Application submission, authorisation and notification procedure for human research projects involving radiation sources

Procedure for:
Clinical trials with therapeutic products capable of emitting ionising radiation

Radiation source as a component of a medicinal product (radiopharmaceuticals)
Category A trials

**Applicant**

**Category A**
Authorised

**Application submission**

**Ethics committee**

**Application**

Formal examination

7 days

Examining scientific, legal and ethical aspects; observance of the Radiological Protection Act (incl. dose estimate)

**Confirmation**

**Project start**

Authorisation

30 days

**Project execution**

Communication

**Changes, notifications and reporting**

**Assessment**

Approval, revoke of approval, suspension

**Project completion**

**Final report**

**Archiving**

Relevant legal texts:

**Authorisation phase**
Art. 28 RPO (Dose limit)

**Implementation phase**
Art. 29, 37, 40–43 ClinO

**Final phase**
Art. 38 ClinO