

10 Dias S, Welton NJ, Caldwell DM, Ades AE. Checking consistency in mixed treatment comparison meta-analysis. *Stat Med* 2010; **29**:932–44.

The use of large patient databases to improve disease understanding and care

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Paradoxical reactions to biologic agents represent clinically important complications that frequently involve the skin. They are difficult to treat and require multidisciplinary patient management. Psoriasis is the most frequent paradoxical reaction and is primarily associated with tumour necrosis factor antagonists. Paradoxical psoriasis results from an exaggerated innate immune response orchestrated by plasmacytoid dendritic cells producing type I interferon, as demonstrated by Conrad et al.¹


In this issue of the *British Journal of Dermatology*, Bataille et al. have investigated the incidence and risk factors for paradoxical reactions to biologic agents in a cohort of patients identified from the database of the 39 university hospitals of the Paris region.² This database contains outpatient and inpatient medical records from more than 11 million patients followed up since 2012. Using an innovative approach including algorithms based on natural language processing, the authors were able to analyse medical records to constitute a cohort of more than 9000 patients treated with a biologic agent, out of whom 297 experienced a paradoxical reaction. They have shown that the incidence of paradoxical reactions with biologic agents, mostly tumour necrosis factor antagonists, is 7.6 per 1000 patient-years. The incidence appears to be higher in patients with inflammatory bowel diseases and in patients with more than one inflammatory disease, confirming clinical impression and previous reports.

The conclusions of the study are robust and the study design and analysis methods open the window to an entire new field of epidemiological research using large datasets beyond traditional specialty boundaries. Large hospital and insurance databases are increasingly used across the globe to answer in a timely manner clinically relevant questions such as during the COVID pandemic.³ The concept of medical data availability and data sharing is important to sustain medical progress.

One important area of improvement in medical research is the ability for academic researchers to have access to data from clinical trials of approved drugs. Since 2014, the pharmaceutical industry has committed to share deidentified individual

patient data for approved medicines and indications with qualified researchers.⁴

We experienced recently that access to clinical data from pharmaceutical companies is still at the embryonic stage, occasionally with the presence of strong resistance.⁵ This experience is in line with recent literature on the subject showing that only a small subset of clinical trial data is available for researchers in different fields of medicine.^{6,7} More efforts are needed in the future to ensure the availability of clinical trial data for researchers to produce high-quality research such as the article by Bataille et al. We owe it to the altruistic patients who participate in research with the aim of advancing clinical care.

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Data availability statement: No new data generated applies.

References

- 1 Conrad C, Di Domizio J, Mylonas A et al. TNF blockade induces a dysregulated type I interferon response without autoimmunity in paradoxical psoriasis. *Nat Commun* 2018; **9**:25.
- 2 Bataille P, Layese R, Claudepierre P et al. Paradoxical reactions and biologic agents: a French cohort study of 9303 patients. *Br J Dermatol* 2022; **187**:676–83.
- 3 Semenzato L, Botton J, Drouin J et al. Chronic diseases, health conditions and risk of COVID-19-related hospitalization and in-hospital mortality during the first wave of the epidemic in France: a cohort study of 66 million people. *Lancet Reg Health Eur* 2021; **8**:100158.
- 4 PhRMA. Principles for responsible clinical trial data sharing. Available at: <http://phrma-docs.phrma.org/sites/default/files/pdf/PhRMAPrinciplesForResponsibleClinicalTrialDataSharing.pdf> (last accessed 24 August 2022).
- 5 Masson Regnault M, Shourick J, Jendoubi F et al. Time to relapse after discontinuing systemic treatment for psoriasis: a systematic review. *Am J Clin Dermatol* 2022; **23**:433–47.
- 6 Danchev V, Min Y, Borghi J et al. Evaluation of data sharing after implementation of the International Committee of Medical Journal Editors data sharing statement requirement. *JAMA Netw Open* 2021; **4**:e2033972.
- 7 Modi ND, Abuhelwa AY, McKinnon RA et al. Audit of data sharing by pharmaceutical companies for anticancer medicines approved by the US Food and Drug Administration. *JAMA Oncol* 2022; in press; doi: <https://doi.org/10.1001/jamaoncol.2022.2867>.