

Incidental Findings Policy – Lay Summary

Clinical studies are an important way in which pharmaceutical researchers assess the safety and efficacy of potential new drugs and devices.

During the course of a clinical study, previously undiagnosed medical conditions unrelated to the aims of the study are sometimes discovered. These are referred to as ‘incidental findings’. When such findings may be of potential health or reproductive importance to the trial participant, Sanofi believes it has an ethical responsibility to help ensure the individual is made aware of the findings.

During the informed consent process, Sanofi study participants will decide whether they want to be notified of any incidental findings. If so, they will also be allowed to designate a healthcare professional to receive such findings who could help them with the clinical interpretation of the findings and the determination of any follow-on actions.

In most cases, it is the local physician-investigator conducting the study for Sanofi who would find an undiagnosed condition, and who will determine whether such a finding should be returned to a participant, in accordance with all applicable national laws and regulations. In making this determination, the investigator will consider whether the finding reveals a substantial risk of a serious health condition or has reproductive importance.

The participant should be aware that neither the sponsor nor the investigator is responsible for confirming the incidental findings. Nor will they be providing medical advice or opinion or be responsible for any subsequent health care decisions based on the findings. In addition, we will not hunt for genetic variations that may identify or predict health or disease but are outside the aims of our research.

In the event that the study participant has opted out of being notified and the finding has consequences for other individuals, for example, the finding relates to a communicable disease, the investigators may seek independent ethical advice before determining next steps.

The health and safety of our study participants are important. We believe that this policy helps ensure study participants are well protected.