

# Proposed WHO Technical Consultation on external competence assessment for malaria microscopy



Malaria Policy Advisory Committee Meeting

17-19 October 2018, Executive Board meeting room

World Health Organization, Geneva, Switzerland

Global **Malaria** Programme



**World Health  
Organization**

- The detection of malaria parasites by light microscopy remains one of the reference methods for diagnosis of malaria used worldwide. It accounts for about half of all laboratory tests performed to confirm malaria infection in clinical settings.

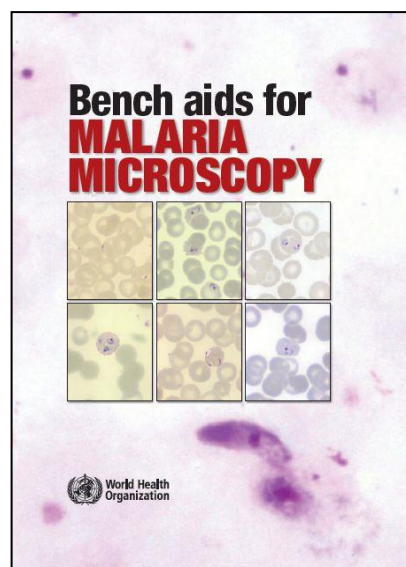
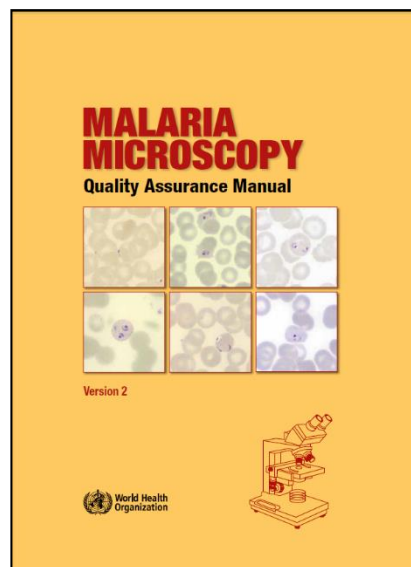
WHO recommends quality-assured rapid diagnostic tests (RDTs) and microscopy as the primary diagnostic tools for the confirmation and management of suspected clinical malaria in all epidemiological situations, including areas of low transmission.

These tools are recommended because of their high diagnostic performance in detecting clinical malaria, wide availability and relatively low cost. Also, RDT and microscopy are considered appropriate for routine malaria surveillance (of clinical cases) in most settings.

	Malaria microscopy slides examined	Malaria RDT examined
2016	208,206,325	184,256,672
2017	194,188,741	188,346,273

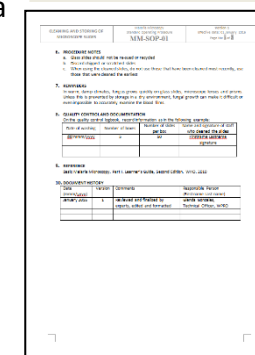
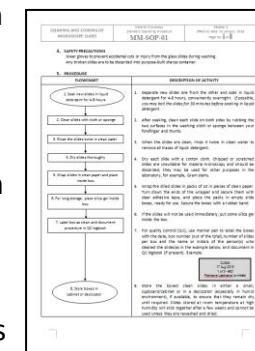
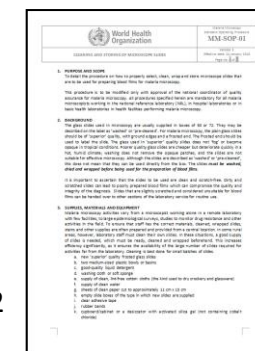
*Source: Data from national malaria programs reported to WHO for World Malaria Report*

# WHO resources and guidance on malaria microscopy

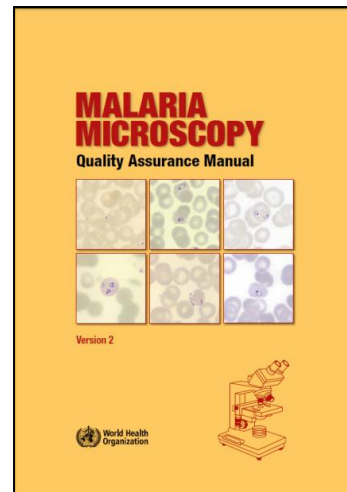
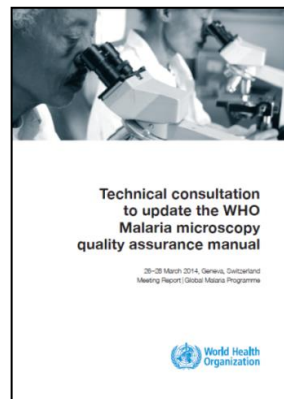
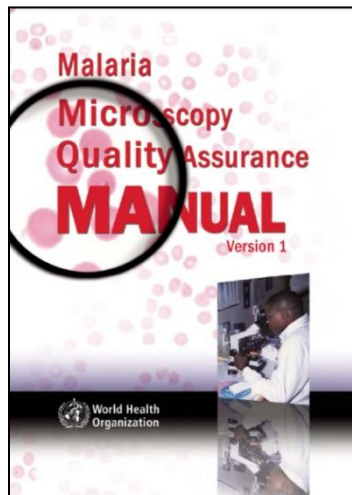


## WHO SOPs for malaria microscopy for basic laboratory services :

- 1 - Cleaning and storing of slides
- 2 - Preparation of Giemsa stock solution
- 3a,b - Preparation of buffered water to pH 7.2
- 3c - QC of Giemsa and buffered water
- 4 - Preparation of Giemsa working solution
- 5a - Collection of finger-prick blood and preparation of blood film
- 5b - Collection of blood by venipuncture preparation of blood films from venous blood collected in tubes with anticoagulant
- 6a - Labelling of malaria blood films
- 6b - Recording and reporting of results
- 7a - Giemsa staining of malaria blood films
- 7b - Ebola virus inactivation during Giemsa staining
- 8 - Examination of blood film
- 9 - Parasite counting
- 10 - Preparation of dry blood spots
- 11 - General safety procedures
- 12 - Use and care of microscopes
- 13 - Management of wastes from malaria diagnostic tests



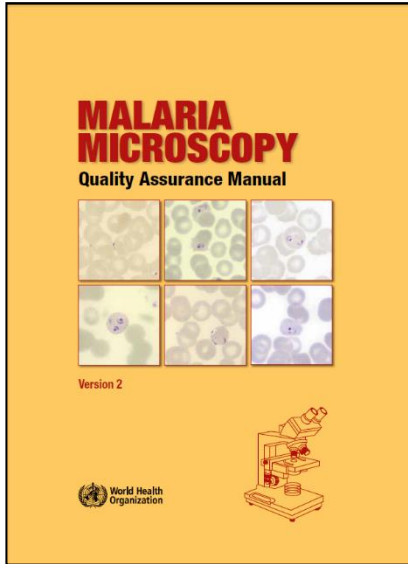
- In 2014 WHO convened a technical consultation to update the WHO Malaria microscopy quality assurance manual (report available at: <http://www.who.int/malaria/publications/atoz/microscopy-qa-report-sep2014.pdf>).



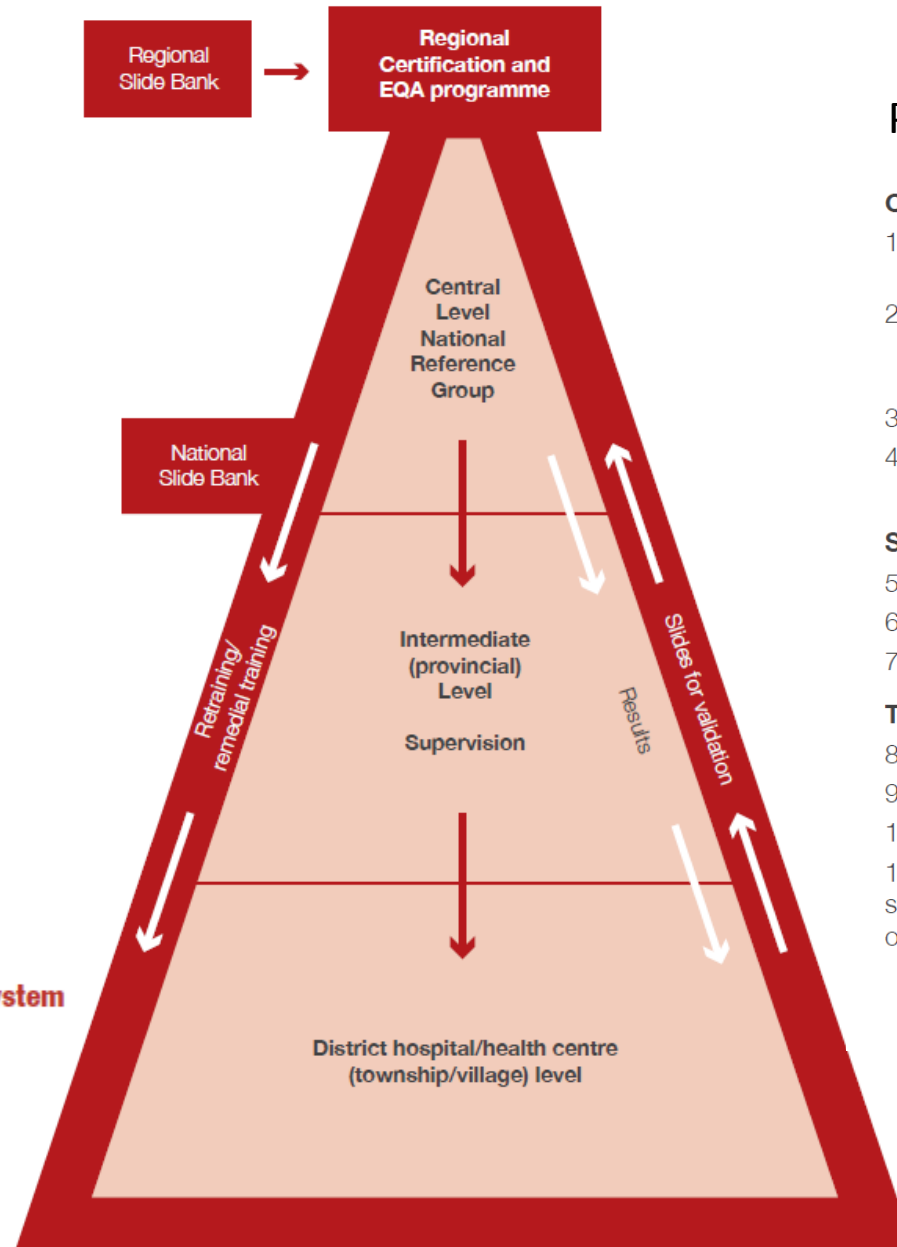
## NEW TOPICS

- Need for QA of malaria microscopy
- Structure and function of a QA system
- Plan of action
- Supplies and equipment
- Self-monitoring of laboratory procedures (ICQ)
- External competence assessment
- National competence assessment programme
- Training of microscopists
- Outreach training and supportive supervision
- Cross-checking malaria slide results
- Proficiency testing scheme
- Reference malaria slide banks

# Quality assurance of malaria microscopy



Structure and function of the quality assurance system



## Phased implementation of the QA system

### Core activities

1. Make a baseline situation analysis of the resources available in the country and gaps in commodities and infrastructure.
2. Identify the QA coordinator and a national core group of microscopists undergoing external competence assessment (ECA) and certified as WHO level 1 or 2.
3. Establish a national steering committee.
4. Ensure policies, guidelines, SOPs and associated commodities and infrastructure.

### Second step

5. Competence assessment
6. Training
7. Supervision

### Third step

8. Cross-checking
9. Proficiency testing
10. On-site evaluation
11. Accreditation of the diagnostic centre to international standards such as ISO 9001:2008, ISO 15189:2012 or ISO 17025:2005



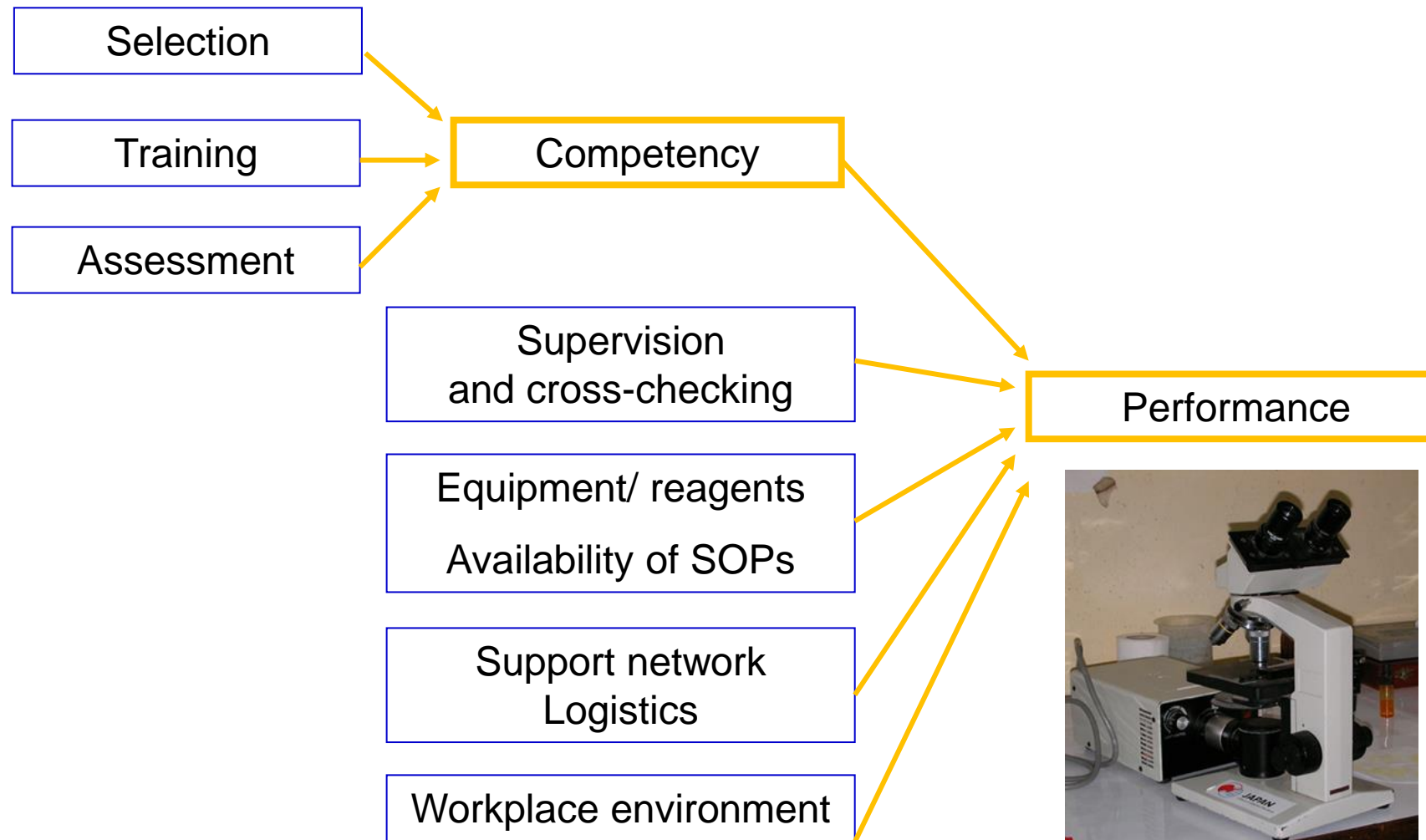
Core activities

Second step

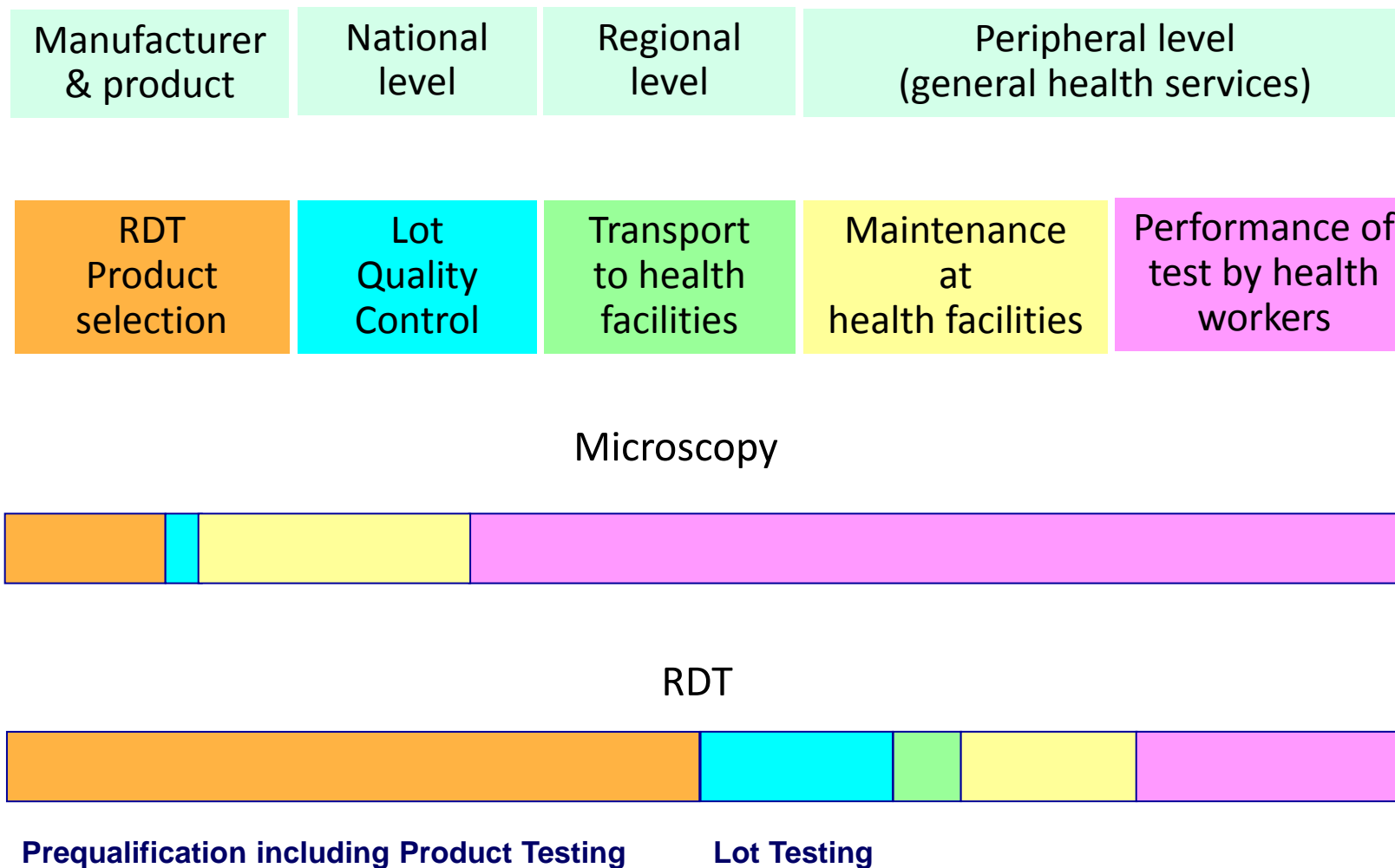
Third step

Mature QMS

# Determinants of microscopy performance



# Relative importance of quality determinants







- WHO has developed and implemented an external competence assessment scheme for malaria microscopy (ECAMM) since 2009. The scheme was started by the WHO SEARO and the WPRO in collaboration with ACTMalaria and the WHO Collaborating Centre for Malaria in Australia. It was later expanded by the WHO WPRO in collaboration with Amref Health Africa and, more recently, the University of Cheikh Anta Diop de Dakar (UCAD). Over the past 2 years, ECAMM was implemented by WHO EMRO. In these four regions, as of September 2018, a total of **182 workshops have been completed, each evaluating ~12 participants, corresponding to around 2000 microscopists.**
- Since 2015, WHO completed 3 workshops to **train 42 ECAMM facilitators** in these regions, to expand the number of experts able to run ECAMM workshops at international and national levels. As a result of this training and mentoring programme, there are **six ECAMM facilitators** who can independently conduct the assessment following the WHO SOPs for this activity, and **additional eight who have run several workshops as co-facilitators and may become ECAMM facilitators in 2019.**



# Number of ECAMM workshops - as of Sept 2018



WHO Region/Countries	Workshops
<b>AFR</b> (Algeria, <b>Angola</b> , Benin, <b>Botswana</b> , Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Congo, Côte d'Ivoire, Democratic Republic of Congo, Equatorial Guinea, <b>Eritrea</b> , <b>Ethiopia</b> , Gabon, Ghana, Guinea, <b>Kenya</b> , Liberia, <b>Madagascar</b> , Malawi, Mali, Mauritania, <b>Mozambique</b> , Namibia, Niger, <b>Nigeria</b> , <b>Rwanda</b> , Sao Tomé & Príncipe, <b>Senegal</b> , South Africa, S. Sudan, <b>Swaziland</b> , Tanzania, Togo, <b>Uganda</b> , Zambia, <b>Zimbabwe</b> )	52
<b>EMRO</b> (Iran, Oman, Pakistan, Somalia, Sudan, Yemen)	7
<b>SEAR</b> (Bangladesh, Bhutan, East Timor, Indonesia, India, Myanmar, Nepal, Sri Lanka, Thailand)	33
<b>WPR</b> (Australia, China, Cambodia, Malaysia, Laos, Papua New Guinea, Philippines, Solomon Islands, Vanuatu, Vietnam)	90
<b>TOTAL</b>	<b>182</b>

ECAMM workshop with full class (~ 12 participants) from same country

- Bi-Regional Workshop for Malaria Microscopy QA, **Kuala Lumpur, April 2005** recommended that courses commence at a national level for senior 'National Core Group' (NCG) microscopists in cooperation with national Ministries of Health. Agreed on establishing a network and that ACTMalaria should coordinate this work – now coordinated by WHO.
- Many expert consultation were held to decide on the course structure, slide set composition, and competency cut-off levels:
  - **Geneva, March 2006** – Assessment methods and grading schemes were endorsed as the WHO model and were utilised in competency assessment courses until October 2008
  - **Geneva, February 2008** - Continued to endorse the current model and also defined changes to the assessment model which were implemented in 2009
- Continuous improvement, especially during Facilitator Training Courses 2015 and 2017: workshop structure and procedures defined in WHO SOPs for ECAMM facilitators

- Duration - five days (from 08:00 to 17:00)
- NOT training – Competency Assessment, with focused Review/Revision
- Pre-ECAMM theory test - 25 general malaria microscopy questions. Does not count towards the competency levels
- Pre-ECAMM practical test – 18 slides, species detection, identification and counts. Does not count towards the competency levels
- Morning presentations (primarily a review) of all aspects of malaria microscopic diagnosis, from specimen collection to diagnostic reporting. No 'wet' practical sessions
- 56 test slides examined over three days
- All slides are provided by the WHO Slide Bank (WHOCC at RITM, Manila, Philippines)

# ECAMM slide set composition



Post Assessment = 56 Slides				
Slide Set	Slide Set	Day 1	Day 2	Day 3
<b>Negatives = 20 Slides</b>	Negatives = 20 slides	7 slides	7 slides	6 slides
<b>Positives = 22 slides</b>	Positive i.e <i>P. falciparum</i> = 10 slides	3 slides	3 slides	4 slides
	Positive i.e Mixed infection = 4 slides	2 slides	1 slides	1 slides
	Positive Species specific ( <i>Pm</i> , <i>Po</i> , <i>Pv</i> ) = 8 slides	2 slides	3 slides	3 slides
<b>Count = 14 slides</b>	Count (200 – 500) = 6 slides	2 slides	3 slides	1 slides
	Count (501 – 2,000) = 6 slides	2 slides	2 slides	2 slides
	40,000 - 100,000 = 2 slides	1 slide	0 slide	1 slide

(These totals may vary from course to course)

Pre-Assessment = 18 Slides		
Slide Set	Slide Set	Monday
<b>Negatives = 5 Slides</b>	Negatives = 5 slides	5 slides
<b>Positives = 8 slides</b>	Positive i.e <i>P. falciparum</i> = 3 slides	3 slides
	Positive i.e Mixed infection = 1 slide	1 slide
	Positive Species specific ( <i>Po</i> , <i>Pv</i> ) = 4 slides	4 slides
<b>Count = 5 slides</b>	Count (200 – 500) = 2 slides	2 slides
	Count (501 – 2,000) = 2 slides	2 slides
	40,000 - 100,000 = 1 slide	1 slide

- The primary aim is to have an objective, formal assessment of the competence of malaria microscopists.

## WHO competence levels and criteria

Competence Level	Parasite detection (%)	Species identification (%)	Parasite count within 25% of true count (%)
<b>1</b>	90-100	90-100	50-100
<b>2</b>	80-89	80-89	40-49
<b>3</b>	70-79	70-79	30-39
<b>4</b>	0-69	0-69	0-29

# External and national competence assessment



## External competency assessment for malaria microscopists (ECAMM)

- Primarily targets national core group of microscopists (including National Reference Laboratory) or microscopists playing key QA roles in the NMP or other national institutions involved in QA of malaria microscopy
- Conducted by an external facilitator designated by WHO
- **Only those who achieved Level 1 or Level 2 are certified on that Level (Level 3 and 4 achieved certificate of participation)**
- **Validity of certificates is 3 years**
- Should be combined with some form of re-training



## National competency assessment for malaria microscopists (NCAMM)

- Targets fully trained and experienced microscopists at subnational level
- Conducted by WHO certified Level 1 from the NCG/NRL, designated by NMP
- Certification is Grade A, B, C, D (to distinguish from ECA)
- Validity of certification is 3 years
- Should be combined with some form of re-training



# Recommended roles based on competence assessment



Level achieved	Recommended roles
1	<ul style="list-style-type: none"><li>• May conduct <b>training of microscopists</b> at international, national and subnational levels (<i>this need additional training such as instructional skills development and advanced courses on malaria diagnosis</i>)</li><li>• May conduct <b>assessment of microscopists at international level</b>, after being selected and deemed suitable, including completing the WHO ECAMM facilitator training course</li><li>• May conduct <b>assessment of microscopists at national and subnational levels</b> (<i>this need additional training on how to conduct competency assessments, instructional skills development, and advanced courses on malaria diagnosis</i>)</li><li>• May <b>conduct blinded cross-checking or validation of slides</b> at national/subnational levels</li><li>• May <b>conduct supervisory visits</b> (<i>this may need additional training on supervision and management</i>)</li><li>• May serve as <b>reference microscopist for therapeutic efficacy studies</b> of antimalarials (<i>this may need more advanced training on malaria diagnosis</i>)</li></ul>



# Recommended roles based on competence assessment



Level achieved	Recommended roles
2	May conduct <b>training of microscopists at national/subnational levels</b> ( <i>this need additional training such as instructional skills development and advanced courses on malaria diagnosis</i> )
3	May <b>provide assistance</b> to WHO-certified Level 1 or 2 during training of microscopists at national/subnational level
4	Should not be involved in training, assessment and cross-checking of slides. Consider the need for refresher training on malaria microscopy.

*Reference: WHO External Competency Assessment for Malaria Microscopists: Program Manual 2017*

# Objectives of the Technical Consultation

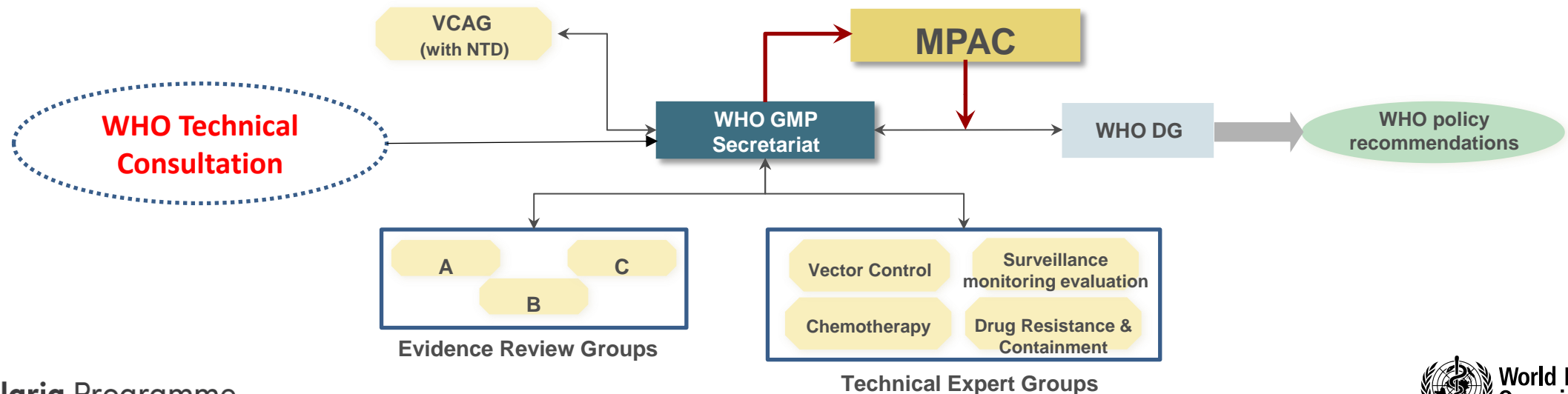


1. To review the results of ECAMM workshops conducted since 2009 by multiple institutions, and to **evaluate the need for updating the current WHO criteria for certification of competence** in relation to detection, species determination and parasite density calculation, including potential impact on certification levels if new criteria will be recommended for adoption.
2. To review experiences of **combination of ECAMM workshops with different forms of microscopy refresher training**, and provide guidance on the ideal mix of training plus assessment, as well as recommendations on revised curricula of the pre-ECAMM refresher training and the ECAMM workshops.
3. To review the **variants of malaria microscopy SOPs** for slide examination in relation to detection, species determination and parasite density calculation adopted by multiple agencies, taking into consideration the SOPs developed by WHO to foster harmonization around common SOPs.
4. To review **e-learning platforms recently developed for malaria microscopy** and their potential application for refresher training and self-assessment, in view of the potential wider dissemination and adoption of these learning tools.

# Process for the WHO Technical Consultation



- GMP/PDT has established a multiagency team to advise on ECAMM activities, including preparations for the technical consultation, including Dr J. Carter (Amref), Prof D. Ndiaye (UCAD) and Mr K. Lilley (Army Malaria Institute), and technical resource persons from the WHO AFRO, EMRO, SEARO and WPRO.
- The technical consultation will involve up to 35 participants, representing independent experts on malaria microscopy; lead facilitators of WHO ECAMM workshops and co-facilitators; experts in microscopy accreditation using different schemes (e.g. from the WHO Region of the Americas/Pan American Health Organization); and experts involved in microscopy training, accreditation, and development of SOPs.
- The technical consultation is planned for 26–28 January 2019, and its conclusions will be presented to the Malaria Policy Advisory Committee (MPAC) in March 2019 for finalization.

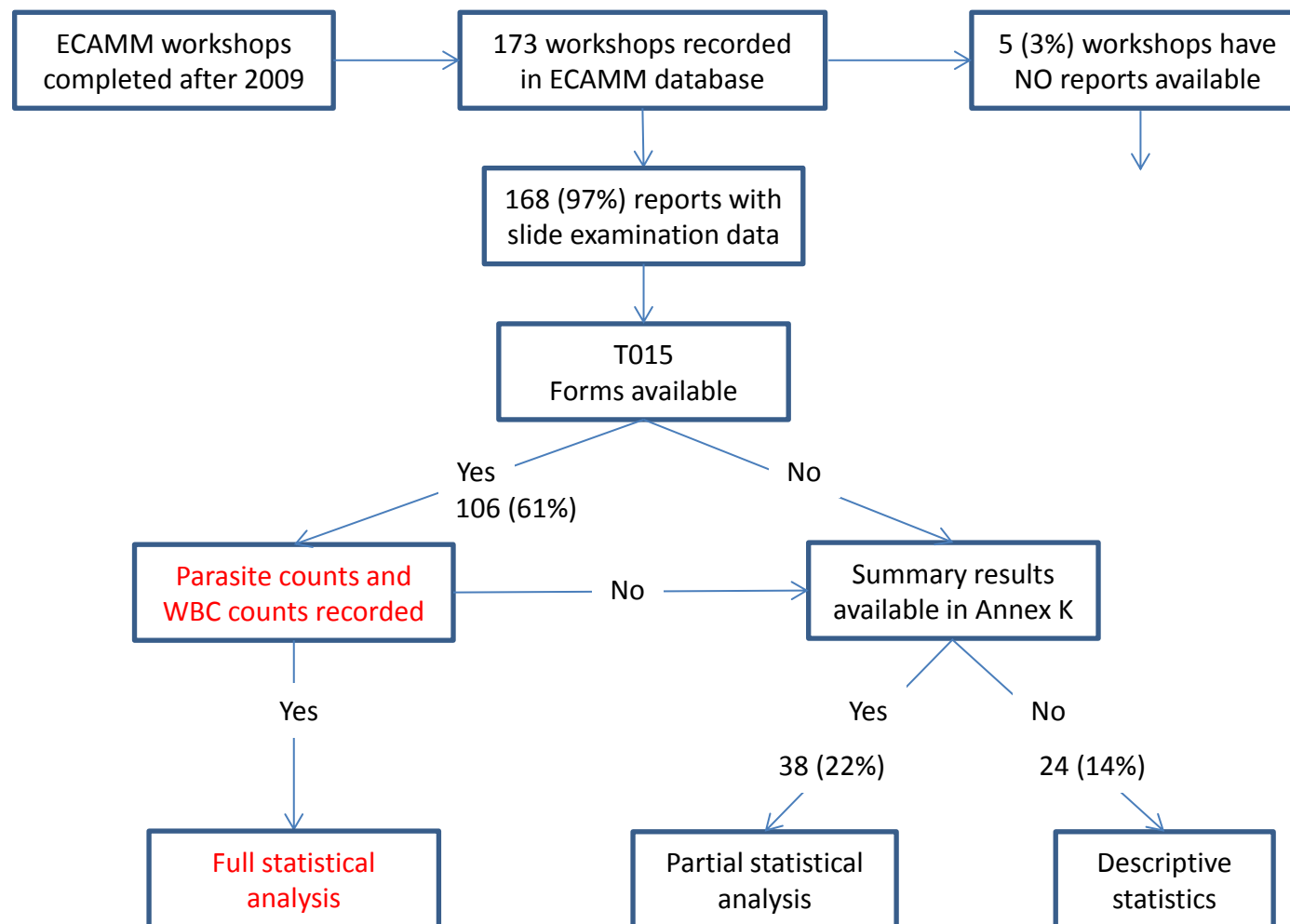


# Plan for data retrieval and analysis



WPRO has coordinated the collation of results of ECAMM workshops completed since 2009. The data entry is being completed and data will undergo soon statistical analysis.

The database will serve as basis for developing a standardized data entry, analysis and reporting system for ECAMM facilitators to generate the participant assessment and summary results.



= over 60'000 individual slide examinations by participants

- Are there general predictors based on participants education level or professional work which are associated with specific levels of competences?
- Is there a correlation between the pre-ECAMM results and the final test results?
- Is it possible to identify predictors of Level 4 competence assessment, based on the pre-ECAMM results?
- What are the major determinants of low competence levels parasite detection, species ID or parasite density estimation?
- For participants who have taken more than one ECAMM workshop, are there clear improvement from one ECAMM to the next? Could this be broken down into detection, identification and quantitation?
- Is there a difference in levels of competence in ECAMM in relation to prior refresher training as compared to the others?
- What is the quantitation accuracy at different parasite densities (e.g. 100-500, 500-2,000, 2,000-20,000 ... parasites/uL)?
- Do the achieved competency levels change if the quantitation cut off is increased from +/- 25% to +/- 50%? If so, in which ranges of densities will a change in this threshold generate major changes in competence levels?
- What will be impact of changing the criteria of accurate species identification for Pf, Pv, Pm and Po?
- If we change the scoring of mixed infections (to 1 point if at least one correct species is identified, currently scored 0) will this change the competency levels?
  - Analysis requiring access to raw data of microscopy slide examinations

# Worldwide E-Learning Course on Malaria Microscopy (WELCOMM)



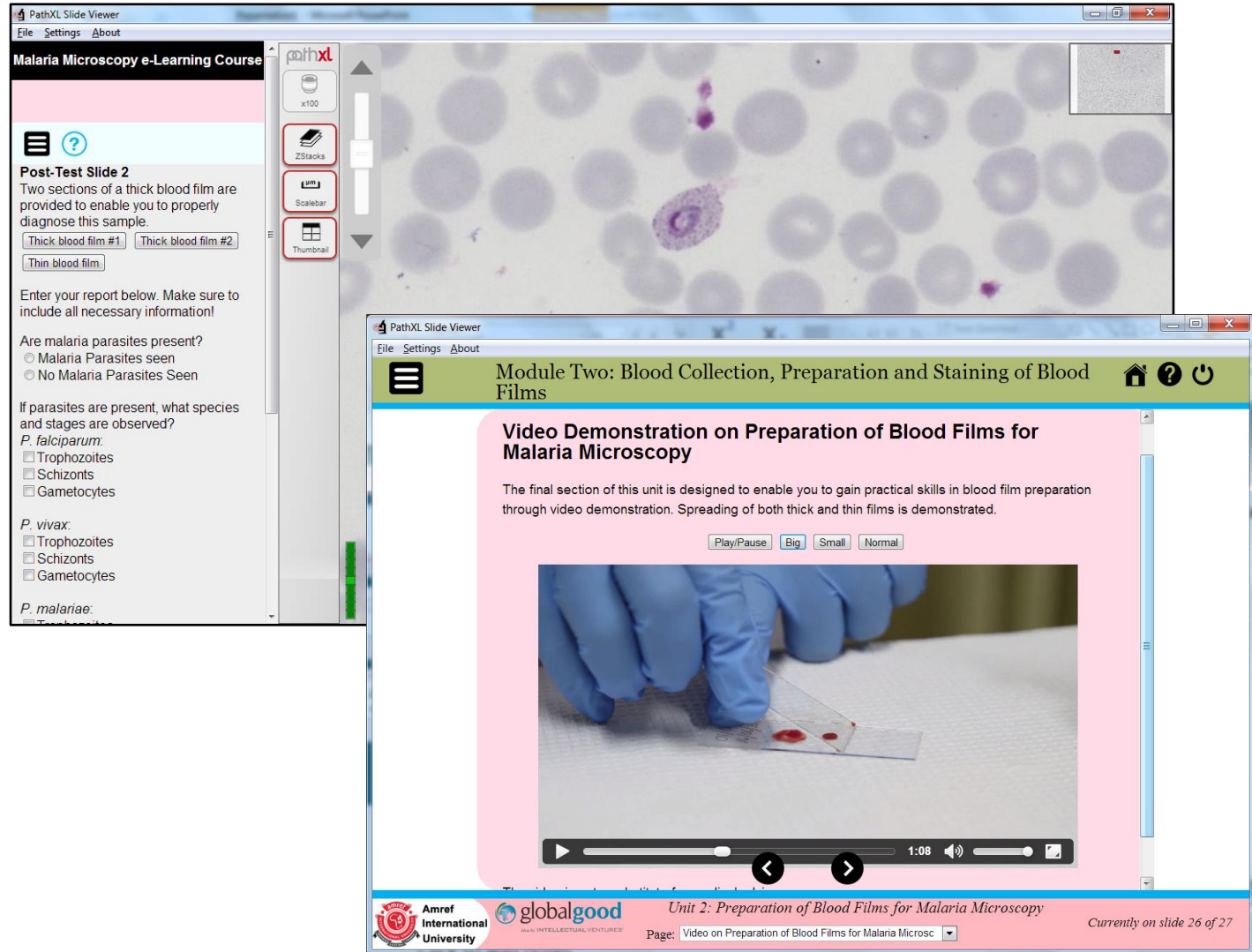
- Amref Health Africa and Global Good have developed the course to address challenges in re-training /refreshing malaria microscopists.
  - Acquiring and maintaining standardized slide banks.
  - Remoteness of microscopists.
  - Interest in self-improvement prior to formal WHO ECAMM assessments.
- Course features:
  - **Accessible:** full course on a USB drive; internet access not required
  - **Virtual Microscope** simulates real microscopy: scanning & focusing at high resolution
  - **Microscopic images:** all malaria parasite species & stages; other blood parasites and artifacts
    - 50 3D slides
    - Several hundreds of other smaller slides
  - **Additional topics:**
    - Overview of malaria
    - Blood film preparation and staining (video clips)
    - Other diagnostic techniques
    - Quality management systems
  - Aimed to be consistent with WHO malaria microscopy training manuals and standards



# Aims of the WELCOMM course

## Make skill improvement readily accessible to all microscopists on their own time

- Structured approach to learning: combines theory and practical
- Content: all aspects of malaria microscopy
- Provide self-improvement prior to taking accreditation courses (e.g. WHO ECA)
- Measurement of performance: quizzes & exercises after each module
- Certification: available on request
- Continuing Professional Development credits: in process
- Affordable course fees
- Sustainability – assured support for website maintenance and course management



The image displays two screenshots of the PathXL Slide Viewer interface. The top screenshot shows a thick blood film slide with a malaria parasite. The bottom screenshot shows a video demonstration of blood film preparation.

**PathXL Slide Viewer - Malaria Microscopy e-Learning Course**

**Post-Test Slide 2**  
Two sections of a thick blood film are provided to enable you to properly diagnose this sample.

Enter your report below. Make sure to include all necessary information!

Are malaria parasites present?  
☐ Malaria Parasites seen  
☐ No Malaria Parasites Seen

If parasites are present, what species and stages are observed?  
*P. falciparum:*  
☐ Trophozoites  
☐ Schizonts  
☐ Gametocytes

*P. vivax:*  
☐ Trophozoites  
☐ Schizonts  
☐ Gametocytes

*P. malariae:*

**PathXL Slide Viewer - Module Two: Blood Collection, Preparation and Staining of Blood Films**

**Video Demonstration on Preparation of Blood Films for Malaria Microscopy**

The final section of this unit is designed to enable you to gain practical skills in blood film preparation through video demonstration. Spreading of both thick and thin films is demonstrated.

Amref International University | globalgood | Unit 2: Preparation of Blood Films for Malaria Microscopy | Page: Video on Preparation of Blood Films for Malaria Microscopy | Currently on slide 26 of 27



# Pricing Structure of the Initial Release

A cost-based method for setting the prices of goods and services has been developed based on a tiered system per country economic status.

- ✓ Participants may request to be certified on the course by the Amref International University.
- ✓ Participants will receive by email an assessment to evaluate their skills (multiple choice questions and microscope slide evaluation) and will receive a Certificate of Achievement after obtaining a passing score.

Price	LIC	LMIC	UMIC	HIC
E-Learning course (Individuals)	60 USD	70 USD	100 USD	150 USD
E-Learning course (Institutions)	2,000 USD	3,000 USD	5,000 USD	10,000 USD
Certification (Individual)	40 USD	80 USD	150 USD	200 USD
Total Individuals (*)	100 USD	150 USD	250 USD	350 USD
Total Institutions (*)	4,000 USD	7,000 USD	12,500 USD	20,000 USD

# WELCOMM Contributors



## Authors/Reviewers

Jane Carter, David Isaboke, David Ocheng (Amref Health Africa)  
Earl Long  
Anderson Chinorumba (WHO AFRO)  
Ken Lilley (Australia Army Malaria Institute)  
Matthew Horning, David Bell, Christine Bachman (Global Good)

## Other contributors and pilot support from:

USAMRU Kenya  
Medical Care Development International  
Kenya Ministry of Health  
Universidad Peruana Cayetano Heredia  
ACT Malaria  
MalariaCare

## Virtual Microscope and Course Software

Philips Digital Pathology (formerly PathXL)  
Vikas Agrawal



# Discussion

