1. Data Extraction, Primary Study-Harm (Grouping)
○ Group1 : _____
○ Group2 : _____
○ Group3 : _____
○ Exclude

2. Did the authors specify if the harms reported encompass ALL the events collected or a selected SAMPLE?
○ Yes : _____
○ No : _____
○ Unclear : _____

3. Were the harms PRE-DEFINED using standardized or precise definitions?
○ Yes : _____
○ No : _____
○ Unclear : _____

4. Were SEVERE events precisely defined?
○ Yes : _____
○ No : _____
○ Unclear : _____

5. Were SERIOUS events precisely defined?
○ Yes : _____
○ No : _____
○ Unclear : _____

6. Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?
○ Yes : _____
○ No : _____
○ Unclear : _____

7. Was the mode of harms collection specified as:
○ Active : _____
○ Passive : _____
○ Not Reported : _____
○ Unclear : _____

8. Did the study specify WHO collected the harms?
○ Yes : _____
○ No : _____
○ Unclear : _____

9. Did the study specify the TRAINING or BACKGROUND of who ascertained the harms (specify)?
○ Yes : _____
○ No : _____
○ Unclear : _____

10. Did the study specify the TIMING and FREQUENCY of collection of the harms (specify)?

○ Yes : _____

○ No : _____

○ Unclear : _____

11. Did the author(s) specify the type of analyses undertaken for harms data (specify)?

○ Yes : _____

○ No : _____

○ Unclear : _____

Table No 1: Type of Intervention/treatment, sample size , Adverse Events (AE), and Withdrawals per group

Type	Total	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7
Type of intervention								
No of Pts assigned								
No of Pts who have AE								
Percent of Pts who have AE								
No of Pts who withdrew due to AE								
Percent of Pts who withdrew								

Table No 2: Identify number (%) of patients who had severe or serious adverse events (AE) per group

Severe AD	Total	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7
Suicidality								
Bleeding								
Low Sodium								
Death								
Other 1 _____								
Other 2 _____								
Other 3 _____								
Other 4 _____								
Other 5 _____								

Table No 3: Identify number (%) of patients who had adverse events (AE) per group

Adverse Events	Total	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7
Sexual Dysfunction								
Anxiety								
Sedation								
Gastrointestinal Disturbance (nausea, vomiting, diarrhea)								
Weight Loss								
Weight Gain								
Change in triglycerides								
Change in glucose								
Sleep disorder (insomnia or hypersomnia)								
Cardiovascular Problems (hypotension, tachycardia, bradycardia)								
Toxicity problems								
Headaches								
Other 1 _____								
Other 2 _____								
Other 3 _____								
Other 4 _____								
Other 5 _____								

278. Data Extractor/Reviewer:

_____

279. Comments:

_____

_____

280. First Reviewer:
_____

281. First Reviewer comments:
_____
_____

282. Second Reviewer:
_____

283. Second Reviewer Comments:
_____
_____

284. Investigators Comments:
_____
_____

285. Go to outcome form
☐ Yes
☐ NO

286. New Question
_____
_____

287. Group
☐ MoCo
☐ MoMo
☐ CoCo
☐ STARD
☐ Other : _____