As stated previously, OCCDS is different from the BDS. There is no PARAM nor AVAL, for example. The more standardized variables commonly occurring in the ADaM OCCDS are described here in tabular format. In general, include all variables from the SDTM dataset and corresponding supplemental qualifiers that are needed for analysis or traceability. For traceability when copying variables from SUPPQUAL, it is recommended to use variable names that exactly match the corresponding SUPPQUAL.QNAM values. Additional study- or therapeutic-area-specific variables may be added as needed but should follow the standard variable-naming conventions described in ADaM/G v1.2 Section 3.3, ADaM Basic Data Structure (BDS) Variables. For example, variables with the 2-letter SDTM prefix are most commonly those that are copied from the SDTM or transposed SUPPQUAL dataset, or the numeric version of the SDTM variable, but not analysis versions of SDTM variables. Choose variable names with care to prevent unintended conflicts with standard names.

As described in ADaM, the 3 rightmost columns of the table (i.e., Core, SubClass ADVERSE EVENT Core, CDISC Notes) provide information about the variables to assist users in preparing their datasets. These columns are not meant to be metadata submitted in define.xml. The Core column describes whether a variable is required (Req), conditionally required (Cond), or permissible (Perm) in the OCCURRENCE DATA STRUCTURE Class. The SubClass ADVERSE EVENT Core column describes whether a variable is required (Req), conditionally required (Cond), permissible (Perm), or not used (Not used) in the ADVERSE EVENT SubClass. The CDISC Notes column provides more information about the variable. In addition, the Type column is being used to define whether the variable is character (Char) or numeric value (Num). More specific information will be provided in metadata.

### SubClass ADVERSE EVENT Variables

OCCDS variables are described later in this section. Variables in an OCCDS dataset that is of SubClass ADVERSE EVENT can include:

- Any variable copied unchanged from ADSL
- Any variable copied unchanged from SDTM AE
  - SubClass ADVERSE EVENT should include all SDTM AE variables with the SDTM core value of Required or Expected.
  - Any variable copied or derived from SDTM F
    - When FA is used as input to the ADVERSE EVENT SubClass dataset, a unique identifier variable, such as FASEQ or FASPID, is required for traceability.
- Any variable copied from content in SDTM SUPPAE
  - It is recommended to use SUPPAE QNAM as the ADVERSE EVENT SubClass dataset variable name, SUPPAEQLABEL as the ADVERSE EVENT SubClass dataset variable label, and SUPPAEQVAL as the ADVERSE EVENT SubClass variable content.
- Derived variables, such as numeric timing variables, TRTEMFL and other indicators, analysis versions of descriptive variables, and other variables derived using the naming conventions described in Section 2.9.7.11, User-specified Variable Naming Conventions

<table>
<thead>
<tr>
<th>Datapoint Traceability Variables for BDS Datasets</th>
<th>ADSL Variables in OCCDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>OCCDS ADVERSE EVENT Variables</td>
<td></td>
</tr>
</tbody>
</table>