Mapping MRI data to SDTM and ADaM

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ABSTRACT

Magnetic Resonance Imaging (MRI) has been used to detect structure damage in spine and sacroiliac joints (SIJ) in clinical trials. The complexity in the data includes multiple time points, multiple methods, high dimensionality and adjudicated readings. The raw data contains information on scoring method, test-type, location, region of interest/feature, laterality and slice, which introduces more than 600 records from each reader at each time point and challenging work for the SDTM and ADaM. For SDTM, we manage to map the data to XP domain. For ADaM, we map it to a Basic Data Structure analysis dataset that contains more than 600 parameters combining information in all dimensions, with additional five parameters for the derived total scores based on the complicated scoring algorithms including how to handle missing data and consolidation of the scores from different readers. To prevent manual typing errors, we avoid the conventional way in writing ADaM specifications and use SAS® program to make the ADaM specifications. To compute the complicated total score and to create the ADaM data sets, we utilize multiple efficient arrays and do loops in the SAS program.

INTRODUCTION

For MRI, the whole spine is imaged in the sagittal plane and the SI joints are imaged using an oblique coronal plane. MRI of the SI joint and whole spine are performed using short tau inversion recovery (STIR) and T1-weighted sequences. No MRI contrast is used. In terms of scoring methodology, there are totally 4 types of scores for the raw data:

Ankylosing Spondylitis Spinal Magnetic Resonance Imaging Activity–Berlin Score
All 23 discovertebral unit (DVUs) of the spine are scored for bone marrow edema. The Berlin method score range is between 0 and 3 (0 = Normal, no lesions; 1 = Mild; 2 = Moderate; 3 = Severe) per DVU, bringing the maximum total score to 69 with higher scores reflecting worse disease (Braun et al. 2003; Lukas et al. 2007).

Spondyloarthritis Research Consortium of Canada (SPARCC)–MRI Score for Spine
All 23 disco-vertebral units (DVUs) (Figure 1) of the spine are scored for bone marrow edema. Each DVU has 3 slices, and each slice is cored on 4 quadrants and 2 additional features with score of 0 (absence of lesions) or 1 (presence of lesions). A single DVU has a scoring range of 0 to 18, and the maximum total score for the whole spine is 414, with higher scores reflecting worse disease (Maksymowych et al. 2005a).

Spondyloarthritis Research Consortium of Canada–MRI Score for Sacroiliac Joints
Both left and right SIJ (Figure 2) are scored for bone marrow edema. Each side has 6 slices, and each slice is scored on 4 quadrants and 2 additional features with score of 0 or 1. Total SIJ SPARCC scores can range from 0 to 72 with higher scores reflecting worse disease (Maksymowych et al. 2005b).

Spondyloarthritis Research Consortium of Canada–SIJ Structural Score (SSS)
Structural lesions in MRIs of the SIJ are assessed using the SPARCC SSS method in which the presence or absence of lesions is scored in SIJ quadrants (for fat metaplasia and erosion) or SIJ halves (for backfill and ankylosis). There are 5 slices for each side. Scoring ranges are fat metaplasia (0 to 40), erosions (0 to 40), backfill (0 to 20), and ankylosis (0 to 20) (Maksymowych et al. 2015). The maximum total score is 120.

For the efficacy reading, there are two primary readers and one possible adjudicator. Each of the primary readers read 100% of the cases, while the adjudicator reads all discrepant cases.

Missing data may present at all scoring levels due to poor quality or missing visits.
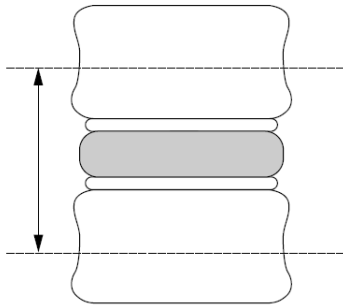
.

Figure 1: Definition of a discovertebral unit (DVU). Figure shows two vertebrae and the intervertebral disc between them. The DVU extends from the midline of one vertebra to the midline of the adjacent vertebra (see arrow). Each DVU is identified by the names of the vertebrae involved (e.g., C2-C3, C3-C4, etc.). [Image taken from X Baraliakos et al, Ann Rheum Dis 2005;64:730–734.]
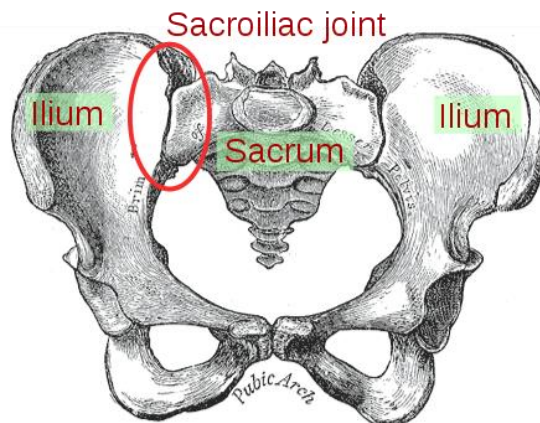

Figure 2: Sacroiliac joint [Image taken from https://en.wikipedia.org/wiki/Sacroiliac_joint.]

MAPPING TO SDTM AND ADAM

The MRI raw data is multi-dimensional and we map the data to SDTM XP domain. In ADaM, we map the data to a basic data structure (BDS) dataset. Table 1 shows the general mapping idea.

Table 1. MRI Raw Data mapping in SDTM and ADaM

Raw Variable	SDTM XP/SUPPXP Mapping	ADaM ADMRIEFF Mapping	Values
STUDYID	STUDYID	STUDYID	
SITEID	SITEID	SITEID	
SUBJID	USUBJID	USUBJID	
DOB	(dropped)		
VISIT	VISIT	VISIT	
VISITNUM	VISITNUM	VISITNUM	1, 8, 999 (for early termination visit)
ASSESSMENT_DATE	XPDTC	ADT	

	XPSCAT	ACAT	Berlin Spine, SPARCC Spine, SPARCC SIJ, SIJ SPARCC SSS
TEST_TYPE			
SLICE	XPGRPID	PARAMCD combining XPTETSCD, XPLOC, SUPPXP.XPLAT, and XPGRPID	1, 2, 3,…
SIDE	SUPPXP.XPLAT		Left, Right
ROI_FEATURE	XPTESTCD		DVU1, …
LOCATION	XPLOC		Cervical, Lumbar
Score_ReaderA	XPORRES where XPEVAL='Reader A'	AVAL where AEVAL='Reader A'	
Initials_ReaderA	QVAL where SUPPXP.QNAM='EVALINT'	AEVAL='Reader A'	
Score_ReaderB	XPORRES where XPEVAL='Reader B'	AVAL where AEVAL='Reader B'	
Initials_ReaderB	QVAL where SUPPXP.QNAM='EVALINT'	AEVAL='Reader B'	
Score_Adjudicator	XPORRES where XPEVAL='Adjudicator'	AVAL where AEVAL='Adjudicator'	
Initials_adjudicator	QVAL where SUPPXP.QNAM='EVALINT'	AEVAL='Adjudicator'	
Campaign	QVAL where SUPPXP.QNAM='CAMPAIGN'		A, B

We use SAS® ARRAY statement and DO loop to set up the defined terminology entries for PARAMCD, PARAM, and PARAMN. This approach may reduce typo from manual typing in EXCEL and also allows for easy modification later on. Below is the SAS code for deriving the ADaM control terminologies for PARAMCD, PARAM and PARAMN:

```
/* Define submission value and decode for PARAMCD of Berlin Spine Scores */
data berlin;
    dataset='ADMRIEFF';
    variable='PARAMCD';
    do i=1 to 23;
      j=i+1;k=i+2;
      submission_value='BSDVU'||left(put(i,best.));
      decode=cat("Berlin Spine DVU",i," (C",j,'-C',k,")");
    end;
run;

/* Define submission value and decode for PARAMCD of SIJ SPARCC SSS Scores */
data sijsss;
    dataset='ADMRIEFF';
    variable='PARAMCD';
    array xptestcd{4} $ xpcd1 xpcd2 xpcd3 xpcd4;
    array xploc{6} $ loc1 loc2 loc3 loc4 loc5 loc6;
    array xplocl{6} $20.  locl1 locl2 locl3 locl4 locl5 locl6;
    array xplat{2} $ side1 side2;
    array xplatl{2} $ sidel1 sidel2;
    array xpgrpid{5} $ slice1 slice2 slice3 slice4 slice5;
    side1='L';side2='R';
    sidel1='Left';sidel2='Right';
    slice1='1';slice2='2';slice3='3';slice4='4';slice5='5';
    loc1='L';loc2='U';loc3='LI';loc4='UI';loc5='LS';loc6='US';
    locl1='Lower';locl2='Upper';locl3='Lower Iliac';locl4='Upper Iliac';
locl5='Lower Sacral';locl6='Upper Sacral';
    do i=1 to 5;
    do j=1 to 2;
```

```sas
do k=1 to 2;
 submission_value='ANK'||strip(xploc[k])||strip(xplat[j])||'S'||strip(xp
 grpid[i]);
 decode="SIJ SSS Ankylosis "||strip(xplocl[k])||' '||strip(xplatl[j])||'
 Slice'|| strip(xpgrpid[i]);
 submission_value='BAC'||strip(xploc[k])||strip(xplat[j])||'S'||strip(xp
 grpid[i]);
 decode="SIJ SSS Backfill "||strip(xplocl[k])||' '||strip(xplatl[j])||'
 Slice '||strip (xpgrpid[i]);
 end;
 do k=3 to 6;
 submission_value='ERO'||strip(xploc[k])||strip(xplat[j])||'S'||strip(xp
 grpid[i]);
 decode="SIJ SSS Erosion "||strip(xplocl[k])||' '||strip(xplatl[j])||'
 Slice '||strip(xpgrpid[i]);
 submission_value='FAT'||strip(xploc[k])||strip(xplat[j])||'S'||strip(xp
 grpid[i]);
 decode="SIJ SSS Fat "||strip(xplocl[k])||' '||strip(xplatl[j])||' Slice
 '||strip(xpgrpid[i]);
 end;
 end;
 end;
 run;

 /* Define submission value and decode for PARAMCD of SIJ SPARCC Scores
 */
 data sijsparcc;
 dataset='ADMRIEFF';
 variable='PARAMCD';
 array xploc{6} $ loc1 loc2 loc3 loc4 loc5 loc6;
 array xplocl{6} $20.  locl1 locl2 locl3 locl4 locl5 locl6;
 array xplat{2} $ side1 side2;
 array xplatl{2} $ sidel1 sidel2;
 array xpgrpid{6} $ slice1 slice2 slice3 slice4 slice5 slice6;
 side1='L';side2='R';
 sidel1='Left';sidel2='Right';
 slice1='1';slice2='2';slice3='3';slice4='4';slice5='5';slice6='6';
 loc1='IS';loc2='LD';loc3='LI';loc4='UI';loc5='LS';loc6='US';
 locl1='Intense Signal';locl2='Lesion Depth';locl3='Lower
 Iliac';locl4='Upper Iliac';locl5='Lower Sacral';locl6='Upper Sacral';
 do i=1 to 6;
 do j=1 to 2;
 do k=1 to 6;

 submission_value=strip(xploc[k])||strip(xplat[j])||'S'||strip(xpgrpid[i
 ]);
 decode="SIJ SPARCC "||strip(xplocl[k])||' '||strip(xplatl[j])||' Slice
 '||strip(xpgrpid[i]);
 end;
 end;
 end;
 run;

 /* Define submission value and decode for PARAMCD of Spine SPARCC
 Scores */

 data spinesparcc;
```

```
 dataset='ADMRIEFF';
 variable='PARAMCD';
array xptestcd{23} $ xpcd1 xpcd2 xpcd3 xpcd4 xpcd5 xpcd6 xpcd7 xpcd8
xpcd9 xpcd10 xpcd11 xpcd12
                    xpcd13 xpcd14 xpcd15 xpcd16 xpcd17 xpcd18 xpcd19
xpcd20 xpcd21 xpcd22 xpcd23;
array xpcdl{23} $ xpcdl1 xpcdl2 xpcdl3 xpcdl4 xpcdl5 xpcdl6 xpcdl7
xpcdl8 xpcdl9 xpcdl10 xpcdl11                 xpcdl12 xpcdl13
xpcdl14 xpcdl15 xpcdl16 xpcdl17 xpcdl18 xpcdl19 xpcdl20 xpcdl21 xpcdl22
xpcdl23;
array xploc{6} $ loc1 loc2 loc3 loc4 loc5 loc6;
array xplocl{6} $20.  locl1 locl2 locl3 locl4 locl5 locl6;
array xpgrpid{3} $ slice1 slice2 slice3;
do w=1 to 23;
xpcdl[w]='DVU'||left(put(w,best.));
if length(xpcdl[w])=3 then xptestcd[w]=xpcdl[w];
else xptestcd[w]=compress(xpcdl[w],'U');
end;

xpcd1='DVU1';xpcd2='DVU2';xpcd3='DVU3';xpcd4='DVU4';xpcd5='DVU5';xpcd6=
'DVU6';xpcd7='DVU7';xpcd8='DVU8';
xpcd9='DVU9';xpcd10='DV10';xpcd11='DV11';xpcd12='DV12';xpcd13='DV13';xp
cd14='DV14';xpcd15='DV15';xpcd16='DV16';
xpcd17='DV17';xpcd18='DV18';xpcd19='DV19';xpcd20='DV20';xpcd21='DV21';x
pcd22='DV22';xpcd23='DV23';
slice1='1';slice2='2';slice3='3';
loc1='IS';loc2='LD';loc3='LA';loc4='UA';loc5='LP';loc6='UP';
locl1='Intense Signal';locl2='Lesion Depth';locl3='Lower
anterior';locl4='Upper anterior';locl5='Lower posterior';locl6='Upper
posterior';
do i=1 to 3;
do j=1 to 6;
do k=1 to 23;
submission_value=strip(xploc[j])||strip(xptestcd[k])||'S'||strip(xpgrpi
d[i]);
decode="Spine SPARCC "||strip(xplocl[j])||' '||strip(xpcdl[k])||' Slice
'||strip(xpgrpid[i]);
end;
end;
end;
run;

data all;
set berlin sijsss sijsparcc spinesparcc;
paramn=_n_;
run;
```

Control terminologies (example):

DATASET	VARIABLE	SUBMISSION_VALUE	DECODE
ADMRIEFF	PARAMCD	BSDVU1	Berlin Spine DVU1 (C2-C3)
ADMRIEFF	PARAMCD	BSDVU2	Berlin Spine DVU2 (C3-C4)
………….	………….	………….	……..……
ADMRIEFF	PARAMCD	ANKLLS1	SIJ SSS Ankylosis lower Left Slice 1

....	....	....	....
ADMRIEFF	PARAMCD	ISLS1	SIJ SPARCC Intense Signal Left Slice 1
....	....	....	....
ADMRIEFF	PARAMCD	UPDV19S3	Spine SPARCC Upper posterior DVU19 Slice 3

SAS code for creating PARAMCD in ADaM dataset:

```
If XPSCAT='Berlin Spine' then PARAMCD=cats("BS",XPTESTCD);
else if XPSCAT='SPARCC Spine' then do;
    if XPLOC='Intense signal' then a='IS';
            else if XPLOC='Lesion depth' then a='LD';
            else if XPLOC='Lower anterior' then a='LA';
            else if XPLOC='Lower posterior' then a='LP';
            else if XPLOC='Upper anterior' then a='UA';
            else if XPLOC='Upper posterior' then a='UP';
            if XPGRPID=1 then c='S1';
            else if XPGRPID=2 then c='S2';
            else if XPGRPID=3 then c='S3';
            if XPTESTCD in
('DVU1','DVU2','DVU3','DVU4','DVU5','DVU6','DVU7','DVU8','DVU9') then
b=XPTESTCD;
            else b=cats('DV',substr(XPTESTCD,4,5));
            PARAMCD=cats(a,b,c);end;
else if XPSCAT='SPARCC SIJ' then do;
    if XPLOC='Intense signal' then a='IS';
            else if XPLOC='Lesion depth' then a='LD';
            else if XPLOC='Lower iliac' then a='LI';
            else if XPLOC='Lower sacral' then a='LS';
            else if XPLOC='Upper iliac' then a='UI';
            else if XPLOC='Upper sacral' then a='US';
            if XPLAT='Left' then b='L';
            else if XPLAT='Right' then b='R';
          c=cat('S',XPGRPID);
            PARAMCD=cats(a,b,c);
end;
else if XPSCAT='SIJ SPARCC SSS' then do;
    if XPTESTCD='ANKYLOS' then a='ANK';
            else if XPTESTCD='BACKFILL' then a='BAC';
            else if XPTESTCD='EROSION' then a='ERO';
            else if XPTESTCD='FAT' then a='FAT';
            if XPLOC='Lower' then b='L';
            else if XPLOC='Upper' then b='U';
            else if XPLOC='Lower iliac' then b='LI';
            else if XPLOC='Lower sacral' then b='LS';
            else if XPLOC='Upper iliac' then b='UI';
            else if XPLOC='Upper sacral' then b='US';
            if XPLAT='Left' then c='L';
            else if XPLAT='Right' then c='R';
            d=cat('S',XPGRPID);
            PARAMCD=cats(a,b,c,d);
end;
```

Then PARAM and PARAMN are added by using formats created from control terminologies in ADaM specification file.

DERIVED PARAMETERS IN ADAM

In ADaM, we add several derived parameters including total score for each category and averaged scores. Table 2 provides a summary for the derived parameters.

Table 2. Summary of the Derived Parameters

PARAMCD	PARAM	Analysis algorithm
BSTS	Berlin Spine total score for the 23 DVUs	If XPCAT='Berlin Spine' and none of the scores is missing, sum over all scores; if there is any missing score, set to missing. Note: This is the current approach, and there will be update in the imputation algorithm in the future.

BSTSAVG	Average of Berlin Spine total score for the 23 DVUs	For ACAT='Berlin Spine' and PARAMCD='BSTS':
		Compute the change score (change from baseline) for each of the primary readers and the adjudicator.
		  a. If adjudicator data exist, average the scores of the adjudicator and the primary reader whose change score is closer to the adjudicator.
		   b. If no adjudicator data exist, average the two primary readers' scores.

SIJTS	SPARCC SIJ total score	If XPCAT='SPARCC SIJ' and none of the scores is missing, sum over all scores; if there is any missing score, set the total score as missing.

SIJTSAVG	Average of SPARCC SIJ total score	For ACAT='SPARCC SIJ' and PARAMCD='SIJTS':
		Compute the change score (change from baseline) for each of the primary readers and the adjudicator.
		  a. If adjudicator data exist, average the scores of the adjudicator and the primary reader whose change score is closer to the adjudicator.
		   b. If no adjudicator data exist, average the two primary readers' scores.

SSSTS	SIJ SPARCC SSS total score	If XPCAT='SIJ SPARCC SSS' and none of the scores is missing, sum over all scores; if there is any missing score, set to missing.

SSSTSAVG	Average of SIJ SPARCC SSS total score	For ACAT='SIJ SPARCC SSS' and PARAMCD='SSSTS':
		  Compute the change score (change from baseline) for each of the primary readers and the adjudicator.
		  a. If adjudicator data exist, average the scores of the adjudicator and the primary reader whose change score is closer to the adjudicator.
		   b. If no adjudicator data exist, average the two primary readers' scores.

SPTS	SPARCC Spine Total score	If XPCAT='SPARCC Spine' and none of the scores is missing, sum over all scores; if there is any missing score, set to missing.
SPTSAVG	Average of SPARCC Spine Total score	For ACAT='SPARCC Spine' and PARAMCD='SPTS': Compute the change score (change from baseline) for each of the primary readers and the adjudicator. a. If adjudicator data exist, average the scores of the adjudicator and the primary reader whose change score is closer to the adjudicator. b. If no adjudicator data exist, average the two primary readers' scores.

Note: The analysis algorithms are based on what we have now and may be updated later per analysis need.

SAS code for deriving the total score using ARRAY and DO loop:

```
/* First we transpose the scores by PARAMN */

proc transpose data=mri out=mrit prefix=c;
by usubjid subjid aeval avisitn acat adt;
id paramn;
var aval;
run;

/* Then we sum the scores using ARRAY and DO loop. Below is an example for
computing the SPARCC Spine total score. */
data mri_sparccspine;
set mrit;
where acat='SPARCC Spine';
aval=0;missn=0;
array s{414} c216-c629;
paramcd='SPTS';
do i=1 to 414;
   aval=s[i]+aval;
   if s[i]=. then missn=missn+1;
end;
run;
```

SAS code for getting the average scores:

```
* First we decide which reader should be selected for averaging by looking at
how close their change scores are to the adjudicator's. We flag the readers
out if a closer change score from the adjudicator's is seen;

 if chg_c=. and chg_a ne . and chg_b ne . then rater2='A/B';
 else if chg_c=. and chg_a ne . and chg_b = . then rater2='A';
 else if chg_c=. and chg_a = . and chg_b ne . then rater2='B';
 else if chg_c ne . and .<abs(chg_a-chg_c)<abs(chg_b-chg_c) then
rater2='A/C';
```

```
 else if chg_c ne . and .<abs(chg_b-chg_c)<abs(chg_a-chg_c) then
rater2='B/C';
 else if chg_c ne . and .<abs(chg_b-chg_c)=abs(chg_a-chg_c) then
rater2='A/B/C';

/*Then we flag the selected readers' scores across all visits */
if index(rater2,'A')>0 then do;if aeval='Reader A' then anl05fl='Y';end;
if index(rater2,'B')>0 then do;if aeval='Reader B' then anl05fl='Y';end;
if index(rater2,'C')>0 then do;if aeval='Adjudicator' then anl05fl='Y';end;
```

The last step is to create the average scores based on the flagged out records. Here is a snapshot of a sample final ADaM dataset:

ACAT	AEVAL	PARAMCD	PARAM	PARAMN	AVAL	BASE	CHG
Berlin Spine	Adjudicator	BSTS	Berlin Spine total score for the 23 DVUs	630	.	.	.
Berlin Spine	Reader A	BSTS	Berlin Spine total score for the 23 DVUs	630	10	25	-15
Berlin Spine	Reader B	BSTS	Berlin Spine total score for the 23 DVUs	630	8	20	-12
Berlin Spine		BSTSAVG	Average of Berlin Spine total score for the 23 DVUs	631	9	22.5	-13.5
SIJ SPARCC SSS	Adjudicator	SSSTS	SIJ SPARCC SSS total score	634	30	40	-10
SIJ SPARCC SSS	Reader A	SSSTS	SIJ SPARCC SSS total score	634	40	30	10
SIJ SPARCC SSS	Reader B	SSSTS	SIJ SPARCC SSS total score	634	50	50	0
SIJ SPARCC SSS		SSSTSAVG	Average of SIJ SPARCC SSS total score	635	40	45	-5
SPARCC SIJ	Adjudicator	SIJTS	SPARCC SIJ total score	632	.	.	.
SPARCC SIJ	Reader A	SIJTS	SPARCC SIJ total score	632	0	0	0
SPARCC SIJ	Reader B	SIJTS	SPARCC SIJ total score	632	0	0	0
SPARCC SIJ		SIJTSAVG	Average of SPARCC SIJ total score	633	0	0	0
SPARCC Spine	Adjudicator	SPTS	SPARCC Spine Total score	638	.	.	.
SPARCC Spine	Reader A	SPTS	SPARCC Spine Total score	638	30	100	-70
SPARCC Spine	Reader B	SPTS	SPARCC Spine Total score	638	20	100	-80
SPARCC Spine		SPTSAVG	Average of SPARCC Spine Total score	639	25	100	-75

CONCLUSION

MRI data for defining structure damage in the spine and SIJ are highly dimensional and complicated. The conventional approach to derive SDTM and ADaM specifications may easily introduce typos and errors. In this paper, we propose to use SAS program to create the specifications. This approach not only can avoid errors and mistakes, but also can reduce repeated work when there is an update in the terminologies. For SDTM, we manage to map the data to XP domain. For ADaM, we map it to a BDS analysis dataset. We

also propose to utilize multiple arrays and do loops to derive total scores in ADaM data sets. This method makes the computation highly efficient.

The future work may include deriving DVU-wised scores and developing algorithm to handle missing data.

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