



Dr. Henning Gädeke

c/o Dr. Michael Makanga

Global Health EDCTP3 Joint Undertaking

56 – 60 Avenue de la Toison d'Or

1060 Brussels

Belgium

August 28, 2025

Letter of endorsement

Dear Sir/Madam,

On behalf of 1Day Sooner, 2093 Philadelphia Pike #6363 Claymont, Delaware 19703-2424 United States, and in accordance with Council Regulation (EU) No 2085/2021 of 19th November 2021 establishing the joint undertakings under Horizon Europe and specifically Article 9 therein, I hereby submit an application to become a contributing partner to the Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3 JU).

1Day Sooner's contributions will support the T5 TBVAC consortium.

1Day Sooner (1Day) is a US-registered non-profit that advocates for the interests of healthy volunteers in high-impact clinical trials worldwide. Much of our work focuses on human challenge studies, in which carefully screened participants voluntarily receive an infection under controlled conditions. Beyond this, 1Day leads science, policy, and ethics campaigns to combat the world's most harmful infectious diseases.

1Day Africa, a regional branch, works to strengthen local capacity for medical research and healthcare delivery across the continent, with a particular focus on infectious diseases.

1Day is a fully remote organization with staff based in Europe, North America, and Africa, including team members in Oxford, UK, and Zambia.

1Day's work supporting EDCPT3 JU objectives is outlined below. All work has been performed as in-kind contributions.

Objective	1Day Sooner's Supporting Activity
To advance development and use of new or improved health technologies for tackling infectious diseases by supporting the conduct of the	• Provide participant recruitment and representation for high-impact studies enrolling healthy participants. • Advocate for accelerated regulatory pathways to reduce trial delays. • Contribute expertise in trial design and volunteer

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clinical trials, in SSA	engagement.
To strengthen research and innovation capacity and the national health research systems in SSA for tackling infectious diseases	• Conduct research on clinical trial participant experiences and participant motivations tailored to SSA contexts. • Knowledge-sharing around ethical trial participation, community engagement, and participant advocacy. • Partner with SSA-based institutions to support clinical trial capacity-building initiatives (joint workshops, research ethics curricula).
To facilitate better alignment of Member States, associated countries and sub-Saharan countries around a common Strategic Research and Innovation Agenda in the field of global health to increase the cost-effectiveness of European public investment	• Use our global advocacy network to broker alignment between governments, civil society, and funders on impactful trials in infectious disease and pandemic preparedness. • Provide policy briefs, strategy papers, and workshops that help coordinate European and African stakeholders. • Showcase how volunteer perspectives can bridge transnational divides, ensuring study priorities reflect community as well as scientific needs.
To strengthen capacity in SSA for epidemic preparedness through effective and rapid research response to develop essential diagnostics, vaccines and therapeutics for early detection and control of emerging diseases of epidemic potential	• Advocate for standing infrastructure for CHIM and infectious disease trials, highlighting lessons from pandemic challenge studies. • Support early-stage community engagement for potential trials on epidemic pathogens, ensuring trust and volunteer readiness in SSA. • Contribute to policy frameworks for rapid deployment of trials, reducing bottlenecks seen during COVID.
To promote productive and sustainable networking and partnerships in the area of global health research building North–South and South–South relationships with multiple private and public-sector organisations	• Use our credibility as a global healthy volunteer advocacy organization to help SSA sites attract additional partnerships and investment. • Support global efforts around participant recruitment and community consultation.

Involvement:

1Day will support local teams in the UK, Uganda, and Senegal in the following ways:

- Participant Engagement in Study Design: support local teams with the conduct of focus groups and surveys with potential volunteers to inform study protocol, consent forms, and recruitment materials, especially around feasibility and acceptability concerns.
- Ongoing Representation: support local teams with the establishment, facilitation, and participation of a Volunteer Advisory Panel (VAP) to provide structured feedback throughout study implementation.

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- Participant Support Services: provide additional educational resources, enrichment events, confidential feedback channels, and participant-facing communications around the study.
- Participant Experience Monitoring and Reporting: collaboration on optional pre-study, mid-study, and exit surveys and interviews, resulting in documentation and potential media coverage of participant experiences.

Deliverables (in collaboration with local team):

- Participant experience reports.
- Volunteer Advisory Panel charter and meeting reports.
- Study and study dissemination-related materials.
- Communications and media support for the study team and participants.

Entities to be Funded / Supported:

- 1Day Sooner Cooperative Participant Organization (CPO) staff and infrastructure for participant engagement.
- Volunteer and community enrichment and engagement-related expenses.

We estimate the total value of this contribution to be €35,000 euros per year or €175,000 over 5 years in in-kind contributions.

We confirm the following:

1. We will comply with the Horizon Europe Regulation (EU) No 2021/695; Council Regulation (EU) No 2085/2021 establishing the joint undertakings under Horizon Europe; the Model Grant Agreement for Horizon Europe and applicable Global Health EDCTP3 JU rules, including the relevant work programmes and in particular the call conditions therein.
2. We will keep all information received in the context of our involvement as contributing partner to the Global Health EDCTP3 JU confidential. This confidentiality obligation applies in particular but is not limited to the areas of Global Health EDCTP3 JU call topic preparation and publication, proposal submission and evaluation, and consortium formation. We further understand that this obligation strictly prohibits the release of confidential information to any legal entities save where specifically authorised by Global Health EDCTP3 JU. Internal dissemination of information within our organisation will be done on the basis of the “need-to-know” principle.
3. We are confident of our ability to fulfil the above commitments and further confirm our understanding that the Global Health EDCTP3 JU will allocate resources to the above topic based on these commitments.
4. The value of our contribution will be based on costs calculated in accordance with Article 6 of the Horizon Europe Model Grant Agreement.

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5. 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 grey ink that reads "Circe McDonald".

Circe Mc Donald

Aug 28, 2025