Returning Individual Research Results and Data to Participants: Experience from the Field

Q&A Fact Sheet for Webinar held on 2 May 2023

To view the case studies, webinar slides, and recordings please visit our website here.

Below is a list of questions (in **bold**) that we did not have time to address during the webinar, coupled with answers kindly provided by panelists. If you have additional questions that are not addressed below, please feel free to reach out to Sylvia Baedorf Kassis at sbaedorfkassis@bwh.harvard.edu or MRCT Center at mrct@bwh.harvard.edu.

General Questions

Do you have any advice on returning individual research results and data in multi-center trials?

One key consideration for multi-center trials is the process used to return results, i.e., will participants access results through an online portal, by email, telephone call, videoconference, or by mail? Whatever method is used to return results, it is essential that the communication is secure and protects the individual's privacy rights. For that reason, study staff at each site should be consulted about how they will implement return of results or data at their site, and everyone should receive the same training on procedures to return participant results. Time allocated to planning and training will help ensure that processes and procedures for return of individual results and data are clearly understood by all involved in the trial and well documented in the study protocol to support participant understanding.

Do any panelists have experience with returning individual results to international participants?

Returning results to participants internationally is challenging, since different countries have different laws and regulations concerning the return of health data. In the EU, regulations are continuing to evolve. There are initiatives such as IMI Facilitate which is developing guidance and frameworks for data return in the EU: https://www.imi.europa.eu/projects-results/project-factsheets/facilitate

What steps can be taken to protect participants who receive individual research results from discrimination?

In the US, there are several laws that address and protect against various aspects of genetic discrimination, including the Americans with Disabilities Act (1990), Health Insurance Portability and Accessibility Act (HIPAA, 1996), and Genetic Information Nondiscrimination Act (GINA, 2008). It is important to understand what the regulations cover, but also what they do not. For instance, GINA protects against employment and health insurance discrimination but does not protect against employer actions nor other types of insurance (e.g., life, long-term care, and disability insurance). Participants, researchers, and healthcare providers need to consider whether research results should be added to the medical record as well as the potential consequences of adding research data into a person's health record. Dr Zallen recommends that before any release occurs, reassurances should be obtained from the health-care provider that such information will not

be placed in the medical record until permission is given by the research participant.[1,2] Patients can find more information here: https://www.genome.gov/about-genomics/policy-issues/Genetic-Discrimination and here: https://www.hhs.gov/hipaa/for-professionals/special-topics/genetic-information/index.html or talk to a Genetic Counselor to explore the potential consequences of receiving genetic results.

What additional considerations apply to the return of individual results and data process when study participants are minors?

Many of the operational and ethical issues addressed in this webinar and in the MRCT Center work (see https://mrctcenter.org/return-of-individual-results/) would apply to both adults and children. For children, there are several additional unique considerations, including 1) obtaining assent to receive their results and data; 2) ensuring age-appropriate information about their data/results is available; and 3) obtaining consent once the child reaches the age of majority, and (4) ensuring parents' access to their child's data is removed once the child is a legal adult.

Are the model processes described in the case studies something Institutional Review Boards (IRBs) can adopt as best practices for researchers?

Several aspects covered in this webinar and in the MRCT Center resources could certainly be used when IRBs are considering best practices for returning results at their centers. You may particularly be interested in the IRB Approval Checklist for Returning IRR. Further guidance for researchers is available in this report from NASEM: https://www.nationalacademies.org/our-work/return-of-individual-specific-research-results-generated-in-research-laboratories

---

Question about the case study: *Returning Non-Validated Test Results*

Why was communication of "potential unconfirmed finding of COVID-19" to the participant's healthcare provider done verbally as opposed to be email? How was documentation maintained?

There is a conflict between the Health Insurance Portability and Accessibility Act (HIPAA) and Clinical Laboratory Improvement Amendments (CLIA) in regard to the return of research for treatment purposes. The unconfirmed findings were meant to be communicated as a precautionary measure only, and not, without further confirmation and validation, to be acted upon clinically. Test results from a CLIA lab were and can be returned directly to the healthcare provider, but not test results from non-CLIA approved laboratories. At the time, the authors developed a process to document unconfirmed findings. Today, however, we would opt to repeat the test results in a CLIA-approved laboratory or perform those tests in a CLIA-approved laboratory from the outset. CLIA-approved lab results can be returned very quickly.

---

[1] Zallen DT, "Alzheimer's disease: risk tests and the medical record", J. Alzheimers Dis. (2022) 90:997-999
[2] Arias JJ, Karlawish, J, "Confidentiality in preclinical Alzheimer disease studies", Neurology (2014) 82: 725-729.

Questions about the case study: *Implementing a Robust, Scalable Participant Data Return Solution*

When is participant data return becoming a standard for Pfizer?

Beginning in June, Pfizer will be returning individual data for all studies at US sites at the end of a study. Moving forward, Pfizer plans to extend that model to EU and rest of world.

When will study data be made available to participants?

Data will be returned at the end of the study, typically 12 months after the primary completion date. Data will be returned at the same time as the Plain Language Study Results Summary (aggregate results of the study).

Which results/data is Pfizer planning to return to participants?

For the initial release, Pfizer is returning primary endpoint data. Early in the clinical development planning, each study team provides input as to the specific primary endpoint data to be returned.

How will Pfizer return data to participants?

Individual data will be returned to participants via the PfizerClinicalTrialAlumni.com portal. Participants are invited to create an account on the portal during study enrollment and throughout the study (materials are provided to the study sites for this purpose). If participants choose to create an account, they can access both the aggregate results of the study (via a link to the published results on Pfizer.com) and their individual results at the end of the study.

What does the typical data return package from Pfizer look like?

The size of a data return package depends upon the study and the data which are being collected. In general, reports are approximately 25 - 50 pages. Each section of the report begins with an introductory paragraph that explains the purpose of the section and offers links to additional supporting materials to help the reader understand both the data presented and medical terminology.

Who do participants talk to if they have questions about their data?

Participants are directed to talk with their healthcare provider if they have any questions about their data.

Do participants opt in to receiving their trial data and results in the informed consent process?

At Pfizer, the return of participant data is not specifically addressed in the informed consent document. Information on how to enroll in PfizerClinicalTrialAlumni.com is provided in patient-facing materials by the study site. Participants can choose to register to receive that data at any time during the study.

Does return of individual data require IRB approval?

Returning any results during an open study requires IRB approval. Returning data at the end of the study, however, does not require IRB approval as it is a post-study activity. Some IRBs do ask about whether a study will be returning results as a matter of respect for participants; sponsors and investigators, therefore, should be prepared to describe the process.

Does Pfizer have access to participant identifiers? How is participant privacy protected in the data return process?

The only identifier that Pfizer retains is a participant-coded identification number, not participant personal identifiers. The portal through which the participants access their data is managed by a trusted third party to ensure a firewall is maintained between sponsor and participant and that deidentification is maintained.

What tactics were used to gain buy-in from the company leadership?

The business case was presented, including participant demand for individual data. Pfizer is committed to health equity and building trust with study participants responding to participants' request for their data was a step towards building and sustaining that trust.