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| **TITLE OF THE STUDY**  |  |
| INDICATION |  |
| METHODOLOGY |  |
| **STUDY COORDINATOR** |  |
| **STEERING COMMITTEE** |  |
| **SPONSORSHIP** |  |
| **BACKGROUND****(clinical need)** |  |
| **RATIONALE****(rationale for treatment)** |  |
| **MAIN CRITERIA FOR INCLUSION** |  |
| **PRIMARY OBJECTIVE****AND PRIMARY ENDPOINT** |  |
| **SECONDARY OBJECTIVES****AND SECONDARY ENDPOINTS** |  |
| **TRIAL DESIGN** |  |
| **STATISTICAL CONSIDERATIONS** **SAMPLE SIZE** |  |
| **TRANSLATIONAL RESEARCH / BIOBANKING** |   |
| **FEASBILITY :**NUMBER OF CENTERSLENGHT OF THE STUDY COMPETITING STUDIESFUNDING |  |