

## Network F

| Process Flow Sub Activities                       | Description of deliverable   |
|---|--|
| <b>Activities</b>                                 |  |
| Network KDD Guidance                              | Provide input into Network KDD (Key Driver Diagram) as it relates to data & measurement strategies   |
| Attend Network Data & measurement Team Meetings   | Kickoff of DCC team where scope is presented. Determine meeting schedule, attendance, roles and responsibilities.  |
| Maintain Measures Table                           | Complete Network Measures Table for Priority measures  |
| Maintain DCC Charter Document                     | Charter document to outline roles and responsibilities of DCC, governing principles.   |
| Maintain Measure Programming Specs                | Development of Measure Programming specs, one per measure.   |
| Identify Data Domains                             | Identify high level data domains for CRFs. (Note, standard forms for Demographics, Labs, Medications will be used to collect common data domains)  |
| Identify External Data Systems                    | Identify external data sources, such as PROs, EHRs, etc where data will be sourced from  |
| Data Flow Diagram                                 | Diagram of how data will be received from external data sources and how the data will be linked  |
| Finalize Protocol / Data Use Agreements / Consent | Identify any additional detail to include in the agreements to ensure proper data linkage is in place to allow for data to be collected in registry (PHI data elements needed)                             |
| Paper Case Report Forms (CRFs)                    | Paper format for each data domain, including questions to ask, frequency, show/hide logic.   |
| Identify External Data System Fields              | Identify data fields coming from external data systems. Need to ensure similar questions are worded on Paper CRF, if applicable. Create read-only CRF for data coming entirely from external system        |
| Registry Build CRF Specs                          | Excel template for CRF Specs to be programmed into Registry, detailing forms, questions and logic.   |
| Registry Implementation Plan                      | Implementation plan document of the Registry for the Network.  |
| Registry Field Configuration                      | Addition of registry questions, implementation of show/hide logic  |
| Test Plan   | Create test plan outlining testing activities  |
| Test Cases  | Write test cases to test registry & measures functionality   |
| Registry Validation Testing                       | Performing testing of Registry features and functionality, as ready.   |
| Measure Programming                               | Programming of Measures into the Registry  |
| Data Upload Specs                                 | For each external data source providing data into the Registry, an upload specification template must be completed to ensure data transfers into Registry properly for measurement and reporting purposes. |
| Site Training Materials                           | Site training materials on how to use the Registry, how to complete data collection forms,   |
| User Acceptance Testing                           | Center users actually test system to ensure it meets their needs.  |

|   |  |
|---|--|
| Charts Produced / Validation                              | QI Charts and reports produced based on mock data entered by end users. Testing of measures to ensure they look as expected. Perform random sample record review on measure validation. Look at basic descriptives for measures (range values are as expected)                     |
| Measures Acceptance                                       | Signoff on measures produced; Production ready   |
| <b>MILES</b>  |  |
| Center training   | Training of centers as they have IRB & Legal Approval  |
| Center Configured   | Collect Center specific information needed as centers receive IRB and Legal Approval. This includes consent information, lab configuration.  |
| User Accounts Created                                     | Identify users at centers and ensure they have accounts prior to needing to enter data   |
| Configure EDT Files for Upload                            | Configure EDT Upload Files in Registry & test to ensure data is properly received (Includes up to 3 external data sources to be identified as a source of data.)   |
| Assist Centers with EDT                                   | Work with centers and data vendors on logistics for receiving data electronically.   |
| Meeting Attendance  | Attend network meetings, community conferences   |
| Registry Training / Guidance documents                    | Create Registry specific training materials and guidance documentation on how to use the Registry  |
| Network Specific Training / Guidance documents & job aids | Define the requirements for and contribute to any special registry training materials which are Network specific (i.e. guidelines for EDT file configuration at the centers)   |
| QI chart Review   | Review network QI charts produced by the registry to ensure charts provide improvement learning & opportunities. Review at the network aggregate as well as the center level. Monitor special cause report to look for needed shifts in centerlines and definition of annotations. |
| Network Measurement Investigation                         | Diagnosing potential issues and opportunities (: e.g., why is the network's July data point so high? Looking at subgroups of the network: e.g., these five centers started this work before the rest, so what do their outcomes look like compared to the others?)                 |
| Center Data Support                                       | Triage and respond to center questions regard data entry best practices and  |
| Data Quality Checks                                       | Monitor quality of data entered into the registry and provide basic feedback   |
| Data Quality Measures                                     | Identify data quality measures & exceptions to implement in Registry (complete bundle, consistency bundle, data exceptions report)   |
| Program Data Quality Measures / Exceptions                | Program and test data quality measures and exceptions reports within Registry  |
| Registry technical support                                | Support centers on technical issues concerning Registry  |
| Registry technical support                                | Monitor & Troubleshoot EDT issues with Centers as they upload data from external sources   |
| Registry Data entry support                               | Support centers on data entry questions on how to enter data for patients in the Registry and respond to questions on condition specific   |
| Registry measure support                                  | Support centers in understanding of measures / charts produced by Registry   |
| Population Management Measures                            | Identify Population Management Measures to produce within Registry   |

|                                |   |
|--------------------------------|---|
| Pre-Visit Planning Report      | Identify Pre-Visit Planning report content and rules (if Network includes)  |
| Population Management Measures | Document network specific technical specifications for Population Management Report   |
| Pre-Visit Planning Report      | Document network specific technical specifications for Pre-Visit Planning Report  |
| Population Management Measures | Develop / Test Population Management Report tools in Registry   |
| Pre-Visit Planning Report      | Develop / Test Pre-Visit Planning Report in Registry (if Network Includes)  |
| Data Exporting                 | Outbound electronic data transfer or exporting of data  |
| Data Import format             | Configuration / programming needed to get data from source system for input into Registry (standard Registry configuration assumes external vendor / system providing data programs format for data export. Additionally, Registry team cannot guarantee that we have the capability to program data to be exported from source system, this would have to be determined on a case by case basis) |

## Registry & DCC Roles & Responsibilities

| Team Member Responsible              | Network-Sponsored Activity | Registry Configuration / Support Activity |
|--------------------------------------|----------------------------|---|
|                                      |                            |   |
| Statistician                         | X                          |   |
| All                                  | X                          |   |
| Statistician                         | X                          |   |
| Data Lead                            | X                          |   |
| Statistician                         | X                          |   |
| Data Manager                         | X                          |   |
| Business Analyst                     | X                          |   |
| Business Analyst                     | X                          |   |
| Clinical Data Lead, Registry Lead    | X                          |   |
| Data Manager                         | X                          |   |
| Business Analyst                     | X                          |   |
| Business Analyst                     | X                          |   |
| Business Analyst, Clinical Data Lead | X                          |   |
| Registry Developer                   |                            | X   |
|                                      |                            | X   |
|                                      |                            | X   |
|                                      |                            | X   |
| Registry Developer                   |                            | X   |
| Business Analyst                     | X                          |   |
| Data Manager                         | X                          |   |
| Centers                              | X                          |   |

|  |   |   |
|--|---|---|
|  |   |   |
| Statistician   | X |   |
| DCC Team; QIC, PI  | X |   |
| <b>STONE: REGISTRY LIVE ; Operational Support Begins</b> |   |   |
| Data Manager, Support Specialist                         | X | X |
| Support Specialist, Data Manager                         | X | X |
| Support Specialist, Data Manager                         | X | X |
|  |   |   |
| Registry Team  |   | X |
|  |   |   |
| Registry Team  |   | X |
| Business Analyst, DCC Team                               | X | X |
|  |   |   |
| Registry Team  |   | X |
|  |   |   |
| Business Analyst   | X |   |
|  |   |   |
|  |   |   |
| Statistician   | X |   |
|  |   |   |
| Statistician   | X |   |
| Data Manager   | X |   |
| Data Manager   | X |   |
|  |   |   |
| Network DCC Team   | X |   |
|  |   |   |
| Registry Team  |   | X |
| Registry Support Team                                    |   | X |
|  |   |   |
|  |   |   |
| Registry Support Team                                    | X | X |
|  |   |   |
| Data Manager   | X |   |
|  |   |   |
| Statistician   | X |   |
|  |   |   |
| Network DCC Team   | X |   |

|                    |   |   |
|--------------------|---|---|
| Network DCC Team   | X |   |
| Business Analyst   | X |   |
| Business Analyst   | X |   |
| Registry Team      |   | X |
| Registry Team      |   | X |
| Registry Developer | X |   |
| Registry Developer | X |   |

[illegible]

|   |   |
|---|---|
|   |   |
|   |   |
|   |   |
|   | X (limited)   |
|   | X   |
|   | X   |
|   |   |
| X |   |
|   |   |
|   | X   |
|   |   |
|   |   |
|   |   |
| X |   |
| X |   |
| X |   |
|   |   |
|   |   |
| X | X   |
| X | X (Support limited to existing EDT formats, does not include setting up new file formats) |
| X |   |
| X |   |
|   |   |



|   |  |
|---|--|
|   |  |
|   |  |
|   |  |
|   |  |
|   |  |
| X |  |
| X |  |