



# Innovation to Impact (I2I)

## Slide Deck

# 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



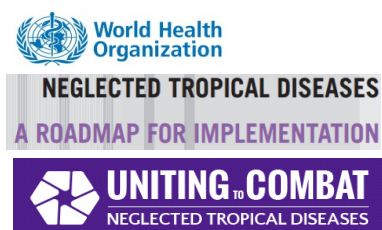
Reduce malaria mortality and incidence by 90% by 2030

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



London Declaration aims for 2020 control, elimination and eradication targets for 10 WHO 2020 Roadmap NTDs<sup>1</sup>

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**

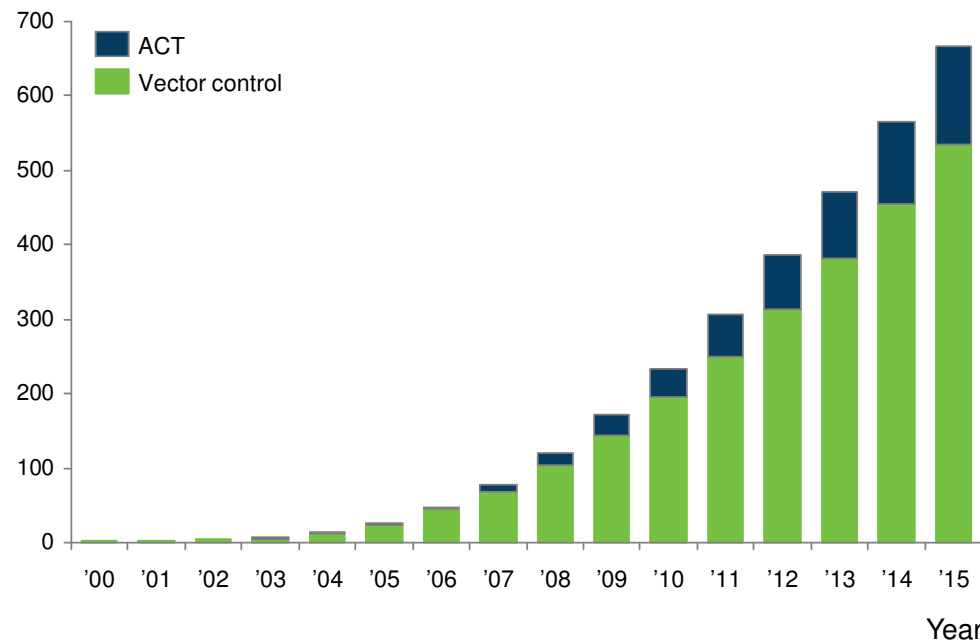
1. Lymphatic Filariasis, Trachoma, Soil-Transmitted Helminths, Onchocerciasis, Schistosomiasis, Leprosy, Dracunculiasis, Visceral Leishmaniasis, Chagas disease and HAT

# 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

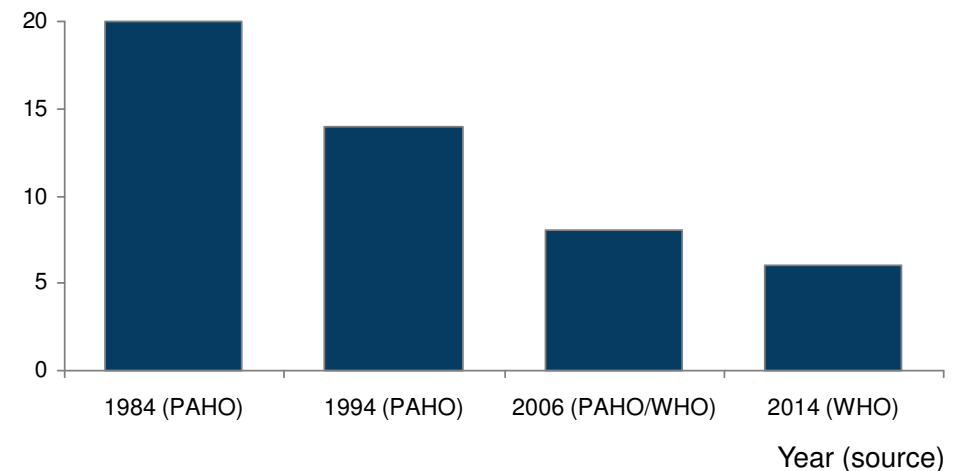
Cumulative cases averted (M)



## 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

Estimated prevalence of Chagas disease 1984–2014 (M)

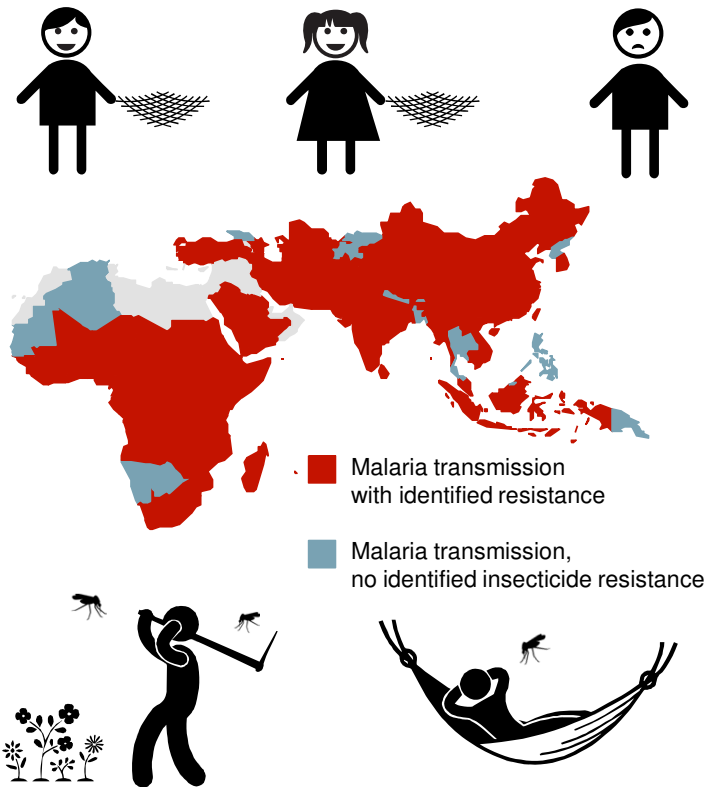


Sources: Bhatt, S., D. J. Weiss, E. Cameron, D. Bisanzio, B. Mappin, U. Dalrymple, K. E. Battle, C. L. Moyes, A. Henry, P. A. Eckhoff, E. A. Wenger, O. Briët, M. A. Penny, T. A. Smith, A. Bennett, J. Yukich, T. P. Eisele, J. T. Griffin, C. A. Fergus, M. Lynch, F. Lindgren, J. M. Cohen, C. L. J. Murray, 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](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 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**



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



**Long delays** in product evaluation and introduction to market

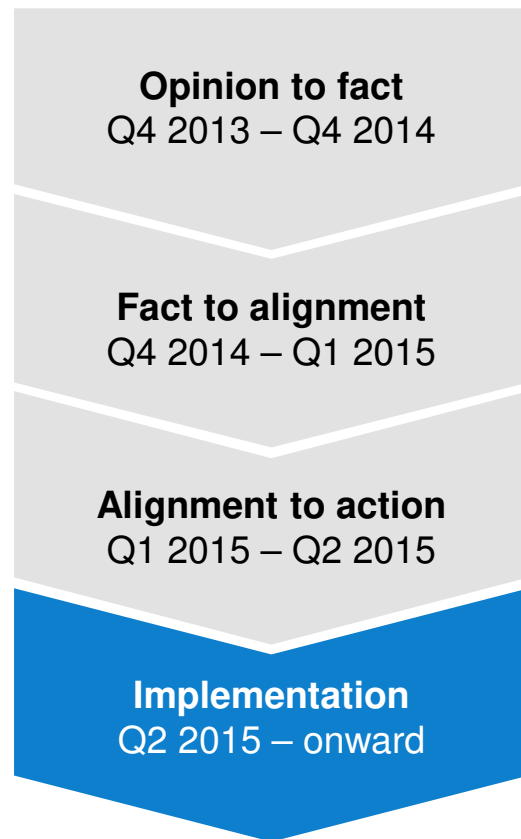


**Lack of systematic quality assurance** systems to ensure efficacious and safe products are delivered to the field sustainably

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 initiated to develop solutions to these challenges

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



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



# I2I workstreams will be supported by the I2I collaboration model



Vision area

Time-limited workstreams

## 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

# I2I advisory board



**Scott Miller, PhD**

- Bill and Melinda Gates Foundation
- Deputy Director, Malaria

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



**Pedro Alonso, MD, PhD**

- World Health Organization (WHO) Global Malaria Programme
- Director

Observer



**To be determined**

- World Health Organization (WHO) Health Systems and Innovation

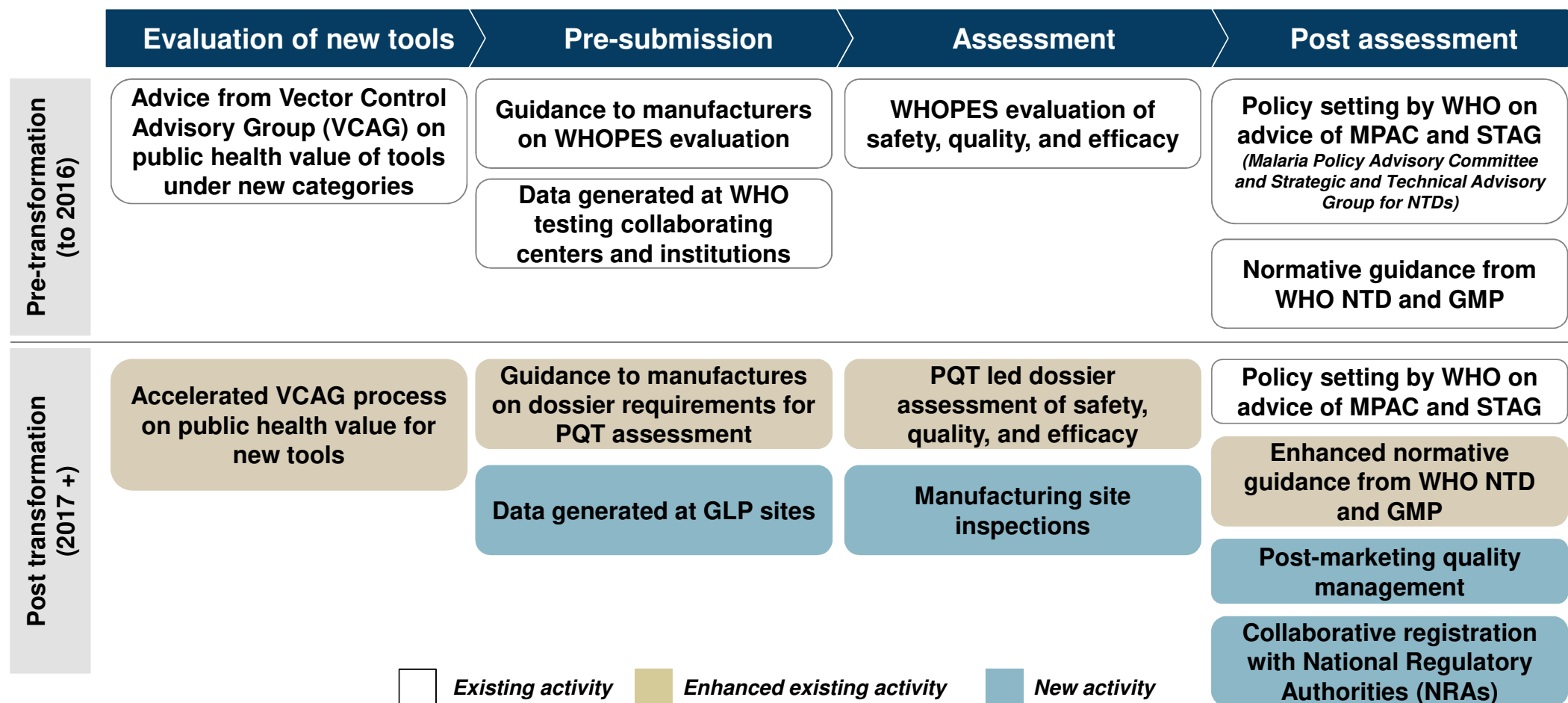
Observer



**To be determined**

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

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



# Transition from NTD (WHOPES) to PQ

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

# Priorities for I2I in 2016

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## **WHO Transition:**

- Equivalency meeting and PQT workshop in October.
- Continuing feedback from workstreams.
- Preparing for launch on 1/1/2017

## **Industry:**

- Ensuring feedback in to key PQT processes around pathways for new AIs, dossier requirements & manufacturing process inspections.
- Engaging with generic manufacturers.

## **GLP:**

- IVCC & WHO supporting GLP site accreditation process
- Collating information on site capacity
- Cataloguing & standardizing product testing SOPs

## **Procurement:**

- Defining value based procurement based on product claims and data needs.
- Updating guidance on product quality assurance.
- IRM issues from policy to testing specifications and capacity.

## **Country Level:**

- Coordinating with PQT on collaborative registration process.

## Key meetings calendar for Q3 and Q4 2016

September	October	November	December
<p><b>14-16 Sep: MPAC (Geneva)</b></p> <p><b>20-21 Sep: GCDPP (Geneva)</b></p>	<p><b>4 Oct: I2I WHO Directors update (call)</b></p> <p><b>17-18 Oct: NTD Equivalency Expert Meeting (Geneva)</b></p> <p><b>26-28 Oct: PQ Dossier Requirements Workshop + Inspections protocol (Geneva)</b></p> <p><b>31 Oct-1 Nov: IVCC ESAC (London)</b></p>	<p><b>2-4 Nov: VCAG Annual Meeting and Gene Drive (Geneva)</b></p> <p><b>13-17 Nov: ASTMH Annual Meeting (Atlanta)</b></p> <p><b>TBD Mid-Nov I2I WHO Senior Director's Update (Geneva)</b></p> <p><b>TBD Nov (during ASTMH): I2I Advisory Board Meeting (Atlanta)</b></p> <p><b>30 Nov-2 Dec: IVCC Board Meeting (Liverpool)</b></p>	<p><b>TBD: Prequalification "Open Doors" meeting</b></p> <p><b>TBD: Collaborative Registration Process with NRAs</b></p>