VIGIBASE ANALYSIS

Drug: nivolumab
Adverse event: a_colitis
Setting: All reports
VigiBase version: September 2024

N° of cases: 44
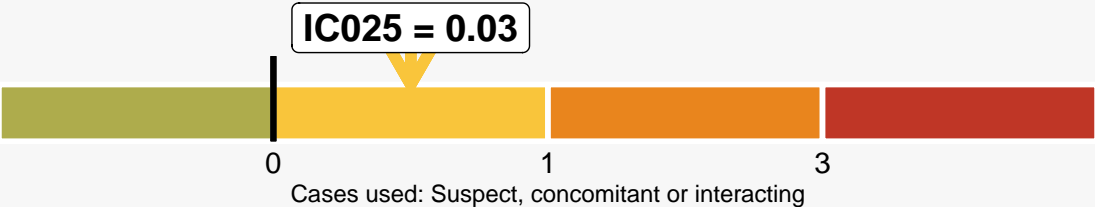

Suspected: 43
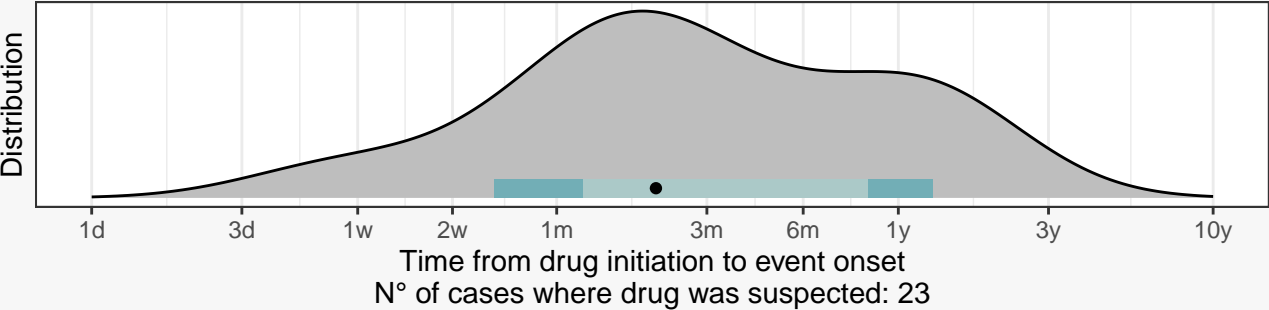Concomitant: 0
Interacting: 1

Rechallenge

Total	19
Positive	12
Rate	63%

Informative rechallenges only

Disproportionality Analysis

IC025 = 0.03

0   1   3

Cases used: Suspect, concomitant or interacting

Time to onset

Distribution

1d   3d   1w   2w   1m   3m   6m   1y   3y   10y

Time from drug initiation to event onset
N° of cases where drug was suspected: 23

50% of patients   80% of patients

d: day, w: week, m: month, y: year
x axis capped at 1 day (min) and 10 years (max)

Created with vigicaen, the R package for VigiBase®

VIGIBASE ANALYSIS

Drug: nivolumab + ipilimumab
Adverse event: a_colitis
Setting: All reports
VigiBase version: September 2024

N° of cases: 18
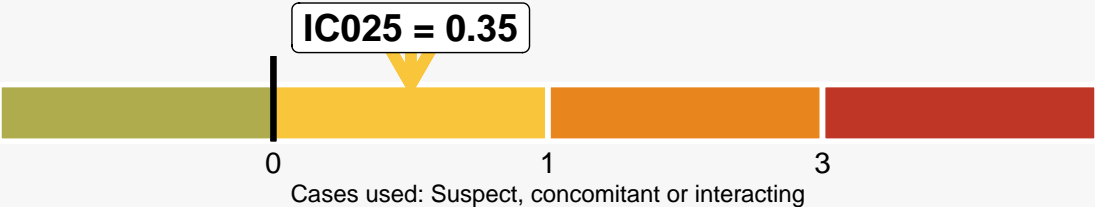
Suspected: 17
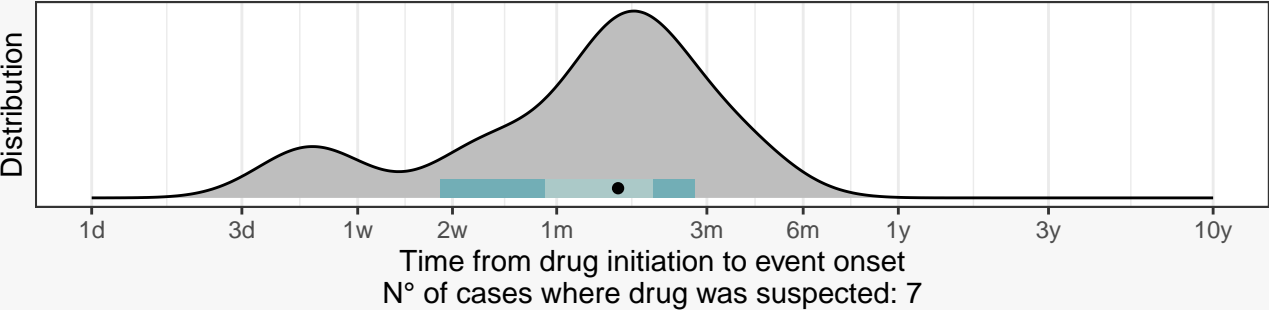Concomitant: 0
Interacting: 1

Rechallenge

Total	8
Positive	3
Rate	38%

Informative
rechallenges only

Disproportionality Analysis

IC025 = 0.35

0   1   3

Cases used: Suspect, concomitant or interacting

Time to onset

Distribution

1d   3d   1w   2w   1m   3m   6m   1y   3y   10y

Time from drug initiation to event onset
N° of cases where drug was suspected: 7

50% of patients   80% of patients

d: day, w: week, m: month, y: year
x axis capped at 1 day (min) and 10 years (max)

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