# GHIT Fund R&D Forum

# Automatic Malaria Diagnostic Device

Project Partner for the Project
Malaria No More Japan

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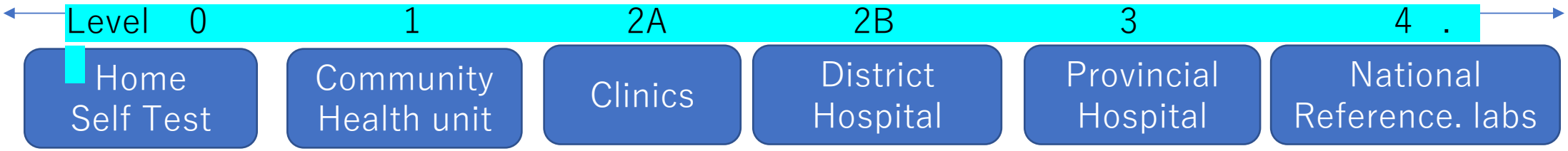
# Background for the project

- Global Standard for Malaria Diagnostics
  1. Microscopy with Giemsa staining by local lab technicians
  2. Rapid Diagnosis Test in all level of health facility




| | | | | | | |
|---|---|---|---|---|---|---|
| User | Lay person | Village Health Worker | Clinic staff | Hospital Staff Lab. technician | Hospital Staff Lab. technician | Lab. technician |
| Device | **RDT** | **RDT** | **RDT** **Handy Devices** | **RDT** **Microscopy** | **RDT** **Microscopy** ELISA Molecular test | **RDT** **Microscopy** ELISA Molecular test |
| Purpose | Self-Assessment +/- | Diagnosis Treatment | Diagnosis Treatment | Diagnosis Treatment Monitoring | Diagnosis Treatment Monitoring | Diagnosis Treatment Monitoring |

# Background for the project

GHIT Fund


- **Unmet Needs** in Malaria Diagnostics at first contacts (Community, Clinic, and hospital for out-patient)

1. User Friendly test method and quick results

Challenges for Giemsa method:

1) A considerable preparation time and well trained skilled technicians
2) They often not available in remote health facilities for Giemsa method.
3) And in the peak season, human error or mis-observation may happen with various conditions. More than 100 samples/day

The disadvantage of RDTs :

1) the results is only + or – as qualitative
2) Produce frequent false negative because of its low sensitivity

malaria NO MORE japan

# Project Objective and Goals

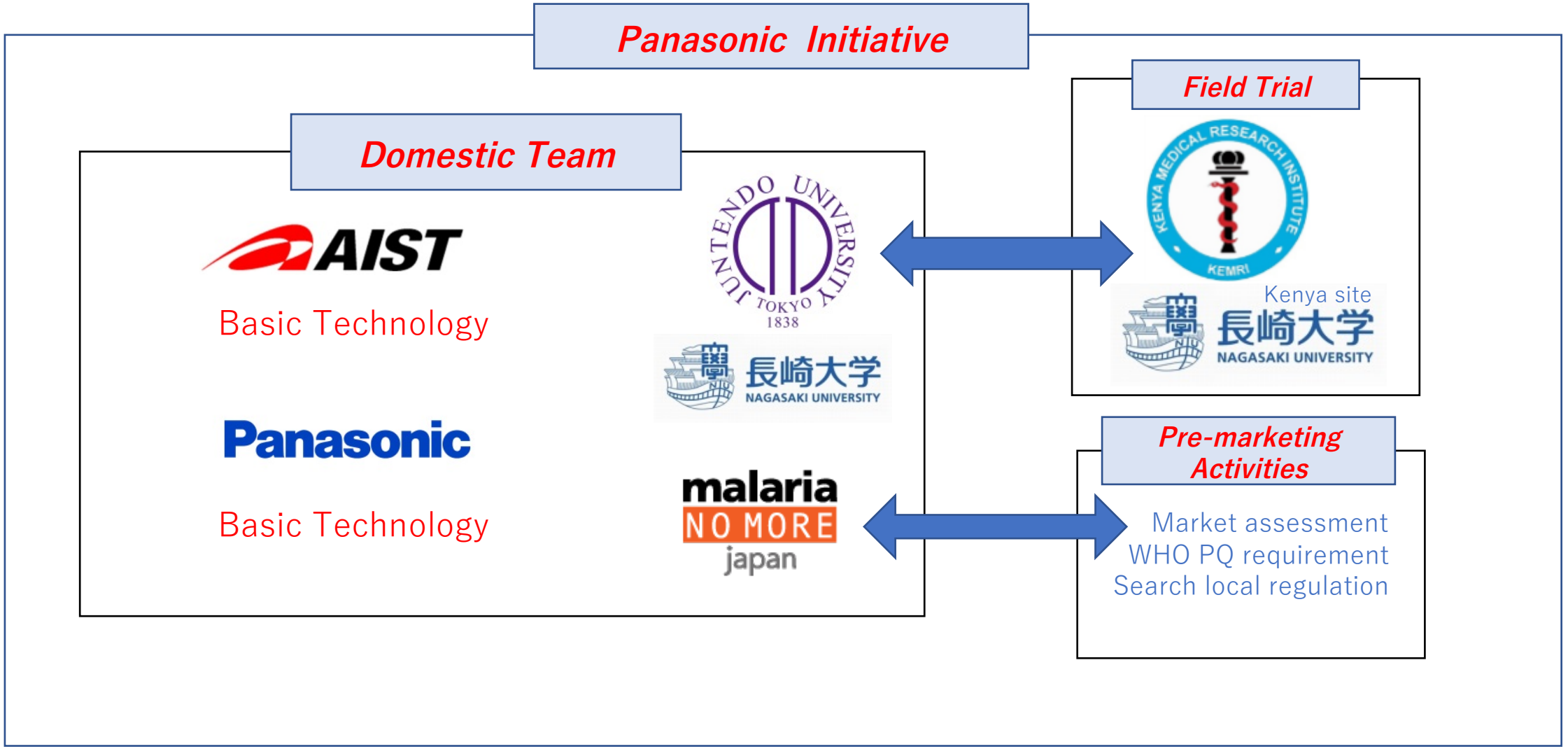
- **Sensitivity** : at least 0.0005% Parasitemia
  Approximately 20 times greater than the current gold standards, such as RDT and Microscopy with Giemsa staining.
  Then, finally in the project we will be targeted to 100times to the current method.

- **User friendly method** : A health worker at local health unit can prepare multiple samples much easily and rapidly. => this means minimum requirements of workload by user such as Clinic staff and Lab technician. Hopefully, mostly automated to be processed in the equipment itself.

- **Quick results** : Hopefully, the test results will appear on monitor in less than 10 minutes as the target.

- **Handy and transportable at local use** : The device will be portable and battery operated.

# Partnership in our project

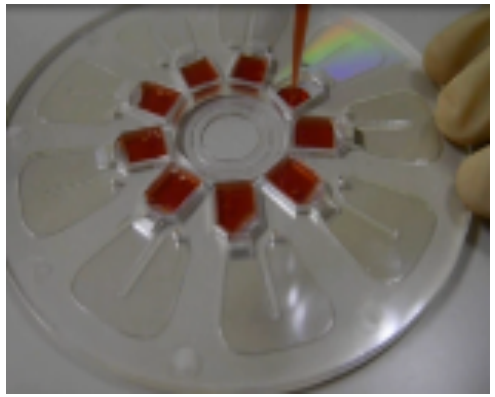


# What we have achieved

- What a local technician should act : **Only three steps**

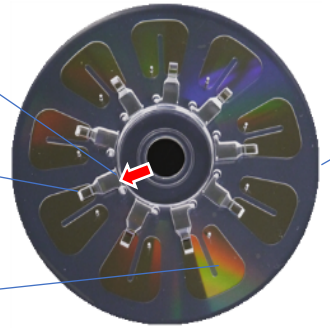
*1. Diluted with PBS*

*2. Injection and Setting.*



*3. Filtrating, staining and Scanning on the disc*

**All in one automatic**




Panasonic

# Lessons learned from the project

- Product Development

1) Difference condition between Local blood sample and Japanese test

- Premarketing

1) Difference between Endemic/Control Stage and Elimination stage in workload of labo technician

2) Adding some functions, such as mobile battery operation and shock absorbing carry case for its transportation might be essentially required for remote and emergency use.

# Comments

- Comments 1:

  We are strongly believe the real opportunity in contribution by this new device in both control stage and elimination stage

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- Comment 2 :

  Most recent WHO MPAC conclusion for low-density infection. It was announced in October 2017.

# 1. Diagnostic workload in lab in clinic/hospital

## Endemic stage

- Malaria diagnostics is **MAIN work** in lab-technicians
- Malaria microscope work is main workforce and cost for hospitals/clinic.
- 100+ microscopy/day (district hospital and clinic)
- Positivity ≧ 60%

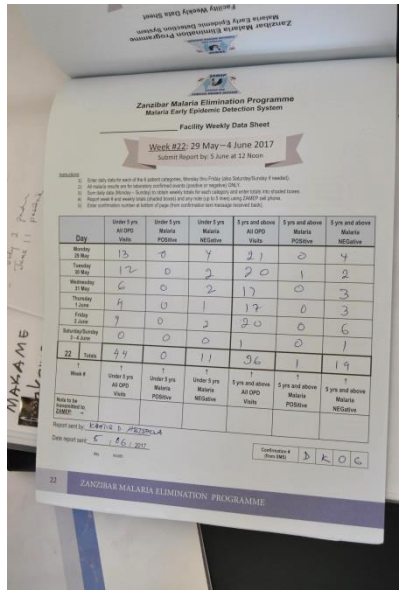
## Elimination stage

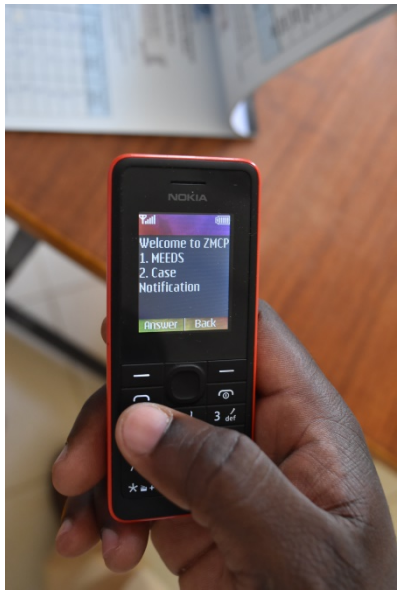
- Malaria diagnostics is **NOT main work** in lab-technicians
  15-25+ microscopy/day
- RDT is also used as part of major malaria diagnostics method (periodical free check at insymptomatic patient as a surveillance and its monitoring)
- Positivity < 10%

# 2. Opportunity of connecting to IT in program office as a breakthrough

## Elimination stage

- For prompt detection of positive case, case management information system “MEEDS” is in operation, based on weekly based reporting.
  → **Real-time based information sharing** by “connecting to information technology” in the center of program office would enhance more quick reaction of case management including vector control.




Positive case
… daily

Endemicity
…weekly


- Weekly basis
- Total test, positive case (5+, <5)

# Comments-2

- Basic question comes from WHO MPAC

WHO MPAC Comments： October 2017

：A number of high sensitive technique are available that detect low-density infections (below 100 parasites/μl). There are currently insufficient evidence to access whether detection of low-density infections using these tools will have a significant impact on transmission.
Until such evidence is generated, these tools should be further evaluated through research activities and are not recommended for development in routine malaria control or elimination.