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Guidelines for Manuscript Preparation and Submission: Clinical Trials Study

Core tip: These *Clinical Trials Study* articles are submitted by any author and describe a pre-planned study of the safety, efficacy, or optimum dosage schedule (if appropriate) of one or more diagnostic, therapeutic or prophylactic technique(s), device(s) or drug(s) selected according to predetermined criteria of eligibility and observed for predefined evidence of favorable and/or unfavorable effects.

You can use the following checklist to help you fulfill the requirements for manuscript submission.

1 FIRST SECTION OF WRITING REQUIREMENTS YES or NO

- 1.1 Title []
- 1.2 Authorship []
- 1.3 Institution []
- 1.4 ORCID number []
- 1.5 Supportive foundations []
- 1.6 CONSORT 2010 Statement []
- 1.7 Corresponding author []
- 1.8 Abstract []
- 1.9 Key words []



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1.10 Core tip []

2 SECOND SECTION OF WRITING REQUIREMENTS YES or NO

2.1 Main text []

2.2 Biostatistics []

2.3 Units []

2.4 Illustrations []

2.5 Tables []

2.6 Notes in illustrations and tables []

2.7 Abbreviations []

2.8 Italics []

2.9 Acknowledgments []

2.10 References []

3 ETHICS POLICIES/STATEMENTS YES or NO

3.1 Institutional review board []

3.2 Clinical trial registration []

3.3 Informed consent []

3.4 Conflict-of-interest []

4 LANGUAGE EDITING FOR MANUSCRIPTS SUBMITTED BY NON-NATIVE SPEAKERS OF ENGLISH YES or NO

5 COPYRIGHT LICENSE AGREEMENT YES or NO

6 STEPS FOR SUBMITTING MANUSCRIPTS YES or NO



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1 FIRST SECTION OF WRITING REQUIREMENTS

All contributions should be written in English; the authors may use either UK or US English language, but the chosen English language usage must be consistent throughout the document. All articles must be prepared with Word-processing Software, using 12 pt Book Antiqua font and 1.5 line spacing with ample margins. Required information for each of the manuscript sections is as follows:

1.1 Title. The title should be no more than 12 words. The title should summarize the core content of the manuscript, so that the reader may readily understand the key concepts and important findings presented within. This type of succinct and impactful statement will serve to catch readers' attention and stimulate their interest in reading the abstract and/or downloading the full paper. It is also strongly recommended that the title include one or two of the key words associated with the manuscript's topical content, to facilitate the paper being readily found by electronic searches of public databases, such as Google or PubMed. Finally, a succinct and impactful title will include minimal nonfunctional words, such as "a," "an," "the," "roles of," *etc.* and will avoid non-standard abbreviations.

1.2 Authorship. Authorship credit should be given in accordance with the standard proposed by the International Committee of Medical Journal Editors (ICMJE) (<http://www.icmje.org/>). Specifically, authorship is merited by (1) substantial contributions to conception and design of the study, acquisition of data, or analysis and interpretation of data; (2) drafting the article or making critical revisions related to important intellectual content of the manuscript; and (3) final approval of the version of the article to be published. Authors should meet conditions 1, 2 and 3. Designation of co-first authors and co-corresponding authors is not permitted. Author names



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(unabbreviated) should be given as first name, middle name (acronym, with no period), and family (sur)name, and typed in bold with the first letter capitalized; a hyphen should be included between the syllables of Chinese names. For example, **Jason Lamontagne, Laura F Steel, Paul V Harper Jr, Bo Yuan, and Wei-Hong Tang.**

1.3 Institution. Author names (unabbreviated) should be given first as first name, middle name (acronym, with no period), and family (sur)name, and typed in bold with the first letter capitalized, with a hyphen included between the syllables of Chinese names, followed by the complete name of the affiliated institution, city, province/state, postcode, and country typed in non-bold. For example, **Xu-Chen Zhang, Li-Xin Mei,** Department of Pathology, Chengde Medical College, Chengde 067000, Hebei Province, China. In the case that multiple authors represent a single institution, the authors will be listed together for that institution; for example, **Giuseppe Losurdo, Domenico Piscitelli, Antonio Giangaspero, Mariabeatrice Principi, Francesca Buffelli, Floriana Giorgio, Lucia Montenegro, Claudia Sorrentino, Annacinzia Amoroso, Enzo Ierardi, Alfredo Di Leo,** Gastroenterology Section, Department of Emergency and Organ Transplantation, University of Bari, 70124 Bari, Italy. In the case that one author represents multiple institutions, the institutions will be listed separately; for example, **Jun Wen,** Department of Liver Surgery and Liver Transplantation Center, West China Hospital, Sichuan University, Chengdu 610041, Sichuan Province, China
Jun Wen, Department of General Surgery, The Third People's Hospital of Chengdu, Chengdu 610031, Sichuan Province, China

1.4 ORCID number. ORCID provides a persistent digital identifier that distinguishes you from every other researcher and, through integration in key research workflows such as manuscript and grant submissions, supports automated linkages between you



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and your professional activities, thereby ensuring that your work is recognized. Please visit the ORCID website at <https://orcid.org/> for more information. All authors must provide their personal ORCID registration number. For example, Marcos Pasarín (0000-0002-4122-1235); Juan G Abraldes (0000-0002-4392-660X); Eleonora Liguori (0000-0002-0244-927X); Beverley Kok (0000-0002-1727-5030); Vincenzo La Mura (0000-0003-4685-7184).

1.5 Supportive foundations. The approved grant application form(s) will be released online, together with the manuscript in order for readers to obtain more information about the study and to increase the likelihood of subsequent citation. Our purpose of publishing the approved grant application form(s) is to promote efficient academic communication, accelerate scientific progress in the related field, and improve productive sharing of research ideas.

Supportive foundation acknowledgment: The complete name(s) of supportive foundation(s) and identification number(s) of grants or other financial support will be provided on the title page of all submitted manuscripts using the following format: **Supported by** the National Natural Science Foundation of China, No. 30224801.

1.6 CONSORT 2010 Statement. In order to improve the quality of Clinical Trials study manuscripts, authors should download and complete the 'CONSORT 2010 checklist of information to include when reporting a randomised trial' to ensure that the manuscript meets the requirements of the CONSORT 2010 Statement. Authors must state on the title page of the manuscript that the guidelines of the CONSORT 2010 Statement have been adopted (see below). Authors must upload the PDF version of the completed checklist to the system.



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Sample wording: The authors have read the CONSORT 2010 Statement, and the manuscript was prepared and revised according to the CONSORT 2010 Statement.

1.7 Corresponding author. Only one corresponding author is allowed. Designation of co-corresponding authors is not permitted. The corresponding author's contact information should be provided in the following format: Author names (unabbreviated) should be followed by the author's title in bold, and the affiliation, complete name of institution, present address, city, province/state, postcode, country, and E-mail typed in non-bold. All the letters in the E-mail address should be typed in lowercase, and separated from the country by a period and a space. For example, **Andrzej S Tarnawski, MD, PhD, DSc (Med), Professor of Medicine, Chief, Gastroenterology, VA Long Beach Health Care System, University of California, Irvine, 5901 E Seventh St, Long Beach, CA 90822, United States.** astarnaw@uci.edu

1.8 Abstract. An informative, structured abstract of no less than 350 words should accompany each manuscript. Abbreviations should be avoided, but if used should be spelled out at first mention. The 5 sections of the structured abstract are: Background, Aims, Methods, Results, and Conclusion. Each section should adhere to the word count thresholds (indicated in parentheses) and the content guidelines below:

BACKGROUND (no more than 100 words)

This section should clearly describe the rationale for the study. It should end with a statement of the specific study hypothesis.

AIM (no more than 20 words)

The purpose of the study should be stated clearly, with no or minimal background



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information, following the format of: "To investigate/study/determine..."

METHODS (no less than 80 words)

This section should describe the materials and methods used for all of the data presented in the proceeding Results section of the abstract. This information should include the following details, as applicable: basic study design (*e.g.*, randomized controlled trial, cross sectional study, cohort study, case series, *etc.*); setting, please specify study location (*e.g.*, primary or tertiary care setting, hospital, general community, *etc.*); number of participants and how they were selected; intervention, the method of administration and the duration.

RESULTS (no less than 120 words)

This section should describe the key findings of the study, including absolute values and risk differences. *P* values should be presented where appropriate. You must provide relevant data to illustrate how the statistical values were obtained (*e.g.*, 6.92 ± 3.86 vs 3.61 ± 1.67 , $P < 0.001$).

CONCLUSION (no more than 30 words)

This section should succinctly and cogently present the findings and implications that are within the scope of the data you have presented in the preceding Results section of the abstract. You should state only conclusions that are directly supported by the evidence presented and the implications of the findings presented. This section should be written in the present tense.

1.9 Key words. Please list 5-10 key words for each paper, which reflect the content of the study and are selected mainly from the meSH Tree. Each key word is to be typed with



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the first letter capitalized, and separated by a semicolon, with no period at the end; for example, Colorectal cancer; Epigenetic analysis

1.10 Core tip. Please write a summary of no more than 100 words to present the core content of your manuscript, highlighting the most innovative and important findings and/or arguments. The purpose of the Core Tip is to attract readers' interest for reading the full version of your article and increasing the impact of your article in your field of study.

2 SECOND SECTION OF WRITING REQUIREMENTS

2.1 Main text. The main text contains Introduction, Materials and methods, Results, Discussion, Acknowledgments, and References.

2.2 Biostatistics. Any manuscript describing a study (basic research and clinical research) that used biostatistics must include a statement in the Materials and Methods section affirming that the statistical review of the study was performed by a biomedical statistician. Statistical review is performed before the submission or after peer-review. The author invites an expert in Biomedical Statistics to evaluate the statistical method(s) used in the study, including but not limited to the *t*-test (group or paired comparisons), chi-square test, ridit, probit, logit and regression (linear, curvilinear, or stepwise) modeling, correlation, analysis of variance, and analysis of covariance. The review by the biomedical statistician is conducted with respect to the following points: (1) Statistical methods are adequately and appropriately described when they are used to verify the results; (2) Statistical techniques are suitable or correct, and compliant with the following Baishideng Publishing Group (BPG) directives; (3) Only homogeneous data can be averaged. Standard deviations are preferred to standard errors. The number of



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observations and subjects (n) is given. Losses in observations, such as drop-outs from the study, are reported; (4) Values, such as ED50, LD50, and IC50, have the 95% confidence limits calculated and have been compared by weighted probit modeling (using the functions described by Bliss and Finney); and (5) The word “significantly” is replaced by its synonyms (if it indicates extent) or the P value (if it indicates statistical significance). Statistical data should be expressed as mean \pm SD or mean \pm SE. Common statistical expressions are identified as: t -test as t ; F -test as F ; chi-square test as χ^2 ; relative coefficient as r ; degree of freedom as df ; number of samples as n ; and probability as P .

Sample wording: The statistical methods of this study were reviewed by [name(s) of individual(s)] from [name(s) of organization(s)]...

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2.3 Units. Use SI units. For example: body mass, m (B) = 78 kg; blood pressure, p (B) = 16.2/12.3 kPa; incubation time, t (incubation) = 96 h; blood glucose concentration, c (glucose) = 6.4 ± 2.1 mmol/L; blood CEA mass concentration, p (CEA) = 8.6-24.5 g/L; CO₂ volume fraction, 50 mL/L CO₂, not 5% CO₂; likewise, for 40 g/L formaldehyde, not 10% formalin; and mass fraction, 8 ng/g, *etc.* Arabic numerals such as 23,243,641 (*i.e.*, 23



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It is necessary to keep all elements compiled in a line-art image. Scale bars should be used rather than magnification factors, with the length of the bar defined in the legend text rather than on the bar itself. Figure file names should identify the figure and panel. Avoid layering type directly over shaded or textured areas in the figure. Uniform presentation should be used for figures showing the same or similar contents; for example, “**Figure 1 Pathological changes of atrophic gastritis after treatment.** A: ...; B: ...; C: ...; D: ...; E: ...; F: ...; G: ...”.

2.5 Tables. Tables must be presented in the order that they appear in the main text of the manuscript (numbered as 1, 2, 3, *etc.*). A brief, one-line title must be provided for each table. Detailed legends should not be included under tables, instead having the information presented in the main text where applicable; the information should complement, but not duplicate the text. Use one horizontal line under the title, a second under the column headings, and a third below the last row of the Table (being above any footnotes). Vertical lines and italics should be omitted.

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Tables must be primarily cell-based and fully editable. Do not use the following to organize data or structure the table: (1) Returns (“Enter” key); (2) Tabs; (3) Spaces; (4) Colored text; (5) Cell shading; and (6) Cells within cells. The software used should be Word (preferred) or Excel. BPG does not allow for graphics, boxes or embedded tables to appear in the main body of the manuscript.

2.6 Notes in illustrations and tables. Data with statistical significance in a figure or table should be denoted using superscripted alphabetical lettering, such as ^a*P* < 0.05 and ^b*P* < 0.01. If there are other series of *P* values, the alphabetical subscripted denotation format is continued, such as ^c*P* < 0.05 *vs* control, ^d*P* < 0.01 *vs* control, ^e*P* < 0.05 *vs* group A, and ^f*P* < 0.01 *vs* group B. Data that are not statistically significant should not be denoted, *i.e.*, *P* > 0.05 is not an allowed denotation.

Other notes in tables or under illustrations should be expressed as F¹, F², F³, or sometimes as other superscripted symbols (Arabic numerals). In a multi-curve illustration, each curve should be labeled with ●, ○, ■, □, ▲, △, *etc.*, in a specified sequence.

2.7 Abbreviations. Standard abbreviations should be defined in the abstract and in the main body of the manuscript upon first mention in the text. In general, terms should not be abbreviated unless they are used three times or more and the abbreviation is helpful to the reader. Permissible abbreviations are listed in Units, Symbols and Abbreviations: A Guide for Biological and Medical Editors and Authors (Ed. Baron DN, 1988) published by The Royal Society of Medicine, London. Certain commonly used abbreviations, such



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as DNA, RNA, HIV, LD50, PCR, HBV, ECG, WBC, RBC, CT, ESR, CSF, IgG, ELISA, PBS, ATP, EDTA, and mAb, do not need to be defined and can be used directly.

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2.9 Acknowledgments. Brief acknowledgments of persons who have made genuine contributions to the manuscript and who endorse the data and conclusions should be included. Authors are responsible for obtaining written permission to use any copyrighted text and/or illustrations.

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The author should number the references in Arabic numerals according to the citation order in the text. The reference numbers will be superscripted in square brackets at the end of the sentence with the citation content or after the cited author's name, with no spaces. For example, "Crohn's disease (CD) is associated with increased intestinal permeability^[1,2]." If references are cited directly in the text, they should be included with the direct citation content within the text; for example, "From references^[19,22-24], we know that...". Before submitting your manuscript, please ensure that the order of citations in the text is the same as in the references section, and also ensure the spelling accuracy of the authors' names. Do not list the same citation twice (*i.e.*, with two different numbers).

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Please provide the PMID number, which is the serial number that roots the abstract for that publication into the PubMed index, and the CrossRef DOI® (Digital Object Identifier) name, which is a unique string created to identify a piece of scholarly content in the online environment for each reference in the References section. The PMID number can be found at <http://www.ncbi.nlm.nih.gov/pubmed> and the DOI name at <http://www.crossref.org/SimpleTextQuery/>. The numbers will be used in the electronic (E)-version of the manuscript.

(3) Style for journal references

For authors' names, the name of the first author should be typed in bold letters; the family (sur)name of all authors should be typed with the first letter capitalized, followed by their abbreviated first and middle initials. For example, an article by Lian-Sheng Ma and Bo-Rong Pan will be written as Ma LS and Pan BR. The title of the cited article will be written in sentence case. The journal title will be written in its abbreviated form (as



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(4) *Style for book references*

For the authors' names, the name of the first author should be typed in bold letters. The family (sur)name of all authors should be typed with the initial letter capitalized, followed by their abbreviated middle and first initials. The book title will follow the authors' names and not be italicized. The publication information will follow, written as punctuated here: publication number, publication place: publication press, year: start page-end page.

BPG uses the reference style outlined by the International Committee of Medical Journal Editors (ICMJE), also referred to as the "Vancouver" style. Example formats are listed below. Additional examples are in the [ICMJE sample references](#).

Journal name abbreviations should be those found in the [National Center for Biotechnology Information databases](#).

PRINT JOURNALS

English-language journal articles (list all authors and include the PMID and DOI, where applicable):

1 Ma L, Chua MS, Andrisani O, So S. Epigenetics in hepatocellular carcinoma: An update and future therapy perspectives. *World J Gastroenterol* 2014; 20: 333-345 [PMID: 24574704 PMCID: PMC3923010 DOI: 10.3748/wjg.v20.i2.333]

Chinese-language journal articles (list all authors and include the PMID and DOI, where applicable):

2 Zhang ZM, Deng H, Zhang C, Yu HW, Liu Z, Liu LM, Wan BJ, Zhu MW. Strategies for diagnosis and treatment of benign and malignant colorectal obstruction. *Shijie Huaren*



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Xiaohua Zazhi 2017; 25: 2597-2604 [DOI: 10.11569/wcjd.v25.i29.2597]

In press articles:

3 **Sipos F**, Constantinovits M, Valcz G, Tulassay Z, Múzes G. Association of hepatocyte-derived growth factor receptor/caudal type homeobox 2 co-expression with mucosal regeneration in active ulcerative colitis. *World J Gastroenterol* 2015; In press

Organization as author:

4 **Diabetes Prevention Program Research Group**. Hypertension, insulin, and proinsulin in participants with impaired glucose tolerance. *Hypertension* 2002; **40**: 679-686 [PMID: 12411462]

Both individual authors and an organization as author:

5 **Vallancien G**, Emberton M, Harving N, van Moorselaar RJ; Alf-One Study Group. Sexual dysfunction in 1, 274 European men suffering from lower urinary tract symptoms. *J Urol* 2003; **169**: 2257-2261 [PMID: 12771764]

No author given:

6 21st century heart solution may have a sting in the tail. *BMJ* 2002; **325**: 184 [PMID: 12142303]

Volume with supplement:

7 **Geraud G**, Spierings EL, Keywood C. Tolerability and safety of frovatriptan with short- and long-term use for treatment of migraine and in comparison with sumatriptan. *Headache* 2002; **42** Suppl 2: S93-99 [PMID: 12028325]

Issue with no volume:

8 **Banit DM**, Kaufer H, Hartford JM. Intraoperative frozen section analysis in revision



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total joint arthroplasty. *Clin Orthop Relat Res* 2002; **(401)**: 230-238 [PMID: 12151900]

No volume or issue:

9 Outreach: Bringing HIV-positive individuals into care. *HRSA Careaction* 2002; 1-6 [PMID: 12154804]

BOOKS

Individual author(s):

10 **Sherlock S**, Dooley J. Diseases of the liver and biliary system. 9th ed. Oxford: Blackwell Sci Pub, 1993: 258-296

Chapter in a book (list all authors):

11 **Lam SK**. Academic investigator's perspectives of medical treatment for peptic ulcer. In: Swabb EA, Azabo S. Ulcer disease: investigation and basis for therapy. New York: Marcel Dekker, 1991: 431-450

Author(s) and editor(s):

12 **Breedlove GK**, Schorfheide AM. Adolescent pregnancy. 2nd ed. Wiczorek RR, editor. White Plains (NY): March of Dimes Education Services, 2001: 20-34

CONFERENCE-RELATED ARTICLES

Conference proceedings:

13 **Harnden P**, Joffe JK, Jones WG, editors. Germ cell tumours V. Proceedings of the 5th Germ cell tumours Conference; 2001 Sep 13-15; Leeds, UK. New York: Springer, 2002: 30-56

Conference papers:



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14 **Christensen S, Oppacher F.** An analysis of Koza's computational effort statistic for genetic programming. In: Foster JA, Lutton E, Miller J, Ryan C, Tettamanzi AG, editors. Genetic programming. EuroGP 2002: Proceedings of the 5th European Conference on Genetic Programming; 2002 Apr 3-5; Kinsdale, Ireland. Berlin: Springer, 2002: 182-191

ELECTRONIC JOURNALS

Electronic journals (list all authors):

15 Huynen MMTE, Martens P, Hilderink HBM. The health impacts of globalisation: a conceptual framework. *Global Health*. 2005; 1: 14. Available from: <https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-1-14> doi.org/10.1186/1744-8603-1-14 [PMID: 21501219 DOI: 10.1186/1744-8603-1-14]

PATENTS

Patents (list all authors):

16 **Pagedas AC**, inventor; Ancel Surgical R&D Inc., assignee. Flexible endoscopic grasping and cutting device and positioning tool assembly. United States patent US 20020103498. 2002 Aug 1

CLINICAL TRIAL

17 **Cannon R.** Riloncept to improve artery function in patients with atherosclerosis. [accessed 2015 Apr 25]. In: ClinicalTrials.gov [Internet]. Bethesda (MD): U.S. National Library of Medicine. Available from: <http://clinicaltrials.gov/show/NCT00417417> ClinicalTrials.gov Identifier: NCT00417417

DEPOSITED ARTICLES (preprints, e-prints, or arXiv)

18 **Krick T, Shub DA, Verstraete N, Ferreiro DU, Alonso LG, Shub M, et al.** Amino acid metabolism conflicts with protein diversity; 1991. Preprint. Available from:



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arXiv:1403.3301v1. Cited 17 March 2014.

PUBLISHED MEDIA (print or online newspapers and magazine articles)

19 Fountain H. For Already Vulnerable Penguins, Study Finds Climate Change Is Another Danger. The New York Times. 29 Jan 2014. Available from: <http://www.nytimes.com/2014/01/30/science/earth/climate-change-taking-toll-on-penguins-study-finds.html> Cited 17 March 2014.

NEW MEDIA (blogs, web sites, or other written works)

20 Allen L. Announcing PLOS Blogs. 2010 Sep 1 [cited 17 March 2014]. In: PLOS Blogs [Internet]. San Francisco: PLOS 2006 - . [about 2 screens]. Available from: <http://blogs.plos.org/plos/2010/09/announcing-plos-blogs/>.

MASTERS' THESES OR DOCTORAL DISSERTATIONS

21 Wells A. Exploring the development of the independent, electronic, scholarly journal. M.Sc. Thesis, The University of Sheffield. 1999. Available from: <http://cumincad.scix.net/cgi-bin/works/Show?2e09>

DATABASES AND REPOSITORIES (Figshare or arXiv)

22 Roberts SB. QPX Genome Browser Feature Tracks; 2013 [cited 2013 Oct 5]. Database: figshare [Internet]. Available from: http://figshare.com/articles/QPX_Genome_Browser_Feature_Tracks/701214

MULTIMEDIA (videos, movies, or TV shows)

23 Hitchcock A, producer and director. Rear Window [Film]; 1954. Los Angeles: MGM.



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