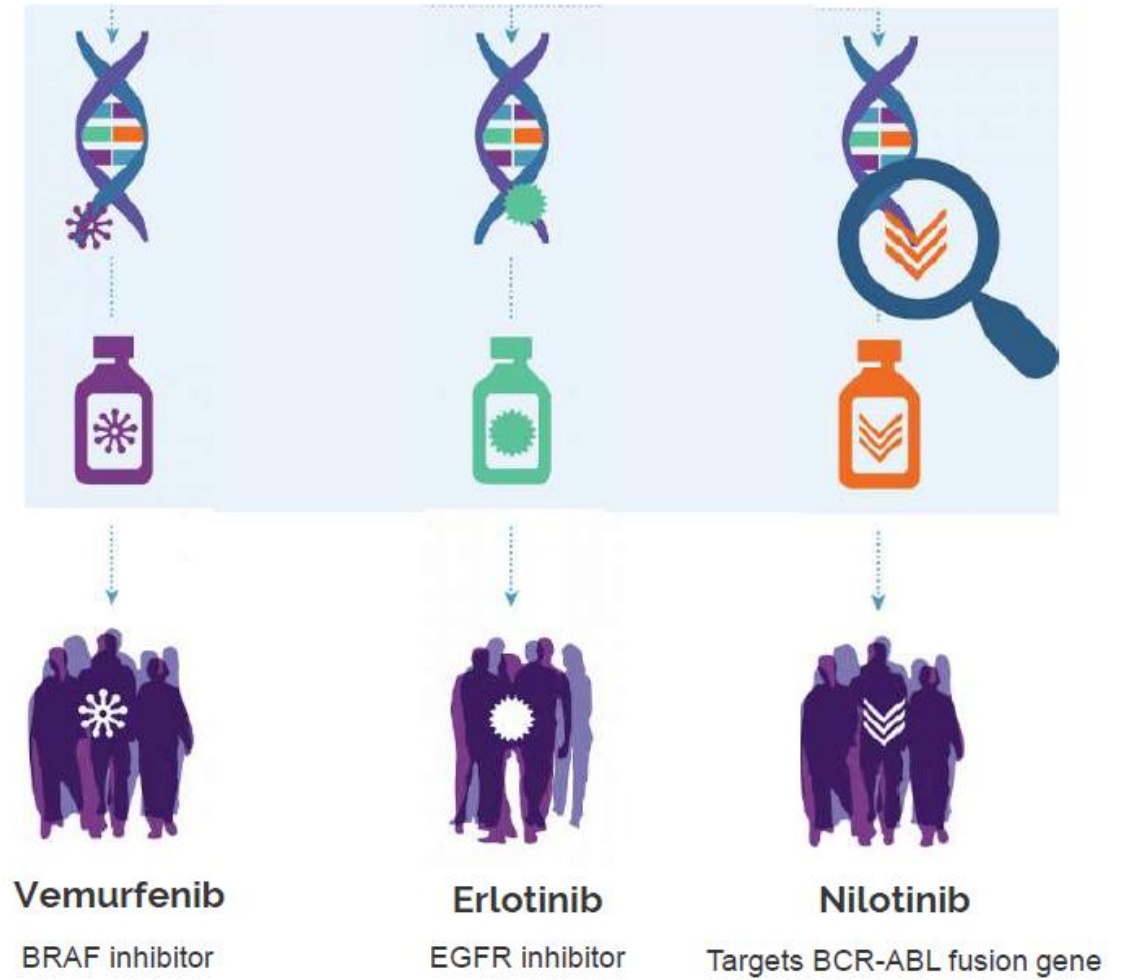


がんゲノムプロファイリング検査における エビデンス収集と評価

フィルジエン株式会社 バイオインフォマティクス部
(support@filgen.jp)

- がんゲノムプロファイリング検査では、次世代シーケンサーを使って検出された遺伝子バリエーションの臨床的意義付けや治療方針の議論が必要で、これには専門的な知識が必要になり、臨床の現場の大きな負担となっています。
- Golden Helix社VarSeq[®]の有償アドオンであるVSClinical AMPでは、体細胞バリエーションなどのバイオマーカーの臨床エビデンスや治療薬、臨床試験情報を提供することで、これらの負担を軽減します。



Annotation

Variant Filtering

Variant Sites	Genotypes	Classification	Compound Het Variants
Chr:Pos	Ref/Alt	Identifier	Proband (NA12878) Mother (NA12891) Father (NA12892)
11:108183167	A/G	rs659243	G_G G_G G_G
13:49033835	G/A	rs20211...	A_G A_G A_G
14:24567498	A/C	rs30211...	C_C C_C C_C
14:73664751	T/G	rs19972...	G_T G_T G_T
14:106208082	G/T	rs11621...	G_T G_T G_T
16:2495482	T/G	rs20154...	G_T T_T G_T

Data Analysis

Genome Browser

- 様々なデータベースを用いて、バリエーションデータ（VCFファイル）へアノテーション付けを実行

- RefSeq Genes
- dbSNP
- ClinVar
- OMIM
- CIViC
- ICGC / TCGA
- MSK Impact
- Orphanet
- BRCA Exchange
- PMKB
- dbNSFP
- REVEL
- CADD
- 1000 Genomes
- NHLBI 6500 Exomes
- ExAC Variant
- gnomAD Exomes/Genomes
- GenomeAsia 100K
- 各種遺伝子パネルのターゲットデータ
- ...など

- アノテーション付けされたバリエーションデータより、任意の検索条件でデータのフィルタリングを行うワークフローを作成

- カバレッジ計算やトリオ解析、表現型情報に基づく遺伝子ランキングなどの解析アルゴリズムを搭載

- ゲノムブラウザーにより、サンプルのバリエーションデータやリードアライメントデータ（BAM/CRAMファイル）、また各種アノテーションを可視化

- 有償アドオンによる機能拡張で、CNV検出や臨床的意義の自動評価、パイプライン機能などが利用可能



VS Clinical (ACMG)

- メンデル遺伝病における生殖細胞系列バリエントを、ACMGガイドラインの33種類の評価基準に基づいて分類し、病源性（Pathogenic）や良性（Benign）の判定を行う
- ガイドラインのうち18種類の評価基準については、バリエントのアレル頻度、機能予測、臨床情報データベースなどを用いて、自動分類を実行
- 専用の分類用ツールを実行することで、VCFファイルに含まれる全バリエントに対して一括で評価を行い、評価結果に基づきバリエントのフィルタリングが可能

VS Clinical (AMP)

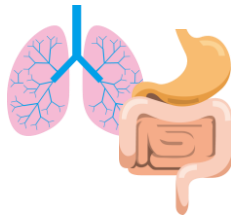
- がんにおける体細胞バリエントの臨床的意義の評価に使用
- 各種バイオマーカー（SNV, InDels, CNV, 融合遺伝子, TMB/MSIなど）をAMPガイドラインのエビデンスレベルで分類し、がんの治療薬や臨床試験情報を含めたレポートを作成
- 主要ながんにおけるバイオマーカー情報などを収録した、専用の知識ベースGolden Helix CancerKBが利用可能
- 体細胞バリエントの腫瘍原性（Oncogenicity）をスコアで評価

Tier	Classification (Therapeutic, Prognostic, Diagnostic)	Evidence Level	Evidence
I	Variants of Strong Clinical Significance	1A	FDA-approved therapy; included in professional guidelines
		1B	Well-powered studies with consensus from field experts
II	Variants of Potential Clinical Significance	2C	FDA-approved therapies in another tumor type or investigational therapies; multiple small studies w/consensus
		2D	Preclinical trials or a few case reports without consensus
III	Variants of Unknown Clinical Significance	3	Not observed at a significant allele frequency in the general or specific subpopulation databases, or pan-cancer or tumor-specific variant databases
IV	Benign or Likely Benign Variants	4	Observed at significant allele frequency in the general or specific subpopulation databases
			No existing published evidence of cancer association

Li et al. "Standards and Guidelines for the Interpretation and Reporting of Somatic Variants in Cancer", 2017

- バイオマーカーに対する、がんの治療方法のアクションビリティに基づいた分類ガイドライン
- 治療薬の感受性や耐性、さらに予後／診断に関する臨床的な評価を、エビデンスレベルで分類を行う

- 同一バイオマーカーの場合でも、がん種ごとに分類結果は異なる
- VSClinical AMPでは、知識ベースから情報を引き出し、バイオマーカーごとのエビデンスレベルを、ソフトウェアが自動的に分類を行う



がん種情報



バイオマーカー



Biomarker	Tumor Type	Clinical Significance
<i>EGFR</i> L858R	Non-Small Cell Lung Cancer	Tier I Level A
<i>TP53</i> R273H	Non-Small Cell Lung Cancer	Tier II Level C
<i>RET</i> Activating Mutation	Non-Small Cell Lung Cancer	Tier I Level A

✓ エビデンスレベル分類



✓ 臨床的解釈



✓ 候補治療薬

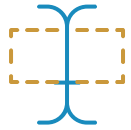


✓ 論文リスト



レポート出力

- がん種とバイオマーカーを入力すると、Golden Helix CancerKBに照合が行われ、自動的にエビデンスレベルや各種の臨床評価情報などが出力される
- Golden Helix CancerKBからの出力結果は、他の知識ベースの情報を参照しながら、編集が可能



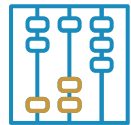
SNVs/Indels, CNVs & Fusion Analysis, Genomic Signatures

様々な遺伝子バリエーションの解析に対応



Evaluation Scripts

スクリプトを利用して、TSO-500、Archer、Ion Torrentなどの結果データをダイレクトにインポート



Combination Biomarkers

陰性所見も含めた、遺伝子バリエーションの複雑な組み合わせにも対応



Golden Helix CancerKB

専門家がキュレーションした、究極の体細胞変異解釈エンジンである知識ベースを搭載



Oncogenicity Classifier

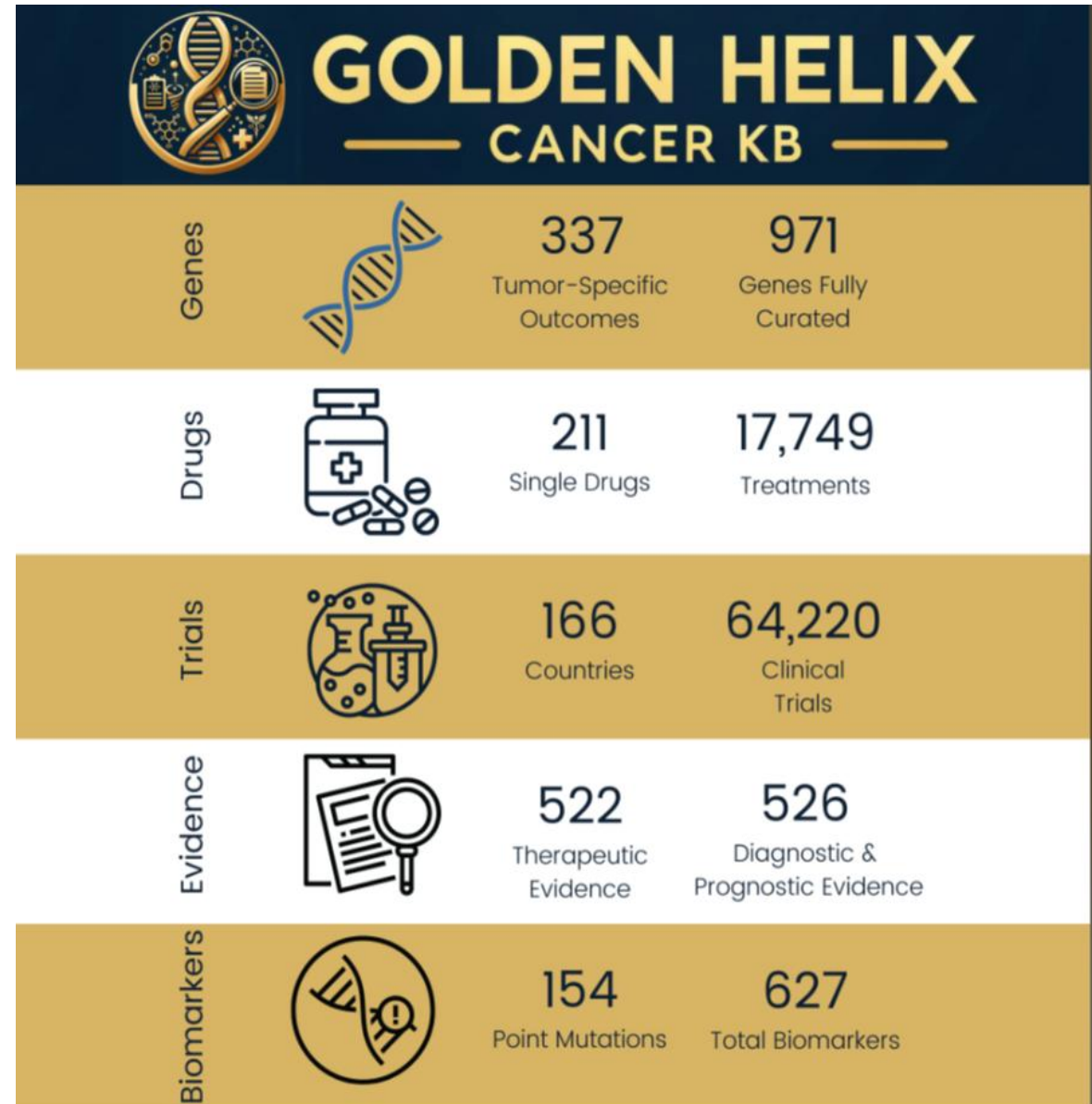
遺伝子パネル、全エクソーム／全ゲノムシーケンスよりドライバー変異を抽出



Global Clinical Trials

高度な検索とフィルターを備えた、グローバルな臨床試験情報が使用可能

- Golden Helix社の臨床エキスパートがマニュアルキュレーションで作成した、がんゲノム医療向けの知識ベース
- 遺伝子またはバイオマーカーごとに、該当がん種のクリニカルエビデンス、臨床的解釈や候補治療薬の組み合わせ、参考論文などの情報が収録されている
- 約1,000個の完全にキュレーションされた遺伝子を掲載
- 主要ながん遺伝子について、腫瘍特異的なアウトカムと頻度を提供
- 150個以上の新しい血液バイオマーカーの説明
- 診断および予後の解釈が100%以上増加
- NCCNガイドライン推奨薬物療法からの200個以上の新しい薬剤感受性解釈
- 患者の治療選択肢とエビデンスの参考となる約65,000件の臨床試験情報



Variants to Evaluate

Small Variants (0) CNVs (0) SVs (0) Genomic Signatures (0) Negative Findings (3)

Gene Variant Mutation (Impact) Origin State Classification Report Last Classified

Variants to Select:

Filter Variants (Variants)

☒ Variant VAF

☐ PIK3CA p.G118D

☒ EGFR p.T790M

☒ EGFR p.L858R

☐ TP53 p.R273H

Mutation Origin:

☐ Germline Suspected ☒ Somatic

Select All Clear All Select

✓ Small Variant

Enter CNV:

EGFR 19

e.x. BRCA2 3-5

Gene Matching Query:

Gene: EGFR

Genomic Region: 7: 55,242,415 - 55,242,513

Clinically Relevant Transcript: NM_005228.5

Number of Exons: 28

Exons Selected: Exon 19

☐ Het Deletion ☒ Deletion ☐ Duplication

☐ Loss of Heterozygosity

Ratio Ratio Z-Score Z-Score

Select

✓ CNV

Enter Fusion:

EML4-ALK

e.x. BCR-ABL1

Genes Matching Query:

Primary Gene: ALK

Genomic Region: 2:29,415,640 - 30,144,452

Clinically Relevant Transcript: NM_004304.5

Secondary Gene: EML4

Genomic Region: 2:42,396,493 - 42,559,688

Clinically Relevant Transcript: NM_019063.5

☐ Automatically Select Primary Gene

Select

✓ Fusion Gene (SV)

Signature:

TMB

Status: High

Quantitative Value:

Unit of Measurement: mut/Mb

Mutation Origin:

☐ Germline Suspected ☒ Somatic

Select

✓ Genomic Signature

- 評価に用いるバイオマーカーは、VCFファイル内のバリエントを選択するか、またはバリエント名を手動で入力
- Small Variantでは体細胞／生殖細胞の選択や、CNVは重複／欠失の設定も行う

EGFR L858R Variant Scoring

Oncogenicity Scoring Recommendations

Recommended to Score Oncogenic:

☒ SC+3	The p.L858R variant occurs in 2676 samples in COSMIC.
☒ CE+3	The p.L858R variant has been previously classified as oncogenic in CIViC.
☒ IP+1	The p.L858R missense variant is predicted to be damaging by both SIFT and PolyPhen2 The leucine residue at codon 858 of EGFR is conserved in all mammalian species The nucleotide c.2573 in EGFR is predicted conserved by GERP++ and PhyloP across 100 vertebrates.
☒ AR+1	The p.L858R variant occurs in an active binding site.
☒ HR+1	The p.L858R variant occurs in a cancer hotspot

Recommended to Score Benign:

No Benign Criteria Recommended

スコアの根拠

Recommendations computed 3 minutes ago - [Rerun](#)

Oncogenicity Classification given Scored Criteria:

Oncogenic (+9)

腫瘍原性スコア

Scored Criteria:

SC+3 CE+3 IP+1 AR+1 HR+1

Oncogenicity Scale and Source:



The Golden Helix Oncogenicity score was developed to provide a criteria-based scoring system similar to the ACMG Guidelines but with the numeric pathogenicity scale introduced by Invitae's Sherlock scoring system. In consultation with the GA4GH Variant Interpretation in Cancer Consortium (VICC) system, the scoring rubric was designed to rank variants by their pathogenicity in the context of cancers. The most common somatic variants in COSMIC were used to tune and benchmark the scoring system along with variants with highly rated clinical evidence in CIViC.

- Small Variantを入力すると、バリエーションごとの腫瘍原性のスコアと分類（Oncogenic, Benign, VUSなど）が表示される
- 腫瘍原性スコアは、データベースの情報やバイオインフォマティクス解析によりソフトウェアが自動で計算し、スコアの算出結果の根拠なども確認が可能

- ✓ Report Tier 1A Drug Sensitivity for EGFR Mutation, EGFR Mutation, EGFR Mutation in Non-Small Cell Lung Cancer:

Drugs: Datopotamab deruxtecan-dlnk

Cancer: Non-Small Cell Lung Cancer (Matching)

Matching Scopes: EGFR Mutation - EGFR L858R (Activating Mutation)
EGFR Mutation - EGFR T790M (Activating Mutation)
EGFR Mutation - EGFR Exon 19 Skipping

Scored Criteria: FDA-approved therapeutic sensitivity evidence

薬剤感受性に関する臨床的解釈

Datopotamab deruxtecan-dlnk (Datroway) is a TACSTD2 (TROP2)-specific antibody-drug conjugate (ADC) composed of a TACSTD2-targeted humanized antibody conjugated to a potent topoisomerase inhibitor (deruxtecan) (PMID: 37387213, 39265124). Datopotamab deruxtecan-dlnk is FDA approved for the treatment of adult patients with locally advanced or metastatic EGFR-mutated non-small cell lung cancer who have received prior EGFR-directed therapy and platinum-based chemotherapy (PMID: 39250535, 39761483, 40516821). FDA approval was based on demonstration of an overall response rate of 45% and a duration of response of 6.5 months for patients treated with the ADC (<https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-datopotamab-deruxtecan-dlnk-egfr-mutated-non-small-cell-lung-cancer>, PMID: 39250535, 39761483, 40516821).

[Less...](#)

Interpretation Actions:

Interpretation History:

[Edit Interpretation...](#)

Previous by CancerKB
a month ago

Inline References for Tier 1A Drug Sensitivity for EGFR Mutation, EGFR Mutation, EGFR Mutation in Non-Small Cell Lung Cancer:

Search Publications...

TROPION-Breast01: Datopotamab deruxtecan vs chemotherapy in pre-treated inoperable or metastatic HR+/HER2- breast cancer.
Future Oncol. 2024 Mar Bardia A et al. PMID 37387213

Datopotamab Deruxtecan Versus Chemotherapy in Previously Treated Inoperable/Metastatic Hormone Receptor-Positive Human Epidermal Growth Factor Receptor 2-Negative Breast Cancer: Primary Results From TROPION-Breast01.
J Clin Oncol. 2025 Jan 20 Bardia A et al. PMID 39265124

Datopotamab Deruxtecan Versus Docetaxel for Previously Treated Advanced or Metastatic Non-Small Cell Lung Cancer: The Randomized, Open-Label Phase III TROPION-Lung01 Study.
J Clin Oncol. 2025 Jan 20 Ahn MJ et al. PMID 39250535

Datopotamab Deruxtecan in Advanced or Metastatic Non-Small Cell Lung Cancer With Actionable Genomic Alterations: Results From the Phase II TROPION-Lung05 Study.
J Clin Oncol. 2025 Apr Sands J et al. PMID 39761483

A Pooled Analysis of Datopotamab Deruxtecan in Patients With EGFR-Mutated NSCLC.
J Thorac Oncol. 2025 Jun 12 Ahn MJ et al. PMID 40516821

TROPION-Breast01: Datopotamab deruxtecan vs chemotherapy in pre-treated inoperable or metastatic HR+/HER2- breast cancer.

PMID: [37387213](#) DOI: [10.2217/fon-2023-0188](#)

> Bardia A et al.

PUBLICATION:
Future Oncol. 2024 Mar

DETAILS:
20(8):423-436.

ABSTRACT:

Improving the prognosis for patients with metastatic HR+/HER2- breast cancer remains an unmet need. Patients with tumors that have progressed on endocrine therapy and/or are not eligible for endocrine therapy had limited treatment options beyond chemotherapy. Antibody-drug conjugates are a novel and promising treatment class in this setting. Datopotamab deruxtecan (Dato-DXd) consists of a TROP2-directed humanized IgG1 monoclonal antibody attached via a serum-stable cleavable linker to a topoisomerase I inhibitor payload. TROPION-Breast01 is an ongoing phase III study that is evaluating the efficacy and safety of Dato-DXd compared with investigator's choice of standard-of-care chemotherapy in patients with inoperable or metastatic HR+/HER2- breast cancer who have received one or two prior lines of systemic chemotherapy in the inoperable or metastatic setting. NCT05104866 (ClinicalTrials.gov).

参考論文の一覧

- エビデンスをクリックすると、臨床的解釈が表示される
- 解釈に用いられた論文とアブストラクトの一覧も表示される

✓ 遺伝子ごとの解釈

☒ Report *EGFR* Clinical Significance:

Interpretation Saved for: All Cancers

Interpretation: [Clear](#)

EGFR (epidermal growth factor receptor) is a proto-oncogene, that encodes a member of the EGFR/ErbB family of tyrosine kinases which also includes ERBB2 (HER2), ERBB3 (HER3), and ERBB4 (PMID: 18259690, 19208461, 22239438, 32219702). EGFR is a cell surface transmembrane glycoprotein and is expressed in tissues of epithelial, mesenchymal, and neuronal origin. EGFR has an important role in regulating normal cellular processes including proliferation, differentiation, development, and survival (PMID: 14666659, 29991287, 32124699, 32593400, 35840984). Oncogenic *EGFR* amplification or mutations in the *EGFR* intracellular domain lead to EGFR overexpression and ligand-independent activation of downstream signaling pathways, resulting either directly or indirectly in increased cell proliferation, angiogenesis, invasion, and metastasis (PMID: 25870793, 29991287, 32069320, 35867821). Germline mutations in the *EGFR* kinase domain are associated with a predisposition to lung cancer (PMID: 30225213, 34670806). Somatic *EGFR* alterations have been reported in lung cancer, glioblastoma, and a variety of additional tumor types (cBioPortal, COSMIC). The most common oncogenic EGFR alterations are gene amplification and missense substitutions.

✓ バリエントごとの解釈

☒ Report EGFR L858R Biomarker Summary:

Matching Scope: EGFR L858R

Cancer: Non-Small Cell Lung Cancer

The *EGFR* p.L858R mutation in exon 21 is one of two classical *EGFR*-activating mutations found in non-small cell lung cancer (NSCLC) (PMID: 30473385, 36099878). *EGFR* p.L858R occurs in the kinase domain within exon 21 and results in ligand-independent phosphorylation of EGFR and other ERBB family proteins (PMID:19922469, 15284455). Structural studies have demonstrated that *EGFR* p.L858R causes destabilization of the inactive conformation of EGFR, resulting in increased receptor dimerization and constitutive EGFR activation (PMID: 17349580, 18031935, 20026433, 22579287). *EGFR* p.L858R results in aberrant downstream signaling through the MAPK and PI3K/AKT pathways, thereby promoting tumorigenesis via altered cell proliferation, differentiation, and migration (PMID: 18045542, 22263017, 25855240, 34455092).

✓ 薬剤ごとの解釈

☒ Report Datopotamab deruxtecan-dlnk:

16 of 16

Name: Datopotamab deruxtecan-dlnk

Commercial Labels: Datroway

Class: Antibody-drug conjugate

Mechanism of Action: TACSTD2 (TROP2)

Status: Approved

Approved For: HR-positive, HER2-negative Breast Cancer, and EGFR-mutated Non-Small Cell Lung Cancer

Indication for Use:

Datopotamab deruxtecan-dlnk (Datroway) is a TACSTD2 (TROP-2)-directed antibody-drug conjugate that is FDA approved for treatment of adult patients with unresectable or metastatic HR-positive, HER2-negative (IHC 0, IHC 1+ or IHC 2+/IHC-) breast cancer who have received prior endocrine-based therapy and chemotherapy (PMID: 37387213, 39265124). This antibody-drug conjugate is also approved for treatment of adults with locally advanced or metastatic *EGFR*-mutated

Description:

Datopotamab deruxtecan-dlnk is a TACSTD2 (TROP2)-specific antibody-drug conjugate (ADC) composed of a TACSTD2-targeted humanized antibody conjugated to a potent topoisomerase inhibitor (deruxtecan) (PMID: 37387213, 39265124). Selective binding of the ADC to TACSTD2 triggers internalization of the ADC complex, deruxtecan-mediated topoisomerase inhibition with accumulation of DNA damage, and cell death (PMID: 34413126, 38434801, 39121594, 39585341).

Resistance Description:

It appears that datopotamab deruxtecan resistance mechanisms may develop over time of therapy in response to adaptation of cancer cells. Potential mechanisms that have been identified include loss of SLFN11, a putative DNA/RNA helicase that sensitizes cells to DNA-damaging agents (PMID: 33653945, 34413126, 34663950). Other possible mechanisms may include alteration in topoisomerase expression, reduction expression of TACSTD2, mutation of *TACSTD2*, altered expression of drug efflux pumps, enhanced DNA damage repair, and activation of pro-survival signaling pathways (PMID: 30897808, 33953682, 34413126).

- 臨床的解釈は、遺伝子レベルやバリエントレベル、さらに薬剤レベルごとのものが確認可能
- 解釈に用いられた論文リストも閲覧可能

[Trials](#) [Drugs](#) [Biomarker](#) [Evidence](#)

Recruiting Trials in:

☒ Filter by distance:

miles of in

Matching Trials (8) [Trials by Drug](#)

☐ NCT06646276

2 of 8

[Summary/Diseases](#) [Inclusion Criteria](#)

Status: ☒ Recruiting

Phase: Phase 3

Start/End: February 25, 2025 → September 5, 2031

Eligibility: Age 18 Years+, Male or Female

Drugs: Atezolizumab + Carboplatin + Etoposide
Bms-986012+Nivolumab + Carboplatin + Etoposide

Diseases: Extensive-Stage Small Cell Lung Cancer

A Study to Compare the Efficacy and Safety of BMS-986012+ Nivolumab Fixed Dose Combination) in Combination With Carboplatin Plus Etoposide to That of Atezolizumab With Carboplatin Plus Etoposide as First-Line Therapy in Participants With Extensive-Stage Small Cell Lung Cancer (TIGOS).

The Purpose of the Study is to Compare the Efficacy and Safety of BMS-986489 (Anti-fucosyl-GM1+ Nivolumab Fixed Dose Combination) in Combination with Carboplatin plus Etoposide to that of Atezolizumab with Carboplatin plus Etoposide as First-Line Therapy in Participants with Extensive-Stage Small Cell Lung Cancer.

Source: ClinicalTrials.gov NCT06646276 (2025-07-01)

[Summary/Diseases](#) [Inclusion Criteria](#) [Sites\(24\)](#)

Sites near Japan

☒ Matsuyama, Japan (Recruiting)
National Hospital Organization Shikoku Cancer Center
Takashi Ninomiya, Site 0319 Ph: +81899991111

☒ Kurume, Japan (Recruiting)
Kurume University Hospital
Koichi Azuma, Site 0292 Ph: 81942317629

☐ Sapporo, Japan (Recruiting)
Hokkaido University Hospital
Yasuyuki Ikezawa, Site 0313 Ph: 011-706-5911

☐ Kobe-shi, Japan (Recruiting)
Kobe City Medical Center General Hospital
Yuki Sato, Site 0323 Ph: 0783024321

☐ Kanazawa, Japan (Recruiting)
Kanazawa University Hospital
Seiji Yano, Site 0321 Ph: 81762652000

- 臨床試験情報の設定エリアにて国名を選択すると、薬剤ごとの臨床試験が下に表示され、内容を確認できる
- 試験名にチェックを入れると、レポートに臨床試験の実施サイトを記載することが可能

レポートの作成



Patient Name
NSCLC Sample

Report Date
(DRAFT)

Tumor Type
NSCLC

Patient Information		Reference Information	Sample Information
Patient Name	NSCLC Sample	Ordering Physician	Specimen Site
DOB		Order Date	Collection Date
Sex	Unknown	Contact/Recipient	Received Date
MRN		Additional	Accession #

This report is generated by software designed to support healthcare professionals by providing recommendations regarding strategy based on detected genotypes. It is imperative that healthcare professionals independently verify and evaluate these recommendations for diagnosis, treatment, or prescription, and not rely solely on this software for making clinical decisions regarding individual patients' treatment and prescription needs.

ABOUT THE TEST

Golden Labs utilizes a Next Generation Sequencing (NGS) based assay of cancer-related genes to detect relevant genes to provide therapeutic guidance, disease diagnostic evidence or prognostic indication. See Methods and Limitations.

RESULTS SUMMARY

Negative Findings

No pathogenic single nucleotide variants, indels, copy number changes, or structural variations found in the following genes: | ROS1 |

Genomic Signatures

The following genomic signature(s) were analyzed for this sample:

TMB: High

Genomic Finding	Number of Findings Detected
Genomic Findings with Clinical Evidence	4
Genomic Findings with Prognostic/Diagnostic Evidence	0
Variants with Potential Significance	0
Germline Alterations	0

GENOMIC FINDINGS WITH EVIDENCE OF CLINICAL SIGNIFICANCE

GENOMIC FINDINGS WITH CLINICAL EVIDENCE

GENOMIC FINDING	FDA-APPROVED THERAPIES IN PATIENT'S TUMOR TYPE	THERAPIES OF POTENTIAL SIGNIFICANCE	RESISTANCE	POTENTIAL CLINICAL ACTION
Unspecified	Afatinib, Atezolizumab, Bevacizumab, Durvalumab,	None	None	Yes, see clinical

Signed Electronically by DRAFT | Medical Director: Leonard McCoy, M.D. | CLIA Number: 1234ABCD | (Not Signed Off)



Patient Name
NSCLC Sample

Report Date
(DRAFT)

Tumor Type
NSCLC

EGFR T790M	Necitumumab, Nivolumab, Pembrolizumab, Ramucirumab (1A) Osimertinib (1A)	None	Afatinib, Dacomitinib, Erlotinib, Gefitinib (1A)	No
EGFR L858R	Afatinib, Afatinib + Cetuximab, Amivantamab-vmjw, Amivantamab-vmjw + Lazertinib, Dacomitinib, Erlotinib, Erlotinib + Ramucirumab, Gefitinib, Osimertinib (1A)	None	None	No
EGFR Exon 19 Skipping	Datopotamab deruxtecan-dlnk (1A)	None	None	No
EGFR L858R				
EGFR T790M				
TMB High	Pembrolizumab (1A)	None	None	No

OTHER REPORTED BIOMARKERS

GENE	TYPE	DESCRIPTION	GENE	TYPE	DESCRIPTION
ALK	Fusion	Fusion with EML4	ROS1	Gene mutation	Negative Finding

GENOMIC FINDING DETAILS

Sensitivity to Drugs:

Tier I - Level A

Afatinib
Atezolizumab
Bevacizumab
Durvalumab
Necitumumab
Nivolumab
Pembrolizumab
Ramucirumab

Resistance to Drugs:

None

Unspecified Drug Sensitivity:

Tier I - Level A

The following targeted therapies are FDA/EMA approved and/or recommended by NCCN guidelines for the treatment of patients with non-small cell lung cancer (NSCLC) with resectable or unresectable/metastatic tumors, of squamous and/or non-squamous histology, whose disease is stable after chemotherapy, or progressed on or following treatment with chemotherapy and/or EGFR/ALK inhibitors (NCCN Guidelines for NSCLC). These therapies are recommended as adjuvant, neoadjuvant, or follow-up therapies, and may be administered as monotherapy or in association with chemotherapy, depending on the medication (NCCN Guidelines for NSCLC). Atezolizumab (Tecentria) (PMID: 27979383) and durvalumab (Imfinzi) (PMID: 28885881, 30280658, 32209338, 33583206, 34731446) are injectable immune checkpoint inhibitor (ICI) monoclonal antibodies (mAbs) that inhibit PD-L1 (PMID: 34937915, 28878676). Pembrolizumab (Keytruda) (PMID: 34262612, 36108662, 36174774, 37272513) and nivolumab (Opdivo, Opdivo Qvantig) (PMID: 35403841, 26028407, 26412456, 29023213, 33449799, 37141544, 38098261) are injectable ICI mAbs that target PD-1

Signed Electronically by DRAFT | Medical Director: Leonard McCoy, M.D. | CLIA Number: 1234ABCD | (Not Signed Off)

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- レポート出力ボタンをクリックすると、バリエーションや臨床的解釈、治療薬、出典論文などの情報をまとめたレポートが作成される
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