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ADAPTING TO PANDEMICS AND THE CLIMATE CRISIS:
THE TRANSITION TO VIRTUAL CROSS-AUDITS AT BBMRI.AT

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BACKROUND

For the past decade, BBMRI.at has operated a national cross-audit programme among participating biobanks. In the face of global crises such as pandemics and climate change, the implementation of innovative collaboration strategies is of paramount importance. We present herein the transition of the BBMRI.at cross-audits to a virtual format.

In the year 2014, the BBMRI node in Austria developed a nation-wide cross-audit programme based on the quality management system (QMS) standard ISO 9001 and applicable CEN technical specifications/ISO standards on the pre-examination phase. The programme employs auditors who are quality management coordinators (QMCs) of the local partner biobanks. The primary objective of this programme is, therefore, not only to provide the BBMRI.at partners with a biobank-specific evaluation of their own processes, but also to enable the auditors, who are the QMCs from the other partner biobanks, to gain a deeper insight into the operations of other biobanks.

The SARS-CoV-2 pandemic had a considerable impact on the Austrian cross-audit programme. The audits were unable to proceed as planned due to restrictions on access to biobanks, which are often located in healthcare facilities, and travel bans. Consequently, BBMRI.at transformed its cross-audit programme into a virtual one, comprising several weeks of document review, virtual auditor meetings and interviews with auditees. This format of virtual cross-auditing will be also maintained in view of the global climate crisis, where travel restrictions are advisable.

The Austrian Virtual Cross-Audit programme is presented thereafter, along with the outcome data from audit evaluation questionnaires.
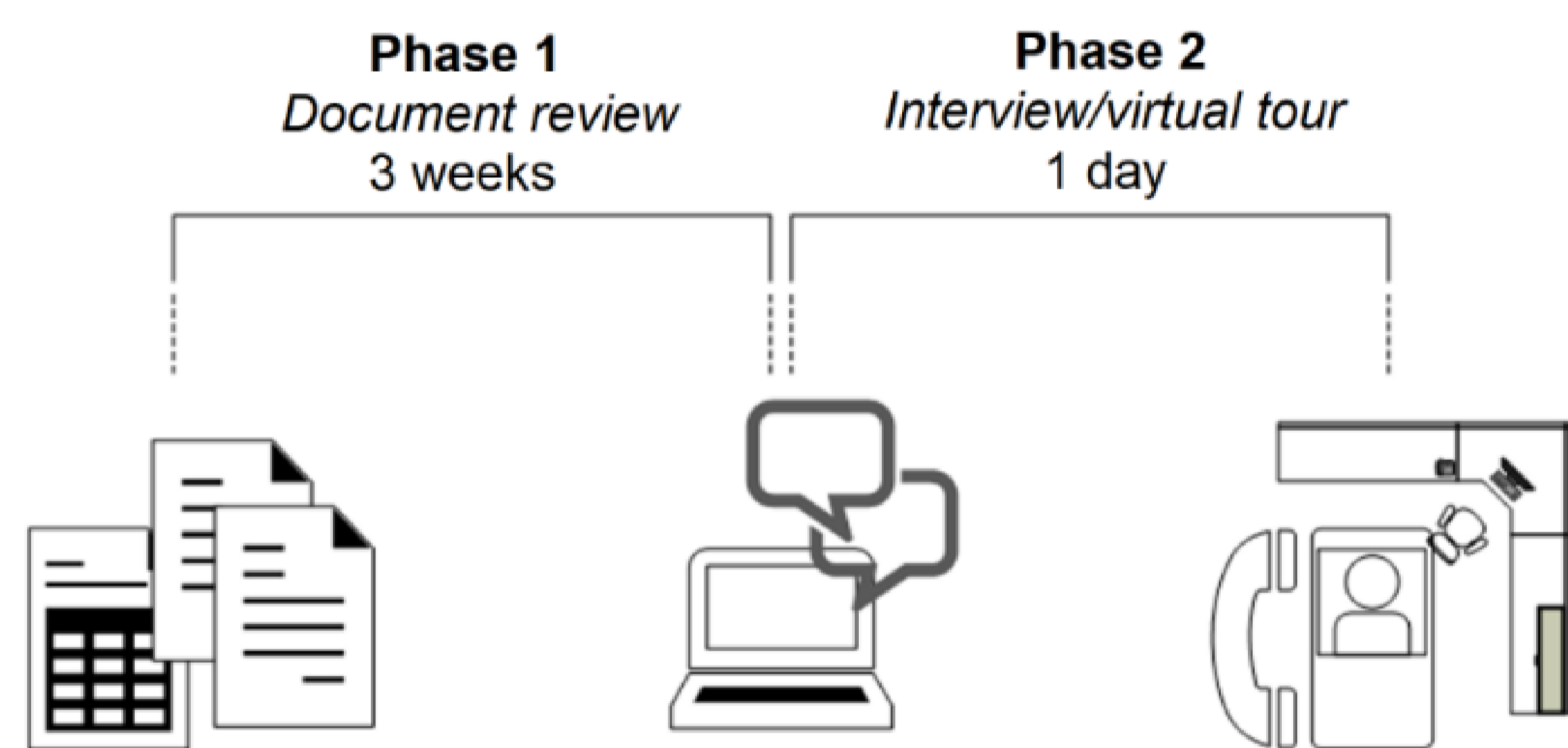
Phase 1
Document review
3 weeks

Phase 2
Interview/virtual tour
1 day

Fig.1: Schematic process of a BBMRI.at virtual cross-audit

METHODS

A BBMRI.at virtual cross-audit consists of the following parts (see Fig. 1):

1 Document review phase
At the beginning, the auditors request documentation relevant for the processes under audit which is then uploaded by the auditees to a file sharing platform. The auditors then have three weeks to check these documents for conformity or to ask for additional documents, if required. Audit checklists for ISO 9001, as well as for applicable CEN-TS/ISO standards on the pre-examination phase are available.

2 Auditor meeting
During a virtual auditor meeting, auditors discuss their impression and collect open points that have to be clarified during the virtual interview. Each auditor focuses on a specific topic and prepares questions for the interview.

3 Virtual interview
At the virtual interview, conformity with the standard is determined in a personal discussion with the audit partners with reference to the document review. Through the checklist-guided questioning, the processes and their interfaces can be audited across documents and differences to the lived practice can be determined accordingly.

Between 2021 and 2024, four virtual cross-audits were performed. In those, a total of ten QMCs audited in different constellations 15 auditees. The audit programme was evaluated at the end using short questionnaires developed with the assistance of ChatGPT 4 (OpenAI, San Francisco, USA), which covered all parts of the process (document review phase, auditor meeting, interview), as well as general aspects of the virtual cross-audit programme.

RESULTS

A total of nine of the ten auditors (90%) and twelve of the 15 auditees (80%) responded to the survey. For the majority of questions, participants were asked to provide a graded response to questions on a scale of 1 to 5, with 1 representing "not at all" and 5 representing "strongly" (see Figs. 2 and 3 for auditors and auditees, respectively). However, for some questions, a text response was requested.
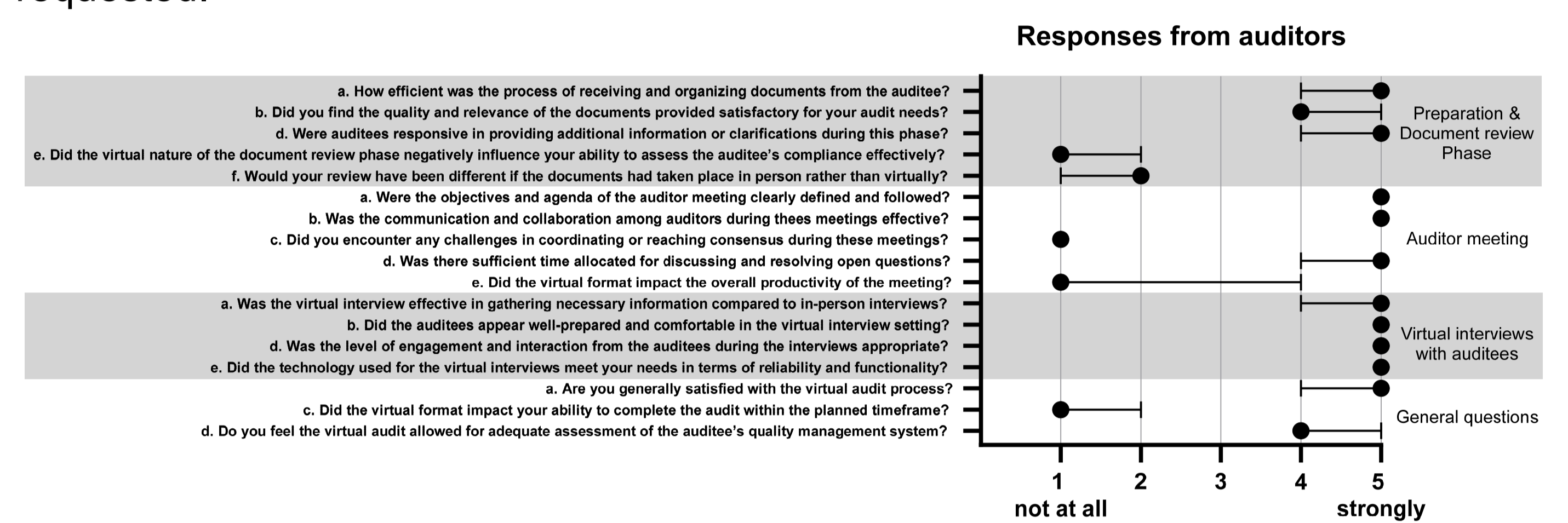
Fig.2: Response from BBMRI.at QMCs acting as cross-auditors (data represent median and interquartile range, N=9 of 10)
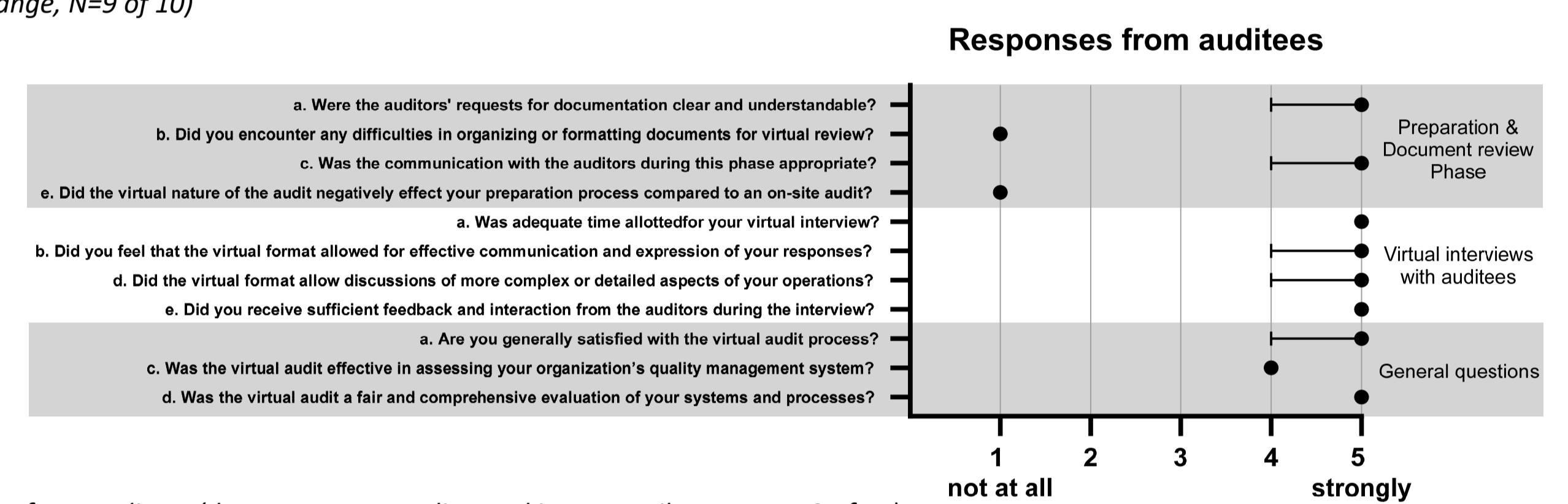
Fig.3: Response from auditees (data represent median and interquartile range, N=9 of 15)

Document review phase
The communication during the document review phase was deemed appropriate by both auditors and auditees. Furthermore, the auditors found the document review prior to the interview to be efficient. The median response to the question of whether an on-site document review would have led to different results was 2/5.

Auditor meeting
The auditor meeting was experienced as sufficient and consensus between auditors was easily reached. However, whether the virtual format impacted the overall productivity of the meeting was viewed more ambiguously.

Virtual interview
Once more, both auditors and auditees rated the virtual interview as an efficient means of communicating the necessary information. The technical support was also rated positively, although the use of camera tours was suggested as a possible improvement (text answer required).

Overall assessment
The survey participants rated the new virtual format highly, with an average score of 5 (interquartile range 4-5, on a scale of 1 to 5, with 5 representing strong satisfaction). However, both auditors and auditees deducted one point from the maximum score for the question of whether the virtual format enabled an effective/adequate assessment of the QMS.

CONCLUSIONS

The transformation of the BBMRI.at cross-audit programme into a virtual format was well received by both auditors and auditees. All phases of the process (document review, auditor meeting and interview) were rated as efficient. The inclusion of virtual camera tours was suggested as a possible improvement. Despite the virtual nature of the audits, an adequate assessment of the QMS was considered achievable.

The BBMRI.at virtual cross-audit programme was desinged in response to travel and access restrictions during the COVID19-pandemic. However, the climate crisis also suggests rethinking excessive travelling. The experiences of the Austrian BBMRI national node, which has now transformed its cross-audit programme into a virtual format, may, therefore, be of particular interest in the international context, where travel leaves an even bigger footprint.

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