**Study title:**

**Principal investigator**

**Co-investigators** (at least one representative of each center)

**Study Summary**

1. **Background**
2. **Study aims**
3. **Endpoints**
   1. **Primary endpoints**:
   2. **Secondary endpoints**:
4. **Study design:** 
   1. **Centers participating:**
   2. **Data acquisition**
   3. **Inclusion criteria**
   4. **Exclusion criteria**
   5. **Definitions**
   6. **Data collection**
   7. **Study variables**
5. **Statistical** **analysis**
6. **Ethical Committee Approval Process**
7. **Study duration and milestones: start date, milestones and completion dates**
8. **Study Budget**