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## Key Dates

<b>Opening Date</b>	May 27, 2021
<b>Letter of Intent for Research Award Due</b>	July 15, 2021
<b>Notification to Proceed with Application</b>	August 16, 2021
<b>Research Award Application Due</b>	September 15, 2021
<b>Research Award Notification</b>	December 15, 2021

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## Research Awards

Value assessment in health care comprises a broad set of methods to synthesize and evaluate the relative benefits and costs of health care interventions. The goal of value assessment is to assist stakeholders, including patients, providers and payers, in making informed decisions to improve health and care efficiency. These assessments are conducted using varied methodological approaches to synthesize data from various sources to guide individual or population-level decisions. For greatest impact, these methods should offer opportunities to incorporate patient characteristics and their preferences to guide treatment decisions.

However, there are a number of limitations of the data sources, methodologies and measures applied in value assessment. For example, there is increased recognition that commonly used approaches of health fail to address patient-centric elements of value, equity considerations, and heterogeneity. Moreover, new approaches to address uncertainty are needed to address challenges in which data sources do not allow for complete capture of important patient-level information. **The PhRMA Foundation seeks proposals to identify and address challenges in research conducted to assess the value (clinical, humanistic, and economic) of medicines and health care services.**

Example topics may include, but are not limited to:

- Patient- and equity-centered frameworks for value assessment
- Selection and reporting of diverse study populations
- Collection and measurement of patient-centered outcomes
- Incorporation of patient-centered outcomes in value assessment
- Heterogeneity of patient preferences or outcomes
- Uncertainty in model parameters or structures
- Consider real-world data
- Value from different stakeholder perspectives
- Ethical considerations
- Development of decision tools
- Measurement and reporting of value elements
- Address measures of health equity

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## Application Process

**The Research Award application process has two stages.**

**Phase 1:** Candidates should submit letters of intent (LOIs) no later than July 15, 2021. LOIs will be reviewed for potential program fit, novelty, importance, rigor and clarity. Details can be found at <http://www.phrmafoundation.org/awards/value-assessment-initiative/research-awards-1/>.

**Phase 2:** Candidates who submit a Letter of Intent will be informed by August 16, 2021 whether they should submit a full application by September 15, 2021. Details of how to submit the application will be explained as well.

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## Letter of Intent Considerations

Evaluating the value of health care interventions is challenging. But, when designed well and used appropriately, tools that quantify the value of a health care treatment can inform decision-making for patients, providers and payers. There are several criteria to consider in developing solutions to drive high-quality value assessment.

**Bold and Novel Approaches** Research Awards are designed to push the envelope further on value assessment methods, such as “how value is derived,” “what influences value” and the “who is affected by value assessment.” Research Awards should reflect bold and innovative ideas to improve value assessment methods and related designs.

**Stakeholder Engagement** A vital step to a successful shift toward a value-driven health care system is ongoing engagement with stakeholders. It is particularly important to incorporate patient perspectives and acknowledging that all individuals are future recipients of health care and are driving factors of high-quality value assessment. Recommendations for patient engagement processes are made available by the National Health Council.<sup>i</sup>

**Real-World Applicability** All funded activities should generate resources, evidence or ideas that can be applied feasibly in the U.S. health care system. Variations in practice patterns or disparities in care (e.g., demographics, socioeconomic status and type of insurance) should also be acknowledged.

**Adherence to Best Practices** Proposed methodology should follow relevant, well-accepted recommendations, such as those published by the Agency for Health Care Research and Quality, International Society for Pharmacoeconomics and Outcomes Research, National Pharmaceutical Council Guiding Practices for Patient-Centered Value Assessment and Second Panel on Cost-Effectiveness in Health and Medicine.<sup>ii</sup>

**Review and Validation** Research activities should be subject to systematic ongoing validation to ensure that accurate, truthful, non-misleading and reproducible findings are generated. Results should not be disseminated until validated through expert review, with input provided by all relevant and qualified stakeholders. The process of review should be well-documented and accompany the dissemination of the results.

**Patient-Centered Decision-Making** Value assessment tools create opportunities to support patient-centered decision-making, if patients and other stakeholders are able to review and customize value information based on their own preferences. For example, the second panel on cost effectiveness in health and medicine recommends that all potential consequences of care should be presented in a transparent and disaggregated form, such as in an “impact inventory table.”<sup>iii</sup> Additionally, all criteria should be quantified and included in assessments, if possible.

**Addressing Uncertainty** Tools or frameworks that assess care value should adequately explain and address all sources of uncertainty (e.g. in parameter selection, decision process, measurement) and conduct and present relevant sensitivity and scenario analysis.

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## Letter of Intent and Application Components

This program is requesting that prospective candidates submit a letter of intent prior to the submission of an application. The letter of intent should include the following:

Letter of Intent Components - Due July 15, 2021

- Descriptive title of proposed paper/ project
- Applicant contact information and CV or biosketch
- Name(s) of other key personnel/collaborators and their CV or biosketch (if applicable)
- Name of affiliated or participating institutions (if applicable)
- Detailed project description, not to exceed 600 words
- Total estimated budget with justification

Candidates will be notified no later than August 16, 2021 regarding the decision of the review committee. The selected submissions will be given instructions to proceed to a full application. The deadline for the full submission is September 15, 2021.

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## Eligibility

Award opportunities are open to all individuals and organizations with specialization in health economics, outcomes research, clinical sciences, health care evaluation or related disciplines.

Eligible applicants should hold an advanced degree in a field of study logically or functionally related to the proposed activities, such as a PhD or equivalent. Interdisciplinary collaboration is highly encouraged.

At least one collaborator must also have a firm commitment from an accredited U.S. university or research organization.

The PhRMA Foundation wants to broaden our reach to expand the efforts in this focus area of using new approaches to capture and assess what is important to patients. The Value Assessment Initiative encourages new researchers to apply for funding. Researchers and collaborators who have received a Value Assessment award or project funding from the PhRMA Foundation in 2020 or 2021 are not eligible to apply.

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## Award Expectations

The PhRMA Foundation is committed to driving real change in health care delivery and recognizes the benefit of shared knowledge. Therefore, the Foundation has established a Value Assessment Research Network to encourage collaboration and dissemination of findings borne out of the program. All award recipients will become members of the Network and be asked to participate in periodic calls, in-person meetings, or presentations

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## Funding

Awards will be available of varying levels up to \$100,000 for a one-year period beginning January 2022. Level of funding will depend on the scope of proposed activities. Candidates should consult the PhRMA Foundation for guidance or questions. The PhRMA Foundation will not support evaluation of specific health care interventions.

Payments are made on a quarterly basis to the institution. A maximum of twenty-percent (20%) of the award may be used for fringe benefits and/or indirect institutional costs.

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### References

- i. National Health Council, Patient Engagement. Available at: <http://www.nationalhealthcouncil.org/public-policy/patient-engagement>
- ii. Agency for Health care Research and Quality (AHRQ) Guidance for the Conduct and Reporting of Modeling and Simulation Studies in the Context of Health Technology Assessment. Available at: <https://effectivehealthcare.ahrq.gov/products/decision-models-guidance/methods>; International Society for Pharmacoeconomics and Outcomes Research Good Practices for Outcomes Research Practices. Available at: <https://www.ispor.org/heor-resources/good-practices>; National Pharmaceutical Council Guiding Practices for Patient-Centered Value Assessment. Available at: <http://www.npcnow.org/guidingpractices>; Sanders GD, Neumann PJ, Basu A, et al. Recommendations for Conduct, Methodological Practices, and Reporting of Cost-effectiveness Analyses: Second Panel on Cost-Effectiveness in Health and Medicine. JAMA. 2016;316(10):1093-1103. doi:10.1001/jama.2016.12195.
- iii. Sanders GD, Neumann PJ, Basu A, et al. Recommendations for Conduct, Methodological Practices, and Reporting of Cost-effectiveness Analyses: Second Panel on Cost-Effectiveness in Health and Medicine. JAMA. 2016;316(10):1093-1103. doi:10.1001/jama.2016.12195.