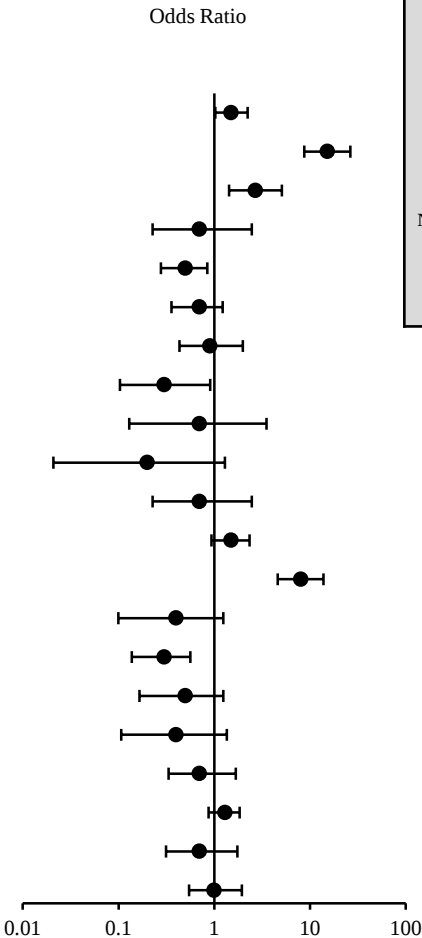


Figure 1.

Univariate Analysis

Explanatory Variables	95% CI			
	Odds ratio	Lower limit	Upper limit	p
Company Profile	1.5	1.0	2.2	0.04
ODD	15.2	8.7	26.3	0.00
Priority Review	2.7	1.4	5.1	0.00
Expedited Review	0.7	0.2	2.5	0.63
Normal Review	0.5	0.3	0.8	0.01
A	0.7	0.4	1.2	0.19
B	0.9	0.4	2.0	0.84
C	0.3	0.1	0.9	0.03
D	0.7	0.1	3.5	0.64
G	0.2	0.0	1.3	0.09
H	0.7	0.2	2.5	0.63
J	1.5	0.9	2.3	0.09
L	8.0	4.6	13.8	0.00
M	0.4	0.1	1.2	0.10
N	0.3	0.1	0.6	0.00
R	0.5	0.2	1.2	0.12
S	0.4	0.1	1.3	0.13
V	0.7	0.3	1.7	0.48
Global Data	1.3	0.9	1.8	0.22
Bridging Study	0.7	0.3	1.7	0.49
Global Study	1.0	0.5	1.9	0.93



Multivariate Analysis

Explanatory Variables	95% CI			
	Odds ratio	Lower limit	Upper limit	p
ODD	17.4	9.6	31.6	0.00
Normal Review	0.3	0.1	0.5	0.00
L	4.9	2.6	9.2	0.00
N	0.5	0.2	1.0	0.06

Hosmer-Lemeshow test		
χ^2	df	p
7.2	4	0.1

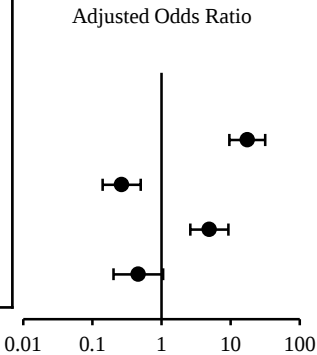
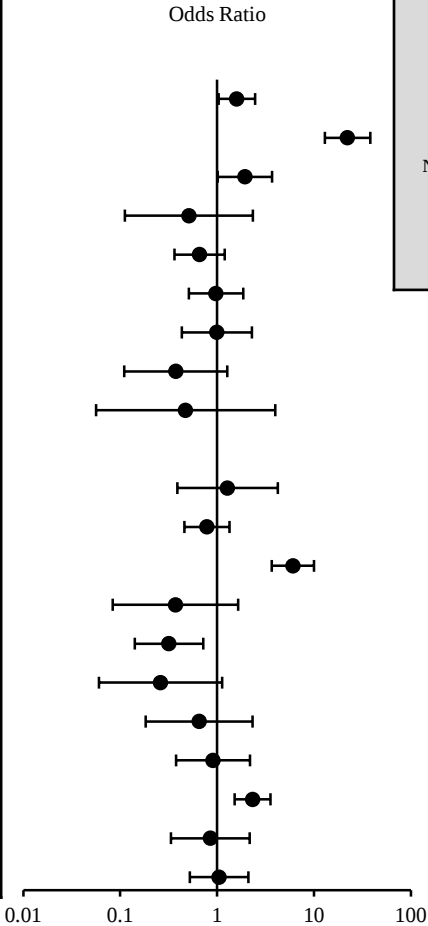


Figure 2.

Univariate Analysis

Multivariate Analysis

Explanatory Variables	95% CI			
	Odds ratio	Lower limit	Upper limit	p
Company Profile	1.6	1.0	2.5	0.03
ODD	22.2	13.0	38.1	0.00
Priority Review	1.9	1.0	3.7	0.04
Expedited Review	0.5	0.1	2.3	0.39
Normal Review	0.7	0.4	1.2	0.17
A	1.0	0.5	1.9	0.94
B	1.0	0.4	2.3	0.99
C	0.4	0.1	1.3	0.12
D	0.5	0.1	4.0	0.49
G	0.0	0.0		1.00
H	1.3	0.4	4.2	0.68
J	0.8	0.5	1.3	0.38
L	6.1	3.7	10.0	0.00
M	0.4	0.1	1.7	0.19
N	0.3	0.1	0.7	0.01
R	0.3	0.1	1.1	0.07
S	0.7	0.2	2.3	0.51
V	0.9	0.4	2.2	0.83
Global Data	2.3	1.5	3.6	0.00
Bridging Study	0.9	0.3	2.2	0.74
Global Study	1.0	0.5	2.1	0.90



Explanatory Variables	95% CI			
	Odds ratio	Lower limit	Upper limit	p
ODD	36.2	18.7	70.3	0.00
Normal Review	0.2	0.1	0.4	0.00
L	3.8	2.0	7.4	0.00
V	4.4	1.5	12.7	0.00
Global Data	2.6	1.4	4.6	0.00

Hosmer-Lemeshow test

χ^2	df	p
5.7	4	0.2

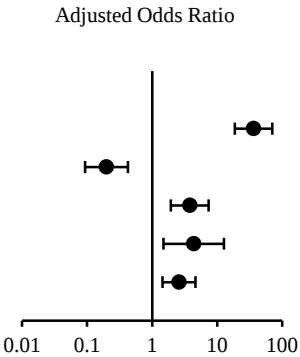


Figure 3.

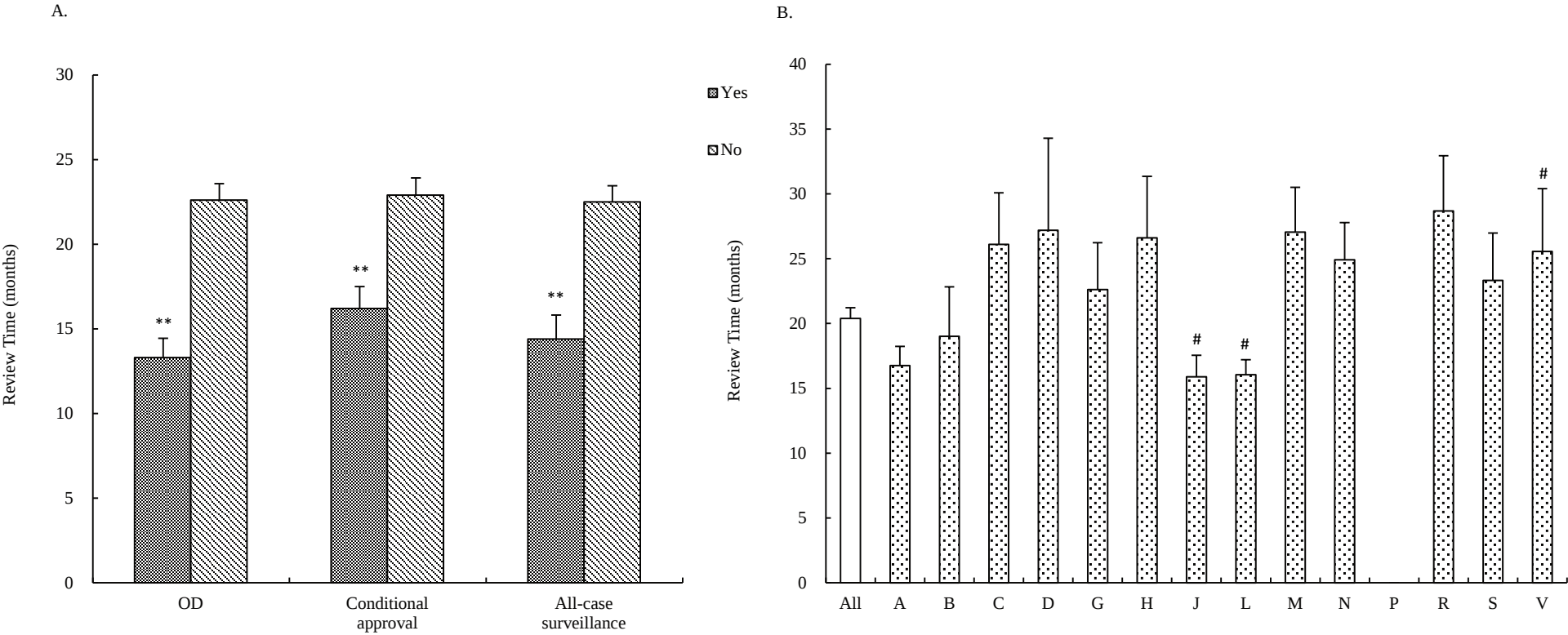
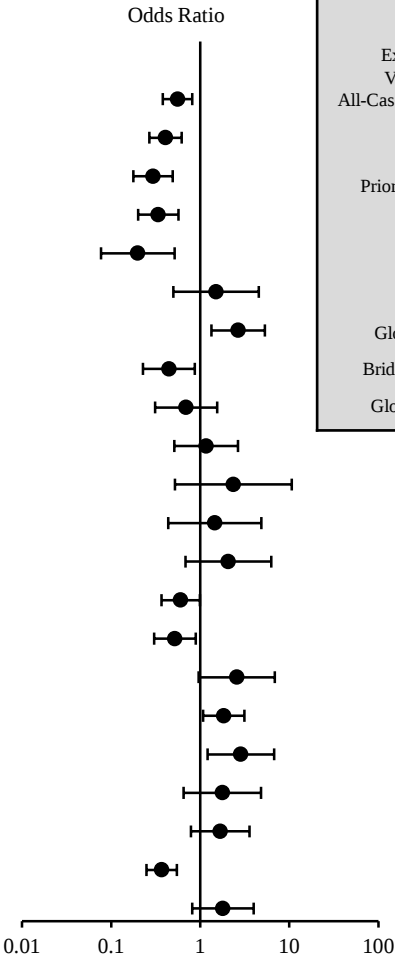


Figure 4.

Univariate Analysis

Explanatory Variables	95% CI			
	Odds ratio	Lower limit	Upper Limit	p
Company Profile	0.6	0.4	0.8	0.00
Conditional Approval	0.4	0.3	0.6	0.00
All-Case Surveillance	0.3	0.2	0.5	0.00
ODD	0.3	0.2	0.6	0.00
Priority Review	0.2	0.1	0.5	0.00
Expedited Review	1.5	0.5	4.6	0.47
Normal Review	2.7	1.3	5.3	0.01
A	0.4	0.2	0.9	0.02
B	0.7	0.3	1.5	0.37
C	1.2	0.5	2.7	0.71
D	2.3	0.5	10.6	0.27
G	1.5	0.4	4.9	0.54
H	2.1	0.7	6.3	0.20
J	0.6	0.4	1.0	0.05
L	0.5	0.3	0.9	0.02
M	2.6	1.0	6.9	0.06
N	1.8	1.1	3.1	0.03
R	2.9	1.2	6.7	0.02
S	1.8	0.7	4.8	0.26
V	1.7	0.8	3.6	0.18
Global Data	0.4	0.2	0.5	0.00
Bridging Study	1.8	0.8	4.0	0.15
Global Study	0.1	0.1	0.4	0.00



Multivariate Analysis

Explanatory Variables	95% CI			
	Odds ratio	Lower limit	Upper Limit	p
All-Case Surveillance	0.5	0.3	1.1	0.07
ODD	0.4	0.2	0.9	0.02
Priority Review	0.2	0.1	0.6	0.00
A	0.4	0.2	0.9	0.02
J	0.7	0.4	1.2	0.15
R	2.4	0.9	6.5	0.08
Global Data	0.5	0.3	0.8	0.00
Bridging Study	2.8	1.1	7.1	0.03
Global Study	0.2	0.1	0.5	0.00

Hosmer-Lemeshow test

χ^2	df	p
4.7	7	0.7

Adjusted Odds Ratio

