

**Methods/Research · Educational evidence summary**

A protocol for route- and formulation-aware medication evidence mapping

This methods article addresses a protocol for route- and formulation-aware medication evidence mapping.

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Abstract

Medication evidence can be attached to an ingredient, a named formulation, a route, or a product combination. Those levels are not automatically interchangeable. This article proposes a protocol for route- and formulation-aware evidence mapping in UnifiedACB. The protocol preserves the original source statement, records the clinical product independently, and assigns a transparent relationship between them. Exact matches, compatible ingredient-level matches, unresolved qualifiers, and incompatible products remain distinguishable. The work described is a design proposal informed by inspection of the existing public record structure; it is not a completed product-by-product adjudication. No source value is changed, and no route-specific value is inferred from an unqualified entry. A future evaluation would test mapping fidelity, unresolved-case handling, and traceability using independently reviewed examples. The intended result is an evidence link whose scope can be understood and reproduced, while pharmacokinetic interpretation and individual clinical risk remain separate questions.

Introduction

A medication name entered during clinical review may contain information that the source table did not: an inhaled route, a patch, an extended-release tablet, or a combination of ingredients. Alternatively, the publication may specify a product more narrowly than the user's query. Treating both names as equivalent can hide the difference between what is being taken and what was actually studied or classified.

The purpose of a mapping protocol is to preserve this relationship explicitly. It should support useful discovery without allowing a convenient search match to become an unsupported clinical assertion. The protocol is proposed here for future implementation and evaluation. It does not add route-adjusted scores or retrospectively qualify source rows that were published without that detail.



Methods

Separate the three statements

The first record would describe the source observation exactly: literal medication label, source version, locator, category, and any route or formulation qualification supplied by the publication. An absent qualifier should be recorded as unspecified in that source. It should not be filled using the most familiar marketed product.

The second record would describe the clinical or search input: ingredient or ingredients, available product name, route, release formulation, and any unresolved term. This record may be incomplete. A query containing only an ingredient name should not be interpreted as proof of a particular product, dose form, or route.

The third record would express the mapping relationship. Proposed states include an exact qualified match, an ingredient-level match with source scope stated, an unresolved qualifier requiring clarification, and an incompatible match. These are evidence-link states, not levels of pharmacologic potency or clinical safety. Their definitions would be fixed before evaluation.

Establish compatibility without inventing equivalence

Mapping would begin with medication identity and then examine qualifications. Shared spelling or a shared ingredient is insufficient to dismiss a route restriction. Combination products require component-level care: a source statement about one ingredient is not automatically a classification of the combination. A release mechanism should not be erased merely because the normalized ingredient is the same.

When the source gives no route, the display could identify the ingredient-level observation while stating that the source did not provide route-specific classification. That differs from asserting that every route has the same value or risk. When the source names a route or formulation, a different clinical product would remain outside that exact evidence match unless a documented source rule supports broader application.

Rules would be written as auditable decisions with examples and counterexamples. Reviewers would have access to the source passage and original label, not only a normalized database term. Disagreements would be resolved with a recorded rationale, or retained as unresolved when the available material does not justify a confident decision.

Plan an evaluation that tests the difficult cases

A proposed evaluation set would include exact matches, abbreviated queries, ambiguous product names, combination products, different release forms, and source entries with or without route qualifiers. It would also include deliberately incompatible pairs. The set should not consist only of common uncomplicated ingredient names, because those do not test the main uncertainty the protocol addresses.

The evaluation would report the number and type of cases, mapping decisions, unresolved outcomes, and reviewer disagreements. No sample size or success target is claimed in this article.



These would be selected in a complete study plan, alongside the intended users and the consequences of each error type.

Results

The current public dataset includes concept-level route and formulation notes, original source labels, source-version identifiers, and observation-level identity status. These fields provide places to retain distinctions, but their presence does not establish that a new route-aware mapping evaluation has been completed. [UnifiedACB public evidence dataset, v3.0 RC12 final](#)

No additional product matches, clinical equivalences, or route-specific categories were created for this article. The result is a proposed mapping structure and evaluation plan. There are no newly measured accuracy figures, adjudication totals, or clinical outcome results.

A completed implementation should produce a traceable answer to two different questions: which source observation was retrieved, and why that observation was judged relevant to the input product. If either question cannot be answered from the retained records, the mapping should be considered insufficiently documented.

Discussion

A useful interface may show an ingredient-level source observation while acknowledging its limited scope. Suppressing all information until every product detail is known can obstruct review; presenting the observation as a perfect product match overstates certainty. A clearly labeled mapping relationship provides a practical way to retain information without concealing the unresolved qualifier.

The distinction is particularly important when a question asks whether a route is “safer.” Mapping can establish what a publication classified. It cannot establish systemic exposure, comparative effectiveness, central effects, or an individual’s risk without relevant pharmacologic and clinical evidence. A source-native ordinal category is not a substitute for that evidence, even when the product name has been matched accurately.

Missingness also has more than one origin. There may be no source observation for the ingredient, an observation with unspecified route, or a qualified observation that does not match the current product. These states should remain distinct. Converting any of them to zero would turn an information limitation into an invented classification.

Maintenance requires a mapping version as well as a source version. A later clarification can change which records are considered compatible without changing the original publication. Historical outputs should retain the relationship used at the time, and a correction should explain whether it changed search discovery, evidence applicability, or an actual source extraction.

The protocol should also account for communication failures. A correct internal state is not sufficient if the wording causes users to infer product equivalence. Future evaluation should therefore examine both the stored mapping and the explanation shown to the reader, using questions that reveal whether route and formulation uncertainty was understood.



Limitations

This proposal does not provide an exhaustive pharmaceutical product dictionary or a validated algorithm for all countries, brands, devices, salts, and release forms. Product availability and naming can vary. The scope of any implementation would need to be declared rather than implied by a broad medication search box.

An independently adjudicated mapping set could improve evidence fidelity, but it would not validate a clinical risk model. Source tables themselves may provide insufficient qualification. Where the evidence remains unspecified, careful mapping can expose the limitation but cannot remove it.

Conclusion

Record the product, the source statement, and the relationship between them separately. Preserve unspecified information and incompatible qualifiers, and evaluate whether users understand the resulting explanation. This approach makes route and formulation meaningful without manufacturing new values or treating a successful name match as proof of clinical equivalence.

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Explore the evidence

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Disclosure

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Educational evidence summary. This content does not provide patient-specific medical advice and does not replace clinical judgment, medication reconciliation, or prescribing guidance.