Steps for Conducting a (Multicenter) Clinical Study

within the SECEC in 2026

1. Study Design

• **Research application form** with draft of the protocol describes objectives, inclusion/exclusion criteria, interventions, assessments, and timeline.
• Preparation of the **Case Report Form (CRF)**: document for clinical data collection.
• **Principal investigator's CV, Good Clinical Practice (GCP).**
• To obtain scientific and technical validation by the research team, statisticians, data managers of participating hospital.

2. Informed Consent

• Written, free, and informed consent of participants is mandatory.
• The participant information sheet must be clear and accessible.
• **Informed consent and participant information for data registration on shoulder and elbow pathology (ICF)**

3. Legal and Regulatory Compliance

• Good Clinical Practice (GCP).
• GDPR (General Data Protection Regulation):
• **Data sharing agreement (DSA): agreement on the sharing of pseudonymized personal data for academic research on behalf of the European Society for Surgery of the Shoulder and Elbow (SECEC)**
• the **sponsor** is the individual surgeon or institution(hospital) that takes ultimate responsibility of the initiation and management of the study.
• National Data Protection Act?
• Bioethics Law?

4. Insurance and Contracts

• Civil liability insurance must cover risks related to the study.
• Research agreements with participating healthcare institutions (via DSA)

5. Local Ethics Committee (CPP) Approval

• A favorable opinion from the local CPP (Committee for the Protection of Persons) is mandatory.
• The submission includes a **Research application form**, **Case Report Form (CRF)**, **participant information sheet and informed consent form (ICF)**, **Principal investigator's CV and GCP**, confidentiality and insurance documents: **Data sharing agreement (DSA), Insurance (if applicable)**

6. Authorization from the National Ethics Committee (if applicable)

• Mandatory if the study involves medicine or a medical device.
• Optional but recommended for other interventional studies (minimal risk).
• Addendum: list of national authorities for assessment, regulation and safety of medicines and medical devices.

7. Registration on the European CTIS Portal

• As of January 1, 2025, all interventional studies must:
  - Comply with Regulation (EU) No. 536/2014.
  - Be submitted via the **Clinical Trials Information System (CTIS**) managed by the EMA (European Medicines Administration. *https://euclinicaltrials.eu/*

8. Ongoing Study Notifications: Monitoring and Reporting

• Annual safety report to be submitted to EMA (if applicable) in collaboration with national agencies.
• Serious Adverse Events (SAEs) must be reported via the CTIS portal.
• Final study report with result analysis.
• Publication and dissemination of results in compliance with scientific transparency standards.
• Substantial amendments to the protocol must be submitted via CTIS in collaboration with national agencies.

9. Special Considerations for Orthopedic Surgery

• Compliance with safety standards for surgical procedures.
• Traceability of implants/medical devices used (**Registries)**
• Potential real-life assessments (registry, post-op observation).