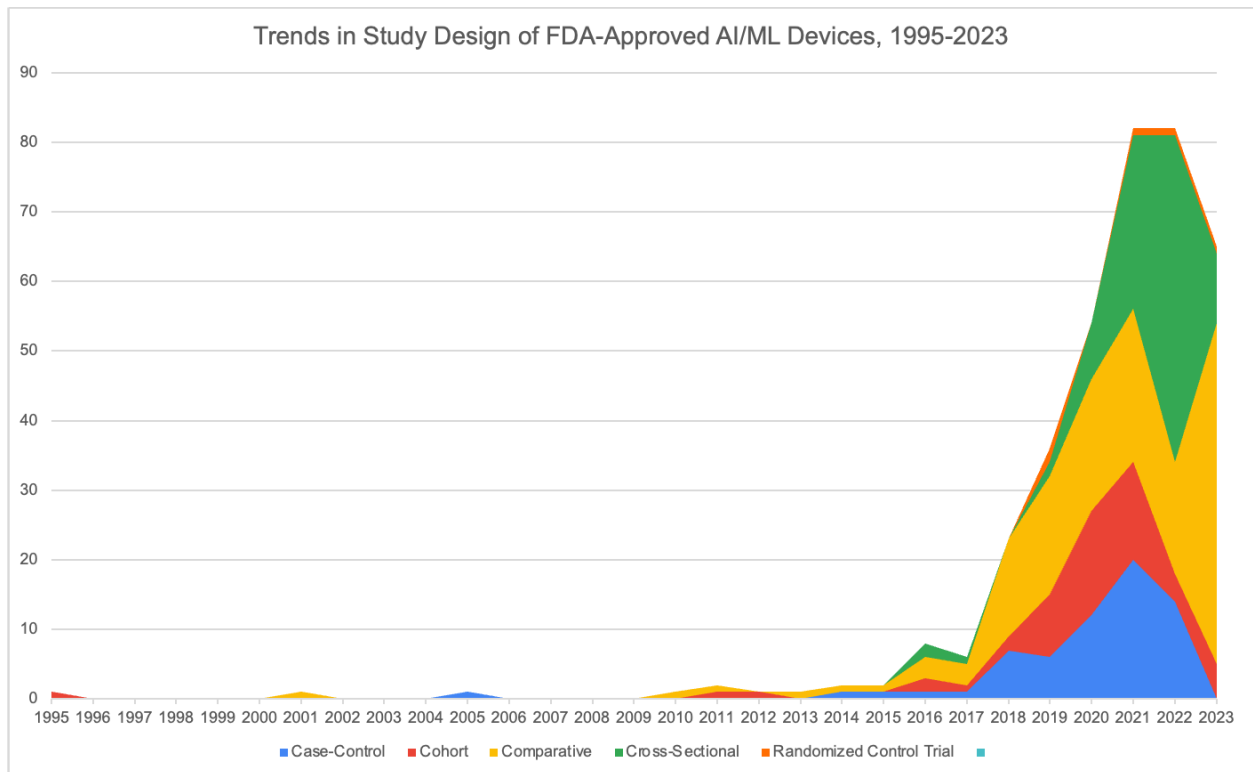


**Supplement Table 1: Classification System for Study Designs for AI/ML Devices**

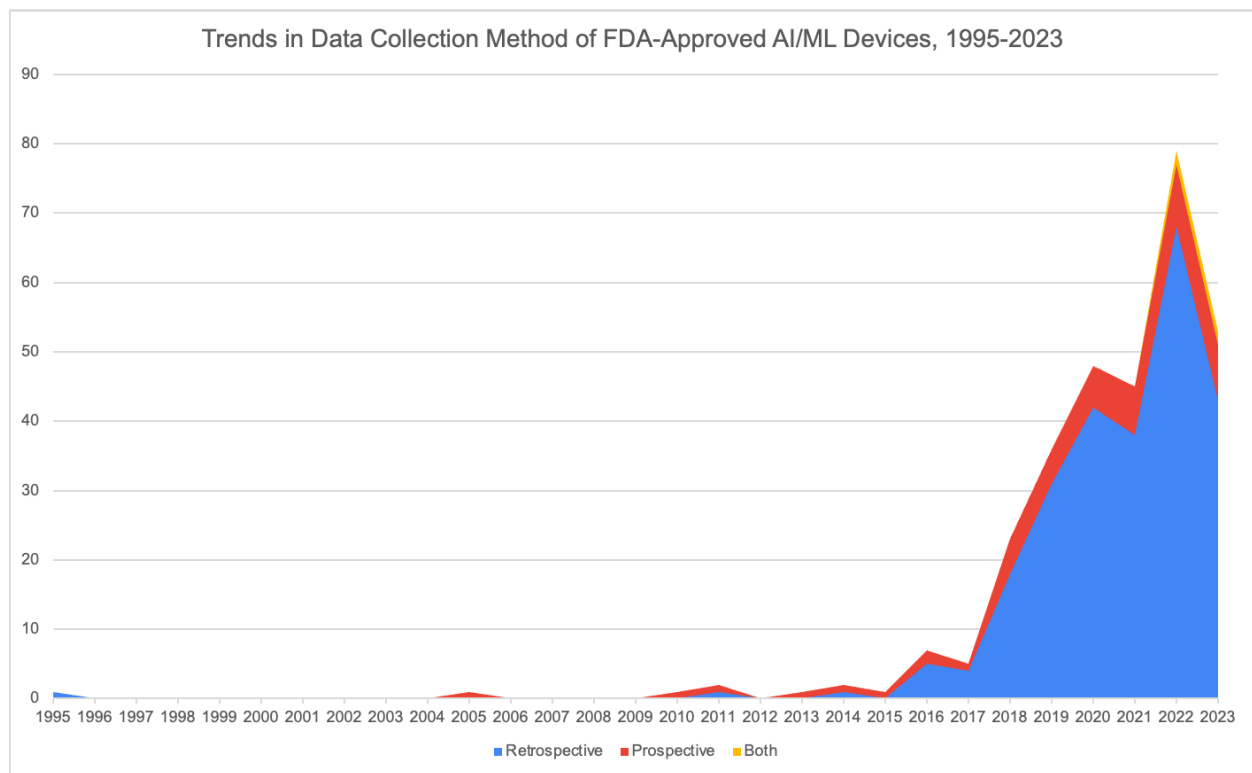
<b>Study Design</b>	<b>Description</b>
Comparative	Studies that directly compare two or more similar groups to analyze differences in outcomes or effects.
Cohort	Studies that follow a group of individuals over a period of time to observe the development of certain outcomes based on exposures or interventions.
Case-Control	Studies that compare individuals with a particular condition (cases) to those without the condition (controls) to identify potential factors associated with the condition.
Cross-Sectional	Studies that analyze data collected from a population at a single point in time to examine relationships between variables or characteristics.
Software Validation	Process of ensuring that software meets specified requirements and functions correctly according to its intended purpose.
RCTs	Randomized Controlled Trials: Studies in which participants are randomly assigned to different groups to compare the effects of treatments or interventions.

**Supplement Figure 1: Trends in Study Design of FDA-Cleared AI/ML Devices, 1995-2023**



AI/ML, artificial intelligence/machine learning; FDA, Food and Drug Administration.

**Supplement Figure 2: Trends in Timing of Data Collection of FDA-Cleared AI/ML Devices, 1995-2023**



AI/ML, artificial intelligence/machine learning; FDA, Food and Drug Administration