This basic results template is intended to help prepare and organize the study information to report results for a 2-arm study in the Protocol Registration System (PRS) for ClinicalTrials.gov. For single-arm studies, “Arm 2” information may be left blank. For 3 or more arms, use Microsoft Word to insert table columns as needed or contact the UCLA PRS Administrator to request assistance.

* Shaded cells (Pink) represent areas to be customized or completed with study-specific information.

|  |
| --- |
| **PARTICIPANT FLOW** |
| **Recruitment details:** *Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and types of location (e.g., medical clinic), to provide context. Example:* At 1 U.S. clinical site (UCLA), 35 patients were enrolled to the study between 10/15/2007 and 12/03/2009 |
| **Pre-assignment details:** *Description of any significant events and approaches for the overall study (e.g., wash out, run-in, transition) following participant enrollment, but prior to group assignment. For example, an explanation of why enrolled participants were excluded from the trial before assignment to groups.* |
| **Reporting Groups:** |
| Arm/Group 1 Title (Description):  |  |
| Arm/Group 2 Title (Description): |  |
| **Period:** *Overall Study* | **Arm 1** | **Arm 2** |
| **Started** |  |  |
| **Completed 4 weeks** |  |  |
| **Completed 12 weeks** |  |  |
| **Not Completed**  |  |  |

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| **BASELINE CHARACTERISTICS** |
| Arm/Group 1 Title (Description):  | Provide if different from Participant Flow Arm 1 Title(Description) |
| Arm/Group 2 Title (Description): | Provide if different from Participant Flow Arm 2 Title(Description) |
|  | **Arm 1** | **Arm 2** | **Overall (total)** |
| **N** |  |  |  |
| **Age (mean +/- std dev)\*** | \_\_\_\_ (\_\_\_\_) | \_\_\_\_ (\_\_\_\_) | \_\_\_\_ (\_\_\_\_) |
| **Gender:** |  |  |  |
|  **Female** |  |  |  |
|  **Male** |  |  |  |
| **Region of Enrollment:** |  |  |  |
|  **U.S.** |  |  |  |
| **Study-specific Baseline Measures, if applicable:** |
|  | \_\_\_\_\_\_ (\_\_\_\_ - \_\_\_\_)\* | \_\_\_\_\_ (\_\_\_\_ - \_\_\_\_)\* | \_\_\_\_\_ (\_\_\_\_ - \_\_\_\_)\* |
|  | \_\_\_\_\_\_ (\_\_\_\_ - \_\_\_\_)\* | \_\_\_\_\_\_ (\_\_\_\_ - \_\_\_\_)\* | \_\_\_\_\_\_ (\_\_\_\_ - \_\_\_\_)\* |

\*Report measure of central tendency (e.g., mean, median) and measure of dispersion (e.g., std dev, range); Measures reported as “Number” do not require a measure of dispersion.

**OUTCOME MEASURES –** ClinicalTrials.gov requires results, and statistical analyses as appropriate, for ALL pre-specified Primary and Secondary Outcome Measures in an [Applicable Clinical Trial (ACT)](https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered).

* Hover mouse over hyperlinked terms to view Help text

Copy and paste the table if reporting multiple Primary Outcomes

|  |
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| **PRIMARY OUTCOME MEASURE** |
| [**Measure Title:**](#Title) |  |
| [**Measure Description:**](#Description) |  |
| [**Analysis Population Description:**](#Analysis_population) |  |
| **Safety Issue?** | *Yes or No* |
| [**Time Frame:**](#Time_Frame) |  |
| Arm/Group 1 Title (Description):  | Provide if different from Participant Flow Arm 1 Title(Description) |
| Arm/Group 2 Title (Description): | Provide if different from Participant Flow Arm 2 Title(Description) |
| **Reporting Groups:** | **Arm 1** | **Arm 2** | **Overall (total)** |
| **N evaluated** |  |  |  |
| [**Result**](#Result) **(**[**Dispersion**](#Dispersion)**)\*** | \_\_\_\_(\_\_\_\_\_) | \_\_\_\_\_\_(\_\_\_\_\_) | \_\_\_\_\_\_(\_\_\_\_\_) |
| **Unit of measure:**  |
| *Click “Add Statistical Analysis” in the PRS as appropriate to describe within and between-group comparisons. Required fields will depend on how you report the outcomes in the table, and the type of analyses performed.*  |

Copy and paste the table if reporting multiple Secondary Outcomes

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| **SECONDARY OUTCOME MEASURE** |
| [**Measure Title:**](#Title) |  |
| [**Measure Description:**](#Description) |  |
| [**Analysis Population Description:**](#Analysis_population) |  |
| **Safety Issue?** | *Yes or No* |
| [**Time Frame:**](#Time_Frame) |  |
| Arm/Group 1 Title (Description):  | Provide if different from Participant Flow Arm 1 Title(Description) |
| Arm/Group 2 Title (Description):  | Provide if different from Participant Flow Arm 2 Title(Description) |
| **Reporting Groups:** | **Arm 1** | **Arm 2** | **Overall (total)** |
| **N evaluated** |  |  |  |
| [**Result**](#Result) **(**[**Dispersion**](#Dispersion)**)\*** | \_\_\_\_(\_\_\_\_\_) | \_\_\_\_\_\_(\_\_\_\_\_) | \_\_\_\_\_\_(\_\_\_\_\_) |
| **Unit of measure:**  |
| *Click “Add Statistical Analysis” in the PRS as appropriate to describe within and between-group comparisons. Required fields will depend on how you report the outcomes in the table, and the type of analyses performed.*  |

Copy and paste the table if reporting multiple Other Pre-Specified Outcomes

|  |
| --- |
| **OTHER PRE-SPECIFIED OUTCOME MEASURE** |
| [**Measure Title:**](#Title) |  |
| [**Measure Description:**](#Description) |  |
| [**Analysis Population Description:**](#Analysis_population) |  |
| **Safety Issue?** | *Yes or No* |
| [**Time Frame:**](#Time_Frame) |  |
| Arm/Group 1 Title (Description):  | Provide if different from Participant Flow Arm 1 Title(Description) |
| Arm/Group 2 Title (Description):  | Provide if different from Participant Flow Arm 2 Title(Description) |
| **Reporting Groups:** | **Arm 1** | **Arm 2** | **Overall (total)** |
| **N evaluated** |  |  |  |
| [**Result**](#Result) **(**[**Dispersion**](#Dispersion)**)\*** | \_\_\_\_(\_\_\_\_\_) | \_\_\_\_\_\_(\_\_\_\_\_) | \_\_\_\_\_\_(\_\_\_\_\_) |
| **Unit of measure:**  |
| *Click “Add Statistical Analysis” in the PRS as appropriate to describe within and between-group comparisons. Required fields will depend on how you report the outcomes in the table, and the type of analyses performed.*  |

**ADVERSE EVENTS** – The PRS has separate modules for reporting Serious Adverse Events (SAEs) and Other (Non-Serious) Adverse Events (AEs)

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| **SERIOUS ADVERSE EVENTS\*** |
|  | **Arm 1** | **Arm 2** | **Total** |
| # participants affected by any SAE/# at risk: |  |  |  |
| **SAE description**  | **System Organ Class\*** | **# affected/at risk** | **# affected/at risk** | **# affected/at risk** |
|  |  |  |  |  |
|  |  |  |  |  |

Add table rows as needed to report additional SAEs

|  |
| --- |
| **OTHER (NON-SERIOUS) ADVERSE EVENTS\*** |
|  | **Arm 1** | **Arm 2** | **Total** |
| # participants affected by any AE/# at risk: |  |  |  |
| **AE description**  | **System Organ Class\*** | **# affected/at risk** | **# affected/at risk** | **# affected/at risk** |
|  |  |  |  |  |
|  |  |  |  |  |

Add table rows as needed to report additional AEs

**\*[MedDRA System Organ Classes (SOC):](http://www.meddra.org/how-to-use/basics/hierarchy)**

1. Blood and lymphatic system disorders
2. Cardiac disorders
3. Congenital, familial and genetic disorders
4. Ear and labyrinth disorders
5. Endocrine disorders
6. Eye disorders
7. Gastrointestinal disorders
8. General disorders and administration site conditions
9. Hepatobiliary disorders
10. Immune system disorders
11. Infections and infestations
12. Injury, poisoning and procedural complications
13. Investigations
14. Metabolism and nutrition disorders
15. Musculoskeletal and connective tissue disorders
16. Neoplasms benign, malignant and unspecified (incl cysts and polyps)
17. Nervous system disorders
18. Pregnancy, puerperium and perinatal conditions
19. Product issues
20. Psychiatric disorders
21. Renal and urinary disorders
22. Reproductive system and breast disorders
23. Respiratory, thoracic and mediastinal disorders
24. Skin and subcutaneous tissue disorders
25. Social circumstances
26. Surgical and medical procedures
27. Vascular disorders