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Single Day Event

Automatic Process to Prepare Programming Codes for NMPA Submission

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Agenda

Background

- NMPA, CDE Guideline
- Challenges

Manual Process

- Manual De-Macro
- Manual Annotation

Automatic Process

- Automatic Annotation
- Automatic De-Macro
- Automatic Reformatting

New Proposal

- Dynamic hierarchy display

Background – NMPA, CDE Guideline

药物临床试验数据递交指导原则

（试行）

（六）程序代码

申办方需要递交的程序代码包括但不限于：分析数据集中衍生变量的衍生过程、疗效指标分析结果的生成过程等。申报资料中递交的程序代码应当易懂①、可读性强，建议提供②充分的注释、避免外部(宏)程序调用③。程序代码一般采用 TXT 文件。

Understandable & readable

Adequate annotation

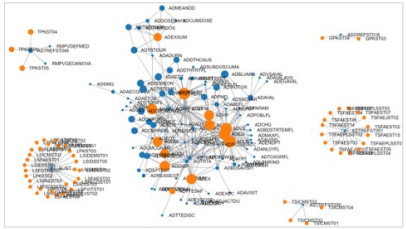
Avoid macro calls

Background - Challenges

Comments in English

```
/*************************************************************************
Original Reporting Effort:
Program Name       : add_watermark.sas
SAS Version        : 9.4
Short Description  : Add watermark to rtf file(s).
Author             : JSONG67
Date               : 03DEC2019
Input              : Location(path) of the rtf files
Output             : rtf files with watermark
Remarks            : The macro will read in the rtf file(s) as dataset(s) and add the watermark. Then out the dataset as rtf file
                     which will replace the former one. Please make sure you've backups of the rtf file or you can reproduce
                     the files.
Assumptions        :
Macro Parameters   : rtfpath    : The path of the rtf files.
                     targetfile: List rtf file name(s) to add watermark, sparated by "|".
                                 Add "-" before the list for exclusion.
                     startwith : List the string(s) which the file names start with to add watermark, sparated by "|".
                                 Add "-" before the list to exclude the file started with these strings.
                     watermark : The string you want to add as the watermark.
Macro Sample Call  :
                     ** Add watermark for all rtf files under the path
                     %add_watermark(rtfpath     = &path.,
                                    watermark   = DRAFT VERSION);
Modification History:
Rev #    Modified By     Reporting Effort    Date       Description
*************************************************************************/
```

Multi-level of nested macros



Annotation translation

Adequate annotation

Understandable & readable

Avoid macro calls

De-Macro Process

Manual Process

Run PME to get the structure of macro calls

Get the target macros need to be decreased

Divide all target macros into batches and assign to different colleagues

Decrease macros to open code and add annotations

Increase readability of the decreased macros

Select macros for Adam programming only

Manually simulation from lower level to higher level

		lev2	lev3	lev4	lev5
adeff	%imwgresp	%bsliss	%ablfl	%refvars	%trtdates
		%bslemp	%plasmabl	%refvars	%trtdates
		%ldisasmt	%therstdt	%trtdates	

ower batch
er batch

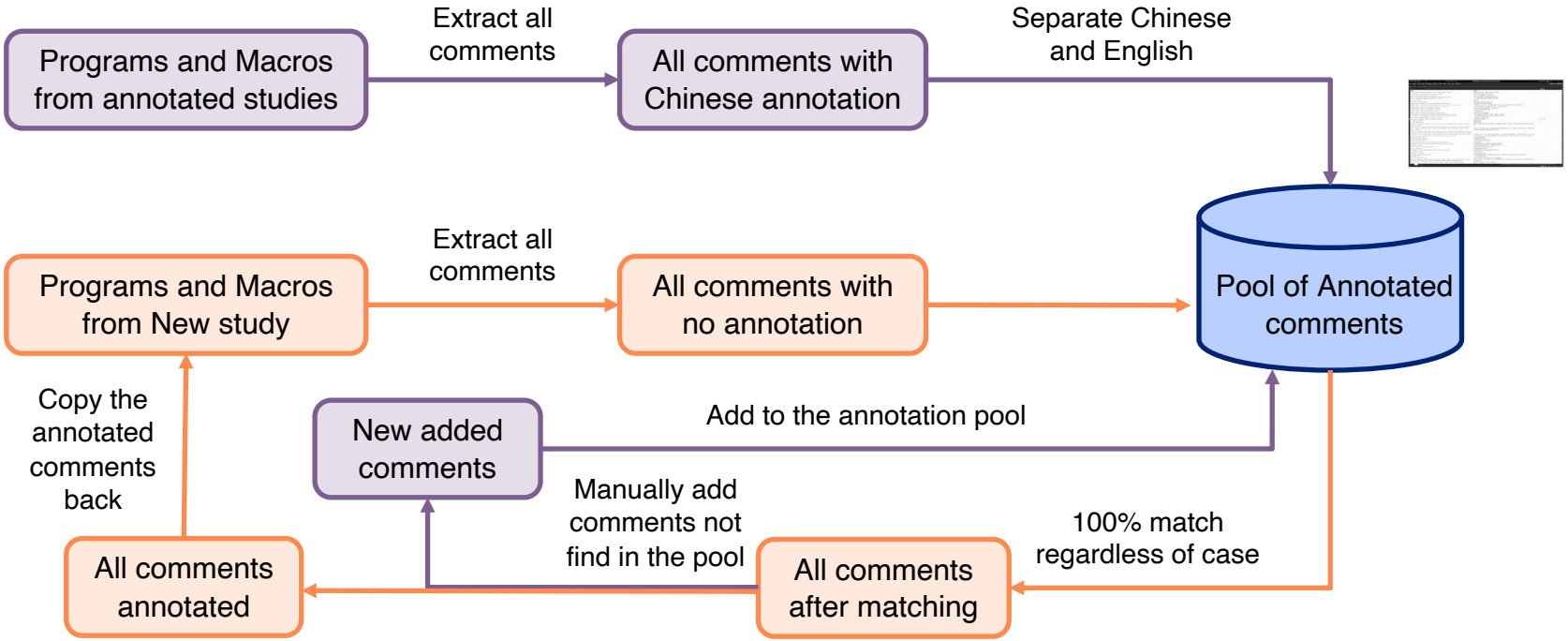
Change sub-macros to open code → Delete checks and debugs and simplify macro header → Translate and add extra annotation

Replace the macro call in upstream macro/program → Decrease upstream macro instead of decreasing a long macro

Rerun ADaM programs and compare with the original data

Get variables from ADSL or simplify code instead of calling macro → Check and modify code logic as a whole → Convert all SAS programs to UTF-8 encoding

Automatic Process - Auto Annotation



Automatic Process - Auto De-Macro

Comments transfer

```
%ComsTrans(prgpath = &prgpath);
```

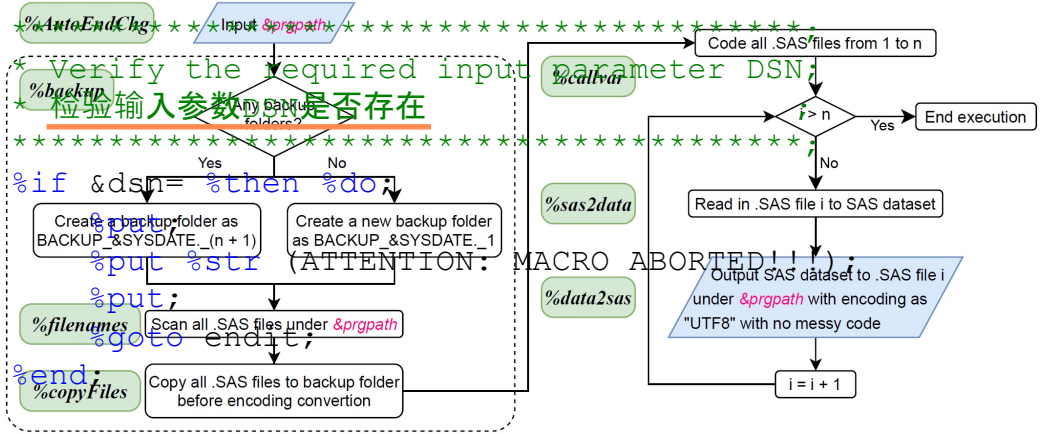
Macro decrease

```
%AllOpenD(AdamList = adsl|adae,
          bjlPath  = &bjl,
          PrgPath  = &Prg,
          AdamPath = &Adam,
         OutPath   = &out);
```

Encoding transfer

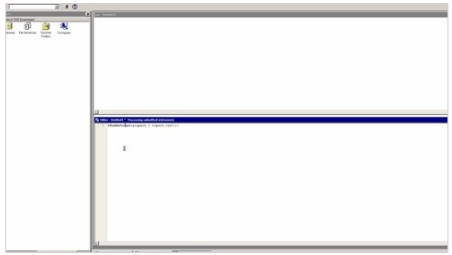
```
%AutoEndChg(prgpath = &testpath)
```

```
%macro test;
data dm;
    set d_in.dm;
    keep studyid usubjid ARM ACTARM;
run;%mend;

/*test com1*/
和通用变量合并 com2.

%if &dsn= %then %do;
    %put;
    %put %str(ATTENTION: MACRO ABORTED!!!);
    %put;
    proc sql;
    %goto endit;
%end;
    create table _dsn as
    select a.*, b.subjid, b.siteid, b.age,
```



Automatic Process - Auto Reformat

```
* 和通用变量合并;
proc sql;
create table _dsn as
select a.*, b.subjid, b.siteid, b.age,
b.ageu, b.sex, b.race, b.country
from dm a
left join d_in.dm b
on a.usubjid = b.usubjid;
quit;
data dm;
set _dsn;
run;
proc datasets;
delete _dsn _dm;
quit;
```



Reformat SAS code in Batch.exe

Reformat SAS code in Batch (run by SAS).exe

```
%RunReformat(prgpath = &testpath);
```

New Proposal - Dynamic hierarchy display

adeff.sas

/*在adsl中加入末次访视日期变量LDISASMT*/

⊖ Open code lines

药物临床试验数据递交指导原则 :WITHDRDT*/

（试行） :THERSTDT */

（六）程序代码

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Open code lines

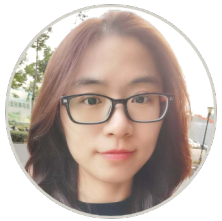
xTM和xxxxDTM变量*/

Contributors

Team Members

Chen, Li *

Sr. Statistical Programmer



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Statistical Programmer

Liu, Tingting *

Statistical Programmer

Peng, Mandy

Principal Statistical Programming Lead

Wang, Jing

SR STATISTICAL PROGRAMMER ANALYST

Special Thanks

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Liu, Lihua *

Statistical Programmer

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STATISTICAL PROGRAMMING LEAD

All other members in NMPA e-sub initiative

** These colleagues are from ICON*

THANK YOU

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