##### Clinical Study Feasibility Check List

|  |  |
| --- | --- |
| **Protocol Title:** | **Protocol Number:** |
| **Questions** | **Yes** | **No** | **N/A** | **Commentaries** |
| **Part 1 – Science, technique and ethics** |  |  |  |  |
| The institution Scientific Committee will evaluate the protocol. |  |  |  |  |
| The protocol is technically feasible. |  |  |  |  |
| The protocol is compatible with the medical field, local authorities and site requirements. |  |  |  |  |
| The protocol admissibility criteria are realistic and well defined in the protocol. |  |  |  |  |
| The comparative product is available in my region. |  |  |  |  |
| The protocol is compatible with the local ethical practices. |  |  |  |  |
|  |  |  |  |  |
| **Part 2 – Subjects**  |  |  |  |  |
| The targeted population is present at my site  |  |  |  |  |
| Competitive studies at my site |  |  |  |  |
| The number of available subjects to recruit within the time limits is confirmed (medical files, computerized listing) |  |  |  |  |
| Subjects’ availability outside my site (advertising) |  |  |  |  |
| The evaluation of the subjects’ participation agreement vs. the protocol requirements has been completed. |  |  |  |  |
| Treatment or tests period acceptable |  |  |  |  |
|  |  |  |  |  |
| **Part 3 – Personnel Availability** |  |  |  |  |
| Investigator: available time to see and treat the patients. |  |  |  |  |
| Investigator: available time to supervise his team |  |  |  |  |
| Investigator: available time to generate, review and submit the study data.  |  |  |  |  |
| Investigator: available time to interact with the sponsor. |  |  |  |  |
| Evaluation of the study required qualified personnel. |  |  |  |  |

**Clinical Study Feasibility Check List**

|  |  |
| --- | --- |
| **Protocol Title:** | **Protocol Number:** |
| **Questions** | **Yes** | **No** | **N/A** | **Commentaries** |
| **Part 4 – Resources** |  |  |  |  |
| Evaluation of tasks delegations  |  |  |  |  |
| Evaluation of the available personnel vs. the study duration |  |  |  |  |
| List of required technical and professional personnel  |  |  |  |  |
| Evaluation of the budget (team remuneration)  |  |  |  |  |
|  |  |  |  |  |
| **Part 5 – Facilities and equipment** |  |  |  |  |
| Evaluation of the personnel working space  |  |  |  |  |
| Evaluation of the subjects’ recruiting and follow-up space |  |  |  |  |
| Evaluation of the space for (secure) storing of the subjects’ study records  |  |  |  |  |
| Evaluation of the space for secure storing of the clinical study material |  |  |  |  |
| Available material in line with the protocol requirements |  |  |  |  |
| Available medical equipment in line with the protocol requirements  |  |  |  |  |
| Secure preserving space for the investigational product (pharmacy or other) |  |  |  |  |
| Local laboratories compatibility  |  |  |  |  |
| Other services compatibility  |  |  |  |  |
| Written agreement confirmation with other site services |  |  |  |  |
| Evaluation of the space for monitoring activities or others |  |  |  |  |
|  |  |  |  |  |
| Part 6 – Others |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |