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| Supplemental Table 3.Protocol deviations (full analysis set). | |
| **Protocol deviation (%)** | **Number of patients**  **(N = 3014)** |
| Number of patients with at least one major protocol deviation | 600 (20) |
| AE/SAE | 44 (1) |
| Disallowed medications | 394 (13) |
| Inclusion or exclusion criteria | 78 (3) |
| Informed consent | 38 (1) |
| Investigational product administration or study treatment | 66 (2) |
| Procedures or tests | 25 (1) |
| Withdrawal criteria | 13 (< 1) |
| AE: adverse event; SAE: serious AE. | |