

個別症例安全性報告データ項目 (E2B(R3)項目)

別紙2

■ 報告分類

Table with columns for Report Classification (市販後, 治験) and Description (AA-DG).

■ 入力条件記号

Legend table for input conditions: ① (必ず記載する項目), □ (他の項目の記載内容によって入力が必要になる項目), ▲ (可能な限り記載する項目), ■ (簡略記載可能な項目), × (記載してはいけない項目).

Main data table with columns for Data Item (R3), Title (R3), Report Classification (未完了報告, 完了報告), Submission (市販後, 治験), Input Conditions, Acknowledgement (ACKコード), and ACK Completion Description. Includes rows for N.1, C.1, and C.1.6.1.r.2.

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Table with columns for Data Item (R3), Title (R3), Report Classification (Incomplete/Completed), City/Country, Input Conditions, and ACK Code. Rows include various report details like 'Reported by', 'Residence', 'Occupation', and 'Contact Information'.

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Table with columns for Report Type (Reported/Completed), Data Item (R3), Title (R3), City/Treatment, Input Condition Supplement, and ACK Code. It contains a detailed list of clinical trial and patient data points with corresponding input values and codes.

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Table with columns for Data Item (R3), Title (R3), Report Category (Incomplete/Completed), Input/Supplemental Conditions, and ACK Code (8 digits). Rows include various clinical data points like death date, parent information, and adverse events.

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Table with columns for data item (R3), report category (uncompleted/completed), adverse event details (market/post-market), and ACK codes. Includes rows for various medical events like death, life-threatening events, and adverse events, as well as clinical trial results and medical products.



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別紙2

Table with columns for Data Item (R3), Title (R3), Report Type (Incomplete/Completed), Market (Japan/Foreign), and Input/Requirement. It lists various medical data points like drug identification, dosage, and adverse events with corresponding validation codes.

