**Completion note:** Complete this form for each routine dataset for a specific trial (separately for each dataset even if multiple datasets from the same source) and file in TMF. *Delete this guidance note.*

| **[Add trial name] Trial** | |
| --- | --- |
| **Date** | dd-mmm-yyyy |
| **Version** | vX.X |
| **Source of Healthcare Systems Data: dataset and provider** | |
| * [Name of source e.g. HES Admitted Patient Care data from NHS Digital] | |
|  | |
| **What was the rationale for using this source of Healthcare Systems Data** | |
| * [Add one or two sentences here then cross-reference more detailed justification in the Data Management Plan] | |
|  | |
| **Dataset identification number** | |
| * [Datasets covered by form for specific trial] *[Cross-reference number to be added by trial team]* | |
|  | |
| **How often are these routine data received?** | |
| * [Frequency] between [year] and [year/TBD] | |
|  | |
| **What is the expected latency of the data?** | |
| * [Latency = Time from the most recent datapoint in the dataset until receipt by the trial team] * This is taken to be ... [add] because … [clarify] | |
|  | |
| **What are the reassurances that these data are fit for purpose?** | |
| * The process by which this routine dataset is constructed has been document clearly in … [Cross-reference to downloadable Position Paper and version specific to dataset] * This dataset has been used in other trials including … [give examples]. * Outside of trials, this data is trusted for use in … [eg HES datasets is used to drive national papers; death dataset is used to make decisions on payments to GPs] * The linkage is sufficient accurate … [Give info] * This dataset has been subjected to data utility study within a trial which showed it to be appropriate for use [Give refs] | |
|  | |
| **What are the risks from using this Healthcare Systems Data in the intended fashion?** | |
| * The risks from relying on this healthcare systems dataset as the only way to obtain data on … are … * The risks from using this healthcare systems dataset to supplement trial-specific data collection of … are * Further information is presented in the Risk Assessment | |
|  | |
| **Any other action required** | |
| * [For example, contribution to ongoing/future data utility studies for particular outcomes] | |
|  | |