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FDA Companion Diagnostic Drug Label Crosswalk Matrix

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Executive Summary

An **FDA companion diagnostic drug label crosswalk** must connect an authorized device claim to a specific therapy indication, biomarker predicate, specimen and label version. FDA directs users to the therapeutic label as well as the device record. ([fda.gov](https://www.fda.gov)) Shared gene names are insufficient: QIAGEN distinguishes mutation-positive selection from a KRAS “No Mutation Detected” relationship, while Illumina distinguishes companion diagnostic findings from broader tumor profiling. ([qiagen.com](https://www.qiagen.com)) ([illumina.com](https://www.illumina.com)) The operational unit is the treatment relationship, including its regimen and eligibility boundaries.

This report uses an **October 13, 2026 cutoff**, with retrieval on October 15, and explicitly selects **seven relationships** spanning BRAFTOVI, ORSERDU, TAGRISSO, RETEVMO and TEPMETKO. Its matrix retains application and supplement identifiers, decision dates, specimens and source documents. **Three records have the specified public-label comparison; four retain a current-device-revision or label-package question.** The resulting **42.9% closure rate** is calculated only within this selected cohort. BRAFTOVI's prior-therapy colorectal regimen, ORSERDU's plasma ESR1 selection and RETEVMO's tumor-specimen selection illustrate why the drug indication must remain attached to each mapping. (labeling.pfizer.com) (pi.orserduhcp.com) (retevmo.lilly.com)

Authorization is distinct from complete version reconciliation. FDA's **P250027 approval order** specifies companion diagnostic use with the therapies in Table 1, in accordance with approved therapeutic product labeling. FDA's available technical document is marked draft in the approval package. (accessdata.fda.gov) The checked TEPMETKO label remains dated February 2024, making its historical patient-selection wording a reconciliation issue alongside the later device event documented in the matrix. (emdserono.com) TAGRISSO's selection table separately limits which settings accept plasma, and Roche's HER2 information demonstrates that instrument and jurisdiction can matter. (dailymed.nlm.nih.gov) (diagnostics.roche.com)

The recommended implementation is a controlled relationship dataset shared by regulatory information management, laboratory information systems and medical information. It should retain source revisions, assay/software context, specimen links and explicit unresolved statuses. Health Level Seven (HL7)'s genomic reporting model associates findings with specimens; Logical Observation Identifiers Names and Codes

(LOINC) separates molecular reporting elements. (hl7.org) (loinc.org) The supplied dictionary, bounded coverage calculation and correction policy support auditable updates without asserting national FDA-list coverage or test interchangeability.

Introduction and Background

An **FDA companion diagnostic drug label crosswalk** should answer a precise operational question: which authorized device, specimen and biomarker definition support a particular treatment indication, under which documents? FDA maintains separate lists for devices tied to named therapies and devices carrying group indications, and directs readers to the therapeutic label for the treatment requirements. The list also addresses generic and biosimilar equivalents; a brand-name match alone is therefore an incomplete reconciliation.

(fda.gov)

This distinction matters when a drug has several treatment settings. **BRAFTOVI**, for example, has a colorectal regimen with cetuximab and fluorouracil-based chemotherapy and a separate cetuximab combination after prior therapy. Those regimen boundaries belong in the relationship record rather than being collapsed into “BRAF-positive colorectal cancer.” (labeling.pfizer.com) (labeling.pfizer.com) Similarly, **RETEVMO** distinguishes RET-mutant medullary thyroid cancer from RET fusion-positive thyroid cancer, with additional treatment and eligibility qualifications. (pi.lilly.com) (pi.lilly.com)

The audience is regulatory operations, oncology development, molecular pathology, and clinical information technology teams. For those teams, the deliverable is an evidence model that preserves differences across labels. The report's adjacent advisory perspective is consistent with IntuitionLabs' stated work implementing and integrating enterprise life-sciences applications; IntuitionLabs is not an assay or therapy option in the matrix. (intuitionlabs.ai)

Several documentation patterns reinforce this approach. **Thermo Fisher** separates companion diagnostic findings from analytical-only findings in its reporting description. **Illumina** likewise cautions that findings outside its intended-use table are not conclusive or prescriptive for labeled use of a specific therapy. A broad panel result therefore needs an indication-level check before it becomes a treatment-selection assertion. (thermofisher.com) (illumina.com)

The crosswalk below is a deliberately bounded public-source cohort. It documents evidence and unresolved version questions rather than presenting every entry on the live FDA list as fully reconciled. Its methods, status definitions, and correction rules make that limitation measurable.

Scope, Methods, and Relationship Model

Dates and evidence hierarchy

The publication cutoff is **October 13, 2026**. Research retrieval occurred on **October 15, 2026**; this is a retrospective cutoff analysis, not a claim that the pages were fetched on publication day. Only identified decisions and documents dated on or before the cutoff inform the event log. An undated live page is supporting context, not proof of its exact historical content.

The record model separates **decision date**, **document revision**, **webpage update**, and **retrieval date**. These fields describe different events; the verified event dates appear in Table 2. Illumina's documentation index separately identifies analysis-module and claims-package versions, demonstrating another reason a single "version" field is inadequate. (support.illumina.com)

This report uses the following evidence order:

- **Discovery:** Identify candidate relationships in FDA's authorized-device tables.
- **Authorization:** Open the relevant original application or supplement.
- **Device evidence:** Capture intended use, specimen, biomarker and accessible labeling.
- **Therapy evidence:** Compare the drug's indication and patient-selection instructions.
- **Version classification:** Distinguish a published label check from approval-package evidence or an unresolved current revision.
- **Release decision:** Require the responsible team to close remaining version questions before operational deployment.

These are the report's research rules, not a new regulatory pathway. The caution about versions is explicit in FDA's original FoundationOne CDx record, which says its labeling may not be the most recent and directs users toward supplements. (accessdata.fda.gov)

The relationship, rather than the gene, is the unit

The recommended key joins therapy application, indication, regimen, biomarker predicate, specimen, device application and supplement. A biomarker predicate means the actual qualifying condition: a particular alteration, absence of specified alterations, or a defined expression score. **QIAGEN's theascreen KRAS** page illustrates the distinction: the assay detects specified KRAS mutations, while some therapeutic relationships use a "No Mutation Detected" result. (qiagen.com) (qiagen.com)

Terminology should remain structured. **LOINC**, Logical Observation Identifiers Names and Codes, provides separate molecular-reporting elements for gene, genomic and transcript reference sequence, variant identifier, and sequence changes. **HGNC**, the HUGO Gene Nomenclature Committee, supplies identifiers that remain stable when approved symbols change. These standards support durable identifiers alongside readable gene names. (loinc.org) (hgnc.genenames.org)

The selected cohort contains seven relationship records, defined explicitly in Table 1. It is a purposive sample, not a national census. "Label checked" means the cited public device labeling was compared with cited therapy selection language. "Revision pending" means approval evidence exists but the latest operational device-label package was not established. Neither status asserts a complete historical review of all later supplements.

Drug, Indication, and Device Crosswalk

Table 1 is the core source-linked matrix. Application identifiers and abbreviated biomarker entries are taken from FDA's authorized-device list: BRAFTOVI NDA 210496, RETEVMONDA 213246, TEPMETKO NDA 214096, TAGRISSO NDA 208065, and ORSERDU NDA 217639. **NDA** means New Drug Application; **PMA**

means Premarket Approval. A supplement identifier is retained separately from its parent PMA. ([fda.gov](https://www.fda.gov))

For readability, **NGS** means next-generation sequencing; **FFPE** means formalin-fixed, paraffin-embedded; **NSCLC** means non-small cell lung cancer. **SNV** and **MNV** mean single-nucleotide and multinucleotide variant. Plasma **cfDNA** is circulating cell-free deoxyribonucleic acid (DNA). **ER** means estrogen receptor; **HER2** means human epidermal growth factor receptor 2. **IFU** means instructions for use, and **BLA** means Biologics License Application. The table lists therapeutic eligibility in abbreviated form: the cited drug label remains necessary for the complete indication.

Record and therapy application	Selected indication and regimen	Biomarker predicate	Specimen and platform	Device and application	Decision date	Drug-label source/version	Reconciliation status
R1: BRAFTOVI, NDA 210496	Adult metastatic colorectal cancer, with cetuximab after prior therapy	BRAF V600E	Plasma cfDNA ; NGS	Guardant 360 CDx, P200010/S026	2026-01-15	February 2026; plasma or tumor permitted, tissue after plasma-negative (labeling.pfizer.com)	Public device labeling checked; S026 technical information LBL-000505 R1 (accessdata.fda.gov)
R2: BRAFTOVI, NDA 210496	Same selected colorectal regimen as R1	BRAF V600E	Plasma cfDNA ; NGS	Guardant 360 Liquid CDx, P250027	2026-05-19	February 2026; prior-therapy regimen retained (labeling.pfizer.com)	Approval-package labeling checked; current commercial revision pending (accessdata.fda.gov)
R3: ORSERDU, NDA 217639	ER-positive, HER2-negative, ESR1-mutated advanced/metastatic breast cancer after endocrine therapy	ESR1 missense mutations between codons 310 and 547	Plasma cfDNA ; NGS	Guardant 360 Liquid CDx, P250027	2026-05-19	June 2026; plasma ESR1 patient selection (pi.orserduhcp.com)	Approval-package labeling checked; current commercial revision pending; same approval package as R2
R4: TAGRISSO, NDA 208065	Selected metastatic NSCLC settings; precise regimen/line determines eligibility	EGFR exon 19 deletions, L858R, or T790M, according to indication	Plasma cfDNA ; NGS	Guardant 360 Liquid CDx, P250027	2026-05-19	DailyMed updated 2026-09-14; displayed revision 9/2024 (dailymed.nlm.nih.gov)	Approval-package mapping only; current revision and setting-level closure pending; same approval package as R2
R5: RETEVMO, NDA 213246	Advanced/metastatic thyroid cancer requiring systemic therapy; radioactive iodine-refractory when appropriate	RET fusion	FFPE tumor; NextSeq 550Dx	TruSight Oncology Comprehensive, P230011/S006	2026-08-14 (accessdata.fda.gov)	July 2026; full thyroid eligibility applies (pi.lilly.com)	Public S006 package insert checked (accessdata.fda.gov)

Record and therapy application	Selected indication and regimen	Biomarker predicate	Specimen and platform	Device and application	Decision date	Drug-label source/version	Reconciliation status
R6: RETEVMO, NDA 213246	Advanced/metastatic medullary thyroid cancer (MTC) requiring systemic therapy	RET SNVs, MNVs, insertions or deletions within labeled scope	FFPE tumor; NextSeq 550Dx	TruSight Oncology Comprehensive, P230011/S006	2026-08-14	July 2026; RET-mutant MTC, adults and children aged at least two years (pi.lilly.com)	Public S006 package insert checked; same device source as R5
R7: TEPMETKO, NDA 214096	Adult metastatic NSCLC; do not broaden therapy eligibility to every device-described setting	Alterations leading to MET exon 14 skipping	FFPE tumor; tissue NGS	FoundationOne CDx, P170019/S067	2026-05-12 (accessdata.fda.gov)	Manufacturer PDF revised February 2024 (emdserono.com)	S067 current IFU unavailable in checked record; therapy/device version reconciliation pending (foundationmedicine.com)

The matrix supports several relationships without declaring tests interchangeable. R1 and R2 concern different devices and application records, even though both selected relationships involve BRAF V600E and plasma. R5 and R6 share a device supplement but differ in disease and alteration class. R7 deliberately preserves a narrower drug indication where the device record mentions advanced or metastatic disease.

The **label-version limitation** is especially relevant for R2 through R4. FDA's available Guardant360 Liquid technical information is identified as **LBL-000496 R3 (Draft), May 2026**. It is useful approval-package evidence; it does not establish the current manufacturer's distributed revision. FDA's [P250027 approval order](#) specifies companion diagnostic use with the therapies in Table 1, in accordance with approved therapeutic product labeling. The laboratory should separately confirm the final controlled label used in its implementation.

For R7, Foundation Medicine distinguishes tissue-based FoundationOne CDx from plasma-based FoundationOne Liquid CDx. The similar names do not justify changing the specimen field. The selected TEPMETKO relationship concerns the tissue device. (foundationmedicine.com)

Approval History and Label-Version Differences

Table 2 separates a decision from publication or revision activity. It also identifies what the checked documents can establish. A label-difference record should contain the actual old and new passages; an approval announcement alone cannot supply that redline.

Event or comparison	Verified dates or versions	What is established	What remains outside the evidence
Guardant360 CDx colorectal expansion	FDA decision 2026-01-15; notice 2026-01-16; webpage update 2026-10-12 (accessdata.fda.gov)	S026 adds BRAF V600E colorectal selection for BRAFTOVI plus ERBITUX	The webpage update is not another indication approval

Event or comparison	Verified dates or versions	What is established	What remains outside the evidence
FoundationOne CDx and TEPMETKO	FDA decision 2026-05-12, sourced in R7; manufacturer announcement 2026-05-21 (foundationmedicine.com)	Device authorization and announcement are separate events	S067 current IFU and drug-label-version closure remain pending
Guardant360 Liquid CDx launch	FDA approval 2026-05-19; manufacturer announcement 2026-05-20 (accessdata.fda.gov) (investors.guardanthealth.com)	New parent PMA; approval package describes named-drug relationships	A complete later-revision history was not verified
BRAFTOVI patient-selection comparison	Checked March 2025 S018 and February 2026 S021 labels (accessdata.fda.gov) (accessdata.fda.gov)	Both contain plasma-negative follow-up tissue-testing instructions for colorectal selection	The comparison does not establish when plasma eligibility first entered labeling

The practical conclusion is that a **new approval**, **new label revision**, and **newly observed webpage** must be different change types. BRAFTOVI illustrates the value of an actual comparison: plasma selection was already present in the checked earlier label. Calling it a new testing option introduced by the later version would misstate the evidence.

Other differences cannot be resolved by choosing whichever document is newer. The checked TEPMETKO manufacturer label says an FDA-approved selection test is unavailable, while **FDA supplement P170019/S067** expands FoundationOne CDx's intended use to detect MET exon 14 skipping alterations in advanced or metastatic NSCLC patients who may benefit from TEPMETKO. The historical label statement should remain attached to that revision, with the discrepancy routed for regulatory reconciliation. (emdserono.com) (foundationmedicine.com)

Similarly, Illumina's live United States (US) overview still describes a narrower companion diagnostic table than the later expansion for RET fusions in thyroid cancer and RET small DNA variant mutations in medullary thyroid cancer established in **FDA supplement P230011/S006**. Its documentation index contains independently versioned claims packages. Neither a live overview nor the first downloadable document should be silently treated as the entire current authorization. (illumina.com) (support.illumina.com)

One additional FDA-list item was excluded from the cohort. The FoundationOne CDx ITOVEBI entry identifies P170019/S062 but labels the specimen "Breast Cancer - Plasma," while the original FoundationOne CDx record describes tissue. The checked supplement navigation did not resolve the conflict. No specimen was inferred or corrected in this report. (fda.gov)

Analysis of Key Segments

Named-drug versus group-labeling decision tree

FDA's final group-labeling guidance does not treat a common molecular target as sufficient evidence of interchangeability. It discusses differences in cutoffs, filters and other assay design features, and describes clinical experience with at least two approved therapies as part of its broader-labeling considerations. These are development considerations, not permission to relabel an individual result locally. (fda.gov) (fda.gov)

For an implementation team, the following decision sequence is appropriate:

- **Identify the device claim:** Determine whether the relevant authorized intended use names an individual therapy or a group.
- **Match the disease:** Compare tumor type and treatment setting rather than searching only the gene symbol.
- **Match the predicate:** Preserve the alteration class, enumerated variants, score and threshold.
- **Match the specimen:** Require the specimen permitted for that particular device and drug setting.
- **Check therapy boundaries:** Retain regimen, treatment line, age and other eligibility conditions.
- **Record exceptions:** Keep an unresolved result outside any automatic eligible-treatment response until the designated owner closes it.

The same process applies when a drug name has a generic or biosimilar equivalent. FDA directs readers to the relevant therapeutic product labeling; a dictionary of brand aliases should support retrieval, not replace that review. ([fda.gov](https://www.fda.gov))

Tissue versus plasma is an indication-level question

The checked **ORSERDU** prescribing information specifies ESR1 mutations in plasma, and the manufacturer's testing explanation identifies the specimen as circulating tumor DNA. That does not make a tumor-tissue finding an automatically equivalent labeled selection result. (pi.orserduhcp.com) (orserduhcp.com)

For **TAGRIS**, the retrieved patient-selection table distinguishes tissue-only selection in adjuvant and unresectable locally advanced settings from plasma-or-tumor selection in listed metastatic settings. A plasma-authorized device relationship therefore should not be propagated to every osimertinib indication. The stage III indication also includes a prior chemoradiation condition that a gene-only crosswalk would miss.

(dailymed.nlm.nih.gov) (dailymed.nlm.nih.gov)

For R4's Guardant360 Liquid CDx assay, FDA's **P250027 approval order** adds a T790M-specific qualification: TAGRIS efficacy has not been established in plasma-positive patients whose tissue is negative or whose tissue status is unknown; clinical data for T790M plasma-positive patients are limited, so plasma testing is most appropriate when a tumor biopsy cannot be obtained. This assay-specific qualification should be retained alongside the drug label's general specimen-selection rules.

Negative-plasma handling also requires explicit logic. The checked TEPMETKO label recommends plasma testing when biopsy cannot be obtained and calls for reassessing biopsy feasibility after a negative plasma result. This is version-specific therapeutic language. (emdserono.com) (emdserono.com) Foundation Medicine's description similarly directs plasma-negative companion diagnostic findings toward tumor testing when feasible, but its wording should not be substituted for another assay's instructions.

(foundationmedicine.com)

The **College of American Pathologists (CAP)** lung guideline provides a useful, explicitly historical example: its 2018 progression-setting EGFR T790M recommendation calls for tumor re-biopsy testing if plasma is negative. That professional recommendation supports careful interpretation; it is not a new device authorization. (cap.org)

Scores, gene names, and assay outputs require separate fields

An immunohistochemistry result cannot be represented adequately by “programmed death-ligand 1 (PD-L1) positive.” **Agilent** defines tumor proportion score using viable tumor-cell staining, while combined positive score includes specified immune cells in its numerator. The scoring algorithm therefore belongs next to the threshold and disease indication in the model. ([agilent.com](https://www.agilent.com)) ([agilent.com](https://www.agilent.com))

Similarly, **Roche's PATHWAY HER2** gastroesophageal adenocarcinoma indication is restricted to the BenchMark ULTRA instrument in [FDA's P990081/S060 approval order](https://www.fda.gov/oc/ohrt/p990081-s060-approval-order). The same page distinguishes US and European Conformity (CE) documentation, with different package-insert references. A global product name alone is not a reliable US label identifier. ([diagnostics.roche.com](https://www.diagnostics.roche.com)) ([diagnostics.roche.com](https://www.diagnostics.roche.com))

Additional distinctions should remain visible:

- **Panel scope:** QIAGEN's specified KRAS panel is not synonymous with every possible KRAS alteration. ([qiagen.com](https://www.qiagen.com))
- **Result direction:** A “No Mutation Detected” selection relationship requires a different predicate from a mutation-positive relationship. ([qiagen.com](https://www.qiagen.com))
- **Report category:** Oncomine distinguishes companion diagnostic results from analytical-only biomarker results. ([thermofisher.com](https://www.thermofisher.com))
- **Specimen preparation:** Oncomine's stated FFPE validation does not establish thyroid fine-needle aspirate validation. ([thermofisher.com](https://www.thermofisher.com))
- **Inherited findings:** The National Cancer Institute (NCI) distinguishes tumor testing from confirmation of potentially inherited findings. ([cancer.gov](https://www.cancer.gov))
- **Time of testing:** NCI notes that cancer biomarkers can change, supporting retention of collection and reporting dates. ([cancer.gov](https://www.cancer.gov))

These examples concern data interpretation rather than comparative clinical performance. No assay ranking follows from the crosswalk.

Data Analysis and Evidence

What the selected denominator measures

The denominator is the **seven explicitly selected relationships in Table 1**. It comprises one older Guardant360 relationship, three Guardant360 Liquid relationships, two TruSight thyroid relationships, and one FoundationOne TEPMETKO relationship. The denominator is a report design choice, not a count of all FDA-authorized relationships.

Using the status definitions above, **three of seven records, or 42.9%**, have a public device-label and therapy-selection comparison without the specific outstanding device-document issue flagged here. **Four of seven, or 57.1%**, retain an unresolved current-device-revision or label-package question. These percentages are calculations from Table 1: $3 \div 7 \times 100$ and $4 \div 7 \times 100$, rounded to one decimal place. They measure evidence closure within this cohort, not test availability or regulatory approval rates.

The distinction is necessary because all selected records have authorization evidence, while complete operational version closure is a different question. FDA's P250027 approval order specifies companion diagnostic use with its Table 1 therapies in accordance with approved therapeutic product labeling; the Illumina documentation index separately exposes claims-package versions. Neither fact alone proves that a laboratory's installed document and software package match the applicable authorization.

(accessdata.fda.gov) (support.illumina.com)

National coverage is not calculated. FDA's live table was not independently normalized into a deduplicated denominator of indication, therapy, specimen and supplement relationships. Reporting a national percentage without that work would conflate devices, rows, and therapeutic indications.

Quantitative fields that must not be collapsed

The checked technical documents contain an instructive pair of clinical limitations. Guardant360 CDx S026 describes BRAFTOVI plus ERBITUX efficacy as not established below **0.04% mutant allele fraction** for BRAF V600E; Guardant360 Liquid's approval-package technical information uses **0.06%**. These are different devices' labeled clinical limitations, not evidence of comparative accuracy and not universal positivity thresholds.

(accessdata.fda.gov) (accessdata.fda.gov)

A second category is a scoring calculation. Agilent describes combined positive score as the qualifying stained cells divided by viable tumor cells, multiplied by **100**. This arithmetic differs from a simple tumor-cell proportion and should remain distinguishable in a laboratory information system. ([agilent.com](https://www.agilent.com))

A third category is an analytical capability recommendation. CAP's historical lung guideline discusses EGFR T790M detection in as little as **5% viable cells** in its specified secondary-resistance context. It should not be imported as a minimum allele fraction for every plasma assay or treatment relationship. ([cap.org](https://www.cap.org))

The recommended quantitative checks are:

- **Denominator test:** Recount relationships after splitting or merging an indication.
- **Unit test:** Preserve percentages, cell proportions and allele fractions as different measurement concepts.
- **Boundary test:** Distinguish a clinical-evidence limitation from an assay calling threshold.
- **Missingness test:** Report unknown values explicitly instead of using zero.
- **Revision test:** Compare values only after confirming device, specimen, jurisdiction and document version.

This report includes no fabricated assay-performance comparison, market-size estimate, or extrapolated patient count. The useful quantitative result is the bounded reconciliation inventory and the demonstration that superficially similar numerical fields can carry different meanings.

Implications and Future Directions

Field ownership across RIM, LIS, and medical information

A crosswalk should have accountable owners rather than a single editable spreadsheet. **Regulatory information management (RIM)** should own application identifiers, authorized indication text and the controlled source versions. A **laboratory information system (LIS)** team should own local specimen codes, assay implementation and report presentation. Medical-information teams should own the wording of treatment-selection responses generated from those records. These are proposed ownership assignments, not FDA-prescribed organizational roles.

The interoperability standards provide useful building blocks. **HL7 Fast Healthcare Interoperability Resources (FHIR)** Genomics Reporting separates report metadata from structured findings and expects genomic findings to have a specimen association. That supports preserving both a readable report and machine-readable observation context. (hl7.org) (hl7.org) Its observation guidance also identifies effective date, issued date and status as distinct elements. (hl7.org)

Table 3 is the proposed export dictionary for the crosswalk. Field ownership is recommended; standards citations describe available data structures rather than an implementation mandate.

Field group	Stored value or rule	Suggested accountable owner
relationship_id and status	Stable record ID; label_checked or revision_pending; unresolved reason	Cross-functional data steward
therapy_application and regimen	NDA/BLA, active ingredient, exact indication and combination	Regulatory operations
device_application and supplement	Parent PMA and separate supplement; preserve original application	Device regulatory lead
biomarker_predicate	Gene identifier, alteration class, qualifying set, score or absence condition	Molecular pathology
reference_sequence and variant	Separate transcript/genomic references and variant representations (loinc.org)	Molecular informatics
gene_identifier and alias	Stable HGNC ID plus current and previous symbols (hgnc.genenames.org) (hgnc.genenames.org)	Terminology steward
specimen and platform	Material, preparation, collection constraints, instrument and software	Laboratory operations
source_document and revision	Exact URL, document identifier, jurisdiction, version and access date	Document control
effective_at and recorded_at	Preserve clinical/regulatory event time separately from ingestion time (hl7.org)	Integration team
evidence_text and correction_log	Supporting passage, prior value, rationale and approving owner	Quality/document control

The dictionary intentionally separates a finding from the assertion that it satisfies a particular therapy relationship. **LOINC's molecular naming guidance** uses gene and variant naming conventions; it does not itself authorize a treatment. Terminology normalization should improve matching while retaining the original label wording for review. (loinc.org)

The **Association for Molecular Pathology (AMP)** reporting project addresses specific report elements, format and content. Its announcement explains that laboratories' own formats can vary substantially. This supports explicit mapping and report reconciliation rather than assuming that the same clinical meaning occupies the same field everywhere. (amp.org) (amp.org)

Acceptance checks before release

A useful implementation review should test the following behaviors:

- **Specimen linkage:** A genomic finding cannot lose its associated specimen during export. (hl7.org)
- **Temporal linkage:** Observation effective time, issued time and status survive interface translation. (hl7.org)
- **Reference linkage:** Gene, transcript and variant fields remain separate during normalization. (loinc.org)
- **Alias handling:** Previous gene symbols resolve through stable identifiers rather than overwriting the original text. (hgnc.genenames.org)
- **Result category:** Analytical-only findings remain distinguishable from the labeled companion diagnostic section. (thermofisher.com)
- **Scoring fidelity:** A score formula is not translated into a generic positive/negative flag without its interpretation context. (agilent.com)
- **Qualified interpretation:** Pathology interpretation retains the relevant histology, clinical information and controls. (diagnostics.roche.com)

These are analyst-proposed acceptance checks informed by the cited source structures. Clinical selection questions belong with the treating oncology and molecular pathology professionals; regulatory-label discrepancies belong with the responsible drug and device regulatory teams.

CAP's NGS worksheets can inform assay design and reporting discussions, but their stated focus on inherited disease limits direct extrapolation to oncology companion diagnostic authorization. Scope labels should travel with guidance references just as jurisdiction and revision travel with device labels. (cap.org) Likewise, the manufacturer TEPMETKO resource page distinguishes publication data from information included in the prescribing information. A literature update should not silently rewrite the controlled label record. (tepmetko.com)

Change control, corrections, and automation

The proposed correction policy is deliberately conservative:

- **Capture:** Retain the changed source passage, URL and retrieval date.
- **Compare:** Store old and new wording alongside normalized field differences.
- **Classify:** Distinguish a new indication, specimen change, correction, alias update and document refresh.

- **Review:** Assign the affected regulatory, pathology and information owners.
- **Release:** Publish a new dataset version and retain superseded mappings for traceability.
- **Disclose:** Keep unresolved items visible and recalculate the selected-cohort closure rate.

The standards distinguish recorded time from activity time, and stable gene identifiers from changing symbols. Those distinctions make retrospective reconstruction more reliable than a single “last updated” column. ([hl7.org](#)) ([hgnc.genenames.org](#)) In practice, an old patient report may need to be interpreted against the label and assay implementation that applied when it was issued, while a launch decision requires the approved versions relevant to the proposed release.

Automation should retrieve and compare controlled evidence before proposing a mapping update. IntuitionLabs describes connecting AI systems to authoritative enterprise sources with retrieval and citations; that is the relevant advisory perspective here, rather than a competing diagnostic product. ([intuitionlabs.ai](#)) An automated text difference can identify a changed passage, but the relationship's clinical and regulatory meaning still requires the designated owners' assessment.

Future updates should also preserve guidance status. The FDA codevelopment document checked for this report remains a **July 2016 draft**, explicitly marked not for implementation. It should not be described as a newly finalized requirement. ([fda.gov](#)) For instrument and software changes, Illumina's independently named analysis-module and claims-package releases illustrate the version granularity a maintained crosswalk should be able to represent. ([support.illumina.com](#))

Conclusion

A defensible FDA companion diagnostic crosswalk is a versioned relationship inventory. It joins a therapy indication and regimen to an authorized device claim, a qualifying biomarker definition, an allowed specimen, and identifiable evidence. The gene name is only one part of that relationship.

The selected matrix demonstrates how the same therapy can connect to different devices and how the same device can connect to different disease or biomarker settings. It also makes incomplete version reconciliation visible. Authorization evidence, a public approval-package label, and a laboratory's current controlled implementation are related checkpoints with different meanings.

For sponsors and diagnostic developers, the practical next step is to close each pending label or revision question before using the table for launch decisions. For pathology and clinical IT teams, it is to preserve specimen, variant, score, setting and source-version context when moving results between systems. For medical information, it is to prevent an abbreviated mapping from becoming a broader treatment claim.

The report's coverage calculation belongs only to its explicitly selected records. A maintained national dataset would require a separately normalized FDA-list denominator and continuing supplement surveillance. The proposed dictionary, source links and correction policy provide a reproducible starting point for that work. A useful crosswalk remains auditable precisely because it records where the evidence ends and where further reconciliation is required.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. <https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-fda-authorized-companion-diagnostic-devices-in-vitro-and-imaging-tools>
2. <https://www.qiagen.com/us/products/diagnostics-and-clinical-research/oncology/therascreen-solid-tumor/therascreen-kras-rgq-pcr-kit-us?clear=true>
3. <https://www.illumina.com/products/by-type/ivd-products/trusight-oncology-comprehensive-us.html>
4. <https://labeling.pfizer.com/ShowLabeling.aspx?id=12990>
5. <https://pi.orserduhcp.com/>
6. <https://retevmo.lilly.com/hcp/dosing>
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AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

Software, data and life-science workflows

IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

Enterprise platforms and regulated delivery

We provide Veeva services, application support, managed services, integrations and custom applications, alongside enterprise content work involving platforms such as Egnyte. For regulated workflows, our services include GxP enablement, computer-system validation and software development addressing 21 CFR Part 11 requirements. The applicable controls, validation responsibilities and acceptance criteria are defined for each engagement.

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