UTF What? A Guide to Using UTF-8 Encoded Data in a SDTM Submission
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ABSTRACT

The acronyms SBCS, DBCS, or MBCS (i.e. single, double, and multi-byte character sets) mean nothing to most statistical programmers. Many do not concern themselves with the encoding of their data, but what happens when data encoding causes SAS to error? The errors produced by SAS and some common workarounds for the issue may not answer important questions about what the issue was or how it was handled.

Though encoding issues can apply to any set of data, this presentation will be geared towards an SDTM submission. Additionally, a common origin of the transcoding error is UTF-8 encoded source data, whose use is rising in popularity by database providers, making it likely that this error will continue appear with greater frequency. Therefore, the ultimate goal of this paper will be to provide guidance on how to obtain fully compliant SDTM data with the intent of submission to the FDA from source datasets provided natively in UTF-8 encoding.

Among other topics, in this paper we first explore UTF-8 encoding, explaining what it is and why it is. Furthermore, we demonstrate how to identify the issues not explained by SAS, and recommend best practices dependent on the situation at hand. Lastly, we review some preventative checks that may be added into SAS code to identify downstream impacts early on. By the end of this paper, the audience should have a clear vision of how to proceed when their clinical database is using separate encoding from their native system.

INTRODUCTION

Character data is stored as a series of bytes. Bytes are made up of bits (binary digits), which are the smallest unit of data in a computer, containing a value of 1 or 0. Typically, bytes consist of eight bits. Bytes can be organized into different sequences to represent a number between 0 and 255. Encoding is how a computer interprets and represents the values within data. Data encoding will consist of a character set, which is the list of characters capable of being represented by the encoding. To connect the byte level data to the desired characters, a coded character set maps the number represented by a byte to its corresponding character.

One distinguishing factor of data encoding types is the number of bytes used to store the characters. Encoding may be a Single Byte Character Set (SBCS), Double Byte Character Set (DBCS) or Multi Byte Character Set (MBCS). A standard SBCS would be LATIN1 Encoding. This encoding consists of the standard ASCII character set, which includes upper and lower case English characters, the digits 0 through 9, and some special and control characters (e.g. $, *, carriage returns, etc.). LATIN1 also includes the extended ASCII character set which includes additional characters used in most Western European languages (e.g. ñ, ø) and additional special characters (e.g. ©, ¿). But the characters within the extended ASCII character set are not all inclusive. The focus is on Western European languages. What about Eastern languages? What about Asian languages, Cyrillic, etc.? These written languages consist of thousands of characters, and one byte is not enough. This is where a DBCS or a MBCS come into use.

Universal character set Transformation Format-8-bit (UTF-8) encoding attempts to represent all characters in all languages. It is capable of representing more than 120,000 characters covering 129 scripts and multiple symbol sets. While the first 128 characters of the ASCII code range may be represented by one byte, other characters within UTF-8 may require up to 4 bytes to be represented (Dutton, 2015).

WHERE YOU ARE AND WHERE YOU NEED TO GO

The SAS session encoding is the encoding that is used by SAS while it works with data. The encoding of a permanent dataset being read into SAS may differ. In these cases, the dataset being read in must be transcoded into the session encoding for SAS to work with it. In many cases, SAS can do this itself by using Cross-Environment Data Access (CEDA).

Adjusting your session encoding differs between programming environments, but in order to determine your session encoding, you can simply use PROC OPTIONS:

```sql
proc options option=encoding;
run;
```
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This will output a message to your log, telling you what encoding you SAS session is using.

```
ENCODING=UTF-8 Specifies the default character-set encoding for the SAS session.
```

### Output 1. Log output generated by PROC OPTIONS.

As for checking the encoding of a permanent dataset, this information is available when using PROC CONTENTS on the permanent dataset:

```
proc contents data=utf8.myDS;
run;
```

The encoding of the dataset is displayed within the PROC CONTENTS output.

<table>
<thead>
<tr>
<th>The CONTENTS Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Set Name</td>
</tr>
<tr>
<td>Member Type</td>
</tr>
<tr>
<td>Engine</td>
</tr>
<tr>
<td>Created</td>
</tr>
<tr>
<td>Last Modified</td>
</tr>
<tr>
<td>Protection</td>
</tr>
<tr>
<td>Data Set Type</td>
</tr>
<tr>
<td>Label</td>
</tr>
<tr>
<td>Data Representation</td>
</tr>
<tr>
<td>Encoding</td>
</tr>
</tbody>
</table>

### Output 2. Output from PROC CONTENTS

While the FDA does not explicitly state requirements for data encoding, there are related standards that must be followed. Per the technical conformance guide, “Variable names, as well as variable and dataset labels should include American Standard Code for Information Interchange (ASCII) text codes only” (Rui, 2016). As for the contents of the data itself, the agency requires only the English language and expects sponsors to remove or convert non-ASCII characters collected in research before submission (U.S. Food and Drug Administration, 2015). This is an important requirement of which to be aware, as the use of free text fields in UTF-8 encoded source data has high potential to capture non-ASCII characters. Also, for reasons on which this paper will elaborate, it can be assumed that the extended-ASCII character set is included in the list of characters that should be removed or converted.

WHERE THE PROBLEMS COME FROM IN YOUR DATA

Taking into consideration the extensiveness of the UTF-8 character set, it is fairly clear how characters from other languages can slip into your data, depending on where the data were collected, investigators and subjects, etc. Unfortunately, even some fairly common characters can still cause issues when transcoding. These characters will most likely come from free text fields, and include characters such as left or right quotes (“ or “ versus “), long dashes (“–“ versus “-“), and other characters that a windows environment might automatically correct for you. Venturing into the extended-ASCII character set is where issues will start to present themselves. To understand why, we need to look at how SAS transcodes the data.

HOW SAS TRANSCODES AND WHY ERRORS HAPPEN

In many situations in which SAS needs to transcode, SAS does the work for you. This is because of Cross-Environment Data Access (CEDA). CEDA allows SAS to do the work behind the scenes. Assuming no issues are encountered, you are left with a simple note in the log.

```
NOTE: Data file RAWDATA.AE.DATA is in a format that is native to another host, or the file encoding does not match the session encoding. Cross Environment Data Access will be used, which might require additional CPU resources and might reduce performance.
```

### Output 1. Log message showing note generated by CEDA.

In other situations, you may not be so lucky. SAS may be unable to transcode the data. To make matters worse, the log errors generated by SAS do not explicitly state where or why SAS encountered the issue.
ERROR: Some character data was lost during transcoding in the dataset DATA.AE. Either the data contains characters that are not representable in the new encoding or truncation occurred during transcoding.

Output 2. Log message showing the error generated by SAS when it is unable to transcode.

Though the error does not guide you to the issue, it gives some context as to why the issue could be happening. Transcoding errors can happen in SAS for two reasons:

1. The dataset being read into SAS has a character that is not representable in the session encoding.
2. Truncation occurred during transcoding.

The first potential issue has a much clearer explanation than the second. As mentioned before, UTF-8 encoding supports more than 120,000 characters. This is vastly greater than the 256 characters handled by LATIN1. If there is no character to transcode to, then the character cannot be transcoded. For example, if in a UTF-8 encoded dataset, the Greek character “Δ” exists – then LATIN1 has no compatible conversion for this, and thus SAS forces the error as the conversion was not successful.

As for the second issue, to understand it, we must first understand what is being truncated. When a SAS length is set on a character variable, the length is not in reference to the number of characters that may be contained, but rather the number of bytes. For an SBCS, these two things are synonymous. If 1 byte = 1 character, then a length of $4 will allow both 4 characters and 4 bytes. But in UTF-8 encoding, 1 character may consist of 1 to 4 bytes. For example, if we look at the word “sofá” on the byte level:

- LATIN1
  
  `01110011 : 01101111 : 01100110 : 11100001`
  
  Figure 1. Outline of byte level data in Latin1 encoding.

- UTF-8
  
  `01110011 : 01101111 : 01100110 : 11000011 : 10100001`
  
  Figure 2. Outline of byte level data in UTF-8 encoding.

Because LATIN1 encoding is a SBCS, each character is represented by one single byte. The character “á” is within the extended ASCII character set, and thus LATIN1 encoding is capable of representing it. In this encoding, the string “sofá” is made up by 4 bytes, and therefore a length of $4 is acceptable.

The trouble arises when we try to transcode this data to UTF-8 without any compensation for variable lengths. While the character “á” is made up on one byte in LATIN1, in UTF-8 it is made up of 2 bytes. Given that the variable length is $4, the last byte of the string “sofá” will be truncated:

`01110011 : 01101111 : 01100110 : 11000011`

Figure 3. Outline of truncated byte level data in UTF-8 encoding.

Note that this truncation issue occurs when transcoding from LATIN1 to UTF-8. Truncation itself is not of concern when moving from UTF-8 to LATIN1, as the LATIN1 will only require identical, if not shorter lengths to represent the same data as UTF-8 because it requires one byte per character. That being said, this assumes that the lengths in the UTF-8 encoded data are not already truncating any values. The string “sofá” can still be captured in UTF-8 data natively with a length of $4, but the last byte of “á” will be truncated off and the character will not display. When trying to transcode this truncated string from UTF-8 to LATIN1, SAS will again error – but this time not because of the truncation itself, but because the first byte of “á” has no direct counterpart in LATIN1, and thus the character in non-representable.

THE DANGER OF ENCODING = ANY | ASCIANY

One thing that makes the issue of encoding differences particularly frustrating is how buried the problem itself can be. Clinical trials can collect a massive amount of data, and within the data may be a single character in an inconvenient location that renders SAS unable to transcode. The “encoding=any” or “encoding=asciiany” options will allow you to import your data and work with it in your session, but it is very important to understand how this works.
First, let us look at the syntax to use "encoding=asciiiany":

```sas
data myDS;
  set utf8.myDS (encoding=asciiiany);
run;
```

The syntax is simple and requires little effort to import the data into SAS with no errors. But what is SAS doing behind the scenes to make this work? Once again, let us look at UTF-8 truncated string of “sofá” with a length of $4$:

```
| 01110011 | 01101111 | 01100110 | 11000011 |
| s | o | f | ? |
```

**Figure 3. Outline of truncated byte level data in UTF-8 encoding.**

By using the option “encoding=asciiiany”, SAS ignores the UTF-8 encoding all together. Instead, SAS will read the data and interpret every byte using their single byte ASCII coded values. SAS cannot magically make up the data lost in truncation, so it needs to interpret the value as something. While the byte “11000011” does not have a coded value in UTF-8, it does have an ASCII coded value. Therefore, SAS will interpret the string as:

```
| 01110011 | 01101111 | 01100110 | 11000011 |
| s | o | f | Ä |
```

**Figure 3. Interpretation of truncated byte level data in UTF-8 encoding using “encoding=asciiiany”.

Now it should be clear that this option should not be used as a *fix*, but rather a temporary workaround to be able to access the data. To make matters worse, this option will not only impact truncated characters like in our string “sofá”, but rather any character made up of 2 bytes or greater in the UTF-8 encoded data. For example:

```
Table 1

<table>
<thead>
<tr>
<th>Binary</th>
<th>UTF-8</th>
<th>ASCII</th>
</tr>
</thead>
<tbody>
<tr>
<td>11000011:10100001</td>
<td>á</td>
<td>Áä</td>
</tr>
<tr>
<td>11000011:10111100</td>
<td>ü</td>
<td>Å¼</td>
</tr>
<tr>
<td>11000011:10111000</td>
<td>ø</td>
<td>Àø</td>
</tr>
<tr>
<td>11000011:10110001</td>
<td>ŋ</td>
<td>Àź</td>
</tr>
</tbody>
</table>
```

**Table 1. UTF-8 encoded double byte characters and how they will be converted using “encoding=asciiiany”**

### IDENTIFYING AND ISOLATING YOUR ISSUES

With mountains of data on hand, it is important to have a tool to isolate and reveal the characters potentially causing issues. The code examples displayed in this paper hinge on modifications of the following syntax (Ziem, 2011).

```sas
<variable>=prxchange('s/\[\x20-\x7F]//', -1, <source>);
```

The function PRXCHANGE allows you to use Perl regular expressions. A regular expression is a special text string for describing search patterns. In a programming language like Perl, they can also be used to do things such as global replaces. The syntax of PRXCHANGE is defined as (PRXCHANGE Function, n.d.):

- PRXCHANGE(perl-regular-expression | regular-expression-id, times, source)

In the code example, the fields are utilized as follows:

- perl-regular-expression | regular-expression-id

Perl regular expression executing a global replace that specifies to remove the lower-ASCII character set, defined by hexadecimal character codes. With only slight changes to this statement, the macro can be modified to do a number of different things. In its current state, it removes the lower ASCII character set, but it can be changed to:

- Replace values outside the lower-ASCII character with other values (see “Locating issues in the data and adding preventative checks”)
- Remove characters outside the lower ASCII character set (see “Cleaning it all out”)
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- Times
  In these examples, our goal is to remove or replace all targeted character in the string. By specifying `-1`, this tells the function to replace matching patterns until the end of source is reached. In these examples, our goal is to remove or replace all targeted character in the string.

- Source
  This is the target string or variable on which the Perl regular expression will be executed.

Following is an example of how this function may be used to remove ASCII characters from a string and leave only the non-ASCII characters:

```plaintext
data example1;
  var1="ßet ÿöû c@ñ'† get ®id of mÊ";
  var2=prxchange('s/[^x20-\x7F]//', -1, var1);
run;

proc print data=example1;
run;
```

Output 3 shows the ASCII characters being removed:

<table>
<thead>
<tr>
<th>Obs</th>
<th>var1</th>
<th>var2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ßet ÿöû c@ñ'† get ®id of mÊ</td>
<td>ßÿöûñ†®Ê</td>
</tr>
</tbody>
</table>

Output 3. Output from a PROC PRINT Statement.

VAR1 contains a string of characters consisting of a mix between characters in the lower-ASCII and extended-ASCII character set. Within VAR2, all lower-ASCII characters have been removed. The benefit of this is to troubleshoot data that may be problematic. If you are to fix the problem, you first must understand what is causing it in the first place. If a transcoding error is encountered, the problem is not coming from lower-ASCII characters, but rather characters outside the lower-ASCII character range. This syntax is a first step towards isolating those characters.

PUT THE CODE TO WORK

This function can be very powerful in creating scripts that help show you where your issues characters are, isolate the issue characters, or remove them completely. While these steps will not fix the fundamental problem, they can give a strong leg up towards understanding the problem and deciding an approach. The following code examples all use this example dataset:

<table>
<thead>
<tr>
<th>Obs</th>
<th>var1</th>
<th>var2</th>
<th>var3</th>
<th>var4</th>
<th>var5</th>
<th>var6</th>
<th>var7</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ßet</td>
<td>ÿöû</td>
<td>c@ñ'†</td>
<td>get</td>
<td>@id</td>
<td>®id</td>
<td>mÊ</td>
</tr>
<tr>
<td>2</td>
<td>ßµ†</td>
<td>ÿص</td>
<td>wصld</td>
<td>ÿص</td>
<td>wan†</td>
<td>†ø</td>
<td>anýway?</td>
</tr>
<tr>
<td>3</td>
<td>Because</td>
<td>sØme</td>
<td>characters</td>
<td>dØn't</td>
<td>like</td>
<td>tØ</td>
<td>transcØde</td>
</tr>
</tbody>
</table>

Input 1. Data to be used in code examples

Isolating your issues

At this point, we understand that the lower-ASCII character set, represented by a single byte in both LATIN1 and UTF-8 encodings, is not the source of the issue. These characters have no issue transcoding between encodings, but rather the characters outside this list may give you trouble. Gathering a list of the unique characters within your dataset allows you to examine what could be causing the issue and decide your next move. The following macro will isolate the unique characters outside of the lower-ASCII character set.
%macro isolate(inds=);
   * Gather character variable names;
   proc contents data=&inds. noprint out=vars (where=(type=2) keep=name type);
    run;

   * Compress macro for removing non-ascii characters;
   %macro rmeasci(var);
    &var.=putxchange('s/\[\x20-\x7F]//', -1, &var.);
   %mend;

   * Loop macro;
   %macro dataset;
    %do j=1 %to %eval(&cnt.);
     %let cds=%scan(&vars.,&j); %rmeasci(&cds);
    %end;
   %mend dataset;

   * Set macro variables for character variables and counts;
   proc sql noprint;
    select name into: vars separated by ' ' from vars;
    select name into: vars2 separated by ',' from vars;
    select count("&vars.",') +1 as cnt into: cnt from vars;
    quit;

   * Run macro through dataset;
   data non_&inds. (keep=bad_char where=(not missing(bad_char)));
    set &inds.;
    %dataset;
    bad_char=cats(&vars2.);
   run;

   proc sql noprint;
    select distinct bad_char into: bad_char separated by '' from non_&inds.;
   run;

   data non_&inds.2 (rename=(string=bad_char));
    vi
     length STRING $1000;
     /* Set length of string */
     string="&bad_char.";
     l1=length(string);
     /* Eliminate duplicates in the string */
     do i = 1 to l1-1;
       ti=substr(string,i,1);
       if ti ^= '00'x then do j = i+1 to l1;
         if ti=substr(string,j,1) then substr(string,j,1)='00'x;
       end;
    end;
    * the COMPRESS function is used to remove the nulls;
    string=strip(compress(string,'00'x));
    keep string;
   run;

   proc print data=non_&inds.2;
    run;
   %mend isolate;
The output of the macro shows you the unique list of non-ASCII characters in your data.

<table>
<thead>
<tr>
<th>Obs</th>
<th>bad_char</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>€¡ýœâœ®Œµ</td>
</tr>
</tbody>
</table>

Output 4. Output from PROC PRINT showing unique non-ASCII characters

Locating issues in the data and adding preventative checks

Isolating the characters causing issues helps, but it does not show you where the characters are in the data. It is also important to understand which observations and variables themselves have the non-ASCII character. First, this requires a modification to our non-ascii function.

```
<variable>=prxchange('s/[^\x20-\x7F]/XX/', -1, <source>);
```

Two changes have been made. The ^ before \x20 to specify that we are replacing characters outside the ASCII character set. Also, "XX" was added after the forward back slash as the replace with value.

The following macro will loop through a dataset, replace all characters outside the lower-ASCII character set with XX, and then compare the changes back to the original dataset – allowing you to view the individual records where non-ascii characters were discovered.

```plaintext
%macro compare(inds=);
    *Gather character variable names;
    proc contents data=&inds. noprint out=vars (where=(type=2) keep=name type);
    run;
    *Compress macro for removing non-ascii characters;
    %macro rmeasci(var);
    &var.=prxchange('s/([^\x20-\x7F])/XX/',' -1, &var.);
    %mend;
    *Loop macro;
    %macro dataset;
    %do j=1 %to %eval(&cnt.);
    %let cds=%scan(&vars.,&j);
    %rmeasci(&cds);
    %end;
    %mend dataset;
    *Set macro variables for character variables and counts;
    proc sql noprint;
    select name into: vars separated by ' ' from vars;
    select count(&vars.,' ')+1 as cnt into: cnt from vars;
    quit;
    *Run macro through dataset;
    data non_&inds.;
    set &inds.;
    %dataset;
    run;
    *Compare results back to original;
    proc compare base=&inds. compare=non_&inds. outbase outcomp outnoequal noprint out=non_diff;
    run;
    *Print discrepancies;
    proc print data=non_diff;
    var _type_ _obs_ &vars.;
    run;
```
*Remove working datasets;
   proc datasets library=work nolist;
       delete non&_nds. non_diff vars;
   run;
%mend compare;

The print resulting from the macro shows each issue record back to back. The original observations show up on the BASE lines. On the COMPARE lines, characters outside of the lower-ASCII character set have been replaced with “XX”.

<table>
<thead>
<tr>
<th>Obs</th>
<th><em>TYPE</em></th>
<th><em>OBS</em></th>
<th>var1</th>
<th>var2</th>
<th>var3</th>
<th>var4</th>
<th>var5</th>
<th>var6</th>
<th>var7</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BASE</td>
<td>1</td>
<td>ße†</td>
<td>ýöû</td>
<td>c@ñ'†</td>
<td>get†</td>
<td>@id</td>
<td>Øf</td>
<td>mÊ</td>
</tr>
<tr>
<td>2</td>
<td>COMPARE</td>
<td>1</td>
<td>XXeXX</td>
<td>XXXXX</td>
<td>c@XX'XX</td>
<td>geXX</td>
<td>XXid</td>
<td>XXf</td>
<td>mXXXXX</td>
</tr>
<tr>
<td>3</td>
<td>BASE</td>
<td>2</td>
<td>ßµ†</td>
<td>whŷ</td>
<td>wØµld</td>
<td>yØµ</td>
<td>want†</td>
<td>tø</td>
<td>anyway?</td>
</tr>
<tr>
<td>4</td>
<td>COMPARE</td>
<td>2</td>
<td>XXXXXX</td>
<td>whXX</td>
<td>wXXXXld</td>
<td>XXXXXX</td>
<td>wanXX</td>
<td>XXXX</td>
<td>anXXwaXX?XX</td>
</tr>
<tr>
<td>5</td>
<td>BASE</td>
<td>3</td>
<td>because</td>
<td>sØme</td>
<td>characters</td>
<td>dØn'†</td>
<td>like</td>
<td>tØ</td>
<td>transcØde</td>
</tr>
<tr>
<td>6</td>
<td>COMPARE</td>
<td>3</td>
<td>XXecause</td>
<td>sXXme</td>
<td>characXXers</td>
<td>dXXn'XX</td>
<td>like</td>
<td>XXXX</td>
<td>XXtranscXXdeXX</td>
</tr>
</tbody>
</table>

Output 5. Output from PROC PRINT showing original record and non-ASCII characters replaced with XX

Cleaning it all out

What if you are left without an option? The database is locked, extended-ASCII characters or non-ASCII characters are sprinkled throughout, and the agreement is that you will remove them at the CDISC level. To be clear, this is far from ideal. If fixing the issues at the source is not an option, then you should consider developing an algorithm to replace the non-ASCII characters with acceptable ASCII counterparts (i.e. “µ” with “u”). In this scenario, removing the non-ASCII characters is not the best option; it is the only one available. Additionally, for this to truly be an appropriate case, the characters to be removed would more likely be invisible characters – things such as carriage returns or control characters within the extended-ASCII character set. It is not recommended to use this method if the characters removed are of some sort of value. This again requires a slight modification to our non-ASCII function.

<variable>=prxchange('s/[^\x20-\x7F]//', -1, <source>);

Now, instead of replacing characters with "XX", the characters non-ASCII characters are replaced with nothing. The following macro will loop through each variable on each observation of your dataset and simply remove the non-ASCII characters encountered.

%macro cleanse(inds=);
   %*Gather character variable names;
   proc contents data=&inds. noprint out=vars (where=(type=2) keep=memlabel name type);
   run;

   %*Grab dataset label to reapply;
   proc sql noprint;
       select distinct strip(memlabel) into: domlabe
   from vars;
   quit;

   %*Compress macro for removing characters outside the lower-ASCII character set;
   %macro rmeasci(var);
      &var.=prxchange('s/[^\x20-\x7F]//', -1, &var.);
   %mend;

   %*Loop macro;
   %macro dataset;
      %do i=1 %to %eval(&cnt.);
         %let cds=%scan(&vars.,&i);
         %rmeasci(&cds);
      %end;
   %mend dataset;

   %*Set macro variables for character variables and counts;
   proc sql noprint;
       select name into: vars separated by ' ' from vars;
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continued

```sql
select count("&vars.",', ')+1 as cnt into: cnt from vars;
quit;
*Run macro through dataset;
data &inds. (label="&domlabel.");
set &inds.;
%dataset;
run;
proc datasets library=work nolist;
delete vars;
run;
%mend cleanse;
```

The dataset resulting from the macro is stripped of characters outside the lower-ASCII character set.

<table>
<thead>
<tr>
<th>Obs</th>
<th>var1</th>
<th>var2</th>
<th>var3</th>
<th>var4</th>
<th>var5</th>
<th>var6</th>
<th>var7</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>e</td>
<td>c@'</td>
<td>ge</td>
<td>id</td>
<td>f</td>
<td>m</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>wh</td>
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Output 6. Output from PROC PRINT showing original only ASCII characters remaining

CONCLUSION

When working with UTF-8 encoded data, most of the time SAS does the work for you. Cross-Environment Data Access is a very useful tool built into SAS that transcodes your data behind the scenes, but due to the nature of encoding, it cannot work flawlessly each and every time. SAS cannot transcode a character if it is not representable by both the source encoding and the session encoding. Additionally, with the multi-byte nature of UTF-8, there is a risk for truncation of values – which is not of concern in LATIN1 encoding.

Despite the many benefits of UTF-8 encoding, caution must be taken when working on a CDISC submission to the FDA. Ultimately, whether a LATIN1 or UTF-8 session encoding is used to create your CDISC datasets is not important. If a UTF-8 encoded session is used, then transcoding issues when working with UTF-8 encoded source data will be avoided. If a LATIN1 session encoding is used, then any errors that occur upon import of the source data must be addressed and understood, as work-arounds like the “encoding=asciiany” option are not acceptable solution. The bottom line is that non-ASCII characters must be removed or converted at some point during development.

Given that issues with non-ASCII characters and transcoding route back to the source, it is best to start these checks at the source itself. If non-ASCII characters are never entered into the data in the first place, then issues downstream will prevented before they can occur. If the “bad” characters make it into the data anyway, then the source data is still the optimal place to have the issue fixed.

Unfortunately, this is not always an option – but the problem still needs to be fixed somewhere. One potential option to eliminate non-ASCII characters at the SDTM level is to determine replacements. Many characters may have an ASCII counterpart that would an acceptable replacement. For example, “µ” could be replaced with “u” without too much concern. If the non-ASCII characters that exist in the source data are all invisible characters, then these could likely be eliminated without significant impact to the data or information loss. Ultimately, decisions must be made based on the issue at hand, and any changes made at the SDTM level should be documented in the Study Data Reviewers Guide (SDRG).

Given the FDA requirement of restricting data to the ASCII character set and submitting data in the English language, additional review measures should be put in place throughout the course of a trial to ensure submission readiness. Not only can the code presented in this paper be used to evaluate and understand problems with encoding at hand, but also to place preventive checks on your data throughout the process of developing your datasets, both CDISC and non-CDISC. Understanding and properly handling any encoding issues encountered in your data is crucial to maintaining quality and traceability. Attacking the issues early on helps ensure that data sent to the FDA will be compatible downstream and will help prevent any last minute delays before submission.
REFERENCES


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