

Table 36 Cumulative number of observed and expected cases of SD following Infanrix hexa in children in their first or second year of life

Time since vaccination (days)	Observed (1st year)	Expected	Observed (2d year)	Expected
0	16	54.4	2	1.98
1	29	108.8	5	3.96
2	42	163.2	6	5.94
3	50	217.6	6	7.92
4	57	272	6	9.9
5	60	326.4	7	11.88
6	60	380.8	7	13.86
7	62	435.2	7	15.84
8	63	489.6	7	17.82
9	65	544	7	19.8
10	65	598.4	7	21.78
11	65	652.8	7	23.76
12	65	707.2	7	25.74
13	65	761.6	8	27.72
14	65	816	8	29.7
15	66	870.4	8	31.68
16	67	924.8	8	33.66
17	67	979.2	8	35.64
18	67	1033.6	8	37.62
19	67	1088	8	39.6

This analysis shows that the number of sudden death cases reported after vaccination with Infanrix hexa is below the number of cases expected in children in their 1st year of life; it is equal or below the number of cases expected in children between in their 2d year of life.

The Company monitors these cases and their reporting frequencies on an ongoing basis.

9.3.1.1.4. Limitations

There are several limitations for Observed/Expected analyses, and several levels of uncertainty. The major factors affecting O/E analyses are related to:

- Underreporting, reporting biases, and incomplete case details.
- Uncertainty on the number of subjects actually vaccinated.
- No age stratification within the two age groups.