Questionnaire to be filled in by the sponsor/CRO for the budget calculation of a clinical trial and for its logistic aspects.

**Name and function of the person providing the information mentioned in this document**

**Name and Function Signature Date**

|  |  |  |
| --- | --- | --- |
| ***Generalities*** | | |
| **Recruitment plan & timeframes** | 1. Number of participants foreseen locally 2. Estimated First Patient First Visit (FPFV) : 3. Estimated recruitment END date : 4. Estimated Last Patient Last Visit (LPLV) : | |
| **Ethics Committee** | Site Ethics Committee Role :  Central 🞎 Local 🞎  <http://www.saintluc.be/recherche/comite-ethique-soumission-initiale.php>  Site does not delegate to sponsor/CRO the EC submission. The documents will be provided to site staff/PI. | |
| **Study timelines** | 1. Estimated date for Ethics Committee Submission : 2. Estimated Site Qualification visit date :   On site 🞎 Phone call 🞎 Web\_TC 🞎   1. Estimated Site Initiation visit date | |
| **Study Communication** | 1. Investigator meetings scheduled? Yes 🞎 No 🞎   Please provide the agenda, location and frequency :   1. Any teleconference or Web meeting scheduled? Yes 🞎 Frequency? No 🞎 | |
| **Study Logistics, Data management, Vendors and Technologies profile**  Shipping materials, Dry ice and prepaid airwaybills will be provided and paid by sponsor | **Central Vendor involved** : Yes 🞎 Please tick the appropriate No 🞎   * E-CRF: * IVRS / IWRS / IRT : * Central ECG\_ERT : * Tablet – ePRO : * E-Pen : * Study Portal \_Investigator Site file * Study Safety Portal : * e\_Device, please specify * Other device provided, please specify * IT specific tools, please specify * Other, please specify : | |
| **Number of internet applications used\_Name and version :**  Please tick the appropriate   * E-CRF: * IVRS / IWRS / IRT : * Central ECG\_ERT : * Tablet – ePRO : * E-Pen : * Study Portal : * Study Safety Portal : * e\_Device, please specify * Other device provided, please specify * IT specific tools, please specify * Other, please specify : | |
| **Any other department involved?** Yes 🞎 specify No 🞎   * Medical Imaging * Other Medico-technic services/ Dpt * Cardiology * Ambulatory Treatment Unit * Pharmacy * Pathology * Other, please specify : * Other, please specify : | |
| **Investigator Site File** 🞎 Paper 🞎 Electronic 🞎 Both | |
| **Safety Report \_CIOMS\_SUSAR’s :**  🞎 Paper  🞎 Electronic, please explain the sponsor procedure and expectation (download, printable, validation, staff access and CA/ Ethic communication\_Notification)  🞎 Both :   1. **Quality of Life Questionnaire?** Yes 🞎\* No 🞎   \* Paper version 🞎 Electronic 🞎\*\*  \*\* e-version : Please specify the connection requirements :   * Does this need to be encoded manually by SN/SC?  Yes 🞎 No 🞎 * Automatically transferred in the e-CRF? Yes 🞎 No 🞎 * Does this need to be sent to Central vendor? Yes 🞎No🞎  1. **Other questionnaires?** Yes 🞎\* No 🞎   \* Paper version 🞎 Electronic 🞎\*\*  \*\* e-version : Please specify the connection requirements :   * Does this need to be encoded manually by SN/SC?  Yes 🞎 No 🞎 * Automatically transferred in the e-CRF? Yes 🞎 No 🞎 * Does this need to be sent to Central vendor? Yes 🞎No🞎 | |
| **IVRS / IWRS/ IRT**   * Pre-screen * Screening * Randomization * Study Medication * Discontinuation * Other, specify * Does the **Drug Accty** need to be encoded by SN/SC in the system?  Yes 🞎 No 🞎 * Patient home-based IVRS call for * Drug Accty Yes 🞎 No🞎 * Visit confirmation Yes 🞎 No🞎 | |
| **ELECTROCARDIOGRAM**  Yes 🞎 No🞎   1. Machine\_Device provided by the sponsor : Yes 🞎 No🞎 NA 🞎 2. Central Vendor 🞎 Local 🞎 Both 🞎     If provided, please specify the connection requirements (fax, modem, mail,…) :  FAX 🞎 Modem 🞎 e-mail 🞎 Other 🞎    If not provided \_ ECG Local   * Please specify Sponsor and protocol expectations and requirements (SoC or not): * Is there any copy to be sent? Yes 🞎 No🞎 * Does this need to be encoded manually by SN/SC?  Yes 🞎 No 🞎   If Central Vendor :   * Report : FAX 🞎 Web Portal 🞎 Both 🞎  Paper- normal courier 🞎 * Does this need to be encoded manually by SN/SC?   Yes 🞎 No 🞎 Automatically transferred in the e-CRF 🞎 | |
| **SITE STAFF**  Does the study need an Independent or Unblinded (other than Pharmacy) Yes 🞎 No🞎   * Reviewer or Assessor * Nurse * Staff member * Other   to give study medication or take blood samples, Data entry and / or other study procedure?    If yes, please specify? | |
| ***Study TRAININGS*** | | |
| **Site Staff Training**  Site staff trained and certified   1. Transcelerate GCP 2. IATA | | **Sponsor requirements, please specify :**  Training certificates needed  for (Application name) and from whom :   1. E-CRF 2. IVRS, IWRS, IRT: 3. ECG\_ERT : 4. Tablet : 5. Therapeutic Area Specific Training (specific assessment):  * **Rheumatology** : BILAG SELENA PGA IJA GRAPPA   Other ?   * **Oncology**: RECIST ? RECIST modified ? iRECIST ? both ? Other ? * **Other Area** :  1. Study Safety Training? 2. Study Portal 3. Study /Protocol Specific Training 4. Unblinded staff? 5. …… 6. ………….. |
| ***Laboratory*** | | |
| Shipping materials, Dry ice and prepaid airwaybills will be provided and paid by sponsor  **Please provide the LAB manual and Lab Visits Flow Chart** | | 1. Central Lab 🞎 Local lab 🞎 Both 🞎   If central lab, Please specify   * Name of the companies * Pre-labelled kits Yes 🞎 No 🞎 * Automatic kits re-supply Yes 🞎 No🞎 * Blood Collection System Monovette® 🞎 or Vacutainer® 🞎 * Lab Report : FAX 🞎 Web Portal 🞎 Both 🞎  Paper- normal courrier 🞎      * Lab samples pick-up : single one 🞎 several 🞎   Ambiant 🞎 Frozen 🞎 Both 🞎   1. **Do the lab results need to be encoded manually by SN/SC?**   Yes 🞎 No 🞎 Automatically transferred in the e-CRF 🞎  **Do the lab results need to be validated manually by PI in the e-CRF?**   1. **Laboratory specific requirements**  * Specific blood samples: PBMC- biomarkers - pharmacokinetics? Yes 🞎 No 🞎 * Please provide time points to be specified * Specific specimen collection procedures? (hood,…, Pk post dose ?) Yes 🞎 No 🞎 * Specific BLINDED Blood / urines / other results during the study? Yes 🞎 No 🞎 * Pathology tissues required? Yes 🞎 No 🞎 * Blinding PLAN ? Yes 🞎 No 🞎  1. **Any devices provided by the sponsor for the temperature log**?   Yes 🞎 If yes, specify No 🞎  If yes, specify: ……………..  ………………………………………………………………………………………………   1. **Sponsor requirements for calibration / certified specific device, please specify** |
| ***Medical Imaging*** | | |
| Please provide the  X-Ray manual and Visits Flow Chart  Shipping materials, X-ray Support, prepaid airwaybills will be provided and paid by sponsor | | 1. Sponsor expectations and protocol requirement   Central Vendor 🞎 Local 🞎 Both 🞎  If central lab, Please specify   * Name of the companies : * Report : FAX 🞎 Web Portal 🞎 Both 🞎  Paper- normal courier 🞎 * Queries communication & resolution process ?  1. Do medical imaging results need to be encoded manually by SN/SC? :   Yes 🞎 No 🞎 Automatically transferred in the e-CRF 🞎 |
| ***Other Services*** | | |
| Please provide the  manual and Visits Flow Chart  Shipping materials, Data Support, prepaid airwaybills will be provided and paid by sponsor | | 1. Sponsor expectations and protocol requirement   Central Vendor 🞎 Local 🞎 Both 🞎  If central vendor, Please specify   * Name of the companies : * Report : FAX 🞎 Web Portal 🞎 Both 🞎  Paper- normal courier 🞎 * Queries communication & resolution process ? * Do the results need to be encoded manually by SN/SC? :   Yes 🞎 No 🞎 Automatically transferred in the e-CRF 🞎  2. Sponsor expectations for data capture not specified in the protocol?  Please specify: (eg Additionnal Vital signs monitoring) |
| ***Monitoring and data requirements*** | | |
| *Please ask for*  *e-Patient File access to your dedicated CRCM* | | **Monitoring PLAN. Please provide sponsor convention and requirements**   1. Monitoring on Site Please specify frequency   Accompagnied SDV will be requested min. ONE month before the expected date   1. REMOTE monitoring by CRA: Yes 🞎 Please specify: ................................ No🞎 2. REMOTE monitoring by Data management (**e-CRF- Central Vendor** ) : Yes 🞎 No🞎   Please specify: ......................................   1. Please provide the Monitoring / Interim Analysis / Data Base lock PLAN 2. Please specify the Study Risk Based Monitoring Indicator 3. Please specify if Specific Adjudication evaluations are requested 4. Please specify the if Specific Adverse Events of Special Interest (AESI) are looked for   **Site will work as follow (cfr Clinical Trial Agreement):**   * **e-CRF data entry 5 to 7 working days upon Final Central Lab Report received** * **Queries resolution 5 working days** |
| ***Site info \_ Contract & Financial*** | | |
|  | | <http://www.saintluc.be/recherche/ctc-documents-promoteurs.php>  Patient reimbursement  : Yes 🞎 No 🞎  If yes, specify: Meal 🞎 Travel / parking 🞎 Working Day indemnity 🞎 Other 🞎    Check –Voucher 🞎 Lump sum 🞎 other 🞎……………………………… |
| ***IMPORTANT NOTES*** | | |
|  | | * Any significant modification to this document occurring after the agreement is being signed will probably lead to an amendment (additional training, CRF modification …). * The study nurses/study coordinators and investigators are regularly trained by the institution (GCP-**3 years for valid certification**, IATA…).   Those valid and existing training certificates must be considered by the sponsor/CRO.   * When a problem occurs with the access to e-CRF, or for any e-CRF’s technical problems, or for any ECG transmission problem, CRA will be asked to contact directly the helpdesk and solve the issue. * Please provide us with the following documents:   + Protocol   + Investigator Brochure   + Informed Consent Form   + Questionnaire pdf and /or paper version   + Paper version of the CRF and /or electronic pdf version   + Manual of Procedure (for each department involved in the trial) : Medical imaging manual, * Pharmacy Manuel, Laboratory manual   + Vendor manual, IT tools manual (e-PRO, tablet ...)   + Sponsor budget proposal and conditions * Name and function of the person providing the information mentioned in this document * <http://www.saintluc.be/recherche/ctc-documents-promoteurs.php> |