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Family of PARAM***: PARAM, PARAMCD, PARAMN, PARCATy(N), PARAMTYP

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Abstract

Creating compliant analysis parameters (and related variables) in Basic Data Structure (BDS) is an important key for successful design of ADaM compliant datasets. Programmers take different approaches in creating analysis parameters in BDS. For ADaM specification writers, there are certain guiding tips to create PARAM and related variables like PARAMCD, PARAMN, PARCATy(N), PARAMTYP for various datasets. Many specification writers struggle to understand and implement concept of PARAM related variables to make 'analysis-ready' datasets in ADaM. Furthermore, there are many challenges in handling PARAM and PARAMCD variables. For instance, creating PARAM and PARAMCD in ADLB datasets from LBTEST and LBTESTCD is tricky. Hence, it can create complexities if those variables are not handled carefully. In addition, it is very important to design other variables like PARCATy(N), PARAMTYP for BDS datasets. By implementing guiding tips, programmers can exploit variables related to PARAM to make ADaM compliant datasets.

Keywords

PARAM, PARAMCD, PARCATy, ADaM, BDS, CDISC, Compliance, PARAMTYP, analysis-ready, analysis parameters

Introduction

It has been interesting as well as challenging to write ADaM specifications for clinical studies. One of the challenge in writing ADaM specification is creating consistent and compliant analysis parameters in Basic Data Structure (BDS). The key foundation of BDS is around the concept of creating analysis parameter in PARAM and PARAMCD variables. Hence, it becomes very important to create parameters carefully for the successful design of ADaM datasets. In addition, ADaM standard is furnished with some other PARAM related variables like PARAMN, PARCATy(N), PARAMTYP to make ADaM compliant and analysis-ready datasets.

When creating analysis parameters in PARAM, ADaM specification writers face various challenges. Firstly, analysis parameters are ambiguous and does not clearly explain the value of AVAL or AVALC. Secondly, the wordings and phrases used in the study for clinical reports (TLFs) are different than the wordings in analysis parameters. Thirdly, sometimes it is challenging to create parameters with basic rules of ADaM like 1:1 mapping in dataset for PARAM and PARAMCD, uniqueness within dataset etc. when there are so many parameters in one datasets (e.g. ADLB). In addition to abovementioned challenges, there are many other difficulties for ADaM specification writers in implementing ADaM concepts.

The goal of this paper is to help ADaM specification writers in creating analysis parameter and related variables by providing some guiding tips and suggestions. In this paper, we have classified our suggestions in mainly two categories –

1. General Considerations - Suggestions on avoiding common mistakes across variables of interest.
2. Specific Considerations - Suggestions for specific variables and specific challenges.

1. **General Considerations**

Most of the programmers and specification writers know about general considerations discussed here. Thus, we will briefly revisit some of the key points.

A. Attributes of each variable like length, label, format etc.

It is very important to follow and cross check with ADaM IG about each variable's attributes and have those attributes in ADaM compliance. It is the first and very important step towards ADaM compliance.

B. 1:1 Relationship of PARAM, PARAMCD, PARAMN

There must be a 1:1 relationship within same dataset among all three variables - PARAM, PARAMCD, PARAMN. It is also highly recommended to have same 1:1 relationship across the submission for PARAM and PARAMCD variables.

Many programmers update wording of parameters in PARAM from one study to another. This can be avoided if standard parameters are created at project level.

C. Make sure to have UNIQUE parameters (PARAM, PARAMCD, PARAMN) within dataset

It is essential to check uniqueness of parameters within dataset. The uniqueness of the parameters means each value of PARAM (and PARAMCD) should correspond to only one definition to derive AVAL or AVALC. For instance, one value of PARAM, Overall Survival (Months), should be derived using only one definition. If there are multiple definitions of 'Overall Survival' then you should create multiple parameters like Overall Survival (Month), Overall Survival for Sensitivity Analysis (Month).

The uniqueness of PARAM is checked during compliance testing at the end of programming. However, it is recommended to create a macro for checking uniqueness of parameters during programming (i.e. at the end of each dataset creation and include this check as a part of validation process). Additionally, we can add some other checks also as per company and ADaM standard. This way, the check of unique parameters within dataset can be performed at the time of programming and not just at the end of programming all datasets. This can save a lot of time.

D. Always check Control Terminology (CT), if any.

There are very selective ADaM variables (like PARAMTYP) that follow NCI Control Terminology (CT). Many other ADaM variables follow sponsor specific Control Terminology (CT) like PARAM, PARAMCD. So, programmers must check that PARAMTYP follows CT or not.

Apart from general considerations, there are various specific tips to be efficient in creating family of PARAM variables. Now, we will discuss specific considerations in detail.

2. **Specific Consideration (specific for each variables)**

We will go over various PARAM related variables one by one.

    A. **PARAM**
- Label: Analysis Parameter or Parameter

Challenge: Creating parameter within specified length and it should clearly explain analysis value (AVAL or AVALC)

It is challenging to create parameter within specified length. Generally, many programmers take 40 as the specified length for PARAM; however, it can go up to 200 as per ADaM IG v1.1. Within a given length, description of parameter should clearly explain the analysis value in AVAL or AVALC.

Some programmers take an approach of putting very long strings in PARAM variable to make clear parameters. However, those long strings go beyond 200 characters.

Suggestions:

1. You must keep mock shells or templates as the goal of ADaM datasets when writing ADaM specifications

This is the first step in creating analysis parameter(s) in BDS datasets. You should try to gauge how the specific values on mock shells will come and from there, you can design a plan to create parameters.

As shown in sample mock shell 1.1, analysis planned are for time to onset of various types of neurological AEs. However, each block in sample mock shell 1.1 is a different type of analysis at granular level. Hence, it is strongly recommended to create a parameter for each block.

Moreover, we have 6 subtypes of data analysis (and not just one) in Sample table 1.1. Hence, you should create six separate parameters to handle the analyses. It is not a good idea to create one general "Time to Onset of Neurologic AEs" and add additional variable to have information on 'Drug Related' and 'Grade 3-5'.

2. PARAM value must explain fully the value of AVAL or AVALC

The analysis value (AVAL or AVALC) may be derived for specific conditions, units, methods, assessors, positions etc. To make it clear, analysis parameter description should represent AVAL (or AVALC) value exactly. For instance, there is an analysis of "Time to onset of neurologic AEs which are Drug Related and have toxicity grade 3-5 as per SAP definition 1" in sample mock shell 1.1. So, the analysis parameter should include parameter which clearly explains the whole i.e. "Time to Onset of Neurologic AEs (per SAP Definition 1)" and AVAL should be also derived accordingly.

If derivation of AVAL includes for any specific unit, method, specimen, position etc. then include them in PARAM value.

3. How to create wording of analysis parameter

Creating PARAM description for each analysis parameter, you can -

- Keep similar text from mock shell tables (reports)

- Keep more consistent across the project
- Include unit, method, assessor in regular text wording or by using bracket

You can include complete analysis parameter to correctly represent value in AVAL or AVALC i.e. exact descriptions including unit, method, position, assessor etc. Moreover, you can try to take text part from clinical study report (CSR) mock shells. Some of examples of parameter from sample mock shells 1.1 are listed below. As shown in example, you can handle multiple definitions by including in bracket also. Some of examples like -

- Time to Onset of Neurologic AEs (per SAP definition 1)
- Time to Onset of Drug Related Neurologic AEs (per SAP definition 1)
- Time to Onset of Drug Related Neurologic AEs Grade 3-5 (per SAP definition 1)
- Time to Onset of Neurologic AEs (per SAP definition 2)
- Time to Onset of Drug Related Neurologic AEs (per SAP definition 2)
- Time to Onset of Drug Related Neurologic AEs Grade 3-5 (per SAP definition 2)

*NOTE: SAP Definition 1 refers to AEs that are reported and confirmed by investigator only. SAP Definition 2 refers to AEs that are reported and confirmed by investigator as well as independent reviewer.

Some other examples (examples of mock shells are not provided) can be -

- Best Overall Response (By Investigator)
- Best Overall Response (By IRC)
- Supine Diastolic Blood Pressure (mmHg)

4. Is it "analysis-ready" or One Proc Away?

Some programmers consider "One Proc Away" as it is just saying to explain parameter is "analysis-ready" and it cannot be applied in literal meaning to create summary table.

However, we suggest and can explain that if parameters are created carefully with ADaM compliance then programmers can produce analysis values in summary table using 'One Proc Away'. 'One Proc Away' does not refer to create complete summary table as in mock shell. However, 'One Proc Away' refers to analysis values in mock shell. That is, can any analysis value in mock shell be generated by one Proc in SAS?

Please see below example codes for generating numbers for sample mock shell 1.2.

```
*Example Code 1;
Proc MEANS DATA = ADAM.ADEX N MEAN MIN MAX STD MEDIAN;
WHERE SAFFL ='Y' AND PARAM = 'NUMBER OF TREATMENT DOSES
RECEIVED'; *We can use PARAMCD, PARAMN also for subsetting.
It is for example;
CLASS TRTA;
VAR AVAL;
RUN;
*Example Code 2;
PROC FREQ DATA = ADAM.ADEX;
```

```
WHERE SAFFL ='Y' AND PARAM ='TREATMENT DOSE RELATIVE
INTENSITY';
TABLE AVALC; *AVALC SHOULD BE ALSO ALIGNED WITH MOCK
SHELL.;
RUN;
```

By keeping PARAM value consistent to reports (TLFs), biostatisticians can identify easily which parameter to use for specific summary table for generating quick numbers for their validation.

5. Consideration of length of variable

Many programmers keep convention of 40 length for PARAM and try to fit the descriptions in 40 characters. However, it is recommended and in compliance with ADaM IG v1.1 to go up to length of 200 for parameter description in PARAM variable. If you are trying to include description within 40 characters, it should not be at cost of abovementioned points of making clear parameter description.

B. PARAMCD
   o Label: Parameter Code
   o Basic ADaM Requirement:
      ▪ Must be UNIQUE within dataset
      ▪ 1-1 Mapping with PARAM within dataset and suggested to have 1:1 mapping across whole submission
      ▪ Length: 8 Char
      ▪ PARAMCD value should start with a letter (not underscore), and be comprised only of letters (A-Z), underscore (_), and numerals (0-9) (to ensure compliance with SAS Version 5 transport file format and Oracle constraints)
   o If possible, PARAMCD should be meaningful.

Challenge: Handling analysis parameter for multiple lab tests in PARAMCD for ADLB

It is challenging to create many PARAMCD in ADLB and any similar ADaM datasets since there can be multiple PARAMCDs from same test. Moreover, high number of laboratory test can add more complexities. In addition, many analyses are performed in both units - SI as well as conventional unit.

Suggestion:

After analyzing all tests and analysis parameters from mock shells, you can design a plan to create PARAMCD using various LB variables like LBCAT, LBMETHOD, LBTESTCD, LBUNIT, LBSPEC etc.

One way is to create by concatenating 1st letter from LBCAT, 1st 4 Char from LBTESTCD, 1st Char of LBMETHOD, 1st character for LBSPEC, one character to indicate SI or conventional unit or no unit.

LBCAT	LBTESTCD	LBMETHOD	LBSPEC	UNIT*	PARAMCD	PARAM
CHEMISTRY	GLUC	HOME TEST METER	BLOOD	mmol/L	CGLUCHBS	Blood Glucose Using Home Test Meter (mmol/L)
CHEMISTRY	GLUC	DIPSTICK	URINE		CGLUCDUN	Urine Glucose Using Dipstick
CHEMISTRY	GLUC	HOME TEST METER	BLOOD	mg/dL	CGLUCHBC	Blood Glucose Using Home Test Meter (mg/dL)
CHEMISTRY	GLUC	DIPSTICK	URINE		CGLUCDUN	Urine Glucose Using Dipstick

*Note: mmol/L is SI unit and mg/dL is conventional unit.

This approach can be applied when there are analyses specific for LBCAT, LBMETHOD, LBTESTCD, LBUNIT, LBSPEC variables.

Many time there are not all listed variable are involved for PARAMCD. For example, if LBCAT, LBMETHOD, LBTESTCD variable based analysis is planed in mock shells then we can apply approach as below.

One way is to create by concatenating 1st letter from LBCAT, 1st 6 Char from LBTESTCD, 1st Char of LBMETHOD.

Many time considering number records in ADLB, it is suggested to create one separate datasets for analysis parameter in SI units and one separate dataset for parameters in CV units.

Challenge: Making PARAMCD meaning full and consistent

Many programmers create PARAMCDs without any pattern or logic to make unique within datasets like NEURO1, NEURO2, NEURO3 etc. NEURO1 does not infer any specific details.

Suggestions:

It is more appropriate to create a consistent convention across the project. For example, in sample mock shell 1.1, you can create convention of creating PARAMCD like below.

If below is list of your planned analyses,

- Time to Onset of Neurologic AEs (per SAP definition 1)
- Time to Onset of Drug Related Neurologic AEs (per SAP definition 1)
- Time to Onset of Drug Related Neurologic AEs Grade 3-5 (per SAP definition 1)
- Time to Onset of Neurologic AEs (per SAP definition 2)
- Time to Onset of Drug Related Neurologic AEs (per SAP definition 2)
- Time to Onset of Drug Related Neurologic AEs Grade 3-5 (per SAP definition 2)
- Above mentioned parameters with "Time to Resolution …" for Neurologic, Respiratory AEs in all combinations.

1st Character for Type (N for Neurological, R for Respiratory)

2nd Character for Onset or Resolution analysis (O or R)

3rd for drug relatedness (R – Related or A - Any)

4th for Grade (3 – for Grade 3-5 or 1- for 1-5)

5th for SAP definition (1, 2)

Still there are 2 characters available to use for adding other criteria, if needed.

Examples -

NRR32   Time to Resolution of Drug Related Neurological AEs of Grade 3-5 (as per SAP Definition 2)

ROA11   Time to Onset of any Respiratory AEs of Grade 1-5 (as per SAP Definition 1)

and so on.

This consistency across project can help programmers to use SAS code from one study to another study without much modifications.

Programmers must capitalize all value of PARAMCD.

C. PARAMN
- o Label: Parameter (N)
- o 1-1 Mapping with PARAM within a dataset

Many time programmers don't create. However, it is suggested to create PARAMN.

Tip: It does not have to be limited from 1-10. It can be extended beyond 1-10 to make good use of PARAMN.

E.g.

100-199 -- > All Hematologic Parameters
200-299 -- > All Urological Parameters

100-199- for SMQ1 related all parameters
200-299- for SMQ2 related all parameters
300-399- for SMQ3 related all parameters

Advantages:

- o Of Course, sorting of parameter in datasets in order of requirement.
- o As it is a numeric version of PARAMCD, it is can help in subsetting conditions in SAS code. E.g. PARAMN = 101;

D. PARCATy and PARCATyN:
- o Label: Parameter Category y
- o 1-1 Mapping between PARCATy and PARCATyN

It is important to know that PARAM to PARCATy relationship should be many-to-one. It should not be created if all PARAM to PARCATy is one-to-one relation.

Many programmers do not create it and do not make use of this variable. One the other hand, they work around in programming. To avoid it, there are some important things to know about PARCATy as below.

- o PARCATy is not just rename of xxCAT variable in SDTM. Hence, it should not be just renamed. It should be created after considering all parameters and how you want to group them from analysis perspective. E.g. To group all analysis parameters related to one biomarker into one class, you may create PARCAT1 and to group all similar analyses across various biomarkers, you can create PARCAT2.
- o PARAM can be associated with only 1 level of PARCATy. It means, one PARAM can be only associated with only one value (i.e. level) of PARCAT1 variable. It can be related to one level of PARCAT2.

- o PARCATy/N allows to do it grouping of PARAMs in multiple ways by creating variable PARCAT1, PARCAT2 etc. for doing grouping differently as per need in mock shell.
- o Advantages:
  - Helps in subsetting various parameters for same summary table.
    E.g. This variable can help in creating summary tables where
    - it needs multiple parameters (e.g. Sample Template 1.1)
    - it makes sense to look together (Different definitions in Sensitivity analysis)
    - various parameters are shown as BY group in same table

E. PARAMTYP
- o This variable is being considered to phase out due to confusion over DTYPE
- o Control Terminology –
  - Not Extensible
  - Possible value will be DERIVED or Null

PARAMTYP is used to indicate traceability when we DERIVE new parameter as a function of some other existing parameter i.e. derived from using any existing parameter

Tip:

If you do operation on any existing parameter and create new parameter, then we use PARAMTYPE.

E.g. For sample mock shell 1.3, parameters for Systolic and Diastolic BP can be created based on data from CRF. However, if we create a new parameter for pulse pressure from difference of Systolic and Diastolic BP, then we should populate PARAMTYPE as DERIVED for parameter Pulse Pressure as shown in sample dataset 1.4.

Conclusion

Variables related to PARAM are the heart of BDS datasets in ADaM. It can be efficient and compliant if analysis parameters are created with guidelines and conventions mentioned in this paper. In addition, we discussed PARAMCD variable with examples to make meaningful and ADaM compliant. ADaM specification writers can make a good use of other variables from PARAM family like PARCATy(N) and PARAMTYP.

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References

1. CDISC ADaM Implementation Guide Version 1.0
2. CDISC ADaM Implementation Guide Version 1.1

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Appendices:

Appendix A - Sample Mock Shell 1.1

```
                    Summary of Time to Onset of Neurologic AEs
                              Safety Population

--------------------------------------------------------------------------------------
                                         TRT A                          TRT B
                                         N= XXX                         N= XXX
--------------------------------------------------------------------------------------

Time to Onset of Neurologic AEs (per SAP Definition 1)
     MEDIAN                              XXX                            XXX
      95% CI                          (XXX - XXX)                    (XXX - XXX)
      MIN - MAX                         XXX - XXX                      XXX - XXX

Time to Onset of Neurologic AEs (per SAP Definition 2)
     MEDIAN                              XXX                            XXX
      95% CI                          (XXX - XXX)                    (XXX - XXX)
      MIN - MAX                         XXX - XXX                      XXX - XXX


Time to Onset of Drug Related Neurologic AEs (per SAP Definition 1)
     MEDIAN                              XXX                            XXX
      95% CI                          (XXX - XXX)                    (XXX - XXX)
      MIN - MAX                         XXX - XXX                      XXX - XXX

Time to Onset of Drug Related Neurologic AEs (per SAP Definition 2)
     MEDIAN                              XXX                            XXX
      95% CI                          (XXX - XXX)                    (XXX - XXX)
      MIN - MAX                         XXX - XXX                      XXX - XXX


Time to Onset of Drug Related Neurologic AEs Grade 3-5 (per SAP Definition 1)
     MEDIAN                              XXX                            XXX
      95% CI                          (XXX - XXX)                    (XXX - XXX)
      MIN - MAX                         XXX - XXX                      XXX - XXX

Time to Onset of Drug Related Neurologic AEs Grade 3-5 (per SAP Definition 2)
     MEDIAN                              XXX                            XXX
      95% CI                          (XXX - XXX)                    (XXX - XXX)
      MIN - MAX                         XXX - XXX                      XXX - XXX


--------------------------------------------------------------------------------------
SAP Definition 1 refers to AEs that are reported and confirmed by investigator only.
SAP Definition 2 refers to AEs that are reported and confirmed by investigator as well as
independent reviewer.
```

Appendix B - Sample Mock Shell 1.2

```
                         Summary of Treatment Exposure
                              Safety Population

--------------------------------------------------------------------------------------
                                         Trt X                         Trt Y
                                         N= XXX                        N=XXX
--------------------------------------------------------------------------------------
 NUMBER OF TREATMENT DOSES RECEIVED
    MEAN (SD)                        XXX (XXX)                     XX (XX)
    MEDIAN (MIN - MAX)            XXX (XXX - XXX)               XXX (XXX - XXX)

 TREATMENT DOSE RELATIVE INTENSITY
    >= 105%                           XX (XX.X)                     XX (XX.X)
    95% to < 105%                     XX (XX.X)                     XX (XX.X)
    70% to < 95%                      XX (XX.X)                     XX (XX.X)
    < 70%                             XX (XX.X)                     XX (XX.X)
    MISSING                           XX (XX.X)                     XX (XX.X)
--------------------------------------------------------------------------------------
```

Appendix C - Sample Mock Shell 1.3

```
                              Summary of Vital Signs
                               All Treated Subjects

-------------------------------------------------------------------------------------
                                                  Trt A           Trt B
                                                  N = XX          N = XX
-------------------------------------------------------------------------------------

SUPINE SYSTOLIC BLOOD PRESSURE (mmHg)
    N                                               XX              XX
    Mean                                            XX              XX
    Median                                          XX              XX
    Min, Max                                      XX, XX          XX, XX
    Standard Deviation                              XX              XX

SUPINE DIASTOLIC BLOOD PRESSURE (mmHg)
    N                                               XX              XX
    Mean                                            XX              XX
    Median                                          XX              XX
    Min, Max                                      XX, XX          XX, XX
    Standard Deviation                              XX              XX

SUPINE PULSE PRESSURE (mmHg)
    N                                               XX              XX
    Mean                                            XX              XX
    Median                                          XX              XX
    Min, Max                                      XX, XX          XX, XX
    Standard Deviation                              XX              XX

-------------------------------------------------------------------------------------
```

Appendix D - Sample dataset 1.4

USUBJID	PARAM	PARAMCD	PARAMTYP	AVAL	BASE	AVISIT
ABC11-11	SUPINE SYSTOLIC BLOOD PRESSURE (mmHg)	SSBP		141	141	Screening
ABC11-11	SUPINE SYSTOLIC BLOOD PRESSURE (mmHg)	SSBP		139	141	Week 1
ABC11-11	SUPINE SYSTOLIC BLOOD PRESSURE (mmHg)	SSBP		136	141	Week 2
ABC11-11	SUPINE SYSTOLIC BLOOD PRESSURE (mmHg)	SSBP		141	141	Week 3
ABC11-11	SUPINE SYSTOLIC BLOOD PRESSURE (mmHg)	SSBP		153	141	Week 4
ABC11-11	SUPINE DIASTOLIC BLOOD PRESSURE (mmHg)	SDBP		99	141	Screening
ABC11-11	SUPINE DIASTOLIC BLOOD PRESSURE (mmHg)	SDBP		96	141	Week 1
ABC11-11	SUPINE DIASTOLIC BLOOD PRESSURE (mmHg)	SDBP		98	141	Week 2
ABC11-11	SUPINE DIASTOLIC BLOOD PRESSURE (mmHg)	SDBP		100	141	Week 3
ABC11-11	SUPINE DIASTOLIC BLOOD PRESSURE (mmHg)	SDBP		100	141	Week 4
ABC11-11	SUPINE PULSE PRESSURE (mmHg)	SPBP	DERIVED	42	141	Screening
ABC11-11	SUPINE PULSE PRESSURE (mmHg)	SPBP	DERIVED	43	141	Week 1
ABC11-11	SUPINE PULSE PRESSURE (mmHg)	SPBP	DERIVED	38	141	Week 2
ABC11-11	SUPINE PULSE PRESSURE (mmHg)	SPBP	DERIVED	41	141	Week 3
ABC11-11	SUPINE PULSE PRESSURE (mmHg)	SPBP	DERIVED	53	141	Week 4

Appendix E - Sample Mock Shell 1.5

```
                      Summary of Prior Cancer Therapies taken by Subject
                                   All Treated Subjects
------------------------------------------------------------------------------------------
                                                       Trt A          Trt B
                                                       N = XX         N = XX
------------------------------------------------------------------------------------------

NUMBER OF PRIOR SYSTEMIC REGIMENS RECEIVED IN METASTATIC SETTING
              1                                        XX (XX.X)      XX (XX.X)
              2                                        XX (XX.X)      XX (XX.X)
              3                                        XX (XX.X)      XX (XX.X)
              >=4                                      XX (XX.X)      XX (XX.X)

PRIOR SYSTEMIC THERAPY REGIMEN SETTING
              ADJUVANT                                 XX (XX.X)      XX (XX.X)
              NEO-ADJUVANT                             XX (XX.X)      XX (XX.X)
              METASTATIC                               XX (XX.X)      XX (XX.X)

BEST RESPONSE TO MOST RECENT PRIOR SYSTEMIC THERAPY REGIMEN
              CR OR PR                                 XX (XX.X)      XX (XX.X)
              SD                                       XX (XX.X)      XX (XX.X)
              PD                                       XX (XX.X)      XX (XX.X)
              UNKNOWN/NOT REPORTED                     XX (XX.X)      XX (XX.X)

------------------------------------------------------------------------------------------
```

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                                    End of Paper

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