Center. Age range: 18 and over.

SUMC-NCI-38, NCI-38 Phase I/II Study of R115777 in Patients With Myeloproliferative Disorders

Chairperson: Peter L. Greenberg. Telephone: 650-725-8355. Lead organization: Stanford University Medical Center. Age range: 21 and over.

AUH-MCP-70612-01, NCI-V98-1485, AUH-MCP-70612-02P

Phase I/II Study of Topotecan, Fludarabine, Cytarabine, and Filgrastim (T-FLAG) Induction Therapy Followed by Maintenance Therapy of Either Peripheral Blood Stem Cells or Isotretinoin in Patients With Poor Prognosis Acute Myeloid Leukemia, Myelodysplastic Syndrome, and Recurrent or Refractory Acute Lymphocytic Leukemia

Chairperson: Emmanuel C. Besa. Telephone: 215-842-6980. Lead organization: Medical College of Pennsylvania Hospital. Age range: 19 to 90.

NU-91H1T, NCI-G00-1688

Phase II Pilot Study of Busulfan and Etoposide With Autologous Bone Marrow Transplantation and Filgrastim (G-CSF) in Patients With Acute Myelogenous Leukemia or Myelodysplastic Syndrome

Chairperson: Martin Stuart Tallman. Telephone: 312-695-6180. Lead organization: Robert H. Lurie Comprehensive Cancer Center, Northwestern University. Age range: Physiologic 65 and under.

WSU-D-696-87, NCI-V93-0345

Phase II Study of Allogeneic or Syngeneic Bone Marrow Transplanta-

tion Following Cyto-reduction With BU/CTX for Low-Risk and BU/ARA-C/CTX for High-Risk Acute Non-lymphocytic Leukemia, Myelodysplastic Syndromes, and Secondary Acute Myeloid Leukemia

Chairperson: Chatchada Karanes. Telephone: 313-745-9082. Lead organization: Barbara Ann Karmanos Cancer Institute. Age range: 60 and under.

CHNMC-IRB-98056, NCI-V99-1533, ALZA-CHNMC-IRB-98056

Phase II Study of Amifostine, Topotecan, and Cytarabine in Patients With Poor Risk Myelodysplastic Syndrome

Chairperson: Henry C. Fung. Telephone: 626-359-8111. Lead organization: ALZA Corporation. Age range: 16 and over.

FHCRC-1478.00, NCI-G00-1793

Phase II Study of Anti-Thymocyte Globulin and Tumor Necrosis Factor Receptor IgG Chimera in Patients With Myelodysplastic Syndrome

Chairperson: H. Joachim Deeg. Telephone: 206-667-5985. Lead organization: Fred Hutchinson Cancer Research Center. Age range: Any age.

CCUM-9906, NCI-T99-0069

Phase II Study of Azacitidine Plus Amifostine in Patients With Myelodysplastic Syndromes

Chairperson: Harry Paul Erba. Telephone: 734-647-8921. Lead organization: University of Michigan Comprehensive Cancer Center. Age range: over 18.

CWRU-1494, NCI-V97-1361

Phase II Study of Busulfan,

Cyclophosphamide, and Allogeneic Bone Marrow Transplantation in Patients With Leukemia, Myelodysplastic Syndromes, Multiple Myeloma, or Lymphoma

Chairperson: Hillard M. Lazarus. Telephone: 216-844-3629. Lead organization: Ireland Cancer Center. Age range: 50 and under.

MSKCC-98017, NCI-G98-1444

Phase II Study of Decitabine for Myelodysplastic Syndromes

Chairperson: Richard C. Frank. Telephone: 212-639-7900. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: 15 and over.

NU-91H4T, NCI-G00-1686

Phase II Study of High Dose Busulfan and Cyclophosphamide Followed By Allogeneic Bone Marrow Transplantation in Patients With Acute Myelogenous Leukemia or Myelodysplastic Syndrome

Chairperson: Martin Stuart Tallman. Telephone: 312-695-6180. Lead organization: Robert H. Lurie Comprehensive Cancer Center, Northwestern University. Age range: 16 to physiologic 60.

FHCRC-1297.00, NCI-H99-0028

Phase II Study of Iodine I 131 Monoclonal Antibody BC8 Plus Cyclophosphamide and Total Body Irradiation Followed by HLA Matched Related or Unrelated Bone Marrow Transplantation in Patients With Advanced Acute Myeloid Leukemia or Myelodysplastic Syndrome

Chairperson: Dana Christine Matthews. Telephone: 206-667-2966. Lead organization: Fred Hutchinson Cancer Research Center. Age range: 2 to 55.

JHOC-98071505, NCI-G99-1544, JHOC-J9852 Phase II Study of Sargramostim (GM-CSF) Following T-cell Depleted Allogeneic Bone Marrow Transplantation in Patients With Myelodysplastic Syndrome

Chairperson: Paul V. O'Donnell. Telephone: 410-614-0205. Lead organization: Johns Hopkins Oncology Center. Age range: 18 to 65.

MCV-CCHR-9504-2X, NCI-G98-1388, DUMC-75951

Phase II/III Randomized Study of Conventional vs T cell Depleted Unrelated Donor Bone Marrow Transplantation for Leukemia, Myelodysplasia, and Lymphoblastic Lymphoma

Chairperson: Lee Ann Jensen. Telephone: 301-435-0066. Lead organization: Massey Cancer Center. Age range: 55 and under.

Non-Hodgkin's Lymphoma

CWRU-4496, NCI-G97-1350, AMC-1C-93

Phase II Study of Oral Combination Chemotherapy and Granulocyte Colony-Stimulating Factor in Elderly Patients With Intermediate and High Grade Non-Hodgkin's Lymphoma

Chairperson: Scot C. Remick. Telephone: 216-844-3361. Lead organization: Ireland Cancer Center. Age range: 60 and over.

Screening

PLCO-1, NCI-P93-0050 A 16-Year Randomized Screening Study for Prostate, Lung, Colorectal, and Ovarian Cancer - PLCO Trial

Chairperson: John K. Gohagan. Telephone: 301-496-8544. Lead organization: Early Detection Branch. Age range: 55 to 74.