Cytel

Working Smarter with AI:
The Evolving Role of the Trial Statistician

Hannes Engberg Raeder, 17th of September 2026

But First…

Not a tool demo
Personal examples from clinical trial statistics
Some use cases require a closed, approved AI environment

Getting Up to Speed

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Getting Up to Speed

AI can turn unfamiliar protocol text into a plain-language summary

2.3 **Refining therapy for subgroups of patients: The HER2 alteration in DCIS**

DCIS is more likely than invasive breast cancer to overexpress HER2. As reported by the Intergroup Study 0011, HER2 was overexpressed in 56% of pure DCIS specimens (including 77% of the comedo subtype), in 22% of DCIS associated with infiltrating ductal carcinoma (IDC), and in only 11% of IDC alone.[25,26]

Recently, the expression profiles of nearly 12,000 annotated genes in 25 cases of pure DCIS and 25 cases of pure infiltrating ductal cancer were compared.[3] HER2 was upregulated 3.9-fold in DCIS compared with invasive breast cancer. HER2 expression in DCIS and in invasive breast cancer within the same neoplasm were concordant in 100% of cancers tested.[27] Thus, interrupting this signal transduction pathway early might prevent development of aggressive (HER2-positive) invasive breast cancer and could have a major impact on breast cancer mortality.

A literature review revealed considerable variability in HER2 expression in DCIS, ranging from 28% to 65% (Table 1). Most investigators used immunohistochemical (IHC) staining to measure HER2 expression. The antibodies used, the methods of fixation, the duration of tissue storage, and the antigen retrieval techniques are only some of the variables that could have affected results. Only one of the studies performed both IHC and fluorescence in-situ hybridization (FISH) testing for HER2 on the same specimens. The investigators, from Rush University Medical Center, evaluated 37 specimens: Twenty-two were HER2-positive by IHC and nineteen of these were also amplified by FISH. No specimens were FISH-amplified and IHC-negative.[28]

This section explains why the study focused on **HER2-positive DCIS**.

DCIS is an early, non-invasive form of breast cancer where abnormal cells are still contained inside the milk ducts. **HER2** is a protein that can make cancer cells grow faster.

Researchers found that HER2 is often more common in DCIS than in invasive breast cancer. This suggested that HER2 may play an important role early in the development of breast cancer.

They therefore wanted to test whether blocking HER2 with trastuzumab could reduce the risk that DCIS returns or later becomes invasive cancer.

The text also explains that HER2 results can vary depending on the laboratory method. The two main tests are:

- **IHC:** measures the amount of HER2 protein
- **FISH:** checks for extra copies of the HER2 gene

In simple terms: the protocol is saying that HER2 may help some DCIS lesions grow, so targeting HER2 could potentially improve treatment.

Getting Up to Speed

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Plan B

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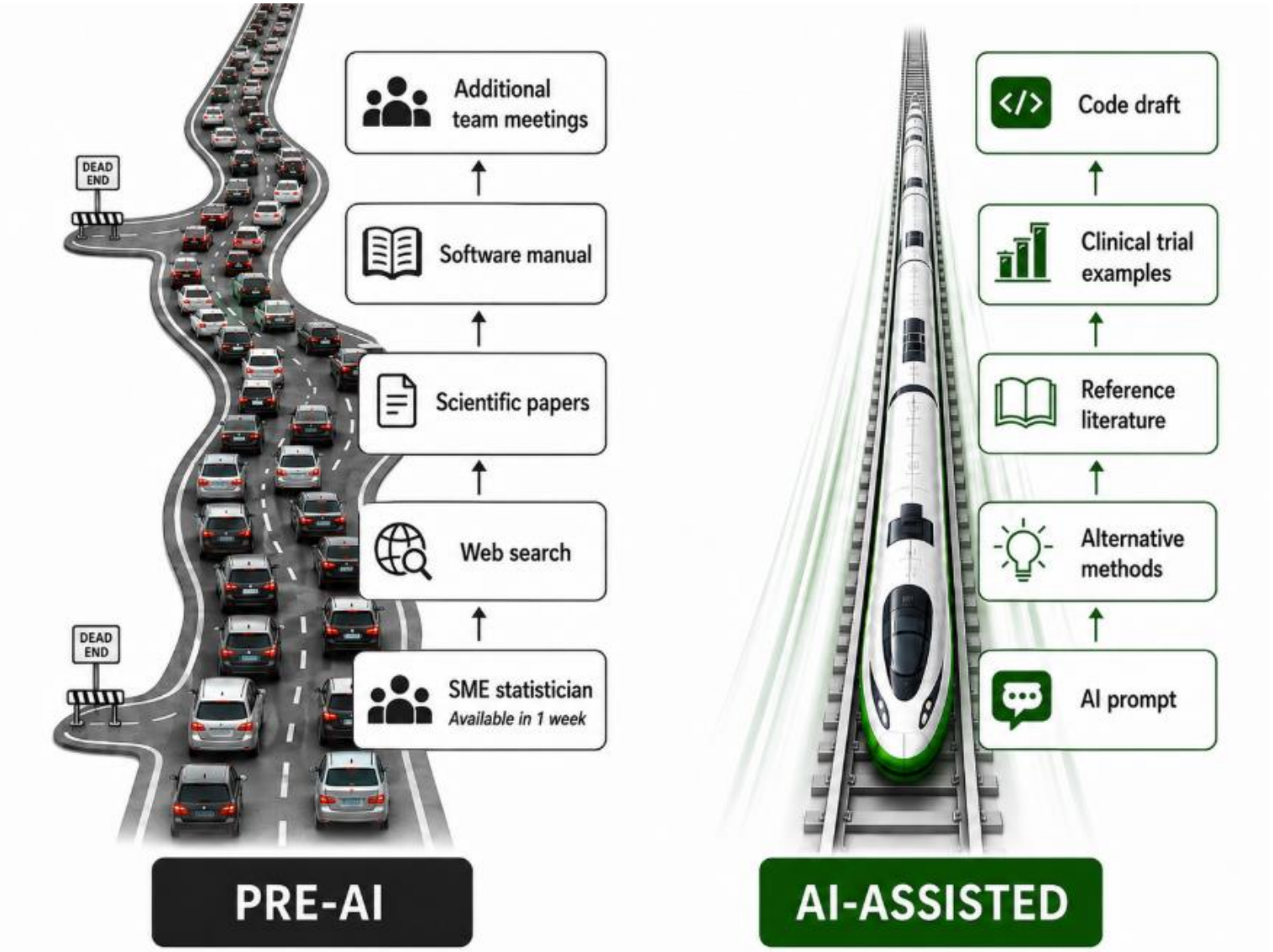
Plan B



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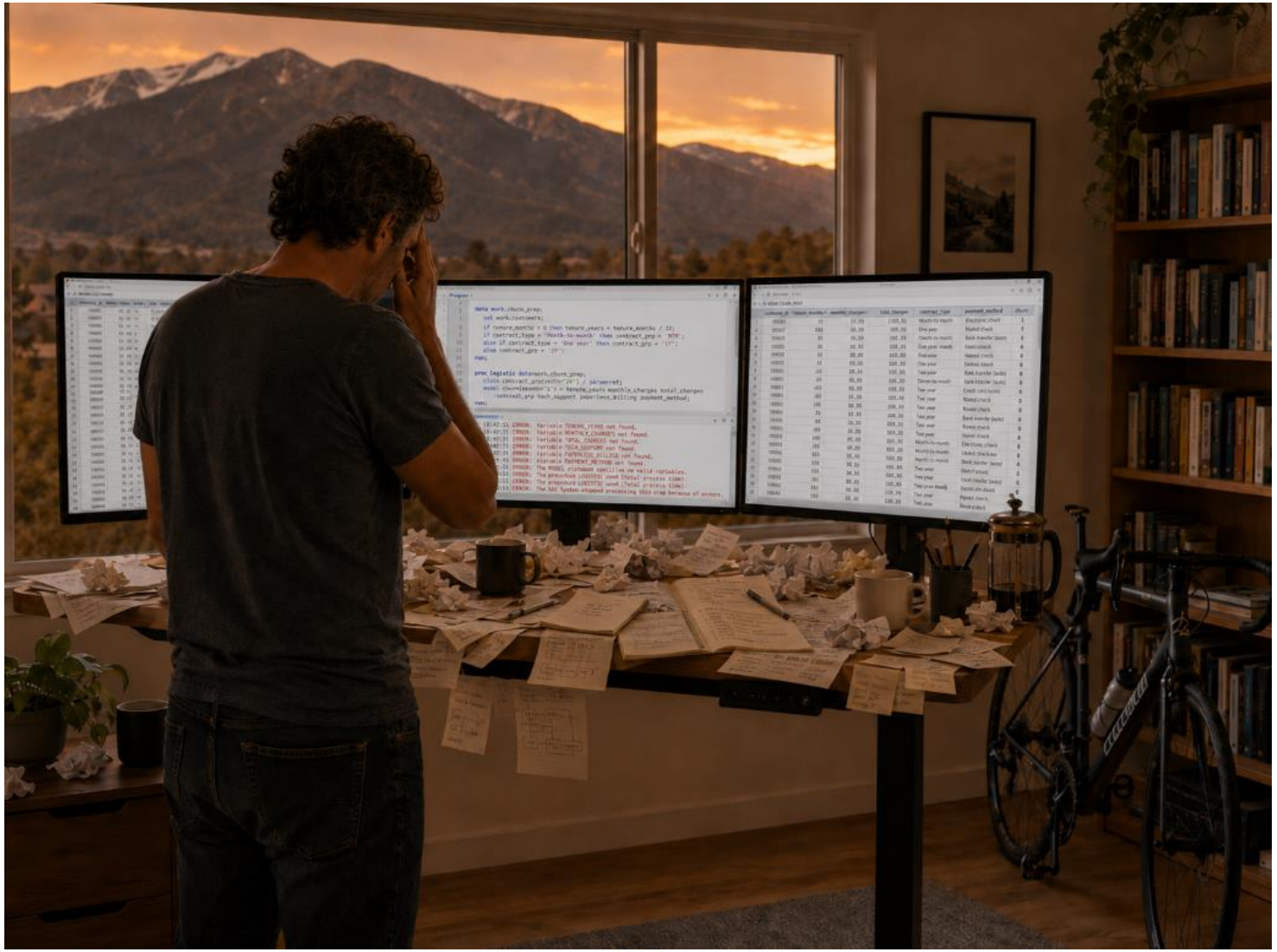
Code Faster, Less Frustration



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Code Faster, Less Frustration

Describe your task briefly and clearly:

Write SAS code to calculate change from baseline for each subject.
Use the attached PROC CONTENTS screenshot to identify the correct variable names and data types. Use variables <xxx>. For each subject, find the baseline row, carry that baseline value forward, and calculate:
change = current value − baseline value
Keep the original dataset structure and add variables for baseline value and change from baseline. Handle missing values safely. Return copy-past friendly code, do not add additional comments.

Alphabetic List of Variables and Attributes

#	Variable	Type	Len	Format	Informat
18	AEACCMED	Num	8	11.	11.
19	AEACCMED_RAW	Char	2	$2.	$2.
20	AEACHCP	Num	8	11.	11.
21	AEACHCP_RAW	Char	2	$2.	$2.
22	AEACHOS	Num	8	11.	11.
23	AEACHOS_RAW	Char	2	$2.	$2.
24	AEACNC	Char	200	$200.	$200.
25	AEACNC_STD	Char	1	$1.	$1.
26	AEACNNO	Num	8	11.	11.
27	AEACNNO_RAW	Char	2	$2.	$2.
28	AECAT	Char	200	$200.	$200.
29	AECAT_STD	Char	200	$200.	$200.
30	AECYCVID	Char	8	$8.	$8.
31	AEDIR	Char	200	$200.	$200.
32	AEDIR_STD	Char	5	$5.	$5.
33	AEDIS	Char	200	$200.	$200.
34	AEDIS_STD	Char	1	$1.	$1.

Code Faster, Less Frustration

Of course, you can also do:

- **Updating existing code**
- **Extending or modify analyses**
- **Code review**
- **Documenting code**

The Unpleasant Surprise

When the protocol, SAP, ADaM specs, and shells do not match

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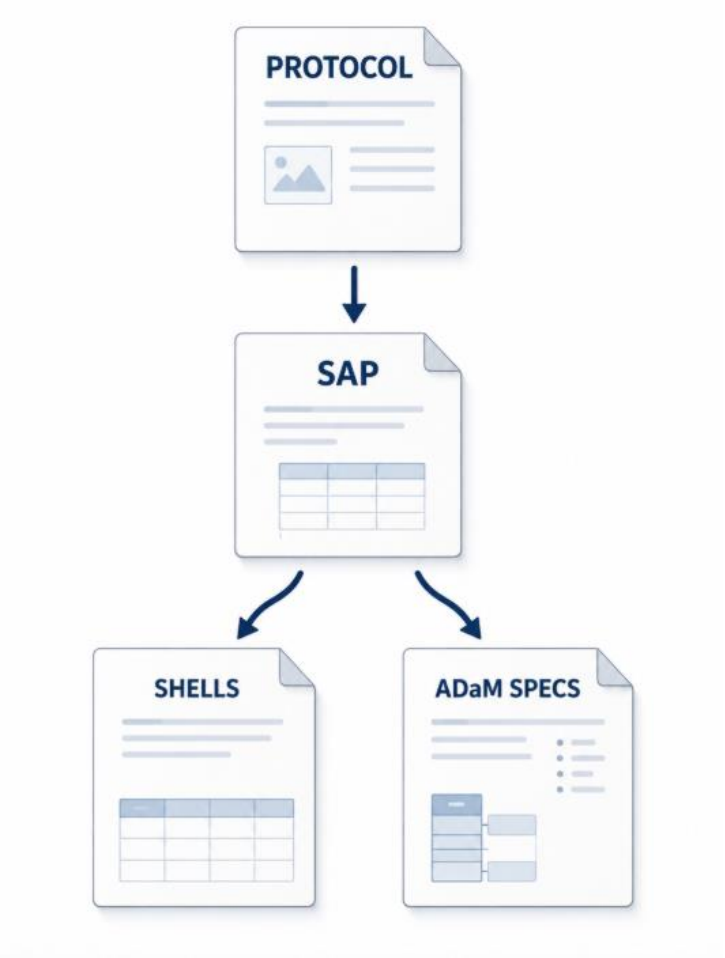
The Unpleasant Surprise

Use AI to check:

- Endpoint wording
- Analysis sets
- Analysis visit window
- Estimand strategies
- Missing data rules
- Shell titles and footnotes



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Lost in Translation

Subject Project XYZ

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Lost in Translation

Getting the Message Across with AI

Hello Maria,

I hope you are doing well.

I wanted to flag a data issue for Site 002 that may need to be handled before the next analysis.
Participant 002-XXXX was randomized to the 50 ug group. According to the current data, the participant received 50 ug for the first dose. For the second dose, it looks like the site may have entered the randomized dose for another participant by mistake.
Based on the available information, it is possible that the participant actually received the correct dose, but the data currently do not reflect this clearly. This means that the treatment exposure in the database may not match what happened at the site.
For the next analysis, we may need to handle this at the programming level, unless the data can be corrected or clarified before the cut-off.

Could you please help confirm the correct dose information for this participant, or advise how this should be handled?

Best regards,
Hannes

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AI Helps. We Still Lead

- **Demonstrate scientific judgment**
- **Regulatory understanding**
- **Lead discussions**

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Q&A