Clinician, nurse or prescriber

Follow a claim from product identity to study design, clinical measurement and communication. This reading route preserves analysis methods, adverse-event uncertainty and the distinction between compounding frameworks. It is an educational reference, not a treatment protocol.



Dr. Lena / fictional visitor

YOUR LEARNING JOURNEY

Create a compact appraisal that separates evidence applicability from enthusiasm and leaves room for negative results and harms. Keep unresolved applicability questions visible.

Appraise the clinical evidence, separate laboratory changes from outcomes, then examine the relevant compounding framework.

This reading aid is not a clinical protocol or professional review. Approval, off-label clinical decisions, compounding and investigational research are distinct questions.

Open the current online guide

Sources and related guides remain accessible on the website. All role paths are open to every reader.

Portrait: fictional illustration, not a real patient, professional reviewer or endorsement. This handbook provides education, not individual medical or legal advice.

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Read in order for a foundation, or use the linked contents to find a specific topic. Page numbers refer to this edition.

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Know which product the evidence describes

A molecule name is a starting point, not a complete product description. Record the active ingredient, chemical form, formulation, route, manufacturer or compounder and the document date. Products using similar names may differ in ways that matter. A result for one preparation does not automatically establish the performance of another.

FDA approval concerns a particular drug product and its authorized labeling. A facility registration, product listing or National Drug Code does not mean FDA has approved the product. A company can have legitimate paperwork for one activity without every product or claim being authorized.

Compounded drugs are prepared under a different framework and are not FDA-approved. They can serve particular patient needs, but FDA does not review each compounded product for safety, effectiveness and quality before marketing in the way it reviews approved medicines. The 503A and 503B pathways have different conditions, explained below.

Investigational means a product or use is being studied; it does not mean success is established. Research-use labeling concerns a claimed purpose and cannot establish suitability for human use. Keep regulatory status, analytical quality and clinical evidence as three separate entries. None can substitute for the other two.

Build a simple comparison: what the paper studied, what the official label describes, and what the current document or service names. Mark missing information rather than filling it with a brand assumption. This comparison is useful for a patient preparing questions and for a professional reviewing a brochure.

Worked learning example

Two documents use the same ingredient name. One describes an approved finished medicine; the other describes bulk powder with a laboratory report. The shared name does not make the powder an approved medicine. Ask what each document actually establishes before carrying claims between them.

READ THE SOURCE

FDA - Is It Really FDA Approved?

FDA - Compounding and FDA: Questions and Answers

Read a study as a complete record

Begin with the primary paper and registry where available. A registry describes a planned or reported study; its presence does not prove benefit. Compare the registered population, outcomes and timing with the published account. Preserve publication date, study period and later update date as different facts.

Write the research question using population, intervention, comparator and outcome. Include species, formulation, route and duration. A comparison against placebo answers a different question from a comparison against an active medicine. A study in one population may leave other groups unrepresented.

Look at how participants entered the analysis. An estimate based on everyone assigned may differ from one describing participants who remained on treatment. Missing observations and treatment discontinuations can affect interpretation. Record the paper’s stated analysis and assumptions instead of merging estimates from different methods.

Check whether an outcome was primary, secondary or exploratory. Multiple measurements increase the opportunity for chance findings; the analysis plan and adjustments matter. A confidence interval describes uncertainty under the analysis assumptions. Statistical significance does not by itself establish a meaningful improvement in daily life.

Read withdrawals, adverse events and serious events alongside benefits. Retain reported causality assessments and comparator counts. Distinguish no event observed from evidence that an event cannot occur. Small studies and short follow-up may have limited ability to characterize uncommon or delayed harms.

Finally, separate the result from its interpretation. Note sponsor involvement, available methods and missing details. A sponsor release can report a development before full results are public; attribute it clearly and leave unresolved methods visible until the paper or registry supplies them.

Worked learning example

A headline reports one percentage while a paper supplies two estimates under different analysis assumptions. Label each estimate with its population and method; do not choose the larger number simply because it makes a stronger headline. The comparison is only meaningful when the definitions travel with the numbers.

READ THE SOURCE

Testing Treatments - evaluating treatment evidence

Testing the person: understand the clinical question

A diagnostic laboratory studies specimens from a person to help assess health or investigate a clinical question. An analytical product laboratory studies material submitted for testing. These are different jobs. A blood report does not identify the contents of a product, and a product COA does not explain a patient’s symptoms or establish whether a treatment is appropriate.

Begin with the question the test is intended to answer. A test directory can explain the specimen required, the measurement method, its intended use, limitations and reporting details. Some tests are useful for one purpose but not another. Ordering recommendations are context-dependent. A list of tests mentioned online is not automatically a useful panel for every person, and this educational guide does not prescribe a monitoring schedule.

When reading a result, keep the patient and specimen identifiers, collection date, units, method and laboratory reference interval together. Reference intervals describe a comparison range used by that laboratory; they are not universal performance targets. Clinical decision thresholds may serve a different purpose from a reference interval. A result needs interpretation alongside symptoms, medical history and other findings, rather than being converted into a diagnosis from one isolated number.

Preparation, collection, transport and specimen condition can affect whether a result is interpretable. A laboratory’s directory may specify handling requirements, specimen stability and reasons for rejecting a sample. Those details belong to the particular test and method. Do not transfer storage information for a blood specimen to a medication, or treat one laboratory’s instructions as universal.

A change over time can raise a useful question without proving its cause. Differences in timing, clinical circumstances or analytical methods may matter. A normal result does not establish that an unapproved product is safe, and an abnormal result does not by itself establish that a product caused harm. The clinician and laboratory can help investigate unexpected or discordant results using the full clinical context.

In the United States, CLIA concerns laboratories testing human specimens for health assessment or diagnosis, prevention or treatment. CMS provides a public lookup for laboratory certification and demographics. Verify the particular performing facility and its certificate rather than assuming all sites within a company are equivalent. CLIA certification is not FDA approval of a peptide product, and it does not transform a product-purity report into a diagnostic test. Example laboratory directories are useful teaching resources, not endorsements or evidence that every listed service suits every person.

An HbA1c report needs context

Labcorp’s HbA1c test page illustrates a useful directory entry: it names the method, specimen requirements, uses and limitations. It explains that conditions affecting red-cell survival and some hemoglobin variants can alter interpretation. If a fictional person’s result changes after several simultaneous changes in health or care, the number alone cannot identify which change caused it. That is a question for clinical assessment, not a product testimonial.

READ THE SOURCE

CMS: Clinical Laboratory Improvement Amendments

CMS: Getting Started With CLIA

CMS: Official CLIA Laboratory Search

ARUP: Testing resources and laboratory directory

Labcorp: Hemoglobin A1c, test 001453

503A and 503B: understand the pathway before the product

Compounding means preparing a medicine for particular needs by combining, mixing or altering ingredients. In the United States, sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act establish different conditions for exemptions from certain federal requirements. They are not product-approval programs. A compounded medicine does not become FDA-approved because a pharmacy holds a license or an outsourcing facility appears in a registration database.

Section 503A concerns compounding by a licensed pharmacist in a state-licensed pharmacy or federal facility, or by a licensed physician. Its prescription condition concerns an identified individual patient. Limited anticipatory compounding can occur under specified conditions before a prescription arrives, but that is not unrestricted authority to supply unassigned office stock. When all applicable conditions are met, the product can qualify for exemptions from premarket approval, adequate-directions labeling and federal current good manufacturing practice requirements. Other requirements still apply.

Section 503B concerns outsourcing facilities, where compounding occurs by or under the direct supervision of a licensed pharmacist. These facilities remain subject to current good manufacturing practice, often abbreviated CGMP. They may obtain individual prescriptions or supply healthcare providers with office stock: medicine held before a particular patient needs it. FDA conducts risk-based inspections, and reporting obligations apply. Registration is not a guarantee that every preparation, practice or transaction complies.

Bulk ingredients have separate eligibility gates. Under 503A, FDA describes an applicable USP/NF monograph route; when no applicable monograph exists, a component-of-an-approved-drug route; or, when neither applies, inclusion on the 503A bulks list. Under 503B, a substance generally needs inclusion on the clinical-need bulks list, or the resulting drug must be on the shortage list at compounding, distribution and dispensing. A monograph is a published quality standard, not approval of every preparation made from the ingredient.

A valid certificate of analysis and manufacture by an FDA-registered establishment are additional bulk-substance conditions, not substitutes for eligibility. Interim enforcement policies are also distinct from the statutory lists: nomination or Category 1 status is not final list inclusion. Other limits, including restrictions involving essentially copies of available medicines, still need attention. Review the specific product, pathway and date rather than assuming that a familiar ingredient or a national shortage headline answers everything.

503A status as of October 31, 2026: interim Categories 1, 2 and 3 are not the final 503A bulks list. Category 1 concerns adequately supported nominations under evaluation; Category 2 identifies significant safety concerns; Category 3 concerns inadequate nomination support. Removal from Category 2 does not itself establish eligibility. An advisory-committee recommendation is nonbinding advice, not list inclusion. Addition to the final list requires FDA rulemaking; other 503A conditions still apply. Read the category record, committee record and final rule separately rather than treating one as a substitute for another.

Illustrative case: the clinic refrigerator

A clinic asks for unnamed-patient inventory. “Our supplier is a compounding pharmacy” does not resolve the office-stock question. The useful next questions concern the facility’s actual pathway, the exact preparation, the relevant federal conditions and applicable state rules. This example is a reading exercise, not clearance to obtain or administer stock.

Status-note sources checked October 31, 2026; this is not a claim that every retained source was re-reviewed.

READ THE SOURCE

FDA - Human Drug Compounding Laws

FDA - Provisions Applicable to Human Drug Compounding

FDA - 503A Bulk Drug Substances

FDA - 503B Bulk Drug Substances

FDA - Interim categories (PDF updated May 14, 2026)

FDA - July 23-24, 2026 PCAC meeting page

Federal Register - PCAC meeting notice, April 16, 2026

Explain a claim with its evidence attached

A reader receives a message from the complete presentation: headline, image, testimonial, spoken words and qualifications. Write down the actual impression before judging the evidence. A document titled “education” can still communicate a product benefit or sales claim.

Keep a claim ledger with the exact wording, intended audience, primary source and relevant limits. Record the population, product, outcome and date. Attach a decision: supported as written, needs narrowing, or unanswered. This makes review repeatable when a sentence moves from a website to a printed handout.

Use plain language without removing uncertainty. Explain an unfamiliar term when it first appears. Put a consequential limitation beside the claim it qualifies. A small disclaimer elsewhere cannot repair an unsupported headline. Separate community reports from controlled evidence and company statements from independently established findings.

Give each document a content owner, version and review date. Preserve sources and consequential limitations when adapting it for another audience. Keep a change record so later readers can identify which claim changed and why.

Worked learning example

An illustrated handout combines a vial photograph with “clinically proven recovery” while its citation is an animal experiment. The evidence does not support that human claim. A useful revision describes the animal study and its limits directly, and removes the unsupported promise.

Changed claims about presentation checked against FTC guidance October 31, 2026.

READ THE SOURCE

FTC - Health Products Compliance Guidance

Where to report a problem and how to check a pharmacy

FDA MedWatch accepts reports of adverse events and product-quality problems. Record the product name, manufacturer or compounder, lot if available, dates, what happened and relevant packaging or photographs; distinguish what you observed from what you suspect caused it. A report communicates a concern and does not itself prove causation.

Use FDA BeSafeRx to learn how to evaluate an online pharmacy, then follow FDA’s state-pharmacy directory to the relevant board’s license lookup. Match the legal name and address, check the current license record and contact the board when an entry is unclear. A license lookup and a product-approval record answer different questions.

Worked learning example - fictional

A package names a dispensing pharmacy different from the website brand. Look up the pharmacy’s legal name and address, not just the platform name. If reporting a damaged container, retain its lot number and describe the damage without assuming which organization caused it.

Sources for this addition checked October 31, 2026.

READ THE SOURCE

FDA - Reporting serious problems

FDA - BeSafeRx

FDA - State pharmacy license lookup directory

Reading path and books

1. Set the evidence standard

Identify study design, comparator and the difference between a measured endpoint and a proposed mechanism.

2. Read the dated journey

Follow the relevant molecule through species-separated chapters instead of merging every phase into one story.

3. Separate product categories

Keep product verification and compounding status distinct from efficacy appraisal.

Continue in the Church Library

Choose the level that fits your background. Book links lead to the Library, where reading options and any affiliate disclosures are shown.

Testing Treatments - Evans, Thornton, Chalmers and Glasziou

Start with fair comparisons and uncertainty. The library entry includes an official free reading option. Published in 2011; use current official sources for regulatory questions.

The Art of Statistics - David Spiegelhalter

Go deeper into denominators, uncertainty and interpreting data. Read alongside the actual study rather than using a statistical slogan as a verdict.

Browse all Library rooms

Examples in practice

These examples identify published resources and their uses; they are not evaluated services.

ARUP - diagnostic testing resources

Diagnostic example: links to a laboratory test directory, specimen information, test fact sheets and clinical decision support. Use the entry for the specific test rather than extrapolating from a company name.

Labcorp - HbA1c test directory example

Diagnostic example: shows how one test page describes methodology, specimen requirements, intended use and limitations. It is a reading exercise, not a recommendation that everyone needs this test.

Questions and explanations

Does the design support this precise clinical claim?

The design must match the claim’s causal and clinical scope. A randomized comparison can support an intervention comparison when its conduct and analysis are appropriate, while an uncontrolled case series cannot reliably separate treatment effects from concurrent changes or natural history. For example, improved pain scores after a procedure in an uncontrolled series do not establish superiority to usual care. State the supported finding first and keep the stronger, untested inference separate.

Which population, formulation, follow-up and analysis generated the reported result?

Extract the eligibility criteria, actual preparation, comparator, follow-up duration and analysis definition before quoting the estimate. Check how discontinuations and missing observations were handled, because estimates under different assumptions answer different questions. For example, an on-treatment estimate and an estimate incorporating outcomes after discontinuation should not be merged into one unlabeled percentage. Preserve the paper’s terminology and identify which estimate is relevant to the discussion.

Is the product being discussed the one actually studied or approved?

Compare the study intervention and current product description at the level of formulation, route, manufacturer or compounder and regulatory record. Evidence about an ingredient does not establish that every preparation bearing its name has equivalent performance. For example, a result for a studied finished injectable product does not validate a separately prepared oral formulation. Document the mismatch and avoid presenting it as a minor detail already resolved by the shared name.

Read the source: it really fda approved

Glossary

Comparator
The reference group or intervention against which an outcome is compared, such as placebo or another treatment.

Endpoint
An outcome defined for a study. A biological measurement and a patient-important outcome are not necessarily the same thing.

Formulation
The composition and presentation of a product, including ingredients beyond the active substance.

Adverse event
An unwanted medical occurrence during observation; occurrence does not itself establish a causal connection to treatment.

Investigational
Under investigation. This describes research status, not proof of safety or benefit.

API
Active pharmaceutical ingredient: the substance intended to provide a medicine’s pharmacological activity. An API is not the same as a finished medicine.

503A / 503B
Different U.S. statutory pathways for qualifying compounded drugs. Neither makes a compounded drug FDA-approved.

CGMP
Current good manufacturing practice: requirements for manufacturing controls and quality. The applicable framework depends on the activity and product.

CLIA
Clinical Laboratory Improvement Amendments: a U.S. framework for laboratories testing human specimens for specified health purposes.

Reference interval
A laboratory’s comparison range for a test in a defined reference population. It is not a diagnosis on its own.

Confidence interval
A range expressing statistical uncertainty under an analysis’s assumptions; it does not remove bias or establish applicability.

Learning worksheet

Study appraisal

Use these prompts to record what you understand, what remains uncertain and which source could answer the question.

Learning prompt	Filled-in fictional example
Study appraisal	Fictional example: Fictional study ledger: 80 adults, placebo comparator, 12-week symptom outcome; missing-data method not supplied. Conclusion: keep the estimate provisional until the full analysis is read.

Record citation, registration identifier, study date and sponsor involvement.

Specify population, intervention, comparator, endpoint and duration.

Write the effect with uncertainty, analysis population, missing-data approach and important limitations.

Record serious harms and the investigators’ causality assessment; identify what remains unanswered.

Educational information, not individualized medical or legal advice.

Explore another perspective in the Community Center