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

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| **Study Design** | **Description** |
| 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**

A graph of a number of trends

Description automatically generated with medium confidence

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**

**A graph with red and blue lines

Description automatically generated**

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