

[Letterhead of the organisation]

Global Health EDCTP3 Joint Undertaking
56 – 60 Avenue de la Toison d'Or
1060 Brussels
Belgium

30 September 2025

Letter of endorsement

Dear Sir/Madam,

On behalf of TNO, I am delighted to offer my support for the **The Research Alliance for Pandemic Innovation & Drug Development (RAPID)** proposal which is under submission.

RAPID aims to address critical gaps in early-phase research, particularly first-in-human (FIH) and Phase I/II trials, for novel products, combinations or medical devices during regional infectious disease outbreaks. The vision is to create a seamless and efficient pathway through these early research phases, ensuring that affected countries can rapidly evaluate and deploy innovative interventions: impacting early in an outbreak to prevent pandemic spread.

Specifically, workpackage 12 focuses on the specific needs of pregnant and lactating women who have often been neglected in the study of novel therapeutics and vaccines in outbreak situations. This places the potential risks of the new products against the very real risk of maternal and fetal or infant death. Whilst it is increasingly recognized that these women must have equitable access to research, we also have a responsibility to ensure that this is done in a precise and informed manner. The use of microdosing and microtracer studies to explore metabolic pathways for novel drugs has been described as a Phase 0 study. This technique has the potential to safely map these processes before moving to a full dosing study, and could be helpful to understand the transfer of drug from mother to breastfed infant.

Whilst the exact outbreak, therapeutic and population is not always possible to predict, we commit to knowledge exchange with the investigators. We anticipate that a combination of in kind knowledge support, consultancy and potential development of a microdosing protocol, together with analysis in our high sensitivity laboratory would reach a monetary value of approximately EUR 100,000.

We accept that additional modalities regarding the provision of our contribution may be defined in subsequent agreements or documents, such as a funding agreement and topic text.

Yours faithfully,

A handwritten signature in blue ink, appearing to read 'S. Erpelinck', with a stylized flourish at the end.

Steven Erpelinck, BSc MBA
Principal Business Developer
Efficient Drug Development
TNO