ESC CONGRESS 2019 31 August- 04 September 2019 - Paris, France Late-Breaking Science Submissions Rules and Guidelines

Late-Breaking Science includes the following types of applications:

Late-Breaking Clinical Trial Late-Breaking Registry Results Clinical Trial Update Basic and Translational Science Hot Line

SUBMISSION GUIDELINES

Submissions are only possible through the online submission services.

Submission deadline is Tuesday 21 May 2019, 11:59 p.m. Central European Time (CET).

Draft Status

As long as you do not click on the submit button (Step 5 of the submission process), your application will be saved in Draft Status, you can re-access it to complete it at any time.

Please note that applications that are in draft status after the deadline will not be considered for selection.

Changes and corrections

Once submitted, it will not be possible to make any corrections to the content or other information (such as presenter details, topic, etc.) In order to correct your submission, you must withdraw it and submit a new version prior to the deadline (see below for withdrawal procedure). Note that such a replacement of your submission is not possible after the submission deadline.

Withdrawal

If you want to withdraw a Late-Breaking Science already submitted, please notify us as quickly as possible at abstracts@escardio.org stating the title and number to be withdrawn.

Note that withdrawal is still possible after the submission deadline.

Data previously submitted as an abstract to ESC Congress 2019

If you have already submitted an abstract (during the Call for abstracts) on this study, indicate the abstract number.

If your study is accepted as a late-breaking submission, you will be asked to withdraw your earlier abstract submission.

In order to submit your application you must complete the following five steps -

Step 1 - General information

Type of submission

You must select one of the following types of submission under which your research can be best classified: **LATE-BREAKING CLINICAL TRIAL**: Reserved for first presentations of the primary endpoint(s) of a new clinical trial

LATE-BREAKING REGISTRY RESULTS: Reserved for presentations of new registry or new data / analyses from a registry. Data must not have been previously presented

CLINICAL TRIAL UPDATE: Reserved for presentations of new data or secondary analysis of a trial where the primary data have been presented previously

BASIC AND TRANSLATIONAL SCIENCE HOT LINE: Particularly important findings of new studies in basic and translational cardiovascular science

Study details

Topic: Select one topic from the list of topics shown to index your research.

Full Title of study: A maximum of 200 characters typed in lower-case letters, except for abbreviations and study names. Please be aware that your title might be truncated if you copy and paste it into the field.

Acronym: If the study to be presented is known through an acronym, please indicate the name of the study (e.g. "EMIT") in this field as well as the full name of the acronym (e.g. "European Mizaverol Trial").

Short title for publication: Enter a short title for ESC publication (ESC TV/ ESC 2019 Mobile App./Scientific programme/ESC 365....) Indicate either the full name of the acronym as entered above (e.g. "European Mizaverol Trial") or a short title for your trial. This title will be used as presentation title if accepted. **Funding Acknowledgements:** All sources of financial support (including governmental grants) for this research should be listed under this heading. All grant funding agency abbreviations should be spelled out. **Trial Registration number:** If available, indicate any reference to your trial registration (number, website link....).

Expected date of trial completion: Applies only for Late-Breaking Clinical Trials & Basic and Translational Science hot lines – Please enter the date at which you expect to have all results ready for communication. **Date primary analysis presented**: Applies only for Clinical Trial Updates – Enter the date at which the trial was first presented.

On behalf of: If applicable, a name of a study group can be mentioned here. Do not list any author names in this field.

Study confidentiality and embargo requirements

Data previously submitted as an abstract to ESC Congress 2019:

If you have already submitted an abstract (during the Call for abstracts) on this study, indicate the abstract number.

If your study is accepted as a late-breaking submission, you will be asked to withdraw your earlier abstract submission.

Submitted Late-Breaking Science should not have been published in any journals and/or online publications nor presented at any congresses. This embargo applies until presentation at the ESC Congress 2019.

Nevertheless, simultaneous publication is authorised.

If you have already submitted or intend to submit your data/results for simultaneous publication, indicate the name of the journal/publication.

Publication information: Journal Publication information is required – specify whether the data have been submitted or will be submitted for simultaneous publication.

Although the data may be submitted to a journal for consideration, it may not be published before the date of the presentation at the ESC Congress 2019. The embargo must remain in place until the start time of the session in which the data will be presented.

Step 2 - Author information and Author list

Your submission must list at least 1 author in order to be completed.

Author list

Enter each author and affiliation using the "Add a new author" module.

The presenter must be included in the author list and positioned as First author.

You can enter up to 15 authors.

NB: The submitter certifies that he/she has permission from all persons he/she enters as co-authors to be listed in this abstract and that they are aware that their names will appear in publications.

If none of the authors is available to present at the congress, the application must be withdrawn.

Institutions

This is a mandatory entry.

Select your institution when you create the presenter and the authors. Once you have entered your city, a list will automatically appear from which you can select your institution. If your institution is not in the list, you have the possibility of creating it. If your city is not in the list, please enter it, press enter then add your institution.

Presenter at the congress: Reconfirm the name of the presenter. **Principal investigator:** Indicate the name of the principal investigator.

Step 3- Study outline

In this part of the submission, you will be asked to provide some outline information depending on the type of submission selected information requested will vary

Multi-centre study

Purpose - You need to summarize the purpose of the study

Design – Study Design information

Sample Size information (Number of Subjects, number of groups, number of persons/group, Population studied info and Intervention performed)

Outcome(s) (Primary endpoints & Secondary endpoints) - 2 sentences max per header

Step 4 - Research content

All abstracts must be submitted in English with accurate grammar and spelling suitable for publication. Abstracts submitted on animal studies: Study must follow the "Principles of laboratory animal care" (NIH Publication no. 85-23 revised 1985) and be in agreement with the national law if applicable.

Please note that any medical research involving human subjects must conform to the principles of the Declaration of Helsinki of the World Medical Association and must have been approved by an IRB.

Do not cut and paste symbols into your text.

Use the symbols provided when you click on the Ω button.

Recommended content structure

<u>Background</u>: In an initial paragraph, provide relevant information regarding the background and purpose of the study, preferably in no more than one or two sentences.

<u>Methods</u>: Briefly state the methods used. Especially for trials where results are not yet available, information on endpoints and statistical power are desirable.

Results: Summarize the results, if available, in sufficient detail to support the conclusions.

Conclusions: State the conclusions reached. It is not satisfactory to state "the results will be discussed."

If results are not available yet but will be available by the time of the presentation, explain the main endpoints that you expect to be able to describe and the conclusions that can be drawn.

NB – Your submission will be used ONLY for review by the selection committee and not published as such by ESC.

For accepted submissions, ESC Press team will have access to this submitted abstract to write the Press Release which you will be asked to review prior to finalisation.

Other Information for content -

In the abstract, use generic drug and product names whenever possible.

The use of commercial drug names, brands and registered trademarks is strictly prohibited.

Drugs should be referred to by the active substance or pharmacological designation.

For experimental and investigational substances, the chemical name should be given.

The names of novel or unique devices can be cited after an explanation of their specific characteristics, but without reference to the company name.

Technical information for content -

Size: The maximum abstract size is 50 lines of 75 characters (3750 characters), but space for tables and figures will be deducted from that count.

Use the save and refresh button at the bottom in order to display the overall size of the abstract in percentage (shown on the left side of the screen). The programme then converts the size in % to display to you when you register it as a draft.

The character limit does not include the title and the authors. Only the abstract text, table and spaces are taken into account.

Table: The table field holds a table without surrounding text. Do NOT COPY your table into the field. You must RECREATE your table using the tools provided.

The maximum size of the table is 12 columns and 20 rows, and you can only enter one table. The title field is optional.

Image: Your Image file must meet the following criteria:

Format: JPEG or GIF Size: less than 1000 Kb

Measures between: 800 pixels(x) x 600 pixels(y)

Please make sure that your picture is readable on the preview. You can only enter one picture, and the title field is optional.

Step 5 - Late-Breaking Science submission preview

Please read through the preview carefully before submitting it, as you cannot change it once submitted.

You will be asked again to confirm that the research has not been published or presented and that you have read and approved the submissions rules (see below for the details of the submission and presentation rules). Do not forget to click on the Submit button to validate your submission.

You will receive an automatic e-mail confirmation. If you do not receive this confirmation for one or more of your submissions, please contact the Scientific Programme Department at abstracts@escardio.org.

SUBMISSION RULES

Submissions

There is no limit to the number of Late-Breaking Science applications an author may submit, but you should not submit the same research twice, even under a different topic.

If you submit two applications with the same content, the submission service will automatically keep the most recent one and withdraw the other.

Note that duplicate draft abstracts will not be deleted nor considered.

Embargo and Publication

The submitter, on behalf of all co-authors, accepts responsibility to ensure that data is not disclosed prior to the session itself or the preceding ESC Press Conference.

The clinical trial results presented at the Congress are embargoed until the start of the session in which the presentation is scheduled. Clinical trial sponsors must comply with the embargo.

The embargo means that results from the trial cannot be presented or announced in any forum (written or oral) except at closed investigator meetings prior to the ESC news conferences. Presentation in Satellite Symposia prior to the session is also prohibited.

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 late breaking clinical trial prior to the end of the embargo, the investigator or organization must notify the ESC Media Relations Department in advance in writing. (press@escardio.org)

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 ESC can provide general advice about how such disclosures might impact its inclusion/continued inclusion in the ESC programme. The ESC reserves the right to remove the presentation from the Hot Line session, to remove the study from consideration for a press release or other promotions, to remove the study from the scientific program entirely.

If above rules are violated, the presentation may be withdrawn from the programme. Failure of investigators or sponsors to honor this embargo will also jeopardize future acceptance of clinical trials of the sponsors and presentations of the principal investigator at scientific sessions of the ESC Congress.

Policies

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 jeopardise future acceptance of applications. Satellite Symposia occurring prior to the Hot Line sessions cannot present the data contained in these sessions. Prior private presentation to the trial investigators is acceptable, but the investigators must be instructed to obey the embargo rules.

Affirmation of originality and copyright transfer of statement

The submitter hereby affirms that the work submitted is original, except for extracts from copyrighted works fully authorised by the copyright holders, and that all statements declared as facts are based on thorough examination and investigation for accurateness.

By submitting your work to the ESC, you consent to have authors' names, affiliation and biographical material being used in connection with the publication of your work.

Author(s) represents and warrants that he/she/they is/are sole author(s) of the work, that all authors have participated in and agree with the content and conclusions of the work, and that the work is original and does not infringe upon any copyright, proprietary, or personal right of any third party.

Submitting/Presenting published or already presented work will jeopardize future acceptance.

Author(s) retain the right, after presentation at the Congress, to subsequently include the work in articles, books, or derivative works that he/she authors or edits provided said use does not imply the endorsement of the ESC.

The submitter signs for all co-authors and accepts responsibility on the present rules for submission and presentation for transferring copyright on behalf of all co-authors.

For accepted submissions, ESC Press team will have access to this submitted abstract to write the Press Release which you will be asked to review prior to finalisation.

ESC reserves the right to provide its press releases a few days before public release to a selected list of Journalists who have previously agreed in writing to respect the ESC embargo policy.

The content belongs to the author(s). However if the study is accepted for presentation, the presenter can agree, on behalf of all co-authors, to transfer and assign to the ESC the rights to edit, publish, reproduce, distribute copies and prepare derivative works such as press release. This includes use in indexes or search databases in print, electronic, or other media.

Presentation given during the session (slides & Video of the presentation) will be, for educational purposes, available on ESC website (post-presentation date and post-congress). The presenter has the option to decline transferring the copyrights to ESC when replying to the invitation.

Conflict of interest

The Congress Programme Committee requests all presenters to display a slide at the beginning of their presentation indicating disclosure information for themselves and all co-authors as applicable, or that they have nothing to disclose. Please state "None" if no conflicts exist.

This will allow the audience to take potential conflicts of interest into account when assessing the objectivity of the presentation.

A potential conflict of interest may arise from various relationships, past or present, such as employment, consultancy, investments and stock ownership, funding for research, family relationship, etc. All potential conflicts of interest must be stated.

This pertains to relationships with pharmaceutical companies, biomedical device manufacturers, or other corporations whose products or services are related to the subject matter of the article. Such relationships include, but are not limited to, employment by an industrial concern, ownership of stock, membership on a standing advisory council or committee, being on the board of directors, or being publicly associated with the company or its products. Other areas of real or perceived conflict of interest could include receiving honoraria or consulting fees or receiving grants or funds from such corporations or individuals representing such corporations.

Data Privacy

By certifying that you have read these Submission rules, you also confirm having received the prior approval from the co-authors to provide their data to the ESC.

The information collected in this CALL FOR LATE-BREAKING SCIENCE is subject to data processing to proceed with the elaboration of ESC Congress 2019 scientific programme.

Provision of personal data is a statutory requirement to list the authors who have contributed to the research submitted.

The recipients of the data are ESC Staff who process the submissions and the ESC Committees and volunteers involved in the scientific programme.

Data collected will be kept for 20 years.

Transfer of personal data to ESC Staff, contractors as well as other ESC related scientific organisations occurs for production, promotion and dissemination of the Congress Content.

In accordance with the chapter 3 of the European Regulation 2016/679 with regards to data protection, you have the right to request from ESC, access to and rectification or erasure of your personal data or restriction of processing concerning your data or to object to processing as well as the right to data portability. This is done thru withdrawal of the submission according to the terms and conditions of withdrawal.

For such, please contact (together with a proof of identity):

Data Privacy
European Society of Cardiology
Les Templiers
2035 Route des Colles
CS 80179 Biot
06903 SOPHIA ANTIPOLIS CEDEX, France

Or by email to dataprivacy@escardio.org

You have the right to lodge a complaint with a supervisory authority, and for information, ESC has appointed a Data Protection Officer that you can reach at dpo@escardio.org

Applicable law

All the rules pertaining to the present submission are governed by and construed in accordance with the laws of France without regard to any conflicts of laws principles thereof that would require the application of the law of any other jurisdiction. Any disputes arising in relation hereto shall be submitted to the exclusive jurisdiction of the French Tribunal de Grande Instance located in Grasse, France.

INFORMATION ON SELECTION AND RESULTS - PRESENTATION RULES

Speakers cannot present in more than one Late-Breaking Science Session.

Results

After the deadline, the system will be closed, and submissions will be forwarded to the Review Committee. Changes or corrections will not be possible after the deadline.

The final selection will be made by the Selection Committee early June 2019. The Review Committee will determine the format, day and time of presentation. For more information about the scientific & educational programme, please go to http://www.escardio.org/Congresses-&-Events/ESC-Congress

Results announcement

An email message will be sent to the submitter early June 2019 with a report on the status of their submission (accepted or rejected).

If the Late-Breaking Science is accepted, notification and further instructions concerning the presentation format will be sent directly to the assigned presenter (indicated in the submission form).

INFORMATION FOR THE PRESENTER

The presenter will be asked to submit an agreement form online before the deadline announced.

Press conferences - A selection of Late-Breaking Science will be presented in an official ESC Press Conference organized by the ESC Press Office. Presenters, or their representatives, will discuss the results of their trials with the media. Participation in these ESC Press Conferences is an integral part of the acceptance process. For more information, please contact press@escardio.org

ESC TV – In addition to the Press Conference, presenters may be required to participate in an ESC TV Interview or contribute with a summary article to the Congress News – further information will be sent accordingly.

If the presenter is contacted by other organizations for interview, articles etc, the presenter must ascertain adherence to the embargo policy before providing any information to third parties.

Being accepted in a Hot Line session implies participation in these activities and communication initiatives in full agreement with the embargo policy.

Slide Presentation:

Hot Line Presenters must make presentation slides available at least 10 days before the congress so they can be sent to the assigned discussants and chairpersons.

A Session rehearsal is organised in the lecture room 15 minutes before the session start. Presenters must be available to attend.

Hot Line Session Presenter Support

An ESC Staff team is dedicated to provide service and logistic support to the presenters before and during the Congress, for the coordination of their ESC activities, congress centre facilities and coordination with ESC Press and Media as may be required.