Appendix C: Results Verification Decision Tree

Flow Chart

Was there a publication linked in the CTG record for the study in question?
- Yes
- No
  - Was the publication published after the study in question’s start date? (If no start date is listed in the CTG record, was the publication published after the study in question’s primary completion date?)
    - Yes
    - No
      - Is the PI listed as an author for the publication? (If no PI is listed in the CTG record, is one of the investigators listed for the publication? If no investigators are listed in the CTG record, is the sponsor listed for the publication?)
        - Yes
        - No
          - Is there a statement in either the abstract or the full text of the publication that the study is associated with the study in question’s NCT number?
            - Yes
            - No
              - Is the publication a full, original research article (i.e., not a review, editorial, letter, etc.)?
                - Yes
                - No
                  - Are the study in question’s results reported in the publication?
                    - Yes
                    - No
                      - Does the publication report on multiple studies?
                        - Yes
                        - No
                          - Category as not being a result publication (N)
                          - Category as a results publication (Y)
                  - Category as not being a result publication (N)
            - Category as not being a result publication (N)
      - Category as not being a result publication (N)
      - Does the publication report on multiple studies?
        - Yes
        - No
          - Category as not being a result publication (N)
          - Category as a results publication (Y)

For interventional studies, are these similar?
- Estimated or actual enrollment (within 10%)
- Allocation
- Intervention model
- Masking
- Primary purpose
- Intervention
- Outcome

For observational studies, are these similar?
- Estimated or actual enrollment (within 10%)
- Observational model
- Time perspective
- Exposure
- Outcome

Is the study title the same as the study in question (i.e., interventional or observational)?
- Yes
- No

Is the study title the same as the study in question (i.e., interventional or observational)?
- Yes
- No

Are the study in question’s results reported in the publication?
- Yes
- No

Does the publication report on multiple studies?
- Yes
- No

For interventional studies, are these similar?
- Estimated or actual enrollment (within 10%)
- Allocation
- Intervention model
- Masking
- Primary purpose
- Intervention
- Outcome

For observational studies, are these similar?
- Estimated or actual enrollment (within 10%)
- Observational model
- Time perspective
- Exposure
- Outcome

If sufficiently similar,
- Category as not being a result publication (N)
- Category as a results publication (Y)

If not sufficiently similar,
- Category as not being a result publication (N)
1. **Was there a publication linked in the CTG record for the study in question?** If no, categorize as irrelevant (I). If yes, move to 2.

2. **Was the publication published after the study in question’s start date?** If no start date is listed in the CTG record, was the publication published after the study in question’s primary completion date? If no, categorize as not being a result publication (N). If yes, move on to 3.

3. **Is the PI listed as an author for the publication?** If no PI is listed in the CTG record, is one of the investigators listed for the publication? If no investigators are listed in the CTG record, is the sponsor listed for the publication? If no, move on to 3a. If yes, move to 3b.
   a. **Is there a statement in either the abstract or the full text of the publication that it is associated with the study in question’s NCT number?** If no categorize as not being a result publication (N). If yes or could not determine move to 3ai
      i. **Is the publication a full, original research article (i.e., not an editorial, letter, etc.)?** If no categorize as not being a result publication (N). If yes or could not determine move to 3aii
      ii. **Is the study type the same as the study in question (i.e., interventional or observational)?** If no categorize as not being a result publication (N). If yes move to 3aiii
      iii. **For interventional studies, are these similar?:** Estimated or actual enrollment (within 20%), Allocation, Intervention model, Masking, Primary purpose, Intervention, Outcome. For observational studies, are these similar?: Estimated or actual enrollment (within 20%), Observational model, Time perspective, Exposure, Outcome. If not sufficiently similar, categorize as not being a result publication (N). If sufficiently similar, move to 3aiv
      iv. **Are the study in question’s results reported in the publication?** If no, categorize as not being a result publication (N). If yes, move to 3av
      v. **Does the publication report on multiple studies?** If no categorize as not being a result publication (N). If yes, categorize as being a result publication (Y).
   b. **Is there a statement in either the abstract or the full text of the publication that the study is associated with the study in question’s NCT number?** If no or could not determine, move to 3Ai. If yes move to 3bi
      i. **Is the publication a full, original research article (i.e., not a review, editorial, letter, etc.)?** If no, categorize as not being a result publication (N). If yes, move to 3bii
      ii. **Are the study in question’s results reported in the publication?** If no categorize as not being a result publication (N). If yes move to 3biii
      iii. **Does the publication report on multiple studies?** If no categorize as being a result publication (Y). If yes categorize as not being a result publication (N).