

# Best Practice for Publication of Health Economics and Outcomes Research/Real-World Evidence (HEOR/RWE)

## A Pilot Study on Guidance Needs and Scope for Development

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### Key points

This pilot study, based on a user survey, identified critical issues around HEOR/RWE publications practices

Barriers to publication efficiency stem from data analysis/content development delays, and issues related to sponsor team, publication agency, target journal and third-party relationships

Respondents suggested a variety of practical considerations to potentially mitigate the identified issues and increase HEOR/RWE publication efficiencies

There was full consensus amongst the survey sample that HEOR/RWE publication processes would benefit from guidance on best practices

### Background

- Unlike the pre-planned/pre-approved analyses of clinical trial data (for which the publications process is guided by established GPP guidelines<sup>1</sup>), HEOR/RWE analyses can continue to evolve from inception to publication, and without the facility of best practice guidelines beyond existing checklists for data reporting (e.g., CHEERS<sup>2</sup>; RECORD<sup>3</sup>) and limited extensions of GPP and ICMJE guidelines<sup>4</sup>
- To meet the robust evidentiary needs of regulatory or payer stakeholders, HEOR/RWE must nonetheless be reported with the same uncompromised ethics, rigor and transparency as clinical trials
- For timely inclusion into submission dossiers there is also need for rapid dissemination of the evidence through peer-reviewed channels
- Because of the rapidly changing nature of inputs (e.g., drug prices, standard of care, etc.) to HEOR/RWE analyses, any delays in dissemination may render study findings to be obsolete
- As a key part of an evolving framework, updated International Society for Medical Publication Professionals (ISMPP) Good Publication Practice (2022) guidelines for publishing company-sponsored biomedical data particularly propose the development of standard operating procedures/working instructions to support specific publications working groups such as HEOR/RWE<sup>1</sup>

### Objectives

By assimilating attitudes and perceived challenges in the HEOR/RWE publications space, this pilot study assessed the needs and scope for developing global, peer-reviewed, HEOR/RWE publication best practices

### Methods

- A LinkedIn (business social media) post invited publication professionals and HEOR/RWE collaborators to respond to a brief online survey that comprised eight questions, including four yes/no and four open ended items
- Survey questions pertained to publication role/title or HEOR/RWE user type, level of HEOR/RWE experience, HEOR/RWE publication difficulties or delays experienced, reasons for such issues how such issues could have been avoided, other potential problems, incidence of cancelled publications or submissions, and the perceived need for best practice guidance

### Results

- Amongst the total n=24 respondents with various roles and titles in publications or research (**Figure 1**), the approximate length of HEOR/RWE experience ranged from 1-20 years (mean 8.2; SD 6.0; median 5); nine respondents had ≥10 years of experience
- Twenty-two respondents (91.5%) indicated that they or their teams had experienced HEOR/RWE publication difficulties/delays

Figure 1. Disposition of survey sample

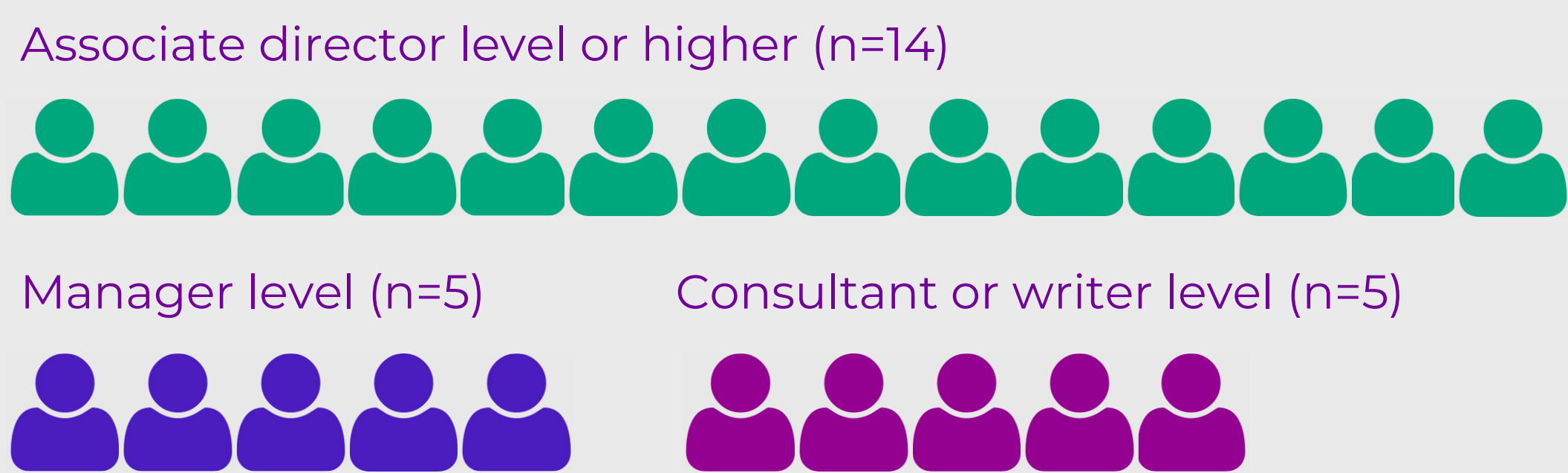
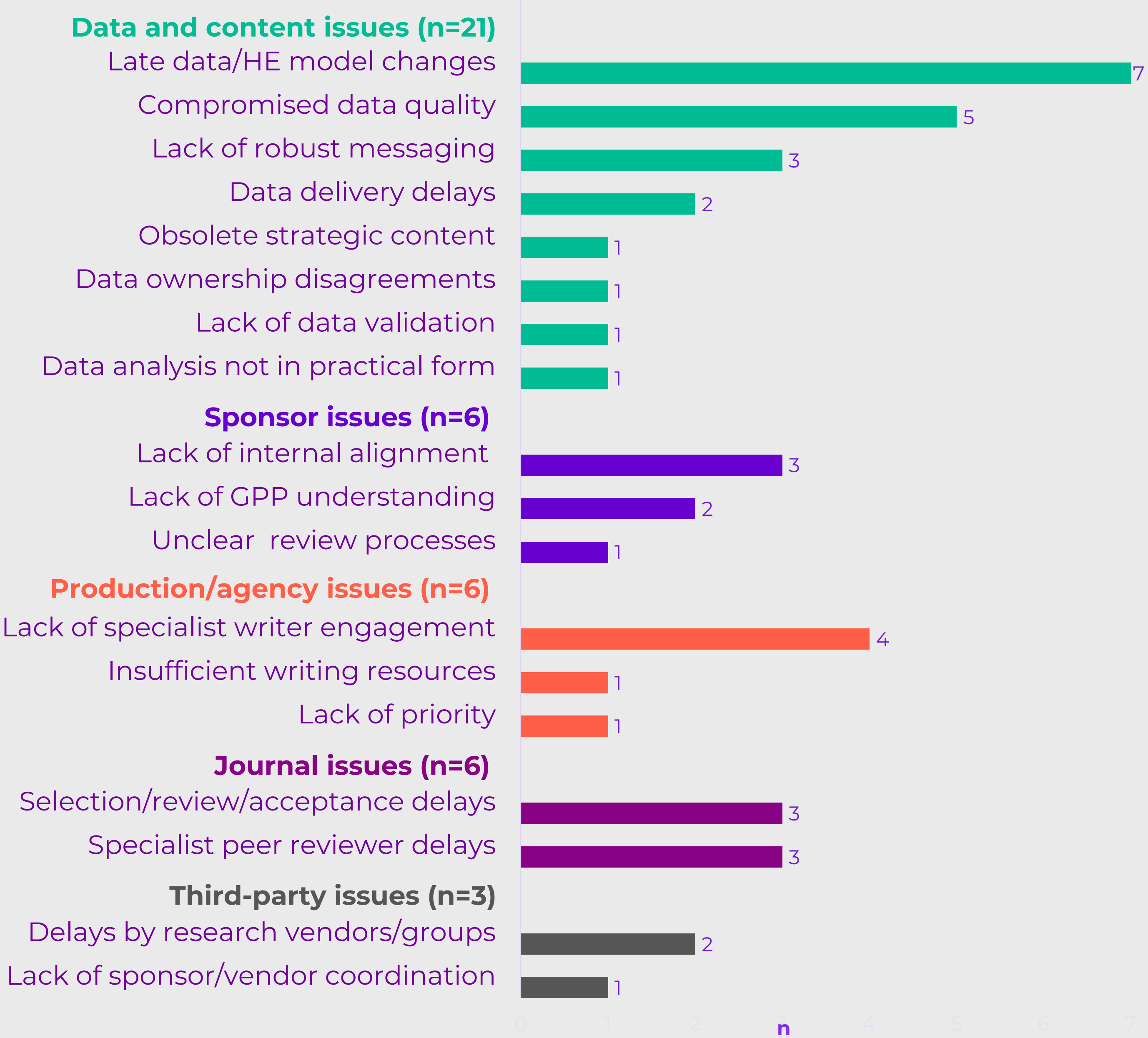
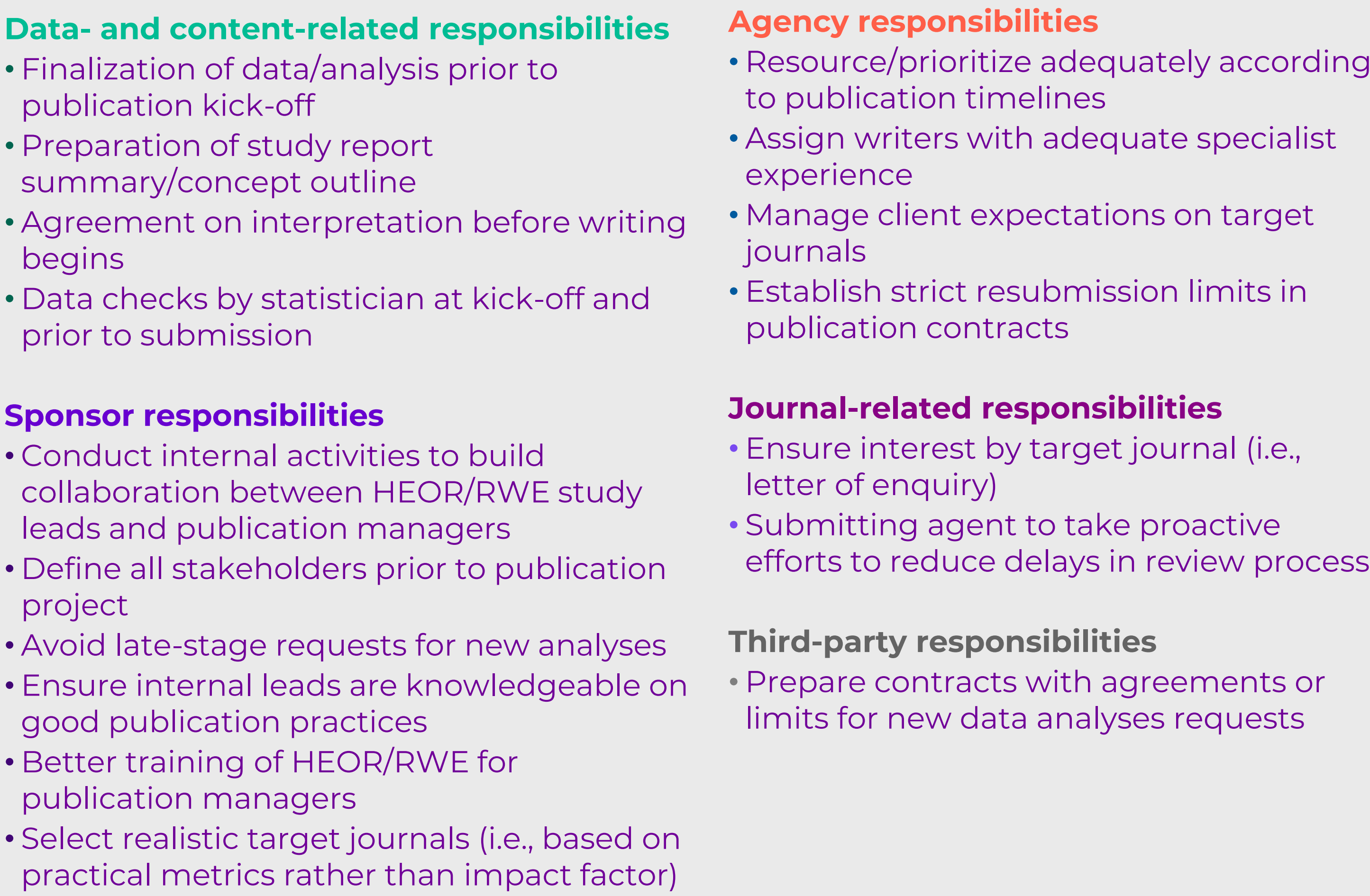


Figure 2. Publication issues identified



- Respondents described 42 discrete types of difficulties/delays; by theme (**Figure 2**), the most common included data and content issues (n=21; especially, late data/HE model changes), sponsor issues (n=6; especially, lack of internal alignment), production/agency issues (n=6; especially lack of specialist writer engagement), journal issues (n=6), and third-party issues (n=3)
- Eight respondents (30.0%) reported experiencing publication cancellations due to such difficulties/delays
- Twenty respondents (83.3%) noted that publication difficulties/delays could have been mitigated and made recommendations for best practice (**Figure 3**)
- All respondents indicated a need for guidance on best practices for successful and efficient HEOR/RWE publications

Figure 3. Suggested practices to mitigate publication issues



### Discussion

- This pilot study pointed to a number critical issues on HEOR/RWE publication practices stemming from perspectives of data and publication content, sponsor, agency, target journal, and third-party collaborations
- Overall, the survey revealed the importance of initiating publications only after the evidence is robustly developed, interpreted, and finalized
- There was full consensus in this survey sample that HEOR/RWE publication processes would benefit from guidance on best practices; however, this outcome may have been a consequence of survey respondent self-selection bias
- The variety of practical considerations to potentially mitigate the identified issues could inform the next stages of developing peer-reviewed, globally accessible HEOR/RWE publications best practice guidelines

**Abbreviations:** CHEERS: Consolidated Health Economic Reporting Standards; GPP: good publication practices; ICMJE: International Committee of Medical Journal Editors; RECORD: REporting of studies Conducted using Observational Routinely collected health Data.  
**References:** 1. DeTora LM et al. *Annals of Int Med.* 2022;175(9):1298-1304. 2. Huseareau D et al. *BMJ* 2022;376. 3. Benchimol EL et al. *PLoS Med* 2015; 12(10). 4. Santos J et al. *Value Health.* 2017;20(10):1227-1242.  
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