CONDUCTING RESEARCH IN A SETTING OF SEVERE POLITICAL INSTABILITY: THE GHESKIO MODEL.

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Samuel Pierre[1], Carl F. Duchatellier[1], Vanessa Rivera[1], Nancy Dorvil[1], Marie Flore Pierre[1], Joseph M.B. Joseph[1], Alexandra Apollon[1], Sean Collins[2], Dennis Israelski[2], Stephano St Preux[1], Sanjana Sundaresan[3], Hongjue Wang[3], Jean W. Pape[1,4], Serena Koenig[5], Patrice Severe[1]

[1]Les Centres GHESKIO, Port-au-Prince, Haiti, [2] Gilead Sciences, Inc., Foster City, USA, [3]Analysis Group, Boston, USA,, [4]Weill Cornell Medical College, New York, USA, [5]Brigham and Women's Hospital, Boston, USA

BACKGROUND

Haiti socio-political crisis



- Chronic
- Severe
- Multidimensional
- Evolutive

GHESKIO Mission

- Research, Service, Training
- Continuous NIH funding since 1982
- Research Staff: 60
- Two campuses
- Community advisory board
- Ethics committee
- Quarterly audits
- 32 Publications in 2022
- 4 International Networks

Through its model, GHESKIO has shown that it is relevant, feasible and ethical to conduct research during the crisis in Haiti.

The GHESKIO Model



Leadership & Communication

- Responsible
- Persistent
- Planning for the worst-case scenario
- Being diplomatic and knowing where to draw the line

Management/Support

- Welcoming environment
- Supportive staff-participant relationships
- Intensive tracking strategies
- Decentralized follow-up
- Hot meal at every study visit
- Package of staple foods for home
- Transportation subsidy
- Phone card at each visit

Ethics

- Non-Compromising
- Participant willingness
- Colleague outreach
- Communication across employee channels
- 2-way feedback (i.e., Whatsapp, email, call)
- Work-from-home execution and infrastructure

Participation & Collaboration

- Community engagement
- Snow balling recruitment
- Team-work
- Flexible & polyvalent staff
- Supportive funding partners

Challenges for Conducting Research during the Crisis in Haiti

IMPLEMENTATION

- Relevant
  - Priorities
  - Resource Allocation
- Feasible
- Ethics
  - Risk/benefit

RECRUITMENT

- Studies are diverse
- 22 ongoing Trials
- Decentralized Clinics
- Transportation/ limited access

METHODS/OUTCOMES

- Mandatory procedures
- In person specimen collections
- Patient follow up
- Retention
- Timing of evaluation

RISK FOR PARTICIPANTS & STAFF

- Security
- Safety monitoring
- Mental health



METHODS

Design	**Non inferiority open label randomized clinical trial**
Regimen	TAF/FTC/BIC vs. LPVr or ATZr + 2 NRTIs
Population	Adult (>17 years) PWHIV virally suppressed on PI-based second-line ART regimen
Sample size	N=386 (193/group)
Primary Outcomes	Viral Suppression <200copies/ml week 48
Secondary Outcomes	Retention in care, grade 3+ AE

RESULTS (Combined for both groups)

Key Variables and Outcomes	
Number with 48 weeks of potential follow-up time	231 (enrollment ongoing)
Sex ratio	128 (55%) female
Median age (IQR)	50 years (IQR: 42, 58)
48-week VL <200 copies/mL	**216 (93.5%)**
48-week VL >/=200 copies/mL	**2 (<1.0%)**
LTFU with VL >/=200 copies/mL	**2 (<1.0%)**
Died (last VL <200 copies/mL)	**2 (<1.0%)**
In care, unable to receive 48-week VL (last VL <200 copies/mL)	**6 (2.6%)**
Premature study discontinuation (last VL < 200 copies/mL)	**3 (1.3%)**

CONCLUSIONS

Outstanding research outcomes are possible in settings of severe political and civil unrest, with a comprehensive approach to social and nutritional support for study participants. Patient-friendly strategies to simplify treatment facilitate adherence during crises. Through its model, GHESKIO has shown that it is relevant, feasible and ethical to conduct research during the current crisis in Haiti.