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

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The Multi-Regional Clinical Trials Center (MRCT Center)

Our Vision
Improve the integrity, safety, and rigor of global clinical trials.

Our Mission
Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.
Return of Individual Research Results (IRR) Project - Timeline

December 2015
- Workgroup to create standard guidelines and criteria related to returning IRR to participants

November 2017
- Original IRR toolkit and guidance documents released

January 2021
- Taskforce to create updated operational and implementation-oriented tools and resources

March 2022
- Release of updated resources, guidance, and project-specific website

April 2023
- Release of 5 case studies detailing experience from the field
MRCT Center Return of Individual Results – 2022 Update

RETURN OF INDIVIDUAL RESEARCH RESULTS

ABOUT | GETTING STARTED | HOW TO RETURN IRR | RESOURCES | TOPICS

Return of Individual Research Results

The MRCT Center is proud to release these updated resources. The guidance, recommendations, and tools on this website can further enable researchers to return individual research results (IRR) to participants.

Learn More

https://mrctcenter.org/return-of-individual-results/
New Resources – IRR Cases Studies of Experiences from the Field

Return of Individual Results Case Study

Supporting Participant Decision-Making
This case study shares an example of how one tool to support decision making for potential participants. The roadblocks above show steps for sponsors to consider when developing their process.

Researcher Roadmap to Return

Return of Routine Lab Results to Participating Patients Case Study
This case study demonstrates how an industry-supported laboratory workflow can increase the number of patients who are able to use the laboratory results.

Sponsor Roadmap to Return

Return of Individual Results Case Study
Implementing a Robust, Scalable Plan
This case study outlines how an industry-sponsored clinical trial design to implement and operationalize a robust, scalable Plan.

Sponsor Roadmap to Return

Return of Individual Results Case Study
Non-Validated Results
This case study describes the return of routine laboratory results to the scientific and medical community.

Researcher Roadmap to Return

Return of Individual Results Case Study
Responsibly Returning Secondary Findings
This case study details the experiences of a research team returning secondary findings to participants in a genetic testing study.

Researcher Roadmap to Return

Jamie’s Story
While in her early 70s, Jamie was diagnosed with multiple sclerosis (MS) when she was 33. She had symptoms consistent with the disease, but it was not diagnosed until years later. Jamie eventually experienced significant symptoms and began to use a wheelchair. She declined to take medications and opted for alternative treatments that were ineffective. Jamie’s symptoms continued to worsen, and she eventually moved to a nursing home. Jamie’s story highlights the importance of early diagnosis and access to effective treatments for MS.

Sponsor Roadmap to Return

Convening a Leadership Group
The sponsor formed a group of key external and external convening relevant technical, operational, ethical, and legal experts.

Group Member | Key Roles in Group
--- | ---
Project Lead | • Highlight importance of returning individual research results
• Identify key stakeholders to ensure IRR process
• Provide operational measures to support these in IRR efforts

Pilot Phase
Before the planning could begin, the project team to access funding for the multi-year initiative. This required a demand from study participants to have access to their IRR. After finding a model that was acceptable and feasible, the team followed a rigorous 8-step process to plan, build, and operationalize the return.

https://mrctcenter.org/return-of-individual-results/resources/case-studies/
Introducing Our Panelists Today
Supporting Participant Decision-Making in Genetic Testing Studies

Jamie Tyrone
Patient Advocate

Doris Zallen
Virginia Tech

Return of Individual Results
Case Study

Supporting Participant Decision-Making in Genetic Testing Studies

This case study shares an example of how one institution created an educational tool to support decision making for potential participants in a genetic testing study.

Jamie’s Story

While in her mid-30s, Jamie was diagnosed with Multiple Sclerosis (MS). With time, her symptoms changed. Unable to explain her condition, her neurologist questioned the diagnosis. As her symptoms continued to wax and wane, it became difficult not to have a diagnosis or possible treatment options.

At the age of 48, 10 years ago, Jamie had an opportunity to participate in a genetic study that she felt would help put pieces of this medical puzzle together. The study investigated whether people would change their behavior if they knew they were genetically at higher risk for certain diseases.

Jamie was motivated to participate because of her MS symptoms, and even though Alzheimer’s disease (AD) was a her family history of AD, she simply wanted it on her radar screen. As an interventional genetic study, Jamie should have received interactive genetic counseling before, during, and after the study. Surprisingly, Jamie received her results electronically while alone, without having any counseling to support or advise her.

Jamie’s results showed that she had two copies of the Apolipoprotein E4 (APOE e4), the most prevalent genetic risk factor for AD. At that time, it was estimated that she had a 99% lifetime risk of succumbing to the disease.

Jamie was faced with a torrent of emotions at receiving this news as she watched her father suffer in the late stages of his own battle with AD.

Doris Zallen
Virginia Tech

Doris felt especially sad that she received this information without any prior preparation or support from the researcher. She contacted the principal investigator (PI) to describe her experience. She shared that she was anxious and upset about her results. The PI’s response was unsympathetic, explaining that Jamie should be appreciative that she could now prepare for and take measures to prevent the onset of AD.

Unsatisfied with the screen and the lack of empathy displayed by the PI, Jamie sought recourses from the IRB, the ethics review board with oversight responsibilities for the study. The IRB informed her that she signed the consent form and that the researchers had met their obligation of informing her of the risk none of her rights had been violated. Later, Jamie was diagnosed with PTSD and even contemplated suicide.

After reading the book “To Test or Not to Test”: written by Doris Zallen, Jamie realized that she was not alone. She knew she had to take action so that other individuals would be spared her experience. Jamie is now an advocate for patients and study participants to ensure that institutions have policies and procedures in place to support participants through the process of enrolling in genetic studies and receiving their results.
Implementing a Robust, Scalable Participant Data Return Solution

Background

Research participants have expressed the desire to access their clinical trial data to gain more control over their personal information and to inform their medical care outside of the research environment. Sponsors and investigators have a responsibility to provide more transparency and engagement with participants. However, a lack of secure data-sharing platforms and other barriers have made it difficult to provide participants with their clinical trial data in a consistent manner.

To address this need and work towards a more patient-centered clinical trial ecosystem, Pfizer is implementing a program to offer clinical trial participants the option to receive their trial data. This initiative acknowledges the significant time, resources, and information that participants contribute, will help empower participants to make more informed healthcare decisions, and may facilitate a more seamless continuity of care beyond the trial. In addition, it is predicted that returning participant data will boost engagement, improve participants’ trial experience, and optimize trial adherence and retention.

Approach

Before the planning could begin, buy-in from the Executive level and throughout the organization was essential to secure funding for this multi-year initiative. This required a sound business case, one that outlined the growing demand from study participants to have access to their individual study data, and illustrated the benefits of fulfilling this goal. Once funding was secured, it was also essential to gain buy-in for the solution from all the groups who would be involved in or impacted by the introduction of a new step in the process of clinical trial reporting.

Pfizer followed a rigorous 4-step process to plan, build, operationalize, and influence best practices regarding participant data return:

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Returning Non-Validated Test Results

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Return of Individual Results
Case Study

Returning Non-Validated Test Results

This case study describes how an IRB navigated returning results of a new COVID-19 assay from a non-CLIA-certified lab during a public health emergency.

IRB Roadmap to Returning Individual Results

- Developing a Policy
- Regulation
- Gala and Study Team
- Organizational Review
- Protocol Review
- Informed Consent
- Investigator Oversight

The roadmap above shows steps for IRBs to consider when a study proposes to return individual results to participants. This case study focuses on the on-study part of the timeline illustrated by the red triangles.

Background

A university was creating a repository for current and future research involving the epidemiology and pathogenesis of emerging viral infections including the coronavirus SARS-CoV-2. A secondary aim was to validate a university-developed assay to test for COVID-19:

Samples were collected from hospital inpatients and outpatients either suspected of exposure to COVID-19 or exhibiting symptoms of infection. Samples were first tested in a non-CLIA-certified laboratory using a university-developed assay. All COVID-19 samples were then re-tested in a CLIA-certified lab to validate the results.

The IRB and researchers considered whether to return unvalidated/positive COVID-19 results from the new assay immediately to treating physicians or participants without waiting for CLIA lab confirmation, or to wait for validation.

Approach

The IRB weighed the risks of waiting to get the samples re-tested in a CLIA-certified lab against the violation of the CLIA regulation if they were to return non-CLIA-certified results to participants.

Due to the unique circumstances posed by the COVID-19 pandemic and the contagiousness and significant health risks associated with the virus, the IRB determined that it was an ethical obligation to alert providers to the following:

- A “potential unconfirmed finding” of a positive COVID-19 test
- Samples were being re-tested in a CLIA-certified lab for confirmation
- The CLIA-certified results would be returned to the providers directly for any required action including mandatory reporting to health authorities and hospital infection control

In the US, 42 CFR 493 sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Other countries may have regulations or quality measures to ensure validity of research results.
Responsibly Returning Secondary Findings

This case details the experience of a research team returning secondary findings to participants in a genetic testing study. The roadmap above shows steps for researchers to consider when planning to return individual results to participants. This case study focuses on the pre- and post-study parts of the timeline illustrated by the green circles and red triangles.

Return of Individual Results
Case Study

Responsibly Returning Secondary Findings

The case details the experience of a research team studying a group of serious disorders, termed Inherited Bone Marrow Failure Syndromes (IMFS), characterized by the failure of bone marrow to produce blood. IMFS has a significant risk of progressing to cancer (such as leukemia and lymphoma) and typically has an underlying inherited genetic cause. A study was designed to identify underlying inherited genetic causes of IMFS in families with multiple affected members.

During the design of the study, the research team planned to return individual genetic testing results of IMFS-related genes to participants. As a consequence of genetic sequencing, the team anticipated that they might discover unrelated but important genetic findings that may need to be shared with participants. During the research study, genetic sequencing revealed that an adult female patient had a previously undiscovered pathogenic variant in BRCA1, a gene that can, but may not, cause cancer. Pathogenic variants in BRCA1 can lead to Hereditary Breast and Ovarian Cancer syndrome, an adult-onset disorder with increased risk of breast and ovarian cancer in females, male breast cancer, and several other cancer risks.

Secondary Findings are genetic test results that provide information about variants in genes unrelated to the primary purpose of the testing.

Approach

Anticipating unrelated but potentially important genetic findings, the research team was able to implement the following structured approach to return secondary findings to participants. The plan outlined a clear path for the research team to implement when secondary findings arose, including the need for ethical and legal considerations while the study was ongoing. Not only did the planning save time and resources, but most importantly, it protected the rights, health, and well-being of the research participants. Based on experience, the research team advised that any plan for the return of secondary genetic findings include detailed guidance on:

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