12 Publication tables, worksheets, and checklists

Table 12.1 Content suggestions for results study publication (PubCont.Tab)

1. Title section
- Descriptive title
- List of author-selected key words indicating general content of paper (useful for readers and as aids to NLM indexers)
- Author(s)
- Source(s) of financial support for the study
- Acknowledgements
- Credit roster
- Address of corresponding author

2. Abstract section
- Purpose of study
- Primary outcome measure
- Test treatment(s)
- Control treatment(s)
- Level of treatment masking
- Number of patients enrolled
- Method of treatment assignment
- Conclusion(s)
- Registration number and site

3. Introduction section
- Historical background of trial
- Rationale for the trial
- Objective(s)
- Rationale for choice of test and control treatment(s)
- Literature review

4. Methods section
- Study population
  - Eligibility and exclusion criteria
  - Method of patient recruitment
- Treatments
  - Study treatments
  - Method of treatment administration
  - Level of treatment masking
  - Treatment proscriptions
  - Methods of measuring treatment adherence
- Outcome measures
  - Primary and secondary outcome measures
  - Diagnostic criteria for outcome measurements
  - Methods for coding and classifying outcomes
- Design specifications
  - Method of randomization
  - Description of safeguards used to ensure integrity of the assignment process
  - List of stratification variables
  - Blocking specifications
  - Description of procedures for packaging and dispensing study medications in the case of masked drug trials
  - Primary outcome measure and rationale for choice
  - Planned length of patient followup and rationale for specification
  - Planned recruitment goal
  - Type I and II error protection levels for planned recruitment goal
- Patient safeguards
  - Outline of steps for obtaining patient consent
  - Method of updating consent
  - Measures taken to protect patient confidentiality
  - Description of procedures used to monitor study results for evidence of treatment effects
- Data collection schedule
  - Sequence of baseline and followup visits
  - List of data items collected
  - Definition of missed visits and dropouts
  - Name of person or agency to contact for copies of data forms, study manuals, etc.
- Data processing
  - Cut-off date for data included in manuscript
  - Description of approach and supporting rationale for dealing with missing data and departures from the treatment protocol (statement especially important if analysis

Table 12.1 Content suggestions for results study publication

method departs from preferred approach)
- Literature references for methods used
- Description of any special analysis procedures not already described in existing literature
- Methods for judging statistical importance of differences observed (e.g., nominal and adjusted *p*-values; confidence intervals)

• Quality control procedures
- General data editing
- Quality control of laboratory tests and for special reading and coding procedures
- Checks on data entry, programming, and analysis
- Other quality controls, such as site visits to clinics, training and certification, etc.

• Performance monitoring
- Measures used for assessing performance of participating clinics and resource centers
- Frequency of performance assessments
- Methods used for reviewing performance monitoring reports and for implementing corrective action based on those reviews

• Treatment monitoring
- Frequency of interim analyses for treatment monitoring
- Methods used to carry out interim analyses
- Individual or group responsible for carrying out interim analyses
- Procedures for implementing protocol changes based on results from interim analyses
- Masking

• Organizational structure
- Number and location of participating centers
- Location of data center
- Location of other resource centers
- Standing committees and their membership
- Mode of funding (e.g., grant or contract, individual or consortium award)
- Policy on investigator conflicts of interest and method used to monitor for potential conflicts of interest

• Other items
- Notation and language conventions in manuscript
- Listing of special actions taken during the trial including:
  · Addition or deletion of treatments
  · Addition or separation of study clinics
  · Data purges because of questions concerning data reliability or accuracy
  · Major modifications of data collection forms or coding procedures during the course of the trial

5. Results section

• Number of patients enrolled by treatment group
• Number of deaths by treatment group
• Comparison of treatment groups for primary and secondary outcome measures using various analytic techniques, including simple comparisons of proportions, as well as lifetable methods, etc.
• Indicators of the completeness of followup by treatment group, such as:
- Number of missed examinations
- Number of dropouts
- Number of patients lost to followup

• Indicators of treatment adherence, such as:
- Comparison of treatment groups using an adherence score or some laboratory measure
- Count of number of patients in each treatment group not receiving any of the assigned treatment

Table 12.1 Content suggestions for results study publication

  - Count of number of patients in each treatment group receiving alternative treatments
- Assessment of the comparability of the treatment groups with regard to important baseline characteristics
- Treatment group comparisons for differences in:
  - Occurrence of serious side effects
  - Rate of hospitalization
  - Other general health indicators
- Treatment comparisons by selected baseline characteristics
- Multiple regression analyses using baseline characteristics to provide adjusted treatment comparisons
- Treatment comparisons by level of adherence
- Treatment comparisons by clinic in multicenter trials
- Other special analyses relating to followup data for a variable (e.g., cholesterol level) to a primary or secondary outcome measure (e.g., death)

6. Discussion section

- Discussion of how reported findings relate to previous studies, paying particular attention to those considered to be new and those that are not consistent with findings of previous studies
- Discussion of the implications of the findings
- Enumeration of questions or areas needing further analysis or research

7. Conclusion section

- Statement of conclusion
- Limits on generalization of the conclusions, including discussion of observed statistical power if no treatment difference is detected

8. Reference section

- List of literature references in required journal format
- Suitable reference citations for:
  - References to previous work
  - Data analysis methods
  - Laboratory methods
  - Coding or reading procedures for abstracting information from special records or documents
  - Treatment methods
  - Study rationale
  - Discussion of results
- List of study documents that may be obtained on request or via study website, such as study manual of operations, study data forms, data listings, data files, etc.

9. Appendix section*

- Description of special procedures needed to understand results, but too detailed to be included in the body of the publication
- List of definitions, codes, diagnostic criteria, etc.
- Special analyses, tabulations, and data listings
- Sample data forms

*Not required if previous publications contain essential details or if authors have provided some other means of supplying them (e.g., by depositing documents containing details in a public repository or by supplying them upon written request) or via study website.

WS 12.1 Paper production worksheet (PaperMon.WS)

When: As soon as paper writing starts

Who: A person in the office of the chair or in the coordinating center

Purpose: To provide data for study leaders in monitoring paper production

Definitions

ancillary publication - A publication bearing on an ancillary aim of a research project; in the case of trials, usually publications from ancillary studies.

primary publication - A publication from a study considered essential in relation to the primary purpose or objective of a research project; in the case of trials, includes publications of primary results and publication on the design, methods, and baseline results of the trial; aka: mainline paper

secondary publication - A study publication related to a secondary study objective; in the case of trials, usually publications devoted exclusively to results for a secondary outcome measure or publications providing added information bearing on a primary result.

A. Identifying information

1. Study name: _____

2. Form completed by: _____

3. Date completed (day-month-year) . . . . . __—___—____

B. Publications

4. Published papers including "in press"?
   ( ) None; skip to next section
   ( ) One or more
   Number . . . . . ____

5. Breakdown of publications represented by total number in item 4 by type
   Primary . . . . . Number ____
   Secondary . . . . . Number ____
   Ancillary . . . . . Number ____
   Total . . . . . Number ____

6. Breakdown of publications represented by total number represented in item 4 by place of publication

   Indexed medical journal . . . . . Number ____

   Book/book chapter . . . . . Number ____

   Other . . . . . Number ____

   Total . . . . . Number ____

7. For papers published (item 4)

   Time from commissioning to publication (if total number in item 4 ≥ 2 give median time) . . . . . _____ wks

   Range of times if total number in item 4 ≥ 2 . . . . . _____ wks _____ wks

8. Publications (including "in press") in last 12 months?
   ( ) None; skip to next section
   ( ) One or more
   Number . . . . . ____

9. For papers published in last 12 months

   Time from commissioning to publication (if number in item 8 ≥ 2 give median time) . . . . . _____ wks

   Time range if number in item 8 ≥ 2 . . . . . _____ wks _____ wks

C. Commissioning/de-commissioning process

10. Does the study have a process for commissioning papers for development?
    ( ) No
    ( ) Yes

11. Who is the commissioning authority (check one)
    ( ) Study chair/PI
    ( ) Study officers
    ( ) Executive committee
    ( ) Steering committee
    ( ) Sponsor
    ( ) Other (specify)

    _____

12. Is the commission for manuscripts time limited?
    ( ) No
    ( ) Yes

    Period of commission . . . . . _____ wks

13. Is there a process for de-commissioning manuscripts?
    ( ) No
    ( ) Yes
    If "yes"
    Does the de-commission involve a formal written notice to manuscript chair?
    ( ) No
    ( ) Yes
    If "yes" does the notice indicate that the manuscript may be reassigned within the study investigatorship for production?
    ( ) No
    ( ) Yes

WS 12.2 Authorship policy worksheet (Author.WS)

When: Early in the course of the trial, well before any paper writing activities

Who: A principal study leader or study officer

Purpose: To lay out policy for authorship attribution on study papers prior to initiation of paper writing activities

Paper types

Ancillary paper: A publication related to an ancillary aim of a research project; in the case of trials, usually publications from ancillary studies.

Primary paper: A publication considered essential in relation to the primary objective of the study; in the case of trials, includes publications of primary results and publications on the design, methods, and baseline results of the trial.

Secondary paper: A paper dealing with a secondary objective of the study

Authorship formats

corporate

corporate author citation: A form of citation with authorship attributed exclusively to a corporate entity; a citation absent the means of identifying the person or persons responsible for authoring the work and a masthead author listing involving only a corporate name (e.g., in a multicenter trial: The XYZ Research Group).

modified corporate author citation: A form of corporate author citation in which names of persons responsible for authoring a work appear in a footnote to the title page or in the credits or acknowledgments section of the work.

conventional

conventional author citation: A form of author citation with authorship attributed exclusively to named persons; an author masthead listing not containing a corporate name.

modified conventional author citation: A form of conventional author citation in which, in addition to named persons, the name of the corporate entity under which the work was done is listed in the masthead listing (e.g., Nancy Jones and Harry Brown for the XYZ Research Group).

Reminders and comments

- Assume that everyone in a research group is concerned about authorship
- When discussing authorship policy among investigators do not assume absence of comment means agreement
- Do not propose and vote on an authorship policy in the same deliberative session
- Policy should be discussed at least twice, separated in time by > 30 days before voting
- Vote by closed ballot
- Review policy at periodic intervals over the trial and modify as necessary

WS 12.2 Authorship policy worksheet

A. Identifying information

1. Study name: _____

2. Form completed by: _____

3. Date completed (day-month-year) . . . . . __—___—_____

B. Paper writing plans

4. Likely start of paper writing activities
   - ( ) During enrollment
   - ( ) End of enrollment, during followup
   - ( ) After end of trial

5. Papers planned (check all that apply)
   - ( ) Baseline results
   - ( ) Design and methods
   - ( ) Design and methods and baseline results
   - ( ) Primary results
   - ( ) Secondary results
   - ( ) Ancillary results
   - ( ) Other (specify)

_____

C. Authorship

6. Primary papers (check one)
   - ( ) Corporate
   - ( ) Modified corporate
   - ( ) Conventional
   - ( ) Modified conventional
   - ( ) Other (specify)

_____

7. Secondary papers (check one)
   - ( ) Corporate
   - ( ) Modified corporate
   - ( ) Conventional
   - ( ) Modified conventional
   - ( ) Other (specify)

_____

8. Ancillary papers (check one)
   ( ) Corporate
   ( ) Modified corporate
   ( ) Conventional
   ( ) Modified conventional
   ( ) Other (specify)

   _____

9. If "modified corporate" checked in any item above indicate policy for where writing committee is listed:
   ( ) Title page
   ( ) Credits section of manuscript
   ( ) Other (specify)

   _____

10. If "modified conventional" checked in any item above indicate whether the attribution to the study research group will be:
    ( ) "for" (e.g., R Jones, B Simth, and A Anderson **for** the XYZ Research Group)
    ( ) "and" (e.g., R Jones, B Simth, and A Anderson **and** the XYZ Research Group)
    ( ) "on behalf of" (e.g., R Jones, B Simth, and A Anderson **on behalf of** the XYZ Research Group)

11. Indicate how authors are chosen for study publications

    Primary papers
    ( ) Study chair/PI
    ( ) Study officers/executive committee
    ( ) Self-selection/volunteers
    ( ) Other (specify)

    _____

    Secondary papers
    ( ) Study chair/PI
    ( ) Study officers/executive committee
    ( ) Self-selection/volunteers
    ( ) Other (specify)

    _____

    Ancillary papers
    ( ) Study chair/PI
    ( ) Study officers/executive committee
    ( ) Self-selection/volunteers

( ) Other (specify)

_____

12. For papers with authors listed in publications, indicate policy on order of listing:

Primary papers

( ) Alphabetic
( ) 1st author then alphabetic order
( ) As ordered by study officers
( ) As specified by senior author
( ) By order of contribution to writing effort
( ) By order of contribution to study
( ) Other (specify)

_____

Secondary papers

( ) Alphabetic
( ) 1st author then others in alphabetic order
( ) As ordered by study officers
( ) As determined by senior author
( ) By order of contribution to writing effort
( ) By order of contribution to study
( ) Other (specify)

_____

Ancillary papers

( ) As determined by senior author
( ) By order of contribution to writing effort
( ) By order of contribution to the ancillary study
( ) Other (specify)

_____

13. Bounds on numbers of persons listed as authors?

Primary papers

( ) No limit
( ) Limit . . . . . Lower ___ Upper ___

Secondary papers

( ) No limit
( ) Limit . . . . . Lower ___ Upper ___

Ancillary papers

( ) No limit

( ) Limit . . . . . Lower ___ Upper ___

D. Review and acceptance procedure

14. Name of study reviewing and accepting body of authorship rules
    ( ) Steering committee
    ( ) Executive committee
    ( ) Study officers
    ( ) Other (specify)

    _____

15. Date of 1st review . . . . . __—___—_____

16. Date of 2nd review . . . . . __—___—_____

17. Date of official acceptance . . . . . __—___—_____

WS 12.3 Paper proposal worksheet (Proposal.WS)

When: Mid course in the trial when plans for paper writing start to jell

Who: Study leaders

Purpose: To provide plans for monitoring the production of papers

Definitions

ancillary publication - A publication bearing on an ancillary aim of a research project; in the case of trials, usually publications from ancillary studies.

commissioned manuscript - A manuscript commissioned by study leaders

investigator-proposed manuscript - A manuscript proposed by a study investigator

primary publication - A publication from a study considered essential in relation to the primary purpose or objective of a research project; in the case of trials, includes publications of primary results and publication on the design, methods, and baseline results of the trial; aka: mainline paper

secondary publication - A study publication related to a secondary study objective; in the case of trials, usually publications devoted exclusively to results for a secondary outcome measure or publications providing added information bearing on a primary result.

A. Identifying information

1. Study name: _____

2. Form completed by: _____

3. Date completed (day-month-year) . . . . . __-___-____

B. The proposal

4. Initiative (check one)
   - ( ) Commissioned by study leaders
   - ( ) Investigator-initiated
   - ( ) Sponsor-initiated
   - ( ) Other (specify)

     _____

5. Type of manuscript (check one)
   - ( ) Primary treatment results
   - ( ) Secondary treatment results
   - ( ) Safety results

( ) Design, methods, and baseline results
( ) Natural history
( ) Ancillary study
( ) Other (specify)

_____

6. Tentative title

_____

7. Target journals

1 _____

2 _____

8. Proposed authorship format; see *Authorship policy worksheet* (WS 12.2) for definitions (check one)
( ) Conventional
( ) Modified conventional
( ) Corporate
( ) Modified corporate
( ) Other (specify)

_____

9. Summary of purpose of paper

_____

_____

_____

10. Data required from coordinating center?
( ) No
( ) Yes (specify types and amounts of data required)

_____

_____

11. Analytical and statistical help required from the coordinating center?
( ) No
( ) Yes

12. Approximate time from commission to first submission of manuscript for publication?
    ( ) 3 months
    ( ) 6 months
    ( ) 9 months
    ( ) Other (specify)

    _____

C. Commissioning and approval

13. Commissioning and approving authority (check one)
    ( ) Study chair/PI
    ( ) Study officers
    ( ) Executive committee
    ( ) Steering committee
    ( ) Other (specify)

    _____

14. Lead author/chair of writing committee

    _____

15. Other authors/members of the writing committee

	Name	Center	Discipline
1			
2			
3			
4			
5			
6			

16. Date of approval or of commissioning . . . . . ___—___—_____

17. Conditions of approval imposed by approving body listed in item 13 (check all that apply)
    ( ) Review and approval of manuscript prior to submission for publication
    ( ) Inclusion of study credit list in finished manuscript
    ( ) Listing of funding source in manuscript

( ) Other (specify)

_____

WS 12.4 Study CV worksheet (CV.WS)

When: Early in the course of the trial

Who: A person designated by the study leadership

Purpose: To maintain a record of study history and accomplishments

Definition

study curriculum vitae - A document similar to that for a person but with the study being the subject of the vitae; giving particulars of the study including history, purpose, design, funding, mode of initiation, centers and related personnel, presentations, and publications, see https://jhuccs1.us/adapt/ for example.

Reminders and recommendations

- Assume need for study CV and proceed accordingly
- The time to produce a log of study activities is when the activities occur
- Study CVs have various uses including those related to renewal of funding and for details required when producing papers or presentations

A. Identifying information

1. Study name: _____

2. Completed by: _____

3. Date completed (day-month-year) . . . . . __-___-____

B. Content checklist

4. Information to be included in CV (check all that apply)
   - ( ) Funding history
   - ( ) Statement of study objectives
   - ( ) Study log/chronology of events
   - ( ) Design summary
   - ( ) Participating centers (past and present)
   - ( ) Committees (past and present)
   - ( ) Enrollment history
   - ( ) Publications
   - ( ) Presentations
   - ( ) Ancillary studies
   - ( ) Glossary of study abbreviations
   - ( ) Other (specify)

_____

C. Maintenance

5. CV custodian: _____

6. CV update frequency
   ( ) As needed
   ( ) At specified time intervals (specify time)

   _____

D. Availability and access

( ) Password-protected website
( ) Open access website
( ) Other (specify)

_____

E. Sign-off approval

7. Name of review and approving body: _____

8. Date of sign-off: . . . . . __—__—____

CL 12.1 Content checklist for results papers (Paper.CL)

A. Identifying information

1. Study name: _____

2. Title of paper

   _____

3. Form completed by: _____

4. Date completed (day-month-year) . . . . . __ __—__ __ __—__ __ __ __

B. Title page checklist

5. Title ≤ 10 words
   ( ) Yes
   ( ) No (shorten)

6. Title form
   ( ) Neutral
   ( ) Declarative

7. Design and methods descriptive terms in title (check all that apply)
   ( ) Trial
   ( ) Randomized
   ( ) Controlled
   ( ) Placebo-controlled
   ( ) Mask/blind
   ( ) Other (specify)

   _____

8. Population descriptors
   ( ) No
   ( ) Yes
   Check all that apply
   ( ) Adults
   ( ) Adolescents
   ( ) Children
   ( ) Infants
   ( ) Elderly
   ( ) Males
   ( ) Females
   ( ) Pregnant females
   ( ) Other (specify)

   _____

9. Disease/treatment descriptors
   ( ) No
   ( ) Yes (list)

   _____

10. Author-selected key words
    ( ) No
    ( ) Yes (list)

    _____

11. Masthead author listing
    ( ) Conventional
    ( ) Modified conventional
        ( ) **and** the XYZ Research Group
        ( ) **for** the XYZ Research Group
        ( ) **on behalf of** the XYZ Research Group
    ( ) Corporate
    ( ) Modified corporate
        ( ) Writing committee listed as footnote to title page
        ( ) Writing committee listed in credits section of manuscript

12. Order of authors in conventional formats
    ( ) Alphabetic
    ( ) Reverse alphabetic
    ( ) Modified alphabetic (1st author followed by others in alphabetic order)
    ( ) Modified reverse alphabetic (1st author followed by others in reverse alphabetic order)
    ( ) As determined by 1st author
    ( ) As determined by commissioning body
    ( ) Other (specify)

    _____

13. Name and address of corresponding author provided?
    ( ) Yes
    ( ) No (provide)

C. Abstract section

14. Structured?
    ( ) Yes
    ( ) No (required in most journals)

15. Content of abstract (check all that apply)
    ( ) Purpose of trial

( ) Primary outcome measure
( ) Test treatment(s)
( ) Control treatment(s)
( ) Level of treatment masking
( ) Number of persons enrolled
( ) Method of treatment assignment
( ) Conclusion(s)
( ) Registration number and registration site

D. Introduction section

16. Rationale for publication of results
    ( ) End of trial
    ( ) Treatment stopped because of harm
    ( ) Treatment stopped because of benefit
    ( ) Other (specify)

    _____

17. Rationale for publication stated in paper?
    ( ) Yes
    ( ) No (revise to state)

18. Content (check all that apply)
    ( ) Historical background of trial
    ( ) Rationale for trial
    ( ) Objective(s) of trial
    ( ) Rationale for choice of test and control treatment(s)
    ( ) Literature review
    ( ) Other (specify)

    _____

E. Methods section

19. Study population and enrollment
    ( ) Eligibility and exclusion criteria
    ( ) Method of patient recruitment
    ( ) Enrollment start and end date
    ( ) Consent process
    ( ) Other (specify)

    _____

20. Study treatments
    ( ) Test treatments
    ( ) Control/comparison treatment
    ( ) Treatment dosage

( ) Method of treatment administration
( ) Level of treatment masking
( ) Treatment contraindications and proscriptions
( ) Other (specify)

_____

21. Outcome measure focused upon in paper (specify)

_____

22. Design specifications (check all that apply)
    ( ) Method of randomization
    ( ) Description of safeguards to ensure the integrity of the assignment process
    ( ) List of stratification variables
    ( ) Blocking specifications
    ( ) Description of procedures for packaging and dispensing study medications (in masked drug trials)
    ( ) Primary outcome measure and rationale for choice
    ( ) Planned length of patient followup and rationale
    ( ) Planned recruitment goal
    ( ) Type I and II error protection levels for planned recruitment goal
    ( ) Other (specify)

_____

23. Patient safeguards
    ( ) Outline of steps for obtaining consent
    ( ) Method of updating consent (especially for long-term followup trials)
    ( ) Measures taken to protect patient confidentiality
    ( ) Description of procedures used to monitor study results for evidence of treatment effects
    ( ) Other (specify)

_____

24. Data collection schedule
    ( ) Sequence of baseline and followup visits
    ( ) Definition of missed visits and dropouts
    ( ) Other (specify)

_____

25. Data processing
    ( ) Cut-off date for data included in manuscript

( ) Description of approach and supporting rationale for dealing with missing data and departures from the treatment protocol
( ) Literature references for analysis methods
( ) Description of any special analysis procedures not already described in existing literature
( ) Methods for judging statistical importance of differences observed (e.g., nominal and adjusted *p*-values; confidence intervals)
( ) Other (specify)

_____

26. Quality control procedures
( ) General data editing
( ) Quality control of laboratory tests and for special reading and coding procedures
( ) Checks on data entry, programming, and analysis
( ) Other quality controls, such as site visits to clinics, training and certification, etc.
( ) Other (specify)

_____

27. Treatment effects monitoring
( ) Frequency of interim analyses for treatment monitoring
( ) Group responsible for monitoring
( ) Methods used to carry out interim analyses
( ) Procedures for implementing protocol changes based on results from interim analyses
( ) Masking
( ) Other (specify)

_____

28. Organizational structure
( ) Number and location of participating centers
( ) Location of data center
( ) Location of other resource centers
( ) Mode of funding (e.g., grant or contract; individual or consortium award)
( ) Other (specify)

_____

29. Other items
( ) Notation and language conventions in manuscript
( ) Addition or deletion of a treatment
( ) Addition or separation of study clinics
( ) Data purges because of questions concerning data reliability or accuracy
( ) Major modifications of data collection forms or coding procedures during the course of the trial

( ) Other (specify)

_____

F. Results section

30. Enrollment and followup
    - ( ) Number of persons enrolled by treatment group
    - ( ) Number of ineligible persons enrolled by treatment group
    - ( ) Assessment of the comparability of the treatment groups with regard to important baseline characteristics
    - ( ) Number of deaths by treatment group
    - ( ) Visit completion rate by treatment group
    - ( ) Numbers of dropouts and person lost to followup by treatment group
    - ( ) Count of persons by treatment group not receiving the assigned treatment
    - ( ) Count of persons receiving an alternative treatment by treatment group
    - ( ) Person years of followup by treatment group
    - ( ) Other (specify)

_____

31. Treatment comparisons
    - ( ) Comparison of treatment groups for primary and secondary outcome measures using various analytic techniques, including simple comparisons of proportions, as well as lifetable methods, etc.
    - ( ) Treatment group comparisons for differences in occurrence of serious side effects, rate of hospitalization, and other general health indicators
    - ( ) Treatment comparisons by selected baseline characteristics
    - ( ) Multiple regression analyses using baseline characteristics to provide adjusted treatment comparisons
    - ( ) Treatment comparisons by clinic (multicenter trials)
    - ( ) Other (specify)

_____

32. Subgroup analyses
    - ( ) By disease state
    - ( ) By age
    - ( ) By gender
    - ( ) By ethnic origin
    - ( ) Other (specify)

_____

33. Tables and figures
    - ( ) Adequately titled?
    - ( ) Column labels for treatment groups consistent across tables?

( ) Totals consistent across tables and figures?
( ) Values in tables decimal aligned?
( ) Other (specify)

_____

G. Discussion and conclusion sections

34. Discussion (check all that apply)
    ( ) Discussion of how reported findings relate to previous studies, paying particular attention to those considered to be new and those that are not consistent with findings of previous studies
    ( ) Discussion of the implications of the findings
    ( ) Enumeration of questions or areas needing further analysis or research
    ( ) Other (specify)

    _____

35. Conclusion (check all that apply)
    ( ) Succinct statement of conclusion
    ( ) Limits on generalization of the conclusions
    ( ) Discussion of observed statistical power if no treatment difference is detected
    ( ) Other (specify)

    _____

H. Referencing and supporting documentation

36. Unconnected references?
    ( ) No
    ( ) Yes (delete references not cited or fix the problem by citing the reference in text)

37. References in order of citation?
    ( ) Yes
    ( ) No (rearrange so in order of citation)

38. Reference format as per journal instruction?
    ( ) Yes
    ( ) No (revise)

39. Referencing for (check all that apply)
    ( ) Previous work
    ( ) Data analysis methods
    ( ) Laboratory methods
    ( ) Coding or reading procedures for abstracting information from special records or documents
    ( ) Treatment methods

( ) Other (specify)

_____

40. Supporting documents available on study website or on request (check all that apply)
    - ( ) Study protocol
    - ( ) Study handbook/manual of operations
    - ( ) Study data forms
    - ( ) Data listing
    - ( ) Analysis dataset
    - ( ) Study website address
    - ( ) Description of special procedures needed to understand results, but too detailed to be included in the body of the publication
    - ( ) Special analyses and tabulations
    - ( ) Other (specify)

_____

I. Credit roster and acknowledgments

41. Study credit roster? (see Form WS 6.3)
    - ( ) Full study credit roster
    - ( ) Partial study credit roster
    - ( ) No study credit roster

42. Acknowledgments and disclosures (check all that apply)
    - ( ) Funding sources
    - ( ) Supplier of study drugs
    - ( ) Grant/contract numbers
    - ( ) Conflict of interest disclosures
    - ( ) Other (specify)

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