

Late-Breaking Clinical Trials

Submission Dates: June 2 – June 23, 2014

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 \$100 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.**

Clinical Trial submission is from June 2 to June 23, 2014 5pm CDT.

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 It must be withdrawn if it is accepted for presentation as a clinical trial.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.

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.

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).

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. 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. 15-19) are not allowed. This embargo policy will be strictly enforced. **Note Exception: Industry announcements required by the SEC (Security Exchange Commission) are allowed upon approval by AHA and will not be considered an embargo break; however, no trial results or data may be revealed or implied.**

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.