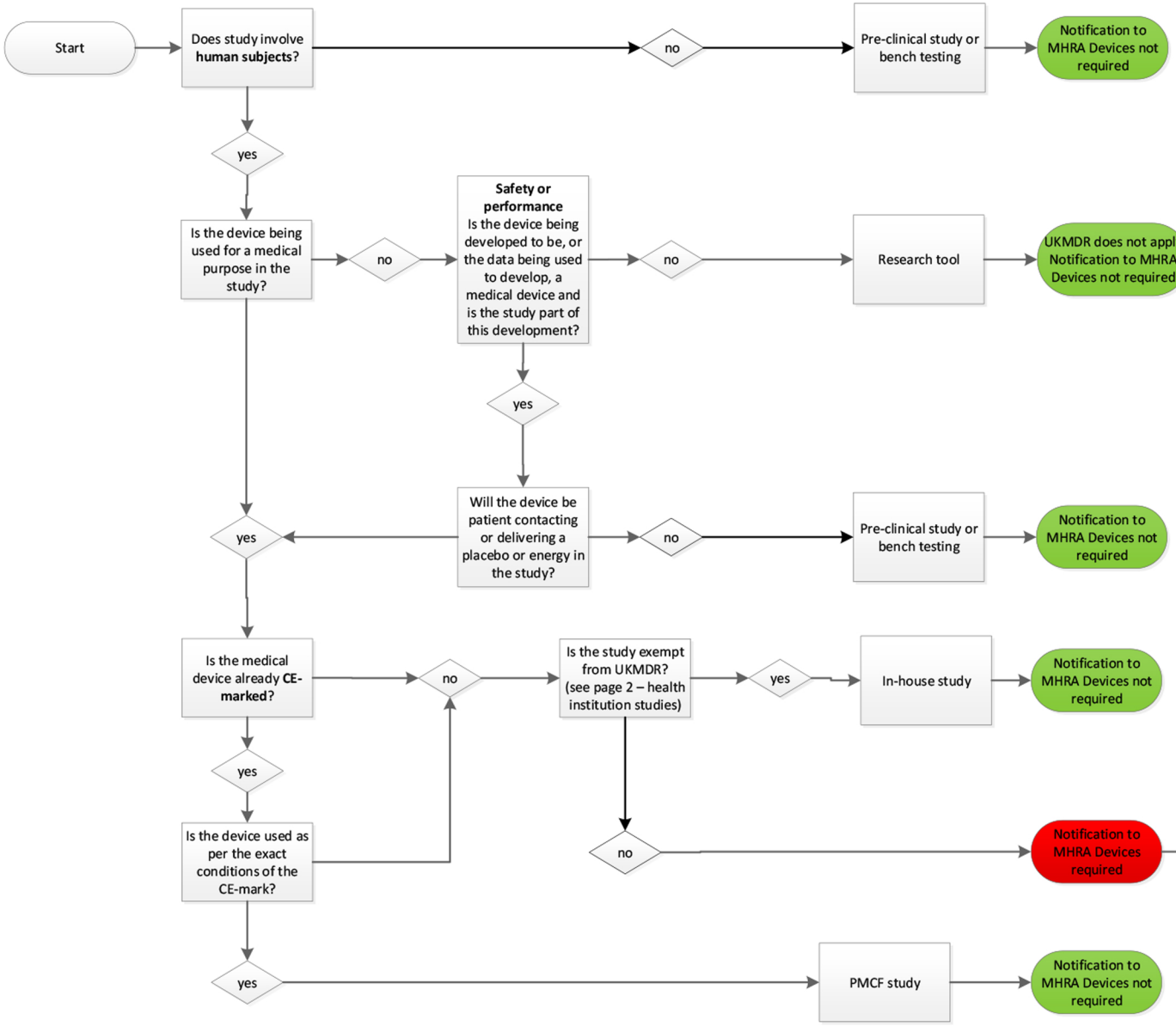
Studies under UKMDR2002



Pre-clinical or bench testing

Non-interventional software study – provides performance data of a medical device using existing data with no safety implications for participants. Could support conformity assessment but may not fit definition of CI if not performed on humans (e.g. software tested using existing patient data, with no patient interaction in study and not informing patient management decisions in study)

Notification required

- CI with medical purpose in study being conducted for conformity assessment
- Includes software studies where information from the device will be used to inform patient management decisions or the patients are interacting with the software in the study
- CI with no medical purpose in study - Provides performance or safety data with potential safety implications for participants (e.g. inhaler delivering placebo / imaging system used on healthy volunteers)
- Transfer of device to third party (from health institution to another, or from manufacturer to health institution)
- Health institution study where there is intent to place device on the market
- NB: Use of device for a medical purpose but study may not be intended to support conformity assessment. May include studies investigating a therapy or conducted with a research objective (e.g. Deep Brain Stimulator intended to investigate brain waves but is also being used to deliver treatment during the study). THESE STUDIES WILL NEED TO BE MODIFIED TO INCLUDE SAFETY/PERFORMANCE OBJECTIVES

Health Institution studies