3 IMPORTANT CONSIDERATIONS OF CARDIOVASCULAR OUTCOMES TRIALS

The FDA 2008 guidance mandates all type 2 diabetes products perform a cardiovascular outcomes trial (CVOT). However, regulators and payers are increasingly demanding such trials for other disease and indications such as chronic kidney disease, dyslipidemia, thrombosis and anemia. According to the Cardiovascular Safety Outcome Trials Think Tank, there are three important considerations before performing such trials.

PLAUSIBILITY
How likely it is that a possible signal indicating risk is real, based on strength of evidence, and/or whether a plausible mechanism of action for potential cardiovascular (CV) harm has been identified

RELEVANCE
What relative and absolute CV risk would need to be excluded to determine that the drug had an acceptable benefit-to-risk balance for its use in the intended patient population

INFLUENCE
How plausibility and relevance influence the timing and approach to further safety assessment

WHAT YOU NEED TO KNOW PRIOR TO A CVOT

Determine whether a pre- or post-approval CVOT is needed

Insight into other clinical studies that have addressed individual therapeutic agents

Alternative approaches for collecting CV data e.g., observational studies, registries and electronic health records (EHRs)

Rationale for a regulatory requirement of CVOT and generalizability of data to other agents in the same class

WHEN DO YOU NEED A CVOT?
CV OUTCOME STUDIES SHOULD BE BASED ON EVIDENCE OF PLAUSIBLE RISK, AS INDICATED BY DATA IN:

The same pharmacologic class

Statistical evidence from the development program itself (e.g., adverse events and biomarkers)

Mechanistic considerations and clinical judgment regarding the disease being observed

The use of post-marketing risk monitoring rather than pre- or post-marketing controlled trials should be considered

ABOUT PAREXEL
Cardiovascular outcomes trials can be expensive, time-consuming and technically complex studies. At PAREXEL, we bring together best minds from scientific, clinical, regulatory and commercial disciplines to help you navigate the challenges in conducting these trials. We provide innovative solutions that can help you more efficiently generate the evidence needed to unlock the value of your products.

IN THE NUMBERS (PAST 5 YEARS)

600 Late Phase studies, including many large complex studies

Our medical operations professionals have managed >41,700 events for CEC adjudication

Optum Partnership with access to Claims Data 150M+ lives & EHR Data 75M+ lives

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