Late-Breaking Clinical Trials
Submission Guidelines

American Heart Association | American Stroke Association
life is why

Submission Dates: June 5 - June 28, 2017, 5pm CDT
Submission Fee: $250

Guidelines for Late-Breaking Clinical Trial Presentations
Late-Breaking Clinical Trials sessions are innovative and provide the latest breakthroughs in clinical science. These sessions provide notable exposure and recognition for studies likely to have a significant impact on clinical practice and/or to make significant advances in a scientific field.

Submission: Abstracts submitted via the Late-Breaking submission process are expected to contain **at a minimum the study design**. Information on the characteristics of the patients enrolled is desirable as well. If available, the major trial results should be summarized and will be maintained in a confidential fashion. Each submission must include a $250 online payment. If accepted, the abstract may be modified in the fall for publication, since the trial data presented at Scientific Sessions will be published electronically on the *Circulation* Web site.

Three categories for submission:

- Late-Breaking Randomized Clinical Trial
- Clinical Trial Update
- High Impact Information from Clinical Registries or Cohort Studies

If your trial is submitted in a Clinical Trial Update, there is no guarantee that your trial will be chosen for a Late-Breaking Clinical Trial plenary session. There may be alternate sessions created for this other category. **Please note embargoed media briefings may not be planned for these alternate sessions.**

Abstracts: An abstract with data that, in whole or in part, is contained in a clinical trial submitted during regular abstract submission (April-June) for presentation in the general program cannot be presented in the regular program at Sessions. It must be withdrawn if it is accepted for presentation as a clinical trial. An abstract submitted during the April-June abstract submission for consideration in the general program that includes information other than the primary data from the clinical trial may be considered for presentation in the regular program at Scientific Sessions on a case-by-case basis and only after presentation of the main trial data, unless other scheduling has been agreed to by the Committee on Scientific Session Program (CSSP) and AHA staff. Please notify program.participant@heart.org if another abstract based on the clinical trial was submitted via the regular abstract submission process.

- The abstract with the overall design and major results which you submitted for consideration may be edited online in preparation for publication in *Circulation*. Further information with a link to the site will be sent to you from AHAScientificSessions@abstractsonline.com. The final abstract provided to AHA will be published in *Circulation*.
- If you submitted an abstract with the same focus as this trial/presentation to the general abstract program, then the abstract must be withdrawn from the program if accepted. If you submitted an abstract(s) with separate analysis apart from this trial/presentation, that is acceptable. Please notify Aimee Wilder

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(aimee.wilder@heart.org) if you receive an acceptance notice for an abstract that is of the same focus as the late-breaking presentation.

- Abstract Copyright Transfer Agreement was collected at time of abstract submission. If you selected "Yes", your abstract will be published in the online *Circulation* supplement and Abstracts on USB. If you selected "No", your abstract will be **EXCLUDED** from publication in online *Circulation* supplement and Abstracts on USB.

Presentations: A trial that is accepted to present in a Late-Breaking Plenary or an alternate session, can ONLY have a single individual to present the trial. Multiple presenters will not be **permitted** as the logistics to support place a strain on the time limitations allotted to the session. This will be strictly enforced.

- We understand that there are often multiple investigators involved in a trial. At this time, please note that only **one presenter** from your trial is allowed to present. Please keep in mind that the Meet the Trialists session provides additional opportunities for other presenters of your trial to participate at Sessions. You ***may*** be receiving an additional information about this later in the year.
- You are allowed up to 15 slides that may be used during your presentation. Please do not exceed this number for any reason. These slides must be shared with the assigned Discussants, Moderators and Panelists.
- We request that a manuscript be submitted if it is available. It will be especially helpful for discussants and moderators to prepare for their presentation in addition to the slides. Please be assured that your information will remain completely confidential.

Embargoed Media Briefing: Late-Breaking Clinical Trials will be considered for embargoed media briefings or other news activities, where select principal investigators or their representatives will discuss the results of their studies and answer questions with members of the media. Times may vary slightly.

AHA/ACC/ESC Acceptance/Embargos: Abstracts related to a clinical trial submitted for consideration for presentation at the American Heart Association, American College of Cardiology and European Society of Cardiology cannot be presented at the other two meetings. After acceptance by one of the organizations, that organization's specific embargo guidelines prevail. An embargo means that results from the trial cannot be presented or announced in any forum prior to presentation at the meeting to which it has been accepted. Violators will be banned from participating in the clinical trials for two full cycles or for two of each organization's meetings (AHA, ACC or ESC).

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AHA Embargo Policies:
Clinical trial results are prohibited from release until date and time of AHA designated embargo time. **For clinical trials the embargo time is the date and time of each session's start time in which the trial is scheduled**. Clinical trial sponsors **must** comply with embargo guidelines established by the American Heart Association.

You are prohibited from sharing written embargoed information with anyone outside of the AHA with the exception of journal manuscript submission. **Note Exception**: **Industry announcements required by the SEC (Security Exchange Commission) must be approved by AHA prior to release and any level of information released without to approval will be considered an embargo break.** However, you may conduct one-on-one embargoed media interviews as long as the reporter agrees to abide by the embargo policy. Failure to honor embargo policies will result in the trial being withdrawn on site and barred from presentation. Failure to honor this embargo policy may also jeopardize future acceptance of clinical trials and presentation at Scientific Sessions. Therefore, it is essential to recognize that presentations at unofficial satellite meetings or unofficial press conferences before the scheduled AHA embargoed media briefings (Nov. 11-15) are not allowed. This embargo policy will be strictly enforced.

Investigator Meetings: The only exceptions to the above mentioned embargo policy is closed investigator meetings for participants in the trial. Such investigator dinners or meetings in which trial results will be discussed should be held the evening before their scheduled presentation after 7 p.m. Central Time to avoid unintended public disclosure of trial results. Graphics (slide or print) that contain key trial results should be kept to a minimum and not distributed. Media or other outside parties may **not** be invited to these events.

Simultaneous Journal Publication of Clinical Trials: Simultaneous publication of Clinical Trials is acceptable and encouraged as long as the embargo policies of the AHA and the involved journals are coordinated. If a clinical trial has been submitted to and accepted for publication, the presenter is responsible for insuring that the journal editor respects the AHA publication embargo policy. Publication of a clinical trial either in print or on a journal web site prior to presentation at Sessions will necessitate withdrawal of the trial from the program.