November 16, 2016

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Gilead Sciences, Inc.

We are writing as a group of U.S., Canadian, and European community advocates and HIV NGO workers to express deep dismay that Gilead has proceeded with the DISCOVER trial of Descovy versus Truvada as PrEP without engaging stakeholders in a substantial or meaningful way.

In 2007, the HIV/AIDS field adopted Good Participatory Practice (GPP), a formal set of guidelines approved by UNAIDS for stakeholder engagement in HIV prevention clinical trials. These guidelines were carefully developed by a robust cross section of experienced, skilled advocates and experts to protect research subjects and their communities and to maximize the potential for effective, ethical, and successful research.

It is astonishing that Gilead has failed to follow GPP guidelines in the design and implementation of DISCOVER, since GPP was developed partly as a response to the failure of previous prevention trials involving tenofovir.

These include the discontinued 2003-2005 trials of tenofovir as PrEP in Cambodia and Cameroon and more subtly the Bangkok IVDU tenofovir PrEP trial. Poor community engagement and resulting dissent during the latter yielded a trial design that could not discern whether the reduction in HIV acquisition was related to parenteral or sexual exposure. Lack of structured engagement among researchers, participants and their communities may have been factors in unfocused recruitment, poor adherence, or lack of trust between participants and researchers which ultimately yielded disappointing results from other biomedical prevention trials.

Failing to enlist the community's help in conducting the already-challenging DISCOVER trial similarly establishes conditions for failure and is fundamentally bad practice. Gilead has never conducted this kind of large HIV prevention trial and frankly lacks the experience and expertise to do so properly according to GPP guidelines.

Those who realize they are at risk of acquiring HIV and who are highly motivated to seek access to Truvada as PrEP often find it to be unavailable, encounter multiple barriers to access, or in some cases must go to extraordinary lengths to obtain it. Individuals who meet the criteria for participation in this trial have a demonstrably high risk of contracting HIV. The efficacy of Descovy as PrEP has obviously not been demonstrated. The potential for these concurrent realities to create perverse incentives for enrollment of individuals who would be better off receiving immediate assistance with accessing Truvada as PrEP heightens our concern.

We acknowledge and appreciate Gilead's recent responses to some of the community's concerns which include a move to amend the protocol to eliminate a requirement that enrollees stop current PrEP use for 30 days prior to entering the DISCOVER trial, plans to create an ad hoc advisory group for the trial, and the appointment of a respected community member to the trial's independent data monitoring committee.

To date, however, Gilead has ignored urgent requests to temporarily halt DISCOVER until the community's serious and immediate concerns can be fully addressed. These include a troubling informed consent document and process as well as marketing materials that fail to accurately or adequately portray the precise nature of the study. GPP provides a blueprint for addressing these shortcomings.

While a November 10, 2016 communiqué from Gilead affirms that they have made a number of changes to the protocol and its implementation, documentation of those changes has not been provided to those of us with whom Gilead shared previous versions. While Gilead states that it has subjected informed consent and marketing materials to additional internal reviews and revisions, the community has not been given a role in those reviews. Despite its promises, Gilead has yet to substantially demonstrate a commitment to real stakeholder engagement or Good Participatory Practice guidelines.

Given the scale and urgency of the matters at hand we demand that Gilead immediately:

- Commit to equitably share responsibility for the creation and operation of two Community Advisory Groups for North America and Europe respectively which will be empowered to address marketing and enrollment of the trial along with other concerns. The community must have a major role in establishing these bodies' terms of reference and the selection of member representatives.
- Consult with these CAGs to enlist collaborating partner organizations experienced with GPP to help Gilead conduct DISCOVER in a manner that is ethical, ensures the wellbeing of the individuals and communities involved, and maximizes its chances of success.
- Impose a temporary halt to enrollment of and withdrawal of current marketing materials for the DISCOVER trial so that these CAGs may have time to meet and adequately inform the trial's operation and in order for individual sites to have an opportunity to engage local stakeholders for guidance related to informed consent, marketing, and recruitment targeting.

Should Gilead fail to impose a temporary halt, our organizations will be forced to consider how best to act and to further inform our communities about the DISCOVER study and its recruitment strategies.

Sincerely,

Treatment Action Group

AIDeS, France

REZO Santé et Mieux-être

PrEPster.info

The Care Center

iwantprepnow.co.uk

European AIDS Treatment Group

AVAC

AIDS Foundation of Chicago

International Rectal Microbicide Advocates

HIV Prevention Justice Alliance

National Female Condom Coalition

A DISCOVER trial factsheet has been developed through an international collaboration of agencies and advocates and can be read here.

Signatures from additional organizations are being accepted through November 30, 2016. Click here to join.