



## Monday Morning Practice Pearls #38

### What are baseline symptoms and how do I capture them?

Before starting a clinical trial, a good baseline (BL) assessment needs to be conducted and **documented**, including:

- Physical exam noting for abnormal findings
- Current signs or symptoms the patient is experiencing at the time of the assessment including when first started (at least month and year)
- Prior medical history
- Current medications, including exact dose, start date (at least month and year), and indication

This information is helpful in providing the baseline assessment from which an AE can be identified and is one factor in assessing AE attribution.

### Definition

Baseline signs and symptoms are defined as those that are present immediately prior to the patient starting the study treatment (e.g., Cycle 1 Day 1 pre-dosing). These are not signs or symptoms that occurred and resolved between the time screening procedures are done and the start of protocol treatment.

*NOTE:* Sponsor's may vary on this, so be aware of your sponsor's requirements.

The participant's pre-existing medical conditions should not be recorded as baseline symptom(s) but should be documented as medical history. However, if the pre-existing medical conditions have a sign or symptom associated with them at the baseline timepoint, then these should also be considered baseline signs and symptoms.

### How is this captured on a CRF?

Some sponsors may have a CRF specifically for baseline symptoms while others may not. How to complete this CRF and any specific nuances (e.g., what to do when BL symptom resolves, what to do when worsens in severity, what to do if resolved but recurs) can typically be found in the CRF instruction manual. C3D/RAVE has a Baseline Symptom CRF.

The table below illustrates some common baseline symptoms and how to record them.

<b>Case Study</b>	<b>CRF</b>	<b>CRF Entry Example</b>
Patient has history of hypertension which is well controlled on an anti-hypertensive agent. Prior to study treatment initiation, BP was normal.	Medical History	Hypertension since 2004
	Concomitant Medication	Lisinopril 20 mg po daily
	Baseline Symptom	Nothing should be entered as BP is normal.
Patient has history of hypertension on an anti-hypertensive agent. Prior to study treatment, BP was 132/84.	Medical History	Hypertension since 2004
	Concomitant Medication	Lisinopril 20 mg po daily
	Baseline Symptom	Hypertension (grade 1). This is determined by the actual BP reading and not based on current medications.
Patient has a history of GERD which is well controlled on anti-reflux agent.	Medical History	GERD since 2008 with intermittent c/o heartburn
	Concomitant Medication	Prilosec 40 mg po daily
	Baseline Symptom	Patient is asymptomatic prior to study treatment so nothing is entered.
Patient has a history of GERD which is controlled on anti-reflux agent. Patient reports that he is experiencing some mild "heartburn" the day study treatment starts.	Medical History	GERD since 2008 with intermittent c/o heartburn
	Concomitant Medication	Prilosec 40 mg po daily
	Baseline Symptom	Gastroesophageal reflux disease (grade 1). Since this is a chronic condition, the AE term GERD is used versus dyspepsia.