



Paper DH04

Look to the Sky: Introducing COMET - the COncomitant MEdication review Tool

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Abstract

The review and evaluation of concomitant medication use by medical teams can be a time-consuming manual task. Study teams frequently create their own programs and procedures, often in isolation, leading to wheel-reinvention and inconsistent cross-study approaches.

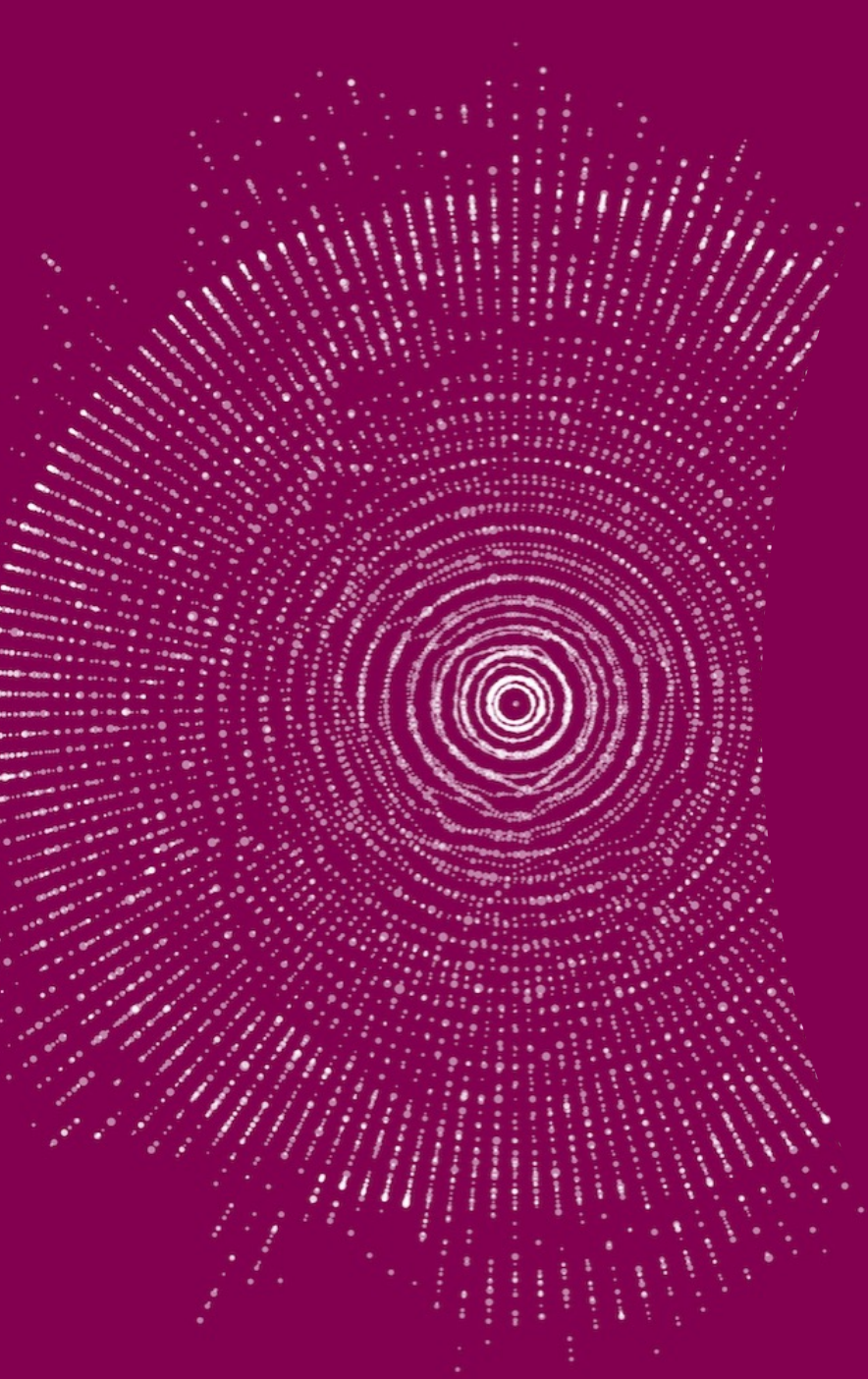
The outcome of these reviews is critical to the identification and reporting of disallowed medication use and potential protocol deviations.

COMET is a SAS tool that compares current data to the previously reviewed iteration, and presents the results in a clear, concise, and easy to use spreadsheet.

Spreadsheet functionality includes filters, persistent comments, new/amended record identification, highlighting of changed values and required re-review indicators – which together make the review process quick and efficient.

This paper will show the life cycle of a COMET report and discuss some of the tricks and hacks utilised in order to fully customise an Excel spreadsheet created by SAS.





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Introduction

COMET 
CO_nME_d review Tool



Introduction

- The review of potential concomitant medications protocol deviations is a common clinical trial procedure
- Typically, these are identified programmatically – then reviewed by a team of medics/specialists
- Review decisions are documented in a spreadsheet
- Can this be more automated?



First Steps

- Study team had already created a specification for the underlying data (DISMED)
- Also had example spreadsheets from other studies

Properties for DISMED_FLAGS

General Columns Advanced Summary

Columns

Name	Type	Length	Label
RECHIST	Charac...	15	Record history
STUDYID	Charac...	21	Study Identifier
usubjid	Charac...	30	Unique Subject Identifier
rescreen	Charac...	2	Patient rescreened
module	Charac...	10	Module
patstat	Charac...	50	Patient Status
CMSPID	Charac...	40	Sponsor-Defined Identifier
CMTRT	Charac...	200	Reported Name of Drug, Med, or Th...
CMSTDTC	Charac...	19	Start Date/Time of Medication
CMENDTC	Charac...	19	End Date/Time of Medication
omongo	Charac...	10	Medication Ongoing
cmreas	Charac...	200	Therapy Reason
CMINDC	Charac...	200	Indication
cmasno	Charac...	40	AE Number(s) for Medication Taken
CMCLASCD	Charac...	20	Medication Class Code
CMCLAS	Charac...	200	Medication Class
CMDECOD	Charac...	200	Standardized Medication Name
CMROUTE	Charac...	200	Route of Administration
CMDOSTOT	Numeric	8	Total Daily Dose
CMDOSU	Charac...	20	Dose Units
CMDOFRQ	Charac...	200	Dosing Frequency per Interval
astdt	Date	8	Analysis Start Date
aendt	Date	8	Analysis End Date
cmsttpt	Charac...	40	Start Relative to Reference Time Point
cmendtpt	Charac...	40	End Relative to Reference Time Point
ASTDY	Charac...	10	Analysis Start Relative Day to Rando...
AENDY	Charac...	10	Analysis End Relative Day to Rando...
adur	Charac...	10	Analysis Duration
astdy2	Charac...	10	Analysis Start Relative Day to First Visit
aendy2	Charac...	10	Analysis End Relative Day to First Visit
cmmult	Charac...	20	Multiple Drug
randdtc	Charac...	19	Randomisation date
RFXSTDTC	Charac...	19	Date/Time of First Study Treatment
RFXENDTC	Charac...	19	Date/Time of Last Study Treatment
fvisdct	Charac...	19	Start Date/Time of First Visit
lvisdct	Charac...	19	End Date/Time of Last Visit
incompl	Charac...	5	Completed Treatment
			Start Date/Time of Withdrawal/Com...
			Check ID Number
			Disallowed medication Filter
			Disallowed Medication Record Flag
			Major / Minor PD
			Important Protocol Deviation Flag
			PD Code
			Physician Comment
			Comment 2

Copy to clipboard

OK Cancel

Study Identifier	Unique Subject Identifier	Patient rescreened	Module	Patient Status	Sponsor-Defined Identifier	Reported Name of Drug, Med, or Therapy	Start Date/Time of Medication	End Date/Time of Medication	Medication Ongoing	Therapy Reason	Indication	AE Number(s) for Medication Taken	Medication Class Code	Standardized Medication Name	Category for Medication	Check ID Number	Disallowed medication Filter	Disallowed Medication Record Flag	Major / Minor PD	Important Protocol Deviation Flag
		N	CM	Early d/c Treatment	CM-12	PREDNISOLONE	2023-02-09	2023-02-23		ADVERSE EVENT	SINUSITIS	2	H02AB	PREDNISOLONE	GENERAL CONCOMITANT MEDICATION	9	Y			
		N	CM	Randomized	CM-10	PROLIA	2023-04-19	2023-04-19		PROPHYLAXIS	OSTEOPOROSIS PREVENTION		M05BX	DENOSUMAB	GENERAL CONCOMITANT MEDICATION	26	Y			
		N	CM	Early d/c Treatment	CM-04	FLUCONAZOLE	2022-07-01		ONGOING	MEDICAL HISTORY	VAGINAL THRUSH		J02AC	FLUCONAZOLE	GENERAL CONCOMITANT MEDICATION	5	Y			
		N	CM	Early d/c Treatment	CM-07	PREDNISOLONE	2023-04-03		ONGOING	ADVERSE EVENT	EXAC OF COPD/FLU	6	H02AB	PREDNISOLONE	GENERAL CONCOMITANT MEDICATION	9	Y			
		N	MINT	Early d/c Treatment	MINT-01	SYMBICORT	2009-01-01	2023-01-15			COPD STABLE MAINTENANCE DOSE		R03AK	BUDESONIDE;FORMOTEROL FUMARATE	MEDICATIONS OF INTEREST	2	Y			
		N	MINT	Early d/c Treatment	MINT-13	SYMBICORT	2023-01-16		ONGOING		COPD STABLE MAINTENANCE DOSE		R03AK	BUDESONIDE;FORMOTEROL FUMARATE	MEDICATIONS OF INTEREST	2	Y			
		N	CM	Randomized	CM-06	VALTREX	2020		ONGOING	MEDICAL HISTORY	GENITAL HERPES		J05AB	VALACICLOVIR HYDROCHLORIDE	GENERAL CONCOMITANT MEDICATION	15	Y			



2

Early Development

COMET 
CO_nME_d review Tool



Initial Development (1)

- First version took only a couple of months to develop
 - Then fine-tuned over 6 months
- DISMED programmed with criteria for potentially disallowed conmeds
- Results then written out to Excel file
- Study team would then review file and add flags including:
 - Decision
 - Major/Minor
 - IPD
 - Comments



Initial Development (2)

- File read back in, and built on at the next trigger point
- Issues encountered reading in Excel over time (variable length/type)
- **Decision: Store COMET as a pairing of Data Set and Excel files**
- *Data sets can be compared at next iteration, and comments/flags from previous Excel merged on*



Data Integrity

- Giving spreadsheets to teams can be problematic for retaining data integrity
 - Data could be changed/deleted
 - Structure could be altered
- SAS is limited in what it can manipulate with ODS EXCEL 😞
- Newer XLSX files are technically ZIP files containing XML.
 - SAS can manipulate ZIP files...and XML! 😊



3

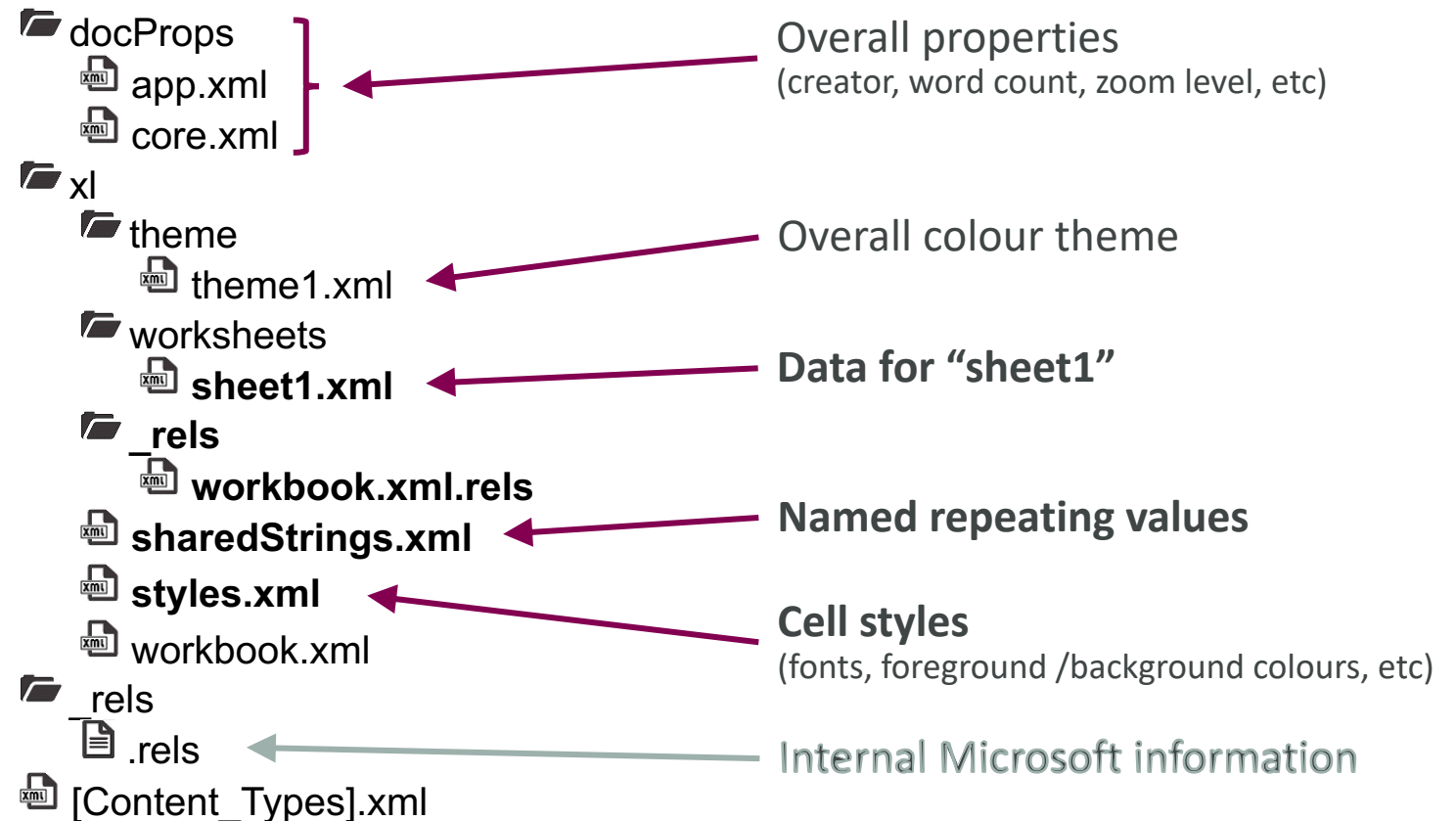
The Interior of an XLSX File

COMET 
CO_nME_d review Tool



Into the XLSX

- All modern Microsoft Office files (DOCX, XLSX, PPTX) are ZIP containers.
- Within them is a rigid structure
- Within these folders, nearly all the data are stored as XML files



Investigating Styles

demo_1

File Home Insert Draw Page Layout Formulas Data Review View Help

Clipboard Font Alignment Conditional Formatting

Format as Table

sheet1.xml

<row r="1" ht="14" customHeight="1">
<c r="A1" s="1" c="s"><v>0</v></c>

B3

	A	B	C	D	E	F	G	H
1	Name	S	Ag	Heig	Weig	blai		
2	Alfred	M	14	69	112.5			
3	Alice	F	13	56.5	84			
4	Barbara	F	13	65.3	98			
5	Carol	F	14	62.8	102.5			
6	Henry	M	14	63.5	102.5			
7	James	M	12	57.3	83			
8	Jane	F	12	59.8	84.5			
9	Janet	F	15	62.5	112.5			
10	Jeffrey	M	13	62.5	84			
11	John	M	12	59	99.5			
12	Joyce	F	11	51.3	50.5			
13	Judy	F	14	64.3	90			
14	Louise	F	12	56.3	77			
15	Mary	F	15	66.5	112			
16	Philip	M	16	72	150			
17	Robert	M	12	64.8	128			
18	Ronald	M	15	67	133			
19	Thomas	M	11	57.5	85			
20	William	M	15	66.5	112			
21								
22								
23								
24								
25								

Demo

Ready

*C:\Users\kpzg826\AppData\Local\Temp\7-ZipPortableTemp\7zE49E313B0\styles.xml - Notepad++

File Edit Search View Encoding Language Settings Tools Macro Run Plugins Window ?

styles.xml

```
<cellXfs count="6">
  (0) <xf numFmtId="0" fontId="0" fillId="2" borderId="0" xfId="0" applyFont="1" applyFill="1" applyBorder="1" applyAlignment="1">
    <alignment horizontal="left"/>
  </xf>
  (1) <xf numFmtId="0" fontId="1" fillId="3" borderId="0" xfId="0" applyFont="1" applyFill="1" applyBorder="1" applyAlignment="1">
    <alignment horizontal="center"/>
  </xf>
  (2) <xf numFmtId="0" fontId="2" fillId="0" borderId="0" xfId="0" applyFont="1" applyFill="1" applyBorder="1" applyAlignment="1">
    <alignment horizontal="left"/>
  </xf>
  (3) <xf numFmtId="164" fontId="2" fillId="2" borderId="0" xfId="0" applyNumberFormat="0" applyFont="1" applyFill="1" applyBorder="1" applyAlignment="1">
    <alignment horizontal="right"/>
  </xf>
  (4) <xf numFmtId="165" fontId="2" fillId="2" borderId="0" xfId="0" applyNumberFormat="0" applyFont="1" applyFill="1" applyBorder="1" applyAlignment="1">
    <alignment horizontal="right"/>
  </xf>
  (5) <xf numFmtId="0" fontId="2" fillId="2" borderId="0" xfId="0" applyFont="1" applyFill="1" applyBorder="1" applyAlignment="1">
    <alignment horizontal="center"/>
  </xf>
</cellXfs>
```

eXtensible Markup Language file length: 2,669 lines: 83 Ln: 57 Col: 20 Pos: 1,398 Unix (LF) UTF-8 INS

*C:\Users\kpzg826\AppData\Local\Temp\7-ZipPortableTemp\7zE49E313B0\styles.xml - Notepad++

File Edit Search View Encoding Language Settings Tools Macro Run Plugins Window ?

styles.xml

```
<font count="3">
  (0) <font>
    <sz val="9.5"/>
    <color rgb="FF003399"/>
    <name val="Arial"/>
  </font>
  (1) <font>
    <b/>
    <sz val="9.5"/>
    <color rgb="FFFFFFF"/>
    <name val="Arial"/>
  </font>
  (2) <font>
    <sz val="9.5"/>
    <color rgb="FF000000"/>
    <name val="Arial"/>
  </font>
</font>
```

length: 2,66 Ln: 59 Col: 31 Pos: 1,556 Unix (LF) UTF-8 INS

*C:\Users\kpzg826\AppData\Local\Temp\7-ZipPortableTemp\7zE49E313B0\styles.xml - Notepad++

File Edit Search View Encoding Language Settings Tools Macro Run Plugins Window ?

styles.xml

```
<fills count="4">
  (0) <fill>
    <patternFill patternType="none"/>
  </fill>
  (1) <fill>
    <patternFill patternType="gray125"/>
  </fill>
  (2) <fill>
    <patternFill patternType="solid">
      <fgColor rgb="FFFFFFF"/>
      <bgColor indexed="64"/>
    </patternFill>
  </fill>
  (3) <fill>
    <patternFill patternType="solid">
      <fgColor rgb="FF6495ED"/>
      <bgColor indexed="64"/>
    </patternFill>
  </fill>
</fills>
```

length: 2,669 Ln: 59 Col: 31 Pos: 1,556 Unix (LF) UTF-8 INS

Sharing/Uniqueness

The image illustrates the relationship between an Excel spreadsheet and its underlying XML representation. It shows three windows:

- Excel (demo_1):** Displays a table with columns Name, Sex, Age, Height, Weight, and blank. The data rows are as follows:

	Name	Sex	Age	Height	Weight	blank
2	Alfred	M	14	69	112.5	
3	Alice	F	13	56.5	84	
4	Barbara	F	13	65.3	98	
5	Carol	F	14	62.8	102.5	
6	Henry	M	14	63.5	102.5	
7	James	M	12	57.3	83	
8	Jane	F	12	59.8	84.5	
9	Janet	F	15	62.5	112.5	
10	Jeffrey	M	13	62.5	84	
11	John	M	12	59	99.5	
12	Joyce	F	11	51.3	50.5	
13	Judy	F	14	64.3	90	
14	Louise	F	12	56.3	77	
15	Mary	F	15	66.5	112	
16	Philip	M	16	72	150	
17	Robert	M	12	64.8	128	
18	Ronald	M	15	67	133	
19	Thomas	M	11	57.5	85	
20	William	M	15	66.5	112	

- sheet1.xml:** Contains XML for the spreadsheet structure, including columns, rows, and data. It references sharedStrings.xml for cell content.
- sharedStrings.xml:** Contains a list of unique strings found in the spreadsheet, indexed from (0) to (27). The strings are: Name, Sex, Age, Height, Weight, blank, Alfred, Alice, M, F, 14, 13, 65.3, 62.8, 63.5, 57.3, 59.8, 62.5, 84, 99.5, 51.3, 64.3, 56.3, 66.5, 72, 64.8, 67, 57.5, 66.5, 112, 150, 128, 133, 85, 112.

Yellow arrows indicate the mapping: 'Name' in the spreadsheet header points to the first entry in sharedStrings.xml, and the value '9' in cell B3 points to the entry for '9' in sharedStrings.xml.



Trial and Error (1)

- Using trial-and-error
 - Edit this simple Excel file
 - examining the changes to the XML afterwards
- I then discovered how many different features of Excel are defined.
- One of the features I was keen to include in the COMET spreadsheet was having a worksheet partially locked for editing
 - I still wanted a handful of columns editable.
 - Currently ODS EXCEL has an “all or nothing” option for worksheet protection



Trial and Error (2)

The image shows two XML files side-by-side: 'sheet1.xml' and 'styles.xml'. In 'sheet1.xml', the first row (row 1) contains cells A1 through F1. Cell A1 contains the value '7', B1 contains '1', C1 contains '2', D1 contains '3', E1 contains '4', and F1 contains '5'. Cell A2 contains the value '8'. In 'styles.xml', the styles for these cells are defined. The style for cell A1 (numFmtId="164") and cell A2 (numFmtId="0") both have the attribute 'protection locked="0"', which means they are unlocked. The styles for cells B1 through F1 (numFmtId="165") have the attribute 'protection locked="1"', which means they are locked. A yellow arrow points from the '7' in cell A1 to the 'protection locked="0"' attribute in the style for cell A1. Another yellow arrow points from the '8' in cell A2 to the 'protection locked="0"' attribute in the style for cell A2. A red circle highlights the 'protection locked="0"' attribute in the style for cell A2.

```
<sheet1.xml>
<cols>
</cols>
<sheetData>
<row r="1" spans="1:6" ht="14.1" customHeight="1" xl4ac:dyDescent="0.2">
<c r="A1" s="7" t="s">
<v>0</v>
</c>
<c r="B1" s="1" t="s">
<v>1</v>
</c>
<c r="C1" s="1" t="s">
<v>2</v>
</c>
<c r="D1" s="1" t="s">
<v>3</v>
</c>
<c r="E1" s="1" t="s">
<v>4</v>
</c>
<c r="F1" s="1" t="s">
<v>5</v>
</c>
</row>
<row r="2" spans="1:6" ht="14.1" customHeight="1" xl4ac:dyDescent="0.2">
<c r="A2" s="8" t="s">
<v>6</v>
</c>
<c r="B2" s="3" t="s">
<v>7</v>
</c>
</row>
</sheetData>
</sheet1.xml>

<styles.xml>
<xf numFmtId="164" fontId="2" fillId="2" borderId="0" xfId="0" applyNumberFormat="1" applyFont="1" applyFill="1" applyBorder="1" applyAlignment="1" applyProtection="1">
<alignment horizontal="right">
<protection locked="0"/>
</xf>
<xf numFmtId="165" fontId="2" fillId="2" borderId="0" xfId="0" applyNumberFormat="1" applyFont="1" applyFill="1" applyBorder="1" applyAlignment="1" applyProtection="1">
<alignment horizontal="right">
<protection locked="0"/>
</xf>
<xf numFmtId="0" fontId="2" fillId="2" borderId="0" xfId="0" applyFont="1" applyFill="1" applyBorder="1" applyAlignment="1" applyProtection="1">
<alignment horizontal="center">
<protection locked="0"/>
</xf>
<xf numFmtId="0" fontId="1" fillId="3" borderId="0" xfId="0" applyFont="1" applyFill="1" applyBorder="1" applyAlignment="1" applyProtection="1">
<alignment horizontal="center">
</xf>
<xf numFmtId="0" fontId="2" fillId="2" borderId="0" xfId="0" applyFont="1" applyFill="1" applyBorder="1" applyAlignment="1" applyProtection="1">
<alignment horizontal="left">
</xf>
<xf numFmtId="0" fontId="0" fillId="2" borderId="0" xfId="0" applyFont="1" applyFill="1" applyBorder="1" applyAlignment="1" applyProtection="1">
<alignment horizontal="left">
</xf>
</styles>
```

- I set the cell locking status manually in Excel to be “unlocked” and resaved the file
- Styles 7+8 are now missing the string `<protection locked="0">`
- This means when worksheet protection is turned on these two cells remain editable.
- If the file is created with ODS EXCEL with options (protect_sheets="on") and then the XML is manipulated, we could control editable cells programmatically.



Another example – Drop-Downs

The first screenshot shows an Excel spreadsheet with a table of names and ages. A drop-down menu is visible in cell B20, showing the options M, F, and X. The second screenshot shows the same spreadsheet with the drop-down menu open, displaying the options M, F, and X. The third screenshot shows the XML code for the data validation, which is a list of values (M, F, X) defined in cells A2:A4. The XML code is as follows:

```
<row r="20" spans="1:6" ht="14.1" customHeight="1" xl4ac:dyDescent="0.2">
  <c r="A20" s="8" t="s">
    <v>26</v>
  </c>
  <c r="B20" s="3" t="s">
    <v>7</v>
  </c>
  <c r="C20" s="4">
    <v>15</v>
  </c>
  <c r="D20" s="5">
    <v>66.5</v>
  </c>
  <c r="E20" s="4">
    <v>112</v>
  </c>
  <c r="F20" s="6"/>
</row>
</sheetData>
<sheetProtection sort="0" autoFilter="0"/>
<autoFilter ref="A1:F20" xr:uid="{00000000-0009-0000-0000-000000000000}"/>
<pageMargins left="0.05" right="0.05" top="0.5" bottom="0.5" header="0" footer="0" />
<pageSetup orientation="portrait" horizontalDpi="300" verticalDpi="300" r:id="rId1" />
<extLst>
  <ext uri="{CCE6A557-97BC-4b89-ADB6-D9C93CAAB3DF}" xmlns:xl4=
    "http://schemas.microsoft.com/office/spreadsheetml/2009/9/main">
    <xl4:dataValidations count="1" xmlns:xm=
      "http://schemas.microsoft.com/office/excel/2006/main">
      <xl4:dataValidation type="list" allowBlank="1" showInputMessage="1"
        showErrorMessage="1" xr:uid="{D846FFCE-31E1-4A1A-A973-05AFD3CE5F35}">
        <xl4:formulal>
          <xm:f>ValidSex!$A$2:$A$4</xm:f>
        </xl4:formulal>
        <xm:sqref>B2:B20</xm:sqref>
      </xl4:dataValidation>
    </xl4:dataValidations>
  </ext>
</extLst>
</worksheet>
```



4

Pulling it All Together

COMET 
COOnMEd review Tool



Excel Feature Requests

- Other requirements were:
 - Shading of certain columns to indicate they are editable
 - Individual cell highlighting to indicate a value changed from the previous review
 - “tooltips” or “flyover” text showing the previous values for these changed data points
- All of these are possible in SAS using various techniques within the ODS EXCEL and PROC REPORT statements
- Additional nice-to-haves that could be done manipulating XML:
 - cell validation
 - individual cell protection
 - Drop down selections
- Fortunately, SAS can read XML files easily
- SAS can also manipulate ZIP files
 - FILENAME statement with the ZIP option



Pulling It All Together

- We have seen how new Excel features can potentially be implemented using SAS
 - Both the creation, and subsequent manipulation of underlying XML
- The Concomitant Medications data we want to report is already set up
- We have established the workflow and method of data storage
 - Periodic execution, storing both Data Set and reviewed XLSX
- Just needed to build macros and routines to manipulate the XML!

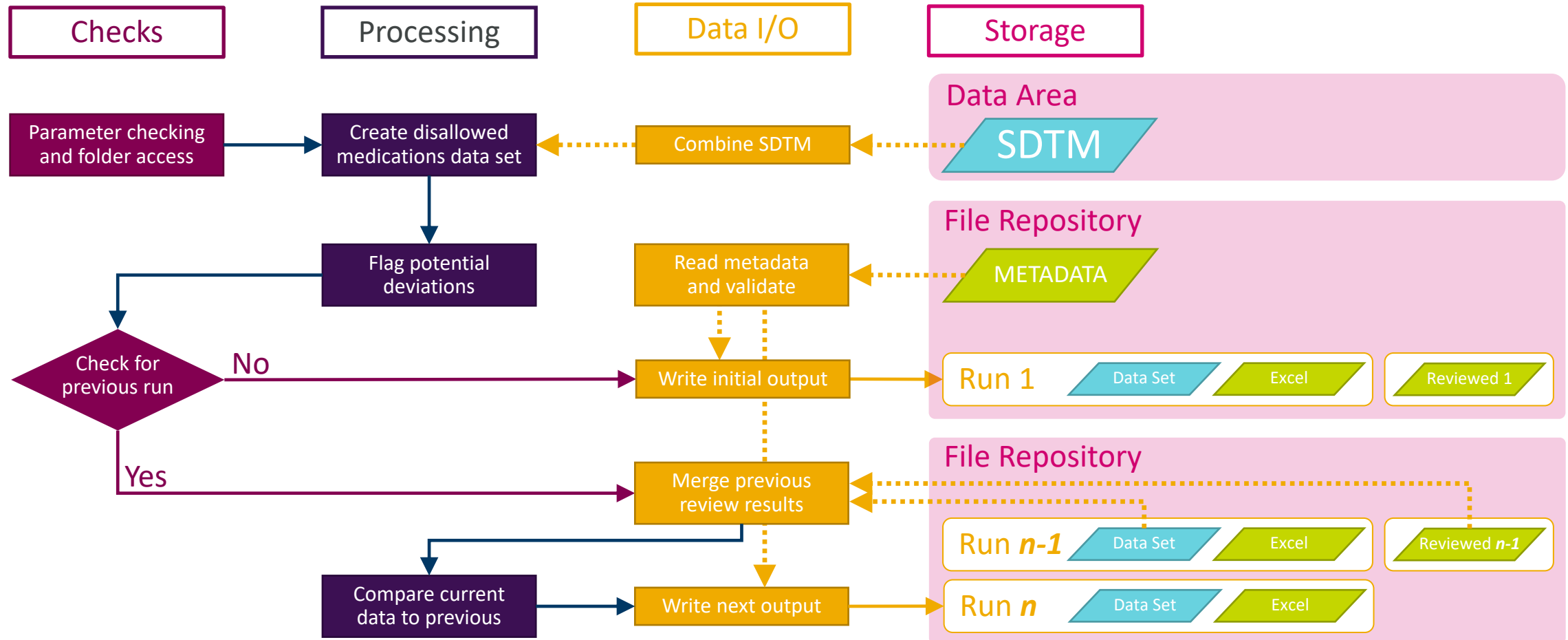


XML Editing

- XML files can be edited within the XLSX by SAS
- XML files are text, so can be read using simple SAS techniques
- Performing find/replace and insertion of code was VERY tricky
 - Any mistakes in ordering or syntax render the XLSX corrupt
- As for the Trial & Error research previously, routines were developed one at a time, and continuously monitored for corruption



Final Workflow



5

Conclusions

COMET 
CO_nME_d review Tool



Conclusions

- COMET was released 2022 and is currently in use by several study teams
- COMET output (dismed.sas7bdat) has remained static, so the XML editing is stable
 - Occasional bug fix (a recent one triggered a confirmed bug report to SAS themselves!)
- The COMET tool has shown an 80% reduction in the volume of work involved in reviewing concomitant medications compared to the previous manual process
- The ability to have frequent incremental reviews has significantly reduced resource bottlenecks around deliverables.
- In addition, COMET has minimised the risk of errors occurring in the programming and has enhanced the quality of the review via the data integrity constraints that were introduced.



Example (1)

Record History	Study Identifier	Unique Subject Identifier	Patient rescreened	Module	Patient Status	Sponsor-Defined Identifier	Reported Name of Drug, Med, or Therapy	Start Date/Time of Medication	End Date/Time of Medication	Medication Ongoing	Therapy Reason	Indication	Check ID Number	Disallowed medication Filter	Disallowed Medication Record Flag	Major / Minor PD	Important Protocol Deviation Flag	PD Code	Physician Comment
Old	D9999C00000	D9999C00000/E0251013	NA	CM	Randomized	CM-0001	SPUTNIK-V	2021-04-29	2021-04-29		PANDEMIC COVID-19	PANDEMIC COVID-19	9	Y	Pending			9.3	Check at next run
Old	D9999C00000	D9999C00000/E0251013	NA	CM	Randomized	CM-0002	DIFENILHIDANTOINA	2008		ONGOING	MEDICAL HISTORY	TRAUMATIC BRAIN INJURY							
Old	D9999C00000	D9999C00000/E0251013	NA	CM	Randomized	CM-0003	TAMSULOSINA	2008-08		ONGOING	MEDICAL HISTORY	PROSTATIC HYPERPLASIA							
Amended	D9999C00000	D9999C00000/E0251013	NA	CM	Randomized	CM-0004	ENALAPRIL	2019-12	2021-10		MEDICAL HISTORY	HYPERTENSION							
Logic changed	D9999C00000	D9999C00000/E0251013	NA	MINT	Randomized	MINT-0001	DELTISONA	2020-12-17	2020-12-21	BEFORE		HISTORIC ASHTMA EXACERBATION	13	Y	*Y	*Minor	*N	2	Comment 1
Logic changed	D9999C00000	D9999C00000/E0251013	NA	MINT	Randomized	MINT-0002	RELVAR ELLIPTA (FLUTICASONA/VILANTEROL 184/22)	1998-05-10		ONGOING		ASTHMA STABLE MAINTENANCE DOSE	13	Y	*Y	*Minor	*N	3	Comment 1
Logic changed	D9999C00000	D9999C00000/E0251013	NA	MINT	Randomized	MINT-0003	SALBUTAMOL	1969		ONGOING		WORSENING OF ASTHMA, WITHOUT EXACERBATION	13	Y	*Y	*Minor	*N	3	Comment 1
Logic changed	D9999C00000	D9999C00000/E0251014	NA	MINT	Screen Failure	MINT-0001	RELVAR ELLIPTA	2018-04-23	2021-05-17	BEFORE		ASTHMA STABLE MAINTENANCE DOSE	13	Y	*Y	*Major	*Y	3	Comment 1
Logic changed	D9999C00000	D9999C00000/E0251014	NA	MINT	Screen Failure	MINT-0002	MEPREDNISONE	2021-01-20	2021-01-23	BEFORE		ASTHMA EXACERBATION PER PROTOCOL	13	Y	*Y	*Major	*Y	2	Comment 1
Logic changed	D9999C00000	D9999C00000/E0251014	NA	MINT	Screen Failure	MINT-0003	FLUTICASONE	2017-02		ONGOING		ALLERGY	13	Y	*Y	*Major	*Y	1	Comment 1



Example (2)

Requirements were to;

- a) Enhance data integrity
- b) Standardise data entry
- c) Expedite team review

Concentration: mg/kg/day

Total Daily Dose: mg/kg/day

Dose Units: ug

Dose: 184

Previous: 239.2

Amended cells
highlighted
(with previous value
pop-up)

Record History	Study Identifier	Unique Subject Identifier	Patient rescreened	Module
Old	D9999C00000	D9999C00000/E0251013	NA	CM
Amended	D9999C00000	D9999C00000/E0251013	NA	CM
Logic changed	D9999C00000	D9999C00000/E0251013	NA	MINT

Record history

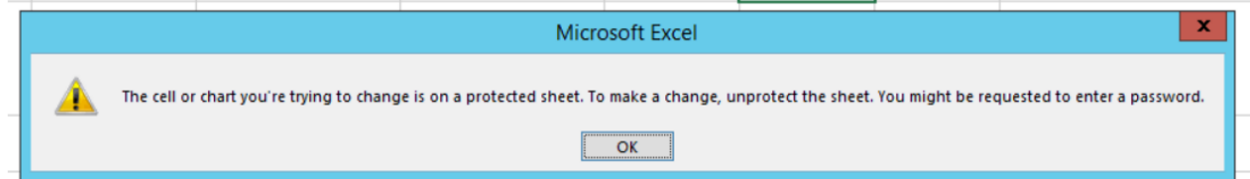
(New, Amended, Old, Logic Changed)

Disallowed medication Filter	Disallowed Medication Record Flag	Major / Minor PD	Important Protocol Deviation Flag	PD Cod
Y	*Y	Minor	*N	3
Y	*Y	*Minor	*N	3

Filters

Restricted dropdowns for key columns

Randomisation date	Date/Time of First Study Treatment	Date/Time of Last Study Treatment	Start Date/Time of First Visit	End Date/Time of Last Visit	Completed Treatment	Start Date/Time of Withdrawal/Completion
	2021-05-17T10:45	2021-05-26T21:30	2021-05-17	2021-05-27		



Only light yellow cells are editable
(to avoid data corruption)



Contact

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COMET

CO_nME_d review Tool

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