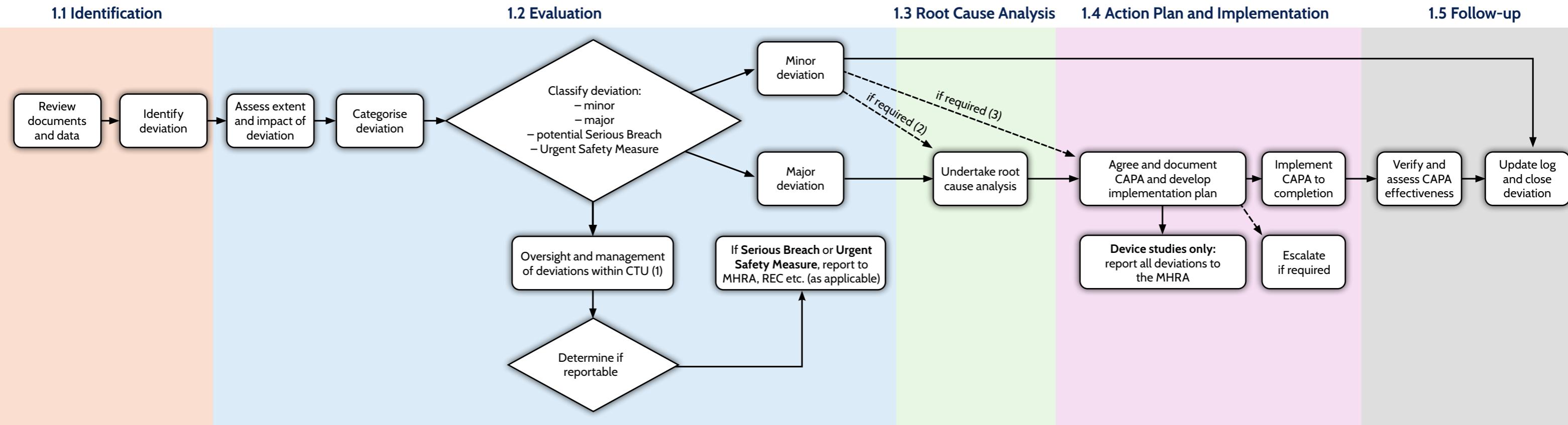


# Protocol Deviations Routemap



1) Oversight and management of deviations within the CTU could be required during any stage. Statistician(s) should be involved where there is potential impact on data integrity.

2) Root cause analysis, CAPA and action plan can also be completed for minor deviations or repeated minor deviations, if deemed necessary.

3) CAPA and action plan should be completed for all protocol deviations occurring in device studies.