
Clinical Trials Unit

Closed Adult Protocols

Disease Site Group Blood & Marrow Transplant

Astellia Pharma Ltd. (UK) Multi-center, Randomized, Double-blind, Placebo-controlled Phase III Trial of the FLT3 Inhibitor Gilteritinib Administered as Maintenance Therapy Following Allogeneic Transplant for Patients with FLT3/ITD AML **PI** Paulson, Kris

BMT CTN 1506 **Co-I** Bow, Eric
Szwajcer, David
Speziali, Craig

AI

Pathologist:

Ethics #: **Date Opened:** 03-Aug-18 **Reason for Closure:**

Site #: **Date Closed:**

BU #: One **# Pts Entered:** 0 **# Pts Pre-Screened:** 6 **Accrual Goal:**

Location: McDermot Only

Notes: BMT study

Kite Pharma, Inc. A Phase 3, Randomized, Open-Label Study Evaluating the Efficacy of Axicabtagene Ciloleucef versus Standard of Care Therapy in Subjects with Relapsed/Refractory Diffuse Large B Cell Lymphoma (ZUMA-7) **PI** Szwajcer, David

Kite Zuma-7 DLBCL **Co-I** Skrabek, Pamela
Paulson, Kris
Kotb, Rami
Minuk, Leonard
Speziali, Craig
Yang, Lin

AI Dawe, Kevin

Pathologist:

Ethics #: B2018:054 **Date Opened:** 21-Aug-18 **Reason for Closure:** Enrollment goal met

Site #: 205 **Date Closed:** 23-Sep-19

BU #: One **# Pts Entered:** 1 **# Pts Pre-Screened:** 7 **Accrual Goal:** 5/yr

Location: McDermot Only

Notes: Pathologist Dr. Jie Lis

Disease Site Group Brain

CCTG A Phase III Trial of Marizomib in Combination with Standard Temozolomide-Based Radiochemotherapy versus Standard Temozolomide-Based Radiochemotherapy Alone in Patients with Newly Diagnosed Glioblastoma (E1709) **PI** Pitz, Marshall

CCTG CE.8 EORTC-1709-BTG* **Co-I** Kakumanu, Saranya
Harlos, Craig

AI

Pathologist:

Ethics #: B2018:088 **Date Opened:** 19-Dec-18 **Reason for Closure:** Met accrual goals

Site #: CARM **Date Closed:** 04-Nov-20

BU #: Three **# Pts Entered:** 7 **# Pts Pre-Screened:** 27 **Accrual Goal:** 4/yr

Location: McDermot Only

Notes:

Disease Site Group Brain

NCIC Phase III Trial on Concurrent and Adjuvant Temozolomide in Chemotherapy in Non-1p/19q Deleted Anaplastic Glioma. The CATNON Intergroup Trial **PI** Pitz, Marshall
CEC.1* **Co-I** Kakumanu, Saranya
Harlos, Craig
AI
Pathologist: M. Del Bigio

Ethics #: B2009:116 **Date Opened:** 14-Jan-10 **Reason for Closure:** Met accrual goal.
Site #: CARM **Date Closed:** 15-Sep-15
BU #: Three **# Pts Entered:** 2 **# Pts Pre-Screened:** 34 **Accrual Goal:** 3/yr x 5 yrs
Location: McDermot Only

Notes:

Novocure EF-25: Pivotal, Open-label, Randomized Study of Radiosurgery with or without Tumor Treating Fields (TTFields) for 1-10 Brain Metastases from Non-small Cell Lung Cancer (NSCLC). EF-25 (METIS) **PI** Kakumanu, Saranya
Novocure EF-25 brain **Co-I** Butler, James
mets* **AI**
Pathologist:

Ethics #: B2017:060 **Date Opened:** 31-Aug-17 **Reason for Closure:** Met accrual goals
Site #: 11-15 **Date Closed:** 28-Feb-23
BU #: Three **# Pts Entered:** 1 **# Pts Pre-Screened:** 14 **Accrual Goal:** 2-5/yr
Location: McDermot Only

Notes:

Orbus Therapeutics Inc. A Phase III, Open-Label Study to Evaluate the Efficacy and Safety of Eflornithine with Lomustine Compared to Lomustinbe Alone in Patients with Anaplastic Astrocytoma That Progress/Recur After Irradiation and Adjuvant Temozolomide Chemotherapy (STELLAR Study) **PI** Pitz, Marshall
Orbus STELLAR AA* **Co-I** Kakumanu, Saranya
Harlos, Craig
AI
Pathologist:

Ethics #: B2017:093 **Date Opened:** 12-Oct-17 **Reason for Closure:** Met accrual goals
Site #: 702 **Date Closed:** 09-Dec-21
BU #: Three **# Pts Entered:** 9 **# Pts Pre-Screened:** 12 **Accrual Goal:** 3/yr
Location: McDermot Only

Notes:

Disease Site Group Breast

Disease Site Group Breast

AstraZeneca AB

A Phase III Double-Blind Randomised Study Assessing the Efficacy and Safety of Capivasertib + Fulvestrant Versus Placebo + Fulvestrant as Treatment for Locally Advanced (Inoperable) or Metastatic Hormone Receptor Positive, Human Epidermal Growth Factor Receptor 2 Negative (HR+/HER2-) Breast Cancer Following Recurrence or Progression On or After Treatment with an Aromatase

AZ 291 Breast

PI Niraula, Saroj

Co-I Grenier, Debjani
Pitz, Marshall
Gordon, Vallerie
Kim, Christina
Desautels, Danielle
Green, Susan
Graham, Jeffrey
Thiessen, Maclean

AI

Pathologist:

Ethics #: B2020:030 (HS2) **Date Opened:** 22-Sep-20 **Reason for Closure:** Met accrual goals

Site #: 1008 **Date Closed:** 13-Oct-21

BU #: Three **# Pts Entered:** 4 **# Pts Pre-Screened:** 18 **Accrual Goal:** 3/yr

Location: McDermot Only

Notes:

CCTG

PALbociclib COLlaborative Adjuvant Study: A Randomized Phase III Trial of Palbociclib with Standard Adjuvant Endocrine Therapy Versus Standard Adjuvant Endocrine Therapy Alone for Hormone Receptor Positive (HR+) / Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Early Breast Cancer (PALLAS)

CCTG MA.37 PALLAS

PI Niraula, Saroj

Co-I Grenier, Debjani
Pitz, Marshall
Gordon, Vallerie
Kim, Christina
Desautels, Danielle
Green, Susan
Graham, Jeffrey
Thiessen, Maclean

AI

Pathologist:

Ethics #: B2017:009 **Date Opened:** 05-Oct-17 **Reason for Closure:** Enrollment goals met

Site #: CARM **Date Closed:** 30-Nov-18

BU #: Three **# Pts Entered:** 5 **# Pts Pre-Screened:** 41 **Accrual Goal:** 5/yr

Location: McDermot & Tache

Notes:

Disease Site Group Breast

Mayo Clinic

GENetic Risk Estimation of Breast Cancer Prior to Breast Cancer Preventing Medications: A Pilot study to determine if a polygenic risk score influences the decision to accept breast cancer preventing medications (Tamoxifen, Raloxifene, or Exemestane) amongst non-BRCA women at risk

GENRE

PI Kim, Julian

Co-I Akra, Mohamed
Cooke, Andrew
Grenier, Debjani
Nashed, Maged
Kim, Christina
Kakumanu, Saranya
Desautels, Danielle
Graham, Jeffrey

AI Beshara, Eren

Pathologist:

Ethics #: B2015:104

Date Opened: 06-May-16

Reason for Closure: Met accrual goals

Site #: N/A

Date Closed: 05-Dec-17

BU #: Three

Pts Entered: 76

Pts Pre-Screened: 217

Accrual Goal: 75 pts total over 2-3 yrs

Location: McDermot & Tache

Notes: Prevention Trials Coordinator is Rhonda Nichol, 7-4160/pager 931-2168

NCIC A Phase III Randomized Trial of Metformin Versus Placebo on Recurrence and Survival in Early Stage Breast Cancer

MA.32

PI Cooke, Andrew

Co-I Grenier, Debjani
Pitz, Marshall
Gordon, Vallerie
Niraula, Saroj
Kim, Christina
Desautels, Danielle
Green, Susan
Graham, Jeffrey
Thiessen, Maclean

AI Beshara, Eren

Pathologist: HSC - C. Santos, S

Ethics #: B2010:160

Date Opened: 18-Jul-12

Reason for Closure: Met accrual goals

Site #: CARM

Date Closed: 22-Jan-13

BU #: Three

Pts Entered: 12

Pts Pre-Screened:

Accrual Goal: 20 pts x 6 months

Location: McDermot & Tache

Notes: Randomization must occur within 12 months of histologic diagnosis of breast cancer

Disease Site Group Breast

NCIC A Randomized Phase III Study of Radiation Doses and Fractionation Schedules for Ductal Carcinoma In Situ (DCIS) of the Breast **PI** Akra, Mohamed
MA.33* **Co-I** Cooke, Andrew
MacIntosh, Ethel
Bashir, Bashir
Nashed, Maged
Gordon, Vallerie
Kim, Christina
Graham, Jeffrey
Thiessen, Maclean
AI
Pathologist: C. Santos

Ethics #: B2009:066 **Date Opened:** 08-Dec-09 **Reason for Closure:** Met accrual goals
Site #: CARM **Date Closed:** 20-Jun-14
BU #: Three **# Pts Entered:** 43 **# Pts Pre-Screened:** 404 **Accrual Goal:** 20/yr x 3 yrs
Location: McDermot & Tache

Notes: RT must begin within 12 wks of last surgical procedure; **Jun.4/14-Do not approach anymore pts due to impending trial closure**

NCIC A Phase III Randomized Study of Adjuvant Combination Chemotherapy and Hormonal Therapy Alone in Women with Previously Resected Axillary Node-Negative Breast Cancer with Various Levels of Risk for Recurrence: Trial Assigning Individualized Options for Treatment (TAILORx); Program for the Assessment of Current Cancer Tests (PACCT-1) **PI** Grenier, Debjani
MAC.12 **Co-I** Pitz, Marshall
Gordon, Vallerie
Niraula, Saroj
Kim, Christina
Desautels, Danielle
Green, Susan
Graham, Jeffrey
Thiessen, Maclean
AI Beshara, Eren
Pathologist: L. Lucman

Ethics #: B2008:033 **Date Opened:** 22-Jan-09 **Reason for Closure:**
Site #: CARM **Date Closed:** 20-Aug-10
BU #: Three **# Pts Entered:** 13 **# Pts Pre-Screened:** **Accrual Goal:** 5-10 in 3 yrs
Location: McDermot, Tache & VGH

Notes: Closed to pre-registration.

Disease Site Group Breast

NCIC A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less.
MAC.15 (SWOG S1007)* RxPONDER: A Clinical Trial Rx for Positive Node, Endocrine Responsive Breast Cancer

PI Grenier, Debjani
Co-I Pitz, Marshall
Gordon, Vallerie
Niraula, Saroj
Kim, Julian
Kim, Christina
Desautels, Danielle
Graham, Jeffrey
Thiessen, Maclean
AI Beshara, Eren
Pathologist:

Ethics #: B2011:135 **Date Opened:** 23-Mar-12 **Reason for Closure:** Met accrual goal.
Site #: CARM **Date Closed:** 15-Oct-15
BU #: Three **# Pts Entered:** 19 **# Pts Pre-Screened:** 899 **Accrual Goal:** 20/yr x 6yrs=120
Location: McDermot & Tache

Notes: Registration must occur within 56 days of the last surgical procedure; ****ACCRUAL ON-HOLD as of Apr. 12/14****;
OPEN TO ACCRUAL as of May 27/14; ***Study closed to Step 1 registration Oct 1/15***

NCIC (IBCSG 24-02) A Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane as Adjuvant Therapies for Pre-Menopausal
MAC.4* Women with Endocrine Responsive Breast Cancer

PI Grenier, Debjani
Co-I Pitz, Marshall
Gordon, Vallerie
Niraula, Saroj
Kim, Christina
Desautels, Danielle
Graham, Jeffrey
Thiessen, Maclean
AI Beshara, Eren
Pathologist: L. Lucman

Ethics #: B2004:184 **Date Opened:** 07-Apr-05 **Reason for Closure:** Met accrual goals
Site #: CARM **Date Closed:** 30-Apr-10
BU #: Three **# Pts Entered:** 4 **# Pts Pre-Screened:** **Accrual Goal:** 5-10/yr (25-50 total)
Location: VGH Only

Notes:

Disease Site Group Breast

NCIC A Randomised, Double-Blind, Parallel Group, Placebo-Controlled Multi-centre Phase III Study to Assess the Efficacy and Safety of Olaparib versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy

NCIC MA.36

PI Niraula, Saroj

Co-I Grenier, Debjani
Pitz, Marshall
Gordon, Vallerie
Kim, Christina
Desautels, Danielle
Green, Susan
Graham, Jeffrey
Thiessen, Maclean

AI Beshara, Eren

Pathologist: B. Lategan, C.Sant

Ethics #: B2015:125 **Date Opened:** 02-Sep-16 **Reason for Closure:** Met accrual goals

Site #: CARM **Date Closed:** 28-May-19

BU #: Three **# Pts Entered:** 1 **# Pts Pre-Screened:** 67 **Accrual Goal:** 5 pts per year

Location: McDermot & Tache

Notes:

NCIC/Roche A Randomized, Multicenter, Double-Blind, Placebo-Controlled Comparison of Chemotherapy plus Trastuzumab plus Placebo versus Chemotherapy plus Trastuzumab plus Pertuzumab as Adjuvant Therapy in Patients with Operable HER2-positive Primary Breast Cancer

MA.34 "APHINITY" / Roche B025126/BIG 4-11*

PI Grenier, Debjani

Co-I Pitz, Marshall
Niraula, Saroj
Kim, Christina
Desautels, Danielle
Graham, Jeffrey
Thiessen, Maclean

AI Beshara, Eren

Pathologist:

Ethics #: B2012:008 **Date Opened:** 09-Jan-13 **Reason for Closure:** Met accrual goal

Site #: CARM **Date Closed:** 28-Jun-13

BU #: Three **# Pts Entered:** 2 **# Pts Pre-Screened:** **Accrual Goal:** 15/yr x 2 yrs

Location: McDermot & Tache

Notes:

Disease Site Group Breast

NRG Oncology

A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chest Wall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy

NSABP B-51* (RTOG 1304)

PI Akra, Mohamed

Co-I Cooke, Andrew
Grenier, Debjani
MacIntosh, Ethel
Pitz, Marshall
Bashir, Bashir
Nashed, Maged
Gordon, Vallerie
Niraula, Saroj
Kim, Julian
Kim, Christina
Rivard, Justin
Desautels, Danielle
Green, Susan
Graham, Jeffrey
Thiessen, Maclean

AI Beshara, Eren

Pathologist: B.Lategan,H.Qiu

Ethics #: B2015:128

Date Opened: 06-Oct-16

Reason for Closure: Met accrual goals

Site #: 054

Date Closed: 28-Dec-20

BU #: Three

Pts Entered: 16

Pts Pre-Screened: 100

Accrual Goal: 3-5 pts/year

Location: McDermot & Tache

Notes: **06Aug2018: Closure of the BAHO/QoL Component**

NSABP

A Clinical Trial to Determine the Efficacy of Five Years of Letrozole Compared to Placebo in Patients Completing Five Years of Hormonal Therapy Consisting of an Aromatase Inhibitor (AI) or Tamoxifen Followed by an AI in Prolonging Disease Free Survival in Postmenopausal Women with Hormone Receptor Positive Breast Cancer

B-42

PI Cooke, Andrew

Co-I Akra, Mohamed
Butler, James
Grenier, Debjani
Liu, Junliang
MacIntosh, Ethel
Pitz, Marshall
Bashir, Bashir
Nashed, Maged
Gordon, Vallerie
Niraula, Saroj
Kim, Christina
Desautels, Danielle
Graham, Jeffrey
Thiessen, Maclean

AI Beshara, Eren

Pathologist: L. Lucman

Ethics #: B2007:057

Date Opened: 30-Oct-07

Reason for Closure: Met accrual goals

Site #: 054

Date Closed: 06-Jan-10

BU #: Three

Pts Entered: 21

Pts Pre-Screened:

Accrual Goal: 10-15/yr (50-75 total)

Location: McDermot, Tache & VGH

Notes:

Disease Site Group Breast

OCOG A Prospective Cohort Study Evaluating Risk of Local Recurrence Following Breast Conserving Surgery and Endocrine Therapy in Low Risk Luminal A Breast Cancer

OCOG LUMINA

PI Akra, Mohamed

Co-I Cooke, Andrew
Grenier, Debjani
MacIntosh, Ethel
Bashir, Bashir
Gordon, Vallerie
Niraula, Saroj
Kim, Julian
Kim, Christina
Kakumanu, Saranya
Desautels, Danielle
Graham, Jeffrey
Thiessen, Maclean

AI

Pathologist:

Ethics #: B2015:111 **Date Opened:** 13-Apr-16 **Reason for Closure:** Met accrual goals
Site #: 2011 **Date Closed:** 23-Jun-17
BU #: Three **# Pts Entered:** 22 **# Pts Pre-Screened:** 93 **Accrual Goal:** 5 pts/year
Location: McDermot & Tache

Notes:

RTOG A Phase III Trial of Accelerated Whole Breast Irradiation with Hypofractionation plus Concurrent Boost versus Standard Whole Breast Irradiation plus Sequential Boost for Early-Stage Breast Cancer

1005*

PI Nashed, Maged

Co-I Cooke, Andrew
Kim, Christina
Desautels, Danielle
Graham, Jeffrey
Thiessen, Maclean

AI Beshara, Eren

Pathologist:

Ethics #: B2012:057 **Date Opened:** 04-Sep-13 **Reason for Closure:** Met accrual goal
Site #: 2219 **Date Closed:** 20-Jun-14
BU #: Three **# Pts Entered:** 6 **# Pts Pre-Screened:** 39 **Accrual Goal:** 20/yr over 4 yrs (80 total)
Location: McDermot & Tache

Notes: **Study entry within 50 days of last dose of chemo/last surgical procedure**

Disease Site Group Gastrointestinal

Disease Site Group Gastrointestinal

CCTG Neoadjuvant Chemotherapy, Excision and Observation for Early Rectal Cancer: **PI** Helewa, Ramzi
The NEO Trial CCTG CO.28 **Co-I** Krahn, Marianne
Wong, Ralph
Gordon, Vallerie
Kim, Christina
Paul, James
Goldenberg, Benjamin
Hyun, Eric
Zhang, Hanbo

CCTG CO.28

AI
Pathologist:

Ethics #: B2017:133 **Date Opened:** 12-Jan-18 **Reason for Closure:** Met accrual goals
Site #: CARM **Date Closed:** 19-May-20
BU #: Three **# Pts Entered:** 4 **# Pts Pre-Screened:** 7 **Accrual Goal:** 5-6/yr
Location: McDermot Only

Notes:

CCTG Circulating Tumour DNA Analysis Informing Adjuvant Chemotherapy in Stage III **PI** Wong, Ralph
Colon Cancer: A Multicentre Phase II/III Randomised Controlled Study **Co-I** Daeninck, Paul
(DYNAMIC-III) Krahn, Marianne
Gordon, Vallerie
Kim, Christina
Paul, James
Goldenberg, Benjamin
Anderson, Brady
Zhang, Hanbo

CCTG CO.29

AI
Pathologist:

Ethics #: B2021:069 (HS2) **Date Opened:** 08-Apr-22 **Reason for Closure:** Met accrual goals
Site #: CARM **Date Closed:** 31-Mar-23
BU #: Three **# Pts Entered:** 17 **# Pts Pre-Screened:** 63 **Accrual Goal:** 10/yr
Location: McDermot Only

Notes:

Disease Site Group Gastrointestinal

NCIC A Phase II/III Trial of Neoadjuvant Folfox with Selective Use of Combined
CRC.7* Modality Chemoradiation versus Preoperative Combined Modality Chemoradation
for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection
with Total Mesorectal Excision (ALLIANCE N1084) (NCIC CRC.7)

PI Gordon, Vallerie
Co-I Akra, Mohamed
Daeninck, Paul
Krahn, Marianne
Maksymiuk, Andrew
Wong, Ralph
Nashed, Maged
Kim, Christina
Paul, James
Goldenberg, Benjamin
Zhang, Hanbo

AI
Pathologist:

Ethics #: B2014:048 **Date Opened:** 03-Oct-14 **Reason for Closure:** Met accrual goals
Site #: CARM **Date Closed:** 28-Dec-18
BU #: Three **# Pts Entered:** 42 **# Pts Pre-Screened:** 165 **Accrual Goal:** 3-5/year
Location: McDermot Only

Notes:

NCIC A Randomized Phase II/III Trial of Preoperative Chemoradiotherapy versus
GA.1* Preoperative Chemotherapy for Resectable Gastric Cancer

PI Akra, Mohamed
Co-I Krahn, Marianne
Wong, Ralph
Bashir, Bashir
Nashed, Maged
Gordon, Vallerie
Kim, Christina
Paul, James
Goldenberg, Benjamin
Zhang, Hanbo

AI
Pathologist: R.Gheorghe, J.D.

Ethics #: B2016:007 **Date Opened:** 02-Nov-16 **Reason for Closure:** Met accrual goals
Site #: 11015 **Date Closed:** 01-Jul-21
BU #: Three **# Pts Entered:** 6 **# Pts Pre-Screened:** 15 **Accrual Goal:** 4 pts/year
Location: McDermot Only

Notes:

Disease Site Group Genitourinary

Disease Site Group Genitourinary

Bayer HealthCare

A Phase III, Randomized, Double-Blind, Placebo-Controlled Trial of Radium-223 Dichloride in Combination with Abiraterone Acetate and Prednisone/Prednisolone in the Treatment of Asymptomatic or Mildly Symptomatic Chemotherapy-Naïve Subjects with Bone Predominant Metastatic Castration-Resistant Prostate Cancer (CRPC)

Bayer 15396* CRPC

PI Saranchuk, Jeff

Co-I Czaykowski, Piotr
Gingerich, Joel
Ong, Aldrich
Koul, Rashmi
Kim, Julian
Dubey, Arbind

AI

Pathologist:

Ethics #: B2014:079

Date Opened: 11-Mar-15

Reason for Closure: Met accrual goal.

Site #: 26004

Date Closed: 22-Aug-16

BU #: Two

Pts Entered: 4

Pts Pre-Screened: 21

Accrual Goal: 10-20 pts/year

Location: McDermot Only

Notes:

CCTG

A Phase II Study of Durvalumab (MEDI4736) With or Without Tremelimumab in Patients with Metastatic Castration Resistant Prostate Cancer - CCTG IND.232

CCTG IND.232 mCRPC

PI Gingerich, Joel

Co-I Czaykowski, Piotr
Bashir, Bashir
Graham, Jeffrey
Zhang, Hanbo

AI

Pathologist:

Ethics #: B2017:008

Date Opened: 28-Jun-17

Reason for Closure: Met accrual goals

Site #: CARM

Date Closed: 01-Oct-19

BU #: Two

Pts Entered: 1

Pts Pre-Screened: 11

Accrual Goal: 3/yr

Location: McDermot Only

Notes:

CCTG

A Phase 3 Randomized Study Comparing Perioperative Nivolumab vs. Observation in Patients with Renal Cell Carcinoma Undergoing Nephrectomy (Prosper RCC) (ECOG-ACRIN EA8143)

CCTG REC.4

PI Graham, Jeffrey

Co-I Czaykowski, Piotr
Gingerich, Joel
Saranchuk, Jeff
Nayak, Jasmir
Zhang, Hanbo

AI

Pathologist:

Ethics #: B2019:101 (HS2)

Date Opened: 28-Jul-20

Reason for Closure: Met accrual goals

Site #: CARM

Date Closed: 09-Jun-21

BU #: Two

Pts Entered: 3

Pts Pre-Screened: 4

Accrual Goal: 4-6/yr

Location: McDermot Only

Notes:

Disease Site Group Genitourinary

Clovis Oncology, Inc. TRITON 3: A Multicenter, Randomized, Open-label Phase 3 Study of Rucaparib versus Physician's Choice of Therapy for Patients with Metastatic Castration-Resistant Prostate Cancer Associated with Homologous Recombination Deficiency **PI** Gingerich, Joel
Clovis 063 mCRPC **Co-I** Czaykowski, Piotr
Dawe, David
Graham, Jeffrey
Zhang, Hanbo

AI

Pathologist:

Ethics #: B2017:018 **Date Opened:** 24-Aug-17 **Reason for Closure:** Met accrual goals
Site #: 14018 **Date Closed:** 03-Mar-22
BU #: Two **# Pts Entered:** 12 **# Pts Pre-Screened:** 124 **Accrual Goal:** 4/yr
Location: McDermot Only

Notes:

Janssen Research & Development A Phase 3 Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations (THOR) **PI** Gingerich, Joel
Janssen 3001 Urothelial **Co-I** Czaykowski, Piotr
Graham, Jeffrey
Zhang, Hanbo

AI

Pathologist:

Ethics #: B2018:044 **Date Opened:** 30-Oct-18 **Reason for Closure:**
Site #: CA10002 **Date Closed:** 17-Feb-23
BU #: Two **# Pts Entered:** 1 **# Pts Pre-Screened:** 30 **Accrual Goal:** 1-2/yr
Location: McDermot Only

Notes:

Merck Sharp & Dohme Corp. A Phase III, Randomized, Double-Blind, Placebo-Controlled Clinical Trial of Pembrolizumab (MK-3475) as Monotherapy in the Adjuvant Treatment of Renal Cell Carcinoma Post Nephrectomy (KEYNOTE-564) **PI** Graham, Jeffrey
Merck 564 RCC **Co-I** Czaykowski, Piotr
Gingerich, Joel
Dawe, David
Zhang, Hanbo

AI

Pathologist:

Ethics #: B2018:087 **Date Opened:** 03-Dec-18 **Reason for Closure:** Met accrual goals
Site #: 0119 **Date Closed:** 12-Jul-19
BU #: Two **# Pts Entered:** 1 **# Pts Pre-Screened:** 10 **Accrual Goal:** 3-5/yr
Location: McDermot Only

Notes:

Disease Site Group Genitourinary

NCIC A Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy versus Immediate Radical Prostatectomy in Patients with High-Risk, Clinically Localized Prostate Cancer (PRC.3) (CALGB-90203)

PI Drachenberg, Darrel

Co-I Chowdhury, Amit
Czaykowski, Piotr
Gingerich, Joel
Ong, Aldrich
Saranchuk, Jeff
Bashir, Bashir
Koul, Rashmi
Graham, Jeffrey
Zhang, Hanbo

AI

Pathologist: I. Aljada

Ethics #: B2008:064 **Date Opened:** 01-Dec-08 **Reason for Closure:** Met accrual goal.

Site #: CARM **Date Closed:** 02-Oct-15

BU #: Two **# Pts Entered:** 16 **# Pts Pre-Screened:** 68 **Accrual Goal:** 10-20/yr x 5 yrs (50 total)

Location: McDermot Only

Notes:

Disease Site Group Gynecological

CCTG A Randomized Phase II Double-Blind Placebo-Controlled Trial of Acetylsalicylic Acid (Asa) in Prevention of Ovarian Cancer in Women with Brea 1/2 Mutations (Stics and Stones)

PI Robinson, Christine

Co-I Dean, Erin
Popowich, Shaundra
Altman, Alon
Kean, Sarah
Roberts, Lesley

AI Adolph, Lauren
Markstrom, Emma

Pathologist:

Ethics #: B2018:061 **Date Opened:** 17-Sep-18 **Reason for Closure:** Sponsor decision

Site #: CARM **Date Closed:** 15-Dec-22

BU #: Two **# Pts Entered:** 2 **# Pts Pre-Screened:** 25 **Accrual Goal:** 5/yr

Location: McDermot & Tache

Notes:

Disease Site Group Gynecological

Clovis Oncology, Inc. ATHENA (A Multicenter, Randomized, Double-Blind, Placebo- Controlled Phase 3 Study in Ovarian Cancer Patients Evaluating Rucaparib and Nivolumab as Maintenance Treatment Following Response to Front-Line Platinum-Based Chemotherapy) **PI** Altman, Alon

Clovis 087 Ovarian (ATHENA) **Co-I** Dean, Erin
Popowich, Shaundra
Robinson, Christine
Kean, Sarah
Roberts, Lesley

AI Adolph, Lauren
Markstrom, Emma

Pathologist:

Ethics #: B2018:123 **Date Opened:** 21-Mar-19 **Reason for Closure:** Met accrual goals
Site #: 14032 **Date Closed:** 21-May-20
BU #: Two **# Pts Entered:** 3 **# Pts Pre-Screened:** 18 **Accrual Goal:** 5-10/yr

Location: McDermot Only

Notes:

Merck Sharp & Dohme Corp. A Multicenter, Open-label, Randomized, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib in Combination with Pembrolizumab Versus Treatment of Physician's Choice in Participants with Advanced Endometrial Cancer **PI** Popowich, Shaundra

Merck 775 Endometrial **Co-I** Dean, Erin
Altman, Alon
Robinson, Christine
Kean, Sarah

AI Markstrom, Emma

Pathologist:

Ethics #: B2018:057 **Date Opened:** 10-Oct-18 **Reason for Closure:** Met accrual goals
Site #: 0108 **Date Closed:** 03-Feb-20
BU #: Two **# Pts Entered:** 5 **# Pts Pre-Screened:** 17 **Accrual Goal:** 5/yr

Location: McDermot Only

Notes:

Merck Sharp & Dohme Corp. A Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial of Pembrolizumab (MK-3475) Plus Chemotherapy Versus Chemotherapy Plus Placebo for the First-Line Treatment of Persistent, Recurrent, or Metastatic Cervical Cancer (KEYNOTE- 826) **PI** Popowich, Shaundra

Merck 826 Cervical **Co-I** Dean, Erin
Altman, Alon
Robinson, Christine
Kean, Sarah
Roberts, Lesley

AI Adolph, Lauren
Markstrom, Emma

Pathologist:

Ethics #: B2018:105 **Date Opened:** 04-Mar-19 **Reason for Closure:** Met accrual goals
Site #: 1725 **Date Closed:** 31-Jan-20
BU #: Two **# Pts Entered:** 3 **# Pts Pre-Screened:** 8 **Accrual Goal:** 5/yr

Location: McDermot Only

Notes:

Disease Site Group Gynecological

NCIC	A Randomized Phase III Trial Comparing Radical Hysterectomy and Pelvic Node Dissection versus Simple Hysterectomy and Pelvic Node Dissection in Patients with Low-Risk Early-Stage Cervical Cancer	PI	Altman, Alon
CX.5		Co-I	Dean, Erin Popowich, Shaundra Robinson, Christine Kean, Sarah Roberts, Lesley
		AI	Adolph, Lauren Markstrom, Emma
		Pathologist:	

Ethics #: B2013:098 **Date Opened:** 21-Jan-14 **Reason for Closure:** Met accrual goals
Site #: CARM **Date Closed:** 29-Nov-19
BU #: Two **# Pts Entered:** 9 **# Pts Pre-Screened:** 31 **Accrual Goal:** 5-10/yr

Location: McDermot & Tache

Notes:

Novocure GmbH	ENGOT-ov50 / INNOVATE-3: Pivotal, Randomized, Open-Label Study of Tumor Treating Fields (TTFields, 200kHz) Concomitant with Weekly Paclitaxel for the Treatment of Recurrent Ovarian Cancer	PI	Altman, Alon
Novocure EF-28 Ovarian		Co-I	Dean, Erin Popowich, Shaundra Robinson, Christine Kean, Sarah
		AI	Markstrom, Emma
		Pathologist:	

Ethics #: B2020:036 (HS2) **Date Opened:** 06-Aug-21 **Reason for Closure:** Met accrual goals
Site #: 11-410 **Date Closed:** 26-Oct-21
BU #: Two **# Pts Entered:** 1 **# Pts Pre-Screened:** 4 **Accrual Goal:** 3-5/yr

Location: McDermot Only

Notes:

TESARO	A Phase 3, Randomized, Double-Blind, Multicenter Study Of Dostarlimab (Tsr-042) Plus Carboplatin-Paclitaxel Versus Placebo Plus Carboplatin-Paclitaxel In Patients With Recurrent Or Primary Advanced Endometrial Cancer (Ruby)	PI	Robinson, Christine
Tesaro RUBY Endometrial		Co-I	Dean, Erin Popowich, Shaundra Altman, Alon Kean, Sarah Roberts, Lesley
		AI	Adolph, Lauren Markstrom, Emma
		Pathologist:	

Ethics #: B2019:109 (HS2) **Date Opened:** 11-Dec-20 **Reason for Closure:** Met accrual goals
Site #: 124022 **Date Closed:** 26-Apr-22
BU #: Two **# Pts Entered:** 1 **# Pts Pre-Screened:** 8 **Accrual Goal:** 3-5/yr

Location: McDermot Only

Notes: Part 1 closed to accrual on January 18, 2021 due to accrual goals being met. Part 2 is open to accrual as of October 7, 2021.** Part 2 Carcinosarcoma Cohort closed to accrual March 9, 2022** **oCohort dMMR/MSI-H closed

Disease Site Group Head & Neck

Disease Site Group Head & Neck

CCTG Randomized Phase II Study of Cisplatin Plus Radiotherapy Versus Durvalumab Plus Radiotherapy Followed by Adjuvant Durvalumab Versus Durvalumab Plus Radiotherapy Followed by Adjuvant Tremelimumab and Durvalumab in Intermediate Risk HPV-Positive Locoregionally Advanced Oropharyngeal Squamous Cell Cancer (LA-OSCC)

CCTG HN.9 H&N*

PI Maksymiuk, Andrew

Co-I Butler, James
Cooke, Andrew
Leylek, Ahmet S.
Gordon, Vallerie
Harlos, Craig

AI

Pathologist:

Ethics #: B2018:056 **Date Opened:** 06-Sep-18 **Reason for Closure:** Sponsor decision
Site #: CARM **Date Closed:** 16-Nov-22
BU #: Three **# Pts Entered:** 7 **# Pts Pre-Screened:** 23 **Accrual Goal:** 5/yr
Location: McDermot Only

Notes:

CCTG A Phase II Single Arm Trial of Elective Volume Adjusted De-Escalation Radiotherapy (Evader) in Patients with Low-Risk HPV-Related Oropharyngeal Squamous Cell Carcinoma

HN.10*

PI Butler, James

Co-I Cooke, Andrew
Leylek, Ahmet S.
Maksymiuk, Andrew
Gordon, Vallerie
Harlos, Craig

AI

Pathologist:

Ethics #: B2019:058 **Date Opened:** 03-Mar-20 **Reason for Closure:** Met accrual goals
Site #: CARM **Date Closed:** 02-Dec-21
BU #: Three **# Pts Entered:** 15 **# Pts Pre-Screened:** 20 **Accrual Goal:** 6/yr
Location: McDermot Only

Notes:

RTOG Phase III Trial of Radiotherapy Plus Cetuxmab Versus Chemoradiotherapy in HPV-Associated Oropharynx Cancer

1016 H&N*

PI Butler, James

Co-I Cooke, Andrew
Leylek, Ahmet S.
Maksymiuk, Andrew
Gordon, Vallerie
Harlos, Craig

AI

Pathologist: C. Penner

Ethics #: B2011:146 **Date Opened:** 26-Jul-12 **Reason for Closure:** Met accrual goals
Site #: 2219 **Date Closed:** 31-Jul-14
BU #: Three **# Pts Entered:** 8 **# Pts Pre-Screened:** 55 **Accrual Goal:** 8/yr x 4 yrs
Location: McDermot Only

Notes:

Disease Site Group Hematology/Hemostasis

Disease Site Group Hematology/Hemostasis

Novo Nordisk A Non-Interventional Post-Authorisation Safety Study (Pass) in Male Haemophilia B Patients Receiving Nonacog Beta Pegol (N9-Gp) Prophylaxis Treatment **PI** Stoffman, Jayson
Novo Nordisk 4031 **Co-I** Houston, Don S.
Hemophilia B Rimmer, Emily
AI
Pathologist:

Ethics #: B2018:140 **Date Opened:** 02-May-19 **Reason for Closure:** Met accrual goal
Site #: 204 **Date Closed:** 25-Jan-21
BU #: One **# Pts Entered:** 1 **# Pts Pre-Screened:** 1 **Accrual Goal:** 2/yr
Location: McDermot Only
Notes:

Disease Site Group Leukemia

Agios Pharmaceuticals Inc. A Phase 3, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study of AG-120 in Combination with Azacitidine in Subjects >18 Years of Age with Previously Untreated and Relapsed Acute Myeloid Leukemia with an IDH1 Mutation Who Are Candidates for Non-Intensive Therapy **PI** Paulson, Kris
Agios 009 AML **Co-I** Moltzan, Catherine
Szwajcer, David
Kansara, Roopesh
Speziali, Craig
Yang, Lin
Menard, Chantalle
AI
Pathologist:

Ethics #: B2017:115 **Date Opened:** 26-Apr-18 **Reason for Closure:** PI decision
Site #: 124104 **Date Closed:** 29-Mar-21
BU #: One **# Pts Entered:** 1 **# Pts Pre-Screened:** 8 **Accrual Goal:** 0-2/yr
Location: McDermot Only
Notes:

NCIC Adult ALL Trial **PI** Paulson, Kris
AL.5 **Co-I** Szwajcer, David
Speziali, Craig
Menard, Chantalle
AI Dawe, Kevin
Pathologist:

Ethics #: B2008:144 **Date Opened:** 28-Jul-09 **Reason for Closure:** met accrual goal
Site #: CARM **Date Closed:** 08-Jan-13
BU #: One **# Pts Entered:** 8 **# Pts Pre-Screened:** **Accrual Goal:** 5/yr (2 yrs)
Location: McDermot Only
Notes:

Disease Site Group Liver

Disease Site Group Liver

Exelixis, Inc. A Randomized, Controlled Phase 3 Study of Cabozantinib (XL184) in Combination with Atezolizumab versus Sorafenib in Subjects with Advanced Hepatocellular Carcinoma Who Have Not Received Previous Systemic Anticancer Therapy **PI** Gordon, Vallerie
Exelixis 312 HCC **Co-I** Krahn, Marianne
Wong, Ralph
Kim, Christina
Paul, James
Goldenberg, Benjamin
AI Kirkpatrick, Iain
Pathologist:

Ethics #: B2019:019 **Date Opened:** 02-Jul-19 **Reason for Closure:** Met accrual goals
Site #: 2012 **Date Closed:** 19-Aug-20
BU #: Three **# Pts Entered:** 2 **# Pts Pre-Screened:** 5 **Accrual Goal:** 2-3/yr
Location: McDermot Only

Notes:

Disease Site Group Lymphoproliferative

Acerta Pharma, BV A Randomized, Multicenter, Open-Label, 3 Arm Phase 3 Study of Obinutuzumab in Combination with Chlorambucil, ACP-196 in Combination with Obinutuzumab, and ACP-196 Monotherapy in Subjects with Previously Untreated Chronic Lymphocytic Leukemia **PI** Banerji, Versha
Acerta 007 CLL **Co-I** Johnston, James
Skrabek, Pamela
Minuk, Leonard
Yang, Lin
AI
Pathologist: A.Perry, M.Nasr

Ethics #: B2015:127 **Date Opened:** 21-Sep-16 **Reason for Closure:** Met accrual goals
Site #: 413 **Date Closed:** 07-Dec-16
BU #: One **# Pts Entered:** 7 **# Pts Pre-Screened:** 19 **Accrual Goal:** 6 pts/year
Location: McDermot Only

Notes:

Astex Pharmaceuticals, Inc. Phase 1-2 Study of the Safety, Pharmacokinetics, and Preliminary Activity of ASTX660 in Subjects with Advanced Solid Tumors and Lymphomas **PI** Kansara, Roopesh
Acerta 01 PTCL & CTCL **Co-I** Moltzan, Catherine
Skrabek, Pamela
Kotb, Rami
Minuk, Leonard
Yang, Lin
Menard, Chantalle
AI
Pathologist:

Ethics #: B2019:110 (HS2) **Date Opened:** 13-Nov-20 **Reason for Closure:** Met accrual goal
Site #: 207 **Date Closed:** 13-Jul-21
BU #: One **# Pts Entered:** 1 **# Pts Pre-Screened:** 1 **Accrual Goal:** 1/yr
Location: McDermot Only

Notes:

Disease Site Group Lymphoproliferative

AstraZeneca A Phase 3b, Multicenter, Open-Label, Single-Arm Study of Acalabrutinib (ACP-196) in Subjects with Chronic Lymphocytic Leukemia (ASSURE) **PI** Banerji, Versha
AZ 312 CLL **Co-I** Yang, Lin
AI

Pathologist:

Ethics #: B2019:086 (HS2) **Date Opened:** 02-Oct-20 **Reason for Closure:** Met accrual goals
Site #: 1002 **Date Closed:** 30-Sep-21
BU #: One **# Pts Entered:** 9 **# Pts Pre-Screened:** 20 **Accrual Goal:** 15/yr
Location: McDermot Only

Notes: **Treatment-naïve cohort closed 4 Nov 2020**

CMRG (MCRN) A Randomized Phase II, Open Label, Study of Daratumumab, Weekly Low-Dose Oral Dexamethasone and Cyclophosphamide With or Without Pomalidomide in Patients With Relapsed and Refractory Multiple Myeloma **PI** Kotb, Rami
CMRG 004 MM (Formerly MCRN 004) **Co-I** Dao, Vi
Rimmer, Emily
Minuk, Leonard

AI Kasian, Jayne

Pathologist:

Ethics #: B2017:145 **Date Opened:** 22-Feb-18 **Reason for Closure:** Accrual goal met
Site #: 14 **Date Closed:** 28-Mar-19
BU #: One **# Pts Entered:** 7 **# Pts Pre-Screened:** 17 **Accrual Goal:** 6-7/yr
Location: McDermot Only

Notes: Formerly known as MCRN

Millennium Pharmaceuticals, Inc. A Randomized, Open-label, Phase 3 Trial of A + AVD Versus ABVD as Frontline Therapy in Patients With Advanced Classical Hodgkin Lymphoma **PI** Skrabek, Pamela
Millennium C25003 HL* **Co-I** Johnston, James
Banerji, Versha
Kotb, Rami
Kansara, Roopesh
Yang, Lin
Menard, Chantalle

AI

Pathologist: M. Nasr

Ethics #: B2014:063 **Date Opened:** 24-Oct-14 **Reason for Closure:** Accrual goal met
Site #: 07009 **Date Closed:** 02-Sep-15
BU #: One **# Pts Entered:** 3 **# Pts Pre-Screened:** 16 **Accrual Goal:** 1-3 pts/year
Location: McDermot Only

Notes:

Disease Site Group Lymphoproliferative

MorphoSys AG A Phase II/III Randomized, Multicenter, Study of MOR00208 with Bendamustine versus Rituximab with Bendamustine in Patients with Relapsed Refractory Diffuse B-Cell Lymphoma (R-R-DLBCL) Who Are Not Eligible for High-Dose Chemotherapy (HDC) and Autologous Stem-Cell Transplantation (ASCT) B-MIND **PI** Skrabek, Pamela

MorphoSys 204 DLBCL **Co-I** Moltzan, Catherine
Kotb, Rami
Kansara, Roopesh
Minuk, Leonard
Yang, Lin
Menard, Chantalle

AI

Pathologist:

Ethics #: B2017:134 **Date Opened:** 06-Jun-18 **Reason for Closure:** Met accrual goals
Site #: 16002 **Date Closed:** 08-Jun-21
BU #: One **# Pts Entered:** 6 **# Pts Pre-Screened:** 15 **Accrual Goal:** 3/yr
Location: McDermot & Tache

Notes:

NCIC A Genetic Risk Stratified, Randomized Phase II Study of Four Fludarabine/Antibody Combinations for Patients with Symptomatic, Previously Untreated Chronic Lymphocytic Leukemia **PI** Banerji, Versha

CL.3 **Co-I** Skrabek, Pamela
Yang, Lin

AI

Pathologist: C. Morales

Ethics #: B2009:044 **Date Opened:** 05-May-10 **Reason for Closure:** Met accrual goal
Site #: CARM **Date Closed:** 17-Aug-12
BU #: One **# Pts Entered:** 9 **# Pts Pre-Screened:** **Accrual Goal:** 8-10/yr x 3.5 yrs
Location: McDermot Only

Notes:

Roche/Genetech A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial Comparing the Efficacy and Safety of Polatuzumab Vedotin in Combination with Rituximab and CHP (R-CHP) Versus Rituximab and CHOP (R-CHOP) in Previously Untreated Patients with Diffuse Large b-cell Lymphoma (POLARIX) **PI** Skrabek, Pamela

Roche GO39942 DLBCL **Co-I** Kotb, Rami
Minuk, Leonard
Yang, Lin
Menard, Chantalle

AI

Pathologist:

Ethics #: B2018:021 **Date Opened:** 25-Aug-18 **Reason for Closure:** Met accrual goals
Site #: 310207 **Date Closed:** 03-Jun-19
BU #: One **# Pts Entered:** 5 **# Pts Pre-Screened:** 20 **Accrual Goal:** 10/yr
Location: McDermot Only

Notes:

Disease Site Group Multi-DSG

Disease Site Group Multi-DSG

Merck Sharp & Dohme Corp. A Multicenter, Open-label Phase 2 Study of Lenvatinib (E7080/MK-7902) Plus Pembrolizumab (MK-3475) in Previously Treated Subjects with Selected Solid Tumors (LEAP-005)
Merck 005 Solid Tumours

PI Desautels, Danielle
Co-I Dean, Erin
Grenier, Debjani
Krahn, Marianne
Pitz, Marshall
Popowich, Shaundra
Wong, Ralph
Gordon, Vallerie
Altman, Alon
Niraula, Saroj
Kim, Christina
Kakumanu, Saranya
Robinson, Christine
Paul, James
Goldenberg, Benjamin
Harlos, Craig
Kean, Sarah
Green, Susan
Graham, Jeffrey
Thiessen, Maclean

AI
Pathologist:

Ethics #: B2019:017 **Date Opened:** 10-Jul-19 **Reason for Closure:** Met accrual goals
Site #: 0201 **Date Closed:** 03-Sep-21
BU #: Three **# Pts Entered:** 4 **# Pts Pre-Screened:** 20 **Accrual Goal:** 5/yr
Location: McDermot Only

Notes:

Disease Site Group Sarcoma

NCIC Pazopanib Neoadjuvant Trial in Non-Rhabdomyosarcoma Soft-Tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib (ARST 1321) (COG ARST 1321)
SRC.6*

PI Banerji, Shantanu
Co-I Akra, Mohamed
MacIntosh, Ethel
Kakumanu, Saranya
Rivard, Justin
AI
Pathologist: Dr. K. Berry

Ethics #: B2015:014 **Date Opened:** 20-Mar-17 **Reason for Closure:** Sponsor decision
Site #: CARM **Date Closed:** 13-Oct-17
BU #: Three **# Pts Entered:** 3 **# Pts Pre-Screened:** 9 **Accrual Goal:** 10-15 pts/year
Location: McDermot & Tache

Notes: Mandatory Med Onc consult prior to signing consent.

Disease Site Group Skin Cancer

Disease Site Group Skin Cancer

CCTG A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon Alpha-2b for Resected High-risk Melanoma (ECOG E1609) **PI** Wong, Ralph
MEC.3 **Co-I** Grenier, Debjani
MacIntosh, Ethel

AI
Pathologist:

Ethics #: B2012:107 **Date Opened:** 12-Feb-13 **Reason for Closure:**
Site #: CARM **Date Closed:** 15-Aug-14
BU #: Two **# Pts Entered:** 1 **# Pts Pre-Screened:** 9 **Accrual Goal:** 2-5/yr x 3 yrs
Location: McDermot Only

Notes:

Merck Sharp & Dohme Corp. Adjuvant Therapy with Pembrolizumab versus Placebo in Resected High- risk Stage II Melanoma: A Randomized, Double-blind Phase 3 Study (KEYNOTE 716) **PI** Wong, Ralph
Merck 716 Melanoma **Co-I** Grenier, Debjani
Rivard, Justin

AI
Pathologist:

Ethics #: B2018:104 **Date Opened:** 01-Mar-19 **Reason for Closure:** Accrual goal met
Site #: 0053 **Date Closed:** 11-Aug-20
BU #: Two **# Pts Entered:** 4 **# Pts Pre-Screened:** 13 **Accrual Goal:** 2-5/yr
Location: McDermot Only

Notes:

NCIC A Phase III Randomized Study of Four Weeks High Dose IFN-a2b in Stage T2b N0, T3a-b N0, T4a-b N0 and T1-4 N1-a, 2a, 3 (Microscopic) Melanoma **PI** Wong, Ralph
ME.10 **Co-I** Grenier, Debjani
MacIntosh, Ethel

AI
Pathologist: K. Von Kuster

Ethics #: B2000:196 **Date Opened:** 01-Jan-01 **Reason for Closure:**
Site #: CARM **Date Closed:** 26-Oct-10
BU #: Two **# Pts Entered:** 4 **# Pts Pre-Screened:** **Accrual Goal:** 5-10/yr (3 yrs)
Location: McDermot Only

Notes: 1 box @ Tache

Disease Site Group Thoracic

Disease Site Group Thoracic

AstraZeneca

A Phase III, Randomized, Double-blind, Placebo-controlled, Multi-center, International Study of Durvalumab or Durvalumab and Tremelimumab as Consolidation Treatment for Patients with Stage I-III Limited Disease Small-Cell Lung Cancer Who Have Not Progressed Following Concurrent Chemoradiation Therapy (ADRIATIC) (D933QC00001)

AZ ADRIATIC SCLC
D933QC00001*

PI Banerji, Shantanu

Co-I Ahmed, Naseer
Chowdhury, Amit
Leylek, Ahmet S.
Maksymiuk, Andrew
Bashir, Bashir
Dawe, David
Kim, Julian
Dubey, Arbind
Paul, James
Harlos, Craig
Green, Susan

AI

Pathologist:

Ethics #: B2019:018

Date Opened: 04-Sep-19

Reason for Closure: Met accrual goal

Site #: 1006

Date Closed: 19-Aug-21

BU #: Two

Pts Entered: 3

Pts Pre-Screened: 12

Accrual Goal: 2/yr

Location: McDermot Only

Notes:

CCTG

A Phase II Randomized Study of Pembrolizumab in Patients with Advanced Malignant Pleural Mesothelioma. CCTG IND.227

CCTG IND.227

PI Dawe, David

Co-I Maksymiuk, Andrew
Banerji, Shantanu
Paul, James
Harlos, Craig
Green, Susan

AI

Pathologist:

Ethics #: B2016:114

Date Opened: 02-May-17

Reason for Closure: Met accrual goals

Site #: CARM

Date Closed: 04-Sep-20

BU #: Two

Pts Entered: 14

Pts Pre-Screened: 19

Accrual Goal: 3/yr

Location: McDermot Only

Notes:

Disease Site Group Thoracic

F. Hoffmann-La Roche Ltd A Phase III, Open-Label, Randomized Study of Atezolizumab and Tiragolumab Compared with Durvalumab in Patients with Locally Advanced, Unresectable Stage III Non-Small Cell Lung Cancer who have not Progressed After Concurrent Platinum-Based Chemoradiation (Skyscraper-03)
Roche GO41854 NSCLC

PI Harlos, Craig
Co-I Maksymiuk, Andrew
Banerji, Shantanu
Dawe, David
Paul, James
Green, Susan
Rittberg, Rebekah

AI
Pathologist:

Ethics #: B2020:092 (HS2) **Date Opened:** 04-Nov-21 **Reason for Closure:** Met accrual goals
Site #: 330853 **Date Closed:** 03-Jan-23
BU #: Two **# Pts Entered:** 0 **# Pts Pre-Screened:** 9 **Accrual Goal:** 3/yr
Location: McDermot Only

Notes:

LOCAL-Dr. Gordon Buduhan Preoperative Treatment with Chemotherapy or Chemoradiation in Esophageal or Gastroesophageal Adenocarcinoma (POWERRANGER)
Local CTx vs CRT
Esophageal*

PI Banerji, Shantanu
Co-I Ahmed, Naseer
Chowdhury, Amit
Leylek, Ahmet S.
Maksymiuk, Andrew
Bashir, Bashir
Dawe, David
Kim, Julian
Paul, James
Harlos, Craig
Kidane, Biniam
Green, Susan

AI Morydz, Kristie
Pathologist: G. Qing

Ethics #: B2015:041 **Date Opened:** 23-Sep-15 **Reason for Closure:** Sponsor decision
Site #: N/A **Date Closed:** 28-Feb-22
BU #: Two **# Pts Entered:** 26 **# Pts Pre-Screened:** 88 **Accrual Goal:** 15/year
Location: McDermot Only

Notes:

Disease Site Group Thoracic

Merck Sharp & Dohme Corp. Merck LEAP-008 NSCLC A Phase 3, Multicenter, Randomized, Open-label Trial to Compare the Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with Lenvatinib (E7080/MK-7902) Versus Docetaxel in Previously Treated Participants with Metastatic Non-Small Cell Lung Cancer (NSCLC) and Progressive Disease (PD) after Platinum Doublet Chemotherapy and Immunotherapy (anti-PD-1/PD-L1 inhibitor) (LEAP-008)

PI Paul, James
Co-I Maksymiuk, Andrew
Banerji, Shantanu
Dawe, David
Harlos, Craig
Green, Susan
AI Morydz, Kristie
Pathologist:

Ethics #: B2019:047 (HS2) **Date Opened:** 14-Sep-20 **Reason for Closure:** Met accrual goals
Site #: 1504 **Date Closed:** 29-Mar-22
BU #: Two **# Pts Entered:** 1 **# Pts Pre-Screened:** 13 **Accrual Goal:** 2/yr
Location: McDermot Only

Notes:

NCIC BRC.2 (ECOG E1505) A Phase III Randomized Trial of Adjuvant Chemotherapy with or without Bevacizumab for Patients with Completely Resected Stage IB (≥ 4 cm) - III A Non-Small Cell Lung Cancer AND a Companion Study, BRC.2E, A Prospective Economic Analysis of NCIC BRC.2 E1505.

PI Maksymiuk, Andrew
Co-I Banerji, Shantanu
Dawe, David
Harlos, Craig
Green, Susan
AI
Pathologist:

Ethics #: B2008:049 **Date Opened:** 26-Nov-08 **Reason for Closure:** Met accrual goal
Site #: CARM **Date Closed:** 20-Sep-13
BU #: Two **# Pts Entered:** 6 **# Pts Pre-Screened:** **Accrual Goal:** 15/yr x 4 yrs(60 total)
Location: McDermot Only

Notes:

NCIC NCIC BR.31 A Phase III Prospective Double Blind Placebo Controlled Randomized Study of Adjuvant MEDI4736 in Completely Resected Non-Small Cell Lung Cancer

PI Dawe, David
Co-I Maksymiuk, Andrew
Banerji, Shantanu
Paul, James
Harlos, Craig
Green, Susan
AI Morydz, Kristie
Pathologist: G.Qing

Ethics #: B2015:102 **Date Opened:** 25-Jan-16 **Reason for Closure:** Met accrual goals
Site #: CARM **Date Closed:** 27-Mar-20
BU #: Two **# Pts Entered:** 8 **# Pts Pre-Screened:** 38 **Accrual Goal:** 5 pts/year
Location: McDermot Only

Notes: Closed to registrations 18 Oct 2019; Closed to enrollment 27 March 2020

Disease Site Group Thoracic

Varian Medical Systems The GPS Trial - Calypso Guided High Precision Stereotactic Ablative Radiosurgery
for Lung Tumors Using Real-Time Tumor Tracking & Respiratory Gating: A
Seamless Phase I/II Prospective Clinical Trial

Local GPS Lung Study*

PI Kim, Julian

Co-I Ahmed, Naseer
Leylek, Ahmet S.
Tan, Lawrence
Bashir, Bashir
Koul, Rashmi
Dubey, Arbind
Kidane, Biniam

AI

Pathologist:

Ethics #: B2017:048 **Date Opened:** 23-Nov-17 **Reason for Closure:** Met accrual goals
Site #: N/A **Date Closed:** 04-Apr-22

BU #: Two **# Pts Entered:** 16 **# Pts Pre-Screened:** 41 **Accrual Goal:** 28 pts over 3 yrs

Location: McDermot Only

Notes:
