Franciscan Missionaries of Our Lady Health System

FMOLHS-GS1 US Data Standards Master Process Implementation Plan

A global plan for the implementation of the GS1 Standards for Health Systems around the United States.

First Edition- Supply Chain

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Acknowledgements

Franciscan Missionaries of Our Lady Health System (FMOLHS) would like to express our gratitude and acknowledge the contributions of several organizations to the development of this implementation guide. It would not have been possible without their time, insights, and expertise. We used the insights from these organizations for developing this implementation guide. Although all of these organizations have been involved in the implementation guide's development, they do not necessarily endorse the guide's recommendations or conclusions.

Organizations

Abbott
Chicago, IL

CR Bard
Murray Hill, NJ

Becton Dickson
Franklin Lakes, NJ

Cerner
Kansas City, MO

Christus Health
Irving, TX

Cook Medical
Bloomington, IN

FSEnet
Waltham, MA

Geisinger Health System
Danville, PA

GHX
Louisville, CO

GS1
Lawrenceville, NJ

USDM
Santa Barbara, CA

Intermountain Health Care
Salt Lake City, UT

Johnson & Johnson
New Brunswick, NJ

Kaiser Permanente
Oakland, CA

Lawson
Flora, IN

Mayo Clinic
Rochester, MN

Medtronic
Minneapolis, MN

Mercy
Chicago, IL

Ohio State University Medical Center
Columbus, OH

Optima Health
Virgina Beach, VA

ROI
St. Louis, MO

Terumo
Somerset, NJ

PROCESS IMPLEMENTATION TEAM CONTROL TABLES

This document reflects the current level of engagement of healthcare organizations when addressing the UDI rule. The content may be of assistance as a resource for understanding current thinking. The reader should be aware that changes will be made frequently and should understand that this relates to FMOLHS' pilot program. In order to control how this initiative transpired at FMOLHS, several controls below were utilized to monitor the revisions so as to not deviate from the scope of the project.

Document Revision Control

Date	Description of the revision	Date completed

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Change Control Log

Date	Description	Reviewer Title

Document Approval

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Name			
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Date			

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1. EXECUTIVE SUMMARY

Based in Baton Rouge, Louisiana the Franciscan Missionaries of Our Lady Health System (FMOLHS) is the leading healthcare innovator in Louisiana. FMOLHS brings together outstanding clinicians, the most advanced technology, forward thinking supply chain and leading research to ensure that its patients receive the highest quality and safest care possible.

The goal of this document is to bring GS1 Data Standards to our healthcare system and provide a roadmap for other healthcare organizations to follow. Inside, you will find a step-by-step instructional guide to implementing these data standards.

Due to the upcoming unique device identifier (UDI) FDA regulations, FMOLHS has taken the initiative to lead the healthcare industry and drive to FDA compliance. Our health system elected to utilize GS1 to help implement data standards. Using their methodology, FMOLHS was able to successfully comply with the FDA's UDI regulations. In addition, FMOLHS has created the *FMOLHS-GS1 US Data Standards Master Process Implementation Plan* outlining the process needed to become compliant with the FDA. This document will help hospitals generate supply chain efficiencies, improve patient care, track medical devices, and reduce costs. Moreover, these data standards extend into clinical areas and electronic health records (EHRs). In the event a device recall is implemented, the healthcare organization will be better equipped to track and facilitate the transition of those items from their facilities.

Additionally, essential components of complying with the FDA's new regulation will be given in a removable guide for you to use. The resources that will be available to you include the following:
- A checklist of major steps to complete during the process
- An example project plan with timeframes included
- A checklist for creating GLNs and connecting suppliers
- A checklist for implementing GTINS

Below is a pictorial of the House designed by GS1 which shows an overview of many of the details found in this document.
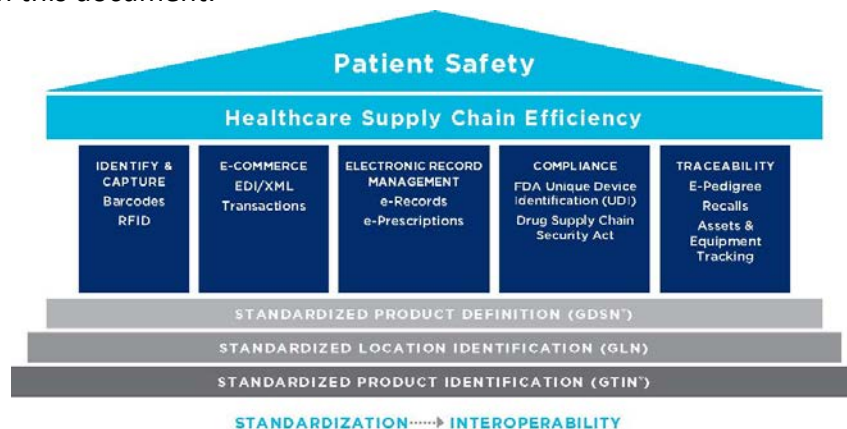
2. PROCESS IMPLEMENTATION

2.1. Objective

The objective of this document is to provide a complement to the Master Project Plan and the Master Network Diagram. The Master Process Implementation Plan will provide further clarification of activities and tasks associated with the implementation of GS1 Global Data Standards across the Health System and guidelines, designed for use as a general roadmap for process development or re-engineering of existing processes.

2.2. FDA Unique Device Identification (UDI) Regulation

The Unique Device Identification (UDI) System is intended to assign a unique identifier to medical devices within the United States. It was signed into law on September 27, 2007, as part of the Food and Drug Administration Amendments Act of 2007. This act includes language related to the establishment of a Unique Device Identification System. Upon implementation, the new system will be able to provide a unique label for each device that will be able to identify the device through distribution and include the lot and serial number.

A national UDI system will create a common vocabulary for reporting and electronic tracking. Currently, analysis of adverse event reports is limited by the fact that the specific devices involved in an incident are often not known with the required degree of specificity. Without a common vocabulary for medical devices, meaningful analysis based on data from existing voluntary systems is problematic. Reliable and consistent identification of medical devices would enable safety surveillance so that the FDA and manufacturers could better identify potential problems and improve patient care.

The UDI is expected to improve patient safety by identifying counterfeit products utilized by hospitals and providing an avenue for medical staff to distinguish between similar devices. In addition, in the event of a device recall, the UDI system will facilitate and improve the recall process, and create efficiencies within the medical system.

Pursuant to the new UDI Rule, a UDI may consist of a device identifier (DI) and a production identifier (PI). The DI will identify the specific model of the device and the labeler of the device. The PI will be used to identify the batch/lot number, serial number, expiration date, date of manufacturing, and any special attributes associated with the device.

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Source:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIBasics/default.htm
Ament, Lucy (November 13, 2006). "AHA calls for medical device identification system". AHA News 42 (23): p. 2.
DiConsiglio, John (September 2007). "Solve a unique challenge". Materials Management in Health Care 16 (9): pp. 24–26

On November 27, 2013 President Obama signed into law the Drug Quality and Security Act (DQSA). The goal was to "minimize opportunities for contamination, adulteration, diversion, or counterfeiting," of pharmaceutical products. The passage of this law started the introduction of full traceability for pharmaceutical products through a supply chain process within 10 years.

The Food and Drug Administration (FDA) has been tasked with establishing a unique device identification (UDI) system to adequately identify medical devices through their distribution and use. When fully implemented, the label of most devices will include a UDI in human- and machine- readable form. Device labelers must also submit certain information about each device to FDA's Global Unique Device Identification Database (GUDID). The public will be able to search and download information from GUDID. The UDI system will be phased in over several years. The table below outlines key compliance dates for the UDI final rule.

Compliance Schedule

UDI COMPLIANCE DATES		
Devices Licensed Under The Public Health Service Act	Labeling requirements Data submission requirements Data format requirements	September 24, 2014
	Direct marking requirements	September 24, 2016
Implantable, Life-Supporting or Life-Sustaining Devices	Labeling requirements Data submission requirements Data format requirements	September 24, 2015
	Direct marking requirements	September 24, 2015
Class 3	Labeling requirements Data submission requirements Data format requirements	September 24, 2014
	Direct marking requirements	September 24, 2016
Class 2	Labeling requirements Data submission requirements Data format requirements	September 24, 2016
	Direct marking requirements	September 24, 2018
Class 1	Labeling requirements Data submission requirements Data format requirements	September 24, 2018
	Direct marking requirements	September 24, 2020
Device Not Classified As Class 1, Class 2, or Class 3	Labeling requirements Data submission requirements Data format requirements	September 24, 2018
	Direct marking requirements	September 24, 2020

2.4. GS1

GS1 is an international not-for-profit association with organizations representing over 110 countries worldwide. Established over 35 years ago, GS1 was utilized by the grocery industry to administer and manage Universal Product Codes (UPC). The GS1 System has evolved into the world's most widely used supply chain standards and include globally-unique numbering formats, barcodes and radio frequency identification (RFID) for capturing identification numbers, data synchronization, and electronic information change for sharing data. In order to improve the efficiency and visibility of supply chains across different sectors, GS1 is dedicated to the design and implementation of global standards.

On December 17, 2013, GS1 received an accreditation by the FDA as the issuing agency for UDIs. Global GS1 Standards meet the government's criteria for UDIs and will help manufacturers comply with the requirements of the new FDI UDI regulation. The International Medical Device Regulator Forum (IMDRF), the FDA, and the European Commission are aiming for a globally harmonized approached to increase patient safety and optimize patient care by using the GS1 standards for UDIs. Below is the design created by GS1 in order to address the new ruling and successfully implement data standards.

The GS1 System of standards enables all stakeholders to efficiently and effectively meet UDI requirements by ensuring interoperability and compatibility within an organization, between organizations and across borders. GS1 has over 110 Member Organizations and more than 2,000 employees worldwide providing support to users on how to implement UDI in their local language and understanding the local situation.

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Source:
http://www.gs1.org/healthcare/udi
Plans within plans: Master projects and subprojects. (2014, January 1). Retrieved December 11, 2014, from https://support.office.com/en-gb/article/Plans-within-plans-master-projects-and-subprojects-e9c8ae07-8f21-4cc4-aedb-101fa6341a70

2.5. Master Project Plan and Subprojects

FMOLHS is driving the initiative to use GS1 Standards for the UDI final rule. As such, the entire scope of the project was not known until FMOLHS began working on the project. As the project progressed, it became apparent that controlling the project as one large project was intractable. FMOLHS decided to break up the [master project plan](#) into smaller projects based on each identified vendor. How these vendors were identified will be discussed in greater detail in a later section.

Creating a master project and subprojects lets you break down a large project and delegate its parts to the appropriate people. In project management terms, assigning subprojects in this manner gives responsibility to those who do the work and matches authority with accountability. There are several reasons to consider when deciding to break up a project into smaller subprojects. For example, FMOLHS is a large healthcare organization and key team members had other professional obligations that demanded their time. This project was very large and required a large amount of detail at each step. Therefore, breaking it into subprojects made it easier to manage for each team member. A single project file is almost always the faster alternative, but the ability to focus on just a part of the project may be worth the trade-off.

2.6. Process Management Plan

The Master Process Implementation Plan will identify and introduce solutions to improve core business processes and quality of service delivery. Implementing GS1 Global Data Standards across the Health System is far reaching and affects the receiving of products, transporting the products within the Health System facilities and delivering the products to the requestor or the stated recipient.

As products move through the re-engineered process, the products will be scanned and traced at every touch point to capture the detailed identity elements of the product including but not limited to manufacturer, lot and expiration date. The data elements may be scanned into the physician's records, the patients' records, and the inventory management systems.

To fully understand the processes across all organizations, multiple methods of training delivery are provided to the employees responsible for scanning the bar codes into the various software applications. Documenting the various processes, overlaps, and hand-offs, is an opportunity to challenge the current process and identify opportunities to re-engineer and integrate automation.

Patient safety, accurate billing, correct and complete documentation, and traceability are processes that benefit from automation and re-engineering. Process Improvement Teams (PIT) lead research initiatives and introduce automation opportunities to establish multi-process data integration and permit workflow automation. PIT teams require the skills and familiarity with

both Lean Six Sigma and Project Management methodologies, therefore each PIT will be led by a Lean Six Sigma Greenbelt or someone with similar knowledge base.

In order to properly manage this process, an integrative approach of five essential Project Management Process Groups based on the Project Management Institute's *Project Management Body of Knowledge* (PMBOK) was utilized. These five Process Groups are highly dependent upon each other and each group is iterative in nature. This design allowed FMOLHS the ability to properly plan for the project and possibly prevent any delays. Below, each process group is described in greater detail.

Initiating Process Group

The Initiation Process is used to define the new project and obtain authorization to start the project. The scope will be defined as well as financial resources will be allotted in order to complete this project. In addition, the project manager will be assigned to oversee the progress of this project. It is important to assign this role to someone who has project management skills; as this project can become a collage of smaller projects that can become unruly at any point in the project. The main goal for this Process Group is to align the stakeholders' expectations and to give transparency to all parties who are invested in this project.

Planning Process Group

The Planning Process Group establishes the total scope of the project. The Initiation Process provides the purpose of the project with the project charter, however a full understanding of the work necessary to complete the project are developed here. The key benefit of the Planning Process is to delineate the strategy and tactics to successfully finish the project. If this Process Group is managed well, it is much easier to get stakeholder buy-in and approval. Refining documents and collecting feedback is a significant part of this process, however this cannot continue indefinitely. Procedures from the organization will dictate when this process will come to an end.

Executing Process Group

The Executing Process Group involves managing teams effectively while orchestrating timeline expectations and reaching benchmark goals. This group will utilized the teams to complete the work defined in the project management plan. During project execution, results may require planning updates and rebaselining of project durations and resource availability. Due to unanticipated risk, change requests may be utilized to alter expectations of the project plan. A large portion of the project's budget will be expanded during this phase.

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Source:
(2013). A guide to the project management body of knowledge (PMBOK guide), fifth edition. 5th ed. Newtown Square, Pa.: Project Management Institute.

Monitoring and Control Process Group

The Monitoring and Controlling Process Group involves tracking, reviewing, and orchestrating the progress of the project. The key benefit of this group is to monitor at regular intervals which will quickly identify variances from the project plan. Continuous monitoring provides transparency into the health of the project and can highlight areas that need additional support. A project manager may require the delegation of additional resources from one area of a project to another in order to bring the lagging area back to compliance. Being proactive about monitoring will mitigate a potential risk into becoming an issue.

Closing Process Group

The Closing Process Group is the culmination of each of the previous Process Groups by concluding all activities associated with the project plan. This Process Group, when marked as complete, represents a formal acceptance of the project and an agreement that the project requirements have been met. It is important for each organization to hold a debriefing session to discuss lessons learned and to archive all relevant project documents for further usage. This will prevent repeated delays that can happen in similar projects.

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Source: (2013). A guide to the project management body of knowledge (PMBOK guide), fifth edition. 5th ed. Newtown Square, Pa.: Project Management Institute

3. HOW TO INITIATE THE PROJECT

The FMOLHS GS1 Global Data Standards Implementation began with the creation of a core process design team and the identification of a larger group of industry stakeholders involved in review, feedback and signoff of activities. The integrated Master Project Plan includes people, process and technologies, project activities, sequence of tasks and sub-tasks, milestones, dependencies, system integration, start and end times, inputs, and outputs.

This section describes the easy to follow steps taken to describe how processes were designed to complement the project activities. It is a guide to establish the implementation team and how the team can be managed.

You will find the "How To" Guide to develop your Master Project Plan, how to identify and include parallel projects, and how to manage the life cycle of the project. This section also addresses the tools you may use to not only track activities, but to evaluate risks, address issues, and communicate effectively to meet your milestones and successfully complete your project.

3.1. Develop Charter

The project charter is the official and formal written agreement and recognition that a project has been initiated. This is authorized by the project sponsor or the organization who is wishing to complete the project. The charter is given to the project manager to outline the parameters of the project. Ideally, the organization will have vetted key stakeholders in order to properly identify key deliverables for the project. Using this project charter link will provide an example of a charter FMOLHS used for this project

3.2. Identify Stakeholders

Some stakeholders will remain for the entirety of the project and others may enter and exit the project throughout the life-cycle of the FMOLHS GS1 Global Data Standards Implementation. Stakeholders consist of the Sponsor, Local Leadership, Manufacturers, Providers, Distributors (if appropriate), and Technology Partners. GS1 Data Standards will touch almost every aspect of the health system. Requestors, purchasing departments, inventory management, transportation, and delivery processes, physician's records, and even the patient's records will be affected by the new data standards. As such, the process owner and the project manager can expect to meet with the Stakeholder Groups at regular intervals.

3.3. Implementation Plan

The Integrated Master Project Plan is the foundation for building the Master Process Implementation Plan. Determine the current state, the future or desired state, and the "how" we are going to get there, often referred to the Action Plan. There are numerous opportunities during the course of implementation of GS1 Global Data Standards across the Health System.

The Process Improvement Teams will enlist the cooperation of the appropriate facility representatives, gather tool requirements, training needs, and evaluate the current state. The team will work closely with the facility representatives, project team and technology partner to develop the desired state. The action plans will be developed and implemented under the supervision of the joint engagement between the Project Team and the Process Implementation Team. In addition, key parts of the project management plan will be developed in order to properly outline the scope of the project and to garner support both financially and politically within the organization.

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Source:
(2013). A guide to the project management body of knowledge (PMBOK guide), fifth edition. 5th ed. Newtown Square, Pa.: Project Management Institut

4. HOW TO PLAN THE PROJECT

Once key stakeholders have been identified and vetted and an official project charter has been authorized, the integrated Master Project plan can begin planning for the next steps in greater detail. This will include generating potential timelines for each phase of the project, deliverables that will be presented upon completion of the project, and various process flows that will need to be developed.

This section describes the acceptance requirements that were created in order to mark the completion of the project. Without these specific deliverables, the project could stall and take unnecessary time and the project sponsors may not be able to accept the project as complete. In addition, you will find the projected timeline FMOLHS utilized as they completed the standardization implementation with each pilot.

You will find the "How To" Guide to develop your Master Project Plan for various roles and responsibilities that will translate to every project and examples of process flows that will be useful as an organization develops their own processes. This section also addresses the tools you may use to track activities and changes to the project plan as delays occur. You will also be provided with the tools to maintain constant communication with your stakeholders.

4.1. Acceptance Requirements

These were divided into different criteria based on the progress of the project and the focus of that particular phase. There were overarching acceptance requirements that were outlined in the project charter, and different requirements between Phase 1 and Phase 2 of the project.

The acceptance requirements are:
- FDA compliant with DQSA
- GS1 Standards compliance; including implementing GLNs and GTINs.
- Interoperability of software across the organization.
- All supplies that flow through the organization's ERP using GTINs.
- All implantable devices will contain a Unique Device Identifier (UDI).

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Source:
(2013). A guide to the project management body of knowledge (PMBOK guide), fifth edition. 5th ed. Newtown Square, Pa.: Project Management Institute
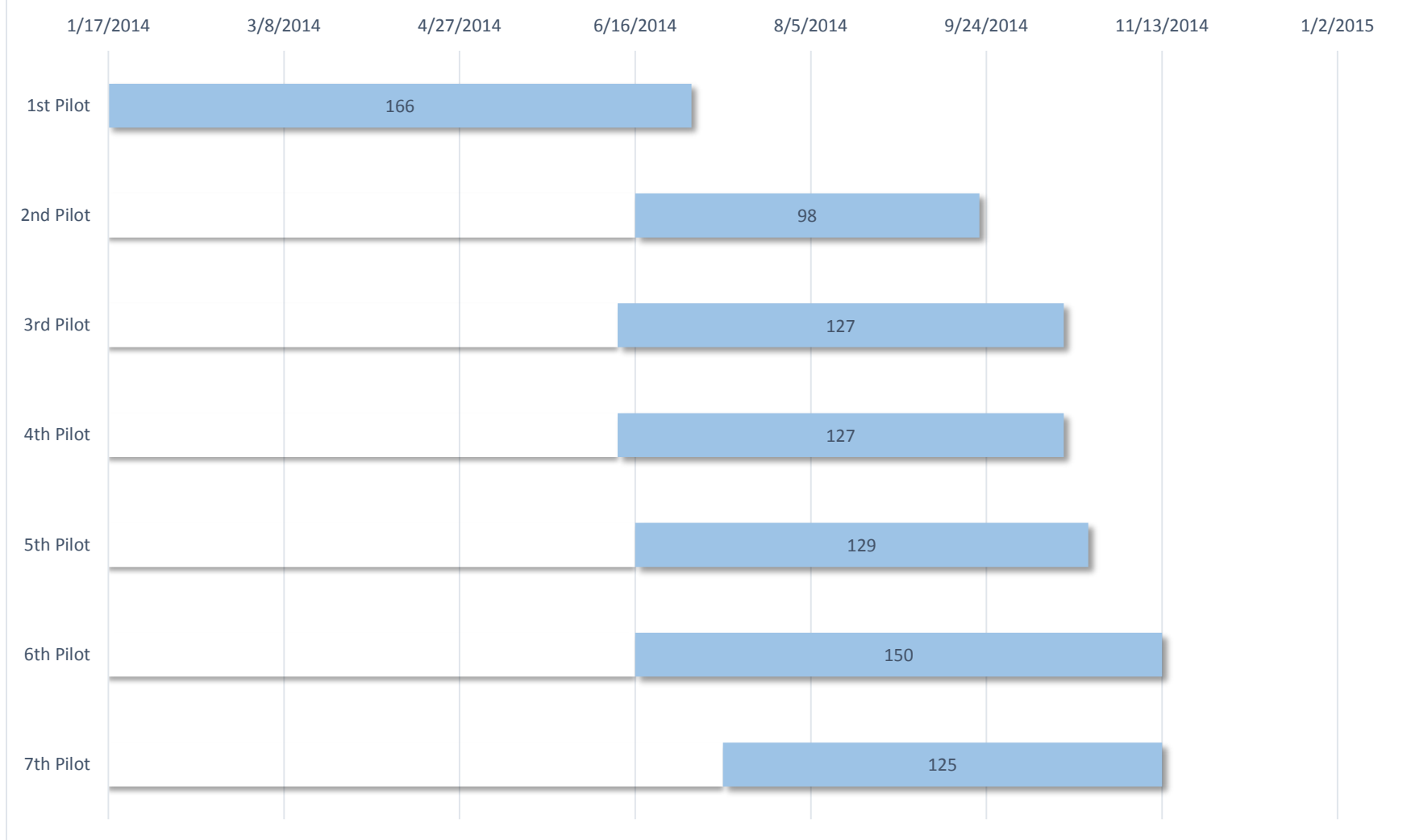
4.2. Project Timelines

The FMOLHS GS1Global Data Standards Implementation timeline is built in a phased design to easily recognize progress and report status. These were analyzed by each vendor that was chosen to be a partner in the pilot. The different processes and specific timelines were estimated and outlined before the start of the project. The stakeholders will approve the timeline for each phase of the implementation. Manufacturing partners, GPO partners and leaders of other parallel projects will participate in recurring status meetings. Below in the table and graph titled *Phased Design for Project Implementation* and *Vendor Pilot Implementation Duration,* the phases for each manufacturer of the project are displayed with respective timeframes. Although each vendor was piloted individually, certain phases may have been either delayed or ran parallel with other vendor pilots. Moreover, you will find that certain tasks are not in chronological order due to these unforeseen delays. This could not have been predicted and was incorporated into the learning portion of FMOLHS' process.

Phase Design for Project Implementation

Franciscan Missionaries of Our Lady Health System	All GLNs set up in ERP	All GTINs set up in ERP	Communication to Purchasing	Complete SuperSaw to GHX* Registration for GLN Transacting	Receive GHX* Approval from vendors	Set up substitution tables in ERP to transact using GLN	Send test PO to vendor to make sure process is working	BIS sets setting change to auto-release PO	Contact Manufacturer regarding 856 set up details	Contact Logistics regarding 856 set up	Go or No-go based on readiness	Go Live
1st Pilot	1/17/2014	5/5/2014	7/2/2014	2/11/2014	2/11/2014	6/10/2014	6/10/2014	6/12/2014	5/14/2014	7/2/2014	7/2/2014	7/2/2014
2nd Pilot	6/16/2014	7/16/2014	8/25/2014	8/25/2014	9/18/2014	9/18/2014	9/22/2014	9/22/2014	9/22/2014	9/18/2014	9/18/2022	9/15/2014
3rd Pilot	6/11/2014	5/30/2014	10/3/2014	10/10/2014	10/12/2014	10/13/2014	10/15/2014	10/15/2014	10/8/2014	10/13/2014	10/14/2014	10/16/2014
4th Pilot	6/11/2014	6/11/2014	10/3/2014	10/10/2014	10/12/2014	10/13/2014	10/15/2014	10/15/2014	10/8/2014	10/13/2014	10/14/2014	10/16/2014
5th Pilot	6/16/2014	6/16/2014	10/3/2014	10/13/2014	10/15/2014	10/16/2014	10/23/2014	10/23/2014	10/13/2014	10/20/2014	10/21/2014	10/23/2014
6th Pilot	6/16/2014	6/16/2014	10/3/2014	11/3/2014	11/5/2014	11/6/2014	11/13/2014	11/13/2014	10/13/2014	11/10/2014	11/11/2014	11/13/2014
7th Pilot	7/11/2014	7/24/2014	10/3/2014	11/21/2014	12/5/2014	11/6/2014	11/13/2014	11/13/2014	10/13/2014	11/10/2014	11/11/2014	11/13/2014

Note: GHX is company FMOLHS partnered with to provide clean data for the GLNs, but this may differ between organizations.*

Vendor Pilot Implementation Duration (Days)

Pilot	Duration
1st Pilot	166
2nd Pilot	98
3rd Pilot	127
4th Pilot	127
5th Pilot	129
6th Pilot	150
7th Pilot	125

Timeline axis: 1/17/2014, 3/8/2014, 4/27/2014, 6/16/2014, 8/5/2014, 9/24/2014, 11/13/2014, 1/2/2015

4.2. Financial Resources

Each organization will have to make an assessment of their finances and the feasibility to implement this plan in a timely fashion. Due to FMOLHS' unique position as a leader for this initiative, the organization did not adhere to a specific budget. This will vary based on each individual organization and their current financial state.

4.3. Expected Project Deliverables:

Project deliverables are the items the team has been asked to produce in order to show progress to key stakeholders. Below are a list of deliverables that were agreed upon once the charter was created. These deliverables will be used as a criteria to know whether or not the project is progressing along as planned.

4.3.1. Master Project Plan

This is an example of a timeline FMOLHS developed for one of the vendor partners. FMOLHS was piloting the entire implementation of this initiative, therefore these timeframes will vary between organizations. Ideally, another organization will be able to use this timeline as a template to gauge their own time investments. More importantly, this vendor was the first vendor chosen due to their readiness to progress further and their willingness to change.

Example Pilot Timeline

Task Name	Duration	Start	Finish	Resource Names
Initiation	94 days	Tue 10/8/13	Fri 2/14/14	Project Sponsor
Planning	125 days	Tue 10/8/13	Mon 3/31/14	Project Manager
OUTPUT: Master Project Management Plan	0 days	Tue 10/8/13	Tue 10/8/13	Project Manager
Planning for the Pilots	78 days	Tue 10/8/13	Thu 1/23/14	Project Manager
Executing	245 days	Tue 10/8/13	Mon 9/15/14	Project Manager
Hardware	90 days	Mon 6/2/14	Fri 10/3/14	Project Manager
Software	90 days	Mon 6/2/14	Fri 10/3/14	Project Manager
Systems	90 days	Mon 6/2/14	Fri 10/3/14	Project Manager
Monitoring	90 days	Mon 6/2/14	Fri 10/3/14	Project Manager

Controlling	90 days	Tue 10/8/13	Mon 2/10/14	Project Manager
Closing	179 days	Tue 10/8/13	Fri 6/13/14	Project Manager

4.3.2. Network Diagram

A network diagram is a graphical representation of the sequence of events for each step in a project. This is a great way to depict each step within a project and demonstrate where dependencies are located. This can assist an organization in determining where each logical step will go as they progress through their own project. This diagram will be determined by the type of relationship each organization has with their vendors. FMOLHS procured items directly through a manufacturer and through a third party distributor. Each avenue produced a different network diagram that needed to be mapped out.

4.4. Project Implementation Roles

4.4.1. Process Roles and Responsibilities

Clear definition of accountability and responsibility is a critical success factor for any Process Implementation Project. Establishing clear lines of communication is one of the largest factors to ensure a project is completed. This will involve delegating particular roles and responsibilities through the implementation process. Without this step, functional staff are unclear as to their roles and responsibilities within the new process and revert back to how the activities were accomplished before. Below in Figure 1, is an example of a table depicting the types of roles that were critical throughout the project implementation and the responsible party.

Figure 1.

Roles and Responsibilities		
Role	**Team Member**	**Responsible for:**
Executive Sponsor		
Project Champion		
Materials Management (MM) Accountable Leader		
MM Vendor Master Analyst		
MM Item Master Analyst		
MM Group Purchase Organization Analyst (GPO)*		
Supply Chain Analyst		
Purchasing Analyst		

Supply Chain Logistics Analyst		
Accounts Payable Analyst		
Enterprise Resource Planning (ERP) Administrator		

Note: FMOLHS utilized a GPO to purchase items but this will vary between organizations.

4.4.2. The RACI Matrix

The RACI Matrix is a tool used to identify various individuals who have a key role in the project. Based on their level of involvement, these individuals can be categorized as responsible, accountable, consulted, and informed. The acronym RACI includes the following:

- **R**esponsible – the person responsible for completing a given task
- **A**ccountable – the person to makes sure the work gets done, and/or that the right decision gets made
- **C**onsulted – one or more people who must be consulted with, prior to a given task being completed
- **I**nformed – one or more people who must be informed after a task is completed or a decision is made

In Figure 2, an example of what a RACI table might look like is displayed.

Figure 2.

Implementing GS1 Data Standards				
	Role 1	**Role 2**	**Role 3**	**Role 4**
Task 1	R	A	C	I
Task 2				
Task 3				
Task 4				
Task 5				
Task 6				
Task 7				

4.4.3. Process Owner

The FMOLHS GS1 Global Data Standards Implementation process owner is responsible for designing the processes necessary to successfully implement GS1 Global Data Standards. The process owner is responsible for the creation, update and approval of required documents to support the process. This role should be filled with someone who is at least a Lean Six Sigma

Green Belt or who can effectively utilize Lean Six Sigma methodology from the department with the most knowledge of the current state. The Process Owner meets with the Project Manager on a regular basis to provide updates, discuss changes, and review the timeline.

4.4.4. Process Improvement Team

The Process Improvement Team is a selected group of people assembled by a process owner. Subject matter experts consist of those involved directly or indirectly with the process. A Yellow Belt or Green Belt will facilitate the use of Six Sigma tools to accomplish its tasks. The Process Improvement Team meets weekly to discuss the status of process development, progress, issues, and risks.

4.4.5. Advisors

The trusted Advisors providing guidance during this project process implementation are GS1 US, The Food and Drug Administration (FDA), The Strategic Marketplace Initiative (SMI), The Louisiana Healthcare Quality Forum, and the Association of Healthcare Resource & Materials Management (AHRMM). Depending on the organization, there will be additional advisors that will be included during the implementation of this project.
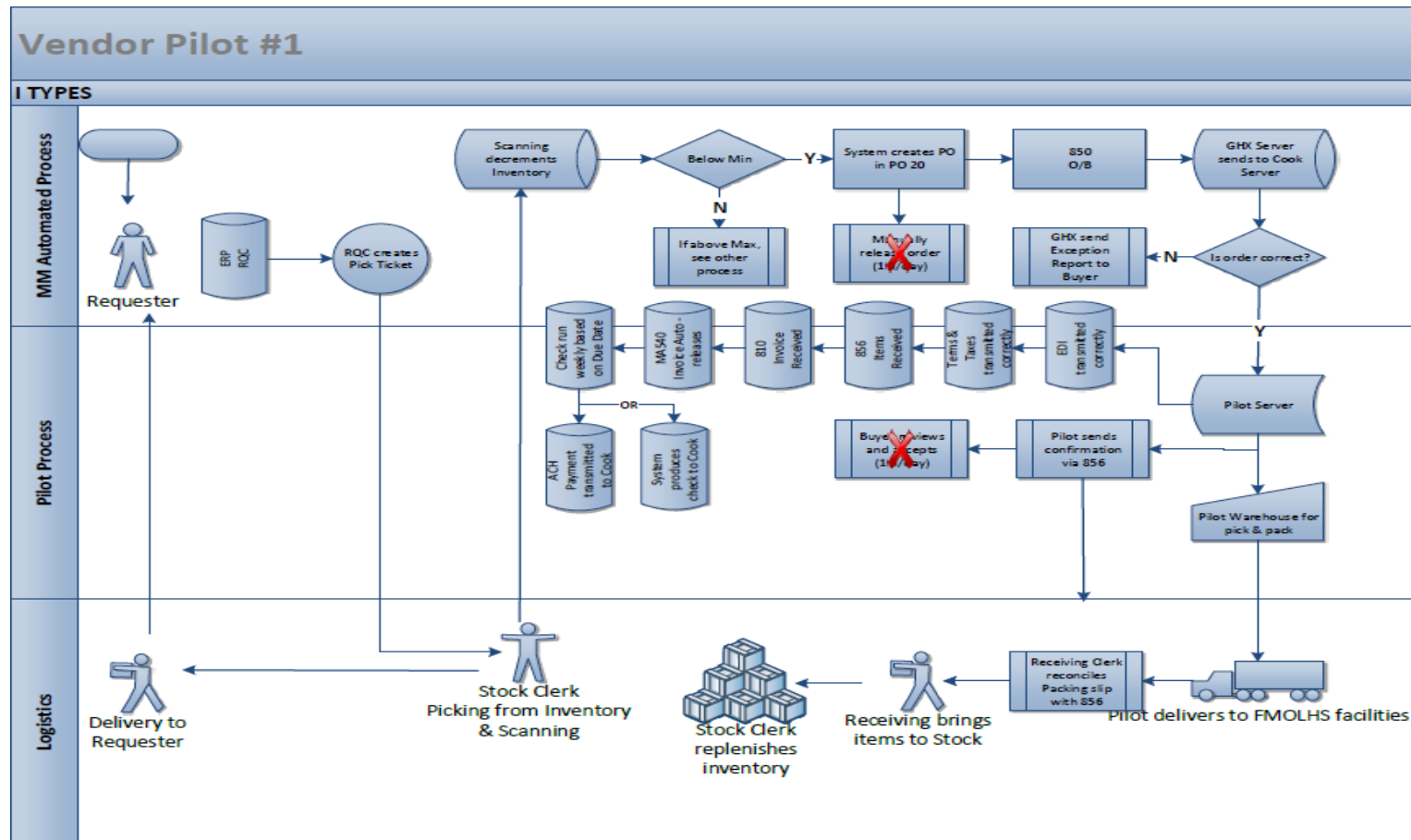
4.5. Process Flow Development

The Planning Phase of the Master Project Plan includes the development of the high-level process flows. The identification of process activities, process integration points, and areas for automation become evident as details of activities are developed. For each new process identified for development or re-engineering,

1. What is the objective of the process?
2. How does it integrate with other processes?
3. What are the activities of the process and how do they flow from a chronological and corresponding standpoint?
4. What are the decision-points and what information is required to make a decision?
5. Which roles participate in the process and what activities do they perform?

4.5.1. Process Flow Example

In order to help organizations understand the types of processes FMOLHS optimized, the figure below *Example Pilot Process Flow* is an example of an FMOLHS process flow mapped out for items known as an "I Type." These are items that are readily available in the inventory of an organization and should be regularly ordered. FMOLHS started with I Types due to the continuity of these items being in stock and the relative ease of mapping this process out. This pilot vendor was chosen for this process because their readiness to accept changes.

Example Pilot Process Flow

4.5.2. Detailed Design

After the high-level process flow diagram is developed, additional details are added to clearly identify the activities supporting each process, such as approvals, policies, procedures and tools.

4.5.2.1. Approvals

Changes are approved by key stakeholders for areas where policies, processes, procedures or tools impact the end-users or require additional costs to implement. For FMOLHS, a standard process was implemented in order to properly approve any changes. FMOLHS retained a centralized Project Management Office (PMO) that would handle formalized changes to any major project for the health system. Any proposed change will go through a formal acceptance procedure and is either accepted or rejected and required additional information. However, a PMO may not be available for each organization. Therefore, a process should be implemented to appoint a Change Approval Committee (CAC) who will handle all changes associated with the project.

4.5.2.2. Policies

Existing policies are followed unless a need to change is identified as the project progresses. Policies are rewritten or developed and submitted for approval by key stakeholders. These will differ from each organization and will serve different purposes based on the organization.

4.5.2.3. Procedures

Detailed procedures are developed and defined as new policies. These procedures will serve as the guide to various activities and milestones as the project progresses. Also, detailed procedures help delegate specific tasks and activities to key stakeholders in the project. This will allow the organization to progress through each stage with fewer hurdles to deal with. For example, a formalized procedure to address any changes to the charter was developed to prevent unnecessary expansion of the project's scope. By implementing this procedure, FMOLHS avoided the addition of unrelated tasks and possible delays.

4.5.2.4. Procurement of Tools

Any project will require the organization to give an assessment of the resources they have available and the resources they need to procure for the project to be successful. FMOLHS had the benefit of already utilizing many of the tools necessary to create a successful implementation of GS1 standards. Therefore, a proper assessment of necessary tools will be required.

Outlining the tools utilized helped keep track of costs associated with the project and provided a better understanding of what would be necessary to complete the implementation. These tools were categorized as anything that would be used by any stakeholder and or costs money to use. Those tools that required some financial investment were placed in an approval process in order to better monitor total costs. Some examples of tools used during the project included:

- Dashboard Gear.
- GHX-Supersaw.
- ERP.
- Item master.
- Vendor master.
- A third party vendor that would provide cleansed standardized data for the organization to use.
- Add-ins—ERP application to upload GTINs.

4.6. Communication Plan

The communication plan outlines the overall approach for communicating with stakeholders about Implementing GS1 Data Standards. It is important to maintain open channels of communication with your stakeholders to keep them informed of the progress that has been made and any delays. For FMOLHS, this was accomplished by initially meeting with key stakeholders and developing an avenue by which they wanted to be communicated with. Several different methods were selected and included—phone conference calls, email, and in-person meetings. By having the communication plan created during the planning phase, FMOLHS would engaged their key stakeholders and prevent any delays by a stakeholder who might have felt uninformed. Below, is an example of a table that was utilized by FMOLHS to identify key contact information from each stakeholder and how they would have wanted to be kept informed.

Communication Plan Contact Information

Contact / Resource Name	Company / Department	Contact Information	Notes

5. HOW TO EXECUTE THE PROJECT PLAN

Until this point, this document has focused on the initiating and planning phases of the project. These are essential phases in the project plan that need to be completed in order to properly identify issues that might arise and prepare the organization for the project work. Without these steps, the project will have unnecessary delays that will waste precious time and resources.

Below you will find a step-by-step procedure on how FMOLHS implemented their plan utilizing the necessary processes set forth in the planning phase. This will be complimented with the "How To" Guide and checklist for your organization. The first step will involve identifying key partnering organizations, more specifically manufacturers who are able to adopt these new process changes into their own companies. Additionally, the process involved picking the first pilot organizations will be discussed to give a better understanding of how to choose which manufacturers to partner with.

Then, this document will walk through the process FMOLHS created in order to fully implement the GLNs, GTINs, and the GDSN into their own processes. This mandate is a requirement from the FDA and will be a key component of the execution phase.

5.1 Process Implementation Structure

Implementing GS1 Global Data Standards across an organization requires a phased approach beginning with identifying the manufacturers and suppliers who have all or most of their products registered with GLN numbers and GTIN numbers. Select one or more manufacturers to participate in a pilot. FMOLHS accomplished this goal by examining the expenses associated with each vendor and selecting the vendors who supplied the most items. Consider using your test environment instead of your production environment. A test environment, is a mode where organizations can simulate the changes and procedures that were implemented in order to examine the effects and address any issues that would arise. For example, this allows an organization to test how well existing software accepts the manufacturers' and suppliers' data.

Next, determine if the existing software supporting the organization's Enterprise Resource Planning (ERP), Vendor Master, and Item Master are capable of capturing the manufacturers and suppliers GLNs and GTINs. For FMOLHS, this was accomplished by utilizing a software ERP representative to help facilitate any issues.

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Source:
(2013). A guide to the project management body of knowledge (PMBOK guide), fifth edition. 5th ed. Newtown Square, Pa.: Project Management Institute

Then, develop and load the GLNs for the health system. Once loaded, select a method to upload the manufacturers and suppliers GTINs into the health system's Item Master. Possible methods to upload GTIN information include utilizing the GDSN or by contacting the vendor and uploading their information into the system. In order to properly upload this information, FMOLHS had to allot time to perform a data cleanse in the item master for all items that are involved in the project. This will ensure "clean" data and prevent any unforeseen delays.

5.2. Picking Organizations to Pilot

FMOLHS assessed the readiness of our electronic data interface (EDI) suppliers to provide GTINS and GLNs. EDIs are transactions conducted using e-commerce instead of conventional methods of interaction. FMOLHS selected each partner based on their level of participation with GS1 US and FDA educational events. A total of seven manufacturers were identified as pilot partners. The remaining five showed interest and were suppliers we purchase from directly as oppose to a distributor of third party items. These five were in different stages of implementing their own GTINs and GLNs.

5.3. Implementing GLNs

The Global Location Number (GLN) is part of the GS1 systems of standards. It is a simple tool used to identify a location and can identify locations uniquely where required. Locations that can utilize a GLN include a physical location like a warehouse, a legal entity such as a company, or even something specific on the shelf of the catheter lab storage closet. In addition, these unique numbers will be universal for every manufacturer shipping items to the organization.

To properly implement GLNs at FMOLHS, the first action required was to reconcile vendors that use ship to account numbers and convert them to FMOLHS' GLN numbers using the GS1 system. FMOLHS had to confirm with each vendor that the account numbers were correct so there would be no mix ups. In addition, FMOLHS had to decide which GLNs will correspond to each of the vendors' account numbers. There can be several GLNs per facility. Depending on the structure of the organization, one facility can have GLNs for different business units or multiple ship to sites. After all the account information is confirmed, FMOLHS completed their GLN registration with GHX using SuperSaw. SuperSaw is a software program from GHX that allows an organization to communicate all pertinent information such as account numbers, GLNs, and ship to addresses to GHX. This will allow GHX the ability to align the organization's information to a vendor to confirm the right items are being sent to the right organization. It is important to note that FMOLHS used SuperSaw for these functions, but other organizations

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Source:
http://www.gs1.org/barcodes/technical/idkeys/gln
http://www.gs1.org/barcodes/technical/idkeys/gtin

http://www.ghx.com/GHX_Learning_Center/Help/WebConnect/Understanding_EDI_Transactions.htm

may use different software or support to complete these transactions. Upon receiving the information, GHX will then send the information to vendors for approval. After GHX has received the approval, FMOLHS will be notified. Substitution tables can then be set up in an organization's ERP to transact using GLN. If further clarification is needed, a step-by-step process for transacting the GLNs is provided in the appendix.

5.4. Implementing GTINs

Global Trade Item Number (GTIN) is an identifier for trade items developed by GS1. Such identifiers are used to look up product information in a database which may belong to a retailer, manufacturer, or other entity. The uniqueness and universality of the identifier is useful in establishing which products correspond in different organizational databases. In order to properly identify products throughout the supply chain, FMOLHS had to match the GTINs with the manufacturers' GTINs for every product. To complete this task, FMOLHS had to verify that manufacturer codes, manufacturer divisions, and manufacturer numbers match records throughout the ERP system. All records for an item must contain the same manufacturer code and division in order to load a GTIN. If the item has been moved from one vendor to another, the previous record must be inactivated. All records must contain GTINs in order to change the setting to submit orders by GTINs. It is important to note that these procedures were unique to FMOLHS and could vary between organizations. If additional clarity is required, a step-by-step process for implementing GTINs is provided in the appendix.

5.5. Selecting a GDSN

The Global Data Synchronization Network (GDSN) is an internet-based, interconnected network of interoperable data pools and a global registry known as the GS1 Global Registry that enables companies around the globe to exchange standardized and synchronized supply chain data with their trading partners using a standardized Global Product Classification.

GDSN assures that data exchanged between trading partners is accurate and compliant with universally supported standards. GDSN consists of supplier/retailer trading partner, data pools that hold and process trading partner data and the GS1 Global Registry, a directory that helps locate data sources and keep relationships between trading partners in sync.

Careful consideration should be given to the selection of a GDSN *data pool provider.* A list of current data pool providers can be found on the GS1 website as well as other valuable GDSN information. To begin the selection process, it is recommended that you narrow the provider candidate list to at least three preferences through preliminary research. To assist you in narrowing the field, you should identify a peer group outside of your organization. This peer group will be solicited for their written opinions, observations, and recommendations regarding the provider candidates you have identified as well as the provider they currently utilize. Once

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Source:
http://www.gs1.org/gdsn

you have compiled the peer group's information, organize their responses in a matrix format. This will provide an easy avenue to share this information with key personnel during the selection process. Request a detailed proposal and information packet from your top three candidates for preview.

Begin the final selection process by identifying key personnel who can assist in validating each candidate. This should include personnel from those departments that will be most impacted by the end product and professionals that will be called upon for assistance or information needed to make your implementation successful. Compile a list of questions and expectations to be used during each candidate's presentation. While scheduling presentations, be sure to include as many key personnel as possible to attend the meeting. This will ensure a more comprehensive selection of a candidate. Closely compare each presentation to the proposals previously submitted. After you have completed each interview, gather notes, concerns, opinions, and questions from those attending the presentations. Send each candidate follow up questions if further clarification is needed. Upon completion of your research, organize all findings in a matrix format for presentation to key personnel. Solicit their top preference and the reason(s) for their choice of provider. Compile a final findings report and reveal your data pool provider based upon the needs of your organization.

5.6. Advance Ship Notice (ASN)

The Advance Ship Notice (ASN) is a type of Electronic Data Interchange (EDI) document used in the exchange of transaction information between trading partners. Known as the EDI 856, a vendor will approve a formal request so the electronic mapping table can be set up to begin receiving the EDI 856. Once the EDI 856 is translated into a computer readable format, a secondary in-house process takes the generated file with the EDI 856 information and moves it into the client's ERP or accounting system. At this stage of the transformation, the EDI 856 has now become a document in the recipient's ERP system available in a form familiar to the users of that system.

5.7. Go/No-Go Decision

A Go/No-Go Decision is a point where an organization will determine if they are ready to move forward with the implementation of the project. For FMOLHS and their partnering organizations, the main consideration was if the GTINs and GLNs would complete a fully automated transaction. To make this decision, FMOLHS would host a conference and invite every key stakeholder to discuss if each individual party is ready to proceed. Any member of the team would raise any concerns and the group would bring it to discussion. If the issue was large enough to hinder progress within the project, the start date would be pushed back. Although this is only one way to complete a Go/No-Go Decision, each organization should mirror

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Source:
http://www.edibasics.com

FMOLHS' efforts to objectively look at their progress before proceeding with the project. An objective list of criteria should be developed in order to properly assess each issue that arises. In addition, a list of steps outlining the process for an organization to "go live" will be necessary to see which step in the process will be affected by the issue. Below are the steps that FMOLHS went through in order to start.

- FMOLHS would call a Go/No-Go meeting with partnering organizations to address any issues that arose and decide whether it will be detrimental to the process.
- FMOHLS coordinated with their Information Technology (IT) team to test EDI Transactions with a live purchase order.
- If Go Live was still a go, FMOLHS would change the setting for their ERP.
- FMOLHS would adjust the electronic orders to pull these purchase orders from the new processes.

5.8. Major Milestones

These milestones were created and implanted into the master project plan. The milestones were developed to address and measure each phase and significant activity. These milestones were unique to FMOLHS and could vary between different organizations. FMOLHS milestones included:

- GLNs loaded for pilot manufacturers.
- GTINS loaded and data cleansed for pilot manufacturers.
- Setting changed to transact using GLN and GTIN (done for each vendor).
- Advanced ship noticed received.
- Delivery of EDI order received.
- Three-way match that compares a product's GTIN, quantity, and price.
- Invoice reconciled and paid.

6. HOW TO MONITOR AND CONTROL THE PROJECT

Executing the processes and procedures will require the most time and resources to complete. However, it is very important for an organization to monitor and control their newly implemented processes in order to gauge their effectiveness and correct any issues that arise. This phase should be completed throughout the entire progress from initiation to close. By continually monitoring the project's progress, FMOLHS was able to make any changes to avoid delays and incorporate any new procedures that were necessary to continue.

This section describes the various tools that FMOLHS used in order to properly monitor their progress. These tools served as a focal point for each team member if an issue developed and the necessary steps to correct them.

You will find the step-by-step guide FMOLHS used to monitor their progress. This will include the timeframes they used to monitor their progress and avenues that were employed to ensure there were no hurdles.

6.2. Project Monitoring

Throughout this project, FMOLHS created several key deliverables that would help control and consolidate any issues that would come up. For example, the process flow maps, detailed procedures, policy documents, RACI, Communication Plan, and approval changes were utilized to monitor project progress.

FMOLHS will need to monitor the transactions that were taking place via the GLNs and the GDSN. In order to do this, FMOLHS analysts would have to pull purchase order history for pilot partnering organizations to use to identify any errors. FMOLHS used Dashboard Gear, a reporting toolkit used to pull data from our ERP. This would make it easier to pull purchase order data for validation. Below are some attributes that were utilized as potential sources of error for a manufacturer to examine.
- Facility ordering
- Part number
- Vendor part number
- GTIN

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Source:
(2013). A guide to the project management body of knowledge (PMBOK guide), fifth edition. 5th ed. Newtown Square, Pa.: Project Management Institute

- Material Type
- Purchase order number
- Purchase order date
- Transaction due date
- Receiving date

These attributes were monitored for a specific amount of time that increased if zero errors occurred. Initially, analysts would monitor transactions daily for two weeks. This would progress to weekly checks for four weeks pending no errors had occurred. Finally, FMOLHS analysts would monitor the purchase orders each month for a total of six months.

6.3. Control Scope

As the project progresses through each phase, new tasks can be created in order to address issues that arise. However, it is important to control the scope of this project to prevent scope creep and expanding the parameters of the project. Generally, scope creep occurs when new tasks are added without going through the proper change controls. Other factors that can create scope creep include not involving users early, underestimating the complexity of the project, and gold plating. FMOLHS developed a formal change request procedure that would address any issues a team member encountered. If the issue was large enough to impede progress, a change request was created and sent to the project sponsors to possibly include in the project scope.

6.4. Control Costs

Along with controlling the project's scope, a project's costs should be continually monitored to ensure increases in expenses are not added for unjustified reasons. FMOLHS had the unique opportunity to not adhere to any budgetary constraints as the project was completed. This will differ between organizations and should be controlled at every phase of the project.

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Source:
(2013). A guide to the project management body of knowledge (PMBOK guide), fifth edition. 5th ed. Newtown Square, Pa.: Project Management Institute
Alliance, University. "Managing Scope Creep in Project Management." Villanova University. 1 Jan. 2015. Web. 13 Jan. 2015. <http://www.villanovau.com/resources/project-management/project-management-scope-creep/#.VLVRYtLF9VY>

6.5. Control Communication

In order to continually inform the project's key stakeholders, the channels of communication had to be monitored to ensure the free flow of information. The key benefit to controlling communication is that all participants are being informed at any moment in time. For FMOLHS, they developed a communication plan during the planning phase in order to address each stakeholder's preference for being informed. This same chart was utilized during the control and monitor phase in order to update them on the progress of the project. In addition, having a continuous open channel of communication allowed stakeholders to give their input and make changes they saw fit. Any changes recommended by a stakeholder would follow the formal change request procedure in order to properly address their concerns. If necessary, additional tasks were added to the project's parameters.

6.6. Potential Issues

FMOLHS was the pioneer for a health system wide implementation of GS1 standards. Being the first to fully implement this system gave FMOLHS the opportunity to deal with unique challenges as the project progressed. As the health system initiated the start date portion of the implementation, new issues occurred. Individuals involved in the project utilized a standardized issue report table to document the issue and how it was resolved. Below in Figure 3, is an example of a table that might be used to help communicate these issues with the project team.

Figure 3.

GS1 Go Live Risks and Issues							
Type	Date Submitted	Location	Description	Reported By	Referred To	Date/Time Resolved	Solution

7. HOW TO CLOSE THE PROJECT

After FMOLHS had successfully completed six months of zero errors in their purchase order transactions, they could formally complete the pilot with that vendor with the acceptance of the deliverables outlined in the charter. This would formally close all the processes involved with that pilot and officially complete this project.

It is important to have a formal meeting with every team member to discuss and evaluate the project. This will allow any prevalent issues to be examined and ways to prevent these issues from being repeated. You can discuss success stories that arose from the project and hurdles that might hinder a team's progress. Additionally, FMOLHS was able to create guides based on their experiences in order to prevent the same errors from happening again. These guides were utilized as FMOLHS moved from one vendor pilot to another. They were able to learn from their past mistakes and prevent delays.

7.1 Evaluation of the Project

Project review and lessons learned are the first step toward closing the project. This was addressed through a conference call with all participants in the implementation of GS1 Global Data Standards across the health system. Hosting this post project evaluation provides a way for team members to see what was achieved by their hard work. Additionally, evaluating the project promotes the need for knowledge sharing. Every stakeholder can provide their account of the project and share what they felt were successes and failures. By allowing this open discussion environment, the organization can ensure similar projects will progress smoother and save time and money.

7.2. Project Review

At the time of this document's creation, FMOLHS was in the process of finishing up their project in its entirety. Therefore, a complete review of the project was not completed. However, as each pilot was completed, FMOLHS hosted a meeting to discuss what the cause of delays were and how they can be avoided. A list of these were compiled in the *Lessons Learned* section.

7.3. Project Goals

At the onset of this project, FMOLHS created goals that outlined the overarching vision of what should have been achieved at the end of the project. These goals are unique to FMOLHS and were linked to several other initiatives that were going on throughout the health system. This project was one of many ways FMOLHS is trying to optimize their supply chain and ultimately the health system. The list below was conceived for FMOLHS' strategic vision and will differ based on each individual organization's needs.

Touchless order

The touchless order is having what was once manual process overtaken by a fully automated process. Like most healthcare organizations, many of FMOLHS' processes are all manually completed. This opens up the organization to the possibility of errors. Having a completely automated process will provide a standardized work flow that will reduce errors to almost zero.

Optimize the supply chain

By automating several steps that were originally manual, FMOLHS should see a decline in the number of errors that are associated with each supply chain function. This will not only translated to improved savings, but improved employee satisfaction with the reduction in time spent resolving issues.

Recall management

 The touchless order will not only prevent avoidable errors, but in the event of a recall there is a full history of where an item is located. Unfortunately, many healthcare organizations do not have the capabilities to track every item they purchase. Moreover, when that item is defective, a large amount of resources are devoted to locating each item. Having a complete history of the item will save countless hours of searching.

Reduce non-value activity

Without having a fully optimized supply chain, there is a large possibility of redundancy in work. Employees' time is spent doing manual processes when they could be spent in more activities that add more value to the organization. By having a standardized supply chain system, employees will have more time to spend on work they find more suitable to their position.

7.4. Lessons Learned

Documenting lessons learned is a very important part of the project plan. It gives the organization the opportunity to properly document any errors that were overcome and prevent the same hurdles from appearing for each vendor. Each organization is different and will vary in their approach for a lessons learned discussion. Therefore, using this Lessons Learned Template will help organizations structure their own meetings. In addition, below are a list of lessons learned the FMOLHS worked through and used to become more efficient at the onset of each new vendor. This will give you an example of the types of response that might be important to note.

- Important to document all tasks and assign priority levels for each task for the project. Include names and responsible parties for each task.

- Assign backups for each individual in the event the main responsible party is absent.
- Make sure the GTIN setting is changed to transmit GTINs.
- Make sure the GTIN can be loaded properly with appropriate digits in your ERP.
- Ensure every key team member is engaged throughout the entire process and understands the important of their task within the timeline.
- Create a procedure for following up with every responsible party to ensure completion of their task and prevent further delays.
- When monitoring your organization's progress, make sure to check purchase orders for cancelled items from the vendor and ensure they are not calculated as an error in your system.
- Make sure you pull needed data i.e. GTIN information, cancelled line items, etc.

7.5. Thank you

Thank you to all the team members who participated in the development of FMOLHS GS1 Global Data Standards Master Process Implementation Plan.

8. CONCLUSION

The FMOLHS GS1 Global Data Standards Master Process Implementation Plan is intended to assist Health Systems across the United States by using this document in conjunction with the Master Project Plan, the Master Network Diagram and associated documents to implement GS1 Global Data Standards within their own health system. In the appendix you will find these items as well as several key materials that will help transition your organization to using data standards. For example, a project checklist is provided to give the organization an idea of how the project should be structured. Likewise, a project charter and a lessons learned template are provided to give your organization tools that can be used during the project. A PowerPoint presentation that was presented by FMOLHS' project manager will be made available to each organization for further clarification of this process. While we tried to address every possible scenario, we understand no two health systems are alike. Therefore, some adjustments and unique circumstances may have to be addressed.

We trust you will use this document to guide you through the process of implementing GS1 Global Data Standards and alleviate many barriers that cause hesitation or prevent you from taking the first steps to a successful implementation. Please share the unique challenges and solutions you developed for the next Health System to benefit from your experience.

9. GLOSSARY

9.1. Definitions

1. Change Approval Committee (CAC) - A committee that makes decisions regarding whether or not proposed changes should be implemented.
2. Change Request - a formal proposal to modify any document, deliverable, or baseline.
3. Class I - A "low risk" medical device. Items like elastic bandages and tongue depressors
4. Class II - A "medium risk" device. Items such as hearing aids and syringes
5. Class III - A highly regulated medical device. Life-supporting or life sustaining devices, like pacemakers and heart valves.
6. Electronic Data Interface (EDI) - Transactions are transactions that are conducted through e-commerce.
7. Enterprise Resource Planning (ERP) - A software application that a company can use to collect, store, manage, and interpret data from many business activities.
8. Global Data Synchronization Network (GDSN) - Network of all supply chain partners who will be able to access identical, up-to-date, reliable product data efficiently. Healthcare organizations can use the network to create and store product information for faster standardization.
9. Global Location Number (GLN) - A location identification number that replaces a custom account and location numbers for organizations.
10. Global Trade Item Number (GTIN) - A standardized product identifier that ensures accuracy of product information at every level of packaging.
11. Global Unique Device Identification Database (GUDID) - A publicly searchable database administered by the FDA that will serve as a reference catalog for every device with an identifier.
12. Gold plating - Act of giving the customer more than what was originally asked for.
13. Group Purchasing Organization (GPO) - An entity that is created to leverage the purchasing power of a group of businesses to obtain discounts from vendors based on the collective buying power of the GPO members.
14. GS1 - GS1 is a neutral, not-for-profit, international organization that develops and maintains standards for supply and demand chains across multiple sectors.
15. Lean Six Sigma - A methodology that relies on a collaborative team effort to improve performance by systematically removing waste.
16. Project Management Body of Knowledge - Describes the entire quantity of theory and learning that encompasses the practice of project management.
17. Project Management Office (PMO) - A group or department within a business, agency or enterprise that defines and maintains standards for project management within the organization.

18. Radio frequency identification (RFID) - The wireless use of electromagnetic fields to transfer data, for the purposes of automatically identifying and tracking tags attached to objects.
19. Scope creep - refers to uncontrolled changes or continuous growth in a project's scope.
20. SuperSaw - GHX software utilized to track GLN transactions.
21. Three way match - a payment verification technique used by the accounts payable department.
22. Unique Device Identifier (UDI) - a system used to mark and identify medical devices within the healthcare supply chain.

10. Network Diagrams

FMOLHS-GS1 Data Standards Network Diagram – Direct

FMOLHS-GS1 Data Standards Network Diagram – Distributed