safineai

Intelligent Microscopes that Automate Pathology Screenings

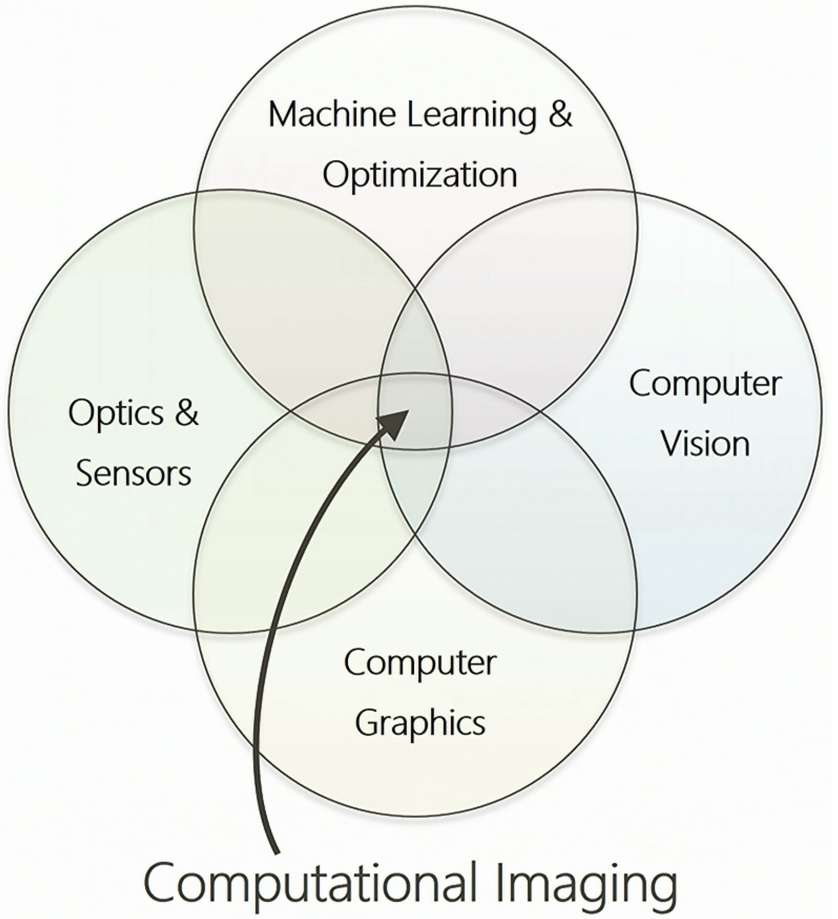
Computational Imaging meets Pathology

Surpass the barriers of traditional imaging!

Co-design optical hardware and processing software

Spin-out from Computational Optics Lab at Duke University

Portable, Self-Learning microscopy for rapid imaging and analysis



Beach Head Market : Blood Analysis

Complete Blood Counts (CBC) and Peripheral Blood Smears (PBS)

$50B Global Market - Most common pathology tests

Important for monitoring patient health

Vital for COVID-19 triaging and diagnosis

Human dependent processes with high skill requirement

Legacy technology for Complete Blood Count

Technology used = Chemical + Optical

Moving parts = High Maintenance and Calibration

Interference between 7 blood cell counts = False Positives

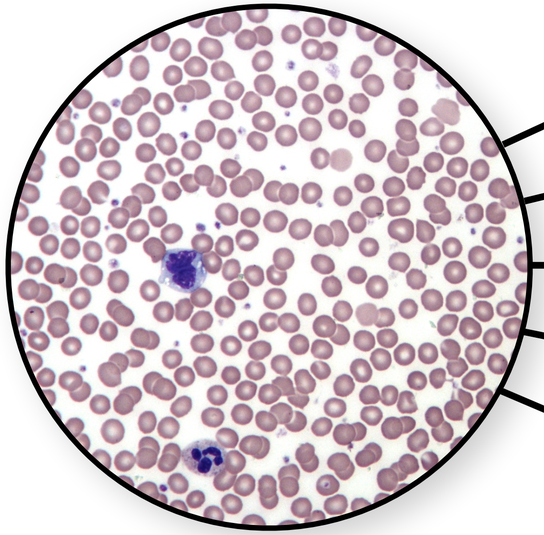
Not the **GOLD** standard!

"Blood Smear" = Final diagnosis = GOLD standard

Automated Hematoanalyzer (AHA)

Blood Smears are visual and important...

Drops of blood on a glass slide + dye, inspected using a microscope



Blood smear under a microscope

Used for...

- **Viral** against **Bacterial** Infections
- Various types of **Blood Cancers**
- **Sickle Cell** Disease and blood **Anemias**
- Infectious diseases like **COVID-19**
- ... and more

... but they are not ordered often enough

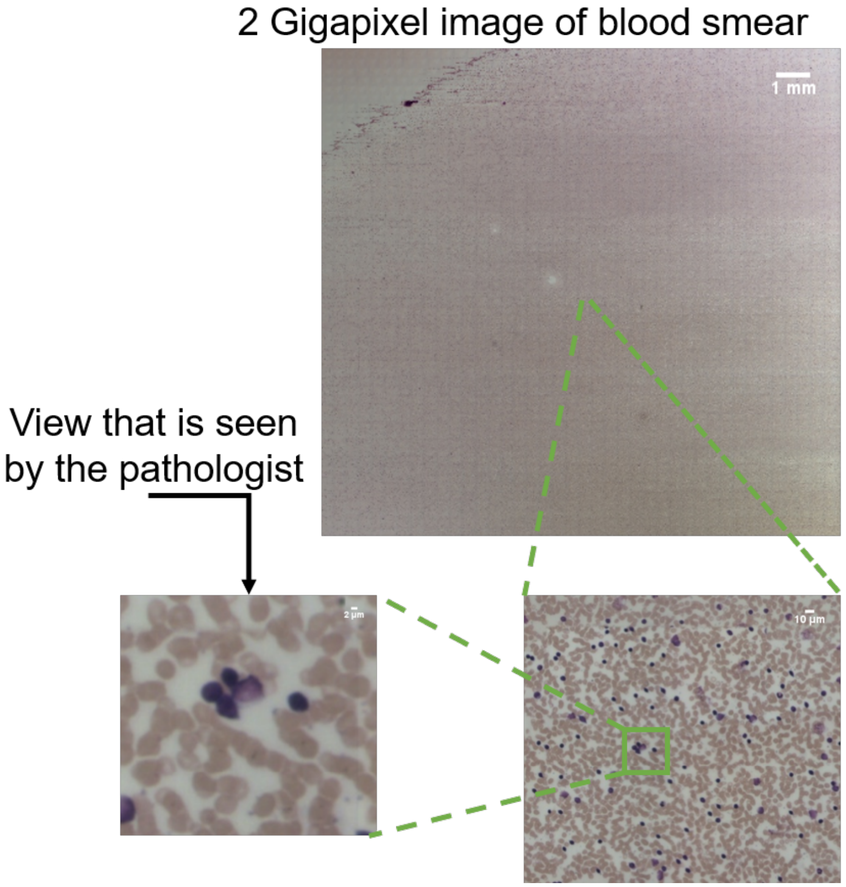
Very tedious

Requires tremendous skill and training

Performed manually using a microscope

70+ possible abnormalities

15	x	20	=	5 Hrs
Minutes per smear		Average smear per day		of manual effort each day



COVID-19 diagnosed using Blood Smears?

Computational Optics Lab at Duke has shown early results for **COVID-19 diagnosis using Blood Smears with > 90% AUC!**

Accuracy will be further improved by incorporating Complete Blood Count

Complete Blood Count (CBC) + Blood Smear (PBS) =
Complete picture + Diagnostic Value

SafineAI will automate CBC and PBS at the GOLD standard

Current

+

Two devices: Automated + Manual

Multiple Components and Reagents

Significant amount of blood (~mL)

High Maintenance, Calibration

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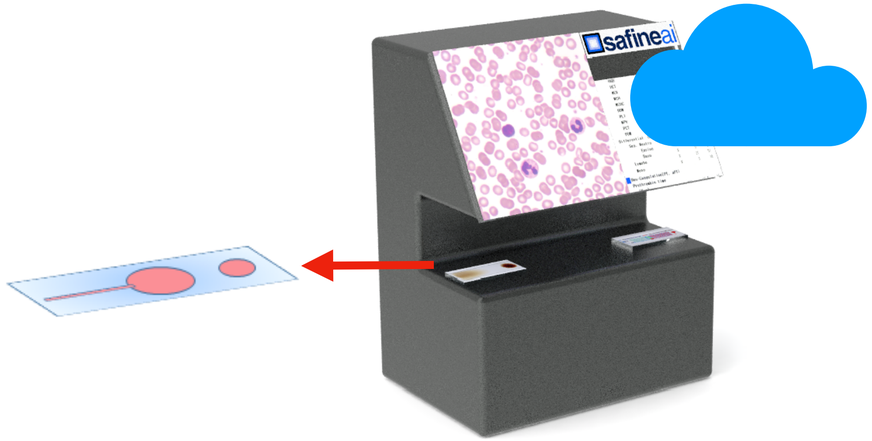


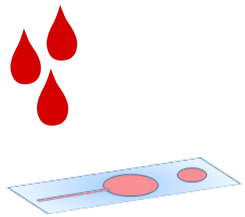
One device: Automated

Simple use, no reagents

Just a few drops of blood (~uL)

No maintenance, Auto-calibration

Technology = optical + computational



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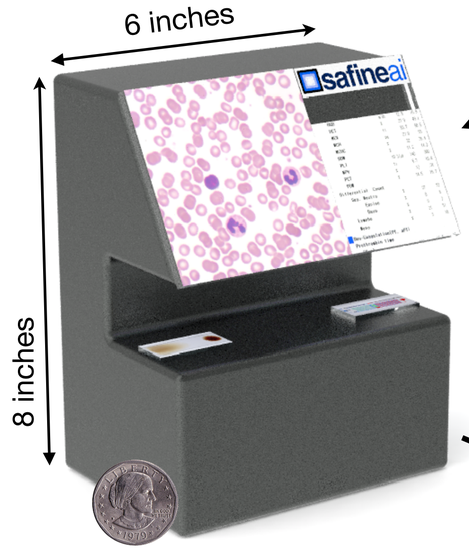
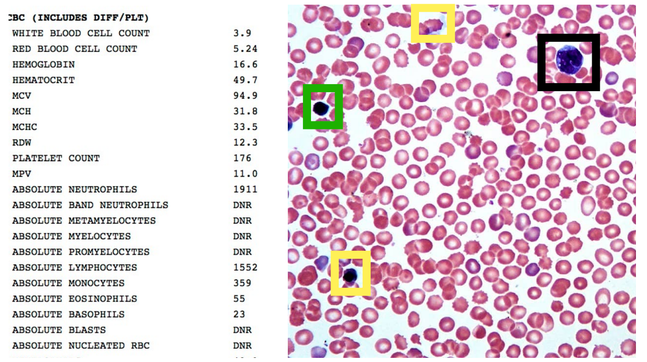


Jointly Optimize

+

Co-design

=



CBC (INCLUDES DIFF/PLT)	
WHITE BLOOD CELL COUNT	3.9
RED BLOOD CELL COUNT	5.24
HEMOGLOBIN	16.6
HEMATOCRIT	49.7
MCV	94.9
MCH	31.8
MCHC	33.5
RDW	12.3
PLATELET COUNT	176
MPV	11.0
ABSOLUTE NEUTROPHILS	1911
ABSOLUTE BAND NEUTROPHILS	DNR
ABSOLUTE METAMYELOCYTES	DNR
ABSOLUTE MYELOCYTES	DNR
ABSOLUTE PROMYELOCYTES	DNR
ABSOLUTE LYMPHOCYTES	1552
ABSOLUTE MONOCYTES	359
ABSOLUTE EOSINOPHILS	55
ABSOLUTE BASOPHILS	23
ABSOLUTE BLASTS	DNR
ABSOLUTE NUCLEATED RBC	DNR

CBC Report and Suspicious Images - high chance of abnormalities

Custom Monolayer chip

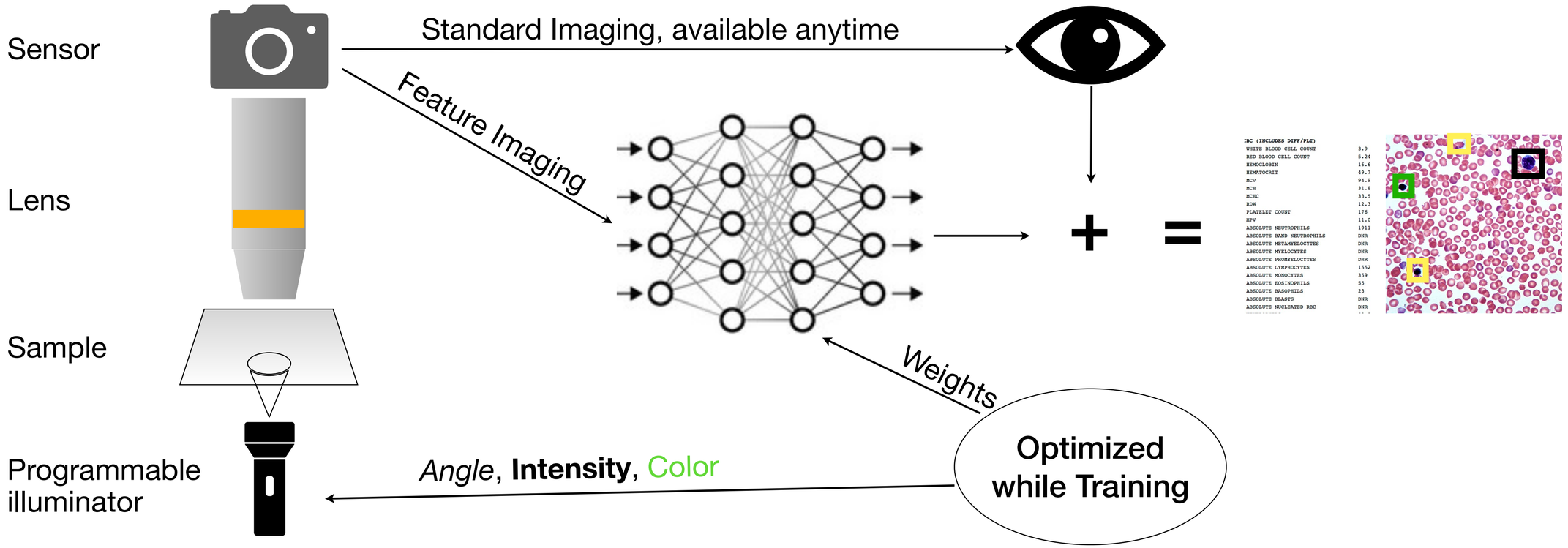
Our Patent Pending Self-Learning H/W

Cloud-connected Machine Learning

High quality results at low data overhead

ML and Optics optimized together

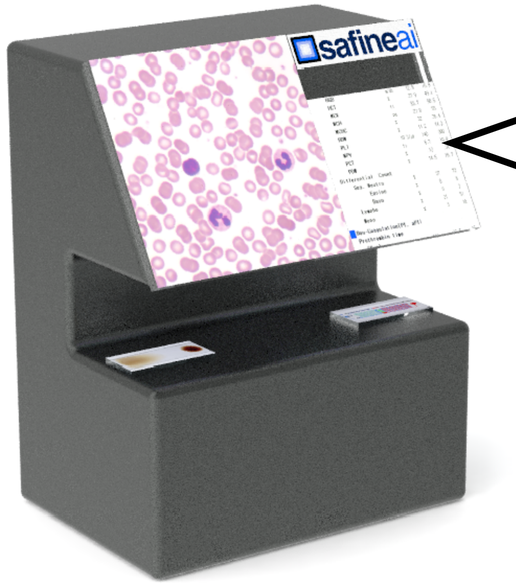
Task influences the information captured

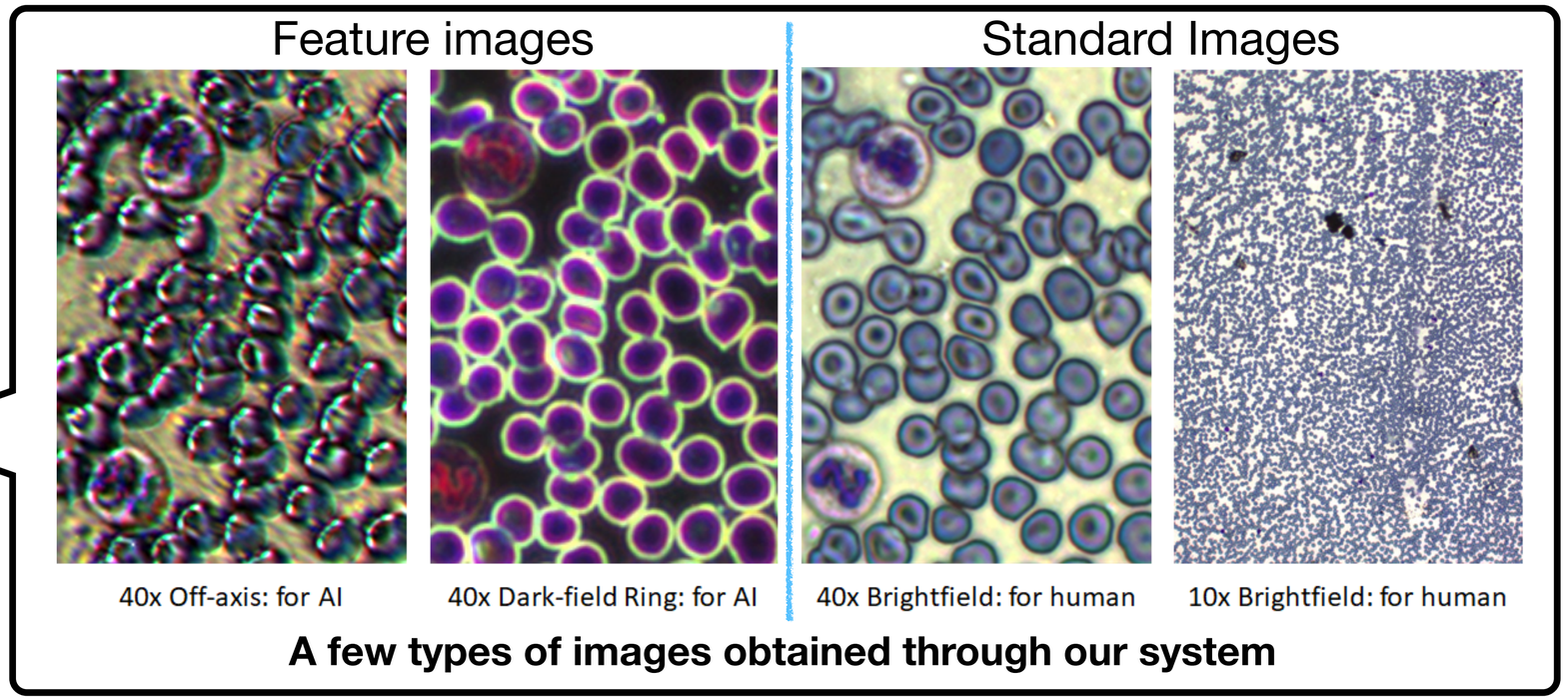


Simplified Optical Pipeline

Image Acquisition makes a big difference!

Best images for AI and humans





A few types of images obtained through our system

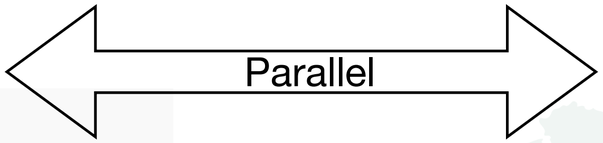
Portable, Affordable (< $2k), Multi-channel microscopy

Feature rich images = more information, less scanning

5x faster acquisition time than a traditional microscope

More and varied data = Better AI

Leverage India and US to reduce time to market by 3x



India

Easy access to large clinical data

Easy device placements in labs

Favorable regulatory and privacy rules

US

Working with Duke Hospital and Computational optics lab

Use field data from India to prove and accelerate technology

Product development and eventual market

Already established partnerships in India

Network of pathology labs from across India

Bhore Path Lab

Koyalkar Pathology

We will create one of the largest datasets of blood images in the world!

We can obtain 3000 blood smears everyday

Not just data - Indian Blood Work Market - $1.6B

Diagnostics as a Service - charge per test

Capital Equipment Cost ~~High~~ Low/Free

50 Average Tests per day per lab

x

$1 We charge per test (tentative)

=

$16,000 SafineAI revenue per lab

$16,000 SafineAI revenue per lab

x

100,000 Pathology labs in India - *35% Organized Labs*

=

$1.6B Total Addressable Market

US Blood Market - $4.6B

Different business models can be considered, separate from India

466M Total tests per year

x

$10 Medicare reimbursement

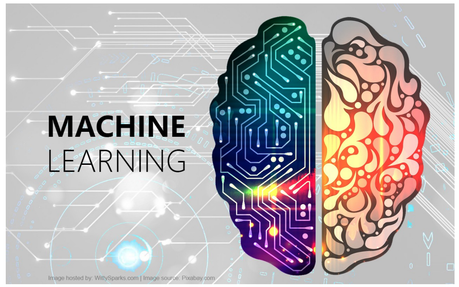
=

$4.6B Total Addressable Market

Why Now?

Integrated Systems

Switch to digital pathology is inevitable

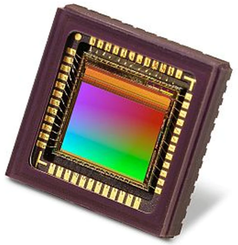


ML is here to stay

FDA has started recognizing the value of ML

Speed and Cost

Fastest ***internet*** speeds at scale and cloud prices halve every three years



Imaging sensors

More efficient and cheaper as mobile tech improves further

A lot more than blood..

We can do everything that a microscope is used for

Lateral Scalability

- Histology & cytology ($30B)
- Hemato Oncology ($5B)

We can ALSO..

Understand disease progressions

Potentially identify new imaging biomarkers

Competition

	AHA (Current)	SigTuple	Sight Dx	Athelas	SafineAI
Blood Abnormality Analysis	✗	Yes	Yes	✗	✓
Images of Abnormalities	✗	Yes	✗	✗	✓
CBC Analysis	Yes	✗	Yes	✗	✓
Custom Device	✗	✗	Yes	Yes	✓
Cloud Based ML Platform	✗	Yes	✗	Yes	✓
Point-of-care	✗	✗	Yes	Yes	Yes
Time	30m	Not Known	10m	10m	**10-15m**
Maintainance	Everyday	Minimal	Minimal	Minimal	**Minimal**

Expert Versatile Team

Hardware

Business

Pratik Bokadia
MEng BME, Duke University

CEO

Dr. Roarke Horstmeyer, PhD
Asst. Prof. BME, Duke University

Scientific Director

Amey Chaware
MS ECE, Duke University

CTO

Machine Learning

Optics

Dr. Pavan Chandra Konda, PhD
PhD Optics, Glasgow University

Hardware Lead

Mahsa Taskindoust
MD Candidate, Duke University

Medicine

Clinical Lead

Kanghyun Kim
PhD Student, Duke University

Imaging Lead

Advisors and Partners

Dr. Joeseph Knight
PhD, MBA
CEO, InnAVasc Medical
Strategy Advisor

Dr. Inga Deakin
PhD, Oxford University
Mentor-in-Residence, Duke BME
Business Advisor

Dr. Mark Harfouche
PhD, CalTech
CEO, Ramona Optics
Technical Advisor

Dr. Carolyn Glass
Co-Director, Computational Pathology, Duke Hospital
Clinical Advisor

Microsoft for Startups

$120000 in Azure Credits
Best Digital Innovation Award

Duke Institute for Health Innovation

Ask

💲**300,000 - for development and to get to next round of funding**

Beta of Imaging system placed in 7 partner pathology labs

User Software

Annotated Dataset of blood cells

WBC differential counting - Peripheral Blood Smear (PBS)

🔨**Strategic Connections**

Pathology Chains, Manufacturers and Regulatory Experts

Appendix

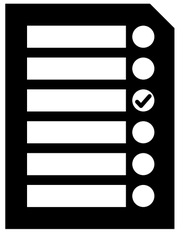
What's in it for a pathology lab/ hospital?

Cost Savings

Reduced Human dependency

More tests

More accurate results



Digital record and report

Regulatory Classification

US

Class 2 (Microscope + Software) with special controls

- Predicate: Athelas Microscope 510(k)
- Predicate: OLO (Sight Diagnostics)

Class 2 Microscope & Class 2 Software

India

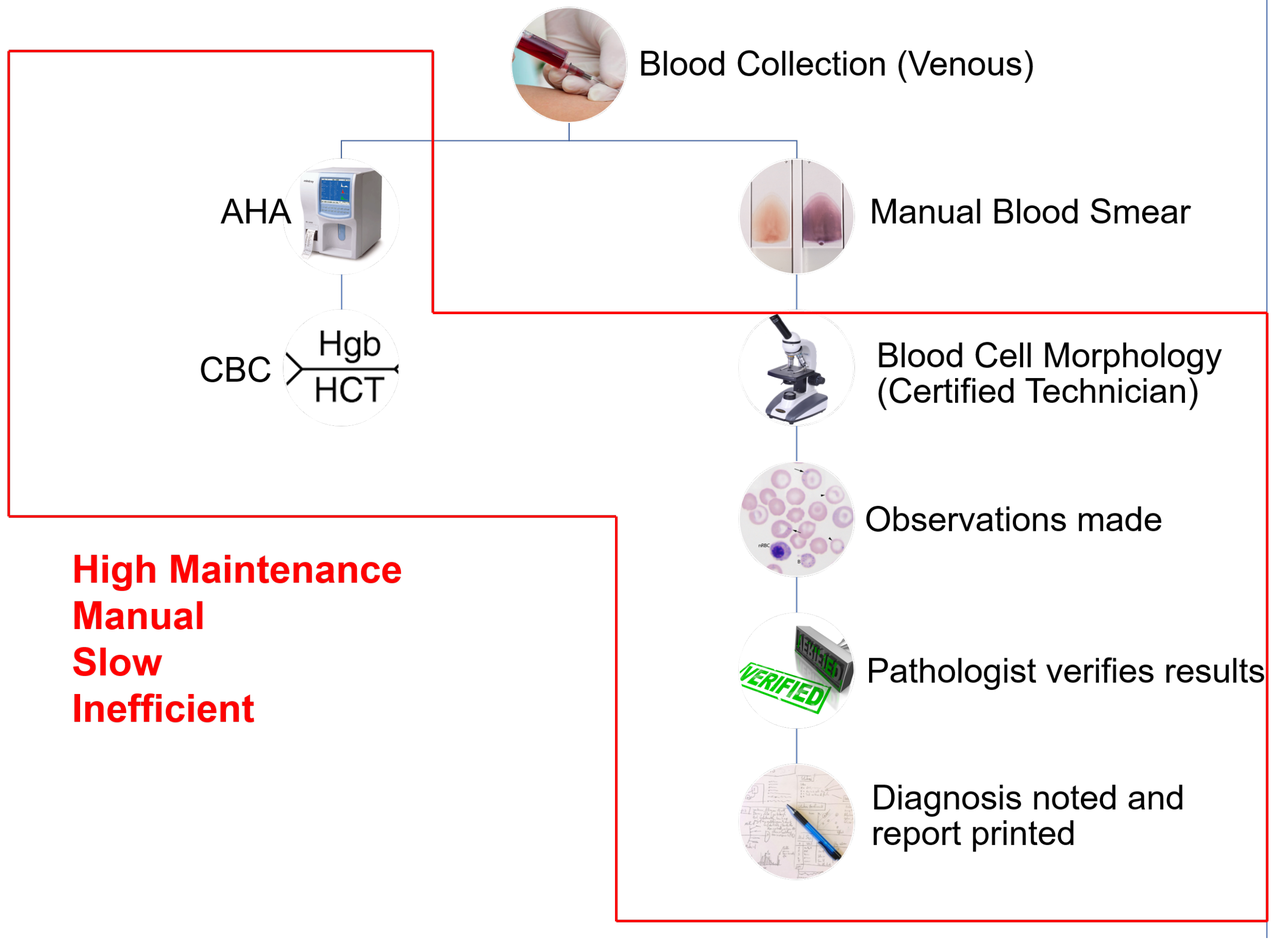
Class B device

Predicate: Whole Slide Imager (WSI)

FDA clearance is accepted in India

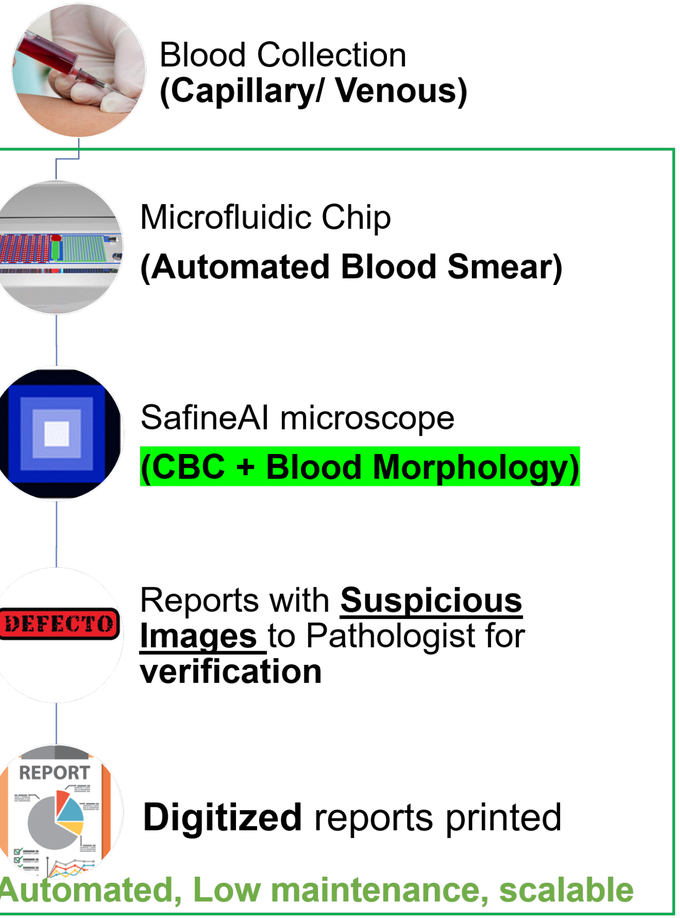
Streamline workflow

Current Workflow



High Maintenance
Manual
Slow
Inefficient

SafineAI Workflow



Next Steps

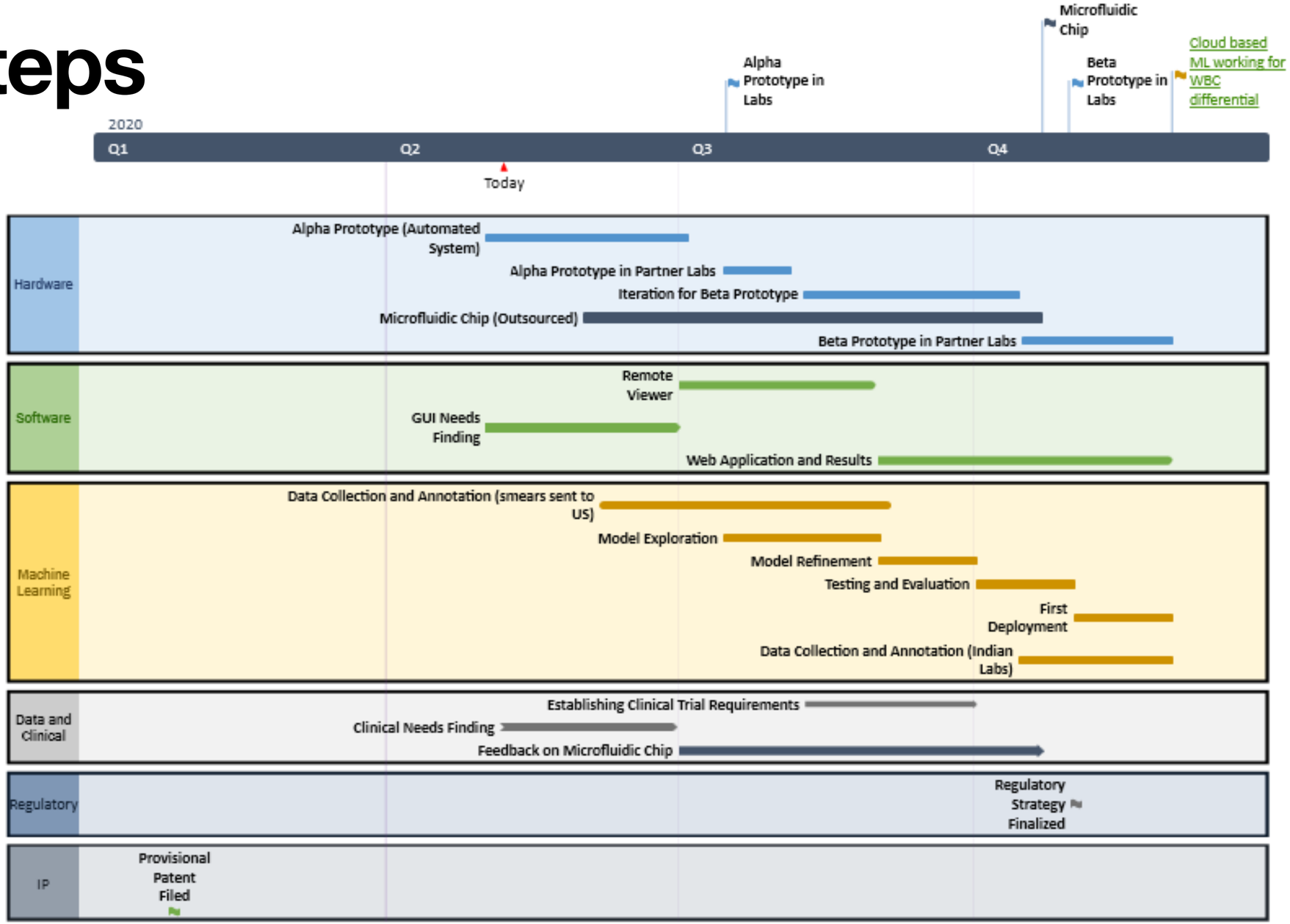

Microfluidic Chip
Cloud based ML working for WBC differential
Alpha Prototype in Labs
Beta Prototype in Labs
2020
Q1
Q2
Q3
Q4
Today
Hardware
Alpha Prototype (Automated System)
Alpha Prototype in Partner Labs
Iteration for Beta Prototype
Microfluidic Chip (Outsourced)
Beta Prototype in Partner Labs
Software
Remote Viewer
GUI Needs Finding
Web Application and Results
Machine Learning
Data Collection and Annotation (smears sent to US)
Model Exploration
Model Refinement
Testing and Evaluation
First Deployment
Data Collection and Annotation (Indian Labs)
Data and Clinical
Establishing Clinical Trial Requirements
Clinical Needs Finding
Feedback on Microfluidic Chip
Regulatory
Regulatory Strategy Finalized
IP
Provisional Patent Filed

Image cropping figure: show large FOV, and then cropped region, and show the ability to narrow in