**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**