

Session III: Facilitating Progress

Moderator: **Bruce Burnett**, Director of Regulatory Affairs, Duke, CTTI Project Team Lead



Open Discussion Questions

Recommendations & Resources Needed

What recommendations and resources should CTTI develop to advance DPM acceptance and use to support decision making?

To whom should those recommendations target?

Metrics to Measure Change

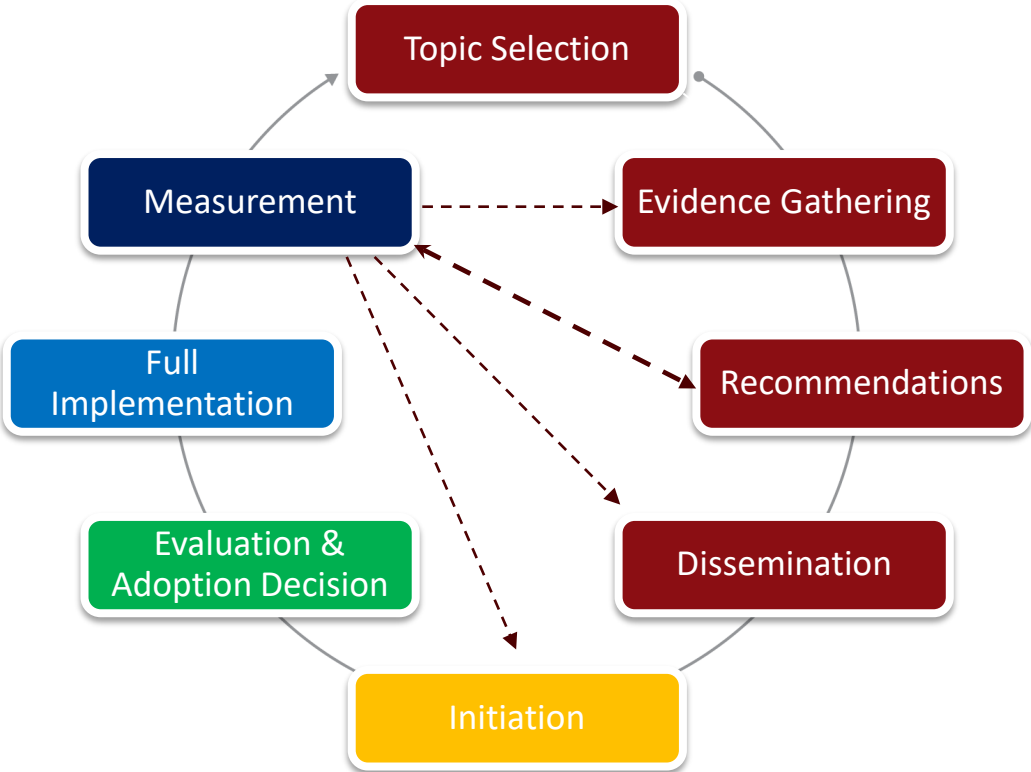
Sara Calvert, CTTI Director of Projects



Looking at CTTI's Role in Adoption

CTTI & Clinical Trial Enterprise

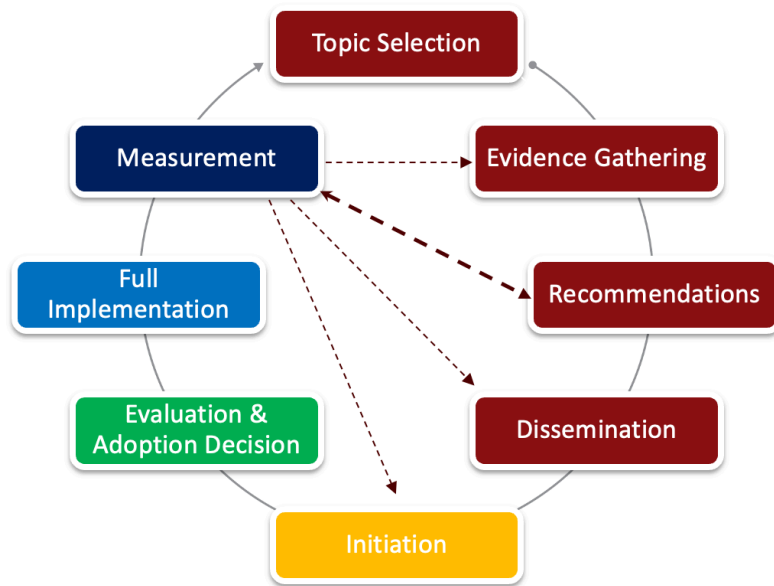
CTTI Staff & Members



Clinical Trial Enterprise
(including CTTI Members)

CTTI's Evolving Role in Measurement

- ▶ We are interested in assessment at the organizational scale:
 - *How does an individual **adopter** of CTTI recommendations assess their progress?*
- ▶ We also care about the full CTE:
 - *How can we quantify the uptake in disease progression modeling across the entire clinical trial **enterprise**?*
 - *How will we know if adoption of DPM is **improving the quality and/or efficiency of trials**?*



How Can We Measure Progress in DPM?

Organizational

Enterprise-wide

| | | |
|---------------------------|--|--|
| Tracking (Process) | <p>How can we know whether change is happening at the organizational level?</p> | <p>How can we know that change is happening across the entire trial enterprise?</p> |
| Outcomes (Value) | | |

Open Discussion Questions

Metrics to Measure **Organizational** Change

What would you look at within an organization to measure adoption of DPM?

How would you measure the ROI from DPM adoption? (i.e. What measure from similar organizations would convince you to adopt or scale DPM?)

Open Discussion Questions

Metrics to Measure **Enterprise-Wide** Change

How would you measure if change is happening at the clinical trial enterprise level?

What are the benefits of this change?

Next Steps & Potential Timeline

March 2023

Q2-Q3 2023

Q4 2023 or Q1 2024

Expert Meeting Summary

- Key themes from meeting will be posted on CTTI Website in early April

Draft Recommendations & Supporting Tools

- DPM Project Team will assess whether additional evidence gathering is necessary
- DPM Project Team drafts recommendations and develops supporting tool(s)

Launch Recommendations

- CTTI convenes a Recommendations Advisory Committee to refine recommendations
- CTTI hosts public webinar to launch recommendations and supporting tools



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“Without deviation from the norm, progress is not possible.”

– Frank Zappa

THANK YOU

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