galvmed.org



GALVmed

Protecting Livestock
Improving Human Lives

AAT Development Program

ISCTRC, Nairobi, September 2025

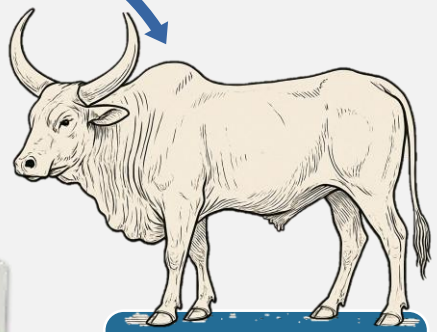
AGENDA



History

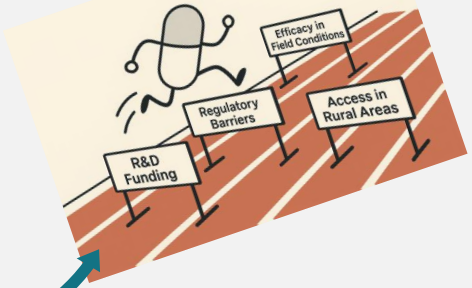
Current Market





What we Want

Why its Difficult





What we Have

A Brief History of AAT Trypanocides

Un bref historique des trypanocides

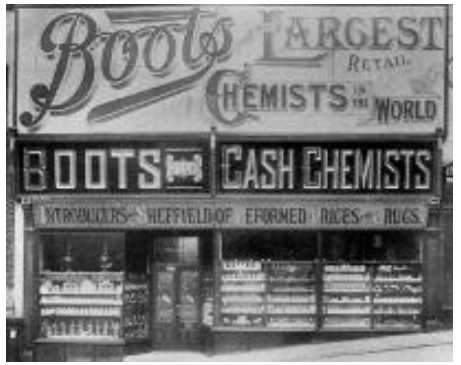
	Therapeutic			Therapeutic and Prophylactic	
	Diminazene	**Homidium**		**Isometamidium**	
Year of Discovery	1955	1952 (Boots Chemists)		1960's	**Année de découverte**
Meat withdrawal	21–35 days	>21 days		30 days	**Temps d'attente (viande)**
Milk withdrawal	3 up to 21 days	> 3days		Nil	**Temps d'attente (lait)**
Safety	Toxic equines and camels at 2x	IM toxic to horses. Carcinogenic		Local reactions in cattle, highly irritant Toxic >2 mg/Kg	**Sécurité**







CONTRAST THIS WITH HAT → **Two new drugs in past 10 years**



The Current Trypanocide Market

Le marché actuel des trypanocides

AAT costs >US$1bn/year and control depends on 3 old drugs

Current Tools

- Poor therapeutic indices
- Increasing Resistance
- Poor quality and counterfeit drugs

Outils actuel

Access & Training

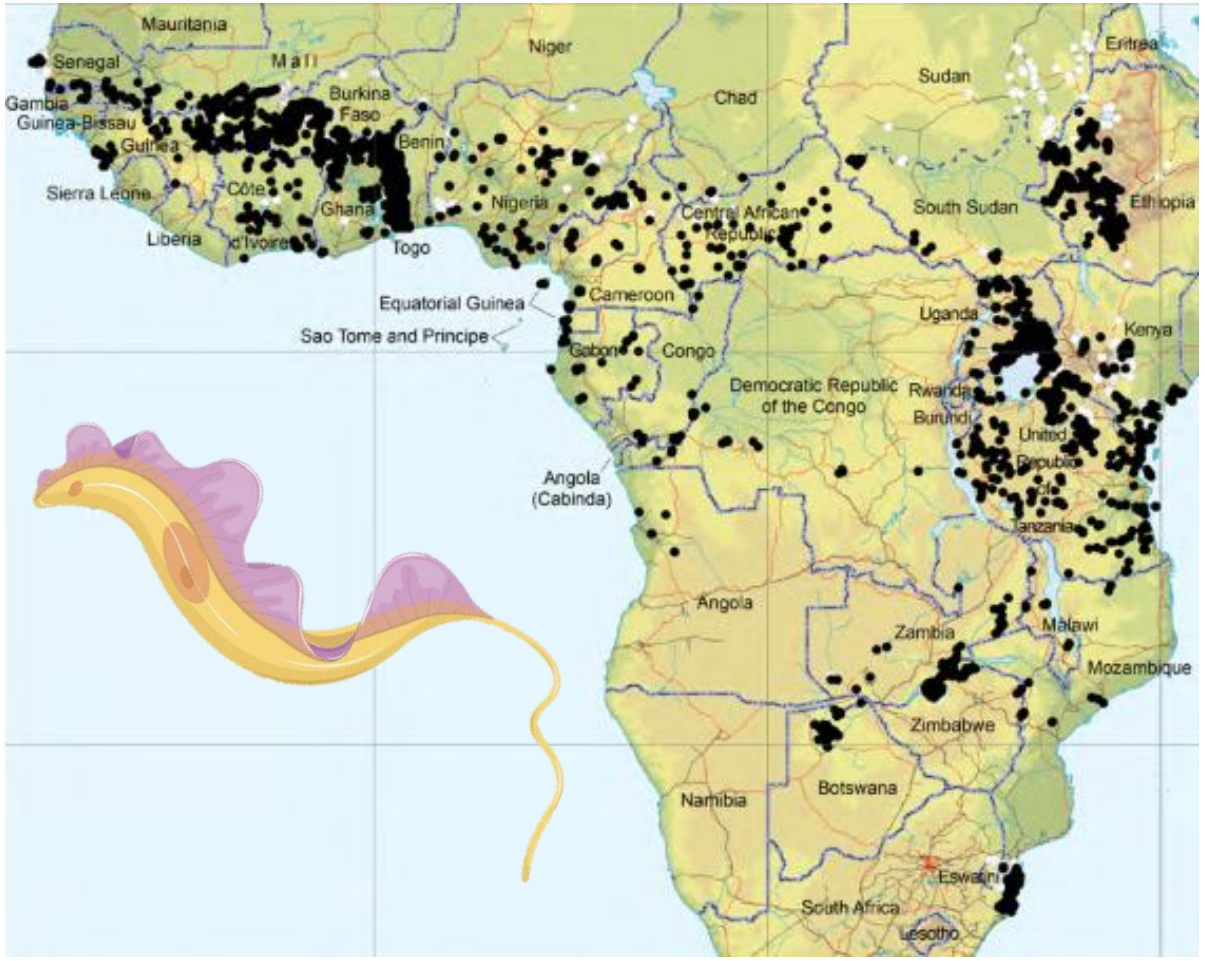
- Lack of training
- Over stretched veterinary extension services
- Inadequate last mile infrastructure

Accès et formation

Investment

- Lack of investment in new tools
- No penside diagnostics
- No vaccines

Investissement

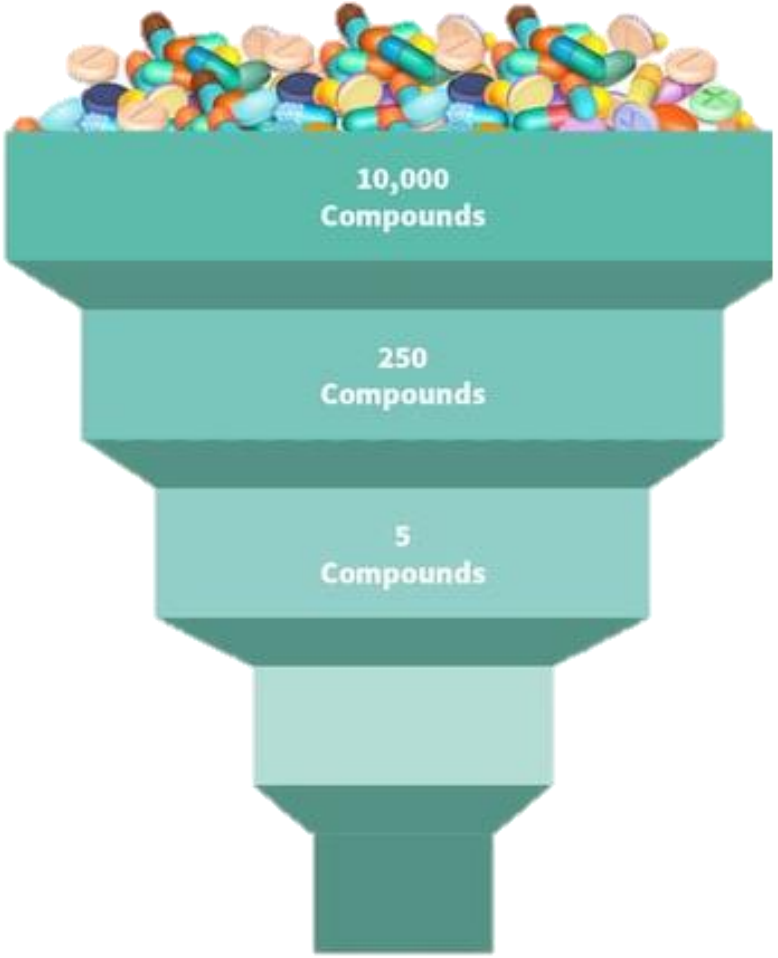


Cecchi et al, The continental atlas of the distribution of tsetse flies in Africa https://doi.org/10.4060/cd2022en

The Animal Health Drug Development Process

Le processus de développement des médicaments vétérinaires

15 ANS



DRUG DISCOVERY	High Throughput screening
CHEMISTRY	API and Cost of Goods Formulation Stability and Packaging
PRODUCT DEVELOPMENT	Lab and Field Efficacy Safety: Target Animal, Food and Environmental
REGISTRATION	Regulatory Target Market Dossier Preparation and Submission
PRODUCT SUPPORT	Distribution Networks Market Education Counterfeit Identification

The Ideal Profile of a New Drug...

Le profil idéal d'un nouveau médicament

Target Species
Cattle >3 months
Including pregnant and lactating



T. congolense

Indication
T. congolense, T. vivax & *T. brucei*
Including resistant strains

T. brucei spp.

T. vivax

Safety and Withdrawal
21 days ≤ Meat ≤28 days
1 day ≤ Milk ≤3 days

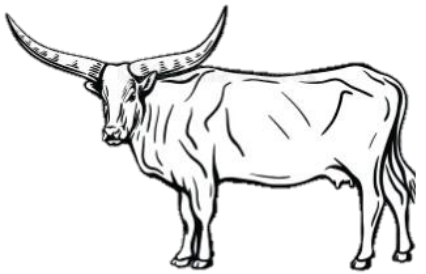
Stability and Presentation
>3 years stability
RTU in pack sizes for SSPs

Dosing and Administration
Single dose curative IM injection

How far have we come?

GALVmed Protecting Livestock Improving Human Lives

Quels progrès a-t-on réalisés?



Acute oral MTD in rats	Definitive DEVTOX rats
Short-term oral repeated dose in rats	Definitive DEVTOX rabbits
28-day oral repeated dose in rats	2-generation reproduction rats
90-day oral repeated dose in rats	Acute reference dose study in dogs
Acute oral MTD in dogs	Genetox Battery for API
Short-term oral repeated dose in dogs	Bacterial Reverse Mutation Assay
Oral repeated dose in dogs	Chromosome Aberration Assay
1-year oral repeated dose in dogs	in-vivo Micronucleus Assay

Dose Determination Studies (Tc, Tv, Tbb)

Dose Confirmation studies (Tc, Tv, Tbb)

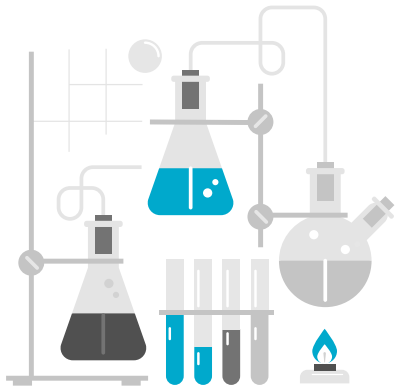
Field Safety and efficacy studies multiple countries

Drug Discovery → **Preliminary Screening** → **Pre-Clinical** Tox, Safety, Dose Determination → **Clinical** Target Animal Safety → **Clinical Human Food Safety** → **Clinical** Lab DC Studies → **Clinical** Field Studies

- TAS adult cattle
- TAS Reproductive Safety
- Injection Site Safety Study

- Exploratory Pharmacokinetic Studies
- Probe tissue and milk radio-residue study
- Metabolic Stability and Comparative Metabolism
- Analytical method development and validation
- Incurred sample storage stability
- Injection site residue study

- Pivotal radioresidue metabolism in beef
- Pivotal radioresidue metabolism in dairy
- Pivotal PK profile beef cattle (i.v. and i.m.)
- Pivotal residue depletion study in beef
- Pivotal residue depletion study in dairy



We Need an Enabling Environment



Current Options

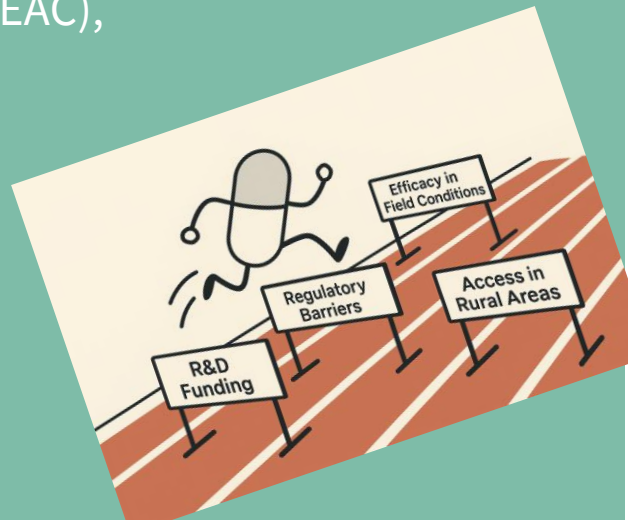
- Outdated, increasingly ineffective and unsafe

First new trypanocidal drug in >60 years

- Guidelines for pharmaceuticals and acaricides but not for trypanocides
- No recent pre-requisites to follow

Diverse Regulatory Landscape

- Mutual Recognition (EAC),
- Centralised (UEMOA)
- National procedures



We need a community approach to bringing this new drug to the market

alec.evans@galvmed.org

GALVmed

Protecting Livestock
Improving Human Lives

galvmed.org

