

Value Assessment and Integration Guide for Digital Therapeutics: A Mixed-Methods Study

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Introduction

Digital therapeutics (DTx) are software products that aim to deliver evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease. [1]. Because of their unique remote accessibility, DTx are typically used in a patient's home environment. They can be scalable treatments that can improve safe healthcare access by removing common barriers such as limited transportation, long waiting room queues that can expose patients to respiratory illness like COVID19, and systemic racism that can present in brick and mortar facilities. [2].

Digital therapeutics have potential to transform healthcare, but they have low adoption [3]. One of the impediments to broader adoption of DTx is lack of standardization of coding, coverage, and reimbursement. There is also a need to standardize the way we discuss and assess outcomes from the use of DTx. [4, 5]. Healthcare decision makers (HCDMs) at employers, state Medicaid agencies (SMAs), insurance carriers, and provider organizations have variable approaches to vetting and deploying DTx. The burden of evaluation lies on HCDMs, which creates fragmentation in different geographic regions and professional arenas as well as backlogs of technologies awaiting review. An initial high-level attempt to standardize benefit coverage design for DTx in Medicaid offered some guidance on how to reduce the burden of evaluation on SMAs [6]. But there remains a need to have a more granular standard guide for assessing DTx within and beyond Medicaid.

Additionally, the aforementioned benefit coverage determination process for DTx in SMAs failed to account for the lack of reliable data across products making product comparison difficult, which can slow coverage and reimbursement decisions. Establishing evaluation tools makes it possible to maintain consistency and transparency when assessing the validity of products' stated goals and ensuring high standards [7, 8, 9].

The Digital Therapeutics Alliance (DTA) developed the Value Assessment and Integration Guide (Guide) to provide HCDMs with a framework to evaluate the value of and enable the implementation of DTx in clinical practice. [10]. DTA is a non-profit that brings together 100 member companies across 17 countries on five continents who are developing and supporting DTx products internationally. In developing the Guide, the DTA built on prior work that standardized DTx nomenclature and taxonomy with the goal of ensuring that there is more consistency in how DTx products are defined, evaluated, and implemented across different healthcare ecosystems. [11]. To ensure fidelity to user feedback, evaluation rigor, and transparency in the process of the development of the Guide, the authors were invited by DTA

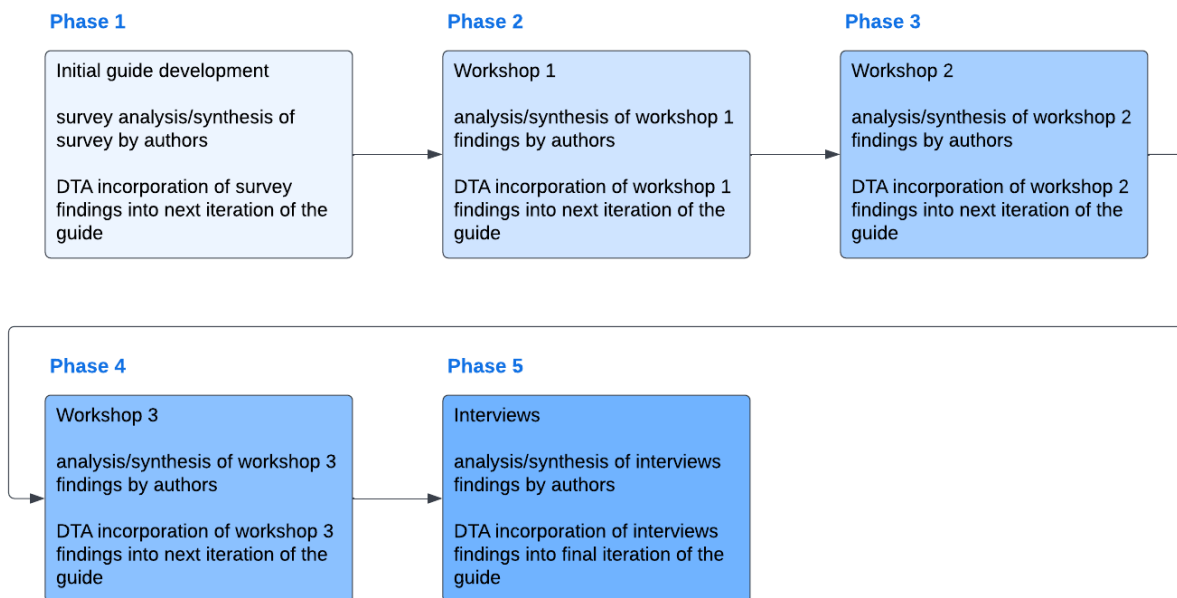
to observe and document HCDM reactions of the Guide. In this mixed-methods study, our aims were to determine the Guide's usefulness and to transparently characterize the development process of the Guide.

Methodology

Research Design

DTA initially developed a first draft of the Guide based on internal staff and DTA member organization subject matter expertise. We subsequently sought HCDMs' input through surveys, workshops, and interviews. Surveys, workshops, and interviews were organized by one group of authors and DTA staff. However, only the authors codified, analyzed, and synthesized the data. DTA used the synthesized data to inform subsequent versions of the guide. (Figure 1) At each of the five phases, we collected input from stakeholders, shared that feedback with DTA in granular and summarized form, and DTA incorporated that feedback into the draft guide at their discretion. The summarized feedback is included in the results section below. The granular feedback can be made available upon request. The subsequent version of the draft guide based on the prior phase input was then presented to the next phase participants. While the final guide (Public Version 1) was the first public facing version of the guide, there were five iterations of the draft guide that were modified iteratively and presented to HCDMs.

Figure 1



Target Population and Sampling Procedure

We used a convenience sampling method to capture HCDM perspectives from a wide range of disciplines. Recruiting campaigns were used to identify HCDMs in the US and outside the US. The target participants for this mixed-methods study included members of the DTA community, DTA Clinician Advisory Board, DTA Payor Advisory Board, and other HCDMs including insurance carrier leaders, employer leaders, government representatives, evaluators, health system administrators, and clinical leaders. Please see Appendices A-C for language used to solicit and engage participants.

Ethical Considerations

HCDMs participated on a voluntary basis and were not compensated. Participants were informed that their feedback and insight was being collected for a study. The data were collected under the Chatham House Rule whereby neither the identity nor the affiliation of the participants were captured nor reported. Accordingly, study participants were subject to minimal risk that was no more than usual compared to their daily work, thus we did not seek institutional board review approval.

Research Instruments

The survey, workshop guide, and interview guide were developed by the authors along with input from DTA staff that was validated from a few initial HCDMs. SurveyMonkey, Miro Boards, and Google Docs were used to collect qualitative data. Please see Appendix D for a list of questions provided by DTA, which helped contextualize development of the survey and the guides.

Administration of the Instrument

Surveys were sent out to targeted HCDMs by DTA staff prior to their participation in a workshop. Three one-hour workshops were administered through Zoom by the authors. HCDMs participants were divided into 3 to 4 groups depending on the number of participants with an internal staff member as lead and a DTA staff as notetaker. Interviews were conducted with select HCDMs that indicated an interest to provide more feedback after workshops.

Surveys, workshops, and interviews were organized by the authors and DTA staff. Qualitative data were collected by the authors and DTA staff. Only the authors codified, analyzed, and synthesized the data. Please see resources E-G for surveys and workshop guides. All instruments were administered in Summer 2021, and specific workshop dates are referenced in the invitations demonstrated in Appendices A-C. Templates for surveys and workshop processes are available in Appendices D-G.

Data Analysis

Qualitative methods

In order to ensure completeness and logical consistency of responses, one of the authors consolidated notes from all data collectors and combined them into a single document and duplicates were removed. The data were then coded and subdivided into themes, subthemes, improvement identifications, and sentiment ratings. The response coding that was used for analysis included 1) whether it recommended an improvement to the Guide or not, 2) its sentiment on a 5-point likert scale with 5 being the most positive sentiment, and 3) a nominal tag summarizing the main point of the response.

A second author then performed their own independent coding of the data in the same manner. The third author then reviewed the coding from the first and second author for coding discrepancies. Any coding discrepancies were openly discussed between the three authors until they reached consensus on a final coding determination.

After coding responses for each feedback session, the responses that recommended specific improvements to the Guide were shared with the DTA team. The DTA team then indicated which responses they incorporated into the next iteration of the guide. We quantified the number and percentage of responses suggesting improvement to the Guide that were incorporated by the DTA team into the next iteration of the guide.

Quantitative methods

We then summarized the responses including counts, sentiment ratings, and averages at the session and aggregate levels. An Analysis of Variance (ANOVA) followed by a Tukey honestly significant difference (HSD) test for multiple comparisons was used to evaluate for significant differences in sentiment ratings between workshops 1, 2, or 3. We compared the Tukey HSDs and Q-statistics at the 0.05 level of significance for the p-value. The descriptive statistics summary data can be seen in Appendices I-N.

Data Availability

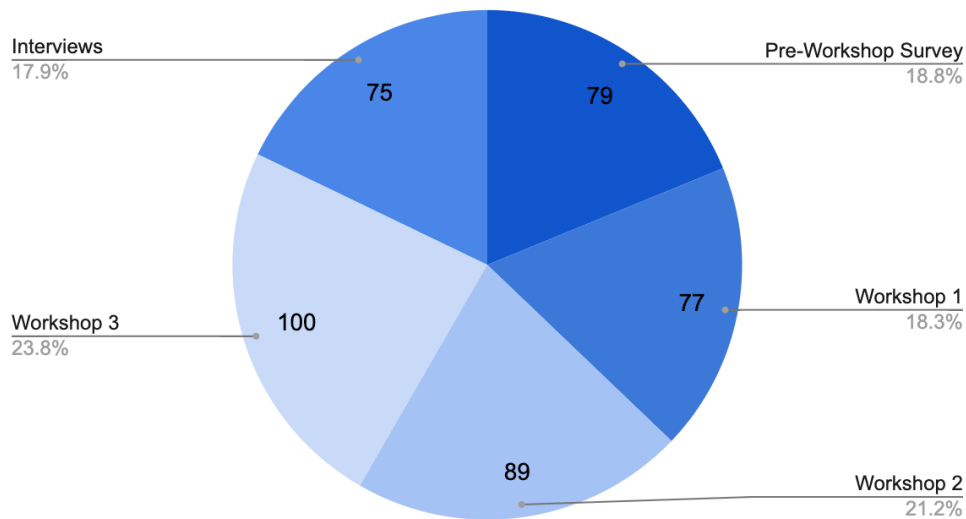
A sample of raw data generated during this study are included in this published article in Appendix H. Appendices I-N include detailed summary data.

Results

A total of 30 HCDMs provided feedback through the pre-workshop survey, 97 HCDMs provided feedback across the three workshops, and 8 H HCDMs provided feedback during the interviews. The first workshop had 26 participants and included HCDMs at US-based health systems and community providers who decide on prescribing and utilizing drugs and devices. The second workshop had 16 participants and focused on US HCDMs at health insurance plans (carriers), PBMs, self-insured employers, and brokers that advise employers on benefits (including private and public entities). The third workshop had 55 participants and included DTA member organization representatives.

Across the survey, workshops, and interviews, there were 420 discrete pieces of feedback or responses collected from individuals that were willing to participate. (Figure 2) Pieces of feedback included responses to survey questions and discrete comments captured during workshops or interviews.

Figure 2. Total Responses by Research Instrument (n=420)



The majority (60%) of the feedback recommended an improvement to the Guide. (Table 1) DTA used just over half (55%) of that feedback to improve the next iteration of the guide. Of the feedback that was not incorporated by DTA, the majority of it did not align with the intended purpose of the guide.

The average sentiment among all responses was 3.1, suggesting a mildly favorable reaction by HCDMs toward the Guide. The average sentiment among responses recommending an improvement to the Guide was slightly lower at 2.9, but still mildly favorable.

Table 1: Improvement Recommendations and Sentiment Ratings

	Count (%)
Total responses	420
Responses recommending an improvement to the Guide	252 (60%)
Responses recommending an improvement to the Guide that DTA incorporated into the next iteration of the Guide	138 (55%)
Average sentiment among all responses	3.1
Average sentiment among responses recommending an improvement to the Guide	2.9

The average sentiment from the workshops was 3.2 and using the Tukey HSD test for multiple comparisons, there were no significant differences in sentiment ratings between workshops 1, 2, or 3 with Tukey’s HSDs (and Q-values and p-values) between workshops 1 and 2, 1 and 3, and 2 and 3 being 0.09 (Q=1.09, p=0.94), 0.29 (Q=3.30, p=0.14), and 0.19 (Q=2.21, p=0.52), respectively.

Table 2. Average Sentiment for Each Workshop

Workshop	Average Sentiment
Workshop 1	3.3
Workshop 2	3.2

Workshop 3	3.0
Total	3.2

The most common tag among responses that did not recommend an improvement to the Guide was for “High-Quality Content.” The most common tag among responses that recommend an improvement to the Guide as well as responses that recommended an improvement and DTA took action on included “Clarify a specific section.” “Need to reorder or modify content” was the most common tag amongst feedback that indicated improvement was needed but DTA did not take action on that feedback.

Table 3: Most Common Content Tags

Designation	Tag
Most common tag among responses that did not recommend an improvement to the Guide	High Quality Content
Most common tag among responses that did recommend an improvement to the Guide	Clarify a specific section
Most common tag among responses that did recommend an improvement to the Guide that DTA incorporated into the next iteration of the Guide	Clarify a specific section
Most common tag among responses that did recommend an improvement to the Guide but DTA did not incorporate into the next iteration of the Guide	Need to reorder or modify content

Discussion

This work generally achieved the primary aim of determining the Guide's usefulness. HCDMs had a moderately favorable reaction to the guide based on the average sentiment among all responses. The majority of the feedback obtained recommended an improvement to the Guide. And the moderately favorable rating remained stable throughout the feedback process across all three workshops. Taken together, these findings suggest that the initial draft of the Guide was generally well-designed and subsequent versions of the Guide did not worsen its quality.

According to HCDMs, the major strength of the Guide was its high quality content. The feedback from HCDMs that most influenced subsequent versions of the guide was clarification of content. Conversely, the most common feedback from HCDMs that did not get incorporated into subsequent iterations of the Guide was to change the order and organization of the Guide. Despite not making major changes to the order and organization of the Guide, DTA incorporated more than half of the improvement suggestions which reflects a successful iterative feedback process. Other themes for improvement which DTA took action on included providing an application and expanding scope. With at least 97 participating HCDMs, the feedback process had some robustness and may be generalizable to other HCDMs at US-based health systems,

community providers, health insurance plans (carriers), PBMs, self-insured employers, and brokers.

In addition to achieving the primary aim of this study, we believe we also achieved our secondary aim of transparently characterizing the development process of the Guide. The process was summarized into five phases. The three types of feedback mechanisms, pre-meeting survey, workshop, and interview, enabled diverse feedback to be gathered. Pre-meeting surveys had the benefit of anonymity. Workshops had the benefit of live and interactive discussion which enabled rich discussion and debate on feedback topics from diverse stakeholders. Interviews had the benefit of deep discussion into specific comments.

Each of the five phases contributed evenly with approximately 1/5th of the comments being generated from each phase and workshops, which comprised 60% of the sessions, contributed 63.3% of the comments. So, no individual phase seemed to overly bias Guide development. In addition to the results section where we characterized feedback findings from each phase, the Appendices provide detailed examples of the language used to solicit and engage participants, raw data with tags and coding, and descriptive statistics summaries.

DTA developed three final versions of the guide: one abridged version that is publicly available (Public Version 1), one non-fillable full version for DTA members and one fillable full version which removes introductions and appendices for DTA members. [12] Of note, DTA intends to continue iterating on the guide after this study and may develop subsequent public versions.

Despite achieving the two aims of the study, it did have some limitations. First, the approach to gathering feedback may have biased the data that was collected. Even though we tried to begin feedback collection with open-ended questions, the types of questions that we asked may have biased the respondents. Additionally, the varying levels of familiarity among respondents with the Guide may have affected their responses. Some respondents had thoroughly reviewed the Guide prior to participating in a feedback session while others may have only skimmed it. Another limitation is the possible lack of generalizability of the Guide beyond HCDMs with preexisting knowledge of DTx. Most respondents had some degree of familiarity with DTx. So it is unclear how useful the Guide will be for HCDMs that are new to DTx. Additionally, the study was not designed nor powered to identify guide usefulness by HCDM sector. Further research could help in clarifying guide usefulness by HCDM type. This study was also limited in that it focused on US based HCDMs. Further research would be helpful in identifying how generalizable the findings are to HCDMs beyond the US. Finally, the sampling frame lacked important HCDMs within the US, namely leaders in the Medicaid space. While outreach was made to recruit them to participate, no State Medicaid leaders participated in the study.

Conclusion

DTx holds promise to scalably, safely, and equitably improve health outcomes by removing barriers to accessibility and by offering novel mechanisms of action to prevent, manage, and treat chronic conditions. With the development of the Guide, DTA has attempted to overcome major impediments to broader adoption of DTx including lack of standardization of coding, coverage, and reimbursement as well as lack of standardized ways to discuss and assess outcomes from the use of DTx. This mixed-methods study found that the Guide was generally well-designed with high quality content and iteratively improved from feedback from a robust albeit not fully representative group of HCDMs. The process for the Guide development was made transparent with the characterization of the five phases of Guide development including a summary of findings from each phase. More research is needed to address some of the

limitations of this study as well as to understand adoption and utility of the Guide after it is publicly launched.

Acknowledgements

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Conflicts of Interest

All of Dr. Ostrovsky's investments can be found at socialinnovationventures.co. Funding for this project was provided by the Digital Therapeutic Alliance.

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Appendix A: Distribution Email Template

Dear DTA Members & Healthcare Decision Makers,

The Digital Therapeutics Alliance (DTA) is developing a 'DTx Value Assessment & Implementation Guide' to provide healthcare decision makers (HCDM) with a framework to evaluate the value and enable the implementation of digital therapeutics (DTx) in clinical practice.

This Guide is in draft form and represents a starting point to enable greater consistency in the ways that HCDMs understand DTx products, evaluate their use in real-world settings, and integrate these products into health ecosystems.

We are inviting HCDMs and DTA members to participate in this targeted comment period, which includes [an initial 3-question response](#) plus potential engagement in a one-hour workshop to be hosted July 12 or 19. *The URL to access the Guide is provided within the survey.*

During this comment period, we are seeking feedback on the Guide's content, format, and overall usefulness. Following this initial phase, the Guide will undergo a final round of revisions and design before it is released publicly. Since this Guide is still under development, we are limiting its distribution to DTA member companies and HCDMs.

We invite you to share this email and survey link with your HCDM colleagues, but please do not post this externally.

Thank you for participating in this process! Please reach out to valueframework@dtxalliance.org with any questions.

Sincerely,
Megan

Appendix B: Targeted Outreach

Version 1:

Dear _____,

DTA is launching a targeted feedback period for healthcare decision makers related to their '*DTx Value Assessment & Integration Guide*.' This draft Guide is intended to enable greater consistency in the ways that HCDMs understand DTx products, evaluate their use in real-world settings, and integrate them into health ecosystems. Since no consistent frameworks currently exist for the assessment and implementation of DTx products in practice, this Guide is an important first step.

Given your members' major role in assessing DTx products and providing patients with appropriate access to this category of medicine, your insights and feedback at both the staff and member levels will provide critical information to ensure that this Guide meets HCDM needs across numerous settings and regions. As DTA works to evolve the content and structure of this draft Guide, the next steps of this process include sending HCDMs a [short survey](#) (*the URL to access the Guide is provided within the survey*), in addition to inviting key leaders to a one-hour workshop hosted on July 12 or 19.

Please reach out to the DTA team at valueframework@dtxalliance.org if you have time for a 30-minute call before next Tuesday. They would appreciate providing more insight on their goals and seeing how they can best engage with your team and select members.

Since this Guide is still in draft form, they are not publicly sharing the Guide's URL, but for your background reference, here is the [Guide's current version](#). We look forward to hearing from you and appreciate your input!

Sincerely,
NAME

Version 2:

Dear _____,

Thank you for sharing the below information with members who may be interested in shaping this foundational DTx evaluation framework:

"The Digital Therapeutics Alliance (DTA) is developing a '*DTx Value Assessment & Integration Guide*' to provide healthcare decision makers (HCDM) with a framework to more consistently evaluate the value and enable the implementation of digital therapeutics (DTx) in clinical practice.

During this target comment period (June-August), DTA is inviting payors and clinicians to provide feedback on the Guide's content, format, and overall usefulness by either:

1. Participating in a one-hour workshop to be hosted July 12 at 3pm ET (*systems and individuals who assess and implement DTx products*) OR July 19 at 3pm ET (*plans, PBMs, self-insured employers, and brokers responsible for designing coverage frameworks*). Please reach out to valueframework@dtxalliance.org to register for

either of these workshops.

2. Providing feedback via [an initial 3-question response](#). *The URL to access this Guide is provided within the survey.*

Thank you for participating in this process!

Please let us know if there is anything we can do to help further facilitate this process.

Sincerely,
NAME

Appendix C: Day of Workshop Reminder

Dear Workshop Participants,

We look forward to meeting with you today to discuss how we can develop and provide healthcare decision makers with a meaningful, usable framework to evaluate the value of and enable the implementation of digital therapeutics in clinical practice.

While it would be helpful for you to take a quick look at this '[DTx Value Assessment & Integration Guide](#)' in advance of our meeting, please don't feel pressured to do a deep dive into each section. Since this Guide is currently in draft form, it represents a starting point for our discussion today.

During our meeting, we will provide a short overview of the Guide's intent and then will break into two cohorts to discuss key aspects of this Guide related to its content, format, and real-world usability. Our time will wrap up with a joint group discussion of key lessons and outcomes.

Please let us know if you have any questions in advance of today's meeting.

Sincerely,
NAME

Appendix D: Contextualizing Questions Provided by DTA

1. What does security look like for digital therapeutics?
2. What does privacy look like?
3. What are the regulatory pathways that may exist?
4. How can digital therapeutics be evaluated from a health economics perspective?
5. What are the best ways for clinical studies to be done and/or evaluated by different entities?

Appendix E: Survey Questions

What is your first impression of this guide?

What 2-3 areas of the Guide are/will be of greatest value to you?

What 2-3 areas of the Guide need to be improved?

Appendix F: HCDM Workshop Guide

Workshop Agenda

- 1 hour total
- 15 min - Intro & going over guide (Megan + Andrey)
 - 1-liner intros verbally
- 5 min - Explaining breakout groups (Esther and Alexis to do zoom breakout group assignments)
 - Explain volunteers for reporting back
- 20 min - Breakout sessions
 - ***Be sure to reiterate that a volunteer will need to report key findings***
 - Group 1: Esther & Megan, Hannah take notes (Esther lead questions, Megan SME)
 - Group 2: Brian & Emilie, Jessica take notes (Brian lead q's, Emilie SME)
 - Andrey: 443-857-8199/slack extra set of hands
- 5 min - Transition/break (Alexis facilitate)
- 15 min - Reflections (Esther)
 - Brian to take notes

Workshop questions

Main Questions:

Divide into breakout rooms. In each group, we should have a lead and someone taking notes.

1. What did you like about the guide? What was most useful?
2. What would you change about the guide?
Please consider which sections are well standardized or need to be standardized to be useful contributions to your current processes
 - a. General Requirements & Intended Use
 - b. Regulatory & Security
 - c. Clinical Impact, Safety, & Effectiveness
 - d. Economic Assessment
 - e. Implementing Digital Therapeutics in Practice
3. How would you go about implementing the guide in your organization?
 - a. *What aspects would you implement? What would this actually look like for you?*
 - b. *What would be the most beneficial format for you to use the guide?*
 - c. *What's the usability and implementation ability?*
4. What would you add to the guide?
 - a. *Optional: Would it be more effective to overlay an evaluation framework over this whole guide, to create a series of evaluation frameworks that correlate to each topic, or to do a mix of the two? Why?*
5. What challenges do you anticipate in using the guide in your organization?
6. How would you know if using the guide was working for your organization?
7. What questions do you have about the guide?

In Reflection:

1. Share out each groups' key findings
2. Identify and discuss any discrepancies between different groups' findings

3. Summarize commonalities among breakout groups
4. Where in the DTx evaluation and implementation process would you use this guide?
5. How do you imagine using this guide in future DTx process? As a reference, for context, or both?

Appendix G: DTA Member Workshop Guide

Workshop Agenda

1 hour total

- 15 min - Intro & going over guide (Megan + Andrey)
- 5 min - Explaining breakout groups (Alexis to do zoom breakout group assignments)
- 30 min - Breakout sessions
 - Group 1: Esther & Megan (Alexis/Emilie)
 - Group 2: Andrey (Jessica/Hannah)
- 5/10 min - Pull both groups together for a final wrap up (Andrey to lead)

Workshop questions

Main Questions:

Divide into breakout rooms, with a lead and note taker.

- What seems to have worked in the sales motions or business development processes in getting manufacturer customers to actually consume digital therapeutics?
 - a. Do you feel these concepts are represented in the guide?
 - b. If not, what might it look like to incorporate these logics into the guide?
- While this Guide is comprehensive in nature, in some cases it may not provide a deep dive into the full clinical and economic evidence review processes that payors may need to undertake. Therefore, are there other resources that could be added to or referenced in the Guide that will enable HCDMs to see this as a singular, fully comprehensive evaluation tool?
- What type of scoring/classification system(s) will be of value to health systems and DTx companies? (*from highest to most detailed levels*)
 - Overall evaluation tool for digital health products to determine whether they meet the definition of a DTx
 - First glance 5-10 question survey at beginning of Guide for HCDMs to determine whether it makes sense to move forward with conducting a deeper product review
 - Clinical evidence evaluation tool to better call out products with stronger levels of scientific rigor
 - Economic comparison of DTx products to comparable medications or other therapies
 - Comprehensive scoring mechanism at end of Guide that enables health systems to assign their own final prioritizations to determine whether/how to move forward with a particular DTx product
 - Other...?
- Willingness for DTA members to complete these profiles and submit them to HCDMs?

- How do we eliminate a sense of bias if members fill this out and directly submit to HCDMs?
- What is the most effective form for the guide's distribution (ex: long form PDF, digital interactive formats, a checklist with appendices people can follow up on, etc)?

Parking lot:

- If we break this Guide down into different “volumes,” should the divisions be based on:
 - a. *Target population*: clinicians vs. payors
 - b. *Review phase*: Product evaluation phase vs. implementation phase
 - c. *DTx product type*: Rx vs. non-Rx products
 - d. *Content type*: Educational background materials vs. evaluation materials
 - e. Other?
- If we create a case study to help payors walk through this with a real-world example, what type of format should we consider developing:
 - a. A mock DTx product in a made-up disease state?
 - b. A series of relevant member company products referenced throughout the Guide where appropriate?
 - c. Site-specific examples (e.g., employer, health system)
 - d. Other?
- Should there be more of an emphasis on the scientific foundation as part of the guide?
 - a. Related to HEOR question
 - 1. More science = consumed more easily

Appendix H: Sample Raw Data (from Workshop 2)

DTA Implementation (0 Not applied, 1 applied)	0	1
Question it responded to	How would you know if using the guide was working for your organization?	What challenges do you anticipate in using the guide in your organization?
Content of feedback	Helps understand the tolerance for partnerships	guide is very long. A lot of these companies are very young though and this kind of rigorous testing is necessary when sharing PHI with another company. It would be nice if the product companies filled out the guide, but their answers would be biased.
Theme	What Success Looks Like	Formatting and Usability
Sub-Theme	Success relates to partnerships	Length makes it difficult for young companies. Product companies filling it out could be useful.
No change (0) / Improve (1)	0	1
Sentiment rating (1-5/5)	4	2

Tag 1	Serves education function	Tailor to end user
Tag 2		product company role
Tag 3		too long
Tag 4		
Source	WS 2	WS 2
Type of healthcare leader	N/A	N/A
Tags	Needs rubric or scoring framework	Needs glossary

Appendix I: Pre-Workshop Survey Results

Question	What 2-3 areas of the Guide are/will be of greatest value to you?	What 2-3 areas of the Guide need to be improved?	What is your first impression of this Guide?	Pre-Workshop Survey Totals
Responses	28	22	29	79
Improve?	2	0	29	31
Improve %	7%	0%	100%	39%
DTA 1	4	15	9	28
DTA 1 and Improve	0	0	9	9
DTA 1 and Improve %	0%	0%	31%	29%
Avg Sentiment	4.1	3.6	3.3	3.7
Avg Sentiment amongst improve=1	2.5	N/A	3.3	3.3
Top tag(s) amongst improve=0	Good comprehensiveness	High quality content	N/A	High quality content
Top tag(s) amongst improve=1	Overly detail	N/A	Need to reorder or modify content	Need to reorder or modify content

Top tag(s) amongst improve=1 AND DTA=0	Overly detail	N/A	Need to reorder or modify content	Need to reorder or modify content
Top tag(s) amongst improve=1 AND DTA=1	N/A	N/A	Clarify a specific section	Clarify a specific section

Appendix J: Workshop 1 Results

Question	What did you like about the guide? What was most useful?	What would you change about the guide?	How would you go about implementing the guide in your organization?	What challenges do you anticipate in using the guide in your organization?	How would you know if using the guide was working for your organization?	What questions do you have about the guide?	What would you add to the guide?	Workshop 1 Totals
Responses	20	18	14	8	7	9	1	77
Improve?	2	17	6	6	5	7	1	44
Improve %	10%	94%	43%	75%	71%	78%	100%	57%
DTA 1	8	7	4	5	2	3	1	30
DTA 1 and Improve	0	7	2	4	2	3	1	19
DTA 1 and Improve %	0%	41%	33%	67%	40%	43%	100%	43%
Avg Sentiment	4.1	2.9	3.3	2.8	2.9	3.0	3.0	3.3
Avg Sentiment amongst improve=1	3.0	2.9	3.0	2.7	2.6	2.9	3.0	2.9

Top tag(s) amongst improve=0	Content is accessible	Helpful with evaluation	Tailor to end user	Needs application	Content is accessible; DTA Role; High Quality Content	Content is accessible; needs application	N/A	Content is accessible
Top tag(s) amongst improve=1	expand scope	Tailor to end user	Need to reorder or modify content	Needs application	Need to reorder or modify content	Need to reorder or modify content	Content is accessible	Need to reorder or modify content
Top tag(s) amongst improve=1 AND DTA=0	expand scope	Tailor to end user	Need to reorder or modify content	needs standardization; overwhelming	Needs application; Need to reorder or modify content	Need to reorder or modify content	N/A	Need to reorder or modify content
Top tag(s) amongst improve=1 AND DTA=1	N/A	Needs application	Needs rubric or scoring framework; Needs to address payment	Needs application	Needs rubric or scoring framework	Need to reorder or modify content	Content is accessible; Needs application	Need to reorder or modify content; Needs application

Appendix K: Workshop 2 Results

Question	How would you go about implementing the guide in your organization?	How would you know if using the guide was working for your organization?	What challenges do you anticipate in using the guide in your organization?	What did you like about the guide? What was most useful?	What would you add to the guide?	What would you change about the guide?	Workshop 2 Totals
Responses	17	5	16	11	21	19	89
Improve?	6	1	12	5	21	19	64
Improve %	35%	20%	75%	45%	100%	100%	72%
DTA 1	7	0	8	5	18	10	48

DTA 1 and Improve	4	0	5	2	18	10	39
DTA 1 and Improve %	67%	0%	42%	40%	86%	53%	61%
Avg Sentiment	3.8	3.6	2.7	4.1	3.0	2.7	3.2
Avg Sentiment amongst improve=1	3.2	3.0	2.4	3.2	3.0	2.7	2.8
Top tag(s) amongst improve=0	Content is accessible	emphasis on sustained use	product company role	Helpful starting place	N/A	N/A	Helpful starting place
Top tag(s) amongst improve=1	Tailor to end user	Need to reorder or modify content	need to modify format	needs application	expand scope	Clarify a specific section; Needs application	expand scope
Top tag(s) amongst improve=1 AND DTA=0	Stakeholder role; Tailor to end user; needs application	Need to reorder or modify content; too long; customizable	need to modify format	Helpful starting place	Clarify a specific section; Clinical effectiveness; Offer case studies; Need to reorder or modify content; needs application	Clarify a specific section	needs application
Top tag(s) amongst improve=1 AND DTA=1	Checklist format is useful; expand scope; product company role; Redundant; Tailor to end user	N/A	expand scope	Needs application	expand scope	expand scope; Product company role	expand scope

Appendix L: Workshop 3 Results

Question	Other questions comments concerns?	What is the most effective form for the guide's distribution (ex: long form PDF digital interactive formats a checklist with appendices people can follow up on etc)?	What is the willingness for DTA members to complete these profiles and submit them to HCDM's?	What seems to have worked in the sales motions or business development processes in getting manufacturer's customers to actually consume digital therapeutics?	What type of scoring/classification system(s) will be of value to health systems and DTx companies (from highest to most detailed levels)?	While this Guide is comprehensive in nature in some cases it may not provide a deep dive into the full clinical and economic evidence review processes that payors may need to undertake. Are there other resources that could be added to or referenced in the Guide that will enable HCDMs to see this as a singular fully comprehensive evaluation tool?	Workshop 3 Totals
Responses	5	17	14	33	19	12	100
Improve?	4	14	7	29	15	8	77
Improve %	80%	82%	50%	88%	79%	67%	77%
DTA 1	2	1	8	24	16	7	58
DTA 1 and Improve	2	0	3	21	13	4	43
DTA 1 and Improve %	50%	0%	43%	72%	87%	50%	56%
Avg Sentiment	3.8	3.3	3.6	2.8	2.7	2.6	3.0
Avg Sentiment amongs	3.5	3.2	3.1	2.8	2.4	2.4	2.8

Top tag(s) amongst improve=1							
Top tag(s) amongst improve=0	Good comprehensiveness	need to modify format	Context for use	Context for use	Tailor to end user	Feedback on samples/Data	Context for use
Top tag(s) amongst improve=1	Clarify a specific section	need to modify format	Context for use	Clarify a specific section	Not a useful tool at this time	Content gap	Clarify a specific section
Top tag(s) amongst improve=1 AND DTA=0	Clarify a specific section; implementation?	need to modify format	Context for use	Context for use	Clarify a specific section	Clarify a specific section; Content gap	need to modify format
Top tag(s) amongst improve=1 AND DTA=1	Clarify a specific section	N/A	Context for use	Clarify a specific section	Not a useful tool at this time	Feedback on samples/Data	Clarify a specific section

Appendix M: Interview Results

Theme	Formatting and Usability	Scope	Social Contexts	Target Audiences and Uses	What Success Looks Like	Interview Totals
Responses	12	25	12	19	7	75
Improve?	10	18	2	5	1	36
Improve %	83%	72%	17%	26%	14%	48%
DTA 1	8	18	6	11	6	49
DTA 1 and Improve	7	15	1	4	1	28
DTA 1 and Improve %	70%	83%	50%	80%	100%	78%
Avg Sentiment	2.7	2.4	2.3	2.2	2.2	2.3
Avg Sentiment amongst improve=1	2.6	2.6	3.5	3.0	2.0	2.7

Top tag(s) amongst improve=0	needs application; Tailor to end user	Tailor to end user	Helpful starting place; needs standardization; Stakeholder role	Tailor to end user	Helpful with evaluation	Tailor to end user; Needs application
Top tag(s) amongst improve=1	Need to reorder or modify content	Clarify a specific section	Clarify a specific section; Need to reorder or modify content	Clarify a specific section	Clarify a specific section	Clarify a specific section
Top tag(s) amongst improve=1 AND DTA=0	Overly detail	expand scope; Need to reorder or modify content; needs standardization	Need to reorder or modify content	Needs rubric or scoring framework	N/A	Need to reorder or modify content
Top tag(s) amongst improve=1 AND DTA=1	Need to reorder or modify content	Clarify a specific section	Clarify a specific section	Clarify a specific section	Clarify a specific section	Clarify a specific section

Appendix N: Results Breakdown

Table 1. Breakdown Pre-Workshop Survey Responses

Question	Responses
What 2-3 areas of the Guide are/will be of greatest value to you?	28
What 2-3 areas of the Guide need to be improved?	22
What is your first impression of this Guide?	29
Pre-Workshop Survey Totals	79

Table 2. Breakdown of Workshop 1 Responses

Question	Responses
What did you like about the guide? What was most useful?	20
What would you change about the guide?	18
How would you go about implementing the guide in your organization?	14
What challenges do you anticipate in using the guide in your organization?	8
How would you know if using the guide was working for your organization?	7
What questions do you have about the guide?	9
What would you add to the guide?	1
Workshop 1 Totals	77

Table 3. Breakdown of Workshop 2 Responses

Question	Responses
How would you go about implementing the guide in your organization?	17
How would you know if using the guide was working for your organization?	5
What challenges do you anticipate in using the guide in your organization?	16
What did you like about the guide? What was most useful?	11
What would you add to the guide?	21
What would you change about the guide?	19
Workshop 2 Totals	89

Table 4. Breakdown of Workshop 3 Responses

Question	Responses
Other questions comments concerns?	5
What is the most effective form for the guide's distribution?	17
What is the willingness for DTA members to complete these profiles and submit them to HCDM's?	14
What seems to have worked in the sales motions or business development processes?	33
What type of scoring/classification system(s) will be of value?	19
Are there other resources that could be added to or referenced in the Guide?	12
Workshop 3 Totals	100

Table 5. Breakdown of Interview Responses

Theme	Responses
Formatting and Usability	12
Scope	25
Social Contexts	12
Target Audiences and Uses	19
What Success Looks Like	7
Interview Totals	75

Table 6. Summary of Survey Results

	Top tag(s) amongst improvements	Top tag(s) amongst improvements and DTA took action
Pre-Workshop Survey	Clarify a specific section	Need to reorder or modify content
Workshop 1	Need to reorder or modify content; Needs application	Need to reorder or modify content
Workshop 2	expand scope	needs application
Workshop 3	Clarify a specific section	need to modify format
Interview	Clarify a specific section	Need to reorder or modify content

Table 7. Summary of Pre-Workshop Survey Results

Question	Top tag(s) amongst improvements	Top tag(s) amongst improvements and DTA took action
What 2-3 areas of the Guide are/will be of greatest value to you?	N/A	Overly detail
What 2-3 areas of the Guide need to be improved?	N/A	N/A
What is your first impression of this Guide?	Clarify a specific section	Need to reorder or modify content
Pre-Workshop Survey Totals	Clarify a specific section	Need to reorder or modify content

Table 8. Summary of Workshop 1 Results

Question	Top tag(s) amongst improvements	Top tag(s) amongst improvements and DTA took action
What did you like about the guide? What was most useful?	N/A	expand scope
What would you change about the guide?	Needs application	Tailor to end user
How would you go about implementing the guide in your organization?	Needs rubric or scoring framework; Needs to address payment	Need to reorder or modify content
What challenges do you anticipate in using the guide in your organization?	Needs application	needs standardization; overwhelming
How would you know if using the guide was working for your organization?	Needs rubric or scoring framework	Needs application; Need to reorder or modify content
What questions do you have about the guide?	Need to reorder or modify content	Need to reorder or modify content
What would you add to the guide?	Content is accessible; Needs application	N/A
Workshop 1 Totals	Need to reorder or modify content; Needs application	Need to reorder or modify content

Table 9. Summary of Workshop 2 Results

Question	Top tag(s) amongst improvements	Top tag(s) amongst improvements and DTA took action
Other questions comments concerns?	Clarify a specific section	Clarify a specific section; implementation?
What is the most effective form for the guide's distribution?	N/A	need to modify format
What is the willingness for DTA members to complete these profiles and submit them to HCDM's?	Context for use	Context for use
What seems to have worked in the sales motions or business development processes?	Clarify a specific section	Context for use
What type of scoring/classification system(s) will be of value?	Not a useful tool at this time	Clarify a specific section
Are there other resources that could be added to or referenced in the Guide?	Feedback on samples/Data	Clarify a specific section; Content gap
Workshop 3 Totals	Clarify a specific section	need to modify format

Table 10. Summary of Workshop 3 Results

Question	Top tag(s) amongst improvements	Top tag(s) amongst improvements and DTA took action
Other questions comments concerns?	Clarify a specific section	Clarify a specific section; implementation?
What is the most effective form for the guide's distribution?	N/A	need to modify format
What is the willingness for DTA members to complete these profiles and submit them to HCDM's?	Context for use	Context for use
What seems to have worked in the sales motions or business development processes?	Clarify a specific section	Context for use
What type of scoring/classification system(s) will be of value?	Not a useful tool at this time	Clarify a specific section
Are there other resources that could be added to or referenced in the Guide?	Feedback on samples/Data	Clarify a specific section; Content gap
Workshop 3 Totals	Clarify a specific section	need to modify format

Table 11. Summary of Interview Results

Theme	Top tag(s) amongst improvements	Top tag(s) amongst improvements and DTA took action
Formatting and Usability	Need to reorder or modify content	Overly detail
Scope	Clarify a specific section	expand scope; Need to reorder or modify content; needs standardization
Social Contexts	Clarify a specific section	Need to reorder or modify content
Target Audiences and Uses	Clarify a specific section	Needs rubric or scoring framework
What Success Looks Like	Clarify a specific section	N/A
Interview Totals	Clarify a specific section	Need to reorder or modify content