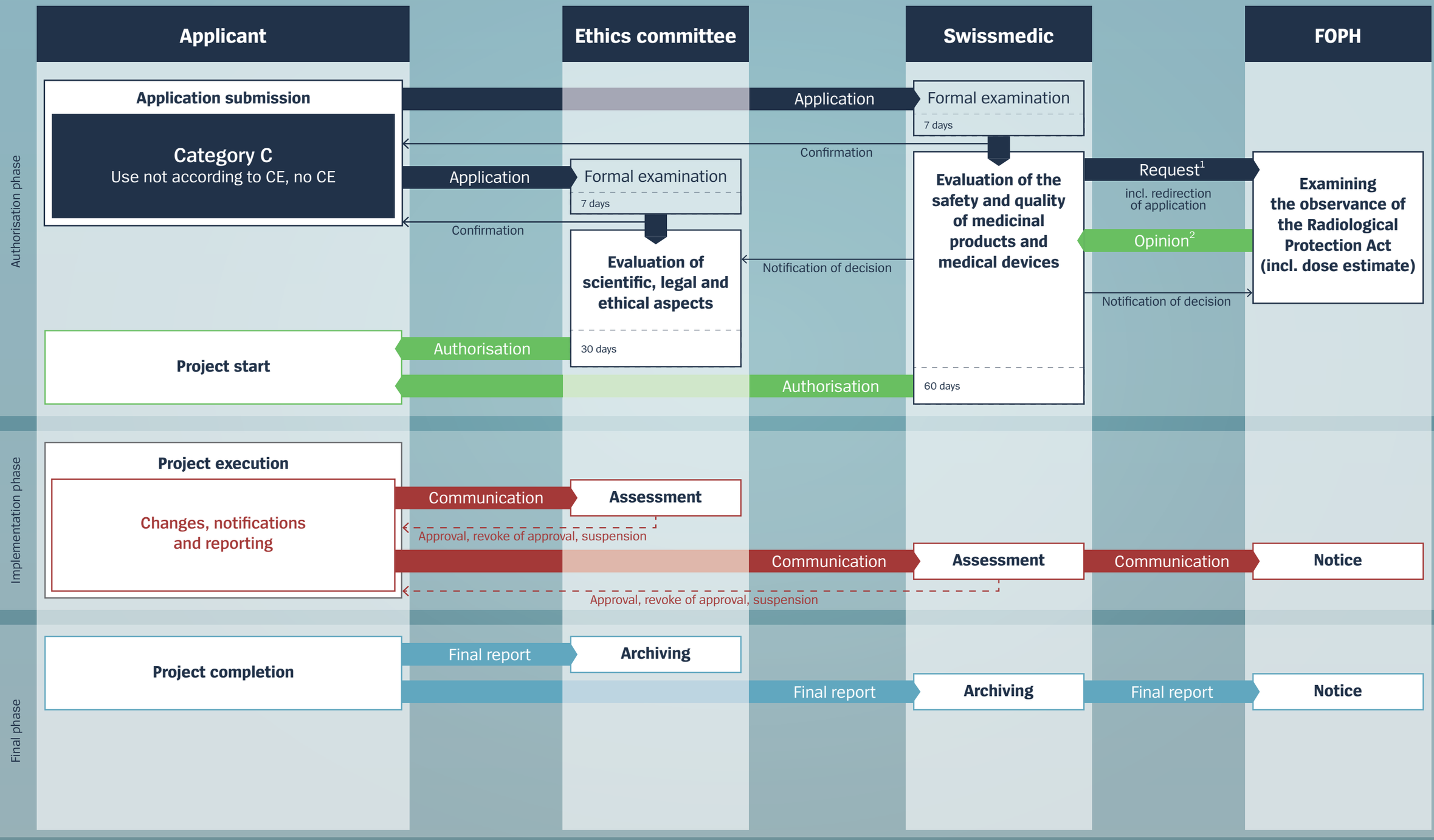
Procedure for:

Clinical trials with therapeutic products capable of emitting ionising radiation

Radiation source as a component of a medical product
Category C trials

5



Relevant legal texts:

Authorisation phase
Art. 24–26, 31, 33, 36 ClinO, Annex 4 nr 5 ClinO
Art. 28 RPO (Dose limit)

Implementation phase
Art. 36, 41, 42 ClinO

Final phase
Art. 36, 38 ClinO

[1] Swissmedic obtains opinion of FOPH for approval
[2] Pursuant to Art. 36 ClinO Swissmedic may approve, insofar as the FOPH has no objection.