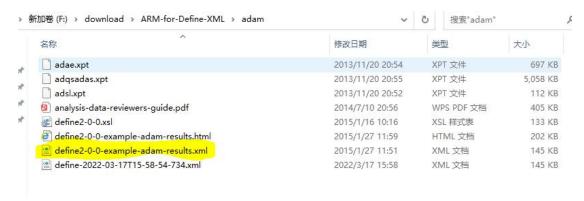
Create Adam Define Using P21

1. Download the package of adam define from CDISC website

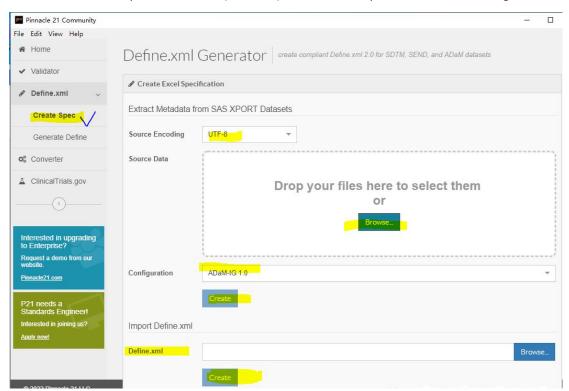
https://www.cdisc.org/standards/data-exchange/define-xml



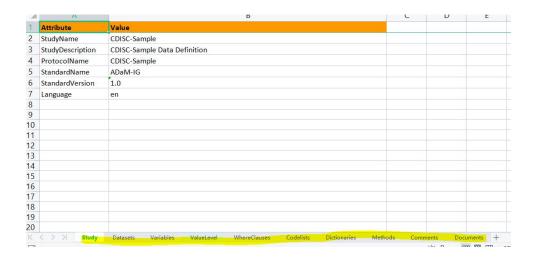
2. Download the P21 and install the software

https://www.pinnacle21.com/

3. Create the adam specification.xlsx (excel file) based on example of adam define using P21



4. Get the spec template from P21, then create your define spec based on this template



5. Import the define spec, and generate the define with P21



- 6. Adjust the details of define.xml according to the example of define.xml
- 7. Check the syntax of define.xml, if which is not shown normally

 Another method: create define.xml using SAS based on it syntax, it's a little difficult if you are
 not familiar with xml syntax.

CDISC-Sample ... CDISC-Sample ... E:\DEFINE\defin... CDISC-Sample ... E:\DEFINE\defin... E:\DEFINE\defin... CDISC-Sample Data Definition CDISC-Sample Data Definition CDISC-Sample Adverse Events Ana Site Identifier ADSL.SITEID KeySequence="2" /> Unique Subject Identifier ADSL.USUBJID /> Act Age ADSL.AGE /> Pooled Age Group 1 ADSL.AGEGR1 /> Pooled Age Group 1 (N) ADSL.AGEGR Safety Population Flag ADSL.SAFFL /> Date of First Exposure to Treatment ADSL.TRTSDT /> Date MethodOID=MT."ADAE.ASTDT" /> Analysis Start Date ADAE.ASTDT MethodOID=MT."ADAE.ASTDY" /> Analysis Start Relative Day ADAE.ASTDY KeySequence="5" MethodOID=MT."ADAE.AENDY" /> Analysis End Relative Day ADAE.AENDY MethodOID=MT. MethodOID=MT."ADAE.ADURU" /> AE Duration Units ADAE.ADURU KeySequence="3" /> Rep AE.AELLT /> Lowest Level Term Code AE.AELLTCD /> Dictionary-Derived Term AE.AEDECOD High Level Term Code AE.AEHLTCD /> High Level Group Term AE.AEHLGT /> High Level Group AE.AEBODSYS /> Primary System Organ Class AE.AESOC /> Primary System Organ Class Code A AE.AESER /> Involves Cancer AE.AESCAN /> Congenital Anomaly or Birth Defect AE.AESCONG AE.AESDTH /> Requires or Prolongs Hospitalization AE.AESHOSP /> Is Life Threatening AE.AESI

PS:

- a. order of the datasets and variables
- b. Check the hyperlink of the external files and codelist/comments/code
- c. Are there some unresolved codelist variables(search CL.XXX)
- d. VLM works normally

- e. Check the syntax of derivation
- f. Note the version of Meddra/Whodrug/Adam IG...

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