







個別症例安全性報告データ項目 (E2B(R3)項目)

別紙2

Main data table with columns for Report Classification (未完了報告, 完了報告), Data Item (R3), Title (R3), and various input fields for adverse events and safety data. Includes sub-columns for '市販後' and '治験' under both report types.



個別症例安全性報告データ項目(E2B(R3)項目)

別紙2

Table with columns for Data Item (R3), Title (R3), Report Type (Incomplete/Completed), Market (Pre/Post), and Input Conditions. It lists various drug safety reporting parameters like identification, dosage, and adverse events.

個別症例安全性報告データ項目 (E2B(R3)項目)

別紙2

Table with columns for Data Item (R3), Title (R3), Report Type (Incomplete/Completed), Market/Study (Pre/Post), Acknowledgment Code (8-digit), and Acknowledgment Description. The table lists various safety report data points like 'Subject ID', 'Drug information', 'Evaluation source', etc., with corresponding input conditions and values.