

Programmed Patient Narratives Using SAS®

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What is Patient Narrative?

(ICH E3 CSR Guidelines)

12.3.2 Narratives of Deaths, Other Serious Adverse Events and Certain Other Significant Adverse Events

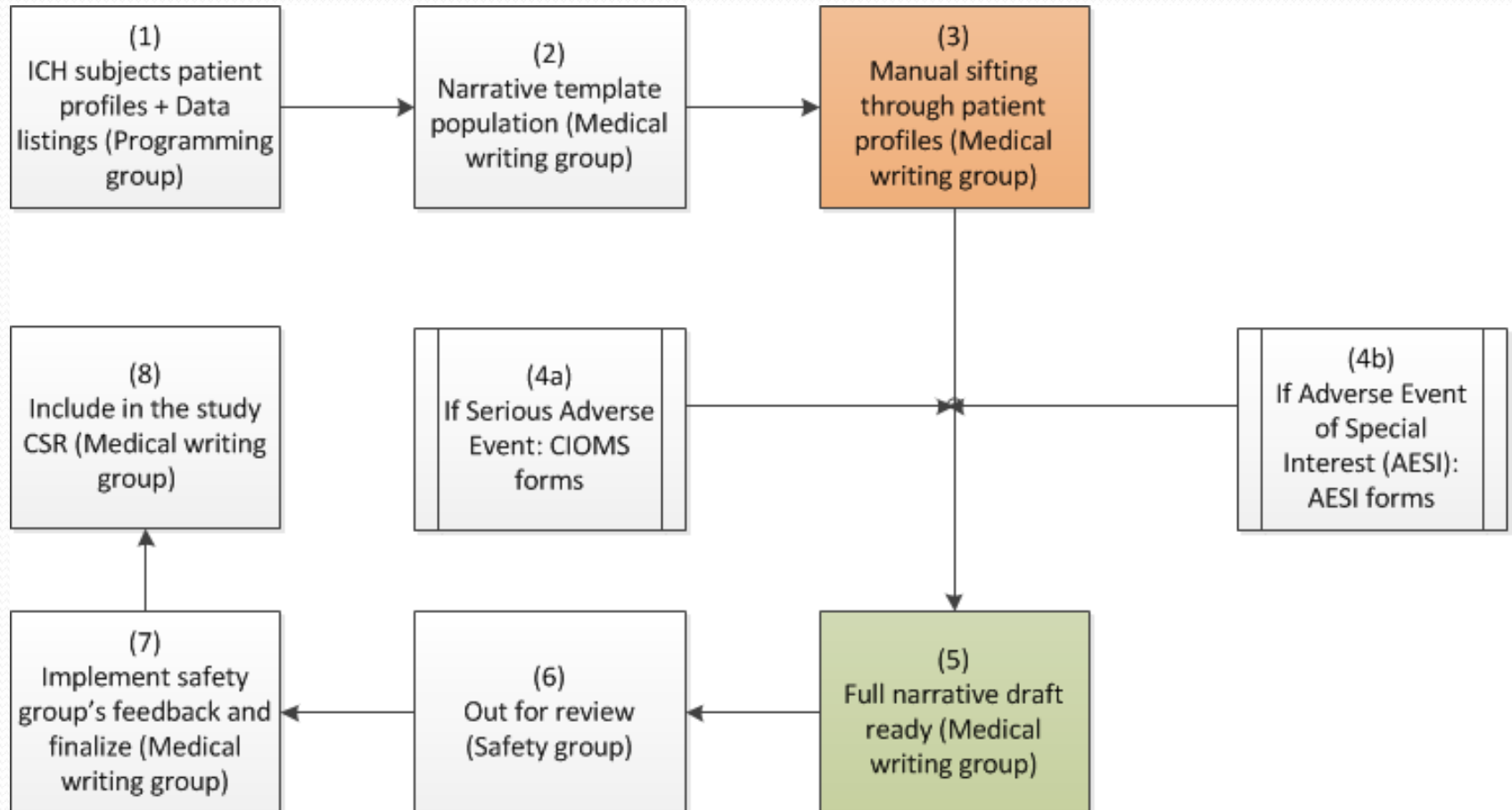
There should be brief narratives describing each death, each other serious adverse event, and those of the other significant adverse events that are judged to be of special interest because of clinical importance. These narratives can be placed either in the text of the report or in section 14.3.3, depending on their number. Events that were clearly unrelated to the test drug/investigational product may be omitted or described very briefly. In general, the narrative should describe the following:

the nature and intensity of event, the clinical course leading up to event, with an indication of timing relevant to test drug/investigational product administration; relevant laboratory measurements, whether the drug was stopped, and when; countermeasures; post mortem findings; investigator's opinion on causality, and sponsor's opinion on causality, if appropriate.

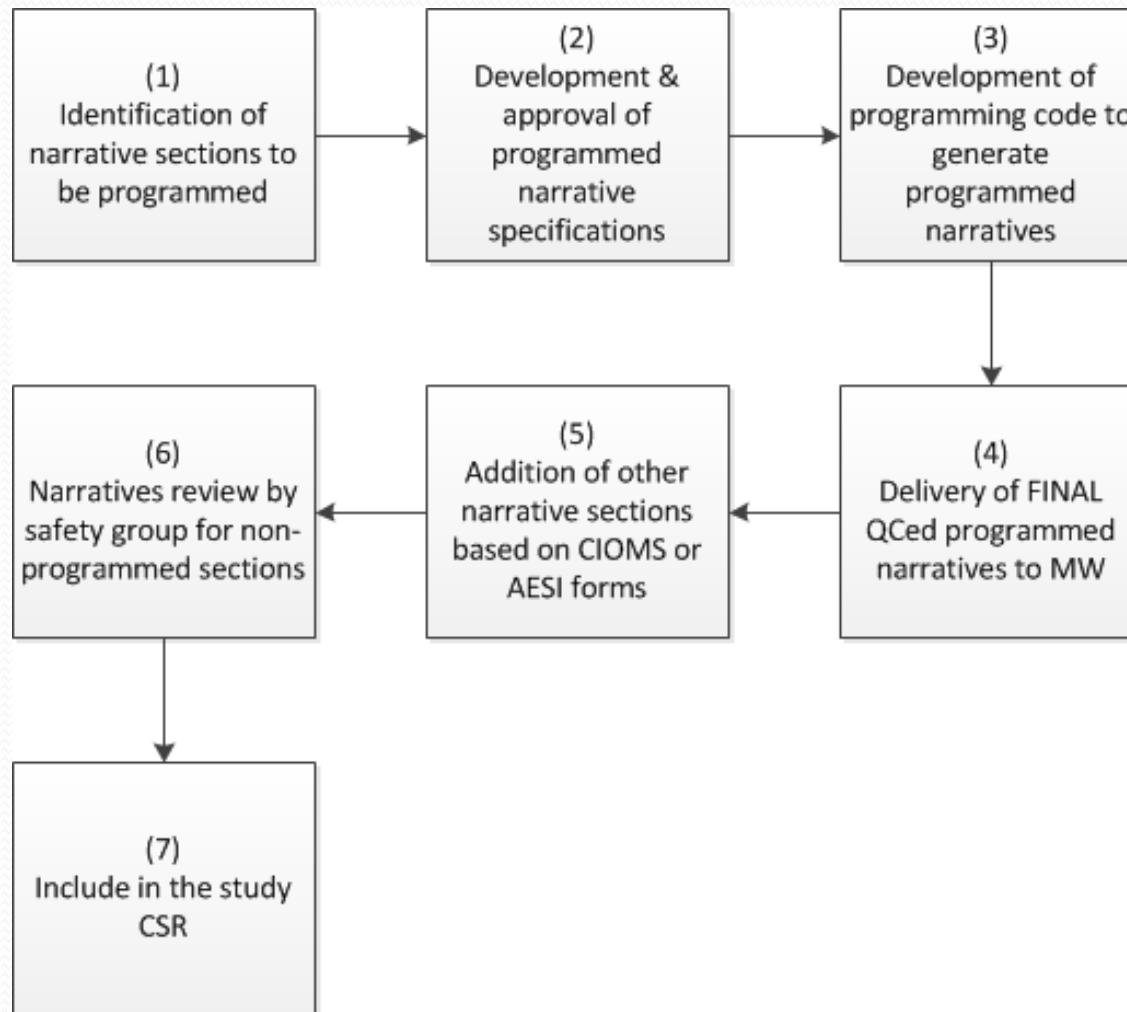
In addition, the following information should be included:

- Patient identifier
- Age and sex of patient; general clinical condition of patient, if appropriate
- Disease being treated (if the same for all patients this is not required) with duration (of current episode) of illness
- Relevant concomitant/previous illnesses with details of occurrence/duration
- Relevant concomitant/previous medication with details of dosage
- Test drug/investigational product administered,

Our Traditional Process



New Process With Programmed Approach



Specifications for Narratives (1)

Subject ID: <dummy ID> (xxx-xxx) {1.1}

Study Treatment in 111XXX000: Drug A 100 times a week {1.2}

Treatment Period in 111XXX000: <date first dose as dd month yyyy> to <date last dose as dd month yyyy> {1.6}

Total Number of Drug A Doses Received in 111XXX000: x {1.7}

Total Number of Placebo Doses Received in 111XXX000: x

Death {1.8}

Date of Death: dd Month yyyy {1.9}

{ 1.3 } **Adverse Event:** <Reported term>

MedDRA Term: <Preferred term>

Total Number of Drug A Doses Received at Event Onset {1.4}: x {1.5}

Total Number of Placebo Doses Received at Event Onset: x

Subject <dummy ID> (xxx-xxx) {2.1}, a 48 {2.2}-year-old white (race not recorded) {2.3} female {2.4}, was enrolled into Study 111XXX000 {2.5} and began a treatment regimen of placebo 100 times a weeks {2.6} on 11 May 2010 {2.7} (Day 1 {2.8}).

No medical history was reported for this subject at the time of study enrollment {2.9}. The subject's reported medical history at the time of study enrollment included (verbatim terms) allergy to tv, movies. Allergies included (verbatim terms) allergy to soap operas, action movies. **No allergies were reported.**

Specifications for Narratives (2)

2. Part 2 – Patient Introduction

2.1. DM.SUBJID

2.2. DM.AGE

2.3. DM.RACE. Note the capitalization here: white, African American, Asian. If race is not reported in the data due to confidentiality reason, then insert “(race not recorded)”. If race is other, then insert “(race listed as ‘other’)”.

2.4. DM.SEX values mapped to “male” or “female”.

2.4.1. Note that this is used to refer to the patient as He/She for the entire narrative.

2.5. DM.STUDYID

2.6. The text “and began a treatment regimen of” concatenated with treatment description as described in section {1.2}

2.7. DM.RFSTDTC

Data Sources Used

SDTM

- DM, DS, EX, MH, CM

ADaM

- ADSL, ADAE

Narrative Sample (1)

Subject ID: 0000000 (111-111)
Study Treatment in 111XX000: DRUG A 100 times a day
Treatment Period in 111XX000: 12 January 2020 to 22 August 2040
Total Number of DRUG A Doses Received in 111XX000: 40

Non-serious Adverse Event of Special Interest: SOMEAE
Dummy MedDRA Term: SOMEAE
Total Number of DRUG A Doses Received at Event Onset: 20

Non-serious Adverse Event Leading to Discontinuation of Study Treatment and
Withdrawal from the Study: OTHERAE
Dummy MedDRA Term: OTHERAE
Total Number of DRUG A Doses Received at Event Onset: 40

Subject 0000000 (111-111), a 200-year-old (race listed as 'anyrace') female, was enrolled into Study 111XX000 and began a treatment regimen of DRUG A 100 times a day and placebo 200 times a day on 11 January 2020 (Day 1).

On 23 January 2020 (Day 380), an adverse event of too much TV was reported, which was classified as a non-serious adverse event by the Investigator. The subject had received 200 doses of DRUG A before onset of the event, with her most recent dose given on 07 January 2020 (Day 364).



(1) Header Section
(Once per subject)



(2) Demography + Medical
history section
(Once per subject)

Narrative Sample (2)

Non-serious Adverse Event of Special Interest: (coded term [reported term]): SOMEAE [SOMEAE]

On the day before event onset, the subject was taking the following dummy concomitant medications: strawberries, bananas, apples, blueberries, pears, pineapple.

While the event was ongoing, the subject also began treatment with action movies (on 23 January 2020).

The event (swelling face) was reported as resolved on 24 January 2020 (Day 385).

The subject's final dose of study treatment was on 30 August 2020 (Day 1000). The subject was withdrawn from the dummy study. Her final assessment in Study 111XX000 was on 15 February 2025 (Day 2000).



(3) AE Section
(Once per subject per AE)



(4) Concluding section
(Once per subject per AE)

Code Snippets (1)

- Use of formats

```
** Format for gender reference **;  
value $genrefs  
'M' = 'his'  
'F' = 'her'  
;  
  ** Format ae severity text in the AE section **;  
value $ser2fmt  
'N' = 'which was classified as a non-serious adverse event by the Investigator.'  
'Y' = 'which was classified as a serious adverse event by the Investigator.'  
;  
  ** Format for AE seriousness to be used in AE section (header of each AE) **;  
value $aeheadfmt  
'Y' = '^~2n^~2n^S={font_weight=bold}Serious Adverse Event (coded term [reported term]):'  
'N' = '^~2n^~2n^S={font_weight=bold}Adverse Event (coded term [reported term]):'  
;
```

Code Snippets (2)

- Formatting of text

```
%global bon boff cr ;  
%let bon = ^S={font_weight=bold} ;  
%let boff = ^S={} ;  
%let cr = ^-2n ;
```

- Building sentence

```
ae_header_txt = "&cr.&cr.&bon." || strip(ser_cat) || " " || "(coded term [reported term]):"  
" || "&boff." || strip(aedecod) || " [" || strip(aeterm) || "]" ;
```

Code Snippets (3)

- To handle text truncation issue

```
data narr_eos_subj_m (keep=usubjid: text2 aedecod aestdtc aeendtc);
  attrib text1 length=$30000 text2 length=$30000;
  set here.narr_eos_subj;

  text1 = TRANWRD(text, "^-2n^-2n", '|');

  i=1;
  DO WHILE (SCAN(text1,i,"|") NE '');
    if i=1 and substr(text1,1,1) = "|" then text2= strip("|") || strip(SCAN(text1,i,"|")) ;
    else if scan(text1,i+1,"|") = '' and
      substr(reverse(text1),1) EQ "|" then text2 = strip(SCAN(text1,i,"|")) || strip("|") ;
    else if scan(text1,i+1,"|") = '' and
      substr(reverse(text1),1) NE "|" then text2 = SCAN(text1,i,"|") ;
    else text2= strip(SCAN(text1,i,"|")) || strip("|") ;
    OUTPUT;
    i=i+1;
  END;

run ;
```

Conclusion

- Saved hundreds of hours of manual work.
- Understanding how study data was collected and mapped was very critical.
- You lose flexibility in terms of narrative writing based on human interpretation.
- Foundation for building more robust and re-usable macro.
- Savings and accuracy improvements greatly outweighed the risks.