FROM TRANSPARENCY TO TANGIBLE VALUE

Implementing Participant Data Return to Enhance Trust, Care, and Equity in Clinical Trials

phuse

Data Transparency Autumn Event

Thursday, September 17, 2026

AGENDA

- What is individual participant data return? What it is not?
- Why return clinical trial data to participants?
- What do external frameworks recommend?
- How do you incorporate patient voices?
- What is Biogen's process?
- What are some lessons learned and next steps?

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What is Participant Data Return (PDR)?

Sharing **the individual data collected during a clinical trial with the person** who participated.

Data may include:

- Treatment group information
- Primary endpoint data
- Adverse events
- Lab tests
- Genetic results
- Imaging
- Any other data collected during the trial

It is also sometimes referred to as:

- ✓ Individual Data Return
- ✓ Return of Individual [Research] Results
- ✓ Return of Individual Participant Data

Note: Clinical trial participants receive data without the sponsor seeing any identifying information about them.

What Individual Participant Data Return is NOT

Common Misconceptions

- **IPD sharing with Researchers** - individual participant data (IPD) is provided in an anonymized format for researchers to conduct other studies /research
  - Registries ask a question about IPD:
    - **ClinicalTrials.gov:** "Indicate if there is a plan to make individual participant data (IPD) available to ***other researchers"***
    - **CTIS:** 'IPD Sharing Statement' collects information on how this data will be made available to ***other researchers***
    - **International Committee of Medical Journal Editors (ICMJE):** "Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration."

- **Overall study scientific results posted on ClinicalTrials.gov, CTIS, or other local registries**

- **Plain Language Results Summaries**

Individual Return vs Results Plain Language Summary (PLS)

Individual Return

Clinical Assessments

MS Relapses

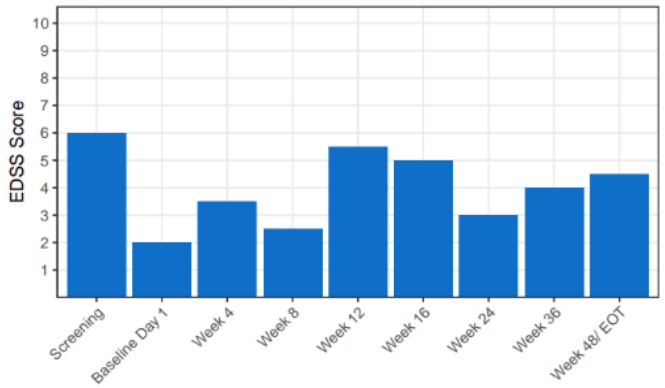
A relapse is when you experience a new or worsening symptom which lasts for 24 hours. If your symptoms worsen because you are sick or overheated, it is not considered a relapse. If you did not experience any relapses in this study, it will also be noted below.

Date	Event
20-Mar-2025	MULTIPLE SCLEROSIS RELAPSE
16-Apr-2025	MULTIPLE SCLEROSIS RELAPSE

Expanded Disability Status Scale (EDSS)

The Expanded Disability Status Scale (EDSS) is a scale used to measure how much you are affected by your MS. It measures your level of disability due to MS, and also helps in understanding changes in disability over time.

Through physical exams and talking about your symptoms, the study doctor gave you a score on 8 measures. These measures were then used to give you a single, total EDSS score. The EDSS score ranges from 0 to 10, with a higher score meaning greater disability. Your results are shown below.



Date	Visit	EDSS Score
26-Jan-2025	Screening	6.0
18-Feb-2025	Baseline Day 1	2.0
18-Mar-2025	Week 4	3.5
15-Apr-2025	Week 8	2.5
13-May-2025	Week 12	5.5
10-Jun-2025	Week 16	5.0
05-Aug-2025	Week 24	3.0
28-Oct-2025	Week 36	4.0

Results PLS

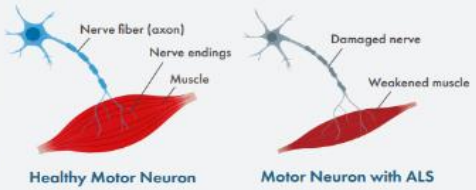
Thank you!

A clinical study participant belongs to the larger research community around the world. By participating in a study, they help researchers answer important health questions and learn about new medications.

In this study, researchers learned more about the investigational drug tofersen and its long-term safety in people with **amyotrophic lateral sclerosis (ALS) caused by a mutation in the superoxide-dismutase 1 (*SOD1*) gene**, also known as ***SOD1*-ALS**.
An investigational drug is one that has not yet been approved for use outside of clinical studies. This is also known as the **study drug**.

Biogen, the sponsor of this study, thanks those who participated and believes it is important to share the overall results of the study. If you have questions, please speak with the doctor or staff at the study research center.

Why was this study done?



Researchers are looking for a drug that may help people with **ALS** who have a ***SOD1* gene mutation**, also known as **SOD1-ALS**.

ALS is a rare disease that damages nerve cells in the brain and spinal cord which help control movement. These nerve cells are called motor neurons. Damage to motor neurons in ALS causes weakness in muscles that may lead to difficulty walking, speaking, eating, and breathing. It is a progressive disease, which means that it slowly gets worse with time.

One of the causes of ALS is a mutation in the ***SOD1* gene**. Mutation of the *SOD1* gene causes an abnormal SOD1 protein to be made. Researchers think this abnormal protein can lead the motor neurons to break down and die.

In this study, the researchers studied a drug called tofersen. Previous studies have shown that tofersen can lower the amount of SOD1 protein that is made by the body. Lower levels of SOD1 protein may slow the worsening of ALS.

In this study, researchers wanted to learn more about the long-term safety of tofersen in participants with *SOD1-ALS*. This study was an extension of an earlier study known as 233AS101. Participants who completed Parts A, B or C of Study 233AS101 were allowed to join this study if they met certain requirements.

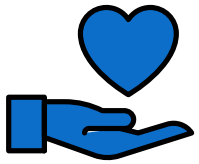
The main questions that the researchers wanted to answer were:

- How many participants had adverse events or serious adverse events?
- What adverse reactions did the participants have?

An **adverse event** is an unwanted health problem that may or may not be caused by the study drug.

An **adverse reaction** is an unwanted health problem that the study doctor thinks is caused by the study drug. This can happen during a clinical study or within a certain amount of time after the study has ended.

Why it matters now



Participants want it – People who join trials consistently say they want their own results, not just the overall study findings, and they increasingly expect access as a condition of their participation.

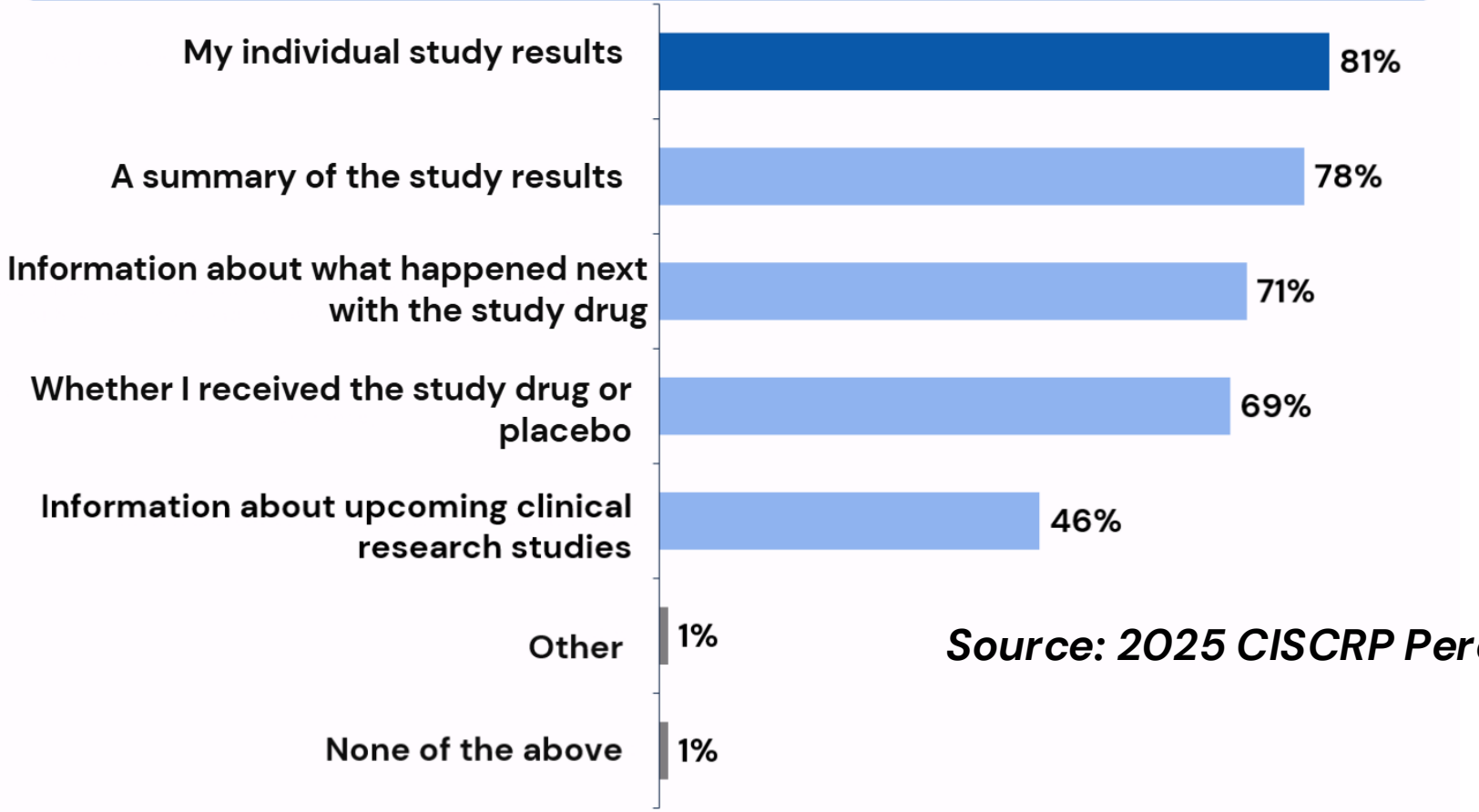
Ethics and equity demand it – Participants take on real burden and risk; returning their data respects that contribution, supports informed care with their own clinician, and helps close gaps for communities historically underserved by research.

The bar has moved – Published guidance (MRCT, TransCelerate, FACILITATE) and evolving regulatory positions have turned data return from an aspiration into an expectation.

EU General Data Protection Regulation - "The data subject shall have the right to obtain from the controller confirmation as to whether or not personal data concerning him or her are being processed, and, where that is the case, access to the personal data." (Chapter 3, Article 15)

What do patients want?

What information would you be most interested in receiving after completing your participation in a clinical research study?
(Select all that apply)



Source: 2025 CISCRP Perceptions & Insights Study

Sample Size = 12,887

WHAT DO THE EXTERNAL FRAMEWORKS RECOMMEND?

Where MRCT, TransCelerate, FACILITATE, and National Academies converge:

- ✓ Plan early – decide what will be returned at protocol design, not after database lock.
- ✓ Make it a choice – participants opt in and can decline without consequence.
- ✓ Return what is meaningful – judge each data point on clinical relevance, analytical validity, and personal utility rather than returning everything.
- ✓ Give results context – plain language, normal ranges, and the reason each measure was collected.
- ✓ Results are not medical advice – point participants to their own clinician for interpretation.

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COMMUNITY ADVISORY BOARD FEEDBACK

An Underrepresented Populations Community Advisory Board (convened by Biogen and CISCRP) met about individual data return in December 2025.

> *I think there is an opportunity to make some of the graphs tell the story a little bit better.*

> *I love the formatting. I love the different headings and different sections…very thorough and amazing.*

Positives

- Clear headers and different sections made the report easy to navigate
- The use of plain language was appreciated
- Charts and graphs helped visualize the data and make it easier to digest
- Inclusion of a 'thank you' (although most felt this could be amplified)

> *To actually get something back after a clinical trial is revolutionary. Thank you for considering that.*

Areas of Opportunity

- Some sections felt too dense – data tables that could be formatted differently could help make information easier to digest
- Line graphs to represent data would be preferred
- Language around gratitude could be enhanced

Overall, the template was well-received. All appreciated seeing a sponsor sharing back data post-trial.

HOW BIOGEN IS RETURNING DATA

With the input of patients and health care providers

Data that is

- Condition-specific
- Meaningful and interpretable outside study context
- Actionable
- Not emotionally charged (unless warranted)

In PDF format (for now)

- Cross-platform
- Can be printed, enlarged or screen-read

Ethically

- Participants opt into receiving the report
- Participants receive reports through their site care team
- Reports are returned to sites via secure portal
- Participant identities remain protected

PATIENT DATA RETURN STAKEHOLDERS

Role/Group	Responsibilities
Clinical Trial Manager	• Lead the choice of the data to be returned • Flag data with special considerations • Ensure Data Stewardship can access the correct data source • Serve as a point of contact for the PDR team
Study Medical Director	• Review report to ensure medical/scientific accuracy, and consistency with existing trial documents and activities
Data Stewardship (PDR Core Team)	• Manage timelines and document reviews • Review data for feasibility • Develop code for integrating data into reports • Perform DV/QC on reports • Generate & distribute reports
Clinical Trial Transparency (PDR Core Team)	• Strategic engagement with the study team • Create study team- and site- facing communications • Secure portal vendor management
Plain Language Center of Excellence (PDR Core Team)	• Write plain language content for report • Align report with Results Plain Language Summary

Core Team Responsibilities

- Decide return strategy
- Architect reports
- Review draft reports
- Develop processes (standards, style guides, conventions, etc.)

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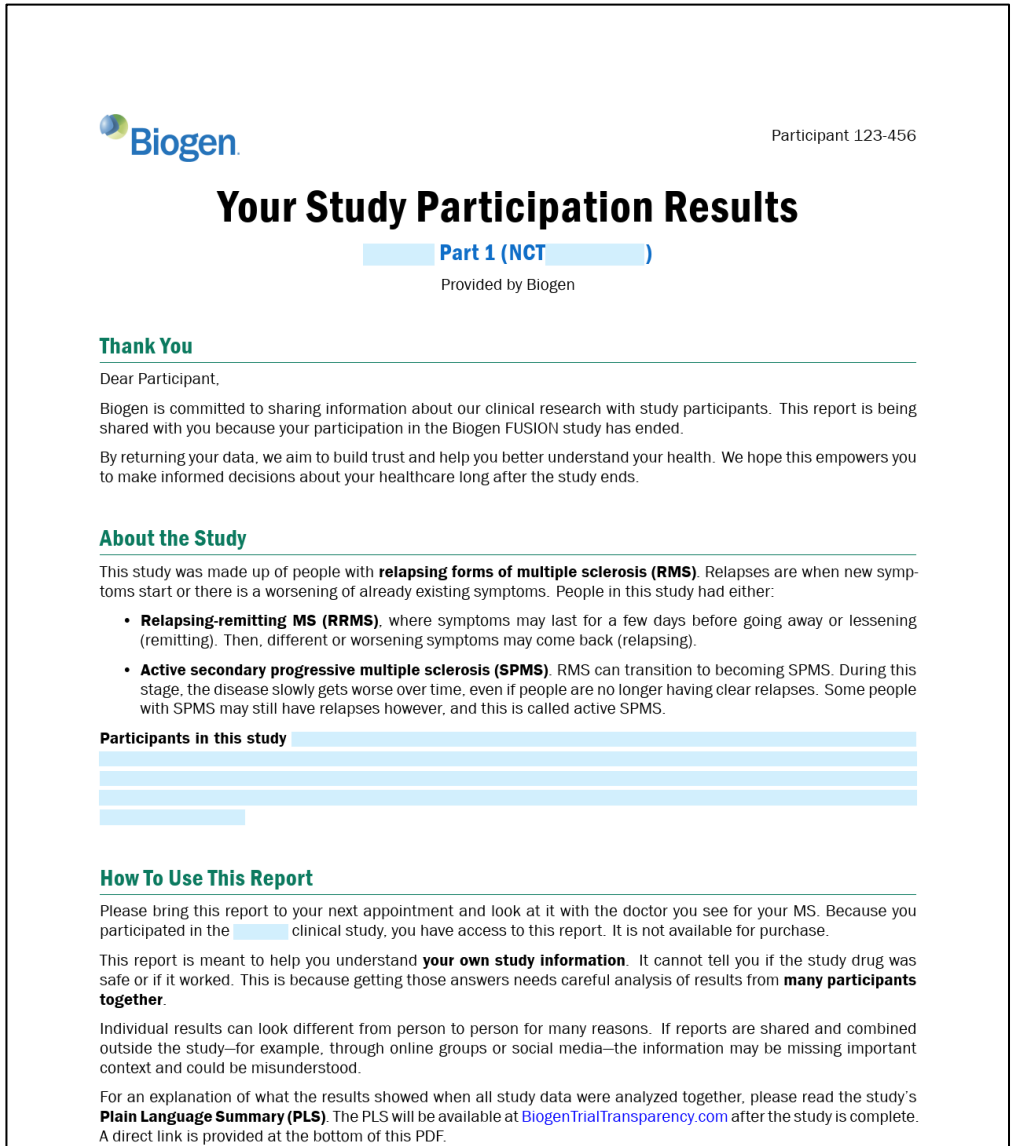
WHAT'S IN A REPORT?



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Participant 123-456

Your Study Participation Results

Part 1 (NCT)

Provided by Biogen

Thank You

Dear Participant,

Biogen is committed to sharing information about our clinical research with study participants. This report is being shared with you because your participation in the Biogen FUSION study has ended.

By returning your data, we aim to build trust and help you better understand your health. We hope this empowers you to make informed decisions about your healthcare long after the study ends.

About the Study

This study was made up of people with **relapsing forms of multiple sclerosis (RMS)**. Relapses are when new symptoms start or there is a worsening of already existing symptoms. People in this study had either:

- **Relapsing-remitting MS (RRMS)**, where symptoms may last for a few days before going away or lessening (remitting). Then, different or worsening symptoms may come back (relapsing).
- **Active secondary progressive multiple sclerosis (SPMS)**. RMS can transition to becoming SPMS. During this stage, the disease slowly gets worse over time, even if people are no longer having clear relapses. Some people with SPMS may still have relapses however, and this is called active SPMS.

Participants in this study

How To Use This Report

Please bring this report to your next appointment and look at it with the doctor you see for your MS. Because you participated in the clinical study, you have access to this report. It is not available for purchase.

This report is meant to help you understand **your own study information**. It cannot tell you if the study drug was safe or if it worked. This is because getting those answers needs careful analysis of results from **many participants together**.

Individual results can look different from person to person for many reasons. If reports are shared and combined outside the study—for example, through online groups or social media—the information may be missing important context and could be misunderstood.

For an explanation of what the results showed when all study data were analyzed together, please read the study's **Plain Language Summary (PLS)**. The PLS will be available at BiogenTrialTransparency.com after the study is complete. A direct link is provided at the bottom of this PDF.

- Salutation & Thank you
- Study Description
- Information about the report
  - Reviewing with your doctor
  - Data privacy
- **Data (in context)**
- Thank you again!
- Resources

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BEST PRACTICES

- **Use plain language** – Avoid jargon and explain complex terms when they first appear
- **Return what is meaningful** – Share data that is condition-specific, interpretable and actionable
- **Give data context** – Describe what data points mean and why we measure them
- **Be clear about use** – Clarify the ways data can and can't be used and direct recipients to review the report with a doctor
- **Communicate with empathy and gratitude** – Address participants directly, be sensitive to emotional findings and say thank you

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EXAMPLE TIMELINE FOR PDR DELIVERY

Study Kickoff
Familiarize study team with PDR initiative, Include PDR in site start-up requirements

Starting 6-12 months before LPO
Secure portal vendor engagement & kickoff; Finalize data spec; Begin drafting report

6 months leading up to LPO
Secure portal live for participant opt-in

DBL - CSR
Reports are finalized and QC'd

CSR + 3 months
Release reports to sites in tandem with Results Plain Language Summaries

6-12 months after return
Shutdown and archive activities

LPO = Last Participant Out
DBL = DataBase Lock
CSR = Clinical Study Report

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LESSONS LEARNED AND NEXT STEPS

Lessons learned:

- ❑ Be clear with study management team about what's being asked of them
- ❑ Scaling up requires a rigidity at odds with personalization
- ❑ Most systems are not built for PDR so don't assume and test what you can
- ❑ PDR team needs to exercise their own judgment
- ❑ A style guide saves time and bandwidth

What comes next:

- ❑ A participant data return playbook, with reusable templates and standards.
- ❑ Modularized Plain Language snippets that can be used like building blocks
- ❑ Broader rollout across the portfolio

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THANK YOU

Participant Data Return Working Group:

Data Stewardship

- Dan Boisvert
- Sam Toscano

Clinical Trial Transparency

- Sudipta Chakraborty
- Alicia Berg
- Morgan Hadley

Clinical Data Management

- Kara Annan

If you're interested in technical details, come see Marianna's talk at the R in Pharma conference: https://rinpharma.com/

The conference is free to attend and takes place 20-21 October 2026

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