

# ACCELERATE DEVICE INNOVATION AND APPROVAL...



Real-world evidence (RWE) is increasingly required to meet regulatory requirements for medical devices. The FDA recommends the use of registry data for post-approval surveillance and the EU requires RWE for most devices.

Through its robust clinical registries, Fivos Health offers granular real world data and follow-up details, including device identifiers, for over 1 million procedures, including vascular and neurovascular. Leverage this resource to shorten the regulatory timeline for swift approval and decision making.

## Fivos Feature

The vascular and neurovascular registries powered by Fivos are governed by Patient Safety Organizations (PSO). The PSO structure allows all patients to be "enrolled," eliminating the need to recruit study participants. This results in more rapid, efficient, flexible, and cost-effective projects.

...with use of **clinical registry data.**

## RETROSPECTIVE STUDY USING REGISTRY DATA



## PROSPECTIVE ANALYSIS - TYPICAL TIMELINE

