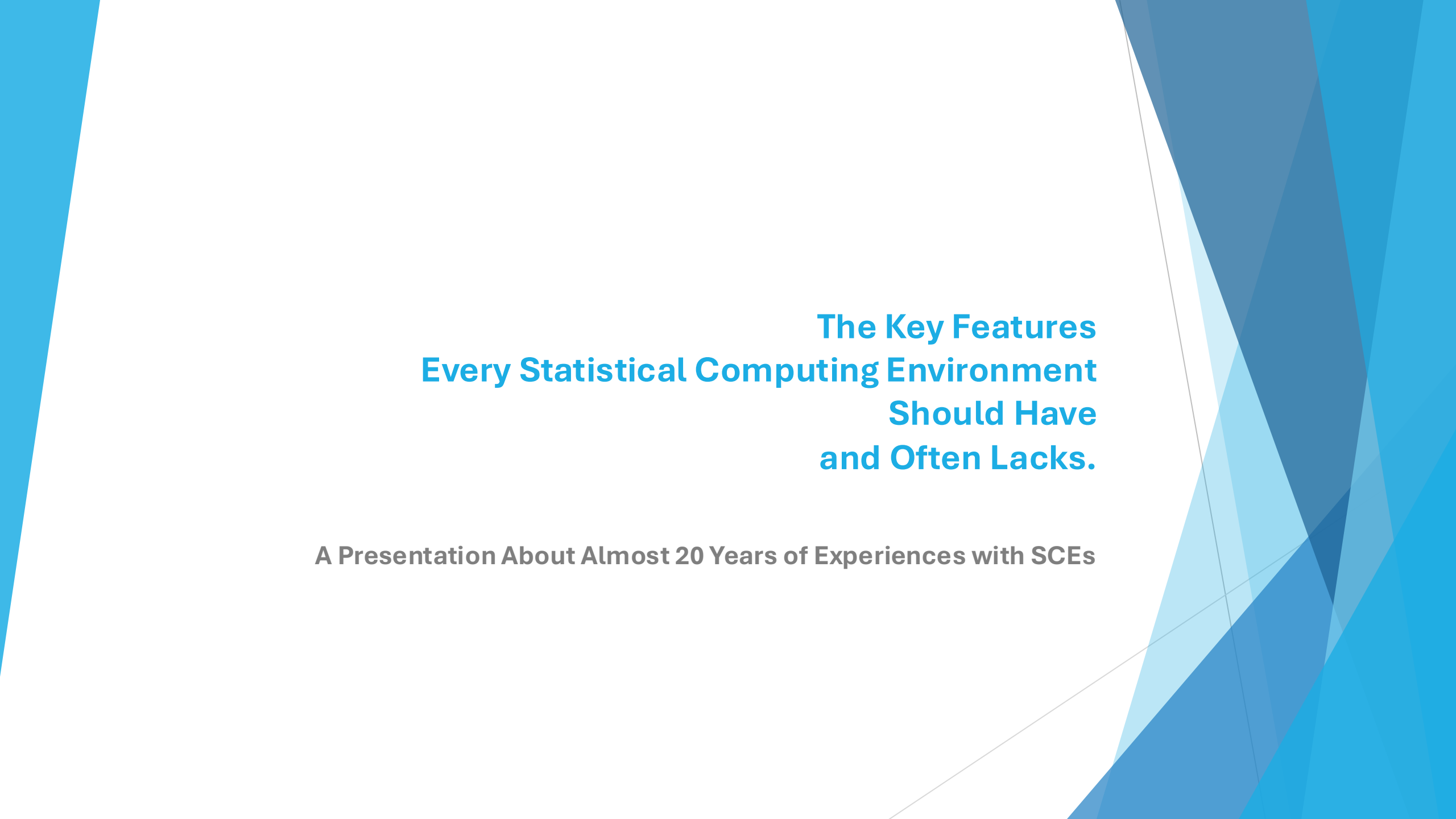


The background of the slide features abstract, overlapping geometric shapes in various shades of blue, ranging from light sky blue to deep navy blue. These shapes are primarily located on the right side and bottom, creating a modern, dynamic feel. The main text is centered on a white background.

# **The Key Features Every Statistical Computing Environment Should Have and Often Lacks.**

**A Presentation About Almost 20 Years of Experiences with SCEs**

# Outline

- ▶ Why this talk?
- ▶ What is the SCE / What should be part of
- ▶ The single Parts and what they should be

# Why this talk?

- ▶ A reflection on nearly 20 years of building and using SCEs.
- ▶ PhUSE Presentation:
  - ▶ How to exchange SAS programs between a “custom” environment and the official SCE solution from an external vendor
- ▶ Why is it required to use an external environment for development?
  - ▶ Vendors often don't see the SCEs as a development environment
  - ▶ Support to store data and results and execute programs

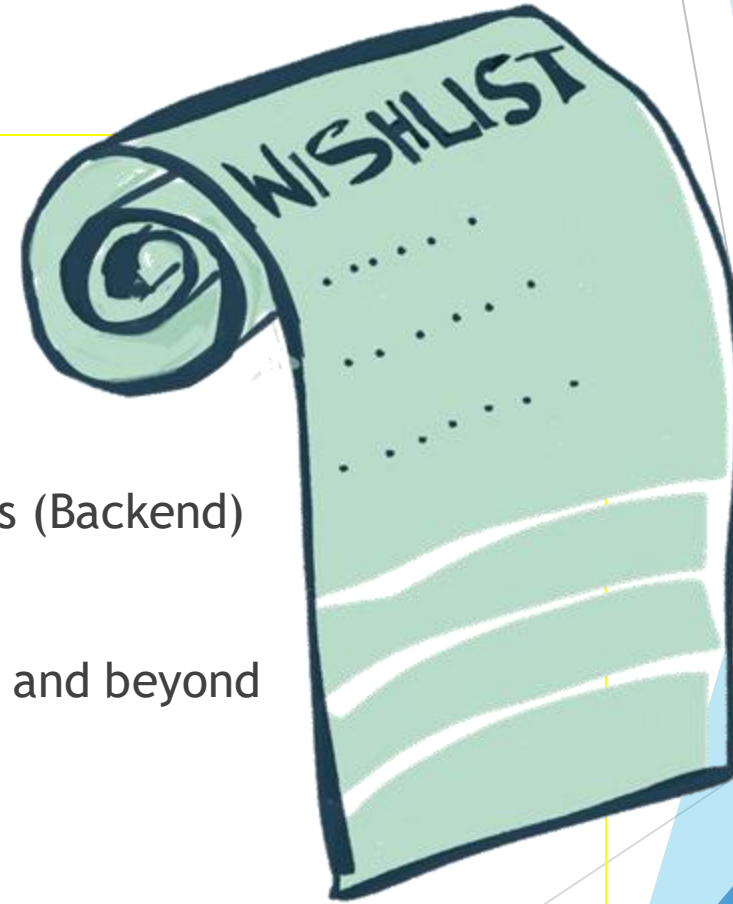
# What is the SCE

- ▶ A „window“ into the Study Analysis
- ▶ Nr. 1 „Application“ for Study Analysts and possibly Statisticians
- ▶ Provide confidence in Data, Programs and Outputs
- ▶ Should be “comfortable” and make some „fun“ when using



# What should be part of an SCE

- ▶ Analyst **want** A Program Editor
- ▶ Scientist **want** A Data Browser, Data Access
- ▶ IT / QA **want** Data Governance, Security, Audit Trails (Backend)
- ▶ Managers **want** Everything from eCRF to Submission and beyond
- ▶ Nobody seem to **want** A Navigator / Explorer



# The Program Editor

```
data step_2;  
  set step_1;  
  ATTRIB outvar LABEL = "Output Variable" FORMAT=8.2;  
  outvar = max(in_var1, in_var2);  
  IF (group = 1) THEN DO; %** That's for "Very high value";  
    IF (15 <= aval) and (aval < 450) and (aval <= (0.8 * _base)) THEN OUTPUT;  
  END;  
  ELSE IF (group = 2) THEN DO; %** That's for "High value";  
    IF (aval < 15) and (aval <= (0.7 * _base)) THEN OUTPUT;  
  END;  
  ELSE PUT "ERROR: Invalid value" &subj_var.= group=;  
RUN;
```

- Display and edit program content



# The Program Editor

```
13 data step_2;  
14     set step_1;  
15     ATTRIB outvar LABEL = "Output Variable" FORMAT=8.2;  
16     outvar = max(in_var1, in_var2);  
17     IF (group = 1) THEN DO; *** That's for "Very high value";  
18         IF (15 <= aval) and (aval < 450) and (aval <= (0.8 * _base)) THEN OUTPUT;  
19     END;  
20     ELSE IF (group = 2) THEN DO; *** That's for "High value";  
21         IF (aval < 15) and (aval <= (0.7 * _base)) THEN OUTPUT;  
22     END;  
23     ELSE PUT "ERROR: Invalid value" &subj_var.= group=;  
24 RUN;  
25
```

- ▶ Display and edit program content
- ▶ Possibly with some nice colours



# The Program Editor

```
13 data step_2;
14     set step_1;
15     ATTRIB outvar LABEL = "Output Variable" FORMAT=8.2;
16     outvar = max(in_var1, in_var2);
17     IF (group = 1) THEN DO; *** That's for "Very high value";
18         IF (15 <= aval) and (aval < 450) and (aval <= (0.8 * _base)) THEN OUTPUT;
19     END;
20     ELSE IF (group = 2) THEN DO; *** That's for "High value";
21         IF (aval < 15) and (aval <= (0.7 * _base)) THEN OUTPUT;
22     END;
23     ELSE PUT "ERROR: Invalid value" &subj_var.= group=;
24 RUN;
```

- ▶ Possibly with some nice colours
- ▶ And some syntax checks

# The Program Editor

```
13 data step_2;
14     set step_1;
15     ATTRIB outvar LABEL = "Output Variable" FORCE;
16     outvar = max(in_var1, in_var2);
17     IF (group = 1) THEN DO; *** That's for "Very high"
18         IF (15 <= aval) and (aval < 450) and (aval <= (0.8 * _base)) THEN OUTPUT;
19     END;
20     ELSE IF (group = 2) THEN DO; *** That's for "High value";
21         IF (aval < 15) and (aval <= (0.7 * _base)) THEN OUTPUT;
22     END;
23     ELSE PUT "ERROR: Invalid value" &subj_var.= group=;
24 RUN;
```

- ▶ Possibly with some nice colours
- ▶ And some syntax checks

# The Program Editor

```
18
19 data step_2;
20     set step_1;
21     ATTRIB outvar LABEL = "Output Variable" FORMAT=8.2;
22     outvar = max(in_var1, in_var2);
23     IF (group = 1) THEN DO; *** Thats for "Very high value";
24         IF (15 <= aval) and (aval < 450) and (aval <= (0.8 * _base)) THEN OUTPUT;
25     END;
26     ELSE IF (group = 2) THEN DO; *** Thats for "High value";
27         IF (aval < 15) and (aval <= (0.7 * _base)) THEN OUTPUT;
28     END;
29     ELSE PUT "ERROR: Invalid value" &subj_var.= group=;
30     END;
    RUN;
```

**ERROR: No matching DO/SELECT statement.**

- ▶ Possibly with some nice colours
- ▶ And some syntax checks

# The Program Editor

```
13 data step_2;  
14     set step_1;  
15     ATTRIB outvar LABEL = "Output Variable" FORMAT=8.2;  
16     outvar = max(in_var1, in_var2);  
17     IF (group = 1) THEN DO; *** That's for "Very high value";  
18         IF (15 <= aval) and (aval < 450) and (aval <= (0.8 * _base)) THEN OUTPUT;  
19     END;  
20     ELSE IF (group = 2) THEN DO; *** That's for "High value";  
21         IF (aval < 15) and (aval <= (0.7 * _base)) THEN OUTPUT;  
22     END;  
23     ELSE PUT "ERROR: Invalid value" &subj_var.= group=;  
24 RUN;  
25
```

- ▶ And some syntax checks
- ▶ Or even better: correct colours

# The Program Editor

```
13 data step_2;  
14   set step_1;  
15   ATTRIB outvar LABEL = "Output Variable" FORMAT=8.2;  
16   outvar = max(in_var1, in_var2);  
17   IF (group = 1) THEN DO; *** That is for "Very high value";  
18     (15 <= aval) and (aval < 450) and (aval <= (0.8 * _base)) THEN OUTPUT;  
19   ELSE IF (group = 2) THEN DO; *** That is for "High value";  
20     (15 <= aval) and (aval <= (0.7 * _base)) THEN OUTPUT;  
21   IF (aval < 15) THEN DO;  
22     END;  
23   ELSE PUT "ERROR: Invalid value" &subj_var.= group=;  
24 RUN;  
25
```

**Name:** STEP\_1  
**Observations:** 12005  
**Variables:** 61

**Call:** MAX(value1 <, value2,...>)  
**Name:** MAX  
**Category:** Descriptive Statistics  
**Description:** Returns the largest value.

**Name:** aval  
**Label:** Analysis Value  
**Type:** NUM  
**Format:** 8.2

**&subj\_var.= USUBJID**

- And some explanations

# The Program Editor

```
32  
33 PROC SORT DATA=input_1; BY var1 var2; RUN;  
34 PROC SORT DATA=input_2; BY var1 var2; RUN;  
35 DATA output;  
36     MERGE input_1 input_2;  
37     BY var1 var2;  
38 RUN;  
39
```

- Some Templates for repetitive code

# The Program Editor

```
13 data step_2;  
14     set step_1;  
15     ATTRIB outvar LABEL = "Output Variable" FORMAT=8.2;  
i 16     outvar = in_var1 / in_var2;  
17     IF (group = 1) THEN DO; *** That's for "Very high value";  
18         IF (15 <= aval) and (aval < "50") and (aval < (9.8 * base)) THEN OUTPUT;  
19     END;  
20     ELSE IF (group = 2)  
21         IF (aval < 15) a  
22     END;  
23     ELSE PUT "ERROR: Invalid value" &subj_var.= group=;  
24 RUN;  
25
```

NOTE: Division by zero detected.

- ▶ Run code interactive and retrieve the log at the correct location.

# The Program Editor

- Show what changed for validation

```
1  /*****  
2  *  
3  * Example Program Header  
4  *  
5  * @purpose This program hosws how the git blame feature looks  
6  *  
7  * @author Michael Weiss  
8  * @date 2025-10-12  
9  *****/  
10  
11 DATA example;  
12     SET sashelp.class;  
13     IF age > 14;  
14     KEEP name age sex weight height;  
15 RUN;  
16  
17 PROC PRINT DATA=example;  
18 RUN;
```

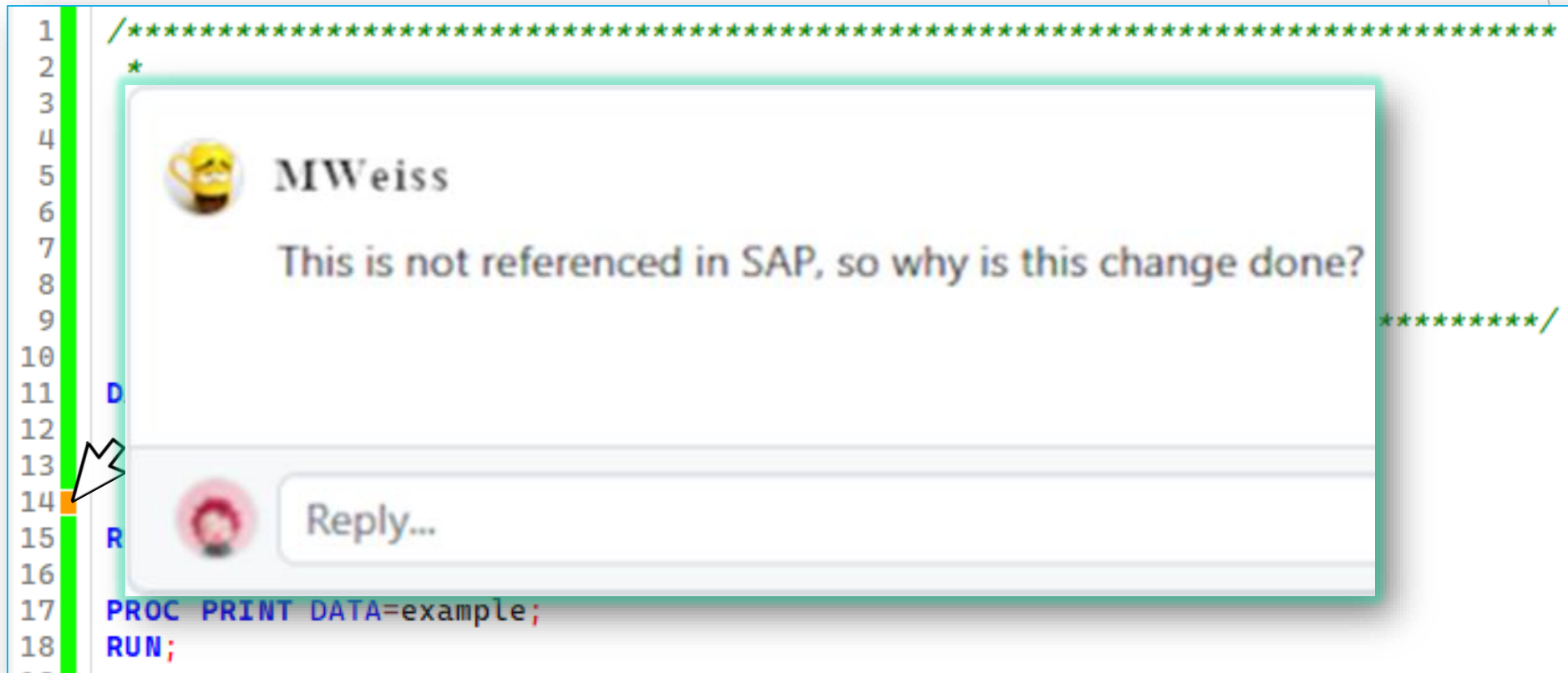
# The Program Editor

- Show what changed for validation

```
1  /*****  
2  *  
3  * Example Program Header  
4  *  
5  * @purpose This program hosws how the git blame feature looks  
6  *  
7  * @author Michael Weiss  
8  * @date 2025-10-12  
9  *****/  
10  
11 DA  
12 13 IF age  
13 14  
14 14 KEEP n  
15 RU  
16  
17 PR  
18 RU 15 RUN;
```

# The Program Editor

- ▶ Allow to add comments



The screenshot displays the SAP Program Editor interface. On the left, a vertical line of line numbers from 1 to 18 is visible. The main editor area contains the following text:

```
1  /*****  
2  *  
3  
4  
5  
6  
7  
8  
9  
10  
11  D  
12  
13  
14  R  
15  
16  
17  PROC PRINT DATA=example;  
18  RUN;
```

A comment box overlay is positioned in the center of the editor. It features a yellow smiley face icon and the name "MWeiss". The text inside the box reads: "This is not referenced in SAP, so why is this change done?". Below the text is a "Reply..." button. A mouse cursor is pointing at the "Reply..." button. The comment box is bordered by a green line. The text "\*\*\*\*\*/" is visible on the right side of the comment box.

# The Data Browser

- ▶ A simple Table that displays the Data

|   | STUDYID      | SUBJID | USUBJID     | TRTP    | TRTPN | TRTA    |
|---|--------------|--------|-------------|---------|-------|---------|
| 1 | CDISCPILO... | 1015   | 01-701-1015 | Placebo | 0     | Placebo |
| 2 | CDISCPILO... | 1015   | 01-701-1015 | Placebo | 0     | Placebo |
| 3 | CDISCPILO... | 1015   | 01-701-1015 | Placebo | 0     | Placebo |
| 4 | CDISCPILO... | 1015   | 01-701-1015 | Placebo | 0     | Placebo |
| 5 | CDISCPILO... | 1015   | 01-701-1015 | Placebo | 0     | Placebo |
| 6 | CDISCPILO... | 1015   | 01-701-1015 | Placebo | 0     | Placebo |
| 7 | CDISCPILO... | 1015   | 01-701-1015 | Placebo | 0     | Placebo |
| 8 | CDISCPILO... | 1015   | 01-701-1015 | Placebo | 0     | Placebo |
| 9 | CDISCPILO... | 1015   | 01-701-1015 | Placebo | 0     | Placebo |

# The Data Browser

- ▶ A simple Table that displays the Data
- ▶ And should display labels

|   | STUDYID<br>Study<br>Identifier | SUBJID<br>Subject<br>Identifier for<br>the Study | USUBJID<br>Unique<br>Subject<br>Identifier | TRTP<br>Planned<br>Treatment | TRTPN<br>Planned<br>Treatment<br>(N) | TRTA<br>Actual<br>Treatment |
|---|--------------------------------|--------------------------------------------------|--------------------------------------------|------------------------------|--------------------------------------|-----------------------------|
| 1 | CDISCILO...                    | 1015                                             | 01-701-1015                                | Placebo                      | 0                                    | Placebo                     |
| 2 | CDISCILO...                    | 1015                                             | 01-701-1015                                | Placebo                      | 0                                    | Placebo                     |
| 3 | CDISCILO...                    | 1015                                             | 01-701-1015                                | Placebo                      | 0                                    | Placebo                     |
| 4 | CDISCILO...                    | 1015                                             | 01-701-1015                                | Placebo                      | 0                                    | Placebo                     |
| 5 | CDISCILO...                    | 1015                                             | 01-701-1015                                | Placebo                      | 0                                    | Placebo                     |
| 6 | CDISCILO...                    | 1015                                             | 01-701-1015                                | Placebo                      | 0                                    | Placebo                     |
| 7 | CDISCILO...                    | 1015                                             | 01-701-1015                                | Placebo                      | 0                                    | Placebo                     |
| 8 | CDISCILO...                    | 1015                                             | 01-701-1015                                | Placebo                      | 0                                    | Placebo                     |
| 9 | CDISCILO...                    | 1015                                             | 01-701-1015                                | Placebo                      | 0                                    | Placebo                     |

# The Data Browser

- ▶ A simple Table that displays the Data
- ▶ And
- ▶ With look

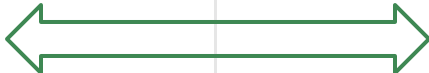
|   | STUDYID<br>Study Identifier | SUBJID<br>Subject Identifier for the Study | USUBJID<br>Unique Subject Identifier | TRTP<br>Planned Treatment | TRTPN<br>Planned Treatment (N) | TRTA<br>Actual Treatment |
|---|-----------------------------|--------------------------------------------|--------------------------------------|---------------------------|--------------------------------|--------------------------|
| 1 | CDISCILO...                 | 1015                                       | 01-701-1015                          | Placebo                   | 0                              | Placebo                  |
| 2 | CDISCILO...                 | 1015                                       | 01-701-1015                          | Placebo                   | 0                              | Placebo                  |
|   |                             |                                            |                                      |                           | 0                              | Placebo                  |
|   |                             |                                            |                                      |                           | 0                              | Placebo                  |
|   |                             |                                            |                                      |                           | 0                              | Placebo                  |
|   |                             |                                            |                                      |                           | 0                              | Placebo                  |
|   |                             |                                            |                                      |                           | 0                              | Placebo                  |
|   |                             |                                            |                                      |                           | 0                              | Placebo                  |
|   |                             |                                            |                                      |                           | 0                              | Placebo                  |



# The Data Browser

- ▶ A simple Table that displays the Data
- ▶ And should display labels
- ▶ With some Highlighting
- ▶ Allow rearrange columns



|   | PARAM<br>Parameter                                                                  | AVISIT<br>Analysis Visit | AVAL<br>Analysis Value | STUDYID<br>Study Identifier | SUBJID<br>Subject Identifier for the Study |
|---|-------------------------------------------------------------------------------------|--------------------------|------------------------|-----------------------------|--------------------------------------------|
|   |  |                          |                        |                             |                                            |
| 1 | Alkaline Phosphatase (...)                                                          | Baseline                 | 34                     | CDISCILO...                 | 1015                                       |
| 2 | Protein (g/L)                                                                       | Baseline                 | 61                     | CDISCILO...                 | 1015                                       |
| 3 | Sodium (mmol/L)                                                                     | Week 12                  | 139                    | CDISCILO...                 | 1015                                       |
| 4 | Calcium (mmol/L)                                                                    | Week 20                  | 2.17                   | CDISCILO...                 | 1015                                       |
| 5 | Sodium (mmol/L)                                                                     | Baseline                 | 140                    | CDISCILO...                 | 1015                                       |
| 6 | Sodium (mmol/L)                                                                     | Week 4                   | 140                    | CDISCILO...                 | 1015                                       |
| 7 | Sodium (mmol/L)                                                                     | Week 6                   | 140                    | CDISCILO...                 | 1015                                       |
| 8 | Sodium (mmol/L)                                                                     | Week 24                  | 140                    | CDISCILO...                 | 1015                                       |
| 9 | Sodium (mmol/L)                                                                     | End of Treat...          | 140                    | CDISCILO...                 | 1015                                       |

# The Data Browser

- ▶ A simple Table that displays the Data
- ▶ And should display labels
- ▶ With some Highlighting
- ▶ Allow rearrange columns
- ▶ And hide columns



|   | PARAM<br>Parameter         | AVISIT<br>Analysis Visit | AVAL<br>Analysis Value | STUDYID<br>Study Identifier | SUBJID<br>Subject Identifier for the Study |
|---|----------------------------|--------------------------|------------------------|-----------------------------|--------------------------------------------|
| 1 | Alkaline Phosphatase (...) | Baseline                 | 34                     | CDISCILO...                 | 1015                                       |
| 2 | Protein (g/L)              | Baseline                 | 61                     | CDISCILO...                 | 1015                                       |
| 3 | Sodium (mmol/L)            | Week 12                  | 139                    | CDISCILO...                 | 1015                                       |
| 4 | Calcium (mmol/L)           | Week 20                  | 2.17                   | CDISCILO...                 | 1015                                       |
| 5 | Sodium (mmol/L)            | Baseline                 | 140                    | CDISCILO...                 | 1015                                       |
| 6 | Sodium (mmol/L)            | Week 4                   | 140                    | CDISCILO...                 | 1015                                       |
| 7 | Sodium (mmol/L)            | Week 6                   | 140                    | CDISCILO...                 | 1015                                       |
| 8 | Sodium (mmol/L)            | Week 24                  | 140                    | CDISCILO...                 | 1015                                       |
| 9 | Sodium (mmol/L)            | End of Treat...          | 140                    | CDISCILO...                 | 1015                                       |

# The Data Browser

- ▶ A simple Table that displays the Data
- ▶ And should display labels
- ▶ With some Highlighting
- ▶ Allow rearrange columns
- ▶ And hide columns
- ▶ And filtered for PARAMCD == "BILI"



|     |  PARAM<br>Parameter | AVISIT<br>Analysis Visit | AVAL<br>Analysis Value | STUDYID<br>Study Identifier | SUBJID<br>Subject Identifier for the Study |
|-----|--------------------------------------------------------------------------------------------------------|--------------------------|------------------------|-----------------------------|--------------------------------------------|
| 110 | Bilirubin (umol/L)                                                                                     | Week 6                   | 5.13                   | CDISCPILO...                | 1015                                       |
| 111 | Bilirubin (umol/L)                                                                                     | Week 26                  | 5.13                   | CDISCPILO...                | 1015                                       |
| 142 | Bilirubin (umol/L)                                                                                     | Week 4                   | 6.84                   | CDISCPILO...                | 1015                                       |
| 143 | Bilirubin (umol/L)                                                                                     | Week 12                  | 6.84                   | CDISCPILO...                | 1015                                       |
| 144 | Bilirubin (umol/L)                                                                                     | Week 16                  | 6.84                   | CDISCPILO...                | 1015                                       |
| 145 | Bilirubin (umol/L)                                                                                     | Week 20                  | 6.84                   | CDISCPILO...                | 1015                                       |
| 146 | Bilirubin (umol/L)                                                                                     | Week 24                  | 6.84                   | CDISCPILO...                | 1015                                       |
| 147 | Bilirubin (umol/L)                                                                                     | End of Treat...          | 6.84                   | CDISCPILO...                | 1015                                       |
| 169 | Bilirubin (umol/L)                                                                                     | Week 2                   | 8.55                   | CDISCPILO...                | 1015                                       |

# The Data Browser

- ▶ A simple Table that displays the Data
- ▶ And should display labels
- ▶ With some Highlighting
- ▶ Allow rearrange columns
- ▶ And hide columns
- ▶ And filtered for PARAMCD == "BILI"
- ▶ And sorted by AVISIT

|     | PARAM<br>Parameter | ▲ AVISIT<br>Analysis Visit | AVAL<br>Analysis Value | STUDYID<br>Study Identifier | SUBJID<br>Subject Identifier for the Study |
|-----|--------------------|----------------------------|------------------------|-----------------------------|--------------------------------------------|
| 169 | Bilirubin (umol/L) | Week 2                     | 8.55                   | CDISCPILO...                | 1015                                       |
| 142 | Bilirubin (umol/L) | Week 4                     | 6.84                   | CDISCPILO...                | 1015                                       |
| 110 | Bilirubin (umol/L) | Week 6                     | 5.13                   | CDISCPILO...                | 1015                                       |
| 170 | Bilirubin (umol/L) | Week 8                     | 8.55                   | CDISCPILO...                | 1015                                       |
| 143 | Bilirubin (umol/L) | Week 12                    | 6.84                   | CDISCPILO...                | 1015                                       |
| 144 | Bilirubin (umol/L) | Week 16                    | 6.84                   | CDISCPILO...                | 1015                                       |
| 145 | Bilirubin (umol/L) | Week 20                    | 6.84                   | CDISCPILO...                | 1015                                       |
| 146 | Bilirubin (umol/L) | Week 24                    | 6.84                   | CDISCPILO...                | 1015                                       |
| 111 | Bilirubin (umol/L) | Week 26                    | 5.13                   | CDISCPILO...                | 1015                                       |



# The Data Browser

- ▶ Count the number of subjects

|      | ▲ USUBJID<br>Unique<br>Subject<br>Identifier | PARAM<br>Parameter             |
|------|----------------------------------------------|--------------------------------|
| 1    | 01010101010                                  | Alkaline Phosphatase (U/L)     |
| 396  | 01010101010                                  | Creatine Kinase (U/L) chang... |
| 397  | 01010101011                                  | Sodium (mmol/L)                |
| 401  | 01010101012                                  | Albumin (g/L)                  |
| 541  | 01010101012                                  | Calcium (mmol/L)               |
| 548  | 01010101012                                  | Cholesterol (mmol/L)           |
| 937  | 01010101012                                  | Calcium (mmol/L)               |
| 945  | 01010101033                                  | Albumin (g/L)                  |
| 952  | 01011001033                                  | Potassium (mmol/L)             |
| 1361 | 01011001034                                  | Urate (umol/L) change fro...   |
| 1362 | 01011001034                                  | Phosphate (mmol/L) chang...    |
| 1363 | 01011001035                                  | Calcium (mmol/L) change f...   |
| 270  | 01011001036                                  | Creatine Kinase (U/L) chang... |
| 273  | 01011001036                                  | Chloride (mmol/L) change ...   |
| 279  | 01011001037                                  | Blood Urea Nitrogen (mmol...   |
| 299  | 01011001037                                  | Urate (umol/L) change fro...   |

# The Data Browser

- ▶ Count again



|      | ▲ USUBJID<br>Unique<br>Subject<br>Identifier | PARAM<br>Parameter             |
|------|----------------------------------------------|--------------------------------|
| 1    | 01010101010                                  | Alkaline Phosphatase (U/L)     |
| 396  | 01010101010                                  | Creatine Kinase (U/L) chang... |
| 397  | 01010101011                                  | Sodium (mmol/L)                |
| 401  | 01010101012                                  | Albumin (g/L)                  |
| 541  | 01010101012                                  | Calcium (mmol/L)               |
| 548  | 01010101012                                  | Cholesterol (mmol/L)           |
| 937  | 01010101012                                  | Calcium (mmol/L)               |
| 945  | 01010101033                                  | Albumin (g/L)                  |
| 952  | 01011001033                                  | Potassium (mmol/L)             |
| 1361 | 01011001034                                  | Urate (umol/L) change fro...   |
| 1362 | 01011001034                                  | Phosphate (mmol/L) chang...    |
| 1363 | 01011001035                                  | Calcium (mmol/L) change f...   |
| 270  | 01011001036                                  | Creatine Kinase (U/L) chang... |
| 273  | 01011001036                                  | Chloride (mmol/L) change ...   |
| 279  | 01011001037                                  | Blood Urea Nitrogen (mmol...   |
| 299  | 01011001037                                  | Urate (umol/L) change fro...   |

# The Data Browser

- ▶ Count again → 9 Subjects



|      | ▲ USUBJID<br>Unique<br>Subject<br>Identifier | PARAM<br>Parameter             |
|------|----------------------------------------------|--------------------------------|
| 1    | 01010101010                                  | Alkaline Phosphatase (U/L)     |
| 396  | 01010101010                                  | Creatine Kinase (U/L) chang... |
| 397  | 01010101011                                  | Sodium (mmol/L)                |
| 401  | 01010101012                                  | Albumin (g/L)                  |
| 541  | 01010101012                                  | Calcium (mmol/L)               |
| 548  | 01010101012                                  | Cholesterol (mmol/L)           |
| 937  | 01010101012                                  | Calcium (mmol/L)               |
| 945  | 01010101033                                  | Albumin (g/L)                  |
| 952  | 01011001033                                  | Potassium (mmol/L)             |
| 1361 | 01011001034                                  | Urate (umol/L) change fro...   |
| 1362 | 01011001034                                  | Phosphate (mmol/L) chang...    |
| 1363 | 01011001035                                  | Calcium (mmol/L) change f...   |
| 270  | 01011001036                                  | Creatine Kinase (U/L) chang... |
| 273  | 01011001036                                  | Chloride (mmol/L) change ...   |
| 279  | 01011001037                                  | Blood Urea Nitrogen (mmol...   |
| 299  | 01011001037                                  | Urate (umol/L) change fro...   |

# The Backend

- ▶ Access Restrictions (Security)
  - ▶ Who is allowed to access
  - ▶ Who is allowed to grant access (Self Assign?)
- ▶ Audit Trail
  - ▶ Who had access
  - ▶ Who used access
- ▶ Lifecycle Management
  - ▶ Status of files (development, validation, production)
  - ▶ How and by whom a file was created / changed
    - ▶ (e.g. manually, by program, by interface)

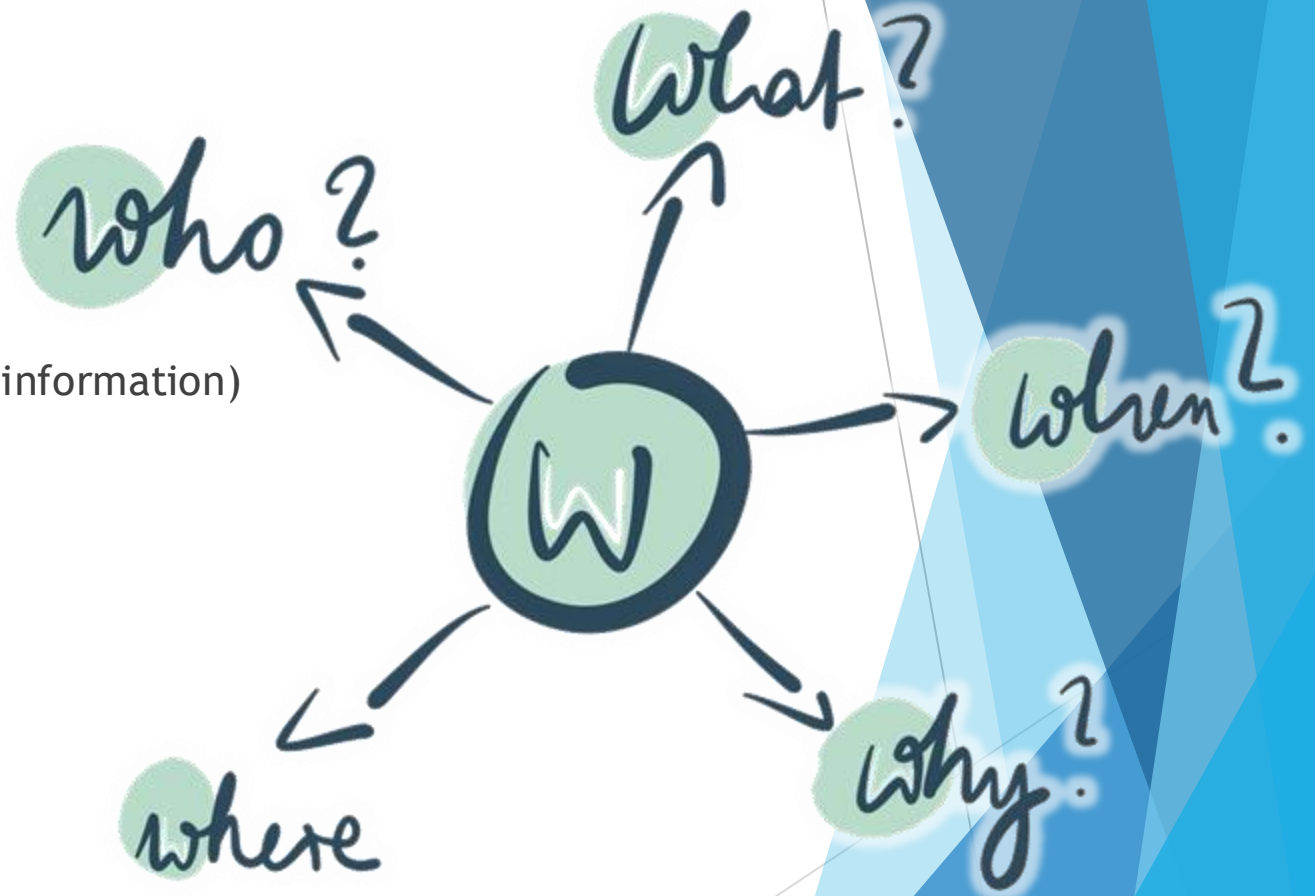


# The Backend

- ▶ Delayed Execution
  - ▶ Timed / Scheduled
  - ▶ On Input Changed (smart ...)
- ▶ Automatic Tracing of Program Flow
  - ▶ Input → Program → Output
  - ▶ [SDTM.LB] → d\_adlb.sas → [ADAM.ADLB] → t\_adlb\_1.sas → t\_adlb\_1.rtf
  - ▶ Marking of „outdated“ output and programs to be rerun
  - ▶ Marking of outputs with lifecycle information based on tracing

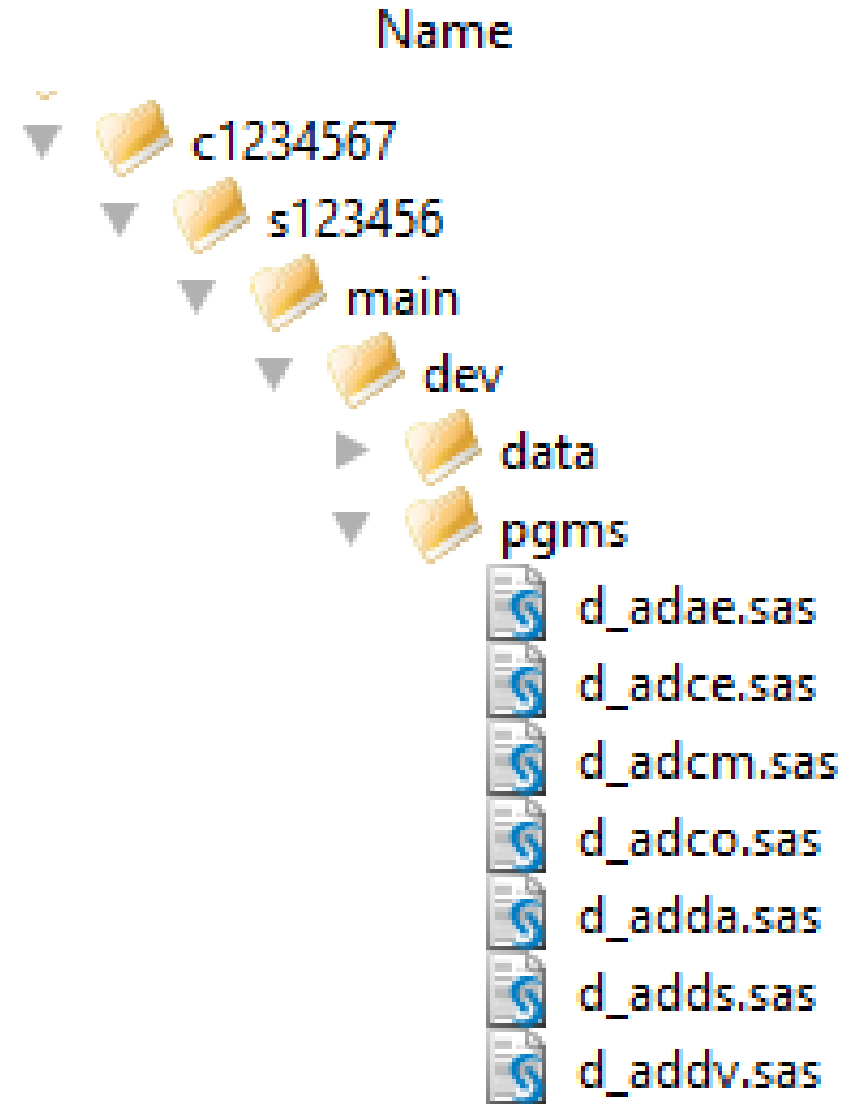
# The Backend

- ▶ Access to Data via API
  - ▶ HTTP(s) based e.g. REST or GraphQL
  - ▶ “Data Sets” and SCE metadata (e.g. lifecycle information)
- ▶ Access to Files via API and Windows Explorer



# The Navigator / Explorer

- ▶ Provide access to the Files inside of the SCE



# The Navigator / Explorer

- ▶ Provide access to the Files inside of the SCE
- ▶ Display additional Information
  - ▶ Size, Date
- ▶ Missing:
  - ▶ Lifecycle (dev, qc, prod)
  - ▶ Author and Writer
  - ▶ Errors/ Warnings in last exec

| Name                                                                                             | Date                | Size     |
|--------------------------------------------------------------------------------------------------|---------------------|----------|
|  c1234567      | 2025-11-03 15:47:11 | 0 Byte   |
| ▼  s123456    | 2025-11-03 15:23:25 | 0 Byte   |
| ▼  main       | 2025-11-03 15:29:20 | 0 Byte   |
| ▼  dev        | 2025-11-07 08:09:29 | 0 Byte   |
| ▶  data       | 2025-11-07 08:09:37 | 0 Byte   |
| ▼  pgms       | 2025-10-28 20:24:27 | 0 Byte   |
|  d_adae.sas   | 2025-09-15 05:31:09 | 47.44 KB |
|  d_adce.sas | 2025-10-11 06:06:47 | 31.56 KB |
|  d_adcm.sas | 2025-10-20 11:16:50 | 77.28 KB |
|  d_adco.sas | 2025-09-16 21:14:40 | 29.63 KB |
|  d_adda.sas | 2025-09-13 11:43:33 | 2.71 KB  |
|  d_adds.sas | 2025-10-26 15:25:25 | 65.99 KB |
|  d_addv.sas | 2025-10-22 09:10:23 | 31.37 KB |

# The Navigator / Explorer

- ▶ Provide access to the Files inside of the SCE
- ▶ Display additional Information
  - ▶ Date, Time, Lifecycle ...
- ▶ Allow Sorting

| Name                                                                                                     | Date  | Size     |
|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|----------|
| ▼ main                                                                                                   | 2025-11-03 15:29:20                                                                      | 0 Byte   |
| ▼ dev                                                                                                    | 2025-11-07 08:09:29                                                                      | 0 Byte   |
| ▼ pgms                                                                                                   | 2025-10-28 20:24:27                                                                      | 0 Byte   |
|  l_adsl.sas           | 2025-09-03 09:01:11                                                                      | 11.32 KB |
|  d_adsl.sas           | 2025-09-05 09:14:29                                                                      | 5.47 KB  |
|  d_adtte.sas          | 2025-09-07 11:21:18                                                                      | 33.10 KB |
|  d_adlb.sas           | 2025-09-08 05:15:38                                                                      | 42.04 KB |
|  d_trialdomains.sas  | 2025-09-12 04:44:08                                                                      | 58.63 KB |
|  t_adlb_1_2.sas     | 2025-09-13 03:30:24                                                                      | 61.62 KB |
|  d_adda.sas         | 2025-09-13 11:43:33                                                                      | 2.71 KB  |
|  t_adlb_eff_1_1.sas | 2025-09-13 23:45:48                                                                      | 32.70 KB |
|  t_admh_2.sas       | 2025-09-14 20:39:37                                                                      | 47.75 KB |
|  d_adae.sas         | 2025-09-15 05:31:09                                                                      | 47.44 KB |
|  d_formats.sas      | 2025-09-15 21:57:04                                                                      | 16.14 KB |

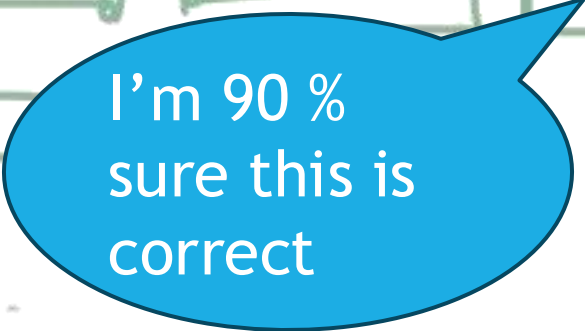
# The Navigator / Explorer

- ▶ Integrate other Systems
  - ▶ SharePoint
  - ▶ eTMF
  - ▶ Data Lakehouse

| Name ▲                     | Date                | Size      |
|----------------------------|---------------------|-----------|
| ▼ c1234567                 | 2025-11-03 15:47:11 | 0 Byte    |
| ▼ s123456                  | 2025-11-07 14:36:19 | 0 Byte    |
| ▼ sp_123456                |                     |           |
| 123456_blankcrf.pdf        | 2025-10-26 12:19:34 | 2.02 MB   |
| 123456_dataguide.pdf       | 2025-10-26 12:19:34 | 90.15 KB  |
| 123456_define.html         | 2025-10-26 12:19:34 | 755.15 KB |
| 123456_define.pdf          | 2025-10-26 12:19:34 | 1.55 MB   |
| 123456_define.xml          | 2025-10-26 12:19:34 | 573.57 KB |
| 123456_PROTOCOL_FINAL.pdf  | 2023-11-28 21:13:48 | 3.32 MB   |
| 123456_SAP_DRAFT.docx      | 2025-02-10 22:32:36 | 1.52 MB   |
| define-v1-updated-html.xsl | 2025-10-26 12:19:34 | 79.32 KB  |
| ▼ etmf_123456              |                     |           |
| tlf_123456_final.docx      | 2023-06-11 04:40:40 | 9.56 MB   |
| main                       | 2025-11-03 15:29:20 | 0 Byte    |
| s123567                    | 2025-08-15 09:24:01 | 0 Byte    |

# AI & LLM in SCEs

- ▶ Integration of LLM in SCE
- ▶ Automatically supply study information to LLM (Context)
  - ▶ Study Metadata
  - ▶ SAP / Protocol
- ▶ LLM can generate code
- ▶ Review / Validation better not by LLM
  - ▶ LLMs not always right
  - ▶ They usually don't ask for "help" but "prefer" to create a wrong answer first
  - ▶ 90% right is 10% wrong. How to find the wrong 10%?
  - ▶ Semantic errors hard to fix by LLM



I'm 90 %  
sure this is  
correct

# That's it

Thanks for listening!

Everything shown here is not just theory - it has been built, used and proven in real SCE.

Now it's time for your questions!



Interested? Ideas? Questions?

Contact:

[michael.weiss@code2be.de](mailto:michael.weiss@code2be.de)

