



Global Evidence Summit

Notable concerns (and insufficient information disclosed) on COI of trials included in a Cochrane SR: piloting TACIT

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I have no actual or potential conflicts of interest.

We are not part of the development group. We were invited as independent users.

<https://tacit.one>



Background

- Conflicts of interest (COI): when a judgement or actions related to a primary interest may be inappropriately influenced by secondary interests.
 - **Funding sources** and COI of the **investigators of primary studies**.
- COI of trial researchers are often underreported and the involvement of trial funders and researchers are not always clear.

Background



Cochrane
Library

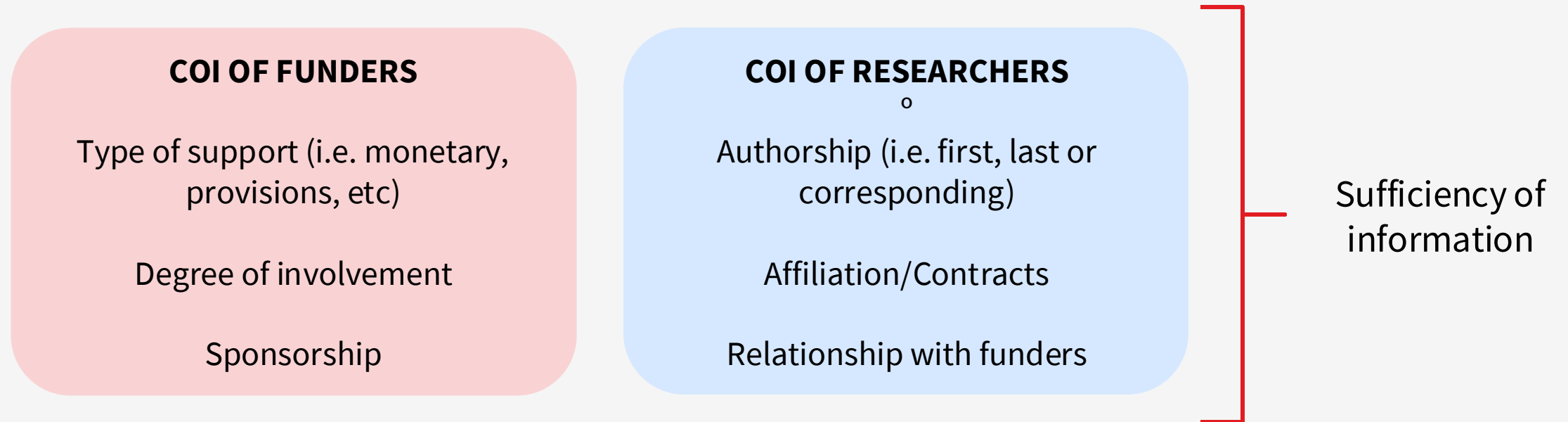
Cochrane Database of Systematic Reviews

Atypical antipsychotics for autism spectrum disorder: a network meta-analysis (Protocol)

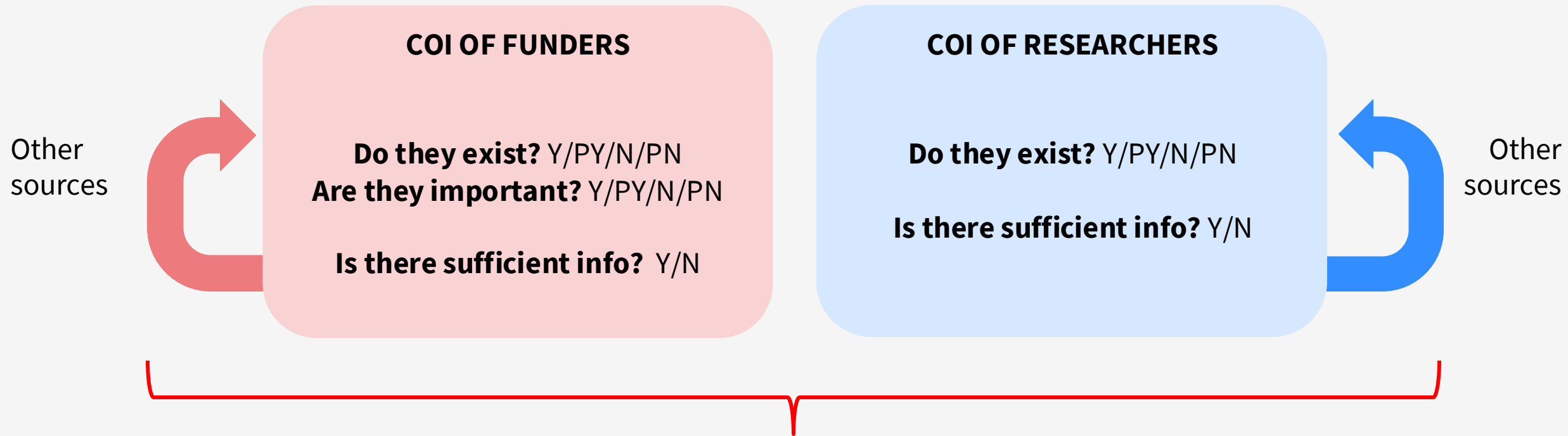
Meza N, Rees R, Escobar Liquitay CM, Franco JVA, Sguassero Y, Williams K, Pringsheim T, Rojas V, Madrid E

Methods

- We analysed 17 randomized clinical trials included in an ongoing Cochrane SR.
- We collected data from conflicts of interest statements, authors' affiliations, acknowledgements, authors' contributions, funding, sponsorship; both in the **main publication** and **other sources** (i.e., web searches, other publications, etc).
- We applied TACIT in order to process:



Methods



Notable concerns on COI in the trial / No notable concerns

Very insufficient info. / Insufficient info. / Sufficient info.

Methods

Table 5. Characteristics indicating whether industry funder involvement is probable or not

Reviewers should decide whether the funders' involvement is probable or not in an industry-funded trial with no reporting of funder involvement. The characteristics below may be used as guidance, but there are no validated criteria or tools developed for such an assessment.

Industry funder involvement probable	Industry funder involvement not probable
<i>Characteristics indicating industry funder probably involved</i>	<i>Characteristics indicating industry funder probably not involved</i>
Trial used for regulatory approval	Academic trial unit named
Molecular compound name used to describe trial drug (e.g., TAS-102 [39])	Sponsor is primary academic researcher or academic institution
Commercial funder's employees involved (e.g., mentioned in acknowledgements)	Little commercial incentive for company involvement (e.g., patent expired on trial drug interventions)
Contract research organisation involved (e.g., mentioned in acknowledgements)	Non-drug and non-device interventions only
Medical writer involved (e.g., mentioned in acknowledgements)	Commercial funding solely amounted to free provision of trial intervention
Commercial funder is also trial sponsor	
Use of ghost authors employed by commercial funder or contract research organisations [33]	

Methods

Table 6. Examples of types of relationships that are judged as *important* or *not important* conflicts of interest

<i>Important</i> conflicts of interest <i>(i.e., significant or major relationships)</i>	<i>Not important</i> conflicts of interest <i>(i.e., trivial or minor relationships)</i>
Advisory board membership	One-time free conference trip
Consultant	One-time small speakers' fee
Speakers' bureau	Participation in sponsored Continuing Medical Education event (i.e., free education and dining)
Paid investigator or member of trial committee in current or previous trial by manufacturer of trial intervention	Unpaid investigator or member of trial committee in current or previous trial by manufacturer of trial intervention
Research funding	
Patent ownership	
Stock ownership	

Results

- 14/17 trials were rated as having notable concerns about COI
 - 10 studies had an important involvement of funders with commercial COI
 - 11 trials had important COI of academic authors
 - In four trials, the concerning data were not disclosed in the primary publication → Other publications, institutional profiles, etc.
- In 14/17 studies the available information was at least insufficient.

Conclusions

- Most of the randomised clinical trials on atypical antipsychotics for ASD raise notable concerns about COI
- There is very insufficient information on COI
- We expect to explore the impact of this findings throughout the results of our NMA (i.e. sensitivity analysis).



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