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 medical product**

**Category A trials**

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**Applicant**

- **Application submission**

**Ethics committee**

- **Application**
  - **Formal examination**
    - 7 days
  - **Confirmation**

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

- **Project start**
  - **Authorisation**
    - 30 days

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**Project execution**

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**Project completion**

- **Final report**
  - **Archiving**

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**Relevant legal texts:**

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

- **Final phase**
  - Art. 38 ClinO