**Instructions to Author:**

This template is intended to both thank participants and provide them with a summary of the aggregate research results of the study. Importantly, the form may need to be changed or modified to be responsive to the specific audience: the participant population in this study.

Each shaded text can be single-clicked and filled in with the appropriate information. Additional return of results resources can be found [here](http://mrctcenter.org/projects/return-of-results-to-participants/) including a [guidance document](http://mrctcenter.org/wp-content/uploads/2017/12/2017-12-07-MRCT-Return-of-Aggregate-Results-Guidance-Document-3.1.pdf) and [toolkit](http://mrctcenter.org/wp-content/uploads/2017/12/2017-12-07-MRCT-Return-of-Aggregate-Results-Toolkit-3.1.pdf) specific to this template.

Delete these instructional text boxes, outlined in GREEN, when you complete the template as well as any other instructional or example text (written in RED).

**Thank you for participating in this study!**

As a clinical study participant, you belong to a large community of people around the world who contribute to science and medicine. You help researchers answer important health questions and help them discover new medical treatments.

We wish to share the overall results of the study that you participated in. We hope that it helps you understand and feel proud of your key role in medical research – we couldn’t have done this without you. If you have questions about the results, please speak with the doctor or staff at your study site.

This summary was completed on [month/year]. Newer information since this summary was written may now exist. This summary includes only results from one single study. Other studies may find different results.

**Here are the results of this study:**

1. Study Name

This study compared [all intervention/treatment names] for people with [disease/condition].

This study is officially known as [All identifying numbers that patients will most likely use (e.g. protocol number, federal number(s), other IDs)]. The official title of the study is: [Official Title] and the short title is [Short Title]

2. Who sponsored this study?

This study was sponsored by [Name Of Sponsor].

If you have questions, please contact [list appropriate contact information and/or resources available] about the study.

3. General information about the clinical trial

This study started on [start date] and ended on [end date]. The study was run in [country(ies) that enrolled patients] and [states or regions, if desired]. This study may finish before other studies that also study [condition/treatment]. When these studies are done, the researchers will look at the results across them all.

The reason we did this study was to [Purpose or main objective of the study].

This study was called a **Phase 2 study**. This Phase 2 study was done to find out if patients’ [conditions] improved by using [drug(s)/device(s)/treatments/interventions].

[Disease/Condition] is [simple explanation of disease/condition].

Standard care for [disease/condition] is [simple explanation of standard treatments].

This trial is important because [why the trial is important to patients/people]

Here is what we already know about the active ingredient, [agent/molecule] in [drug/treatment]:[A simple, general sentence that gives context of what is already known about the agent, molecular profile, etc. (e.g. from consent forms, other studies)].

**-Add This Section for Clinical Trials that Stop Early-**

**This study was stopped earlier than planned, which is not uncommon in clinical research.**

This study stopped early because [Use examples below, or your own simple explanation. If there is more than one reason, list all that apply.].

**EXAMPLES of reasons why studies stop early**

… too many participants had side effects (see below).

*… [drug generic name]* did not improve patient results.

… *[drug generic name]* was not as effective as expected *[comparator]*.

… *[drug generic name]* was much more effective than expected. *[if applicable, add]* The study was stopped so all participants had a chance to take *[drug generic name]*.

… not enough people joined the study.

**Since the study stopped early, here’s what will happen next:**

* [Next step. Use examples below or create your own simple steps. Use as many bullets as necessary]

**EXAMPLES of next steps:**

* + Change in return dates
	+ Where participants can get further information or answers if questions arise.]
	+ For **Side effects**: to whom participants should report ongoing events or issues, where to get more information, treatment, or prevention, if appropriate.
	+ For **Efficacy**: anticipated next steps for the compound/device or indication, and who is available to discuss potential access to the compound.
	+ For **Futility**: a clear interpretation for participants explaining that the drug/device was not likely to be more effective than the comparator with reasonable certainty, whether development will/will not continue, etc.
	+ **Low accrual**: potential reasons for low accrual, if evident.
		- NOTE: be careful with language - do NOT inadvertently “blame” participants.]

4. What patients/people were included in this study?

This study included:

* [Specific patient population to whom this study applies, including healthy volunteers]
* Participants were chosen by [simple explanation of how participants were chosen] and divided into groups by [simple explanation of how participants were divided into groups, stratified, etc]
* [Pediatric regulatory details if appropriate]

Plain Language Explanation of Randomization:

**[Patients/People]** in the study were put into **[#]** groups by chance (randomized) to reduce differences between the groups. Each patient had the same chance to be selected for any group in the study.

**[Total Study Sample Size]**  patients/people agreed to be part of this study. **[# in Group A]** were in **[Group A]** and **[# in Group B]** were in **[Group B]**.

**Add** additional groups (arms) if applicable. If there are **special circumstances** (e.g. induction therapy, transplant), a brief **simple description** can be added.

**[# lost to attrition]** left the study before it was done.

[#] patients/people came from [Country A], [#] patients/people came from [Country B; list as many as necessary]

Consider using/editing the **graphic below** to illustrate group allocation – click the graphic to edit the text and add or remove columns.

Other **“Smart Art”** styles can be found under the **“Insert”** tab in Microsoft Word.

5. Which medicines [or vaccines] were studied?

* [Drugs/devices/therapies/interventions involved, with generic names] were used in this study.
* Patient selection was impacted by [molecular analysis and/or integral markers that impacted patient selection and/or intervention/treatment].
* This study also used a placebo, which is a treatment that does not have an active ingredient meant to affect your health, but still looks and seems like medicine. For this study, the placebo was [Description of placebo used].

Create separate Group listings **(below)** for **each arm** in the trial. Use only text that is applicable to your study and change the sample structure as needed.

For examples of plain language descriptions of **common response/endpoint measurements**, refer to the endpoint table in the MRCT Center [Return of Results toolkit](http://mrctcenter.org/resources/2017-11-22-template-mrct-return-aggregate-results-participants-toolkit-version3-1/).

**[Group A]** got [description of study procedures] over [number study visits]. To prevent/help with side effects, this group also got [medicine/regiments used to prevent/lessen side effects].

**[Group B]** got [description of study procedures] over [number study visits]. To prevent/help with side effects, this group also got [medicine/regiments used to prevent/lessen side effects].

This study went for [number] [weeks/months/years], and [simple description of intervention/treatment timeframe].

To see how well [intervention/treatment] worked, we measured [description of response/endpoint measurement].

Consider a **simple graphic** that helps people/patients understand the study. This could include a simple schema, patient flow and other pertinent information. **Below is an example**, click to edit text and add or remove levels, or click the **“Insert”** tab in Microsoft Word to make your own simple **“Smart Art”.**

Provide **simple descriptions** of any companion studies, follow-up data, etc. that are included in the study or have clinically relevant results.

6. What were the side effects?

Common and serious medical issues that happened during the study are listed here. Not all [people/patients] in this study experienced side effects.

A side effect was considered common if [explanation of cutoff, e.g. 15% or more of participants had it]. We also report **serious** side effects, even if they were not common.

Plainly state any objectives or statistically valid endpoints that dealt directly with side effects. “Pre-specified” safety secondary endpoints may be one of the exceptions to the general rule of only reporting primary endpoints.

List events >5%, or whatever percentage is used by the sponsor. **Keep denominators consistent (ie 1 in 10, 2 in 10)**.

Minimize acronyms/medical terms and explain any that are used.

**List for each study arm OR include comparison between arms for each event listed.**

**Side effects in** **[Group A]**

* Common side effects were [all common side effects].
* Serious but rare side effects were [serious rare side effects].

**Side effects in [Group B]**

* Common side effects were [all common side effects].
* Serious but rare side effects were [serious rare side effects].

**Side effects in [Group C]**

* Common side effects were [all common side effects].
* Serious but rare side effects were [serious rare side effects].

7. What were the overall results of the study?

**-Lead with the Following Text Only for Studies that Close Early-**

Because this study was stopped early, we will not know answers to [many/most/any] of the questions that were studied. This is a summary of what was learned while the study was open. Study details are listed after the results for more information.

**-Include the Following Text for All Studies-**

**NOTE:** always use absolute factors, not relative hazards or risks.

Results can be grouped in different ways, including the medicine given, the side effects, the responses etc. If this is a randomized trial, a simple chart could also list comparisons.

**If composite endpoints are used it may be better to include bolded headings for each endpoint, followed by a brief, simple explanation in one to two sentences.**

These results are for[the specific population that was studied, including age and gender breakdown. Include eligibility criteria, including specific genetic mutations (when appropriate)].

Results are limited to the particular people studied and cannot be assumed to be true for everybody. Not all participants in each part of the study had the same results.

**The study found that:**

* [# of patients/people] in **[Group A]** [(list the intervention/treatment used in Group A, then include information for each additional cohort if applicable)] had/experienced **[endpoint one]** and **[# of patients/people]** had/experienced **[endpoint two]**.
* [# of patients/people] in **[Group B]** [(list the intervention/treatment used in Group A, then include information for each additional cohort if applicable)] had/experienced **[endpoint one]** and **[# of patients/people]** had/experienced **[endpoint two]**.

Include each identified primary endpoint as a separate bullet and in **simple terms** with numeracy principles on how many people tolerated the dose, adverse events reported, etc.

Include the primary endpoint and safety data that are important to the overall results of the trial.

Refer to the response/endpoint table in the MRCT Center [Return of Results toolkit](http://mrctcenter.org/resources/2017-11-22-template-mrct-return-aggregate-results-participants-toolkit-version3-1/).

Again, **results can be grouped in different ways – do what is clearest and makes the most sense for your study.**

8. How has this study helped patients and researchers?

This research helps future patients and families by helping us understand more about each medicine being studied.

Include a general comment on what this study contributed to the relevant area of research and potential next steps to build on that knowledge. Mention if further studies are planned. See suggestions for neutral language and simplified endpoint descriptions in the MRCT Center [Return of Results toolkit](http://mrctcenter.org/resources/2017-11-22-template-mrct-return-aggregate-results-participants-toolkit-version3-1/).

Findings from this study will be used [general next steps that help explain context].

**EXAMPLES of findings next steps include:**

* “in other studies to compare this drug with other treatments for [patients with condition/disease];”
* “to combine with other treatments in [patients with condition/disease],
* “to seek approval from the [EMA/FDA/other agency];”
* “inform doctors about a new way to treat people”.]

9. Are there plans for further studies?

[Include whether other related trials are ongoing, or if further trials are planned.]

10. Where can I find more information about this study?

To learn more about this study, visit [provide URL link for this protocol here, e.g. on clinicaltrials.gov, EudraCT]More information may also be available by looking up the official number or title, or by going to [list any websites that may have plain language information, non-scientific articles, etc.].

You can also find more details about this study at:

* [List all applicable citations and websites that are not listed in clinicaltrials.gov or EudraCT. This can include resources as well as articles.]
* This study was sponsored by [List each sponsor, including company, government, consortium, and/or private funders]*.* [Sponsor(s)] [is/are]available at [contact information].

For more information about the disease/condition:

* [List any resources or links that may list additional publications or information about the disease/condition.; avoid links to promotional language]

For general information about research studies, go to: [list appropriate, helpful websites]

**EXAMPLES of helpful websites include:**

* [*https://www.clinicaltrials.gov/ct2/about-studies/learn*](https://www.clinicaltrials.gov/ct2/about-studies/learn)*,*
* [*http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm*](http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm)*,*
* *http://www.ema.europa.eu/ema/index.jsp?curl=pages/special\_topics/general/general\_content\_000489.jsp&mid=WC0b01ac058060676f*

This research was important. Thank you for helping us understand more about [drug generic name(s) or intervention studied]. If you have questions, please talk to your [study doctor, trial designee, whomever the plan states, or, if that person is no longer available, family doctor].

***Thanks again for being part of this study.***

***We do research to try to find the best ways to help patients,
 and you helped us to do that.***

*Optional box or image*

Logo, icon or other image if relevant or helpful.