Data Dictionary for Publications\_Data

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**Note:** For additional information relating to the study, refer to the full study report.

**Additional Note:** Instances of "PW" in this data dictionary refer to the PI, Paije Wilson

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# **1. Identifying Information**

**Note:** Exported directly from ClinicalTrials.gov (CTG) on 6/6/2022.

## **A. Locations in Excel Sheet**

Columns A through G

## **B. Data Elements**

Refer to ClinicalTrials.gov's [Glossary of Common Site Terms](https://www.clinicaltrials.gov/ct2/about-studies/glossary).

# **2. Publication Record Information**

**Note:** In this context, publication record refers to a PubMed record for the publication

## **A. Locations in Excel Sheet**

Columns H through T

## **B. Data Elements**

**Link to publication in CTG record (*Column H*)** (Link to the publication record listed in the "More Information" section of the ClinicalTrials.gov (CTG) record)

* **[Link to publication record]**
* **[Blank]** (no link to a publication record was listed in the "More Information" section of the CTG record)

**Automatically indexed (*Column I*)** (Was the linked publication record automatically indexed into the "More Information" section of the CTG record?)

* **Y: Yes** (the linked publication record was automatically indexed into the CTG record)
* **N: No** (the linked publication record was manually added into the CTG record)
* **I: Irrelevant** (no link to a publication record was listed in the "More Information" section of the CTG record)

**Link type (for manually added publication record links) (*Column J*)** (For publication record links added manually to the CTG record, what was their categorization when using the XML view in the CTG record?)

**Note:** The XML view is accessible by adding **?resultsxml=true** to the end of the CTG record link

* **C: Citation** (the field code <reference> is assigned to the publication record link)
* **R: Result** (the field code <results reference> is assigned to the publication record link)
* **I:** **Irrelevant** (either:
  + 1) the publication record link was added automatically to the CTG record, and thus doesn't have a categorization, or
  + 2) no link to a publication record was listed in the "More Information" section of the CTG record)

**PubMed [si] test (*Column K*)** (Was the publication record retrieved when searching the NCT number with the [si] field tag in PubMed? E.g., **NCT04363203[si]**)

* **Y: Yes** (the publication record was retrieved by a [si] search)
* **N: No** (the publication record was not retrieved by a [si] search)

**PubMed [tw] test (*Column L*)** (Was the publication record retrieved when searching the NCT number with the [tw] field tag in PubMed? E.g., **NCT04363203[tw]**)

* **Y: Yes** (the publication record was retrieved by a [tw] search)
* **N: No** (the publication was not retrieved by a [tw] search)

**PMID (*Column M*)** (PMID of the publication record linked in the "More Information" section of the CTG record or of the publication record found using the [si] or [tw] search)

* **[PMID]**
* **[Blank]: Irrelevant** (there was no publication record link in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search)

**NCT number included somewhere in the publication record (*Column N*)** (Was the NCT number included somewhere in the publication record associated with the CTG record?)

* **Y: Yes** (the NCT number was included in the publication record)
* **N: No** (the NCT number was not included in the publication record)
* **I: Irrelevant** (no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search)

**Associated data link back to CTG record (*Column O*)** (Did the publication record have an "Associated Data" link back to the CTG record?)

* **Y: Yes** (the publication record had an "Associated Data" link back to the CTG record)
* **N: No** (the publication record did not have an "Associated Data" link back to the CTG record)
* **I: Irrelevant** (no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search)

**LinkOut link back to CTG record (*Column P*)** (Did the publication record have a "LinkOut" link back to the CTG record?)

* **Y: Yes** (the publication record had a "LinkOut" link back to the CTG record)
* **M: Link to multiple CTG records** (the publication record had a "LinkOut" link to a page containing multiple CTG records, one of which was the CTG record of interest)
* **N: No** (the publication record did not have a "LinkOut" link back to the CTG record)
* **I: Irrelevant** (no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search)

**Abstract link back to CTG record (within text) (*Column Q*)** (Did the publication record have a link in its abstract back to the CTG record?)

* **Y: Yes** (the publication record had a link in its abstract back to the CTG record)
* **N: No** (Either
  + 1) the publication record did not have a link in its abstract back to the CTG record, or
  + 2) the publication record did not have an abstract)
* **I: Irrelevant** (no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search)

**Publication date (*Column R*)** (Publication date listed in the publication record)

**Note:** When electronic publication dates and publication dates are both presented, the earliest date is used

* **[Month Year]: Month and year** (month and year the publication was published. Note: if no month is present, used "NM" in place of month)
* **I: Irrelevant** (no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search)

**Publication published before start date (*Column S*)** (Was the publication record's listed publication date before the CTG record's listed start date?)

* **Y: Yes** (the publication was published before the CTG record's listed start date)
* **N: No** (the publication was published after the CTG record's listed start date)
* **I: Irrelevant** (no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search)

**Publication published before primary completion date (*Column T*)** (Was the publication record's listed publication date before the CTG record's listed primary completion date?)

* **Y: Yes** (the publication was published before the CTG record's listed primary completion date)
* **N: No** (the publication was published after the CTG record's listed primary completion date)
* **I: Irrelevant** (no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search)

# **3. Results Publication Verification**

**Note:** Refer to the Decision Tree for information on what data are collected. Only publications that had publication dates after the CTG record's listed start date were included for the following data collection.

**Note:** In this context, publication record refers to a PubMed record for the publication

## **A. Location in Excel Sheet**

Columns U through AL

## **B. Data Elements**

**PI/investigator/sponsor listed as author (*Column U*)** (Is the principal investigator (PI) from the CTG record listed as an author in the publication record? If no PI is listed in the CTG record, is one of the investigators from the CTG record listed as an author in the publication record? If no investigators are listed in the CTG record, is the sponsor from the CTG record listed in the publication record?)

* **Y: Yes** (either the PI, an investigator, or the sponsor from the CTG record are listed in the publication record)
* **N: No** (neither the PI, an investigator, or the sponsor from the CTG record are listed in the publication record)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date)

**NCT statement in abstract or full text (*Column V*)** (Is there a statement in either the abstract or the full text of the publication that the study is directly associated with the CTG record's NCT number? E.g., listing "**Trial registration: NCT04363203**," or "**This study was registered at clinicaltrials.gov: NCT04363203**," etc.). Just mentioning or citing an NCT number (e.g., "This study reuses data from NCT… etc.") does not count

* **Y: Yes** (there is a statement in either the abstract or the full text of the publication that the study is directly associated with the CTG record's NCT number)
* **N: No** (there is not a statement in either the abstract or the full text of the publication that the study is directly associated with the CTG record's NCT number)
* **C: Could not determine** (the CTG record's NCT number is not in the abstract, but PW could not verify if the CTG record's NCT number was in the full text due to issues accessing the full text)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date)

**Original research article (*Column W*)** (Is the publication a full, original research article? In this context, to be considered a full, original research article the publication must have an introduction, methods, results, conclusion, and discussion section; and cannot be a review, editorial, commentary, or letter)

* **Y: Yes** (the publication is a full, original research article)
* **N: No** (the publication is not a full, original research article)
* **C: Could not determine** (PW could not verify if the publication was a full, original article due to issues accessing the full text)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date, or
  + 3) the publication did not meet past, relevant criteria on the Decision Tree)

**Results reported (*Column X*)** (Are the CTG record's results reported in the publication?)

* **Y: Yes** (the CTG record's results are reported in the publication)
* **N: No** (the CTG record's results are not reported in the publication)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date, or
  + 3) the publication did not meet past, relevant criteria on the Decision Tree)

**Multiple trials reported (*Column Y*)** (Are multiple trial results reported in the publication?)

* **Y: Yes** (multiple trial results are reported in the publication)
* **N: No** (multiple trial results are not reported in the publication; i.e., only the CTG record's results are reported in the publication)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date, or
  + 3) the publication did not meet past, relevant criteria on the Decision Tree)

**Same study type (*Column Z*)** (Is the publication's study type the same as that listed in the "Study Type" in the "Study Design" section of the CTG record? I.e., interventional or observational?)

* **Y: Yes** (the study type is the same as the study type listed in the CTG record)
* **N: No** (the study type is not the same as the study type listed in the CTG record)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date, or
  + 3) the publication did not meet past, relevant criteria on the Decision Tree, or
  + 4) the publication has already met enough criteria on the Decision Tree to be marked as a results publication)

**Same estimated enrollment (*Column AA*)** (*For interventional studies:* Is the study's estimated or total enrollment similar to (i.e., within 20%) that listed in the "Estimated" or "Actual Enrollment" in the "Study Design" section of the CTG record?)

* **Y: Yes** (the study's estimated or total enrollment similar to that listed in the "Estimated" or "Actual Enrollment" in the CTG record)
* **N: No** (the study's estimated or total enrollment is not similar to that listed in the "Estimated" or "Actual Enrollment" in the CTG record)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date, or
  + 3) the publication did not meet past, relevant criteria on the Decision Tree, or
  + 4) the publication has already met enough criteria on the Decision Tree to be marked as a results publication

**Same allocation (*Column AB*)** (*For interventional studies:* Is the study's allocation the same as that listed in the "Allocation" in the "Study Design" section of the CTG record?)

* **Y: Yes** (the study's allocation is the same as that listed in the "Allocation" in the CTG record)
* **N: No** (the study's allocation is not the same as that listed in the "Allocation" in the CTG record)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date, or
  + 3) the publication did not meet past, relevant criteria on the Decision Tree, or
  + 4) the publication has already met enough criteria on the Decision Tree to be marked as a results publication

**Same interventional model (*Column AC*)** (*For interventional studies:* Is the study's interventional model the same as that listed in the "Interventional Model" in the "Study Design" section of the CTG record?)

* **Y: Yes** (the study's interventional model is the same as that in the "Interventional Model" in the CTG record)
* **N: No** (the study's interventional model is not the same as that in the "Interventional Model" in the CTG record)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date, or
  + 3) the publication did not meet past, relevant criteria on the Decision Tree, or
  + 4) the publication has already met enough criteria on the Decision Tree to be marked as a results publication

**Same masking (*Column AD*)** (*For interventional studies:* Is the study's masking the same as that listed in the "Masking" in the "Study Design" section of the CTG record?)

* **Y: Yes** (the study's masking is the same as that listed in the "Masking" in the CTG record)
* **N: No** (the study's masking is not the same as that listed in the "Masking" in the CTG record)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date, or
  + 3) the publication did not meet past, relevant criteria on the Decision Tree, or
  + 4) the publication has already met enough criteria on the Decision Tree to be marked as a results publication)

**Same primary purpose (*Column AE*)** (*For interventional studies:* Is the study's primary purpose the same as that listed in the "Primary Purpose" in the "Study Design" section of the CTG record?)

* **Y: Yes** (the study's primary purpose is the same as that listed in the "Primary Purpose" in the CTG record)
* **N: No** (the study's primary purpose is not the same as that listed in the "Primary Purpose" in the CTG record)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date, or
  + 3) the publication did not meet past, relevant criteria on the Decision Tree, or
  + 4) the publication has already met enough criteria on the Decision Tree to be marked as a results publication)

**Same estimated enrollment (*Column AF*)** (*For observational studies:* Is the study's estimated or total enrollment similar to (i.e., within 20%) that listed in the "Estimated Enrollment" or "Actual Enrollment" in the "Study Design" section of the CTG record?)

* **Y: Yes** (the study's estimated or total enrollment is similar to that listed in the "Estimated Enrollment" or "Actual Enrollment" in the CTG record)
* **N: No** (the study's estimated or total enrollment is not similar to that listed in the "Estimated Enrollment" or "Actual Enrollment" in the CTG record)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date, or
  + 3) the publication did not meet past, relevant criteria on the Decision Tree, or
  + 4) the publication has already met enough criteria on the Decision Tree to be marked as a results publication)

**Same observational model (*Column AG*)** (*For observational studies:* Is the study's observational model the same as that listed in the "Observational Model" in the "Study Design" section of the CTG record?)

* **Y: Yes** (the study's observational model is the same as that listed in the "Observational Model" in the CTG record)
* **N: No** (the study's observational model is not the same as that listed in the "Observational Model" in the CTG record)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date, or
  + 3) the publication did not meet past, relevant criteria on the Decision Tree, or
  + 4) the publication has already met enough criteria on the Decision Tree to be marked as a results publication)

**Same time perspective (*Column AH*)** (*For observational studies:* Is the study's time perspective the same as that listed in the "Time Perspective" in the "Study Design" section of the CTG record?)

* **Y: Yes** (the study's time perspective is the same as that listed in the "Time Perspective" in the CTG record)
* **N: No** (the study's time perspective is not the same as that listed in the "Time Perspective" in the CTG record)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date, or
  + 3) the publication did not meet past, relevant criteria on the Decision Tree, or
  + 4) the publication has already met enough criteria on the Decision Tree to be marked as a results publication)

**Same intervention/exposure (*Column AI*)** (Is the study's intervention or exposure the same as that listed in the CTG record?)

* **Y: Yes** (the study's intervention or exposure is the same as that listed in the CTG record)
* **N: No** (the study's intervention or exposure is not the same as that listed in the CTG record)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date, or
  + 3) the publication did not meet past, relevant criteria on the Decision Tree, or
  + 4) the publication has already met enough criteria on the Decision Tree to be marked as a results publication)

**Same primary outcome (*Column AJ*)** (Is the study's primary outcome the same as that listed in the "Primary Outcome Measures" in the "Outcome Measures" section of the CTG record?)

* **Y: Yes** (the study's primary outcome is the same as that listed in the "Primary Outcome Measures" in the CTG record)
* **N: No** (the study's primary outcome is not the same as that listed in the "Primary Outcome Measures" in the CTG record)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date, or
  + 3) the publication did not meet past, relevant criteria on the Decision Tree, or
  + 4) the publication has already met enough criteria on the Decision Tree to be marked as a results publication)

**Decision (*Column AK*)** (Based on the above, relevant data, is the publication a results publication for the CTG record?)

* **Y: Yes** (the publication is a results publication for the CTG record)
* **N: No** (the publication is not a results publication for the CTG record)
* **I: Irrelevant** (either:
  + 1) no link to a publication record was listed in the "More Information" section of the CTG record and no publication record was found using the [si] nor [tw] search, or
  + 2) the publication was published before the CTG record's listed start date)

**Notes (*Column AL*)** (Notes on the results verification data collected for the publication)

* **[Textual Entries]**