MDD Advisory Group Meeting
February 16, 2022
1:00-2:00 pm
Meeting Summary

Attendees

Nathaniel Counts, Mental Health America
Rahul Dhanda, Ph.D., Neurocrine Biosciences, Inc.
Andrew Smith, Depression Bipolar Support Alliance (DBSA)
Patrick Gillard, PharmD, AbbVie
Michael Grabner, Ph.D., HealthCore
Raquel Halfond, Ph.D., American Psychological Association
Mohannad Kusti, M.D., M.P.H., Pivot Onsite Innovations
Debra Lerner, MSc, Ph.D., Tufts Clinical and Translational Science Institute, Tufts Medical Center
Andrew Lyzenga, American Psychiatric Association
Karen Moseley, Health Enhancement Research Organization (HERO)
Cheryl Neslusan, Ph.D. , Janssen Scientific Affairs,
Kevin Ronneberg, MD, HealthPartners
Andrew Smith, Depression and BiPolar Support Alliance
Elizabeth Stafford, NAMI
Becky Yowell, American Psychiatric Association

IVI Staff and Partners
Rick Chapman, IVI
Jennifer Bright, IVI
Richard Xie, IVI
Erica deFur Malik, IVI
Tiffany Huth, IVI
Jordana Schmier, OPEN Health

Agenda
Summary of Comments Received
Discussion

- Target patient population
- List of scenarios when people with MDD switch treatments
- Time to response

Summary Comments Received
IVI received 17 submitted comments, representing multiple stakeholder perspectives including patients, clinicians, researchers, manufacturers, employers, and payers. Comments were constructive and many offered suggestions on potential data sources and partners, references to derive model inputs, and potential applications of the model. The comments suggested the need

for IVI to clarify our analytic approaches and highlighted the ongoing challenges to find appropriate data sources as model inputs. With the input from the AG discussion on February 16, our next steps would be to review the references shared through public comments, conduct additional targeted literature searches (beyond meta-analyses) to identify appropriate inputs or assumptions, and further revise our protocol.

General comments from the AG include:

- This is a very ambitious economic model. Some simplifying assumptions are probably needed to ensure that it is feasible within the model development time frame and provide useful insights to decision makers.
- The model needs to clearly document the data gaps and the assumptions made.
- Modeling a lifetime horizon might be especially challenging due to the lack of long-term evidence.
- While numerous evidence gaps have been noted, the model can shed light on prioritized areas for future research and data collection efforts.

In its initial review of the comments, IVI identified three areas in need of further discussion from the Advisory Group.

Target Patient Population

Multiple stakeholders commented on the target population for the model and inquired about how IVI intended to incorporate co-occurring health conditions for its target population. In particular, several comments referenced the significant proportion of people with MDD that were also diagnosed with substance use disorder (SUD). IVI asked the Advisory Group to comment on whether the target patient population should include those with SUD as a comorbid condition.

Comments from the AG include:

- Given its high prevalence, the AG suggest that those with SUD should not be excluded. However, AG members also noted the complexity in modeling the impacts of MDD treatments among this subgroup.
- One AG member expressed concern that there could be limited efficacy data for this subgroup, and the model should note the source of data inputs and uncertainties.

IVI's action step: IVI will examine the inclusion of MDD patients with SUD in key studies to inform model inputs, and may conduct additional literature searches before making a decision.

Treatment Switching

There were multiple comments asking for clarification about when a person might switch treatments in the model. IVI offered three scenarios and asked the AG for additional suggestions. The three scenarios when someone might switch in the MDD model include:

- Safety/adverse reactions, including side effects
- Lack of response after adequate treatments
- Per clinical guidelines, augmentation if "partial response"

The AG noted the additional reasons a person might switch treatments in the real-world context, including:

- Affordability of treatment
- Preferences for treatments
- Ability to access treatment

AG members also encouraged IVI to clearly describe the scenarios in which people with MDD will discontinue treatments entirely in the real world.

IVI's action step: In the final protocol, IVI will include the additional reasons that people with MDD will switch or discontinue treatments.

Time to Response

Several comments suggested that time to achieve response following treatment initiation is an important factor for the long-term outcomes for people with MDD. In the real world, there is a wide range of time (from 2 weeks to 8 weeks) window during which people achieve response. IVI sought feedback on whether early responder is an important indicator for long-term treatment outcomes, and how this should be explicitly modeled in the MDD model (e.g., the appropriate model cycle length). AG members provided the following input:

- Clinical guidelines by American Psychological Association and American Psychiatric Association included useful references to time to respond window.
- A shorter cycle might provide the flexibility to modeling patient heterogeneity in achieving response.
- The model will need to consider the appropriate dose timing and recommended duration of treatment.

IVI's action step: IVI will further review clinical guidelines, conduct additional targeted literature review on the association of early response with long-term efficacy, and work with our modeling partners to revise the model specifications as needed.

IVI will share potential use case research studies with the Advisory Group and ask for insight on prioritization, potential partnerships and other applications.