Innovation to Impact (I2I) in Vector Control

I2I Convening | March 22-23

March 22 agenda

Agenda item	Timing
Breakfast	8:00–8:30
Welcome (from I2I Leadership Team; I2I AB Chair)	8:30–10:00
Break	10:00–10:30
WHO transformation	10:30–12:30
Lunch	12:30–13:30
Working session: (a) Primer on WHO Prequalification & (b) Value-based procurement	13:30–15:00
Break	15:00–15:30
Working session: (a) Discussion of country-level engagement & (b) Normative guidance	15:30–17:00
Recap of March 22 discussions and decisions made	17:00–18:00
Break	18:00–19:00
Dinner and drinks	19:00–21:00

I2I advisory board

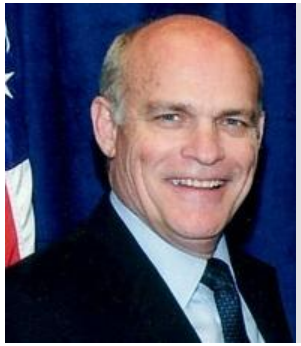
Don Bundy, PhD
- Bill and Melinda Gates Foundation
- Senior Advisor and Deputy Director Neglected Tropical Diseases

Initial chair

Joy Phumaphi
- African Leaders Malaria Alliance (ALMA)
- Executive Secretary

Christopher Game
- The Global Fund to Fight AIDS, Tuberculosis, and Malaria
- Chief Procurement Officer

Nick Hamon, PhD
- Innovative Vector Control Consortium (IVCC)
- CEO



Timothy Ziemer, Rear Admiral US Navy (Retired)
- US President's Malaria Initiative (PMI)
- US Global Malaria Coordinator

Atsuko Hirooka
- Sumitomo Chemical
- Associate Officer, Environmental Health Division

Rotating industry representative

Dirk Engels, MD, PhD
- World Health Organization (WHO) HIV/AIDS, TB, Malaria and NTD Cluster
- Director, Department of Control of Neglected Tropical Diseases

Observer

Lembit Rago, MD, PhD
- World Health Organization (WHO) Health Systems and Innovation
- Head, Regulation of Medicines and other Health Technologies

Observer

TBD
- Funder TBD (could be filled by potential additional funder of effort)
- TBD

Welcome to the I2I Director

Angus Spiers

- Senior Malaria Technical Advisory at USAID
- Deputy Director, Malaria and Child Survival at PSI
- Regional Malaria Advisory at UNICEF
- PhD, Liverpool School of Tropical Medicine

Reducing the impact of vector-borne diseases is global priority

Ambitious, yet achievable goals set for disease control; all include vector control as key part of their strategy

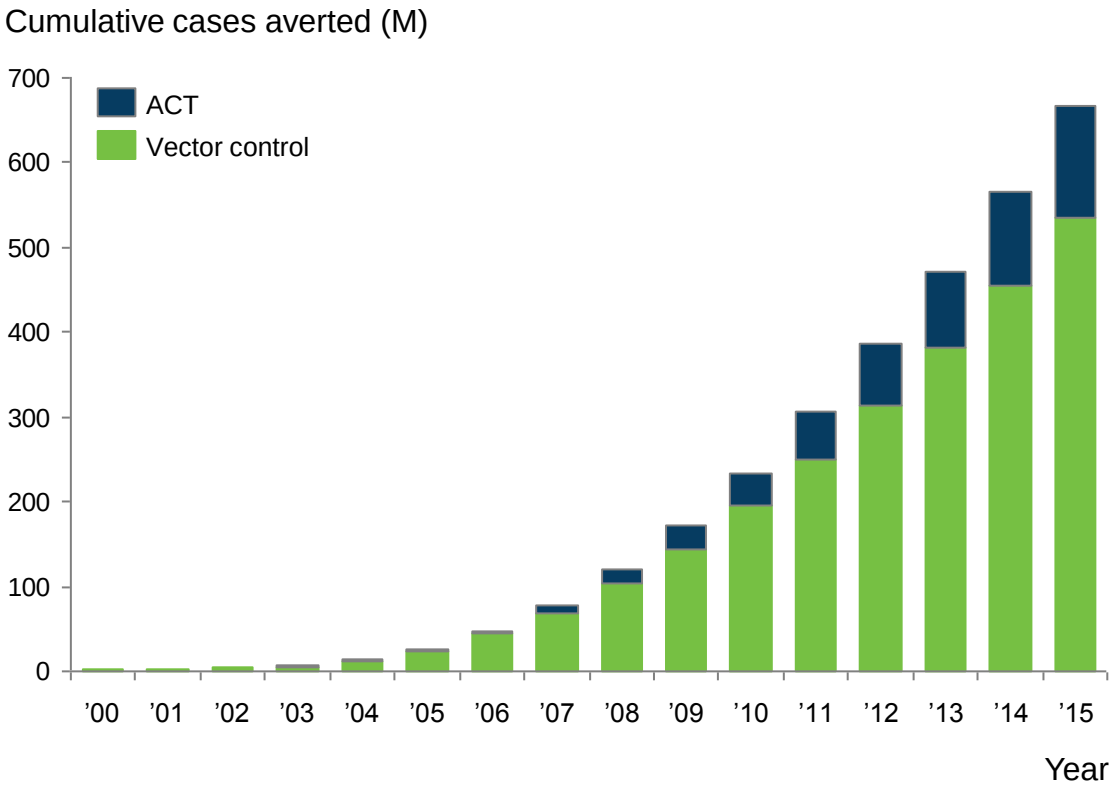
	Vision	Role of vector control in strategy
World Health Organization GLOBAL TECHNICAL STRATEGY FOR MALARIA 2016–2030	Reduce malaria mortality and incidence by 90% by 2030	Universal access to quality-assured, appropriate vector control 1st priority
FROM Aspiration TO Action	A malaria-free world by 2040	Innovative vector control methods needed
World Health Organization NEGLECTED TROPICAL DISEASES A ROADMAP FOR IMPLEMENTATION; UNITING TO COMBAT NEGLECTED TROPICAL DISEASES	London Declaration aims for 2020 control, elimination and eradication targets for 10 WHO 2020 Roadmap NTDs[1]	Vector control plays role in control of dengue and Chagas disease, leishmaniasis, lymphatic filariasis and schistosomiasis

"No one . . . should die from the bite of a mosquito, a sandfly, a blackfly or a tick."– Dr. Margaret Chan

1. Lymphatic Filiariasis, Trachoma, Soil-Transmitted Helminths, Onchocerciasis, Schistosomiasis, Leprosy, Dracunculiasis, Visceral Leishmaniasis, Chagas disease and HAT

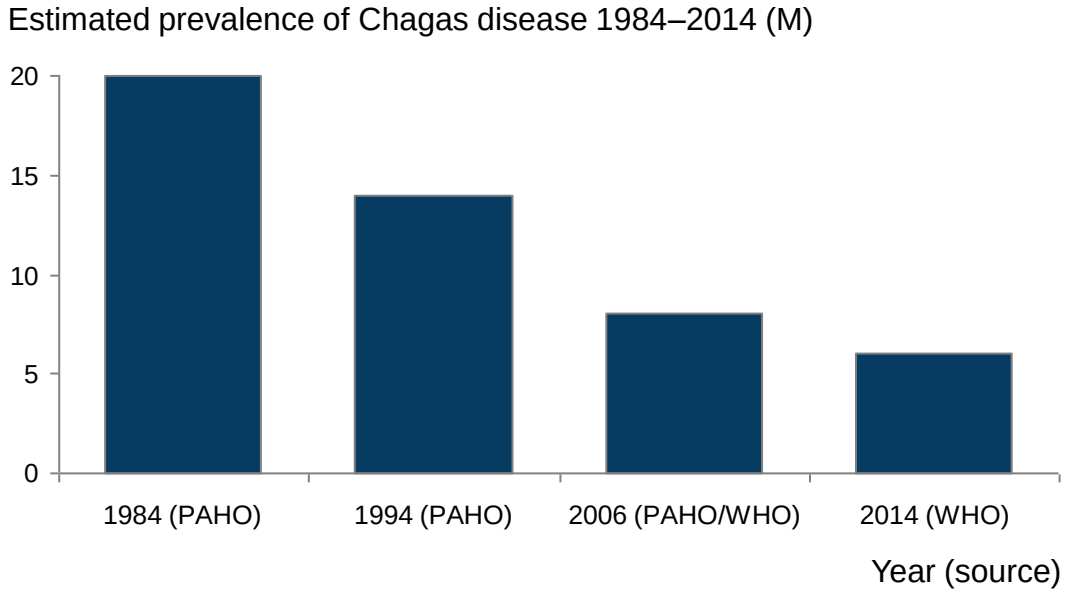
Vector control contributed significantly to progress towards reducing the burden of malaria and NTDs over the past 15 years . . .

Vector control responsible for ~80% of malaria cases averted in past 15 years



Vector control also played critical role in combating neglected tropical diseases

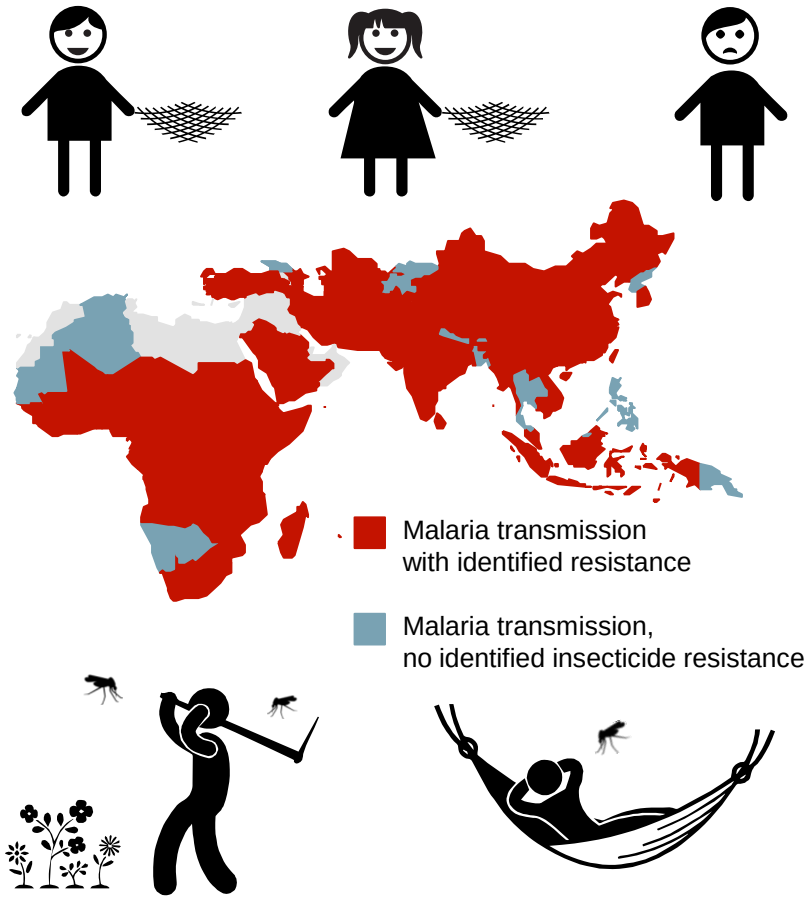
South American countries have **more than halved the incidence of Chagas disease** through mapping, **insecticide spraying**, and surveillance



Sources: Bhatt, S., D. J. Weiss, E. Cameron, D. Bisanzio, B. Mappin, U. Dalrymple, K. E. Battle, C. L. Moyes, A. Henry, P. A. Eckhoff, E. A. Wenger, O. Briët, M. A. Penny, T. A. Smith, A. Bennett, J. Yukich, T. P. Eisele, J. T. Griffin, C. A. Fergus, M. Lynch, F. Lindgren, J. M. Cohen, C. L. J. Murray, D. L. Smith, S. I. Hay, R. E. Cibulskis, and P. W. Gething. "The Effect of Malaria Control on Plasmodium Falciparum in Africa between 2000 and 2015." *Nature* 526.7572 (2015): 207-11. Web. IVCC, WHO Global Plan for Insecticide Resistance 2012, Interviews, Lies Durnez and Marc Coosemans "Residual Transmission of Malaria" 2013.
WHO. "Neglected Tropical Diseases: A Statistical Update – Latest Data Available" http://www.who.int/neglected_diseases/NTD__A_statistical_update_latest_data_available.pdf?ua=1.
Massad, E. "The Elimination of Chagas' Disease from Brazil." *Epidemiol. Infect. Epidemiology and Infection* 136.09 (2007): n. pag. Web.

...but the vector control ecosystem must overcome challenges of coverage, resistance & gaps in protection to meet global malaria & NTD disease goals

Incomplete access to and insecticide resistance threatens current tools and new tools are needed to protect across settings



To solve these challenges, we must improve innovation, efficiency and quality

Innovation

Dis-incentives for innovation and investment in the development of novel vector control tools

Efficiency

Long delays in product evaluation and introduction to market

Quality

Lack of systematic quality assurance systems to ensure efficacious and safe products are delivered to the field sustainably

Sources: IVCC, WHO Global Plan for Insecticide Resistance 2012, Interviews, Lies Durnez and Marc Coosemans "Residual Transmission of Malaria" 2013, "2015 World Malaria Report"

I2I has come a long way and is implementing solutions to these challenges

I2I has come a long way over the past 3 years . . .

Opinion to fact
Q4 2013 – Q4 2014

Fact to alignment
Q4 2014 – Q1 2015

Alignment to action
Q1 2015 – Q2 2015

Implementation
Q2 2015 – onward

Today

. . . and has achieved significant progress in improving the vector control ecosystem

Innovation

- Industry committed to increasing partnership
- Shifting to manufacturer generated data

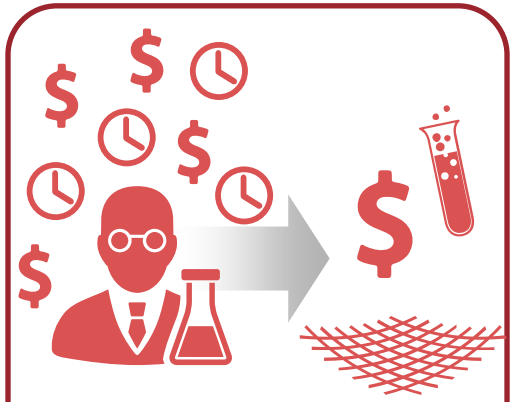
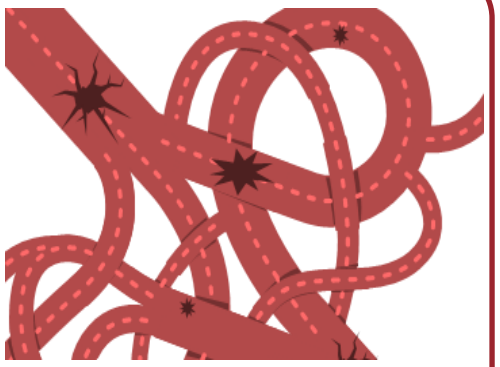
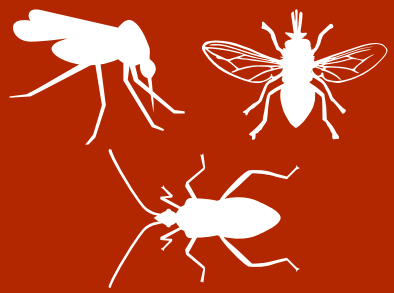
Efficiency

- WHO NTD and PQ change plan execution initiated
- Progress towards value-based procurement

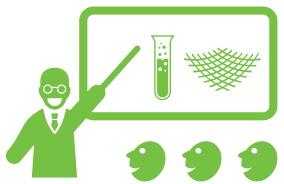
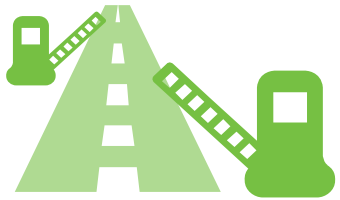
Quality

- Consensus at WHO equivalency consultation to enhance quality controls for all products
- WHO developing quality control system

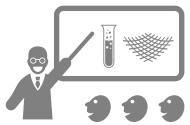
I2I stakeholders are transforming the vector control ecosystem

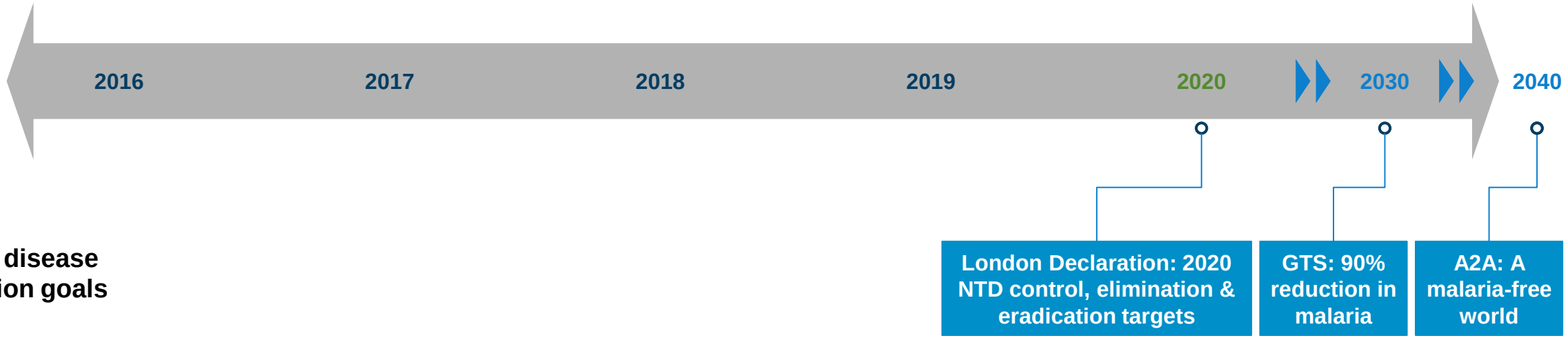
Vision area:	Innovation	Evaluation & registration	Procurement	Impact
Before	 Insufficient incentives	 Long delays & no QC	 Slow guidance & price-driven	 Delayed access

More than 30 stakeholder organizations engaged in developing the I2I vision to improve the vector control ecosystem

Workstreams	1 Industry engagement	2a WHO transformation 2b GLP site accreditation 2c Pathway for new AIs	3 Procurement	4 Country-level impact
After	Increased investments 	Efficient evaluation 	Accelerated, value-based procurement 	Effective products in the field 

Transforming the vector control ecosystem over the next 5 years will lay the foundation for achieving global targets for the reduction of malaria & NTDs

Vision area:	Innovation	Evaluation & registration	Procurement	Impact
Vision under implementation of I2I	Increased investments 	Efficient evaluation 	Accelerated, value-based procurement 	Effective products in the field 



Global disease reduction goals

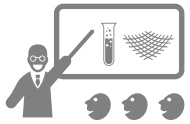
Note: Timing to be confirmed by workstreams

Innovation: Will improve market conditions and lead to the development of needed innovative, effective products

Vision area: **Innovation**

Vision under implementation of I2I

Increased investments



Market conditions improved[1]

New tools & AIs

2016 2017 2018 2019 2020 2030 2040

Global disease reduction goals

London Declaration: 2020 NTD control, elimination & eradication targets

GTS: 90% reduction in malaria

A2A: A malaria-free world

Note: Timing to be confirmed by workstreams
1. E.g., full data ownership at GLP sites, equivalency, value-based procurement

Evaluation & registration: Will implement a fair, predictable, and efficient global evaluation system by 2017

Vision area: **Evaluation & registration**

Vision under implementation of I2I

Efficient evaluation

PQ begins vector control assessment

2016 | 2017 | 2018 | 2019 | 2020 | 2030 | 2040

Accelerated pathway for new products

Initial GLP accreditation

Global disease reduction goals

London Declaration: 2020 NTD control, elimination & eradication targets

GTS: 90% reduction in malaria

A2A: A malaria-free world

Note: Timing to be confirmed by workstreams

Procurement: Will facilitate improved normative guidance & enhanced value based procurement

Vision area:

Procurement

Vision under implementation of I2I

Accelerated, value-based procurement

Normative guidance improved

Procurement agencies consider including **additional traits**[2]

2016 | 2017 | 2018 | 2019 | 2020 | 2030 | 2040

Procurement agencies consider including **durability metrics in ITN procurement**[1]

Global disease reduction goals

London Declaration: 2020 NTD control, elimination & eradication targets

GTS: 90% reduction in malaria

A2A: A malaria-free world

Note: Timing to be confirmed by workstreams
1. Pending expert review from WHO VCTEG 2. Pending evidence-based review

Impact: Will ensure high-quality innovative products are used broadly and effectively in the field

Vision area:

Impact

Vision under implementation of I2I

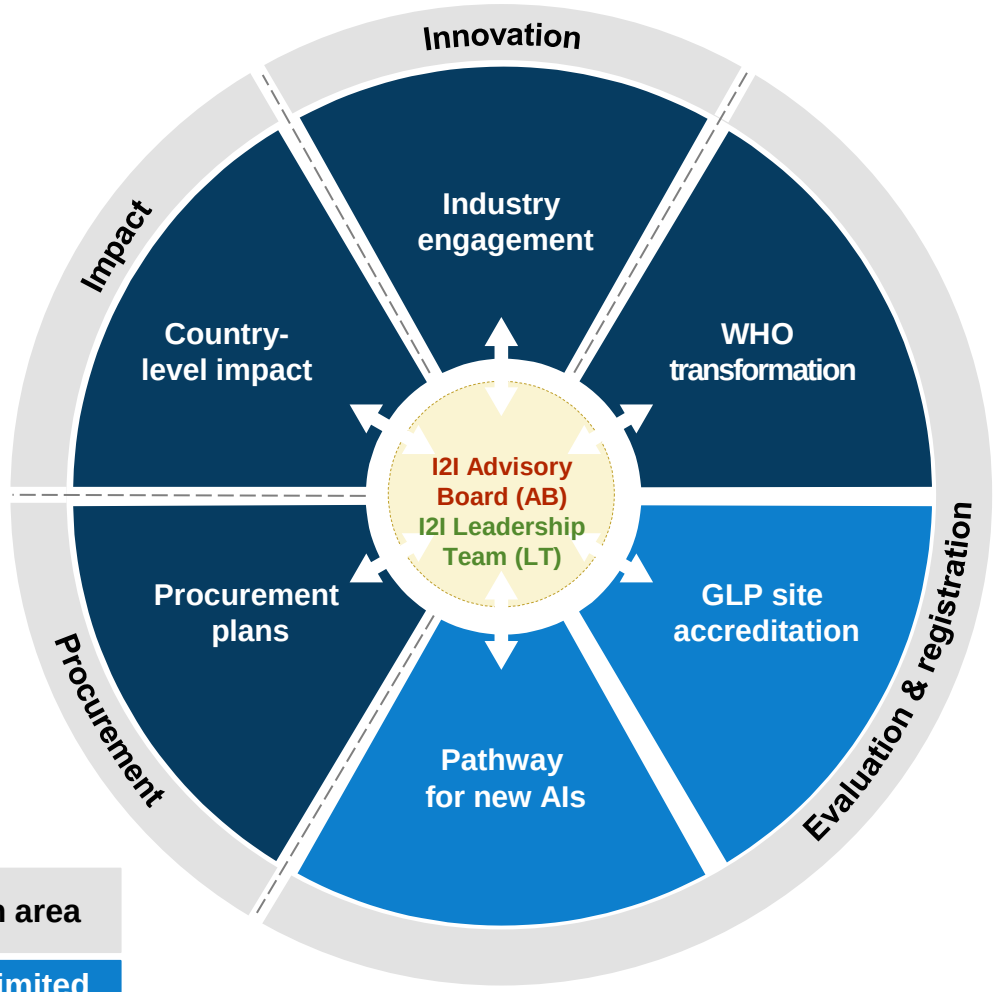
Effective products in the field

Global disease reduction goals

- **London Declaration: 2020 NTD control, elimination & eradication targets**
- **GTS: 90% reduction in malaria**
- **A2A: A malaria-free world**

Note: Timing to be confirmed by workstreams

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

Objectives for today

1 **Recap overall I2I vision, align on 2016 objectives, and solidify commitment of stakeholders to implementation**

- Assess what has been achieved and identify gaps to achieving ambitious 2016 objectives and overall vision

2 **Ensure all stakeholders understand the value of each workstream's progress to implementation of I2I Vision**

3 **Resolve technical and non-technical issues in small group working sessions**

Overall goal to further strengthen collaboration and momentum for implementation

March 22–23 Convening: Agenda

March 22

	Agenda item	Timing
	Breakfast	8:00–8:30
	Welcome (from I2I Leadership Team; I2I AB Chair) ▪ Recap of progress ▪ Overview of I2I vision and objectives ▪ Introduce I2I governance structure ▪ Q&A	8:30–10:00
	Break	10:00–10:30
	WHO transformation ▪ Overview of the transformation and key achievements ▪ NTD: Progress summary ▪ PQ: Intro to Prequalification ▪ Q&A	10:30–12:30
	Lunch	12:30–13:30
1	**Working session:** (a) Primer on WHO Prequalification & (b) Value-based procurement	13:30–15:00
	Break	15:00–15:30
2	**Working session:** (a) Discussion of country-level engagement & (b) Normative guidance	15:30–17:00
	Recap of March 22 discussions and decisions made	17:00–18:00
	Break	18:00–19:00
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March 23

	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
3	**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
4	**Working session 4:** (a) Convening of industry working group & (b) I2I collaboration model	15:00–16:30

Working sessions | Social time (break or meal) | Plenary

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

To download the materials presented at the convening, please go to:

http://www.innovationtoimpact.org/convening

Complimentary wifi network: The Dupont Circle Hotel

Guiding principles for convening

Today is an opportunity for key I2I stakeholders to discuss the future of the vector control landscape. To facilitate a successful meeting, we suggest the following guiding principles:

Forward looking

- Not a detailed review of past performance
- Focus on constructive dialogue and partnership

Time limits

- Stay within allotted time for your presentation and working session
- Things not completed in working sessions should be addressed in workstreams, with additional follow-ups as needed

Action oriented

- Focus on solutions to outstanding questions and achievable, key next steps to drive change forward
- Ensure buy-in and ownership of solutions

Do you have any questions or input on the I2I vision or near-term priorities?

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Introductions

WHO NTD

Dr. Raman Velayudhan, Coordinator, Vector Ecology & Management
Department of Control of Neglected Tropical Diseases (NTD)
Workstream lead

WHO PQT

Dr. Mark McDonald, Coordinator, Prequalification Team (PQT)
Regulation of Medicines and other Health Technologies
Workstream lead

WHO GMP

Dr. Abraham Mnzava, Coordinator, Vector Control Unit
Global Malaria Program (GMP)

World Health Organization

I2I WHO transformation team leaders

Agenda

1	**Overview of transformation *(~20 mins)***	**Raman V., Mark M., Abraham M.**
2	**NTD progress (~30 mins)** ▪ Overview of NTD grant ▪ Key achievements to date ▪ End state for NTD vector control activities	**Raman V.**
3	**Normative guidance activities *(~10 mins)*** ▪ Summary of enhanced normative guidance for NTD and GMP	**Abraham M.**
4	**PQT system *(~30 mins)*** ▪ Introduction to PQT ▪ Explanation of current PQT systems (Rx, Vx, Dx) and successes ▪ Overview of PQT grant ▪ Timeline for change	**Mark M.**
5	**Split of functions *(~10 mins)*** ▪ How we will work together	**Raman V., Mark M., Abraham M.**

We will welcome questions at the end of the presentation

Recall: WHO transformation supports innovation, efficiency and quality

End state vision

Innovation	Increased partnership, prioritization and investments in the development of new vector control tools and AIs driven by an **improved and standardized vector control evaluation**, registration and procurement system
Evaluation	**Fair, predictable and efficient global evaluation system based on manufacturer generated data, systematic quality controls and clear pathways for novel public health AIs**
Registration	Harmonized and streamlined registration processes further relying on a **strong evaluation system**
Procurement	Enabled by global standards, testing of product attributes and **normative guidance**
Impact	**High quality, broadly and effectively used innovative products** in the field to support global and national strategies

WHO vision of success:

Greater drive for development of innovative high quality products and efficient evaluation systems in place, with normative guidance to support effective use of products in the field

Recall: WHO leadership is strongly committed to vector control reform

WHO has initiated ambitious reforms in response to needs of vector control community

- WHO **recognizes the need for reforms** regarding evaluation of innovative tools, improving quality in the system, standardized vector control evaluation and timely development of normative guidance, etc.
- To support the development, evaluation, quality control, adoption, and sound management of pesticides, **a detailed plan for the WHO transformation was presented** at the June I2I convening
- Since then, **WHO has been awarded 2 grants** based on the plan to improve evaluation systems and procedures, and to strengthen vector control normative functions.
- Material shown today is **reflective of the progress made by NTD, GMP, and PQT** towards the goals of the WHO transformation

WHO leadership clearly expressed full support of this change

Quotes from selected members of WHO leadership

"A global health agenda that gives higher priority to vector control could save many lives and avert much suffering."

"I fully support this WHO vector control change and am looking forward to see significant progress by the end of 2016 and celebrate success in 2017."

Margaret Chan,
Director-General WHO

"I2I is a really important vector control reform, in line with WHO reforms for drugs, vaccines and diagnostics."

Marie-Paule Kieny,
Assistant Director-General for Health Systems and Innovation

Recall: WHO reform will deliver several benefits to all key stakeholders in the space

For industry

Faster, clearer and more transparent vector control product evaluation system

- Revised evaluation committee and procedures
- Data generation by manufacturers and increased emphasis on innovation
- Stronger pre-submission guidance support to manufacturers

For NRAs

More transparent global evaluation system in support of countries and regional systems

- Stronger support to national registration through more transparent global evaluation
- Increased support and guidance on registration, capacity strengthening and quality control

For procurers

Faster evaluation and strengthened development of normative guidance for innovative tools

- More efficient evaluation to enable innovative tools to be available faster to procurers
- Timely and strengthened development of normative guidance of innovative tools and new product categories

For countries

Decreased incidence of vector-borne disease

- Higher quality and appropriate use of effective products in the field
- Stronger support to monitor and manage resistance and life cycle pesticide management

Implementation of WHO transformation has already started

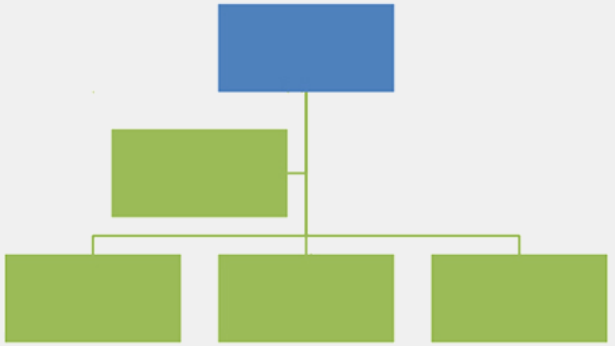
Consolidated input

Consolidated stakeholder input on WHO change activities (e.g. convening input, peer reviews)

Submitted grants

Submitted and received approval on WHO NTD and WHO PQT grants from BMGF

Began implementation



Began implementation of NTD grant (October 2015) and PQT grant (January 2016)

Overview of WHO transformation changes in the evaluation of vector control products

	Evaluation of new tools	Pre-submission	Assessment	Post assessment
Pre-transformation (to 2016)	Advice from Vector Control Advisory Group (VCAG) on public health value of tools under new categories	Guidance to manufacturers on WHOPES evaluation Data generated at WHO testing collaborating centers and institutions	WHOPES evaluation of safety, quality, and efficacy	Policy setting by WHO on advice of MPAC and STAG *(Malaria Policy Advisory Committee and Strategic and Technical Advisory Group for NTDs)* Normative guidance from WHO NTD and GMP
Post transformation (2017 +)	Accelerated meetings of VCAG on public health value for tools under new categories	Guidance to manufactures on dossier requirements for PQT assessment Data generated at GLP sites	PQT led dossier assessment of safety, quality, and efficacy Manufacturing site inspections	Policy setting by WHO on advice of MPAC and STAG Enhanced normative guidance from WHO NTD and GMP Post-marketing quality management Collaborative registration with National Regulatory Authorities (NRAs)

Existing activity *Enhanced existing activity* *New activity*

NTD, PQT, and GMP will collaborate to achieve transformation end goals

		NTD	PQT	GMP
Evaluation functions	**Innovation and efficiency**	▪ Capacity building for **GLP site accreditation** ▪ **Transition evaluation** function to PQT ▪ Accelerate **review of tools under new categories**	▪ Transition **vector control product assessment system** into PQT	▪ Accelerate **review of tools under new categories**
	Quality		▪ Build **quality** control system for **evaluation and post marketing**	
Normative functions		▪ **Enhance normative guidance** activities		▪ **Enhance normative guidance** activities
Other		▪ Develop **revenue model** ▪ Proactively **communicate** with stakeholders	▪ Develop **revenue model** ▪ Proactively **communicate** with stakeholders	▪ **Collaborate** with NTD and PQT on all major activities

NTD, GMP, and PQT to collaborate closely through monthly project management committee meetings throughout transformation

Agenda

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4	**PQT system *(~30 mins)*** ▪ Introduction to PQT ▪ Explanation of current PQT systems (Rx, Vx, Dx) and successes ▪ Overview of PQT grant ▪ Timeline for change	**Mark M.**
5	**Split of functions *(~10 mins)*** ▪ How we will work together	**Raman V., Mark M., Abraham M.**

We will welcome questions at the end of the presentation

Key NTD activities to achieve transformation have been defined in the recently awarded grant

1. **Increased drive for development of innovative vector control products for public health**
2. **Efficient and transparent evaluation processes for efficacy, safety and quality**
3. **Implemented robust communication plan with member states**
4. **Increased appropriate use and management of innovative vector control interventions**
5. **Long-term sustainable support for NTD VC activities**

Key activities to implement NTD grant through 2017

Outcomes	2015	2016	2017
1 Increased drive for development of innovative vector control products for public health	▪ **Pilots** on dossier review and pre-submission guidance for ~3 products	▪ Data **generation** shifting to manufacturers through GLP/GEP accreditation of testing sites ▪ Consultation on **equivalency**	▪ Data **generation** fully shifted to manufacturers through GLP/GEP accreditation of a total of eight testing sites
2 Efficient and transparent evaluation processes for efficacy, safety and quality	▪ Detail process, **timeline and activities** for transferring VC product evaluation function to PQT/RHT	▪ Revise current evaluation process to **increase efficiency and transparency** during transition	▪ VC product evaluation function **moved to RHT/PQT** complete by 1/1/2017
3 Implemented robust communication plan with member states		▪ **Position paper** on WHO transition benefits written and reviewed	▪ **Ongoing communication** through regional meetings, website update
4 Increased appropriate use and management of innovative vector control interventions	▪ Clear **delineation** of evaluation, normative, policy and technical functions	▪ Definition and guidance (e.g., on product use by countries) in place for new **product categories** ▪ **Expand normative guidance** for operational vector control	▪ Increased support to countries for **life-cycle management** of pesticide products and accelerate registration process
5 Long-term sustainable support for NTD VC activities	▪ Joint **governance model** established for NTD/PQT/GMP	▪ **Cost analysis** conducted for future NTD VC activities ▪ **Staff hired and trained** to support transition	▪ **Revenue model** developed for NTD vector control activities

Significant progress has already been made

Achievements to date	Detail
Equivalency consultation	▪ **Equivalency process and criteria for vector control products reviewed** to build consensus among group – Held on 2/1-2, participation from equivalent and innovator manufacturers, procurers, NRAs, country programs, WHO etc. – Additional AgroCare feedback has been communicated to WHO
Dossier review pilot	▪ **Accepted manufacturer generated data** for evaluation during ongoing dossier review pilot (in transition plan)
GLP sites	▪ **Began implementation of GLP accreditation** plan in 4 countries – India, Malaysia, Iran, China – *Details to be given in GLP session*

Broad alignment achieved at **Equivalency Consultation**

Recommended increase in regulatory standards for vector control products

Equivalency consultation was attended by a comprehensive group of stakeholders: WHO/JMPS, regulatory, innovators & generic manufacturers, procurers, vector borne disease control programs, textile experts, NGOs, donors

Group made following suggestions for the WHO, which will be considered during transition to PQT assessment:

- 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 in conjunction with other perspectives (e.g. Agrocare comments) during transition to PQT assessment

Dossier review pilot has successfully accepted manufacturer generated data into WHO evaluation process

Dossier pilot	▪ Pilot program to test process of WHO acceptance of manufacturer accepted data

Initial pilot objectives	**Progress to date**
1 **Accelerate the availability** of innovative products on the market through faster reviews	Avoided duplicative testing for two IRS products (1 of 3 sites) & 1 larvicide currently in WHOPES evaluation with manufacturer generated data
2 Have the WHO **demonstrate willingness** to transform through near-term change	Demonstrated commitment to change with acceptance of manufacturer generated data for assessment
3 Enable **manufacturers and WHO to learn** about the new assessment process	WHOPES transition plan in place

After implementation, NTD/GMP will shift focus to providing enhanced normative guidance for vector control products

Current role	Role in 2017+
Participate in review of new tools through VCAG	Participate in new tools review through accelerated VCAG or ERG systems
Oversee WHOPES testing processes	Accredit GLP sites for generation of manufacturer data
Run WHOPES assessment activities	Participate in pre-submission guidance & dossier assessment activities with PQT
Issue normative guidance and policies for vector control	Issue enhanced normative guidance and policies for vector control

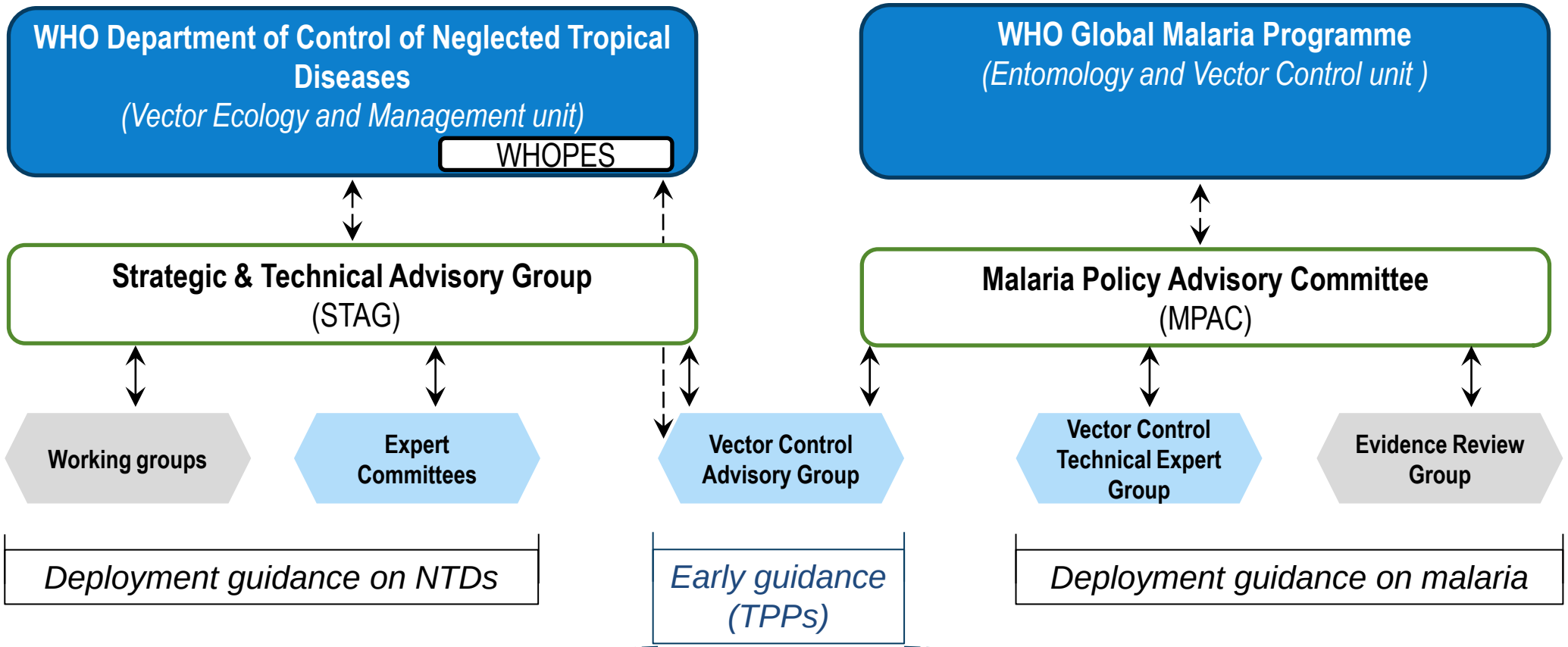
Focus of next section

Agenda

1	**Overview of transformation *(~20 mins)***	**Raman V., Mark M., Abraham M.**
2	**NTD progress (~30 mins)** ▪ Overview of NTD grant ▪ Key achievements to date ▪ End state for NTD vector control activities	**Raman V.**
3	**Normative guidance activities *(~10 mins)*** ▪ Summary of enhanced normative guidance for NTD and GMP	**Abraham M.**
4	**PQT system *(~30 mins)*** ▪ Introduction to PQT ▪ Explanation of current PQT systems (Rx, Vx, Dx) and successes ▪ Overview of PQT grant ▪ Timeline for change	**Mark M.**
5	**Split of functions *(~10 mins)*** ▪ How we will work together	**Raman V., Mark M., Abraham M.**

We will welcome questions at the end of the presentation

Current WHO policy setting process for vector control tools and products



- Review and assess the concept/proof of principle of new tools/technologies
- Make recommendations to WHO to further determine the appropriate use under programme conditions/requirements

Principles of design for WHO normative guidance process (NTD/GMP/PQT)

1. **Early guidance on Target Product Profiles (TPPs)**
   - Guidance on generating data to fit Target Product Profiles (TPPs)
   - Need to balance between entry for new products and ensuring safety and efficacy
   - Guidance on data to be generated during pilot testing for efficacy
   - Disease programs (GMP and NTD) determine public health value; PQT will assess data on safety, efficacy, and quality of products (similar to process in medicines)

2. **Iterative data generation by respective disease programmes**
   - Initial review establishes product safety
   - Initial review enables ongoing data generation and review to refine TPPs, efficacy claims, and to finalize the deployment guidance after efficacy is established

3. **Establishment of product efficacy**
   - Modified product within an existing category – entomological endpoints
   - Product within a new category – entomological and epidemiological endpoints and risk assessment

4. **WGs (including Evidence Review Group) / EAGs convened on a by-intervention basis**
   - Experts are customized for the tool / intervention to ensure the right expertise
   - Normative guidance bodies (e.g., MPAC and STAG) advise on the convening of EAGs/WGs
   - ERGs can be convened quickly as needed for a given product

5. **A strengthened WHO secretariat to screen initial submissions to determine the appropriate path that products should take**

Future WHO normative guidance process and assessment of potential public health application for new vector control tools – by function

FUNCTIONS	ACTIVITIES	EXPERT GROUPS – NTD / GMP / PQT (ADVISORY FUNCTION ONLY)
EVALUATION OF POTENTIAL PUBLIC HEALTH APPLICATION	1. Early normative guidance on Target Product Profiles (TPP) 2. Iterative data generation 3. Establishment of product efficacy	**VCAG**
GUIDELINES	**Development of:** outcome criteria, testing requirements, risk assessment guidance and quality control criteria and any associated guidance documents	**WG**
	Risk assessment methodology (ad hoc experts)	**EAG**
	Specifications (JMPS or ad hoc experts)	
OUTCOME	Validated intervention concept & Target Product Profile.	**VCAG**
POLICY	Issuance of operational guidance on deployment of new tools for disease control	**STAG / MPAC**

Agenda

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   - Key achievements to date
   - End state for NTD vector control activities

3. **Normative guidance activities *(~10 mins)*** — **Abraham M.**
   - Summary of enhanced normative guidance for NTD and GMP

4. **PQT system *(~30 mins)*** — **Mark M.**
   - Introduction to PQT
   - Explanation of current PQT systems (Rx, Vx, Dx) and successes
   - Overview of PQT grant
   - Timeline for change

5. **Split of functions *(~10 mins)*** — **Raman V., Mark M., Abraham M.**
   - How we will work together

We will welcome questions at the end of the presentation

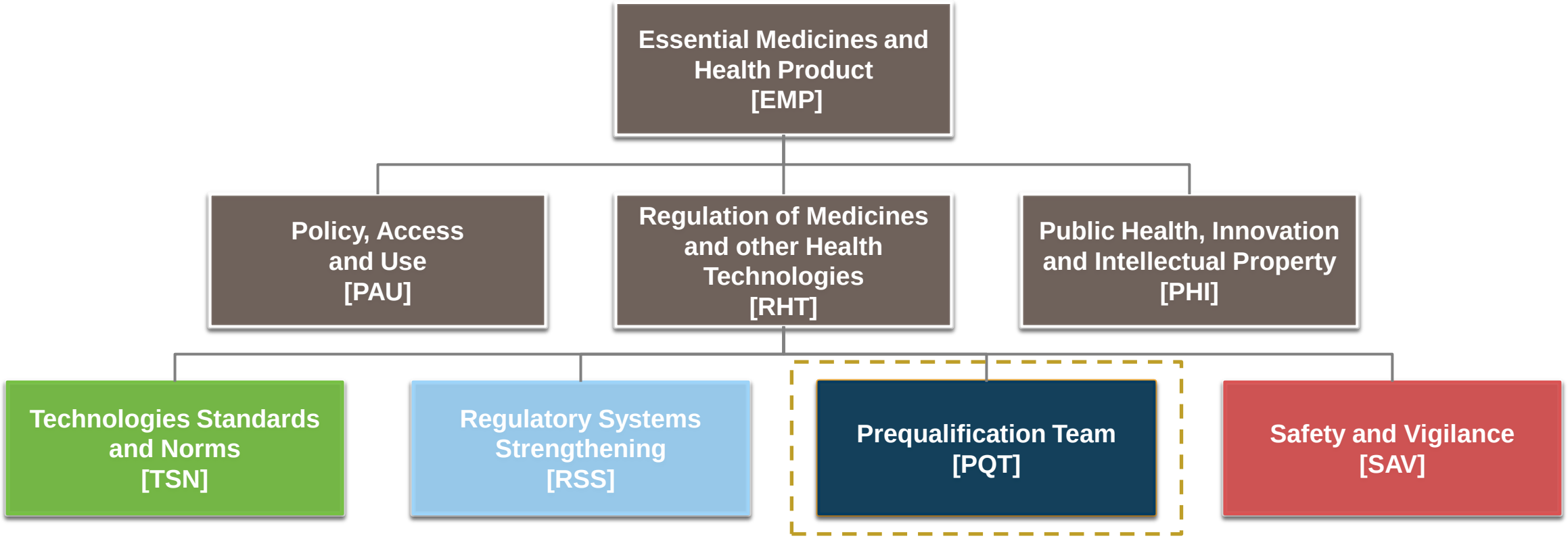
WHO Prequalification Team (PQT) embodies public health values

- WHO prequalification embodies and continuously **demonstrates public health values**
- WHO prequalification is an **objective, independent process**. The standards upon which it is based, have been developed and are updated according to **rigorous scientific evidence** and via an international consultative process
- WHO prequalification promotes **regulatory transparency** by making the results of its decisions publicly available, and promotes equity through information sharing and transfer of skills and knowledge
- The WHO Prequalification Team **strives for excellence**: both in performance and by continuously improving its knowledge and expertise
- It is **innovative and responsive to new challenges**, as demonstrated by its contribution to development paediatric medicines, fast-track assessment of products in emergencies and, works collaboratively and optimally, and supports many others — regulators, manufacturers, procurers and health care providers

Will work to tailor and incorporate values into PQT vector control assessments

Prequalification team coordinates closely with related groups at WHO

The prequalification team actively participates in: strengthening regulatory systems, developing international regulatory guidelines, monitoring product quality and assisting countries to establish monitoring systems



PQT was created in response to the need of procurement agencies & member states for safe, efficacious, and quality-assured health products

Diagnostics	Medicines	Vaccines
Origin ▪ Substandard performance of HIV assays in sub-Saharan Africa Response: HIV Test Kit Evaluation Programme (1988) **PQT beginning** ▪ 2010	**Origin** ▪ Request by WHO MS to assess the quality, safety and efficacy of low-cost and new FDCs HIV/AIDS generic medicines **PQT beginning** ▪ 2001	**Origin** ▪ Request by UNICEF and PAHO to evaluate quality, safety and efficacy of vaccines in the context of national immunization programmes **PQT beginning** ▪ 1987

Today, the prequalification team is responsible for the assurance of safety, quality, and efficacy of diagnostics, medicines, and vaccines

Diagnostics (Dx)
assessment of in-vitro diagnostics (IVDs) & male circumcision devices (MCDs)

Medicines (Rx)
assessment of finished pharmaceutical products (FPPs) and active pharma-ceutical ingredients (APIs)

Vaccines (Vx)
assessment of vaccines and immunization devices (ImDs)

Inspections
of manufacturing sites

Laboratory evaluation and testing
of Dx and Vx

and

Laboratory prequalification
of Rx quality control laboratories (QCLs)

Technical assistance
to manufacturers, NRAs and other stakeholders

Facilitation of National regulatory approval
for Dx, Rx and Vx

Beginning 1/1/2017, PQT will be responsible for the safety, efficacy, and quality assurance of vector control products

WHO prequalified products are widely accepted and procured in Member States

As of June 2015

Medicines

99% of Antiretrovirals procured by Global Fund in 2014 were prequalified

- 38 quality control laboratories
- 79 active pharmaceutical ingredients
- 416 finished pharmaceutical products

Diagnostics

80% of HIV rapid diagnostic tests procured in 2013 are prequalified

- 45 in vitro diagnostics
- 2 male circumcision devices

Vaccines

100% of products procured by donors are prequalified

- 136 vaccines
- 282 immunization devices

WHO vector control product assessment function moving from WHOPES to WHO PQT

The new WHO system, effective in 2017, will:

1. Harmonize vector control product assessment process with PQT's assessment of medicines, diagnostics, and vaccines
2. Increase efficiency and transparency of product assessment process
3. Increase quality assurance and continual assessment of products

Key PQ activities to achieve transformation have been defined in the recently awarded grant

1. **Improve quality and efficiency of vector control assessment**
2. **Assist NRAs to optimize national registration times**
3. **Develop a sustainable model for short- to mid-term future of PQT**
4. **Prequalify and maintain prequalification status of products**
5. **Communicate with stakeholders to build strong trust in WHO prequalification systems**

Overview of the PQT grant

Objectives	Key activities
1 **Improve quality and efficiency of vector control assessment**	▪ Create and staff vector control assessment group within PQT based on model of other PQT groups and WHOPES ▪ Develop quality assessment systems for vector control products
2 **Assist NRAs to optimize national registration times**	▪ Identify and engage NRA contacts and pilot collaborative registration[1] procedure
3 **Develop a sustainable PQT model**	▪ Determine fee structure / funding model for vector control evaluation in PQT
4 **Prequalify and maintain prequalification status of vector control products**	▪ Conduct assessments of vector control products in PQT system as of 1/1/17, including quality, safety, and efficacy assessments ▪ Conduct post marketing quality inspections of manufacturing sites and finished products based on risk assessment protocols
5 **Communicate with stakeholders to build strong trust in WHO prequalification systems**	▪ Engage with relevant stakeholders to communicate changes in WHO vector control evaluation system, and build strong trust is WHO prequalification systems

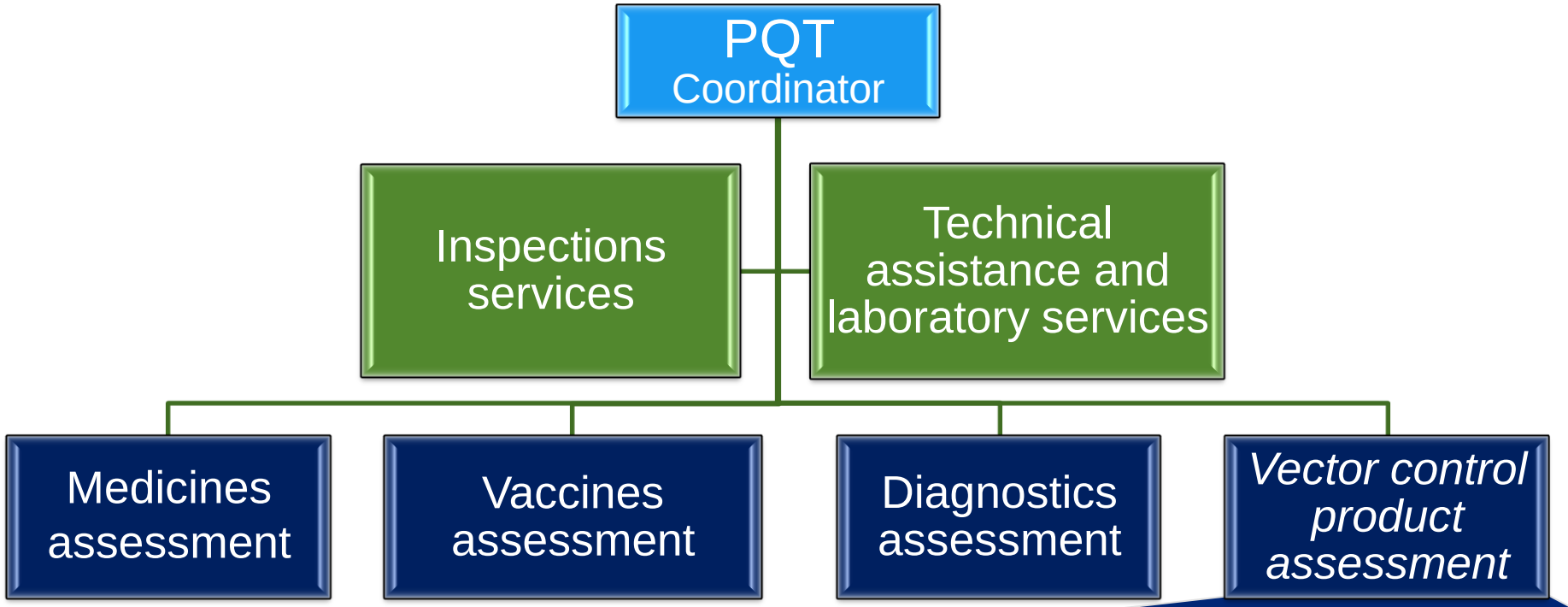
1. Collaborative procedure with NRAs to facilitate the assessment and accelerated national registration of WHO-prequalified products

PQT experience in other product areas will translate to vector control evaluation

PQT Experience	▪ Assessment framework from other PQT product areas applicable for vector control products

- Comprehensive pre-submission consultations with manufacturers
- Assessment session to review evidence for quality, safety and efficacy of products
- Site inspections for Good Manufacturing Practices / Quality Management Systems, Good Laboratory Practice, and Good Clinical Practice
- Stability studies to demonstrate useful life of products
- Control of variations to products and their manufacturing processes
- Post-approval monitoring of quality and safety
- Cooperating and relying on decisions of other regulators where possible to avoid duplication
- Collaborative registration procedure to facilitate NRA approvals
- Easy to use informational website and information tracking system for manufacturers

Vector control product assessment will exist as one of four PQ product streams



Proposed vector control staff			
	▪ Vector control product group leader ▪ Case/project manager	▪ Formulation chemist ▪ Human and environmental risk assessor	▪ Entomologist ▪ Lead inspector for vector control sites

PQT currently designing new vector control assessment system according to five principles

Design principles	Examples
I Replicate successful assessment review format of other PQ product streams	Develop dossier assessment session process for vector control products
II Replicate successful quality management system of other PQ product streams	Ensure quality through ongoing manufacturing inspections and product testing
III Incorporate relevant experiences from WHOPES and SRA[1] vector control assessments	Maintain high standards for assessment through transition to manufacturer generated data
IV Design transparent, flexible system with appropriate capacity for rapid product review	Build appropriate capacity in PQT for rapid reviews
V Design information and communication systems with manufacturer and end user in mind	Easy to use, online systems for tracking submissions, status, and quality events

1. Stringent regulatory authority

PQT transformation activities

Activities	2016	2017
1 **Assessment**	▪ Develop **transition plan** with NTD ▪ Establish **assessment processes /** protocols ▪ **Staff vector control group** in PQT, identify experts for assessment session	▪ Perform ongoing **product assessment** including use of manufacturer generated data ▪ **Presubmission guidance** to manufacturers on dossier content
2 **Inspections**	▪ Develop **inspection processes** and protocols ▪ Staff and train **inspectors** for vector control product manufacturing	▪ Perform **quality** activities for all products ▪ Maintain online **adverse event** tracking system
3 **Communication**	▪ Create **communication** plan with NTD ▪ Publish **processes, timelines,** and relevant **protocols** on website ▪ Establish NRA **collaborative registration** procedure	▪ Application information and status available to each manufacturer **online** ▪ Assessment **outcomes available** online ▪ Pilot **collaborative registration** for vector control products
Milestones	**Q2/3 2016:** PQT participation in VC assessments **Q2/3 2016**: First stakeholder meetings	**1/1/17:** PQT accepts dossiers and performs quality activities **Q3/4 2017**: PQT begins VC collaborative registration pilot

PQT will provide opportunities for stakeholder input throughout the transformation period

- As WHO PQT designs the vector control evaluation process throughout 2016, there will be opportunities for input from stakeholders on specific topics, e.g.:
  - Pathways for products
  - Quality assurance inspections
  - Dossier content
  - Information management system

- Events will be held throughout 2016 and beyond to provide information on PQT vector control evaluation and gather input, e.g.:
  - Ongoing: stakeholder meetings (beginning Q2 2016)
  - End of 2016: informational meeting on final processes and protocols of PQT vector control assessment
  - Ongoing: webinars to provide topic-specific updates
  - Ongoing: regular updates to PQ vector control website *(anticipated launch Q2 2016)*

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We will welcome questions at the end of the presentation

NTD, PQT, and GMP will continue to coordinate closely throughout process for vector control product assessment and guidance

	Activities		Transition *(pre-2017)*	Target *(2017 - ...)* Established prod.	Target *(2017 - ...)* New tools
Prototype	Decision on possible public health benefit and pursuing further development	Evaluate PH value of new VC tools (incl. technical advice to manufacturers)	**N/A** (for established products VCAG for new VC tools)	**N/A**	**NTD/GMP** (**PQT** involved)
		Dev. of safety / efficacy standards for prototype evaluation			**NTD/GMP/PQT**
Product	Development of standards	Dev. of safety / efficacy standards for product PQ	**NTD** (**PQT** consulted in general and **PQT** will have primary lead of developing new manufacturing quality product evaluation requirements)	**PQT** (**NTD/GMP** involved)	**PQT** (**NTD/GMP** involved)
		Development of manufacturing qual. standards for product PQ			
	PQ product review	Review of PQ dossiers and decision on PQ listing			
		Manufacturing quality of PQ listing process			
	Post-listing	On-going safety / efficacy / quality evaluation			
		Utilization normative guidance	**NTD/GMP**		

Do you have any questions?

March 22 agenda

Agenda item	Timing
Breakfast	8:00–8:30
Welcome (from I2I Leadership Team; I2I AB Chair)	8:30–10:00
Break	10:00–10:30
WHO transformation	10:30–12:30
Lunch	12:30–13:30
Working session: (a) Primer on WHO Prequalification & (b) Value-based procurement	13:30–15:00
Break	15:00–15:30
Working session: (a) Discussion of country-level engagement & (b) Normative guidance	15:30–17:00
Recap of March 22 discussions and decisions made	17:00–18:00
Break	18:00–19:00
Dinner and drinks	19:00–21:00

March 22 agenda

Agenda item	Timing
Breakfast	8:00–8:30
Welcome (from I2I Leadership Team; I2I AB Chair)	8:30–10:00
Break	10:00–10:30
WHO transformation	10:30–12:30
Lunch	12:30–13:30
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Recap of March 22 discussions and decisions made	17:00–18:00
Break	18:00–19:00
Dinner and drinks	19:00–21:00

We will split into two groups for the first working session: 13:30–15:00pm

Recommendation only: Participants free to go to session of choice

Primer on WHO Prequalification

Presenter

World Health Organization

M. McDonald

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, M. Lumpkin, D. Strickman

Industry: A. Butenhoff, A. Bywater, A. Hirooka, B. Johnen, R. McAllister, M. Meier, C. Ogihara, F. Schmitt, E. Weinmueller

IVCC: N. Hamon, D. Malone, M. Mondy, L. Rossi

NRAs: B. Bouato, L. C. Kafita , C. Kanema

Procurers: J. Cutler, M. Fotheringham, A. Jafarov, J. Woziniak

WHO: V. Akula,, A. Mnzava, D. Mubangizi , M. Ward, R. Yadav

Rapporteur

TBD

Dupont Ballroom *(general session room)*

Value-based procurement

Presenter

PMI

C. Fornadel

VESTERGAARD IMPACTING PEOPLE

SUMITOMO CHEMICAL

J. Lucas

H. Pates Jamet

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, S. Miller, S. Nazzaro, M. Reddy, V. Williams, J. Zhou

Industry: R. Arrington, T. Bonertz, R. Bosselmann, R. Flinn, J. Invest, B. Jany, T. H. Larsen, K. Mori

IVCC: T. McLean, S. Rees

NMCPs: N. Frempong, E. Orefuwa

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

WHO: D. Engels, E. Temu, R. Velayudhan

Rapporteur

TBD

Georgetown room

Agenda

1. Prequalification process today for medicines
2. Benefits of prequalification
3. Questions and discussion

Recall: Today, the prequalification team is responsible for the assurance of safety, quality, and efficacy of diagnostics, medicines, and vaccines

Diagnostics (Dx)
assessment of in-vitro diagnostics (IVDs) & male circumcision devices (MCDs)

Medicines (Rx)
assessment of finished pharmaceutical products (FPPs) and active pharma-ceutical ingredients (APIs)

Vaccines (Vx)
assessment of vaccines and immunization devices (ImDs)

Inspections
of manufacturing sites

Laboratory evaluation and testing
of Dx and Vx

and

Laboratory prequalification
of Rx quality control laboratories (QCLs)

Technical assistance
to manufacturers, NRAs and other stakeholders

Facilitation of National regulatory approval
for Dx, Rx and Vx

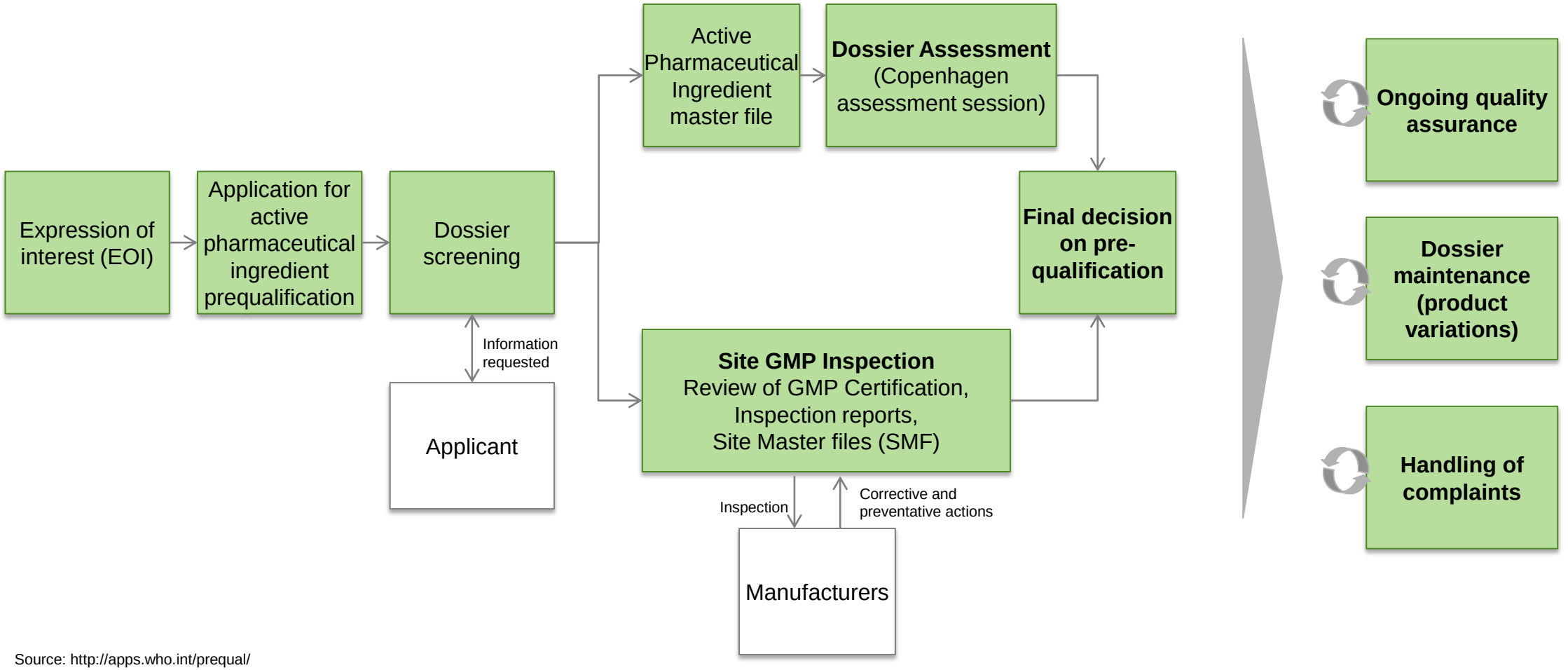
Beginning 1/1/2017, PQT will be responsible for the safety, efficacy, and quality assurance of vector control products

Example prequalification process: Medicines prequalification today

Pre submission

Assessment and inspection

Post assessment



Source: http://apps.who.int/prequal/

Recall: PQT experience in other product areas will translate to vector control evaluation

PQT Experience	▪ Assessment framework from other PQT product areas applicable for vector control products

- Comprehensive pre-submission consultations with manufacturers
- Assessment session to review evidence for quality, safety and efficacy of products
- Site inspections for Good Manufacturing Practices / Quality Management Systems, Good Laboratory Practice, and Good Clinical Practice
- Stability studies to demonstrate useful life of products
- Control of variations to products and their manufacturing processes
- Post-approval monitoring of quality and safety
  - Post marketing field tests of finished products
  - System for adverse event reporting from manufacturers, end users, procurers etc.
  - Risk assessment matrix protocol to determine frequency of quality assessments / inspections
- Cooperating and relying on decisions of other regulators where possible to avoid duplication
- Collaborative registration procedure to facilitate NRA approvals
- Easy to use informational website and information tracking system for manufacturers

Benefits of prequalification: Procurers

We expect similar benefits for the vector control community

- In 2012, WHO PQT **enabled procurement of around ~US$ 2.4 billion** (~US$ 1,550 million for Vx, ~ US$ 730 million for Rx and ~US$ 95 million for Dx), and potentially an additional ~US$ 300−600 million of national and private markets, of quality-assured products

- WHO PQT, its handling of variations, follow-up monitoring (including testing), and investigation of product complaints, ensures that procured products continue to meet standards for quality, safety and efficacy. Agencies procuring these products **save considerable time and resources** that would otherwise have to be dedicated to similar duplicative activities

- PQ increases fair competition among quality products, contributing to **market sustainability and lower prices**

- WHO PQ enabled Rx procurers to save around US$ 1 billion in 2012, **equivalent to a return on investment (ROI) of 75:1**

Source: L Rago. 2014; Added value of WHO Prequalification. Updates from product streams (medicines, vaccines and diagnostics), IPC 2014, Washington DC

Benefits of prequalification: Regulators

We expect similar benefits for the vector control community

- **PQ facilitates collaboration between regulators and promotes avoiding duplication of testing and review**

- **Collaboration in scientific assessment**
  - Prequalification is done collectively by regulators, for regulators
  - High involvement of developing country regulators
  - Participates proactively in International Generic Drug Regulators Pilot (GDRP)
  - Participates in Developing Country Vaccines Regulatory Network (DCVRN)

- **Collaboration in inspections**
  - Developed and developing country inspectorates involved in inspections process

- **Collaboration in quality control laboratories**

Source: L Rago. 2014; Added value of WHO Prequalification. Updates from product streams (medicines, vaccines and diagnostics), IPC 2014, Washington DC

Benefits of prequalification: Manufacturers

We expect similar benefits for the vector control community

- Prequalification is a "seal" of quality and **increases trust from buyers and regulators**
- Attaining prequalification is the **only means to access some procurement pools** (e.g. GAVI, UNICEF / PAHO vaccines)
- WHO PQT **approves variations very promptly**, which can enable manufacturers to generate savings and satisfy supply demands
- The collaborative procedure for accelerating national registration of finished pharmaceutical products and vaccines helps manufacturers gain **speedier access to markets** while also substantially accelerating access to urgently-needed medical products.
- PQ offers **regulatory advice and technical assistance** in product development phase

Source: L Rago. 2014; Added value of WHO Prequalification. Updates from product streams (medicines, vaccines and diagnostics), IPC 2014, Washington DC

Benefits of prequalification: Populations and patients

We expect similar benefits for the vector control community

- By ensuring accurate diagnosis, prevention and treatment, prequalified diagnostics, medicines and vaccines **save and improve the quality of lives**
- Prequalified vaccines are used in **134 countries, and in approximately 64% of the global birth cohort**
- **6.5 of 8 million people receiving HIV treatment** in 2012 were receiving WHO-prequalified antiretrovirals
- In 2013, **80% of HIV rapid diagnostic tests** procured worldwide by major international procurement agencies were prequalified

Source: L Rago. 2014; Added value of WHO Prequalification. Updates from product streams (medicines, vaccines and diagnostics), IPC 2014, Washington DC

Do you have any questions?

Value-based procurement working session: Objectives and agenda

Objectives:	**Understand procurers' procurement guidelines** **Understand industry and other stakeholders' perspectives on what an ideal value-based purchasing approach would look like** **Identify specific activities to potentially add to procurement workstream work plan**

	Detailed agenda	Time	Presenter
1	▪ Presentation of official procurement guidelines & value-based purchasing criteria	~15 min	**PMI, Global Fund & UNITAID**
	▪ Q&A on official procurement guidelines	~15 min	
2	▪ Suggestions from industry on value-based procurement & consequences of current practices	~15 min	**Croplife**
	▪ Discussion of how to address concerns	~15 min	
3	▪ Summary of areas of alignment, open questions, & next steps	~30 min	**TBD**
		Total: 90 min	

IRS Procurement Specifications

Compounds have passed WHOPES phase III & on WHOPES manufacturers list

If new formulation, can procure after phase II

If new AI, can use in hut trials after phase II

Tenders by class

Based on:

- Susceptibility of local vectors to insecticide
- Length of efficacy vs. malaria transmission season

Can procure specific insecticide compound within a class if sufficient data/justification

Competitive awards judged on cost, local registration status (yes/no), delivery timeline

Included in PMI's Programmatic Environmental Assessment

LLIN Procurement Specifications

At minimum, MUST HAVE an interim status recommendation from WHOPES

Phase II testing necessary

- Equivalency status based only on Phase 1 laboratory studies is insufficient
- Phase 1 studies do not determine performance under field conditions where other factors come into play

In order to compete for a tender, PMI applies these additional criteria

- Past performance
- Financial viability
- Programmatic consistency
- Product included in PEA
- Manufacturer QA and safety procedures
- Must meet or exceed WHOPES LLIN specifications for netting material and construction
- Physical characteristics of the netting must adhere to international standards

Once deemed eligible, winner of tender generally based on total cost (QA, shipping, freight)**, with consideration of past performance and delivery timeline**

Value-based vector control procurement criteria

PMI believes in value-based vector control purchasing through competitive procurement of globally recommended vector control products based on transparent, universally accepted technical evaluation criteria & evaluation metrics

VBP involves using country epidemiological, entomological, & operational data to identify suitable products that provide effective coverage

- Data is interpreted through WHO normative guidance

Vector control product categories should:

- Have their own minimum standards for public health efficacy
- Be specific enough to address defined control issues
- Be broad enough to allow free and open competition between manufacturers of similar products within that category

Aspirational products that exceed the minimum standards in a category are encouraged, but procurement decisions will be based on demonstrable cost-effectiveness based on country context & field evaluation

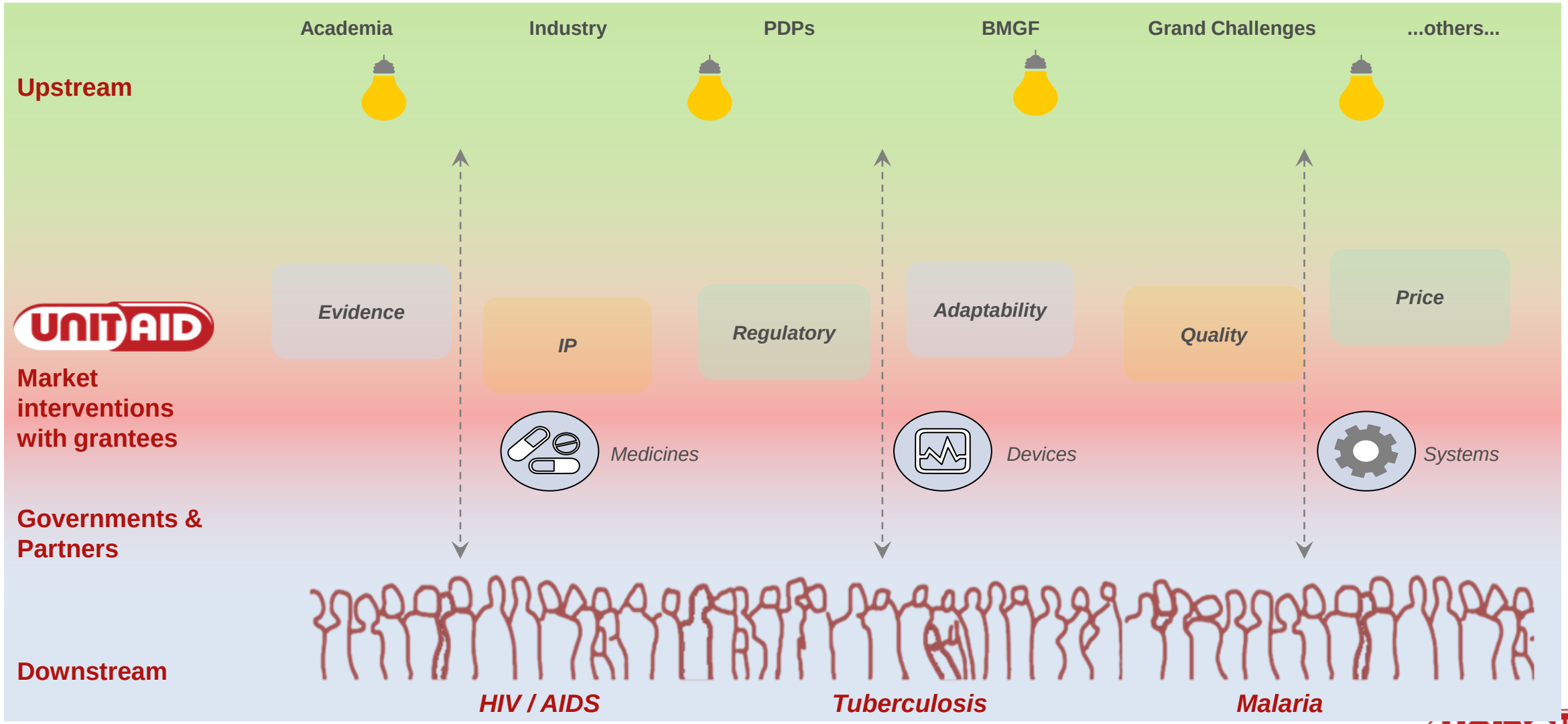
The Global Fund: New Market Shaping Strategy (Nov 2015)

Official rule/policy	Source of official rule/policy	Process to modify
Strategic objective: Support efforts to stimulate innovation through: - Supporting innovative product adoptions - Applying various procurement practices to incentivize innovation - Signaling interest in innovation and support technical and development partners (such as WHO) - Including innovation in the tender evaluation and allocation criteria **Strategic objective: Accelerate the adoption of new and /or cost-effective products through:** - Coordinating with partners to develop and implement "roadmaps" for key product needs - Accelerating introduction of high-priority new products with partners to reduce the risk of market entry, and - Optimizing product selection within WHO guidance	Market Shaping Strategy	These are new modifications as per the latest Global Fund Board Meeting which allows the Global Fund to enhance its support of innovations (November 2015)

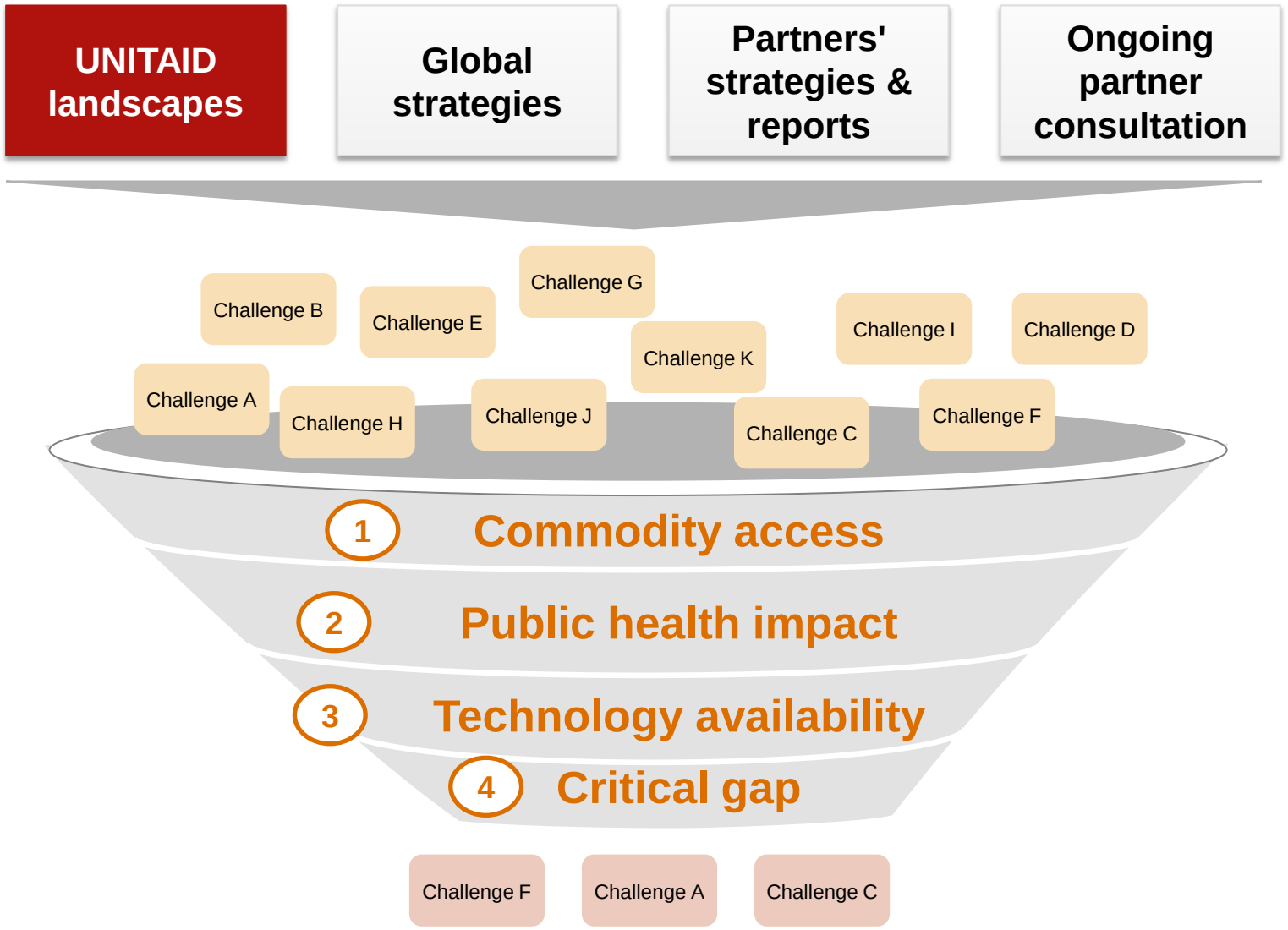
The Global Fund: Value-based procurement criteria

Overall	▪ The design of the latest procurement strategies/tenders support maintaining flexibilities and form an accommodating base for changes (in regulatory environment and innovative products).
LLIN	▪ 55% weighting for price ▪ 45% weighting for technical elements including: – Origination (suppliers who have invested in products which are currently under WHOPES evaluation are scored according to the number of products) – Development and Investment: Suppliers with proven investments in new product(s) score additional points – Other technical criteria (customer proximity and asset ownership) ▪ Framework Agreements with multiple suppliers support changes to market dynamics, regulatory environment, and allow new technologies/products to be introduced during contract implementation terms
Other	▪ No other vector control products procured by the Global Fund procurers.

UNITAID connects the upstream to the downstream and enables others to do "more with less"



Systematic analysis to prioritize challenges where UNITAID can add value



Areas for intervention endorsed by Executive Board in Nov 2015

Malaria

- Accelerate adoption of innovative **vector control tools**
- Optimize introduction of tools for treatment of **severe malaria**
- Access to preventive chemotherapy in **pregnant women**

Related issues: engagement with private-sector care-providers, middle-income countries

Dimensions of market health

Overarching principles

- Apply to markets for medicines or technologies to effectively prevent, diagnose or treat a particular disease or condition

- Market-shaping activities should ensure that interventions in one dimension of market health do not have negative long-term consequences on other dimensions

- Long-term viability (i.e., market health is sustainable with limited intervention from international public actors) is important but may not be applicable to all market segments

Working definition of a healthy market health

Innovation

There is a robust pipeline of new products, regimens or formulations intended to improve clinical efficacy, reduce cost, or better meet the needs of end-users, providers or supply chain managers.

Availability

New and/or superior evidence-supported, quality-assured products are rapidly introduced in the market and made available to those in LMICs. Adequate and sustainable supply exists to meet global needs.

Quality

Medicine or technology is available at a high standard of quality, and there is reliable information on the quality of the product (final, finished product as well as starting and intermediary materials).

Working definition of a healthy market health (2)

Affordability

Medicine/technology is offered at the lowest possible price that is sustainable for suppliers and does not impose an unreasonable financial burden on governments, donors, individuals, or other payers.

Demand/ adoption

Countries, programmes, providers, and end-users rapidly introduce and adopt the most cost-effective products (within their local context).

Delivery

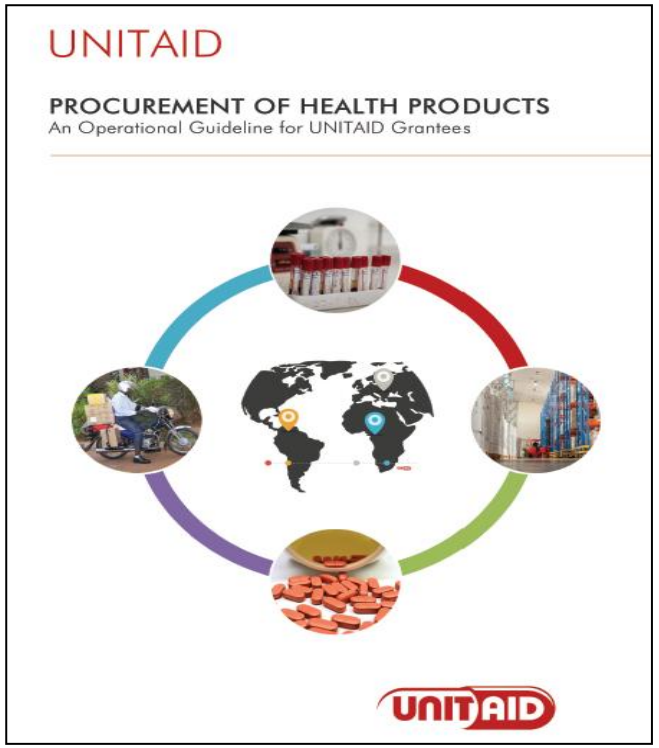
Supply chain systems (including quantification, procurement, storage, and distribution) function effectively to ensure that products reach end users in a reliable and timely way.

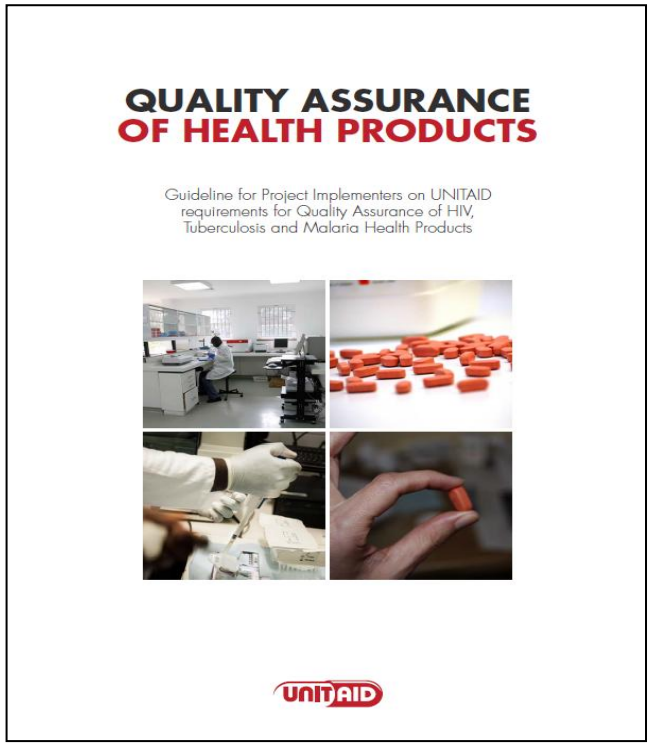
UNITAID Procurement

- Procurement undertaken by grantees in certain UNITAID projects
  - procurement strategy agreed between UNITAID and grantee

- UNITAID's procurement approach is harmonized to international best practices, including quality assurance standards and procedures

- 2 key guidance documents:





UNITAID procurement (2)

- A project's procurement strategy should be:
  - designed to achieve the market-shaping and country support goals of the individual project
  - designed to maximize competition among product manufacturers to support healthy, sustainable markets and to ensure affordable pricing, value for money and optimal access
  - informed by market information and in-country intelligence

Do you have any questions about value-based procurement guidelines?

Industry Vision for an Ideal procurement system

I2I Meeting, Washington

March 2016

Industry Vision for an Ideal procurement system

Market dimensions	Recommendations
Innovation	1. Incorporate new product introduction within value for money indicators 2. Appropriately categorize innovative products and include them in procurement 3. Value companies that develop innovative products 4. Value cost effectiveness and health impact of innovations (i.e. “Value for Money”) under field conditions

Industry Vision for an Ideal procurement system

Market dimensions	Recommendations
Quality	1. Require Phase II testing before VC products are eligible for procurement 2. Enforce pre-shipment and post-shipment in country inspections 3. Support field monitoring of VC product performance 4. Report quality issues appropriately 5. Give lower score to manufacturers who fail QA inspections leading to lower allocations 6. Clarify priorities for product improvements
Affordability	1. Assess the cost-effectiveness of interventions 2. Consider the total landed cost in the evaluation of commercial offers 3. Enable the most efficient utilization of production capacity 4. Provide reliable forecasts 5. Through market shaping ensure that capacities match needs

Industry Vision for an Ideal procurement system

Market dimensions	Recommendations
Delivery	1. Strengthen supply chain systems, country capacity and ownership 2. Ensure that warehouse and logistics in country are properly planned 3. Place purchase orders and pick-up VC products as per agreed timelines 4. Consider phased delivery approaches and plan production accordingly

Market dimensions	Recommendations
Delivery	Strengthen supply chain systems and country capacity and ownership
Other	Data on demand levels, funding commitments and allocated volumes to be publically available

CropLife INTERNATIONAL

Questions for discussion

What recommendations should we prioritize?

Where are we aligned?

What would we need to implement to achieve the areas of alignment?

What are the open questions?

What are the next step to resolve these questions?

March 22 agenda

Agenda item	Timing
Breakfast	8:00–8:30
Welcome (from I2I Leadership Team; I2I AB Chair)	8:30–10:00
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Second working session: 15:30–17:00pm

Recommendation only: Participants free to go to session of choice

Normative guidance

Presenter

World Health Organization

A. Mnzava
R. Velayudhan

PMI

C. Fornadel

Rapporteur

TBD

Participants

Academia & other global health partners: K. Bahl, A. Costero-Saint Denis, A. Court, L. Hall, S. James, S. Jennings, H. Koenker, K. Malmud-Roam, M. Rao, D. Summa

Bill and Melinda Gates Foundation: P. Berry, M. Lumpkin, S. Miller, S. Nazzaro, D. Strickman, V. Williams, J. Zhou

Industry: R. Arrington, T. Bonertz, R. Bosselmann, A. Butenhoff, A. Bywater, R. Flinn, A. Hirooka, B. Jany

Industry (cont.): B. Johnen, J. Invest, T. H. Larsen, J. Lucas, R. McAllister, M. Meier, K. Mori, C. Ogihara, H. Pates Jamet, F. Schmitt, E. Weinmueller

IVCC: D. Malone, S. Rees, L. Rossi

Procurers: A. Cameron, M. Fotheringham, M.T. Jallow, J. Kolaczinski, A. Leonard, S. Turner, J. Wallace

WHO: V. Akula, D. Engels, M. McDonald, D. Mubangizi, M. Ward

Dupont Ballroom *(general session room)*

Discussion of country-level engagement

Presenter

A. Spiers

Rapporteur

TBD

Participants

Academia & other global health partners: C. Mbogo, J. Phumaphi, M. Renshaw

Bill and Melinda Gates Foundation: S. George, H. Kettler, M. Reddy

IVCC: M. Mondy, T. McLean, N. Hamon

NRAs: B. Bouato, L. C. Kafita , C. Kanema

NMCPs: N. Frempong, E. Orefuwa

Procurers: J. Cutler, A. Jafarov, E. Jensen, J. Woziniak

WHO: E. Temu, R. Yadav

Georgetown room

Country-level impact working session: Objectives and agenda

Objectives:	**Discuss potential models of engagement with country representatives** **Receive feedback on possible models of country-level engagement**

	Detailed agenda	Time	Presenter
1	▪ Presentation on country-level impact	~20 min	**Angus Spiers**
2	▪ Suggestions from country representatives on possible engagement modalities/Open Q&A	~55 min	
3	▪ Summary of areas of alignment, open questions, & next steps	~15 min Total: 90 min	**Angus Spiers**

Engagement of countries is crucial for the success of I2I

1. **Country engagement needed to ensure I2I designs effective solutions**
   - I2I benefits from the input of countries

2. **Country engagement needed to ensure impact of I2I is realized in countries**
   - Countries benefit by ensuring I2I's solutions are implementable

Responding to country-level questions can help ensure 1 I2I designs effective solutions and 2 impact of I2I is realized in countries

I2I seeks to address challenges...

Dis-incentives for innovation & investment in the development of novel tools for vector control

Long delays in product evaluation & introduction to market, lack of systematic quality controls & manufacturer data protection

Slow development of normative guidance, for innovative tools and IVM

Products recommended for use in country **largely based on price**, not variations in efficacy

Lack of & slow access to innovative products needed to support global & national strategies & **low quality** products used in field

...that require answering a variety of questions

What type of vector control products do countries **need and want**?

How can products be registered more quickly in country **without sacrificing efficacy, safety, or quality**?

What normative guidance do countries **need** and how can they receive it **more quickly**?

What **performance traits** of vector control products are needed and valued in country?

How can national and local authorities **adopt new AIs and innovative products** and **better monitor quality**?

Answering these questions may require input through a dual engagement model

Answering stakeholder questions...

What type of vector control products do countries **need and want**?

How can products be registered more quickly in country **without sacrificing efficacy, safety, or quality**?

What normative guidance do countries **need** and how can they receive it **more quickly**?

What **performance traits** of vector control products are needed and valued in country?

How can national and local authorities **adopt new AIs and innovative products** and **better monitor quality**?

...may require two types of engagement

Country participation in workstreams for implementation partnership

A sounding board to engage I2I across workstreams

Workstream-level & sounding board engagement across all topics can help answer stakeholder questions

I2I seeks to answer questions...

What type of vector control products do countries **need and want**?

How can products be registered more quickly in country **without sacrificing efficacy, safety, or quality**?

What normative guidance do countries **need** and how can they receive it **more quickly**?

What **performance traits** of vector control products are needed and valued in country?

How can national and local authorities **adopt new AIs and innovative products** and **better monitor quality**?

...through close partnership with country stakeholders

- **NMCPs , NTDCP, and NRAs** consult with industry on needs
- **NRAs** help ensure improved PQ evaluation system and participate in collaborative registration; **NMCPs, NTDCP** submit efficacy reports to WHO PQ
- **NMCPs, NTDCP** provide input on needs & WHO plans to improve normative guidance
- **NMCPs, NTDCP** provide input on performance traits
- **NRAs, NMCPs, NTDCP** provide input to I2I across workstreams

A proposed model for workstream engagement

Goal	▪ **To facilitate the ongoing partnership needed for implementation of the I2I vision** ▪ **To engage on specific content to support each workstream in achieving its objectives**

How countries can be engaged in workstreams

Engagement can focus on engaging the most critical country reps[1] for each workstream

Country reps will:

- Support implementation
- Raise issues as needed
- Participate in workstream-led outreach & consultations[2]

Suggested engagement by workstream

1 **Industry engagement**	▪ **NMCPs, NTDCP & NRAs** consult on ad-hoc basis
2a **WHO transformation**	▪ **NRAs**: Regular consultations with PQ ▪ **NMCPs, NTDCP:** Regular consultations with NTD & GMP
2b **GLP accreditation**	▪ **GLP sites:** Workstream members
2c **Pathway for new AIs**	▪ **NRAs:** Workstream members, participation in regular consultations & collaborative registration (PQ)
3 **Procurement**	▪ **NMCPs, NTDCP:** Workstream members

1. E.g., NRAs or NMCPs, key countries 2. E.g., WHO outreach in PQ grant

Questions for discussion

Key questions

Are these the relevant topics on which we should engage you? What other topics may be relevant?

How best should we engage you when your input is needed? At what level of detail?

What suggestions do you have for sharing perspectives across I2I workstreams?

How frequent and what mix of touchpoints would be most effective?

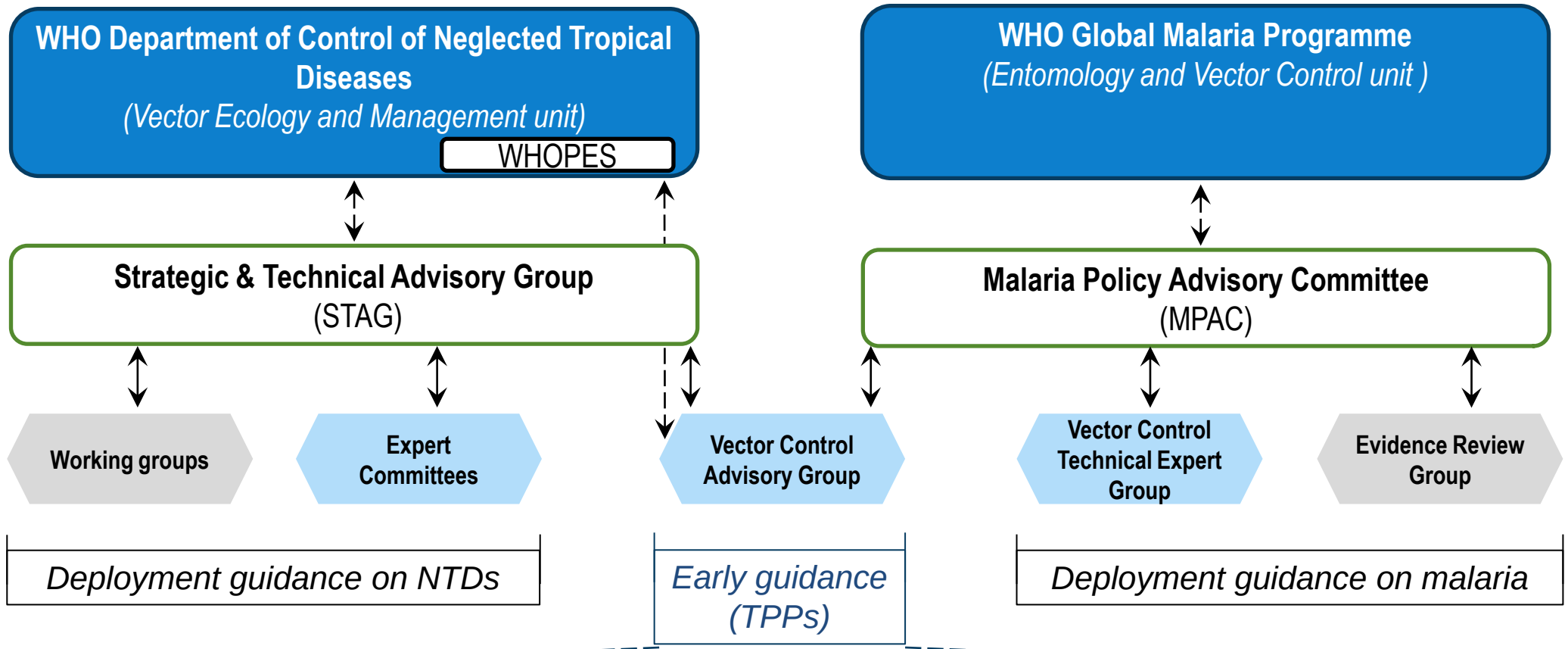
Any other suggestions?

Normative guidance working session: Objectives and agenda

Objectives:	**Understand the WHO's plan for normative guidance** **Share feedback/questions in an effort to improve & support this transformation** **Identify specific activities to potentially add to procurement workstream workplan**

	Detailed agenda	Presenter	Time
1	▪ Presentation on principles / processes	**Raman/Abraham**	~15 min
	▪ Q&A on principles / processes		~15 min
2	▪ Presentation on procurement normative guidance outstanding questions & future goals	**Christen**	~15 min
	▪ WHO answers	**Raman/Abraham**	~15 min
3	▪ Summary of areas of alignment, open questions, & next steps	**TBD**	~30 min
			Total: 90 min

Current WHO policy setting process for vector control tools and products



- Review and assess the concept/proof of principle of new tools/technologies
- Make recommendations to WHO to further determine the appropriate use under programme conditions/requirements

Principles of design for WHO normative guidance process (NTD/GMP/PQT)

1. **Early guidance on Target Product Profiles (TPPs)**
   - Guidance on generating data to fit Target Product Profiles (TPPs)
   - Need to balance between entry for new products and ensuring safety and efficacy
   - Guidance on data to be generated during pilot testing for efficacy
   - Disease programs (GMP and NTD) determine public health value; PQT will assess data on safety, efficacy, and quality of products (similar to process in medicines)

2. **Iterative data generation by respective disease programmes**
   - Initial review establishes product safety
   - Initial review enables ongoing data generation and review to refine TPPs, efficacy claims, and to finalize the deployment guidance after efficacy is established

3. **Establishment of product efficacy**
   - Modified product within an existing category – entomological endpoints
   - Product within a new category – entomological and epidemiological endpoints and risk assessment

4. **WGs (including Evidence Review Group) / EAGs convened on a by-intervention basis**
   - Experts are customized for the tool / intervention to ensure the right expertise
   - Normative guidance bodies (e.g., MPAC and STAG) advise on the convening of EAGs/WGs
   - ERGs can be convened quickly as needed for a given product

5. **A strengthened WHO secretariat to screen initial submissions to determine the appropriate path that products should take**

Future WHO normative guidance process and assessment of potential public health application for new vector control tools – by function

FUNCTIONS	ACTIVITIES	EXPERT GROUPS – NTD / GMP / PQT (ADVISORY FUNCTION ONLY)
EVALUATION OF POTENTIAL PUBLIC HEALTH APPLICATION	1. Early normative guidance on Target Product Profiles (TPP) 2. Iterative data generation 3. Establishment of product efficacy	**VCAG**
GUIDELINES	**Development of:** outcome criteria, testing requirements, risk assessment guidance and quality control criteria and any associated guidance documents	**WG**
	Risk assessment methodology (ad hoc experts)	**EAG**
	Specifications (JMPS or ad hoc experts)	
OUTCOME	Validated intervention concept & Target Product Profile.	**VCAG**
POLICY	Issuance of operational guidance on deployment of new tools for disease control	**STAG / MPAC**

2

PMI & UNITAID questions on WHO normative guidance plan

Outstanding questions	Procurers' "blue-sky thinking" view of the way forward
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?	▪ VCAG function recognizes 1st in class products, develops eval. criteria for class ▪ Then, WHOPES/PQ evaluates 2nd product in the class based on the efficacy criteria established by VCAG in order to be listed as part of the class[1] ▪ **Simultaneously, VCTEG creates normative guidance around that class of product**, which would apply to all products in the class

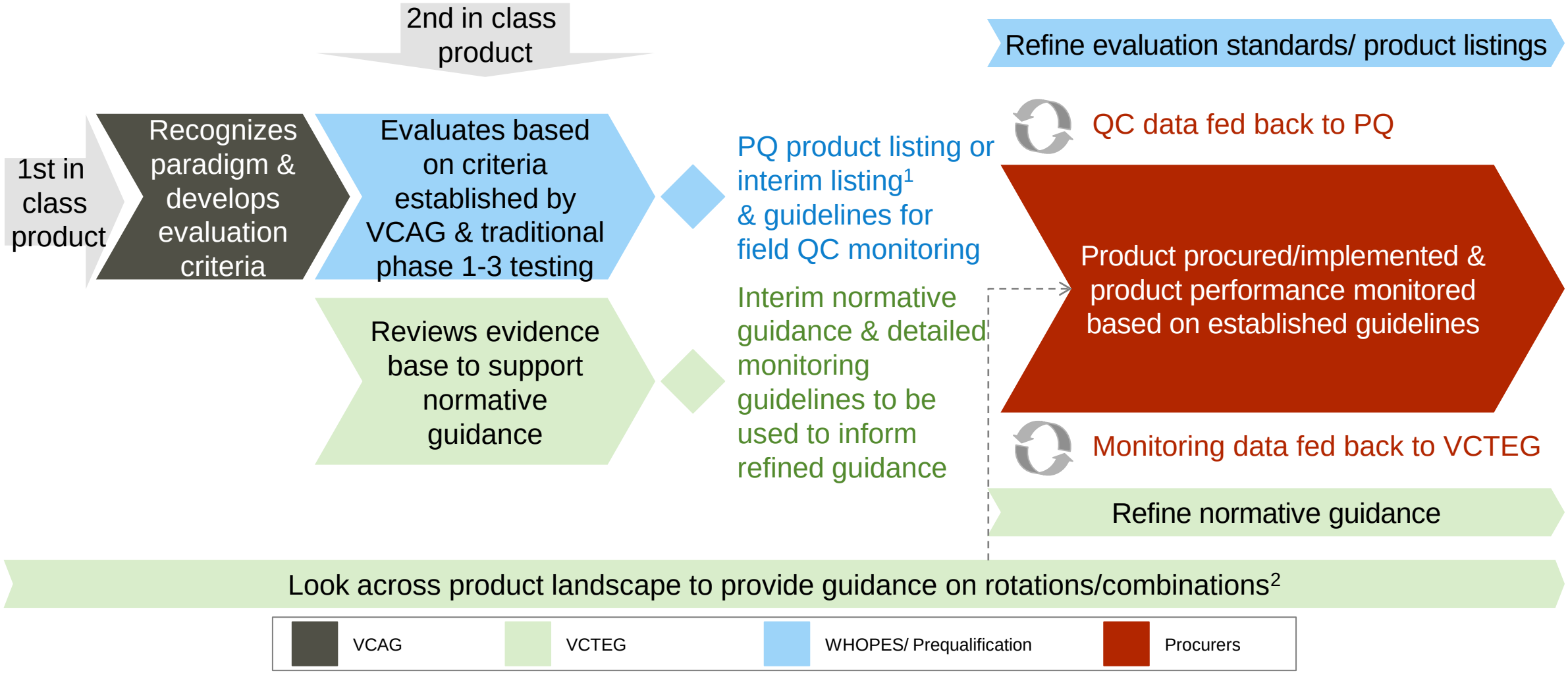
2 How can we ensure the data needed for normative guidance is available ASAP after products are evaluated?	▪ VCAG/PQ & VCTEG **align on data needed** for PQ listing & interim normative guidance up front (e.g., type of studies, endpoints, countries, contexts)
	▪ Manufacturer submits **eval. packet & initial data proposing where/how to use**
	▪ **Simultaneously**, (a) Product evaluated for efficacy against agreed standards (phase I/II/III) & (b) Evidence base to support normative guidance reviewed
	▪ **With interim recommendation** from WHO, there is at least enough data for:
	  ▪ **Interim guidance for pilot implementation**
	  ▪ **Recommendations for any further data collection needs**, including detailed **monitoring guidelines** to ensure comparability/usability of results

1.Previously called WHOPES recommendation

PMI & UNITAID questions on WHO normative guidance plan

Outstanding questions	Procurers' "blue-sky thinking" view of the way forward
3 Who is responsible for further data collection to support normative guidance?	▪ Procurers/implementers/countries can support monitoring efforts in the field, but will not be able to support RCTs for all new products ▪ RCTs would likely need to be **funded by manufacturers/academic grants**
4 What is the process to review interim normative guidance incorporating data from pilot field monitoring/further trials & provide a revised recommendation?	▪ **Continuously iterative process** ▪ Field data generated using **agreed upon monitoring/evaluation criteria** (e.g., LLIN durability data generated by procurers) ▪ A body **regularly reviews any new evidence** to update normative guidance (may be necessary to move away from in-person, biannual meetings)
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?	▪ **Start now reviewing modes of action** in order to provide guidance on how new tools would best be incorporated into a resistance management program – Understand what insecticides may be coming online in the next few years by looking across the development landscape for new VC tools

DRAFT: Diagram of high-level normative guidance process



1.Previously called WHOPES recommendation 2. Feeds into procurement decisions

Questions to guide discussion

Can we take products we know are currently on the market or in the pipeline and walk them through the new normative guidance system/plan to better understand how the process will play out?

- *Permanet 3* – How do other nets that have PBO get officially recognized as belonging to the same class?
  - Was recognized as first in class
  - Goal is for normative guidance that is generated to be applied to all nets in PBO class to accelerate procurement

- *Interceptor G2 and Olyset Duo* – Under new system, what group would create the interim guidance for these products? What data will they need?
  - Currently under WHOPES evaluation
  - Goal is for them to be used appropriately upon receiving an interim recommendation

Do you have any questions about the process for normative guidance?

Questions for discussion

Where are we aligned?

What would we need to do to implement the areas of alignment?

What are the open questions?

What are the next step to resolve these questions?

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Working session summary: Primer on prequalification

Key takeaways

Prequalification assesses product dossiers against safety, efficacy, and quality requirements

- VC system will be based on existing PQT processes
- PQT will deliver benefits to procurers, manufacturers, regulators, and populations through a faster, more efficient, and more transparent process
- Normative guidance owned by NTD / GMP

New processes and timelines are being developed for vector control products, which will increase efficiency while ensuring quality products

Collaboration with NRAs will be a major focus of PQ

- Collaborative registration of vector control products with PQT to speed time to market
- Assistance with capacity building in countries via the Regulatory Systems Strengthening team
- Political considerations to be taken into acct

Next steps

PQT to develop detailed pathways with requirements and timelines for vector control products in 2016

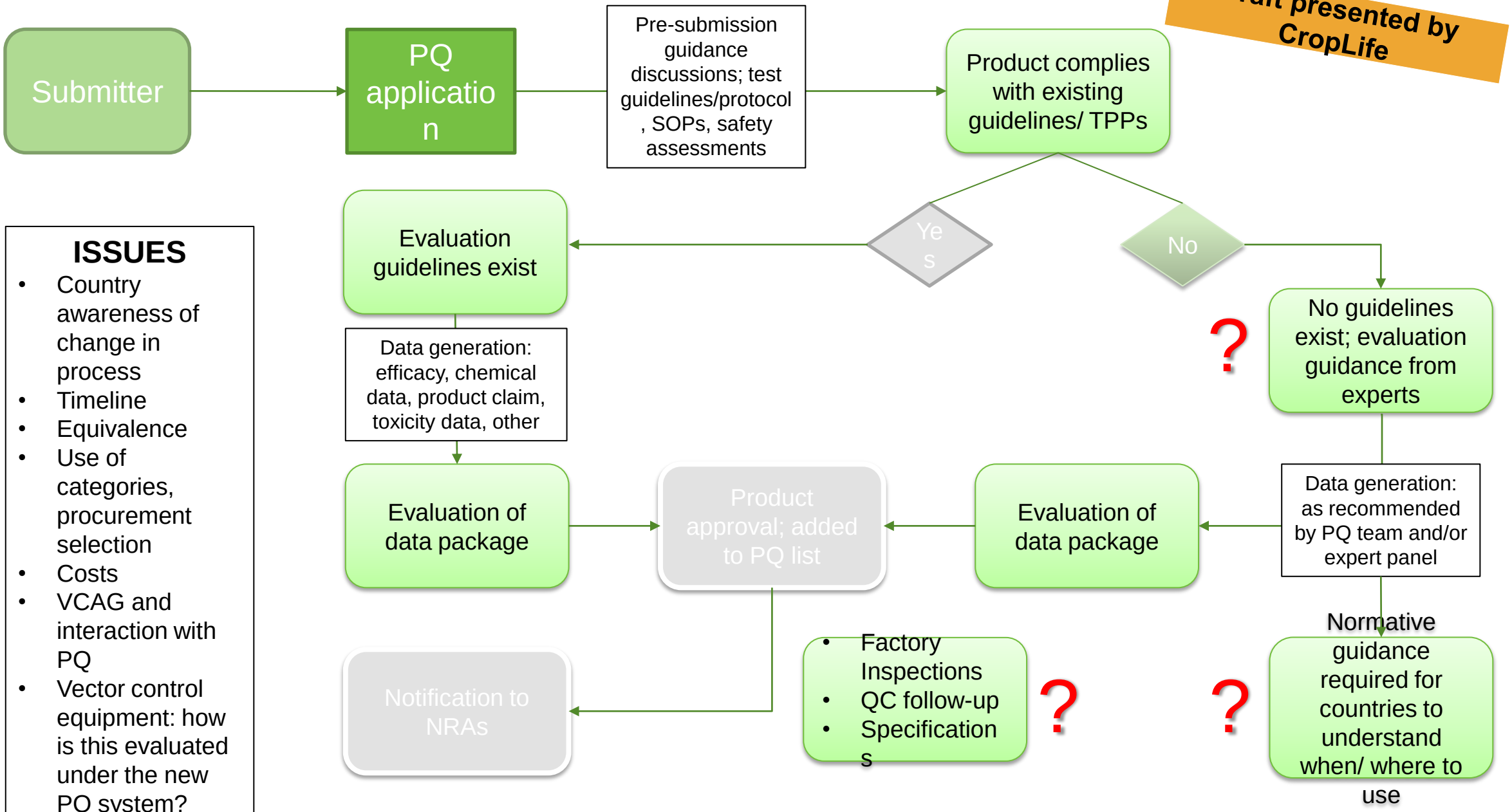
- PQT will share these draft pathways for comment with stakeholders before 2017

Overall, PQT will engage stakeholders throughout the development process

- Croplife shared a potential pathway for vector control products

CropLife Vector Control Team's understanding of new Vector Control Product 'approval' process, under development within I2I

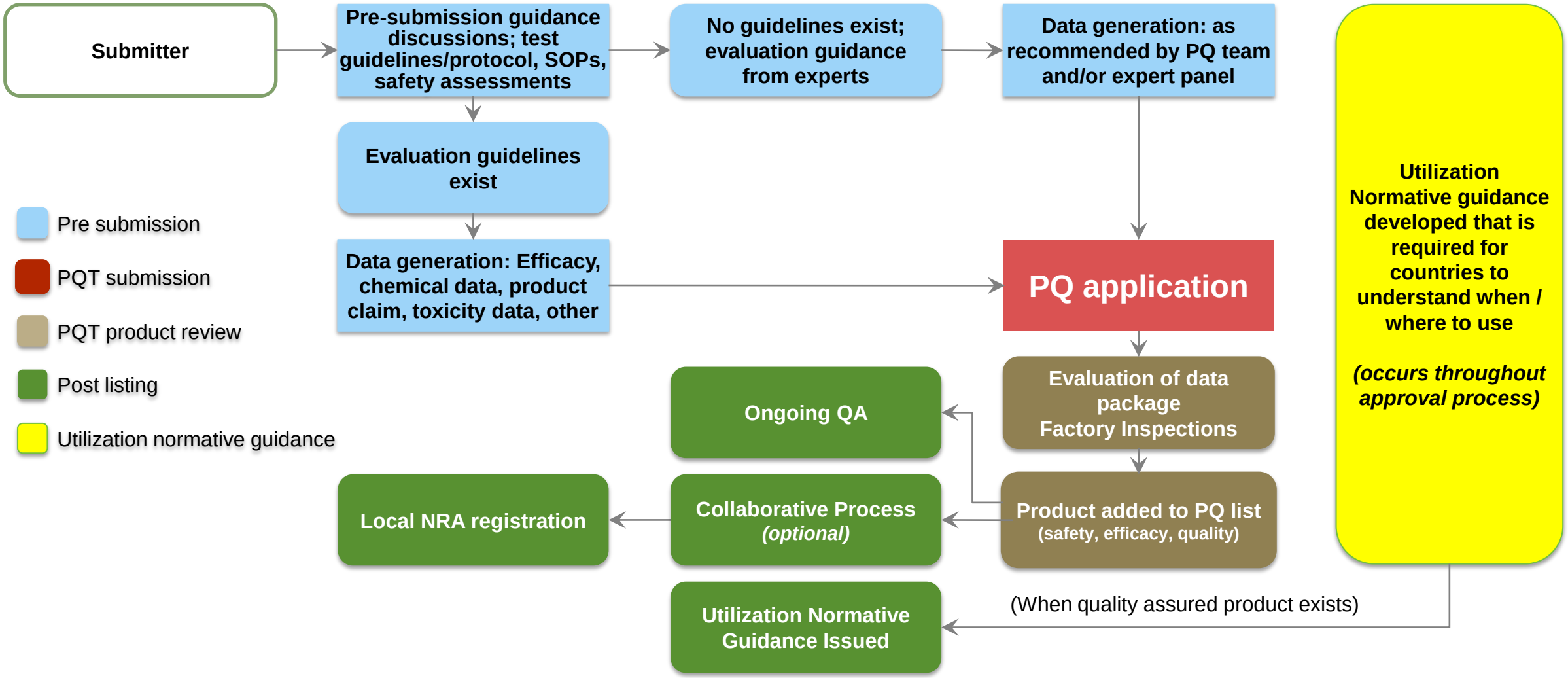
Draft presented by CropLife



ISSUES

- Country awareness of change in process
- Timeline
- Equivalence
- Use of categories, procurement selection
- Costs
- VCAG and interaction with PQ
- Vector control equipment: how is this evaluated under the new PQ system?

Anticipated high level vector control product approval process in 2017+



NTD, PQT, and GMP will continue to coordinate closely throughout process for vector control product assessment and guidance

	Activities		Transition *(pre-2017)*	Target *(2017 - ...)* Established prod.	Target *(2017 - ...)* New tools
Prototype	Decision on possible public health benefit and pursuing further development	Evaluate PH value of new VC tools (incl. technical advice to manufacturers)	**N/A** (for established products VCAG for new VC tools)	**N/A**	**NTD/GMP** (**PQT** involved)
		Dev. of safety / efficacy standards for prototype evaluation			**NTD/GMP/PQT**
Product	Development of standards	Dev. of safety / efficacy standards for product PQ	**NTD** (**PQT** consulted in general and **PQT** will have primary lead of developing new manufacturing quality product evaluation requirements)	**PQT** (**NTD/GMP** involved)	**PQT** (**NTD/GMP** involved)
		Development of manufacturing qual. standards for product PQ			
	PQ product review	Review of PQ dossiers and decision on PQ listing			
		Manufacturing quality of PQ listing process			
	Post-listing	On-going safety / efficacy / quality evaluation			
		Utilization normative guidance	**NTD/GMP**		

Working session summary: Value-based procurement

Key discussion points and perspectives

Summary of points from PMI, UNITAID, and Global Fund:

- Critical to follow evidence based normative guidance from WHO
- Countries define the vector control program and tools
- Country-level demand is provided to procurers, which may sometimes be filtered or adjusted based on TRP (technical review panels)
- Several decisions have been made prior to orders reaching procurement offices, and these decisions shape demand

Industry perspectives on procurement:

- Greater transparency: publishing of scores, pricing offered, and volumes allocated
- Can't wait for definitive evidence of resistance, need to start actively managing now
- Critical that value of innovation is reflected in price—without incentive for development, innovation will not occur.
- Prices of innovative products will drop as procurement scales

Open questions for workstream

What actions can procurers take to encourage adoption of innovative products, even without changed normative guidance?

Is there a role for preliminary guidance (e.g., guidance that emerged from emergency VCAG meeting) that enables procurement of innovative products?

Can normative guidance can be simplified for countries to facilitate country vector control planning and procurement decisions?

How can procurers balance need for universal coverage with need to mitigate future resistance?

Working session summary: Country-level engagement

Key takeaways

Country participation directly in workstreams can support implementation partnership

Country workstream can serve as a sounding board for engagement across workstreams

Need to leverage regional bodies to avoid duplication, amplify efforts, and build capacity

- Will help bring other countries into I2I
- Will encourage further harmonization of regulatory requirements between states
- Will allow engagement with political decision makers to ensure cross-Ministerial collaboration to improve vector control

Next steps

I2I LT to develop detailed list of potential strategic regional partners with timelines for engagement in 2016

- I2I LT will share draft list of partner engagement with stakeholders (regulatory and entomological stakeholders in particular)

I2I LT will engage stakeholders to ensure consistent communication and develop cadence for continued engagement

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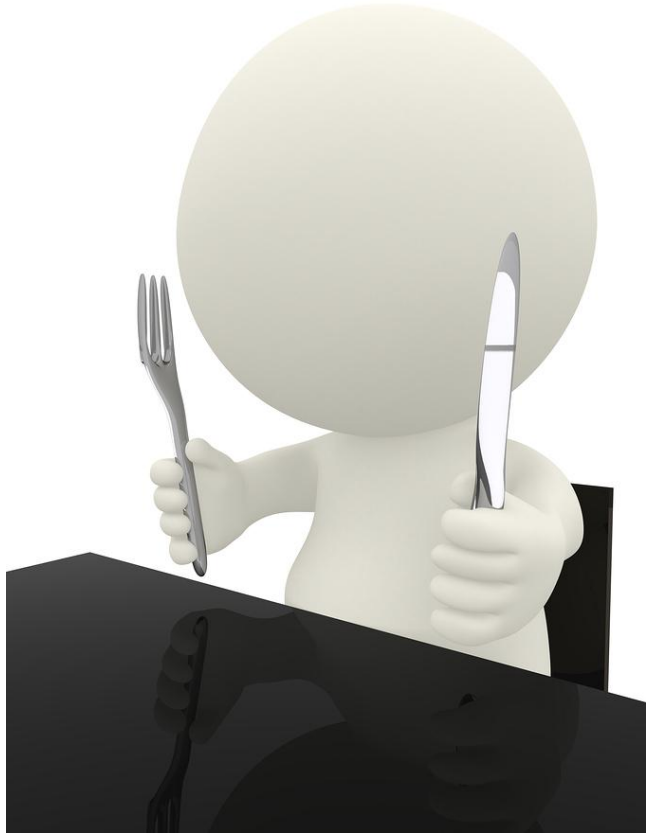
Thank you for your engagement today

Please rejoin us at 7:00pm for cocktails followed by dinner in the Glover Park Ballroom



Please arrive return tomorrow for an 8:30am start. Breakfast will be available from 8:00-8:30am

	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
3	**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
4	**Working session 4:** (a) Convening of industry working group & (b) I2I collaboration model	15:00–16:30

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