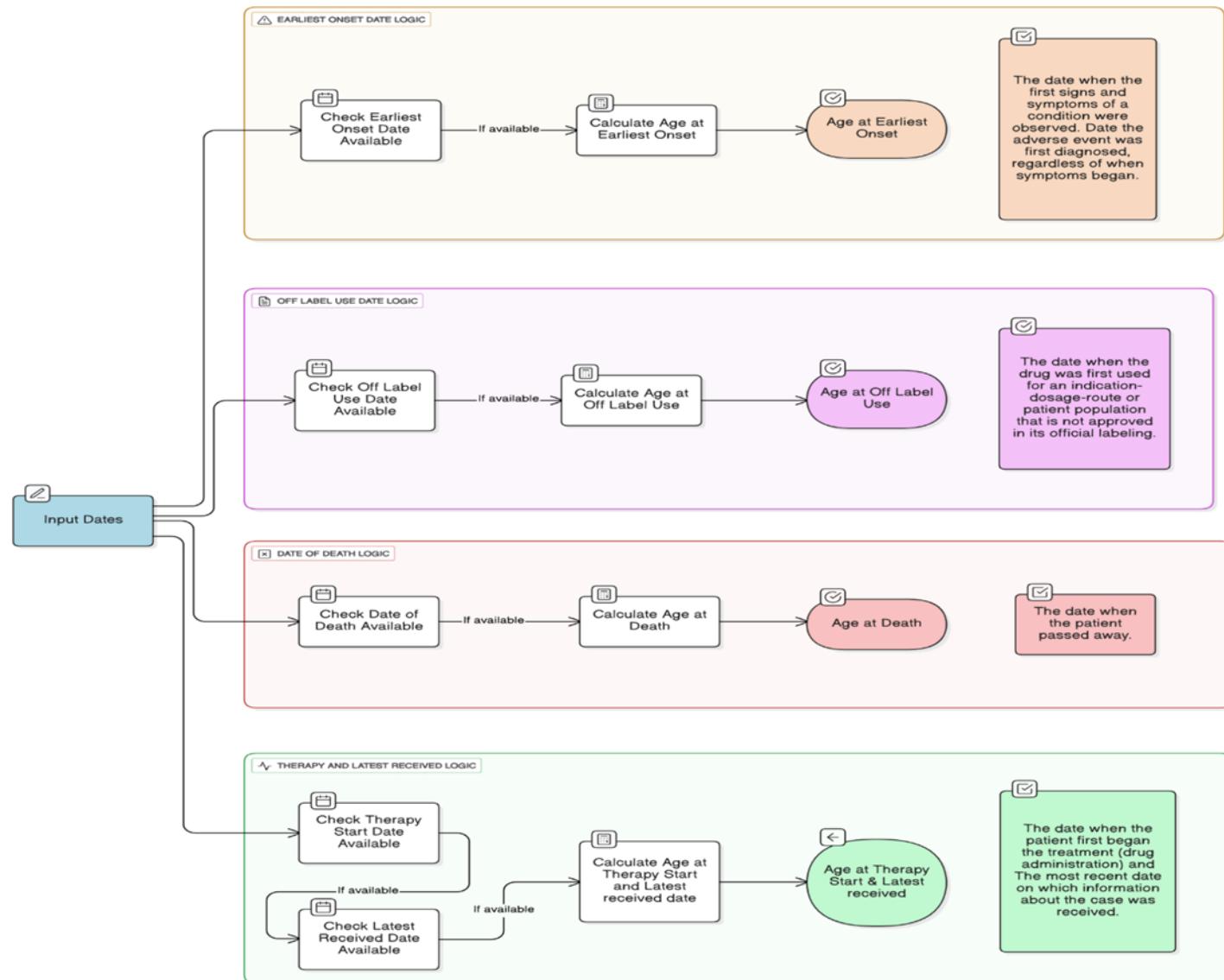


Age Calculation Logic



Age and Age Group



Fetus

Neonate: < 4 weeks

Infant: ≥ 4 weeks to < 24 months

Child: ≥ 24 months to < 12 years

Adolescent: ≥ 12 years to < 18 years

Adult: ≥ 18 years to < 65 years

Decade Demonstration Table

0-9 Years	1 Decade
10-19 Years	2 Decade
20-29 Years	3 Decade
30-39 Years	4 Decade
40-49 Years	5 Decade
50-59 Years	6 Decade
60-69 Years	7 Decade
70-79 Years	8 Decade
80-89 Years	9 Decade

Scenarios and Actions to be taken

- The Manual checkbox must be ticked whenever manually entering the ‘Age at the time of event’ or ‘Age group’
- If the Age Group is unknown, select “Unknown” Null Flavor from the dropdown.
- If the decade does not match the age group, manually update age group as reported, and specify in the narrative.
- When a parent initiates a report regarding his/her child and does not specify the age of the child, it should NOT be assumed that this reference meets the age group of 2 to 13 years (including when a children’s product was administered).
- For fetal ICSRs, enter “Fetus” as age group.
- The subjects date of birth should not be entered into the safety database for interventional clinical trials even if the DOB is provided in the source document.
- Where date of birth and earliest onset date is provided and conflicts with a reported age, retain the auto-calculated age in the structured field and query the reporter, as applicable.
- Where earliest event onset date is not provided, utilize other information provided to determine age and/or age group
- For ICSRs processed in final review workflow, if the age group is not provided and cannot be calculated it will default as unknown.

Age Error Analysis

Root Cause Analysis

