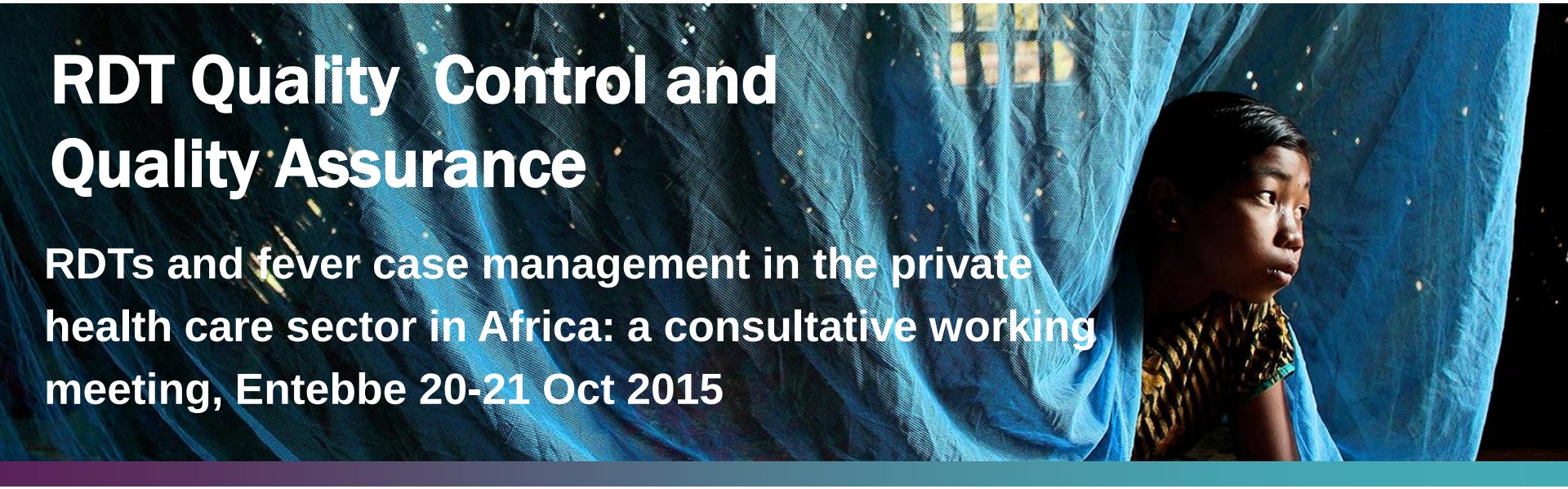
FIND

Because diagnosis matters



RDT Quality Control and Quality Assurance

RDTs and fever case management in the private health care sector in Africa: a consultative working meeting, Entebbe 20-21 Oct 2015

Dr. Daniel Kyabayinze, Dr. Sandra Incardona, & Dr Iveth Gonzalez
Malaria and Acute Febrile Syndrome programme

The quality of RDTs can be assured!

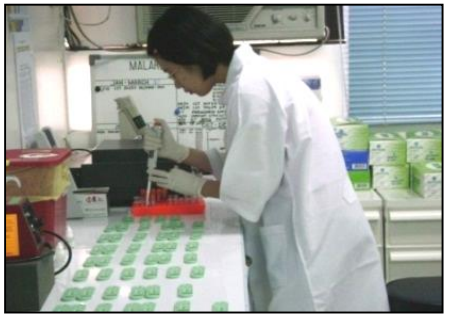
Only good quality RDTs are procured, based on the WHO RDT Product Testing:

Panel Detection Score (PDS):
Score for consistent detection of parasite samples at low parasite densitiy (200 p/ul)

WHO procurement guidelines:
PDS for Pf at 200 p/ul ≥ 75%
PDS for Pv at 200 p/ul ≥ 75%
False positive rate < 10%
Invalid rate < 5%

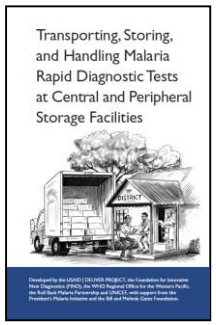
For every RDT lot coming into the country:

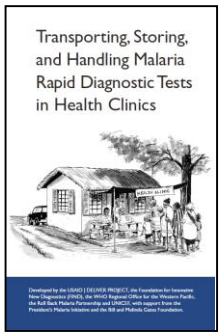
RDTs are Lot Tested in reference laboratories:
(RITM, Philippines and IPC, Cambodia)
ONLY RDT lots with a PASS report are released for distribution in the countries

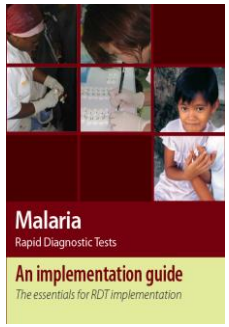


RDTs transported and stored in the field :

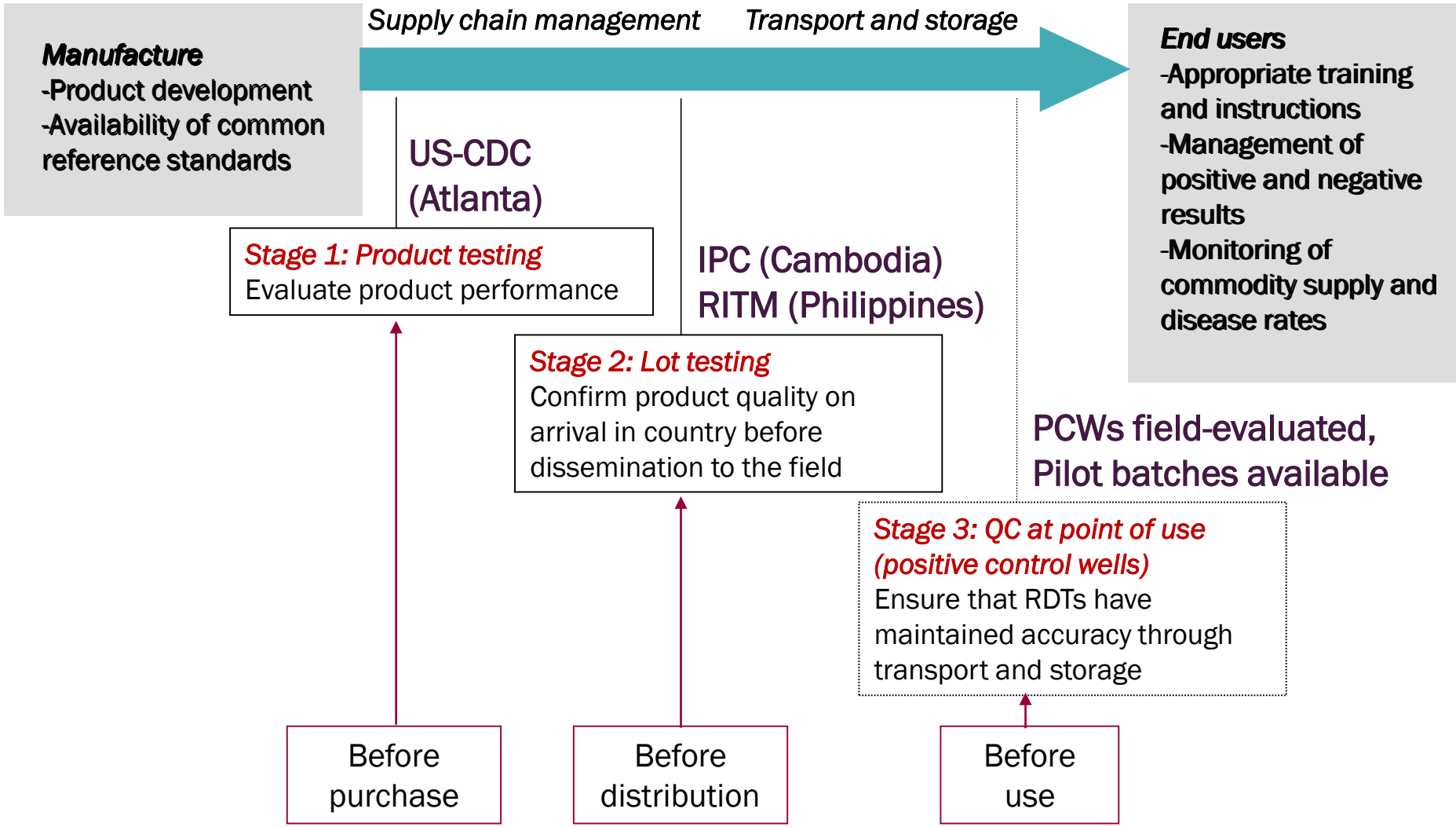
Follow transport and storage guidelines:
If transport/storage is done well, risk of degradation is very low







Current status of the Programme – 2015: Testing based on frozen blood samples



Malaria RDT Lot Testing *[Stage 2]*

- current format -

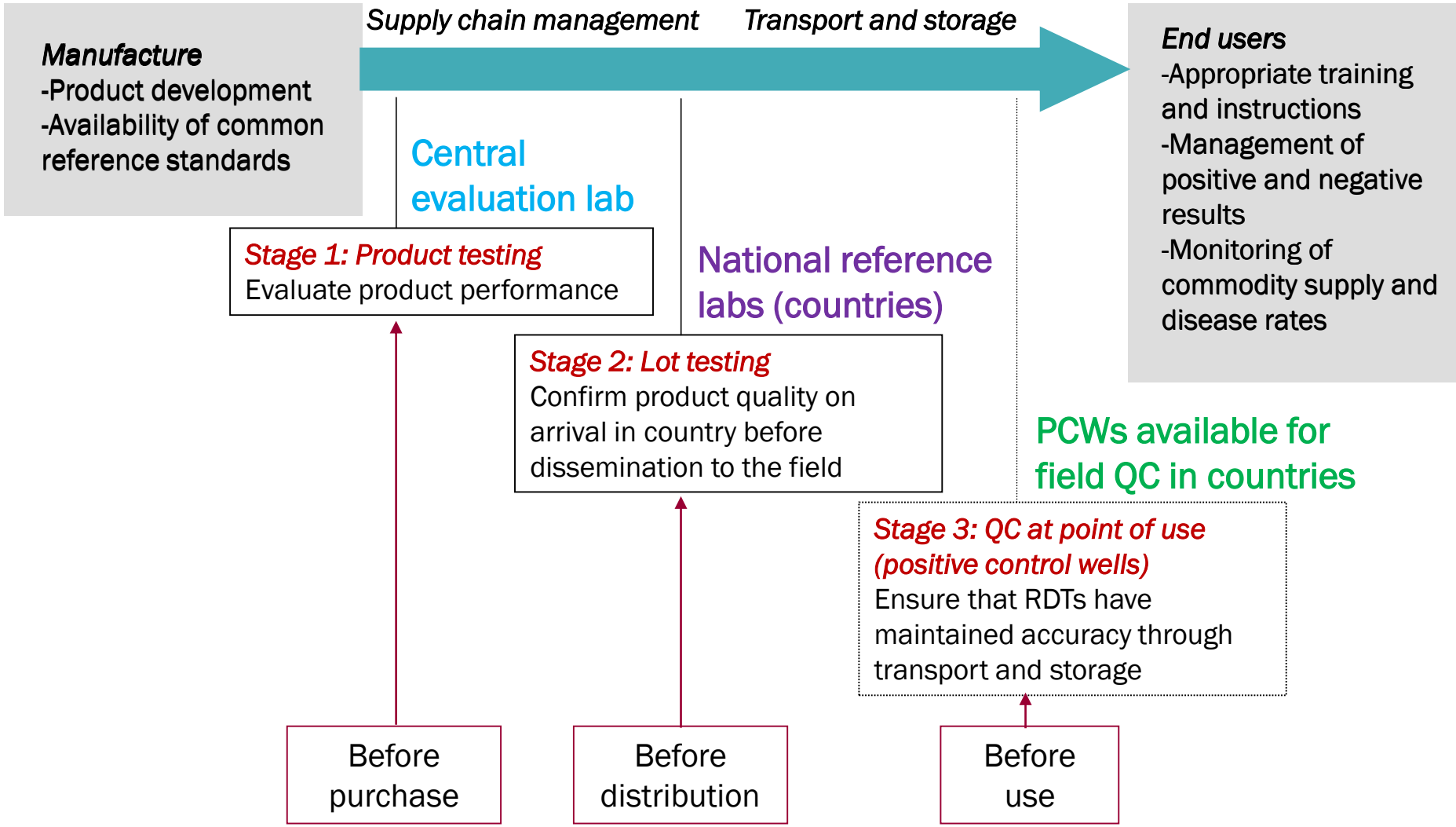
- QC of RDT lots directly after purchase (pre-shipment)
  or in-country before distribution in the field (post-shipment)

- Two WHO-FIND reference Lot Testing laboratories:
  - closely supervised, annual EQA assessments
  - turnover of 5 days between RDTs receipt and report issue

- *Institut Pasteur, Cambodia (IPC)*
- *Research Institute of Tropical Medicine, Philippines (RITM)*

- Lot Testing also supported in some other labs
  - Nigeria CMUL, in the frame of the 'Private Sector RDTs project'
  - NIMR New Delhi, India, with national funding

The future of the Programme – transition starting 2015/16: Testing based on recombinant panels



Moving forward with QA/QC of RDTs

It is crucial to build capacity in the countries to be able to:

- Conduct their own lot testing, and have local capacity to cross-check any RDTs failing in the field
- Do field QC of RDTs, with all the tool becoming available now (troubleshooting guide, PCWs etc.)
- Need a clear process for acting on field problems, with RDTs or also accessories

Additional slides

	Current Programme (Product -/ Lot Testing only)	Future Programme (Product -/Lot Testing + QC in the field)
Panels used for testing	- Infected patient blood or cultured parasites - Standardized at low parasite density - Stored at -70°C	- Recombinant malaria antigens - Standardized at concentrations equivalent to the low parasite density - Stored at room T°
Accessibility of panels	- Wild-type samples: only accessible to WHO-FIND labs - Cultured samples: available to manufacturers	- Same recombinant panels available to all users (under different formats), including national reference labs and manufacturers
Places for testing	- Product Testing at US-CDC - Lot Testing in 2 WHO-FIND labs	- Product Testing in central lab - Lot Testing in national reference labs, with confirmatory testing in central lab - Field QC by end users (positive control wells) - Development/production QC by manufacturer
Cost and sustainability	- High operating costs - Requiring donor funding and unsustainable on the long term	- Low operating costs - Can be supported through fees for users of the system - Sustainable on the long-term

Future plans for field QC of RDTs

Tools being developed, for implementation as part of the UNITAID-funded ‘private sector RDTs project’:

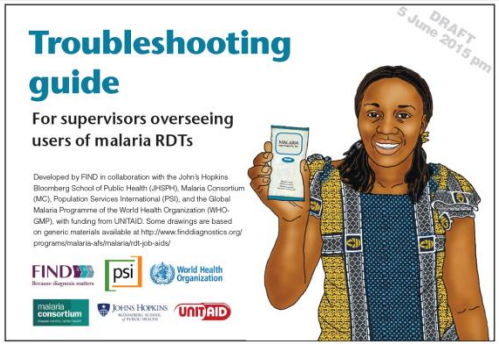
1. Troubleshooting guide

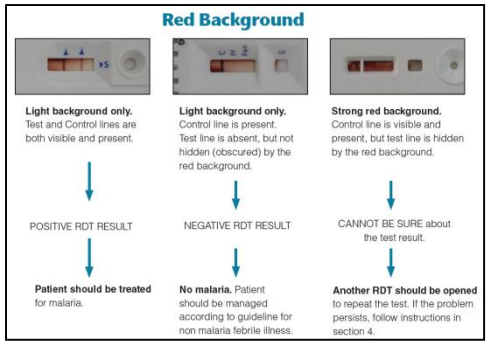
2. Protocol for acting on RDT problems in the field

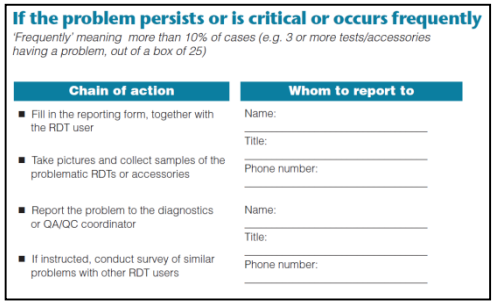
3. PCWs for monitoring quality of RDTs at end-users level

Troubleshooting guide

- List of issues encountered in the field, e.g. invalid tests, red background,etc. Recommendations on use of
  - accessories,
  - blood transfer devices
- Possible actions to correct any errors made by the user
- Instructions to follow in case of persistent/frequent problems (reporting to supervisors etc.)



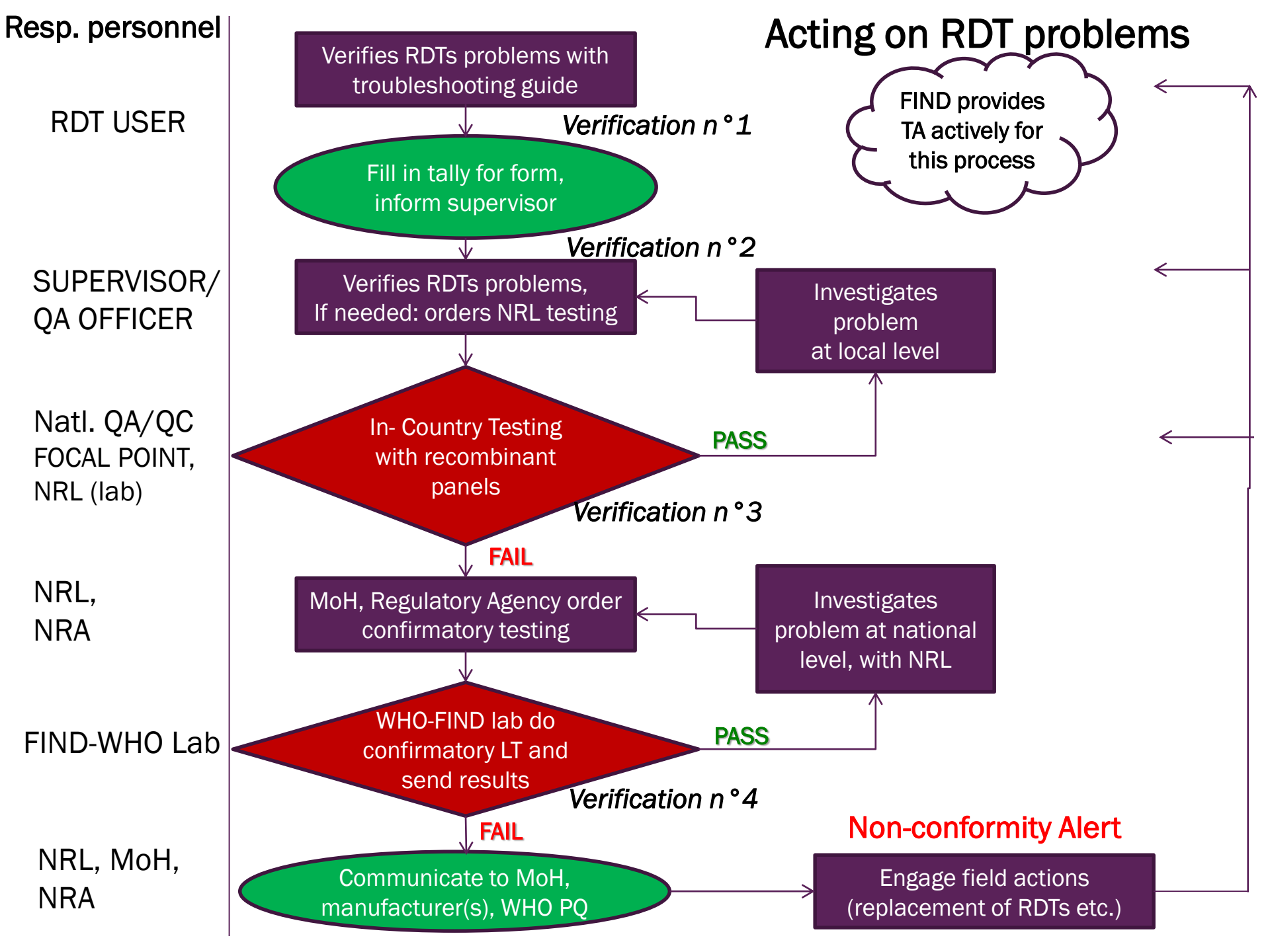




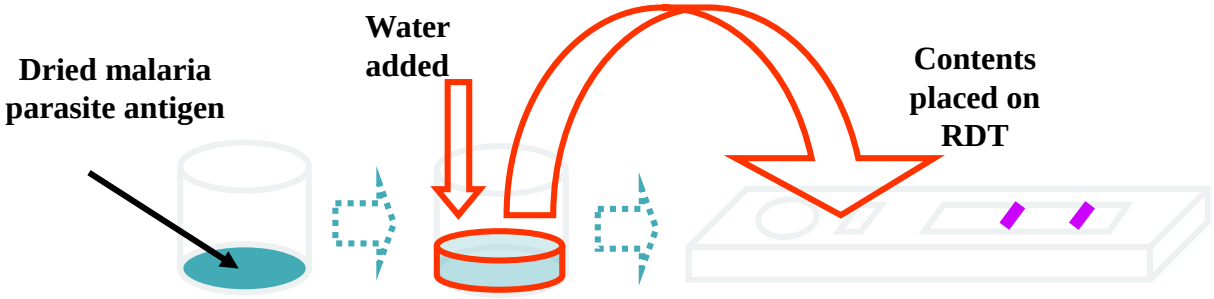
Proposed protocol and report forms in case of field problems with RDTs

- Defining who does what in case of field problems, e.g. troubleshooting, verification visits, cross-checking of RDT quality, reporting of confirmed problems, actions such as re-call of RDTs etc. Standard report forms to compile relevant info
- All to be implemented in the private sector project
- Coordination with NMCP and regulatory bodies to ensure alignment with each one's roles and responsibilities

Acting on RDT problems



QC at end user level using Positive Control Wells (PCWs)



- Small polypropylene tubes coated with dried recombinant proteins (HRP2, pLDH and aldolase)
- Concentrations equivalent to 200 parasites per microlitre of blood
- Re-constituted with buffer using a dropstir
- Transferred to a malaria RDT using a transfer device

Prototype PCW

QC at end user level with Positive Control Wells (PCWs)

- Publishing field evaluations in Uganda and Laos

- Current status of development:
  - first batches done, ready to be packaged and shipped for field implementation

- Plans:
  - implementation in the private sector project before end 2015
  - use at the supervisors level, as a tool to assess competency, check quality of local RDT stocks, and reassure users

FUTURE PLANS: introduce PCWs also in the public sector