

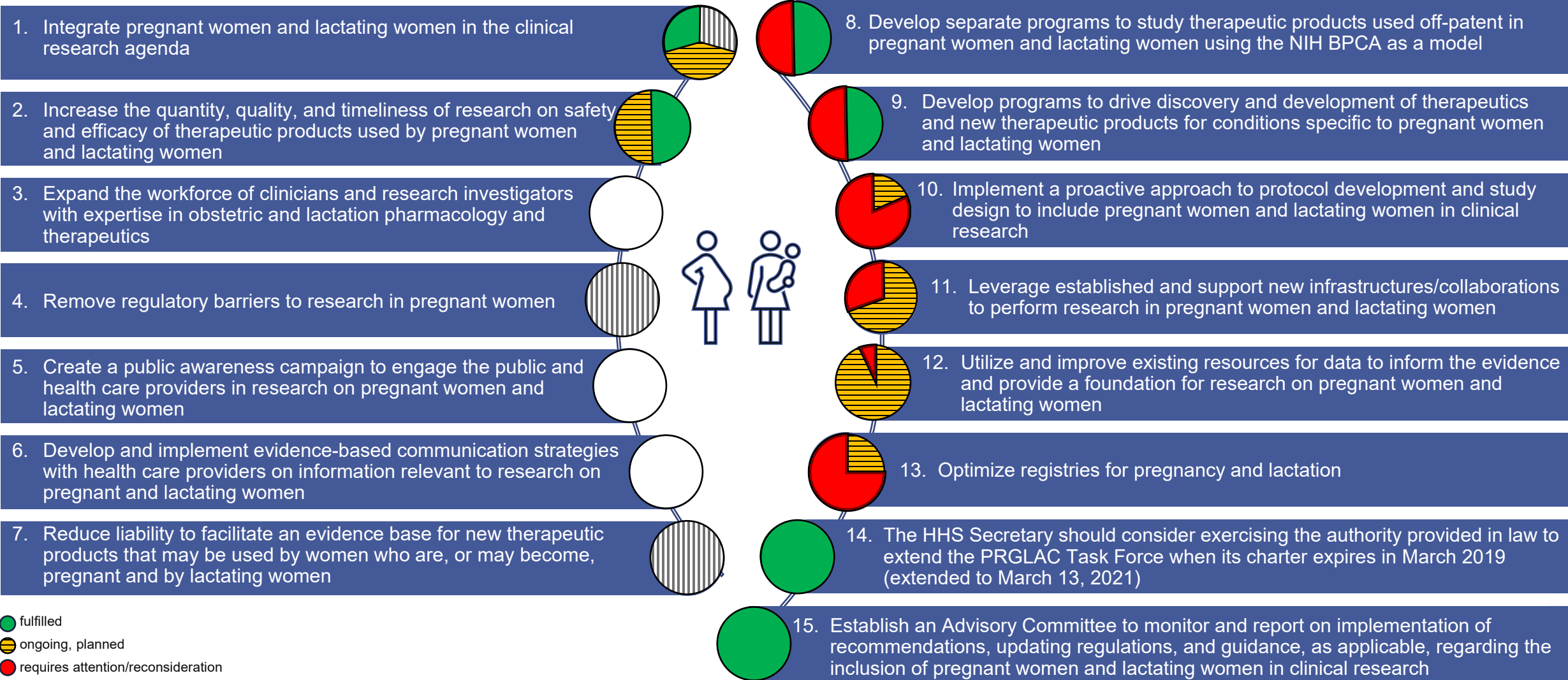
PRGLAC Implementation Working Group of NACCHD

Meeting Three

March 22, 2024



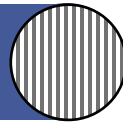
PRGLAC Recommendations - Pregnancy



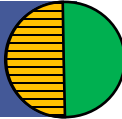
- fulfilled
- ongoing, planned
- requires attention/reconsideration

PRGLAC Recommendations - Lactation

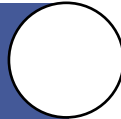
1. Integrate pregnant women and lactating women in the clinical research agenda



2. Increase the quantity, quality, and timeliness of research on safety and efficacy of therapeutic products used by pregnant women and lactating women



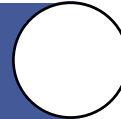
3. Expand the workforce of clinicians and research investigators with expertise in obstetric and lactation pharmacology and therapeutics



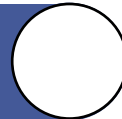
4. Remove regulatory barriers to research in pregnant women



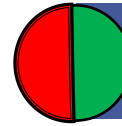
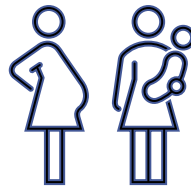
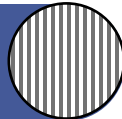
5. Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women



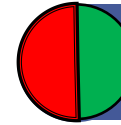
6. Develop and implement evidence-based communication strategies with health care providers on information relevant to research on pregnant and lactating women



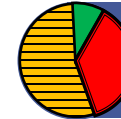
7. Reduce liability to facilitate an evidence base for new therapeutic products that may be used by women who are, or may become, pregnant and by lactating women



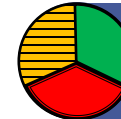
8. Develop separate programs to study therapeutic products used off-patent in pregnant women and lactating women using the NIH BPCA as a model



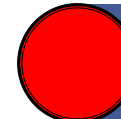
9. Develop programs to drive discovery and development of therapeutics and new therapeutic products for conditions specific to pregnant women and lactating women



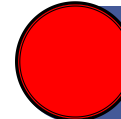
10. Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research



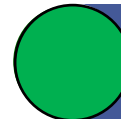
11. Leverage established and support new infrastructures/collaborations to perform research in pregnant women and lactating women



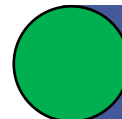
12. Utilize and improve existing resources for data to inform the evidence and provide a foundation for research on pregnant women and lactating women






13. Optimize registries for pregnancy and lactation



14. The HHS Secretary should consider exercising the authority provided in law to extend the PRGLAC Task Force when its charter expires in March 2019 (extended to March 13, 2021)



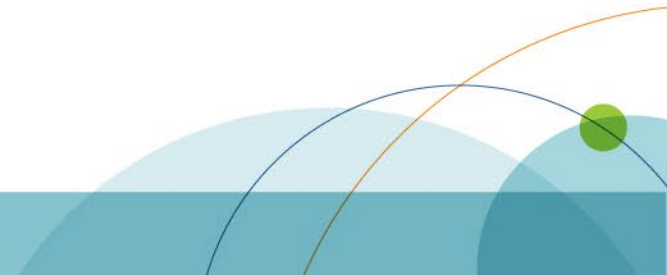
15. Establish an Advisory Committee to monitor and report on implementation of recommendations, updating regulations, and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research

-  fulfilled
-  ongoing, planned
-  requires attention/reconsideration

Congressional Language

Report Language from Consolidated Appropriations Act of 2023 (P.L. 117-328).


The Committee includes \$200,000 for the creation of an Advisory Committee to monitor and report on the implementation of the recommendations from the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). PRGLAC's 2020 Implementation Plan called for the creation of an Advisory Committee to monitor and report on implementing recommendations, updating regulations, and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical trials. Additionally, the Committee directs the Secretary to submit a report to Congress within 180 days of the date of enactment of this Act outlining the Department's progress on implementing each of PRGLAC's 15 recommendations from the Implementation Plan it submitted to the Secretary in August 2020 (H. Report: 117-403).



The Working Group of Council and Objectives

Recommended in the Implementation Plan (Recommendation #15)

The Working Group will:

- Review publicly available materials pertaining to implementation progress
 - Invite speakers from relevant Federal agencies or non-federal entities to discuss progress to-date on PRGLAC implementation plan, including possible barriers
 - Report their findings to NICHD Council and submit the report to Congress
 - Implementation progress
 - Provide recommendations to facilitate implementation, where necessary
 - Advise reconsideration, as relevant
- 

Review of Implementation Progress by Cluster

Cluster A: Conduct clinical research and trials

Cluster B: Education, outreach, training, and career development

Cluster C: Policy, regulatory, and liability

Cluster D: Registries and real-world data

Cluster E: Novel drug discovery and development



Today's Clusters

Cluster A: Conduct clinical research and trials



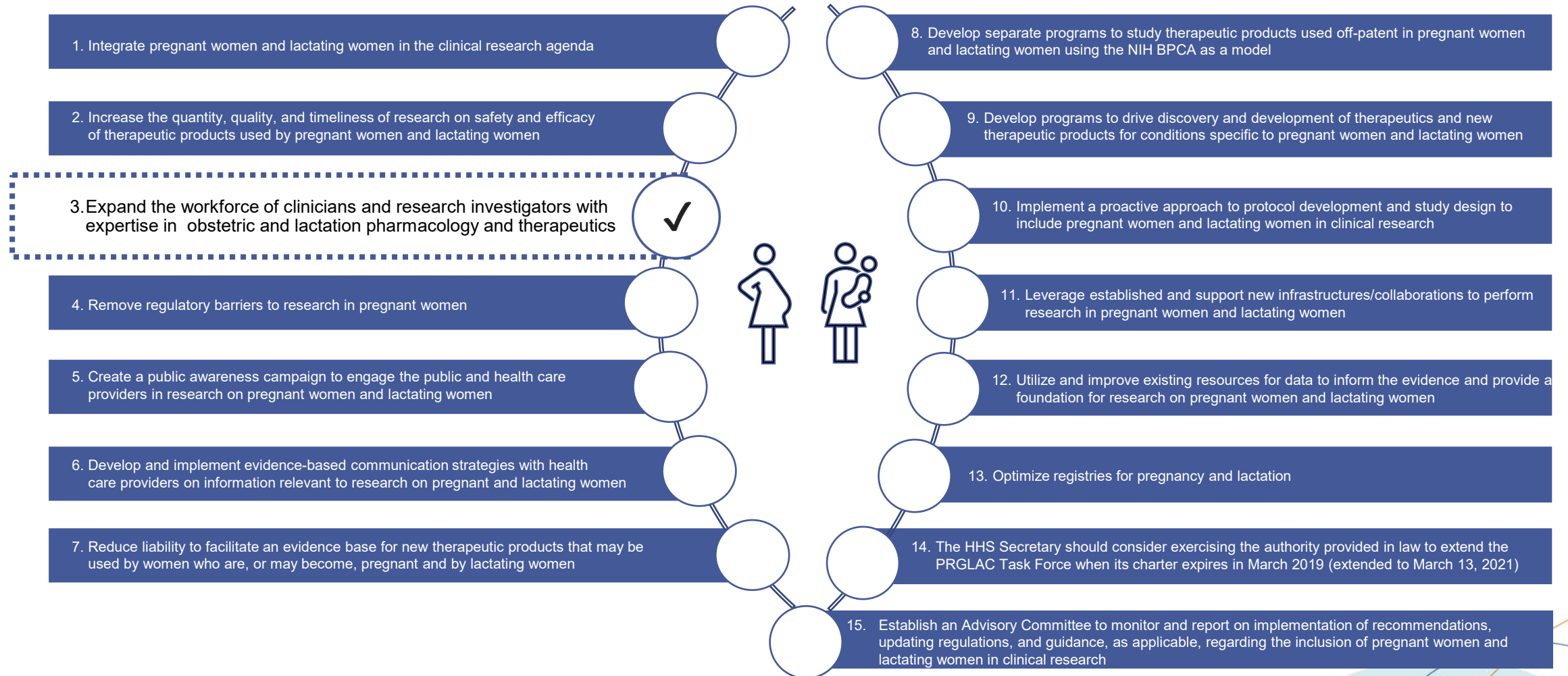
Cluster B: Education, outreach, training, and career development

Cluster C: Policy, regulatory, and liability

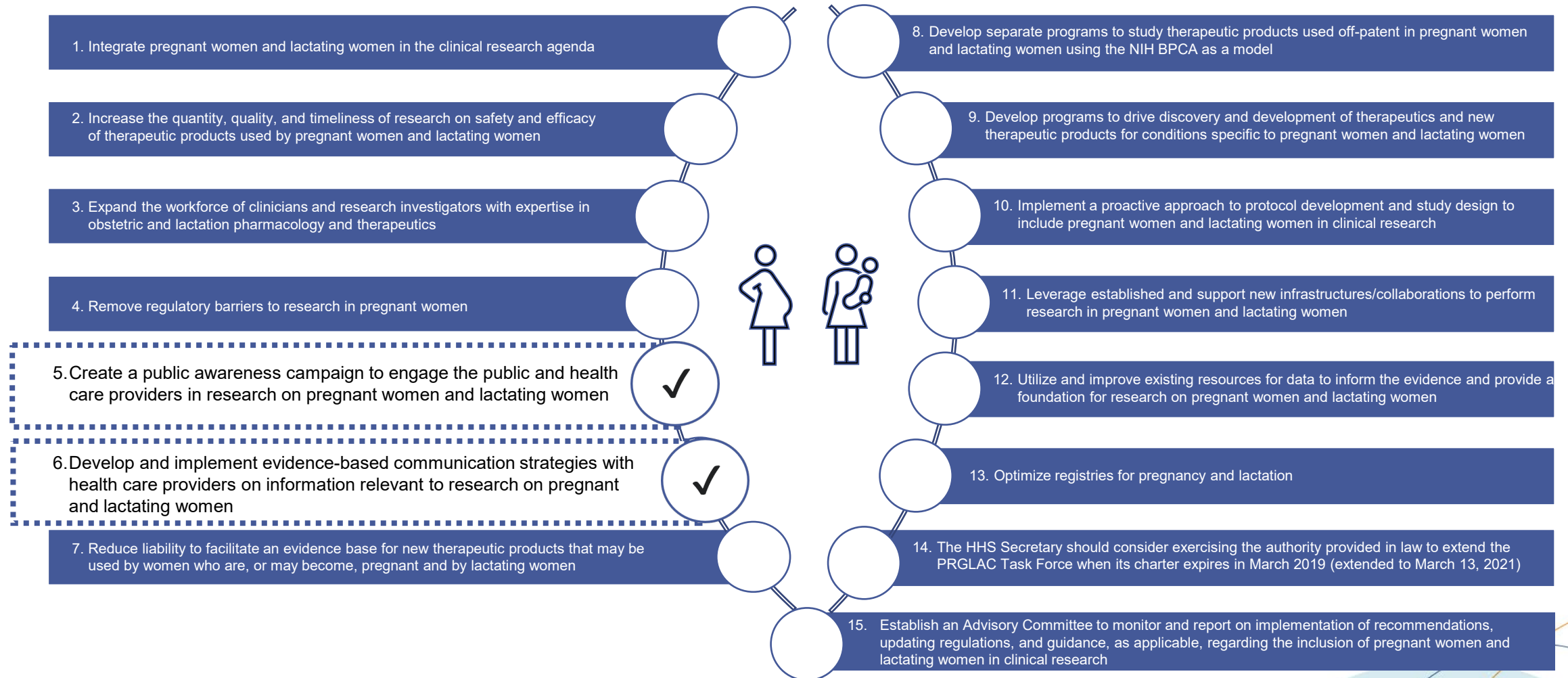
Cluster D: Registries and real-world data

Cluster E: Novel drug discovery and development

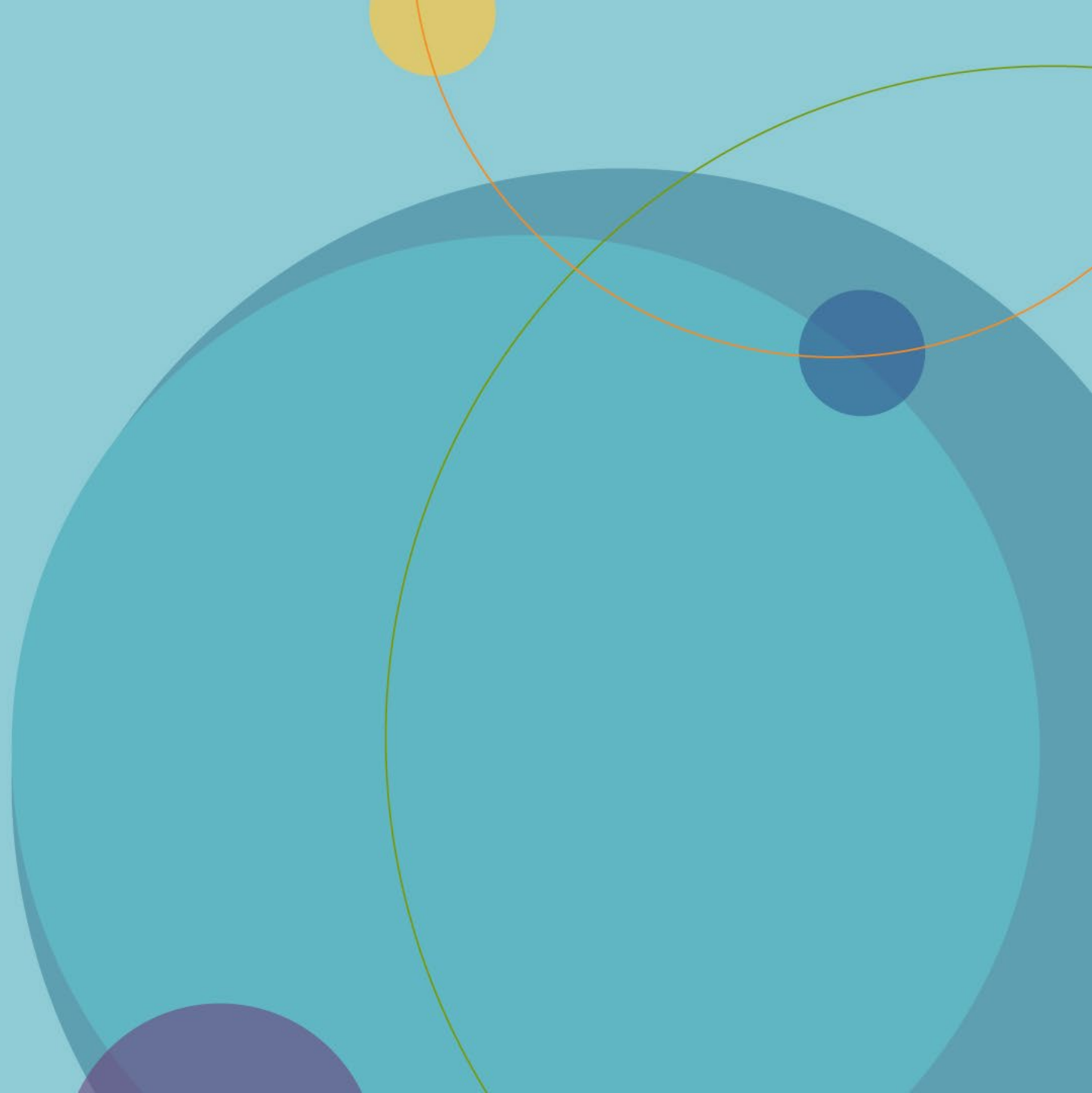
Today's Focus – Session I



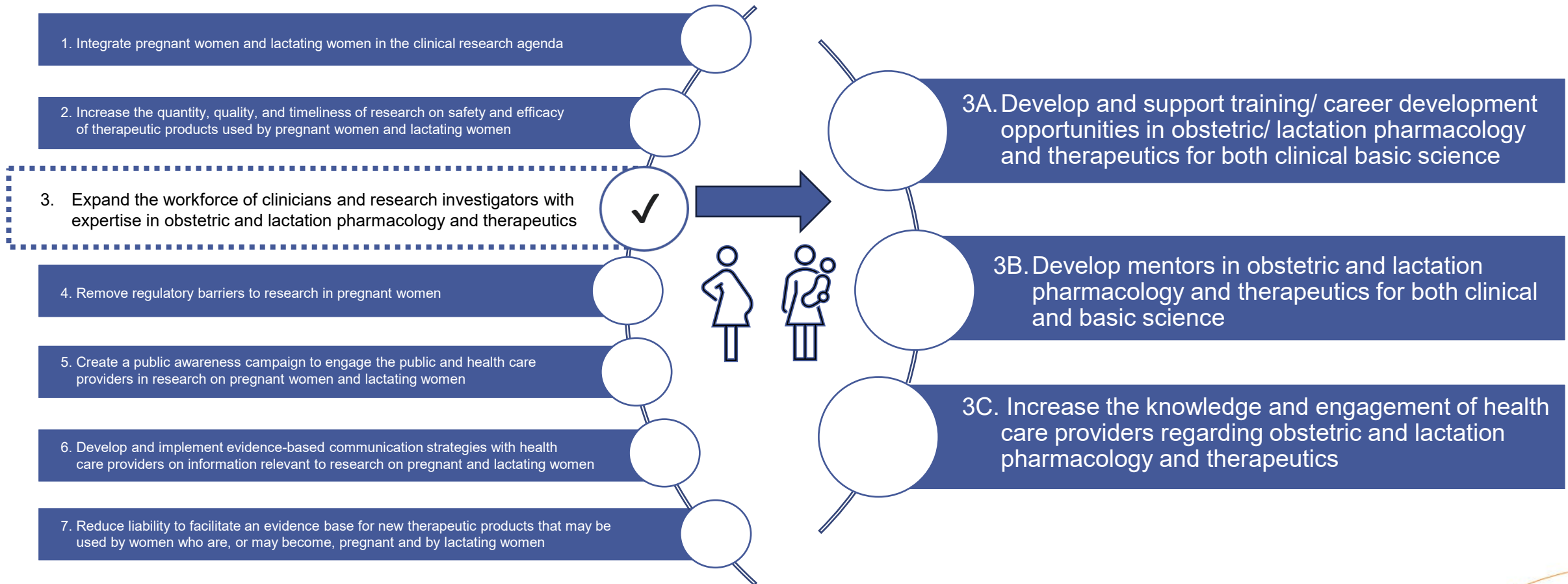
Today's Focus – Session II



Session I

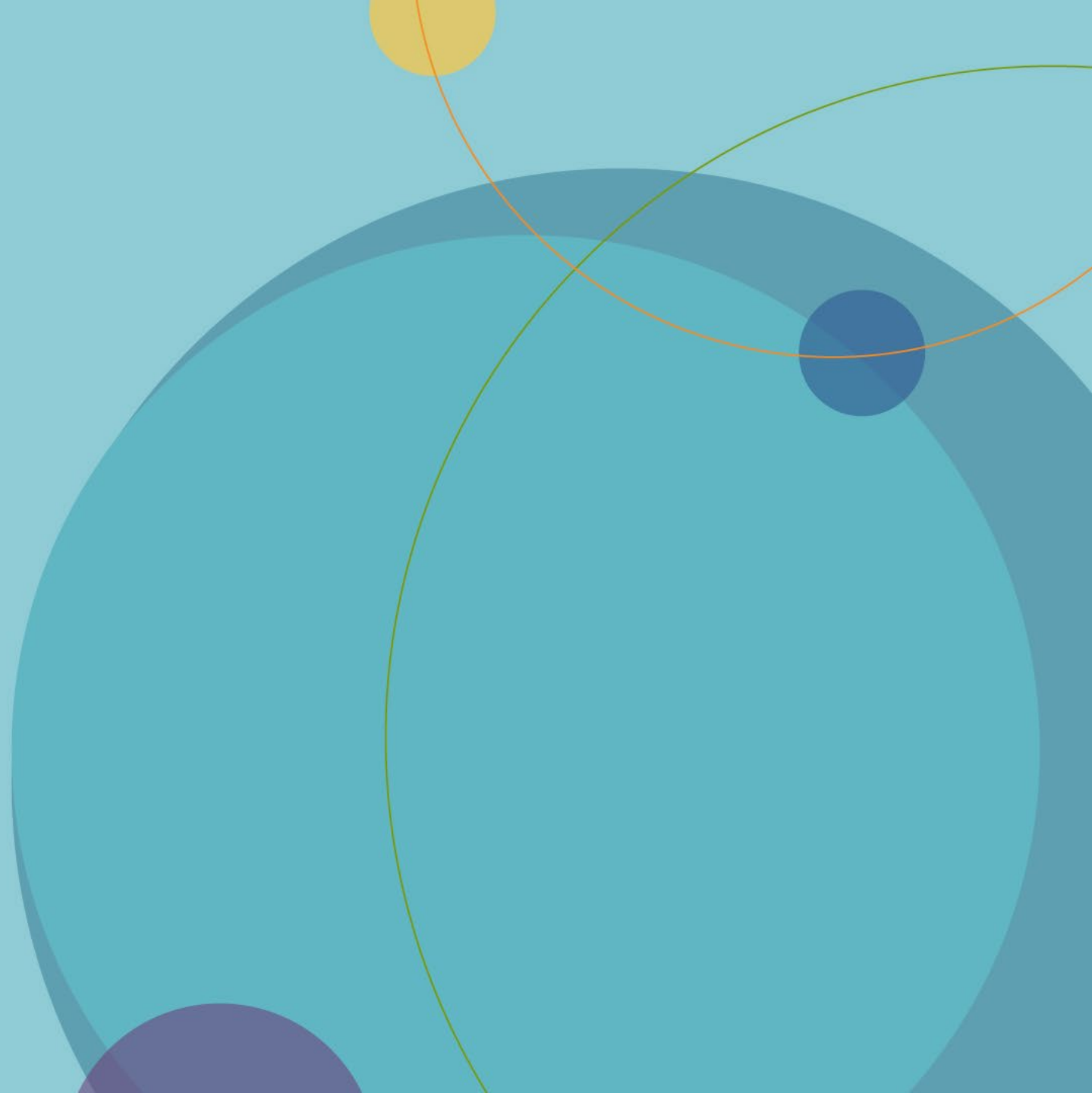


Recommendation 3: Expand the workforce of clinicians and research investigators with expertise in obstetric and lactation pharmacology and therapeutics

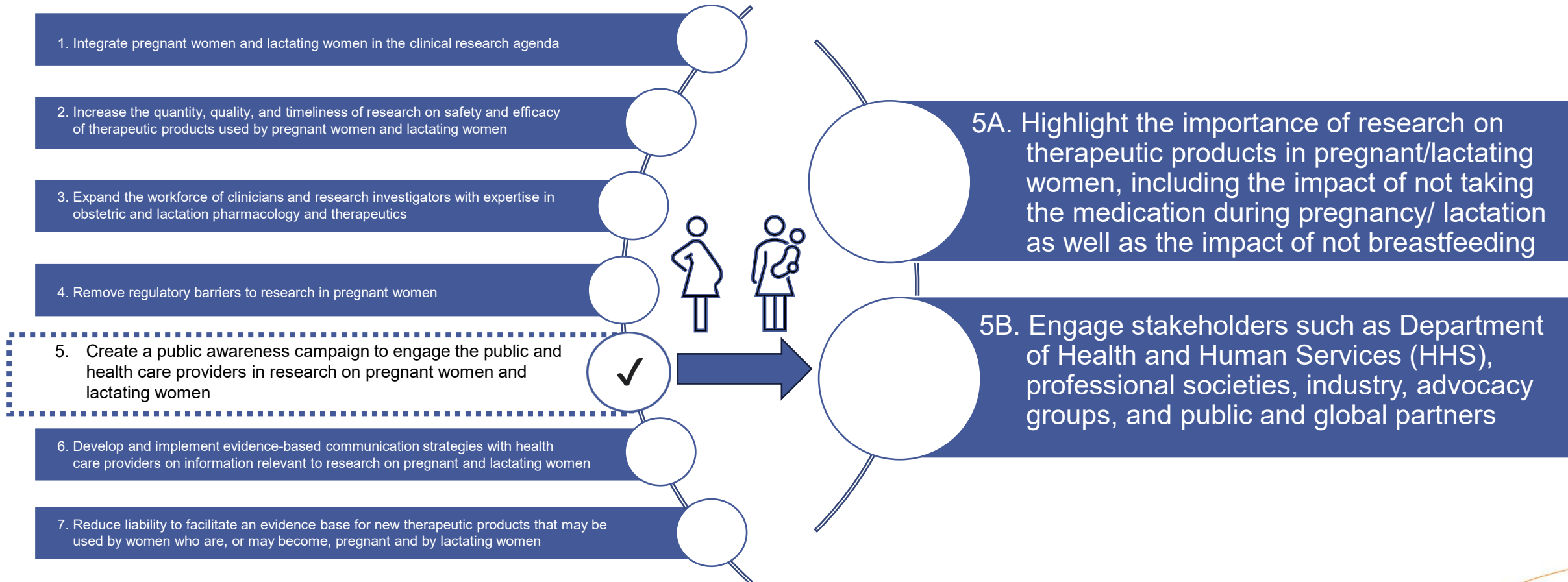


Session II

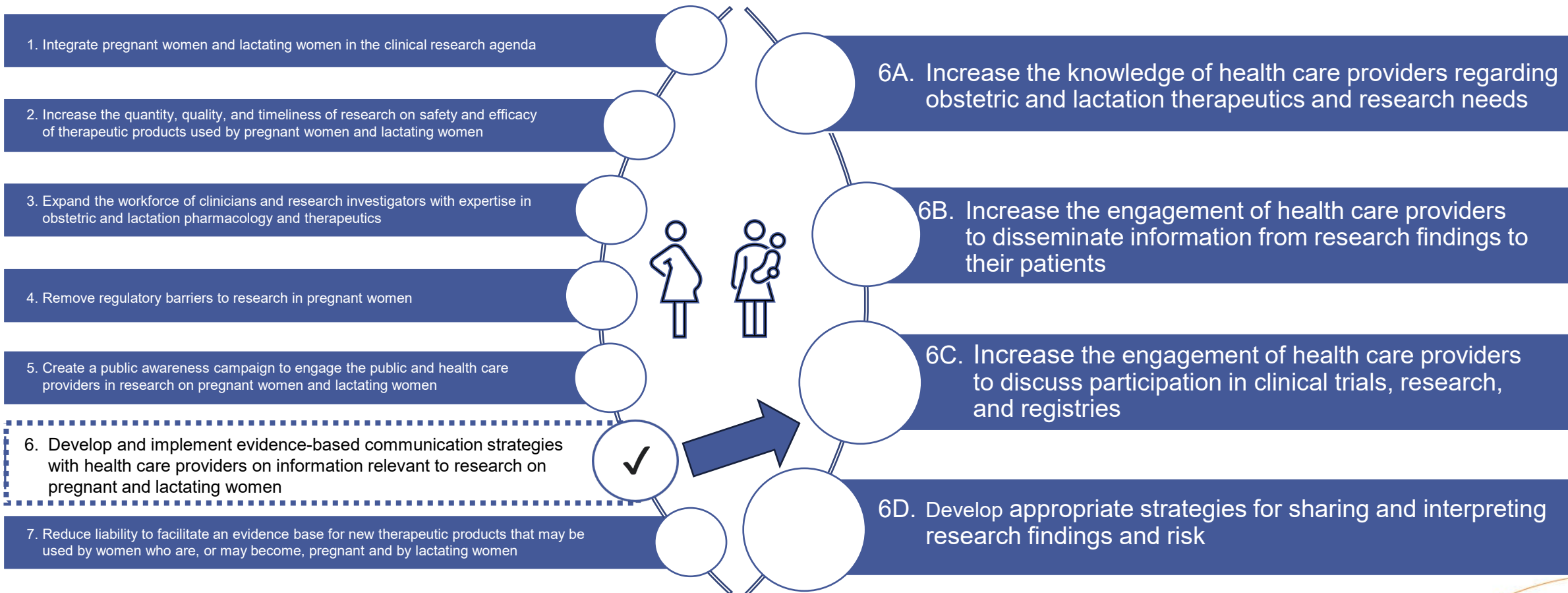
Recommendations 5 and 6



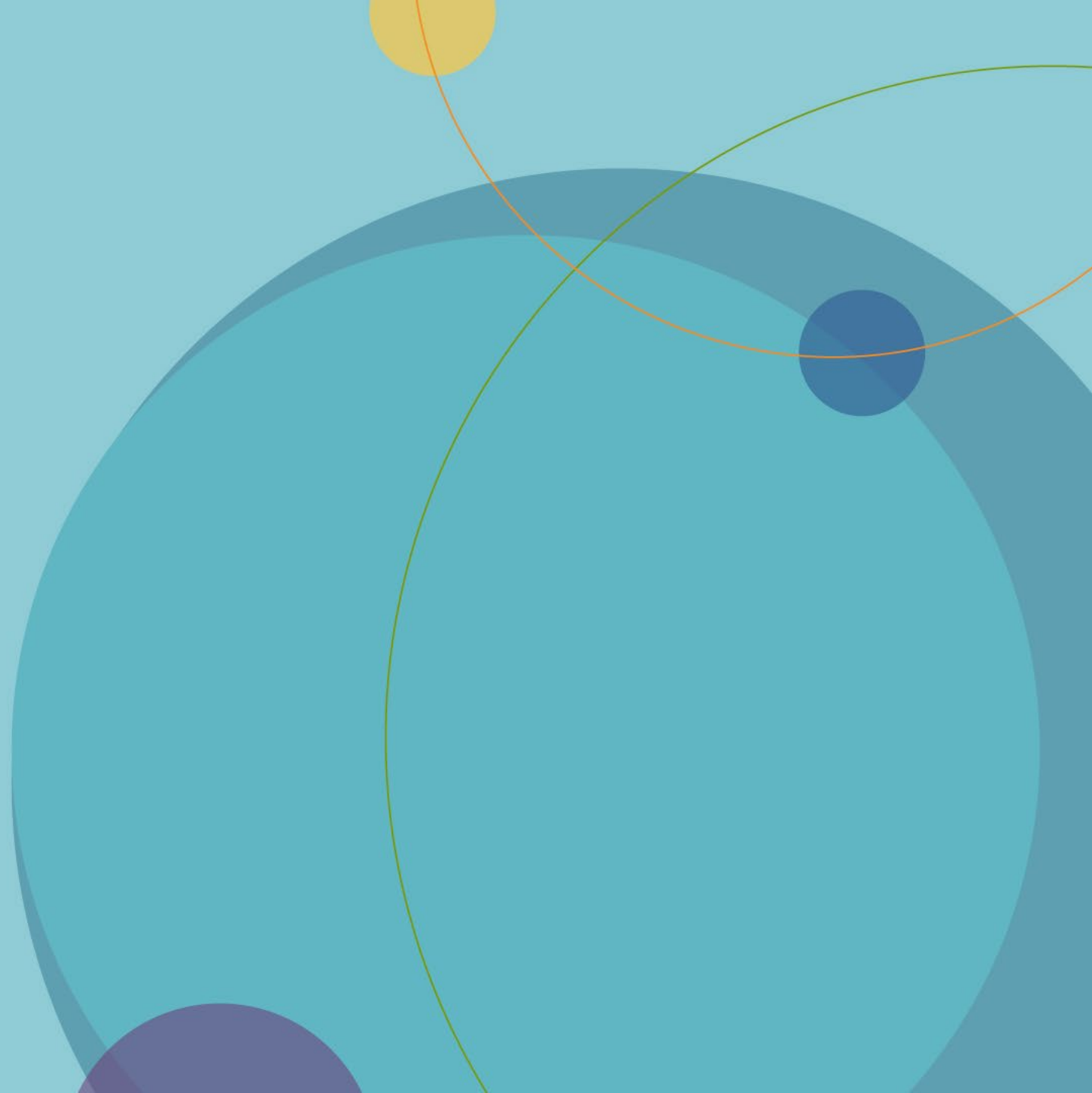
Recommendation 5: Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women



Recommendation 6: Develop and implement evidence-based communication strategies with health care providers on information relevant to research on pregnant women and lactating women

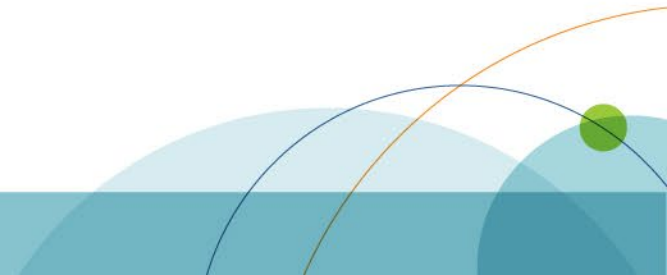


Session III

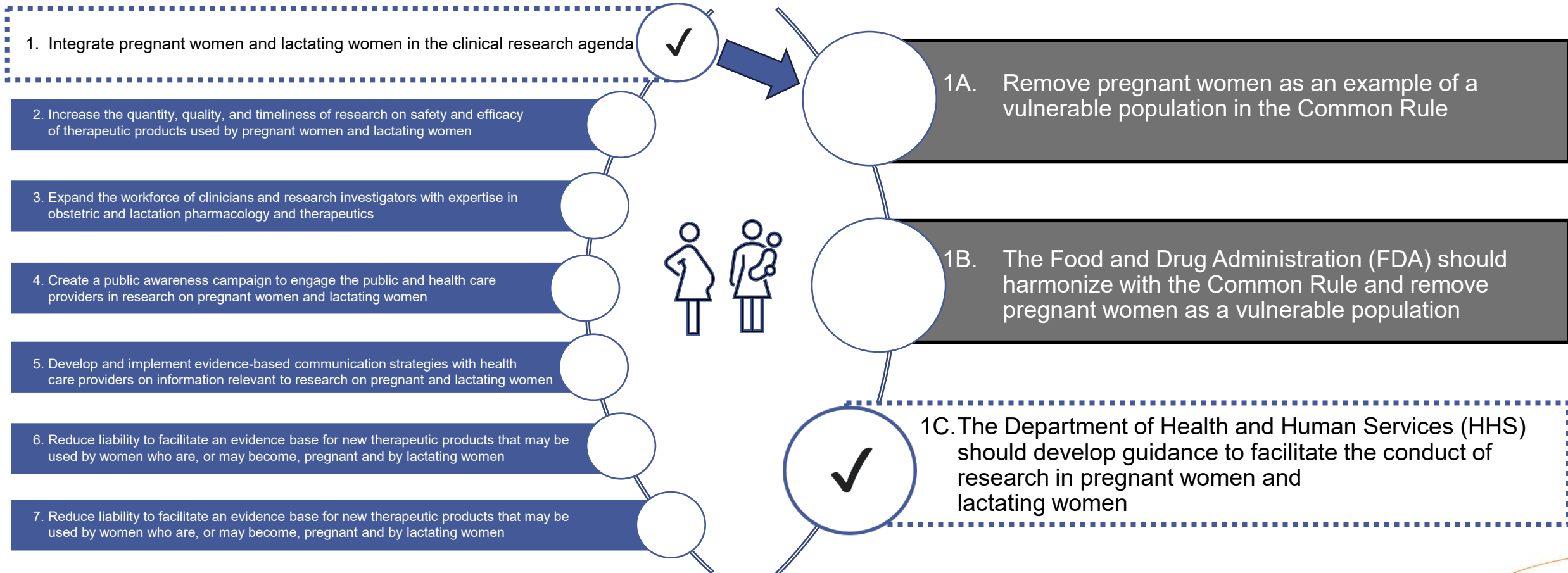


Follow-up on past items

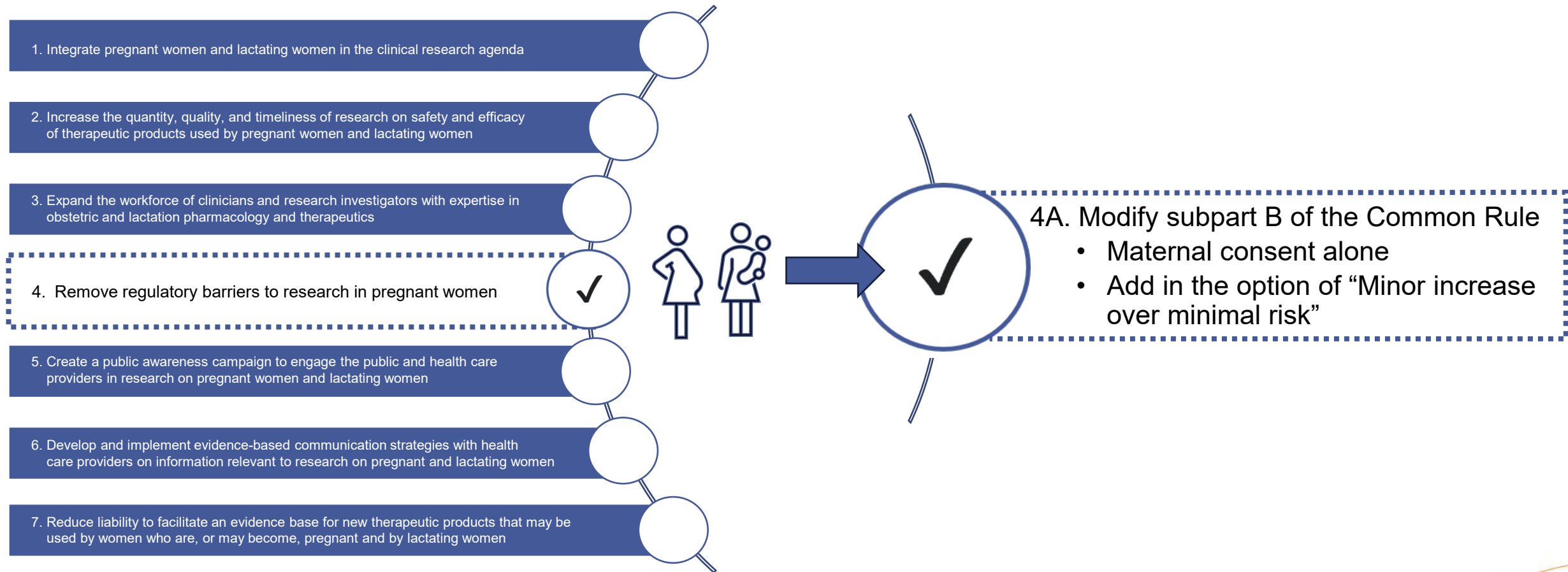
- Awaiting pending OHRP Update
 - Recommendations 1C, 4A, and 10A
- Handling recommendations that may require Congressional action – e.g., funding, legislative proposals
 - Recommendations 8A, 9B



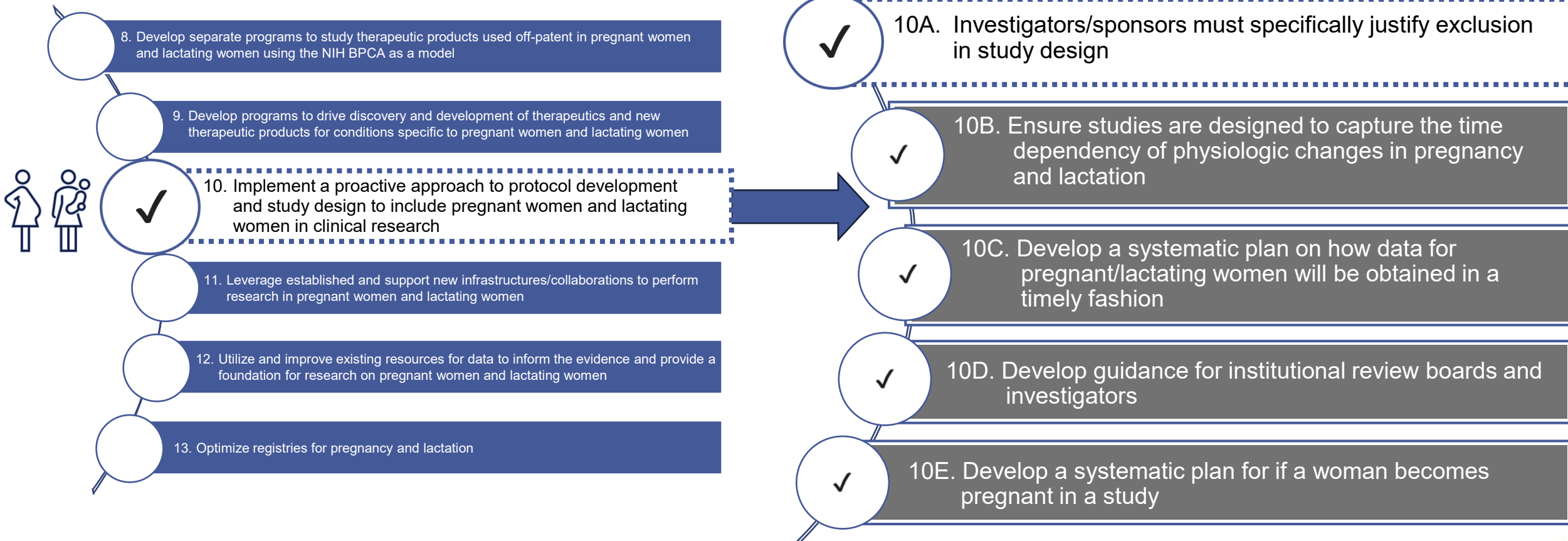
Recommendation 1: Include and integrate pregnant women and lactating women in the clinical research agenda



Recommendation 4: Remove regulatory barriers to research in pregnant women



Recommendation 10: Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research



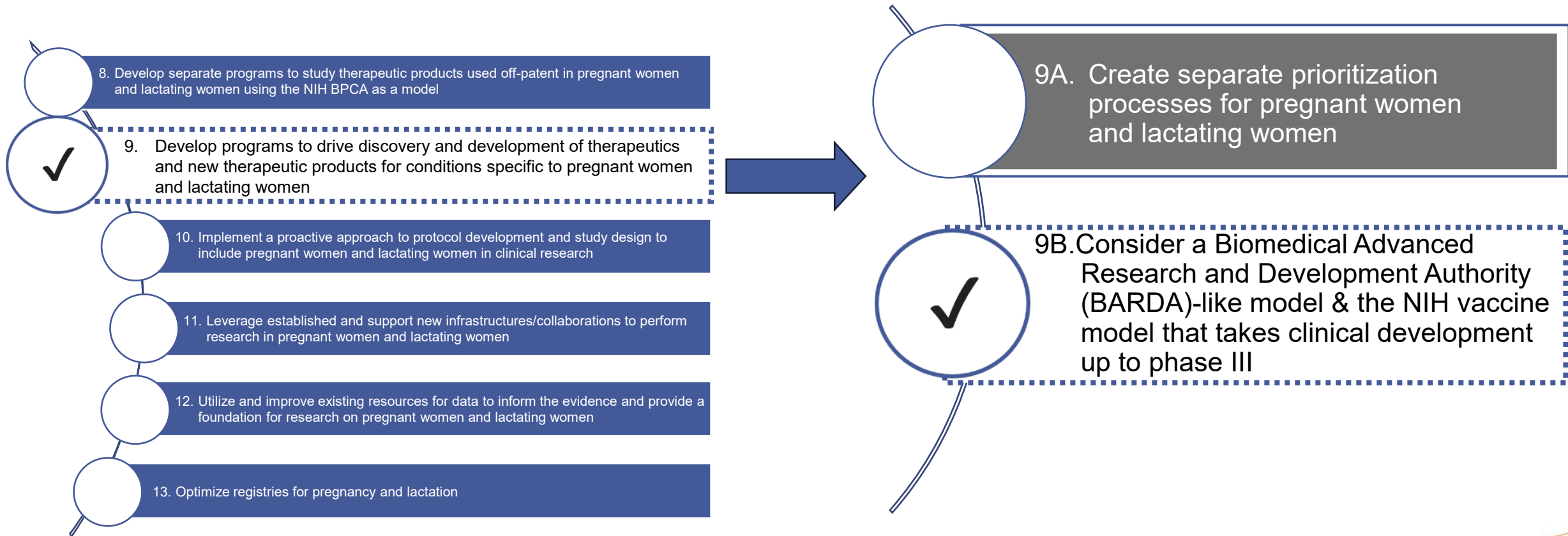
Recommendation 8: Develop separate programs to study therapeutic products used off-patent in pregnant women and lactating women using the NIH BPCA as a model

- 8. Develop separate programs to study therapeutic products used off-patent in pregnant women and lactating women using the NIH BPCA as a model
- 9. Develop programs to drive discovery and development of therapeutics and new therapeutic products for conditions specific to pregnant women and lactating women
- 10. Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research
- 11. Leverage established and support new infrastructures/collaborations to perform research in pregnant women and lactating women
- 12. Utilize and improve existing resources for data to inform the evidence and provide a foundation for research on pregnant women and lactating women
- 13. Optimize registries for pregnancy and lactation

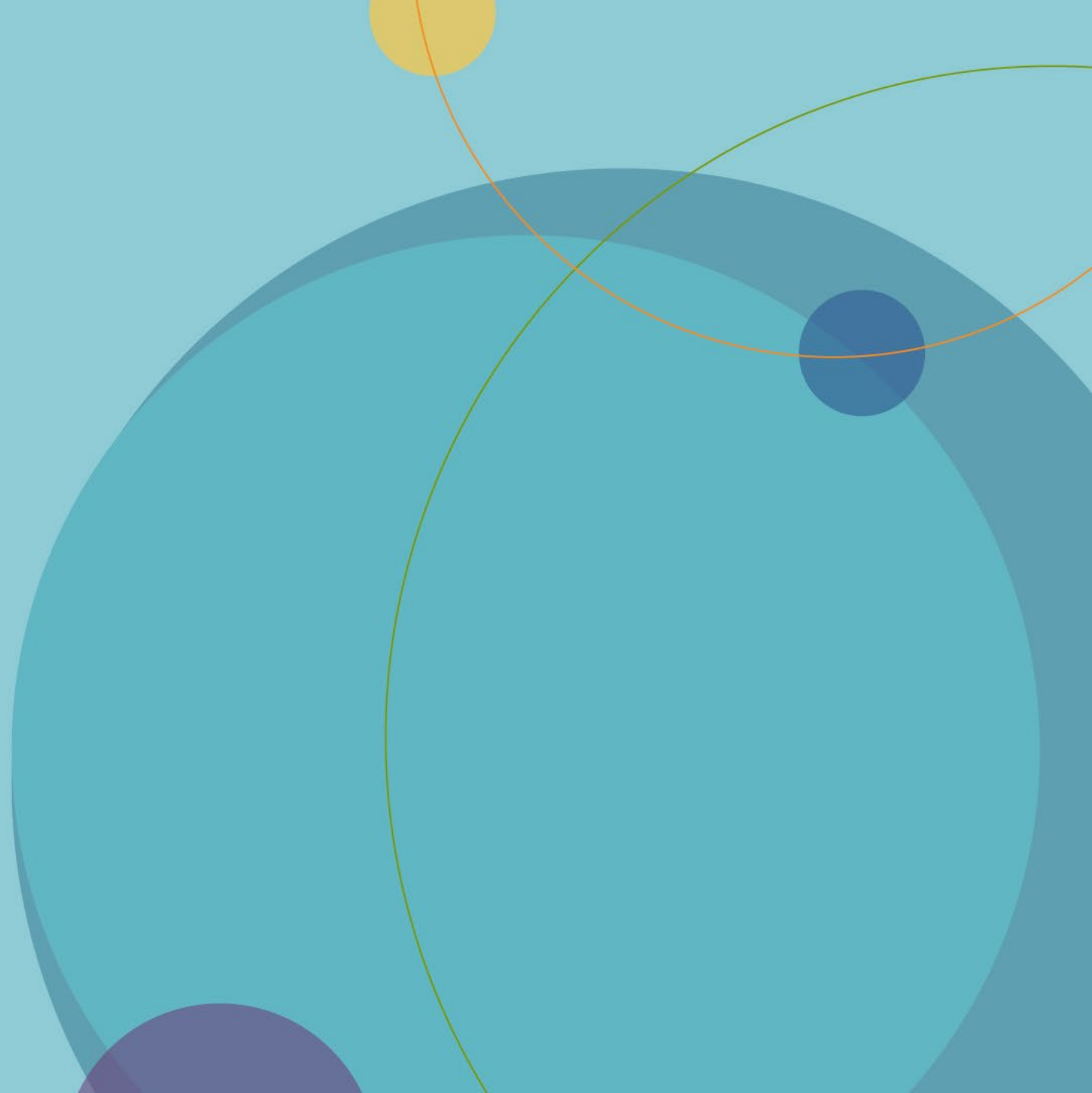


- 8A. Provide specific funding
- 8B. Develop separate prioritization processes for therapies and/or conditions in pregnant women and lactating women

Recommendation 9: Develop programs to drive discovery and development of therapeutics and new therapeutic products for conditions specific to pregnant women and lactating women

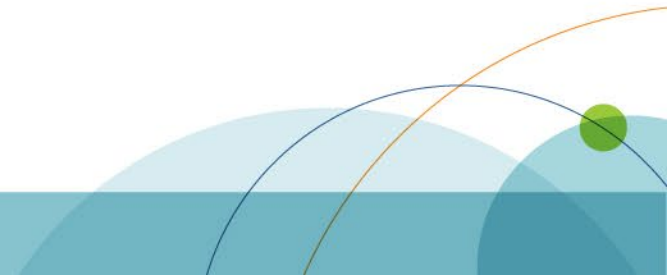


Final Report Development



Report Development Discussion

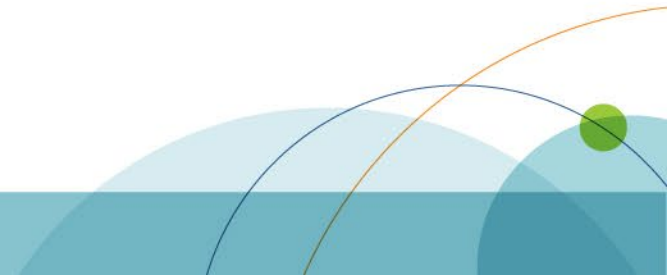
- Report development best practices
- Handling major disagreements and/or lack of concurrence in the report
- Scope of the report



Recommendation 15

Establish an Advisory Committee to monitor and report on implementation of recommendations, updating regulations, and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research PRGLAC is a formal advisory committee constituted under the Federal Advisory Committee Act.

Recommendation 15 of its 2018 report to the Secretary and to Congress called for an additional advisory body to monitor implementation of the recommendations, so consideration was deferred until PRGLAC developed an implementation plan for the other recommendations. *However, the current PRGLAC recommends that, once its charter expires in 2021, another committee with a similar range of expertise should be established to ensure that the steps recommended by PRGLAC are implemented and progress is monitored.*



Report Development: Outline

Section 1: Introduction

- Overview of original PRGLAC, the working group, meetings, and information gathering activities

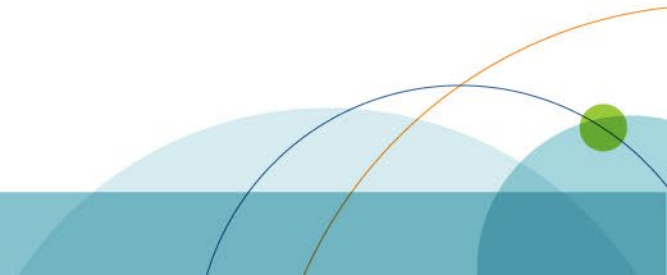
Section 2: Implementation updates

- One subsection for each recommendation
- Includes classifications (Done, in progress, not started) with nuanced justifications
- Includes specific considerations for each original recommendation (if applicable)

Section 3: Themes

- Overarching themes

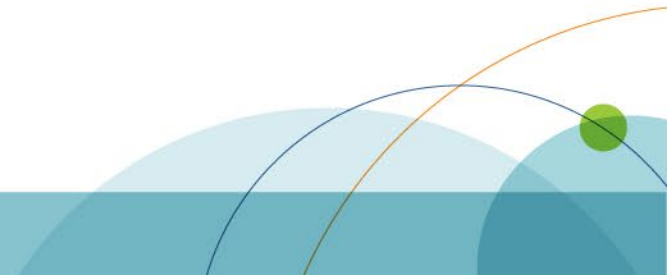
Section 4: Conclusion



Report Development Discussion

Section 3: Overarching Themes

- Difference in challenges and in Implementation Plans for lactation and pregnancy
 - ◆ Need to clearly distinguish between the two in the report
- Ownership over recommendations may be disparate or unclear
- Multiple stakeholders (public and private)
- Some recommendations require additional resources or Congressional action
- Others?



Report Development: Timeline

| Task | Assigned to | Timeline | Duration |
|---|------------------------|-------------------|----------------|
| Draft report | NICHD + Science Writer | March 25-April 23 | Approx. 4 week |
| Co-Chairs review | Co-Chairs | April 23- May 9 | 2 weeks |
| Working Group review | WG Members | May 13-24 | 10 days |
| Incorporate feedback develop Council presentation | NICHD | May 24-31 | 1 week |
| Final Council presentation | Co-Chairs | June 3, 2024 | -- |
| Report Submitted to Council | NICHD | End of June | -- |
| Report Submitted to Congress | NICHD | End of July | -- |

Questions and Feedback

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