

Using Al to Scalably Screen for Retinal Diseases, Stroke, and Heart Disease

Early diagnosis and intervention can **prevent blindness**, **save** countless **lives** & **eliminate** massive amounts of **downstream spending**.



Problems

Vision Impairment and Blindness

iHS targets the leading causes of blindness: Age related Macular Degeneration (AMD), Diabetic Retinopathy (DR), Hypertensive Retinopathy (HR) & Glaucoma.

Early detection is essential, but...

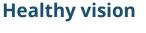
These diseases typically have no symptoms – it's often too late to reverse them by the time patients visit Ophthalmologist. Early detection & preventive care are essential: there's no treatment after progression.

... over 50% of at-risk population NOT screened

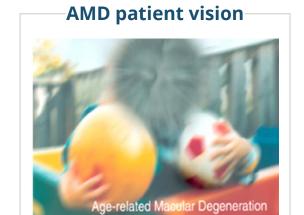
Conventional (manual) screening depends on PCP referral to specialists; many patients don't comply at all and everyone faces delay due to ophthalmologist access issues. The majority of the at-risk population is not being served until it is too late.

Heart Disease and Stroke: Inadequate screening

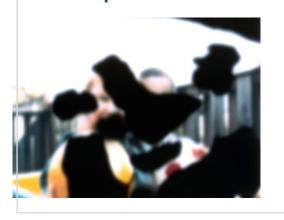
Two of the Top 5 causes of death are not well screened for today. Over 40% of at-risk population is NOT currently being screened.







DR patient vision





Glaucoma patient vision

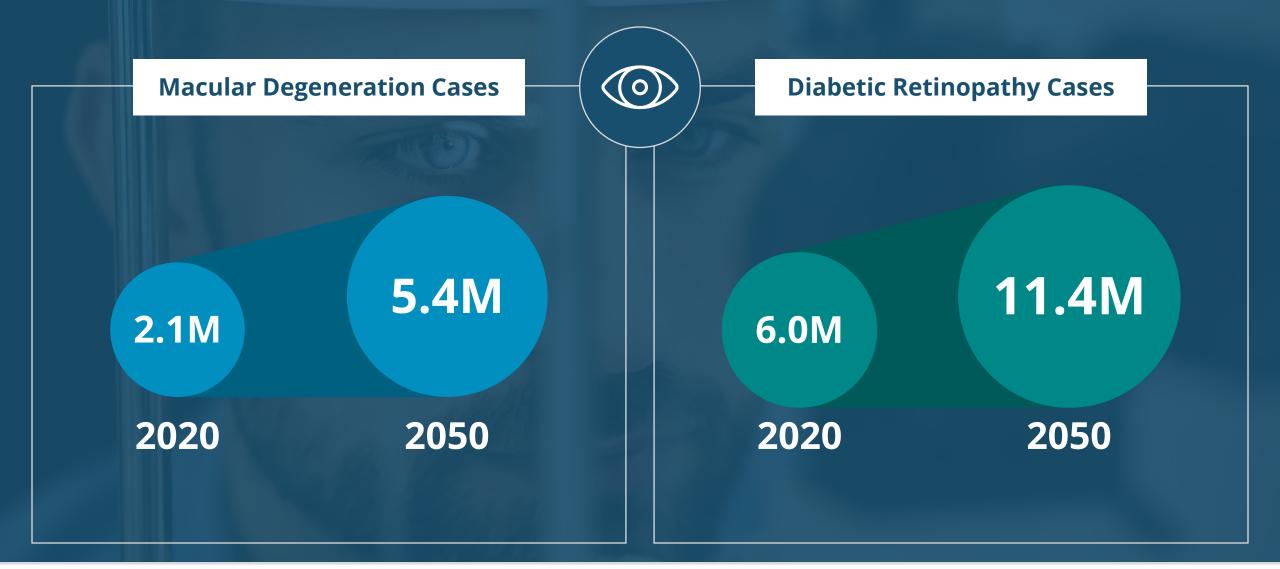




Stroke



Eye Conditions are Expected to Grow





Opportunity:

Develop and deploy retinal-imaging-based diagnostic platform for use in primary care

"The Eyes are the Window to... Your Health"









Highly Accessible

iHS' approach makes screening for multiple diseases accessible in primary care settings.

Low cost, small footprint, no specialty training required

Super efficient

Specialist appointment takes weeks or months; iHS removes the bottlenecks, meeting patients where they are.

iHS offers screening in same PCP visit; entire process <5 minutes

Reimbursable

A dedicated CPT code (92229) in USA; can be used by PCP practices. **Thiqa and Daman** (Abu Dhabi Approved)

Automated Al-analyzed screening is now financially viable

Large, Growing Need

80M people will be diabetic and 108M will be over 50 by 2030 in US alone. 6M in UAE; >10M in Australia

188M+ candidates (in USA) screening for DR and AMD alone

<u>Current Approach</u>: PCP visit → Specialist referral → Specialist screening → Vision-saving preventive care 35% of all patients do NOT go to specialist appointment; 50% in underserved markets



The Product iPredict



Captures images & medical parameters

(min. training req. – less than an hour) (Both eyes captured – less than 2 min.)

Initial Focus: AMD & DR Screening



Uploads data via telemedicine application

(less than 1 or 2 min.)

Click to see how it works: <u>iPredict3 3 - YouTube</u>



Fully automated AI program

- screens DR, AMD and Glaucoma
- <u>predicts</u> AMD, CHD, stroke, and other diseases (less than 1 min.!)



Optimized clinical workflow

- produces actionable report
- <u>creates referral</u> to Ophthalmologist or cardiologist/neurologist if needed (less than 1 min)



Benefits

Accurate

>95%

Accurate in screening DR and AMD – comparable to or better than an expert

Fast

<5min

For the entire procedure (imaging, analysis, & report)

Convenient

Specialists not needed

Automatic image evaluation (system refers to ophthalmologist if warranted) Effective

Early Detection

Technology ready for largescale screening (enables a shift to primary care) Economical



Adds easy revenue for Clinics (and decreases downstream healthcare cost)



Manual Analysis

Need specialist visit; takes days for the report; many patients drop out



iPredict

Screening same day as PCP visit Automatic report within 5 minutes



Over 98% of DR and AMD cases, and nearly **100%** of normal cases are correctly identified by iPredict.

Metric	DR	AMD
Sensitivity	0.976	0.989
Specificity	0.994	0.995
AUC	0.99	0.99



Performance details

Tools	iHealthscreen	95% Cl for Accuracy
AMD Screening	Overall accuracy 96.1% (AUC 0.99)	95.5% – 96.7%
AMD Prediction (2-year)	Overall accuracy 89.61%	86.8% to 92.0%
DR Screening	Overall accuracy 97.9% sensitivity - 99.21%, specificity - 97.59% (AUC 0.99)	97.6% to 98.2%
Glaucoma Screening	Overall accuracy 94.14% (AUC 0.95)	92.0% to 95.8%
Cardiovascular Disease Prediction (5- year)	Overall accuracy 75.8% (AUC 0.78)	72.1% to 78.8%
Stroke Prediction (5-year)	Overall accuracy 82.4%	76.2% to 89.2%
Heart Attack Prediction	Overall accuracy 83.14%	76.4% to 90.3%

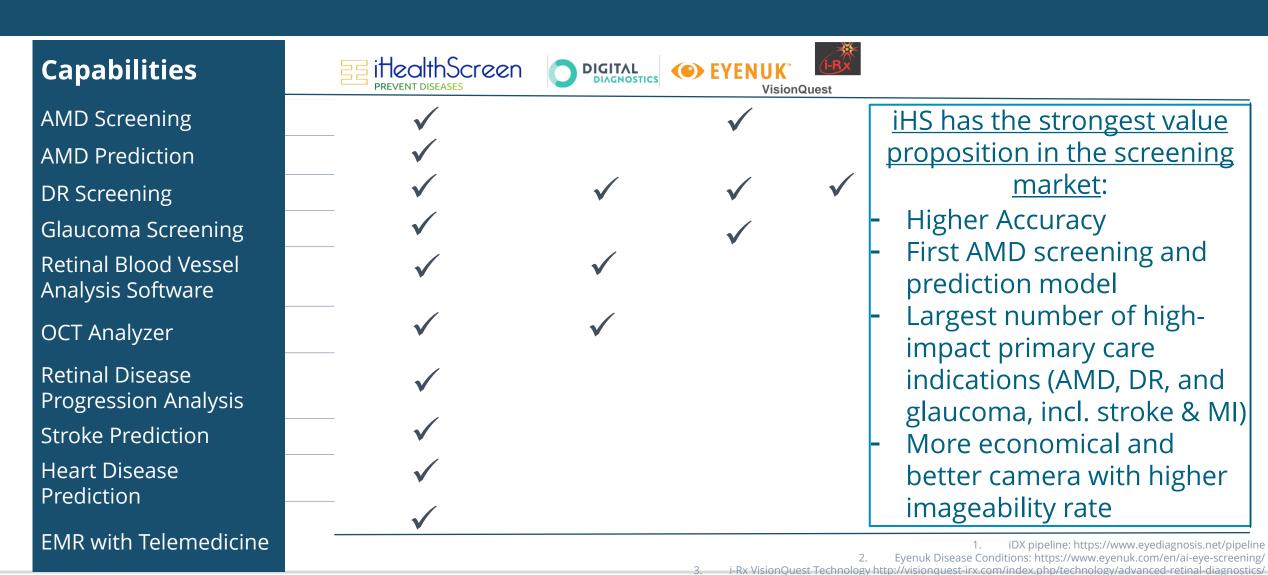


IP/Regulatory Status

itus	FDA Status Pre-meeting completed (DR)	
nt (submitted)		
Awarded	Pre-meeting - completed	
Awarded	Pre-meeting	
submitted)	Pre-meeting	
17/41712)	N/A	
ight	HIPAA Compliant	
/ri	yright	



Competition





iHealthScreen's Accomplishments

Developed and Validated

- HIPAA compliant telemedicine tool **iPredict**™ (AMD prediction trial approved by Mount Sinai IRB and started in four clinics)
- DR, AMD and glaucoma screening tool
 (Simultaneous screening for up to 3 eye diseases; trial ongoing)
- State-of-the-art **Stroke Prediction System** (It outperforms popular methods in preliminary studies)
- Cardiovascular disease Prediction System (Predicts multiple types of heart-related diseases; outperforms popular methods in preliminary studies)



First prediction model for Late AMD; featured work at ARVO 2018/Macular News; Featured at American Academy of Ophthalmology 2020





and TGA/Australian and Abu Dhabi Health approved

to market in EU and other countries, seeking partners; have signed licensing agreement with a large hospital and a camera company



HUB71 & START-UP New York Program (10 years tax-free)



Won NIH SBIR Phase I and II grants; ~\$2.7M; Customer segment determination/validation through rigorous NIH I-Corps process (national program)



One US Patent was Awarded, and 3 provisional patent applications submitted



Two FDA pre-submission meetings - the AMD 510K application submitted; DR 510K is in the final stage of submission



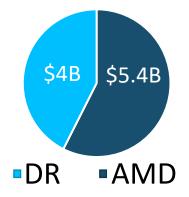
First in EU, Australia and the Golf region (DoH, Abu Dhabi; others to follow) - Thiqa and Daman (insurance) approved



US Market Size

iHS Revenue per Provider

\$9.4B



\$50K/yr. per practice

188M patients x \$50 (DR and AMD screening combined)

DR Screening (diabetics) – 80M AMD Screening (Age >50) – 108M

209,000 Primary Care Physicians

40% of the total revenue ($$50 \times 5 \times 50 \times 10$)

\$50 – per patient;

5 – days of the week

50 – weeks of the year

10 – estimated patients/day

US Market Size

iHS Revenue per Provider

\$7.35B

147M patients x \$50 (stroke and heart disease screening

(117M patients x \$50) Americans 50+ years

(30M patients x \$50) Americans aged 35-50 with obesity or hypertension or current smokers

209,000 Primary Care Physicians

\$50K/yr. per practice

40% of total revenue (\$50 x 5 x 50 x 10)

\$50 – per patient;

5 – days of the week

50 – weeks of the year

10 – estimated patients/day



Now Ready to Enter: Eye Disease <u>UAE Market:</u> Australian Market

\$300M



\$1.8B Middle East

(6M patients x \$50)

Combined for DR, AMD and Glaucoma screening Stroke and Heart Disease will make it **\$600M**

DR Screening (diabetics) – 2M AMD Screening (Age >50) – 2M or above Glaucoma Screening 2M or above

*Projected market size – GULF COUNTRIES: \$1.8B (3x UAE) – 5 diseases

\$960M

Australian Market; eye diseases only

\$1.9B

+ CHD and stroke

DR Screening (diabetics) – 1.2M AMD Screening (Age >50) – 8M or above Glaucoma Screening (Age 40+): 10M



Projected Revenue

Markets	Years				
	2023	2024	2025*	2026	2027
USA	\$1.8M	\$9.3M	\$29.15M	\$67.2M	\$110.6M
Australia	\$150K	\$1.5M	\$15M	\$30M	\$40M
EU	\$0K	\$50K	\$1.5M	\$10M	\$25M
UAE	\$500K	\$1.5M	\$5M	\$10M	\$20M
Total Revenue	\$2.5M	\$12.3	\$50.6M	\$117.2M	\$195.6M
Expense	\$6.9M	\$12.6M	\$29.9M	\$56.6M	\$86.3M
EBITA	-\$4.3M	-\$290K	\$20.7M	\$60.5M	\$109.3M

^{*}Glaucoma FDA clearance Australia/EU - \$15/screening USA/UAE: \$20/screening



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Comparable

Company	Pre-FDA 510k Raise	Post-FDA 510k Raise
iDX (Only DR Screening)	\$22.1M (4 angels' round)	\$33M (Series A) \$75M (Series B)
iHealthScreen (AMD and DR)	\$5M	\$50-\$80M
	Timeline 24 months	

Metric	iHealthScreen	iDX-DR
Sensitivity	97.6%	96.8%
Specificity	99.4%	87.0%
AUC	0.99	0.98



Potential Exit

Company	Pre-FDA 510k	Post-FDA 510k Valuation
Based on AMD and DR	Valuation \$25M	\$250M
	10x in 24 months	
	Timeline 24 months	



Management Team USA



Alauddin Bhuiyan, PhD President and CEO

15+ years experience and a leader In this area

Harvard Scholar

Prestigious Endeavor Australia Fellow

Have 2 US Patents, many applications and led commercially available software product



Thomas Gerson
Chief Financial Officer

the proven ability to identify and align an emerging growth companies and maximizing potential value creation and financial returns



20+ years of Lead Finance roles with multiple bioscience companies



15+ years experience and a leader In this area



Lori Lonczak, RPh, MBA

Commercial Lead

Sales and marketing executive with experience leading brands ranging from start-up to \$3B in annual revenue



Experienced in product branding In healthcare



Kate Adams, MBA
Chief Marketing Officer

Experienced Marketing executive in the life science industry

Former Director of Marketing Quest Diagnostic, US

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Former VP, Marketing at HistoRx



Experienced Marketing executive in the life science industry



Scientific Advisory Board

Legal and Regulatory Team





Prof. Theodore SmithOphthalmology, Mount Sinai,
30+ years Exp.





Prof. Tien WongOphthalmology, DUKE-NUS,
20+ years exp.





professional

Prof. Nasir MemonDirector, Cybersecurity, NYU, 30+ years exp.



Travis Millman, MAPP
Strategic Advisor
Serial entrepreneur, digital health and medical device

Former VP, Pearson Clinical Assessment. Consulted to Philips Healthcare and Samsung NEXT digital health portfolio.





Lina KontosFDA consultant
Hogan Lovells





Steve KennyPatent Attorney
Foley Hoag LLP





Beth RobertsReimbursement Consultant
Hogan Lovells





Gary SchallCompany Lawyer
Partner, WilmerHale

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Funding Strategy, Timing, and Next Steps



Pre/Series A (\$5M)
Use of funds

\$5M for Q1'23-Q4'23

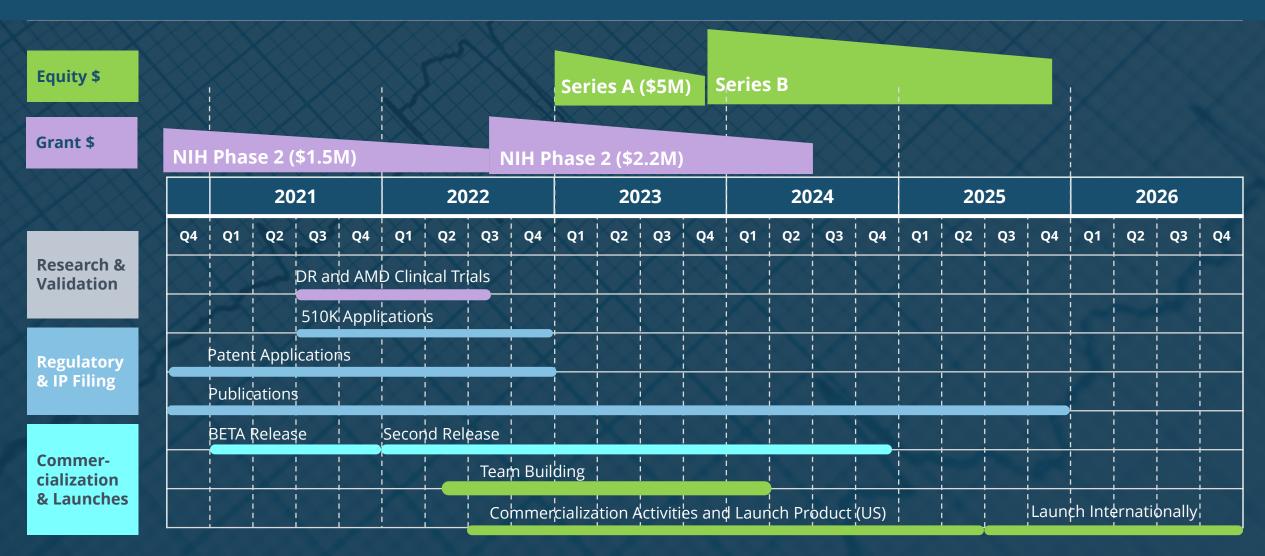
Will use the proceeds to:

- EU/UAE/Australia Market Entry Team Build
- Conclusion of clinical studies for FDA. USA, and
- Completion of FDA 510k clearance cycle for first product (DR and AMD screening)
- Fund marketing, sales, and support activities, and
- Continue R&D on additional indications (AMD, glaucoma & stroke prediction)
- Start the clinical trials for Stroke and Heart Attack Prediction
- Ready for Series A

With FDA clearance, product evaluation by multiple prospective customers, and reimbursement validated across multiple payors, risk will have been substantially mitigated.



Leveraged Equity and Grant Funding Plan





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Thank You!

We would love for you to join us in our quest to save vision, lives and healthcare costs

Alauddin Bhuiyan, Ph.D.

President and CEO iHealthScreen Inc., NY

bhuiyan@iHealthScreen.org (718) 926-9000

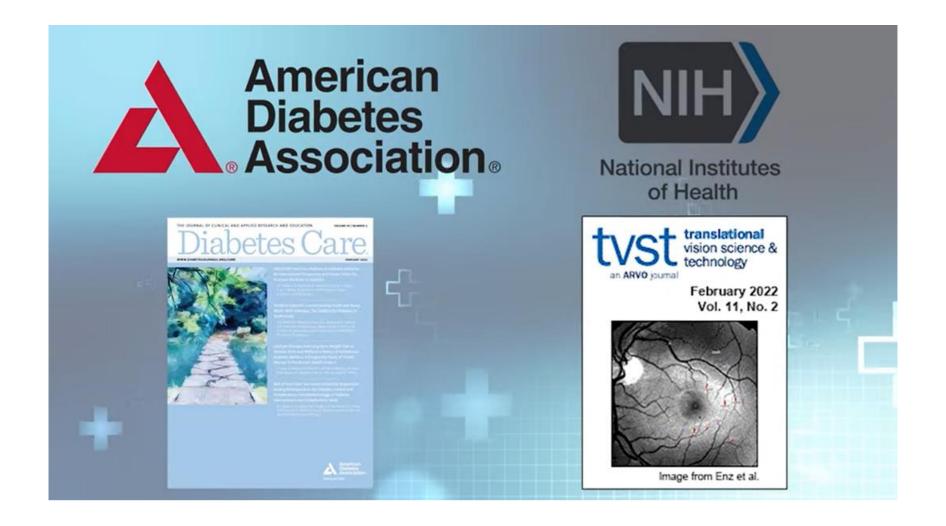
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Results are Published in the Top Scientific Journals





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Team USA R&D



Dr. Alauddin BhuiyanChief Scientist



Ms. Ciara Serpa Research Associate



Msr. Aysha Choudhury
Office Assistant



Mr. Arun GovindaiahSenior Research Engineer



Ms. Fariah Nuha Research Associate



Team UAE



Alauddin Bhuiyan, PhD

15+ years experience and a leader In this area

Harvard Scholar

Prestigious Endeavor Australia Fellow



Ms. Leyla Azizova
Advisor, Business
Development

Senior Director, Dawn Health.

Trusted advisor in shaping the agenda of governments and private sector players.



Mr. Jassim Al Rahma

Advisor, Business Development, and Investors Relations

General Manager, Emirates Angels.

18+ years leading the implementation, development, and design for business and development



Mr. Ahmed ElarabiSnr. Business Dev Exec.

8+ years of experience in healthcare



Ms. Noor Abushaiwsh
Business Dev Executive



Mr./Ms. XX (hiring)
Regional Sales Leader



Team Bangladesh: Developers



Ms. Ferdousi Akhter Manager



Md. Jakir Hossain Sr. Software Engineer



Noni Gopal Sutradhar Rinku Team Lead



Md. Mizanur Rahman Senior Software Engineer



Mahbubul Alam Full-stack Engineer



Md Sarwar HoshenSoftware Engineer



Abdullah Al Muhid Software Engineer



Md. Sabbir Sattar Mukit Junior Software Engineer



Tanvir Ahmed KhanEngineer / Tester



Md. Tamim Tanvir Ui/UX Designer



Ariful Hasan KawshiqBusiness Development Executive



Nasir Uddin Sarker Assistant manager



Aticul IslamDigital Marketing Specialist



iHealthScreen's Goals & Spending Alignment



Clinical Milestone – Initiate and Complete Clinical Trials for AMD and DR Screening

- Forecasted Expense through 2023 ~\$1M
 - Marketing in UAE/Australia/EU
 - Complete Prospective Trial; FDA 510k Submission
 - Secured needed regulatory consultants



G&A Milestone – Building Corporate Infrastructure

- Forecasted G&A Expense through 2023 ~\$0.5M
 - Complete necessary patent work to protect intellectual property
 - Build financial risk management and controls
 - Establish vendor relationships for cameras



Commercial Milestone – Prepare for Revenue Launch USA and globally

- Forecasted Selling Expense through 2023-24 ~\$4.5M
 - Create branding and marketing materials prior to launch
 - Hire Commercial leadership and initial sales team to be ready Day 1
- FDA approvals/clearance of AMD prediction and glaucoma screening



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Reimbursement Status

Product/Service	Reimbursement Code	Description
DR Screening	CPT 92229 (~\$50 both eyes)	Reimburse yearly screening for diabetic patient
AMD Screening	CPT 92229 (in case of pathology); New or same CPT code	Reimburse patient with AMD pathology; will obtain CPT code
Glaucoma screening	и и	
AMD Prediction	и и	
Stroke/heart disease Prediction	ıı ıı	
Telemedicine	99203 (new patient) and 99213 (old patient); (\$73 per patient)	Reimburse 15 minutes telemedicine-based consultation

Reimbursement codes are already available (amount varies with states) and being used for DR and AMD Screening along with telemedicine services, so we can generate revenue immediately after FDA approval.



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Go To Market Strategies

Drive Product Benefit Messaging to Target-Health Professionals, Large Primary Care Clinics and Concierge/Telemedicine Companies

- Target PCPs, Geriatricians, Endocrinologists, and Concierge Medicine/Telemedicine Companies
- Utilize "hunter"/"cultivator"/strategic access selling model
- Drive customized differentiating launch messages to sell clinical/administrative stakeholders
- Sell/present data at target conferences
- Advertise in medical journals and via digital media
- Develop and execute public relations plan

Ensure Market Awareness, Access and Reimbursement

- Ensure ophthalmologists are aware and supportive
- Assess the value of new clinical and health economic studies
- Notify and/or sell to top-IDNs including Kaiser, VA-DOD, 5 large national health plans, large private primary care groups/clinics

Assess New Clinical Stakeholders (e.g., optometrists)

Sales Force Will Ramp Up Over Time, Starting with 8 Reps in the NY/Metro Area

2023 (1st Quarter)

8 sales reps (hunter/cultivator combo role)
1 VP, Sales
1 Strategic Access Manager

2023

24 reps (8 hunters, 16 cultivators)

1 VP, Sales

3 District Managers

3 Strategic Access Mangers

2024

40 reps (13 hunters, 27 cultivators)

1 VP, Sales

5 District Managers

5 Strategic Access Managers



Partners and Alliances























Media Coverage















These partnerships will allow us to **collaborate** for clinical trials, to **expand** nationally and internationally, and also to **publish** at high-impact factor journals



Al based Screening in USA



Collaboration with Mount Sinai Hospital, NY, USA



Prof. Theodore Smith, Ophthalmologist & Chief Scientific advisor, demonstrate AI based Screening



Trial site at Hill Side Clinic, Queens, NY



Trial Site: Union Sq. Clinic, Mount Sinai, USA



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Eye Screening in Abu Dhabi Mall on World Sight Day (Social Awareness Program: October 13-14, 2022)

On Going
Eye Campaigi



Screened -A DR Patient (diagnosed)





Team picture: supporters - Abu Dhabi Mall and Emirates Angels, the optometrist, member iHealthScreen



DR Screening in Bangladesh



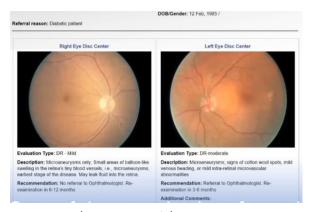
Contract Handover between BADAS & iHealthScreen for 5.5M registered Diabetic Patients eye screening countrywide.



Mobile Lab Services for countrywide BADAS Diabetic centres



DR Screening Booth in BiHS General Hospital, Mirpur, Dhaka

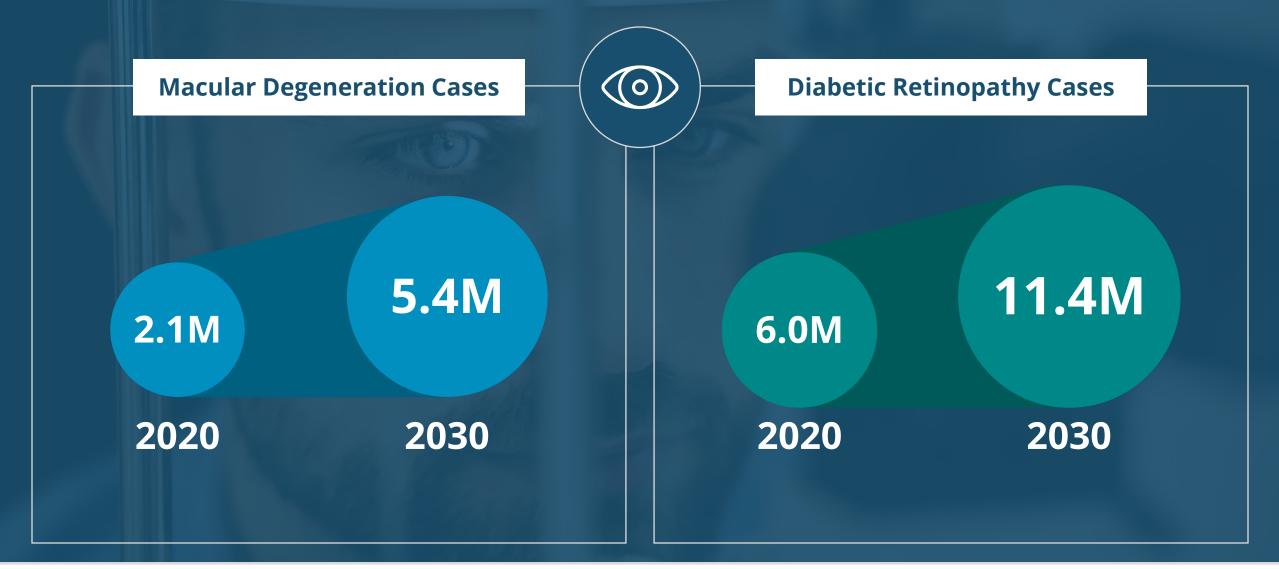


Research Survey with BADAS, Funded by Bangladesh Govt. (DG Health)



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Eye Conditions are Expected to Grow





High costs of treatment

Macular Degeneration



Diabetic Retinopathy

\$10B

Direct cost of treatment

>\$5B

Direct cost of treatment

