National Biotechnology CONFERENCE

MAY 17-20, 2021

AAPS SEEKS POSTER ABSTRACT SUBMISSIONS that present data-driven, novel research in the pharmaceutical sciences.





NEXT IN SEQUENCE? NUCLEIC-ACID-BASED THERAPIES:

Current State and Future Promise



ANTIBODY THERAPIES:

Tackling New Frontiers



CELL THERAPIES:

The Future of Regenerative Medicine



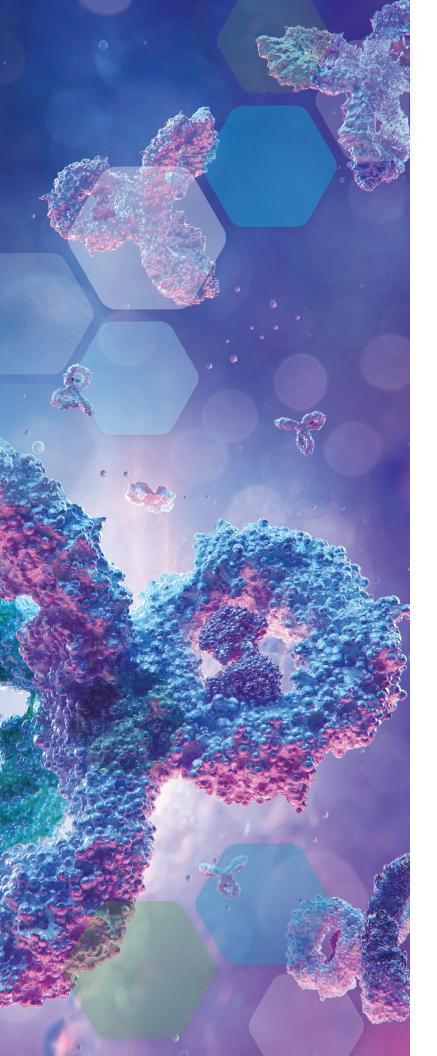
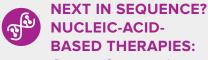


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Each abstract proposal must relate to one of the program's three tracks.



Current State and Future Promise





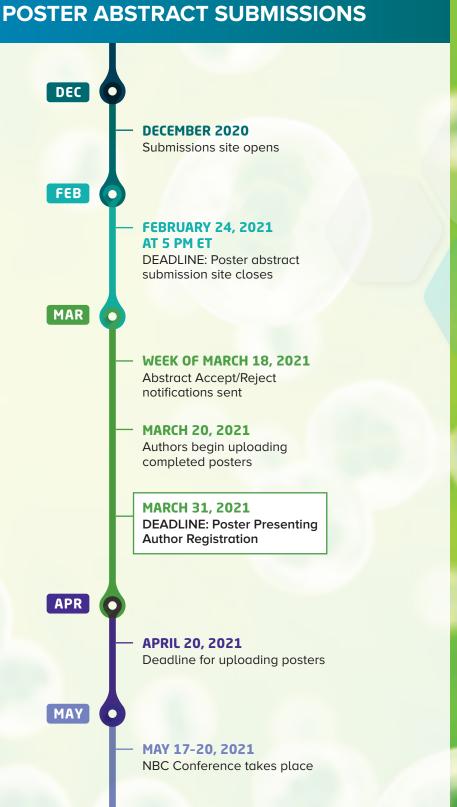
This track will explore the current state of nucleic-acid (NA)-based therapies with a comprehensive look across the applications, barriers to success, and the development cycle for these medicines. Nucleic-acid-based therapies have the potential to tackle diseases that arise due to genetic errors in an individual's DNA. By using various methodologies, scientists can modify or reduce the expression of faulty genes that cause disease or eliminate the nucleic acid material of infectious agents. COVID-19 has increased the attention afforded RNA-based vaccine candidates, while CRISPR-CAS9 and gene editing approaches continue blazing new trails for indications that were previously deemed untreatable. Even though nucleic-acid-based therapies now span a wide spectrum of therapeutic opportunities, significant challenges for development, manufacturing, delivery, and regulatory approaches remain.

This track will explore current developments in the antibody therapies field, including antibody-drug conjugates and other novel therapeutic approaches. Monoclonal antibodies as a product class have become a benchmark for successful biologics therapies and have set new standards for how recombinant therapeutics are developed, manufactured, and approved. Advances in methods used for designing antibodies, including knowledgebased computational approaches combined with molecular simulations, are helping improve the accuracy of de novo design methods and the customization of functionality of antibodies.

This track will take a comprehensive look at stateof-the-art developments in the field of cell therapies. Transplantation of unmodified cells to replace or repair damaged tissue, or the use of engineered human cells as treatment for a variety of diseases and conditions, including cancer, is gaining momentum. Although cell therapy holds immense promise to treat a variety of difficult to treat diseases, the field is facing significant challenges, especially in manufacturing, supply chain, and storage stability, as well as the use of raw and ancillary materials. Regulating live therapies brings its own challenges, especially as several therapies cross the biologics/ device interface.

IMPORTANT ABSTRACT DATES

(ALL DATES SUBJECT TO CHANGE)



ABSTRACT AND POSTER POLICY

By submitting an abstract for presentation at the AAPS National Biotechnology Conference, you agree to abide by the conditions and policies provided below, as well as the decisions of the NBC Abstract Screening Committee and AAPS staff.

Direct questions about this policy to abstracts@aaps.org.

Permissions/Clearances

It is the responsibility of the author(s) to obtain the necessary permissions and clearances for all research, information, and graphics used in both the abstract and the poster. AAPS assumes no liability or responsibility for the publication of any material that is submitted.

Use of the AAPS logo in any abstract submission or poster presentation is STRICTLY PROHIBITED.

Registration Requirement for Participation and Publication

The presenting author is required to participate in the meeting to have the poster included in the collection. If the presenting author is unable to participate during the meeting, a coauthor is required to assume the responsibilities of the presenting author and represent the poster. If no authors are able to participate in the meeting, a presenter may be appointed that is not an author of the abstract.

The presenter or presenting author is required to register either as a full-conference, one-day, exhibitor, or exhibit-hall-only attendee for the meeting by the presenting author registration deadline, or AAPS will withdraw the abstract/poster. Withdrawn abstracts/posters will not be published online or included in the poster collection.

Exhibitors who are presenters or presenting authors must complete their registrations by the presenting author deadline even if they are using an exhibitor registration provided by their employer.

Posters Must Include the Accepted Abstract

Posters that are uploaded for presentation must include the accepted abstract, including all methods used and data resulting from the research. The title of the poster must match, verbatim, the title of the accepted abstract.

Omitting data from a poster presentation that was included in the submitted abstract is unethical. Authors and organizations violating these requirements will be subject to penalties including withdrawal of their paper and their being barred from submitting to any future AAPS meeting.

ABSTRACTS MUST BE SUBMITTED TO THE SUBMISSION WEBSITE BY 5:00 PM ET ON THE INDICATED DEADLINE DATE.

Abstracts submitted after this deadline or by different means will be rejected without review.

DATA SUPPORTING THE CONCLUSION OF THE ABSTRACT MUST BE DEVELOPED PRIOR TO SUBMISSION.

Abstracts stating that data will be developed between the time of submission and the time of the meeting will be rejected without review.



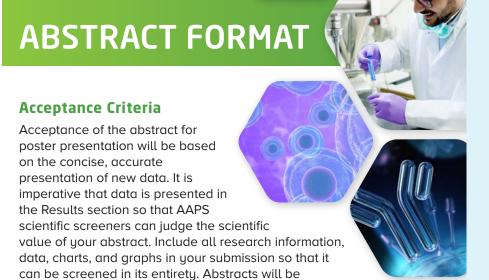
USE GOOGLE'S CHROME BROWSER TO SUBMIT YOUR ABSTRACT.

The submission site is not compatible with Microsoft Edge/Internet Explorer as well as some other browsers.

The submission system can be accessed at <u>Submission Site</u>.

To ensure receipt of all abstract-related correspondence, add the following addresses to your contact list:

support@conferenceabstracts.com scorecard@cadmiumcd.com abstracts@aaps.org homricht@aaps.org



Is the CONCLUSION of the research data driven?

reviewed and scored based on the following:

- How EXCITING/NOVEL will viewers find this research?
- How well does the RESEARCH incrementally advance its field?
- How well does the author's selected strategy for evaluating the HYPOTHESIS suit the project?

Rejections

AAPS reviews each abstract to ensure it is qualified for consideration. Abstracts that do not meet the requirements outlined above are rejected. Causes for rejection include:

- · Lack of data.
- Acknowledgements were included in the abstract, preventing a blind review.
- Affiliation or company name(s) were included in the abstract, preventing a blind review (product names are permitted).
- · Commerciality.
- · Inconsistent or ambiguous data.
- · Reviews of literature.
- · Lack of novelty or innovation.
- Stating that data or information will be included in the poster presentation.
- · Previously published research.
- Including previously published information in your research without referencing the information in the abstract submission.
- Failure to follow format guidelines (Purpose, Methods, Results, Conclusion, References, Acknowledgements).
- Failure to upload tables or charts as images as directed (tables and/or charts are not to be included in the text box for the Purpose, Methods, Results, or Conclusion. Tables and/or charts must be uploaded as images—refer to the Abstract Format section above).
- Failure to submit one strong abstract instead of several abstracts presenting the same work. The submission of multiple abstracts covering the same or similar work is discouraged and may be rejected by the committee.

ABSTRACTS MUST CONTAIN THE FOLLOWING ELEMENTS

DATA, including all research information, charts, and graphs. AAPS rejects any abstract that is not based on data.

TITLE in headline style: 200-character limit with no period at the end

AUTHORS: NEW! Limit of 13 authors

AFFILIATIONS: 1 affiliation per author

PURPOSE: paragraph format

METHODS: paragraph format

RESULTS: paragraph format

CONCLUSIONS: paragraph format

REFERENCES: Reference any previously published material used in your research.

IMAGES in jpg format. Do not include images in the Purpose, Methods, Results, or Conclusion sections.

TABLES AND/OR CHARTS:

Do not include tables or charts in the Purpose, Methods, Results, or Conclusion sections. These should be converted to an image and uploaded in the Images section (3 images are allowed).

ACKNOWLEDGEMENTS, DISCLAIMERS, FUNDING, AND OTHER DISCLOSURE OR CONFLICT OF INTEREST STATEMENTS:

This area should include any disclaimers, acknowledgements, funding, and other disclosure or conflict of interest statements, such as ethics approvals for animal use or human participation, that would prevent a blind review. This information will not be available to reviewers during the review process.

ABSTRACT LENGTH AND IMAGES

Abstracts may contain a maximum of 800 words.

1 to 3 images in jpg format may be included.

Data tables must be uploaded as one of three possible images and not included in the abstract text boxes.

ABSTRACT FORMAT CONTINUED

Encore Presentations

AAPS accepts encore presentations, which are abstracts and posters that have been presented elsewhere. No abstract or resulting poster may be displayed at the National Biotechnology Conference or any other AAPS event without the review and approval of the NBC Abstract Screening Committee, regardless of prior presentation elsewhere.

Abstract Revisions

- Revisions can be made at any time before the poster abstract submission deadline listed under the important dates.
- If you revise your abstract submission, you must be sure to save your changes and click Submit. Failure to complete all the steps will result in an incomplete submission, and your abstract will not be sent to the Abstract Screening Committee. Revisions cannot be made after the poster abstract submission deadline.
- Author names and affiliation or company names will be published as submitted. Be sure you have the correct and current author information. No changes may be made after the submission deadline, including adding or removing authors.
- Proofread, spell-check, and make sure all authors are listed on your abstract before submitting. Abstracts will be presented in conference materials exactly as they appear at the time of submission.

Notification of Receipt and Verification of Submission

- You will receive an immediate email confirmation of completion when you have successfully submitted the abstract. This notification only confirms receipt of your submission and is not a notification of acceptance.
- If you do not receive an immediate email confirmation, your submission is not complete. You will need to return to the submission site to complete the submission process.
- If you return to the submission site to review or make changes to your abstract for any reason, you must complete all submission steps again in order to be sure your abstract is successfully submitted.



Each year, AAPS rejects a few dozen abstracts - many "without review," which means the abstracts were not qualified for consideration and were never shown to a panel of scientific screeners.

HERE ARE THE TOP 4

REASONS THIS HAPPENS:

1. The abstract did not contain any data.

AAPS will not accept an abstract that is not based on data that has already been developed.

2. The abstract is too commercial.

AAPS welcomes the research conducted by any scientist, but it does not permit sales pitches.

- 3. The abstract does not follow the formatting and guidelines outlined in this document.
- 4. The abstract contained author, company name, or affiliation, preventing a blind review process.

SCREENING PROCESS

QUALIFIED ABSTRACTS are reviewed by a blind panel of at least 3 scientists who score each abstract based on these questions:

QUESTION #1

Is the CONCLUSION of the research data driven?

QUESTION #2

How EXCITING/ NOVEL will viewers find this research?

QUESTION #3

How well does the RESEARCH incrementally advance its field?

QUESTION #4

How well does the author's selected strategy for evaluating the HYPOTHESIS suit the project?

Authors of accepted abstracts and posters will abide by the decisions and instructions of AAPS. In the event that authors fail to follow AAPS' policies and instructions, their abstract(s) and/or poster(s) will be removed from AAPS' displays. Authors may also have their acceptances rescinded and, in extreme cases, may see themselves and the organizations they represent barred from future meetings.

Notification of Acceptance/Rejection

Notification of accept/reject and other pre-submission deadline correspondence will be sent to the submitting author. Once accepted, additional communications will be sent to the designated presenting author.

Appeals

Appeals based on proposed additions or changes to an abstract or poster that has already been submitted will be rejected without consideration by AAPS as these changes constitute a new abstract or poster.

To appeal the rejection or withdrawal of an abstract or poster, the submitting author must email the following to appeals@aaps.org within 5 business days of AAPS issuing the rejection:

- Email Subject Line: Appeal and the Abstract Submission ID Number
- 2. Abstract title
- 3. Contact information for the submitter
- 4. Statement explaining on what grounds the author feels AAPS should reverse its decision

Appeals submitted by someone other than the submitter of the abstract, or by any means other than stated above, do not constitute an appeal and will be rejected without review.

Upon receiving a request for an appeal, the NBC Abstract Screening Committee Chair will seat a Review Committee of three members. The Review Committee will:

- 1. Consider the policies and requirements for abstracts and posters as described in AAPS' materials
- 2. Review the abstract as submitted
- 3. Review the reasoning behind the rejection
- 4. Review the argument provided by the submitting author

The Review Committee will not consider any proposed changes to the abstract as submitted.

The final decision will be communicated to the author by email.

SCREENING PROCESS CONTINUED

Registration Requirement

If selected for presentation, authors presenting posters must:

- Register as a full-conference, one-day, exhibitor, or exhibit-hall-only attendee for the 2021 AAPS National Biotechnology Conference by midnight ET on the presenting author registration deadline listed under important dates.
- The posters of authors who fail to register by the deadline will be withdrawn from AAPS' collection of posters.
- Coauthors may present in place of the presenting author, if notification is made to AAPS at <u>abstracts@aaps.org</u>. The presenting coauthor must have a completed registration before the change in presenting author can be made.
- A presenter who is not an author or coauthor of the abstract may present the poster if no authors are able to participate. Changes in the presenter or presenting author must be sent to AAPS at abstracts@aaps.org.
- Authors working in an exhibitor's booth may register as an exhibitor, but their registration must be completed by midnight ET on the presenting author registration deadline indicated under important dates.

Change in Presenting Author

All requests for a change in presenter or presenting author after the final submission deadline must be sent by the submitting author to AAPS at abstracts@aaps.org and include the Submission ID Number as well as the name and email address of the new presenter or presenting author. No authors may be added after the submission deadline.

Poster Schedule

AAPS will notify presenting authors of the scheduled day, time, and assigned poster number by email.

- If you do not receive notification, contact AAPS at <u>abstracts@aaps.org</u> for an update on the scheduling of your abstract.
- Notifications will be sent only to the designated presenting author.

 AAPS will not change the presentation schedule to accommodate a presenting author's personal schedule. All posters will be included in the collection and available in the online platform.

Cancellation Policy and Substitution

- All requests for refunds and/or substitutions must be submitted in writing and emailed to AAPS@experient-inc.com.
- If you cancel your registration on/before March 31, 2021, you will be refunded your registration fee minus an administration fee of \$100 for members/ non-members, or \$50 for students/postdocs.
- No refunds will be given for "no shows" or for cancellations received on or after April 1, 2021.
- Refunds will be credited back to the original credit card used for payment.
- Substitutions from the same company may be submitted in writing at any time without penalty. If the membership status of the substitute differs from that of the original registrant, a refund or additional charge at the current rate may apply.
- Membership cancellation requests must be sent in writing by email to membership@aaps.org within 30 days of the membership start date. AAPS membership is non-transferrable and this offer is not valid if you have taken advantage of discounted member pricing during your current membership term.

Abstract/Poster Withdrawal

The submitting author may withdraw their abstract or poster at any time.

To withdraw, send written notification to <u>abstracts@aaps.org</u>, and include:

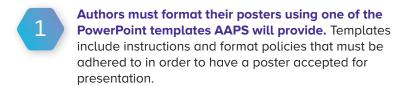
- Submission ID Number (Assigned Poster Number if withdrawing after poster schedule is issued)
- 2. Abstract title
- 3. Names of authors
- 4. Contact information for the submitter

AAPS will acknowledge all withdrawal notifications by email.

Withdrawal is not complete until AAPS issues notification of withdrawal to the submitting author.

POSTER REQUIREMENTS

All posters are presented in a digital format.



The poster title must match the accepted abstract word-for-word/verbatim. No edits or changes are permitted.

The poster must describe all the methods used and data generated by the research. Omitting data from a poster that was described in the abstract is an ethical violation that may result in the poster being removed and the author, and the organization represented by the author, being barred from future meetings.

Authors of accepted abstracts and posters will abide by the decisions and instructions of AAPS. In the event that authors fail to follow AAPS' policies and instructions, their posters will be removed from AAPS' online collection. Authors may also have their acceptance rescinded and, in extreme cases, may see themselves, and the organizations they represent, barred from future meetings.

Posters must be uploaded by April 20, 2021.

AAPS recommends uploading posters as soon as they are complete. All posters are reviewed prior to display by AAPS to ensure proper formatting.



FREQUENTLY ASKED QUESTIONS

? Do I have to be a member of AAPS to submit an abstract?

No. Membership is not required.

Can a paper previously presented be submitted?

Encore presentations are acceptable and do not need to be referenced as an Encore presentation. Previously published research is not allowed.

Who owns the copyright on the abstract and poster?

The author(s)* maintains copyright of the abstract and poster, including all proprietary rights other than copyrights, such as patent rights.

*The submitting author is responsible for all authors knowing that their names appear on the abstract.

? How will AAPS use my abstract?

If the abstract is accepted for poster presentation at the conference, the abstract will be displayed on the conference website/mobile app before, during, and after the meeting for a limited amount of time and on the AAPS member website after the conference.

? How will AAPS use my poster?

If your abstract is accepted for poster presentation at the conference, your poster, which will include the abstract text plus other relevant information and graphics, will be available for display throughout the conference.

Will my poster be on the app or in the Proceedings?

Your abstract and poster will appear in the conference website, available to registrants only, and will be available on the AAPS website for members-only viewing after the meeting.

POSTER ABSTRACT TRACKS/TOPICS (REVIEW GROUPS)

2021 AAPS NATIONAL BIOTECHNOLOGY CONFERENCE

THE NBC WILL HAVE THREE TRACKS and your abstract must relate to one of them in order to be considered. Each track is divided into three subtracks: Preclinical Discovery/ Clinical Pharmacology; Development/Formulation/Delivery; and CMC/Quality/Regulatory/Analytical, Bioanalytical.

REVIEW GROUP (Track, Subtrack, Secondary Topic, Subtopic) SELECTION PROCESS

Select the TRACK that best fits your research:

NEXT IN SEQUENCE?
NUCLEIC-ACID-BASED THERAPIES:
Current State and Future Promise



CELL THERAPIES:
The Future of Regenerative Medicine

Select the SUBTRACK that best fits your research.

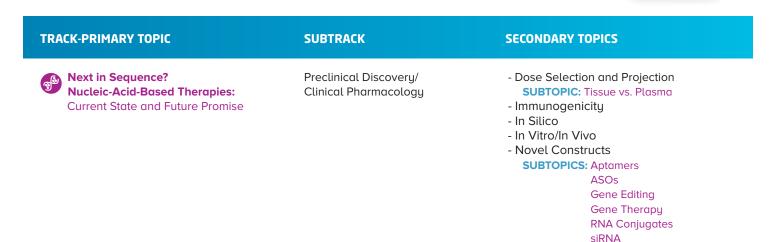
Select the SECONDARY TOPIC that best fits your research.

Select the SUBTOPIC that best fits your research.

SUBMITTED ABSTRACTS MUST RELATE TO A TRACK!

IMPORTANT NOTE:

In the submission site, the structure below—Track, Subtrack, Secondary Topic, and Keywords—are referred to as Review Groups. You will be prompted to select the Review Group that best fits your abstract. For screener sign-up, you will choose all that apply to your expertise.



POSTER ABSTRACT TRACKS/ TOPICS (REVIEW GROUPS) CONTINUED

TRACK-PRIMARY TOPIC	SUBTRACK	SECONDARY TOPICS
Next in Sequence? Nucleic-Acid-Based Therapies: Current State and Future Promise	Development/ Formulation/Delivery	- Biomarkers of Clinical Effect and Response - Delivery Technologies SUBTOPICS: Novel Excipients Stability and Packaging Considerations
Next in Sequence? Nucleic-Acid-Based Therapies: Current State and Future Promise	CMC/Quality/Regulatory/ Analytical, Bioanalytical	 Drug Exposure Analysis in Blood/Tissue Impurity Specifications in BLA, DNA, CMC Nanoparticle Characterization New Applications of Existing Technology New Technology Product Attributes and Efficacy Link Regulatory Approaches for Novel Therapies
Antibody Therapies: Tackling New Frontiers	Preclinical Discovery/ Clinical Pharmacology	 Immunogenicity In Silico In Vitro/In Vivo Linker Chemistry Novel Payloads Novel Targeted Constructs
Antibody Therapies: Tackling New Frontiers	Development/ Formulation/Delivery	- Biomarkers of Response - Clinical Effect - Delivery Methods SUBTOPICS: Continuous Metered Release Novel Excipients Slow Release Stability and Packaging Considerations
Antibody Therapies: Tackling New Frontiers	CMC/Quality/Regulatory/ Analytical, Bioanalytical	 Drug Exposure Analysis in Blood/Tissue New Applications of Existing Technology New Technology Product Attribute Characterization Regulatory Approaches for Novel Therapies Regulatory Considerations for Multi-functional Molecules Release Tests
		continued on following page



POSTER ABSTRACT TRACKS/ TOPICS (REVIEW GROUPS) CONTINUED

TRACK-PRIMARY TOPIC	SUBTRACK	SECONDARY TOPICS
Cell Therapies: The Future of Regenerative Medicine	Preclinical Discovery/ Clinical Pharmacology	 Allogeneic Autologous Bacteria or Exosomes as Carriers of Target Molecules Immunogenicity In Silico In Vitro/In Vivo New Targets and Applications Red Cell Therapies
Cell Therapies: The Future of Regenerative Medicine	Development/ Formulation/Delivery	- Activity - Ancillary Materials - Biomarkers of Response - Clinical Logistics - Delivery Technologies - Subtopics: Novel Excipients - Stability and Packaging - Considerations - Formulation - Off-the-Shelf Products - Subtopic: Stability and Packaging - Considerations - Supply Chain
Cell Therapies: The Future of Regenerative Medicine	CMC/Quality/Regulatory/ Analytical, Bioanalytical	 In Vivo Characterization of Cell Expansion Manufacturing New Applications of Existing Technology New Technology Regulatory Approaches for Novel Therapies Regulatory Considerations Release Criteria Stability Supply Chain - Manufacturing to Bedside

