

Review of over 15 years post-marketing safety surveillance spontaneous data for the human rotavirus vaccine (*Rotarix*) on intussusception

Journal: Drug Safety

Authorship: Tina Singh¹, Frédérique Delannois¹, François Haguinet¹, Lifeter Yenwo Molo¹

Affiliations:

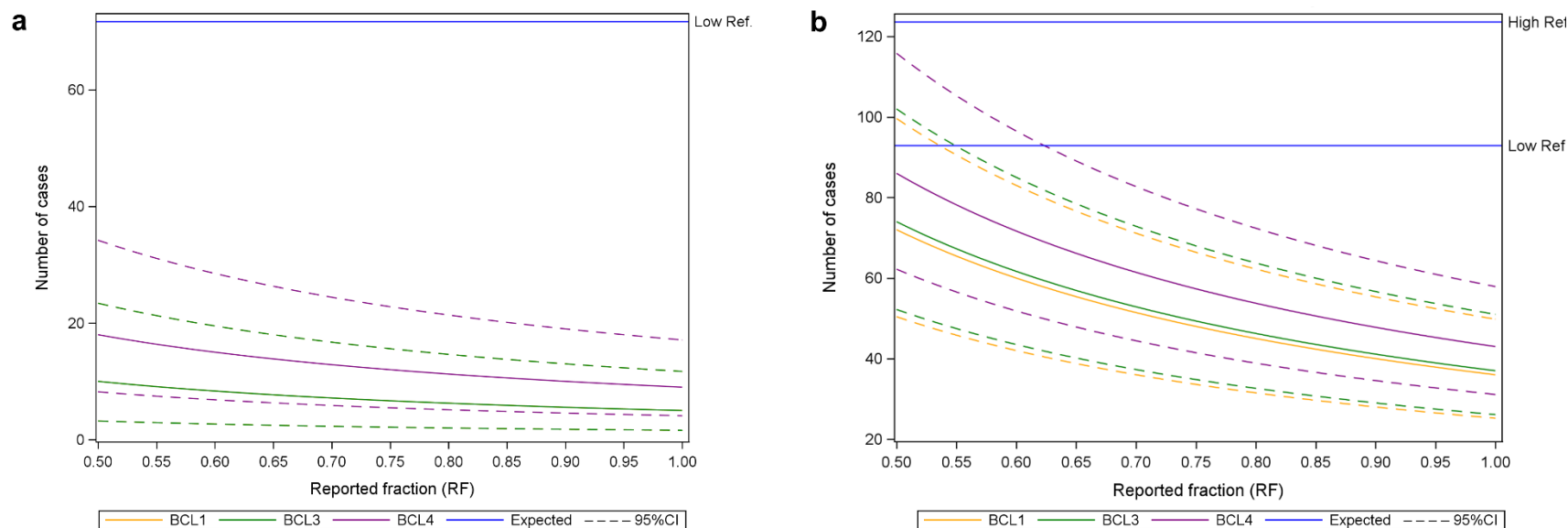
¹GSK, Avenue Fleming 20, 1300 Wavre, Belgium

Corresponding author:

Tina Singh

tina.x.singh@gsk.com

Electronic supplementary material 6 Significance area for the equality test of observed and expected incidences within 7 days (day 0–day 6) after the second dose according to the reported fraction of events in (a) the United States and (b) Japan



BCL1, Brighton Collaboration Working Group level 1; BCL3, Brighton Collaboration Working Group levels 1–3; BCL4, Brighton Collaboration Working Group levels 1–4; Low Ref. – High Ref., range of expected cases according to background incidence rates (high ref is out of scale on panel A); 95% CI, 95 percent confidence interval. Total number of doses was 10,945,330 for the United States and 3,406,093 for Japan.