Innovation to Impact (I2I) in Vector Control

I2I Convening | March 22-23

March 23 agenda

Agenda item	Timing
Breakfast	8:00–8:30
Procurement: Progress summary, discussion on 2016 objectives and Q&A	8:30–9:20
GLP: Progress summary (including update from DQTF), discussion on 2016 objectives and Q&A	9:20–10:15
Break	10:15–10:30
Presentation on issues facing NRAs in Sub-Saharan Africa	10:30–10:50
Working session: (a) PQ QA discussion & (b) GLP: Discussion of outstanding questions[1]	10:50–12:00
Lunch	12:00–13:00
Summary of March 23 discussions and decisions made	13:00–13:30
Closing statement ▪ Review of convening progress ▪ Overall alignment on 2016 objectives and definition of success	13:30–15:00
Working session 4: (a) Convening of industry working group & (b) I2I collaboration model	15:00–16:30

Procurement: Plenary

Session	Detail	Presenter
Plenary (March 23, 8:30-9:20, ~50 min)	**Presentation on the workstream progress and 2016 objectives** (next steps and high-level goals) *(~10 min)*	**Christen**
	Summarize normative guidance & value-based procurement working session discussions & next steps from working sessions *(~20 min)*	**Christen**
	Q&A *(~20 min)*	**Christen & all workstream members**

Workstream includes representatives from procuring orgs & key partners

Other buyers of LLINs TBD and select national program and regulatory heads may also be invited to join

Bill & Melinda Gates Foundation	**Susie Nazzaro**
unicef	**S. Turner, J. Woziniak**
The Global Fund To Fight AIDS, Tuberculosis and Malaria	**Aziz Jafarov, Jan Kolaczinski**
UNITAID	**Ali Cameron**
PMI	**Christen Fornadel, Megan Fotheringham, John Gimnig, Elissa Jensen, Alexis Leonard, Julie Wallace**
World Health Organization	**Abraham Mnzava, Raman Velayudhan, Rajpal Yadav**

Procurement workstream meeting monthly to tackle collaborative issues

Procurement workstream has two main objectives

1 Enable procurers to further accelerate procurement of innovative tools...

Collective input provided to WHO on needed normative guidance to support the roll out of new tools

- Including interim recommendation of new tools & consultation provided on WHO plan

Collective input provided to WHO PQ to support their development of a product review process that can generate an interim endorsement of a new product

- Via an Expert Review Panel (ERP)
- To allow procurement aimed at generation of field data to inform development of normative guidance

Solution facilitated to resistance testing paper shortage

- To enable data generation needed for normative guidance

2 ...and to enhance value-based procurement

Existing value based procurement traits and changes to procurement criteria communicated to suppliers and feedback on additional measures received

LLIN durability specifications incorporated into procurement decisions

- Pending results of intra-lab validation study (ongoing now) and WHO process for product evaluation on how to incorporate into accompanying clear, structured normative guidance

Additional product performance/quality traits (AI residuality, resistance management, durability, etc.) examined for inclusion in procurement criteria

- Pending results of WHO process for product evaluation and accompanying clear, structured normative guidance; collective input provided to WHO on desired product evaluation traits

Other commitments include providing support for field monitoring quality control of products & additional commitments in individual operational plans

Progress already made against key objectives, with aim to establish plan to accelerate procurement & enhance value-based procurement by EOY

Objectives		2016 objectives	Progress to date	Next steps
1 Accelerate procurement	Normative guidance	**Clear input provided on needed normative guidance, including interim normative guidance**	▪ WHO shared briefing & held Q&A session ▪ Procurers consolidated list of questions & ideal state ▪ *Detailed working session recap to follow*	▪ Investigate possibility of implementing ideal state (WHO) ▪ Answer outstanding questions (PMI) ▪ *Recap to follow*
	Interim product endorsement			
	Resistance testing paper shortage			
2 Value-based procurement	Communication of value-based procurement			
	LLIN durability specifications			
	Additional product performance/ quality traits			

Progress already made against key objectives, with aim to establish plan to accelerate procurement & enhance value-based procurement by EOY

Objectives	2016 objectives	Progress to date	Next steps
1 Accelerate procurement: Normative guidance			
1 Accelerate procurement: **Interim product endorsement**	**Input provided on interim review of products**	▪ N/A: On hold until PQ plan fully defined, input requested	▪ Gather collective input for WHO PQ once plan shared (PMI) ▪ Gather input on data generation process to allow for normative guidance feedback (may use PBO nets as pilot case)
1 Accelerate procurement: Resistance testing paper shortage			
2 Value-based procurement: Communication of value-based procurement			
2 Value-based procurement: LLIN durability specifications			
2 Value-based procurement: Additional product performance/ quality traits			

Progress already made against key objectives, with aim to establish plan to accelerate procurement & enhance value-based procurement by EOY

Objectives	2016 objectives	Progress to date	Next steps
1 Accelerate procurement: Normative guidance			
1 Accelerate procurement: Interim product endorsement			
1 Accelerate procurement: **Resistance testing paper shortage**	**Resolution of testing paper issue facilitated**	▪ Discussed the problem causing the delay in the supply of resistance testing papers	▪ Will be discussed at WHO meeting to revise susceptibility guidelines in April ▪ Need to look into alternative suppliers/manufacturer supply of papers
2 Value-based procurement: Communication of value-based procurement			
2 Value-based procurement: LLIN durability specifications			
2 Value-based procurement: Additional product performance/ quality traits			

Progress already made against key objectives, with aim to establish plan to accelerate procurement & enhance value-based procurement by EOY

Objectives	2016 objectives	Progress to date	Next steps
1 Accelerate procurement: Normative guidance			
1 Accelerate procurement: Interim product endorsement			
1 Accelerate procurement: Resistance testing paper shortage			
2 Value-based procurement: **Communication of value-based procurement**	**All stakeholders have robust understanding of existing procurement criteria**	▪ Procurers shared briefing & held Q&A session ▪ Industry consolidated recommendations ▪ Detailed working session recap to follow	▪ Follow-up to answer outstanding questions (PMI, Global Fund, UNITAID)
2 Value-based procurement: LLIN durability specifications			
2 Value-based procurement: Additional product performance/ quality traits			

Progress already made against key objectives, with aim to establish plan to accelerate procurement & enhance value-based procurement by EOY

Objectives	2016 objectives	Progress to date	Next steps
1 Accelerate procurement: Normative guidance			
1 Accelerate procurement: Interim product endorsement			
1 Accelerate procurement: Resistance testing paper shortage			
2 Value-based procurement: Communication of value-based procurement			
2 Value-based procurement: **LLIN durability specifications**	**Durability integrated into procurement decisions** ▪ Pending results of inter-lab validation and clear, structured normative guidance	▪ Inter-lab validation studies started and expect completion by end Q1 2016 ▪ In process of setting up two field studies (Benin and Malawi to correlate RD scores with field durability monitoring results	▪ Produce independent report drafted by textiles expert with no current ongoing LLIN studies (WHO) ▪ Convene a consultation with disease experts, textiles experts, and other stakeholders by early Q2 2016 (WHO) ▪ Decision on what tests to incorporate with inclusion, if relevant, by launch of PQ program, Jan 1 2017 (by PQ and WHOPES)
2 Value-based procurement: Additional product performance/ quality traits			

Progress already made against key objectives, with aim to establish plan to accelerate procurement & enhance value-based procurement by EOY

Objectives	2016 objectives	Progress to date	Next steps
1 Accelerate procurement: Normative guidance			
1 Accelerate procurement: Interim product endorsement			
1 Accelerate procurement: Resistance testing paper shortage			
2 Value-based procurement: Communication of value-based procurement			
2 Value-based procurement: LLIN durability specifications			
2 Value-based procurement: **Additional product performance/ quality traits**	**Partners define & share priorities for additional desired product traits to be evaluated (e.g., AI residuality, resistance management)** ▪ Provide input to WHO on additional desired testing/normative guidance requirements	▪ Planning to address in Q3 2016	▪ Define & share priorities for additional desired product traits for evaluation (PMI, Global Fund, UNITAID, other stakeholders) ▪ Develop plan to enable inclusion of traits (All)

Recall: PMI & UNITAID questions on WHO normative guidance plan

1. **How exactly will the functions of VCAG, WHOPES, VCTEG, & MPAC work together in the new PQ system, so that data on products is fed across functions, resulting in one harmonized recommendation?**
2. **How can we ensure the data needed for normative guidance is available ASAP after products are evaluated?**
3. **Who is responsible for further data collection to support normative guidance?**
4. **What is the process to review interim normative guidance incorporating data from pilot field monitoring/further trials & provide a revised recommendation?**
5. **What is the process for looking at all new VC products in aggregate in order to provide appropriate guidance on rotations/ combinations to deploy?**

Do you have any questions about the procurement workstream or to its members?

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GLP: Plenary

Session	Detail	Presenter
GLP plenary *(55 minutes)*	1 **Intro** *(~5 min)*	**Mark**
	2 **GLP workstream** *(~5 min)* ▪ High-level overview of purpose of GLP accreditation and next steps ▪ Share list of GLP sites	**Dave/ Rajpal**
	3 **Progress made by WHO** *(~10 min)* ▪ Summary of progress ▪ Discussion of 2016 objectives	**Rajpal**
	4 **Progress made by IVCC** *(~10 min)* ▪ Summary of progress ▪ Discussion of 2016 objectives	**Dave**
	5 **DQTF progress update** *(~10 min)*	**John Lucas**
	6 **Q&A** *(~15 min)*	**Dave/ Rajpal/ John Lucas**

1

Work to build network of GLP sites supports transition to WHO PQ

WHO NTD & IVCC work today...

Development and revision of testing guidelines, protocols, & SOPs...

Creation of network of GLP-accredited sites...

... supports establishment of WHO PQ system by '17

...will support PQ evaluation of high-quality data

- No expectation of short-term changes to evaluation guidelines
- WHO PQT / NTD / GMP will maintain testing guidelines in the long term
- Up-to date guidelines needed in interim

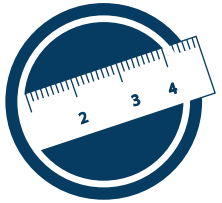
...to enable WHO PQ dossier review of manufacturer generated data

- WHO PQ requires GLP for dossier review

WHO PQ supports ongoing work to improve data quality

Good Laboratory Practices (GLP) work to generate high-quality data part of developing quality control systems for testing vector control products

GLP assures regulators that testing data have been generated along quality standards...



GLP is a quality system for planning, performing, monitoring, recording, and reporting **non-clinical health and environmental safety studies**

GLP assures regulatory authorities that **data submitted reflect study results**

- Data can therefore be relied upon when making efficacy assessments

...enabling policy changes

WHO will review dossiers of data generated at GLP-accredited sites

Manufacturers can directly contract GLP-accredited sites

- Data ownership decision between manufacturers and site
- May streamline data generation process
  - No need for both industry & WHO-run trials after full transition to PQ

GLP workstream has three main outputs to generate high-quality data

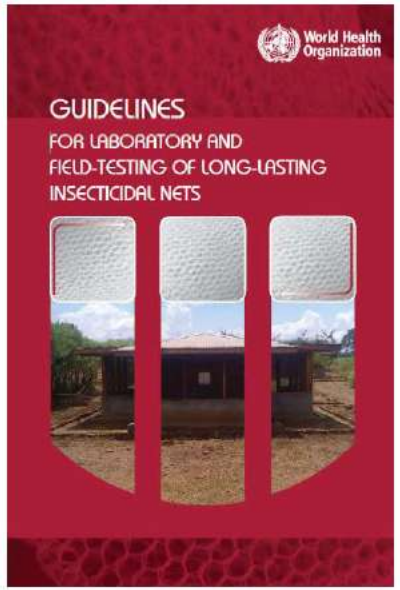
a **Accreditation of test sites to GLP to test 4 categories of products – LLINs, IRS, mosquito larvicides, space spraying**

b **Development of Standard Operating Procedures (SOPs)**

c **Revision of guidelines and SOPs where necessary**

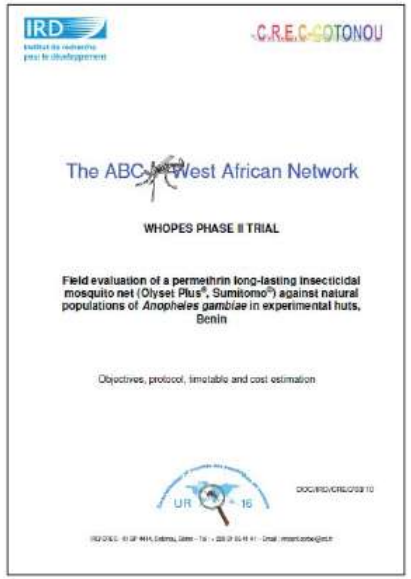
Quick definitions of guidelines, protocols, & SOPs

Testing guidelines



- For each type of product
- Provides guidance and describes steps for laboratory and field testing

Protocols



- For each trial
- Outlines requirements, activities, resources, documentation, & schedules

SOPs

IVCC_EH_001_V01_Sprayer Calibration (1).docx
IVCC_EH_001_V01_Sprayer Calibration.docx
IVCC_EH_002_V01_Transportation of Mosquitoes.docx
IVCC_EH_003_V01_Sugar Soaked Cotton Wool.docx
IVCC_EH_004_V01 Cone bioassay.docx
IVCC_EH_004_V01_APP_Cone bioassay data sheet.docx
IVCC_EH_004_V01_APP_Cone bioassay data sheet_GS comments.docx
IVCC_EH_005_V01 Exp Hut Post Spray Clean.docx
IVCC_EH_005_V01 Exp Hut Post Spray Clean_GS comments.docx
IVCC_EH_006_V01_Scoring Mosquito Mortality.docx
IVCC_EH_006_V01_Scoring Mosquito Mortality_GS comments.docx
IVCC_EH_007_01_Spray Calculations Record Sheet.docx
IVCC_EH_007_01_Spray Calculations Record Sheet_GS changes.docx
IVCC_EH_007_V01_Spray Calculations for IRS Applications.docx

- Formalize & standardize
- Others can repeat studies
- Should be resource available for all
- Not inflexible (deviations allowed)

For discussion today

GLP workstream meeting regularly to tackle collaborative issues

Current representatives

IVCC

Dave Malone
Alex Wright

World Health Organization

Rajpal Yadav
Abraham Mnzava
Mark McDonald

Data Quality Task Force

John Lucas
Industry + overlap with academia

Institutions
(to be invited)

- Representatives from sites targeted for GLP accreditation
- GLP authorities

Invited experts/ consultants

Graham Small

Sites IVCC & WHO will work with for accreditation

	Region	Site	Current testing capabilities[1]: Products				Phases		
IVCC to lead	West Africa	Institut Pierre Richet (IPR), Institut National de Santé Publique, Cote d'Ivoire	LLIN	IRS			1	2	3
		Institut de Recherche en Sciences de la Santé (IRSS) Centre Muraz, Bobo Dioulasso, B.F.	LLIN	IRS			1	2	3
		CREC, Cotonou (in collaboration with LSHTM), Benin	LLIN	IRS			1	2	3
		Centre Suisse de Recherches Scientifiques en Cote d'Ivoire, CSRS, Cote d'Ivoire	LLIN				1	2	3
	East Africa	Kilimanjaro Christian Medical University College, Moshi, Tanzania	LLIN	IRS			1	2	3
		Ifakara Health Institute, Bagamayo Research & Training Centre, Tanzania	LLIN					2	3
WHO to lead	Americas	Brazil or Mosquito and Fly unit, Florida, USA (TBD)			SS	Larv		2	3
		Centro Regional de Investigación en Salud Pública, Tapachula, Mexico (tentative)		IRS				2	3
	Western Pacific	Vector Control Research Unit, Universiti Sains Malaysia, Penang, Malaysia			SS	Larv		2	3
		Institute for Medical Research, Kuala Lumpur, Malaysia	LLIN	IRS				2	3
		WHO CC - Centre for Disease Control, Beijing, China			SS	Larv		2	3
	South East Asia	WHO CC - National Institute of Malaria Research (NIMR), Delhi, India	LLIN	IRS		Larv	1	2	3
		WHO CC - Vector Control Research Centre, Puducherry, India	LLIN	IRS				2	3
	Eastern Mediterranean	School of Public Health, Tehran, Iran	LLIN	IRS		Larv		2	3

Already GLP accredited or close to accreditation

1. GLP-accredited sites should be able to expand to test other product categories, phases over time
Note: 14 sites in initial plan - Additional sites to be self-accredited using GLP SOP package

Identification of test sites outside of Africa & administrative arrangements with test sites

Test sites outside of Africa selected based on:

- Product testing capability
- Phase capabilities
- Regional diversity
- Existing level of capabilities

Administrative arrangements with test sites

- Manufacturers can directly contract GLP-accredited sites
  - Data ownership decision between manufacturers and site

Current testing capabilities[1]:

			Products				Phases		
WHO to lead	Americas	Brazil or Mosquito and Fly unit, Florida, USA (TBD)			SS	Larv		2	3
		Centro Regional de Investigación en Salud Pública, Tapachula, Mexico (tentative)		IRS				2	3
	Western Pacific	Vector Control Research Unit, Universiti Sains Malaysia, Penang, Malaysia			SS	Larv		2	3
		Institute for Medical Research, Kuala Lumpur, Malaysia	LLIN	IRS				2	3
		WHO CC - Centre for Disease Control, Beijing, China			SS	Larv		2	3
	South East Asia	WHO CC - National Institute of Malaria Research (NIMR), Delhi, India	LLIN	IRS		Larv	1	2	3
		WHO CC - Vector Control Research Centre, Puducherry, India	LLIN	IRS				2	3
	Eastern Mediterranean	School of Public Health, Tehran, Iran	LLIN	IRS		Larv		2	3

Progress and next steps: Facility audits

	Sites	Audit date
Americas	Brazil or Mosquito and Fly unit, Florida, USA (TBD)	**2017**
	Centro Regional de Investigación en Salud Pública, Tapachula, Mexico (tentative)	**2017**
Western Pacific	Vector Control Research Unit, Universiti Sains Malaysia, Penang, Malaysia	**03/2016**
	Institute for Medical Research, Kuala Lumpur, Malaysia	**03/2016**
	WHO CC - Centre for Disease Control, Beijing, China	**06/2016**
South East Asia	WHO CC - National Institute of Malaria Research (NIMR), Delhi, India	**04/2016**
	WHO CC - Vector Control Research Centre, Puducherry, India	**04/2016**
Eastern Mediterranean	School of Public Health, Tehran, Iran	**05/2016**

Progress	Completed	Scheduled	Not yet scheduled

Progress and next steps: Communication with accreditation authorities

	Sites	Accreditation bodies
Americas	Brazil or Mosquito and Fly unit, Florida, USA (TBD)	Not yet determined
	Centro Regional de Investigación en Salud Pública, Tapachula, Mexico (tentative)	Not yet determined
Western Pacific	Vector Control Research Unit, Universiti Sains Malaysia, Penang, Malaysia	Department of Standards Malaysia
	Institute for Medical Research, Kuala Lumpur, Malaysia	Department of Standards Malaysia
	WHO CC - Centre for Disease Control, Beijing, China	ICAMA (To be confirmed)
South East Asia	WHO CC - National Institute of Malaria Research (NIMR), Delhi, India	National GLP Compliance Monitoring Authority, New Delhi
	WHO CC - Vector Control Research Centre, Puducherry, India	National GLP Compliance Monitoring Authority, New Delhi
Eastern Mediterranean	School of Public Health, Tehran, Iran	Institute of Standards and Industrial Research of Iran (www.isiri.com)

Planned content for GLP training/quality control systems workshop

1. **Introduction to GLP**
2. **Fundamental components of a quality management system based on the principles of GLP**
3. **Documentation required for a GLP compliant quality management system**
4. **SOPs**
   - 'What is an SOP?'
   - 'How to write a good SOP'
5. **Interactive sessions**
   - Development of SOPs relating to test methods in WHOPES guidelines – workshop delegates split into small groups, each drafting a number of SOPs
   - Critiquing of drafted SOPs – all workshop delegates
   - Practical, hands on sessions in which SOPs will be followed during the conduct of a laboratory test – workshop delegates split into small groups, each group setting up their own tests
   - Discussion of the results of the test and feedback on the – all workshop delegates
6. **Workshop discussion and wrap-up session**

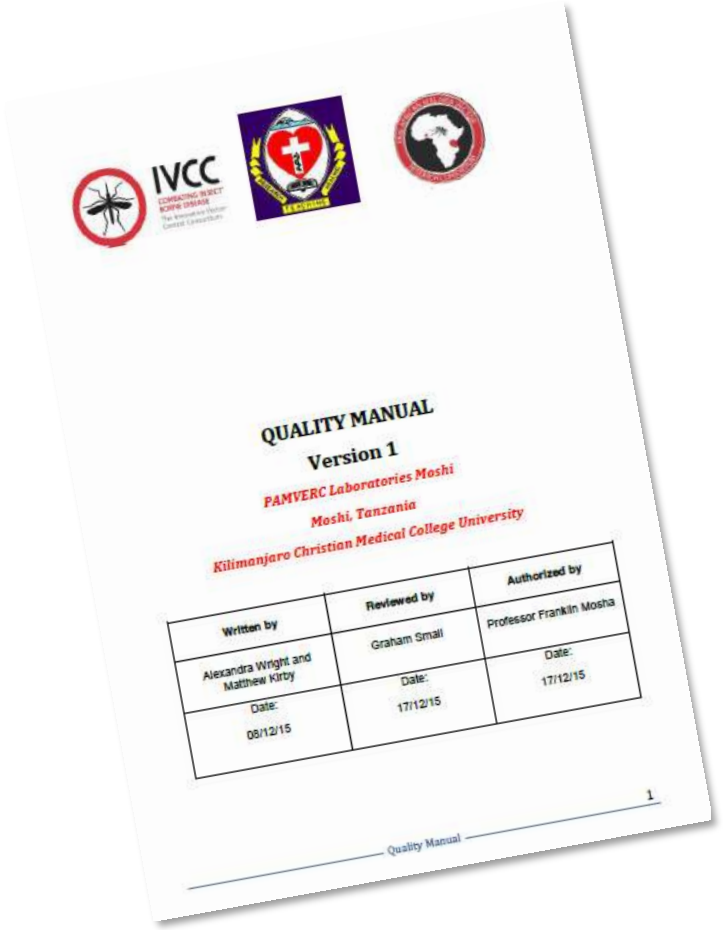
GLP training workshop to be held from
May 30th – June 3rd, 2016 in Penang, Malaysia

IVCC: Progress……..

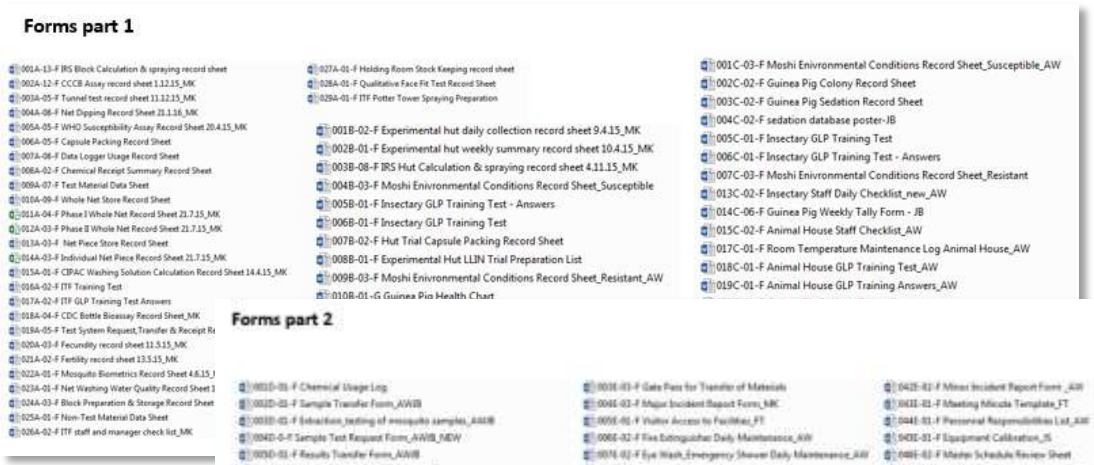
Summary of Progress since June 2015

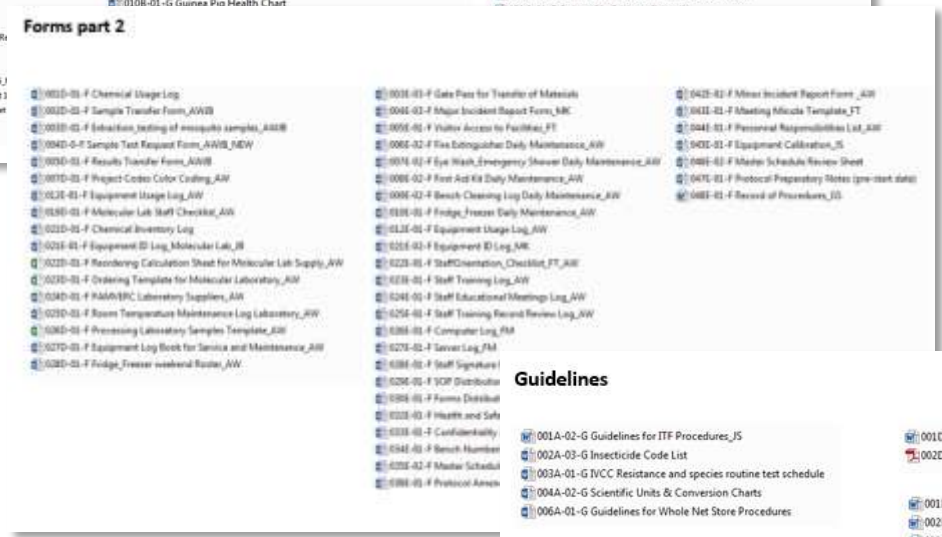
- **KCMUCo**
  - Developed Quality Manual and SOPs
  - Upgraded Facilities and Equipment
  - Submitted application to SANAS

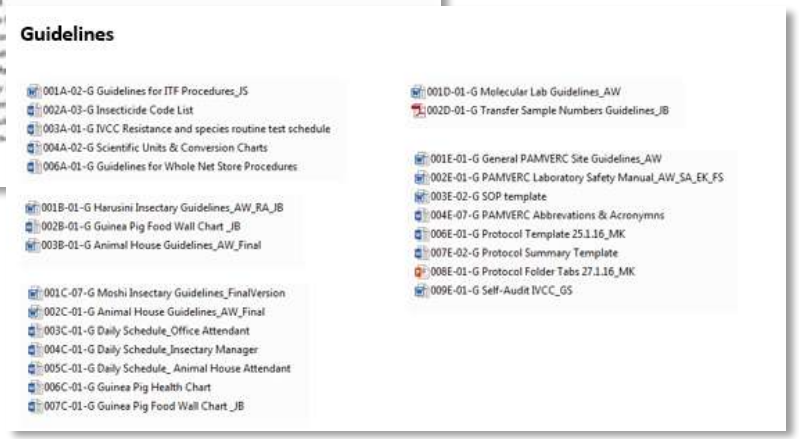
- **GLP Manual**
  - Produced and Shared with GLP Work Stream



KCMUCo Documentation…..







KCMUCo Facility Upgrades


Emergency eye wash and shower

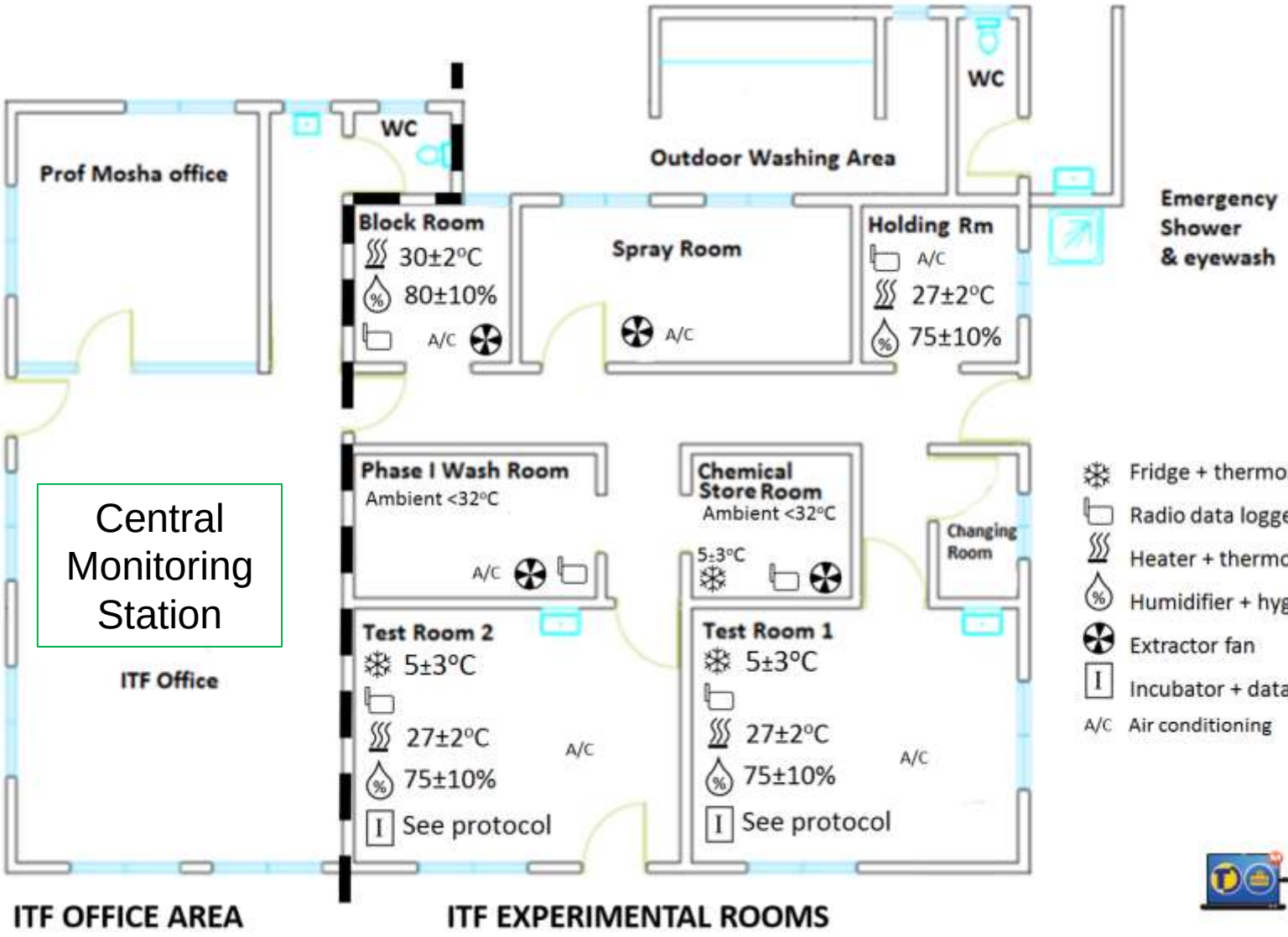

‘Biometric’ security doors


Guinea pig tagging

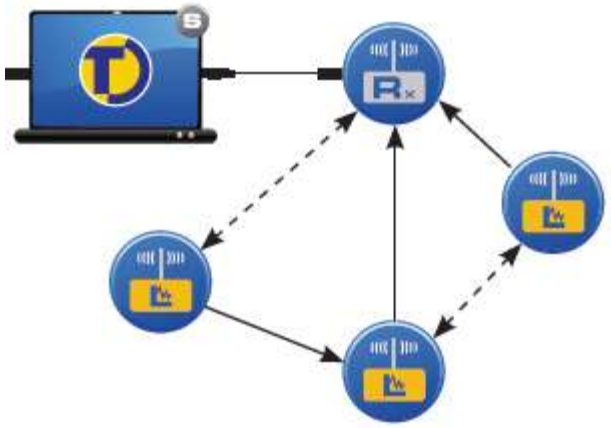

Equipment records

Yet more new buildings

WIRELESS ENVIRONMENTAL MONITORING



Fridge + thermometer
Radio data logger
Heater + thermostat
Humidifier + hygrostat
Extractor fan
Incubator + data logger
A/C Air conditioning



NET PROCESSING WITH BARCODE SYSTEM

1. Overview of net system

1. Whole nets received from partner company, logged in **whole net store record** using company care tag barcode, then later given unique id and whole net tag dependent on whether to be used for phase I or phase II testing

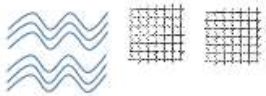
Type A
40-50 Candidate nets
(net to be evaluated)

Type B
40-50 Reference nets
(positive control)

PHASE I

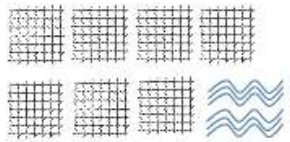
2. 14x pieces cut from 4x nets of each type. Pieces are cut, labelled with **barcoded tags** from the **phase I whole net record** and logged following **net pieces store record**

2x pieces per net for regeneration time study



5x unwashed pieces per net for chemical analysis

7x pieces per net for wash resistance study



3. 12 pieces per net...

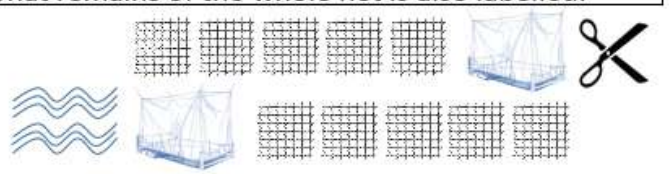
...sent to partner company for chemical analysis

6. All pieces cut in phase II (including step 3)...

PHASE II

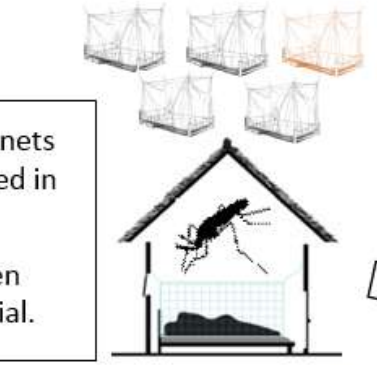
2. 12-16x nets of each type taken for each phase II trial *(multiple trials may be run)*

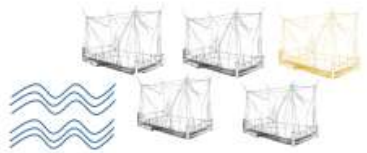
3. 5x pieces cut from 1x net of each type; same net then washed and 5x more pieces cut. Pieces are labelled with **barcoded tags** from the **phase II whole net record** and logged in **net pieces store record** & what remains of the whole net is also labelled.



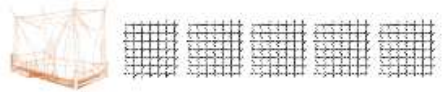
4. Half of remaining nets used whole unwashed in hut trial.

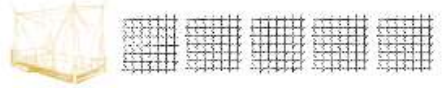
Half are washed, then used whole in hut trial.



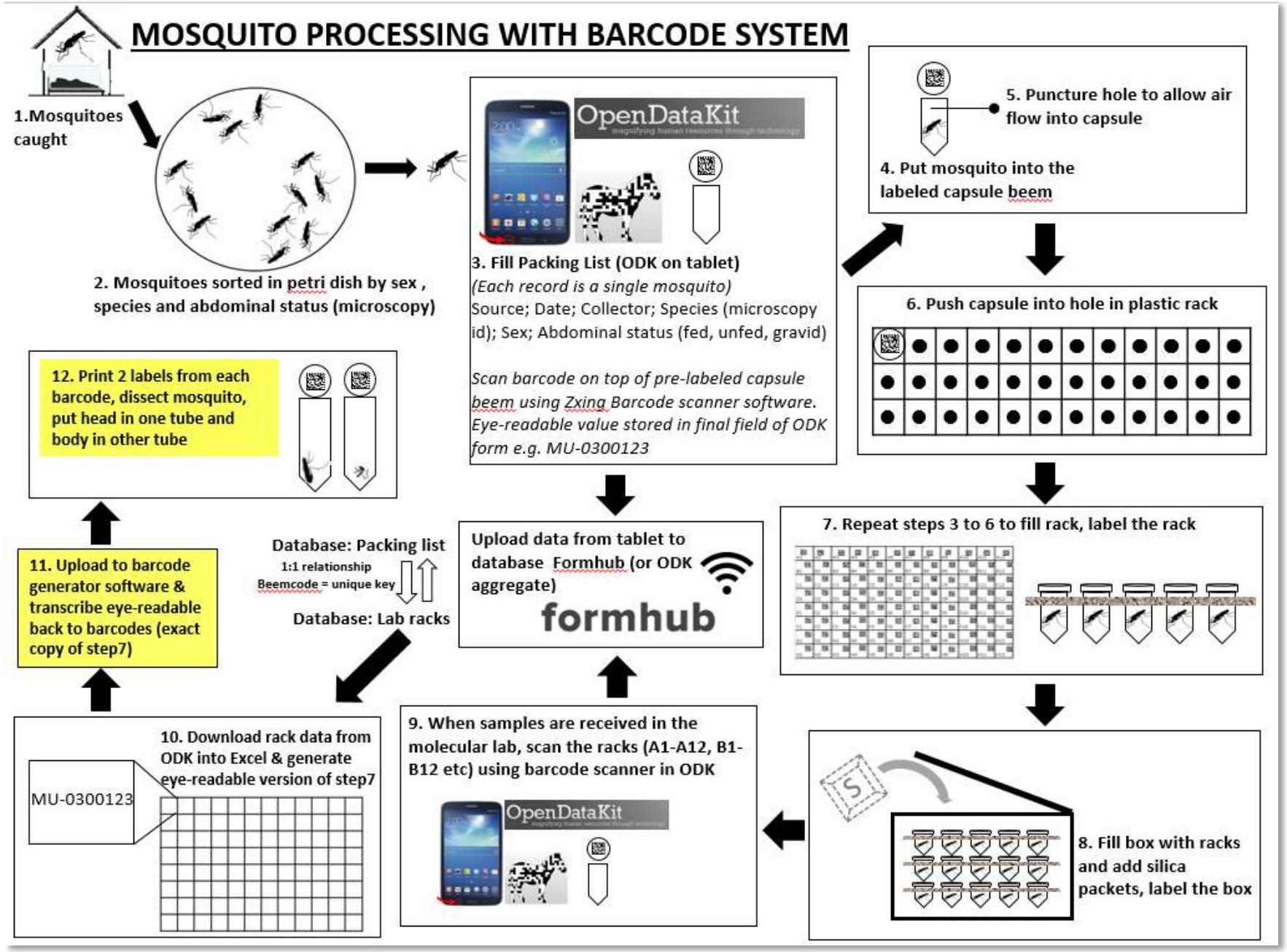


5. 5x pieces cut from 2x net of each type
(1 washed, 1 unwashed)

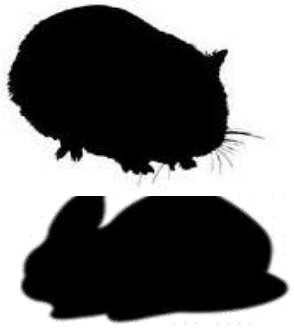




MOSQUITO PROCESSING WITH BARCODE SYSTEM

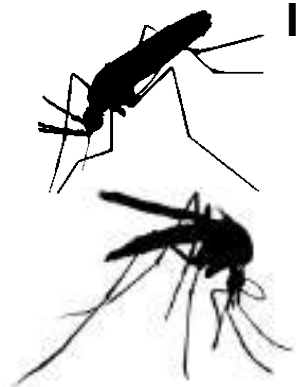


ANIMAL HOUSE



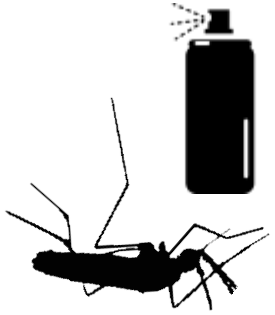
- Forms ✓
- SOPs ✓
- Guidelines ✓
- Training ✓
- Assessment ✓

INSECTARY



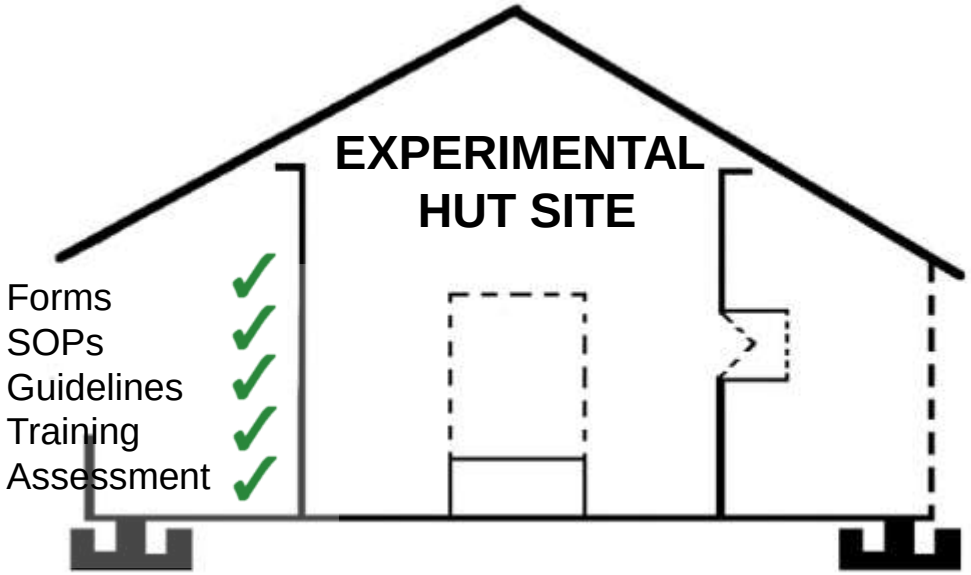
- Forms ✓
- SOPs ✓
- Guidelines ✓
- Training ✓
- Assessment ✓

INSECTICIDE TEST FACILITY



- Forms ✓
- SOPs ✓
- Guidelines ✓
- Training ✓
- Assessment ✓

EXPERIMENTAL HUT SITE



- Forms ✓
- SOPs ✓
- Guidelines ✓
- Training ✓
- Assessment ✓

Progress and next steps: Facility audits

	Sites	Audit date
Tanzania	Killimanjaro Christian Medical University College (KCMUCo), Moshi	09/2015
	Ifakara Health Institute (IHI), Bagamoyo	XX/2016
Cote d'Ivoire	Centre Suiss de Recherche Scientifique (CSRS), Abidjan	02/2016
	Institute Pierre Richet (IPR) , Bouake	02/2016
Burkina Faso	Institut de Recherche en Science de la Santé (IRSS), Bobo-Dioulasso	XX/2016
Benin	Centre de Recherche Entomologique de Cotonou (CREC), Cotonou	XX/2016

Progress	Completed	Scheduled	Not yet scheduled

IVCC: Generic Timeline for Accreditation

	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Phase I - Laying down the scene												
Baseline audit / Gap Analisis	■											
Initial Training	■	■										
Development of SOPs and QM Systems		■	■									
Self Audit				■								
Phase II - Systems and process setup												
On-Site Audit					■							
Development of Quality Manual						■	■					
On site audit								■				
Phase III - Accreditation												
Application for Accreditation Submission									■			
On site auditor training									■			
Accreditation										■	■	■

Accreditation – Current Status of Trial Sites

Institution:		KCMUCo	CREC	IRSS	CSRS	IHI	IPR
Standard Operating Procedures (SOPs)	SOPs for studies						
	SOPs for standard test methods						
	SOPs for equipment usage, calibration & maintenance						
	SOPs for insect rearing						
	SOPs for chemicals (receipt, storage, usage, waste disposal)						
	SOPs for computer systems						
	SOPs for archiving						
	SOPs for staff (training records, designated persons etc)						
Documentation & Systems	Chemical acknowledgment of receipts						
	Chemical usage records						
	Material Safety Data Sheets						
	Equipment maintenance & calibration records						
	Daily temperature records (insectaries, testing facility and chemicals store)						
	Insect culturing records						
	Computer software validation records						
	Secure computer systems (password protection, access permissions, antivirus software protection)						
	Security of electronic data (backup and secondary back up of electronic files)						
Study Specific Records	Study code book and study master schedule						
	Study paperwork kept in a study folder						
	Signed and dated study protocols						
	Study amendment and deviation forms						
	Record of study procedures						
	Signed raw data sheets						
	Checked and signed calculation sheets						
	Signed calibration and treatment application records						
	Signed and dated final study reports						
Archiving of Studies & Study-related Documentation	Secure archive accessible only to archivists						
	Nominated archivist and deputy archivist						
	Indexes for archived studies and study-related documentation (hard copies and electronic copies)						
	Archive retrieval forms						
	Electronic archive accessible only to archivists						
	Electronic study folders placed into CD/DVD						

= developed and implemented

= currently being developed

= not yet developed

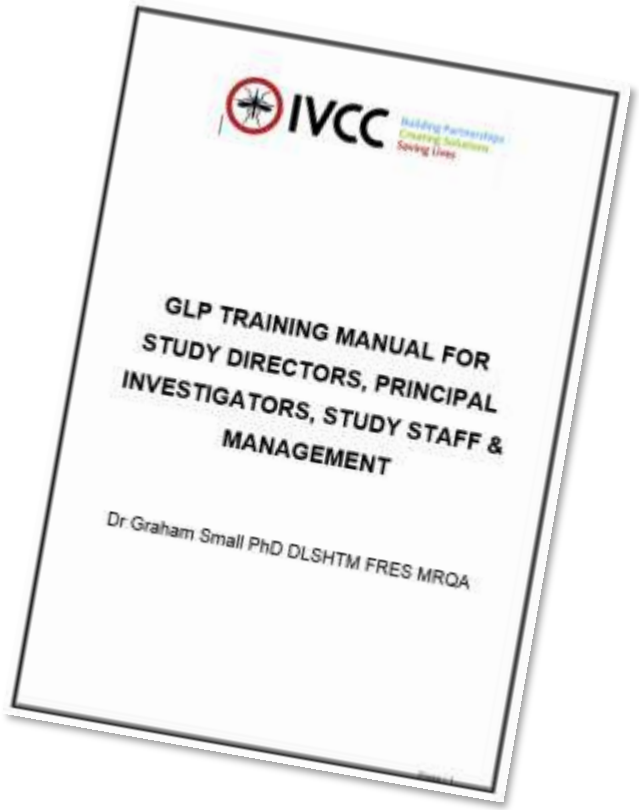
IVCC: Progress……..

Objectives for 2016

- KCMUCo
  - Finalise Quality Manual and SOPs
  - Confirm GLP Accreditation
  - Conduct 1st GLP Study - Phase II IRS

- CREC/CSRS/IHI/IPR/IRSS
  - Complete Audits
  - Provide Pathway to accreditation for each site
  - Support each site towards accreditation

- GLP Manual
  - Finalise



Data Quality Task Force update

Original Focus of DQTF:

- Improving data quality through implementation of GLP
- Improvement of existing and development of new test and / or application methods
- Experimental design and statistical analysis

Scope:

- Broad covering any VC intervention and vector borne disease
- Initial focus: IRS

Data Quality Task Force update

Core Group: An Informal group, pooling resources, working to prevent duplication of effort

- WHOPEs/GMP - Rajpal Yadav
- VCT John Lucas
- IVCC Dave Malone
- CDC John Gimnig
- BMGF Dan Strickman
- VCWG : Steve Lindsay as focal point for academia:
- Experts as needed

Data Quality Task Force update

Key benefits of improved quality:

- Generating data that are reliable, repeatable and auditable
- Ability to compare products and trials more reliably.
- Better /more efficient use of limited resources (staff, experimental sites, finances, time etc)
- Expedite products through WHOPES
- Improved time to market, faster PH impact
- Quicker contribution of new a.i.s in malaria elimination

Data Quality Task Force update

Key Activities

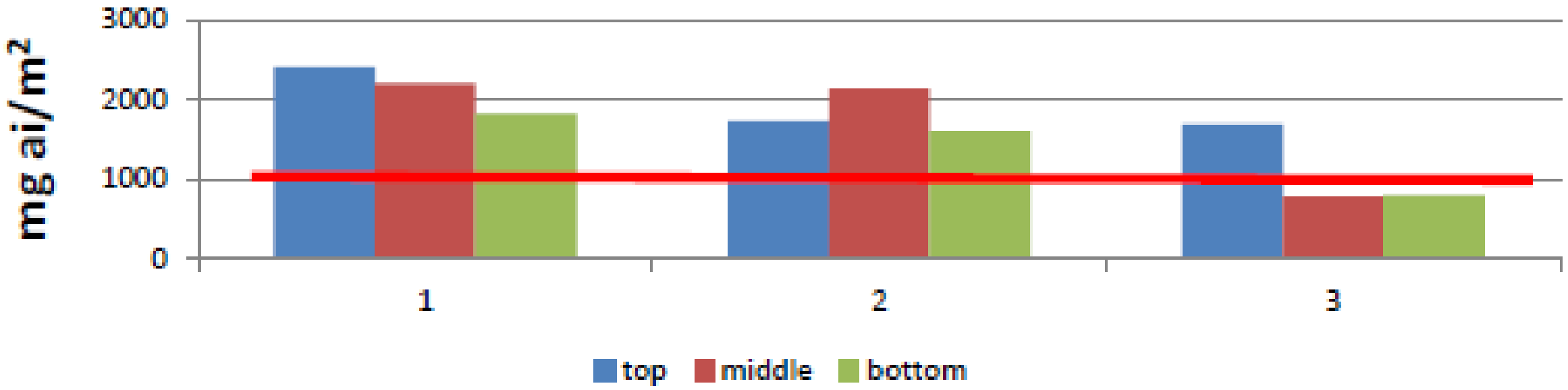
- Inventory of existing SOPs
- Identifying required SOPs
- Drafting new SOPs
- Development of Track sprayer
- Evaluation of Track sprayer – initial studies

Data Quality Task Force update

Examples of SOPs identified for development

- Building of East and West African style experimental huts;
- Refurbishment of experimental huts;
- Cleaning of the experimental huts post spraying;
- Spray calculations for IRS applications;
- Use of sprayers (including sprayer calibration and calculation of actual application rates post spraying);
- Determination of the quality of IRS applications;
- Cone bioassays in experimental huts;
- Preparation of sugar-soaked cotton wool for maintaining adult mosquitoes during transportation;
- Collection and evaluation of wild, free-flying mosquitoes in experimental huts;
- Scoring mosquito mortality;
- Safe disposal of insecticide waste.
- Transportation of mosquitoes used in cone bioassays;

Variation in dose rate in experimental huts:
Mud walls (3 sites)
IRS with Control Flow Valve



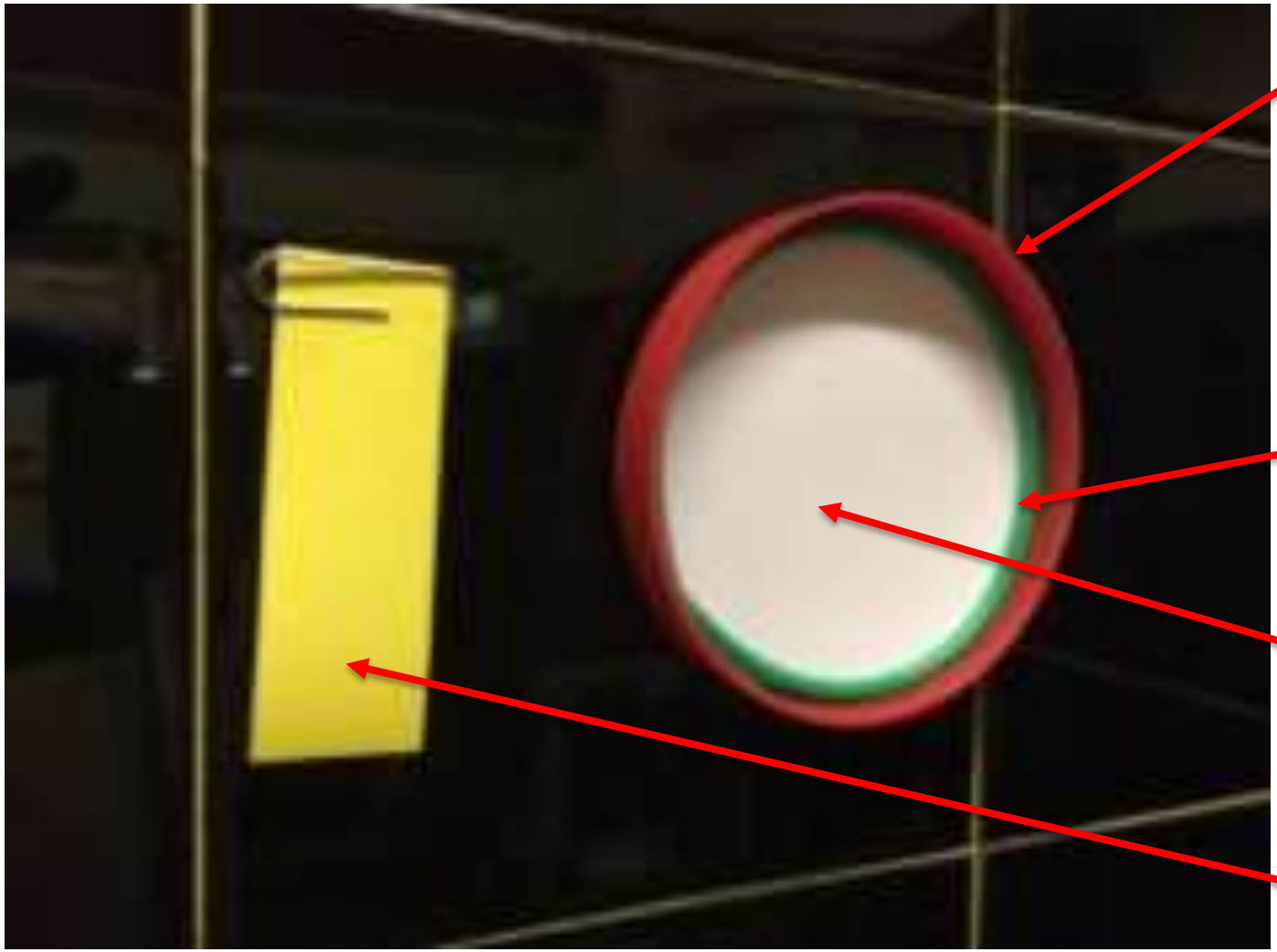
Development and testing of the Micron® Track Sprayer

IVCC Building Partnerships Creating Solutions Saving Lives

MICRON GROUP

Test Chamber at Micron

Experimental Set Up



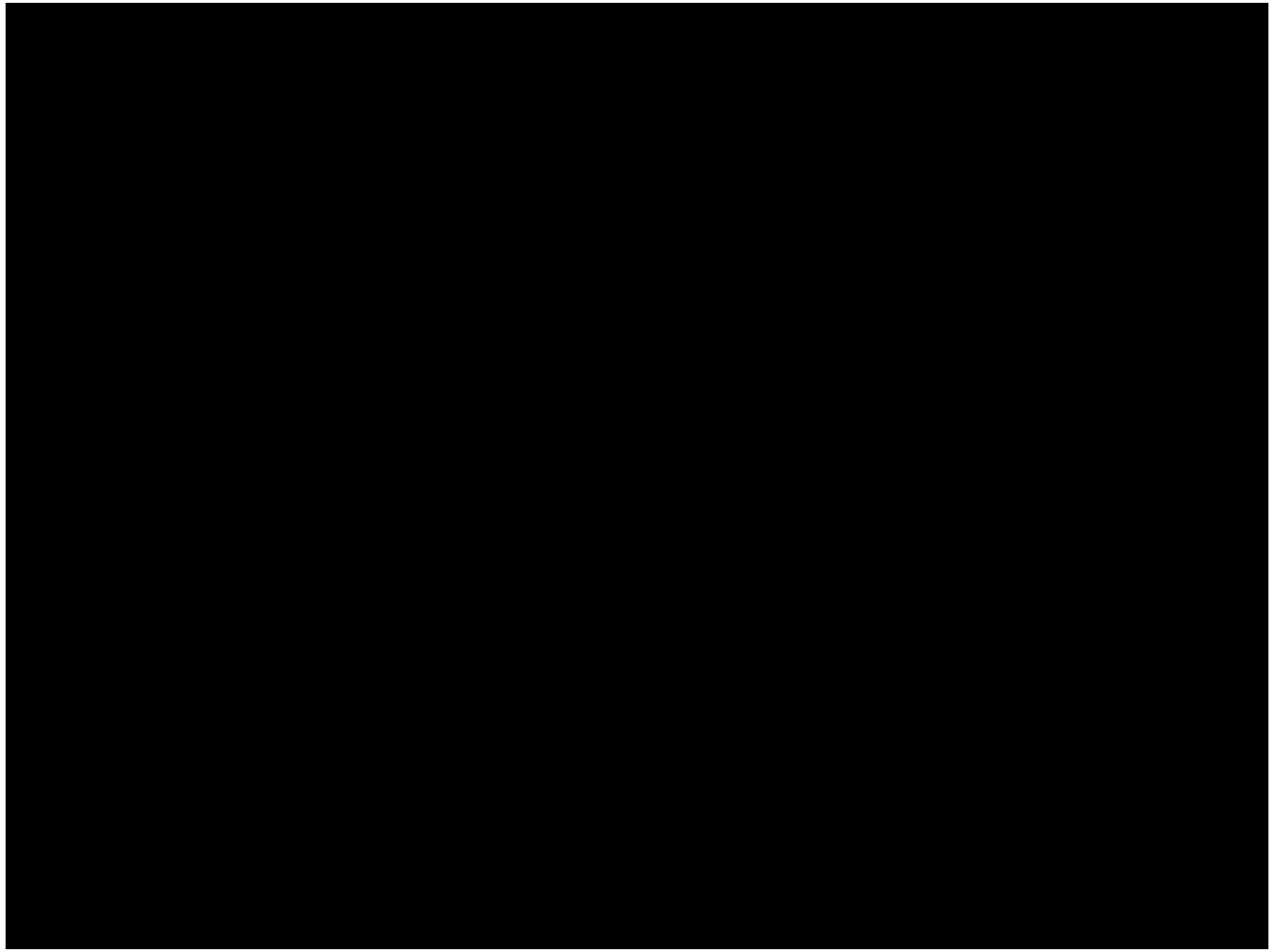
Plastic lid acts to prevent liquid running onto filter paper. Held on wall with Velcro pad

Plastic ring holds paper in place

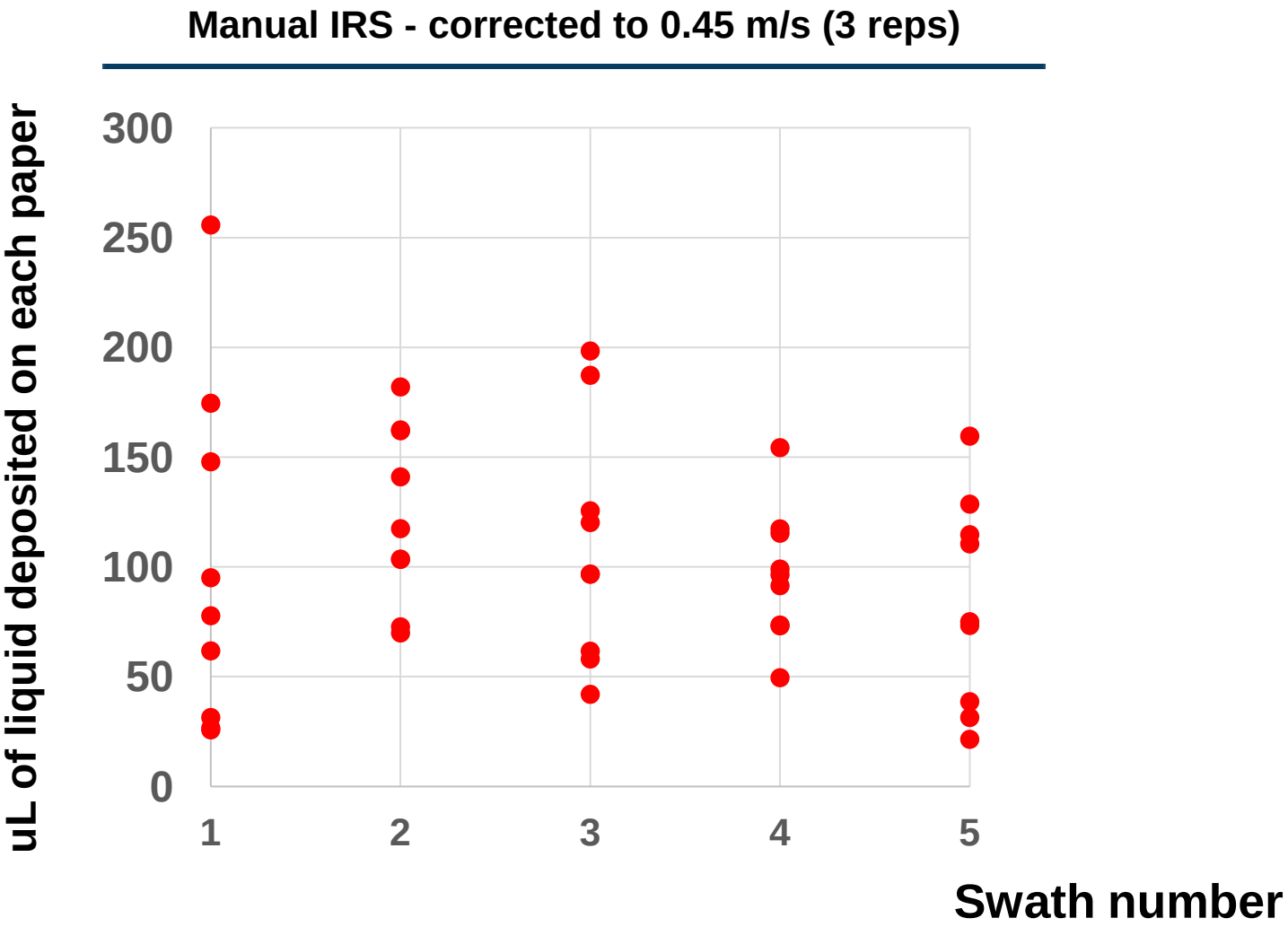
Filter paper

Water Sensitive paper

Track Sprayer in use



Performance of track sprayer and manual IRS at 0.45 m/s



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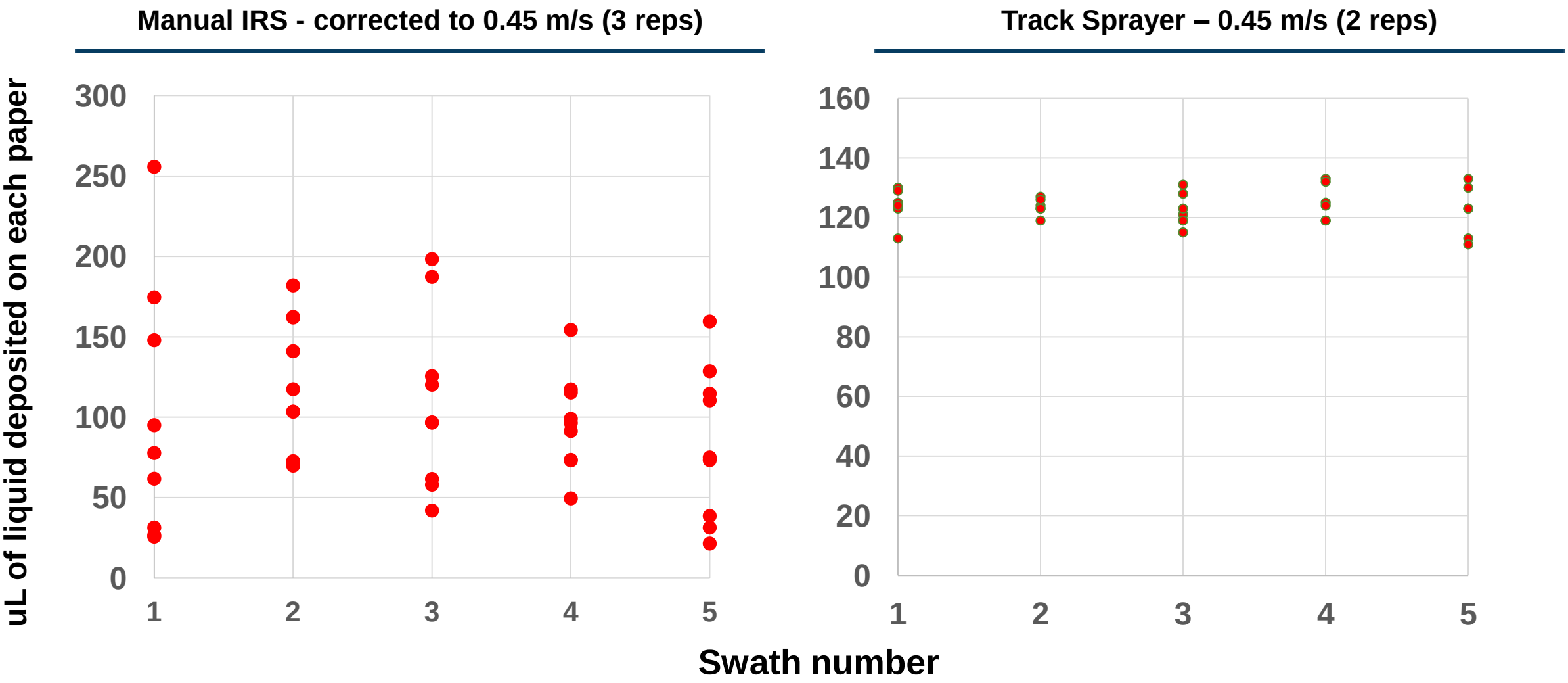

Data Quality Task Force

Experimental huts: Design considerations

Cracks in experimental hut cement floor

- May allow ants to enter
- Ants can remove dead or KD mosquitoes.
- Fill cracks with flexible sealant/plaster
- New builds to include insect-proof membrane (e.g. Termimesh®) in the hut base.

West African Hut wall dimensions

- 70 cm wide spray swaths (chalk lines) results in spraying into a corner
- Affects evenness of dosing
- Ceiling of hut is angled

Data Quality Task Force update

Next steps

- Clarification of role of DQTF in i2i
- Drafting SOPs for LLINs
- Inventory of SOPs for other GL tests (larvicides, Space sprays)
- Funding development of statistical guidelines and tools for IRS, LNs (Proposal - TBD)
- Detailed evaluation of Track sprayer
- Inventory of Experimental huts, design improvements

Do you have any questions for the GLP workstream or issues to raise?

March 23 agenda

Agenda item	Timing
Breakfast	8:00–8:30
Procurement: Progress summary, discussion on 2016 objectives and Q&A	8:30–9:20
GLP: Progress summary (including update from DQTF), discussion on 2016 objectives and Q&A	9:20–10:15
Break	10:15–10:30
Presentation on issues facing NRAs in Sub-Saharan Africa	10:30–10:50
Working session: (a) PQ QA discussion & (b) GLP: Discussion of outstanding questions[1]	10:50–12:00
Lunch	12:00–13:00
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Inter-state Pesticides Committee for Central Africa (CPAC)

Presentation Agenda

1. Common Regulation & CPAC implementation process
2. Current situation and constraints
3. Conclusion: Proposed solutions

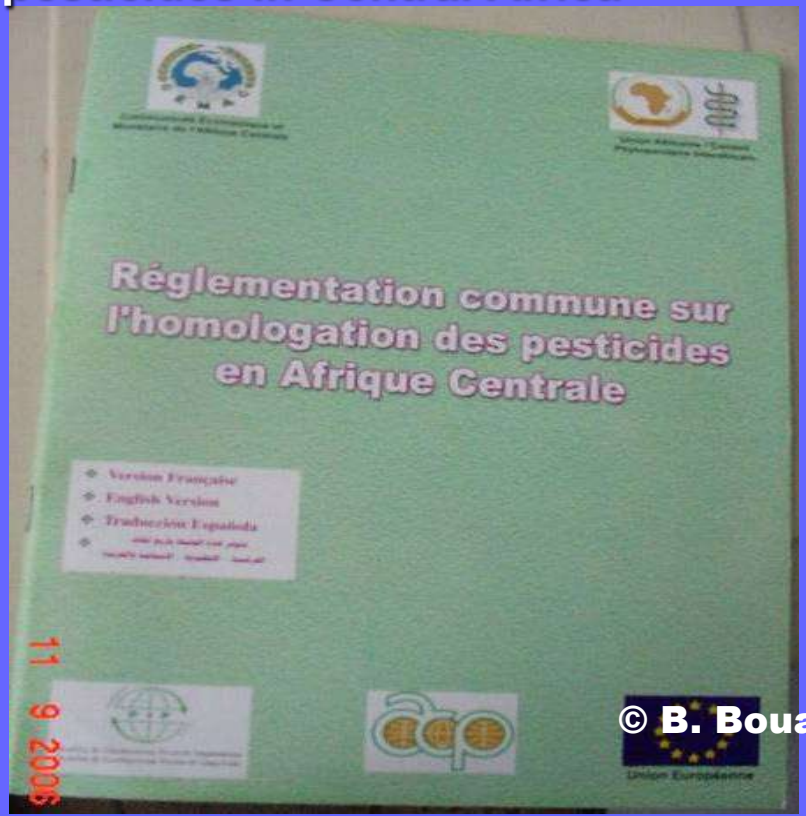
The problem: Uncontrolled marketing and circulation of pesticides in the Central African area

Context: Out of the 6 CEMAC member countries (Chad, Cameroon, Central African Republic, Equatorial Guinea, Gabon, & Republic of the Congo)**, only Cameroon & Chad had a pesticides management system more or less regulated**

Therefore, some pesticides become obsolete/ outdated and pollute the environment

The solution: Creation of CPAC to harmonize regulation of pesticide management in the CEMAC region

CPAC is responsible for executing the common regulation binding the registration of pesticides in Central Africa



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CPAC is represented in every member state by a branch, including 3 experts/ official representatives per country, who took an oath at the Communitarian Court of Justice

- Many trainings were conducted for country experts & the standing secretariat, with the support of partners

CPAC is represented in each country by a expert unit, linked by an interconnected IT network, responsible for:

- Coordination on the implementation of CPAC decisions at a national level;
- Coordination on the fight against pesticides counterfeiting and fraud;
- Acting as intermediaries between CPAC & the National Management Committee of Pesticides (CNGP);
- Collecting and analyzing the information, transferring the information to CPAC in order to offer updates on the status of pesticide management in Central Africa;
- Etc.


Congo


Chad


CAR


Equatorial Guinea


Gabon

Creation of National Management Committee of Pesticides (CNGP)[1]: Example of Chad

CNPGs are state structures that were created according to agreed-upon, harmonized mandates from CPAC

They assume the sovereign, regulatory function of the states and are overseen by CPAC units

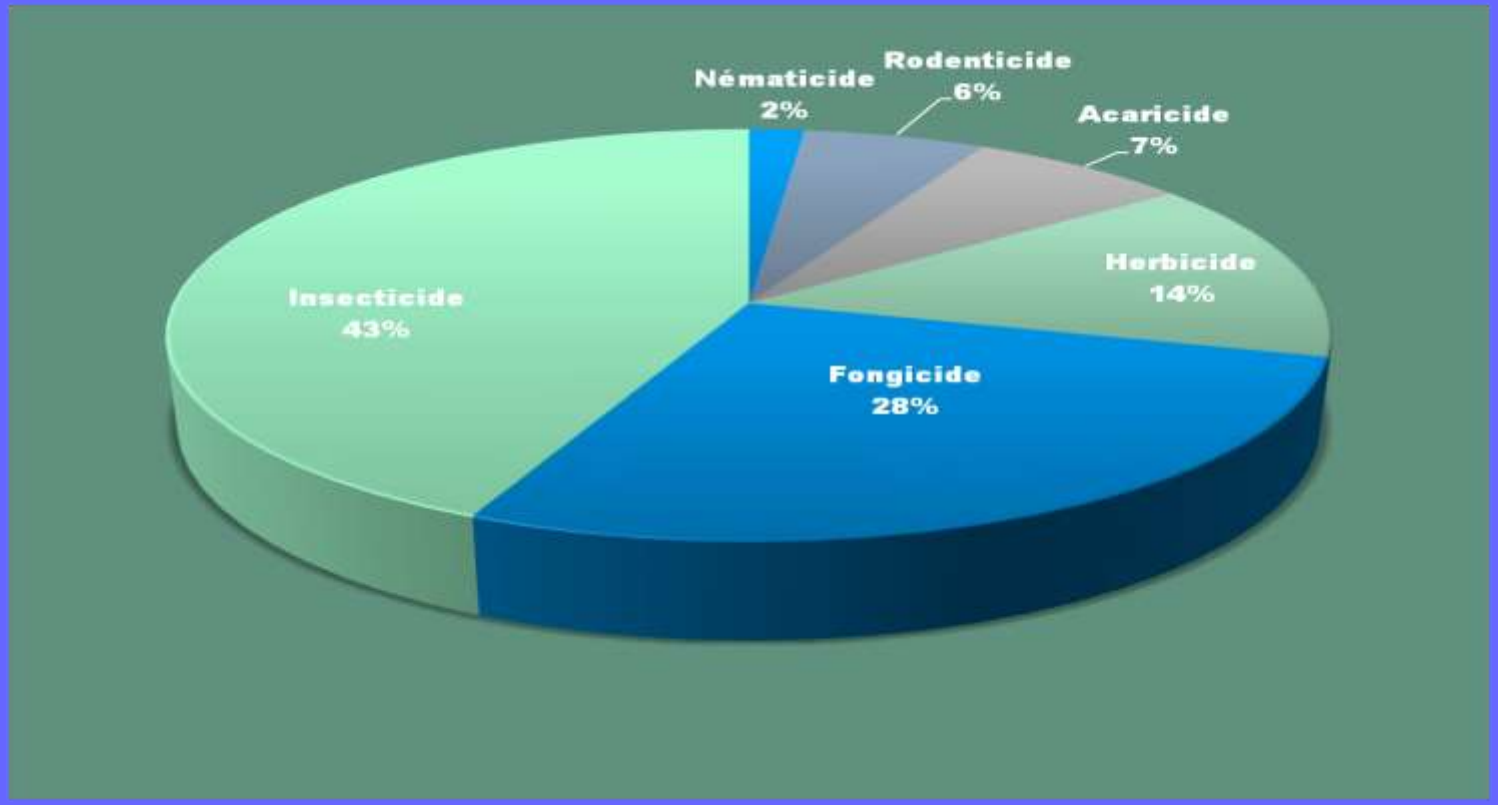
CNGPs have been created in Congo, CAR, Chad, & Equatorial Guinea

- The creation of CNGPs in the other countries is in progress

1. Comités Nationaux de Gestion de Pesticides

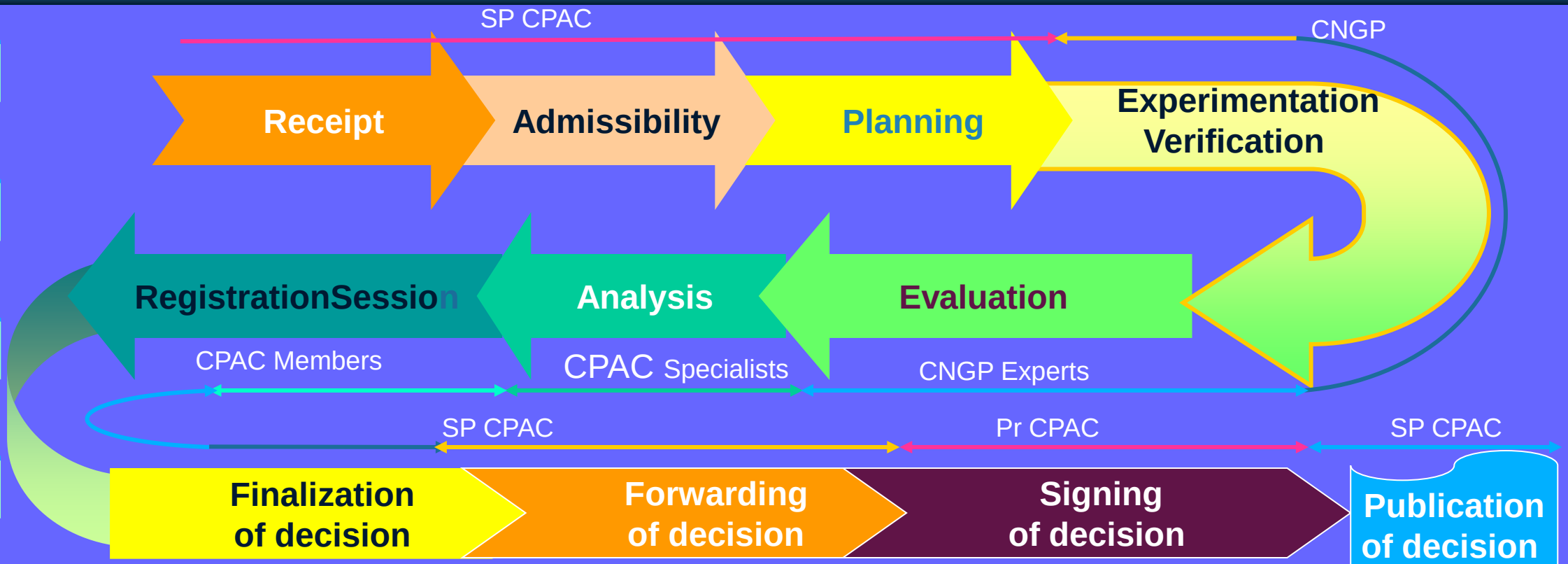
CPAC

Current status of the management of pesticides in the CEMAC zone, 2013



A little more than 600 formulations, comprising around 200 active substances, are in circulation in the CEMAC zone.

Outline of Registration file processing circuit common to CPAC



SPCPAC:: *Permanent Secretariat of the Central Africa Pesticides Committee*
CNGP *: NationaLPesticide Management Committees*
PrCPAC *: President of Central Africa Pesticides Committee*

Constraints/Shortcomings

1. CPAC was established for the entire Central African region ECCAS (Economic Community of Central African States), and includes 11 countries. But, due to lack of capacity, this initiative has concentrated on the six member states of CEMAC. While the 5 other CEEAC countries, who are not part of CEMAC, have the same problems & some countries, such as Sao Tome & Principe & the DRC, have expressed their interest in becoming CPAC members;
2. CPAC does not yet master the management of public health and hygiene pesticides, especially of those used in vector control;
3. The scientific functioning of CPAC is currently disturbed by political-administrative problems.

Proposed Solutions

1. **Integrate the other 5 central African countries into CPAC:**
   - ✓ Organize a reunion of experts from all 11 member countries of ECCAS;
   - ✓ Revive the CPAC units which were created in the CEMAC zone and establish these units in the other 5 member countries of ECCAS;
2. **Train the experts of central Africa in the management of public health and hygiene pesticides, and especially of those used in vector control;**
3. **Revive the scientific remit of CPAC, in addition to the political and administrative remits**

CPAC

Conclusion: Advantages of harmonizing Pesticide Management Policies

- Optimization and increase of security of the Pesticides Market
- At a subregional level, the Regional Pesticide Homologation Committees in Central Africa will decrease market access barriers (more detail on following slide)
- Counterfeiting and fraud will no longer benefit from the relaxed borders and spread rapidly
- Supervision and monitoring of vector control procedures:
  - Traceability of actions, with the possibility of rectifying them
  - State infrastructure and expertise complementarity
- Etc.

Conclusion: Reducing market access barriers for the CEEAC region

1. **The pooling of expertise & infrastructure, as well as the harmonization of procedures regarding pesticide management, will stabilize the ECCAS market, of about 145 million potential consumers, attracting investors through:**
   - The adoption of a single regulatory framework, common for all 11 countries
   - The reorganization of the 11 national registration commissions into a single common registration body, to serve all 145 million consumers. Investors will only apply to a single common registration committee to meet the 145 million consumers

2. **Counterfeiting and fraud will be prevented in a more effective manner once the post-registration control and monitoring operations are harmonized and managed by a strong sub-regional network. Thus, good quality pesticides will have easier access to the market, without the threat of the unfair competition created by counterfeiting and fraud**

Conclusion

- Once the market is secured and optimized, counterfeiting and fraud under control, vector control and management policies harmonized, the sensitization, information and training system functional, the effectiveness of action will be guaranteed.
- If this vector control regulation system is operational, it will be able to mobilize and channel the efforts of all partners into a unique direction in order to avoid the dispersion of these efforts.

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Third working session: 10:50–12:00pm

Recommendation only: Participants free to go to session of choice

PQ QA discussion

Presenter

World Health Organization

M. McDonald
D. Mubangizi

Participants

Academia & other global health partners: K. Bahl, A. Court, L. Hall, H. Koenker, J. Phumaphi, M. Renshaw

Bill and Melinda Gates Foundation: S. George, H. Kettler, M. Lumpkin, S. Nazzaro, V. Williams, J. Zhou

Industry: T. Bonertz, R. Bosselmann, A. Butenhoff, A. Bywater, A. Hirooka, B. Jany, B. Johnen, T. H. Larsen, K. Mori, H. Pates Jamet, F. Schmitt, E. Weinmueller

Procurers: A. Cameron, M.T. Jallow, E. Jensen, J. Kolaczinski, A. Leonard, S. Turner, J. Wallace, J. Woziniak

IVCC: N. Hamon, T. McLean, S. Rees, L. Rossi

NMCPs: N. Frempong, E. Orefuwa

NRAs: B. Bouato, L. C. Kafita

WHO: D. Engels, A. Mnzava, M. McDonald, M. Ward

Rapporteur

TBD

Dupont Ballroom *(general session room)*

GLP: Discussion of outstanding questions[1]

Lead

World Health Organization

R. Yadav

IVCC

D. Malone

Participants

Academia & other global health partners: A. Costero-Saint Denis, S. James, S. Jennings, K. Malmud-Roam, C. Mbogo, M. Rao, D. Summa

Bill and Melinda Gates Foundation: P. Berry, D. Strickman, S. Miller, M. Reddy

Industry: R. Arrington, R. Flinn, J. Invest, J. Lucas, R. McAllister, M. Meier, C. Ogihara

Procurers: J. Cutler, C. Fornadel, M. Fotheringham, A. Jafarov

IVCC: M. Mondy

NRAs: C. Kanema

WHO: V. Akula, E. Temu

Rapporteur

TBD

Georgetown room

1. Plan for SOP revision & publication, selection of accreditation pathways, communication plan for test sites, role of DQTF, etc.

Key takeaways from the Equivalency Consultation

Current equivalency process tests specifications, TC/TK, and hazard; not efficacy or AI release profile through product life

- Broad recognition that equivalency process is valuable for market, but should be reevaluated to ensure products are efficacious, in addition to safe, throughout intended duration of use

General consensus that equivalency process does not ensure that equivalent products have the same efficacy in the field as originators

- Procurers show preference to originator products due to efficacy concerns and compensation for development cost
  - PMI conducts phase II testing before procurement, GF weights originator products in procurement decisions
- CropLife shared data showing an equivalent product did not perform equivalently to the originator net in efficacy tests
- Some countries (China & Nigeria (which retests all products)) retest equivalents locally; China requires one year of efficacy data

Broad alignment on the need for additional quality measures for both equivalent and originator products; in-line with PQT evaluation

- Enthusiasm exists for new system and additional quality tests by WHO from all stakeholders
- New system will include manufacturing inspections, field tests, post-marketing evaluations (including variations), and post-marketing monitoring and surveillance

Consensus suggestions generated during meeting; to be considered by WHO during creation of PQT vector control evaluation system in 2016

Suggestions from equivalency consultation attendees include developing robust quality assurance and control processes

Inclusion of additional efficacy data requirements for equivalency

- **For LLIN**: phase 1 required for interim recommendation, phase 2 for full recommendation
  - Explore durability criteria when nets are distributed in field for full recommendation of LLINs
  - Use of pass fail criteria only after tests are validated
- **For IRS**: phase 2 for full recommendation (skip phase 1)
- **Space spray, larvicides**: phase 2 for full recommendation

Development of robust QA/QC process including overall manufacturing process submitted for evaluation of originator and equivalent products

- Postmarketing evaluation (including post marketing variations)
- Post launch monitoring and surveillance
- Field testing

Identification of research needs for validation, development, and addition of laboratory tests for specifications to evaluate long term durability and long term stability for slow or controlled release products for both originator and equivalent products

Suggestions to be considered by WHO during transition to PQT assessment; Additional comments made by Agrocare since consultation

Suggestions for quality standards broadly in line with current PQT system for medicines, diagnostics, and vaccines

	Assessment of bioequivalence studies	Pre-listing manufacturing site inspections	Post-listing manufacturing site inspections	Post-listing quality assurance
Description	**Assessments of bioequivalence studies to ensure Good Clinical Practice (GCP)** ▪ Occurs for each study on a risk adjusted basis	**Manufacturing site inspections to ensure Good Manufacturing Practice (GMP)** ▪ Occurs during dossier assessment before PQ listing ▪ Based on Site Master File[2] (SMF) submitted with dossier	**Manufacturing site inspections to ensure Good Manufacturing Practice (GMP)** ▪ Occurs after PQ listing, based on risk assessment protocols ▪ Includes assessment of post listing variations in manufacturing site or process	**Field sampling and testing of finished products in WHO Prequalified GLP certified laboratories** **Maintenance of database for adverse quality events from stakeholders (incl. users, procurers, manufacturers)**

Vector control quality assessment will be modeled after other PQT systems; detailed information and protocols available online[1]

1. http://apps.who.int/prequal/ 2. http://apps.who.int/prequal/info_general/documents/TRS961/TRS961_Annex14.pdf

Suggestions for quality standards broadly in line with current PQT system for medicines, diagnostics, and vaccines

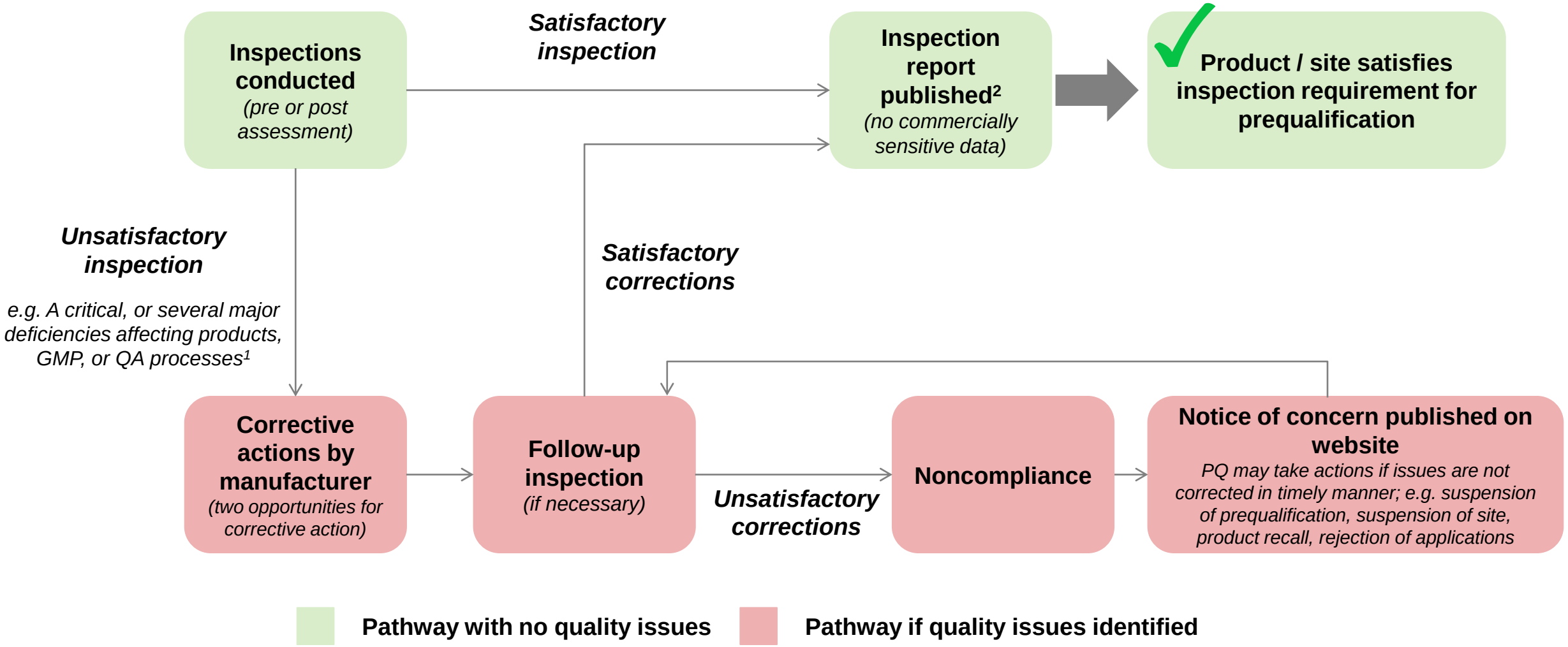
	Assessment of bioequivalence studies	Pre-listing manufacturing site inspections	Post-listing manufacturing site inspections	Post-listing quality assurance
Frequency	**Inspection of site, methods, and data for each bioequivalence study** ▪ Generally occurs once for each study at the discretion of PQT	**Inspection of each manufacturing site before PQ listing**	**Regular inspections of manufacturing sites on a ~3 year basis** ▪ More frequently based on adverse quality events, notices of concern, or recent product variation ▪ Less frequently if recently inspected by qualified stringent regulatory authority	**Scheduled and random inspections of finished products in WHO Prequalified GLP certified laboratories** **Adverse quality events collected in database**

Vector control quality assessment will be modeled after other PQT systems; detailed information and protocols available online[1]

1. http://apps.who.int/prequal/ 2. http://apps.who.int/prequal/info_general/documents/TRS961/TRS961_Annex14.pdf

Inspections process for prequalified medicines

Manufacturers given opportunity to correct non-critical inspection deficiencies before action is taken by PQT[1]



Source: http://apps.who.int/prequal/assessment_inspect/info_inspection.htm 1. Critical deficiencies or misrepresentations will result in immediate action
2. http://apps.who.int/prequal/WHOPIR/pq_whopir.htm

WHO PQT Medicines: Target inspection timelines

- ✓ **First inspection: 6 months from dossier acceptance for assessment or from site confirms it is ready.**
- ✓ **Surveillance/Routine monitoring inspection:**
  - ✓ **Due date:** risk-based, 1 – 3 years from date of previous inspection
  - ✓ **Actual date:** ± 3 months from due date.
- ✓ **Notification:**
  - ✓ Announced: 1 – 2 months before inspection.
  - ✓ Unannounced/shot announced: 0 – 7 days before inspection
- ✓ **Onsite days: 3 – 5 days.**
- ✓ **Report: 30 days from last date of inspection.**
- ✓ **CAPAs: 30 days from receipt of report (max 2 rounds, comprehensive, on CDs and not hard copies)**
- ✓ **Closing of inspection: 6 months from inspection.**
- ✓ **Follow-up inspection: 6 months from inspection**

Do you have any questions?

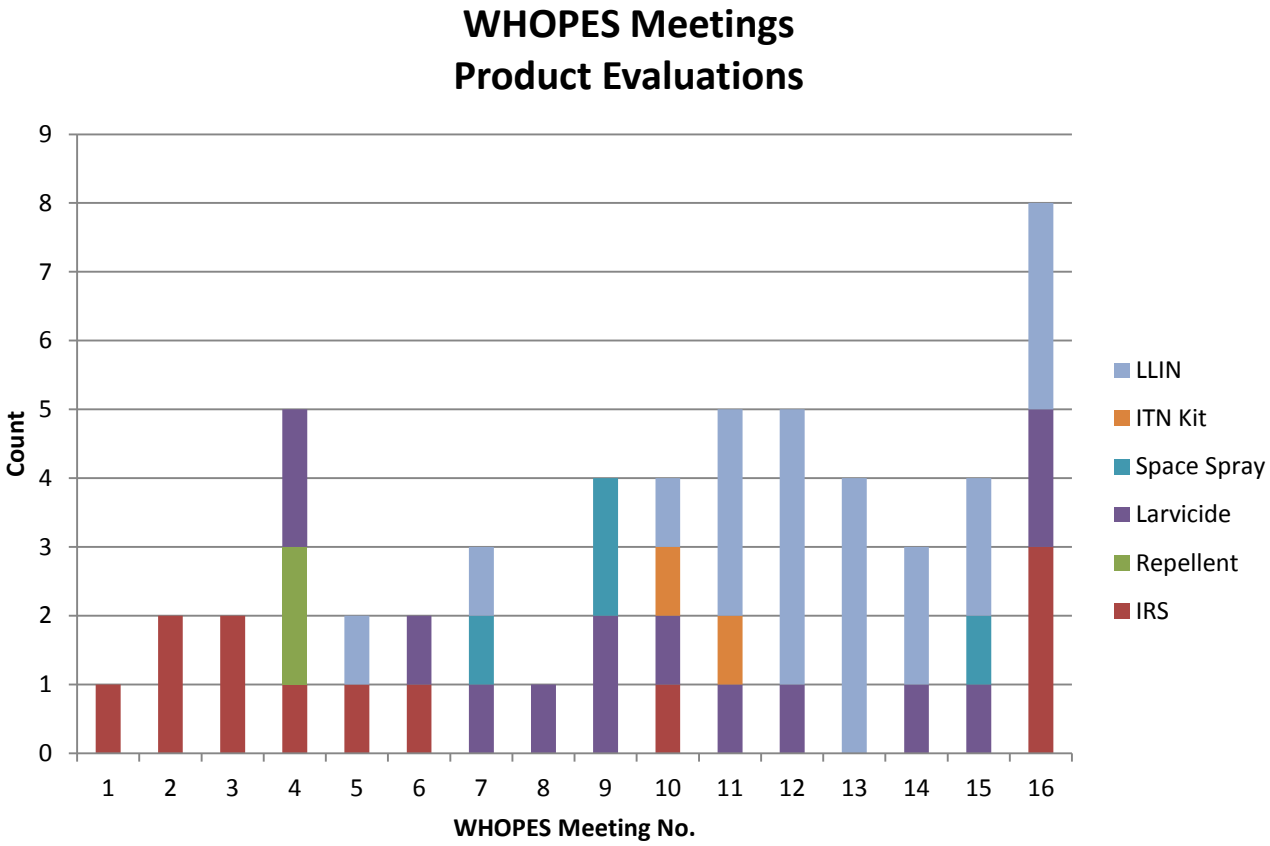
GLP working session: Objectives and agenda

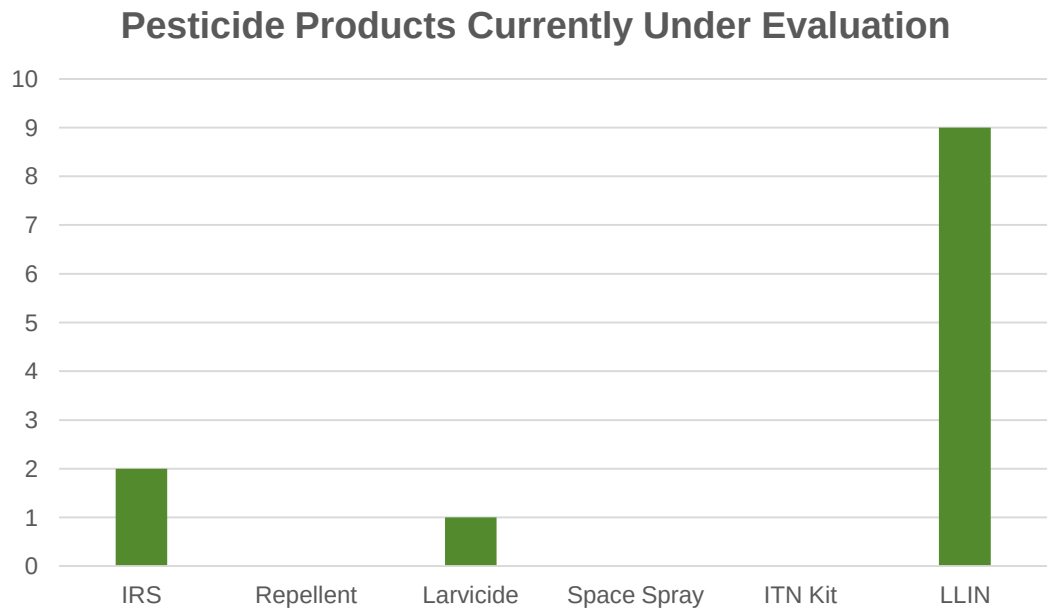
Objectives:	**Align on capacity needs** **Align on path forward to add additional GLP capacity** **Identify path forward on SOPs** **Identify other specific next steps to potentially add to GLP workstream plan**

	Detailed agenda	Time	Presenter
1	▪ Capacity mapping: Needs now and to 2025 – Testing capability – Seasonality – Resistance insect colonies & R status of wild, test species, etc. (VCAG Guidelines)	~20 min	**Rajpal/Dave** (tentative)
2	▪ Process for adding CROs (Eurofins etc) & accepting companies doing their own GLP ▪ Adding other institutions that want to become accredited, e.g. Muheza (do we need, budget?)	~20 min	**Dave** (tentative)
3	▪ SOPs: Timelines – detailed discussion by continent, site etc – How to manage, coordinate, share – SOPs and ownership/confidentiality – Where to hold SOP templates for general use, who should host – Develop list of SOPs needed for LNs IRS, SS, Larvicide	~30 min	**Dave** (tentative)
		Total: 70 min	

Capacity Mapping

Are we planning sufficient capacity ?





Alignment with VCAG

THIRD MEETING
OF THE
VECTOR CONTROL ADVISORY GROUP

ANNEX 3. GUIDELINES FOR TESTING NEW LONG-LASTING INSECTICIDAL NET PRODUCTS TO SUBSTANTIATE EFFICACY CLAIMS IN AREAS OF HIGH INSECTICIDE RESISTANCE

1. STAGE I – LABORATORY TESTING

1.3. What resistance strains should be tested?

i. Standard strains that represent the broad spectrum of major insecticide resistance mechanisms currently known to exist in mosquito vector populations should act as the reference test strains for next-generation LLINs. A list of the standard strains of insecticide-resistant mosquitoes which may be procured for testing is given at the end of this document.

2. STAGE 2 – EXPERIMENTAL HUT STUDIES

2.2. Site criteria

Experimental hut studies need to be conducted in areas where the mosquito population has high levels (RR > 10-fold) of well-characterized pyrethroid resistance. For data to be accepted, the resistance profile and species composition of the site must be determined immediately prior to, or at the same time as, the trial.

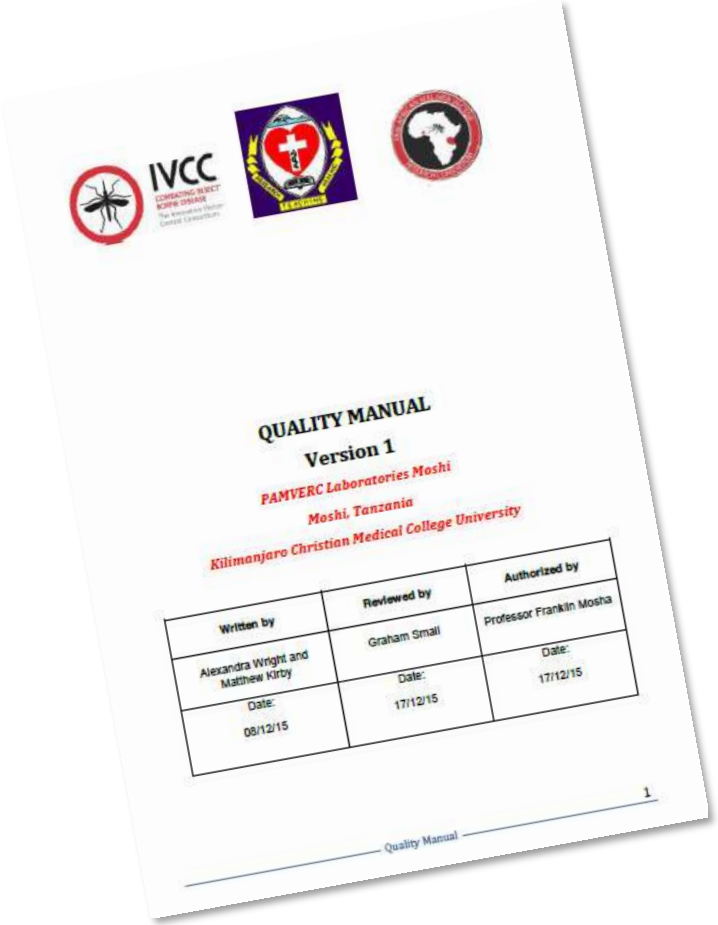
Are we considering requirement for evaluating against resistant mosquitoes?

Additional GLP facilities…….

1. **Contract Research Organisations with capacity to conduct GLP vector control trials (Eurofins/I2L Research/Syntech etc.) ?**
2. **Companies doing their own GLP studies ?**
3. **Other institutions that want to become accredited e.g. NIMR, Muheza Tanzania ?**
4. **Reviewing, updating supporting current sites beyond accreditation ?**

Standard Operating Procedures (SOPs)

- Listing of SOPs required for the conduct of vector control product evaluations
  - LLINs
  - IRS
  - Space Spray
  - Larvicide
  - Repellent
- How do we manage, coordinate and share SOPs?
- Issues of ownership and confidentiality?
- Hosting of SOPs for general use?



Do we need further workshops to resolve?

March 23 agenda

Agenda item	Timing
Breakfast	8:00–8:30
Procurement: Progress summary, discussion on 2016 objectives and Q&A	8:30–9:20
GLP: Progress summary (including update from DQTF), discussion on 2016 objectives and Q&A	9:20–10:15
Break	10:15–10:30
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Working session: (a) PQ QA discussion & (b) GLP: Discussion of outstanding questions[1]	10:50–12:00
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Closing statement ▪ Review of convening progress ▪ Overall alignment on 2016 objectives and definition of success	13:30–15:00
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Working session summary: PQ QA discussion

Key takeaways

PQ quality assurance system for vector control to be based off of principles from PQ medicines QA and international standards (e.g., ISOs)

- 4 part quality assurance system in PQ today: Assessment of studies, pre-listing site inspections, post listing site inspections, and ongoing post listing quality assurance

QA system for vector control will be phased in pragmatically after 1/1/17, and customized to circumstances of vector control

Next steps

QA system will be developed by PQT in 2016 with input from vector control experts and other stakeholders

- Specifics will be announced well in advance of 1/1/17

Working session summary: GLP – Discussion of outstanding questions

Key takeaways

Sites selected for GLP accreditation should be able to test new product types & resistant strains

- Now most products reviewed are LLINs & IRS, but in the future, many products (Wolbachia, etc.) may not be pesticides
- VCAG guidelines exist for testing resistance, but outstanding questions remain, especially for evaluating resistant strains

Robust communication needed so that more sites can become accredited (through their own financing)

- Although more sites will want support for accreditation, funding is limited & need to see business need
- Opportunity to approach QC & agriculture GLP accredited sites in Africa about entomological capabilities, including government sites
- NMCPs and NRAs need to be engaged to ensure understanding the data generated by GLP is as robust and acceptable as WHOPES CC data

Consensus in working group that research organizations (Eurofins, Syntech, etc.) **and companies should be able to use their own GLP sites for dossiers**

Next steps

Conduct a capacity analysis to ensure that I2I supported GLP sites are building capacity for new products (e.g., transgenic mosquitos, resistant strains)

Prioritize development and publication of SOPs for testing resistant mosquitoes

Communicate policy changes about GLP and involve scientists from African sites in future discussions

- Sites that are motivated to (a) become accredited or (b) expand entomological test capacity should be engaged
- Financial support through I2I is limited, but training of local GLP experts can coordinate and train additional sites
- Share GLP manuals and SOPs broadly

IR-4 is hosting non-confidential SOP library in short term, WHO may host in the longer term

Data Quality Task Force to sit within GLP workstream, to focus on longer-term, quality issues

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Significant progress made between London & Washington convenings

Key topics discussed in London	Progress presented in Washington
Manufacturer generated data & data ownership	▪ Significant progress made in GLP site accreditation & mapping of timelines ▪ WHO accepting manufacturer generated data (generated at non-GLP sites)
Equivalency consultation	▪ Reached consensus on suggestions for criteria for equivalency – Participation from equivalent and innovator manufacturers, procurers, NRAs, country programs, WHO etc.
Country-level engagement	▪ Significant increase in country involvement ▪ Path forward to continue to increase country- and regional-representative engagement

For discussion: Action items to address coming out of Washington convening

Working session	Topic	Action item	Who	When
March 22 13:30–15:00	Primer on WHO Pre-Qualification	Develop pathways with requirements and timelines	PQT	
	Value-based procurement	Define opportunities to catalyze normative guidance	Procurement workstream	
March 22 15:30–17:00	Normative guidance	Share existing classes of new tools (paradigms)	NTD	
	Discussion of country-level engagement	Develop strategy and timeline for country & regional engagement	I2I LT	
March 23 10:50–12:00	PQ QA discussion	Create QA standards for VC-products	PQT	
	GLP: Discussion of outstanding questions	Finalize GLP manual	IVCC	

Other key action items?

Key success factors going forward to maintain momentum

1 **Continue to develop creative, effective, lasting solutions**

- Design the right solutions – not the easy solutions

2 **Build on current momentum to develop ambitious timelines and deliver quick-wins**

- "Don't let the perfect be the enemy of good"

3 **Maintain open communication and close collaboration between all stakeholders**

- Sustainable collaboration facilitating honest elevation of issues and rigorous tracking of results
- Channel feedback to I2I Leadership Team to enable iteration and improvement

Robust implementation oversight structure should ensure ongoing collaboration and progress

Illustrative cadence

Workstream meetings

- Push progress on collaborative tasks
- Check-in on individual stakeholder progress

Robust implementation oversight structure should ensure ongoing collaboration and progress

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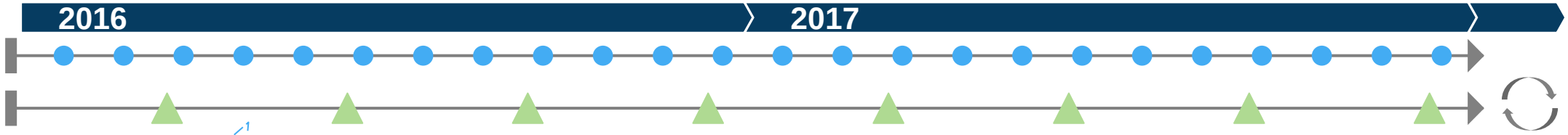

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Formal I2I check-ins

- Track detailed progress against implementation timelines
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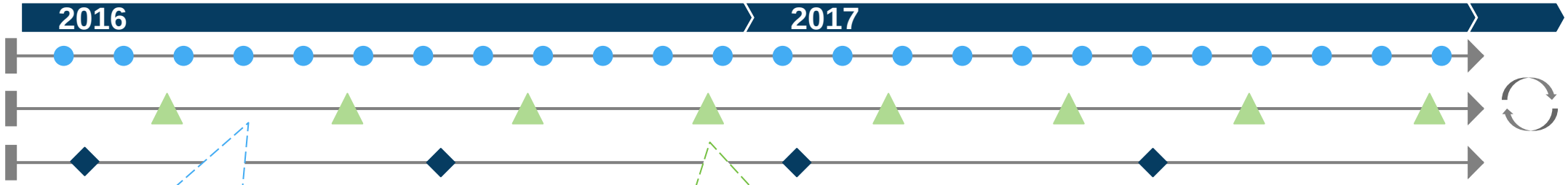

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Convenings

- Celebrate progress against implementation timelines
- Discuss issues, adapt plans as needed
- Provide broader, external, community perspective

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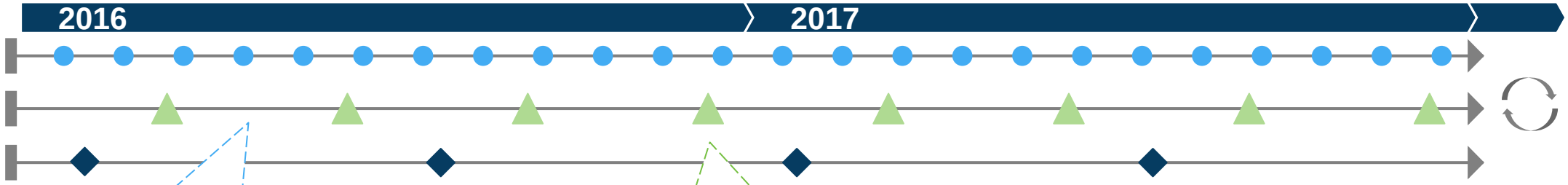

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Do not let regularity of meetings prevent raising issues as they occur & I2I LT will check-in with key stakeholders on an ad-hoc basis

Robust implementation oversight structure should ensure ongoing collaboration and progress

I2I's door is always open

Angus Spiers

angus.spiers@innovation2impact.org

+1-202-615-4499

Do not let regularity of meetings prevent raising issues as they occur & I2I LT will check-in with key stakeholders on an ad-hoc basis

Do you have any final questions or thoughts to share?

Thank you for your engagement over the past two days!

With your continuing hard work and collaboration, we can contribute to reducing the burden of malaria and NTDs

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Final, post-convening working session: 15:00-15:45pm

Convening of industry members

Lead	Participants
BILL & MELINDA GATES foundation D. Strickman	**Industry:** R. Arrington, F. Baud, T. Bonertz, R. Bosselmann, A. Butenhoff, A. Bywater, R. Flinn, A. Hirooka, J. Invest, B. Jany, B. Johnen, T. H. Larsen, J. Lucas, R. McAllister, M. Meier, K. Mori, C. Ogihara, H. Pates Jamet, F. Schmitt, E. Weinmueller **Bill and Melinda Gates Foundation:** J. Zhou

Kalorama Room

I2I collaboration model with workstream leads,

Lead	Participants
A. Spiers	**Academia & other global health partners:** C. Mbogo, J. Phumaphi, M. Renshaw **Bill and Melinda Gates Foundation:** S. George, H. Kettler, V. Williams , **IVCC:** D. Malone, M. Mondy, L. Rossi, N. Hamon **NRAs:** B. Bouato, L. C. Kafita, C. Kanema **NMCPs:** N. Frempong, E. Jensen, J. Kolaczinski, E. Orefuwa, J. Wallace **Procurers**: C. Fornadel, C. Game **WHO:** D. Engels, A. Mnzava, R. Velayudhan, R. Yadav

Georgetown room

Industry working session: Objectives and agenda

Objectives:

Discuss working session topics and consolidate industry perspectives

Align on next steps for workstream

	Detailed agenda	Time	Presenter
1	Guided discussion on industry perspectives on working session topics	~45 min	**Dan Strickman**
2	Summary of areas of alignment, open questions, & next steps	~20 min	**Angus Spiers**

Detailed agenda

Guided discussion

This is your opportunity to share your thoughts with other members, liaisons and I2I leadership. We'd like to go around the room to give everyone an opportunity to share their thoughts on three topics:

1. What is your overall view of the progress and risks associated with I2I?
2. What is your sense of opportunities and challenges in specific industry requirements for each workstream?
3. What do you think are the critical next steps for the industry workstream?

We will not be able to get to a solution for open questions in this time—our goal is to create a list of topics for further discussion ahead

Summary

We will collate the feedback and next steps to share with I2I leadership in the final 20 minutes of this session

Liaisons should emerge from the summary with priority topics to share with their respective workstreams

- Focus should be on open issues/questions as well as potential solutions

1. Requires multiple members from WHO NTD, WHO GMP, and UNITAID at convening

The following is the outcome of the industry working session discussion and was not previously presented

Working session summary: Convening of industry working group

Key takeaways

Industry workstream requests clarification on 5 key topics covered at I2I convening:

- Where are time savings expected in the new pathway?
- How will manufacturer-generated data be accepted before 2017?
- How will normative guidance change from the current system?
- Will manufacturing site inspections be required for products currently on market, or just future products?
- In what cases can VCAG provide policy setting (e.g., can Zika response be used as a template for future policy setting)?

Next steps

The industry workstream has committed to three proposals in the coming months

- High level suggested data requirements for PQT dossiers for range of vector control categories
- Recommendations on normative guidance
- Proposed updates to IRS guidelines

Workstream to engage with industry members not present at convening to ensure broad industry perspectives represented in deliverables (including additional manufacturers of non-innovator products)

Next steps for industry workstream

Align on scheduling of next workstream meeting

- Aiming for a call in May
- Agenda will include Terms of Reference document and liaison updates

Liaisons summarize feedback from this session and follow up with respective workstreams

- Consolidated industry perspectives should be shared with other workstreams prior to next industry call
- We will provide support in the next couple weeks to align with workstream leads on engagement strategy

Align on Terms of Reference

- Initial draft of the Industry workstream Terms of Reference will be sent in next week
- If you have feedback, send notes to Kristen (earle.kristen@bcg.com) by April 20th for discussion at next workstream call

Collaboration model working session: Objectives and agenda

Objectives:	**Discuss plan for I2I collaboration model** **Receive feedback on possible model improvements**

	Detailed agenda	Time	Presenter
1	▪ Guided discussion on I2I collaboration model	~40 min	**Angus Spiers**
2	▪ Summary of areas of alignment, open questions, & next steps	~5 min Total: 45 min	**Angus Spiers**

Key success factors going forward to maintain momentum

1

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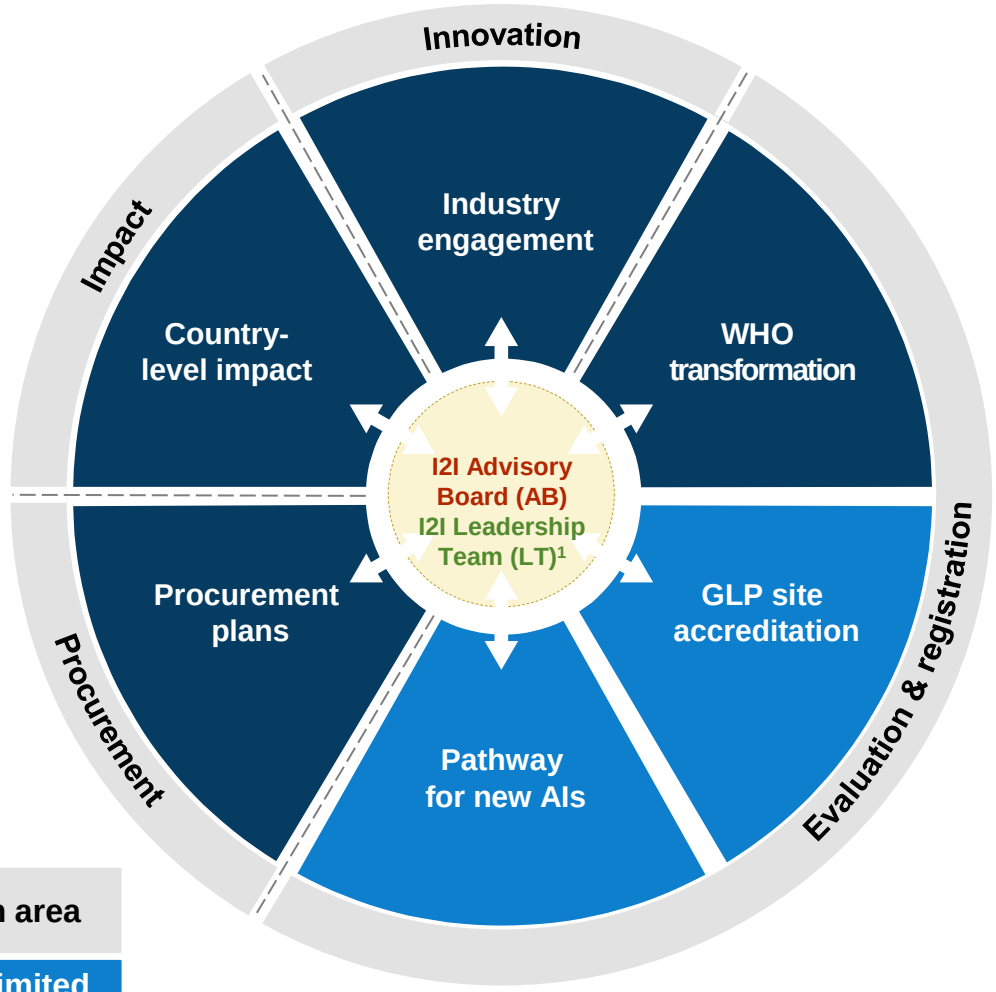
3

Maintain open communication and close collaboration between all stakeholders

- Sustainable collaboration facilitating honest elevation of issues and rigorous tracking of results
- Channel feedback to I2I Leadership Team to enable iteration and improvement

I2I workstreams will be supported by the I2I collaboration model



I2I Advisory Board (AB)

- Sets strategic direction
- Provide thought partnership to solve critical challenges

I2I Leadership Team (LT)

- Helps workstreams deliver on the overall goal and workstream specific objectives
- Coordinates across workstreams and partners with workstreams to solve challenges

Workstreams

- Lead implementation of I2I vision

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Illustrative cadence

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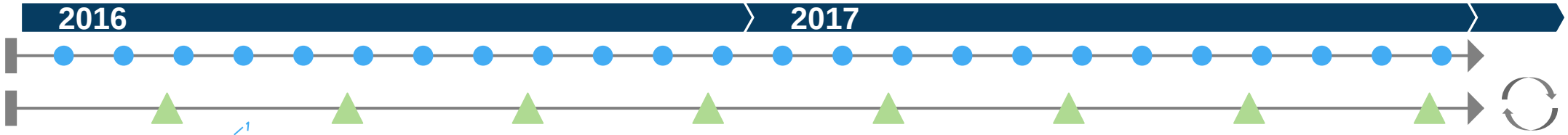

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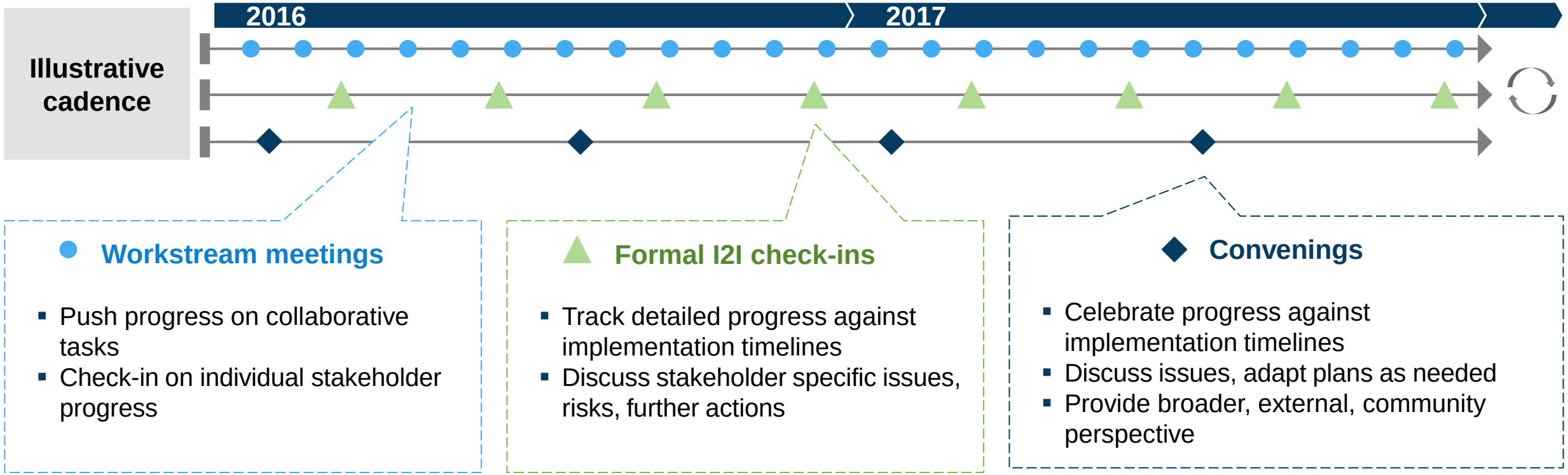

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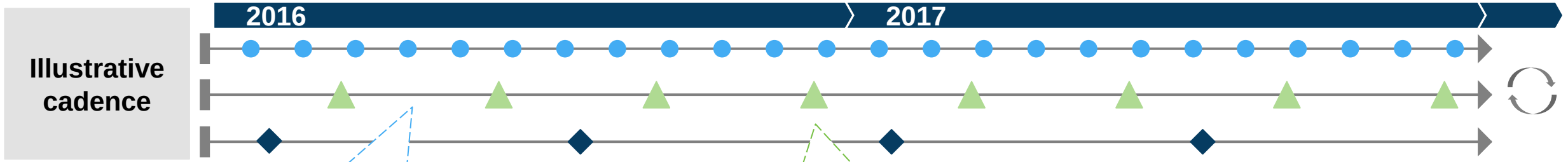

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Do not let meetings prevent raising issues as they occur; I2I LT always has its "doors open"

Does the collaboration model meet your needs to deliver on I2I's vision?

Key questions

Are there any other success factors to maintain momentum that we should consider?

Would you recommend more or less frequent touchpoints?

Is the planned mix of touchpoints (calls, meetings, convenings) **effective?**

Is there any other support that would help you achieve your workstream's objectives?

Any other suggestions to improve I2I's collaboration model?