Updates

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1. How many patients received additional anti-epileptic medications within the 60 minutes of the study medication infusion?

In Form 501c, there are 317 patients received additional medications in total, and all of them received medication within the 60 minutes accorrding to `F501CQA_min`. Only 116 of them can be mapped to the 478 patients pool. So I assume there are some irrelevant patients in Form 501c. Since part of patients were removed for data analysis, there are 105 out of 421 patients received additional anti-epileptic medications within the 60 minutes.

2. What are these additional medications stratified by age (< 18 yo), (18-65 yo), (>65 yo)?

age_group	#	%
<18	52	52/217(23.96%)
18-65	41	41/130(31.54%)
>65	12	12/74(16.22%)
Total	105	105/421(24.94%)

To keep consistent with our age group setting, I offered another version of table as below.

age_group	#	%
<18	52	52/217(23.96%)
18-60	38	38/130(29.23%)

age_group	#	%
>60	15	15/74(20.27%)
Total	105	105/421(24.94%)

I understand “them” in following requirement as the whole patients pool (421)

Success is based on the outcome1 from derived form

I am confused about your requirement about the comparison between intubation and success / intensive care and success, since they are not opposite category. I list how I deal with these variables and the contingency table below.

3. How many of them ended up with mechanical intubation compared to those successfully treated with the study medications alone?

For the variable for intubation after the 60 minutes I get from form 104 (F104Q34), some of patients haven’t been recorded. I hope it is appropriate to treat them as 0. Also, one patients might be recorded multiple times with different Adverse event name. Once they receive intubation, I treat it as a “Yes” no matter what adverse event it is.

intubation	Success	Failure
Yes	12	119
No	194	96

4. How many of them ended up with intensive care unit admission compared to those successfully treated with the study medications alone?

As the code from investigator data dictionary, when the variable = 2, I treat it as a Yes.

intensive care	Success	Failure
Yes	86	177
No	120	38