Request for Application #2020-038

G6PD Mobile Results Interpretation App and Engine

I. Summary of deadlines

The expected schedule for this application is outlined in the following table. Note that PATH reserves the right to modify this schedule as needed. All parties will be notified simultaneously of any changes through a modification posted on www.path.org/about/current-request-proposal/.

Release of Request for Application	July 6, 2020
Q&A submissions	Due: July 13, 2020, at 11 a.m. PDT Responses: July 20, 2020, at 5 p.m. PDT
Applications due	**August 14, 2020, at 5 p.m. PDT**
Applicants notified of decision	September 2020

II. PATH statement of business

As an international nonprofit organization, PATH works to save lives and improve health, especially among women and children. We accelerate innovation across five health areas—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. Learn more at www.path.org.

III. Background and timeline

A. Project background

The Diagnostics Program at PATH conducts research and development, technical evaluation, introduction, and technology transfer of low-cost, rapid, novel, and easy-to-use diagnostic tests that are appropriate for use in developing-country health systems. We ensure that innovative diagnostics are available, accessible, and adoptable. We design and test new tools in the lab and the field. We help

countries integrate diagnostics into markets and health systems. We create quality assurance programs to support their use. And we advocate for policies that make new diagnostic technologies sustainable around the world.

Plasmodium (P.) vivax is the most common species of malaria in countries close to eliminating the disease. The two commercially available drugs that can cure *P. vivax* are contraindicated for individuals with low levels of an enzyme called glucose-6-phosphate dehydrogenase (G6PD). G6PD deficiency is a genetic condition shared by 400 million people globally. Patients with G6PD deficiency are at risk of severe hemolysis upon exposure to tafenoquine or high primaquine doses required for cure of *P. vivax* malaria. PATH and our partners have advanced a point-of-care diagnostic device to measure G6PD activity. This test device, known as the STANDARD™ G6PD Test, is manufactured by SD Biosensor (South Korea) and is now commercially available in several malaria-endemic countries. This product could be enhanced through digital connectivity to improve its use and workflow including patient data management, accurate results interpretation, quality control, and patient referral and monitoring.

The Diagnostics Program, in collaboration with Digital Square, seeks to develop a digital solution to successfully transfer and interpret data from the STANDARD G6PD Test device into a digital solution. Successful data transfer and interpretation is defined as user-friendly, accurate, and comprehensive. The digital solution would improve the test's use and workflow and support clinical case management of malaria. PATH will partner with mobile health developers to develop, test, and implement solutions in a manner that will be interoperable with health systems in high-priority countries for malaria control and elimination. At minimum, the digital solution will include an image capture and processing function in addition to a results interpretation calculator.

B. Proposed project timeline

PATH anticipates that subawards will be 3 to 6 months and end by March 2021. As part of PATH's due diligence, we will conduct pre-award evaluations of all shortlisted candidates. In addition to project-specific deliverables based on individual scopes of work, PATH will require applicants to provide, at minimum, quarterly narrative and financial reports to support their work.

IV. Scope of work and deliverables

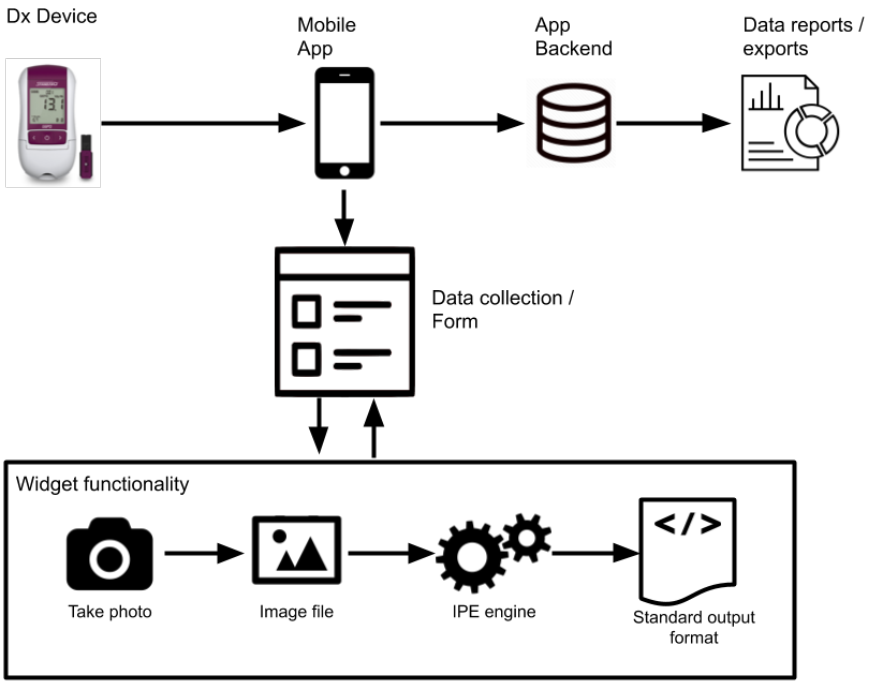
A. Scope of work

PATH is seeking applications to develop an open source, mobile phone–based solution that will facilitate the reading of results from a digital diagnostic device and storing the results against a unique patient identifier/patient record. We prefer a solution that adds to an existing tool/global good. So, the proposed solution should leverage an existing mobile health application that is used at scale.

The envisaged solution will facilitate the following use scenario:
The user will access the mobile app and select the workflow/form/section that allows the capturing of G6PD data. Upon having the patient data inputted or retrieved (an existing patient), the user will then select a "capture device screen" field/widget that will allow them to take a photograph of the device's LCD display. The mobile app will read the image, extract the data found on the screen, and present the data to the user for verification against the captured image (allowing the user to correct fields where there may be misinterpretation by the image processing engine [IPE]). Once accepted as correctly matching the device results, the data will be used in a decision support flow to provide feedback to the user of the app. The data will also be attached to the patient's record/file and stored centrally on the app's backend

service/server. The app's server will allow for data export and reports. See Figure 1 for conceptual flow of the digital solution.

Figure 1. Conceptual flow of the solution.



Work packages

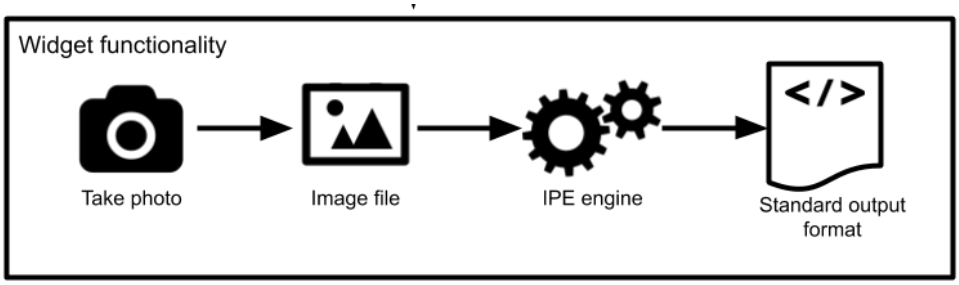
The proposed solution is expected be framed around three work packages (WPs) that cover the two key technical components and an implementation work package:

1. **Technical components**
   a. WP1: Generic Android image processing engine (IPE)
   b. WP2: Results Interpretation Module mobile application
2. **WP3: Implementation scope/app hosting**

WP1: Generic Android image processing engine (IPE)

The envisaged function of the IPE is to facilitate the use of computer vision, and possibly machine learning, to interpret an image from the STANDARD G6PD device display. The IPE is envisaged to be a reusable Android library/engine that may be adopted by other mobile tools to interpret the G6PD data screens for inclusion in their apps. The IPE is expected to be able to interpret the image (camera capture) and extract the data. The expected output of the IPE is a standard format (e.g., HL7 FHIR) that records the device values and metadata (e.g. date/time stamps, user information, etc.). The IPE is expected to be activated from within a mobile applications interface (e.g., via a form widget or similar). See Figure 2 for desired widget functionality.

Figure 2. Desired widget functionality.



Applicants are encouraged to propose appropriate methodologies to interpret the images, such as optical character recognition (OCR), or machine learning, etc. The solution will need to run on an Android device and work in an offline state (i.e., not send and process the image in the cloud).

Examples of the STANDARD G6PD device screen images are shown in Figure 3. A library of images will be made available to the successful applicant.

Figure 3. Example screen images from the STANDARD G6PD device.

<u>Device screen data elements</u>

- Date
- Sample number (0–500)
- Code chip number
- Control mode
- Total hemoglobin result (__.__ g/dl, Hi, Lo)
- Error messages (all errors with E-XX)
- G6PD result (__.__ U/g Hb, Hi, NA)

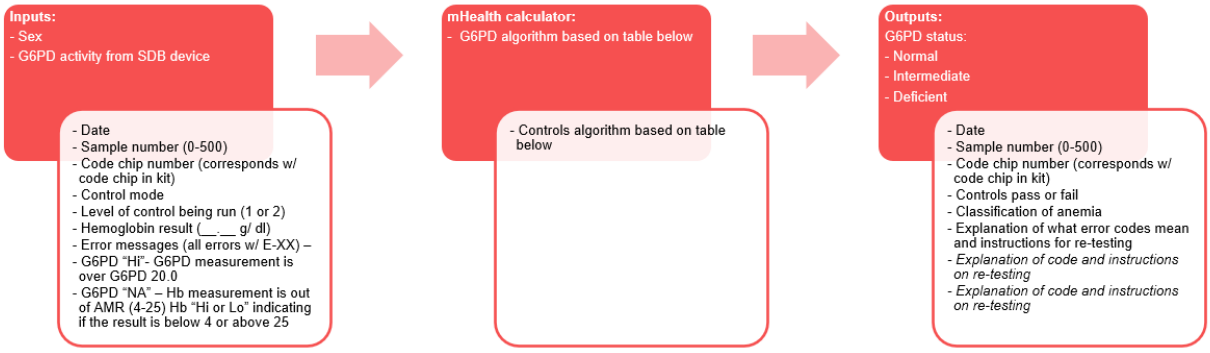
Note: The scope is focused on the Android OS due to its prevalence in low- and middle-income country (LMIC) settings. Applicants are welcome to propose solutions that are crosscutting mobile platforms but as a minimum the solution must be well suited for the most prevalent mobile OS in LMIC settings.

WP2: Results Interpretation Module mobile application

The Results Interpretation Module mobile application is a field support tool that will allow health workers to confirm that the correct treatment decisions are being made by providing digital support to the review and interpretation of the data from the diagnostic device.

The IPE is expected to form part of a larger solution that focuses on the capture and curation of data around the larger use case. The Results Interpretation Module mobile application will allow field workers to capture new patient data and/or recall a registered patient and capture the G6PD data points. As the data being interpreted from the diagnostic device form part of a treatment plan, the app must allow the user to review the data that has been "read" from the image to confirm accuracy and/or make adjustments prior to submitting the data or utilizing the data as part of a decision support flow (full requirements to be discussed on award). See Figure 4 for the decision support flow.

Figure 4. Overview of the calculation/decision support flow.



G6PD classification thresholds for inform G6PD algorithm

Male		Female	
G6PD deficient	≤ 4.0 U/g Hb	G6PD deficient	≤ 4.0 U/g Hb
G6PD normal	≥ 4.1 U/g Hb	G6PD intermediate	4.1-6.0 U/g Hb
		G6PD normal	≥ 6.1 U/g Hb

STANDARD G6PD Control Level 1 and Level 2 ranges to inform controls algorithm

No	Control level	Range	
		G6PD	T-Hb
1	STANDARD™ G6PD Control-Level 1	0.0-3.0 U/g Hb	8.0-12.0 g/dL
2	STANDARD™ G6PD Control-Level 2	6.0-10.0 U/g Hb	13.0-17.0 g/dL

This functionality will be possible either as a standalone functionality of the app and/or as part of an existing workflow or form process. The mobile solution must allow the configuration of the G6PD thresholds on a per-implementation basis (i.e., not set as uniform for all implementations).

Requirements

A full set of requirements will need to be discussed and refined with the successful applicant upon award, and this activity is expected to be part of the project. To provide input and guidance, an initial set of requirements are included in Appendix: Requirements. The requirements are inclusive of, but not limited to, the following functionality:

- Captures and stores patient demographic information.

- Works in offline mode.
- Adheres to best practices around user privacy, confidentiality, and password management.
- Stores audit logs for interactions with the system.
- Logs interpretation results and source images.
- Allows data export and access.

The envisaged solution will provide an interoperable set of interfaces that leverage existing health standards (such as HL7 FHIR, mADX, etc.) to be able to exchange data with existing and future clinical management or surveillance digital tools in the country.

The proposal must outline a summary of the reporting and data export functionality to the approach. Please highlight use of pre-existing reports and dashboards in the proposed solution. At a minimum, the system must provide data export functionality.

Applicants are encouraged to review the requirements to better understand the scope as well as to identify matches to existing solutions and/or propose value-add features and functionalities to the team.

Overall notes

Due to the nature of the existing STANDARD G6PD device, the option of Bluetooth sync functionality is not the priority use case. The focus of this award is on the image capture approach to the solution.

Applicants are strongly encouraged to build on existing platforms. We will pay special attention to applications that include the proposed mobile solution in an existing solution suite. Although new builds are not excluded, any such proposal would need to provide reasons for the need to develop a platform from scratch.

There is a strong preference for solutions that are based on open source tools and technologies that have a global access/free platform/tier.

WP3: Implementation scope/app hosting

Applicants are asked to provide a separate work package that will frame the costs and activities of undertaking an implementation of the solution (hosting, training, support, etc.) for a minimum of 12 months with additional costing packages inclusive of 3 years and 5 years. The implementation/hosting scope will **not form part of this budget** but will serve as an illustration toward a total cost of ownership model for the solution. The focus countries for the implementations are Brazil, Ethiopia, India, Indonesia, and Thailand.

B. Deliverables

The deliverables of this application are framed as the following technical components:

- Software artifacts
    - Android image processing engine (IPE) that can be leveraged by other tools
    - Results Interpretation Module mobile application solution (app and backend)
- Documentation
    - Refined requirements documentation
    - Architecture and design documentation

- User manual and implementation guide
- Developer and implementer documentation
- Quality assurance and test approaches (e.g., verification report)

All software is expected to have a sound and robust testing approach. As the solution is providing support to clinical decision-making, it is important to have transparency in any machine interpretation and to thoroughly test all aspects to ensure reliable and repeatable operations and results.

The final solution will undergo a set of stage tests to ensure that all requirements are met and the overall deliverables approved.

Licensing

New work developed under this award will be made available under an open source license; if the application is based on an existing tool, include how that tool is licensed.

If the existing platform is not open source, please ensure that there is a global access policy in place that outlines the ease of access/marginal costs for LMICs to leverage the service.

V. Application requirements—cost

The magnitude of the requirement for this application is US$50,000. This amount is just an estimate provided for informational purposes to the offerors and is not binding.

The applicant should provide a detailed explanation of costing and describe the reasonableness of each proposed cost in the budget narrative. Costs must be broken down by work package (component) area.

PATH will evaluate the quoted prices and hourly rates. No analysis will be performed on quotes determined as nonresponsive or if the technical quote is determined to be technically unacceptable. The price/business evaluation will be conducted in accordance with the quoted utility-based solution and proposed labor categories, their rates, and an evaluation matrix. PATH will conduct an analysis to determine if all quoted prices are reasonable. This evaluation is conducted with the expectation of adequate price competition and will rely heavily on market forces to determine whether proposed prices are fair and reasonable. The comparison of proposed prices in response to this solicitation uses the preferred and intended price analysis technique.

PATH will also compare the proposed prices to historical prices paid for the same or similar services and the independent government cost estimate. Other techniques and procedures may be used to ensure quoted prices are fair and reasonable. A cost realism analysis will be performed to determine whether the quoted level of effort is realistic for the work to be performed, reflects a clear understanding of the requirements, and is consistent with the unique methods of performance set forth in the company's technical quote.

Required elements

The Cost Application must include a budget narrative, detailing the cost and cost basis applied in generating the application. The Cost Application must also include a detailed budget that is itemized along the cost categories defined below. This detailed budget should be submitted in an unlocked Excel spreadsheet and must include the following information:

- Personnel—at minimum, the budget should detail:
  - All proposed staff/positions with daily rates.
  - Total number of days in total level of effort according to key staff.

- Itemization of all other costs (e.g., agency costs, service tax, administrative costs, supplies, etc.).
- Estimated schedule of other anticipated expenses (travel, subawardee resources, supplies, outside resources, etc.).
- Details of all subcontracting of work; this includes proposed consultants and subawardees.

The Cost Application shall begin with a summary budget detailing costs in the following categories:

Description	**Total cost (USD)**
Personnel	
Fringe Benefits	
Travel	
Equipment	
Supplies	
Other Direct Costs	
Contractual	
Consultants	
Total Direct Costs	
Indirect Costs	
Total Project Costs	

Special note on indirect costs

Indirect costs are overhead expenses incurred as a result of the project but not easily identified with the project's activities. These are administrative expenses that are related to overall general operations and are shared among projects and/or functions. Examples include executive oversight, existing facilities costs, accounting, grants management, legal expenses, utilities, and technology support.

If your organization includes indirect costs in the budget, you must provide a Negotiated Indirect Cost Rate Agreement with the US Government or 3 years of audited financials to PATH to validate the use of this rate.

VI. Application requirements—technical

Provide a narrative on your technical approach to accomplish the scope of work identified in section IV, including:

- Description of technical approach that includes:
  - Problem statement and solution approach.
  - How your solution will accomplish each subtask in this application.
  - How your solution will scale to growing needs of users across the globe.
  - Notional roadmap for your solution, aligned to the subtasks in this application.
  - Potential obstacles and plans to overcome them.
  - Completed 2020-038 RFA Initial Requirements Checklist (www.path.org/about/current-request-proposal/).
- Timeline to meet the deliverables.
- Identification of major internal and external resources.
- Profile of relevant corporate qualifications.
- Profile of relevant experience and examples of related work.
- Staffing plan accompanied by curriculum vitae (CV) for key technical positions.
- List of certifications possessed by each key technical personnel.
- Number of years in business.
- Annual revenue.

If your company has more than one location, please indicate these qualifications for the site that is responding.

VII. Additional attachments

1. **Illustrative work plan.** An illustrative first-year work plan timeline should be included in an annex. This work plan should include illustrative results and describe specific interventions to achieve those results. The illustrative work plan should describe specific interventions (activities) planned for the relevant tasks and should include a timeline providing target dates for achievement of milestones and illustrative results.
2. **Resumes and letters of commitment for all proposed key personnel.** A complete and current resume must be submitted for each key personnel position, detailing the requisite qualifications and experience of the individual. Qualifications, experience, and skills shall be placed in chronological order starting with most recent information.
3. **Staffing plan.** Offerors shall include a staffing plan, including specific position titles and the approximate level of participation for each position (percentage of full time equivalent [FTE] and time period).
4. **Third-tier subawardee agreements, contracts, or commitment.** Offerors may submit any agreements, contracts, or commitments they have with any potential third-tier subawardees.
5. **Past performance information sheets.**

6. **Awards.** Include any information on awards or certifications.

VIII. Application evaluation criteria

The following is a list of significant criteria against which applications will be assessed.

1. Technical approach that conforms to all of the components listed in Section VI above (**40 points**):
   - Description of technical approach.
   - Timeline to meet the deliverables.
   - Identification of major internal and external resources.
   - Qualifications.
   - Profile of relevant experience and examples of related work.
   - Staffing plan accompanied by CVs for key technical positions.
   - List of certifications possessed by each key technical personnel.
   - Number of years in business.
2. Experience—to be validated by past performance references (**15 points**).
3. Experience with mobile app development and image interpretation/data extraction—to be validated by past performance references (**15 points**).
4. Costs, as detailed in Section V (**30 points**).

Note: PATH reserves the right to revise and/or include additional criteria.

IX. Instructions and deadlines for responding

A. PATH contacts

Program contact: Athena Anderle, aanderle@path.org

Administrative contact: Fayna Yahiaoui, fyahiaoui@path.org

Technical lead contact: Carl Fourie, cfourie@path.org

B. Q&A email

During the RFA submission process, applicants are welcome to submit questions related to RFA # 2020-038 via email to aanderle@path.org by July 13, 2020, at 11 a.m. PDT. Responses will be posted on July 20, 2020, at 5 p.m. PDT.

C. Applications due: August 14, 2020

Completed applications should be submitted by email to the PATH contacts listed above. The subject line of the email should read: “RFA # 2020-038 - (Applicant name)”

We advise that you send files in commonly recognized Microsoft formats. We will not accept responsibility for resolving technical transmission problems with applications.

D. Conclusion of process

Applicants will be notified directly of the decision in September 2020. Final award is subject to the terms and conditions included in this solicitation, as well as to successful final negotiations of all applicable terms and conditions affecting this work.

X. Terms and conditions of the solicitation

A. Notice of nonbinding solicitation

PATH reserves the right to reject any and all bids received in response to this solicitation and is in no way bound to accept any application. The applications submitted through this RFA process are the responsibility of the submitter and do not necessarily reflect the views of PATH and Digital Square.

B. Confidentiality

All information provided by PATH as part of this solicitation must be treated as confidential. In the event that any information is inappropriately released, PATH will seek appropriate remedies as allowed. Applications, discussions, and all information received in response to this solicitation will be held as strictly confidential, except as otherwise noted.

C. Conflict of interest disclosure

Suppliers bidding on PATH business must disclose, to the procurement contact listed in the RFA, any actual or potential conflicts of interest. Conflicts of interest could be present if there is a personal relationship with a PATH staff member that constitutes a significant financial interest, board memberships, other employment, and ownership or rights in intellectual property that may be in conflict with the supplier's obligations to PATH. Applicants and PATH are protected when actual or perceived conflicts of interest are disclosed. When necessary, PATH will create a management plan that provides mitigation of potential risks presented by the disclosed conflict of interest.

D. Communication

All communications regarding this solicitation shall be directed to appropriate parties at PATH indicated in Section IX. A. Contacting third parties involved in the project, the review panel, or any other party may be considered a conflict of interest and could result in disqualification of the application.

E. Acceptance

Acceptance of an application does not imply acceptance of its terms and conditions. PATH reserves the option to negotiate on the final terms and conditions. We additionally reserve the right to negotiate the substance of the finalists' applications, as well as the option of accepting partial components of an application if appropriate.

F. Right to final negotiations

PATH reserves the option to negotiate on the final costs and final scope of work and also reserves the option to limit or include third parties at PATH's sole and full discretion in such negotiations.

G. Third-party limitations

PATH does not represent, warrant, or act as an agent for any third party as a result of this solicitation. This solicitation does not authorize any third party to bind or commit PATH in any way without our express written consent.

H. Application validity

Applications submitted under this request shall be valid for 90 days from the date the application is due. The validity period shall be stated in the application submitted to PATH.

Appendix: Requirements

Below is an initial guide as to the foundational requirements of the envisaged solution. These are to be refined by the applicants as the first step of the proposal.

Req #	Requirement (The system should…)
1	Allow user to capture data offline
2	Allow user to work offline
3	Allow user to access app on an Android tablet
4	Allow user to use app with auto capture on an Android phone
5	Allow user to use app with auto capture on an Android tablet
6	Allow the user to enter client basic demographic information
7	Generate an ID to enable unique identification of clients/patients across points of service
8	Allow the user to search based on partial information
9	Allow the user to search for client records, based on a combination of any of the fields used for registration or given some demographic information
10	Warn the user of possible match to already existing client to avoid duplication
11	Allow update of client details and prompt the user to confirm the changes
12	Patient demographic and clinical information collected is configurable.
13	Allow user to capture images from device camera and route to auto-capture data
14	Allow user to upload images to auto-capture data
15	Allow user to manually enter data from screen
16	Allow user to validate auto-captured data
17	Allow user to manually update auto-captured data to correct it
18	Assign patient classification based on predetermined thresholds of G6PD activity
19	Determine recommended malaria treatment based on patient classification
20	Allow user to document details of the counselling they have provided to the client
21	Store method used for data capture (image, Bluetooth, manual, manual override)
22	Allow configuration of G6PD classification thresholds
23	Store photos for validation on the mobile app server for future validation and auditing as needed

Req #	Requirement (The system should…)
24	Allow user to upload images and provide actual / correct data interpretation to improve accuracy of auto-capture of data
25	Provide an interoperable set of interfaces (standards based) to be able to exchange data with existing and future clinical management or surveillance digital tools in country
26	The ability to create visualizations and reports from data
27	Calculator should be available with or without the link to patient record
28	Provide encrypted communication between components
29	Enable deployment in an environment subject to power loss
30	Work in an environment that is subject to loss of connectivity
31	Allow for offline and online functionality
32	Provide access for authorized users
33	Adhere to best practice password management practices
34	Allow the user to change their own password
35	Provide role-based access to the system
36	Log system interactions by user
37	Log system logins and logouts
38	Log all activities performed by the user
39	Log access to views of individual client records
40	Log exchange of data with other systems
41	Log all data and system errors
42	Allow user with permission to create a new user and temporary password
43	Allow cascading user management and assignment of roles
44	Allow allowed users to enable and disable another user
45	Allow admin user to request password reset
46	Show the number of records that are not yet synchronized
47	Be user friendly for people with low computer literacy
48	Provide informative error messages and tooltips
49	Alert the user when navigating away from the form without saving
50	Support real time data entry validation and feedback to prevent data entry errors from being recorded

Req #	Requirement (The system should…)
51	Simplify data recording through predefined drop-down or searchable lists, radio buttons, check boxes
52	Support multiple languages
53	Use industry standard user interface practices and apply them in a consistent manner throughout the system
54	Easy to learn and intuitive to enable user to navigate between pages
55	Allow the user to configure workflows and business rules to accommodate differences between facilities
56	Provide access to data through APIs
57	Be interoperable with external systems through mediator
58	Provide ability for allowed users to view confidential data
59	Anonymize data that is exported and from the system
60	Provide robust security and access policies and process to access the systems
61	Allow for data to be synchronized locally at a facility and central server
62	Allow for data exchange and efficient synchronization across multiple facilities and points of service when the internet is available, even when it is intermittent and slow.
63	Provide guidance to the users to better support clinical guidelines and best clinical practices
64	Allow the user to configure the system centrally
65	Allow the user to configure business rules in accordance with guidelines and SOPs
66	Communicate with external systems through mediators
67	Exchange data with other approved systems