Plenary session Welcome (from I2I Leadership Team; AB Chair)

Date: 3/22/16, 08:30-10:00 ET

Key takeaways:

- Introduction of the I2I advisory board and director Angus Spiers
- We have come a long way in the fight against malaria, and the majority progress in the last 15 years has been due to advancements in vector control
- I2I has been gathering momentum since 2013 and is now well into the implementation phase with progress underway to achieve long term goals
- The I2I Leadership Team and Advisory Board are committed to coordinating between workstreams and creating a path forward for the initiative to achieve its goals

Decisions made:

- N/A

Presentation: Tim Zeimer, Janet Zhou, Angus Spiers: ***See slides on page 2-19 of "March 22 materials" at www.innovationtoimpact.org/convening***

Plenary session WHO Transformation

Date: 3/22/16, 10:30-12:30 ET

Key takeaways:

- The WHO transformation in vector control is a collaboration between three departments in the WHO: Global Malaria Programme (GMP), Neglected Tropical Diseases (NTD), and the Prequalification team (PQT; under Essential Medicines and Other Health Products)
- The transformation will support a faster, more transparent, and strong vector control evaluation system incorporating strengthened quality control activities and normative guidance
- Two grants have been approved from the Gates foundation to support the WHO transformation effort through 2017 (PQT) and 2018 (NTD)
- Broad progress has been made in the NTD grant, including the dossier review pilot, equivalency consultation, and GLP site accreditation.
- The new evaluation process in the prequalification team, which will begin as of 1/1/2017, is under development and will be based off of the successful framework of the prequalification programs in medicines, vaccines, and diagnostics
- Attendees are eager to see more detail on timelines for the WHO transition, and detail on new processes for PQT including regulatory pathways for products

Decisions made:

- N/A

Presentation: Raman Velayudhan, Dr. Mark McDonald, Dr. Abraham Mnzava: ***See slides on page 22-57 of "March 22 materials" at www.innovationtoimpact.org/convening***

Working session 1a: Primer on WHO Prequalification

Date: 3/22/16, 13:30-15:00 ET

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 will be owned by NTD/GMP
- New processes and timelines are being developed for vector control products, which will increase efficiency while ensuring the quality of products in the field
- Collaboration with NRAs will be a major focus of PQ
    - Collaborative registration of vector control products with PQT can speed time to market
    - Assistance with capacity building in countries provided via the Regulatory Systems Strengthening team
    - Political considerations of individual countries and regions must be taken into account during collaborative registration

Decisions made:

- PQT to develop detailed pathways with requirements and timelines for vector control products in 2016 and will share for comment with stakeholders before 2017
- Overall, PQT will engage stakeholders throughout the development process

Presentation: Mark McDonald: ***See slides on page 61-69 of "March 22 materials" at www.innovationtoimpact.org/convening***

Working session 1b: Value-based procurement

Date: 3/22/16, 13:30-15:00 ET

Key takeaways:

- PMI, UNITAID and Global Fund shared procurers' perspectives, with some key similarities and differences
    - Critical for procurers to follow evidence-based normative guidance from WHO
    - Countries must create demand for products (more so for Global Fund), but cannot request specific products (must be room for competition on tender)
    - Procurers include innovation criteria to varying degrees, to ensure competition and minimum standards are met
    - Several decisions are made prior to orders reaching procurement offices, and these shape demand (e.g. at the country level and TRP)
- Industry's ideal procurement scenario

- Industry would benefit from greater transparency in procurement tenders, and would like to see publication of scores, prices offered, and volumes allocated
- Critical that value of innovation is reflected in price, which will decrease as larger volumes are procured
- Resistance is inevitable and we should not wait until definite evidence is available to reflect this in procurement decisions

Decisions made:

- N/A

Presentation: Christen Fornadel, Aziz Jafarov, Alexandra Cameron, Helen Pates-Jamet: ***See slides on page 70-91 of "March 22 materials" at www.innovationtoimpact.org/convening***

Working session 2a: Discussion of country-level engagement

Date: 3/22/16, 15:30-17:00 ET

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

Decisions made:

- 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

Presentation: Angus Spiers: ***See slides on page 95-101 of "March 22 materials" at www.innovationtoimpact.org/convening***

Working session 2b: Normative guidance

Date: 3/22/16, 15:30-17:00 ET

Key takeaways:

- Guidelines for classification of new tools into classes/subclasses are not well understood by stakeholders
  - VCAG has recognized 8 novel paradigms – unlikely that more are needed
  - Within class, unique features of each product must be taken into account as part of guidance

- Normative guidance must be a process that runs in parallel with evaluation, not sequentially
- Alignment that response system must be agile, with call for increased interim guidance

Decisions made:

- Novel paradigm classes need to be better communicated, with consideration given to whether certain classes should be lumped or others split into multiple classes moving forward
- Need forward-looking guidance on resistance strategy to effectively use new products in rotation, combination

Presentation: Abraham Mnzava, Raman Velayudhan, Christen Fornadel: ***See slides on page 102-111 of "March 22 materials" at www.innovationtoimpact.org/convening***

Plenary session on Summary of March 22 discussions and decisions made

Date: 3/22/16, 17:00-18:00 ET

Key takeaways:

- N/A

Decisions made:

- N/A

Presentation: Maude Meier, Mark McDonald, Hannah Koenker, Naana Frempong, Scott Miller:
See slides on page 113-118 of "March 22 materials" at www.innovationtoimpact.org/convening

Plenary session on Procurement: Progress summary, discussion on 2016 objectives, and Q&A

Date: 3/23/16, 08:30-9:20 ET

Key takeaways:

- Procurement workstream's objectives are to accelerate procurement of innovative tools and enhance value-based procurement
- The current priorities are working with WHO on normative guidance and identifying next steps to enhance value based procurement

Decisions made:

- Workstream will establish plan to accelerate and enhance value based procurement in 2016
- On its next call, the procurement workstream will discuss:
    - How to get products into the field faster in the absence of normative guidance (e.g., advanced procurement methods, using other data sources such as CDC and academia)
    - What procurers can do to address industry suggestions (e.g., aggregating demand)
    - Sharing a perspective on lumping vs. splitting product categories for normative guidance
    - Providing a perspective on outstanding questions for interim normative guidance:

- How can we ensure data needed for normative guidance is available shortly after evaluation?
- Who is responsible for further data collection to support normative guidance?
- What process should be followed for interim normative guidance?
- What is the process for looking at new VC products in aggregate to provide appropriate guidance on rotations/combinations to deploy?

Presentation: Christen Fornadel: ***See slides on page 2-12 of "March 23 materials" at www.innovationtoimpact.org/convening***

Plenary session on GLP: Progress summary (including update from DQTF), discussion on 2016 objectives, and Q&A

Date: 3/23/16, 09:20-10:15 ET

Key takeaways:

- Strong progress made on GLP site accreditation. Focus will continue to be on developing guidelines, protocols, and SOPs to hit accreditation targets

Decisions made:

- GLP workstream will finalize GLP quality manual, accredit 4 WHO sites, and conduct study at Moshi

Presentation: Deus Mubangizi, Rajpal Yadav, Dave Malone, John Lucas: ***See slides on page 14-52 of "March 23 materials" at www.innovationtoimpact.org/convening***

Plenary session on issues facing NRAs in sub-Saharan Africa

Date: 3/23/16, 10:30-10:50 ET

Key takeaways:

- Regional regulatory bodies (CPAC) for pesticides can reduce registration hurdles and expedite time to market

Decisions made:

- WHO PQT and regulatory systems strengthening teams will continue conversations on collaborative registration and strengthening regional bodies

Presentation: Benoit Bouato: ***See slides on page 55-66 of "March 23 materials" at www.innovationtoimpact.org/convening***

Working session 3a: PQ QA discussion

Date: 3/23/16, 10:50-12:00 ET

Key takeaways:

- QA system for vector control will be based on existing principles in PQT and international standards, customized for specific circumstances of vector control
- System to be pragmatically phased in after 1/1/17

Decisions made:

- VC quality assurance system will be developed by PQT in 2016 with input from VC experts and other stakeholders

Presentation: Deus Mubangizi: ***See slides on page 69-75 of "March 23 materials" at www.innovationtoimpact.org/convening***

Working session 3a: GLP: Discussion of outstanding questions

Date: 3/23/16, 10:50-12:00 ET

Key takeaways:

- Sites selected for GLP accreditation should be able to test new product types & resistant strains
- Now most products reviewed are LLINs & IRS, but in the future, many products (Wolbachia) may not be pesticides
- VCAG guidelines exist for testing resistance, but outstanding questions remain, especially for evaluating resistant strains
- Robust communication needed so that more sites can become accredited (through their own financing)
- Although more sites will want support for accreditation, funding is limited & need to see business need
- Opportunity to approach QC & agriculture GLP accredited sites in Africa about entomological capabilities, including government sites
- NMCPs and NRAs need to be engaged to ensure understanding that the data generated by GLP is as robust and acceptable as WHOPES CC data
- Consensus in working group that research organizations (Eurofins, Syntech) and companies should be able to use their own GLP sites for dossiers

Decisions made:

- Workstream will conduct a capacity analysis to ensure that I2I supported GLP sites are building capacity for new products (e.g., transgenic mosquitoes, resistant strains)
- Prioritize development and publication of SOPs for testing resistant mosquitoes
- Communicate policy changes about GLP and involve scientists from African sites in future discussions
- Sites that are motivated to (a) become accredited or (b) expand entomological test capacity should be engaged
- Financial support through I2I is limited, but training of local GLP experts can coordinate and train additional sites

- Test sites can be run by a private organization or company, assuming that the country-level regulatory authorities will accept the data
- Will share GLP manuals and SOPs broadly
- IR-4 is hosting non-confidential SOP library in short term, WHO may host in the longer term
- Data Quality Task Force to sit within GLP workstream, to focus on longer-term, quality issues

Presentation: Rajpal Yadav, David Malone: ***See slides on page 76-80 of "March 23 materials" at www.innovationtoimpact.org/convening***

Plenary session on Summary of March 23 discussions

Date: 3/23/16, 13:00-13:30 ET

Key takeaways:

- N/A

Decisions made:

- N/A

Presentation: Mark McDonald, Maude Meier: ***See slides on page 83-84 of "March 23 materials" at www.innovationtoimpact.org/convening***

Plenary session on Summary of March 23 discussions

Date: 3/23/16, 13:00:-13:30 ET

Key takeaways:

- N/A

Decisions made:

- N/A

Presentation: Angus Spiers: ***See slides on page 86-95 of "March 23 materials" at www.innovationtoimpact.org/convening***

Working session 4a: Convening of industry working group

Date: 3/23/16, 15:00-16:30 ET

Key takeaways:

- Industry workstream requests clarification on 5 key topics discussed at convening:
    - Where are time savings expected in the new pathway?
    - How will manufacturer generated data be accepted before 2017?
    - How will normative guidance change from the current system?
    - Will manufacturing site inspections be required for products currently on the market, or just future products?

- In what cases can VCAG provide policy setting (e.g. can Zika response be used as a template for future policy setting)?

Decisions made:

- The industry workstream has committed to several deliverables in the coming months:
  - High level suggested data requirements for PQT dossiers for range of vector control categories
  - Recommendations on normative guidance
  - Suggested updates to IRS guidelines (IRS guidelines need to be updated, and industry should play a key part in this activity)
- Workstream to engage with industry members not present at convening to ensure broad industry perspectives represented in deliverables

Presentation: Hannah Kettler: ***See slides on page 98-101 of "March 23 materials" at www.innovationtoimpact.org/convening***

Working session 4b: I2I collaboration model

Date: 3/23/16, 15:00-16:30 ET

Key takeaways:

- As workstreams begin implementing, it will be important for I2I LT to liaise with them often to alleviate bottlenecks, flag issues as needed, and connect to other workstreams.

Decisions made:

- I2I LT to reach out to workstream leads to discuss how I2I LT can facilitate workstream achievement of deliverables and cadence of touchpoints.

Presentation: Angus Spiers: ***See slides on page 102-109 of "March 23 materials" at www.innovationtoimpact.org/convening***