

# INTEGRATE

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# The ISTH-ANRS 0409s INTEGRATE study: an adaptive platform trial for the development of new treatments to combat Lassa Fever in West Africa

- WHO R&D blueprint: listed Lassa Fever (LF) as a priority disease for urgent research and development
- Ribavirin is the recommended treatment of LF in endemic countries, including Nigeria
  - Data underlying its supposed efficacy as well as the choice of the dose regimen are now widely questioned (*Salam et al, Plos NTD, 2021; Eberhardt et al, IJID, 2019*)
  - Hematological side effects critical in Lassa patients, contra-indicated in pregnancy
  - Around 12% in-hospital mortality under Ribavirin regimen (*Duvignaud et al. LGH 2021*)
- Several drug candidates have been identified in early stages of development : favipiravir, ARN 75039, LHF 535, Arevirumab



# INTEGRATE therapeutic trial

**ISTH-ANRS 0409s INTEGRATE: Efficacy, tolerability and safety of new or repurposed drugs against Lassa Fever in West Africa**

**Sponsors:** Irrua Specialist Teaching Hospital (ISTH), Nigeria; Inserm – ANRS MIE, France

**International Principal Investigators:** Marie Jaspard (ALIMA, Inserm-APHP) ; Sylvanus Okogbenin (ISTH) ; Michael Ramharter (BNITM)

**Funding:** EDCTP3, Department of Defense USA, ANRS MIE, DZIF

**Sites currently funded:**

Nigeria : Federal Medical Center of Owo (FMCO) - Ondo State, ISTH - Edo State, Abubakar Tafawa Balew University (ATBU) Teaching Hospital - Bauchi State (ATBU)

Liberia : Phebe Hospital



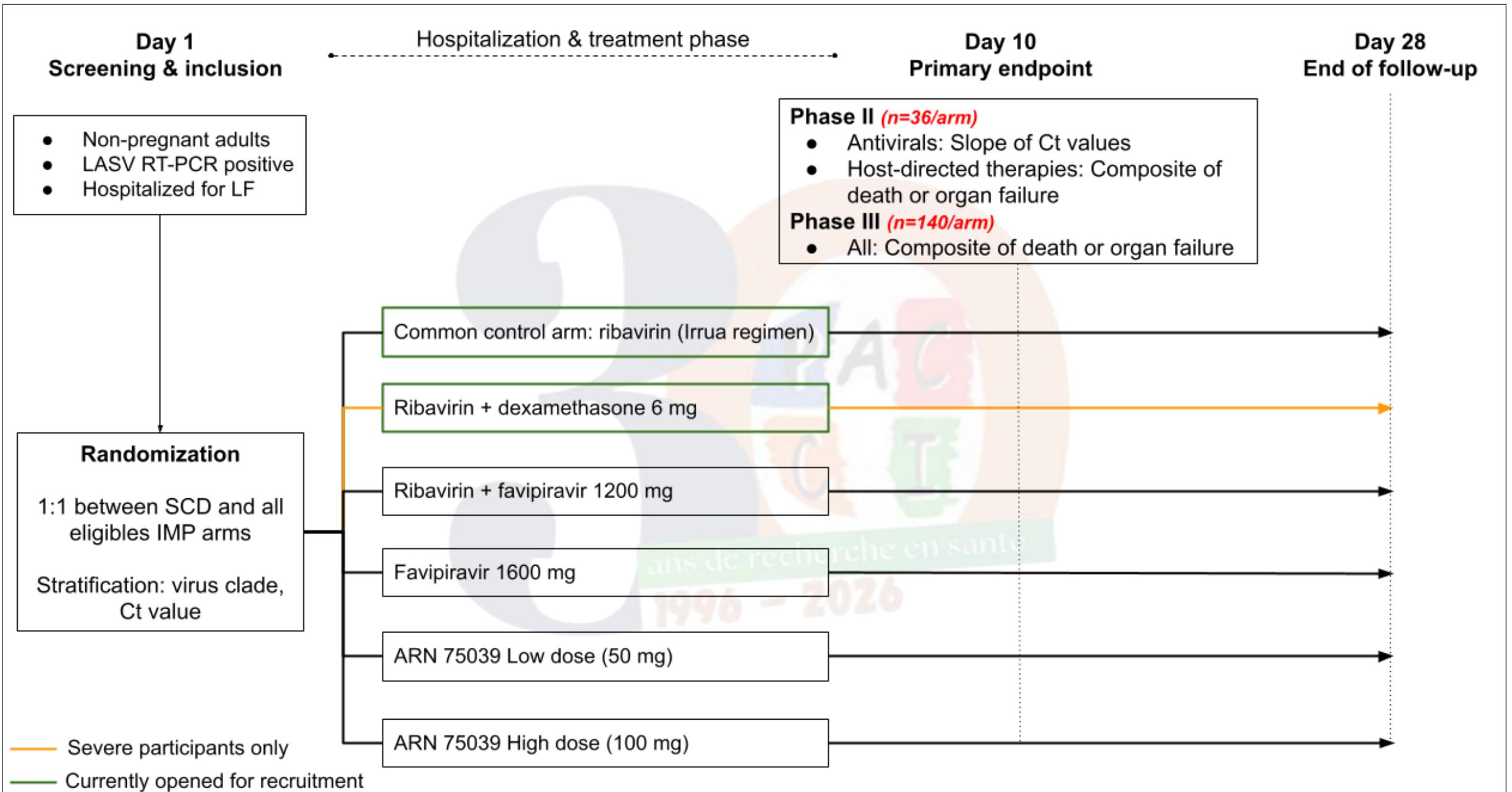
# Trial objectives

## Primary objective

- Compare efficacy of investigational medicinal products (IMPs) to standard of care (ribavirin) in preventing death or organ failure in hospitalized Lassa fever patients

## Secondary objectives

- Compare safety and tolerability of IMP regimens
- Evaluate clinical, virological, and biological parameters
- Describe pharmacokinetics and develop PK/PD models of IMPs



# Primary composite endpoint at D10

Parameter (any of the following)	Measurement definition
Death	Yes/No
New onset of acute kidney failure	KDIGO 3
New onset of acute respiratory failure	SpO <sub>2</sub> /FiO <sub>2</sub> ≤ 315
New onset of shock	Mean Blood Pressure (MBP) < 65 mmHg OR Systolic Blood Pressure (SBP) < 90 mmHg (measured twice with a time interval of 5 min) AND Lactate > 2 mmol/L (after the two measurements)

# Trial update

- Two sites currently opened in Nigeria: FMCO, ISTH
  - ATBU (Nigeria) and Phebe (Liberia) expected to open in early 2026
- Two arms currently recruiting severe participants
  - Dexamethasone + ribavirin arm
  - Ribavirin arm
- Four additional arms expected to start recruitment in early 2026 on severe and non-severe participants
  - Favipiravir – *Toyama Chemical* (2 additional arms)
  - ARN-75039 – *Arisan Therapeutics* (2 additional arms)
- 38 participants already enrolled since May 2025



Recruitment sites in Nigeria by the end of feb 2026

# Conclusion

- First adaptive platform trial for Lassa fever therapeutics
- Regional capacity building for clinical research and sponsorship
- Potential to transform Lassa fever treatment outcomes
- Paediatric Investigational Plan and compassionate use for pregnant women to be developed
- Health authorities and health care systems will have access to solid evidence to better develop and implement informed health policies

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- Clinical trial participants and their families
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Merci de votre attention ...

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