

## Baseline

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"Baseline", is the point from which change is measured. In trials, observations for baselines have to be made before initiation of treatment. The baseline period of observation ends when a person is assigned to treatment – typically the point at which treatment assignment becomes known to clinic personnel.

In an ideal world, persons are not randomized until all required baseline data have been collected. But the world is far from ideal and, hence, sometimes randomization takes place before essential baseline data have been collected. There is the temptation in those cases to "extend" the baseline period of observation to provide a wider window for collection of baseline data. The argument is that the effect of treatment is likely to be negligible at the outset and, therefore, values recorded at or shortly after initiation of treatment are still valid baseline measures. In trials where it is not possible to start or administer treatment at the point of randomization (eg, where administration requires hospitalization as with most surgical forms of treatment) the temptation to "extend" is even greater.

However, the reality is that all such "extensions" create "slippery roads" best not traveled. With drugs there is no way to know when they start to exert effects. Some effects may be gradual and others may be instant. In any case, extending the baseline period to the point of initiation has the potential of generating biased baseline data if the time of initiation is differential by treatment group (eg, as virtually assured in settings where the test treatment is a surgical treatment and the comparison treatment is "no treatment" or "best medical treatment").

**baseline** *adj* - 1. Of, relating to, or concerned with that which occurs just prior to or in conjunction with some act or **event**. 2. Of, relating to, or concerned with that which occurs in close proximity to some act or event (before or after). *Usage note*: Limit to uses in the sense of defn 1. Avoid in the sense of defn 2. See notes for **baseline** *n* and **baseline period**.

**baseline** (Bl, BL) *n* - [general] 1. A **time point** or **period** (as in **baseline period**) from which subsequent **measurements** or activities are timed. 2. A **point** or **measure** for assessing subsequent **change**. 3. An **observation**, series of observations, measurement, or series of measurements made or recorded at a designated point in **time**, or within a designated **time interval**, that serves as a basis for gauging change from that point forward in time. [trials] 4. **baseline period** 5. An observation, set of observations, measurement, or series of measurements made or recorded on a **treatment unit** just prior to or in conjunction with **treatment assignment** or initiation of treatment that serves as a basis for gauging change in relation to treatment assignment. 6. An observation, series of observations, measurement, or series of measurements made or recorded at some point after **enrollment** in relation to some act or event that serves as a basis for gauging change (eg, a blood pressure measurement made in relation to an increase in dosage of an anti-hypertensive drug to measure the effect of the increase). *Usage note*: Subject to varying uses in the context of trials, especially in relation to uses in the sense of defns 5 and 6. Most uses are in the sense of defn 5 but may, on occasion, be in the sense of defn 6. Typically, in the context of trials, unless otherwise indicated, the term should be reserved for characterizations that are appropriately thought of as being at baseline in the sense of defn 5 (see note for **baseline** *adj*) or in the sense of defn 1 for **baseline period**. However, even if the user is careful to limit usage to observations made prior to treatment assignment or initiation, ambiguities still arise when the term is used as if always applying to a single time point (eg, as implied by the phrase *at baseline*) when that is not the case. Baseline observations in most trials arise from a series of **baseline examinations**, separated in time by days, weeks, or, in some cases, months (see **baseline period**). Hence, the time of observation for one baseline variable, relative to another, may be different (eg, as would be the case with baseline blood pressure measured at the **randomization visit** and baseline body weight measured one week prior to

that visit at a prior baseline examination). The user is responsible for making the time differences among the variables represented in the baseline **dataset** known when describing the trial and its results. A certain amount of variability in the timing of one baseline observation or measurement relative to another and in the amount of time preceding the point of treatment assignment or initiation is unavoidable (except in cases where all required observations can be made at the same **clinic visit** and where that visit also serves as the **treatment assignment visit**). Unacceptably large variation is typically avoided by use of **time windows** specifying permissible **time intervals** within which the different observations are to be made and the maximum permissible separation allowed for any single observation relative to the point of treatment assignment or initiation. The size of permissible separations will be a function of the importance of proximal linkages of one observation to another and of the individual observations to the point of treatment assignment or initiation. Observations considered to be highly correlated and where the **correlations** are important for establishing **valid** baselines will be required to be more closely linked in time than where such correlations are modest or unimportant. Similarly, observations subject to wide variation from one time to another for the same person may be observed several times at different time points in the **baseline period** and averaged, or may be required to have been made in a narrow time window with its upper limit affixed to the act of treatment assignment or initiation.

**baseline period** *n* - [general] A **period** of **time** that is used to perform procedures needed to assess the suitability and eligibility of a **study candidate** for **enrollment** into a **study**, to collect required **baseline data**, and to carry out **consent processes**. [trials] 1. The period for a person or **treatment unit** defined by the start of the first **data collection visit** and ending with **assignment to treatment** or start of treatment. 2. Such a period ending with a **visit** or time point occurring shortly after **assignment to treatment** or the start of treatment. 3. A period of time during the course of treatment or **followup** of a person or treatment unit, usually marked by some **event**, process, or procedure, in which new **measurements** or **observations** are made to serve as a base for gauging subsequent change. 4. **enrollment period** *rt*: **baseline observation period, close-out period, followup period, lead-in period, run-in period, treatment period, treatment and followup period** *Usage note*: Avoid in the sense of defn 2 without qualification (see note for **baseline** *adj*) and in the sense of defn 4. Provide qualifying detail for uses in the sense of defn 3. Traditionally, the point defining the end of the **baseline period** in trials is marked by **treatment assignment** or initiation of **treatment**. The tendency to "stretch" the baseline period, as in defn 2, arises from a desire to reduce missing **baseline data**. Clearly, the utility of an observation as a baseline, in the strict sense of usage, is diminished if there is any possibility of the observation being influenced by treatment or treatment assignment. Hence, the practice is not recommended, even if the time interval following treatment assignment or initiation of treatment is small and even if the likelihood of treatment having had an effect on the **variable** being observed within that interval is small. See also notes for **baseline** *adj* and for **baseline** *n*.

Dictionary entries with baseline as a base or modifier term

**baseline** *adj*

**baseline** (Bl, BL) *n*

**baseline adaptive randomization** *n*

**baseline adaptive treatment assignment** *n*

**baseline characteristic** *n*

**baseline comparability** *n*

**baseline composition** *n*

**baseline data** *n*

**baseline difference** *n*

**baseline examination** *n*  
**baseline observation** *n*  
**baseline observation period** *n*  
**baseline period** *n*  
**baseline results paper** *n*  
**baseline study** *n*  
**baseline subgroup** *n*  
**baseline subgrouping variable** *n*  
**baseline variable** *n*  
**baseline visit** *n*  
**design, methods, and baseline results paper** *n*