

Oncology

Effect-Size Predictions

Using Data-free Virtual Clinical Trials

96% accuracy across 180 Oncology trials

Overall: 96% across all 604 validated trials



BioinvestGPT

Evidence Dossier

April 8, 2026

Platform Credentials at a Glance

96% Prospective Prediction Accuracy
Across 180 validated trials (of 604 total) | Two-sided p < 0.0001

- EA 100% Ex-Ante

Every prediction certified and sent to clients before trial results were known
- RG Industrial Rigor

Validated against real FDA/EMA clinical readouts
- EP Empirical Certainty

Statistically significant with two-sided p < 0.0001

Data-Free	White-Box	Head-to-Head	180 of 604
Zero-Patient Input	Root Cause Explained	vs. Standard of Care	Two-Sided p < 0.0001 ● LIVE

STRATEGIC VALUE PILLARS

Zero-Data Advantage

NO DATA SHARING

Predictions require **zero proprietary patient data**, eliminating **IP liability** and privacy friction.

2M VIRTUAL PATIENTS

Pre-built, **clinically validated** virtual cohorts delivering rigorous **effect-size predictions** across all major indications.

Eliminating Blind Spots

SURROGATE DETECTION

Simultaneously predicts early surrogates (**ORR/PFS**) and final efficacy (**OS**) to expose **hidden discordances**.

FUTURE-PROOFING

Benchmarks against **competitor** pipeline drugs to ensure **superiority at launch**, not just at trial start.

Identify Biological Root Cause

BEYOND BLACK-BOX

Every prediction is backed by **biological root cause identification**, not opaque probability scores.

ACTIONABLE DRIVERS

Pinpoints specific **failure/success drivers: target selection, drug design, delivery method, or patient stratification**.



Effect-Size Portfolio Gating Spectrum

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180 of 604 validated trials

HAZARD RATIO GO/NO-GO THRESHOLD SPECTRUM

GO	Strongly Superior	HR < 0.3	Transformative clinical benefit — megablockbuster potential
GO	Moderately Superior	HR 0.3–0.6	Commercially sufficient — blockbuster potential
----- HR = 0.6 THRESHOLD -----			
NO-GO	Weakly Superior	HR 0.6–0.8	Marginal benefit — likely insufficient for market differentiation
NO-GO	Non-Superior	HR 0.8–1.0	No meaningful advantage over current standard of care
NO-GO	Inferior to SoC	HR 1.0–1.2	Patient harm risk — trial likely to fail primary endpoint

Configurable Threshold

Clients may select any HR value as the GO/NO-GO boundary based on their commercial case. We use HR = 0.6 as the default threshold for effect-size GO/NO-GO prospective predictions. GO = commercially sufficient effect size; NO-GO = commercially insufficient. See Trial Detail pages for each ex-ante validated prediction.

EX-ANTE PREDICTION ACCURACY

SCALE 161 Drug Assets 83.9% First-in-Class ratio	COVERAGE 110 Sponsors Public biopharma footprint	LEAD TIME 218 Days Average advance prediction window
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Full dataset: 96.0% (604 trials) | Filtered: 95.6% (180 trials) | Delta: -0.5pp

Predictive Performance Intelligence

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180 prospectively validated GO/NO-GO predictions

– IMPAIRMENT NO-GO correct rate

Negative Predictive Value (NPV)

99%

115/116 NO-GO predictions validated
 $TN / (TN + FN)$

99% of BioinvestGPT NO-GO predictions are prospectively independently validated, signaling **cost savings** from lackluster drugs. A NO-GO signal reliably identifies commercially insufficient FIC/BIC assets before Phase III spend, **preventing impairment write-downs**.

++RELIABILITY GO/NO-GO correct rate

Accuracy

96%

172/180 validated prospective predictions
 $(TP + TN) / (TP + TN + FP + FN)$

96% of BioinvestGPT GO/NO-GO predictions are correct for any-stage FIC/BIC assets, **nearly 10 times higher** than the industry's current best level (5–10%). BioinvestGPT prospectively predicts both drug successes and failures with **near-perfect reliability**.

++REVENUE GO correct rate

Positive Predictive Value (PPV)

89%

57/64 GO predictions validated
 $TP / (TP + FP)$

89% of BioinvestGPT GO predictions are prospectively independently validated as commercially sufficient drugs. A GO signal identifies **blockbuster FIC/BIC assets** with high reliability, enabling **revenue-maximizing** portfolio predictions.

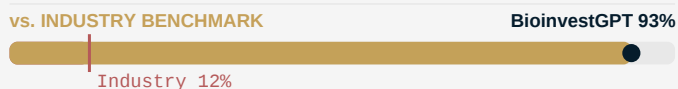
++RELIABILITY GO/NO-GO bias-free rate

F1-Score

93%

Harmonic mean of Precision and Recall
 $2 \times TP / (2 \times TP + FP + FN)$

Both GO and NO-GO predictions are almost **equally likely to be correct**, even though **blockbuster drugs are much rarer**. The model does not simply guess "failure" — it **makes the right call on both sides**.



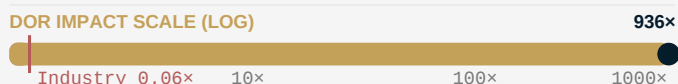
++RELIABILITY GO/NO-GO reliability rate

Diagnostic Odds Ratio (DOR)

936×

936× more likely correct than incorrect
 $(TP \times TN) / (FP \times FN)$

BioinvestGPT GO/NO-GO predictions is **936 times more likely to correctly identify blockbuster assets** (true positives) and **rule out commercially insufficient assets** (true negatives), compared with the chance of making an incorrect prediction.



* The F1-Score and DOR for current drug GO/NO-GO prospective prediction approach is estimated based on the industry 10% nomination rate (boehringer-ingelheim.com/science-innovation/human-health-innovation/drug-discovery).

Therapeutic Area Breakdown

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Exhibit 1

Prediction accuracy remains consistently high across all therapeutic domains

BioinvestGPT's validation dataset spans 1 major therapeutic area, demonstrating that predictive accuracy is not an artifact of concentration in any single domain.



1. Source: BioinvestGPT validated prediction database. Classification based on clinical readout outcomes.
2. Therapeutic area mapping uses standardized groupings across 1 domain. Accuracy = (TP + TN) / Total.

Sponsors Coverage Breakdown

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Exhibit 2

Validation spans 110 public biopharma sponsors across all market capitalizations

Coverage spans large-cap through small-cap sponsors, confirming model generalizability is not concentrated in any single company cohort.

BNTX (BioNTech)	100.0%
MKKGY (Merck KGaA)	100.0%
ZNTL (Zentalis Pharmaceutical...)	100.0%
PFE (Pfizer)	100.0%
MRUS (Merus)	100.0%
GSK (GlaxoSmithKline)	100.0%
GILD (Gilead Sciences)	75.0%
ALXO (ALX Oncology)	100.0%
AFMD (Affimed)	100.0%
RVMD (Revolution Medicines)	100.0%
LLY (Eli Lilly and Company)	100.0%
ARVN (Arvinas / Pfizer)	66.7%
AZN (AstraZeneca)	66.7%
CADL (Candel Therapeutics)	100.0%
COGT (Cogent Biosciences)	100.0%
EXEL (Exelixis)	100.0%
RHHBY (Roche Group)	100.0%
SDGR (Schrödinger)	100.0%
NUVL (Nuvalent)	100.0%
SMMT (Summit Therapeutics)	100.0%

Total unique sponsors: 110 | Average accuracy across top sponsors: 95.4%

1. Search sponsor name on data.bioinvestgpt.com to access the company-specific audited timestamped ex-ante predictions and readout validations.

Drug Innovation & Modality Coverage Breakdown

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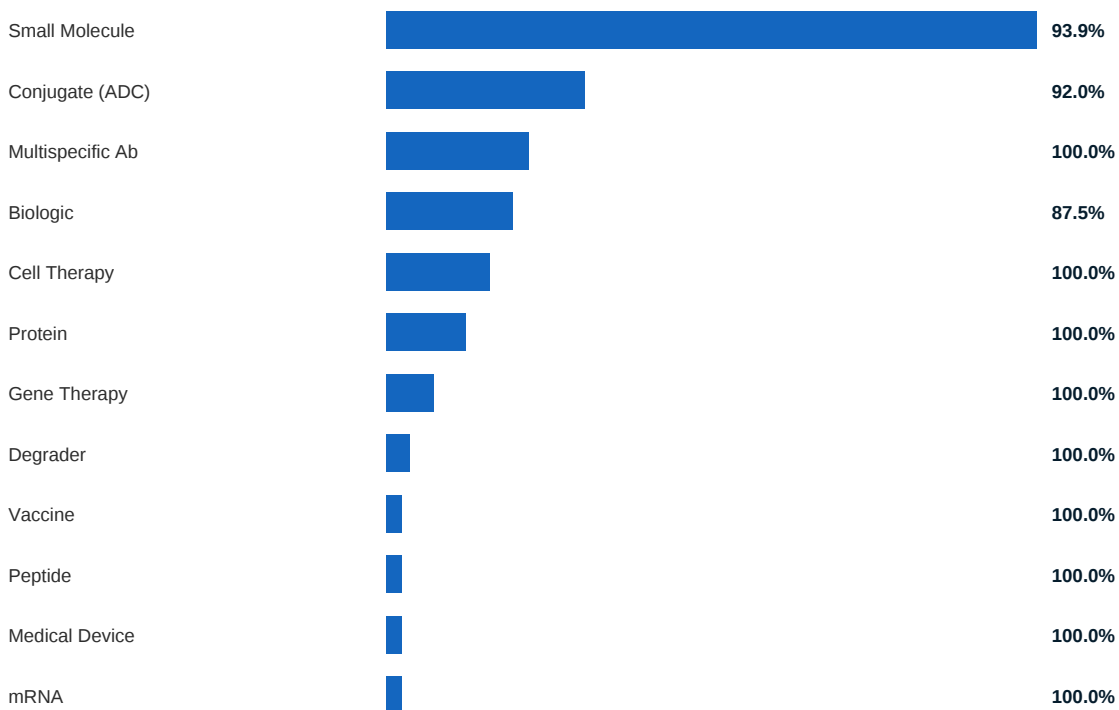
Exhibit 3

Validated across 161 distinct drug assets spanning 12 modalities

DRUG CLASSIFICATION



DRUG MODALITY DISTRIBUTION



Drug Assets Coverage Breakdown

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Exhibit 4

Validated across 161 distinct drug assets with consistently high prediction accuracy

Evorpacept (ALX148)	100.0%
ZN-c3	100.0%
Bezuclastinib	100.0%
Petosemtamab (MCLA-158)	100.0%
Tiragolumab	100.0%
Pirtobrutinib (LOXO-305)	100.0%
belantamab mafodotin	100.0%
Patritumab Deruxtecan	100.0%
Ziftomenib	100.0%
ZN-c3 (azenosertib)	100.0%
Sirexatamab (DKN-01)	100.0%
CAN2409	100.0%
RMC-6236	100.0%
Uproleselan (GMI-1271)	100.0%
BNT327/PM8002	100.0%
TransCon IL-2 ^{2/3} Pembrolizumab	100.0%
Zanidatamab	100.0%
TERN-701	100.0%
INKmune	100.0%
XmAb819	100.0%
Gedatolisib	100.0%
Zanzalintinib	100.0%
Ciforadenant	100.0%

Total unique drug assets: 161 | Average accuracy across top drugs: 100.0%

1. Search drug name on data.bioinvestgpt.com to access the drug-specific audited timestamped ex-ante predictions and readout validations.

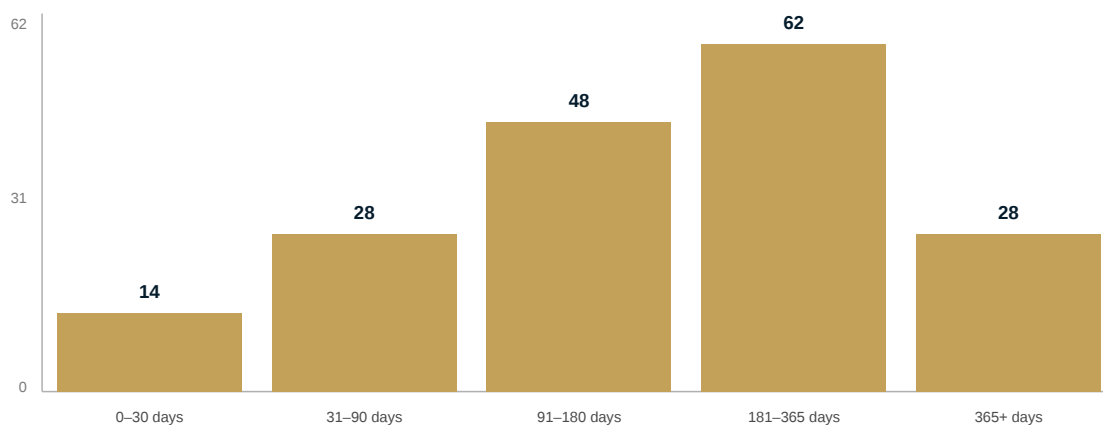
Temporal Integrity: Prospective Proof

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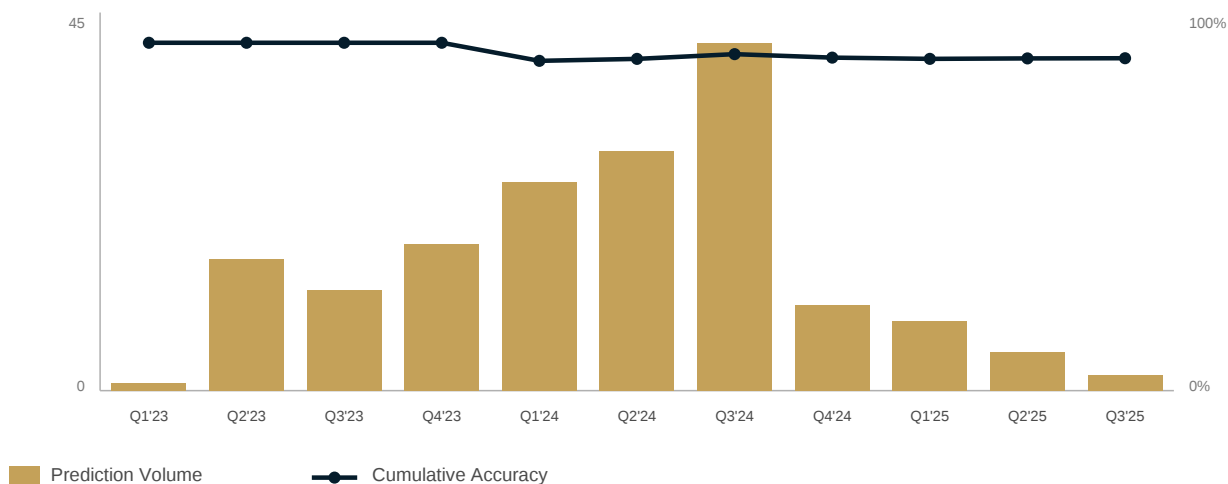
Exhibit 5

100% of predictions issued before clinical readout with median lead time of 218 days

LEAD TIME DISTRIBUTION



QUARTERLY PREDICTION VOLUME & CUMULATIVE ACCURACY



All 180 predictions were certified ex-ante, with an average lead time of 218 days before clinical readout. This temporal integrity is cryptographically verifiable and eliminates any possibility of post-hoc fitting.

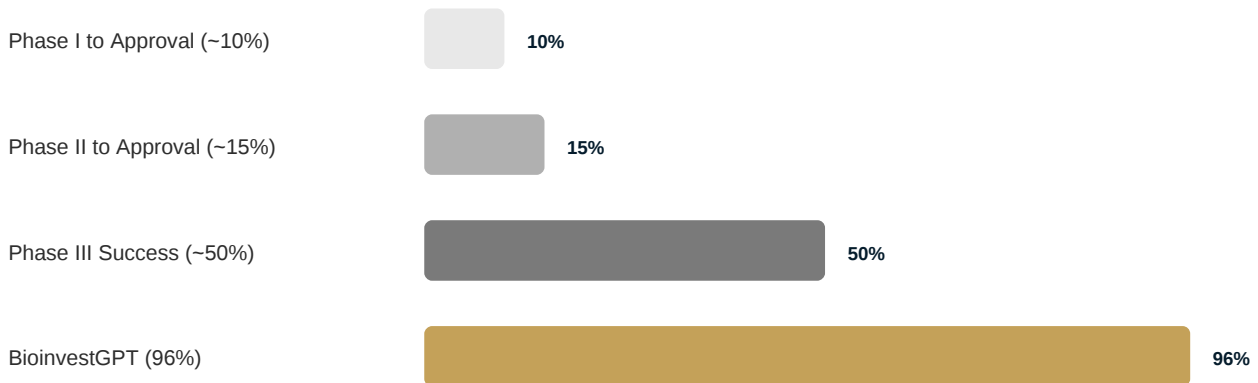
Competitive Benchmark Analysis

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Exhibit 6

BioinvestGPT demonstrates multi-order-of-magnitude improvement over industry baselines

CLINICAL DEVELOPMENT SUCCESS RATES



QUANTITATIVE BENCHMARK

Metric	BioinvestGPT	Industry Avg	Context
Accuracy	95.6%	~10-15%	Phase I-to-approval historical rate
Precision (PPV)	89.1%	~11%	Avg drug approval probability
NPV	99.1%	~60%	Combined Phase I-III attrition detection
F1-Score	93.4%	12%	Based on industry 10% nomination rate
DOR	936.4x	0.06x	Based on industry 10% nomination rate
Lead Time	218 days	0 days	Post-hoc industry standard

Note: Industry success rates measure population-level probability of a drug advancing through clinical development phases. BioinvestGPT predicts phase-agnostic effect-size-based clinical benefit using $HR = 0.6$ as the GO/NO-GO threshold to classify commercially sufficient vs. insufficient drugs, with all predictions certified ex-ante. The comparison illustrates the magnitude of predictive alpha, not a direct methodological equivalence.

REDIRECTABLE R&D CAPITAL

\$34.5B

115 of 116 NO-GO predictions validated × \$300M avg trial cost

CAPTURED PORTFOLIO VALUE

\$57.0B

57 of 64 GO predictions validated × \$1B avg revenue

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
590	Zanidatamab NCTID: NCT05152147 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: biparatopic anti-HER2 inhibitor Area: Neoplasms Indication: 1L HER2-positive Advanced or Metastatic Gastric and Esophageal Cancers Human Patients: 920 Sponsor: Jazz Pharmaceuticals (JAZZ)	Date: 19 Jan 2025 Quarter: Q2'25 Batch 3 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS for [zanidatamab + tislelizumab + chemotherapy] at least numerically superior to [zanidatamab + chemotherapy]; both superior to [trastuzumab + chemotherapy]) Commercial: SUCCESS (commercially sufficient clinical benefit in OS for [zanidatamab + tislelizumab + chemotherapy] at least numerically superior to [zanidatamab + chemotherapy]; both superior to [trastuzumab + chemotherapy])	Readout: 17 Nov 2025 Lead Time: 302 days in advance Interpretation: zanidatamab + tislelizumab + chemotherapy achieved superiority in both PFS and OS compared with the control arm trastuzumab plus chemotherapy; whereas zanidatamab + chemotherapy achieved superiority in PFS only (not in OS) compared with the control arm trastuzumab plus chemotherapy	Correct Prediction Conclusion: statistically significant (superior PFS for both doublet and triplet combo therapies) and commercially sufficient (superior OS for triplet combo therapy) Classification: True Positive (TP)
782	Bezuclastinib NCTID: NCT05208047 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: TKI inhibitor Area: Neoplasms Indication: Gastrointestinal Stromal Tumors (GIST) Human Patients: 442 Sponsor: Cogent Biosciences (COGT)	Date: 13 Oct 2023 Quarter: 2H'23 Batch 24 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit)	Readout: 10 Nov 2025 Lead Time: 759 days in advance Interpretation: bezuclastinib + sunitinib achieved 16.5 months mPFS vs 9.2 months mPFS achieved by sunitinib monotherapy (p<0.0001); bezuclastinib+sunitinib achieved 46% ORR vs 26% ORR achieved by sunitinib monotherapy (p<0.0001); wait for OS data	Correct Prediction Conclusion: statistically significant (ORR/PFS) and commercially TBD Classification: True Positive (TP)
1853	Bemarituzumab NCTID: NCT05111626 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: FGFR2B inhibitor Area: Neoplasms Indication: 1L advanced gastric cancer/ GEJ cancer with FGFR2b over expression Human Patients: 515 Sponsor: Amgen (AMGN)	Date: 4 Dec 2024 Quarter: Q1'25 Batch 12 Technical: SUCCESS (statistically significant additive clinical benefit in ORR/PFS superior to nivolumab + chemotherapy) Commercial: SUCCESS (commercially sufficient additive clinical benefit in OS superior to nivolumab + chemotherapy)	Readout: 4 Nov 2025 Lead Time: 335 days in advance Interpretation: bemarituzumab + chemotherapy + nivolumab failed to deliver sufficient efficacy in PFS/ORR and further development has been discontinued	Missed Prediction Note: due to suboptimal modeling of drug MoA for ORR/PFS that has been permanently improved Conclusion: statistically insignificant (ORR/PFS) and commercially maybe sufficient (OS) Classification: False Positive (FP)
1697	TERN-701 NCTID: NCT06163430 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: BCR ABL1 myristoyl-pocket-binding TKI inhibitor Area: Neoplasms Indication: Relapsed/refractory Chronic Myeloid Leukemia Human Patients: 100 Sponsor: Terns Pharmaceuticals (TERN)	Date: 24 Jul 2024 Quarter: Q3'24 Batch 19 Technical: SUCCESS (statistically significant clinical benefit in CR) Commercial: partial SUCCESS (commercially sufficient clinical benefit in CR non-superior non-inferior to ELVN001 for CML patients without T315I mutation) partial FAILURE (commercially insufficient clinical benefit in CR inferior to ELVN001 for CML patients with either T315I mutation or asciminib intolerance)	Readout: 3 Nov 2025 Lead Time: 467 days in advance Interpretation: TERN701 achieved 64% MMR at week 24	Correct Prediction Conclusion: statistically probably significant and commercially TBD Classification: True Positive (TP)
1301	INKmune NCTID: NCT06056791 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: cell therapy MoA: NK cell activator Area: Neoplasms Indication: Metastatic Castration Resistant Prostate Cancer (mCRPC) Human Patients: 30	Date: 21 Aug 2024 Quarter: Q4'24 Batch 13 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 30 Oct 2025 Lead Time: 435 days in advance Interpretation: INKmune has met its primary endpoint and has not met the "reduction in tumour load" secondary endpoint	Correct Prediction Conclusion: statistically probably insignificant (ORR) and commercially probably insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Immune Bio (INMB)			
2024	Petosemtamab (MCLA-158) NCTID: NCT03526835 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: anti-EGFR-LGR5 bispecific antibody Area: Neoplasms Indication: 1L/2L/3L metastatic colorectal cancer (mCRC) Human Patients: 523 Sponsor: Merus (MRUS)	Date: 16 May 2025 Quarter: Q3'25 Batch 9 Technical: SUCCESS (statistically significant clinical benefit in PFS/ORR for petosemtamab monotherapy non-inferior to FTD-TPI + bevacizumab in the 3L MSS mCRC clinical setting) SUCCESS (statistically significant clinical benefit in PFS/ORR for petosemtamab + FOLFIRI/FOLFOX slightly-to-moderately superior to FOLFIRI/FOLFOX + bevacizumab in the 1L/2L MSS mCRC clinical setting) Commercial: SUCCESS (commercially sufficient clinical benefit in OS for petosemtamab monotherapy moderately-to-strongly superior to FTD-TPI + bevacizumab in the 3L MSS mCRC clinical setting) SUCCESS (commercially sufficient clinical benefit in OS for petosemtamab + FOLFIRI/FOLFOX moderately superior to FOLFIRI/FOLFOX + bevacizumab in the 1L/2L MSS mCRC clinical setting)	Readout: 24 Oct 2025 Lead Time: 161 days in advance Interpretation: Petosemtamab plus FOLFOX/FOLFIRI for 1L mCRC achieved 50-80% ORR (8/10 with 3 unconfirmed) slightly-to-moderately superior to 53% achieved by bevacizumab plus FOLFOX/FOLFIRI (see add'l link below); Petosemtamab plus FOLFOX/FOLFIRI for 2L mCRC achieved 46-62% cORR (6/13 with 2 unconfirmed) moderately-to-strongly superior to 11% achieved by bevacizumab plus FOLFOX/FOLFIRI (10.1093/annonc/mdv197); Petosemtamab mono therapy achieved 10% cORR (2/20) slightly superior to 6.1% cORR achieved by FTD-TPI plus bevacizumab (10.1056/NEJMoa2214963)	Correct Prediction Conclusion: statistically significant (superior-to-SoC ORR for 1L/2L/3L mCRC) and commercially TBD Classification: True Positive (TP)
2017	XmAb819 NCTID: NCT05433142 Phase: Phase 1 Class: First-In-Class Modality: bispecific antibody MoA: bispecific antibody that binds both ENPP3 and CD3 Area: Neoplasms Indication: 2L+ advanced clear cell renal cell carcinoma (ccRCC) Human Patients: 95 Sponsor: Xencor (XNCR)	Date: 13 May 2025 Quarter: Q3'25 Batch 7 Technical: FAILURE (statistically insignificant clinical benefit in ORR/PFS compared with placebo with moderate toxicity) Commercial: FAILURE (commercially insufficient clinical benefit in OS strongly inferior to cabozantinib)	Readout: 24 Oct 2025 Lead Time: 164 days in advance Interpretation: XmAb819 achieved 20% cORR (4/20) with 1 Grade 4 TEAE (5%); which is non-superior to the SoC cabozantinib that achieved 21% cORR (see add'l link below)	Correct Prediction Conclusion: statistically probably insignificant (non-superior ORR) and commercially TBD Classification: True Negative (TN)
1945	Gedatolisib NCTID: NCT05501886 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: dual mTOR/PI3K inhibitor Area: Neoplasms Indication: PIK3CA WT and MT advanced or metastatic HR+ / HER2- breast can Human Patients: 701 Sponsor: Celcuity (CELCE)	Date: 27 Mar 2025 Quarter: Q2'25 Batch 13a Technical: partial SUCCESS (statistically significant yet moderate additive clinical benefit in ORR/PFS for gedatolisib + fulvestrant + palbociclib moderately superior to SoC alpelisib + fulvestrant for PIK3CA MT population slightly superior to SoC fulvestrant for PIK3CA WT population despite with additional gedatolisib-related toxicity) partial FAILURE (statistically insignificant additive clinical benefit in ORR/PFS for gedatolisib + fulvestrant non-superior to SoC fulvestrant for both PIK3CA MT population and PIK3CA WT with additional gedatolisib-related toxicity) Commercial: partial FAILURE (commercially insufficient additive clinical benefit in OS for gedatolisib + fulvestrant + palbociclib at most numerically superior to SoC alpelisib + fulvestrant for PIK3CA MT population and non-superior to SoC fulvestrant for PIK3CA WT population despite with additional gedatolisib-related toxicity) FAILURE (commercially insufficient additive clinical benefit in OS for gedatolisib +	Readout: 20 Oct 2025 Lead Time: 207 days in advance Interpretation: gedatolisib + palbociclib + fulvestrant ("gedatolisib triplet") achieved 9.3 months mPFS strongly superior to 2.0 months achieved by fulvestrant monotherapy (HR= 0.24; P<0.0001) yet achieved 23.7 months mOS only numerically superior to 18.5 months achieved by fulvestrant monotherapy (HR=0.69 P=0.1328); wait for MT population data	Correct Prediction Conclusion: statistically significant (superior mPFS) and commercially insufficient (non-superior mOS) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
		fulvestrant non-inferior to SoC for both PIK3CA MT population PIK3CA WT population with additional gedatolisib-related toxicity)		
2011	Zanzalintinib NCTID: NCT05425940 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: multi-receptor TKI Area: Neoplasms Indication: 2L MSI-high Metastatic Colorectal Cancer Human Patients: 901 Sponsor: Exelixis (EXEL)	Date: 7 May 2025 Quarter: Q3'25 Batch 6 Technical: partial FAILURE (statistically maybe significant yet very weak clinical benefit for XL092 + atezolizumab in ORR/PFS at most numerically superior to regorafenib) Commercial: FAILURE (commercially insufficient clinical benefit for XL092 + atezolizumab in OS non-superior to regorafenib)	Readout: 20 Oct 2025 Lead Time: 166 days in advance Interpretation: zanzalintinib + atezolizumab achieved statistically significant yet very weak OS in the ITT population (HR = 0.8 p=0.0045) yet statistically insignificant OS in the subset of patients without liver metastases (p = 0.087); compared with the regorafenib mono therapy	Correct Prediction Conclusion: partially statistically significant and commercially insufficient Classification: True Negative (TN)
1786	Tiragolumab NCTID: NCT04513925 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-TIGIT inhibitor Area: Neoplasms Indication: Non-small Cell Lung Cancer (NSCLC) Human Patients: 829 Sponsor: Roche Group (RHHBY)	Date: 15 Sep 2024 Quarter: Q4'24 Batch 17b Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS numerically superior to durvalumab monotherapy) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to durvalumab monotherapy)	Readout: 18 Oct 2025 Lead Time: 398 days in advance Interpretation: tiragolumab + atezolizumab failed to achieve the primary endpoint non-superior to the SoC durvalumab in either mPFS (14.2 months vs 13.8 months) or OS (not reached vs 54.8 months)	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1121	Ciforadenant NCTID: NCT05501054 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: adenosine A2a Receptor Antagonist Area: Neoplasms Indication: 1L metastatic renal cell cancer (RCC) Human Patients: 50 Sponsor: Corvus Pharmaceuticals (CRVS)	Date: 8 May 2025 Quarter: Q3'25 Batch 6 Technical: FAILURE (statistically insignificant additive clinical benefit to nivolumab + ipilimumab in ORR/PFS compared with placebo) Commercial: FAILURE (commercially insufficient additive clinical benefitS to nivolumab + ipilimumab in OS)	Readout: 17 Oct 2025 Lead Time: 162 days in advance Interpretation: ciforadenant + ipilimumab + nivolumab achieved 46% ORR and 11 months mPFS; non-superior to ipilimumab + nivolumab that achieved 42% ORR and 11.6 months mPFS (see add'l link below); ciforadenant + ipilimumab + nivolumab achieved a numerical improvement of OS HR by 0.05 compared with ipilimumab + nivolumab (0.69 vs 0.74)	Correct Prediction Conclusion: statistically insignificant (non-superior ORR/PFS) and commercially insufficient (non-superior OS) Classification: True Negative (TN)
1849	Zolbetuximab (IMAB362) NCTID: NCT03816163 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: anti-CLDN18.2 inhibitor Area: Neoplasms Indication: 1L metastatic pancreatic adenocarcinoma (PDAC) Human Patients: 393 Sponsor: Astellas Pharma (ALPMY)	Date: 3 Dec 2024 Quarter: Q1'25 Batch 12 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS due to dose-limiting toxicity whose degree depends on claudin 18.2 expression levels) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to SoC alone)	Readout: 14 Oct 2025 Lead Time: 315 days in advance Interpretation: zolbetuximab + gemcitabine plus nab-paclitaxel failed to achieve superiority in OS compared with zolbetuximab + gemcitabine plus nab-paclitaxel alone	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1936	iberdomide NCTID: NCT04975997 Phase: Phase 3 Class: Best-In-Class Modality: molecular glue degrader MoA: cereblon E3 ligase modulator that degrades IKZF1 and IKZF3 Area: Neoplasms	Date: 4 Apr 2025 Quarter: Q3'25 Batch 1 Technical: SUCCESS (statistically significant additive clinical benefit to daratumumab + dexamethasone (Iber-Dd) in ORR/PFS moderately superior to bortezomib + daratumumab + dexamethasone (DvD) and non-superior-non-inferior to belantamab mafodotin +	Readout: 23 Sep 2025 Lead Time: 172 days in advance Interpretation: iberdomide in combination with daratumumab and dexamethasone (IberDd) achieved a statistically significant superiority in MRD negativity (a deeper assessment than ORR) compared with the central arm of daratumumab/ bortezomib/dexamethasone (DvD);	Correct Prediction Conclusion: statistically significant (MRD negativity/ORR) and commercially TBD Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Indication: Relapsed or Refractory Multiple Myeloma Human Patients: 864 Sponsor: Bristol Myers Squibb (BMY)	pomalidomide + dexamethasone(BPd)) Commercial: SUCCESS (commercially sufficient additive clinical benefit to daratumumab + dexamethasone (Iber-Dd) in OS moderately superior bortezomib + daratumumab + dexamethasone (DvD) and slightly superior to belantamab mafodotin + pomalidomide + dexamethasone(BPd))	wait for OS data	
1929	Rezatapopt (PC14586) NCTID: NCT04585750 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: p53 reactivator Area: Neoplasms Indication: advanced Solid Tumors Harboring a TP53 Y220C Mutation Human Patients: 300 Sponsor: PMV Pharmaceuticals (PMVP)	Date: 14 Feb 2025 Quarter: Q2'25 Batch 11 Technical: partial SUCCESS (statistically significant yet moderate clinical benefit as monotherapy in ORR/PFS compared with placebo) Commercial: FAILURE (commercially insufficient clinical benefit as monotherapy in OS non-superior to SoC)	Readout: 10 Sep 2025 Lead Time: 208 days in advance Interpretation: Rezatapopt achieved 33% ORR; moderately superior to chemotherapy that achieved 10-20% ORR for advanced solid tumors (see add'l link below); wait for OS data	Correct Prediction Conclusion: statistically significant (superior ORR/PFS) and commercially TBD Classification: True Positive (TP)
2051	Zipalertinib (TAS6417) NCTID: NCT05967689 Phase: Phase 2 Class: Best-In-Class Modality: small molecule MoA: 3rd-gen pan-mutant wt-sparing EGFR TKI Area: Neoplasms Indication: ex20in-mt advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) Human Patients: 224 Sponsor: Taiho Oncology / Cullinan Therapeutics (CGEM)	Date: 31 Jul 2025 Quarter: Q4'25 Batch 6 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS compared with placebo at least numerically superior to osimertinib for cohort A/B/C/D) Commercial: SUCCESS (commercially sufficient clinical benefit in OS slightly-to-moderately superior to osimertinib for cohort A/B/C/D)	Readout: 9 Sep 2025 Lead Time: 40 days in advance Interpretation: Zipalertinib achieved a 62.5% ORR for 1L ex20in-mt NSCLC; moderately superior to osimertinib that achieved 25% ORR (see add'l link below); Zipalertinib achieved 21.9% ORR for 2L ex20in-mt NSCLCs; moderately superior to osimertinib that achieved 5% ORR (see DOI-10.1016/j.jto.2022.100459); wait for OS data	Correct Prediction Conclusion: statistically significant (superior ORR/PFS) and commercially TBD Classification: True Positive (TP)
1729	Pumitamig (BNT327) NCTID: NCT06449209 Phase: Phase 2 Class: First-In-Class Modality: bispecific antibody (bsAb) MoA: anti-PDL1 and anti-VEGF Area: Neoplasms Indication: untreated extended-stage small-cell lung cancer (ES-SCLC) Human Patients: 110 Sponsor: BioNTech (BNTX)	Date: 9 Aug 2025 Quarter: Q4'25 Batch 5 Technical: partial SUCCESS (statistically significant yet moderate additive clinical benefit in ORR/PFS numerically superior to ICI+chemotherapy as 1L treatment and numerically superior to chemotherapy as 2L/3L treatment) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate additive clinical benefit in OS numerically superior to ICI+chemotherapy as 1L treatment and numerically superior to chemotherapy as 2L/3L treatment)	Readout: 8 Sep 2025 Lead Time: 30 days in advance Interpretation: Pumitamig + chemotherapy achieved 76.3% cORR and 6.8 months mPFS; numerically superior to the SoC atezolizumab + chemotherapy that achieved 60% cORR and 5.2 months mPFS (see add'l link below); wait for OS data	Correct Prediction Conclusion: statistically significant (numerically superior in ORR/PFS) and commercially TBD Classification: True Negative (TN)
1955	Pirtobrutinib (LOXO-305) NCTID: NCT05023980 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: non-covalent BTK inhibitor Area: Neoplasms Indication: Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL) Human Patients: 309	Date: 30 Mar 2025 Quarter: Q2'25 Batch 13b Technical: partial SUCCESS (statistically significant clinical benefit in ORR/PFS slightly superior to rituximab + bendamustine; slightly inferior to zanubrutinib/venetoclax + obinutuzumab) Commercial: FAILURE (commercially insufficient clinical benefit in OS non-superior to rituximab +	Readout: 8 Sep 2025 Lead Time: 162 days in advance Interpretation: pirtobrutinib achieved superiority in PFS compared with bendamustine plus rituximab; wait for detailed PFS data for comparison with zanubrutinib/venetoclax + obinutuzumab; wait for OS data	Correct Prediction Conclusion: statistically significant (superior PFS compared with bendamustine plus rituximab) and commercially TBD Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Eli Lilly and Company (LLY)	bendamustine; slightly inferior to zanubrutinib/venetoclax + obinutuzumab)		
1721	SGR-2921 NCTID: NCT05961839 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: CDC7 inhibitor Area: Neoplasms Indication: Relapsed / Acute Myeloid Leukemia or Myelodysplastic Syndrome Human Patients: 66 Sponsor: Schrödinger (SDGR)	Date: 6 Aug 2024 Quarter: Q4'24 Batch 4 Technical: FAILURE (statistically insignificant (additive) clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient (additive) clinical benefit in OS)	Readout: 14 Aug 2025 Lead Time: 373 days in advance Interpretation: SGR-2921's further development has been discontinued due to unfavourable clinical benefit/risk profile	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1956	Pirtobrutinib (LOXO-305) NCTID: NCT05254743 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: non-covalent BTK inhibitor Area: Neoplasms Indication: Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL) Human Patients: 662 Sponsor: Eli Lilly and Company (LLY)	Date: 30 Mar 2025 Quarter: Q2'25 Batch 13b Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ORR/PFS at most slightly superior to ibrutinib) Commercial: FAILURE (commercially insufficient clinical benefit in OS non-superior to ibrutinib)	Readout: 29 Jul 2025 Lead Time: 121 days in advance Interpretation: pirtobrutinib achieved non-inferiority in ORR compared with ibrutinib; wait for PFS/OS data	Correct Prediction Conclusion: statistically insignificant (non-superior) and commercially TBD Classification: True Negative (TN)
1561	Onvansertib NCTID: NCT06106308 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: PLK1 inhibitor Area: Neoplasms Indication: KRAS/NRAS-mutant 1L mCRC Human Patients: 113 Sponsor: Cardiff Oncology (CRDF)	Date: 24 Apr 2024 Quarter: Q3'24 Batch 2 Technical: FAILURE (statistically insignificant additive clinical benefit in ORR with additive toxicity) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS with additive toxicity)	Readout: 29 Jul 2025 Lead Time: 461 days in advance Interpretation: onvansertib 30mg + chemotherapy + bevacizumab achieved 49% cORR that's numerically superior to 30% cORR achieved by chemotherapy + bevacizumab (no p-value provided); onvansertib 30mg + chemotherapy + bevacizumab achieved statistically insignificant mPFS improvement compared with chemotherapy + bevacizumab (no p-value provided)	Correct Prediction Conclusion: statistically probably insignificant and commercially TBD (wait for OS data) Classification: True Negative (TN)
1751	belantamab mafodotin NCTID: NCT04484623 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-BCMA ADC Area: Neoplasms Indication: Relapsed / Multiple Myeloma Human Patients: 302 Sponsor: GlaxoSmithKline (GSK)	Date: 15 Aug 2024 Quarter: Q4'24 Batch 7 Technical: partial SUCCESS (statistically significant additive clinical benefit in PFS superior to bortezomib when combined with pomalidomide + dexamethasone) partial FAILURE (statistically insignificant additive clinical benefit in ORR non-superior to bortezomib) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to bortezomib when combined with pomalidomide + dexamethasone)	Readout: 17 Jul 2025 Lead Time: 336 days in advance Interpretation: belantamab mafodotin + bortezomib + dexamethasone (BvD) achieved 48% reduction in the risk of progression (PFS HR = 0.52 p=0.0001) and statistically insignificant reduction in the risk of death (OS HR = 0.77 p = 0.1896) compared with daratumumab + bortezomib + dexamethasone (DvD)	Correct Prediction Conclusion: statistically significant (PFS) and commercially insufficient (FDA disapproval recommendation due to overall insufficient OS benefit given insignificant OS in DREAMM 8 despite significant OS in DREAMM 7) Classification: True Negative (TN)
1750	belantamab mafodotin NCTID: NCT04246047 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-BCMA ADC Area: Neoplasms Indication: Relapsed / Multiple Myeloma	Date: 15 Aug 2024 Quarter: Q4'24 Batch 7 Technical: partial SUCCESS (statistically significant additive clinical benefit in PFS superior to daratumumab when combined with bortezomib + dexamethasone) partial FAILURE (statistically insignificant additive clinical benefit in ORR)	Readout: 17 Jul 2025 Lead Time: 336 days in advance Interpretation: belantamab mafodotin + bortezomib + dexamethasone (BvD) achieved 59% reduction in the risk of progression (PFS HR = 0.41 p<0.001) and 42% reduction in the risk of death (OS HR=0.58 p=0.00023) compared with	Correct Prediction Conclusion: statistically significant (PFS) and commercially insufficient (FDA disapproval recommendation due to overall insufficient OS benefit given insignificant OS in DREAMM 8 despite significant OS in DREAMM 7)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Human Patients: 494 Sponsor: GlaxoSmithKline (GSK)	non-superior to daratumumab) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to daratumumab when combined with bortezomib + dexamethasone)	daratumumab + bortezomib + dexamethasone (DvD)	Classification: True Negative (TN)
780	Bezuclastinib NCTID: NCT05186753 Phase: Phase 2 Class: Best-In-Class Modality: small molecule MoA: cKIT D816V-mutation inhibitor Area: Neoplasms Indication: Indolent or Smoldering Systemic Mastocytosis Human Patients: 237 Sponsor: Cogent Biosciences (COGT)	Date: 14 Jan 2025 Quarter: Q3'25 Batch 2 Technical: SUCCESS (statistically significant additive clinical benefit in MS2D2 non-superior-to avapritinib) Commercial: SUCCESS (commercially sufficient additive clinical benefit featuring superior-to-avapritinib efficacy in OS and superior-to-avapritinib toxicity)	Readout: 7 Jul 2025 Lead Time: 174 days in advance Interpretation: bezuclastinib achieved placebo-adjusted -8.9 point in TSS/MS2D2 at week 24 (-24.3 bezuclastinib vs -15.4 placebo; 58% improvement over placebo; p=0.0002); numerically superior to avapritinib's placebo-adjusted -6.4 point in TSS/MS2D2 at week 24 (-15.6 avapritinib vs -9.2 placebo; 70% improvement over placebo; p < 0.003) (see add'l link below)	Correct Prediction Conclusion: statistically significant (TSS/MS2D2) and commercially TBD (wait for OS data) Classification: True Positive (TP)
1248	Zidesamtinib (NVL-520) NCTID: NCT05118789 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: small molecule MoA: CNS-penetrant mutant-selective ROS1 inhibitor Area: Neoplasms Indication: Advanced NSCLC and Other Solid Tumors Human Patients: 359 Sponsor: Nuvalent (NUVL)	Date: 15 Aug 2024 Quarter: Q4'24 Batch 11 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS against placebo non-inferior to repotrectinib for tumors with ROS1 fusion without TRK fusion) Commercial: SUCCESS (commercially sufficient clinical benefit in OS superior to repotrectinib for tumors with ROS1 fusion without TRK fusion)	Readout: 24 Jun 2025 Lead Time: 313 days in advance Interpretation: Zidesamtinib achieved 44% ORR; superior to pembrolizumab + ipilimumab that achieved 20-30% confirmed ORR for EGFRwt advanced NSCLC patients (see DOI-10.1016/j.lungcan.2018.12.015) and slightly superior to repotrectinib that achieved 38% ORR for ROS1-positive advanced NSCLC (see add'l link below)	Correct Prediction Conclusion: statistically significant and commercially TBD Classification: True Positive (TP)
1623	Venetoclax NCTID: NCT04401748 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: BCL2 inhibitor Area: Neoplasms Indication: 1L higher-risk myelodysplastic syndrome (HR-MDS) Human Patients: 531 Sponsor: AbbVie (ABBV)	Date: 24 Feb 2025 Quarter: Q2'25 Batch 12a Technical: SUCCESS (statistically significant additive clinical benefit in CR) Commercial: SUCCESS (commercially sufficient additive clinical benefit in OS)	Readout: 16 Jun 2025 Lead Time: 112 days in advance Interpretation: venetoclax + azacitidine failed to meet the primary endpoint of OS (HR = 0.908 p = 0.3772) compared with azacitidine alone	Missed Prediction Note: due to suboptimal modelling of venetoclax's MoA for 1L HR-MDS that has been permanently improved Conclusion: statistically insignificant and commercially insufficient Classification: False Positive (FP)
1722	SGR1505 NCTID: NCT05544019 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: allosteric MALT1 inhibitor Area: Neoplasms Indication: relapsed/refractory B-cell malignancies Human Patients: 52 Sponsor: Schrödinger (SDGR)	Date: 6 Aug 2024 Quarter: Q4'24 Batch 4 Technical: SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS) Commercial: SUCCESS (commercially sufficient (additive) clinical benefit in OS)	Readout: 12 Jun 2025 Lead Time: 310 days in advance Interpretation: SGR1505 achieved a 22% ORR for median 4L+ patients	Correct Prediction Conclusion: statistically significant and commercially TBD (wait for OS data) Classification: True Positive (TP)
1650	177Lu-PSMA-617 NCTID: NCT04720157 Phase: Phase 3 Class: First-In-Class Modality: radionuclide drug conjugate MoA: anti-PSMA radionuclide drug conjugates	Date: 2 Jul 2024 Quarter: - Batch - Technical: FAILURE (statistically insignificant additive clinical benefit in rPFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 2 Jun 2025 Lead Time: 335 days in advance Interpretation: pluvicto + SoC achieved statistically significant clinical benefit in PFS compared with SoC alone; yet failed to achieve statistically significant clinical benefit in OS compared with SoC alone	Correct Prediction Conclusion: statistically significant (PFS) and commercially insufficient (non-superior OS) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Neoplasms Indication: 1L PSMA-positive metastatic hormone-sensitive prostate cancer (mHSPC) Human Patients: 1145 Sponsor: Novartis Pharmaceuticals (NVS)	OS)		
820	IMA203 NCTID: NCT03686124 Phase: Phase 1 Class: First-In-Class Modality: cell therapy MoA: autologous anti-PRAME TCR-T cell therapy Area: Neoplasms Indication: Recurrent Refractory Solid Tumors Human Patients: 476 Sponsor: Immatics (IMTX)	Date: 29 Jul 2024 Quarter: Q3'24 Batch 20 Technical: SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS) Commercial: partial SUCCESS (commercially maybe sufficient yet weak (additive) clinical benefit in OS)	Readout: 31 May 2025 Lead Time: 306 days in advance Interpretation: IMA203 achieved 56% cORR and 6.1 months mPFS that are moderately superior to SoC chemotherapy's 3.7 months mPFS and 10% ORR; IMA203 achieved 15.9 months mOS that's slightly superior to SoC chemotherapy's 14 months mOS (see add'l link below)	Correct Prediction Conclusion: statistically significant (ORR/PFS) and commercially maybe sufficient (slightly superior OS) Classification: True Positive (TP)
1667	Ivonescimab NCTID: NCT06396065 Phase: Phase 3 Class: First-In-Class Modality: bispecific antibody MoA: anti-PD-1 and anti-VEGF Area: Neoplasms Indication: 2L advanced EGFR-mutant NSCLC Human Patients: 420 Sponsor: Summit Therapeutics (SMMT)	Date: 9 Aug 2024 Quarter: Q4'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS non-superior to carboplatin + pemetrexed combotherapy) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate additive clinical benefit in OS numerically superior to carboplatin + pemetrexed combotherapy)	Readout: 30 May 2025 Lead Time: 294 days in advance Interpretation: ivonescimab + chemotherapy achieved statistically significant clinical benefit in PFS compared with the SoC chemotherapy (HR=0.52; p<0.0001); yet failed to achieve statistically significant clinical benefit in OS compared with the SoC chemotherapy (HR=0.79 p=0.057)	Correct Prediction Conclusion: statistically significant (PFS) and commercially insufficient (non-superior OS) Classification: True Negative (TN)
1782	Patritumab Deruxtecan NCTID: NCT05338970 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-HER3 ADC conjugated with a TOP1 inhibitor payload Area: Neoplasms Indication: advanced NSCLC Human Patients: 586 Sponsor: Daiichi Sankyo Company / Merck & Co. (DSNKY/MRK)	Date: 9 Sep 2024 Quarter: Q4'24 Batch 16 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ORR/PFS numerically superior to chemotherapy yet numerically inferior to BL-B01D1); partial FAILURE (statistically insignificant clinical benefit in tolerability inferior to chemotherapy yet numerically superior to BL-B01D1) Commercial: FAILURE (commercially insufficient clinical benefit in OS inferior to chemotherapy yet numerically superior to BL-B01D1)	Readout: 29 May 2025 Lead Time: 262 days in advance Interpretation: patritumab deruxtecan failed to achieve statistically significant clinical benefit in OS compared with the SoC chemotherapy; and achieved 5.8 months mPFS; slightly superior to 5.6 months mPFS achieved by the SoC chemotherapy (HR = 0.77 (see add'l link below); BLA voluntarily withdrawn	Correct Prediction Conclusion: statistically significant yet weak efficacy (PFS) and commercially insufficient (non-superior OS) Classification: True Negative (TN)
1672	Trodelv (sacituzumab govitecan-hziy) NCTID: NCT05382299 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-TROP2 ADC with SN38 payload Area: Neoplasms Indication: 1L metastatic Triple-Negative Breast Cancer (TNBC) Human Patients: 540 Sponsor: Gilead Sciences (GILD)	Date: 9 Jul 2024 Quarter: Q3'24 Batch 15 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in PFS/ORR maybe superior to chemotherapy) Commercial: FAILURE (commercially insufficient clinical benefit in OS non-superior to chemotherapy)	Readout: 23 May 2025 Lead Time: 318 days in advance Interpretation: trodelvy achieved statistically significant superior-to-chemotherapy clinical benefit in PFS (without disclosure of the specific data and p-value; indicating probably weak efficacy in PFS); OS data not mature yet no OS detriment was observed	Correct Prediction Conclusion: statistically probably weakly significant (PFS) and commercially TBD (pending OS data); Classification: True Negative (TN)
1462	Petosemtamab (MCLA-158)	Date: 14 Feb 2024 Quarter: Q2'24 Batch 3	Readout: 22 May 2025 Lead Time: 463 days in advance	Correct Prediction

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT03526835 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: anti-EGFR-LGR5 bispecific antibody Area: Neoplasms Indication: 1L R/M HNSCC Human Patients: 567 Sponsor: Merus (MRUS)	Technical: SUCCESS (statistically significant additive clinical benefit as 1L treatment for HNSCC) Commercial: SUCCESS (commercially sufficient additive clinical benefit as 1L treatment in OS superior to chemo + pembrolizumab)	Interpretation: petosemtamab + pembrolizumab achieved 63% ORR; 9 months mPFS; and 79% 12-month OS; superior to pembrolizumab + chemotherapy's 36% ORR; 5.8 months mPFS; and 53% 12-month OS (see add'l link below)	Conclusion: statistically significant (ORR/PFS) and commercially sufficient (superior OS) Classification: True Positive (TP)
1773	Ficerafusp Alfa (BCA101) NCTID: NCT04429542 Phase: Phase 1 Class: First-In-Class Modality: bispecific antibody MoA: bispecific antibody with anti-EGFR and anti-TGFBeta targets Area: Neoplasms Indication: EGFR-driven Advanced Solid Tumors Human Patients: 292 Sponsor: Bicara Therapeutics (BCAX)	Date: 26 Aug 2024 Quarter: - Batch - Technical: partial SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS numerically superior to cetuximab yet inferior to petosemtamab as monotherapy or in combination with pembrolizumab) Commercial: FAILURE (commercially insufficient (additive) clinical benefit in OS inferior to chemotherapy/cetuximab/petosemtamab as monotherapy or in combination with pembrolizumab)	Readout: 22 May 2025 Lead Time: 269 days in advance Interpretation: ficerafusp alfa + pembrolizumab achieved 54% ORR; 7.4 months mPFS; and 61.5% 12-month OS (see DOI-10.1200/JCO.2025.43.16_suppl.601); inferior to petosemtamab + pembrolizumab's 63% ORR; 9 months mPFS; and 79% 12-month OS (see add'l link below)	Correct Prediction Conclusion: statistically significant (ORR/PFS) and commercially insufficient (inferior-to-petosemtamab OS) Classification: True Negative (TN)
1812	Avutometinib (VS-6766) NCTID: NCT05669482 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: small molecule MoA: MEK inhibitor Area: Neoplasms Indication: 1L Pancreatic Ductal Adenocarcinoma (PDAC) Human Patients: 40 Sponsor: Verastem (VSTM)	Date: 26 Oct 2024 Quarter: Q1'25 Batch 3 Technical: SUCCESS (statistically significant additive clinical benefit in ORR/PFS superior to SoC chemotherapy alone) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to SoC chemotherapy alone)	Readout: 22 May 2025 Lead Time: 208 days in advance Interpretation: avutometinib + defactinib + gemcitabine plus nab-paclitaxel (GnP) achieved 83% ORR (10/12); superior to GnP's 63% ORR for 1L PDAC (see add'l link below)	Correct Prediction Conclusion: statistically significant (ORR) and commercially TBD (PFS/OS data pending) Classification: True Positive (TP)
1781	ADCT-602 NCTID: NCT03698552 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: ADC MoA: anti-CD22 ADC conjugated with a PBD-dimer cytotoxin SG3249 Area: Neoplasms Indication: Recurrent or Refractory B-cell Acute Lymphoblastic Leukemia (ALL) Human Patients: 57 Sponsor: ADC Therapeutics (ADCT)	Date: 9 Sep 2024 Quarter: Q4'24 Batch 16 Technical: SUCCESS (statistically significant clinical benefit in CR/CRi/ORR/PFS against placebo yet non-superior non-inferior to inotuzumab ozogamicin) Commercial: FAILURE (commercially insufficient clinical benefit in OS non-superior non-inferior to inotuzumab ozogamicin)	Readout: 14 May 2025 Lead Time: 247 days in advance Interpretation: ADCT602's further development has been discontinued due to insufficient benefit-risk profile	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
1895	Belrestotug NCTID: NCT06472076 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-TIGIT inhibitor Area: Neoplasms Indication: PDL1 high Non-small-cell Lung Cancer (NSCLC) Human Patients: 1000 Sponsor: GlaxoSmithKline / iTeos Therapeutics (GSK / ITOS)	Date: 30 Jan 2025 Quarter: Q2'25 Batch 7 Technical: FAILURE (statistically insignificant additive clinical benefit in ORR/PFS non-superior to pembrolizumab monotherapy) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS inferior to pembrolizumab monotherapy)	Readout: 13 May 2025 Lead Time: 103 days in advance Interpretation: belrestotug + dostarlimab failed to achieve statistically significant clinical benefit in PFS compared with dostarlimab mono therapy	Correct Prediction Conclusion: statistically insignificant (PFS) and commercially insufficient Classification: True Negative (TN)
1317	VCAR33	Date: 7 Nov 2023	Readout: 8 May 2025	Correct Prediction

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT05984199 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: cell therapy MoA: allogeneic anti-CD33 CAR-T cell therapy Area: Neoplasms Indication: Relapsed or Refractory AML After Allogeneic Hematopoietic Cell Transplant Human Patients: 38 Sponsor: Vor Biopharma (VOR)	Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Lead Time: 548 days in advance Interpretation: VCAR33's further development has been discontinued	Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
1316	VOR33 NCTID: NCT04849910 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: cell therapy MoA: allogeneic CRISPAR/CAS9 genome-edited anti-CD33 HSPC cell therapy VOR33 + anti-CD33 ADC mylotarg Area: Neoplasms Indication: CD33+ acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS) Human Patients: 67 Sponsor: Vor Biopharma (VOR)	Date: 7 Nov 2023 Quarter: 2H'23 Batch 27 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 8 May 2025 Lead Time: 548 days in advance Interpretation: VOR33 + mylotarg's further development has been discontinued	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
1240	Eftilagimod alpha NCTID: NCT04811027 Phase: Phase 2 Class: First-In-Class Modality: fusion protein biologic MoA: a Soluble LAG-3 Fusion Protein Area: Neoplasms Indication: Recurrent or Metastatic HNSCC Human Patients: 171 Sponsor: Immutep (IMMP)	Date: 4 Sep 2023 Quarter: 2H'23 Batch 17 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit)	Readout: 5 May 2025 Lead Time: 609 days in advance Interpretation: efti + pembrolizumab achieved 17.6 months mOS; superior to 10.7 months mOS achieved by cetuximab + chemotherapy or 11.3 months mOS achieved by anti-PD1 therapy + chemotherapy	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1592	REC-2282 NCTID: NCT05130866 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: small molecule MoA: HDAC inhibitor Area: Neoplasms Indication: Progressive Neurofibromatosis Type 2 (NF2) Mutated Meningiomas Human Patients: 92 Sponsor: Recursion Pharmaceuticals (RXRX)	Date: 11 May 2024 Quarter: Q4'24 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet very weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit with inferior-to-microsurgery/radiosurgery efficacy)	Readout: 5 May 2025 Lead Time: 359 days in advance Interpretation: REC2282 failed to achieve statistically significant improvement in efficacy whose further development has thus been discontinued	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1818	REC-4881 NCTID: NCT05552755 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: oral non-ATP-competitive MEK1/MEK2 inhibitor Area: Neoplasms Indication: Familial Adenomatous Polyposis (FAP) Human Patients: 67 Sponsor: Recursion	Date: 3 Nov 2024 Quarter: Q1'25 Batch 6 Technical: partial SUCCESS (statistically maybe significant yet moderate clinical benefit in polyp burden at week 12 against placebo with a positive duration-response relationship) Commercial: SUCCESS (commercially sufficient clinical benefit in in polyp burden at week 24 superior to celecoxib)	Readout: 4 May 2025 Lead Time: 182 days in advance Interpretation: REC4881 achieved a median 43% reduction in polyp burden at week 13; superior to celecoxib's 28% reduction in polyp burden at week 24 (see add'l link below)	Correct Prediction Conclusion: statistically probably significant and commercially probably sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Pharmaceuticals (RXRX)			
1093	Evorpaccept (ALX148) NCTID: NCT04675294 Phase: Phase 2 Class: First-In-Class Modality: fusion protein biologic MoA: CD47 blocker Area: Neoplasms Indication: Advanced Head and Neck Squamous Cell Carcinoma (HNSCC) Human Patients: 189 Sponsor: ALX Oncology (ALXO)	Date: 25 Jun 2024 Quarter: Q4'24 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit as 1L treatment in ORR non-superior to pembrolizumab + chemotherapy) Commercial: FAILURE (commercially insufficient additive clinical benefit as 1L treatment in 12-month OS non-superior to pembrolizumab + chemotherapy)	Readout: 25 Apr 2025 Lead Time: 304 days in advance Interpretation: evorpaccept + SoC failed to achieve statistically significant clinical benefit in ORR/PFS/OS compared with SoC alone	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1092	Evorpaccept (ALX148) NCTID: NCT04675333 Phase: Phase 2 Class: First-In-Class Modality: fusion protein biologic MoA: CD47 blocker Area: Neoplasms Indication: Advanced Head and Neck Squamous Cell Carcinoma (HNSCC) Human Patients: 172 Sponsor: ALX Oncology (ALXO)	Date: 25 Jun 2024 Quarter: Q4'24 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit as 1L treatment in ORR non-superior to pembrolizumab + chemotherapy) Commercial: FAILURE (commercially insufficient additive clinical benefit as 1L treatment in 12-month OS non-superior to pembrolizumab + chemotherapy)	Readout: 25 Apr 2025 Lead Time: 304 days in advance Interpretation: evorpaccept + SoC failed to achieve statistically significant clinical benefit in ORR/PFS/OS compared with SoC alone	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1195	Tovecemig (CTX009) NCTID: NCT05506943 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: bispecific antibody MoA: bispecific antibody that inhibits both DLL4 and VEGF-A Area: Neoplasms Indication: advanced biliary tract cancers Human Patients: 150 Sponsor: Compass Therapeutics (CMPX)	Date: 3 Nov 2024 Quarter: Q1'25 Batch 4 Technical: SUCCESS (statistically significant additive clinical benefit in ORR/PFS superior to paclitaxel monotherapy regardless of DLL4 baseline expression) Commercial: partial SUCCESS (commercially sufficient additive clinical benefit in OS superior to paclitaxel monotherapy for high-DLL4-baseline-expression patients) partial FAILURE (commercially insufficient additive clinical benefit in OS non-superior to paclitaxel monotherapy for low-DLL4-baseline-expression patients)	Readout: 1 Apr 2025 Lead Time: 149 days in advance Interpretation: tovecimig + paclitaxel achieved 17.1% ORR superior to 5.3% ORR for paclitaxel alone (p=0.031); PFS and OS data not mature yet	Correct Prediction Conclusion: statistically significant (ORR) and commercially TBD (OS pending) Classification: True Positive (TP)
552	Relacorilant NCTID: NCT05257408 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: oral non-steroidal glucocorticoid receptor antagonist Area: Neoplasms Indication: platinum-resistant ovarian cancer Human Patients: 381 Sponsor: Corcept Therapeutics (CORT)	Date: 14 Apr 2024 Quarter: Q4'24 Batch 9 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 31 Mar 2025 Lead Time: 351 days in advance Interpretation: relacorilant + chemotherapy achieved statistical significance in both PFS improvement (HR=0.70 p=0.008) and OS improvement (HR=0.69 p=0.012) compared with chemotherapy alone	Missed Prediction Note: due to suboptimal indication-specific glucocorticoid receptor modelling that has been permanently i... Conclusion: statistically significant and commercially sufficient Classification: False Negative (FN)
971	Amivantamab NCTID: NCT04487080 Phase: Phase 3 Class: First-In-Class Modality: bispecific antibody MoA: bispecific antibody anti-EGFR and anti-MET inhibitor	Date: 5 Apr 2023 Quarter: Q2'2023 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (non-superior)	Readout: 26 Mar 2025 Lead Time: 721 days in advance Interpretation: amivantamab + lazertinib achieve statistically significant clinical benefit in mOS (HR = 0.75 p < 0.005) compared with osimertinib; In contrast amivantamab	Correct Prediction Conclusion: statistically significant and commercially probably insufficient (negligible OS benefit) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Neoplasms Indication: EGFR-mutant Non-Small Cell Lung Cancer (NSCLC) Human Patients: 1074 Sponsor: Johnson & Johnson (JNJ)		+ lazertinib has 12% grade ≥ 3 SAE; inferior to 1% grade ≥ 3 SAE for osimertinib; The overall clinical benefit of amivantamab + lazertinib is grade 1 negligible (according to ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE V1.1 EVALUATION FORM 2A (see add'l link below)	
1249	MRT-2359 NCTID: NCT05546268 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: molecular glue degrader MoA: anti-GSPT1 molecular glue degrader Area: Neoplasms Indication: MYC-driven advanced solid tumours Human Patients: 174 Sponsor: Monte Rosa Therapeutics (GLUE)	Date: 30 Sep 2023 Quarter: 2H'23 Batch 18 Technical: FAILURE (statistically maybe significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 20 Mar 2025 Lead Time: 537 days in advance Interpretation: MRT2359 achieved 8% ORR (1/13) for MYC-positive patients and 3% ORR (1/37) for all patients; further development in SCLC; NSCLC; NE tumors discontinued due to low efficacy except for AR-resistant CRPC	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1836	Luveltamab Tazevibulin NCTID: NCT06555263 Phase: Phase 2 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: anti-FOLR1 ADC conjugated with SC209 payload Area: Neoplasms Indication: Advanced or Metastatic Non-small Cell Lung Cancer (NSCLC) Human Patients: 43 Sponsor: Sutro Biopharma (STRO)	Date: 9 Nov 2024 Quarter: Q1'25 Batch 9 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in ORR/PFS) Commercial: FAILURE (commercially sufficient clinical benefit in OS inferior to SoC)	Readout: 13 Mar 2025 Lead Time: 124 days in advance Interpretation: luvelta's further development has been discontinued due to insufficient benefit-risk profile	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
1424	Vepdegestrant NCTID: NCT05909397 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: PROTAC-based ER degrader Area: Neoplasms Indication: 1L ER+HER2-advanced breast cancer Human Patients: 59 Sponsor: Arvinas / Pfizer (ARVN / PFE)	Date: 15 Jan 2024 Quarter: Q1'24 bespoke Batch Q1'24 bespoke Technical: partial SUCCESS (statistically maybe significant additive clinical benefit) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit non-superior-to Letrozole as 1L treatment)	Readout: 11 Mar 2025 Lead Time: 421 days in advance Interpretation: vepdegestrant + palbociclib's further development has been discontinued probably due to uncompetitive clinical benefit compared with vepdegestrant + atirromociclib	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
1423	Vepdegestrant NCTID: NCT05654623 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: PROTAC-based ER degrader Area: Neoplasms Indication: ER+HER2- advanced breast cancer Human Patients: 624 Sponsor: Arvinas / Pfizer (ARVN / PFE)	Date: 15 Jan 2024 Quarter: Q3'24 Batch 8 Technical: SUCCESS (statistically significant clinical benefit as 2L treatment) Commercial: SUCCESS (commercially sufficient clinical benefit superior to fulvestrant as 2L treatment)	Readout: 11 Mar 2025 Lead Time: 421 days in advance Interpretation: vepdegestrant met the primary endpoint in PFS (HR < 0.60) for ESR1m population but not the ITT population; OS data not mature	Missed Prediction Note: tentatively missed prediction for PFS only ; ultimately could still be correct prediction should OS... Conclusion: statistically insignificant (PFS) and commercially TBD Classification: False Positive (FP)
1673	HexaBody-CD38 (GEN3014)	Date: 9 Jul 2024 Quarter: Q3'24 Batch 15	Readout: 10 Mar 2025 Lead Time: 244 days in advance	Correct Prediction

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT04824794 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-CD38 mAb with Fc-domain-specific E430G mutation Area: Neoplasms Indication: relapsed or refractory multiple myeloma (RRMM) Human Patients: 130 Sponsor: Genmab / Johnson & Johnson (GMAB / JNJ)	Technical: SUCCESS (statistically significant clinical benefit in PFS/ORR superior to daratumumab for RRMM) Commercial: SUCCESS (commercially sufficient clinical benefit in CR/OS superior to daratumumab for RRMM)	Interpretation: GEN3014 achieved 55% ORR and 7% CR; superior to 52% ORR and 2% CR achieved by the daratumumab arm	Conclusion: statistically significant (ORR) and commercially probably sufficient (CR) Classification: True Positive (TP)
1586	Ompenaclid NCTID: NCT05983367 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: SLC6A8 inhibitor Area: Neoplasms Indication: 2L RAS-mutant Metastatic Colorectal Cancer (mCRC) Human Patients: 70 Sponsor: Merck KGaA (MKKGY)	Date: 8 May 2024 Quarter: - Batch - Technical: FAILURE (statistically insignificant additive clinical benefit to bevacizumab + chemotherapy in ORR) Commercial: FAILURE (commercially insufficient additive clinical benefit to bevacizumab + chemotherapy in OS)	Readout: 7 Mar 2025 Lead Time: 303 days in advance Interpretation: ompenaclid received negative topline data and discontinued further development	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1015	Rusfertide NCTID: NCT05210790 Phase: Phase 3 Class: First-In-Class Modality: peptide MoA: peptide mimetic of hepcidin Area: Neoplasms Indication: Polycythemia Vera (PV) Human Patients: 250 Sponsor: Protagonist Therapeutics (PTGX)	Date: 26 Oct 2024 Quarter: Q1'25 Batch 2 Technical: SUCCESS (statistically significant additive clinical benefit in phlebotomy eligibility superior to both phlebotomy alone and phlebotomy + hydroxyurea/ruxolitinib) Commercial: SUCCESS (commercially sufficient additive clinical benefit in PROMIS Short Form score superior to both phlebotomy alone and phlebotomy + hydroxyurea/ruxolitinib)	Readout: 3 Mar 2025 Lead Time: 128 days in advance Interpretation: rusfertide as an add-on treatment has met both the primary endpoint with 44% placebo-adjusted improvement in clinical response rate (p<0.0001) and four key secondary endpoints (phlebotomy/hematocrit control/PROMIS Fatigue SF8a/MFSAF TSS-7)	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
511	casdatifan (AB521) NCTID: NCT05536141 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: HIF2alpha inhibitor Area: Neoplasms Indication: 3L treatment for metastatic clear cell renal cell carcinoma (ccRCC) Human Patients: 302 Sponsor: Arcus Biosciences (RCUS)	Date: 14 Feb 2025 Quarter: Q2'25 Batch 11 Technical: SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS compared with placebo) Commercial: SUCCESS (commercially sufficient (additive) clinical benefit in OS non-inferior to cabozantinib as a monotherapy and superior to cabozantinib as a combotherapy)	Readout: 15 Feb 2025 Lead Time: 1 days in advance Interpretation: casdatifan 100mg QD achieved 33% ORR and >6.8 months mPFS; superior to belzutifan that achieved 22% ORR and 5.6 months mPFS; as 3L treatment for ccRCC (10.1056/NEJMoa2313906) and non-inferior to cabozantinib that achieved 21% ORR and 7.4m mPFS as 3L treatment for ccRCC (see the add'l link below)	Correct Prediction Conclusion: statistically significant and commercially TBD (wait for OS data) Classification: True Positive (TP)
1803	CRB701 NCTID: NCT06265727 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: ADC MoA: anti-nectin4 Area: Neoplasms Indication: 2L treatment for nectin4-overexpressing advanced solid tumors Human Patients: 420 Sponsor: Corbus Pharmaceuticals (CRBP)	Date: 19 Oct 2024 Quarter: Q1'25 Batch 1 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS in 2L/3L clinical setting non-inferior-non-superior to enfortumab vedotin for nectin4-overexpressing advance solid tumors) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in OS non-inferior-non-superior to enfortumab vedotin in 2L/3L clinical setting for nectin4-overexpressing)	Readout: 14 Feb 2025 Lead Time: 118 days in advance Interpretation: CRB701 monotherapy achieved 44% ORR as 2L treatment for mUC patients previously treated with enfortumab vedotin (EV); comparable to EV monotherapy that achieve 37.5%-46.8% ORR as 2L treatment for mUC patients previously treated with chemo + anti-PD1 therapies (see add'l link below and DOI-10.1007/s00432-024-05717-2)	Correct Prediction Conclusion: statistically significant (in ORR non-superior non-inferior to EV) and commercially TBD (wait for OS data) Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
		advance solid tumors that don't have FDA-approved drugs)		
1861	AZD0171 NCTID: NCT04999969 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-LIF inhibitor Area: Neoplasms Indication: 1L treatment for advanced pancreatic ductal adenocarcinoma (PDAC) Human Patients: 126 Sponsor: AstraZeneca (AZN)	Date: 7 Dec 2024 Quarter: Q1'25 Batch 13 Technical: SUCCESS (statistically significant additive clinical benefit in ORR/PFS compared with chemotherapy alone) Commercial: SUCCESS (commercially sufficient additive clinical benefit in OS superior to chemotherapy alone)	Readout: 6 Feb 2025 Lead Time: 61 days in advance Interpretation: AZD0171 + durvalumab + chemotherapy hasn't met the efficacy threshold and further development discontinued without disclosure of data	Missed Prediction Note: due to suboptimal drug MoA model that has been permanently corrected Conclusion: statistically insignificant and commercially insufficient Classification: False Positive (FP)
1087	Ziftomenib NCTID: NCT05735184 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: MENIN-MLL1 inhibitor Area: Neoplasms Indication: R/R NPM1-m Acute Myeloid Leukemia Human Patients: 212 Sponsor: Kura Oncology (KURA)	Date: 26 Oct 2024 Quarter: Q1'25 Batch 2 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in CR/EFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 5 Feb 2025 Lead Time: 102 days in advance Interpretation: ziftomenib achieved statistically significant CR/CRh without disclosing the actual CR/CRh data (which usually indicates unremarkable results); probably inferior to venetoclax + azacitidine's 24-38% CR/CRh (see the add'l link below) combotherapy TBD	Correct Prediction Conclusion: statistically significant and commercially probably insufficient (as monotherapy) Classification: True Negative (TN)
1777	Cemiplimab NCTID: NCT05208944 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: telomere-targeting agent THIO Area: Neoplasms Indication: 3L advanced NSCLC Human Patients: 182 Sponsor: Maia Biotechnology (MAIA)	Date: 2 Sep 2024 Quarter: Q4'24 Batch 15 Technical: partial SUCCESS (statistically significant moderate additive clinical benefit in ORR/PFS as 3L+ treatment) partial FAILURE (statistically maybe significant yet very weak additive clinical benefit in ORR/PFS as 2L treatment) Commercial: partial SUCCESS (commercially sufficient yet moderate additive clinical benefit in OS in combination with cemiplimab superior to chemotherapy + cemiplimab as 3L+ treatment) partial FAILURE (commercially insufficient additive clinical benefit in OS in combination with cemiplimab non-superior to chemotherapy + cemiplimab as 2L treatment)	Readout: 4 Feb 2025 Lead Time: 155 days in advance Interpretation: THIO + cemiplimab achieved 16.9 months mOS (12.5 months mOS as the 95% CI lower bound); superior to the SoC chemotherapy that achieved 10.1 months mOS (see the add'l link below). wait for 2L data.	Correct Prediction Conclusion: statistically significant and commercially sufficient (3L) Classification: True Positive (TP)
1081	ZN-c3 (azenosertib) NCTID: NCT05743036 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: Wee1 inhibitor Area: Neoplasms Indication: BRAF V600E mutant colorectal cancer Human Patients: 44 Sponsor: Zentalis Pharmaceuticals (ZNTL)	Date: 25 Jun 2024 Quarter: Q3'24 Batch 14 Technical: partial SUCCESS (statistically significant additive clinical benefit in patients with high CCNE1 expression) Commercial: FAILURE (commercially insufficient additive clinical benefit regardless of CCNE1 expression)	Readout: 29 Jan 2025 Lead Time: 218 days in advance Interpretation: azenosertib + encorafenib + cetuximab achieved 35-41% confirmed ORR as 1L treatment yet 0% confirmed ORR as 2L treatment. Hence; azenosertib + encorafenib + cetuximab hasn't met the efficacy threshold and further development discontinued	Correct Prediction Conclusion: statistically probably insignificant (combotherapy for patients not stratified by CCNE1 expression) yet weak additive efficacy and commercially insufficient (combotherapy discontinued) Classification: True Negative (TN)
1076	ZN-c3 (azenosertib) NCTID: NCT05198804 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: Wee1 inhibitor Area: Neoplasms	Date: 25 Jun 2024 Quarter: Q3'24 Batch 14 Technical: partial SUCCESS (statistically significant additive clinical benefit in patients with high CCNE1 expression)	Readout: 29 Jan 2025 Lead Time: 218 days in advance Interpretation: azenosertib monotherapy 400mg QD5/2 achieved a 31.3% confirmed ORR (5/16) in CCNE1+ patients; azenosertib + niraparib hasn't met the efficacy	Correct Prediction Conclusion: statistically partially significant (monotherapy for CCNE1+ patients only) yet weak additive efficacy and commercially probably insufficient (combotherapy discontinued)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Indication: 2L advanced ovarian cancer Human Patients: 117 Sponsor: Zentalis Pharmaceuticals (ZNTL)	Commercial: overall FAILURE (commercially insufficient additive clinical benefit regardless of CCNE1 expression)	threshold and further development discontinued	Classification: True Negative (TN)
526	Sirexatamab (DKN-01) NCTID: NCT05480306 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-DKK1 inhibitor Area: Neoplasms Indication: 2L MSS Colorectal Cancer Human Patients: 189 Sponsor: Leap Therapeutics (LPTX)	Date: 28 Apr 2024 Quarter: Q3'24 Batch 4 Technical: FAILURE (statistically maybe significant yet very weak additive clinical benefit to SoC in PFS) Commercial: FAILURE (commercially insufficient additive clinical benefit to SoC in OS)	Readout: 28 Jan 2025 Lead Time: 275 days in advance Interpretation: sirexatamab + bevacizumab + chemotherapy achieved a 12% delta in confirmed ORR (35% vs 23%); compared with bevacizumab + chemotherapy	Correct Prediction Conclusion: statistically maybe significant yet weak additive efficacy and commercially probably insufficient (weak additive ORR) Classification: True Negative (TN)
525	Sirexatamab (DKN-01) NCTID: NCT04363801 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-DKK1 inhibitor Area: Neoplasms Indication: Gastric or Gastroesophageal Cancer Human Patients: 232 Sponsor: Leap Therapeutics (LPTX)	Date: 28 Apr 2024 Quarter: Q3'24 Batch 4 Technical: FAILURE (statistically maybe significant yet very weak additive clinical benefit to SoC in PFS) Commercial: FAILURE (commercially insufficient additive clinical benefit to SoC in OS)	Readout: 28 Jan 2025 Lead Time: 275 days in advance Interpretation: sirexatamab + tislelizumab + chemotherapy achieved a 3% delta in confirmed ORR (52% vs 49% in average) and -2.5 months delta in PFS (8.69 months in average vs 11.2 months in average) compared with tislelizumab + chemotherapy (though the median PFS for tislelizumab plus chemotherapy in the Phase 3 Rationale-305 study was 6.9 months (95% CI- 5.7; 7.2); further developments discontinued due to weak efficacy	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
921	Emiltatug Ledadotin (XMT-1660) NCTID: NCT05377996 Phase: Phase 1 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: DAR-6 anti-B7-H4 ADC with an AF-HPA payload Area: Neoplasms Indication: Triple Negative Breast Cancer Breast Cancer Endometrial Cancer Ovarian Cancer Fallopian Tube Cancer Primary Peritoneal Cavity Cancer Adenoid Cystic Carcinoma Human Patients: 319 Sponsor: Mersana Therapeutics (MRSN)	Date: 14 Apr 2024 Quarter: Q3'24 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit with high toxicity) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 10 Jan 2025 Lead Time: 271 days in advance Interpretation: XMT1660 achieved 19% confirmed ORR for all B7-H4 high patients across all doses (11/57)	Correct Prediction Conclusion: statistically maybe significant yet weak clinical efficacy (low ORR) and commercially probably insufficient Classification: True Negative (TN)
1390	Dostarlimab (TSR-042) NCTID: NCT03602859 Phase: Phase 3 Class: Best-In-Class Modality: monoclonal antibody MoA: anti-PD1 mAb inhibitor Area: Neoplasms Indication: 1L combotherapy treatment for advanced ovarian cancer Human Patients: 1402 Sponsor: GSK (GSK)	Date: 15 Aug 2024 Quarter: Q4'24 Batch 7 Technical: SUCCESS (statistically significant additive clinical benefit in ORR/PFS) Commercial: FAILURE (commercially maybe sufficient yet very weak additive clinical benefit in OS)	Readout: 20 Dec 2024 Lead Time: 127 days in advance Interpretation: dostarlimab + SoC + niraparib +/- bevacizumab achieved statistical significance in PFS yet failed to achieve statistical significance in OS; compared with SoC + niraparib +/- bevacizumab	Correct Prediction Conclusion: statistically significant (PFS) and commercially insufficient (OS) Classification: True Negative (TN)
1485	PYX106	Date: 9 Apr 2024 Quarter: Q3'24 Batch 12	Readout: 19 Dec 2024 Lead Time: 254 days in advance	Correct Prediction

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT05718557 Phase: Phase 1 Class: First-In-Class Modality: monoclonal antibody MoA: anti-SIGLEC-15 inhibitor Area: Neoplasms Indication: dvanced solid tumors Human Patients: 60 Sponsor: Pyxis Oncology (PYXS)	Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in PFS/OS/ORR) Commercial: FAILURE (commercially insufficient clinical benefit)	Interpretation: PYX106 is safe yet probably ineffective (no ORR data disclosed for 45 patients) and its further development discontinued	Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
1708	KB707 NCTID: NCT06228326 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: gene therapy MoA: intratumorally injected HSV1-delivered IL2 and IL12 Area: Neoplasms Indication: advanced non-small cell lung cancer (NSCLC) Human Patients: 140 Sponsor: Krystal Biotech (KRYS)	Date: 31 Jul 2024 Quarter: Q3'24 Batch 21 Technical: partial SUCCESS (statistically maybe significant clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 18 Dec 2024 Lead Time: 140 days in advance Interpretation: KB707 achieved 27% confirmed ORR (6/33) for any advanced NSCLC patients; non-superior to pembrolizumab + ipilimumab that achieved 20-30% confirmed ORR for EGFRwt advanced NSCLC patients (10.1016/j.lungcan.2018.12.015) and inferior to osimertinib that achieved 71% ORR for EGFRmut advanced NSCLC patients (10.1056/NEJMoa1612674); OS data pending	Correct Prediction Conclusion: statistically significant yet weak (in ORR) and commercially probably insufficient (in ORR with OS data pending) Classification: True Negative (TN)
428	AFM24 NCTID: NCT05109442 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: EGFR x CD16A tetravalent NK cell engager Area: Neoplasms Indication: Selected Advanced/Metastatic EGFR-expressing Cancers Human Patients: 148 Sponsor: Affimed (AFMD)	Date: 29 Feb 2024 Quarter: Q2'24 Batch 9 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit for refractory/relapsed EGFRwt and EGFRmut solid tumors)	Readout: 17 Dec 2024 Lead Time: 292 days in advance Interpretation: FM24 + atezolizumab achieved 18% confirmed ORR (6/33) for EGFRwt advanced NSCLC patients; numerically inferior to pembrolizumab + ipilimumab that achieved 20-30% confirmed ORR (10.1016/j.lungcan.2018.12.015); AFM24 + atezolizumab achieved 24% confirmed ORR (4/17) for EGFRmut advanced NSCLC patients; inferior to osimertinib that achieved 71% ORR (10.1056/NEJMoa1612674)	Correct Prediction Conclusion: statistically significant yet weak (in ORR) and commercially insufficient Classification: True Negative (TN)
1421	Palbociclib NCTID: NCT02947685 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: CDK4/6 inhibitor Area: Neoplasms Indication: HR+/HER2+ advanced breast cancer Human Patients: 496 Sponsor: Pfizer (PFE)	Date: 15 Jan 2024 Quarter: Q1'24 Batch 15 Technical: partial SUCCESS (statistically significant additive clinical benefit in PFS but not in OS) Commercial: partial SUCCESS (commercially sufficient yet limited additive clinical benefit in PFS but not in OS)	Readout: 13 Dec 2024 Lead Time: 333 days in advance Interpretation: palbociclib + anti-HER2 therapy + endocrine therapy achieved 44.3 months mPFS; superior to anti-HER2 therapy + endocrine therapy that achieved 29.1 months mPFS (p=0.0074); OS analysis remains immature yet palbociclib's improvement in 5-year survival rate is small (74.3% vs 69.8% HR 0.86; 95% CI)	Correct Prediction Conclusion: statistically significant (in PFS) and commercially TBD (wait for OS data) Classification: True Positive (TP)
1770	BBI-825 NCTID: NCT06299761 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: RNR inhibitor Area: Neoplasms Indication: advanced solid tumours with resistance oncogene amplifications Human Patients: 42 Sponsor: Boundless Bio (BOLD)	Date: 29 Aug 2024 Quarter: - Batch - Technical: FAILURE (statistically insignificant clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 12 Dec 2024 Lead Time: 105 days in advance Interpretation: BBI825's further development has been discontinued due to insufficient benefit-risk profile	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
851	lunresertib (RP-6306) and camonsertib (RP-3500) NCTID: NCT04855656	Date: 18 Jan 2023 Quarter: 1H'23 Batch 1 Technical: partial SUCCESS	Readout: 12 Dec 2024 Lead Time: 694 days in advance Interpretation: lunresertib +	Correct Prediction Conclusion: statistically maybe significant yet weak (in ORR) and

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: PKMYT1 inhibitor and ATR inhibitor Area: Neoplasms Indication: Advanced Solid Tumors Human Patients: 364 Sponsor: Repare Therapeutics (RPTX)	(statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	camonsertib achieved 18.5% confirmed ORR (5/27) for endometrial cancer; which is non-superior to pembrolizumab + lenvatinib that achieved 38% ORR (DOI: 10.6004/jadpro.2022.13.1.4); lunresertib + camonsertib achieved 16.7% confirmed ORR (4/24) for platinum-resistant ovarian cancer; which is inferior to chemotherapy + bevacizumab that achieved 27.3% ORR	commercially insufficient (in ORR) Classification: True Negative (TN)
1686	Imlunestrant NCTID: NCT04975308 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: oral next-gen SERD Area: Neoplasms Indication: 2L HR+/HER2-Metastatic Breast Cancer Human Patients: 866 Sponsor: Eli Lilly and Company (LLY)	Date: 17 Jul 2024 Quarter: Q3'24 Batch 18 Technical: partial SUCCESS (statistically significant clinical benefit in PFS/OS non-superior non-inferior to fulvestrant/exemestane) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in combination with abemaciclib as all-oral regimens; despite non-superior efficacy in PFS/OS compared with fulvestrant/exemestane + abemaciclib)	Readout: 11 Dec 2024 Lead Time: 147 days in advance Interpretation: imlunestrant + SoC failed to achieve statistical significance in PFS compared with SoC alone in all patients (5.6 months vs 5.5 months; p=0.12); imlunestrant + abemaciclib achieved statistical significance in PFS compared with imlunestrant alone in all patients (9.4 months vs 5.5 months p<0.001); OS data immature	Correct Prediction Conclusion: partially statistically insignificant (monotherapy in PFS) and partially statistically significant (combination in PFS) and commercially TBD (wait for OS data) Classification: True Positive (TP)
420	CAN2409 NCTID: NCT02768363 Phase: Phase 2 Class: First-In-Class Modality: oncolytic viral gene therapy MoA: AAV-mediated intratumoral delivery of HSV-TK as an oncolytic viral therapy Area: Neoplasms Indication: newly diagnosed prostate cancer Human Patients: 187 Sponsor: Candel Therapeutics (CADL)	Date: 6 Aug 2024 Quarter: Q4'24 Batch 4 Technical: FAILURE (statistically insignificant clinical benefit in PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 11 Dec 2024 Lead Time: 127 days in advance Interpretation: CAN2409 failed to achieve statistical significance in DFS	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
421	CAN2409 NCTID: NCT01436968 Phase: Phase 3 Class: First-In-Class Modality: oncolytic viral gene therapy MoA: AAV-mediated intratumoral delivery of HSV-TK as an oncolytic viral therapy Area: Neoplasms Indication: localized prostate cancer Human Patients: 711 Sponsor: Candel Therapeutics (CADL)	Date: 6 Aug 2024 Quarter: Q4'24 Batch 4 Technical: FAILURE (statistically insignificant additive clinical benefit in DFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 11 Dec 2024 Lead Time: 127 days in advance Interpretation: CAN2409 + RT achieved statistically significant 14.5% relative improvement in DFS at month 54 (not the prespecified month 60) over RT alone (p=0.0155); CAN2409 + RT probably failed to achieve statistical significance in OS improvement (no mentioning of OS data in the topline readout)	Correct Prediction Conclusion: statistically significant yet weak (borderline for DFS) and commercially insufficient (for OS) Classification: True Negative (TN)
522	Palazestrant (OP-125) NCTID: NCT05508906 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: CERAN and SERD Area: Neoplasms Indication: 2L treatment for HR+/HER2- Metastatic Breast Cancer Human Patients: 155	Date: 18 Jun 2023 Quarter: 2H'23 Batch 6 Technical: partial SUCCESS (statistically significant additive clinical benefit for OP-1250 + ribociclib) partial FAILURE (statistically insignificant additive clinical benefit for OP-1250 + alpelisib) Commercial: partial SUCCESS (commercially sufficient additive clinical benefit)	Readout: 10 Dec 2024 Lead Time: 541 days in advance Interpretation: palazestrant + ribociclib achieved 27% ORR (10/37); superior to both sacituzumab govitecan's 21% ORR and chemotherapy's 14% ORR (see add'l link below); no data disclosed for OP-1250 + alpelisib	Correct Prediction Conclusion: statistically significant and commercially TBD (wait for OS data) Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Olema Pharmaceuticals (OLMA)	clinical benefit for OP-1250 + ribociclib) partial FAILURE (commercially insufficient additive clinical benefit for OP-1250 + alpelisib)		
1490	AFM28 NCTID: NCT05817058 Phase: Phase 1 Class: First-In-Class Modality: bispecific antibody MoA: CD123 x CD16A tetravalent NK cell engager Area: Neoplasms Indication: Relapsed / Acute Myeloid Leukemia Human Patients: 30 Sponsor: Affimed (AFMD)	Date: 29 Feb 2024 Quarter: Q2'24 Batch 9 Technical: FAILURE (statistically insignificant clinical benefit in ORR/CR) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 9 Dec 2024 Lead Time: 284 days in advance Interpretation: AFM28 achieved 31% CR/CRi (5/16 for 250mg and 300mg); inferior to SoC that achieved 69% CR/CRi (see add'l link below)	Correct Prediction Conclusion: statistically maybe significant and commercially insufficient Classification: True Negative (TN)
1550	R906289 Monosodium (R289 Na) NCTID: NCT05308264 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: IRAK1/IRAK4 inhibitor Area: Neoplasms Indication: R/R Lower-risk Myelodysplastic Syndromes (LR MDS) that have exhausted all the other treatment options Human Patients: 34 Sponsor: Rigel Pharmaceuticals (RIGL)	Date: 15 Apr 2024 Quarter: Q4'24 Batch 11 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 9 Dec 2024 Lead Time: 238 days in advance Interpretation: R289 achieved 40% hematologic responses (40% mg QD) and 30% RBC-TI (30% mg QD) for 8 week and 1 Grade3 AST/Grade4 ALT TEAE	Correct Prediction Conclusion: statistically significant and commercially TBD (wait for OS data) Classification: True Positive (TP)
1739	Anitocabtagene-autoleucel NCTID: NCT05396885 Phase: Phase 2 Class: First-In-Class Modality: CAR-T therapy MoA: anti-BCMA D-Domain CAR-T cell therapy Area: Neoplasms Indication: Relapsed or Refractory Multiple Myeloma Human Patients: 110 Sponsor: Arcellx (ACLX)	Date: 10 Aug 2024 Quarter: Q4'24 Batch 6 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS non-superior to Carvykti) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in CR/OS non-superior to Carvykti)	Readout: 9 Dec 2024 Lead Time: 121 days in advance Interpretation: anito-cell achieved 97% ORR and 62% CR/sCR; non-superior to Carvykti that achieved 98% ORR and 67% sCR	Correct Prediction Conclusion: statistically significant and commercially maybe sufficient (non-superior to Carvykti) Classification: True Negative (TN)
1175	RMC-6236 NCTID: NCT05379985 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: tri-complex RAS(ON) multi-selective inhibitor Area: Neoplasms Indication: RAS Mutant Advanced Solid Tumors Human Patients: 614 Sponsor: Revolution Medicines (RVMD)	Date: 16 Jul 2023 Quarter: 2H'23 Batch 11 Technical: - Commercial: FAILURE (commercially insufficient clinical benefit non-superior to RAS(OFF) inhibitors)	Readout: 2 Dec 2024 Lead Time: 505 days in advance Interpretation: RMC6236 achieved 9% ORR (9% ORR is low and probably non-superior to KRAS(OFF) G12C inhibitors)	Correct Prediction Conclusion: statistically maybe significant and commercially probably insufficient Classification: True Negative (TN)
1176	RMC-6291 NCTID: NCT05462717 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: tri-complex RAS(ON) multi-selective inhibitor Area: Neoplasms	Date: 16 Jul 2023 Quarter: 2H'23 Batch 11 Technical: - Commercial: FAILURE (commercially insufficient clinical benefit non-superior to RAS(OFF) inhibitors)	Readout: 2 Dec 2024 Lead Time: 505 days in advance Interpretation: RMC6291 achieved 0% ORR (0% ORR means non-superior to KRAS(OFF) G12C inhibitors)	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Indication: Colorectal Cancer (CRC) patients previously treated with KRAS(OFF) G12C inhibitors Human Patients: 222 Sponsor: Revolution Medicines (RVMD)			
985	NovoTTF-200T NCTID: NCT03377491 Phase: Phase 3 Class: First-In-Class Modality: medical device MoA: a device delivering low-intensity; wave-like; alternating electric fields to tumor sites Area: Neoplasms Indication: Pancreatic Cancer Human Patients: 571 Sponsor: Novocure (NVCR)	Date: 21 Aug 2024 Quarter: Q4'24 Batch 13 Technical: FAILURE (statistically maybe significant yet very weak additive clinical benefit in PFS) Commercial: partial SUCCESS (commercially maybe sufficient yet weak additive clinical benefit in OS)	Readout: 2 Dec 2024 Lead Time: 103 days in advance Interpretation: TTFields + SoC achieved 16.20 months mOS compared with 14.16 months in patients who received SoC alone (p=0.039); no PFS data announced in topline readout (usually indicating unremarkable PFS data)	Correct Prediction Conclusion: statistically significant (PFS data pending) and commercially sufficient (weakly superior OS) Classification: True Positive (TP)
1669	JANX007 NCTID: NCT05519449 Phase: Phase 1 Class: First-In-Class Modality: bispecific antibody MoA: anti-PSMA/CD3 protease-activated albumin-binding TCE Area: Neoplasms Indication: Metastatic Castration-Resistant Prostate Cancer (mCRPC) Human Patients: 105 Sponsor: Janux Therapeutics (JANX)	Date: 9 Jul 2024 Quarter: Q3'24 Batch 15 Technical: SUCCESS (statistically significant yet weak clinical benefit in ORR/PFS/rPFS against placebo) Commercial: partial FAILURE (commercially insufficient clinical benefit in ORR/PFS/rPFS inferior to Pluvicto) partial SUCCESS (commercially maybe sufficient yet weak clinical benefit in OS maybe superior to Pluvicto)	Readout: 2 Dec 2024 Lead Time: 146 days in advance Interpretation: JANX007 achieved 7.4 months PFS (median 5L); which is inferior to 8.5months PFS achieved by Lu-117-PSMA-617 + SoC (median 3L); JANX007 probably achieved 25% confirmed ORR (2/8; inferred from the reported 50% ORR that glossed over the number of confirmed and unconfirmed responses); which is inferior to 30% ORR achieved by Lu-117-PSMA-617 + SoC (median 3L)	Correct Prediction Conclusion: statistically significant yet weak and commercially TBD (wait for OS data) Classification: True Negative (TN)
1761	Capivasertib NCTID: NCT04493853 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: pan-ATK small molecule inhibitor Area: Neoplasms Indication: Hormone-Sensitive Prostate Cancer Human Patients: 1012 Sponsor: AstraZeneca (AZN)	Date: 19 Aug 2024 Quarter: Q4'24 Batch 12 Technical: SUCCESS (statistically significant additive clinical benefit in rPFS) Commercial: partial SUCCESS (commercially maybe sufficient yet weak additive clinical benefit in OS)	Readout: 26 Nov 2024 Lead Time: 99 days in advance Interpretation: capivasertib + SoC achieved superior rPFS compared with SoC alone; OS data not mature	Correct Prediction Conclusion: statistically significant and commercially TBD Classification: True Positive (TP)
1429	Tiragolumab NCTID: NCT04294810 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-TIGIT mAb inhibitor Area: Neoplasms Indication: Non-Small Cell Lung Cancer Human Patients: 620 Sponsor: Roche Group (RHHBY)	Date: 18 Jan 2024 Quarter: Q1'24 Batch 16 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 26 Nov 2024 Lead Time: 313 days in advance Interpretation: tiragolumab failed to achieve additive clinical benefit in OS	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1484	PYX-201 NCTID: NCT05720117 Phase: Phase 1 Class: First-In-Class Modality: ADC	Date: 9 Apr 2024 Quarter: Q2'24 Batch 14 Technical: FAILURE (statistically insignificant clinical benefit in PFS/OS/ORR)	Readout: 20 Nov 2024 Lead Time: 225 days in advance Interpretation: PYX201 achieved 26% ORR for advanced solid tumors; which is inferior to other targeted	Correct Prediction Conclusion: statistically maybe significant and commercially insufficient (weak efficacy)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	MoA: anti-fibronectin-EDB ADC with cathepsin B-cleavage mediated release of auristatin payload Area: Neoplasms Indication: advanced solid tumor Human Patients: 80 Sponsor: Pyxis Oncology (PYXS)	Commercial: FAILURE (commercially insufficient clinical benefit)	therapies for advanced solid tumors; e.g. 56% ORR of Enhertu for HER2+ advanced solid tumors (refer to additional press link for AstraZeneca's data)	Classification: True Negative (TN)
1103	OTX-2002 NCTID: NCT05497453 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: mRNA medicine MoA: LNP-encapsulated mRNAs of ZF-DNMT and ZF-KRAB proteins Area: Neoplasms Indication: advanced solid tumor Human Patients: 190 Sponsor: Omega Therapeutics (OMGA)	Date: 27 Feb 2024 Quarter: Q2'24 Batch 9 Technical: partial SUCCESS (statistically significant yet weak clinical benefit for OTX2002 monotherapy and OTX2002 combotherapies) Commercial: FAILURE (commercially insufficient additive clinical benefit due to the inferior-to-atezolizumab+b evacizumab efficacy of OTX2002 combotherapies)	Readout: 14 Nov 2024 Lead Time: 261 days in advance Interpretation: OTX2002 achieved 50% DCR for HCC in line with historical benchmark range for approved TKIs and PD1 monotherapies (29-65%) and its further development is discontinued	Correct Prediction Conclusion: statistically probably significant and commercially insufficient (weak efficacy) Classification: True Negative (TN)
1371	NXP800 NCTID: NCT05226507 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: anti-HSF1 inhibitor Area: Neoplasms Indication: ADR11a-mutated ovarian cancer Human Patients: 61 Sponsor: Nuvectis Pharma (NVCT)	Date: 8 Dec 2023 Quarter: Q1'24 Batch 10 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 14 Nov 2024 Lead Time: 342 days in advance Interpretation: NXP800 achieved at most 9% ORR (1/11 unconfirmed); which is non-superior to the 8-13% ORR by nivolumab or PLD/GEM (Journal of Clinical Oncology DOI-10.1200/JCO.21.00334)	Correct Prediction Conclusion: statistically significant yet weak and commercially insufficient Classification: True Negative (TN)
1779	Letetresgene autoleucel (lete-cel; GSK3377794) NCTID: NCT03967223 Phase: Phase 2 Class: First-In-Class Modality: cell therapy MoA: anti-NY-ESO-1 TCR T-cell therapy Area: Neoplasms Indication: advanced synovial sarcoma (SS) or myxoid/round cell liposarcoma (MRCLS) Human Patients: 103 Sponsor: Adaptimmune Therapeutics (ADAP)	Date: 9 Sep 2024 Quarter: Q4'24 Batch 16 Technical: partial SUCCESS (statistically maybe significant yet moderate additive clinical benefit in ORR/PFS as 1L treatment with moderate toxicity) SUCCESS (statistically significant additive clinical benefit in ORR/PFS as 2L treatment with moderate toxicity) Commercial: partial FAILURE (commercially insufficient additive clinical benefit in OS as 1L treatment) partial SUCCESS (commercially maybe sufficient yet weak additive clinical benefit in OS as 2L treatment)	Readout: 13 Nov 2024 Lead Time: 65 days in advance Interpretation: lete-cel + SoC as 2L treatment achieved 42% ORR and 5.3 months PFS which is superior to the SoC alone (1L data not reported)	Correct Prediction Conclusion: statistically significant (2L) and commercially TBD (2L OS not mature) Classification: True Positive (TP)
1616	Pimicotinib(ABSK021) NCTID: NCT05804045 Phase: Phase 3 Class: Best-In-Class Modality: small molecule MoA: anti-CSF1R inhibitor Area: Neoplasms Indication: tenosynovial giant cell tumor (TGCT) Human Patients: 90 Sponsor: Merck KGaA (MKKGY)	Date: 14 May 2024 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to pexidartinib)	Readout: 12 Nov 2024 Lead Time: 182 days in advance Interpretation: pimicotinib achieved 50.8% placebo-adjusted ORR at week 25 (p<0.0001); which is superior to pexidartinib's 39% placebo-adjusted ORR at week 25 (P<0.0001)	Correct Prediction Conclusion: statistically significant and commercially sufficient; correct prediction Classification: True Positive (TP)
1624	Tamibarotene NCTID: NCT04797780 Phase: Phase 3	Date: 15 May 2024 Quarter: Q3'24 Batch 10 Technical: FAILURE (statistically	Readout: 12 Nov 2024 Lead Time: 181 days in advance Interpretation: Tamibarotene failed to	Correct Prediction Conclusion: statistically insignificant and commercially

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Class: First-In-Class Modality: small molecule MoA: RARalpha agonist Area: Neoplasms Indication: Myelodysplastic Syndrome with RARA gene overexpression Human Patients: 550 Sponsor: Syros Pharmaceuticals (SYRS)	insignificant additive clinical benefit in CR) Commercial: FAILURE (commercially insufficient additive clinical benefit OS)	achieve additional benefit in CR as the primary efficacy endpoint	insufficient Classification: True Negative (TN)
943	Revumenib (SNDX-5613) NCTID: NCT04065399 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: MENIN-MLL1 inhibitor Area: Neoplasms Indication: mNPM1-mutant relapsed/refractory Leukemias Human Patients: 413 Sponsor: Syndax Pharmaceuticals (SNDX)	Date: 18 Jun 2023 Quarter: 2H'23 Batch 6 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 12 Nov 2024 Lead Time: 513 days in advance Interpretation: Revumenib achieved 23% CR/CRh; which is inferior to CLT019's 81% CR	Correct Prediction Conclusion: statistically significant and commercially insufficient (non-superior efficacy compared with SoC) Classification: True Negative (TN)
1780	Mipasetamab Uzoptirine (ADCT-601) NCTID: NCT05389462 Phase: Phase 1 Class: First-In-Class Modality: ADC MoA: anti-AXL ADC conjugated with a PBD-dimer cytotoxin SG3199 Area: Neoplasms Indication: advanced solid tumours Human Patients: 128 Sponsor: ADC Therapeutics (ADCT)	Date: 9 Sep 2024 Quarter: Q4'24 Batch 16 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS for advanced solid tumors regardless of AXL amplification status in 2L/3L clinical settings) SUCCESS (statistically significant clinical benefit in ORR/PFS superior to chemotherapy for advanced solid tumors with AXL amplification in 2L/3L clinical settings) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS for advanced solid tumors regardless of AXL amplification status in 2L/3L clinical settings) partial FAILURE (commercially maybe sufficient yet very weak clinical benefit in OS at most numerically superior to chemotherapy for advanced solid tumors with AXL amplification in 2L/3L clinical settings)	Readout: 7 Nov 2024 Lead Time: 59 days in advance Interpretation: ADCT601's further development has been discontinued due to insufficient benefit-risk profile	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
1471	NKX019 NCTID: NCT05020678 Phase: Phase 1 Class: First-In-Class Modality: cell therapy MoA: allogeneic anti-CD19 CAR-NK cell therapy Area: Neoplasms Indication: relapsed/refractory B cell malignancies Human Patients: 150 Sponsor: Nkarta (NKTX)	Date: 15 Feb 2024 Quarter: Q2'24 Batch 6 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to anti-CD19 CAR-T cell therapies)	Readout: 7 Nov 2024 Lead Time: 266 days in advance Interpretation: NKX019's further development has been forgone based on data review	Correct Prediction Conclusion: statistically probably insignificant and commercially probably insufficient Classification: True Negative (TN)
1018	TNG462 NCTID: NCT05732831 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: selective MTAP-mull-cell-specific PRMT5 inhibitor Area: Neoplasms	Date: 28 Jul 2024 Quarter: Q3'24 Batch 20 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS) Commercial: SUCCESS (commercially sufficient clinical benefit in OS)	Readout: 6 Nov 2024 Lead Time: 101 days in advance Interpretation: TNG462 achieved 43% ORR for relapsed/refractory cholangiocarcinoma; superior to 5% ORR achieved by second-line chemotherapy for advanced biliary tract cancer; including cholangiocarcinoma (Lancet DOI-	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view:

Oncology

#	Clinical Trial	Certified Prediction	Validation	Result
	Indication: MTAP-deleted Solid Tumors Human Patients: 159 Sponsor: Tango Therapeutics (TNGX)		10.1016/S1470-2045(21)00027-9)	
1019	TNG908 NCTID: NCT05275478 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: selective MTAP-mull-cell-specific PRMT5 inhibitor Area: Neoplasms Indication: MTAP-deleted Solid Tumors Human Patients: 192 Sponsor: Tango Therapeutics (TNGX)	Date: 28 Jul 2024 Quarter: Q3'24 Batch 20 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS) Commercial: partial SUCCESS (commercially maybe sufficient yet weak clinical benefit in OS)	Readout: 6 Nov 2024 Lead Time: 101 days in advance Interpretation: TNG908 exhibited overall weak efficacy (active for non-CNS solid tumors yet inactive for GBM)	Correct Prediction Conclusion: statistically maybe significant and commercially insufficient Classification: True Negative (TN)
1298	SC291 NCTID: NCT05878184 Phase: Phase 1 Class: Best-In-Class Modality: CAR-T therapy MoA: anti-CD19 CAR T cell therapy Area: Neoplasms Indication: r/r B-cell malignancies Human Patients: 16 Sponsor: Sana Biotechnology (SANA)	Date: 21 Oct 2024 Quarter: 2H'23 Batch 24 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit due to inferior efficacy for NHL and non-superior efficacy for CLL compared with other anti-CD19 CAR T cell therapies)	Readout: 4 Nov 2024 Lead Time: 14 days in advance Interpretation: SC291 development discontinued without further disclosure of data	Correct Prediction Conclusion: statistically probably significant and commercially insufficient Classification: True Negative (TN)
1441	Uproleselan (GMI-1271) NCTID: NCT03616470 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: selective E-selectin antagonist Area: Neoplasms Indication: Relapsed / Acute Myeloid Leukemia Human Patients: 388 Sponsor: GlycoMimetics (GLYC)	Date: 16 Feb 2024 Quarter: Q2'24 Batch 6 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in OS) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 29 Oct 2024 Lead Time: 256 days in advance Interpretation: uproleselan failed to achieve the EFS primary efficacy endpoint	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1765	RMC-9805 NCTID: NCT06040541 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: KRAS-G12D-ON inhibitor Area: Neoplasms Indication: KRAS G12D-Mutant Solid Tumors Human Patients: 444 Sponsor: Revolution Medicines Inc. (RVMD)	Date: 27 Aug 2024 Quarter: Q4'24 Batch 14 Technical: SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS superior to tumor-specific SoC) Commercial: FAILURE (commercially insufficient (additive) clinical benefit in OS non-superior to tumor-specific SoC)	Readout: 25 Oct 2024 Lead Time: 59 days in advance Interpretation: RMC9805 achieved 30% ORR; where is superior to the SoC chemotherapy's 9%-16% ORR (see add'l link below)	Correct Prediction Conclusion: statistically significant (superior in ORR) and commercially TBD (OS data not mature) Classification: True Positive (TP)
1700	TYRA-300 NCTID: NCT05544552 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: N540K-mutation-specific FGFR3 antagonist	Date: 27 Jul 2024 Quarter: Q3'24 Batch 20 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS with superior-to-erdafitinib safety) Commercial: SUCCESS	Readout: 25 Oct 2024 Lead Time: 90 days in advance Interpretation: TYRA300 achieved 54.5% ORR and 10% SAE (Gr3 only no Gr4); superior to erdafitinib's 71% SAE (both Gr3 and Gr4) (Lancet DOI-	Correct Prediction Conclusion: statistically significant (superior in safety) and commercially TBD (OS data not mature) Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Area: Neoplasms Indication: Advanced Urothelial Carcinoma and Other Solid Tumors With FGFR3 Gene Alterations Human Patients: 310 Sponsor: Tyra Biosciences (TYRA)	(commercially sufficient clinical benefit in OS/CR superior to erdafitinib)	10.1016/S1470-2045(21)00660-4	
1130	naporafenib (ERAS254) NCTID: NCT05907304 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: RAF inhibitor Area: Neoplasms Indication: RAS-mutant advanced solid tumors Human Patients: 115 Sponsor: Erasca (ERAS)	Date: 25 Jun 2023 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS against placebo) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 24 Oct 2024 Lead Time: 487 days in advance Interpretation: naporafenib + trametinib achieved only 30% ORR; non-superior to trametinib monotherapy that achieved 33% ORR for advanced melanoma (10.1002/onco.13795)	Correct Prediction Conclusion: statistically insignificant (in ORR) and commercially TBD (OS data not mature) Classification: True Negative (TN)
1329	NX-5948 NCTID: NCT05131022 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: BTK degrader Area: Neoplasms Indication: Relapsed/Refractory B-cell Malignancies Human Patients: 292 Sponsor: Nurix Therapeutics (NRIX)	Date: 20 Nov 2023 Quarter: 2H'23 Batch 28 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to SoC BTK inhibitors)	Readout: 19 Oct 2024 Lead Time: 334 days in advance Interpretation: NX5948 achieved 69.2%; which is inferior to acalabrutinib's 80-85% ORR (see doi.org/10.1182/bloodadvances.2023011307)	Correct Prediction Conclusion: statistically significant and commercially insufficient (inferior to SoC BTK inhibitors) Classification: True Negative (TN)
1551	Belzupacap Sarotalocan (AU-011) NCTID: NCT05483868 Phase: Phase 1 Class: First-In-Class Modality: conjugate MoA: HPV nanoparticles conjugated with infrared-activated IR700 as a photodynamic therapy Area: Neoplasms Indication: Bladder Cancer Human Patients: 21 Sponsor: Aura Biosciences (AURA)	Date: 20 Apr 2024 Quarter: Q3'24 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ORR/CR) Commercial: FAILURE (commercially insufficient clinical benefit for AU011 with inferior-to-pembrolizumab/tebentafusp-monotherapy efficacy in OS)	Readout: 17 Oct 2024 Lead Time: 180 days in advance Interpretation: Bel-sar achieved 50% CR (4/8); inferior to pembrolizumab's 100% CR at any time (ASCO 19 KEYNOTE-057)	Correct Prediction Conclusion: statistically significant and commercially insufficient (weak clinical benefit) Classification: True Negative (TN)
1782	Patritumab Deruxtecanc NCTID: NCT05338970 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-HER3 ADC conjugated with a TOP1 inhibitor payload Area: Neoplasms Indication: advanced NSCLC Human Patients: 586 Sponsor: Daiichi Sankyo Company / Merck & Co. (DSNKY/MRK)	Date: 9 Sep 2024 Quarter: Q4'24 Batch 16 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ORR/PFS numerically superior to chemotherapy yet numerically inferior to BL-B01D1); partial FAILURE (statistically insignificant clinical benefit in tolerability inferior to chemotherapy yet numerically superior to BL-B01D1) Commercial: FAILURE (commercially insufficient clinical benefit in OS inferior to chemotherapy yet numerically superior to BL-B01D1)	Readout: 24 Sep 2024 Lead Time: 15 days in advance Interpretation: statistically significant improvement in PFS over the SoC chemotherapy (without disclosure of the specific data and p-value; indicating probably weak efficacy in PFS).	Correct Prediction Conclusion: statistically probably weakly significant (in PFS) and commercially TBD (OS data not mature) Classification: True Negative (TN)
1602	BDTX1535	Date: 12 May 2024 Quarter: Q3'24 Batch 7	Readout: 23 Sep 2024 Lead Time: 134 days in advance	Correct Prediction

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT05256290 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: small molecule MoA: 4th-gen CNS-penetrant EGFR masterkey inhibitor that targets classical; non-classical; and resistance EGFR mutations Area: Neoplasms Indication: advanced EGFRm-NSCLC Human Patients: 200 Sponsor: Black Diamond Therapeutics (BDTX)	Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS with non-superior-to-osimertinib efficacy in the clinical setting of 1L EGFR-mutant NSCLC and non-superior-to-chemotherapy efficacy in the clinical setting of 2L EGFR-C797S-mutation NSCLC)	Interpretation: 23% cORR (5/22) and 36% overall ORR (8/22); significantly better than placebo.	Note: Correct Technical prediction (commercial data TBD) Conclusion: statistically significant and commercially TBD (OS data not available) Classification: True Positive (TP)
1734	BTN211-01 NCTID: NCT04503278 Phase: Phase 1 Class: First-In-Class Modality: CAR-T MoA: anti-CLDN6 CAR-T cell and CLDN6 mRNA vaccine Area: Neoplasms Indication: Advanced solid tumors Human Patients: 145 Sponsor: BioNTech (BNTX)	Date: 9 Aug 2024 Quarter: Q4'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit in ORR/PFS as monotherapy or in combination with CLDN6 mRNA vaccine) Commercial: FAILURE (commercially insufficient clinical benefit in OS as monotherapy or in combination with CLDN6 mRNA vaccine)	Readout: 17 Sep 2024 Lead Time: 39 days in advance Interpretation: BTN211-01 with/without CARVac achieved 5% real ORR (not counting tumor marker responses; there were 3/64 patients who achieved PR or CR) in testicular/ovarian cancer; very low efficacy.	Correct Prediction Note: Correct Technical prediction (commercial data TBD) Conclusion: statistically maybe significant (against placebo) and commercially TBD Classification: True Negative (TN)
1732	BNT327/PM8002 NCTID: NCT05918445 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: anti-PDL1 and anti-VEGF bsAb Area: Neoplasms Indication: advanced RCC Human Patients: 380 Sponsor: BioNTech (BNTX)	Date: 9 Aug 2024 Quarter: Q4'24 Batch 5 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS against placebo) Commercial: FAILURE (commercially insufficient clinical benefit in OS non-superior to pembrolizumab + lenvatinib)	Readout: 17 Sep 2024 Lead Time: 39 days in advance Interpretation: BNT327 achieved 25% cORR + 10.9-month mPFS as 2L for ccRCC; which is non-superior to 43% ORR + 14.6-month mPFS achieved by Lenvatinib + Everolimus (Lancet doi-10.1016/S1470-2045(15)00290-9) and BNT327 achieved 36% cORR + 15.1-month mPFS as 1L for nccRCC; which is non-superior to 49% ORR + 17.9-month mPFS achieved by pembrolizumab + lenvatinib in KEYNOTE-B61 study (Lancet DOI-10.1016/S1470-2045(23)00276-0).	Correct Prediction Note: Correct Technical prediction (commercial data TBD) Conclusion: statistically significant (against placebo) and commercially TBD Classification: True Positive (TP)
1733	BNT113 NCTID: NCT04534205 Phase: Phase 2 Class: First-In-Class Modality: mRNA vaccine MoA: HPV16 E6/7 RNA-LPX mRNA vaccine Area: Neoplasms Indication: Head and Neck Cancer Human Patients: 285 Sponsor: BioNTech (BNTX)	Date: 9 Aug 2024 Quarter: Q4'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS against pembrolizumab) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS non-superior to pembrolizumab + chemotherapy as 1L SoC)	Readout: 17 Sep 2024 Lead Time: 39 days in advance Interpretation: BNT113 + pembrolizumab achieved 40% uORR + 3.9-month mPFS; which is non-superior to 36% ORR + 4.9-month mPFS achieved by chemo + pembrolizumab in KEYNOTE-048 (Lancet DOI-10.1016/S0140-6736(19)32591-7).	Correct Prediction Conclusion: statistically maybe significant (yet weak additive efficacy) and commercially TBD Classification: True Negative (TN)
1731	BNT327/PM8002 NCTID: NCT05756972 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: bispecific antibody MoA: anti-PDL1 and anti-VEGF bsAb Area: Neoplasms Indication: Non-Small-Cell Lung Cancer Human Patients: 374 Sponsor: BioNTech (BNTX)	Date: 9 Aug 2024 Quarter: Q4'24 Batch 5 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS non-superior to carboplatin + pemetrexed combotherapy) Commercial: partial SUCCESS (commercially maybe sufficient yet moderate additive clinical benefit in OS numerically superior to carboplatin + pemetrexed combotherapy)	Readout: 17 Sep 2024 Lead Time: 39 days in advance Interpretation: BNT327 + chemotherapy achieved 37% cORR; numerically superior to 29% cORR achieved by chemotherapy alone; BNT327 + chemotherapy achieved 61% Grade 3 TEAE; inferior to 20-40% Grade 3 TEAE achieved by chemotherapy alone (see 10.1177/1758834016644155).	Correct Prediction Conclusion: statistically maybe significant (slightly higher ORR with inferior tolerability) and commercially TBD Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view:

Oncology

#	Clinical Trial	Certified Prediction	Validation	Result
1784	BT8009 NCTID: NCT04561362 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: bicycle toxin conjugate MoA: anti-nectin4 BTC with MMAE payload Area: Neoplasms Indication: metastatic urothelial cancer Human Patients: 329 Sponsor: Bicycle Therapeutics (BCYC)	Date: 12 Sep 2024 Quarter: Q4'24 Batch 17a Technical: partial SUCCESS (statistically significant (additive) clinical benefit in ORR/PFS numerically inferior to enfortumab vedotin in 2L/3L clinical setting for nectin4-overexpressing advance solid tumors) Commercial: SUCCESS (commercially sufficient (additive) clinical benefit in OS non-inferior-non-superior to enfortumab vedotin in 2L/3L clinical setting for nectin4-overexpressing advance solid tumors that don't have FDA-approved drugs)	Readout: 14 Sep 2024 Lead Time: 2 days in advance Interpretation: BT8009 achieved 36.8% cORR (14/38); lower than enfortumab vedotin 40.6% cORR (NEJM DOI-10.1056/NEJMoa2035807).	Correct Prediction Conclusion: statistically significant (numerically inferior to enfortumab vedotin) and commercially TBD Classification: True Positive (TP)
1778	INCB0123667 NCTID: NCT05238922 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: CDK2 inhibitor Area: Neoplasms Indication: Solid Tumors Human Patients: 340 Sponsor: Incyte Corporation (INCY)	Date: 9 Sep 2024 Quarter: Q4'24 Batch 16 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in ORR/PFS with moderate toxicity) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 14 Sep 2024 Lead Time: 5 days in advance Interpretation: INCB123667 achieved 24.3% ORR (<25% is generally accepted as weak efficacy) without positive dose-response relationship.	Overall Correct Prediction Conclusion: statistically maybe significant (yet weak efficacy) and commercially TBD Classification: True Negative (TN)
1416	ponsegromab NCTID: NCT05546476 Phase: Phase 2 Class: First-In-Class Modality: monoclonal antibody MoA: anti-GDF15 mAb inhibitor Area: Neoplasms Indication: Cancer Cachexia Human Patients: 187 Sponsor: Pfizer (PFE)	Date: 15 Jan 2024 Quarter: Q1'24 Batch 15 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 14 Sep 2024 Lead Time: 243 days in advance Interpretation: ponsegromab exhibited non-positive dose-response relationship and failed to meet key secondary/exploratory endpoints (at most 4-point increase in FAACT-ACS; at most 2-point increase in FAACT-5IASS; CRCSD; physical activity; gait endpoints).	Correct Prediction Conclusion: statistically probably insignificant and commercially insufficient Classification: True Negative (TN)
661	TransCon IL-2^{2/3} Pembrolizumab Chemotherapy drug TransCon TLR7/8 Agonist Surgery NCTID: NCT05081609 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: protein prodrug MoA: IL-2 ^{2/3} agonist Area: Neoplasms Indication: Solid Tumor Malignancies Human Patients: 473 Sponsor: Ascendis Pharma (ASND)	Date: 29 Aug 2024 Quarter: Q4'24 Batch 14 Technical: partial SUCCESS (statistically significant additive clinical benefit for TransCon IL2 for certain cancer subindications only); partial FAILURE (statistically insignificant clinical benefit for TransCon TLR7/8) Commercial: partial SUCCESS (commercially sufficient additive clinical benefit for TransCon IL2 for certain cancer subindications only); partial FAILURE (commercially insufficient clinical benefit for TransCon TLR7/8)	Readout: 13 Sep 2024 Lead Time: 15 days in advance Interpretation: TransCon chemotherapy achieved 11% cORR for PROC (2/18 including 4 discontinued patients); much lower than targeted therapy mirvetuximab soravtansine (32.4% ORR for FRalpha-expressing PROC).	Overall Correct Prediction Conclusion: statistically probably insignificant (very weak efficacy) and commercially TBD Classification: True Negative (TN)
1247	NVL-655 NCTID: NCT05384626 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: CNS-penetrant mutant-selective ALK inhibitor Area: Neoplasms Indication: Advanced NSCLC and Other Solid Tumors Human Patients: 400	Date: 15 Aug 2024 Quarter: Q4'24 Batch 11 Technical: partial SUCCESS (statistically significant clinical benefit in ORR/PFS against placebo for all cohorts; non-superior to lorlatinib/alectinib for cohort 2c/2d/2e/2f) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit in OS without	Readout: 9 Sep 2024 Lead Time: 25 days in advance Interpretation: NVL655 achieved 38% confirmed ORR vs. 48% confirmed ORR achieved by lorlatinib in NCT01970865.	Correct Prediction Conclusion: statistically significant (against placebo non-superior to lorlatinib) and commercially TBD Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view:

Oncology

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Nuvalent (NUVL)	mutation-specific stratification; superior to lorlatinib for cohort 2a/2b/2c/2d/2e/2f; non-superior to alectinib for cohort 2c/2d/2e/2f)		
975	RLY-2608 NCTID: NCT05216432 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: pan-mutant-selective (H1047X; E542X; and E535X) PI3Kalpha inhibitor Area: Neoplasms Indication: Advanced Breast Cancer Human Patients: 400 Sponsor: Relay Therapeutics (RLAY)	Date: 11 Jul 2024 Quarter: Q3'24 Batch 16 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit in ORR/PFS non-superior to alpelisib; in combination with fulvestrant and/or palbociclib/ribociclib) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS inferior to alpelisib; in combination with fulvestrant and/or palbociclib/ribociclib)	Readout: 9 Sep 2024 Lead Time: 60 days in advance Interpretation: RLY2608 + fulvestrant achieved 30% confirmed ORR and 9.2months mPFS vs. 26.6% confirmed ORR and 11months mPFS achieved by alpelisib + fulvestrant.	Correct Prediction Note: Correct Technical prediction (commercial data TBD) Conclusion: statistically significant (ORR/PFS non-superior to alpelisib + fulvestrant) and commercially TBD Classification: True Positive (TP)
1666	Ivonescimab (AK112) NCTID: NCT05499390 Phase: Phase 3 Class: First-In-Class Modality: bispecific antibody MoA: anti-PD-1 and anti-VEGF tetravalent bsAb Area: Neoplasms Indication: Advanced Non-small-cell Lung Cancer Human Patients: 398 Sponsor: Summit Therapeutics (SMMT)	Date: 9 Jul 2024 Quarter: Q3'24 Batch 15 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS superior to pembrolizumab) Commercial: SUCCESS (commercially sufficient clinical benefit in OS superior to pembrolizumab)	Readout: 8 Sep 2024 Lead Time: 61 days in advance Interpretation: Median PFS of 11.14 Months vs. 5.82 Months by pembrolizumab and serious TRAEs were 20.8% vs. 16.1%; respectively; in ivonescimab and pembrolizumab arms.	Correct Prediction Conclusion: statistically significant and commercially sufficient (superior) Classification: True Positive (TP)
1304	Cabozantinib NCTID: NCT03937219 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: RTK inhibitor Area: Neoplasms Indication: Renal Cell Carcinoma Human Patients: 855 Sponsor: Exelixis (EXEL)	Date: 31 Oct 2023 Quarter: Q1'24 Batch 3 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 24 Aug 2024 Lead Time: 298 days in advance Interpretation: cabozantinib failed to achieve additive clinical benefit in OS	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1358	Tafasitamab Rituximab Lenalidomide Placebo NCTID: NCT04680052 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-CD19 Fc-enhanced mAb Area: Neoplasms Indication: Relapsed / (R / R) Follicular Lymphoma Marginal Zone Lymphoma Human Patients: 654 Sponsor: Incyte Corporation (INCY)	Date: 30 Nov 2023 Quarter: Q3'24 Batch 16 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit)	Readout: 15 Aug 2024 Lead Time: 259 days in advance Interpretation: superior to the SoC (Lenalidomide + Rituximab) for both PFS (primary endpoint met) and CR (secondary endpoint met).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1560	TBio-4101 Pembrolizumab NCTID: NCT05576077 Phase: Phase 1 Class: First-In-Class Modality: cell therapy MoA: autologous TIL cell therapy Area: Neoplasms Indication: Advanced Solid	Date: 23 Apr 2024 Quarter: Q3'24 Batch 2 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR) Commercial: FAILURE (commercially insufficient additive clinical benefit in	Readout: 14 Aug 2024 Lead Time: 113 days in advance Interpretation: 25% ORR achieved by TBio-4101 + pembrolizumab for MSI-stable CRC vs 30%-40% ORR achieved by regorafenib+ novolumab (Fakih et al. Huyck 2023 eClinicalMedicine).	Correct Prediction Conclusion: statistically significant yet weak and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Tumors Human Patients: 60 Sponsor: Turnstone Biologics (TSBX)	OS)		
1535	LTX-315 Part 1 VP-315 Part 2 NCTID: NCT05188729 Phase: Phase 2 Class: First-In-Class Modality: oncolytic peptide therapy MoA: oncolytic peptide immunotherapy derived from bovine lactoferrin Area: Neoplasms Indication: Basal Cell Carcinoma Human Patients: 80 Sponsor: Verrica Pharmaceuticals (VRCA)	Date: 9 Apr 2024 Quarter: Q2'24 Batch 14 Technical: SUCCESS (statistically significant clinical benefit in clinical clearance) Commercial: FAILURE (commercially insufficient clinical benefit inferior to imiquimod)	Readout: 14 Aug 2024 Lead Time: 127 days in advance Interpretation: 51% CR lower than 80% CR achieved by imiquimod (DOI- 10.1016/j.jaad.2003.11.066).	Correct Prediction Conclusion: statistically significant and commercially insufficient (inferior to imiquimod) Classification: True Negative (TN)
1743	KZR-261 NCTID: NCT05047536 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: small molecule SEC61 inhibitor Area: Neoplasms Indication: Advanced Solid Malignancies Human Patients: 61 Sponsor: Kezar Life Sciences (KZR)	Date: 10 Aug 2024 Quarter: Q4'24 Batch 6 Technical: FAILURE (statistically insignificant clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS)	Readout: 13 Aug 2024 Lead Time: 3 days in advance Interpretation: 0% ORR and trial terminated	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1625	Tamibarotene Venetoclax Azacitidine NCTID: NCT04905407 Phase: Phase 2 Class: First-In-Class Modality: synthetic retinoid MoA: RARalpha agonist Area: Neoplasms Indication: Acute Myeloid Leukemia Human Patients: 95 Sponsor: Syros Pharmaceuticals (SYRS)	Date: 15 May 2024 Quarter: Q3'24 Batch 10 Technical: FAILURE (statistically insignificant additive clinical benefit in CR) Commercial: FAILURE (commercially insufficient additive clinical benefit OS)	Readout: 12 Aug 2024 Lead Time: 89 days in advance Interpretation: CR/CRi achieved by tamibarotene + SoC vs 70% CR/CRi achieved by SoC; and trial terminated.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1554	EO-3021 NCTID: NCT05980416 Phase: Phase 1 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: DAR-2 anti-claudin18.2 ADC with MMAE as payload Area: Neoplasms Indication: Pancreas Neoplasm Stomach Neoplasm Gastrointestinal Neoplasms Digestive System Neoplasm Neoplasms by Site Neoplasms Human Patients: 120 Sponsor: Elevation Oncology (ELEV)	Date: 23 Apr 2024 Quarter: Q3'24 Batch 2 Technical: partial SUCCESS (statistically significant yet moderate additive clinical benefit due to dose-limiting toxicity whose degree depends on claudin 18.2 expression levels) Commercial: FAILURE (commercially insufficient additive clinical benefit with non-superior-to-zolbetuximab efficacy and non-superior-to-zolbetuximab toxicity)	Readout: 6 Aug 2024 Lead Time: 105 days in advance Interpretation: EO-3021 achieved 20% ORR which is significantly lower than 47% ORR achieved by EO-3021 in previous Chinese-only study; 42.8% ORR for CLDN18.2 > 20% and 0% ORR for Claudin 18.2 <20% Four dose-limiting toxicities at 2.9mg/kg dose.	Overall Correct Prediction Conclusion: statistically significant (moderate ORR) and commercially insufficient Classification: True Negative (TN)
1095	Evorpcept (ALX148) NCTID: NCT05002127	Date: 25 Jun 2024 Quarter: Q3'24 Batch 14	Readout: 31 Jul 2024 Lead Time: 36 days in advance	Correct Prediction Conclusion: statistically significant

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Phase: Phase 2 Phase 3 Class: First-In-Class Modality: fusion protein biologic MoA: anti-CD47 blocker Area: Neoplasms Indication: Advanced HER2+ Gastric Cancer Human Patients: 450 Sponsor: ALX Oncology (ALXO)	Technical: SUCCESS (statistically significant additive clinical benefit to trastuzumab + ramucirumab + paclitaxel in ORR as 2L/3L treatments for advanced HER2-overexpressing gastric cancer for phase 2) Commercial: SUCCESS (statistically significant additive clinical benefit to trastuzumab + ramucirumab + paclitaxel in OS as 2L/3L treatments for advanced HER2-overexpressing gastric cancer for phase 3)	Interpretation: evorpacept+TRP achieved an ORR of 40.3% vs 26.6% achieved by TRP (a 13.7% delta which is lower than 30% delta at interim).	and commercially sufficient Classification: True Positive (TP)
456	Pamrevlumab + Gemcitabine + Nab-paclitaxel or Pamrevlumab + FOLFIRINOX Placebo + Gemcitabine + Nab-paclitaxel or Placebo + FOLFIRINOX Placebo + Gemcitabine + Nab-paclitaxel or Placebo + FOLFIRINOX NCTID: NCT03941093 Phase: Phase 3 Class: First-In-Class Modality: monoclonal antibody MoA: anti-CTGF mAb inhibitor Area: Neoplasms Indication: Locally Advanced Pancreatic Cancer Human Patients: 284 Sponsor: FibroGen (FGEN)	Date: 15 May 2024 Quarter: Q3'24 Batch 12 Technical: partial SUCCESS (statistically maybe significant additive clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 30 Jul 2024 Lead Time: 76 days in advance Interpretation: OS endpoint not met (p=0.55).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1175	RMC-6236 NCTID: NCT05379985 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: pan-RAS-mutation ON inhibitor Area: Neoplasms Indication: RAS Mutant Advanced Solid Tumors Human Patients: 474 Sponsor: Revolution Medicines (RVMD)	Date: 16 Jul 2023 Quarter: 2H'23 Batch 11 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit non-superior to RAS(OFF) inhibitors)	Readout: 15 Jul 2024 Lead Time: 365 days in advance Interpretation: 20-21% ORR at week 14 vs 16% ORR achieved by Nal-IRI + 5-FU/LV for any PDAC (see add link for Nal-IRI data in Lancet) or 21% ORR achieved by Sotorasib in CodeBreak 100 trial NEJM.	Correct Prediction Conclusion: statistically significant and commercially probably insufficient (weak ORR improvement) Classification: True Negative (TN)
1240	Eftilagimod alpha Pembrolizumab NCTID: NCT04811027 Phase: Phase 2 Class: First-In-Class Modality: fusion protein biologic MoA: a Soluble LAG-3 Fusion Protein Area: Neoplasms Indication: Recurrent or Metastatic HNSCC Human Patients: 171 Sponsor: Immutep (IMMP)	Date: 4 Sep 2023 Quarter: 2H'23 Batch 17 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit)	Readout: 12 Jul 2024 Lead Time: 312 days in advance Interpretation: 35.5% ORR vs 30.8% ORR for chemo+pembrolizumab in CPS <1 population (Burntress et al. 2022 J. Clin Oncol).	Correct Prediction Conclusion: statistically significant (superior to SoC ORR) and commercially TBD (OS data pending) Classification: True Positive (TP)
849	RP-6306 NCTID: NCT05147350 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: oral PKMYT1 inhibitor Area: Neoplasms Indication: Advanced Solid Tumors Human Patients: 36	Date: 15 Feb 2024 Quarter: Q2'24 Batch 5 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 26 Jun 2024 Lead Time: 132 days in advance Interpretation: 12% confirmed ORR (4/33) vs 30%-50% ORR for other X+ FOLDIRI combotherpies.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Repare Therapeutics (RPTX)			
1478	LYL797 NCTID: NCT05274451 Phase: Phase 1 Class: First-In-Class Modality: CAR-T therapy MoA: Epi-R-enhanced c-JUN-overexpressing anti-ROR1 CAR-T therapy Area: Neoplasms Indication: Solid Tumors Human Patients: 54 Sponsor: Lyell Immunopharma (LYEL)	Date: 18 Feb 2024 Quarter: Q2'24 Batch 7 Technical: SUCCESS (statistically significant clinical benefit in ORR/PFS/OS) Commercial: SUCCESS (commercially sufficient clinical benefit superior to other CAR-T therapies for ROR1+ advanced solid tumors)	Readout: 26 Jun 2024 Lead Time: 129 days in advance Interpretation: 40% ORR (superior to 27% placebo-adjusted ORR by trodelvy for advanced TNBC in ASCENT study) yet with 35% grade>3 TEAEs (pneumonitis and hypoxia).	Overall Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1585	Xevinapant (Debio 1143) Cisplatin Intensity Modulation Radiation Therapy (IMRT) Placebo NCTID: NCT04459715 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: oral IAP inhibitor Area: Neoplasms Indication: Squamous Cell Carcinoma of the Head and Neck Human Patients: 730 Sponsor: Merck KGaA (MKKGY)	Date: 8 May 2024 Quarter: Q3'24 Batch 10 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/EFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 24 Jun 2024 Lead Time: 47 days in advance Interpretation: unlikely to meet EFS primary endpoints and discontinued.	Overall Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1610	Xevinapant IMRT Placebo NCTID: NCT05386550 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: oral IAP inhibitor Area: Neoplasms Indication: Head and Neck Cancer Human Patients: 166 Sponsor: Merck KGaA (MKKGY)	Date: 14 May 2024 Quarter: - Batch - Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in DFS) Commercial: FAILURE (commercially insufficient additive clinical benefit in OS)	Readout: 24 Jun 2024 Lead Time: 41 days in advance Interpretation: unlikely to meet DFS primary endpoints and discontinued.	Overall Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
407	Trilaciclib Placebo Gemcitabine Carboplatin NCTID: NCT04799249 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: CDK4/6 inhibitor Area: Neoplasms Indication: TNBC - Triple-Negative Breast Cancer Human Patients: 194 Sponsor: G1 Therapeutics (GTHX)	Date: 5 Feb 2024 Quarter: Q1'24 Batch 17 Technical: SUCCESS (statistically significant additive clinical benefit in OS) Commercial: SUCCESS (commercially sufficient additive clinical benefit in OS)	Readout: 24 Jun 2024 Lead Time: 140 days in advance Interpretation: OS endpoint not met	Missed Prediction Note: due to suboptimal combotherapy causal modeling in metastatic TNBC that has been permanently correcte... Conclusion: statistically insignificant and commercially insufficient Classification: False Positive (FP)
1079	ZN-c3 NCTID: NCT04814108 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: Wee1 inhibitor Area: Neoplasms Indication: Uterine Serous Carcinoma Human Patients: 76	Date: 25 May 2023 Quarter: Q2'23 Batch 21a Technical: FAILURE (statistically insignificant clinical efficacy in ORR in placebo-controlled trial and moderate clinical toxicity) Commercial: FAILURE (commercially insufficient clinical benefit regardless of CCNE1 expression)	Readout: 18 Jun 2024 Lead Time: 390 days in advance Interpretation: high toxicity resulting in clinical hold.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Sponsor: Zentalis Pharmaceuticals (ZNTL)			
1077	ZN-c3 NCTID: NCT04158336 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: Wee1 inhibitor Area: Neoplasms Indication: Solid Tumors Human Patients: 146 Sponsor: Zentalis Pharmaceuticals (ZNTL)	Date: 25 May 2023 Quarter: - Batch - Technical: FAILURE (statistically insignificant clinical efficacy and high clinical toxicity) Commercial: FAILURE (commercially insufficient clinical benefit regardless of CCNE1 expression)	Readout: 18 Jun 2024 Lead Time: 390 days in advance Interpretation: high toxicity resulting in clinical hold.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1078	ZN-c3 NCTID: NCT05128825 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: Wee1 inhibitor Area: Neoplasms Indication: High-Grade Serous Ovarian; Fallopian Tube or Primary Peritoneal Cancer Human Patients: 102 Sponsor: Zentalis Pharmaceuticals (ZNTL)	Date: 25 May 2023 Quarter: - Batch - Technical: partial SUCCESS (statistically significant additive clinical benefit in patients with high CCNE1 expression) Commercial: FAILURE (commercially insufficient additive clinical benefit regardless of CCNE1 expression)	Readout: 18 Jun 2024 Lead Time: 390 days in advance Interpretation: high toxicity resulting in clinical hold.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
614	SL-172154 NCTID: NCT05275439 Phase: Phase 1 Class: First-In-Class Modality: fusion protein biologic MoA: CD47-CD40 fusion protein Area: Neoplasms Indication: Acute Myeloid Leukemia (AML) / Myelodysplastic Syndrome (MDS) Human Patients: 160 Sponsor: Shattuck Labs (STTK)	Date: 25 Jun 2023 Quarter: 2H'23 Batch 7 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 14 Jun 2024 Lead Time: 355 days in advance Interpretation: 67% ORR (MDS vs 73% ORR and 73% CR/mCR for azacitidine) and 43% ORR (AML; vs 69% ORR and 45% CR for a azacitidine + magrolimab as 1L for TP53 mutant AML).	Correct Prediction Conclusion: no additive efficacy compared with SoC 1L; thus commercially insufficient Classification: True Negative (TN)
940	SNDX-5613 (Revumenib) Chemotherapy Regimen 1 Chemotherapy Regimen 2 NCTID: NCT05326516 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: menin/KMT2A inhibitor Area: Neoplasms Indication: R / R Acute Human Patients: 30 Sponsor: Syndax Pharmaceuticals (SNDX)	Date: 18 Jun 2023 Quarter: 2H'23 Batch 13 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 14 Jun 2024 Lead Time: 362 days in advance Interpretation: 52% confirmed CR (vs 81% CR for CLT019).	Correct Prediction Conclusion: statistically significant yet non-superior compared with SoC CAR-T; thus commercial insufficient Classification: True Negative (TN)
1489	AFM13 AB-101 Cyclophosphamide Fludarabine Interleukin-2 NCTID: NCT05883449 Phase: Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: CD30 x CD16A tetravalent NK cell engager Area: Neoplasms Indication: Relapsed or Refractory Hodgkin Lymphoma	Date: 29 Feb 2024 Quarter: Q2'24 Batch 9 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 12 Jun 2024 Lead Time: 104 days in advance Interpretation: 87.5% ORR (lower than 100% ORR for AFMD alone).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Peripheral T Cell Lymphoma Human Patients: 154 Sponsor: Affimed (AFMD)			
661	TransCon IL-2 ^{2/3} Pembrolizumab Chemotherapy drug TransCon TLR7/8 Agonist Surgery NCTID: NCT05081609 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: protein prodrug MoA: IL-2 ^{2/3} agonist Area: Neoplasms Indication: Solid Tumor Malignancies Human Patients: 473 Sponsor: Ascendis Pharma (ASND)	Date: 12 Apr 2023 Quarter: Q2'23 Batch 8 Technical: SUCCESS (mono); SUCCESS (combo + pembrolizumab); SUCCESS (combo + chemo); FAILURE (combo + TransCon TLR7/8) Commercial: SUCCESS (mono); SUCCESS (combo + pembrolizumab); SUCCESS (combo + chemo); FAILURE (combo + TransCon TLR7/8)	Readout: 3 Jun 2024 Lead Time: 418 days in advance Interpretation: 40% ORR (IL2 + TLR7/8) for advanced melanoma (40-48% for BRAF-mutated BRAF/MEK inhibitors or 29% for BRAF-wild-type ipilimumab + pembrolizumab); 25% ORR (IL2) for colorectal cancer (vs 12-16.4% ORR for regorafenib + ICI or cetuximab + chemo); 100% ORR (IL2 + pembro) for SCLC (40% ORR for larlatamab).	Correct Prediction Conclusion: statistically significant and commercially partially insufficient (IL2 + TLR7/8) yet commercially partially sufficient (other arms) Classification: True Negative (TN)
1546	CNTY-101 IL-2 Lymphodepleting Chemotherapy NCTID: NCT05336409 Phase: Phase 1 Class: First-In-Class Modality: CAR-NK cell therapy MoA: allogeneic anti-CD19 CAR-iNK cells with Allo-Evasion edits; IL-15 support; and EGFR safety switch Area: Neoplasms Indication: CD19-Positive B-Cell Malignancies Human Patients: 75 Sponsor: Century Therapeutics (IPSC)	Date: 14 Apr 2024 Quarter: Q3'24 Batch 1 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit inferior to anti-CD19 CAR-T cell therapies)	Readout: 3 Jun 2024 Lead Time: 50 days in advance Interpretation: 40-60% ORR (vs 74.1% ORR Anti-CD19 CAR-T cell therapy HR001).	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
910	Tildacerfont NCTID: NCT05370521 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: CRF1R antagonist Area: Neoplasms Indication: Polycystic Ovary Syndrome Human Patients: 27 Sponsor: Spruce Biosciences (SPRB)	Date: 7 Aug 2023 Quarter: 2H'23 Batch 8 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 3 Jun 2024 Lead Time: 301 days in advance Interpretation: significant reduction in DHEAS -12.4% vs placebo +5.7% was observed (p = 0.020; vs -12% by metformin).	Overall Correct Prediction Conclusion: statistically significant and commercially insufficient (non-superior) Classification: True Negative (TN)
1334	Darovasertib NCTID: NCT05907954 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: potent selective oral PKC inhibitor Area: Neoplasms Indication: Localized Ocular Melanoma Human Patients: 82 Sponsor: IDEAYA Biosciences (IDYA)	Date: 18 Mar 2024 Quarter: Q2'24 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 3 Jun 2024 Lead Time: 77 days in advance Interpretation: 75% confirmed eye saved.	Correct Prediction Conclusion: statistically significant and commercially sufficient (no neoadjuvant SoC established for ocular melanoma) Classification: True Positive (TP)
506	AB680 Etrumadenant Zimberelimab Bevacizumab m-FOLFOX-6 regimen Regorafenib Sponsor: IDEAYA Biosciences (IDYA)	Date: 18 Jun 2023 Quarter: Q1'24 Batch 5 Technical: FAILURE (statistically insignificant additive clinical benefit)	Readout: 2 Jun 2024 Lead Time: 350 days in advance Interpretation: 17.3% ORR and 19.7 months mOS (vs 19% ORR and	Overall Correct Prediction Conclusion: statistically significant yet commercially insufficient (non-superior) pending more

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT04660812 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: selective dual antagonist of the A2a and A2b receptors Area: Neoplasms Indication: Metastatic Colorectal Cancer Human Patients: 227 Sponsor: Gilead Sciences / Arcus Bioscience (GILD/RCUS)	Commercial: FAILURE (commercially insufficient additive clinical benefit)	21.4months OS by the FOLFIRI/bevacizumab alone without zimberelimab as 2L mCRC treatment in the SPIRITT trial).	cohorts data Classification: True Negative (TN)
1094	Evorpcept (ALX148) Enfortumab Vedotin NCTID: NCT05524545 Phase: Phase 1 Class: First-In-Class Modality: fusion protein biologic MoA: anti-CD47 blocker Area: Neoplasms Indication: Urothelial Carcinoma Human Patients: 30 Sponsor: ALX Oncology (ALXO)	Date: 22 Jul 2023 Quarter: - Batch - Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 2 Jun 2024 Lead Time: 316 days in advance Interpretation: 50% ORR (20 patients receiving treatments) vs. 64.5% ORR for pembrolizumab + enfortumab).	Overall Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1495	Sacituzumab Govitecan-hziy Paclitaxel Docetaxel Vinflunine NCTID: NCT04527991 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-TROP2 ADC with SN38 payload for lysosomal-degradation-mediated intracellular release Area: Neoplasms Indication: Metastatic or Locally Advanced Unresectable Urothelial Cancer Human Patients: 696 Sponsor: Gilead Sciences (GILD)	Date: 5 Mar 2024 Quarter: Q2'24 Batch 10 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit with superior-to-chemotherapy efficacy in OS)	Readout: 30 May 2024 Lead Time: 86 days in advance Interpretation: OS primary endpoint not met.	Missed Prediction Note: due to suboptimal drug MoA modeling that has been permanently corrected. Conclusion: statistically insignificant and commercially insufficient (non-superior) Classification: False Positive (FP)
406	Trilaciclib in Patients Receiving Sacituzumab Govitecan-hziy NCTID: NCT05113966 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: CDK4/6 inhibitor Area: Neoplasms Indication: Triple Negative Breast Cancer Human Patients: 30 Sponsor: G1 Therapeutics (GTHX)	Date: 28 Apr 2023 Quarter: Q2'23 Batch 18 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit for Trudelvy)	Readout: 28 May 2024 Lead Time: 396 days in advance Interpretation: 17.9 mOS vs 12.1 OS (trudelvy alone).	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1303	IK-930 NCTID: NCT05228015 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: oral TEAD inhibitor Area: Neoplasms Indication: Advanced Solid Tumors Human Patients: 198 Sponsor: Ikena Oncology (IKNA)	Date: 31 Oct 2023 Quarter: 2H'23 Batch 25 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 28 May 2024 Lead Time: 210 days in advance Interpretation: 0% ORR.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1542	CG0070 Pembrolizumab	Date: 15 Apr 2023	Readout: 24 May 2024	Correct Prediction

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Injection n-dodecyl-B-D-maltoside NCTID: NCT04387461 Phase: Phase 2 Class: First-In-Class Modality: oncolytic virus therapy MoA: oncolytic adenovirus genetically engineered with an E2F1 promoter region to replicate only in Rb-defective cells and a GM-CSF transgene Area: Neoplasms Indication: Non-Muscle Invasive Bladder Cancer Human Patients: 35 Sponsor: CG Oncology (CGON)	Quarter: Q2'24 Batch 15 Technical: SUCCESS (statistically significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit with superior-to-pembrolizumab-monotherapy efficacy in CR/PFS/OS)	Lead Time: 405 days in advance Interpretation: 54% CR (vs 42% CR for pembrolizumab alone).	Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1587	M9140 M9140 Bevacizumab Capecitabine NCTID: NCT05464030 Phase: Phase 1 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: anti-CEACAM5 ADC that delivers a payload inhibiting TOP1 Area: Neoplasms Indication: Colorectal Cancer Human Patients: 200 Sponsor: Merck KGaA (MKKGY)	Date: 8 May 2024 Quarter: - Batch - Technical: FAILURE (statistically maybe significant yet weak (additive) clinical benefit in ORR) Commercial: FAILURE (commercially insufficient (additive) clinical benefit in OS)	Readout: 23 May 2024 Lead Time: 15 days in advance Interpretation: 7.5% cORR and 12.9-13.9 months OS and 15% TEAE discontinuation (vs 39% ORR for SoC FOLFOX + bevacizumab) (Source- ASCO abstract 231480).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
993	sigvotatug vedotin (SGN-B6A) pembrolizumab cisplatin carboplatin NCTID: NCT04389632 Phase: Phase 1 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: anti-alphavbeta6 integrin ADC that delivers MMAE as payload Area: Neoplasms Indication: Carcinoma Non-Small Cell Lung Squamous Cell Carcinoma of Head and Neck HER2 Negative Breast Neoplasms Esophageal Squamous Cell Carcinoma Esophageal Adenocarcinoma Gastroesophageal Junction Adenocarcinoma Ovarian Neoplasms Cutaneous Squamous Cell Cancer Exocrine Pancreatic Adenocarcinoma Urinary Bladder Neoplasms Uterine Cervical Neoplasms Stomach Neoplasms Human Patients: 824 Sponsor: Pfizer (PFE)	Date: 15 Apr 2023 Quarter: Q2'23 Batch 14 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (superior to anti-TROP2 ADC)	Readout: 23 May 2024 Lead Time: 404 days in advance Interpretation: 20% ORR NSCLC and 3.5 months PFS and 13% TEAE discontinuation (vs 17% ORR for Trodelvy Heist et al. Camidge 2017 J Clinical Onco).	Correct Prediction Conclusion: statistically significant and commercially numerically superior to anti-TROP2 ADC Classification: True Positive (TP)
1422	Brentuximab Vedotin With Pembrolizumab NCTID: NCT04609566 Phase: Phase 2 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: anti-CD30 ADC with MMAE as payload Area: Neoplasms Indication: Melanoma Non-small	Date: 15 Jan 2024 Quarter: Q1'24 Batch 5 Technical: partial SUCCESS (statistically significant yet weak additive clinical benefit to pembrolizumab more for melanoma than for NSCLC or HNSCC) Commercial: FAILURE (commercially insufficient additive clinical benefit with non-superior-to-SoC efficacy in	Readout: 23 May 2024 Lead Time: 129 days in advance Interpretation: 13-21% ORR and 12.9-13.9 months OS and 17% TEAE discontinuation (vs 11.5-12 months OS for chemo alone or more for chemo+X).	Correct Prediction Conclusion: statistically significant and commercially non-superior to SoC (chemo alone) Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Cell Lung Cancer Squamous Cell Carcinoma of the Head and Neck Human Patients: 140 Sponsor: Pfizer (PFE)	ORR/PFS/OS)		
1420	PF-07248144 Fulvestrant Letrozole Palbociclib PF-07220060 NCTID: NCT04606446 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: anti-KAT6A/KAT6B inhibitor Area: Neoplasms Indication: Locally Advanced or Metastatic ER+ HER2- Breast Cancer Locally Advanced or Metastatic Castration-resistant Prostate Cancer Locally Advanced or Metastatic Non-small Cell Lung Cancer Human Patients: 186 Sponsor: Pfizer (PFE)	Date: 15 Jan 2024 Quarter: Q1'24 Batch 5 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 23 May 2024 Lead Time: 129 days in advance Interpretation: 11.4% ORR (mono 5 prior therapy) and 30.4% ORR (PF07248144 + fulvestrant 1 prior therapy) vs 7-10% fulvestrant (mono) vs 52.3% ORR enhertu destiny-breast04.	Overall Correct Prediction Conclusion: statistically significant and commercially non-superior to SoC (enhertu) Classification: True Negative (TN)
1292	AN0025 and Chemoradiotherapy NCTID: NCT05191667 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: PGE2 EP4 inhibitor Area: Neoplasms Indication: Esophageal Cancer Human Patients: 32 Sponsor: Adlai Nortye (ANL)	Date: 19 Oct 2023 Quarter: - Batch - Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 23 May 2024 Lead Time: 217 days in advance Interpretation: 50% ORR (6/12) vs 63.5% ORR (1L tislelizumab + chemo; 68-88% ORR for CRT alone doi- 10.3390/cancers15010010).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
428	AFM24 Atezolizumab 840 MG in 14 ML Injection NCTID: NCT05109442 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: EGFR x CD16A tetravalent NK cell engager Area: Neoplasms Indication: Selected Advanced/Metastatic EGFR-expressing Cancers Human Patients: 148 Sponsor: Affimed (AFMD)	Date: 29 Feb 2024 Quarter: Q2'24 Batch 9 Technical: partial SUCCESS (statistically maybe significant yet very weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit for refractory/relapsed EGFRwt and EGFRmut solid tumors)	Readout: 23 May 2024 Lead Time: 84 days in advance Interpretation: 6.6% ORR and 5.9 month PFS vs 35-50% ORR and 4.7-6.4 month PFS for SoC (nintedanib plus docetaxel VARGADO study doi- 10.1016/j.esmoop.2023.100879).	Correct Prediction Conclusion: statistically significant and commercially insufficient (non-superior to SoC) Classification: True Negative (TN)
1025	BLU-222 Carboplatin Ribociclib Fulvestrant NCTID: NCT05252416 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: CDK2 inhibitor Area: Neoplasms Indication: Advanced Solid Tumors Human Patients: 366 Sponsor: Blueprint Medicines (BPMC)	Date: 28 Apr 2023 Quarter: Q2'23 Batch 18 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit as monotherapy or combination therapy)	Readout: 23 May 2024 Lead Time: 391 days in advance Interpretation: <5% ORR (unconfirmed) vs 22-23% ORR for SoC (16% ORR for chemo & 37-55% ORR enhertu).	Correct Prediction Conclusion: statistically significant and commercially inferior to SoC Classification: True Negative (TN)
1196	CTX-471 pembrolizumab NCTID: NCT03881488 Phase: Phase 1	Date: 26 Jul 2023 Quarter: 2H'23 Batch 8 Technical: SUCCESS (statistically	Readout: 23 May 2024 Lead Time: 302 days in advance Interpretation: 26% ORR vs 22-23%	Correct Prediction Conclusion: statistically significant and commercially TBD

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	Class: First-In-Class Modality: monoclonal antibody (mAb) MoA: CD137 agonist Area: Neoplasms Indication: Metastatic or Locally Advanced Malignancies Human Patients: 157 Sponsor: Compass Therapeutics (CMPX)	significant additive clinical benefit) Commercial: SUCCESS (commercially sufficient additive clinical benefit yet maybe non-superior to SoC)	ORR for SoC (ARX517); OS data pending.	Classification: True Positive (TP)
764	ARV-766 Part A&B ARV-766 + Abiraterone Part C&D NCTID: NCT05067140 Phase: Phase 1 Class: First-In-Class Modality: PROTAC MoA: PROTAC-based AR remover Area: Neoplasms Indication: Metastatic Prostate Cancer Human Patients: 220 Sponsor: Arvinas (ARVN)	Date: 13 May 2024 Quarter: Q3'24 Batch 8 Technical: SUCCESS (statistically significant clinical benefit in PSA/PFS) Commercial: SUCCESS (commercially sufficient clinical benefit for the ARV766 + abiraterone combotherapy in OS)	Readout: 23 May 2024 Lead Time: 10 days in advance Interpretation: 50% PSA50 and 10% TEAE-related discontinuation vs 45% PSA50 for docetaxel doi-10.1002/pros.22844.	Correct Prediction Conclusion: statistically significant and commercially sufficient TBD Classification: True Positive (TP)
1122	KT-253 NCTID: NCT05775406 Phase: Phase 1 Class: Best-In-Class Modality: small molecule MoA: MDM degrader Area: Neoplasms Indication: relapsed or refractory (R/R) high grade myeloid malignancies; acute lymphocytic leukemia (ALL); R/R lymphoma; and R/R solid tumors Human Patients: 70 Sponsor: Kymera Therapeutics (KYMR)	Date: 14 Aug 2023 Quarter: Q1'24 Batch 5 Technical: FAILURE (statistically maybe significant yet very weak clinical benefit in ORR/PFS) Commercial: FAILURE (commercially insufficient clinical benefit in OS inferior to SoC)	Readout: 23 May 2024 Lead Time: 283 days in advance Interpretation: 15.8% ORR far lower than 40% ORR by SoC (doi-10.1177/2040620720955006).	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1462	MCLA-158 + Pembrolizumab NCTID: NCT03526835 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: bispecific antibody MoA: anti-EGFR-LGR5 bispecific antibody Area: Neoplasms Indication: 1L HNSCC Human Patients: 567 Sponsor: Merus (MRUS)	Date: 14 Feb 2024 Quarter: Q2'24 Batch 3 Technical: SUCCESS (statistically significant additive clinical benefit as 1L treatment for HNSCC) Commercial: SUCCESS (commercially sufficient additive clinical benefit as 1L treatment in OS superior to chemo + pembrolizumab)	Readout: 23 May 2024 Lead Time: 99 days in advance Interpretation: 67% ORR for combo superior to 27.3% ORR for SoC.	Correct Prediction Conclusion: statistically significant and commercially TBD (pending OS data) Classification: True Positive (TP)
419	Aglatimagene besadenovec (CAN-2409) NCTID: NCT04495153 Phase: Phase 2 Class: First-In-Class Modality: oncolytic viral gene therapy MoA: AAV-mediated intratumoral delivery of HSV-TK as an oncolytic viral therapy Area: Neoplasms Indication: Stage III/IV NSCLC Human Patients: 90 Sponsor: Candel Therapeutics (CADL)	Date: 9 Apr 2024 Quarter: Q2'24 Batch 15 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in ORR/PFS/OS) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 23 May 2024 Lead Time: 44 days in advance Interpretation: 20.6 months mOS (vs 11.6 mOS by docetaxel in a similar setting; yet the data's rigor has been questioned; and the SoC may be docetaxel + X combo (doi.org/10.1136/esmoopen-2017-000236).	Correct Prediction Conclusion: statistically significant and commercially maybe insufficient Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
977	MCLA-145 NCTID: NCT03922204 Phase: Phase 1 Class: First-In-Class Modality: bispecific antibody MoA: anti-PD-L1 and anti-CD137 bispecific antibody Area: Neoplasms Indication: Advanced or Metastatic Malignancies Human Patients: 118 Sponsor: Merus (MRUS)	Date: 16 Jun 2023 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit anti-PD1 mono clinical efficacy)	Readout: 23 May 2024 Lead Time: 342 days in advance Interpretation: 9.6% ORR for mono and 10.5% ORR for combo.	Correct Prediction Conclusion: statistically significant and partially commercially sufficient (ORR is superior to pembrolizumab monotherapy) Classification: True Positive (TP)
666	ERAS-007 Encorafenib Cetuximab Palbociclib NCTID: NCT05039177 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: small molecule MoA: ERK1/2 inhibitor Area: Neoplasms Indication: Advanced Gastrointestinal Malignancies Human Patients: 102 Sponsor: Erasca (ERAS)	Date: 1 Dec 2023 Quarter: Q1'24 Batch 1 Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 17 May 2024 Lead Time: 168 days in advance Interpretation: 40% ORR for treatment-naïve cohort which is inferior to the 47.7% cORR achieved by EC+binimetinib (DOI-10.1200/JCO.22.01693); terminated due to low efficacy.	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1239	CAB-ROR2-ADC PD-1 inhibitor NCTID: NCT03504488 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: anti-ROR2 ADC Area: Neoplasms Indication: TNBC or Head & Neck Cancer (Ph1) and NSCLC or Melanoma (Ph2) Human Patients: 420 Sponsor: BioAtla (BCAB)	Date: 30 Nov 2023 Quarter: - Batch - Technical: partial SUCCESS (statistically significant yet weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 14 May 2024 Lead Time: 166 days in advance Interpretation: 7% ORR for melanoma (vs 21-36% ORR by anti-PD1 + anti-CLTA4 / TIL cell therapy).	Correct Prediction Conclusion: statistically significant yet commercially insufficient Classification: True Negative (TN)
1235	Ozuriftamab Vedotin (BA3021) PD-1 inhibitor NCTID: NCT05271604 Phase: Phase 2 Class: First-In-Class Modality: antibody-drug conjugate (ADC) MoA: anti-ROR2 ADC Area: Neoplasms Indication: Head and Neck Cancer Human Patients: 80 Sponsor: BioAtla (BCAB)	Date: 3 Sep 2023 Quarter: 2H'23 Batch 18 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 14 May 2024 Lead Time: 254 days in advance Interpretation: 15% ORR for SCCHN (vs 13-16% ORR by anti-PD1).	Correct Prediction Conclusion: statistically significant yet commercially insufficient Classification: True Negative (TN)
812	Vobramitamab Duocarmazine NCTID: NCT05551117 Phase: Phase 2 Class: First-In-Class Modality: ADC MoA: anti-B7-H3 ADC with DUBA payload for lysosomal-protease-cleavage-mediated intracellular release Area: Neoplasms Indication: Metastatic Castration Resistant Prostate Cancer Human Patients: 382 Sponsor: MacroGenics (MGNX)	Date: 3 Mar 2024 Quarter: Q2'24 Batch 10 Technical: partial SUCCESS (statistically maybe significant yet weak clinical benefit with high toxicity) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 9 May 2024 Lead Time: 67 days in advance Interpretation: 25% ORR (vs 30% ORR for 177Lu-PSMA-617 + SoC in the same setting of 2L mCRPC in phase 3); 93%-95% TEAEs.	Correct Prediction Conclusion: commercially insufficient due to weak efficacy and high toxicity. Classification: True Negative (TN)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
1441	Uproleselan (GMI-1271) NCTID: NCT03616470 Phase: Phase 3 Class: First-In-Class Modality: small molecule MoA: selective E-selectin antagonist Area: Neoplasms Indication: Relapsed / Acute Myeloid Leukemia Human Patients: 388 Sponsor: GlycoMimetics (GLYC)	Date: 16 Feb 2024 Quarter: Q2'24 Batch 6 Technical: partial SUCCESS (statistically maybe significant yet weak additive clinical benefit in OS) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 6 May 2024 Lead Time: 80 days in advance Interpretation: OS primary endpoint not met.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
744	Setanaxib Pembrolizumab NCTID: NCT05323656 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: NOX1/NOX4 dual inhibitor Area: Neoplasms Indication: Squamous Cell Carcinoma of Head and Neck (SCCHN) Human Patients: 55 Sponsor: Calliditas Therapeutics (CALT)	Date: 22 Dec 2023 Quarter: Q1'24 Batch 11 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 6 May 2024 Lead Time: 136 days in advance Interpretation: base percentage change in tumor size primary endpoint not met yet PFS/OS secondary endpoints showed positive trends (not significant).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1543	CG0070 n-dodecyl-B-D-maltoside NCTID: NCT04452591 Phase: Phase 3 Class: First-In-Class Modality: oncolytic virus therapy MoA: oncolytic adenovirus genetically engineered with an E2F1 promoter region to replicate only in Rb-defective cells and a GM-CSF transgene Area: Neoplasms Indication: Non-Muscle Invasive Bladder Cancer Unresponsive to Bacillus Calmette-Guerin Human Patients: 190 Sponsor: CG Oncology (CGON)	Date: 15 Apr 2024 Quarter: Q2'24 Batch 15 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially maybe sufficient clinical benefit with maybe inferior-to-pembrolizumab efficacy in CR/PFS)	Readout: 3 May 2024 Lead Time: 18 days in advance Interpretation: 75.2% CR any time at month 12 (vs 100% CR any time for pembrolizumab at month 12. ASCO 19 KEYNOTE-057); no grade 3 TEAE.	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1373	Trastuzumab deruxtecan Capecitabine Paclitaxel Nab-Paclitaxel NCTID: NCT04494425 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-HER2 mAb inhibitor conjugated with TOP1 inhibitor Area: Neoplasms Indication: Metastatic Breast Cancer Human Patients: 866 Sponsor: AstraZeneca / Daiichi Sankyo Company (AZN / DSNKY)	Date: 12 Dec 2023 Quarter: Q1'24 Batch 10 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to chemotherapy)	Readout: 29 Apr 2024 Lead Time: 139 days in advance Interpretation: PFS superior to SoC; OS not mature yet with early positive trend.	Correct Prediction Conclusion: statistically significant and commercially probably sufficient Classification: True Positive (TP)
1493	ACR-368 Gemcitabine OncoSignature NCTID: NCT05548296 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: CHEK1/CHEK2 small molecule inhibitor with OncoSignature predictive	Date: 3 Mar 2024 Quarter: Q2'24 Batch 10 Technical: SUCCESS (statistically significant clinical benefit in the OncoSignature positive arm) Commercial: SUCCESS (commercially sufficient clinical benefit in the OncoSignature positive	Readout: 24 Apr 2024 Lead Time: 52 days in advance Interpretation: 50% ORR for oncosignature positive arm vs 0% Orr for oncosignature negative arm (p=0.0038) vs 42.3% ORR of mirvetuximab soravtansine for patients selected by FOLRalpha; anti-correlation between dosage and	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	biomarkers Area: Neoplasms Indication: Ovarian Carcinoma; Endometrial Adenocarcinoma; and Urothelial Carcinoma Human Patients: 390 Sponsor: Acrivon Therapeutics (ACRV)	monotherapy arm with superior efficacy over the OncoSignature negative combotherapy arm)	efficacy.	
1508	ELVN-001 NCTID: NCT05304377 Phase: Phase 1 a/1b Class: Best-In-Class Modality: small molecule MoA: BCR-ABL1 and T315I selective tyrosine kinase inhibitor Area: Neoplasms Indication: Chronic Myeloid Leukemia Human Patients: 180 Sponsor: Enliven Therapeutics (ELVN)	Date: 18 Mar 2024 Quarter: Q2'24 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 11 Apr 2024 Lead Time: 24 days in advance Interpretation: 44% cumulative MRR even for previously treated with asciminib.	Correct Prediction Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1211	FLX475 Pembrolizumab NCTID: NCT03674567 Phase: Phase 1 Phase 2 Class: Best-In-Class Modality: small molecule MoA: CCR4 antagonist Area: Neoplasms Indication: Advanced Cancer Human Patients: 323 Sponsor: RAPT Therapeutics (RAPT)	Date: 10 Aug 2023 Quarter: 2H'23 Batch 12 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 10 Apr 2024 Lead Time: 244 days in advance Interpretation: 15.6% ORR (vs 27.3% ORR by pembrolizumab alone as 2L for advanced HNSCC in KEYNOTE-048.	Overall Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1137	Ac225-PSMA I&T NCTID: NCT05219500 Phase: Phase 2 Class: First-In-Class Modality: radioligand therapy MoA: anti-PSMA mAb conjugated to alpha particle-emitting cytotoxic isotope Actinium-225 Area: Neoplasms Indication: Metastatic Castration Resistant Prostate Cancer (mCRPC) Human Patients: 115 Sponsor: Fusion Pharmaceuticals (FUSN)	Date: 1 Dec 2023 Quarter: Q1'24 Batch 1 Technical: SUCCESS (statistically significant clinical benefit) Commercial: partial SUCCESS (commercially sufficient clinical benefit non-inferior and non-superior to SoC)	Readout: 9 Apr 2024 Lead Time: 130 days in advance Interpretation: 50% PSA50 33% ORR (vs 57.6% PSA50 and 50.7% ORR of Pluvicto or 42% ORR PSA50 and 60% ORR of PNT2002 in advanced mCRPC).	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Positive (TP)
1482	VIP236 NCTID: NCT05712889 Phase: Phase 1 Class: First-In-Class Modality: small molecule drug conjugate (SMDC) MoA: alpha5beta3-integrin-specific SMDC with NE-cleavage-mediated release of CPT payload Area: Neoplasms Indication: Advanced Cancer Human Patients: 24 Sponsor: Vincerx Pharma (VINC)	Date: 26 Feb 2024 Quarter: Q2'24 Batch 8 Technical: SUCCESS (statistically significant clinical benefit in PFS/OS/ORR) Commercial: SUCCESS (commercially sufficient clinical benefit)	Readout: 8 Apr 2024 Lead Time: 42 days in advance Interpretation: safer yet with 0% ORR.	Missed Prediction Note: due to suboptimal modelling of linker that has been permanently corrected Conclusion: statistically insignificant and commercially insufficient Classification: False Positive (FP)

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
1344	GRT-C901 GRT-R902 Atezolizumab Ipilimumab Fluoropyrimidine plus leucovorin Bevacizumab NCTID: NCT05141721 Phase: Phase 2 Phase 3 Class: First-In-Class Modality: cancer vaccine MoA: modified-chimpanzee-adenoviral patient-specific neoantigen vaccine Area: Neoplasms Indication: Metastatic Colorectal Cancer Human Patients: 700 Sponsor: Gritstone bio (GRTS)	Date: 26 Nov 2023 Quarter: Q1'24 Batch 7 Technical: SUCCESS (statistically significant yet weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 1 Apr 2024 Lead Time: 127 days in advance Interpretation: weak PFS trend that's not statistically significant yet.	Correct Prediction Conclusion: statistically significant yet commercially insufficient (weak efficacy) Classification: True Negative (TN)
1307	CT-0508 Pembrolizumab NCTID: NCT04660929 Phase: Phase 1 Class: First-In-Class Modality: CAR-Macrophage therapy MoA: anti-HER2 CAR-M1 Area: Neoplasms Indication: HER2-positive Adenocarcinoma Bile Duct Cancer Biliary Tract Cancer Bladder Cancer Breast CancerBreast Neoplasm Carcinoma Ductal Carcinoma Hepatocellular Cancer Lung Cancer Non-Small Cell Carcinoma Ovarian Epithelial Carcinoma Small Cell Carcinoma Squamous Carcinoma Transitional Cell Colorectal Cancer Esophagogastric Junction Neoplasms Inflammatory Breast Cancer Stomach Neoplasms Malignant Neoplasms Ovarian Neoplasms Pancreatic Cancer HER2- positive Solid Tumors HER2-positive Breast Cancer HER2-positive Gastric Cancer HER-2 Protein Overexpression HER-2 Gene Amplification Prostate Cancer Head and Neck Cancer Endometrial Cancer Lung Cancer Small Cel Human Patients: 48 Sponsor: Carisma Therapeutics (CARM)	Date: 31 Oct 2023 Quarter: 2H'23 Batch 26 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 1 Apr 2024 Lead Time: 153 days in advance Interpretation: safe yet terminated due to insufficient efficacy.	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
984	NovoTTF-200M device Best Standard of Care NCTID: NCT02831959 Phase: Phase 3 Class: First-In-Class Modality: medical device MoA: a device delivering low-intensity; wave-like alternating electric fields to the location of the tumor Area: Neoplasms Indication: Brain Metastases From Non-small Cell Lung Cancer (NSCLC) Human Patients: 270 Sponsor: NovoCure (NVCR)	Date: 22 Dec 2023 Quarter: Q1'24 Batch 12 Technical: partial SUCCESS (statistically significant yet weak additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 27 Mar 2024 Lead Time: 96 days in advance Interpretation: 21.9month vs 11.3month time to intracranial progression (p=0.016) OS secondary endpoint not met.	Correct Prediction Conclusion: statistically significant yet commercially insufficient (no OS benefit) Classification: True Negative (TN)
1059	Paltusotine	Date: 14 Aug 2023	Readout: 12 Mar 2024	Correct Prediction

Validated Trial Evidence: Filtered Registry (180 of 604 trials)

Filtered view: **Oncology**

#	Clinical Trial	Certified Prediction	Validation	Result
	NCTID: NCT05361668 Phase: Phase 2 Class: First-In-Class Modality: small molecule MoA: SST2R agonist Area: Neoplasms Indication: Carcinoid Syndrome Human Patients: 36 Sponsor: Crinetics Pharmaceuticals (CRNX)	Quarter: 2H'23 Batch 12 Technical: SUCCESS (statistically significant clinical benefit) Commercial: SUCCESS (commercially sufficient clinical benefit superior to octreotide)	Lead Time: 211 days in advance Interpretation: 63% reduction flushing frequency and 60% reduction in bowel movement frequency p<0.0001; both superior to the 20-35% reduction in flushing and bowel movement achieved by SoC (DOI- 10.1093/annonc/mdy293.007).	Conclusion: statistically significant and commercially sufficient Classification: True Positive (TP)
1347	Ziftomenib NCTID: NCT04067336 Phase: Phase 1 Phase 2 Class: First-In-Class Modality: small molecule MoA: Menin-MLL1 inhibitor Area: Neoplasms Indication: Relapsed or Refractory Acute Myeloid Leukemia Human Patients: 199 Sponsor: Kura Oncology (KURA)	Date: 28 Nov 2023 Quarter: - Batch - Technical: SUCCESS (statistically significant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 30 Jan 2024 Lead Time: 63 days in advance Interpretation: 65% ORR with 70% Top CR; non-superior to chemo's 60%-70% CR.	Correct Prediction Conclusion: statistically significant and commercially insufficient Classification: True Negative (TN)
1408	Sacituzumab Govitecan-hziy (SG) Docetaxel NCTID: NCT05089734 Phase: Phase 3 Class: First-In-Class Modality: ADC MoA: anti-TROP2 ADC with SN38 payload for lysosomal-degradation-mediated intracellular release Area: Neoplasms Indication: Non-Small Cell Lung Cancer (NSCLC) Human Patients: 603 Sponsor: Gilead Sciences (GILD)	Date: 5 Jan 2024 Quarter: Q1'24 Batch 13 Technical: partial SUCCESS (statistically maybe significant yet weak additional clinical benefit in OS compared with docetaxel) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 22 Jan 2024 Lead Time: 17 days in advance Interpretation: OS primary endpoint not met.	Correct Prediction Conclusion: statistically insignificant and commercial insufficient Classification: True Negative (TN)
508	AB680 Zimberelimab Nab-paclitaxel Gemcitabine NCTID: NCT04104672 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: CD73 inhibitor Area: Neoplasms Indication: Advanced Pancreatic Cancer Human Patients: 195 Sponsor: Arcus Biosciences (RCUS)	Date: 18 Jun 2023 Quarter: Q1'24 Batch 5 Technical: FAILURE (statistically insignificant additive clinical benefit) Commercial: FAILURE (commercially insufficient additive clinical benefit)	Readout: 16 Jan 2024 Lead Time: 212 days in advance Interpretation: ORR/OS/PFS endpoints not met for both Q+ SoC and QZ+ SoC with mOS trend (15 vs 12 months for SoC).	Correct Prediction Conclusion: statistically insignificant and commercially insufficient Classification: True Negative (TN)
1279	ORIC-944 NCTID: NCT05413421 Phase: Phase 1 Class: First-In-Class Modality: small molecule MoA: PRC2 inhibitor Area: Neoplasms Indication: Metastatic Prostate Cancer Human Patients: 42 Sponsor: ORIC Pharmaceuticals (ORIC)	Date: 11 Oct 2023 Quarter: Q1'24 Batch 9 Technical: FAILURE (statistically insignificant clinical benefit) Commercial: FAILURE (commercially insufficient clinical benefit)	Readout: 8 Jan 2024 Lead Time: 89 days in advance Interpretation: no efficacy data on key secondary endpoints ORR/PFS yet advancing combination therapy forward only (widely accepted strong sign of weak efficacy).	Correct Prediction Conclusion: commercial insufficient Classification: True Negative (TN)

Appendix: Statistical Methodology & Glossary

KPI FORMULAS

Accuracy

$$(TP + TN) / (TP + TN + FP + FN)$$

Precision (PPV)

$$TP / (TP + FP)$$

NPV

$$TN / (TN + FN)$$

F1-Score

$$2 \times TP / (2 \times TP + FP + FN)$$

DOR

$$(TP \times TN) / (FP \times FN)$$

Sensitivity

$$TP / (TP + FN)$$

Specificity

$$TN / (TN + FP)$$

GLOSSARY

Ex-Ante / Prospective

Prediction issued before outcome is known; timestamped proof

TP

True Positive — predicted blockbuster drug-indication pair with moderately or strongly superior to SoC clinical benefit with HR < 0.6, confirmed by clinical readout

TN

True Negative — predicted non-blockbuster drug-indication pair with weakly superior or inferior to SoC clinical benefit with HR > 0.6, confirmed by clinical readout

FP

False Positive — predicted blockbuster drug-indication pair with moderately or strongly superior to SoC clinical benefit with HR < 0.6, contradicted by clinical readout

FN

False Negative — predicted non-blockbuster drug-indication pair with weakly superior or inferior to SoC clinical benefit with HR > 0.6, contradicted by clinical readout

FIC

First-In-Class — novel mechanism of action and indication pair, no approved precedent

BIC

Best-In-Class — improved agent within an established class

DOR

Diagnostic Odds Ratio — measures discriminative power

MoA

Mechanism of Action — how a drug exerts its therapeutic effect

SoC

Standard of Care — current best available treatment

NCTID

ClinicalTrials.gov trial identifier (e.g., NCT12345678)

DATA PROVENANCE

- All predictions in this dossier are sourced from the BioinvestGPT validated prediction database.
- Each prediction is independently verifiable via its unique index number on data.bioinvestgpt.com.
- Clinical readout outcomes are sourced from official company press releases, ClinicalTrials.gov results, and peer-reviewed literature.
- This dossier was generated on April 8, 2026.

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Clinical trials are inherently uncertain. Regulatory approval, commercial success, and patient outcomes depend on numerous factors beyond the scope of this analysis, including but not limited to: regulatory authority decisions, manufacturing capabilities, competitive dynamics, payer coverage, and post-marketing safety signals.

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with > 90% Ex-Ante Accuracy

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