Role of the Sponsor (Funder) in Research Studies

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Disclosures

No financial conflicts

- Editor, JAMA Internal Medicine
- Funding from Arnold Ventures LLC, Greenwall Foundation, NHLBI

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Lines that raise concern

"The sponsor…"

–Chose the sites

–Adjudicated the endpoints

–Participated in writing

–Reviewed the paper

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The NEW ENGLAND JOURNAL of MEDICINE

Transcatheter Mitral-Valve Repair in Patients with Heart Failure

The trial was sponsored by Abbott. The protocol, available at NEJM.org, was designed by the principal investigators and the sponsor in accordance with the principles delineated by the Mitral Valve Academic Research Consortium.[4,11] The protocol was approved by the investigational review board at each participating center, and all the patients provided written informed consent. The sponsor participated in site selection and management and in data analysis. The principal investigators had unrestricted access to the data, wrote the manuscript, and vouch for the accuracy and completeness of the data and analyses and for the fidelity of the trial to the protocol.

Total payments from Abbott (2015-2021)

1st author / Co-PI:
- $45,058.72 in general payments
- $54,696.00 in research funding

2nd author:
- $102,267.56 in general payments

3rd author:
- $129,410.09 in general payments
- $1,787.50 in research funding

Last author / Co-PI:
- $7,408.76 in general payments
- $378,073.46 in research funding

Stone GW, Lindenfeld J, Abraham WT, et al. Transcatheter Mitral-Valve Repair in Patients with Heart Failure. *N Engl J Med*. 2018;379(24):2307-2318. doi:10.1056/NEJMoa1806640

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The NEW ENGLAND JOURNAL of MEDICINE

Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients

The study was designed by the sponsor, Edwards Lifesciences, and by the executive committee, which included the first two authors, three interventional cardiologists (who were the coprincipal investigators), along with six other academic authors (three cardiac surgeons). The sponsor funded the studies and participated in the selection and management of the sites, the collection of data, and data monitoring. The executive committee met in person every 6 to 8 weeks to monitor all aspects of the conduct of the trial. Members of the executive committee had unrestricted access to the data after the database was locked and prepared all drafts of the manuscript. The sponsor's statistician performed the data analysis, which was duplicated and verified by the independent statisticians at the

[redacted]

Total payments from Edwards (2015-2021)

1st author / Co-PI:
- **$14,434.98 in general payments**
- **$268,300.00 in research funding**

2nd author / Co-PI:
- **$67,604.57 in general payments**
- **$2,722,248.10 in research funding**

Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med*. 2011;364(23):2187-2198. doi:10.1056/NEJMoa1103510

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Guidelines for High-Quality Research

- Independent, highly qualified academic investigators
- Don't need sponsor's "help" to:
  - Put together/run trial
  - Do data analysis
  - Write up results
  - AKA influence the results

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THE WALL STREET JOURNAL.

How Drug Firm Paid for Study By University, Then Yanked It

By Ralph T. King Jr.Staff Reporter of The Wall Street Journal

April 25, 1996 2:30 am ET

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Drugmaker vetoed publication of study

- Dr. Betty Dong (UCSF Pharmacy) funded by Boots Pharmaceuticals
- Results: generic drugs had bio-equivalence to Synthroid
- UC has since banned contracts allowing funder control of publication

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King, Ralph T. How drug firm paid for study by university, then yanked it. *Wall Street Journal* https://www.wsj.com/articles/SB830387635451455000? Published April 25, 1996.

Moving forward

- Journals (ICMJE) should consider restricting role of sponsor for submitted papers
  - Example of clinical trial registration requirement

- Investigators should be independent of sponsor in all aspects of study design, data analysis, and writing

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Thank you!

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