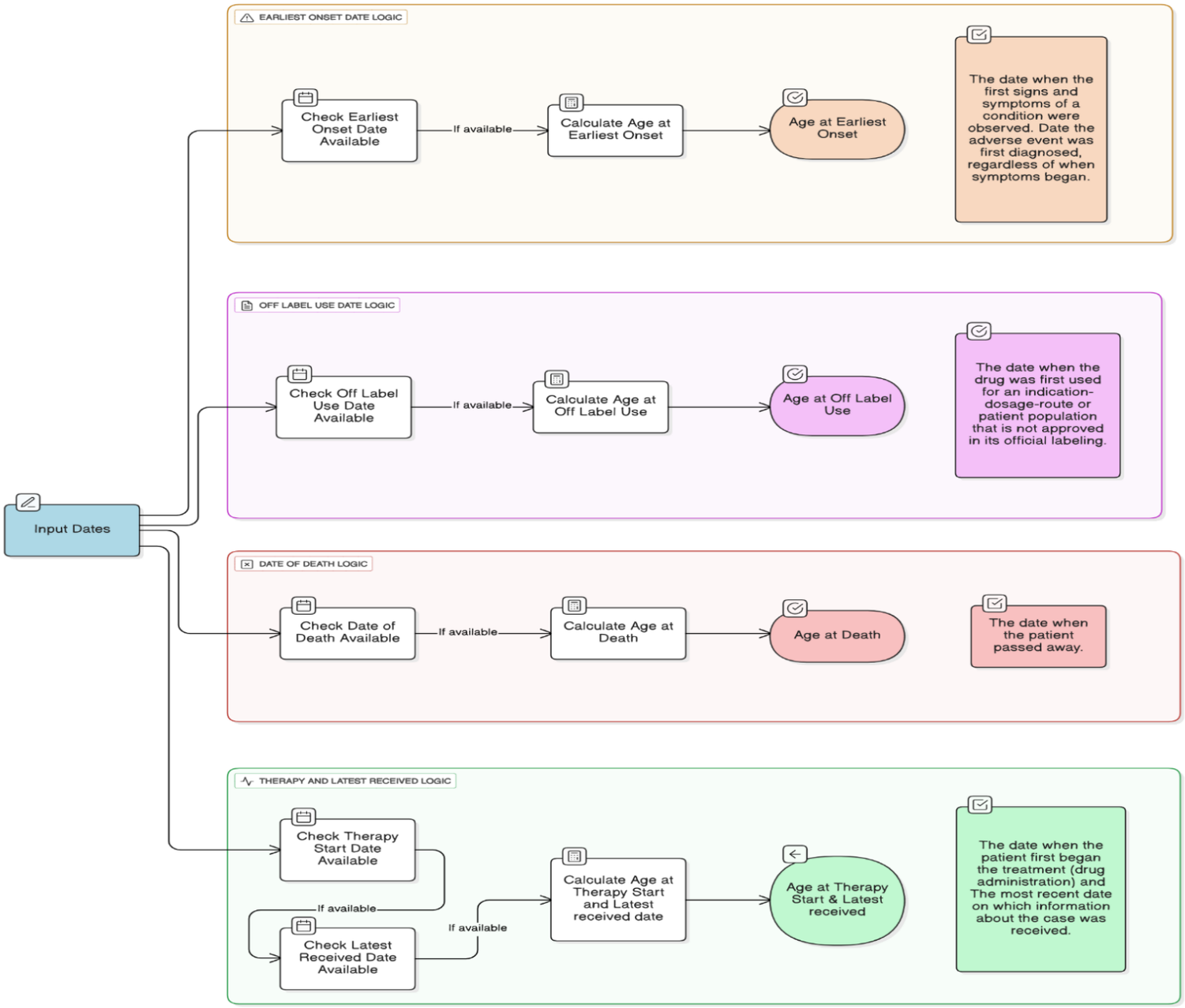
Age Calculation Logic



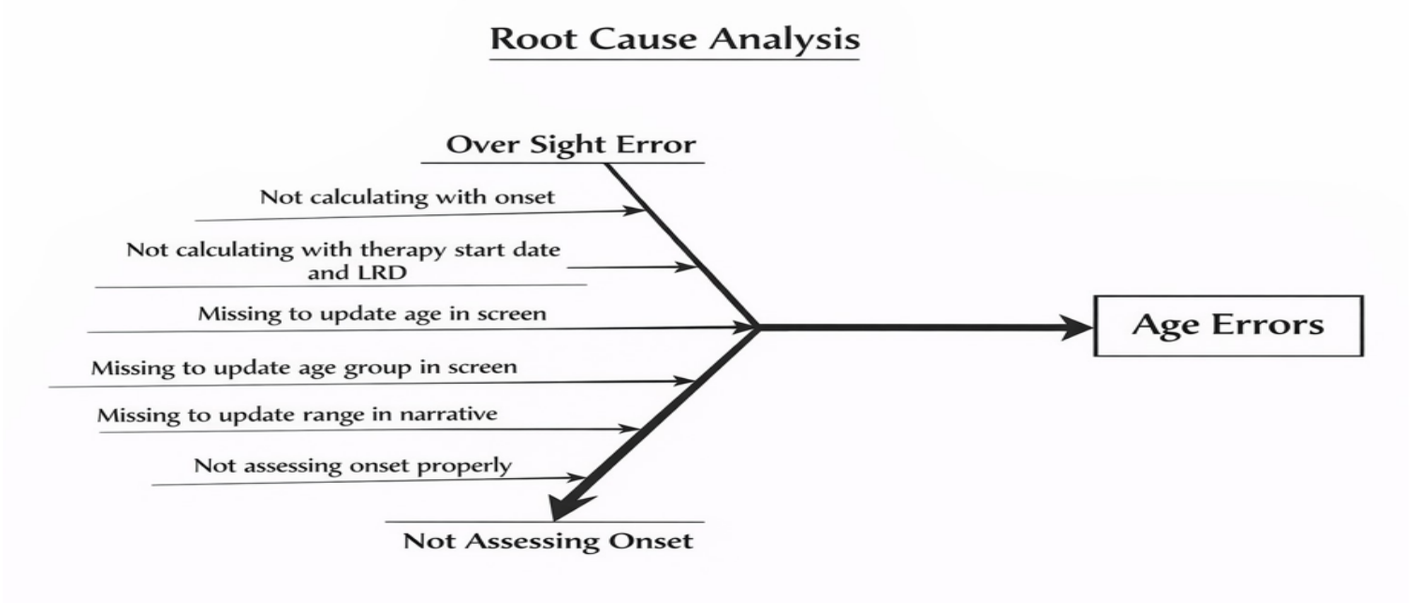
Age and Age Group

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	Elderly: ≥ 65 years

Age Group & Decade Demonstration Table

Date of Birth	Onset Date	Age at Event	Decade	Age Group
01-May-2024	25-May-2024	0 years, 3 weeks, 3 days	1st decade	Neonate
01-May-2023	25-Mar-2024	10 months, 24 days	1st decade	Infant
01-May-2015	25-Mar-2024	8 years, 10 months	1st decade	Child
01-May-2008	25-Mar-2024	15 years, 10 months	2nd decade	Adolescent
01-May-1998	25-Mar-2024	25 years, 10 months	3rd decade	Adult (Early)
01-May-1985	25-Mar-2024	38 years, 10 months	4th decade	Adult (Mid)
01-May-1975	25-Mar-2024	48 years, 10 months	5th decade	Adult (Late)
01-May-1965	25-Mar-2024	58 years, 10 months	6th decade	Adult (Older)
01-May-1955	25-Mar-2024	68 years, 10 months	7th decade	Elderly
01-May-1950	25-Mar-2024	73 years, 10 months	8th decade	Elderly (Old)

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