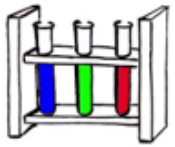
Market Access Initiatives: NgenIRS and the New Nets Project

Christen Fornadel | January 2019

RBM VCWG Meeting

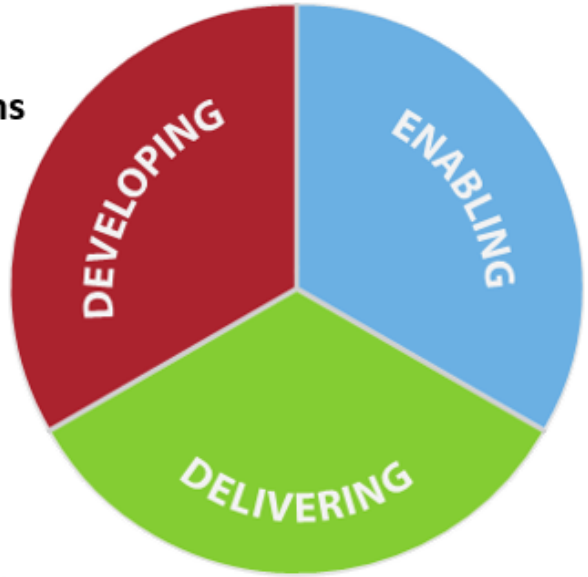
IVCC Strategic Framework: 'End to End' Product Development



New public health insecticides with novel modes of action

Long lasting IRS formulations and dual active ingredient LLINs

Solutions blocking outdoor disease transmission



Building stakeholder partnerships

Improvements in the reliability and consistency laboratory and field data

Improved and efficient application technology for IRS

Integrated Vector Management, Insecticide Resistance Management and Integrated interventions

IVCC NgenIRS

The New Nets Project

Access, Delivery and Market Shaping

IMPACT

IVCC Access Objectives

- **Minimising time to optimal impact**
  - Regulatory and normative process (I2I)
  - Market Analysis and Intervention (NgenIRS and NNP)

- **Supporting evidence and impact based deployment of innovative vector control technologies**
  - Creating the evidence of impact and cost effectiveness (NgenIRS and NNP)
  - Modelling Tools and Data for Country and Global level decision making (Imperial College malaria tools development)
  - Supporting the case for Global funding of new vector control products (Economic models of the costs and impact)

- **Effective and sustainable management of products as Insecticide Resistance Management tools**
  - Supporting creation of Policy, Guidelines and Standard Operating Procedures (Providing evidence and implementation experience)
  - Sustainable management of the New AIs (Stakeholder Alliance for Resistance management)

- **Sustaining vector control innovation**
  - Sustainable Global Access Plans (Binding partner agreements)
  - Robust competitive markets (NgenIRS and NNP providing market pull)
  - Sustainable Target Product Profiles (Feedback from field experience to product design)

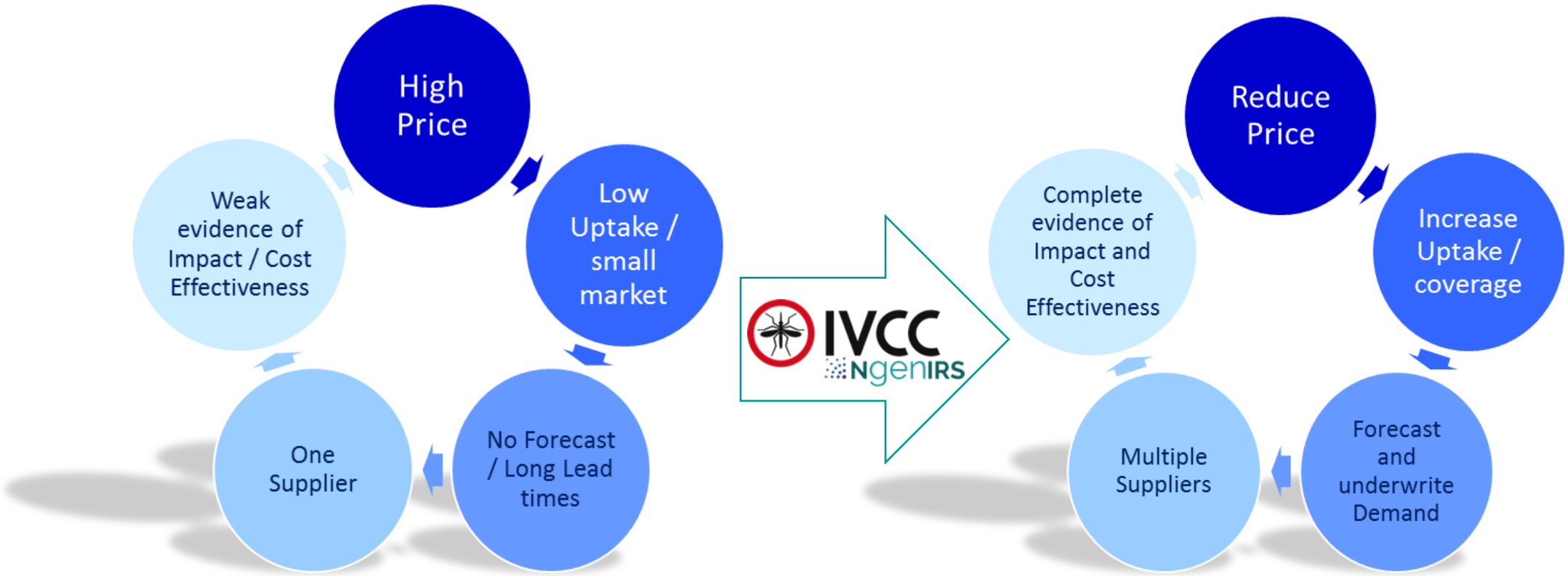
Next Generation IRS (NgenIRS)

Programmatic Update

Reversing the Spiral: Next Generation IRS

The Market for 3rd Generation IRS
Underlying Causes of Shortcomings

Market Shaping Intervention



Next Generation IRS Project

Demand	Accelerate uptake of 3GIRS products
Market stability	Improve global forecast for 3GIRS products
Competition	Support new WHO approved 3GIRS products from several manufacturers
Affordability	Reduce prices of 3GIRS products
Evidence	Gather and disseminate evidence of cost effectiveness and impact of 3GIRS

What we do in PARTNERSHIP

The NgenIRS project is a 4 year Unitaid-funded market shaping initiative

Launched early 2016

Investment of $65.1 million

Unitaid
Innovation in Global Health

Goal

Increased use of 3GIRS products in Insecticide Resistance Management (IRM) programmes

Outcome

A sustainable, growing and competitive market for effective 3GIRS products at affordable prices

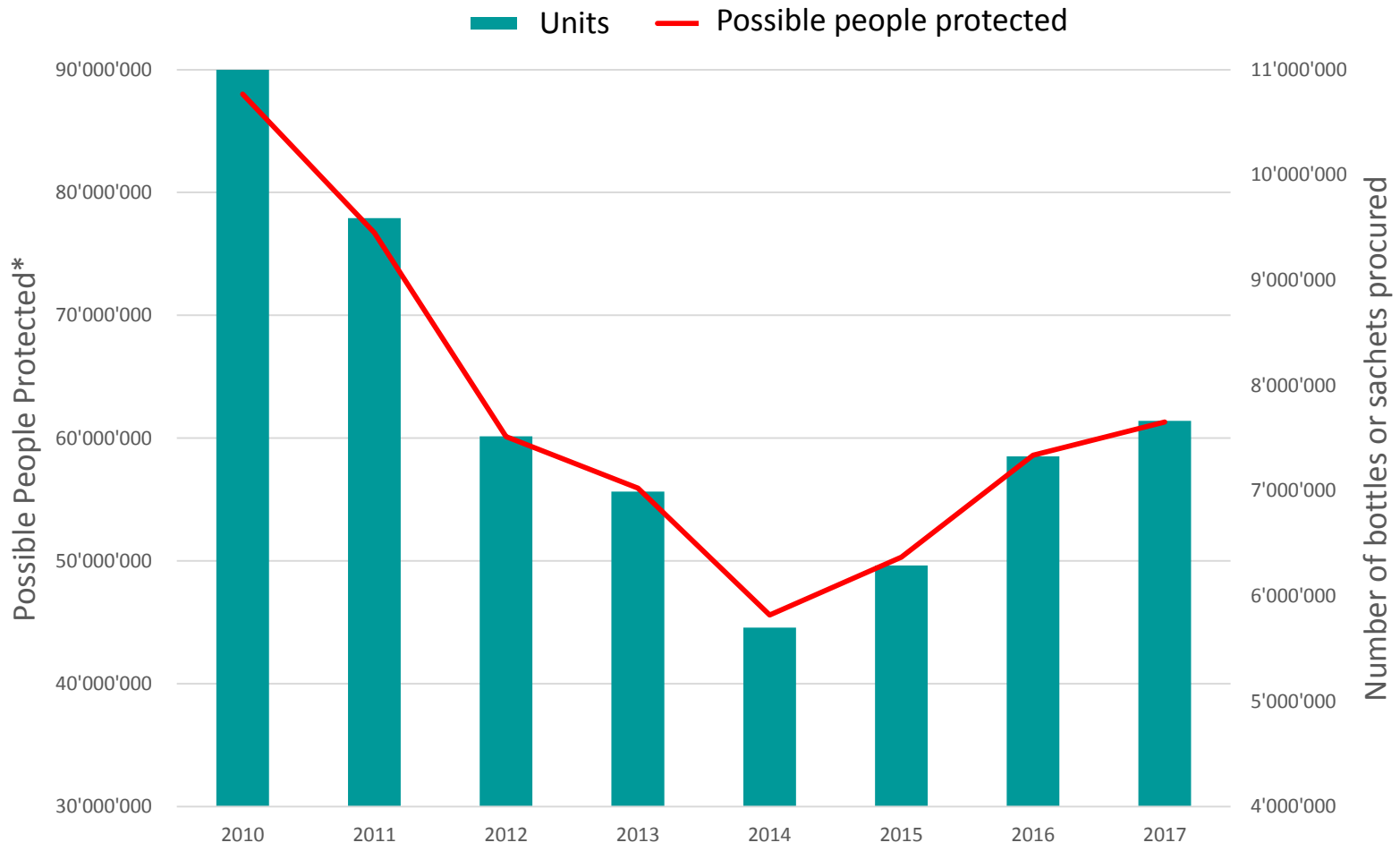
USAID FROM THE AMERICAN PEOPLE · CDC · U.S. President's Malaria Initiative · The Global Fund To Fight AIDS, Tuberculosis and Malaria · Abt Associates · PATH · Bill & Melinda Gates foundation · syngenta · Sumitomo Chemical · Bayer · BASF We create chemistry

Next Generation IRS Project Accomplishments

Demand	Accelerate uptake of 3GIRS products	Downward market trend reversed with over 30 countries procuring 3GIRS with donor and domestic funding
Market stability	Improve global forecast for 3GIRS products	Development of global forecasting tool provides manufacturers with the ability to plan better and reduce costs
Competition	Support new WHO approved 3GIRS products from several manufacturers	From only 1 product in 2016 to 3 products with two more in the pipeline
Affordability	Reduce prices of 3GIRS products	Prices reduced from over $23 per unit to an average about $16 and trending to $15 or less by 2020
Evidence	Gather and disseminate evidence of cost effectiveness and impact of 3GIRS	Compelling evidence showing impact and cost-effectiveness of IRS in combination with LLINs and MDA

Reversing the Downward Trend in IRS Demand

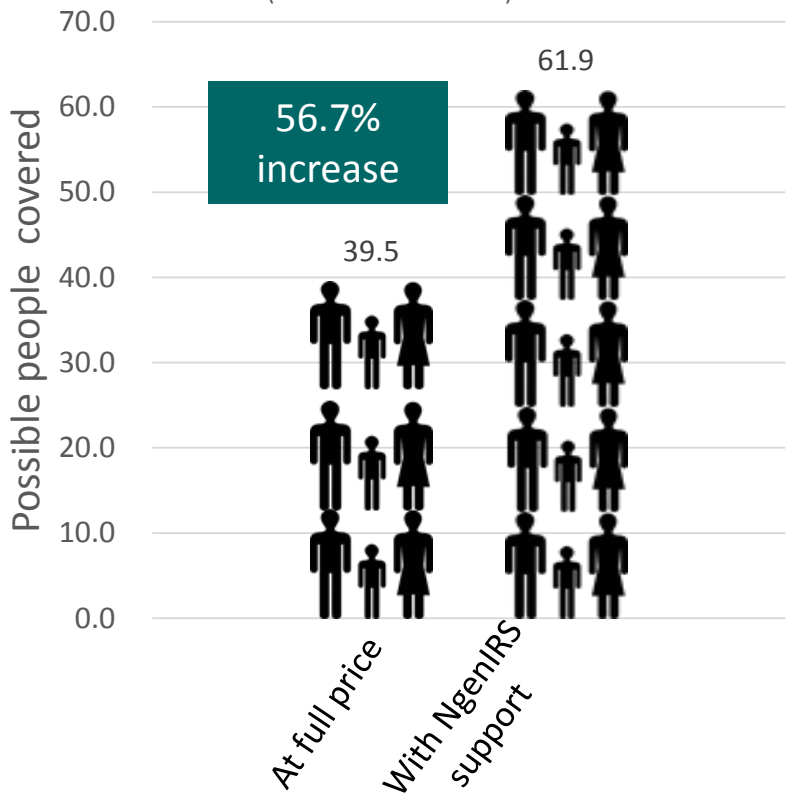
Estimated IRS insecticide volumes procured in Africa 2010 - 2017



* Assumes an average of 8 people protected per unit of IRS; Data source: WHO and consultation with NMCPs and implementation partners

Cumulative impact estimates: 2016-2018

Estimated increase in possible number of people protected in NgenIRS co-payment partner programmes
(2016-2018 combined)



Co-payment Partner Coverage Expansion

Year	People protected by NgenIRS copaid volumes	Possible people protected with same budget at full price	Possible increase in people protected thru NgenIRS	% increase in people protected
2016	5,917,099	3,786,730	2,130,369	56.3%
2017	25,441,963	15,422,057	10,019,906	65.0%
2018*	30,572,979	20,322,263	10,250,715	50.4%
totals	**61,932,041**	**39,531,051**	**22,400,990**	56.7%

An additional 14 million people are estimated to have been protected by 3GIRS procured at NgenIRS negotiated volume discount pricing during the same 3 year period.

* 2018 Coverage data are estimates pending final reporting

NgenIRS Public Health Impact

61.9 Million people

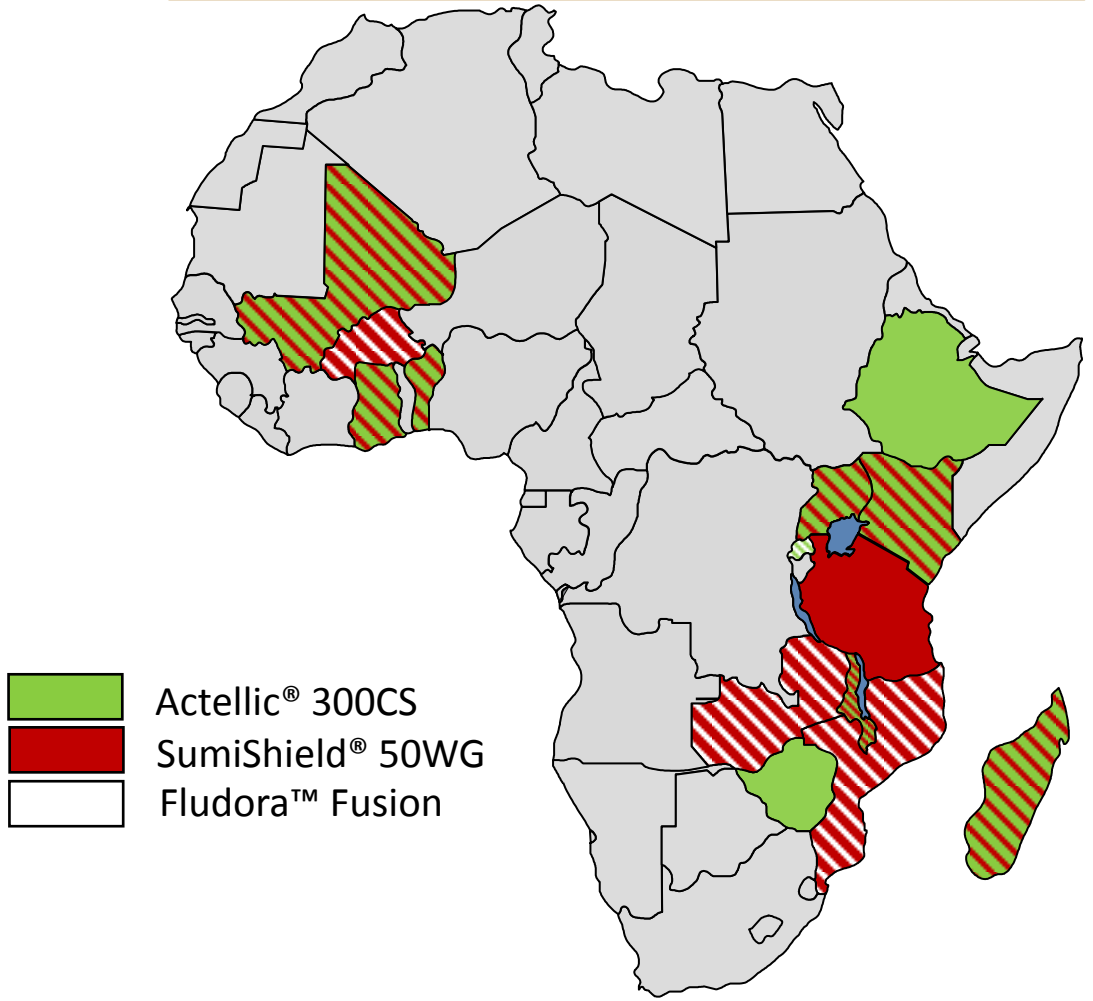
Estimated number of
people protected
throughout Africa by IRS programs receiving NgenIRS co-payment support (2016-2018)

Between 2.6 and 5.2m malaria cases averted

Between 7,900 and 15,800 lives saved

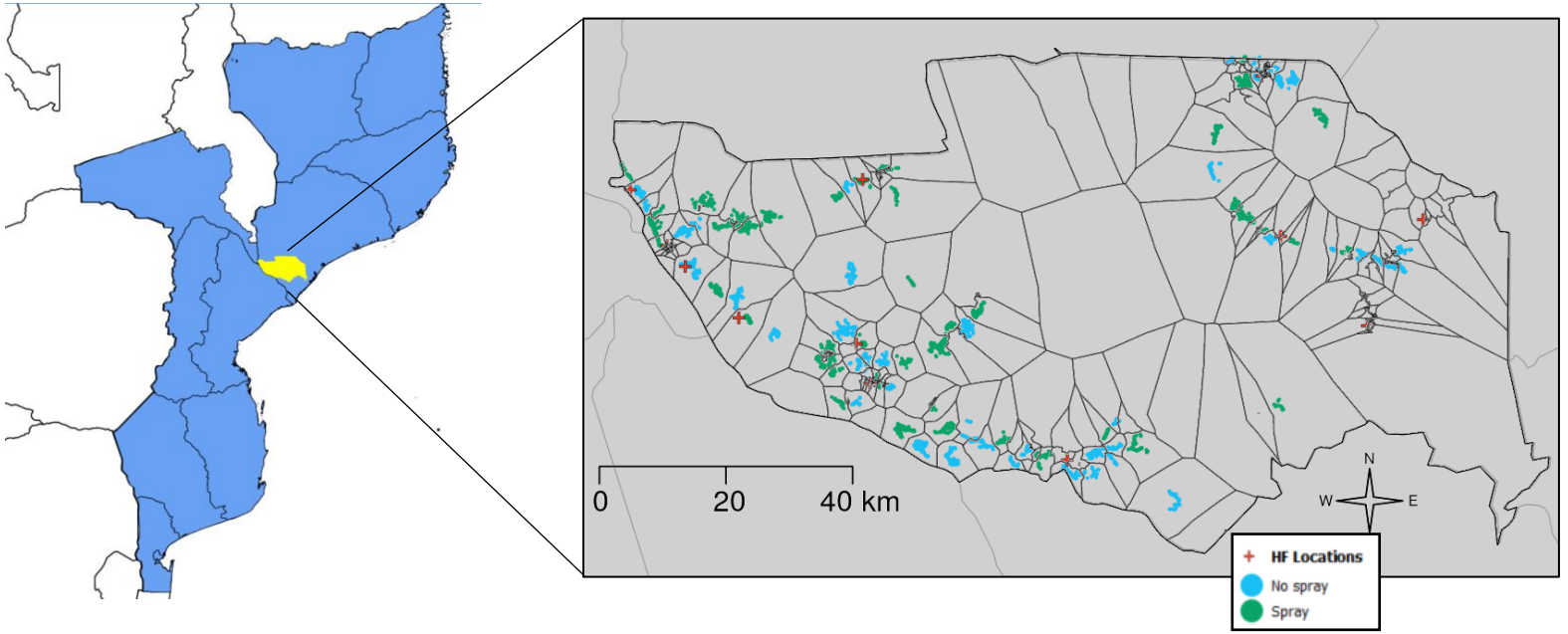
Estimated number of cases averted and lives saved by IRS programs receiving NgenIRS co-payment support (2016-2018)

11 of 14 NgenIRS partner countries are planning to spray multiple 3GIRS products in 2019



Evidence Base Being Established to Show Impact and Cost-effectiveness of 3GIRS

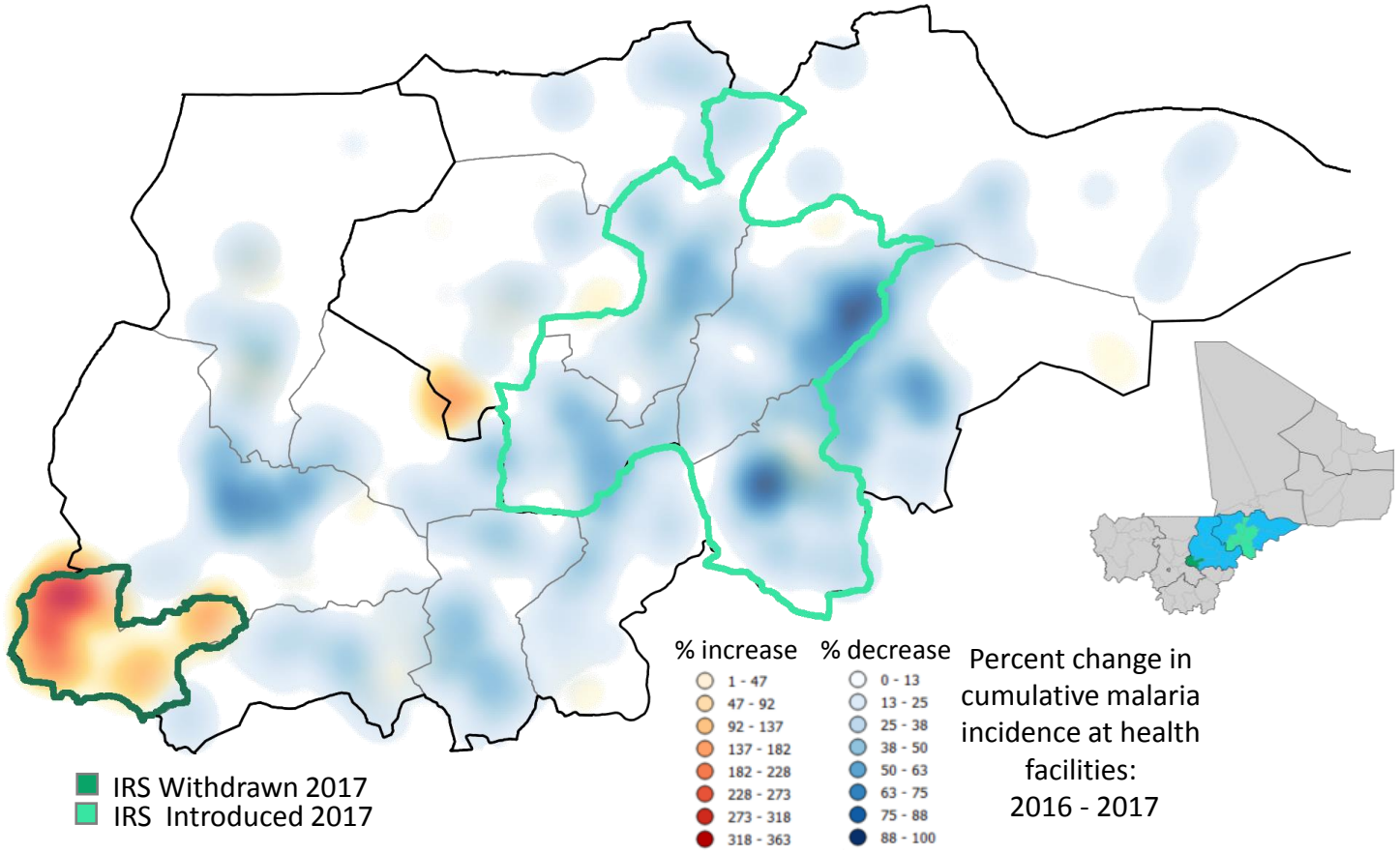
- Cluster Randomized Trial in Mozambique: The impact of 3GIRS in addition to standard LLINs



- 85% reduction in *An. funestus* densities in 2018
- 20% reduction in cohort incidence
- Odds of infection reduced 46% in 2018 prevalence survey
- 3rd year extension to look at SumiShield

Evidence Base Being Established to Show Impact and Cost-effectiveness of 3GIRS

- Observational (non-randomized) evidence of impact – Mali
- 2017 PMI AIRS IRS operations were shifted from Ségou region to Mopti Region



- Removal of 3GIRS from Bla District in Mali resulted in 70% increase in incidence.
- Cost of IRS in Mali's Ségou region was estimated at $33.75 per case averted*

*Wagman et al. Malar J (2018) 17:19

Evidence Base Being Established to Show Impact and Cost-effectiveness of 3GIRS

- Use of 3GIRS associated with 26% and 47% reductions in malaria cases in Zambia and Uganda respectively

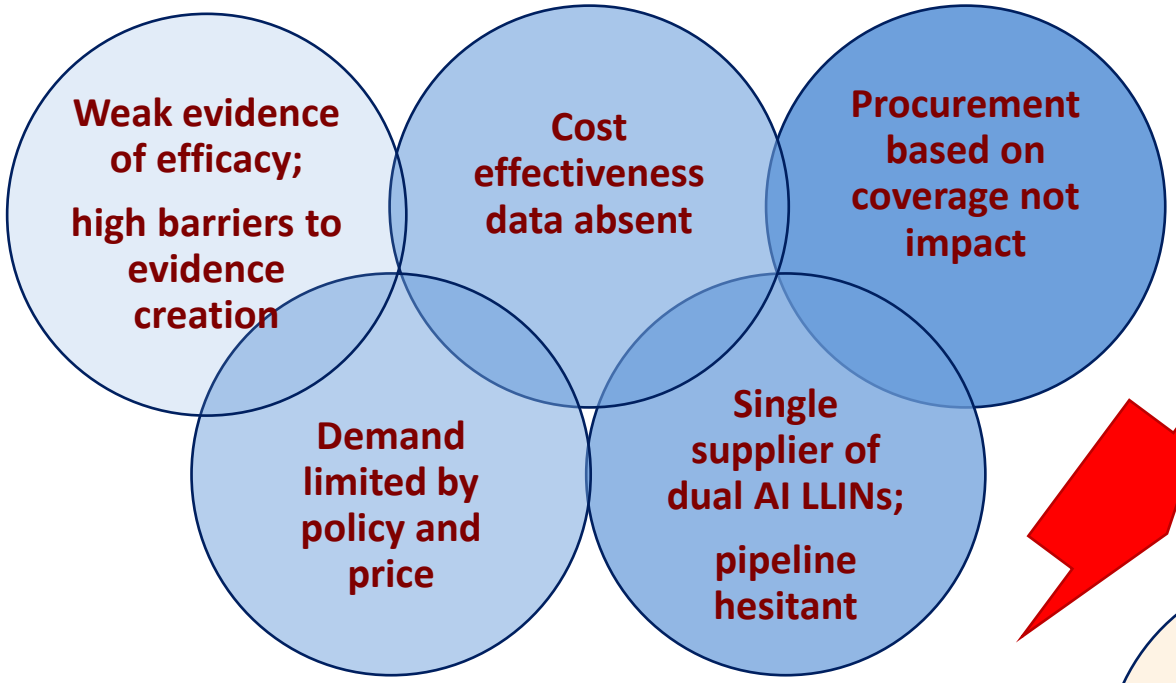
- Retrospective analyses looking at epidemiological and entomological data will continue in Burkina Faso, Ghana, Mali, Zambia

*Wagman et al. Malar J (2018) 17:19

New Nets Project (NNP)

Programmatic Update

New Nets Project Scope



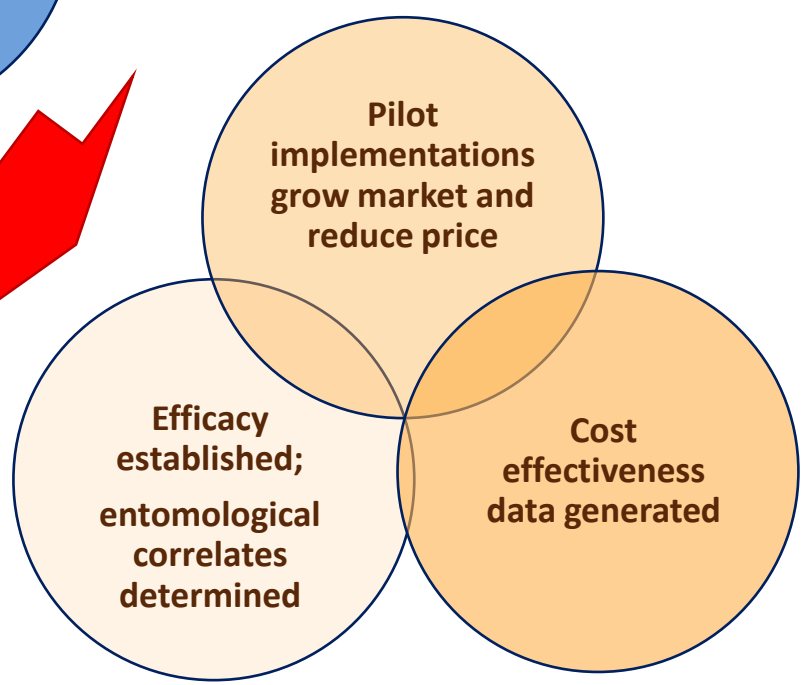
Current status of Dual AI LLIN Market

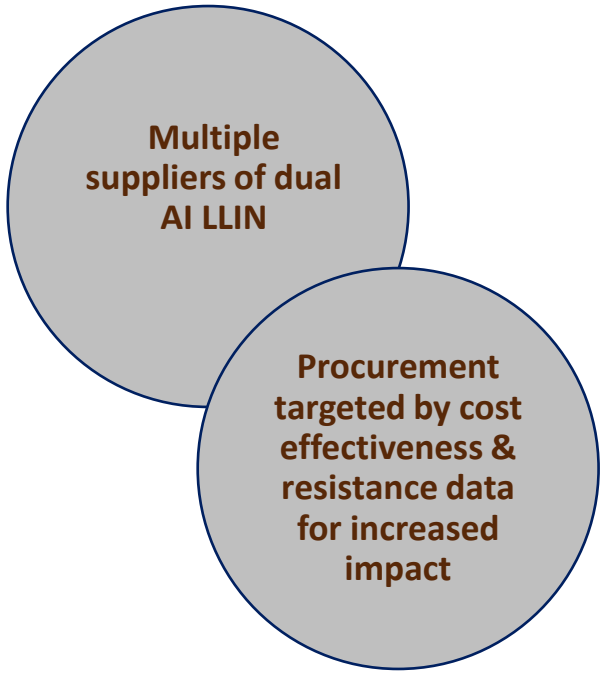
Unitaid

The Global Fund
To Fight AIDS, Tuberculosis and Malaria

CDC USAID FROM THE AMERICAN PEOPLE
President's Malaria Initiative

BILL & MELINDA GATES foundation





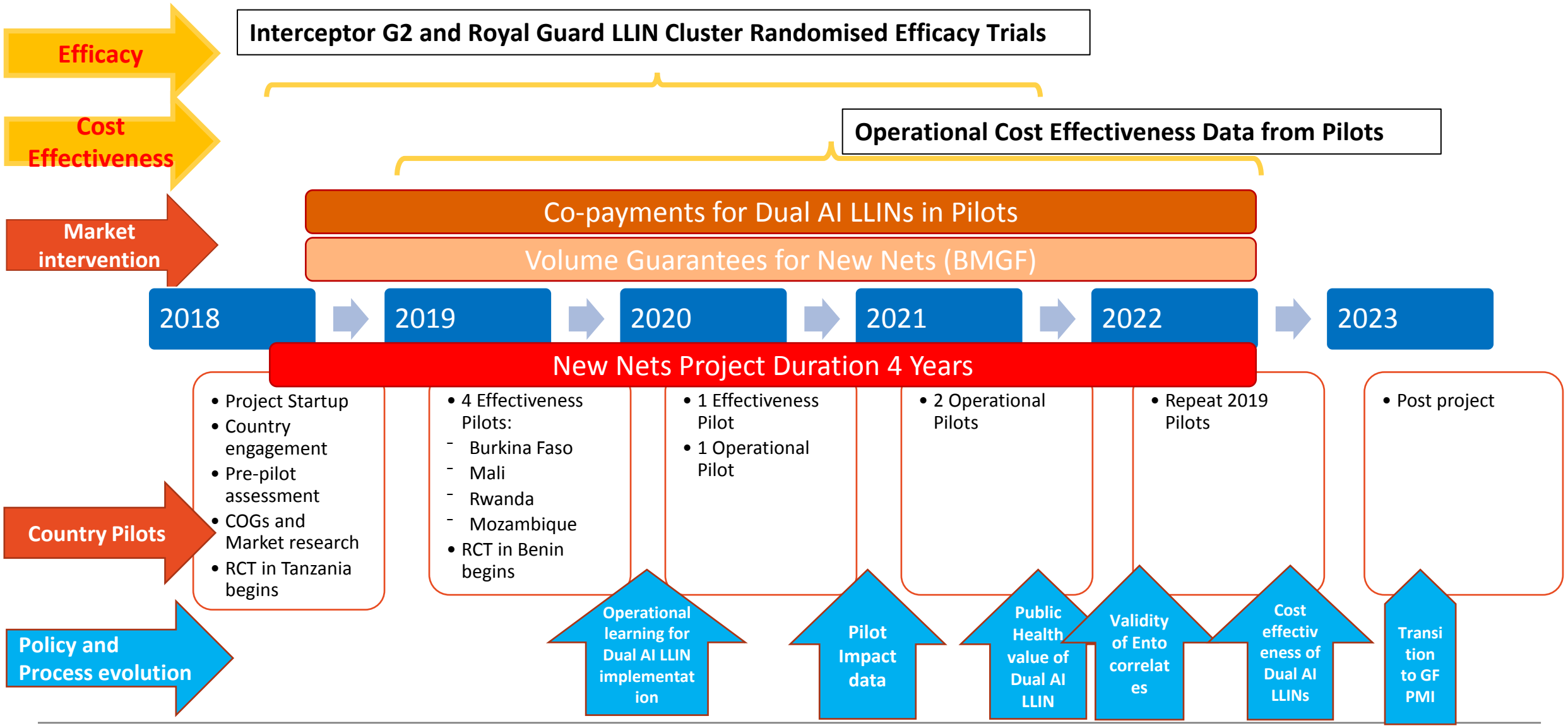
Outcome of the New Nets Project

Next Phase TBD

New Nets Project Team Roles

- IVCC Lead and Coordinator
  - Negotiations with Industry Partners,
  - Co-Payment system and contracts to reduce price.
  - COGs understanding and ability to get Industry to cooperate on COGs.
  - Links to the vector control product development pipeline.
  - Links to Ag Chem CEO forum and the ask from industry.
- PATH
  - Cost effectiveness determination from pilot implementations
- PSI
  - Technical assistance to pilot implementations
- LSHTM
  - Cluster Randomised trials of Dual AI LLINs and Entomological Correlates in trials
- Tulane
  - Cost effectiveness trials and data collection design
- Imperial College
  - Modelling of trials design and implementation impact
- LSTM
  - Entomological correlates of epidemiological Impact

New Nets Project Overview



Overview of Cluster Randomized Trials

	Benin	Tanzania
Funder	UNITAID/Global Fund via IVCC	The Department of Health and Social Care UK, DFID, MRC and Wellcome; top-off & hut trial from BMGF
Organizations Involved	CREC/LSHTM	NIMR/KCMUCo/LSHTM
Type	RCT with associated hut trial	RCT with associated hut trial
Location	Cove, Zagnanado, Ouinhi in Zou Department, Benin	Misungwi (southern Lake Victoria)
Local Vectors	*An. gambiae* and *An. coluzzii*	*An. gambiae*, *An. arabiensis*, *An. funestus*
Dates	Sept 2018 - Aug 2022 (1 year baseline, net distr. Dec 2019, + 2 years post-intervention)	Net distribution January 2019, + 2 years post-intervention
Arms/Nets tested	3 arms: Royal Guard, IG2, Interceptor	4 arms: Royal Guard, IG2, Olyset Plus, Interceptor

Benin RCT

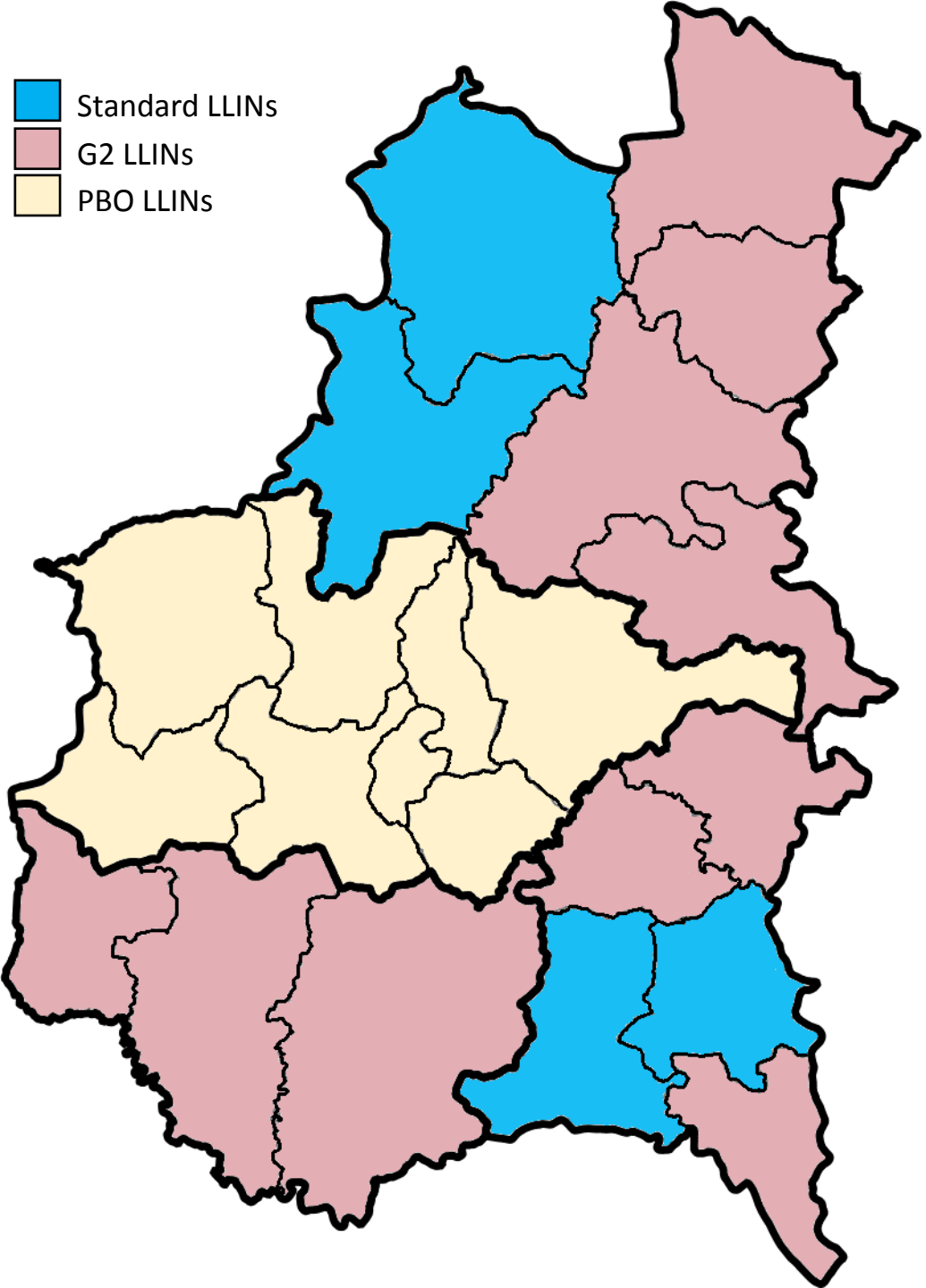
Designed to be complimentary to Tanzania RCT to provide second data set for VCAG review of additional public health value of IG2 and Royal Guard

Epidemiological Data	Indicators collected	• 1°: malaria incidence in 6-10y • 2°: x-sectional prevalence in 6-10y, anaemia in U5s
	# of subjects	• incidence: 25 children*60 total clusters • prevalence: 40 HH *60 total clusters
	Frequency of collection	• incidence: 2x/month for 24 m. • prevalence: 2x total (@12m and 24m)
Field Entomological Data	Indicators	• 2° study indicator: EIR • mosquito density, indoor/outdoor ratio, parity rate, proportion with misshapen ovaries
	Sample size	• 8 HH per cluster * 60 clusters
	Frequency	• each cluster visited once/2months
	Insecticide resistance testing	• frequency and intensity to perm, alpha, PPF, chlorfenapyr in 3 clusters per arm (9 total) • screening subset for vgsc, cyp6
Net Data	Indicators collected	• bioefficacy via WHO cone, cylinder, or tunnel test • chemical content by HPLC • fabric integrity via hole counting • net ownership/access/use

New Net Effectiveness Pilots

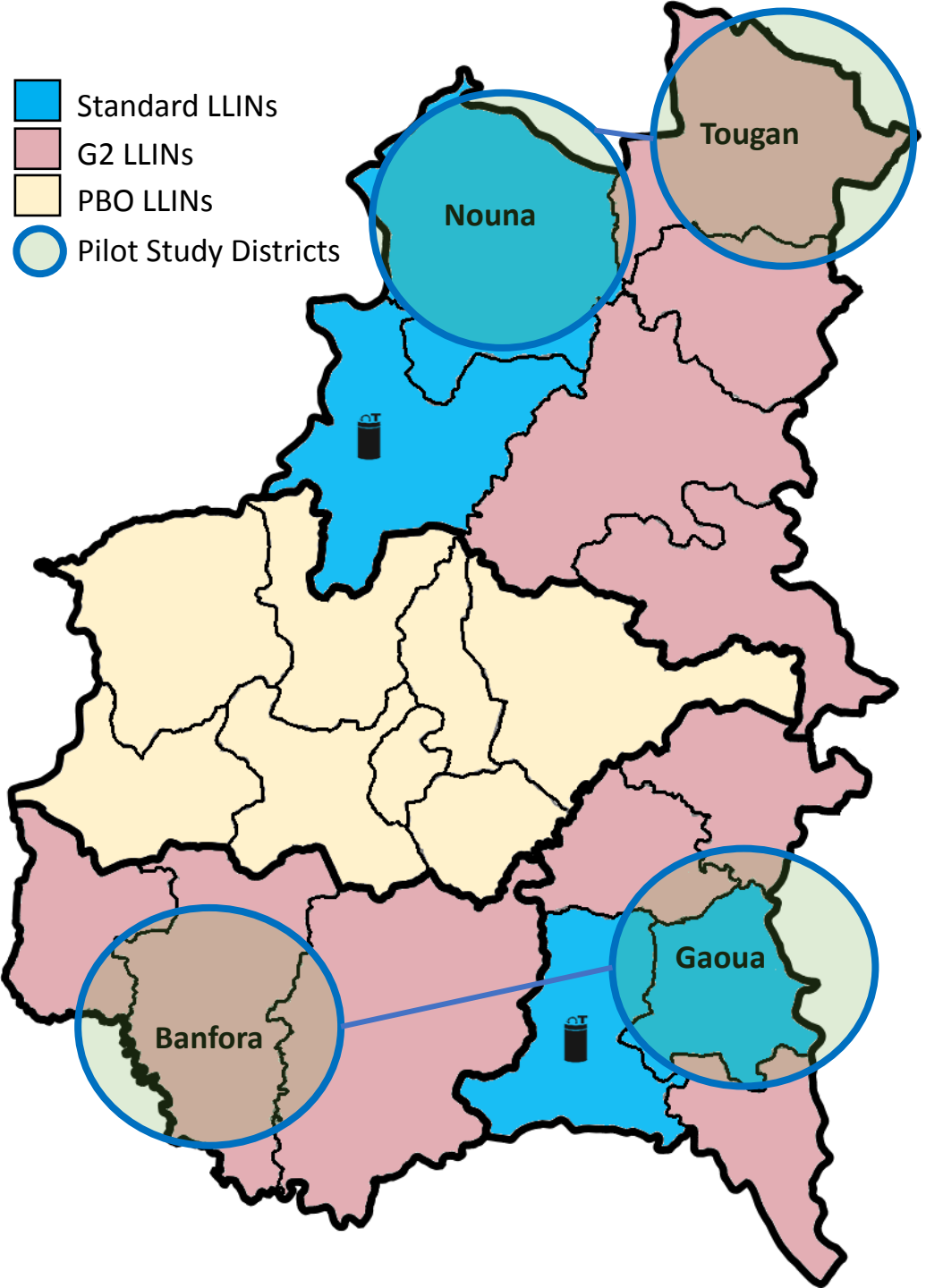
- Will provide data for cost-effectiveness evaluations
- Five pilots
- Criteria for pilot country selection:
  - SSA Global Fund or PMI country – high disease burden and constrained resources
  - Documented pyrethroid resistance
  - Planned campaign in targeted year
  - Country stability and preparedness to participate in a new LLIN campaign
  - Logistics capabilities to store and distribute LLINs to the right area
  - High performing surveillance system
  - Capacity for entomological studies
  - The pilot countries are split over Africa (East, West, Central, Southern)

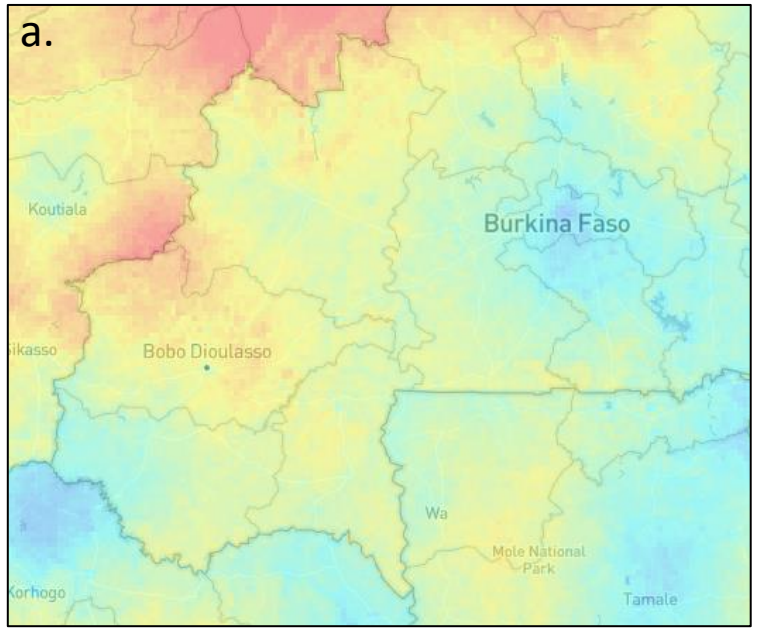
First pilot deployment = Burkina Faso in June 2019

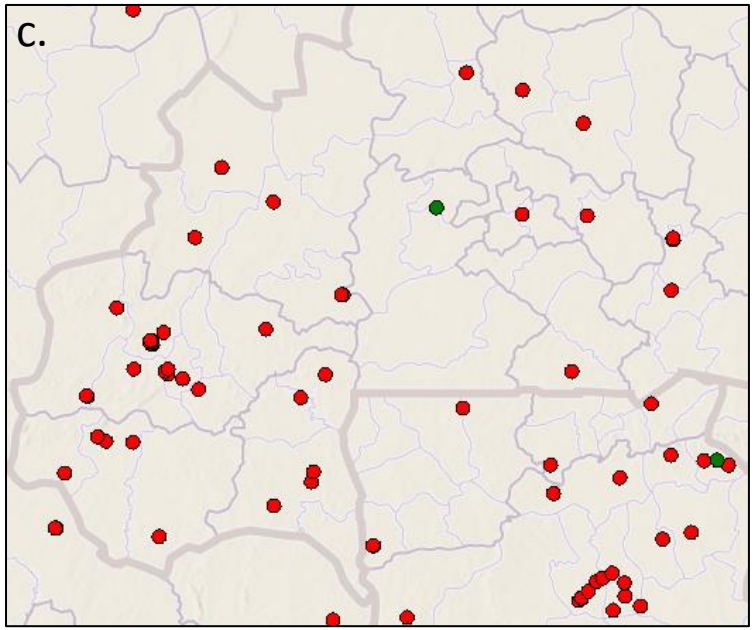


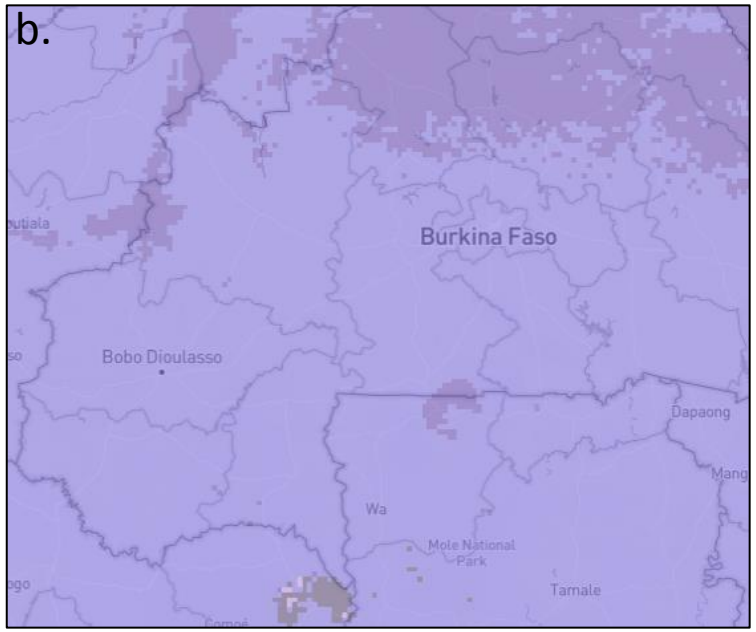
In New Net Project pilot countries, upcoming mass distribution campaigns will utilize a combination of LLIN types.

- Some districts will distribute G2 LLINs
- Some districts will distribute standard LLINs







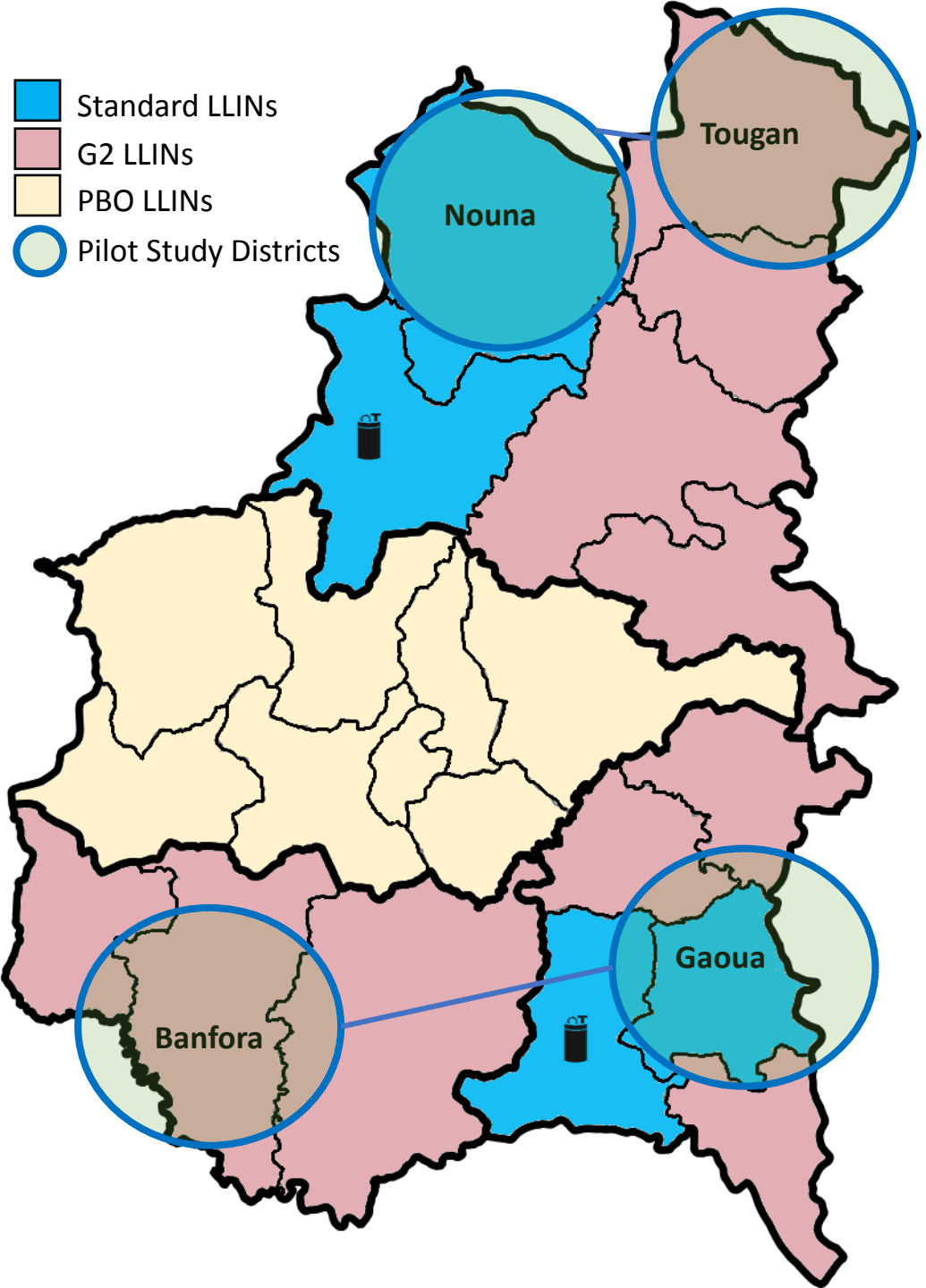


Pilot Study districts are matched in terms of:

(a) Disease burden (prevalence and reported case incidence)

(b) Vector species composition

(c) Insecticide resistance profile



In each pilot district (IG2 and Standard LLIN comparator), enhanced surveillance activities will monitor the impact of mass LLIN distribution on:

Vector bionomics
- Species compositions & densities
- Species-specific biting patterns
- Sporozoite rates & EIR estimates

Malaria epidemiology
- Passive case incidence
- Annual infection prevalence surveys

Human behavioral determinants of risk,
as the intersection between
- Time at risk of mosquito blood feeding
- Human activities not protected by a bed net

These datasets will feed into a broader analysis of the cost-effectiveness of dual AI LLINs

Ento/Epi Correlates

Can Phase II experimental hut trial outcomes serve as a surrogate for epidemiological and transmission outcomes ?

LSHTM and Imperial:

- Huts constructed in vicinity of both Benin and Tanzania RCTs
- Nets: standard washed or field sampled over time
- Ento outcomes modelled to determine how predictive of trial results

Companion work by LSTM funded by BMGF:

- Augment Tanzania and Benin hut trials, add huts to Burkina Faso pilot
- Behavior tracking around nets
- Investigation of sublethal effects
- Detailed field resistance data collection
- Model data and compare with field ento/epi
- Define min set of ento data to predict epi outcomes

*Massue et al. Malar J (2016) 15:165

Thank you for you continued support and collaboration!!!