{Network}
LHS Registry
Implementation Plan

Version History			
Version Number	Date	Revised By	Reason for Revision

Contents

1. Purpose

The Network Registry Implementation Plan is used to present information needed for customization and configuration of a Network for onboarding to the LHS Registry Platform. This document is intended to be a living document to describe the setup and confirmation of the Network. As additional information is provided for implementation of the Network onto the LHS Registry, the high-level content will be incorporated into the Implementation Plan.

2. Content

2.1 Registry Domain Information

Content	Description	Network Information
Registry URL	Network to provide their official name to use as part of the URL/Website for Centers. (LHSRegistry is acquiring the domain LHSRegistry so network will have the domain of X.LHSRegistry.org where X is the Network Name)	{Insert official network name} i.e. https://Network.LHSRegistry.org
Registry Logo	Insert official Registry Logo to be used on login page, Registry pages and reports	{paste logo here} if logo does not exist, specify Name and preferred font
Color Scheme	Specify the preferred color scheme to use for the Registry pages	Provide color(s) for branding. If color palette definition exists, please provide this detailed information (i.e. shade of blue to use)

2.2 User Access & Security

Within User access and Security, please specify the Types of Users and their roles which will be allowed.

User/Role Type	Role Description
Network PI	Access to view aggregate level measures across all Centers
Network Data Manager	Access to view center level data for purposes of data quality and answering user support tickets
Network Regulatory	Access to provide consent information for new centers as

Specialist	they join the network.
Network QIC	Access to view aggregate level measures across all Centers
Network Statistician	Access to view aggregate level measures across all Centers
Registry Support Staff	Access to view center level data for purposes of data quality and answering user support tickets
Center Physician Lead	Full access, including insert, edit and delete rights to their center. Center level users only have access to their center level information and to network aggregate reports. (Note: If network allows for sharing of center level aggregate charts this should be specified here)
Center Team Members	Full access, including insert, edit and delete rights to their center. Center level users only have access to their center level information and to network aggregate reports. (Note: If network allows for sharing of center level aggregate charts this should be specified here)

2.3 Registry Measures

Content	Description	Network Information
Registry Measure Table	Measure Table specifying only those measures which will be implemented in Registry	Measure Table Version Document (include Measure table of just those measures being implemented)
Measure Operational Definitions	Measure Operational Definition for each Measure specified in Registry Measure Table	Specify Measure Operational Definition Versioned document for each document provided (include 1 document per operational definition)
Measure Stratification Variables	Specify the Measure Stratification variables which should allow for drill down across measures (if stratification only applies to certain measures, specify)	Include Measure Stratification variables which should be allowed. Examples include by Provider, Age Group, Gender, Disease Type (specify field for this)

2.4 Registry Data Domains

Content	Description	Network Information
Patient Level PHI Data Collected	Listing of fields collected when enrolling patients. This information is largely considered to be PHI and therefore must be specified in appropriate legal and regulatory agreements.	Provide detailed data elements which will be collected when a patient is enrolled into the Registry. Below are some considerations, specify which ones are required (add or remove as appropriate for Network): First Name Last Name

		Date of Birth (required) Gender (required) MRN (External Identifier) Other External Identifier types
Consent Information	Specify how many different consent forms will be used.	Indicate how many consent forms will be used per center in the study. Research consent
Data Domains	Network to provide the various data domains which will exist for capture of information. (A CRF should be provided for each data domain)	Listing of data domains included in the Registry Data Entry. Examples include: Enrollment Visit PRO Labs Medications Disposition / Activation
Case Report Forms	Case Report form per data domain to show flow of information for developer	Version of Case Report Forms provided
Case Report Form Specifications	Excel Specifications document which details how the Registry should be structured, including any logic for show/hide, warnings, required fields, list of values.	Provide CRF Specifications document and note the Version number of the CRF Specifications document

2.5 External Data Sources

Content	Description	Network Information
External Data Sources	Listing of all possible data sources where data will be uploaded. For each data source, specify the data domain, external data source type and provide an External Data Source Specification document.	For each external data source, provide the following: External Data Source: Data Domain: Specification Document Version: