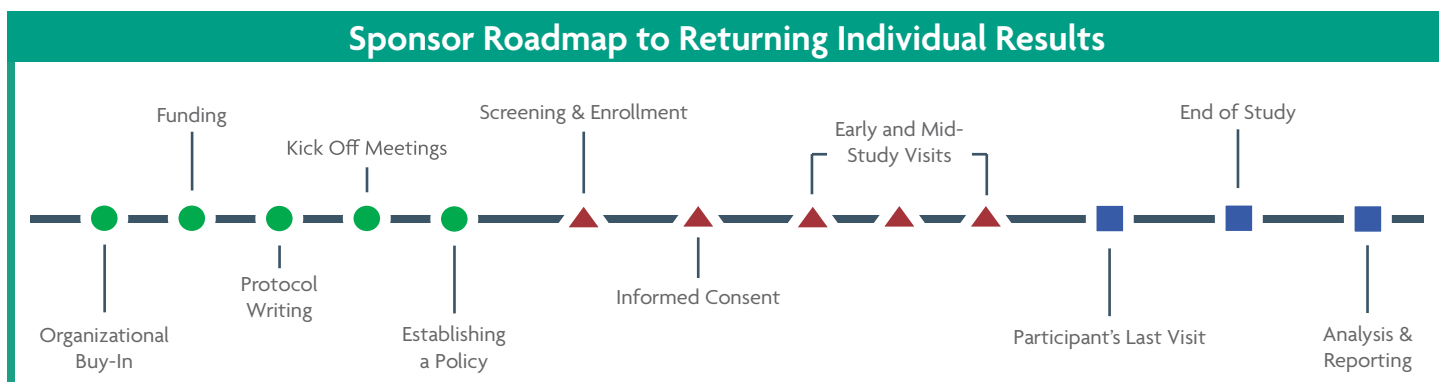


## Returning Routine Lab Results to Participants During a Clinical Trial

*This case study demonstrates how an industry sponsor operationalized returning routine laboratory results to participants during an ongoing, multi-site clinical trial.*



*The roadmap above shows steps for sponsors to consider when planning to return individual results to participants.. This case study focuses on the pre-study part of the timeline illustrated by the green circles.*

### Background

An industry sponsor conducted a pilot study as part of an ongoing clinical trial to demonstrate the feasibility of providing participants with select routine laboratory results. It was anticipated that receiving these individual research results would enable participants to partake in managing their care and to share relevant information with their healthcare provider. The pilot was an element of a larger patient engagement initiative, conducted in US locations, subject to Federal and State regulations, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule.

### Approach

The sponsor recognized the need to be proactive in planning how to return the results of these routine tests to participants during the pilot. The sponsor's goal was to identify potential barriers to returning individual results to participants and design practical solutions before the larger clinical study encountered preventable issues.

### Convening a Leadership Group

The sponsor formed a group of key internal and external stakeholders to gather perspectives, focusing on convening relevant technical, operational, ethical, and legal expertise.

Group Member	Key Roles in Group	Example
Project Lead	<ul style="list-style-type: none"> <li>Highlight importance of returning individual research results (IRR)</li> <li>Identify other key stakeholders to involve in IRR process</li> <li>Provide operational resources to support clinical teams in IRR efforts</li> </ul>	Aligning IRR with data transparency and patient experience strategies to demonstrate additional ways to engage patients and share meaningful information with them beyond their participation in the study.

Group Member	Key Roles in Group	Example
Principal Investigator (PI) and Study Coordinators	<ul style="list-style-type: none"> <li>Discuss with PIs and study coordinators to ensure they understand the process for IRR at their sites</li> <li>Provide guidance on how to answer questions from participants related to IRR</li> </ul>	The PI and study coordinators were informed of the process and asked to inform participants that their data would be reviewed by the PI before they were made available to them, and that if there were concerns, the PI would reach out prior to returning any data.
Legal Counsel	<ul style="list-style-type: none"> <li>Determine how to meet relevant state, federal, and international data privacy requirements</li> <li>Clarify the role of the IRB in reviewing and approving IRR plans</li> </ul>	The sponsor engaged with external legal counsel with expertise in reviewing relevant state, federal, and international data privacy requirements, including HIPAA (U.S.) and General Data Protection Regulation (GDPR) (E.U.).
IT, Security, and Compliance	<ul style="list-style-type: none"> <li>Establish, test, and provide technical support for electronic methods of returning results</li> <li>Troubleshoot any issues that arise</li> </ul>	An email contact was provided on the portal where participants accessed their results to mitigate participants' technical difficulties.

Inviting the right team members to design and implement the process, providing trainings and resources for study staff, and creating documents and procedures were critical to the success of the pilot.

### The Importance of Training the Site

Training and educational materials for sites helped to ensure that the PI and study coordinators were able to convey the same information accurately about how and when individual results would be returned to participants.

Internal resources included:

- Robust data specifications detailing which results from a study would be shared, when the results would be available, and for how long they would be accessible
- Study-specific FAQs (provided to sites prior to study implementation)

External trainings and resources included:

- Online demonstrations and videos
- Physical training materials and study-specific FAQs
- A defined process for escalating any participant questions or concerns to the PI

### Adding Results Sharing into the Protocol

For the pilot study, the process for sharing results was integrated into the existing clinical trial protocol and informed consent process.

Some key considerations that arose include:

- Ensuring that no personal identifying information (PII) or personal health information (PHI) would be received by the sponsor
- Deciding which specific results could reasonably be shared with participants
- Deciding when and for how long to make the data available to participants, and whether and how to allow for sharing with healthcare providers

Additional, study-specific considerations include:

- Whether the study is blinded or open-label
- Whether screening and/or study data will be shared

*In the pilot, general laboratory data relevant to participant safety was selected as the first data to return to participants*

## Implementing the Result-Sharing Plan

Study participants were offered the opportunity to participate (opt-in) and consented to data-sharing through an IRD-approved “Data Sharing Authorization” form. They were also given information in the participant pamphlet to clarify which results participants would be able to receive, when, and why, and instructions as to how to address medical questions to the PI.

After review by the PI for any anomalous or clinically actionable results, participants could access their data via a secure website where individual laboratory results collected at study visits were available to participants directly. The website enabled easy, real-time access to individual results and participants could save these data to their own medical record or share them electronically with healthcare providers. The PI and study coordinators at study sites could view the same data as the participants, which was helpful when participants asked for assistance in interpreting the results that were provided.

*“The patients all thought it was a great idea. They can access the data when needed at PCP visits and it empowers them to be a part of their own care.”*  
- Site Coordinator

## Outcomes

### Challenges

- A large financial commitment was needed to build a platform and add sharing data as a part of the service package provided to trial participants, a resource commitment that required buy-in from sponsor leadership.
- There was an initial learning curve as site staff learned how to navigate this additional process with participants. The challenge was mitigated by providing comprehensive trainings and educational resources.

### Successes

- Due to the success of the pilot study and the value it demonstrated, a portal was developed to provide resources and services to participants in this sponsor’s studies, including the return of IRR.
- A data-sharing template was created for future study teams who wish to share data in their studies.
- The study site reported that participants were more prepared for their visits and more engaged with the study thanks to the ongoing sharing of routine results.
- The engagement with participants led sites to advocate for what participants stated that they wished to receive through the study.

## Key Takeaways

**Convene an institutional multidisciplinary group of stakeholders early in the planning process.**

**Start small, learn, and iterate to fit your plan into each institution.**  
Consider beginning with a few pilots and seek patient and stakeholder feedback after each.

**Create educational and training materials for your research team to ensure everyone is prepared to address participants’ questions.**

**Integrate your results-sharing plan into the study protocol.**  
Be as clear as possible about your approach