# THE LANCET Gastroenterology & Hepatology

## Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

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## **SUPPLEMENTARY MATERIALS**

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#### **Study Sites and Teams**

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Peter Mariuz and Catherine A. Bunce from University of Rochester Adult HIV Therapeutic Strategies (CRS: 31787; CRS Grant: UM1AI069511). Edgar Turner Overton and Olivia Hogue from Alabama CRS (CRS: 31788; CRS Grant: UM1AI069452). Kiat Ruxrungtham and Sivaporn Gatechompol from Thai Red Cross AIDS Research Centre (TRC-ARC) (CRS: 31802; CRS Grant: UM1AI069399).



Supplementary Figure 1. Study sites participating in the ACTG A5360 MINMON trial.

## Supplementary Table 1. Recruitment by Study Site

Site Name	Number of participants recruited
Hospital Nossa Senhora da Conceicao, Brazil	68
Instituo de Pesquisa Clinica Evandro Chagas, Brazil	63
Thai Red Cross AIDS Research Centre (TRC-ARC), Thailand	61
Chiang Mai University HIV Treatment (CMU HIV Treatment), Thailand	49
Joint Clinical Research Center (JCRC) Kampala, Uganda	15
University of the Witwatersrand Helen Joseph (WITS HJH) CRS, South Africa	8
Penn Therapeutics, USA	8
Puerto Rico AIDS Clinical Trials Unit, USA	7
Johns Hopkins University, USA	5
University of California, San Diego AntiViral Research Center, USA	5
Family Clinical Research Unit (FAM-CRU), South Africa	4
University of Alabama, USA	4
Brigham and Women's Hospital Therapeutics (BWHT), USA	4
Case Western Reserve University, USA	4
University of North Carolina, Chapel Hill, USA	4
University of Cincinnati, USA	4
Columbia Physicians and Surgeons (P and S), USA	4
Greensboro, USA	4
Houston AIDS Research Team (HART), USA	4
Massachusetts General Hospital (MGH), USA	4
New Jersey Medical School Clinical Research Center, USA	4
Northwestern University, USA	4
Ohio State University, USA	4
Rush University, USA	4
The Miriam Hospital (TMH), USA	4
Trinity Health and Wellness Center, USA	4
University of California, Los Angeles CARE Center, USA	4
University of California, San Francisco HIV/AIDS, USA	4
University of Colorado Hospital, USA	4
University of Pittsburgh, USA	4
University of Rochester Adult HIV Therapeutic Strategies Network, USA	4
University of Southern California, USA	4
Vanderbilt Therapeutics (VT), USA	4
Washington University Therapeutics (WT), USA	4
Weill Cornell Chelsea, USA	4
Weill Cornell Uptown, USA	4
Whitman Walker Health, USA	4
The Ponce de Leon Center, USA	3

### Supplementary Table 2. Unplanned Study Visits

Country	Age in years	Sex at birth	Days since SOF/VEL initiation	Reason for visit	Visit related to a reportable Adverse Event	Visit resulted in SOF/VEL discontinuation	Sustained Virologic Response	
			1	Grade 4 sodium abnormality detected at entry	No	No		
South Africa	67	Male	4	Repeat sodium	No	No	Yes	
			11	Repeat sodium	No	No		
Thailand	27	Male	5	Follow-up of liver function test	No	No	Yes	
USA	53	Male	5	Symptoms of upper respiratory infection	Yes	No	Yes	
Uganda	51	Male	7	Participant felt unwell	No	No	Yes	
Uganda	49	Male	13	Participant complained of frequent micturition	No	No	Yes	
Uganda	31	Male	22	Participant complained of headache and dizziness	No	No	Yes	
D 11	63	Female	34	Community acquired pneumonia	No	No		
Brazil			46	Clarification about treatment	No	No	Yes	
D 1	35	Male	40	Papular rash	No	No	Yes	
Brazil			43	Rash on face and thorax	No	No		
Thailand	42	Male	43	Repeat AST/ALT from previous visit	No	No	Yes	
			48	Participant complained of weakness	Yes	No		
South Africa	51	Female	49	Participant requested to visit site to repeat hemogram	No	No	Yes	
			50	Participant came to site for counseling and administration of vitamin B12 for management of pernicious anemia	No	No		
Thailand	30	Male	48	Repeat AST/ALT	No	No	Yes	
USA	59	Male	72	Blood evaluations to evaluate dizziness and other symptoms	No	No	Yes	
Thailand	34	Male	85	Participant diagnosed with HIV and wanted to start antiretroviral therapy	No	No	Yes	
Brazil	63	Female	96	Grade 2 rash	Yes	No	Yes	
USA	59	Female	151	Participant came in early for study visit	No	No	No	

Country	Days since SOF/VEL initiation	Description of SAE	Toxicity Grade	Related to SOF/VEL	Resulted in SOF/VEL discontinuation	SAE outcome
USA	20	Respiratory Failure	3	No	No	Recovered
South Africa	48	Anemia	4	No	No	Recovered
Thailand	53	Drug overdose	3	No	No	Recovered
Thailand	65	Dyspepsia	3	No	No	Recovered
Thailand	67	Pneumonia	3	No	No	Recovered
USA	89	Depression	3	No	Not applicable*	Resolving
Thailand	101	Acute myocardial infarction	4	No	Not applicable*	Recovered
USA	127	Acute right ventricular failure	3	No	Not applicable*	Recovered
Thailand	131	Diverticular perforation	3	No	Not applicable*	Recovered
USA	148	Hypertension	3	No	Not applicable*	Recovered
South Africa	157	Seizure	3	No	Not applicable*	Recovered
USA	168	Acute kidney injury	3	No	Not applicable*	Recovered
USA	178	Urinary tract infection	3	No	Not applicable*	Recovered
USA	193	Suicidal ideation	3	No	Not applicable*	Recovered

#### Supplementary Table 3. Serious Adverse Events Reported Between Entry and Week 28

\*Not applicable as study medication was completed