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| **Subject ID** | **Date of deviation** | **Date identified** | **Deviation identified by** | **Deviation description**  **(incl. possible reasons for deviation and action taken)** | **Dev. type (code)** | **Deviation classification (number)** | **Resulted in AE?** | **Did subject continue in study?** | **Meets IEC reporting req. (yes/no)** | **IEC reporting date** | **Meets Fimea reporting req.**  **(yes/no)** | **Fimea reporting date** | **Investigator’s**  **signature** |
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Protocol Deviation Codes:

A – Consent Procedures

B – Inclusion/Exclusion Criteria

C – Concomitant Medication/Therapy

D – Laboratory Assessments/Procedures

E – Study Procedures

F – Serious Adverse Event Reporting/Unanticipated Adverse Device Effect

G – Randomization Procedures/Study Drug Dosing

H – Visit Schedule/Interval

I – Efficacy Ratings

J – Other

Protocol Deviation Classification Number:

1 – Minor

2 – Major

3 – Critical