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|  | **Data Management Requirements Checklist** |
| **Study title:**  *Give study title to which this SOP applies* |

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| **General Project/Study Information** |
| **Project /Study acronym or Registration code**  |  |
| **Sponsor** |  |
| **Principal Investigator** |  |
| **Type of Project/study**(Select all that apply) | 0 Clinical trial (specify phase …)0 Observational study0 Epidemological study0 Diagnostic study0 Qualitative study0 Other, specify: |
| **Study protocol** | 0 Final version available or due for \_ \_/\_ \_/\_ \_ \_ \_ (DD/MM/YYYY) |
| **Expected Study Start** **(First participant first visit)** | \_ \_ / \_ \_ / \_ \_ \_ \_ (DD/MM/YYYY) |
| **Expected Study End****(Last participant last visit)** | \_ \_ / \_ \_ / \_ \_ \_ \_ (DD/MM/YYYY) |
| **# subjects (estimated)** |  |
| **# visits/subject** |  |
| **# data points/subject** |  |

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| **DM / ICT Information – User Requirement Specifications** |
| **Adherence to regulations, standards & Funder needs**(Select all that apply) | 0 GDPR or other privacy regulation0 Good Clinical Practice0 Good Clinical Laboratory Practice0 ISO 90010 ISO 270010 FDA 21 CFR part 110 Local regulation, specify:0 CDISC , specify 0 CDASH 0 SDTM 0 ADaM 0 XML0 MedDRA0 WHO drug0 FAIR data sharing principles0 Other, specify: |
| **Type of data**(Select all that apply) | 0 Demographic data0 Clinical/medical data0 Laboratory data0 Epidemological survey data0 GPS data0 Qualitative data (e.g. social, anthroplogical etc.)0 Other, specify: |
| **Type of data collection** (Select all that apply) | 0 Paper0 Electronic0 Other, specify: |
| **Type of data entry**(Select all that apply) | 0 Single data entry0 Double data entry0 Offline entry0 Online entry0 Other, specify: |
| **Type of data collection tools**(Select all that apply) | 0 Laptop, specify number: \_ \_0 PC, specify number: \_ \_0 Tablets, specify number: \_ \_0 Smart phone, specify number: \_ \_0 Barcode reader, specify number: \_ \_0 Other, specify: |
| **Type of data backup**(Select all that apply) | 0 On server, specify where (institution, country): 0 On data collection tools, specify:0 On external memory0 Other, specify: |
| **Specifications Software****(Front end; back end; Operating system etc.)** | **Name(s):** |
| **Specifications Hardware** | **Name(s):**  |
| **Specific DM/ICT documentation**  | 0 DM / ICT SOPs0 Data Management Plan (DMP), specify format or template: * 0 ALERRT DMP template
* 0 DMP tool
* 0 DMP online
* 0 Horizon 2020
* 0 Other, specify:

0 DM/ ICT reports, specify ……………………………….…………………………………………………………………...0 Other, specify: |
| **Estimated HR needed** | 0 Data Entry Clerk(s) : ☐1 ☐ 2-5 ☐ more than 50 Data Reviewer : ☐1 ☐ 2-5 ☐ more than 50 Data Manager : ☐1 ☐ 2-5 ☐ more than 50 Monitor : ☐1 ☐ 2-5 ☐ more than 50 Medical Coder : ☐1 ☐ 2-5 ☐ more than 50 Database administrator: : ☐1 ☐ 2-5 ☐ more than 50 Help Desk : ☐1 ☐ 2-5 ☐ more than 50 Other, specify: |
| **Estimated Timelines** | Activities CRF finalizationDatabase/eCRF testingFirst participant first visitLast participant last visitDatabase lockData sharing | Estimated date (dd/mm/yyyy): |
| **Estimated DM & ICT Costs** | **Human resources:** **Software:****Hardware:****Other:**  |
| **Notes:** |

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| **Read & Approved** |
| Project coordinator  | Other, if applicable | Central Data Manager |
| Name, Signature & Date | Name, Signature & Date | Name, Signature & Date |