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|  | **Essential DM/IT documentation** |
| **Study title**: *Give study title to which this applies* |

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| **Templates: blank documentation with preference prepared at project initiation** |
| * Subject identification code list (1)
* Subject screening log (1)
* Subject enrolment log (1)
* (Annotated) Case Report Form (CRF) (1)
* CRF and eCRF approval form
* (DM) Training Log (1)
* TMG / DM meeting minutes template
* Protocol violation form
* Data Clarification Form (paper query form, if applicable)
* CRF tracking log
* SAE report (inital/follow up) form
* SAE reconciliation form
* DB Lock checklist
* DB (Un) Lock Approval form
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| **Documents: with preference prepared at project initiation** |
| * DM/ICT SOPs (1)
* Normal value / ranges Laboratory tests (1)
* Data Management Plan (2)
* Data Review Plan (= Data Validation Plan)
* DM section in Study protocol
* User list for database/eCRF (with user role & access rights) (1)
* Software contract & license agreement
* IT specifications (software & hardware)
* Randomization list, enveloppes + allocation sheet
* System Validation documentation (1)
* DM training pack (data collection/entry/medical coding guidelines…) (1)
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| **Documents: other** |
| * Data Management Report (2)
* Data sharing Agreement
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(1)= Required by GCP (2) = Required by some funders, editors