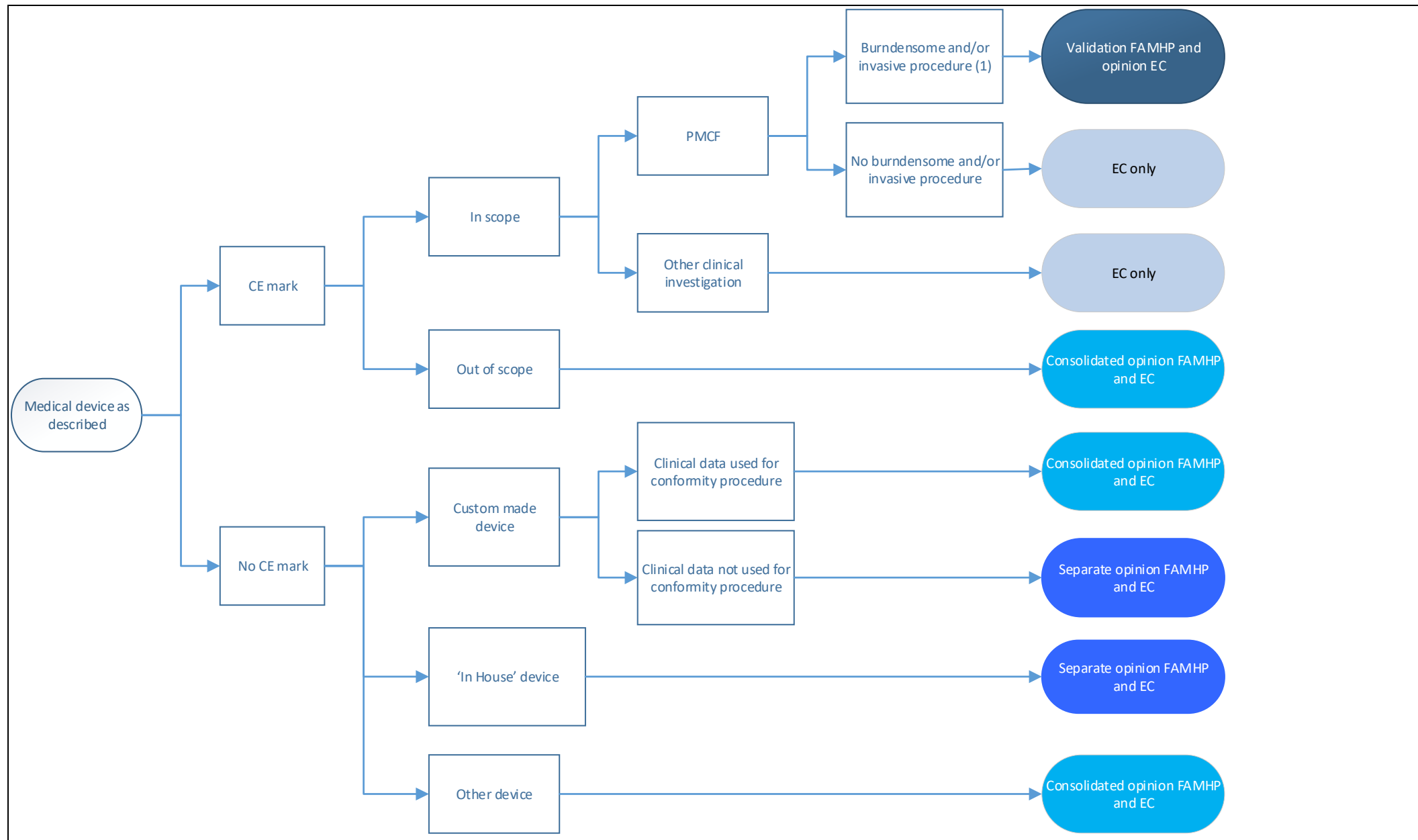


Regulatory pathways and safety reporting for a clinical investigation with a medical device



(1) Burndensome and/or invasive procedure: a procedure that may cause pain, discomfort, fear, disruption of personal life and activities, or other unpleasant experiences.