

Current Practices in Author Agreements for Industry-sponsored Publications

Sonia A. Schweers¹, Clair Fisher², Tam Nguyen-Cao³, Radhika Bhatia⁴, Jackie Marchington⁵, Keith H. Goldman⁶, Shannon Stahl¹, Taija Koskenkorva⁷, Bhakti Kshatriya⁸, on behalf of ISMPP Author Agreement Subcommittee

¹Bristol Myers Squibb, Princeton, NJ, USA; ²Clair Fisher Ltd, London, UK; ³Claritas Scientific LLC, Chapel Hill, NC, USA; ⁴UCB Pharma, Slough, UK; ⁵IPG Health Medical Communications Ltd, Oxford, UK; ⁶AbbVie, North Chicago, IL, USA; ⁷Novartis Pharma AG, Switzerland; ⁸Publication Practice Counsel™, Truposha LLC, Lutz, FL, USA



INTRODUCTION

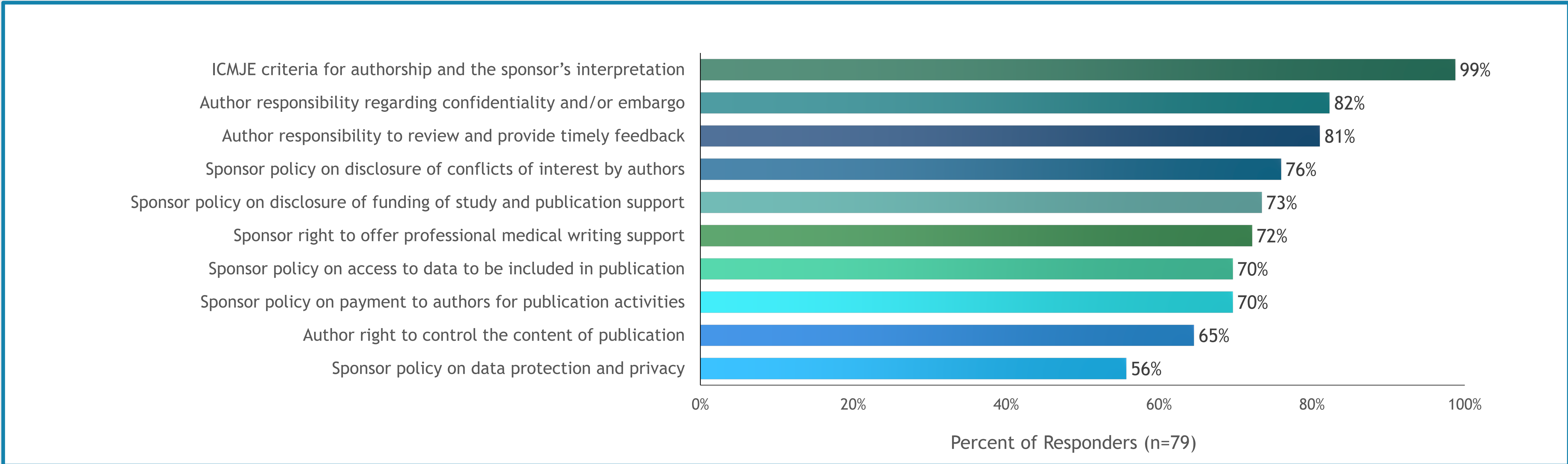
- The ISMPP Author Agreement Subcommittee was formed by members of the Global Transparency Trends and Ethics and Standards committees, to co-develop best practices and a template for author agreements (AAs).
- This survey was conducted to understand current industry AA practices.

Methods

- A 31-question survey was developed by members of the ISMPP Author Agreement Subcommittee.
- The survey was conducted using SurveyMonkey® (Palo Alto, CA), a web-based survey software tool.
- The survey invitation and link were sent by ISMPP to 801 ISMPP members affiliated with pharmaceutical, biotech, and/or device companies on December 1, 2022.
- The survey was open for 2 weeks and an email reminder was sent a week prior to closing the survey.
- Survey questions related to use of the agreements were presented only to those who reported using the AAs consistently.
- Survey data were kept strictly confidential and anonymized.
- Descriptive statistics were used to analyze the data.

Authorship criteria, author’s responsibilities related to confidentiality and/or embargo, and timely review are the most common topics included in Author Agreements for industry-sponsored publications

Figure 2. Top 10 Topics Included in AAs

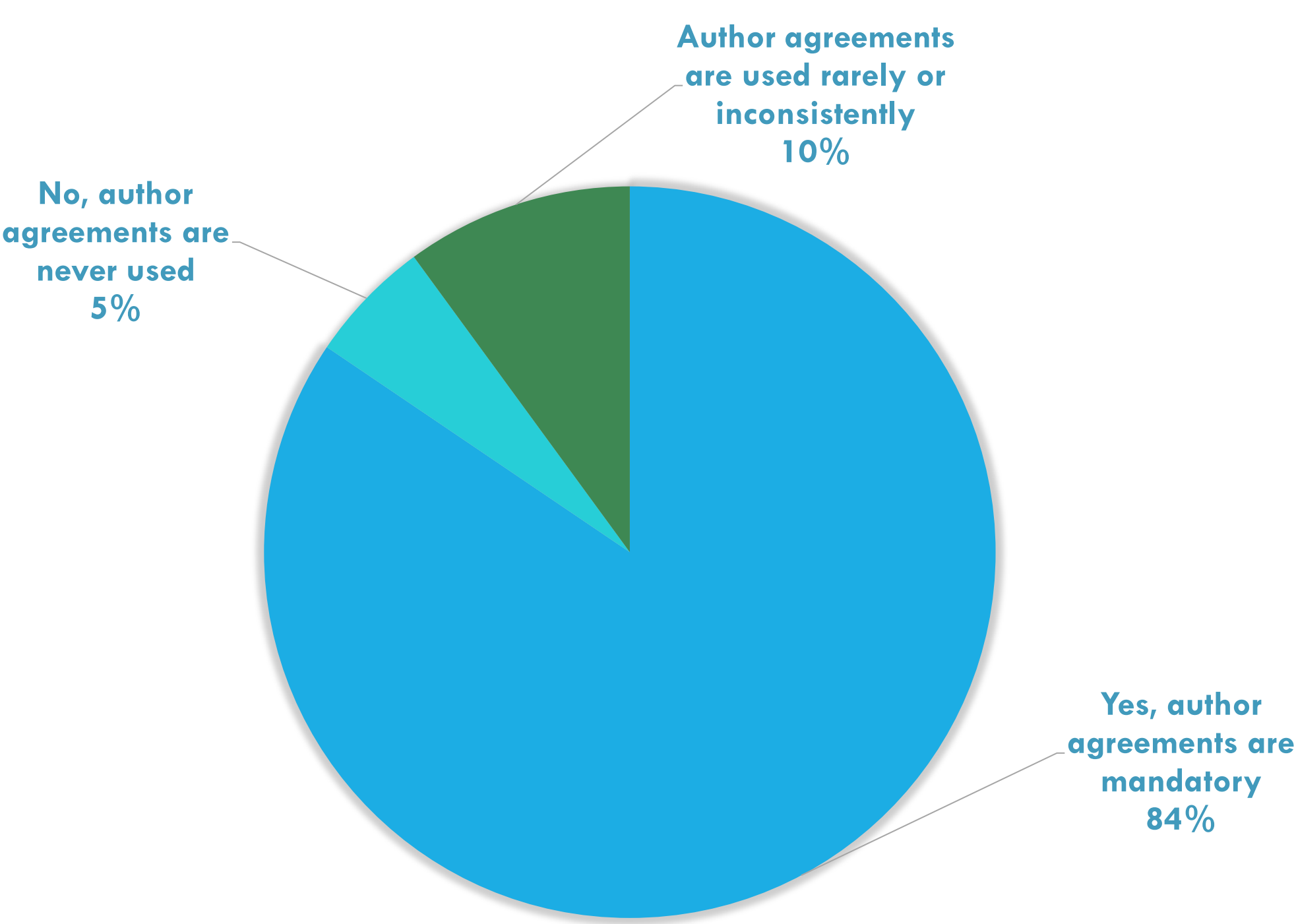


Results

Demographics

- 219 ISMPP members responded to the survey, for a 27% (219/801) response rate.
 - Majority (80%, 175/219) of responders reported employment with a pharmaceutical company compared to 13% (29/219) and 7% (15/219) who were employed by biotech and device companies, respectively.
 - 91% (93/102) reported a dedicated department/team for scientific publications.
 - Most responders (73%, 75/102) have worked in publications for 5 or more years.
- 84% (185/219) reported mandatory use of AAs, 5% (12/219) reported not using AAs, and 10% (22/219) reported using them rarely or inconsistently (Figure 1).

Figure 1. Use of Author Agreements Among ISMPP Industry Members (n=219)



Companies not Using Author Agreements Consistently

- The reasons reported for not using AAs were: never used before (44%, 12/27), no publication team (26%, 7/27), previously used but stopped using (11%, 3/27), and other reasons (44%, 12/27), including new company and lack of resources.
- Barriers preventing use of AAs were: insufficient information on benchmarking, risk, and best practices (67%, 18/27), insufficient resources (59%, 16/27), and not enough internal support (44%, 12/27).
- When not using AAs, authors are informed of roles, responsibilities and expectations via email (56%, 15/27), kickoff meeting/call (15%, 4/27), or in other ways (7%, 2/27). However, 22% (6/27) of responders said that authors are not informed.

Willingness to Adopt AAs Among Companies not Using AAs

- 82% (23/28) indicated they would be interested in adopting AAs.
- The most helpful potential resources for adoption of AAs were AA templates (48%, 13/27) and ISMPP position statement and/or training (26%, 7/27).

Companies Using Author Agreements Consistently

- Among responders using AAs consistently, the most common topics covered by AAs were: ICMJE criteria and sponsor’s interpretation (99%, 78/79), author responsibility related to confidential information and/or embargo (82%, 65/79), and timely review (81%, 64/79) (Figure 2).
 - The topics included in AAs that have proven to be the most helpful in discussions with authors were: rights and responsibilities of authors (77%, 58/75), and sponsors (44%, 33/75), and disclosure of conflicts of interest (39%, 29/75).
- Types of Research**
- AAs were reported to be used for publications of company-sponsored clinical research (Phase 1–4) with (97%, 76/78) or without (79%, 62/78) writing/editorial support.
 - AAs were also used for publications of company sponsored non-clinical research (eg, HEOR, preclinical), with (85%, 66/78) or without (65%, 51/78) writing/editorial support.

Publication Types

- Majority of responders use AAs for manuscripts (100%, 77/77), review articles (99%, 76/77), and abstracts/presentations (94%, 72/77).

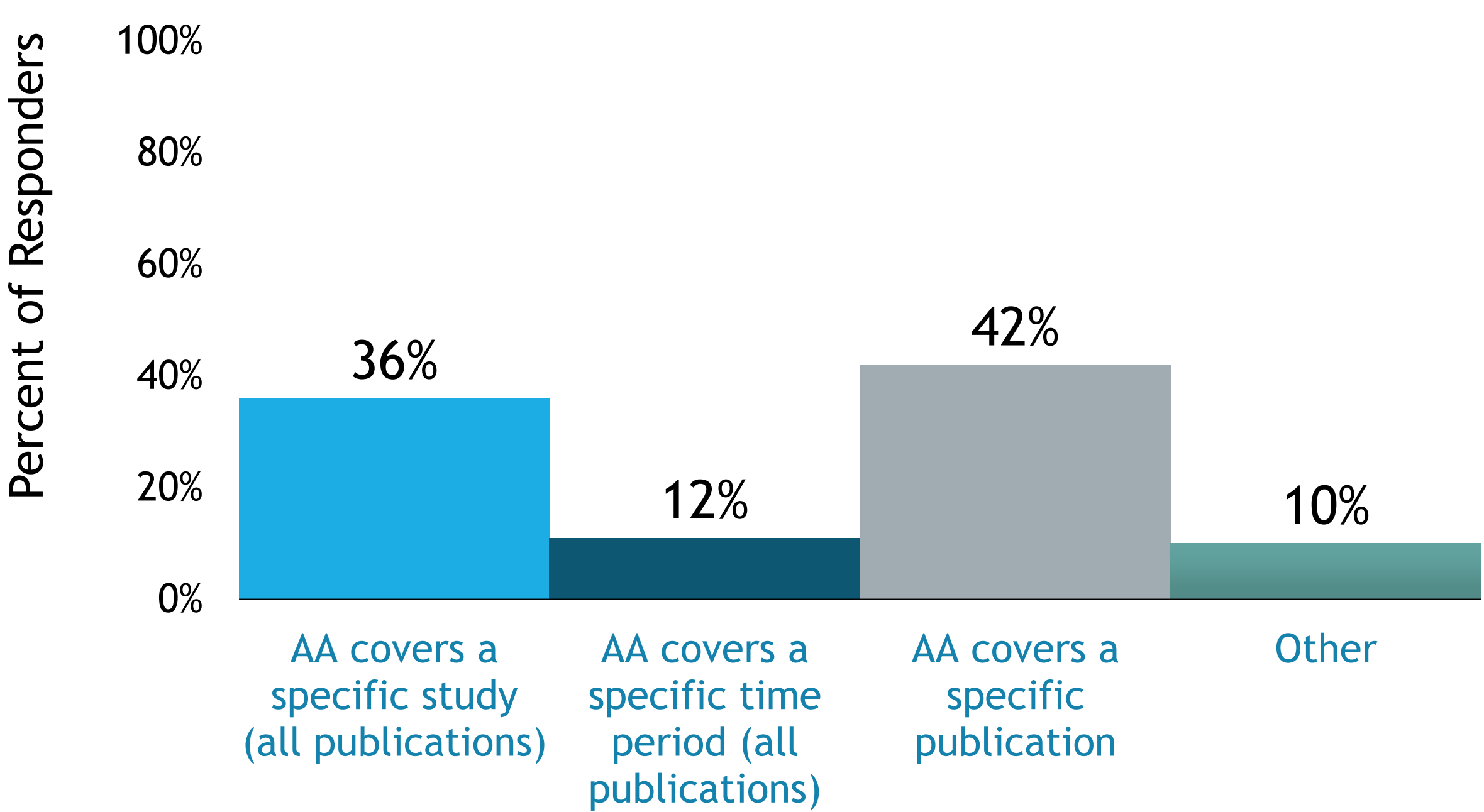
AA Types

- Majority of responders (76%, 59/78) use the same AA for all publications and data types.
- Other responders use different AAs depending on the type of data (3%, 2/78), type of publication (5%, 4/78), or geographic location of the author (4%, 3/78).

AA Scope

- 42% (32/77) of responders use the AA to cover a specific publication (each new abstract or manuscript requires a new agreement).
- 36% (28/77) of responders cover all publications for one specific study with the same AA. 12% (9/77) of responders cover all publications during a given time period with the AA (Figure 3).

Figure 3. Scope of Author Agreements Used by ISMPP Industry Members (n=77)



Discussion

- While most responders use AAs consistently, as recommended by GPP, there is inconsistency in the scope and topics covered by the agreement.
- External authors working with different companies will likely be exposed to different AA topics and processes.
- This survey provides a benchmark of best practices for industry-sponsored publications.
- Limitations include conducting the survey among ISMPP industry members only, who are more likely to be familiar with AA best practices than non-members.
- The ISMPP Author Agreement Subcommittee plans to co-develop a template for AAs and best practices guide to promote consistency and transparency in industry authorship practices.



CONCLUSIONS

- Among ISMPP industry members, 84% of responders reported that AAs were mandatory for industry-sponsored publications.
- 82% of responders not currently using AAs would be interested in adopting them; 48% would find an AA template useful.

References

- DeTora LM, et al. Good Publication Practice (GPP) Guidelines for Company-Sponsored Biomedical Research: 2022 Update. *Ann Intern Med.* 2022;175:1298-1304. doi:10.7326/M22-1460.

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