QPS: Supporting Drug Labeling Studies

Plan the evidence for initial approval and future indications

Start with the intended use

Define the indication, population, dose, route and expected benefit.
Build the road map to tie every proposed label statement to supporting evidence.

NONCLINICAL FOUNDATION

Pharmacology, toxicology and DMPK establish biological rationale, exposure and safety limits.

Decision: Is human testing justified?

CLINICAL READINESS

Align manufacturing, formulation, validated assays and sample handling with the clinical plan.

Decision: Is the final product formulation and dosage ready for clinical trials?

PHASE I AND II

Characterize safety pharmacokinetics and pharmacodynamics. Establish proof of concept, select doses and test meaningful endpoints.

Decision: Can the product and dosage be confirmed to move to Phase III?

PHASE III STUDIES

Establish efficacy and characterize safety in the intended population.

Decision: Does the evidence support the proposed use?

SUBMISSION AND INITIAL LABELING

Prepare the Regulatory package for the initial indication based on the evidence gathered in preclinical and clinical studies, then submit.

Outcome: Regulatory review determines approval and labeling.

LABELING EVIDENCE IS BUILT THROUGHOUT DEVELOPMENT

Food effects, drug-drug interactions, organ impairment, bioequivalence, PK/PD, efficacy/safety, and special populations are all clinical trials to consider according to the product and it's intended use.

POST APPROVAL

Monitor safety and effectiveness

Continue to gather efficacy and safety information via Real World Evidence studies. Conduct post approval studies if that is a condition of product approval.

LABEL EXPANSION

Build a new evidence plan

Define the new indication, population or regimen. Reassess gaps; return to Phase II and confirmatory studies when needed. Additional nonclinical or Phase I work may also be required. Submit the evidence for regulatory review.

Contact QPS to Get Your Next Study Started
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