Building an Open Source LIS Technologies Community of Practice

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Executive Summary

Laboratories are a pillar of any care, treatment, and prevention program and the data they generate are critical for clinical decision making, disease screening, monitoring, blood safety and surveillance. Good laboratory practice (GLP) and standards-based laboratory accreditation requires a laboratory to utilize a standardized system to collect, analyze, report, and store laboratory data. Electronic Laboratory Information System (LIS) are software that are used to support good laboratory practice. LIS are a crucial component for the effective management and operation of a clinical laboratory and the assurance of reliable and timely laboratory results. Data generated by these laboratories must be shared throughout the enterprise health (eHealth) architecture, or the health information systems (HIS) ecosystem, that manages information in a care, treatment, and prevention program.

Concerned with costs and ownership, many developing countries have increasingly looked to open source solutions for implementation within their laboratory network. OpenELIS Global and BLIS have both been a common choice for implementation, but efforts across these programs and countries have lacked coordination of design and development of the technologies. This has resulted in a milieu of forked code bases with overlapping and duplicative functions and features, and an inability for collaboration or sharing across projects. In addition, much of the interfacing with laboratory testing instruments has been specific for that implementation, and tightly coupled to its software. This results in an intensive and burdensome process for additional or upgraded instruments to be added, and impossible to generalize for broader use. In a recent assessment of these two technologies and their landscape, many developers and implementers expressed strong desire for this ability to collaborate and share. In addition, Ministries of Health and laboratories expressed the need for a community of lab informatics experts to turn to for additional support and sharing to strengthen their systems and implementations. Lastly, Ministries, donors, and implementers voiced the recognized urgent need for integrating the LIS into the broader HIS ecosystem in order to truly achieve a higher quality health care, treatment, and prevention program for their country.

This proposal aims to address those needs through the creation and coordination of an LIS community of practice to coordinate efforts on several widely-used mature open source LIS products - OpenELIS Global, BLIS, Senaite (formerly Bika) an open source independent lab instrument interface software called OpenLabConnect, and the integration of these technologies into the broader facility-level and upper-level HIS ecosystem.

Consortium Team

University of Washington Clinical Informatics Research Group (CIRG) (http://cirg.washington.edu) designs, develops, builds, and operates information systems that securely manage health information for projects in the Clinical, Public Health, and Global Health Informatics domains. Working in the Global Health domain for over 12 years, CIRG is one of the premier lab informatics expert organizations, having led numerous lab informatics programs and projects throughout the world; including developing, implementing, and advising on OpenELIS Global, BLIS, OpenLabConnect, and LIS standards-based interoperability projects for governments in Haiti, Cote d'Ivoire, Kenya, Mozambique, Cameroon, Namibia, and Vietnam. CIRG leadership serves in multiple open source foundations and communities in both contributor and leadership roles.

IntelliSOFT Consulting (http://www.intellisoftkenya.com/) is a leading Kenyan software development and consultancy firm that specializes in

the healthcare industry. Their primary focus is in the areas of Health Management Information Systems, Laboratory Information Systems, and Health Research Support Systems. The company's overall goal is advancing the use of Information and Communication Technology to support the provision of quality healthcare services. IntelliSOFT leadership has partnered with University of Washington for nearly a decade on multiple projects throughout Africa, including development and support for OpenELIS Global, BLIS, and standards-based interoperability for integration into the HIS ecosystem.

RTI International (https://www.rti.org/) works with governments and nongovernmental organizations in 92 countries. RTI possesses an array of subject-matter expertise, among them: health information systems (HIS), information and communications technologies (ICT), health informatics, epidemiology, and disease surveillance. RTI has in-depth experience in HIS strengthening. Recently, in Tanzania and Zimbabwe, RTI provided technical assistance to the ministries of health in areas that included strategy, capacity building, ICT, and data demand and information use. In both countries, RTI led the national rollout of the District Health Information System 2 (DHIS2). In Zimbabwe, for the CDC-funded Zimbabwe Health Information and Support Project (ZimHISP), RTI also led the LIMS deployment. As an OpenHIE Lead organization, RTI serves as part of a group of organizations that help steer the conceptual and practical direction of the OpenHIE community, using an organizational partnership model.

Naralabs (https://naralabs.com/) is an implementer and founding member of the Bika Open- Source LIMS project. Based in Barcelona, Spain, Naralabs is a company specializing in LIMS and offers professional technology services and engineering, such as consulting, implementation, training, system maintenance, and technical support. BikaLIMS is currently being used in Argentina, Australia, Canada, Colombia, Costa Rica, France, Germany, Guatemala, India, Liberia, Namibia, Nigeria, Portugal, Puerto Rico, South Africa, Spain, Trinidad and Tobago, United States, and Zimbabwe.

Proposal

Our team aims to support the building of a community of practice to serve as an organizational home for the open source laboratory information systems, OpenELIS Global and BLIS, and the independent open source laboratory instrument interface software, OpenLabConnect. In addition, the team aims to support building out of the laboratory sub-community of practice under the OpenHIE community to develop the workflows, transactions, technologies, and supporting materials for integrating laboratory information systems into the larger facility-level and upper-level eHealth ecosystems using the OpenHIE design pattern and technologies.

OpenELIS Global, BLIS, and Senaite are long-standing well-regarded open source laboratory information systems (LIS/LIMS) that have been widely implemented across national laboratory networks in multiple low and middle income countries (LMIC). Traditionally seen as competitive products, they often serve in compatible roles within the national network due to providing different levels of functionality targeted at different types of laboratories. OpenELIS is aimed at more advanced, comprehensive labs, such as reference laboratories with rigorous processes and complex workflows. BLIS is aimed at small facility-based labs with limited testing and staff often serving in multiple roles throughout the laboratory. As such, developers and implementers often work with both systems on programs. Multiple organizations have been involved in the development and implementation of these software. To date, despite voiced desire by these groups for shared code and space for collaboration, there has been little coordination of the design and development across these implementations. As a result, numerous forks of the code bases and supporting documentation exist across a very confusing and fragmented LIS landscape. Lacking a coordinating body, developers and implementers spend wasted effort and resources examining the options, creating duplicative functions that are not able to be leveraged from other code bases, and learning from trial and error.

We propose the creating and coordinating of the LIS community of practice, independent of specific implementation funded projects and broader than a single specific platform, focus on the following areas:

- Coordination for a network of developers, implementers, laboratory experts, and maintainers for technical, materials, and knowledge sharing related to LIS in LMIC;
- Maintaining a shared online space for community member communication, documentation and supporting materials, and other

community functions as determined needed;

- Curation of standards and best practices for LIS, and stewardship of a supporting implementation guide for integration into workflows, transactions, and technologies.
- Identifying opportunities for merging of code bases, or migration to a shared code base, to strengthen the efforts on LIS products;
- Developing a shared technical roadmap for products where applicable; and,
- Providing or coordinating technical support for members and projects through the community.

A unique aspect of laboratory informatics is automation with laboratory analyzer instruments. Historically in open source LIS, interfacing with these instruments has been accomplished through a labor-intensive process of point-to-point programming to access these proprietary machines data. With the release of the open source software OpenLabConnect (https://github.com/OpenLabConnect/OpenLabConnect), connecting to instruments can now be accomplished through a decoupled mediator which transports and transforms the data and commands to the proper destination in a standardized format for consumption. Currently, this software is limited to use with OpenELIS. But there has been strong consensus among LIS developers that this is needed for any LIS. Therefore, we propose having a dedicated funded team to work within the community to:

- Expand the OpenLabConnect software APIs and workflows for use with multiple LIS for instrument interfacing;
- Develop documentation and supporting materials for the OpenLabConnect software; and,
- Provide technical support to community members for implementation and use of the software.

In addition, laboratory data must be accessible beyond the laboratory information system to support high quality clinical care, early warning systems, supply chain management, and program monitoring. As such, our team proposes supporting the coordination of a laboratory information systems subcommunity under the OpenHIE organization to develop the workflows, transactions, technologies, and supporting materials for integrating laboratory information systems into the larger facility-level and upper-level eHealth ecosystems using the OpenHIE design pattern and technologies. If agreed to by the aforementioned community members for the OpenELIS, BLIS, and OpenLabConnect technologies, this could be the same community, all housed under OpenHIE. Because of the maturity of OpenHIE and the ability for multiple reference applications to interact under that umbrella, this would ensure efficient coordination efforts and a more robust LIS community.

In addition to the community coordinating efforts under OpenHIE, to further LIS integration with the larger HIS ecosystem and to start towards providing reference LIS applications for use with the OpenHIE design pattern and technologies, our team would propose leading the following activities under this effort:

- Development of specifications for interoperability of LIS to the Shared Health Record, DHIS2, and OpenMRS; and,
- Assessment of efforts to develop interoperability of both OpenELIS, BLIS, and Senaite to that specification.

Expected outcomes from this funding include:

- An open source LIS community of practice that OpenELIS, BLIS, Senaite, and OpenLabConnect (or any other LIS technology or tool) developers, implementers, and users can share and collaborate on technologies, materials, and informatics;
- Expansion of the decoupled OpenLabConnect software for instrument interfacing with additional LIS products;
- LIS interoperability subcommunity for OpenHIE identifying and building out standards-based and needs-based workflows for integration into the larger facility-level and upper-level HIS ecosystem.

Use Cases, User Stories, and Activities

We propose to carry out activities in the following areas:

1. Community of practice building of active developers, implementers, and domain experts for creation and use of LIS technologies, and LIS interactions with other systems in the HIS ecosystem.
2. Curation of LIS standards and best practices as resources, along with developing the implementation guides detailing the workflows, transactions, technologies, and supporting materials for integrating laboratory information systems into the larger facility-level and upper-level eHealth ecosystems using the OpenHIE design pattern and technologies.
3. Development of LIS technologies that support the general use case of collecting test results data into the LIS from the automated laboratory analyzers

Activity 1: Community of Practice Building

Through RTI's position as an OpenHIE Lead organization, we will follow the established process within the OpenHIE community for establishing a sub-community, engaging participants, and conducting activities. Our focus over the next year will be on:

- Creating a digital home for LIS knowledge sharing, collaborations, and technology offerings
- Engaging LIS implementers, developers, users, and experts in the community
- Identifying opportunities for interactions of members to strengthen the knowledge base, resource library, and technology offerings within the community
- Building a shared roadmap for community collaboration on LIS tools and technologies, while encouraging the sharing of individual product and organization roadmaps within the community for identification of alignment and collaboration opportunities.
- Performing an assessment of the open source LIS landscape (functions, technologies, implementations, support/community) to guide content prioritization, identify opportunities for consolidation, and engage additional community participants.

Measures for success

Activity	YR 1 Outputs	Outcomes
Create digital home	1 Virtual community established created within OpenHIE housing appropriate communication tools and processes	People can gather, share, and collaborate through an established space
Engage LIS implementers	4 open source software codebase hosts are engaged in the community and consider themselves "members" or "partners" 6 LIS development and implementing teams are engaged in the community and consider themselves "members" or "partners"	The community houses a group of organizations and codebases that for sharing LIS expertise, best practices, and code
Identify opportunities for interactions and collaborations	2 opportunities identified for members to collaborate on a community project.	Community members begin to come to the community to find shared interests and goals for collaboration on projects

Shared Roadmap	4 LIS technical product roadmaps are shared publicly on the community space 1 community shared roadmap has been created for a community prioritized and collaboration project	Community members can easily see what other LIS products pathways are and identify opportunities for overlapping goals and interests. The community has a process for identifying and prioritizing shared goals and interests for code to be slated for development.
Assessment	1 LIS Landscape assessment completed and published	Evidence provided for content prioritization. Opportunities are identified for consolidation. Additional potential community members identified for engagement.

Activity 2: LIS Standards and Best Practices, Implementation Guide

The LIS community of practice will replicate the pattern set by the other sub-communities in the OpenHIE organization to curate applicable LIS standards and best practices into a resource repository. In addition, the consortium will be focused on developing an implementation guide for using these standards, how to implement the LIS tools and technologies using the OpenHIE design pattern.

Some examples of resources to look at including in the curation, include:

1. APHL Guidebook for Implementation of Laboratory Information Systems in Resource-Poor Settingsand APHL LIS High Level Requirements
2. Public Health Informatics Institute (PHII) Requirements for Public Health Laboratory Information Management Systems and Logical Design
3. Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework and Profiles[6] and the IHE Patient Identifier and Demographics Query PIX/PDQ Profile
4. International Organization for Standardization (ISO) ISO/TC 215 Health Informatics Standards
5. The Kenyan Ministry of Health Standards and Guidelines for Electronic Laboratory Information Systems in Kenya
6. Malawi, Zambia, Mozambique, and Namibia Ministry of Health LIS Selection Criteria and Process

Measures for success

Activity	YR 1 Outputs	Outcomes
Establish resource repository	Resource repository established in the LIS community virtual space	Community members can publish or search in the resource repository to share or use knowledge from other members and LIS experts
Curate and publish LIS best practices and standards	Curated and vetted LIS best practices and standards available for specific use cases	Community members have a repository of best practices and standards for their LIS development, implementation, and use for the context that they need.

Create Implementation Guide	1 Implementation guide published	LIS implementers will have a guide for the various phases and steps of LIS implementation using the OpenHIE design pattern.

Activity 3: Development of LIS Technologies

The coalition proposes to resource a technology development team to focus on a specific use case commonly required to address by most LIS implementations. Part of this team's mission will be to create a community development process that will foster further open source collaboration on LIS technologies. The second focus of team will be to work towards solving this specific use case utilizing that community development process.

Community Development Process

Since open source communities cannot always rely on long-term engagement of a core team of developers, it is imperative that the LIS community prioritize the creation and implementation of a community development process that will enable productive collaboration from distributed team of multiple contributors coming as freelance individuals or from an organization, with varying levels of commitment. This activity will result in a community that is not owned by a single organization, and is not reliant upon a single organization's core team and contributions for long-term sustainability of the community.

Specifically, the coalition will need to setup the following:

- Shared software development tracking tools, such as a shared JIRA instance;
- Process for prioritizing roadmap(s) for collaborative technologies development;
- Process for validating design and architecture proposals prior to development;
- Asynchronous discussion tools;
- Development and release process; and,
- Coding conventions, developer privileges such as commits, and onboarding processes for new developer contributors.

Technologies Development

As part of this proposal, the core technology development team will work on expanding the decoupled laboratory interface tool, OpenLabConnect. The goal of the development will be to expand the compatibility with two additional LIS (BLIS and Senaite), and to improve the mediators for additional laboratory analyzer support. In doing so, the following activities will be conducted:

- Assessment of existing analyzer interface approaches with BLIS and Senaite to leverage lessons learned, identify technical specifications for compatibility with those systems, and to identify possible code for supporting the expansion of OpenLabConnect;
- With the community, design and build specification to expand OpenLabConnect; Validate specifications with community;
- Development of prototype, QA, initial release;

- Develop documentation and supporting materials; and,

- Engagement of Implementation Partner for Pilot Testing and Feedback.

In addition to the specific development of a product, the team also intends to gain a better understanding of the development effort needed to make the LIS products listed compatible with some of the other systems within the OpenHIE architecture. The team will conduct the following activities:

- Explore specifications for interoperability of LIS to the Shared Health Record, DHIS2, and OpenMRS; and,
- Assessment of efforts to develop interoperability of OpenELIS, BLIS, and Senaite to that specification.

Measures for success

Activity	YR 1 Outputs	Outcomes
Establish a community development process	Established shared software development tracking tools, and published process for using and managing the tools	Technical PMs, BAs, and Developers will have an agreed upon established process for collaborating on technical projects.
	Published process for prioritizing roadmap(s) for collaborative technologies development	
	Published process for validating design and architecture proposals prior to development	
	Asynchronous discussion tools established with published process for using and managing the tools	
	Community agreed upon and published coding conventions, developer privileges such as commits, and onboarding processes for new developer contributors	
Development of OpenLabConnect Interfaces	1 Assessment published of existing analyzer interface approaches with BLIS and Senaite to leverage lessons learned, identify technical specifications for compatibility with those systems, and to identify possible code for supporting the expansion of OpenLabConnect	An expanded decoupled OpenLabConnect software for supporting multiple LIS to analyzer interfaces is available to LIS developers and implementers
	1 published functional and 1 published technical specification to expand OpenLabConnect	Improved LIS to analyzer interfacing with improved data quality and automation in the laboratories
	Completed initial development of prototype of expanded OpenLabConnect	
	Published documentation and supporting materials	
	1 Implementation Partner identified for feedback and pilot testing	
Additional Interoperability	Published draft of concepts for interoperability of LIS to the Shared Health Record, DHIS2, and OpenMRS	Improved interoperability design between LIS and other HIS in the eHealth architecture and ecosystem.
	1 published assessment of efforts to develop interoperability of OpenELIS, BLIS, and Senaite to that specification.	

Digital Health Technologies

This proposals fundamental mission is to utilize existing digital health tools and technologies to build a community of practice home for collaboration of LIS developers, implementers, decision-makers, and users. As such, we are focused on bringing together a small number of existing mature and common tools and technologies for the start of our proposed work. However, we will welcome the interest of other open source LIS technologies to join our mission at any point in our community building.

OpenHIE will serve as the LIS Community of Practice home. OpenHIE is a long-standing open source community of practice that serves as a the parent community for multiple sub-communities focused on the specific types of components, types of external systems, and the interactions & transactions within a larger national eHealth architecture. Created in 2013, the OpenHIE collaborative has defined a comprehensive design pattern for the national eHealth architecture in low-and-middle income countries. The collaborative offers example reference applications, and health information standards to serve as the component or external system functions, with published implementation guides, defined standards, and other resources available. The laboratory domain is currently unaddressed in the OpenHIE collaborative, although it is identified as a necessary external system within the national eHealth architecture as designed by OpenHIE.

OpenELIS is a standards-based open source laboratory information system that was initially developed by state public health laboratories in Iowa and Minnesota to support standard laboratory business processes as defined by the Association of Public Health Laboratories (APHL). It was forked and adapted into OpenELIS Global in 2009 by University of Washington CIRG to support both the basic and advanced clinical laboratory workflows in low-and-middle income countries. Since then, it has been continuously improved upon by multiple organizations to meet both a broader set of LMIC laboratory use cases and needs, and adapted by implementers for specific local and regional context. It has been implemented in Haiti, Cote d'Ivoire, Vietnam, Kenya as part of the national eHealth architectures, and is integrated as part of the core offering of the Bahmni HMIS distribution, used across multiple countries. We will leverage some of the core work previously done within OpenELIS Global for standards-based data exchange with laboratory analyzers, with other systems in the health facility, and with systems and components from the larger eHealth architecture.

The Basic Laboratory Information System (BLIS) was developed in 2009 by Georgia Tech C4G with support from the U.S. Centers for Disease Control (CDC). Using the initial implementation in Cameroon as the setting of required functionality, the system focused on "keeping it simple" for facility-based laboratories in LMIC. Since then, multiple organizations have forked the codebase to improve upon those functions, modernize the technologies, and adapt for specific local context needs. Widely used under CDC funded programs, BLIS is a mature product that maintains its mission to be simplistic for its userbase, while providing some more advanced functions behind the scenes to automate the workflow processes. BLIS will be used as part of the prototype for the development activities that involve data exchange with laboratory analyzers.

SENAITE (formally Bika LIMS) was built from the ground up as a modern web application server in 2004 and was released publicly as open source software in 2005. Since then the system has added support for microbiology and branches for health care, water quality management and inter-laboratory proficiency testing. It is a derivative work of Bika LIMS software, built on top of Plone CMS with Python as its main programming language. It is developed under the paradigm of continuous integration (CI) and continuous delivery (CD) ensuring that can be reliably released at any time.

There have been many architectural changes with respect to its predecessor Bika LIMS. The one we would like to highlight is that we have moved away from the monolithic application Bika LIMS was. We have developed SENAITE as a system of independent add-ons. This makes the application much easier to maintain and to contribute to. Now the system focus on high performance and stability, interoperativity (it ships with an integrated JSON API), and ease of use (it has an intuitive user interface (UI) and –experience (UX)). Today SENAITE is sustained by a collective of users, developers and sponsors to keep to professional standards and away from proprietary pricing models. SENAITE will be used to prototype data exchange formats for laboratory analyzers.

OpenLabConnect is an open source software that specifically addresses the workflow between the laboratory information system and the electronic laboratory analyzers with the laboratory. Using the OpenHIM software as its core interface engine, the software includes mediators

for transporting results data from multiple analyzers, transforming those results into a readable standardized format, supporting the validation process for those results to be accepted into the LIS, and finally, interfacing with the LIS for recording of the results. The software was built by APHL, UW CIRG, and Global CyberSoft staff in 2015 for the Vietnam MOH Laboratory Department, specifically supporting the interaction with OpenELIS as a proof of concept for their specific national implementation. The consortium will build upon this work to generalize the tools for use with multiple LIS systems and improved ability to support multiple types of analyzers.

Standards and Best Practices: These technologies have been built with a variety of international laboratory standards and data exchange standards, including the use of LOINC coding, IHE profiles for workflows and data exchange, and HL7 messaging. The consortium will work to identify opportunities to strengthen the use of standards within these technologies to be broadly compatible with other HIS components and systems within the HIS ecosystem, and especially in low resource settings, where expensive or complicated standards may not be easily adaptable. Under this opportunity, we will begin by pursuing an environmental scan, through the OpenHIE community meetings and literature reviews, to identify a list of commonly used open source LIS data exchange and interoperability standards. Long term, outside of this opportunity, we will include the exploration of development of mediators and tools for standards-based data exchange between the LIS and other components and systems.

Community Feedback

The LIS community of practice will operate as a forum for both participants and the broader digital health community to provide input, share knowledge, and give feedback. Since the LIS CoP will largely operate under the OpenHIE community, this serves as a perfect mechanism to engage with the broader digital health community that are involved in the other aspects of the HIS ecosystem. With this outreach, the LIS CoP will need to decidedly engage the larger OpenHIE community for input on the various standards and best practices being curated and defined where they interact with the other components and systems in the OpenHIE architecture. The LIS CoP should make public all ongoing work for input and feedback, as well as, directly request input on materials quarterly.

In addition to the OpenHIE community engagement, the laboratory system is a critical component to a country's health system. As such, there are many other global goods with overlapping scopes and interoperability needs with the lab systems. The LIS community will actively engage with the other global goods awardees to seek out collaboration on those areas. The following are a list of technologies that are in other Digital Square proposals that we feel would constitute strong potential for interactions for knowledge sharing and interoperability development:

- OpenMRS - interactions of patient identification, test orders, and test results;
- DHIS2 - interactions of sending aggregate lab data for program monitoring;
- Bahmni - LIS is a core component of Bahmni, and has sought the support of an LIS community to support that component within it's system;
- OCL - terminology to be utilized across the HIS systems, including LIS;
- OpenHIM - a core component to our decoupled instrument interface tool, OpenLabConnect; and,
- OpenLMIS - we would seek interactions to be developed for logistics and stock management of laboratory inventory within LIS workflows.

Beyond these direct and sought out interactions, the consortium will identify opportunities for presentation and publication of knowledge in informatics forums, participation in open source health systems discussion boards, and broadly disseminate knowledge about the experience and knowledge gained in building out the LIS community.

Global Good Maturity Model Self-Assessment

OpenHIE Assessment: https://docs.google.com/spreadsheets/d/1R1Jro_jKqIJ08U6ie_b7jdIJzQezbiru1i09_FN5ctM/edit#gid=1364833400

OpenLabConnect Assessment:
https://docs.google.com/spreadsheets/d/16uR_2trjE_UT5nzZnz4uT9CXxTRHOuCIQ3ku_jbR9YE/edit#gid=608072941

Workplan

Link to the workplan is here: https://docs.google.com/spreadsheets/d/1EyiaJnl_VmTaz5qwk_O9pJ2FkDuU0BNX9uN_Qw6Q0Pk/edit#gid=0