

## CHNw Oncology Research Protocols (Open to Enrollment)

4/2/2024

Multiple Disease Sites		NCT #	Study Drug MOA	Indication/Population	Biomarker Target	Sites Open
TAPUR	The Targeted Agent and Profiling Utilization Registry (TAPUR) Study <b>(Bedano)</b>	<a href="#">NCT02693535</a>	Various	Various	Various	<b>Indy</b>
Day101-102b	A Phase 1b/2, Subprotocol of DAY101 in Combination with Pimasertib for Patients with Recurrent, Progressive, or Refractory Solid Tumors and MAPK Pathway Aberrations <b>(O'Neil)</b>	<a href="#">NCT04985604</a>	CNS-penetrant, small-molecule, type II pan-RAF kinase inhibitor	In Dose Escalation Solid tumors with BRAF alterations; now enrolling in Backfill Cohort 2: BRAF-mutated solid tumor, Dose Level (1,2) & Backfill Cohort 3: NRAS-mutated solid tumor, Dose Level (1,2)	MAPK pathway alterations	<b>North and East</b>
AbbVie M21-410	NSCLC, HNSCC and Advanced Solid Tumors: ABBV-514 Monotherapy and in Combination with Pembrolizumab or Budigalimab <b>(N. Reddy)</b>	<a href="#">NCT05005403</a>	ABBV-514 is a T-regs cell depleter	R/R Solid tumors	NA	<b>Indy</b>
LOXO G12C	A Phase 1/2 Study of LY3537982 in Patients with KRAS G12C-Mutant Advanced Solid Tumors <b>(N. Reddy)</b>	<a href="#">NCT04956640</a>	KRAS G12C Inhibitor	Other Solid Tumors	KRAS G12C	<b>Indy</b>
Kronos Bio KB-0742-1001	Phase 1, First in Human, Open-Label Dose Escalation and Cohort Expansion Study of KB-0742 in Patients with Relapsed or Refractory Solid Tumors or Non-Hodgkin Lymphoma <b>(N. Reddy)</b>	<a href="#">NCT04718675</a>	CDK-9 Inhibitor	Relapsed or Refractory Solid Tumors; Cohort A: TNBC, Cohort B: soft tissue sarcomas <i>(1-23-24: enrollment paused)</i>	MYC or MYC Paralog	<b>North and South</b>
Amgen 20220127	A Phase 1/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 in Combination With IDE397 in Subjects With Advanced MTAP-null Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT05975073</a>	Methylthioadenosine (MTA)-cooperative protein arginine methyltransferase 5 (PRMT5) inhibitor	Part 1: MTAP-null or lost MTAP expression solid tumors	MTAP-null	<b>Indy</b>
Janssen 61186372NSC1003	An Open-Label, Multicenter, Dose Escalation Phase 1b study to Assess the Safety and Pharmacokinetics of Subcutaneous Delivery of Amivantamab, a Human Bispecific EGFR and cMET Antibody for the Treatment of Advanced Solid Malignancies (PALOMA) <b>(O'Neil)</b>	<a href="#">NCT04606381</a>	Amivantamab - a human bispecific EGFR and cMET antibody	Solid malignancy that is metastatic or unresectable & may derive benefit from EGFR or cMET directed Tx	may derive benefit from EGFR or cMET directed Tx	<b>North and East</b>

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<p>Amgen 20210023 Amgen 193</p>	<p>A Phase 1/1b/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 Alone and in Combination with Docetaxel in Subjects with Advanced MTAP-null Solid Tumors <b>(O'Neil)</b></p>	<p><a href="https://clinicaltrials.gov/ct2/show/study/NCT05094336">NCT05094336</a></p>	<p>PRMT5 Inhibitor</p>	<p>Advanced MTAP-null Solid Tumors Dose Expansion: 1c: NSCLC, 1e: BTC, 1f: HNSCC, 1g: PDAC, 1h: Basket (can include: NSCLC, BTC, HNSCC, PDAC)</p>	<p>MTAP-null</p>	<p><b>North and East</b></p>
<p>AbbVie M21-404</p>	<p>A Phase 1 First in Human Study Evaluating Safety, Pharmacokinetics and Efficacy of ABBV-400 in Adult Subjects with Advanced Solid Tumors <b>(O'Neil)</b></p>	<p><a href="https://clinicaltrials.gov/ct2/show/study/NCT05029882">NCT05029882</a></p>	<p>ADC consisting of a c-MET-targeting antibody; potent inhibitor of topoisomerase 1 (TOP1) payload</p>	<p>Advanced Solid Tumors - MetAMP Tumor Agnostic</p>	<p>cMET</p>	<p><b>North and South</b></p>
<p>Artios ART0380C001</p>	<p>A Phase I/IIa, Open-label, Multi-center Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of the ATR Kinase Inhibitor ART0380 Administered Orally as Monotherapy and in Combination to Patients with Advanced or Metastatic Solid Tumors <b>(O'Neil)</b></p>	<p><a href="https://clinicaltrials.gov/ct2/show/study/NCT04657068">NCT04657068</a></p>	<p>ART0380</p>	<p>Advanced or metastatic solid tumors w/ATM alterations Part B4: solid tumors (other than endometrial)</p>	<p>ATM</p>	<p><b>North</b></p>

<b>Breast</b>			<b>Study Drug MOA</b>	<b>Indication/Population</b>	<b>Biomarker Target</b>	<b>Sites Open</b>
CTGT MA.39	A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer <b>(Weed)</b>	<a href="#">NCT03488693</a>	RT	Low-risk breast cancer (Oncotype DX ≤25) or T3N0 disease	ER+	<b>Indy</b>
AstraZeneca D8534C00001	A Phase III, Double-blind, Randomised Study to Assess Switching to AZD9833 (a Next Generation, Oral SERD) + CDK4/6 Inhibitors (Palbociclib or Amemaciclib) vs. Continuing NSAI + CDK4/6 Inhibitors in HR+/HER2- MBC Patients with Detectable ESR1 Mutation Without Clinical or Radiological Progression During 1L Treatment with NSAI + CDK4/6 Inhibitor - A ctDNA Guided Early Switch Study (SERENA-6) <b>(Mayer)</b>	<a href="#">NCT04964934</a>	Oral SERD	HR+/HER2- MBC	ESR1 Mutation	<b>Indy</b>
BCCR	Breast Cancer Collaborative Registry <b>(Agarwala)</b>	<a href="#">NCT00666731</a>	NA	Early breast cancer	NA	<b>Indy</b>
Janssen 61186372NSC1003	An Open-Label, Multicenter, Dose Escalation Phase 1b study to Assess the Safety and Pharmacokinetics of Subcutaneous Delivery of Amivantamab, a Human Bispecific EGFR and cMET Antibody for the Treatment of Advanced Solid Malignancies (PALOMA) <b>(O'Neil)</b>	<a href="#">NCT04606381</a>	Amivantamab - a human bispecific EGFR and cMET antibody	Solid malignancy that is metastatic or unresectable & may derive benefit from EGFR or cMET directed Tx - including breast	may derive benefit from EGFR or cMET directed Tx	<b>North and East</b>
AbbVie M21-410	NSCLC, HNSCC and Advanced Solid Tumors: ABBV-514 Monotherapy and in Combination with Pembrolizumab or Budigalimab <b>(N. Reddy)</b>	<a href="#">NCT05005403</a>	ABBV-514 is a T-regs cell depleter	TNBC	NA	<b>Indy</b>
Seagen SGNB7H4V-001	A Phase I Study of SGN-B7H4V in Advance Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT05194072</a>	ADC - CPI of the B7 family	Part C: TNBC; HER2-negative, HR-positive breast cancer (3/27/24: pre-screening, anticipating cohort will open 4/4)	Exploratory	<b>North</b>
Kronos Bio KB-0742-1001	Phase 1, First in Human, Open-Label Dose Escalation and Cohort Expansion Study of KB-0742 in Patients with Relapsed or Refractory Solid Tumors or Non-Hodgkin Lymphoma <b>(N. Reddy)</b>	<a href="#">NCT04718675</a>	CDK-9 Inhibitor	Cohort A: TNBC (1-23-24: enrollment paused)	MYC or MYC Paralog	<b>North and South</b>
Volastra VLS-1488-2201	A phase I/II study of VLS-1488 (an oral KIF18A inhibitor) in subjects with advanced cancer <b>(O'Neil)</b>	<a href="#">NCT05902988</a>	Oral KIF18A Inhibitor	Escalation - TNBC Expansion - TNBC (1-31-24: no slots available)	KIF18A	<b>North and South</b>

<b>Lung</b>			<b>Study Drug MOA</b>	<b>Indication/Population</b>	<b>Biomarker Target</b>	<b>Sites Open</b>
SignalChem SLC-391-102	A Single-Arm, Open-Label, Phase 1b/2 Study of SLC-391, an AXL Inhibitor, in Combination with Pembrolizumab in Subjects with Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC) (SKYLITE) <b>(N. Reddy)</b>	<a href="#">NCT05860296</a>	Selective AXL Inhibitor	NSCLC (enrolling in Phase 1b - SLC-391 100mg BID + 200mg Q3W Pembrolizumab; SLC-391 150mg BID + 200mg Q3W Pembrolizumab) <i>(1-10-24: all slots filled)</i>	AXL/TYRO3/MER	<b>North and South</b>
LOXO G12C	A Phase 1/2 Study of LY3537982 in Patients with KRAS C12C-Mutant Advanced Solid Tumors <b>(N. Reddy)</b>	<a href="#">NCT04956640</a>	KRAS G12C Inhibitor	NSCLC 1st line, NSCLC w Brain mets Combo therapy - NSCLC 1st line (pembro)	KRAS G12C	<b>Indy</b>
Janssen 61186372NSC1003	An Open-Label, Multicenter, Dose Escalation Phase 1b study to Assess the Safety and Pharmacokinetics of Subcutaneous Delivery of Amivantamab, a Human Bispecific EGFR and cMET Antibody for the Treatment of Advanced Solid Malignancies (PALOMA) <b>(O'Neil)</b>	<a href="#">NCT04606381</a>	Amivantamab - a human bispecific EGFR and cMET antibody	Solid malignancy that is metastatic or unresectable & may derive benefit from EGFR or cMET directed Tx - including NSCLC, mesothelioma	may derive benefit from EGFR or cMET directed Tx	<b>North and East</b>
AbbVie M21-410	NSCLC, HNSCC and Advanced Solid Tumors: ABBV-514 Monotherapy and in Combination with Pembrolizumab or Budigalimab <b>(N. Reddy)</b>	<a href="#">NCT05005403</a>	ABBV-514 is a T-regs cell depleter	NSCLC	NA	<b>Indy</b>
Seagen SGNB7H4V-001	A Phase I Study of SGN-B7H4V in Advance Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT05194072</a>	ADC - CPI of the B7 family	NSCLC	Exploratory	<b>North</b>
Amgen 20210023 Amgen 193	A Phase 1/1b/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 Alone and in Combination with Docetaxel in Subjects with Advanced MTAP-null Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT05094336</a>	PRMT5 Inhibitor	Advanced MTAP-null Solid Tumors Dose Expansion: 1c: NSCLC	MTAP-null	<b>North and East</b>
AbbVie M21-404	A Phase 1 First in Human Study Evaluating Safety, Pharmacokinetics and Efficacy of ABBV-400 in Adult Subjects with Advanced Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT05029882</a>	ADC consisting of a c-MET-targeting antibody; potent inhibitor of topoisomerase 1 (TOP1) payload	metAMP squamous or nonsquamous NSCLC, post platinumbased chemo + CPI or TKI <i>(12-4-23: no slots available)</i>	cMET	<b>North and South</b>

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Kronos Bio KB-0742-1001	Phase 1, First in Human, Open-Label Dose Escalation and Cohort Expansion Study of KB-0742 in Patients with Relapsed or Refractory Solid Tumors or Non-Hodgkin Lymphoma <b>(N. Reddy)</b>	<a href="#">NCT04718675</a>	CDK-9 Inhibitor	Cohort A: NSCLC; Cohort B: SCLC <i>(1-23-24: enrollment paused)</i>	MYC or MYC Paralog	<b>North and South</b>
Merus MCLA-129-CL01	Phase 1/2 Dose Escalation and Expansion Study Evaluating MCLA-129, a Human Anti-EGFR and Anti-cMET bispecific Antibody, in Patients with Advanced NSCLC and Other Solid Tumors <b>(N. Reddy)</b>	<a href="#">NCT04868877</a>	Human Anti-EGFR and Anti-cMET bispecific Antibody	NSCLC <i>(12-21-23: enrollment on hold)</i>	EGFR and cMET alterations	<b>North</b>
Amgen 20220127	A Phase 1/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 in Combination With IDE397 in Subjects With Advanced MTAP-null Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT05975073</a>	Methylthioadenosine (MTA)-cooperative protein arginine methyltransferase 5 (PRMT5) inhibitor	Part 2: MTAP-null or lost MTAP expression NSCLC	MTAP-null	<b>Indy</b>
Tempus TP-CA-002 (GEMINI)	TEMPUS NSCLC SURVEILLANCE STUDY: A Longitudinal Circulating Tumor DNA (ctDNA) Biomarker Profiling Study of Patients with Non-Small Cell Lung Cancer (NSCLC) Using Comprehensive Next-Generation Sequencing (NGS) Assays <b>(N. Reddy)</b>	<a href="#">NCT05236114</a>	NA	NSCLC	NA	<b>Indy</b>
Volastra VLS-1488-2201	A phase I/II study of VLS-1488 (an oral KIF18A inhibitor) in subjects with advanced cancer <b>(O'Neil)</b>	<a href="#">NCT05902988</a>	Oral KIF18A Inhibitor	Escalation - Sq-NSCLC Expansion - Sq-NSCLC	KIF18A	<b>North and South</b>
Lilly J3M-MC-JZQB	SUNRAY-01, A Global Pivotal Study in Participants with KRAS G12C-Mutant, Locally Advanced or Metastatic Non-Small Cell Lung Cancer Comparing First-Line Treatment of LY3537982 and Pembrolizumab vs Placebo and Pembrolizumab in those with PD-L1 expression ≥50% or LY3537982 and Pembrolizumab, Pemetrexed, Platinum vs Placebo and Pembrolizumab, Pemetrexed, Platinum regardless of PD-L1 Expression <b>(N. Reddy)</b>	<a href="#">NCT06119581</a>	LY3537982 in combination with Pembrolizumab Pemetrexed and Platinum	KRAS G12C-Mutant, Locally Advanced or Metastatic NSCLC <i>(only enrolling in the Dose Optimization [LY3537982 + Pembrolizumab] cohort)</i>	KRAS G12C-Mutant	<b>North and South</b>

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<b>Hematology</b>			<b>Study Drug MOA</b>	<b>Indication/Population</b>	<b>Biomarker Target</b>	<b>Sites Open</b>
TAPUR	The Targeted Agent and Profiling Utilization Registry (TAPUR) Study <b>(Bedano)</b>	<a href="#">NCT02693535</a>	Various	Multiple Myeloma, B cell NHL	Various	<b>Indy</b>
Kronos Bio KB-0742-1001	Phase 1, First in Human, Open-Label Dose Escalation and Cohort Expansion Study of KB-0742 in Patients with Relapsed or Refractory Solid Tumors or Non-Hodgkin Lymphoma <b>(N. Reddy)</b>	<a href="#">NCT04718675</a>	CDK-9 Inhibitor	Cohort A: non-Hodgkin Lymphoma <i>(1-23-24: enrollment paused)</i>	MYC or MYC Paralog	<b>North and South</b>

Head and Neck			Study Drug MOA	Indication/Population	Biomarker Target	Sites Open
EA3161	A Phase II/III Randomized Study of Maintenance Nivolumab versus Observation in Patients with Locally Advanced, Intermediate Risk HPV Positive OPCA <b>(Mayer)</b>	<a href="#">NCT03811015</a>	Nivo v. Obs	HPV + OPCA	HPV +	Indy
Janssen 61186372NSC1003	An Open-Label, Multicenter, Dose Escalation Phase 1b study to Assess the Safety and Pharmacokinetics of Subcutaneous Delivery of Amivantamab, a Human Bispecific EGFR and cMET Antibody for the Treatment of Advanced Solid Malignancies (PALOMA) <b>(O'Neil)</b>	<a href="#">NCT04606381</a>	Amivantamab - a human bispecific EGFR and cMET antibody	Solid malignancy that is metastatic or unresectable & may derive benefit from EGFR or cMET directed Tx - including SCCHN, Medullary	may derive benefit from EGFR or cMET directed Tx	North and East
Seagen SGNTV-001	Open Label Phase 2 Study of Tisotumab Vedotin for Locally Advanced or Metastatic Disease in Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT03485209</a>	ADC that is TF target	SCCHN (2-5-24: initial Part F safety run-in phase complete, enrollment paused for the 28-day DLT period)	Tissue Factor (TF) expressing tumors	Indy
Exelixis XL092-002	A Dose-Escalation and Expansion Study of the Safety and Efficacy of XL092 in Combination with Immuno-Oncology Agents in Subjects with Unresectable Advanced or Metastatic Solid Tumors (STELLAR 002) <b>(O'Neil)</b>	<a href="#">NCT05176483</a>	Next-gen Oral TKI	<b>Escalation Complete</b> Expansion: HCC 1L (12-4-23: arm 1 closed, arm 2 remains open)	NA	North and South
AbbVie M21-410	NSCLC, HNSCC and Advanced Solid Tumors: ABBV-514 Monotherapy and in Combination with Pembrolizumab or Budigalimab <b>(N. Reddy)</b>	<a href="#">NCT05005403</a>	ABBV-514 is a T-regs cell depleter	HNSCC	NA	Indy
Amgen 20210023 Amgen 193	A Phase 1/1b/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 Alone and in Combination with Docetaxel in Subjects with Advanced MTAP-null Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT05094336</a>	PRMT5 Inhibitor	Advanced MTAP-null Solid Tumors Dose Expansion: 1f: HNSCC	MTAP-null	North and East
Seagen SGNB7H4V-001	A Phase I Study of SGN-B7H4V in Advance Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT05194072</a>	ADC - CPI of the B7 family	ACC - head and neck	Exploratory	North
Merus MCLA-129-CL01	Phase 1/2 Dose Escalation and Expansion Study Evaluating MCLA-129, a Human Anti-EGFR and Anti-cMET bispecific Antibody, in Patients with Advanced NSCLC and Other Solid Tumors <b>(N. Reddy)</b>	<a href="#">NCT04868877</a>	Human Anti-EGFR and Anti-cMET bispecific Antibody	HNSCC (12-21-23: enrollment on hold)	EGFR and cMET alterations	Dose Exp: Must start on a Monday (D5 blood draw for C1), 4 hr EOI PKs (expansion), 2 hr infusions

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<p>Volastra VLS-1488-2201</p>	<p>A phase I/II study of VLS-1488 (an oral KIF18A inhibitor) in subjects with advanced cancer <b>(O'Neil)</b></p>	<p><a href="#">NCT05902988</a></p>	<p>Oral KIF18A Inhibitor</p>	<p>Escalation - HNSCC (not nasopharynx, sinonasal or lip) Expansion - HNSCC (not nasopharynx, sinonasal or lip)</p>	<p>KIF18A</p>	<p><b>North and South</b></p>
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Gyn			Study Drug MOA	Indication/Population	Biomarker Target	Sites Open
Janssen 61186372NSC1003	An Open-Label, Multicenter, Dose Escalation Phase 1b study to Assess the Safety and Pharmacokinetics of Subcutaneous Delivery of Amivantamab, a Human Bispecific EGFR and cMET Antibody for the Treatment of Advanced Solid Malignancies (PALOMA) <b>(O'Neil)</b>	<a href="#">NCT04606381</a>	Amivantamab - a human bispecific EGFR and cMET antibody	Solid malignancy that is metastatic or unresectable & may derive benefit from EGFR or cMET directed Tx - including ovarian	may derive benefit from EGFR or cMET directed Tx	<b>North and East</b>
Kronos Bio KB-0742-1001	Phase 1, First in Human, Open-Label Dose Escalation and Cohort Expansion Study of KB-0742 in Patients with Relapsed or Refractory Solid Tumors or Non-Hodgkin Lymphoma <b>(N. Reddy)</b>	<a href="#">NCT04718675</a>	CDK-9 Inhibitor	Cohort A: Ovarian (1/23/24: enrollment paused)	MYC or MYC Paralog	<b>North and South</b>
SGNB7H4V-001 Seagen B7	A Phase I Study of SGN-B7H4V in Advance Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT05194072</a>	ADC - CPI of the B7 family	High-grade serous ovarian cancer (epithelial ovarian, primary peritoneal, or fallopian tube); Endometrial carcinoma	Exploratory	<b>North</b>
Zentalis ZN-c3-005 GOG-3066	A Phase 2 Open-Label, Multicenter, Study to Evaluate Efficacy and Safety of ZN-c3 in Subjects with High-Grade Serous Ovarian, Fallopian Tube or Primary Peritoneal Cancer (DENALI) <b>(N. Reddy)</b>	<a href="#">NCT05128825</a>	WEE-1 Inhibitor	Part 1b: high cyclin E1 protein expression (regardless of CCNE1 gene amp status); Part 2: <i>Cohort 2A</i> CCNE1 gene amplified, <i>Cohort 2B</i> CCNE1 non-amplified/cyclin E1 IHC-Positive, <i>Cohort 2C</i> CCNE1 non-amplified/cyclin E1 IHC-Low/Negative	CCNE1 amplification, cyclin E1 protein expression	<b>Indy</b>
Volastra VLS-1488-2201	A phase I/II study of VLS-1488 (an oral KIF18A inhibitor) in subjects with advanced cancer <b>(O'Neil)</b>	<a href="#">NCT05902988</a>	Oral KIF18A Inhibitor	Escalation - HGSO, Ovarian carcinosarcoma, CN-high endometrial/uterine; Expansion - HGSO, CN-high endometrial/uterine	KIF18A	<b>North and South</b>
Artios ART0380C001	A Phase I/IIa, Open-label, Multi-center Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of the ATR Kinase Inhibitor ART0380 Administered Orally as Monotherapy and in Combination to Patients with Advanced or Metastatic Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT04657068</a>	ART0380	Advanced or metastatic solid tumors w/ATM alterations Part B3: endometrial (2/29/24: Part B3 - enrollment on hold)	ATM	<b>North</b>

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<p>Kelun SKB264-II-06</p>	<p>A Multicenter, Open-label, Phase 2, Basket Study to Evaluate the Efficacy and Safety of SKB264 in Combination with Pembrolizumab in Subjects with Selected Solid Tumors <b>(N. Reddy)</b></p>	<p><a href="https://clinicaltrials.gov/ct2/show/study/NCT05642780">NCT05642780</a></p>	<p>TROP2 monoclonal antibody (mAb) of immunoglobulin (Ig)G1 class &amp; toxin molecule KL610023</p>	<p>2L Cervical Cancer, 1L Urothelial Carcinoma, 2L+ Ovarian Cancer (3/29/24: <i>screening expected to close around 4/15/24</i>)</p>	<p>TROP2</p>	<p>North</p>
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Genitourinary			Study Drug MOA	Indication/Population	Biomarker Target	Sites Open
AstraZeneca D910PC00001	A Phase III Randomized, Open-label, Multicenter study to Determine the Efficacy and Safety of Durvalumab in Combination with Tremelimumab and Enfortumab Vedotin or Durvalumab in Combination with Enfortumab Vendotin for Perioperative Treatment in Patients Ineligible for Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer (VOLGA) <b>(Sonnenburg)</b>	<a href="#">NCT03924895</a>	Durvalumab (Anti-PD-L1) +/- Enfortumab Vedotin (Anti-Nectin-4) &/or Tremelimumab (anti CTLA-4)	Patients Ineligible for Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer (2/10/24: cT2N0 is closed)	stratified by PD-L1 status	<b>Indy</b>
Janssen 61186372NSC1003	An Open-Label, Multicenter, Dose Escalation Phase 1b study to Assess the Safety and Pharmacokinetics of Subcutaneous Delivery of Amivantamab, a Human Bispecific EGFR and cMET Antibody for the Treatment of Advanced Solid Malignancies (PALOMA) <b>(O'Neil)</b>	<a href="#">NCT04606381</a>	Amivantamab - a human bispecific EGFR and cMET antibody	Solid malignancy that is metastatic or unresectable & may derive benefit from EGFR or cMET directed Tx - including RCC	may derive benefit from EGFR or cMET directed Tx	<b>North and East</b>
Exelixis XL092-002 STELLAR 002	A Dose-Escalation and Expansion Study of the Safety and Efficacy of XL092 in Combination with Immuno-Oncology Agents in Subjects with Unresectable Advanced or Metastatic Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT05176483</a>	Next-gen Oral TKI	<b>Escalation Complete</b> Expansion: nccRCC 1L Arms 1 & 2 open	NA	<b>North and South</b>
Volastra VLS-1488-2201	A phase I/II study of VLS-1488 (an oral KIF18A inhibitor) in subjects with advanced cancer <b>(O'Neil)</b>	<a href="#">NCT05902988</a>	Oral KIF18A Inhibitor	Escalation - Bladder (transitional cell)	KIF18A	<b>North and South</b>

<b>Gastrointestinal</b>			<b>Study Drug MOA</b>	<b>Indication/Population</b>	<b>Biomarker Target</b>	<b>Sites Open</b>
Janssen 61186372NSC1003	An Open-Label, Multicenter, Dose Escalation Phase 1b study to Assess the Safety and Pharmacokinetics of Subcutaneous Delivery of Amivantamab, a Human Bispecific EGFR and cMET Antibody for the Treatment of Advanced Solid Malignancies (PALOMA) <b>(O'Neil)</b>	<a href="#">NCT04606381</a>	Amivantamab - a human bispecific EGFR and cMET antibody	Solid malignancy that is metastatic or unresectable & may derive benefit from EGFR or cMET directed Tx - including HCC, CRC, GE	may derive benefit from EGFR or cMET directed Tx	<b>North and East</b>
AbbVie M21-404	A Phase 1 First in Human Study Evaluating Safety, Pharmacokinetics and Efficacy of ABBV-400 in Adult Subjects with Advanced Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT05029882</a>	ADC consisting of a c-MET-targeting antibody; potent inhibitor of topoisomerase 1 (TOP1) payload	GEA Part 3 (10-19-23: cohort closed)	cMET	<b>North and South</b>
AbbVie M21-410	NSCLC, HNSCC and Advanced Solid Tumors: ABBV-514 Monotherapy and in Combination with Pembrolizumab or Budigalimab <b>(N. Reddy)</b>	<a href="#">NCT05005403</a>	ABBV-514 is a T-regs cell depleter	Panc, Gastric/GEJ	NA	<b>Indy</b>
Amgen 20210023 Amgen 193	A Phase 1/1b/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 Alone and in Combination with Docetaxel in Subjects with Advanced MTAP-null Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT05094336</a>	PRMT5 Inhibitor	Advanced MTAP-null Solid Tumors Dose Expansion: 1e: BTC; 1g: PDAC	MTAP-null	<b>North and East</b>
CG Pharma CG-745-2-08	A Phase 1b/2, Dose-escalation, Randomized, Multicenter study of Maintenance Ivaltinostat plus Capecitabine or Capecitabine Monotherapy in Patients with Metastatic Pancreatic Adenocarcinoma Whose Disease Has Not Progressed on First Line FOLFIRINOX Chemotherapy <b>(O'Neil)</b>	<a href="#">NCT05249101</a>	pan-HDAC inhibitor	Metastatic Pancreatic [Phase 2 (Ivaltinostat 250 mg/m <sup>2</sup> )]	NA	<b>Indy</b>
LOXO G12C	A Phase 1/2 Study of LY3537982 in Patients with KRAS G12C-Mutant Advanced Solid Tumors <b>(N. Reddy)</b>	<a href="#">NCT04956640</a>	KRAS G12C Inhibitor	Pancreatic, CRC	KRAS G12C	<b>Indy</b>
Merus MCLA-129-CL01	Phase 1/2 Dose Escalation and Expansion Study Evaluating MCLA-129, a Human Anti-EGFR and Anti-cMET bispecific Antibody, in Patients with Advanced NSCLC and Other Solid Tumors <b>(N. Reddy)</b>	<a href="#">NCT04868877</a>	Human Anti-EGFR and Anti-cMET bispecific Antibody	GC/GEJ and ESCC (12-21-23: enrollment on hold)	EGFR and cMET alterations	<b>North</b>
SGNB7H4V-001 Seagen B7	A Phase I Study of SGN-B7H4V in Advance Solid Tumors <b>(O'Neil)</b>	<a href="#">NCT05194072</a>	ADC - CPI of the B7 family	Cholangiocarcinoma or gallbladder carcinoma	Exploratory	<b>North</b>
TAPUR	The Targeted Agent and Profiling Utilization Registry (TAPUR) Study <b>(Bedano)</b>	<a href="#">NCT02693535</a>	Various	CRC - Nivo and Ipi cohort (BRCA1 and BRCA2 mutation)	Various	<b>Indy</b>

Oncology Research - Open Protocols List

Exelixis XL092-303 STELLAR-303	A Randomized Open-Label Phase 3 Study of XL092 + Atezolizumab vs Regorafenib in Subjects with Metastatic Colorectal Cancer <b>(O'Neil)</b>	<a href="#">NCT05425940</a>	Next-gen Oral TKI	Colorectal Cancer <i>(12-20-23: enrolling subjects with non-liver metastases only)</i>	RAS wild-type MSS/MSI-low	<b>Indy</b>
Volastra VLS-1488-2201	A phase I/II study of VLS-1488 (an oral KIF18A inhibitor) in subjects with advanced cancer <b>(O'Neil)</b>	<a href="#">NCT05902988</a>	Oral KIF18A Inhibitor	Escalation - Gastric adenocarcinoma (not EBV+), CRC, ESCC, Esophageal adenocarcinoma, GEJ Expansion - Gastric adenocarcinoma (not EBV+), CRC, ESCC, Esophageal adenocarcinoma	KIF18A	<b>North and South</b>
AbbVie M24-311	A Phase 2, Randomized Study to Evaluate Safety, Efficacy, and Optimal Dose of ABBV-400 in Combination with Fluorouracil, Folinic Acid, and Bevacizumab in Previously Treated Subjects with Unresectable Metastatic Colorectal Cancer <b>(O'Neil)</b>	<a href="#">NCT06107413</a>	c-Met targeting antibody conjugated to a potent inhibitor of Top1 payload	CRC	c-Met	Indy

<b>Melanoma</b>			<b>Study Drug MOA</b>	<b>Indication/Population</b>	<b>Biomarker Target</b>	<b>Sites Open</b>
Day101-102b	A Phase 1b/2, Subprotocol of DAY101 in Combination with Pimasertib for Patients with Recurrent, Progressive, or Refractory Solid Tumors and MAPK Pathway Aberrations <b>(O'Neil)</b>	<a href="#">NCT04985604</a>	CNS-penetrant, small-molecule, type II pan-RAF kinase inhibitor	In Dose Escalation Melanoma <i>(8-22-23: no open slots)</i>	MAPK pathway alterations	<b>North and East</b>