

ACC.21 Late-Breaking Clinical Trial (LBCT) Submission Policies and Procedures

The deadline for LBCT submissions is Tuesday, January 26, 2021, 1:00 p.m. ET. All submission must be entered through our online system.

Notification of all acceptances will be provided in early March. **If your submission is accepted as an LBCT, you are required to immediately withdraw any other type of submission of the same research.** See item #11 below. Failure to do so may result in an embargo break, which could subject LBCT to penalties, including removal from the LBCT program. Send withdrawals to hhopper@acc.org.

General Information

- These sessions provide notable exposure and recognition for studies likely to significantly affect clinical practice. Potential presenters must complete an online application outlining the purpose, design, and methods of the study. Evaluation for presentation in the Late-Breaking Clinical Trial (LBCT) sessions will be based on the impact and novelty of the research; rigor of the design/methods; major clinical endpoints; and the quality of the statistical plan. Priority will be given to trials whose results will be presented for the first time at ACC.21.
- Investigators need not be ACC members to participate.
- There is a \$349 non-refundable processing fee for each late-breaking application submitted payable online by credit card only.
- No reimbursement for travel, hotel or per diem expenses will be given to ACC.21 faculty and presenters. The registration fee is waived for accepted late-breaking presenters; however, a registration form must be completed to obtain a hotel reservation and meeting badge. If you have not already registered, visit <https://accscientificsession.acc.org/en/Registration-and-Hotels>. If you have already registered and paid the registration fee, please request a refund in writing by sending an email to ACC@maritz.com.
- Notification will be sent to the person who submitted the application with final disposition information by the end of January.
- General information subject to change due to circumstances beyond the ACC's control.
- This year three ACC LBCT sessions will be cosponsored with major journals: *Journal of the American College of Cardiology (JACC)*, *Journal of the American Medication Association (JAMA)*, and *New England Journal of Medicine (NEJM)*.
 - All accepted LBCTs are eligible for review by the journals.
 - Each accepted LBCT will be considered for rapid review and online journal publication, at the discretion of the Journal editors, with the release timed to coincide with presentation at ACC.21.

- Acceptance to a journal requires that the trial investigators comply with all procedural deadlines and policies of that journal and agree to submit a completed manuscript at the journal's required deadline if the LBCT is accepted for publication.
- There is no relationship between selection for publication in a particular journal and being selected to present in that journal's cosponsored session.

Policies

1. All submitting authors must file up-to-date disclosures in order to enter the submission system for LBCTs. You must file disclosures for yourself before submitting your research (<http://disclosures.acc.org/>), and all Lead Investigators also must disclose for themselves by February 25.
2. Applications must be **SUBMITTED BY 1:00 P.M. EASTERN TIME ON TUESDAY, JANUARY 26, 2019. The meeting organizers are not responsible for submissions that are not submitted by this deadline date.**
3. Submissions with system status of "incomplete" cannot be processed.
4. Submission of an application constitutes a commitment by the author(s) to present if accepted. Failure to present and register for the meeting, if not justified, will jeopardize future acceptance of applications.
5. There is no limit to the number of applications an investigator may submit. If selected, the presenter must be one of the coauthors listed.
6. Multiple investigators should not submit the same research; applications that appear to be replicate versions of a single study will be rejected.
7. Follow all instructions for completing the submission. Be sure to structure the content into Background, Methods, Results, and Conclusion (if known) sections. Please keep in mind that for LBCTs, final results may not be known at the time of submission.

You will be able to select from five types of submissions:

- LBCT: Major study
 - Multicenter observational study or registry
 - Secondary analysis of major clinical trial
 - Smaller study/randomized clinical trial
 - Other
8. Clarity of expression will be considered in the review process. The overall quality of language used should assure comprehension by the reader.
 9. Use a maximum of five unique abbreviations in the body of the application. No abbreviations should appear in the title. Place abbreviations in parentheses after the full word the first time it appears. Abbreviations increase the difficulty of reading and evaluating applications, which will be considered in the review process.

10. If authors' names appear on more than one application, their names must appear and be spelled identically on each application in order to facilitate proper indexing. Whenever possible, do not list authors with initials only.
11. **Any abstract presenting data that in whole or part is contained in an LBCT submission** that was accepted to be presented in the ACC.21 general abstract program cannot be presented as a poster, oral presentation or moderated poster and **must be withdrawn if that trial is accepted for presentation as an LBCT**. Please notify Heidi Hopper hhopper@acc.org if another abstract based on the LBCT was accepted via the regular abstract submission process and needs to be withdrawn. **Failure to do so may result in a broken embargo and could subject the LBCT and presenters to penalties, including removal from the LBCT program.**
12. After the deadline, the system will be closed, and submissions will be forwarded for the reviewing process. An author may not revise or resubmit an application in order to make changes or corrections after the deadline. Proofread applications carefully to avoid errors before they are submitted. ACC is not authorized to make changes to a submission. If you choose to withdraw an application after the submission deadline, this request must be received by ACC in writing. Please notify Heidi Hopper at hhopper@acc.org.
13. Applications are not eligible for consideration if the data has been presented at a U.S. or international meeting held before the ACC.21 meeting.
14. Applications are not eligible for consideration if the data have been published before the ACC.21 meeting.
15. Any human experimentation must conform to the principles of the Declaration of Helsinki of the World Medical Association.
16. The ACC.21 Program Committee endorses the position of the American Association for the Advancement for Science in requiring assurances of the responsible use of animals in research. All submissions for consideration must be in compliance with the guidelines.
17. The presenting author and lead investigator for each submission will be asked to comply with the ACC "Statement on Disclosure (Vested Interest) and Conflict of Interest for Accredited Educational Activities" policy. Indication of the relationship, the associated commercial entity and level of support is required for each presenting author. Authors will be asked to submit this information no later than February 25.

Again this year: Abstracts will be considered “complete” without coauthor disclosures and will go to review as long as all submission elements are complete. The presenter and lead investigator must disclose by February 25. **You do not need to take any action at this stage: ACC staff will contact lead investigators separately to obtain these disclosures as a condition of submission.** Failure of either person to provide disclosure information will result in the removal of an accepted trial from the program. The presenting author and lead investigator must submit disclosures through ACC’s disclosure website, <http://disclosures.acc.org>. Lead investigators with expired or nonexistent disclosure information will automatically be sent email

notification. In addition, all presenters at ACC.21 must display a slide at the beginning of their presentation indicating disclosure information for themselves and the lead investigator as applicable, or that they have nothing to disclose.

18. The submitter acts on behalf of all coauthors and in submitting an application, transfers to ACCF the copyright and all other rights in the material comprising the application if the application is accepted. Coauthors reserve the following: a) all proprietary rights other than copyright, such as patent rights; and b) the right to use all or part of the application in future works of their own. The meeting organizers, as holder of the copyright on the accepted application, reserve all rights of reproduction, distribution, performance, display, and the right to create derivative works in both print and digital formats.
19. All submitted LBCT applications are disclosed to members of the peer review selection committee, as well as to ACC employees and contractors as necessary in connection with the annual meeting. Applications that are accepted for presentation are summarized for publication after the Annual Scientific Session and are not available to the public in advance of the meetings. Applications not accepted for presentation are not summarized, and are ordinarily not disclosed outside of ACC and persons associated with the selection process (i.e., the peer review committee). Notwithstanding these policies and procedures, ACCF is not subject to any confidentiality requirements with respect to submitted applications. In addition, compliance with any disclosure or nondisclosure requirements that apply to researchers or research sponsors (whether under federal securities laws, contract agreement, or otherwise) is the sole responsibility of the researcher and/or sponsor, and not the ACC.
20. All authors must read and comply with the ACCF embargo policy, which states that scientific study results accepted for presentation during the Annual Scientific Session & Expo must not be released prior to the official embargo time at ACC.21, which is generally time of presentation. Anyone determined by ACCF to have violated the embargo policies may be withdrawn from the program and/or otherwise sanctioned. Understanding the embargo time is the sole responsibility of the investigator. Click here to read the [ACC.21 Media Communications Policies](#) carefully.
 - If an investigator or sponsoring organization believes that it is required for legal reasons or for issues related to public health to release information about a LBCT prior to the end of the embargo, the investigator or organization must notify the ACC Media Relations Department in advance in writing. The written notification must provide the legal rationale for requiring early disclosure. Notification must also include who would receive the information, how and when the information would be disclosed, and a description, template release, or copy of any press releases or other public statements that would be distributed. With appropriate advance notice, the ACC can provide general advice about how such disclosures might impact its inclusion/continued inclusion in the ACC program. The ACC reserves the right to remove the presentation

from the Late Breaking Clinical Trials program, to remove the study from consideration for a press release or other promotions, to remove the study from the scientific program entirely.

- Some, though not all, LBCTs may be selected for an ACC press conference. LBCTs not selected for a press conference remain under embargo until the time of the presentation.
- Presentation or discussion of scientific research results at satellite events or press conferences prior to the scheduled Annual Scientific Session & Expo scientific presentation is strictly forbidden.
- The only exception to the above mentioned embargo rule are closed investigator meetings for participants in the trial. These meetings must be held at the Annual Scientific Session & Expo and may be held May 15-17, 2021, provided they are held during the designated time slots as outlined in the Non-Accredited Satellite Event Guidelines and are approved through the Satellite Event Request Form approval process. Only exhibitors at ACC.21, ACC's Annual Scientific Session & Expo, and universities and non-profit organizations that are affiliated with or supported by one or more exhibiting companies, may request permission to hold investigator meetings.
- In the event that media representatives contact authors, presenters and/or company sponsors, any information must be given with the understanding that scientific research results are to remain under embargo until the time of presentation or ACC-sponsored press conference. Responsibility for information shared in this manner rests solely with the disclosing authors, presenters and/or company sponsors.

Accepted Submissions

Titles and presenters of accepted presentations will be listed in the online program planning tools by early March

The person submitting an accepted application will receive an email by early March. The submitter will be asked to reconfirm the name and contact information of the presenter.

ACC is committed to providing the audience and faculty the best education environment possible. The ACC uses an all-electronic format for audiovisual requirements. All meeting rooms utilizing audiovisual equipment will be networked. Presentations will be downloaded from a central server and sent to the respective meeting room on a secured site. The Presentation Site will open in February for presenters to upload their files in advance. **As a presenter of a Late-Breaking Clinical Trial, you are required to submit a draft of your presentation two weeks in advance of the meeting (or earlier, depending on whether your submission is also accepted for publication in one of the three journals ACC is working with this**

The logo for ACC.21, featuring the text "ACC.21" in a bold, blue, sans-serif font on a white, irregularly shaped background.A dark blue banner with white text that reads "NEW DATES! ATLANTA May 15 - 17".

year). ACC will also be enforcing the requirement that speakers must check in at the Speaker Ready Room onsite at least 3 hours prior to presentation.

Presentation from personal laptops or memory sticks will not be permitted. Files will be sent electronically from the Speaker Ready Room to the appropriate session room. DO NOT take your presentation directly to the session room. Any Mac-based presentations must be converted to a compatible PC format such as PowerPoint, Flash, or PDF format. There will be technicians in the Speaker Ready Room to assist presenters with the conversion process if needed. The computers in the Speaker Ready Room will be configured with hardware and software exactly like computers in the session rooms.

A listing of the audiovisual hardware/software provided in each of the education rooms will be indicated on the Presenter's Agreement.