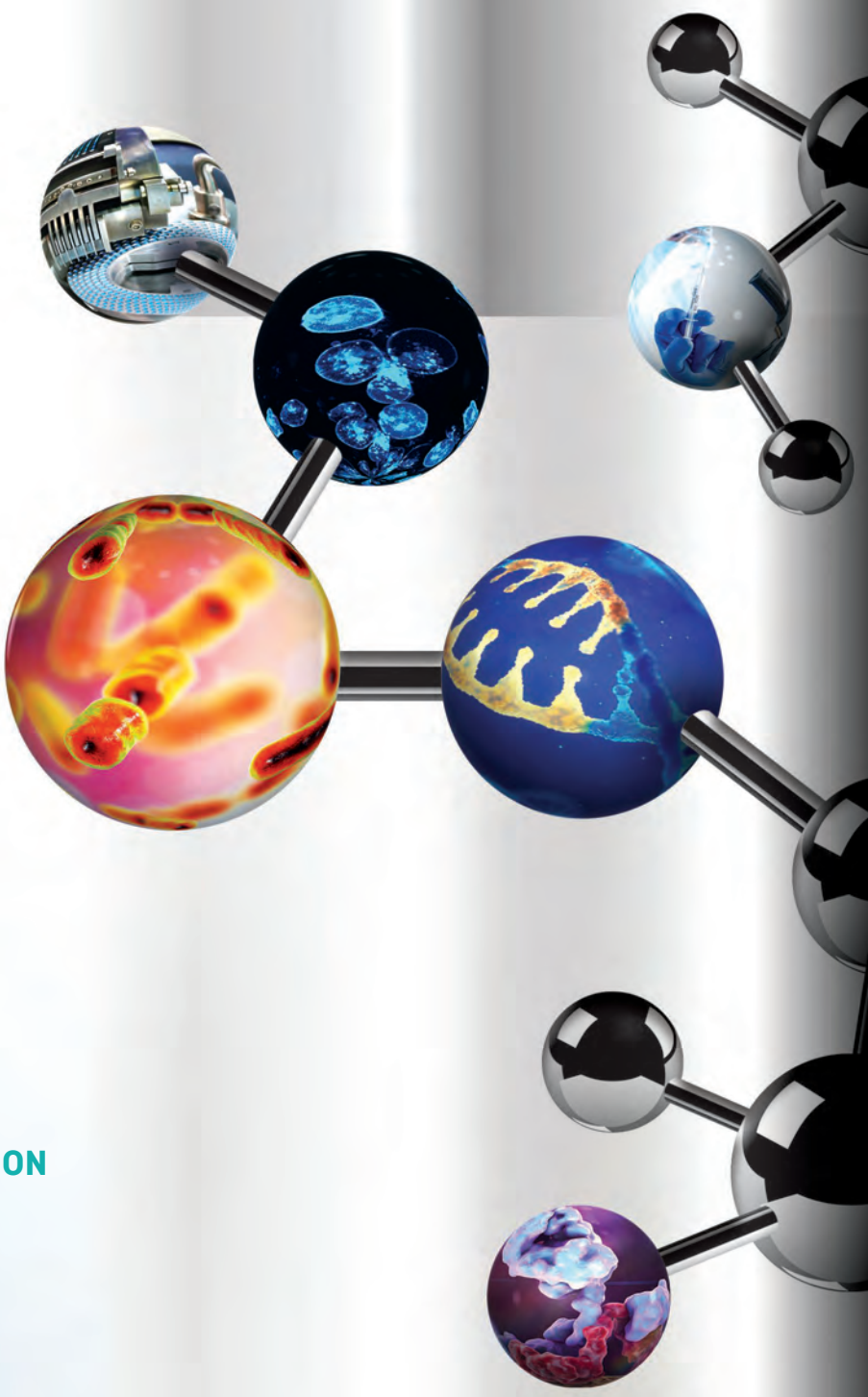
aaps PharmSci 360 OCT 17-20 2021

CALL FOR POSTER ABSTRACTS



AAPS SEEKS POSTER ABSTRACT SUBMISSIONS THAT PRESENT DATA-DRIVEN, NOVEL RESEARCH IN THE PHARMACEUTICAL SCIENCES.

- DISCOVERY AND BASIC RESEARCH
- PRECLINICAL DEVELOPMENT
- BIOANALYTICS
- CLINICAL PHARMACOLOGY
- MANUFACTURING AND ANALYTICAL CHARACTERIZATION
- FORMULATION AND DELIVERY

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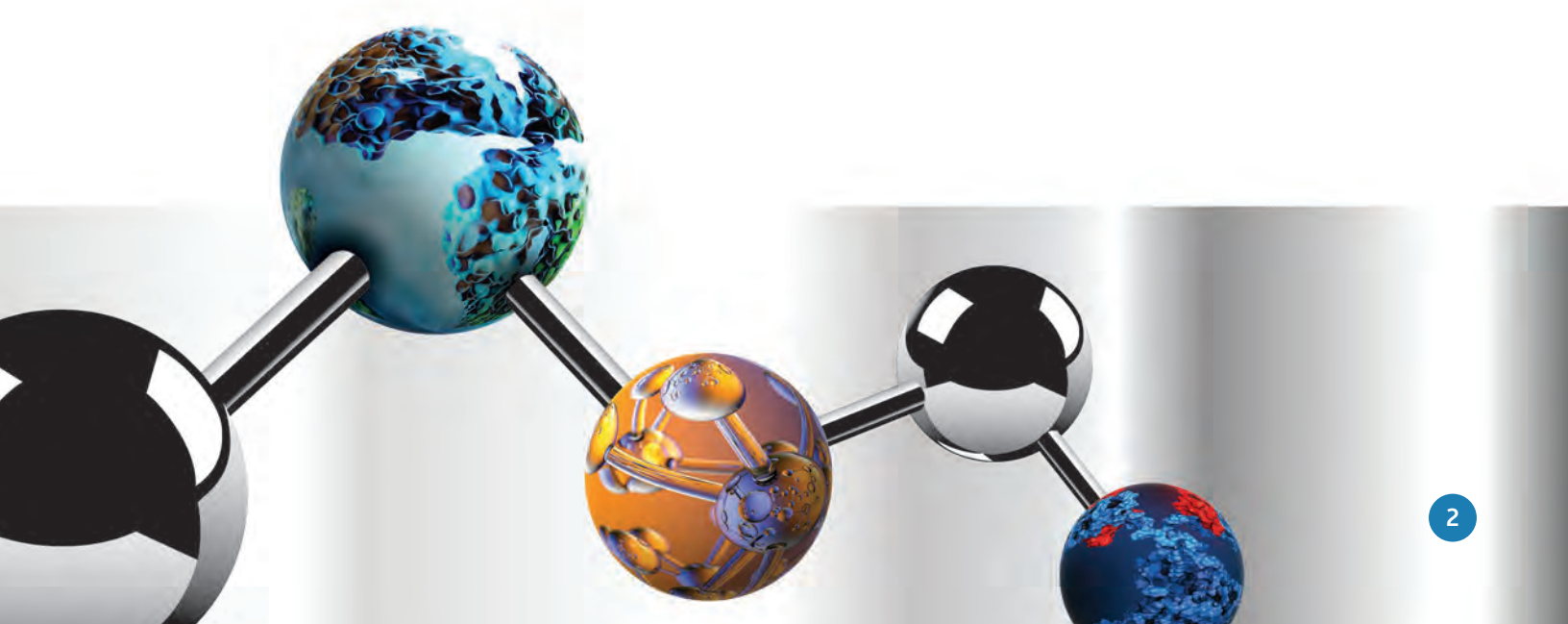


TRACKS/TOPICS

aaps PharmSci 360®

PharmSci 360's scientific program is built on six tracks that cover the pharmaceutical discovery and development process. Five of these tracks are divided into two subtracks: Biomolecular and Chemical. The Discovery and Basic Research track is not split into subtracks.

DISCOVERY AND BASIC RESEARCH

Basic research advances fundamental knowledge and predictions that form the scientific foundation for progress in applied science. Discovery research leads to new scientific ideas, theories, applications, and ways of thinking that form the basis of growth and development in different fields. Generating this critical knowledge is the first step toward therapeutic innovation, providing new tools, and stimulation for new approaches to novel drugs and their development. Most basic research is conducted by universities and other non-profit organizations. Without essential breakthroughs in Discovery and Basic Research, the advancement of subsequent applied research toward novel therapies becomes stifled. Thus, Discovery and Basic Research are key elements for both advancing science and identifying new approaches in the prevention and treatment of human disease.

In the context of drug development, Discovery and Basic Research provides the scientific framework for introducing novel therapeutics and implementing their application. Examples of Discovery and Basic Research include, but are not limited to, identification and characterization of novel targets, receptors, and signaling pathways; discovery and optimization of novel hit, lead, and drug candidate molecules; novel formulation approaches; innovative delivery devices; the study and characterization of drug metabolizing enzymes and transporters; as well as understanding underlying disease biology and pathophysiology.

PRECLINICAL DEVELOPMENT

Preclinical development is a stage of research that begins before testing in humans (clinical pharmacology) can begin. It can take place in either in vitro (glass) or in vivo (organisms, cells, animals). At this stage—during preclinical modeling—two questions are addressed:

- Is there enough evidence that this drug is safe
- Is there enough evidence that this drug actually works (efficacy)

There is both an exploratory component and a regulatory component to this stage. An example of exploratory would be that, during the study, the scientist alters their methods to try to predict the likely safety concerns. Based on what they find, the regulatory body (FDA, for example) will provide them with a safety margin within which they can continue to work. A regulatory example might be that when the scientist chooses and presents their candidate (the drug that has been the safest and shows the most efficacy, i.e., the drug they want to move into human trials) the regulatory body looks at their research and defines the dose/concentrations that can be used and provides the final approval for clinical (human) trials.

Products studied in preclinical development may include new medical devices, drugs, gene therapy solutions, or diagnostic tools. Only one in 5,000 products that gets to the preclinical development stage becomes an approved drug.

BIOANALYTICS

Bioanalysis covers the quantitative measurement of xenobiotics (small molecule/chemical entities found within an organism that are not naturally produced or expected—like a drug) and large biomolecules (macromolecules, proteins, DNA, large molecule drugs, metabolites) in biological systems (like people).

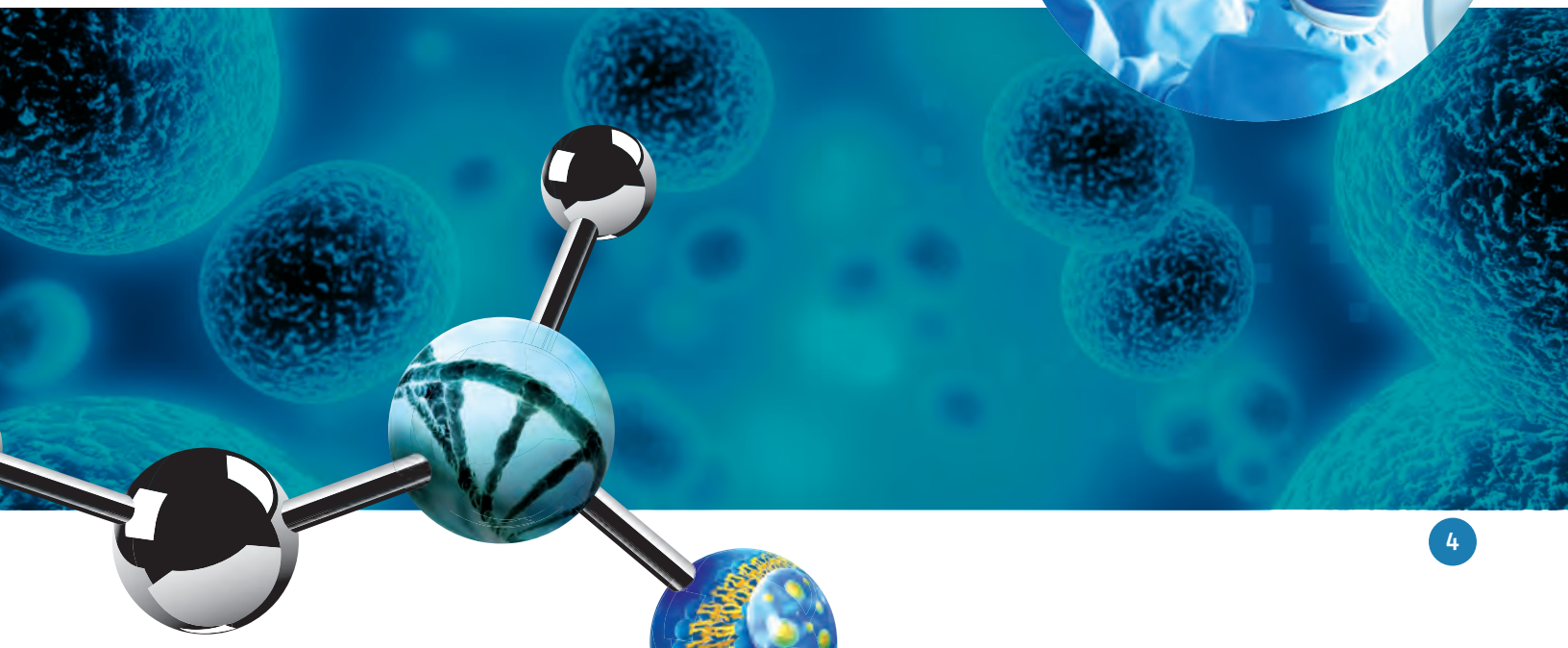
The focus of bioanalysis in the pharmaceutical industry is to provide a quantitative measurement of the drug for the purpose of pharmacokinetics (how it moves in the body), toxicokinetics (the rate at which the drug enters and exits the body), bioequivalence (how the drug amount is the same or different in different biological systems—like dogs vs. humans or babies vs. adults), and exposure-response (pharmacokinetic/pharmacodynamics [PKPD] studies). Bioanalysis also applies to drugs used for illicit purposes, forensic investigations, anti-doping testing in sports, and environmental concerns.

Bioanalysis was traditionally thought of in terms of measuring small molecule drugs. However, the past twenty years has seen a resurgence in biopharmaceuticals (large molecules) which have been developed to address many of the same diseases as small molecules. These larger biomolecules have presented their own unique challenges to quantification.

CLINICAL PHARMACOLOGY

Clinical pharmacology is the study of drugs in humans. It has a broad scope—it can refer to the discovery of new target molecules to the effects of drug use in whole populations.

Clinical pharmacologists in the laboratory setting study biomarkers, pharmacokinetics, drug metabolism, and genetics. In the office setting, they design and evaluate clinical trials, create and implement regulation guidelines for drug use, and look at drug use on local and global scales. In the clinical setting, they work directly with patients, participate in experimental studies, and investigate adverse reactions and interactions.



MANUFACTURING AND ANALYTICAL CHARACTERIZATION

This track explores the critical science and engineering procedures for manufacturing both small and large molecule drug substances and drug products. This complex process can be subdivided into a series of unit operations broadly covering process design and development, scale up, transition to commercial manufacturing, innovations in manufacturing technologies to enable flexibility, cost-effectiveness, intelligent systems, and continuous processing in both synthetic and biologics manufacturing.

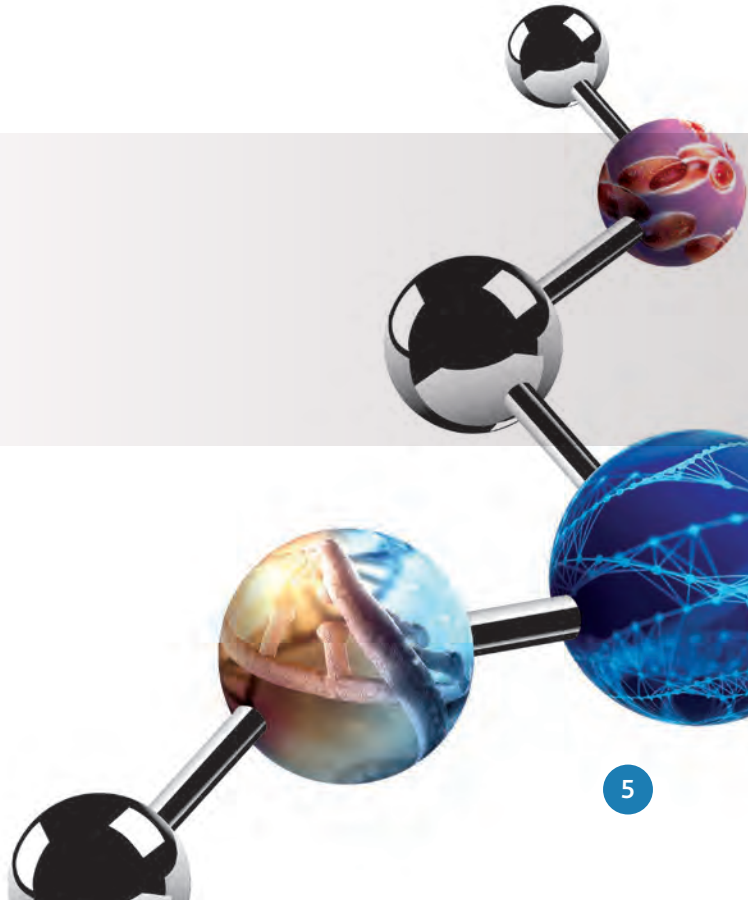
Key analytical characterization methods and lifecycle management to assure quality include broad analytical research areas pertaining to the SISPQ (safety, identity, strength, purity, and quality) of drug substances and drug products, both at release and during stability. Topics covered include, but are not limited to: challenges for analytics, new analytical methods/instrumentation, particulate characterization/quantification for parenteral products, analytical methods capable of controlling multiple attributes, pCQA/CQA identification, control strategies, and primary packaging. This track also covers topic-related regulatory and development strategy considerations.

FORMULATION AND DELIVERY

This track focuses on the key challenges surrounding pharmaceutical formulation in which different excipients and the pharmaceutically active drug substance are combined to produce a suitable drug product. Aspects covered include the latest advancements in formulation development such as challenges in bioavailability enhancement, poor solubility/precipitation, aggregation, excipients, viscosity reduction, administration equipment compatibility, and chemical and physical stabilization. Formulation technology improvements for novel therapeutic modalities such as cell and gene therapies are also addressed.

The delivery aspect explores novel devices and non-traditional formulations including, but not limited to overcoming biological barriers, particulate-based delivery systems, microneedle dermal patches, hydrogels, advanced vaccines, long-acting delivery, implants, prefilled syringes, auto-injectors, patch pumps, and inhalation devices. This track also covers topic-related regulatory and development strategy considerations.

A COMPLETE LISTING of 2021 PharmSci 360 Tracks, Subtracks, Primary Topics, and Subtopics can be found on pages 14–30 at the end of this guide.



IMPORTANT DATES

ALL DATES ARE SUBJECT TO CHANGE.

VISIT
www.aaps.org/posters
for updates.

EARLY POSTER ABSTRACT SUBMISSIONS

ACCEPTED MARCH 1 - MAY 5, 2021

MAR

MONDAY, MARCH 1
Open for submissions

MAY

WEDNESDAY, MAY 5
at 5 PM ET
Submission deadline

WEEK OF MAY 31
Abstract accept/
reject notifications

JUN

WEDNESDAY, JUNE 16
Presenting author registration deadline

WEEK OF JUNE 28
Schedule notifications

WEDNESDAY, JUNE 30
Poster uploading begins

BEST ABSTRACT AND BEST POSTER AWARDS

Only Early Poster Abstract Submissions are eligible for these awards. Authors of accepted early poster abstract submissions are automatically considered. See Awards information on page 12 for details.

LATE-BREAKING POSTER ABSTRACT (LBPA) SUBMISSIONS

ACCEPTED JUNE 2 - JULY 21, 2021

There is a non-refundable, per abstract submission fee of $50 per student and $100 per non-student to submit a Late-Breaking Poster Abstract. Submission fees are payable by credit card only.

JUN

WEDNESDAY, JUNE 2
Open for submissions

JUL

WEDNESDAY, JULY 21
at 5 PM ET
Submission deadline

AUG

FRIDAY, AUGUST 13
Abstract accept/reject
notifications

SEP

TUESDAY, SEPTEMBER 7
Presenting author registration deadline

WEDNESDAY, SEPTEMBER 8
Schedule notifications

THURSDAY, SEPTEMBER 9
Poster uploading begins

MONDAY, SEPTEMBER 27
Deadline for all poster uploads

ATTENTION: Early poster abstract and LBPA authors who have had their abstracts accepted are required to register for PharmSci 360 by the special registration dates highlighted above.

POLICY

By submitting an abstract for presentation at AAPS PharmSci 360, you agree to abide by the conditions and policies provided below, as well as the decisions of the AAPS 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 before submitting an abstract. 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 PUBLICATION AND SCHEDULING

The presenting author is required to attend the meeting to present the poster. If the presenting author is unable to attend the meeting, a co-author is required to assume the responsibilities of the presenting author.

The 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 presented during the meeting.

Exhibitors who are presenting authors must complete their registrations by the presenting author registration 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 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 BEFORE 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 or some other browsers.

The submission system can be accessed at Submission Site.

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

ABSTRACT FORMAT

ACCEPTANCE CRITERIA

Acceptance of the abstract for presentation will be based on the concise, accurate presentation of new data. It is imperative that data is presented in the results section so that AAPS scientific screeners can judge the scientific value of your abstract. Include all research information, data, charts, and graphs in your submission so that it can be screened in its entirety. Abstracts will be reviewed and scored based on the following:

- Is the CONCLUSION of the research data driven?
- 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 instead of including it in the abstract.
- 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, Conclusions, 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 Conclusions. Tables and/or charts must be uploaded as images—see column to the right).
- 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 (*Optional)

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: Limit of 13 authors

AFFILIATIONS: 1 affiliation per author

PURPOSE: in paragraph format

METHODS: in paragraph format

RESULTS: in paragraph format

CONCLUSIONS: in 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 Conclusions sections.

***TABLES AND/OR CHARTS:** Do not include tables or charts in the Purpose, Methods, Results, or Conclusions sections. These should be converted to images and uploaded in the Images section.

***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 **as many as 800 words**.

Limit of 3 images in jpg format may be included.

ABSTRACT FORMAT

ENCORE PRESENTATIONS

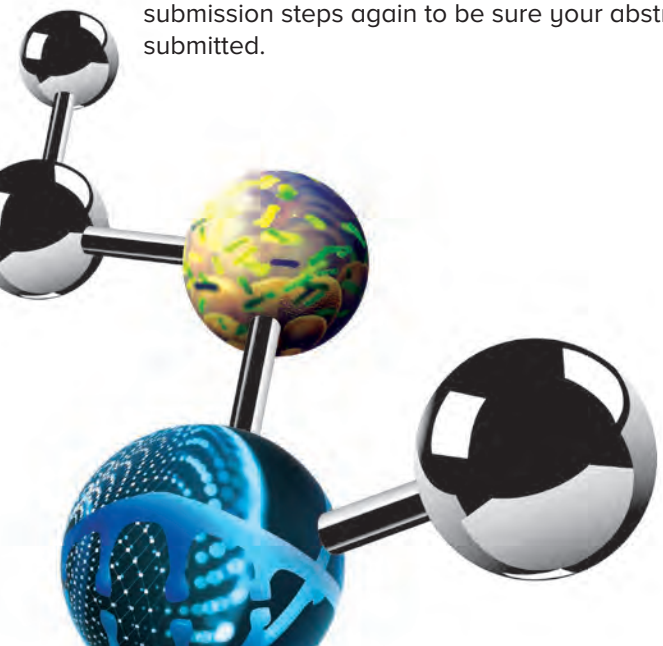
AAPS accepts encore presentations, which are research or posters that have been presented elsewhere. However, all abstracts must be approved by a team of AAPS scientific screeners, regardless of presentation elsewhere.

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 save your changes and resubmit. 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.
- 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 must 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 to be sure your abstract is successfully submitted.



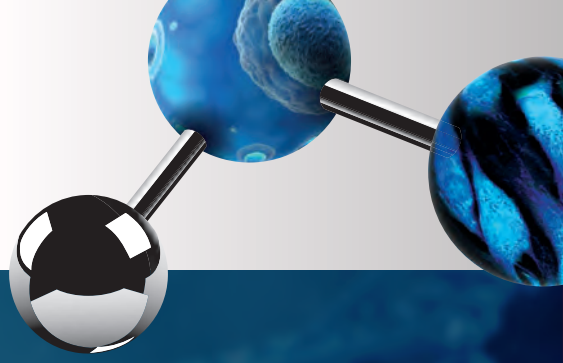
TOP 4 REASONS ABSTRACTS ARE REJECTED

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' web-based and in-person displays. Authors may also have their acceptances rescinded and, in extreme cases, may see themselves and the organizations they represent barred from future meetings.

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:

1. 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 author, 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 AAPS 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 or poster as submitted
3. Review the reasoning behind the rejection
4. Review the argument advanced 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.

REGISTRATION REQUIREMENT

If selected for presentation, authors presenting posters must:

- Register as a full-conference, one-day, exhibitor, or exhibit-hall-only attendee for PharmSci 360 by midnight ET on the day of the **presenting author registration deadline** listed under important dates.
- Include your abstract submission ID number at the start of the registration process.
- Present the poster in person at the time and location scheduled by AAPS.

The posters of authors who fail to register by the deadline or who fail to present at the scheduled time will be withdrawn from AAPS' web-based and in-person catalog of posters.

A co-author may present in place of the presenting author if notification is sent to AAPS at abstracts@aaps.org. The presenting co-author must have completed registration before the change in presenting author can be made.

Authors working in an exhibitor's booth may register as an exhibitor, but their registration must be completed by midnight ET on the day of the **presenting author registration deadline** indicated under important dates.

AAPS will not change the presentation schedule to accommodate a presenting author's personal schedule.

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.

SCREENING PROCESS

APPLY FOR A TRAVELSHIP When You Submit Your Abstract!

Each year, AAPS offers thousands of dollars in travelships to help bring the best science to PharmSci 360!

Travelships are awarded based on best screening scores to qualified student and postdoc authors.

Visit www.aaps.org/travelships for more information.

CHANGE IN PRESENTING AUTHOR

If there is a change in presenting author after the final submission deadline, the submitting author must contact AAPS at abstracts@aaps.org and include the Submission ID Number as well as the name and email address of the new presenting author. The new presenting author must be a co-author on the originally submitted abstract. No other authors will be added after the submission deadline.

POSTER SCHEDULING

- AAPS will notify presenting authors of the scheduled day, time, location, and assigned poster number by email by the date indicated under important dates.
- If you do not receive notification at that time, contact AAPS at abstracts@aaps.org for an update on the scheduling of your abstract.
- Schedule 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.

CANCELLATION POLICY AND SUBSTITUTION

- All requests for refunds and/or substitutions must be submitted in writing and emailed to aaps@martiz.com.
- If you cancel your registration on/before September 21, 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 September 22, 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 for members who have taken advantage of discounted member pricing during their current membership term.

ABSTRACT/POSTER WITHDRAWAL

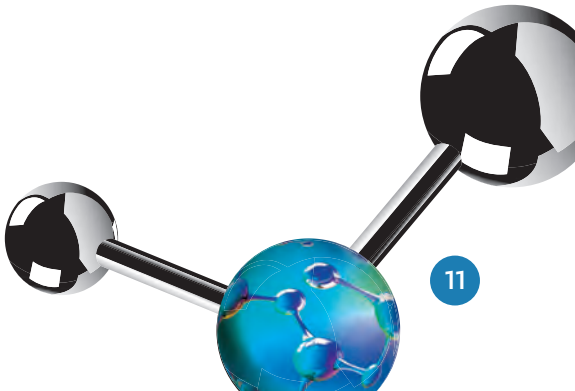
The submitting author may withdraw their abstract or poster at any time.

To withdraw, send written notification to abstracts@aaps.org, and include:

1. 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. No paper posters are allowed.

1. **Authors must format their posters using one of the PowerPoint templates provided by AAPS.** Templates include instructions and format policies that must be adhered to in order to have a poster accepted for presentation.

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

3. **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.

4. **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' web-based and in-person displays. Authors may also have their acceptance rescinded and, in extreme cases, may see themselves, and the organizations they represent, barred from future meetings.

5. **Posters must be uploaded by September 27, 2021.** AAPS recommends uploading posters as soon as they are complete. All posters are reviewed before display by AAPS to ensure proper formatting.

ABSTRACT/POSTER-BASED AWARDS

BEST ABSTRACT AWARD

AAPS selects the best abstracts from hundreds of submissions for display at PharmSci 360 each year! The Best Abstract Award brings attention to the most exciting research found in the posters, based on abstracts that are submitted and screened before the event.

The highest ranked abstracts, as determined by screeners during AAPS' blind abstract screening process, that have been authored by qualified candidates, are automatically forwarded for consideration to the AAPS Awards Committee. Candidates are not required to complete an application form.

Presenting authors must meet the following requirements:

- Must be an AAPS member at time of poster submission
- Must be the single lead author of the abstract
- Abstract must be ranked by screeners in the top 10% of abstracts for one of the following groups:
  - Graduate students
  - Postdoctoral candidates
  - Young academic scientists with fewer than 3 years in academia
  - Young industrial scientists with fewer than 3 years in industry
  - AAPS members who do not meet the criteria for one of the above categories

Awardees will receive an award ribbon to wear throughout the meeting, as well as recognition in the form of signs or other visuals in the Solution Center (Exhibit Hall) directing attention to the winning posters during the meeting.

BEST POSTER AWARD

The top posters presented at PharmSci 360 are selected for recognition because of the importance scientifically impactful posters have in advancing the pharmaceutical sciences. Abstracts that are selected for poster presentation at PharmSci 360 offer a key mechanism for scientists to share the recent results of their research with the scientific community. Timely communication of research can have a significant impact on the thoughts and actions of other researchers.

AAPS will automatically identify candidates from the AAPS Best Abstract Award recipients. Candidates do not complete an application form.

- Must be an AAPS member at time of poster submission
- Must be the presenting author of the poster
- Poster must be submitted by deadline according to the submission process AAPS requires for poster authors

Awardees will receive an award ribbon and recognition in the form of signs or other visuals in the Solution Center (Exhibit Hall) directing attention to the winning posters (abstracts) during the meeting.

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.

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; in the Poster Café during the conference; 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 during the author(s) presentation period and throughout the conference through all digital poster monitors. It will also be accessible to attendees through the online poster collection. After the meeting, AAPS will make all posters available to AAPS members.

WILL MY POSTER BE ON THE APP?

Your abstract will appear in the preconference website/mobile app. 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.

WHO CAN RECORD MY POSTER PRESENTATION?

Poster presentations cannot be audio- or video-recorded in the exhibit hall without prior written permission from AAPS. To get permission to record your poster presentation, contact abstracts@aaps.org.

IS A PRESENTATION AT AAPS A PUBLICATION OR A PRESENTATION AT THE MEETING?

A presentation at an AAPS meeting can be considered both a publication and a presentation.

I AM AN INTERNATIONAL ATTENDEE WAITING ON A VISA. WHAT IF I DO NOT RECEIVE MY VISA BY THE PRESENTING AUTHOR REGISTRATION DEADLINE?

International attendees waiting on their visas should register for the meeting for at least one day of the conference by the presenting author registration deadline. With a valid registration, your abstract will be scheduled for poster presentation. When you receive your visa, your registration can be updated to Full Conference by contacting aaps@martiz.com. If you do not receive your visa, you must contact abstracts@aaps.org by October 17, and provide a copy of your rejection notification from visa application. You will then receive a full registration refund. Membership fees are only refundable within the first 30 days after purchase.

TRACKS-SUBTRACKS / TOPICS
REVIEW GROUPS

2021 AAPS PHARMSCI 360

THERE ARE SIX ROBUST TRACKS covering all aspects of the pharmaceutical sciences. Five tracks are divided into two subtracks: Biomolecular and Chemical. The Discovery and Basic Research track is not split into subtracks.

Important Note: In the submission site, the structure below—Track-Subtrack, Primary Topic, and Subtopic—are referred to as Review Groups. You will be prompted to select the Review Group that best fits your abstract.

REVIEW GROUP (TRACK-SUBTRACK/TOPIC) SELECTION PROCESS

1. Select the TRACK-SUBTRACK that best fits your research:
   - **Discovery and Basic Research (DBR)**
   - **Preclinical Development**
   - **Bioanalytics**
   - **Clinical Pharmacology**
   - **Manufacturing and Analytical Characterization**
   - **Formulation and Delivery**
2. Select the SUBTRACK (Biomolecular or Chemical).
   Does not apply to Discovery and Basic Research.
3. Select the PRIMARY TOPIC that best fits your research.
4. From your Primary Topic, select the best SUBTOPIC for your research. If no listed term fits your research, select "Other."
   Note: There may not be a Subtopic available for your Primary Topic.

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Discovery and Basic Research	Bioanalytical	New Applications of Existing Technology New Approaches New Technology
Discovery and Basic Research	Biology	Biomarkers Cell Therapy CAR-T, STEM Cell, Other Cellular and Molecular Pathways Gene Therapy Immunogenicity In Silico In Vitro In Vivo Metabolizing Enzymes Omics Protein Binding Protein/Gene Engineering and Expression Receptor/Target Interactions Target Identification Transporter Other

TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Discovery and Basic Research	Medicinal Chemistry	Combinatorial Chemistry Fragment Based Design In Silico Based Design Natural Products Novel Drug Modality Peptides and Other Large Molecules Rational Drug Design Small Molecules Structure Activity Relationship Synthetic Chemistry
Discovery and Basic Research	Pharmaceutics	Drug Delivery Novel Systems Drug Delivery Ocular Drug Delivery Transdermal Drug Transport and Transporters Modeling and Simulation: New Approaches Molecular Biopharmaceutics Novel Drug Modality Pharmaceutical Polymers Pharmacokinetics
Discovery and Basic Research	Pharmacology	Behavioral Pharmacology Bioanalytical Biomarkers Cell Death and Differentiation DNA Damage and Repair Drug Abuse Drug-Drug Interactions Epigenetics and Epigenetic Therapy Experimental Therapeutics Gene Therapy Immunotherapy and Immunopharmacology Natural Products Neuropharmacology Omics (genomics, metabolomics, epigenomics, proteomics) Oncology (hematologic malignancies) Oncology (solid tumors) Orphan Drugs and Rare Diseases Pharmacokinetics Quantitative Pharmacology Signal Transduction Systems Pharmacology Toxicology Vaccines
Preclinical Development Biomolecular	ADME	In Vitro - Biotransformation In Vitro - Protein Binding In Vitro - Transporter In Vitro - Other In Vivo In Vivo - PK/PD Novel Drug Modality/Novel Drug Delivery Optimization of Protein Design Payload-Linker Identification/Optimization Pharmacokinetics Screening Tools for Candidate Optimization Other

TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Preclinical Development Biomolecular	Omics	Genomics Metabolomics Proteomics
Preclinical Development Biomolecular	Immunogenicity	Factor in Species Selection Impact on Exposure Impact on Safety Assessment Immunogenicity Risk Assessment
Preclinical Development Biomolecular	Safety	Cellular and Molecular Toxicity De-risking Strategies Immuno-toxicity IND Enabling Studies Mechanistic Toxicity Screening Toxicity Studies Other
Preclinical Development Biomolecular	Translation	Drug-Drug Interactions Human Dose Projections - Allometric Human Dose Projections - Pharmacokinetics (PBPK) Human Dose Projections - Other Model Based Drug Development Novel Drug Modality/Novel Drug Delivery PK/PD Other
Preclinical Development Chemical	ADME	In Vitro - Metabolizing Enzymes In Vitro - Protein Binding In Vitro - Transporter In Vitro - Other In Vivo Pharmacokinetics Screening Tools for Candidate Optimization Other
Preclinical Development Chemical	Omics	Genomics Metabolomics Proteomics
Preclinical Development Chemical	Immunogenicity	Factor in Species Selection Impact on Exposure Impact on Safety Assessment Immunogenicity Risk Assessment
Preclinical Development Chemical	Safety	Cellular and Molecular Toxicology De-risking Strategies Immuno-toxicity IND Enabling Studies Mechanistic Toxicity Screening Toxicity Studies Other
Preclinical Development Chemical	Translation	Drug-Drug Interactions Human Dose Projections - Allometric Human Dose Projections - Physiologically Based Human Dose Projections - Other Model Based Drug Development PK/PD Other

TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Bioanalytics Biomolecular	Analyte Stability	Ex Vivo In Vitro Solution
Bioanalytics Biomolecular	Bioanalytical Innovations and Applications	n/a
Bioanalytics Biomolecular	Bioanalytical Risk Assesment and Strategy	n/a
Bioanalytics Biomolecular	Biomarker Quantification	Biomarker/Pharmacodynamic Measurement Clinical Qualification Diagnostic Development (including companion diagnostics) Disease Heterogeneity Assessments Exosome Flow Cytometry Methods High Content Data Analysis Hybrid Methods (e.g., IP/LCMS) Imaging Methods Ligand Binding Assay (LBA) Methods Mass Spectrometry (LC-MS) Methods New Matrices New Modalities Omics PCR Methods Preanalytical Variables Single-Cell-Based Biomarkers Target Engagement/Receptor Occupancy Vaccines
Bioanalytics Biomolecular	Drug Quantification	Endogenous Homologs Quantification Flow Cytometry Methods Hybrid Methods (e.g., IP/LCMS) Imaging Methods Ligand Binding Assay (LBA) Methods Mass Spectrometry (LC-MS) Methods PCR Methods Other Methods/Techniques Therapeutic Drug Monitoring Post-marketing Commitment Surrogate Analyte
Bioanalytics Biomolecular	Immunogenicity	Binding Antibody Methods Cell-Based Methodologies Neutralizing Antibody Methods Immunogenicity Risk Assessments Immunogenicity Prediction
Bioanalytics Biomolecular	In Vivo and Ex Vivo Biotransformation	ADC Metabolism Evaluation of In Vivo Biotransformation Impact of Biotransformation on Immunogenicity Impact of Biotransformation on PK Molecule Variants Quantification Ex Vivo
Bioanalytics Biomolecular	Life Cycle Management of Bioanalytical Methods	Collaboration with Other Partners (Co-development) Data Management General Life Cycle Management Methods Transfer and CRO Management

TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Bioanalytics Biomolecular	Novel Modalities	ADCs Alternative Scaffold CAR-T Cell-Based Therapy Encapsulated Drugs (Lipid, Nanoparticle, etc.) Multi-specific Antibodies Nanoparticle Based Modalities Oligos, RNAs, and Locked Nucleic Acids Viral Vectors Other Novel Modalities
Bioanalytics Biomolecular	Reagents and Reference Standards	Characterization and Quality Control Life Cycle Management Stability
Bioanalytics Biomolecular	Regulations (BMV/GLP/GCP/CLIA)	Biomarkers Drug (and Metabolites) GCP/GLP Compliance for Bioanalytical Labs General Topics ICH and Harmonization Immunogenicity and Risk Assessment Samples and Reagent Stability
Bioanalytics Biomolecular	Samples and Laboratory Management	Bioanalytical Documentation and Reports Biorepositories Informed Consent Laboratory Information Management System (LIMS) Patient-Centric Sampling (microsampling and dried blood spots) Post-Collection Sample Condition and Record Management
Bioanalytics Biomolecular	Vaccines	Binding Antibody Methods Cell-Based Methodologies Correlates of Protection Neutralizing Antibody Methods
Bioanalytics Chemical	Analyte Stability	Ex Vivo In Vitro Solution
Bioanalytics Chemical	Bioanalytical Innovations and Applications	n/a
Bioanalytics Chemical	Bioanalytical Risk Assessment and Strategy	n/a
Bioanalytics Chemical	Biomarker Quantification	Biomarker/Pharmacodynamic Measurement Clinical Qualification Diagnostic Development (including companion diagnostics) Disease Heterogeneity Assessments Exosome Flow Cytometry Methods High Content Data Analysis Hybrid Methods (e.g., IP/LCMS) Imaging Methods

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TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Bioanalytics Chemical	Biomarker Quantification *Continued*	Ligand Binding Assay (LBA) Methods Mass Spectrometry (LC-MS) Methods New Matrices New Modalities Omics PCR Methods Preanalytical Variables Single-Cell-Based Biomarkers Target Engagement/Receptor Occupancy
Bioanalytics Chemical	Drug Quantification	Endogenous Homologs Quantification Flow Cytometry Methods Hybrid Methods (e.g., IP/LCMS) Imaging Methods Ligand Binding Assay (LBA) Methods Mass Spectrometry (LC-MS) Methods PCR Methods Other Methods/Techniques Therapeutic Drug Monitoring Post-marketing Commitment Surrogate Analyte
Bioanalytics Chemical	Immunogenicity	Binding Antibody Methods Cell-Based Methodologies Immunogenicity Prediction Immunogenicity Risk Assessments Neutralizing Antibody Methods
Bioanalytics Chemical	In Vivo and Ex Vivo Biotransformation	ADC Metabolism CYP450 Assessment Evaluation of In Vivo Biotransformation Impact of Biotransformation on Immunogenicity Impact of Biotransformation on PK Metabolite Quantification
Bioanalytics Chemical	Life Cycle Management of Bioanalytical Methods	Collaboration with Other Partners (Co-development) Data Management General Life Cycle Management Methods Transfer and CRO Management
Bioanalytics Chemical	Novel Modalities	ADCs Alternative Scaffold CAR-T Cell-Based Therapy Encapsulated Drugs (Lipid, Nanoparticle, etc.) Multi-specific Antibodies Nanoparticle Based Modalities Oligos, RNAs, and Locked Nucleic Acids Viral Vectors Other Novel Modalities
Bioanalytics Chemical	Reagents and Reference Standards	Characterization and Quality Control Life Cycle Management Stability

TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Bioanalytics Chemical	Regulations (BMV/GLP/GCP/CLIA)	Biomarkers Drug (and Metabolites) GCP/GLP Compliance for Bioanalytical Labs General Topics ICH and Harmonization Immunogenicity and Risk Assessment Samples and Reagent Stability
Bioanalytics Chemical	Samples and Laboratory Management	Bioanalytical Documentation and Reports Biorepositories Informed Consent Laboratory Information Management System (LIMS) Patient-Centric Sampling (microsampling and dried blood spots) Post-Collection Sample Condition and Record Management
Clinical Pharmacology Biomolecular	Biomarkers	Clinical Qualification Disease Heterogeneity Assessments High Content Data Analysis Observational/Epidemiology Studies
Clinical Pharmacology Biomolecular	Biostatistical Methodologies	Bayesian Methods Regulatory Recommendations Statistical Analysis Models Statistical Reporting Tools/Software Other
Clinical Pharmacology Biomolecular	Clinical Trials	Designs and Methodology Dosing Strategies Ethics in Clinical Trials Modeling and Simulation Monitoring Patient Stratification Regulatory Guidance Other
Clinical Pharmacology Biomolecular	Immunogenicity	Clinical Relevance Immunogenicity Risk Assessments Integrated Summary of Immunogenicity Post-marketing Surveillance REMS
Clinical Pharmacology Biomolecular	In Vitro Studies	ADME Biomarkers/Pharmacodynamic Measures Blood to Plasma Partitioning Drug Transport and Drug Interactions Genetic Variation/PGx Testing Protein Binding Other
Clinical Pharmacology Biomolecular	Modalities	ADCs Alternative Scaffold CAR-T CD3 Bispecifics

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TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Clinical Pharmacology Biomolecular	Modalities *Continued*	Cell-Based Therapy Encapsulated Drugs (lipid, nanoparticle, and viral vectors) Multispecific Antibodies Nanoparticle-Based Oligos, RNAs, and Locked Nucleic Acids Vaccines Other
Clinical Pharmacology Biomolecular	Modeling and Simulation	Absorption Model Allometric Scaling Comparator Modeling Decision Making Dose Project/Selection/Justification Imaging Based Approach In Vivo-In Vitro Correlation (IVIVC) Modeling Maternal/Fetal PK Model Pediatric Model Pharmacometrics Physiologically Based Pharmacokinetics (PBPK) Model PK/PD Modeling Population PK Modeling Quantitative Systems Pharmacology (QSP) Tools/Software Translational Modeling Other
Clinical Pharmacology Biomolecular	Regulatory Guidance/ Submissions	CDISC Clinical Study Reports (CSRs) Clinical Trial Protocols CTD/eCTD Models 1 to 5 Data Management FDA/EMA/PMDA Meetings Labeling NDA/BLA/ANDA Submissions Safety Other
Clinical Pharmacology Biomolecular	Type of Human Studies	Bioequivalence Biosimilars Diseased Population Drug-Drug Interaction (DDI) First-Time-in-Human (FTIH) Food Effect Geriatric Multiple Ascending Dose (MAD) Organ Impairment Pediatric Radio-Labeled Mass Balance and ADME Relative and Absolute BA Single Ascending Dose (SAD) Thorough QT/QTc (TQT) Other
Clinical Pharmacology Chemical	Biomarkers	Clinical Qualification Disease Heterogeneity Assessments High Content Data Analysis Observational/Epidemiology Studies

TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Clinical Pharmacology Chemical	Biostatistical Methodologies	Bayesian Methods Regulatory Recommendations Statistical Analysis Models Statistical Reporting Tools/Software Other
Clinical Pharmacology Chemical	Clinical Trials	Designs and Methodology Dosing Strategies Ethics in Clinical Trials Modeling and Simulation Monitoring Patient Stratification Regulatory Guidance Other
Clinical Pharmacology Chemical	Immunogenicity	Clinical Relevance Immunogenicity Risk Assessments Integrated Summary of Immunogenicity Post-marketing Surveillance REMS
Clinical Pharmacology Chemical	In Vitro Studies	ADME Biomarkers/Pharmacodynamic Measures Blood to Plasma Partitioning Drug Transport and Drug Interactions Genetic Variation/PGx Testing Protein Binding Other
Clinical Pharmacology Chemical	Modeling and Simulation	Absorption Model Allometric Scaling Comparator Modeling Decision Making Dose Project/Selection/Justification Imaging Based Approach In Vivo-In Vitro Correlation (IVIVC) Modeling Maternal/Fetal PK Model Pediatric Model Pharmacometrics Physiologically Based Pharmacokinetics (PBPK) Model PK/PD Modeling Population PK Modeling Quantitative Systems Pharmacology (QSP) Tools/Software Translational Modeling Other
Clinical Pharmacology Chemical	Regulatory Guidance/ Submissions	CDISC Clinical Study Reports (CSRs) Clinical Trial Protocols CTD/eCTD Models 1 to 5 Data Management FDA/EMA/PMDA Meetings Labeling NDA/BLA/ANDA Submissions Safety Other

TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Clinical Pharmacology Chemical	Type of Human Studies	Bioequivalence Biosimilars Diseased Population Drug-Drug Interaction (DDI) First-Time-in-Human (FTIH) Food Effect Geriatric Multiple Ascending Dose (MAD) Organ Impairment Pediatric Radio-Labeled Mass Balance and ADME Relative and Absolute BA Single Ascending Dose (SAD) Thorough QT/QTc (TQT) Other
Manufacturing and Analytical Characterization Biomolecular	Analytical	Combination Products Excipients Immunogenicity Impurities Modality Specific Methods - Cell Therapy Modality Specific Methods - Free Oligonucleotide Modality Specific Methods - Gene Therapy Modality Specific Methods - Protein Modality Specific Methods - Vaccine/ Tolerance Induction Modality Specific Methods - Other New Technology Potency/Bioassay (Sub)visible Particles Other
Manufacturing and Analytical Characterization Biomolecular	Automation	Computer Validation Other
Manufacturing and Analytical Characterization Biomolecular	Biosimilar Manufacturing	Biosimilarity Assessment Patent Protection Other
Manufacturing and Analytical Characterization Biomolecular	Drug Product Manufacturing and Development	Aseptic Technologies - Mixing, Sterilization, and Filling Cell Therapies Freezing and Thawing Immunogenicity and Critical Quality Attributes Lyophilization and Drying Technologies Manufacturing and Assembly of Drug/Device Combinations Manufacturing of Drug Delivery Systems Primary Packaging - Container Closure Integrity Primary Packaging - Syringes Primary Packaging - Vials Primary Packaging - Other Process Characterization and Optimization

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TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Manufacturing and Analytical Characterization Biomolecular	Drug Product Manufacturing and Development *Continued*	Protein Aggregation and Degradants Secondary Packaging Storage Considerations Vaccines Viral and Non-viral Vectors and Gene Therapy Visible and Subvisible Particles Visual Inspection Other
Manufacturing and Analytical Characterization Biomolecular	Drug Substance Manufacturing and Development	API Packaging and Storage Cell Line Development Cell Therapies Clonality Assessments Expression Systems - Cellular and Cell-Free Genetic and Cell Line Engineering Mammalian Cell Culture Media Development Microbial/Yeast Fermentation Process Optimization and Intensification Protein Aggregation during Processing and Immunogenicity Purification and Virus Removal Vaccines Virus Safety/Removal Viral and Non-viral Vectors and Gene Therapy Other
Manufacturing and Analytical Characterization Biomolecular	General Aspects and Strategies	Change Control CMO Management Drug Master Files Drug Substance and Drug Product Shipment Electronic Records Handling Control Substances (DEA) Inspections and GMP Lean Manufacturing/Six Sigma/ Operational Excellence Life Cycle Management Manufacturing Economics Materials Management and Warehousing Regulatory Strategy Supply Chain Other
Manufacturing and Analytical Characterization Biomolecular	Health, Safety, and Environment	Containment and Isolators High-Potent Drug Manufacturing OEL and PDE Other
Manufacturing and Analytical Characterization Biomolecular	Innovative/Novel Processing Technologies and Concepts	For Use in Drug Product Manufacture For Use in Drug Substance Manufacture Other
Manufacturing and Analytical Characterization Biomolecular	Integrated and Continuous Processing and Manufacturing	For Use in Drug Product Manufacture For Use in Drug Substance Manufacture Other

TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Manufacturing and Analytical Characterization Biomolecular	Manufacture of Clinical Supplies	Blinding of Comparator Drugs Phase Appropriate GMP Speed to Patient Other
Manufacturing and Analytical Characterization Biomolecular	Plant Engineering and Maintenance	Facility Design Legacy Facility Innovation/Renovation Media Media Fills Media/Buffer Preparation and Fluid Management Modeling and Scheduling Multiproduct Batch Plants Modular Manufacturing Plant Incident Investigations Other
Manufacturing and Analytical Characterization Biomolecular	Process Design and Controls	Cleaning Validation Control of Impurity Formation In-Process Controls Process Analytical Technology and Parametric/Real-Time Release Process Modeling and Simulations Process Validation/Continuous Process Validation QbD and Assessment of Process Parameters Scale-Up/Process Transfers Statistical Process Controls and Six Sigma Use of Prior Knowledge and Risk-Based Approaches Other
Manufacturing and Analytical Characterization Biomolecular	Single-Use and Disposable Systems	For Use in Drug Product Manufacture For Use in Drug Substance Manufacture Leachables and Extractables Other
Manufacturing and Analytical Characterization Chemical	Analytical	Continuous/Real-Time Release Drug Release Measurement - Biorelevant Dissolution Drug Release Measurement - Cascade Impaction Drug Release Measurement - Dissolution Drug Release Measurement - Forms Drug Release Measurement - Other Excipients Impurities and Degradation - Forced Degradation Impurities and Degradation - Impurity Quantitation Impurities and Degradation - In Silico Predecision of Stability Impurities and Degradation - Other Method Development Strategies Model Maintenance New Analytical Technologies Physical Characterization Techniques Process Analytical Technology and Continuous Release Testing Real Time Release Testing Other

TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Manufacturing and Analytical Characterization Chemical	Automation	Computer Validation Other
Manufacturing and Analytical Characterization Chemical	Drug Product Manufacturing and Development	Aseptic Technologies and Sterilization - Filling Aseptic Technologies and Sterilization - Filtration Aseptic Technologies and Sterilization - Mixing Aseptic Technologies and Sterilization - Other Bulk Packaging Freezing and Thawing Immunogenicity and Critical Quality Attributes Liquids Manufacture - Oral and Topical Liquids Liquids Manufacture - Other Lyophilization and Drying Technologies Manufacturing and Assembly of Drug/Device Combinations Manufacturing of Aerosols and DPI Manufacturing of Drug Delivery Systems Primary Packaging - Blisters Primary Packaging - Bottles Primary Packaging - Container Closure Integrity Process Optimization Secondary Packaging Semi-solids Manufacture - Cremes Semi-solids Manufacture - Liposomes, Solid Lipid Nanoparticles Semi-solids Manufacture - Other Shipping Studies Solids Manufacture - Capsules Solids Manufacture - Drug Product Intermediates Solids Manufacture - Mini-tablets Solids Manufacture - Powders Solids Manufacture - Tablets and Granules Solids Manufacture - Other Storage Considerations Visual Inspection Other
Manufacturing and Analytical Characterization Chemical	Drug Substance Manufacturing and Development	API Kilo Lab API Packaging and Storage Control of Impurity Formation Crystal Structure/Polymorph Screening Crystallization Development Filtration Genotoxic Impurities Immunogenicity and Critical Quality Attributes Milling and Micronization Technologies Particle Size Control Process Chromatography Process Optimization Purification Other

TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Manufacturing and Analytical Characterization Chemical	General Aspects and Strategies	Change Control CMO Management Drug Master Files Drug Substance and Drug Product Shipment Electronic Records Handling Control Substances (DEA) Inspections and GMP Lean Manufacturing/Six Sigma/ Operational Excellence Life Cycle Management Manufacturing Economics Materials Management and Warehousing Regulatory Strategy Supply Chain Other
Manufacturing and Analytical Characterization Chemical	Generic Manufacturing	Patent Protection Pharmaceutical Equivalence Assessment Other
Manufacturing and Analytical Characterization Chemical	Health, Safety, and Environment	Containment and Isolators Explosion Protection Green Chemistry High-Potent Drug Manufacturing OEL and PDE Solvent Recovery Other
Manufacturing and Analytical Characterization Chemical	Innovative/Novel Processing Technologies and Concepts	For Use in Drug Product Manufacture For Use in Drug Substance Manufacture Other
Manufacturing and Analytical Characterization Chemical	Integrated and Continuous Processing and Manufacturing	For Use in Drug Product Manufacture For Use in Drug Substance Manufacture Other
Manufacturing and Analytical Characterization Chemical	Manufacture of Clinical Supplies	Blinding of Comparator Drugs Phase Appropriate GMP Other
Manufacturing and Analytical Characterization Chemical	Plant Engineering, Equipment, and Maintenance	Clean Media Facility Design Media Media Fills Modeling and Scheduling Multiproduct Batch Plants Modular Manufacturing Plant Incident Investigations Other

TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Manufacturing and Analytical Characterization Chemical	Process Design and Controls	Cleaning Validation Control of Impurity Formation In-Process Controls Process Analytical Technology and Parametric/Real-Time Release Process Modeling and Simulations Process Validation QbD and Assessment of Process Parameters Robustness/CPV Continuous Process Verification Scale-Up/Process Transfers Statistical Process Controls and Six Sigma Use of Prior Knowledge and Risk-Based Approaches Other
Manufacturing and Analytical Characterization Chemical	Single-Use and Disposable Systems	For Use in Drug Product Manufacture For Use in Drug Substance Manufacture Leachables and Extractables Other
Formulation and Delivery Biomolecular	Administration	DP Handling In-Use Compatibility Nasal/Pulmonary Ocular Otic Potent Modalities Sterility and Microbiology Strategies Transdermal Other
Formulation and Delivery Biomolecular	Drug Delivery	Extended Release (Non-implant) Implants On Body Delivery Systems (OBDS) Other Routes of Administration - Ocular Other Routes of Administration - Otic Other Routes of Administration - Transdermal and Topical Other Routes of Administration - Other Other
Formulation and Delivery Biomolecular	Drug Delivery, Devices, and Drug Device	Design Control Hardware Human Factor Engineering New Delivery Technologies Patient-Centric Development Software

TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Formulation and Delivery Biomolecular	Formulation	Cell Therapy Free Oligonucleotide Gene Therapy Protein - Developability Assessment Protein - Excipients Protein - High-Throughput Screening Protein - Lyo Protein - Syringes Protein - Topics Protein - Other Vaccine/Tolerance Induction Other
Formulation and Delivery Biomolecular	Primary Packaging	Compatibility Container Closure Integrity Extractables/Leachables New Materials
Formulation and Delivery Biomolecular	Regulatory Considerations	Accelerated Approval Pathways Bioequivalence Biosimilars Innovative Technologies Inspections and GMPs Large Market Developments New Regulations and Guidances Risk Assessment Implementation Smaller Market Developments Stability Requirements (Sub)visible Particles
Formulation and Delivery Chemical	Biopharmaceutics	BCS, DCS Bioequivalence (also Regulatory) Comparability Assessments IVIVC Predictive Modeling Other
Formulation and Delivery Chemical	Drug Delivery	Extended Release (Non-implant) Implants Other Routes of Administration - Ocular Other Routes of Administration - Otic Other Routes of Administration - Transdermal and Topical Other Routes of Administration - Other Nanoparticles Other
Formulation and Delivery Chemical	Drug Delivery, Devices, and Drug Device	Design Control Hardware Human Factor Engineering New Delivery Technologies Patient-Centric Development Software

TRACKS-SUBTRACKS/TOPICS REVIEW GROUPS

TRACK-SUBTRACK	PRIMARY TOPIC	SUBTOPIC
Formulation and Delivery Chemical	Formulation	Advanced Dissolution Testing Amorphous and Co-crystal Systems Bioavailability Enhancement Drug Substance Properties Excipients Fixed Dose Combinations Inhalation and Nasal Oral - Immediate Release Oral - Modified Release Parenterals Predictive Modeling Preformulation Special Populations
Formulation and Delivery Chemical	Primary Packaging	Compatibility Container Closure Integrity Extractables/Leachables New Materials
Formulation and Delivery Chemical	Regulatory Considerations	Accelerated Approval Pathways Bioequivalence Biosimilars Innovative Technologies Inspections and GMPs Large Market Developments New Regulations and Guidances Patient Focused Drug Development Guidelines Risk Assessment Implementation Smaller Market Developments Stability Requirements (Sub)visible Particles