

Outcome Measures

- Protocol/statistical analysis **plan must be submitted/uploaded with results** and will be public for studies with a primary completion date of 1/18/2017 or later
 - Ensure coherence among protocol and registration for primary, secondary and “other” outcomes
 - PRS reviewers may assume all outcomes are primary or secondary unless specified in the protocol as other or exploratory
 - Protocol upload must contain a cover page with official title, NCT #, and version date
- All Primary and Secondary outcomes are required (tertiary/exploratory are optional)
- Label outcomes as “primary” or “secondary” per the protocol

*Guidance for Outcome Measure
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Outcome Measures

- More registrations get rejected for inadequate Outcome Measure precision or inaccurate or multiple time frames than anything else.
- Outcome Measures should be specific and indicate what is being measured and is (or planned to be) reported.
- Remember the mantra: *Outcome Measures must be measurable outcomes.*

*Guidance for Outcome Measure
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Outcome Measure Tips: Title

- Include the metric (i.e. scale, score, number, percentage)

 Ex: Safety


 Ex: Safety, as measured by number of subjects with at least one AE


- Be clear and concise; omit verbs

 Ex: To determine the maximum tolerated dose of Drug A in patients with breast cancer.

 Ex: Maximum Tolerated Dose of Drug A in patients with breast cancer

- List outcomes separately

 Ex: All-cause mortality, hospitalizations, ER visits

 Ex: Number of deaths, Number of hospitalizations, Number of ER visits Should be listed as 3 separate outcomes

- Exception: if a composite score of multiple measures will be used

- Example: Count of individuals who experience any of the following: all-cause mortality, hospitalizations, and emergency room visits

Guidance for Outcome Measure
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Outcome Measure Tips: Description

- If a scale will be used, include the range and meaning of the scores
 - Example: The Hamilton Depression Rating Scale is used for rating the severity of depressive symptoms. Total score range is from 0 to 50, with higher scores indicating greater severity of depression.
- If a scale is not linear (e.g. logarithmic), that would be good to note as well.

*Guidance for Outcome Measure
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Outcome Measure Tips: Time Frame

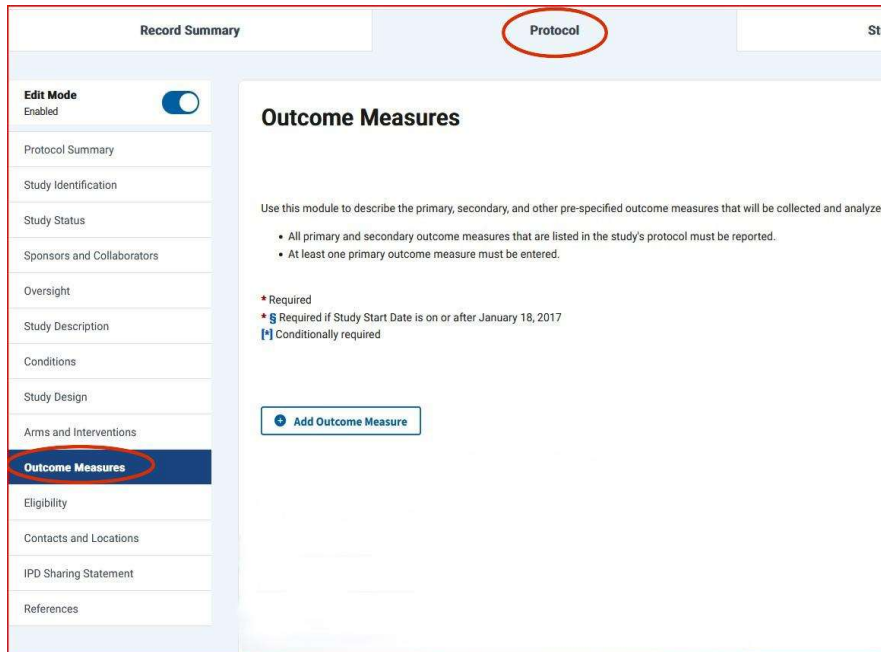
- Be specific (e.g. # of minutes, weeks, months)
 - Ex: Baseline, week 2
 - Ex: During hospitalization, approximately 5 days
 - Ex: Post-intervention, week 12
- If multiple time points are included:
 - If measuring change between the time points, add the word “change” to the title
 - If not measuring change, each time point needs to be listed as a separate outcome measure
- Remember that completion dates should reflect completion of data collection for your outcome measures. Refer back to study status section.

Average time, expected average time, or max assessment time would all be acceptable when the protocol cannot specify precise time frame

Guidance for Outcome Measure continues on next slide

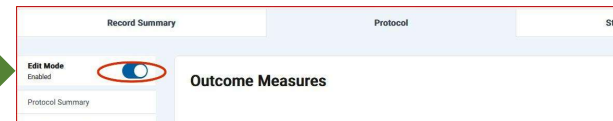
Adding Outcome Measures

-Navigate to the Outcome Measures Section on the Protocol Tab.



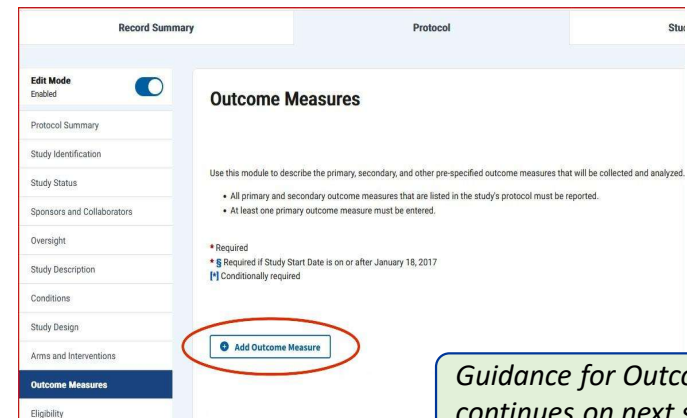
The screenshot shows the 'Protocol' tab selected in the top navigation bar. On the left sidebar, the 'Outcome Measures' menu item is highlighted and circled in red. The main content area displays the 'Outcome Measures' section with instructions and a list of requirements. A green arrow points from this screenshot to the next one.

-Make sure Edit Mode is enabled.



The screenshot shows the 'Outcome Measures' section with the 'Edit Mode' toggle switch in the 'Enabled' position, circled in red. A green arrow points down from this screenshot to the next one.

-Click to add outcomes.



The screenshot shows the 'Outcome Measures' section with the 'Add Outcome Measure' button circled in red. A green arrow points from this screenshot to the final text box.

Guidance for Outcome Measure continues on next slide

Outcome Measures: Example 1



Title * ⓘ

To determine the effect of Remuverol on pain in adults with Condition A ×

183 characters left

Description [*] ⓘ

999 characters allowed

Time Frame * ⓘ

Baseline, 12 weeks ×

236 characters left



Title * ⓘ

Change from baseline in pain, as measured by the Visual Analog Scale (VAS) ×

180 characters left

Description [*] ⓘ

Scores are measured on a 100mm VAS. The VAS ranges from 0 to 100 with 0 indicating no pain and higher scores indicating greater pain. ×

866 characters left

Time Frame * ⓘ

Baseline, 12 weeks ×

236 characters left

There are 2 time points, so the word “change” is added to the title

The Title includes the scale that will be used to assess change in pain

The Description includes the range of the scale and what the scale means

Guidance for Outcome Measure continues on next slide

Outcome Measure: Example 2



Title * ⓘ

To assess safety of Remuverol ×

225 characters left

Description [*] ⓘ

999 characters allowed

Time Frame * ⓘ

End of study ×

242 characters left



Number of participants that experience at least one adverse event ×

189 characters left

Description [*] ⓘ

Adverse events will only include those that are determined to be related to the study drug. ×

908 characters left

Time Frame * ⓘ

End of study (24 weeks) ×

231 characters left

The title includes the specific measurement that will be used and the metric for how the collected measurement will be aggregated.

The Description defines “outcome measure”. What information is being collected and how it is being collected.

The Time Frame includes the specific length of time. Specific time point(s) and overall duration of evaluation must be specified.