

# Being Research Data

Bruce Rosenblum

VP of Content and Workflow Solutions  
of Wiley Partner Solutions, former CEO  
of Inera, and 2020 NISO Fellow



## MUSCLE & NERVE

CLINICAL RESEARCH ARTICLE | [Open Access](#) | 

### Safety and activity of anti-CD14 antibody IC14 (atibuclimab) in ALS: Experience with expanded access protocol

Dario Gelevski BS, Grace Addy BS, Margot Rohrer RN, Caroline Cohen BS, Aimee Roderick MPH, BSN, RN, Allison Winter BS, Judith Carey RN, Jennifer Scalia NP-BC, Megan Yerton AB ... [See all authors](#) ▾

First published: 19 December 2022 | <https://doi.org/10.1002/mus.27775> | Citations: 2

 SECTIONS



PDF



TOOLS



SHARE

## Abstract

### Introduction/Aims

IC14 (atibuclimab) is a monoclonal anti-CD14 antibody. A previous phase 1 trial of 10 participants with amyotrophic lateral sclerosis (ALS) demonstrated initial safety of IC14 in an acute treatment setting. We provided long-term treatment with IC14 to individuals with ALS via an expanded access protocol (EAP) and documented target engagement, biomarker, safety, and disease endpoints.

MUSCLE  
& NERVE

CLINICAL RESEARCH ARTICLE | [Open Access](#) | 

## Safety and activity of anti-CD14 antibody IC14 (atibuclimab) in ALS: Experience with expanded access protocol

Dario Gelevski BS, Grace Addy BS, Margot Rohrer RN, Caroline Cohen BS, Aimee Roderick MPH, BSN, RN, Allison Winter BS, Judith Carey RN, Jennifer Scalia NP-BC, Megan Yerton AB ... [See all authors](#) ▾

First published: 19 December 2022 | <https://doi.org/10.1002/mus.27775> | Citations: 2

☰ SECTIONS

PDF

TOOLS

SHARE

### Abstract

#### Introduction/Aims

IC14 (atibuclimab) is a monoclonal anti-CD14 antibody. A previous phase 1 trial of 10 participants with amyotrophic lateral sclerosis (ALS) demonstrated initial safety of IC14 in an acute treatment setting. We provided long-term treatment with IC14 to individuals with ALS via an expanded access protocol (EAP) and documented target engagement, biomarker, safety, and disease endpoints.

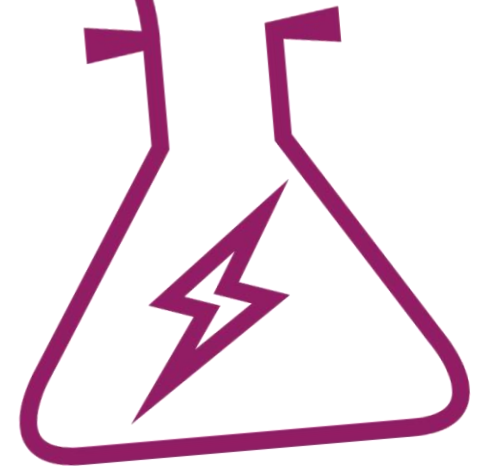
# Becoming research data

A little background



# Becoming research data

- Diagnosed with ALS 6 years ago
- Enrolled in phase 3 clinical trial for promising experimental treatment
- Trial concluded 11 months later
- Enamored with being part of the research process; Inspired to work with amazing researchers





# Becoming research data

- Joined every available research study
- By 2020, no longer qualified for clinical trials
- Offered expanded access program (EAP) opportunity in June 2020

At the Healey Center, we are dedicated to developing effective treatments for ALS and to providing people with ALS access to potentially beneficial therapies.



*Healey & AMG Center Director Merit Cudkowicz, MD, MSc and Co-Director of the NCRI Sabrina Paganoni, MD, PhD explains how the Expanded Access Program increases access to experimental treatments for patients with ALS, while participant Shawn Sarbacker of TechVsALS shares what the EAP program means to him.*

Here's why I'm  
excited!

## MUSCLE & NERVE

CLINICAL RESEARCH ARTICLE | [Open Access](#) |   

### Safety and activity of anti-CD14 antibody IC14 (atibuclimab) in ALS: Experience with expanded access protocol

Dario Gelevski BS, Grace Addy BS, Margot Rohrer RN, Caroline Cohen BS, Aimee Roderick MPH, BSN, RN, Allison Winter BS, Judith Carey RN, Jennifer Scalia NP-BC, Megan Yerton AB ... [See all authors](#) ▾

First published: 19 December 2022 | <https://doi.org/10.1002/mus.27775> | Citations: 2

☰ SECTIONS

 PDF

 TOOLS

 SHARE

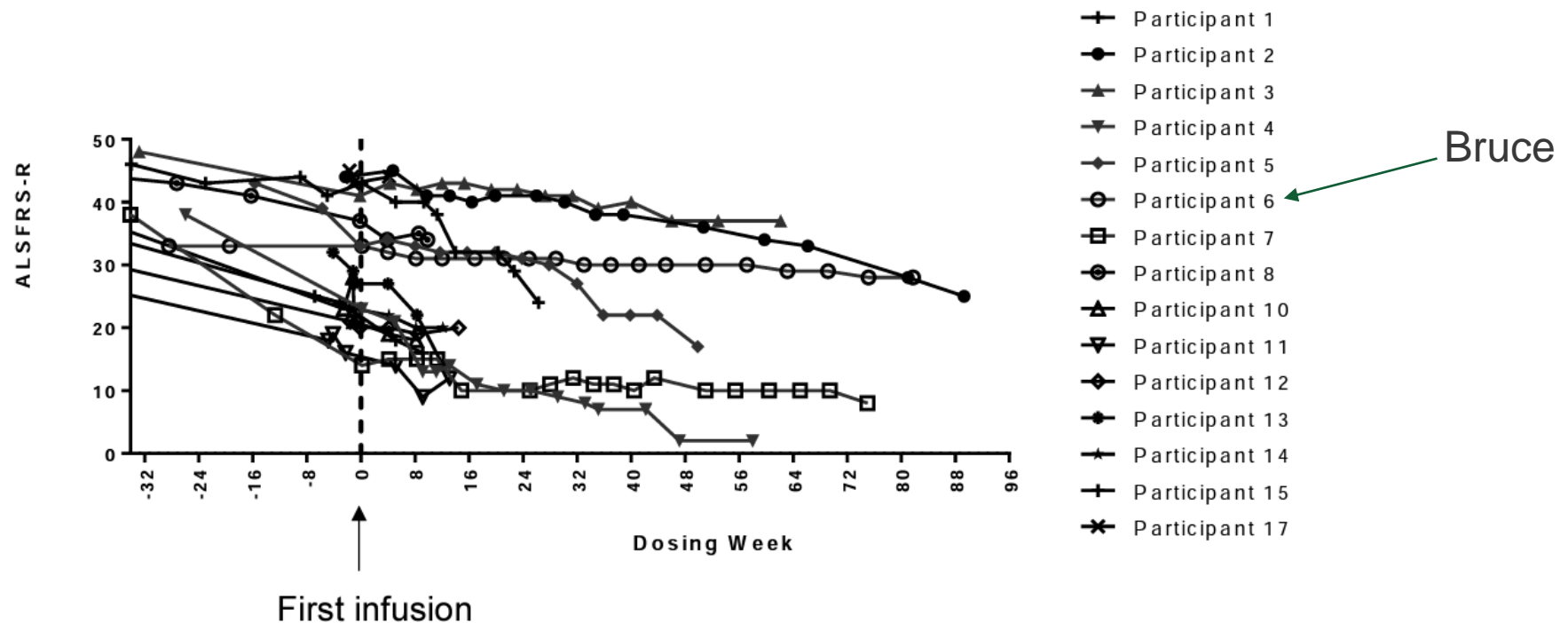
#### Abstract

##### Introduction/Aims

IC14 (atibuclimab) is a monoclonal anti-CD14 antibody. A previous phase 1 trial of 10 participants with amyotrophic lateral sclerosis (ALS) demonstrated initial safety of IC14 in an acute treatment setting. We provided long-term treatment with IC14 to individuals with ALS via an expanded access protocol (EAP) and documented target engagement, biomarker, safety, and disease endpoints.

# Why I'm excited

- Being a data point in a published research paper
- Published in a Wiley journal—this feels like family for me





# Why I'm excited

- **Dario Gelevski**, first author and early-career researcher at Mass General
- **Dr. Merit Cudkowicz**—Director of the Sean M. Healey & AMG Center for ALS, Chief of Neurology at Mass General, Julieanne Dorn Professor of Neurology at Harvard Medical School—is an ALS clinician, researcher, leader, and mentor to young researchers



# Moving the needle



# Researching researchers



# Researching researchers

- Research patient as publisher advocate
- Here's what I've learned frustrates researchers



# Challenge: Overly complex author instructions

- “What really drags an investigator down is the formatting which differs from journal to journal and is extremely detailed and at times hard to figure out”
  - An ALS researcher

Correspondence | [Open Access](#) | [Published: 10 May 2023](#)

## Saving time and money in biomedical publishing: the case for free-format submissions with minimal requirements

[Amy Clotworthy](#), [Megan Davies](#), [Timothy J. Cadman](#), [Jessica Bengtsson](#), [Thea O. Andersen](#), [Manik Kadawathagedara](#), [Johan L. Vinther](#), [Tri-Long Nguyen](#) & [Tibor V. Varga](#) ✉

[BMC Medicine](#) 21, Article number: 172 (2023) | [Cite this article](#)

4341 Accesses | 410 Altmetric | [Metrics](#)

### Abstract

#### Background

Manuscript preparation and the (re)submission of articles can create a significant workload in academic jobs. In this exploratory analysis, we estimate the time and costs needed to meet the diverse formatting requirements for manuscript submissions in biomedical publishing.

## PLOS ONE

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

### Scientific sinkhole: The pernicious price of formatting

Allana G. LeBlanc ✉, Joel D. Barnes, Travis J. Saunders, Mark S. Tremblay, Jean-Philippe Chaput

Published: September 26, 2019 • <https://doi.org/10.1371/journal.pone.0223116>

Article	Authors	Metrics	Comments	Media Coverage	Peer Review
✉					

#### Abstract

Introduction  
Materials and methods  
Results  
Discussion  
Supporting information  
Acknowledgments  
References

Reader Comments  
Figures

#### Abstract

##### Objective

To conduct a time-cost analysis of formatting in scientific publishing.

##### Design

International, cross-sectional study (one-time survey).

##### Setting

Internet-based self-report survey, live between September 2018 and January 2019.

##### Participants



# Challenge: Overly complex submission systems

- “Not to mention my fights with... submission systems (for example, entering every co-author affiliation one by one etc)”
  - An ALS researcher

My Co-Authors					
Order	Name	Institution, Department	E-Mail	Edit	Delete
1	Author, Alice <i>Corresponding Author</i>	ScholarOne, QA Charlottesville, Virginia, United States	Alice.Author@journal.com		

Add a New Co-Author

Special Characters

req E-Mail:

Find

req Sal. Select...

req First (Given) Name:

Middle Name:

req Last (Family) Name:

Institution:

Department:

req Country Germany

State/Province

req City

ResearcherID

Find a ResearcherID

☐ This person is the formal Corresponding Author as denoted on the title page of the manuscript

If you have multiple Institutions and Departments for this author, click [here](#).

+ Add To My Authors

Clear

# Challenge: Unnecessary author proof queries

AQ5: AUTHOR: As per journal style ORCID is required. Please provide.

**B** **I** **U** **x<sup>1</sup>** **x<sub>1</sub>** **Ω**

ORCID for authors:

Dario Gelevski: <https://orcid.org/0000-0002-8287-5331>  
Katherine M. Burke: <https://orcid.org/0000-0002-5820-5880>  
James D. Berry: <https://orcid.org/0000-0003-0898-6081>  
Sabrina Paganoni: <https://orcid.org/0000-0003-0505-1168>  
Merit E. Cudkowicz: <https://orcid.org/0000-0002-7075-1681>

  Save  Cancel

# Key resource: Time

---

*“The key resource in research is not money but the time of researchers. More efficient research management allows more time for research to be done.”*

Source: [Scholarly Kitchen article "Smorgasbord: Trends from the Spring 2023 Meetings and Conferences"](#)

## Key resource: Time

Researchers have only so many hours in a day; if they can spend one less hour on a research article because we have implemented improved workflows and better technology, that's one more hour they can spend on research to try to save my life, and the lives of all ALS patients.



# The OA question





# Open Access



“Why are Open Access publishing fees so high?”

The researcher is the publisher's customer

# You can be research data, too!

---

1. Go to <https://clinicaltrials.gov/>
2. Enter the name of a condition or disease.
3. Press “Search.”
4. On the results page, check “Recruiting” and “Accepts healthy volunteers” in the left-hand column and press “Apply.”
5. Narrow the results by other criteria, such as geographic location, age, and gender.
6. Choose a trial, contact the researcher listed in the trial information.

## Get involved!

# Active colon cancer studies and trials accepting healthy volunteers

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
2	<input type="checkbox"/>	Recruiting	<a href="#">TVB 2640 for Resectable Colon Cancer Other Resectable Cancers; a Window Trial.</a>	<ul style="list-style-type: none"> <li>Colon Cancer</li> </ul>	<ul style="list-style-type: none"> <li>Drug: TVB-2640</li> <li>Other: Placebo</li> </ul>	<ul style="list-style-type: none"> <li>University of Kentucky Lexington, Kentucky, United States</li> </ul>
3	<input type="checkbox"/>	Recruiting	<a href="#">A Study of Using Social Networks to Encourage Three Peers to Complete Screening for Colorectal Cancer</a>	<ul style="list-style-type: none"> <li>Colon Cancer Screening</li> </ul>	<ul style="list-style-type: none"> <li>Other: FITx3 intervention and CRC education</li> <li>Other: Colorectal Cancer (CRC) education alone</li> </ul>	<ul style="list-style-type: none"> <li>Memoiral Sloan Kettering Basking Ridge (All Protocol Activities) Basking Ridge, New Jersey, United States</li> <li>Memorial Sloan Kettering Monmouth (All Protocol Activities) Middletown, New Jersey, United States</li> <li>Memorial Sloan Kettering Bergen (All Protocol Activities) Montvale, New Jersey, United States</li> <li>(and 4 more...)</li> </ul>
4	<input type="checkbox"/>	Recruiting	<a href="#">Effect of a Prehabilitation Mobile Application Versus Standard of Care Before Colon Cancer Surgery.</a>	<ul style="list-style-type: none"> <li>Prehabilitation</li> <li>mHealth</li> <li>Usability</li> </ul>	<ul style="list-style-type: none"> <li>Device: PREHapp</li> </ul>	<ul style="list-style-type: none"> <li>Hospital General Universitario de Elche Elche, Alicante, Spain</li> </ul>
5	<input type="checkbox"/>	Recruiting	<a href="#">Efficacy of Colonoscopy, Colon Capsule and Fecal Immunological Test for Colorectal Cancer Screening</a>	<ul style="list-style-type: none"> <li>Colon Cancer</li> <li>Rectum Cancer</li> </ul>	<ul style="list-style-type: none"> <li>Procedure: optical colonoscopy</li> <li>Procedure: colon capsule endoscopy</li> <li>Diagnostic Test: fecal immunological test (FIT)</li> </ul>	<ul style="list-style-type: none"> <li>CH Colmar Colmar, Alsace, France</li> <li>CHU de Bordeaux - Hôpital Haut-Lévêque Pessac, Aquitaine, France</li> <li>CHU de Dijon Dijon, Bourgogne, France</li> <li>(and 16 more...)</li> </ul>
6	<input type="checkbox"/>	Recruiting	<a href="#">R vs L Lateral Decubitus Positioning in Colonoscopy</a>	<ul style="list-style-type: none"> <li>Colonic Adenoma</li> <li>Colonic Cancer</li> </ul>	<ul style="list-style-type: none"> <li>Procedure: Colonoscopy - Position Change</li> </ul>	<ul style="list-style-type: none"> <li>Health Sciences Centre Saint John's, Newfoundland and Labrador, Canada</li> </ul>
7	<input type="checkbox"/>	Recruiting	<a href="#">Gastrointestinal Biomarkers in Tissue and Biological Fluid Samples From Patients and Healthy Participants</a>	<ul style="list-style-type: none"> <li>Colorectal Cancer</li> <li>Esophageal Cancer</li> <li>Gastric Cancer</li> <li>(and 2 more...)</li> </ul>	<ul style="list-style-type: none"> <li>Genetic: protein analysis</li> <li>Genetic: proteomic profiling</li> <li>Other: biologic sample preservation procedure</li> </ul>	<ul style="list-style-type: none"> <li>Vanderbilt-Ingram Cancer Center - Cool Springs Nashville, Tennessee, United States</li> <li>Vanderbilt-Ingram Cancer Center at Franklin Nashville, Tennessee, United States</li> </ul>



# You can be research data, too!

---

1. Go to <https://clinicaltrials.gov/>
2. Enter the name of a condition or disease.
3. Press “Search.”
4. On the results page, check “Recruiting” and “Accepts healthy volunteers” in the left-hand column and press “Apply.”
5. Narrow the results by other criteria, such as geographic location, age, and gender.
6. Choose a trial, contact the researcher listed in the trial information.

## Get involved!



Thank You!

[brosenblum@wiley.com](mailto:brosenblum@wiley.com)