

### **16.1.1 Protocol and Amendments**

The following protocols and protocol amendments were issued for this study. See [Section 9.8.1](#) for details.

[Version 1.0](#), dated 10Dec2015

[Version 2.0](#), dated 26Feb2016 ([Summary of Changes](#), dated 26Feb2016)

[Version 3.0](#), dated 25Aug2016 ([Summary of Changes](#), dated 25Aug2016)

[Version 4.0](#), dated 05Dec2016 ([Summary of Changes](#), dated 05Dec2016)

[Version 5.0](#), dated 12Nov2019 ([Summary of Changes](#), dated 12Nov2019)

[Version 6.0](#), dated 21Sep2021 ([Summary of Changes](#), dated 21Sep2021)