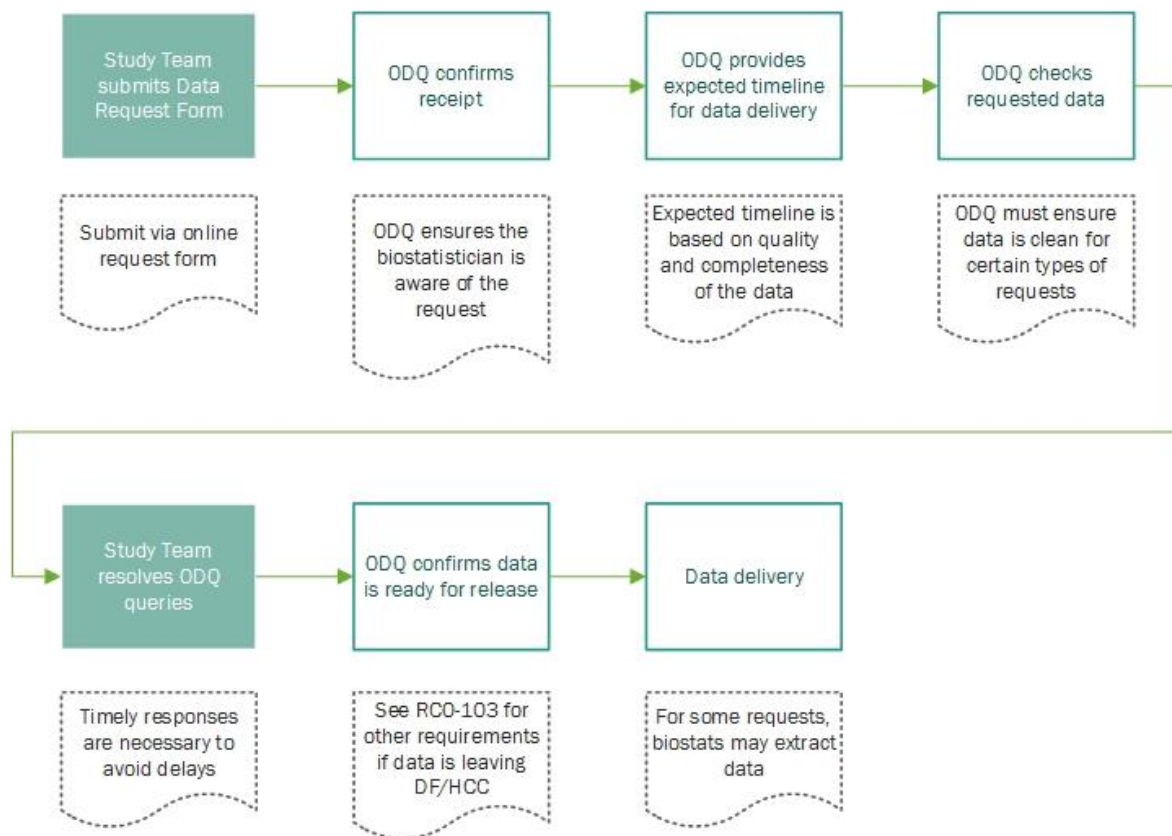


DF/HCC Operations for Human Research
Data Requests**1. BACKGROUND:**

The Office of Data Quality (ODQ) facilitates requests for data generated by DF/HCC Investigator-Sponsored research and captured in the InForm EDC system. The data request process ensures that applicable policies and requirements are satisfied, and high quality research data is provided for use.

2. ASSOCIATED DF/HCC POLICIES:

2.1. [DATA-100](#)

3. PROCEDURE:**3.1. Overview of the Data Request Process** (more details below)

3.1.1. To request data from an Investigator-Sponsored protocol where data is maintained in InForm EDC, please submit an online [Data Request Form](#) to ODQ.

DF/HCC Operations for Human Research
Data Requests

*Note: If you will be using the DF/HCC Biostatistics Core for data analysis, please make sure to provide the required notification to the biostatistician. See:

<http://www.dfcc.harvard.edu/research/core-facilities/biostatistics/>

3.1.2. Research teams should be prepared to resolve queries on the data during the data request process. The number of new queries generated by ODQ depends on the quality and quantity of data requested. If a significant amount of the requested data is missing or queries are not being answered in a timely manner, ODQ reserves the right to place a request on hold until those issues have been resolved. Study teams are strongly encouraged to verify that data entry is up to date prior to submitting a data request.

3.1.1. The Data Quality Manager or ODQ Director assigns each request to a Data Quality Analyst (DQA) and determines whether the data must be cleaned. The table below outlines some general criteria that are used to make this determination:

Abstract/Presentation	Data must be clean.
Manuscript/Publication	Data must be clean.
FDA Annual Reporting	Data should be clean whenever possible.
Grant Submission	Data should be clean whenever possible.
Data Requested by Third Party	Data must be clean unless specifically allowed per contract/policy exception.
Interim Analysis	For a formal interim analysis (planned in the protocol and/or to determine future conduct of the study) data must be clean.
ClinicalTrials.gov Results Reporting	Data should be clean whenever possible.

3.1.2. The assigned DQA will verify the protocol's IRB status, run a missing forms report (MFR) for the protocol, and email the requestor to confirm receipt. The Overall PI and biostatistician are copied to ensure they are aware of the request. The biostatistician may need to approve the request before any data can be delivered. The DQA will provide an estimated completion date for the request based on the complexity of the request and current workload.

3.1.2.1. If a monitor is known to be assigned to the trial, the monitor will also be copied and asked to resolve any pending monitor queries on the requested data.

3.1.3. The DQA will perform the necessary quality checks on the data to ensure proper data capture, consistency, and completeness. The DQA will review the protocol and ensure data entry is consistent with the protocol requirements. In addition, the DQA will verify data has been entered per the general guidelines below, as applicable. Any discrepancies or missing data related to the request will be queried.

Version: May 15, 2018

Maintained by: Office of Data Quality (ODQ)

DF/HCC Operations for Human Research
Data Requests**General Guidelines**

<p>Enter a field level Comment when the data entered does not match what is expected per protocol (e.g., a procedure done out of window, a pill count is unexpected based on the length of cycle). In addition, if a protocol-required item is entered as Not Done, Not Applicable, or Unknown, ODQ will look for an explanation in the comment. If no comment is provided, ODQ may query the data to verify that the deviation from the protocol was intentional and not a data entry error. Comments can be added to most fields by clicking on the comment bubble next to each field.</p>
<p>All Timepoint start dates should be coded per the form instructions located on the Date of Visit Form. Unless the protocol specifies otherwise, timepoints must be entered in sequential order and should not gap, overlap or repeat. Timepoints should also fall within the reporting period length specified by the protocol. Any deviation from the timepoints specified in the protocol should be noted as a comment. In addition, once a timepoint has been created, it cannot be deleted. A form level comment should also be entered for all forms created in error. A form level comment can be added by clicking the comment bubble at the top right of the form.</p>
<p>The Date of Visit (DOV) is a system form and is required for most visits. The DOV form should be completed and data entry must follow the instructions on the form.</p>
<p>Assessment Dates: Please enter the actual date of assessment (rather than the scheduled date of assessment). The assessment date must be within window per protocol. If not per protocol schedule, a comment should be added.</p>
<p>InForm uses dynamic questions and forms to facilitate data entry. Dynamic forms and questions only appear when required, based on how previous questions have been answered in the system. If trigger questions are incomplete, dynamic forms and questions may not appear. Once a form has been triggered, it cannot be deleted. Instead, a form level comment should also be entered for all forms created in error. A form level comment can be added by clicking the comment bubble at the top right of the form.</p>
<p>The first visit in InForm (typically Baseline) captures information collected prior to registration. If patient is registered on Day 1 and information was collected on Day 1 prior to registration it should be coded in this visit.</p>
<p>The Demographics Form is usually read-only, and captures registration information from the OnCore registration. If information on this form is incorrect, it needs to be corrected in OnCore.</p>
<p>Vital Signs forms have expected ranges associated with height and weight. Values outside of the expected range will be queried. Please double check to make sure the value is correct – often the value is wrong because of the units expected by the form.</p>
<p>Toxicity Codes are entered according to the CTCAE version in use on the protocol. The toxicity description and category will automatically fill once a code is entered. Enter a single toxicity code if there is a unifying diagnosis for multiple symptoms (e.g., cough, runny nose, and headache all due to an upper respiratory infection). In the absence of a unifying diagnosis, report each symptom or event individually. “Other” codes (ending in 999) should be avoided and only used when there is no more appropriate code available. If an “Other” code must be used, it must have the correct body system category (two letters prior to 999) and a description/comment must be entered to identify the event.</p>
<p>Toxicity Grade Changes are captured with an end date on the initial event, and a new entry capturing the start date of the new grade. The end date for the initial event should be the same day as, or day prior to, the start date of the new grade.</p>
<p>Toxicity End Dates should be updated throughout the study. Most protocols require continuing toxicities to be followed until resolution. For toxicities that continued until a subject was taken off study, the off-study date should be entered as the end date.</p>
<p>Tox Summary forms ask if there are any new toxicities or changes to toxicity information at each timepoint. These forms must be filled out correctly for the MFR to be updated. Questions should be answered based on the assessment period/timepoint the form is in. For example, if there is a single Tox Summary assessment in Cycle 2, questions should be answered for the time period from Cycle 2 Day 1 through the day prior to Cycle 3 Day 1.</p>
<p>The Off Treatment Date should be date of last administered treatment, unless otherwise defined in the protocol or on the form itself. The Off Study Date is the date that the patient will not be followed anymore and no more data collections will take place. The MFRs check the data against the subject status in OnCore as well, so be sure to update the Off Treatment and Off Study information in OnCore.</p>

Version: May 15, 2018

Maintained by: Office of Data Quality (ODQ)

DF/HCC Operations for Human Research
Data Requests

The **Follow-Up** visit is used to report survival and post-treatment assessments as required per the protocol. Unless otherwise defined in the protocol or on the form itself, it is expected that the Follow-Up Date of Visit reflect the date of the first follow-up assessment and have a corresponding assessment date coded in Section 1 of the Follow-Up form. Subsequent follow-up assessments should be coded in this section as they are performed, and survival should be updated after patient contact accordingly.

Survival information needs to be updated per protocol. ODQ will issue queries if the survival information has not been updated, even if the form appears complete in InForm.

3.1.4. Data is considered clean when all the following conditions are met:

- Data entry for the requested data points is complete.
- ODQ has reviewed the requested data and performed the necessary quality checks.
- Any queries on the requested data (including queries issued by monitors) have been answered by the study team and closed by ODQ (or the monitor, when applicable).

3.1.5. Once any required data verification and data cleaning steps have been performed, the DQA will notify the requestor, PI, and biostatistician that the data request is complete. If indicated in the original request, the DQA will extract and deliver the raw, unfiltered data set.

3.1.5.1. In some cases, ODQ will notify the biostatistician that they can directly pull the data at the completion of a data request. This typically occurs when a formal analysis is being performed (e.g., to publish) or the requestor has specified an output that requires manipulation of the data (e.g., a summary table). DQAs are unable to re-format, sort, filter, summarize, or otherwise manipulate the data that is extracted from InForm.