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SUPPQUAL – Where's My Mommy?

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ABSTRACT

When using CDISC standards, there may be situations in which a field has been collected on a CRF or included in a vendor data transfer which seems to be clinically relevant but is not "topic" data belonging in a standard or custom SDTM domain (any of the three general observation classes). Since non-standard variables cannot be added to SDTM domains, this data typically gets mapped to a SUPPQUAL (Supplemental Qualifiers) dataset, but what do we do when there is not an obvious "parent" record corresponding to this data within one of the SDTM domains? This paper will provide a set of guidelines to use to determine how best to handle these situations.

INTRODUCTION

Now that more and more people are becoming familiar with CDISC and the SDTM data standard, it seems that it should be easier to implement and use this standard, however in practice virtually every study seems to have those one or two (or more!) forms or modules that stump and challenge even the more seasoned CDISC users. One of these challenges is the "floating supplemental qualifier". While reviewing or working with specifications on several projects, I have encountered the situation where there was a qualifier variable mapped to SUPPQUAL which had no "parent" to link to…..essentially, a lost child….leading to the question "Where's my Mommy?". This situation is not CDISC compliant, so we need to address it. A few options are available – find a parent, figure out an alternate mapping to SDTM, or do not map it to SDTM altogether.

The Supplemental Qualifiers dataset is designed to capture any non-SDTM variables, but has a tendency to get abused by having any data which does not map to a standard SDTM domain and variable essentially "dumped" into SUPPQUAL. This dataset is not just a bucket to capture any data which doesn't fit elsewhere, but is intended to represent a relationship or association between data values where the data in SUPPQUAL serves as a qualifier for an observation in one of the general observation classes. The variables IDVAR (identifying variable) and IDVARVAL (identifying variable value) provide the linkage between records by identifying the variable to join on and the variable value of the specific record(s) which are related. If a proper linkage is not established, compliance checks (such as these from OpenCDISC) may identify issues with the datasets:

Rule ID	Message	Description	Category	Type
SD0074	Referenced Domain not found	Identifies Supplemental Qualifiers domain reference to a key variable that isn't defined in the target domain	Consistency	Error
SD0076	Referenced key variable not found	Identifies Supplemental Qualifiers domain reference to a key variable that isn't defined in the target domain	Consistency	Error
SD0078	Referenced record not found	Identifies Supplemental Qualifiers domain reference to a record that doesn't exist in the target domain	Cross-reference	Error

GUIDELINES FOR RESOLUTION:

To best resolve this situation, one should consider:

1) Does it actually belong in a SDTM domain and not SUPPQUAL?

   a) Give this data a second look – is it actually topic data and possibly just not presented in the same way as other topic data? Does it have qualifiers of its own?
   b) It may not be the same class as other data collected on the page, but is still topic data – perhaps it is Findings About an Event or Intervention. Use the new FA domain!

2) Is there a not-so-obvious parent?

   a) Review the context to determine what this data is describing or related to. It may be related to information in another section of the form or on another form altogether. Alternately, it may be related to the entire form or be a subject-level qualifier.

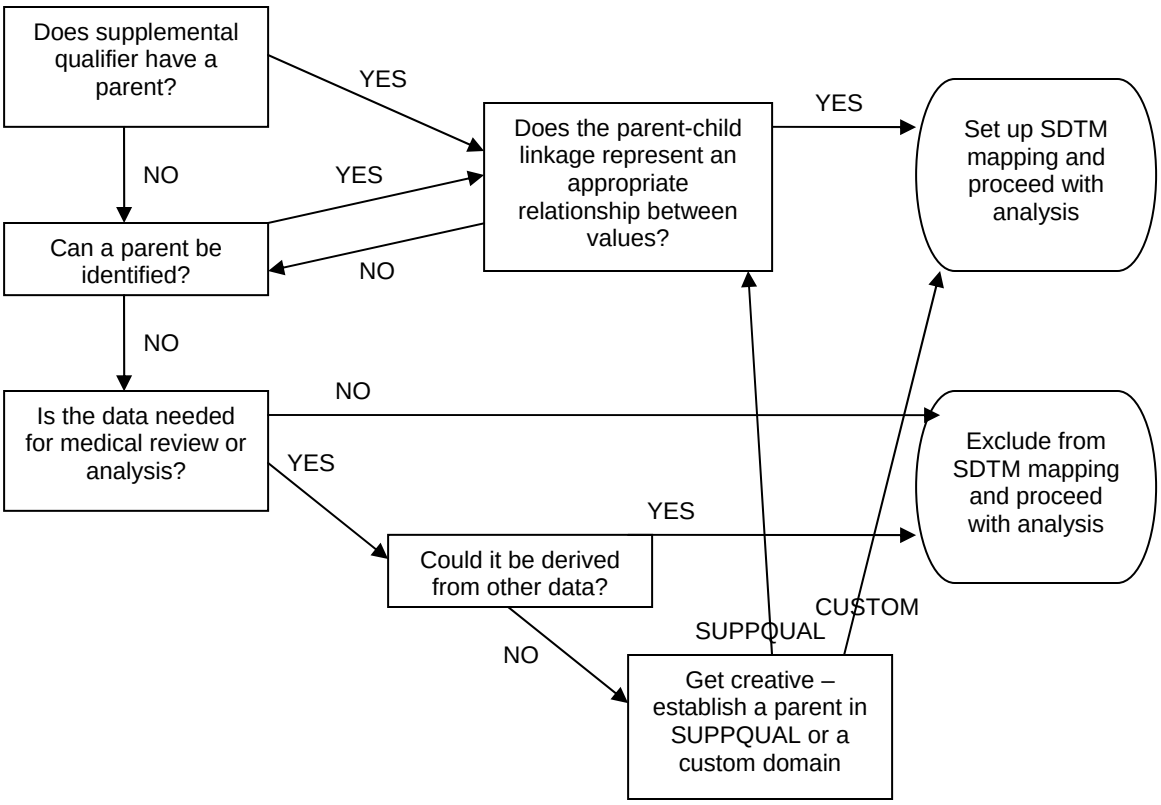
3) If it is definitely not topic data and a parent cannot be found, then we need to ask: Is the data actually needed?

   a) If the data is purely administrative (prompt questions, etc.), it does not need to be mapped.
   b) Is the data clinically important or useful for medical review?
   c) Is the data needed for any tables, figures, or listings?

4) When all else fails: It's time to get creative

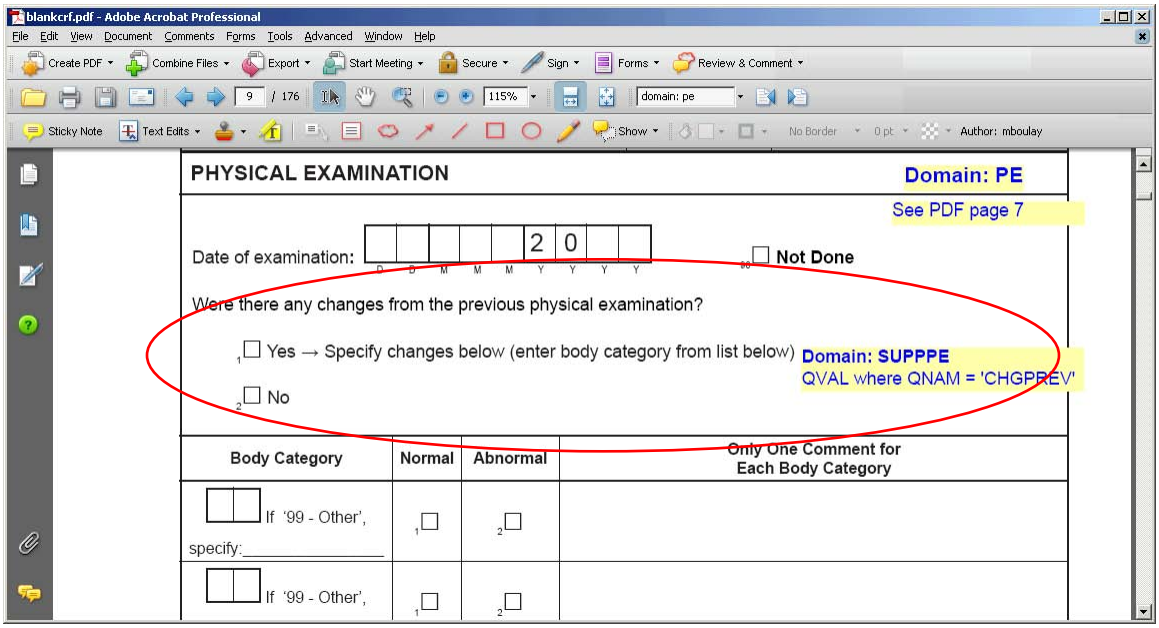
   a) Perhaps the collection field itself indicates the topic data and a record can be generated in one of the SDTM domains to link the qualifier to.
   b) If there is no other solution and you must have this data captured in SDTM, then you may need to create a custom domain to hold the values from these data fields.

DECISION CHART:



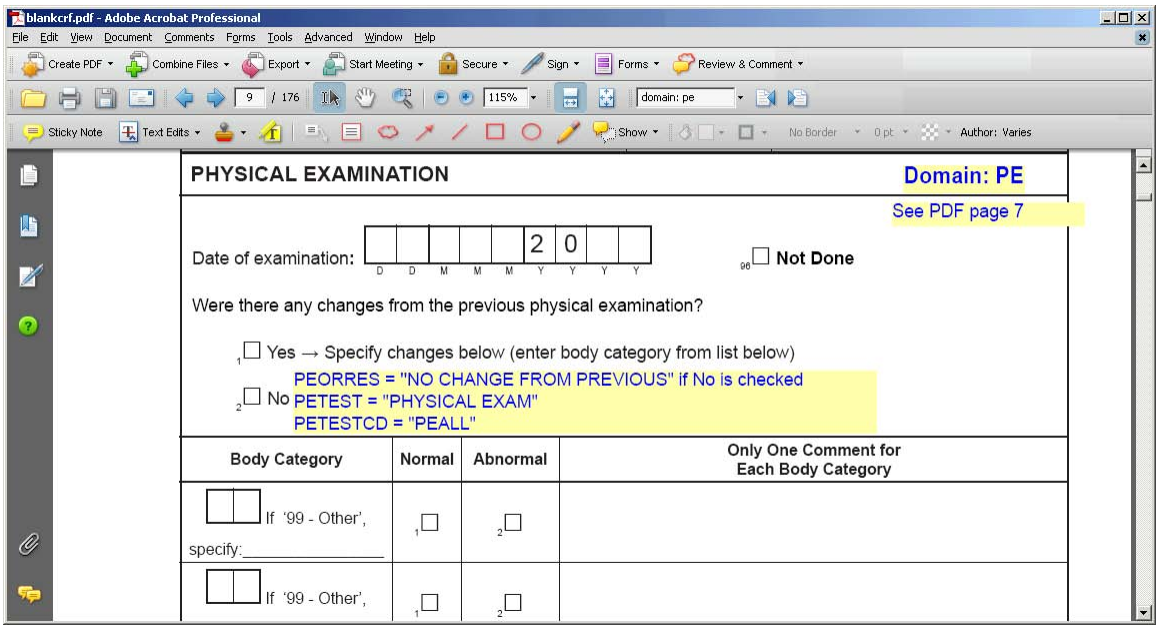
EXAMPLES

Example 1:

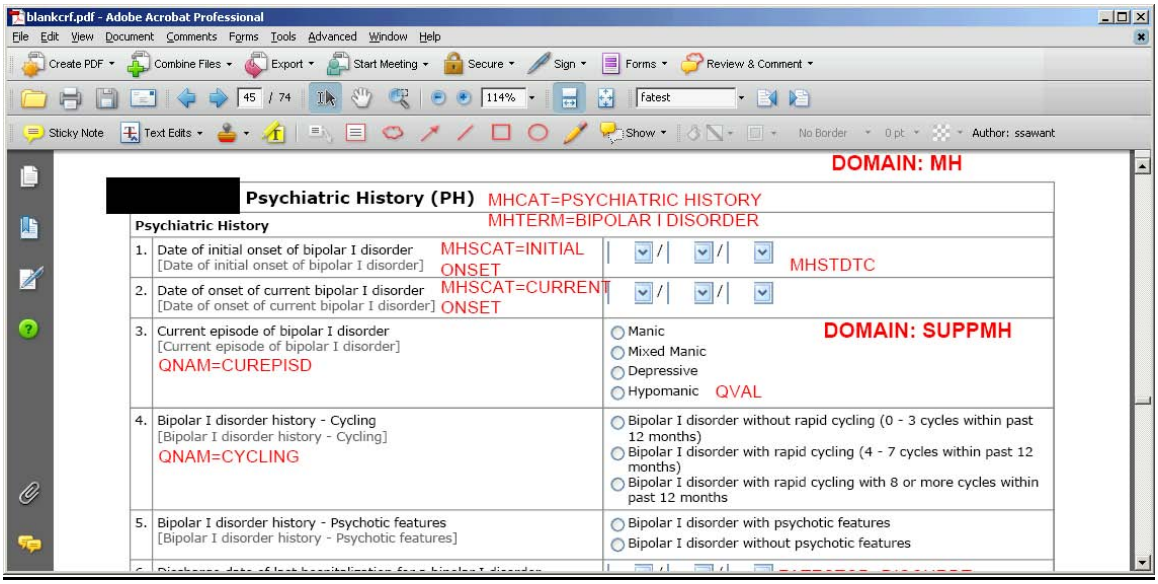


In this physical examination module, if 'No' were to be selected, then there would be no other data from this form and thus nothing to link to in the PE (physical examination) domain. Initial thoughts were that this could be linked to the full physical examination done at screening, but this information was not describing the screening physical examination results plus this change from previous examination question was assessed at multiple visits, so it would not be possible to distinguish the records (and would cause duplicates in SUPPPE).

Since the focus at the post-screening visits was on changes from the screening examination, this information was actually considered to be topic data and thus belonged in PE. The fact that a subject did not have changes from the previous examination was in itself a finding. Hence the annotations and mapping were changed to generate a record with PETESTCD = "PEALL" and PEORRES indicating that there were no changes:

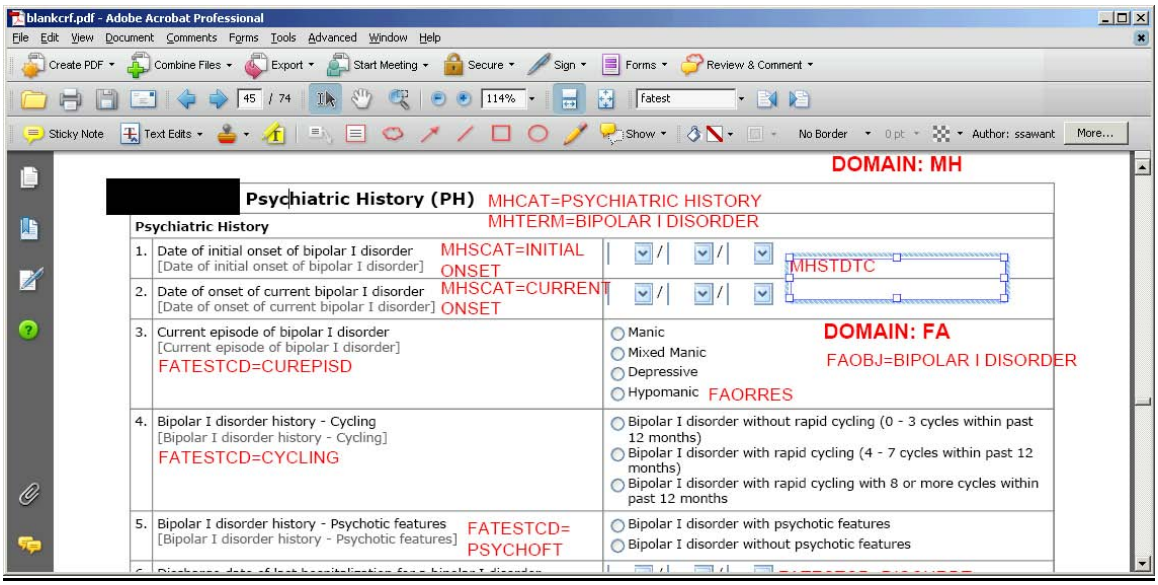


Example 2:

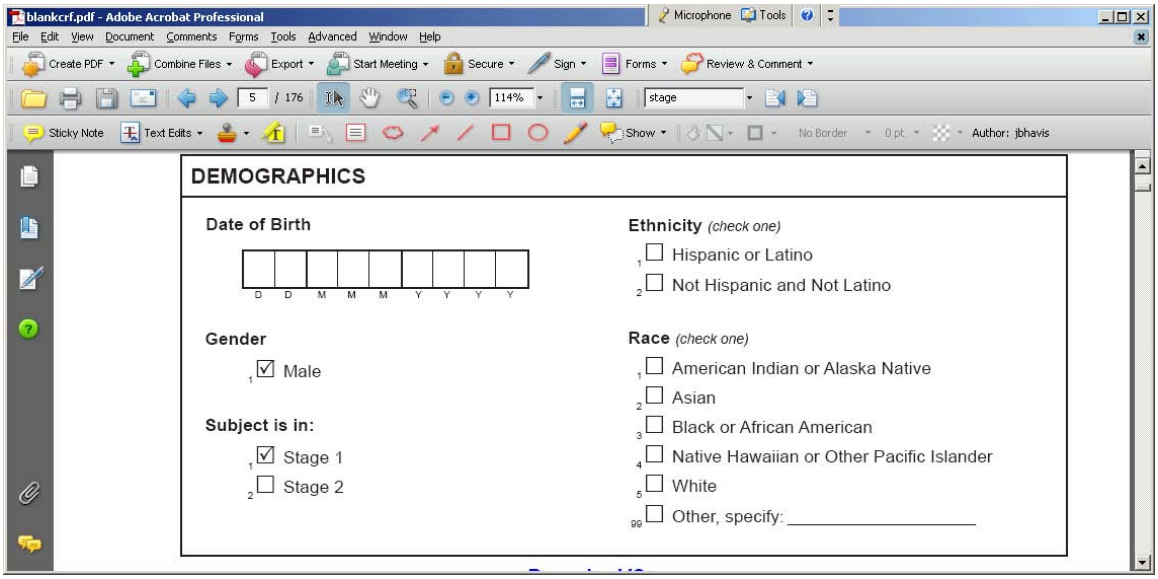


In this module, there are multiple questions for psychiatric history pertaining to the status of the subject's Bipolar disorder. The initial thought was to map the responses to SUPPMH based on the first two items being mapped to the MH (medical history) domain, however the questions did not necessarily refer only to the two collected dates in items 1 and 2, but described the overall nature of the subject's experience with Bipolar disorder.

Since each of the questions following question #2 were findings about the subject's Bipolar disorder (a prerequisite for this study), the Findings About Events or Interventions domain (FA) was used instead:

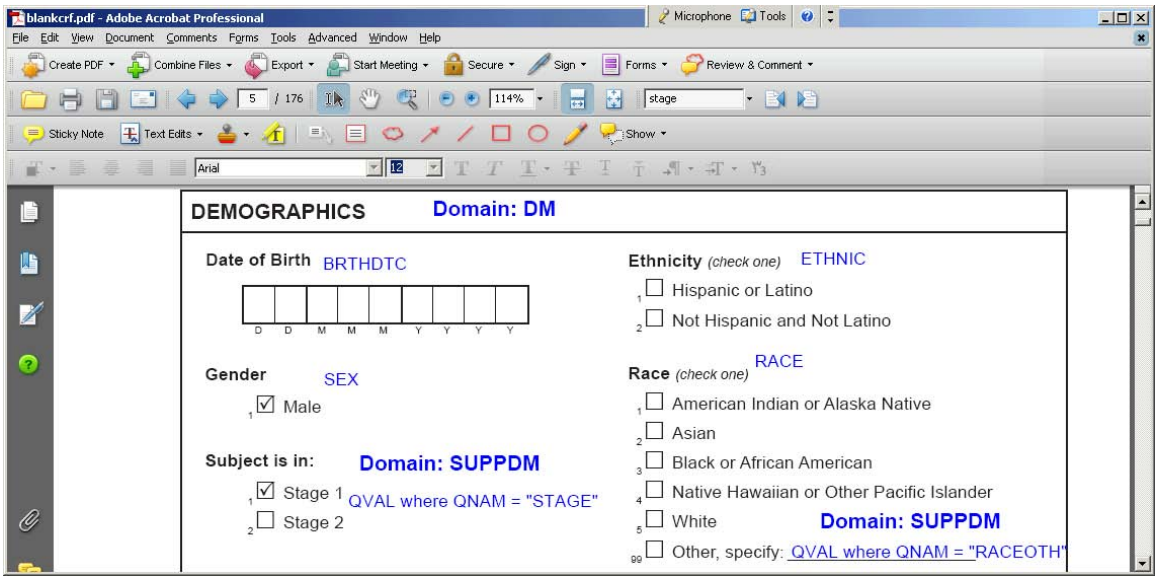


Example 3:

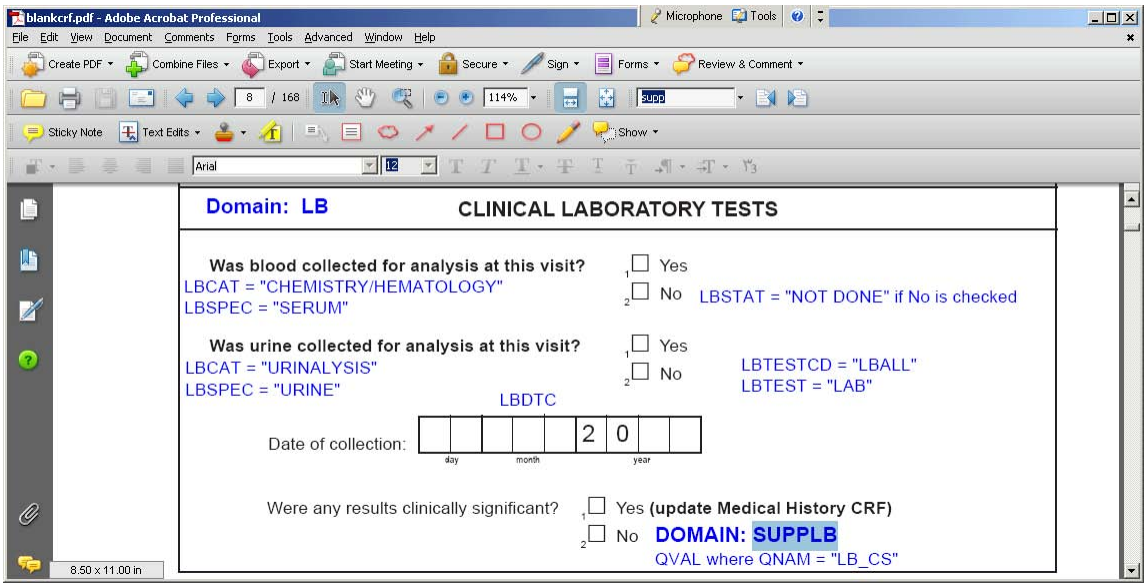


In this example, the study stage is collected in the demographics module. The study has two stages with different treatment regimens and assessment schedules. This information does not directly describe or relate to any other data collected here; however it is critical for the statistical analysis.

Although there is no obvious parent data point, this data is in fact relevant for each subject and affects all data collected for the subject, therefore it can be mapped to SUPPDM and be related to the corresponding USUBJID as a whole. In these cases, the IDVAR and IDVARVAL are left null in the supplemental qualifiers dataset:

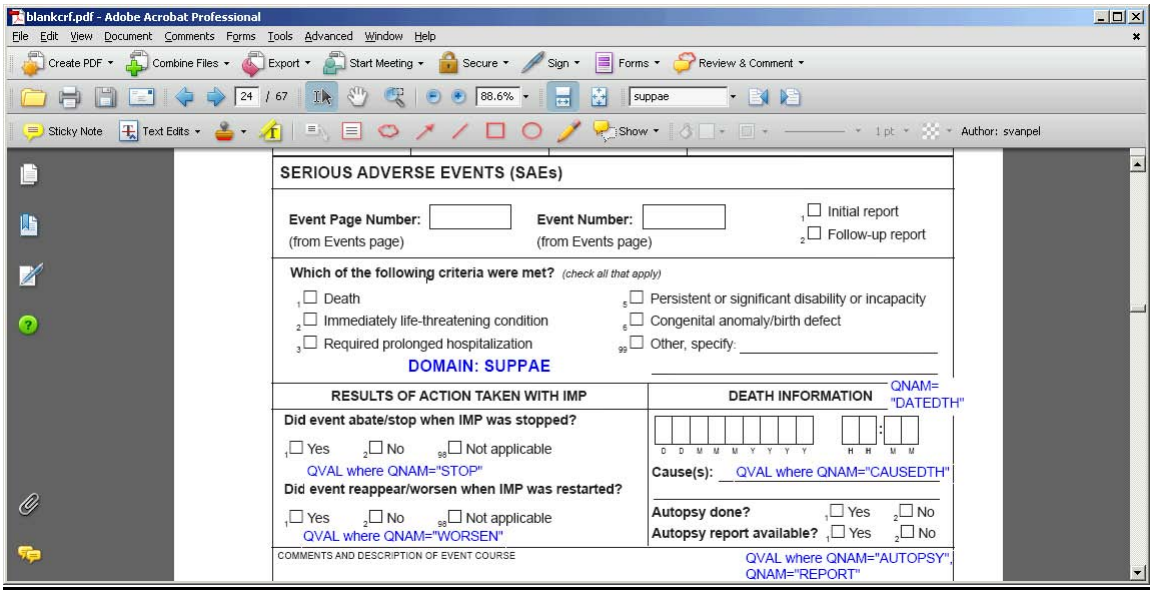


Example 4:



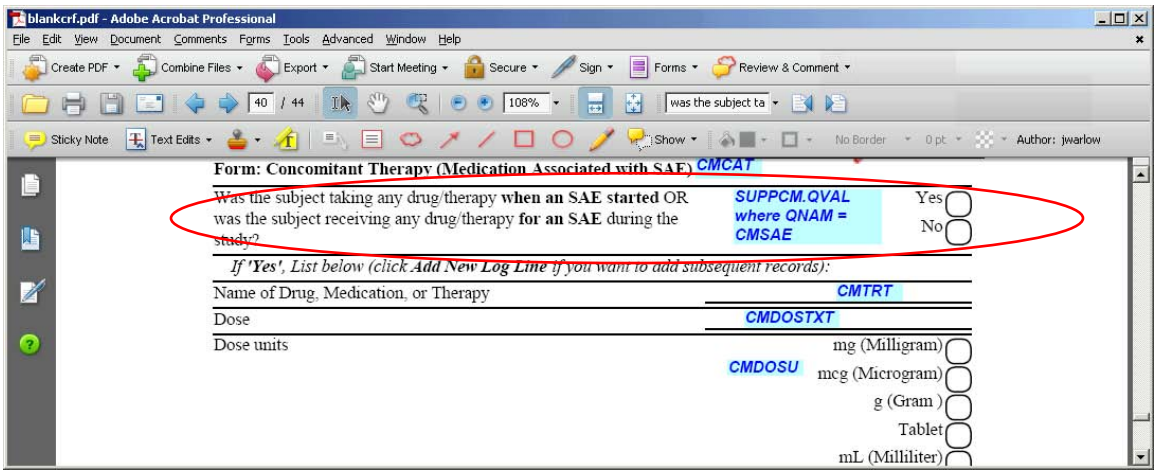
In this laboratory example, there is a very general question about clinical significance of results (coming separately via central lab). Since no specific results of clinical significance are noted, we need to determine how to link this information back to the results in the LB (laboratory tests) domain. Without knowing which specific results are actually clinically significant, this information must be tied back to all of the blood and urine clinical laboratory tests from this visit, requiring the establishment of LBGRPID values in the LB domain in order to group these lab results together and use as the IDVAR in SUPPLB.

Example 5:



In this SAE form, important information was collected pertaining to the status of the serious adverse event, relationship to IMP, as well as to any resulting deaths. The information was needed for reporting and it described a serious adverse event, but the event in question was not explicitly identified here. In this case, the event page number and event number had to be used to determine the parent event by matching up to the main AE form (page number and line number) and identifying the corresponding AESEQ (AE domain sequence number). It was important that these forms were reconciled to ensure that there was always a match on page number and event number, else the SAE qualifiers would not be linked to a parent record.

Example 6:



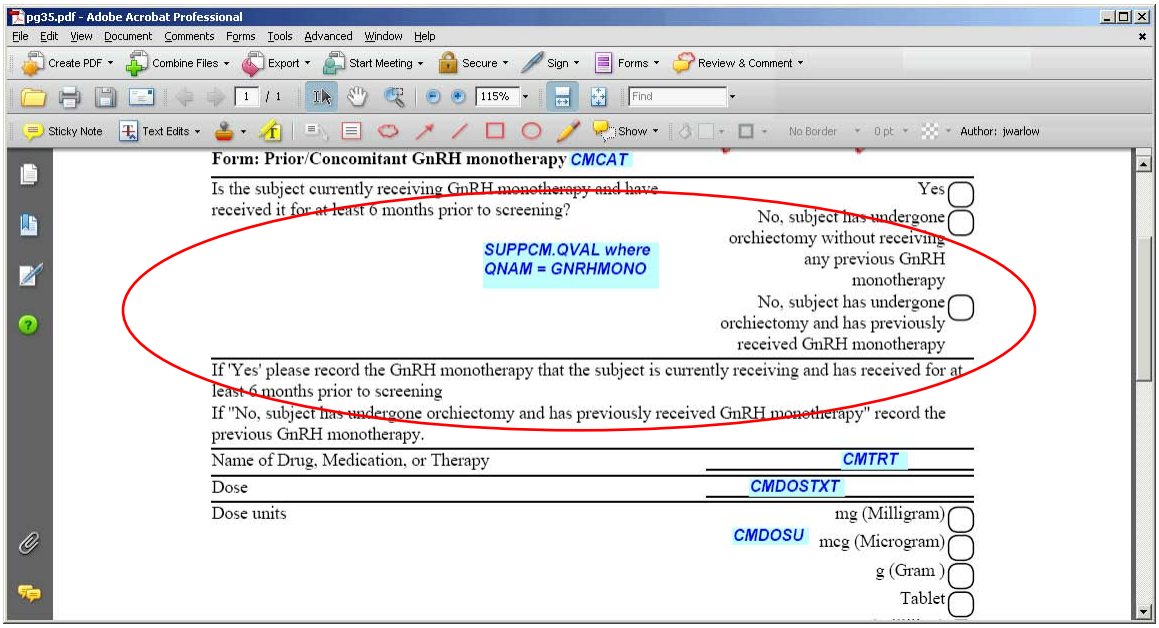
In this concomitant therapy form, if 'No' were to be checked for this question, there would be no other data from this form and thus nothing to link to in the CM (concomitant medications) domain.

We checked with the project team to determine if this information was truly needed.

If No → Change annotation to '[NOT SUBMITTED]' and only output the actual drugs/therapies used

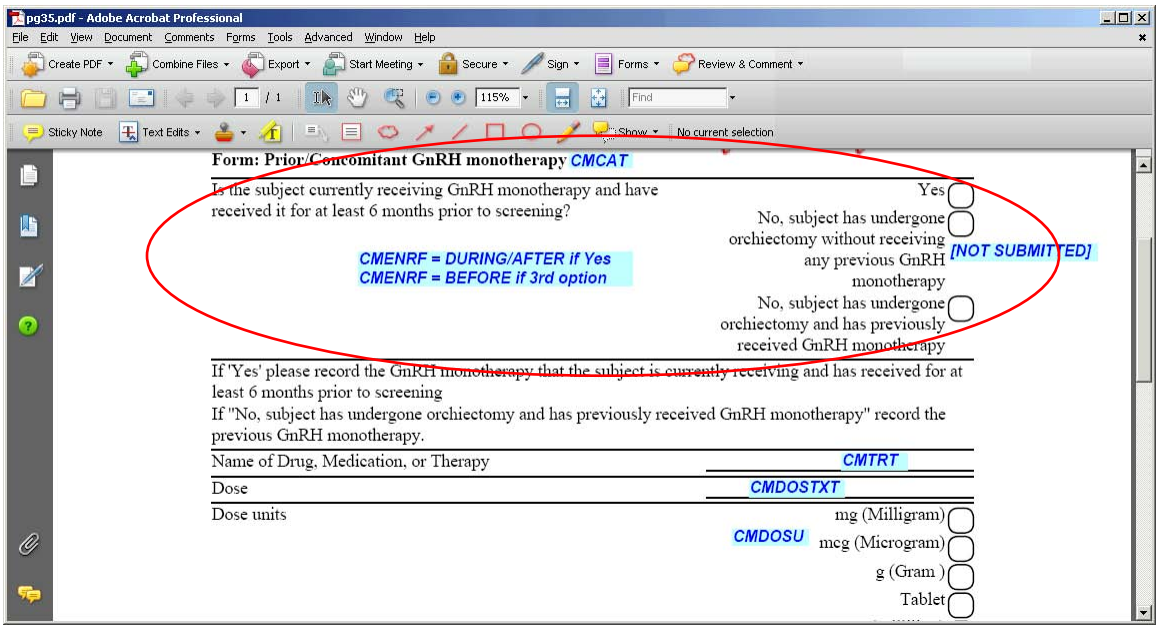
If Yes → The lack of SAE related drug/therapy could be derived in ADaM by crosschecking the subjects with this CMCAT to the DM (demographics) domain and identifying subjects who did not take these drugs/therapies.

Example 7:



In this example, if the second option were to be checked, there would be no other data from this form and thus nothing to link to in the CM (concomitant medications) domain, yet it was important to be able to distinguish between the different possible options.

We got a little creative and figured that we could denote the time period via CMENRF. Similar to Example 6, the second option could then be '[NOT SUBMITTED]' since we would be able to identify these subjects by crosschecking CM with DM.



CONCLUSION

The floating supplemental qualifier is a compliance issue which must be addressed prior to submitting data. Any "lost children" will be identified by compliance checking tools such as WebSDM or OpenCDISC. A thorough review of mapping specifications can help to catch this issue up front, but one must be careful in determining an appropriate solution which adheres to CDISC SDTM guidelines and specifications, keeping in mind the full context of the situation and the impact of the modified mapping strategy in terms of programming, medical review, and regulatory review.

REFERENCES

CDISC. *Study Data Tabulation Model*. Retrieved from http://www.cdisc.org/sdtm.

OpenCDISC. *CDISC Validation Rules Repository*. Retrieved from http://www.opencdisc.org/projects/validator/cdisc-validation-rules-repository

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