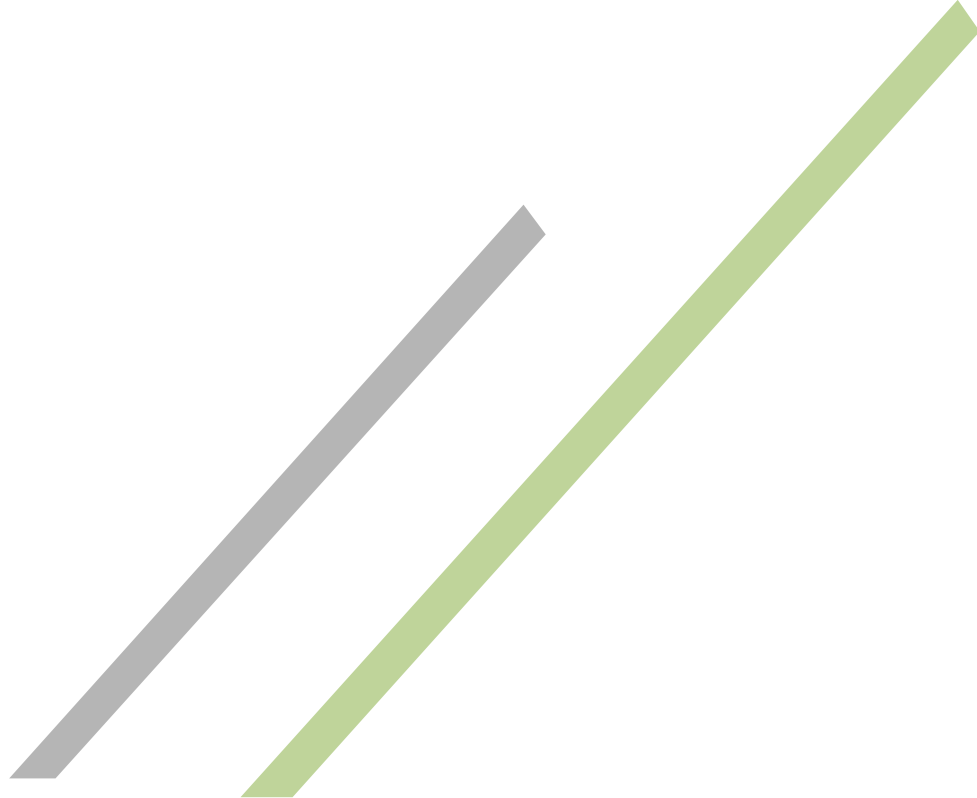




A LABOR SAVING MACRO FOR PROGRAMMED PATIENT NARRATIVES

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What is a Patient narrative?

(ICH E3 Guidelines)

2

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

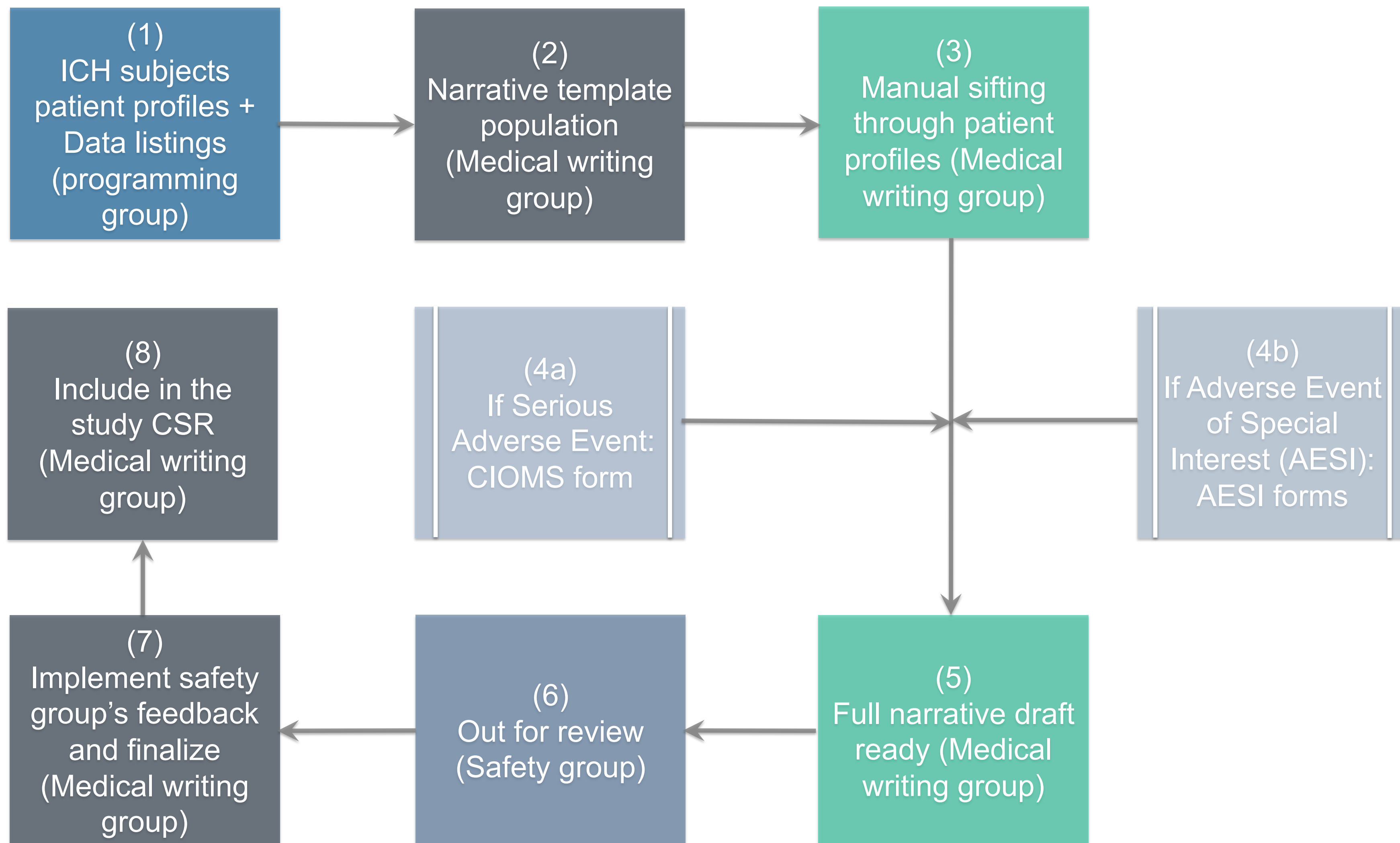
There should be brief narratives describing each death, each other serious adverse event, and those of the other significant adverse events that are judged to be of special interest because of clinical importance. These narratives can be placed either in the text of the report or in section 14.3.3, depending 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:

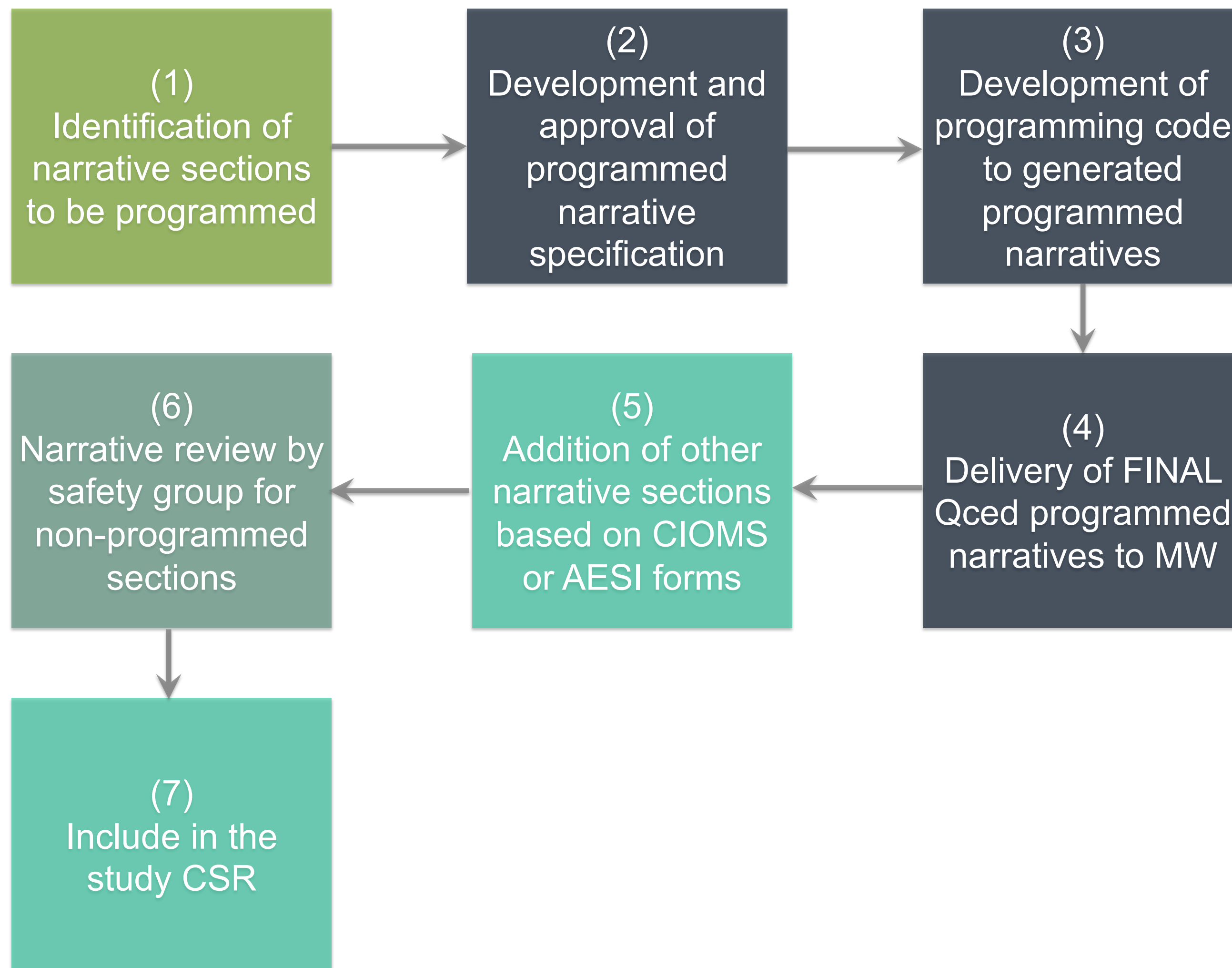
- ☐ Patient identifier
- ☐ Age and sex of patient; general clinical condition of patient, if appropriate Disease being treated (if the same for all patients this is not required) with duration (of current episode) of illness
- ☐ Relevant concomitant/previous illnesses with details of occurrence/duration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

Our Traditional Process



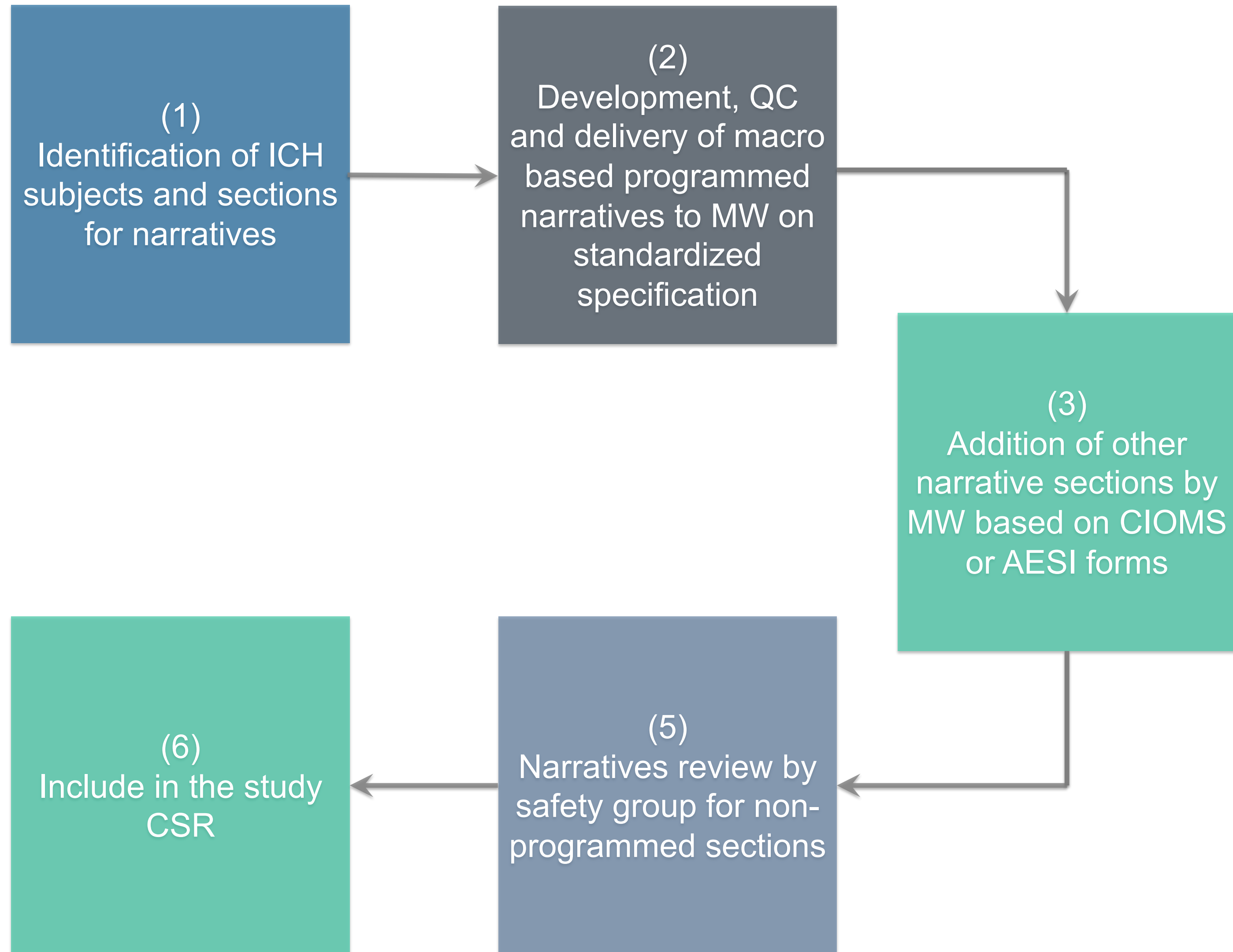
Programmed Patient Narrative

(1st Step at Automation)*



*Girase P, Boisvert D, Kurnala V, "Programmed Patient Narratives Using SAS® "PhUSE 2016, Paper AD09.

Macro based narrative generation process



Specification for structure of narratives

(Double-blind or Open Label Studies)

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

Study Treatment in <Study ID>: <Study treatment label> {1.2}

Treatment Period in <Study ID>: <date of first dose as dd Month yyyy> to <date of last dose as dd Month yyyy> {1.6}

Total Number of <Study treatment label 1> Doses Received in <Study ID>: x {1.7}

Total Number of <Study treatment label 2> Doses Received in <Study ID>: x {1.7}

Death {1.8}

Date of Death: dd Month yyyy {1.9}

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

MedDRA Term: <Preferred term>

Total Number of <Study treatment label 1> Doses Received at Event Onset: x

Total Number of <Study treatment label 2> Doses Received at Event Onset: x

Specification of algorithms

(Double-blind or Open Label Studies)

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}

Specification for structure of narratives

(Studies with different parts)

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

Study Treatment in <Study ID> Part 2: <Study treatment label> {1.2}

Treatment Period in <Study ID> Part 2: <date of first dose as dd Month yyyy> to <date of last dose as dd Month yyyy> {1.6}

Total Number of Days on <Study Treatment 1> in <Study ID> Part 1: x {1.7}

Total Number of Days on <Study Treatment 1> in <Study ID> Part 2: x {1.7}

Death {1.8}

Date of Death: dd Month yyyy {1.9}

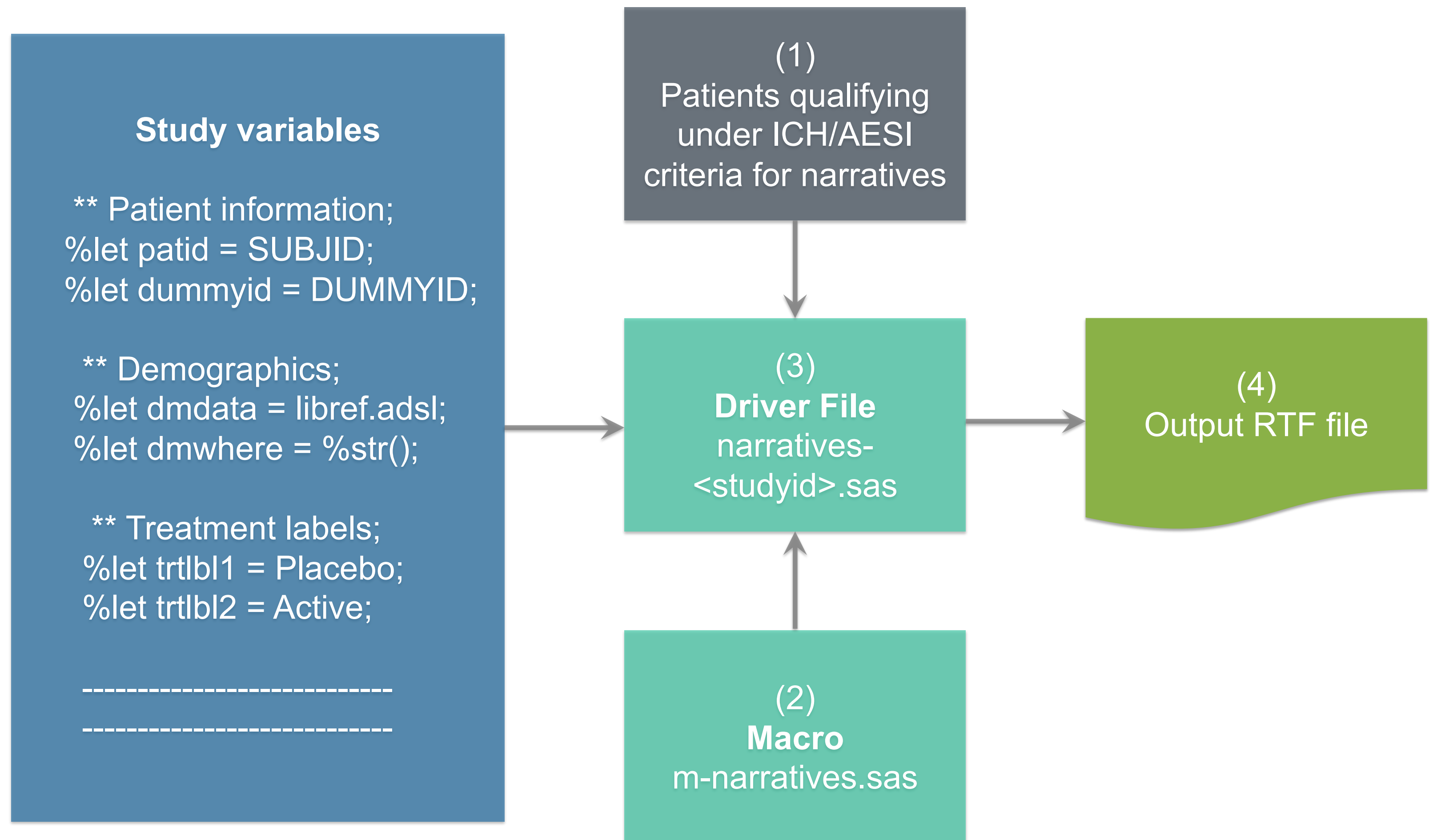
{1.3} **Adverse Event:** <Reported term>

MedDRA Term: <Preferred term>

Total Number of Days on <Study treatment label 1> at Event Onset: x {1.4}

Total Number of <Study treatment label 2> Doses Received at Event Onset: x

Design of SAS ® Macro



Narrative header options

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

Study Treatment in <Study ID>: <Study treatment label> {1.2}

Treatment Period in <Study ID>: <date of first dose as dd Month yyyy> to <date of last dose as dd Month yyyy> {1.6}

Total Number of <Study treatment label 1> Doses Received in <Study ID>: x {1.7}

Total Number of <Study treatment label 2> Doses Received in <Study ID>: x {1.7}

Death {1.8}

Date of Death: dd Month yyyy {1.9}

{1.3} Adverse Event: <Reported term>

MedDRA Term: <Preferred term>

Total Number of <Study treatment label 1> Doses Received at Event Onset: x

Total Number of <Study treatment label 2> Doses Received at Event Onset: x

XXXX Use Prior to Study Drug Administration: x {1.10}

XXXXXX XXXX Score: {1.11}

Visit: Score

Screening: xx

Baseline: xx

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XXXXXX Assessment: {1.12}

Visit: Evaluator, Result

Baseline: R1, xx,xxx.xx

24 Hours: R1, xx,xxx.xx

24 Hours: R2, xx,xxx.xx

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Time from XXXX to Treatment: xxx {1.13}

Baseline XXXXX Category: xxx {1.14}

DEFAULT HEADER

CUSTOM HEADER

```
*** Any additional information (from source 1);
%let add1data = libref.adsl;
%let add1where = ;

%let add1var1 = <variable name>;
%let add1var2 = ;
%let add1var3 = ;
%let add1var4 = ;
%let add1var5 = ;
%let add1var6 = ;

%let add1bl1 = XXXX use prior to study drug administration;
%let add1bl2 = ;
%let add1bl3 = ;
%let add1bl4 = ;
%let add1bl5 = ;
%let add1bl6 = ;

*** Any additional information (from source 2);
%let add2data = libref.adxxxx;
%let add2where = %str(paramcd = 'XXXXXX' and aval ne .);
%let add2day = avisit;
%let add2srt = avisitn;
%let add2var1 = aval;
%let add2var2 = ;
%let add2bl1 = XXXXX XXXX Score;
%let add2slbl = %str(Visit: Score);

*** Any additional information (from source 3);
%let add3data = libref.xx;
%let add3where = %str(xtested = 'XXXXXX' and xxorres ne ' ');
%let add3day = visit;
%let add3srt = xxseq;
%let add3var1 = xxeval;
%let add3var2 = xxorres;
%let add3bl1 = XXXXX Assessment;
%let add3slbl = %str(Visit: Evaluator, Result);

*** Any additional info that needs to be appended (from source 4);
%let add4data = libref.adsl;
%let add4where = %str();

%let add4var1 = <variable name 1>;
%let add4var2 = <variable name 2>;
%let add4var3 = ;
%let add4var4 = ;
%let add4var5 = ;
%let add4var6 = ;

%let add4bl1 = Time from XXXX to Treatment;
%let add4bl2 = Baseline XXXXX Category;
%let add4bl3 = ;
%let add4bl4 = ;
%let add4bl5 = ;
%let add4bl6 = ;
```

Customized header output sample

Subject ID: 111-111
 Study Treatment in XXXXX: Placebo
 Treatment Period in XXXXX: 10 June 2020 to 11 June 2020
 Total Number of Placebo Doses Received in XXXXXX: 40
 Serious Adverse Event: Some AE
 MedDRA Term: SOME AE
 Total Number of Placebo Doses Received at Event Onset: 20
 XXXX use prior to study drug administration: Yes
 XXXXX XXXX Score:
 Visit: Score
 Screening: 1
 Baseline: 2
 xx Hours: 3
 Day xx: 4
 Day yy: 5
 Day zz/Final Vst: 5

XXXXXX Assessment:
 Visit: Evaluator, Result
 Baseline: X1, 21,000.11
 Baseline: X2, 21,001.11
 xx Hours: X1, NA
 yy Hours: X2, NA
 Day xx: X1, NA
 Day xx: X2, NA
 Day yy: X1, 50,000.22
 Day zz: X2, 50,023.22
 Time from XXXX to Treatment: >x to <= x.x hours
 Baseline XXXXX Category: <=2

Narrative body

Subject xxx-xxx (<dummy ID> {2.1}, a xx {2.2}-year-old white (race not recorded){2.3} female {2.4}, was enrolled into Study <Study ID> {2.5} and began a treatment regimen of <study treatment label 1 and study treatment label 2> {2.6} on dd Month yyyy {2.7} (Day 1 {2.8}).

{3.1}Adverse Event: (coded term [reported term]):

SOME AE {3.3} [SOME AE ON SOME SIDE OF THE BODY {3.3}]

SAE Number: XXXXXXXXXX {3.4}

On dd Month yyyy {4.1} (Day xx {4.2}), an adverse event of some ae {4.4} was reported, which was classified as a serious or non-serious adverse event {4.6} by the Investigator. The subject had received <number> doses of <Study treatment label 1> or <Study treatment label 2> before onset of the event, with his or her most recent dose given on <dd Month yyyy (Day xx)> {4.7}.

```
%let study = %upcase(&Protocol); ** {2.5};
%let patid = subjid; ** {2.1};
%let dummyid = dummyid; ** {2.1};

%let trtval1 = %str(0);
%let trtval2 = %str(1);

%let trtlbl1 = %str(Placebo); ** {2.6};
%let trtlbl2 = %str(XXXXXXX); ** {2.6};

*** Treatment start and stop dates;
%let trtstart = trtsdt; ** {2.7};
%let trtstop = trtedt;

*****
** Adverse Events
*****
%let aedata = libref.adae; ** {3.1};
%let aestart = astdt; ** {4.1};
%let aeend = aendt;
%let aestday = astdy; ** {4.2};
%let aeenday = aendy;
```

Macro
Parameters

Specification

Subject 111-111, a xx-year-old white male, was enrolled into Study XXXXXX and began a treatment regimen of Placebo on 10 June 2020 (Day 1).

Serious Adverse Event: (coded term [reported term]): SOME AE [SOME AE]

SAE Number: xxxxxxxxxxxx

On 08 September 2020 (Day xx), an adverse event of some AE was reported, which was classified as a serious adverse event by the Investigator. The subject had received x doses of Placebo before onset of the event.

Output

Conclusion

- ❑ Robust solution applicable across studies with similar design.
- ❑ Saved hundreds of manual hours of narrative writing.
- ❑ CDISC standards helped with automation.
- ❑ Could not automate sections that needed human interpretation.

