MOXIDECTIN FOR ONCHOCERCIASIS ELIMINATION

Studies completed

Studies in preparation

- **Michel Mandro, Tony Ukety (investigators studies in DRC),**
- **Nicholas Opoku (investigator study in Ghana)**
- **C. Chesnais, J. Kamgno, M. Boussinesq (investigator study in Cameroon)**

- **Mark Sullivan (Founder and Managing Director, Medicines Development for Global Health),**
- **Annette C. Kuesel (TDR)**

WHO/APOC/TDR/Kuesel

On the road from Monrovia to Lofa County, Liberia (J. Kealy)


9Q-CMU

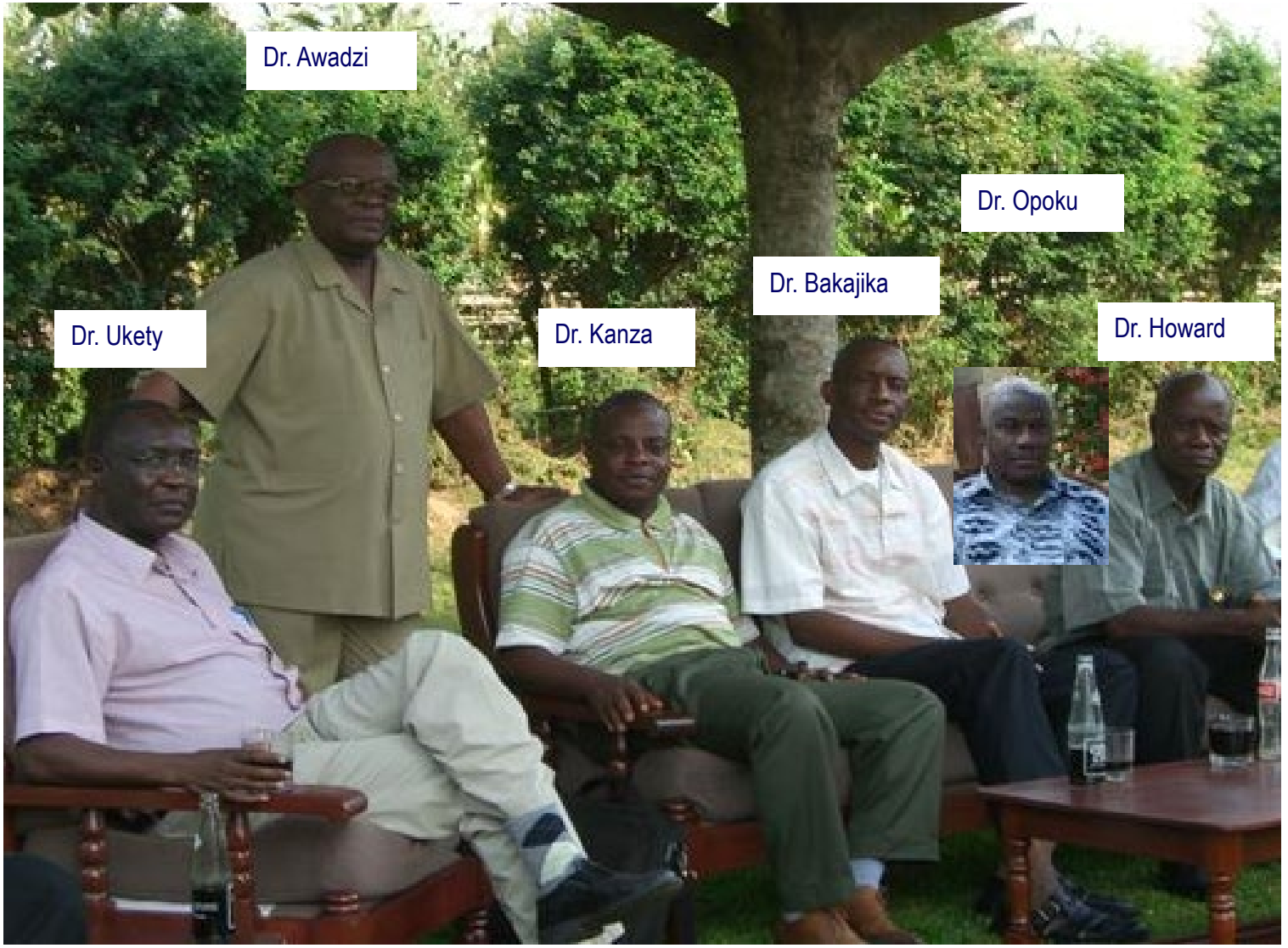
CLINICAL STUDIES TO US FDA REGULATORY APPROVAL JUNE 2018

6 Phase 1 pharmacokinetic and safety studies in healthy volunteers

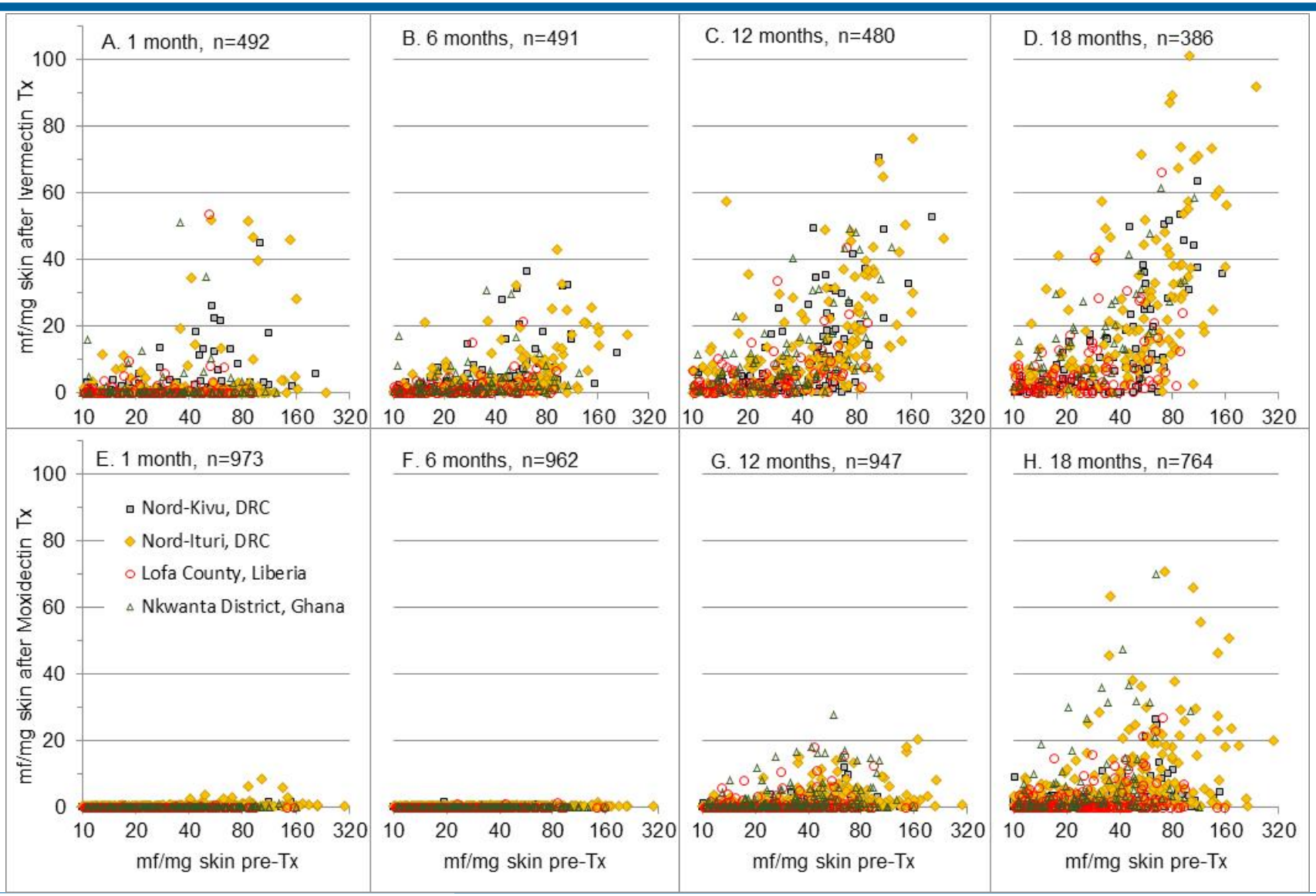
- First in Human dose ranging study with liquid formulation
- Relative bioavailability of liquid and tablet formulation developed for onchocontrol programme use
- Milk-excretion study
- Drug interaction study
- Food effect study
- Cardiovascular safety study

2 comparative SINGLE DOSE safety and efficacy studies in *O. volvulus* infected volunteers

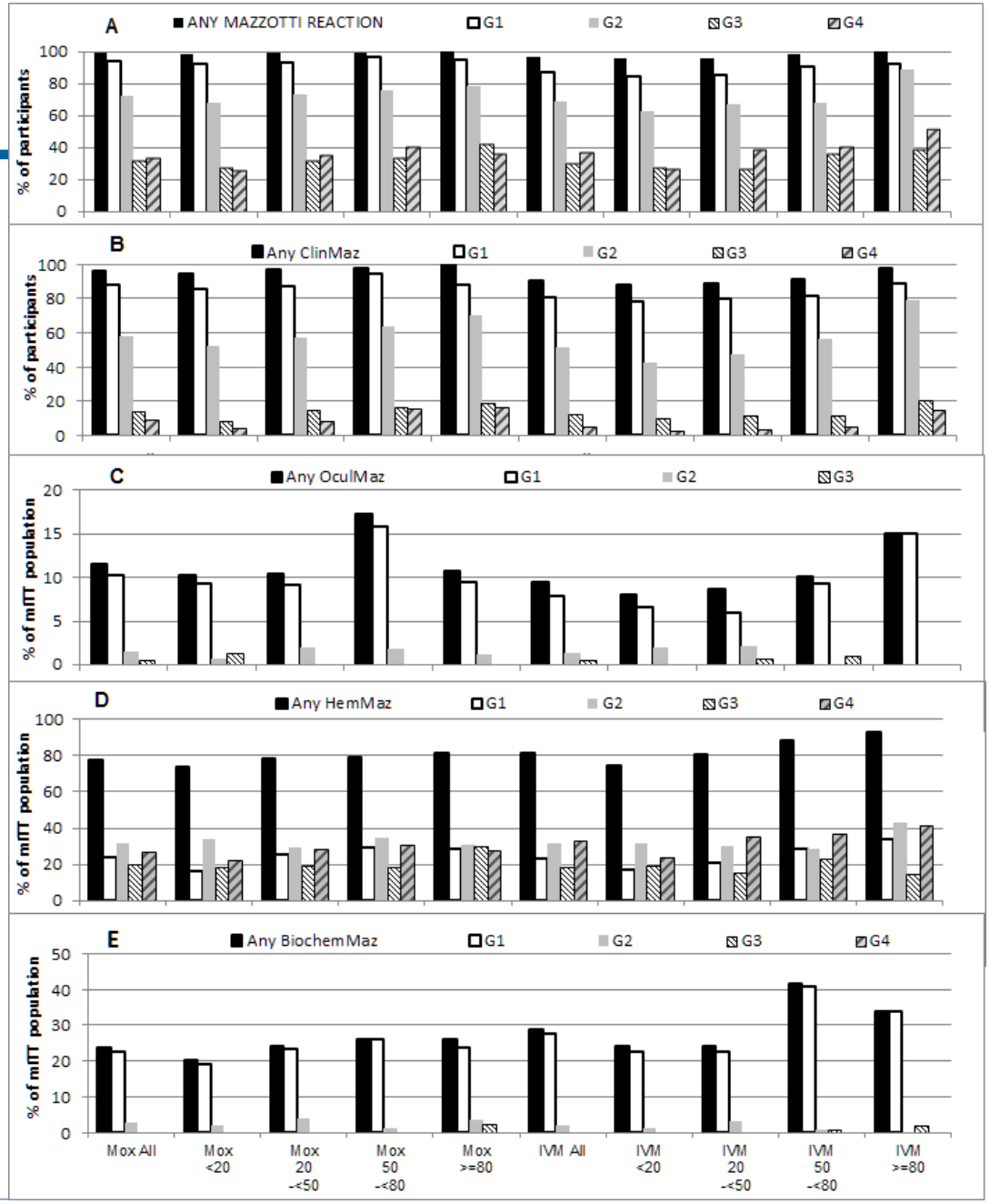
- Phase 2 study (Ghana, dose ranging)
- Phase 3 study (Ghana, DRC, Liberia, 8 mg)


Dr. Awadzi
Dr. Ukety
Dr. Kanza
Dr. Bakajika
Dr. Opoku
Dr. Howard

PHASE 3 EFFICACY DATA FOR US FDA APPROVED DOSE OF 8MG



PHASE 3 SAFETY DATA



STUDIES FOR ONCHOCERCIASIS IN PREPARATION

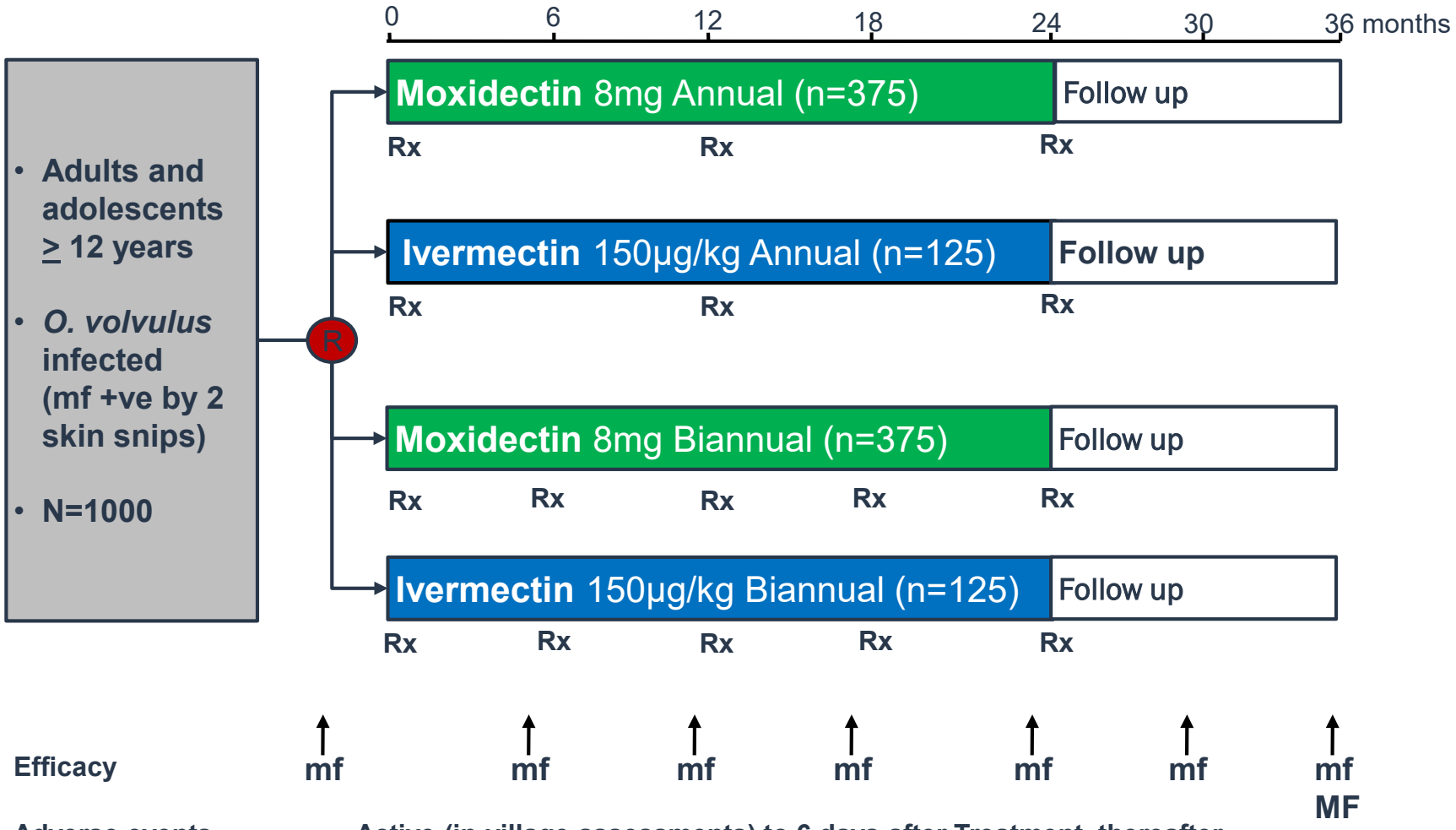
Multi-dose comparative efficacy study (DRC)

Single dose comparative safety study (DRC)

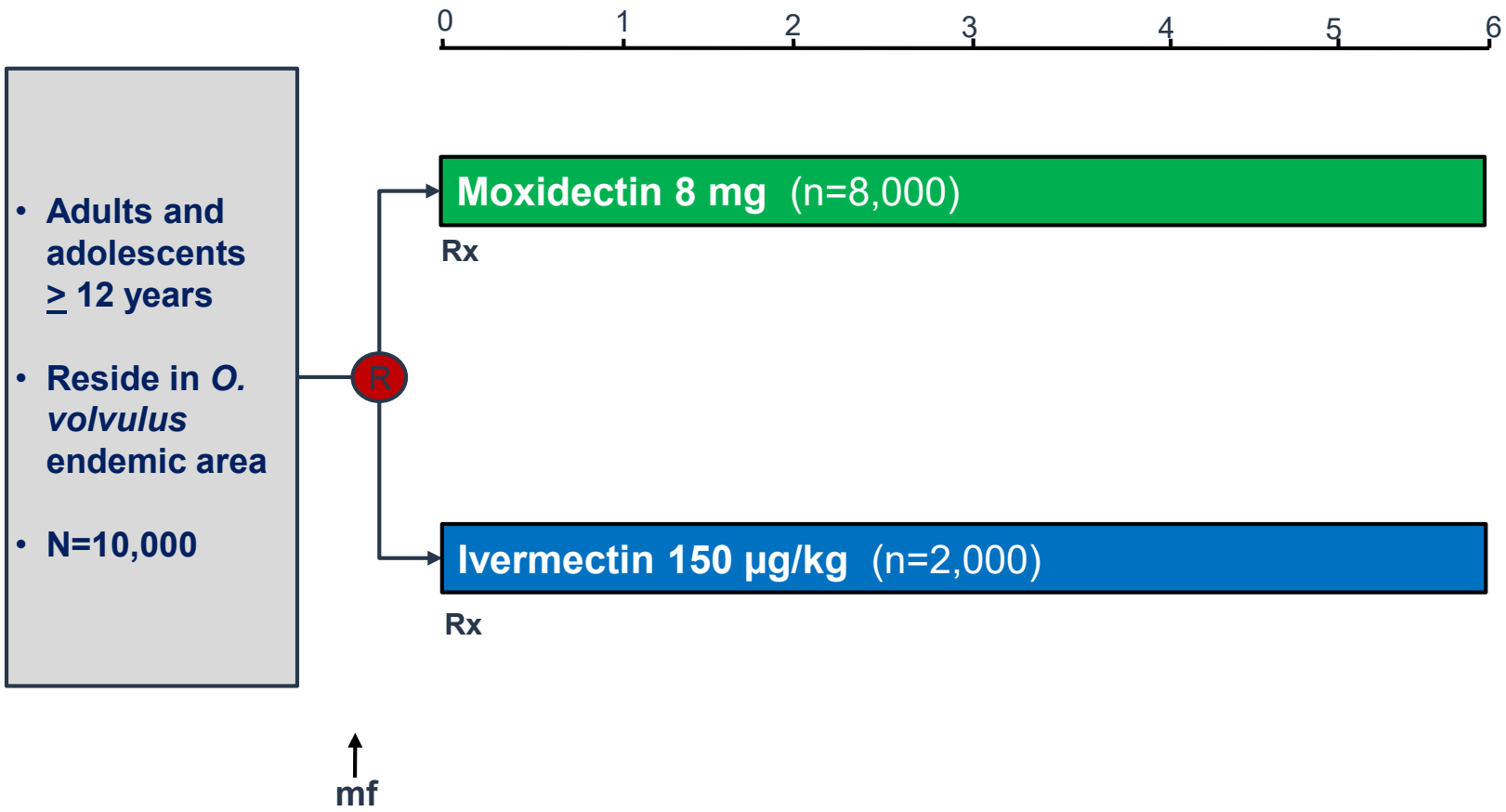
Pharmacokinetic and safety study in < 12 year olds (Ghana)

Single dose comparative safety and efficacy study in *Loa loa* infected individuals (Cameroon)

MULTI-DOSE COMPARATIVE EFFICACY STUDY (ITURI)



SINGLE DOSE COMPARATIVE SAFETY STUDY



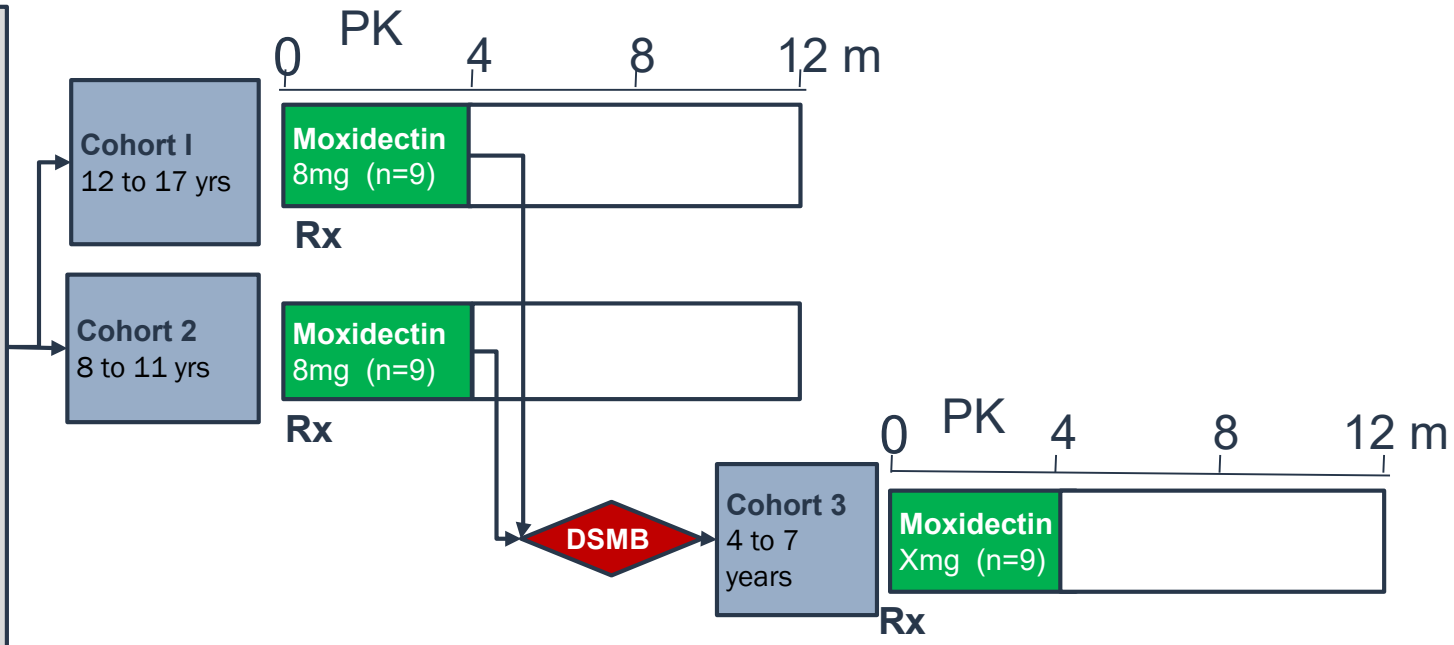
PK-SAFETY STUDY TO IDENTIFY SAFE DOSE IN 4-11 YEAR OLDS

Adolescents and Children with/at risk of *O. Volvulus*

(from meso- or hyperendemic Volta region of Ghana)

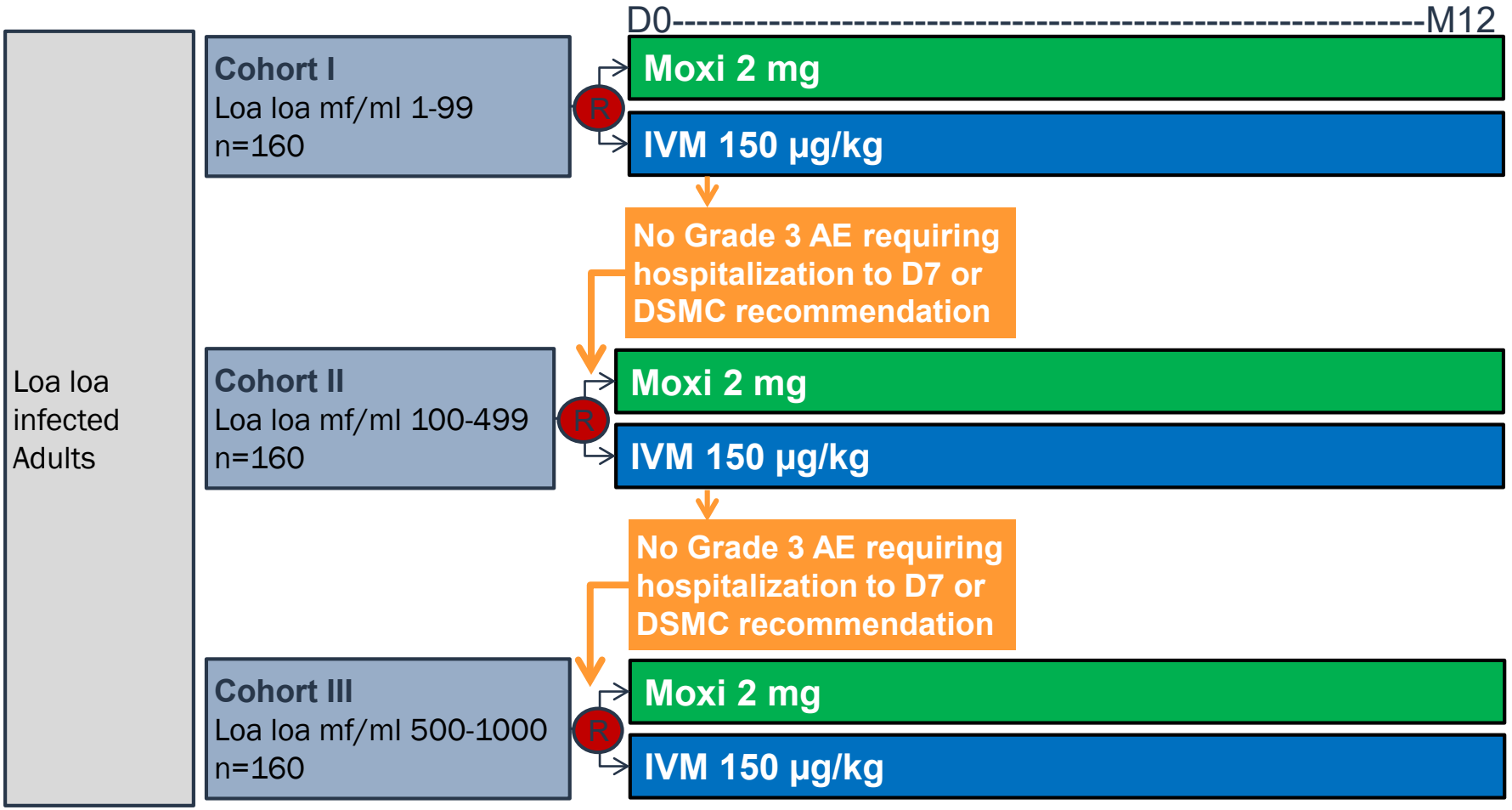
Exposure will be assessed but not required for study eligibility

N=9/per cohort



Pharmacokinetic sampling: Hour 0, 1, 2, 4, 8, 24; day 3, 7, 14 and 28; Week 12
Safety: Adverse Events, physical examination, changes in vital signs, laboratory values
Dose Selection for Cohort 3: safety profile, pharmacokinetic data, pharmacokinetic modelling

ASCENDING INTENSITY OF INFECTION EFFICACY-SAFETY STUDY IN LOA LOA INFECTED INDIVIDUALS



Efficacy: TBS preTx, D1, D7, D15, D90, D180, D365

Safety: Active FU in village D1-D7, adverse events, laboratory values (CBC, proteinurea, leukocyturia, liver function)