

# NATIONAL

409/NDA/DPS/06/2021

# DRUG



Safe Drugs Save Lives

# AUTHORITY

28<sup>th</sup> June 2021

## CIRCULAR NO. 043

**Attention: Sponsors and Principal Investigators.**

### **National Drug Authority Statement on Conduct of Clinical Trials during the COVID-19 lockdown**

The National Drug Authority would like to issue the following guidance during this time of disruption of clinical trial activities due to the ongoing second wave of COVID-19 in Uganda.

1. In compliance with the Presidential directive as well as the Ministry of Health guidance, the Clinical Trials Unit will continue to review applications and any critical submissions remotely. Any meetings whether initiated by NDA or our esteemed clients will be hosted and attended virtually on an agreed upon date.
2. To reduce exposure to the COVID-19 virus from surfaces like paper documents and also to facilitate continued review of the applications remotely, clients intending to submit their applications are requested to submit them **electronically** to [clinicaltrials@nda.or.ug](mailto:clinicaltrials@nda.or.ug). Please ensure that any PDF documents are searchable to ease the review process. Please note that only **complete** submissions will be scheduled for evaluation in line with the usual NDA procedures.
3. The National Drug Authority encourages researchers to limit administrative submissions/notifications with no immediate bearing on participant safety or trial integrity during this period until the return to normalcy.
4. Principal Investigators and Sponsors remain responsible for putting in place mechanisms that are feasible to ensure safe continuity of clinical care and administration and monitoring of trial medicines in line with the principles of Good Clinical Practice.

For additional guidance, please refer to the National guidelines for conduct of research during the COVID-19 pandemic, July 2020 which are accessible at:

<https://www.unhro.org.ug/assets/images/resources/covidnationalguidelines.pdf>

David Nahamya

**SECRETARY TO THE AUTHORITY**

#### HEAD OFFICE

Plot 19 Lumumba Avenue P.O. Box 23096, Kampala, Uganda  
Tel: (+256) 417 788 100/1 (+256) 417 788 124/417 788 129  
Toll Free: 0800 101 999, 0791 415 555  
Website: [www.nda.or.ug](http://www.nda.or.ug), Email: [ndaug@nda.or.ug](mailto:ndaug@nda.or.ug)  
Facebook: Uganda National Drug Authority  
Twitter: @UNDAuthority  
**NATIONAL DRUG QUALITY CONTROL LABORATORY**  
Tel: (+256) 414 540 067 / (+256) 414 583 095

#### OUR MISSION

Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products

#### REGIONAL OFFICES

Central Region, Nakawa- Tel: +256 393 261 548,  
Western Nile Region, Arua - Tel: +256 414 671 033,  
South Western Region, Mbarara- Tel: +256 414 671 034,  
South Eastern Region, Jinja - Tel: +256 434 122 176,  
Eastern Region, Tororo - Tel: +256 392 004 308,  
Western Region, Hoima- Tel: +256 465 440 688,  
Northern Region, Lira- Tel: +256 414 671 032