# SETTING OF AN OBSERVATORY OF CLINICAL TRIAL DATA SHARING, RESEARCH INTEGRITY AND JOURNAL EDITORS

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## BACKGROUND

IMPACT (**IMP**rove **A**ccess to **C**linical **T**rial data) Observatory was established in October 2014 in Split, Croatia, with the aim of monitoring the transition of clinical research regarding transparency of trial data.[1]

The methodology of the Observatory includes scoping reviews of literature, surveys, interviews, and assessments of relevant initiatives and repositories.

By repeating a survey conducted in 2009 on WAME members,[2] the Observatory is attempting to determine the changes of perception, policies and practices of editors regarding various levels of public disclosure of patient-oriented research data.

## METHODS

An anonymous and voluntary questionnaire was sent using the SurveyMonkey platform to all registered WAME members (n=1632) on 13 August 2015, with two reminders sent in September. The survey consisted of 38 questions.

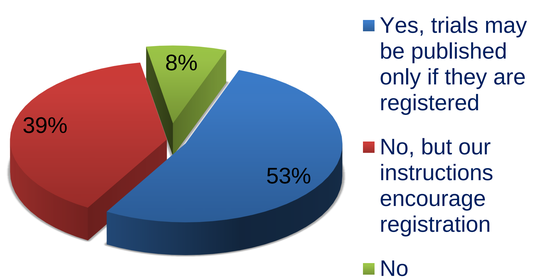
Response rate till 18 September was 85 (5%). Sociodemographic characteristics of respondents are shown in Table 1. Most respondents journals are full open access journals (n=65, 77%), and not indexed in PubMed (n=44,52%).

Table 1. Sociodemographic characteristics of WAME members (n=85).

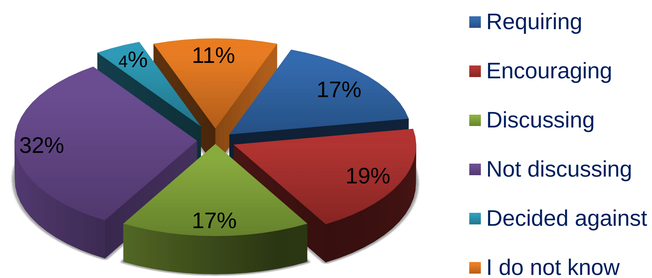
| Characteristic | Mean ± SD |
|---|---|
| Age (years) | 48 ± 13 |
| **Sex** | **n (%)** |
| Male | 15 (18) |
| Female | 69 (82) |
| **Position** | **n (%)** |
| Editor in Chief | 55 (65) |
| Associate Editor | 9 (11) |
| Other (Deputy/Managing/Section editor) | 21 (24) |

## RESULTS

**Does your journal require clinical trials to be registered in an ICMJE- or WHO-approved trial register?**




**How would you characterize your journal's current position on sharing raw data from patient-oriented research including clinical trials?**




**Are you aware of any initiatives that encourage the publication and sharing of participant-level data?**

**No, 82%**

**Yes, 18%**

Table 2. Respondents' (n=65) personal opinion on which aspects of clinical trials should be publicly available?

| Opinion | n (%) |
|---|---|
| None | 2 (3) |
| Summary of trial protocol | 33 (51) |
| Full protocol | 36 (55) |
| Summary of results | 37 (57) |
| All results | 30 (46) |
| Individual (de-identified/anonymized) participant data - raw data | 20 (31) |
| Statistical code | 22 (34) |
| Clinical Study Report (if it exists) | 28 (44) |
| All trial documentation (including consent forms and all data collection instruments) | 22 (34) |
| Full financial disclosure of the research | 41 (63) |

## CONCLUSION

- Initial results indicate that many journals still do not require registration of clinical trials before their publication, nor do they require authors to publicly share raw data. Additionally, despite the recent increase of data sharing initiatives, the large majority of editors are unaware of their existence.
- As our current response rate is only 5%, we refrain from making direct comparison with the results from 2009 study and generalizing our findings until we obtain more responses.
- Nevertheless, the high reported unawareness of data sharing initiatives coupled with the fact than more than two thirds of editors disagreed that raw data should be made publicly available, indicate a need for a greater dialog between stakeholders involved in data sharing.

## ACKNOWLEDGMENTS

Karmela Krleža-Jerić was awarded a NEWFELPRO Fellowship (Marie Sklodowska Curie and Croatian Government Grant) to set up the IMPACT observatory. Ana Marušić is the chair of WAME Research Committee.

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