Guidance for Medical Writers for Returning Aggregate Results

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Disclaimer

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Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.
Objectives

• Apply health literacy principles for returning results to participants
• Review templates for communicating study results — including Phase 1, Phase 2 and Phase 3 studies and clinical trials that stop early — as developed by a multi-stakeholder work group
• Discuss how to communicate various endpoints in simple language
• Learn about using simple language to communicate summary results
• Rationale for returning aggregate results to participants

• Return of Results Guidance Document
  – Process flow of returning results
  – Methods for returning results
  – Content of results summaries
  – Health and numerical literacy

• Return of Results Toolkit
  – Templates for communicating study results
  – Neutral language guidance
  – Endpoint table
Rationale for returning aggregate results to participants
Declaration of Helsinki –
Ethical Principles for Medical Research Involving Human Subjects

- Paragraph 26:

  All medical research subjects should be given the option of being informed about the general outcome and results of the study.

http://www.wma.net/en/30publications/10policies/b3/
(last amended October 2013)

Sponsor of a clinical trial must submit “a summary of the results of the clinical trial together with a summary that is understandable to a layperson, and the clinical study report, where applicable, within the defined timelines.”

**Article 37:** Irrespective of the outcome of a clinical trial, within one year from the end of a clinical trial in all Member States concerned, the sponsor shall submit to the EU database a summary of the results of the clinical trial.

EU Requires posting laypersons summary to EU Portal beginning in 2017
### Patient/Participant Perspective in the U.S.

<table>
<thead>
<tr>
<th>Patients / Study Volunteers</th>
<th>Research Professionals</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 90% want to know the results of their clinical trial&lt;sup&gt;1&lt;/sup&gt;</td>
<td>• 98% of study staff would like to provide results to their volunteers&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
<tr>
<td>• 91% never hear back from study staff or sponsor&lt;sup&gt;2&lt;/sup&gt;</td>
<td>• 95% of research ethics board chairs strongly support (Canadian survey)&lt;sup&gt;5&lt;/sup&gt;</td>
</tr>
<tr>
<td>• If not informed, 68% would not participate in future trials&lt;sup&gt;3&lt;/sup&gt;</td>
<td></td>
</tr>
</tbody>
</table>

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Multi-Regional Clinical Trials Center Response
Return of results: MRCT Center workgroup

**Academic/Medical Center:**
- Carmen Aldinger – MRCT Center
- Mark Barnes - Ropes & Gray, LLP / MRCT Center
- Barbara Bierer - Brigham & Women's Hospital/MRCT
- Assunta De Rienzo - Brigham & Women's Hospital
- Alla Digilova – MRCT Center
- Rebecca H Li – MRCT Center
- Holly Fernandez Lynch - Harvard Law School
- Pearl O'Rourke - Partners HealthCare
- Nesri Padayatchi - Univ. of KwaZulu-Natal
- Amish Shah - MRCT / Harvard Law School
- Zachary Shapiro – MRCT/ Harvard Law School
- Patrick Taylor - Children's Hospital, Boston
- Sarah White - Partners HealthCare
- Elizabeth Witte – Harvard Medical School
- Sabune Winkler – Harvard Medical School

**Industry/Trade Associations:**
- Salvatore Alesci – PhRMA
- Richard Bergstroem – EFPIA
- Elizabeth Garofalo - Novartis Pharma AG
- Laura Hagan - Merck Serano
- Sandra Hayes-Licitra – Johnson & Johnson
- Angelika Joos – Merck Sharp & Dohme
- Barbara Kress – Merck
- Sarah Larson – Biogen Idec
- David Leventhal – Pfizer
- Craig Lipset – Pfizer
- Laurie Myers – Merck (CO-CHAIR)

**Alex Nasr – AbbVie**
**Mary Ann Plummer – J&J (prior CO-CHAIR)**
- Sandy Prucka – Lilly
- Ben Rotz – Lilly
- Beth Roxland – Johnson & Johnson
- Jessica Scott – GSK

**Institutional Review Boards:**
- David Forster - WIRB Copernicus Group
- Mary Oster – NE IRB
- Jim Saunders - NE IRB

**Nonprofit:**
- Behtash Bahador – CISCRP
- Phyllis Frosst - Personalized Medicine Coalition
- Zach Hallinan – CISCRP
- Marc Wilenzick – International AIDS Vaccine Initiative

**Patient Advocates:**
- Nicola Bedlington – European Patients Forum
- Deborah Collyar – PAIR (COCHAIR)
- David Haerry – European AIDS Treatment Group
- Cheryl Jernigan - Susan G. Komen
- Yann LeCam – EURODIS
- Marcello Losso - HIV RAMOS
- Jane Perlmutter – Gemini Group

**Research/Consulting Firms:**
- Barbara Godlew - The FAIRE Company, LLC
- Pierre Gervais - QT Research
- Paulo Lacativa - CCBR Clinical Research
- David Walling – Collaborative NeuroScience
Goals

- Develop standards and best practices.
- Ensure principles are respectful of global cultural expectations.
- Address perceived barriers to widespread implementation.

Rationale:

Returning results allows sponsors and investigators to recognize and honor the essential contributions and volunteerism of clinical trial participants.

Expectations of academic, industry, not-for-profit sponsors similar

Returning results is a key aspect of improving transparency and increasing public trust.

Scope:

Communication and dissemination of summary research results to individual participants.
The MRCT Center Tools

An **ROR Guidance Document** for groups wishing to return results including:

- Logistics and detailed processes for results sharing
- Content of research result summaries
- Cultural and health literacy considerations
- Timing


An **ROR Toolkit** including:

- Templates for Phase 1, 2 & 3, studies ending early
- Neutral language guide
- Endpoints language guide


Go to: mrctcenter.org -- Resources – Return of aggregate results
Process Flow for Returning Results

• Pre-Study preparation
  • Include data transparency in organizational preparation, policies, processes
  • Establish level/timing/delivery
  • Resource planning

• Protocol Development
  • Offer participants an opportunity to receive study results
  • Include a section on returning results in Informed Consent Form

• During study conduct
  • Consider letter of appreciation
  • Prepare for last study visit of participant
  • Keep intermittent engagement with participant thereafter

• When study ends
  • Prepare and review summary document
  • Adhere to global regulatory framework and health literacy principles
Methods of returning aggregate results

• **To Whom:**
  • All participants who have been enrolled and agreed to receive results

• **Several Methods of Return:**
  • Internet based methods (flexible, cost-effective, current, security may be important)
  • Interactive methods (e.g., face-to-face meeting(s), telephone call(s), two-way online meeting(s), dynamic email exchange, etc.)
  • One-way communications (e.g. video summary, automated phone message, printed materials)

• **Timing:**
  • Within 1 year of completion or ‘end of study’
Participant Clinical Trial Results Summaries - Process

- Write in unbiased and not promotional language
- Obtain review by independent and objective editor(s) and patient representative(s)
- Translate into additional languages consistent with translations of informed consent
- Make available an individual from the study site or neutral informed third party to answer questions for participants
- Make provisions for vulnerable populations and other instances
- Consider as to whether to inform, and whom to inform, in the event of a participant’s death
- Use plain language (sixth-eight grade reading level)
- Apply health and numeracy principles
Health Literacy: Overview

- Health Literacy is not the same as one’s ability to read.
  - Health Literacy refers to the “capacity to make sound health decisions in the context of everyday life – at home, in the community, at the workplace, in the healthcare system, in the market place, and in the political arena.” (Consensus Paper 2013, Making Health Literacy a Priority in EU Policy)
- Even those with adequate health literacy can struggle at times to understand health information, and appreciate clear communication.
Example of translating into plain language

• Researchers were looking for a better way to treat knee pain in people with osteoarthritis. Osteoarthritis is a degenerative disease that involves the degradation of articular joints and subchondral bone, as a result of mechanical stress on the area.

In plain language:

• Osteoarthritis refers to a progressive joint disease or “wear and tear.” This is the most common condition of the joints and occurs when the cartilage or cushion between joints breaks down, leading to stiffness, swelling and pain.
Health Literacy Principles: Implementation

- Plain language
- Use active voice and short sentences
- Formatting to aid comprehension:
  - Presentation of the “big picture” before the details
  - Headlines to organize information
  - Descriptive headers and subheadings
  - Limited use of tables and charts
  - Adequate “white space”
  - Minimum of 12-point font
  - Sufficient contrast between font and background color
  - Avoidance of text in ALL CAPS
- For more information: Appendices 3 and 4 of Guidance Document
Secondhand smoke hurts adults too.
The longer you are around secondhand smoke, the more likely it is to hurt you.
Non-smokers who breathe smoke at home or at work are more likely to become sick and die from heart disease and lung cancer. Studies show that secondhand smoke may cause other serious diseases, too.

Secondhand smoke is bad for your heart.
Breathing secondhand smoke makes the platelets in your blood behave like those of a regular smoker. Even a short time in a smoky room causes your blood platelets to stick together. Secondhand smoke also damages the lining of your blood vessels. In your heart, these bad changes can cause a deadly heart attack.

Secondhand smoke changes how your heart, blood, and blood vessels work in many ways. Adults who breathe 5 hours of secondhand smoke daily have higher "bad" cholesterol that clogs arteries.

Document A

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Document B

Numeracy: Overview

- The ability to use basic probability and mathematical concepts to explain mathematical and statistical terms.

- Numeracy principles in health literacy focus on simple explanations, instead of using complex fractions, percentages or statistical terms.
Numeracy Principles: Implementation

- Less is more – how critical are the numbers?
- Provide fewer choices – choose strategically which options to show
- Do the math – calculate or convert numbers, readers are unlikely to conduct even basic math
- Give numbers meaning and context – explain what the numbers mean
- Use common terms and imaginable formats
- Use visuals
- Use whole numbers
- Use consistent denominators and timeframe
- Natural frequencies vs percentages? – “1 out of 10” may be more useful than percentages because it gives context and imagery
Example

14%

Or

About 1 in 7
In 20% (or 1 in 5) of patients, tumors got at least 30% smaller.

In 80% (or 4 in 5) of patients, tumors did not get at least 30% smaller.
Return of results templates

Template for Communication of Study Results

**SPONSORS**: This template helps create clear summaries of clinical trials. Replace the (guidelines in red brackets) with your text; delete this heading.

*If written to study participants, include the following*

Thank you for participating in this study.

You and other volunteers helped researchers answer important health questions.

Here we describe the results of this study.

*If written for the general public, start here:*

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.

**Phase 1 Study**

This study searched for a safe dose of [interventions/treatments] for people with [disease/condition].

*Place a simple title for the study in the box above. Sponsors may consider using the same simple title as in the registry. If drug names are used, list both generics and also where brand names® can be found.*

**Phase 2 and 3 Studies**

This study compared [interventions/treatments] for people with [disease/condition].

*Place a simple title for the study in the box above. If drug names are used, consider including both generic and brand names®, if brand names are not used, help participants find brand names elsewhere.*

**Why the study was done**

**Phase 1 Study**

This was the first time this [treatment/drug/device/intervention] was studied in humans. This study was done to find the highest [dose/amount] of the drug/treatment that people could take without having severe side effects. Side effects include unexpected medical
Participant Clinical Trial Results Summaries - Content

• Thank You

• Title and purpose of the study

• Why the study was done

• Study information (patient population, drugs, start & end date, countries)

• How the study worked (how participants were divided into groups)

• Side effects

• Summary of results

• Final comments (official study title, where to get more information)
<table>
<thead>
<tr>
<th>Content</th>
<th>Example</th>
</tr>
</thead>
</table>
| Thank You                                 | *Thank you for participating in this study.*
As a clinical study participant, you belong to a large community of participants around the world. You help researchers answer important health questions and help them discover new medical treatments. .... |
| Title/Purpose of the study                | **Phase 1 studies:**
This study searched for a safe dose of [interventions/treatments] for people with [disease/condition.]
**Phase 2 and 3 studies:**
This study compared [interventions/treatments] for people with [disease/condition.] |
| Why the study was done                    | **Phase 2 study:**
This study was done to find out if patients’ conditions improved by using the [drug(s)/device(s)/treatments/interventions].
**All phases of studies:**
*A simple explanation of the disease/condition and what standard treatments may exist* |
<table>
<thead>
<tr>
<th>Content</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why the study was done (cont.)</td>
<td><strong>For clinical trials that stop early:</strong></td>
</tr>
<tr>
<td></td>
<td>This study was stopped earlier than planned. This can happen for many reasons.</td>
</tr>
<tr>
<td></td>
<td>This study stopped early because <em>[add one of the possible statements below, or your own simple explanation, to this sentence. If there is more than one reason, list all that apply.]</em></td>
</tr>
<tr>
<td></td>
<td>... too many participants had side effects (see below).</td>
</tr>
<tr>
<td></td>
<td>... <em>[drug generic name]</em> did not improve patient results.</td>
</tr>
<tr>
<td></td>
<td>... <em>[drug generic name]</em> was not as effective as expected <em>[comparator]</em>.</td>
</tr>
<tr>
<td></td>
<td>... <em>[drug generic name]</em> was much more effective than expected. <em>[if applicable, add]</em> The study was stopped so all participants had a chance to take <em>[drug generic name]</em>.</td>
</tr>
<tr>
<td></td>
<td>... not enough people joined the study.</td>
</tr>
<tr>
<td></td>
<td><em>[Include a statement about what will happen next. ...]</em></td>
</tr>
<tr>
<td></td>
<td>• For side effects ..</td>
</tr>
<tr>
<td></td>
<td>• For efficacy ...</td>
</tr>
<tr>
<td></td>
<td>• For futility ...</td>
</tr>
<tr>
<td></td>
<td>• Low accrual: ....</td>
</tr>
</tbody>
</table>
### Study information

This study included:

- [Specific patient population to whom this study applies, including healthy volunteers]
- [All drugs, devices, therapies and interventions involved in the study, with generic names.]

This study **started** on [mo./year] and **ended** on [mo./year]. The study was run in [country(ies) that enrolled patients].

This study may finish before other studies that also study this. When they are all done, the researchers will look at the results across the studies.

### How the study worked

[Provide a simple explanation of how participants were chosen, divided into groups, stratified, etc. OR if patients/physicians can choose which therapy they can have.]

**Phase 2 and 3 studies:**

**Group A** got [simple explanation of study regimen for first arm. ...]
**Group B** got [simple explanation of study regimen for second arm. ...]
## Participant Clinical Trial Results Summaries - Content

<table>
<thead>
<tr>
<th>Content</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Side effects</td>
<td>Common and serious medical issues that happened during the study are listed here. Not all [<em>people/patients</em>] in this study experienced side effects.</td>
</tr>
<tr>
<td></td>
<td><strong>Phase 1 study:</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Issues [in Group A] included:</strong></td>
</tr>
<tr>
<td></td>
<td>• [List events &gt;5% or whatever percentage is used by the sponsor.]</td>
</tr>
<tr>
<td></td>
<td>• [Minimize acronyms/medical terms and explain any that are used.]</td>
</tr>
<tr>
<td></td>
<td><strong>Issues [in Group B] included:</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Issues [in Group C] included:</strong></td>
</tr>
<tr>
<td></td>
<td>[#] of side effects were seen in Group B, and [#] of side effects were seen in Group C. No higher doses were tested because of the number of side effects seen in Group C.</td>
</tr>
<tr>
<td>Summary of results</td>
<td>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.</td>
</tr>
<tr>
<td>Content</td>
<td>Example</td>
</tr>
<tr>
<td>---------</td>
<td>---------</td>
</tr>
</tbody>
</table>
| Summary of results (cont.) | **Phase 1 study:**  
*Results of a Phase 1 study usually include what the body does to the drug and what the drug does to the body. They also try to find the best dose that people can take safely.*  

**Phase 2 and 3 Studies**  
*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 statistically significant comparisons.* |
| Final comments | This study is officially known as *All identifying numbers that patients will most likely use (e.g. protocol number, federal number(s), other IDs), followed by the official title of the study.*  

To learn more about this study:  
• ![URL link for this protocol here, e.g. on clinicaltrials.gov, EudraCT](Link)  
• ![List all applicable citations and websites that are not listed in clinicaltrials.gov](Link) |
## Content

| Final comments (cont.) | For more information about the disease/condition:  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• [List any resources or links that may list additional publications or information]</td>
</tr>
</tbody>
</table>

For general information about research studies, go to [list appropriate sites, e.g., https://www.clinicaltrials.gov/ct2/about-studies/learn](https://www.clinicaltrials.gov/ct2/about-studies/learn)

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, talk to your family doctor]. You can also contact [list appropriate contact information and/or resources available as determined by the plan.] about the study or your part in it.

*Thanks again for being part of this study.*
Example of Return of Results Template

• A Clinical Trial of a New Combination of Two Cancer Drugs for Breast Cancer

OR

• A Clinical Trial for a drug to treat knee pain in people with arthritis

OR

• A Pilot Study of Acupuncture Treatment for Swallowing Problems in Head and Neck Cancer Patients
## Neutral Language Guide

<table>
<thead>
<tr>
<th>Language to <strong>avoid</strong></th>
<th>Language to <strong>consider</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>This study proved...</td>
<td>This study found that... This does not mean everyone in that group had these results.</td>
</tr>
<tr>
<td>This study proved that using <code>&lt;drug A&gt;</code> to prevent <code>&lt;disease/condition&gt;</code> is effective.</td>
<td>This study found that people with <code>&lt;disease/condition&gt;</code> who got <code>&lt;drug A&gt;</code> had <code>&lt;primary endpoint&gt;</code>.</td>
</tr>
<tr>
<td>This means that <code>&lt;Drug A&gt;</code> is better than <code>&lt;Drug B&gt;</code></td>
<td>In this study, people who got <code>&lt;drug A&gt;</code> had more <code>&lt;study endpoint&gt;</code> than some people who got <code>&lt;Drug B&gt;</code> with the same health conditions.</td>
</tr>
<tr>
<td><code>&lt;Drug A&gt;</code> is better tolerated than <code>&lt;Drug B&gt;</code></td>
<td>In this study, fewer patients who took <code>&lt;Drug A&gt;</code> had <code>&lt;list specific adverse events&gt;</code> than patients who took <code>&lt;Drug B&gt;</code>.</td>
</tr>
</tbody>
</table>

Similar principles have been suggested by TransCelerate BioPharma:  
[Recommendations for Drafting Non-Promotional Lay Summaries of Clinical Trial Results](#)
Examples of translating into neutral language

• One promising finding was that tumors got at least 30% smaller in 20% of patients.
Examples of translating into neutral language

- One promising finding was that tumors got at least 30% smaller in 20% of patients.

- The study found that tumors got at least 30% smaller in 20% of patients.
Examples of translating into neutral language

• This study proved that two thirds of the patients (66%) survived their breast cancer for at least one year after starting the study drugs.
Examples of translating into neutral language

• This study proved that two thirds of the patients (66%) survived their breast cancer for at least one year after starting the study drugs.

• In this study, two thirds of the patients (66%) survived their breast cancer for at least one year after starting the study drugs.
Endpoint Descriptions and Examples

• Toolkit lists common clinical trial endpoints
  – Definition with a general description
  – Examples of simple, plain language for research results summaries

• Endpoints included:
  Composite Endpoint
  Dose Escalation
  Exploratory Biomarker
  Mortality / Overall Survival
  Morbidity
  Non-Inferiority
  Patient-Reported Outcomes
  Prevention / Incidence
  Progression-Free Survival
  Surrogate Endpoint
## Endpoint Descriptions and Examples

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Description of the type of endpoint</th>
<th>Example in simple, plain language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite</td>
<td>A composite endpoint, as the primary endpoint, combines multiple outcomes (e.g. death, getting sick again (relapse), serious event) and test results into one measure of how well the drug/therapy/device works. This is useful when there are many different outcomes that can happen during a trial. This can also be called a combined or multi-part endpoint.</td>
<td>“The XXX study measured [patients/people] to see if those in Group A (ABC treatment) or Group B (XYZ treatment) lived longer, had fewer heart attacks, or fewer hospital visits for heart failure. These events were measured together (combined) because each one is quite rare. Researchers also wanted to see if the drug worked in patients who had all 3 conditions. The study found that there was no change in the number of events for [patients/people] in Group A or Group B.”</td>
</tr>
</tbody>
</table>
## Endpoint Descriptions and Examples

<table>
<thead>
<tr>
<th>Endpoint</th>
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<th>Example in simple, plain language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Inferiority</td>
<td>Non-inferiority endpoints are designed to show that a new treatment or drug is not worse than the control (or other comparison drug) by a pre-specified amount (also termed the non-inferiority margin). Efficacy can, in fact, be worse if there are other benefits (e.g., fewer side effects).</td>
<td>[Need to include some specific comparisons between the arms before stating the following sentence.]</td>
</tr>
</tbody>
</table>
<pre><code>                                                             |                                                                                                                                                                                                                                    | “This study showed that Group A (insulin A) was not different than Group B (standard insulin therapy) in lowering the level of hemoglobin in red blood cells in Type 1 diabetic patients. Patients in Group B had fewer side effects of upset stomach and nausea than those in Group B.” |
</code></pre>
## Endpoint Descriptions and Examples

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<thead>
<tr>
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<th>Example in simple, plain language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient-Reported Outcomes</td>
<td>This study asked patients about their [list the main purpose of the questionnaire: e.g., symptoms, activity level, quality of life, income and/or happiness] and if the measurement changed based on whether a patient got A or B. The primary endpoint is less XXX based on the YYY scale. This scale measures ZZZ and how this changes over time.</td>
<td>“Patients answered questions to measure pain, stiffness, and how well people climbed stairs, stood or bent over. Questions were asked during each study visit. About 1 in 2 people (50%) in Group A had less knee pain. About 1 in 4 people (25%) in Group B had less knee pain. This means that patients in Group A (x treatment) had less knee pain than patients in Group B (y treatment/placebo).”</td>
</tr>
</tbody>
</table>
Summary

- Write in plain language, short sentences, active voice
- Use headlines and “white space” to organize information
- Give numbers meaning and context
- Use the provided templates
- Write in neutral, non-promotional language
- Describe the study endpoint in simple language
Outlook

• Return of results to participants may become the expectation and practice in clinical research.

• If similar to the U.S. studies, research participants world wide may want to receive information about the clinical trial to which they participated.

• Funding and resources for return of results and training for writing summary results should be provided as an anticipated component of human subjects research.

• Logistics, content, processes, standard methodologies and approaches must be delineated for populations inside and outside of US, UK and EU.
Next Steps for the MRCT Center Efforts

- Return of individual level results (incidental findings, results of study arm, clinical and research findings)
- Return of results in integrative medicine
- Adoption of guidance for non-Western cultures
- Return of aggregate results
  - Released Guidance Document Version 2.0
  - Apply principles and templates to a number of studies, collecting feedback from participants as to comprehension and preferences
Comments, questions and discussion

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Program Manager

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