

# Long list of conflicts of interest in industry-funded drug trials are counterproductive and opaque for readers

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2 Title: Long list of conflicts of interest in industry-funded drug trials are counterproductive3 and opaque for readers

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- 3 atopic dermatitis, observational study

#### 1 MANUSCRIPT

2

#### 1. Introduction

Conflict of interest (COI) has been widely accepted as a mandatory item of reporting.[1] The optimal method for declaring COI remains unclear and varies from brief statements to extensive lists.[2,3] We hypothesise that exhaustive lists, encompassing all financial relationships with drug companies spanning many years (whether related to the study drug or not) are counterproductive and opaque. The objective was to determine whether the use of lengthy lists of COIs creates difficulties for readers in identifying the most relevant COIs in dermatological industry-funded randomised controlled trials (RCTs) of drug treatments.

#### 10 **2.** Methods

A recruited panel of typical dermatology journal readers (UK dermatology clinicians and researchers) completed an online cross-sectional survey about COIs in a purposive sample of four RCTs published in leading journals. Each paper had a long list of COIs, covering more than a third of a page, on the topic of a commercial drug for a single skin condition. The primary outcome was the percentage of readers correctly identifying the company that developed the drug with authors who had a direct conflict with that company for the four papers included, assessed independently by three authors who acted as a reference standard.

## 18 **3. Results**

A total of 23 readers completed the survey (response rate 44%). Six (26%) were exclusively clinicians and 17 (73.9%) were research active (**Table**). No readers correctly identified direct COIs of authors to the experimental drugs (**Figure**). All 23 readers correctly identified the companies producing these drugs. Median time per paper taken to try and identify the authors with direct COI was 6 minutes [4-8]. Readers reported a median score of 3 [2-4] for confidence in their COI conclusions, indicating moderate confidence (6-point Likert scale; 1: no confidence to 6: complete confidence). Scores obtained by readers with an exclusive clinical activity were lower than the scores obtained by researchers. Free comments
 highlighted challenges in discerning relevant COIs.

#### **4. Discussion**

Identifying authors with relevant COIs from long lists of COIs is counterproductive. 4 5 According to our readers' comments and previous literature, [4] several modifiable factors 6 could have contributed to challenges in accurately identifying relevant COIs, such as dense 7 paragraphs, small font, initialled names rather than full names, information split across 8 different pages and declaration of COIs in an appendix. In some senses, such COIs have 9 become the exhaustive "small print" for terms and conditions that few people read on many websites. There is a need for transparency to avoid analysis bias and facilitate interpretation 10 11 of COIs.[5] We suggest that a clear and simple statement should indicate which authors have a direct financial conflict with the product. We advocate for more reader-friendly and clear 12 13 COI disclosures, which could be facilitated using an "ACE" framework denoting the Author(s) who received financial support from Company X (...a subsidiary of Company Y) who 14 15 developed/manufactured the Experimental treatment drug [name of drug] in this study. Others 16 have suggested a similar approach.[4] The standard full ICMJE COI statement could remain at the end of the article for those who need the detail. 17

#### **1 ABBREVIATIONS**

- 2 COI: Conflict of Interest
- 3 RCT: Randomised Controlled Trial

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## **18 COMPETING INTERESTS**

19 The authors declare no competing interest.

## 20 ETHICS APPROVAL

21 Not applicable

#### 22 TRANSPARENCY DECLARATION

23 The lead author affirms that this manuscript is an honest, accurate, and transparent account of

the study being reported; that no important aspects of the study have been omitted; and that

1 any discrepancies from the study as planned (and, if relevant, registered) have been

2 explained.

## **3 DATA SHARING**

4 Data supporting the study findings will be available from the corresponding author on

5 reasonable request.

## 6 **REGISTRATION**

- 7 This prospective observational study was registered on the  $22^{nd}$  of December 2022 at the
- 8 Centre of Evidence Based Dermatology registration portal. The protocol can be accessed at
- 9 https://www.nottingham.ac.uk/research/groups/cebd/documents/protocol-coi.pdf.

# **REFERENCES**

2	1.	International Committee of Medical Journal Editors. Author Responsibilities
3		Conflicts of Interest. Recommendations for the Conduct, Reporting, Editing, a
4		Publication of Scholarly Work in Medical Journa
5		https://www.icmje.org/recommendations/browse/roles-and-responsibilities/author-
6		responsibilitiesconflicts-of-interest.html [accessed 26th February 2024]
7	2.	Bauchner H, Fontanarosa PB, Flanagin A. Conflicts of interests, authors, and journal
8		new challenges for a persistent problem. JAMA 2018; 320:2315-2318.
9		https://doi.org/10.1001/jama.2018.17593
10	3.	Grundy Q, Dunn AG, Bero L. Improving researchers' conflict of interest declaration
11		BMJ 2020;368:m422. <u>https://doi.org/10.1136/bmj.m422</u>
12	4.	Agrawal D, Haque W. Transparent disclosure of conflicts of interest. JAMA 201
13		321:1728. https://doi.org/10.1001/jama.2019
14	5.	Boutron I, Page MJ, Higgins JPT, Altman DG, Lundh A, Hróbjartsson A. Chapter
15		Considering bias and conflicts of interest among the included studies. In: Higgins JF
16		Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochra
17		Handbook for Systematic Reviews of Interventions version 6.0 (updated July 201
18		Cochrane, 2019.

# 1 **TABLE.** General readers' characteristics

## 2

Characteristics	N = 23	
Gender, <i>n</i> (%)		
Female	14 (60.9)	
Male	9 (39.1)	
Age (years)	34 [31-44.5]	
Number of scientific articles read by month	5 [4.0-10.0]	
Professional role, n (%)		
Clinician	6 (26.1)	
Researcher	7 (30.4)	
Both clinician and researcher	10 (43.5)	
Work setting for clinicians, <i>n</i> (%)*		
Public practice (NHS)**	16 (100)	
Private practice**	2 (12.5)	
Number of years within dermatology specialty (1 <sup>st</sup> year of	7 [3.0-15.25]	
residency)*		

3 Data are expressed as median [IQR] or number (%)

4 \*Not applicable for 7 readers with an exclusive research activity

5 \*\*A reader can have multiple activities

- **FIGURE.** Outcomes stratified by paper and readers' characteristics
- 2 Primary outcome (percentage of readers who correctly both identified the company that
- *developed the drug and whether any (and which) of the authors have a direct conflict with*
- *that company for the 4 papers included) stratified by paper and readers' characteristics*
- 5 (created with flourish.studio: <u>https://flourish.studio</u>).

# 1 Supplemental file

- 2 Appendix 1. Methods
- 3 Appendix 2. Search strategy in Medline (equation research used in the GREAT database)
- 4 Appendix 3. Characteristics of included studies and extracted data