Version 2.0 of the CORE Reference Terminology Table

This resource is Table 2 in Hamilton S, Bernstein AB, Blakey G, Fagan V, Farrow T, Jordan D, Seiler W, Gertel A, (the Budapest Working Group [BWG]). Critical Review of the TransCelerate Template for Clinical Study Reports (CSRs) and Publication of Version 2 of the CORE Reference (Clarity and Openness in Reporting: E3-based) Terminology Table. Research Integrity and Peer Review 2019 (http://dx.doi.org/10.1186/s41073-019-0075-5).

Term	**Definition**	**Example**	2-arm, parallel-group study (Group A: Test Product; Group B: placebo) 8 weeks of randomised treatment	
Objective	The goal a trial is designed to achieve in terms of the scientific questions to be answered		Demonstration of anti-hypertensive efficacy of Test Product	
			Scenario I	**Scenario II**
Hypothesis	Statement relating to the possible different effect of the interventions on an outcome		H_0: The proportion of responders at Week 8 in Group A is lower or equal relative to Group B H_1: The proportion of responders at Week 8 in Group A is higher than in Group B	H_0: The mean change at Week 8 in Group A is equal or greater relative to Group B H_1: The mean change at Week 8 in Group A is lower than in Group B
Measurement	Process of recording the value of a variable (a quantitative value requires a unit; the same value may be expressed in different units [e.g. mg/mL vs. mmol/dL])		Recording of blood pressure (BP) [mmHg]	
Procedure	Specific test carried out on the subject, specimen or data		Sphygmomanometry (common method to measure BP) after 10 minutes in supine position	
Assessment / evaluation	Systematic judgment on the recorded value(s) of a variable. Judgment is based on specific (typically subjective) criteria.		Clinical relevance of diastolic BP values outside of normal ranges at Week 4 and Week 8 (yes/no)	
Variable	A measureable attribute, phenomenon or event that have either qualitative or quantitative values which may be expected to vary over time and within and/or between subjects Note: A variable is an entity to be captured either directly on the CRF or as a derived value (i.e. calculated from other CRF-recorded data).	Recorded (on CRF)	- Diastolic blood pressure at Baseline [mmHg] - Diastolic blood pressure at Week 4 [mmHg] - Diastolic blood pressure at Week 8 [mmHg]	
		Derivation Level 1 (subject level)	- Absolute change in diastolic BP from Baseline to Week 4 [mmHg] - Absolute change in diastolic BP from Baseline to Week 8 [mmHg]	
		Derivation Level 2	(subject level) - Responder* at Week 4 [yes/no] - Responder* at Week 8 [yes/no]	(population level) - ***Mean change in diastolic BP from Baseline to Week 4 [mmHg]*** - ***Mean change in diastolic BP from Baseline to Week 8 [mmHg]***
		Derivation Level 3	(population level) - ***Proportion of responders* at Week 4 [%]*** - ***Proportion of responders* at Week 8 [%]***	*not applicable*

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Term	**Definition**	**Example** 2-arm, parallel-group study (Group A: Test Product; Group B: placebo) 8 weeks of randomised treatment
Endpoint	Variable that pertains to an objective of a trial Note: The primary endpoint should be linked to a hypothesis.	Endpoints set in ***bold Italics*** Primary endpoints ***underlined***
Estimand	Set of pre-specifications for the handling, analysis and interpretation of data in the context of the objectives of a clinical study	• Population: All randomised subjects, analysed as randomised (i.e. not as treated) and irrespective of intercurrent events • Intercurrent event Application of rescue medication • Endpoint: Scenario I: Responders at Week 8 [% yes/no] Scenario II: Change in diastolic BP from Baseline to Week 8 [mmHg] • Population-level summary: Scenario I: Proportion of responders at Week 8 [%] Scenario II: Mean difference in endpoint Notes: The specification of the test statistics does not form part of an estimand. For each endpoint, a separate estimand may be specified.

* Response defined as reduction (relative to Baseline) in diastolic blood pressure ≥ 15 mmHg

Legend

This Table is Version 2.0 of the original CORE Reference Terminology Table, first published integral to CORE Reference (page 32 of Version 1.0 CORE Reference dated 03 May 2016). The red text represents the updated text on estimands. This updated educational resource is Table 2 in http://dx.doi.org/10.1186/s41073-019-0075-5 and is also posted at www.core-reference.org