

Unqualified Test Name Term List

1. Purpose

One of the key drivers of the development of the Unqualified Test Name Term List is to improve data quality.

The list is designed as an optional tool for MedDRA users to identify instances where unqualified test name terms have been inappropriately recorded in data fields designated for other data elements such as adverse events/adverse reactions (AEs/ARs), etc.

2. Background

SOC *Investigations* contains unqualified terms for the names of investigations or tests, e.g., PT *Blood glucose*, and qualified terms for the qualitative results of investigations, e.g., PT *Blood glucose increased*. The unqualified terms are intended to point to an actual value in a separate database field. For example, in the section for Results of Tests and Procedures in the ICH E2B ICSR electronic transmission standard, unqualified terms may be used in the data element capturing the test name; test results are captured by descriptive text or numeric values, not MedDRA terms.

Unqualified test name terms therefore have a specific use and are not intended for data fields capturing information such as adverse events/adverse reactions, medical history, or indications. Organizations may have developed their own lists to identify unqualified test name terms; however a list developed and maintained by the MSSO serves as a standardized query for MedDRA users to check data quality.

3. Use of the Unqualified Test Name Term List

This list could be helpful to users in regulatory authorities and industry as a standardized query to check data quality in clinical trial and pharmacovigilance databases by identifying the inappropriate use of unqualified test name terms in data fields other than the test name data element.

The Unqualified Test Name Term List is intended as a recommendation only, providing a standard tool for checking coding quality at the data entry level. It is a comprehensive list of all unqualified test name terms at the Preferred Term (PT) and Lowest Level Term (LLT) levels in SOC *Investigations*.

4. Development of the Unqualified Test Name Term List

The preparation of the Unqualified Test Name Term List consisted of identifying all PTs and LLTs in SOC *Investigations* **without** qualifiers. This was done by first identifying the PTs with qualifiers representing a finding or result, and then removing those terms from the list, leaving only the unqualified PTs. Unqualified LLTs (current and non-current) are also included in the list.

The table below shows examples of some of the qualifiers identified:

Normal	Abnormal	Increased	Decreased
Positive	Negative	Present	Absent
Depression	Elevation	High	Low
Improved	Worsened	Fluctuation	Undetectable

The list comprises unqualified test name terms and codes and is maintained and updated by the MSSO with each MedDRA release.