Background
The novel coronavirus SARS-CoV-2 has unleashed a global pandemic and an unprecedented public health crisis. Biomedical strategies to diagnose, prevent, and treat COVID-19 are urgently needed, and efforts to rapidly develop these tools are underway worldwide. However, the need for accelerated research and the realities of social distancing do not obviate the importance of civil society input; rather, it necessitates innovative engagement structures, mechanisms, and actions.

Many global health advocates have recognized the need to engage civil society to ensure the ethical, efficient advancement of R&D and global access to urgently needed interventions. Given that the COVID-19 community is global, a broadly representative structure will be required. However, the first months of the pandemic have made it clear that people are not at equal risk. Differences in geography, political response, race, gender, class, and occupation have created remarkable, if unsurprising, disparate risks of infection, severe disease, and death. The communities most at risk must be given an important voice in the R&D process at every level.

Fortunately, the global research enterprise is not starting from scratch—there are platforms, normative frameworks, and research-literate community networks to facilitate effective, creative community engagement for COVID-19 R&D. A global mechanism to ensure community input can be built on the foundation of the long history of effective participatory community engagement in global health research. Participation in research is enshrined as an ethical and moral imperative in the Denver Principles, the Declaration of Helsinki, and legally-binding international human rights law. Practical, applied guidance on community engagement exists in the Good Participatory Practice (GPP) principles and the application of GPP for many diseases, including emerging pathogens. Existing community advisory structures in other research fields¹, including HIV, TB, and hepatitis C have created networks of research-literate advocates committed to advancing ethical health research. While the most impacted communities for COVID-19 may not always overlap with those involved with other infectious disease research, the template for identifying communities and rapidly engaging with them has already been developed.

Building on existing structures, a COVID-19 Advocates Advisory Board is being developed to ensure the strategic engagement of civil society in COVID R&D.

Mission
Strategically engage civil society and community representatives to ensure the ethical, inclusive, efficient, and accelerated advancement of research and development for urgently needed interventions to combat COVID-19, as well as global access to proven interventions, especially among historically vulnerable and disenfranchised communities.

Considerations
The structure of the COVID-19 Advocates Advisory Board (CAAB) must carefully and strategically consider the following:

- **Representation**: The COVID-19 pandemic has impacted everyone on the globe in different ways. Therefore, community and civil society voices on the CAAB must be representative of varied age groups, geographies, and societal sectors. The CAAB should also intentionally include members of sub-populations or cohorts of people who face a higher risk of COVID-19, bear a greater proportion of its

¹ Examples include: AfroCAB, Global TB CAB, World CAB, Coalition to Accelerate and Support Prevention Research (CASPR), ATAC, EATG/ECAB, NIH DAIDS Community Partners, HIV Prevention Trial Design Academy.
burden, may be targeted for research involvement, and may be less familiar with representing their communities.

- **Existing Capacity**: Strong global civil society engagement and activist mechanisms around research already exist, with years of research literacy and advocacy experience. The CAAB need not necessarily be a new structure, but could instead build on the established strength and capacity of these mechanisms and the lessons learned from other emerging pathogens, such as Ebola and Zika. While much of the history of R&D advocacy originated in the HIV field, significant expertise exists within the fields of TB, Hepatitis C, and neglected tropical diseases, with strong leadership based in low- and middle-income countries and among disenfranchised populations.

- **Unique Circumstances**: Civil society engagement for COVID-19 will inherently look different than it has for epidemics such as HIV and TB. R&D is moving at a rapid pace, this disease uniquely impacts everyone in the world, innovative trial designs and research approaches are being implemented, uncertainty about the disease is high, disinformation and mistrust of science is endemic, and the potential social benefit from research may be unprecedented. While research must move forward urgently, civil society engagement and robust scientific methods must not be compromised. As such, we must consider how best to innovate within engagement processes.

- **Speed and Innovation**: The nature of the COVID-19 epidemic and regulatory guidelines differ extensively from country to country. While it will be important to have a standing reference body, other ad hoc engagement mechanisms should be employed in the immediate term to engage around specific trials, research methods, or issues regarding the advancement of the research agenda. And given the volume and speed of COVID research, the CAAB must consider additional innovations to ensure relevance and responsiveness to this unprecedented global challenge. Further, it will be important to ensure an ongoing dialogue with scientists, sponsors and funders as science is assessed and CAAB concerns are raised.

- **Global Access**: It is crucial to ensure access is considered from bench to bedside, in line with Global Principles and with contributions from other Access to Medicines (A2M) partners, such as building pressure to attach conditions to funding contracts that reflect the global A2M principles.

**Proposed Structure**

The initiative will be led by a steering committee made up of individual experts and institutional representatives who are aligned in their commitment to the CAAB’s principles and purpose. Given that differences in geography, race, gender, class, and occupation have created disparate risk of infection, severe disease, and death, it is extremely important that the steering committee includes a broad diversity of representatives, including from communities most at risk. The steering committee will be advisory in nature and communicate through monthly calls. The steering committee will identify opportunities for engagement, share information across workstreams, and discuss issues of importance within the research landscape.
Given the breadth of content, diversity of issues, and potential advocacy actions, work will be divided into parallel workstreams (diagnostics, treatment, vaccines). These workstreams will be led by bi-lateral teams (TBD) who will be responsible for defining the composition of advisory members (sharing across workstreams as relevant), implementing necessary training, and facilitating opportunities for research input. Workstream leads will be in regular communication and ensure strategic coordination across workstreams.

**Proposed Workflow**

Given the rapid pace of COVID research and the urgent need for civil society engagement, the steering committee proposes that workstreams simultaneously build literacy on COVID research while also facilitating linkages with ongoing and planned research programs. This will ensure community input into current research while allowing the exact nature of the CAAB to be formed based on civil society feedback and the evolving research landscape.

To prevent redundancies, workstream leads will collectively map research literacy topics, prospective members, and targets (e.g., industry/product developers, research groups, funders). Advisory members will initially come from civil society organizations selected for specific research/program expertise and involvement in existing engagement structures (per footnote above). Workstreams will also proactively solicit additional participants to ensure broad representation, including potential trial participants, those at high risk of severe C19, C19 survivors, and healthcare professionals. Workstreams will collaborate and share resources where relevant/effective.

The initial step will be to conduct a series of global civil society engagement webinars – a **CSO C19 Series** – around key trials, products, research issues (e.g., SOLIDARITY, trial endpoints, COVID vaccine pipeline/timeline, COVID research consortia, human challenge trials) and access concerns. These webinars/calls will be targeted to health research and policy-focused civil society organizations, especially those that may be particularly relevant to the given call topic and interested in actively engaging in research design, implementation, and access advocacy. The objectives of this series include but are not limited to:

- Build a common civil society understanding and capacity around COVID research, which can be tailored and adapted to different contexts and communities.
- Identify and act upon identified priorities and ethical, equity or other concerns;
- Identify mechanisms to ensure civil society perspectives and priorities are incorporated into COVID research, and any products developed are accessible to all people in need.
- Identify an appropriate structure for the CAAB, including specific individuals as potential members.
- Coordinate scientifically accurate information templates that can be adapted for a variety of contexts.

At the same time, workstream leads will facilitate links between key advocates and research sponsors and product developers that may be better addressed through focused discussions and audiences instead of broader CSO Series calls.

The steering committee and workstream leads will track progress, outcomes, and other metrics and evolve the process, participant make-up, and structure as necessary. If it is determined that a standing body is an appropriate mechanism, appropriate steps will be taken.

**Resources, Timeline, and Support**

AVAC has initial donor support for the above set of activities to occur over a 3-6-month period. AVAC will hire a consultant to drive the process; a Scope of Work will be developed and agreed with the SC. At a specific timepoint, the SC will review the progress of this work, the future direction, and the overall scope of work entailed. They will determine if additional funds need to be raised for the ongoing CAAB effort, and agree on a fundraising strategy.