GRAPHICAL ABSTRACT SAMPLE WORK

A meta-research study revealed several challenges in obtaining placebos for investigator-initiated drug trials

SAMPLE WORK

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TRIAL

Conduct of trial

Conduct of trial:

- 6% (6 of 101) already cancelled a trial due to lack of placebos
- 27% (27 of 101) adapted design of a trial due to lack of matching placebos



Corresponding author/Investigator

79 obtained placebos from other sources

28 obtained placebos from drug manufacturer

- 19 (68%) wanted to see study protocol

22 Investigators who obtained placebos from other sources (n=79) reported that they approched drug manufacturer unsuccessfully

- 7 could not provide
- 6 no interest
- 4 costs too high
- 3 patent expired
- 2 avoid conflict of interests

Other sources

- Hospital pharmacy (n=32)
- Other manufacturer (n=19)
- Other pharmacies (n=15)
- Other (n=13)[a]

How to accomplish matching?

- Capsules (n=25)
- Saline (n=22)
- Similar or matching tablets (n=17)
- Other (n=15)[b]

Placebos

Median: 58,286 US$ per trial
→ 10.3% of trial budgets (n=24)

- 21 of 102 investigators used non-matching placebos
- Only 1 publication labelled them correctly

Drug manufacturer/Industry



Hypothesis in the interest of drug manufacturer

	Yes	NO
49 of 101 (48%)		29 of 101 (28%)

23 of 101 (23%) unsure/no answer

obtained drugs	47%	17%
obtained placebos	37%	17%

SAMPLE WORK

Adapted from : Speich, B., Logullo, P., Deuster, S., Marian, I. R., Moschandreas, J., Taji Heravi, A., Gloy, V., Briel, M., Hopewell, S., & MAking Randomized Trials Affordable (MARTA) Group (2021). A meta-research study revealed several challenges in obtaining placebos for investigator-initiated drug trials. Journal of clinical epidemiology, 131, 70–78. https://doi.org/10.1016/j.jclinepi.2020.11.007

CONCLUSION: Addressing placebo access barriers is essential to support independent trials, enhance methodological quality, and promote transparent, unbiased evidence generation in investigator-initiated drug research.