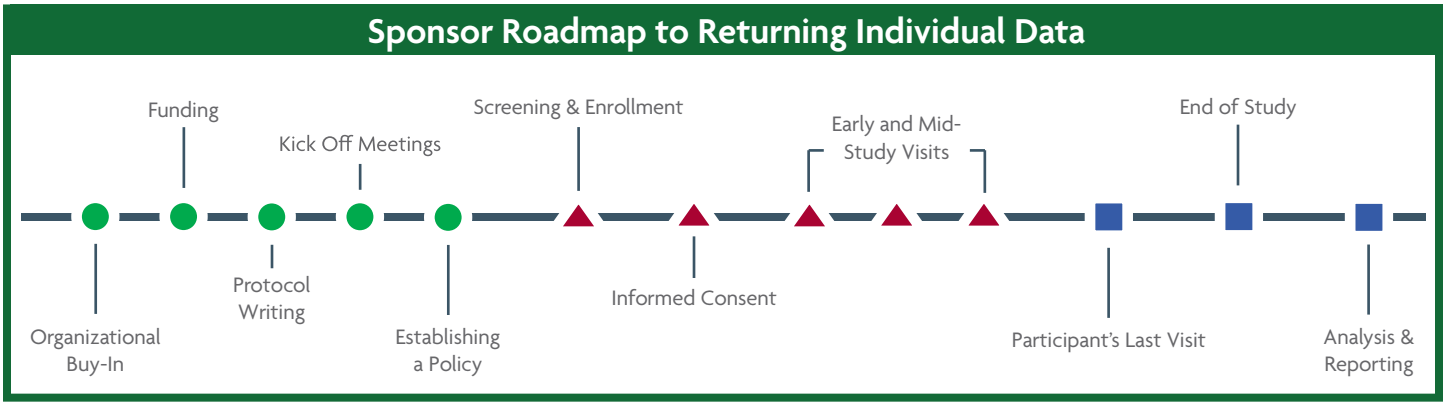
MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Implementing a Robust, Scalable Participant Data Return Solution

This case study outlines how an industry sponsor designed an initiative to return clinical trial data to participants.



The roadmap above shows steps for sponsors to consider when planning to return individual data to participants. This case study focuses on the post-study part of the timeline illustrated by the blue squares.

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 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:

Plan	Build	Operationalize	Influence
Establish industry best practices for health information exchange and sharing.	Design a digital data return capability that allows participants to access their data in various formats securely.	Receive organizational commitment for process changes needed to support data return at scale.	Contribute recommendations to influence industry initiatives for participant data return.

Step 1

Plan

In the Planning phase, the Pfizer team conducted a market research study to evaluate and understand participant and provider preferences around clinical trial data return. The team then evaluated what data to return, how to return it, and how to maximize impact.

Key takeaways:

- Return as much usable data to participants as possible
- Participants and healthcare providers (HCPs) prefer PDF to make printing and uploading to electronic health records easier
- Participant impact is maximized and HCP burden is minimized when context and graphical visualizations are provided

Insights gained from market research drove the design of the participant data return package in order to meet the needs identified for the best participant experience.

Step 2

Build

In the Build phase, the project was divided into 3 components, with the approach at each step guided by some key questions aimed at proactively addressing potential challenges that had been identified.

Data File Creation	How do we securely collate and structure the study data, and what does it look like to participants?
Data Return Infrastructure	How do we technically deliver a safe and secure solution, without compromising data integrity, participant privacy, or regulatory requirements?
User Experience & Participant Access	How will participants request, access, view, and download their data in a secure, user-friendly manner without compromising personal privacy?

The participant data return package was created in Pfizer's Clinical Data Analysis and Reporting System (CDARS) using CDISC datasets. The final package is comprised of the following sections as applicable and in accordance with the Clinical Development Plan:

- Introduction
- Personal Information
- Treatment Arm
- Adverse Events
- Primary Outcome Measures
- Concomitant Meds
- Primary Diagnosis
- Reported Medical History
- Quantitative Lab Results
- Qualitative Labs Results
- Vital Signs
- ECG Results
- Physical Exam Results
- Non-Drug Treatments
- Where to learn more

Throughout the document, there are a variety of hyperlinks to take participants directly to additional supporting materials, such as Medline Medical Encyclopedia, Clinicaltrials.gov, Plain Language Study Results Summary, and a unit conversion calculator.

Pfizer's team designed a secure infrastructure for moving data return files from CDARS to the Pfizer Clinical Trial Alumni Platform, allowing participants to opt-in to receive their data and access it on-demand after the end of the study.

Step 3

Operationalize

Before Participant Data Return could be moved into production, it was essential to confirm that the organization supported implemention of the new tools and procedures on an ongoing basis. Pfizer obtained internal agreement to include the Disclosure and Data Return Plan in their Clinical Development Plan and communicated the details throughout the organization, including:

Global Regulatory Affairs

Global Biometrics & Data Management

Worldwide Medical & Safety

Data Science & Analytics

Medical Writing

Information Management

Health Literacy

Participant Experience

Legal

Clinical Trial Solutions

Step 4

Influence

The Data Return Solution has been shared with external industry consortia, highlighting key learnings gathered in the planning, building, and implementation processes, and addressing the critical questions of **what** data to share, **how** to share it, and how to **maximize impact.**

Preliminary feedback from patient advocates has been very positive and also provided useful suggestions for changes to make to the Data Return Package. Patient advocates were especially enthusiastic to see their needs and requests for data return being listened to and that data are being presented in clear graphical formats.

This initiative has contributed to building excitement and momentum for the adoption of participant data return solutions across industry. The hope is for this type of comprehensive, participant-centered data return solution to become the norm for industry trials worldwide.

Outcomes and Plans

After completion of two pilot studies, operational processes will be embedded into the organization and scaled so that all US observational and interventional studies will return participant data starting in 2023, as defined in their Clinical Development Plan.

Looking ahead, Pfizer aim to broaden and deepen the Data Return Solution to address some of the following:

1. Returning additional data and file types to participants, which may include raw spreadsheets of data, imaging files, audio files, genomics data, etc.
2. Enabling additional ways to receive data, such as through AppleHealthKit and electronic health records
3. Expanding data return to markets outside of the US
4. Exploring data return during trials

Key Takeaways

Obtain buy-in from organizational leadership.
This is essential for the successful implementation of participant data return as many aspects of the organization are involved.

Embed the solution in your organization.
For a solution to be sustainable, it must be embedded into operational processes, resourced efficiently, and communicated effectively.

Inform participants.
Ensure you inform participants that they have the option to receive their data. Clearly explain how and when they can access it.

Seek feedback.
Don't assume you know what participants want: it may vary by study. Ask which data are important and valuable for them to receive and when.