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ENGINEERING SCIENCE

PRAXIS III

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DESIGN PITCH DOCUMENT — AUTOMATED  
MICROSCOPIC MALARIAL DIAGNOSIS

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## 1 Executive Summary

E-Health Africa (eHA) provides clinical lab malarial tests. However, it struggles to keep up with the need for accurate malarial tests as it is based in an endemic country—Nigeria. The diagnostic process is slow as it involves five independent tests, it requires skilled lab technicians, and it is prone to human error. eHA requires a streamlined solution for testing malaria in their labs. The bottleneck emerges from an “impedance mismatch” between skilled workers available and the timeline of a testing epoch. The goal of our design is to provide a solution to improve the efficiency and accuracy of malaria diagnoses for eHA and other less economically developed endemic countries.

Our team believes that automating the different tests such as hematology analyzing, microscopy, and RDTs will lessen the need for highly trained clinical technicians, increase efficiency, and improve the accuracy of diagnoses. In addition, by automating the analysis, eHA can utilize a larger subgroup of their staff to process patient samples, as the staff would not need the training and experience to accurately identify malaria.

Our design is scoped down to a single manual diagnostic test: the microscopy test. Microscopy malaria tests are the most standard type of testing for endemic countries and the false negatives can typically be attributed to human error. Our final design aims to replace the microscopy step in malaria diagnosis with user-friendly machine learning software that takes and uploads a photo of a blood smear that is then run through an algorithm that classifies the blood as either containing or not containing malaria. The results are then presented as a PDF report that is viewed by the technician. Our prototypes consist of some hardware that attaches a cell phone to the eyepiece of a microscope, a user interface that takes and uploads the photo, a segmentation model that isolates parasites in a cell, a malaria classifier that uses a convolutional neural network to classify a cell, and a generated PDF report.

Some of the key design decisions made include adding the user interface and generated PDF in addition to the algorithm, using a command line interface instead of a Jupyter notebook, using a ResNet with 152 layers for our neural network, monitoring receiving operator characteristic curves to improve statistical robustness, and modularizing the functionalities of our model.

## **2 Introduction to the Design**

### **2.1 Situation**

Malaria has been identified as one of the most serious health issues today. It has a substantial and steady burden on Nigeria and other less economically developed endemic regions of tropical Africa. Clinics like e-Health Africa (eHA) host the necessary resources to fight a fraction of an international issue that infects 300 million people per year, and greatly impacts the lives of many more.

According to the opportunity statement, eHA's mission is "to build stronger health systems through the design and implementation of data-driven solutions that respond to local needs and provide underserved communities with the tools to lead healthier lives" [6]. To test for malaria, rapid diagnostic testing (RDT) is used which requires different machines for different parameters, each of which takes a different amount of time to make a diagnosis. The five machines include a microscope, hematology analyzer, chemistry analyzer, urinalysis machine, and blood glucose meter, all of which are used simultaneously. The only machine that is automated is the urinalysis machine; the rest are used by lab technicians.

Research Project Manager at eHA, Tolulope Oginni, commented on some of the issues associated with malaria diagnoses at eHA:

- RDT produces faint lines that are hard to read and prone to human error
- Malaria microscopy tests require highly trained staff; however, interpretations can be subjective and are prone to human error
- Diagnostic accuracy is of utmost importance, particularly for children under the age of five and pregnant women
- eHA would like to automate tests such as the RDT and microscopy test

According to the synopsis and additional information provided by Tolulope, eHA requires a streamlined solution for testing malaria in their labs and that the bottleneck lies in an "impedance mismatch" between skilled workers available and the timeline of a testing epoch.

### **2.2 Stakeholders**

- The primary stakeholder is e-Health Africa (including the Research Project Manager Tolulope Oginni and the lab technicians)
- The Nigerian patients requiring testing for malaria
- The equipment manufacturers
- The University of Toronto (including our team and the FaCT) and Georgia State University

### **2.3 Preliminary Scope**

The scope of this project will be narrowed down to automating the malaria microscopy testing as its false negatives are largely attributed to lack of training, most endemic malaria testing centers already use microscopy diagnosis, and it requires skilled technicians which can bottleneck the throughput of diagnostic results.

## 2.4 Value Proposition

Our automated diagnosis software aims to help malaria testing clinics who need faster results, higher accuracy, and the ability to allocate resources toward treatment instead of diagnosis, by replacing the microscopy step in malaria testing with a machine learning solution.

One of the sustainability goals identified by the United Nations is for everyone to have good health and well-being. This goal aims to “ensure healthy lives and promote well-being for all”. By enabling faster, more accurate diagnoses at eHA and similar service environments, clinics will increase their throughput, spend more effort on providing treatments and diagnosing difficult cases, administer treatments faster, and spend more resources on treating more vulnerable populations. This will help to improve the health and well-being of the Nigerian patients as described by the UN sustainability goal. This is crucial because epidemics have numerous negative impacts, including forcing caretakers to take a leave from work, social distancing, and closed schools and other public services, all of which take a toll on the society and economy. Vulnerable populations suffer disproportionately because they have limited access to healthcare and financial support. By improving local health, Nigerian citizens would benefit from reduced limitations on time, monetary, and education restraints.

## 2.5 Requirements Overview

After careful consideration of each stakeholders’ needs, we have converged on **six high-priority objectives: accuracy, precision, usability, efficiency, safety, and interpretability**. The technicians require proper safety, the ability to interpret the data produced by our design, and a machine that is easy to use with minimal training; the patients require accurate, precise, and efficient results. **The low-priority objectives are transparency, affordability, assembly, maintainability, and testability**. The equipment manufacturers require the machine to be easily assembled; both the equipment manufacturers and e-Health Africa require the design to need as little maintenance as possible; our team requires the data produced to be transparent and the design to be easily testable. To validate our design, it will be tested with a set of sample data.

## 2.6 Final Design and Prototype

Our final design is user-friendly machine learning software that takes and uploads a photo of a blood smear which is then run through an algorithm that classifies the blood sample as either positive, negative, or unknown. This information is then presented in a PDF report that is generated by a computer to be viewed by a technician. The final design directly aligns with our value proposition as it speeds up diagnosis time, has improved accuracy, and will allow the clinic to dedicate more resources toward treating rather than diagnosing malaria. Our design also meets all of the previously outlined requirements, as it improves accuracy, precision, and efficiency, is easily used by a lab technician, has a high degree of safety, and provides easily interpretable results.

Our prototypes consist of the following:

- CAD generated hardware that mounts a cell phone camera to the eyepiece of a microscope
- A user interface on a cell phone that takes and uploads an image of a blood smear viewed through a microscope

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The code and demos of the prototype are included in a folder named 'Prototype' in the team's Sharepoint folder

- A segmentation model that draws bounding boxes around cells that will be fed into the classifier
- A malaria classifier that uses a convolutional neural network to classify whether or not a cell contains malaria parasites
  - We created one prototype that uses a Jupyter notebook and another prototype that uses a command line interface
- A generated PDF report [See Appendix E] that contains the patient’s information, their diagnosis, a confidence prediction, and the images of the analyzed cells with their bounding boxes
- A user manual and supplementary document for understanding the statistical robustness of the model

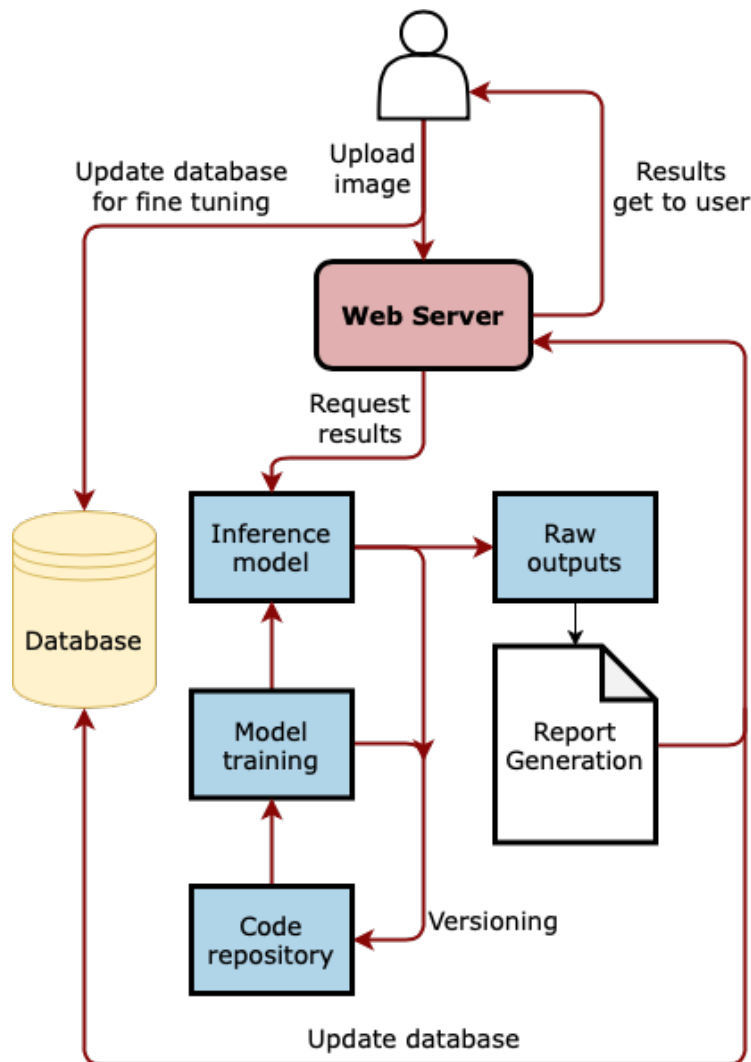


Figure 1: Systems diagram

To arrive at our final design, we first scoped the project into what was possible to address. Through functional decomposition, we arrived at a solution of automating the microscopy step in the diagnosis procedure. From here we converged on a deep learning based solution as it meets all of

our previously defined requirements. We then decomposed the solution into a number of *epics* and made each one its own module which could then be integrated together in the final software. One of the key design decisions that led us to these *epics* was to separate the malaria classifier from the segmentation model. This decision was made because unlike the sample data available to us, real life data is not separated into individual cells but is rather a single image of a blood smear so our software requires an algorithm that will segment the blood smear into its individual cells.

### 3 Select Background Details

#### 3.1 Understanding the Stakeholders

##### Primary Stakeholders

- The primary stakeholder is e-Health Africa including the Research Project Manager Tolulope Oginni and the lab technicians. This tool will help the lab technicians by speeding up the technical aspect of their job, letting them analyze more malaria tests in a shorter amount of time. eHA may require staffing changes to accommodate the new machinery and may need to re-train the lab technicians. The overall procedure for diagnosing malaria will also be slightly different. Although in this case eHA is the primary stakeholder, the solution created can be used with many other stakeholders that require malaria testing.

##### Secondary Stakeholders

- One secondary stakeholder is the Nigerian patients requiring testing for malaria. An automated microscope would allow malaria testing to be faster, giving patients their results quicker. Automated machinery also reduces human error, reducing the likelihood of a false positive or false negative result. This directly aligns with the UN sustainability goal for good health and well-being.
- Another secondary stakeholder is the equipment manufacturers, whose job will be directly impacted by the new proposed microscope design. They may require new machinery and training to produce the new design.
- The final secondary stakeholder is the University of Toronto (including our team and the FaCT) since they are the organizers of this project, and Georgia State University since their role in the project will be affected by the chosen design.

#### 3.2 Scope

Using functional decomposition, we broke down the problem into its key components: the five machines used to diagnose malaria. Since we cannot automate all five machines, we further scoped the problem down to automation of the microscope since we discovered from our stakeholders that this is the bottleneck of the problem. The microscopy process consists of preparing and analyzing the slides, and we chose to move forward with the slide analysis. We can also only tackle the problem from either a software or hardware approach, and we decided on a software (specifically machine intelligence) approach. Thus, after scoping down the situation we are focusing on automating the process of determining whether a blood sample has malaria from the microscope using machine intelligence.

The primary goal of our prototype is to test and demonstrate our malaria classification algorithm on sample data, which can eventually be used in the e-Health Africa clinic. Our prototype aims to provide us the accuracy and confidence of our algorithm. This relates to the UN sustainability



goal for good health and well-being as our design will increase accuracy in malaria diagnosis and increase the rate of diagnoses in Nigeria, allowing patients to be diagnosed and thus treated faster. This is directly in line with our value proposition as our design aims to improve the malaria diagnosis procedure by increasing the throughput and accuracy of diagnoses.

### **3.3 Service Environment**

The design we are proposing must be usable in a lab environment, specifically in the e-Health Africa lab. The machinery must also be manufacturable in a standard factory.

### **3.4 Previous Approaches**

#### **3.4.1 Single Cell Classification**

A research study by Rajaraman et al. showed that using a CNN based deep learning model on segmented cells (single cells from a blood sample) resulted in 98.6% accuracy in malaria detection, which is the current state-of-the-art [7]. This approach, however, only performs classification on single well-segmented cells that have been carefully curated by-hand.

#### **3.4.2 Whole Slide Bounding Box**

There have also been a couple of other approaches that aim to draw boxes around the parasites in an image of a slide sample [3]. These methods do not have statistically robust solutions for handling a large variation of slide samples. They do offer a transparent solution that could potentially improve the efficiency of the diagnosis process, however, these methods do not assist with the classification of the parasitized cells. From our research, this seems to be the bottleneck in the entire process as the lack of training as well as the tedious nature of the task reduce the reliability of the results while slowing down the diagnosis.

#### **3.4.3 Hardware for Automating Microscopic Diagnosis**

We also found several projects that have provided hardware for automating microscopic imaging [5]. These projects aimed to provide an “imaging plugin” for microscopes so that the existing machinery could be easily integrated with the software that automates the diagnosis process. These hardware solutions are, however, powered by rather primitive algorithms that do not provide informative results that accelerate the diagnosis without making compromises on the reliability of the results. The main improvements we can offer here are on the side of statistically robust results by providing even-more-robust deep-learning models. We aim to provide a solution that gives the best of what previous approaches have to offer, while structuring our design such that its flaws are easily surfaced. This would allow lab technicians to benefit from the efficiency gains our solutions provides, while being able to manually intervene and quickly resolve the issue when our system does not meet the required standards.

### 3.5 Detailed Requirements

#### 3.5.1 Higher Priority Requirements (HPR)

Objective	Metrics	Constraints	Criteria
Accuracy (HPR1)	Percentage of false negatives and total percentage of correctly diagnosed samples	False negative rate must be less than 19.4% (a false negative rate from a similar service environment) [1]. The overall accuracy of conclusive results should be at least 80% to be comparable of technician accuracy [2].	Less false negatives is better and higher accuracy is better
Precision / Uncertainty (HPR2)	The distribution of results which is conveyed in the confidence interval	The confidence intervals should at least bound at least 80% of the results	The higher the precision, the better
Usability (HPR3)	Level of training required to follow instructions correctly	Must be usable by at least the lab technicians without additional training	The less training required to follow the better
Efficiency (HPR4)	Time taken to test per slide sample. Measured as wall-clock-time	Must be at least as efficient as the original processing pipeline	The more efficient the better
Safety (HPR5)	The number of hazards associated with the machine	Follow safety standard from the "ANNEX I – General safety and performance requirements" [8]	The fewer hazards associated with the machine the better
Interpretability of Results (HPR6)	The number of output variables that can easily be traced back to a supplied input, i.e. how easy is it to interpret the why the results look as such	The result must be understood by regular technicians	The easier to interpret the output, the better

### 3.5.2 Lower Priority Requirements (LPR)

Objective	Metrics	Constraints	Criteria
Affordability (LPR1)	Cost of materials and manufacturing	Less than \$150 CAD	Lower cost is preferred
Transparency of Model (LPR2)	How well lab technicians can draw a cause/effect relationship to avoid the solution being a black-box, which can be measured by using feedback surveys	The solution must indicate at least the most significant factor in concluding a result	The easier to draw a cause and effect relationship between data and results, the better
Maintainability (LPR3)	How often the machine requires external maintenance	The design should not require external maintenance once setup	The less maintenance required the better
Assembly (LPR4)	How many resources are required to assemble the design	Existing staff members should be able to assemble the design	The less resources required the better
Testability (LPR5)	How long it takes to confirm the design is functioning properly	The final design must be testable	The less time required, the better

## 4 Methods and Key Design Decisions

### 4.1 Design Process

A key aspect of our Project Management (PM) Plan [See Appendix C] was the division of our project into epics. Epics are defined as sections of the work that can be divided into further sub-tasks [4], as in Figure 3. The epics were as follows: malaria classification, statistical robustness, report generation, microscope mounting hardware, slide segmentation, and user interface. The division of our project into smaller objectives was highly useful for both delegating tasks and improving efficiency. From our epics we were able to map out a timeline for our project over the course of a few months, as depicted in Figure 2 below.

We divided up our requirements into three sections: core algorithmic performance (requirements associated with the machine learning algorithm), non-algorithmic performance (requirements associated with other aspects of the pipeline), and service environment (requirements imposed upon us due to the setting in which the solution must work). The requirements are divided up as follows:

- **Core-algorithmic performance requirements:** Accuracy (HPR1), precision / uncertainty (HPR2), efficiency (HPR4)
- **Non-algorithmic performance requirements:** Usability (HPR3), interpretability of results (HPR6), transparency of model (LPR2), testability (LPR5)
- **Service environment requirements:** Safety (HPR5), affordability (LPR1), maintainability (LPR3), assembly (LPR4)

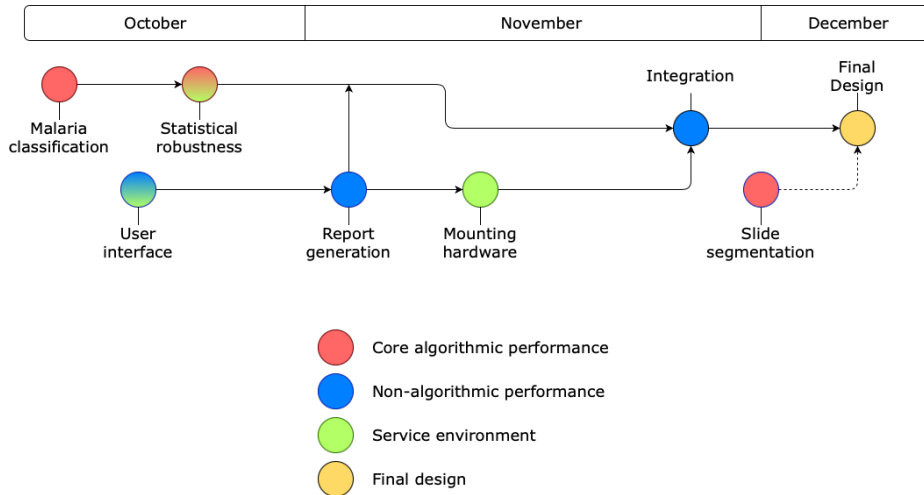


Figure 2: Timeline of project progress

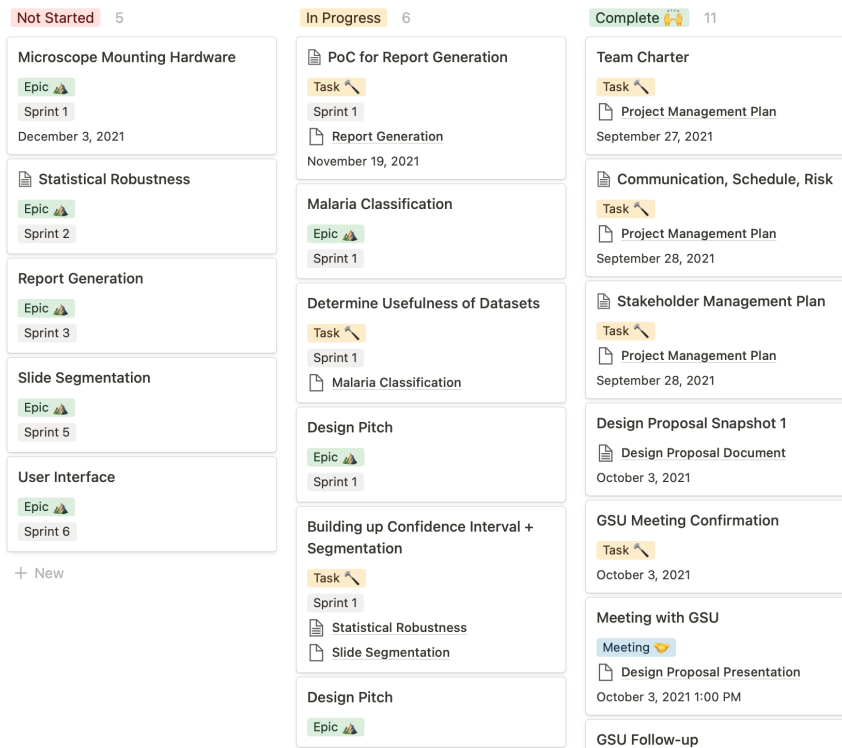


Figure 3: Kanban board showing epics, tasks, and sprints

When dividing work among team members, we used the roles assigned in our PM Plan. Nishkrit, George, and Charles took on the technical roles of designing the software and hardware of our project. Emily served as the bridge between the technical and nontechnical aspects of the project, including research. Amy was in charge of translating the technical parts of the project into the design pitch. By using our PM Plan, we were able to allocate the appropriate tasks to each member to maximize efficiency.

We also took our team values of empathy, novelty, sustainability, and efficiency into account when both analyzing the stakeholders’ situation and designing our product. We practiced empathy when

developing an understanding of the current situation at the eHA clinic and the lab technicians' current difficulties by making our design easily accessible. Our design can be accessed from any device with an internet connection or installed on a computer. We also considered novelty, sustainability, and efficiency when generating our requirements and objectives.

## 4.2 Key Design Decisions

Some of the key design decisions made in our project include the following:

- As part of our prototypes, we decided to add a user interface and generated PDF on top of our algorithm. This decision was to increase the usability of our solution, particularly for the lab technicians who will now only require minimal training.
- We chose to write the algorithm using a command line interface (CLI) configurable model using Pytorch Lightning instead of a Jupyter notebook. CLIs have numerous important functions. They have the ability to train the model, run predictions, easily export the model to different formats, tune hyperparameters, run validation and testing on the model, write a configuration YAML file that automatically saves weights, and create a directory with all of the different configurations from which it can select the best one. This makes variance of the design more feasible, as without using a CLI we could not test numerous variations of the model.
- We decided to use a deep Residual Network (ResNet) with 152 layers because it performs the best for the needs of our model. ResNet is a deep learning model that uses skip connections over several layers, which makes training faster and more accurate. It is also pre-trained on ImageNet, which is a huge image dataset of which the images are classified into 1000 different objects, which helps the model avoid overfitting the malaria cells. Overfitting is when the model memorizes certain training examples and generalizes poorly to new inputs.
- To improve the statistical robustness of our design, we chose to monitor receiving operator characteristic (ROC) curves along with the binary diagnosis given to the patient. ROC curves are plots that determine the characteristic of a binary classifier versus a threshold. They are widely used, particularly in a medical setting, because they provide more information than a binary classification. Other statistical values can also be derived from it, including variance and confidence prediction.
- We chose to modularize functionalities of our model. This means that each epic is separated into its own module in our code that is then connected all together. This decision was made because it is easier to modify as it is not required for someone to understand the entirety of the algorithm to modify a certain part of the code.

## 4.3 Prototype Verification and Validation

Through testing of our prototype, we have gathered the following data in regards to our previously defined requirements:

Objective	Results
Accuracy (HPR1)	Our design has a false negative rate of 0.16%, which is lower than 19.4%, and an accuracy of 94%, which is higher than 80%
Precision/Uncertainty (HPR2)	Our design has a built-in feature that allows lab technicians to define the threshold for precision and certainty they require.
Usability (HPR3)	Our design can be easily used by a lab technician with minimal training due to its simple user interface and easily interpretable results
Efficiency (HPR4)	It takes $80 \text{ ms} \pm 10 \text{ ms}$ to diagnose a slide sample, which is faster than the time taken for a lab technician to view the sample, input the result, and generate a report
Safety (HPR5)	There are minimal hazards associated with our design as the lab technicians are only required to interact with the camera to take the photo of the blood smear and the generated PDF report with the final diagnosis
Interpretability of Results (HPR6)	The results generated from our algorithm are easily interpretable in the format of a PDF report
Affordability (LPR1)	Our design costs approximately \$15 for the hardware to mount the cell phone to the microscope (under the assumption that the lab technicians have a cell phone with a camera and a computer that can generate the PDF)
Transparency of Model (LPR2)	The generated PDF report includes photos of the cells used to classify the blood sample, giving the technicians the ability to clearly identify how the algorithm diagnosed the patient
Maintainability (LPR3)	Our design does not require any maintenance after its initial setup other than in the event that the hardware breaks
Assembly (LPR4)	The hardware is easy to attach to the existing microscope and the software is easily downloadable onto a cell phone and computer
Testability (LPR5)	Our final prototype is testable and able to give us statistically robust results with a confidence prediction

#### 4.4 Our Design in Comparison to Previous Approaches

Our design is a novel, state-of-the-art approach that takes data directly from the slide sample viewed under a microscope and generates a diagnosis. From our research we can confirm that our solution is the first of its kind to combine slide segmentation, malaria classification, and report generation. Our proposed design is an improved combination of multiple previous approaches.

In comparison to the research study by Rajaraman et al. that classified a single cell as infected or uninfected, our design improves upon their solution as their approach only classifies on cells that have been previously segmented by-hand, whereas our approach both segments and classifies the

data directly from the blood smear. Similarly, in comparison to approaches that only draw bounding boxes around cells but do not classify the data, our solution is again an improvement as we both segment and classify the data directly viewed from the microscope. Our design also builds upon previous hardware approaches to this problem as we combine a statistically robust deep-learning solution with hardware that captures an image of a blood smear viewed through the microscope.

#### **4.5 Global Virtual Collaboration Reflection**

Our global virtual collaboration with Georgia State University was notably helpful in the creation of our design. We were able to take the feedback we received from our Design Proposal into consideration when moving forward with the project. The questions provided by our GSU counterpart were particularly helpful in finding the weakest points of our proposal so that we could make our design stronger in the end. For example, she questioned the user interface of which we had not allocated a lot of thought, indicating to us that it was an area in which we needed to delegate more of our time.

## **5 Discussion of the Final Outcome**

### **5.1 Validity of Our Solution**

According to our value proposition, our design aims to help malaria testing clinics by improving the speed and accuracy of the diagnostic procedure. By automating the microscopy step in malaria diagnosis, the process of classifying a blood sample as containing or not containing malaria is faster, has a higher accuracy than a human diagnosis, and allows clinics to increase their throughput and reallocate resources toward providing treatment and diagnosing difficult cases.

Our design primarily aids the eHA clinic including its lab technicians by speeding up the technical part of their work, allowing more malaria tests to be carried out in a shorter amount of time. These faster, more accurate results also allow patients to receive their diagnosis and treatment more quickly, improving the local health in Nigeria. Improved local health directly aligns with the UN sustainability goal for good health and well-being and will benefit Nigerian citizens greatly.

### **5.2 Limitations and Assumptions**

The limitations on our design include the following:

- The entire pipeline is not fully automated to diagnose a patient. Ideally, the entire process from a patient's blood being collected to the patient receiving their diagnosis should be fully automated. Due to time constraints, this project has only automated a subset of this pipeline, namely from the slide prepared with a blood smear being viewed under a microscope to the patient's diagnosis being generated as a PDF. [See Appendix D]
- The underlying model is still a black-box. A neural network is by nature a black-box, meaning its interior functionalities cannot be interpreted by the user. This is a limitation because in the event that a technician wants to further understand why the neural network made a classification, the information is not available.

Some assumptions we made when designing our solution include:

- The slide is in focus and captures interesting parts of the sample
- The cells are well-pigmented

- The lab technicians have read and understood the user manual
- There is someone experienced who can set up our solution

### 5.3 Feasibility of the Design

Through the creation and testing of our prototype, we were given information on the accuracy of our malaria classification algorithm, its associated confidence prediction, and the speed at which it can diagnose a patient. This allowed us to assess the feasibility of our design in terms of our previously defined requirements. Specifically, by testing our prototype we were able to determine the accuracy, precision, usability, efficiency, and safety of our design and how interpretable the results are.

### 5.4 Team Contribution to Prototype

- **Amy:** Managed the prototype progress by making sure that the team followed the PM Charter and Plan. Lead documentation efforts for the design pitch and communication between stakeholders.
- **Charles:** Worked on building Cell Segmentation models and an early prototype for report generation.
- **Emily:** Researched and implemented algorithms for adding statistical robustness to a model. Generated the graphics for final prototype.
- **George:** Created the web server with a frontend for our main server which includes a report template and automated report generation. Assembled the software pipeline to link all major components (UI, model, and report generation) with the server.
- **Nishkrit:** Built, trained, and fine tuned the ResNet ML model and CLI tools.

## 6 Conclusion and Next Steps

In conclusion, our design provides a valid solution to the stakeholder opportunity by automating the microscopy step, which in turn makes malaria classification in a blood sample faster, has a higher accuracy than a human diagnosis, and allows clinics to allocate more of their resources toward malaria treatment. Our prototype provides us with accuracy estimates, confidence prediction, and the speed taken to run the full diagnosis, which confirm its improved accuracy and diagnostic rate. Thus, our prototype supports our claims in terms of the validity of the design.

Moving forward, we would like to automate the entire data collection pipeline, from when the patient's blood is collected to the report being mailed to the patient. This would consist of the automation of blood smear slide preparation and report distribution, both of which we have not yet looked into. Something else we would like to look into is Bayesian neural networks to get more robust statistics. We would also like to work on bootstrapping the model with new images directly from the eHA clinic as it would be beneficial for the model to be trained with data that has been collected under the conditions of the clinic (for example, the clinic's lighting). Finally, as a next step we would like improve our existing algorithm by implementing vision transformers.

Overall, our design would be of great value to both the eHA clinic and its patients as it has the ability to increase the throughput of diagnoses and improve accuracy. Our design could also be used by future engineering design teams in numerous other settings; for example, in the use of diagnosing a different disease, as any dataset can be plugged into the model.



## References

- [1] Pedro Berzosa et al. “Comparison of three diagnostic methods (microscopy, RDT, and PCR) for the detection of malaria parasites in representative samples from Equatorial Guinea”. In: *Malaria Journal* 17 (Sept. 2018), p. 333. ISSN: 1475-2875. DOI: [10.1186/s12936-018-2481-4](https://doi.org/10.1186/s12936-018-2481-4). URL: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6142353/> (visited on 10/24/2021).
- [2] Samweli Bushukatale Billy Ngasala. “Evaluation of malaria microscopy diagnostic performance at private health facilities in Tanzania”. en. In: *Malar J* 18 375 (). DOI: <https://doi.org/10.1186/s12936-019-2998-1>. URL: <https://malariajournal.biomedcentral.com/articles/10.1186/s12936-019-2998-1> (visited on 11/26/2019).
- [3] Margarita Gamarra et al. “Split and merge watershed: A two-step method for cell segmentation in fluorescence microscopy images”. en. In: *Biomedical Signal Processing and Control* 53 (Aug. 2019), p. 101575. ISSN: 17468094. DOI: [10.1016/j.bspc.2019.101575](https://doi.org/10.1016/j.bspc.2019.101575). URL: <https://linkinghub.elsevier.com/retrieve/pii/S1746809419301491> (visited on 10/24/2021).
- [4] Kent McDonald. *Epic Confusion*. 2018. URL: <https://www.agilealliance.org/epic-confusion/>.
- [5] Billy Ngasala and Samweli Bushukatale. “Evaluation of malaria microscopy diagnostic performance at private health facilities in Tanzania”. In: *Malaria Journal* 18.1 (Nov. 2019), p. 375. ISSN: 1475-2875. DOI: [10.1186/s12936-019-2998-1](https://doi.org/10.1186/s12936-019-2998-1). URL: <https://doi.org/10.1186/s12936-019-2998-1> (visited on 10/24/2021).
- [6] Praxis III Teaching Team. *Opportunity Statement*.
- [7] Sivaramakrishnan Rajaraman et al. “Pre-trained convolutional neural networks as feature extractors toward improved malaria parasite detection in thin blood smear images”. en. In: *PeerJ* 6 (Apr. 2018). Publisher: PeerJ Inc., e4568. ISSN: 2167-8359. DOI: [10.7717/peerj.4568](https://doi.org/10.7717/peerj.4568). URL: <https://peerj.com/articles/4568> (visited on 10/24/2021).
- [8] *Z - Annex (1) I - General safety and performance requirements - CHAPTER 1 - General requirements Archives*. en-GB. URL: <https://www.medical-device-regulation.eu/category/z-annex-i-general-safety-and-performance-requirements-chapter-1-general-requirements/> (visited on 10/24/2021).

## Appendices

### A Team

#### A.1 Team Values

As a team, our core values are empathy, sustainability, novelty, efficiency, and learning. We aim to keep these values in consideration during all of our engineering design work and produce designs that bring significant value to our stakeholders. Throughout this engineering design project we’ve continuously improved our empathy skills when designing for a particular stakeholder by actively trying our best to understand situations that we have not personally experienced. When designing our final solution, we made sure it was a novel, efficient, and sustainable design that would bring a high level of value to our stakeholders’ lives. Finally, we all set out on this project with the goal of

improving both our technical and interpersonal skills and learning as much as possible about the malaria diagnostic procedure and how it can be automated. With all of this said, we are the team best suited to solve this particular problem because individually we all bring our own unique skillset, making us collectively strong in both technical and nontechnical abilities. Since we take on projects with an empathetic mindset, aspire to learn as much as we can, and aim to design a sustainable, novel, and efficient product, we are able to provide the best design possible for e-Health Africa.

## **A.2 Team Member Responsibilities**

**Amy:** Throughout the project, Amy was the project manager. She was responsible for overseeing and managing project operations, facilitating meetings, keeping track of progress, and writing and editing reports. In particular, for the design pitch Amy focused on translating the technical material from her teammates into the organized design pitch document, brochure, and presentation. Her past experiences in engineering design projects, specifically in managing teams and writing reports, and her technical experience in machine learning were assets when it came to contributing to this project. Her skills and experiences allowed her to guide her highly skilled teammates in producing a successful engineering design project. Furthermore, her personal values for empathetic design, learning, and innovation directly align with the team's values, contributing to the implementation of the team's value statement in the final project.

**Charles:** Throughout the project, Charles worked more on the technical side of the project. He was responsible for working on the segmentation for the cell images, which was later put into the pipeline to generate the diagnosis reports. In addition, he was responsible for managing risks and costs for the project. His past experience in finance and machine learning has made him an ideal candidate for risk management and the technical side of the project. His skills allowed him to collaborate with his highly skillful teammates on the machine learning algorithm. Moreover, his understanding for communications, bias, and empathetic design has made him a great contributor to the final project.

**Emily:** Throughout the project, Emily took on a role that required both technical knowledge and management abilities. She was responsible for stakeholder management, overseeing and managing project operations, facilitating meetings, keeping track of progress, and writing and editing reports. In particular, for the design pitch Emily focused on explaining the statistical robustness part of the design. Throughout the whole semester, Emily always stayed on top of everything the team has asked her to do and went above and beyond. She led the project and the whole group moving forward. Her past experiences in engineering design projects, specifically in managing teams and writing reports, and her technical experience in statistics and machine learning made her an indispensable contributor to the final project. Her skills and experiences allowed her to help produce a very successful engineering design project. Furthermore, her personal values for empathetic design, learning, and innovation directly align with the team's values, contributing to the implementation of the team's value statement in the final project.

**George:** Throughout the project, George was the software engineering lead. He was responsible for building out most of the software for the prototype. In particular, this involved writing the code for the software pipeline, including the server, frontend, and report generation modules. His past experience in software development through industry internships, freelance projects, and open source contributions has helped to contribute to the team. Moreover, his background working on large software projects gave him the technical expertise to understand the process and best practices

for software projects, which allowed him to succeed in this role. Furthermore, his personal values for empathy in engineering design, innovation, and eagerness to directly align with the team's values, which contributed to the implementation of the team's value statement in the final project.

**Nishkrit:** Throughout the project, Nishkrit was the technical expert who lead the team forward. He was responsible for overseeing and managing project operations, hand-coding machine learning algorithms, collaborating with George, Emily and Charles on the technical sides of the project, and helping Amy write and edit reports. In particular, for the design pitch Nishkrit focused on explaining the prototype and the whole design process to the audience, as well as answering questions. His past experiences in CAD design, training and testing machine learning models, engineering design projects (specifically in managing teams and writing reports) and his extremely skillful technical experience in machine learning were assets when it came to contributing to this project. His superior skills and experiences allowed him to guide his highly skilled teammates in producing a successful engineering design project. Furthermore, his personal values for empathetic design, learning, and innovation directly align with the team's values, contributing to the implementation of the team's value statement in the final project.

## **B Bill of Materials**

The only real cost associated with our software solution is the cost of GPU compute to train the model. Note, however, that this is just a one-time cost that is incurred during the development of the model. As our team had access to a powerful GPU, we didn't have to attend to these costs directly, but if someone were to try and replicate our results, they would also require access to a GPU, or might have to pay for one through a cloud service. These costs would vary based on the GPU provider. We also would need \$15 CAD to 3D print the microscope mounting hardware.

## **C Project Management Plan Artifacts**

### **C.1 Team Charter**

About the Team

- Team name: Teamies
- Team goals: To create a working product from which stakeholders will benefit from
- Shared values: Empathy, novelty, sustainability, efficiency

Project Team Meeting Plan

- Meeting schedule
  - Our team will meet three times per week: twice during studio, and every Friday from 9-11 am
  - Everyone is responsible for adding meetings into their own schedules; if a meeting is at an irregular time, Emily will send a reminder text via Signal
- Ground rules
  - Each team member will make the team aware of an instance that arises where they cannot make the regular meeting time; the team will then refer to our when2meet to decide on an appropriate time to reschedule

- Each meeting will begin with a quick update from each member regarding any progress on Notion
- Collaboration tools
  - Each meeting will begin with a quick update from each member regarding any progress on Notion
  - when2meet will be used for scheduling meetings
  - Notion will also be used for any other management tasks
- Plan for personal constraints, emergencies, lateness, or other circumstances when work cannot be submitted on time
  - Each team member will openly communicate any scheduling conflicts to the other team members as soon as possible so the workload can be rearranged

#### Project Roles and Responsibilities

- Emily: Note-taker, timekeeper, researcher, project planner, global team peer liaison, global client liaison
- Charles: Project planner, risk coordinator, issues coordinator, cost coordinator, global team peer liaison, global client liaison
- Amy: Project coordinator, facilitator, presenter, editor
- George: Systems engineer, component purchase coordinator, 3D-print/laser cut liaison
- Nishkrit: Design engineer, technical researcher, presenter, coordinator

## C.2 Communication and Schedule

#### Team Communications

- The agreed frequency of communication will be at least once per week with weekly in-person team meetings
- Progress will be communicated via Signal, Notion, and verbally during team meetings
- Communication issues will be addressed on Notion via the Roadmap page; issues can also be brought up during team meetings (an extra meeting may be scheduled if the issue is of high priority)
- A data dictionary for interdisciplinary terms will be kept on the Jargon page on Notion

#### Project Schedule

- Milestones and deadlines will be kept on the To-Do and Roadmap pages on Notion
- Emily will be in charge of updating the schedule on the Roadmap
- An issues log will be kept on the To-Do page with each issue flagged as a “bug”

## C.3 Risk Management Plan

## C.4 Stakeholder Management

- The key external stakeholders include:
  - e-Health Africa clinics

Risk	Risk Description	Risk Category	Probability	Priority	Potential Impact on Desi...	Strategy	Risk Response
COVID-19	Risk for Getting COVID if getting together too often with numerous stakeholders	Disease	Medium	High	Would slow down team's operation	50/50 Online and in-person meetings	Re-Distribute each team member's task
Costs	Risk for not considering the total cost of the design solution	Cost	Low	High	Unable to build the design because of the budget issue	Take costs into consideration in every step when forming the solutions	Reduce the total cost of the design if had to
Technical	Final Design does not meet Stakeholder's Need	Technical	Medium	High	The overall framing and designing process could go well but missing the point of the design in the end, which could result in a failure design.	Take a step back and think about the overall goal more frequently during each step	
Fabrication Risk	Risk for mis-fabricating prototypes	Technical	High	High	The Final Design could not function well	Carefully examine every measure we have before prototyping	Re-Prototype
Long horizon feedback plans	Risk for changing long-term goals if feedback	Planning	Medium	Medium	Slow down the design process, keep redefining the goals but not many progress made	Make the goals more short-term, like weekly goals and daily goals.	Shorten the durations of each goals, make sure each goals is achievable and doable in a week.

Figure 4: Our Risk Management Plan

- Tolulope Oginni
- Equipment manufacturers
- University of Toronto
- Georgia State University
- The preferred method for engaging with the external stakeholders is via the FaCT
- We will communicate with the GSU student biweekly via email and Zoom

## C.5 Decision-Making

Decision-making and approach to conflict:

- Discussions will be facilitated using the following four steps:
  1. identify problems
  2. generate alternatives
  3. reach a decision
  4. follow-up
- To make decisions, the team will:
  - Be open to one another's ideas
  - Adapt a decision-making process that everyone agrees on before proceeding to make a final decision
  - Use the FDCR Model
  - Set internal deadlines to facilitate the decision-making system
  - Have a clear timeline of the project, when to do what, when to make decisions and etc.
- Process for making decisions when the team is not in agreement:
  - Everyone will take a step back and analyze the pros and cons; then the team will vote
  - A mediator will cool down the conflict
  - Everyone will be empathetic, have a mutual understanding of other's perspectives, and try to understand from another person's perspective
  - The team will always have backup alternatives to each idea; if one idea is not working, the team will then move to the alternatives upon which everyone has agreed

### **C.6 Scope, Cost, and Procurement**

- Amy and Nishkrit will be in charge of monitoring the project's scope
- Charles will be in charge of the budget and any costs required for the project
- Charles and George will be in charge of procuring any items needed

### **D Stats for Nerds**

The "Stats for Nerds" appendix is attached at the end of this document.

### **E Sample Generated Report**

A sample of the generated report is attached at the end of this document.