CLINICAL THERAPEUTICS
The International Peer-Reviewed Journal of Drug Therapy

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DESCRIPTION

Clinical Therapeutics provides peer-reviewed, rapid publication of recent developments in drug and other therapies as well as in diagnostics, pharmacoconomics, health policy, treatment outcomes, and innovations in drug and biologics research. In addition, Clinical Therapeutics features updates on specific topics collated by expert Topic Editors. Clinical Therapeutics is read by a large international audience of scientists and clinicians in a variety of research, academic, and clinical practice settings. Articles are indexed by all major biomedical abstracting databases.

Published articles range from pivotal studies exploring new chemical entities in large, multicenter trials to those exploring repurposing of marketed agents. Additionally, pilot studies; reports that assess drug safety and tolerability in all phases of development; new routes of administration and new formulations; pharmacokinetic, bio-availability, and biosimilarity; and changes in practice guidelines and standards, are all of interest for publication. Clinical Therapeutics also understands the importance of strengthening the body of evidence surrounding particular agents through the publication of replication studies, negative trials, and failed trials.

Beyond the clinic, we seek reports that examine the real-world implications of therapeutics such as comparative effectiveness and pharmacoconomics studies as well as work that has implications for health policy. Commentaries, which include perspectives and contemporary issues, are sought to offer a balance of viewpoints and scholarly opinion on a broad array of drug-related topics. Case reports, which remain a vital part of our mission, offer clinically valuable lessons. All manuscripts are peer reviewed by independent clinicians or scientists for clinical relevance, technical accuracy, methodological rigor, clarity, and objectivity using a blind review process.

In addition to feature articles published monthly, each issue of Clinical Therapeutics features a specific theme section dedicated to an annual update of a specific topic area. A special guest editor will comprise each update with reviews, commentaries, and original research highlighting what’s new or controversial in the topical specialty. Authors are invited to submit manuscripts for consideration in the topic updates, identifying submissions as such in their cover letters. Submissions not selected for the updates will be considered for general publication. Submit your manuscript at https://www.editorialmanager.com/clinther.
AUDIENCE

Research Clinicians in Academia and Industry, Practicing Physicians, Pharmacologists, and Specialists in Pharmacoeconomics, Outcomes Research and Health Policy.

ABSTRACTING AND INDEXING

Current Contents - Clinical Medicine
Chemical Abstracts
Current Opinion Series
Cancerlit
BIOSIS Citation Index
De Haen Drug Data
Embase
International Pharmaceutical Abstracts
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GUIDE FOR AUTHORS

INTRODUCTION
Clinical Therapeutics provides peer-reviewed, rapid publication of recent developments in drug and other therapies as well as in diagnostics, pharmacoeconomics, health policy, treatment outcomes, and innovations in drug and biologics research. In addition Clinical Therapeutics features updates on specific topics collated by expert Topic Editors. Clinical Therapeutics is read by a large international audience of scientists and clinicians in a variety of research, academic, and clinical practice settings. Articles are indexed by all major biomedical abstracting databases.

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- For Review articles: A flat fee of USD $2500
- For Commentaries, Brief Reports, Pilot Studies, and Case Reports: A flat fee of USD $2000
- For Research Letters: A flat fee of USD $1000

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ARTICLE TYPES

Original Research

Submissions categorized as Original Research describe substantive, well-controlled clinical research projects including clinical trials, pharmacokinetic/pharmacodynamic studies, meta-analyses, observational studies, health economic evaluations, and epidemiologic studies. Manuscripts should be prepared as described (See PREPARATION AND FORMATTING) and must provide enough detail about the study design, population, interventions, data collection and analysis methods, and outcomes to permit study replication. Data must be original and presented in accordance with journal policies (See EDITORIAL POLICIES) and EQUATOR Reporting Guidelines for the applicable study design (eg, CONSORT for randomized trials, STROBE for observational studies, CHEERS for economic evaluations, PRISMA for meta-analyses).

Abstract: ≤400 words, structured (See Abstract)
Keywords: 4-6 terms
Main Text: ≤6000 words, structured as follows: Introduction, Participants and Methods, Results, Discussion, Conclusions
Table/Figures: ≤8
References: Required, unlimited
Supplemental Material: Allowed, unlimited length (See Supplemental Material)

Reviews

Comprehensive, evidence-based narrative and systematic reviews are welcome. For the Pharmacoeconomics, Outcomes, and Health Policy section, only systematic reviews will be considered. Authors should contact the editorial office to discuss the topic area to avoid duplication with previously submitted or accepted manuscripts.

Systematic reviews should critically assess available data on a specific topic relevant to clinical practice, disease prevention, diagnostics, therapeutics, or health policy. Systematic reviews should follow PRISMA guidelines (http://www.prismastatement.org/index.htm) and include a PRISMA-style flow diagram (as a Figure or Supplemental Material) and checklist for review. The Methods section should identify the databases that were searched, search terms used, and inclusion/exclusion criteria for identified articles; an assessment of the validity of reviewed studies; and a summary that includes future directions for studies in this area. Each study mentioned in the review should include the study design, a description of the study population (age range, disease/severity), the dose and duration of each treatment administered, and the data and P values to accompany any valid comparisons. While not required, prospective registration of systematic review protocols is strongly encouraged. If available, the protocol registration number, registry name, and URL should be indicated in the Methods. Systematic reviews should be identified as such in the title or subtitle.

Abstract: ≤400 words, structured (See Abstract)
Keywords: 4-6 terms
Main Text: ≤6000 words, structured as follows: Introduction, Methods, Results. Discussion, Conclusions
Tables/Figures: ≤6
References: Required, unlimited
Supplemental Material: Allowed, unlimited length (See Supplemental Material)

Narrative reviews should provide up-to-date information relevant to clinical practice, public health, or clinical-stage development of therapeutics and/or diagnostics. Narrative reviews should not focus solely on the authors' own work. Narrative reviews should include an Introduction that describes the background, purpose, and perspective of the article; a Methods section that describes the approach and literature search criteria (if any). A separate Results section is not required. Each study mentioned in the review should include the study design, a description of the study population (age range, disease/severity), the dose and duration of each treatment administered, and the data and P values to accompany any valid comparisons. Discussion of pre-clinical data is permitted to complement discussion of therapeutic/diagnostic strategies and their development. Narrative reviews must be identified as such in the Abstract and Methods.

Abstract: ≤400 words, structured (See Abstract)
Keywords: 4-6 terms
Main Text: ≤6000 words, structured as follows: Introduction, Methods, Results (optional), Discussion, Conclusions
Tables/Figures: ≤6
References: Required, unlimited
Supplemental Material: Allowed, unlimited length (See Supplemental Material)

Commentaries

These papers should address an important and current issue in clinical practice, health policy, or therapeutics/diagnostics research from the author's perspective. All clinical recommendations should be supported by relevant published guidelines or peer-reviewed literature. Evidence-based statements must be clearly distinguished from author opinion. Discussion of pre-clinical data is permitted to complement discussion of therapeutic/diagnostic strategies and their development. The submission should include a descriptive title, a brief Abstract, an Introduction, pertinent information detailing the position of the paper, a Discussion, a Conclusion (which may be part of the discussion), and references.

Abstract: ≤300 words, unstructured (See Abstract)
Keywords: 4-6 terms
Main Text: 3000-3500 words, structured as follows: Introduction, Discussion, Conclusions
Tables/Figures: ≤5
References: ≤60, required
**Brief Reports**

These papers are reports of preliminary clinical investigations that are narrowly focused or provide limited findings. The submission should include a descriptive and succinct title, a structured Abstract, an Introduction that specifies the importance of the study, a Methods section, Results, a Discussion, a Conclusion, and references. Although these submissions are shorter in length, Brief Reports must adhere to the journal's ethical requirements and data reporting policies (See EDITORIAL POLICIES).  
*Abstract:* ≤250 words, structured (See Abstract)  
*Keywords:* 4-6 terms  
*Main Text:* 2000-3000 words, structured as follows: Introduction, Methods, Discussion, Conclusions  
*Tables/Figures:* ≤3  
*References:* ≤30, required  
*Supplemental Material:* Allowed, unlimited (See Supplemental Material)

**Pilot Studies**

A pilot study is a preliminary, exploratory, preparatory, small-sample effort undertaken to decide whether a larger study is warranted. The sample size is too small to permit generalizability, but it should provide a window into what a larger trial would look like. The submission should include a descriptive and succinct title, a structured Abstract, an Introduction that specifies the importance of the study, a Methods section, Results, a Discussion, a Conclusion, and references. Pilot Studies must adhere to the journal's ethical requirements and data reporting policies (See EDITORIAL POLICIES).  
*Abstract:* ≤250 words, structured (See Abstract)  
*Keywords:* 4-6 terms  
*Main Text:* 2000-3000 words, structured as follows: Introduction, Methods, Discussion, Conclusions  
*Tables/Figures:* ≤3  
*References:* ≤30, required  
*Supplemental Material:* Allowed, unlimited (See Supplemental Material)

**Research Letters**

These letters are focused on previously published studies from which new findings have been generated. Since methods and other informative material are contained in the original paper, they can be referenced rather than repeated. Alternatively, research letters can describe novel or hypothesis-generating research that may stimulate further investigation or alert readers to clinically relevant but preliminary findings. These submissions should include a descriptive and succinct title; an Introduction that specifies the rationale for the report, beginning with a statement similar to "This communication provides..."; a description of any new methods and results; a Discussion/Conclusion section; and selected references. Please note that Research Letters may be chosen, at the editor's discretion, to be published online only. In such instances, authors will be informed of this decision at acceptance and are free to withdraw their submission. Online only articles are indexed and are available in full text or PDF formats identical to that of print articles.  
*Abstract:* None  
*Keywords:* 4-6  
*Main Text:* 1000-2000 words, structured as follows: Introduction, Methods, Discussion, Conclusions  
*Tables/Figures:* ≤2  
*References:* ≤30, required  
*Supplemental Material:* Not permitted

**Case Reports**

Case reports are retrospective analyses of one, two, or three clinical cases. Case reports are an important part of post-marketing surveillance. They serve an alerting function by informing about new, unusual, or unexpected events. These events may be adverse drug reactions, drug-drug interactions, or drug-disease interactions. Before submitting a case report, the author(s) must conduct a thorough literature search as well as a review of product labeling when a drug is involved. This will reduce the reporting of what may already be well known.  

Reports of suspected adverse drug reactions should provide a description of the event, details regarding the implicated medication (e.g., purpose, when initiated), effects of discontinuation or re-challenge, treatment for the reaction, and duration of patient follow-up, if any. Evidence for causality must be strong. In the case of adverse drug events, use of the Naranjo Adverse Drug Reaction probability scale to determine the likelihood that the events were drug-related (Naranjo

Importantly, authors should clearly indicate in the cover letter whether the case was part of a larger study or meta-analysis, and whether the case was reported in aggregate elsewhere.

The report should include a descriptive, succinct title; an introduction; a well-documented case description; discussion; conclusions; and references. The Introduction should announce the subject and purpose of the report, including statements of why the case is important and how the literature search was performed. The Case Description should include a narrative account of the case with brief, pertinent clinical, laboratory, and medication information. The Discussion should comment on evidence that the case is new or unusual and consider possible alternative explanations for case features. The Conclusions should provide a summary of the adverse drug reaction-medication relationship, how to treat it, and how to avoid it. (For more information about what constitutes a good case report, see Vandenbroucke JP. In defense of case reports and case series. Ann Intern Med. 2001;134:330-334 and DeBakey L, DeBakey S. The case report. I. Guidelines for preparation. Int J Cardiol. 1983;4:357-364.)

To be considered, authors must provide documentation of patient informed consent to publish, which can be attached to the cover letter. All identifying information must be masked per HIPAA guidelines prior to submission. (See Ethical Considerations for Case Reports).

Please note that Case Reports may be selected, at the editor's discretion, to be published online only. Additionally, authors may be asked to reduce the length of the report substantially if similar cases were reported previously. In such cases, authors will be informed of the decision to forgo print at acceptance. Online only articles will be indexed and available as full text or PDF, identical to that of print articles.

Abstract: None
Keywords: 4-6
Main Text: 1500-3500 words, structured as follows: Introduction, Case Description, Discussion, Conclusions
Tables/Figures: ≤2
References: ≤15, required
Supplemental Material: Not permitted

Letters to the Editor
These are objective, constructive, or educational critiques of papers published in Clinical Therapeutics. Accepted letters will be sent to the author of the original paper for a response. Each letter and response is published together. Alternatively, letters may focus on topical issues that are of interest to readers of Clinical Therapeutics.

Abstract: None
Keywords: None
Main Text: ≤1000 words, unstructured
Tables/Figures: ≤1
References: Required, ≤5
Supplemental Material: Not permitted

Video Articles
Clinical Therapeutics encourages authors who have presented a talk at a meeting to convert their talk into a video production for online publication. A pre-submission inquiry is required for this type of submission. See Video Article Guidelines for preparation instructions.

Declaration of generative AI in scientific writing
The below guidance only refers to the writing process, and not to the use of AI tools to analyse and draw insights from data as part of the research process.

Where authors use generative artificial intelligence (AI) and AI-assisted technologies in the writing process, authors should only use these technologies to improve readability and language. Applying the technology should be done with human oversight and control, and authors should carefully review and edit the result, as AI can generate authoritative-sounding output that can be incorrect, incomplete or
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Statement: During the preparation of this work the author(s) used [NAME TOOL / SERVICE] in order to [REASON]. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

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Clinical Therapeutics (CT) permits the submission of manuscripts that have been posted on preprint servers, including bioRxiv. CT does not consider the posting of manuscripts to a preprint server as a prior publication, provided that the following conditions are met: The manuscript has not undergone peer review. Upon submission of a manuscript to CT, authors must acknowledge in the Cover Letter that the manuscript has been posted on a preprint server and must provide all associated accession numbers or DOIs. The preprint version may not have been indexed in MEDLINE or PubMed. Versions of a manuscript that have been altered as a result of the CT peer review process may not be posted on a preprint server. Upon acceptance and publication in CT, the CT DOI is to be considered the one representing this published work in all credits, citation, and attributions. Upon publication in CT, authors are responsible for updating the archived preprint with a DOI and link to the published version of the article. Authors should disclose that the article has been posted on a preprint server in the Acknowledgments/Disclosures section of the paper.

**Reporting sex- and gender-based analyses**

**Reporting guidance**

For research involving or pertaining to humans, animals or eukaryotic cells, investigators should integrate sex and gender-based analyses (SGBA) into their research design according to funder/sponsor requirements and best practices within a field. Authors should address the sex and/or gender dimensions of their research in their article. In cases where they cannot, they should discuss this as a limitation to their research's generalizability. Importantly, authors should explicitly state what definitions of sex and/or gender they are applying to enhance the precision, rigor and reproducibility of their research and to avoid ambiguity or conflation of terms and the constructs to which they refer (see Definitions section below). Authors can refer to the Sex and Gender Equity in Research (SAGER) guidelines and the SAGER guidelines checklist. These offer systematic approaches to the use and editorial review of sex and gender information in study design, data analysis, outcome reporting and research interpretation - however, please note there is no single, universally agreed-upon set of guidelines for defining sex and gender.

**Definitions**

Sex generally refers to a set of biological attributes that are associated with physical and physiological features (e.g., chromosomal genotype, hormonal levels, internal and external anatomy). A binary sex categorization (male/female) is usually designated at birth (“sex assigned at birth”), most often based solely on the visible external anatomy of a newborn. Gender generally refers to socially constructed roles, behaviors, and identities of women, men and gender-diverse people that occur in a historical and cultural context and may vary across societies and over time. Gender influences how people view themselves and each other, how they behave and interact and how power is distributed in society. Sex and gender are often incorrectly portrayed as binary (female/male or woman/man) and unchanging whereas these constructs actually exist along a spectrum and include additional sex categorizations and gender identities such as people who are intersex/have differences of sex development (DSD) or
identify as non-binary. Moreover, the terms "sex" and "gender" can be ambiguous—thus it is important for authors to define the manner in which they are used. In addition to this definition guidance and the SAGER guidelines, the resources on this page offer further insight around sex and gender in research studies.

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**PREPARATION AND Formatting**

The basic elements of all submissions are as follows, and details on each item are provided below. Manuscripts, tables, figures, and supplemental material must be submitted in their original file formats; do not submit PDFs.

1. **Document Requirement**
   - Cover Letter Required
   - ICMJE Form(s) Required for each author
   - Declaration of Interest Required
   - Title Page Required
   - Highlights Required for Original Research
   - Graphical Abstract Optional
   - Manuscript File (without author details) Required for new and revised submissions
   - Tables Optional
   - Figures Optional
   - Supplemental Material Optional for Original Research, Reviews, Brief Reports, and Pilot Studies
   - Response to Review Required for revised submissions
   - Marked Manuscript File (with tracked changes, without author details) Required for revised submissions

**Double-anonymized review**

This journal uses double-anonymized review, which means the identities of the authors are concealed from the reviewers, and vice versa. More information is available on our website. To facilitate this, please include the following separately:

- **Title page (with author details):** This should include the title, authors' names, affiliations, and a complete address for the corresponding author including an e-mail address. Authors may provide their individual contribution statement on the title page if they are not using the CRediT roles.
- **Anonymized manuscript (no author details):** The main body of the paper (including the legends, references, and any acknowledgments) should not include any identifying information, such as the authors' names or affiliations.

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A cover letter is required for all article types. To facilitate double-anonymized peer review, the cover letter must be uploaded as a separate file in Word of PDF format; it will not be made available to reviewers. The cover letter should include:

- Title, authors, number of pages, and numbers of tables and figures
- Indication that the paper has been read and approved by all authors
- Name of the Special Section in which the paper is to be included, if applicable
- Information about any previous presentation of the data (eg, abstract, poster or presentation at a meeting or published on an preprint service [provide DOI])
- Information about the existence of any closely related manuscripts that have been submitted for simultaneous consideration to the same or another journal
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**Declaration of Interest**

All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential competing interests include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. Authors must disclose any interests in two places: 1. A summary declaration of interest statement in the title page file (if double-anonymized) or the manuscript file (if single-anonymized). If there are no interests to declare then please state this:
‘Declarations of interest: none’. This summary statement will be ultimately published if the article is accepted. 2. Detailed disclosures as part of a separate Declaration of Interest form, which forms part of the journal's official records. It is important for potential interests to be declared in both places and that the information matches. More information.

Authors should declare the role of study sponsors, if any, in the study design; in the collection, analysis and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

**Title Page**

To facilitate double-anonymized peer review, the title page must be uploaded as a separate file in the original file format; it will not be made available to reviewers.

**Essential title page information**

- **Title.** Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible. See Title.
- **Author names and affiliations.** Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. You can add your name between parentheses in your own script behind the English transliteration. Following each author name, indicate the highest academic degree(s) obtained. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower-case superscript letter immediately after the author's name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name and, if available, the e-mail address of each author.
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The manuscript file should contain the following items: title, abstract, clinical trial registration (if applicable), keywords, main text, acknowledgments, figure/table legends, references. These items are described in detail below. All author names and identifying information must be removed from the manuscript file to facilitate double-anonymized peer review. The manuscript file should be structured according to article type, be double-spaced, include page numbers, and follow AMA style except as indicated below (See Style).
Title
The title should be concise, informative, and focused on the study objective. Statements about the conclusion(s) of the work should be avoided. Randomized controlled trials, meta-analyses, and systematic reviews should be identified as such in the title. Subtitles can be used to provide supplementary information (e.g., study design); however, titles should be able to stand alone. Use nonproprietary drug names (See Names of Drugs and Devices); avoid abbreviations and formulae where possible.

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Structured abstracts are required for Original Research (≤400 words), Reviews (≤400 words), Brief Reports (≤250 words), and Pilot Studies (≤250 words). Structured abstracts should contain sufficient detail as directed by the extension to the CONSORT statement for abstracts, and should be formatted as follows:

Purpose: Briefly provides the frame of reference for the reader and identifies the knowledge gap that the article seeks to address; clearly states the purpose of the research; and identifies the scientific hypotheses and questions being asked.

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Immediately after the abstract, provide 4-6 keywords, using American spelling and avoiding general and plural terms and multiple concepts (avoid, for example, ’and’, ’of’). Be sparing with abbreviations: only abbreviations firmly established in the field may be eligible. These keywords will be used for indexing purposes.

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**Conclusions:** The main conclusions of the study should be present

Acknowledgments
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Drugs should be referred to by their universally accepted generic names, not by proprietary names, unless the specific trade name is essential to the methods or discussion. In such cases, use the proprietary name once and the generic or descriptive name thereafter. US adopted names (USANs) are acceptable. If unnamed compounds are referred to, as much information as possible (eg, class of compound) should be included and published references to the compound should be provided. If this is not possible because of intellectual property reasons, then this should be stated.

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clinicians guess assignments? Sham procedures must also be described in detail. We are instituting this change as part of our ongoing effort to facilitate replication of findings from trials. All too often this valuable information is omitted from published trial results. When appropriate these descriptions may be designated as Supplemental Digital Content. For more information, see Shader RI. Placebos, Active Placebos, and Clinical Trials. Clin Ther. 2017;39(3):451-454.

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For submissions to *Clinical Therapeutics*, a statement about safety should explicitly include the time period and only when there is a clear absence of harm as determined by relevant questioning, observation, and testing. It is possible that a drug or biologic may be considered tolerable at the same time that tests show it to be unsafe (e.g., a lengthened QTc interval). Conversely, a drug may be considered safe by all objective assessments, and yet produce side effects that can contribute to high degrees of dose interruption or discontinuation. Furthermore, a drug may also be considered prima facie unsafe when pharmacogenomic information suggests it will yield unwanted metabolites in certain individuals or be highly prone to clinically significant drug interactions with frequently used additional agents or foods. Safety assessments may need to be different for different age groups (e.g., effects on growth and development in children and youth, increased propensity to falls in the elderly, effects on life style for active adults). It is also important to remember that safety concerns may stem from excipients added during the manufacturing process rather than from the drug or biologic per se.) For more information, see Shader RI. Safety Versus Tolerability. Clin Ther. 2018;40(5):672-673.

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Because case reports place patient-specific information into the public domain, *Clinical Therapeutics* requires that authors obtain written consent to publish case details. Cases involving patients under 18 require assent by children and/or youth as well as written consent from a parent or guardian. In the United States, case reports must comply with the Health Insurance Portability and Accountability Act of 1996 (HIPPA) regulations. While some institutions exempt case reports that de-identify the patient completely, *Clinical Therapeutics* requires consent to publish even if the case details have been de-identified. Authors must:

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The slide set presentation will consist of:

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- Maximum length of videos is 4.5 minutes.
- Video file may not exceed 100 MB.
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