Enabling Individual Participant Data Return

March 28, 2024, 9:00 AM EST

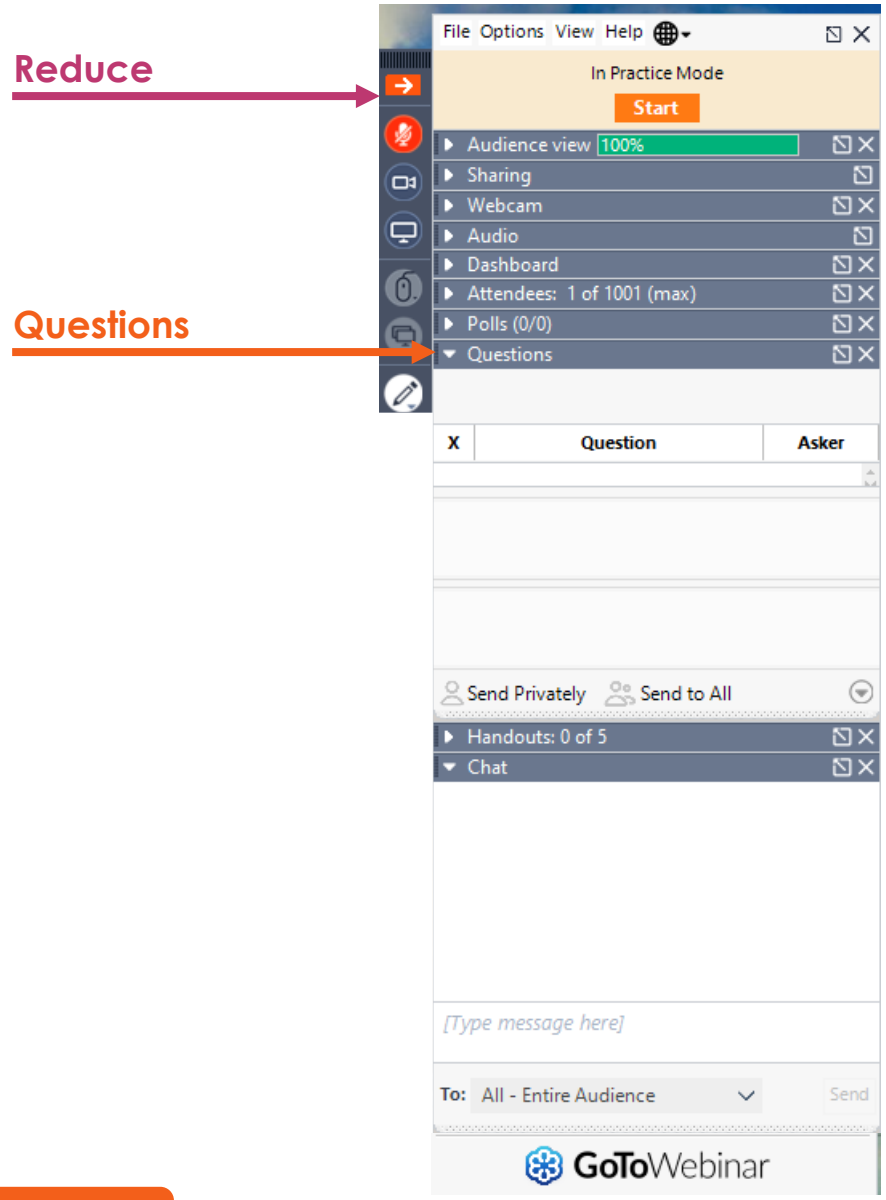
Agenda

Topic

- Welcome, Webinar Logistics & Ground Rules
- Individual Participant Data Return Background
- Overview of TransCelerate's Individual Participant Data Return Initiative & (iPDR) Package
- Q&A with Expert Panelists

Logistics for the Webinar

- **All participants will be muted for this call.**
- **For audio**: Connect to audio to listen to presentations via your computer or phone
- **You can reduce the control panel for a better view of the presentation**
- **To submit a question to the presenters**:
  - Type your question in the Questions panel and click Send.



Reminder: This webinar may be recorded in whole or in part.

TransCelerate BIOPHARMA INC.

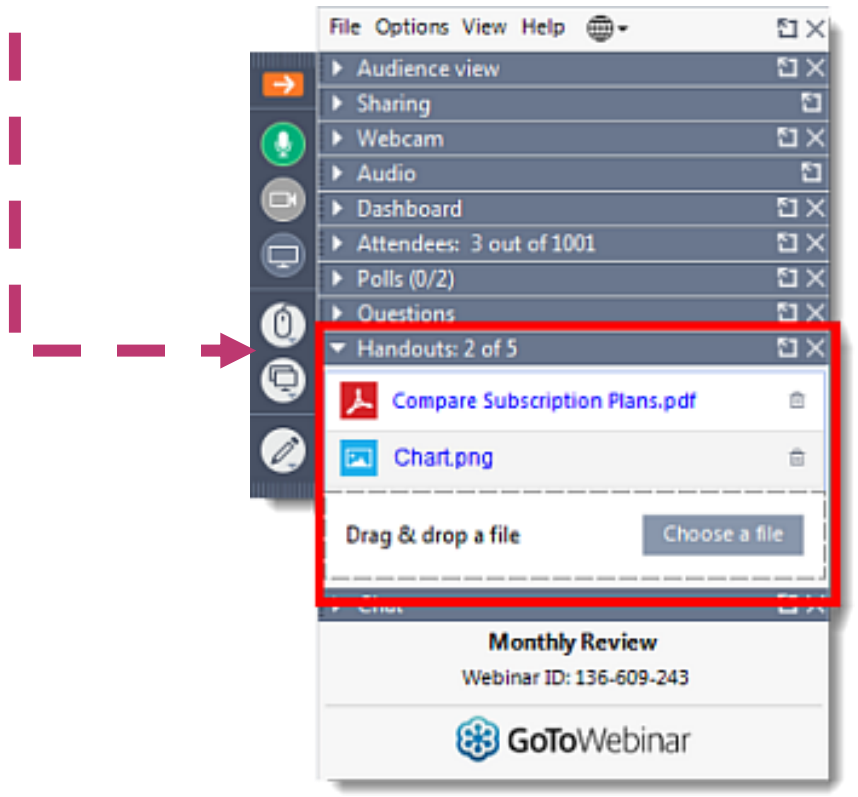
Ground Rules

- **We want to make this discussion helpful and answer as many of your questions as we can, so here are some quick ground rules:**
  - Participation is voluntary, as is using TransCelerate assets/tools
  - The responsibility for compliance with laws and regulations is owned by the solution adopter.
  - You don't have to identify what company you work for
- **Things we would ask you <u>not to discuss</u>**:
  - What vendors/sites / CROs you are using or not using
  - Any issues you have with any vendors/sites/CROs
  - Your long-term development plans
  - Anything related to pricing or costs
- **We can't answer questions about**:
  - Vendors
  - Costs of using/implementing TransCelerate assets/tools
  - Which member companies are using the assets/tools

Please download the webinar handout

All attendees have a webinar handout with links to the content discussed and other resources from the TransCelerate Participant Data Return Initiative.

Handouts Panel



TransCelerate is a Not-for-Profit Entity Created to Foster Collaboration

Our mission is to collaborate across the global biopharmaceutical R&D community to identify, prioritize, design, and facilitate the implementation of solutions designed to drive the efficient, effective, and high-quality delivery of new medicines.

A Member-Driven Mission

Experts from across our participating Member Companies dedicate their time to TransCelerate.

TransCelerate **identifies the issues and challenges** facing our industry.

TransCelerate **designs and delivers practical solutions** for global adoption by any stakeholder.

Who are our Members?

View a full list of our members

Membership* is available to biopharmaceutical research and development organizations that engage in innovative discovery, development and manufacturing of new medicines

* to be eligible for membership, companies must meet specified eligibility criteria.

TransCelerate BIOPHARMA INC.

Thank you to our Team Members!

Name	Member Company
Lynn Wetherwax	Amgen
Rupa Gupta	Amgen
Jean Sposaro	BMS
Melissa Cabral	BMS
Joanna Culver	GSK
Swapna Pothula	GSK
Carine Lemouzy	Novartis

Name	Member Company
Anusha KR	NovoNordisk
David Leventhal	Pfizer
Paula Boyles	Pfizer
Angela Bilkhu	Roche
Elizabeth Abba-Theogaraj	Roche
Sabri Miled	Sanofi
Kristi Whiteside	UCB

Our Expert Speaker Today

Angela Bilkhu

Global Patient Partnership Leader, Rare Blood Disorders.,
Roche

Individual Participant Data Return Background

Polling Question #1

What is your experience with individual participant data return?

- Beginner
- Intermediate
- Expert
- Not Applicable

What are some examples* of individual participant data return?

Examples of Individual Participant Data Return may include, but is not limited to:

- Individual study participant-level data, including health data, collected from and generated by a study participant throughout the conduct of a clinical study. This may include enrolment or screening period data, which are protocol defined within the schedule of assessments/activities
- Individual study participant information and test results derived from:
  - Procedures defined within the study protocol and schedule of assessments/activities but do not constitute study results
  - Samples collected from the study participant during the progress of the study
- Individual participant information and test results derived from samples collected from the study participant during the progress of the study

Individual Participant Data Return (per the examples outlined above) is different from **Lay Person Summary Aggregate Results Return** (e.g., a summary of the results of the clinical study together with a summary that is understandable to a layperson, and the clinical study report, where applicable).

For more references which include definitions of individual participant data return, please refer to: [Participant Data Return Resource Pack]

*These examples are not all inclusive

TransCelerate BIOPHARMA INC.

Why Now?

1

Increased awareness and understanding about the value of participant data in addressing unmet medical needs

2

Ecosystem emphasis on flexibility and personalized approaches that will optimize inclusion, diversity & health equity

3

Advancements in clinical data collection and digital health options designed to reduce burden & inefficiency

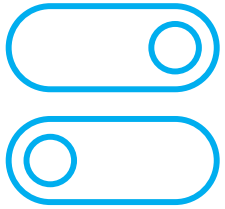
4

Reduce the gaps in healthcare and clinical research through interoperability

Potential Benefits of Individual Participant Data Return

Demonstrate value and respect for clinical trial participants, **build trusted partnerships** and facilitate access to clinical trials at **a participants point of care**

Enhance public trust, fairness, and transparency, which in turn may **facilitate more diverse and inclusive participation** in clinical trials and **improve health equity and access**



Empower clinical trial participants to be equal partners in improving health outcomes by providing them the option of opting-in or opting-out of receiving the data they contribute

Many organizations are working to problem solve / collaborate on this topic

TransCelerate BIOPHARMA INC.	Participant Data Return Initiative
MULTI-REGIONAL CLINICAL TRIALS THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD	Return of Individual Results
innovative health initiative	FACILITATE
Pfizer	Returning Clinical Data to Patients

List not exhaustive. Please refer to the Participant Data Return Resource Pack for more information.

Why TransCelerate?

TransCelerate BIOPHARMA INC.

- Strength and breadth of Health Authority & Sponsor **collaboration experience**
- Credibility and **track record** in **practical execution** of solutions for broader industry
- Capable of **leading** and **convening** various stakeholder groups
- **Existing** and **planned TransCelerate solutions** can be **leveraged** to meet project needs

TransCelerate BIOPHARMA INC.

Complementary TransCelerate Efforts

- Recommendations for Drafting Non-Promotional Lay Summaries of Clinical Trial Results
- Participant Thank You Letters
- Patient Experience Gratitude Toolkit
- Personalized Clinical Trials Framework

Overview of the Individual Participant Data Return Initiative & (iPDR) Package

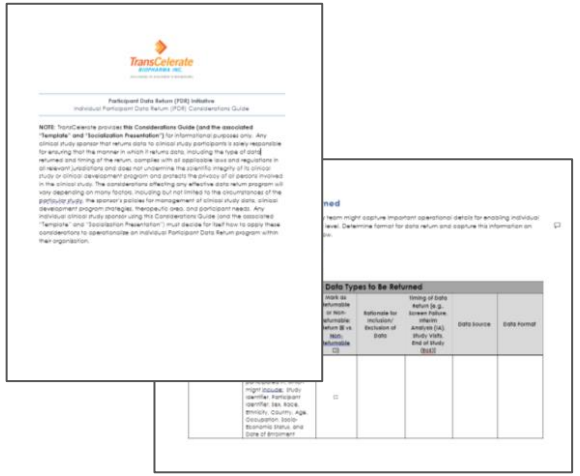
The iPDR initiative has launched the Individual Participant Data Return Package, a solution that provides general considerations to enable data return to clinical trial participants

Individual Participant Data Return Package

Socialization Presentation
A presentation to educate key internal stakeholders of the potential value of returning participant data in clinical studies and to obtain support to operationalize within sponsor organization

Considerations Guide
Provides considerations for implementing the return of individual data

Template
Provides a customizable template example of how a study team might capture important operational details for enabling individual data return at a study or program level

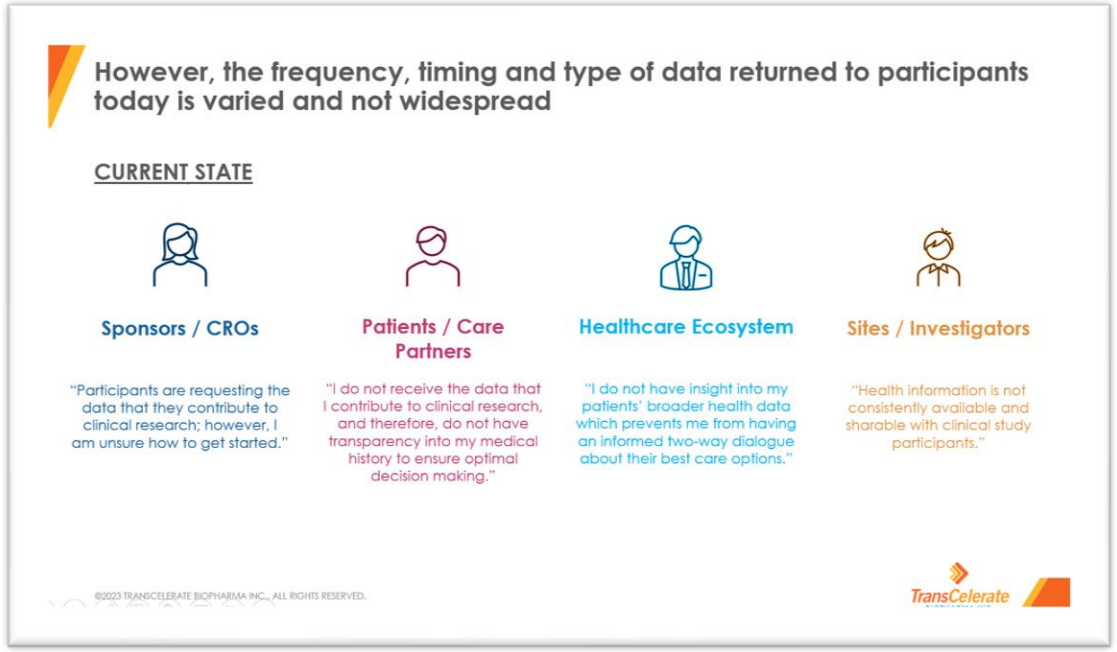


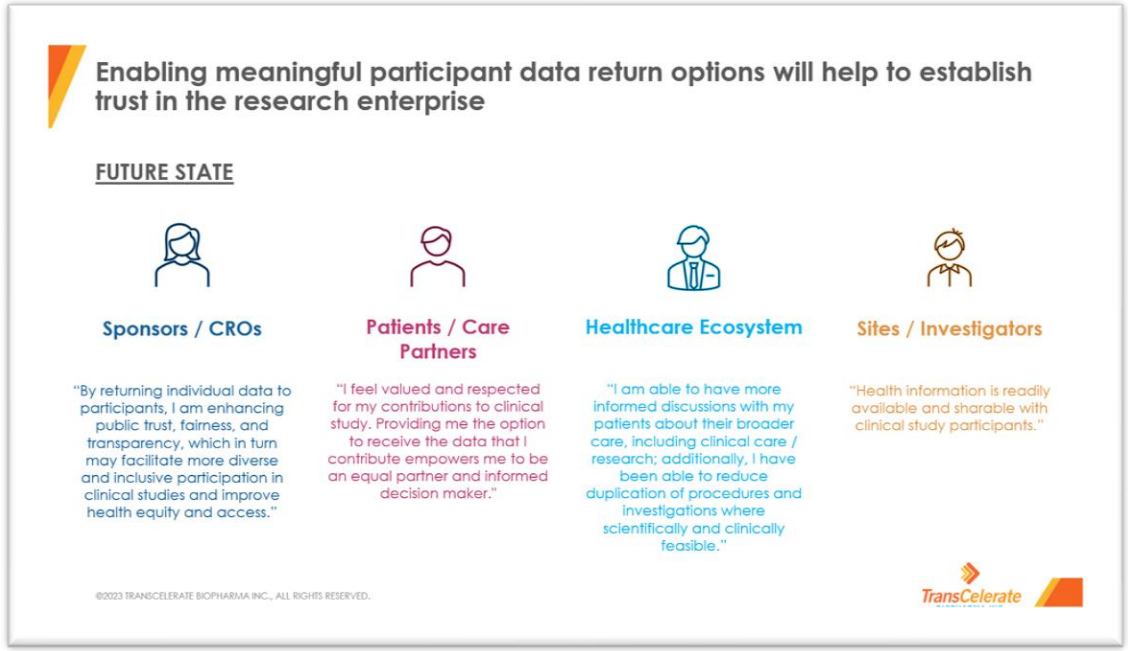
TransCelerate BIOPHARMA INC.

Individual Participant Data Return Package

Socialization Presentation

Individual Participant Data Return Socialization Presentation : intended to support Participant Data Return Implementation Team(s) to facilitate the internal socialization of individual participant data return with leadership and colleagues, and to provide introduction materials and links to documents.





TransCelerate BIOPHARMA INC.

Individual Participant Data Return Package

Considerations Guide

Individual Participant Data Return Considerations Guide: Intended to:

- Provide a greater level of understanding and awareness for sponsors who may be considering individual data return options or are looking to implement a strategy for managing individual requests for participant data.
- Support stakeholders in implementing individual study participant data return via:
  - Key considerations for developing systematic processes.
  - Approaches for returning individual data back to clinical study participants who choose to receive it in a way that is most meaningful to them.

Considerations are tied to the following themes:

Individual Participant Data Return Package

Template

Individual Participant Data Return Template: Intended to facilitate decisions and align key stakeholders while exploring approaches to provide individual study participants with the option of receiving their clinical study data / results

2.0 Core Data Types to Be Returned

The table below is an example of how a study team might capture important operational details for enabling individual participant data return at a study or program level.

Program ID/No.: [Insert Program ID/No. here]

or

Protocol ID/No.: [Insert Protocol ID/No. here]

Core Data Types to Be Returned

Data Type: Individual Participant Level	Description and Examples	Mark as Returnable or Non-Returnable: (Return ☒ vs. Non-Returnable ☐)	Rationale for Inclusion/ Exclusion of Data	Timing of Data Return [e.g., Screening/ Enrollment, Interim Analysis (IA), Study Visits, End of Study (EoS)]	Data Source	Data
Demographics	Data about the participant and the study that they participated in, which might include: Study Identifier, Participant Identifier, Sex, Race, Ethnicity, Country, Age, Occupation, Socio-Economic Status, and Date of Enrollment.	☐				
Treatment Received	The treatment(s) or study drug(s) that the participant received with information about dosage, delivery type (e.g., injection, oral, etc.), and duration (e.g., study day received).	☐				
Medical History and Conditions*	A list of a participant's reported medical history / conditions with start dates and end dates.	☐				
Adverse Events / Serious Adverse Events*	A participant's reported adverse events over the course of a study.	☐				
Concomitant Medications	A list of participant's medications took during the study unrelated to the study drug itself, with information about the study day(s) taken and potentially medication classification.	☐				

Call-to-Action

View the Individual Participant Data Return (iPDR) Package

Be proactive! Historically, when industry is slow to adapt, regulators have mandated a solution.

Engage early on with key stakeholders and partner with others in the ecosystem to identify ways to incorporate individual participant data return into existing processes

As you leverage the Individual Participant Data Return (iPDR) Package, we want to hear more about your experience! Please let us know by visiting the Engage With Us page.

TransCelerate BIOPHARMA INC.

Thank you!

Contact Us!
Events@transceleratebiopharmainc.com

Individual Participant Data Return (iPDR) Package

Please reach out with any additional questions regarding TransCelerate's Participant Data Return initiative or the Individual Participant Data Return Package

Panel Introductions

Disclaimer

Responses have been sourced from a variety of panelists and do not necessarily represent the views of all (or their respective organisations)

Meet Our Expert Panel

Ashley Pachter
TransCelerate
Program Director

Paula Boyles

Pfizer / TransCelerate

Angela Bilkhu

Roche / TransCelerate

Amy Fesmire-Baus

BMS / Patient Advocate

Sylvia Baedorf Kassis

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

Johanna Blom

University of Modena / IHI

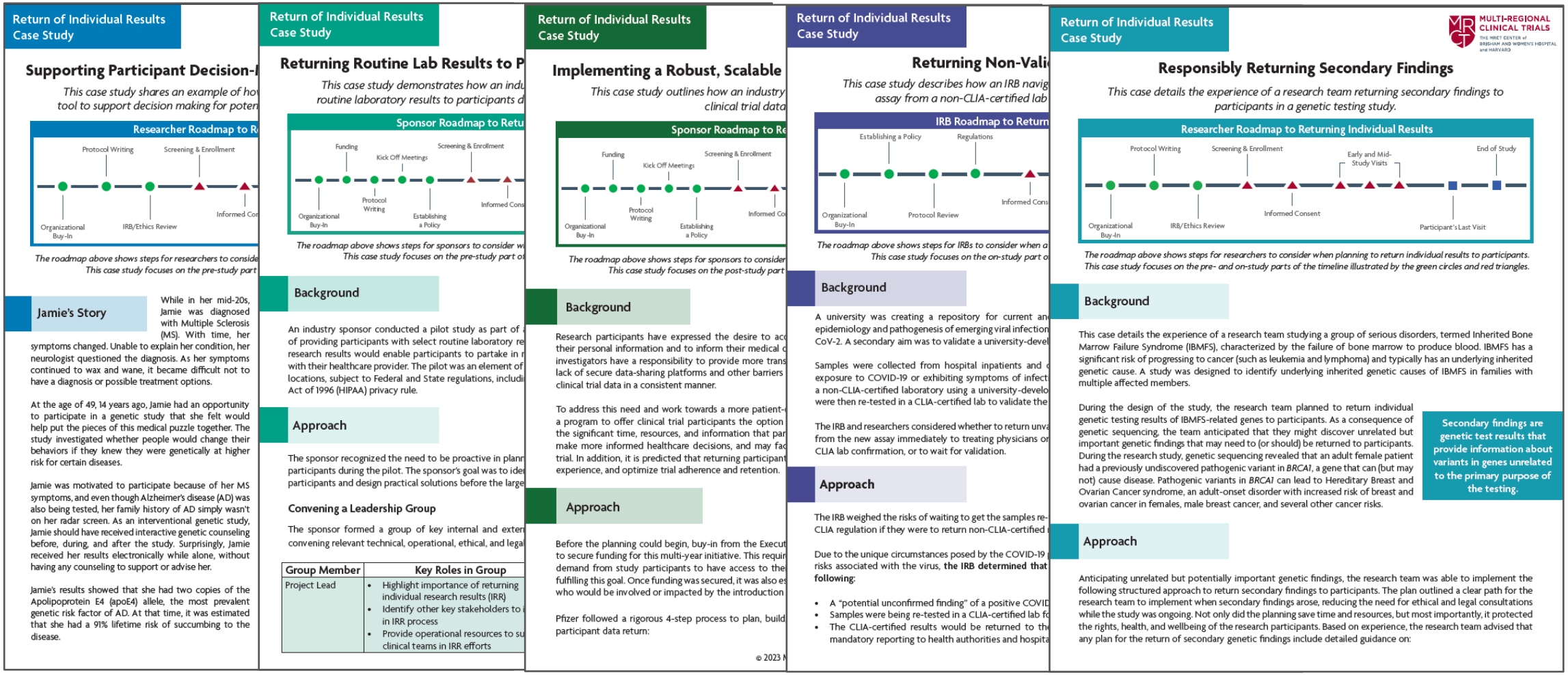
If you have a question, **please denote to whom** the question is directed.
Note: depending on time, we will not be able to answer all questions

As a reminder, we can't answer questions about:

- Vendors
- Costs of using/implementing TransCelerate assets/tools
- Which member companies are using the assets/tools

TransCelerate BIOPHARMA INC.

MRCT Center - IRR Case Studies



Return of Individual Results Case Study

Supporting Participant Decision-M

This case study shares an example of ho tool to support decision making for poten

Researcher Roadmap to R

Protocol Writing · Screening & Enrollment · Informed Cor · Organizational Buy-In · IRB/Ethics Review

The roadmap above shows steps for researchers to conside This case study focuses on the pre-study part

Jamie's Story

While in her mid-20s, 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 49, 14 years ago, Jamie had an opportunity to participate in a genetic study that she felt would help put the pieces of this medical puzzle together. The study investigated whether people would change their behaviors 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 also being tested, her family history of AD simply wasn't 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 (apoE4) allele, the most prevalent genetic risk factor of AD. At that time, it was estimated that she had a 91% lifetime risk of succumbing to the disease.

Return of Individual Results Case Study

Returning Routine Lab Results to P

This case study demonstrates how an indu routine laboratory results to participants d

Sponsor Roadmap to Retu

Funding · Kick Off Meetings · Screening & Enrollment · Informed Cons · Organizational Buy-In · Protocol Writing · Establishing a Policy

The roadmap above shows steps for sponsors to consider w This case study focuses on the pre-study part o

Background

An industry sponsor conducted a pilot study as part of of providing participants with select routine laboratory re research results would enable participants to partake in r with their healthcare provider. The pilot was an element of locations, subject to Federal and State regulations, includi Act of 1996 (HIPAA) privacy rule.

Approach

The sponsor recognized the need to be proactive in plann participants during the pilot. The sponsor's goal was to ide participants and design practical solutions before the large

Convening a Leadership Group

The sponsor formed a group of key internal and exter convening relevant technical, operational, ethical, and legal

Group Member	Key Roles in Group
Project Lead	• Highlight importance of returning individual research results (IRR) • Identify other key stakeholders to i in IRR process • Provide operational resources to su clinical teams in IRR efforts

Return of Individual Results Case Study

Implementing a Robust, Scalable

This case study outlines how an industry clinical trial data

Sponsor Roadmap to Re

Funding · Kick Off Meetings · Screening & Enrollment · Informed Co · Organizational Buy-In · Protocol Writing · Establishing a Policy

The roadmap above shows steps for sponsors to consider This case study focuses on the post-study part

Background

Research participants have expressed the desire to acc their personal information and to inform their medical c investigators have a responsibility to provide more trans lack of secure data-sharing platforms and other barriers clinical trial data in a consistent manner.

To address this need and work towards a more patient- a program to offer clinical trial participants the option the significant time, resources, and information that par make more informed healthcare decisions, and may fac trial. In addition, it is predicted that returning participant experience, and optimize trial adherence and retention.

Approach

Before the planning could begin, buy-in from the Execut to secure funding for this multi-year initiative. This requir demand from study participants to have access to the fulfilling this goal. Once funding was secured, it was also es who would be involved or impacted by the introduction

Pfizer followed a rigorous 4-step process to plan, build participant data return:

© 2023 M

Return of Individual Results Case Study

Returning Non-Vali

This case study describes how an IRB navig assay from a non-CLIA-certified lab

IRB Roadmap to Return

Establishing a Policy · Regulations · Informed Cons · Organizational Buy-In · Protocol Review

The roadmap above shows steps for IRBs to consider when a This case study focuses on the on-study part o

Background

A university was creating a repository for current an epidemiology and pathogenesis of emerging viral infection CoV-2. A secondary aim was to validate a university-devel

Samples were collected from hospital inpatients and exposure to COVID-19 or exhibiting symptoms of infect a non-CLIA-certified laboratory using a university-develo were then re-tested in a CLIA-certified lab to validate the

The IRB and researchers considered whether to return unva from the new assay immediately to treating physicians or CLIA lab confirmation, or to wait for validation.

Approach

The IRB weighed the risks of waiting to get the samples re- CLIA regulation if they were to return non-CLIA-certified

Due to the unique circumstances posed by the COVID-19 risks associated with the virus, **the IRB determined that following:**

- A "potential unconfirmed finding" of a positive COVID
- Samples were being re-tested in a CLIA-certified lab fo
- The CLIA-certified results would be returned to th mandatory reporting to health authorities and hospita

Return of Individual Results Case Study

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

Responsibly Returning Secondary Findings

This case details the experience of a research team returning secondary findings to participants in a genetic testing study.

Researcher Roadmap to Returning Individual Results

Protocol Writing · Screening & Enrollment · Early and Mid-Study Visits · End of Study · Organizational Buy-In · IRB/Ethics Review · Informed Consent · Participant's Last Visit

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 on-study parts of the timeline illustrated by the green circles and red triangles.

Background

This case details the experience of a research team studying a group of serious disorders, termed Inherited Bone Marrow Failure Syndrome (IBMFS), characterized by the failure of bone marrow to produce blood. IBMFS 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 IBMFS in families with multiple affected members.

During the design of the study, the research team planned to return individual genetic testing results of IBMFS-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 (or should) be returned to 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 disease. 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, reducing the need for ethical and legal consultations while the study was ongoing. Not only did the planning save time and resources, but most importantly, it protected the rights, health, and wellbeing 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:

https://mrctcenter.org/return-of-individual-results/resources/case-studies/

TransCelerate BIOPHARMA INC.

The MRCT Center Clinical Research Glossary: New Words, New Opportunities

LOCATION:
Virtual

DATE:
April 2, 2024

TIME:
12pm – 1pm, EST

SPEAKERS:

DEB COLLYAR
Founder and President
Patient Advocates In Research

CHRIS DECKER
President and CEO
CDISC

ERIN MUHLBRADT
Biomedical/Clinical Information Specialist
NCI - Enterprise Vocabulary Services

MODERATED BY:

SYLVIA BAEDORF KASSIS
Program Director
MRCT Center

REGISTER NOW!

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

cdisc

https://mrctcenter.org/tribe-events/glossary-webinar/

TransCelerate BIOPHARMA INC.

TransCelerate BIOPHARMA INC.
Accelerating Answers.

TransCelerate Public Webinars

"Pharmacovigilance Agreement Solutions You Didn't Realize You Needed"

Presentation Overview:

Join us for an overview of TransCelerate's Pharmacovigilance Agreements Optimization (PVAO) Initiative, which includes a suite of solutions designed to help organizations enhance their PVA process. These solutions can help organizations improve their processes and potentially achieve more efficient negotiations with business partners globally.

The webinar will include:

- An overview of the Pharmacovigilance Agreements Optimization (PVAO) Initiative that could be used to inform and/or help streamline the end-to end PVA process.
- A deeper dive into the two most recent solutions:
  - **Timelines Benchmarking:** Aggregate benchmarking data on exchange timelines.
  - **Audit Process Efficiencies:** Suite of solutions providing marketing partner audit considerations.
- Q&A will address audience questions on the PVAO solution.

Ideal Attendees:

Alliance Managers, Safety Scientists, Pharmacovigilance Managers, Officers, Associates, Specialists, Directors, Pharmacovigilance Licensing, Experts, Leads.

Safety Data Exchange Agreement Managers, Officers, Associates, Specialists, Directors, Patient Safety Directors, Managers, Officers, Associates, Specialists, Global and Local Patient Safety, Pharmacovigilance Country Head(s), QPPV, Local QPPV, Business Development and Licensing (BD&L) Directors, Associate Directors, Managers

Featured Panelists:

Yvonne Gibble

Executive Director, Pharmacovigilance Partner Strategy & Management,
Merck Sharpe & Dohme, LLC

Beth MacEntee Pileggi

Senior Director, Safety Information Management & Automation,
Johnson & Johnson

Wendy Manko Singer

Associate Vice President, Individual Case Medical Review, Global Clinical Safety & Pharmacovigilance,
Merck Sharpe & Dohme, LLC

Jonathan Rowell

Senior Director, Head of Pharmacovigilance QA,
Johnson & Johnson

May 16, 2024

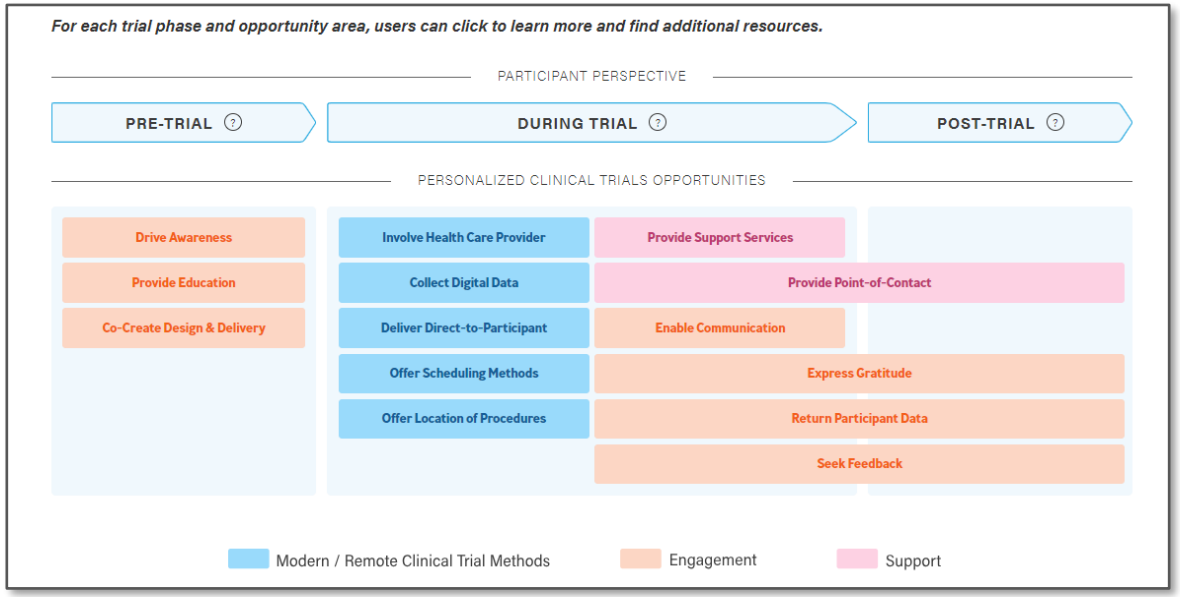
10:00AM to 11:00AM EST

Scan QR code to sign up.

TransCelerate webinars may be recorded in whole or in part.

Polling Question #2

How confident do you feel that you could use this iPDR Package to return data to clinical study participants in future studies?



Thank you for joining us!