



# The Pediatric Praziquantel Consortium

Helping children with Schistosomiasis

On behalf of the Consortium,  
Dr. Remco de Vruh (Lygature)  
Consortium coordinator

**December 8th, 2017**

GHIT Fund R&D Forum, Tokyo



# A new public-private partnership to address a high unmet medical need in young children

High  
Prevalence

High  
Medical  
need

Pre-school  
aged children  
neglected

Estimated 27 Mio young children infected or at risk of schistosomiasis in Sub-Saharan Africa

Current treatment (praziquantel 600mg tablets) cannot be administered to young children

→ clear **unmet medical need** for a suitable **pediatric** formulation for the children aged **3 months to 6 years**



Founded in 2012

# The Pediatric Praziquantel Consortium

International non-profit R&D Consortium with a focus on extended partnership into endemic countries

In kind and/or in cash contribution

Continually seeking funding and advice from external experts and partners

International Expert Panel (World Health Organization) as observer

Grants :  
Bill & Melinda Gates Foundation  
GHIT Fund (3x)

MERCK

astellas

Swiss TPH



Consortium Board

Consortium Team

farmanguinhos  
Instituto de Tecnologia em Fármacos

simCYP

SCI  
Schistosomiasis  
Control Initiative

lygature

KEMRI (Kenya)

Université Félix Houphouët-Boigny  
(Cote d'Ivoire)

Exit begin of Oct 2017

To join end of Dec 2017





True innovation

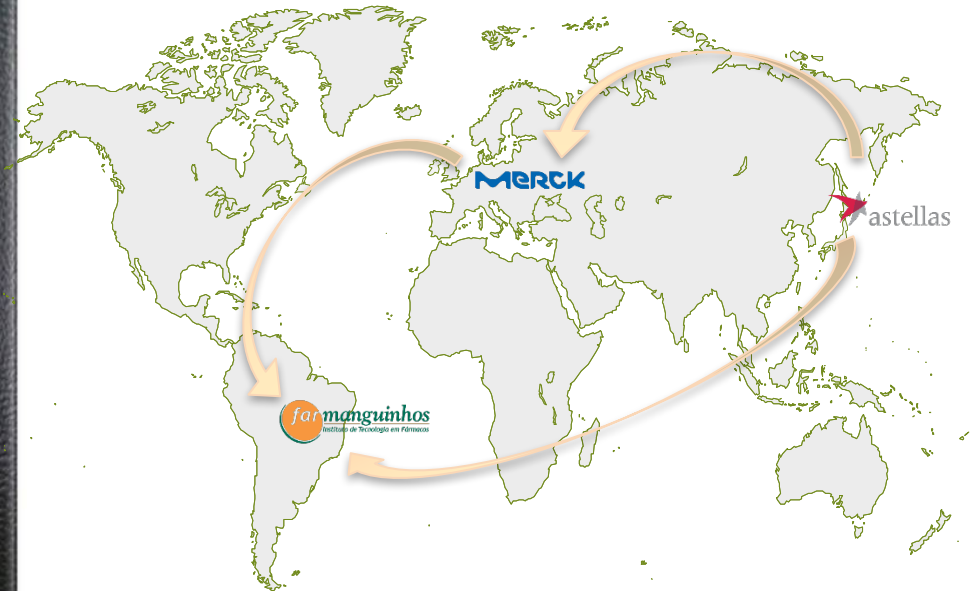
# L-PZQ and rac-PZQ oro-dispersible tablets (ODTs)

- Orally disintegrating
- Improved taste
- Conventional manufacturing process



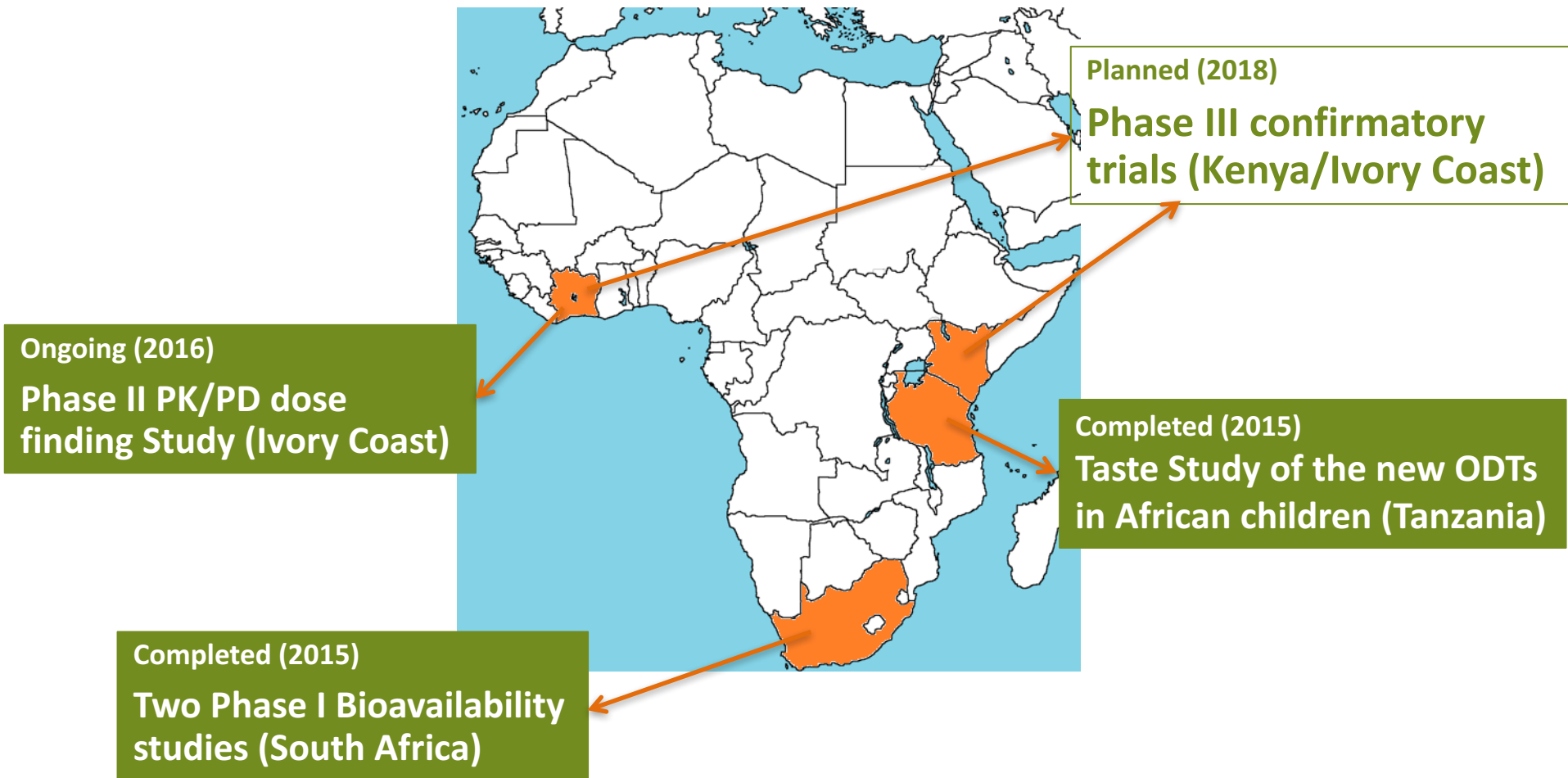
Cesol 600 mg  
Current commercial tablet

PZQ new ODT  
150 mg tablet





# Full clinical development program for PZQ-ODTs





# Capacity building - Strengthening Health infrastructure

## Clinical research facility annex refurbished (Ivory Coast - Man region)

BEFORE



11.03.2016, pre-study visit

AFTER



15.06.2016, initiation visit





# Capacity building - Strengthening R&D infrastructure



Study team supervised by the PI (Prof. N'Goran), members of the Merck & Swiss TPH team

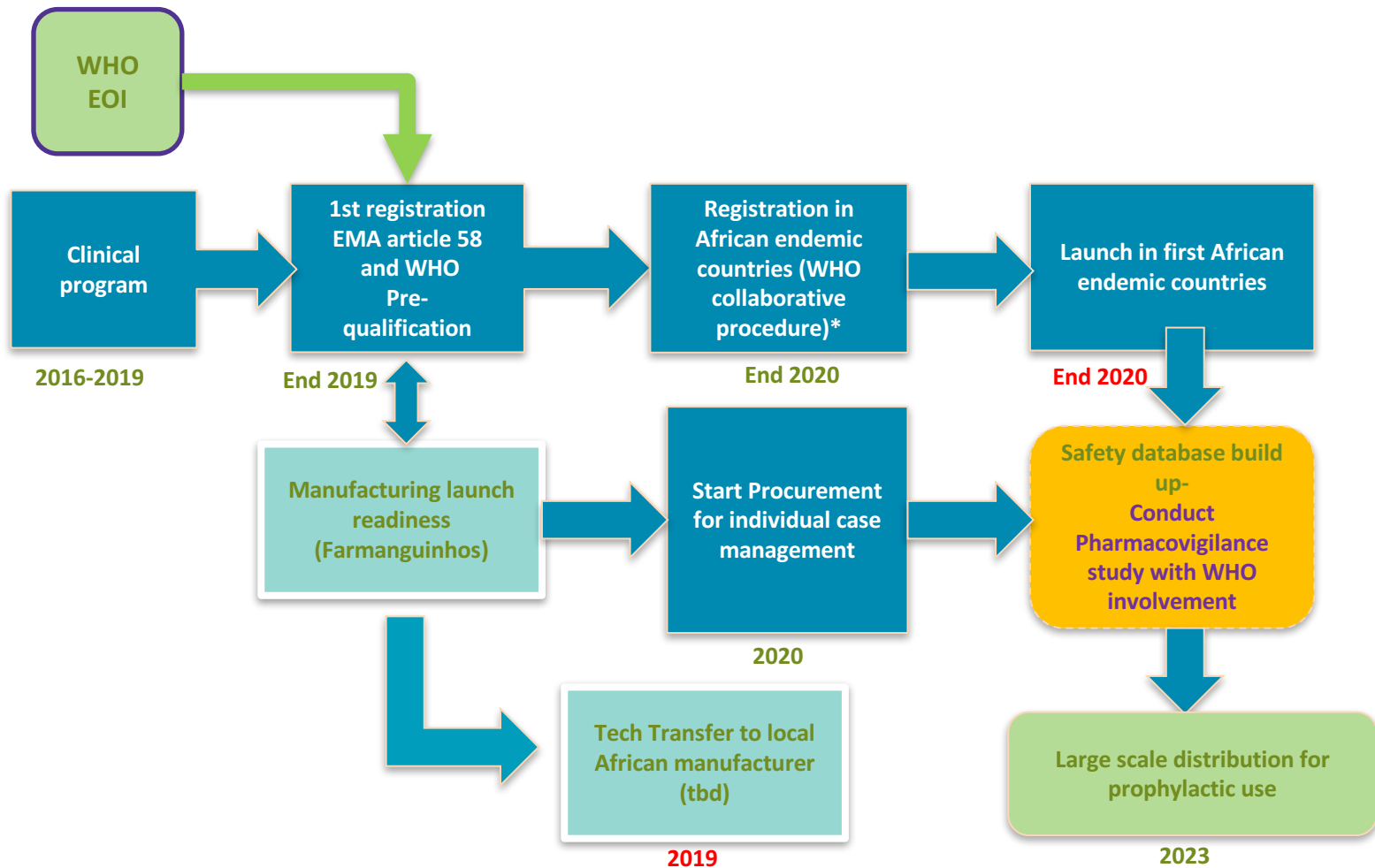
## Blood sampling and Dry Blood Spot method







# Next steps: Regulatory & Manufacturing plan







One key for success

# Communication & stakeholder engagement



Consortium Team and Board representatives  
together with African regulatory experts  
(Geneva, 2014)

## Access expert meeting in Q3 2018

Key stakeholders: Consortium partners, our funders, NTD control program funders, WHO, UNICEF, KOLs and possibly endemic country decision makers



<http://www.pediatricpraziquantelconsortium.org>  
<http://www.merckgroup.com/mghi.html>