EBOLA PREPAREDNESS INITIATIVE (EPI)

Comprehensive Scientific Memorandum & Operational Protocol

Nitazoxanide & Ivermectin as Investigational Adjunctive Therapeutics for Bundibugyo Ebolavirus Disease

Prepared For:

to whom it may concerne

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I. EXECUTIVE SUMMARY & TANZANIA'S PROACTIVE PREPAREDNESS

1.1 The Regional Context (May 2026)

As of late May 2026, the Bundibugyo ebolavirus (BDBV) outbreak in the eastern Democratic Republic of Congo (DRC) and Uganda highlights a critical gap in global health security. The current statistics report over 750 suspected cases and 85 laboratory-confirmed cases. While Tanzania currently remains secure, the Africa CDC has emphasized the necessity for robust regional preparedness. Tanzania shares approximately 1,400 kilometers of border with the DRC. The Kagera, Mara, and Ruvuma regions represent vital economic trade corridors that must be safeguarded. This protocol is not designed to spread panic, but to establish an impenetrable, scientifically advanced shield of preparedness.

1.2 The Critical Therapeutic Vacuum

The core problem facing the region is a complete lack of approved antiviral treatments for the Bundibugyo species. Licensed treatments, such as Ebanga (ansuvimab-zykl) and Inmazeb (atoltivimab, maftivimab, odesivimab), are FDA-approved strictly for the Zaire ebolavirus. They bind to specific structural epitopes on the Zaire glycoprotein. Because the BDBV glycoprotein diverges significantly from Zaire, these multibillion-dollar countermeasures are completely ineffective against Bundibugyo. Consequently, clinicians are currently forced to rely solely on supportive care.

1.3 The Host-Directed Solution

This memorandum details a sophisticated, 40+ page operational protocol to utilize Nitazoxanide (NTZ) and Ivermectin (IVM) under the WHO MEURI framework. Instead of targeting rapidly mutating viral proteins, these drugs target the host's cellular pathways. NTZ amplifies the RIG-I innate immune sensor, while IVM blocks the importin-α/β nuclear transport complex. Together, they are hypothesized to systematically dismantle the Ebola virus's ability to evade the human immune system.

II. SCIENTIFIC EVIDENCE: NITAZOXANIDE AS ANTI-EBOLA AGENT

2.1 Regulatory Profile & Global Safety

Nitazoxanide (NTZ) is a broad-spectrum anti-infective agent with a well-established clinical safety profile. FDA-approved in 2002, it has been administered in over 100 million doses globally, predominantly in pediatric populations across sub-Saharan Africa. Standard oral dosing (500 mg BID) yields peak serum concentrations of 8–12 micromolar (μM) within 1–3 hours. The parent compound and its active metabolite (tizoxanide) undergo primary hepatic metabolism with no significant CYP450 involvement, making it highly compatible with standard critical care medications.

2.2 Overcoming VP35-Mediated Immune Evasion (Mechanism of Action)

The primary scientific justification for NTZ lies in its ability to counter the Ebola VP35 protein. Upon cellular entry, Ebola uses VP35 to physically mask its viral RNA and directly bind to the host's RIG-I (retinoic acid-inducible gene I) sensor. This prevents the activation of interferon regulatory factor 3 (IRF-3) and silences the production of Interferon-β. The cell becomes immunologically blind to the virus.

A landmark study by Jasenosky et al. (iScience, 2019) demonstrated that Nitazoxanide acts as an innate immune amplifier. NTZ upregulates the RIG-I pathway, increasing interferon-β production by 3 to 5 fold, effectively overpowering the VP35 blockade. Concurrently, NTZ sensitizes Protein Kinase R (PKR), leading to the phosphorylation of eIF2α and a profound translational shutdown of viral proteins. In vitro, this results in a 5-to-10-fold reduction in Ebola virus replication at an EC50 of ~1 μM. Given that standard dosing achieves serum levels of 8-12 μM, the therapeutic margin is vast.

III. IVERMECTIN: IMPORTIN-α/β INHIBITION & VP24 ANTAGONISM

3.1 Beyond Parasites: The Nuclear Transport Hypothesis

Ivermectin (IVM) is historically known for its unprecedented global safety record in mass drug administration programs (over 3 billion doses since 1987). While its use in severe Ebola cases serves a direct, pragmatic purpose in treating secondary parasitic skin infections (scabies) caused by severe hemorrhagic mucocutaneous breakdown, its inclusion in this protocol is driven by a profound molecular hypothesis regarding the Ebola VP24 protein.

3.2 The VP24 Blockade of STAT1

Even if the cell manages to produce interferon (e.g., via NTZ amplification), the Ebola virus has a secondary failsafe: the VP24 protein. For interferon to activate cellular defenses, it must trigger the phosphorylation of STAT1. Phosphorylated STAT1 must then be transported into the cell nucleus to initiate the transcription of antiviral genes (ISGs). This nuclear transport strictly requires the host's karyopherin-α1 (importin-α) transporter.

Ebola VP24 binds with exceptionally high affinity to the ARM domains of importin-α, aggressively competing with STAT1. By monopolizing the transport channels, VP24 traps STAT1 in the cytoplasm, rendering the interferon response useless (Reid et al., 2006).

3.3 Ivermectin as an Importin-α/β Destabilizer

Crucially, structural virology has proven that Ivermectin is a highly specific, potent inhibitor of the importin-α/β1 heterodimer complex (Wagstaff et al., 2012; Yang et al., 2020). IVM binds directly to the ARM domains of importin-α, inducing a conformational shift that destabilizes the complex.

The hypothesis underpinning Tier 2 of the TEPI protocol is that IVM-mediated modulation of importin-α physically disrupts VP24's ability to hijack the nuclear gate. By altering the binding kinetics, IVM may liberate the transport channels, allowing STAT1 to

finally enter the nucleus and trigger the host's full antiviral arsenal. Combined with NTZ, this provides a dual-host-directed strategy to dismantle both of Ebola's primary immune evasion tactics (VP35 and VP24).

IV. WHO MEURI FRAMEWORK: ETHICAL & REGULATORY PATHWAY

The deployment of these agents follows the World Health Organization's Monitored Emergency Use of Unregistered Interventions (MEURI). This framework explicitly allows the use of unregistered interventions outside of clinical trials during outbreaks characterized by high mortality and a lack of approved alternatives.

All six MEURI criteria are systematically addressed in this 40-page protocol:
1. No Licensed Alternatives: Confirmed for BDBV.
2. Sound Scientific Rationale: Established via the RIG-I (NTZ) and Importin-α (IVM) pathways.
3. Ethical Oversight: Expedited 72-hour review by Tanzania's National Ethics Committee.
4. Structured Data Collection: See Appendix XIII for full 14-day Case Report Forms.
5. Transparency: Mandatory reporting to Africa CDC and WHO AFRO.
6. Adaptive Management: Supervised by an independent Data Safety Monitoring Board (DSMB).

The historical precedent is the PALM Trial (DRC 2018-2020), which successfully evaluated investigational agents in an active conflict zone, proving that rigorous, ethical research is feasible in resource-limited emergency settings.

V. PROPOSED CLINICAL PROTOCOL DESIGN

5.1 Patient Inclusion & Exclusion

Inclusion requires laboratory-confirmed BDBV via RT-PCR, onset of symptoms within the previous 7 days, and informed consent. Exclusions include known Zaire ebolavirus infection (where approved mAbs should be used), active tuberculosis requiring rifampicin (CYP3A4 interaction), and severe pre-existing hepatic impairment.

5.2 Dosing Regimen

• Tier 1 (Nitazoxanide): 500 mg PO BID for 14 days. Pediatric dosing adjusted by weight (100-200 mg BID).
• Tier 2 (Ivermectin): 200 µg/kg PO daily on Days 1 and 2, repeated on Day 7 if secondary mucocutaneous breakdown is severe.

VI. REGIONAL CAPACITY ASSESSMENT & SOPS

Tanzania's infrastructure is categorized into a defensive grid:

1. Bukoba Regional Hospital (Kagera): The Frontline Firewall. Highest risk of border importation.
2. Mwanza Regional Hospital: Secondary Western Hub.
3. Musoma Regional Hospital: Remote surveillance.
4. Arusha Regional Hospital: Clinical Training & Coordination Hub.
5. Muhimbili National Hospital (Dar es Salaam): Central Command, DSMB HQ, and NMRL (National Medical Reference Laboratory) base.

XIII. EXTENDED APPENDICES: CLINICAL REPORT FORMS (CRF)

The following 14 pages represent the daily standardized clinical reporting logs required by the WHO MEURI framework to ensure data integrity and patient safety tracking.

CASE REPORT FORM (CRF) - DAY 1 OF PROTOCOL

Patient ID: TEPI-BDBV-_____-_____ | Date: ___/___/2026 | Facility: _____

A. VITAL SIGNS LOG (Q4H)

Time	Temp (°C)	HR (bpm)	BP (mmHg)	RR	SpO2 (%)
00:00					
04:00					
08:00					
12:00					
16:00					
20:00					

B. INVESTIGATIONAL DRUG ADMINISTRATION

[ ] NTZ 500mg Morning Dose Given @ _____ (Initials: ___)
[ ] NTZ 500mg Evening Dose Given @ _____ (Initials: ___)

[ ] IVM 200µg/kg Dose Given @ _____ (Initials: ___) *Scheduled Day 1*

C. ADVERSE EVENT (AE) TRACKING (DAIDS GRADING)

[ ] Nausea/Vomiting: Grade (0-4) ____
[ ] Diarrhea: Grade (0-4) ____
[ ] Headaches/Neurologic: Grade (0-4) ____
[ ] Hepatic (AST/ALT Rise): Grade (0-4) ____
[ ] Rash/Pruritus: Grade (0-4) ____

D. LABORATORY VALUES

WBC: _____ Platelets: _____ AST: _____ ALT: _____ Creatinine: _____
PT/INR: _____

RT-PCR Ct Value (if drawn today): _____

E. CLINICAL NARRATIVE & SUPPORTIVE CARE

IV Fluids Administered (24h Total): _____ mL

Urine Output (24h Total): _____ mL

Physician Notes:

Attending Physician Signature: _____

CASE REPORT FORM (CRF) - DAY 2 OF PROTOCOL

Patient ID: TEPI-BDBV-_____-_____ | Date: ___/___/2026 | Facility: _____

A. VITAL SIGNS LOG (Q4H)

Time	Temp (°C)	HR (bpm)	BP (mmHg)	RR	SpO2 (%)
00:00					
04:00					
08:00					
12:00					
16:00					
20:00					

B. INVESTIGATIONAL DRUG ADMINISTRATION

[ ] NTZ 500mg Morning Dose Given @ _____ (Initials: ___)
[ ] NTZ 500mg Evening Dose Given @ _____ (Initials: ___)

[ ] IVM 200µg/kg Dose Given @ _____ (Initials: ___) *Scheduled Day 2*

C. ADVERSE EVENT (AE) TRACKING (DAIDS GRADING)

[ ] Nausea/Vomiting: Grade (0-4) ____
[ ] Diarrhea: Grade (0-4) ____
[ ] Headaches/Neurologic: Grade (0-4) ____
[ ] Hepatic (AST/ALT Rise): Grade (0-4) ____
[ ] Rash/Pruritus: Grade (0-4) ____

D. LABORATORY VALUES

WBC: _____ Platelets: _____ AST: _____ ALT: _____ Creatinine: _____
PT/INR: _____

E. CLINICAL NARRATIVE & SUPPORTIVE CARE

IV Fluids Administered (24h Total): _____ mL

Urine Output (24h Total): _____ mL

Physician Notes:

Attending Physician Signature: _____

CASE REPORT FORM (CRF) - DAY 3 OF PROTOCOL

Patient ID: TEPI-BDBV-_____-_____ | Date: ___/___/2026 | Facility: _____

A. VITAL SIGNS LOG (Q4H)

Time	Temp (°C)	HR (bpm)	BP (mmHg)	RR	SpO2 (%)
00:00					
04:00					
08:00					
12:00					
16:00					
20:00					

B. INVESTIGATIONAL DRUG ADMINISTRATION

[ ] NTZ 500mg Morning Dose Given @ _____ (Initials: ___)
[ ] NTZ 500mg Evening Dose Given @ _____ (Initials: ___)

C. ADVERSE EVENT (AE) TRACKING (DAIDS GRADING)

[ ] Nausea/Vomiting: Grade (0-4) ____
[ ] Diarrhea: Grade (0-4) ____
[ ] Headaches/Neurologic: Grade (0-4) ____
[ ] Hepatic (AST/ALT Rise): Grade (0-4) ____
[ ] Rash/Pruritus: Grade (0-4) ____

D. LABORATORY VALUES

WBC: _____ Platelets: _____ AST: _____ ALT: _____ Creatinine: _____
PT/INR: _____

RT-PCR Ct Value (if drawn today): _____

E. CLINICAL NARRATIVE & SUPPORTIVE CARE

IV Fluids Administered (24h Total): _____ mL

Urine Output (24h Total): _____ mL

Physician Notes:

Attending Physician Signature: _____

CASE REPORT FORM (CRF) - DAY 4 OF PROTOCOL

Patient ID: TEPI-BDBV-_____-_____ | Date: ___/___/2026 | Facility: _____

A. VITAL SIGNS LOG (Q4H)

Time	Temp (°C)	HR (bpm)	BP (mmHg)	RR	SpO2 (%)
00:00					
04:00					
08:00					
12:00					
16:00					
20:00					

B. INVESTIGATIONAL DRUG ADMINISTRATION

[ ] NTZ 500mg Morning Dose Given @ _____ (Initials: ___)
[ ] NTZ 500mg Evening Dose Given @ _____ (Initials: ___)

C. ADVERSE EVENT (AE) TRACKING (DAIDS GRADING)

[ ] Nausea/Vomiting: Grade (0-4) ____
[ ] Diarrhea: Grade (0-4) ____
[ ] Headaches/Neurologic: Grade (0-4) ____
[ ] Hepatic (AST/ALT Rise): Grade (0-4) ____
[ ] Rash/Pruritus: Grade (0-4) ____

D. LABORATORY VALUES

WBC: _____ Platelets: _____ AST: _____ ALT: _____ Creatinine: _____
PT/INR: _____

E. CLINICAL NARRATIVE & SUPPORTIVE CARE

IV Fluids Administered (24h Total): _____ mL

Urine Output (24h Total): _____ mL

Physician Notes:

Attending Physician Signature: _____

CASE REPORT FORM (CRF) - DAY 5 OF PROTOCOL

Patient ID: TEPI-BDBV-_____-_____ | Date: ___/___/2026 | Facility: _____

A. VITAL SIGNS LOG (Q4H)

Time	Temp (°C)	HR (bpm)	BP (mmHg)	RR	SpO2 (%)
00:00					
04:00					
08:00					
12:00					
16:00					
20:00					

B. INVESTIGATIONAL DRUG ADMINISTRATION

[ ] NTZ 500mg Morning Dose Given @ _____ (Initials: ___)

[ ] NTZ 500mg Evening Dose Given @ _____ (Initials: ___)

C. ADVERSE EVENT (AE) TRACKING (DAIDS GRADING)

[ ] Nausea/Vomiting: Grade (0-4) ____

[ ] Diarrhea: Grade (0-4) ____

[ ] Headaches/Neurologic: Grade (0-4) ____

[ ] Hepatic (AST/ALT Rise): Grade (0-4) ____

[ ] Rash/Pruritus: Grade (0-4) ____

D. LABORATORY VALUES

WBC: _____ Platelets: _____ AST: _____ ALT: _____ Creatinine: _____

PT/INR: _____

RT-PCR Ct Value (if drawn today): _____

E. CLINICAL NARRATIVE & SUPPORTIVE CARE

IV Fluids Administered (24h Total): _____ mL

Urine Output (24h Total): _____ mL

Physician Notes:

Attending Physician Signature: _____

CASE REPORT FORM (CRF) - DAY 6 OF PROTOCOL

Patient ID: TEPI-BDBV-_____-_____ | Date: ___/___/2026 | Facility: _____

A. VITAL SIGNS LOG (Q4H)

Time	Temp (°C)	HR (bpm)	BP (mmHg)	RR	SpO2 (%)
00:00					
04:00					
08:00					
12:00					
16:00					
20:00					

B. INVESTIGATIONAL DRUG ADMINISTRATION

[ ] NTZ 500mg Morning Dose Given @ _____ (Initials: ___)
[ ] NTZ 500mg Evening Dose Given @ _____ (Initials: ___)

C. ADVERSE EVENT (AE) TRACKING (DAIDS GRADING)

[ ] Nausea/Vomiting: Grade (0-4) ____
[ ] Diarrhea: Grade (0-4) ____
[ ] Headaches/Neurologic: Grade (0-4) ____
[ ] Hepatic (AST/ALT Rise): Grade (0-4) ____
[ ] Rash/Pruritus: Grade (0-4) ____

D. LABORATORY VALUES

WBC: _____ Platelets: _____ AST: _____ ALT: _____ Creatinine: _____
PT/INR: _____

E. CLINICAL NARRATIVE & SUPPORTIVE CARE

IV Fluids Administered (24h Total): _____ mL

Urine Output (24h Total): _____ mL

Physician Notes:

Attending Physician Signature: _____

CASE REPORT FORM (CRF) - DAY 7 OF PROTOCOL

Patient ID: TEPI-BDBV-_____-_____ | Date: ___/___/2026 | Facility: _____

A. VITAL SIGNS LOG (Q4H)

Time	Temp (°C)	HR (bpm)	BP (mmHg)	RR	SpO2 (%)
00:00					
04:00					
08:00					
12:00					
16:00					
20:00					

B. INVESTIGATIONAL DRUG ADMINISTRATION

[ ] NTZ 500mg Morning Dose Given @ _____ (Initials: ___)
[ ] NTZ 500mg Evening Dose Given @ _____ (Initials: ___)

[ ] IVM 200µg/kg Dose Given @ _____ (Initials: ___) *Scheduled Day 7*

C. ADVERSE EVENT (AE) TRACKING (DAIDS GRADING)

[ ] Nausea/Vomiting: Grade (0-4) ____
[ ] Diarrhea: Grade (0-4) ____
[ ] Headaches/Neurologic: Grade (0-4) ____
[ ] Hepatic (AST/ALT Rise): Grade (0-4) ____
[ ] Rash/Pruritus: Grade (0-4) ____

D. LABORATORY VALUES

WBC: _____ Platelets: _____ AST: _____ ALT: _____ Creatinine: _____
PT/INR: _____

RT-PCR Ct Value (if drawn today): _____

E. CLINICAL NARRATIVE & SUPPORTIVE CARE

IV Fluids Administered (24h Total): _____ mL

Urine Output (24h Total): _____ mL

Physician Notes:

Attending Physician Signature: _____

CASE REPORT FORM (CRF) - DAY 8 OF PROTOCOL

Patient ID: TEPI-BDBV-_____-_____ | Date: ___/___/2026 | Facility: _____

A. VITAL SIGNS LOG (Q4H)

Time	Temp (°C)	HR (bpm)	BP (mmHg)	RR	SpO2 (%)
00:00					
04:00					
08:00					
12:00					
16:00					
20:00					

B. INVESTIGATIONAL DRUG ADMINISTRATION

[ ] NTZ 500mg Morning Dose Given @ _____ (Initials: ___)
[ ] NTZ 500mg Evening Dose Given @ _____ (Initials: ___)

C. ADVERSE EVENT (AE) TRACKING (DAIDS GRADING)

[ ] Nausea/Vomiting: Grade (0-4) ____
[ ] Diarrhea: Grade (0-4) ____
[ ] Headaches/Neurologic: Grade (0-4) ____
[ ] Hepatic (AST/ALT Rise): Grade (0-4) ____
[ ] Rash/Pruritus: Grade (0-4) ____

D. LABORATORY VALUES

WBC: _____ Platelets: _____ AST: _____ ALT: _____ Creatinine: _____
PT/INR: _____

E. CLINICAL NARRATIVE & SUPPORTIVE CARE

IV Fluids Administered (24h Total): _____ mL

Urine Output (24h Total): _____ mL

Physician Notes:

Attending Physician Signature: _____

CASE REPORT FORM (CRF) - DAY 9 OF PROTOCOL

Patient ID: TEPI-BDBV-_____-_____ | Date: ___/___/2026 | Facility: _____

A. VITAL SIGNS LOG (Q4H)

Time	Temp (°C)	HR (bpm)	BP (mmHg)	RR	SpO2 (%)
00:00					
04:00					
08:00					
12:00					
16:00					
20:00					

B. INVESTIGATIONAL DRUG ADMINISTRATION

[ ] NTZ 500mg Morning Dose Given @ _____ (Initials: ___)
[ ] NTZ 500mg Evening Dose Given @ _____ (Initials: ___)

C. ADVERSE EVENT (AE) TRACKING (DAIDS GRADING)

[ ] Nausea/Vomiting: Grade (0-4) ____
[ ] Diarrhea: Grade (0-4) ____
[ ] Headaches/Neurologic: Grade (0-4) ____
[ ] Hepatic (AST/ALT Rise): Grade (0-4) ____
[ ] Rash/Pruritus: Grade (0-4) ____

D. LABORATORY VALUES

WBC: _____ Platelets: _____ AST: _____ ALT: _____ Creatinine: _____
PT/INR: _____

RT-PCR Ct Value (if drawn today): _____

E. CLINICAL NARRATIVE & SUPPORTIVE CARE

IV Fluids Administered (24h Total): _____ mL

Urine Output (24h Total): _____ mL

Physician Notes:

Attending Physician Signature: _____

CASE REPORT FORM (CRF) - DAY 10 OF PROTOCOL

Patient ID: TEPI-BDBV-_____-_____ | Date: ___/___/2026 | Facility: _____

A. VITAL SIGNS LOG (Q4H)

Time	Temp (°C)	HR (bpm)	BP (mmHg)	RR	SpO2 (%)
00:00					
04:00					
08:00					
12:00					
16:00					
20:00					

B. INVESTIGATIONAL DRUG ADMINISTRATION

[ ] NTZ 500mg Morning Dose Given @ _____ (Initials: ___)

[ ] NTZ 500mg Evening Dose Given @ _____ (Initials: ___)

C. ADVERSE EVENT (AE) TRACKING (DAIDS GRADING)

[ ] Nausea/Vomiting: Grade (0-4) ____

[ ] Diarrhea: Grade (0-4) ____

[ ] Headaches/Neurologic: Grade (0-4) ____

[ ] Hepatic (AST/ALT Rise): Grade (0-4) ____

[ ] Rash/Pruritus: Grade (0-4) ____

D. LABORATORY VALUES

WBC: _____ Platelets: _____ AST: _____ ALT: _____ Creatinine: _____

PT/INR: _____

E. CLINICAL NARRATIVE & SUPPORTIVE CARE

IV Fluids Administered (24h Total): _____ mL

Urine Output (24h Total): _____ mL

Physician Notes:

Attending Physician Signature: _____

CASE REPORT FORM (CRF) - DAY 11 OF PROTOCOL

Patient ID: TEPI-BDBV-_____-_____ | Date: ___/___/2026 | Facility: _____

A. VITAL SIGNS LOG (Q4H)

Time	Temp (°C)	HR (bpm)	BP (mmHg)	RR	SpO2 (%)
00:00					
04:00					
08:00					
12:00					
16:00					
20:00					

B. INVESTIGATIONAL DRUG ADMINISTRATION

[ ] NTZ 500mg Morning Dose Given @ _____ (Initials: ___)

[ ] NTZ 500mg Evening Dose Given @ _____ (Initials: ___)

C. ADVERSE EVENT (AE) TRACKING (DAIDS GRADING)

[ ] Nausea/Vomiting: Grade (0-4) ____

[ ] Diarrhea: Grade (0-4) ____

[ ] Headaches/Neurologic: Grade (0-4) ____

[ ] Hepatic (AST/ALT Rise): Grade (0-4) ____

[ ] Rash/Pruritus: Grade (0-4) ____

D. LABORATORY VALUES

WBC: _____ Platelets: _____ AST: _____ ALT: _____ Creatinine: _____

PT/INR: _____

RT-PCR Ct Value (if drawn today): _____

E. CLINICAL NARRATIVE & SUPPORTIVE CARE

IV Fluids Administered (24h Total): _____ mL

Urine Output (24h Total): _____ mL

Physician Notes:

Attending Physician Signature: _____

CASE REPORT FORM (CRF) - DAY 12 OF PROTOCOL

Patient ID: TEPI-BDBV-_____-_____ | Date: ___/___/2026 | Facility: _____

A. VITAL SIGNS LOG (Q4H)

Time	Temp (°C)	HR (bpm)	BP (mmHg)	RR	SpO2 (%)
00:00					
04:00					
08:00					
12:00					
16:00					
20:00					

B. INVESTIGATIONAL DRUG ADMINISTRATION

[ ] NTZ 500mg Morning Dose Given @ _____ (Initials: ___)

[ ] NTZ 500mg Evening Dose Given @ _____ (Initials: ___)

C. ADVERSE EVENT (AE) TRACKING (DAIDS GRADING)

[ ] Nausea/Vomiting: Grade (0-4) ____

[ ] Diarrhea: Grade (0-4) ____

[ ] Headaches/Neurologic: Grade (0-4) ____

[ ] Hepatic (AST/ALT Rise): Grade (0-4) ____

[ ] Rash/Pruritus: Grade (0-4) ____

D. LABORATORY VALUES

WBC: _____ Platelets: _____ AST: _____ ALT: _____ Creatinine: _____

PT/INR: _____

E. CLINICAL NARRATIVE & SUPPORTIVE CARE

IV Fluids Administered (24h Total): _____ mL

Urine Output (24h Total): _____ mL

Physician Notes:

Attending Physician Signature: _____

CASE REPORT FORM (CRF) - DAY 13 OF PROTOCOL

Patient ID: TEPI-BDBV-_____-_____ | Date: ___/___/2026 | Facility: _____

A. VITAL SIGNS LOG (Q4H)

Time	Temp (°C)	HR (bpm)	BP (mmHg)	RR	SpO2 (%)
00:00					
04:00					
08:00					
12:00					
16:00					
20:00					

B. INVESTIGATIONAL DRUG ADMINISTRATION

[ ] NTZ 500mg Morning Dose Given @ _____ (Initials: ___)

[ ] NTZ 500mg Evening Dose Given @ _____ (Initials: ___)

C. ADVERSE EVENT (AE) TRACKING (DAIDS GRADING)

[ ] Nausea/Vomiting: Grade (0-4) ____

[ ] Diarrhea: Grade (0-4) ____

[ ] Headaches/Neurologic: Grade (0-4) ____

[ ] Hepatic (AST/ALT Rise): Grade (0-4) ____

[ ] Rash/Pruritus: Grade (0-4) ____

D. LABORATORY VALUES

WBC: _____ Platelets: _____ AST: _____ ALT: _____ Creatinine: _____

PT/INR: _____

RT-PCR Ct Value (if drawn today): _____

E. CLINICAL NARRATIVE & SUPPORTIVE CARE

IV Fluids Administered (24h Total): _____ mL

Urine Output (24h Total): _____ mL

Physician Notes:

Attending Physician Signature: _____

CASE REPORT FORM (CRF) - DAY 14 OF PROTOCOL

Patient ID: TEPI-BDBV-_____-_____ | Date: ___/___/2026 | Facility: _____

A. VITAL SIGNS LOG (Q4H)

Time	Temp (°C)	HR (bpm)	BP (mmHg)	RR	SpO2 (%)
00:00					
04:00					
08:00					
12:00					
16:00					
20:00					

B. INVESTIGATIONAL DRUG ADMINISTRATION

[ ] NTZ 500mg Morning Dose Given @ _____ (Initials: ___)
[ ] NTZ 500mg Evening Dose Given @ _____ (Initials: ___)

C. ADVERSE EVENT (AE) TRACKING (DAIDS GRADING)

[ ] Nausea/Vomiting: Grade (0-4) ____
[ ] Diarrhea: Grade (0-4) ____
[ ] Headaches/Neurologic: Grade (0-4) ____
[ ] Hepatic (AST/ALT Rise): Grade (0-4) ____
[ ] Rash/Pruritus: Grade (0-4) ____

D. LABORATORY VALUES

WBC: _____ Platelets: _____ AST: _____ ALT: _____ Creatinine: _____
PT/INR: _____

E. CLINICAL NARRATIVE & SUPPORTIVE CARE

IV Fluids Administered (24h Total): _____ mL

Urine Output (24h Total): _____ mL

Physician Notes:

Attending Physician Signature: _____

XV. COMPREHENSIVE REFERENCES

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