



Clinical Microbiome Trials

The Crucial Role of Standardised Metadata

Microbiome research is rapidly expanding. Out of over 440,000 registered clinical trials, about 4,500 are microbiome-based.

Analysing metadata collections reveals significant variability, highlighting the need for international guidelines set by health authorities to ensure consistency and comparability across datasets.

The **Human Microbiome Action** project is paving the way for consensus in this process.

THE PROBLEM IN NUMBERS

- Only **50%** of clinical trials on the microbiome collect data on antibiotic usage.
- Only **one-third** of clinical trials on the microbiome have microbiome outcomes.
- Just over **20%** gather initial information on pre-/probiotic use.
- Additionally, Standard Operating Procedures (SOPs) are crucial, as sample preparation methods can significantly impact results.

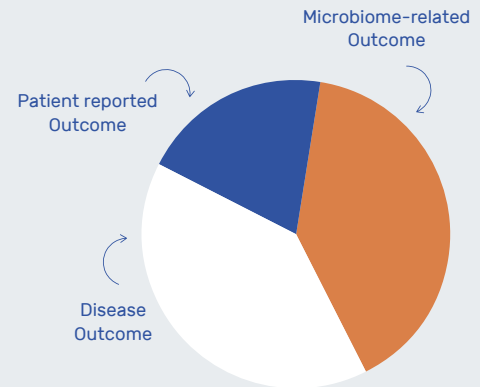


Figure 1: Clinical trials on the microbiome with microbiome-related outcomes.



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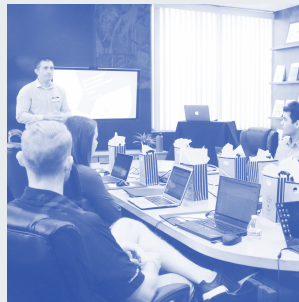
TOWARDS A SOLUTION

Our focus is to ensure robust and reproducible microbiome research outcomes.

Through Delphi consensus involving **70 experts**, we have identified a list of:

Minimal clinical metadata requirements.

Interpretation of clinical outcomes and effects on the microbiome.



SOPs for sample collection, analysis, and producing results on microbiome clinical trials

CONCLUSION

- ✓ The standardisation of clinical metadata is paramount.
- ✓ Microbiome research needs to seek consensus and validation of minimal clinical metadata for microbiome-based clinical trials to ensure robust and reproducible outcomes.
- ✓ The dissemination of the proposed standards is key to this endeavour.

Ready to contribute to the advancement of microbiome research standards?

Join our Stakeholder Advisory Board to provide strategic advice or engage with the ***European Microbiome Centres Consortium*** to foster interdisciplinary collaboration.

For further information, please visit our website humanmicrobiomeaction.eu. Follow the @SciFoodHealth [Twitter/X](#) and [LinkedIn](#) accounts or connect through the [Sustainable Food Systems Network Microbiome Subgroup](#).

Visit our zenodo.org community for all published and upcoming scientific publications.

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