The ARQAT Delphi

The ARQAT Board, presented by Dr. Marian Reven

September 29, 2024, 4-8pm

Sonesta Airport, Nashville, TN, USA

WVU IRB #2205571104

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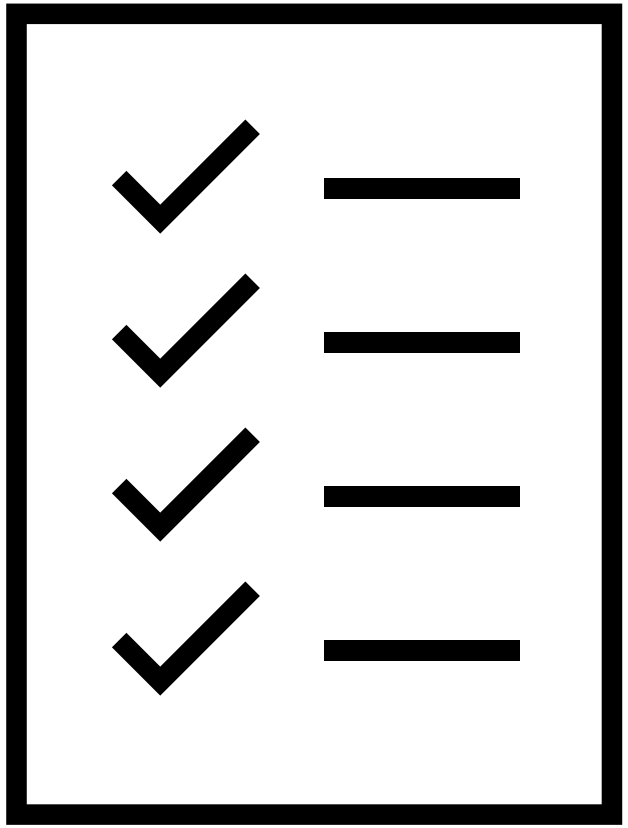
To do

Media Release Form https://forms.gle/U5fxwywMwih8UZsh9

- Introduction
- Mission, Vision, Goals
- Background ARQAT & TREATS
- Relationship to research community
- Delphi project
- Question & Answer



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Mission, Vision, Goals

OUR MISSION: To create and disseminate tools and guidelines that clearly outline the highest standard in nonpharmacologic aromatic research and reporting.

OUR VISION: Aromatic research reporting will improve, promoting a robust evidence-base for the use of aromatics in health care and wellness.

OUR GOALS: To publish the quality assessment tool in a peer-reviewed journal and conduct a Delphi process research study to establish reporting guidelines for aromatic research. Obtain funding to support ongoing activities of ARQAT.

ARQAT TIMELINE

Created 08/2024

ARQAT

- Aromatic Research Quality Appraisal Taskforce (ARQAT)
- 501c3 nonprofit in the United States
- Founded in 2021 and 100% online until today
- https://www.arqat.org

TREATS Checklist & Explanatory Doc

- Transparent Reporting for Essential oil & Aroma Therapeutic Studies (TREATS) checklist
- Work began in March of 2021
- Available for download from our website
- Published late 2023, publication in print June 2024, open access
- https://www.liebertpub.com/doi/pdf/10.1089/jicm.2023.0006

Translations Policy

Modeled after the PRISMA Group translations policy

Sept 21, 2024--First official translation of TREATS: Brazilian Portuguese with special thanks to Mayra de Castro

Please see the website for the policy and contact us at info@arqat.org

Background

Ties to the larger research community

Nothing new under the sun.

Ecclesiastes 1:9

- The move to improve the quality of research reporting is nothing new. Since the 1990s, guidelines have been published to recommend those components of research articles that ought to be included to promote clarity and utility (Altman & Simera, 2016).

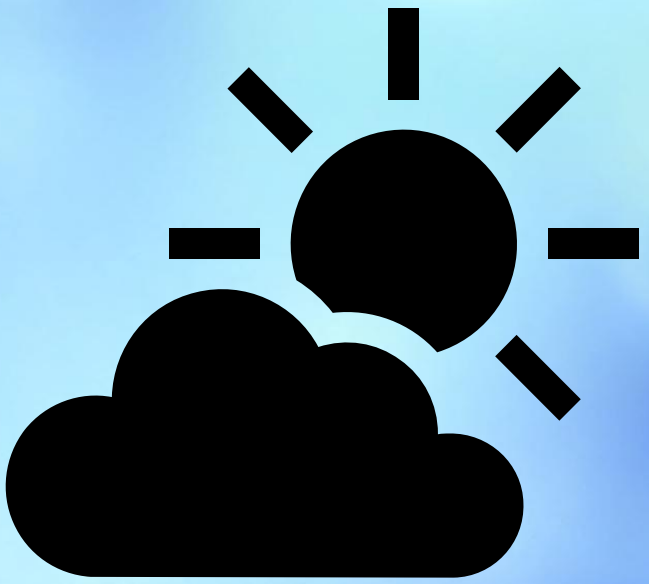
Work on original CONSORT*

Work on the original CONSORT began in 1993, on October 7 and 8 when the Standards of Reporting Trials (SORT) group met.

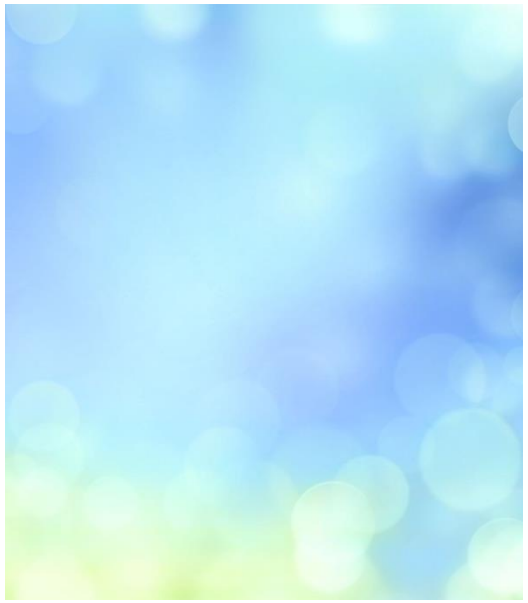
During these two days they crafted a proposed list of 24 items to be included in the report of a trial, provided empirical evidence (elaboration), and a format to show how these items could be included (Begg, 1996).

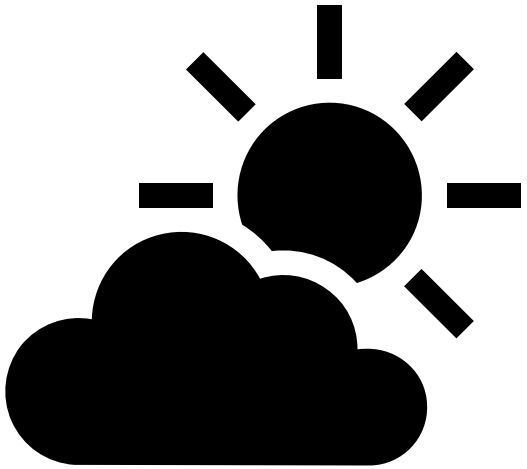
Independently, and approximately five months later (March 14-16, 1994), another group, the Asilomar Working Group on Recommendations for Reporting of Clinical Trials in the Biomedical Literature, met to discuss similar challenges.

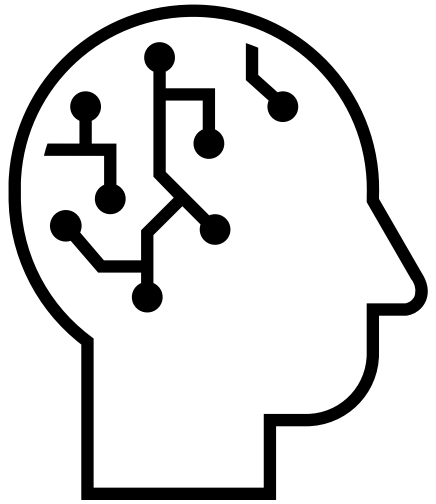
Their proposal was wider ranging including a call for input from the wider community ("Call for Comments on a Proposal To Improve Reporting of Clinical Trials in the Biomedical Literature," 1994)



*The CONsolidated Standards Of Reporting Trials (CONSORT) Statement provides a minimum standard set of items to be reported in published clinical trials.







Timely Ideas & Parallel Work

"...information that is often forgotten because it seems either self-evident or unimportant to the authors, but which is essential to really understand, replicate, or implement the intervention." (Moonaz et al., 2021, p. 807)

Improving the quality of reporting of randomized controlled trials

- Begg and colleagues (1996)
- *Improving the quality of reporting of randomized controlled trials*
- cited by 4895
- “Evidence produced repeatedly over the last 30 years indicates a wide chasm between what a trial should report and what is actually published in the literature” (Begg et al., 1996, p. 637).

Does use of the CONSORT Statement impact the completeness of reporting of randomised controlled trials published in medical journals?

- Does it help?
- Cochrane Review re: journal endorsements (Turner et al., 2012)
- The first guideline to include a checklist was the CONsolidated Standards Of reporting Trials (CONSORT) statement which has been shown effective in improving research reporting quality.

Use of Reporting Guidelines: CONSORT

More complete

Does not hinder

Journals not sending clear message

1998 CONSORT created

2005 endorsed by close to 152 general and specialty journals of medicine

2012-close to 600

2016-continues to increase in high impact factor journals

Turner et al. (2012); Shamseer et al. (2016)

Example from Dentistry

In a review by Sarkis-Onofre et al. (2020), it was found that randomized controlled trials (RCTs) found on PubMed in 2017 in journals that endorsed use of the CONSORT did show reporting quality improvement.

Perspective: Authors adhere more to conventional reviews rather than additional reviews. It appears this means that if an author were to use a Reporting Guideline from the start, they are much more likely to adhere to high methodological standards

It is therefore recommended, to improve reporting quality and overall usefulness of published research, authors should be aware of and use reporting guidelines from the outset of their studies (Cobo et al., 2011).

Adherence to CONSORT criteria between 2000 and 2020 as it relates to heart failure randomized controlled trials (RCTs)
(Jalloh et al., 2024)

Heart failure is a major cause of morbidity and mortality in older adults. Randomized controlled trials inform health policy and practice, but the accurate interpretation of results is dependent on clear and transparent reporting.

Trials with lower CONSORT adherence were published in lower impact journals.

“Suboptimal reporting of primary RCT results can introduce bias and may lead to misinterpretation of treatment effect. Pooling such trials for systematic reviews and meta-analyses can amplify biases and impact the quality of care offered to patients with HF.” (Jalloh et al., 2024, p. 1379)

Room for Improvement

New era dawning

Liu, S.-H., Lin, T.-H., & Chang, K.-M. (2013). The physical effects of aromatherapy in alleviating work-related stress on elementary school teachers in Taiwan. *Evidence-Based Complementary and Alternative Medicine*, *2013*, 1–8. https://doi.org/10.1155/2013/853809 (EXAMPLE OF ROOM FOR IMPROVEMENT)

Purpose: This study is a continuation (good thing) of a previous study of schoolteachers in Taiwan and work-related stress. The aims of this study were to clarify the beneficial effects of aromatherapy on elementary school teachers in Taiwan considering a placebo and varying workloads.

Design: The method appears to be a crossover design with each participant receiving each of the two interventions, twice, one week apart.

Sample: Twenty-nine healthy volunteers, mainly female, average age, 41-years with a normal BMI

Data collection: Quantitative data at baseline and post intervention.

Instruments: Quantitative using Beck Anxiety Inventory (BAI) at baseline. Blood pressure pre and post. Electrocardiogram (ECG) pre and post to assess heart rate variability (HRV).

Results: Results from natural bergamot diffusion were found to have a significant difference for the variables of LF, LF%, HF%, and LF/HF. Synthetic diffusion resulted in no significant changes. The aroma treatment had a weak effect on young teachers who had a heavy workload or on those with abnormal BMI having a heavy workload.

Strengths: The researchers are clear about their hypotheses and rationale for performing this study. Details about study conduct are provided.

Weaknesses: Stress was measured using an instrument designed to measure anxiety. Design was not explained clearly. Blinding mentioned but not explained.

Liu, S.-H., Lin, T.-H., & Chang, K.-M. (2013). The physical effects of aromatherapy in alleviating work-related stress on elementary school teachers in Taiwan. *Evidence-Based Complementary and Alternative Medicine*, *2013*, 1–8. https://doi.org/10.1155/2013/853809 (EXAMPLE OF ROOM FOR IMPROVEMENT)

Aromatic-focused assessment

Strengths
Rationale for the study is clearly stated
Bergamot can be considered sustainable
Diffuser type and company are provided

Weaknesses
For Bergamot essential oil no source, country of origin, Latin binomial, extraction method, or chemical analysis were reported
Synthetic oil, no information provided
No details about diffuser maintenance
No details on dimensions of room or air flow
No mention of aromatherapist
No mention of olfactory function or bias

Good study to replicate
Would need to have more details
Older study, contact may be difficult

Windows of opportunity

1. Researchers use reporting guidelines and quality appraisal checklists during study creation and conduct
2. Peer reviewers and journal editors using all available tools during critique
3. Educators and schools, funding agencies, and editors of all platforms for publication including journals (in print and online), research outlets, and organizations that publish research and reviews

It is time for an Extension for Aromatics

- CONSORT
  - NPT (Non-Pharmacologic Therapies)
    - Key features include: Item 1—in the abstract, include a description of the experimental treatment, comparator, care providers, centers, and blinding status; Item 3—eligibility criteria for centers and those performing the interventions (e. g. consulting a certified aromatherapist*); Item 4—details of the interventions including how and when they were actually administered; Item 4B—details about how the interventions were standardized (saying that the “standard of care” was used in the study is not adequate) (Boutron et al., 2008)
  - Herbal
    - This comes closer with item 4A: Herbal medicine product name, 4B: Characteristics of the herbal product, 4C: Dosage regime and quantitative description, and 4F: Practitioner description (Gagnier et al., 2006).

AROMATIC RESEARCH QUALITY APPRAISAL TASKFORCE

TREATS-RG

Next step:

Seeking consensus

What is a Delphi method?

- The Delphi method is a group-based process
- The goal is to explore the existence of consensus among a diverse group of handpicked experts.
- The Delphi method was developed at the RAND Corporation in the early 1950s
- The four key characteristics of the Delphi method are:
  1. anonymity
  2. iterative data collection
  3. participant feedback
  4. statistical determination of group response

https://www.rand.org/pubs/commentary/2023/10/generating-evidence-using-the-delphi-method.html

Delphi has become best practice

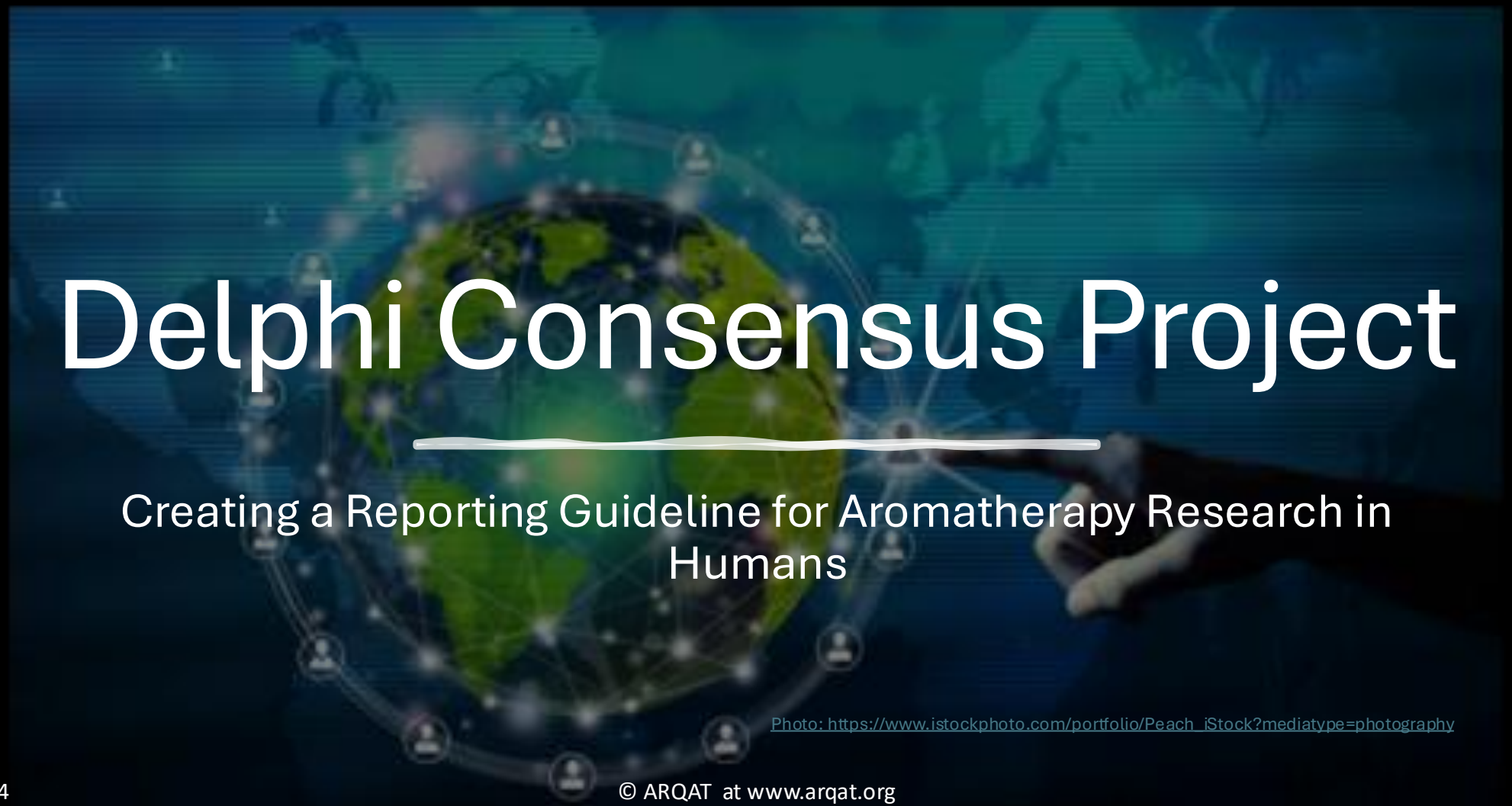
The method is used by different disciplines to:

- make forecasts
- identify research priorities
- explore likely impacts of different policy options
- develop performance metrics
- create clinical guidelines

https://www.rand.org/pubs/commentary/2023/10/generating-evidence-using-the-delphi-method.html

Delphi Consensus Project

Creating a Reporting Guideline for Aromatherapy Research in Humans



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Our Plan & Protocol

- Evidence built on evidence
  - Extensive research into processes
  - The *a priori* item consensus criteria have been carefully considered
  - Pilot testing of all rounds
  - Ethical/Institutional Review Board (IRB) approval #2205571104

REDCap WVU Survey Platform

- Secure
- Save, sign out, return using password
- Responses may be downloaded to your computer
- Up to 3 weeks to respond

Details of Rounds in the Delphi Survey

- Round 1 will be the most involved
- Round 1 will include Demographic information
  - Confirm that your name & affiliation can be published
- Rounds 2&3 will be less involved (20-30 minutes)
- Round 2&3 will include your name (Not full demographics)
- Round 4, if needed, may only include one or few questions
- ALL ROUNDS include the Explanatory Document to download. In Round 1 you will be asked to check “Yes” that you have this document

Timeline (Subject to change)

Rounds	Emailed	Due back	Time & Task
1	October 16, 2024	November 6, 2024	3 weeks survey
Break for holidays			8 weeks analysis
2	January 8, 2025	January 29, 2025	3 weeks survey
			6 weeks analysis
3	March 12, 2025	April 2, 2025	3 weeks survey
			2 weeks analysis
4 (if needed)	April 16, 2025	May 1, 2025	3 weeks survey

Items in the Delphi Survey Round 1

48 items have been developed and will be assessed in the Delphi rounds

1) title
2) characterization of essential oil(s)/volatile extract(s)
3) rationale for study design and choice of plant materials
4) aromatherapist involvement and safe handling of essential oils
5) topical application methods and dosage regime
6) inhalation methods and dosage regime
7) participant olfactory capacity and experience

Rating Process

5-point Likert scale during each round
Relevance for inclusion means the item is believed to be necessary for minimum clear and complete reporting of aromatherapy research in humans

The Likert scale responses are:

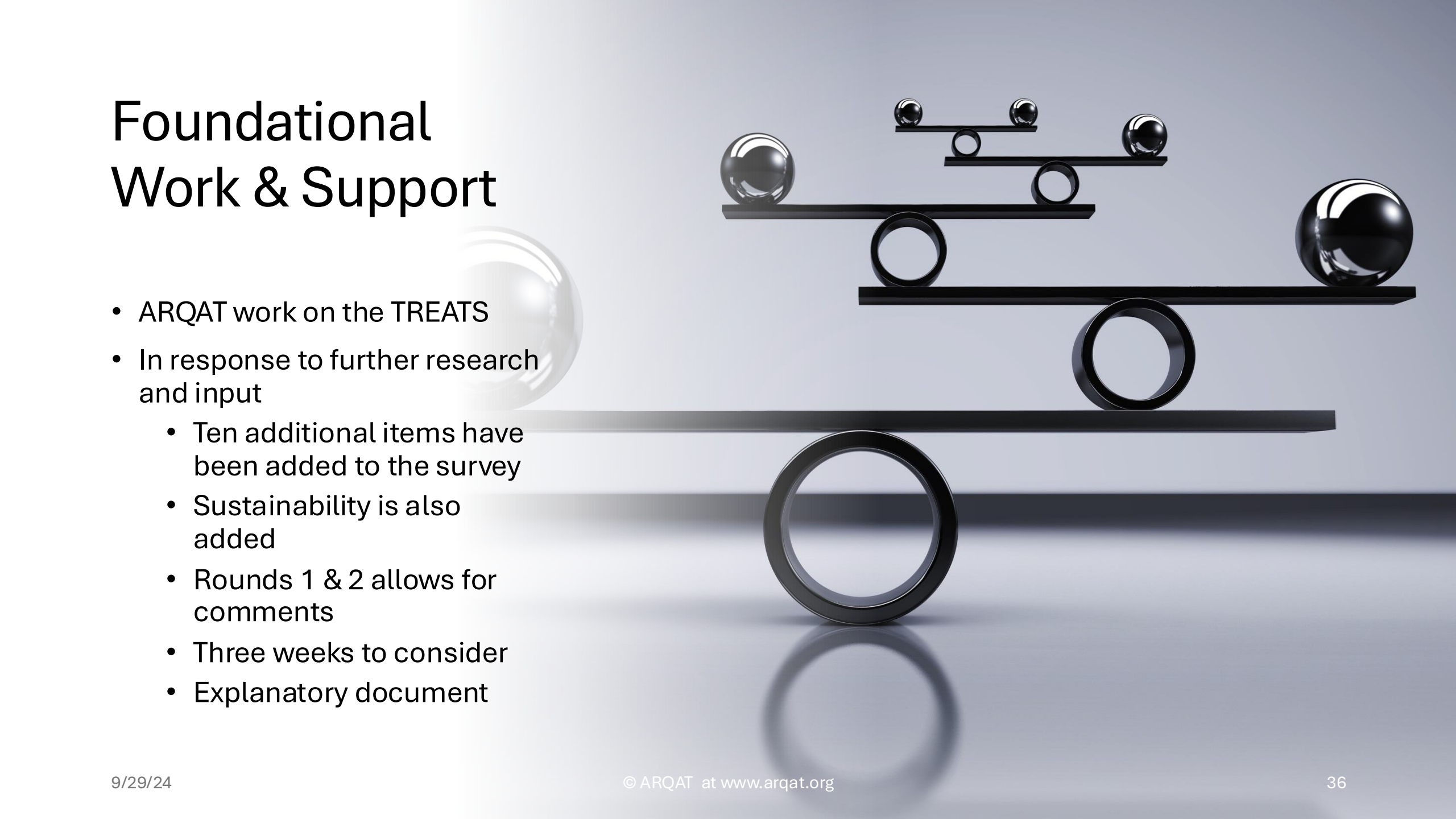
1) of no importance
2) of little importance
3) important
4) very important
5) extremely important
6) not my area of expertise*

*Items rated as 6) will not be included in the calculation of items to be included and excluded.

Delphi Round Details

- Relevance for inclusion means the item is believed to be necessary for minimum clear and complete reporting of aromatherapy research in humans
- All data will be anonymized, aggregated, and shared with participants at the end of each Round
- Up to 4 Rounds
- Comments accepted in Rounds 1 & 2
- NOTE: Comments from Round 1 may generate New Items for Round 2 only. Round 2 comments will be considered but may not generate a New Item.

Foundational Work & Support



- ARQAT work on the TREATS
- In response to further research and input
  - Ten additional items have been added to the survey
  - Sustainability is also added
  - Rounds 1 & 2 allows for comments
  - Three weeks to consider
  - Explanatory document

Questions, Comments, Concerns?

Contact Information

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Website: https://www.arqat.org

Thank you!

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