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# Author Guidelines

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This document outlines how to prepare the following article types for submission:

- Clinical Trial Protocol
- Clinical Trial Evaluation
- Drug Evaluation
- Device Evaluation
- Vaccine Evaluation
- Podcast
- Patient Perspective
- How I Treat

We recommend you read these guidelines in full before submitting your article.

For unsolicited submissions of any of the above article types, a pre-submission enquiry to the [Editor](#) is welcome.

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## Article types considered

	Bioanalysis	Biomarkers in Medicine	CNS Oncology	Colorectal Cancer	Epigenomics	Future Cardiology	Future Medicinal Chemistry	Future Microbiology	Future Neurology	Future Oncology	Future Rare Diseases	Future Science OA	Future Virology	Hepatic Oncology	Immunotherapy	Lung Cancer Management	Melanoma Management	Nanomedicine	Neurodegenerative Disease Management	Pain Management	Personalized Medicine	Pharmacogenomics	Regenerative Medicine	Therapeutic Delivery
Clinical Trial Evaluation	✗	✗	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗
Clinical Trial Protocol	✗	✗	✓	✓	✗	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✗
Device Evaluation	✗	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✓
Drug Evaluation	✗	✗	✓	✓	✗	✓	✗	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	✓
Vaccine Evaluation	✗	✗	✗	✗	✗	✓	✗	✓	✓	✓	✓	✗	✓	✓	✓	✗	✗	✗	✗	✗	✗	✗	✗	✓
Podcast	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Patient Perspective	✗	✗	✓	✓	✗	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✗	✗	✗	✗
How I Treat	✗	✗	✓	✓	✗	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✗	✗	✗	✗

## At-a-glance article formatting checklists

	Word count range	Practice Points	Abstract	Keywords	Intro.	Intro. to the trial	Background and rationale	Design	Data analysis	Discussion	Conclusion	Article Highlights	Ref. limit
<a href="#">Clinical Trial Protocol</a>	2000–4000	*	✓	✓ (5–8)	✓	✓	✓	✓	✗	✗	✓	✓	~50
<a href="#">Clinical Trial Evaluation</a>	2000–4000	*	✓	✓ (5–8)	✓	✓	✓	✓	✓	✓	✓	✓	~50

	Word count range	Abstract	Keywords	Intro.	Overview of the field	Intro. to compound/device/vaccine	Pharmacology	Clinical efficacy	Real-world evidence	Safety and tolerability	Regulatory affairs	Conclusion	Article Highlights	Ref. limit
<a href="#">Drug Evaluation</a>	4000–6000	✓	✓ (5–8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	~80
<a href="#">Device Evaluation</a>	4000–6000	✓	✓ (5–8)	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	~80
<a href="#">Vaccine Evaluation</a>	4000–6000	✓	✓ (5–8)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	~80

	Word count range	Abstract	Keywords	Body of the article	Future Perspective	Article Highlights	Ref. limit
<a href="#">Podcast</a>	1500–3000	✓	✓ (5–8)	✓	✗	✗	~10
<a href="#">Patient Perspective</a>	2000–4000	✓	✓ (5–8)	✓	✓	✓	~40
<a href="#">How I Treat</a>	4000–6000	✓	✓ (5–8)	✓	✓	✓	~80

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## Article types

Expert Medicine journals publish a range of article types, descriptions of which are outlined below. Authors are encouraged to consult the '[at-a-glance formatting checklist](#)' for details on word counts and other formatting requirements.

The information below gives an overview of the requirements for each article type published by Expert Medicine. However, authors should consult the International Committee for Medical Journal Editors (ICMJE) "*Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*" (<https://www.icmje.org/recommendations/>), in particular the section on "*Preparing a Manuscript for Submission to a Medical Journal*" prior to submitting to a Expert Medicine journal, for more detailed information.

### Clinical Trial Protocol

**Aim:** The aim of a Clinical Trial Protocol is to provide a concise review of the rationale and design of an ongoing trial (providing patient recruitment has not been completed at the time of submission) or cluster/program of studies. Authors are encouraged to discuss the implications of the study's results on clinical practice. Clinical Trial Protocols undergo external peer review. Reporting should follow the SPIRIT criteria (<https://www.spirit-statement.org>). A summary of required sections is provided below, but further information on these should be taken from the SPIRIT checklist. In addition, a completed SPIRIT checklist should be provided as Supplementary Material on submission of the article.

**Focus:** Authors should restrict their discussion to the indication investigated in the trials.

**Timing:** Trials are selected to be reviewed based on their relevance to the journal's audience and the potential implications of their findings to the field. Thus timing is critical and it is important that the deadlines set by the Editor are met. However, if you feel there is a need to delay publication, for instance to discuss new data presented at a scientific meeting or to coincide with the publication of primary literature, the Editor will be happy to accommodate such requests.

**Word limit:** 2000–4000 words (excluding abstract, article highlights, references & figure/table legends)

**Required sections** (for a more detailed description see [Article sections](#)):

- Title (maximum 120 characters)
- Author(s) names & affiliations
- Abstract (maximum 200 words)
- Plain language summary (optional; maximum 250 words)
- Keywords (5–8)
- Body of article
  - Introduction
    - Background and rationale
    - Objectives
    - Trial Design
  - Methods
    - Methods: Participants, interventions, and outcomes
    - Methods: Assignment of interventions (for controlled trials only)
    - Methods: Data collection, management, and analysis

- Methods: Monitoring
      - Ethics and dissemination
      - Conclusion
- Article Highlights
- References: target of approximately 50 references
- Reference annotations
- Acknowledgements: author acknowledgements, plus, where relevant, details of individuals who contributed to the article, but who did not fulfill the [criteria](#) to be listed as authors
- Disclosures: to include author contributions, disclosure statement, disclosure of any writing assistance (and the funding source for this), funding information, ethical declaration, data sharing statement and any other relevant information. For more information, see [below](#)
- Figures/Tables: should be submitted as separate files (see guidelines [below](#))

## Clinical Trial Evaluation

**Aim:** The aim of a Clinical Trial Evaluation is to provide a concise review of an individual trial or cluster/program of studies. For completed trials, each review summarizes all aspects of the trial, including the rationale, study design, timelines, results and data analysis. Authors are encouraged to discuss the implications of the study on clinical practice. Clinical Trial Evaluations undergo external peer review.

**Focus:** Authors should restrict their discussion to the indication investigated in the trials. It is recommended that national/regional regulatory product guidelines are followed, particularly in terms of indications and dosage. Additionally, for investigational products not yet licensed for any indication, the manuscript should make reference to this from the outset.

**Timing:** Several factors contribute to the selection of trials to be reviewed, including scientific need, emergence of new important clinical data, launches/approval of new indications, and the requirement for an alternative appraisal of the literature. Thus timing is critical and it is important that the deadlines set by the Editor are met. However, if you feel there is a need to delay publication, for instance to discuss new data presented at a scientific meeting or to coincide with the publication of primary literature, the Editor will be happy to accommodate such requests.

**Word limit:** 2000–4000 words (excluding abstract, article highlights, references & figure/table legends)

**Required sections** (for a more detailed description see [Article sections](#)):

- Title (maximum 120 characters)
- Author(s) names & affiliations
- Abstract (maximum 200 words)
- Plain language summary (optional; maximum 250 words)
- Keywords (5–8)
- Body of article
  - Introduction
  - Introduction to the trial
  - Background and rationale
  - Design
  - Data analysis (if applicable)
  - Discussion
  - Conclusion
- Article Highlights

- References: target of approximately 50 references
- Reference annotations
- Acknowledgements: author acknowledgements, plus, where relevant, details of individuals who contributed to the article, but who did not fulfill the [criteria](#) to be listed as authors
- Disclosures: to include author contributions, disclosure statement, disclosure of any writing assistance (and the funding source for this), funding information and any other relevant information. For more information, see [below](#).
- Figures/Tables: should be submitted as separate files (see guidelines [below](#))

## Drug Evaluation

**Aim:** The aim of a Drug Evaluation is to provide a concise review of the pharmacology, clinical efficacy and tolerability of a drug. Authors are encouraged to provide a critical appraisal of the most important and up-to-date information on the role of the drug in clinical practice. Drug Evaluations undergo external peer review.

**Focus:** Authors should restrict their discussion to licensed indications and it is recommended that national/regional regulatory product guidelines are followed, particularly in terms of indications and dosage. When a drug is discussed outside of its approved license, readers should be made aware of this fact in the first instance. For investigational drugs not yet licensed for any indication, the manuscript should make reference to this from the outset.

**Timing:** Several factors contribute to the selection of drugs to be reviewed, including scientific need, emergence of new important clinical data, launches/approval of new indications, and the requirement for an alternative appraisal of the literature. Thus timing is critical and it is important that the deadlines set by the Editor are met. However, if you feel there is a need to delay publication, for instance to discuss new data presented at a scientific meeting or to coincide with the publication of primary literature, the Editor will be happy to accommodate such requests.

**Word limit:** 4000–6000 words (excluding abstract, article highlights, references & figure/table legends)

**Required sections** (for a more detailed description see [Article sections](#)):

- Title (maximum 120 characters)
- Author(s) names & affiliations
- Abstract (maximum 200 words)
- Plain language summary (optional; maximum 250 words)
- Keywords (5–8)
- Body of article
  - Introduction
  - Overview of the field
  - Introduction to the compound
  - Pharmacology
  - Clinical efficacy
  - Real-world evidence (if applicable)
  - Safety and tolerability
  - Regulatory affairs
  - Conclusion
- Article Highlights
- References: target of approximately 80 references
- Reference annotations

- Acknowledgements: author acknowledgements, plus, where relevant, details of individuals who contributed to the article, but who did not fulfill the [criteria](#) to be listed as authors
- Disclosures: to include author contributions, disclosure statement, disclosure of any writing assistance (and the funding source for this), funding information, and any other relevant information. For more information, see [below](#).
- Figures/Tables: should be submitted as separate files (see guidelines [below](#))

## Device Evaluation

**Aim:** Device Evaluation articles should provide an independent perspective on the objective assessments of specific devices in development or clinical use to help inform clinical practice. Ideally, the review should encompass all aspects of the product, including basic technology, with the primary focus on clinical work and real-world evidence. Using the literature reviewed, authors are encouraged to critically appraise the most important and up-to-date information and discuss how the device is likely to impact management of specific diseases. Device Evaluations undergo external peer review.

**Focus:** Authors should restrict their discussion to licensed indications and it is recommended that national/regional regulatory product guidelines are followed, particularly in terms of indications. When a device is discussed outside of its approved license, readers should be made aware of this fact in the first instance. For investigational devices not yet licensed for any indication, the manuscript should make reference to this from the outset.

**Timing:** Several factors contribute to the selection of devices and technologies to be reviewed, including scientific need, emergence of new important clinical data, launches/approval of new indications, and the requirement for an alternative appraisal of the literature. Thus, timing is critical and it is important that the deadlines set by the Editor are met. However, if you feel there is a need to delay publication, for instance to discuss new data presented at a scientific meeting or to coincide with the publication of primary literature, the Editor will be happy to accommodate such requests.

**Word limit:** 4000–6000 words (excluding abstract, article highlights, references & figure/table legends)

**Required sections** (for a more detailed description see [Article sections](#)):

- Title (maximum 120 characters)
- Author(s) names & affiliations
- Abstract (maximum 200 words)
- Plain language summary (optional; maximum 250 words)
- Keywords (5–8)
- Body of article
  - Introduction
  - Overview of the field
  - Introduction to the device
  - Clinical efficacy
  - Real-world evidence (if applicable)
  - Safety and tolerability
  - Regulatory affairs
  - Conclusion
- Article Highlights
- References: target of approximately 80 references
- Reference annotations

- Acknowledgements: author acknowledgements, plus, where relevant, details of individuals who contributed to the article, but who did not fulfill the [criteria](#) to be listed as authors
- Disclosures: to include author contributions, disclosure statement, disclosure of any writing assistance (and the funding source for this), funding information, and any other relevant information. For more information, see [below](#).
- Figures/Tables: should be submitted as separate files (see guidelines [below](#))

## Vaccine Evaluation

**Aim:** The aim of a Vaccine Evaluation is to provide a concise review of the development, clinical efficacy and tolerability of a vaccine. Authors are encouraged to provide a critical appraisal of the most important and up-to-date information on the role of the vaccine in clinical practice. Vaccine Evaluations undergo external peer review.

**Focus:** Authors should restrict their discussion to licensed indications and it is recommended that national/regional regulatory product guidelines are followed, particularly in terms of indications and dosage. When a vaccine is discussed outside of its approved license, readers should be made aware of this fact in the first instance. For investigational vaccines not yet licensed for any indication, the manuscript should make reference to this from the outset.

**Timing:** Several factors contribute to the selection of vaccines to be reviewed, including scientific need, emergence of new important clinical data, launches/approval of new indications, and the requirement for an alternative appraisal of the literature. Thus, timing is critical and it is important that the deadlines set by the Editor are met. However, if you feel there is a need to delay publication, for instance to discuss new data presented at a scientific meeting or to coincide with the publication of primary literature, the Editor will be happy to accommodate such requests.

**Word limit:** 4000–6000 words (excluding abstract, article highlights, references and figure/table legends)

**Required sections** (for a more detailed description see [Article sections](#)):

- Title (maximum 120 characters)
- Author(s) names & affiliations
- Abstract (maximum 200 words)
- Plain language summary (optional; maximum 250 words)
- Keywords (5–8)
- Body of article
  - Introduction
  - Overview of the field
  - Introduction to the vaccine
  - Pharmacology
  - Clinical efficacy
  - Real-world evidence (if applicable)
  - Safety and tolerability
  - Regulatory affairs
  - Conclusion
- Article Highlights
- References: target of approximately 80 references
- Reference annotations
- Acknowledgements: author acknowledgements, plus, where relevant, details of individuals who contributed to the article, but who did not fulfill the [criteria](#) to be listed as authors

- Disclosures: to include author contributions, disclosure statement, disclosure of any writing assistance (and the funding source for this), funding information, and any other relevant information. For more information, see [below](#)
- Figures/Tables: should be submitted as separate files (see guidelines [below](#))

## Podcast

**Aim:** Podcast articles offer a different channel to inform health care professionals of new literature. Our podcast articles are peer-reviewed. These can be standalone podcast articles or podcasts that accompany a manuscript. These can be on any topic that fits within scope to the specified journal, ranging from interviews, patient perspectives on treatments to clinical trial protocols or research.

**Requirements:** Original submission should include a discussion guide. The discussion guide will be peer reviewed. Providing satisfactory peer review and author revisions, you will be asked to record the podcast and provide a matching transcript for submission. The podcast file should be provided as an mp4 file. If the podcast and transcript do not reflect the discussion guide further peer review or edits might be required. At the beginning of the podcast recording and transcript the authors should mention that all funding and disclosure information is available on the article homepage at Taylor & Francis Online ([www.tandfonline.com](http://www.tandfonline.com)). All podcast articles are published open access with a transcript of the podcast to aid discoverability. All standalone podcast articles are subject to an APC of \$2500. If you would like to receive an example, please contact [pubsols@tandf.co.uk](mailto:pubsols@tandf.co.uk)

**Word limit:** 1500–3000 words for the transcript (excluding abstract and references)

**Required sections** (for a more detailed description see [Article sections](#)):

- Title – 120 character word count
- Author(s) name and affiliation
- Abstract (maximum 200 words)
- Plain language summary (optional; maximum 250 words)
- Keywords (5–8)
- Body of article - Provide content as discussion guide
  - Discussion guide requires 5-6 talking points with 3-5 bullet points within each talking point. If you would like to receive an example, please contact [pubsols@tandf.co.uk](mailto:pubsols@tandf.co.uk)
- References: approximately 10 references
- Acknowledgements: author acknowledgements, plus, where relevant, details of individuals who contributed to the article, but who did not fulfill the [criteria](#) to be listed as author
- Disclosures: to include author contributions, disclosure statement, disclosure of any writing assistance (and the funding source for this), funding information, and any other relevant information. For more information, see below.

## Patient Perspective

**Aim:** Patient perspectives are personal commentaries authored by those closely impacted by long-term health conditions, for example patients, advocates, relatives, or caregivers & HCP. The sharing of these personal experiences aims to enhance the voices of patients and their advocates, ensuring that addressing the challenges of living with health conditions and their impact on patient's lives are placed at the forefront of strategies to develop and improve clinical practice. Patient Perspective articles undergo external peer review; however, reviewers will be briefed to review these articles for quality and relevance of argument only. They will not necessarily be expected to agree with the author's position. Taylor & Francis require that in addition to the above statements, authors request

patients to complete the Consent to Publish form before submission of an article and that authors keep a copy of these forms on record. If images are included in the article, authors must obtain Consent to Publish from the author using the Consent to Publish form [here](#). Please see our full image guidance [here](#). Healthcare professionals may be included as co-authors to provide an insight into the patient's relationship with members of their medical team, providing that all co-authors meet our authorship criteria.

**Word limit:** 2000–4000 words (excluding abstract, article highlights, references and figure/table legends)

**Required sections** (for a more detailed description see [Article sections](#)):

- Title (maximum 120 characters)
- Author(s) names & affiliations
- Abstract (maximum 200 words)
- Plain language summary (optional; maximum 250 words)
- Keywords (5–8)
- Body of article
  - Introduction
  - Patient's journey
  - Conclusion
- Article Highlights
- References: approximately 40 references
- Reference annotations
- Acknowledgements: author acknowledgements, plus, where relevant, details of individuals who contributed to the article, but who did not fulfill the [criteria](#) to be listed as authors
- Disclosures: to include author contributions, disclosure statement, disclosure of any writing assistance (and the funding source for this), funding information, and any other relevant information. For more information, see [below](#)
- Figures/Tables: should be submitted as separate files (see guidelines [below](#))

## How I Treat

**Aim:** How I Treat articles allow authors to provide an expert perspective on the treatment of certain diseases, describing their own experiences and providing practical considerations and guidance for the successful treatment of the disease. These are not intended to be case studies. How I Treat articles have the same basic structure and length as Review articles; however, they should be more speculative and forward-looking. They offer the author the opportunity to present criticism, address controversy or provide a personal angle on a significant issue. Authors are encouraged to be opinionated, with all positions concisely and clearly argued and referenced. How I Treat articles undergo external peer review; however, reviewers will be briefed to review these articles for quality and relevance of argument only. They will not necessarily be expected to agree with the author's position.

**Word limit:** 4000–6000 words (excluding abstract, article highlights, references and figure/table legends)

**Required sections** (for a more detailed description see [Article sections](#)):

- Title (maximum 120 characters)
- Author(s) names & affiliations
- Abstract: 200 words.
- Plain language summary (optional; maximum 250 words)
- Keywords (5–10)

- Body of article
- Future perspective
- Article highlights
- References: target of approximately 80 references
- Reference annotations
- Acknowledgements: author acknowledgements, plus, where relevant, details of individuals who contributed to the article, but who did not fulfill the [criteria](#) to be listed as authors
- Disclosures: to include author contributions, disclosure statement, disclosure of any writing assistance (and the funding source for this), funding information, and any other relevant information. For more information, see [below](#)
- Figures/Tables: should be submitted as separate files (see guidelines below)

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## Article sections

The following list provides notes on the key article sections; authors should consult the '[at-a-glance formatting checklists](#)' to determine which sections are required for their submission.

### Front material – all article types

#### Title

Concisely and clearly conveys the scope/novelty of the article including any key words or phrases people might use to search on the topic; not more than **120 characters**. The title should contain no brand names. Should not include abbreviations if possible, and should avoid redundant language such as "A study of..."

#### Author(s) names & affiliations

Including full name, address and e-mail. Where available, authors should also add their ORCID iD during the manuscript submission process.

#### *Patient authorship:*

Taylor & Francis is supportive of the inclusion of patients in all stages of research, including in the authorship of papers. Patient authors should be aware that they must provide an email address during submission to allow communications relating to the progress of their paper. In the event that the patient author is the corresponding author, please note that the email address provided upon submission will be published in the final article and made available to the general public. Patient authors should carefully consider whether to use an existing personal email address or to create an alternate email address that can be used for their authored works. Patient authors can include:

- A person who lives with or is affected by a disease or condition (i.e., a broad definition of patient that includes those with lived conditions or receiving health or social care, caregivers, family members and members of patient advocacy groups who represent them)
- A person who provides unique and valuable input from the patient perspective to the publication.
- Patients must meet the ICMJE authorship criteria. You can find the criteria for this on our defining authorship page here: <https://authorservices.taylorandfrancis.com/editorial-policies/defining-authorship-research-paper/>. Authors are encouraged to refer to [this tool](#),

which highlights how each of the four criteria above can be interpreted from the patient author perspective.

Further useful information for patient authors can be found here:

<https://authorservices.taylorandfrancis.com/editorial-policies/guidance-for-patient-authors/>

**Group authorship:** When a group name is included as an author (i.e., the XYZ Study Group), the respective group member names should be listed in the acknowledgements section. In relevant Medline/PubMed-indexed journals, these individuals are acknowledged as contributors to the article. The submitting author/agent should therefore ensure that group member names are included in full, are spelled correctly, and appear in the order they wish them to be listed on Medline/PubMed. More guidance from Medline can be found here:

<https://www.nlm.nih.gov/bsd/policy/authorship.html>.

### Abstract

Not more than **200 words**; no references should be cited in the abstract. The abstract should highlight the importance of the field under discussion within the journal’s scope, and clearly define the parameters of the article. For Clinical Trial Protocols the trial registry name, registration identification number, and the URL for the registry must be included at the end of the abstract. This should be in the following format: “Clinical trial registration: www.clinicaltrials.gov identifier is NCTXXXXXX”.

### Plain language summary (within article)

Plain language summaries (PLS) within an article are a short, text-only summary of the article with any technical jargon removed. PLS should be of a similar length to a regular abstract or shorter (no more than 250 words) and are featured within an article alongside the main abstract (and on PubMed, for journals that are indexed there). Wherever possible, PLS should be submitted at the same time as the manuscript. Expert Medicine encourages publication of PLS, but submission is not mandatory.

We recommend structuring the PLS as a series of questions, such as:

- What is this article about?
- What were the results?
- What do the results of the study mean?

### Example:

**What is this summary about?:** Sodium oxybate is a medicine for narcolepsy symptoms. It contains a high level of sodium. Should people taking sodium oxybate and their doctors worry about the sodium increasing their risk of heart or cardiovascular problems? This is a summary of an article that reviewed 20 years of published data to answer that question.

**What were the results?:** We found that sodium oxybate was not linked to cardiovascular risks, such as heart attacks or strokes.

**What do the results mean?:** This suggests that the sodium in sodium oxybate may not add cardiovascular risk for people with narcolepsy. People currently taking sodium oxybate should talk to their doctor to ask if they need to be concerned about the sodium in their medicine. People who take sodium oxybate are unlikely to need to change their sodium oxybate medicine because of the sodium.

## Keywords

Up to eight keywords (minimum of five; including therapeutic area, mechanism[s] of action etc.) plus names of drugs, devices and vaccines mentioned in the text.

## Body of the article – Clinical Trial Protocols & Clinical Trial Evaluations

The article content should be arranged under relevant headings and subheadings to assist the reader. Where available the clinical trial registration number should be included on the first mention of the trial in the main body of text. Mention of other trials should also include the relevant registration number, where available.

### Introduction

- Background and rationale
- Objectives
- Trial Design

### Methods (Clinical Trial Protocols only)

- Methods
  - Study setting
  - Eligibility criteria
  - Interventions
  - Outcomes
  - Participant timeline
  - Sample size
  - Recruitment
- Methods: Assignment of interventions (for controlled trials only)
  - Sequence generation
  - Allocation concealment mechanism
  - Implementation
  - Masking
- Methods: Data Collection, management and analysis
  - Data Collection methods
  - Data management
  - Statistical methods
- Methods: Monitoring
  - Data monitoring
  - Harms
  - Auditing

### Ethics and dissemination (Clinical Trial Protocols only)

### Data analysis (Clinical Trial Evaluations only)

### Discussion (Clinical Trial Evaluations only)

### Conclusion

Concluding remarks on the information presented in the review.

## Body of the article – Drug/Device/Vaccine Evaluations

The article content should be arranged under relevant headings and subheadings to assist the reader.

## Introduction

Incorporating basic information on disease incidence and prevalence, unmet medical need and present management guidelines (highlighting regional variations where appropriate).

### Overview of the field

- What are the unmet needs of currently available therapies/devices/vaccines?
- What other products are in the clinic/late development?

### Introduction to the compound/device/vaccine

#### Pharmacology (Drug Evaluations & Vaccine Evaluations only)

- Chemistry
- Pharmacodynamics
- Pharmacokinetics and metabolism

#### Clinical efficacy

- Phase I studies
- Phase II studies
  - Optional: Summary table of phase I and II trial results
- Phase III studies
  - Optional: Summary table of phase III trial results

#### Real-world evidence (if applicable)

- Discussion of any evidence derived from real-world studies with the product

#### Safety and tolerability

- Including a table summarizing safety outcomes in clinical trials.

#### Regulatory affairs

- Including information on the status of the product, i.e., where is currently approved, in which countries it is approved and for what indications. Should cover EU, USA and rest of the world where appropriate.

#### Conclusion

- Concluding remarks on the data presented in the review.

## End material – all article types

### Article Highlights

A series of bulleted summary points that illustrate the main topics discussed in the article. Article Highlights are not required for Podcast articles.

#### Example:

- Fampridine-Sustained Release is the only drug approved to treat walking disability in patients with multiple sclerosis.
- Around a third of the patients on treatment achieve a significant improvement.
- The effects appear soon after the start of the treatment, are long-lasting, but disappear soon after the drug is withdrawn.
- So far, it is not possible to predict whether a patient will be a responder or not.
- The efficacy of the treatment should be assessed after 2–4 weeks.
- The dose is 10 mg daily, and should not be increased due to the risk of seizures.
- It is contraindicated in patients with renal impairment, history of seizures or on treatment with OCT2 inhibitors.
- The adverse events are mild to moderate and transitory. The most frequently reported were insomnia, headache, fatigue, back pain, dizziness, nausea and balance disorders.

## Acknowledgements

Author acknowledgements, plus, where relevant, details of individuals who contributed to the article, such as study group members, or those who contributed but who did not fulfill the [criteria](#) to be listed as authors.

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59. Cardillo TM, Sharkey RM, Rossi DL, Arrojo R, Mostafa AA, Goldenberg DM. Synthetic lethality exploitation by an anti-Trop-2-SN-38 antibody–drug conjugate, IMMU-132, plus PARP inhibitors in *BRCA1/2*-wild-type triple-negative breast cancer. *Clin. Cancer Res.* 23(13), 3405–3415 (2017).
- **This preclinical study demonstrated antitumor responses of an anti-Trop2 antibody–drug conjugate in both mouse and monkey models.**

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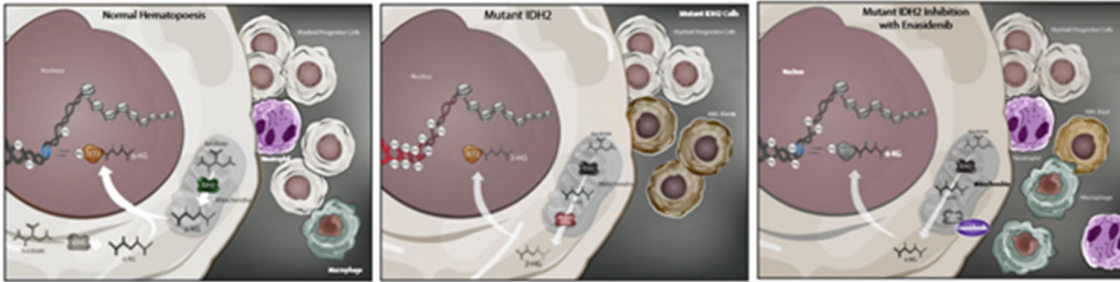
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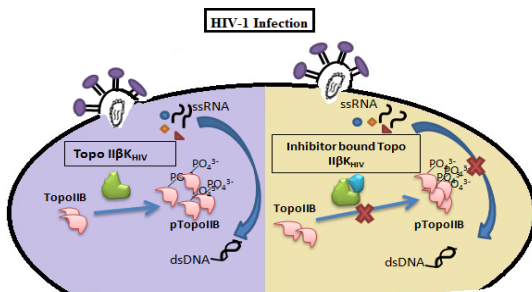
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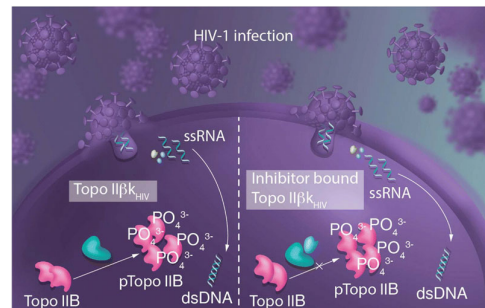
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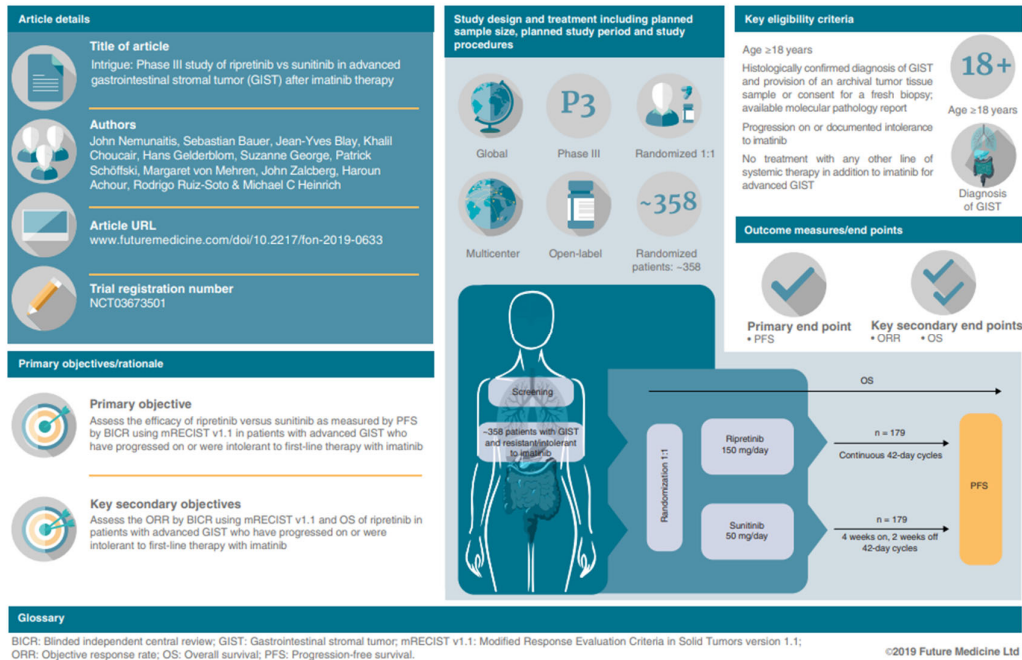


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