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| --- | --- | --- | --- | --- | --- |
| **Study Name** | **Sponsor** | **Actual CRF vers.** | **Change asked by** | **Date of request** | **Change No.** |
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| **CRF CHANGE MANAGEMENT TEMPLATE** |

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| **Change request description** | | | | | **Data manager action** | | |
| Form name | Variable name | New item? | Problem encoutered | Solution proposal/Describe the risk if the change is not implemented | Date | By | Test in draft mode successful? |
|  |  | ⭘Yes ⭘No |  |  |  |  | ⭘Yes ⭘No |
|  |  | ⭘Yes ⭘No |  |  |  |  | ⭘Yes ⭘No |
|  |  | ⭘Yes ⭘No |  |  |  |  | ⭘Yes ⭘No |
|  |  | ⭘Yes ⭘No |  |  |  |  | ⭘Yes ⭘No |
|  |  | ⭘Yes ⭘No |  |  |  |  | ⭘Yes ⭘No |

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| **Risk analysis** | | **Change updates** | |
| Impact on the CRF Design? | ⭘Yes ⭘No | New ‘Cross Disciplinary CRF Design Validation’ version |  |
| New paper CRF version |  |
| New Codebook version |  |
| New DMP version |  |
| How critical are the changes? Impact on the Database Validation? | ⭘Low ⭘High | New ‘Database Validation against functional specification’ version |  |
| Impact on the protocol? | ⭘Yes ⭘No | New Protocol/amendment version |  |
| New amendment? | ⭘Yes ⭘No | New amendment reference |  |
| Impact on the existing data? If yes, specify | ⭘Yes ⭘No |  |  |
| Impact on already locked/ monitored/ signed pages? If yes, specify | ⭘Yes ⭘No |  |  |
| If new item(s) are planned, will they be populated for all patients already enrolled? | ⭘Yes ⭘No |  |  |
| Impact on the paper CRF/eCRF guidelines? | ⭘Yes ⭘No | New guidelines version |  |
| Impact on the existing edit checks ? | ⭘Yes ⭘No | New Edit checks version |  |
| Impact on end-users testing? | ⭘Yes ⭘No | New End users system testing version |  |
| Impact on end-users training? | ⭘Yes ⭘No | New End users training version |  |
| Impact on the statistical analysis scripts? | ⭘Yes ⭘No |  |  |
| Impact on the data extraction program? | ⭘Yes ⭘No | New data extraction program version |  |
|  |  | Global change communication is done? | ⭘Yes ⭘No |

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| --- | --- | --- | --- |
| **Authorisation for change** | | | |
| Date | By | Approval for the change Yes/No | Signature |
|  |  | ⭘Yes ⭘No |  |
|  |  | ⭘Yes ⭘No |  |

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| --- | --- | --- | --- |
| **Switching the study into the Production mode** | | | |
| Date | By | Study switch to the production mode Yes/No | Signature |
|  |  | ⭘Yes ⭘No |  |