Resources to Aid Ethical Review of Clinical Studies

An Exploratory Scoping Review : Identifying Gaps and Opportunities

Summary

We need accessible guidelines and resources to support ethical review of clinical studies.

We curated 233 German and English resources from stakeholders' websites, highlighting gaps and opportunities.

This collection can serve as (1) a **foundation for developing tools and resources** and (2) a **database** for future research on their quality and alignment with user needs.

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Preprint

Data

Background

Clinical trials require review by research ethics committees (RECs). The quality of this review depends on both the documentation submitted by applicants and the evaluative skills of REC members. High-quality documentation relies on applicants' ability to navigate ethical, legal, and methodological requirements. Accessible guidelines and resources can aid medical researchers and REC members in navigating these requirements and the review process.

Aim

To explore and qualitatively describe the pool of available resources on the websites of a purposively selected sample of relevant stakeholders.

Which types of resources are already available and which topics do they cover?

Methods

We conducted an *explorative* search on the websites of 12 national umbrella organizations (6 German- and 6 English-language), 3 international umbrella organizations, and 16 national RECs from major university hospitals (8 German- and 8 English-language). We mapped the identified resources qualitatively onto ethical principles detailed by 35 checkpoints and analyzed their content thematically.

We extracted a total of **233** resources including: templates (n = 134, 58.5%), guidelines (n = 62, 26.6%), checklists (n = 23, 9.9%), tools (n = 5, 2.2%), flowcharts (n = 5, 2.2%), glossaries (n = 3, 1.3%), and one (0.4%) software program.

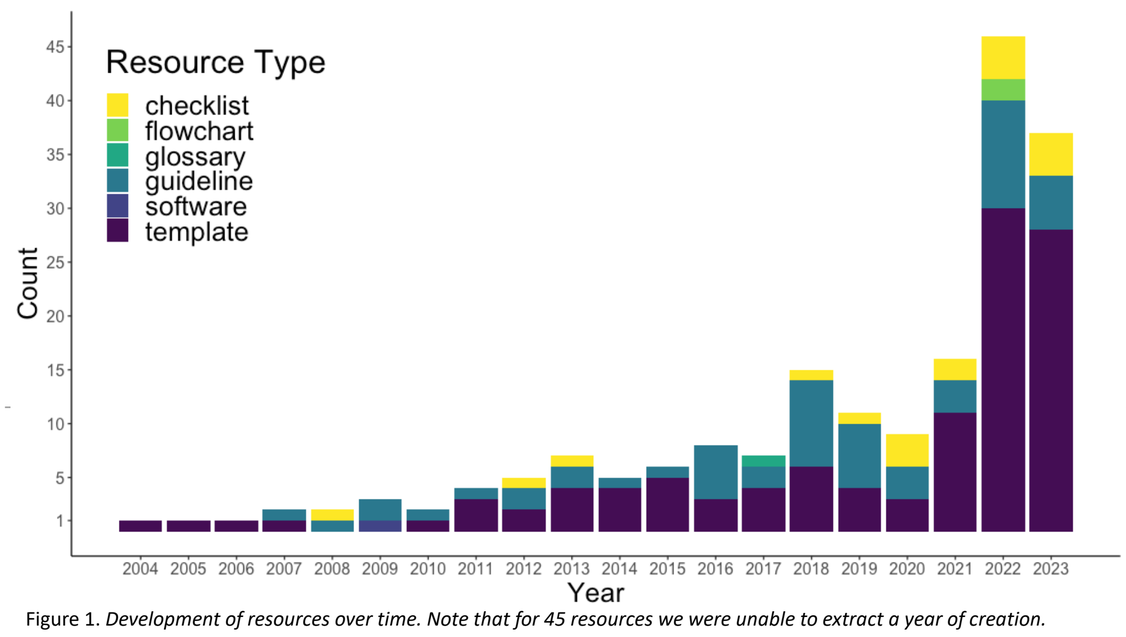

Figure 1. *Development of resources over time. Note that for 45 resources we were unable to extract a year of creation.*

Results

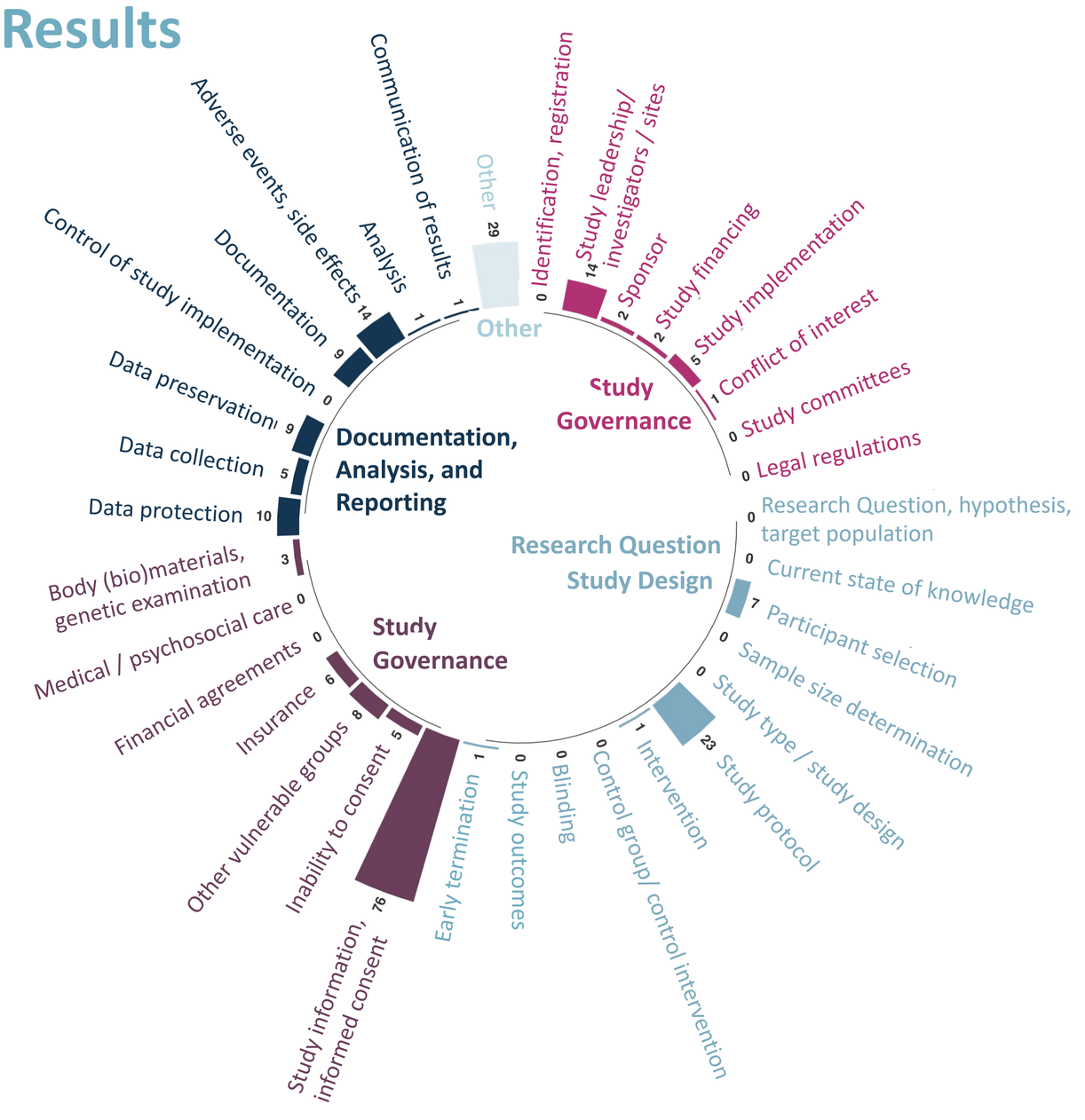

Figure 2. *Number of resources available per checkpoint associated with the guiding principles of ethical clinical research.*

Conclusion

While much support is available for aspects such as participant information and informed consent, it is lacking for study design, analysis and biometrics.

Next Steps

1. **Extend Scoping Review**: Broaden the scope to include resources from *all* relevant stakeholders focusing on Germany.
2. **Conduct Needs Assessment**: Evaluate the need for additional resources or services to support the ethical review processes and *beyond*.

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