SOFTWARECPR®

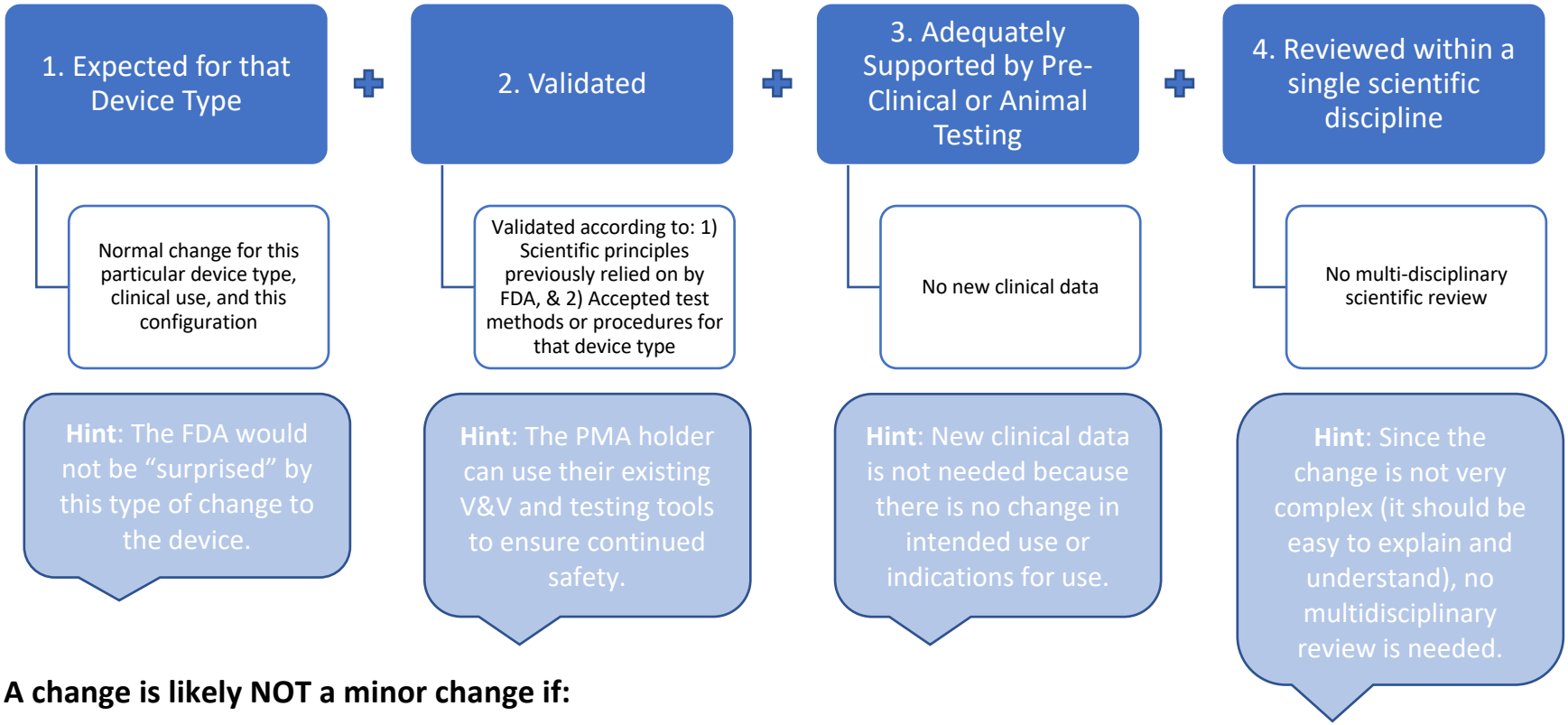
CRISIS PREVENTION AND RECOVERY, LLC

# REAL-TIME PMA SUPPLEMENT: CHECKLIST

# "Real-Time PMA Supplement: Checklist" Job Aid
## prepared by Amy Sellers with input from SoftwareCPR® Partner, John Murray

*A device modification is appropriate for real-time PMA Supplement review if it is a minor, expected change.*[1]

### A change is likely a minor change if it is (all four must be true):




### A change is likely NOT a minor change if:

- The change will modify the intended use of the device
- The change will modify the patient population for the device
- The change will modify a risk item in the device

[1]Checklist based on the December 2019 FDA Guidance document *Real-Time Premarket Approval Application (PMA) Supplements*.