Principles on

Post-Trial Access to Investigational Products

The ability to conduct research with human subjects is a privilege. Sanofi recognizes that during a clinical trial, some participants may have benefited from the experimental product – but they do not have access to the product after their participation in the trial has ended because is not approved or on the market. Under these circumstances, Sanofi may provide access to the experimental product post-trial but before it is approved or on the market. This is referred to as "post-trial access".

Sanofi 's decision to grant post-trial access will depend on the participant's medical need, including the availability of alternative therapies and an assessment of what is known about the benefits and risks of the experimental product. Sanofi will consider granting post-trial access even when the trial was discontinued or had negative outcomes, as long as the trial was not stopped for major safety issues.

Sanofi evaluates each request on a case-by-case basis, weighing all of the following criteria:

- The participant must have a serious or life-threatening condition and does not qualify for another ongoing Sanofi clinical trial for the same disease or condition.
- The treating physician and/or investigator has determined that post-trial access is the best medical option for the patient,
- The experimental product must not already be approved/authorized in that indication or must not be available by other means in the country where the trial was conducted.
- The request for post-trial access must come via the trial investigator (study doctor).
- The participant must have been a part of the trial in which the experimental product was administered.
- The administration of the product must have resulted in clinical benefit to the individual based on the investigator's assessment of the participant's

response to the intervention and what is known about the risks of using the experimental product at the time of the decision, in consultation with Sanofi.
- Sanofi must have an adequate supply of experimental product to both provide it to the patient requesting access and, if applicable, to support on-going clinical trials that are critical to getting the new treatment approved.

Post-trial access to an experimental product must be in compliance with all applicable national and local laws and regulations.

Post-trial responsibilities are shared among all stakeholders: sponsor, investigator, health care provider, health care system and the participant. If continuing medical care and/or infrastructure are necessary for the appropriate provision of the investigational product post-trial, all stakeholders must work together to ensure their provision.

Sanofi's post-trial access responsibilities will be periodically re-evaluated during the course of the participant's post-trial access. If new information becomes known about the experimental product, the ongoing health of the individual and/or market availability of the product or alternative therapies, posttrial access may be terminated. This includes situations where ongoing trials of the investigational product may be stopped due to safety concerns or other issues.

Principles on Post-Trial Access to Investigational Products approved by Sanofi Bioethics Committee (first approval in September 2017 – last review in June 2022)