

LETTER

Along the Way

Meredith Nahm Zozus

An older data manager had an opportunity to guide a younger one. Choosing from what she had heard from colleagues, witnessed, or learned the hard way, discover what she advised.

Keywords: Manage Clinical Research Data

One day, an older data manager had an opportunity to guide a younger one. Choosing from what she had heard from colleagues, witnessed, or learned the hard way, she said:

Make sure you know about all the study data, their source(s), and how they will be used. It is your responsibility to get them safely to the analysis.

Keep the end in mind. I mean the primary endpoints, the analysis needs, and curating the data for reuse – both science and regulatory decision-making require reproducibility.

The data processing and checking should be aligned with the data type and source; the effort should be aligned with the risk.

Remember that operations performed on data must be specified. Those performed by humans and machines must be checked, though you will use different methods for each.

Along the way:

- Collect the raw data and let the computer make the calculations; in fact, let the computer do as much as possible.
- Check for data problems early and often; in fact, do everything as early as possible.

- Remember that managing the data lifecycle is the key to managing the data, and using the data is the key to managing the study.
- Remember that all data must have a source; all changes to data must have a reason and all changes must be traceable.
- Stay audit-ready and document anything that does not go according to plan, remember the response should be aligned with the risk.

There will always be problems along the way. Expect challenges. Remain vigilant. Communicate frequently with your colleagues on the study team so that you work swiftly and in concert to overcome any challenges. You will need your team and they will need you.

Your field is changing more quickly than you are. You might need a Large Language Model (LLM) to keep up. Try to learn something new every day, along the way.

Meredith Nahm Zozus

Competing Interests

The author has no competing interests to declare.

How to cite this article: Zozus MN. Along the Way. *Journal of the Society for Clinical Data Management*. 2025; 5(1): 3, pp. 1–2. DOI: <https://doi.org/10.47912/jscdm.419>

Submitted: 22 December 2024

Accepted: 13 January 2025

Published: 27 March 2025

Copyright: © 2025 SCDM publishes JSCDM content in an open access manner under a Attribution-Non-Commercial-ShareAlike (CC BY-NC-SA) license. This license lets others remix, adapt, and build upon the work non-commercially, as long as they credit SCDM and the author and license their new creations under the identical terms. See <https://creativecommons.org/licenses/by-nc-sa/4.0/>.



Journal of the Society for Clinical Data Management is a peer-reviewed open access journal published by Society for Clinical Data Management.

OPEN ACCESS A circular icon with a stylized 'O' and 'A' inside, representing the Open Access logo.