Usage restrictions in open access publications as considerations for the evolution of publication planning: a single-company analysis of clinical research records from a publication management system

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Background

- Open access (OA) is a publishing model that facilitates free online access to publications, thereby ensuring that research can be accessed and used by the broadest possible audience.
- As well as enhancing reach, OA can help to build trust in the medical/scientific community, foster scholarly collaboration and ultimately improve patient care by providing healthcare professionals with broader access to peer-reviewed publications.
- In OA publishing, a journal publisher may offer authors the option to publish content under one of several Creative Commons (CC) licenses.[1]
- When publication planning, it is important to consider the intended onward use of the materials, including the needs and priorities of the organization, because the more restrictive licenses may impede further dissemination and the subsequent impact of the research.

Objective

- To investigate OA status and CC license types of Takeda-sponsored clinical publications to support informed publication planning.

Methods

- Takeda-supported, peer-reviewed articles published/e-published between January 1, 2020 and November 30, 2024 were collected from Takeda's publication management system, iEnvision.
- A large language model-based classification tool was used to label study type (animal or human) and clinical phase with expert validation.
  - Publications were categorized as phase 3 primary articles or 'all other', which included all clinical articles other than phase 3 primary ones.
  - Animal studies, preclinical/nonclinical studies and literature reviews were excluded.
- OA status was assessed and CC licenses were categorized as seen below.

CC license category	Included licenses
CC BY	CC BY and CC0
CC BY-NC	CC BY-NC and CC BY-NC-SA
CC BY-NC-ND	CC BY-NC-ND
Other, free access	No CC license apparent (may have a publisher-specific license/ OA policy), but content freely accessible
None	No CC license apparent and content not freely available

Key

BY: credit must be given to the creator
NC: noncommercial use only
ND: no derivatives or adaptations of the work are permitted
SA: ShareAlike; adaptations must be shared under the same terms

References

1. Creative Commons. About CC licenses. Available from: https://creativecommons.org/share-your-work/cclicenses/ (Accessed March 19, 2025).
2. Ellison TS *et al. BMJ Open* 2019;9:e028655.

Disclosures

SW and AS are employees and stockholders of Takeda Development Center Americas, Inc. JD-J, ES and TR are employees of Oxford PharmaGenesis. HB is an employee and shareholder of Oxford PharmaGenesis. SW was unable to participate in the final stages owing to a period of illness; authors agree that SW met the definition of authorship and contributed substantially to the research and conceptualization.

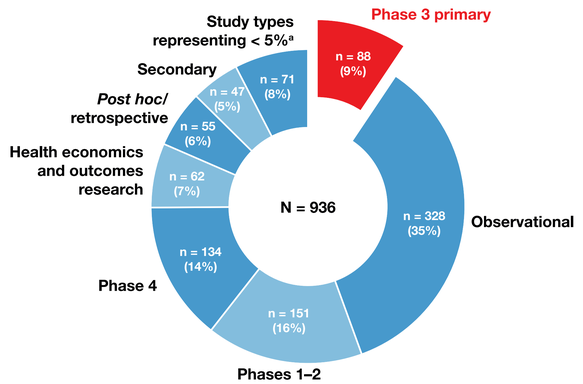
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Results and interpretation

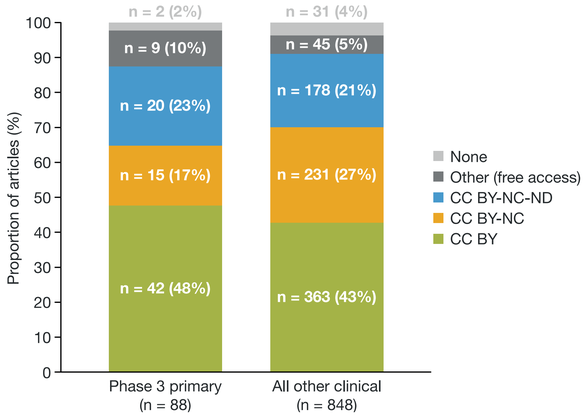
- Of 1263 iEnvision records, 936 were included: 88 were phase 3 primary articles and 848 were other clinical articles (**Figure 1**).
  - The most frequent study type in the other clinical articles category was observational (n = 328; 35%).
- Almost all articles were OA (**Figure 2**).
  - Phase 3 primary articles: 98% were OA and 40% had a noncommercial license (CC BY-NC or CC BY-NC-ND).
  - Other clinical articles: 96% were OA and 48% had a noncommercial license.

Figure 1. Included study types.



[a]Examples of study types representing < 5% included: indirect treatment comparisons, meta-analyses, pharmacokinetics/ pharmacodynamics, phase 0, pooled analyses, qualitative analyses and systematic literature reviews.

Figure 2. License type for phase 3 primary articles and other clinical articles.



Potential consequences of restrictions on different stakeholders

Healthcare professionals

- Healthcare professionals may have different levels of access to publications through their institutions or according to country, which may affect their ability to share these publications with their patients.
- Limiting the access of healthcare professionals to peer-reviewed publications can act as an impedance to patient care and scientific collaboration.

Patients, caregivers and advocacy groups

- Copyright and post-publication restrictions, particularly for plain language summaries of publications, can create barriers to patient/caregiver engagement in their own knowledge building and may reduce trust and transparency.

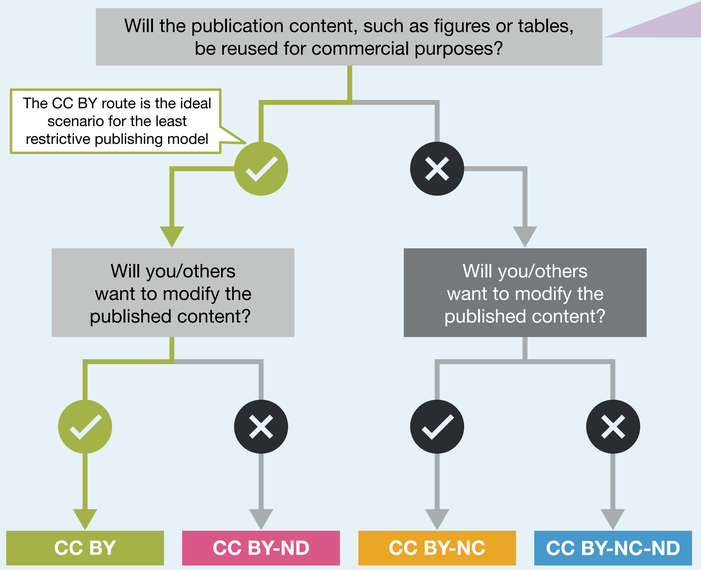
General public and medical research communities

- Access restrictions to full datasets or results can be barriers to scholarly discussion and/or transparency.
- Some CC license types may restrict usage with artificial intelligence tools, for example, those used in conducting literature analyses.

Study/publication sponsors

- Pharmaceutical companies have a responsibility to support educational initiatives that may be limited by usage restrictions.
- Published content is regularly reused for multiple purposes through a range of platforms; NC and/or ND licenses may prevent onward use by healthcare professionals or other groups, and NC restrictions can incur substantial long-term costs.

CC license type decision tree



Suggestions for publication planning

Publication proposal/ endorsement stage

- Consider communication needs and strategy with the core scientific publication team
- Identify possible onward uses of content, including format, beyond the published article

Initial author engagement

- Educate authors on the impact of any target journal license restrictions on onward use
- Target journal selection should consider audience, reach, accessibility and other factors

Onward use

- Leading medical journals sometimes impose restricted options for industry-sponsored work[2]
- Engage publishers early to confirm CC license options, associated costs (usually as APCs, or fees associated with figure reproduction) and if onward uses such as PLSPs are permitted

APC, article processing charge; PLSP, plain language summary of a publication.

Conclusions

- While almost all included publications in the analysis were OA, approximately half had usage restrictions.
- The implications of usage restrictions on various stakeholders should be considered during the early stages of publication planning.
- The life of published content does not stop with journal publication of the article. OA research, available under a CC BY license, offers the least restrictive reuse with the most options for further education of a diverse audience.