

A pharmacovigilance study of the adverse event “photosensitivity reaction” in children versus adolescents

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INTRO

- Dermatologists rely on reference lists to facilitate diagnosis of **drug-induced photosensitivity reactions**
- Lists compiled from data of **adult patients**
- Drug safety **analyses rarely focus on pediatric patients**

METHODS

- Observational, retrospective, pharmacovigilance study in FDA pharmacovigilance data from 2004Q1 to 2021Q3
- Which drugs are strongly associated with the adverse event (AE) “photosensitivity reaction”?
- Reporting Odds Ratio (ROR) and 95%-confidence intervals
- By age group 0-5, 6-11, 12-17, 18-64 and 65+.



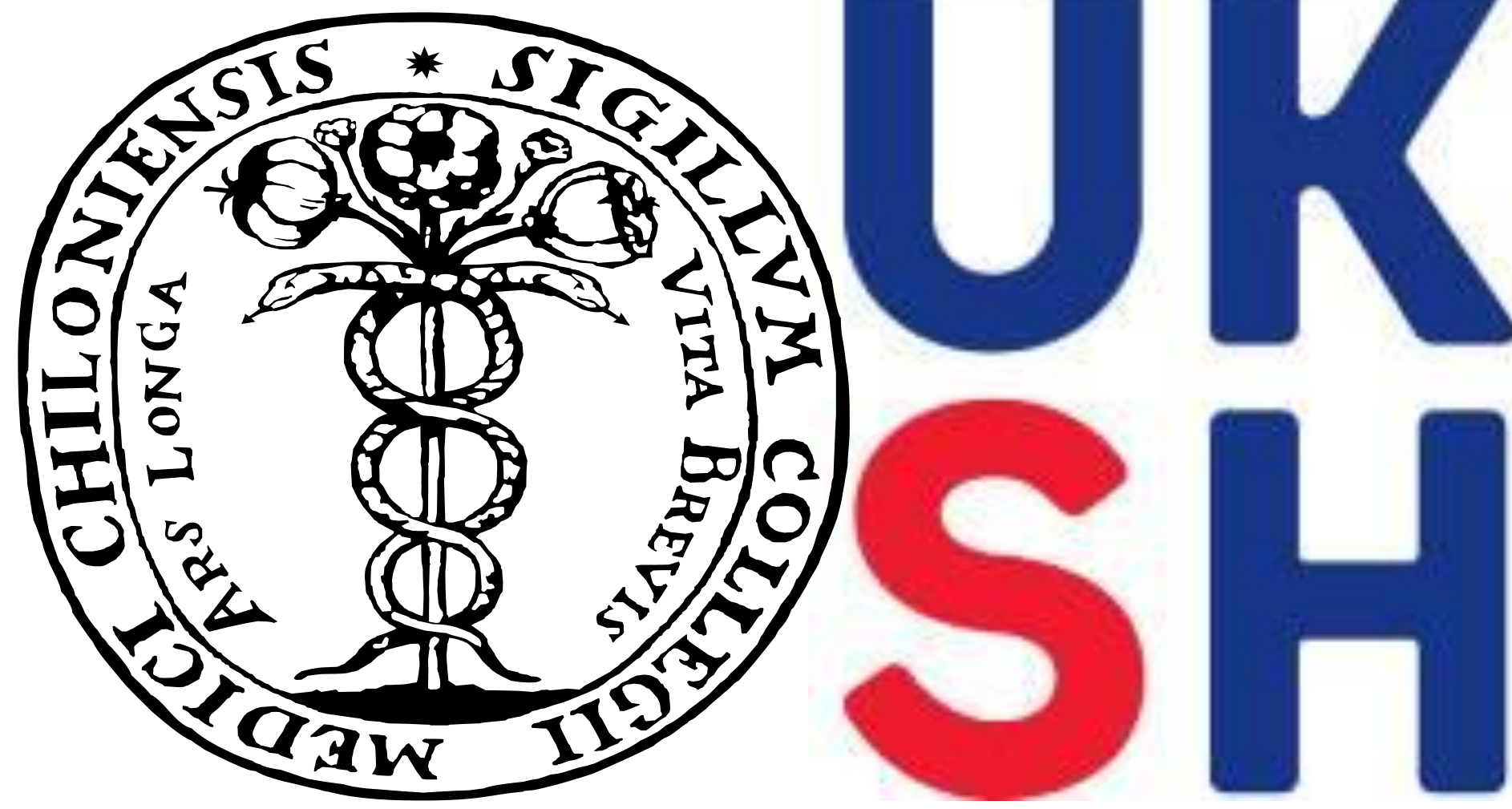
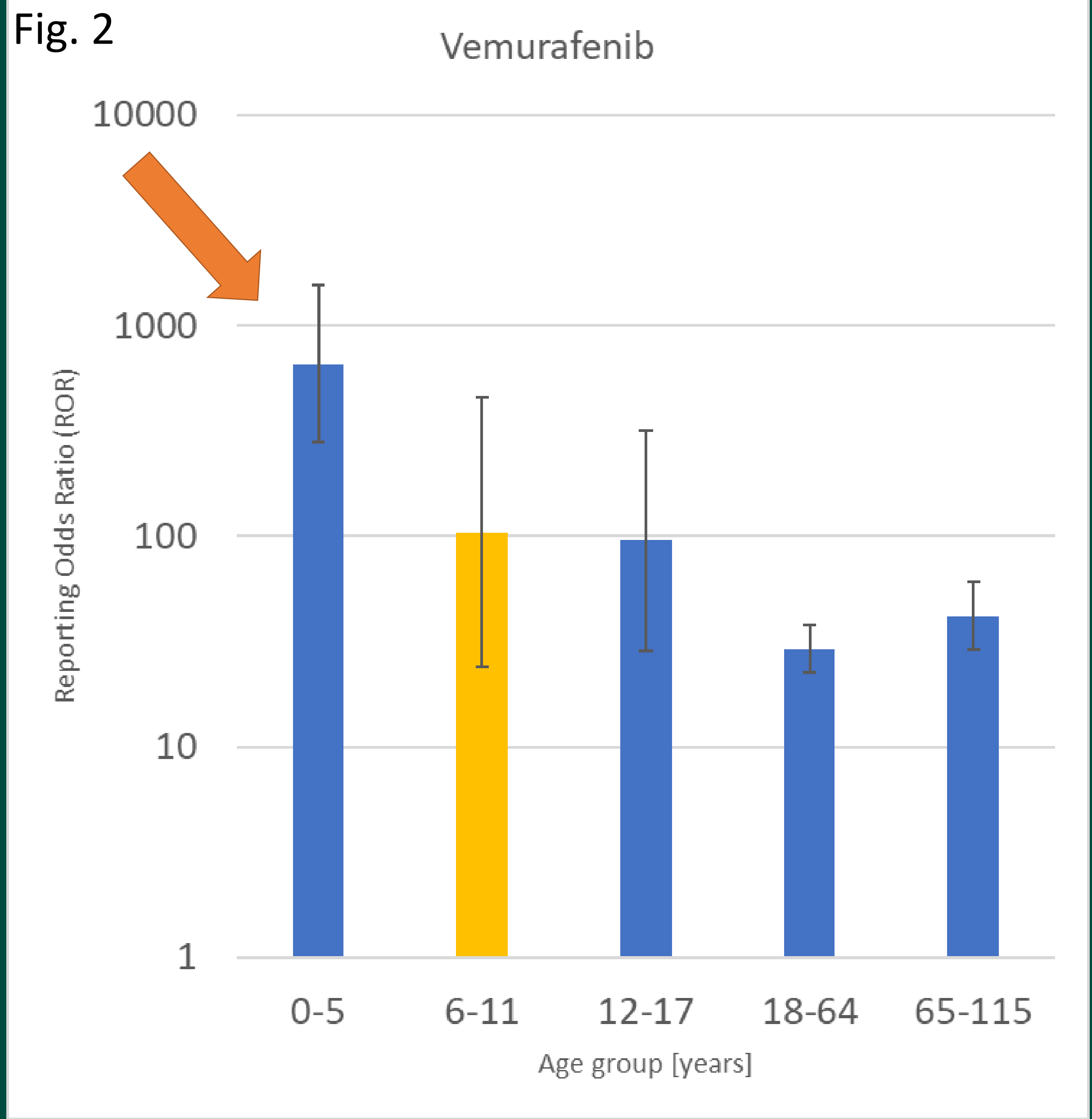
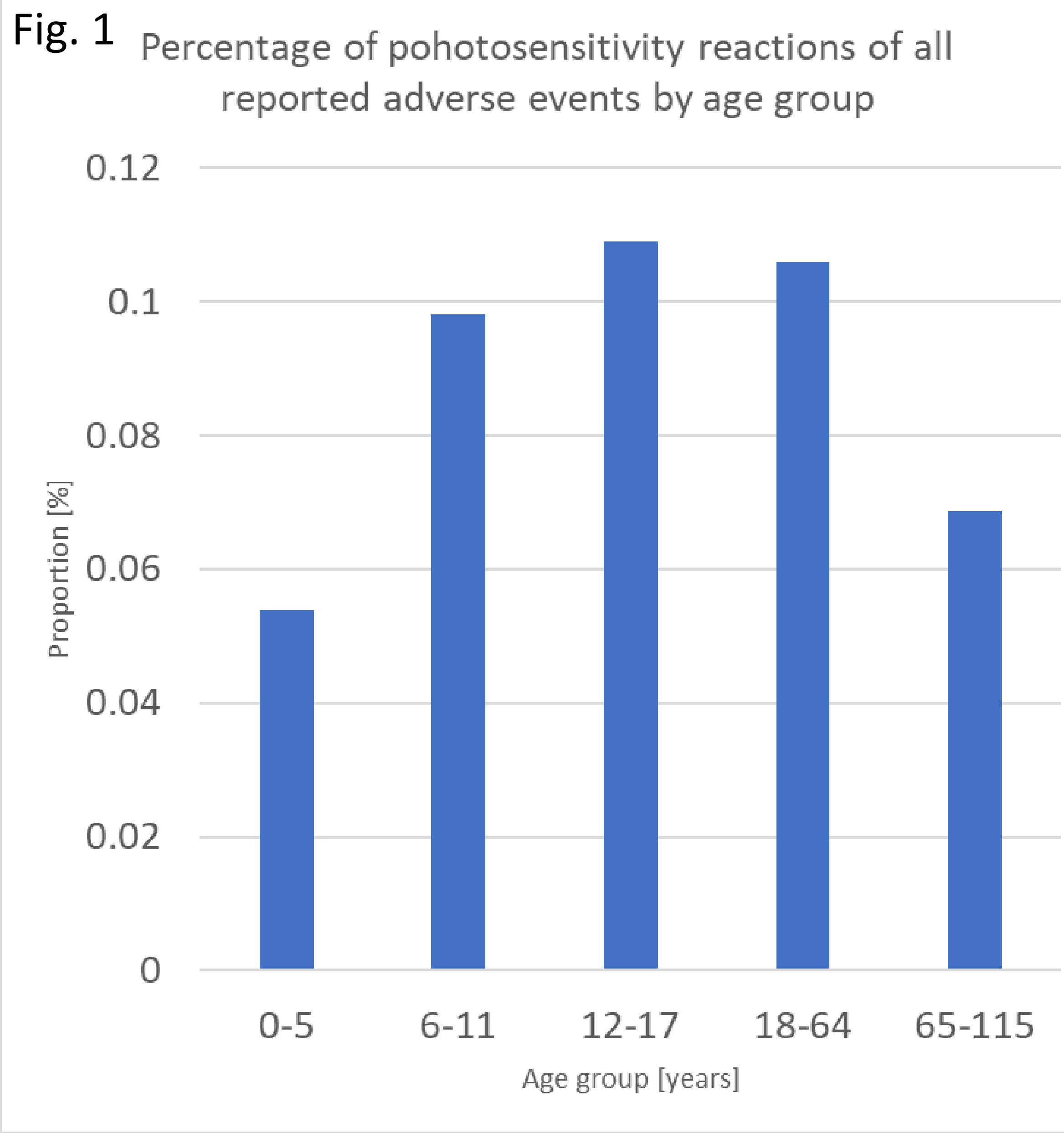
RESULTS

- n = 4,739,450 reports with data on patients’ ages considered
- n = 3975 photosensitivity reactions (= rate 0.092%)
- Most cases reported for adolescents and adults (fig. 1)
- Risk of photosensitivity reaction for 0-5 year olds is highest with vemurafenib and voriconazole (rate 24%; and 6% resp., fig. 2)
- Similar pattern for other drugs (supp. figs.)

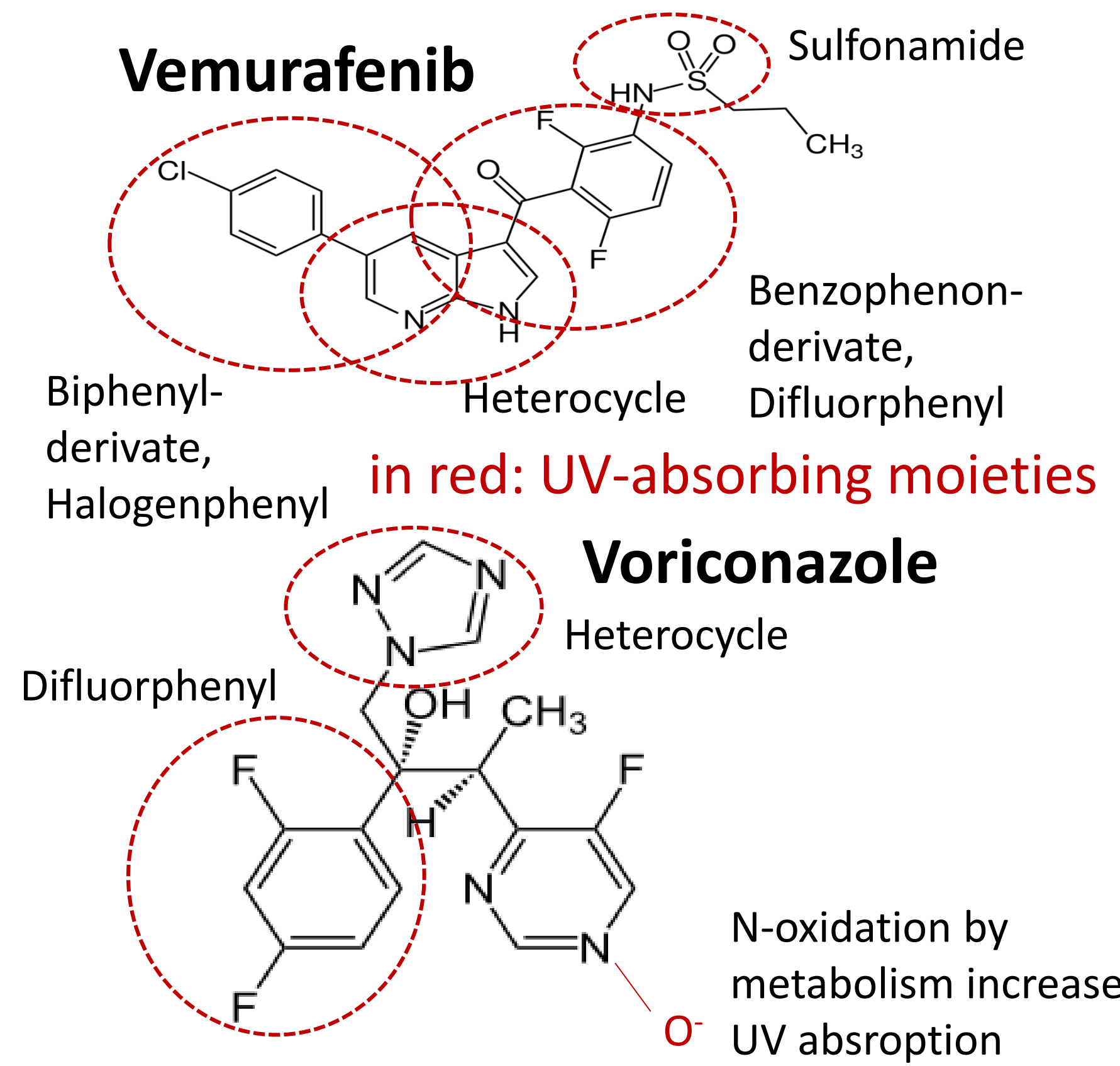
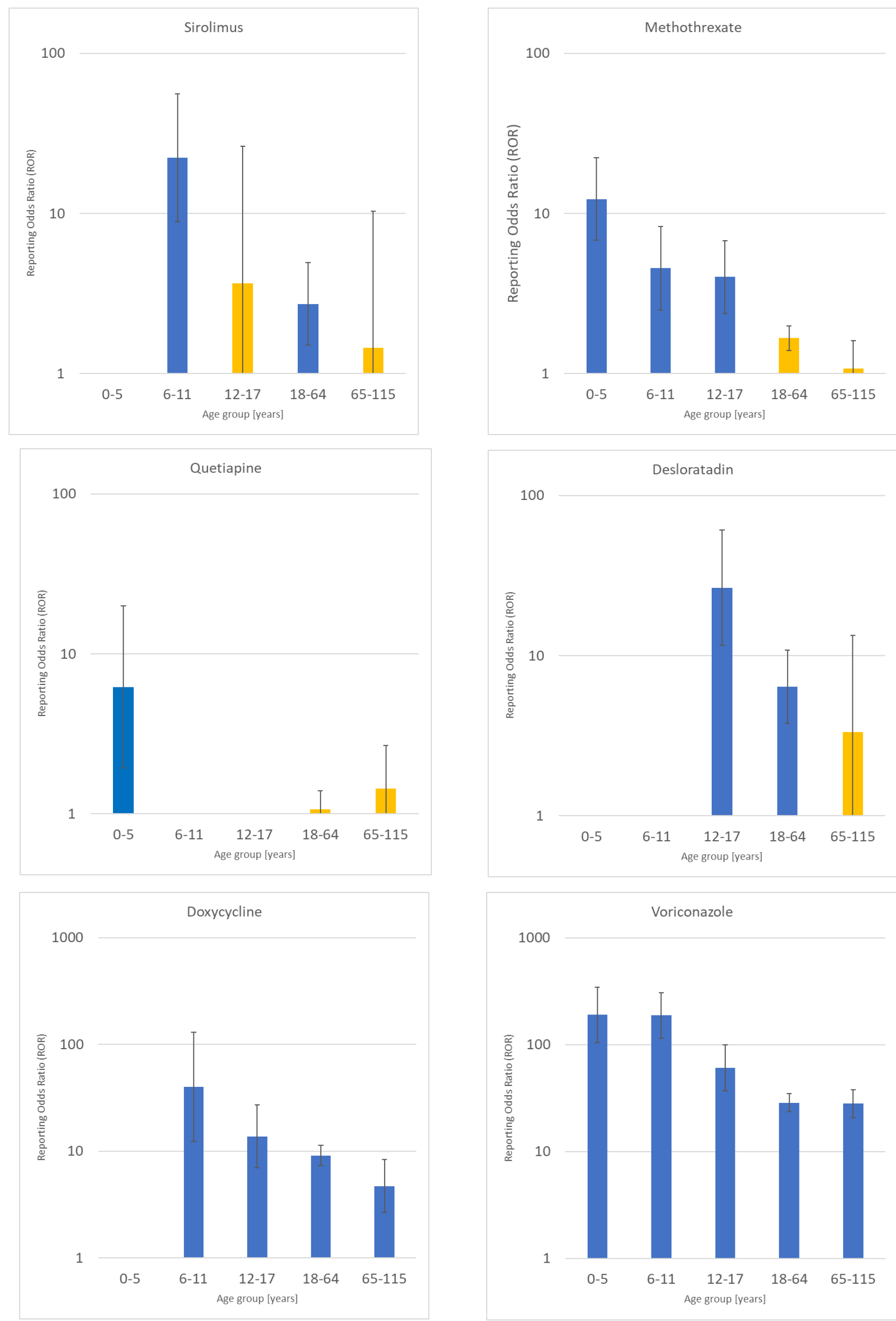
DISCUSSION

- Vemurafenib was so far unknown to frequently cause this AE in children (Jew et al. Pediatr Dermatol . 2019 Jan;36(1):e62-e63)
- Confounding by sunburn-predisposing dermatologic disease was ruled out

Use sunscreen for pediatric patients on vemurafenib!



■ = Signal for an ADR according to the statistical criteria of Evans ($n \geq 3$, proportional reporting ratio ≥ 2 , Chi-squared ≥ 4 ($p < 0.05$))
■ = No ADR according to the statistical criteria of Evans (Pharmacoepidemiol Drug Saf. 2001;10(6):483-6)



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