# NATIONAL CANCER INSTITUTE CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE (CTAC)

## GASTRIC AND ESOPHAGEAL CANCERS WORKING GROUP

# WORKING GROUP REPORT APPENDIX 2 – LANDSCAPE OF NCI-SUPPORTED GASTRIC AND ESOPHAGEAL CANCERS CLINICAL TRIALS NOVEMBER 9, 2022

REPORT ACCEPTED ON NOVEMBER 9, 2022
THE CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE

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#### **GLOSSARY**

Abbreviation	Name
ATR	Ataxia Telangiectasia and Rad3 Related Protein
CAR	Chimeric Antigen Receptor
CLDN18.2	Claudin 18 Isoform A2
CTLA4	Cytotoxic T-Lymphocyte-Associated Protein 4
EGFR	Epidermal Growth Factor Receptor
FGF	Fibroblast Growth Factor
GITR	Glucocorticoid-induced Tumor Necrosis Factor Receptor
HER2	Human Epidermal Growth Factor Receptor 2
HSP-90	Heat Shock Protein 90
LAG3	Lymphocyte Activation Gene 3 Protein
PARP	Poly (ADP Ribose) Polymerase
PD-1	Programmed Cell Death Protein 1
PDL1	Programmed Death Ligand 1
TIGIT	T-Cell Immunoreceptor with Ig and Immunoreceptor Tyrosine-Based Inhibitor Motif
	Domains
TIM3	T-cell immunoglobulin and mucin domain-containing protein 3
VEGF	Vascular Endothelial Growth Factor

#### **OVERVIEW**

To describe the current landscape of clinical trials related to gastric and esophageal cancers, the Working Group reviewed output generated from NCI's Clinical Trials Reporting Program (CTRP) database. CTRP is a comprehensive database of cancer clinical trials that have been open to patient accrual on or after January 1, 2009. The system's structured data are coded to facilitate cancer trial search and retrieval. CTRP lists trials sponsored by NCI, including intramural trials in the NIH Clinical Center, as well as those directly funded by NCI through grants, e.g., National Clinical Trials Network (NCTN), NCI Community Oncology Program (NCORP), Experimental Therapeutics Clinical Trials Network (ETCTN), and/or contracts. Furthermore, CTRP encompasses all trials ongoing in NCI Designated Cancer Centers, including investigator-initiated trials and industry-led trials. Automated data feeds provide initial registration and updates for trials closely managed by NCI, such as NCTN and NCORP, whereas staff in cancer centers register their center's clinical trials, including any associated grant numbers.

The Working Group reviewed two (2) datasets: gastric and esophageal cancers treatment clinical trials and non-cancer treatment / other clinical trials (which encompass diagnostic, screening, prevention, supportive care, device, basic sciences, health services research, treatment of Barrett's esophagus, and other studies).

### GASTRIC AND ESOPHAGEAL CANCERS TREATMENT CLINICAL TRIALS Methods

On September 30, 2021, a CTRP query was run for all interventional trials coded with the terms 'gastric (stomach) cancer' and/or 'esophageal cancer'. In order to view the most current landscape of treatment clinical trials, the query was filtered using the following criteria.

#### Inclusion and Exclusion Criteria

- Trials with a primary purpose of 'treatment' and the following status were included:
  - Recruiting: Participants are currently being recruited, whether or not any participants have yet been enrolled.
  - Not yet recruiting: Study registered, but participants are not yet being recruited.
  - Active, not recruiting: Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled.
  - Suspended: Study halted prematurely but potentially will resume.
- Trials with the following status were excluded:
  - Completed: The study has concluded normally; participants are no longer receiving an intervention or being examined (that is, last participant's last visit has occurred).
  - Terminated: Study halted prematurely and will not resume; participants are no longer being examined or receiving intervention.
  - Withdrawn: Study halted prematurely, prior to enrollment of first participant.

#### Summary

Based on the 'Methods' delineated above, 216 gastric and esophageal cancers treatment trials were identified.

The 216 trials were further analyzed by a medical oncologist who identified the class of agent under evaluation for each trial. Forty-one percent address immunotherapies while 20% involve targeted therapies. The remainder address chemotherapy (12%), radiation therapy (8%), HER2 therapies (8%), antibody-drug conjugates (6%), and surgery (5%).

Targeted therapies include EGFR, ATR, combination therapies, FGF, HSP-90, PARP inhibitors, VEGF, and other targeted therapies. More than half (55%) of immunotherapy trials involve anti-PD-1/P-L1 or CTLA4 therapies.

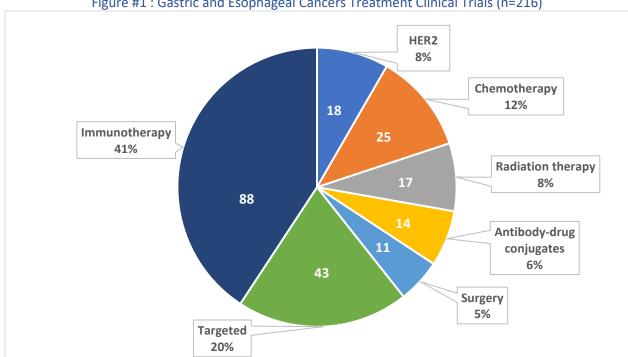


Figure #1: Gastric and Esophageal Cancers Treatment Clinical Trials (n=216)

#### NON-CANCER TREATMENT / OTHER CLINICAL TRIALS Methods

On September 30, 2021, a CTRP query was run for all interventional trials coded with the terms 'qastric (stomach) cancer' and/or 'esophageal cancer'.

In order to broaden the search for other clinical trials, an additional CTRP query was run on November 29, 2021 with the following parameters:

- Other disease trials coded with subterms 'Helicobacter Pylori infection', 'Helicobacter Pylori-Associated Gastritis', and 'Pyloric Stenosis'
- Other disease trials coded with subterm "Barrett Esophagus"

- Cancer-related syndrome trials with keyword "esophageal" with primary purpose 'diagnostic', 'screening', 'prevention', 'supportive care', 'device', 'basic science', 'health services research', and 'other'
- Cancer-related syndrome trials with keyword "gastric" with primary purpose 'diagnostic', 'screening', 'prevention', 'supportive care', 'device', 'basic science', 'health services research', and 'other'

On December 2, 2021, additional input was solicited from the NCI Division of Cancer Prevention, who identified two (2) additional diagnostic interventional trials, which at the time were not yet registered in CTRP: one trial related to the diagnosis of Barrett's Esophagus and esophageal adenocarcinoma and another trial related to the diagnosis of Barrett's Esophagus.

#### Inclusion and Exclusion Criteria

The identified trials were then filtered using the following criteria:

- Trials with the following status were included:
  - Recruiting: Participants are currently being recruited, whether or not any participants have yet been enrolled.
  - Active, not recruiting: Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled.
  - Not yet recruiting: Trial registered, but participants are not yet being recruited.
- Trials with the following status were excluded:
  - Completed: The study has concluded normally; participants are no longer receiving an intervention or being examined (that is, last participant's last visit has occurred).
  - Terminated: Study halted prematurely and will not resume; participants are no longer being examined or receiving intervention.
  - Withdrawn: Study halted prematurely, prior to enrollment of first participant.
  - Suspended: Study halted prematurely but potentially will resume.

Each trial was reviewed and a disease type applied manually: 'Barrett's esophagus or Barrett's esophagus and Esophageal Cancer', 'Esophageal Cancer', 'Gastric cancer', or 'Esophageal and gastric cancer'.

#### Summary

Of the 52 identified trials, the majority addressed diagnosis (20 trials, 38%) and supportive care (12 trials, 23%). Among the five (5) trials whose primary purpose is listed as "other", two (2) were device studies; two (2) were health-services research studies; and one (1) study was a basic science study.

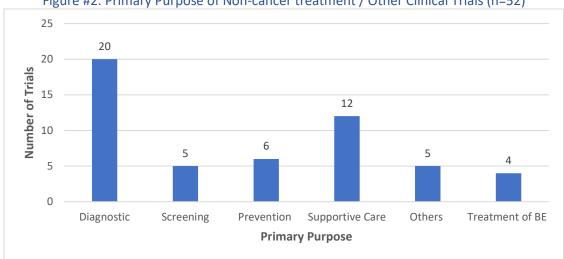


Figure #2: Primary Purpose of Non-cancer treatment / Other Clinical Trials (n=52)

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#### Gastric and Esophageal Cancers Treatment Clinical Trials

#### Immunotherapy Clinical Trials (n=88)

Table #1: Immunotherapy Clinical Trials: Anti-PD-1/PDL1 or CTLA4 (n=48)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT02872116	A Randomized, Multicenter, Open-Label, Phase 3 Study of Nivolumab Plus Ipilimumab or Nivolumab in Combination With Oxaliplatin Plus Fluoropyrimidine Versus Oxaliplatin Plus Fluoropyrimidine in Subjects With Previously Untreated Advanced or Metastatic Gastric or Gastroesophageal Junction Cancer	III	Active, not recruiting	Bristol-Myers Squibb	2032
NCT03143153	A Randomized Phase 3 Study of Nivolumab Plus Ipilimumab or Nivolumab Combined With Fluorouracil Plus Cisplatin Versus Fluorouracil Plus Cisplatin in Subjects With Unresectable Advanced, Recurrent or Metastatic Previously Untreated Esophageal Squamous Cell Carcinoma	III	Active, not recruiting	Bristol-Myers Squibb	939
NCT03430843	A Randomized, Controlled, Open-label, Global Phase 3 Study Comparing the Efficacy of the Anti-PD-1 Antibody Tislelizumab (BGB-A317) Versus Chemotherapy as Second Line Treatment in Patients With Advanced Unresectable/Metastatic Esophageal Squamous Cell Carcinoma	III	Active, not recruiting	BeiGene	513
NCT03783442	A Randomized, Placebo-Controlled, Double-Blind Phase 3 Study to Evaluate the Efficacy and Safety of Tislelizumab (BGB-A317) in Combination With Chemotherapy as First-Line Treatment in Patients With Unresectable, Locally Advanced Recurrent or Metastatic Esophageal Squamous Cell Carcinoma	III	Active, not recruiting	BeiGene Company Limited	649

Table #1: Immunotherapy Clinical Trials: Anti-PD-1/PDL1 or CTLA4 (n=48)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT02494583	A Randomized, Active-Controlled, Partially Blinded, Biomarker Select, Phase III Clinical Trial of Pembrolizumab as Monotherapy and in Combination With Cisplatin+5-Fluorouracil Versus Placebo+Cisplatin+5-Fluorouracil as First-Line Treatment in Subjects With Advanced Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma	III	Active, not recruiting	Merck and Company Inc	763
NCT02564263	A Phase III Randomized Open-Label Study of Single Agent Pembrolizumab vs Physicians' Choice of Single Agent Docetaxel, Paclitaxel, or Irinotecan in Subjects With Advanced/Metastatic Adenocarcinoma and Squamous Cell Carcinoma of the Esophagus That Have Progressed After First-Line Standard Therapy (KEYNOTE- 181)	Ш	Active, not recruiting	Merck and Company Inc	628
NCT03675737	A Phase 3, Randomized, Double-blind Clinical Study of Pembrolizumab (MK-3475) Plus Chemotherapy Versus Placebo Plus Chemotherapy as First-line Treatment in Participants With HER2 Negative, Previously Untreated, Unresectable or Metastatic Gastric Orgastroesophageal Junction Adenocarcinoma (KEYNOTE-859)	III	Active, not recruiting	Merck and Company Inc	1542
NCT03777657	A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Clinical Study Comparing the Efficacy and Safety of Tislelizumab (BGB-A317) Plus Platinum and Fluoropyrimidine Versus Placebo Plus Platinum and Fluoropyrimidine as First-Line Treatment in Patients With Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma	III	Active, not recruiting	BeiGene Company Limited	980

Table #1: Immunotherapy Clinical Trials: Anti-PD-1/PDL1 or CTLA4 (n=48)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT02559687	A Phase II Study of Pembrolizumab Monotherapy in Third Line Previously Treated Subjects With Advanced/Metastatic Adenocarcinoma or Squamous Cell Carcinoma of the Esophagus or Advanced/Metastatic Siewert Type I Adenocarcinoma of the Esophagogastric Junction (KEYNOTE-180)	II	Active, not recruiting	Merck and Company Inc	121
NCT02971956	A Phase II Study of Pembrolizumab in Refractory Advanced Esophageal Cancer	Ш	Active, not recruiting	Dana-Farber Harvard Cancer Center	51
NCT02443324	An Open-Label, Multicenter, Phase 1 Study of Ramucirumab Plus Pembrolizumab in Patients With Locally Advanced and Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma, Non-Small Cell Lung Cancer, Transitional Cell Carcinoma of the Urothelium, or Biliary Tract Cancer	I	Active, not recruiting	Eli Lilly and Company	155
NCT02642809	A Pilot Study Combining Pembrolizumab with Locally Delivered Radiation Therapy for the Treatment of Metastatic Esophageal Cancers	I	Active, not recruiting	Siteman Cancer Center at Washington University	18
NCT02743494	A Randomized, Multicenter, Double Blind, Phase III Study of Adjuvant Nivolumab or Placebo in Subjects With Resected Esophageal, or Gastroesophageal Junction Cancer	III	Active, not recruiting	Bristol-Myers Squibb	760
NCT03221426	A Phase III, Randomized, Double-Blind, Clinical Trial of Pembrolizumab (MK-3475) Plus Chemotherapy (XP or FP) Versus Placebo Plus Chemotherapy (XP or FP) as Neoadjuvant/Adjuvant Treatment for Subjects With Gastric and Gastroesophageal Junction (GEJ) Adenocarcinoma (KEYNOTE-585)	III	Active, not recruiting	Merck and Company Inc	1000

Table #1: Immunotherapy Clinical Trials: Anti-PD-1/PDL1 or CTLA4 (n=48)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03189719	A Randomized, Double-Blind, Placebo-Controlled Phase III Clinical Trial of Pembrolizumab (MK-3475) in Combination With Cisplatin and 5-Fluorouracil Versus Placebo in Combination With Cisplatin and 5- Fluorouracil as First-Line Treatment in Subjects With Advanced/Metastatic Esophageal Carcinoma (KEYNOTE-590)	III	Active, not recruiting	Merck and Company Inc	749
NCT02830594	Combining Pembrolizumab and Palliative Radiotherapy in Gastroesophageal Cancer to Enhance Anti-Tumor T Cell Response and Augment the Abscopal Effect	II	Active, not recruiting	City of Hope Comprehensive Cancer Center	14
NCT02954536	Phase II Trial of Pembrolizumab in Combination with Trastuzumab, Fluoropyrimidine, and Platinum Chemotherapy in First Line Stage IV HER2-Positive Metastatic Esophagogastric (EG) Cancer	II	Active, not recruiting	Memorial Sloan Kettering Cancer Center	37
NCT02639065	A Phase II Study Evaluating Safety and Efficacy of Durvalumab (MEDI4736) Following Multi-modality Therapy in Esophageal Cancer: Big Ten Cancer Research Consortium BTCRC-ESO14-012	II	Active, not recruiting	Shadia Jalal, MD	39
NCT02730546	Phase 1b/2 Clinical Trial of Neoadjuvant Pembrolizumab plus Concurrent Chemoradiotherapy with Weekly Carboplatin and Paclitaxel in Adult Patients with Resectable, Locally Advanced Adenocarcinoma of the Gastroesophageal Junction or Gastric Cardia	1/11	Active, not recruiting	Mayo Clinic in Rochester	34
NCT02734004	A Phase I/II Study of MEDI4736 (Anti-PD-L1 Antibody) in Combination With Olaparib (PARP Inhibitor) in Patients With Advanced Solid Tumors	1/11	Active, not recruiting	AstraZeneca Pharmaceuticals LP	427
NCT04208958	Phase 1 Study of VE800 and Nivolumab in Patients With Selected Types of Advanced or Metastatic Cancer	1/11	Active, not recruiting	Vedanta Biosciences, Inc.	111

Table #1: Immunotherapy Clinical Trials: Anti-PD-1/PDL1 or CTLA4 (n=48)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT05041153	A Pilot Study of Pembrolizumab and Lenvatinib Combination Therapy in Patients with Previously Treated Advanced Gastroesophageal Adenocarcinoma	Early Phase I	Not yet recruiting	M D Anderson Cancer Center	15
NCT03748134	A Multicenter, Double-Blind, Randomized Phase 3 Clinical Trial Evaluating the Efficacy and Safety of Sintilimab vs. Placebo, in Combination With Chemotherapy, for First-Line Treatment of Unresectable, Locally Advanced, Recurrent, or Metastatic Esophageal Squamous Cell Carcinoma (ORIENT-15)	III	Recruiting	Innovent Biologics (Suzhou) Co. Ltd.	676
NCT02918162	A Phase II Study of Chemotherapy and Immune Checkpoint Blockade with Pembrolizumab in the Perioperative and Maintenance Treatment of Locoregional Gastric or GE Junction Adenocarcinoma	II	Recruiting	NYP/Columbia University Medical Center/Herbert Irving Comprehensive Cancer Center	40
NCT03064490	Pembrolizumab, Radiotherapy, and Chemotherapy in Neoadjuvant Treatment of Malignant Esophago-Gastric Diseases (PROCEED)	II	Recruiting	Duke University Medical Center	38
NCT03257163	A Phase II Study of Preoperative Pembrolizumab for Mismatch-Repair Deficient and Epstein-Barr Virus Positive Gastric Cancer Followed by Chemotherapy and Chemoradiation with Pembrolizumab	II	Recruiting	Rutgers Cancer Institute of New Jersey	40
NCT03488667	A Phase II Study of Perioperative mFOLFOX (Fluorouracil, Leucovorin, and Oxaliplatin) Chemotherapy plus Pembrolizumab (MK-3475) Combination in Patients with Potentially Resectable Adenocarcinoma of the Gastroesophageal Junction (GEJ) and Stomach (MISP #52216)	II	Recruiting	University of Kansas Cancer Center	40

Table #1: Immunotherapy Clinical Trials: Anti-PD-1/PDL1 or CTLA4 (n=48)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT02998268	Randomized, Multicenter Phase II Study of Pembrolizumab in Combination With Chemotherapy and Chemoradiation in Locally Advanced Esophageal Adenocarcinoma	II	Recruiting	NYP/Weill Cornell Medical Center	42
NCT02908906	A First-in-Human, Open-label, Phase 1/2 Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Activity of JNJ- 63723283, an Anti-PD-1 Monoclonal Antibody, in Subjects With Advanced Cancers	1/11	Recruiting	Janssen Research & Development, LLC	250
NCT03776487	Pilot Study of Dual Checkpoint Inhibition Followed by Immuno-Chemoradiation in Patients with Resectable Gastric Adenocarcinoma (Concept ID 2016-NIV-0551)	1/11	Recruiting	M D Anderson Cancer Center	30
NCT03539822	A Phase I/II trial of Cabozantinib in Combination with Durvalumab (MEDI4736) with or without Tremelimumab in Patients with Advanced Gastroesophageal Cancer and Other Gastrointestinal (GI) Malignancies (CAMILLA)	1/11	Recruiting	University of Kansas Cancer Center	30
NCT03490292	Phase I/II Trial of Perioperative Avelumab in Combination with Chemoradiation in the Treatment of Stage II/III Resectable Esophageal and Gastroesophageal Junction Cancer	1/11	Recruiting	University of Wisconsin Hospital and Clinics	24
NCT03233724	Phase I/II Evaluation of Oral Decitabine/Tetrahydrouridine as Epigenetic Priming for Pembrolizumab Immune Checkpoint Blockade in Inoperable Locally Advanced or Metastatic Non-Small Cell Lung Cancers, Esophageal Carcinomas, or Pleural Mesotheliomas	1/11	Recruiting	National Cancer Institute	85
NCT03395847	A Pilot Study of Pembrolizumab Monotherapy in Patients with Previously Treated Advanced Gastroesophageal Adenocarcinoma	Early Phase I	Recruiting	M D Anderson Cancer Center	15

Table #1: Immunotherapy Clinical Trials: Anti-PD-1/PDL1 or CTLA4 (n=48)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT04592913	A Randomized, Double-blind, Placebo-controlled, Phase III Study of Neoadjuvant-Adjuvant Durvalumab and FLOT Chemotherapy Followed by Adjuvant Durvalumab in Patients With Resectable Gastric and Gastroesophageal Junction Cancer (GC/GEJC)	III	Recruiting	AstraZeneca Pharmaceuticals LP	900
NCT04210115	A Randomized, Double-blind, Placebo-controlled Phase 3 Trial of Pembrolizumab (MK-3475) Versus Placebo in Participants With Esophageal Carcinoma Receiving Concurrent Definitive Chemoradiotherapy (KEYNOTE 975)	III	Recruiting	Merck and Company Inc	600
NCT03604991	A Phase II/III Study of Peri-Operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma	11/111	Recruiting	ECOG-ACRIN Cancer Research Group	278
NCT04089904	A Phase II Trial of Neoadjuvant Pembrolizumab for Resectable Early Stage Gastroesophageal Adenocarcinoma	II	Recruiting	University of Chicago Comprehensive Cancer Center	33
NCT04021108	Phase II Study of Short Course FOLFOX Chemotherapy With Either Nivolumab or Nivolumab + Radiation in the First Line Treatment of Metastatic or Unresectable Gastroesophageal Cancers (BMS Protocol CA209-76L)	II	Recruiting	NYP/Weill Cornell Medical Center	74
NCT04069273	Phase 2 Study of Novel SEQUEnced Immunotherapy (Pembrolizumab) With Anti-angiogenesis and Chemotherapy in Advanced Gastric and gastroesophageaL Junction (GEJ) Adenocarcinoma	II	Recruiting	Harry H Yoon	58
NCT04757363	A Phase II Study of Nivolumab in Combination with FOLFOX and Regorafenib in Patients with HER2-Negative Metastatic Esophagogastric Cancer	II	Recruiting	Memorial Sloan Kettering Cancer Center	35

Table #1: Immunotherapy Clinical Trials: Anti-PD-1/PDL1 or CTLA4 (n=48)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03342937	A Single Arm, Phase II Study of Pembrolizumab, Oxaliplatin, and Capecitabine in the First Line Treatment of Patients with Gastro-Esophageal Cancer (KeyLARGO)	=	Recruiting	Duke University Medical Center	35
NCT04363801	A Phase 2a, Multicenter, Open-Label Study of DKN-01 in Combination With Tislelizumab ± Chemotherapy as First-Line or Second-Line Therapy in Adult Patients With Inoperable, Locally Advanced or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (DisTinGuish)	II	Recruiting	Leap Therapeutics, Inc.	72
NCT04114136	A Phase II Clinical Trial of Anti-PD-1 mAb Therapy Alone or with Metabolic Modulators to Reverse Tumor Hypoxia and Immune Dysfunction in Solid Tumor Malignancies	II	Recruiting	University of Pittsburgh Cancer Institute (UPCI)	108
NCT02962063	Phase Ib/II Study of Induction Chemotherapy and Durvalumab (MEDI4736) and Tremelimumab with Chemoradiation for Esophageal and Gastroesophageal Junction Adenocarcinoma	1/11	Recruiting	Memorial Sloan Kettering Cancer Center	36
NCT03474640	A Phase 1, Multicenter, Open-label Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of TAB001 in Subjects With Advanced Malignancies	-	Recruiting	Shanghai Junshi Bioscience Co., Ltd.	258
NCT03784326	Pilot Study of Perioperative Chemotherapy plus Immunotherapy Followed by Surgery in Localized Esophageal and Gastroesophageal Adenocarcinoma	Early Phase I	Recruiting	M D Anderson Cancer Center	30
NCT03918499	A Phase 1b/2 Trial of the IRX-2 Regimen and Pembrolizumab in Patients with Advanced Gastric and Gastroesophageal Junction (GEJ) Adenocarcinoma	1/11	Suspended	City of Hope Comprehensive Cancer Center	20

Table #2: Immunotherapy Clinical Trials: Anti-tumor viruses (n=3)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03921021	Phase 2 Study of Telomelysin (OBP-301) in Combination With Pembrolizumab in Esophagogastric Adenocarcinoma	П	Recruiting	NYP/Weill Cornell Medical Center	41
NCT04521621	A Phase 1b/2 Clinical Study of Intratumoral Administration of V937 in Combination With Pembrolizumab (MK-3475) in Participants With Advanced/Metastatic Solid Tumors	1/11	Recruiting	Merck and Company Inc	185
NCT04391049	Phase I Trial with Expansion Cohort of OBP-301 (Telomelysin) and Definitive Chemoradiation for Patients with Locally Advanced Esophageal and Gastroesophageal Adenocarcinoma Who Are Not Candidates for Surgery	I	Recruiting	NRG Oncology	21

#### Table #3: Immunotherapy Clinical Trials: CAR Therapies (n=3)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT05035407	A Phase I Trial of T Cell Receptor Gene Therapy Targeting KK-LC-1 for Gastric, Breast, Cervical, Lung and Other KK-LC-1 Positive Epithelial Cancers	I	Not yet recruiting	National Cancer Institute	100
NCT04404595	Open-label, Multicenter, Phase 1b Clinical Trial to Evaluate the Safety and Efficacy of Autologous Claudin 18.2 Chimeric Antigen Receptor T-cell Therapy in Patients With Advanced Gastric or Pancreatic Adenocarcinoma	-	Recruiting	Carsgen Therapeutics, Ltd.	30
NCT04752358	A Phase 2 Open-Label Clinical Trial of ADP-A2M4CD8 in Subjects With Advanced Esophageal or Esophagogastric Junction Cancers	Ш	Recruiting	Adaptimmune Limited	45

Table #4: Immunotherapy Clinical Trials: Cell Therapies (n=3)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03278626	A Phase I/II Open Label Multi-Center Study of Immune Checkpoint Therapy with Nivolumab for Patients with Locally Advanced Esophageal Squamous Cell Carcinoma	1/11	Active, not recruiting	Laura and Isaac Perlmutter Cancer Center at NYU Langone	56
NCT03735290	A Randomized, Open-label, Multi-center, Phase 1b/2 Trial Evaluating the Safety and Efficacy of Intratumorally- administered Ilixadencel in Combination With Checkpoint Inhibitor (CPI) in Advanced Cancer Subjects Who Are Candidates for CPI Therapy	I/II	Active, not recruiting	Immunicum AB	150
NCT04668833	Phase II Study of Autologous Lymphocyte Infusions after Radiation Therapy to Mitigate Radiation Induced Lymphopenia and Enhance Immune Reconstitution in Patients with Solid Tumor Malignancies	II	Recruiting	M D Anderson Cancer Center	20

Table #5: Immunotherapy Clinical Trials: CLDN18.2 (n=6)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03505320	A Phase 2 Study of Zolbetuximab (IMAB362) as Monotherapy, in Combination With mFOLFOX6 (With or Without Nivolumab) and in Combination With Pembrolizumab in Subjects With Metastatic or Locally Advanced Unresectable Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Whose Tumors Have High or Intermediate Claudin (CLDN) 18.2 Expression	=	Active, not recruiting	Astellas Pharma Global Development, Inc.	116
NCT03653507	A Phase 3, Global, Multi-Center, Double-Blind, Randomized, Efficacy Study of Zolbetuximab (IMAB362) Plus CAPOX Compared With Placebo Plus CAPOX as First- line Treatment of Subjects With Claudin (CLDN) 18.2- Positive, HER2-Negative, Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma	III	Recruiting	Astellas Pharma Global Development, Inc.	500
NCT04900818	A Phase 1 Study of TJ033721 in Subjects With Advanced or Metastatic Solid Tumors	1	Recruiting	I-Mab Biopharma Co. Ltd.	108
NCT03504397	A Phase 3, Global, Multi-Center, Double-Blind, Randomized, Efficacy Study of Zolbetuximab (IMAB362) Plus mFOLFOX6 Compared With Placebo Plus mFOLFOX6 as First-line Treatment of Subjects With Claudin (CLDN)18.2-Positive, HER2-Negative, Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma	III	Recruiting	Astellas Pharma Global Development, Inc.	550
NCT04260191	A Global Phase 1 Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of the Half-life Extended Bispecific T-cell Engager AMG 910 in Subjects With Claudin 18.2-Positive Gastric and Gastroesophageal Junction Adenocarcinoma	I	Recruiting	Amgen, Inc.	70
NCT04396821	A Phase I Clinical Trial to Evaluate the Safety, Tolerability and Pharmacokinetics of TST001 in Patients With Locally Advanced or Metastatic Solid Tumors	I	Recruiting	Mabspace Biosciences (Suzhou) Co., Ltd.	114

Table #6: Immunotherapy Clinical Trials: Cytokines (n=3)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT04847466	A Phase II Study of Immunotherapy Combination: Irradiated PD-L1 CAR-NK Cells Plus Pembrolizumab Plus N-803 for Subjects With Recurrent/Metastatic Gastric or Head and Neck Cancer	II	Not yet recruiting	National Cancer Institute	55
NCT04594811	A Multicenter, Open-label, Randomized, Phase 2 Study of NT-I7 in Combination With Nivolumab Versus Nivolumab Monotherapy in Subjects With Advanced or Metastatic Gastric or Gastro-Esophageal Junction or Esophageal Adenocarcinoma Who Progressed on or Intolerant to 2 or More Prior Lines of Systemic Therapy	II	Recruiting	NeoImmuneTech	145
NCT03798626	Phase Ib Study of Gevokizumab in Combination With Standard of Care Anti-cancer Therapies in Patients With Metastatic Colorectal Cancer, Gastroesophageal Cancer and Renal Cell Carcinoma	ı	Recruiting	Novartis Pharmaceuticals Corporation	172

#### Table #7: Immunotherapy Clinical Trials: GITR (n=1)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03126110	A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies	1/11	Active, not recruiting	Incyte Biosciences International Sàrl	45

Table #8: Immunotherapy Clinical Trials: Immunology Combinations (n=1)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT02935634	A Phase 2, Fast Real-time Assessment of Combination Therapies in Immuno-ONcology Study in Participants With Advanced Gastric Cancer (FRACTION-Gastric Cancer)	II	Active, not recruiting	Bristol-Myers Squibb	600

Table #9: Immunotherapy Clinical Trials: LAG3 (n=4)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03662659	A Randomized, Open-label, Phase II Clinical Trial of Relatlimab (Anti-LAG-3) and Nivolumab in Combination With Chemotherapy Versus Nivolumab in Combination With Chemotherapy as First-Line Treatment in Patients With Gastric or Gastroesophageal Junction Adenocarcinoma	=	Active, not recruiting	Bristol-Myers Squibb	250
NCT03044613	Phase IB Trial of Induction Nivolumab or Nivolumab/ Relatlimab prior to Concurrent Chemoradiation in Patients with Operable Stage II/III Esophageal/ Gastroesophageal Junction Cancer	_	Active, not recruiting	Johns Hopkins University/Sidney Kimmel Cancer Center	32
NCT03219268	A Phase 1, First-in-Human, Open-Label, Dose Escalation Study of MGD013, A Bispecific DART® Protein Binding PD- 1 and LAG-3 in Patients With Unresectable or Metastatic Neoplasms	l	Active, not recruiting	MacroGenics Inc	352
NCT03697304	An Open-label, Phase II, Platform Trial Evaluating Safety and Efficacy of Multiple BI 754091 Anti-PD-1 Based Combination Regimens in PD-(L)1 naïve and PD-(L)1 Pretreated Patient Populations With Advanced and/or Metastatic Solid Tumours Who Have Had at Least One Line of Systemic Therapy	II	Recruiting	Boehringer Ingelheim Pharmaceuticals Inc	260

Table #10: Immunotherapy Clinical Trials: TIGIT (n=5)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT04543617	A Phase III, Randomized, Double-Blind, Placebo- Controlled Study of Atezolizumab With or Without Tiragolumab (Anti-TIGIT Antibody) in Patients With Unresectable Esophageal Squamous Cell Carcinoma Whose Cancers Have Not Progressed Following Definitive Concurrent Chemoradiotherapy	III	Recruiting	Hoffmann-La Roche	750
NCT03281369	A Phase Ib/II, Open-Label, Multicenter, Randomized, Umbrella Study Evaluating the Efficacy and Safety of Multiple Immunotherapy-Based Treatment Combinations in Patients With Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Cancer or Esophageal Cancer (Morpheus-Gastric and Esophageal Cancer)	I <b>/</b> II	Recruiting	Hoffmann-La Roche	410
NCT04047862	Phase 1/1b Study Investigating Safety, Tolerability, PK and Antitumor Activity of Anti-TIGIT Monoclonal Antibody BGB-A1217 in Combination With Anti-PD-1 Monoclonal Antibody Tislelizumab in Patients With Advanced Solid Tumors	I	Recruiting	BeiGene Company Limited	444
NCT02964013	A Phase 1 Trial of MK-7684 as Monotherapy and in Combination With Pembrolizumab in Subjects With Advanced Solid Tumors	I	Recruiting	Merck and Company Inc	492
NCT04772989	A Phase 1/1b Study to Evaluate the Safety and Tolerability of AB308 in Combination With AB122 in Participants With Advanced Malignancies	ı	Recruiting	Arcus Biosciences, Inc.	154

Table #11: Immunotherapy Clinical Trials: TIM3 (n=1)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03708328	An Open Label, Multicenter, Dose Escalation and Expansion, Phase 1 Study to Evaluate Safety, Pharmacokinetics, and Preliminary Anti-Tumor Activity of RO7121661, a PD-1/TIM-3 Bispecific Antibody, in Patients With Advanced and/or Metastatic Solid Tumors	_	Active, not recruiting	Hoffmann-La Roche	280

Table #12: Immunotherapy Clinical Trials: Vaccines (n=3)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT04246671	Phase 1/2 Expansion Cohorts Trial of Intravenous Administration of TAEK-VAC-HerBy Vaccine Alone and in Combination With HER2- and PD-1/PD-L1 Antibodies in Patients With Advanced HER2-expressing Cancer	1/11	Recruiting	Bavarian Nordic	45
NCT04041310	A Phase I/IIa, Multicenter, Open-Label Study of Nous-209 Genetic Vaccine for the Treatment of Microsatellite Unstable Solid Tumors	I	Recruiting	Nouscom SRL	84
NCT04111172	A Phase 2A, Dose-Finding Study of Ad5.F35-hGCC-PADRE Vaccine in Adults with Gastrointestinal Adenocarcinomas at Risk of Relapse Post Definitive Surgery and Standard Therapy	II	Suspended	Thomas Jefferson University Hospital	81

Table #13: Immunotherapy Clinical Trials: Miscellaneous (n=7)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT04117958	A Global Phase 1 Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of the Half-life Extended Bispecific T-cell Engager AMG 199 in Subjects With MUC17-Positive Solid Tumors Including Gastric, Gastroesophageal Junction, Colorectal, and Pancreatic Cancers	-	Recruiting	Amgen, Inc.	150
NCT04682431	A Phase 1a/1b Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of PY159 as a Single Agent and In Combination With Pembrolizumab in Subjects With Advanced Solid Tumors	I	Recruiting	Pionyr Immunotherapeutics Inc	216
NCT03165994	A Phase 2 Study of APX005M in Combination With Concurrent Chemoradiation as Neoadjuvant Therapy for Resectable Esophageal and Gastroesophageal Junction Cancers	=	Recruiting	Apexigen, Inc.	26
NCT04060342	A Phase 1/2, First-in-Human, Open-label, Dose Escalation Study of GB1275 Monotherapy and in Combination With an Anti-PD-1 Antibody in Patients With Specified Advanced Solid Tumors or in Combination With Standard of Care in Patients With Metastatic Pancreatic Adenocarcinoma, Followed by Basket Expansion of GB1275 With Standard of Care or in Combination With an Anti-PD-1 Antibody in Patients With Specified Metastatic Solid Tumors	1/11	Recruiting	GB006, Inc., a wholly owned subsidiary of Gossamer Bio, Inc.	242
NCT03834948	A Phase 1/2 Multicenter, Open-Label, Dose-Escalation and Dose-Expansion Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Antitumor Activity of AO-176	1/11	Recruiting	Arch Oncology	183
NCT04895709	A Phase 1/2 Study of BMS-986340 as Monotherapy and in Combination With Nivolumab in Participants With Advanced Solid Tumors	1/11	Recruiting	Bristol-Myers Squibb	185

#### Table #13: Immunotherapy Clinical Trials: Miscellaneous (n=7)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT0441953	A Phase 1, First In Human Study of DS-1055a in Subjects With Relapsed or Refractory Locally Advanced or Metastatic Solid Tumors	I	Recruiting	Daiichi Sankyo Co., Ltd.	40

#### Targeted Therapies Clinical Trials (n=43)

Table #14: Targeted Therapy Clinical Trials – EGFR (n=2)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT00655876	A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation for Patients with Esophageal Cancer Who Are Treated Without Surgery	III	Active, not recruiting	Radiation Therapy Oncology Group	420
NCT00183898	Phase II Study of Oxaliplatin and Xeloda and Cetuximab as First Line Treatment for Metastatic or Unresectable Gastric or Gastroesophageal Junction Cancer	II	Active, not recruiting	USC / Norris Comprehensive Cancer Center	53

Table #15: Targeted Therapy Clinical Trials – ATR (n=4)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT04704661	Phase 1/1B Study of DS-8201a in Combination with ATR Inhibition (AZD6738) in Advanced Solid Tumors with HER2 Expression (DASH Trial)	I	Recruiting	University of Texas MD Anderson Cancer Center LAO	15
NCT04535401	Phase I/Ib Trial of ATR Inhibitor BAY 1895344 in Combination with FOLFIRI in GI Malignancies with a Focus on Metastatic Colorectal and Gastric/Gastroesophageal Cancers	I	Recruiting	University of Pittsburgh Cancer Institute LAO	90
NCT04095273	A Multicenter, Non-randomized, Open-label Phase 1b Study to Determine the Maximum Tolerated and Recommended Phase 2 Dose of the ATR Inhibitor BAY1895344 in Combination With Pembrolizumab and to Characterize Its Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity in Patients With Advanced Solid Tumors	I	Recruiting	Bayer Corporation	80
NCT03641313	A Phase 2 Single-Arm Study of M6620 in Combination with Irinotecan in Patients with Progressive TP53 Mutant Gastric and Gastro-Esophageal Junction Cancer	II	Suspended	Yale University Cancer Center LAO	28

#### Table #16: Targeted Therapy Clinical Trials – Combination (n=1)

NCT II	)	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT02213	3 <u>289</u>	PANGEA-IMBBP: Personalized Antibodies for Gastro- Esophageal Adenocarcinoma - A 1st Pilot Metastatic Trial of Biologics Beyond Progression	II	Active, not recruiting	University of Chicago Comprehensive Cancer Center	104

Table #17: Targeted Therapy Clinical Trials – FGF (n=4)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03694522	FIGHT: A Phase 2 Randomized, Double-Blind, Controlled Study Evaluating Bemarituzumab (FPA144) and Modified FOLFOX6 in Patients With Previously Untreated Advanced Gastric and Gastroesophageal Junction Cancer: Phase 2  Preceded by Dose-Finding in Phase 1	II	Active, not recruiting	Five Prime Therapeutics, Inc.	155
NCT03343301	FIGHT: A Phase 3 Randomized, Double-Blind, Controlled Study Evaluating FPA144 and Modified FOLFOX6 in Patients With Previously Untreated Advanced Gastric and Gastroesophageal Cancer: Phase 3 Preceded by Dose Finding in Phase 1A	_	Active, not recruiting	Five Prime Therapeutics	10
NCT04604132	A Phase 1b/2 Study of Derazantinib as Monotherapy and Combination Therapy With Paclitaxel, Ramucirumab or Atezolizumab in Patients With HER2-negative Gastric Adenocarcinoma Expressing FGFR2 Genetic Aberrations	1/11	Recruiting	Basilea Pharmaceutica	254
NCT04189445	A PHASE 2 STUDY OF FUTIBATINIB IN PATIENTS WITH SPECIFIC FGFR ABERRATIONS	II	Recruiting	Taiho Pharmaceutical Company Limited	115

#### Table #18: Targeted Therapy Clinical Trials – HSP-90 (n=2)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT01167114	A Phase 2 Clinical Trial of STA-9090 in Previously Treated Patients with Advanced Esophagogastric Cancers	II	Active, not recruiting	Dana-Farber Harvard Cancer Center	41
NCT03095781	Phase Ib Trial of Pembrolizumab and XL888 in Patients with Advanced Gastrointestinal Malignancies	I	Recruiting	Emory University Hospital/Winship Cancer Institute	50

Table #19: Targeted Therapy Clinical Trials – PARP Inhibitor (n=7)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03427814	PARALLEL 303: A Phase 2, Double-blind, Randomized Study of BGB-290 Versus Placebo as Maintenance Therapy in Patients With Inoperable Locally Advanced or Metastatic Gastric Cancer That Responded to Platinum- based First-line Chemotherapy	II	Active, not recruiting	BeiGene	128
NCT04725994	An Open-Label, International, Multicenter, Phase 1b Study to Assess the Safety, Tolerability, and Efficacy of IDX-1197 in Combination With XELOX (Capecitabine and Oxaliplatin) or Irinotecan in Patients With Advanced Gastric Cancer	I	Recruiting	Idience Co., Ltd.	100
NCT04550494	A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients with Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response	П	Recruiting	National Cancer Institute LAO	36
NCT03840967	A Phase II Study Evaluating Safety and Efficacy of Niraparib in Patients With Previously Treated Homologous Recombination (HR) Defective or Loss of Heterozygosity (LOH) High Metastatic Esophageal/Gastroesophageal Junction/Proximal Gastric Adenocarcinoma	11	Recruiting	Shadia Jalal, MD	43
NCT04209686	Phase 2 Study of Paclitaxel, Pembrolizumab and Olaparib in Previously Treated Advanced Gastric Adenocarcinoma	II	Recruiting	Johns Hopkins University/Sidney Kimmel Cancer Center	36

## Table #19: Targeted Therapy Clinical Trials – PARP Inhibitor (n=7)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03995017	A Phase I/II Trial of Rucaparib in Combination with Ramucirumab with or without Nivolumab in Previously Treated Patients with Advanced Gastric and Esophageal Adenocarcinoma (RiME)	1/11	Recruiting	University of Kansas Hospital-Westwood Cancer Center	52
NCT03150810	A Phase 1b Study to Assess the Safety, Tolerability and Clinical Activity of BGB-290 in Combination With Temozolomide (TMZ) in Subjects With Locally Advanced or Metastatic Solid Tumors	1/11	Recruiting	BeiGene Company Limited	150

Table #20: Targeted Therapy Clinical Trials – VEGF (n=8)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT01747551	Randomized, Double-Blind, Placebo Controlled Phase II Study of FOLFOX+/-Ziv-Aflibercept in Patients with Advanced Esophageal and Gastric Cancer	II	Active, not recruiting	Dana-Farber Harvard Cancer Center	64
NCT04099641	A Phase 2, Multicenter Open-label, Non-randomized Study of Bavituximab Plus Pembrolizumab in Patients With Advanced Gastric or Gastroesophageal Cancer Who Have Progressed on or After at Least One Prior Standard Therapy	II	Active, not recruiting	OncXerna Theraputics, Inc.	80
NCT03141034	Ramucirumab plus Irinotecan in Patients with Previously Treated Advanced Gastric or Gastro-Esophageal Junction Adenocarcinoma	II	Active, not recruiting	Siteman Cancer Center at Washington University	40
NCT02773524	A Randomised Phase III Double-Blind Placebo-Controlled Study of Regorafenib in Refractory Advanced Gastro- Oesophageal Cancer (AGOC)	III	Recruiting	Australasian Gastro- Intestinal Trials Group	350
NCT03008278	A Phase 1/2 Study of Olaparib in Combination with Ramucirumab in Metastatic Gastric and Gastroesophageal Junction Adenocarcinoma (10017760)	1/11	Recruiting	Yale University Cancer Center LAO	49
NCT04579757	An Open-Label Phase Ib/II Study of Surufatinib in Combination With Tislelizumab in Subjects With Advanced Solid Tumors	1/11	Recruiting	Hutchison Medipharma Limited	120
NCT03407976	A Phase I/II Open Label Study of the Safety and Efficacy of Apatinib Administered to Patients with Advanced Malignancies to Improve Sensitivity to Pembrolizumab in the Second- or Later-Line Setting (APPEASE)	1/11	Recruiting	Huntsman Cancer Institute/University of Utah	119

## Table #20: Targeted Therapy Clinical Trials – VEGF (n=8)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03321630	A Phase II Study of Lenvatinib, a Multi-Targeted Tyrosine Kinase Inhibitor, Combined with Pembrolizumab for the Treatment of Metastatic Gastroesophageal Cancer Patients Who Have Progressed on First or Subsequent Line Therapies	II	Recruiting	Laura and Isaac Perlmutter Cancer Center at NYU Langone	29

Table #21: Targeted Therapy Clinical Trials – Miscellaneous (n=15)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT02530437	A Phase 1B/2 Study of Taladegib in Combination with Weekly Paclitaxel, Carboplatin, and Radiation in Localized Adenocarcinoma of the Esophagus or Gastroesophageal Junction	1/11	Active, not recruiting	M D Anderson Cancer Center	66
NCT03997448	Phase II Study of the Combination of Abemaciclib and Pembrolizumab in Locally Advanced Unresectable or Metastatic Gastroesophageal Adenocarcinoma: Big Ten Cancer Research Consortium BTCRC-GI18-149	II	Active, not recruiting	University of Wisconsin Hospital and Clinics	34
NCT04164979	Phase 2 Study of Cabozantinib Combined with Pembrolizumab in Metastatic or Recurrent Gastric and Gastroesophageal Adenocarcinoma (mGC)	II	Recruiting	UC Irvine Health/Chao Family Comprehensive Cancer Center	27
NCT04460937	A Phase 1 Trial Combining WEE1 Inhibitor Adavosertib (AZD1775) with Radiation Therapy for Metastatic or Inoperable and Ineligible for Definitive Chemoradiation Esophageal and Gastroesophageal Junction Cancer	I	Recruiting	Ohio State University Comprehensive Cancer Center LAO	33
NCT03715933	An Open-Label, Multicenter, First-in-Human, Dose- Escalation Phase 1 Study of INBRX-109 in Subjects With Locally Advanced or Metastatic Solid Tumors Including Sarcomas	I	Recruiting	Inhibrx, Inc.	172
NCT04682158	Propranolol with Standard Chemoradiation for Esophageal Adenocarcinoma – A Combined Single Arm and Randomized Cohort Phase II Study	II	Recruiting	Roswell Park Cancer Institute	133

Table #21: Targeted Therapy Clinical Trials – Miscellaneous (n=15)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT04383938	Study of APR-246 in Combination With Pembrolizumab in Subjects With Solid Tumor Malignancies	1/11	Recruiting	Aprea Therapeutics	118
NCT03129139	A Phase 1, Multi-Center, Open-Label, Dose-Escalation, Safety, Pharmacokinetic, and Pharmacodynamic Study of Minnelide™ Capsules Given Alone or in Combination With Protein-Bound Paclitaxel in Patients With Advanced Solid Tumors	_	Recruiting	Minneamrita Therapeutics LLC	66
NCT04505839	First-In-Human Dose-Escalation Study of STP1002 in Patients With Advanced-Stage Solid Tumors	l	Recruiting	ST Pharm Co., Ltd.	30
NCT04145297	UTAH: A Phase I Trial of Ulixertinib (BVD-523) and Hydroxychloroquine in Patients with Advanced MAPK- Mutated Gastrointestinal Adenocarcinomas	I	Recruiting	Huntsman Cancer Institute/University of Utah	12
NCT04344795	Phase 1a/1b Open Label Dose-escalation and Expansion Study of TPST-1495 as a Single Agent in Subjects With Solid Tumors	-	Recruiting	Tempest Therapeutics	117
NCT04834778	A Multicenter, Open-label, Phase 1a Study of HC-5404-FU in Subjects With Advanced Solid Tumors	1	Recruiting	HiberCell, Inc.	24
NCT01142388	Randomized Phase II Study of Paclitaxel with or without the Anti-IGF-IR mAb Cixutumumab (IMC-A12) as Second Line Treatment for Patients with Metastatic Esophageal or GE Junction Cancer	II	Active, not recruiting	ECOG-ACRIN Cancer Research Group	90

Table #21: Targeted Therapy Clinical Trials – Miscellaneous (n=15)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT02646748	A Platform Study Exploring the Safety, Tolerability, Effect on the Tumor Microenvironment, and Efficacy of Pembrolizumab + INCB Combinations in Advanced Solid Tumors	I	Active, not recruiting	Incyte Corporation	159
NCT04000529	A Phase Ib, Open-label, Multi-center Study to Characterize the Safety, Tolerability, and Preliminary Efficacy of TNO155 in Combination With Spartalizumab or Ribociclib in Selected Malignancies	I	Recruiting	Novartis Pharmaceuticals Corporation	126

## Table #22: HER2 Clinical Trials (n=18)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03615326	A Phase III, Randomized, Double-blind Trial Comparing Trastuzumab Plus Chemotherapy and Pembrolizumab With Trastuzumab Plus Chemotherapy and Placebo as First-line Treatment in Participants With HER2 Positive Advanced Gastric or Gastroesophageal Junction Adenocarcinoma (KEYNOTE 811)	III	Active, not recruiting	Merck and Company Inc	732
NCT00680901	A Phase III Study for ErbB2 Positive Advanced or Metastatic Gastric, Esophageal, or Gastroesophageal Junction Adenocarcinoma Treated With Capecitabine Plus Oxaliplatin With or Without Lapatinib	III	Active, not recruiting	Novartis Pharmaceuticals Corporation	545
NCT01196390	A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma	Ш	Active, not recruiting	NRG Oncology	591
NCT04014075	A Phase 2, Open-label, Single-arm Trial of Trastuzumab Deruxtecan (DS 8201a) in HER2-positive, Unresectable or Metastatic Gastric or Gastro-esophageal Junction (GEJ) Adenocarcinoma Subjects Who Have Progressed on or After a Trastuzumab-containing Regimen (DESTINY- Gastric02)	II	Active, not recruiting	Daiichi Sankyo Inc	79
NCT01191697	Phase II Trial of CAPOX+Bevacizumab+Trastuzumab for Patients with HER2-Positive Metastatic Esophagogastric Cancer	II	Active, not recruiting	Dana-Farber Harvard Cancer Center	36
NCT01526473	A Phase I Study to Evaluate the Antitumor Activity and Safety of DUKE-002-VRP(HUHER2-ECD+TM), an Alphaviral Vector Encoding the HER2 Extracellular Domain and Transmembrane Region, in Patients with Locally Advanced or Metastatic Human Epidermal Growth Factor Receptor 2-Positive (HER2+) Cancers Including Breast Cancer	ı	Active, not recruiting	Duke University Medical Center	30

## Table #22: HER2 Clinical Trials (n=18)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03783936	A Single Arm, Multi-center Phase 2 Trial of mFOLFOX6 + Trastuzumab + Avelumab in First-line, Metastatic, HER2- amplified Gastric and Esophageal Adenocarcinomas	II	Active, not recruiting	Autumn McRee, MD	18
NCT04499924	A Randomized, Double-blind, Placebo-controlled, Active Comparator Phase 2/3 Study of Tucatinib in Combination With Trastuzumab, Ramucirumab, and Paclitaxel in Subjects With Previously Treated, Locally-advanced Unresectable or Metastatic HER2+ Gastric or Gastroesophageal Junction Adenocarcinoma (GEC)	11/111	Recruiting	Seagen Inc.	578
NCT04150640	Phase 2 Trial of 5-Fluorouracil, Oxaliplatin and Liposomal Irinotecan (plus Trastuzumab for HER2-Positive Disease) during 1st Line Treatment of Advanced Esophageal and Gastric Adenocarcinoma	II	Recruiting	University of Wisconsin Hospital and Clinics	34
NCT04510285	A Single-Arm Pilot Study of Adjuvant Pembrolizumab plus Trastuzumab in HER2+ Esophagogastric Tumors with Persistent Circulating Tumor DNA Following Curative Resection	II	Recruiting	Memorial Sloan Kettering Cancer Center	24
NCT04430738	A Phase 1b/2 Dose Escalation and Expansion Study of Tucatinib in Combination With Trastuzumab and Oxaliplatin-based Chemotherapy for HER2+ Gastrointestinal Cancers	1/11	Recruiting	Seagen Inc.	65
NCT04492488	An Open-Label, Multi-center Phase I/II Dose Escalation and Expansion Study to Assess the Safety, Efficacy and Pharmacokinetics of MRG002 in Patients With HER2-Positive Advanced Solid Tumors and Locally Advanced or Metastatic Gastric/Gastroesophageal Junction (GEJ)  Cancer	1/11	Recruiting	Shanghai Miracogen Inc.	129
NCT03847168	Phase I Study of KN026 in HER2 Expressing Breast Cancer, Astric/Gastroesophageal Junction Cancer and Other Locally Advanced/Metastatic Solid Tumors	I	Recruiting	Jiangsu Alphamab Biopharmaceuticals Co., Ltd	20

## Table #22: HER2 Clinical Trials (n=18)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT02892123	Phase I Trial of ZW25 in Patients With Locally Advanced (Unresectable) and/or Metastatic HER2-expressing Cancers	ı	Recruiting	Zymeworks Inc.	418
NCT04082364	Phase 2/3 Trial to Evaluate Margetuximab in Combination With INCMGA00012 and Chemotherapy or MGD013 and Chemotherapy in Patients With Metastatic or Locally Advanced, Treatment-naïve, HER2-Positive Gastric or Gastroesophageal Junction Cancer	11/111	Recruiting	MacroGenics Inc	860
NCT03255070	A Phase 1, Multicenter, Open-label, Multiple Dose- escalation and Expansion Study of ARX788, as Monotherapy in Advanced Solid Tumors With HER2 Expression	I	Recruiting	Ambrx, Inc.	190
NCT03448042	A Phase I, Open-Label, Dose-Escalation Study of the Safety and Pharmacokinetics of BTRC4017A Administered Intravenously in Patients With Locally Advanced or Metastatic HER2-Expressing Cancers	I	Recruiting	Genentech Inc.	449
NCT01522768	A Phase II Study of Afatinib and Paclitaxel in Patients with Advanced HER2-Positive Trastuzumab Refractory Advanced Esophagogastric Cancer	II	Active, not recruiting	Memorial Sloan Kettering Cancer Center	27

Table #23: Chemotherapy Clinical Trials (n=25)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT02037048	A Phase II Trial of Modified FOLFOX-6 Induction Chemotherapy Followed by Esophagectomy and Post- Operative Response Based Concurrent Chemoradiotherapy in Patients with Locoregionally Advanced Adenocarcinoma of the Esophagus, Gastro- Esophageal Junction, and Gastric Cardia	II	Active, not recruiting	Case Comprehensive Cancer Center	66
NCT00911820	A Randomized, Multicenter, Phase II Trial of Cisplatin, Irinotecan, and Bevacizumab (PCA) vs. Docetaxel, Cisplatin, Irinotecan, and Bevacizumab (TPCA) in Advanced Esophageal and Gastric Cancer	II	Active, not recruiting	Dana-Farber Harvard Cancer Center	86
NCT01333033	Randomized Phase II Trial of PET Scan-Directed Combined Modality Therapy in Esophageal Cancer	II	Active, not recruiting	Alliance for Clinical Trials in Oncology	254
NCT01498289	A Randomized Phase II Pilot Study Prospectively Evaluating Treatment for Patients Based on ERCC1 (Excision Repair Cross-Complementing 1) for Advanced/Metastatic Esophageal, Gastric or Gastroesophageal Junction (GEJ) Cancer	II	Active, not recruiting	SWOG	225
NCT01307956	A Phase II Study of Neo-adjuvant Therapy with Oxaliplatin, Leucovorin, 5-Fluorouracil, Panitumumab (Vectibix) and Radiation in Patients with Locally Advanced Adenocarcinoma of the Esophagus or Gastroesophageal Junction	II	Active, not recruiting	University of Nebraska Medical Center	23
NCT01095120	A Phase II Study of Tesetaxel Administered at a Flat Dose Once Every 21 Days as Second-line Therapy to Subjects With Advanced Gastric Cancer	II	Active, not recruiting	Genta Inc	27
NCT01372202	A Phase 2 Study of Paclitaxel with Cisplatin vs Fluoropyrimidine with a Platinum Agent for Neoadjuvant Therapy in Operable Esophageal Cancer Based on CHFR Methylation Status in Diagnostic Biopsies	II	Active, not recruiting	Johns Hopkins University/Sidney Kimmel Cancer Center	25

Table #23: Chemotherapy Clinical Trials (n=25)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT01715233	A Phase II Study Investigating CHFR Methylation Status as a Biomarker for Taxane Sensitivity Using Modified Docetaxel, Cisplatin and 5 Flourouracil in Patients with Metastatic Esophageal, Gastroesophageal and Gastric Cancer	II	Active, not recruiting	Johns Hopkins University/Sidney Kimmel Cancer Center	130
NCT00381706	Randomized Phase II Study of ECF-C, IC-C, or FOLFOX-C in Metastatic Esophageal and GE Junction Cancer	Ш	Active, not recruiting	Alliance for Clinical Trials in Oncology	270
NCT00086996	Oxaliplatin Plus Protracted Infusion 5-Fluorouracil and Radiation for Potentially Curable Esophageal Cancer: A Phase II Trial with Molecular Correlates	II	Active, not recruiting	SWOG	85
NCT00964080	A Phase Ib/II Study of MBP-426 in Patients With Second Line Gastric, Gastro Esophageal, or Esophageal Adenocarcinoma	1/11	Active, not recruiting	Mebiopharm Company Limited	62
NCT04074343	A Phase 1b Multicenter Study of TAS-102 in Combination with Irinotecan in Patients with Advanced Recurrent or Unresectable Gastric and Gastroesophageal Adenocarcinoma after at Least One Line of Treatment with a Fluoropyrimidine and Platinum Containing Regimen	_	Active, not recruiting	UC Irvine Health/Chao Family Comprehensive Cancer Center	20
NCT02970539	A Phase 1b Study of Oraxol in Combination With Ramucirumab in Patients With Gastric, Gastro- esophageal, or Esophageal Cancers	-	Active, not recruiting	Athenex, Inc.	36
NCT03279237	A Pilot Study of FOLFIRINOX in Combination with Neoadjuvant Radiation for Gastric and GE Junction Cancers	ı	Active, not recruiting	Dana-Farber Harvard Cancer Center	25
NCT02358863	A Pilot Study of Molecular Profile-Directed Chemotherapy for Metastatic HER2(-) Esophagogastric Adenocarcinoma (mEGA)	Early Phase I	Active, not recruiting	MedStar Georgetown University Hospital	20

Table #23: Chemotherapy Clinical Trials (n=25)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT02234180	Randomized Phase II Double Blind Study of Adjuvant Regorafenib vs Placebo in Patients with Node Positive Esophageal Cancer That Completed Pre-operative Therapy	=	Active, not recruiting	Academic and Community Cancer Research United	105
NCT01573468	A Randomized, Double-blind Study of Capecitabine Plus Tesetaxel Versus Capecitabine Plus Placebo as Second-line Therapy in Subjects With Gastric Cancer	II	Recruiting	Genta Inc	580
NCT03283761	A Phase II Study of FOLFOX Combined with Nab-Paclitaxel (FOLFOX-A) in Treatment of Metastatic or Advanced Unresectable Gastric, Gastro-Esophageal Junction Adenocarcinoma	II	Recruiting	Northwestern University	39
NCT03686488	A Phase II Study of TAS 102 in Combination with Ramucirumab in Advanced, Refractory Gastric, or Gastroesophageal Junction (GEJ) Adenocarcinoma	=	Recruiting	Moffitt Cancer Center	25
NCT04028167	Phase II Study of Induction FLOT Followed by Neoadjuvant Chemoradiation in Patients with Resectable Adenocarcinoma of the Esophagus or Gastroesophageal Junction	=	Recruiting	University of Colorado Hospital	40
NCT02366819	PERIOP-FOLFIRINOX: A Pilot Trial of Perioperative Genotype-Guided Irinotecan Dosing of gFOLFIRINOX for Locally Advanced Gastroesophageal Adenocarcinoma	I	Recruiting	University of Chicago Comprehensive Cancer Center	65
NCT04097028	Use of Trifluridine/Tipiracil (TAS-102) and Oxaliplatin as Induction Chemotherapy in Resectable Esophageal and Gastroesophageal Junction (GEJ) Adenocarcinoma	=	Recruiting	Roswell Park Cancer Institute	45
NCT04660760	Ramucirumab plus Trifluridine/Tipiracil (TAS-102) for Patients with Previously Treated Advanced Gastric or Gastroesophageal Junction Adenocarcinoma: An Investigator-Initiated, Randomized Non-Inferiority Phase 2 Study	=	Recruiting	Academic and Community Cancer Research United	116

Table #23: Chemotherapy Clinical Trials (n=25)

NCT ID	Official Title		Current Study Status	Lead Organization	Target Enrollment
NCT03588039	Phase 1 Study With Expansion Cohorts to Assess the Safety, Tolerability, and Activity of Oraxol (Paclitaxel + HM30181A) in Combination With Pembrolizumab in Subjects With Advanced Solid Malignancies		Recruiting	Athenex, Inc.	114
NCT04931823	A Phase 1, Multicenter, Single Agent Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Preliminary Evidence of Antitumor Activity of CPO-100 in Adult Patients With Advanced Solid Tumors	I	Recruiting	Conjupro Bio- Pharmaceuticals Inc	142

Table #24: Radiation Therapy Clinical Trials (n=17)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT00052910	Phase III Intergroup Trial of Adjuvant Chemoradiation after Resection of Gastric or Gastroesophageal Adenocarcinoma		Active, not recruiting	Alliance for Clinical Trials in Oncology	540
NCT01512589	Phase IIB Randomized Trial of Proton Beam Therapy versus Intensity-Modulated Radiation Therapy for the Treatment of Esophageal Cancer	II	Active, not recruiting	M D Anderson Cancer Center	180
NCT02213497	Phase I Dose Escalation of Neoadjuvant Proton Beam Radiotherapy with Concurrent Chemotherapy in Locally Advanced Esophageal Cancer  Active, not recruiting Pennsylvania/Abramson Cancer Center		30		
NCT01449864	A Feasibility and Registration Study of Proton Radiotherapy for Upper Gastrointestinal and Biliary Malignancies	Early Phase I	Active, not recruiting	I Pennsylvania/Δhramson	
NCT03801876	Phase III Randomized Trial of Proton Beam Therapy (PBT) versus Intensity Modulated Photon Radiotherapy (IMRT) for the Treatment of Esophageal Cancer		Recruiting	NRG Oncology	300
NCT03482791	A Phase II Study of Proton Beam Therapy in the Treatment of Esophageal Cancer	II	Recruiting	Siteman Cancer Center at Washington University	40
NCT03161522	A Randomized Trial Comparing Early Local Chemoradiation Therapy +/- Surgery versus Systemic Therapy for Patients with Esophageal or Gastric Cancer with Oligometastases	II	Recruiting	M D Anderson Cancer Center	100
NCT04368702	Clinical Onboard Utilization of Image Guided Radiation Therapy with Magnetic Resonance (CONFIRM): A Master Protocol	1/11	Recruiting	Dana-Farber Harvard Cancer Center	60

Table #24: Radiation Therapy Clinical Trials (n=17)

NCT ID	Official Title		Current Study Status	Lead Organization	Target Enrollment
NCT04046575	Phase I Study of Radiation Dose Intensification with Accelerated Hypofractionated Intensity Modulated Radiation Therapy and Concurrent Carboplatin and Paclitaxel for Inoperable Esophageal Cancer		Recruiting	Siteman Cancer Center at Washington University	20
NCT04147819	A Phase 1 Open-label, First-in-human, Multi-center Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Anti-tumor Activity of Thorium-227 Labeled Antibody-chelator Conjugate BAY2701439, in Participants With Advanced HER2-expressing Tumors		Recruiting	Bayer Corporation	213
NCT03094884	Phase I Study of Neoadjuvant Pulsed Low Dose Rate Radiation with Concurrent Chemotherapy for Non-Small Cell Lung Cancer and Esophageal Cancer	_	Recruiting	Fox Chase Cancer Center	40
NCT04615013	A Phase 1 Study of NBTXR3 activated by Radiotherapy with Concurrent Chemotherapy for Adenocarcinoma of the Esophagus	''		24	
NCT04523818	A Phase Ib Trial of Preoperative Short-Course		Recruiting	M D Anderson Cancer Center	30
NCT03610711	REACTION (Radiation Enhanced Assessment of Combination Therapies in Immuno-Oncology) – Nivolumab or Nivolumab in Combination with Other Immuno-Oncology (IO) Agents after Targeted Systemic Radiation in Patients with Advanced Esophagogastric Cancer	I	Recruiting	Johns Hopkins University/Sidney Kimmel Cancer Center	30
NCT04162665	MR-Guided Pre-Operative RT in Gastric Cancer	NA	Recruiting	Siteman Cancer Center at Washington University	36

## Table #24: Radiation Therapy Clinical Trials (n=17)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT04248452	A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA)	Ш	Suspended	ECOG-ACRIN Cancer Research Group	314
NCT04846309	Hypoxia Imaging for Esophageal Cancer to Guide Personalized Radiation Therapy	I	Suspended	Huntsman Cancer Institute/University of Utah	16

Table #25: Antibody-drug Conjugates Clinical Trials (n=14)

NCT ID	Official Title		Current Study Status	Lead Organization	Target Enrollment
NCT02341625	A Phase I/IIa Study of BMS-986148, a Mesothelin Directed Antibody Drug Conjugate, in Subjects With Select Advanced Solid Tumors  Active, not recruiting		Bristol-Myers Squibb	407	
NCT02187848	A First-in-Human Study for the Evaluation of the Safety, Pharmacokinetics and Antitumor Activity of SAR408701 in Patients With Advanced Solid Tumors	1/11	Active, not recruiting	Sanofi Aventis	313
NCT04084366	A Phase 1/2, Open-Label, Dose-Escalation and Cohort- Expansion Study Evaluating the Safety, Pharmacokinetics, and Therapeutic Activity of OBI-999 in Patients With  Advanced Solid Tumors  Active, not recruiting  OBI Pharma, Inc		OBI Pharma, Inc	185	
NCT02564900	Phase 1, Two-Part, Multicenter, Non-randomized, Open- label, Multiple Dose First-In-Human Study of DS-8201A, in Subjects With Advanced Solid Malignant Tumors	ı	Active, not recruiting	Daiichi Sankyo Co., Ltd.	278
NCT04225117	An Open-label, Multicenter, Multicohort, Phase 2 Study		Recruiting	Astellas Pharma Global Development, Inc.	240
NCT04032704	Open-Label Phase 2 Study of Ladiratuzumab Vedotin (LV)		Seagen Inc.	264	
NCT04379596	A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants With HER2 Overexpressing Gastric Cancer (DESTINY-GastricO3)	II	Recruiting	AstraZeneca Pharmaceuticals LP	255

Table #25: Antibody-drug Conjugates Clinical Trials (n=14)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT03602079	A Phase I-II, FIH Study of A166 in Locally Advanced/Metastatic Solid Tumors Expressing Human Epidermal Growth Factor Receptor 2 (HER2) or Are HER2 Amplified That Did Not Respond or Stopped Responding to Approved Therapies	1/11	Recruiting	Klus Pharma Inc.	82
NCT03221400	A Phase 1/2a, Open-label, Multicenter Study to Assess		Recruiting	Tarveda Therapeutics	340
NCT04602117	Evaluating the Safety of Weekly Paclitaxel With Trastuzumab Duocarmazine (SYD985) in Patients With Metastatic Cancer: A Phase I/Ib Trial	I	Recruiting	Recruiting QuantumLeap Healthcare Collaborative	
NCT04137289	A First-in-human Phase Ia/b, Open Label, Multicentre, Dose Escalation Study of BI 905711 in Patients With Advanced Gastrointestinal Cancers	ı	Recruiting	Boehringer Ingelheim Pharmaceuticals Inc	140
NCT04695847			EMD Serono Research & Development Institute, Inc.	84	
NCT04044859	A Phase 1 Dose Escalation Study To Assess Safety And Efficacy Of ADP-A2M4CD8 In HLA-A2+ Subjects With MAGE-A4 Positive Tumors	1	Recruiting	Adaptimmune Limited	45
NCT04171141	A PHASE 1 DOSE ESCALATION AND EXPANSION STUDY EVALUATING THE SAFETY, TOLERABILITY, PHARMACOKINETICS, PHARMACODYNAMICS AND ANTI TUMOR ACTIVITY OF PF-07062119 IN PATIENTS WITH ADVANCED GASTROINTESTINAL TUMORS	ı	Recruiting	Pfizer Inc	130

Table #26: Surgery Clinical Trials (n=11)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT02891447	A Phase II Study of Cytoreduction, Gastrectomy, and Hyperthermic Intraperitoneal Chemoperfusion (HIPEC) in Patients with Gastric Adenocarcinoma and Carcinomatosis or Positive Cytology		Active, not recruiting	M D Anderson Cancer Center	30
NCT03330028	A Phase I Study of Hyperthermic Intraperitoneal		Active, not recruiting	M D Anderson Cancer Center	48
NCT04034251	A Phase II Study of Intraperitoneal and Intravenous Paclitaxel Chemotherapy With Oral Capecitabine for II Recruiting National C Gastric Adenocarcinoma With Peritoneal Carcinomatosis		National Cancer Institute	74	
NCT04762953	Phase II Trial of Sequential Systemic Therapy plus Intraperitoneal Paclitaxel in Gastric/GEJ Cancer Peritoneal Carcinomatosis	II	Recruiting	UC Irvine Health/Chao Family Comprehensive Cancer Center	20
NCT04308837	A Phase II Trial of Neoadjuvant Laparoscopic Hyperthermic Intraperitoneal Chemotherapy (HIPEC) with Chemoradiation (Carboplatin and Taxol) as First Line Treatment for Patients with Local Regional Advanced Gastric Cancer	erthermic Intraperitoneal Chemotherapy (HIPEC) with themoradiation (Carboplatin and Taxol) as First Line reatment for Patients with Local Regional Advanced  II Recruiting at Mount Sinai		29	
NCT04107077	A Phase IIa Study of Laparoscopic Hyperthermic Intraperitoneal Chemotherapy (HIPEC) and PD-L1 Expression in Gastric Cancer with Peritoneal Metastases	II	Recruiting	University of Chicago Comprehensive Cancer Center	21
NCT04329494	Safety and Efficacy of Pressurized Intraperitoneal Aerosolized Chemotherapy (PIPAC) in Ovarian, Uterine, Appendiceal, Colorectal, and Gastric Cancer Patients with Peritoneal Carcinomatosis (PC)	ı	Recruiting	City of Hope Comprehensive Cancer Center	16

## Table #26: Surgery Clinical Trials (n=11)

NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
NCT04220827	A Phase I Study of Intraperitoneal Paclitaxel in Patients with Gastric Adenocarcinoma and Carcinomatosis or Positive Cytology		Recruiting	M D Anderson Cancer Center	24
NCT03092518	Phase II Trial of Heated Intraperitoneal Chemotherapy and Gastrectomy for Gastric Cancer With Positive Peritoneal Cytology	II	Recruiting	National Cancer Institute	40
NCT03259763	EUS-Guided Gastroenterostomy versus Enteral Stenting for Palliation of Malignant Gastric Outlet Obstruction: A Randomized Clinical Trial	II	Recruiting	Johns Hopkins University/Sidney Kimmel Cancer Center	96
NCT04583488	A Phase I Study of Intraperitoneal Docetaxel in Combination with mFOLFOX6 for Gastric Cancer Patients with Peritoneal Carcinomatosis	I	Recruiting	Johns Hopkins University/Sidney Kimmel Cancer Center	30

# NON-CANCER TREATMENT / OTHER CLINICAL TRIALS

# **Gastric and Esophageal Cancer**

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## Non-cancer Treatment / Other Clinical Trials

Table #27: Diagnostic Clinical Trials (n=20)

Disease Type	NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
Gastric	NCT01939275	64Cu-DOTA-Trastuzumab Positron Emission Tomography in Patients with Gastric Cancer	NA	Active not recruiting	City of Hope Comprehensive Cancer Center	22
Esophageal, gastric	NCT02023996	Pilot Trial of PET Imaging with 89Zr-DFO- Trastuzumab in Esophagogastric Cancer	NA	Active not recruiting	Memorial Sloan Kettering Cancer Center	55
Esophageal	NCT03151642	A Pilot Study of Diffusion Weighted MRI to Assess Esophageal Tumor Response to Neoadjuvant Chemoradiation	NA	Active not recruiting	University of Pennsylvania/Abramson Cancer Center	44
Barrett's	NCT02864043	Identification of Features Associated With Dysplasia Using the NvisionVLE® Imaging System Pilot Trial	NA	Active not recruiting	NinePoint Medical	150
Esophageal	NCT04400292	Does the Concept of the Sentinel Lymph Node Apply to Esophageal Cancer? A Prospective Assessment of Near- Infrared Image-Guided Lymphatic Mapping and Sentinel Lymph Node Identification in Esophageal Cancer	II	Recruiting	Memorial Sloan Kettering Cancer Center	60
Esophageal	NCT03578224	Contrast-Enhanced Ultrasound Identification of Sentinel Nodes in Esophageal Cancer	NA	Recruiting	Thomas Jefferson University Hospital	40

Table #27: Diagnostic Clinical Trials (n=20)

Disease Type	NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
Barrett's, esophageal	NCT04295811	A Multicenter Case-Control Study of the Efficacy of EsoGuard on Samples Collected Using EsoCheck, Versus Esophagogastroduodenoscopy, for the Diagnosis of Barrett's Esophagus With and Without Dysplasia, and for Esophageal Adenocarcinoma	NA	Recruiting	Lucid Diagnostics, Inc.	470
Esophageal	NCT03385343	Staging of Superficial Esophageal Adenocarcinoma Using Volumetric Laser Endomicroscopy	NA	Recruiting	Mayo Clinic in Rochester	60
Esophageal	NCT03403465	Intratreatment FDG-PET during Radiation Therapy for Gynecologic and Gastrointestinal Cancers (Adaptive PET II)	II	Recruiting	Duke University Medical Center	130
Esophageal, gastric	NCT02584244	Feasibility of the LUM Imaging System for Detection of Gastrointestinal Cancers	1/11	Recruiting	Lumicell, Inc.	66
Esophageal, gastric	NCT04161781	Pilot Trial of 18F-BMS-986229 PET in Esophagogastric Cancer	I	Recruiting	Memorial Sloan Kettering Cancer Center	35
Esophageal	NCT04188535	RELAY: Repeated Magnetic Resonance Imaging Examinations to Analyze and Assess Your Cancer: A Prospective Study on the Use of Serial Magnetic Resonance Imaging in the Assessment of Changes during Treatment with Radiation Therapy	I	Recruiting	Dana-Farber Harvard Cancer Center	86
Barrett's	NCT03366012	The Acceptability of a Rapid Esophageal Adenocarcinoma Risk Test (REACT)	NA	Recruiting	NYP/Columbia University Medical Center/Herbert	100

Table #27: Diagnostic Clinical Trials (n=20)

Disease Type	NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
					Irving Comprehensive Cancer Center	
Barrett's	NCT03417570	Cap Assisted Upper Endoscopy versus High Definition White Light Endoscopy and Narrow Band Imaging Alone in the Detection of Visible Lesions Barrett's Esophagus: A Randomized Tandem Study	NA	Recruiting	Siteman Cancer Center at Washington University	170
Barrett's, esophageal	NCT03961945	Minimally Invasive Molecular Approaches for the Diagnosis of Barrett's Esophagus and Esophageal Adenocarcinoma	NA	Recruiting	Mayo Clinic	1350
Barrett's	NCT03852576	Phase 1B Study of KSP/QRH Dimer for Detection of Neoplasia in the Esophagus(BETRNet)	I	Recruiting	University of Michigan	50
Gastric	NCT04535414	Phase II Randomized Trial of Bethesda Protocol Compared to Cambridge Method for Detection of Early Stage Gastric Cancer in CDH1 Mutation Carriers	=	Not yet recruiting	National Cancer Institute	350
Gastric	NCT05038098	Magnetic Sentinel Lymph Node Mapping in Gastric Cancer, Safety and Feasibility Clinical Trial	I	Not yet recruiting	M D Anderson Cancer Center	20
Esophageal	NCT05028725	Investigation of a Novel Strategy for Early Detection of Esophageal Squamous Cell Carcinoma	NA	Not yet recruiting	University of California San Francisco	289

# Table #27: Diagnostic Clinical Trials (n=20)

Disease Type	NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
Gastric	NCT04105062	Evaluation of LS301 Uptake in Tumors of Patients Undergoing Liver, Pancreas, or Gastric Surgery	1/11	Not yet recruiting	Siteman Cancer Center at Washington University	115

Table #28: Screening Clinical Trials (n=5)

Disease Type	NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
Barrett's	NCT04293458	A Multicenter, Single-Arm Study of the Efficacy of EsoGuard(TM) on Samples Collected Using EsoCheck(TM) Versus Esophagogastroduodenoscopy for the Diagnosis of Barrett's Esophagus in an At-Risk Screening Population	NA	Recruiting	Lucid Diagnostics, Inc.	1000
Barrett's	NCT02018367	Accuracy, Yield, and Clinical Impact of a Low-Cost High Resolution Microendoscope in the Early Diagnosis of Esophageal Adenocarcinoma	II	Recruiting	Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	100
Esophageal	NCT02029937	High Resolution Microendoscopy for the Detection of Esophageal Squamous Cell Neoplasia: A Randomized, Multicenter Trial of Accuracy, Yield, and Clinical Impact	=	Recruiting	Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	1300
Barrett's, esophageal	NCT04214119	EsophaCap for the Detection of Early Adenocarcinoma	III	Recruiting	Johns Hopkins University/Sidney Kimmel Cancer Center	2000
Barrett's	NCT04880044	Detection of Barrett's Esophagus in Patients without GERD Symptoms	NA	Not yet recruiting	Case Comprehensive Cancer Center	500

## Table #29: Prevention Clinical Trials (n=6)

Disease Type	NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
Barrett's	NCT01298999	Randomized, Placebo-Controlled Trial of YF476, a Gastrin Receptor Antagonist, in Barrett's Esophagus	II	Active not recruiting	NYP/Columbia University Medical Center/Herbert Irving Comprehensive Cancer Center	20
Barrett's	NCT02521285	Effect of Aspirin on Biomarkers of Barrett's Esophagus after Successful Eradication of Barrett's Esophagus with Radiofrequency Ablation	II	Active not recruiting	M D Anderson Cancer Center	40
Barrett's	NCT02089386	Tamoxifen to Treat Barrett's Metaplasia	Early Phase I	Active not recruiting	Siteman Cancer Center at Washington University	12
Gastric	NCT02782949	Randomized, Double-Blind, Placebo- Controlled Trial of Meriva® (Curcuminoids) as a Candidate Chemoprevention Agent for Gastric Carcinogenesis	II	Active not recruiting	Mayo Clinic in Rochester	50
Gastric	NCT02794428	Targeted Chemoprevention of Gastric Carcinogenesis in High Risk Populations	11	Recruiting	Vanderbilt University/Ingram Cancer Center	76
Barrett's	NCT04939051	Obeticholic Acid for Prevention in Barrett's Esophagus	II	Not yet recruiting	University of Michigan Comprehensive Cancer Center	30

Table #30: Supportive Care Clinical Trials (n=12)

Disease Type	NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
Esophageal, gastric	NCT01970306	A Prospective Phase II Trial to Evaluate Esophageal Reinforcement with ACell Gentrix Surgical Matrix: A Degradable Biologic Scaffold Material	=	Active not recruiting	Memorial Sloan Kettering Cancer Center	86
Esophageal	NCT02864355	Does Perioperative Goal Directed Therapy Using Flotrac Improve Outcomes in Esophagectomy Patients	NA	Active not recruiting	Medical University of South Carolina	140
Esophageal	NCT02027948	A Nutritional Management Algorithm in Older Patients with Locally Advanced Esophageal Cancer	NA	Active not recruiting	Memorial Sloan Kettering Cancer Center	36
Esophageal	NCT03243734	A Prospective Single Arm Multicenter Study Evaluating the Effects of Spray Cryotherapy in Patients With Persistent Local Esophageal Cancer	NA	Active not recruiting	US Endoscopy Group Inc.	51
Esophageal	NCT02965976	Double-Arm, Randomized Study of Botulinum Toxin Injection as a Pyloric Drainage Procedure for Minimally Invasive Esophagectomy (Phase II)	II	Recruiting	Roswell Park Cancer Institute	50
Esophageal, gastric	NCT03133650	A Phase I Trial of Vascular-Targeted Photodynamic Therapy in Esophagogastric Cancer Patients with Moderate to Severe Dysphagia	1	Recruiting	Memorial Sloan Kettering Cancer Center	36
Esophageal, gastric	NCT03819088	Effects on QOL When Zinc is Supplemented in Patients with Upper GI Cancer on Chemotherapy	Ш	Recruiting	Emory University Hospital/Winship Cancer Institute	100
Esophageal	NCT04607590	Yoga Program for Couples Coping with Cancer	NA	Recruiting	M D Anderson Cancer Center	600

Table #30: Supportive Care Clinical Trials (n=12)

Disease Type	NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
Gastric	NCT04602026	Re-Defining Frailty and Improving Outcomes through Prehabilitation (RIOT Trial)	NA	Recruiting	Ohio State University Comprehensive Cancer Center	50
Gastric	NCT05056805	"SurgeryStrong". Preoperative Strength Exercise and Nutrition Program in Patients Completing Neoadjuvant Chemoradiation Therapy for Pancreatic and Gastric Cancer: A Randomized Trial Testing Effects on Strength, Fitness, Health-Related Quality of Life, and Perioperative Outcomes	NA	Recruiting	M D Anderson Cancer Center	48
Esophageal, gastric	NCT04072393	A Pilot Trial of Cardiac Rehabilitation for Patients with Lung or Esophageal Cancer Receiving Definitive Radiation Therapy	NA	Recruiting	Siteman Cancer Center at Washington University	20
Esophageal	NCT04029857	Nutritional Supplementation for Esophageal Cancer Patients Undergoing Trimodality Therapy	III	Not yet recruiting	M D Anderson Cancer Center	200

Table #31: Other Clinical Trials: Device, Health Service Research, and Basic Science (n=5)

Disease Type	NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
Barrett's	NCT02729948	Use of a Tethered Capsule Endoscope in Screening for Barrett's Esophagus	NA	Active not recruiting	Fred Hutch/University of Washington Cancer Consortium	5
Gastric	NCT04251403	A Novel Approach to the Surveillance of Pre-Malignant Gastric Lesions	Early Phase I	Recruiting	NYP/Columbia University Medical Center/Herbert Irving Comprehensive Cancer Center	10
Esophageal, gastric	NCT03986502	Pilot Randomized Study of a Proactive Financial Navigation Intervention in Patients with Newly Diagnosed Gastric and Gastroesophageal Junction (GEJ) Adenocarcinoma	NA	Recruiting	Fred Hutch/University of Washington Cancer Consortium	284
Esophageal, gastric	NCT04449679	Real-Time Monitoring of Chemotherapy Side Effects in Patients with Gastro-Intestinal Malignancies	NA	Recruiting	Thomas Jefferson University Hospital	65
Barrett's	NCT03459339	Coordinating Center: Natural History of Barrett's Esophagus Using Tethered Capsule Endomicroscopy	NA	Recruiting	Massachusetts General Hospital	500

Table #32: Treatment of Barrett's Esophagus (n=4)

Disease Type	NCT ID	Official Title	Phase	Current Study Status	Lead Organization	Target Enrollment
Barrett's	NCT02514525	Multi-center Clinical Study to Evaluate the C2 CryoBalloon Focal Ablation System for the Treatment of Patients With Previously Untreated Dysplastic Barrett's Epithelium	NA	Active, not recruiting	C2 Therapeutics, Inc.	150
Barrett's	NCT03364114	Interscope Endorotor® Mucosal Resection System With Continued Ablative Therapy In Subjects With Refractory Dysplastic Barrett's Esophagus	NA	Recruiting	Interscope, Inc.	120
Barrett's	NCT03554356	Nitrous Oxide For Endoscopic Ablation of Refractory Barrett's Esophagus (NO FEAR-BE)	NA	Recruiting	UNC Lineberger Comprehensive Cancer Center	70
Barrett's	NCT05107219	Pilot Study of GCC Agonists to Identify a Cyclic-GMP Signal in Duodenal Tissue of Volunteers	Early Phase I	Not yet recruiting	University of Wisconsin Hospital and Clinics	39