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Decimal calculation on BDS parameter

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Introduction

- Accurate decimal precision in BDS datasets is essential for maintaining data integrity, supporting reproducible analysis and meeting regulatory expectations.
- Each parameter may require different levels of decimal accuracy based on its nature, measurement sensitivity and intended use in statistical outputs.
- This presentation explores the application of decimal calculations within basic dataset structures.



Agenda

1. Overview of Decimal Precision in BDS
2. Impact on statistical analysis and reporting
3. Case study and SAS Implementation
4. Summary Tables and Output Interpretation
5. Best Practices and Recommendations



Overview of Decimal Precision in BDS

Why Decimal Accuracy Matters in Clinical Datasets

Data Integrity and Reproducibility:

- Decimal precision is fundamental for maintaining the integrity of clinical datasets.

Regulatory Compliance:

- Regulatory agencies (e.g., FDA, EMA) require that clinical trial data be accurate, complete, and traceable

Parameter-Specific Needs:

- Different parameters in a BDS dataset require varying levels of decimal precision. For example, laboratory measurements often demand more decimal places than categorical variables to maintain scientific rigor

Preventing Data Discrepancies:

- Consistent decimal rules across datasets help prevent rounding errors and misinterpretation of results

Transparency and Traceability:

- Proper decimal handling supports transparency in clinical trial documentation.



Impact on statistical analysis and reporting

Statistical Significance:

Decimal accuracy directly influences the interpretation of statistical significance. Overly precise or insufficiently rounded numbers can mislead readers about the reliability of results. Best practices recommend expressing means and standard deviations to one digit beyond the instrument's accuracy and rounding p-values and confidence intervals appropriately for clarity.

Consistency in Reporting:

Aligning decimal precision between raw and derived data strengthens the credibility of clinical trial reports. Rounding should be applied only at the final stage of reporting, not during intermediate calculations, to avoid loss of information and ensure consistency.



Decimal precision handling in LB datasets

⚠ USUBJID	⚠ LBCAT	⚠ LBTESTCD	⚠ VISIT	⚠ LBDTC	③ LBORRES
101	HEMATOLOGY	WBC	SCREENING	2024-01-01T09...	9
101	HEMATOLOGY	WBC	DAY1	2024-01-03T09...	9.1
101	HEMATOLOGY	WBC	WEEK1	2024-01-08T09...	3.63
101	HEMATOLOGY	WBC	WEEK2	2024-01-15T09...	4.13
101	HEMATOLOGY	WBC	WEEK4	2024-01-29T09...	4.223
101	HEMATOLOGY	BASO	SCREENING	2024-01-01T09...	1.22
101	HEMATOLOGY	BASO	DAY1	2024-01-03T09...	1.1
101	HEMATOLOGY	BASO	WEEK1	2024-01-08T09...	1
101	HEMATOLOGY	BASO	WEEK2	2024-01-15T09...	1.11
101	HEMATOLOGY	BASO	WEEK4	2024-01-29T09...	1
102	HEMATOLOGY	WBC	SCREENING	2024-01-01T09...	6.02
102	HEMATOLOGY	WBC	DAY1	2024-01-03T09...	3.6
102	HEMATOLOGY	WBC	WEEK1	2024-01-08T09...	3.6
102	HEMATOLOGY	WBC	WEEK2	2024-01-15T09...	4
102	HEMATOLOGY	WBC	WEEK4	2024-01-29T09...	4
102	HEMATOLOGY	BASO	SCREENING	2024-01-01T09...	1
102	HEMATOLOGY	BASO	DAY1	2024-01-03T09...	1
102	HEMATOLOGY	BASO	WEEK1	2024-01-08T09...	1
102	HEMATOLOGY	BASO	WEEK2	2024-01-15T09...	1
102	HEMATOLOGY	BASO	WEEK4	2024-01-29T09...	1
101	CHEMISTRY	ALT	SCREENING	2024-01-01T09...	19
101	CHEMISTRY	ALT	DAY1	2024-01-03T09...	12
101	CHEMISTRY	ALT	WEEK1	2024-01-08T09...	15
101	CHEMISTRY	ALT	WEEK2	2024-01-15T09...	14
101	CHEMISTRY	ALT	WEEK4	2024-01-29T09...	19



Analysis structure in SAP

- Calculated means and medians will be tabulated to one or more decimal place than the original data.
- Minimum and maximum values will be tabulated to the same number of decimal places as the original data.
- Standard deviation will be tabulated to two or more decimal places than the original



Case Study

Step 1-

Determine the highest number of decimal places used for each parameter.

```
if LBORRES > .z then do;  
    cval = trim(left(compress(put(LBORRES, best.))));  
end;  
if int(LBORRES) = LBORRES then decimal = 0;  
    else if indexc(cval, '.') >= 0 then do;  
        decimal = length(trim(left(scan(charval, 2, '.'))));  
    end;  
run;
```



Case study

USUBJID	LBCAT	LBTESTCD	VISIT	LBDTC	LBORRES	cval	decimal
101	HEMATOLOGY	WBC	SCREENING	2024-01-01T09...	9.1	9.1	1
101	HEMATOLOGY	WBC	DAY1	2024-01-03T09...	3.62	3.62	2
101	HEMATOLOGY	WBC	WEEK1	2024-01-08T09...	4.13	4.13	2
101	HEMATOLOGY	WBC	WEEK2	2024-01-15T09...	4.223	4.223	3
101	HEMATOLOGY	WBC	WEEK4	2024-01-29T09...	6.02	6.02	2
101	HEMATOLOGY	BASO	SCREENING	2024-01-01T09...	1.22	1.22	2
101	HEMATOLOGY	BASO	DAY1	2024-01-03T09...	1.1	1.1	1
101	HEMATOLOGY	BASO	WEEK1	2024-01-08T09...	1	1	0
101	HEMATOLOGY	BASO	WEEK2	2024-01-15T09...	1.11	1.11	2
101	HEMATOLOGY	BASO	WEEK4	2024-01-29T09...	1	1	0
102	HEMATOLOGY	WBC	SCREENING	2024-01-01T09...	6.02	6.02	2
102	HEMATOLOGY	WBC	DAY1	2024-01-03T09...	3.6	3.6	1
102	HEMATOLOGY	WBC	WEEK1	2024-01-08T09...	3.6	3.6	1
102	HEMATOLOGY	WBC	WEEK2	2024-01-15T09...	4	4	0
102	HEMATOLOGY	WBC	WEEK4	2024-01-29T09...	4	4	0
102	HEMATOLOGY	BASO	SCREENING	2024-01-01T09...	1	1	0
102	HEMATOLOGY	BASO	DAY1	2024-01-03T09...	1	1	0
102	HEMATOLOGY	BASO	WEEK1	2024-01-08T09...	1	1	0
102	HEMATOLOGY	BASO	WEEK2	2024-01-15T09...	1	1	0
102	HEMATOLOGY	BASO	WEEK4	2024-01-29T09...	1	1	0
101	CHEMISTRY	ALT	SCREENING	2024-01-01T09...	19	19	0
101	CHEMISTRY	ALT	DAY1	2024-01-03T09...	12	12	0
101	CHEMISTRY	ALT	WEEK1	2024-01-08T09...	15	15	0
101	CHEMISTRY	ALT	WEEK2	2024-01-15T09...	14	14	0
101	CHFMISTRY	AI T	WFFK4	2024-01-29T09...	19	19	0



Case Study

Step 2-

Identify the maximum precision across all parameters.

/ Use PROC UNIVARIATE to get the maximum decimal count per parameter */*

```
proc univariate data=lb1 noprint;  
    by LBTESTCD;  
    var decimal;  
    output out=lb2 max=decimal;  
run;
```

LBTESTCD	decimal
ALT	0
BASO	2
WBC	3



Case Study

Step 3 -

Assessing Overall Length and Decimal Detail.

```
data lb3;
  set lb2;
  /* form1 = 8 + (1 if decimal > 0) + decimal */
  form1 = 8 + (decimal > 0) + decimal;
  /* form2 = just the decimal value */
  form2 = decimal;
run;
```

SPECIFICATION:

decimal - represents the number of decimal places required by a lab value.

form1 - calculates the total display width for numeric formatting.

form2 - simply retains the decimal precision.

Page Break			
LBTESTCD	decimal	form1	form2
ALT	0	8	0
BASO	2	11	2
WBC	3	12	3



Case study

Step 4

```
data LB4;
  length labnum $200;
  set LB3 end=eof;

  /* Initialize and increment count */
  count + 1;

  *** RECORD-COUNT LABEL TO EACH PARAMETER NAME ***;
  labnum = "1_" || compress(count);
  call symput(labnum, trim(left(LBTESTCD)));

  *** TOTAL NUMBER OF PARAMETERS INTO A MACRO VARIABLE ***;
  if eof then call symput('topitest', compress(count));

run;

/* Display total number of parameters */
%put &topitest;
```

SPECIFICATION:

Count +1 automatically initializes count to 0 and increments it by 1 for each record.

Labnum produces value like 1_1, 1_2, 1_3 to create a stable, ordered identifier for each lab parameter.

Call symput creates a macro variable named 1_1, 1_2 etc to store the corresponding LBTESTCD value.

 labnum	 LBTESTCD	 decimal	 form1	 form2	 count
1_1	ALT	0	8	0	1
1_2	BASO	2	11	2	2
1_3	WBC	3	12	3	3



Case Study

Step 5

```
data LB5;
```

```
length totfnum backnum $10;
```

```
set LB4 end=eof;
```

```
totfnum = "f_" || compress(count);
```

```
backnum = "b_" || compress(count);
```

```
call symput(totfnum, trim(left(form1)));
```

```
call symput(backnum, trim(left(form2)));
```

```
run;
```

This creates macro variables f_1, f_2, ... holding form1, and b_1, b_2, ... holding form2 for each row in LB4 (where count was created earlier).

SPECIFICATION:

totfnum identifies a numeric format width
backnum identifies the number of decimal places.

 totfnum	 backnum	 labnum	 LBTESTCD	 decimal	 form1	 form2	 count
f_1	b_1	l_1	ALT	0	8	0	1
f_2	b_2	l_2	BASO	2	11	2	2
f_3	b_3	l_3	WBC	3	12	3	3



Case study

Step 6

Use Proc univariate to calculate descriptive statistics.

```
proc univariate data=lb0 noprint;
```

```
  by lbcats LBTESTCD visit;
```

```
  var LBORRES;
```

```
  output out=LB6
```

```
    n=n
```

```
    mean=mean
```

```
    std=std
```

```
    median=median
```

```
    min=min
```

```
    max=max;
```

```
run;
```

LBCAT	LBTESTCD	VISIT	n	mean	std	max	median	min
CHEMISTRY	ALT	DAY1	1	12	.	12	12	12
CHEMISTRY	ALT	SCREENING	1	19	.	19	19	19
CHEMISTRY	ALT	WEEK1	1	15	.	15	15	15
CHEMISTRY	ALT	WEEK2	1	14	.	14	14	14
CHEMISTRY	ALT	WEEK4	1	19	.	19	19	19
HEMATOLOGY	BASO	DAY1	2	1.05	0.0707106781	1.1	1.05	1
HEMATOLOGY	BASO	SCREENING	2	1.11	0.1555634919	1.22	1.11	1
HEMATOLOGY	BASO	WEEK1	2	1	0	1	1	1
HEMATOLOGY	BASO	WEEK2	2	1.055	0.0777817459	1.11	1.055	1
HEMATOLOGY	BASO	WEEK4	2	1	0	1	1	1
HEMATOLOGY	WBC	DAY1	2	3.61	0.0141421356	3.62	3.61	3.6
HEMATOLOGY	WBC	SCREENING	2	7.56	2.1778888861	9.1	7.56	6.02
HEMATOLOGY	WBC	WEEK1	2	3.865	0.374766594	4.13	3.865	3.6
HEMATOLOGY	WBC	WEEK2	2	4.1115	0.1576848122	4.223	4.1115	4
HEMATOLOGY	WBC	WEEK4	2	5.01	1.428355698	6.02	5.01	4



Case study

Step 7

```
options mprint mlogic symbolgen;
```

```
proc sql noprint;
  select distinct LBTESTCD
  into :code_1-, :code_9999
  from lb6;
quit;
```

```
%macro lab();
```

```
data labs_out;
  length _col $50 _col2 $10;
  set lb6;
```

```
/* Assuming these variables exist in LABS */
array values (6) n mean std median min max;
```

```
do stat = 1 to 6;
  %do w = 1 %to &toptest;
```

```
/* Replace "code" with the base name of your macro variable family */
if strip(LBTESTCD) = "&&code_&w" then do;
```

```
  select (stat);
```

```
  when (1) do; /* N */
```

```
    %if %eval(&&b_&w) = 0 %then %do;
```

```
      _col = put(values(stat), %eval(&&f_&w - 1).); /* integer */
```

```
    %end;
```

```
    %else %do;
```

```
      _col = put(values(stat), %eval(&&f_&w - 1 - &&b_&w).); /* integer with reduced width */
```

```
    %end;
```



Case study

```
_col2 = "N";
end;

when (2) do; /* Mean */
    _col1 = put(mean, %eval(&&f_&w + 1).%eval(&&b_&w + 1));
    _col2 = "Mean";
end;

when (3) do; /* SD */
    _col1 = put(std, %eval(&&f_&w + 2).%eval(&&b_&w + 2));
    _col2 = "SD";
end;

when (4) do; /* Median */
    _col1 = put(median, %eval(&&f_&w + 1).%eval(&&b_&w + 1));
    _col2 = "Median";
end;

when (5) do; /* Min */
    %if %eval(&&b_&w) = 0 %then %do;
        _col1 = put(min, %eval(&&f_&w - 1).); /* integer */
    %end;
    %else %do;
        _col1 = put(min, %eval(&&f_&w).%eval(&&b_&w)); /* decimals */
    %end;
    _col2 = "Min";
end;

when (6) do; /* Max */
    %if %eval(&&b_&w) = 0 %then %do;
        _col1 = put(max, %eval(&&f_&w - 1).); /* integer */
    %end;
```



Case study

```
        otherwise; /* do nothing */

    end; /* select */

    output;
end; /* LBTESTCD match */

%end; /* w-loop */
end; /* stat-loop */
run;

%mend lab;
%lab;
```

Final dataset

[illegible]



Best Practices:

1. Maintain full precision for calculations; round only for display.
2. Use SAP and source data to determine required decimal places.
3. Separate calculation variables (e.g., AVAL, CHG, BASE) from display variables (e.g., AVALC, CHGC).
4. Document rounding logic for transparency and reproducibility.



Conclusion

Managing decimal precision in LB datasets with multiple parameters is essential for ensuring data accuracy, regulatory compliance, and meaningful statistical analysis. By systematically mapping each laboratory parameter to its appropriate decimal format and applying consistent rounding rules, you maintain the integrity and clarity of clinical trial results.



References

[Archive Page | PHUSE](#)

[D is for Dynamic, putting Dynamic back into CDISC](#)

[Different Decimal Places For Different Lab Tests](#)

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