STOP
Stopping Transmission Of intestinal Parasites

EDCTP

# Ivermectin/albendazole fixed-dose combination for an integrated MDA strategy

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# STH targeted for elimination as a public health problem

Mass drug administration **(MDA)** programmes

Improving water, sanitation and hygiene **(WASH)** conditions

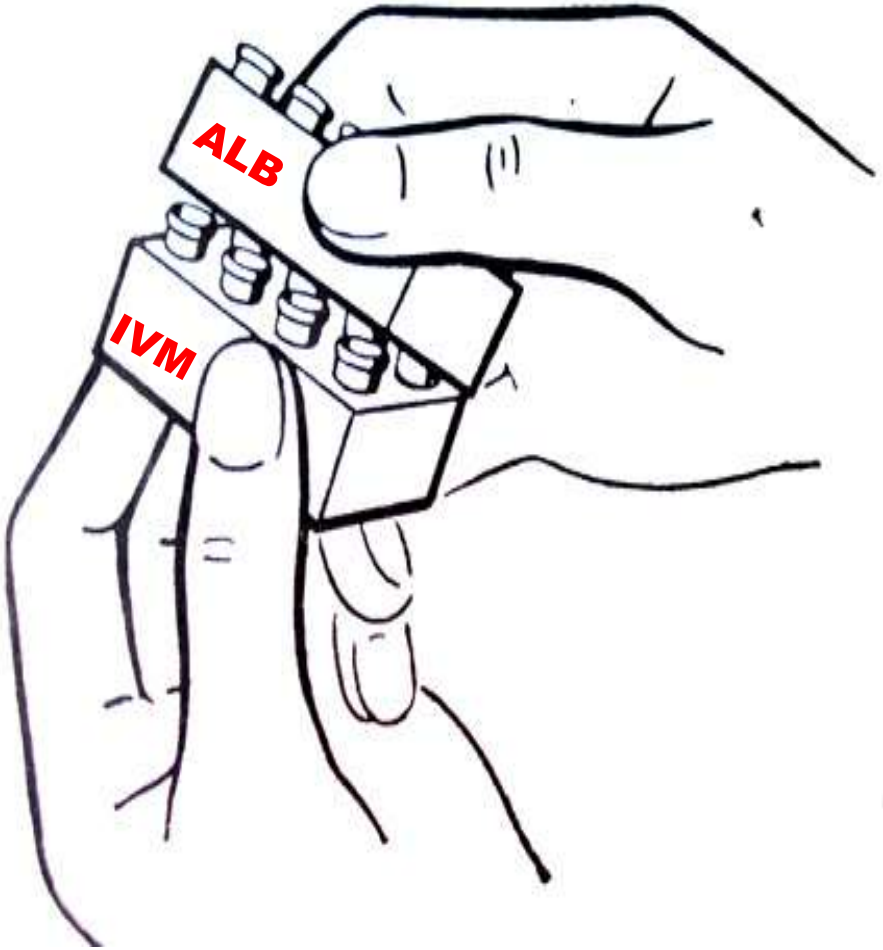
Ending the neglect to attain the Sustainable Development Goals: a road map for neglected tropical diseases 2021–2030. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.

# Challenges for the control of STH

## Mass drug administration defaults

- Short-term strategy/reinfection
- Need of high coverage and compliance
- Adults as reservoir
- **Drug efficacy**
- **Drug resistance**

# Our solution: a fixed-dose combination of ALB and IVM



# Cómo organizamos el consorcio/socios africanos?

**STOP 1 (2018-2023)**
**STOP 2 (2020-2022)**
**STOP2030 (2024-2027)**
**SICONTROL (2025-2029)**

The Netherlands:
University of Leiden

United Kingdom:
London School of Hygiene and Tropical Medicine

ISGlobal

Spain:
Laboratorios Liconsa

Spain:
Universidad de León

- El rol de la industria farmacéutica (Liconsa)
- Socios históricos colaboradores (Mozambique)
- Algunas condiciones propias del país (*T. solium* en SICONTROL, MDA en STOP2030)

Ethiopia:
Bahir Dar University

Kenya:
KEMRI

Mozambique:
CISM

**+ Fundación Mundo Sano**
**+ Ghana Health Services**
**+ others…**

# Challenges of the IVM-ALB fixed-dose combination (FDC)

1) Demostrate the **safety of high and fixed doses** of IVM (no need to adjust by weight)

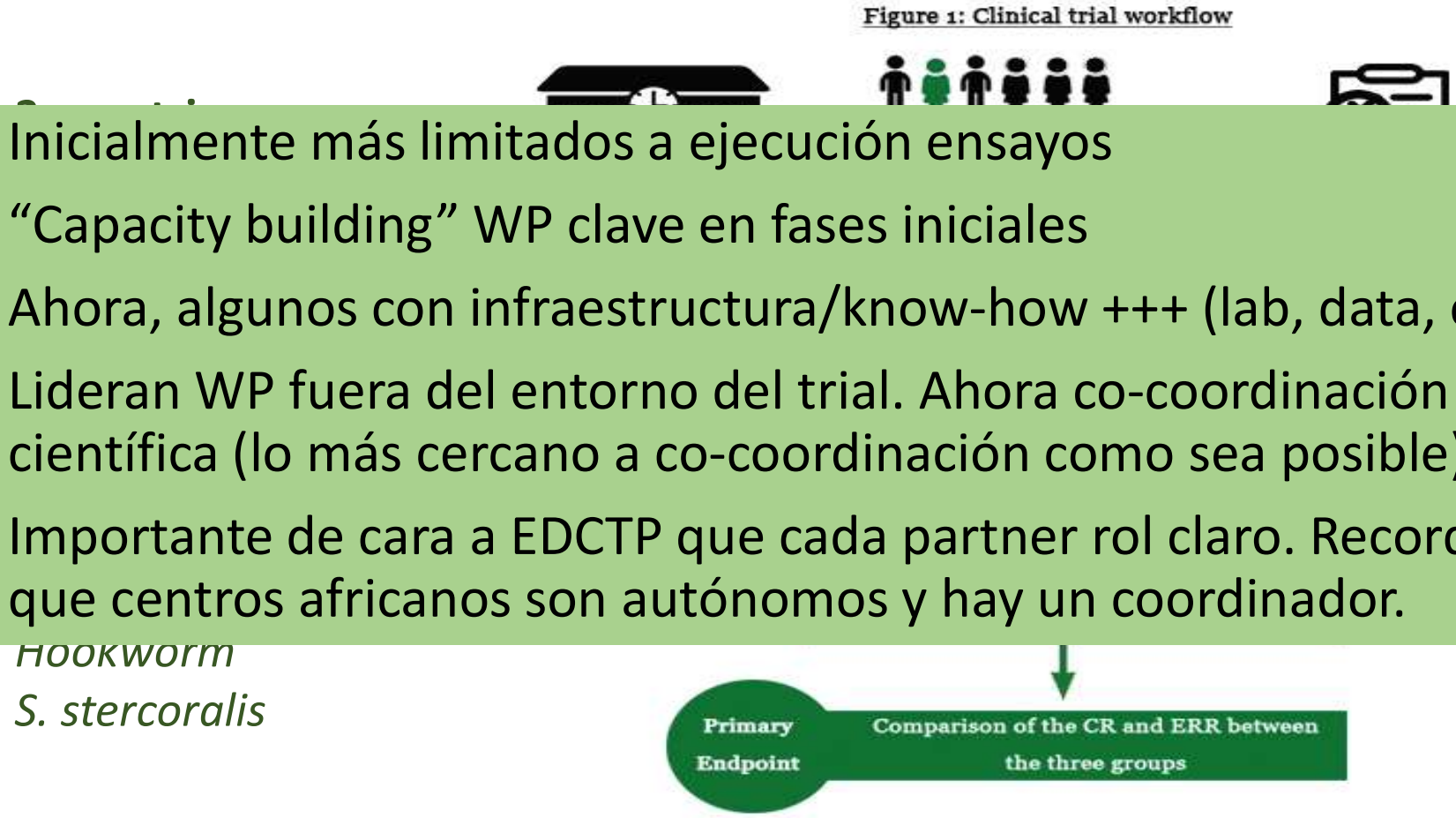
2) Complete **pharmaceutical development of FDC** and its **bioavailaibity** (vs coadministration)

3) Demonstrate **safety and efficacy of FDC (STOP Project)**

**4) Regulatory approval (STOP Project)**

# Que papel desempeñan en el proyecto?

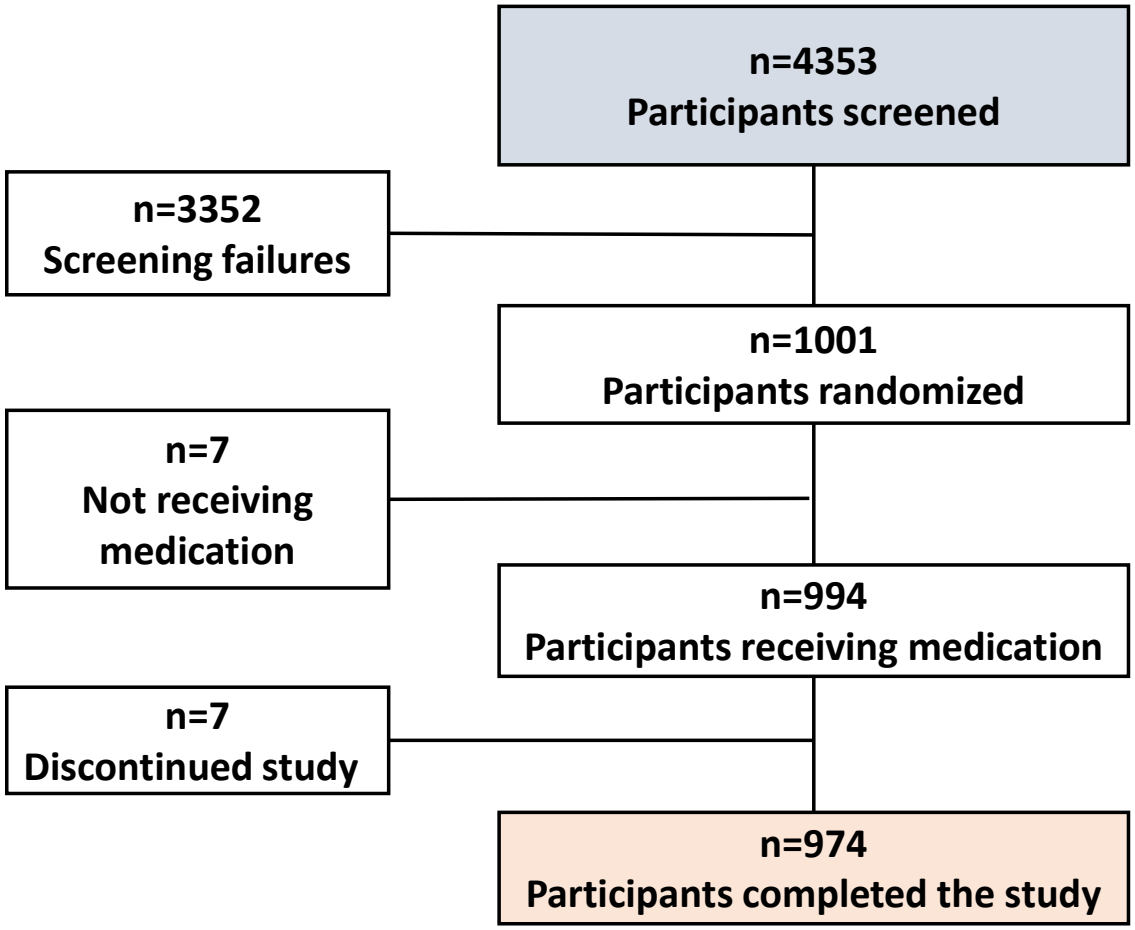
**Randomized, controlled, adaptive phase II/III clinical trial**




- Inicialmente más limitados a ejecución ensayos
- “Capacity building” WP clave en fases iniciales
- Ahora, algunos con infraestructura/know-how +++ (lab, data, etc…)
- Lideran WP fuera del entorno del trial. Ahora co-coordinación científica (lo más cercano a co-coordinación como sea posible).
- Importante de cara a EDCTP que cada partner rol claro. Recordar que centros africanos son autónomos y hay un coordinador.

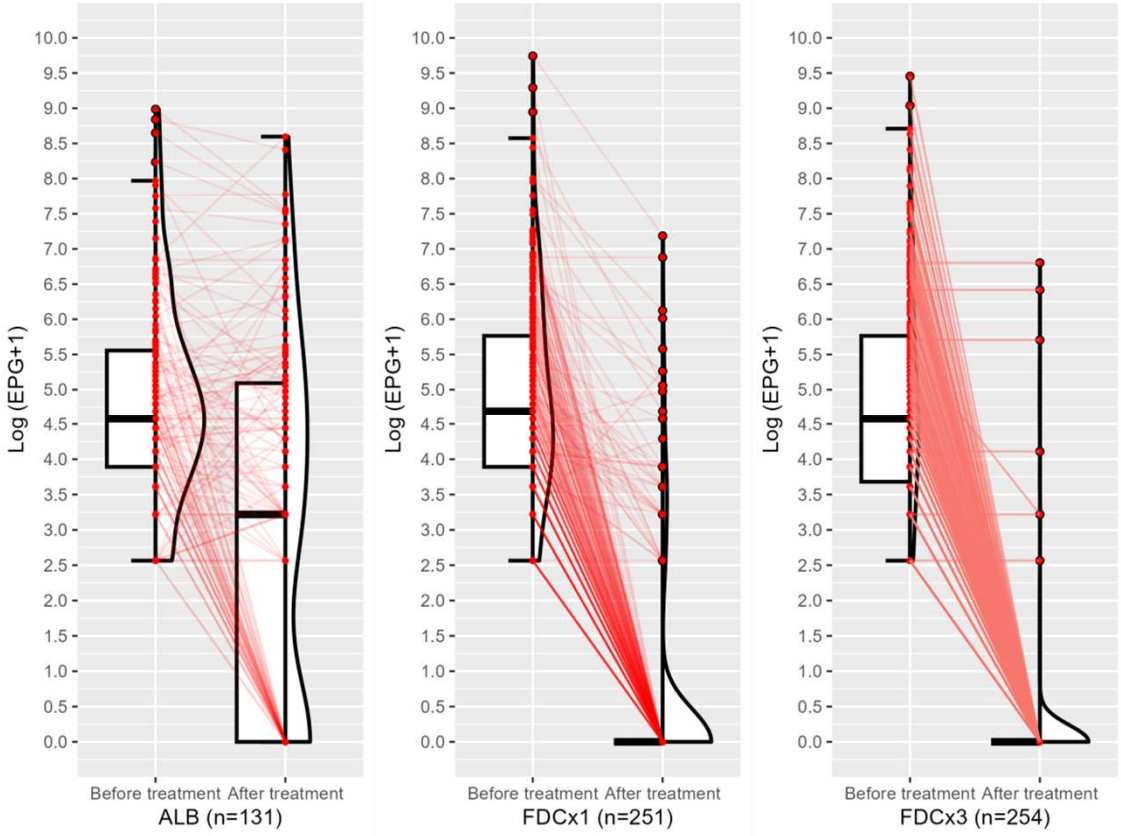
*Hookworm*
*S. stercoralis*

# STOP project: Trial profile



# Efficacy against *T. trichiura*

| Variable | ALB | FDCx1 | FDCx3 |
|---|---|---|---|
| **Participants positive for infection** | | | |
| **Before treatment** | 131 | 251 | 254 |
| **After treatment** | 84 | 43 | 7 |
| **Cure rate — % (95% CI)** | 35.9 (27.7-44.1) | 82.9 (77.5-87.2) | 97.2 (95.2-99.3) |
| **Difference in CR (vs. ALB)** | - | 47.0 | 61.3 |



# STOP project: Highlights

**INNOVATIVE FDC** with high potential **IMPACT IN PUBLIC HEALTH** and for guiding national and global policies

Increased efficacy for STH,
**INCLUDING FOR S. STERCORALIS**

Potential for
**INTEGRATION WITH OTHER NTD** (LF, scabies…)

Strong component of **REGULATORY ACTIVITIES** with **PREQUALIFICATION GOALS**

# Algunas ideas a compartir (mi experiencia personal)

- EDCTP siempre en posición de ayudar. Si hay problemas hablar con ellos. También por temas de presupuesto.
- Selección cuidadosa de colaboradores, y sus roles.
- Atención a WP de health economics, implementation/social science
- EDCTP quieren que las cosas pasen: IMPACTO
- Pensar en el paquete regulatorio, intentar no secuenciar el trabajo


THANK YOU !